Acceptance Test Manual

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    - PostgreSQL
    - OpenSSL License
    - Original SSLeay License
    - gawk
    - Ghostscript
    - MariaDB and FreeTDS
    - QtAV
    - FFmpeg
    - c3.js
    - d3.js
    - jwt-cpp
    - QXlsx

Preface

DFdiscover Release 5.11.3

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Getting Help

For software support, Please contact the DFdiscover team:

- via email, 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 phsyical 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.

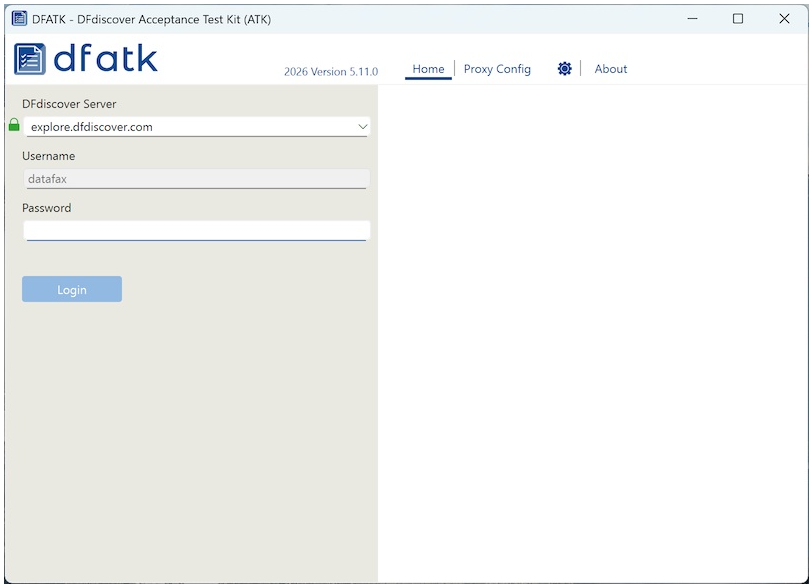
Notes

- 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.

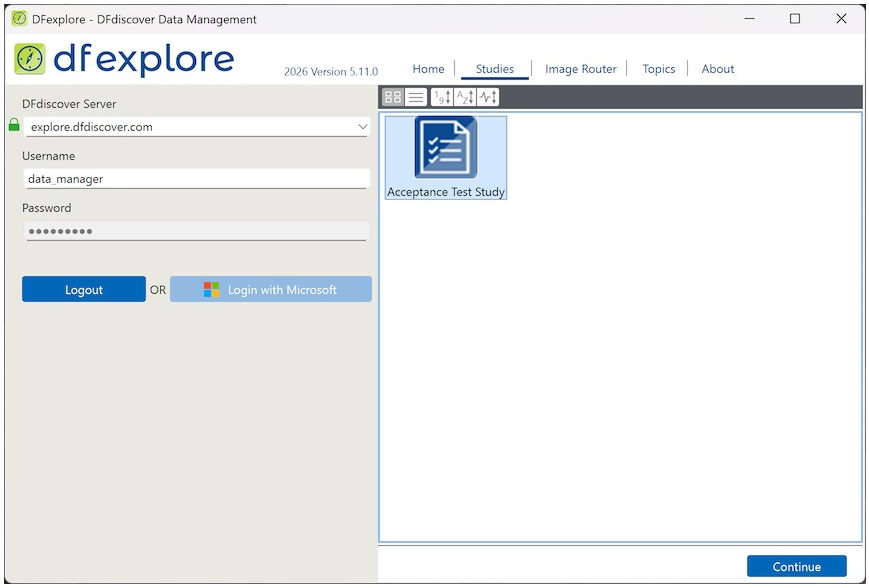
How to start **DFATK**

- 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.

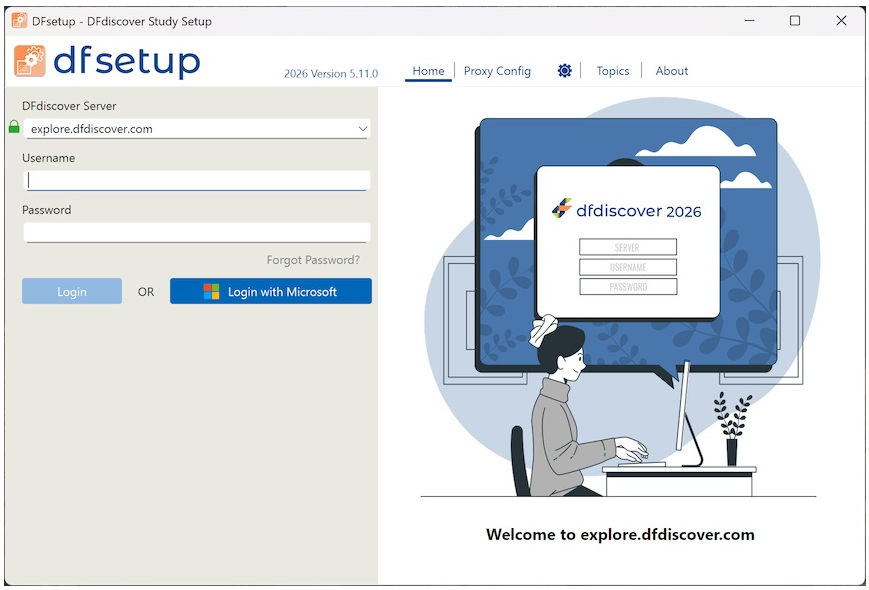


2. During the first login of data_coordinator, data_manager, site_monitor or site_invest a new password must be chosen. Choose and enter a new password in both the **New Password** and **Confirm Password** fields. Click OK to set the new password and dismiss the dialog. Choose **254 Acceptance Test Study**, 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.

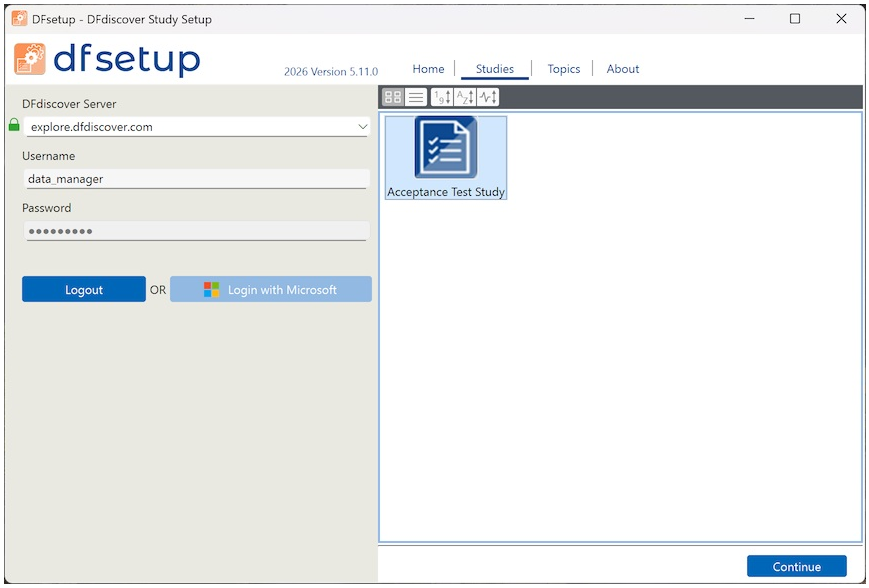
How to start DFsetup

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.

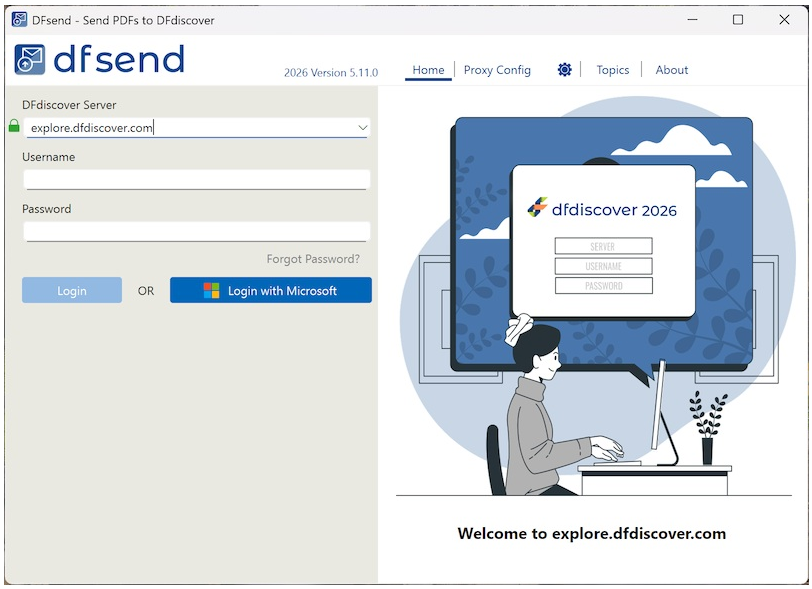


2. In the studies selection dialog, highlight the entry for **254 Acceptance Test Study**. Click Continue to continue.



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.

1 Module 1. Installation and Initialization

Overview

Prerequisites:

- Licensed and Configured DFdiscover 5.11.3 installed on Study Server
- DFdiscover supported email service running on Study Server (Example: postfix)
- DFdiscover 5.11.3 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 defintion imaging.
9. Start the Acceptance Test Study control panel application.

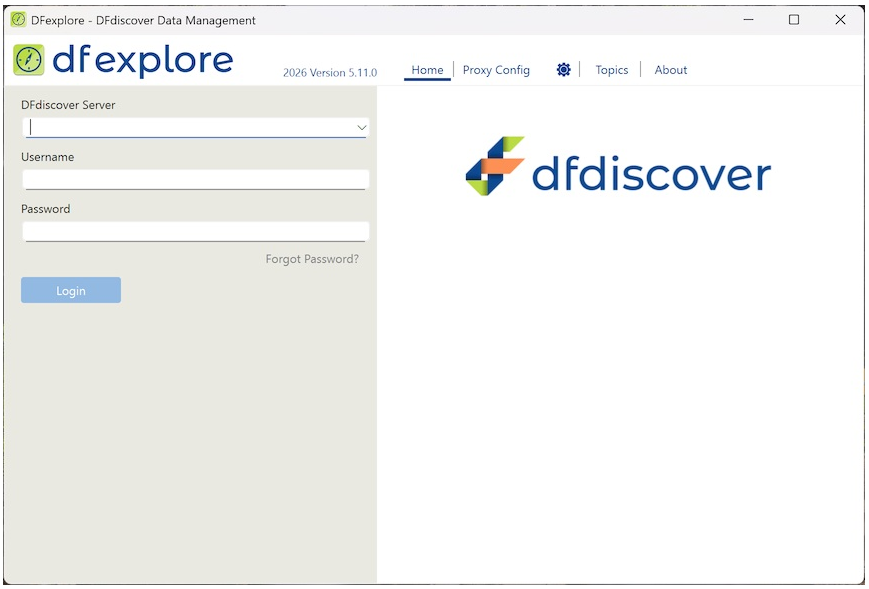
Estimate of Time Required: 30 Minutes

1.1 Confirm version information can be obtained for DFdiscover

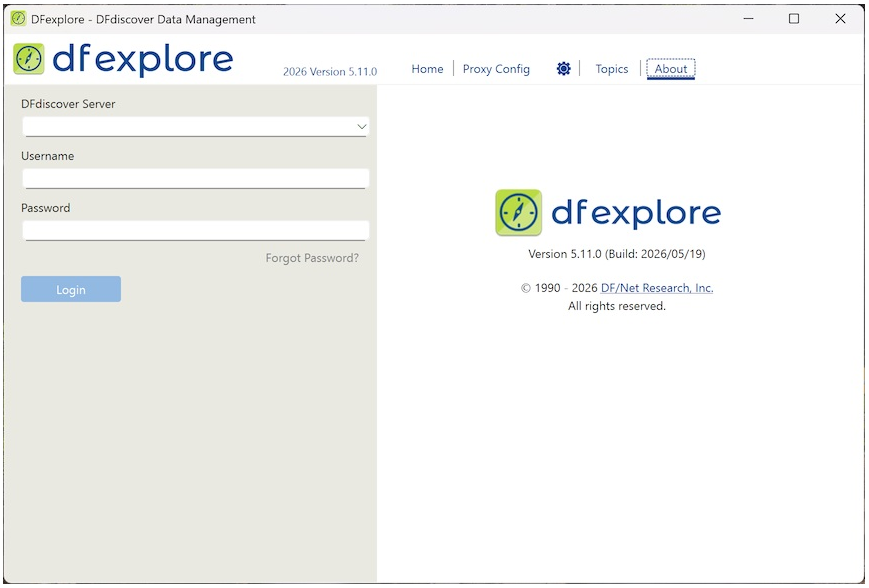
1.1.1. Confirm the Acceptance Test Kit is installed on the following Linux operating system:

- Red Hat / CentOS
- SUSE

1.1.2. Confirm **DFdiscover** version information by starting **DFexplore**.



1.1.3. In the login dialog, click **About**. Confirm that the version information in the dialog matches the installed software Version 5.11.3.



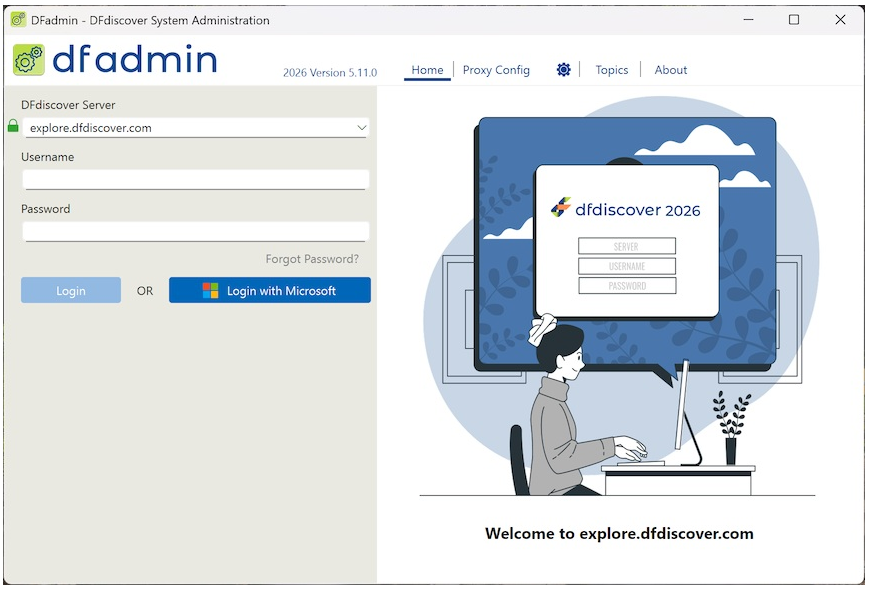
1.1.4. If the version is not DFdiscover 2026 Version 5.11.3, you must stop at this point. The Acceptance Test Kit is specifically designed for release DFdiscover 2026 Version 5.11.3.

1.1.5. Exit **DFexplore**.

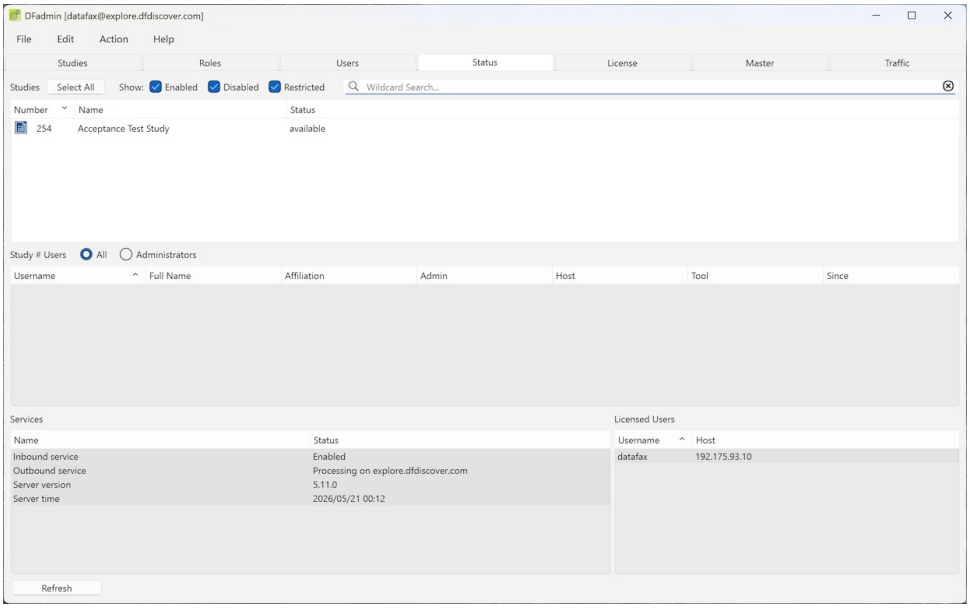
1.2 Obtain super-user privileges and remove older Acceptance Test Study, if one exists

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.

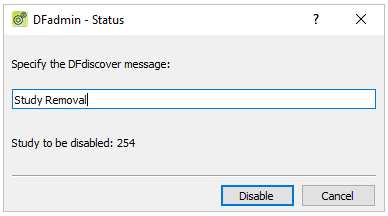
1.2.1. Start **DFadmin**. Login to your **DFdiscover Server** as datafax.



1.2.2. 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.



