

# Acceptance Test Manual

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## Preface

### DFdiscover Release 5.11.0

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### Getting Help

For software support, Please contact the DFdiscover team:

- via email, [help@dfnetresearch.com](mailto:help@dfnetresearch.com).
- Visit our website, <https://www.dfnetresearch.com>.

### Conventions

A number of conventions have been used throughout this document.

Any freestanding sections of code are generally shown like this:

```
# this is example code
code = code + overhead;
```

If a line starts with # or %, this character denotes the system prompt and is not typed by the user.

Text may also have several styles:

- Emphasized words are shown as follows: **emphasized** words.
- Filenames appear in the text like so: dummy.c.
- Code, constants, and literals in the text appear like so: main.c.
- Variable names appear in the text like so: nBytes.
- Text on user interface labels or menus is shown as: **Printer name**, while buttons in user interfaces are shown as **Button**.
- Menus and menu items are shown as: **File** > **Exit**.

## Introduction

### Objective

The objective of the Acceptance Test Kit (ATK) is to provide **DFdiscover** clients with an acceptance test plan which can be executed to:

- Verify the correct installation of the **DFdiscover** software in their own environment.
- Confirm the core **DFdiscover** functionality in their own environment.
- Demonstrate, by means of passed tests, correct operation of tested functionality and core requirements of the **DFdiscover** software.

### Approach

The Acceptance Test Kit has these features:

- Functional approach - i.e., based on meeting data management objectives.
- Follows a logical data flow and processing path from user's viewpoint.
- Starts with a complete study already setup using the **DFdiscover** software.
- A series of tests organized within modules, are linked to the core requirements of the **DFdiscover** software. These modules are core to the use of the ATK. Each module has a start action, a detailed script of user steps and an end action.
- User is given defined input and expected output for objective verification.
- Not an exhaustive test of every button, menu or GUI in every **DFdiscover** application.

### The Kit

The Acceptance Test Kit contains:

- Manual: descriptions of tests, organized within functional modules.
- Control Panel application and instructions for setting the study to base state. The Control Panel application controls the start, stop and interim states of all modules.
- Study: simple blood pressure study already setup, which includes plate definitions, edit checks and look-up tables.
- Database: includes several completed subject cases existing at various states (i.e., entered data, submitted and awaiting data entry, awaiting outbound transmission, or EDC data entry).
- Case Report Forms.

### Instructions

To perform the Acceptance Test Kit:

- Module 1 provides instructions on installation and initialization. Module 1 must be completed first.
- The Control Panel application sets each module to a known base state. Use the **Begin** button to start each module.
- Modules are presented in logical order from study setup to data entry and reviews. Any module, beginning with module 2, can be skipped if it deals with topics that are not relevant to your use of the software.
- Within each module, tests must be executed in order.
- Execute module completion, by clicking **End** once all module tests have been performed.
- Complete test summary in the form of the [ATK worksheet](#) and, if necessary, [discrepancy reports](#).

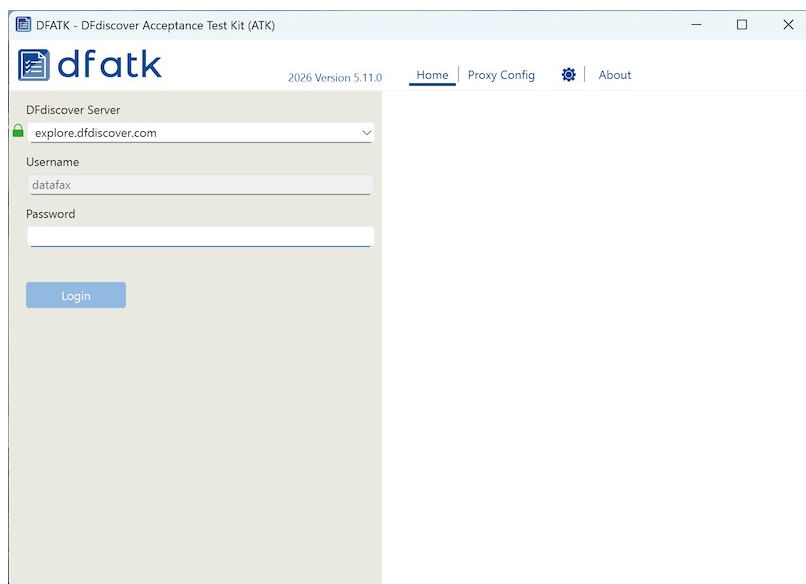
NOTE: The provided ATK worksheet provides a convenient checklist for each module allowing for a physical deliverable for documentation purposes. Included with this checklist is the discrepancy report template, which can be used to track any unexpected issues or test discrepancies encountered while running the ATK. These forms are able to be completed digitally using a web browser for interactive field inputs or supported Adobe PDF tool to fill in input fields, or manually using printed paper copies.

### Notes

- Every module uses **DFATK** and must be run as datafax. Refer to [Module 1 \(Installation & Initialization\)](#).
- References to **DFdiscover Server** value will be the name of *your* **DFdiscover** server.
- Images in this manual are of the applications running in the Windows 11 operating system. If you are running the applications on macOS, the appearance of the windows, dialogs and default button layouts will differ slightly from those shown here.
- Screen colors may appear as a black background with a white CRF foreground. These are the **DFsetup** default colors. The colors in illustrations have been modified (reversed) for clarity.
- If you do not have a printer connected to the **DFdiscover** server (e.g. if you are a hosted client), a valid email address is required for data\_coordinator, data\_manager, site\_monitor or site\_invest to receive all module specific PDF files. Refer to [Creating a role and permissions for data\\_coordinator, data\\_manager, site\\_monitor or site\\_invest, Step 5](#).

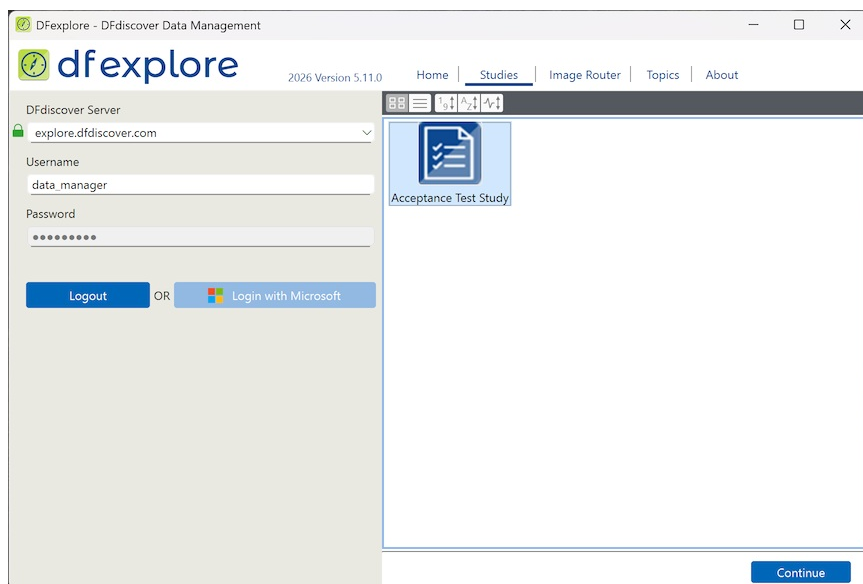
## How to start DFATK

- Start **DFATK**. **DFATK** is also known as the Control Panel, in the **DFATK** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. (This will differ from the value shown here.). As the Control Panel must be run as datafax, the **Username** field cannot be edited. Enter the previously specified password for datafax and click **Login**.



## How to start DFexplore

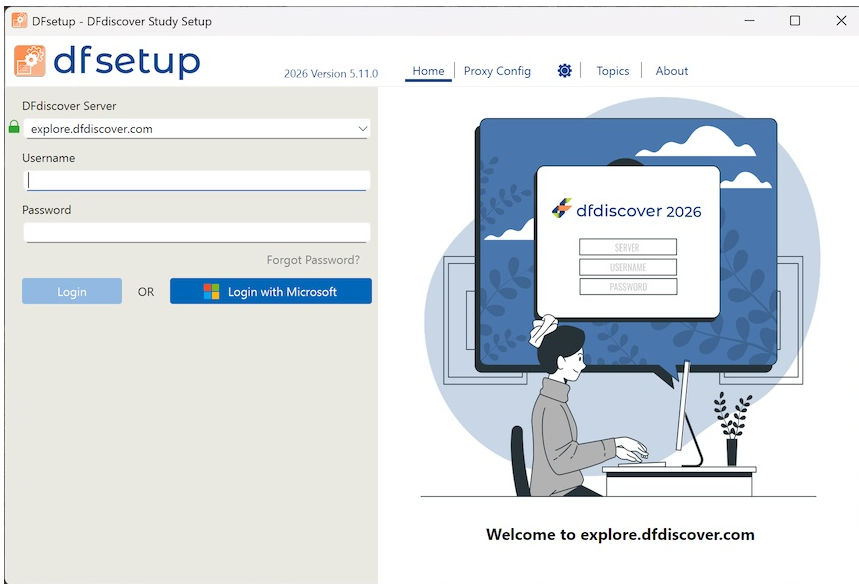
1. Start **DFexplore**. In the **DFexplore** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. (This will differ from the value shown here.) Enter data\_coordinator, data\_manager, site\_monitor or site\_invest in the **Username** field and the previously assigned password in the **Password** field. Click **Login** to login.



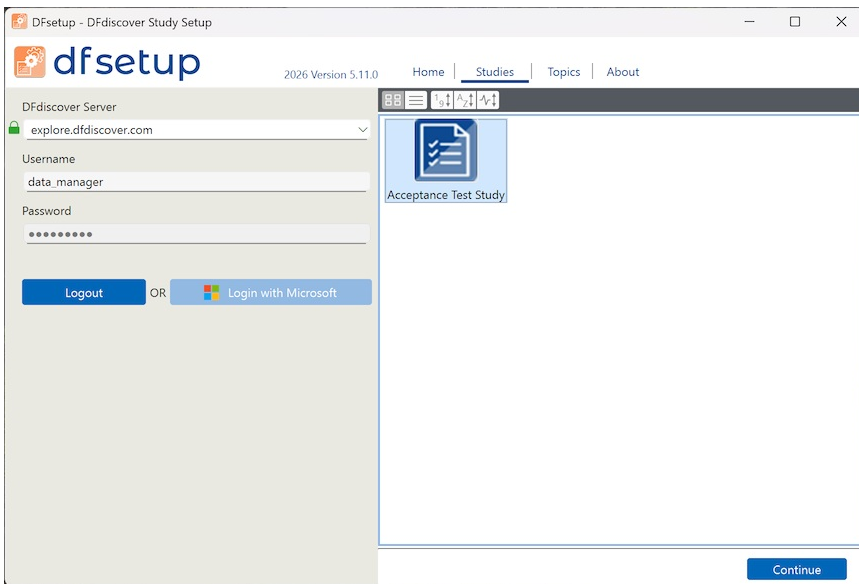
2. During the first login of data\_coordinator, data\_manager, site\_monitor or site\_invest a new password must be chosen. Choose and enter a new password in both the **New Password** and **Confirm Password** fields. Click **OK** to set the new password and dismiss the dialog. Choose **254 Acceptance Test Study**, click **Continue**. If your **DFdiscover** server does not allow the re-use of previous passwords, you will be required to set either data\_coordinator, data\_manager, site\_monitor or site\_invest's password to something other than the initial password chosen previously. The password you choose must satisfy the password requirements specific to your **DFdiscover** server and will be needed in the remainder of the modules.

## How to start DFsetup

1. Start **DFsetup**. In the **DFsetup** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. (This will differ from the value shown here.) Enter `data_manager` in the **Username** field and the previously assigned password in the **Password** field. Click **Login** to login.

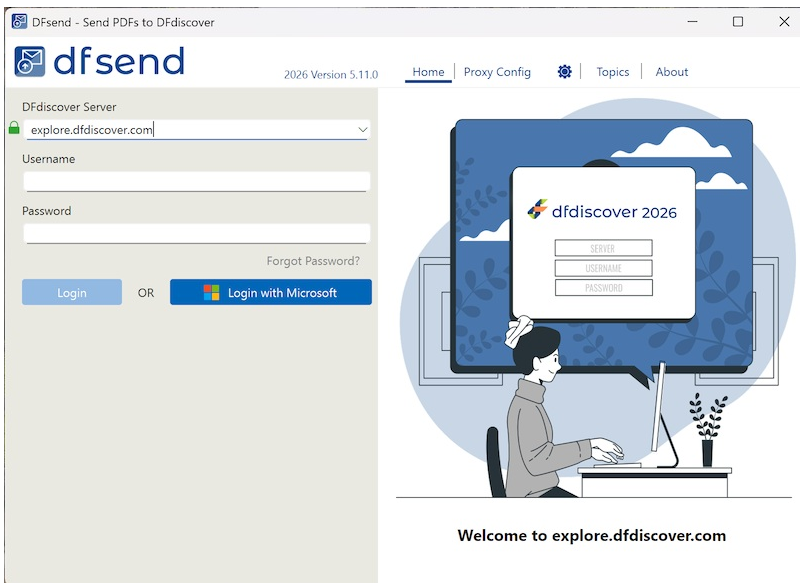


2. In the studies selection dialog, highlight the entry for **254 Acceptance Test Study**. Click **Continue** to continue.



## How to start **DFsend**

- Start **DFsend**. In the **DFsend** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. (This will differ from the value shown here.) Enter `data_coordinator`, `data_manager`, `site_monitor` or `site_invest` in the **Username** field and the previously assigned password in the **Password** field. Click **Login** to login.



NOTE: If an account with a 2-factor authentication method is used to login, then the you will need to enter the code sent to the 2-factor authentication method selected in **DFadmin** upon logging in with a password.

## Module 1. Installation and Initialization

### Overview

#### Prerequisites:

- Licensed and Configured DFdiscover 5.11.0 installed on Study Server
- DFdiscover supported email service running on Study Server (Example: postfix)
- DFdiscover 5.11.0 Client Tools Installation on Local Computer
- Super-user level access on Study Server for Installation of DFATK Packages

**Client Tools Used:** DFATK, DFExplore, DFAdmin

**Purpose:** This module installs the DFATK modules, defines and imports the Acceptance Test Study to the DFdiscover server, and configures the DFdiscover user accounts for all following ATK Modules. This module is intended to be run by a systems administrator or IT staff due to server access requirements. This module is a prerequisite for all following modules.

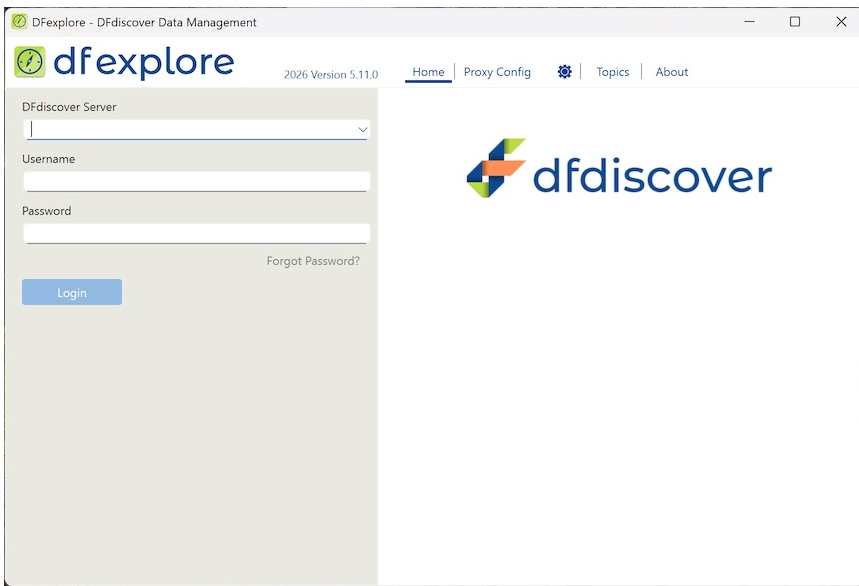
### Tests & Requirements

1. Confirm version information can be obtained for DFdiscover.
2. Obtain super-user privileges and remove older Acceptance Test Study, if one exists.
3. Install the Acceptance Test Study.
4. Define Acceptance Test Study to the DFdiscover server.
5. Create a role and permissions for datafax.
6. Creating study roles and permissions.
7. Creating user accounts and assigning study permissions.
8. Enable high definition imaging.
9. Start the Acceptance Test Study control panel application.

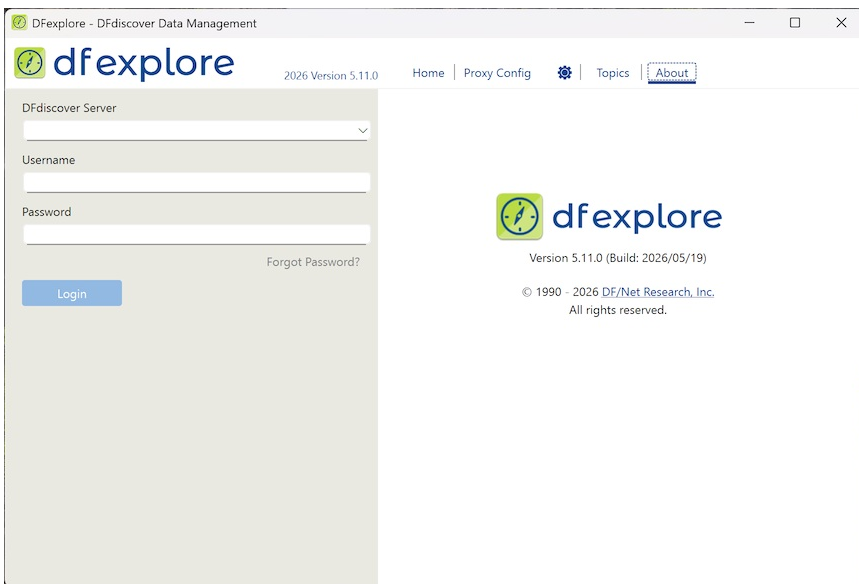
Estimate of Time Required: 30 Minutes

### Confirm version information can be obtained for DFdiscover

1. Confirm the Acceptance Test Kit is installed on the following Linux operating system:
  - Red Hat / CentOS
  - SUSE
2. Confirm **DFdiscover** version information by starting **DFExplore**.



3. In the login dialog, click **About**. Confirm that the version information in the dialog matches the installed software Version 5.11.0.

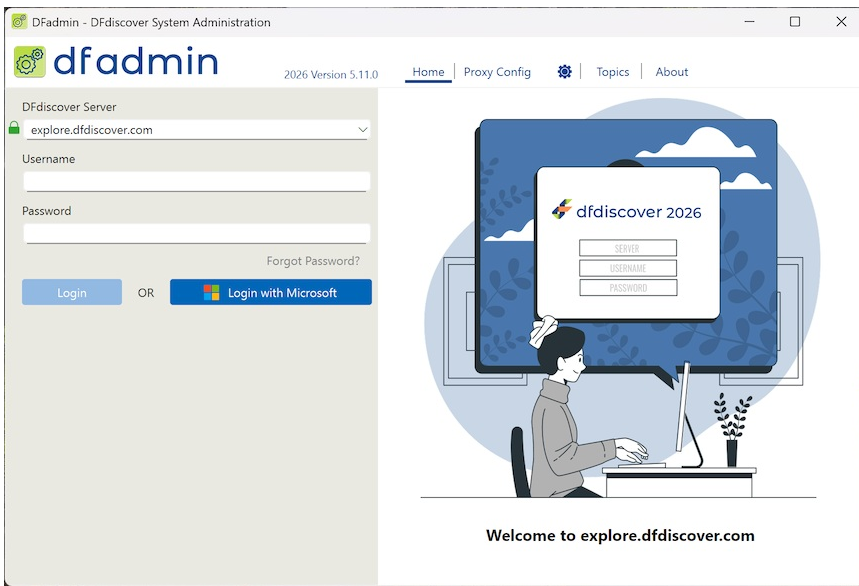


4. If the version is not DFdiscover 2026 Version 5.11.0, you must stop at this point. The Acceptance Test Kit is specifically designed for release DFdiscover 2026 Version 5.11.0.
5. Exit **DFExplore**.

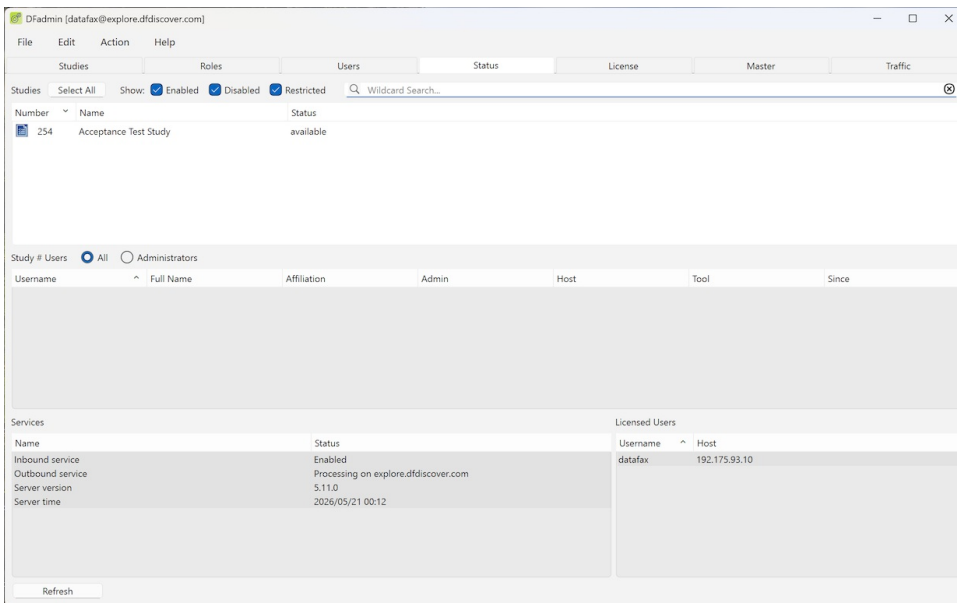
## Obtain super-user privileges and remove older Acceptance Test Study, if one exists

**NOTE:** This step is required only if **254 Acceptance Test Study** already exists on your **DFdiscover** server. If it does not currently exist on your **DFdiscover** server, skip this section and continue with [Install the Acceptance Test Study](#). If an earlier version does exist on your server, delete it prior to installation by following these steps.

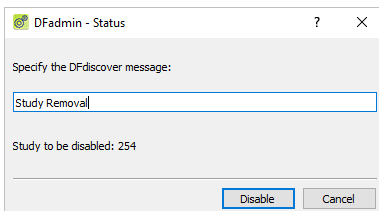
1. Start **DFAdmin**. Login to your **DFdiscover Server** as datafax.



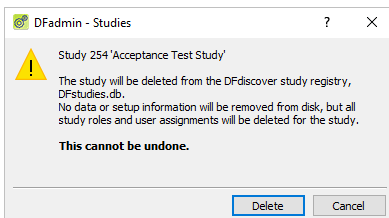
- Specify a **Username** of datafax, and the assigned user password in the **Password** field. Click **Login** to complete login and continue. Click **Status** Tab. The list of studies defined on your **DFdiscover Server** will be displayed in the studies list.



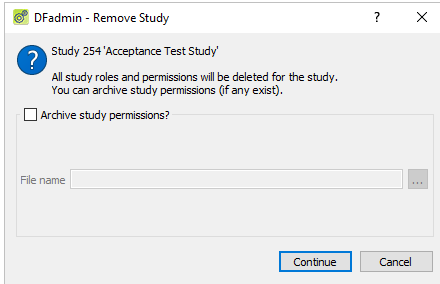
- Select the entry for **254 Acceptance Test Study** from the list of studies. Select **Action** > **Disable study**>. In the confirmation dialog, enter the text Study Removal.



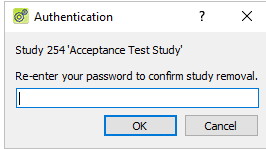
- Click **Disable** to disable the Acceptance Test Kit.
- Click **Studies** tab. Select the entry for **254 Acceptance Test Study** if it is not already highlighted. Click **Delete**. From the 3 delete options, choose **Remove Study from DFdiscover**.
- Click **Delete** in the confirmation dialog to continue with the delete.



- In the **Remove Study** dialog, Uncheck (disable) **Archive Study Permissions** and click **Continue**.



- To confirm, enter the password for datafax and click **OK**. Close the study removal confirmation dialog by clicking **OK**.



## Install the Acceptance Test Study

**NOTE:** Existing Acceptance Test Kit directories, `val254` and `.val254_states`, must be removed prior to installation of the DFdiscover 2026 Version 5.11.0 Acceptance Test Kit. This is because the study directory structure and/or base states have changed with DFdiscover 2026 Version 5.11.0.

If the directories are present at this time, installation of the DFdiscover 2026 Version 5.11.0 Acceptance Test Kit will create TAR file of the existing installation and re-install the updated DFdiscover 2026 Version 5.11.0 `val254` and `.val254_states` directories.

- The DFATK-5.11-0.x86\_64.rpm file can be found on [www.dfnetwork.com](http://www.dfnetwork.com) in the Support section. After downloading the DFATK-5.11-0.x86\_64.rpm execute the installation using **rpm** on OpenSUSE & RHEL operating systems. The installation defaults to the `/opt/studies` directory, this can be changed using the **rpm --prefix=NEUPATH** flag.

- New installations using **rpm**, which will automatically download and install any dependencies required:

```
# rpm -ivh DFATK-5.11-0.x86_64.rpm
```

**OR**, specify an alternative installation location:

```
# rpm -ivh --prefix=NEUPATH DFATK-5.11-0.x86_64.rpm
```

**NOTE:** Use of **rpm --prefix=NEUPATH** does not alter current definitions of `DFstudyspaces.db` or `DFstudies.db`. These files must be manually updated to include the specified prefix pathing.

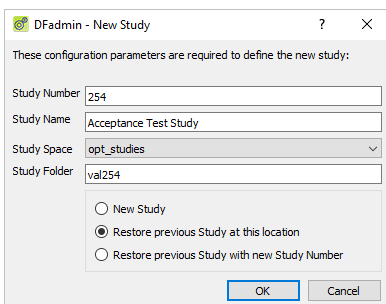
- Confirm the presence of **254 Acceptance Test Study** with the command:

```
# ls -d /opt/studies/val254
```

## Define Acceptance Test Study to the DFdiscover server

- Return to **DFadmin**, select the **Studies** tab. Add a definition for **254 Acceptance Test Study**. Click **New** and complete the dialog with the following values:

- Study Number:** 254
- Study Name:** Acceptance Test Study
- Study Space:** `opt_studies` (or the name of the Study Space for the `/opt/studies` directory)
- Study Folder:** `val254`
- Select **Restore previous Study at this location**

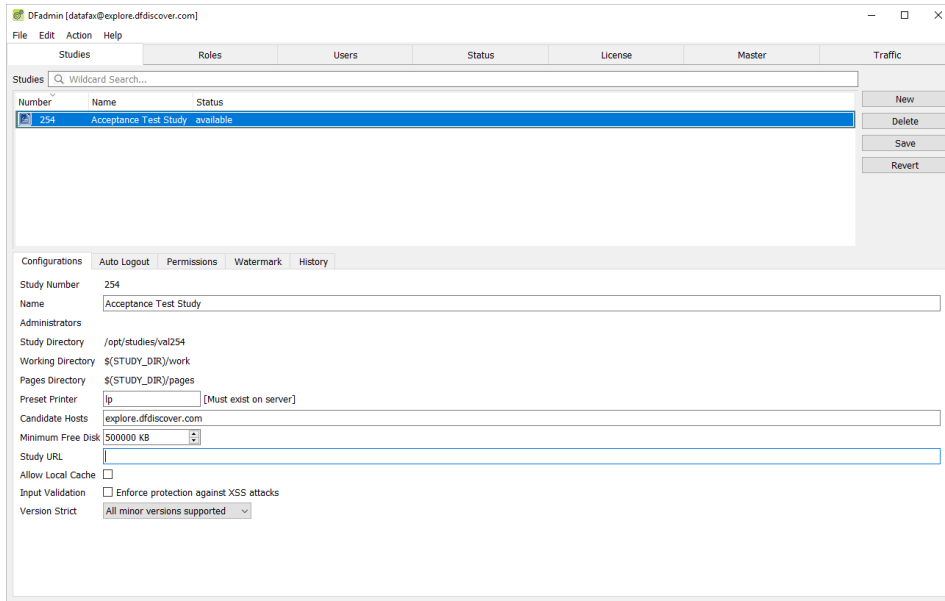


**NOTE:** The name of your Study Space may differ from that shown here if the Study Space is something other than `opt_studies` on your **DFdiscover** server.

- Click **OK** to confirm the action and add an entry for **254 Acceptance Test Study** to the list of studies.

- Verify configuration information and set the **Preset Printer**. Select the newly added **254 Acceptance Test Study** entry from the list of studies. Click **Configurations** tab and enter

the name of a networked printer in the **Preset Printer** field.

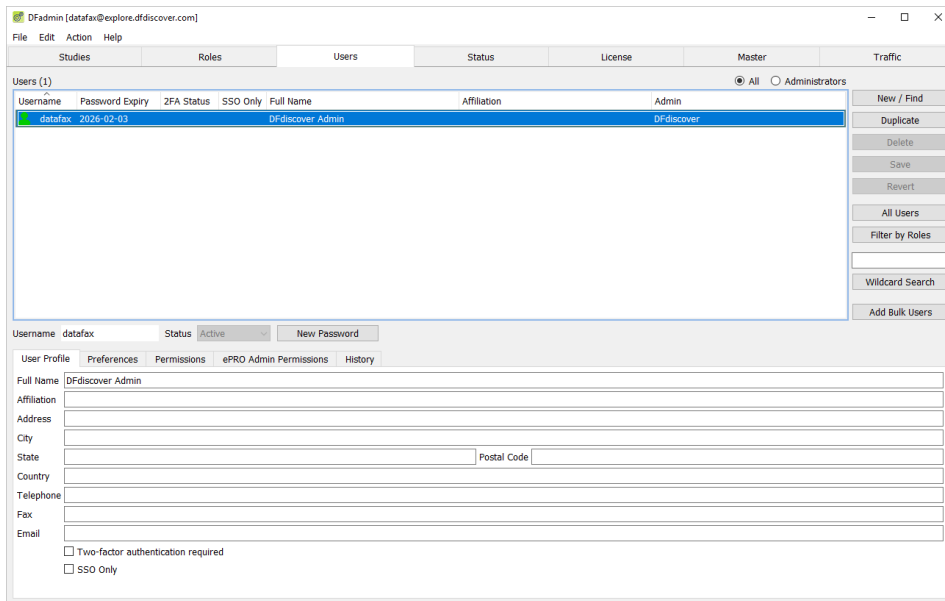


4. Choose **All minor versions supported** from the **Version Strict** drop-down.
5. Select **File** > **Save** or click **Save** to save the configuration information.

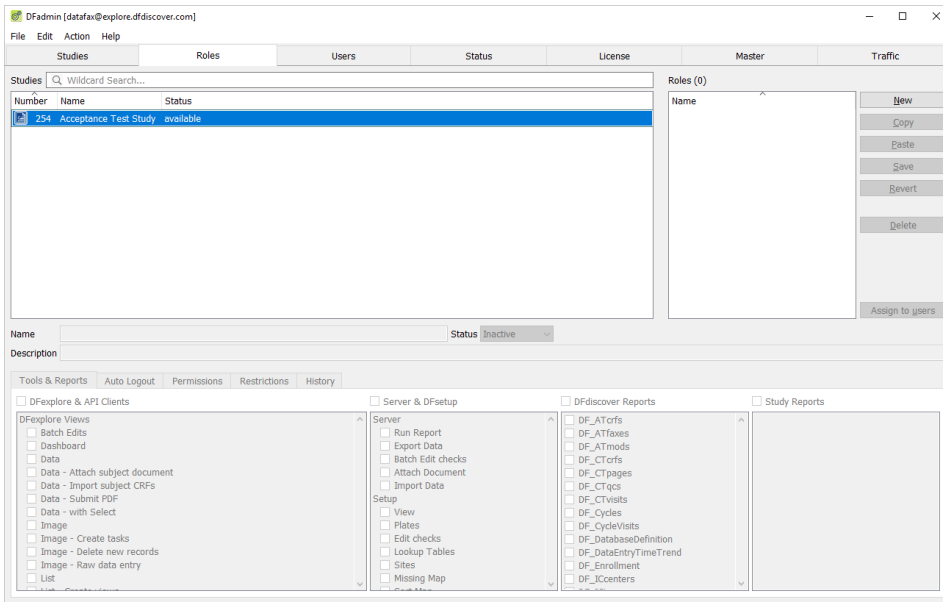
## Create a role and permissions for datafax

User datafax is already defined on your **DFdiscover** installation, however, you must grant user datafax a role and permissions to be able to access **254 Acceptance Test Study**.

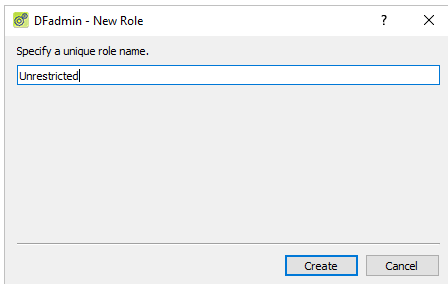
1. Click **Users** tab. Confirm that user datafax is present in the Username column for one user row.



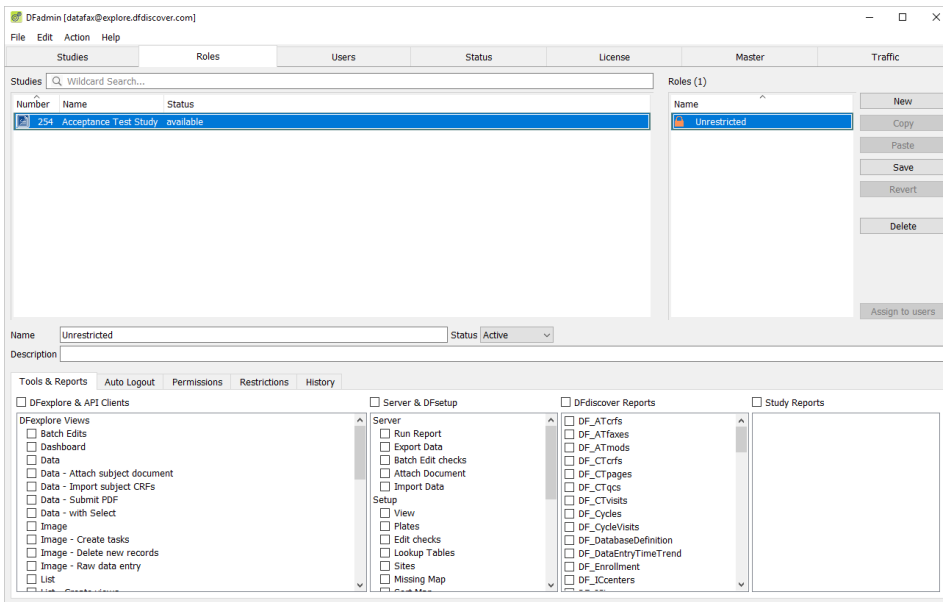
2. Create a Role for user datafax. Begin this task by clicking the **Roles** tab.



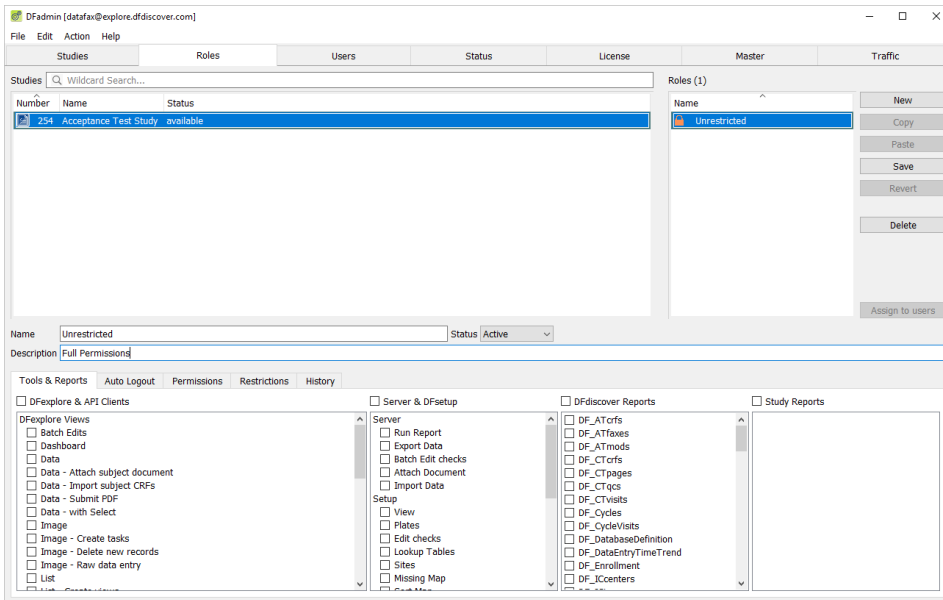
3. Within the list of studies, locate and choose the entry for **254 Acceptance Test Study**. Click **New** to add a new user role. In the dialog, enter the role name **Unrestricted**.



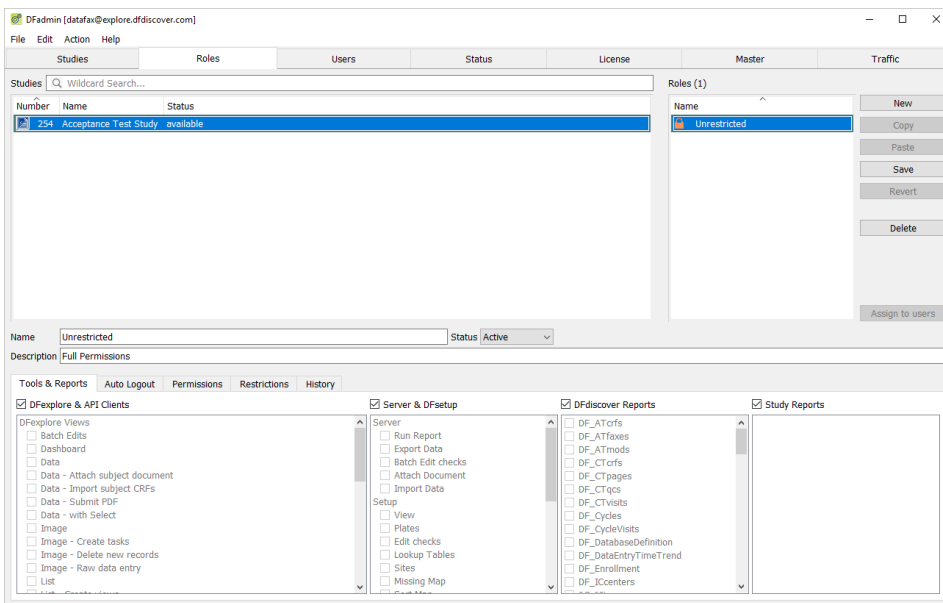
4. Click **Create** to create the new role **Unrestricted**.



5. Define **Tools & Reports** permissions for the **Unrestricted** role. Highlight **Unrestricted** in the **Roles** list to make it the active role. Enter **Full Permissions** in the **Description** field.



6. Click **Tools & Reports** tab below the **Description** field. Check (enable) each of the following: **DFexplore & API Clients**, **Server & DFsetup**, **DFdiscover Reports**, and **Study Reports**.

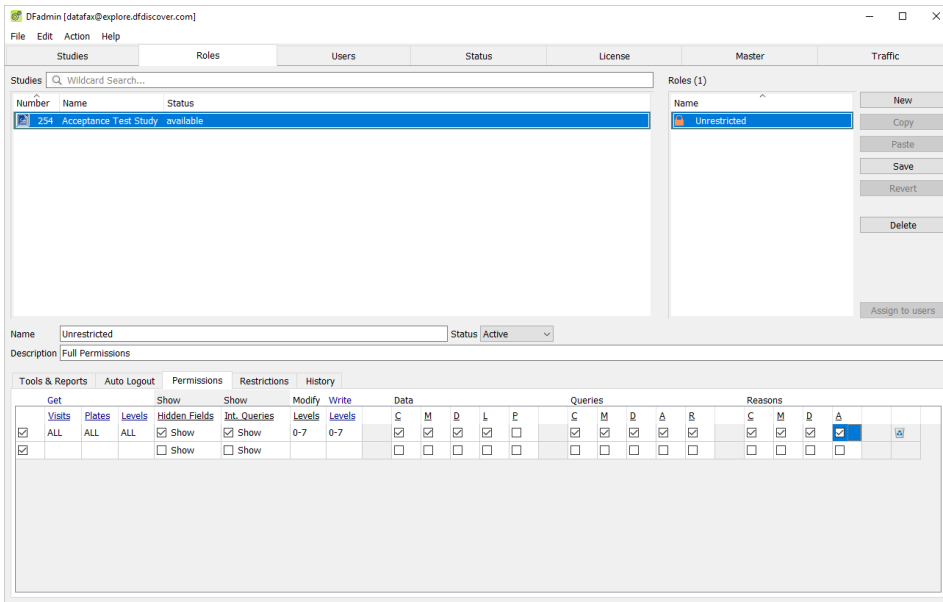


7. Click **Auto Logout** tab. If not already enabled, check (enable) the **Inherit from Study** box to override the default Auto Logout settings with those of the ATK study.

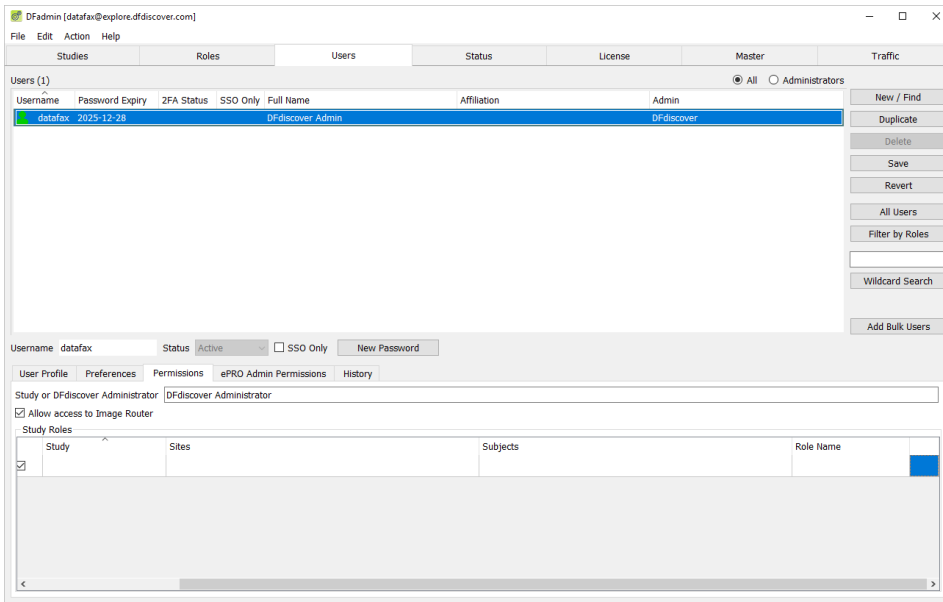
8. Click **Permissions** tab.

9. Set data permissions as follows:

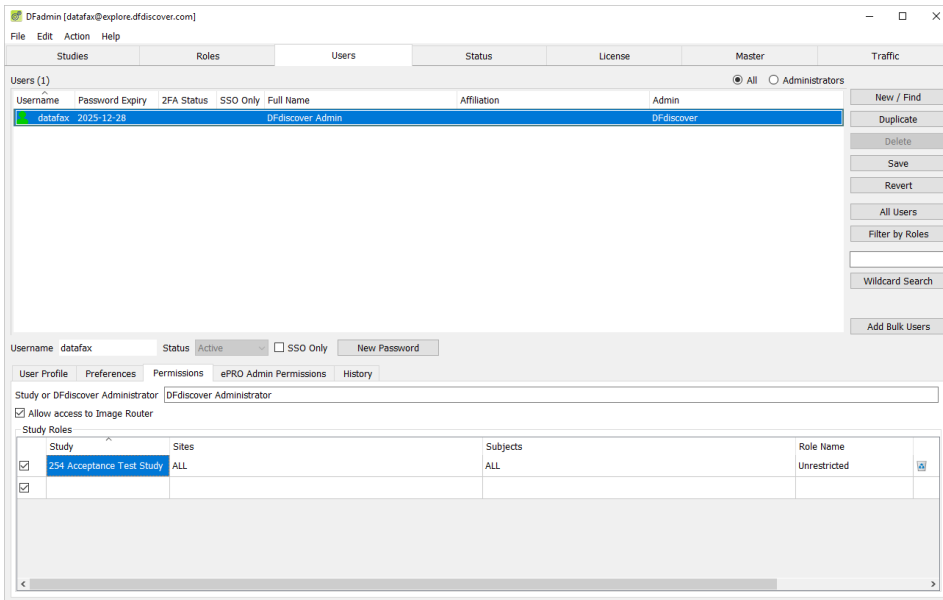
- o **Visits** = ALL
- o **Plates** = ALL
- o **Levels** = ALL
- o Check (enable) **Show Hidden Fields**
- o Check (enable) **Show Int. Queries**
- o **Modify** = 0-7
- o **Write Levels** = 0-7
- o **Data** = Check (enable) CMDL (Create, Modify, Delete, Missed), but not P (Password)
- o **Queries** = Check (enable) CMDAR (Create, Modify, Delete, Approve, Reply)
- o **Reasons** = Check (enable) CMDA (Create, Modify, Delete, Approve)



10. Select **File** > **Save** or click **Save** to save settings for role Unrestricted.
11. Still as datafax and with the **DFadmin** application open, click **Users** tab.
12. Set permissions for datafax. Click the entry for datafax from the list of users to make it active. Click **Permissions** tab. Check (enable) **Allow access to Image Router**.



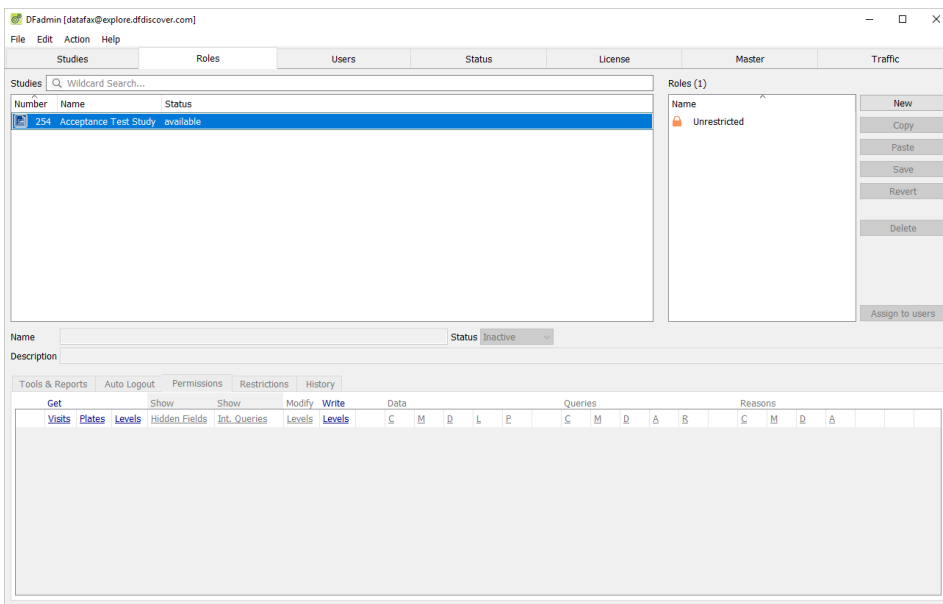
13. To assign a study to datafax, click the blank area below the **Study** heading. Select **254 Acceptance Test Study** from the **Study** drop-down. Set:
  - o **Sites** = All
  - o **Subjects** = All
  - o **Role Name** = Unrestricted



14. Click **Save** to save the role and permissions for datafax.

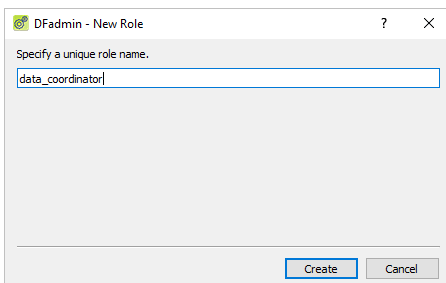
## Creating study roles and permissions

1. Create a Role for user data\_coordinator. Begin this task by clicking the **Roles** tab.

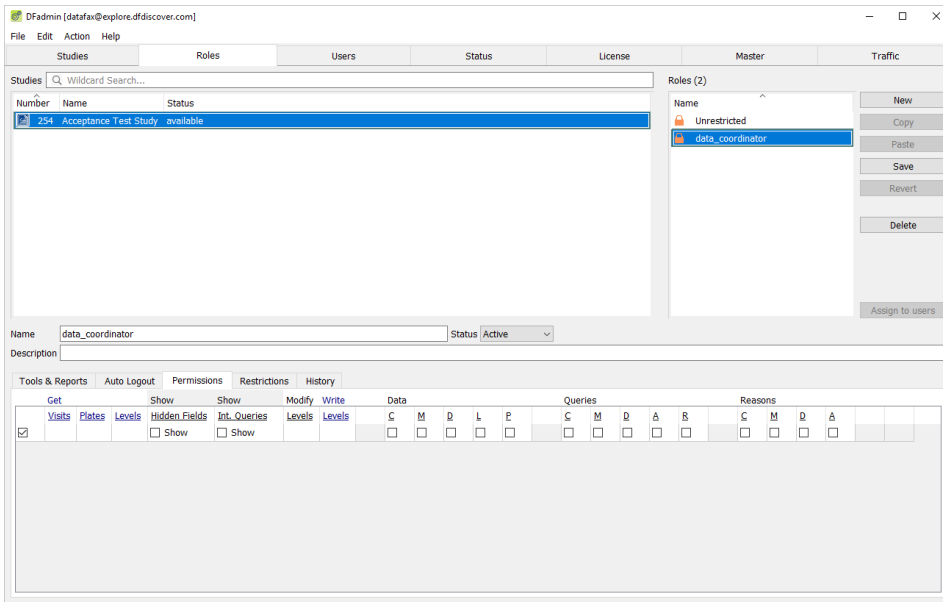


**NOTE:** If the role already exists, confirm the permissions and settings described in [Step 2](#) to [Step 8](#) and make changes where necessary.

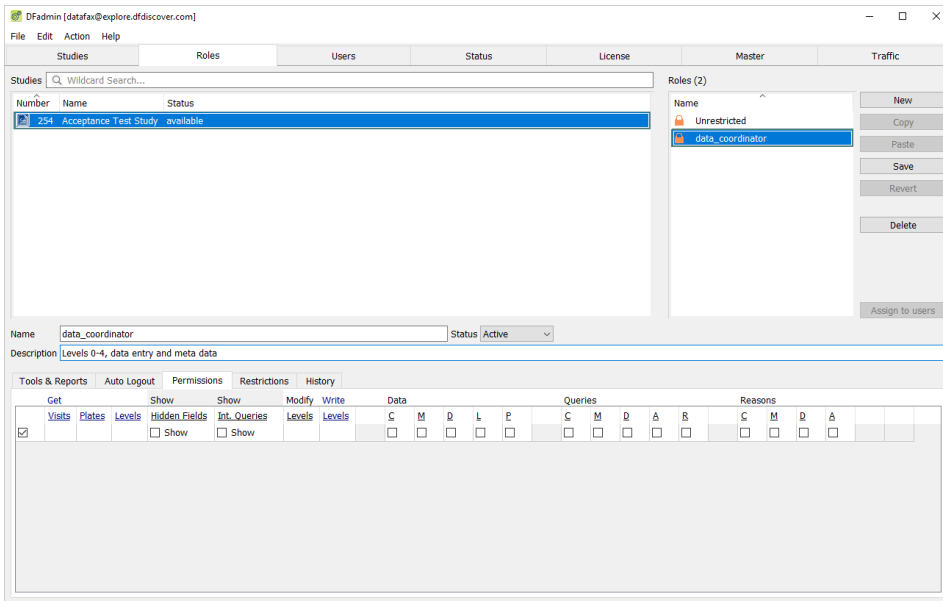
2. In the list of studies, locate and choose **254 Acceptance Test Study**. Click **New** to add a new user role. In the confirmation dialog, enter the role name data\_coordinator.



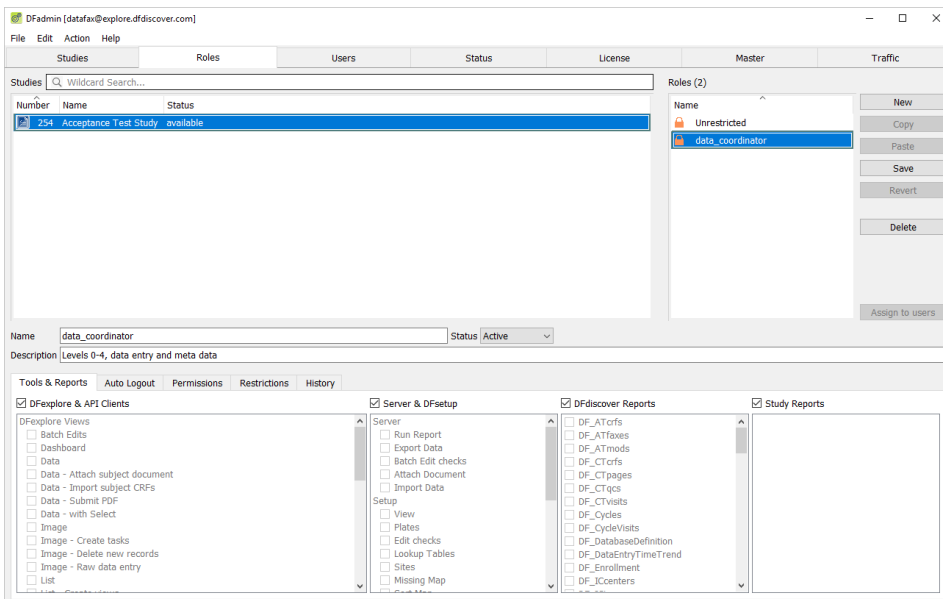
3. Click **Create** in the New Role dialog to apply the role name.



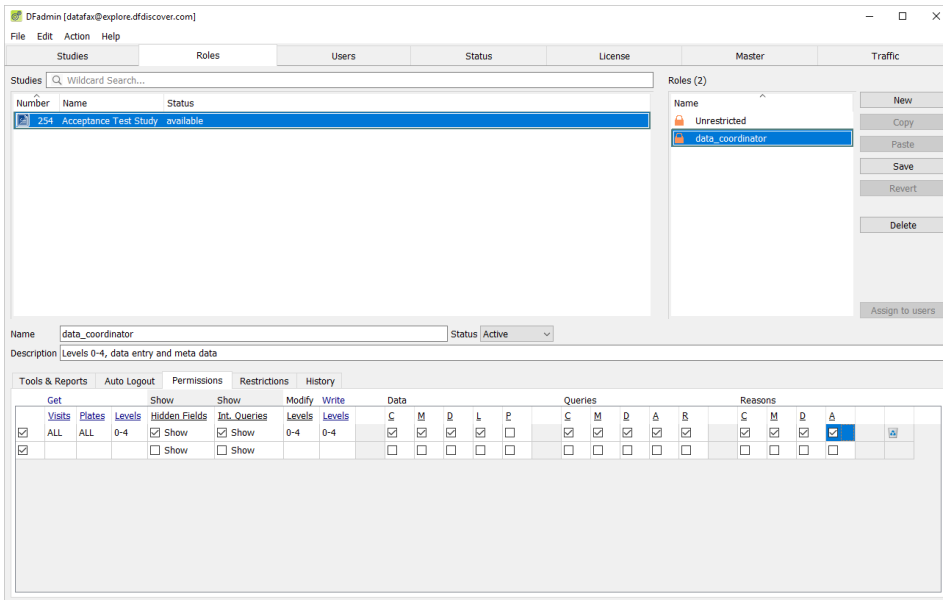
4. In the **Description** field enter: Levels 0-4, data entry and meta data.



5. Click **Tools & Reports** tab. Check (enable) each of the following: **DFexplore & API Clients**, **Server & DFsetup**, **DFdiscover Reports**, and **Study Reports**.

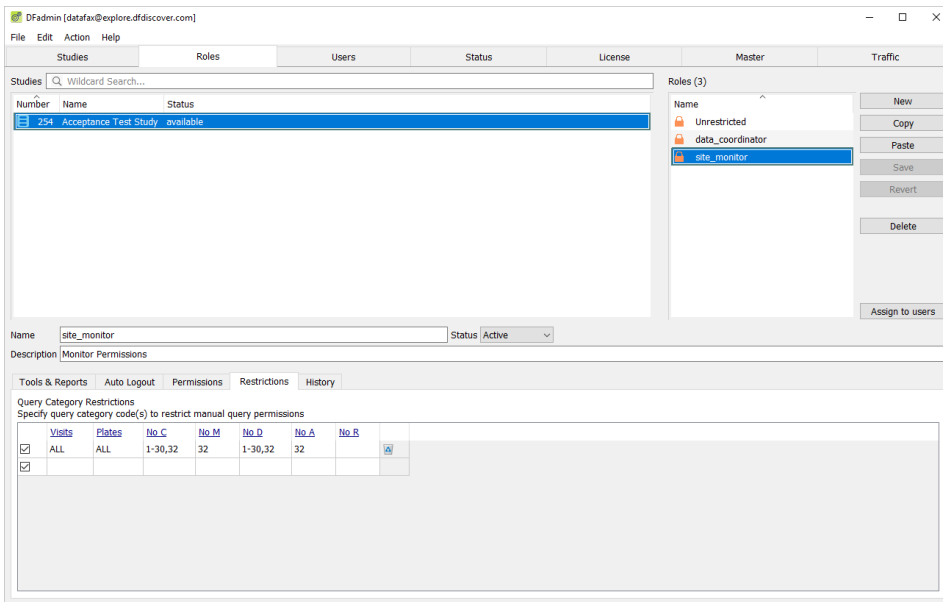






9. Click **Save** to save the role.
10. Click **Copy** then **Paste**, specify a role name of site\_monitor. Click **Create**.
11. Click **Restrictions** tab.
12. Enter a **Description** of Monitor Permissions. Set query restrictions as follows:
  - o **Visits** = ALL
  - o **Plates** = ALL
  - o **No C** = 1-30,32
  - o **No M** = 32
  - o **No D** = 1-30,32
  - o **No A** = 32
  - o **No R** = blank

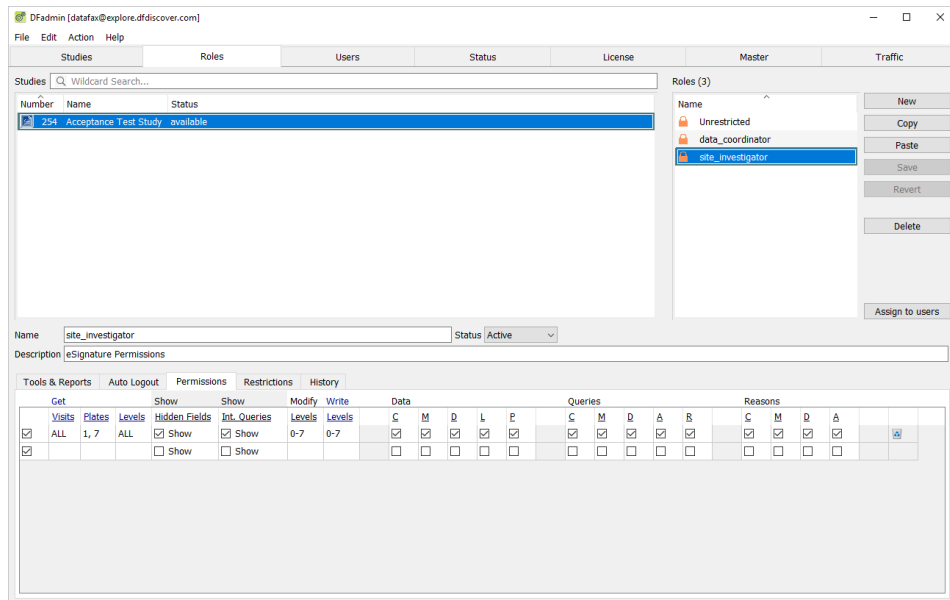
Click **Save**.



13. Select data\_coordinator role, click **Copy** then **Paste**, specify a role name of site\_investigator. Click **Create**.
14. Click **Permissions** tab.
15. Enter a **Description** of eSignature Permissions. Set data permissions as follows:
  - o **Visits** = ALL
  - o **Plates** = 1,7
  - o **Levels** = ALL

- Check (enable) **Show Hidden Fields**
- Check (enable) **Show Int. Queries**
- **Modify** = 0-7
- **Write Levels** = 0-7
- **Data** = Check (enable) CMDLP (Create, Modify, Delete, Lost, Password)
- **Queries** = Check (enable) CMDAR (Create, Modify, Delete, Approve, Reply)
- **Reasons** = Check (enable) CMDA (Create, Modify, Delete, Approve)

Click **Save**.

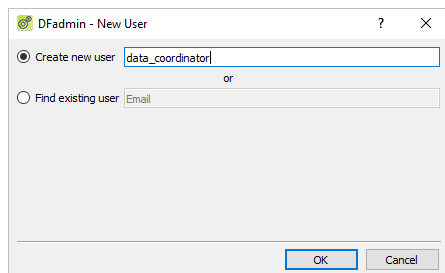


## Creating user accounts and assigning study permissions

1. Still as datafax and with the **DFadmin** application open, click **Users** tab to open the user definition window.
2. Determine if user `data_coordinator` has already been defined. Review the list of users to determine if an entry exists for user `data_coordinator`.

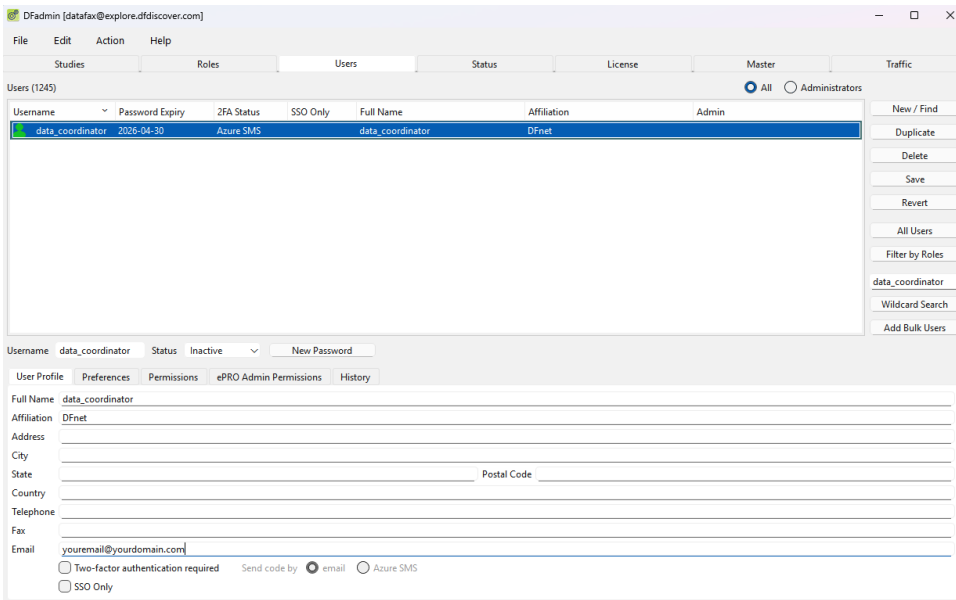
NOTE: If an entry for `data_coordinator` cannot be located in the list of users, complete [Step 3](#) to [Step 12](#) inclusive.

3. Click **New/Find** to add a **DFdiscover** account for user `data_coordinator`. In the dialog, select **Create new user** enter the **Username** `data_coordinator` as shown.



4. Click **OK** to add `data_coordinator` to the list of users. An empty icon represents `data_coordinator`, the status of `data_coordinator` is set to **Inactive**.
5. Choose the `data_coordinator` entry from the list of users if it is not already highlighted. Click **User Profile** tab. Enter these settings:
  - **Full Name** = `data_coordinator`
  - **Affiliation** = DFnet
  - **Email** = Your email address

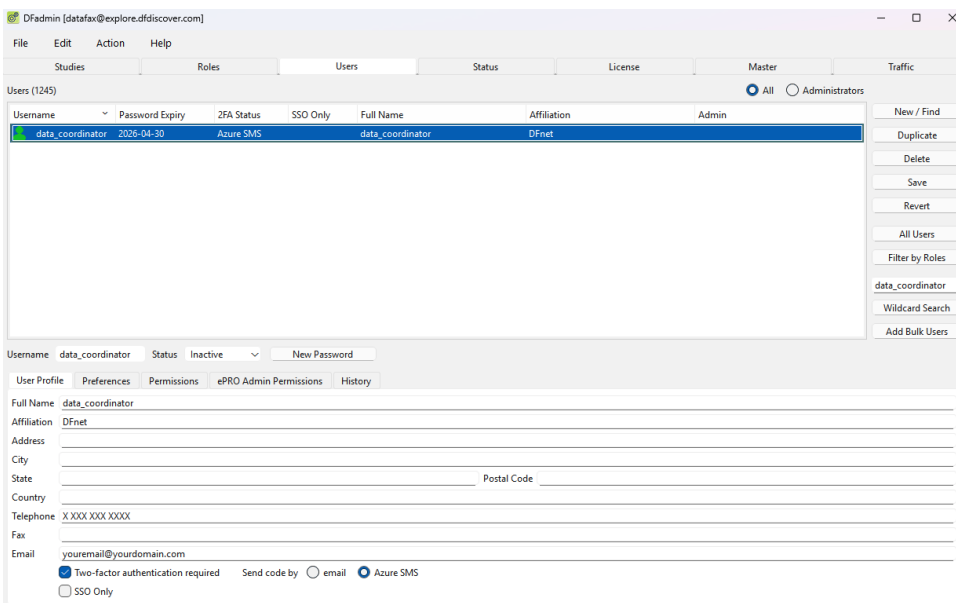
NOTE: A valid email address is required to receive module specific PDF files if you have not specified a printer in the **Master** view.



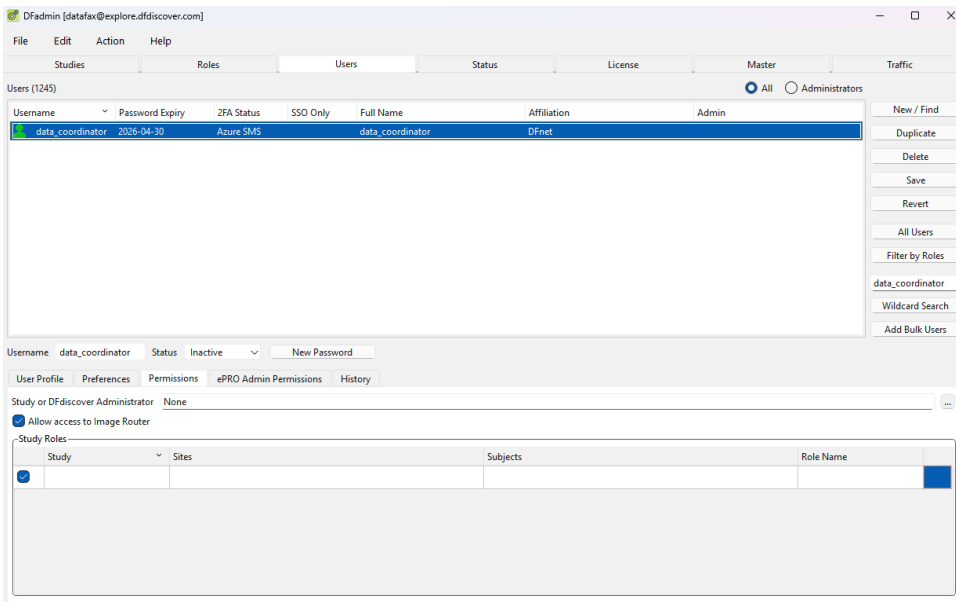
6. If your server is configured to support Azure SMS services, and your cell phone number is within the supported region, then additionally enter these settings into the **User Profile** section, otherwise, skip to [Step 7](#):

- **Telephone** = Your Cell Phone Number
- **Two-factor authentication required** = Checked (enabled)
- **Send code by** = Azure SMS

NOTE: Phone numbers entered for Azure SMS services must match the format for the Azure SMS configuration and region for your Azure Instance. Phone numbers must additionally include the country and area code of the designated number.

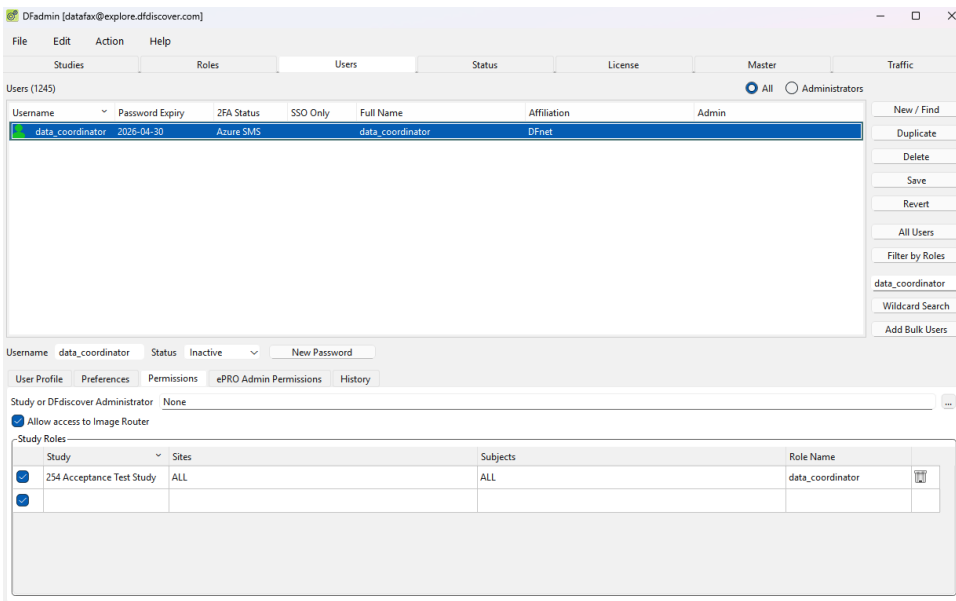


7. No further user profile information is needed. Click **Save**.
8. With user data\_coordinator still as the active user, click **Permissions** tab. Check (enable) **Allow access to Image Router**.

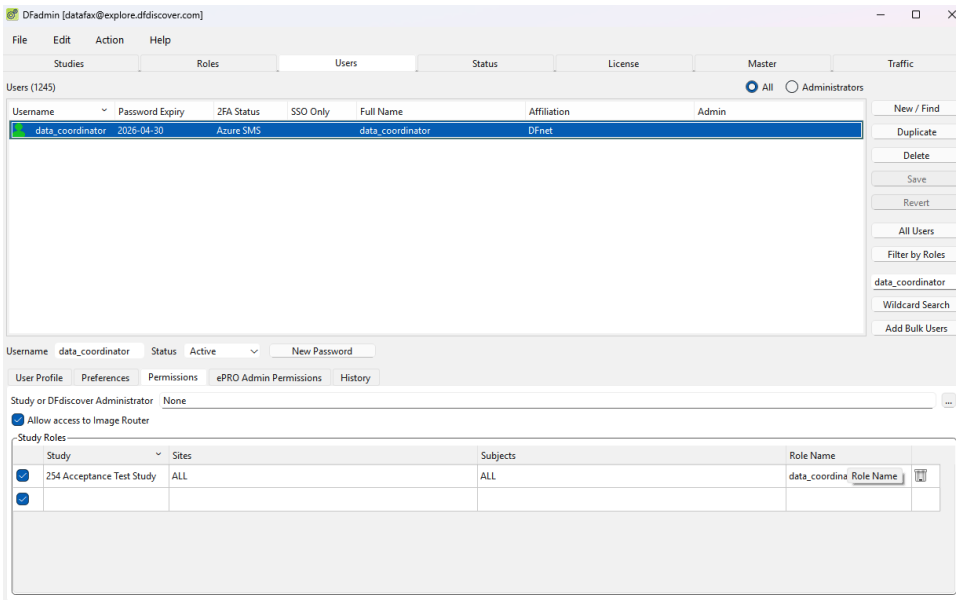


9. To assign a study to data\_coordinator, click the blank area below the **Study** heading. Select **254 Acceptance Test Study** from the **Study** drop-down. Set:

- o **Sites** = All
- o **Subjects** = All
- o **Role Name** = data\_coordinator



10. Select **Active** from the **Status** drop-down list to change the status from Inactive to Active for user data\_coordinator.



11. Assign a **DFdiscover** password for data\_coordinator by clicking **New Password**. Enter a password of your choice in place of the auto-generated system password.

NOTE: Remember the password assigned in this step as it is needed in future tests.

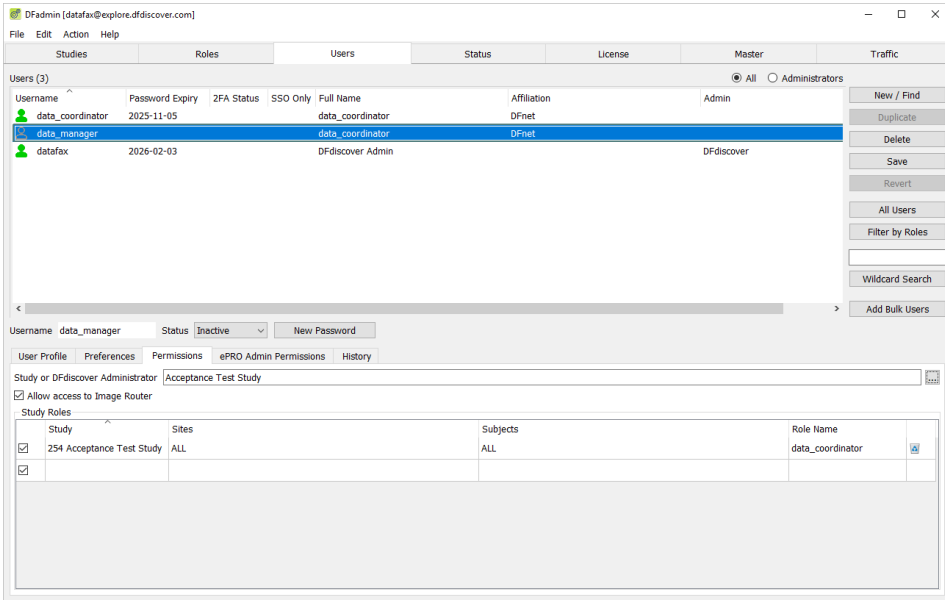
12. Locate and choose the entry for user data\_coordinator in the list of users. Click **Permissions** tab and confirm the following settings. If any of the following permissions do not appear as shown below, set them now.

- o **Allow access to Image Router** box is checked (enabled)
- o **254 Acceptance Test Study** is assigned to user data\_coordinator.
- o **Sites = ALL**
- o **Subjects = ALL**
- o **Role Name = data\_coordinator**

13. Save all previously entered permissions, roles and password by clicking **Save**.

14. With data\_coordinator as the active user, click **Duplicate**. In the dialog enter a username of data\_manager. Click **Create**.

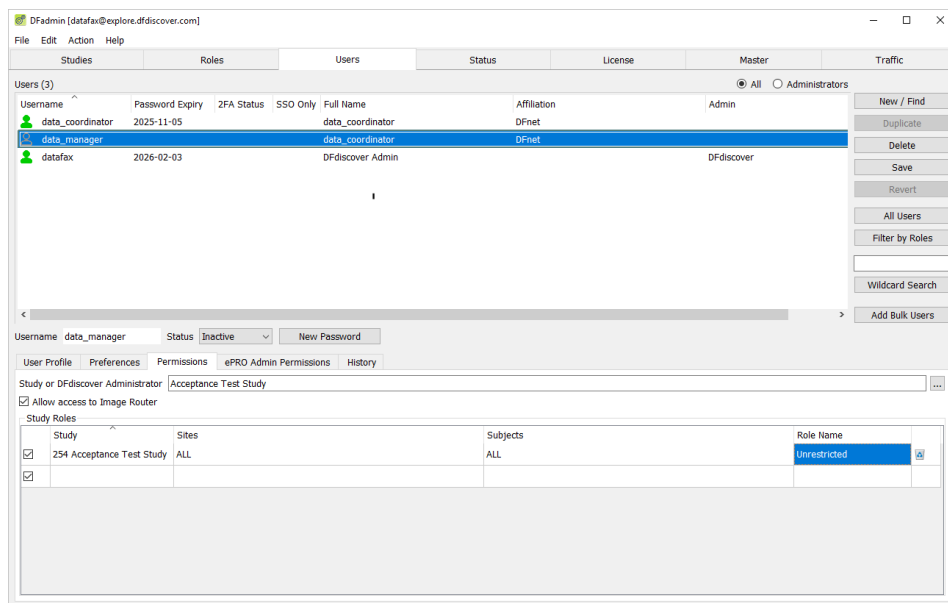
15. Specify a **Full Name** of data\_manager. Click **Permissions** tab, then [...] within the **Study or DFdiscover Administrator**. Select **Study Admin for Selected Studies**, check (enable) **254 Acceptance Test Study**. Click **OK**.



16. Confirm the **Study Roles** permissions. If any of the following permissions do not appear as shown below, set them now.

- o **Allow access to Image Router** box is checked (enabled)
- o **254 Acceptance Test Study** is assigned to user data\_manager.
- o **Sites = ALL**

- **Subjects = ALL**
- **Role Name = Unrestricted**



17. Verify the status for data\_manager. If data\_manager is set to **Inactive**, select **Active** from the **Status** drop-down list.

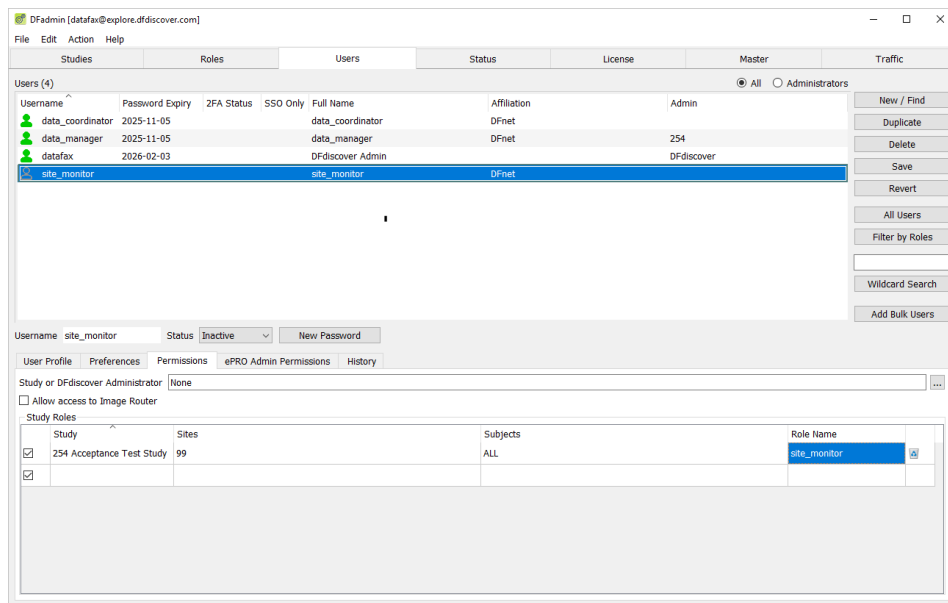
18. Assign a **DFdiscover** password for data\_manager by clicking **[New Password]**. Enter a password of your choice in place of the auto-generated system password. Click **[Save]**.

NOTE: Remember the password assigned in this test step as it is needed in future tests.

19. Click data\_coordinator to make it the active user. Click **[Duplicate]**. In the dialog enter a username of site\_monitor. Click **[Create]**

20. Specify a **Full Name** of site\_monitor. Click **Permissions** tab and confirm the following settings. If any of the following permissions do not appear as shown below, set them now.

- **Allow access to Image Router** box is unchecked (disabled)
- **254 Acceptance Test Study** is assigned to user site\_monitor.
- **Sites = 99**
- **Subjects = ALL**
- **Role Name = site\_monitor**

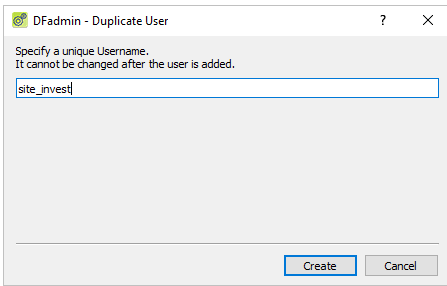


21. Verify the status for site\_monitor. If site\_monitor is set to **Inactive**, select **Active** from the **Status** drop-down list.

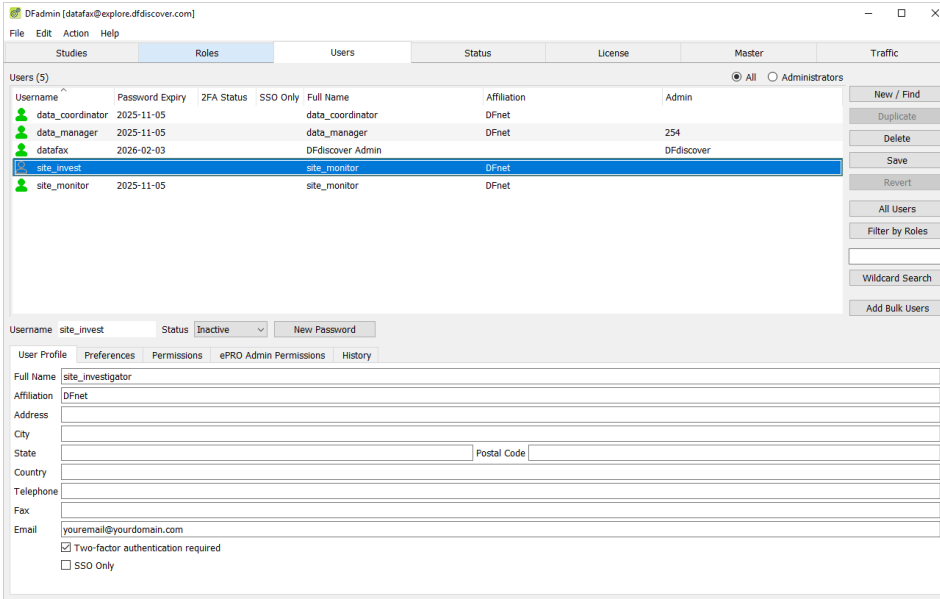
22. Assign a **DFdiscover** password for site\_monitor by clicking **[New Password]**. Enter a password of your choice in place of the auto-generated system password. Click **[Save]**.

NOTE: Remember the password assigned in this test step as it is needed in future tests.

23. With site\_monitor as the active user, click **[Duplicate]**. In the dialog enter a username of site\_invest. Click **[Create]**

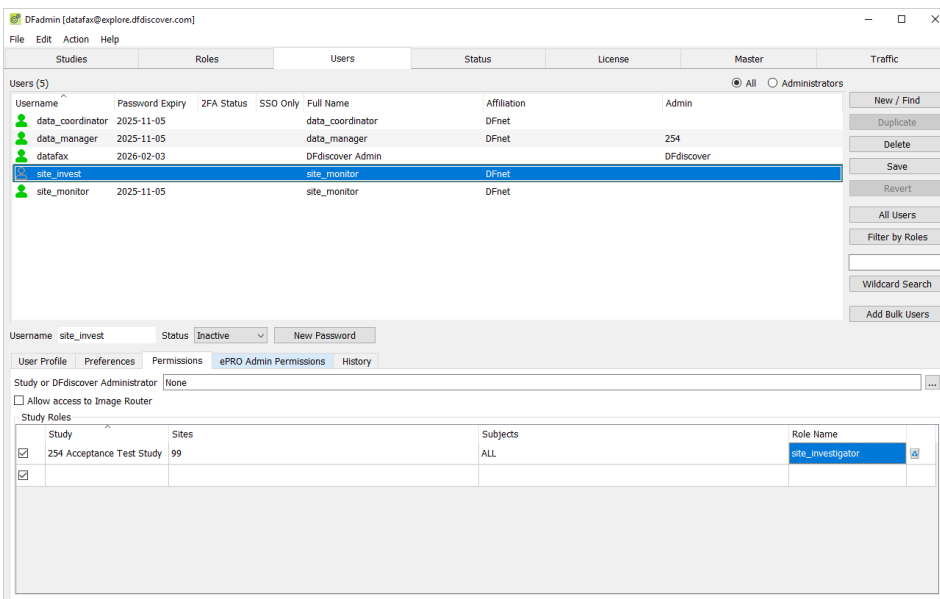


24. Specify a **Full Name** of site\_investigator. Check (enable) **Two-factor authentication required**. When 2-factor authentication is enabled, you will need to enter an email address. Alternatively, if Azure SMS is configured and enabled on your server, you may enter a phone number in the supported region of your Azure SMS configuration in the **telephone** field, and select Azure SMS in the **Send code by** field.



25. Click **Permissions** tab and confirm the following settings. If any of the following permissions do not appear as shown below, set them now.

- o **Allow access to Image Router** box is unchecked (disabled)
- o **254 Acceptance Test Study** is assigned to user site\_invest.
- o **Sites** = 99
- o **Subjects** = ALL
- o **Role Name** = site\_investigator

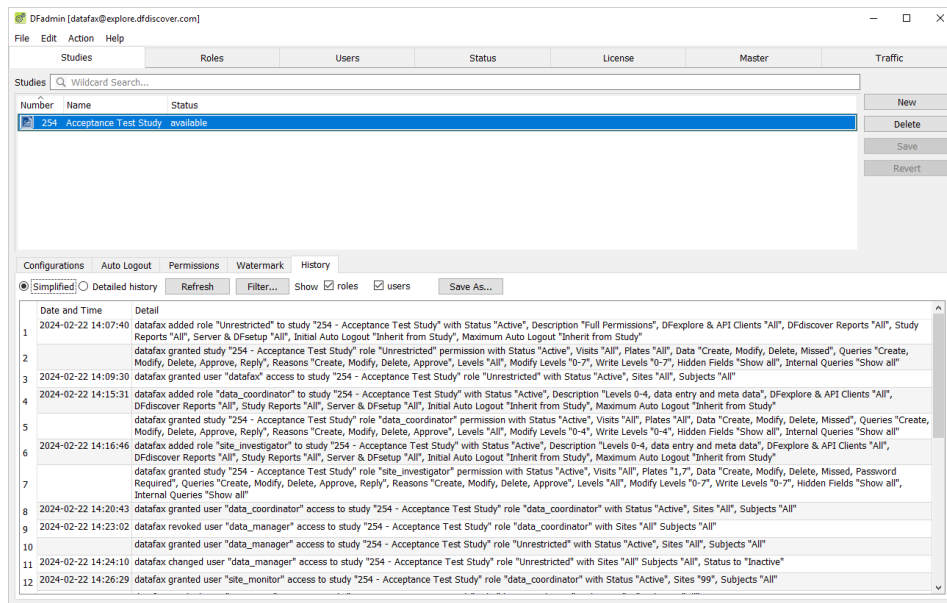


26. Verify the status for site\_invest. If site\_invest is set to **Inactive**, select **Active** from the **Status** drop-down list.

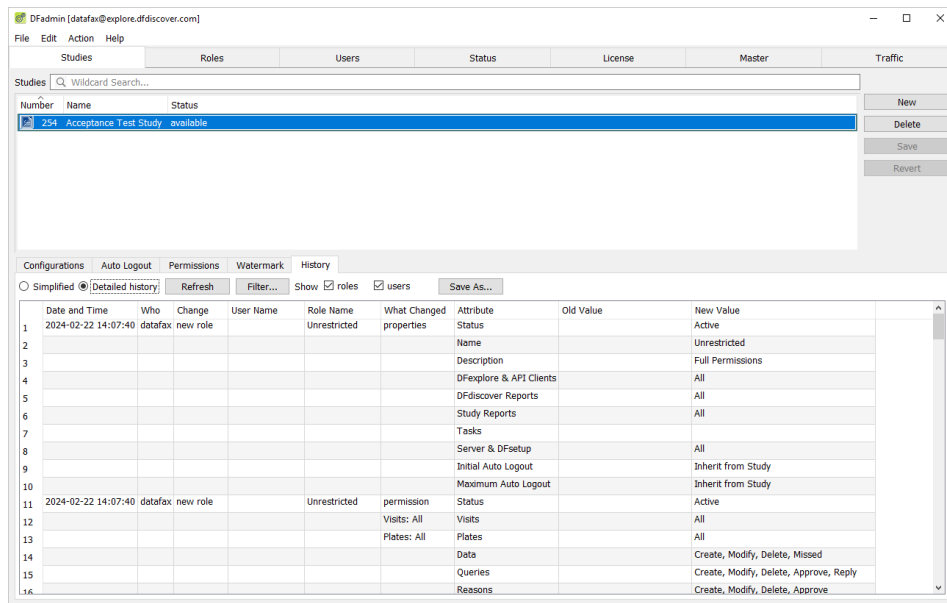
27. Assign a **DFdiscover** password for site\_invest by clicking **New Password**. Enter a password of your choice in place of the auto-generated system password. Click **Save**.

NOTE: Remember the password assigned in this test step as it is needed in future tests.

28. Click **Studies** tab followed by **History** tab. The study history is displayed in **Simplified** view.



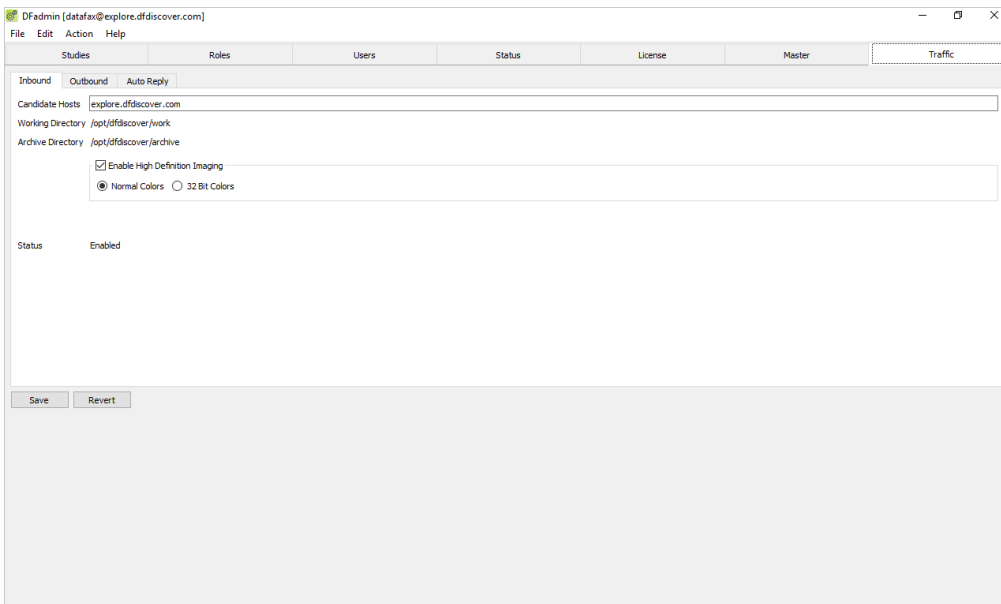
29. Select **Detailed history** to view the detailed history of changes.



30. Click **Save As...**. In the resulting dialog specify a filename of module1\_studyhistory.xlsx, click **Save**.

## Enable high definition imaging

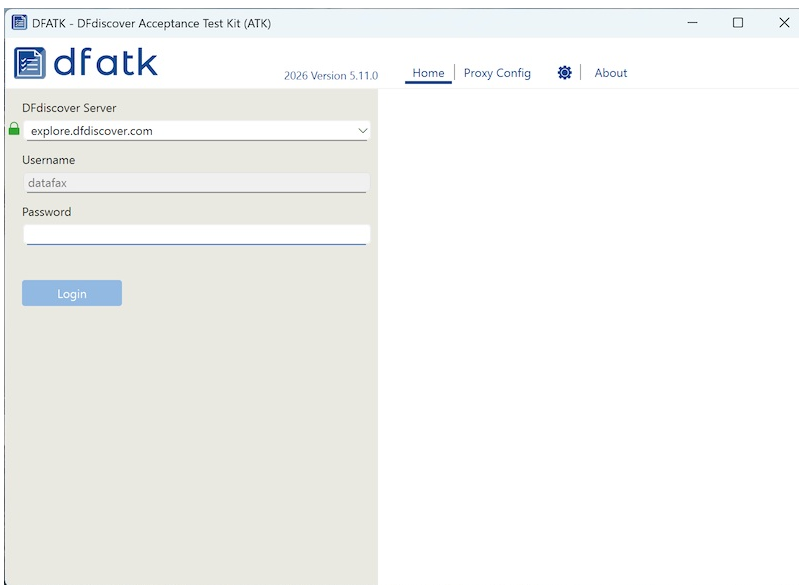
1. To enable high definition imaging, click the **Traffic** tab. Within that view, click the **Inbound** tab to display the Inbound view.
2. Check **Enable High Definition Imaging**. The **Normal Colors** checkbox is enabled by default. If it is not, enable it. Click **Save** to save the settings.



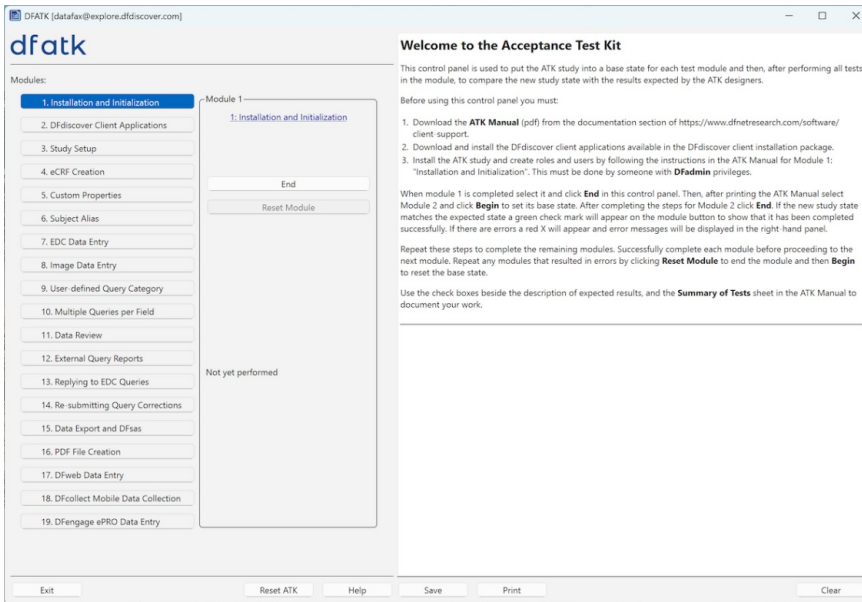
3. Select **File** > **Exit** to close **DFadmin**.

## Start the Acceptance Test Study Control Panel application

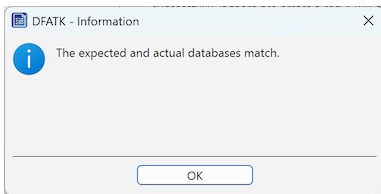
1. The remaining steps in this module require datafax privileges. Open the **DFATK** (Control Panel) login dialog.



2. Enter the name of the **DFdiscover** Server on which the Acceptance Test Kit has been installed. As the Acceptance Test Kit Control Panel must be run as datafax, the **Username** field cannot be edited. Enter the previously specified password for datafax and click **Login**.



3. In the Control Panel, confirm that Module **1. Installation and Initialization** is the current module and that its status is **Not yet performed**. Click **End** to complete Module 1. Installation and Initialization.



## Module 2. DFdiscover Client Applications

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
- Email address configured for site\_monitor

**Client Tools Used:** DFATK, DFExplore, DFAdmin, DFSetup, DFsend

**Purpose:** This module tests the DFdiscover client tools to ensure that they have been properly installed and that all basic views and documentation are intact. This Module additionally tests sending of data through **DFsend** to verify operation of the image router.

### Tests & Requirements

1. Send PDF images to **DFExplore**.
2. Resetting a user login password.
3. Verify the online user documentation. Open the Image Router and verify the appearance of the Welcome Image.
4. Open the Acceptance Test Study and verify the standard **DFExplore** views.
5. Start **DFSetup** and verify version information.
6. Verify the online setup documentation. Open the Acceptance Test Study setup and verify the standard **DFSetup** views.

Estimate of Time Required: 20 minutes

### Begin Module 2. DFdiscover Client Applications

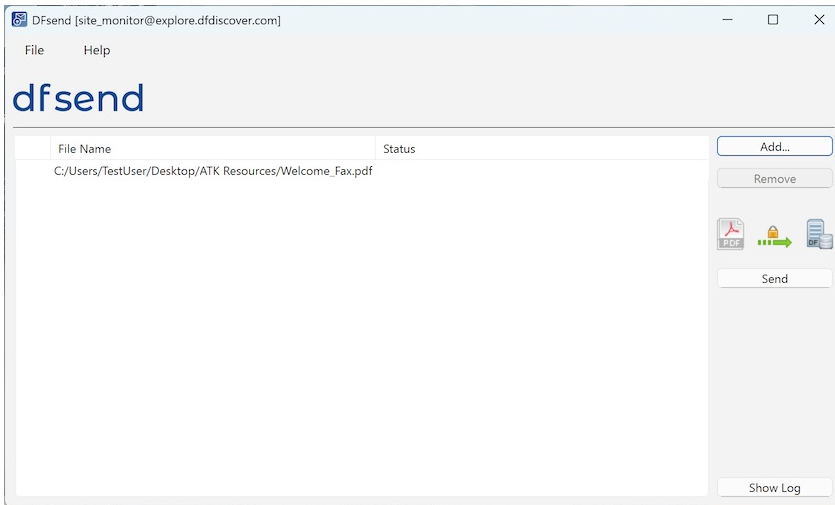
1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **2. DFdiscover Client Applications** followed by **Begin** to begin this module.

### Send PDF images to **DFExplore**

1. Click **Send Welcome Image** to email a copy of **Welcome\_Fax.pdf** to site\_monitor. Clicking more than once will result in multiple pages arriving to your email inbox.

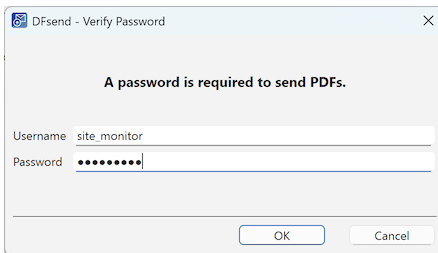
NOTE: Save the **Welcome\_Fax.pdf** file received via email to your local computer. This file is required to complete the remainder of this module. Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address is required for site\_monitor to receive the module specific PDF files.

2. Start **DFsend**, login as user site\_monitor as described in ["How to start DFsend"](#).
3. Click **Add**. From the **Select PDF Files** file selection dialog, locate the previously saved **Welcome\_Fax.pdf** file. Select the file, Click **Open**.

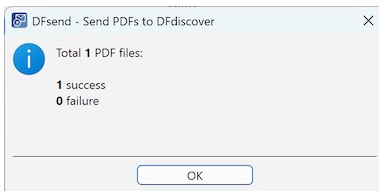


NOTE: Alternatively documents can also be added by dragging-and-dropping the desired PDF files from a local file folder into the list area.

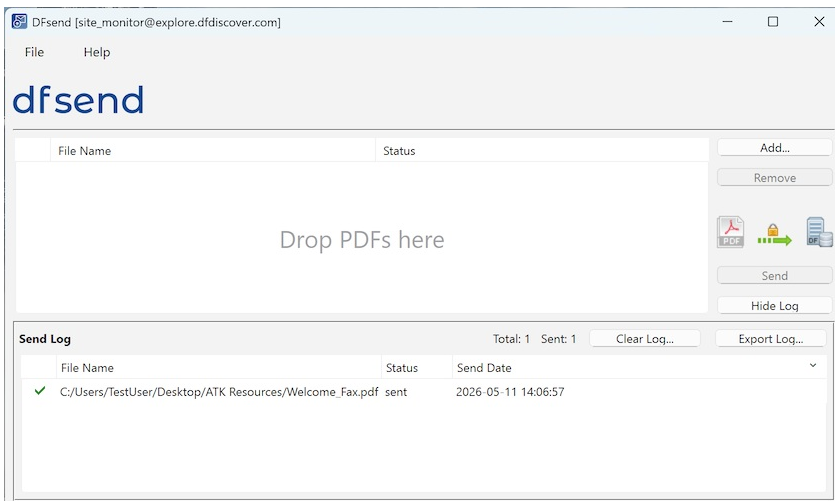
4. Click **Send**. In **Verify Password** dialog, enter site\_monitor in the **Username** field and the previously assigned password in the **Password** field. Click **OK**.



5. In the resulting **Send PDFs to DFdiscover** dialog, confirm **1 success** and **0 failure** are shown. Click **OK**.



6. Click **Show Log** to review the **DFsend** transmission history.

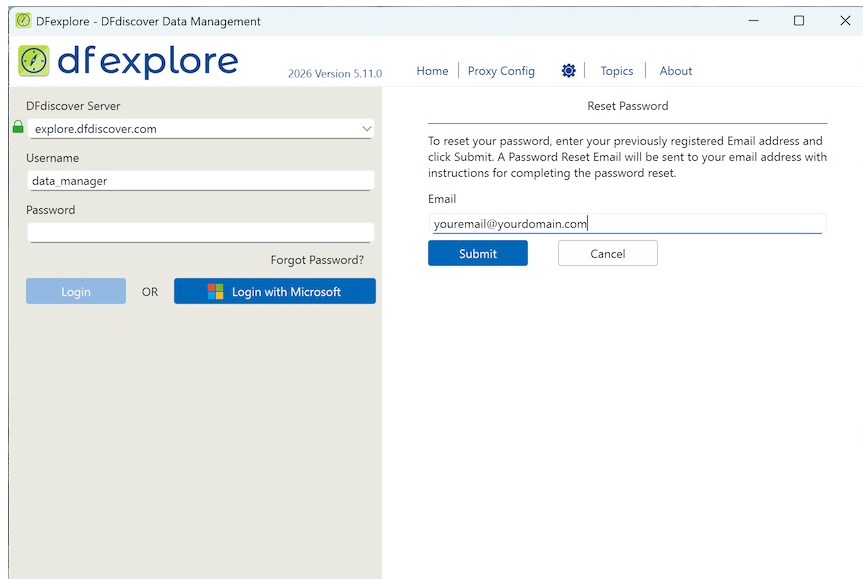


7. Select **File** > **Exit**.

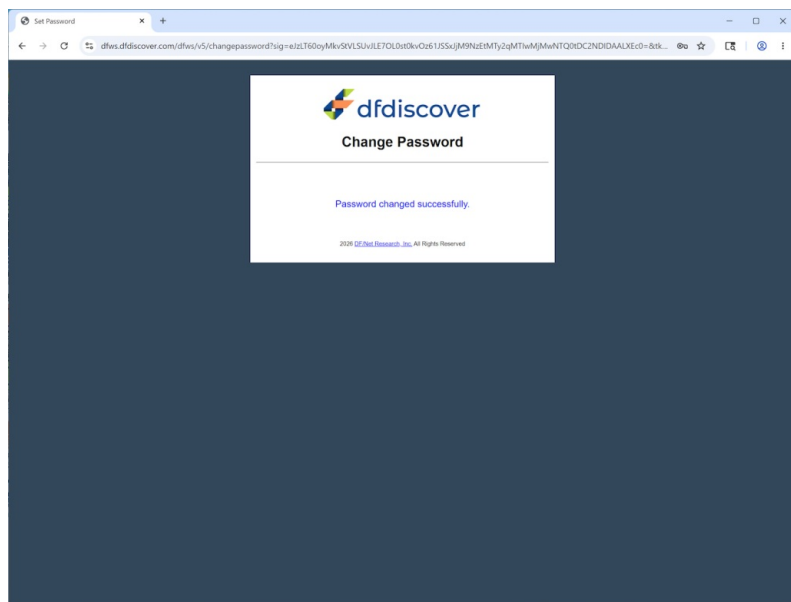
NOTE: Wait 2-3 minutes prior to proceeding to **DFExplore**.

## Resetting a user login password

1. Start **DFExplore**, enter `data_manager` in the Username field of the login dialog, and click **Forgot Password?**.
2. In the Reset Password dialog, enter the email address associated with the `data_manager` account and click **Submit**. A confirmation message appears: **Instructions to change your password have been emailed to you.**



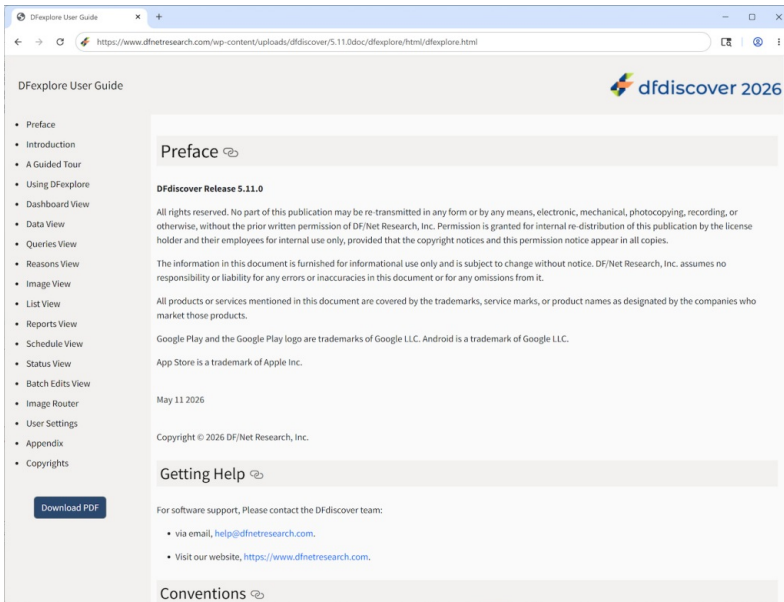
3. Open the password reset email from your **DFdiscover** server and click the provided link to reset the `data_manager` password.
4. Enter and confirm a new password, then click **Update**.



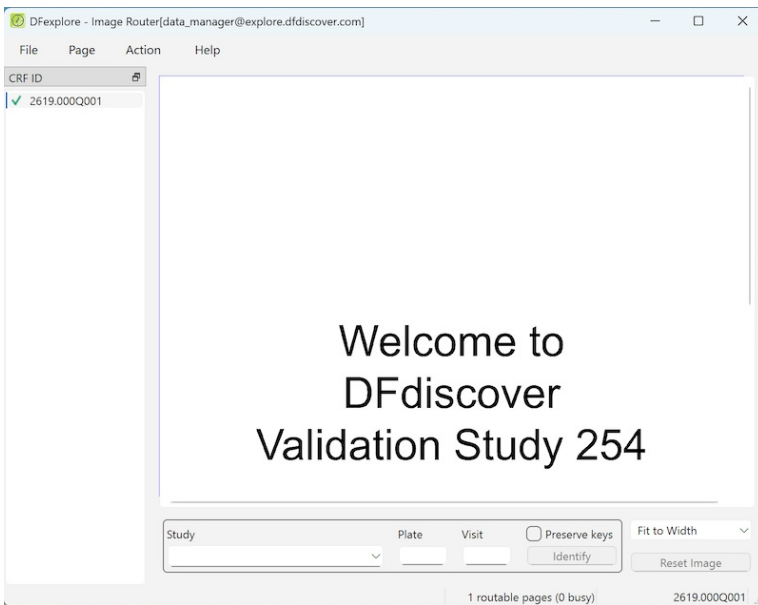
5. A message confirming **Password changed successfully**, is displayed in your browser, and a notification email is sent to the address associated with the `data_manager` account.

## Verify the online user documentation. Open the Image Router and verify the appearance of the Welcome Image

1. Return to **DFExplore**, login as user `data_manager` and choose **254 Acceptance Test Study** as described in [How to start DFExplore](#).
2. Select **Help** > **Topics** to access the documentation. In the documentation window click **Preface**, confirm the documentation version number matches the installed software Version 5.11.0. Select **File** > **Close** to dismiss the documentation window.

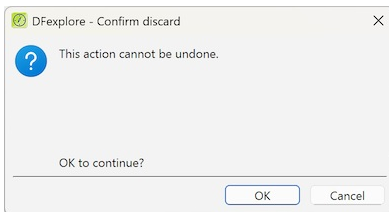


3. Select **File** > **Close Study** to exit the study.
4. In the **DFExplore** login dialog, Click **Image Router** to start the Image Router. Locate the Welcome image by selecting the page from the list of documents in the **CRF ID** panel.



**NOTE:** Any pages that have been received and which **DFdiscover** could not identify as CRFs for any of the studies registered at your site, will be found in the Image Router. The Welcome image is added during initialization of the module. If there are more pages than the Welcome image in your Image Router window, you may need to locate the Welcome image in the list of images in the **CRF ID** panel.

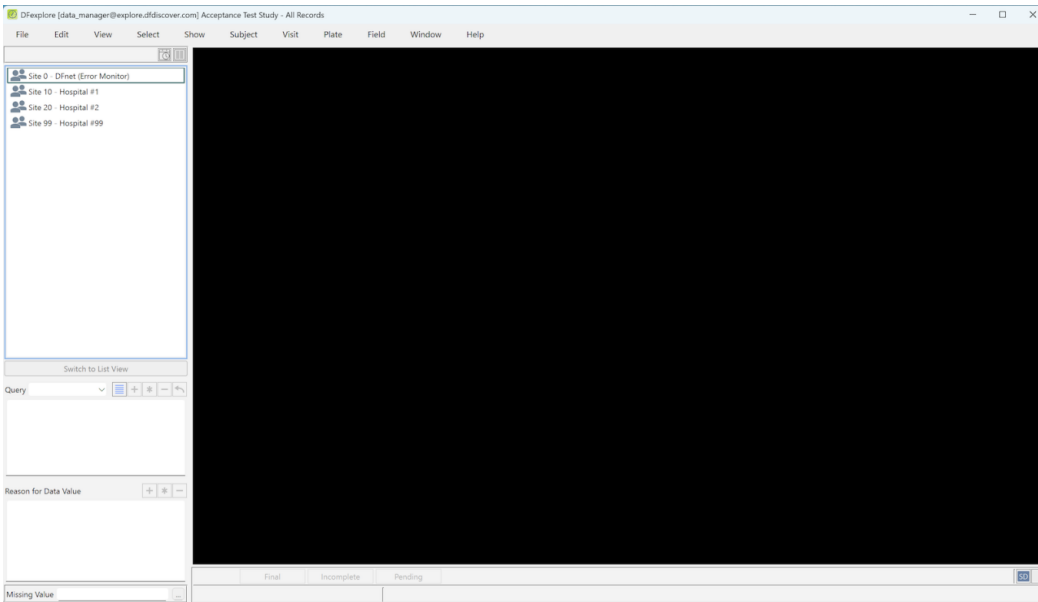
5. Print the Welcome image from the Image Router by selecting **Page** > **Print**. Choose your locally installed printer, choose **All** for **Page Range**, and click **Print**.
6. Delete the Welcome image from the Image Router by selecting **Action** > **Discard**. Click **OK** to confirm the discard action.



7. Select **File** > **Close Image Router** to exit the Image Router. The study selection dialog is presented.

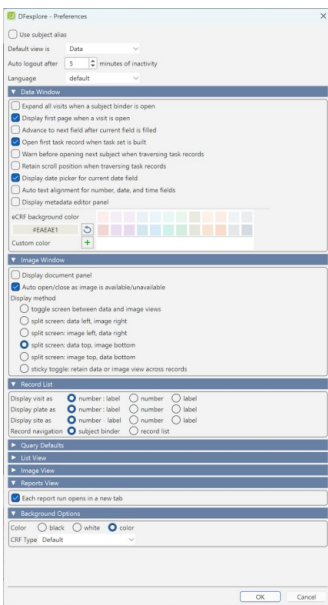
## Open the Acceptance Test Study and verify the standard **DFExplore** views

1. In the study selection dialog, highlight the entry for **254 Acceptance Test Study**. Click **Continue**.

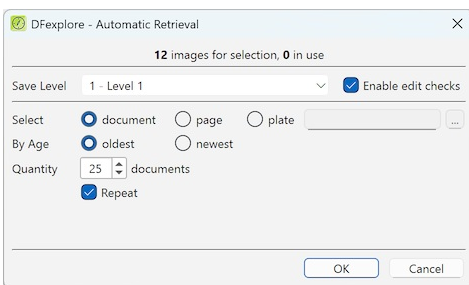


NOTE: If this step is performed within 60 seconds of closing the Image Router window, the **Username**, **Password** and list of studies are still visible. If more than 60 seconds have elapsed, you will first need to re-enter the **Password** for data\_manager, and click **Login** to view the study selection dialog. Then highlight the entry for 254 Acceptance Test Study and click **Continue**.

2. Select **File** > **Preferences**. In the **Preferences** dialog, open each panel and set the options exactly as illustrated. When finished, click **OK** to save the settings and close the dialog.

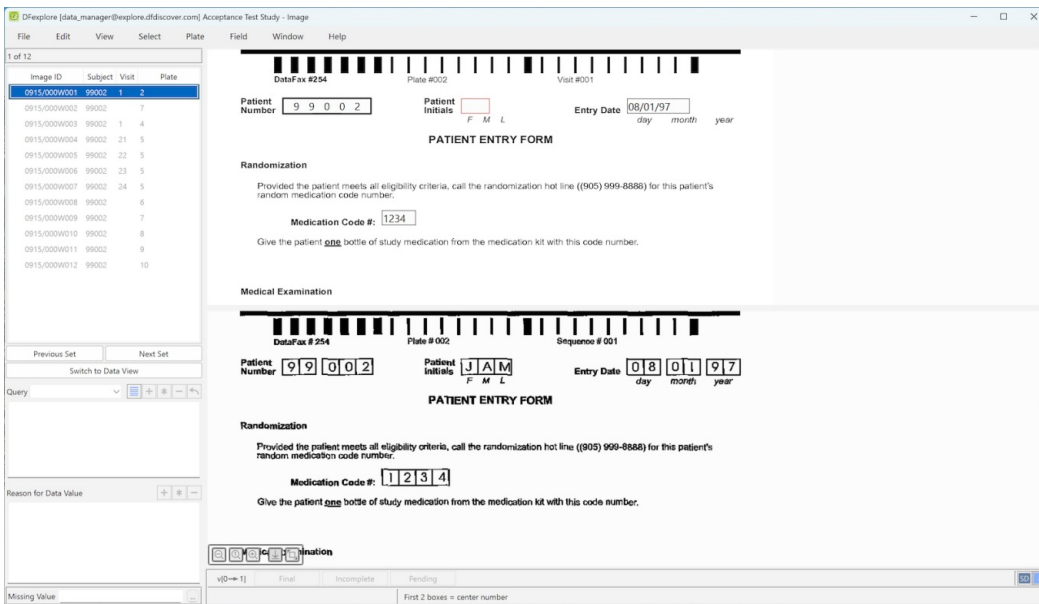


3. Select **View** > **Image** to make **Image** view the current view. Set **Quantity** = 25. Do not change any other settings in the **Automatic Retrieval** dialog and click **OK** to retrieve the new documents.

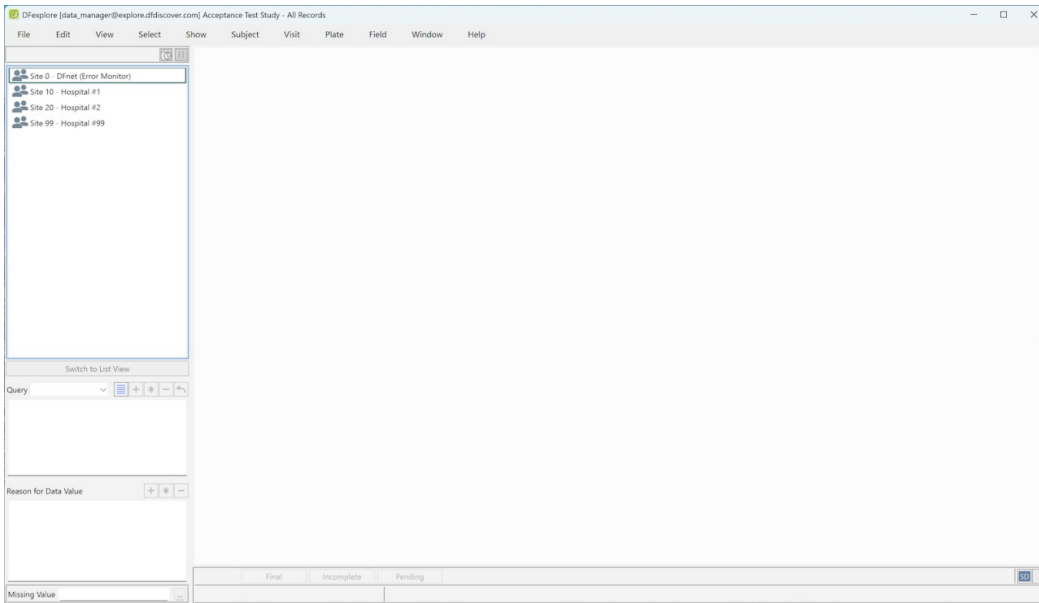


NOTE: The record retrieval dialog displays the last retrieval mode from the session preferences for each user on each computer. If data\_manager previously used **DFexplore** in another mode, you may not see the **Automatic Retrieval** dialog that is illustrated. You may see a different record retrieval dialog. When this happens, click **Cancel** in that record retrieval dialog. Then select **Select** > **Automatic Retrieval** and, as necessary, correct the settings in the resulting dialog so that they match the illustration.

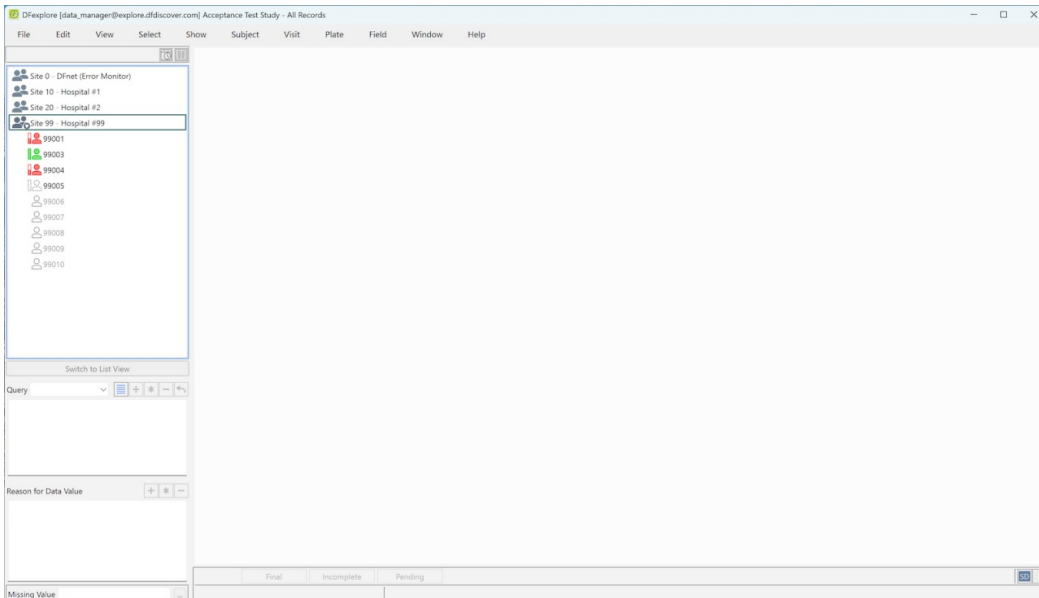
4. **Image** view becomes the current view, 12 new records are displayed in the record list panel, and the first record is highlighted. The main window displays the data record in the top pane and document image in the bottom pane.



5. Select **View** > **Data** to change to **Data** view. In the confirmation dialog, click **OK** to release the set of image records.



6. Double-click the entry for **Site 99 - Hospital #99** in the record list panel. The site opens to display the subject list. The subject list displays all enrolled subjects and the next 5 potential subjects for the site.



7. Double-click the entry for **Subject 99004** to list all visits for that subject. Select **Subject** > **Expand All Visits**. In the record list panel, locate the **6: Form 6** entry belonging to the **30: Study Termination** visit. Click it to make it the active page in the main data window.

The screenshot shows the Dfexplorer interface with the 'Subject' menu open and 'Expand All Visits' selected. The main window displays the 'PATIENT EVALUATION REPORT' for Subject 99004, Form 6. The report is in English and contains two questions: '1. Convenience: How convenient did you find the 1 pill/day regimen?' and '2. Swallowing: How easy was it to swallow the pills?'. A vertical line is drawn on the scale for question 1, indicating a response level between 'Not Very Convenient' and 'Very Convenient'.

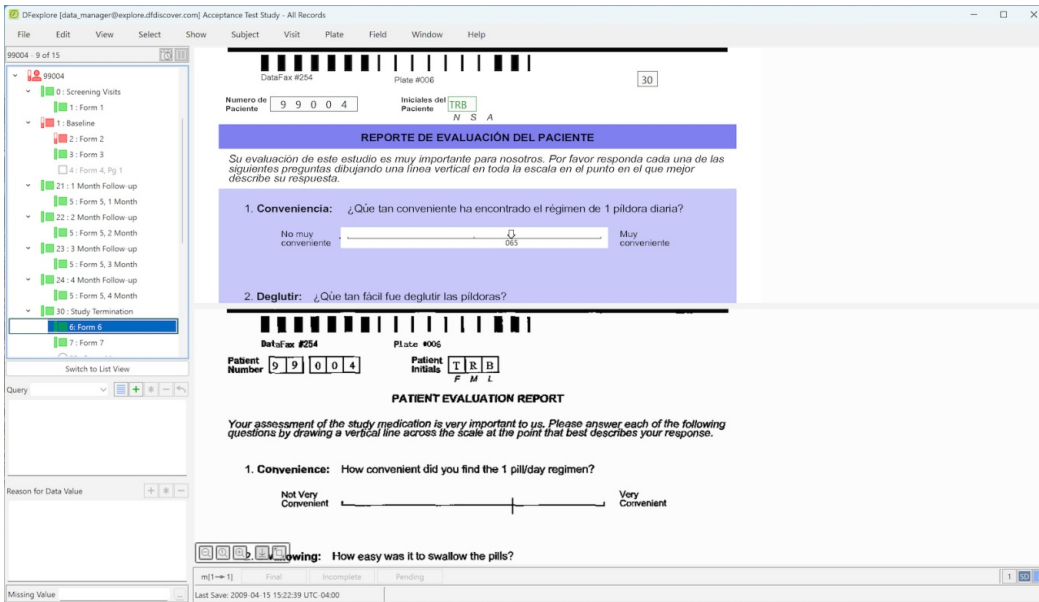
8. **6: Form 6** has been defined in the study setup with colored, multi-language backgrounds as well as the default black/white English background for the data entry screen. Select **File** > **Preferences**. In the **Preferences** dialog, change:

- **CRF Type** from **Default** to **Dutch**

Click **OK** to save the preferences and close the dialog. Confirm that the background CRF in the data window has refreshed to the Dutch version.

The screenshot shows the Dfexplorer interface with the 'Subject' menu open and 'Expand All Visits' selected. The main window displays the 'PATIENT EVALUATIE RAPPORT' for Subject 99004, Form 6. The report is in Dutch and contains two questions: '1. Gemak: Hoe ervaart U het gemak van het innemen van 1 pil per dag?' and '2. Slikken: Hoe gemakkelijk zijn de pillen doo te slikken?'. A vertical line is drawn on the scale for question 1, indicating a response level between 'Niet gemakkelijk' and 'Zeer gemakkelijk'.

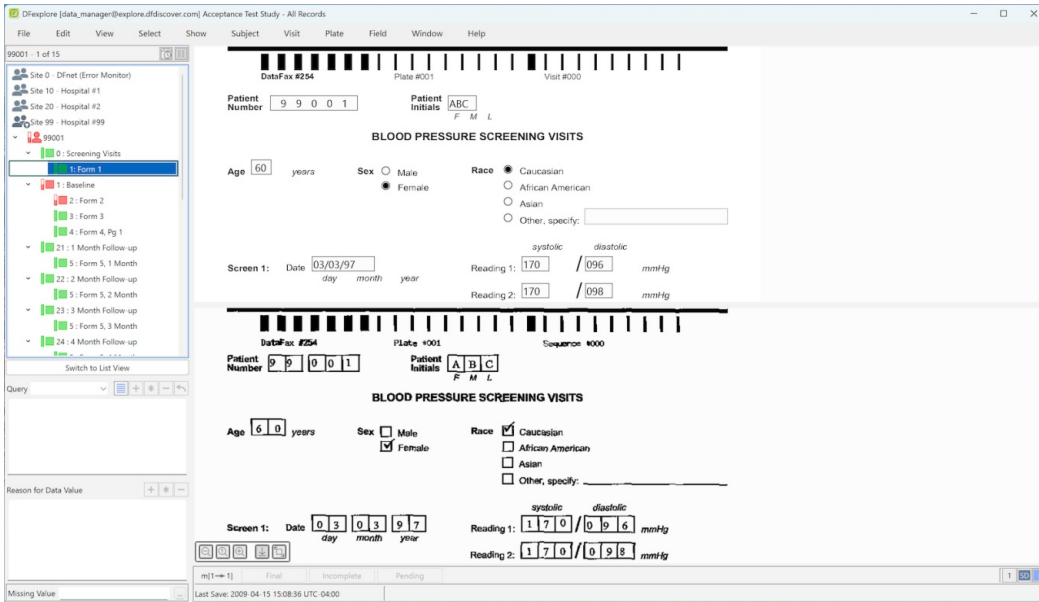
9. Re- Select **File** > **Preferences**. Change the **Background Options** choice for **CRF Type** from **Dutch** to **Spanish**. Click **OK** to apply the preferences and close the dialog.



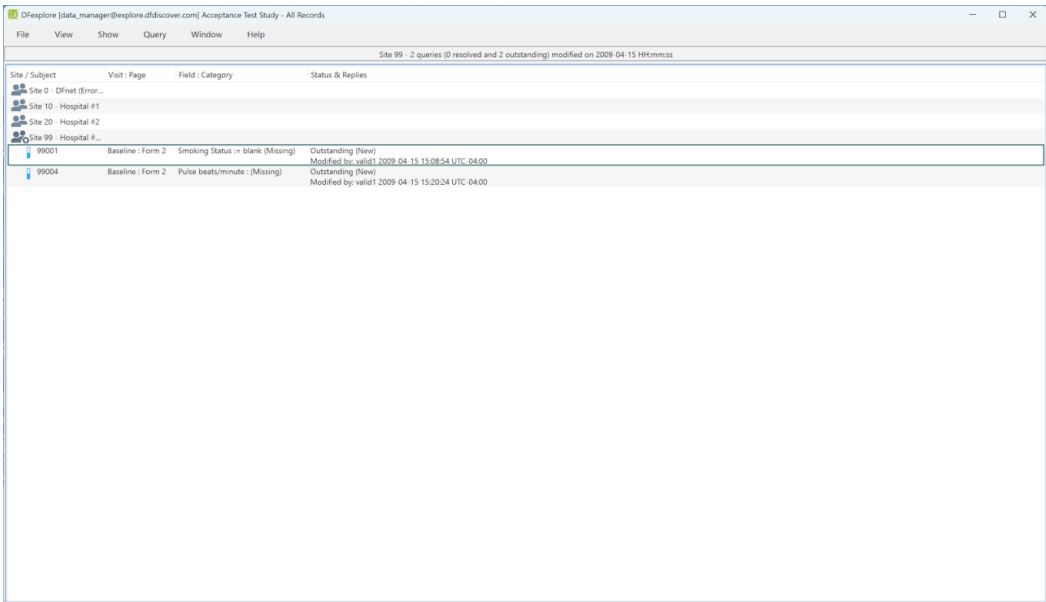
10. Re- Select **File** > **Preferences**. Reset the **Background Options** for **CRF Type** to **Default**. Click **OK** to save the preferences and close the dialog.



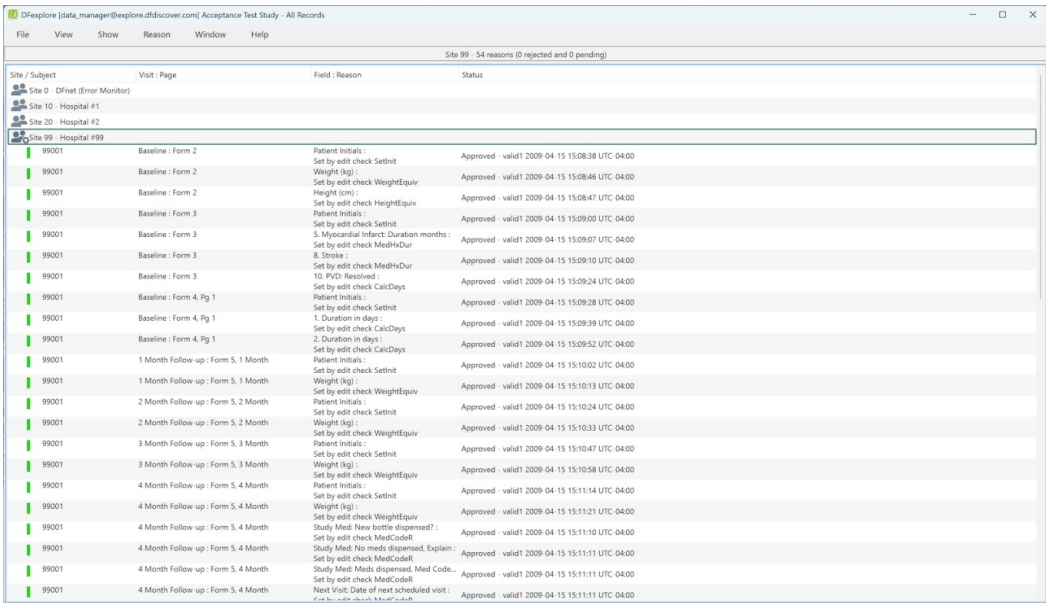
11. Double-click the entry for **99001**. This closes **99004** and opens the list of visits for **99001**. Select **Subject** > **Expand All Visits** to open all visits and pages for subject **99001**. In the record list panel, locate **1: Form 1** under **0: Screening Visits**. Click it to open the page in the main data window.



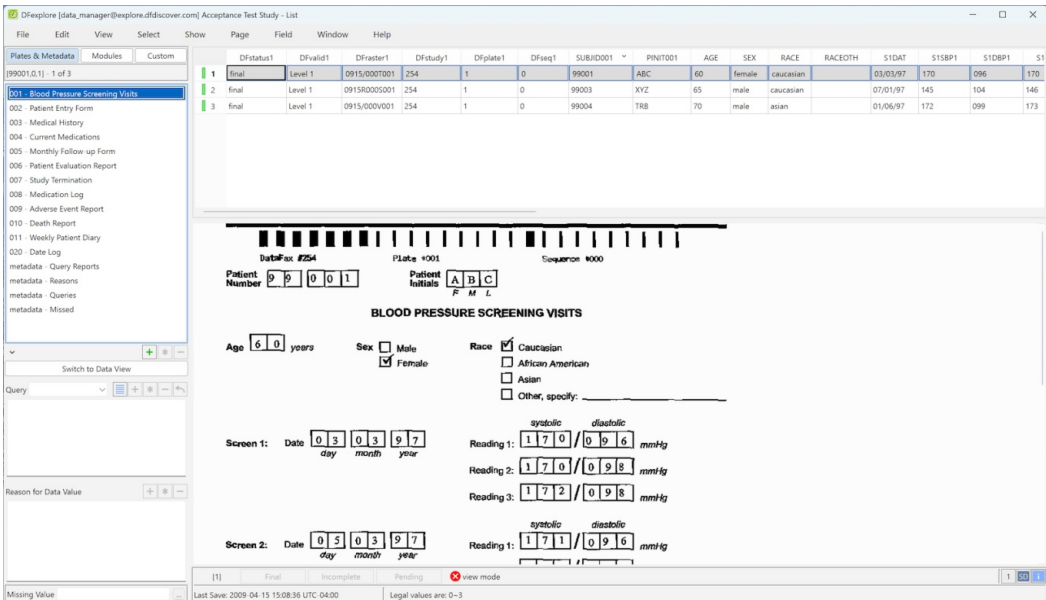
12. Select **View** > **Queries** to switch to Queries View. Select **Show** > **All Queries** to display all queries for the current subject.



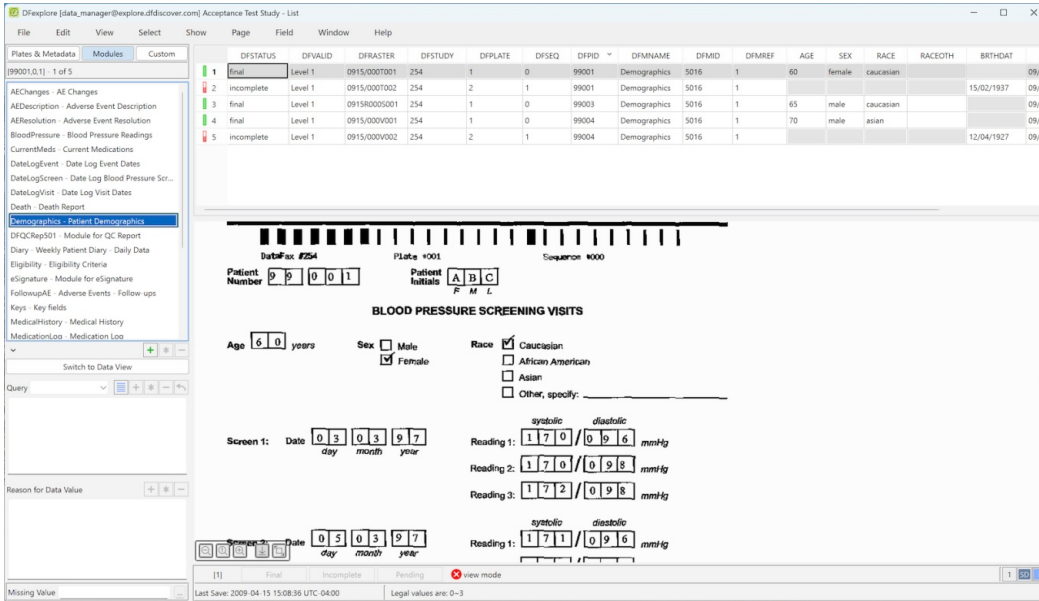
13. Select **View** > **Reasons** to switch to Reasons View. Select **Show** > **All Reasons**.



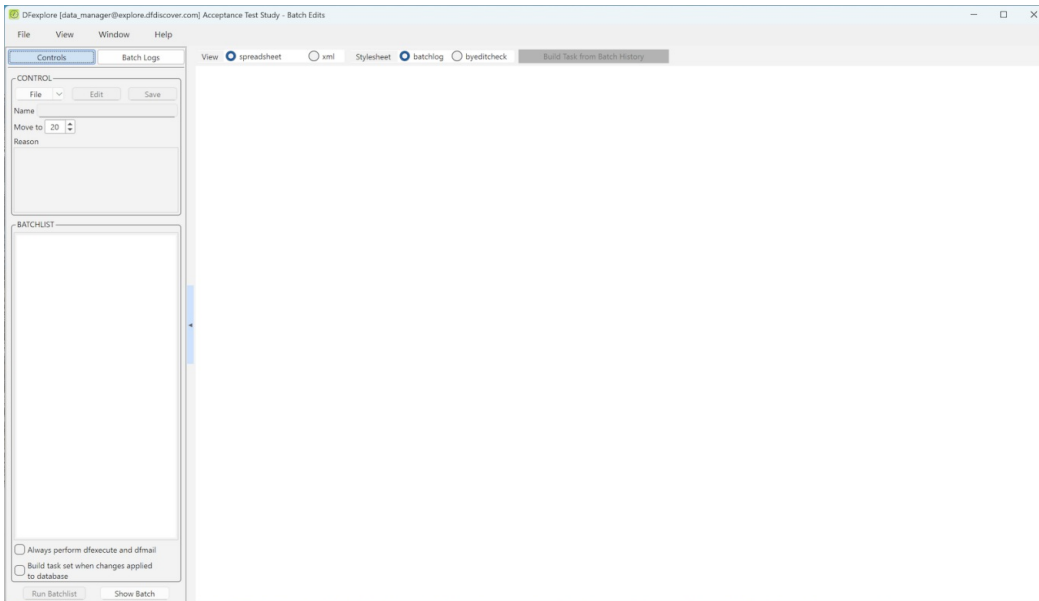
14. Select **View** > **List** to switch to List View. Confirm that the **Plates & Metadata** tab is highlighted at the top of the record list panel. Click **001 - Blood Pressure Screening Visits** from the list of plates.



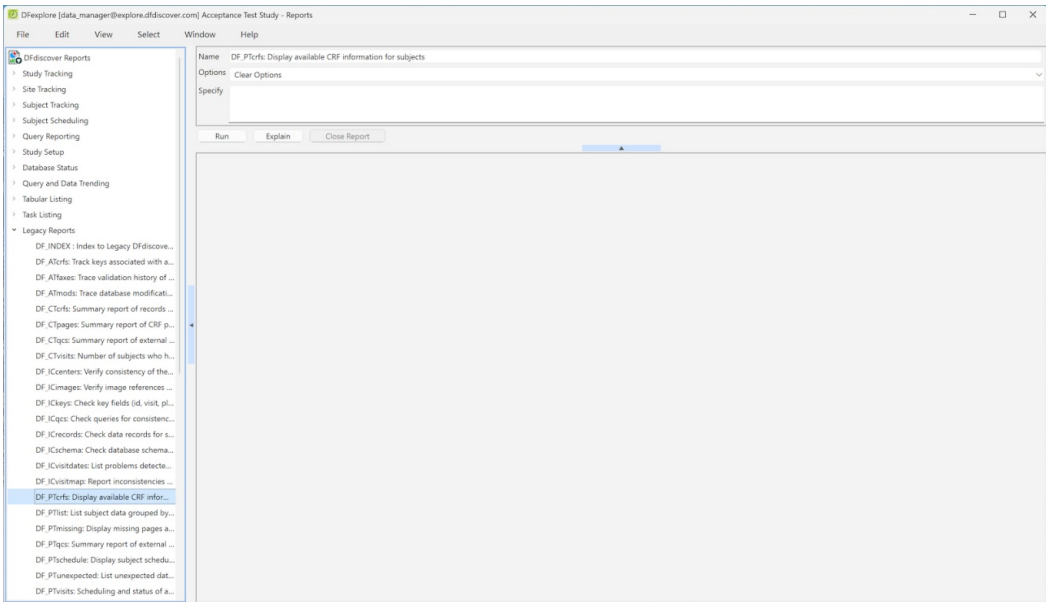
15. Choose the **Modules** tab at the top of the list panel to display a list of all modules defined for the study. Click **Demographics - Patient Demographics** module.



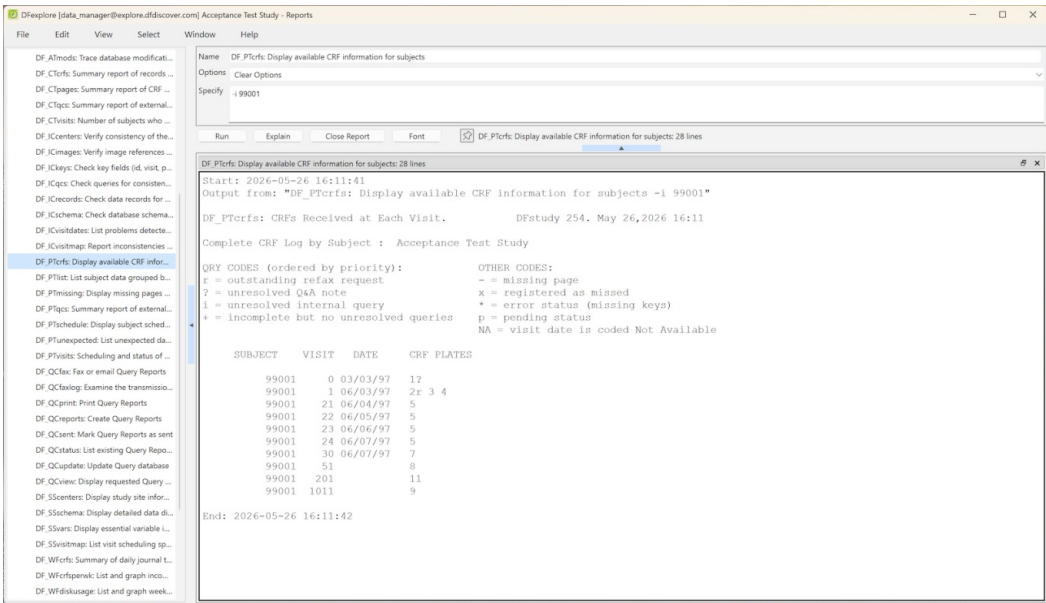
16. Select **View** > **Batch Edits** to switch to **Batch Edits View**.



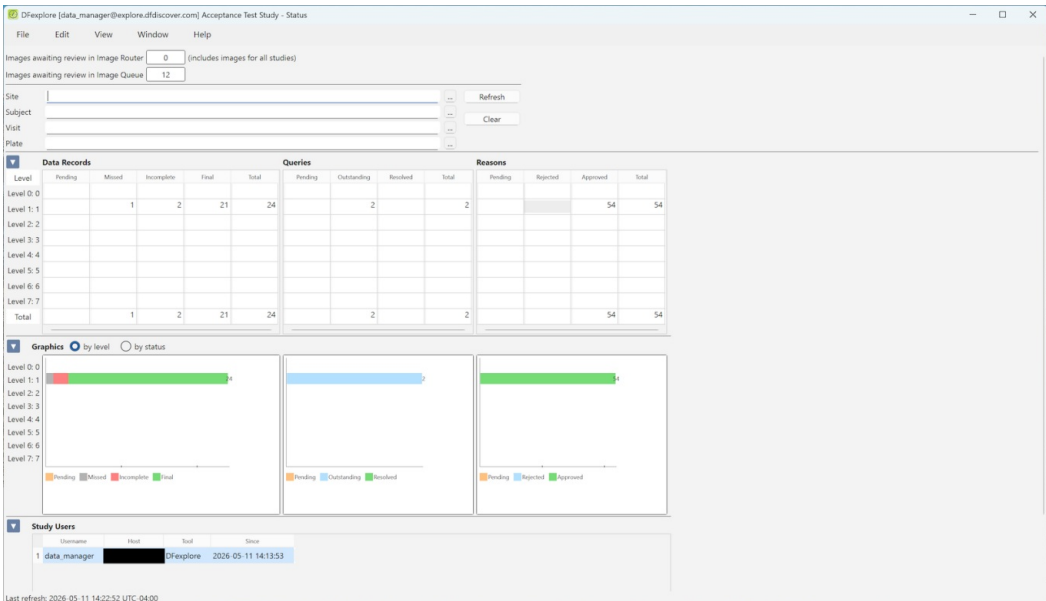
17. Select **View** > **Reports** to switch to **Reports View**. In the reports list panel, double-click **Dfdiscover Reports** followed by **Legacy Reports**. Highlight the report **DF\_PTcrfs** from the list of **Legacy Reports**.



18. In the **Specify** field, enter the report option `-i 99001`. Click **Run** to run the report for subject **99001**. Examine the output displayed in the output window.



19. Select **View** > **Status** to switch to **Status View**.



NOTE: Any pages that have been received and which **DFdiscover** could not identify as study CRFs will be found in the Image Router. As a result, the number of **Images awaiting review in Image Router** may differ from what is shown here.

20. Select **View** > **Dashboard** to display the **Dashboard View**. Click **...**, select **Record status tabular view** and **Record status chart**. Click **OK**.

The screenshot shows the DFExplore Dashboard. On the left, there is a sidebar with navigation options like 'Data entry and review', 'Review queries', and 'Subject scheduling'. The main area is divided into two panels. The left panel, 'Record status tabular view', contains a table with columns 'Records' and 'Count'. The right panel, 'Record status chart', contains three pie charts: 'Record Status (24)', 'Query Status (2)', and 'Reason Status (54)', each with a legend indicating the status counts.

Records	Count
New CRFs (all sites)	12
Pending records	0
Missed records	1
Incomplete records	2
Final records	21
Pending queries	0
Outstanding queries	2
Resolved queries	0
Pending reasons	0
Rejected reasons	0
Approved reasons	54

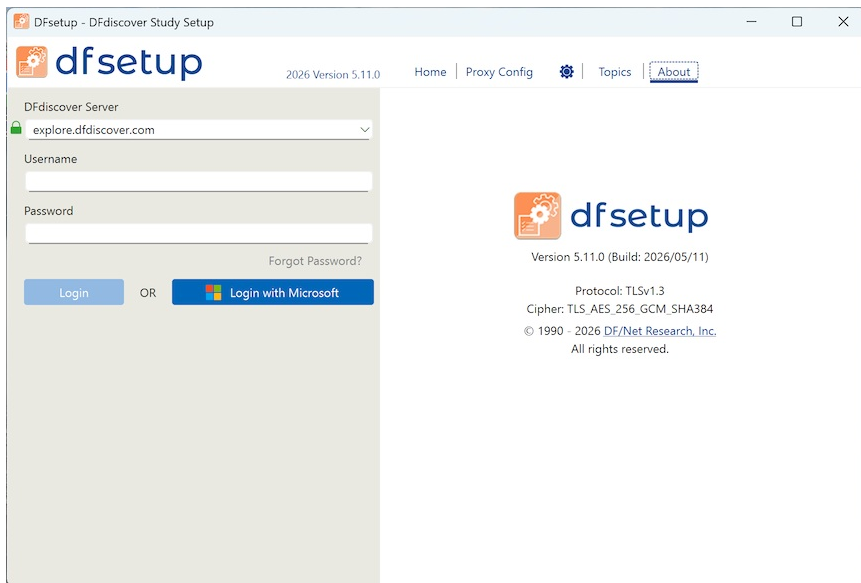
21. Select **View** > **Schedule** to display the **Schedule View**. Click **Refresh** to display the scheduling information.

The screenshot shows the DFExplore Schedule View. It features a sidebar with filters and a main area with several data tables. The 'Subject Schedule' table shows subject visits and dates. The 'Missing and Overdue' table lists subjects with missing pages. The 'Visit Schedule Info' table provides details on screening and follow-up visits. The 'Unexpected Visits and Plates' table shows 'No Unexpected'. The 'Cycles' table lists screening and scheduled cycles. The 'Correction Queries' table shows outstanding missing data. The 'Cycle Visits' table shows the status of various visits. The 'Clarification Queries' table shows 'No Clarification Queries'.

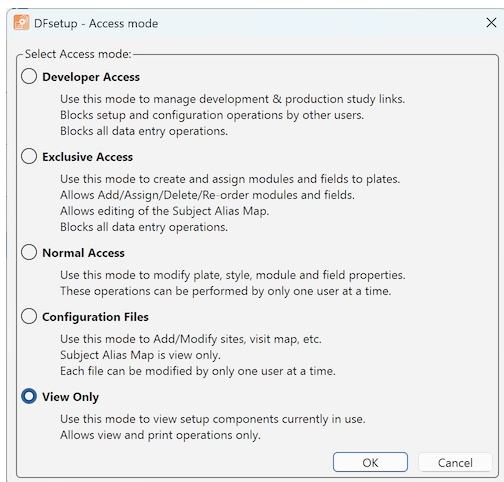
22. Select **File** > **Exit** to exit **DFExplore**.

## Start **DFsetup** and verify version information

1. Start **DFsetup**, login as **data\_manager** as described in "[How to start DFsetup](#)".
2. In the login dialog, click **About**. Confirm that the version information in the dialog matches the installed software Version 5.11.0.

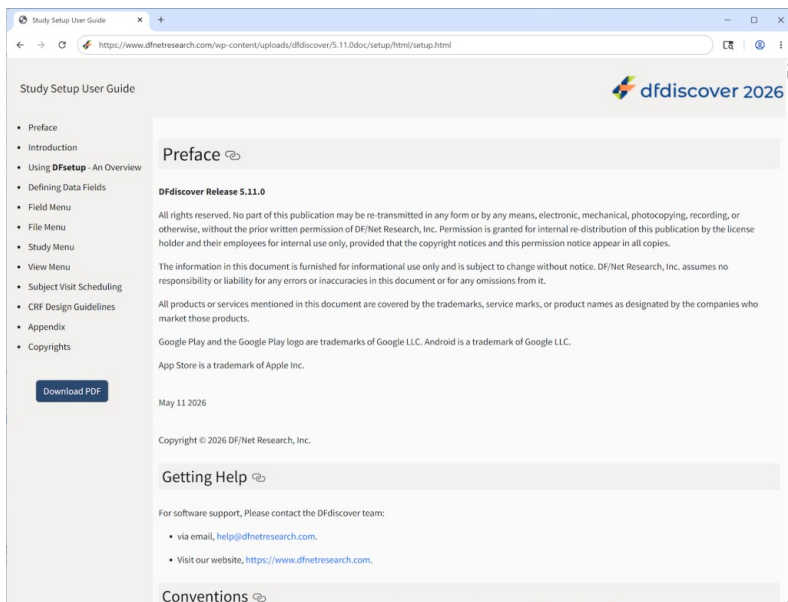


3. Choose **254 Acceptance Test Study**, select **View Only** and click **OK** to continue. The main **DFsetup** window opens.



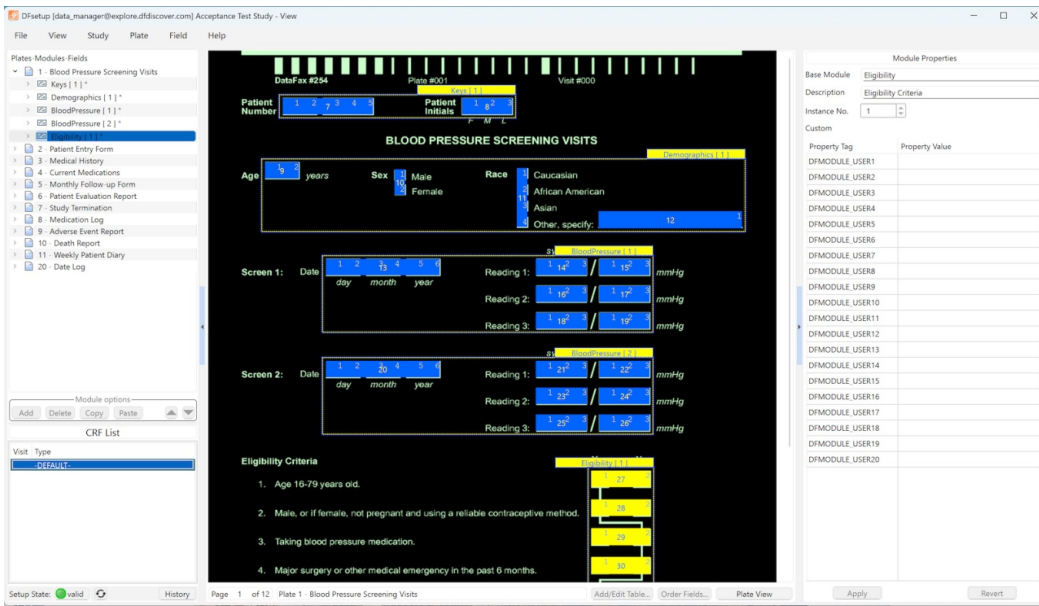
Verify the online setup documentation. Open the Acceptance Test Study setup and verify the standard **DFsetup** views

1. Select **Help** > **Topics** to access the documentation. In the documentation window click **Preface**, confirm the documentation matches the installed software Version 5.11.0. Select **File** > **Close** to dismiss the documentation window.

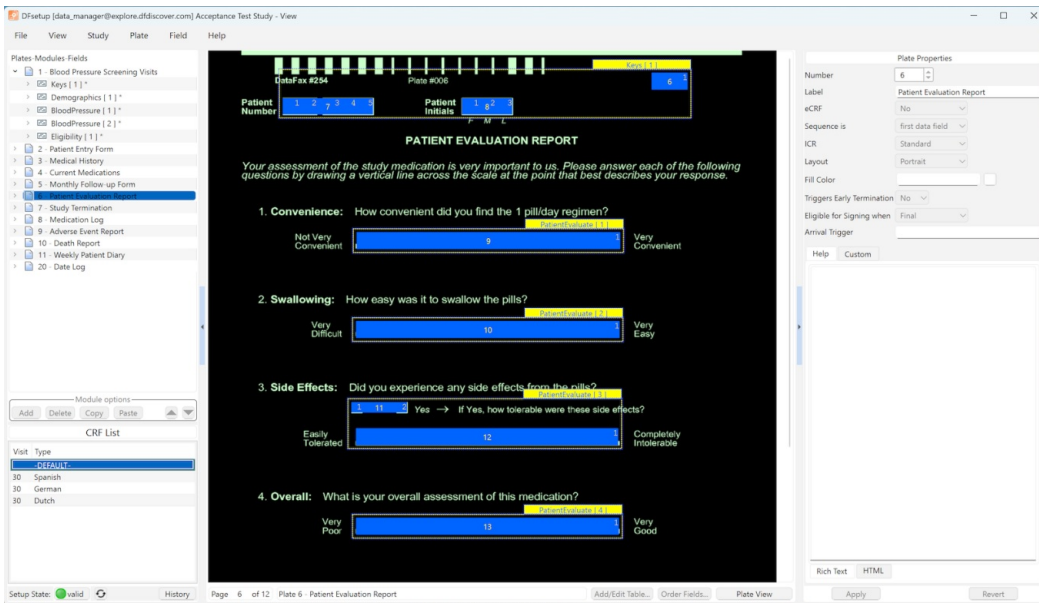


2. Select any plate entry in the **Plates-Modules-Fields** list panel to make that plate the active plate. The main window is refreshed with the CRF view of the plate definition, which includes widgets for all modules and fields. Click any field widget on the current plate to make that field the active field.

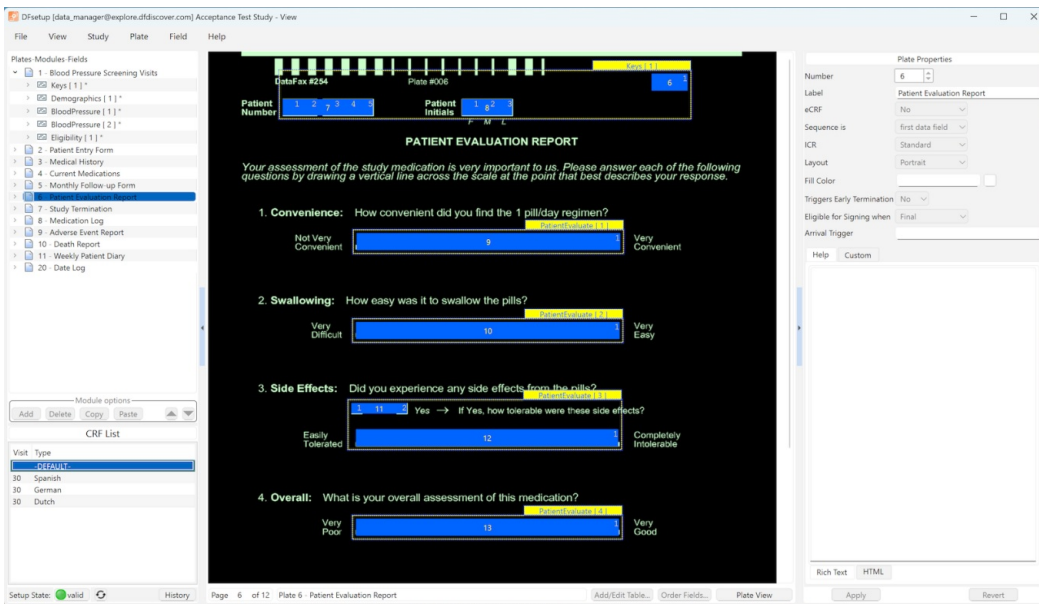
NOTE: DFsetup remembers the last active plate from your previous DFsetup session so your main DFsetup window may display a different plate as the active plate.



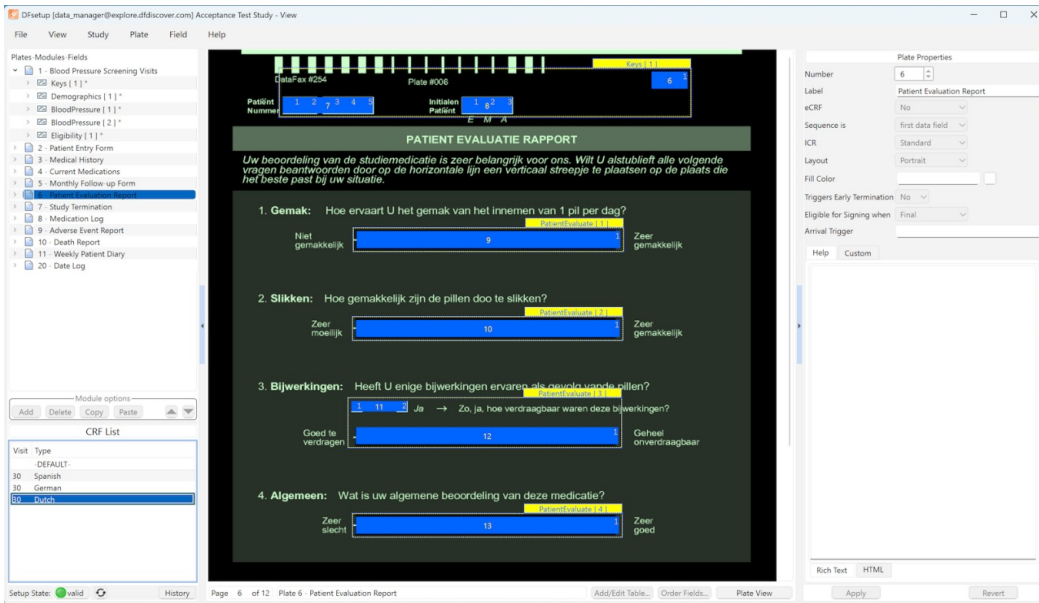
3. Select the **2 - Patient Entry Form** entry from the list panel to make plate 2 the active plate. Click **Plate View** > **Field List** to replace the Plate view with a listing of all **plate 2** fields and their properties. Click **Field List** > **Plate View** to return to the Plate view of plate 2.



4. Select the entry for **6 - Patient Evaluation Report** from the list panel to make plate 6 the active plate. Examine the CRF List panel displayed in the bottom-left of the screen. Each entry represents a unique multi-language color background associated with plate 6. This study database has been defined to include colored, multi-language CRF backgrounds for plate 6, with the default background being black/white English. The default English background and some of these multi-language backgrounds were accessed previously in [Open the Acceptance Test Study and verify the standard DFExplore views.](#)

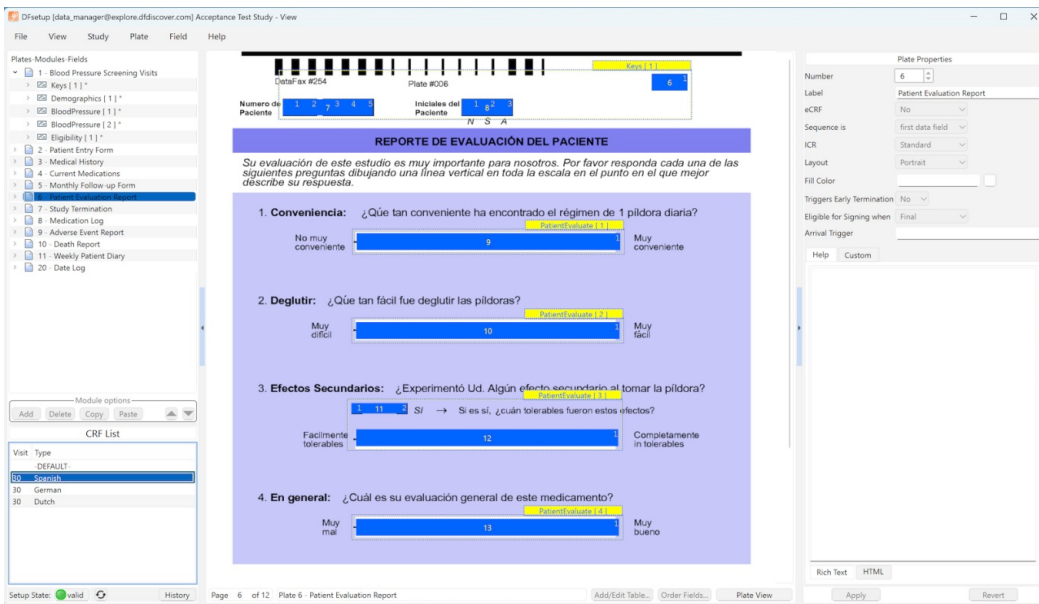


5. From the CRF List panel, choose the entry **30 Dutch**.

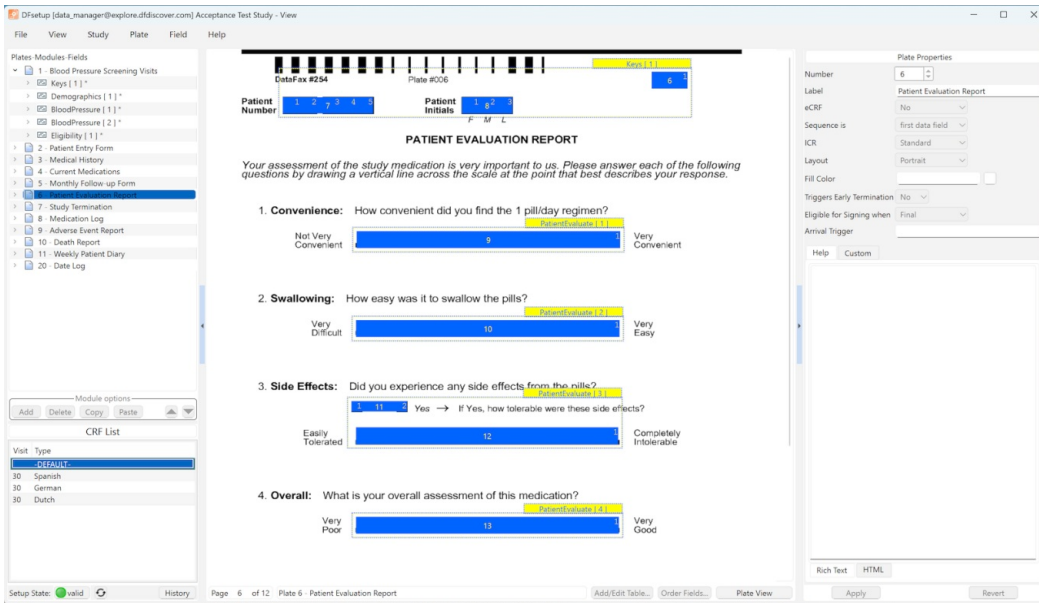


6. Select **File** > **Preferences**. In the **Preferences** dialog, choose **Color** for **Background Color**. Click **OK** to close the **Preferences** dialog.

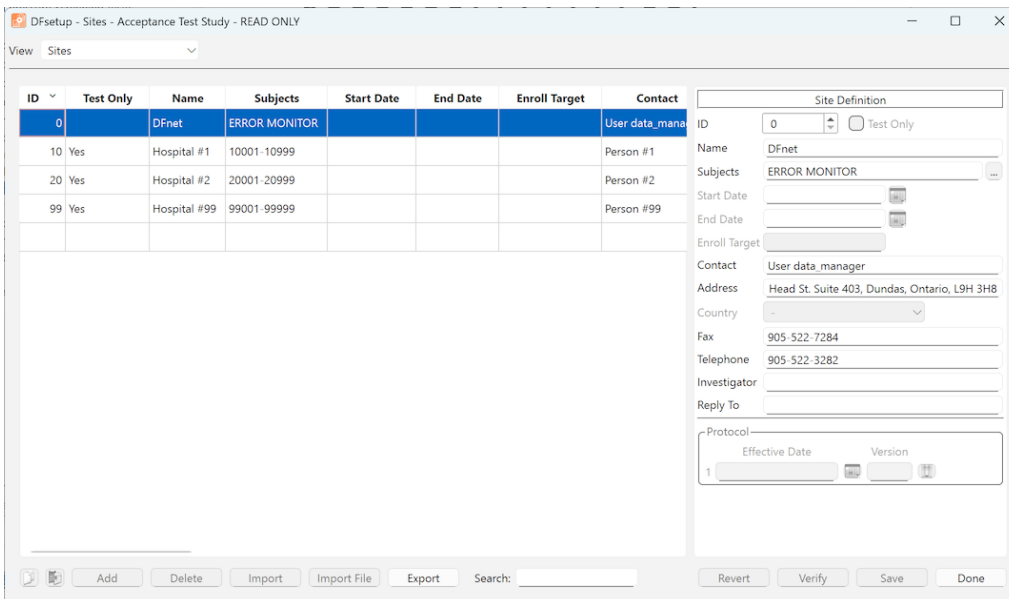
7. From the CRF List panel, choose the entry **30 Spanish**.



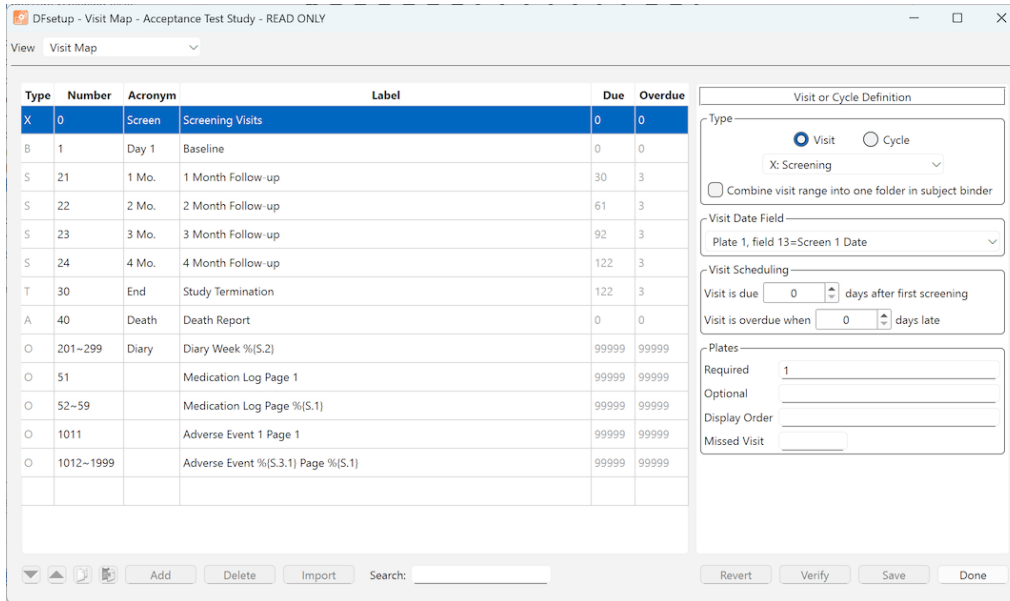
8. Return to the default (English) CRF background for plate 6 by choosing **DEFAULT** in the CRF List panel.



9. Select **View > Sites** to open the **Sites** editor. Review the contents.



10. Select **View** > **Visit Map** to open the **Visit Map** editor. Visually confirm that the expected contents are displayed. Click **Done** to close the editor.



11. Select **File** > **Exit** to close **DFsetup**.

## End Module 2. DFdiscover Client Applications

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 2. DFdiscover Client Applications.

## Module 3. Study Setup

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
- Email address configured for site\_monitor

**Client Tools Used:** DFATK, DFexplore, DFsetup, DFsend

**Purpose:** This module tests the configuration of study properties and schema information (styles, modules, fields, plates, etc.) using **DFsetup** as well as the ability to send study information to the study for the purposes of data entry using **DFsend**.

### Tests & Requirements

- Permitted users can gain exclusive access to **DFsetup** to modify a study setup.
- Define Global study preferences and apply settings to **DFsetup**.
- Create and modify a new style (Comment).
- Create and modify a new module (Death).
- Assign Field definitions to a newly created module.
- Assign a module's field definitions to a plate.
- Correct field ordering on the current plate to set field traversal order for data entry.
- Use copy and paste to create repeating module and field references on a plate.
- Create user-defined query category codes.
- Submit a copy of the newly defined Plate 11 into the study database and retrieve the page in **DFexplore** Image View.
- Enter and save all data on the submitted plate 11.

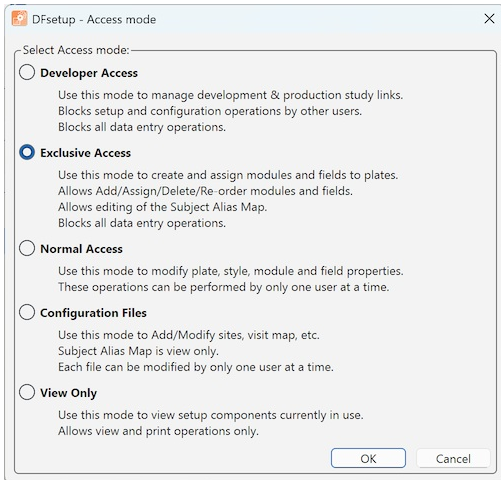
Estimate of Time Required: 20 Minutes

### Begin Module 3. Study Setup

- Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
- Click **3. Study Setup** followed by **Begin** to begin this module.

## Permitted users can gain exclusive access to **DFsetup** to modify a study setup

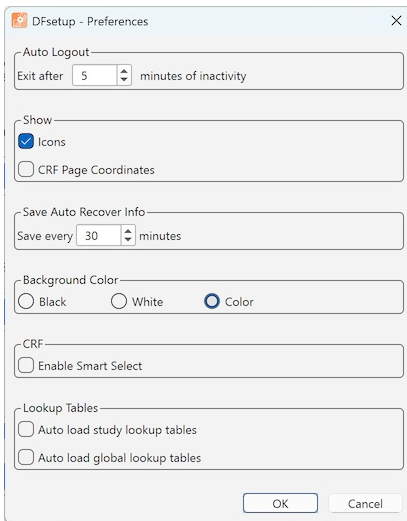
1. This module requires user data\_manager to have exclusive access to the 254 Acceptance Test Study database, the Control Panel must be closed. Click **[Exit]**.
2. Start **DFsetup**, login as data\_manager and choose **254 Acceptance Test Study** as described in "[How to start DFsetup](#)".
3. Choose **Exclusive Access** and click **[OK]**. **Exclusive Access** allows you to create and modify plates, styles and fields, and to define all setup configuration files.



4. Select **[File]** > **[Preferences]** to open the **Preferences** dialog. Set:

- **Exit after \_\_\_ minutes of inactivity = 5**
- **Background Color = Color**

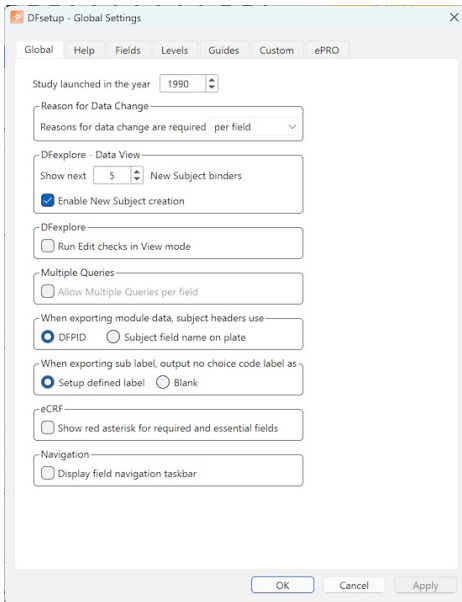
Click **[OK]** to save and close the dialog.



## Define Global study preferences and apply settings to **DFsetup**

1. Select **[Study]** > **[Global Settings]** to open the **Global Settings** dialog. Click **Global** tab. Confirm that:
  - **Study launched in the year = 1990**
  - **Reasons for data change are required = per field**
  - **Show next \_\_\_ New Subject binders = 5**
  - Check (enable) **Enable New Subject creation**
  - Uncheck (disable) **Run Edit checks in View mode**
  - Uncheck (disable) **Show red asterisk for required and essential fields**

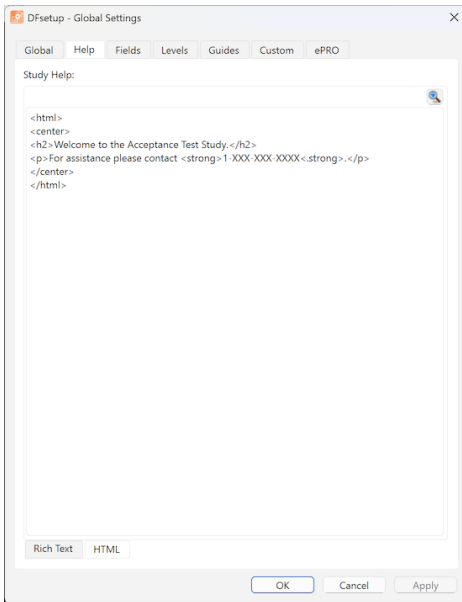
If these options are not set this way, modify them now and click **[Apply]**.



2. Click **Help**. Select **HTML** tab. Enter the following:

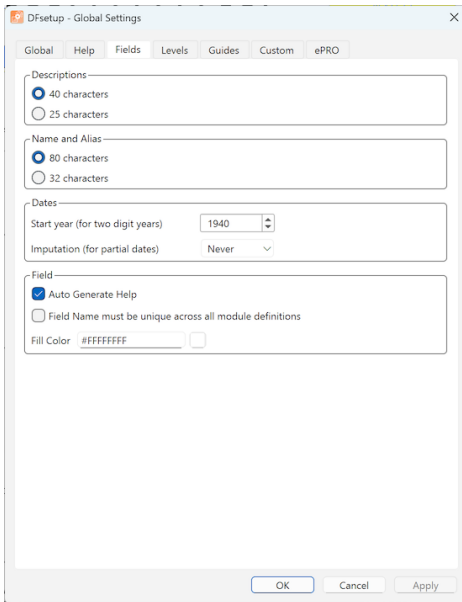
```
<html>
<center>
<h2>Welcome to the Acceptance Test Study.</h2>
<p>For assistance please contact <strong>1-XXX-XXX-XXXX</strong>.</p>
</center>
</html>
```

Click **Apply**.

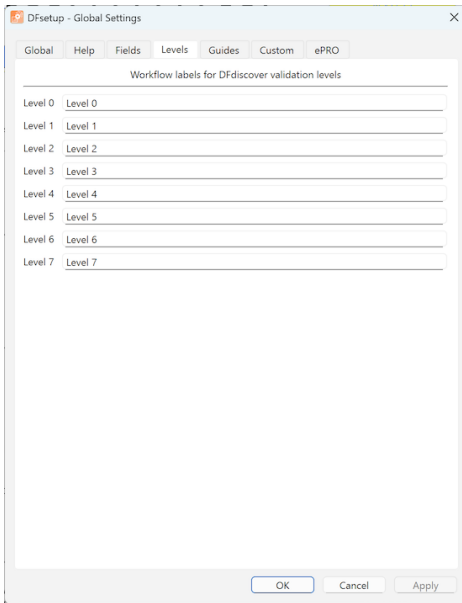


3. Click **Fields** tab, and set:

- **Descriptions** = 40 characters
- **Start year (for two digit years)** = 1940
- **Imputation (for partial dates)** = Never
- Check (enable) **Auto Generate Help**
- Uncheck (disable) **Field Name must be unique across all module definitions**
- Do not edit **Fill Color**

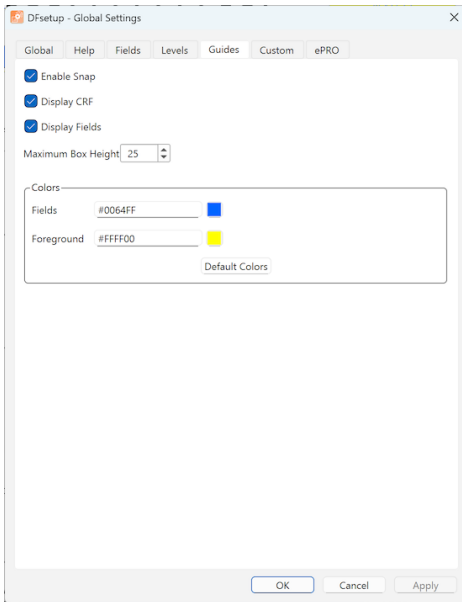


4. Click **Levels** tab. Confirm that the workflow labels of Level 0, Level 1, and through to Level 7 are used.

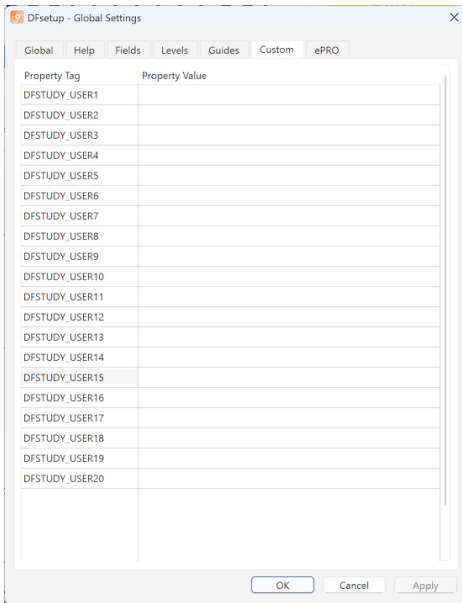


5. Click **Guides** tab. Confirm/change:

- o Check (enable) **Enable Snap**
- o Check (enable) **Display CRF**
- o Check (enable) **Display Fields**
- o Set **Maximum Box Height** = 25
- o No changes are required to **Colors Fields** or **Foreground**

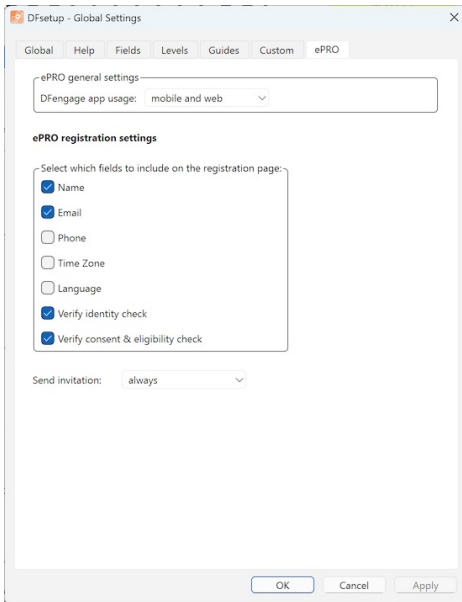


6. Click **Custom** tab. Confirm that all Property Values are blank.



7. Click **ePRO** tab. Confirm the default **ePRO registration settings**:

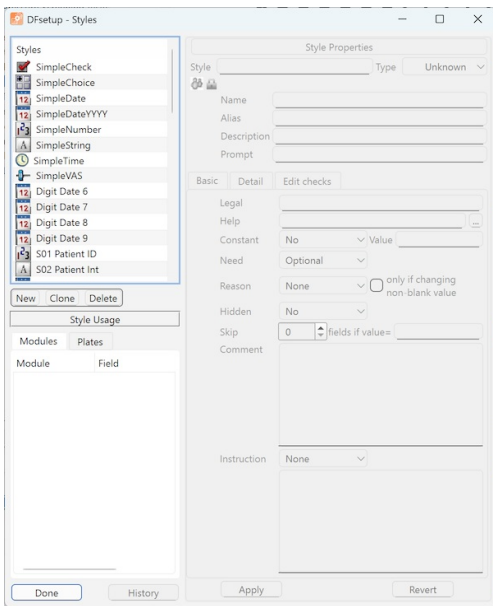
- o Checked (enabled) **Name**
- o Checked (enabled) **Email**
- o Checked (enabled) **Verify identity check**
- o Checked (enabled) **Verify consent & eligibility check**
- o Send Invitation: **always**



8. Click **OK** to save changes and exit the dialog.

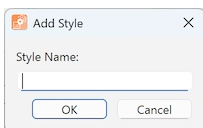
## Create and modify a new style (Comment)

1. Select **View** > **Styles** from the menubar.



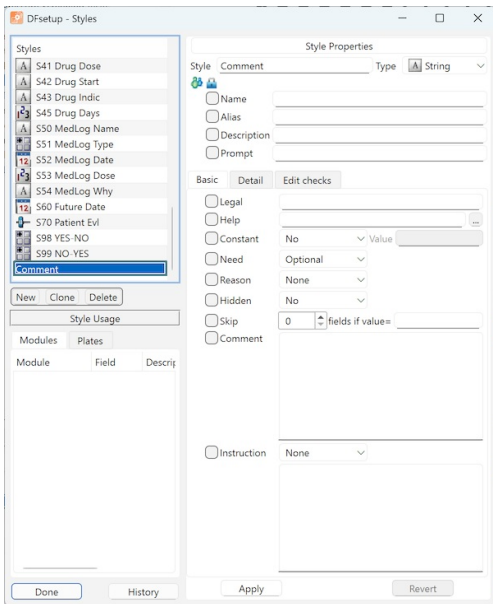
**NOTE:** The style names and information appearing in your **Styles** dialog may be different from those shown here. You should see the standard **DFdiscover** Simple styles.

2. Within the **DFsetup-Styles** dialog, locate the style name **SimpleString**. Click **SimpleString** to select it as the current style. Click **Clone** to duplicate this style.



3. Provide a Style name of **Comment** in the Style dialog and click **OK**.

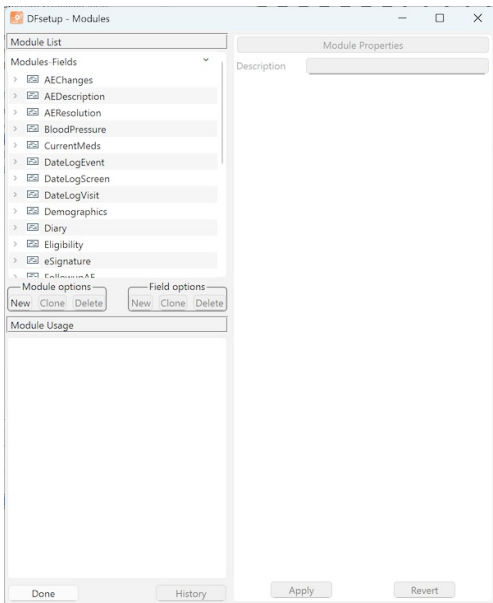
4. Click **Comment** to make it active, and confirm the **Style Properties Basic** tab displays the style properties as shown.



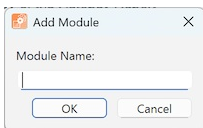
5. Click **Detail** tab, Change the **Store** property from 1 to 200. Check (enable) the  to the left of the **Store** property to lock this setting in the Comment style. Click **Apply** to apply the modifications. Click **Done** to close the **Style Properties** dialog.

## Create and modify a new module (Death)

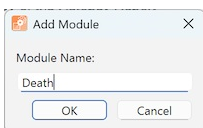
1. Choose **10 - Death Report** entry from the **Plates-Modules-Fields** list panel to make plate 10 the active plate. Select **View** > **Modules** to open the module definition dialog.



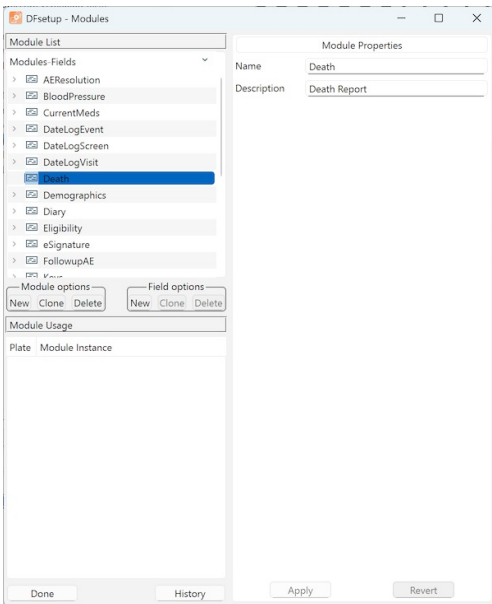
2. Click **Module options** **New**.



3. Enter a name of Death in the **Add Module** dialog. Click **OK** to save.

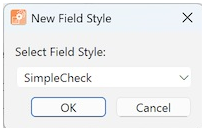


4. With the **Death** module selected as the active module, confirm that the Name Death appears in the **Module Properties** window. In the **Description** field, enter Death Report. Click **Apply**.

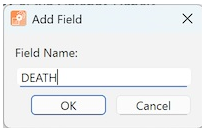


## Assign Field definitions to a newly created module

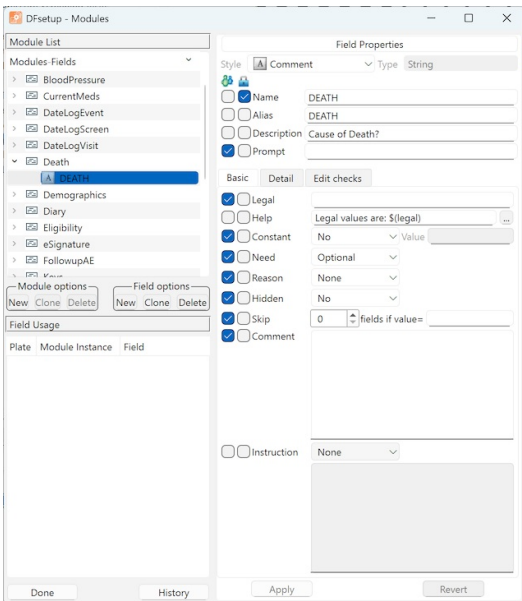
1. Choose **Death** module defined in ["Create and modify a new module \(Death\)."](#) to make it the active module. Click **Field options** **New**.



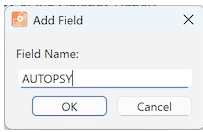
2. To create a field definition for "Cause of Death", choose **Comment** from the **Style** pull-down list, click **OK**.
3. Enter the name **DEATH** for the **Field Name:** and click **OK**.



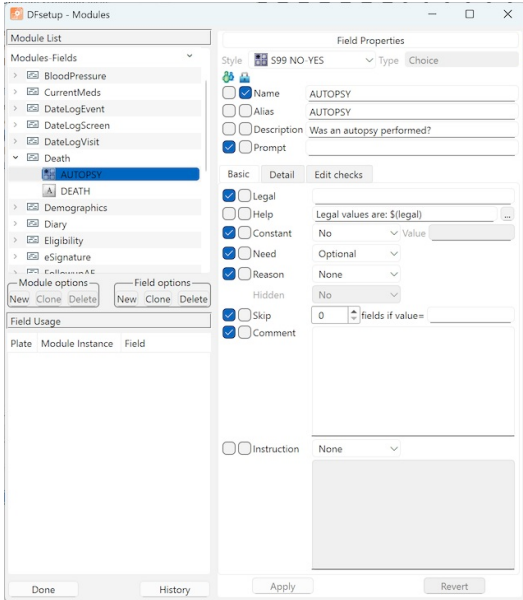
4. Within the **Field Properties**, enter a **Description** of Cause of Death?. Click **Apply**.



5. Click **Field options** **New**. In the resulting **New Field Style** dialog, choose **S99 NO-YES** from the **Styles** pull-down list. Click **OK**.
6. Enter the name **AUTOPSY** for the **Field Name:** and click **OK**.



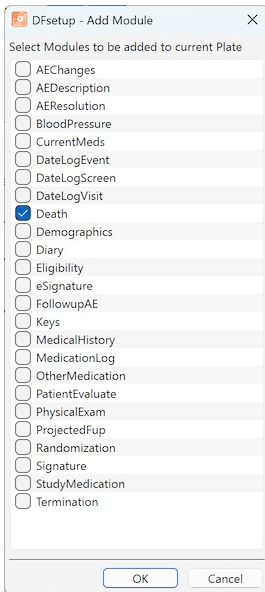
7. Within the **Field Properties**, enter a **Description** of Was an autopsy performed?. Click **Apply**.



8. Click **Done**.

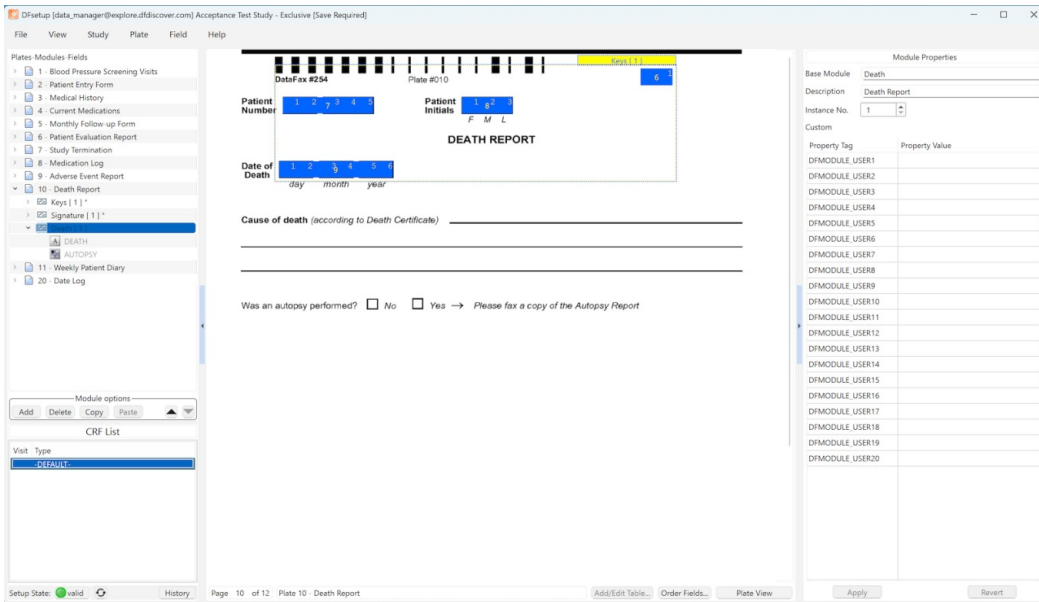
## Assign a module's field definitions to a plate

1. Still with **10 - Death Report** as the active plate, create the field references (layouts) for the **Cause of death** and **autopsy** fields defined in ["Assign Field definitions to a newly created module."](#) First add the **Death** module to plate **10-Death Report** by clicking **Add** from the **Module options**. Locate and choose **Death** module from the list of modules.

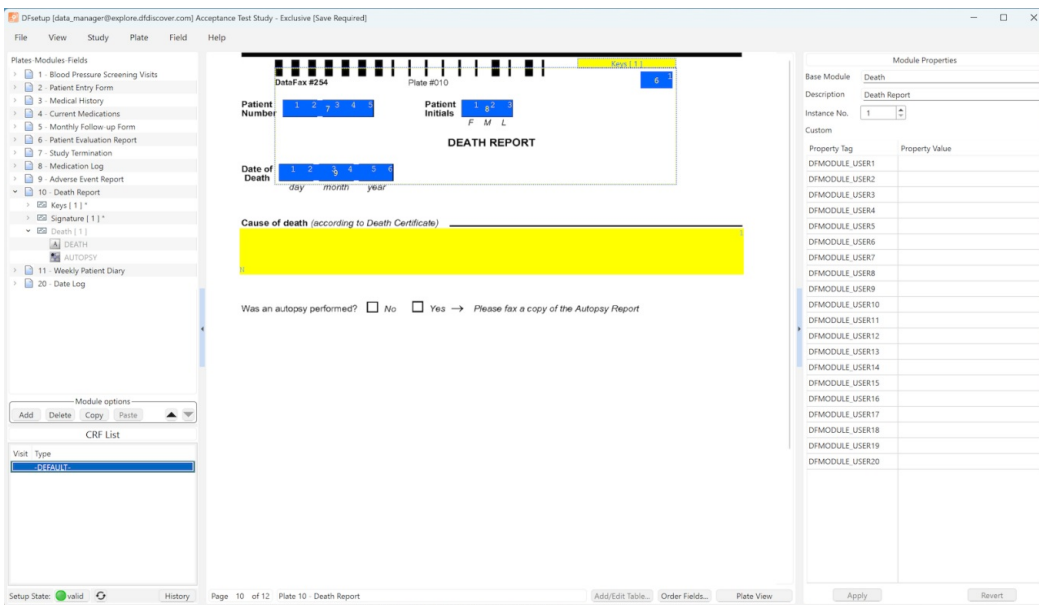


2. Click **OK** to add the **Death** module to plate **10-Death Report**.

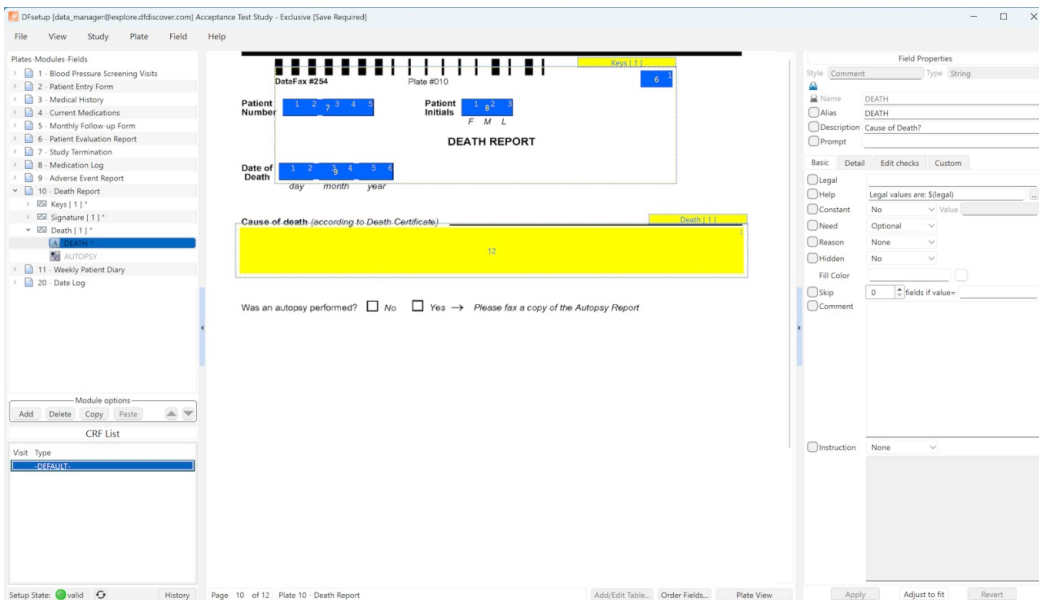
3. Click **[>]** to the left of **Death [1]** module entry in the **Plates-Modules-Fields** list to show all field definitions within the **Death [1]** module.



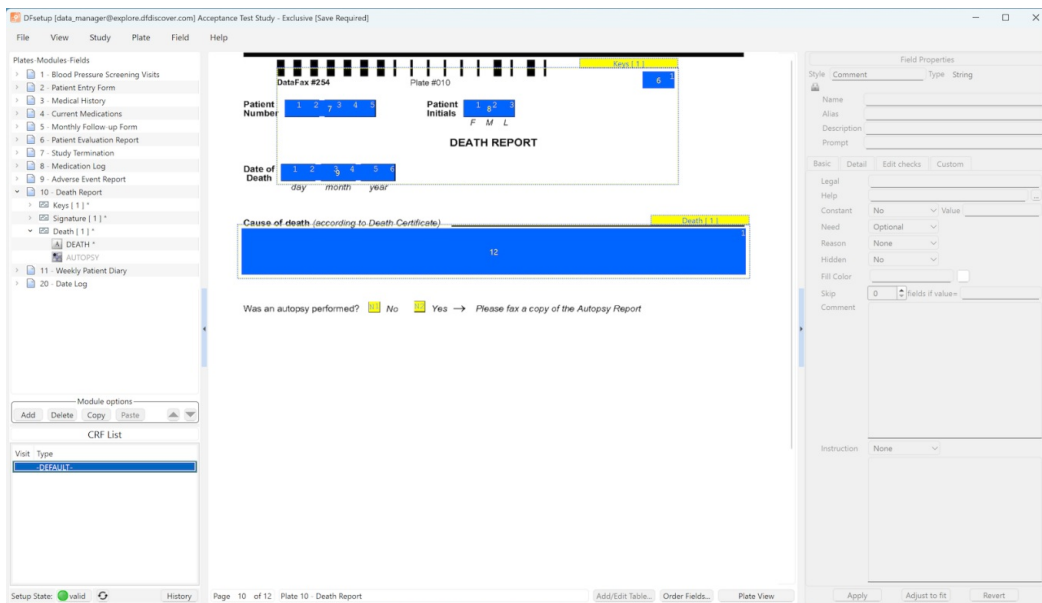
4. Create a field reference for the **Cause of Death**. Using the mouse, select **Click** the leftmost end of the second longest lines on the plate background. Holding down the **left** mouse key and **Control**, drag up and across to the rightmost end of the line. Release the mouse key to create a string field widget.



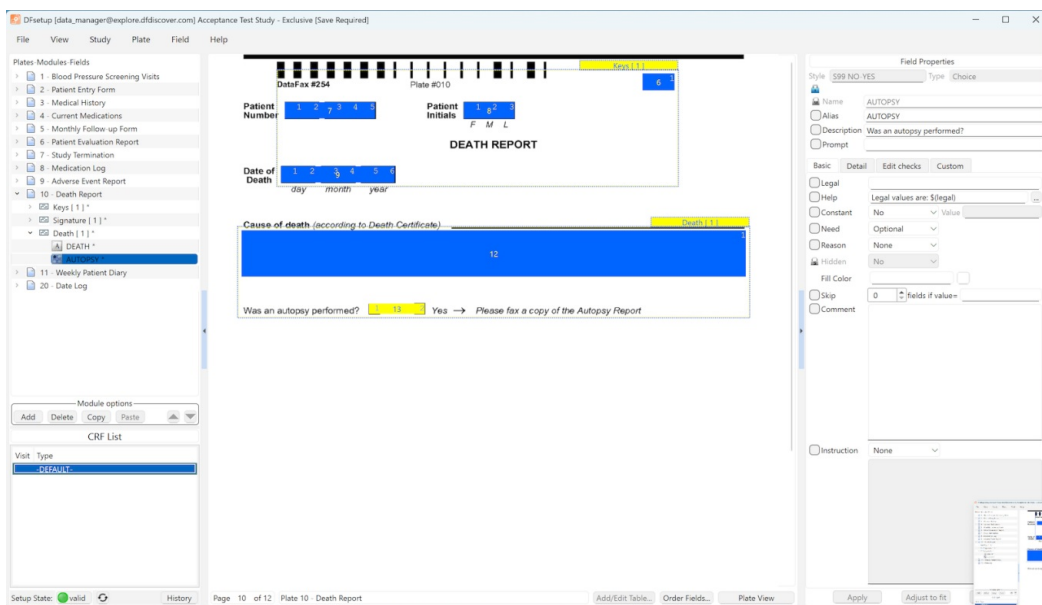
5. Select the **DEATH** field in the **Plates-Modules-Fields** listing to assign a field definition.



6. Create a field reference for the **Was an autopsy performed?** field. Using the mouse, **click** the middle of the **No** box on the plate background. Next **click** the middle of the **Yes** box on the plate background. This defines the position of each response option for the **AUTOPSY** field.

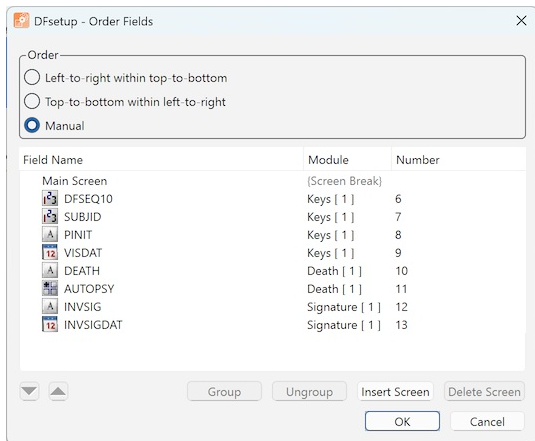


7. Select the **AUTOPSY** field in the **Plates-Modules-Fields** listing to assign a field definition.

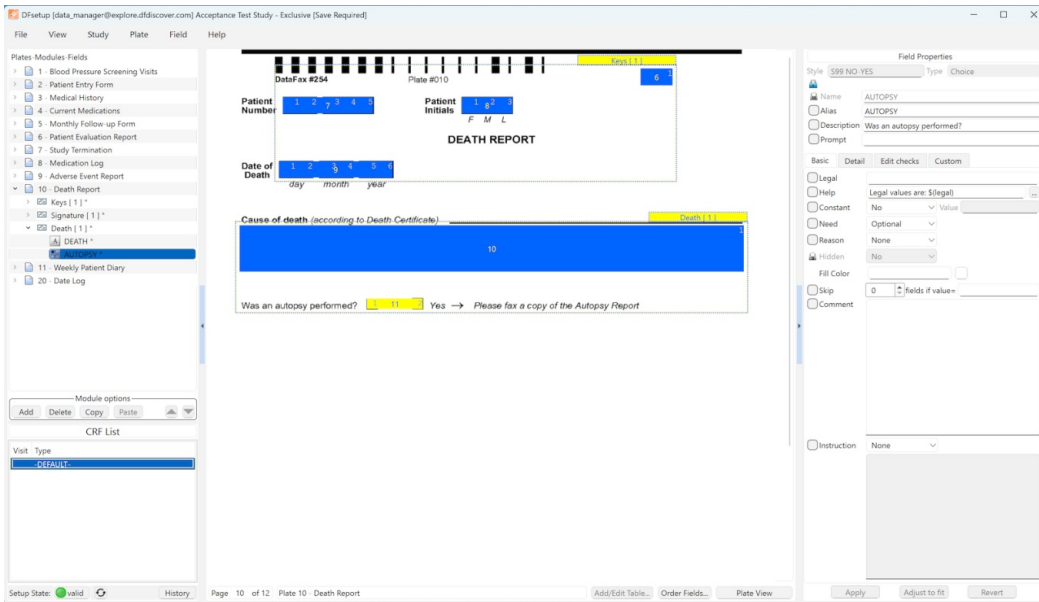


**Correct field ordering on the current plate to set field traversal order for data entry**

1. All fields are now defined on plate 10 - **Death Report**. Select **Field** > **Order**. In the dialog, sort the fields as shown, by using the arrow buttons.



2. Click **OK** to apply the selected field order.



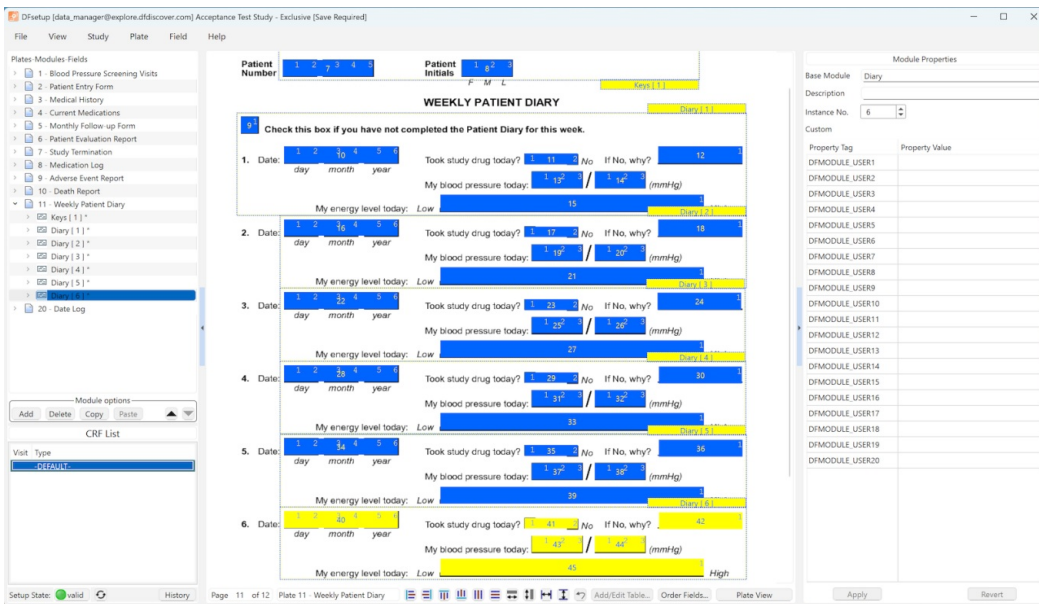
3. Click [∨] to the left of **10-Death Report** in the **Plates-Modules-Fields** list to collapse all plate **10 - Death Report** modules.

## Use copy and paste to create repeating module and field references on a plate

1. Click **11 - Weekly Patient Diary** to make it the active plate. Scroll to view all module and field references on the plate.

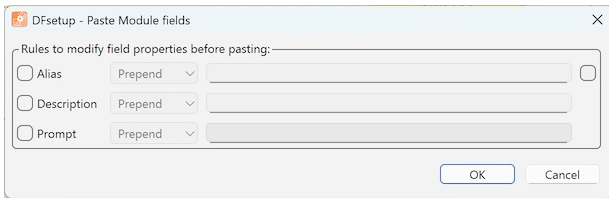


2. Click [⌵] to the left of **11-Weekly Patient Diary** to expand the list of modules defined on the current plate. Choose **Diary[6]** from the list.

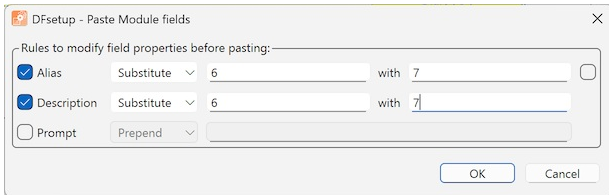


3. Click **Copy** from the **Module options**.

4. Click **Paste** from the **Module options**.



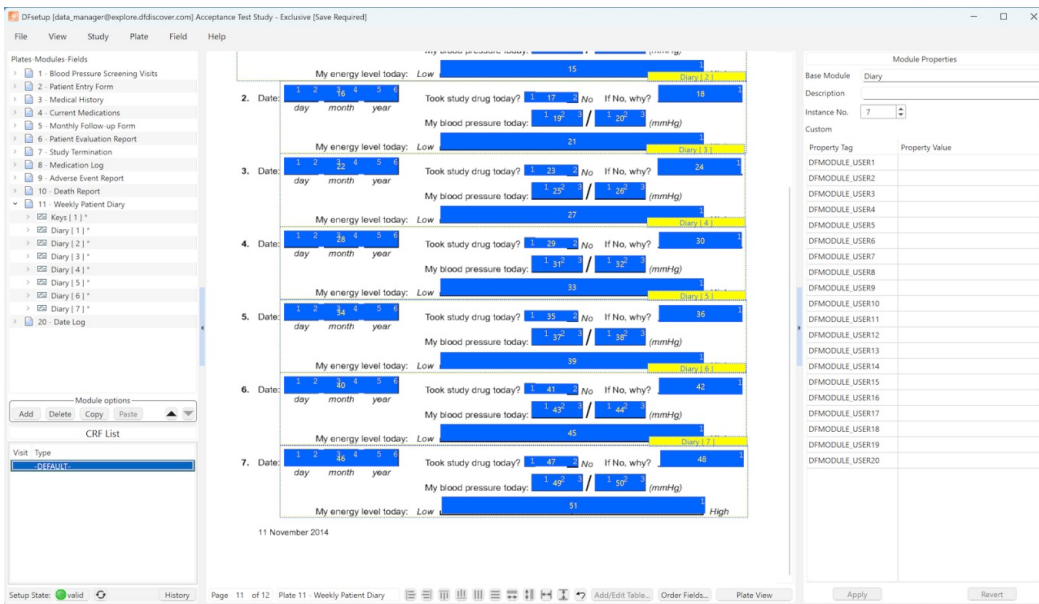
5. In the **Paste Module fields** dialog specify the substitution shown, which modifies the **Alias** and **Description** fields.



6. Click **OK** in the **Paste Module fields** dialog to perform the paste operation.



7. With the block of fields still highlighted, use the mouse to drag the block of field reference widgets and position them over top of their respective field outlines on the plate background. **Click** anywhere on the plate background to release the pasted block.



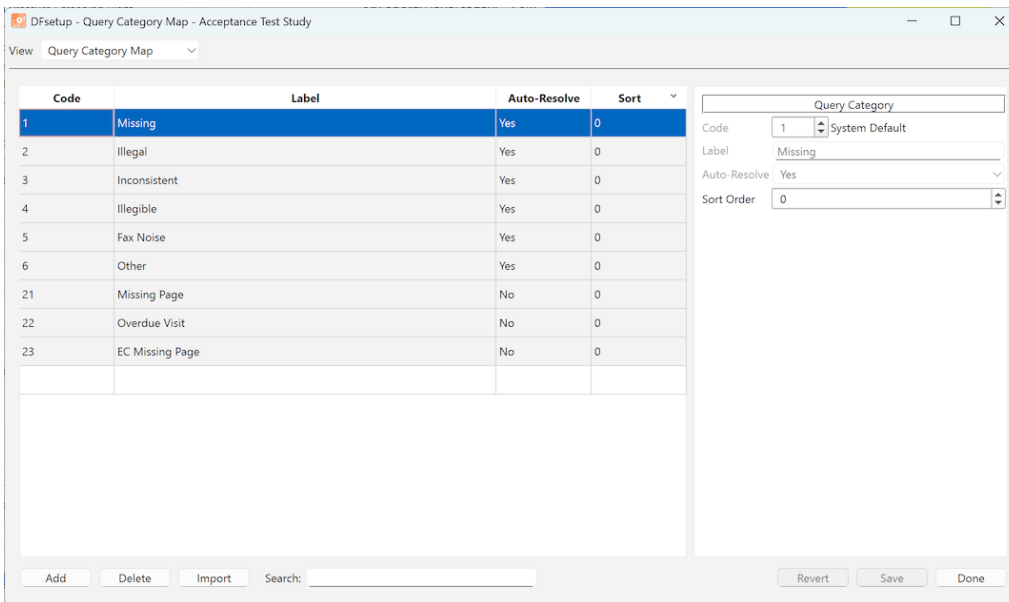
8. One by one select each **Diary[7]** field reference widget. Examine the **Field Properties** window for each and confirm that the **Alias** and **Description** properties contain the correct substitution character of 7.
9. Select **File** > **Save [Required]**. Click **History**. The setup change history is displayed.
10. Save the **DFsetup** history as **module3\_setuphistory.xlsx** by clicking **Save As...** > **Save**. Open the saved **.xlsx** file and verify that its contents match the **DFsetup - History** output before closing the history dialog by clicking **X**.

DFsetup - History for Plate 11: Weekly Patient Diary (last 30 days)								
	Date and Time	Who	Change	Plate	Module	Field	What Changed	Attribu
1	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	11:	115:	Dfdiscover Screen Status	Field N
2	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	11:	116:	Dfdiscover Create Stamp	Field N
3	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	11:	117:	Dfdiscover Modify Stamp	Field N
4	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5090: Keys	10490: DIARYWK	Study Week #	Encryp
5	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5090: Keys	10488: SUBJID	Patient Number	Encryp
6	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5090: Keys	10489: PINIT	Patient Initials	Encryp
7	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5091: Diary	10590: NODIARY	Check this box if no diary completed	Encryp
8	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5091: Diary	10592: DDATE	1. Diary Date	Start Y
9								Encryp
10	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5091: Diary	10493: DDRUG	1. Took study drug today?	Encryp
11	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5091: Diary	10494: DWHY	1. If No, why?	Encryp
12	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5091: Diary	10495: DSYSBP	1. My blood pressure today - systolic	Encryp
13	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5091: Diary	10496: DDSBP	1. My blood pressure today - diastolic	Encryp
14	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5091: Diary	10497: DENERGY	1. My energy level today	Encryp
15	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5092: Diary	10598: DDATE	2. Diary Date	Start Y
16								Encryp
17	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5092: Diary	10499: DDRUG	2. Took study drug today?	Encryp
18	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5092: Diary	10500: DWHY	2. If No, why?	Encryp
19	2026-05-11 16:53:33	data_manager	change plate field	11: Weekly Patient Diary	5092: Diary	10501: DSYSBP	2. My blood pressure	Encryp

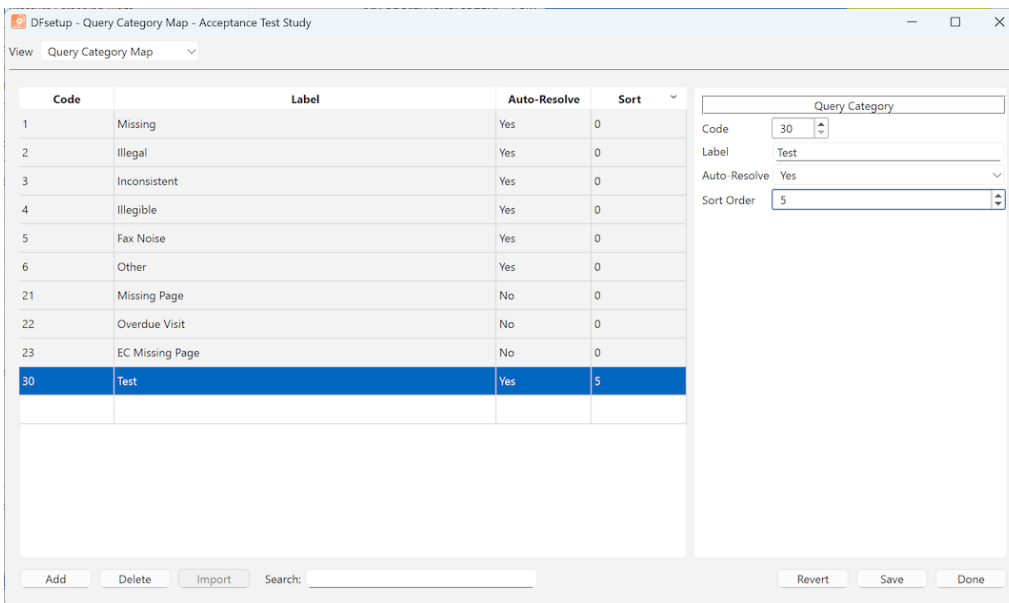
History for  study  styles  modules  plates Filter plates 11 fields 11-# Limit to last 30 days Refresh Save As...

## Create user-defined query category codes

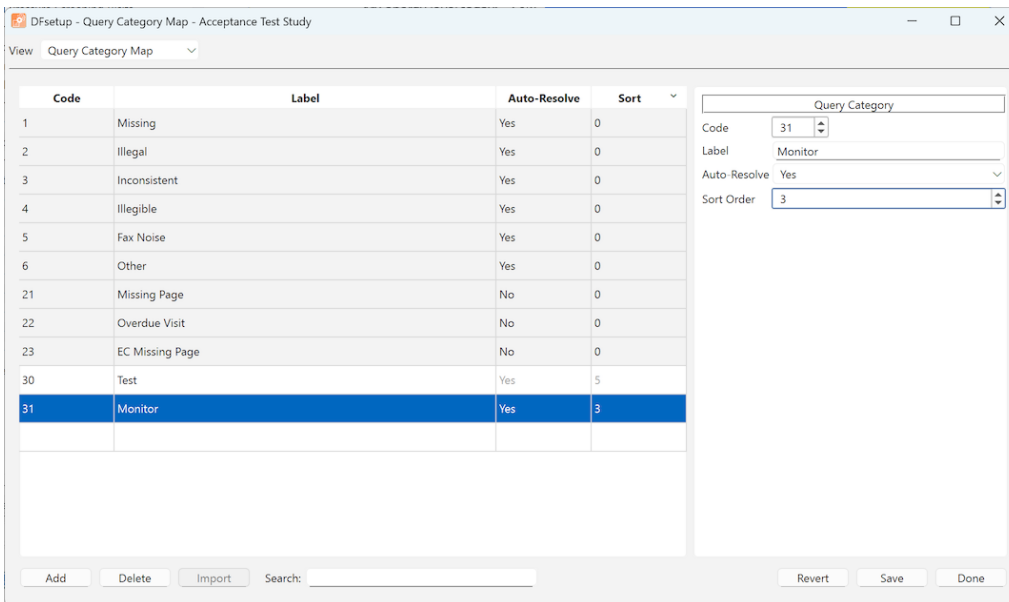
1. Select **View** > **Query Category Map**.



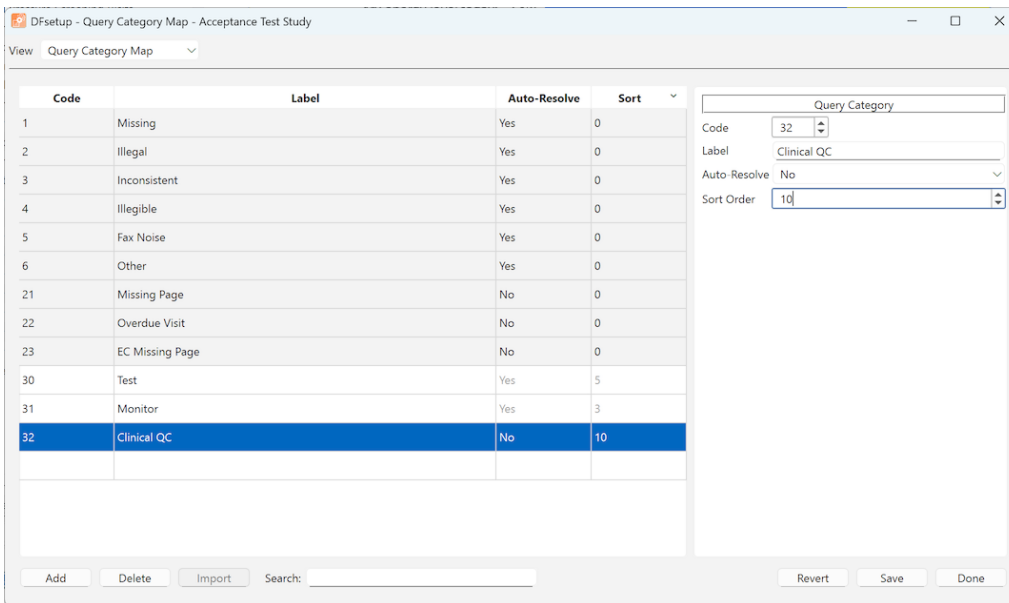
- Click **Add**. The **Code** field is auto-filled with a value of 30. Press **Tab** to advance to the **Label** field. Enter Test for the **Label** field. Select Yes from the **Auto-Resolve** drop-down. Set **Sort Order** to 5.



- Click **Add**. The **Code** field is auto-filled with a value of 31. Without altering the code number, enter Monitor for the **Label** field. Select Yes from the **Auto-Resolve** drop-down. Set **Sort Order** to 3.

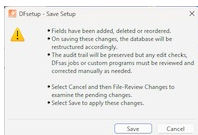


4. Click **Add**. Without altering the code number, enter Clinical QC for the **Label** field. Select No from the **Auto-Resolve** drop-down. Set **Sort Order** to 10.



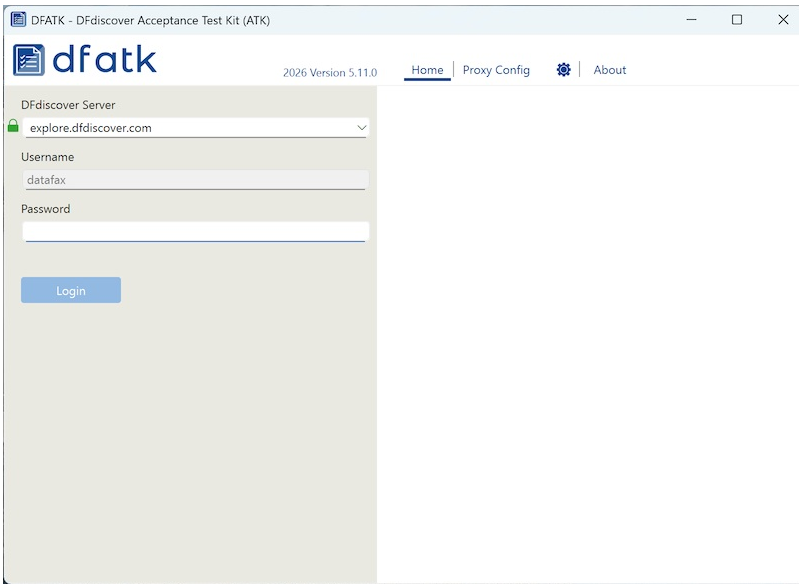
5. Click **Save** followed by **Done** to close the dialog.

6. Select **File** > **Save [Required]** to save all modifications. Click **Save** in the warning dialog. Select **File** > **Exit** to close **DFsetup**.



**Submit a copy of the newly defined Plate 11 into the study database and retrieve the page in DFExplore Image View**

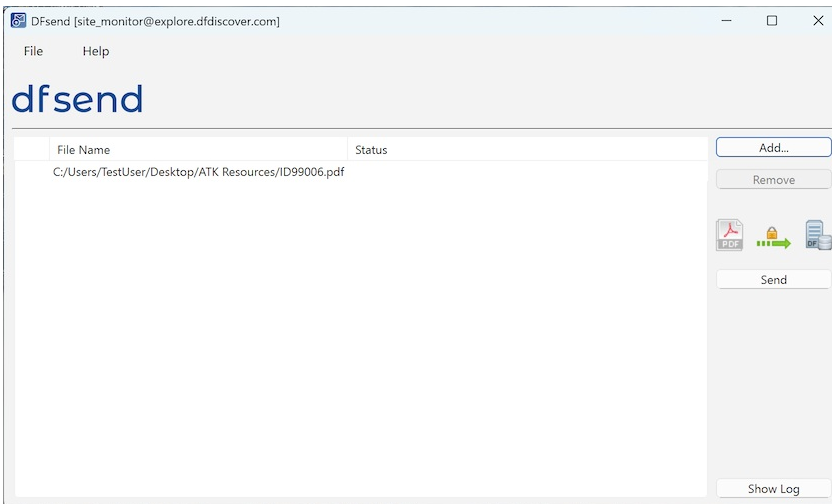
1. To complete the remainder of Module 3. Study Setup, the Control Panel is needed. Start the Control Panel as datafax as described in [Module 1 \(Installation & Initialization\)](#).



- Click **[Send ID 99006]** to email a copy of **ID99006.pdf** to `site_monitor`. Clicking more than once will result in multiple pages arriving to your email inbox.

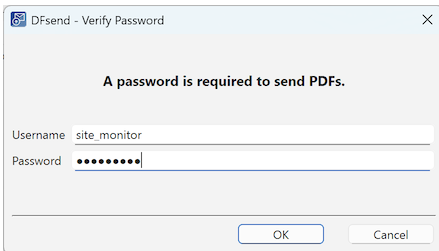
NOTE: Save the **ID99006.pdf** file received via email to your local computer. This file is required to complete the remainder of this module. Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address is required for `site_monitor` to receive the module specific PDF files.

- Start **DFsend** and login as user `site_monitor`, as described in ["How to start DFsend"](#).
- Click **[Add]**. From the **Select PDF Files** file selection dialog, locate the previously saved **ID99006.pdf** file. Select the file and click **[Open]**.

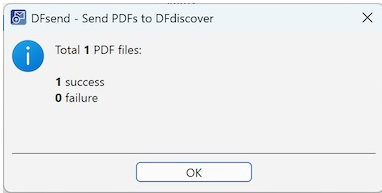


NOTE: Documents can also be added by dragging-and-dropping the desired PDF files from a local file folder into the list area.

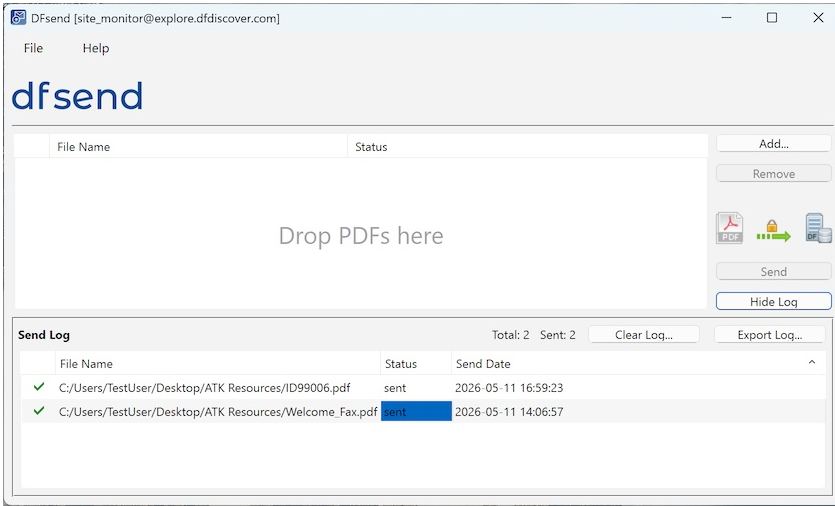
- Click **[Send]**. In **Verify Password** dialog, enter `site_monitor` in the **Username** field and the previously assigned password in the **Password** field. Click **[OK]**.



- In the resulting **Send PDFs to DFdiscover** dialog, confirm **1 success** and **0 failure** are shown. Click **[OK]**.



7. Click **Show Log** to review the **DFsend** transmission history.

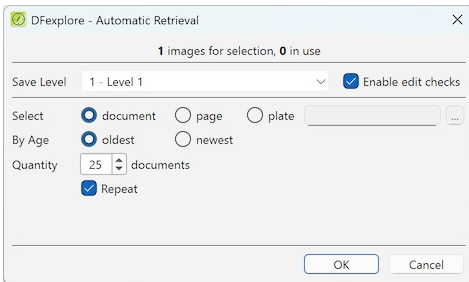


8. Select **File** > **Exit**.

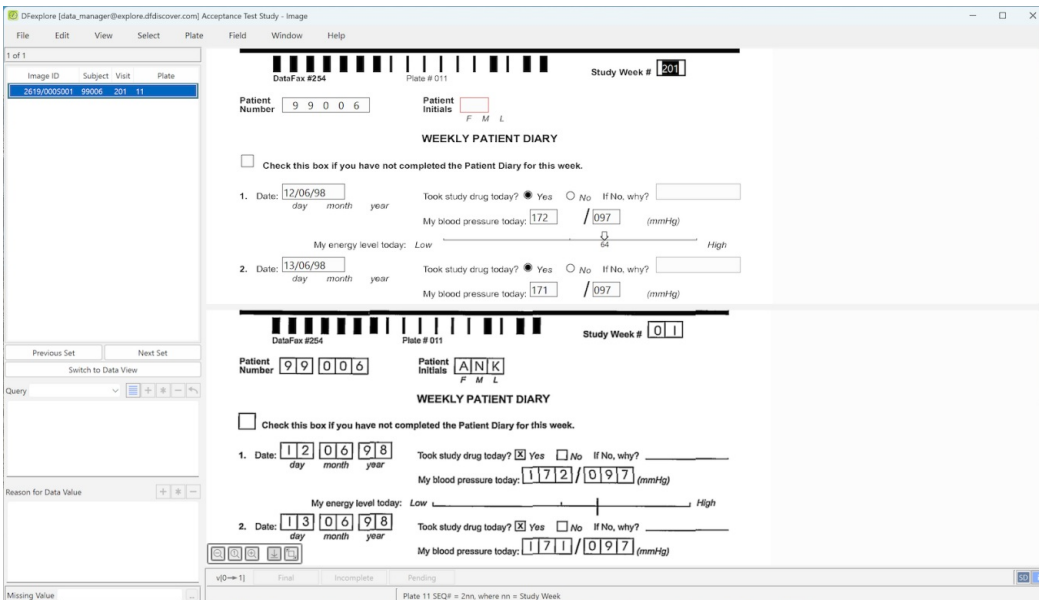
NOTE: Wait 2-3 minutes prior to proceeding to **DFexplore**.

9. Start **DFexplore**, login as user **data\_manager** and choose **254 Acceptance Test Study** as described in "[How to start DFexplore](#)".

10. Select **View** > **Image**.



11. Do not change any settings in the **Automatic Retrieval** dialog, click **OK** to retrieve the image.



12. Select **[Plate]** > **[Show Field Properties]** to display a listing of properties for all fields on the current page. Locate field numbers **46** to **51** that were created in [Use copy and paste to create repeating module and field references on a plate.](#) Verify the settings and click **[OK]**.

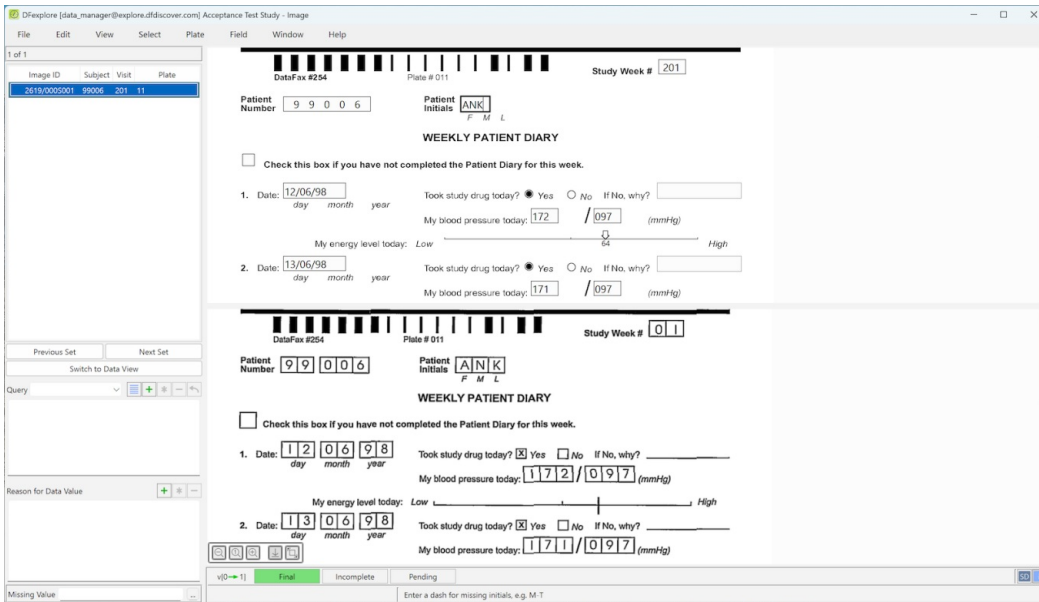
No.	Name	Description	Style	Need	Type	Format	Legal
6	DIARYWK	Study Week #	SimpleNumber	Essential	Number	2nn	201-299
7	SUBJID	Patient Number	S01 Patient ID	Essential	Number		\$(ids)
8	PINIT	Patient Initials	S02 Patient Int	Required	String		
9	NODIARY	Check this box if no diary completed	SimpleCheck	Optional	Check		
10	DDATE	1. Diary Date	SimpleDate	Optional	Date	dd/mm/yy	
11	DDRUG	1. Took study drug today?	S98 YES-NO	Optional	Choice		0,2,1
12	DWHY	1. If No, why?	SimpleString	Optional	String		
13	DSYSBP	1. My blood pressure today - systolic	S20 Systolic BP	Optional	Number	nnn	60-300
14	DDSBP	1. My blood pressure today - diastolic	S21 DiastolicBP	Optional	Number	nnn	30-150

### Enter and save all data on the submitted plate 11

1. Upon retrieval of plate **11-Weekly Patient Diary**, the cursor is on the **Study Week #** field. Enter the **Study Week #** value as it appears on the CRF image. Note that a prefix of 2 is hardcoded in the **Study Week #** field so that the resulting value will appear as 201. Press **[Tab]** to advance to the **Patient Number** field.

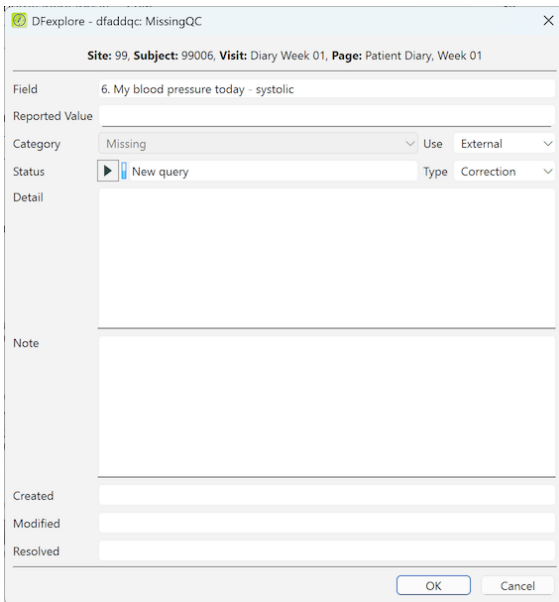
The screenshot shows two instances of the 'Weekly Patient Diary' form. The top instance is for 'Study Week # 201' and the bottom instance is for 'Study Week # 011'. Both forms show fields for Patient Number, Patient Initials, Date, and Blood Pressure.

2. Enter the **Patient Number** as it appears on the CRF image. Press **[Tab]** to move to the **Patient Initials** field. Enter ANK as per the CRF image and press **[Tab]** to advance to the next field.



- Starting with the **Check this box...** field, enter all data for **11-Weekly Diary Report** as it appears on the CRF image in the lower half of the split-screen window. Press **[Tab]** to move from field to field until field **6. My blood pressure today** is the current field. Leave the field blank as per the CRF image and press **[Tab]**. The **Add Query** dialog is presented.

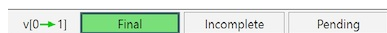
NOTE: During document submission, the ICR may fail on one or more of the fields on the **Plate 11-Weekly Patient Diary** page. You will need to enter values into those fields that have been missed or misread by the ICR. To correct VAS scales, make the desired **VAS scale** the current field on the data record. Locate the corresponding VAS scale on the CRF image. Using the **left** mouse button, select the leftmost end of the scale, followed by the intersection point, and then the rightmost end of the scale on the CRF image. Specifically VAS scale item #4 requires modification from 70 to 71.



- Click **[Cancel]** in the **Add Query** dialog to close the dialog. The 2nd blood pressure field (diastolic) gets the focus. Leave the field blank as per the CRF image and **[Tab]** off the field. Again, click **[Cancel]** in the resulting **Add Query** dialog.

5. Enter the remaining fields on **Plate 11-Weekly Patient Diary** as per the CRF image. Once a value has been entered in the last VAS field (**7. My energy level today**), press **[Tab]**. This makes the save buttons active at the bottom of the data record.

6. With the focus on the save buttons, click **[Final]** to save the record to the database with the status Final.



7. Select **[File]** > **[Exit]** to close **DFExplore**.

## End Module 3. Study Setup

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **[End]** to confirm successful completion of Module 3. Study Setup.

## Module 4. eCRF Creation for DFdiscover

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor

**Client Tools Used:** DFATK, DFExplore, DFsetup

**Purpose:** This module tests the creation of eCRF plates in **DFsetup**, data entry into eCRF plates in **DFExplore**, as well as user preferences unique to eCRF plates in **DFExplore**.

### Tests & Requirements

1. eCRF creation in **DFsetup**.
2. eCRF background color preferences.
3. Entering eCRF data.

Estimate of Time Required: 20 Minutes

### Introduction

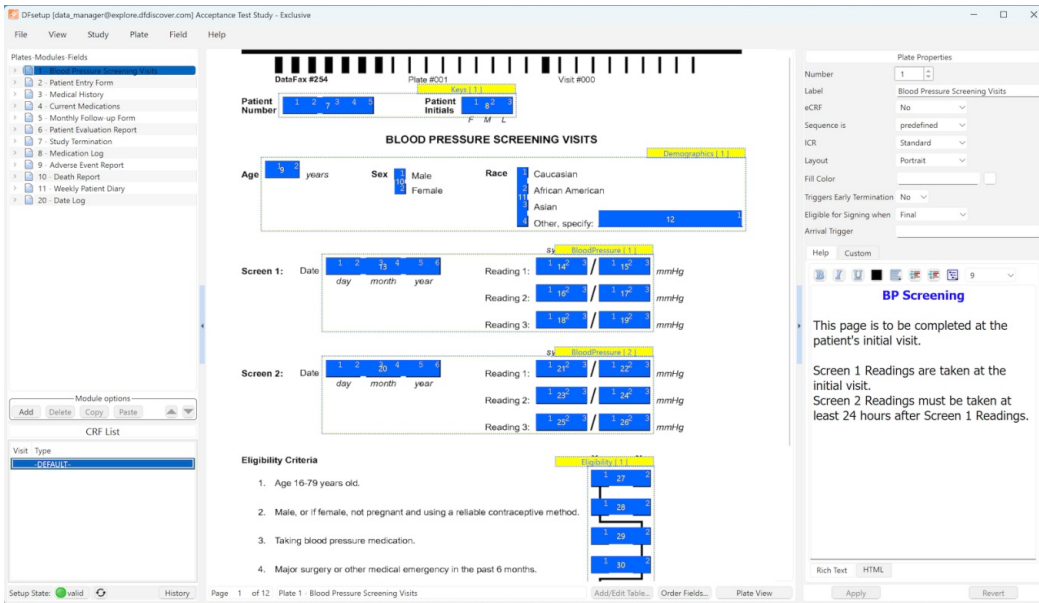
This module utilizes Electronic case report forms (eCRFs) which you will create using **DFsetup** without a **PostScript®** or PDF file. eCRFs do not contain barcodes and are therefore only suitable for entry via EDC.