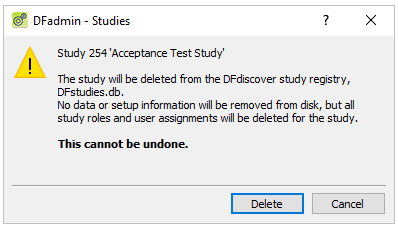
1.2.3. Select the entry for **254 Acceptance Test Study** from the list of studies. Select Action > Disable study>. In the confirmation dialog, enter the text Study Removal.



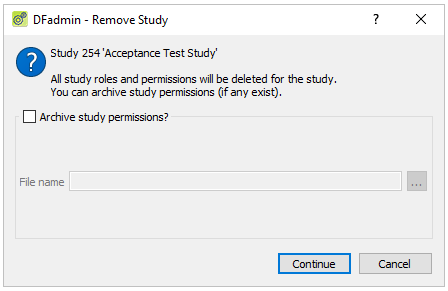
1.2.4. Click Disable to disable the Acceptance Test Kit.

1.2.5. 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**.

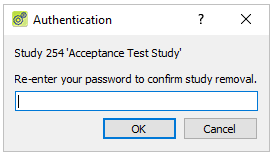
1.2.6. Click Delete in the confirmation dialog to continue with the delete.



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



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



1.3 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 5.11.3 Acceptance Test Kit. This is because the study directory structure and/or base states have changed with DFdiscover 2026 Version 5.11.3.

If the directories are present at this time, installation of the DFdiscover 2026 Version 5.11.3 Acceptance Test Kit will create TAR file of the existing installation and re-install the updated DFdiscover 2026 Version 5.11.3 val254 and .val254_states directories.

- The DFATK-5.11-3.x86_64.rpm file can be found on www.dfnetresearch.com in the Support section. After downloading the DFATK-5.11-3.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=NEWPATH** flag.
  - New installations using **rpm**, which will automatically download and install any dependencies required:

```
# rpm -ivh DFATK-5.11-3.x86_64.rpm
```

  OR, specify an alternative installation location:

```
# rpm -ivh --prefix=NEWPATH DFATK-5.11-3.x86_64.rpm
```

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

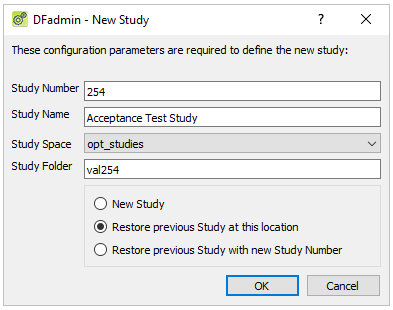
  - Confirm the presence of **254 Acceptance Test Study** with the command:

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

1.4 Define Acceptance Test Study to the DFdiscover server

1.4.1. 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**

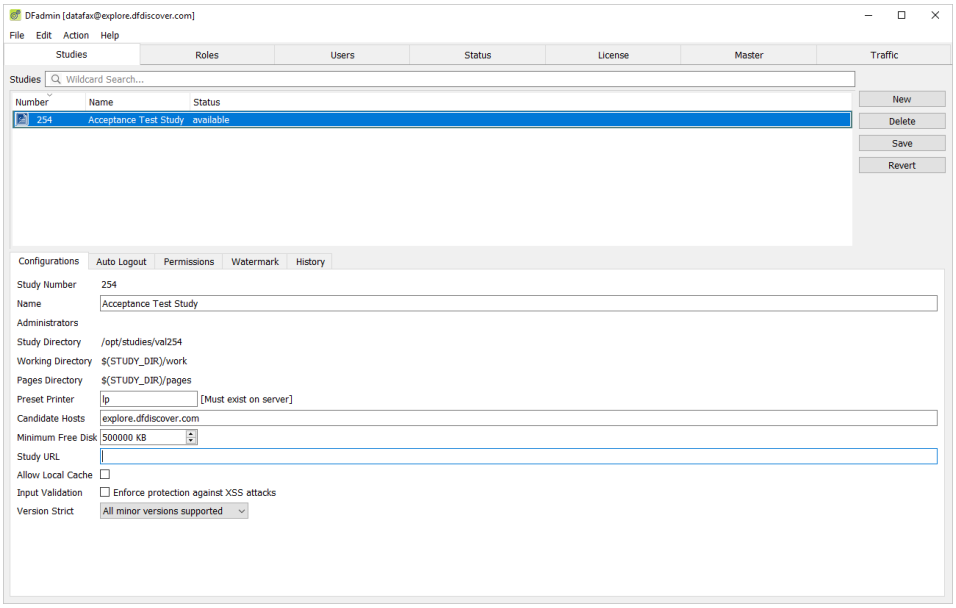


NOTE: The name of your Study Space may differ from that shown here if the Study Space is something other than opt_studies on your **DFdiscover** server.

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

1.4.3. 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.



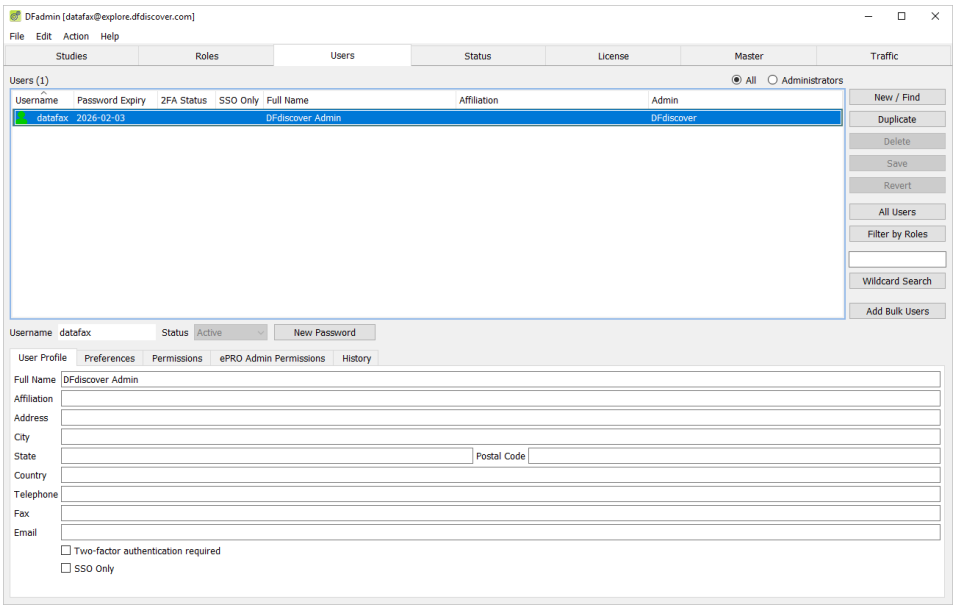
1.4.4. Choose **All minor versions supported** from the **Version Strict** drop-down.

1.4.5. Select File > Save or click Save to save the configuration information.

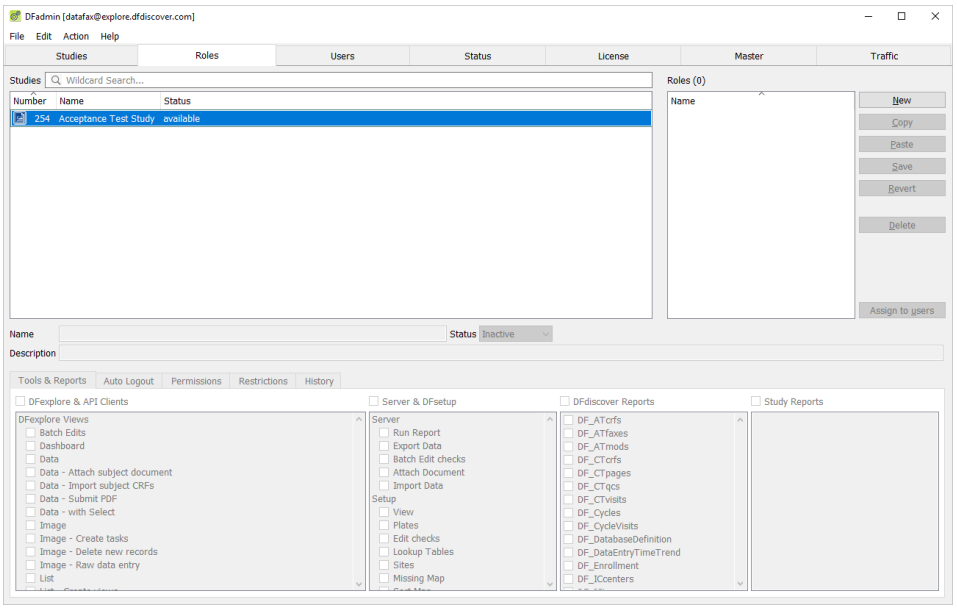
1.5 Create a role and permissions for datafax

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**.

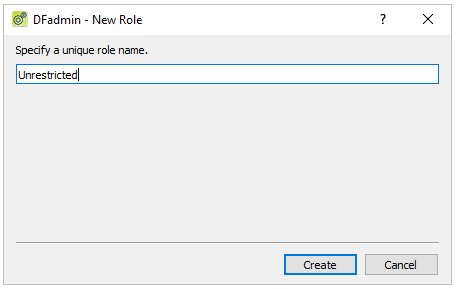
1.5.1. Click **Users** tab. Confirm that user datafax is present in the Username column for one user row.



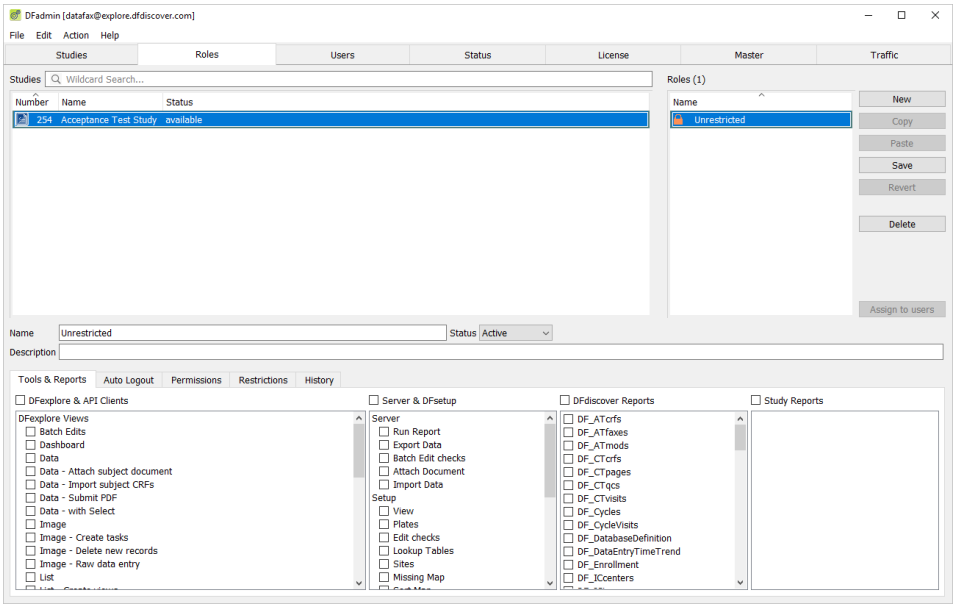
1.5.2. Create a Role for user datafax. Begin this task by clicking the **Roles** tab.



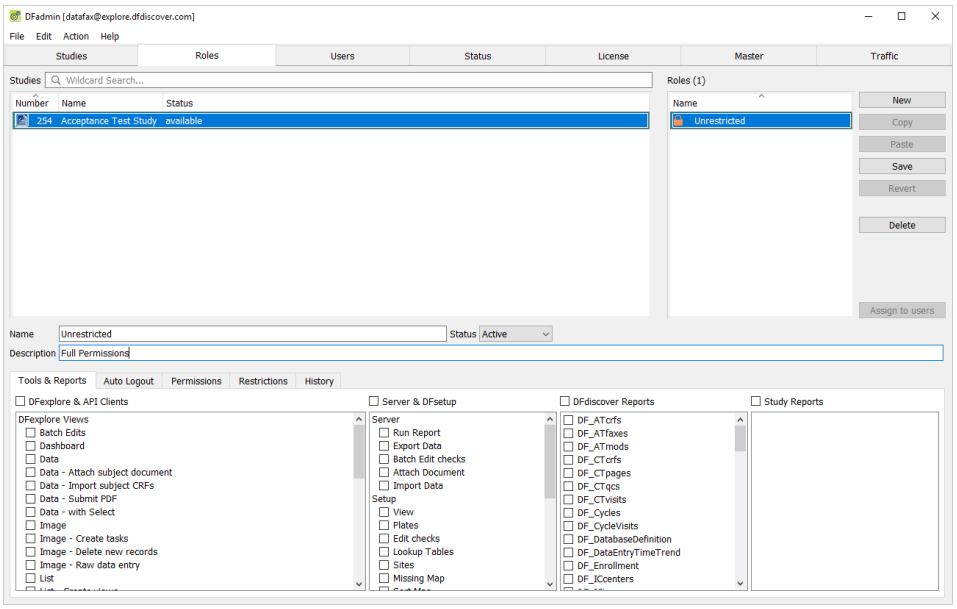
1.5.3. Within the list of studies, locate and choose the entry for **254 Acceptance Test Study**. Click New to add a new user role. In the dialog, enter the role name Unrestricted.



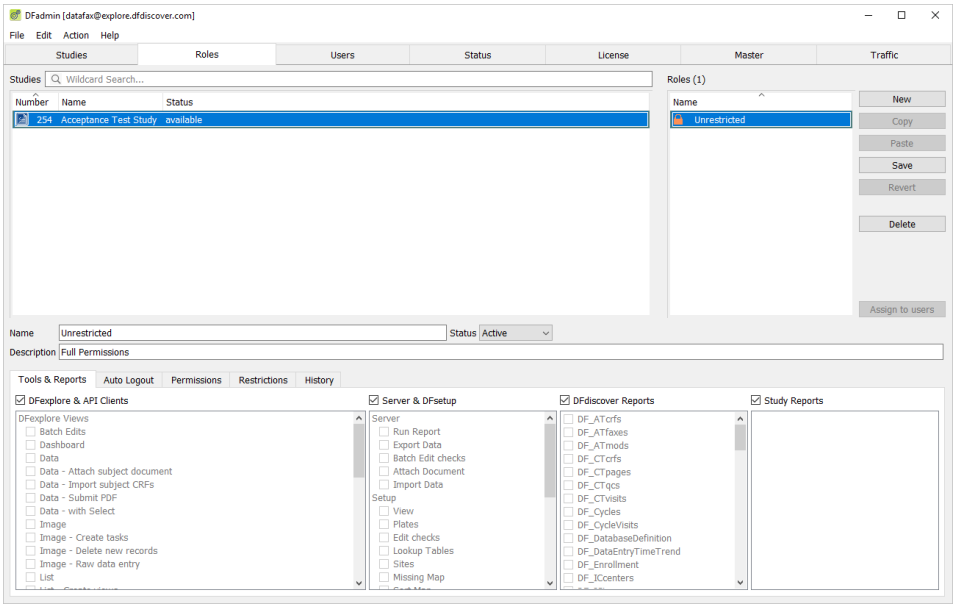
1.5.4. Click Create to create the new role Unrestricted.



1.5.5. 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.



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

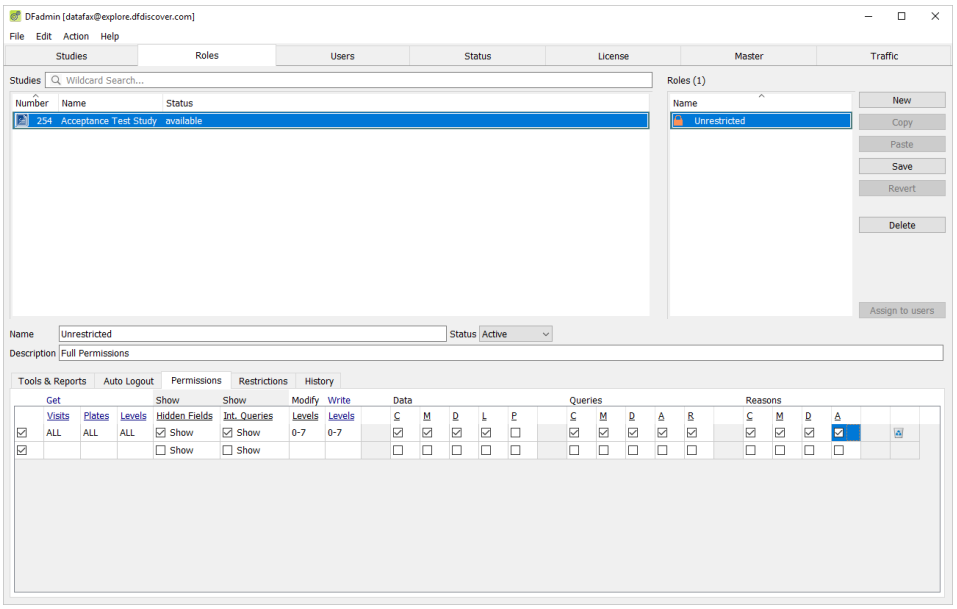


1.5.7. Click **Auto Logout** tab. If not already enabled, check (enable) the **Inherit from Study** box to override the default Auto Logout settings with those of the ATK study.