### Begin Module 4. eCRF Creation for DFdiscover

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **[4. eCRF Creation]** followed by **[Begin]** to begin this module.
3. This module requires user data\_manager to have exclusive access to the 254 Acceptance Test Study database. The Control Panel must be closed. Click **[Exit]**.

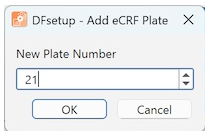
### eCRF creation in **DFsetup**

1. Start **DFsetup**, login as user `data_manager` and choose **254 Acceptance Test Study** as described in ["How to start DFsetup"](#)
2. Choose **Exclusive Access** and click **OK**. **Exclusive Access** allows you to create and modify plates, styles and fields, and to define all setup configuration files.



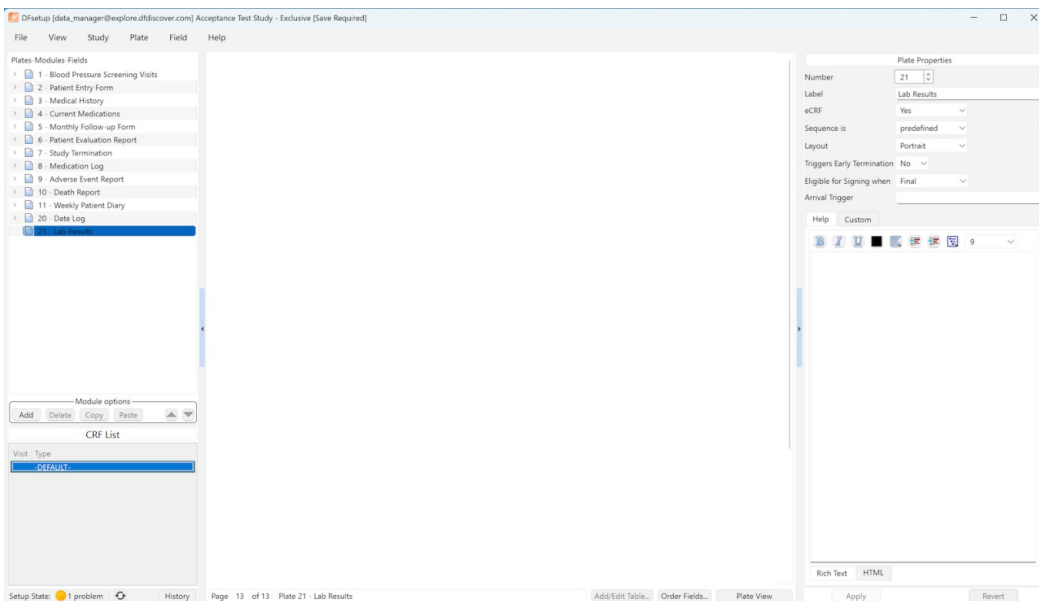
**NOTE:** The main **DFsetup** window displays the last plate to be active in the user's previous **DFsetup** session. For this reason, you may see a different plate from what is displayed in the above illustration.

3. Select **Study** > **Add eCRF Plate**. In the **Add eCRF Plate** dialog enter a **New Plate Number** of 21. Click **OK**.

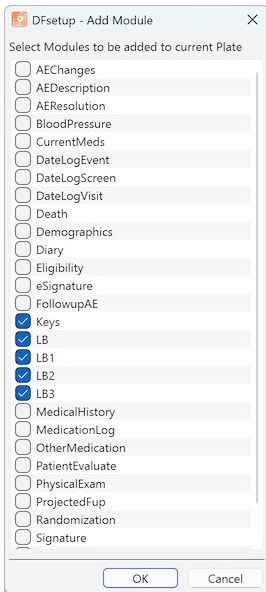


4. In the **Plate Properties** set:
  - o **Label** = Lab Results
  - o **eCRF** = Yes
  - o **Sequence is** = predefined
  - o **Triggers Early Termination** = No
  - o **Layout** = Portrait
  - o **Eligible for Signing When** = Final

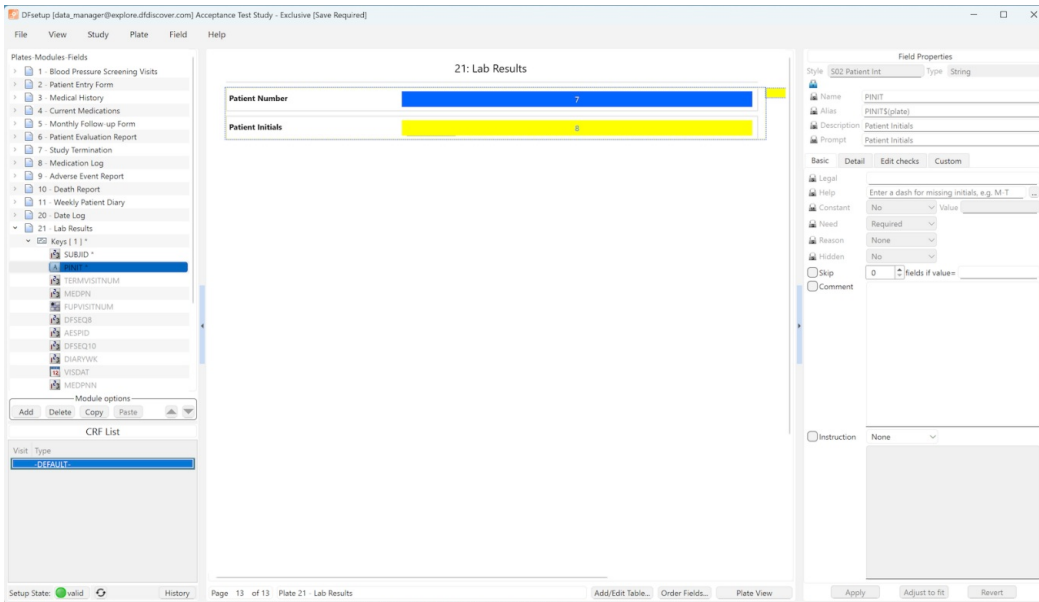
Click **Apply**.



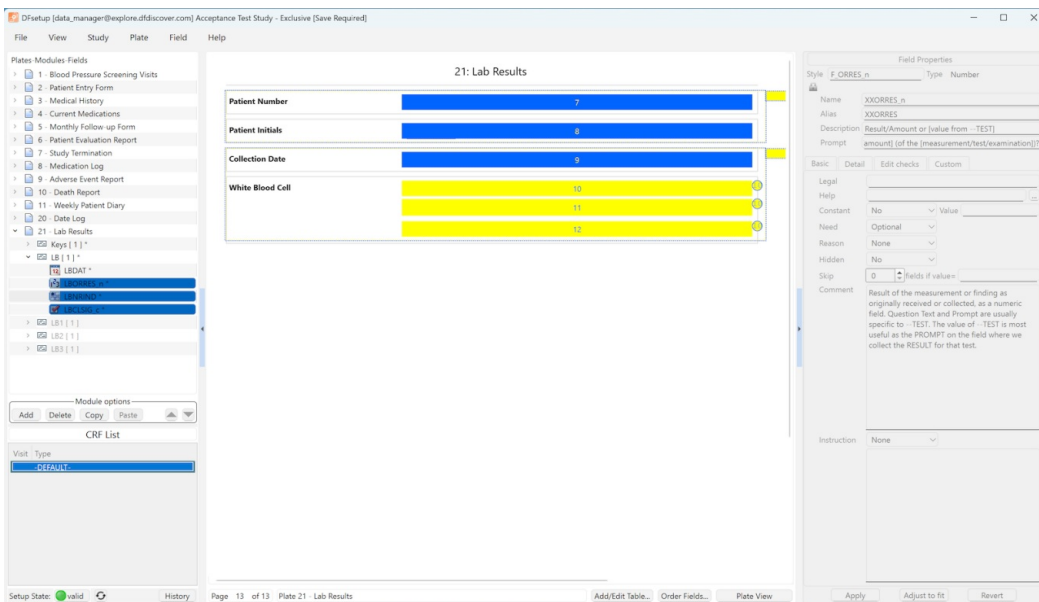
5. Within **Plates-Modules-Fields Module options** Click **Add**. Check (enable) **Keys, LB, LB1, LB2, LB3** modules, click **OK**.



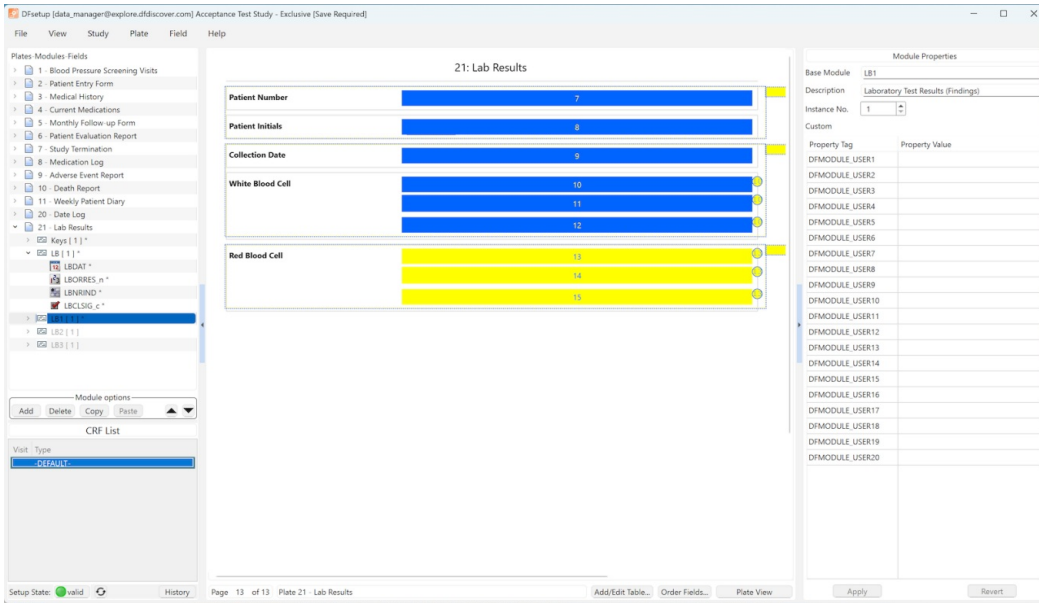
6. Double-click the **Keys [1]** module to expand the list of fields. Using your mouse, click and drag the **SUBJID** and **PINIT** fields onto the **21: Lab Results** eCRF.



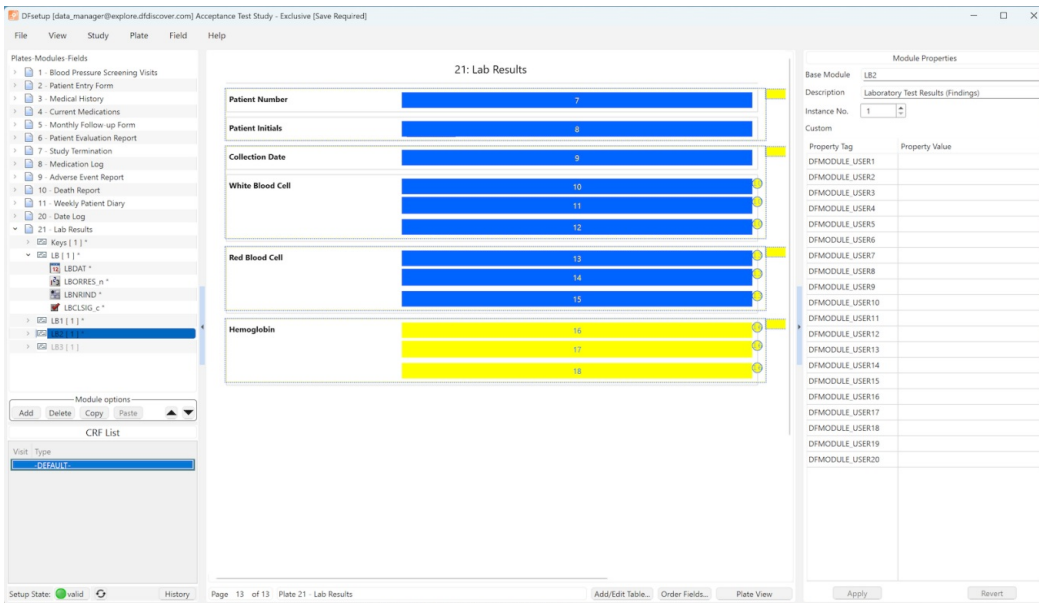
7. Click **LB [1]** module, drag the module onto the eCRF, select **LBORRES\_n**, **LBNRIND** and **LBCLSIG\_c** fields by holding **Shift** and clicking on the fields. Select **Field** > **Group**.



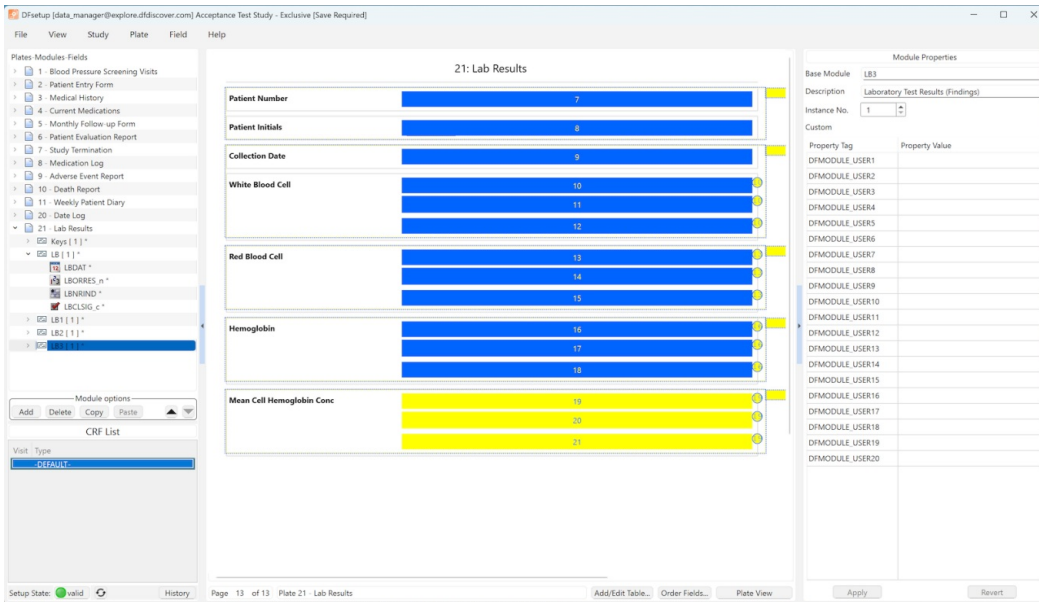
8. Click **LB1 [1]** Module, drag the module onto the eCRF. Select **Field** > **Group**.



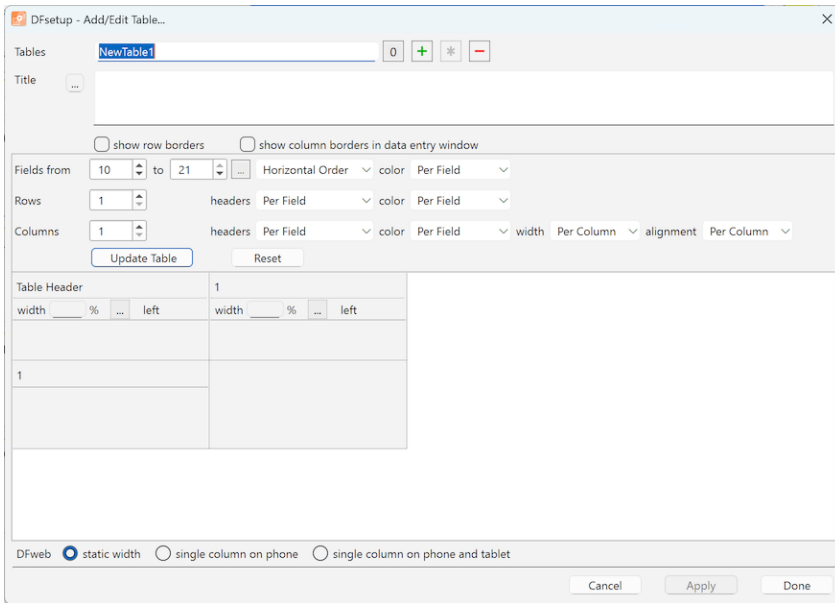
9. Click **LB2 [1]** Module, drag the module onto the eCRF. Select **Field** > **Group**.



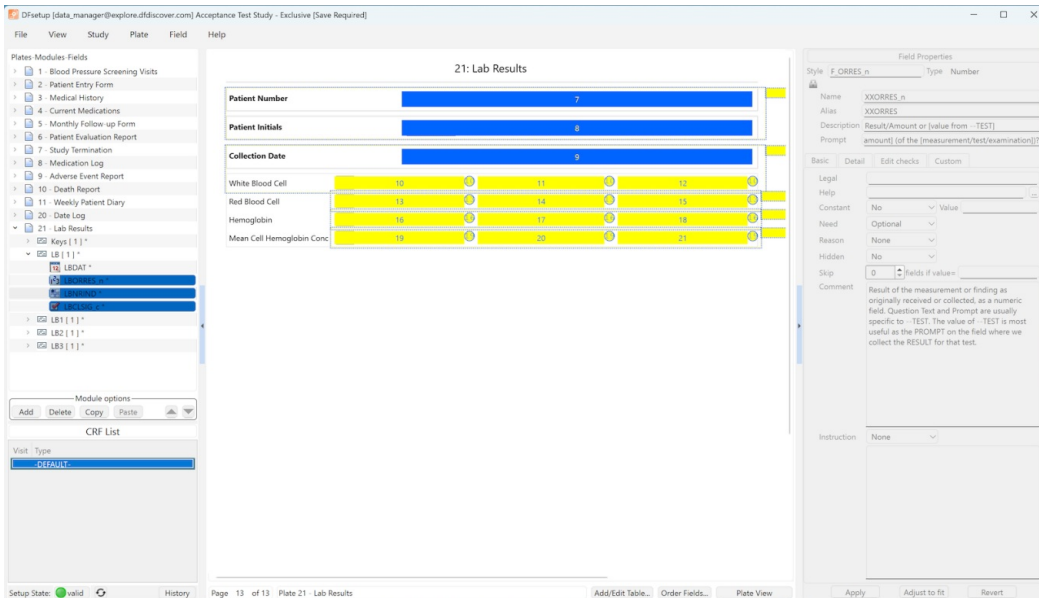
10. Click **LB3 [1]** Module, drag the module onto the eCRF. Select **Field** > **Group**.



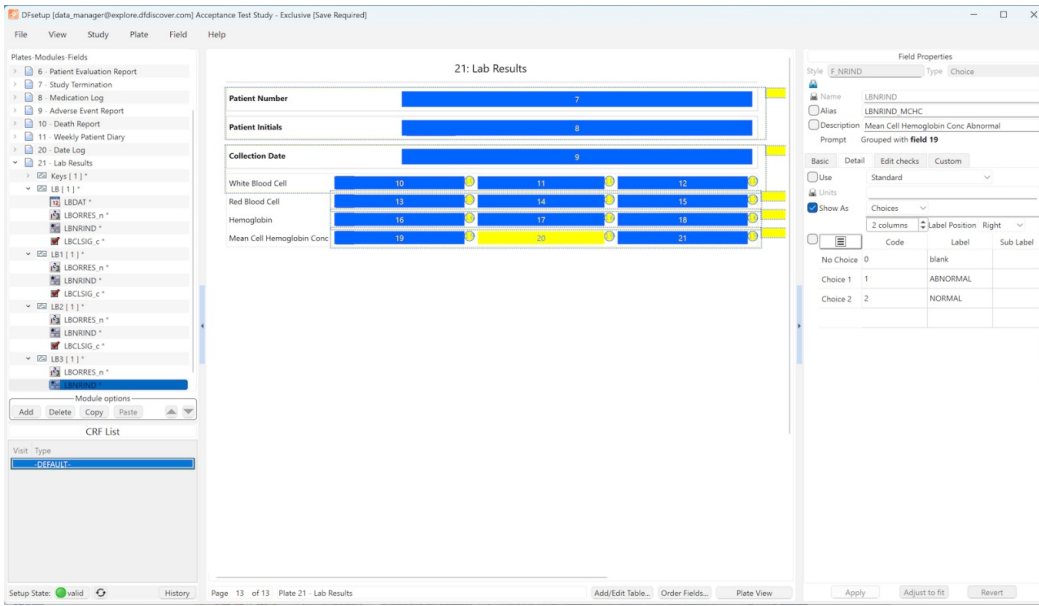
11. Select fields 10 through 21 by holding **Shift** and clicking on the fields. Select **Field** > **Add/Edit Table**.



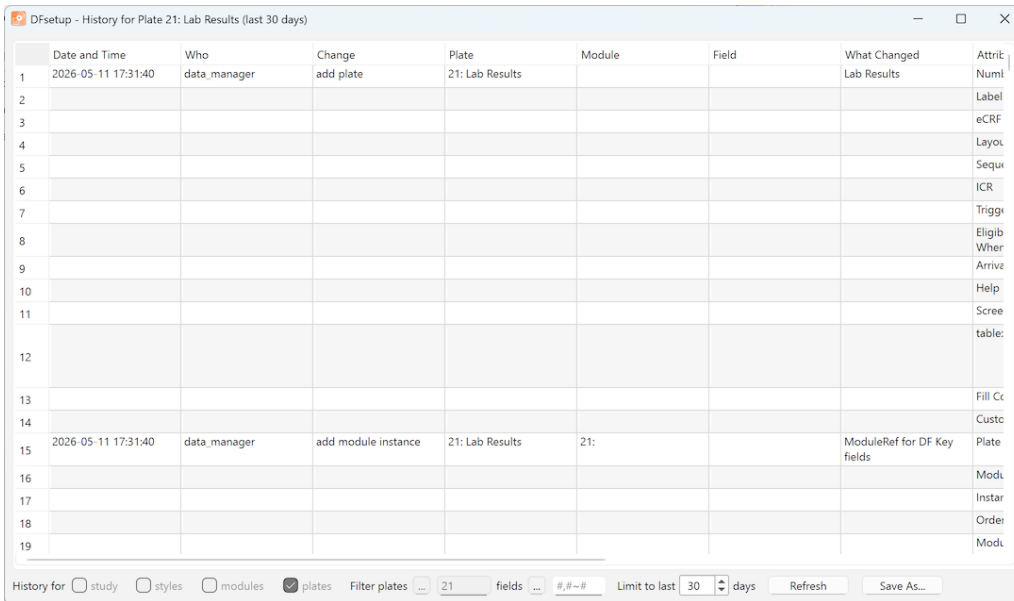
12. In the Add/Edit Table dialog, specify 4 rows and 3 columns. Under Rows > headers, select **Field Prompt** from the dropdown. Click **Update Table**. In column 2, select **show coding label** and specify width as 35%. In column 3, select **show coding label**. Under **DFweb**, select **single column on phone and tablet**. Click **Apply** and **Done**.



13. Select field 11 **LBNRIND\_WBC**, in the Field Properties click **Detail**. Modify the column display from **3 columns** to **2 columns**. Click **Apply**. Perform the same actions for field 14 **LBNRIND\_RBC**, field 17 **LBNRIND\_HGB** and field 20 **LBNRIND\_MCHC**.



14. Select **File** > **Save [Required]**. Click **History**. The setup change history is displayed.

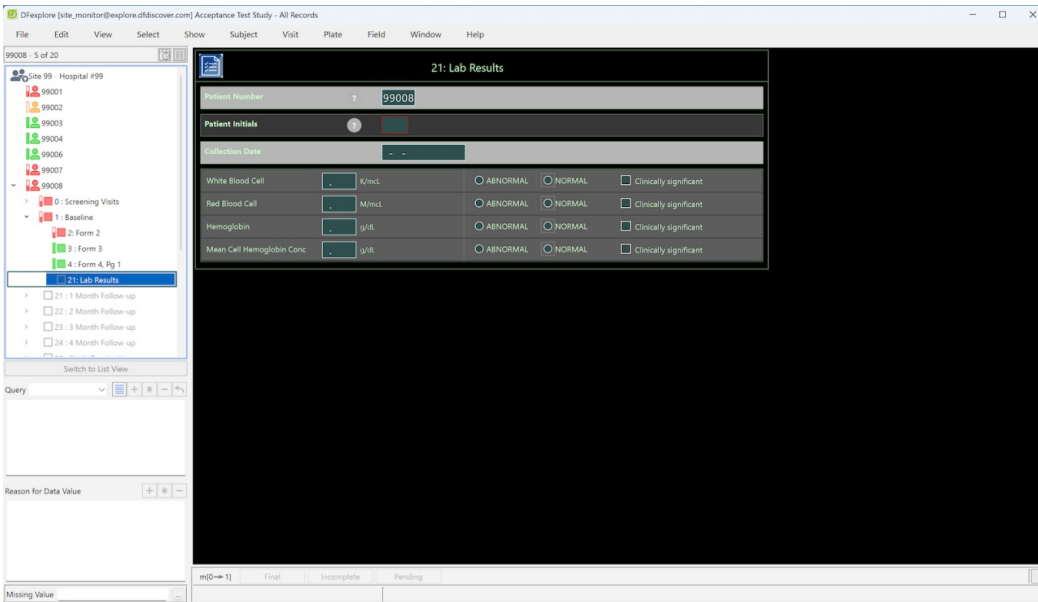


15. Save the **DFsetup** history as module4\_setuphistory.xlsx by clicking **Save As...** > **Save**. Open the saved .xlsx file and verify that its contents match the **DFsetup - History** output before closing the history dialog by clicking **X**.
16. Select **File** > **Exit** to close **DFsetup**.

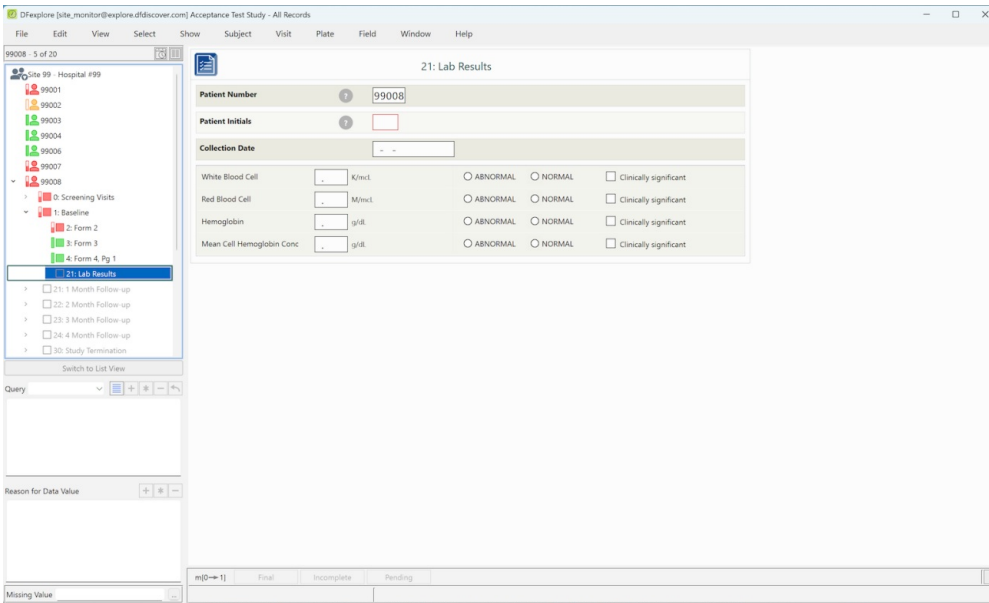
## eCRF background color preferences

1. Start **DFexplore**, login as user **site\_monitor** and choose **254 Acceptance Test Study** as described in "[How to start DFexplore](#)".
2. Click **Site 99 - Hospital #99 > 99008 > 1: Baseline > 21: Lab Results** to make it the active page.

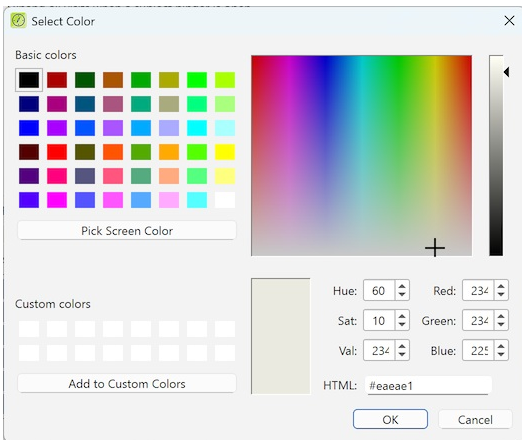
**NOTE:** **DFexplore** stores previously defined user preferences. If **site\_monitor** previously used **DFexplore** and modified user preferences, you may see a different background than what is illustrated below.



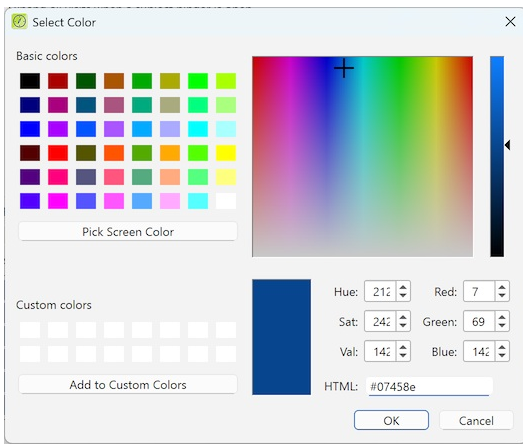
3. Select **File** > **Preferences**, click **Background Options** to expand the preferences. Click **Color** then **OK** to apply the changes.



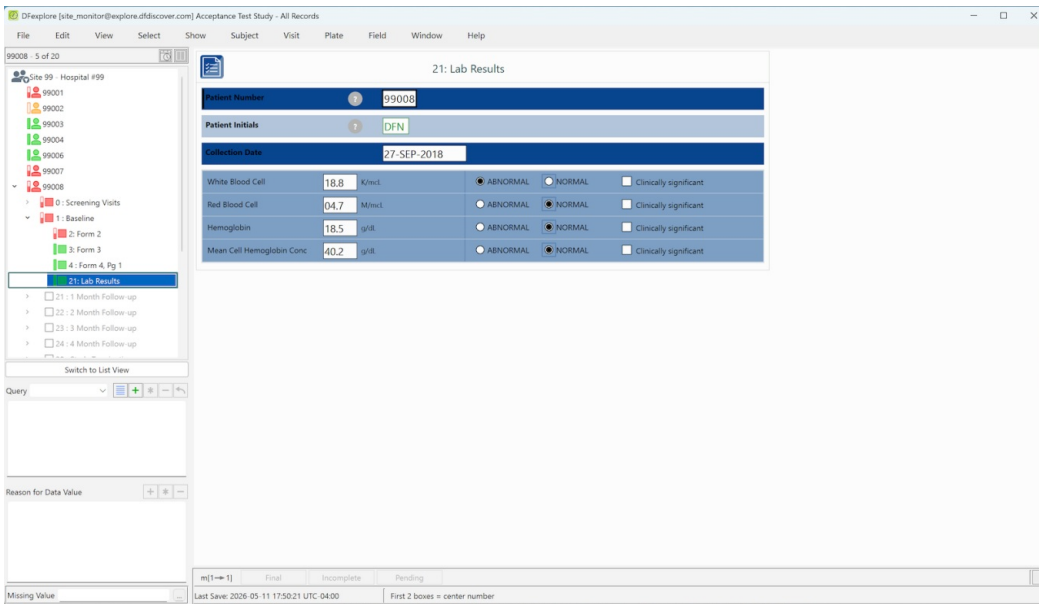
4. Select **File** > **Preferences** > **Data Window**, within **eCRF background color**, click **+** to open the **Select Color** window.



5. Enter **HTML:#07458e**.

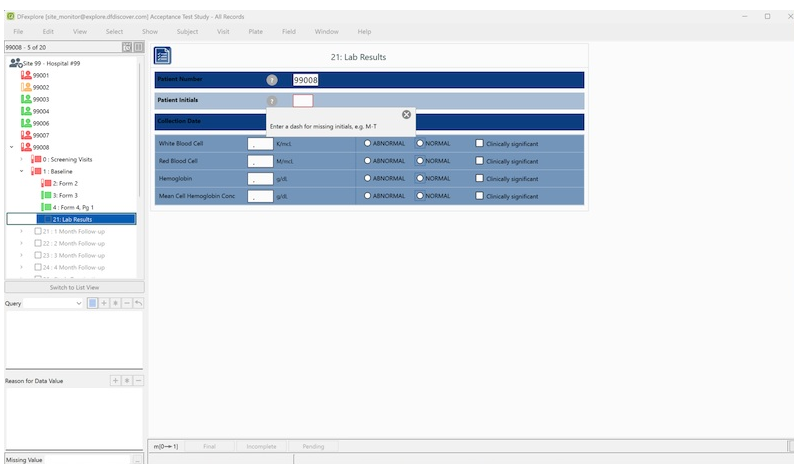


6. Click **OK** to close the **Select Color** window, click **OK** to apply your color preferences.



## Entering eCRF data

1. Click **?** within the **Patient Initials** field to display the field level help. Click **[X]** to close the help dialog.

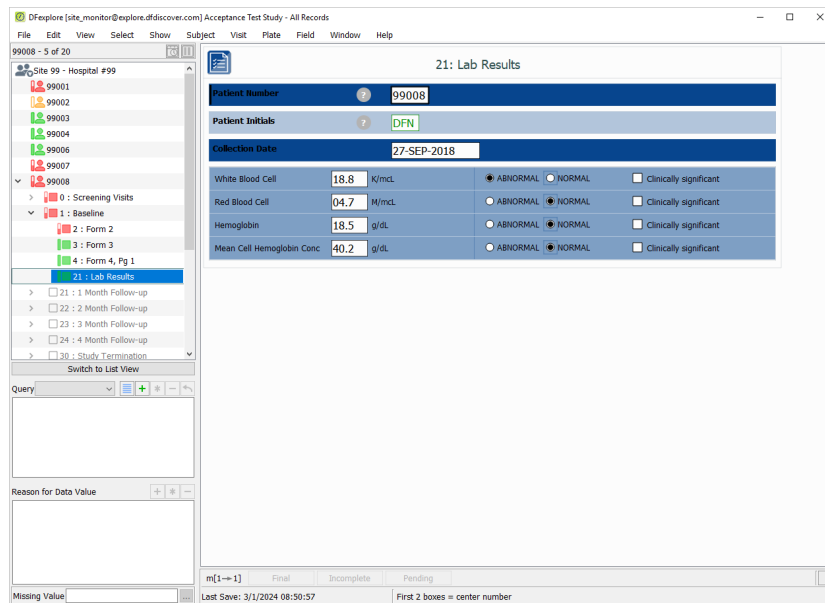


2. With subject **99008 21: Lab Results** as the current eCRF, click **Patient Initials**. The initials are pre-filled as a result of the edit check SetInitedscribed in [Module 8. Image Data Entry. Set](#):

- o **Collection Date** = 27-SEP-2018
- o **White Blood Cell** = 18.8, Check (enable) **Abnormal**.
- o **Red Blood Cell** = 4.7, Check (enable) **Normal**
- o **Hemoglobin** = 18.5, Check (enable) **Normal**

- Mean Cell Hemoglobin Conc = 40.2, Check (enable) Normal

Click **[Final]** to save the data record.



3. Select **[File]** > **[Exit]** to close **DFExplore**.

## End Module 4. eCRF Creation for DFdiscover

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **[End]** to confirm successful completion of Module 4. eCRF Creation.

## Module 5. Custom Properties

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor

**Client Tools Used:** DFATK, DFExplore, DFsetup

**Purpose:** This module tests the definition of custom properties defined at the study, plate, module, and field level. It additionally tests the creation of custom list views and data export from custom lists views involving custom properties.

### Tests & Requirements

1. Defining Custom Properties in **DFsetup**.
2. Adding Global Custom Property values.
3. Adding Plate, Module and Variable level Custom Property values
4. Exporting Custom Properties in **DFsetup**.
5. Edit checks execution of Custom Properties.
6. Creating subject data lists and exporting data views.
7. **DFExplore** Database Definition Report exporting.

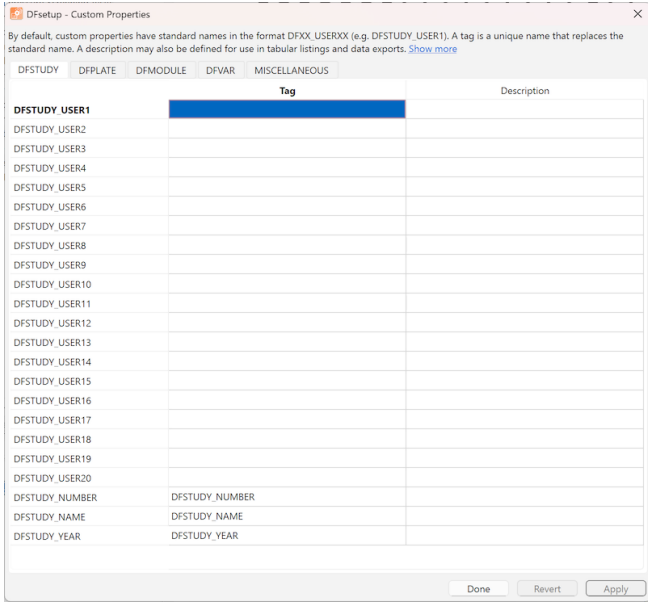
Estimate of Time Required: 30 Minutes

## Begin Module 5. Custom Properties

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **[5. Custom Properties]** followed by **[Begin]** to begin this module.
3. This module requires user data\_manager to have exclusive access to the 254 Acceptance Test Study database, the Control Panel must be closed. Click **[Exit]**.

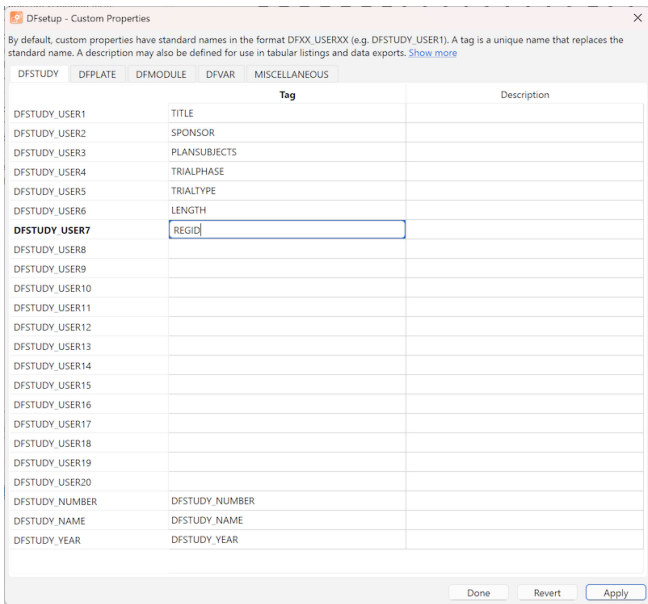
## Defining Custom Properties in DFsetup

1. Start **DFsetup**, login as **data\_manager** and choose **254 Acceptance Test Study** as described in **"How to start DFsetup"**.
2. Choose **Exclusive Access** and click **OK**. **Exclusive Access** allows you to create and modify plates, styles and fields, and to define all setup configuration files.
3. Select **Study** > **Custom Properties**.

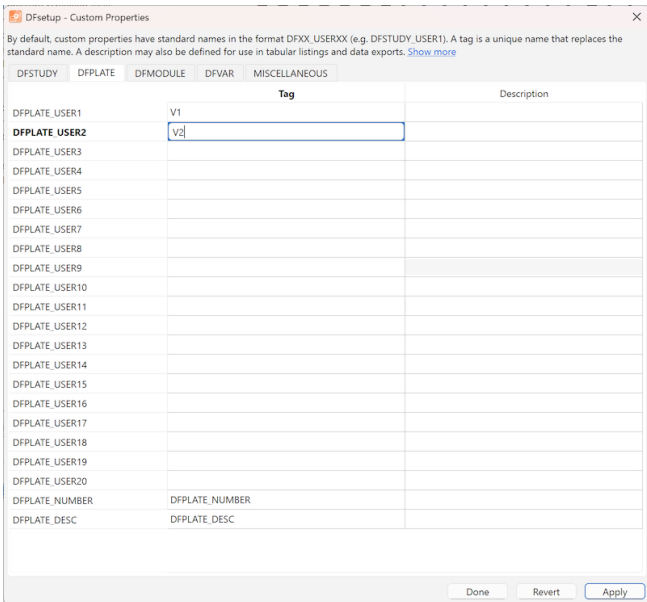


4. Click **DFSTUDY** tab, followed by the empty **Tag** cell for **DFSTUDY\_USER1** to make it the active field.
5. Beginning with **DFSTUDY\_USER1** cell. Enter the Custom Properties for **DFSTUDY** as follows:

- **DFSTUDY\_USER1** = TITLE
- **DFSTUDY\_USER2** = SPONSOR
- **DFSTUDY\_USER3** = PLANSUBJECTS
- **DFSTUDY\_USER4** = TRIALPHASE
- **DFSTUDY\_USER5** = TRIALTYPE
- **DFSTUDY\_USER6** = LENGTH
- **DFSTUDY\_USER7** = REGID

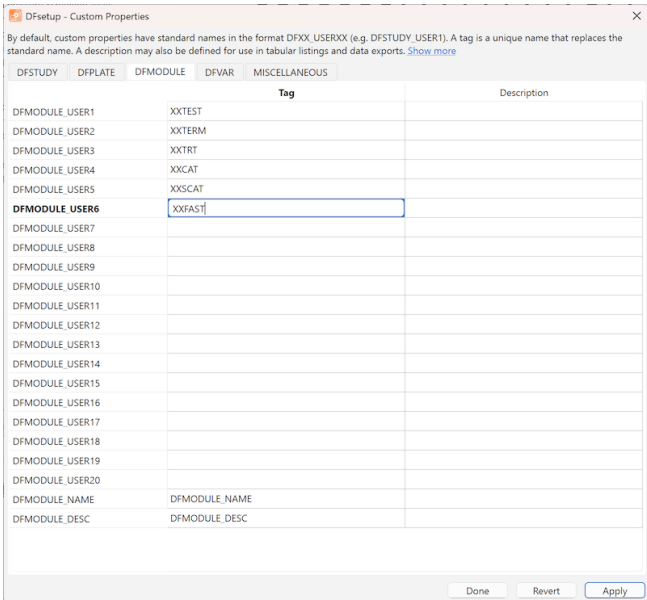


6. Click **DFPLATE** tab, followed by the empty **Tag** cell for **DFPLATE\_USER1**. Enter the Custom Properties for **DFPLATE** as follows:
- **DFPLATE\_USER1** = V1
  - **DFPLATE\_USER2** = V2



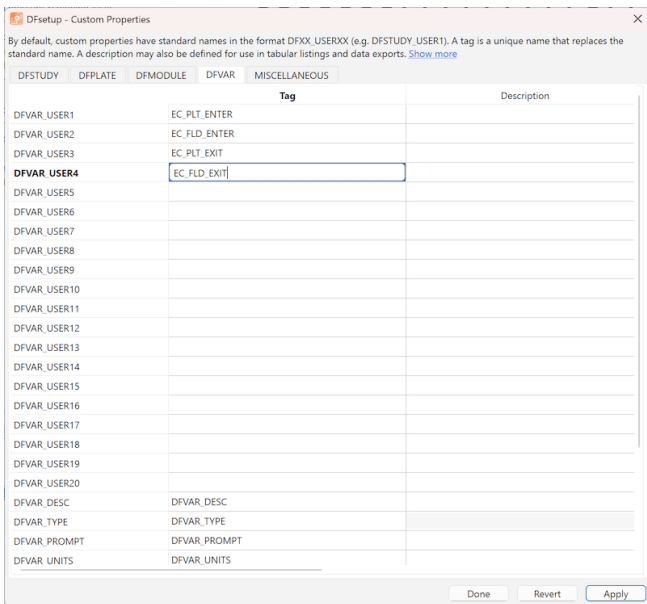
7. Click **DFMODULE** tab, followed by the empty **Tag** cell for **DFMODULE\_USER1**. Enter the Custom Properties for **DFMODULE** as follows:

- o **DFMODULE\_USER1** = XXTEST
- o **DFMODULE\_USER2** = XXTERM
- o **DFMODULE\_USER3** = XXTRT
- o **DFMODULE\_USER4** = XXCAT
- o **DFMODULE\_USER5** = XXSCAT
- o **DFMODULE\_USER6** = XXFAST



8. Click **DFVAR** tab, followed by the empty cell for **DFVAR\_USER1**. Enter the Custom Properties for **DFVAR** as follows:

- o **DFVAR\_USER1** = EC\_PLT\_ENTER
- o **DFVAR\_USER2** = EC\_FLD\_ENTER
- o **DFVAR\_USER3** = EC\_PLT\_EXIT
- o **DFVAR\_USER4** = EC\_FLD\_EXIT

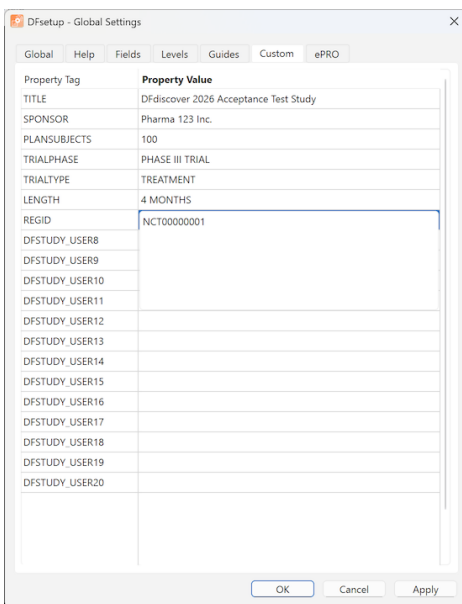


9. Click **Apply** > **Done** to apply the newly defined Custom Property values.

## Adding Global Custom Property values

1. Select **Study** > **Global Settings**>. Click **Custom** tab.
2. In the **Custom** tab set the following **Property Values**:
  - **TITLE** = DFdiscover 2026 Acceptance Test Study
  - **SPONSOR** = Pharma 123 Inc.
  - **PLANSUBJECTS** = 100
  - **TRIALPHASE** = PHASE III TRIAL
  - **TRIALTYPE** = TREATMENT
  - **LENGTH** = 4 MONTHS
  - **REGID** = NCT00000001

Click **OK** to save and dismiss the dialog.

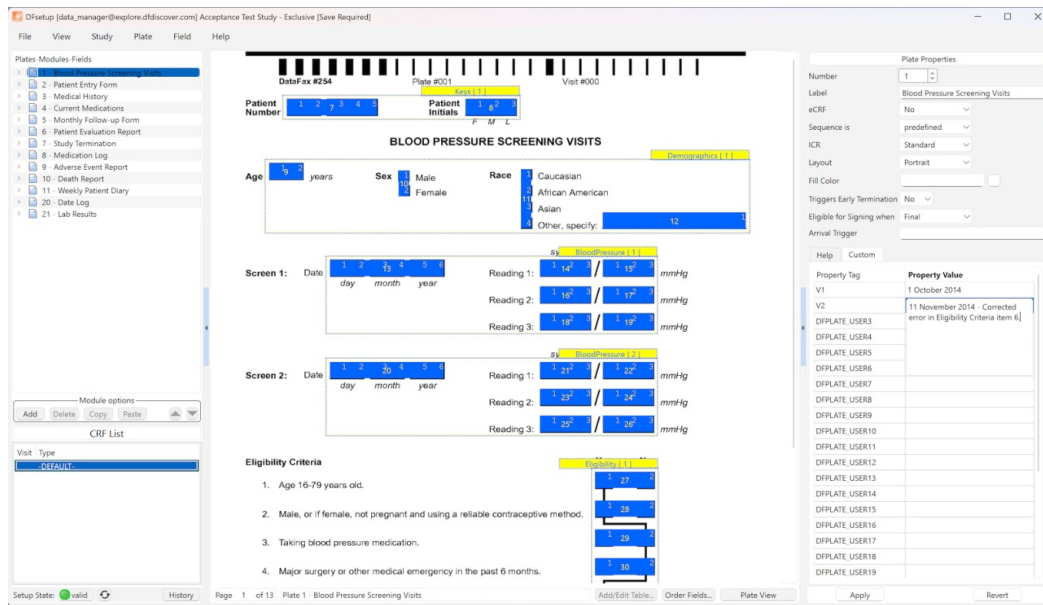


## Adding Plate, Module and Variable level Custom Property values

1. Click **1 - Blood Pressure Screening Visits** to make it the active page. Within the **Plate Properties** window click **Custom** tab.
2. Enter the **Property Value** tags as follows:
  - **V1** = 1 October 2014

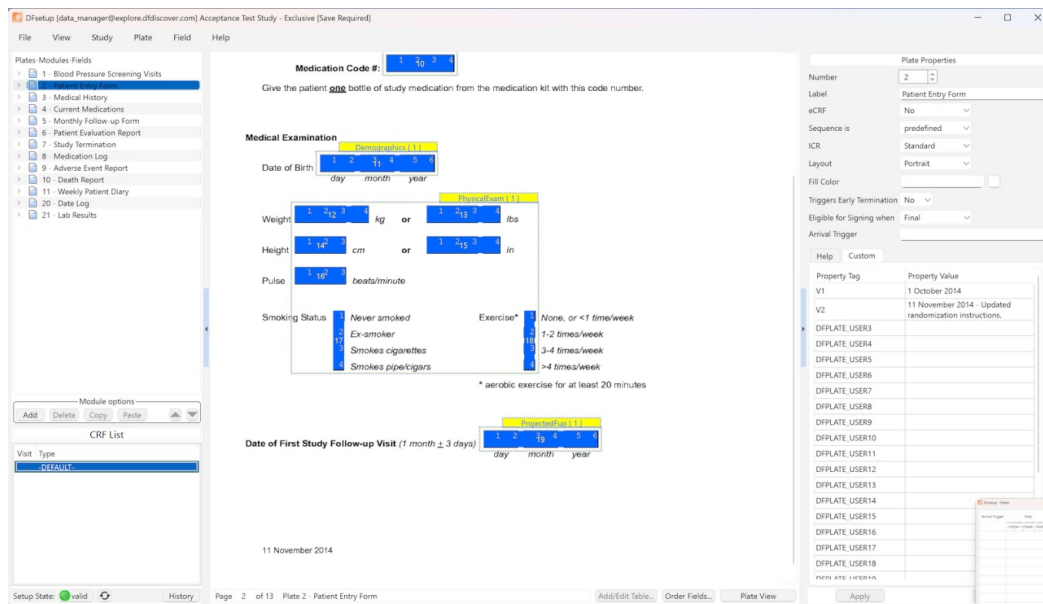
- o V2 = 11 November 2014 - Corrected error in Eligibility Criteria item 6.

Click **Apply**.

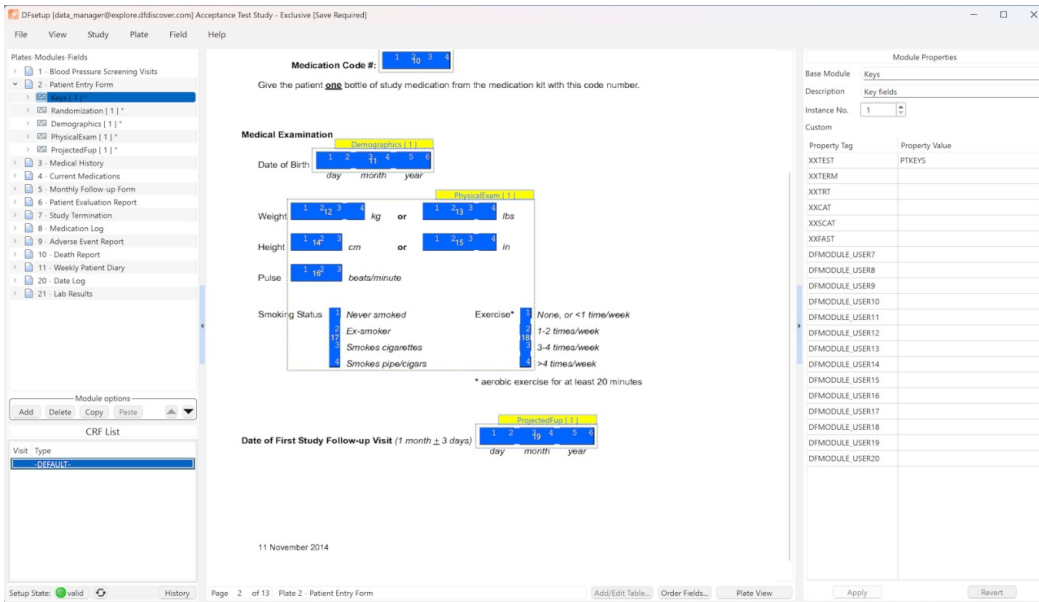


3. Select **View** > **Plates**.

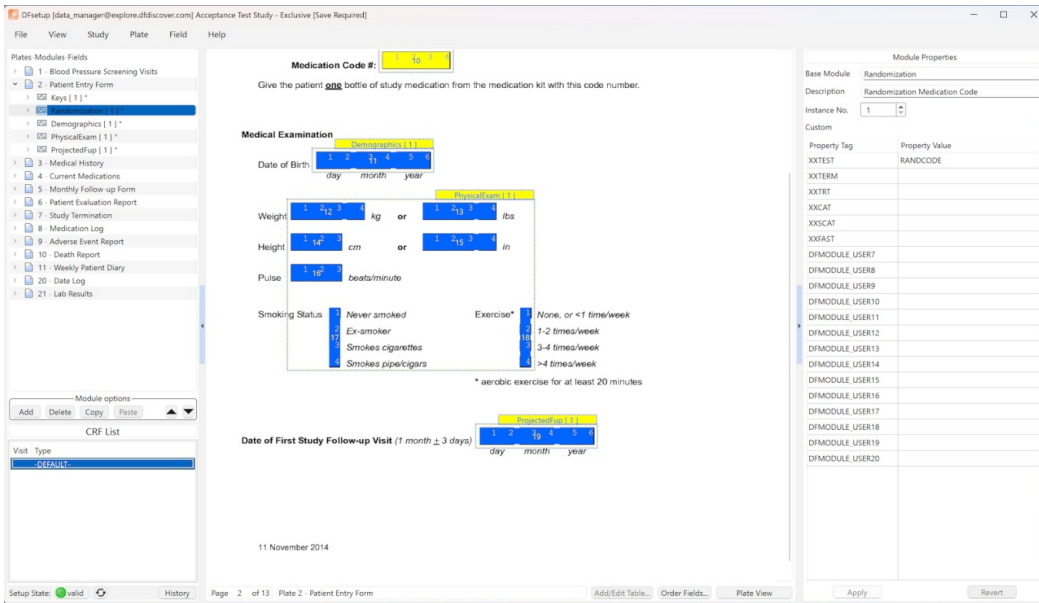
4. Within row 2 **Patient Entry Form** navigate to the V1 Property Value cell. Enter 1 October 2014. In the V2 cell enter 11 November 2014 - Updated randomization instructions.. Click **Apply**, **Done**.



5. From the **Plates-Modules-Fields** window double-click **2 - Patient Entry Form**. Click **Keys [1]** to make the module active.
6. In the **Module Properties** window specify **PTKEYS** for the **XXTEST Property Value**. Click **Apply**.

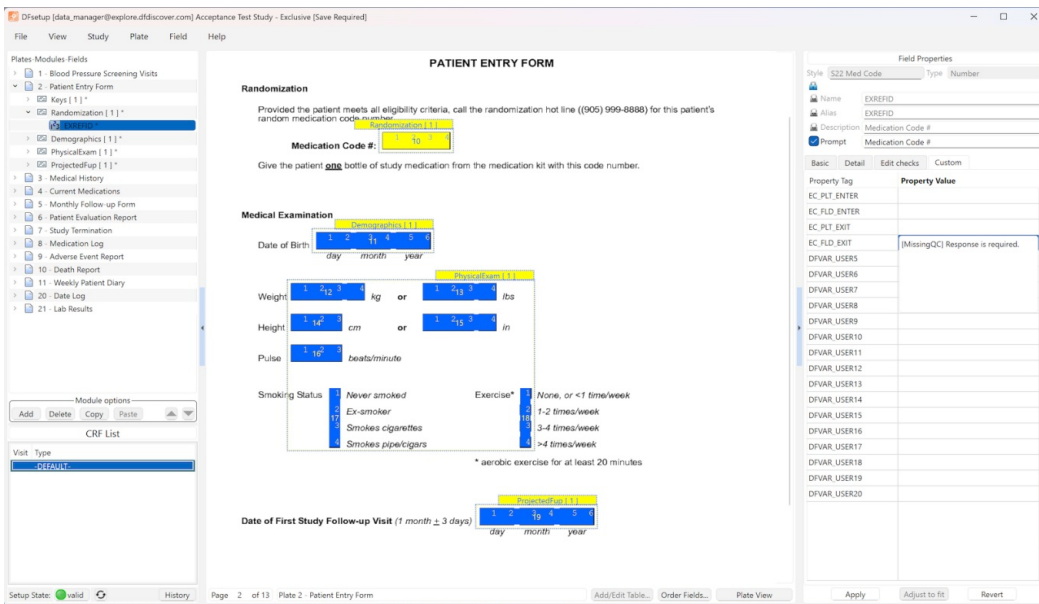


7. Double-click **Randomization [1]**. In the **Module Properties** window specify **RANCODE** for the **XXTEST** Property Value. Click **Apply**.



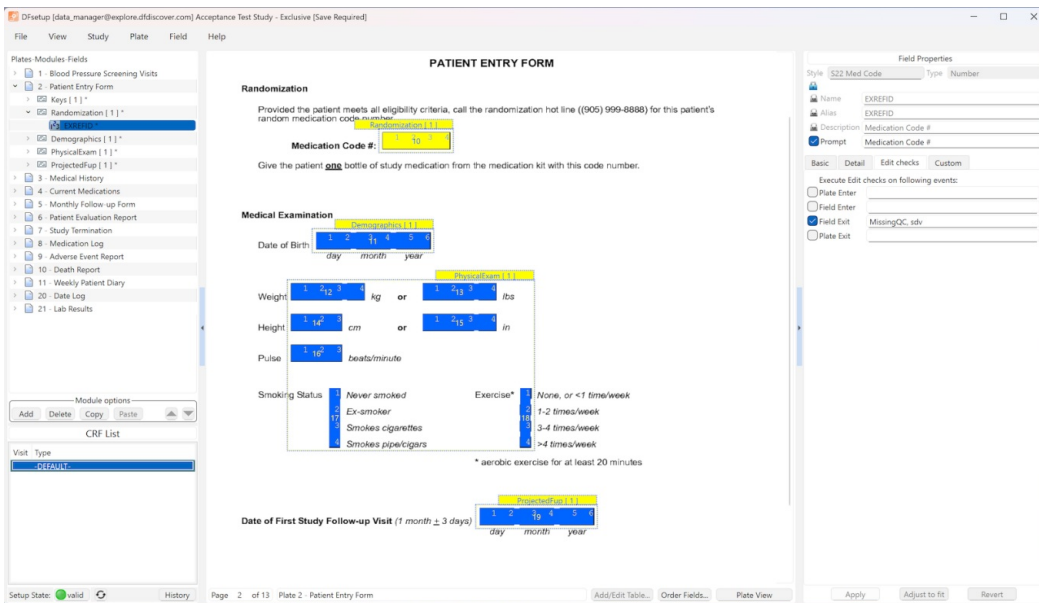
8. Select **Medication Code #** field. Click **Custom** from the **Field Properties** window.

9. Enter **[MissingQC]** Response is required. in the **EC\_FLD\_EXIT** Property Value.

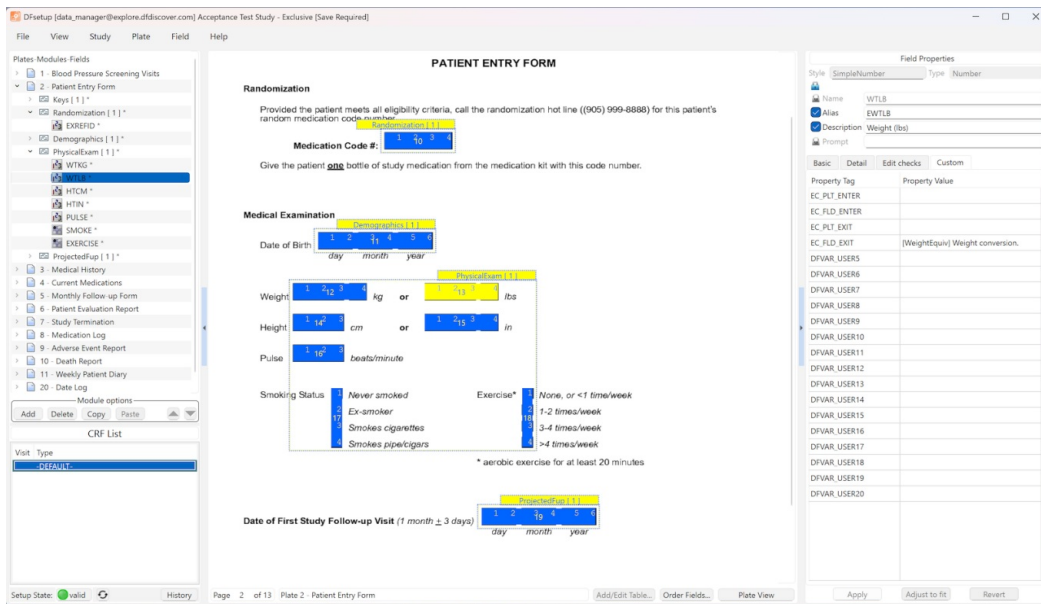


10. Click **Edit checks** tab within the **Field Properties** window.

11. Enter **MissingQC, sdv** next to **Field Exit**, click **Apply**.



12. Click **Weight (lbs)** field, then **Custom**. Enter **[WeightEquiv] Weight conversion.** in the **EC\_FLD\_EXIT Property Value**. Click **Apply**.



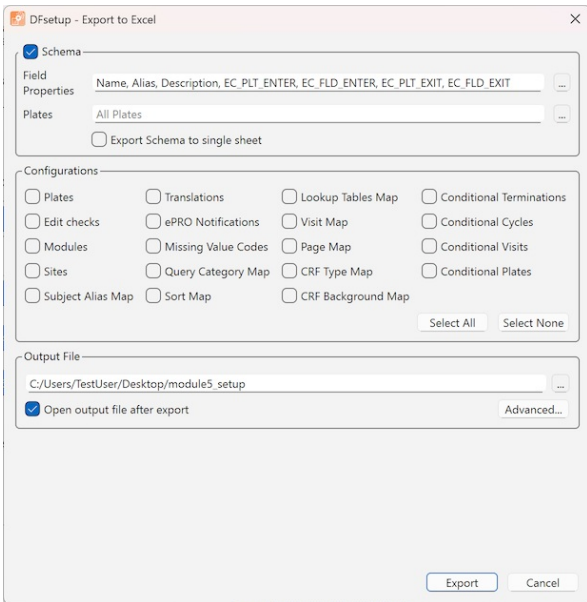
13. Select **File** > **Save [Required]**. Click **History**. The setup change history is displayed.

Date and Time	Who	Change	Plate	Module	Field	What Changed	Attribut
2026-05-14 00:17:51	data_manager	change plate	2: Patient Entry Form			Patient Entry Form	Custom
2026-05-14 00:17:51	data_manager	change module instance	2: Patient Entry Form	5032: Keys		Key fields	Custom
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5032: Keys	10220: SUBJID	Patient Number	Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5032: Keys	10221: PINIT	Patient Initials	Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5032: Keys	10222: VISDAT	Entry Date	Start Yee
							Encrypte
2026-05-14 00:17:51	data_manager	change module instance	2: Patient Entry Form	5033: Randomization		Randomization	Custom
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5033: Randomization	10223: EXREFID	Medication Code #	Field Exi
							Custom
							Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5034: Demographics	10224: BRTHDAT	Date of Birth (dd/mm/yyyy)	Start Yee
							Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5035: PhysicalExam	10225: WTKG	Weight (kg)	Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5035: PhysicalExam	10226: WTLB	Weight (lbs)	Custom
							Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5035: PhysicalExam	10227: HTCM	Height (cm)	Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5035: PhysicalExam	10228: HTIN	Height (inches)	Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5035: PhysicalExam	10229: PULSE	Pulse (beats/min)	Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5035: PhysicalExam	10230: SMOKE	Smoking Status	Encrypte
2026-05-14 00:17:51	data_manager	change plate field	2: Patient Entry Form	5035: PhysicalExam	10231: EXERCISE	Exercise	Encrvote

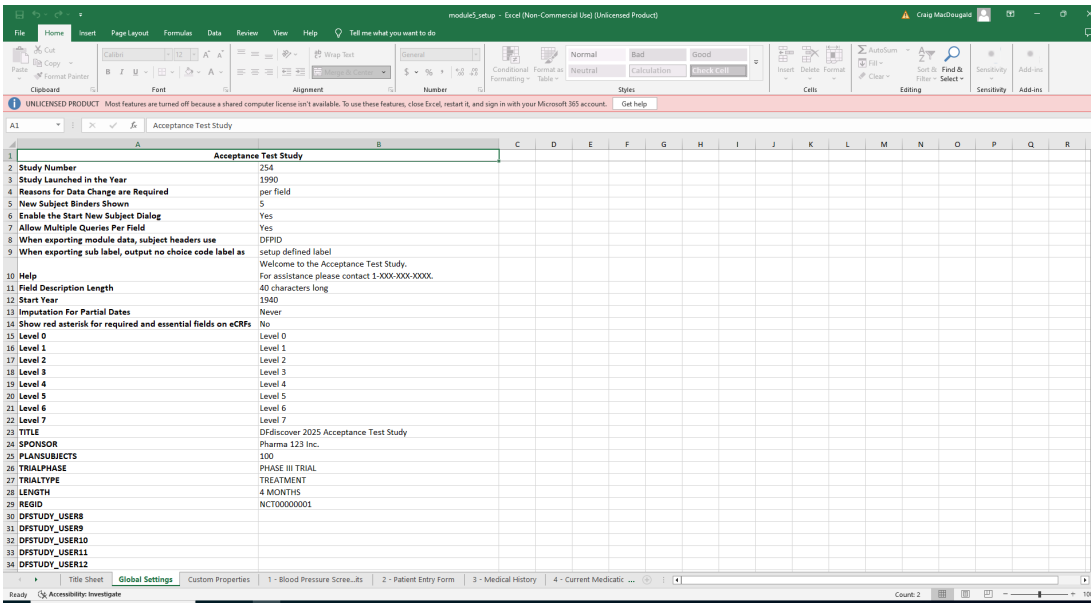
1. Save the **DFsetup** history as **module5\_setuphistory.xlsx** by clicking **Save As...** > **Save**. Open the saved .xlsx file and verify that its contents match the **DFsetup - History** output before closing the history dialog by clicking **X**.

## Exporting Custom Properties in DFsetup

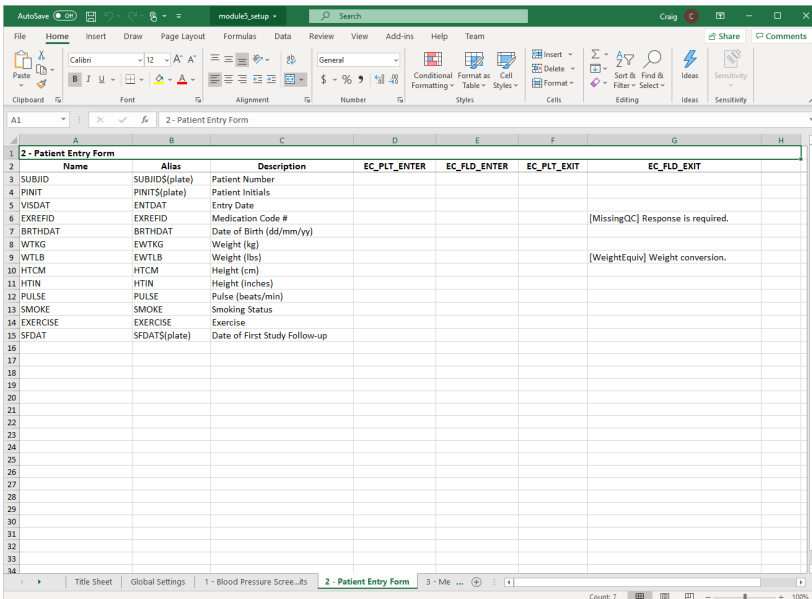
1. Select **File** > **Export Setup** > **Excel**.
2. Click **Field Properties** **...**.
3. In the resulting dialog, click **Select none**.
4. Select **Name**, **Alias**, **Description**, **EC\_PLT\_ENTER**, **EC\_FLD\_ENTER**, **EC\_PLT\_EXIT** and **EC\_FLD\_EXIT**. Click **OK**.
5. Specify **module5\_setup.xlsx** as the **Output File** name, enable (check) **Open output file after export**. Click **Export**.



6. In the exported Excel file open the **Global Settings** tab to view the newly defined Global Property tags.



7. Click **2 - Patient Entry Form** to view the newly defined Plate Custom Property tags. Return to DFsetup.

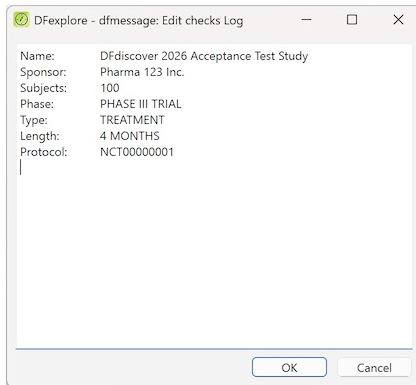


8. Select **File** > **Exit** to close **DFsetup**.

## Edit checks execution of Custom Properties

1. Start **DFexplore**, login as **data\_coordinator** and choose **254 Acceptance Test Study** as described in ["How to start DFexplore"](#). Upon logging in a **dfmessage** edit check dialog is displayed containing the **DFsetup-Global Settings Custom** property tags defined in ["Defining Custom Properties in DFsetup"](#). Click **OK** to close the dialog.

**NOTE:** If **data\_coordinator** has been set up for 2-factor authentication with Azure SMS, you may need to wait for a 1-time code to arrive at the phone number as defined in **DFAdmin**.

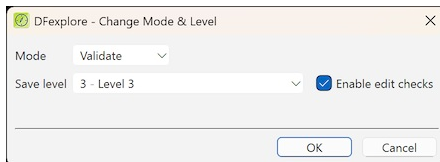


2. Select **File** > **Preferences**, click **Background Options** to expand the preferences. Click **Color** then **OK** to apply the changes.

3. Select **Select** > **Change Mode & Level**. Set:

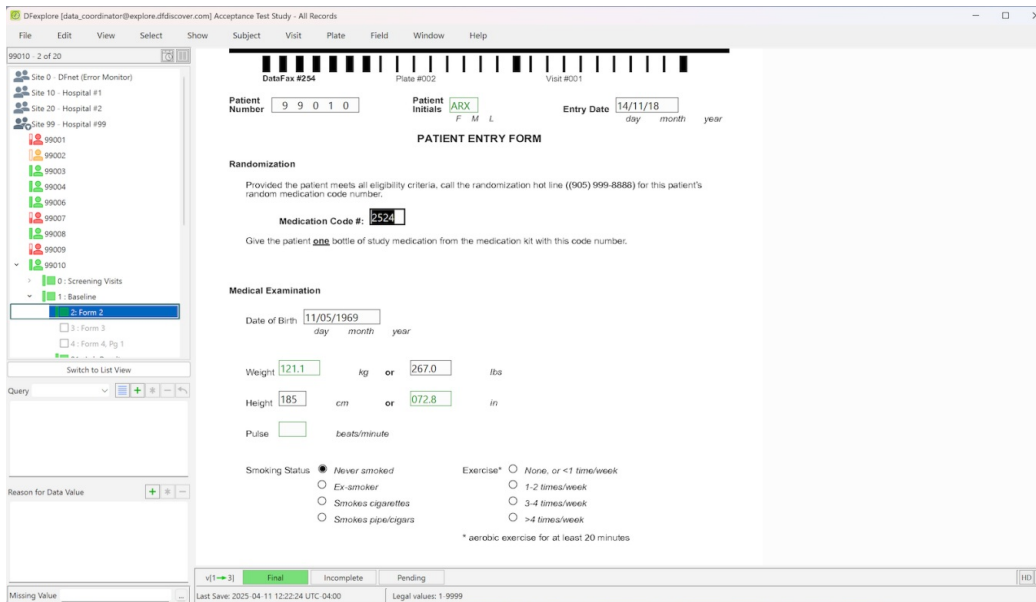
- **Mode** = Validate
- **Save level** = 3 - Level 3
- Check (enable) **Enable edit checks**.

Click **OK**.



4. Double-click **Site 99 - Hospital #99 > 99010 > 1 : Baseline > 2 : Form 2**.

5. Click anywhere on the page background to make the fields active. Press **Tab** to advance to the **Medication Code #** field.



6. Press **Tab** to exit the field and execute the **sdv** edit check.

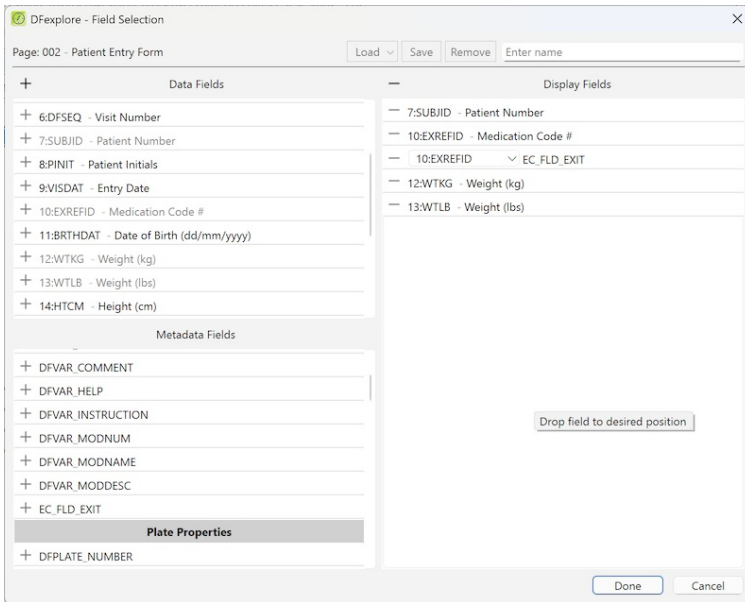
- Click **[OK]** to add the edit check containing the **Custom Property Value's** added in "[Defining Custom Properties in DFsetup.](#)".
- Press **[Tab]** to advance through the remainder of the fields on the **Patient Entry Form** page. Verify that the Save information bar at the bottom of the screen indicates that the saved page will be assigned a record **level of 3**. Click **[Incomplete]**.

## Creating subject data lists and exporting data views

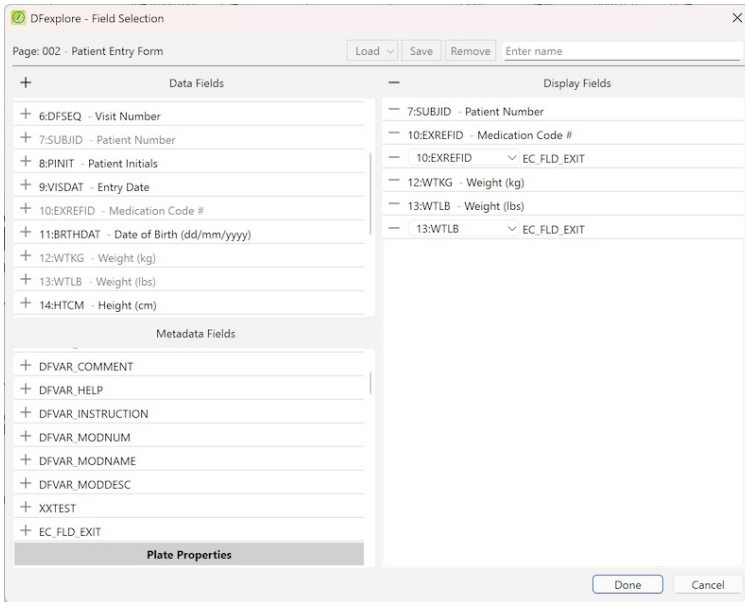
- Select **[View]** > **[List]**.
- Click **002 - Patient Entry Form**.
- Select **[Select]** > **[Field Selection]** to show the listing of all data fields and their metadata properties defined for the plate. In the **Data Fields** window, click **+** next to fields **7:SUBJID** , **10:EXREFID** , **12:WTKG** , **13:WTLB**.

**NOTE:** Alternatively fields can also be added by dragging-and-dropping the desired fields from the **Data Fields** or **Metadata Fields** windows to the **Display Fields** window.

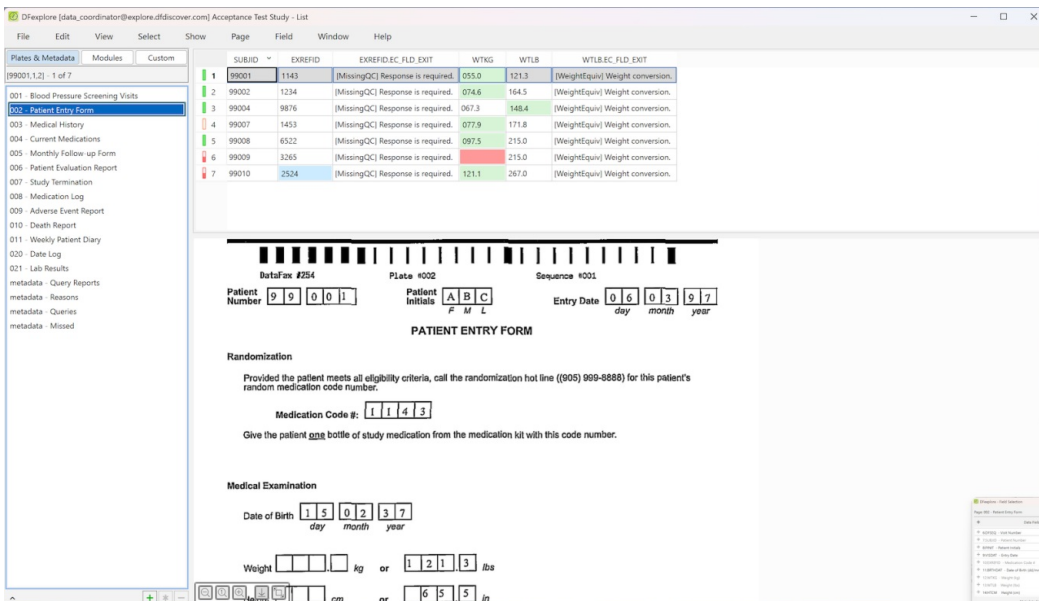
- In the **Metadata Fields** window, click **+** next to field **EC\_FLD\_EXIT** to add the field to the **Display Fields** window. From the drop-down select **10:EXREFID**, click and drag the field to be below the **10:EXREFID - Medication Code #** field.



5. Return to the **Metadata Fields** window, click **+** next to field **EC\_FLD\_EXIT** to add the field to the **Display Fields window**. From the drop-down select **13:WTLB**.



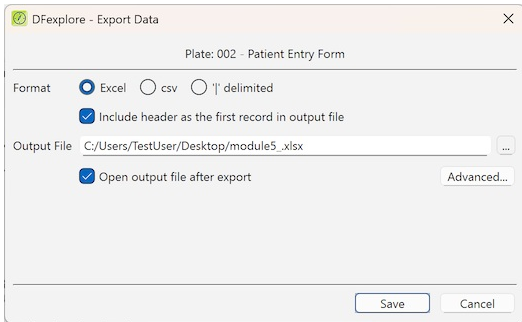
6. Click **Done** to apply the field selection criteria and close the dialog.



7. Select **File** > **Export Data** to save the data to a local file. In the dialog, set:

- o **Format** = Excel
- o Check (enable) **Include header as the first record in output file**.

8. Click **[...]** next to **Output File**. Choose a directory in the file selection dialog, enter module5\_data.xlsx as the filename, and click **Save**. Click **Save** to create/write the file and close the dialog.

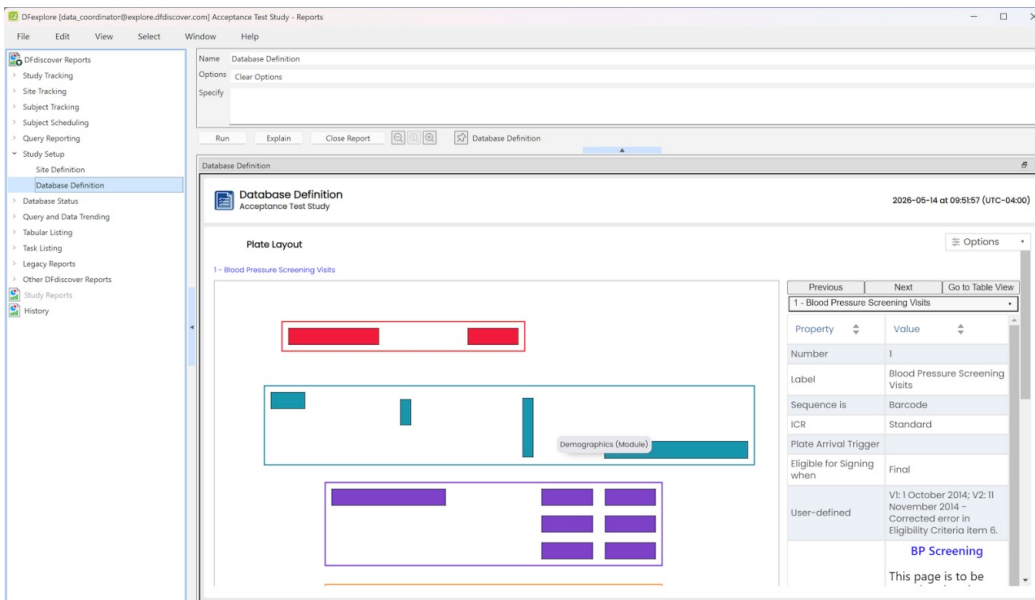


## DFExplore Database Definition Report exporting

1. Select **View** > **Reports**.

2. Double-click **DFdiscover Reports** > **Study Setup** > **Database Definition**.

3. Click **Run**.



4. Select **File** > **Save Output as** > **Excel**.

5. Click **[...]** next to **Output File**. Choose a directory in the file selection dialog, enter module5\_definitions.xlsx as the filename and click **Save**. Check (enable) **Open output file after export** and click **Save**.

## End Module 5. Custom Properties

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).

2. Click **End** to confirm successful completion of Module 5. Custom Properties.

## Module 6. Subject Alias

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - o datafax : Unrestricted
  - o data\_manager : Unrestricted
  - o site\_monitor : site\_monitor
- Email address configured for site\_monitor

**Client Tools Used:** DFATK, DFExplore, DFsetup, DFsend  
DFdiscover 5.11.0

**Purpose:** This module tests the definition and use of subject alias maps and related options within DFdiscover, in both live data viewing and data export scenarios.

## Tests & Requirements

1. Importing and Modifying Subject Alias Map using **DFsetup**.
2. Subject Alias Tracking (Reports).
3. Exporting Subject Alias data.

Estimate of Time Required: 20 Minutes

## Begin Module 6. Subject Alias

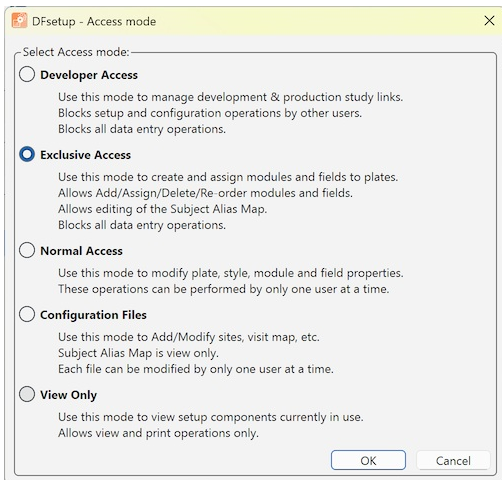
1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **6. Subject Alias** followed by **Begin** to begin this module.
3. Click **Send Subject Alias Map** to email a copy of **subject\_alias\_map.csv** to data\_manager. Clicking more than once will result in multiple files arriving to your email inbox.

**NOTE:** Save the **subject\_alias\_map.csv** file received via email to your local computer. This file is required to complete the remainder of this module. Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address is required for data\_manager to receive the module specific files.

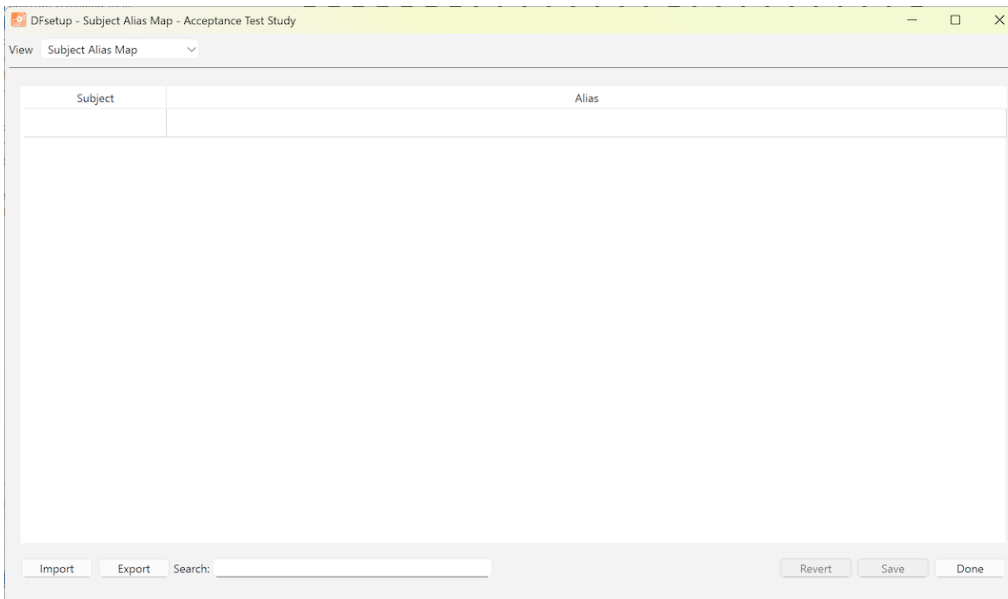
1. This module requires user data\_manager to have exclusive access to the 254 Acceptance Test Study database, the Control Panel must be closed. Click **Exit**.

## Importing and Modifying Subject Alias Map using **DFsetup**

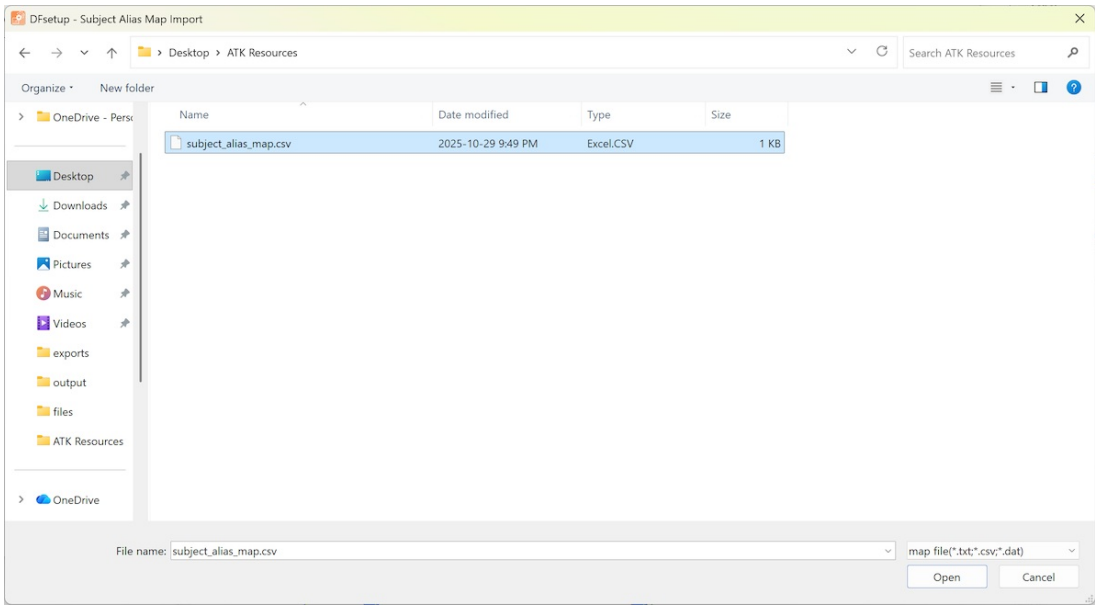
1. Start **DFsetup**, login as user data\_manager and choose **254 Acceptance Test Study** as described in ["How to start DFsetup"](#).
2. Choose **Exclusive Access** and click **OK**. **Exclusive Access** allows you to edit the Subject Alias Map.



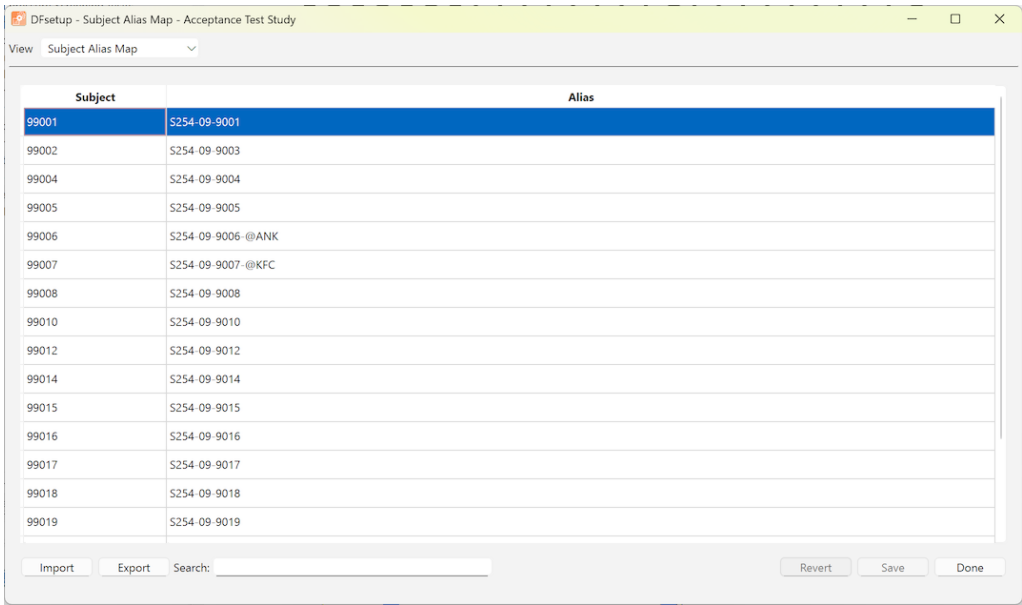
3. Select **View** > **Subject Alias Map**.



4. Click **Import**. From the file selection dialog, locate the previously saved **subject\_alias\_map.csv** file.



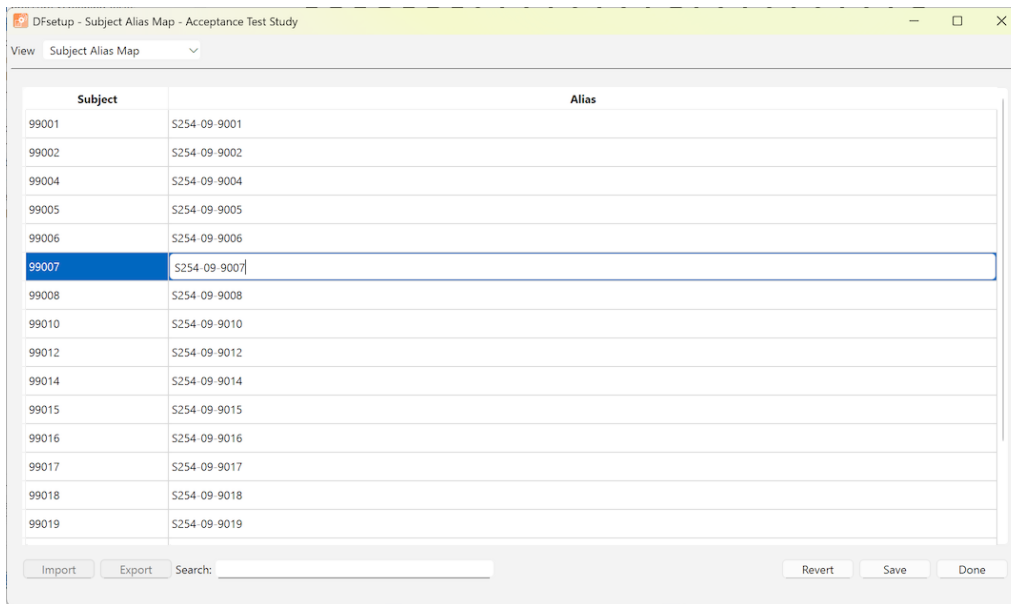
5. Select the file, click **Open**, then **Save**.



NOTE: Clicking **Save** triggers the initial import of the Subject Alias Map to be logged in DFsubjectaliasmap.log which leads to the output produced in "[Subject Alias Tracking \(Reports\)](#)".

6. Modify the following **Alias** definitions:

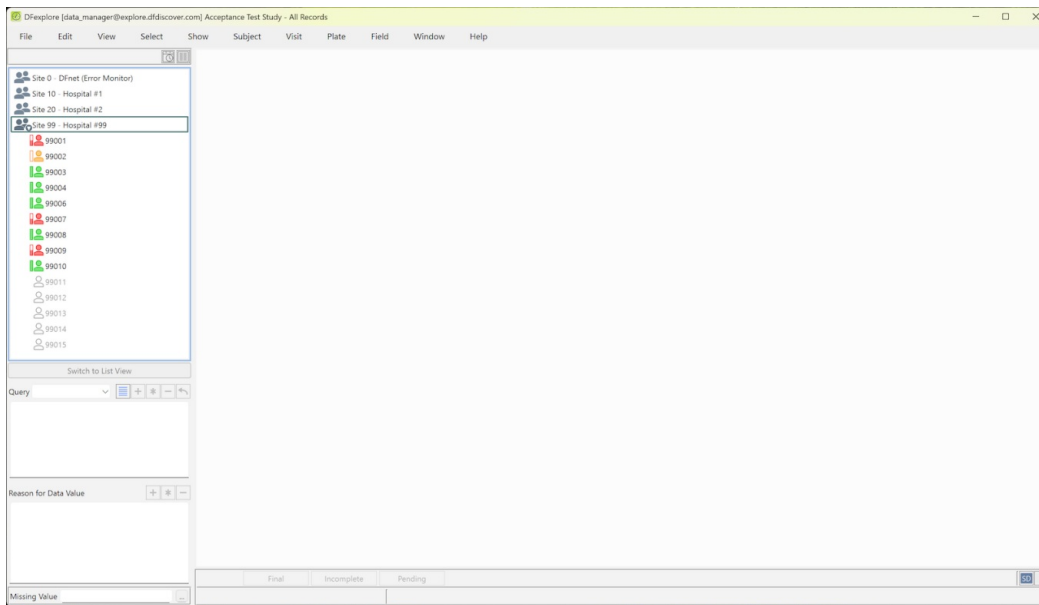
- 99002 from S254-09-9003 to S254-09-9002
- 99006 from S254-09-9006-@ANK to S254-09-9006
- 99007 from S254-09-9007-@KFC to S254-09-9007



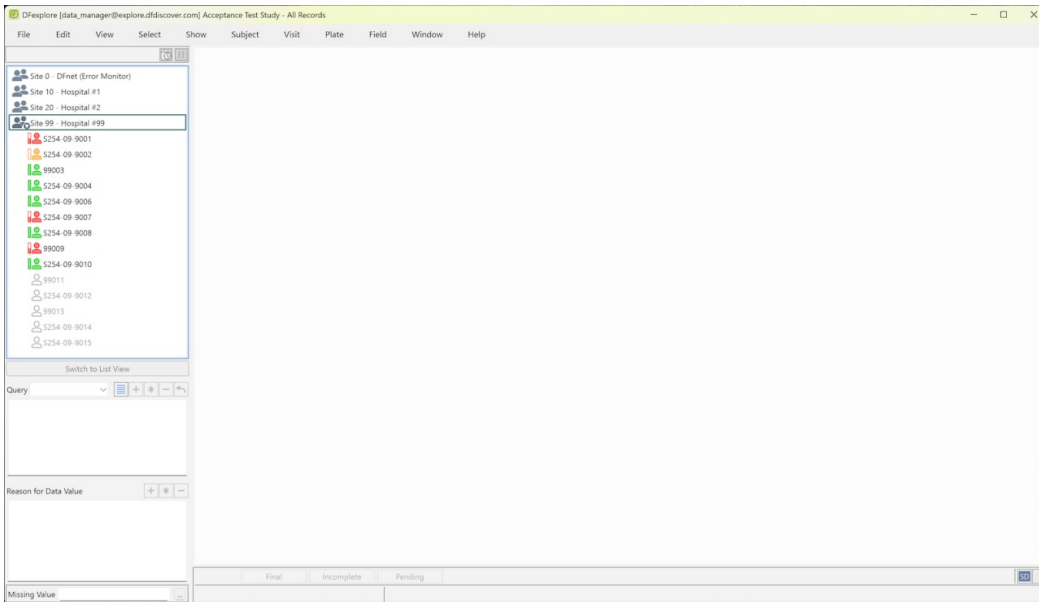
7. Click **S**ave then **D**one to apply the modifications to the **Subject Alias Map**.
8. Select **F**ile > **E**xit to close **DFsetup**.

## Creating Subjects using Subject Alias

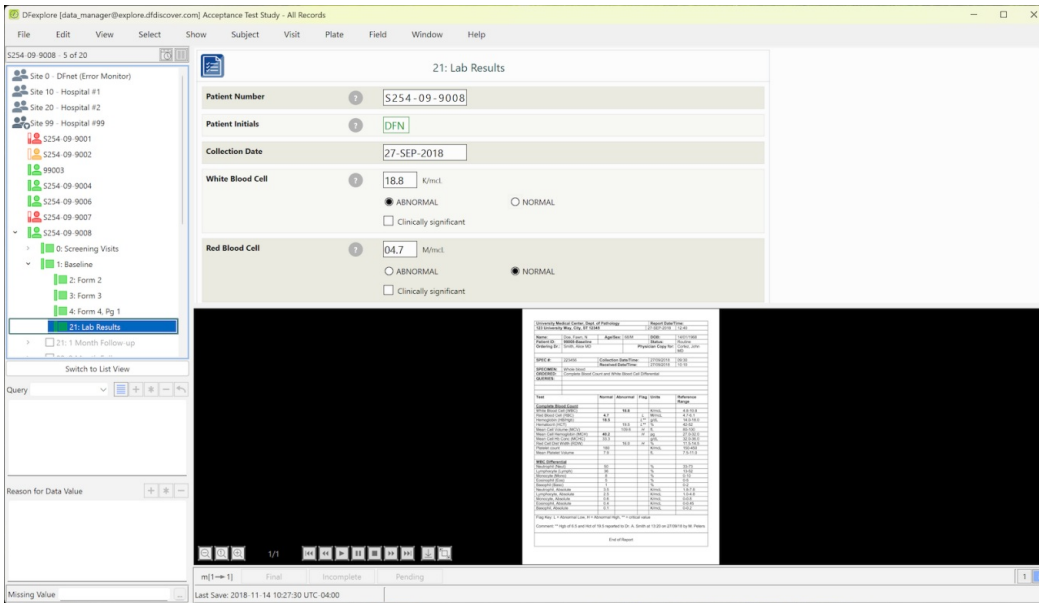
1. Start **DFexplore**, login as user `data_manager` and choose **254 Acceptance Test Study** as described in "[How to start DFexplore](#)".
2. Double-click **Site 99 - Hospital #99** to open the list of available subjects.



3. Select **F**ile > **P**references. Check (enable) **U**se subject alias. Click **O**K. The Subject ID list now displays the Subject Alias Mapping as defined in **DFsetup**.



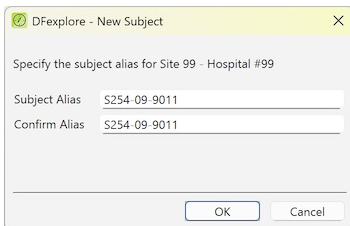
4. Click **Site 99 - Hospital #99** > **S254-09-9008** > **1: Baseline** > **21: Lab Results** to make it the active page.



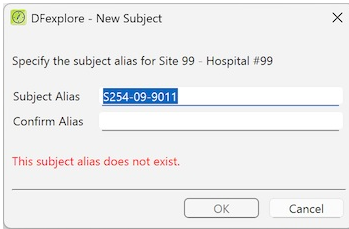
5. Select **[Subject]** > **[New Subject]**. Set:

- o **Subject Alias** = S254-09-9011
- o **Confirm Alias** = S254-09-9011

Click **[OK]**.

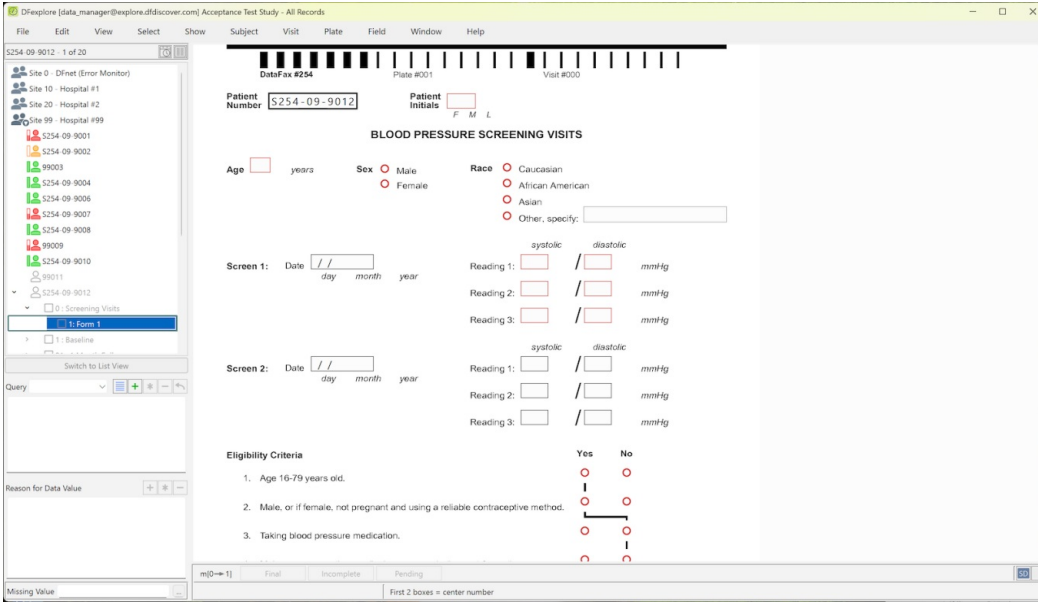


6. The message **This subject alias does not exist** is displayed. Click **[Cancel]** to dismiss the **New Subject** dialog.

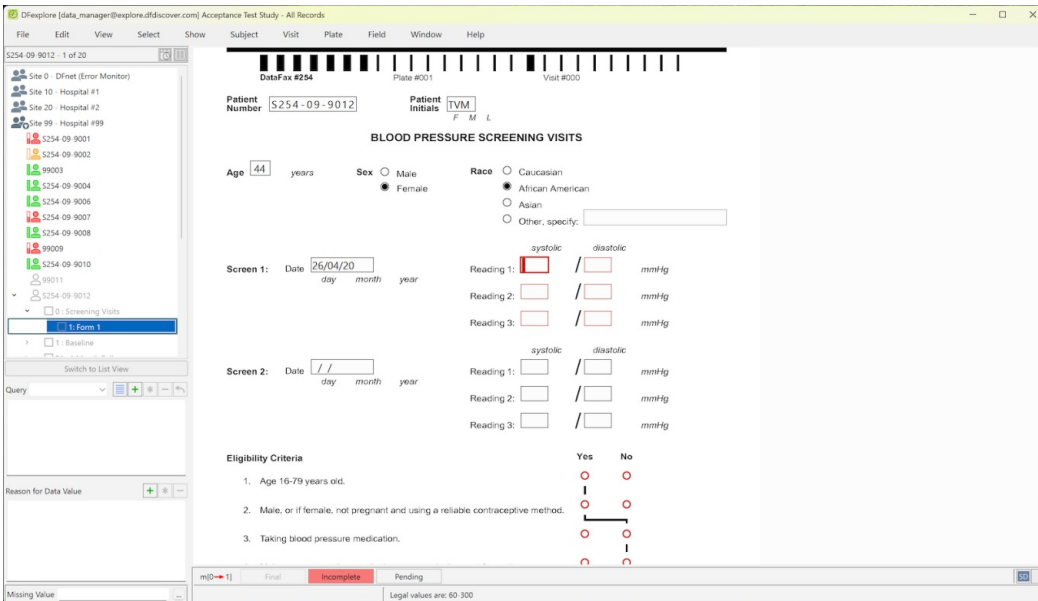


NOTE: All Subject Alias definitions are required to be defined within **DFsetup**. Users are unable to add new Subject Alias definitions within **DFexplore**.

- Double-click **S254-09-9012** then entry for **0 : Screening Visits** to display the list of pages belonging to the visit. Page **1 : Form 1** becomes the active page. The data window redraws with the plate background and related data entry fields.



- Click anywhere on the plate background - this moves the mouse and keyboard focus to the data window.
- Beginning at the **Patient Number** field, press **Tab** to advance to the **Patient Initials**. Enter the initials TVM Press **Tab** to advance to the **Age** field.
- Beginning with the **Age** field set the following values:
  - Age** = 44
  - Sex** = Female
  - Race** = African American
  - Screen 1** = 26/04/20



- As outstanding required data fields exist on the page it must be saved to the database with a status of **Incomplete**. Click **Incomplete**.

12. Select **View** > **List**. Select **001 - Blood Pressure Screening Visits**.

The screenshot shows the Dfdiscover software interface. On the left, a navigation pane lists various report types, with '001 - Blood Pressure Screening Visits' selected. The main window displays a table of patient visits with columns for visit ID, status, level, date, and patient information. Below the table, a detailed form for 'Blood Pressure Screening Visits' is shown, including fields for patient number, date, age, sex, race, and multiple blood pressure readings (systolic and diastolic).

13. Confirm an entry exists for **S254-09-9012**.

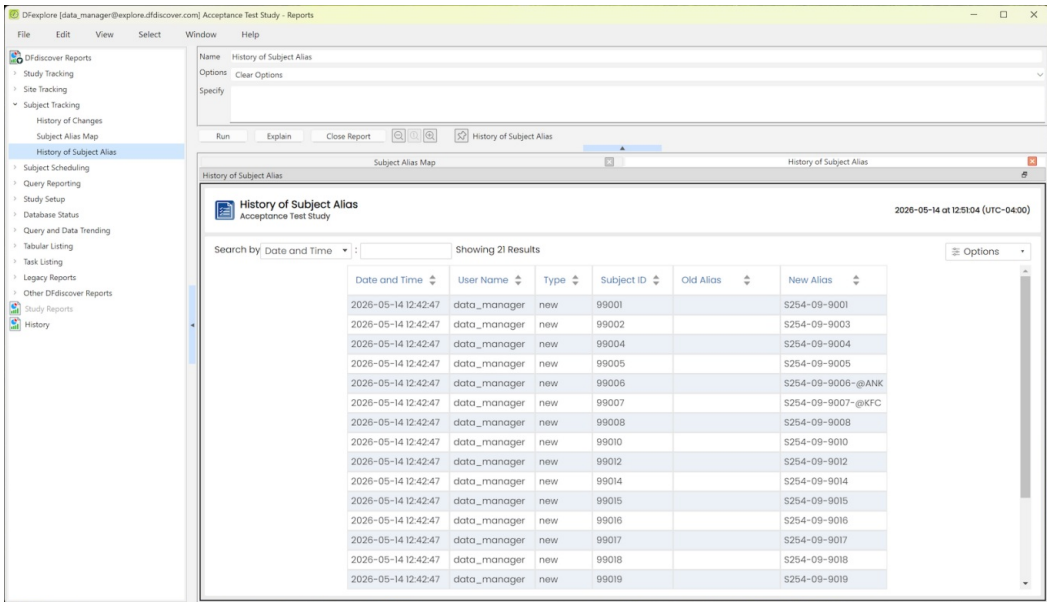
## Subject Alias Tracking (Reports)

1. Select **View** > **Reports** to switch to **Reports** View. In the reports list panel, double-click **Dfdiscover Reports** followed by **Subject Tracking**. Highlight the report **Subject Alias Map**. Click **Run**.

The screenshot shows the Dfdiscover software interface in the 'Reports' view. The left navigation pane shows 'Dfdiscover Reports' > 'Subject Tracking' > 'Subject Alias Map' selected. The main window displays the 'Subject Alias Map' report, which shows a list of 18 results. The report is titled 'Subject Alias Map' and 'Acceptance Test Study', dated '2020-05-14 at 12:50:51 (UTC-0400)'. The results are displayed in a table with columns for 'Subject ID' and 'Subject Alias'.

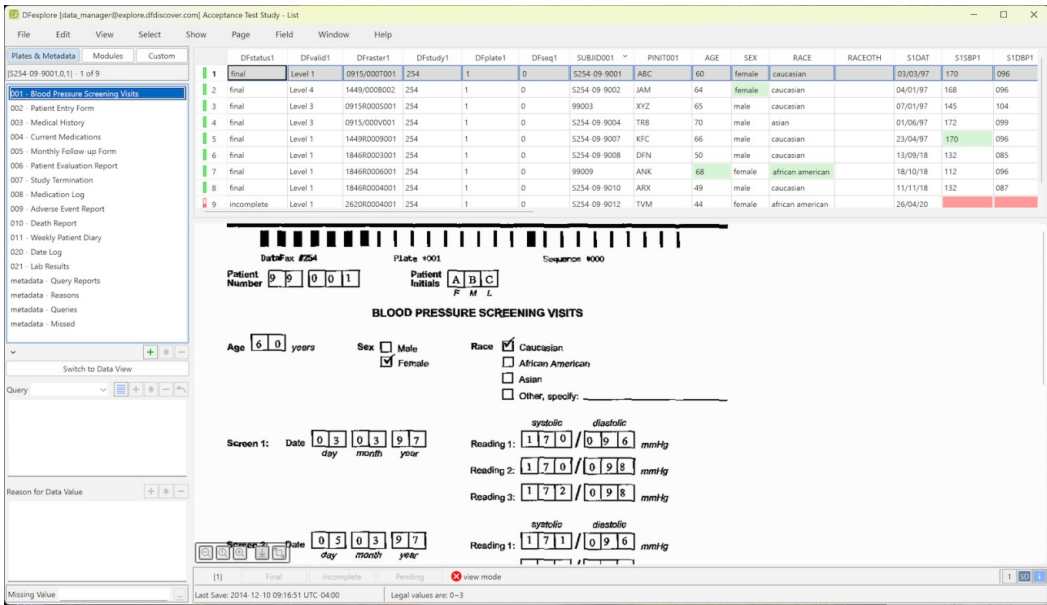
Subject ID	Subject Alias
99001	S254-09-9001
99002	S254-09-9002
99004	S254-09-9004
99005	S254-09-9005
99006	S254-09-9006
99007	S254-09-9007
99008	S254-09-9008
99010	S254-09-9010
99012	S254-09-9012
99014	S254-09-9014
99015	S254-09-9015
99016	S254-09-9016
99017	S254-09-9017
99018	S254-09-9018
99019	S254-09-9019
99020	S254-09-9020

2. Click **History of Subject Alias** Report then **Run**.

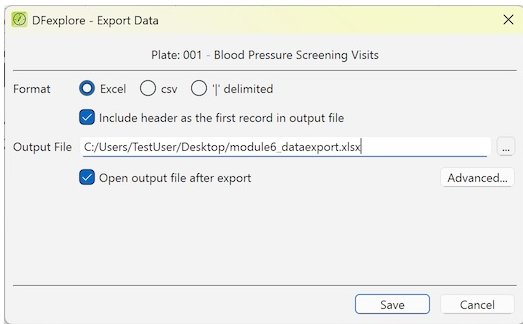


## Exporting Subject Alias data

1. Select **View** > **List**.
2. Confirm that **001 - Blood Pressure Screening Visits** is still the active plate.



3. Select **File** > **Export Data**.
4. In **Export Data** dialog set:
  - o **Format** = Excel
  - o Check (Enable) **Include header as the first record in the output file**.
  - o Check (enable) **Open output file after export**
5. Click **Output File** [...]. In the file selection dialog, choose a directory in which to save the Excel file. Once a directory has been chosen, append the file name module6\_dataexport.xlsx to the directory name. Click **Save**.



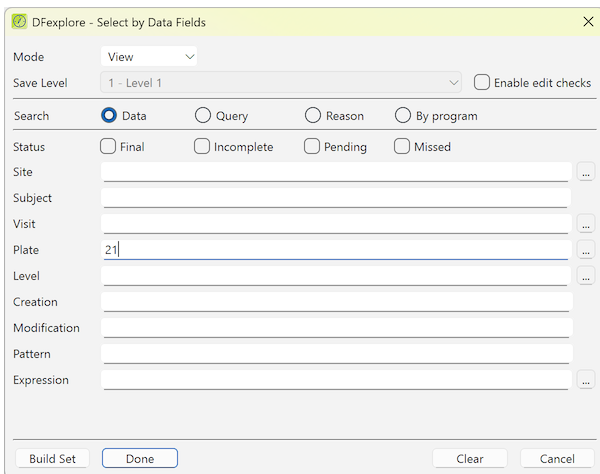
6. After saving, the file module6\_dataexport.xlsx opens. The **SUBJID** displays the Subject Aliases.

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	DFSEQ	SUBJID	PINIT	AGE	SEX	RACE	RACEOTH	SDAT	SBP1	DBP1	SBP2
final	Level 1	0915/000T001	254	1	0	S254-09-9001	ABC	60	female	caucasian		2450510	170	96	170
final	Level 4	1449/000B002	254	1	0	S254-09-9002	JAM	64	female	caucasian		2450452	168	96	170
final	Level 3	0915R0005001	254	1	0	99003	XYZ	65	male	caucasian		2450455	145	104	146
final	Level 3	0915/000V001	254	1	0	S254-09-9004	TRB	70	male	asian		2450600	172	99	173
final	Level 1	1449R0009001	254	1	0	S254-09-9007	KFC	66	male	caucasian		2450561	170	96	172
final	Level 1	1846R0003001	254	1	0	S254-09-9008	DFN	50	male	caucasian		2458374	132	85	137
final	Level 1	1846R0006001	254	1	0	99009	ANK	68	female	african american		2458409	112	96	125
final	Level 1	1846R0004001	254	1	0	S254-09-9010	ARX	49	male	caucasian		2458433	132	87	130
Incomplete	Level 1	2020R0002001	254	1	0	S254-09-9012	TVM	44	female	african american		2458965			

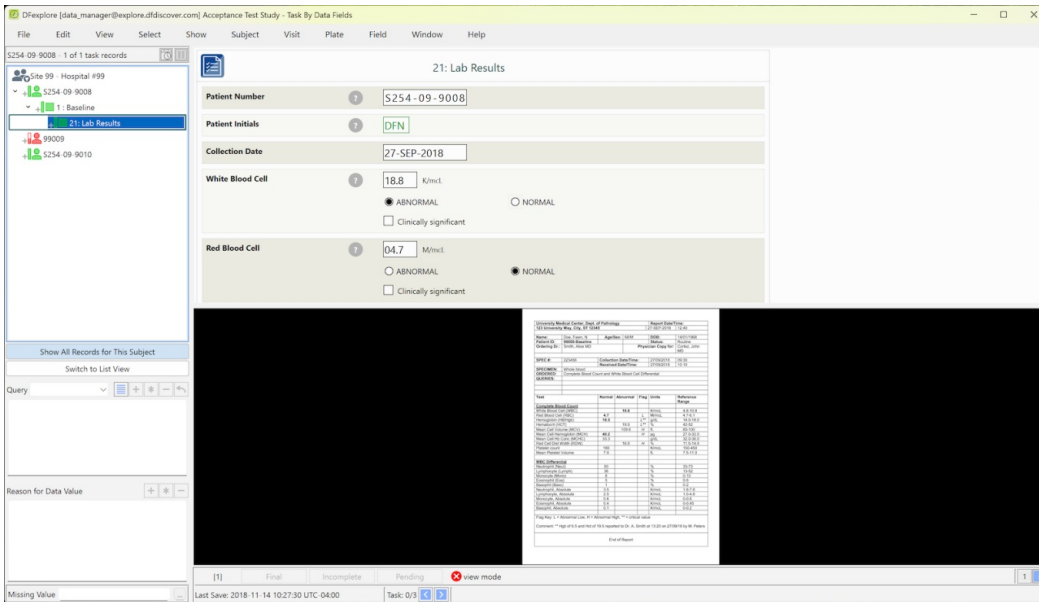
7. Return to **DFExplore**. Select **View** > **Data**.