1.5.8. Click **Permissions** tab.

1.5.9. Set data permissions as follows:

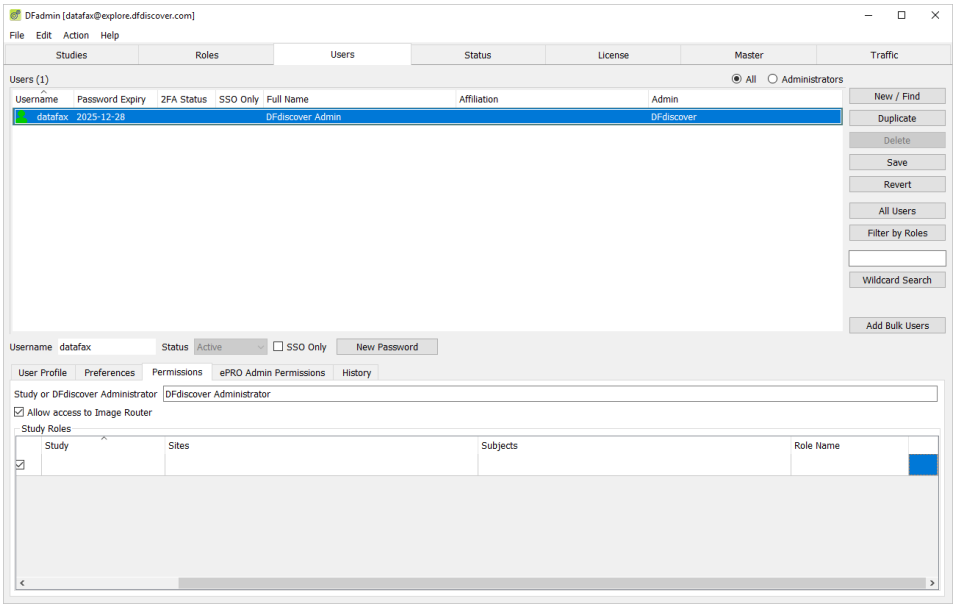
- **Visits** = ALL
- **Plates** = ALL
- **Levels** = ALL
- Check (enable) **Show Hidden Fields**
- Check (enable) **Show Int. Queries**
- **Modify** = 0-7
- **Write Levels** = 0-7
- **Data** = Check (enable) CMDL (Create, Modify, Delete, Missed), but not P (Password)
- **Queries** = Check (enable) CMDAR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



1.5.10. Select File > Save or click Save to save settings for role Unrestricted.

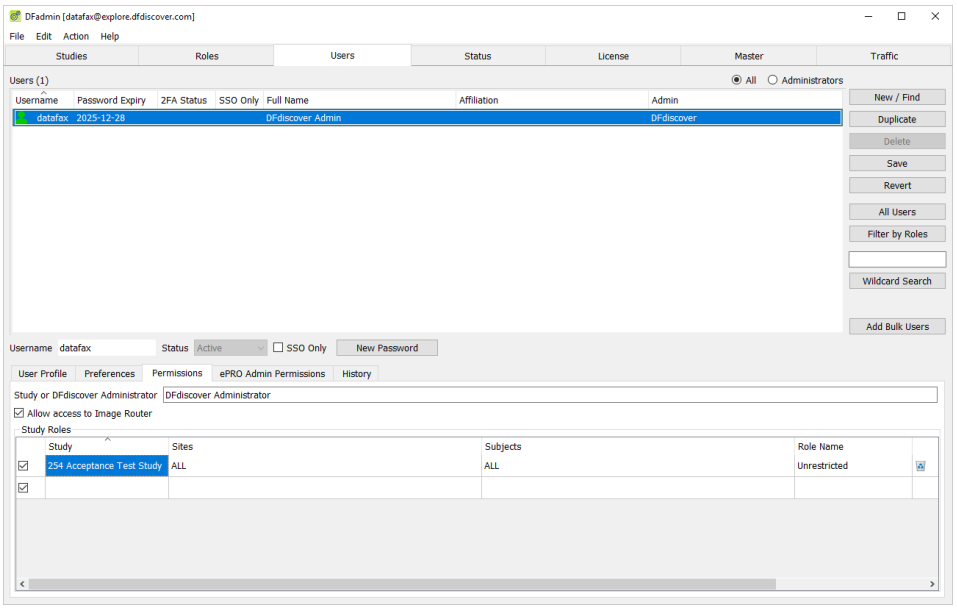
1.5.11. Still as datafax and with the **DFadmin** application open, click **Users** tab.

1.5.12. 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**.



1.5.13. 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:

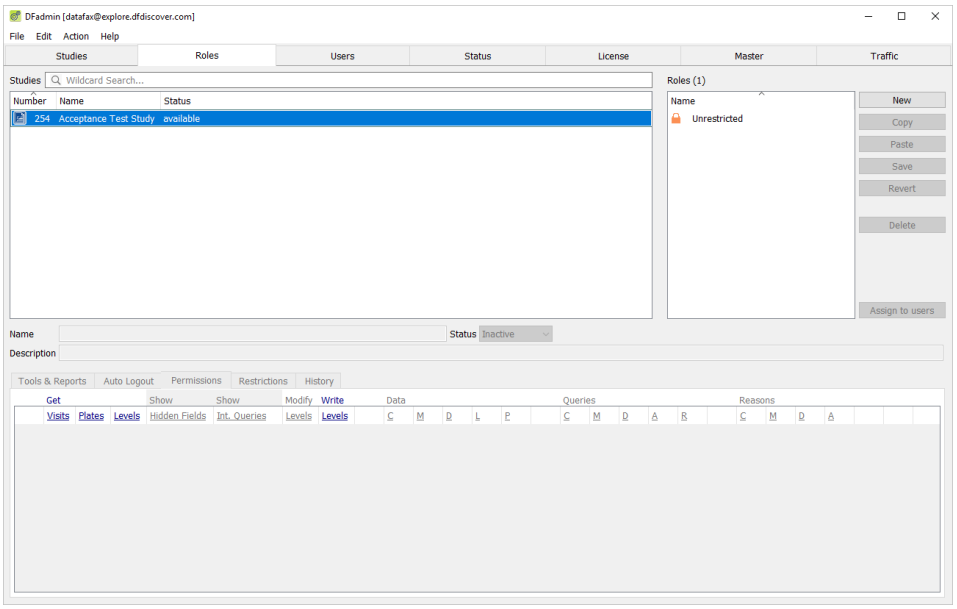
- **Sites** = All
- **Subjects** = All
- **Role Name** = Unrestricted



1.5.14. Click Save to save the role and permissions for datafax.

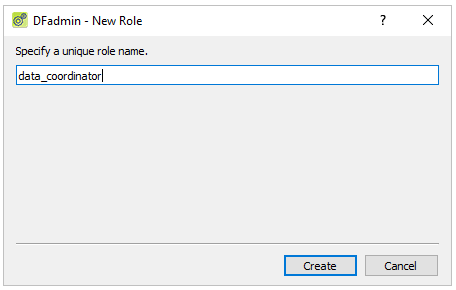
1.6 Creating study roles and permissions

1.6.1. Create a Role for user data_coordinator. Begin this task by clicking the **Roles** tab.

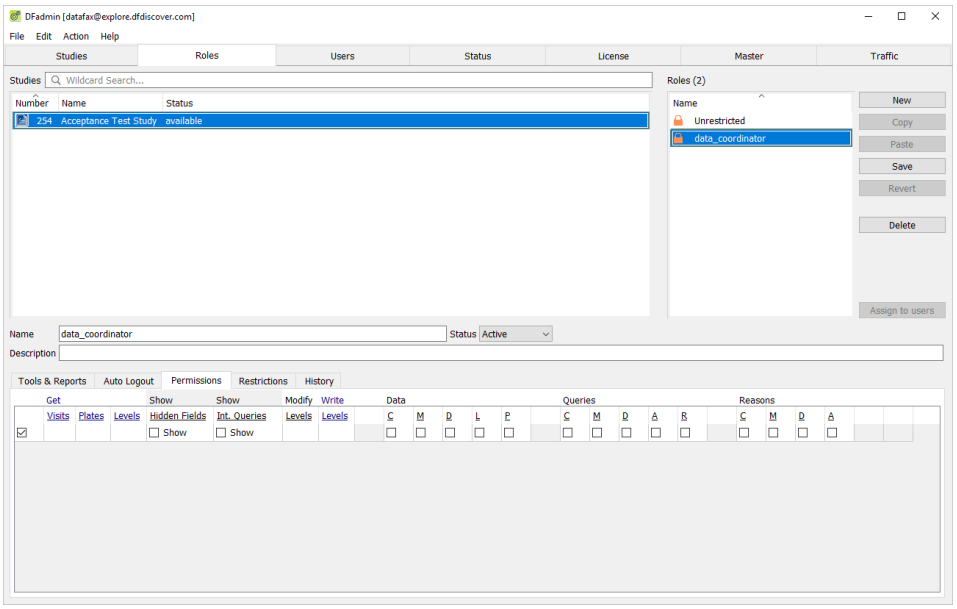


NOTE: If the role already exists, confirm the permissions and settings described in Step 2 to Step 8 and make changes where necessary.

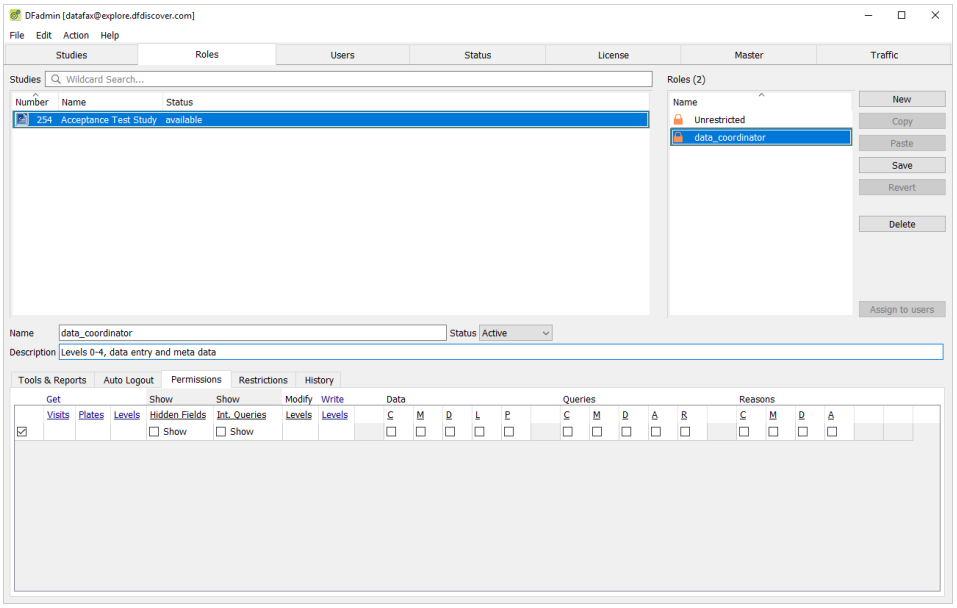
1.6.2. In the list of studies, locate and choose **254 Acceptance Test Study**. Click New to add a new user role. In the confirmation dialog, enter the role name data_coordinator.



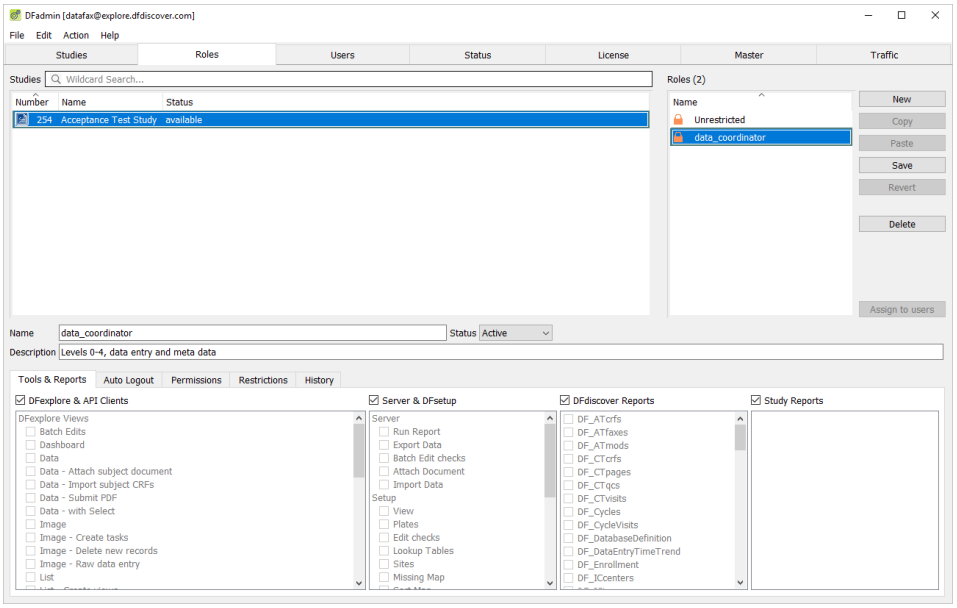
1.6.3. Click Create in the New Role dialog to apply the role name.



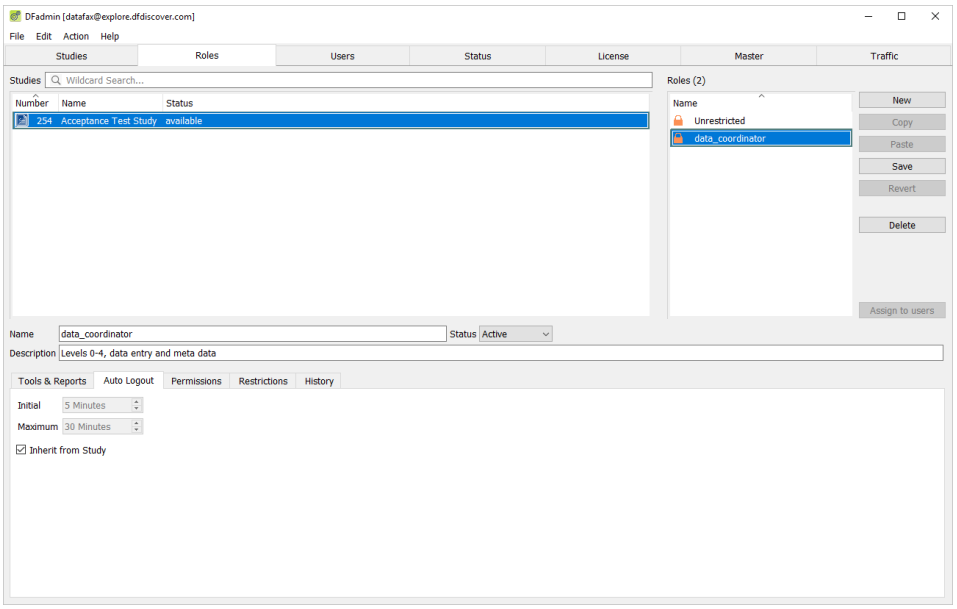
1.6.4. In the **Description** field enter: Levels 0-4, data entry and meta data.



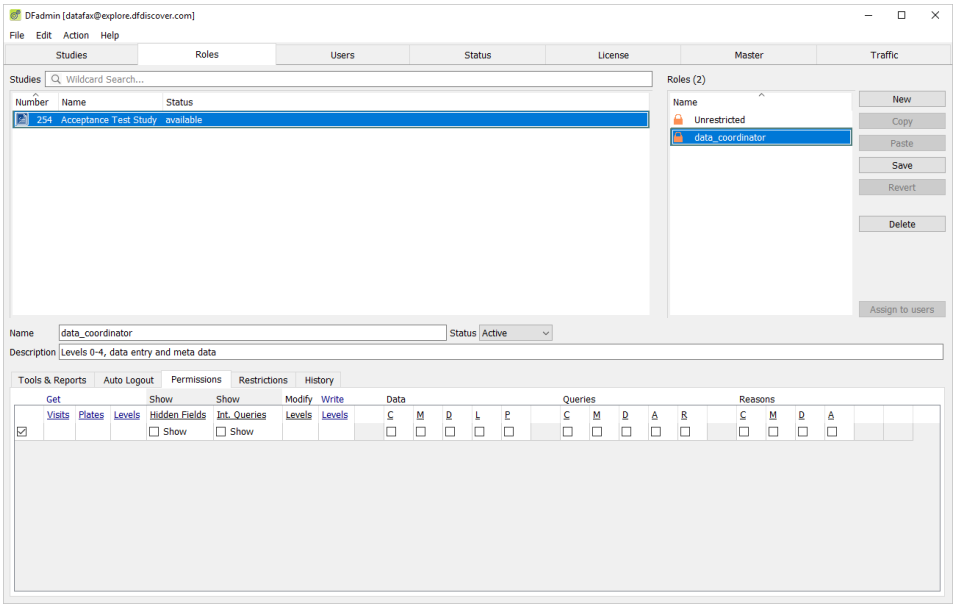
1.6.5. Click **Tools & Reports** tab. Check (enable) each of the following: **DFexplore & API Clients**, **Server & DFsetup**, **DFdiscover Reports**, and **Study Reports**.



1.6.6. Click **Auto Logout** tab. If not already checked (enabled), check **Inherit from Study** to override the default Auto Logout setting with the study setting.