8. Create a task record set by selecting **Select** > **By Data Fields**. Set:

- o **Mode = View**
- o **Plate = 21**



9. Click **Done** then **OK**.

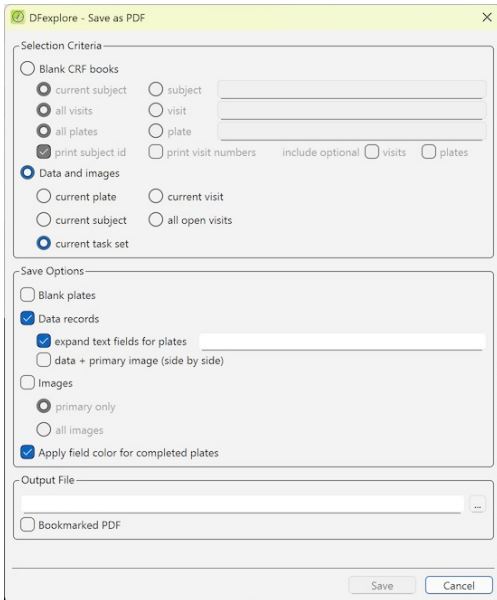


10. Select **File** > **Save as PDF**.

11. In the **Selection Criteria** panel,
- Select (enable) **Data and images** followed by **current task set**

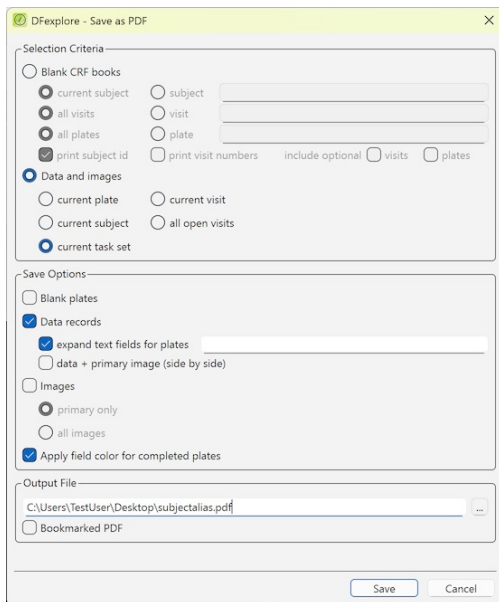
In the **Save Options** panel,

- Check (enable) **Data records** and **expand text fields for plates**
- Check (enable) **Apply field color for completed plates**



12. Click **Output File** [...]. In the file selection dialog, choose a directory in which to save the PDF. Once a directory has been chosen, append the file name `subjectalias.pdf` to the directory name. Click **Save**.

13. Complete the specification by clicking **Save**. There will be a busy pause while the PDF of completed data pages and their primary images is created.



14. Locate and open the previously saved subjectalias.pdf file. Confirm the **Patient Number** fields within the PDF are identical to that shown in **DFEExplore Data View**.
15. Select **[File] > [Preferences]**. Uncheck (disable) **Use subject alias**. Click **[OK]**.
16. Select **[File] > [Exit]** to close **DFEExplore**.

## End Module 6. Subject Alias

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **[End]** to confirm successful completion of Module 6. Subject Alias.

## Module 7. EDC Data Entry

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
- Email address configured for site\_monitor

**Client Tools Used:** DFATK, DFEExplore

**Purpose:** This module performs tests relating to electronic data capturing (EDC), as well as related functions. Data will be entered manually interactively as well as test the operations and use of tasks, queries, and marking/unmarking data as missed.

### Tests & Requirements

1. Login to **DFEExplore** and the Acceptance Test Study and confirm the list of sites, subjects and assessments in the record list window.
2. Enter and save new data using EDC data entry for Subject 99007.
3. Add reasons to explain entered data values.
4. Enter and save Plate 3, Subject 99007 as a pending record.
5. Mark and save unavailable data as missed. Unmark available data as missed.
6. Retrieve and modify existing data using a predefined task and save modifications to the database.
7. Confirm audit trail information for entered and modified data.

Estimate of Time Required: 20 minutes

### Begin Module 7. EDC Data Entry

Every module uses **DFATK** and must be run as datafax.

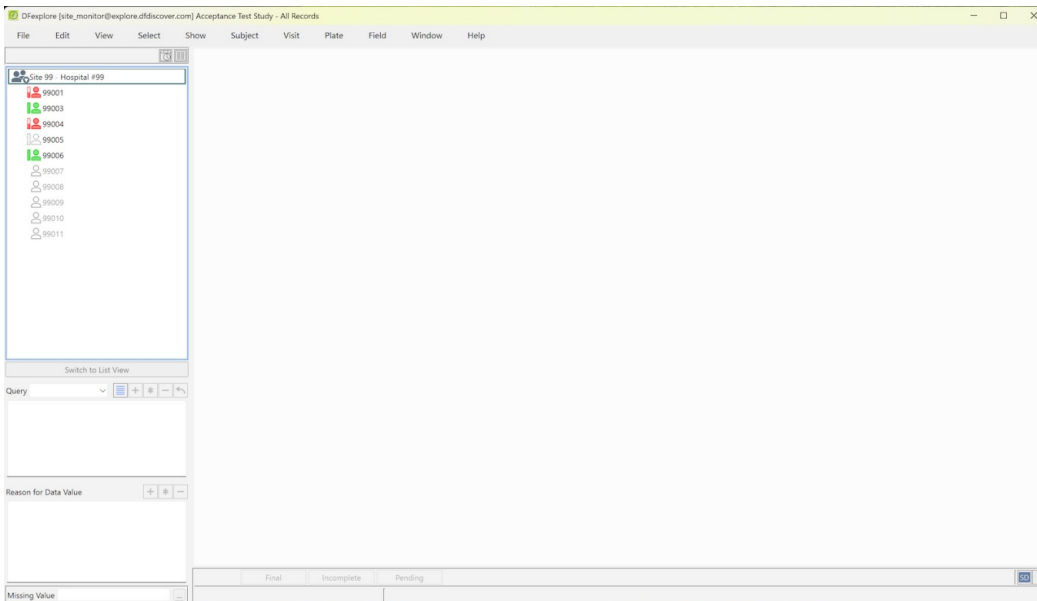
1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **[7. EDC Data Entry]** followed by **[Begin]** to begin this module.
3. Click **[Send ID 99007]** to email a copy of **ID99007\_module7.pdf** to site\_monitor. Clicking more than once will result in multiple pages arriving to your email inbox.

NOTE: Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address is required for site\_monitor to receive the module specific PDF files.

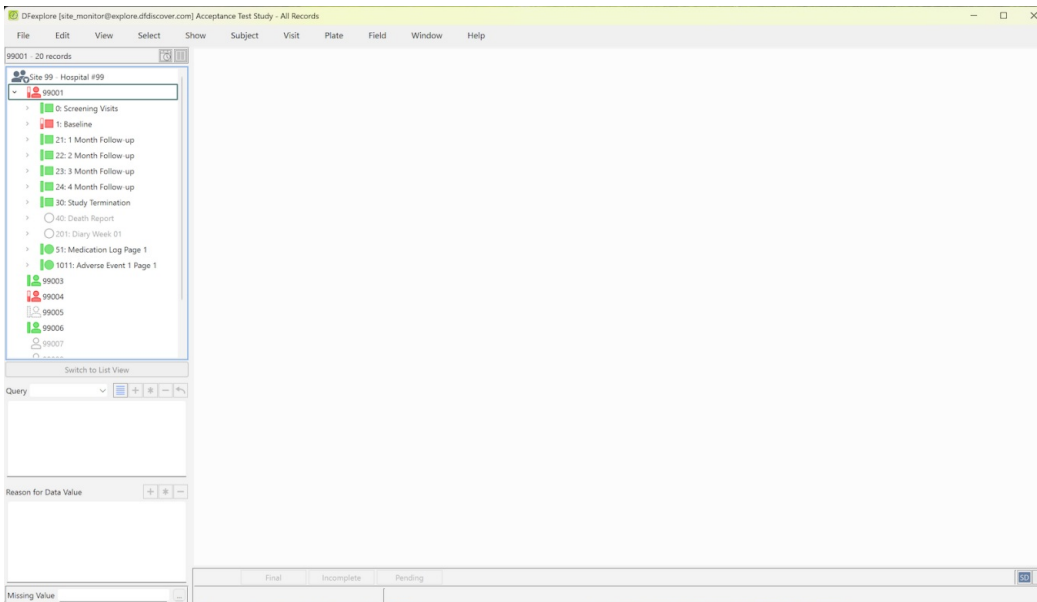
Wait 2-3 minutes prior to proceeding to **DFExplore**.

## Login to **DFExplore** and inspect the list of sites, subjects and visits in the record list window

1. Start **DFExplore**, login as site\_monitor and choose **254 Acceptance Test Study** as described in ["How to start DFExplore"](#)
2. Confirm that only **Site 99 - Hospital #99** is available.



3. Double-click entry for Subject **99001** to select and open the subject binder. A list of available visits is displayed.

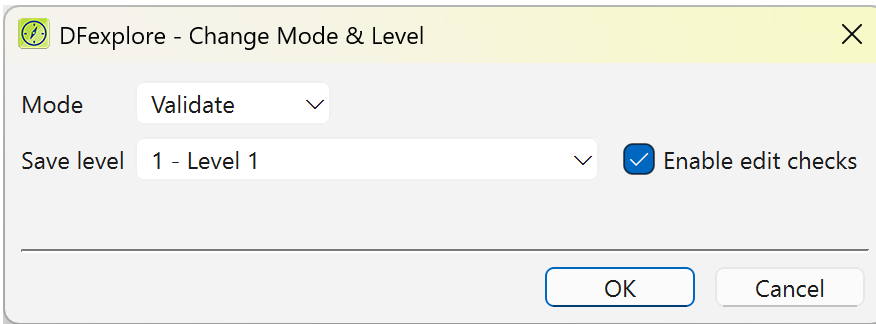


4. Double-click entry for the highlighted **1 : Baseline** visit to display the list of pages belonging to the visit.
5. Close the subject binder for Subject 99001 by double-clicking **Site 99 - Hospital #99** in the record list panel.

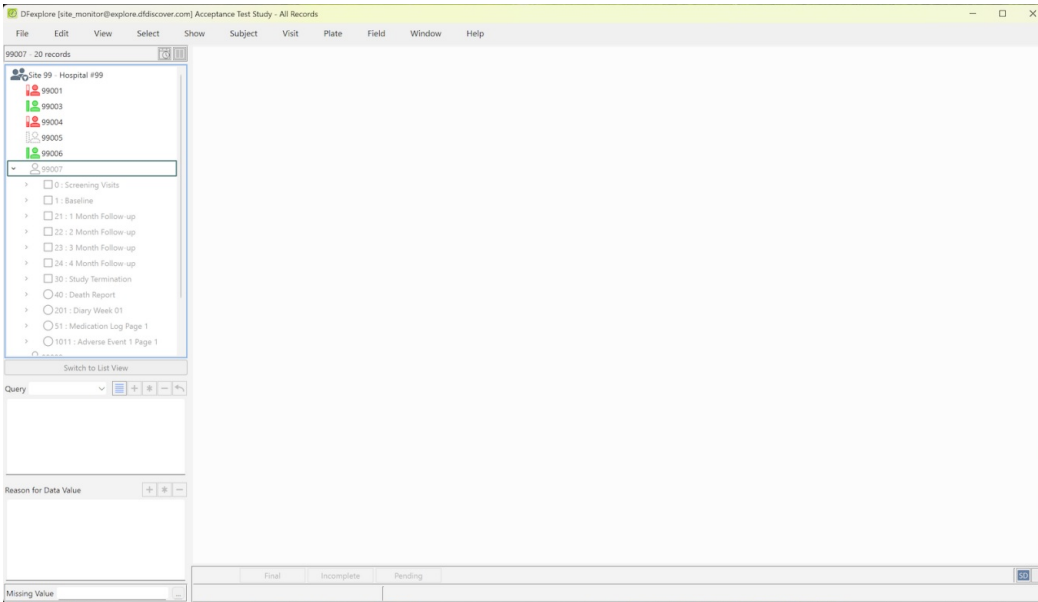
## Enter and save new data using EDC data entry for Subject 99007

1. Using the paper CRFs that were printed or emailed at the beginning of this module ([Step 2](#)). Select **Select** > **Change Mode & Level** to set the working mode and data entry level. In the dialog, set:
  - o **Mode** = Validate
  - o **Save level** = 1 - Level 1
  - o Check **Enable edit checks**

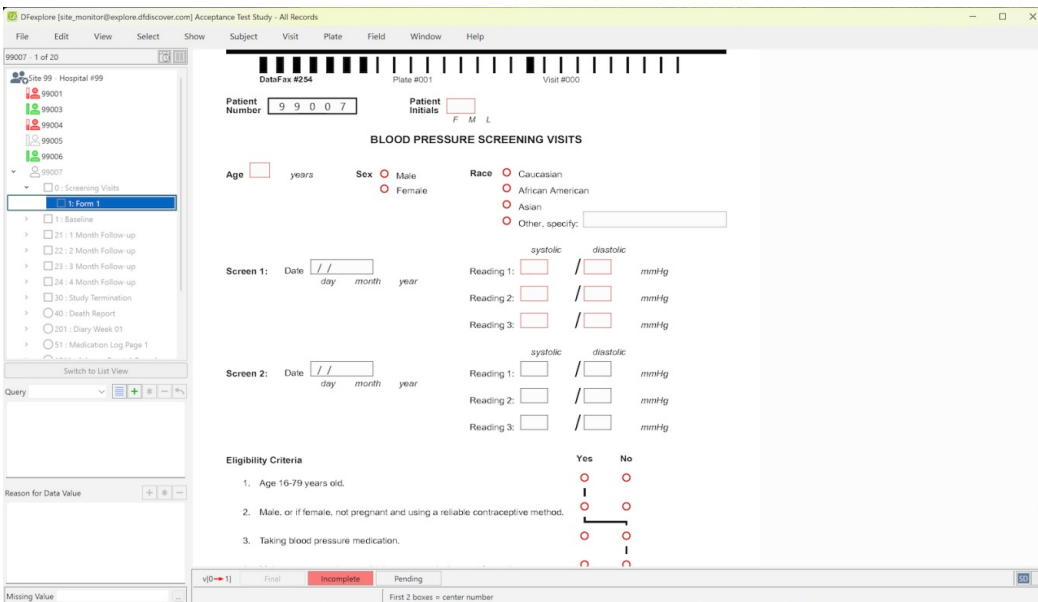
Click **OK**.



2. Double-click **Site 99 - Hospital #99** entry in the record list panel. Double-click Subject **99007**.



3. Double-click the **0 : Screening Visits** entry to display all pages belonging to the visit.



4. **1 : Form 1** becomes the active page. The data window redraws with the plate background and related data entry fields.

5. Click anywhere on the plate background - this moves the mouse and keyboard focus to the **data** window.

6. Beginning at the **Patient Number** field, press **Tab** to advance to the **Patient Initials**. Enter the initials as they appear on the printed CRF. Press **Tab** to advance to the next field.

99007: 1 of 20

Site 99 - Hospital #99

99001  
99003  
99004  
99005  
99006  
99007

0 - Screening Visits

1 - Form 1

1 - Baseline  
21 - 1 Month Follow-up  
22 - 2 Month Follow-up  
23 - 3 Month Follow-up  
24 - 4 Month Follow-up  
30 - Study Termination  
40 - Death Report  
201 - Diary Week 01  
S1 - Medication Log Page 1

Switch to List View

Query

Reason for Data Value

Missing Value

DataFax #254 Plate #001 Visit #000

Patient Number 99007 Patient Initials KFC

**BLOOD PRESSURE SCREENING VISITS**

Age  years Sex  Male  Female Race  Caucasian  African American  Asian  Other, specify:

Screen 1: Date  /  /  day month year Reading 1:  /  mmHg systolic diastolic  
Reading 2:  /  mmHg  
Reading 3:  /  mmHg

Screen 2: Date  /  /  day month year Reading 1:  /  mmHg systolic diastolic  
Reading 2:  /  mmHg  
Reading 3:  /  mmHg

Eligibility Criteria

Criteria	Yes	No
1. Age 16-79 years old.	<input type="radio"/>	<input type="radio"/>
2. Male, or if female, not pregnant and using a reliable contraceptive method.	<input checked="" type="radio"/>	<input type="radio"/>
3. Taking blood pressure medication.	<input type="radio"/>	<input type="radio"/>

v0 -> 1 Final Incomplete Pending

Enter a dash for missing initials, e.g. M-T

7. Continuing from the **Age** field, press **[Tab]** to advance through the fields individually. Enter all remaining data as it appears on the printed CRF. Although leading zeros may not always appear on the paper CRF, be sure to enter leading zeros where necessary. After entering the **Eligibility Criteria #6**, press **[Tab]** to make the save buttons active.

99007: 1 of 20

Site 99 - Hospital #99

99001  
99003  
99004  
99005  
99006  
99007

0 - Screening Visits

1 - Form 1

1 - Baseline  
21 - 1 Month Follow-up  
22 - 2 Month Follow-up  
23 - 3 Month Follow-up  
24 - 4 Month Follow-up  
30 - Study Termination  
40 - Death Report  
201 - Diary Week 01  
S1 - Medication Log Page 1

Switch to List View

Query

Reason for Data Value

Missing Value

Screen 1: Date 23/04/16 day month year Reading 1: 107 / 096 mmHg systolic diastolic  
Reading 2: 172 / 098 mmHg  
Reading 3: 172 / 098 mmHg

Screen 2: Date 25/04/16 day month year Reading 1: 180 / 096 mmHg systolic diastolic  
Reading 2: 169 / 096 mmHg  
Reading 3: 170 / 096 mmHg

Eligibility Criteria

Criteria	Yes	No
1. Age 16-79 years old.	<input type="radio"/>	<input type="radio"/>
2. Male, or if female, not pregnant and using a reliable contraceptive method.	<input checked="" type="radio"/>	<input type="radio"/>
3. Taking blood pressure medication.	<input type="radio"/>	<input type="radio"/>
4. Major surgery or other medical emergency in the past 6 months.	<input checked="" type="radio"/>	<input type="radio"/>
5. Patient has signed informed consent and agrees to return for monthly follow-up visits.	<input checked="" type="radio"/>	<input type="radio"/>
6. Systolic blood pressure 160-200 mmHg or Diastolic blood pressure 95-100 mmHg on Reading 3 at both Screen 1 and Screen 2.	<input checked="" type="radio"/>	<input type="radio"/>

Patient is Eligible

Once Completed, Please Fax This Form to (###)###-####.

11 November 2014

v0 -> 1 Final Incomplete Pending

Legal values are: 0,2,1

8. As no data problems exist on the entered page, the page can be saved to the database with a **Final** status. Click **[Final]**.

## Add reasons to explain entered data values

1. To open a new visit for Subject **99007**, double-click the entry labeled **1 : Baseline** in the record list panel.

99007 - 2 of 20

Site 99 - Hospital #99

99001  
99003  
99004  
99005  
99006  
99007

0: Screening Visits

1: Form 1

2: Form 2

3: Form 3

4: Form 4, Pg 1

21: Lab Results

21: 1 Month Follow-up

22: 2 Month Follow-up

23: 3 Month Follow-up

24: 4 Month Follow-up

Switch to List View

Query

Reason for Data Value

Missing Value

99007 - 2 of 20

DataFax #254 Plate #002 Visit #001

Patient Number 9 9 0 0 7 Patient Initials F M L Entry Date / / day month year

**PATIENT ENTRY FORM**

**Randomization**

Provided the patient meets all eligibility criteria, call the randomization hot line (905) 999-8888 for this patient's random medication code number.

Medication Code #:

Give the patient **one** bottle of study medication from the medication kit with this code number.

**Medical Examination**

Date of Birth / / day month year

Weight . kg or . lbs

Height cm or in

Pulse beats/minute

Smoking Status  Never smoked  Ex-smoker  Smokes cigarettes  Smokes pipe/cigars

Exercise\*  None, or <1 time/week  1-2 times/week  3-4 times/week  >4 times/week

\* aerobic exercise for at least 20 minutes

v0 -> 1 Final Incomplete Pending

First 2 boxes = center number

- Click anywhere on the plate background - this moves the mouse and keyboard focus to the data window.
- With **Patient Number** as the active field, attempt to edit the pre-filled value, note that this is not possible. Press **Tab** to advance to **Patient Initials**. The SetNit edit check executes upon entry to the field. If the initials are available on the 1 : **Form 1** (previously entered), they are brought forward and populate the **Patient Initials** field.

99007 - 2 of 20

Site 99 - Hospital #99

99001  
99003  
99004  
99005  
99006  
99007

0: Screening Visits

1: Form 1

2: Form 2

3: Form 3

4: Form 4, Pg 1

21: Lab Results

21: 1 Month Follow-up

22: 2 Month Follow-up

23: 3 Month Follow-up

24: 4 Month Follow-up

Switch to List View

Query

Reason for Data Value

Missing Value

99007 - 2 of 20

DataFax #254 Plate #002 Visit #001

Patient Number 9 9 0 0 7 Patient Initials KFC F M L Entry Date / / day month year

**PATIENT ENTRY FORM**

**Randomization**

Provided the patient meets all eligibility criteria, call the randomization hot line (905) 999-8888 for this patient's random medication code number.

Medication Code #:

Give the patient **one** bottle of study medication from the medication kit with this code number.

**Medical Examination**

Date of Birth / / day month year

Weight . kg or . lbs

Height cm or in

Pulse beats/minute

Smoking Status  Never smoked  Ex-smoker  Smokes cigarettes  Smokes pipe/cigars

Exercise\*  None, or <1 time/week  1-2 times/week  3-4 times/week  >4 times/week

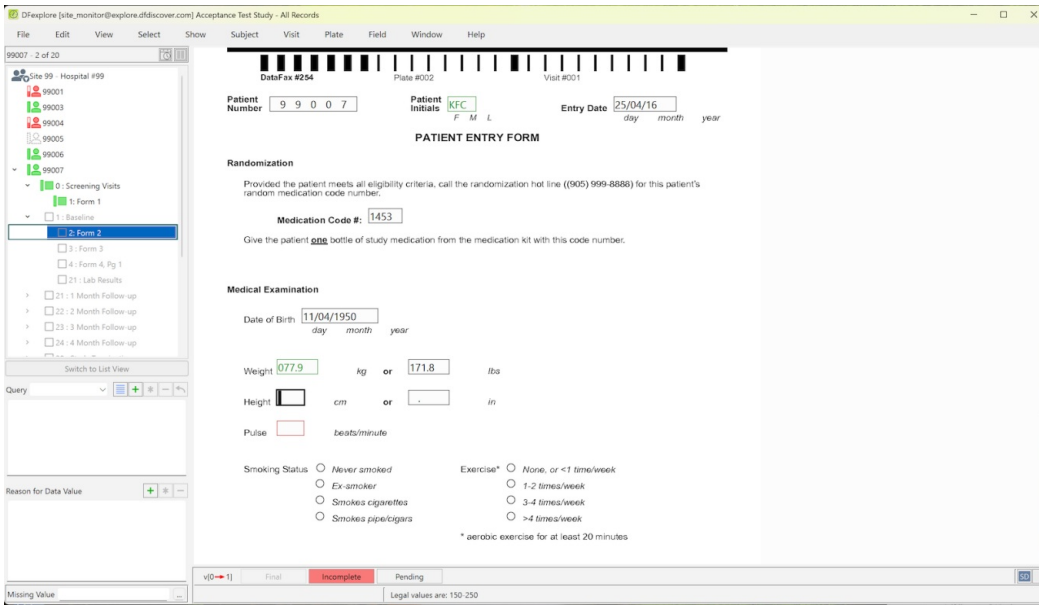
\* aerobic exercise for at least 20 minutes

v0 -> 1 Final Incomplete Pending

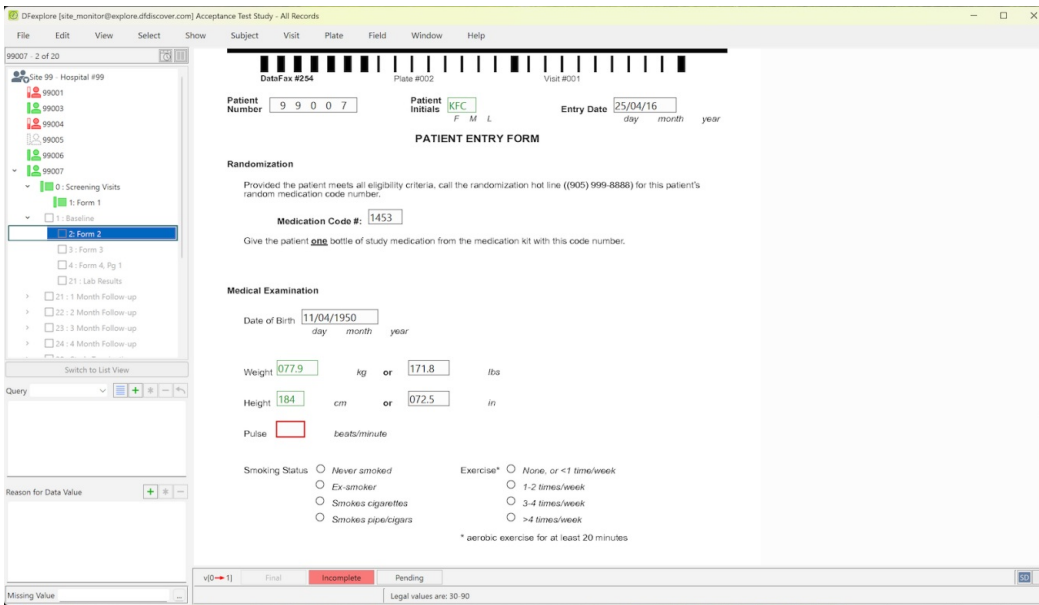
Enter a dash for missing initials, e.g. M-T

- Press **Tab** to advance through each field and enter the data as it appears on the printed CRF, up to and including **Weight (lbs)**. Press **Tab** to exit the **Weight (lbs)** field and execute the WeightEquiv edit check. The WeightEquiv edit check calculates and enters the equivalent value in the blank **Weight (kg)** field.

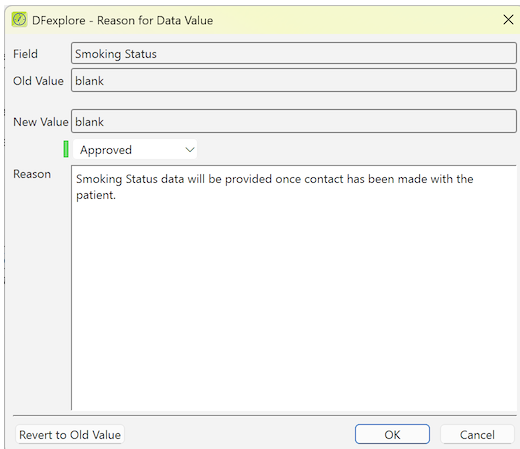
NOTE: Ensure the **Date of Birth** is entered using the dd/mm/yyyy format.



- The HeightEquiv edit check is similar to the WeightEquiv edit check. If only one of the two height values are entered, the edit check calculates and enters the equivalent value for the blank field. Press **Tab** to exit the **Height (in)** field and enter the value as it appears on the printed CRF (including leading zeros). Press **Tab** to exit the field.



- Enter the value of the **Pulse** field as it appears on the printed CRF. Press **Tab** to advance to the **Smoking Status** field.
- Select **Field** **Add Reason For Data Value** or click **+** in the **Reason for Data Value** window. In the resulting dialog, choose **Approved** from the pull-down list.
- Enter the text Smoking Status data will be provided once contact has been made with the patient. for the **Reason** property. Click **OK**, press **Tab** to advance to the **Exercise** field.



- Select **Field** **Add Reason For Data Value** or click **+** in the **Reason for Data Value** window. Choose **Pending** from the pull-down list.

- Enter the text Exercise data will be provided once contact has been made with patient. for the **Reason** property. Click **OK**, press **Tab** to advance to the **Date of First Study Follow-up Visit** field.

- Enter the **Date of First Study Follow-up Visit** and press **Tab** to advance to the save field. Verify that **Final** is highlighted. Do not save the page with this status as the **Smoking Status** and **Exercise** fields have yet to be completed. Click **Pending**.

## Enter and save Plate 3, Subject 99007 as a pending record

- Subject **99007 3 : Form 3** becomes the current record. Click anywhere on the page background to make the fields active for entry.

	No		Yes		Duration Years & Months	Currently on Treatment		Resolved and/or Controlled	
						No	Yes	No	Yes
Hypertension	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Atrial Fibrillation	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Cardiac EG Arrhythmia	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Valvular Heart Disease	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Myocardial Infarction	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kidney Disease	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stroke	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Transient Ischemic Attacks	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Peripheral Vascular Disease	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Other (specify)	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Starting at the **Patient Number** field, press **Tab** to advance to the **Patient Initials** field. The SetInit edit check executes upon entry to the field.

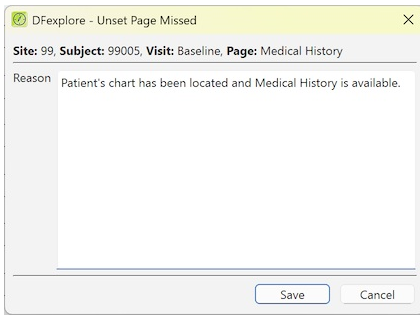
- Continuing at **Patient Initials**, press **[Tab]** to advance through each field and enter the data as it appears on the printed CRF. The medical conditions that appear pre-printed on the CRF page have been defined as constant values in the study setup. As a result, these fields cannot be edited. Press **[Tab]** to advance to the save buttons. As data for **Major Surgery** is not yet complete, click **[Pending]** to save the page with status **Pending**.

## Mark and save unavailable data as missed. Unmark available data as missed

- Baseline 4 : **Form 4, Pg 1** is now the active page. As no data is available for this page, Select **[Plate]** > **[Set Page Missed]**.

- In the dialog, choose **Data not available** value from the **Reason** pull-down list. Enter Medication information is missing from patient's chart. as the **Detail**.
- Click **[OK]** to register the page as missed.
- Double-click Subject **99005** in the record list. From the now open list of visits for that subject, double-click the **1 : Baseline** visit.
- All pages for that visit are displayed.

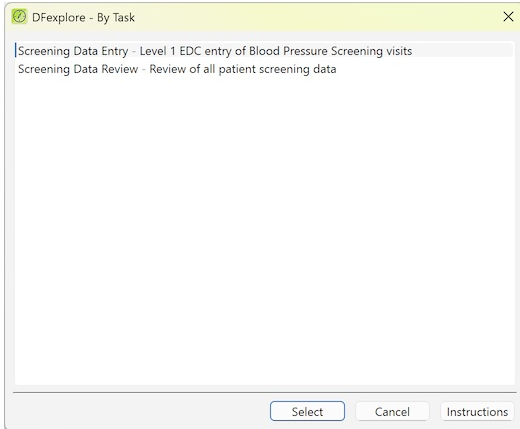
- Choose **3 : Form 3**. Select **[Plate]** > **[Unset Page Missed]**.
- Enter the text Patient's chart has been located and Medical History is available. in the **Reason** field. Click **[Save]** to unset **3 : Form 3** as missed.



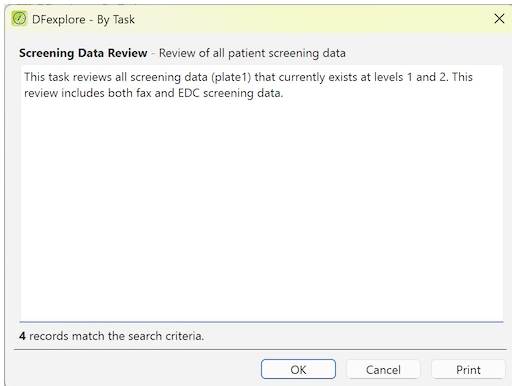
8. Double-click **Site 99 - Hospital #99** entry in the record list. This closes all open subject binders for **Site 99 - Hospital #99**.

## Retrieve and modify existing data using a predefined task and save modifications to the database

1. Select **Select** > **By Task** to view the list of predefined data entry and data management tasks.



2. Click **Screening Data Review** from the list, then **Select** to load the task and its selection criteria. This task is used to review all screening plate 1s that exist at level 1 or 2 and save them to level 3. Examine the lower left of the dialog to determine the number of records that match the task search criteria. Confirm that the number is 4.



3. Click **OK** to bring forward all records that match the task criteria.

DFExplore [site\_monitor@explora.dfdiscovers.com] Acceptance Test Study - Task: Screening Data Review

99001: 1 of 1 task records

Site 99 - Hospital #99

99001 - Screening Visits

Form 1

99003

99004

99007

Show All Records for This Subject

Switch to List View

Query

Reason for Data Value

Missing Value

DataFax #254 Plate #001 Visit #000

Patient Number 9 9 0 0 1 Patient Initials ABC

BLOOD PRESSURE SCREENING VISITS

Age 60 years Sex  Male  Female Race  Caucasian  African American  Asian  Other, specify:

Screen 1: Date 03/03/97 Reading 1: 170 / 096 mmHg Reading 2: 170 / 098 mmHg

DataFax #254 Plate #001 Visit #000

Patient Number 9 9 0 0 1 Patient Initials ABC

BLOOD PRESSURE SCREENING VISITS

Age 60 years Sex  Male  Female Race  Caucasian  African American  Asian  Other, specify:

Screen 1: Date 03/03/97 Reading 1: 170 / 096 mmHg Reading 2: 170 / 098 mmHg

v(1-3) Final Incomplete Pending

Last Save: 2009-04-15 15:08:36 UTC-04:00 Task: 0/4 1/3 First 2 boxes = center number

4. Beginning with the first task record for Subject 99001, press **[Tab]** to advance through all fields on the page, comparing their values to those on the CRF image in the image window. When **Eligibility Criteria #5** is the current field, Select **Field** > **Add Query** or click **+** in the **Query** window.

DFExplore - Add Query

Site: 99, Subject: 99001, Visit: Screening Visits, Page: Form 1

Field 5. Patient has signed informed consent

Reported Value Yes

Category Monitor Use External

Status  New query Type Clarification

Detail We have not received this patient's informed consent form. Please send it by fax or email without delay.

Note

Created

Modified

Resolved

OK Cancel

5. In the **Add Query** dialog, set:
- **Category** = Monitor
  - **Use** = External
  - **Status** = New query
  - **Type** = Clarification
  - **Detail** enter We have not received this patient's informed consent form. Please send it by fax or email without delay.

6. Click **OK** to apply the query.
7. Press **Tab** to advance through the remaining fields on the page. Once all fields have been traversed, press **Tab** to make the save buttons active.
8. Click **Incomplete** to save the current task record to the database at level 3.
9. Batch validate the remaining records in the task list to raise their level to level 3. Select **Select** > **Batch Validate**. In the dialog, set:
  - o **Move record level to = 3 - Level 3**
  - o Choose **All currently selected task records**

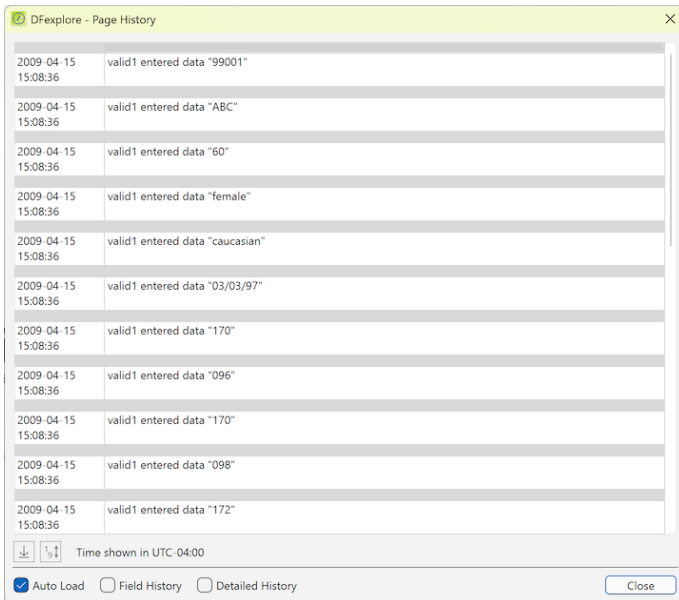
Click **Batch Validate**.

10. Enter **Username** of site\_monitor and the corresponding password in the verification dialog. Click **OK** to batch validate the task records to level 3 and dismiss the dialog.

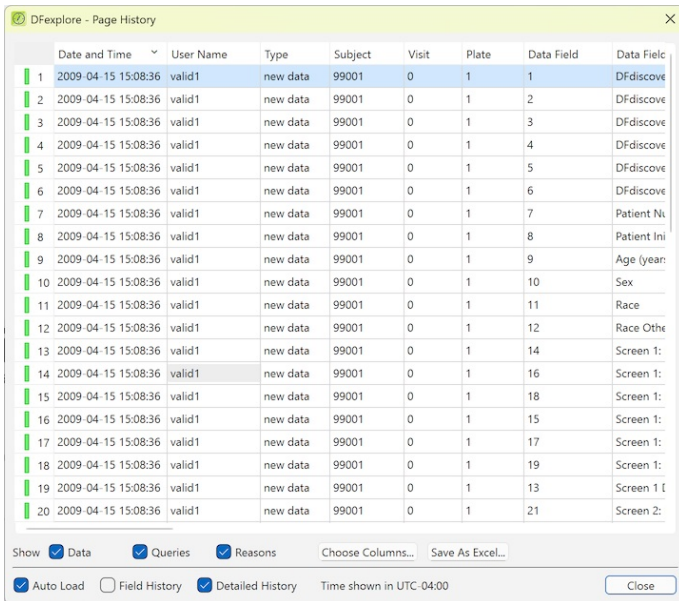
11. Review the details in the summary dialog. Click **OK** to close the summary dialog and complete the batch validation operation.

## Confirm audit trail information for entered and modified data

1. Return to Subject **99001 > 0 : Screening Visits > 1 : Form 1**.
2. Select **Plate** > **List History of All Changes on This Page** to display the **Plate** > record's history. The default page history dialog is displayed.



3. Check (Enable) **Auto Load** and **Detailed History** to enable advanced plate history.



4. Save the **DFExplore - Page History** as module7-edc-history.xlsx by clicking **Save As Excel...**, check (enable) **Open output file after export..** click **Save**. Open (if not already opened) the saved .xlsx file and verify that its contents match the **DFExplore - Page History** output before closing the history dialog by clicking **Close**.

5. Select **File > Exit** menu to close and exit **DFExplore**.

## End Module 7. EDC Data Entry

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 7. EDC Data Entry.

## Module 8. Image Data Entry

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
  - data\_coordinator : data\_coordinator
- Email address configured for site\_monitor
- (Optional) - SMS or email 2-factor authentication setup with data\_coordinator

NOTE: For configuration of 2-factor authentication, see [Module 1\(Installation & Initialization\) test step 6](#) for details on configuring accounts with 2-factor authentication

**Purpose:** This module tests automated data entry and image processing in **DFexplore** using data sent through **DFsend**. Multiple records are created and modified, image-only features testing, batch validation of records, queries, and reasons are also tested during this module.

## Tests & Requirements

1. Submit PDF images to **DFexplore**.
2. Login to **DFexplore** and confirm the receipt of new pages in the Status View.
3. Login to the Image Router and route a misidentified page to the Acceptance Test Study new record queue.
4. Login to **DFexplore** and confirm receipt of the routed page in the Status View.
5. Retrieve new images in **DFexplore** Image View.
6. Enter Plate 1 (Form 1) for Subject 99002.
7. Enter Plate 2 (Form 2) for Subject 99002.
8. Enter Plate 3 (Form 3) for Subject 99002.
9. Enter Plate 4 (Form 4) for Subject 99002.
10. Compare the resolutions between Standard Definition (SD) and High Definition (HD).
11. Edit an existing query.
12. Delete an existing query.
13. Change data and record a reason for data change.
14. Batch validate all opened pages for Subject 99002 to level 2.
15. Confirm the status of entered pages in Status View.

Estimate of Time Required: 30 Minutes

## Begin Module 8. Image Data Entry

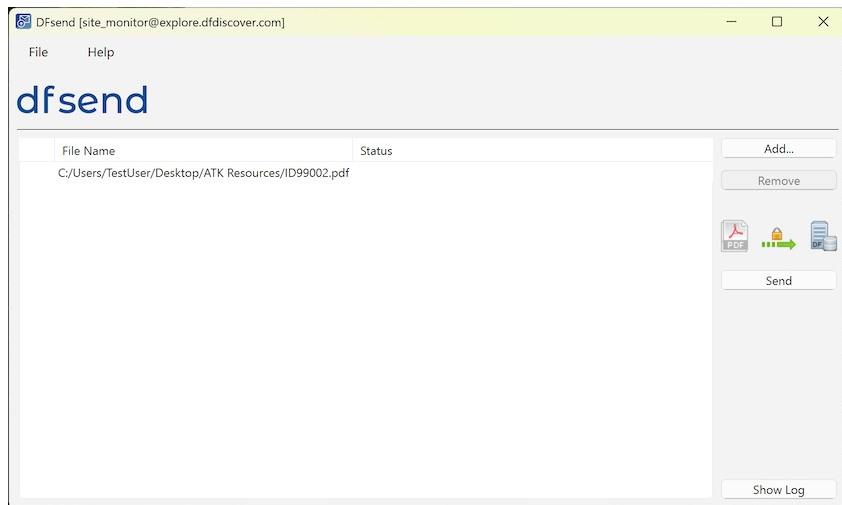
1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **[8. Image Data Entry]** followed by **[Begin]** to begin this module.

## Send PDF images to DFexplore

1. Click **[Send ID 99002]** to email a copy of **ID99002.pdf** to site\_monitor. Clicking more than once will result in multiple pages arriving to your email inbox.

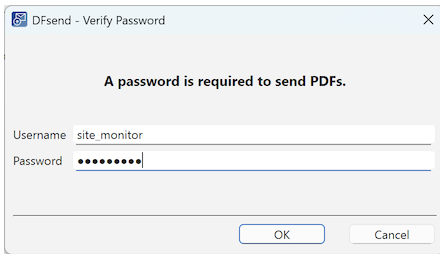
NOTE: Save the **ID99002.pdf** file received via email to your local computer. This file is required to complete the remainder of this module. Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address is required for site\_monitor to receive the module specific PDF files.

2. Start **DFsend** as described in ["How to start DFsend"](#).
3. Click **[Add]**. From the **Select PDF Files** file selection dialog. Locate the previously saved **ID99002.pdf** file. Select the file. Click **[Open]**.

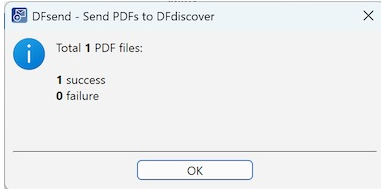


NOTE: Documents can also be added by dragging-and-dropping the desired PDF files from a local file folder directly into the list area.

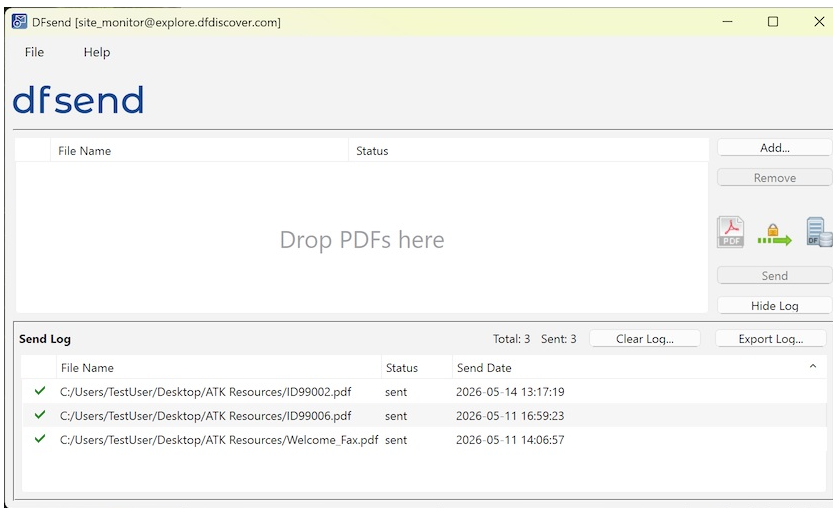
4. Click **[Send]**. In **Verify Password** dialog, enter site\_monitor in the **Username** field and the previously assigned password in the **Password** field. Click **[OK]**.



5. In the resulting **Send PDFs to DFdiscover** dialog, confirm **1 success** and **0 failure** are shown. Click **OK**.



6. Click **Show Log** to review the **DFsend** transmission history.



7. Select **File** > **Exit**.

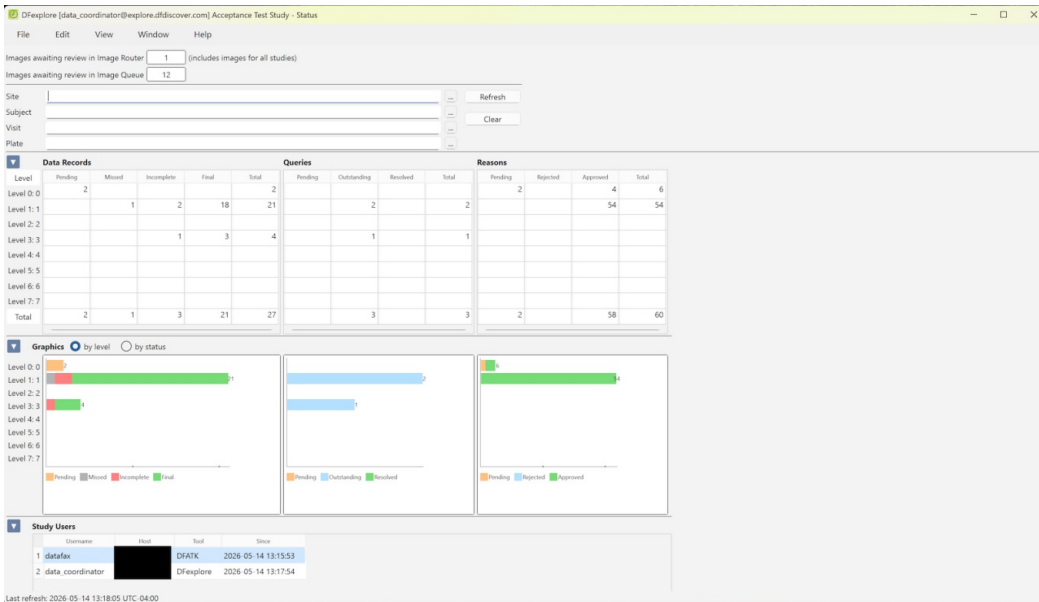
**NOTE:** Wait 2-3 minutes prior to proceeding to **DFexplore**.

### Login to **DFexplore** and confirm the receipt of new pages in the Status View

1. Start **DFexplore** and login as `data_coordinator` and choose **254 Acceptance Test Study** as described in ["How to start DFexplore"](#)

**NOTE:** If `data_coordinator` has been set up for 2-factor authentication with Azure SMS, you may need to wait for a 1-time code to arrive at the phone number as defined in **DFadmin**.

2. Select **View** > **Status**. Examine the count displayed for **Images awaiting review in Image Queue**.

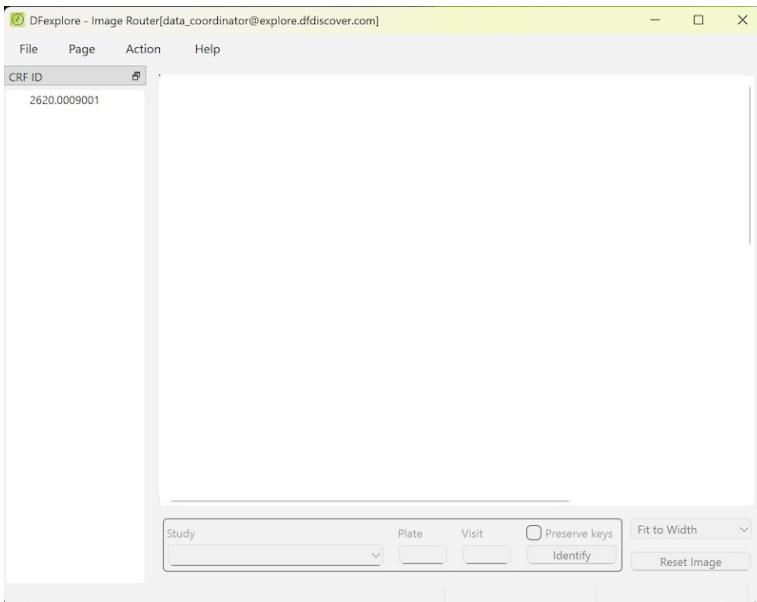


NOTE: Although 13 records were submitted, only 12 will be awaiting validation. The first page in the document has an unreadable barcode. As the barcode could not be identified for the page, it has been routed to the **Image Router** instead of to 254 Acceptance Test Study.

3. Select **File** > **Close Study** to return to the login dialog and list of available studies.

## Login to the Image Router and route a misidentified page to the Acceptance Test Study new record queue

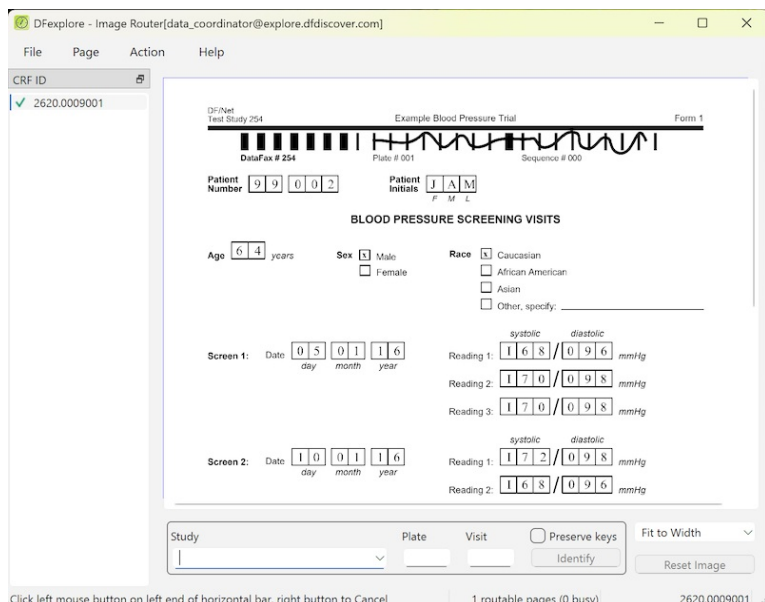
1. In the DFExplore login dialog, click **Image Router** to open the **Image Router**.



2. Locate the CRF for Subject Number **99002**, **Plate 1**, **Sequence 0 (Form 1)**, and select the page from the list of images in the **CRF ID** window.

NOTE: Any pages that have been received and which **DFdiscover** could not identify as CRFs for any of the studies registered at your site, will be found in the **Image Router**. If there are more pages than those added by execution of the **DFATK**, you may need to locate the 254 Acceptance Test Study page in the listing of images.

3. Select **Action** > **Rotate/Shift/Identify** to correctly identify the CRF for Subject **99002**, Plate 1, Sequence 0.



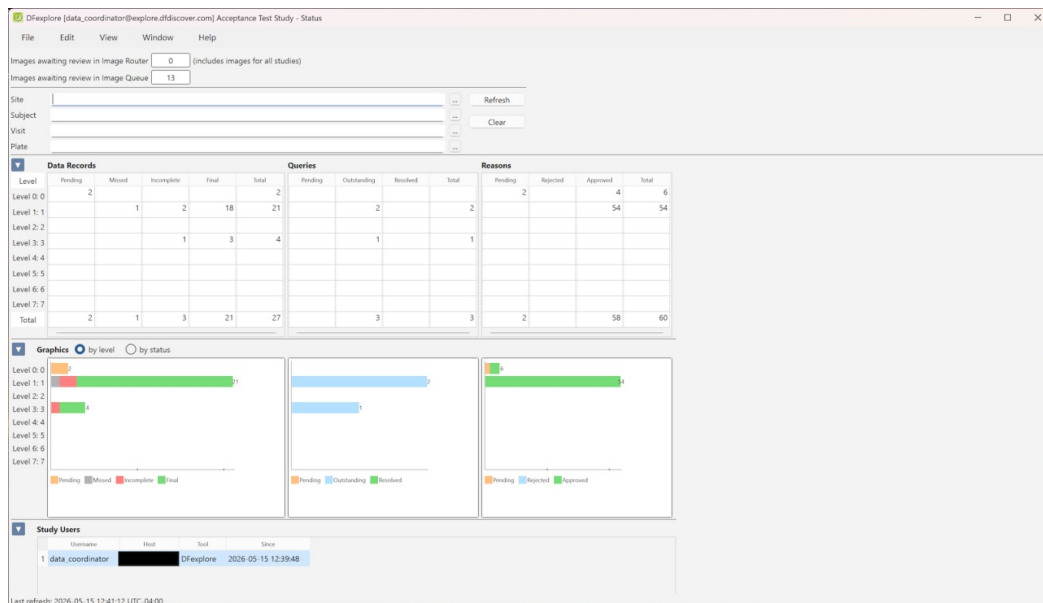
- Click leftmost end of the horizontal barcode line. Drag the cross-hairs across the solid barcode line then click rightmost end of the line.
- Select **254 - Acceptance Test Study** from the Study drop-down list. Enter **Plate** and **Visit** numbers, as illustrated. Click **Identify** to identify the record.



- Select **File** > **Close Image Router** to exit the **Image Router** and return to the **DFExplore** login dialog.

## Login to **DFExplore** and confirm receipt of the routed page in the Status View

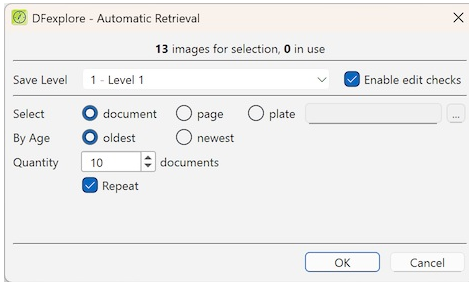
- Choose **254 Acceptance Test Study** and click **Continue**. If the list of studies closes before a selection is made you will need to log back into **DFExplore** by re-entering the **Username** and **Password** for user **data\_coordinator**.
- Select **View** > **Status** to examine the count displayed for **Images awaiting review in the Image Queue**. This count has increased by 1 as a result of a misidentified page being routed.



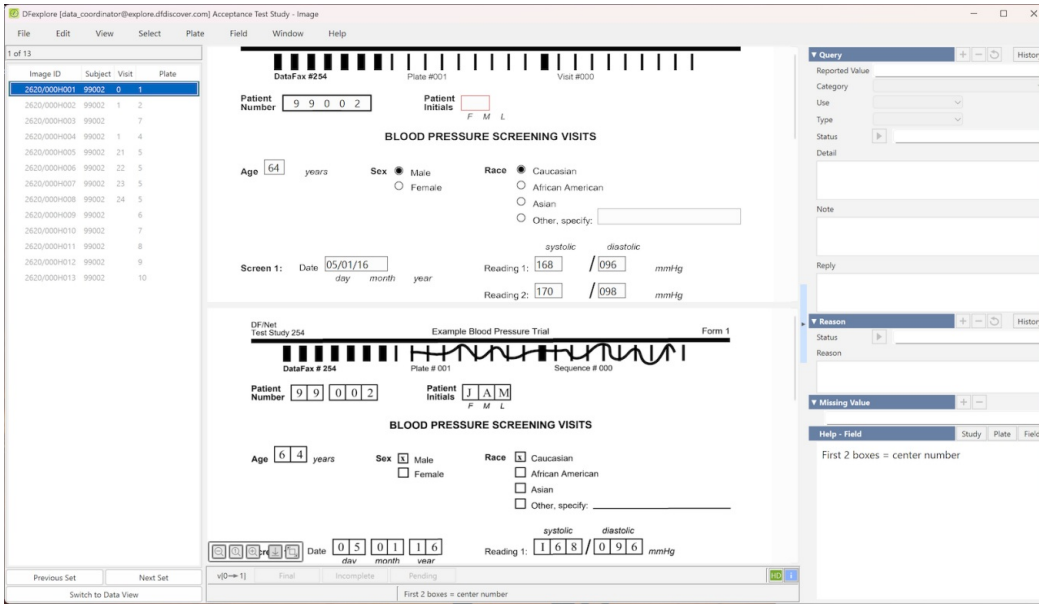
## Retrieve new images in **DFExplore** Image View

- Select **View** > **Image**. In the **Automatic Retrieval** dialog,
  - Set **Save level** = 1 - Level 1
  - Check (enable) **Enable Edit Checks**
  - Select** = document
  - By Age** = oldest
  - Quantity** \_\_ documents = 10

- o Check (enable) **Repeat**



2. Click **OK** in the **Automatic Retrieval** dialog to bring forward all new images awaiting data entry.



## Enter Plate 1 (Form 1) for Subject 99002

1. With the first page of **BLOOD PRESSURE SCREENING VISITS** for Subject **99002** displayed, make the page active for data entry by clicking anywhere on the page background using the mouse.

**NOTE:** In your normal image entry process, you must always pay careful attention to the accuracy of the ICR data. You will need to do the same here. It is possible that the new pages contain ICR errors that you will need to correct during entry. In particular, it is important that you correct any key fields (visit and/or subject numbers) that may have been misread as these are critical to the identification and storage of the data. Note that the ICR data records on your screen may not match exactly those shown in the examples throughout this module.

2. Correctly enter **Patient Number** and **Patient Initials** as per the CRF image. Press **Tab** to advance to the **Age** field.
3. The MissingQC edit check is programmed to pop up a Query note if any of the following fields are left blank: **Age**, **Sex**, **Screen 1 Date** and all **Screen 1 blood pressure** readings. Test this edit check on the **Age** field by making this field blank. Press **Tab** to exit the **Age** field. When the **Add Query** window pops up, click **Cancel** to ignore and return to complete the field as per the CRF image, before proceeding to the next field.

4. Enter the **Sex** and **Race** fields as they appear on the CRF image. Press **[Tab]** to advance to the **Screen 1 date** field and enter its value 05/01/16 followed by all blood pressure readings for Screen 1 date.
5. The ScreenDates edit check is executed on exit from the **Screen 2 Date** field. It checks that the **Screen 2** Date follows the **Screen 1** Date by at least one day. Enter a **Screen 2** Date of 04/01/16, which precedes the **Screen 1** Date of 05/01/16, then press **[Tab]** to exit the field. After verifying the message in the confirmation dialog, click **[OK]**.

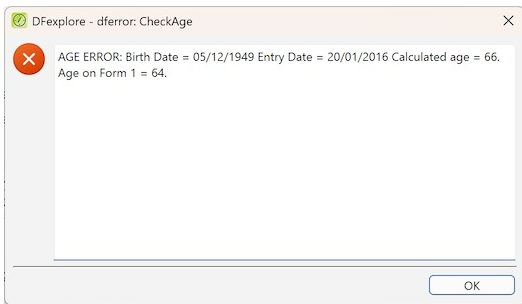
6. Return to the **Screen 2 date** field and enter the date and all **Screen 2 blood pressure** values as they appears on the CRF image.
7. **Step 1** to **Step 6** test the entry of specific data fields. Any field that has not been correctly entered (by you or the **DFdiscover** ICR) is now completed by entering the values as they appear on the CRF image. After entering the last data field **Eligibility Criteria #6**, press **[Tab]** to exit the field to make the Save buttons at the bottom of the data entry window active.
8. As no data problems exist on the entered page, the page can be saved to the database with a status of **Final**. Do this by clicking **[Final]** with the mouse or by pressing the space bar.

Enter Plate 2 (Form 2) for Subject 99002

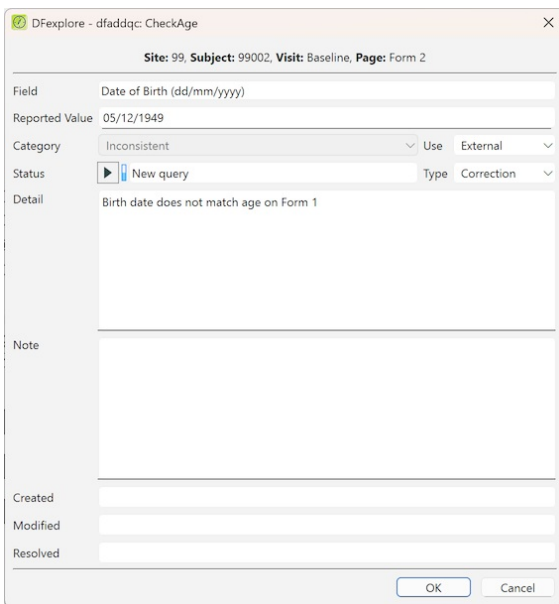
1. Correctly enter **Patient Number** per the CRF image. Press **Tab** to advance to the **Patient Initials** field. The SetNitedit check automatically completes the **Patient Initials** field if the initials are available on the **Screening Form (Plate 1)**.

**NOTE:** The **Patient Number** must be entered correctly on the data record for the SetNitedit check to execute. When an edit check changes a field's value, the changed field will automatically be assigned a default reason and the field's color will change to green to show that an approved reason exists.

2. Correctly enter the **Entry Date**, **Medication Code #** values per the CRF image and **Date of Birth** in dd/mm/yyyy format. The CheckAge edit check calculates the Subject's age from the **Entry Date** and **Date of Birth** fields, and compares this value with the value entered for **Age** on Plate 1. If these values disagree, an error message is displayed. Press **Tab** to exit **Date of Birth** field to execute the CheckAge edit check.



3. Click **OK** in the error message window to bring forward the query dialog. Click **OK** in the query dialog to attach a query to the **Date of Birth** field.



4. Press **Tab** to advance to the **Weight (kg)** field. Do not enter a value as the corresponding field on the CRF image is blank. Continue on to the **Weight (lbs)** field and enter the value that appears on the CRF image. If only one of the 2 weight fields are completed, the WeightEquiv edit check calculates and enters the equivalent value for the blank Weight field. Press **Tab** to exit the **Weight (lbs)** field executing the WeightEquiv edit check.
5. Press **Tab** to advance to the **Height (cm)** field. Do not enter a value as the corresponding field on the CRF image is blank. Continue on to the **Height (in)** field and enter the value that appears on the CRF image. If only one of the 2 height fields is completed, the HeightEquiv edit check calculates and enters the equivalent value for the blank Height field. Press **Tab** to exit the **Height (in)** field executing the HeightEquiv edit check.
6. [Step 1](#) to [Step 5](#) test specific data fields. Any field that has not been entered (by you or the **DFdiscover** ICR) is now completed by entering the values as they appear on the CRF image. After entering the last data field (**Date of First Study Follow-up Visit**), press **Tab** to exit the field to make the save buttons active.
7. As an outstanding query exists on the **Date of Birth** field, the page must be saved to the database with a status of **Incomplete**. Click **Incomplete** with the mouse or by pressing the space bar.

NOTE: If outstanding queries and/or illegal values exist on a data record, DFdiscover will never allow the record to be assigned the status Final.

## Enter Plate 3 (Form 3) for Subject 99002

1. **Plate 3** has been incorrectly identified by DFdiscover as **Plate 7** (the data record and CRF image do not match). Before data entry can begin, the record must first be correctly identified by correcting the barcode. To do this, Select **Plate** > **Change Barcode**.

2. In the **Change Barcode** dialog, set the **Page** to **003**. Do this by clicking [...] to display a listing of all defined study plates, then select the entry **003 - Medical History** from the list. Click **OK** to close the dialog.

3. Set the **Visit** by clicking [...] to display a listing of all defined study visits, select **1 - Baseline** from the list. Click **OK** to close the visit listing dialog. Click **OK**.

4. Confirm the change to the barcode by clicking **OK** in the warning dialog.

**NOTE:** When a barcode is changed, all data fields on the data record (top half of the screen), will be blanked of their previous ICR values as these are no longer correct. The correct values must be entered manually.

5. Correctly enter **Patient Number** as per the CRF image. Press **Tab** to advance to the **Patient Initials** executing the SetInitedit check as in ["Enter Plate 2 \(Form 2\) for Subject 99002."](#)
6. Press **Tab** to advance to the **1. Hypertension** No/Yes field and check the response indicated on the CRF image. Press **Tab** to advance to the **Duration, Years** field and leave it blank as per the CRF image. Press **Tab** to advance to the **Duration, Months** field and enter the number of months 06 as they appear on the CRF image. The MedHxDuredit check completes the **Duration** fields by entering zeros into the **Years** field if only **Months** are given, and zeros into the **Months** field if only **Years** are given. Press **Tab** to exit the **Duration, Months** field to execute the MedHxDuredit check.

7. Enter the remaining values for **1. Hypertension** and enter all fields for **2. Atrial Fibrillation**. Press **Tab** to advance to the first No/Yes field for **3. Other Cardiac EG Arrhythmia**.
8. A skip has been set on the No/Yes fields for each medical history item such that if "No" is selected, the remaining fields for that medical history item are skipped and the user is taken to the next item. Enter the correct values for medical history items 3. to 6. to execute the skip.
9. Enter all values for **7. Diabetes** up to and including the **Currently on Treatment** field. Press **Tab** to advance to the **Resolved and/or Controlled** field which has been left blank on the CRF image. Select **Field** > **Add Query** or click **+**. In the **Add Query** dialog, set:
  - o **Category** = Missing
  - o **Status** = New query
  - o **Use** = External
  - o **Type** = Correction

Click **OK**.

NOTE: DFExplore attempts to infer the **Category**, **Status**, **Use** and **Type** information when a query is being added. It is important to verify the query settings and correct them if necessary, before applying the query to the data field.

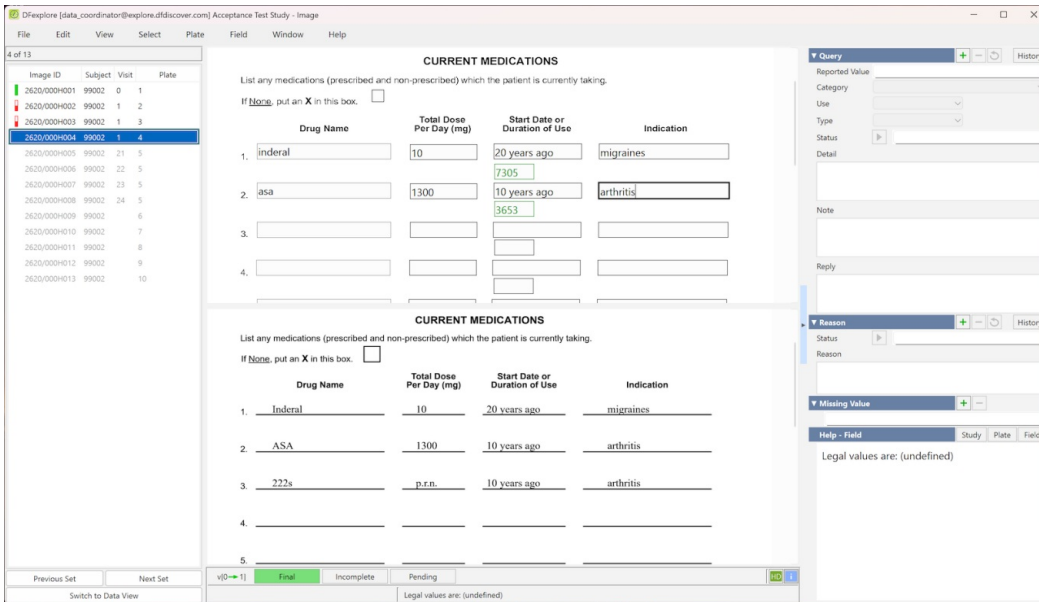
10. For medical history items 8. to 11., enter the appropriate values per the CRF image. Press **[Tab]** to advance to the text field for the first **12. Major surgery (specify)** to make it the current field.
11. Enter the correct values in all fields for the first Major Surgery. Input hip replacement up to and including the **How long ago** response. An edit check, CalcDays, attempts to read the **How long ago** text field to calculate the number of days prior to study entry that surgery occurred. The calculated value automatically populates the hidden field to the right of these text fields. Pressing **[Tab]** off the **How long ago** field executes CalcDaysedit check.

12. Press **[Tab]** to advance to the 2nd Major Surgery item. Input endarterectomy and perform the same steps as in [Step 11](#). Enter the date 06/07/1995 for July 6/95 in the **How long ago** field.

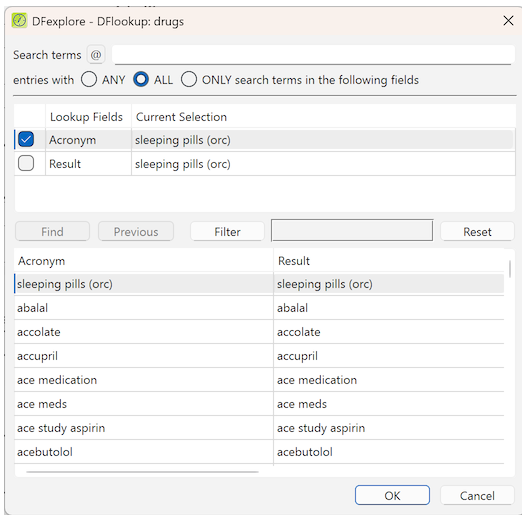
13. [Step 5](#) to [Step 12](#) test specific data fields. Any field that has not been entered (by you or the DFdiscover ICR) is now completed by entering the values as they appear on the CRF image. After entering the last data field, press **Tab** off of the field to make the save buttons at the bottom of the data entry window active.
14. Click **Incomplete** with the mouse or by pressing the space bar. As an outstanding query exists on the **7. Diabetes, Resolved and/or Controlled** field, the page must be saved to the database with a status of **Incomplete**.

## Enter Plate 4 (Form 4) for Subject 99002

1. Correctly enter **Patient Number**, **Patient Initials** and both **Medications Page Number** fields per the CRF image. As for the previous pages, the SetInitedit check automatically completes the **Patient Initials** field. Press **Tab** to advance to the **1. Drug Name** field.
2. In **1. Drug Name** type the text **Inderal** as it appears on the CRF image. The **Drug Name** fields have been mapped to lower case in their setup definitions. Therefore, all entered text will appear as lower case regardless of the case typed.
3. Enter all data for the first 2 drugs (Inderal and ASA) as it appears on the CRF image. The CalcDaysedit check that is present on **Plate 3 (Medical History)** is also present on the **Start Date or Duration of Use** fields. During data entry, confirm that the hidden fields contain the calculated values as shown below.

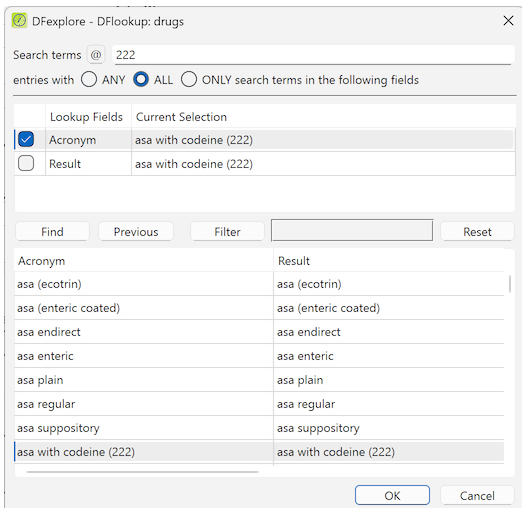


4. Press **Tab** to advance to the **3. Drug Name** field. An edit check, DrugLookup, has been programmed to match the entered drug text with an entry in a lookup table. Enter the 3rd drug name 222s and press **Tab** to exit the field executing DrugLookup edit check. (If an entry can not be found in the lookup table, a search dialog is displayed.)

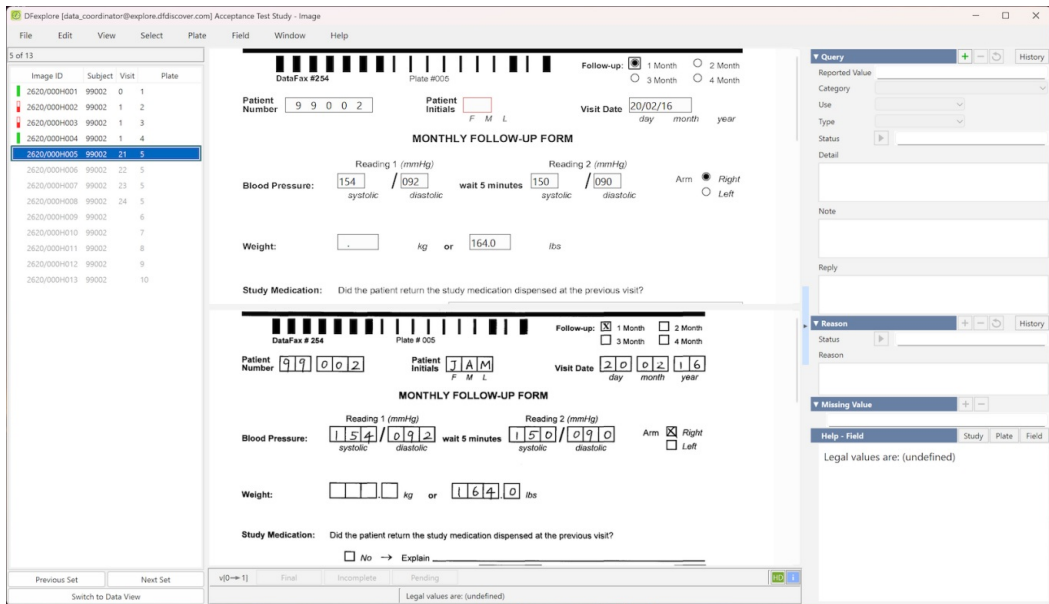


5. In the search dialog,
  - Check (enable) **Acronym**
  - Uncheck (disable) **Result**
  - Input (enter) 222 in the **Search terms**

Click **Find**. Once the match **asa with codeine (222)** is found, click **OK**.

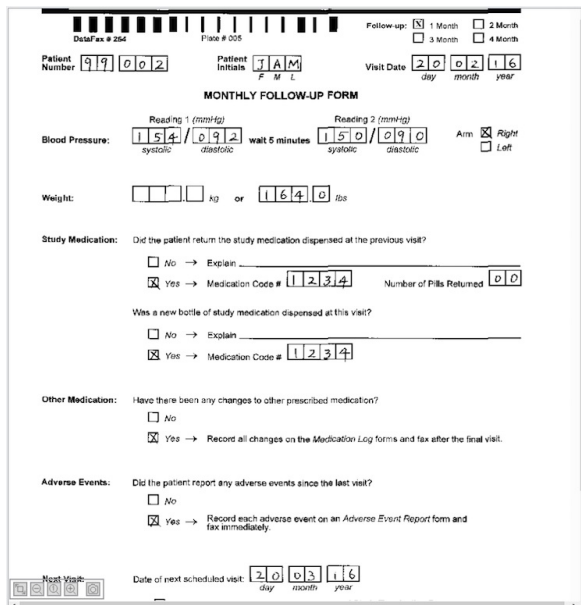


- Enter the remaining values for the 3rd drug field and press **Tab** to advance to **4. Drug Name** field. A skip has been set on each of the Drug Name fields such that if the field is blank, the remaining fields for that drug are skipped. Press **Tab** to advance through the remaining **Drug name** fields, and leave them blank as per the CRF image, to execute the skip.
- Step 1 to Step 6** test specific data fields. Any field that has not been entered (by you or the **DFdiscover** ICR) is now completed by entering the values as they appear on the CRF image. After entering the last data field, press **Tab** to exit the field and make the save buttons at the bottom of the data entry window active.
- As no data problems exist on the entered page, the page can be saved to the database with a status of **Final**. Do this by clicking **Final** or by pressing the space bar.



### Compare the resolutions between Standard Definition (SD) and High Definition (HD)

- With **MONTHLY FOLLOW-UP FORM** for subject **99002** as the active page, verify that the **SD** button is shown at the bottom-right corner of the main data entry screen. Examine the quality of the SD image.



**NOTE: DFExplore** remembers this setting from the last use. If module 8. Image Data Entry was previously executed, the button will already show **HD**. In this case, continue with **"Edit an existing query."**

- Five hidden buttons and can be displayed and identified at the bottom-left corner of the main data entry screen. To show these buttons, place the mouse anywhere on the image. To identify each button, hover the mouse over top of it.

- Click until the image reaches its maximum size. Examine the enlarged SD image.



- Click at the bottom-right corner of the data entry screen, switching the label to **HD**. Confirm that the background color of **HD** is green as shown.



5. Examine the HD image. Verify that the HD image is clearly visible and there is a noticeable difference between the HD image and the previous SD image.

**MONTHLY FOLLOW-UP FORM**

Reading 1 (mmHg) systolic: 154 / diastolic: 092 wait 5 minutes Reading 2 (mmHg) systolic: 150 / diastolic: 090 Arm:  Right  Left

Weight:    kg or    lbs

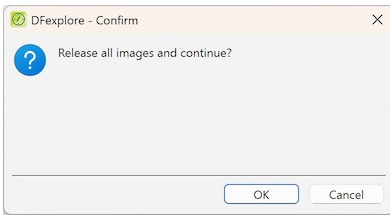
Study Medication: Did the patient return the study medication dispensed at the previous visit?  
 No → Explain \_\_\_\_\_  
 Yes → Medication Code #     Number of Pills Returned

Was a new bottle of study medication dispensed at this visit?  
 No → Explain \_\_\_\_\_  
 Yes → Medication Code #

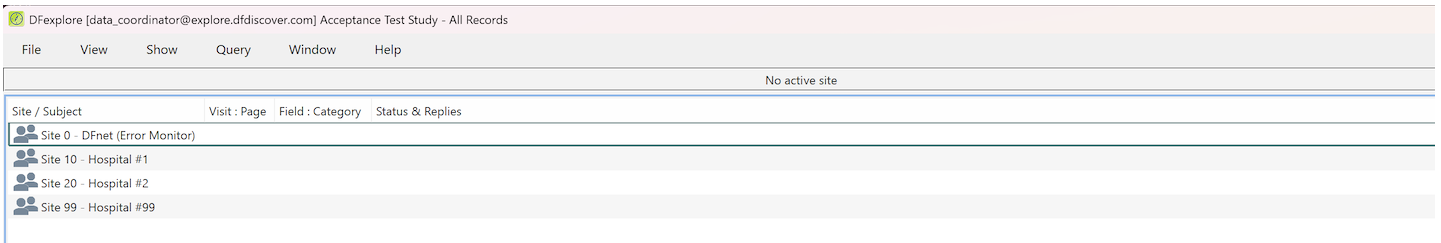
Other Medication: Have there been any changes to other prescribed medication?  
 No  
 Yes → Record all changes on the Medication Log forms and fax after the final visit.

### Edit an existing query

1. Select **View** > **Queries** to change from Image View to Queries View.



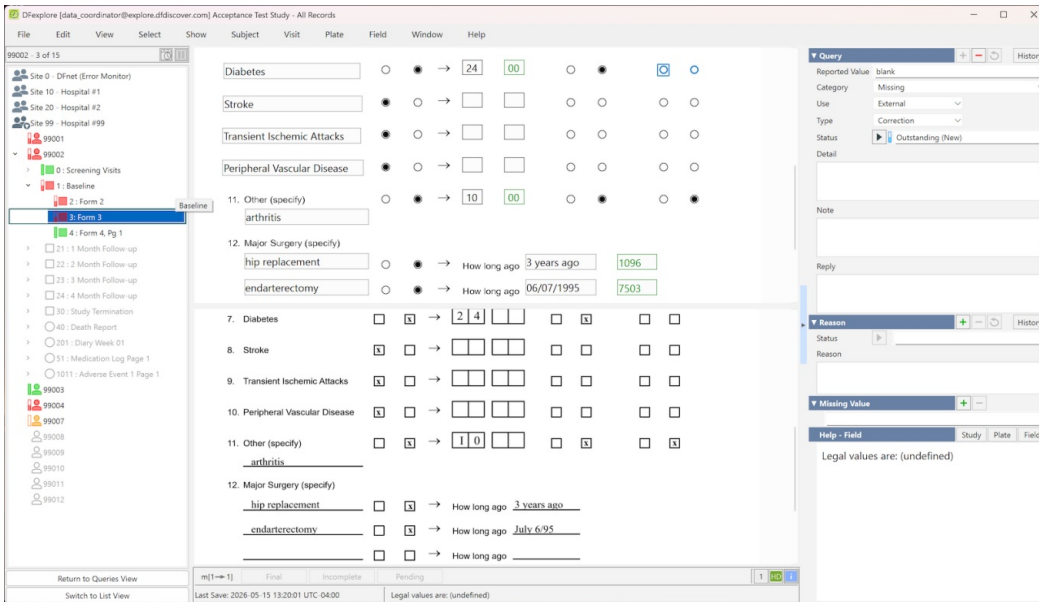
2. Click **OK** in the confirmation dialog to release the Image View records and open Queries View.



3. In the Queries View site list, double-click icon **Site 99 - Hospital #99** to list the queries for that site. Select **Show** > **Outstanding Queries** to display all outstanding/unresolved queries for **Site 99 - Hospital #99**.

Site / Subject	Visit : Page	Field : Category	Status & Replies
Site 0 - DFnet (Error...)			
Site 10 - Hospital #1			
Site 20 - Hospital #2			
Site 99 - Hospital #...			
99001	Screening Visits : Form 1	5. Patient has signed informed consent := Yes (Other) Detail: We have not received this patient's informed consent form. Please send it by fax or email without delay.	Outstanding (New) Modified by: valid1 2016-10-07 13:47:03 UTC-04:00
99001	Baseline : Form 2	Smoking Status := blank (Missing)	Outstanding (New) Modified by: valid1 2009-04-15 15:08:54 UTC-04:00
99002	Baseline : Form 2	Date of Birth (dd/mm/yyyy) := 05/12/1949 (Inconsistent) Detail: Birth date does not match age on Form 1	Outstanding (New) Modified by: data_coordinator 2026-05-15 13:15:37 UTC-04:00
99002	Baseline : Form 3	7. Diabetes: Resolved := blank (Missing)	Outstanding (New) Modified by: data_coordinator 2026-05-15 13:20:01 UTC-04:00
99004	Baseline : Form 2	Pulse beats/minute : (Missing)	Outstanding (New) Modified by: valid1 2009-04-15 15:20:24 UTC-04:00

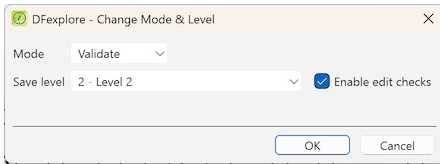
4. Locate the query for Subject **99002, Baseline : Form 3**. This is the query that was added to the field **7. Diabetes, Resolved and/or Controlled** in ["Enter Plate 3 \(Form 3\) for Subject 99002"](#). Double-click the query to be taken directly to the page and queried field.



5. Select **Select** > **Change Mode & Level**. In the dialog, set:

- **Mode** = Validate
- **Save level** = 2 - Level 2
- Check (enable) **Enable edit checks**

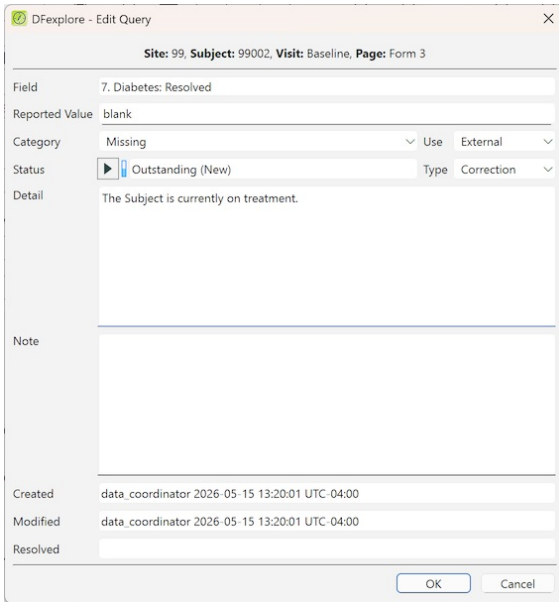
Click **OK** to apply the changes.



6. Select **Field** > **Edit Query** or click **\***. In the dialog, set:

- **Status** = Resolved NA from the pull-down list.
- Enter The Subject is currently on treatment. in the **Detail** field

Click **OK** to apply the edits.



## Delete an existing query

1. The queried field **7. Diabetes, Resolved and/or Controlled** maintains the focus. If not, make it the current field. Select **Field** > **Delete Query** or click **-**.

2. Click **OK** to perform the query deletion.

3. Click **Delete** in the confirmation dialog.

## Change data and record a reason for data change

1. With **3:Form 3, Medical History** as the current page, press **Tab** to advance to **11. Other (specify)**. Change the existing data value of arthritis to arthritis (knees) and Select **Field** > **Add Reason for Data Value** or click **+**.

2. In the **Reason for Data Value** dialog, confirm that the **Old Value** and **New Value** fields display the data values shown. Choose **Pending** from the status list to change the reason's Status to Pending. Enter the text Location of arthritis (knees) was provided verbally by the site. in the **Reason** field. Click **OK** to close the dialog and save the reason for data change to the database. Press **Tab** to advance to the next field.

3. Press **Tab** to advance through the remaining fields on the **Medical History** page until the save buttons at the bottom of the screen become active. Click **Final** to save the modified page to the database at level 2.

## Batch validate all opened pages for Subject 99002 to level 2

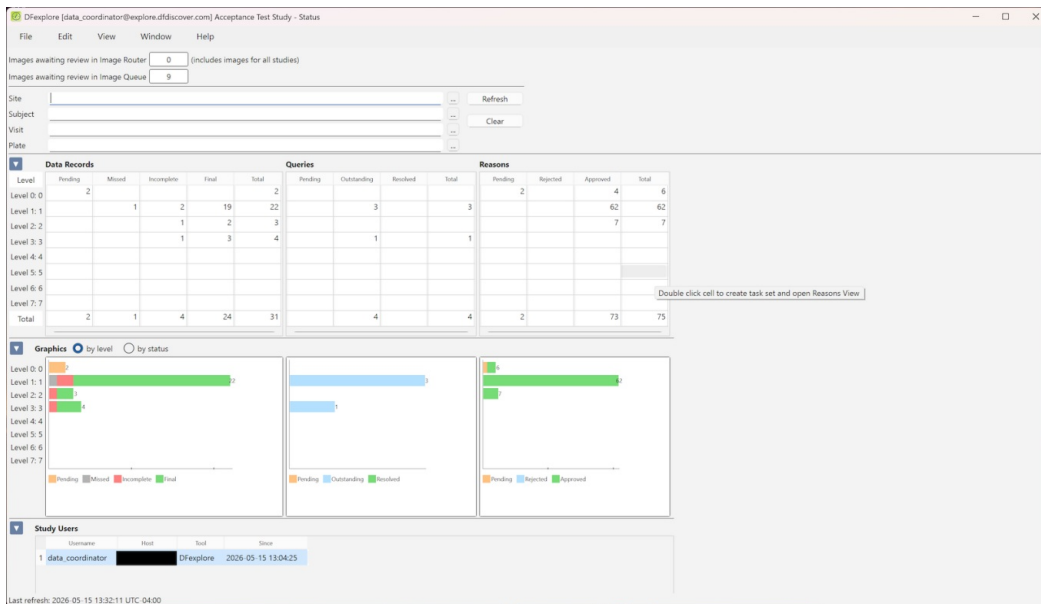
1. Still working at Save Level 2 with the pages previously opened for Subject **99002**, Select **Select** > **Batch Validate**. Confirmed credentials are needed to complete this action.
2. Choose **2-Level 2** from the **Move record level** to pull-down list. Choose **All open pages for current subject**. Click **Batch Validate**. Confirmed credentials are needed to complete this action.

3. Enter `data_coordinator` as the **Username** and the previously assigned password. Click **OK** to batch validate the selected records.

4. Click **OK** to close the summary dialog and complete the batch validation operation.

## Confirm the status of entered pages in Status View

1. Select **View** > **Status** to close Image view and release all pages in the record list and open **Status** view.
2. Confirm that the number of images awaiting review is now 9.



3. Select **File** > **Exit** to close and exit **DFExplore**.

## End Module 8. Image Data Entry

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 8. Image Data Entry.

## Module 9. User-defined Query Category Types

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - data\_coordinator : data\_coordinator
- (Optional) - SMS or email 2-factor authentication setup with data\_coordinator

NOTE: For configuration of 2-factor authentication, see [Module 1 \(Installation & Initialization\) test step 6](#) for details on configuring accounts with 2-factor authentication

**Client Tools Used:** DFATK, DFExplore, DFsetup

**Purpose:** This module tests the enabling and user-defined queries in DFdiscover, as well as confirming the correct functioning and data integrity of custom query categories whose definitions are removed after a query is applied.

### Tests & Requirements

- Retrieve an existing data record in **DFExplore**.
- Apply a user-defined Category query.
- Add a reason for Data Value to explain entered data.
- Edit an existing query.
- Delete a user-defined Query Category that is used by an existing query.
- Delete a user-defined Category query.

Estimate of Time Required: 30 Minutes

## Begin Module 9. User-defined Query Category Types

- Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
- Click **9. User-defined Query Category** followed by **Begin** to begin this module.

### Retrieve an existing data record in **DFExplore**

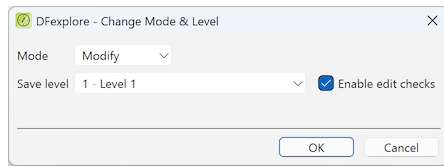
- Start **DFExplore**, login as data\_coordinator and choose **254 Acceptance Test Study** as described in ["How to start DFExplore"](#)

NOTE: If data\_coordinator has been set up for 2-factor authentication with Azure SMS, you will may to wait for a 1-time code to arrive at the phone number as defined in **DFAdmin**.

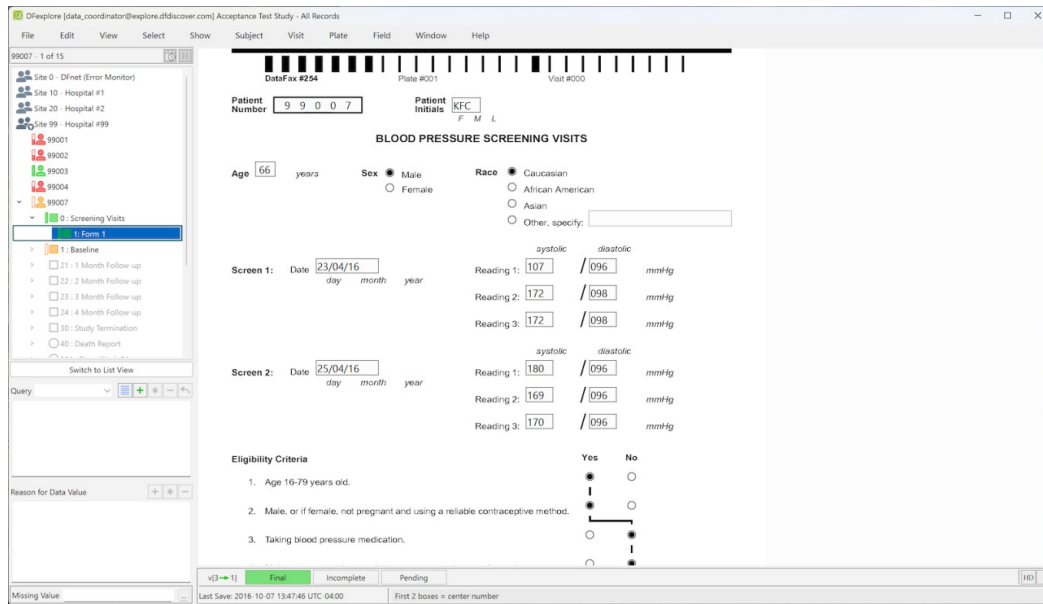
2. Select **Select** > **Change Mode & Level**. Within the dialog, set:

- o **Mode** = Validate
- o **Save level** = 1 - Level 1
- o Check (enable) **Enable edit checks**

Click **OK** to apply these settings.



3. Double-click the folder for **Site 99** and then double-click subject **99007** to open the subject binder. Locate **0: Screening Visits** in the list of visits for subject **99007**, and double-click this entry to open task records for this subject. Press **Tab** to advance through the fields until **Screen 2, Reading 1 systolic blood pressure** becomes the current field.



## Apply a user-defined Category query

1. With **Screen 2, Reading 1 systolic blood pressure** as the current field, select **Field** > **Add Query** or click **[+]** to open the **Add Query** dialog. In the dialog, confirm that **Monitor, Test** and **Clinical QC** are present in the **Category** pull-down list. Set:

- o **Category** = Test
- o **Use** = External
- o **Type** = Clarification
- o **Status** = New query
- o **Detail** = This value is out of our reference range. Please review.

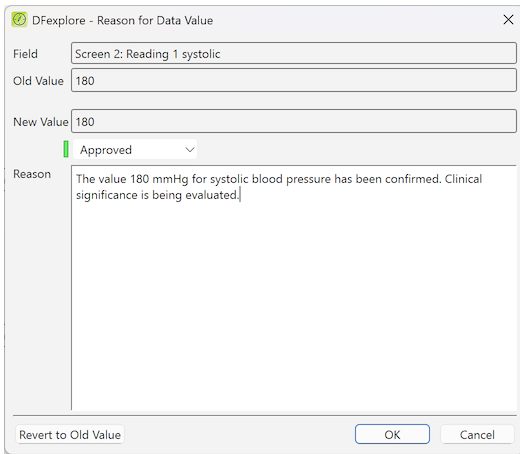
- Click **OK** to apply the query to the **Screen 2, Reading 1 systolic blood pressure** field. Note that the field becomes blue. Examine the details in the **Query** window that appears near the bottom left of the screen.

- Press **Tab** to advance through the remaining fields on the page without making any changes. Press **Tab** to advance to the save buttons at the bottom of the data screen. Click **Incomplete** to save the page.

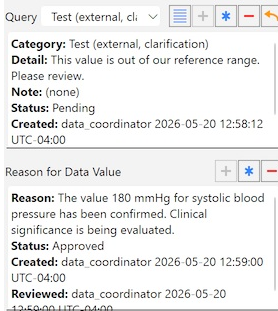
## Add a reason for Data Value to explain entered data

- With **BLOOD PRESSURE SCREENING VISITS** as the active page, press **Tab** to advance through the fields until **Screen 2, Reading 1 systolic blood pressure** becomes the current field. Select **Field** > **Add Reason For Data Value** or click **+** to open Reason for Data Value dialog.

- In the **Reason** field, enter The value 180 mmHg for systolic blood pressure has been confirmed. Clinical significance is being evaluated..



- Click **OK** to apply the reason to the **Screen 2, Reading 1 systolic blood pressure** field. Note that this field is the current field and the field becomes orange. Examine the details in the **Reason** window that appears near the bottom left of the screen.



**NOTE:** If a user-defined Category Code is defined with auto-resolution in **DFsetup**, adding a reason to a field that has a query with such a category will change the query status from outstanding to pending.

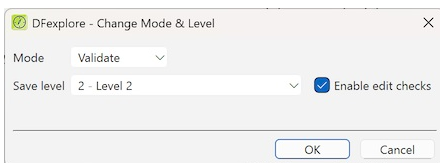
- From the **Screen 2, Reading 1 systolic blood pressure** field, press **Tab** to advance through the remaining fields on the page without making any changes. Press **Tab** to advance to the Save buttons at the bottom of the data screen to make them active. Click **Final** to save the page.

## Edit an existing query

- Select **View** > **Queries**. Select **Show** > **Pending Queries** to display all pending queries for **Site 99 - Hospital #99**.

Site 99 - 1 pending queries modified on 2026-05-20 HH:mm:ss			
Site / Subject	Visit : Page	Field : Category	Status & Replies
Site 0 - DFnet (Error...			
Site 10 - Hospital #1			
Site 20 - Hospital #2			
Site 99 - Hospital #...			
99007	Screening Visits : Form 1	Screen 2: Reading 1 systolic := 180 (Test) Detail: This value is out of our reference range.	Pending Modified by: data_coordinator 2026-05-20 12:58:12 UTC-04:00

- Double-click entry for subject **99007, Screening Visits: Form 1** to be taken directly to the page and the pending field.
- In Data View, Select **Select** > **Change Mode & Level**. In the dialog, set:
  - Mode** = Validate
  - Save level** = 2 - Level 2
  - Check **Enable edit checks**



- Click **OK** to apply and close the **Change Mode & Level** dialog. The current field is **Screen 2, Reading 1 systolic blood pressure**.
- Select **Field** > **Edit Query** or click **\***. In the dialog,
  - Set **Use** as Internal
  - Delete the existing text in the **Detail** field
  - Enter See Reason for Data Value. in the **Note** field

Click **OK** to apply the edits.

DFExplore - Edit Query

Site: 99, Subject: 99007, Visit: Screening Visits, Page: Form 1

Field: Screen 2: Reading 1 systolic

Reported Value: 180

Category: Test Use Internal

Status: Pending Type Clarification

Detail: This value is out of our reference range. Please review.

Note: See reason for Data Value.

Created: data\_coordinator 2026-05-20 12:58:12 UTC: 04:00

Modified: data\_coordinator 2026-05-20 12:58:12 UTC: 04:00

Resolved:

OK Cancel

6. From the **Screen 2, Reading 1 systolic blood pressure** field, press **Tab** to advance through the remaining fields on the page without making any changes. Press **Tab** to advance to the save buttons at the bottom of the data screen to make them active. Click **Final**.
7. Select **File** > **Exit** to close and exit **DFExplore**.

## Delete a user-defined Query Category that is used by an existing query

1. Start **DFsetup**, login as **data\_manager** and choose **254 Acceptance Test Study** as described in ["How to start DFsetup"](#).
2. Choose **Normal Access** and click **OK**.

DFSetup - Access mode

Select Access mode:

**Developer Access**  
Use this mode to manage development & production study links.  
Blocks setup and configuration operations by other users.  
Blocks all data entry operations.

**Exclusive Access**  
Use this mode to create and assign modules and fields to plates.  
Allows Add/Assign/Delete/Re-order modules and fields.  
Allows editing of the Subject Alias Map.  
Blocks all data entry operations.

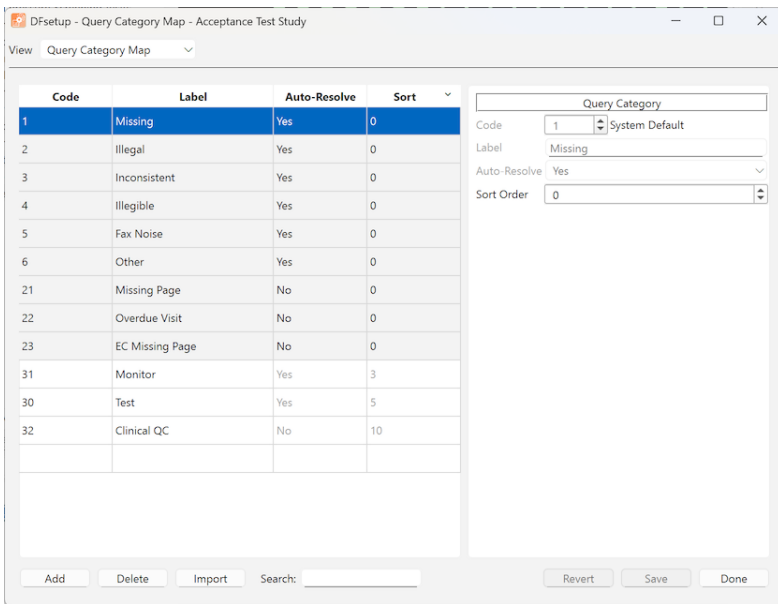
**Normal Access**  
Use this mode to modify plate, style, module and field properties.  
These operations can be performed by only one user at a time.

**Configuration Files**  
Use this mode to Add/Modify sites, visit map, etc.  
Subject Alias Map is view only.  
Each file can be modified by only one user at a time.

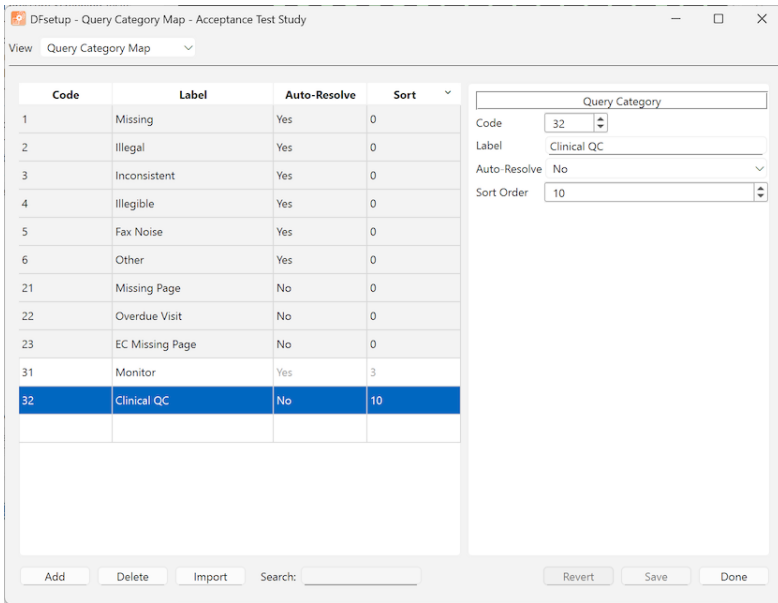
**View Only**  
Use this mode to view setup components currently in use.  
Allows view and print operations only.

OK Cancel

3. Select **View** > **Query Category Map**.



4. In the **Query Category Map** dialog, locate the entry that has **Code 30** and **Label Test**. Click the entry to highlight it, then click **Delete**. Click **Save** and **Done**.



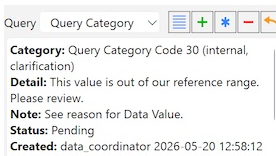
5. Select **File** > **Exit** to close **DFsetup**.

## Delete a user-defined Category query

1. Start **DFexplore**, login as `data_coordinator` and choose **254 Acceptance Test Study** as described in ["How to start DFexplore"](#)

**NOTE:** If `data_coordinator` has been set up for 2-factor authentication with Azure SMS, you may need to wait for a 1-time code to arrive at the phone number as defined in **DFadmin**.

2. Double-click the folder for **Site 99 - Hospital #99** to display a list of available subjects. Double-click subject entry **99007** in the subject list to open the subject binder. Locate the **0: Screening Visits** visit for subject **99007** and double-click this entry. Press **Tab** to advance through the fields until **Screen 2, Reading 1 systolic blood pressure** becomes the current field. Examine the details in the **Query** window. If an existing query contains a user-defined category, and that category definition has been removed from **DFsetup**, the query in **DFexplore** displays **Query Category Code 30**.



3. Select **Field** > **Delete Query** or click **[ - ]**.

4. Click **OK** to perform the query deletion.

DFExplore - Delete Query

Site: 99, Subject: 99007, Visit: Screening Visits, Page: Form 1

Field: Screen 2: Reading 1 systolic

Reported Value: 180

Category: Query Category Code 30 Use: Internal

Status: Pending delete Type: Clarification

Detail: This value is out of our reference range. Please review.

Note: See reason for Data Value.

Created: data\_coordinator 2026-05-20 12:58:12 UTC-04:00

Modified: data\_coordinator 2026-05-20 13:01:12 UTC-04:00

Resolved:

OK Cancel

5. Click **Delete** in the confirmation dialog.

DFExplore - Confirm

? This action will delete a field query.

OK to delete it?

Delete Cancel

6. Press **Tab** to advance through the remaining fields on the **Blood Pressure Screening Visits** page until the save buttons at the bottom of the screen become active. Click **Final**.

7. Click **File** > **Exit** to exit **DFExplore**.

## End Module 9. User-defined Query Category Types

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 9. User-defined Query Category.

## Module 10. Multiple Queries Per Field

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
  - data\_coordinator : data\_coordinator
- Email address configured for site\_monitor
- (Optional) - SMS or email 2-factor authentication setup with data\_coordinator

NOTE: For configuration of 2-factor authentication, see [Module 1\(Installation & Initialization\) test step 6](#) for details on configuring accounts with 2-factor authentication

**Client Tools Used:** DFATK, DFExplore, DFsetup, DFsend

**Purpose:** This module tests the enabling of multiple queries per field options in **DFsetup** allowing for a single field to have more than one query applied to it at a time, the restructuring of the Study to allow for this option, and subsequent use of multiple queries within a single field. General query functions are tested, including creation, modification, deletion, and replying to queries, as well query resolving.

### Tests & Requirements

- Submit PDF images to DFdiscover.
- Enable multiple queries per field in **DFsetup**.
- Retrieve submitted CRF in **DFExplore** Image View.
- Enter Plate 9 for Subject 99002.
- Apply multiple queries to a field.
- Select and edit an existing query in a field that has multiple queries.

7. Select and reply to an existing query in a field that has multiple queries.
8. Select and delete an existing query in a field that has multiple queries.

Estimate of Time Required: 30 Minutes

## Begin Module 10. Multiple Queries Per Field

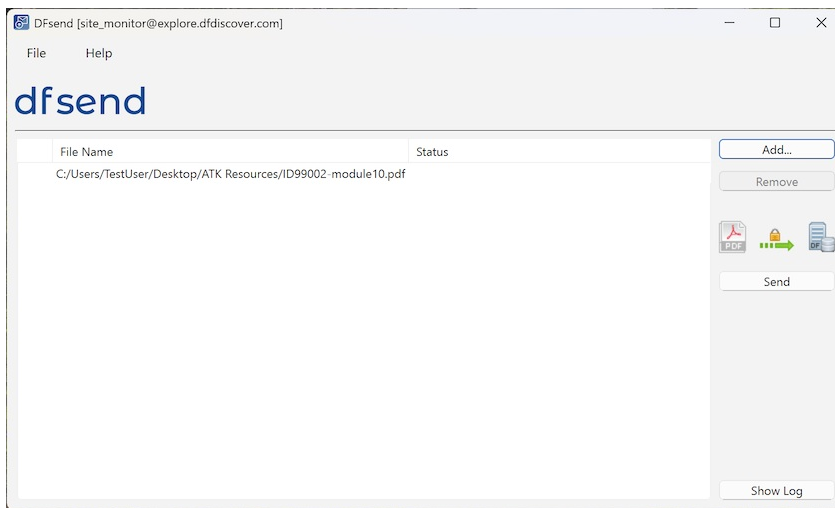
1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **10. Multiple Queries Per Field** followed by **Begin** to begin this module.
3. Click **Send ID 99002** to email a copy of **ID99002-module10.pdf** to site\_monitor. Clicking more than once will result in multiple files arriving to your email inbox.

NOTE: Save the **ID99002-module10.pdf** file received via email to your local computer. This file is required to complete the remainder of this module. Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address is required for site\_monitor to receive the module specific PDF files.

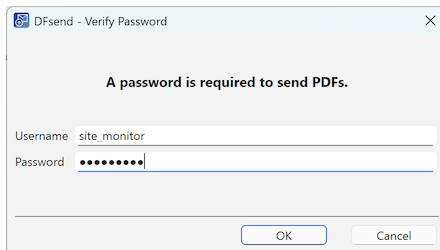
4. The following steps require exclusive access to the 254 Acceptance Test Study database. To facilitate exclusive access, close **DFATK** by clicking **Exit**.

## Submit PDF images to DFdiscover

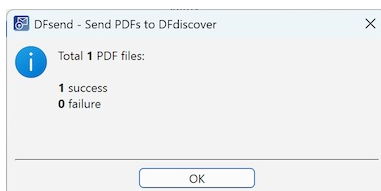
1. Start **DFsend**, login as user site\_monitor as described in ["How to start DFsend"](#).
2. Click **Add**. From the **Select PDF Files** file selection dialog, locate the previously saved **ID99002-module10.pdf** file. Select the file, click **Open**.



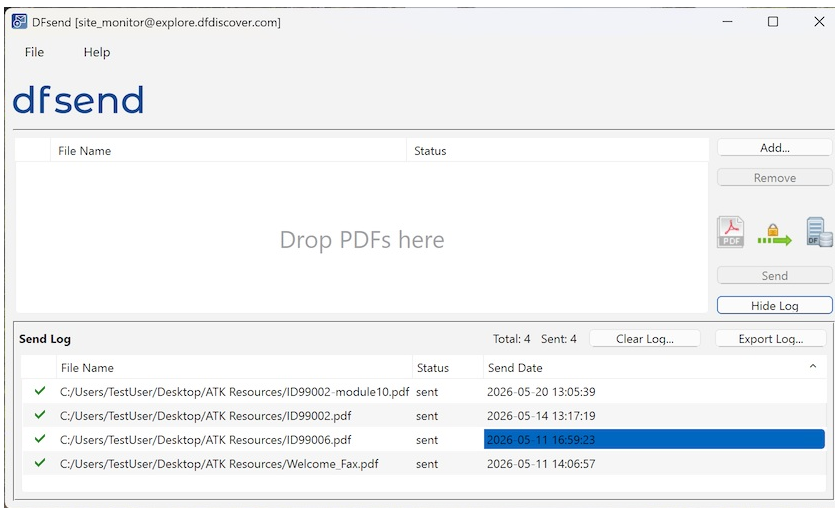
3. Click **Send**, enter site\_monitor in the **Username** field and the previously assigned password in the **Password** field. Click **OK**.



4. In the resulting **Send PDFs to DFdiscover** dialog, confirm **1 success** and **0 failure** are shown. Click **OK**.



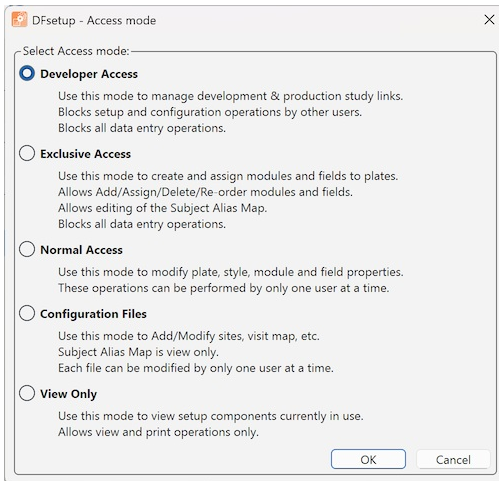
5. Click **Show Log** to confirm successful transmission of the **ID99002-module10.pdf** file to **DFdiscover**.



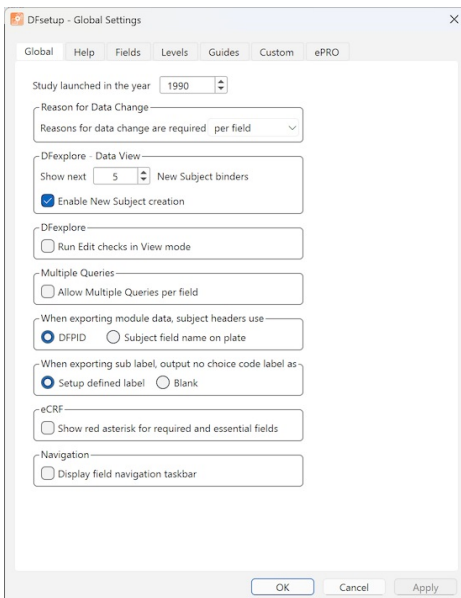
6. Select **File** > **Exit**.

## Enable multiple queries per field in DFsetup

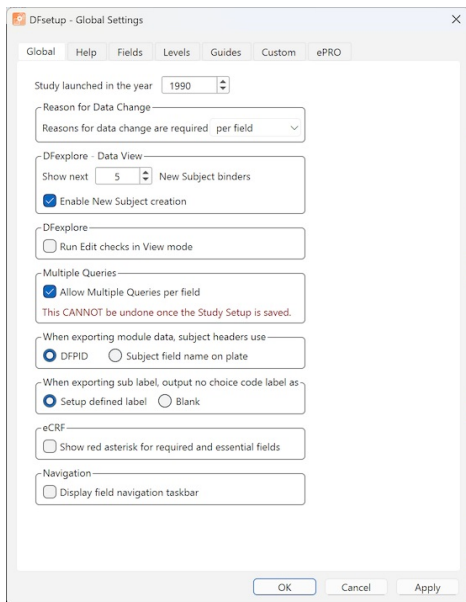
1. Start **DFsetup**, login as user **data\_manager** and choose **254 Acceptance Test Study** as described in ["How to start DFsetup"](#).
2. Choose **Developer Access** in the **Access mode** dialog, click **OK**.



3. The main window for **DFsetup** is displayed. Select **Study** > **Global Settings**.



4. Click **Global** tab in the **Global Settings** dialog. Check (enable), if not already checked, **Allow Multiple Queries per field**. The warning message: **This CANNOT be undone once the Study Setup is saved** is displayed.



5. Click **OK** to close the **Global Settings** dialog.
6. Select **File** > **Save [Required]**, followed by **File** > **Exit**.

## Retrieve submitted CRF in DFexplore Image View

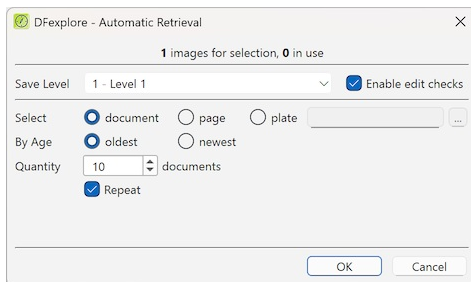
1. Start **DFexplore**, login as user `data_coordinator` and choose **254 Acceptance Test Study** as described in ["How to start DFexplore"](#)

**NOTE:** If `data_coordinator` has been set up for 2-factor authentication with Azure SMS, you may need to wait for a 1-time code to arrive at the phone number as defined in **DFAdmin**.

2. The main window for **DFexplore** is displayed. Select **View** > **Image**.
3. In the **Automatic Retrieval** dialog, set:
  - o **Save level = 1 - Level 1**
  - o Check (enable) **Enable Edit Checks**
  - o **Select = document**
  - o **By Age = Oldest**
  - o **Quantity \_\_ documents = 10**
  - o Check (enable) **Repeat**

Confirm the settings.

Click **OK**.



4. The first image retrieved is the **Adverse Event Report CRF**.

The screenshot shows the Dfexplorer interface with two Adverse Event Report forms. The top form is for Patient 990002, and the bottom form is for Patient 990002. The 'Adverse Event Report No.' field in the top form is highlighted in red. The interface includes a menu bar (File, Edit, View, Select, Plate, Field, Window, Help), a toolbar, and a main content area with two forms. The top form has the following fields: Patient Number (990002), Patient Initials (F M L), Adverse Event Report No. (01-2), Intensity (4), Relationship to Study Drug (2), Action(s) Taken (2), Outcome (2), and Is This A Serious Event? (No). The bottom form has the following fields: Patient Number (990002), Patient Initials (J A M), Adverse Event Report No. (01-1), Intensity (4), Relationship to Study Drug (2), Action(s) Taken (2), Outcome (1), and Is This A Serious Event? (Yes). The status bar at the bottom indicates 'v(0) - 1' and 'Legal values are: 1-99'.

## Enter Plate 9 for Subject 99002

1. The **Adverse Event Report No.** field is highlighted as the current field. Enter the value from the CRF image if it is not already correctly auto-filled. Press **Tab** to advance to the **AE Identifier** field. The AESEQNUM2 edit check executes upon entry to the **AE Identifier** field. The data value in the field is updated.

The screenshot shows the Dfexplorer interface with two Adverse Event Report forms. The top form is for Patient 990002, and the bottom form is for Patient 990002. The 'Adverse Event Report No.' field in the top form is highlighted in green. The interface includes a menu bar (File, Edit, View, Select, Plate, Field, Window, Help), a toolbar, and a main content area with two forms. The top form has the following fields: Patient Number (990002), Patient Initials (F M L), Adverse Event Report No. (01-1), Intensity (4), Relationship to Study Drug (2), Action(s) Taken (2), Outcome (2), and Is This A Serious Event? (No). The bottom form has the following fields: Patient Number (990002), Patient Initials (J A M), Adverse Event Report No. (01-1), Intensity (4), Relationship to Study Drug (2), Action(s) Taken (2), Outcome (1), and Is This A Serious Event? (Yes). The status bar at the bottom indicates 'v(0) - 1' and 'Number AEs sequentially'.

2. Press **Tab** to advance to the **Patient Number** field.
3. Beginning at the **Patient Number** field, correctly enter the data per the CRF image, up to and including the **Intensity** field. Tabbing from the **Intensity** field, a user-defined edit check executes and the **dfaddqc: Severity** dialog is displayed.

4. Click **OK** to apply the edit check. The field becomes blue, and the next field **Relationship to Study Drug** becomes the current field.

5. Correctly enter each data field on the page per the CRF image, up to and including the **Description** field.

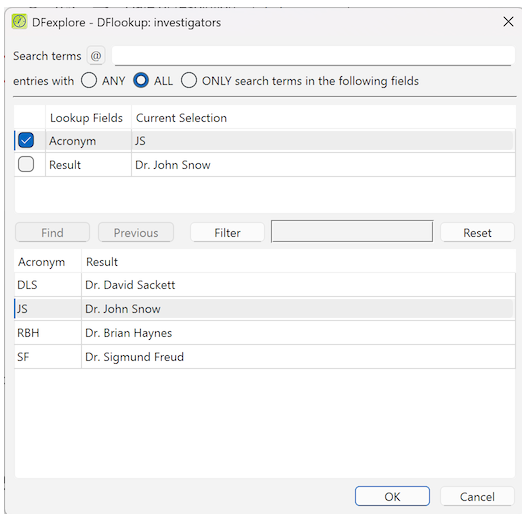
Do not enter any text in the **Description** field as the corresponding field on the CRF image is blank. Upon tabbing off this field, the **dfaddqc: MissingQC** dialog appears.

Confirm that **Missing** is displayed in the **Category** field.

6. Click **OK**. This applies the edit check to the **Description** field. The field becomes blue, and the **AECOTERM** becomes the current field.

7. From the **AECOTERM** field, press **Tab** through all remaining fields until the **Investigator's Signature** field becomes the current field.

Tabbing from the **Investigator's Signature** field, the **DFlookup: investigators** dialog appears. Highlight Dr. John Snow and click **OK**.



8. Enter the **Date** field value. Press **Tab** to advance to the save status bar to make it active. Click **Incomplete** to save the changes.

## Apply multiple queries to a field

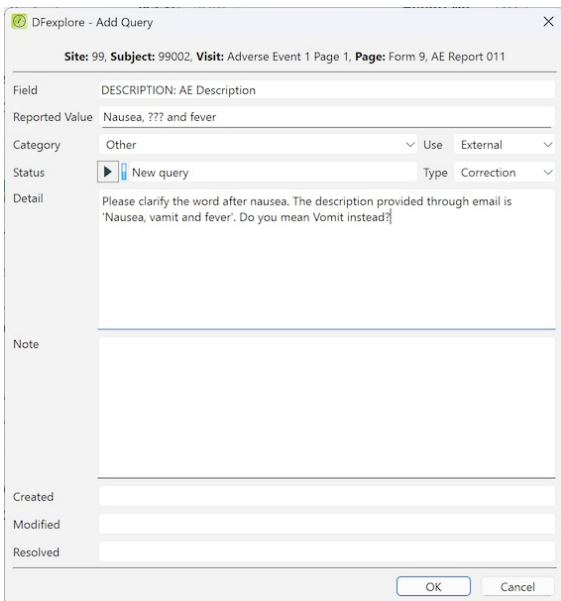
1. With the **Adverse Event Report** displayed as the current page, make the page active by clicking anywhere on the page background using the mouse. Press **Tab** to advance through the fields until **Description** becomes the current field. Note that the **Description** field is blank and has an unresolved query with the category **Missing (external, correction)**. Enter the text Nausea, ??? and fever.