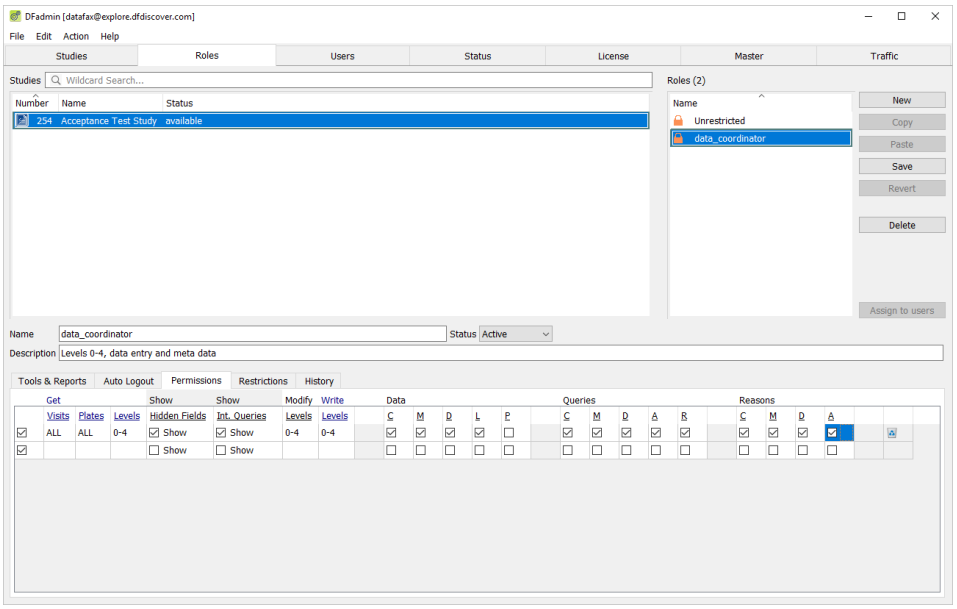


1.6.7. Click **Permissions** tab.



1.6.8. Set data permissions with the following settings:

- **Visits** = ALL
- **Plates** = ALL
- **Levels** = 0-4
- Check (enable) **Show Hidden Fields**
- Check (enable) **Show Int. Queries**
- **Modify Levels** = 0-4
- **Write** = 0-4
- **Data** Check (enable) = CMDL (Create, Modify, Delete, Lost), but not P (Password).
- **Queries** Check (enable) = CMDAR (Create, Modify, Delete, Approve, Reply)
- **Reasons** Check (enable) = CMDA (Create, Modify, Delete, Approve)



1.6.9. Click Save to save the role.

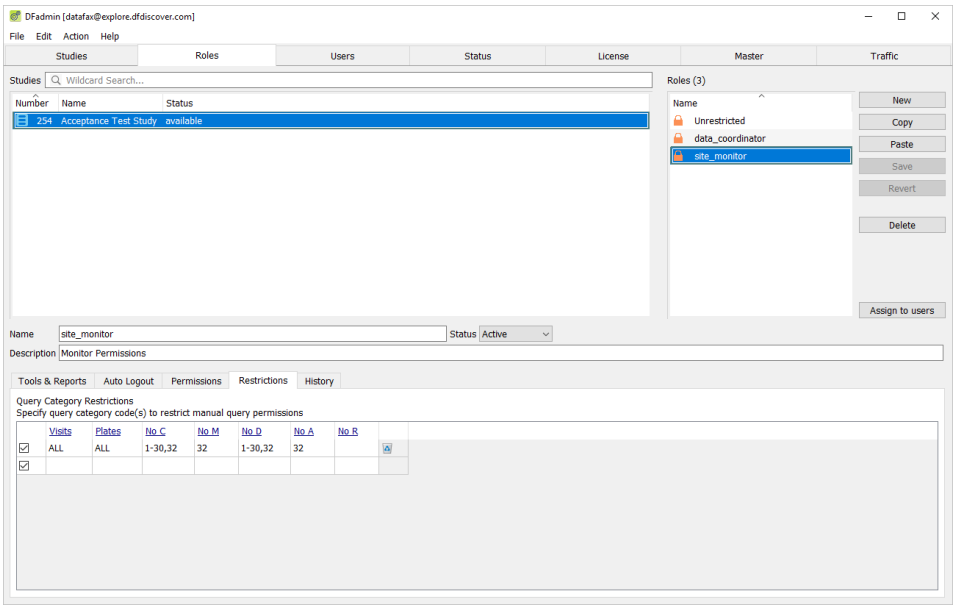
1.6.10. Click Copy then Paste, specify a role name of site_monitor. Click Create.

1.6.11. Click **Restrictions** tab.

1.6.12. Enter a **Description** of Monitor Permissions. Set query restrictions as follows:

- **Visits** = ALL
- **Plates** = ALL
- **No C** = 1-30,32
- **No M** = 32
- **No D** = 1-30,32
- **No A** = 32
- **No R** = blank

Click Save.



1.6.13. Select data_coordinator role, click Copy then Paste, specify a role name of site_investigator. Click Create.

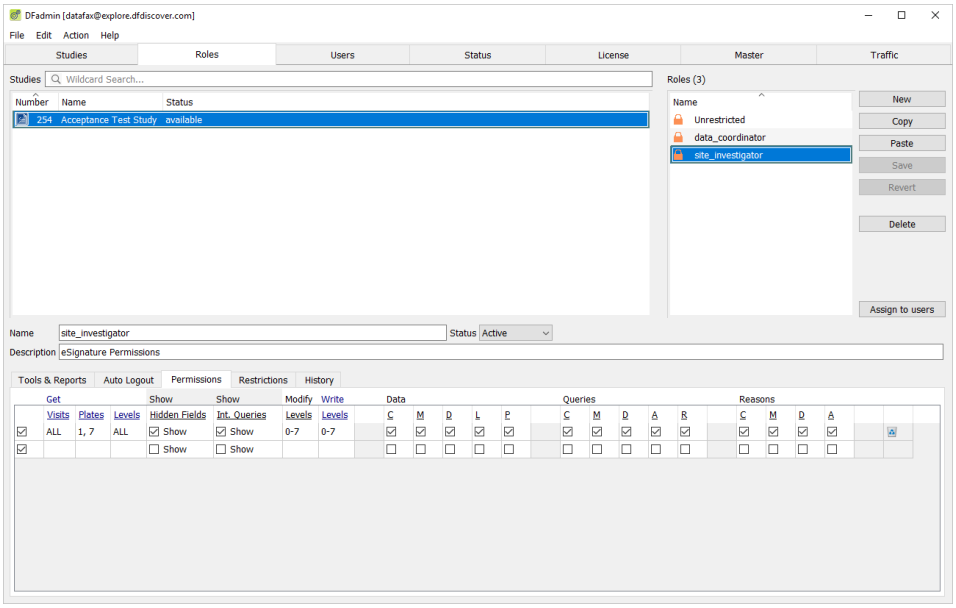
1.6.14. Click **Permissions** tab.

1.6.15. Enter a **Description** of eSignature Permissions. Set data permissions as follows:

- **Visits** = ALL
- **Plates** = 1,7
- **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.



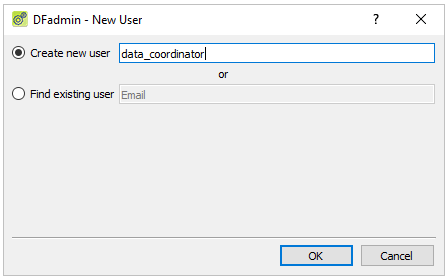
1.7 Creating user accounts and assigning study permissions

1.7.1. Still as datafax and with the **DFadmin** application open, click **Users** tab to open the user definition window.

1.7.2. 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.

1.7.3. 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.

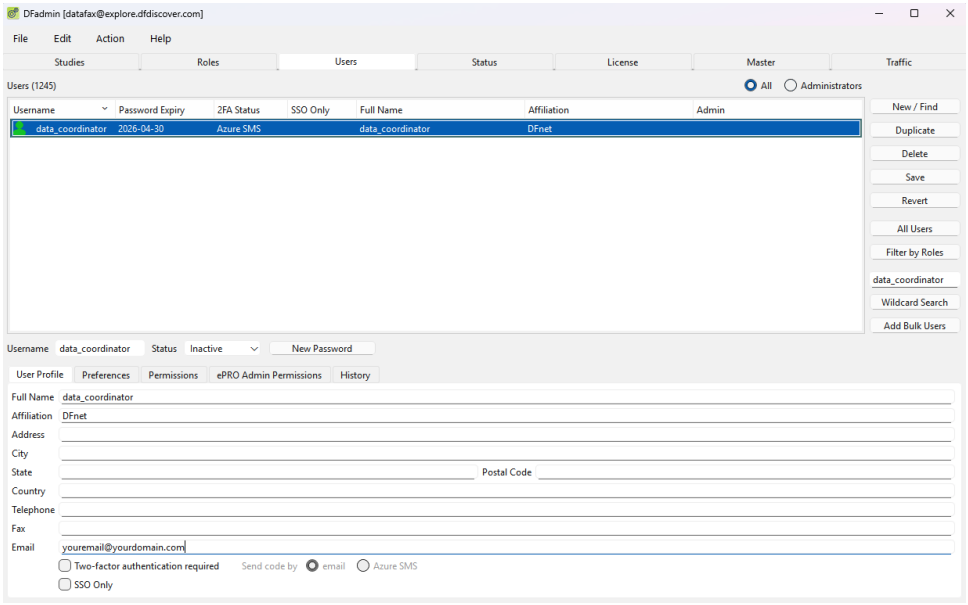


1.7.4. Click OK to add data_coordinator to the list of users. An empty icon represents data_coordinator, the status of data_coordinator is set to **Inactive**.

1.7.5. 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

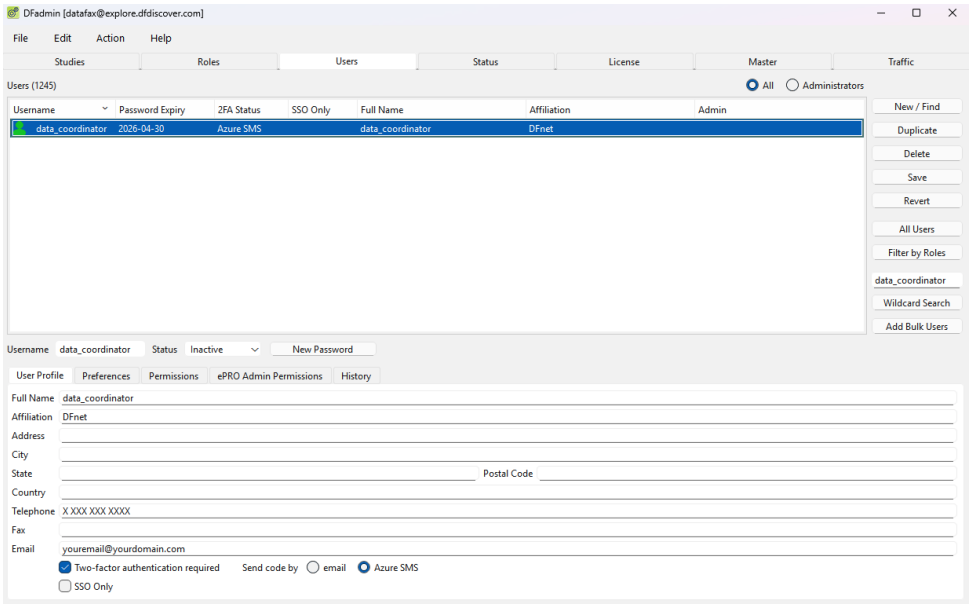
> NOTE: A valid email address is required to receive module specific PDF files if you have not specified a printer in the **Master** view.



1.7.6. 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:

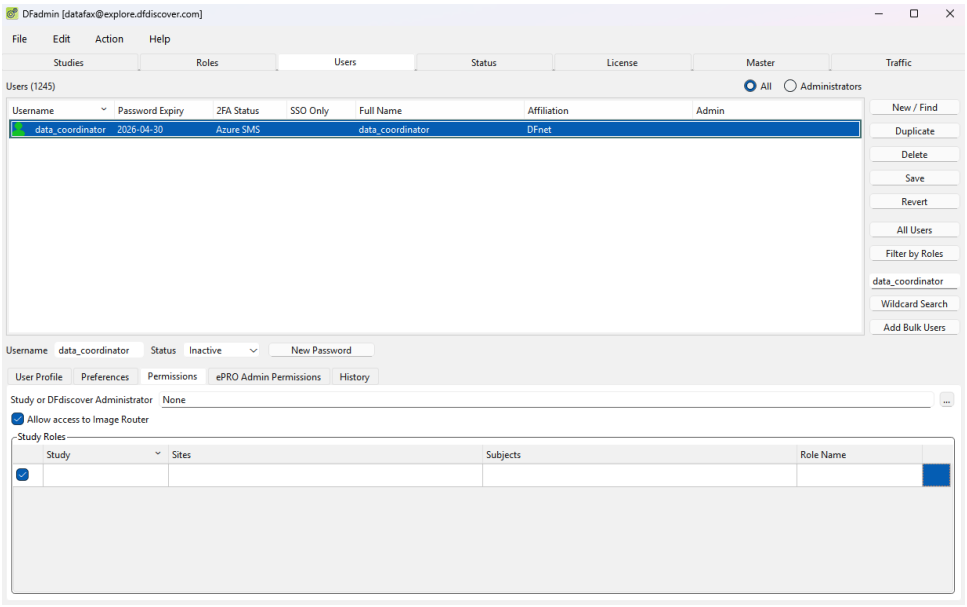
- **Telephone** = Your Cell Phone Number
- **Two-factor authentication required** = Checked (enabled)
- **Send code by** = Azure SMS

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.



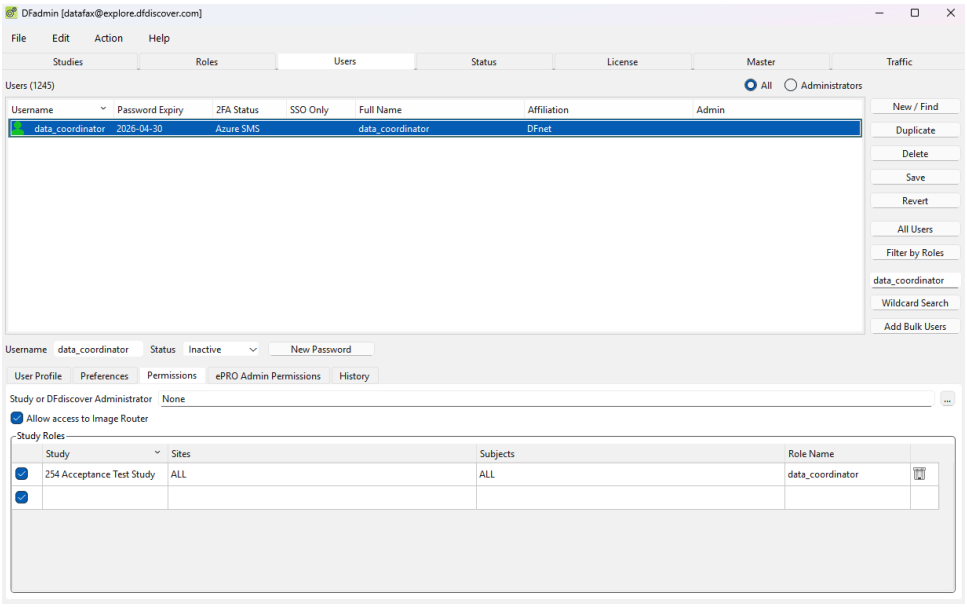
1.7.7. No further user profile information is needed. Click Save.

1.7.8. With user data_coordinator still as the active user, click **Permissions** tab. Check (enable) **Allow access to Image Router**.

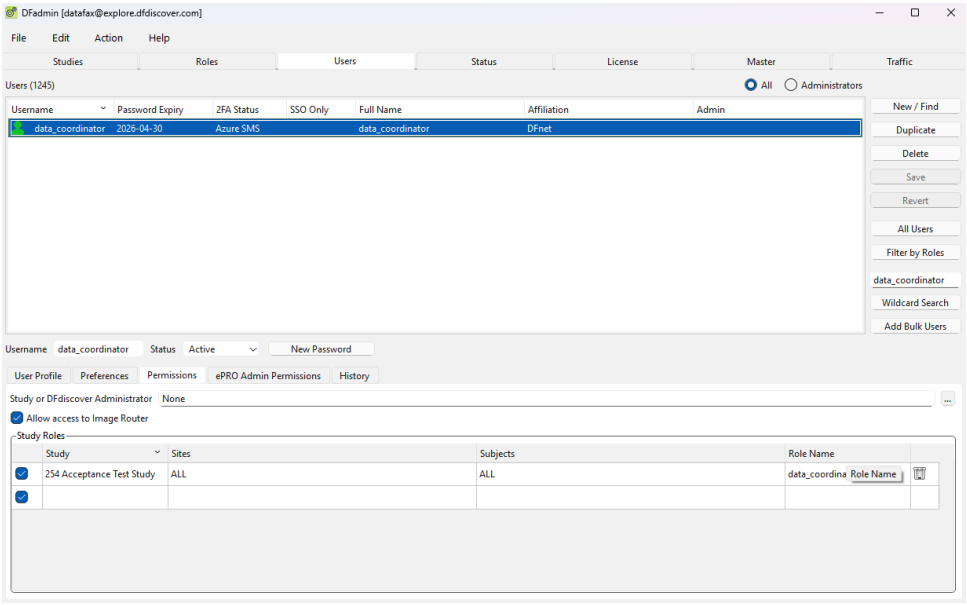


1.7.9. To assign a study to data_coordinator, click the blank area below the **Study** heading. Select **254 Acceptance Test Study** from the **Study** drop-down. Set:

- **Sites** = All
- **Subjects** = All
- **Role Name** = data_coordinator



1.7.10. Select **Active** from the **Status** drop-down list to change the status from Inactive to Active for user data_coordinator.



1.7.11. 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.

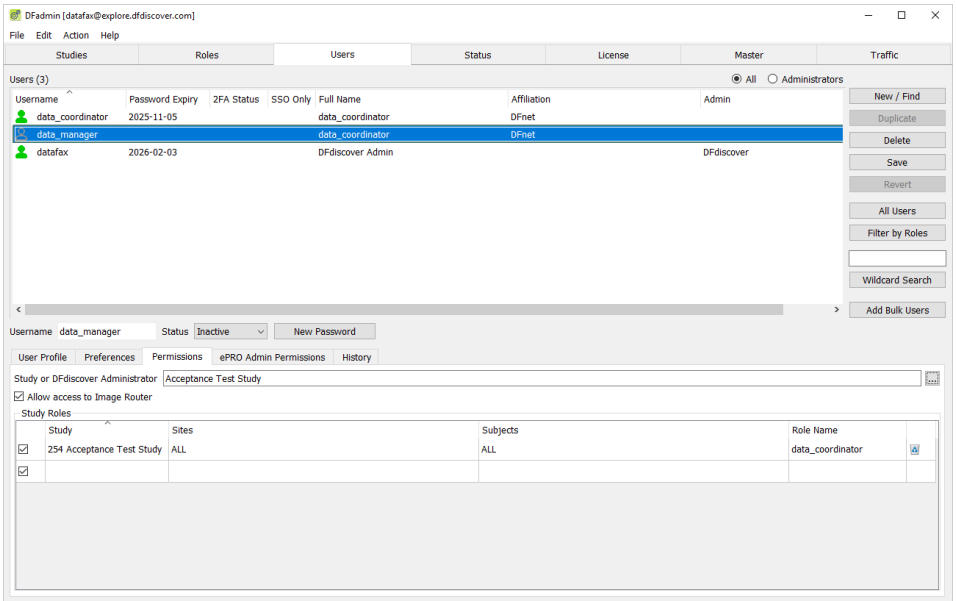
1.7.1. Locate and choose the entry for user data_coordinator in the list of users. Click **Permissions** tab and confirm the following settings. If any of the following permissions do not appear as shown below, set them now.

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

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

1.7.3. With data_coordinator as the active user, click Duplicate. In the dialog enter a username of data_manager. Click Create.

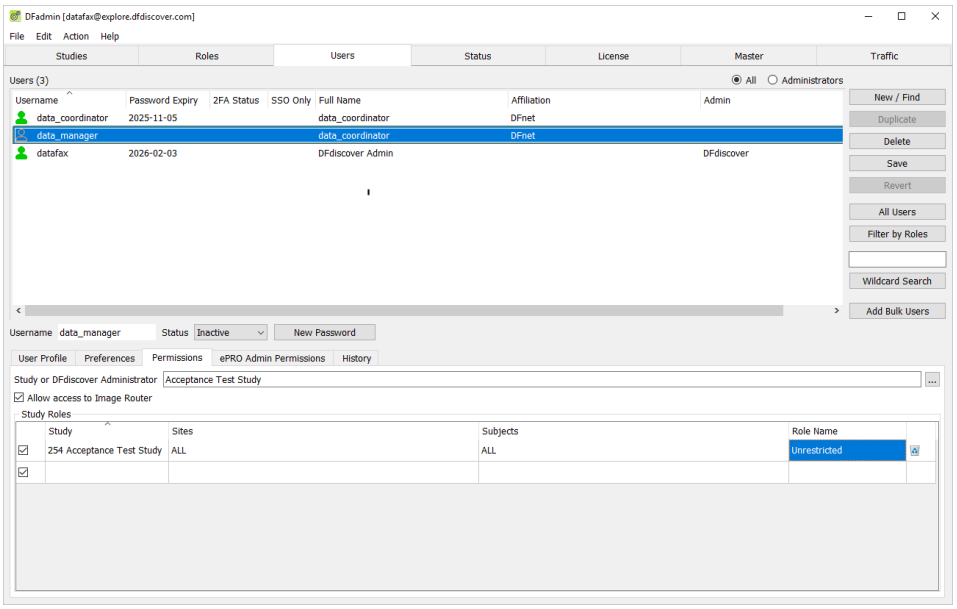
1.7.4. Specify a **Full Name** of data_manager. Click **Permissions** tab, then ... within the **Study or DFdiscover Administrator**. Select **Study Admin for Selected Studies**, check (enable) **254 Acceptance Test Study**. Click OK.



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

- **Allow access to Image Router** box is checked (enabled)
- **254 Acceptance Test Study** is assigned to user data_manager.
- **Sites** = ALL
- **Subjects** = ALL

- **Role Name** = Unrestricted



1.7.6. Verify the status for data_manager. If data_manager is set to **Inactive**, select **Active** from the **Status** drop-down list.

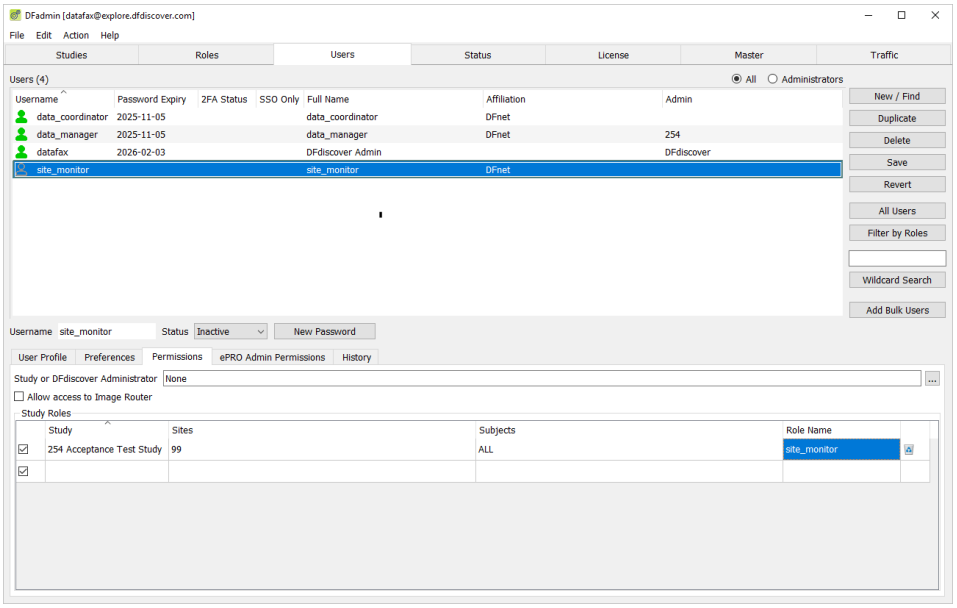
1.7.7. Assign a **DFdiscover** password for data_manager by clicking New Password. Enter a password of your choice in place of the auto-generated system password. Click Save.

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

1.7.1. Click data_coordinator to make it the active user. Click Duplicate. In the dialog enter a username of site_monitor. Click Create

1.7.2. 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

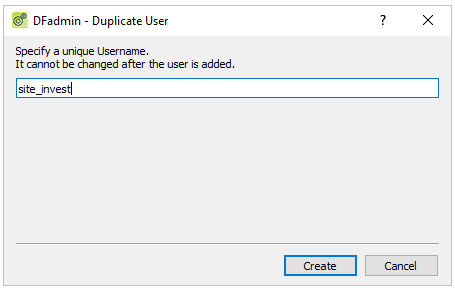


1.7.3. Verify the status for site_monitor. If site_monitor is set to **Inactive**, select **Active** from the **Status** drop-down list.

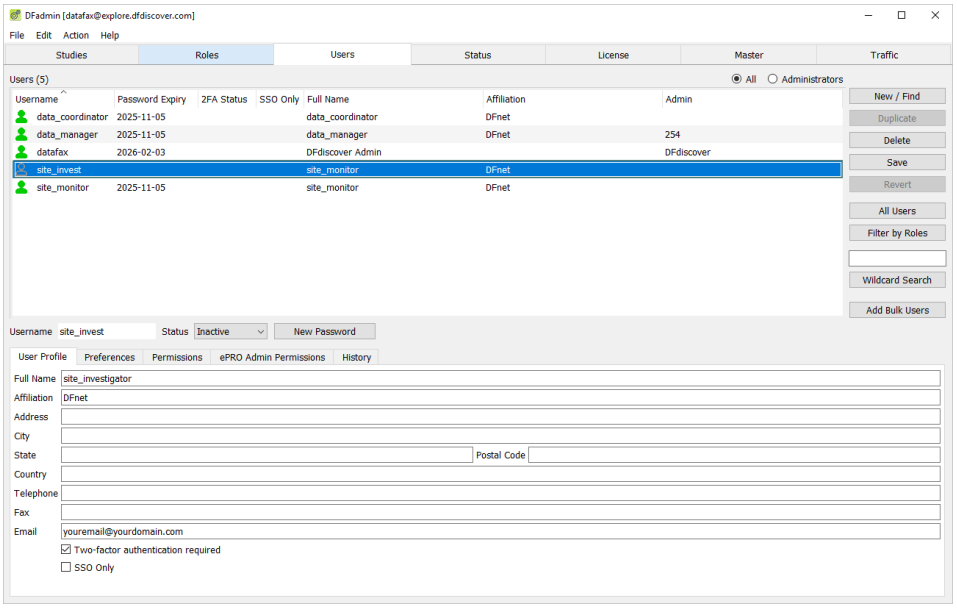
1.7.4. Assign a **DFdiscover** password for site_monitor by clicking New Password. Enter a password of your choice in place of the auto-generated system password. Click Save.

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

1.7.5. With site_monitor as the active user, click Duplicate. In the dialog enter a username of site_invest. Click Create

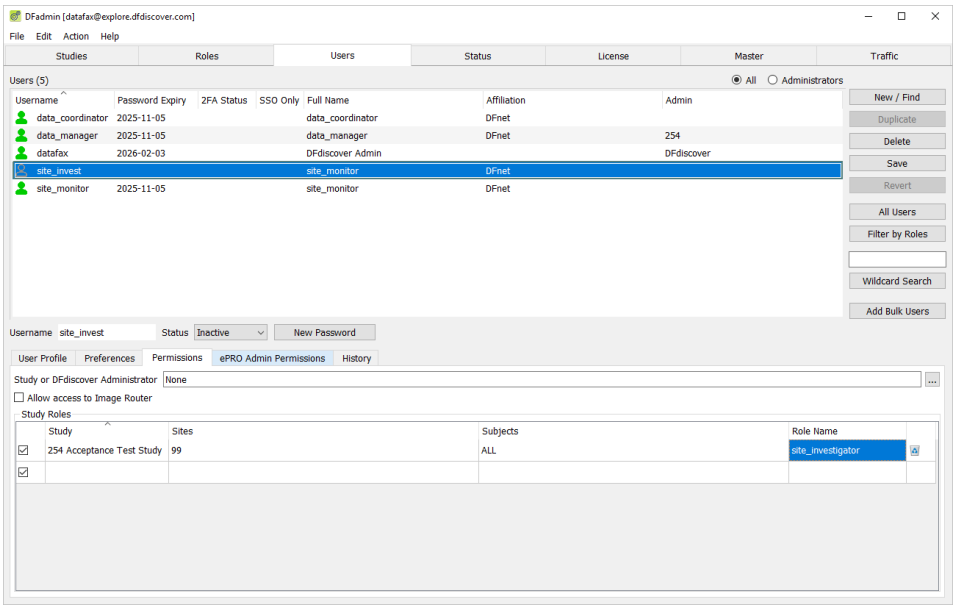


1.7.6. Specify a **Full Name** of site_investigator. Check (enable) **Two-factor authentication required**. When 2-factor authentication is enabled, you will need to enter an email address. Alternatively, if Azure SMS is configured and enabled on your server, you may enter a phone number in the supported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



1.7.7. 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_invest.
- **Sites** = 99
- **Subjects** = ALL
- **Role Name** = site_investigator

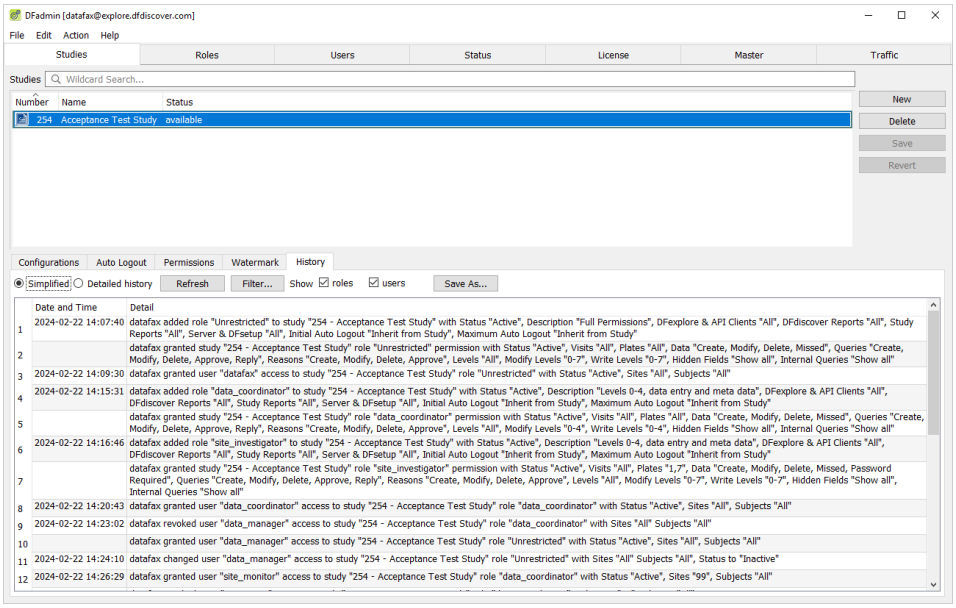


1.7.8. Verify the status for site_invest. If site_invest is set to **Inactive**, select **Active** from the **Status** drop-down list.

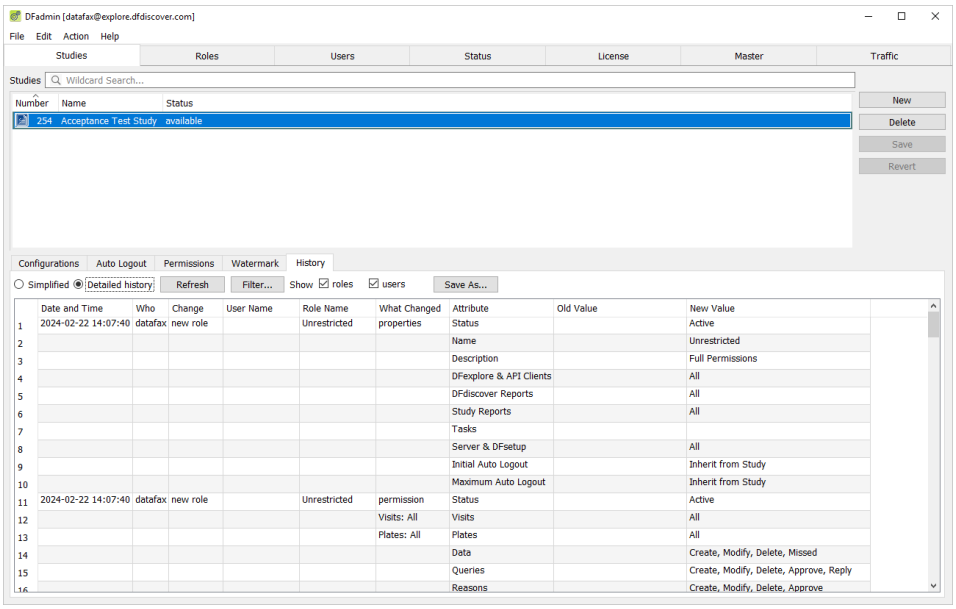
1.7.9. Assign a **DFdiscover** password for site_invest by clicking New Password. Enter a password of your choice in place of the auto-generated system password. Click Save.

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

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



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

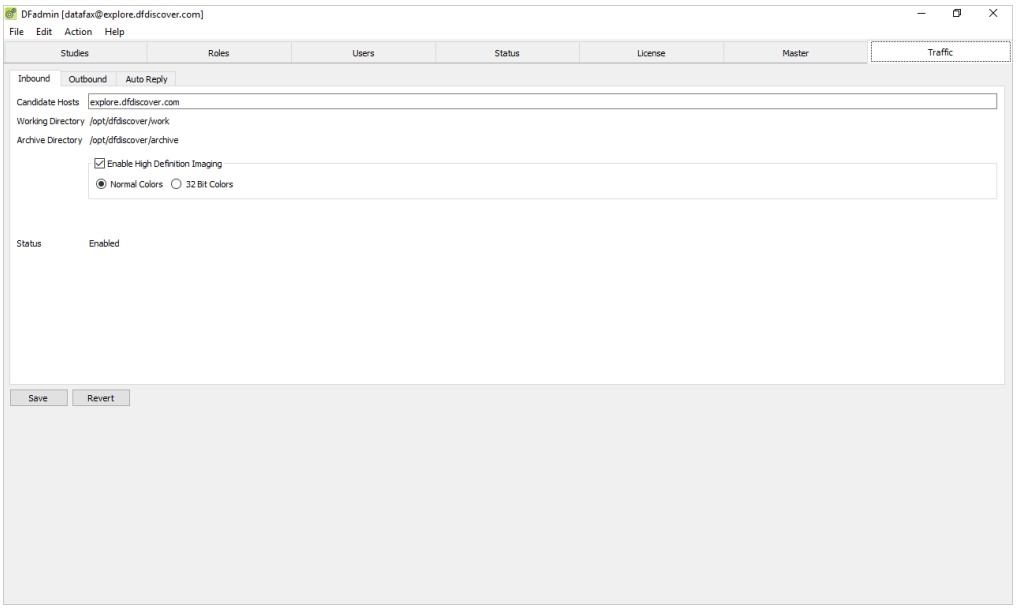


1.7.3. Click Save As... . In the resulting dialog specify a filename of module1_studyhistory.xlsx, click Save.

1.8 Enable high definition imaging

1.8.1. To enable high definition imaging, click the **Traffic** tab. Within that view, click the **Inbound** tab to display the Inbound view.