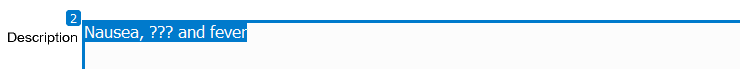
2. Select **Field** > **Add Query** or click **+**. In the dialog, confirm **Category** type **Missing** is disabled. Set:

- **Category** = Other
- **Use** = External
- **Type** = Correction
- **Status** = New query
- **Detail** = Please clarify the word after nausea. The description provided through email is 'Nausea, vomit and fever'. Do you mean Vomit instead?

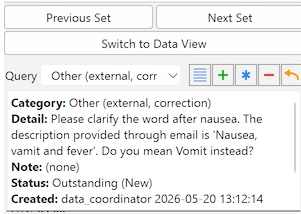
**NOTE:** Multiple queries can be added to a single field, but each query must have a unique Query Category type. Therefore, a Category will be disabled if it has been previously used on the same field where a new query is to be added.



3. Click **OK** to apply the query. Confirm that the Description field is the current field with the query count '2' displaying on the top left corner of the field widget, and the field becomes blue.

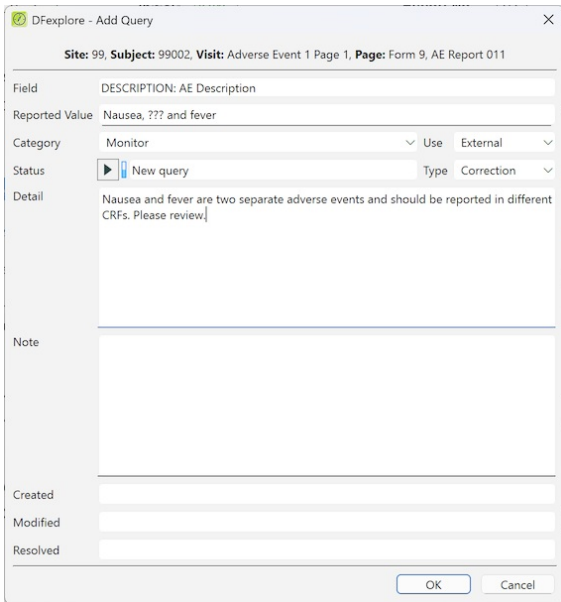


4. With the focus still on the **Description** field, examine the details in the **Query** window that appears at the bottom left corner of the main data entry screen.



5. Select **Field** > **Add Query** or click **+** to add the third query to the **Description** field. In the dialog, set:

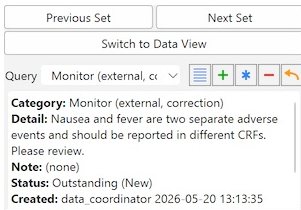
- o **Category** = Monitor
- o **Use** = External
- o **Type** = Correction
- o **Status** = New query
- o **Detail** = Nausea and fever are two separate adverse events and should be reported in different CRFs. Please review.



6. Click **OK** to apply the query. Confirm that the **Description** field is the current field with the query count 3 displaying on the top left corner of the field widget, and the field becomes blue.

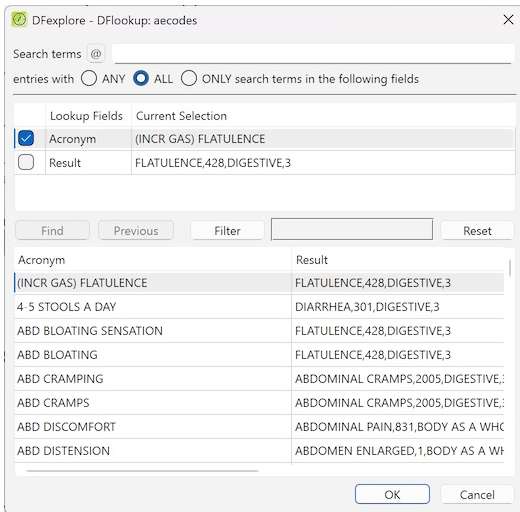


7. With the focus still on the **Description** field, examine the details in the **Query** window that appears at the bottom left corner of the main data entry screen.



**NOTE: The query list reflects the query sort order that has been defined by the user in DFsetupQuery Category Map.**

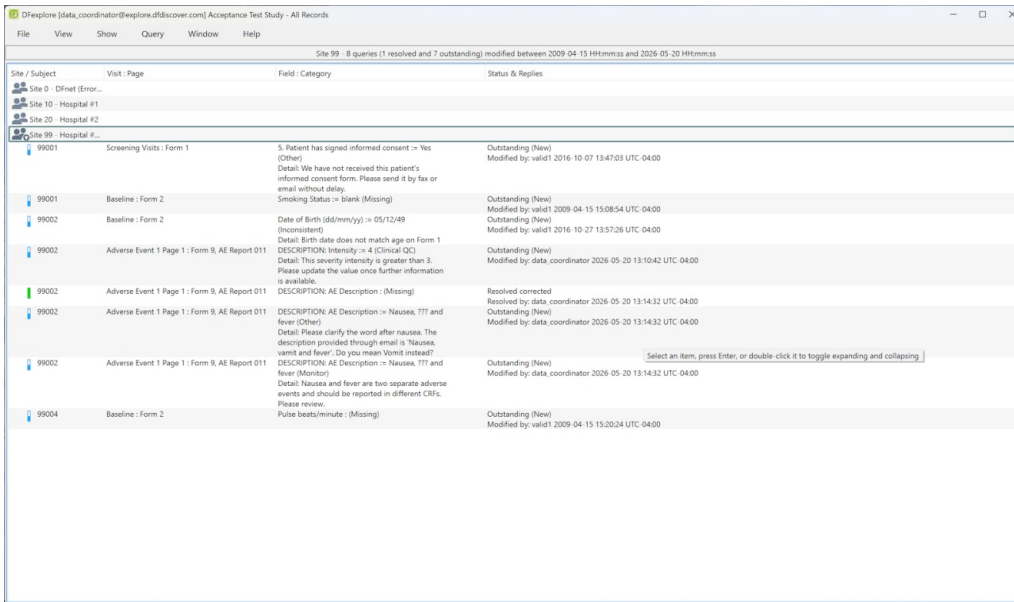
8. Press **Tab** to exit the **Description** field, the DFlookup: aecodes window appears. Click **Cancel** in the window to close the dialog. The next field **AECOTERM** becomes the current field.



9. Press **Tab** to advance through the remaining fields on the page without making any changes. Press **Tab** to advance to the save buttons at the bottom of the data screen to make them active. Click **Incomplete**.

## Select and edit an existing query in a field that has multiple queries

1. With the **Adverse Event Report** page still active, Select **View** > **Queries** to open the **Queries** View window. In the resulting confirmation dialog, click **OK** to release all Image records. Select **Show** > **All Queries**. Double-click **Site 99 - Hospital #99**. Locate and confirm that the Queries window displays the three queries that have been applied to the **AE Description** field for Subject **99002**.



2. Select **Show** > **Outstanding Queries**. Locate and confirm that two unresolved queries with categories **Other** and **Monitor** on the **AE Description** field of Subject **99002** are displayed.

Site / Subject	Visit / Page	Field / Category	Status & Replies
Site 0 - Dfnet (Error...)			
Site 10 - Hospital #1			
Site 20 - Hospital #2			
Site 99 - Hospital #...			
99001	Screening Visits : Form 1	S. Patient has signed informed consent => Yes (Other) Detail: We have not received this patient's informed consent form. Please send it by fax or email without delay. Smoking Status => Blank (Missing)	Outstanding (New) Modified by: valid1 2016-10-07 13:47:03 UTC-04:00
99001	Baseline : Form 2	Date of Birth (dd/mm/yyyy) => 05/12/49 (Inconsistent)	Outstanding (New) Modified by: valid1 2009-04-15 15:08:54 UTC-04:00
99002	Baseline : Form 2	Date of Birth (dd/mm/yyyy) => 05/12/49 (Inconsistent)	Outstanding (New) Modified by: valid1 2016-10-27 13:57:26 UTC-04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: Intensity => 4 (Clinical QC) Detail: This severity intensity is greater than 3. Please update the value once further information is available.	Outstanding (New) Modified by: data_coordinator 2026-05-20 13:10:42 UTC-04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: AE Description => Nausea, ??? and fever (Other) Detail: Please clarify the word after nausea. The description provided through email is 'Nausea, vomit and fever'. Do you mean Vomit instead?	Outstanding (New) Modified by: data_coordinator 2026-05-20 13:14:32 UTC-04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: AE Description => Nausea, ?? and fever (Monitor) Detail: Nausea and fever are two separate adverse events and should be reported in different CRFs. Please review.	Outstanding (New) Modified by: data_coordinator 2026-05-20 13:14:32 UTC-04:00
99004	Baseline : Form 2	Pulse beats/minute: (Missing)	Outstanding (New) Modified by: valid1 2009-04-15 15:20:24 UTC-04:00

3. Double-click entry containing the query category **Other** in the **Description** field of Subject **99002, Adverse Event 1 Page 1: Form 9, AE Report 011**.

The screenshot shows the 'ADVERSE EVENT REPORT' form for Subject 99002. The form is in 'Validate' mode. The description field contains 'Nausea, ??? and fever'. The 'Query' dropdown is set to 'Other (external, correction)'. The status is 'Outstanding (New)'. The 'Save level' is set to '2 - Level 2'. The 'Enable edit checks' checkbox is checked.

4. Select **[Select] > Change Mode & Level**. In the dialog, set:

- o **Mode** = Validate
- o **Save level** = 2 - Level 2
- o Check (enable) **Enable edit checks**

Click **[OK]** to apply the changes.

The 'Change Mode & Level' dialog box shows the following settings: Mode: Validate, Save level: 2 - Level 2, and Enable edit checks: checked. The OK and Cancel buttons are visible at the bottom.

5. Delete the text ??? in the description field and enter vomiting instead. Examine the query window. From the **Query** drop-down choose **Other (external, correction)** query in the query list.

The 'Query' window shows the 'Other (external, correction)' query selected. The description field contains 'Nausea, vomit and fever'. The status is 'Pending'. The 'Created' date is 'valid1 2016-10-30 14:13:03 UTC-04:00'.

6. With the focus on the **Other (external, correction)** query **Description** field, select **Field** > **Edit Query**, or click the **\*** to open the dialog. set:

- Select **Pending** from the **Status** pull-down.
- Enter The correction was provided via email. in the **Note** field.

Click **OK** to apply the edits.

## Select and reply to an existing query in a field that has multiple queries

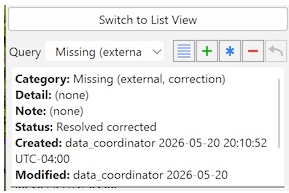
1. Select **Monitor (external correction)** from the **Query** pull-down to make the query active.

2. Select **Field** > **Reply to Query** or click **\*** to open the dialog. Enter Fever will be removed to a different Adverse Event Report form. in the **New Reply** field.

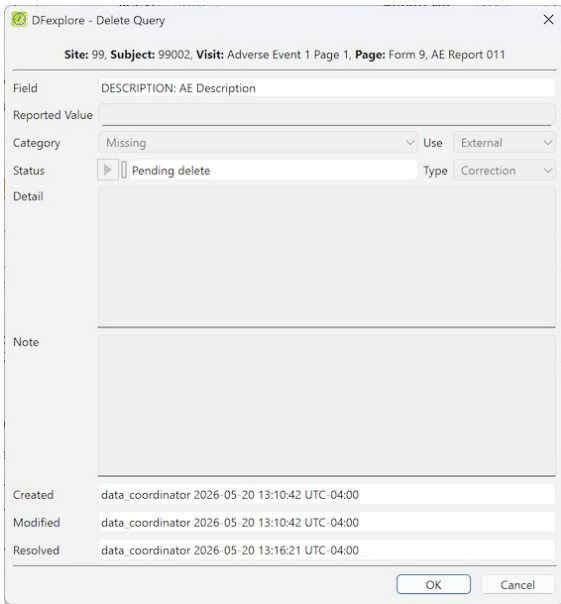
3. Click **OK** to close the dialog. Examine the information present in the **Query** window.

## Select and delete an existing query in a field that has multiple queries

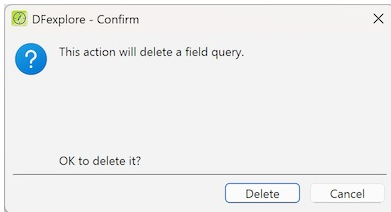
1. Choose **Missing (external, correction)** from the **Query** pull-down list. The query list in the query window displays the **Missing (external, correction)** query. Confirm that the first query is defined with **Category: Missing (external, correction)** and a **Status: Resolved corrected**.



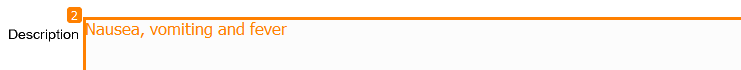
2. Select **Field** > **Delete Query** or click to open the **Delete Query** dialog.



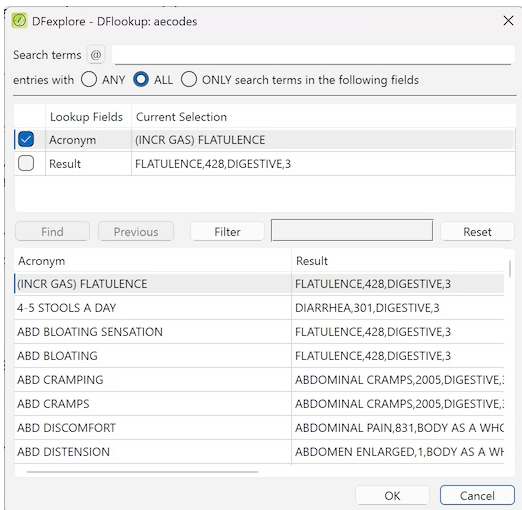
3. Click **OK** to perform the query deletion.



4. Click **Delete** in the **Delete Query** confirmation dialog. Confirm that the **Description** field remains as the active field and has the query count 2 displaying on the top left corner of the field widget.



5. Press **Tab** to exit the **Description** field, and a **DFlookup: aecodeswindow** appears. Click **Cancel** in the window to close the dialog. The next field **AECOTERM** becomes the current field.



6. Press **Tab** to advance through the remaining fields on the **Adverse Event Report** page until the **Incomplete** at the bottom of the screen becomes active. Click **Incomplete** to save the modified page.

7. Select **File** > **Exit** to close and exit **DFExplore**.

## End Module 10. Multiple Queries Per Field

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **End** to confirm successful completion of Module 10. Multiple Queries Per Field.

## Module 11. Data Review

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
- Email address configured for site\_monitor

**Client Tools Used:** DFATK, DFExplore, DFsetup

**Purpose:** This module tests the processes of reviewing data in **DFExplore**, including queries and reasons, and validating data and queries to different levels. Included in this module is the use of different data selection methods and data expressions in **DFExplore**, and the use of batch edit checks.

### Tests & Requirements

1. Retrieve all data for Site 99 that exists at level 3.
2. Review and approve a pending reason for data value, and approve a selected query in a field that has multiple queries.
3. Review and move approved reasons for data values to a higher workflow level, and review queries in a field that has multiple queries.
4. Data review and add a query to inconsistent data.
5. Review and complete pending data for Subject 99007.
6. Confirm audit trail information for reviewed and modified data.
7. Run batch edit checks to verify data integrity.
8. Use a data expression to retrieve specific subject information.
9. Use cross-plate data criteria to retrieve specific subject information.

Estimate of Time Required: 20 Minutes

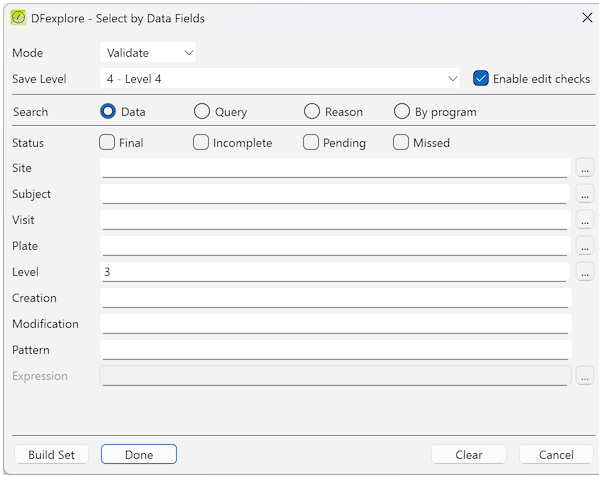
### Begin Module 11. Data Review

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **11. Data Review** followed by **Begin** to begin this module.
3. Click **Send ID 99007** to email a copy of **ID99007\_module11.pdf** to site\_monitor. Clicking more than once will result in multiple pages arriving to your email inbox.

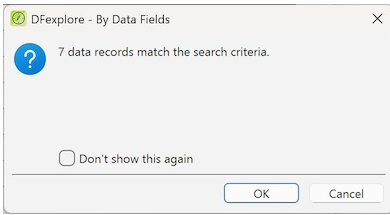
NOTE: Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address is required for site\_monitor to receive the module specific PDF files.

### Retrieve all data for Site 99 that exists at level 3

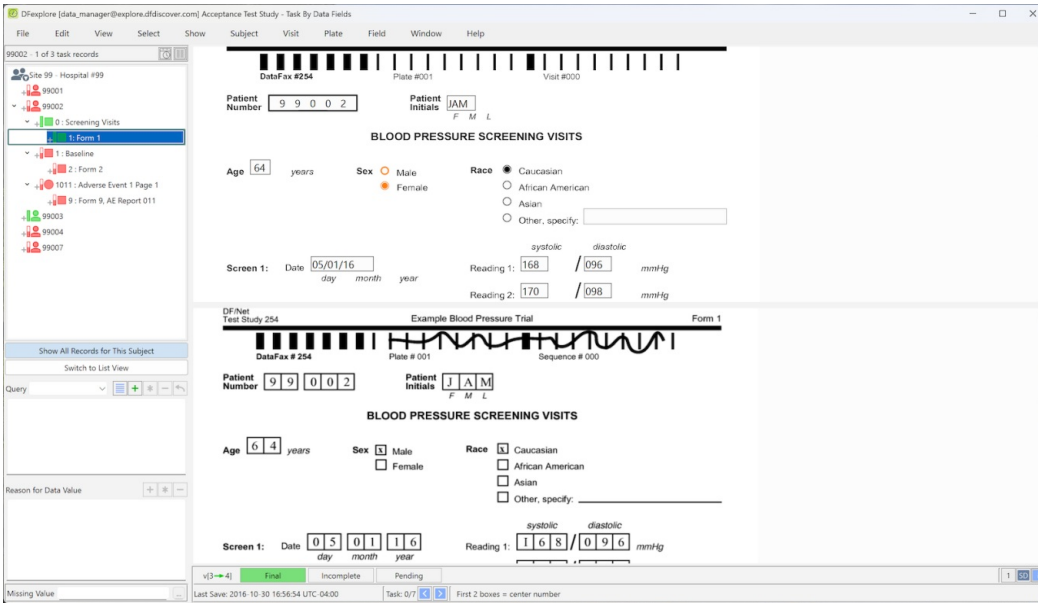
1. Start **DFExplore**, login as user data\_manager and choose **254 Acceptance Test Study** as described in ["How to start DFExplore"](#)
2. Select **Select** > **By Data Fields** from the menubar to open the **Select By Data Fields** retrieval dialog. In the dialog, set:
  - **Mode** = Validate
  - **Save level** = 4 - Level 4
  - **Search** = Data
  - **Level** = 3
  - Check (enable) **Enable edit checks**



3. Click **Done**. In the confirmation dialog, click **OK** to retrieve data records that match the criteria.

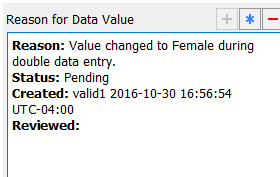


4. Double-click entry for Subject **99002** to open the subject binder.

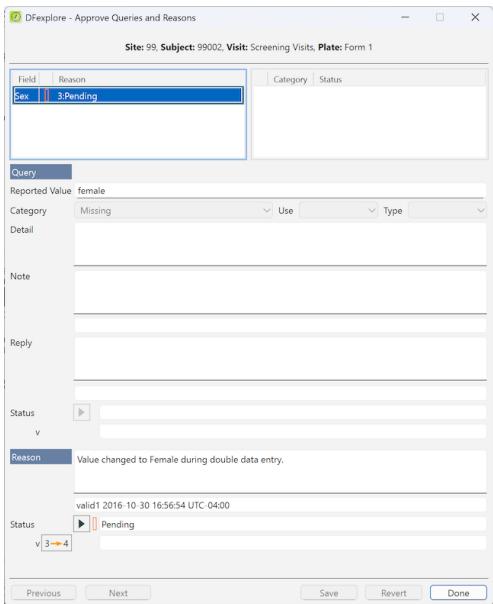


**Review and approve a pending reason for data value, and approve a selected query in a field that has multiple queries**

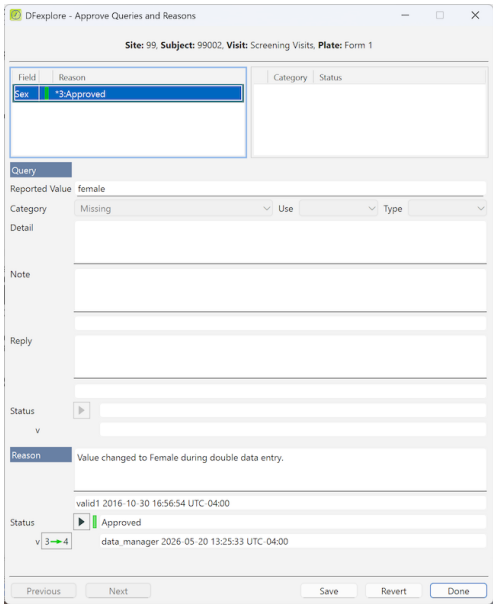
1. **1: Form 1 (BLOOD PRESSURE SCREENING VISITS)** for Subject **99002** is the active page. Press **Tab** to advance to the **Sex** field. Examine the information in the **Reason for Data Value** window.



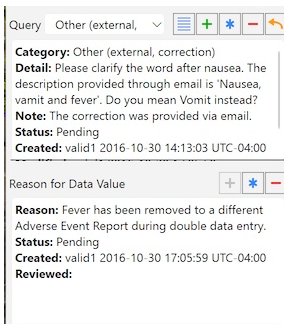
2. Select **Field** > **Approve Queries and Reasons**. Examine the information in the dialog.



3. Select **Approved** from the **Status** pull-down. Confirm that the approved reason shows **v 3 -> 4**.



4. Click **Save** and **Done** to close the dialog.
5. Do not make any other changes to the data on the current page and press **Tab** to advance to the save buttons. Click **Final** to save the page and its reason at level 4.
6. Click **9: Form 9, AE Report 011**.
7. Click anywhere on the page background to make the fields active. Press **Tab** to advance to the **Description** field. Examine the information displayed in this field and the information in the corresponding **Query** window.



8. Select **Field** > **Approve Queries and Reasons**. Select the **Monitor** query. Examine the information in the dialog.

DFxplorer - Approve Queries and Reasons

Site: 99, Subject: 99002, Visit: Adverse Event 1 Page 1, Plate: Form 9, AE Report 011

Field	Reason	Category	Status
DESCRIPTION: AE Description	3: Pending	Other	3: External - Pending
		Monitor	3: External - Pending

**Query**

Reported Value: Nausea, ??? and fever

Category: Monitor Use External Type Correction

Detail: Nausea and fever are two separate adverse events and should be reported in different CRFs. Please review.

Note:

valid1 2016-10-30 14:13:03 UTC 04:00

Reply: Fever will be removed to a different Adverse Event Report form.

valid1 2016-10-30 14:23:13 UTC 04:00

Status: Pending

Reason: Fever has been removed to a different Adverse Event Report during double data entry.

valid1 2016-10-30 17:05:59 UTC 04:00

Status: Pending

Buttons: Previous, Next, Save, Revert, Done

9. Select **Resolved corrected** from the **Status** in the **Query** section. Confirm that the CRF will be moved from level v3→4, and **Status** from **Pending** to **Resolved corrected**.

DFxplorer - Approve Queries and Reasons

Site: 99, Subject: 99002, Visit: Adverse Event 1 Page 1, Plate: Form 9, AE Report 011

Field	Reason	Category	Status
DESCRIPTION: AE Description	3: Pending	Other	3: External - Pending
		Monitor	3: External - Resolved corrected

**Query**

Reported Value: Nausea, ??? and fever

Category: Monitor Use External Type Correction

Detail: Nausea and fever are two separate adverse events and should be reported in different CRFs. Please review.

Note:

valid1 2016-10-30 14:13:03 UTC 04:00

Reply: Fever will be removed to a different Adverse Event Report form.

valid1 2016-10-30 14:23:13 UTC 04:00

Status: Resolved corrected

Reason: Fever has been removed to a different Adverse Event Report during double data entry.

valid1 2016-10-30 17:05:59 UTC 04:00

Status: Pending

Buttons: Previous, Next, Save, Revert, Done

10. Click **Save**. The **Approve Queries and Reasons** dialog changes from displaying the query with category **Monitor** to displaying the query with category **Other** as shown. Click **Done**.

11. Press **Tab** to exit the **Description** field. Upon leaving the field, the DrugLookup edit check is executed and the **DFlookup:AECODES** dialog appears. Click **Cancel**.

Lookup Fields	Current Selection
<input checked="" type="checkbox"/> Acronym	(INCR GAS) FLATULENCE
<input type="checkbox"/> Result	FLATULENCE,428,DIGESTIVE,3

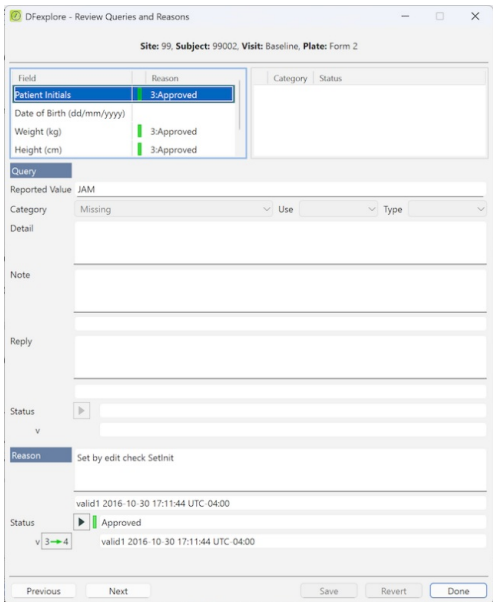
  

Acronym	Result
(INCR GAS) FLATULENCE	FLATULENCE,428,DIGESTIVE,3
4-5 STOOLS A DAY	DIARRHEA,301,DIGESTIVE,3
ABD BLOATING SENSATION	FLATULENCE,428,DIGESTIVE,3
ABD BLOATING	FLATULENCE,428,DIGESTIVE,3
ABD CRAMPING	ABDOMINAL CRAMPS,2005,DIGESTIVE,3
ABD CRAMPS	ABDOMINAL CRAMPS,2005,DIGESTIVE,3
ABD DISCOMFORT	ABDOMINAL PAIN,831,BODY AS A WHC
ABD DISTENSION	ABDOMEN ENLARGED,1,BODY AS A WHC

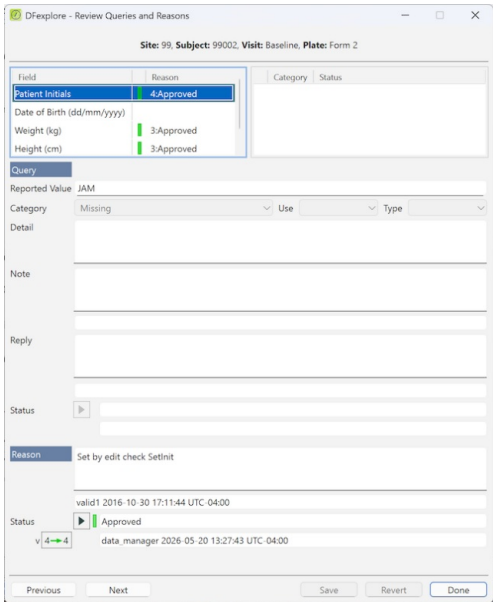
12. Do not make any other changes to the data and press **Tab** to advance to the save buttons. Click **Incomplete** to save the page at level 4.

## Review and move approved reasons for data values to a higher workflow level, and review queries in a field that has multiple queries

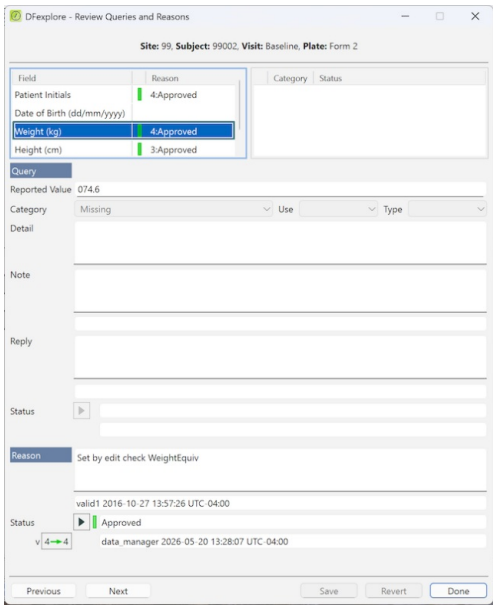
1. Double-click Subject **99002**. Select entry for **2 : Form 2**. Select **Field** > **Review Queries and Reasons** to review all queries and reasons that are present on the page.



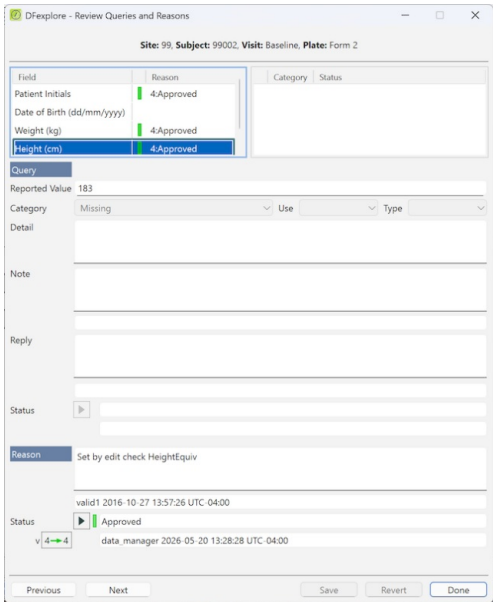
- Working with the highlighted entry for **Patient Initials**, confirm that the **Status** is set to **Approved** and the level button displays **v 3-4**. Click **v 3-4** to move the approved reason from level 3 to level 4 without making any other modifications.



- Select the 3rd Reason entry **Weight (kg)**. Confirm that the **Status** is set to **Approved** and **v 3-4** is displayed. Click **v 3-4** to move the approved reason from level 3 to level 4 without making any other modifications.



4. Select the 4th Reason entry **Height (cm)**. Confirm that the **Status** is set to **Approved** and v 3 -> 4 is displayed. Click v 3 -> 4 to move the approved reason from level 3 to level 4 without making any other modifications.



5. Once each of the 3 approved reasons have been reviewed, click **Done**.
6. As an outstanding query remains on the **Date of Birth** field, click **Incomplete** to save.
7. Continuing with the **ADVERSE EVENT REPORT** as the current page, click anywhere in the data entry screen to make the page active. Press **Tab** to advance through the fields until the **Description** field becomes the current field. Select **Field** > **Review Queries and Reasons**. Examine the information in the dialog.

8. Click the second query with the **Category** type **Monitor** and a status of **4: External - Resolved corrected**. Click **Done** to close the dialog.

9. Press **Tab** to exit the **Description** field. Upon leaving the **Description** field, the DrugLookupedit check is executed and **DFlookup:aecodes** dialog appears. Click **Cancel**.

10. Do not make any other changes to the data on the current page and press **Tab** to advance to the save buttons. Click **Incomplete**.

## Data review and add a query to inconsistent data

1. Double-click Subject **99007** entry in the record list to open task records for this subject. Press **Tab** to advance through the fields until **Screen 1, Reading 1 systolic blood pressure** becomes the current field.
2. Select **Field** > **Add Query** or click **+** to open the **Add Query** dialog. In the dialog, set:
  - o **Category** = Inconsistent
  - o **Use** = External
  - o **Type** = Clarification
  - o **Status** = New query
  - o Enter This value is inconsistent with all other BP readings. Please explain. in the **Detail** field.

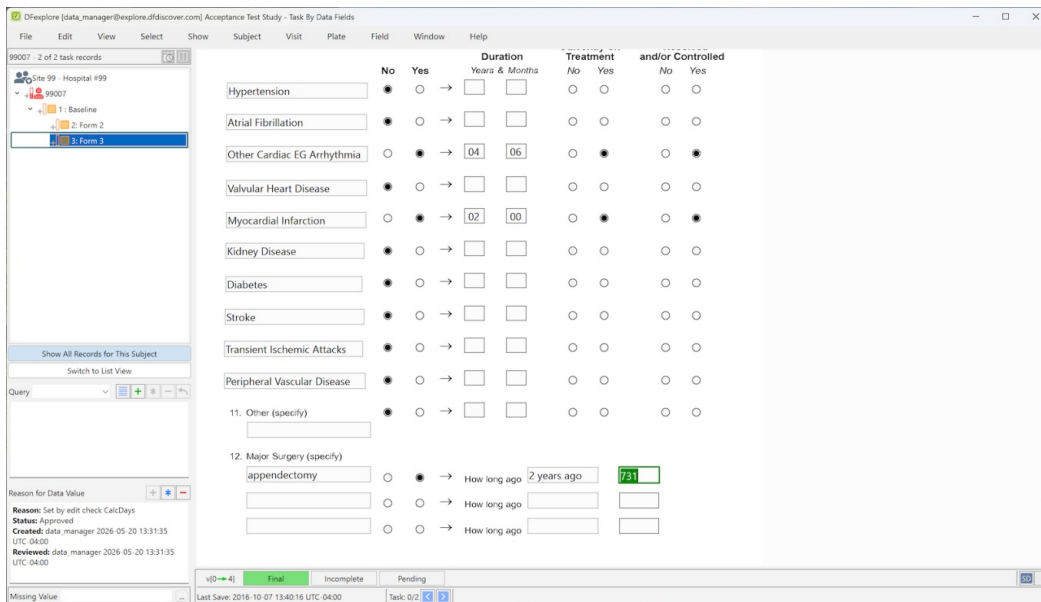
3. Click **OK** to apply the query.
4. Press **Tab** to advance through the remaining fields on the page until the save buttons become active. Click **Incomplete** to save the page.

## Review and complete pending data for Subject 99007

1. Release the current task set and retrieve all pages in the database that have been saved with status **Pending**. Do this by selecting **Select** > **By Data Fields**. In the dialog set:
  - o **Mode** = Validate
  - o **Save level** = 4 - Level 4
  - o **Search** = Data
  - o **Status** = Pending

Leave the retrieval **Level** field blank.

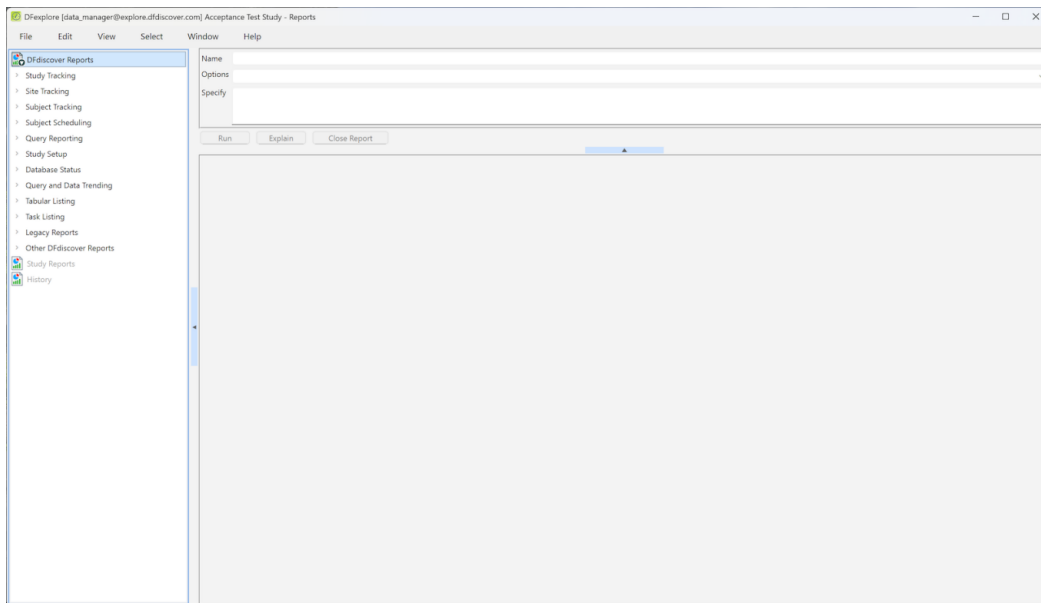
2. Click **Done**. In the confirmation dialog, click **OK** to retrieve data records that match the search criteria.
3. Select Subject **99007** > **1 : Baseline** > **3: Form 3** from the record list and click anywhere on the page background to make it the active page. Beginning with the **Patient Number** field, press **Tab** to advance through the fields until the first **Major Surgery** text field is the current field. Enter all **Major Surgery** information as it appears in the following image. Press **Tab** to exit the last data field to make the save buttons active.



4. As there are no outstanding problems on the page and the data is now complete, click **[Final]** to change the page status from **Pending** to **Final** at level 4.
5. Select **[Select]** > **[All Records]** to release all task records from the current set. Click **[OK]** in the dialog to clear the main **Data View** window.

## Confirm audit trail information for reviewed and modified data

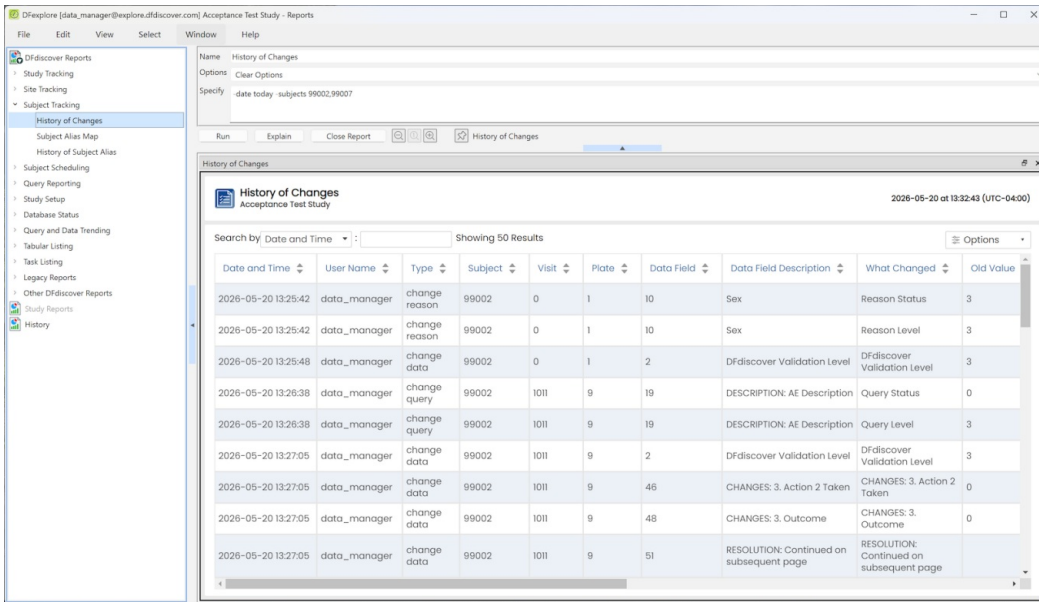
1. Select **[View]** > **[Reports]**, **Reports View** becomes the current view.



2. Click the **Subject Tracking** section and choose report **History of Changes** from the list of reports. To review all data modifications made to Subject **99002** and **99007**. Enter `-date today -subjects 99002,99007` in the **Specify** field.

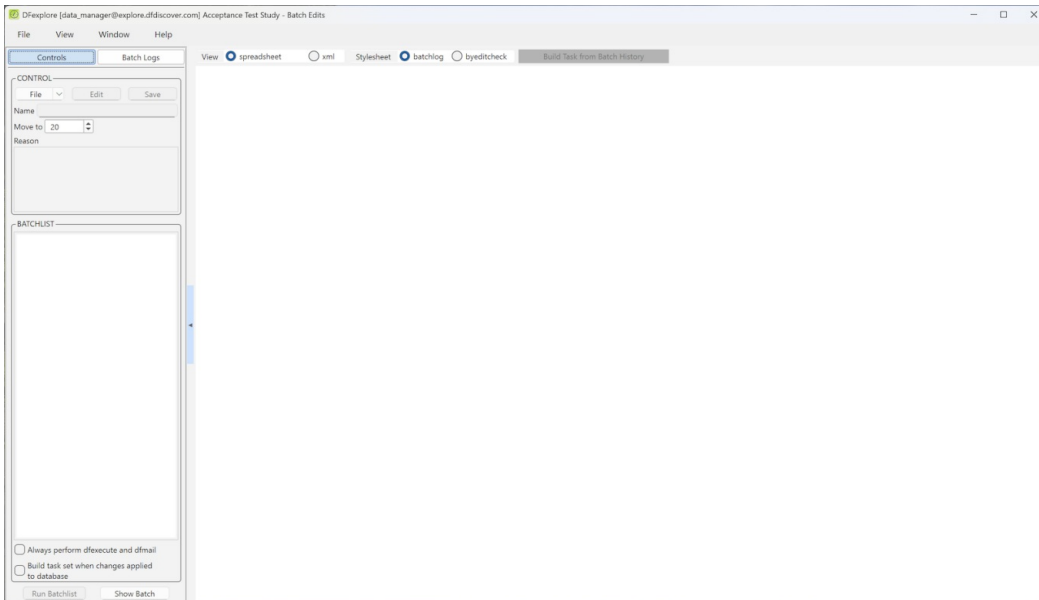
Name	History of Changes
Options	Clear Options
Specify	-date today -subjects 99002,99007

3. Click **[Run]** to execute the **History of Changes** report. Examine the output.

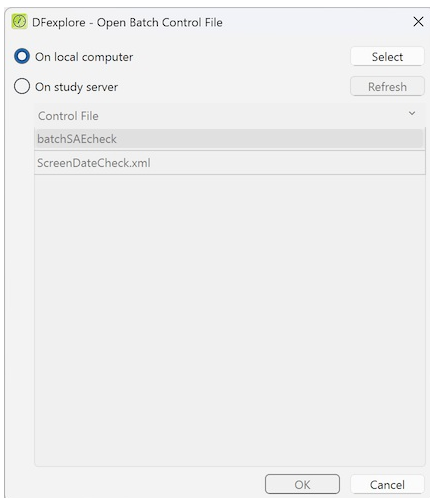


## Run batch edit checks to verify data integrity

1. Select **View** > **Batch Edits**. **Batch Edits** becomes the current view.

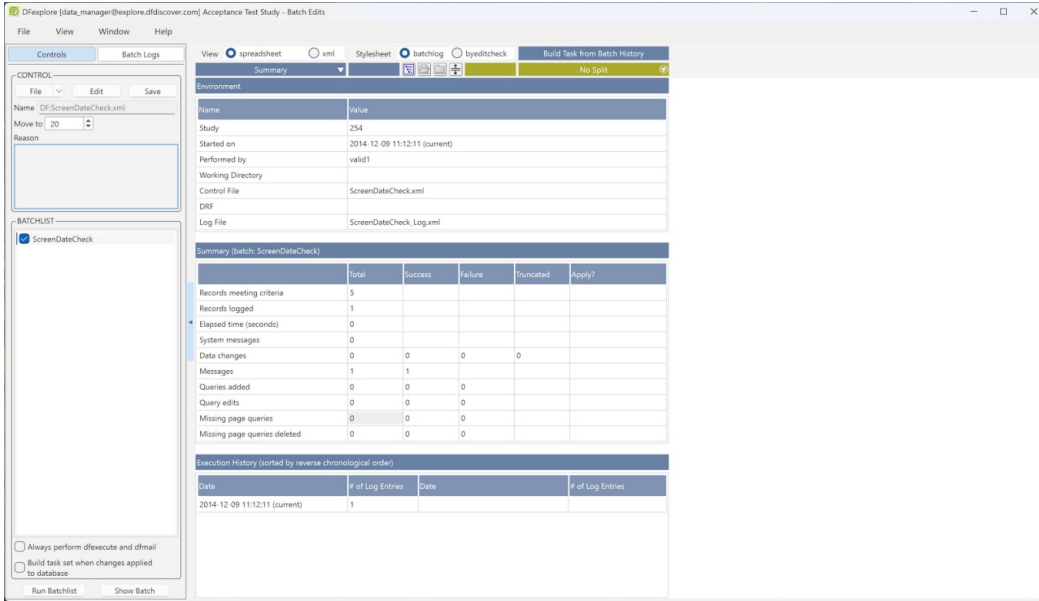


2. With the **Controls** tab as the current view. Click **File** > **Open Control File** from the drop-down list.



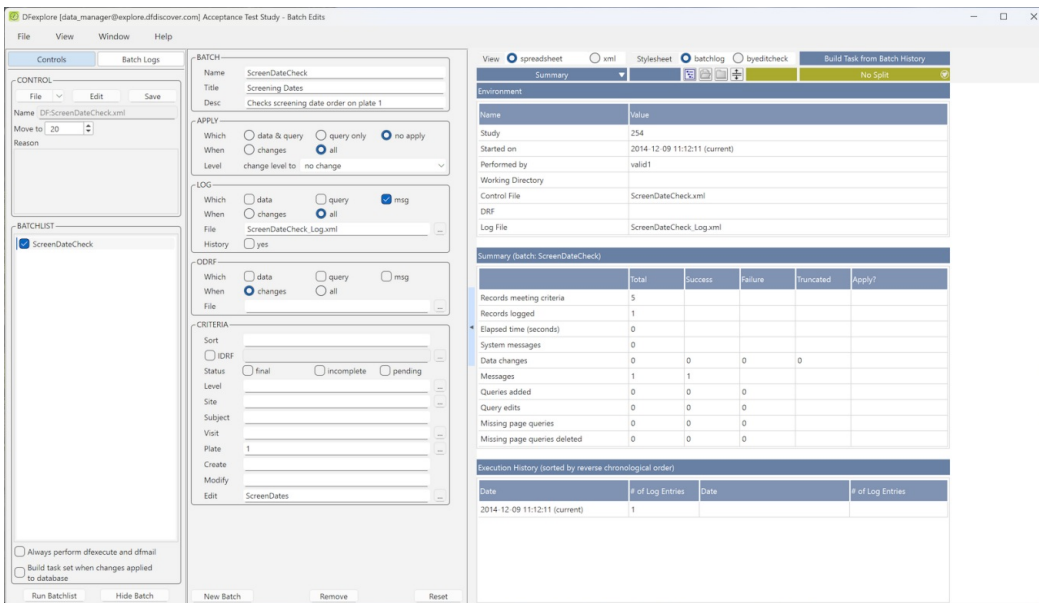
3. In the **Open Batch Control File** dialog, select (enable) the **On study server** option to display a list of available control files that are located on the study server for the 254

Acceptance Test Study. Choose ScreenDateCheck.xml from the list and click **OK** to load the control file.



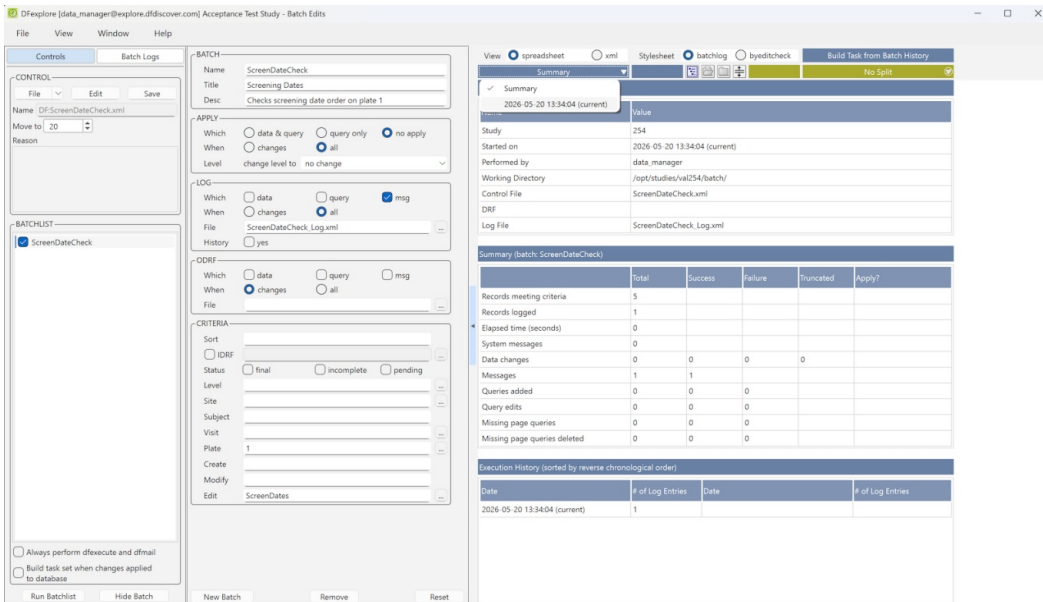
4. Click **Show Batch** to ensure the settings are as shown below. Click **Hide Batch** to hide the settings.

**NOTE:** The ScreenDateCheck.xml control file executes the edit check ScreenDates which verifies that the **Screen 1** and **Screen 2** dates on all plate 1s (Blood Pressure Screening Form) are in sequential order with the **Screen 1** date coming before the **Screen 2** date.

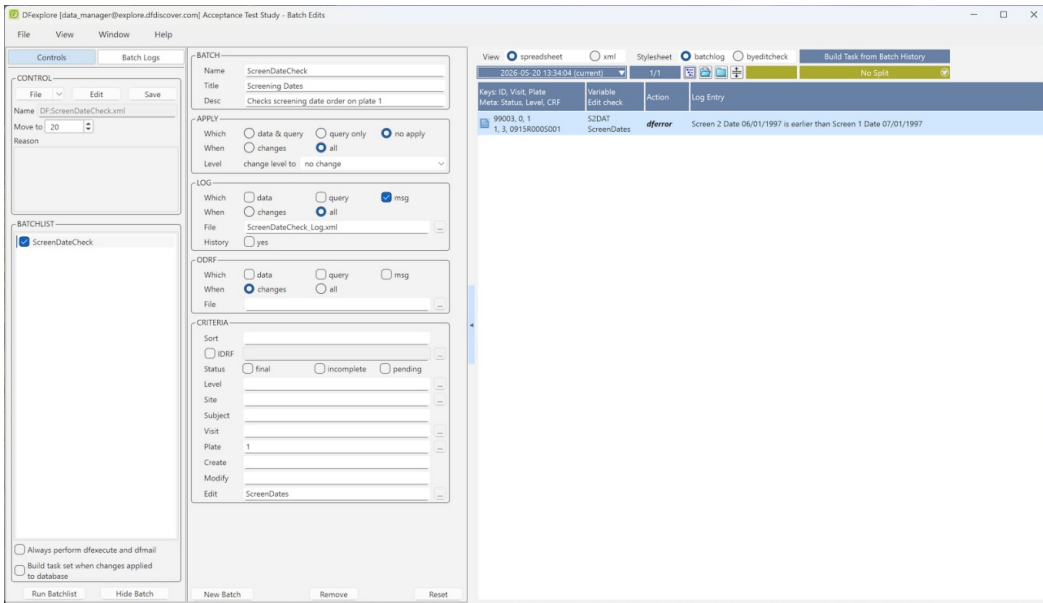


5. Click **Run Batchlist** to run the current batch program. Click **Run** in the confirmation dialog.

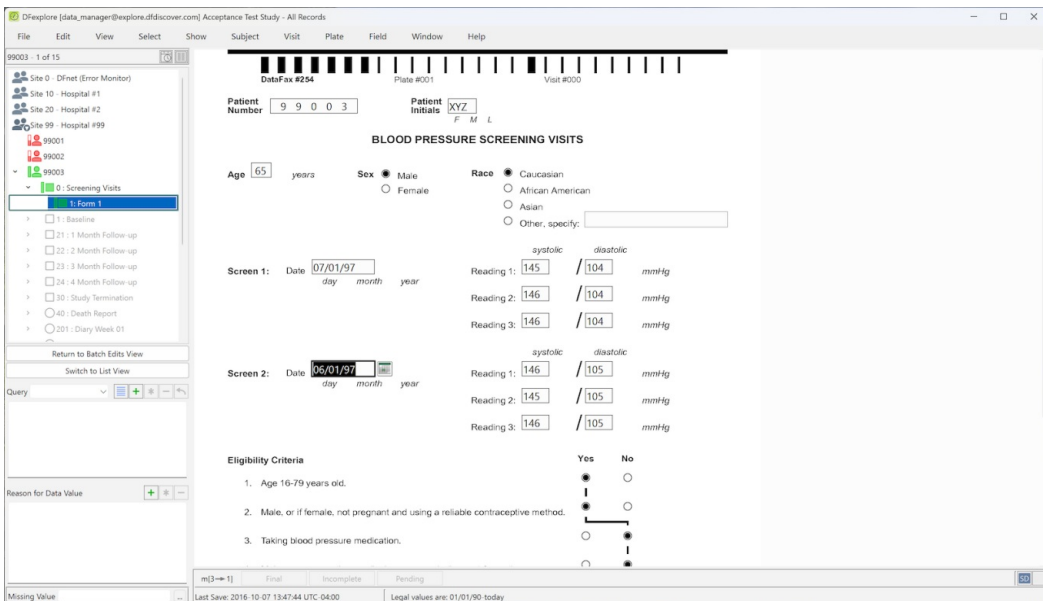
6. From the **Summary** drop-down list, choose the item identified as '(current)'.



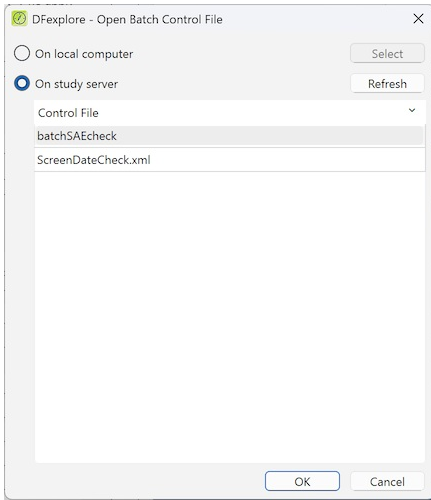
7. The edit check ScreenDates checks the Screen 1 and Screen 2 dates on Form 1 (plate 1) and determines if they are out of sequence. Examine the log entry message.



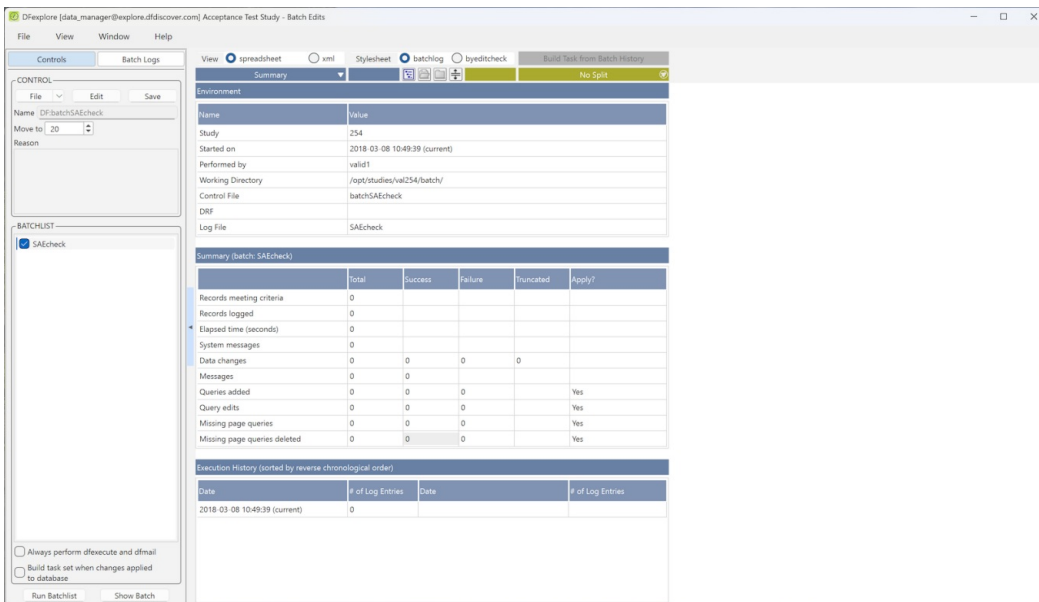
8. Double click the entry to be taken to Data View. Examine the values in the Screen 1 and Screen 2 date fields.



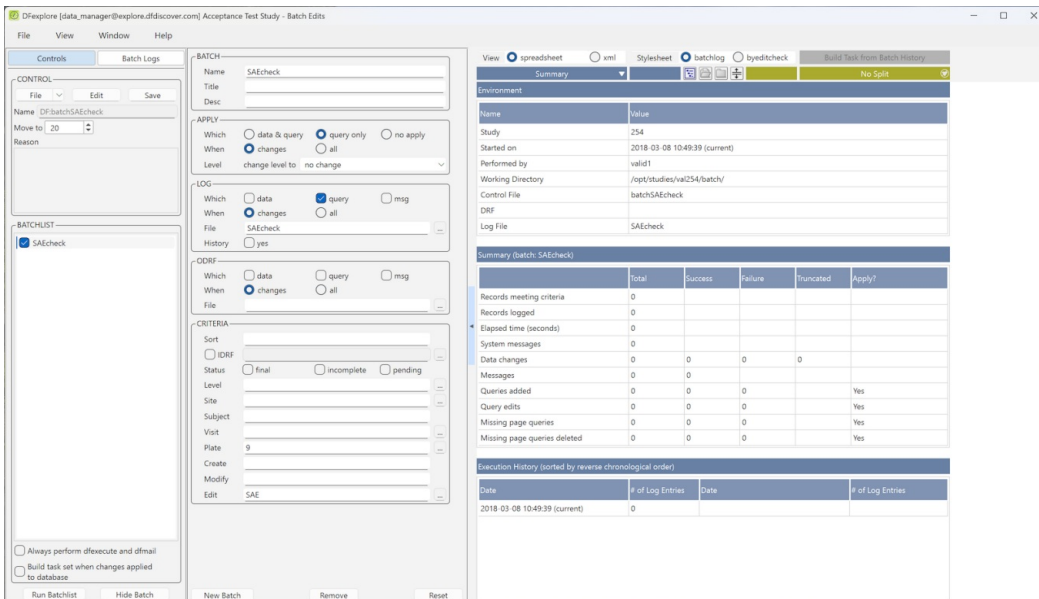
9. Select **View** > **Batch Edits**. With the **Controls** tab as the current view, click **File** > **Open Control File** from the drop-down list.



10. In the **Open Batch Control File** dialog, select (enable) the **On study server** option to display a list of available control files that are located on the study server for the 254 Acceptance Test Study. Choose **batchSAEcheck** from the list and click **OK** to load the control file.



11. Click **Show Batch** to ensure the settings are as shown below. Click **Hide Batch** to hide the settings.



NOTE: The batchSAEcheck.xml control file applies a query to **Is This A Serious Event** field on plate 009 when the response to this field is inconsistent with the value in the **Intensity** field of the same plate.

- Click **Run Batchlist** to run the current batch program. Enter the Username and Password of the current user, click **OK**.

- From the **Summary** drop-down list, choose the item identified as '(current)'.

Summary (batch: SAEcheck)	Total	Success	Failure	Truncated	Apply?
Records meeting criteria	2				
Records logged	1				
Elapsed time (seconds)	0				
System messages	0			0	
Data changes	0	0	0	0	
Messages	0	0			
Queries added	1	1	0		Yes
Query edits	0	0	0		Yes
Missing page queries	0	0	0		Yes
Missing page queries deleted	0	0	0		Yes

- Double-click the entry to be taken to **Data View**.

- The **Intensity** field becomes the current field. Verify that Intensity has a value of 4 with the query count '2' displaying on the field widget and the field is blue. Continue tabbing through the fields until the field **Is This A Serious Event?** has the focus. Confirm that the 'No' box is marked for this field.

- Return back to the **Intensity** field by using **Shift + Tab** keys. With the focus on **Intensity**, examine the details in the **Query** window, and confirm that the batch edit check with the category **Monitor** has been added to this field.

Query Monitor (externi) [Icons]

**Category:** Monitor (external, correction)  
**Detail:** The severity intensity is greater than 3, but the question 'Is This A Serious Event?' is answered 'No'. This is inconsistent with the study protocol. Please review.  
**Note:** (none)  
**Status:** Outstanding (New, in report and sent)

NOTE: The query list is presented in accordance with the query sort order defined in [Module 3.9 Create user-defined query category codes](#).

17. Double-click **Site 99 - Hospital #99** entry to close all subject binders.

## Use a data expression to retrieve specific subject information

- Still in **Data View**, determine which subjects have had adverse events. Do this by selecting **Select** > **By Data Fields** to open the **Select by Data Fields** window. In the dialog, set:
  - Mode = View**
  - Plate = 5**
  - Level = 1-4**

Do not select any Status check box.

- Click **Expression** [Icon] to open the **Expression Editor** dialog.

Field	Name	Description	Type
1	1:DFSTATUS	Record Status	choice (code)
2	2:DFVALID	Validation Level	choice (code)
3	3:DFRASTER	Image ID	string
4	4:DFSTUDY	Study Number	number
5	5:DFPLATE	Plate Number	number
6	6:FUPVISITNUM	Follow-up Month	choice (code)
7	7:SUBJID	Patient Number	number
8	8:PINIT	Patient Initials	string
9	9:VISDAT	Visit Date	date
10	10:SBP1	Blood Pressure: Reading 1 systolic	number
11	11:DBP1	Blood Pressure: Reading 1 diastolic	number
12	12:SBP2	Blood Pressure: Reading 2 systolic	number
13	13:DBP2	Blood Pressure: Reading 2 diastolic	number
14	14:BPARM	Blood Pressure: Arm	choice (code)
15	15:WTKG	Weight (kg)	number
16	16:WTLB	Weight (lbs)	number
17	17:DAPERFR	Study Med: Did patient return study med?	choice (code)
18	18:DADESCR	Study Med: Not returned, Explain	string
19	19:DAREFIDR	Study Med: Meds returned, Med Code #	number

**Symbols**

- (
- )
- == equals
- != not equal
- ~ contains
- !~ not contains
- >= greater equal
- > greater
- <= less equal

**Codes**

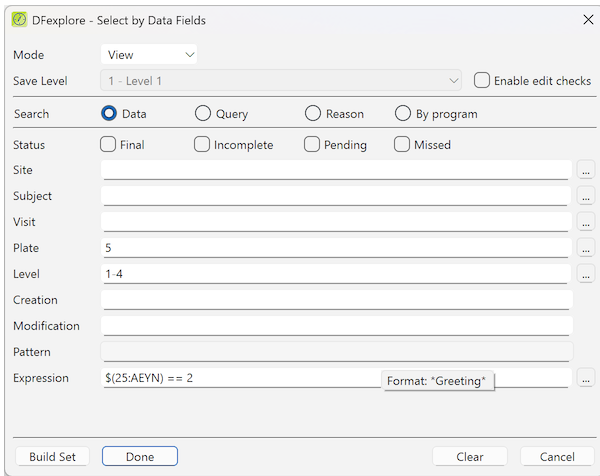
- 0 missed
- 1 final
- 2 incomplete
- 3 pending

**Functions**

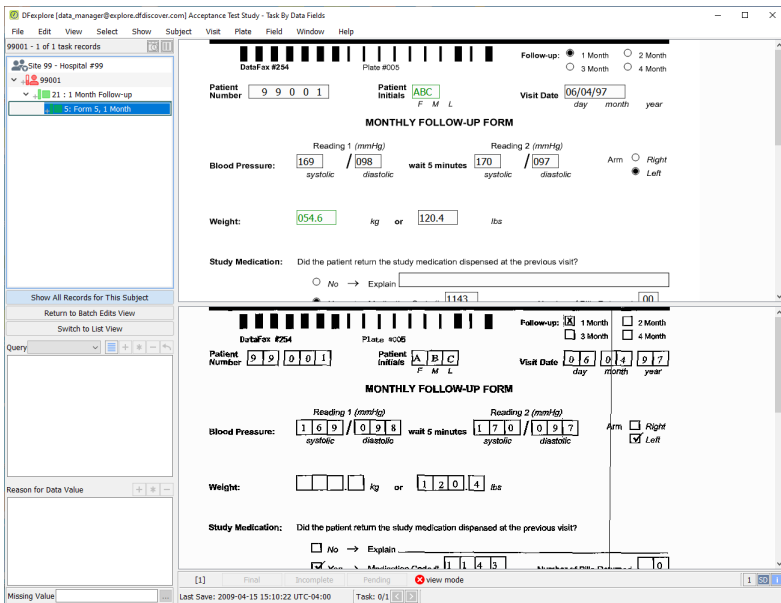
- concat (s1, s2)
- day (n)
- decimal (n)
- field (s, n)

Buttons: Reset, OK, Cancel

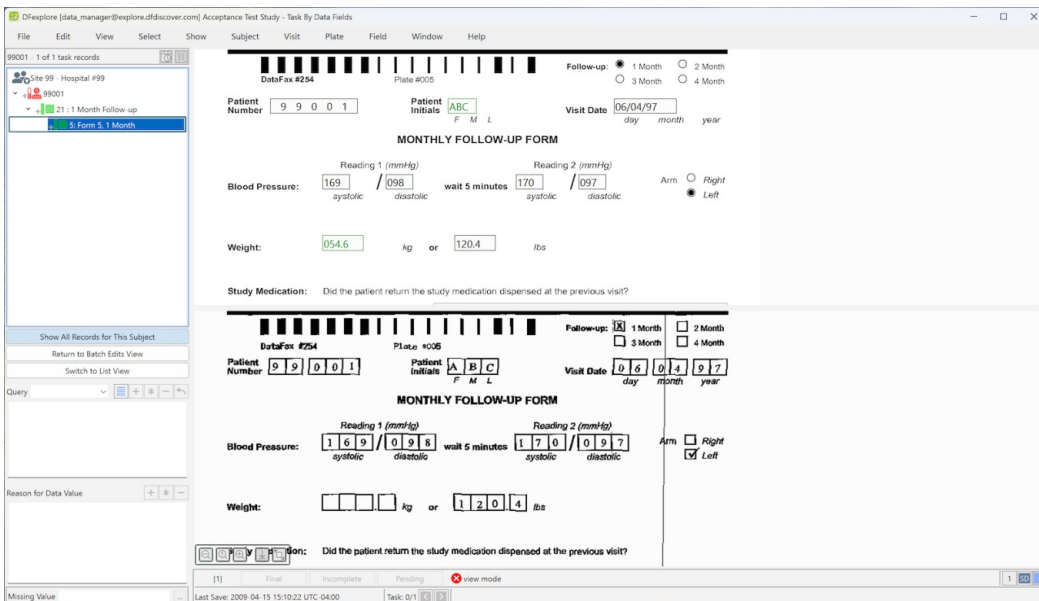
- Do the following to build an expression that searches for the occurrence of adverse events: In the **Expression Editor**, select **25:AEYN** from **Fields**. From the **Symbols** list choose **== equals**. From the **Codes** list choose **2 Yes**. Click **OK** to add the expression to the Expression field in the **Select by Data Fields** retrieval dialog.



4. Click **Done** to apply the settings. Click **OK** in the confirmation dialog to retrieve the 1 data record that matches the expression and retrieval criteria.



5. Scroll down the current page for Subject **99001** to locate the adverse event question. Confirm that the **Yes** choice has been entered in response to the question **Did the patient report any adverse events since the last visit?**
6. Confirm that a corresponding adverse event report has been submitted for Subject **99001**. Do this by clicking **Show All Records for This Subject** located below the subject binder list. Scroll through the list of assessments until the **1011 : Adverse Event 1 Page 1** entry. Select the list entry for **9: Form 9, AE Report 011**.



Use cross-plate data criteria to retrieve specific subject information

1. Select **Select** > **All Records** to release all task records from the previous test. Click **OK** in the resulting confirmation dialog. Select **Select** > **By Data Fields** to open the **Select by Data Fields** dialog, click **Clear** to clear the previous retrieval specifications and reset the dialog.

2. The steps that follow search for and retrieve all patients in the database that are  $\geq 50$  years old, male and have a history of diabetes. Within the **Select by Data Fields** dialog, click **...** next to the **Subject** field to open the **Subjects** dialog and then choose **ALL** as the value for **Select subjects that match**.

3. Begin by building an expression for the first subject criterion of Age. Working in the **Criterion #1** block, specify **Visit** = 0. Click **...** next to **Plate** to open a list of study plates. In the list double-click entry **001 - Blood Pressure Screening Visits** to populate the **Plate** field (plate 1 contains the Age data field). Click **...** next to **Field** to get a listing of all fields defined on the selected plate 1. Double-click **AGE** to populate the Field specification. Using the **Condition** drop-down menu, choose  **$\geq$  greater than or equal** to assign a retrieval Condition. Finally, specify **50** in **Value**.

- Click **Retrieve** to retrieve the number of subjects that match the specified Age criterion. Click **Add** to add a new criterion block in preparation for the specification of the 2nd retrieval criterion (Male).
- Build an expression for the second subject criterion of Male. Working in the **Criterion #2** block, specify **Visit = 0**. Click **...** next to **Plate** to open a list of study plates. In the list double-click entry **001 - Blood Pressure Screening Visits** to populate the **Plate** field (plate 1 contains the Sex data field). Click **...** next to **Field** to get a listing of all fields defined on plate 1. Double-click entry **SEX** to populate the Field specification. Using the Condition drop-down menu, choose **== equal** to assign a retrieval Condition. Select **1 Male** from the **Value** pull-down.

DFExplore - Subjects

Select subjects that match ALL of these criteria.

Criterion #1

Status ... Level ...

Visit ... 0

Plate ... 001 - Blood Pressure Screening Visits

Field ... 9 - AGE (Age (years))

Condition ... >= greater than or equal

Value ... 50

Retrieve 5 subjects match Clear

Criterion #2

Status ... Level ...

Visit ... 0

Plate ... 001 - Blood Pressure Screening Visits

Field ... 10 - SEX (Sex)

Condition ... == equal

Value ... 1

Retrieve Clear

Add Remove Done Cancel

- Click **Retrieve** to retrieve the number of subjects that match the specified Sex criteria. Click **Add** to add a new criteria block in preparation for the specification of the 3rd retrieval criteria (history of diabetes).
- Build an expression for the third subject criterion of diabetes history. Working in the **Criterion #3** block, specify **Visit = 1**. Click **...** next to the **Plate** label to open a list of study plates. In the list double-click entry **003 - Medical History** to populate **Plate** (plate 3 contains the Diabetes data field). Click **...** next to **Field** to get a listing of all fields defined on the selected plate 3. Double-click entry **MHOCCUR (7. Diabetes: N/Y)** to populate the Field specification. Using the Condition drop-down menu, choose **== equal** to assign a retrieval Condition. Select **2 Yes** from the **Value** pull-down.

DFExplore - Subjects

Select subjects that match ALL of these criteria.

Criterion #1

Status ... Level ...

Visit ... 0

Plate ... 001 - Blood Pressure Screening Visits

Field ... 9 - AGE (Age (years))

Condition ... >= greater than or equal

Value ... 50

Retrieve 5 subjects match Clear

Criterion #2

Status ... Level ...

Visit ... 0

Plate ... 001 - Blood Pressure Screening Visits

Field ... 10 - SEX (Sex)

Condition ... == equal

Value ... 1

Retrieve 3 subjects match Clear

Criterion #3

Status ... Level ...

Visit ... 1

Plate ... 003 - Medical History

Field ... 46 - MHOCCUR (7. Diabetes: N/Y)

Condition ... == equal

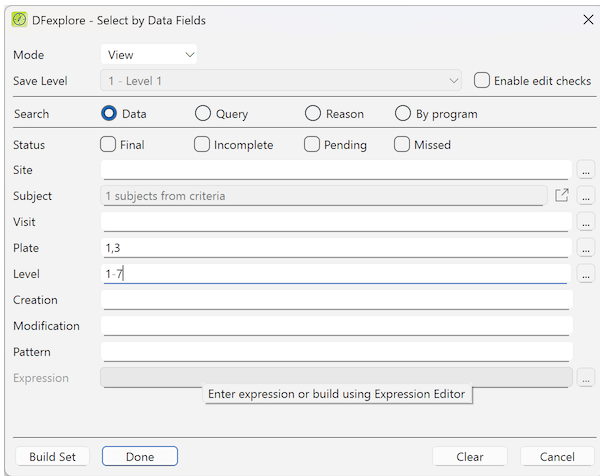
Value ... 2

Retrieve Clear

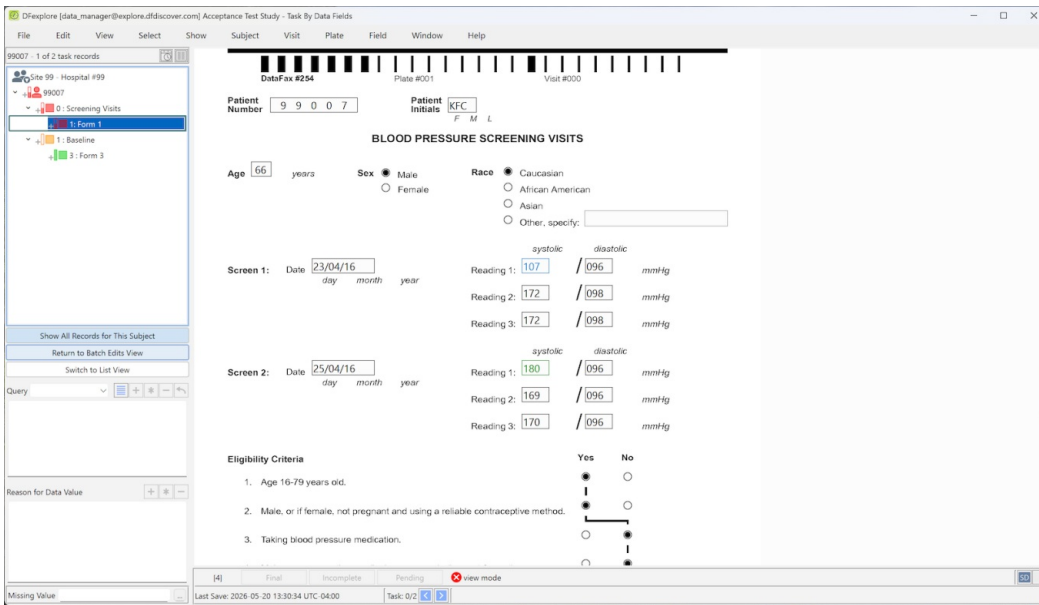
Add Remove Done Cancel

- Click **Retrieve** to retrieve the number of subjects that match the specified Diabetes history criteria. Click **Done** to find the subjects that match ALL three of the criteria specifications and close the Subject Criteria dialog.
- In the **Select by Data Fields** dialog, set:
  - Mode = View
  - Plate = 1,3
  - Level = 1-7

to retrieve only those plates having the Age, Sex and Diabetes history information for the matching subjects.



10. Click **Done** in the dialog to apply the settings. Click **OK** in the confirmation dialog to retrieve the 2 data records that match the subject, plate and level specifications.



11. With **0 : Screening Visits, 1 : Form 1** for Subject **99004** as the active page, locate the **Age** and **Sex** fields. Confirm that the subject's **Age**  $\geq$  **50** and **Sex=****male**.

12. Select **1 : Baseline, 3 : Form 3** for Subject **99004** to open the Medical History page. Scroll down the page to locate the **7. Diabetes** field. Confirm that this field is checked 'Yes'.

13. Select **File** > **Exit** to close Data View and exit **DFExplore**.

## End Module 11. Data Review

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 11. Data Review.

## Module 12. External Query Reports

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - data\_coordinator : data\_coordinator
- (Optional) - SMS or email 2-factor authentication setup with data\_coordinator

NOTE: For configuration of 2-factor authentication, see [Module 1\(Installation & Initialization\) test step 6](#) for details on configuring accounts with 2-factor authentication

**Client Tools Used:** DFATK, DFExplore

**Purpose:** This module tests the use of various built-in DFdiscover reports to perform integrity checks and query operations on the database, including automated query creation, creation of query reports, verifying data status with reports, as well as testing for proper authorization of report execution based on user permissions. Exporting of generated reports will be tested, as well as testing DFdiscover's ability to send outbound messages through the server's email service. Results from reports are also compared to study data to ensure consistency.

## Tests & Requirements

1. Obtain database query metrics and details using Status and List Views to review all outstanding queries prior to query report creation.
2. Run database integrity check report DF\_XXkeys to export all key fields and visit dates from required plates in the database.
3. Use Data View to check, and if necessary correct, illegal visit dates by retrieving the problems keys identified by DF\_XXkeys.
4. Execute DF\_QCupdate to update the query database and lock all records for query report generation.
5. Execute DF\_QCreports to create a standard, 3-part external query report for a study site.
6. Confirm the status of external queries following query report creation.
7. Execute DF\_QCstatus to verify that a new query report was created by listing all reports in the QC/NEW directory.
8. Execute DF\_QCview to display the newly created query report.
9. Execute DF\_QCprint to print the query report from the QC/NEW directory.
10. Comparing several examples from the printed query report against their corresponding queries in the study database.
11. Execute DF\_QCfax to email the query report to a valid email account.
12. Verify the status of the queries in the sent report.

Estimate of Time Required: 40 Minutes

## Begin Module 12. External Query Reports

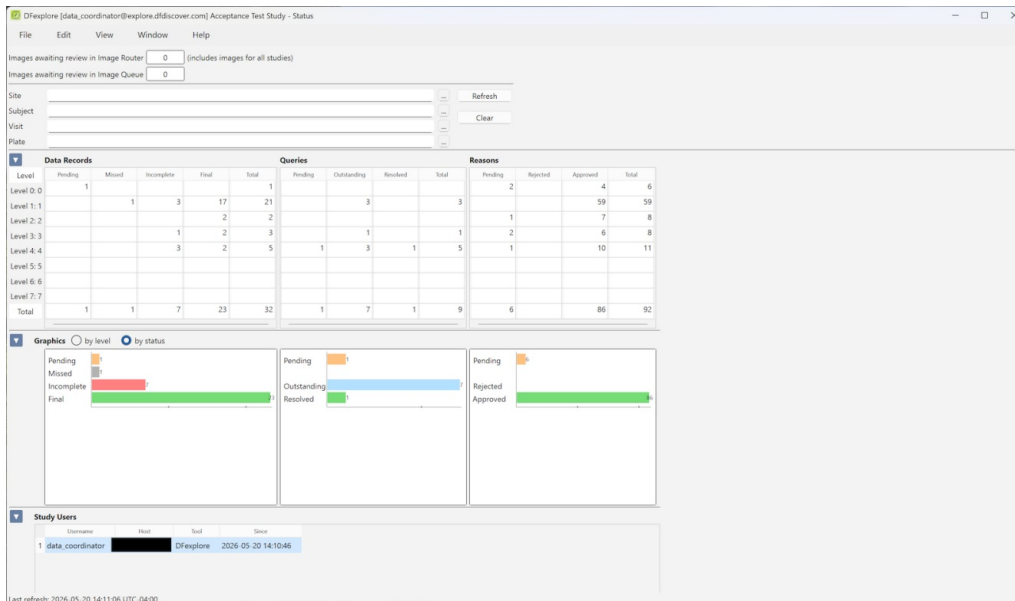
1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **12. External Query Reports** followed by **Begin** to begin this module.

## Obtain database query metrics and details using Status and List Views to review all outstanding queries prior to query report creation

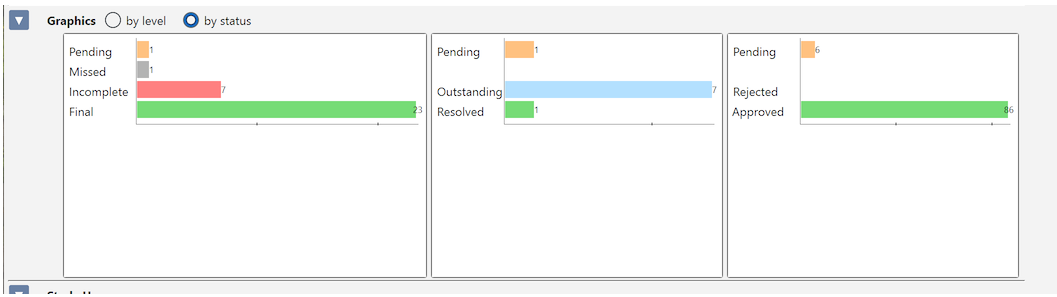
1. Start **DFExplore**, login as user `data_coordinator` and choose **254 Acceptance Test Study** as described in ["How to start DFExplore"](#)

**NOTE:** If `data_coordinator` has been set up for 2-factor authentication with Azure SMS, you may need to wait for a 1-time code to arrive at the phone number as defined in **DFAdmin**.

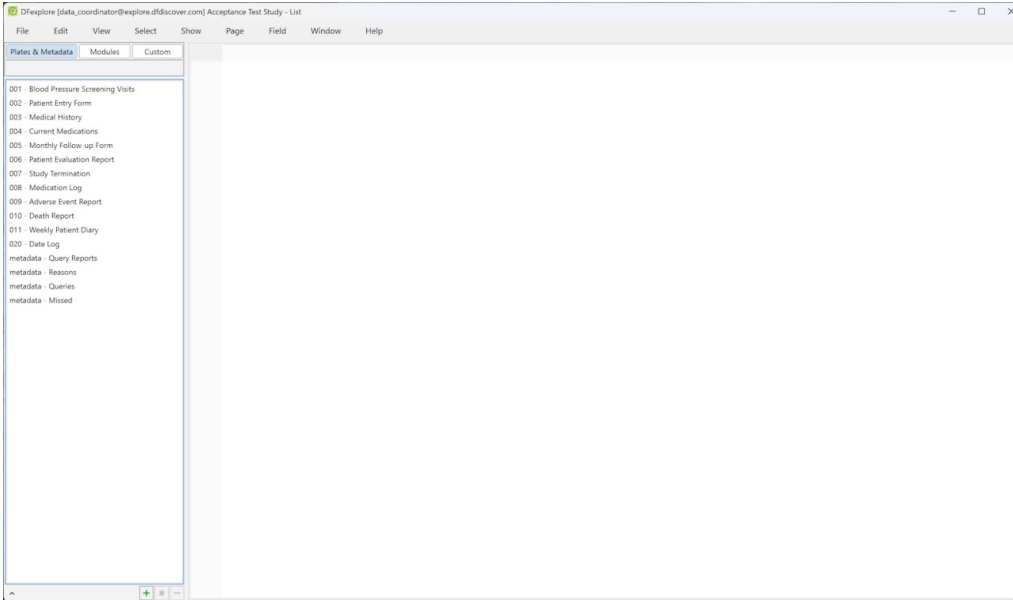
2. Select **View** > **Status**. Examine the **Queries** table to view the status and count of all queries in the database.



3. Open the **Graphics** section and select the toggle button for **by status**. Confirm the count of Pending and Outstanding queries.



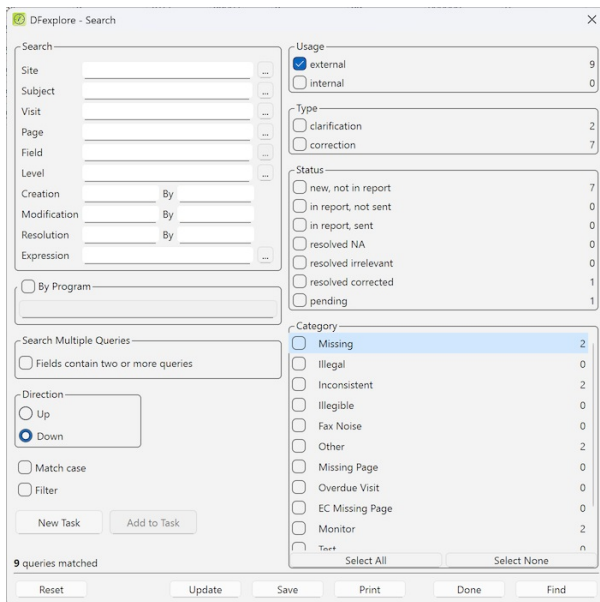
4. Select **View** > **List**. Select the **Plates & Metadata** tab.



5. Click **metadata - Queries** to display information about database queries.

	DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	DFSEQ	DFPID	DFQCFLD	DFQCCTR	DFQCRPT	DFQCPAGE	DFQCREFLY
99001,0,1   1 of 9	1	3	0000,0000000	254	1	0	99001	28	99	000000	0	
001 - Blood Pressure Screening Visits	2	1	0000,0000000	254	2	1	99001	14	99	000000	0	
002 - Patient Entry Form	3	1	0000,0000000	254	2	1	99002	8	99	000000	0	
003 - Medical History	4	1	0000,0000000	254	9	1011	99002	9	99	000000	0	
004 - Current Medications	5	1	0000,0000000	254	9	1011	99002	9	99	000000	0	
005 - Monthly Follow up Form	6	0	0000,0000000	254	9	1011	99002	16	99	000000	0	
006 - Patient Evaluation Report	7	5	0000,0000000	254	9	1011	99002	16	99	000000	0	valid1 16/10/30 14:23:13 Fever will be removed to a d
007 - Study Termination	8	1	0000,0000000	254	2	1	99004	13	99	000000	0	
008 - Medication Log	9	1	0000,0000000	254	1	0	99007	11	99	000000	0	

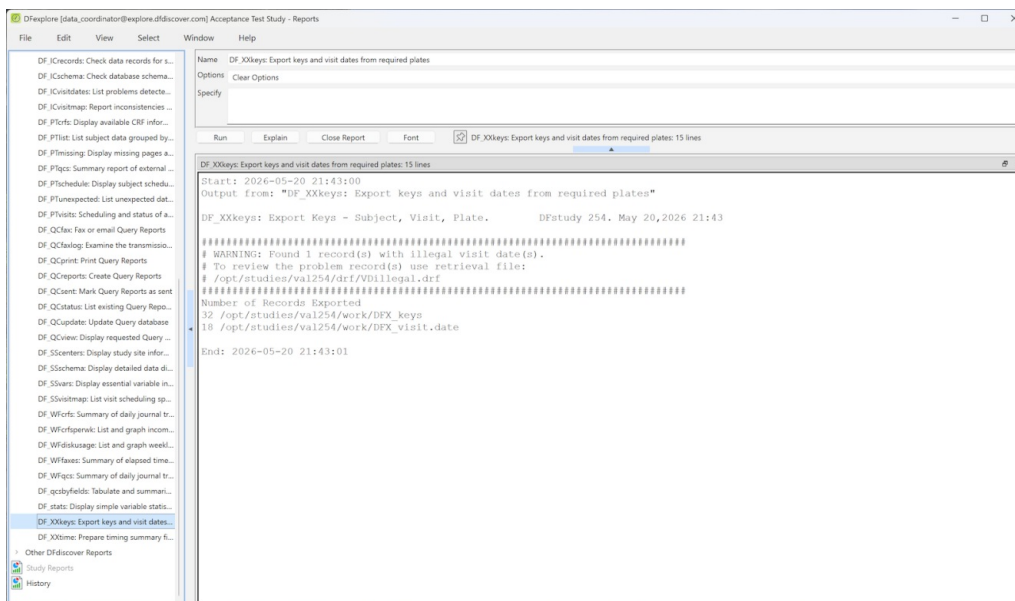
6. Select **Select** > **Search** to specify query search criteria. In the search dialog, check (enable) the **Usage = external**, click **Update** to update the dialog with details and a count of external queries.



7. Click **Done** to close the Search dialog.

## Run database integrity check report DF\_XXkeys to export all key fields and visit dates from required plates in the database

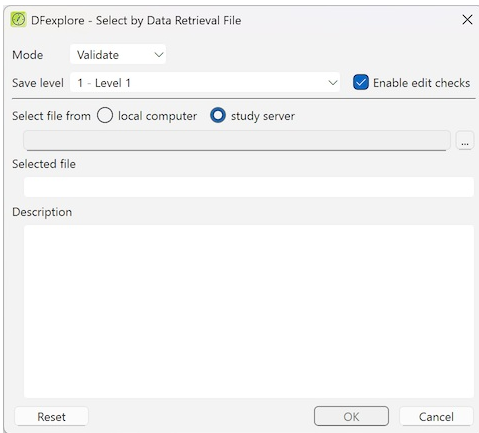
1. Select **View** > **Reports** to change from List View to **Reports** View.
2. Double-click DFdiscover Reports then Legacy Reports list by clicking **>**. Select the report DF\_XXkeys from the list. Click **Explain** to view a detailed description of the report. As options do not exist for this report, click **Run** to execute DF\_XXkeys.



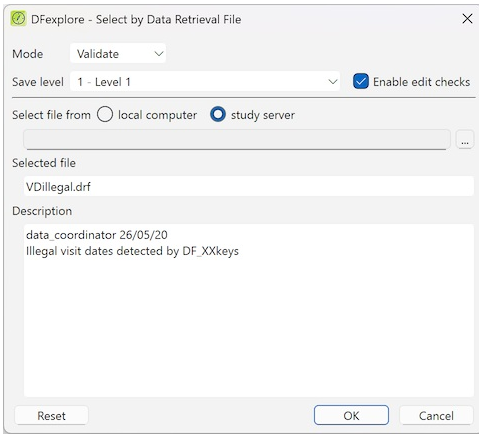
3. In **Step 2**, DF\_XXkeys detected an illegal visit date. As indicated by the message in the reports window, a data retrieval file called VDIllegal.drf was created. This file contains the plate(s) on which the illegal visit date was detected, and can be reviewed and edited in **Data** View. Click **Close Report** to close the report output window. Select **View** > **Data** to change to **Data** View.

## Use Data View to check, and if necessary correct, illegal visit dates by retrieving the problems keys identified by DF\_XXkeys

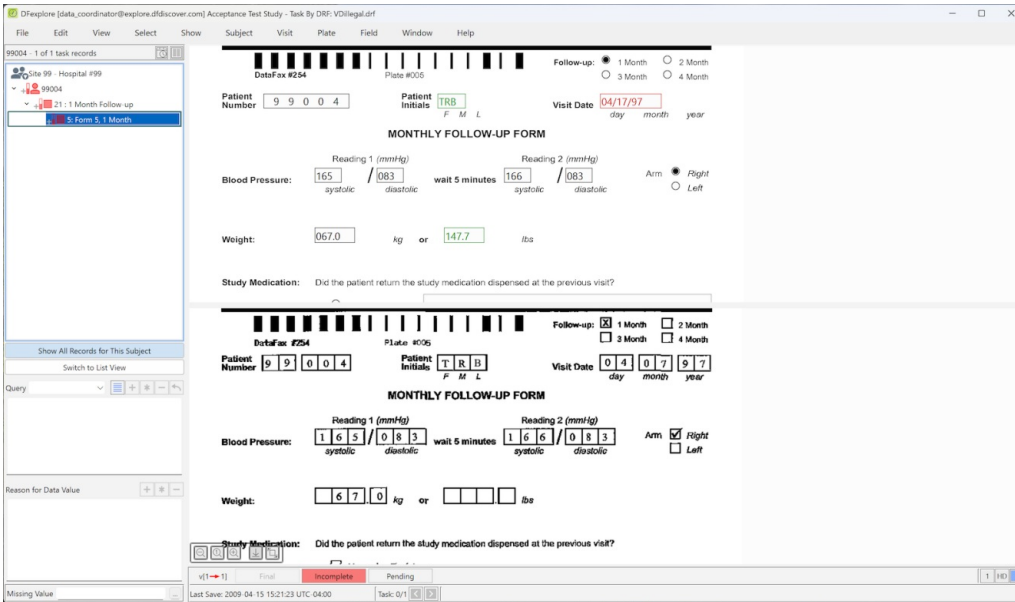
1. To review the data retrieval file created in **Step 2**, select **Select** > **By Data Retrieval File**. In the retrieval file dialog, set:
  - o **Mode** = Validate
  - o **Save level** = 1 - Level 1
  - o Check (enable) **Enable edit checks**
  - o **Select file from** = study server



2. To locate the data retrieval file VDIllegal.drf, click [...] next to **Select file from**. In the file selection dialog, choose the file VDIllegal.drf, then click [OK].



3. Click [OK] in the dialog. Click [OK] in the resulting confirmation dialog to retrieve all data records having illegal visit dates.

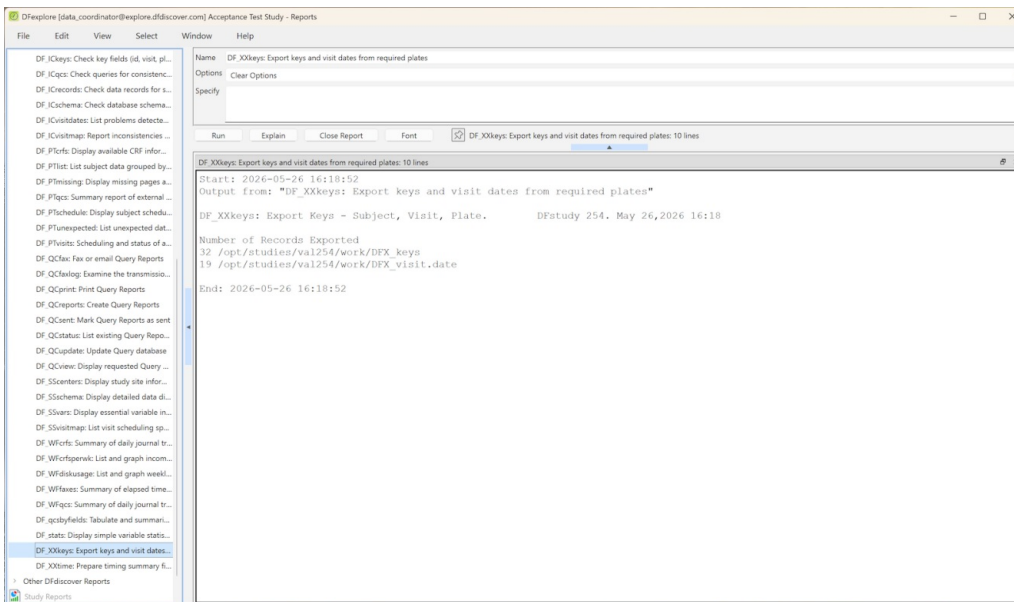


4. Click anywhere in the page to make it active for data entry. Starting with the **Follow-up** choice field, press [Tab] to advance to the **Visit Date**. The Visit Date value has been entered as 04/17/97 (an illegal date), rather than 04/07/97 as shown on the CRF image. Enter the correct date and press [Tab] to exit the field.

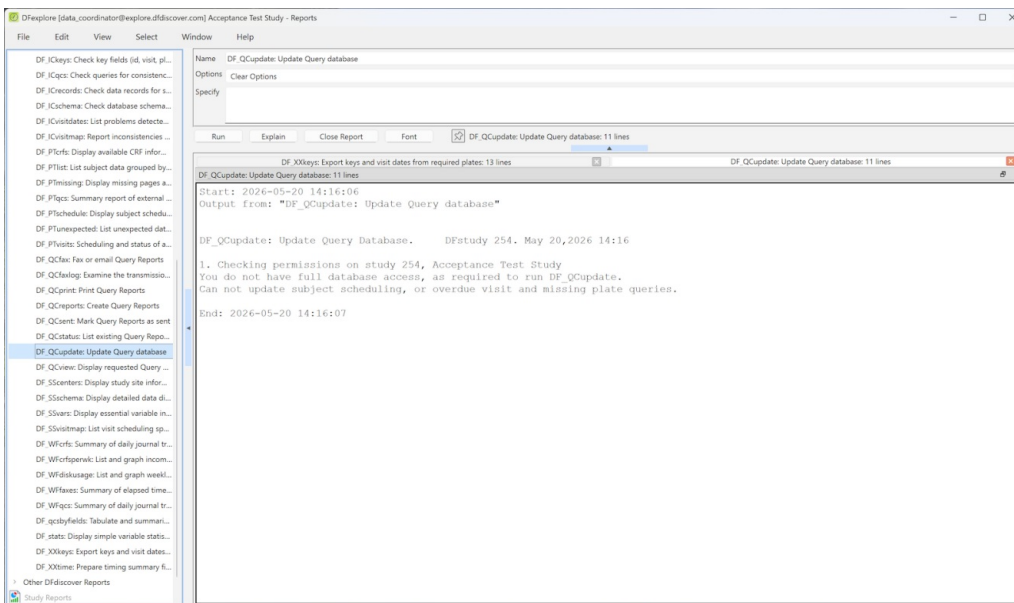
5. As problems no longer exist on the corrected page, the page can be saved with a status of **Final**. Click [Final] to save the page.

## Execute DF\_QCupdate to update the query database and lock all records for query report generation

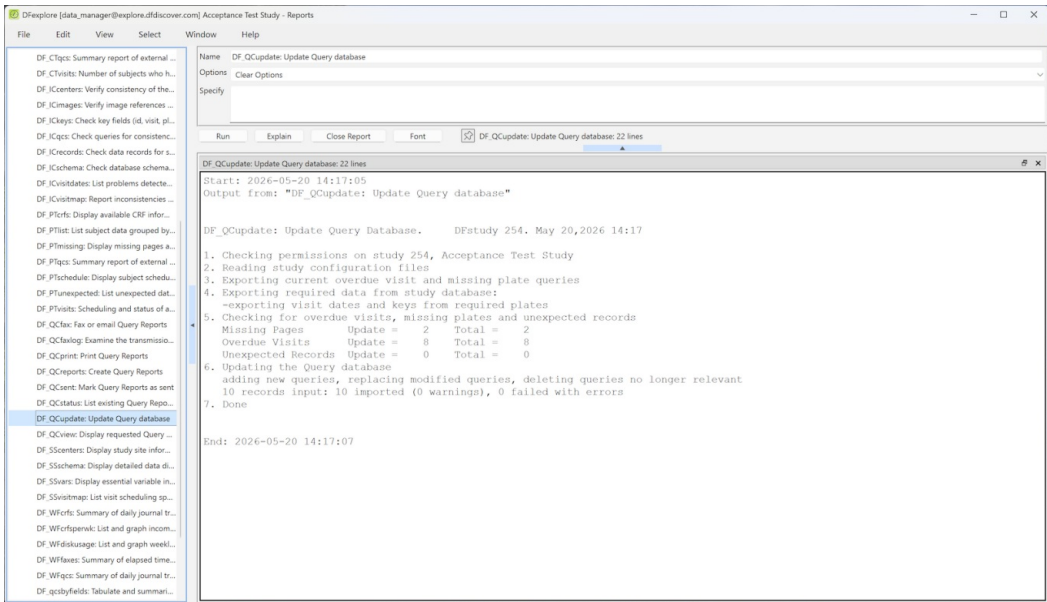
1. Select [Select] > [All Records], click [OK]. Select [View] > [Reports] to return to **Reports** View. Again choose the report name DF\_XXkeys from the list and click [Run]. Confirm that the output no longer reports illegal visit dates.



2. Choose **DF\_QCupdate** from the list of **Legacy Reports** and click **Explain** to view a report description. Do not enter any options in the **Specify** field and click **Run** to update the Query database.

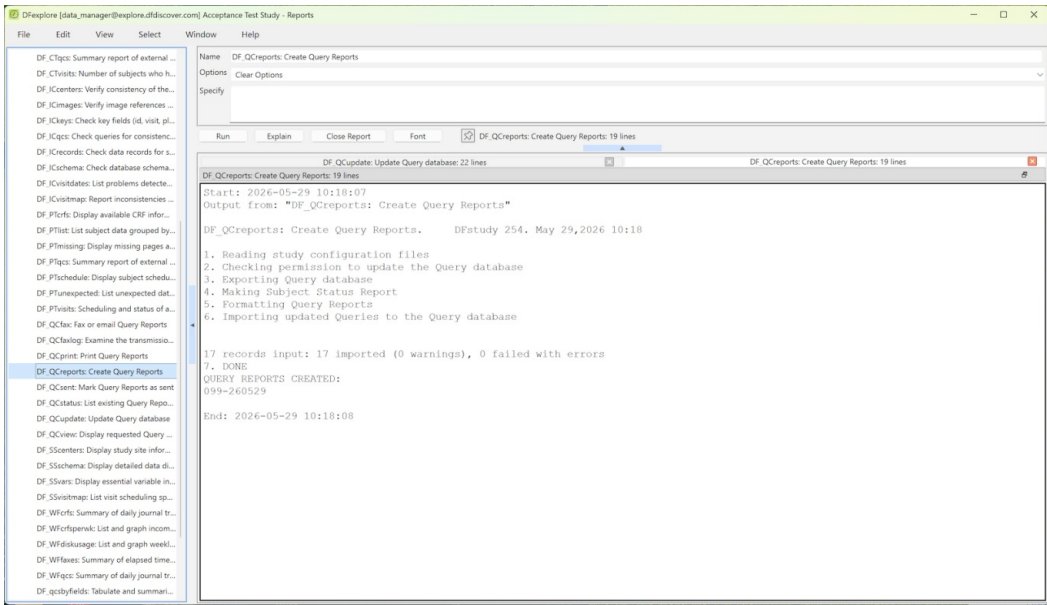


3. A user requires unrestricted permissions to execute **DF\_QCupdate**. As user `data_coordinator` is restricted to database Modify and Write levels of 0-4 (as set in [Module 1. Installation and Initialization](#)), it is not possible to execute **DF\_QCupdate** successfully. Click **File** > **Exit** to close **DFExplore**.
4. Start **DFExplore**, login as user `data_manager` as described in ["Obtain database query metrics and details using Status and List Views to review all outstanding queries prior to query report creation."](#)
5. Select **View** > **Reports**.
6. Double-click **DFdiscover Reports**, expand **Legacy Reports** by clicking **⌵**. Choose **DF\_QCupdate** from the list of reports. Click **Run** to execute **DF\_QCupdate** with the correct permissions.



## Execute DF\_QCreports to create a standard, 3-part external query report for a study site

1. Choose **DF\_QCreports** from the list of **Legacy Reports** and click **Explain** to view a report description.
2. Do not enter any options in the Specify field so that a complete query report is generated. Click **Run** to execute **DF\_QCreports**.

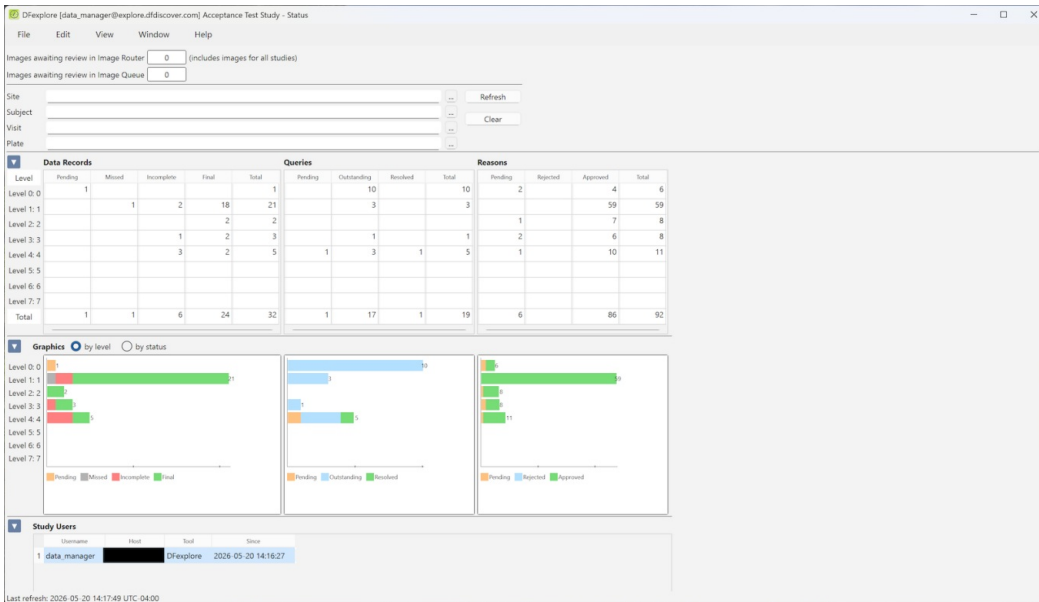


**NOTE:** **DFdiscover** report numbers are comprised of a site number followed by the date of report creation (as yy/mm/dd). The two are separated by a hyphen. Your Query report has been created for Site 99 and the date of creation is the date on which DF\_QCreports was executed (i.e.today).

3. To print the output, select **File** > **Print**. In the **Print** dialog, the Printer Name field contains the name of your printer. Click **Print**. Keep this printout to reference the query report number in "[Comparing several examples from the printed query report against their corresponding queries in the study database.](#)". Click **Close Report** to close the report output window.

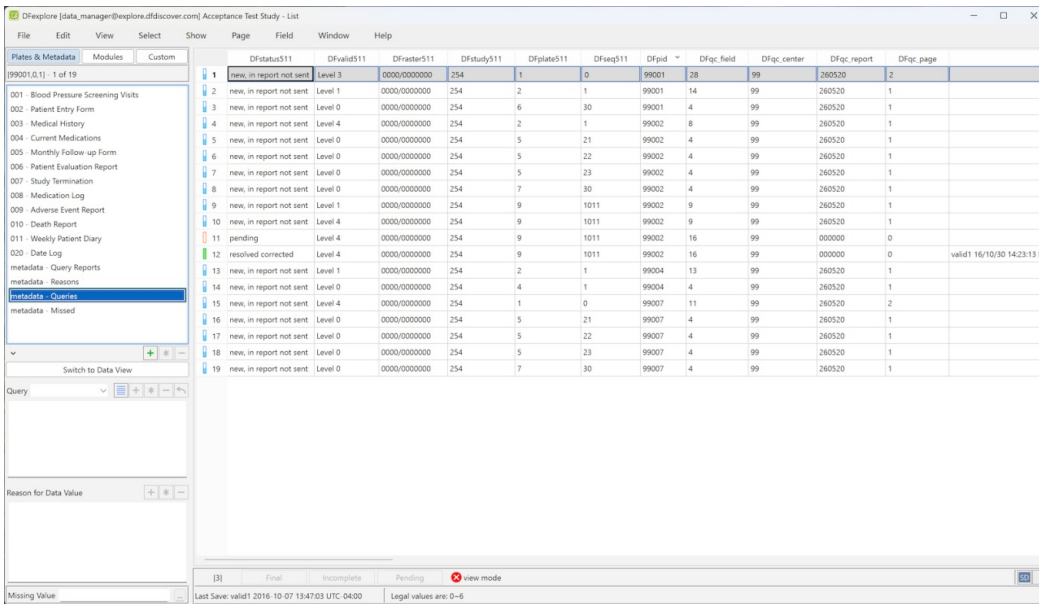
## Confirm the status of external queries following query report creation

1. Select **View** > **Status**. Click **Refresh** to update the database counts. Examine the **Queries** table to view the status and count of all queries in the database.

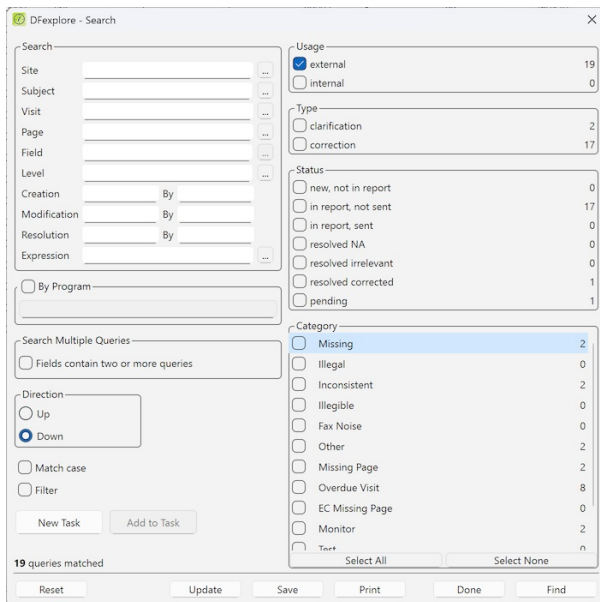


NOTE: The counts in the Queries table have changed because the query database has been updated by the running of the report **DF\_QCupdate** in "[Execute DF\\_QCupdate to update the query database and lock all records for query report generation.](#)". If applicable, DF\_QCupdate will create new queries for missing pages and overdue visits based on the study scheduling information present in the study visit map files.

2. Select **View** > **List**.
3. Click **metadata - Queries** to display information about database queries.



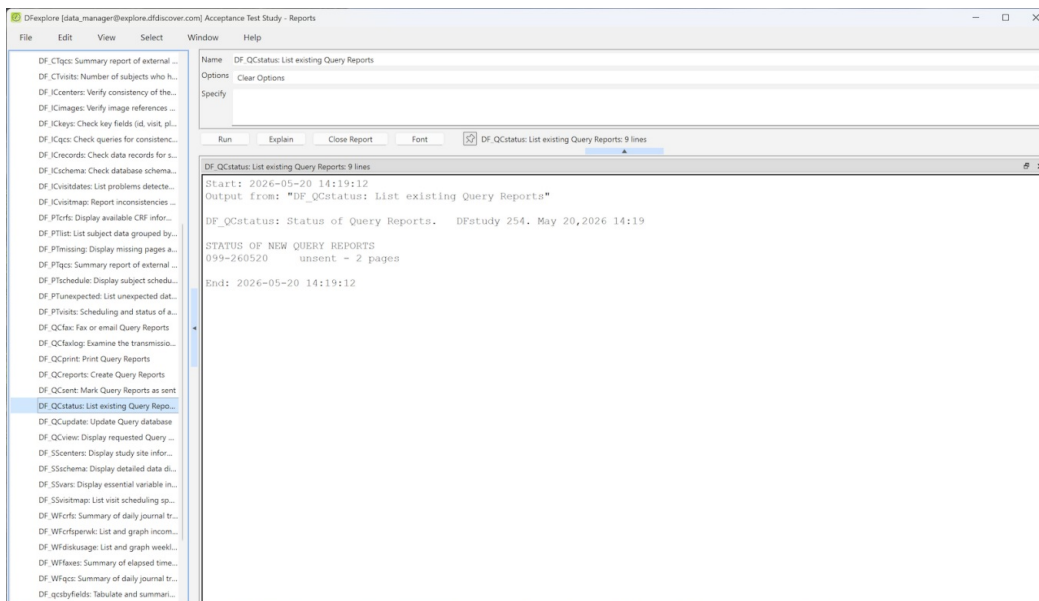
4. Select **Select** > **Search** to specify a set of query search criteria. In the resulting search dialog, select (enable) **Usage = External** and click **Update** to update the dialog with details and a count of external queries.



5. Click **Done** to close the dialog.

## Execute DF\_QCstatus to verify that a new query report was created by listing all reports in the QC/NEW directory

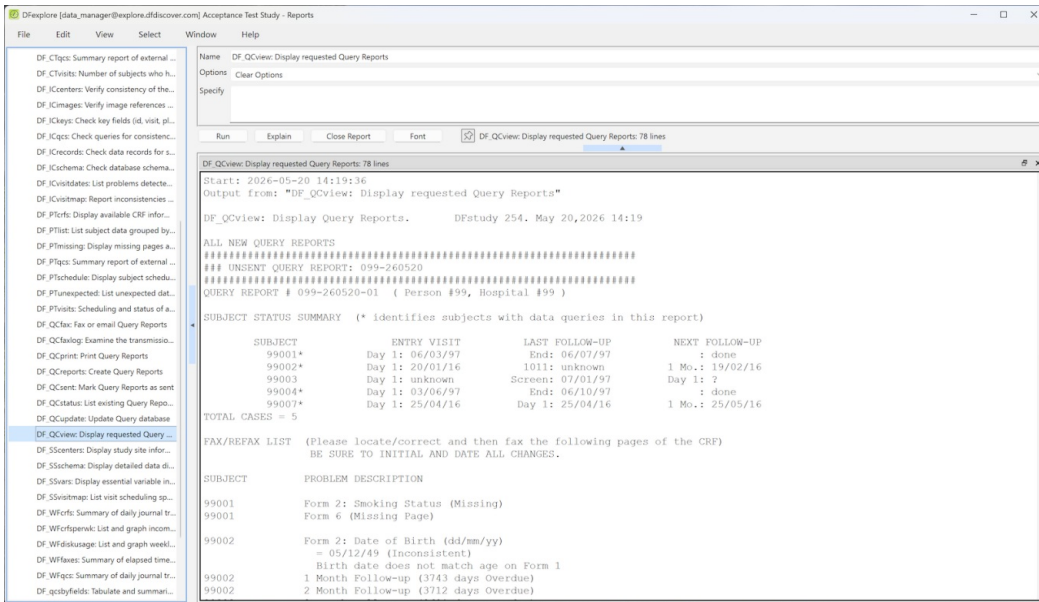
1. Select **View** > **Reports**.
2. From the list of **Legacy Reports**, select **DF\_QCstatus** and click **Explain** to view a report description. As a query report was created but not sent, click **Run** to obtain the status of all query reports currently in the study QC/NEW directory.



3. Click **Close Report** to close the report output window.

## Execute DF\_QCview to display the newly created query report

1. To display the query report created for **Site 099 - Hospital #99**, choose **DF\_QCview**. Click **Explain** to view a description of the report. As the report for **Site 099 - Hospital #99** still resides in the QC/NEW directory (it has not yet been sent to the site), click **Run** to execute **DF\_QCview**.



2. Click **Close Report** to close the report output window.

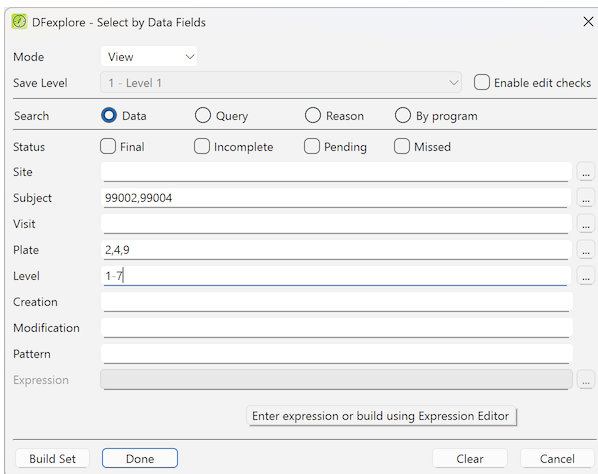
## Execute DF\_QCprint to print the query report from the QC/NEW directory

1. If your Dfdiscover server is connected to a printer, print a copy of the query report for **Site 099 - Hospital #99** by choosing **DF\_QCprint**. Click **Explain** to view a description of the report. Enter -u number of your query report in the **Specify** field. Click **Run** to execute **DF\_QCprint**. If your Dfdiscover server is not connected to a printer, you can instead you can choose to print the query report displayed in the **DF\_QCview** output window from the previous step or keep a copy of the text to use with the following steps.
2. Click **Close Report** to close the report output window.

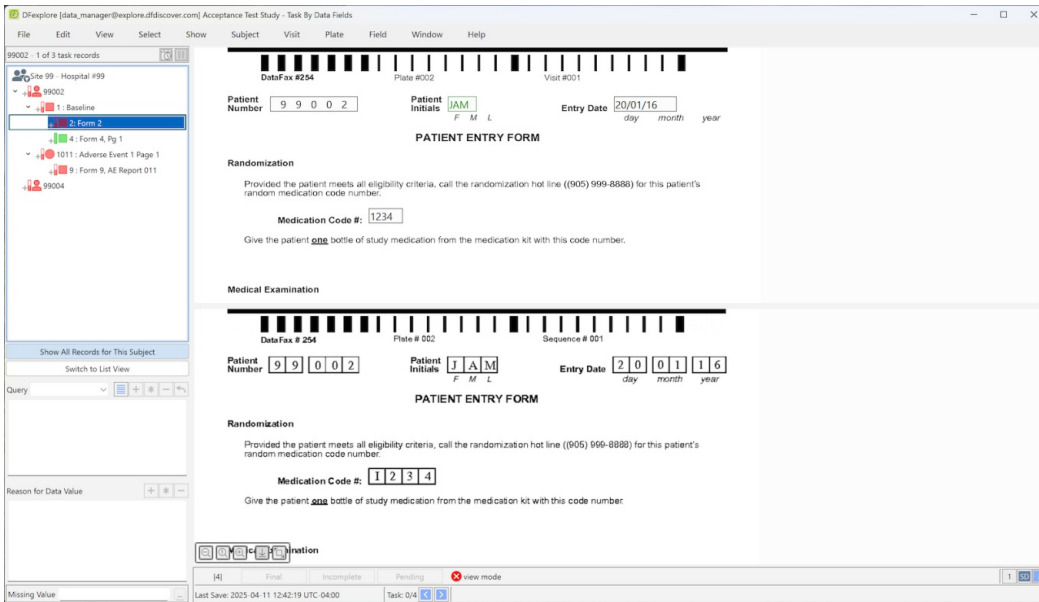
## Comparing several examples from the printed query report against their corresponding queries in the study database

**NOTE:** For this test you will need to reference the query report printed in ["Execute DF\\_QCprint to print the query report from the QC/NEW directory."](#) to verify the information contained in the report against the study database. Three examples of queries will be verified in this test. You may choose to check the remainder of the queries yourself.