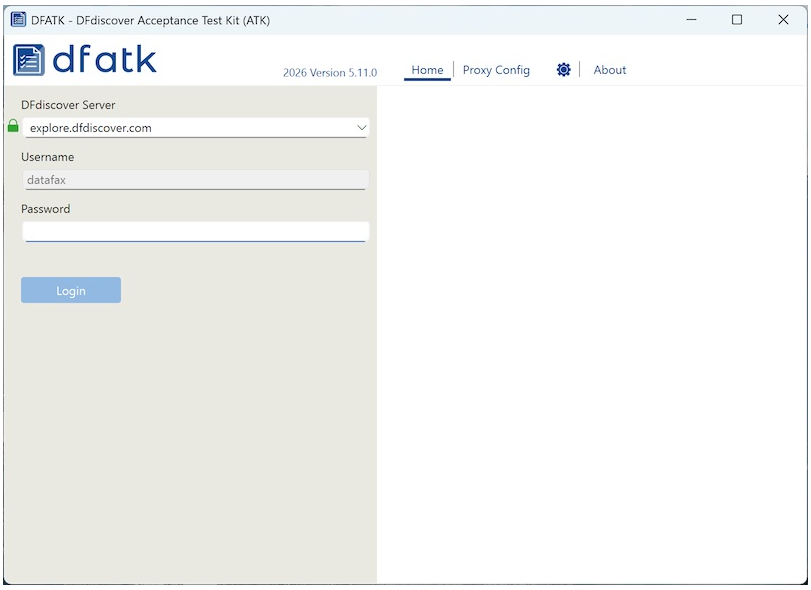
1.8.2. Check **Enable High Definition Imaging**. The **Normal Colors** checkbox is enabled by default. If it is not, enable it. Click Save to save the settings.



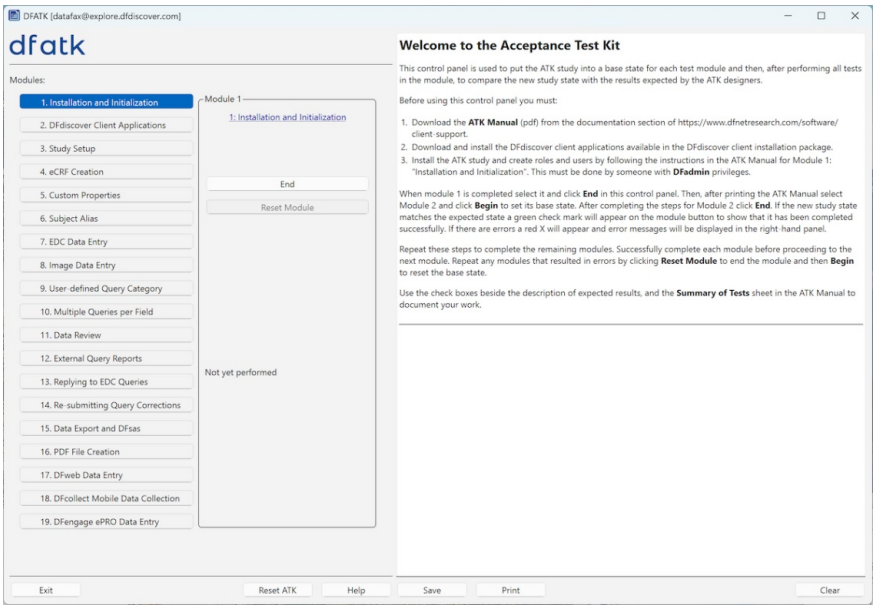
1.8.3. Select File > Exit to close **DFadmin**.

1.9 Start the Acceptance Test Study Control Panel application

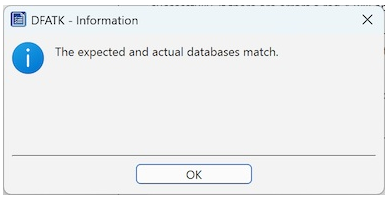
1.9.1. The remaining steps in this module require datafax privileges. Open the **DFATK** (Control Panel) login dialog.



1.9.2. 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.



1.9.3. 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.



2 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.

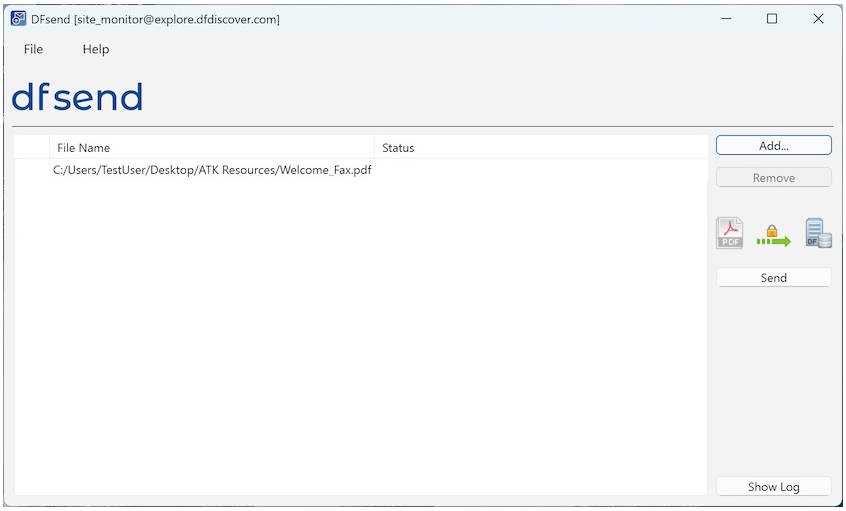
2.1 Send PDF images to **DFexplore**

2.1.1. 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.

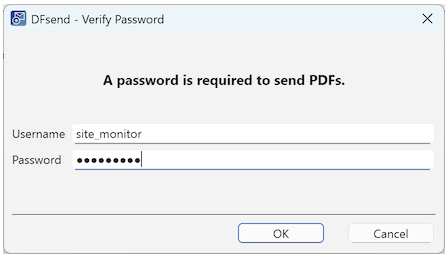
2.1.1. Start **DFsend**, login as user site_monitor as described in "How to start **DFsend**".

2.1.2. Click Add. From the **Select PDF Files** file selection dialog, locate the previously saved **Welcome_Fax.pdf** file. Select the file, Click Open.

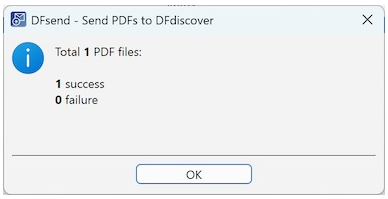


NOTE: Alternatively documents can also be added by dragging-and-dropping the desired PDF files from a local file folder into the list area.

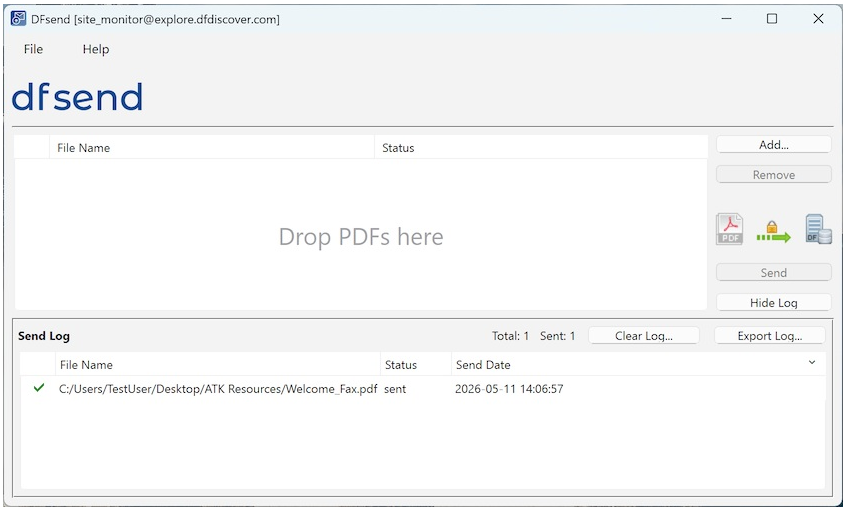
2.1.3. Click Send. In **Verify Password** dialog, enter site_monitor in the **Username** field and the previously assigned password in the **Password** field. Click OK.



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



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



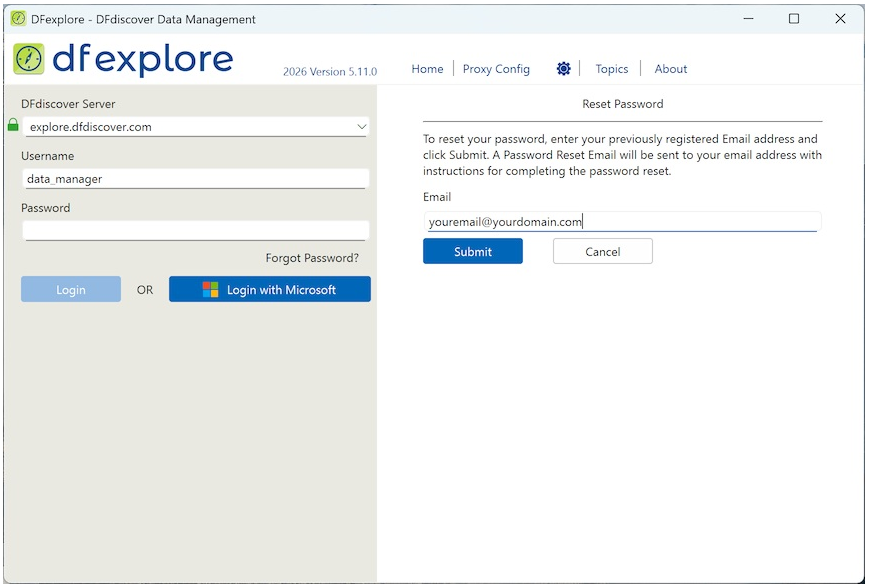
2.1.6. Select File > Exit.

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

2.2 Resetting a user login password

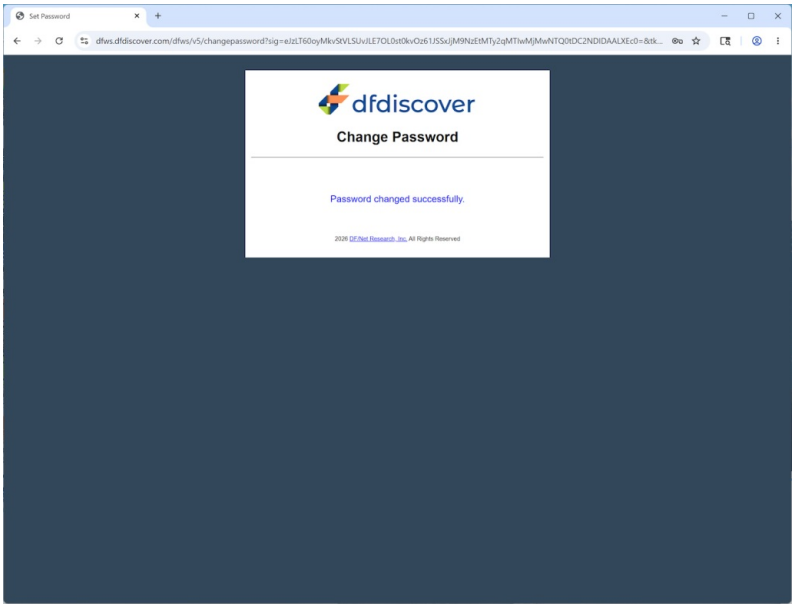
2.2.1. Start **DFexplore**, enter data_manager in the Username field of the login dialog, and click Forgot Password?.

2.2.2. 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.**



2.2.3. Open the password reset email from your **DFdiscover** server and click the provided link to reset the data_manager password.

2.2.4. Enter and confirm a new password, then click Update.

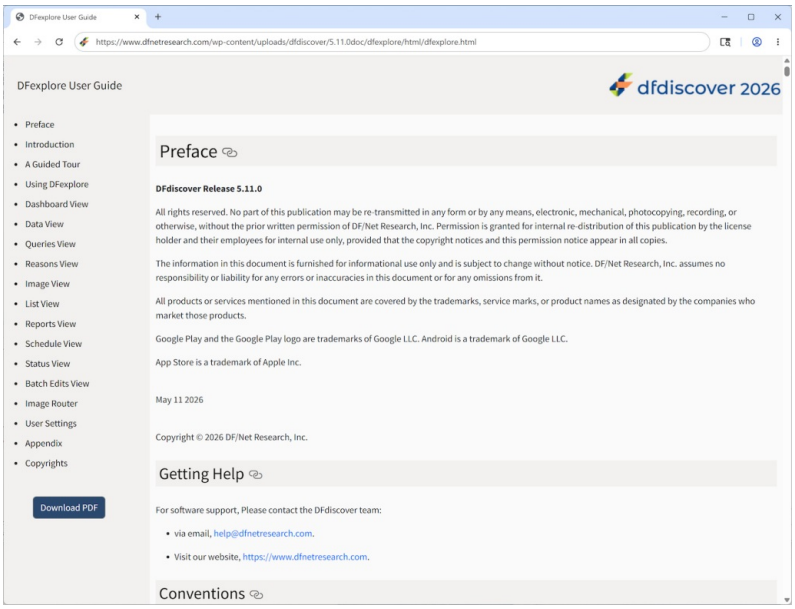


2.2.5. A message confirming **Password changed successfully.** is displayed in your browser, and a notification email is sent to the address associated with the data_manager account.

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

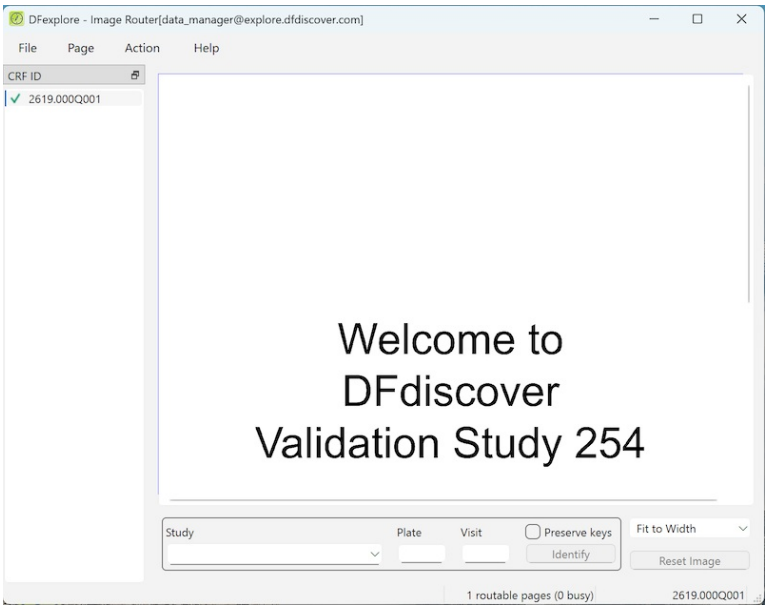
2.3.1. Return to **DFexplore**, login as user data_manager and choose **254 Acceptance Test Study** as described in How to start **DFexplore**.

2.3.2. Select **Help** > Topics to access the documentation. In the documentation window click **Preface**, confirm the documentation version number matches the installed software Version 5.11.3. Select File > Close to dismiss the documentation window.



2.3.3. Select File > Close Study to exit the study.

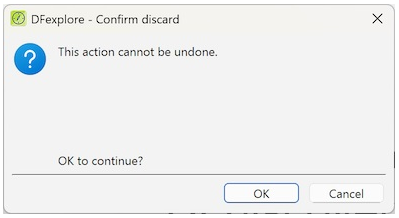
2.3.4. In the **DFexplore** login dialog, Click Image Router to start the Image Router. Locate the Welcome image by selecting the page from the list of documents in the **CRF ID** panel.



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.

2.3.5. 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.

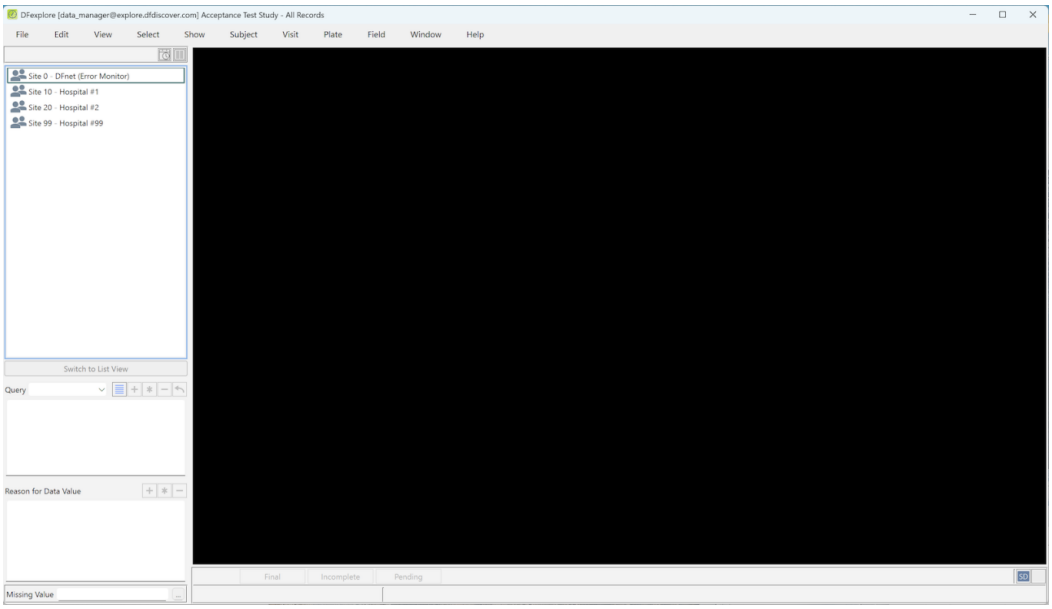
2.3.6. Delete the Welcome image from the Image Router by selecting Action > Discard. Click OK to confirm the discard action.