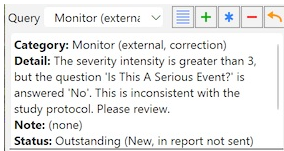
1. In the printed query report, find the entries for patients 99002 and 99004 in the FAX/REFAX section of the report. For patient 99002, locate the entry for Form 9, AE Report 011 having multiple queries in the Intensity field. For patient 99004, locate the entry for Form Number 4, Pg 1 having the category "Missing Page". Form 4 corresponds to Plate 4 in the database. Now locate the entry for Form Number 2, having the category "Pulse beats/minute (Missing)". Form 2 corresponds to Plate 2 in the database.
2. Select **View** > **Data**.
3. Select **Select** > **By Data Fields**. In the dialog, set:
  - o **Mode** = View.
  - o **Subject** = 99002,99004
  - o **Plate** = 2,4,9
  - o **Level** = 1-7



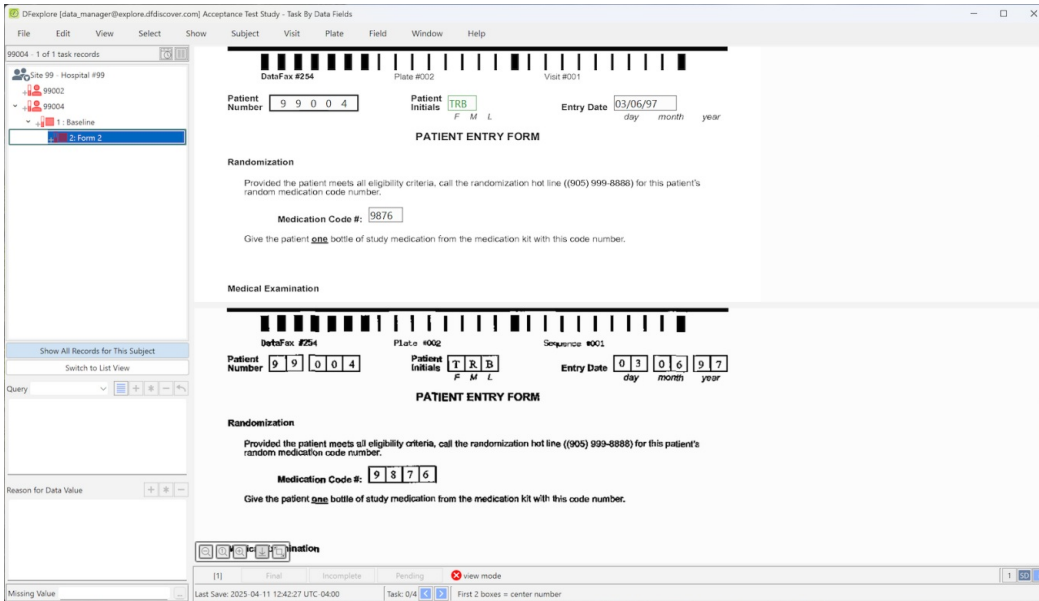
4. Click **Done** then **OK** to apply the record selection criteria and retrieve the applicable pages.



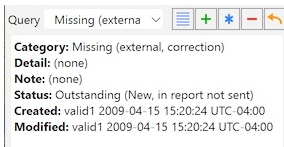
- Highlight the **9: Form 9, AE Report 011** page in the record list. Press **[Tab]** to advance through the fields until **Intensity** becomes the current field. Confirm that this field is blue and the query count "2" is displayed on the field widget. Examine the **Query** window to view the details of the field queries. Verify that the information in the **Query** window is consistent with the corresponding printed Query report.



- In the record list, double-click entry for subject **99004**.



- Press **[Tab]** to advance to the **Pulse** field to make it the current field. Verify that the field is blue (indicating that an outstanding query exists). Examine the **Query** to view the details of the query.



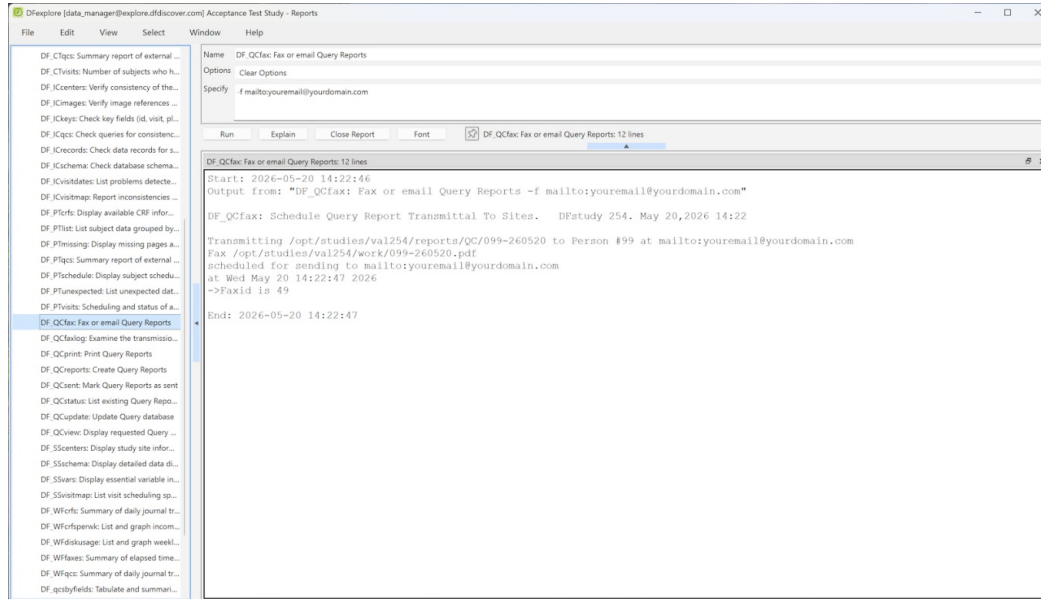
- Examine the record list for the entry for **Form 4** for Subject **99004** (identified as a **Missing Page** on the query report).
- Select **[Select] > [All Records]**. Confirm the settings:
  - Mode = Modify
  - Save level= 1 - Level 1

- Enable (check) edit checks

Click **OK** to release the task set and display all records in the database.

## Execute DF\_QCfax to email the query report to a valid email account

1. Select **View** > **Reports**.
2. Choose **DF\_QCfax** and click **Explain** to view a description of the report. Send the query report generated in ["Execute DF\\_QCreports to create a standard, 3-part external query report for a study site."](#) to a valid email address. Enter -f mailto:user@localhost in the **Specify** field, substituting "user@localhost" with your email address as defined on your mail system. Click **Run** to execute **DF\_QCfax**.



3. Wait for several minutes, then check the recipient's email account for the arrival of the query report emailed in [Step 2](#). Once the report has arrived, click **Close Report** to close the report output window.

## Verify the status of the queries in the sent report

1. Select **View** > **Status**. Click **Refresh** to update the database counts. Examine the **Queries** table to view the status and count of all queries in the database.

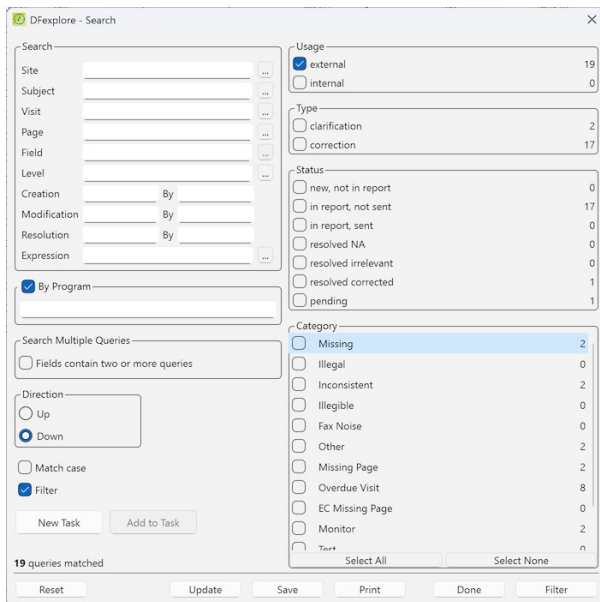
NOTE: The counts in the **Queries** table are the same as those in [Step 1](#) because queries have been sent to the site but not resolved.

2. Select **View** > **List**, and click **Plates & Metadata**.
3. Select **File** > **Preferences**. Click **List View** to expand that sub-panel and enable **Label for Display coded field as**. Click **OK**. To display information about database queries, click **metadata - Queries**.

The screenshot shows the Dfexplorer application window with the 'Queries' table displayed in List View. The table has columns for ID, status, level, Dfvalue, Dfraster, Dfstudy, Dfplate, Dfseq, Dfpid, Dfqc field, Dfqc center, Dfqc report, and Dfqc page. The table contains 19 rows of data, with various statuses like 'new, in report not sent', 'pending', and 'resolved corrected'. The 'metadata - Queries' sub-panel is expanded in the left sidebar.

ID	Status	Level	Dfvalue	Dfraster	Dfstudy	Dfplate	Dfseq	Dfpid	Dfqc field	Dfqc center	Dfqc report	Dfqc page
1	new, in report not sent	Level 3	0000/0000000	254	1	0	99001	28	99	260520	2	
2	new, in report not sent	Level 1	0000/0000000	254	2	1	99001	14	99	260520	1	
3	new, in report not sent	Level 0	0000/0000000	254	6	30	99001	4	99	260520	1	
4	new, in report not sent	Level 4	0000/0000000	254	2	1	99002	8	99	260520	1	
5	new, in report not sent	Level 0	0000/0000000	254	5	21	99002	4	99	260520	1	
6	new, in report not sent	Level 0	0000/0000000	254	5	22	99002	4	99	260520	1	
7	new, in report not sent	Level 0	0000/0000000	254	5	23	99002	4	99	260520	1	
8	new, in report not sent	Level 0	0000/0000000	254	7	30	99002	4	99	260520	1	
9	new, in report not sent	Level 1	0000/0000000	254	9	1011	99002	9	99	260520	1	
10	new, in report not sent	Level 4	0000/0000000	254	9	1011	99002	9	99	260520	1	
11	pending	Level 4	0000/0000000	254	9	1011	99002	16	99	000000	0	
12	resolved corrected	Level 4	0000/0000000	254	9	1011	99002	16	99	000000	0	valid 16/10/30 14:23:13 Fe
13	new, in report not sent	Level 1	0000/0000000	254	2	1	99004	13	99	260520	1	
14	new, in report not sent	Level 0	0000/0000000	254	4	1	99004	4	99	260520	1	
15	new, in report not sent	Level 4	0000/0000000	254	1	0	99007	11	99	260520	2	
16	new, in report not sent	Level 0	0000/0000000	254	5	21	99007	4	99	260520	1	
17	new, in report not sent	Level 0	0000/0000000	254	5	22	99007	4	99	260520	1	
18	new, in report not sent	Level 0	0000/0000000	254	5	23	99007	4	99	260520	1	
19	new, in report not sent	Level 0	0000/0000000	254	7	30	99007	4	99	260520	1	

4. Select **Select** > **Search** to specify a set of query search criteria. In the resulting search dialog, select (enable) **Usage = external**. Click **Update** to update the dialog with details and a count of external queries.



5. Click **[Done]** to close the Search dialog.
6. Select **[File]** > **[Exit]** to close and exit **DFExplore**.

## End Module 12. External Query Reports

- Return to the **DFATK** application. Click **[End]** to confirm successful completion of Module 12. External Query Reports.

## Module 13. Replying to EDC Queries, eSignatures

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
  - site\_invest : site\_investigator
- Email address configured for site\_monitor
- (Optional) SMS or email 2-factor authentication configuration for site\_invest

NOTE: For configuration of 2-factor authentication, see [Module 1\(Installation & Initialization\) test step 6](#) for details on configuring accounts with 2-factor authentication

**Client Tools Used:** DFATK, DFExplore, DFsetup

**Purpose:** This module tests replying to EDC queries within **DFExplore**. Furthermore, it serves as the primary test for **DFExplore**'s eSignature module, testing the application, removal and re-application of eSignatures.

### Tests & Requirements

1. Determine a count of outstanding/outstanding queries in Status View.
2. Review outstanding queries in Queries View.
3. Using EDC, locate and reply to outstanding clarification queries.
4. Add an Electronic Signature (eSign) to a set of completed subject records.
5. Verify removal and re-application of eSignatures.

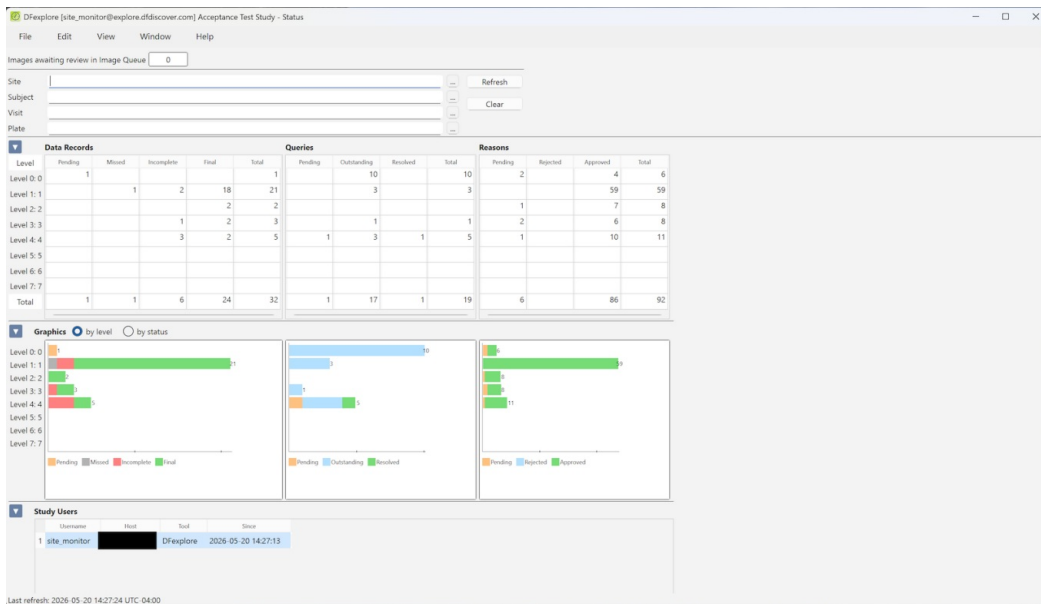
Estimate of Time Required: 30 Minutes

## Begin Module 13. Replying to EDC Queries, eSignatures

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#) .
2. Click **[13. Replying to EDC Queries]** followed by **[Begin]** to begin this module.

### Determine a count of outstanding queries in Status View

1. Start **DFExplore**, login as site\_monitor and choose **254 Acceptance Test Study** as described in "[How to start DFExplore](#)".
2. Select **[View]** > **[Status]**. Examine the **Queries** table to view the status and count of all queries.



3. Locate the **Outstanding** column that displays a count of 17 in the Total row. Double-click 17 to retrieve the records containing the 17 outstanding queries.

4. In the Database Status task Specification dialog set:

- o **Mode = Validate**
- o **Save level = 1 - Level 1**
- o Check (enable) **Enable Edit checks**
- o **Search queries and open check (enable) Queries View?**

Click **Yes** to display a dialog confirming the retrieval. In the confirmation dialog, click **OK** to open **Queries View**.

Site / Subject	Visit / Page	Field / Category	Status & Replies
99001	Screening Visits : Form 1	5. Patient has signed informed consent => Yes (DFter) Detail: We have not received this patient's informed consent form. Please send it by fax or email without delay.	Outstanding (New, in report and sent) Modified by: valid1 2016-10-07 13:47:03 UTC: 04:00
99001	Baseline : Form 2	Smoking Status => Blank (Missing)	Outstanding (New, in report and sent) Modified by: valid1 2009-04-15 15:08:54 UTC: 04:00
99001	Study Termination : Form 6	Missing Page	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00
99002	Baseline : Form 2	Date of Birth (dd/mm/yy) => 05/12/49 (Inconsistent) Detail: Birth date does not match age on Form 1	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:33:36 UTC: 04:00
99002	1 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00
99002	2 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00
99002	3 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00
99002	Study Termination	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: Intensity => 4 (Monitor) Detail: The severity intensity is greater than 3, but the question 'Is This A Serious Event?' is answered 'No'. This is inconsistent with the study protocol. Please review.	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:44:59 UTC: 04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: Intensity => 4 (Clinical QC) Detail: This severity intensity is greater than 3. Please update the value once further information is available.	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:32:58 UTC: 04:00
99004	Baseline : Form 2	Pulse beats/minute : (Missing)	Outstanding (New, in report and sent) Modified by: valid1 2009-04-15 15:20:24 UTC: 04:00
99004	Baseline : Form 4, Pg 1	Missing Page	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00
99007	Screening Visits : Form 1	Screen 1: Reading 1 systolic => 107 (Inconsistent) Detail: This value is inconsistent with all other BP	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:38:40 UTC: 04:00
99007	1 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00
99007	2 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00
99007	3 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00
99007	Study Termination	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC: 04:00

## Review outstanding queries in Queries View

1. Select **Show** > **Outstanding Queries** to verify that you are seeing only outstanding queries for subjects in **Site 99 - Hospital #99**.

Site / Subject	Visit / Page	Field / Category	Status & Replies
Site 99 - Hospital #...	Screening Visits : Form 1	5. Patient has signed informed consent => Yes (Other) Detail: We have not received this patient's informed consent form. Please send it by fax or email without delay.	Outstanding (New, in report and sent) Modified by: valid1 2016-10-07 13:47:03 UTC-04:00
99001	Baseline : Form 2	Smoking Status => blank (Missing)	Outstanding (New, in report and sent) Modified by: valid1 2009-04-15 15:08:54 UTC-04:00
99001	Study Termination : Form 6	Missing Page	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	Baseline : Form 2	Date of Birth (dd/mm/yy) => 05/12/49 (Inconsistent) Detail: Birth date does not match age on Form 1	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:35:36 UTC-04:00
99002	1 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	2 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	3 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	Study Termination	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: Intensity => 4 (Monitor) Detail: The severity intensity is greater than 3, but the question 'Is This A Serious Event?' is answered 'No'. This is inconsistent with the study protocol. Please review.	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:32:58 UTC-04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: Intensity => 4 (Clinical QC) Detail: This severity intensity is greater than 3. Please update the value once further information is available.	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:32:58 UTC-04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: AE Description => Nausea, ??? and fever (Other) Detail: Please clarify the word after nausea. The description provided through email is 'Nausea vomit and fever'. Do you mean Vomit instead? Note: The correction was provided via email.	Pending Modified by: valid1 2016-11-01 17:32:58 UTC-04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: AE Description => Nausea, ??? and fever (Monitor) Detail: Nausea and fever are two separate adverse events and should be reported in different CRFs. Please review.	Resolved corrected Resolved by: valid1 2016-11-01 17:32:25 UTC-04:00 Replied by: valid1 2016-10-30 14:23:13 UTC-04:00 Reply Text: Fever will be removed to a different Adverse Event Report form.
99004	Baseline : Form 2	Pulse beats/minute : (Missing)	Outstanding (New, in report and sent) Modified by: valid1 2009-04-15 15:20:24 UTC-04:00
99004	Baseline : Form 4, Pg 1	Missing Page	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99007	Screening Visits : Form 1	Screen 1: Reading 1 systolic => 107 (inconsistent) Detail: This value is inconsistent with all other BP readings. Please explain.	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:38:40 UTC-04:00
99007	1 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent)

2. Examine **Queries View** to confirm:

- The **Status & Replies** column displays **Outstanding (New, in report and sent)** for all queries.
- An entry exists for Subject **99001** , Screening Visits Form 1, 5. Patient has signed informed consent.
- An entry exists for Subject **99007** , Screening Visits Form 1, Screen 1 Reading 1 systolic.

Using EDC, locate and reply to outstanding clarification queries

1. Locate the entry for Subject **99001**, **Screening Visits Form 1, 5. Patient has signed informed consent**. Double-click the query to switch to **Data View** and make the queried page and field active. Examine the information present in the **Query** window.

3. Taking blood pressure medication.

4. Major surgery or other medical emergency in the past 6 months.

5. Patient has signed informed consent and agrees to return for monthly follow-up visits.

6. Systolic blood pressure 160-200 mmHg or Diastolic blood pressure 95-100 mmHg on Reading 3 at both Screen 1 and Screen 2.

Patient is Eligible

Once Completed, Please Fax This Form to (#)###-####.

11 November 2014

Date of Birth: 05/12/49      Plate #001      Sequence #000

Patient Number: 99001      Patient Initials: A B C / F M L

**BLOOD PRESSURE SCREENING VISITS**

Age: 60 years      Sex:  Male      Race:  Caucasian  
 African American  
 Asian  
 Other, specify: \_\_\_\_\_

Screen 1: Date: 03/03/17      systolic: 170      diastolic: 96 mmHg  
 day month year      Reading 1:      mmHg

Reading 2: 170 / 98 mmHg

Missing Value:      Last Save: 2016-10-07 13:47:03 UTC-04:00      Task: 0/16      Legal values are: 0,1

2. Select **Field** > **Reply to Query** or click . In the dialog, enter Informed consent was sent to study coordinator by email on March 20. in the **New Reply** field.

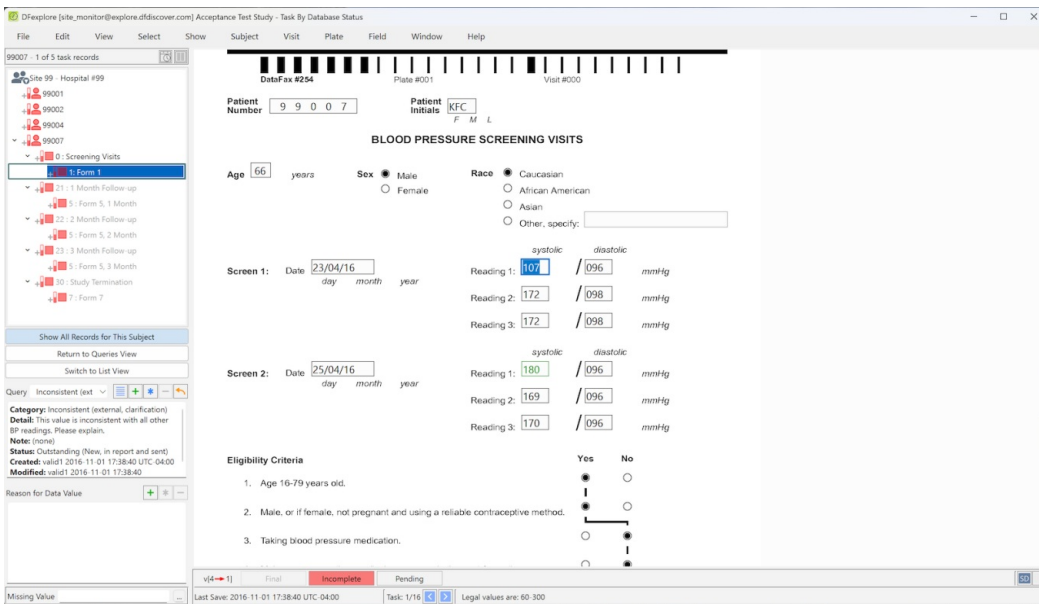
3. Click **OK** to apply the reply to the queried field. Examine the information present in the **Query** window.


4. Do not enter or change data in any of the remaining fields on the current page. Click **Final** to save the current page and the query reply to the database.

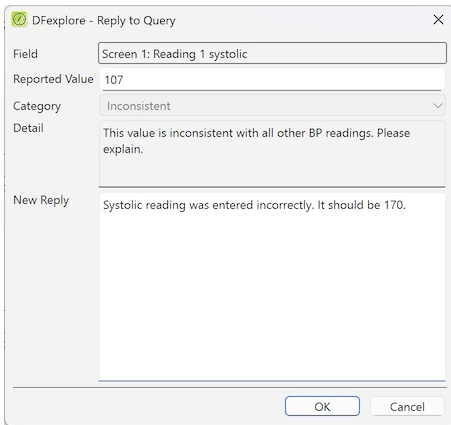
5. From the record list window, click **Return to Queries View**. Examine the list of queries.

Site / Subject	Visit / Page	Field / Category	Status & Replies
99001	Baseline : Form 2	Smoking Status => blank (Missing)	Outstanding (New, in report and sent) Modified by: valid1 2009-04-15 15:08:54 UTC-04:00
99001	Study Termination : Form 6	Missing Page	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	Baseline : Form 2	Date of Birth (dd/mm/yy) => 05/12/49 (inconsistent) Detail: Birth date does not match age on Form 1	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:35:36 UTC-04:00
99002	1 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	2 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	3 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	Study Termination	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: Intensity => 4 (Monitor) Detail: The severity intensity is greater than 3, but the question 'Is This A Serious Event?' is answered 'No'. This is inconsistent with the study protocol. Please review.	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:44:59 UTC-04:00
99002	Adverse Event 1 Page 1 : Form 9, AE Report 011	DESCRIPTION: Intensity => 4 (Clinical QC) Detail: This severity intensity is greater than 3. Please update the value once further information is available.	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:32:58 UTC-04:00
99004	Baseline : Form 2	Pulse beats/minute : (Missing)	Outstanding (New, in report and sent) Modified by: valid1 2009-04-15 15:20:24 UTC-04:00
99004	Baseline : Form 4, Pg 1	Missing Page	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99007	Screening Visits : Form 1	Screen 1: Reading 1 systolic => 107 (inconsistent) Detail: This value is inconsistent with all other BP readings. Please explain.	Outstanding (New, in report and sent) Modified by: valid1 2016-11-01 17:38:40 UTC-04:00
99007	1 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99007	2 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99007	3 Month Follow-up	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00
99007	Study Termination	Overdue Visit	Outstanding (New, in report and sent) Modified by: valid1 2016-11-06 20:42:35 UTC-04:00

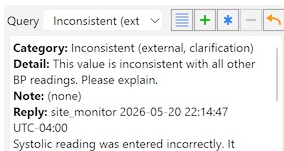
6. Locate the entry for Subject **99007, Screening Visits: Form 1, Screen 1: Reading 1 systolic**. Double-click the systolic blood pressure query to switch to **Data View** and make the queried page and field active. Examine the information present in the **Query** window.



7. Select **Field** > **Reply to Query** or click  in the dialog, enter Systolic reading was entered incorrectly. It should be 170. in the **New Reply** field.



8. Click **OK** in the **Reply to Query** dialog to apply the reply to the queried field. Examine the information present in the **Query** window.



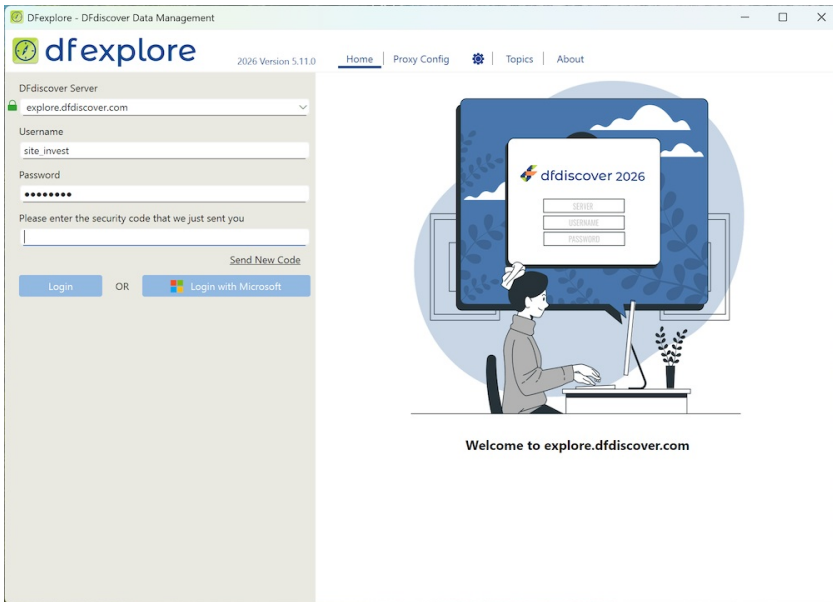
9. Click **Final** to save the current page and the query reply to the database.

10. Select **File** > **Exit** to close and exit **DFExplore**.

## Add an Electronic Signature (eSign) to a set of completed subject records

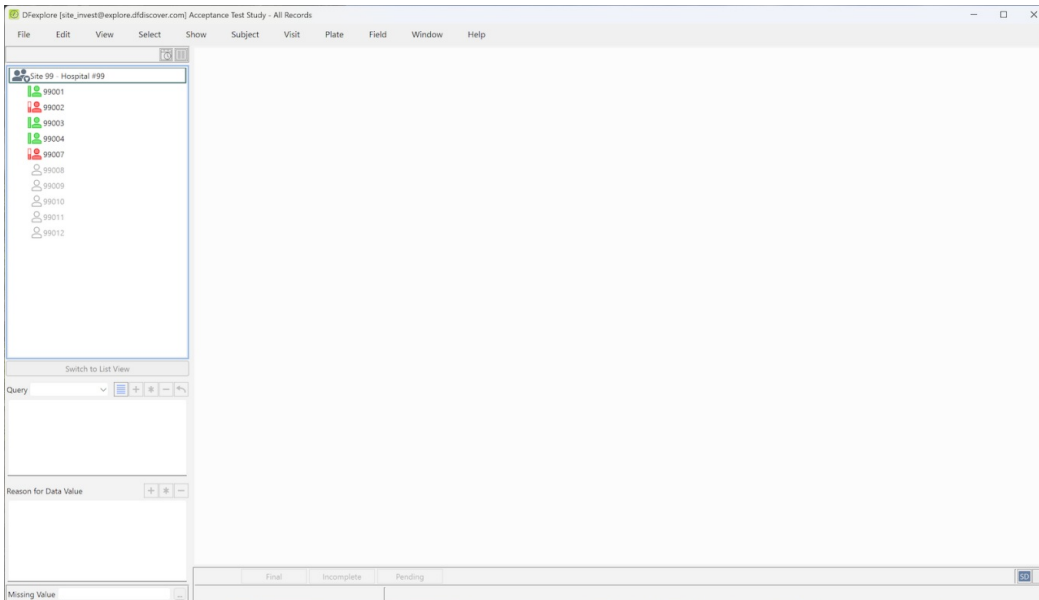
**NOTE:** eSignatures require password permission to be set in the user role at the **DFadmin** level. The Password permission must be granted for the specific eSignature plate.

1. Start **DFExplore**, login as user `site_invest` and open the **254 Acceptance Test Study** as described in (["How to start DFExplore"](#)).
2. As user `site_invest` has 2FA enabled, enter security code received by email or SMS as previously defined.



NOTE: Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address or phone number is required for site\_invest to receive 2FA codes.

3. Select **File** > **Preferences**, click **Background Options** to expand the preferences. Click **Color** > **OK** to apply the changes.



4. Locate subject **99003**, double-click its entry to expand a list of visits for Subject **99003**.
5. Double-click **30 : Study Termination**. Select **7: Form 7** to open a new **STUDY TERMINATION** form.

6. Click anywhere in the screen background to begin data entry. Enter the form data as shown below:

- Press **[Tab]** to advance to the **eSignature Reason** field. This field and the remaining fields on the page are used to capture eSignature reason, name, date and time, respectively. Press **[Tab]**, attempt to enter any name in the **Investigator's Signature** field.
- Press **[Tab]** to advance to the remaining 2 eSignature fields. Again attempt to manually enter data into each of these fields. Press **[Tab]** to exit the last field on the page ( **eSignature Time** ) to make the save buttons active.
- Click **[Final]** to save and eSign the **STUDY TERMINATION** form.

- In the **dfpassword** confirmation dialog enter the user name **site\_invest** and the corresponding password used for login in ["Add an Electronic Signature \(eSign\) to a set of completed subject records."](#) . Click **[Sign]** to apply the electronic signature to the current **STUDY TERMINATION** page.
- In the **DFExplore - eSignature Reason** dialog select **Approved** from the dropdown, click **[OK]**.

12. Examine the 4 eSignature fields at the bottom of the page.

13. Select **File** > **Exit** to close and exit **DFExplore**.

## Verify removal and Re-application of eSignatures

1. Start **DFExplore**, login as user `site_monitor` and open the **254 Acceptance Test Study** as described in ( ["How to start DFExplore"](#) ).

2. Locate subject **99003** , double-click its entry to expand a list of visits for Subject **99003** .

3. Double-click **30 : Study Termination** . Select **7: Form 7** to open the **STUDY TERMINATION** form.

4. Click **2. Last dose of study medication was taken on** field. Select **Field** > **Add Query** or click **+** to open the **Add Query** dialog. In the dialog, set:

- o **Category** = Monitor
- o **Use** = External
- o **Type** = Clarification
- o **Status** = New query
- o Enter Investigator to confirm last dose taken with subject during clinic visit. in the **Note** field.

5. Click **OK** to apply the query.

6. Press **Tab** to advance to the **Unknown** field. Un-check (disable) the checkbox.

99003 - 10 of 15

Site 99 - Hospital #99

99001

99002

99003

0: Screening Visits

1: Baseline

21: 1 Month Follow-up

22: 2 Month Follow-up

23: 3 Month Follow-up

24: 4 Month Follow-up

30: Study Termination

6: Form 6

7: Form 7

30: Form 11

40: Death Report

201: Diary Week 01

31: Medication Log Page 1

1011: Adverse Event 1 Page 1

Switch to List View

Query

Reason for Data Value

Investigator's Signature: site\_investigator

Date: 20/05/26

Approved

14:34:29

Final Incomplete Pending

Last Save: 2026-05-20 14:34:29 UTC-04:00

7. Press **Tab** to advance through the remaining fields on the page until the save buttons become active. Click **Incomplete** to save the page.
8. Select **File** > **Exit** to close and exit **DFExplore**.
9. Start **DFExplore**, login as user `site_invest` and open the **254 Acceptance Test Study** as described in (["How to start DFExplore"](#)).
10. Locate subject **99003**, double-click its entry to expand a list of visits for Subject **99003**.
11. Double-click **30 : Study Termination**. Select **7: Form 7** to open the **STUDY TERMINATION** form.

99003 - 2 of 2

Site 99 - Hospital #99

99001

99002

99003

99004

99007

99008

99009

99010

99011

99012

0: Screening Visits

30: Study Termination

7: Form 7

Switch to List View

Query

Reason for Data Value

Investigator's Signature: blank

Date: / /

Resolved Corrected

Last Save: 2026-05-20 14:36:01 UTC-04:00

12. Press **Tab** to advance to **2. Last dose of study medication was taken on** field. Select **Field** > **Edit Query** or click **\*** to open the **Edit Query** dialog. Select **Resolved Corrected**. Enter Confirmed date of last medication dose verbally with subject during clinic visit. in the **Note** field.

13. Click **OK** to close the dialog.
14. Enter the **2. Last dose of study medication was taken on date** as 02/06/16 .
15. Press **Tab** to advance to the **eSignature Reason** field. This field and the remaining fields on the page are used to capture eSignature reason, name, date and time, respectively. Press **Tab**, attempt to enter any name in the **Investigator's Signature** field.
16. Press **Tab** to advance to the remaining 2 eSignature fields. Again attempt to manually enter data into each of these fields. Press **Tab** to exit the last field on the page (**eSignature Time**) to make the save buttons active.
17. Click **Final** to save and eSign the **STUDY TERMINATION** form.

18. In the **dfpassword** confirmation dialog enter the user name `site_invest` and the corresponding password used for login in "[Add an Electronic Signature \(eSign\) to a set of completed subject records.](#)". Click **Sign** to apply the electronic signature to the current **STUDY TERMINATION** page.
19. In the **DFexplore - eSignature Reason** dialog select **Reviewed** from the dropdown, click **OK**.

20. Examine the 4 eSignature fields at the bottom of the page.

21. Select **File** > **Exit** to close and exit **DFexplore**.

## End Module 13. Replying to EDC Queries, eSignatures

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 13. Replying to EDC Queries, eSignatures.

## Module 14. Re-submitting Query Corrections

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - site\_monitor : site\_monitor
  - data\_coordinator : data\_coordinator
- Email address configured for site\_monitor
- (Optional) SMS or email 2-factor authentication configuration for data\_coordinator

NOTE: For configuration of 2-factor authentication, see [Module 1 \(Installation & Initialization\) test step 6](#) for details on configuring accounts with 2-factor authentication

**Client Tools Used:** DFATK, DFexplore, DFsend

**Purpose:** This module tests the resolution and update of queries in **DFexplore** from CRF images submitted through **DFsend**.

### Tests & Requirements

- Submit PDF images to DFdiscover.
- Verify that all CRFs have arrived successfully in Image view.
- Retrieve submitted CRFs using **DFexplore** Image View.
- Enter Form 2, Subject 99001, resolve outstanding queries, and save the corrected CRF to the database.
- Enter Form 2, Subject 99002, resolve outstanding queries, and save the corrected CRF to the database.
- Enter Form 4, Subject 99004.
- Enter Form 2, Subject 99004, resolve outstanding queries, and save the corrected CRF to the database.
- Select and resolve a query in a field that has multiple queries.
- Review and approve a pending query reply for Form 1 for Subject 99002.
- Review, correct and approve a pending query reply for Form 1, Subject 99007.
- Confirm query resolution by examining the database status.

Estimate of Time Required: 30 Minutes

### Begin Module 14. Re-submitting Query Corrections

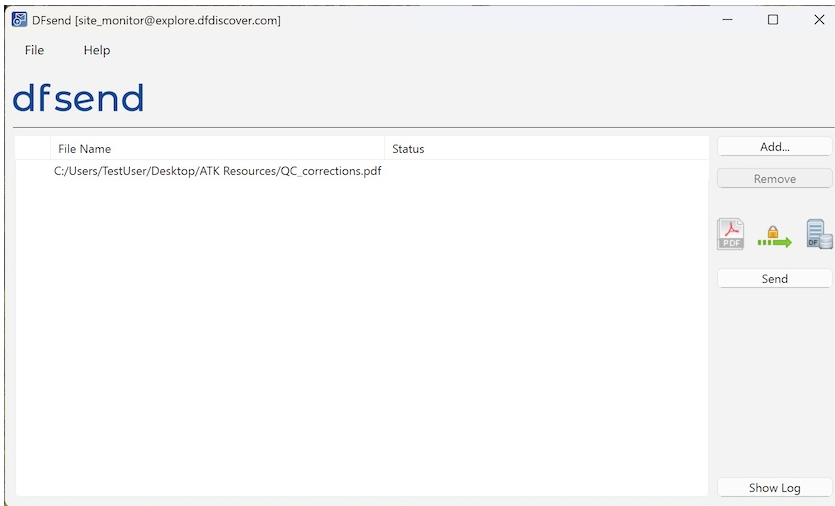
- Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
- Click **14. Re-submitting Query Corrections** followed by **Begin** to begin this module.

### Submit PDF images to DFdiscover

- Click **Send Query Corrections** to email a copy of **QC\_corrections.pdf** to site\_monitor. Clicking more than once will result in multiple pages arriving to your email inbox.

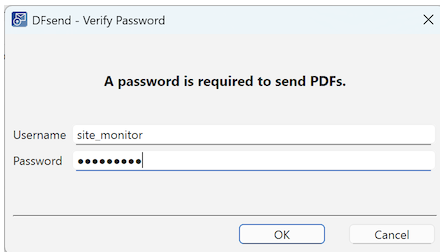
NOTE: Save the **QC\_corrections.pdf** file received via email to your local computer. This file is required to complete the remainder of this module. Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address is required for site\_monitor to receive the module specific PDF files.

- Start **DFsend**, login as user site\_monitor as described in ["How to start DFsend"](#).
- Click **Add**. From the **Select PDF Files** file selection dialog, locate the previously saved **QC\_corrections.pdf** file. Select the file, Click **Open**.

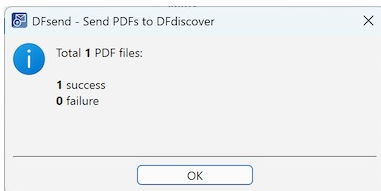


NOTE: Documents can also be added by dragging-and-dropping the desired PDF files from a local file folder directly into the list area.

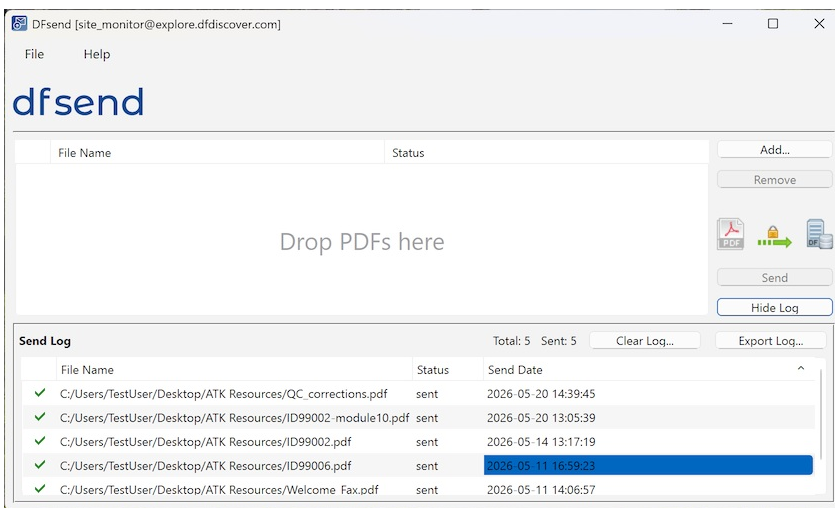
- Click **[Send]**, enter site\_monitor in the **Username** field and the previously assigned password in the **Password** field. Click **[OK]**.



- In the resulting **Send PDFs to DFdiscover** dialog, confirm **1 success** and **0 failure** are shown. Click **[OK]**.



- Click **[Show Log]** to confirm successful transmission of the **QC\_corrections.pdf** file to **DFdiscover**.



- Select **[File]** > **[Exit]**.

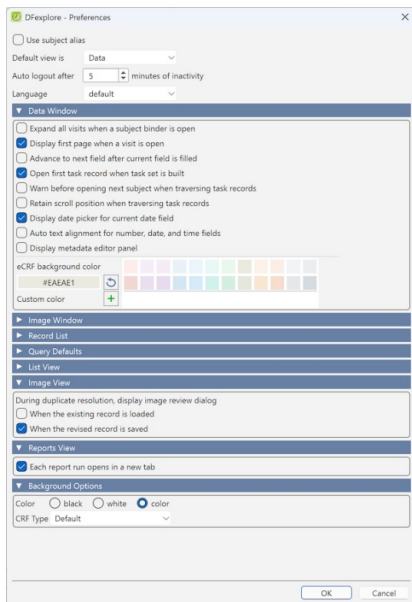
NOTE: Wait 2-3 minutes prior to proceeding to **DFexplore**.

### Verify that all CRFs have arrived successfully in Image view

- Start **DFexplore**, login as user data\_coordinator and choose **254 Acceptance Test Study** as described in ["How to start DFexplore"](#)

NOTE: If data\_coordinator has been set up for 2-factor authentication with Azure SMS, you may need to wait for a 1-time code to arrive at the phone number as defined in DFAdmin.

- Select **File** > **Preferences**. In the **Preferences** dialog, click  from **Image View** section. Select (enable) **When the revised record is saved**. Click **OK** to save and close the **Preferences** dialog.



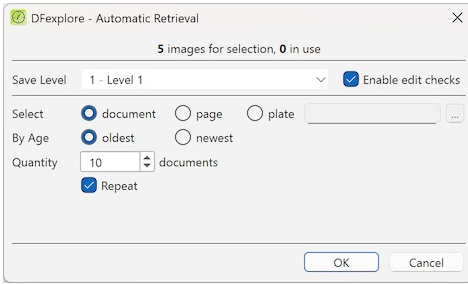
- Select **View** > **Status**. Examine the information displayed for the Images awaiting review in Image Queue, **Data Records** and **Queries** tables.

Level	Data Records				Total	Queries				Total	Reasons				Total
	Pending	Mixed	Incomplete	Final		Pending	Outstanding	Resolved	Total		Pending	Rejected	Approved	Total	
Level 0.0	1				1		10		10		2		4	6	
Level 1.1		1	2	21	24	2	3		5				61	61	
Level 2.2				2	2						1		6	7	
Level 3.3				2	2						2		6	8	
Level 4.4			2	2	4	1	2	1	4		1		10	11	
Level 5.5															
Level 6.6															
Level 7.7															
Total	1	1	4	27	33	3	15	1	19		6		87	93	

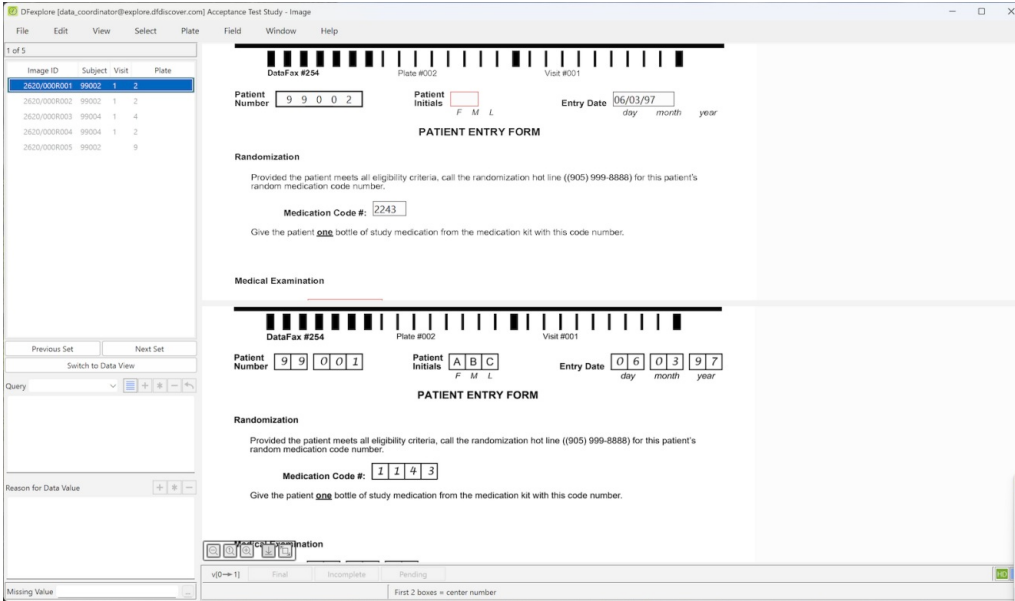
NOTE: The number of pages awaiting review in the Image Router may be different from that shown here as this number includes pages for all studies on the DFdiscover server, not only those that belong to the 254 Acceptance Test Study.

## Retrieve submitted CRFs using Dfexplore Image View

- Select **View** > **Image**, in the resulting **Automatic Retrieval** dialog set:
  - Check (enable) **Enable Edit Checks**
  - Save level** = 1 - Level 1
  - Select** = document
  - By Age** = oldest
  - Quantity** = 10

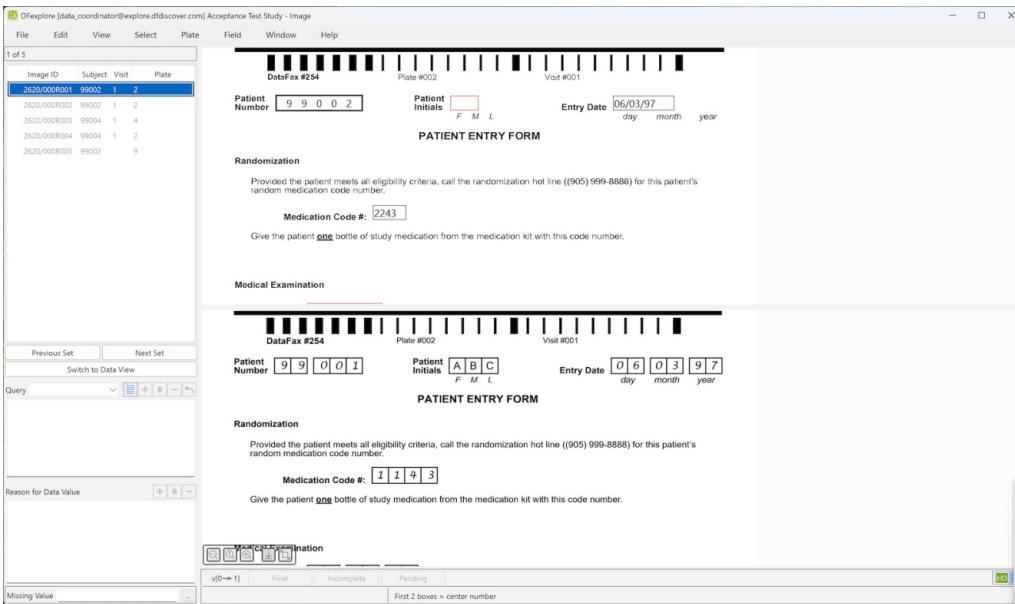


2. Click **OK** to bring forward all new images awaiting data entry.



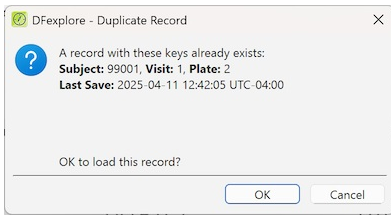
Enter Form 2, Subject 99001, resolve outstanding queries, and save the corrected CRF to the database

1. With **PATIENT ENTRY FORM** for Subject **99001** as the current page, click anywhere on the page background to make the page active for data entry. Beginning with the **Patient Number** field, verify that the correct Subject **99001** is displayed. If the **Patient Number** is incorrect, correct it by selecting **[Plate]** > **[Change Barcode]**, specify a **Subject** of 99001. Click **OK**. Press **[Tab]** to exit the field.

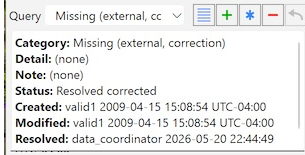


**NOTE:** In your normal image entry process, you must always pay careful attention to the accuracy of the ICR data. You will need to do the same here. It is possible that the new pages contain ICR errors that you will need to correct during entry. In particular, it is important that you correct any key fields (visit and/or subject numbers) that may have been misread as these are critical to the identification and storage of the data. Note that the ICR data records on your screen may not match exactly those shown in the examples throughout this module.

2. Click **OK** to load the data from the existing subject **99001**, **PATIENT ENTRY FORM**.

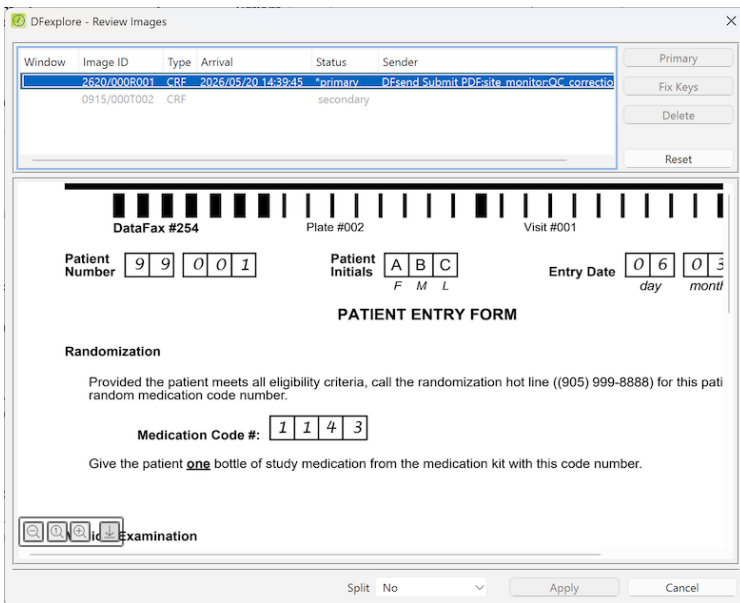


- Press **Tab** to advance from field to field, and verify that data is the same as that found on the CRF image. Note that some fields may contain values that have been assigned by edit checks. Stop when the **Smoking Status** field becomes the current field. Examine the details in the **Query** window. Enter the data as it appears on the image.

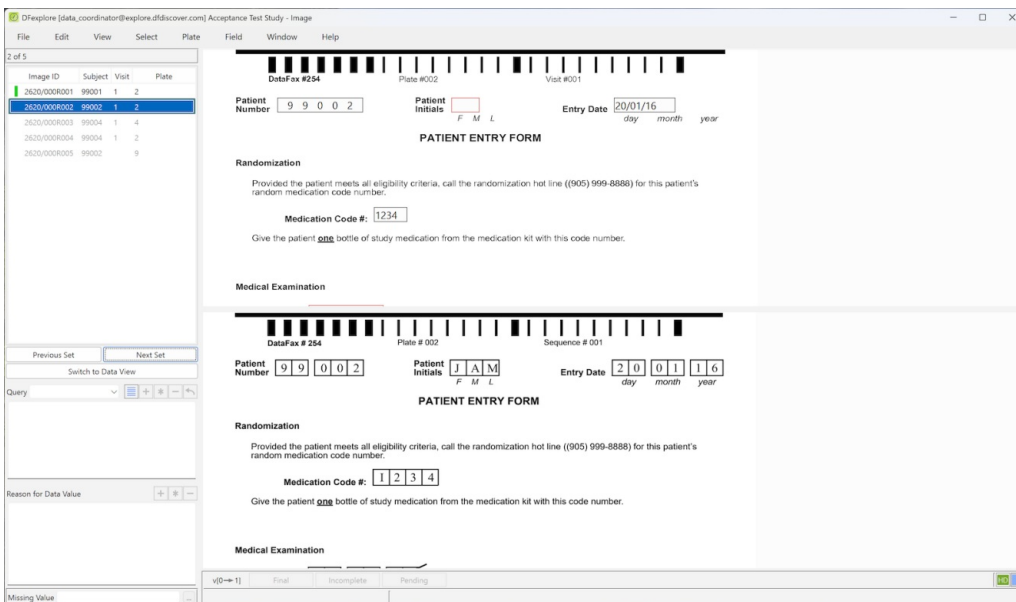


NOTE: When data is entered into a field that contains an outstanding missing value query of type **Correction**, the query is automatically resolved by **DFdiscover** as the missing data has now been provided. The color green indicates that the query has been resolved.

- Continue tabbing through the remaining fields on the page to verify that the data in the fields is the same as the CRF image. Once the save buttons become active at the bottom of the record, click **Final** to save the corrected page.



- Using the scroll bars, examine the primary image and locate the corrected **Smoking Status** field to verify that this is the same image that was saved with the corrected data record in "**Enter Form 2, Subject 99001, resolve outstanding queries, and save the corrected CRF to the database.**". Click **Cancel** to exit the **Review Images** dialog.



6. Return to the saved page for Subject **99001** by selecting it from the Image Queue list. Examine the bottom right corner of the main data entry screen.

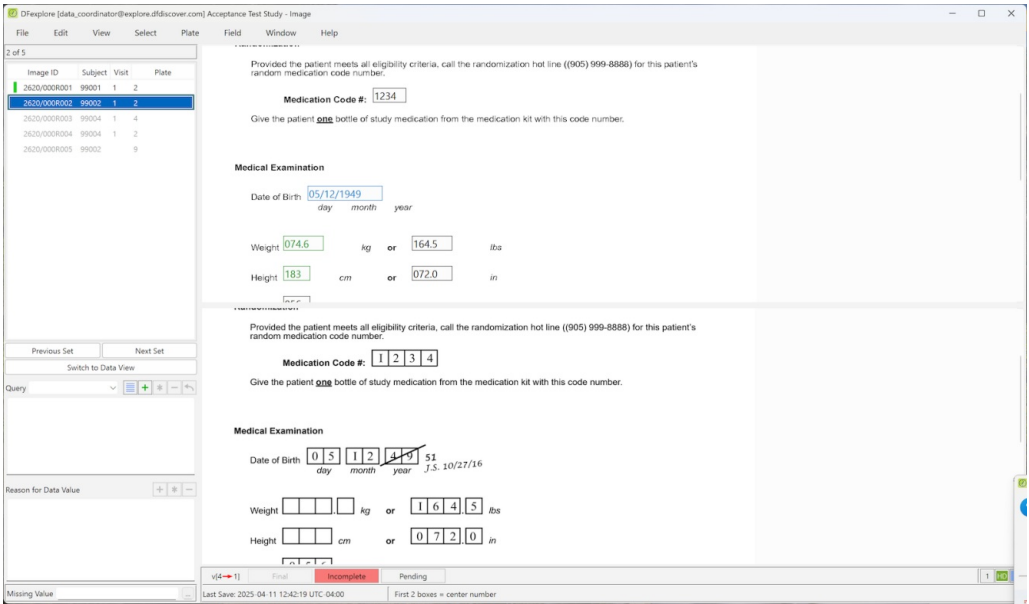


**Enter Form 2, Subject 99002, resolve outstanding queries, and save the corrected CRF to the database**

1. From the new Image Queue, click the 2nd entry in the list (Subject 99002) to make it the current page. Click anywhere on the page background to make the page active for data entry. Beginning with the **Patient Number** field, enter the correct subject 99002 and press **Tab** to exit the field.

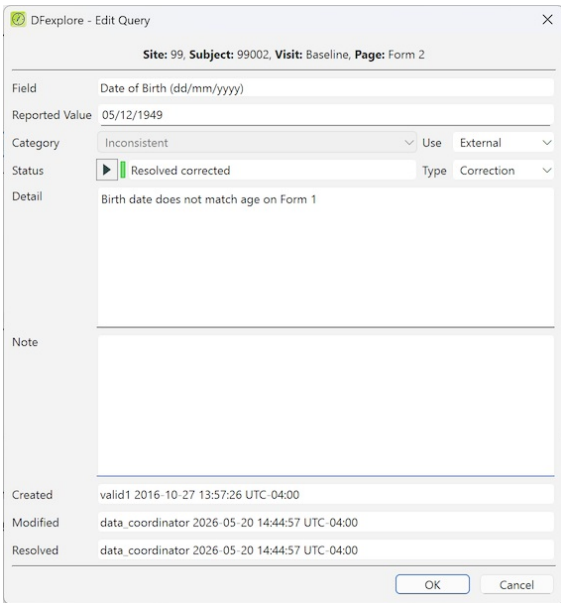


2. Click **OK** to load the data from the existing Subject **99002, PATIENT ENTRY FORM**.

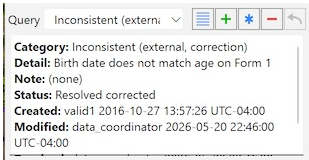


3. Press **Tab** to advance from field to field, and verify that data is the same as that found on the CRF image. Stop when the **Date of Birth** field becomes the current field. Examine the details in the **Query** window.

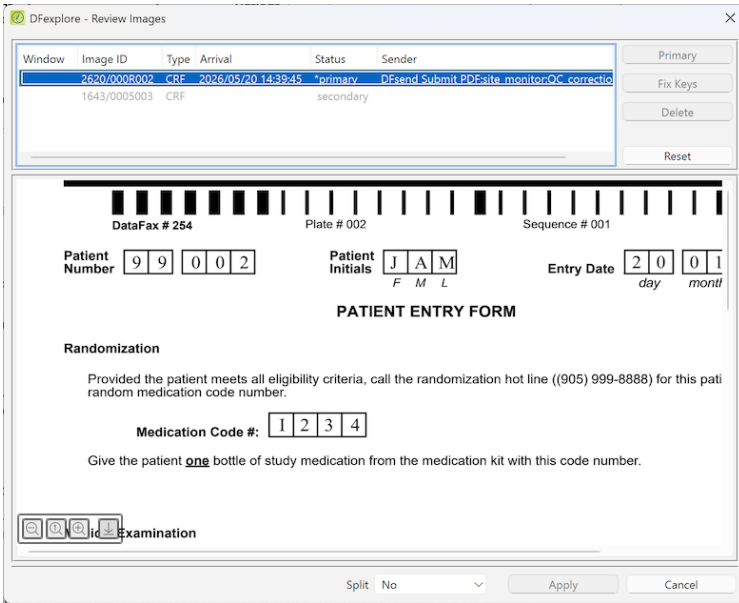
4. Enter the corrected date value 05/12/1951, as it appears on the image of the CRF. With **Date of Birth** as the current field, select **Field** > **Edit Query** or click **\***.



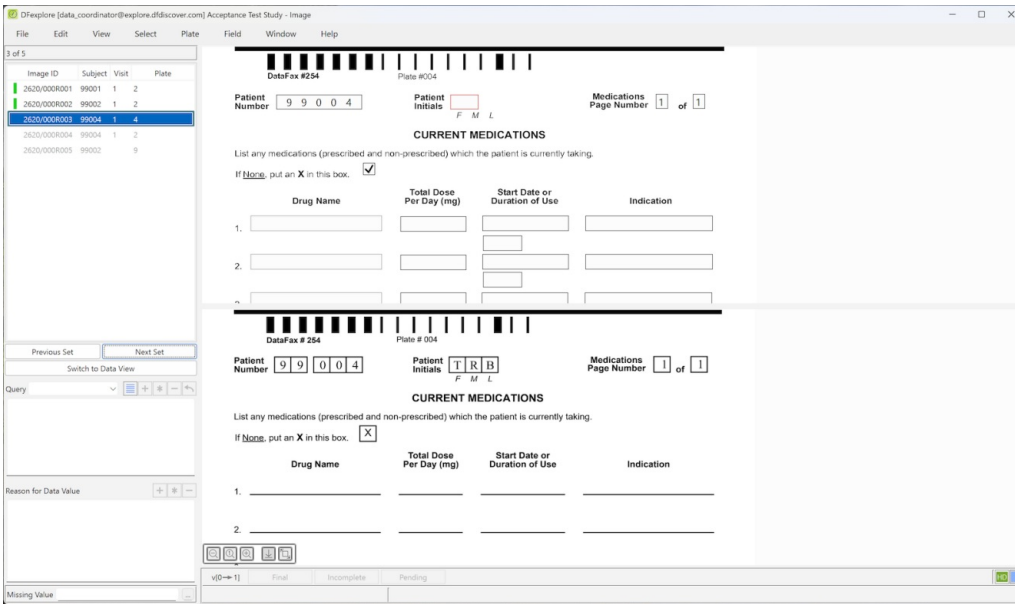
5. Select **Resolved corrected** from the **Status** pull-down. Click **OK** to apply the change to the query status. Examine the Query window.



6. Continue tabbing through the remaining fields on the page to verify that the data in the fields is the same as the CRF image. Note that some fields may contain values assigned by edit checks. Once the save buttons at bottom of the record become active click **Final** to save the corrected page.



7. Using the scroll bars, examine the primary image and locate the corrected **Date of Birth** field to verify that this is the same image as was saved with the corrected data record in ["Enter Form 2, Subject 99002, resolve outstanding queries, and save the corrected CRF to the database."](#) Click **Cancel** to close the Review Images dialog.

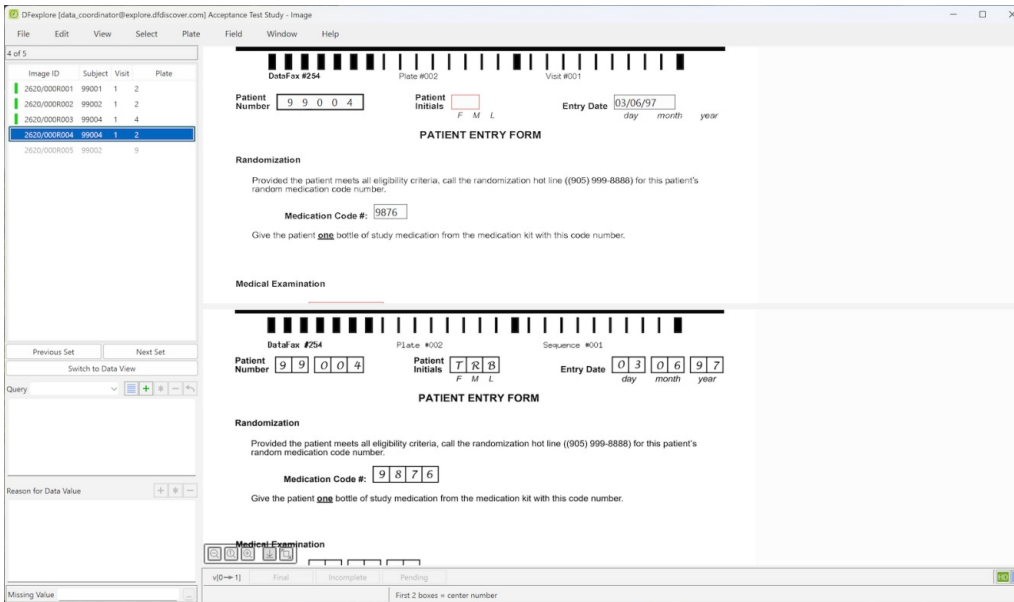


## Enter Form 4, Subject 99004

1. Click anywhere on the page background to make the page active for data entry. Beginning with the **Medications Page Number** field, enter 1 as shown on the CRF image. Press **Tab** to exit the field and move to the Patient Number. Enter the number shown on the CRF image and leave the field.

**NOTE:** The CURRENT MEDICATIONS form for Subject 99004 has been flagged as Missing in the Query report of Module 12. As a result, arrival of this plate will not trigger the Duplicate Record warning because the page does not currently exist in the study database.

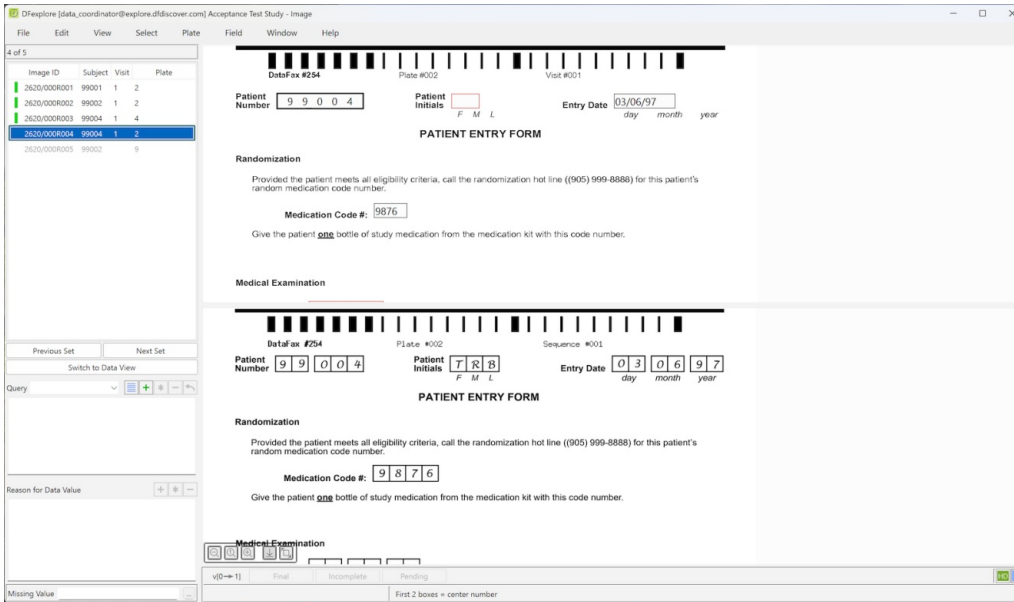
2. Enter all fields on the data record as they appear on the CRF image. Once the save buttons at bottom of the record become active, click **Final** to save the entered page.



NOTE: The Review Images window does not appear upon saving Form 4, Subject 99004 because a duplicate page does not exist for this set of keys.

## Enter Form 2, Subject 99004, resolve outstanding queries, and save the corrected CRF to the database

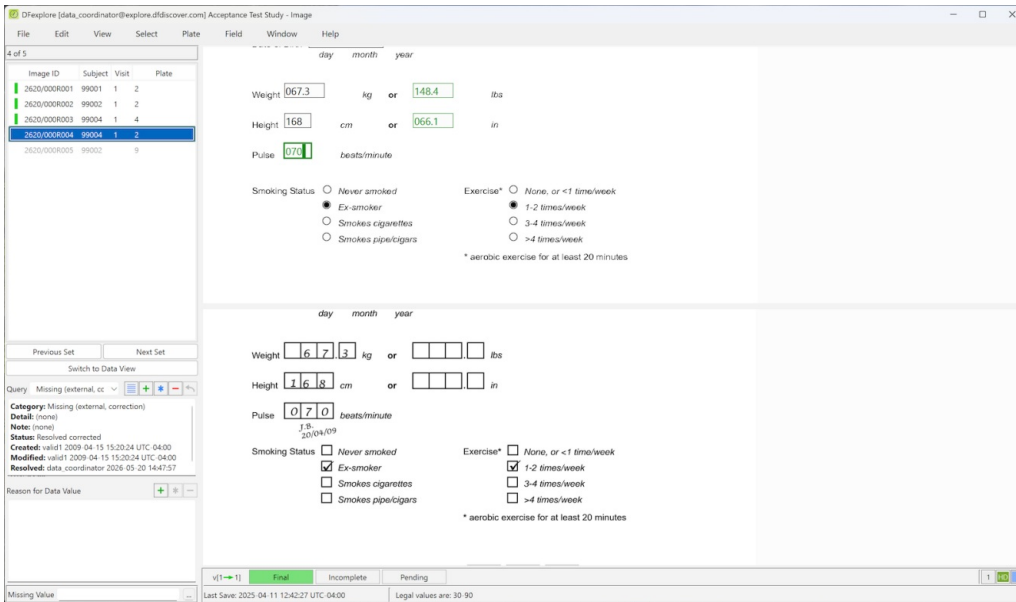
1. Click anywhere on the page background to make the page active for data entry. Beginning with the **Patient Number**, enter 99004 as shown on the CRF image. Press **Tab** to exit the field.



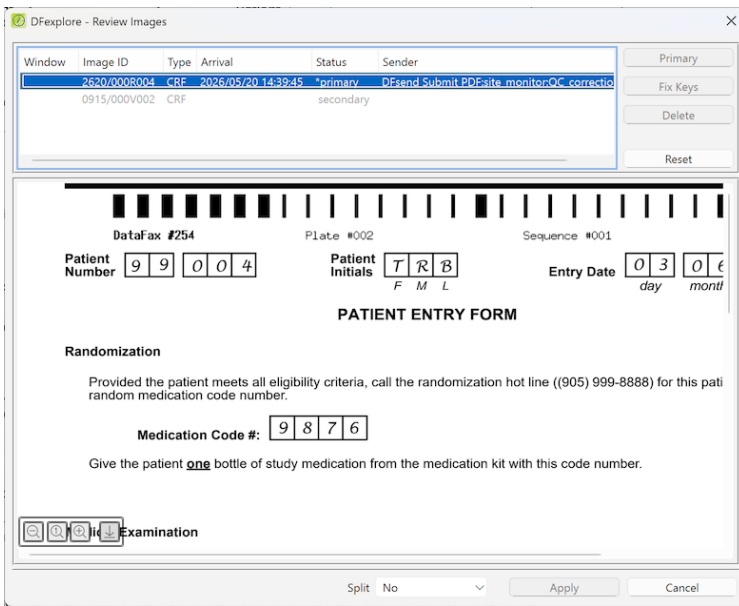
2. Click **OK** to load the data from the existing Subject **99004, PATIENT ENTRY FORM**.



3. Press **Tab** to advance from field to field, and verify that data is the same as that found on the CRF image. Note that some fields may contain values assigned by edit checks. Stop when the queried **Pulse** field becomes the current field. Examine the details in the **Query** window.
4. Enter the correct response as it appears on the image of the corrected CRF. Examine the details in the **Query** window and press **Tab** to exit the corrected **Pulse** field.



- Continue tabbing through the remaining fields on the page to verify that the data in the fields is the same as the CRF image. Once the save buttons at the bottom become active, click **Final** to save the corrected page to the database.
- Using the scroll bars, examine the primary image and locate the corrected Pulse field to verify that this is the same image as was saved with the corrected data record in [Step 3](#). Click **Cancel** to close the **Review Images** window.



## Select and resolve a query in a field that has multiple queries

- With the **ADVERSE EVENT REPORT Form for Patient Number 99002** as the current plate, click anywhere on the page background to make the page active. Beginning with the **Adverse Event Report No.** field, enter the value as shown on the CRF image. Press **Tab** to exit this field and advance to the **AE Identifier** field. Upon entering the AE Identifier field, the edit check AESEQNUM2 automatically complete this field. Press **Tab** to exit the AE Identifier field to advance to the **Patient Number** field. Verify that the correct Subject **99002** is displayed for the **Patient Number** field. If the number is incorrect, correct it and press **Tab** to exit the field.



- Click **OK** to load the data from the existing Subject **99002, ADVERSE EVENT REPORT FORM**.

The screenshot displays two instances of the 'ADVERSE EVENT REPORT' form. The top form is for Patient 99002, Visit 1, Page 1. The 'Intensity' field is set to 4, and the 'Is This A Serious Event?' field is 'No'. The 'Description' is 'Nausea and vomiting'. The bottom form is for Patient 99002, Visit 1, Page 2. The 'Intensity' field is set to 2, and the 'Is This A Serious Event?' field is 'Yes'. The 'Description' is 'Nausea and vomiting'. The 'Query' window on the left shows a query for 'Monitor (external, correction)' with a status of 'Outstanding'.

3. Correctly enter each data field on the page per the CRF image, up to the **Intensity** field. Confirm that the Intensity field has a value of 4, and contains 2 unresolved queries.
4. Enter the correct value 2 for **Intensity** field per the CRF image. Examine the details in the **Query** window.

The Query window shows the following details for the 'Monitor (external, correction)' query:

- Category:** Monitor (external, correction)
- Detail:** The severity intensity is greater than 3, but the question 'Is This A Serious Event?' is answered 'No'. This is inconsistent with the study protocol. Please review.
- Note:** (none)
- Status:** Outstanding (New, in report and sent)

5. Select **Field** > **Edit Query** or click **\***. Choose **Resolved corrected** from the **Status** pull-down. Click **OK** to apply the edits.

The 'Edit Query' dialog box shows the following details for the 'Monitor (external, correction)' query:

- Field:** DESCRIPTION: Intensity
- Reported Value:** 4
- Category:** Monitor (external, correction)
- Status:** Resolved corrected
- Detail:** The severity intensity is greater than 3, but the question 'Is This A Serious Event?' is answered 'No'. This is inconsistent with the study protocol. Please review.
- Note:** (none)
- Created:** valid1 2016-11-01 17:44:59 UTC -04:00
- Modified:** data\_coordinator 2026-05-20 14:49:17 UTC -04:00
- Resolved:** data\_coordinator 2026-05-20 14:49:17 UTC -04:00

6. With the focus still on the **Intensity** field, examine the details in the **Query** window. Select the **Clinical QC** query from the **Query** drop-down, and examine its details.

The Query window shows the following details for the 'Clinical QC (external, correction)' query:

- Category:** Clinical QC (external, correction)
- Detail:** This severity intensity is greater than 3. Please update the value once further information is available.
- Note:** (none)
- Status:** Outstanding (New, in report and sent)
- Created:** valid1 2016-11-01 17:32:58 UTC -04:00
- Modified:** valid1 2016-11-01 17:32:58 UTC -04:00

7. Select **Field** > **Edit Query** or click **\*** in the dialog, choose **Resolved corrected** from the **Status** pull-down. Click **OK** to apply the edits.

DFxplorer - Edit Query

Site: 99, Subject: 99002, Visit: Adverse Event 1 Page 1, Page: Form 9, AE Report 011

Field DESCRIPTION: Intensity

Reported Value 4

Category Clinical QC Use External

Status Resolved corrected Type Correction

Detail This severity intensity is greater than 3. Please update the value once further information is available.

Note

Created valid1 2016-10-30 14:09:08 UTC-04:00

Modified data\_coordinator 2026-05-20 14:49:47 UTC-04:00

Resolved data\_coordinator 2026-05-20 14:49:47 UTC-04:00

OK Cancel

8. Press **Tab** to advance through the fields, and verify that the data is the same as that found on the CRF image. Note that upon leaving the Description field, an edit check is executed and **DFlookup:aecodes** dialog appears. Click **Cancel** to close the **DFlookup:aecodes** dialog.

DFxplorer - DFlookup:aecodes

Search terms @

entries with  ANY  ALL  ONLY search terms in the following fields

Lookup Fields Current Selection

Acronym (INCR GAS) FLATULENCE

Result FLATULENCE,428,DIGESTIVE,3

Find Previous Filter Reset

Acronym	Result
(INCR GAS) FLATULENCE	FLATULENCE,428,DIGESTIVE,3
4-5 STOOLS A DAY	DIARRHEA,301,DIGESTIVE,3
ABD BLOATING SENSATION	FLATULENCE,428,DIGESTIVE,3
ABD BLOATING	FLATULENCE,428,DIGESTIVE,3
ABD CRAMPING	ABDOMINAL CRAMPS,2005,DIGESTIVE,3
ABD CRAMPS	ABDOMINAL CRAMPS,2005,DIGESTIVE,3
ABD DISCOMFORT	ABDOMINAL PAIN,831,BODY AS A WHC
ABD DISTENSION	ABDOMEN ENLARGED,1,BODY AS A WHC

OK Cancel

9. Continue tabbing through the remaining fields on the page and verify that the data in the fields is the same as the CRF image. Once the save buttons become active at the bottom of the record, click **Incomplete** to save the corrected page to the database. Upon clicking **Incomplete**, the **Review Images** dialog appears. Click **Cancel** to close the **Review Images** window.

DFxplorer - Review Images

Window	Image ID	Type	Arrival	Status	Sender
	2620/000R008	CRF	2026/05/20 14:39:45	*primary	DFsend_Submit_PDF/site_monitor/QC_correctio
	1644/000/7001	CRF		secondary	

Primary  
Fix Keys  
Delete  
Reset

DataFax #254 Plate #009

Patient Number 9 9 0 0 2 Patient Initials J A M Adverse Event Report No. 0 1

F M L Event No.

**ADVERSE EVENT REPORT**

1. DESCRIPTION OF ADVERSE EVENT

Event Start Date	Intensity	Relationship to Study Drug	Action(s) Taken	Outcome	Is Serious
2 2 0 2 1 6	2	2	2	1	<input type="checkbox"/> Yes

Description Nausea and vomiting

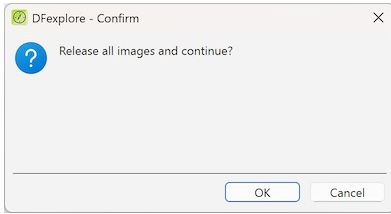
2. CHANGES

the study, use this form to record all changes in this Adverse Event until it is resolved or the study is terminated. Fax all additions to this form immediately, and if the above event is serious, call the Clinical Safety Department.

Split No Apply Cancel

## Review and approve a pending query reply for Form 1 for Subject 99002

1. Select **View** > **Queries**.



2. Click **OK** in the confirmation dialog to release the **Image View** records and open **Queries View**.
3. Select **Show** > **Pending Queries** to display only queries for which a resolution is pending. Double-click **Site 99 - Hospital #99** entry to display all pending queries.

Site / Subject	Visit / Page	Field / Category	Status & Replies
Site 99 - Hospital #99	99001	Screening Visits: Form 1	5. Patient has signed informed consent => Yes (Other). Detail: We have not received this patient's informed consent form. Please send it by fax or email without delay.
Site 99 - Hospital #99	99002	Adverse Event 1 Page 1: Form 9, AE Report 011	DESCRIPTION: AE Description => Nausea, TTT and fever (Other). Detail: Please clarify the word after nausea. The description provided through email is 'Nausea, vomit and fever'. Do you mean Vomit instead? Note: The correction was provided via email. Screen 1: Reading 1: systolic => 107 (Inconsistent) Detail: This value is inconsistent with all other BP readings. Please explain.
Site 99 - Hospital #99	99007	Screening Visits: Form 1	Screening Visits: Form 1

4. Locate the pending query for Subject **99001**, **5. Patient has signed informed consent**. Double-click the query to make the queried field and page the current page. Examine the information in the **Query** window.

5. Patient has signed informed consent and agrees to return for monthly follow-up visits.

Once Completed, Please Fax This Form to (###)###-####.

11 November 2014

**BLOOD PRESSURE SCREENING VISITS**

Age: 60 years    Sex:  Male    Race:  Caucasian

Screen 1: Date: 03/03/17    Reading 1: 170/96 mmHg

Screen 2: Date: 03/09/17    Reading 2: 170/98 mmHg

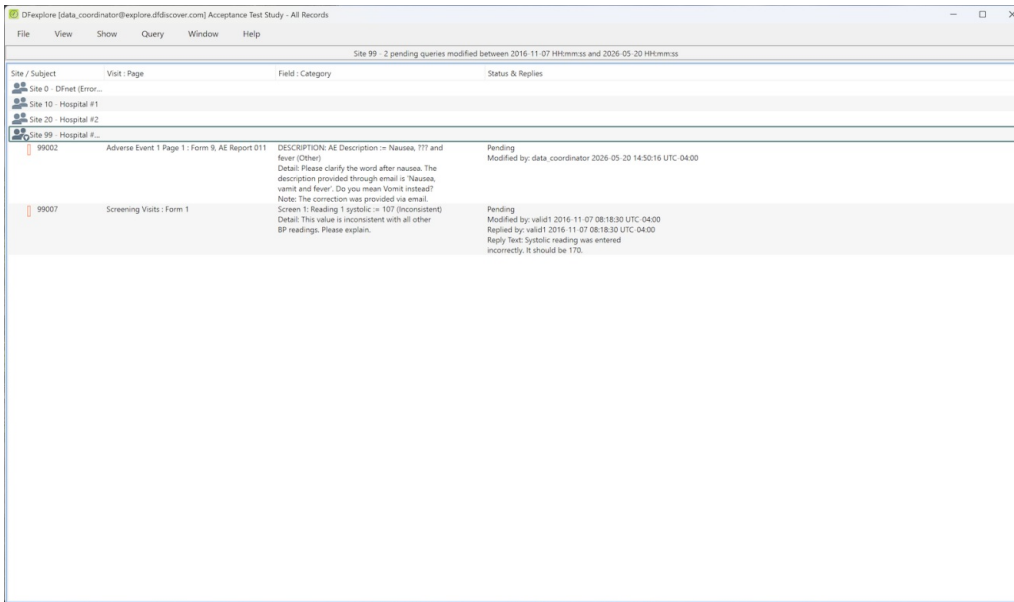
5. Select **Field** > **Approve Queries and Reasons** to review all queries and reasons that are present on the current page.

6. Choose **Resolved corrected** from the **Status** pull-down. Enter Signed informed consent was received March 20, 2009. in the **Note** field.

7. Click **Save** to apply the **Resolved corrected** status to the query. Click **Done** to close the **Approve Queries and Reasons** dialog.

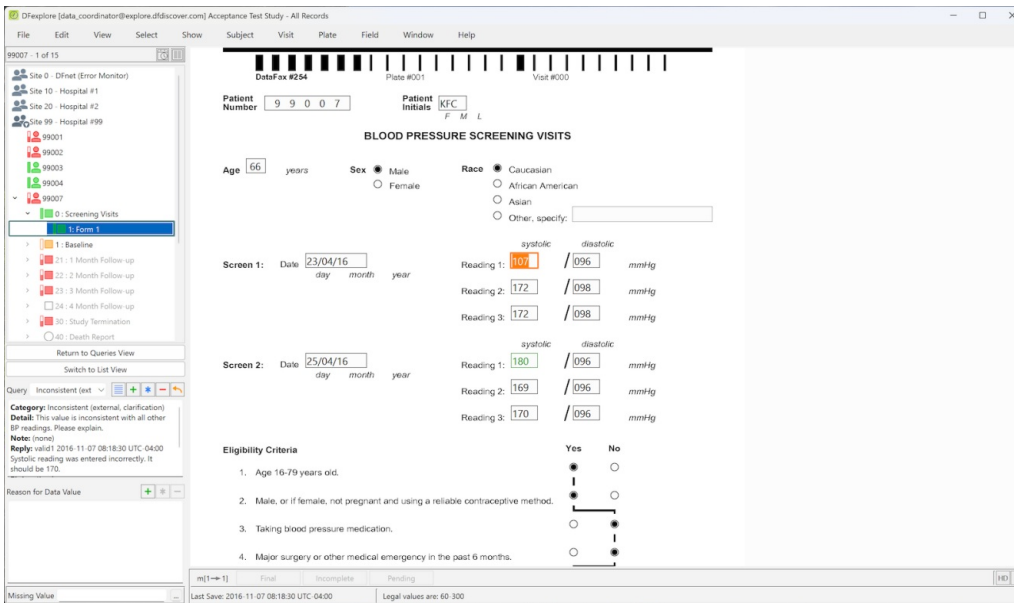
8. Do not change any other data or metadata on the **0 : Screening Visits** page for Subject **99001**. Make the save buttons at the bottom of the screen active and click **Final** to save the data record and query to the database.

9. In the record list window, click **Return to Queries View** to return to Queries View to process the pending query for Subject **99007**.



## Review, correct and approve a pending query reply for Form 1, Subject 99007

1. Locate the pending query for Subject **99007**, **Screen 1: Reading 1 systolic**. Double-click the query to make the queried field and page current. Examine the information in the Query window.



2. Select **Field** > **Approve Queries and Reasons** to review all queries and reasons that are present on the current page.

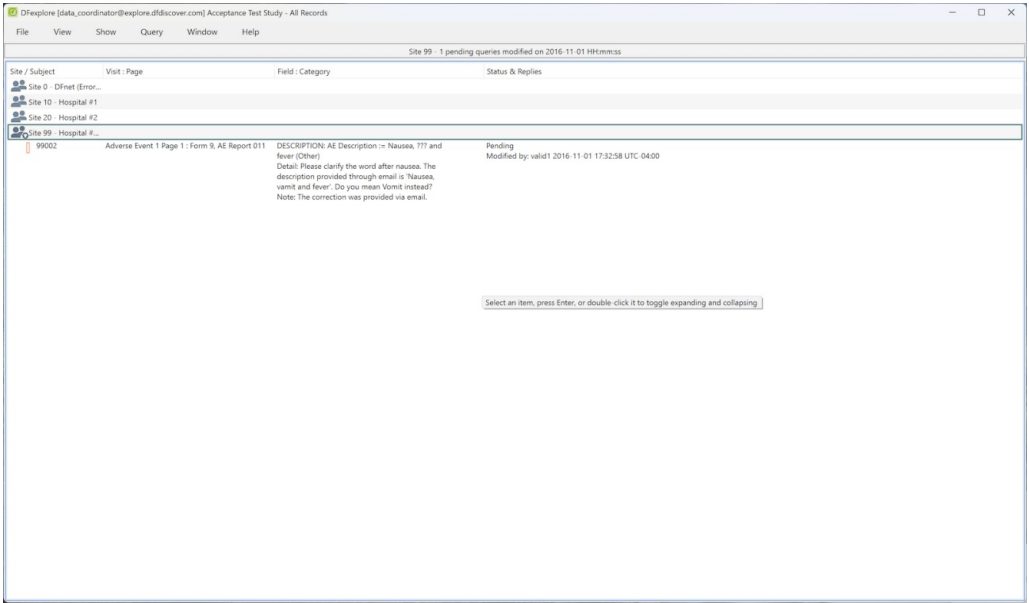
3. Choose **Resolved corrected** from the **Status** pull-down.

4. Click **Save** to apply the **Resolved corrected** status to the query. Click **Done** to close the **Approve Queries and Reasons** dialog.

5. The query reply indicates that the **Screen 1: Reading 1 systolic** value should be 170. With the focus still on the **Screen 1: Reading 1 systolic** field on the page, change the value to 170.

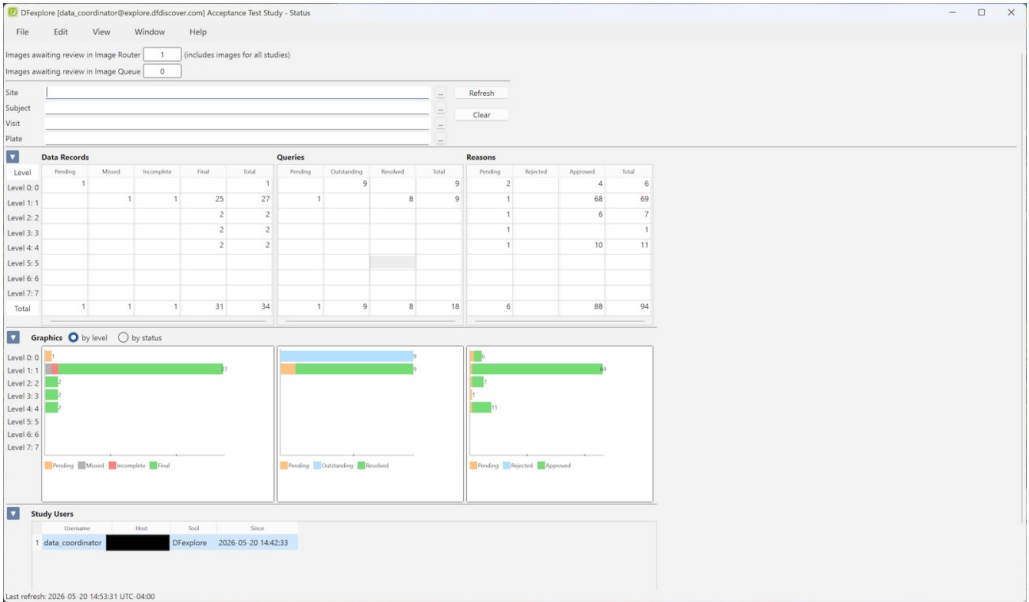
6. Click **Final** to save the data record and query to the database.

7. In the record list window, click **Return to Queries View** to return to Queries View.



## Confirm query resolution by examining the database status

1. Select **View** > **Status**. Examine the information displayed for the Image Queue, Data Records and Queries tables.



2. Select **File** > **Exit** to close Status View and exit **DFExplore**.

## End Module 14. Re-submitting Query Corrections

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 14. Re-submitting Query Corrections.

## Module 15. Data Export and DFsas

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
- Email configured for data\_manager

**Client Tools Used:** DFATK, DFExplore

**Purpose:** This module tests **DFExplore**'s ability to export data using the DFsas utility.

### Tests & Requirements

1. Export date values in calendar format and save the exported data to a file on the local computer.
2. Export date values from the database and save the exported data to a file on the local computer.
3. Examining data values according to user-specified criteria.
4. Query the database for specific data values.
5. Create a DFsas job file according to user-specified criteria.
6. Create a SAS job file and data files using the DFsas job file criteria.
7. Compare the contents of SAS data files with the actual data in the database.

Estimate of Time Required: 30 Minutes

## Begin Module 15. Data Export and DFsas

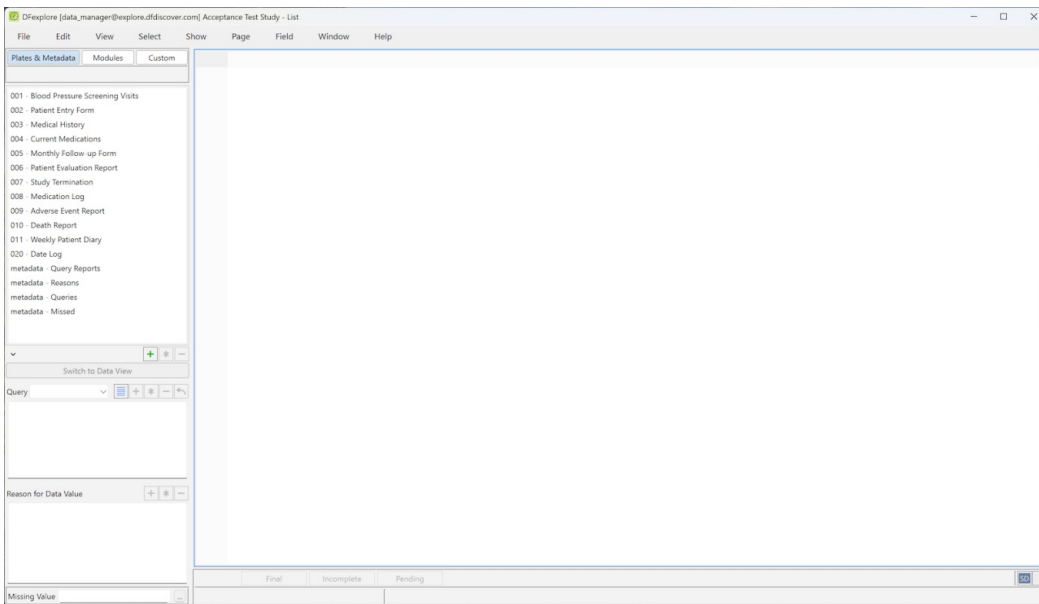
1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **15. Data Export and DFsas** followed by **Begin** to begin this module.
3. Click **Send ID 99006** to email a copy of **ID99006\_diary.pdf** to data\_manager. Clicking more than once will result in multiple pages arriving to your email inbox.

NOTE: Refer to "[Creating user accounts and assigning study permissions.](#)" as a valid email address is required for data\_manager to receive the module specific PDF files. Wait 2-3 minutes prior to proceeding to **DFExplore**.

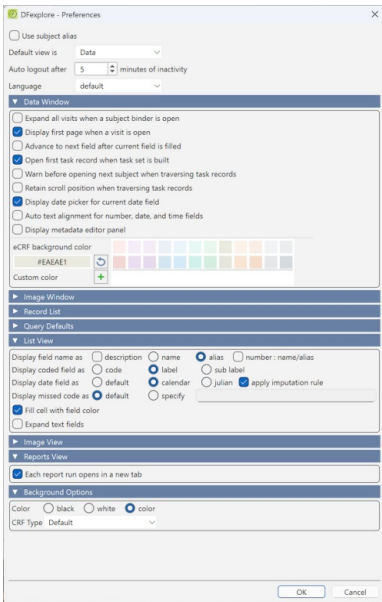
## Export date values in calendar format and save the exported data to a file on the local computer

All data exported in the following tests will be output to the **DFExplore List View** screen rather than saved to a file. **List View** does have 3 save options: **Export Data**, **Save Data Retrieval File** and **Save As PDF**.

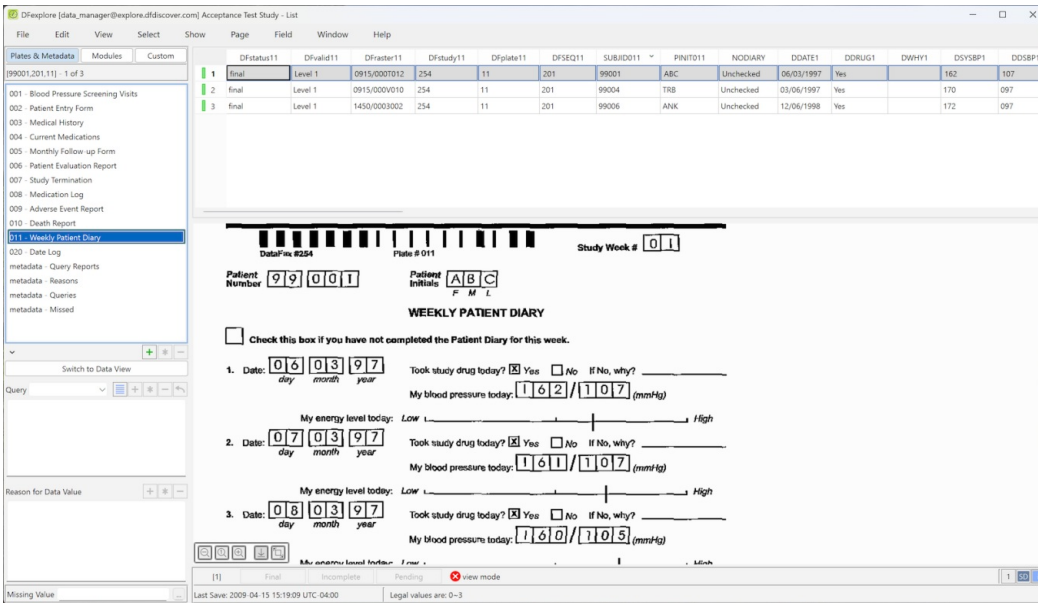
1. Start **DFExplore**, login as user data\_manager and choose **254 Acceptance Test Study** as described in "[How to start DFExplore](#)"
2. Select **View** > **List**.



3. Select **File** > **Preferences**. In the dialog, locate the **List View** panel. Click **OK** and enter the **List View** settings as follows:
  - o **Display field name as** = alias
  - o **Display coded field as** = label
  - o **Display date field as** = calendar
  - o Check (enable) **apply imputation rule**
  - o **Display missed code as** = default
  - o Check (enable) **Fill cell with field color**
  - o Uncheck (disable) **Expand text fields**



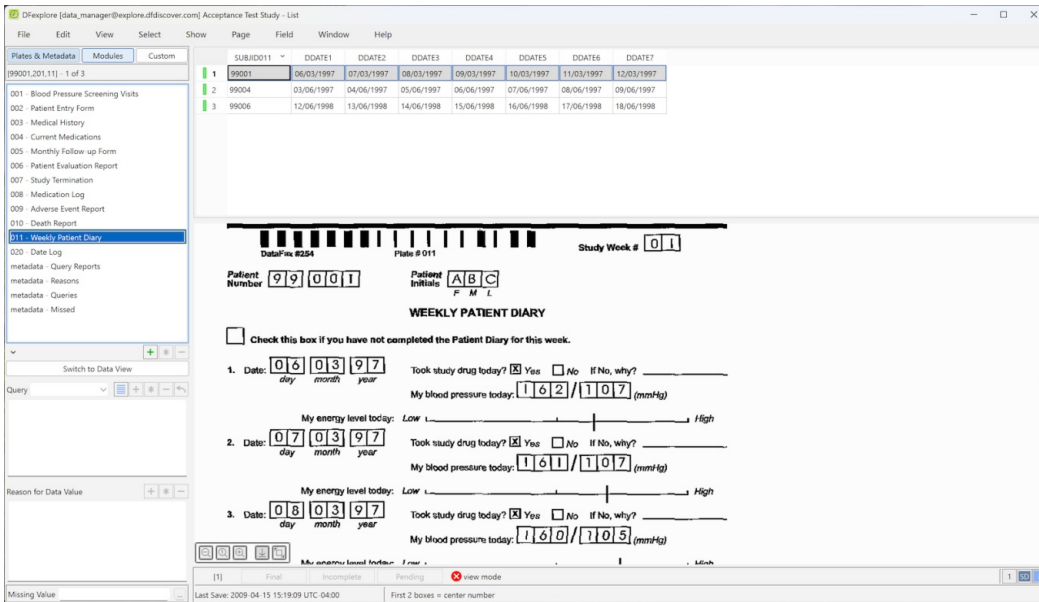
- Click **OK** to close the dialog.
- In the main **List View** window, **Plates & Metadata** panel, click **011 - Weekly Patient Diary**.



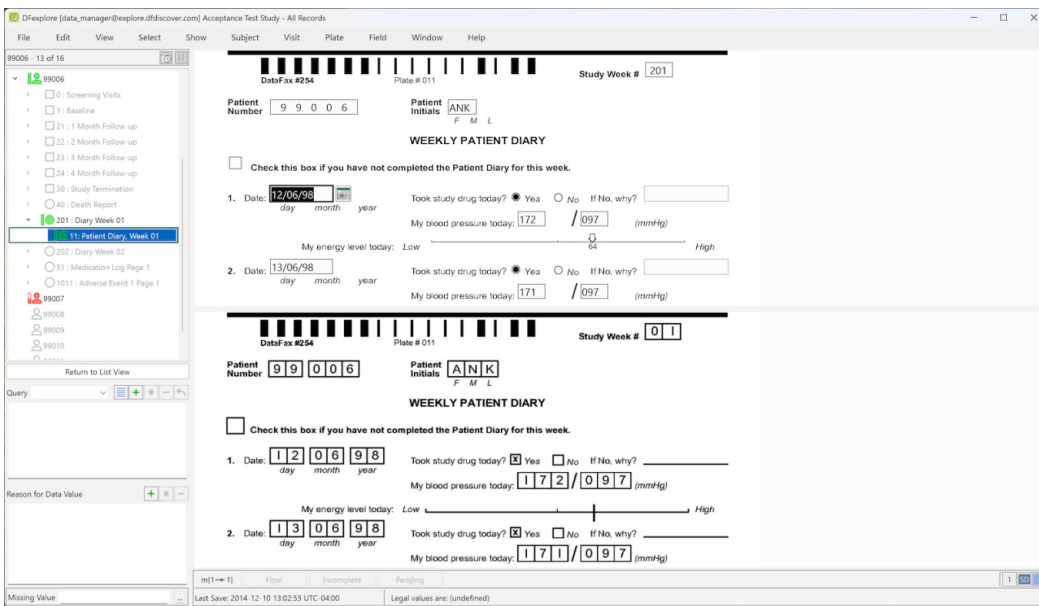
- Select **Select** > **Field Selection** to show the listing of all data fields and their metadata properties defined for the plate. In the **Data Fields** window, click **[+]** next to fields **7:SUBJID011,10:DDATE1,16:DDATE2,22:DDATE3,28:DDATE4,34:DDATE5,40:DDATE6** and **46:DDATE7**. The fields are added to the **Display Fields** window.

NOTE: Alternatively fields can also be added by dragging-and-dropping the desired fields from the **Data Fields** or **Metadata Fields** windows to the **Display Fields** window.

- Click **Done** to apply the field selection criteria and close the dialog.



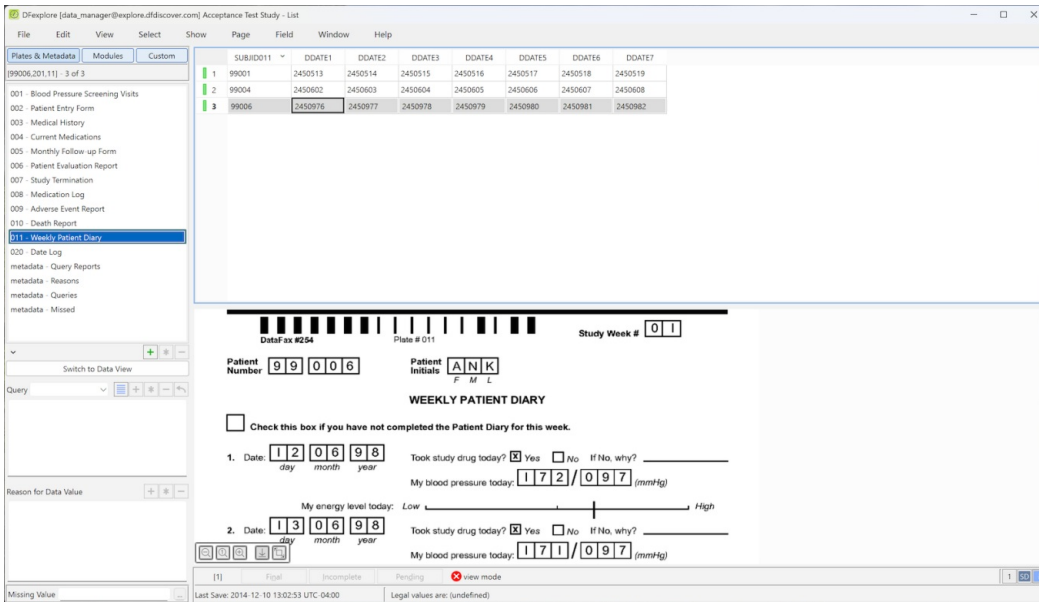
- Examine each of the exported date fields. Locate the field column for **DDATE1** in the table. This is field 10, **1. Date** on the **WEEKLY PATIENT DIARY** page. In ["Submit a copy of the newly defined Plate 11 into the study database and retrieve the page in DFExplore Image View."](#) this field was defined with the format dd/mm/yy (a 2-digit year). Verify that field 10 has been correctly exported in calendar (4-digit year) format.
- Double-click **DDATE1** cell for ID 99006 in the table. This takes you to the corresponding date field in the **WEEKLY PATIENT DIARY** page in **Data View**. Confirm that the date values are the same as those on the printed **WEEKLY PATIENT DIARY** for Subject 99006.



- In the record list, click **Return to List View** to be taken back to the date fields in **List View**. Confirm that the date values displayed are the same as those on the printed **WEEKLY PATIENT DIARY**, except now in calendar (4-digit year) format.

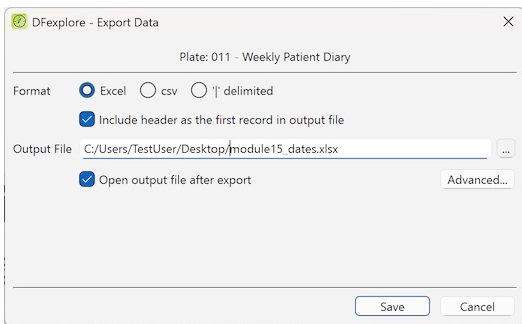
## Export date values from the database and save the exported data to a file on the local computer

- Select **File** > **Preferences**. In the **List View** panel, choose **julian** as the value of **Display date field as**. Click **OK** to apply the settings and close the dialog. Confirm that the exported date values are now in julian format.

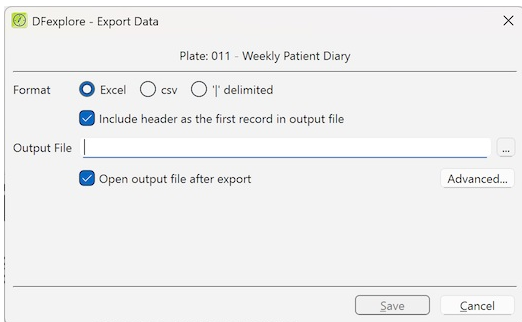


2. Select **File** > **Export Data** to save the dates to a local file. In the dialog, set:

- o **Format = Excel**
- o Check (enable) **Include header as the first record in output file**
- o Check (enable) **Open output file after export**



3. Click **...** next to **Output File**. Choose a directory in the file selection dialog, enter module15\_dates.xlsx as the filename, and click **Save**. Click **Save** to create/write the file and close the dialog.



4. The file module15\_dates.xlsx opens. Confirm the contents and then close the file.

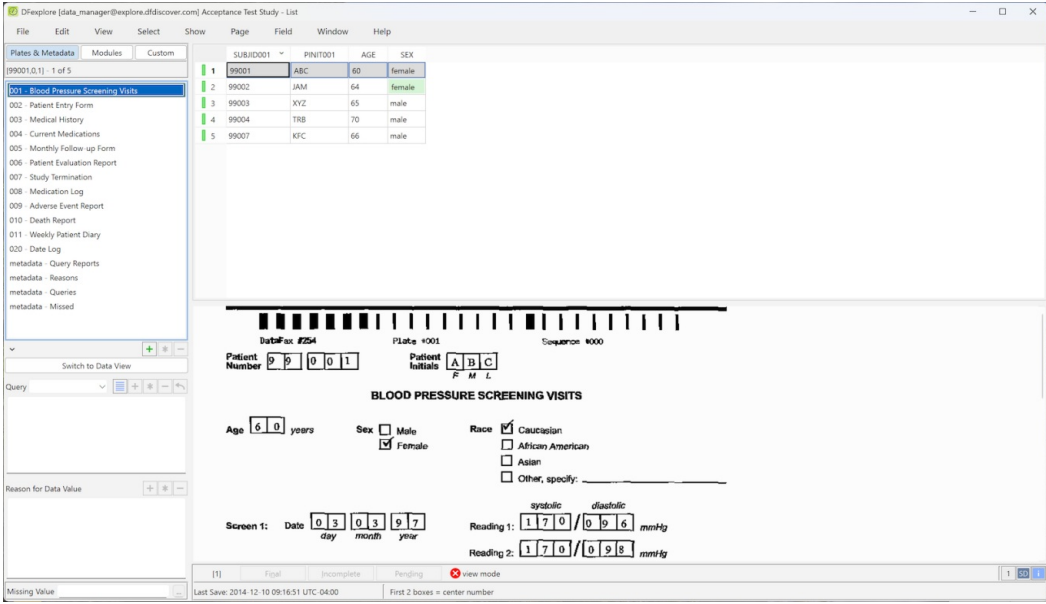
	A	B	C	D	E	F	G	H
	SUBJID011	DDATE1	DDATE2	DDATE3	DDATE4	DDATE5	DDATE6	DDATE7
	99001	2450513	2450514	2450515	2450516	2450517	2450518	2450519
	99004	2450602	2450603	2450604	2450605	2450606	2450607	2450608
	99006	2450976	2450977	2450978	2450979	2450980	2450981	2450982

## Examining data values according to user-specified criteria

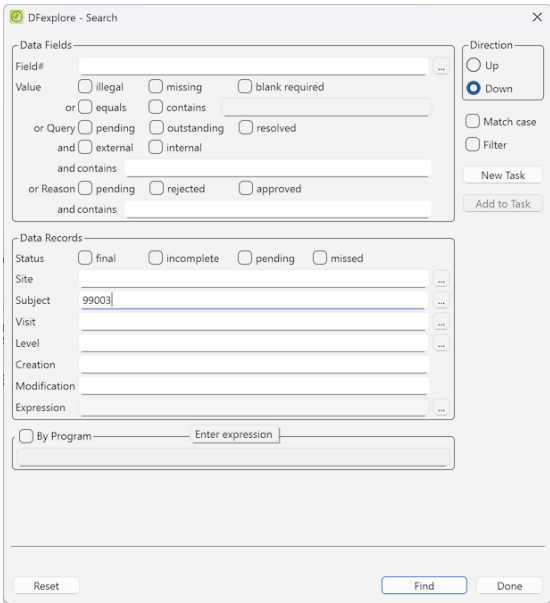
1. From the list of plates, select plate **001 - Blood Pressure Screening Visits** to make it current.
2. Select **Select** > **Field Selection**. In the **Data Fields** window, click **+** next to fields **7:SUBJID001,8:PINIT001,9:AGE,10:SEX**. The fields are added to the **Display Fields** window.

NOTE: Fields can also be added by dragging-and-dropping the desired fields from the **Data Fields** or **Metadata Fields** windows to the **Display Fields** window.

3. Click **Done** to apply the field selection criteria and close the dialog. Examine each of the data fields.



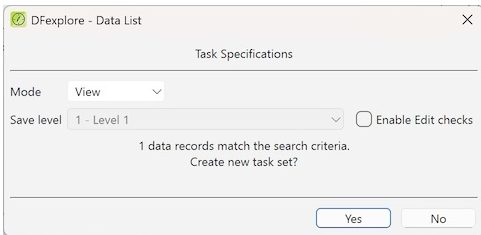
4. To search for specific subject data, Select **Select** > **Search**. Enter 99003 in the **Subject** field.



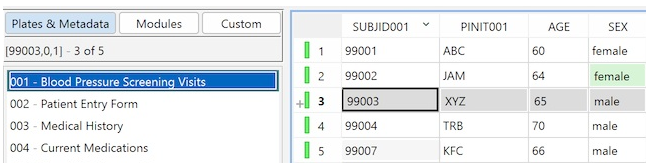
5. Click **Find** to start the search. Examine the message in the bottom-left corner of the dialog as well as the highlighted entry in the **List View** table.

6. Click **Find Next** to locate a 2nd match (if one exists) in the **List View** table.

7. Click **New Task** to create a task set of records that match the search criteria. In the resulting dialog, change the **Mode** to **View**.



8. Click **Yes** in the **Data List** dialog to create the task set. Examine the message in the bottom-left corner of the **Search** dialog, then click **Done** to close the dialog.

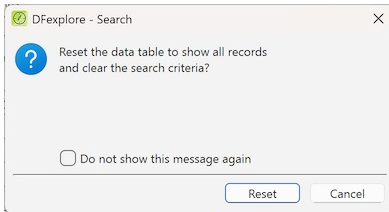


9. Click **Switch to Data View** to open **Data View** and review the **List View** task record. Examine the **Data View** record list and confirm that only the task record for Subject **99003** is

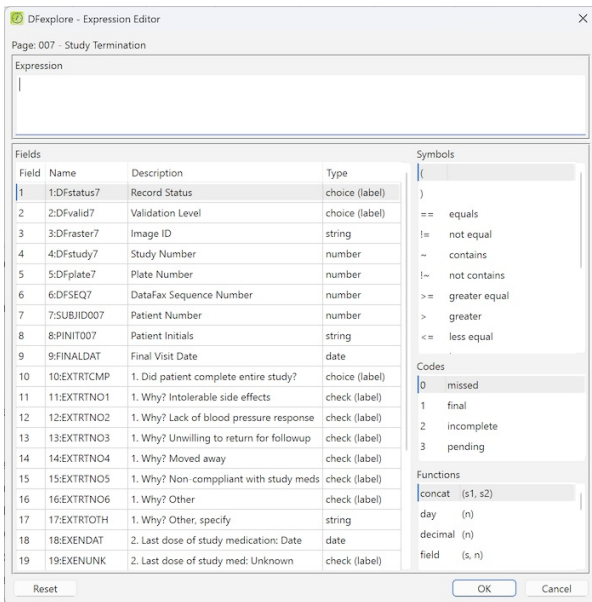
displayed. Click **Return to List View**.

## Query the database for specific data values

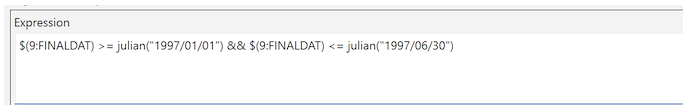
1. Select **File** > **Preferences**. In the dialog, locate the **List View** panel. Choose **default** for **Display date field as**. Click **OK** to save the setting and close the dialog.
2. Click **007 - Study Termination** to make it the current page. Select **Select** > **Search** to open the **Search** dialog.
3. Click **Reset** and **Reset** in the resulting dialogs to clear all previously specified search criteria.



4. Click **...** next to the **Expression** field. The **Expression Editor** opens.



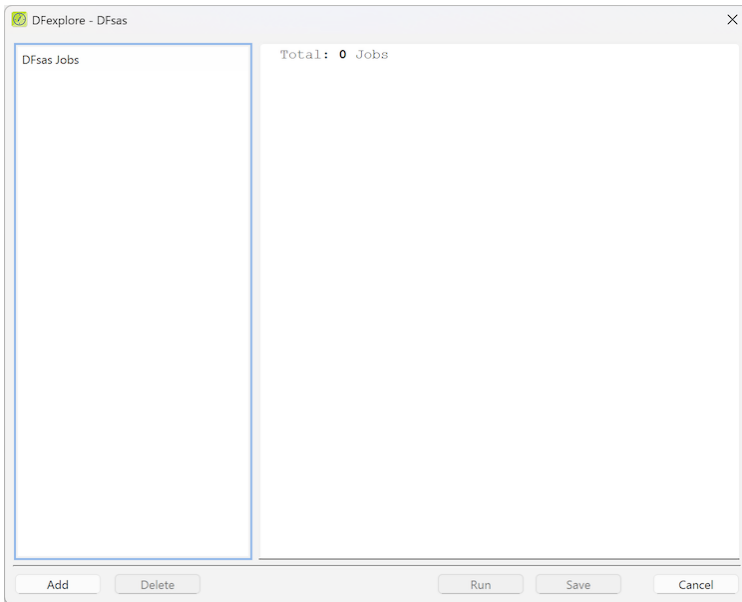
5. For the first part of the query, select **9:FINALDAT** from the **Fields** table. Next, click **>=** in the Symbols list. Choose **julian** from the Functions list. In the **Expression** field, enter the date "1997/01/01" (including the quotes). Close the parentheses. To build the second part of the query, click **&&** From the Symbols list, followed by field **9:FINALDAT** from the **Fields** table. Next, click **<=** in the Symbols list. Choose **julian** from the Functions list. In the **Expression** field, enter the date "1997/06/30" (including the quotes). Close the parentheses. Click **OK**.



6. Click **Find** to locate all subjects that have study termination dates that match the specified search expression.
7. Click **Find Next** to locate the next match.
8. Do not continue the search and click **Done** to close the **Search** dialog.

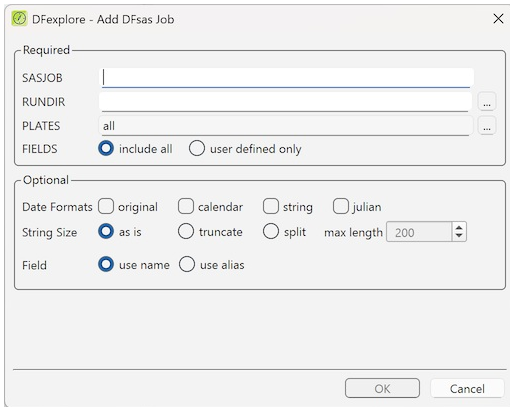
## Create a DFsas job file according to user-specified criteria

1. Select **File** > **DFsas**. The **DFsas** dialog opens.

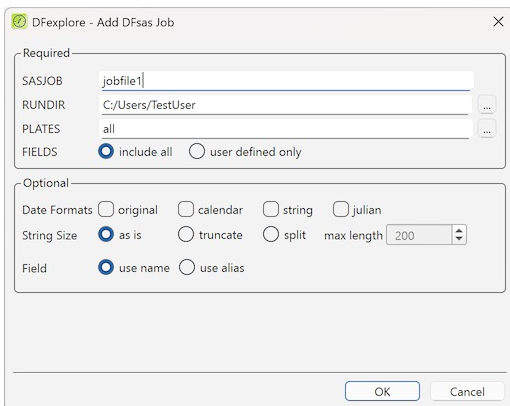


NOTE: If you have previously executed this module as data\_manager, the **DFsas Jobs** panel may display **jobfile1** and possibly other files. If **jobfile1** is already in the list, highlight **jobfile1** and click **Delete** before continuing with this module.

2. Click **Add** to create a new **DFsas** job.

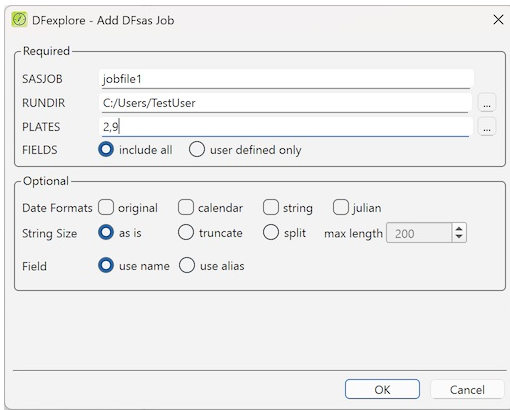


3. Enter **SASJOB** = jobfile1. Click **RUNDIR** [...] to display the file selection dialog. Choose a directory to save "jobfile1" and click **Open**.



NOTE: The **RUNDIR** directory was specified as C:\Users\Public\ in this example. Given the directory structure on your local computer, you may have chosen a different value for **RUNDIR**.

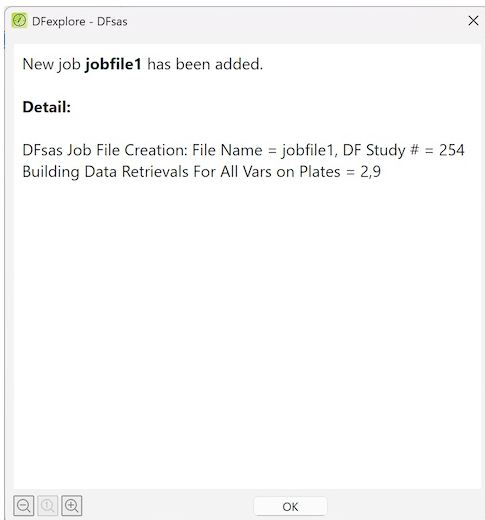
4. Click **PLATES** [...] to view all defined study plates. From the list, hold **Control** key (**Command** on macOS) and click the entries for **002 - Patient Entry Form** and **009 - Adverse Event Report** to highlight them. Click **OK**. Choose **FIELDS** = include all.



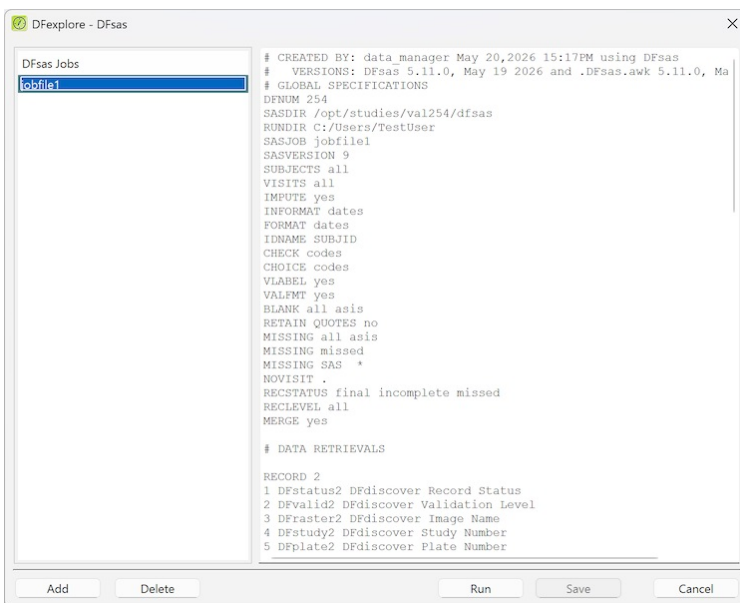
5. In the **Optional** panel set:

- Check (enable) only **calendar** for **Date Formats**
- **String Size** = as is
- **Field** = use alias

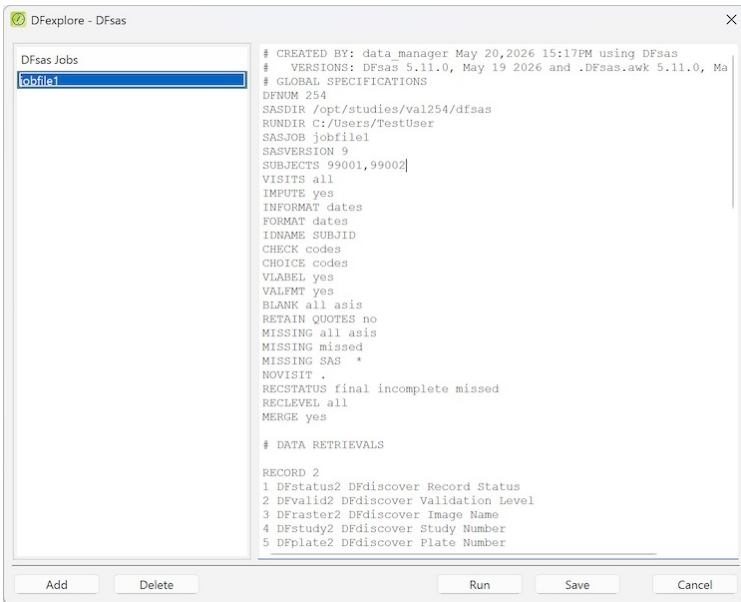
Click **OK** to create and add jobfile1.



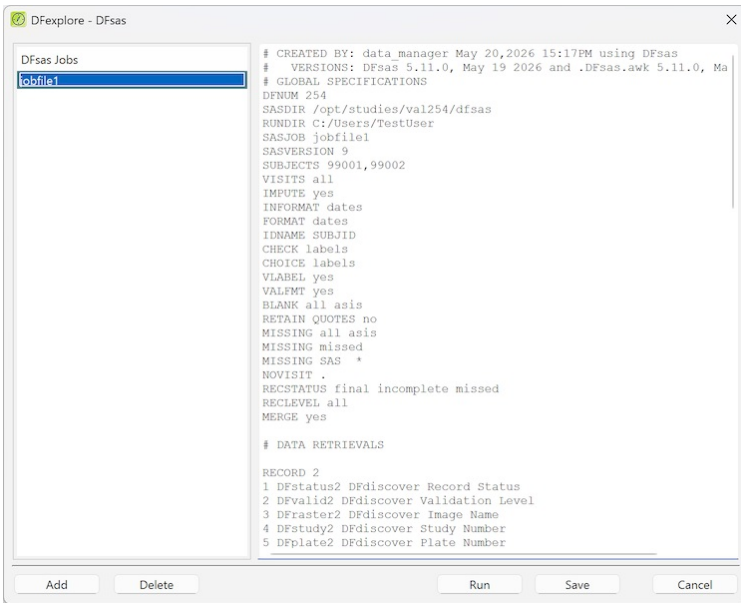
6. Click **OK** in the summary confirmation dialog.



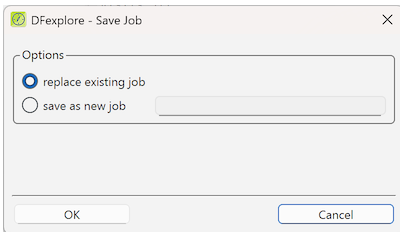
7. Edit the **SUBJECTS** global specification in the new jobfile1 by selecting it from **DFsas Jobs** panel. In the main window, change the text SUBJECTS all to SUBJECTS 99001,99002. This will limit the created SAS data files to subjects 99001 and 99002 only.



8. Locate the global specifications for **CHECK** and **CHOICE**. Change CHECK codes to CHECK labels and CHOICE codes to CHOICE labels.

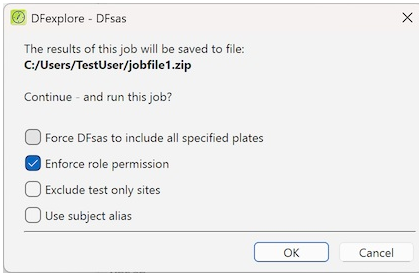


9. Click **Save** to save the changes. In the resulting confirmation dialog, choose **replace existing job** and click **OK**.

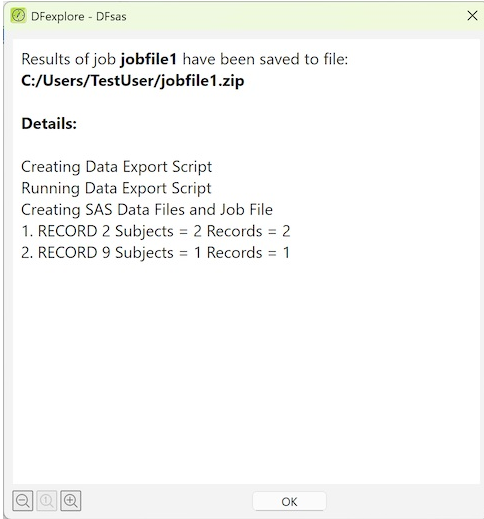


## Create a SAS job file and data files using the DFsas job file criteria

1. In the **DFsas** window, highlight jobfile1. Click **Run** to create SAS job and data files.



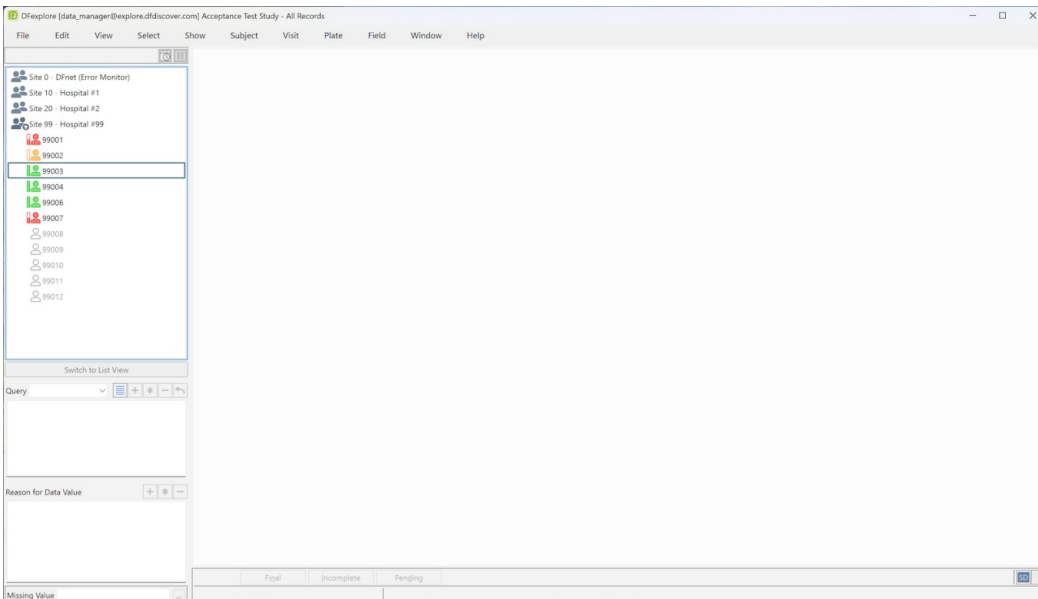
2. In the confirmation dialog, do not check **Force DFSas to include all specified plates**. The SAS job and data files will not include empty plates. Click **OK** to continue and run the DFSas job. After a pause while the job runs, the results dialog appears. Click **OK** to close the dialog.



3. Using the file explorer, locate the directory previously specified as the value of **RUNDIR**. Confirm that jobfile1.zip is present. Double-click jobfile1.zip to unzip the file. Open the jobfile1 folder and confirm that the files jobfile1, jobfile1.sas, jobfile1.d01 and jobfile1.d02 are present.
4. With a text editor, open the data file jobfile1.d01. Examine the contents and confirm that it contains 2 data records - one for each of subjects 99001 and 99002. Print the file (you will need to reference this printed output in ["Compare the contents of SAS data files with the actual data in the database."](#) and then close the text editor application.
5. With the same text editor, open the data file jobfile1.d02. Examine the contents and confirm that it contains 1 data record. Print the file (you will need to reference this printed output in ["Compare the contents of SAS data files with the actual data in the database."](#) and then close the text editor application.

## Compare the contents of SAS data files with the actual data in the database

1. Click **Cancel** to dismiss the **DFSas** dialog. Select **Select** > **All Records**. Without changing any settings, click **OK**.
2. Select **View** > **Data** to change from List View to Data View. In the record list, double-click icon for the open Subject **99003** to close the subject binder. The list now displays all subjects for **Site 99 - Hospital #99**.



3. Double-click Subject **99001**. Select **Subject** > **Expand All Visits**. Locate the entry for **2: Form 2** within the **1: Baseline** visit and select it from the list to open the data record.

99001 - 2 of 16

Site 0 - Dfnet (Error Monitor)  
 Site 10 - Hospital #1  
 Site 20 - Hospital #2  
 Site 99 - Hospital #99

99001  
 0: Screening Visits  
 1: Form 1  
 2: Form 2  
 3: Form 3  
 4: Form 4, Pg 1  
 21: 1 Month Follow-up  
 5: Form 5, 1 Month  
 22: 2 Month Follow-up  
 5: Form 5, 2 Month  
 23: 3 Month Follow-up  
 5: Form 5, 3 Month  
 24: 4 Month Follow-up

Query

Reason for Data Value

Missing Value

DataFax #254 Plate #002 Visit #001

Patient Number 9 9 0 0 1 Patient Initials A B C Entry Date 06/03/97  
 F M L F M L day month year

**PATIENT ENTRY FORM**

**Randomization**  
 Provided the patient meets all eligibility criteria, call the randomization hot line ((905) 999-8888) for this patient's random medication code number.

DataFax #254 Plate #002 Sequence #001

Patient Number 9 9 0 0 1 Patient Initials A B C Entry Date 06 03 97  
 F M L F M L day month year

**PATIENT ENTRY FORM**

**Randomization**  
 Provided the patient meets all eligibility criteria, call the randomization hot line ((905) 999-8888) for this patient's random medication code number.

Medication Code #: 1 1 4 3  
 Give the patient one bottle of study medication from the medication kit with this code number.

**Medical Examination**  
 Date of Birth 1 5 0 2 3 7  
 day month year

kg or 1 2 1 3 lbs

me[1--1] Fetal Incomplete Pending 2 0 1  
 Last Save: 2014-12-10 10:56:40 UTC-04:00

4. Compare the values in each field of the data record with those values in the printout of the data file jobfile1.d01.
5. Double-click Subject **99002** from the record list. Select **Subject** > **Expand All Visits**. Locate the entry for **2: Form 2** within the **1: Baseline** visit and select it from the list to open the data record.

99002 - 2 of 15

Site 0 - Dfnet (Error Monitor)  
 Site 10 - Hospital #1  
 Site 20 - Hospital #2  
 Site 99 - Hospital #99

99001  
 99002  
 0: Screening Visits  
 1: Baseline  
 2: Form 2  
 3: Form 3  
 4: Form 4, Pg 1  
 21: 1 Month Follow-up  
 5: Form 5, 1 Month  
 22: 2 Month Follow-up  
 5: Form 5, 2 Month  
 23: 3 Month Follow-up  
 5: Form 5, 3 Month

Query

Reason for Data Value

Missing Value

DataFax #254 Plate #002 Visit #001

Patient Number 9 9 0 0 2 Patient Initials J A M Entry Date 08/01/97  
 F M L F M L day month year

**PATIENT ENTRY FORM**

**Randomization**  
 Provided the patient meets all eligibility criteria, call the randomization hot line ((905) 999-8888) for this patient's random medication code number.

DataFax #254 Plate #002 Sequence #001

Patient Number 9 9 0 0 2 Patient Initials J A M Entry Date 08 01 97  
 F M L F M L day month year

**PATIENT ENTRY FORM**

**Randomization**  
 Provided the patient meets all eligibility criteria, call the randomization hot line ((905) 999-8888) for this patient's random medication code number.

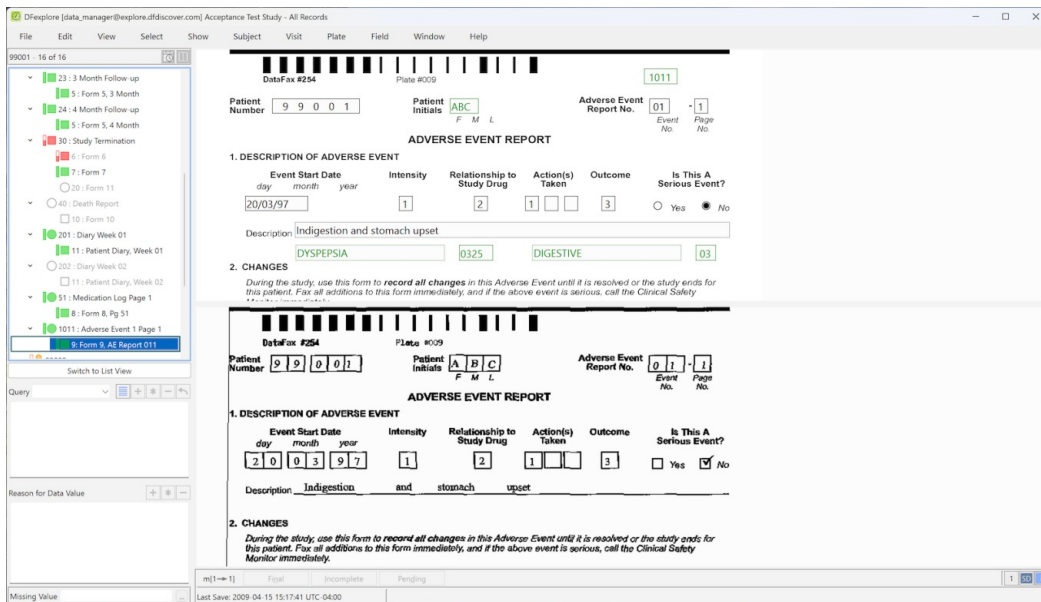
Medication Code #: 1 2 3 4  
 Give the patient one bottle of study medication from the medication kit with this code number.

**Medical Examination**  
 Date of Birth 0 5 1 2 3 2  
 day month year

kg or 1 6 4 5 lbs

me[1--1] Fetal Incomplete Pending 2 0 1  
 Last Save: 2014-12-10 10:59:18 UTC-04:00

6. Beginning with Subject **99002**, **Baseline**, **Form 2**, compare the values in each field of the data record with those values in the printout of the data file jobfile1.d01.
7. Double-click Subject **99001** to re-open the subject binder. Select **Subject** > **Expand All Visits**. Locate the entry for **9: form 9, AE Report 011** within the **1011: Adverse Event 1 Page 1** visit and select it from the list to open the data record.



8. Compare the values in each field of the data record in **DFExplore** with those values in the printout of the data file jobfile1.d02.
9. Select **File** > **Exit** to close **DFExplore**.

## End Module 15. Data Export and DFSas

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 15. Data Export and DFSas.

## Module 16. PDF File Creation

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted

**Client Tools Used:** DFATK, DFExplore

**Purpose:** This module tests PDF file creation in **DFExplore**, including standard, bookmarked, and encrypted CRFs; blank CRFs; and complete subject packages.

### Tests & Requirements

1. Retrieve existing data according to user-specified criteria.
2. Saving **DFExplore** data to a standard PDF document.
3. Saving **DFExplore** blank CRF books to a standard PDF document.
4. Viewing a standard PDF data file using a PDF viewer application.
5. Saving **DFExplore** data to an encrypted bookmarked PDF file.
6. Open and view an encrypted bookmarked PDF file using a PDF viewer application.
7. Create a complete subject package PDF file that includes data records, CRF images and audit trail.
8. Open and view a PDF subject package using a PDF viewer application.

Estimate of Time Required: 30 Minutes

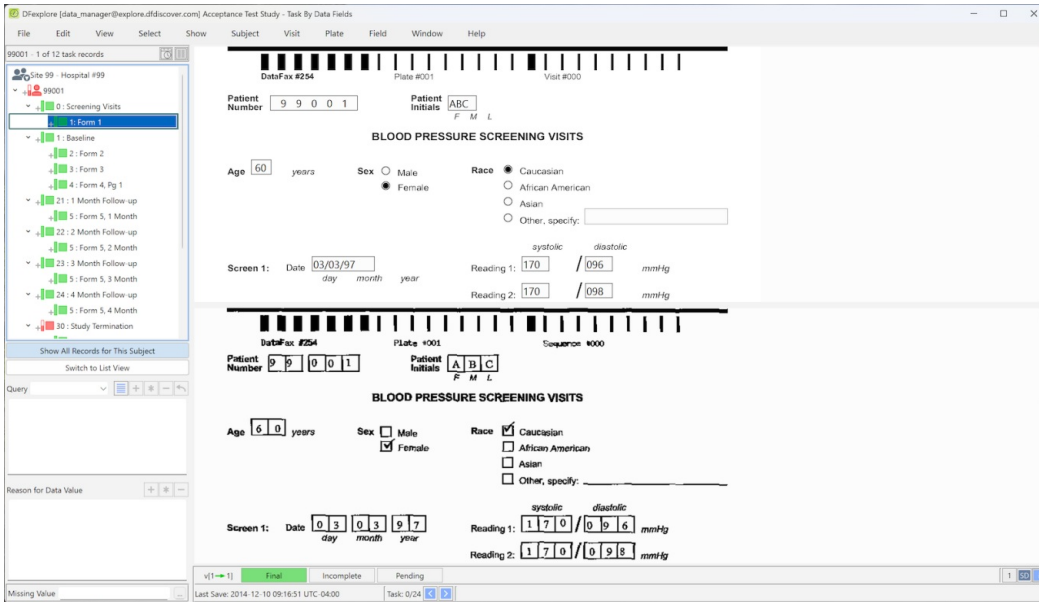
### Begin Module 16. PDF File Creation

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click **[16. PDF File Creation]** followed by **Begin** to begin this module.

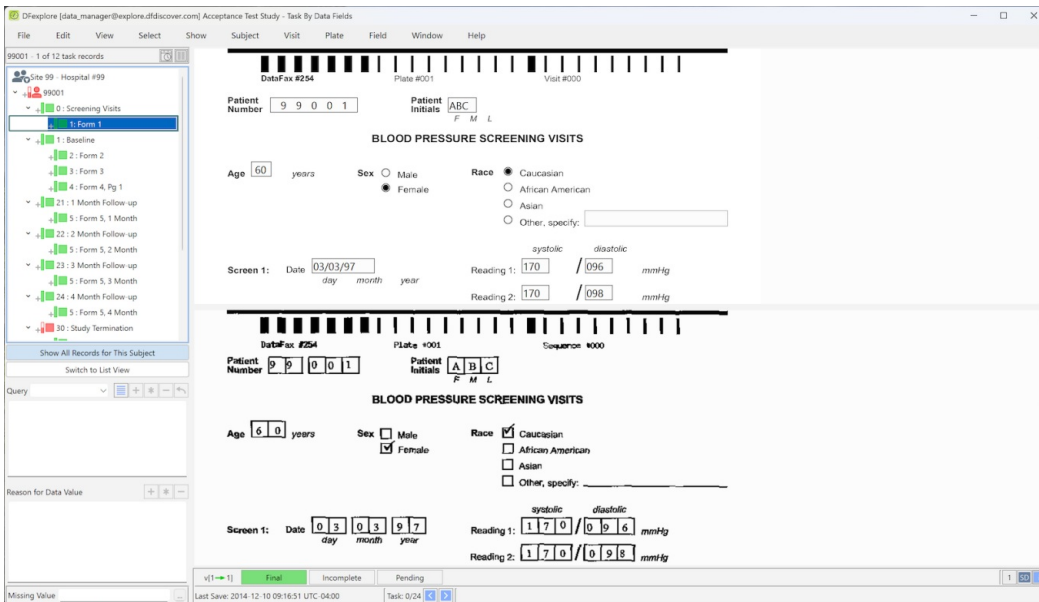
### Retrieve existing data according to user-specified criteria

1. Start **DFExplore**, login as user data\_manager and choose **254 Acceptance Test Study** as described in ["How to start DFExplore"](#)
2. Select **[Select]** > **[By Data Fields]**. Set retrieval criteria as follows:
  - **Mode** = Validate

- o **Save level = 1 - Level 1**
- o **Search = Data**
- o **Subject = 99001,99002**
- o **Level = 1-4**



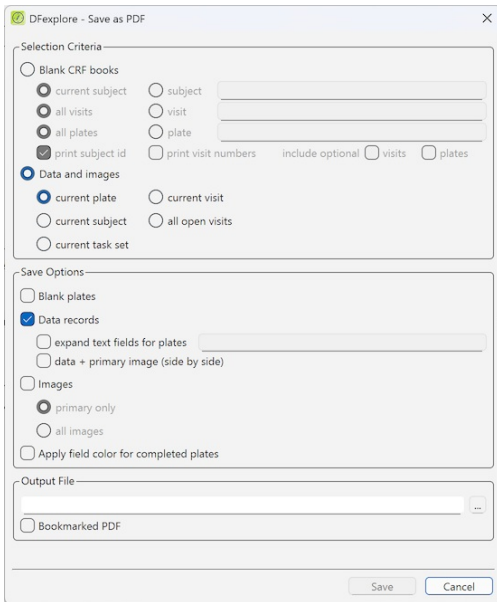
3. Click **Build Set** to retrieve all data records that match the specified criteria. Click **OK** in the confirmation dialog, and finally click **Done** to create a task set of the retrieved data.



4. Scroll the record list panel to confirm that 2 subjects, 99001 and 99002, have been retrieved. Double-click the entry for Subject 99002 to open and lock all records for the subject.

## Saving DfExplore data to a standard PDF document

1. Select **File** > **Save as PDF**.

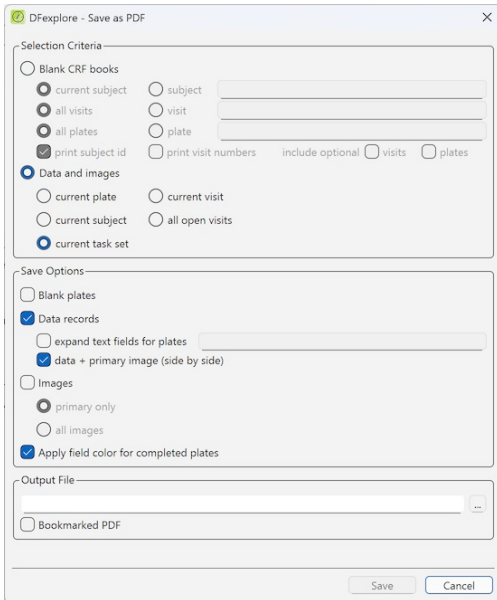


2. In the **Selection Criteria** panel,

- Select (enable) **Data and images** followed by **current task set**

In the **Save Options** panel,

- Check (enable) **Data records** and **data + primary image (side by side)**
- Check (enable) **Apply field color for completed plates**



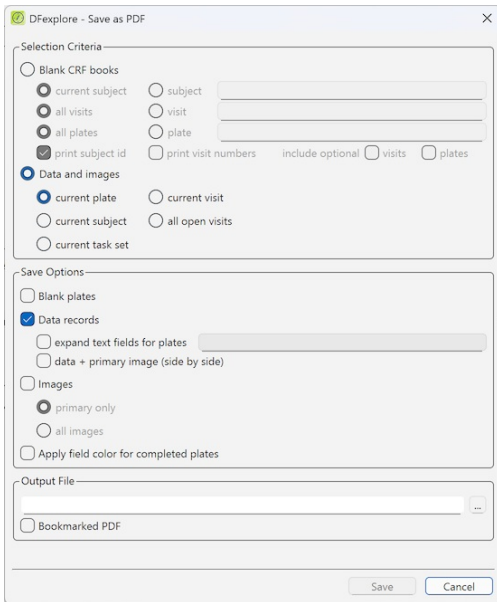
3. Click **Output File** . In the file selection dialog, choose a directory in which to save the PDF file. Once a directory has been chosen, append the file name subjects.pdf to the directory name. Click **Save**.

4. Complete the specification by clicking **Save**. There will be a busy pause while the PDF file of completed data pages and their primary images is created.

**NOTE:** The save directory in this test was chosen to be C:\Users\Public. Your save directory may be different.

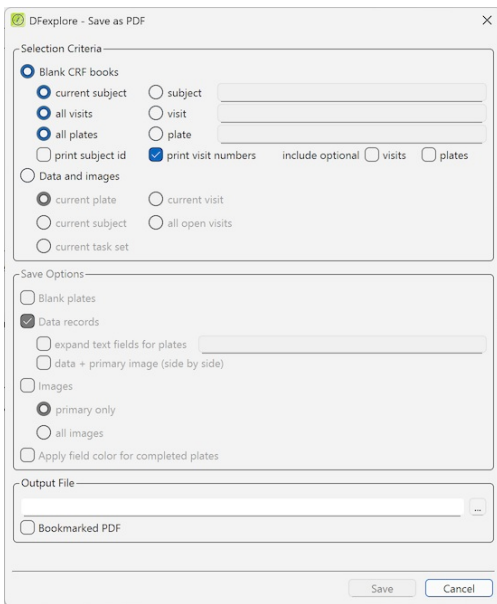
## Saving DFexplore blank CRF books to a standard PDF document

1. Select **File** > **Save as PDF**.



2. In the **Selection Criteria** panel,

- o Select (enable) **Blank CRF books**, followed by **all visits**, **all plates**.
- o Un-check (disable) **print subject id**
- o Check (enable) **print visit numbers**



3. Click **Output File** [...]. In the file selection dialog, choose a directory in which to save the PDF file.

Once a directory has been chosen, append the file name `blankssubject.pdf` to the directory name. Click **Save**.

4. Complete the specification by clicking **Save** followed by **Yes** in the resulting dialog. There will be a busy pause while the PDF file is created.

NOTE: The save directory in this test was chosen to be `C:\Users\Public`. Your save directory may be different.

## Viewing a standard PDF data file using a PDF viewer application

1. A PDF viewer application, such as **Acrobat Reader**, is required for this step. Start the PDF viewer application. Locate the directory in which the PDF file `subjects.pdf` was saved in "[Saving DFExplore data to a standard PDF document.](#)". Open `subjects.pdf`.

NOTE: All PDF files opened in this test and in the remainder of this module are illustrated using **Acrobat Reader**. If you are using a different PDF viewer application, the appearance of your document may differ from that shown here. It may also be necessary to rotate the PDF image so that it is displayed in landscape format.

2. Examine the PDF document.

Acceptance Test Study

The image shows two completed CRF forms for blood pressure screening visits. The left form is dated 11 November 2014 and the right form is dated 14 April 2009. Both forms include patient information, screening dates, readings, and eligibility criteria.

**Form 1 (Left):** Patient # 79001, Visit #001. Patient Name: A B C. Age: 60 years. Sex: Male. Race: Caucasian. Screen 1: 03/03/97. Readings: 117/0/019/2 mmHg, 117/0/019/8 mmHg, 117/2/019/8 mmHg. Screen 2: 05/03/97. Readings: 117/1/019/6 mmHg, 116/9/019/6 mmHg, 117/0/019/6 mmHg. Eligibility criteria are marked as follows: 1. Yes, 2. No, 3. No, 4. No, 5. Yes, 6. No. Patient is Eligible.

**Form 2 (Right):** Patient # 79001, Visit #001. Patient Name: A B C. Age: 60 years. Sex: Male. Race: Caucasian. Screen 1: 05/03/97. Readings: 117/0/019/6 mmHg, 117/0/019/6 mmHg, 117/2/019/6 mmHg. Screen 2: 03/03/97. Readings: 117/1/019/6 mmHg, 116/9/019/6 mmHg, 117/0/019/6 mmHg. Eligibility criteria are marked as follows: 1. No, 2. No, 3. No, 4. No, 5. Yes, 6. No. Patient is Eligible.

3. Locate the directory in which the PDF file blanksubject.pdf was saved in "[Saving DFExplore blank CRF books to a standard PDF document.](#)". Open blanksubject.pdf.
4. Examine the PDF document. Confirm the PDF document was printed without the presence of Subject ID numbers.

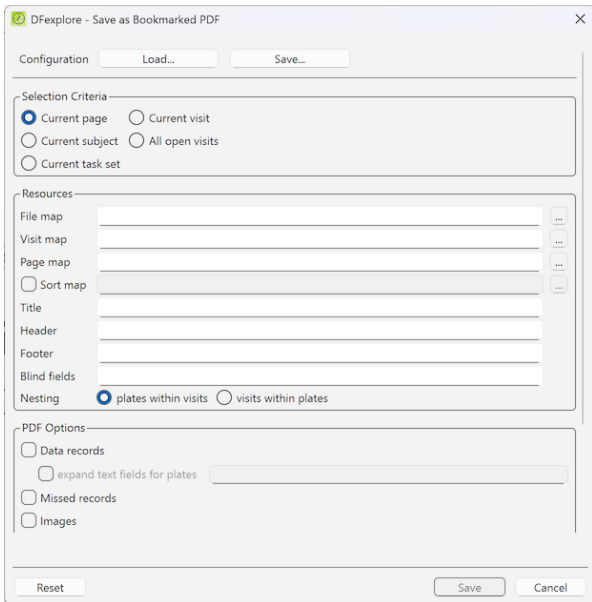
The image shows a blank CRF form for blood pressure screening visits, dated 11 November 2014. The form includes fields for patient information, screening dates, readings, and eligibility criteria.

**Form 3 (Left):** Patient # [ ], Visit #001. Patient Name: [ ]. Age: [ ] years. Sex: Male/Female. Race: Caucasian/African American/Asian/Other. Screen 1: [ ]/[ ]/[ ]. Readings: [ ]/[ ]/[ ] mmHg, [ ]/[ ]/[ ] mmHg, [ ]/[ ]/[ ] mmHg. Screen 2: [ ]/[ ]/[ ]. Readings: [ ]/[ ]/[ ] mmHg, [ ]/[ ]/[ ] mmHg, [ ]/[ ]/[ ] mmHg. Eligibility criteria are marked as follows: 1. [ ], 2. [ ], 3. [ ], 4. [ ], 5. [ ], 6. [ ]. Patient is Eligible.

5. Exit the PDF viewer application.

Saving DFExplore data to an encrypted bookmarked PDF file

1. With the task set of records from "[Retrieve existing data according to user-specified criteria.](#)" (Subjects 99001 and 99002) still the current set, click the record for Subject 99002, Form 1 to set it as the current page. Select **File** > **Save As Bookmarked PDF** to open the dialog.



2. In the **Selection Criteria** panel,

- Select (enable) **Current subject**

In the **Resources** panel,

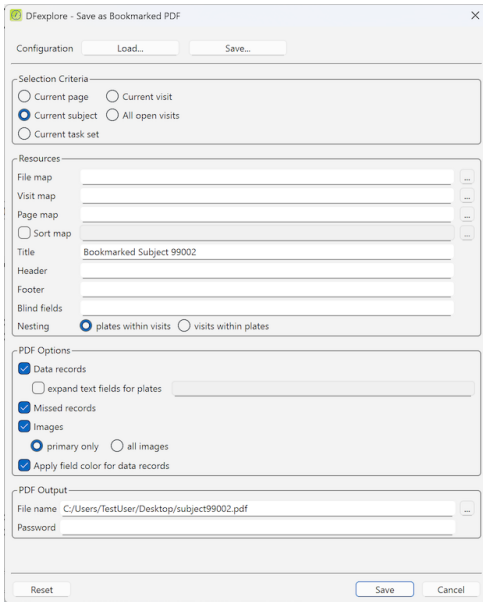
- Enter a **Title** of Bookmarked Subject 99002
- Use the default Nesting **plates within visits**

In the **PDF Options** panel,

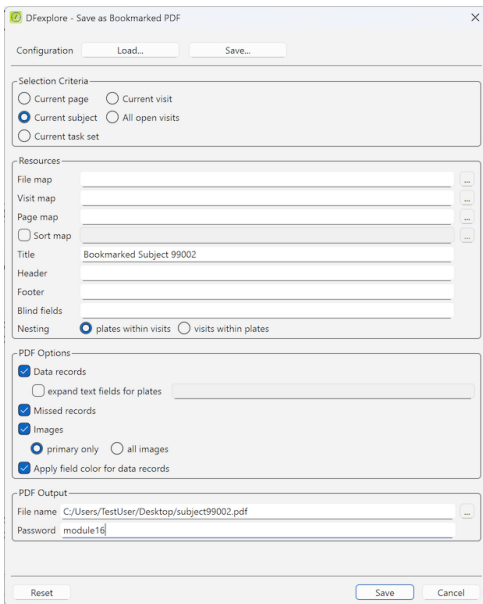
- Check (enable) **Data records**
- Check (enable) **Missed records**
- Check (enable) **Images** and select (enable) **primary only**
- Check (enable) **Apply field color for data records**

In the **PDF Output** panel,

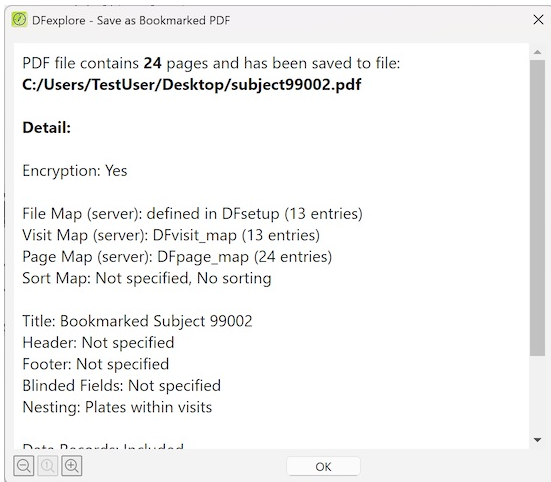
- Select an **Output File** directory using the file selection dialog and set the file name to subject99002.pdf.



3. Enter module16 as the value for **Password**.



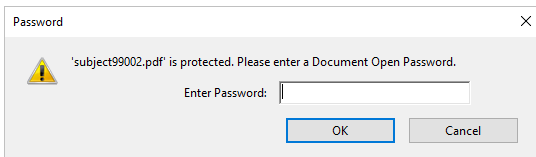
4. Click **Save** to create a password encrypted PDF file of completed data pages and primary images for Subject 99002.



5. Click **OK** to close the dialog.

## Open and view an encrypted bookmarked PDF file using a PDF viewer application

1. A PDF viewer application is required for this test. Start the PDF viewer application. Locate the directory created in ["Saving DFEExplore data to an encrypted bookmarked PDF file."](#). Locate and open subject99002.pdf.



2. In the **Password** dialog enter module16 as the password. This matches the password that was specified at file creation in ["Saving DFEExplore data to an encrypted bookmarked PDF file."](#). Once the password has been entered, the PDF file opens.

**BLOOD PRESSURE SCREENING VISITS**

Patient Number: 99002 Patient Initials: JAM  
 Age: 64 years Sex: Female Race:  Caucasian  
 African American  
 Asian  
 Other, specify: \_\_\_\_\_

Screen 1: Date: 04/01/97  
 Reading 1: 168/096 mmHg  
 Reading 2: 170/098 mmHg  
 Reading 3: 170/098 mmHg

Screen 2: Date: 08/01/97  
 Reading 1: 172/098 mmHg  
 Reading 2: 168/096 mmHg  
 Reading 3: 166/094 mmHg

**Eligibility Criteria**

	Yes	No
1. Age 16-79 years old.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Male, or if female, not pregnant and using a reliable contraceptive method.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Taking blood pressure medication.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. Major surgery or other medical emergency in the past 6 months.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Patient has signed informed consent and agrees to return for monthly follow-up visits.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Systolic blood pressure 160-200 mmHg or Diastolic blood pressure 95-105 mmHg on Reading 3 at both Screen 1 and Screen 2.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

↓  
Patient is Eligible

Once Completed, Please Fax This Form to (888)###-####.

11 November 2014

3. Open all bookmarks for Subject 99002.

**BLOOD PRESSURE SCREENING VISITS**

Patient Number: 99002 Patient Initials: JAM  
 Age: 64 years Sex: Female Race:  Caucasian  
 African American  
 Asian  
 Other, specify: \_\_\_\_\_

Screen 1: Date: 04/01/97  
 Reading 1: 168/096 mmHg  
 Reading 2: 170/098 mmHg  
 Reading 3: 170/098 mmHg

Screen 2: Date: 08/01/97  
 Reading 1: 172/098 mmHg  
 Reading 2: 168/096 mmHg  
 Reading 3: 166/094 mmHg

**Eligibility Criteria**

	Yes	No
1. Age 16-79 years old.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Male, or if female, not pregnant and using a reliable contraceptive method.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Taking blood pressure medication.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. Major surgery or other medical emergency in the past 6 months.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Patient has signed informed consent and agrees to return for monthly follow-up visits.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Systolic blood pressure 160-200 mmHg or Diastolic blood pressure 95-105 mmHg on Reading 3 at both Screen 1 and Screen 2.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

↓  
Patient is Eligible

Once Completed, Please Fax This Form to (888)###-####.

11 November 2014

4. In the bookmark panel, each data record is represented by the suffix **(data)** to distinguish it from the primary CRF image. Click entry **Form 2 (data)** to make the Form 2 data record the active page. Click entry **Form 2** to make the Form 2 primary CRF image the active page.

5. Exit the PDF viewer application. In **DFexplore**, select **View** > **Data**. Then, select **Select** > **All Records**. This will release the task set of records for Subjects 99001 and 99002. Click **OK** in the resulting dialog to retain the default settings.

## Create a complete subject package PDF file that includes data records, CRF images and audit trail

1. Select **File** > **Create Subject Packages**.

DFxplorer - Create Subject Packages

Configuration Load... Save...

Subject Selection  
Create one bookmarked PDF for each of the following:  
Subjects: all subjects

Selection Criteria  
Visit:   
Plate:

Resources  
File map:   
Visit map:   
Page map:   
 Sort map:   
Title:   
Header:   
Footer:   
Blind fields:   
Nesting:  plates within visits  visits within plates

PDF Options  
 Data records  
 expand text fields for plates:   
 Missed records  
 Images  
 primary only  all images  
 Include subject history in format:  legacy  simplified  detailed (Excel only)  
Bookmark label: Data and Metadata Change History  
 Apply field color for data records

PDF Output  
Output folder:   
File prefix:   
Password:

Close this window when creating packages has completed

Reset Start Cancel

2. In the **Subject Selection** section, choose **Subjects** from the drop-down and enter 99001,99002,99003 to create complete subject packages for Subjects 99001, 99002 and 99003.

DFxplorer - Create Subject Packages

Configuration Load... Save...

Subject Selection  
Create one bookmarked PDF for each of the following:  
Subjects: 99001,99002,99003

Selection Criteria  
Visit:   
Plate:

Resources  
File map:   
Visit map:   
Page map:   
 Sort map: DFpdf\_g pagemap: blank for default DFpage\_map  
Title:   
Header:   
Footer:   
Blind fields:   
Nesting:  plates within visits  visits within plates

PDF Options  
 Data records  
 expand text fields for plates:   
 Missed records  
 Images  
 primary only  all images  
 Include subject history in format:  legacy  simplified  detailed (Excel only)  
Bookmark label: Data and Metadata Change History  
 Apply field color for data records

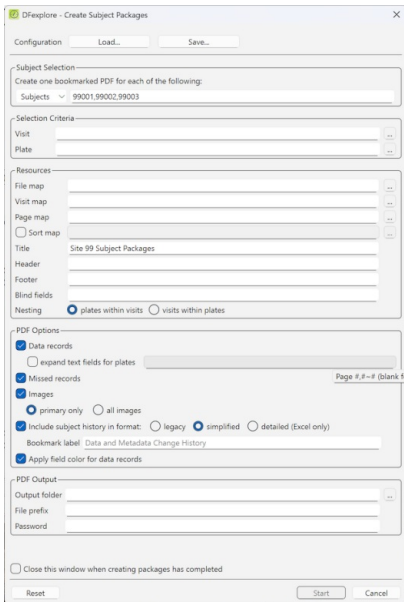
PDF Output  
Output folder:   
File prefix:   
Password:

Close this window when creating packages has completed

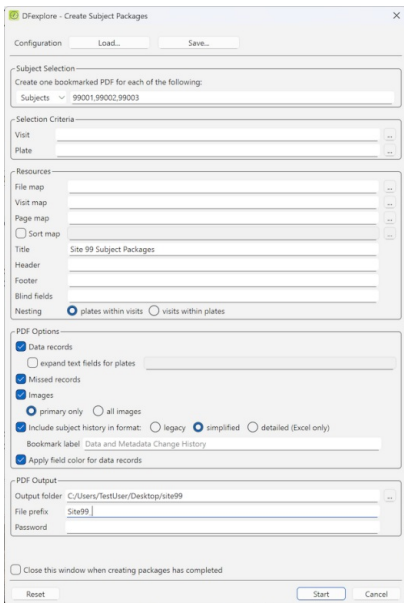
Reset Start Cancel

3. In the remainder of the dialog specify the following settings:

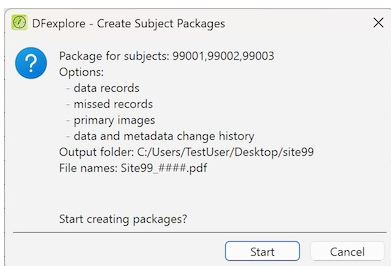
- o **Title** = Site 99 Subject Packages
- o Check (enable) **Data records**
- o Check (enable) **Missed records**
- o Check (enable) **Images**
- o Check (enable) **primary only**
- o Check (enable) **Include subject history in format** and **simplified**
- o Check (enable) **Apply field color for data records**



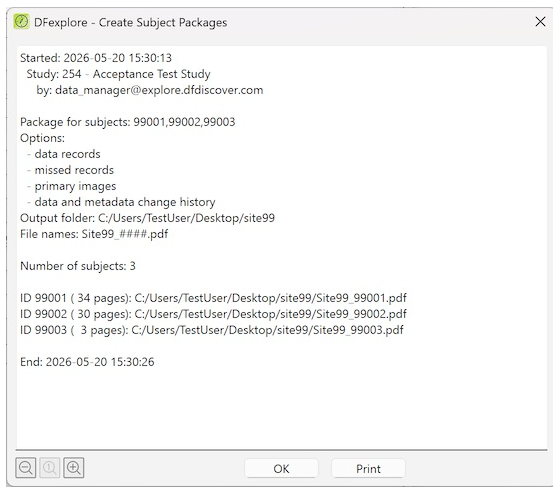
- Specify a PDF output folder by first clicking **Output folder** [...] to view the directory structure for the local computer. Select a directory in which to save the subject package PDF files.
- Specify a file prefix to be prepended to each subject package created. Enter Site99\_ in the **File prefix** field.



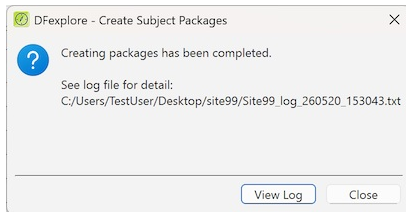
- Do not encrypt the subject packages to be generated by leaving the **Password** field empty. Click **Start** to begin generating a complete subject package for each of the specified subjects 99001, 99002 and 99003.



- Verify that the output in the confirmation dialog specifies packages for subjects 99001, 99002 and 99003. Click **Start** to start package creation.



8. In the confirmation dialog, click **View Log**. Review the output. Click **OK** to close the log.



9. The main **Create Subject Packages** dialog is displayed. Click **Cancel** to close this dialog.

## Open and view a PDF subject package using a PDF viewer application

1. A PDF viewer application is required for this test. Start the PDF viewer program. Locate and open the directory in which the PDF subject packages were saved in [Step 7](#). Locate files Site99\_99001.pdf, Site99\_99002.pdf and Site99\_99003.pdf.
2. Open the subject package for Site99\_99001.pdf.
3. Open all bookmarks for Subject 99001.
4. In the record list, each data record is represented by the term **(data)** to distinguish it from its primary CRF image. Click entry **Form 2 (data)** to make the Form 2 data record the active page. Click entry **Form 2** to make the Form 2 primary CRF image the active page.
5. In the bookmark list click the entry for **Data and Metadata Change History** to display the complete audit trail report for Subject 99001.
6. Exit the PDF viewer application to close both the file Site99\_99001.pdf and PDF viewer.
7. Select **File** > **Exit** to close and exit **DFExplore**.

## End Module 16. PDF File Creation

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 16. PDF File Creation.

## Module 17. DFweb Data Entry

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- DFws 5.11.0 installed and properly configured on DFws server
- DFweb 5.11.0 installed and properly configured on DFweb server
- DFdiscover license with DFWS license feature on the DFdiscover server
- DFweb compatible browser installed on local test device
  - Mozilla Firefox
  - Google Chrome
  - Apple Safari
  - Microsoft Edge
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
  - site\_invest : site\_investigator
- Email configured for site\_monitor
- (Optional) SMS or email 2-factor authentication configuration for site\_invest

NOTE: For configuration of 2-factor authentication, see [Module 1\(Installation & Initialization\) test step 6](#) for details on configuring accounts with 2-factor authentication

**Purpose:** This module tests all main DFdiscover functionality with respect to **DFweb**. Data capture, review, document management, and eSignature functionality. The module additionally uses **DFexplore** to verify save data levels of data entered using **DFweb**.

## Tests & Requirements

1. Verify **DFweb** version information, logging into **DFweb** and **DFweb** site certificate verification.
2. Resetting a user login password.
3. Copying URL and changing user passwords.
4. Creating a new subject, entering subject data.
5. Adding, modifying and resolving queries.
6. Adding, reviewing and downloading subject documents.
7. Add an Electronic Signature (eSign) to a set of completed subject records.
8. Verify removal and re-application of eSignatures.
9. Verify **DFweb** saves eSignature task data to the specified save level.

Estimate of Time Required: 25 Minutes

## Begin Module 17. DFweb Data Entry

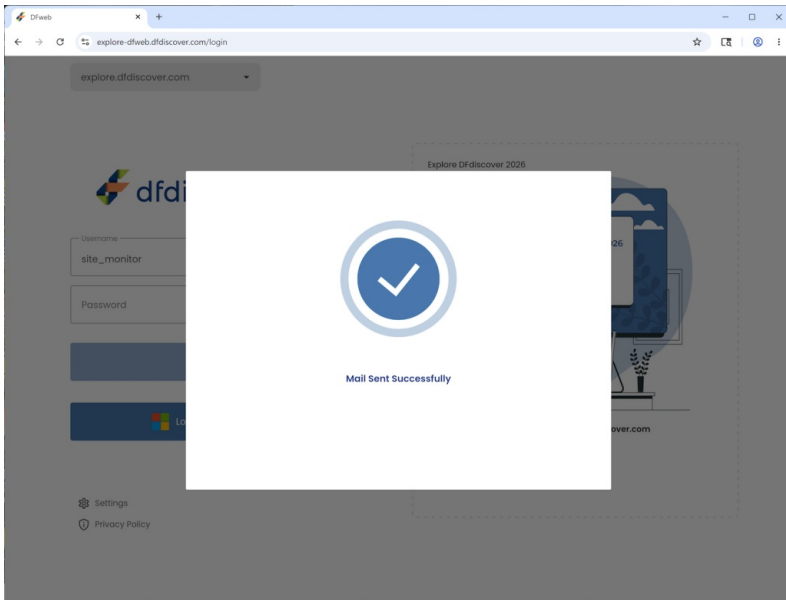
1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click [\[17. DFweb Data Entry\]](#) followed by [\[Begin\]](#) to begin this module. Click [\[Send ID 99008\]](#).

NOTE: Save the labreport99008\_module17.pdf file received via email to your local computer. This file is required to complete [Adding, reviewing and downloading subject documents](#). Refer to [Creating user accounts and assigning study permissions](#). as a valid email address is required for data\_coordinator, data\_manager, site\_monitor or site\_invest to receive the module specific PDF files.

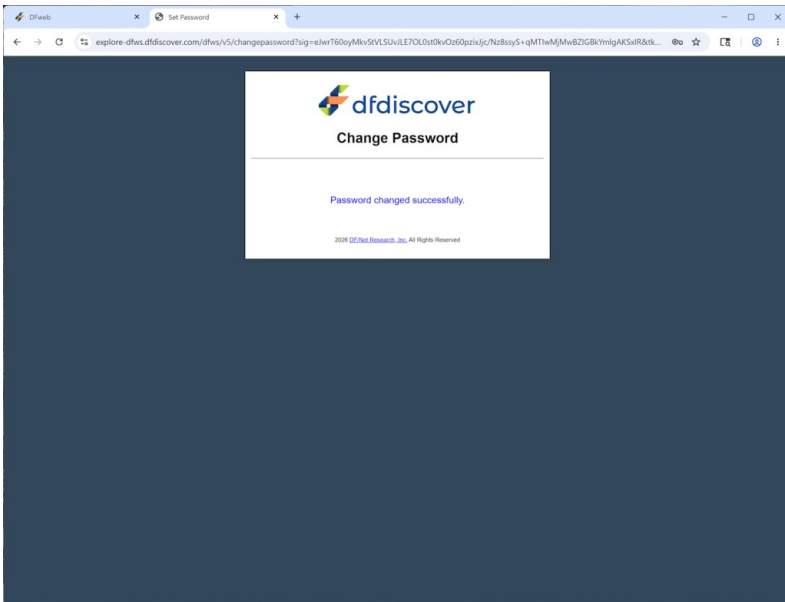
## Resetting a user login password

NOTE: All remaining tests performed in this module have been completed using **Google Chrome**. Results and/or test steps may vary with other browsers.

1. Open a web browser and navigate to <https://dfweb.dfdiscoverserver.com/login> or the **DFweb** URL provided by your administrator. In the **DFweb** login dialog, enter the **DFdiscoverserver** name that has been provided by your administrator. Click [\[Continue\]](#), enter site\_monitor in the Username field of the login dialog, and click [\[Forgot Password?\]](#).
2. In the Reset Password dialog, enter the username and email address associated with the site\_monitor account and click [\[Send Email\]](#). A confirmation message appears: **Mail Sent Successfully**.



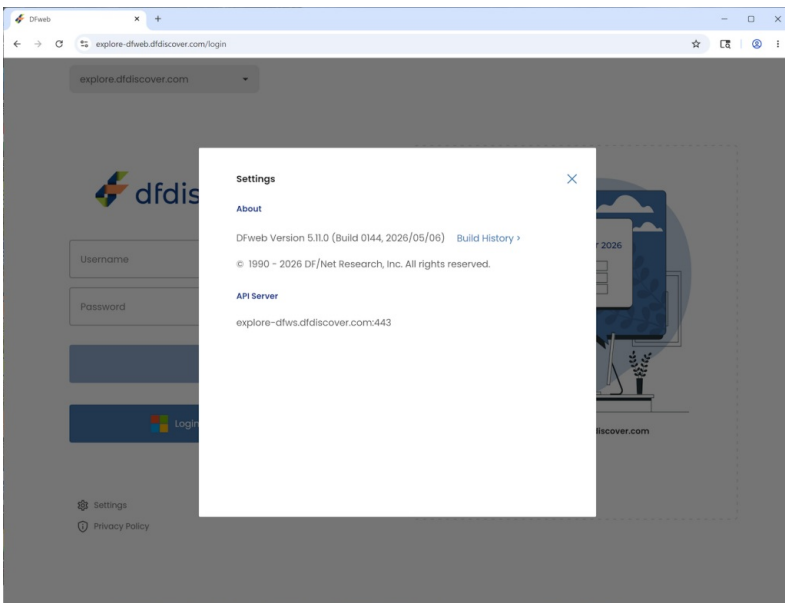
3. Open the password reset email from your **DFdiscoverserver** server and click the provided link to reset the site\_monitor password.
4. Enter and confirm a new password, then click [\[Update\]](#).



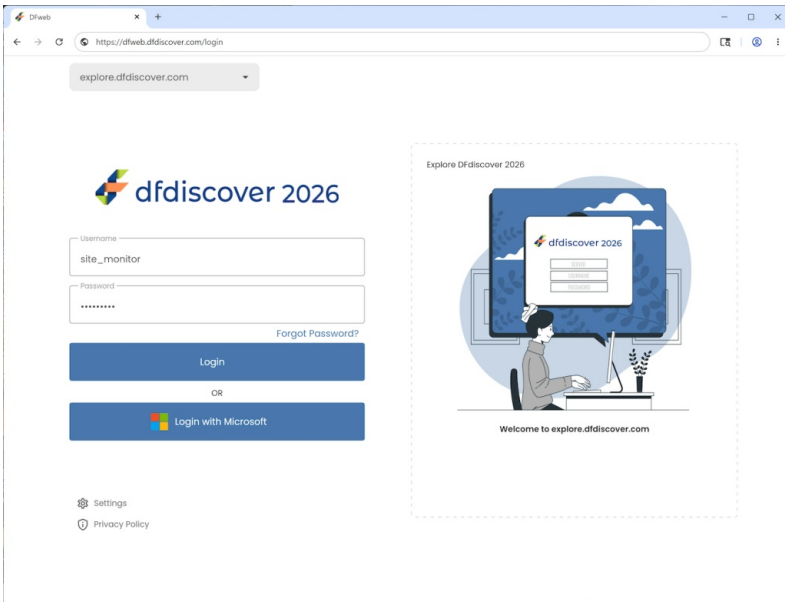
5. A message confirming **Password changed successfully.** is displayed in your browser, and a notification email is sent to the address associated with the `site_monitor` account.

### Verify DFweb version information, logging into DFweb and DFweb site certificate verification

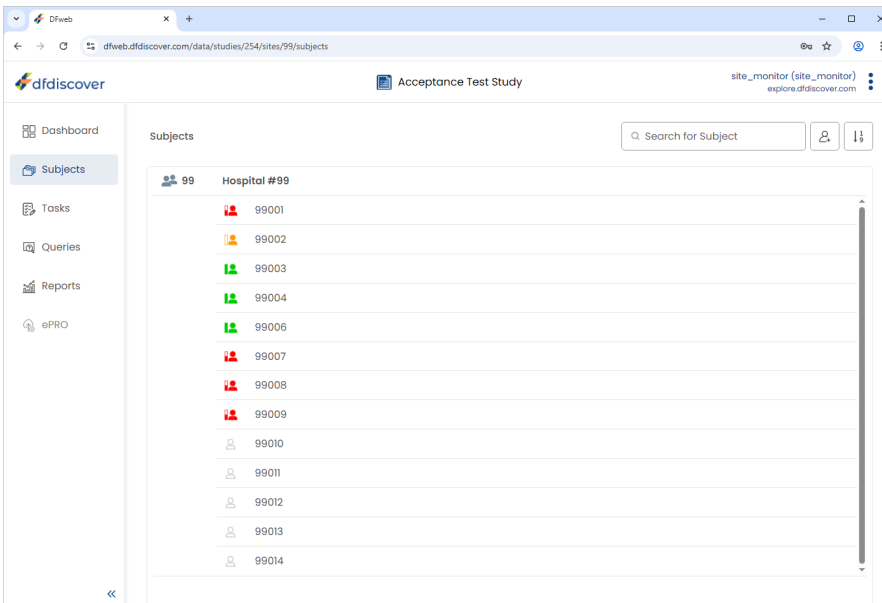
1. Open a web browser and navigate to <https://dfweb.dfdiscover.com/login> or the DFweb URL provided by your administrator, Click  Settings, verify the version information: **DFweb Version 5.11.0** is displayed.



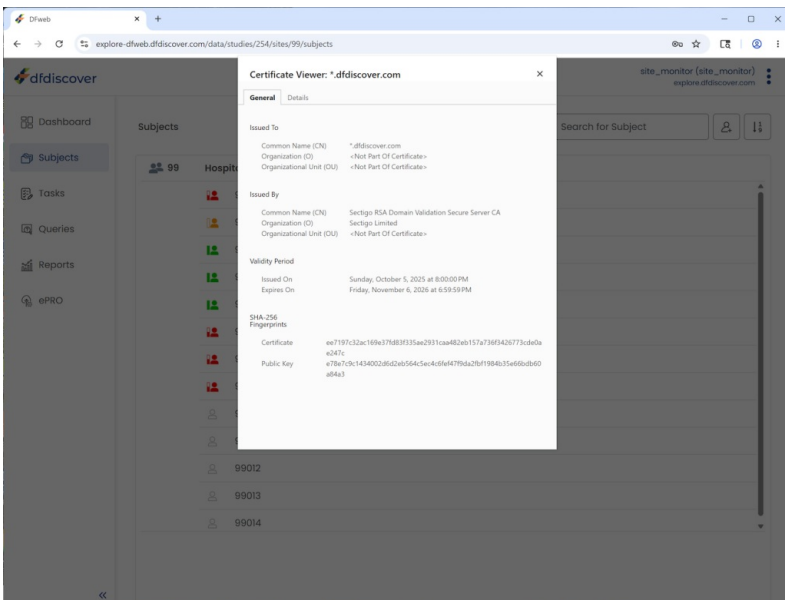
2. Enter `site_monitor` in the **Username** field and the previously assigned password in the **Password** field. Click `Login` to login.





3. A list of subjects for **Hospital #99** is displayed.

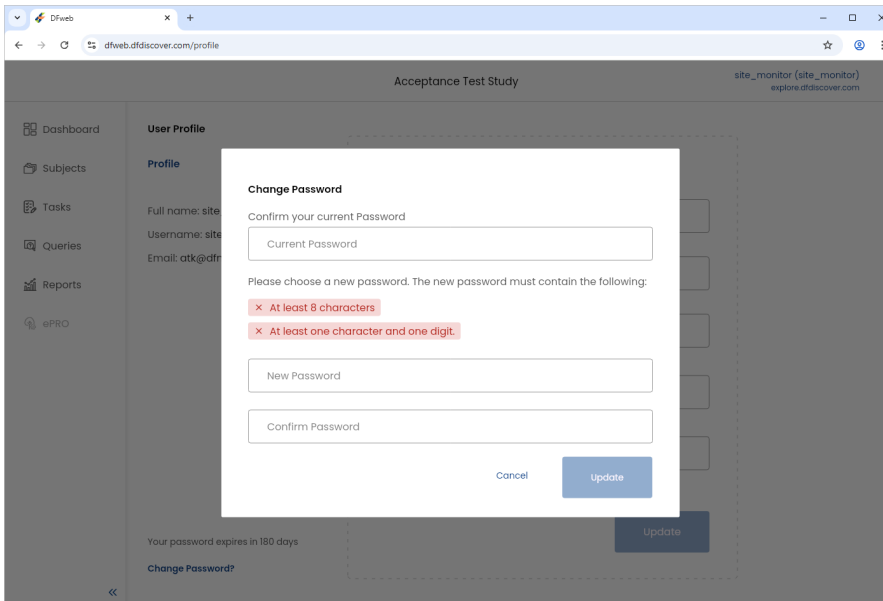


4. Click the **View Site Information** icon from the web browser address bar. Select **Connection is secure** > **Certificate is valid**. The website trust certificate is displayed for the current **DFweb** address, click **OK** or **X** to close the window.



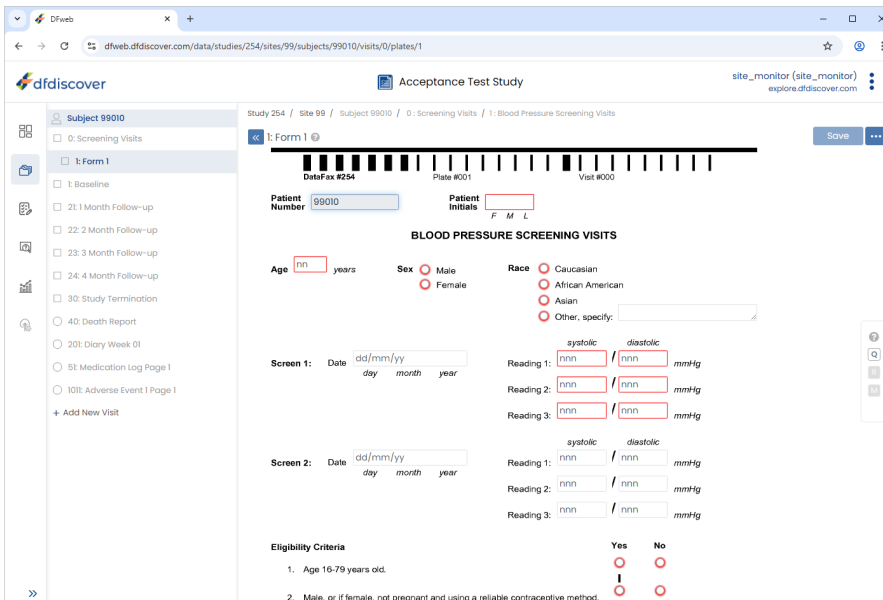
## Copying URL and changing user passwords


1. From the **Subjects** list, click Subject **99002** to open the **0: Screening Visits 1:Form 1** page.
2. Copy the **DFweb** URL by clicking  > **Copy URL**.
3. Open a new browser tab, paste the copied URL into the new browser tab, click **Enter**. The pasted URL in the new tab re-directs you to the **DFweb** login page. Login again using **site\_monitor** credentials, upon logging in confirm you are taken to the same subject data record as the previous web browser tab. Close the web browser tab.
4. Click  > **User Profile** > **Change Password** to view the **Change Password** window. Click **Cancel**.



## Creating a new subject, entering subject data

1. Click **Subjects**, select **99010** to open the **0: Screening Visits 1:Form 1** page.



2. Click **Patient Initials** enter ARX, Set:
  - o **Age (years)** = 49
  - o **Sex** = male
  - o **Race** = caucasian
  - o **Screen 1 Date** = Click  icon, select 11-Nov-2018

Click **SAVE**.

Study 254 / Site 99 / Subject 99010 / 0: Screening Visits / 1: Blood Pressure Screening Visits

1: Form 1

DataFax #254 Plate #001 Visit #000

Patient Number 99010 Patient Initials ARX

Age 49 years Sex Male Race Caucasian

BLOOD PRESSURE SCREENING VISITS

Screen 1: Date 11/11/18 Reading 1: systolic diastolic mmHg

Screen 2: Date dd/mm/yy Reading 1: systolic diastolic mmHg

Eligibility Criteria

- Age 16-79 years old.
- Male, or if female, not pregnant and using a reliable contraceptive method.

3. Select **1:Baseline > 21:Lab Results** page. Click **Patient Initials** field.

**NOTE:** The Setnitedit check executes upon entry to the field. If the initials are available on **1 : Form 1** (previously entered), they are retrieved and populate the **Patient Initials** field.

Study 254 / Site 99 / Subject 99010 / 1: Baseline / 21: Lab Results

21: Lab Results

\* Patient Number 99010

\* Patient Initials ARX

Collection Date DD-MMM-YYYY

White Blood Cell n.n.n k/mcl  ABNORMAL  NORMAL  Clinically significant

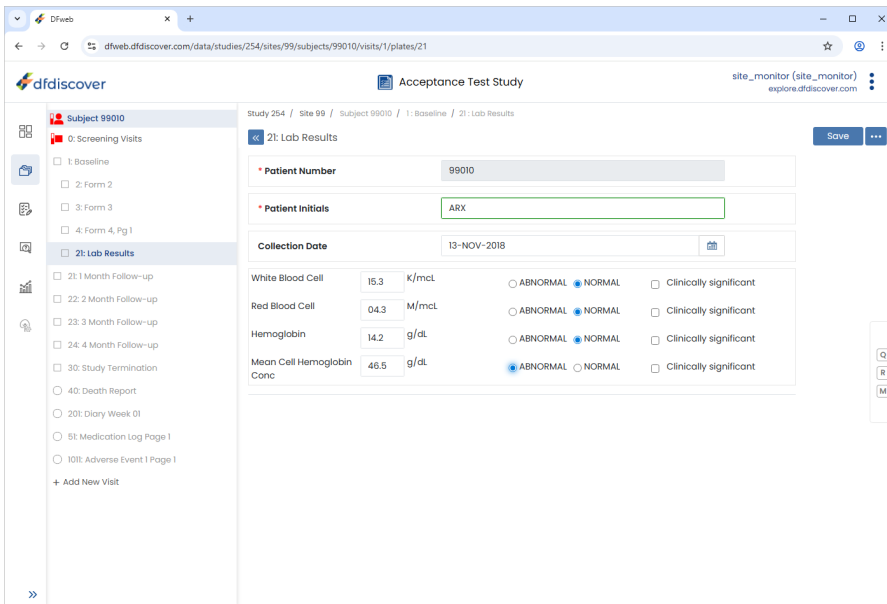
Red Blood Cell n.n.n M/mcl  ABNORMAL  NORMAL  Clinically significant

Hemoglobin n.n.n g/dl  ABNORMAL  NORMAL  Clinically significant

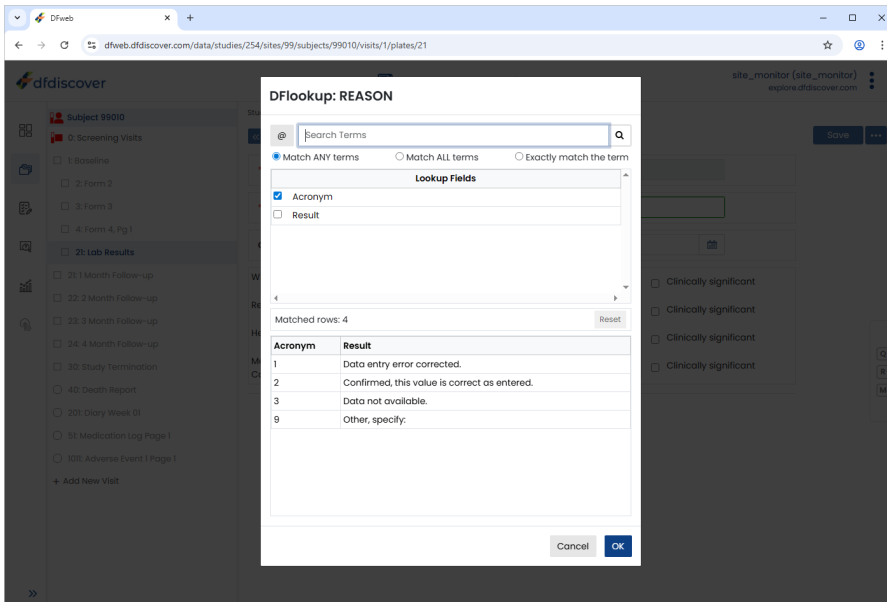
Mean Cell Hemoglobin Conc n.n.n g/dl  ABNORMAL  NORMAL  Clinically significant

4. Set the remaining fields within the **21: Lab Results** form as follows:

- **Collection Date** = 13-NOV-2018
- **White Blood Cell** = 15.3, Check (enable) **NORMAL**
- **Red Blood Cell** = 04.3, Check (enable) **NORMAL**
- **Hemoglobin** = 14.2, Check (enable) **NORMAL**
- **Mean Cell Hemoglobin Conc** = 46.5, Check (enable) **ABNORMAL**



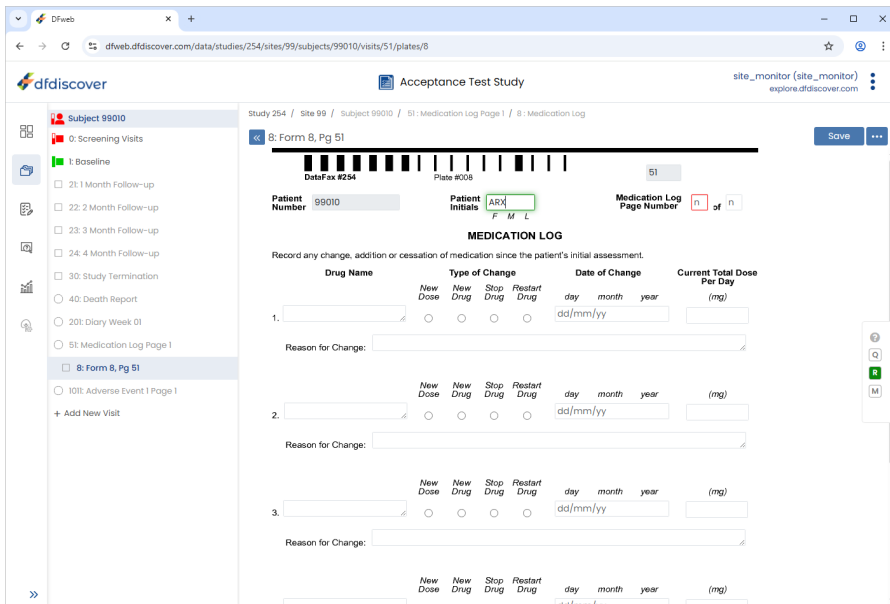
5. Click **R** to open the **Reason for Data Value** dialog. Click **...** next to **Reason**. The **DFlookup: REASON** dialog is displayed.



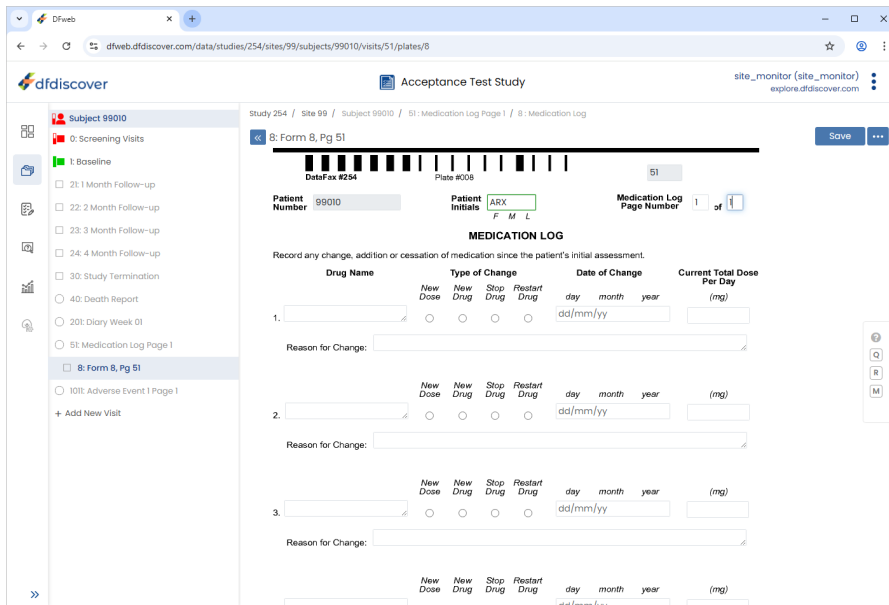
6. Select the **Result** of Confirmed, this value is correct as entered., Click **OK**, followed by **Apply** then **SAVE**.

7. Select **51: Medication Log Page 1 > 8: Form 8, Pg 51** page. Click **Patient Initials** field.

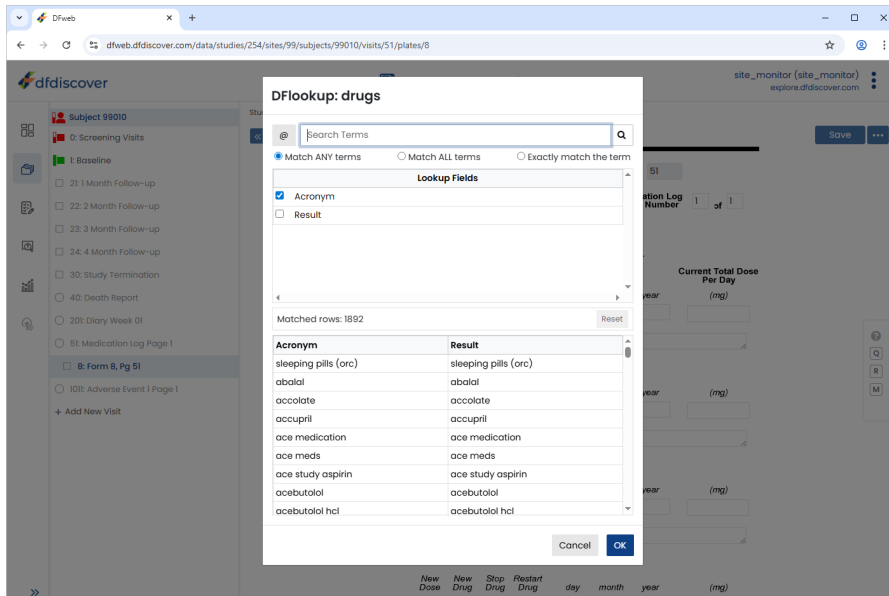
**NOTE:** The SetInitedit check executes upon entry to the field. If the initials are available on **1 : Form 1** (previously entered), they are retrieved and populate the **Patient Initials** field.



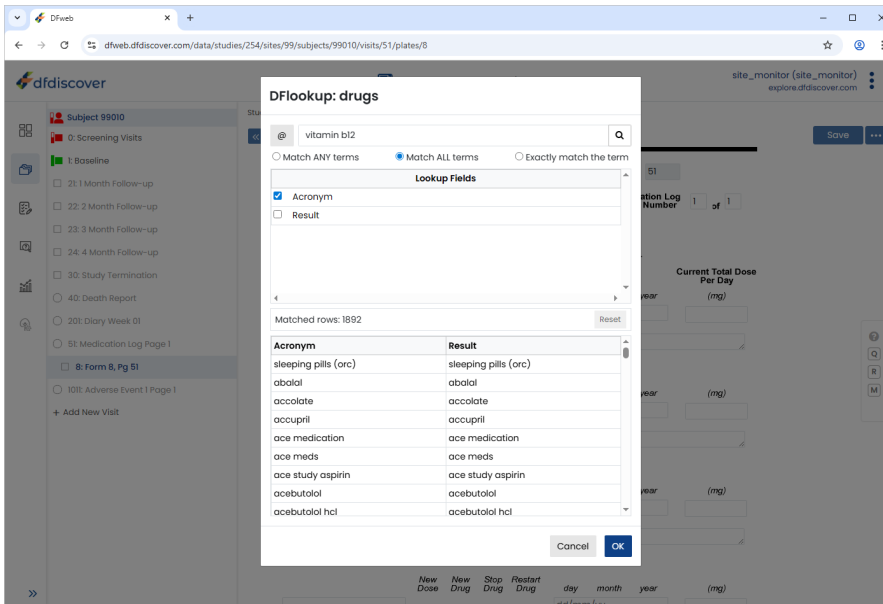
8. Press **Tab**. In the Medication Log Page Number field, enter values 1 of 1.




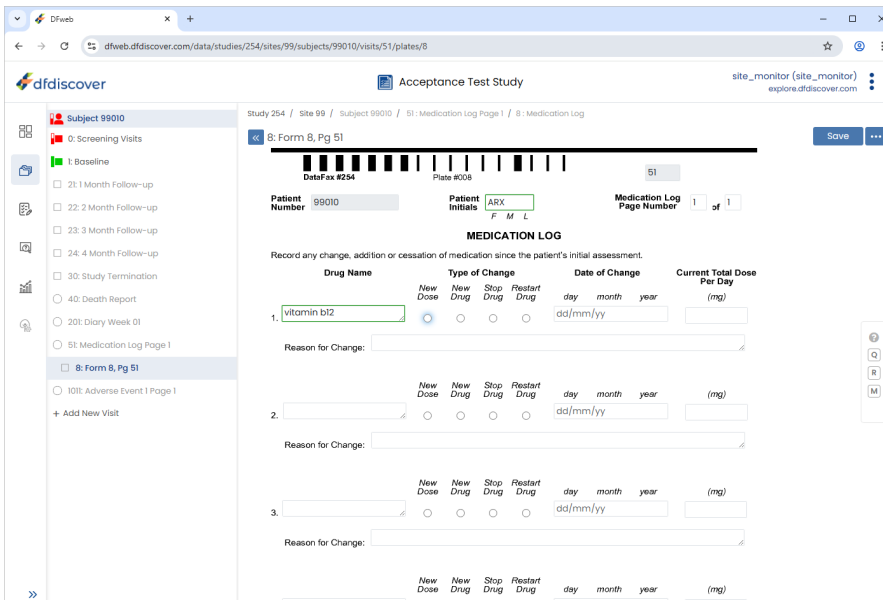
9. Press **Tab** to advance to 1. Drug Name field. Enter Vitamin B-12 in the 1. Drug Name text field, press **Tab**. Upon leaving the field, an edit check is executed and **DFlookup: drugs** dialog appears.



10. Enter vitamin b12 in the **Search Terms**, Check **Match ALL terms** and click  to filter the results.



11. Select the result of **vitamin b12** from the table. Click . The **1. Drug Name** field becomes auto-populated with vitamin b12 result.



12. Beginning with the **Type of Change** field complete the remaining data fields as follows:

- o **Type of Change** = Select **New Drug**
- o **Date of Change** = Select 15/11/18
- o **Current Total Dose Per Day** = 250
- o **Reason for Change** = Increased Mean Cell Hemoglobin Conc.

Click .

Study 254 / Site 99 / Subject 9910 / SI : Medication Log Page 1 / 8 : Medication Log

8: Form 8, Pg 51

DFweb

dfweb.dfdiscovers.com/data/studies/254/sites/99/subjects/9910/visits/51/plates/8

dfdiscovers

Acceptance Test Study

site\_monitor (site\_monitor)  
explore.dfdiscovers.com

Subject 9910

0: Screening Visits

1: Baseline

21: 1 Month Follow-up

22: 2 Month Follow-up

23: 3 Month Follow-up

24: 4 Month Follow-up

30: Study Termination

40: Death Report

201: Diary Week 01

51: Medication Log Page 1

101: Adverse Event 1 Page 1

+ Add New Visit

Study 254 / Site 99 / Subject 9910 / SI : Medication Log Page 1 / 8 : Medication Log

8: Form 8, Pg 51

Save

More

DataFax #254 Plate #008 51

Patient Number 9910 Patient Initials ARX F M L Medication Log Page Number 1 of 1

**MEDICATION LOG**

Record any change, addition or cessation of medication since the patient's initial assessment.

Drug Name	Type of Change				Date of Change			Current Total Dose Per Day (mg)
	New Dose	New Drug	Stop Drug	Restart Drug	day	month	year	
1. vitamin b12	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	15	11	18	250
Reason for Change: Increased Mean Cell Hemoglobin Conc.								
2.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	dd	mm	yy	
Reason for Change:								
3.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	dd	mm	yy	
Reason for Change:								
4.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	dd	mm	yy	
Reason for Change:								

13. Select 1: Baseline > 4 : Form 4, Pg 1. Click **More** > **Set Page Missed** to open the **Set Page Missed** dialog.

DFweb

dfweb.dfdiscovers.com/data/studies/254/sites/99/subjects/9910/visits/1/plates/4

dfdiscovers

Acceptance Test Study

site\_monitor (site\_monitor)  
explore.dfdiscovers.com

Subject 9910

0: Screening Visits

1: Baseline

2: Form 2

3: Form 3

4: Form 4, Pg 1

21: Lab Results

21: 1 Month Follow-up

22: 2 Month Follow-up

23: 3 Month Follow-up

24: 4 Month Follow-up

30: Study Termination

40: Death Report

201: Diary Week 01

51: Medication Log Page 1

101: Adverse Event 1 Page 1

+ Add New Visit

Study 254 / Site 99 / Subject 9910 / SI : Medication Log Page 1 / 8 : Medication Log

4: Form 4, Pg 1

Save

More

Set Missed Page

Subject 9910 / Visit 1 / Plate 4

\* Reason: Select Reason...

Details:

Cancel Apply

Drug Name	Total Dose Per Day (mg)	Start Date or Duration of Use	Indication
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

14. In the dialog, choose **Other Reason** value from the **Reason** pull-down list. Enter Medication information provided on the Medication Log Page. as the **Detail**.

DFweb

dfweb.dfdiscovers.com/data/studies/254/sites/99/subjects/9910/visits/1/plates/4

dfdiscovers

Acceptance Test Study

site\_monitor (site\_monitor)  
explore.dfdiscovers.com

Subject 9910

0: Screening Visits

1: Baseline

2: Form 2

3: Form 3

4: Form 4, Pg 1

21: Lab Results

21: 1 Month Follow-up

22: 2 Month Follow-up

23: 3 Month Follow-up

24: 4 Month Follow-up

30: Study Termination

40: Death Report

201: Diary Week 01

51: Medication Log Page 1

101: Adverse Event 1 Page 1

+ Add New Visit

Study 254 / Site 99 / Subject 9910 / SI : Medication Log Page 1 / 8 : Medication Log

4: Form 4, Pg 1

Save

More

Set Missed Page

Subject 9910 / Visit 1 / Plate 4

\* Reason: Other reason

Details: Medication information provided on the Medication Log Page

Cancel Apply

Drug Name	Total Dose Per Day (mg)	Start Date or Duration of Use	Indication
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

15. Click **Apply** to register the page as missed.


The screenshot shows the Dfdiscover interface for 'Acceptance Test Study'. The left sidebar lists visits: 0: Screening Visits, 1: Baseline, 2: Form 2, 3: Form 3, 4: Form 4, Pg 1 (selected), 21: Lab Results, 22: 1 Month Follow-up, 23: 2 Month Follow-up, 24: 3 Month Follow-up, 25: 4 Month Follow-up, 30: Study Termination, 40: Death Report, 201: Diary Week 01, 51: Medication Log Page 1, and 101: Adverse Event 1 Page 1. The main content area shows '4: Form 4, Pg 1' with a 'Missed' dialog box. The dialog has 'Missed' and 'Save' buttons. Below the dialog, the form fields for 'Patient Number' (99010), 'Patient Initials' (F M L), and 'Medications Page Number' (1 of 1) are visible. The 'CURRENT MEDICATIONS' section includes a table with columns: Drug Name, Total Dose Per Day (mg), Start Date or Duration of Use, and Indication. There are 8 rows for data entry.

16. Click **Subjects**, select 99009 > 1: Baseline > 2: Form 2. Click **...** > **Unset Page Missed** to open the **Unset Missed Page** dialog.






The screenshot shows the Dfdiscover interface for 'Acceptance Test Study'. The left sidebar lists visits: 0: Screening Visits, 1: Baseline, 2: Form 2 (selected), 3: Form 3, 4: Form 4, Pg 1, 21: Lab Results, 22: 1 Month Follow-up, 23: 2 Month Follow-up, 24: 3 Month Follow-up, 25: 4 Month Follow-up, 30: Study Termination, 40: Death Report, 201: Diary Week 01, 51: Medication Log Page 1, and 101: Adverse Event 1 Page 1. The main content area shows '2: Form 2' with a 'Unset Missed Page' dialog box. The dialog has a 'Reason' input field, 'Cancel', and 'Apply' buttons. Below the dialog, the form fields for 'Randomization' (Medication Code #: nnnn), 'Medical Examination' (Date of Birth: dd/mm/yyyy, Weight: nnn.n kg or nnn.n lbs, Height: nnn cm or nnn.n in, Pulse: nnn beats/minute, Smoking Status: Never smoked, Ex-smoker, Smokes cigarettes, Exercise\*: None, or <1 time/week, 1-2 times/week, 3-4 times/week) are visible.

17. Enter a reason of Data to be captured during chart review.. Click **Apply**

## Adding, modifying and resolving queries

- From the sidebar bar, Click . Locate and select the outstanding query for Subject 99008 > 0:Screening Visits > 1:Form 1.

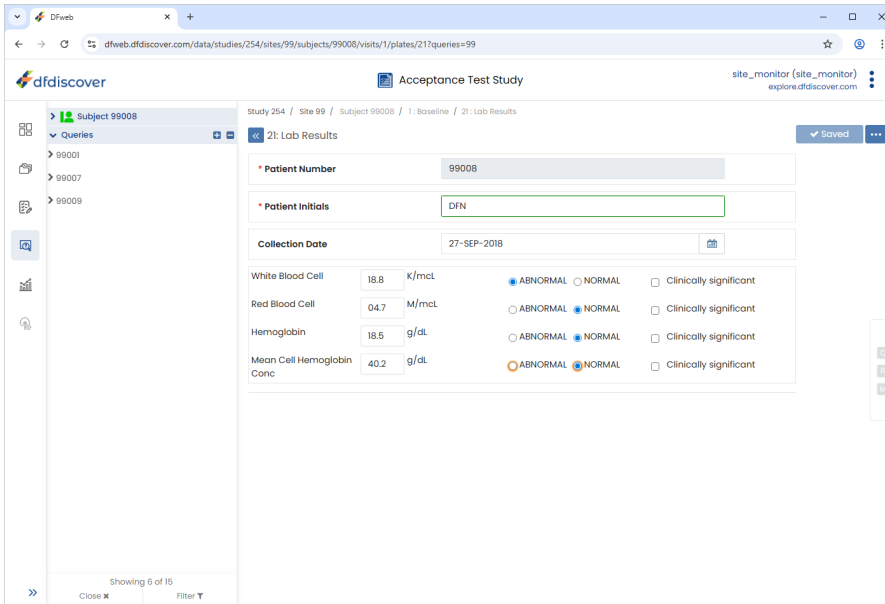
Screening Visit	Date	Reading 1 (systolic/diastolic mmHg)	Reading 2 (systolic/diastolic mmHg)	Reading 3 (systolic/diastolic mmHg)
Screen 1	13/09/18	132 / 085	137 / 089	127 / 081
Screen 2	20/09/18	125 / 089	127 / 082	128 / 082

- Change **6. Systolic and diastolic BP criteria** from 'Yes' to 'No', Click  then , select **Resolved** from the **Status** drop-down list. Click  >  and  to save the data record changes.

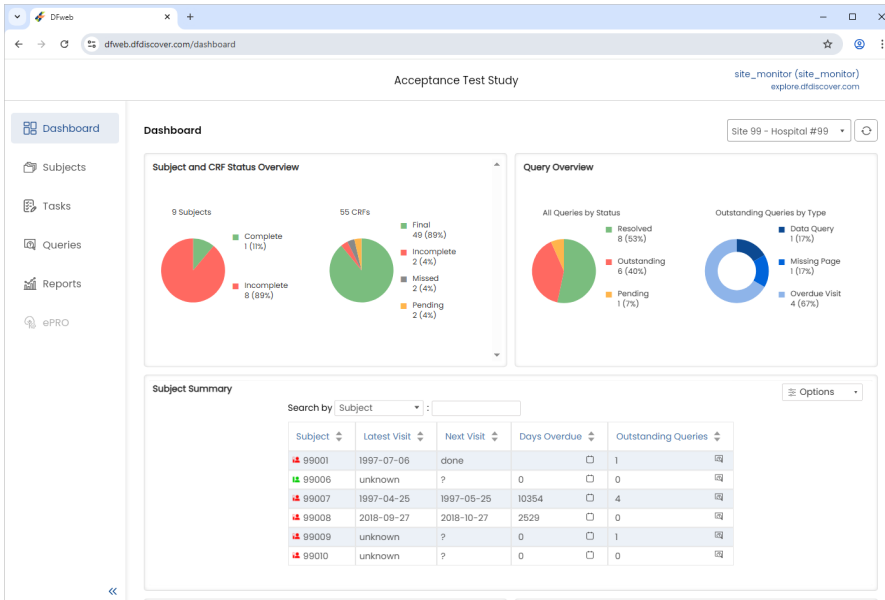
3. Click **99008** > **1:Baseline** > **2: Form 2**. Select **Date of Birth (dd/mm/yyyy)** query. Correct **Date of Birth (dd/mm/yyyy)** to 14/01/1968.

4. Click **Q** then **\***, select **Resolved** from the **Status** drop-down list. Click **Apply** > **Close** to save the query changes. Click **SAVE**.

5. Click **21: Lab Results**, select the outstanding query. Click **R**. Enter Lab value confirmed as out of range. in the **Reason** field. Click **Apply**, followed by **SAVE**.



6. Click **☰**.



7. Within the **Queries Overview** dashboard, click **Outstanding** (Red portion) under the **All Queries by Status** pie chart. The **Queries Overview** table is displayed showing all outstanding queries for the site.
8. In the **Queries Overview** table locate and select the outstanding query for subject **99009**.
9. Select **Asian** in the **Race** field. Click **Save**.

Study 254 / Site 99 / Subject 99009 / 0 : Screening Visits / 1 : Blood Pressure Screening Visits

1: Form 1

DataFax #254 Plate #001 Visit #000

Patient Number 99009 Patient Initials ANK F M L

### BLOOD PRESSURE SCREENING VISITS

Age 44 years Sex  Male  Female Race  Caucasian  African American  Asian  Other, specify: \_\_\_\_\_

Screen 1: Date 18/10/18 Reading 1: 112 / 096 mmHg  
 Reading 2: 125 / 087 mmHg  
 Reading 3: 133 / 081 mmHg

Screen 2: Date 25/10/18 Reading 1: 125 / 092 mmHg  
 Reading 2: 130 / 087 mmHg  
 Reading 3: 131 / 092 mmHg

Eligibility Criteria

Criteria	Yes	No
1. Age 16-79 years old.	<input checked="" type="radio"/>	<input type="radio"/>
2. Male, or if female, not pregnant and using a reliable contraceptive method.	<input checked="" type="radio"/>	<input type="radio"/>

10. Return to the **Dashboard** page by Clicking

11. Click , within the **Queries Overview** dashboard, click **Outstanding** under the **All Queries by Status** pie chart. The **Queries Overview** table is displayed showing all outstanding queries for the site. Confirm the outstanding query for subject **99009** is no longer present.

Acceptance Test Study

Site 99 - Hospital #99

#### Subject and CRF Status Overview

9 Subjects: Complete 1 (11%), Incomplete 8 (89%)

55 CRFs: Final 50 (91%), Incomplete 1 (2%), Missed 2 (4%), Pending 2 (4%)

#### Query Overview

Queries (Outstanding)

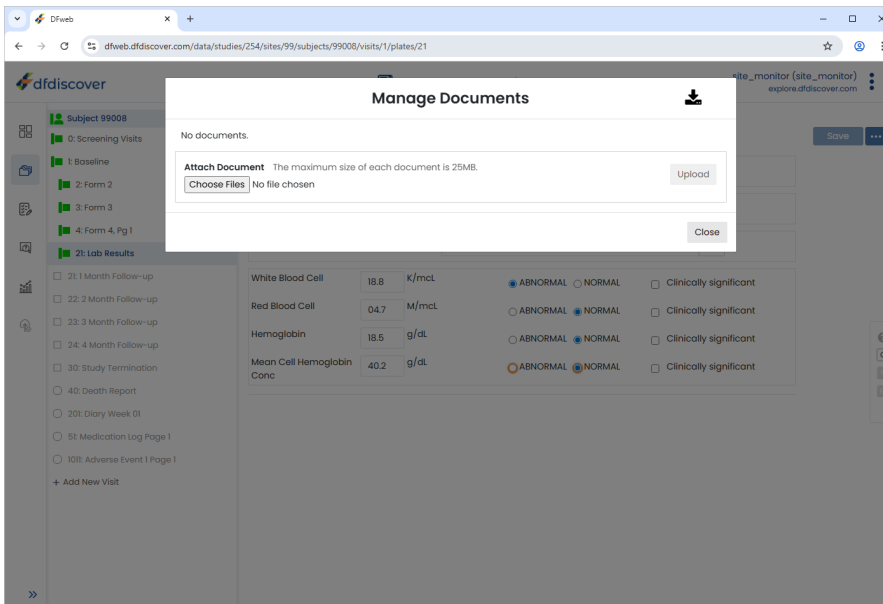
Site	Subject	Visit	Plate	Field	Category
99	99001	30	6	7	Missing Page
99	99007	21	5	7	Overdue Visit
99	99007	22	5	7	Overdue Visit
99	99007	23	5	7	Overdue Visit
99	99007	30	7	7	Overdue Visit

#### Subject Summary

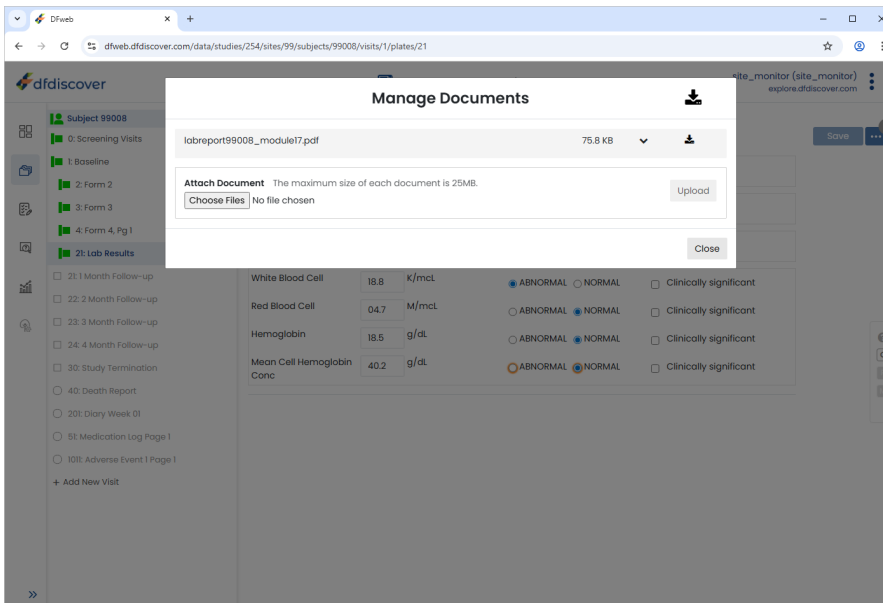
Subject	Latest Visit	Next Visit	Days Overdue	Outstanding Queries
99001	1997-07-06	done	0	1
99006	unknown	?	0	0
99007	1997-04-25	1997-05-25	10354	4
99008	2018-09-27	2018-10-27	2529	0
99009	unknown	?	0	0
99010	unknown	?	0	0

## Adding, reviewing and downloading subject documents

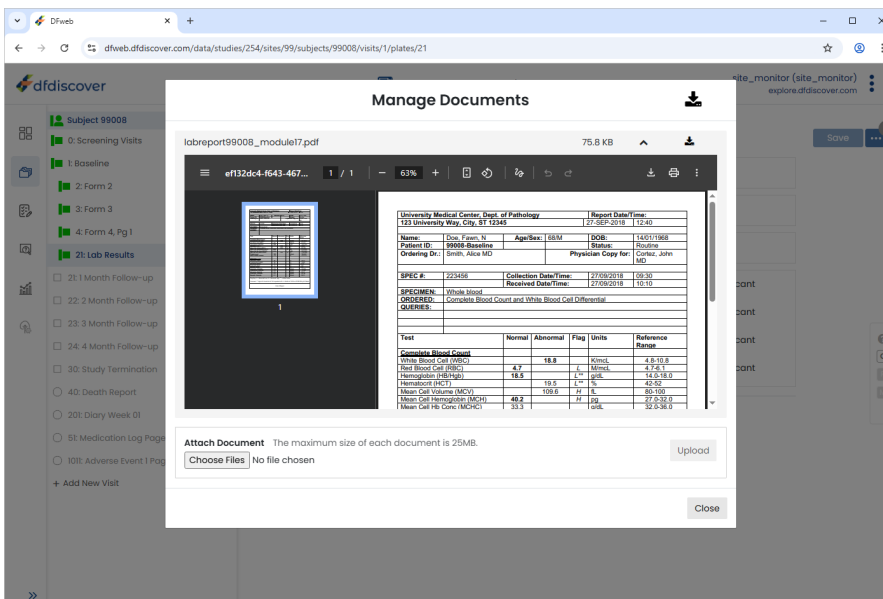
1. From the sidebar, select **Subjects > 99008 > 1: Baseline > 21: Lab Results**. Click **Manage documents** to open the **Manage documents** window.



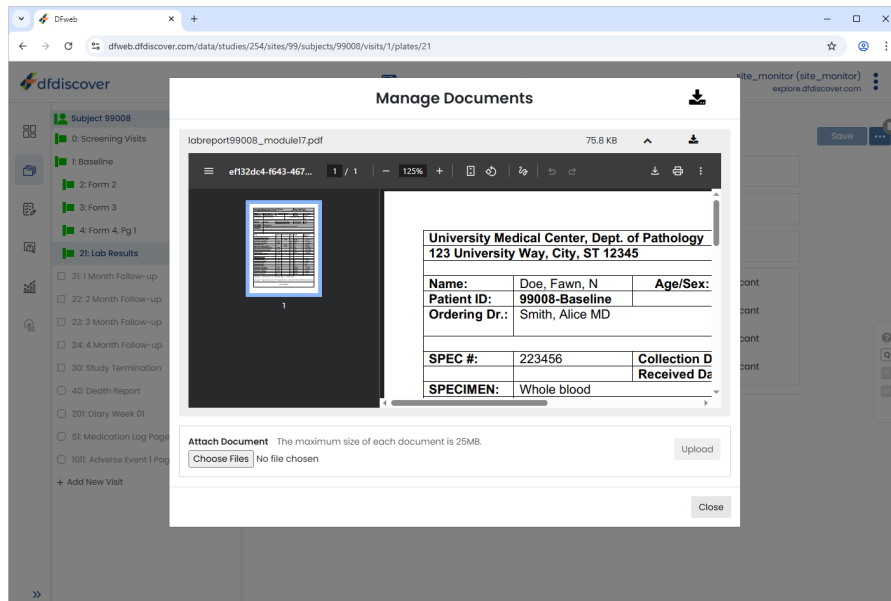
2. Click **Choose Files**, select the previously saved labreport99008\_module17.pdf (Refer to [Step 2](#)). Click **Open** > **Upload** to upload the document.





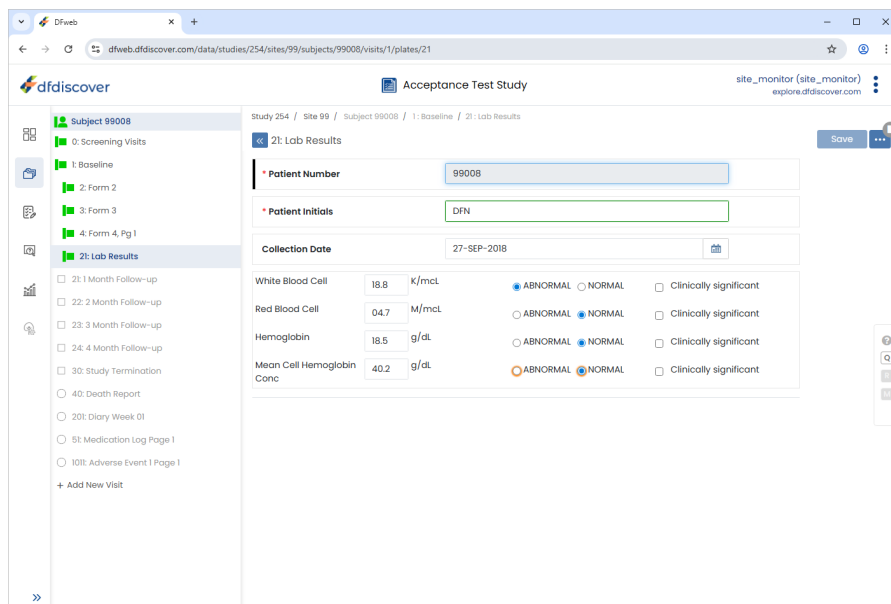
3. Click **▼** to view the newly uploaded document.




4. The document can be zoomed in/out by using the navigation buttons within the document window.



5. Click **Close** to close the **Manage Documents** window. Notice the  icon has now changed to  indicating the data record now has associated documents.



6. Click  > **Logout** to exit **DFweb**.

## Add an Electronic Signature (eSign) to a set of completed subject records

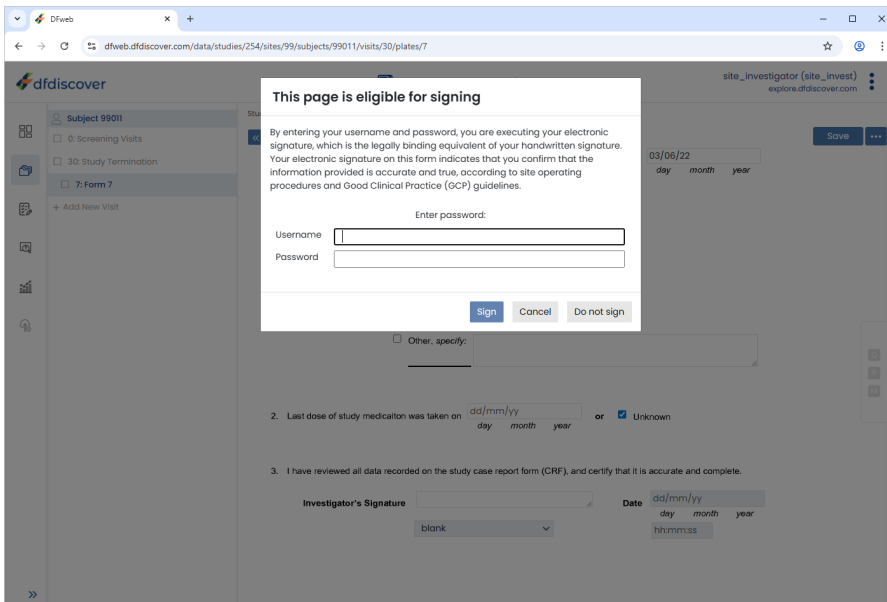
**NOTE:** eSignatures require password permission to be set in the user role at the **DFadmin** level. The Password permission must be granted for the specific eSignature plate.

- In the **DFweb** login dialog, enter site\_invest in the **Username** field and the previously assigned password in the **Password** field. Click **Login** to login.
- As user site\_invest has 2FA enabled, enter security code received by email or SMS as previously defined.

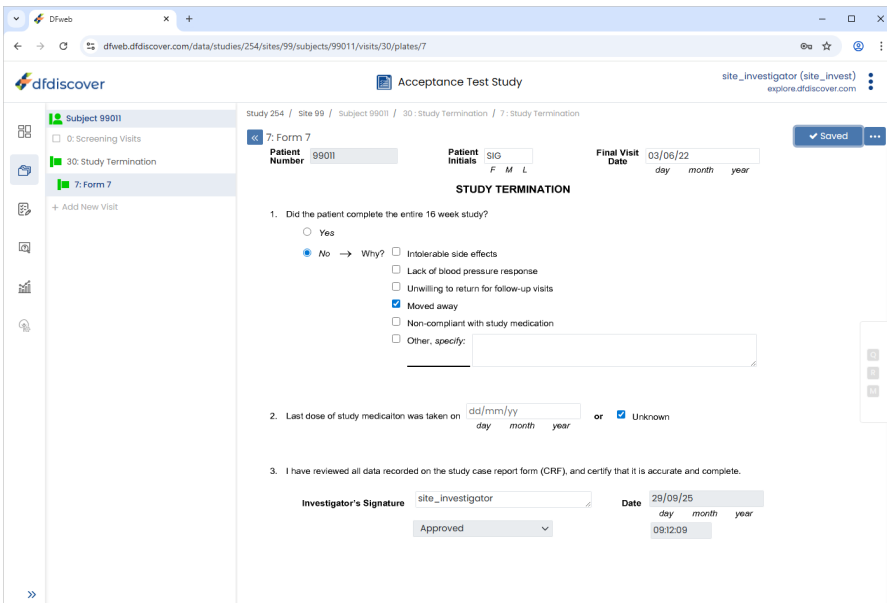
**NOTE:** Refer to [Creating user accounts and assigning study permissions](#), as a valid email address or phone number is required for site\_invest to receive 2FA codes.

- From the **Subjects** list, click Subject **99011** > **30: Study Termination** > **7: Form 7**.
- Click **Patient Initials** enter SIG, Set:
  - Final Visit Date** = 03/06/22
  - 1. Did the patient complete the entire 16 week study?** = **No**
  - Check (enable) **Moved away**
  - 2. Last dose of study medication was taken on** = Check (enable) **Unknown**

Click **SAVE** to save and eSign the **Study Termination** form.



- In the **dfpassword** confirmation dialog enter the user name `site_invest` and the corresponding password. Click **Sign** to apply the electronic signature to the current page.
- In the **DFExplore - eSignature Reason** dialog select **Approved** from the dropdown, click **OK**.



- Examine the 4 eSignature fields at the bottom of the page.
- Click **Logout** to exit **DFweb**.

## Verify removal and Re-application of eSignatures

- In the **DFweb** login dialog, enter `site_monitor` in the **Username** field and the previously assigned password in the **Password** field. Click **Login** to login.
- From the **Subjects** list, click **Subject 99011 > 30: Study Termination > 7: Form 7**.
- Click **2. Last dose of study medication was taken on** field. Click **Q** to open the **Add Query** dialog. In the dialog, set:
  - Category** = Monitor
  - Enter Investigator to confirm last dose taken with subject during clinic visit. in the **Note** field.
  - Click **Apply** > **Close**.
- Press **Tab** to advance to the **Unknown** field. Un-check (disable) the checkbox. Click **SAVE**.

Study 254 / Site 99 / Subject 99011 / 30: Study Termination / 7: Study Termination

7: Form 7

DataFax #254 Plate #007 30

Patient Number 99011 Patient Initials SIG Final Visit Date 03/06/22

STUDY TERMINATION

1. Did the patient complete the entire 16 week study?

Yes

No → Why?

- Intolerable side effects
- Lack of blood pressure response
- Unwilling to return for follow-up visits
- Moved away
- Non-compliant with study medication
- Other, specify:

2. Last dose of study medication was taken on  or  Unknown

3. I have reviewed all data recorded on the study case report form (CRF), and certify that it is accurate and complete.

Investigator's Signature  Date

5. Click **Logout** to exit DFweb.

6. In the DFweb login dialog, enter site\_invest in the **Username** field and the previously assigned password in the **Password** field. Click **Login** to login.

7. From the sidebar, Click **Tasks**.

Acceptance Test Study

Tasks

5 eSignatures - Study Termination - eSignatures **Start**

This task is to be used for applying eSignatures to Study Termination forms.

5 records match the search criteria

5 Screening Data Entry - Level 1 EDC entry of Blood Pressure Screening visits

5 Screening Data Review - Review of all patient screening data

8. Locate the **eSignatures - Study Termination - eSignatures** task. Click **Start**.

9. From the **Subjects** list, click Subject 99011 > **30: Study Termination** > **7: Form 7**.

10. Click the **2. Last dose of study medication was taken on** field. Click then **\***. Select **Resolved** from the **Status** drop-down list. Enter Confirmed date of last medication dose verbally with subject during clinic visit. in the **Note** field. Click **Apply** > **Close**.

11. Enter the **2. Last dose of study medication was taken on** date as 02/06/22. Click **SAVE**.

12. In the **dfpassword** confirmation dialog enter the user name `site_invest` and the corresponding password used for login in [Add an Electronic Signature \(eSign\) to a set of completed subject records](#). Click **Sign** to apply the electronic signature to the current page.

13. In the **DFexplore - eSignature Reason** dialog select **Reviewed** from the dropdown, click **OK**.

Study 254 / Site 99 / Subject 99011 / Visits/30 / Plates/7 / Task=eSignatures

dfdiscover Acceptance Test Study site\_investigator (site\_invest) explore.dfdiscover.com

7: Form 7

DataFax #254 Plate #007 30

Patient Number 99011 Patient Initials SIG Final Visit Date 03/06/22

F M L day month year

**STUDY TERMINATION**

1. Did the patient complete the entire 16 week study?

Yes  No → Why?

- Intolerable side effects
- Lack of blood pressure response
- Unwilling to return for follow-up visits
- Moved away
- Non-compliant with study medication
- Other, specify: \_\_\_\_\_

2. Last dose of study medication was taken on 02/06/22 or  Unknown

day month year

3. I have reviewed all data recorded on the study case report form (CRF), and certify that it is accurate and complete.

Investigator's Signature site\_investigator Date 29/09/25

day month year

Reviewed 09:18:14

Task: 1 of 5 complete

14. Examine the 4 eSignature fields at the bottom of the page.

15. Click **Close** to close **Tasks** view. In the resulting warning dialog click **Continue**.

16. Click **View Page History** to open the **Page History** window. The **Page History** is displayed, Click **OK** to close the window.

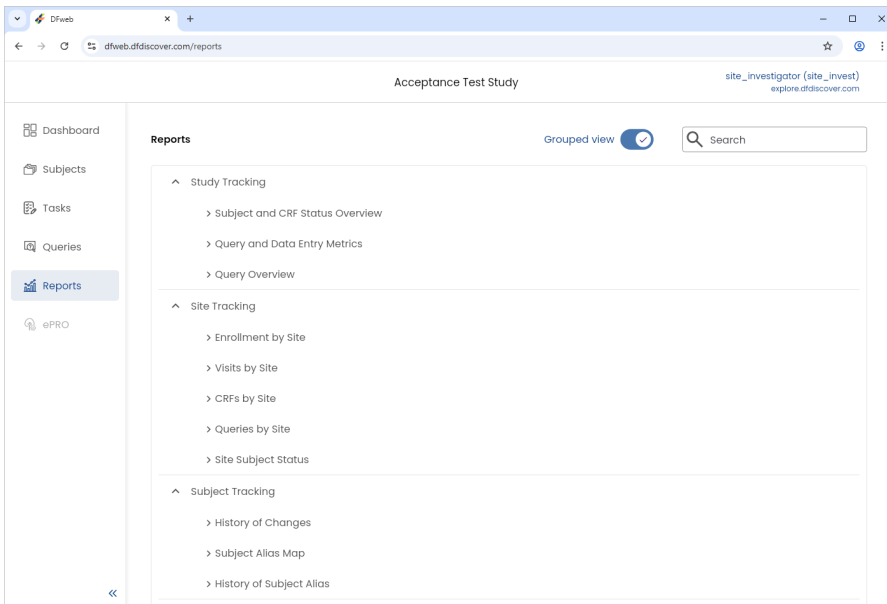
Page History

Field	Value	Timestamp	User
Field: DataFax Sequence Number	site_invest entered data '30'	2025-09-29 09:12:09	site_invest
Field: Patient Number	site_invest entered data '99011'	2025-09-29 09:12:09	site_invest
Field: Patient Initials	site_invest entered data 'SIG'	2025-09-29 09:12:09	site_invest
Field: Final Visit Date	site_invest entered data '03/06/22'	2025-09-29 09:12:09	site_invest
Field: 1. Did patient complete entire study?	site_invest entered data 'No'	2025-09-29 09:12:09	site_invest
Field: 1. Why? Moved away	site_invest entered data 'Checked'	2025-09-29 09:12:09	site_invest
Field: 2. Last dose of study medication: Date	site_invest entered data '02/06/22'	2025-09-29 09:18:14	site_invest
	site_invest resolved "Monitor" query as corrected		
	site_invest modified "Monitor" query with Note "Confirmed date of last medication dose verbally with subject during clinic visit."		
	site_monitor created "Monitor" query with Note "Investigator to confirm last dose taken with subject during clinic visit"; Type "Correction", Use "External"	2025-09-29 09:14:04	site_monitor
Field: 2. Last dose of study medication: Unknown			

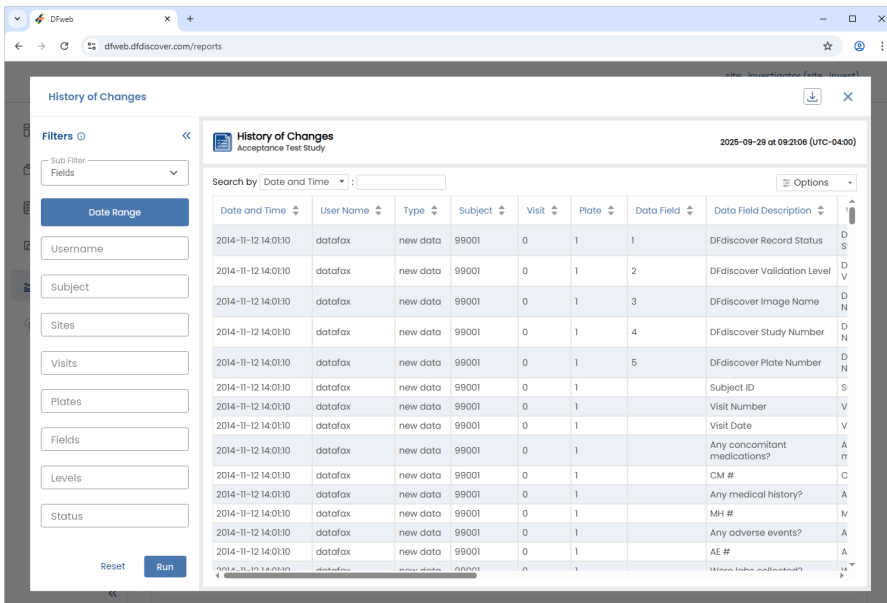
Times shown in UTC-04:00

OK

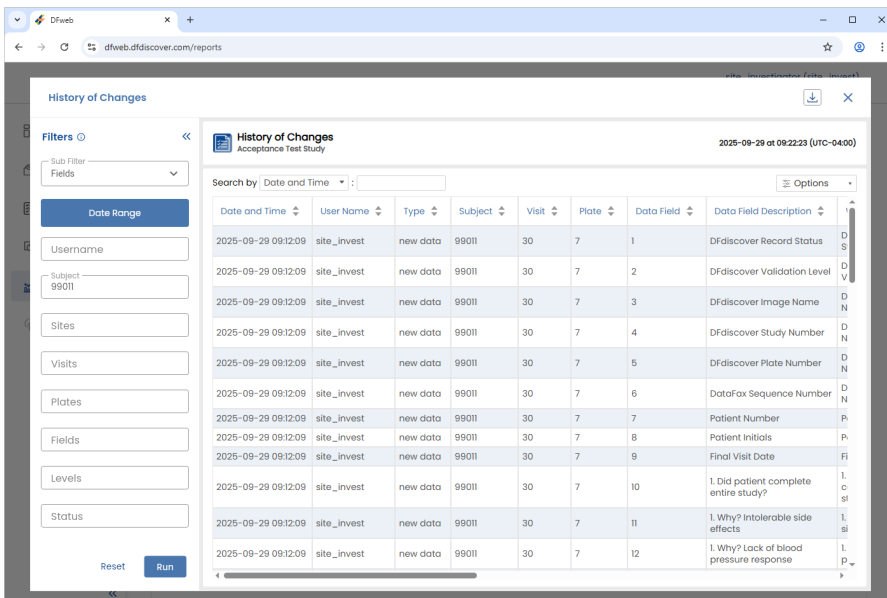
17. Click **Grouped View**, enable (toggle on) **Grouped View**.



18. Select **History of Changes** under the **Subject Tracking** reports list.



19. Enter 99011 in the **Subject** field, click **Date Range** in the resulting dialog select the current date and click **OK** > **Run**. The **History of Changes** report updates to display the requested data. Click **X** to close the report.



20. Click **Logout** to exit **DFweb**.

## Verify **DFweb** saves eSignature task data to the specified save level

1. Start **DFexplore**, login as **data\_manager** and choose **254 Acceptance Test Study** as described in "[How to start DFexplore](#)"
2. Select **View List**. Click **007 - Study Termination**. Confirm **DFVALID** displays as "4" for subject **99011**.

	DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	TERMVISITNUM	SUBJID	PINIT	VISDAT	EXTRICOMP	EXTRIND1	EXTRIND2	EXTRIND3	EXTRIND4
1	1	1	0915/0007009	254	7	30	99001	ABC	06/07/97	2	0	0	0	0
2	1	1	1449/0008011	254	7	30	99002	JAM	07/05/97	2	0	0	0	0
3	1	1	1450R0001001	254	7	30	99003	XYZ	08/01/97	1	0	0	0	0
4	1	1	0915/000V009	254	7	30	99004	TRB	06/10/97	2	0	0	0	0
5	1	4	2630R0005001	254	7	30	99011	SIG	03/06/22	1	0	0	0	1

3. Select **File Exit** to close **DFexplore**.

## End Module 17. DFweb Data Entry

- Return to the **DFATK** application. Click **End** to confirm successful completion of Module 17. **DFweb**.