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

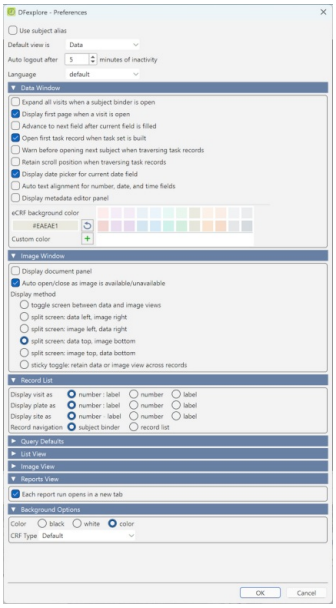
2.4 Open the Acceptance Test Study and verify the standard **DFexplore** views

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

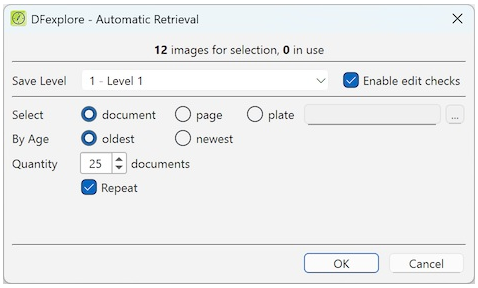


NOTE: If this step is performed within 60 seconds of closing the Image Router window, the **Username**, **Password** and list of studies are still visible. If more than 60 seconds have elapsed, you will first need to re-enter the **Password** for data_manager, and click Login to view the study selection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

2.4.2. 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.



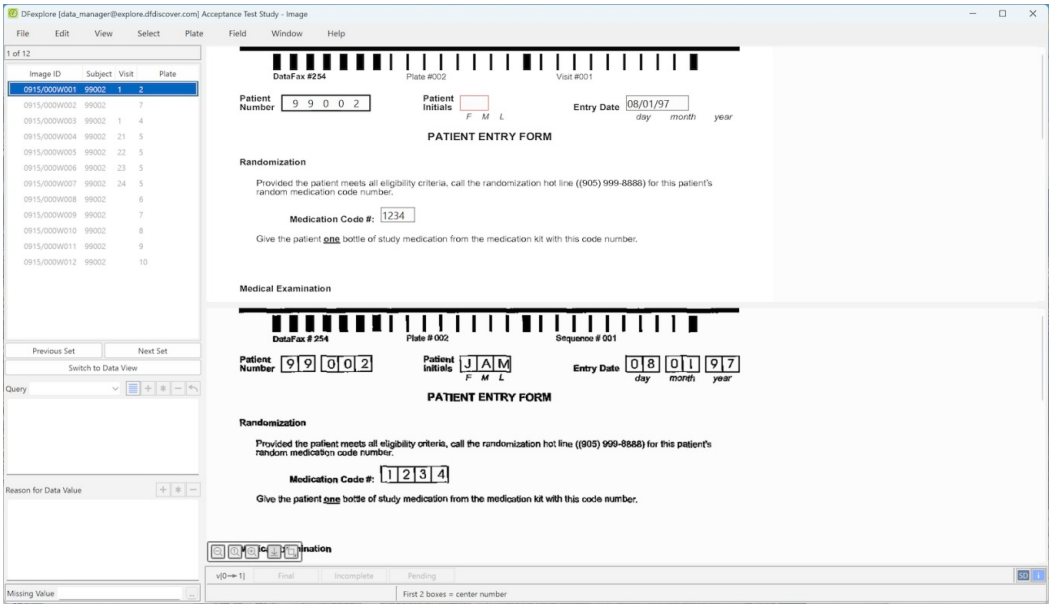
2.4.3. Select View > Image to make **Image** view the current view. Set **Quantity** = 25. Do not change any other settings in the **Automatic Retrieval** dialog and click OK to retrieve the new documents.



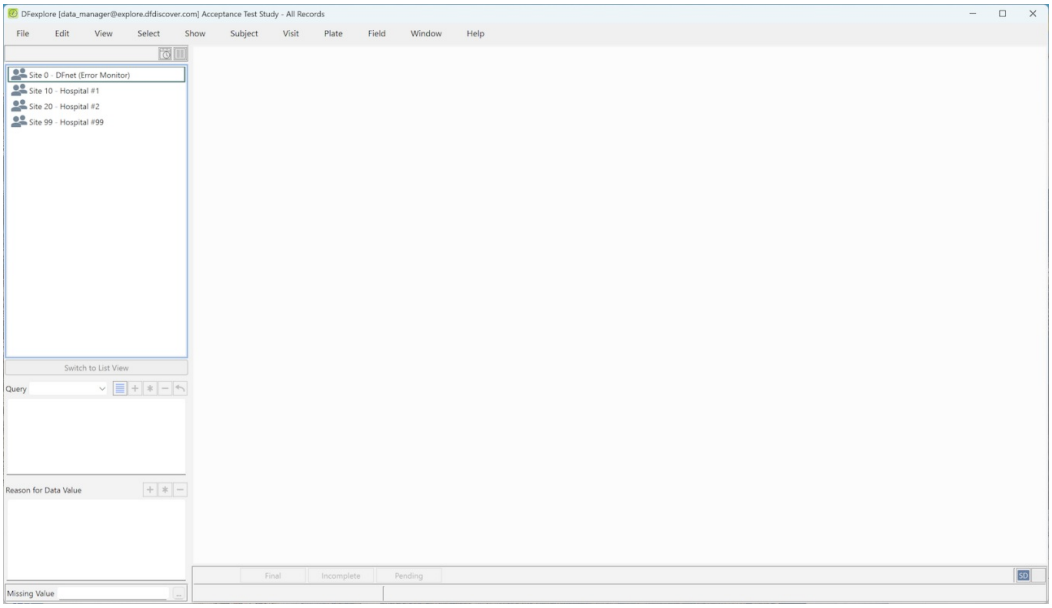
NOTE: The record retrieval dialog displays the last retrieval mode from the session preferences for each user on each computer. If data_manager previously used **DFexplore** in another mode, you may not see the **Automatic Retrieval** dialog that is illustrated. You may see a different record retrieval 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.

2.4.4. **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

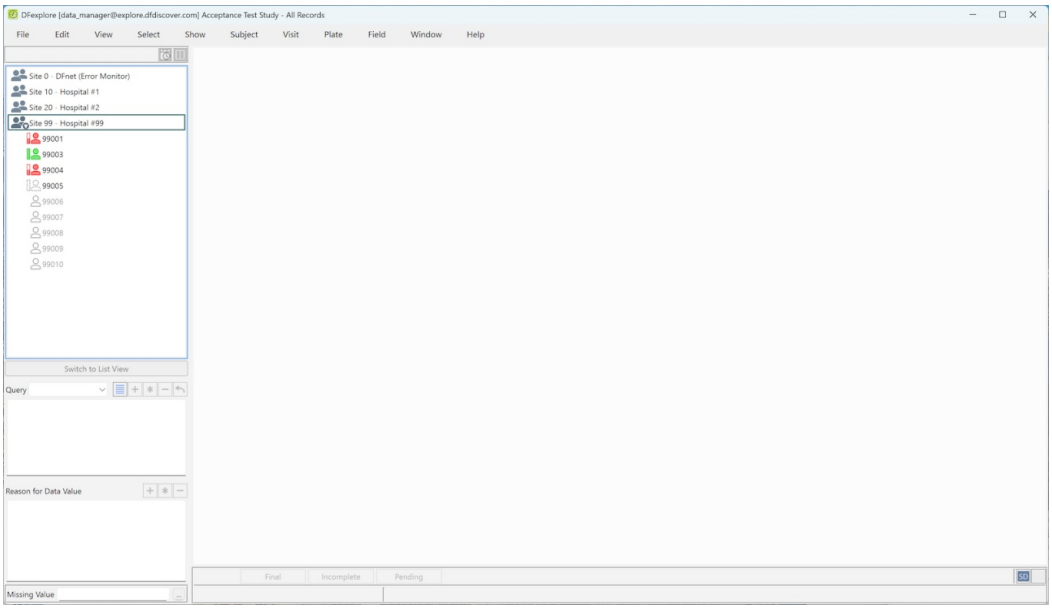
the top pane and document image in the bottom pane.



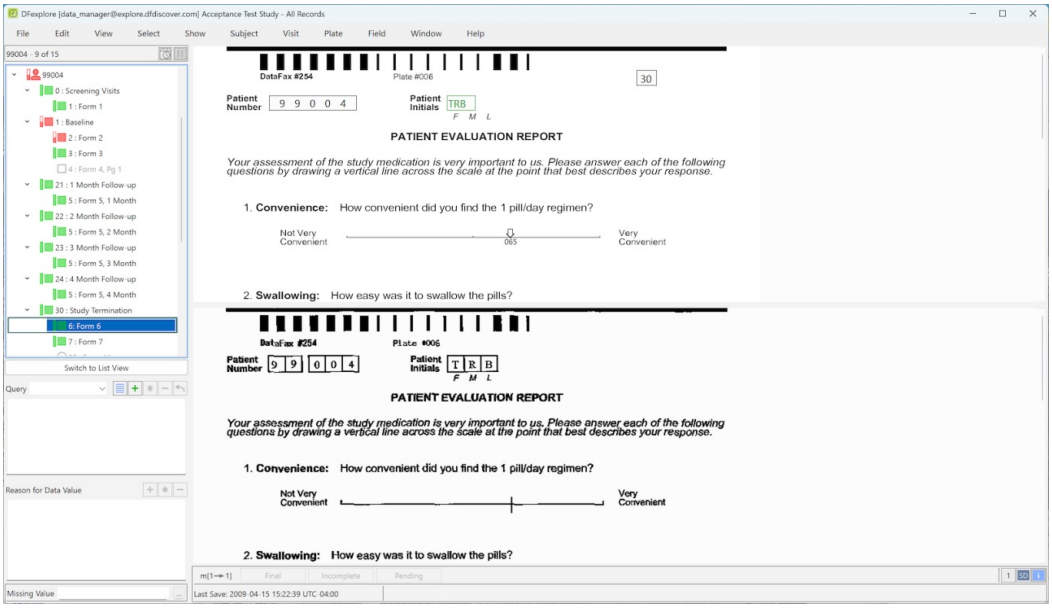
2.4.5. Select View > Data to change to **Data** view. In the confirmation dialog, click OK to release the set of image records.



2.4.6. 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.



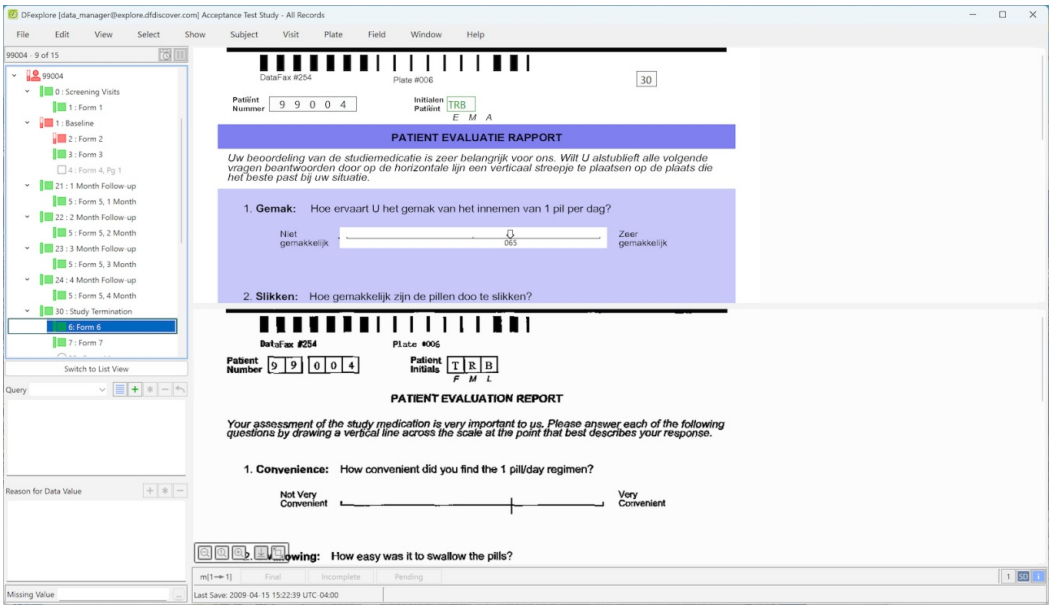
2.4.7. Double-click the entry for **Subject 99004** to list all visits for that subject. Select Subject > Expand All Visits. In the record list panel, locate the **6: Form 6** entry belonging to the **30 : Study Termination** visit. Click it to make it the active page in the main data window.



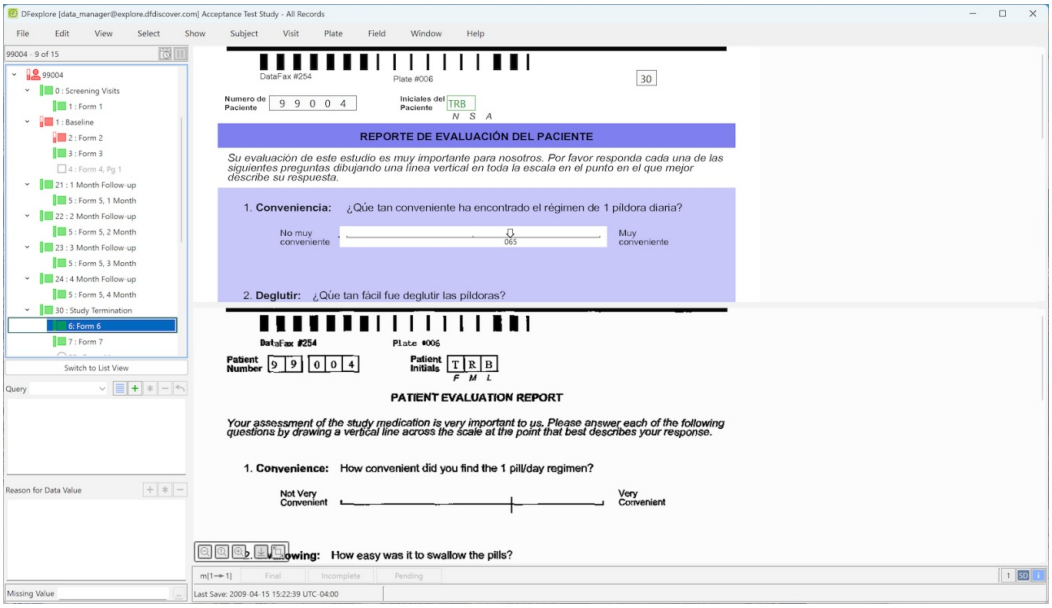
2.4.8. **6: Form 6** has been defined in the study setup with colored, multi-language backgrounds as well as the default black/white English background for the data entry screen. Select File > Preferences. In the **Preferences** dialog, change:

- **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.



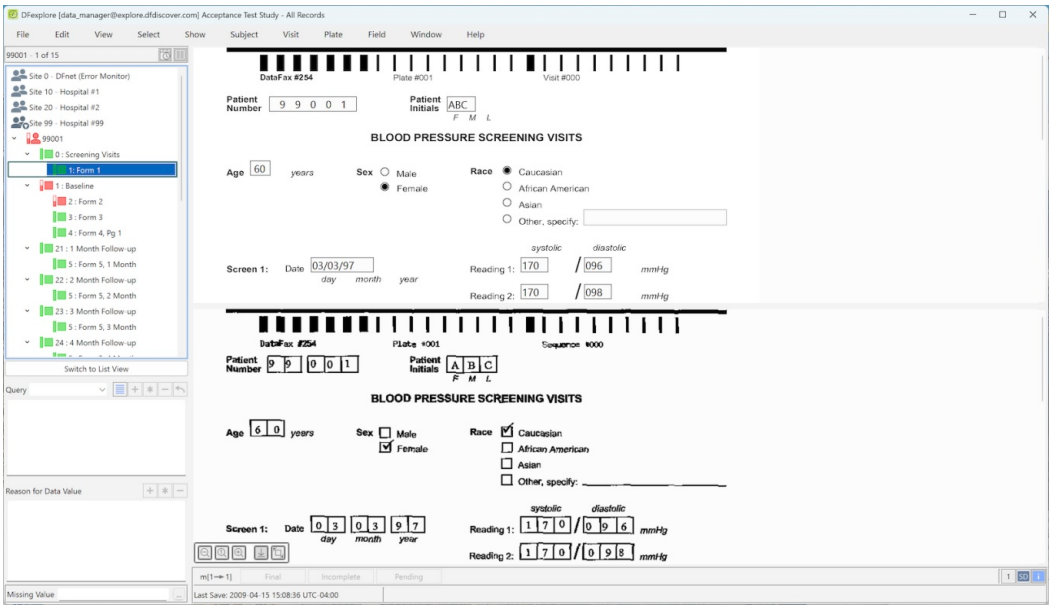
2.4.9. Re- Select File > Preferences. Change the **Background Options** choice for **CRF Type** from **Dutch** to **Spanish**. Click OK to apply the preferences and close the dialog.