## Module 18. DFcollect Mobile Data Collection

### Overview

#### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- DFws 5.11.0 installed and properly configured on DFws server
- Valid DFdiscover license with DFWS and DFCOLLECT license features on DFdiscover server
- Mobile Device with DFcollect 5.11.0 installed from the Google Play Store or Apple App Store
  - Mobile Device requires **Android™** 10 or later, or **iOS®/iPadOS®** 16 or greater
  - Mobile Device will also need to have access to network to send live data to DFdiscover
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
  - site\_invest : site\_investigator
- (Optional) SMS or email 2-factor authentication configuration for site\_invest

NOTE: For configuration of 2-factor authentication, see [Module 1\(Installation & Initialization\) test step 6](#) for details on configuring accounts with 2-factor authentication

**Client Tools Used:** DFATK, DFexplore, DFcollect

**Purpose:** This module tests the functionality of **DFcollect** to test online and offline data entry, data review, query resolution, document management, and eSignatures. Data entered with **DFcollect** is then verified with **DFexplore**.

### Tests & Requirements

1. Installation and App preferences.
2. Resetting a user login password.
3. Online data record creation.
4. Download subject data for offline use.
5. Create data records in offline mode, query resolution and adding reasons for data values.
6. Sync data collected offline to your **DFdiscover** server.
7. Clearing **DFcollect** cache.

8. Adding, reviewing and downloading subject documents.
9. Confirming data sent to the server using **DFexplore**.
10. Add an Electronic Signature (eSign) to a set of completed subject records.
11. Verify removal and re-application of eSignatures.
12. Verify **DFcollect** saves eSignature task data to the specified level.
13. Verify no saved data remains upon uninstallation and reinstallation of **DFcollect**.

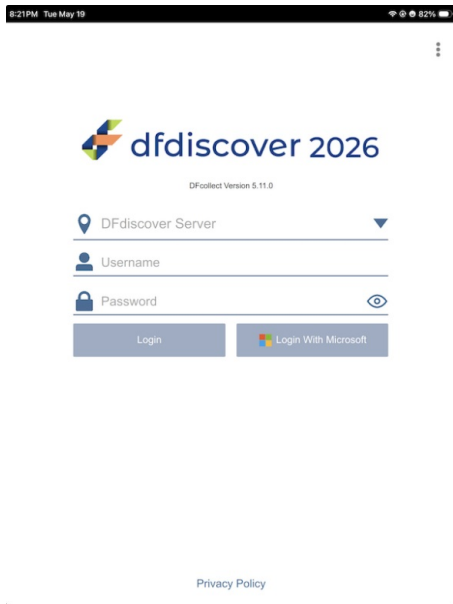
Estimate of Time Required: 35 Minutes

## Begin Module 18. DFcollect Mobile Data Collection

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click [18. DFcollect Mobile Data Collection](#) followed by [Begin](#) to begin this module.

## Installation, App preferences

1. Download and install **DFcollect** from [Google Play™](#) or [Apple® App Store®](#) to your mobile device or tablet, or use the link provided by your administrator.
2. Open **DFcollect**.

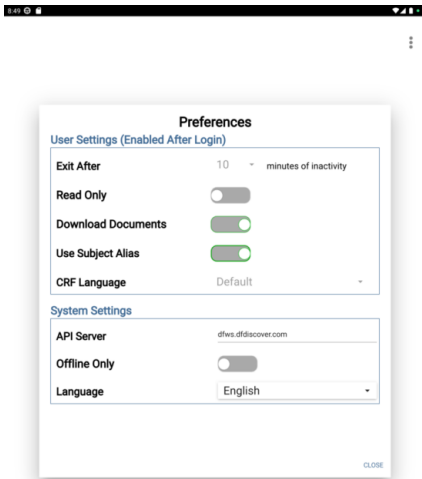


3. Click [☰](#) > [Preferences](#). Set:

### System Setting

- **API Server** = your API servername
- **Offline Only** = Disabled (greyed out)

Click [Close](#) to apply settings.



Privacy Policy

- Click > **About DFcollect**. Confirm that the version information in the about dialog matches the installed **DFcollect** Version 5.11.0. Click **Close** to return to the **DFcollect** login screen.

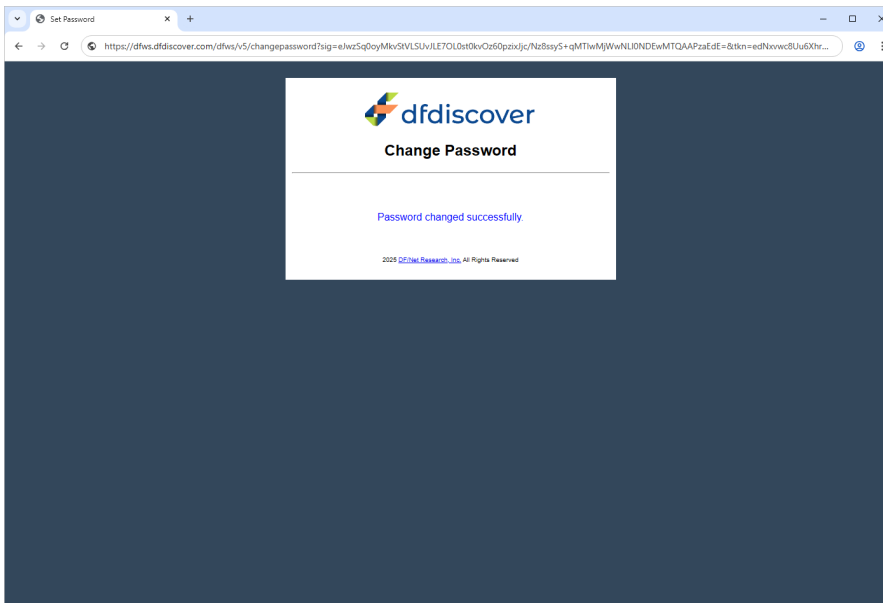


## Resetting a user login password

- Click > **Forgot Password?**.
- In the **Forgot Password** dialog, enter the **DFdiscover Server** name that has been provided by your administrator, enter `site_monitor` in the Username field and enter the email address associated with the `site_monitor` account and click **OK**. A confirmation message appears: **A password reset link has been sent to your email account.**



3. Open the password reset email from your **DFdiscover** server and click the provided link to reset the site\_monitor password.
4. Enter and confirm a new password, then click [Update](#).



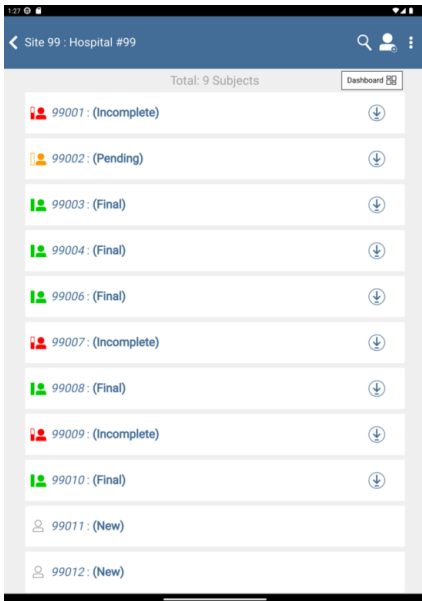
5. A message confirming **Password changed successfully**. is displayed in your browser, and a notification email is sent to the address associated with the site\_monitor account.

## Online data record creation

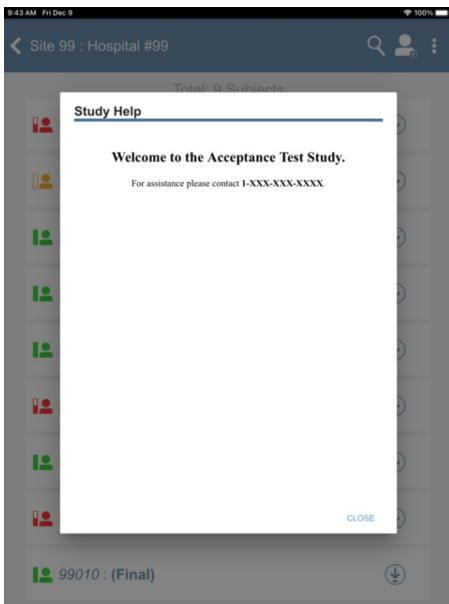
1. Return to **DFcollect**. In the **DFcollect** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. Enter site\_monitor in the **Username** field and the previously assigned password in the **Password** field. Click [Login](#) to login.




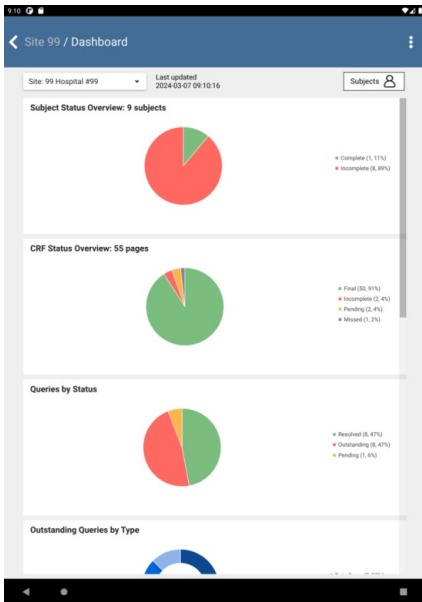
2. From the list of available studies, click **254 Acceptance Test Study**, if not already opened.
3. Click **99: Hospital #99** to display a list of available subjects.



4. Click **>** **Study Help** to view any study related help messages. Click **Close** to close the **Study Help** window.



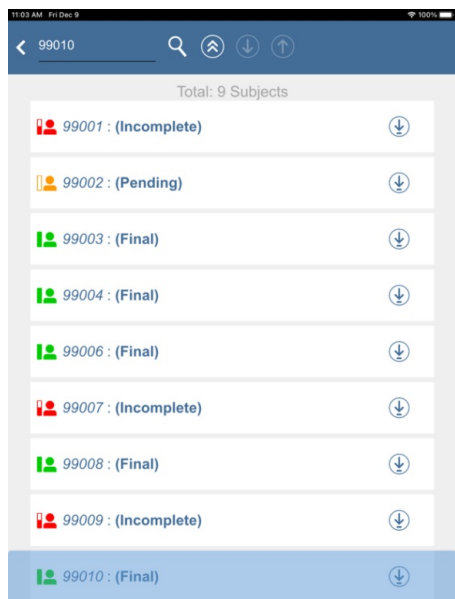
5. Click  to open **Dashboard** view.



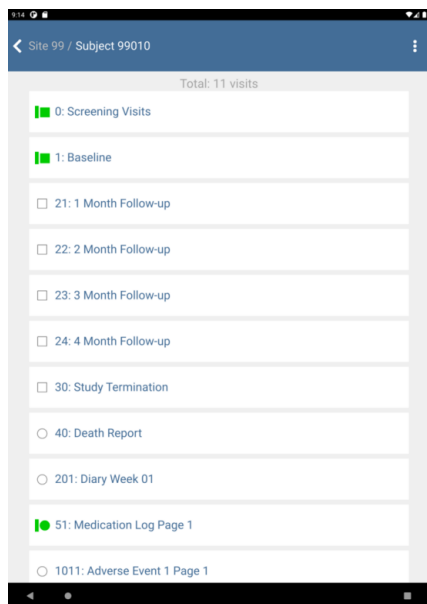
6. Click **View Outstanding Queries** located under **Outstanding Queries by Type** to view all outstanding queries.

Subject	Visit	Record	Field	Category	Status
99001	30	6	Missing Page	Missing Page	Outstanding
99007	21	5	1 Month Follow-up	Overdue Visit	Outstanding
99007	22	5	2 Month Follow-up	Overdue Visit	Outstanding
99007	23	5	3 Month Follow-up	Overdue Visit	Outstanding
99007	30	7	Study Termination	Overdue Visit	Outstanding
99009	0	1	Age (years)	Inconsistent	Outstanding
99009	0	1	Race	Missing	Outstanding
99009	1	2	Pulse (beats/min)	Illegal	Outstanding

- Click **Close** to return to the subject listing.
- Click **🔍** to search for a subject ID number, enter 99010. Click **🔍**, subject **99010 : (Final)** gains the focus.



- Click subject **99010 : (Final)** to view the list of study visits.



- Click **1: Baseline > 2: Form 2. Plate Form 2** becomes the active page.

Study 254 / Site 99 / Subject 99010 / 1 : Baseline / 2 : Form 2

\*Patient Number ②  
99010

\*Patient Initials ②  
Q R M

Entry Date ②  
dd/mm/yy Q R M

\*Medication Code # ②  
0000 Q R M

\*Date of Birth (dd/mm/yy) ②  
dd/mm/yy Q R M ?

\*Weight (kg) ②  
000.0 kg Q R M

\*Weight (lbs) ②  
000.0 lbs Q R M

Height (cm) ②  
000 cm Q R M

Height (inches) ②  
000.0 in Q R M

11. Click **Patient Initials**. The initials automatically populate this field as a result of the edit check SetInitdescribed in [Module 8. Image Data Entry](#). Set:

- **Entry Date** = Click 📅, select 14/11/18.
- **Medication Code #** = 2524
- **Date of Birth** = Click 📅, select 11/05/1969.

Click 🗑️.

Study 254 / Site 99 / Subject 99010 / 1 : Baseline / 2 : Form 2

\*Patient Number ②  
99010

\*Patient Initials ②  
ARX Q R M

Entry Date ②  
14/11/18 Q R M

\*Medication Code # ②  
2524 Q R M

\*Date of Birth (dd/mm/yy) ②  
11/05/69 Q R M ?

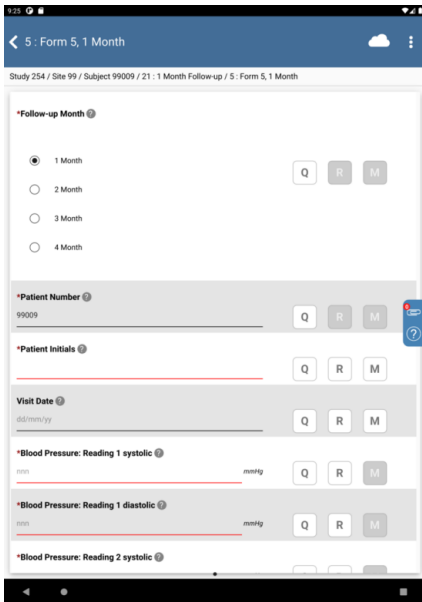
\*Weight (kg) ②  
000.0 kg Q R M

\*Weight (lbs) ②  
000.0 lbs Q R M

Height (cm) ②  
000 cm Q R M

Height (inches) ②  
000.0 in Q R M

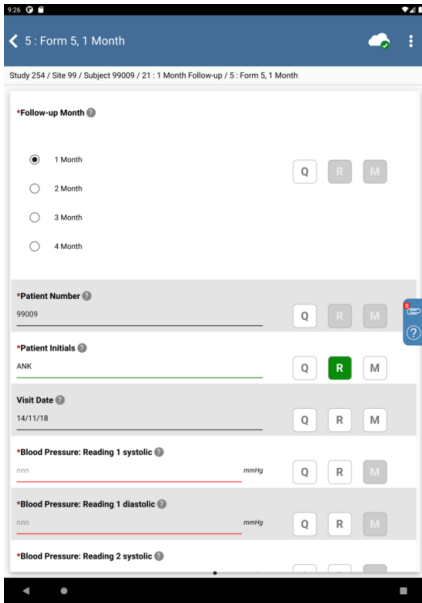
12. Click < > 99009 : (Incomplete) > 21: 1 Month Follow-up > 5: Form 5, 1 Month.





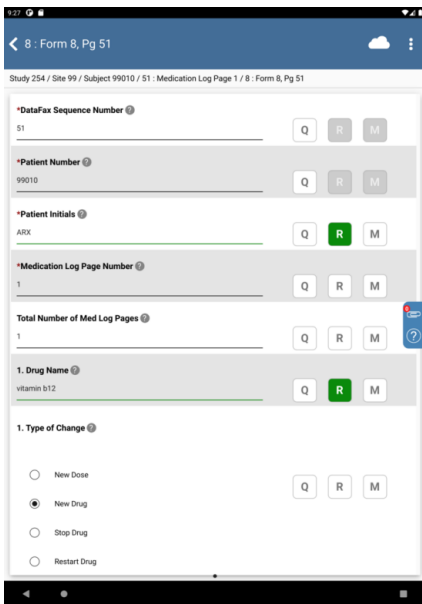
13. Click **Patient Initials**. The initials automatically populate this field as a result of the edit check SetInitdescribed in [Module 8. Image Data Entry](#). Set:

- **Visit Date** = Click , select 14/11/18.

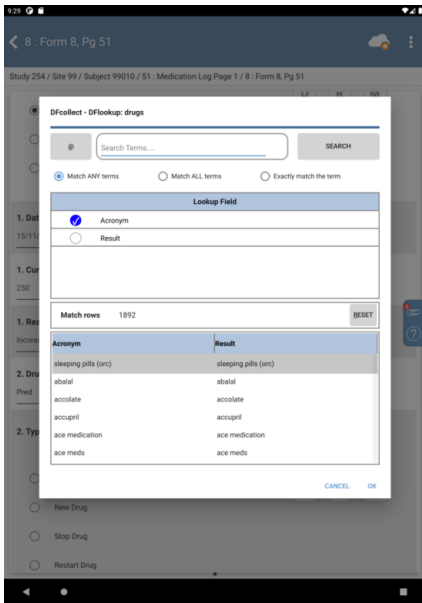
Click .



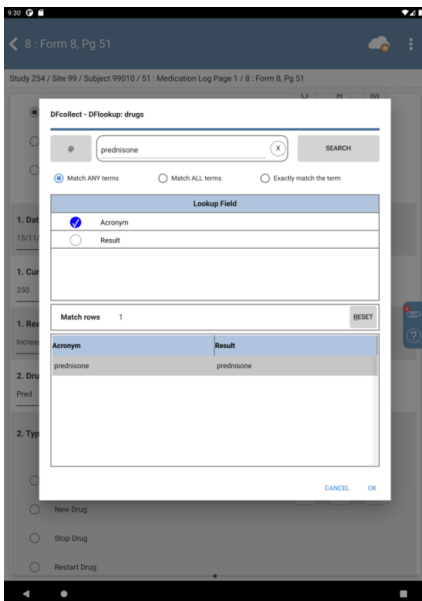
14. Click  >  > 99010 : (Incomplete) 51: Medication Log Page 1 > 8: Form 8, Pg 51.



15. Enter Pred in the **2. Drug Name** text field, select the **Type of Change** field. Upon leaving the field, an edit check is executed and **DFlookup: drugs** dialog appears.



16. Enter prednison in the **Search Terms**, Check **Match ANY terms**. Click **Search** to filter results.



17. Locate the entry for **prednisone** in the results table. Double-click the entry to auto-populate the field. The **2. Drug Name** field is auto-populated with prednisone, the field contains a **Reason for Data Value** and **Type of Change** field gains focus.

8 : Form 8, Pg 51

Study 254 / Site 99 / Subject 99010 / 51 : Medication Log Page 1 / 8 : Form 8, Pg 51

New Drug  
 Stop Drug  
 Restart Drug

1. Date of Change ②  
 15/11/18

1. Current Total Dose Per Day (mg) ②  
 250

1. Reason for Change ②  
 Increased Mean Cell Hemoglobin Conc.

2. Drug Name ②  
 prednisone

2. Type of Change ②  
 New Dose  
 New Drug  
 Stop Drug  
 Restart Drug

18. Beginning with the **Type of Change** field complete the remaining data fields as follows:

- **Type of Change** = Select **New Drug**
- **Date of Change** = Select 22/11/18
- **Current Total Dose Per Day** = 250

Click

8 : Form 8, Pg 51

Study 254 / Site 99 / Subject 99010 / 51 : Medication Log Page 1 / 8 : Form 8, Pg 51

prednisone

2. Type of Change ②  
 New Dose  
 New Drug  
 Stop Drug  
 Restart Drug

2. Date of Change ②  
 22/11/18

2. Current Total Dose Per Day (mg) ②  
 250

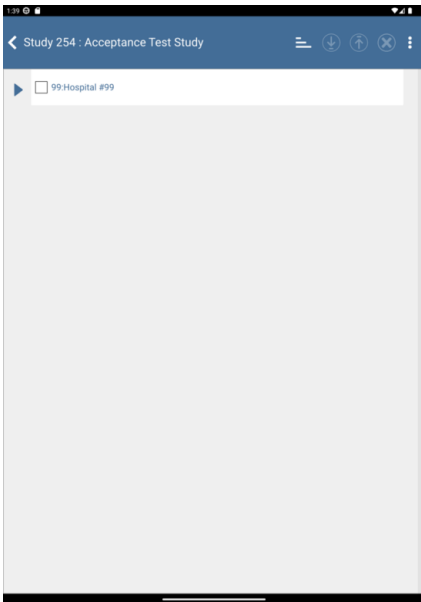
2. Reason for Change ②

3. Drug Name ②

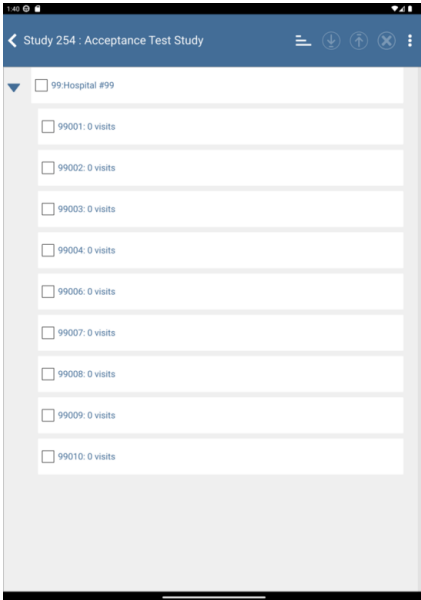
3. Type of Change ②

## Download subject data for offline use

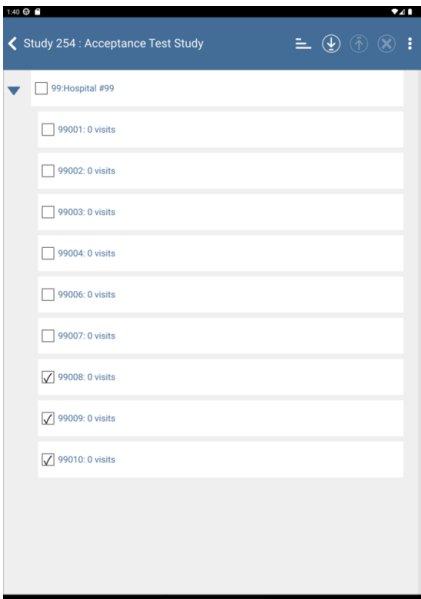
1. Click > **Storage & Syncing**.



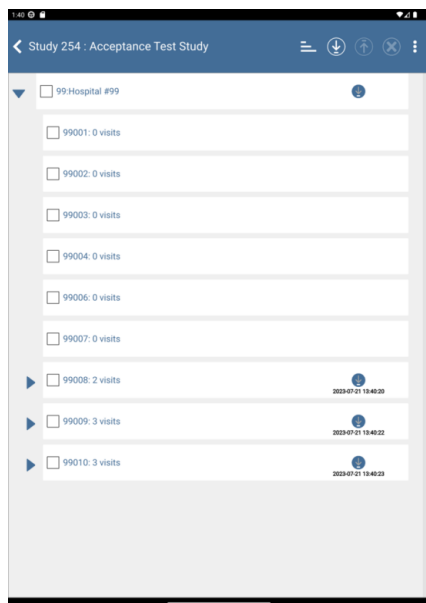
2. Click  to show the subject listing for **99: Hospital #99**.




3. Check (enable) subjects **99008: 0 visits**, **99009: 0 visits** and **99010: 0 visits**.





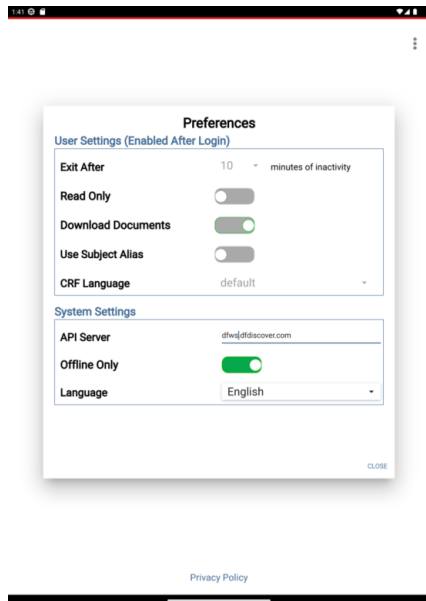
- Click  to download the subjects. After completion, click  to dismiss the **Download Progress: Data** window. Upon successful download there is an  icon showing the date and time the download was performed.




- Click  > **Logout** to logout of **DFcollect**.

## Create data records in offline mode, query resolution and adding reasons for data values

- Click  > **Preferences** > **Offline Only** toggle button to enable Offline Only mode (becomes green). Click .



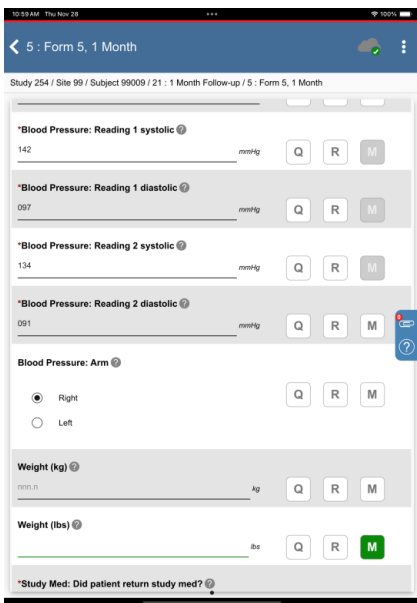
- In the **DFcollect** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. Enter `site_monitor` in the **Username** field and the previously assigned password in the **Password** field. Click  to login.



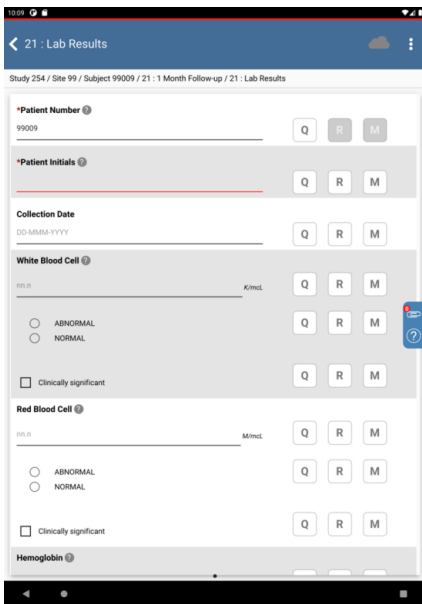
3. Click **99: Hospital #99 > 99009 : (incomplete) > 21: 1 Month Follow-up > 5: Form 5, 1 Month**. Set:

- o **Blood Pressure: Reading 1: systolic = 142, diastolic = 097**
- o **Blood Pressure: Reading 2: systolic = 134, diastolic = 091**
- o **Blood Pressure: Arm = Right**
- o **Weight (lbs) =** Click **M**, select **Missing Value** from the **Code** drop-down list. Click **Apply**.


Click **+**. Click **Cancel** in the resulting **Add Query** dialog.

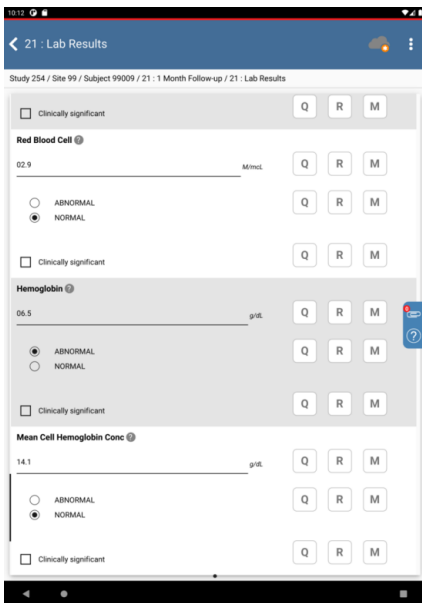


4. Click **K** > **21: Lab Results**.



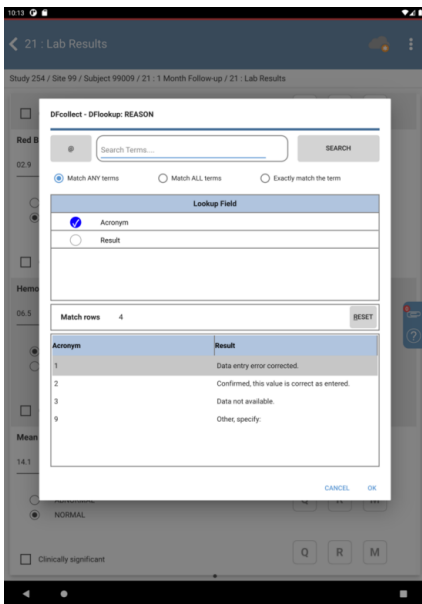
5. Click **Patient Initials**. The initials automatically populate this field as a result of the edit check SetInitdescribed in [Module 8. Image Data Entry](#). Set:

- **Collection Date** = Click , select 11-NOV-2018.
- **White Blood Cell** = 07.8, check (enable) **NORMAL**
- **Red Blood Cell** = 02.9 check (enable) **NORMAL**
- **Hemoglobin** = 06.5, check (enable) **ABNORMAL**
- **Mean Cell Hemoglobin Conc** = 14.1, check (enable) **NORMAL**

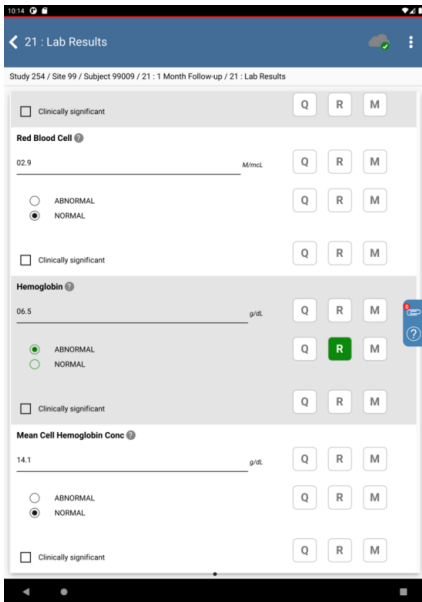


6. Click , to the right of the **Hemoglobin** "[ABNORMAL/NORMAL]" field.

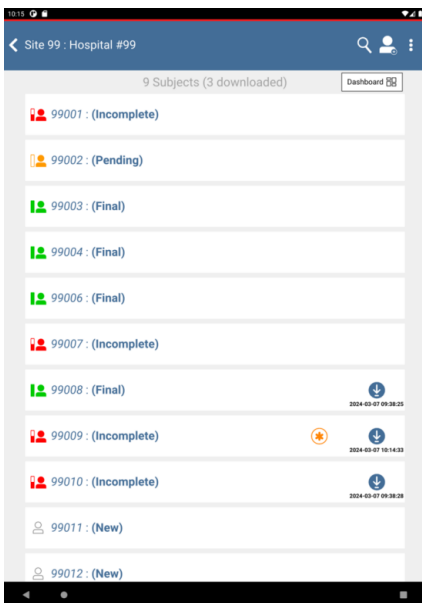
7. Click  next to **Reason**. The **DFlookup: REASON** dialog is displayed.




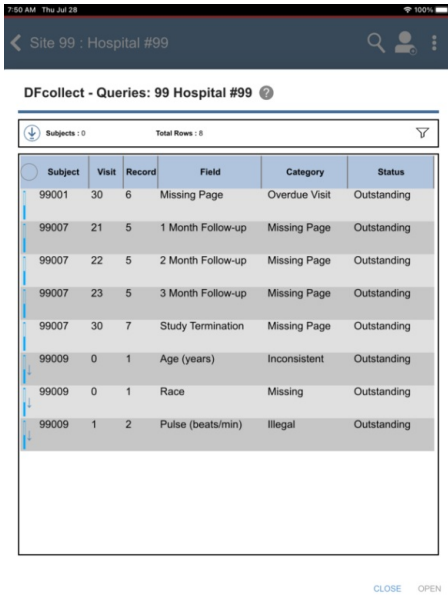
8. Select the **Result of Confirmed, this value is correct as entered.**, Click **OK**, followed by **Apply** then Click **Apply**.



9. Return to the subject listing for **99: Hospital #99** by clicking **<** **>** **<**.




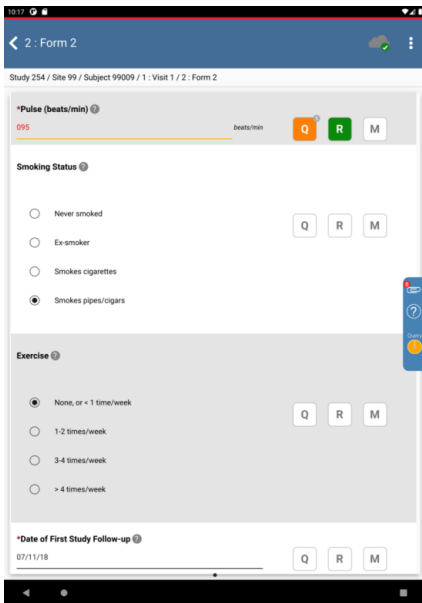
10. Click  > **Query View** to view outstanding queries.




Subject	Visit	Record	Field	Category	Status
99001	30	6	Missing Page	Overdue Visit	Outstanding
99007	21	5	1 Month Follow-up	Missing Page	Outstanding
99007	22	5	2 Month Follow-up	Missing Page	Outstanding
99007	23	5	3 Month Follow-up	Missing Page	Outstanding
99007	30	7	Study Termination	Missing Page	Outstanding
99009	0	1	Age (years)	Inconsistent	Outstanding
99009	0	1	Race	Missing	Outstanding
99009	1	2	Pulse (beats/min)	Illegal	Outstanding

11. Locate and select the outstanding query for subject **99009** > **Pulse(beats/min)** field. Click **Open**. The **Pulse(beats/min)** field gains focus.


12. Click **R** next to the **Pulse** field. In the **Reason** field specify Value of 95 for pulse is confirmed.. Click **Apply** > .



Study 254 / Site 99 / Subject 99009 / 1 : Visit 1 / 2 : Form 2

**\*Pulse (beats/min)**  beats/min **Q** **R** **M**

95


**Smoking Status** 

Never smoked **Q** **R** **M**

Ex-smoker

Smokes cigarettes

Smokes pipes/cigars


**Exercise** 

None, or < 1 time/week **Q** **R** **M**


1-2 times/week

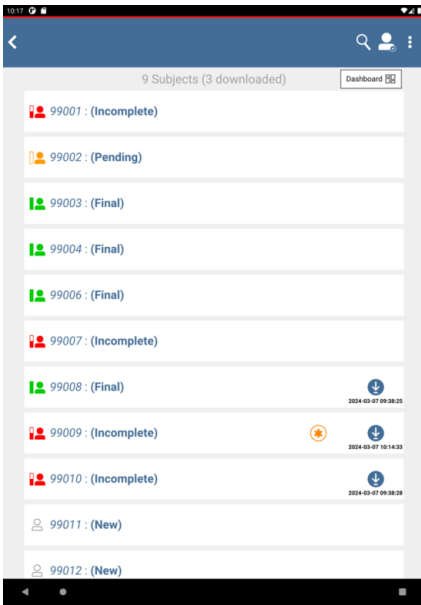
3-4 times/week

> 4 times/week

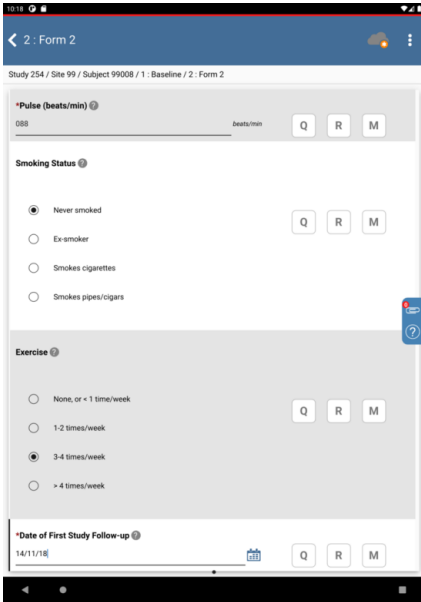
**\*Date of First Study Follow-up** 



07/11/18 **Q** **R** **M**

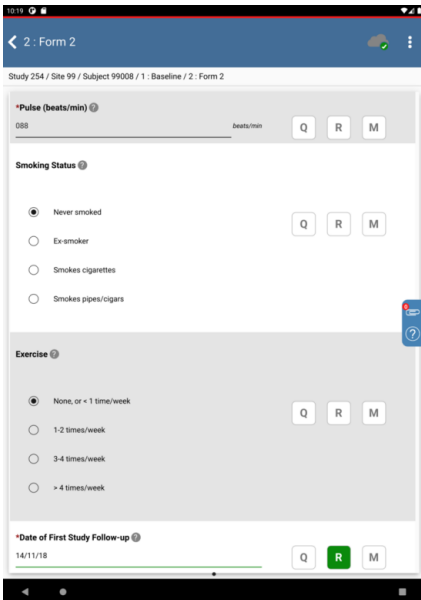
13. Click  to return to **Query View**. Confirm the outstanding query for **99009** > **Pulse(beats/min)** field is no longer present. Click **Close**.



14. Click **99008 : (Final)** > **1: Baseline** > **2: Form 2**. In the **Date of First Study Follow-up** field click , select 14/11/18.



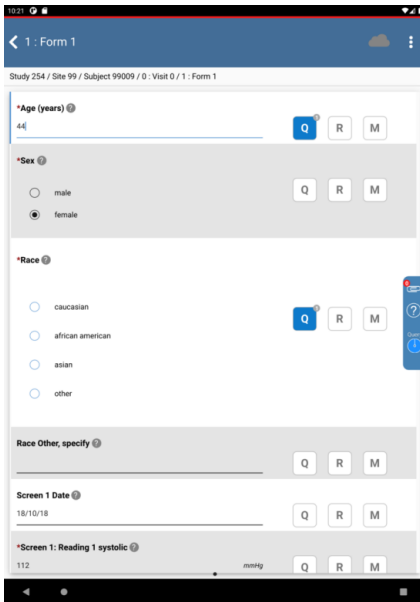
15. Click . In the **Reason** field specify Subject has to reschedule due to conflict.. Click Apply > .



16. Return to the subject listing for **99: Hospital #99** by clicking **<** > **<**. Re-open **Query View** by clicking **:** > **Query View**.



17. Locate and select the outstanding query for subject **99009 > Age (years)**. Click **Open**. The **Age (years)** field gains focus.



18. Correct **Age (years)** from 44 to 68. Click **Q** > **\***, select **Resolved** from the **Status** drop-down list. Click **Apply** > **Close**.

Study 254 / Site 99 / Subject 99009 / 0 - Visit 0 / 1 : Form 1

\*Age (years) 68 Q R M

\*Sex  male  female Q R M

\*Race  caucasian  african american  asian  other Q R M

Race Other, specify Q R M

Screen 1 Date 18/10/18 Q R M

\*Screen 1: Reading 1 systolic 112 Q R M

19. Click **Race**. Select **african american**, the query box changes from outstanding to resolved. Click

Study 254 / Site 99 / Subject 99009 / 0 - Visit 0 / 1 : Form 1

\*Age (years) 68 Q R M

\*Sex  male  female Q R M

\*Race  caucasian  african american  asian  other Q R M

Race Other, specify Q R M

Screen 1 Date 18/10/18 Q R M

\*Screen 1: Reading 1 systolic 112 Q R M

20. Click to return to **Query View**. Confirm the outstanding query for **99009 > Age (years) and Race** fields are no longer present. Click **Close**.

7:54 AM Thu Jul 26 100%

DFcollect - Queries: 99 Hospital #99

Subjects: 0 Total Rows: 5

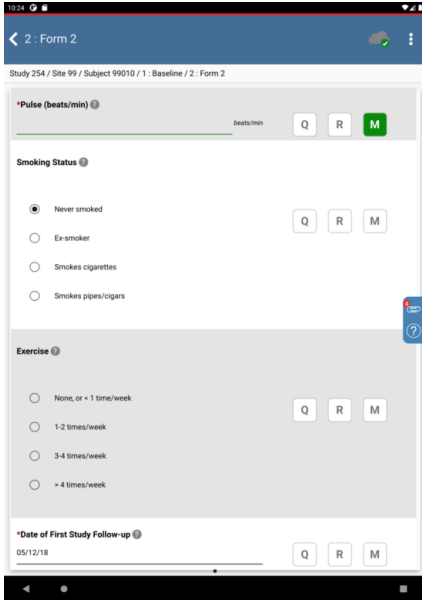
Subject	Visit	Record	Field	Category	Status
99001	30	6	Missing Page	Overdue Visit	Outstanding
99007	21	5	1 Month Follow-up	Missing Page	Outstanding
99007	22	5	2 Month Follow-up	Missing Page	Outstanding
99007	23	5	3 Month Follow-up	Missing Page	Outstanding
99007	30	7	Study Termination	Missing Page	Outstanding

CLOSE OPEN

21. Click **99010 : (Incomplete) > 1: Baseline > 2: Form 2**. Set:
  - **Weight (lbs)** = 267.0, click **OK** in the resulting dialog.
  - **Height (in)** = 072.8
  - **Pulse** = click **M**, select **Missing Value** from the **Code** drop-down list.
  - **Smoking Status** = Never smoked
  - **Date of First Study Follow-up** = Click **📅**, select 05/12/18.

Click **🏠**.

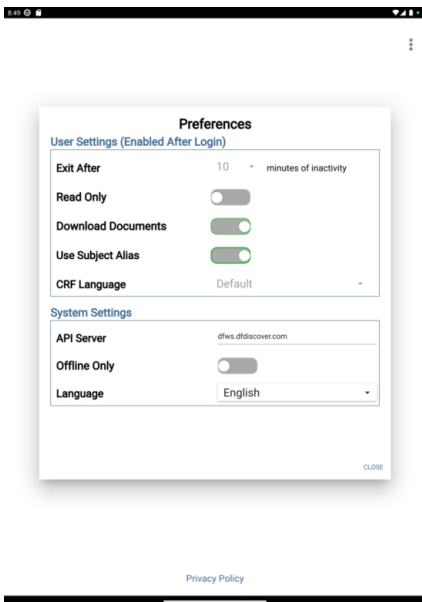
NOTE: The **Weight (kgs)** and **Height (cm)** fields are auto-populated as a result of edit checks.



22. Click **☰ > Logout**, to logout of **DFcollect**.


## Sync data collected offline to your **DFdiscover** server

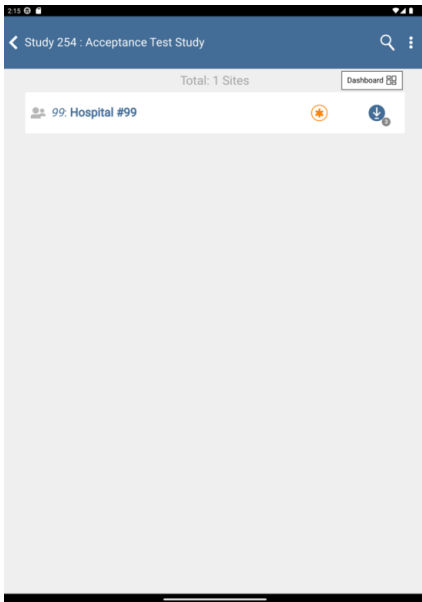
1. Click **☰ > Preferences > Offline Only** toggle button to disable the Offline Only mode (becomes greyed out). Click **Close**.




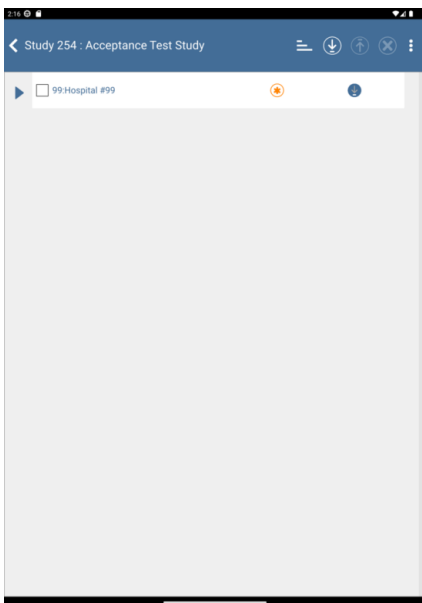
2. In the **DFcollect** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. Enter `site_monitor` in the **Username** field and the previously assigned password in the **Password** field. Click **Login** to login.



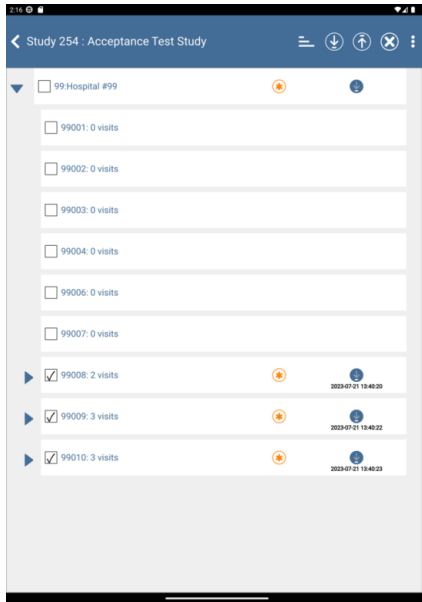
3. Upon logging into **DFcollect**, the  icon is displayed next to **99: Hospital #99** indicating there are cached changes in **DFcollect** that have not been saved to the database.






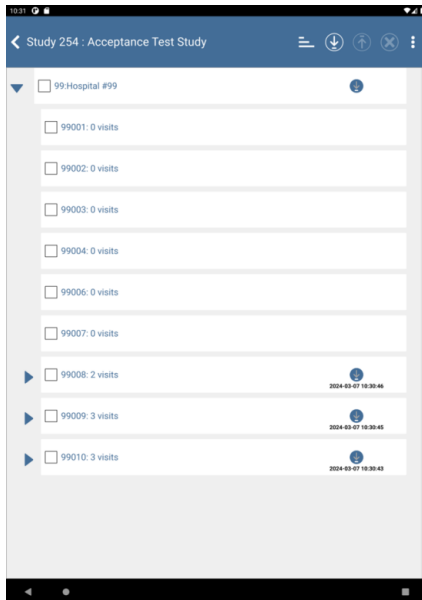
4. Click  > **Storage & Syncing**.



5. Click  to expand list of subjects. Check (enable) subjects **99008: 2 Visits**, **99009: 3 visits** and **99010: 3 visits**.

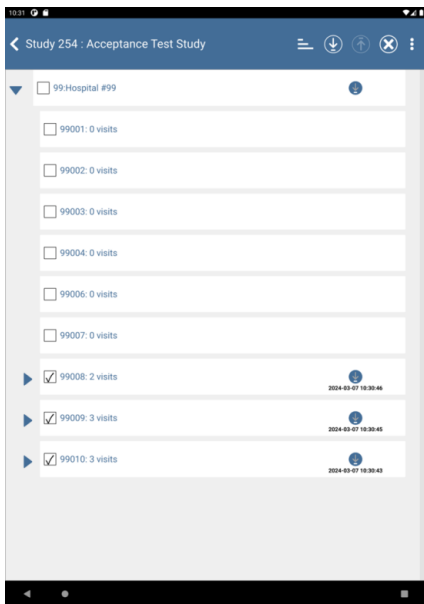


6. Click  to upload the previously entered subject data. When the upload is complete, click  to dismiss the **Upload Progress** window. The  icon shows the date and time of successful upload.

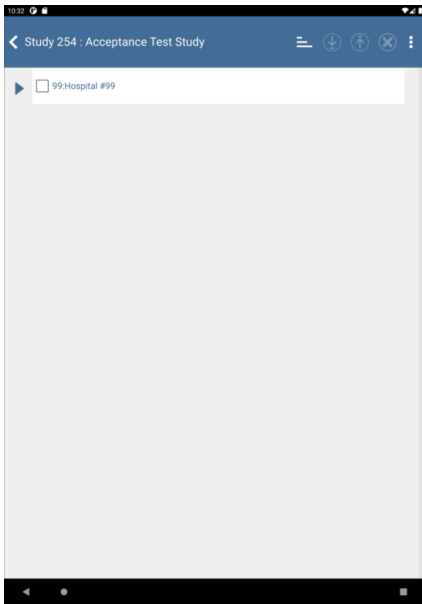


## Clearing DFcollect cache


1. Check (enable) subjects **99008: 2 visits** , **99009: 3 visits** and **99010: 3 visits**.

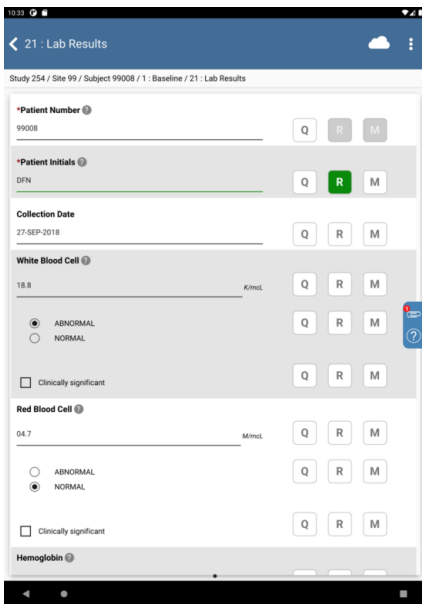



2. Click  then **Apply** within the **Delete Records from Storage** dialog. The  icon showing the date and time are cleared.

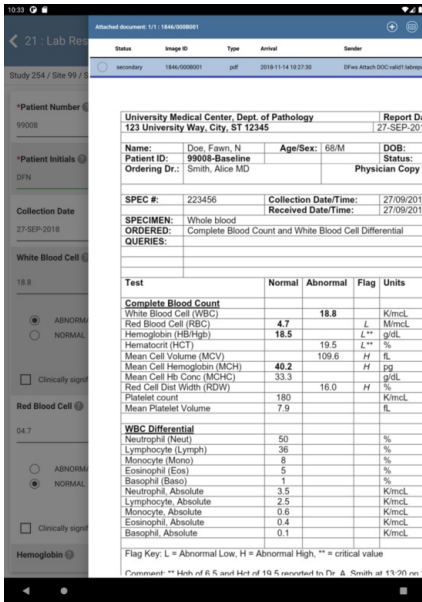



## Adding, reviewing and downloading subject documents

1. Click  > **99008 : (Final) > 1: Baseline > 21: Lab Results**.



2. Click  to view the attached documents.



3. Click  > **Logout**.

## Confirming data sent to the server using DFExplore

1. Start **DFExplore**, login as **data\_manager** and choose **254 Acceptance Test Study** as described in ["How to start DFExplore"](#)
2. Select **Site 99: Hospital #99** > subject **99009** > **0: Screening Visits** > **1: Form 1**. Verify and review the data uploaded is correct.
  - o **Age (years)** = 68 with a resolved corrected query.
  - o **Race** = 2 (african american) with a resolved corrected query.
3. Select **File** > **[Exit]** to close **DFExplore**.


## Add an Electronic Signature (eSign) to a set of completed subject records

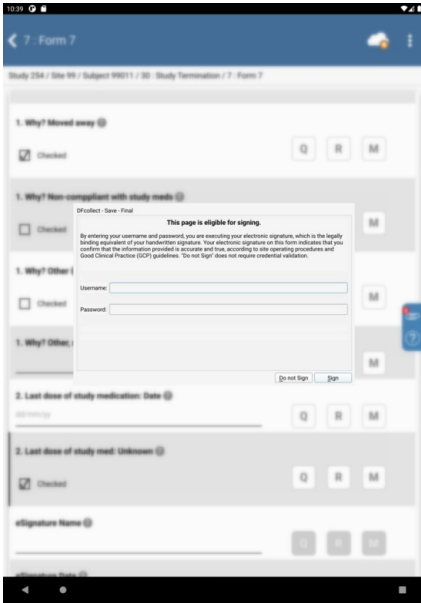
NOTE: eSignatures require password permission to be set in the user role at the **DFAdmin** level. The Password permission must be granted for the specific eSignature plate.

1. In the **DFcollect**; login dialog, enter the **DFdiscover Server** name that has been provided by your administrator. Enter **site\_invest** in the **Username** field and the previously assigned password in the **Password** field. Click **[Login]** to login.
2. As user **site\_invest** has 2FA enabled, enter security code received by email or SMS as previously defined.

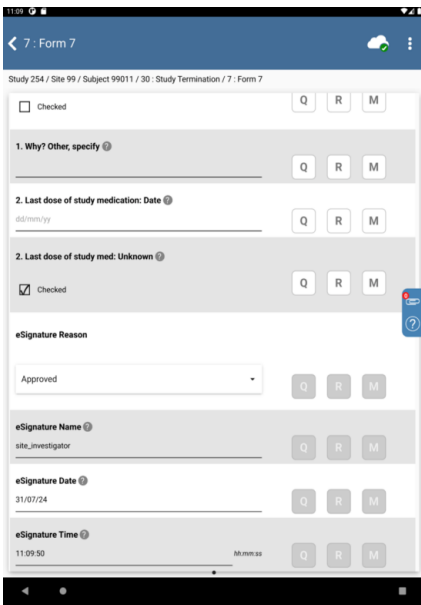
NOTE: Refer to ["Creating user accounts and assigning study permissions."](#) as a valid email address or cell phone number is required for **site\_invest** to receive 2FA codes.


3. From the **Subjects** list, click Subject **99011** > **30: Study Termination** > **7: Form 7**.

4. Click **Patient Initials** enter SIG, Set:
  - o **Final Visit Date** = 03/06/22
  - o **1. Did patient complete the entire study?** = **No**
  - o Check (enable) **Why? Moved away**
  - o Check (enable) **2. Last dose of study medication: Unknown**
  - o Click  to save and eSign the **Study Termination** form.



5. In the **dfpassword** confirmation dialog enter the user name site\_invest and the corresponding password. Click **Sign** to apply the electronic signature to the current page.
6. In the **DFcollect - eSignature Reason** dialog select **Approved** from the dropdown, click **OK**.




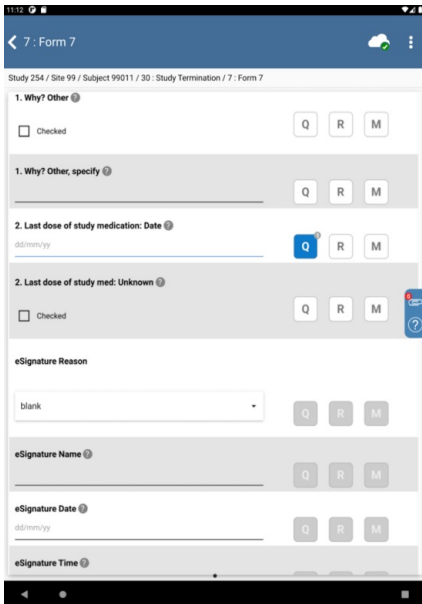
7. Examine the 4 eSignature fields at the bottom of the page.
8. Click  > **Logout** to exit **DFcollect**.

## Verify removal and re-application of eSignatures

1. In the **DFcollect** login dialog, enter the **DFdiscover Server** name that has been provided by your administrator. Enter site\_monitor in the **Username** field and the previously assigned password in the **Password** field. Click **Login** to login.
2. From the **Subjects** list, click Subject **99011 > 30: Study Termination > 7: Form 7**.
3. Click **2. Last dose of study medication: Date** field. Click **Q** to open the **Add Query** dialog. In the dialog, set:
  - o **Category** = Monitor
  - o Enter Investigator to confirm last dose taken with subject during clinic visit. in the **Note** field.


o Click **Apply** > **Close** to apply the query.

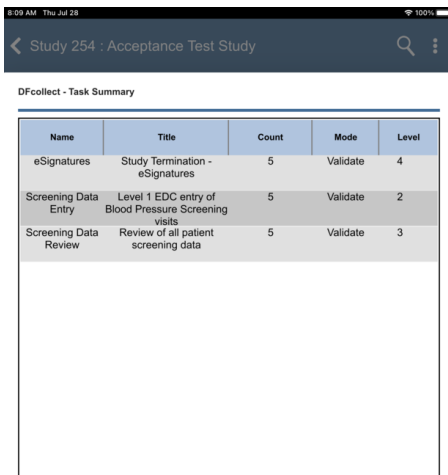
4. Advance to the **2. Last dose of study med: Unknown** field. Un-check (disable) the checkbox. Click .



5. Click  > **Logout** to exit **DFcollect**.

6. In the **DFcollect** login dialog, enter the **DFdiscover Server** name that has been provided by your administrator. Enter `site_invest` in the **Username** field and the previously assigned password in the **Password** field. Click **Login** to login.

7. Click  > **Task listing**.



Name	Title	Count	Mode	Level
eSignatures	Study Termination - eSignatures	5	Validate	4
Screening Data Entry	Level 1 EDC entry of Blood Pressure Screening visits	5	Validate	2
Screening Data Review	Review of all patient screening data	5	Validate	3

CLOSE OPEN

8. Locate the **eSignatures - Study Termination - eSignatures** task. Click **Open**.

DFcollect - Task : eSignatures

Total Records : 0   Selected Records : 0   Subjects : 0

Site	Subject	Visit	Plate
99	99001	30	7
99	99002	30	7
99	99003	30	7
99	99004	30	7
99	99011	30	7

CLOSE   OPEN

9. From the **Subjects** list, select subject **99011 > 30: Study Termination > 7: Form 7**. Click **Open**

10. Click the **2. Last dose of study medication: Date** field. Click **Q** then **\***. Select **Resolved** from the **Status** drop-down list. Enter Confirmed date of last medication dose verbally with subject during clinic visit. in the **Note** field. Click **Apply**, **Close**.

Study 254 / Site 99 / Subject 99011 / 30 : Visit 30 / 7 : Form 7

1. Why? Moved away **Q**  Checked **Q** **R** **M**

1. Why? Non-compliant with study meds **Q**  Checked **Q** **R** **M**

1. Why? Other **Q**  Checked **Q** **R** **M** **?**

1. Why? Other, specify **Q**  Checked **Q** **R** **M**

2. Last dose of study medication: Date **Q**  **Q** **R** **M**

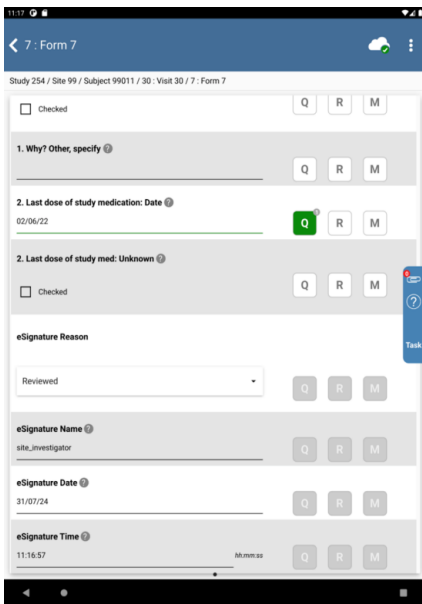
2. Last dose of study med: Unknown **Q**  Checked **Q** **R** **M**

eSignature Reason

11. Enter the **2. Last dose of study medication: Date** as 02/06/22. Click **Q**.

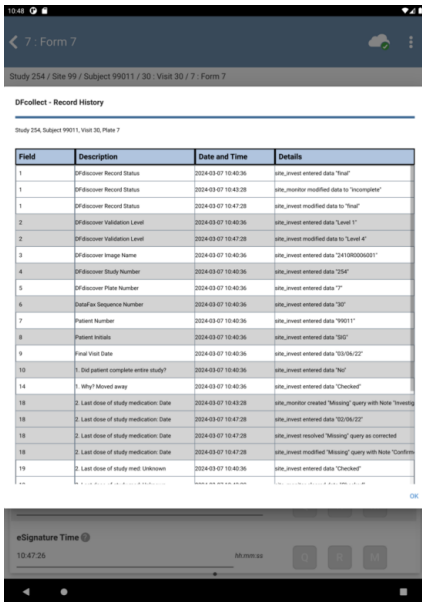
12. In the **dfpassword** confirmation dialog enter the user name site\_invest and the corresponding password used for login in ["Add an Electronic Signature \(eSign\) to a set of completed subject records."](#). Click **Sign** to apply the electronic signature to the current page.

13. In the **DFcollect - eSignature Reason** dialog select **Reviewed** from the dropdown, click **OK**.



14. Examine the 4 eSignature fields at the bottom of the page.

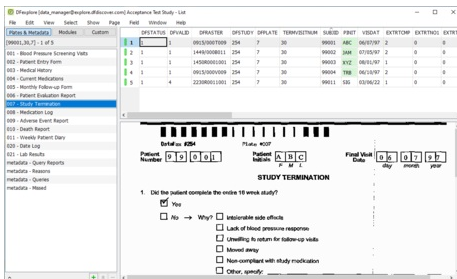
15. Click > **Page History** to open the **Page History** window. The **Page History** is displayed, Click **OK** to close the window.



16. Click > **Logout** to exit **DFcollect**.

## Verify **DFcollect** saves eSignature task data to the specified level

1. Start **DFExplore**, login as data\_manager and choose **254 Acceptance Test Study** as described in ["How to start DFExplore"](#)
2. Select **View** > **List**. Click **007 - Study Termination**. Confirm **DFVALID** displays as "4" for subject **99011**.



3. Select **File** > **Exit** to close **DFExplore**.

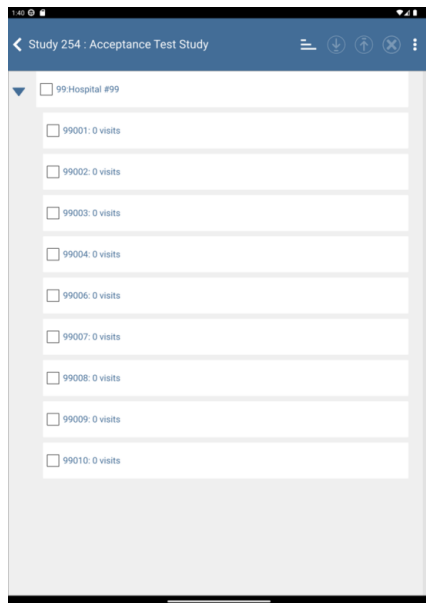
## Verify no saved data remains upon uninstallation and reinstallation of **DFcollect**.

1. In the **DFcollect** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. Enter **site\_monitor** in the **Username** field and the previously **DFdiscover 5.11.0**

assigned password in the **Password** field. Click **Login** to login.



2. Click **>** **Storage & Syncing**.
3. Click **>** to show the subject listing for **99: Hospital #99**.
4. Select at least one subject id that contains data, and click **>** to download the subject(s). After completion, click **OK** to dismiss the **Download Progress: Data** window. Upon successful download there is an **>** icon showing the date and time the download was performed.
5. Click **>** **Logout** to logout of **DFcollect**. Then, close the application.
6. Using your mobile device's normal uninstallation tools, uninstall/remove **DFcollect** from the device.
7. Using the same steps from the [Installation, App Preferences](#) section of this chapter, re-install DFcollect on your device. Once done, re-open the application and log in as **site\_monitor**.
8. Click **>** **Storage & Syncing**, then **>** to show the subject listing for **99: Hospital #99**.
9. Check the subjects that you had previously downloaded in [step 4](#), verify that there is no existing data downloaded for this subject. There should be no **>** icon indicating that the subject has stored data, and the option to delete the subject data should not be present.



10. Logout of **DFcollect** and close the application as in [step 5](#)

## End Module 18. DFcollect Mobile Data Collection

1. Return to the **DFATK** application. Click **End** to confirm successful completion of Module 18. DFcollect.

## Module 19. DFengage ePRO Data Entry

## Overview

### Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- DFws 5.11.0 installed and properly configured on DFws server
- DFweb 5.11.0 installed and properly configured on DFweb server
- DFengage 2.5 installed and properly configured on DFengage server
- Valid DFdiscover license with DFWS and DFENGAGE features on DFdiscover server
- Mobile Device with DFengage installed from the Google Play Store or Apple App Store
  - Mobile Device requires Android Version 8.0 or higher, or iOS version 14.4 or higher
  - Mobile Device will also need to have access to network to send live data to DFdiscover
- User accounts and roles:
  - datafax : Unrestricted
  - data\_manager : Unrestricted
  - site\_monitor : site\_monitor
  - dfeproagent created according to [System Administrator User Guide](#)

**Client Tools Used:** DFATK, DFexplore, DFadmin, DFsetup, DFweb, DFengage

**Purpose:** This module tests all functionality related to the **DFengage** mobile and web applications for ePRO data capture from study participants. It includes the creation of ePRO user accounts in **DFadmin** and the management of ePRO users in **DFweb** as well as verification of data submitted from **DFengage** in **DFexplore**.

## Tests & Requirements

1. Create **DFengage** users role in **DFadmin**
2. Add bulk **DFengage** users accounts to **DFadmin**
3. Installation and initial **DFengage** login.
4. Complete a task in online mode.
5. Complete a task in offline mode.
6. Sync data collected offline to your **DFdiscover** server.
7. Resetting a user login password.
8. Enter data in **DFengage** web.
9. Configure and receive **DFengage** notifications.
10. Confirm data sent to the server using **DFexplore**.

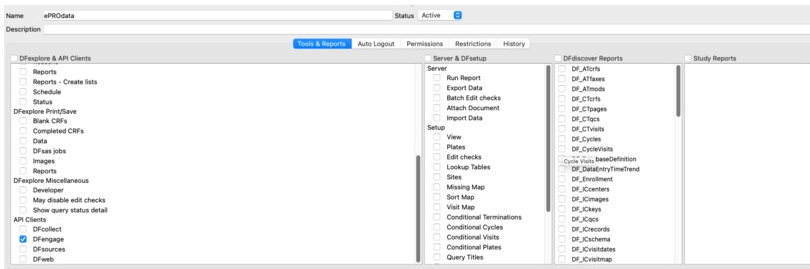
Estimate of Time Required: 35 Minutes

## Begin Module 19. DFengage ePRO Data Entry

1. Start **DFATK** as described in [Module 1 \(Installation & Initialization\)](#).
2. Click [19. DFengage ePRO Data Entry](#) followed by [Begin](#) to begin this module.

## Create DFengage users role in DFadmin

1. Start **DFadmin**. Login to your **DFdiscover** Server as datafax.
2. Specify a **Username** and datafax, and the assigned user password in the **Password** field. Click [Login](#) to complete login and continue.
3. Create a role for **DFengage** users. Begin this task by clicking the **Roles** tab.
4. Within the list of studies, locate and choose the entry for 254 Acceptance Test Study. Click [New](#) to add a new user role. In the dialog, enter the role name ePROdata.
5. Click [Create](#) to create the new role ePROdata.
6. Define **Tools & Reports** permissions for the ePROdata role. Highlight ePROdata in the **Roles** list to make it the active role. Enter ePROdata user permissions in the **Description** field.
7. Click **Tools & Reports** tab below the **Description** field. Set each of the following:
  - In the **DFexplore & API Clients** panel,
    - Check (Enable) **Data** within **DFexplore Views**
    - Check (Enable) **DFengage** and **DFweb** within **API Clients**
  - In the **Server & DFsetup** panel,
    - Check (Enable) **View** within **Setup**



8. Click **Permissions** tab.

9. Set plates 31-34 data permissions as follows:

- o **Visits** = 301-303,310-319
- o **Plates** = 31-34
- o **Levels** = ALL
- o **Modify** = 1-5
- o **Write Levels** = 1
- o **Data** = Check (enable) CM (Create, Modify)
- o **Reasons** = Check (enable) M (Modify)

Get	Show			Modify	Write	Data	Queries					Reasons											
	Visits	Plates	Levels				Hidden Fields	Int. Queries	Levels	Levels	C	M	D	L	P	C	M	D	A				
<input checked="" type="checkbox"/>	301-3...	31-34	ALL	<input type="checkbox"/> Show	<input type="checkbox"/> Show	1-5	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>				<input type="checkbox"/> Show	<input type="checkbox"/> Show			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Set plate 30 data permissions as follows:

- o **Visits** = 300
- o **Plates** = 30
- o **Levels** = ALL
- o **Modify** = 1
- o **Write Levels** = 1

Get	Show			Modify	Write	Data	Queries					Reasons											
	Visits	Plates	Levels				Hidden Fields	Int. Queries	Levels	Levels	C	M	D	L	P	C	M	D	A				
<input checked="" type="checkbox"/>	301-3...	31-34	ALL	<input type="checkbox"/> Show	<input type="checkbox"/> Show	1-5	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	300	30	ALL	<input type="checkbox"/> Show	<input type="checkbox"/> Show	1	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>				<input type="checkbox"/> Show	<input type="checkbox"/> Show			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. Select **File** > **Save** or click **Save** to save settings for role ePROdata.

12. Select site\_monitor to make it the active user. Click **ePRO Admin Permissions**.

13. To assign a study to site\_monitor, click the blank area below the **Study** heading. Select **254 Acceptance Test Study** from the **Study** drop-down. Set:

- o **Type** = Admin
- o **Sites** = 99

Select **File** > **Save** or click **Save**.

14. Select dfeproagent to make it the active user. Click the **Permissions** tab and assign add a row for the ATK study:

- o **Study** = 254 Acceptance Test Study
- o **Sites** = ALL
- o **Subjects** = ALL
- o **Role Name** = ePROdata

Select **File** > **Save** or click **Save**.

## Add bulk DFengage users accounts to DFadmin

1. Still as datafax and with the **DFadmin** application open, click **Users** tab to open the user definition window.

2. Click **Add Bulk Users**.

3. In the resulting **Add Bulk Users** dialog, set:

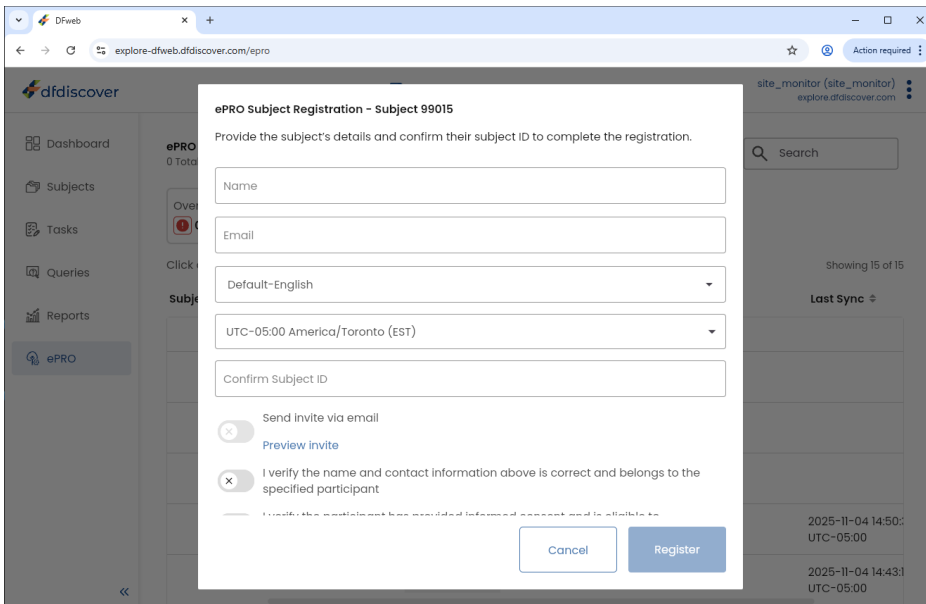
- o **Study** = Select **254 Acceptance Test Study** - **Role** = Select **ePROdata**
- o **Username Prefix** = atk\_
- o **Subjects Range** = 99001-99015
- o Check (enable) **Preview usernames**

- Set an **Initial Password** by entering a password of your choice.
- Click **Add 15 user accounts**, in the resulting confirmation dialog click **Yes** to add the defined user accounts.

Click **Close**.

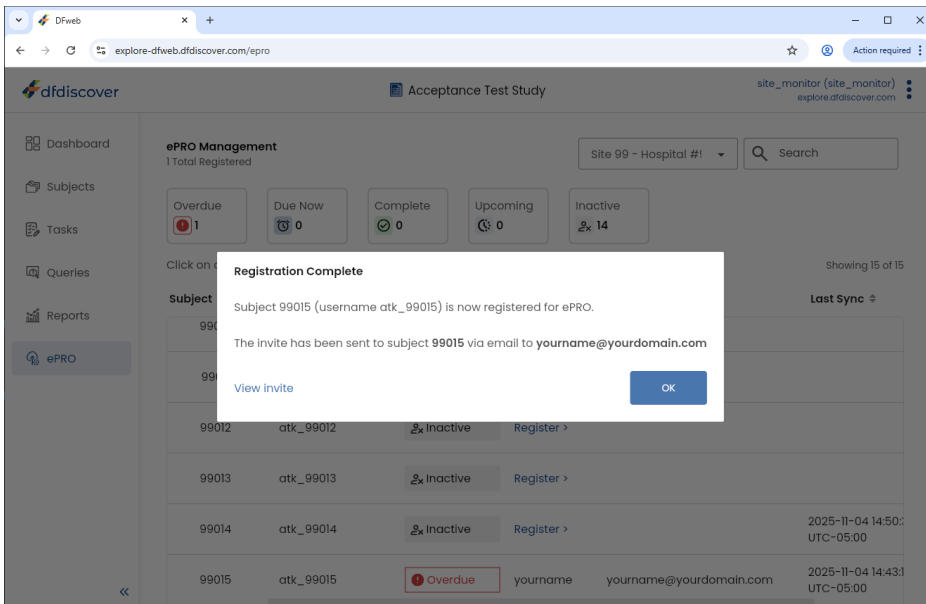
**IMPORTANT:** Remember the password assigned in this step as it is needed in future tests.

4. Choose the **atk\_99015** entry from the list of users. Click **Permissions** tab. Confirm the following permissions are set:
  - **Study** = Select **254 Acceptance Test Study**
  - **Sites** = 99
  - **Subjects** = 99015
  - **Role Name** = **ePROdata**
5. Select **File** > **Save** > **Exit** to close **DFadmin**.
6. Open a web browser and navigate to <https://dfweb.dfdiscover.com/?server=explore.dfdiscover.com&api=dfws.dfdiscover.com> or the DFweb URL provided by your administrator, enter **site\_monitor** in the Username field of the login dialog, and the previously assigned password in the **Password** field. Click **Login** to login.
7. From the sidebar, Click **ePRO**. Locate the subject 99015 with username **atk\_99015**, click **Register**.

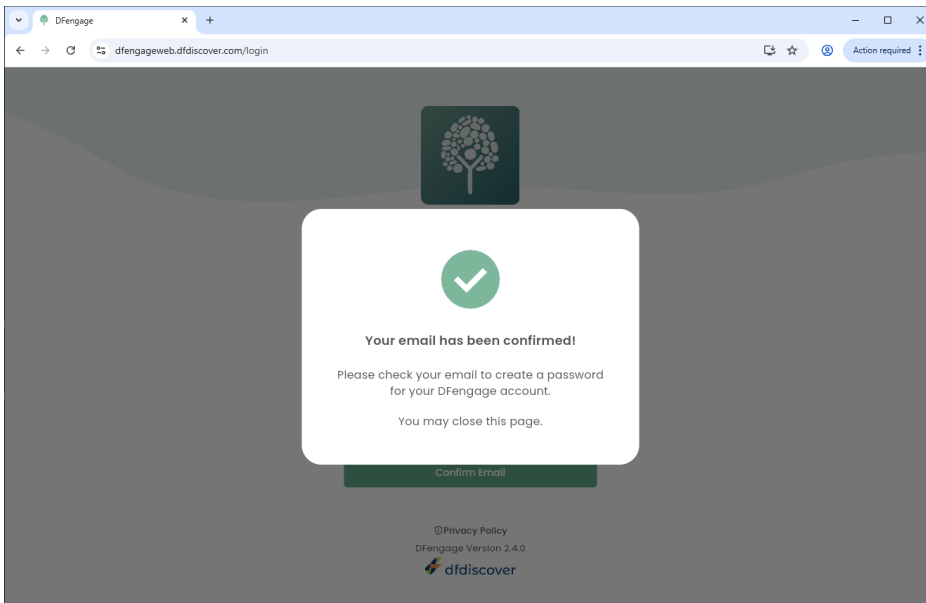


8. In the resulting **ePRO Subject Registration** dialog set:
  - **Name** = yourname
  - **Email** = youremail
  - **Language** = default
  - **Timezone** = Your local timezone
    - **Confirm Subject ID** = 99015
    - **Toggle (enable)** = Send invite via email
    - **Toggle (enable)** = I verify the name and contact information above is correct and belongs to the specified participant.
    - **Toggle (enable)** = I verify the participant has provided informed consent and is eligible to participate

Click **Register** > **OK**.



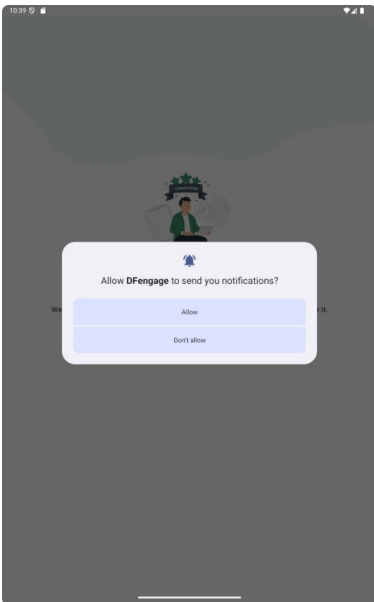
- Click [View invitation](#), confirm the displayed invite is the same as the one received to your email address specified in the previous step. Click [Click here to activate your account](#).
- Enter the email address specified during the **ePRO Subject Registration** process. Click [Confirm Email](#). A confirmation dialog is displayed presenting the information below.



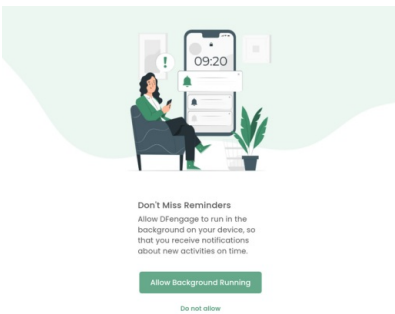
- Close the **DFengage** web browser window.

## Installation and initial DFengage login

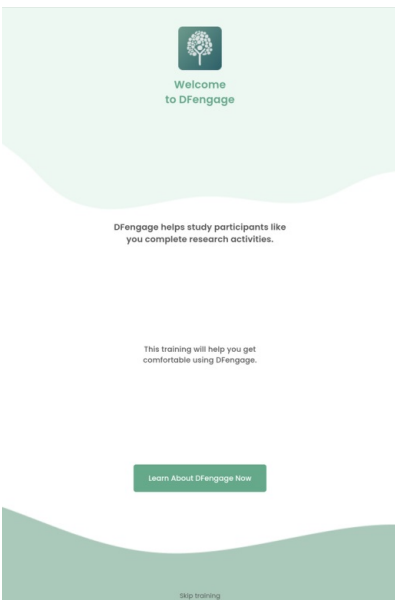
- Open a web browser and navigate to <https://dfweb.dfdiscovers.com/?server=explore.dfdiscovers.com&api=dfws.dfdiscovers.com> or the DFengage web URL provided by your administrator, enter `site_monitor` in the Username field of the login dialog, and the previously assigned password in the **Password** field. Click [Login](#) to login.
- From the sidebar, Click **ePRO**. Select subject 99015 with username `atk_99015` to open the **ePRO Subject Details** dialog.
- Click **Get link/QR code** and under the Login Link section use the link or QR code to install **DFengage**, and then once it's installed click the link or scan the QR code again to auto-fill the server, API, and username
- Open **DFengage**.
- Click [Get Started](#).
- Enter the previously assigned password in the **Password** field. Click [Login](#) to login. The change password dialog is presented. Enter a password of your choice, click [Set new password](#).
- The **Pincode setup** dialog is presented. Enter any 4-digit numeric pincode. Click [Continue](#).
- DFengage** may ask to enable notifications. Click [Allow](#) or follow your device's instructions to enable notifications. If no such prompt appears, proceed to [step 11](#)



10. **DFengage** may ask to run in the background. Click [Allow Background Running](#) and follow any steps needed to enable background running. If no such prompt appears, proceed to [step 11](#).



11. Select **default** from the **Pick Your Language** dropdown, click [Continue](#). The **DFengage** training prompt is displayed. Click [Learn about DFengage now](#).



12. Proceed through the tutorial by clicking **Next** until you reach the end of the first section. Click **Learn More About DFengage** to continue to the second section of the tutorial.

Well done! Now you're ready to complete activities in DFengage.

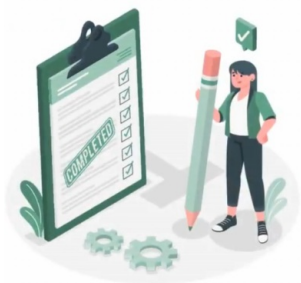


[Learn More About DFengage](#)

[← Go back to previous screen](#)  
Skip training

13. Click **Next** to proceed until all training slides are complete. Click **See Today's Activities** to proceed to the main activity page.

**DFengage Training Complete!**



You've successfully completed the training.

[See Today's Activities](#)

[View this training again from the settings page](#)

## Complete a task in online mode

1. Click **Start** next to **eDiary Day 1**.
2. Click **Today's date**, Select a date of 01 Jun 2023. Click **OK**, the date field is displayed as 01/06/2023. Click **Next**.

Exit eDiary Day 1

10:14

\*Today's date:

01/06/2023

Previous Next

3. Complete the remaining **eDiary Day 1** questions by entering the following and clicking **Next** on each screen:

- o **What time is it?** = 14:45, the time field is displayed as 14:45:00. Click **OK**
- o **The first set of questions relate to reactions at or around the site of vaccination.**
  - **Is there redness?** = Y
  - **Maximum severity of redness** = Does not interfere with activity.
  - **Medication taken for redness?** = N
- o **Check the box next to each symptom you have experienced today:**
  - **Nausea** = Checked (enabled)
  - **Headache** = Unchecked (disabled)
  - **Fatigue** = Checked (enabled)
  - **Joint Aches** = Unchecked (disabled)
  - **Muscle Aches** = Unchecked (disabled)
  - **No Symptoms** = Unchecked (disabled)
- o **On a scale of 1 to 10, with 1 being the least and 10 being the worst pain imaginable , how severe were your symptoms today?** = 7
- o **Please take your temperature using the provided thermometer. Record your temperature here (degrees F)** = 98.4

Click **Finish**.

Exit eDiary Day 1

10:14

Please take your temperature using the provided thermometer. Record your temperature here (\*):

98.4 Fahrenheit

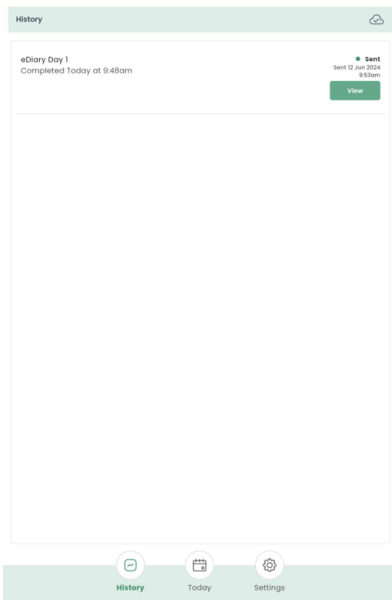
Previous Finish

Ready to submit your responses?  
No further changes will be possible.

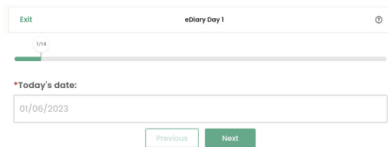
No Yes

4. Click **Yes** to confirm your submission.

5. Click the **History** button to open the history page. The completed **eDiary Day 1** displays as **Sent** with the date and time sent.



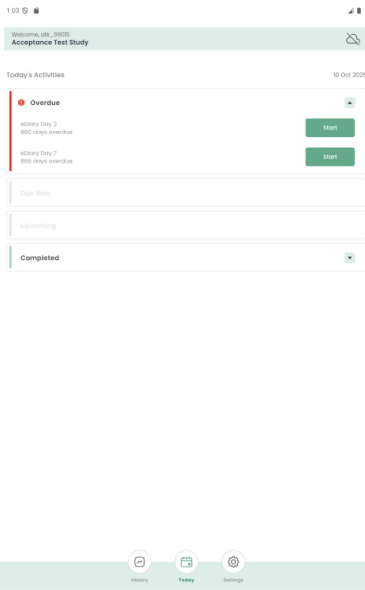
6. Click **View** for the sent **eDiary Day 1** entry. Confirm that the fields are unable to be changed.



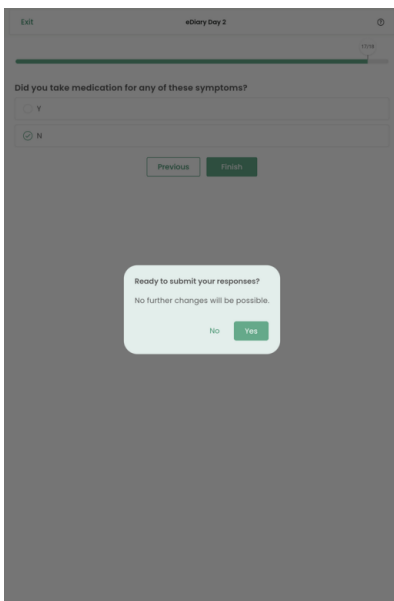
7. Close the **DFengage** application.

## Complete a task in offline mode

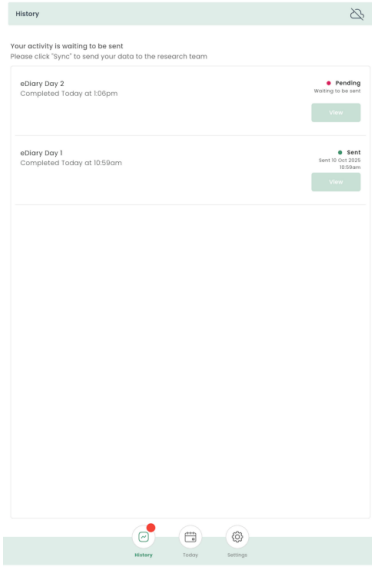
1. Switch your device to airplane mode or otherwise disconnect from the internet.
2. Open **DFengage**, login with your pincode. Click **Start** next to **eDiary Day 2** (plate 32).



3. Click **Today's date**, Select a date of 02 Jun 2023. Click **OK**, the date is displayed as 02/06/2023. Click **Next**.
4. **What time is it?** enter 17:30, click **OK**, the time field shows as 17:30:00. Click **Next**.
5. Confirm you have reviewed the instructions by checking (enabling) **Read and Understood (Continue to next screen)**. Complete the remaining **eDiary Day 2** questions by entering the following and clicking **Next** on each screen:
  - o **Pain** = Quite a bit
  - o **Redness** = Not at all
  - o **Swelling** = A little bit
  - o **Itching** = A little bit
  - o **Nausea/Vomiting** = Not at all
  - o **Headache** = Not at all
  - o **Fatigue** = Very Much
  - o **General feeling unwell** = Quite a bit
  - o **Joint aches** = Not at all
  - o **Muscle aches** = A little bit
  - o **Other Symptoms?** = N
  - o **Did you take medication for any of these symptoms?** = N
6. Click **Finish** > **Yes** to save the questionnaire.



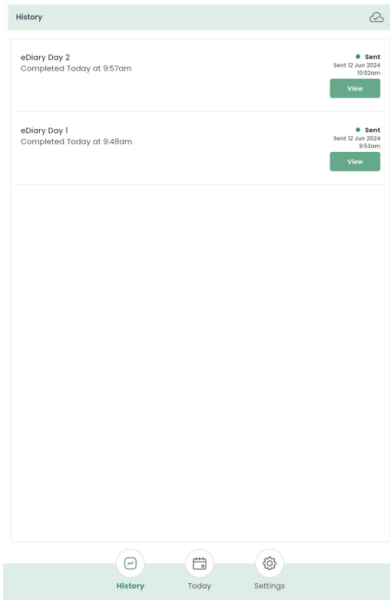
7. Click **History**, confirm **eDiary Day 2** as **Pending** with the current date and time of completion, and **eDiary day 1** is synced (displayed as **Sent**).



8. Close **DFengage** application.

## Sync data collected offline to your **DFdiscover** server

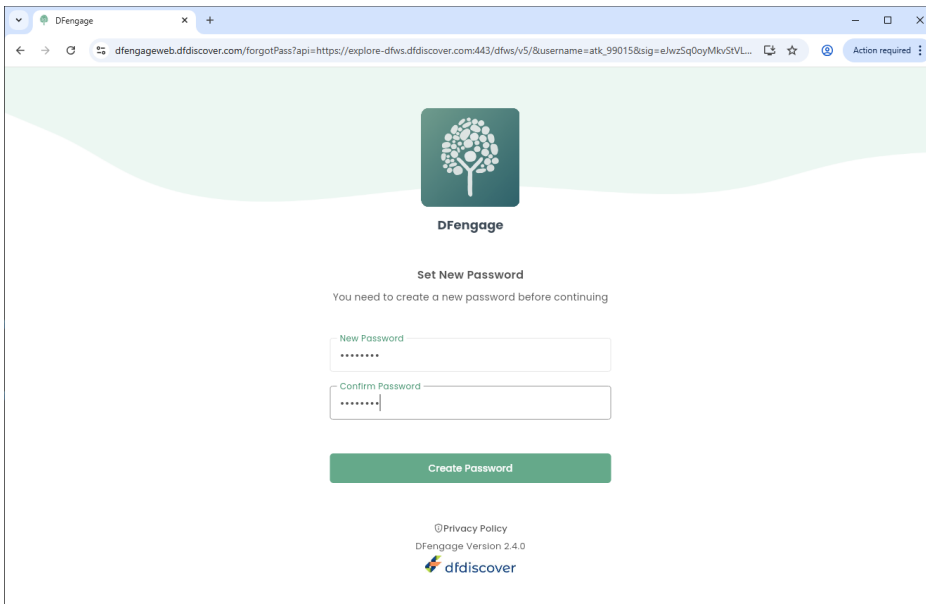
1. Switch off airplane mode on your device or otherwise re-connect to the internet.
2. Open **DFengage**, login with your pin code. Go to **History** and confirm you are shown as online. If the **eDiary Day 2** questionnaire is still shown as Pending, click **Sync** to send the questionnaire to the server. Once complete, confirm that **eDiary Day 2** is shown as **sent** with the expected date and time.



3. Close **DFengage** application.

## Resetting a user login password

1. Open a web browser and navigate to <https://dfengage.dfdiscover.com/?server=explore.dfdiscover.com&api=dfws.dfdiscover.com> or the DFengage web URL provided by your administrator.
2. Enter a **Username** of `atk_99015`. Click the **Forgot Password** link on the login page. In the **Forgot Password** dialog:
  - Enter the email address associated with the `atk_99015` account
 Click **OK**.  
 You should see a confirmation message: *Email Sent*.
3. Open the password reset email from your **DFdiscover** server and click the provided link to reset the `atk_99015` password.
4. The **DFengage** web **Set New Password** page is opened. Enter and confirm a new password, then click **Create Password**.



5. A message confirming **Password set. Logging in.** is displayed in your browser, and a notification email is sent to the address associated with the `atk_99015` account. You are logged into **DFengage** web.
6. Return to **DFweb** login as user `site_monitor` and Click **ePRO**. Select subject 99015 with username `atk_99015` to open the details dialog.
7. Under **View logs**:
  - Click **ePRO account log** to verify registration audit trail, Click **Back**.
  - Click **ePRO access log** to verify login, start and submit activity, Click **Back**.
  - Click **Get link/QR code** under **Login Link**, then click **Copy Link**.

## Enter data in DFengage Web

1. Open a web browser and paste the previously copied login link into the address bar. Confirm that the **DFengage 2.5.0** version is displayed, and that the **Username** and **Server Name** fields are auto-populated.
2. In the **DFengage** login dialog, enter the assigned password in the **Password** field. Click **Login**.
3. Select **default** from the list of **Available Languages**, click **Continue**.
4. Click **Next** to proceed through all training slides. Once complete, click **See Today's Activities** to continue to the main activity page. From there, open the activity labeled **eDiary Day 7**.
5. Click the date selector icon, verify that a future date cannot be selected and select a date of 10 Oct 2025. Click **OK**, the date field is displayed as 10/10/2025. Click **Next**.
6. Complete the remaining **eDiary Day 7** questions by entering the following values and clicking **Next** on each screen:
  - **What time is it?** = 13:20, the time field is displayed as 13:20:00. Click **OK**
  - **The first set of questions relate to reactions at or around the site of vaccination.**
    - **Is there redness?** = Y
    - **Maximum severity of redness** = Does not interfere with activity.
    - **Medication taken for redness?** = N
    - **Any pain or discomfort around the vaccine site?** = Y
    - **On a scale of 1 to 99, with 1 being the least and 99 being the worst pain imaginable, how severe were your symptoms today?** = Enter 100 to verify the warning message shown, then correct the number to 49.
    - **Medication taken for pain?** = Y
    - **List medication taken for pain** = Tylenol 500mg
    - **Any itching around the vaccine site?** = N
    - **How hot does the vaccine site feel?** = Not hot at all
    - **This next set of questions relate to general symptoms. Enter your temperature this evening** = 34.7
    - **Medication taken for fever?** = N
    - **Have you experienced joint aches?** = N
    - **Any Muscle aches?** = N
    - **Have you felt hot, flushed or sweaty?** = N
    - **Any headaches** = N

- **Have you felt more tired than normal?** = N
- **Have you felt nauseous?** = N
- **Have you felt generally unwell?** = N
- **Have you experienced any other symptoms** = N

Click **Finish** > **Yes** to save the questionnaire.

7. Click **History** to open the history page. Confirm that **eDiary Day 7** is marked as **Sent** with correct date and time.
8. Click **Logout** to exit the **DFengage web** application.

## Configure and receive DFengage notifications

1. Start **DFsetup**, login as **data\_manager**, and choose **254 Acceptance Test Study** in normal access mode as described in "[How to start DFsetup](#)".
2. Click **View** > **ePRO Notifications** in the file menu to open the ePRO Notifications dialog.
3. Select the Generic New Activity Reminder notification entry with **ID 1**. Confirm the following properties are defined for this notification:
  - **Days** = 0
  - **Hours** = 0
  - **Minutes** = 0
  - **Direction** = After
  - **Title** = New Activity
  - **Message** = It's time for your next activity. Please open the app to complete it now.

The screenshot shows the 'ePRO Notifications' dialog in DFsetup. On the left, a table lists two notifications:

ID	Label	Langs	Visit	Timing	Status
1	Generic New ...	1	All	-	Active
2	Generic Overdu...	0	All	-	Active

On the right, the configuration panel for notification ID 1 is shown:

- ID:** 1
- Label:** Generic New Activity Reminder
- Active:**
- Notification Type:** Due - Sent at scheduled time
- Visit Reference:** All Visits
- Notification Timing:**
  - Set Time
  - Offset from Visit
  - Days:** 0
  - Hours:** 0
  - Minutes:** 0
  - Direction:** After
- Notification Content:** Default-Englis
- Title:** New Activity
- Message:** It's time for your next activity. Please open the app to complete it now.

4. Click the Generic Overdue Activity Reminder notification with **ID 2**. Confirm the following properties are defined for this notification:
  - **Days** = 0
  - **Hours** = 0
  - **Minutes** = 0
  - **Direction** = After
  - **Title** = Overdue Activity
  - **Message** = Oops, you missed your last activity. Let's get back on track now.

ID	Label	Langs	Visit	Timing	Status
1	Generic New ...	1	All	-	Active
2	Generic Overdue...	1	All	-	Active

ID: 2, Label: Generic Overdue Activity Reminder, Active:

Notification Type: Overdue - Sent only if linked activity incomplete

Visit Reference: All Visits

Notification Timing:  Set Time,  Offset from Visit

Days: 0, Hours: 0, Minutes: 0, Direction: After

Notification Content: Default-Englis, Clear

Title: Overdue Activity

Message: An activity for {{STUDY\_NAME}} is overdue. Please open the app to complete it as soon as possible.

Add, Delete, Duplicate, History, Revert, Save, Done

5. Click **Add** to add a new notification with ID 3. Enter the information for the new notification as follows and click **Save** to add the new notification to the study.

- o **Label** = Upcoming Survey 9am
- o **Active** = Checked (enabled)
- o **Notification Type** = Due - Sent at scheduled time
- o **Visit Reference** = Visit 315 - ePRO Day 2 Survey T-09:00
- o **Notification Timing**
  - **Offset from Visit** = Checked (selected)
  - **Days** = 0
  - **Hours** = 0
  - **Minutes** = 5
  - **Direction** = Before
- o **Title** = {{PARTICIPANT\_NAME}}, a new survey is coming!
- o **Message** = A new survey for {{STUDY\_NAME}} will be available in 5 minutes. We would greatly appreciate your feedback.

ID	Label	Langs	Visit	Timing	Status
1	Generic New ...	1	All	-	Active
2	Generic Overdue...	1	All	-	Active
3	Upcoming ...	1	Visit 315	-5 min	Active

ID: 3, Label: Upcoming Survey, Active:

Notification Type: Due - Sent at scheduled time

Visit Reference: Visit 315 - ePRO Day 2 Survey T-09:00

Notification Timing:  Set Time,  Offset from Visit

Days: 0, Hours: 0, Minutes: 5, Direction: Before

Notification Content: Default-Englis, Clear

Title: {{PARTICIPANT\_NAME}}, a new survey is coming!

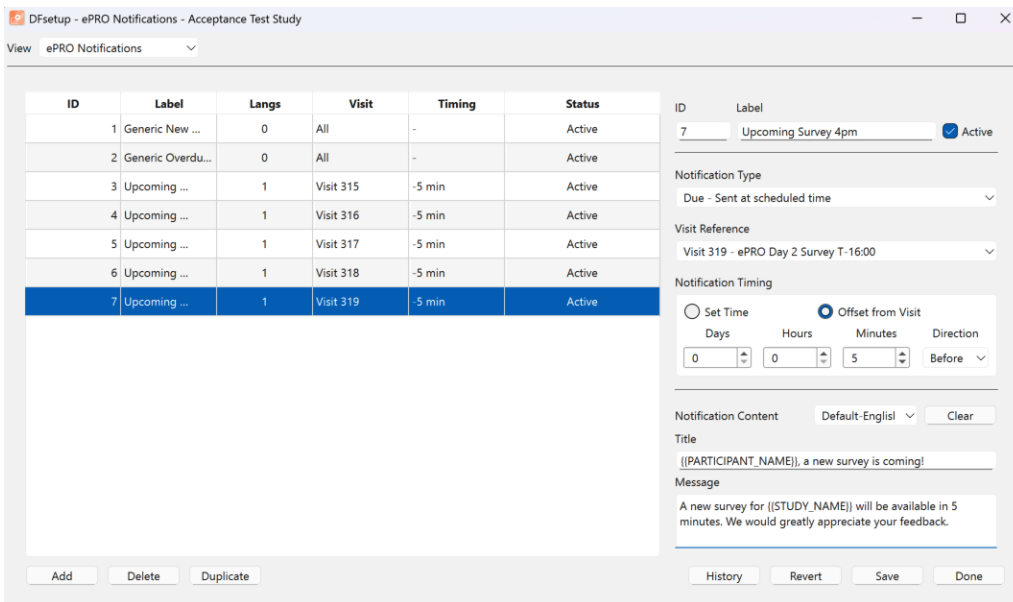
Message: A new survey for {{STUDY\_NAME}} will be available in 5 minutes. We would greatly appreciate your feedback.

Add, Delete, Duplicate, History, Revert, Save, Done

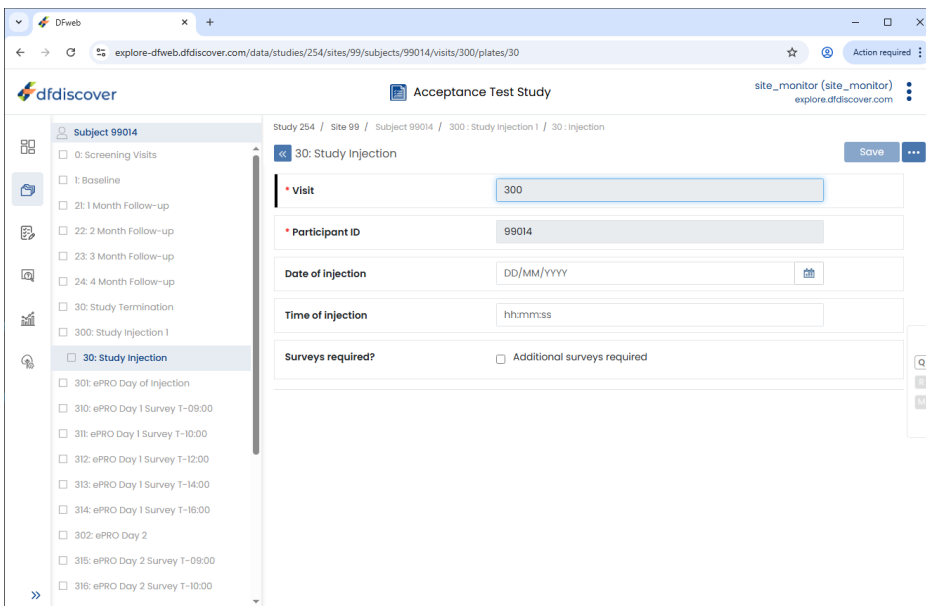
6. For each of the remaining ePRO Day 2 Survey visits outlined in the visit map:

- o Visit 316 - ePRO Day 2 Survey T-10:00
- o Visit 317 - ePRO Day 2 Survey T-12:00
- o Visit 318 - ePRO Day 2 Survey T-14:00
- o Visit 319 - ePRO Day 2 Survey T-16:00

With notification ID 3 selected, click **Duplicate** to create a new notification for each of the above visits, substituting the **Visit Reference** field for the appropriate visit and **Label** value to reflect the corresponding time (**10am, 12pm, 2pm, 4pm**).



- Click **Save** to save changes to the notifications and then **Done** to close the ePRO notifications dialog. Then Click **File** > **Exit** to quit **DFSetup**.
- Open a web browser and navigate to <https://dfweb.dfdiscovers.com/?server=explore.dfdiscovers.com&api=dfws.dfdiscovers.com> or the DFweb URL provided by your administrator, enter site\_monitor in the Username field of the login dialog, and the previously assigned password in the **Password** field. Click **Login** to login.
- Click **Subjects**, select **99014 > 300: Study Injection 1** to open the **30: Study Injection** page.



- Click **Date of Injection**, set:
    - Date of Injection** = Yesterday's date
    - Time of Injection** = 10:00:00
    - Surveys required?** = Check (enable) **Additional surveys required**
- Click **Save**. Click **Logout** to exit **DFweb**.
- Open the **DFEngage** mobile application. Login as user `atk_99014` (See: [DFEngage Login](#)). Select **default** from the **Pick Your Language** dropdown, click **Continue**.
  - Close **DFEngage** on the device and await the time designated for one of the custom notifications defined in [step 5](#) and [step 6](#) (9am, 10am, 12pm, 2pm, 4pm). 5 minutes before the generic notification arrives, confirm that the expected custom notification arrives.

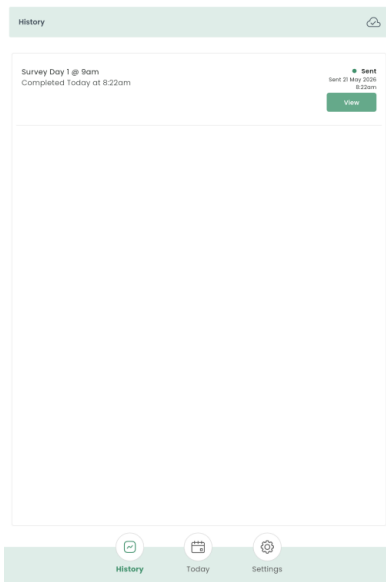
NOTE: as the date of injection was already set to Yesterday's date in [step 10](#), the notification system may send additional notifications prior to the scheduled notifications outlined in this step and the following steps, as prior default notification times may have already passed.

- Wait for an additional 5 minutes until scheduled notification time. Verify that **two notifications** are received at the expected time: one for the **overdue survey on Day 1**, one for the **new survey on Day 2**.
- Click either of the notifications to open **DFEngage** and enter PIN to login.
- Click **Start** next to the **Survey Day 1 @9am** set:
  - Click **Today's date**, Select a date of 04 Nov 2025. Click **OK**

- Please indicate on the scale how your health is TODAY. = 74
- How would you rate your pain on average = 6

Click **Finish**, then **Yes** to submit the **Survey Day 1 @9am** survey.

16. Click **History** and Confirm the entry for **Survey Day 1 @9am**.



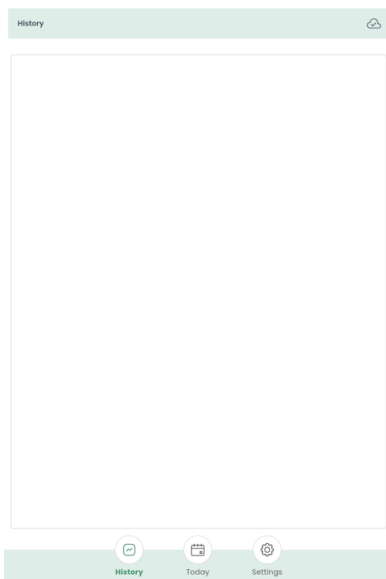
17. Click **Settings** > **Logout** > **Logout**.

18. Login again as user atk\_99014 (See: [DFengage Login](#)). This time selecting **French** from the **Pick Your Language** dropdown, click **Continue**.

19. Verify the questionnaire descriptions are in **French**. Locate **Journal électronique Jour 1**, click **Start**, verify **Today's date** is displayed as **Date du jour** .

## Confirm logout of **DFengage** application clears data history

1. Still logged into **DFengage**, click **History**.
2. In the History Page, confirm that no entries exist.



3. Click **Settings** > **Logout** > **Logout**.

## Confirm data sent to the server using **DFexplore**

1. Login to **DFexplore**, Open subject **99015** > **301: ePRO Date of Injection** > **31: eDiary Day 1**. Confirm the data previously entered now appears in **DFexplore**.
2. Select **Page** > **List History of Changes on This Page**, check (enable) **Detailed History**. Confirm the audit trail is present.

## End Module 19. DFengage ePRO Data Entry

1. Return to the **DFATK** application. Click **End** to confirm successful completion of Module 19. DFengage ePRO Data Entry.

# ATK Worksheet

## Using the Worksheet

As you work through the ATK, you may find it beneficial to have a worksheet to keep track of which modules you have completed.

For that purpose, print this chapter and mark the steps and modules as you progress.

After completion of the ATK, keep the printed worksheet together with your installation and qualification materials.

## Module 1. Installation and Initialization

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Confirm version information can be obtained for DFdiscover.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Obtain super-user privileges and remove older Acceptance Test Study, if one exists.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Install the Acceptance Test Study.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Define Acceptance Test Study to the DFdiscover server.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Create a role and permissions for datafax.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Creating study roles and permissions.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Creating user accounts and assigning study permissions.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Enable high definition imaging.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	9. Start the Acceptance Test Study Control Panel application.
DFdiscover RPM & Build Date	<input type="text"/>
Server FQDN & OS	<input type="text"/>
Server Azure SMS Config & Region	<input type="text"/>
DFdiscover Tools Build Version & Date	<input type="text"/>
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 2. DFdiscover Client Applications

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Send PDF images to <b>DFexplore</b>
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Resetting a user login password.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Verify the online user documentation. Open the Image Router and verify the appearance of the Welcome Image.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Open the Acceptance Test Study and verify the standard <b>DFexplore</b> views.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Start <b>DFsetup</b> and verify version information.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Verify the online setup documentation. Open the Acceptance Test Study setup and verify the standard <b>DFsetup</b> views.
DFdiscover Tools Build Version & Date	<input type="text"/>
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 3. Study Setup

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Permitted users can gain exclusive access to <b>DFsetup</b> to modify a study setup.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Define Global study preferences and apply settings to <b>DFsetup</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Create and modify a new style (Comment).
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Create and modify a new module (Death).
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Assign Field definitions to a newly created module.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Assign a module's field definitions to a plate.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Correct field ordering on the current plate to set field traversal order for data entry.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Use copy and paste to create repeating module and field references on a plate.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	9. Create user-defined query category codes.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	10. Submit a copy of the newly defined Plate 11 into the study database and retrieve the page in <b>DFexplore</b> Image View.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	11. Enter and save all data on the submitted plate 11.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 4. eCRF Creation for DFdiscover

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. eCRF creation in <b>DFsetup</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. eCRF background color preferences.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Entering eCRF data.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 5. Custom Properties

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Defining Custom Properties in <b>DFsetup</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Adding Global Custom Property values.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Adding Plate, Module and Variable level Custom Property values.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Exporting Custom Properties in <b>DFsetup</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Edit checks execution of Custom Properties.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Creating subject data lists and exporting data views.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. <b>DFexplore</b> Database Definition Report exporting.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 6. Subject Alias

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Importing and Modifying Subject Alias Map using <b>DFsetup</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Creating Subjects using Subject Alias.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Subject Alias Tracking (Reports).
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Exporting Subject Alias data.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 7. EDC Data Entry

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Login to <b>DFexplore</b> and the Acceptance Test Study and confirm the list of sites, subjects and assessments in the record list window.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Enter and save new data using EDC data entry for Subject 99007.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Add reasons to explain entered data values.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Enter and save Plate 3, Subject 99007 as a pending record.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Mark and save unavailable data as missed. Unmark available data as missed.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Retrieve and modify existing data using a predefined task and save modifications to the database.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Confirm audit trail information for entered and modified data.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 8. Image Data Entry

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Submit PDF images to <b>DFExplore</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Login to <b>DFExplore</b> and confirm the receipt of new pages in the Status View.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Login to the Image Router and route a misidentified page to the Acceptance Test Study new record queue.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Login to <b>DFExplore</b> and confirm receipt of the routed page in the Status View.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Retrieve new images in <b>DFExplore</b> Image View.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Enter Plate 1 (Form 1) for Subject 99002.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Enter Plate 2 (Form 2) for Subject 99002.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Enter Plate 3 (Form 3) for Subject 99002.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	9. Enter Plate 4 (Form 4) for Subject 99002.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	10. Compare the resolutions between Standard Definition (SD) and High Definition (HD).
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	11. Edit an existing query.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	12. Delete an existing query.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	13. Change data and record a reason for data change.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	14. Batch validate all opened pages for Subject 99002 to level 2.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	15. Confirm the status of entered pages in Status View.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 9. User-defined Query Category Types

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Retrieve an existing data record in <b>DFExplore</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Apply a user-defined Category query.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Add a reason for Data Value to explain entered data.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Edit an existing query.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Delete a user-defined Query Category that is used by an existing query.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Delete a user-defined Category query.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 10. Multiple Queries Per Field

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Submit PDF images to DFdiscover.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Enable multiple queries per field in <b>DFsetup</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Retrieve submitted CRF in <b>DFexplore</b> Image View.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Enter Plate 9 for Subject 99002.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Apply multiple queries to a field.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Select and edit an existing query in a field that has multiple queries.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Select and reply to an existing query in a field that has multiple queries.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Select and delete an existing query in a field that has multiple queries.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 11. Data Review

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Retrieve all data for Site 99 that exists at level 3.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Review and approve a pending reason for data value, and approve a selected query in a field that has multiple queries.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Review and move approved reasons for data values to a higher workflow level, and review queries in a field that has multiple queries.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Data review and add a query to inconsistent data.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Review and complete pending data for Subject 99007.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Confirm audit trail information for reviewed and modified data.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Run batch edit checks to verify data integrity.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Use a data expression to retrieve specific subject information.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	9. Use cross-plate data criteria to retrieve specific subject information.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 12. External Query Reports

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Obtain database query metrics and details using Status and List Views to review all outstanding queries prior to query report creation.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Run database integrity check report DF_XXkeys to export all key fields and visit dates from required plates in the database.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Use Data View to check, and if necessary correct, illegal visit dates by retrieving the problems keys identified by DF_XXkeys.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Execute DF_QCupdate to update the query database and lock all records for query report generation.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Execute DF_QCreports to create a standard, 3-part external query report for a study site.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Confirm the status of external queries following query report creation.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Execute DF_QCstatus to verify that a new query report was created by listing all reports in the QC/NEW directory.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Execute DF_QCview to display the newly created query report.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	9. Execute DF_QCprint to print the query report from the QC/NEW directory.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	10. Comparing several examples from the printed query report against their corresponding queries in the study database.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	11. Execute DF_QCfax to email the query report to a valid email account.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	12. Verify the status of the queries in the sent report.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 13. Replying to EDC Queries, eSignatures

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Determine a count of outstanding/outstanding queries in Status View.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Review outstanding queries in Queries View.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Using EDC, locate and reply to outstanding clarification queries.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Add an Electronic Signature (eSign) to a set of completed subject records.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Verify removal and Re-applicaton of eSignatures.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 14. Re-submitting Query Corrections

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Submit PDF images to DFdiscover.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Verify that all CRFs have arrived successfully in Image view.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Retrieve submitted CRFs using <b>DFexplore</b> Image View.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Enter Form 2, Subject 99001, resolve outstanding queries, and save the corrected CRF to the database.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Enter Form 2, Subject 99002, resolve outstanding queries, and save the corrected CRF to the database.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Enter Form 4, Subject 99004.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Enter Form 2, Subject 99004, resolve outstanding queries, and save the corrected CRF to the database.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Select and resolve a query in a field that has multiple queries.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	9. Review and approve a pending query reply for Form 1 for Subject 99002.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	10. Review, correct and approve a pending query reply for Form 1, Subject 99007.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	11. Confirm query resolution by examining the database status.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 15. Data Export and DFsas

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Export date values in calender format and save the exported data to a file on the local computer.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Export date values from the database and save the exported data to a file on the local computer.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Examining data values according to user-specified criteria.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Query the database for specific data values.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Create a DFsas job file according to user-specified criteria.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Create a SAS job file and data files using the DFsas job file criteria.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Compare the contents of SAS data files with the actual data in the database.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 16. PDF File Creation

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Retrieve existing data according to user-specified criteria.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Saving <b>DFExplore</b> data to a standard PDF document.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Saving <b>DFExplore</b> blank CRF books to a standard PDF document.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Viewing a standard PDF data file using a PDF viewer application.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Saving <b>DFExplore</b> data to an encrypted bookmarked PDF file.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Open and view an encrypted bookmarked PDF file using a PDF viewer application.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Create a complete subject package PDF file that includes data records, CRF images and audit trail.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Open and view a PDF subject package using a PDF viewer application.
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 17. DFweb Data Entry

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Verify <b>DFweb</b> version information, logging into <b>DFweb</b> and <b>DFweb</b> site certificate verification.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Resetting a user login password.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Copying URL and changing user passwords.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Creating a new subject, entering subject data.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Adding, modifying and resolving queries.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Adding, reviewing and downloading subject documents.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Add an Electronic Signature (eSign) to a set of completed subject records.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Verify removal and Re-application of eSignatures.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	9. Verify <b>DFweb</b> saves eSignature task data to the specified save level.
DFweb URL used for testing	<input type="text"/>
DFweb Version & Build Date	<input type="text"/>
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 18. DFcollect Mobile Data Collection

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Installation and App preferences.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Resetting a user login password.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Online data record creation.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Download subject data for offline use.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Create data records in offline mode, query resolution and adding reasons for data values.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Sync data collected offline to your <b>DFdiscover</b> server.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Clearing <b>DFcollect</b> cache.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Adding, reviewing and downloading subject documents.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	9. Confirming data sent to the server using <b>DFexplore</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	10. Add an Electronic Signature (eSign) to a set of completed subject records.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	11. Verify removal and Re-application of eSignatures.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	12. Verify <b>DFcollect</b> saves eSignature task data to the specified level.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	13. Verify no saved data remains upon uninstallation and reinstallation of <b>DFcollect</b> .
DFws API used for testing	<input type="text"/>
DFcollect Version & Build Date	<input type="text"/>
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

## Module 19. DFengage ePRO Data Entry Data Entry

Pass/Fail	Testing step
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	1. Create <b>DFengage</b> users role in <b>DFadmin</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	2. Add bulk <b>DFengage</b> users accounts to <b>DFadmin</b> .
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	3. Installation and initial <b>DFengage</b> login.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	4. Complete a task in online mode.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	5. Complete a task in offline mode.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	6. Sync data collected offline to your <b>DFdiscover</b> server.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	7. Resetting a user login password.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	8. Enter data in <b>DFengage</b> web.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	9. Configure and receive <b>DFengage</b> notifications.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	10. Confirm Logout of <b>DFengage</b> application clears data history.
<input type="checkbox"/> Pass <input type="checkbox"/> Fail	11. Confirm data sent to the server using <b>DFexplore</b> .
DFws API used for testing	<input type="text"/>
DFengage Web URL used for testing	<input type="text"/>
DFengage Version & Build Date	<input type="text"/>
Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

# Discrepancy Report

Discrepancy Reports should be completed whenever an unexpected result is obtained during the execution of the ATK. A discrepancy may be a difference in the actual result from the expected result, a system malfunction, an error in the ATK documentation, or an error in the ATK Control Panel or study setup. Complete one report per incident.

- Assign each report a unique Discrepancy Report Number. You may want to simply sequentially number the reports starting at 1, or you may want to use a more elaborate numbering system.
- Record the particulars about your system. This includes the DFdiscover Release being tested at your site (e.g., 5.11.0 ), the Server Operating System and Version.
- Record the Test Number that you were executing when the problem occurred. This is the number that identifies the current step in the plan (e.g., 6.4.5).
- Describe, as accurately and as completely as possible, the problem that occurred. Include any error messages that appeared on screen. Can someone who was not sitting at the computer when the problem occurred understand your description?
- If you were able to work around the problem and continue, describe the workaround that was used.
- Record your name, title, signature and the current date on the report. Sign it.
- If the discrepancy appears to be an error that needs resolution by DFnet, forward the report to DFnet via email to [help@dfnetresearch.com](mailto:help@dfnetresearch.com). Record that a copy of the report has been sent to DFnet and the date that it was sent.
- If a resolution to the problem becomes available, either internally, or from DFnet provide a description of that resolution and the date.

## Discrepancy Information

Discrepancy Report Number	<input type="text"/>
DFdiscover Release	<input type="text"/>
Server Operating System and Version	<input type="text"/>
Problem	<input type="text"/>
Immediate Workaround	<input type="text"/>
Problem Resolution	<input type="text"/>

## Signature and Date

Completed By (Print name)	<input type="text"/>
Title	<input type="text"/>
Date	<input type="text"/>
Signature	<input type="text"/>

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## QtAV

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## d3.js

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## jwt-cpp

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## QXlsx

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