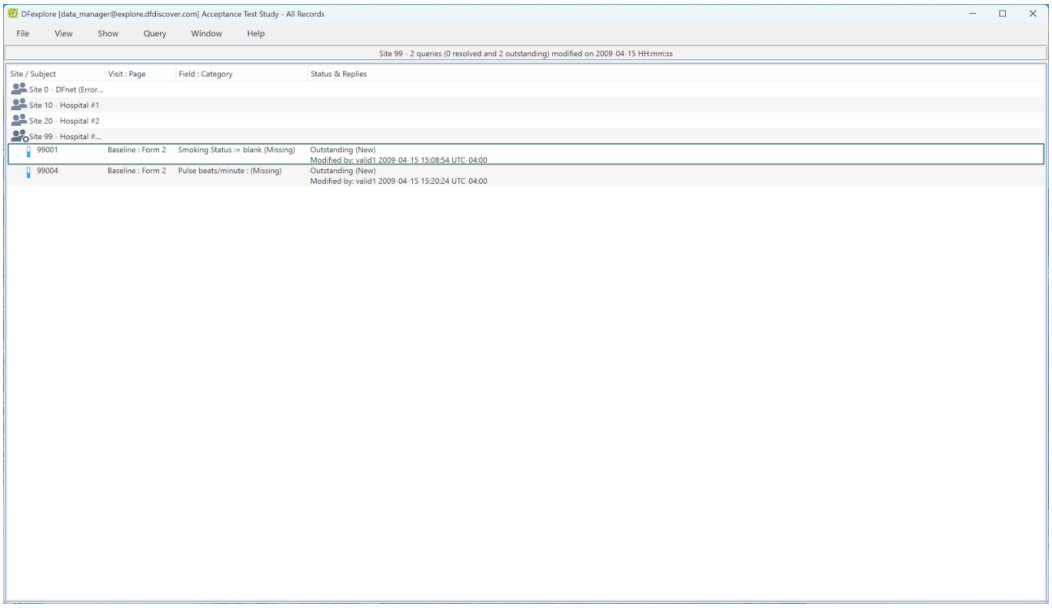
2.4.10. Re- Select File > Preferences. Reset the **Background Options** for **CRF Type** to **Default**. Click OK to save the preferences and close the dialog.



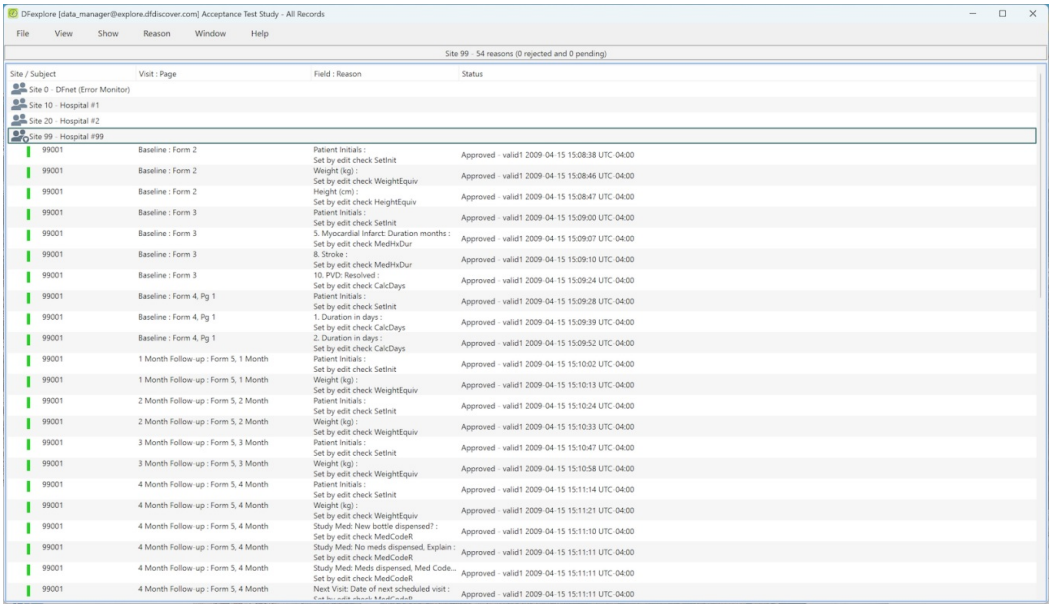
2.4.11. Double-click the entry for **99001**. This closes **99004** and opens the list of visits for **99001**. Select Subject > Expand All Visits to open all visits and pages for subject **99001**. In the record list panel, locate **1: Form 1** under **0 : Screening Visits**. Click it to open the page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



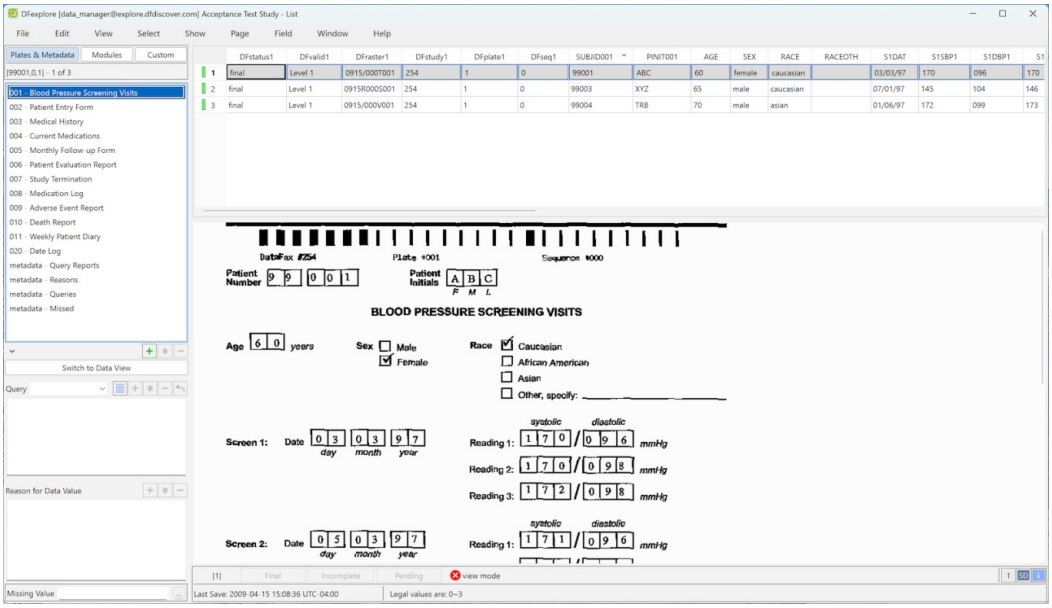
2.4.12. Select View > Queries to switch to Queries View. Select Show > All Queries to display all queries for the current subject.



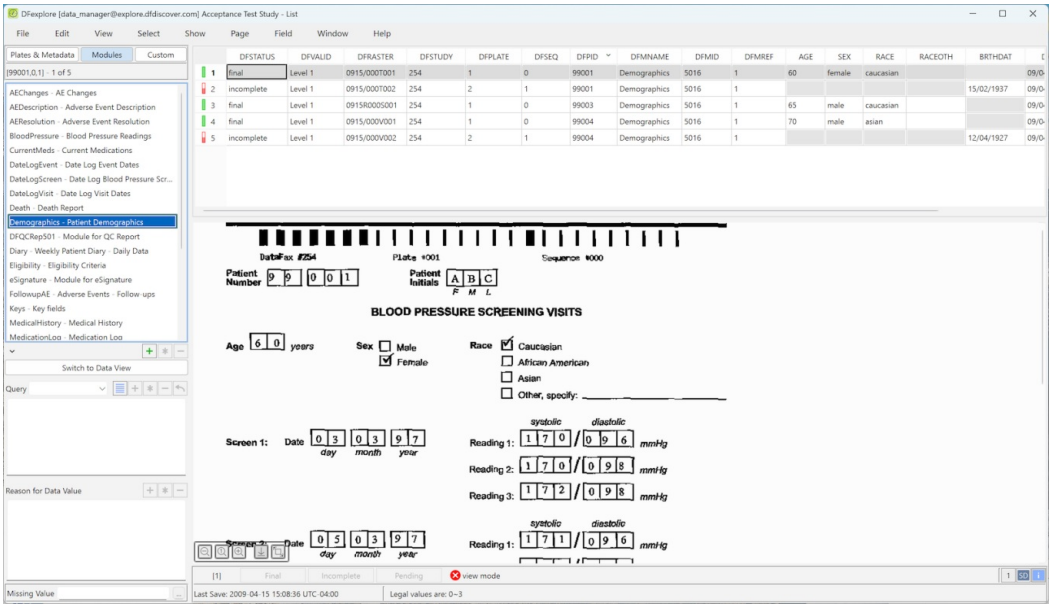
2.4.13. Select View > Reasons to switch to Reasons View. Select Show > All Reasons.



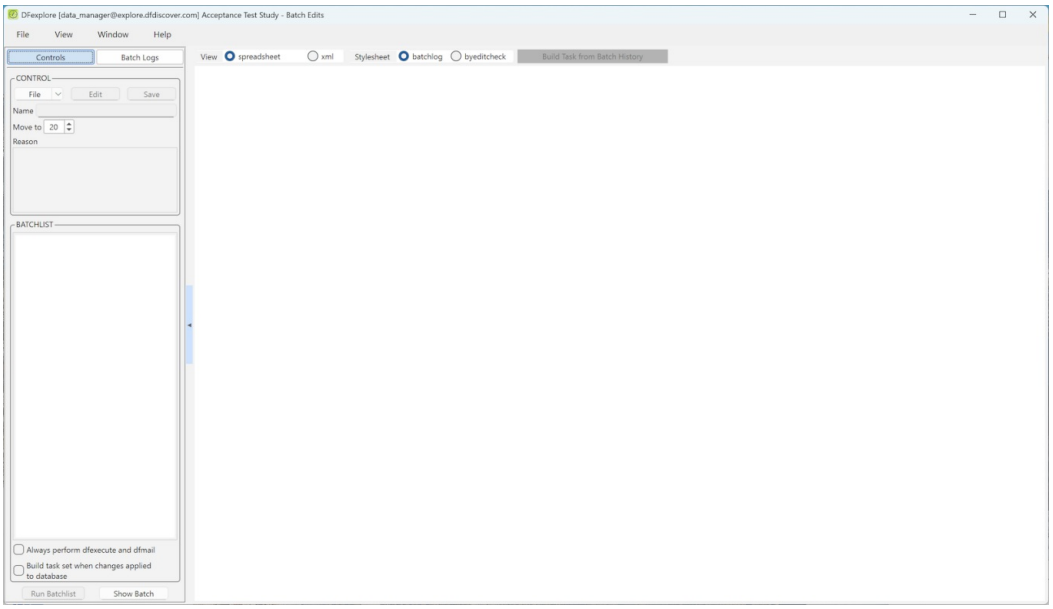
2.4.14. Select View > List to switch to List View. Confirm that the **Plates & Metadata** tab is highlighted at the top of the record list panel. Click **001 - Blood Pressure Screening Visits** from the list of plates.



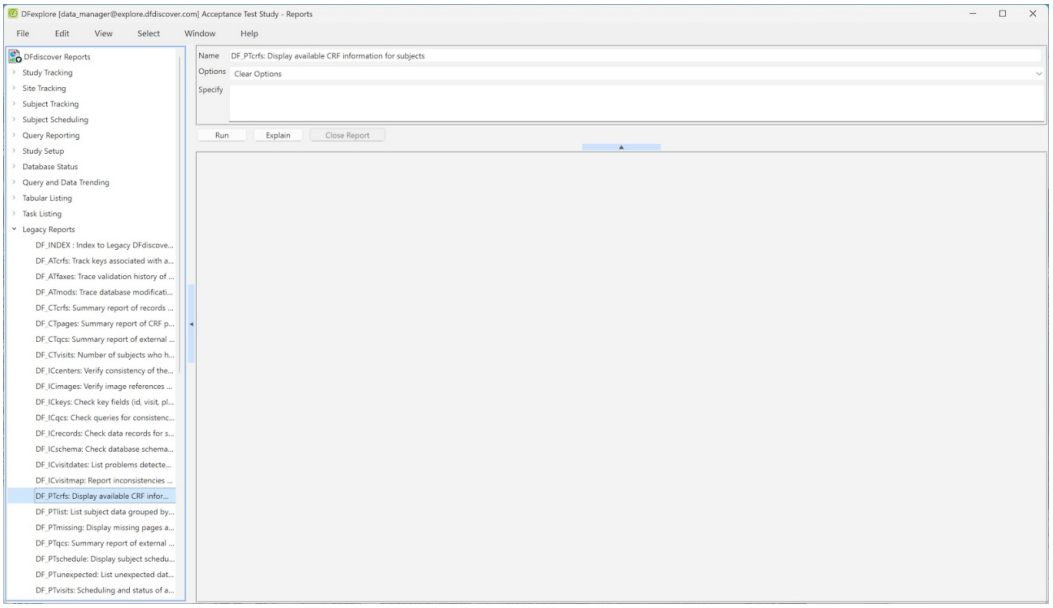
2.4.15. Choose the **Modules** tab at the top of the list panel to display a list of all modules defined for the study. Click **Demographics - Patient Demographics** module.



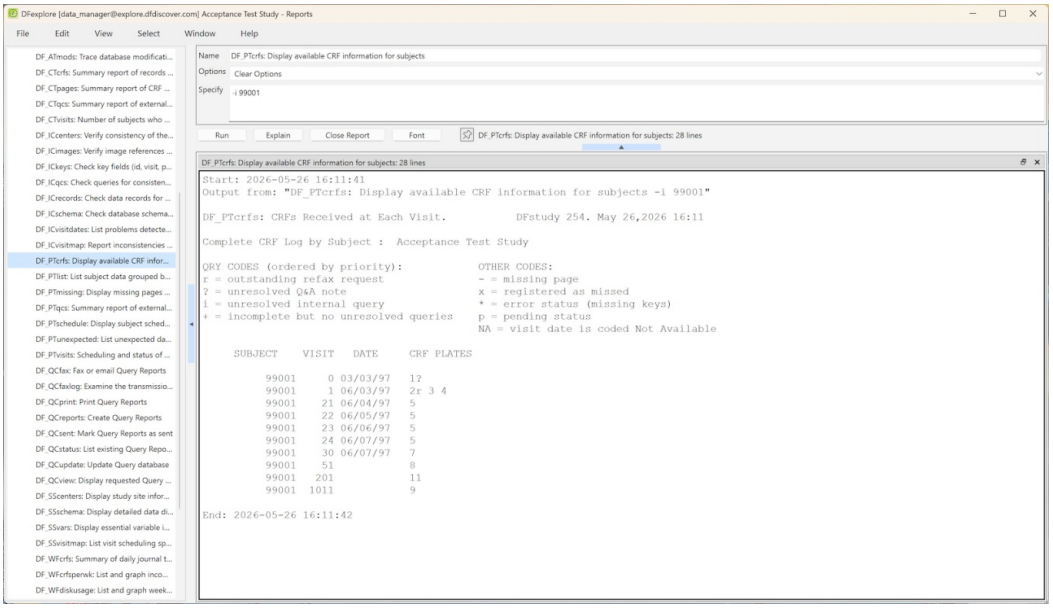
2.4.16. Select View > Batch Edits to switch to **Batch Edits** View.



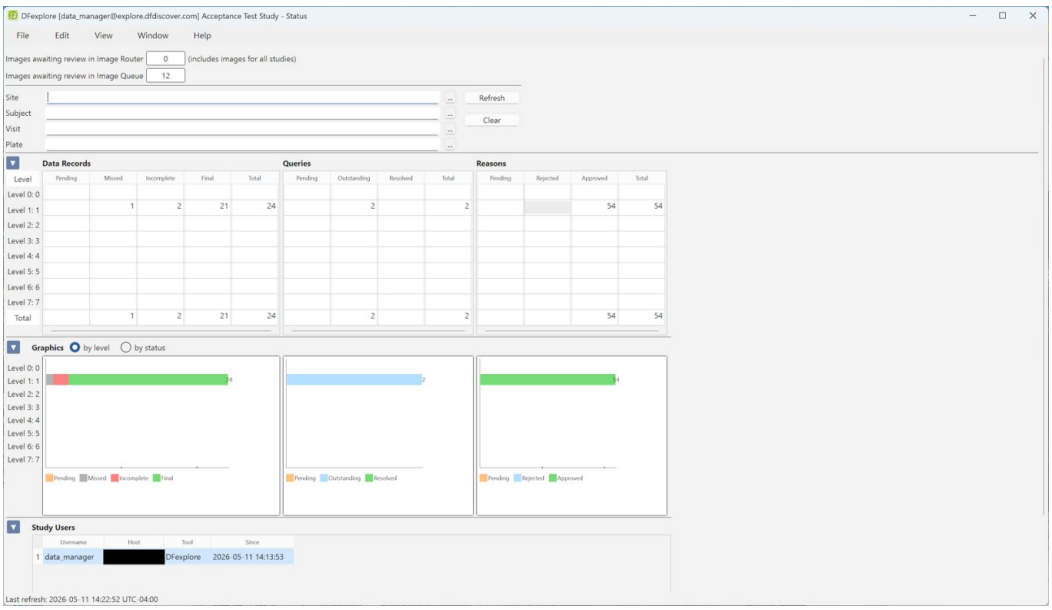
2.4.17. Select View > Reports to switch to **Reports** View. In the reports list panel, double-click **DFdiscover Reports** followed by **Legacy Reports**. Highlight the report **DF_PTcrfs** from the list of **Legacy Reports**.



2.4.18. 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.

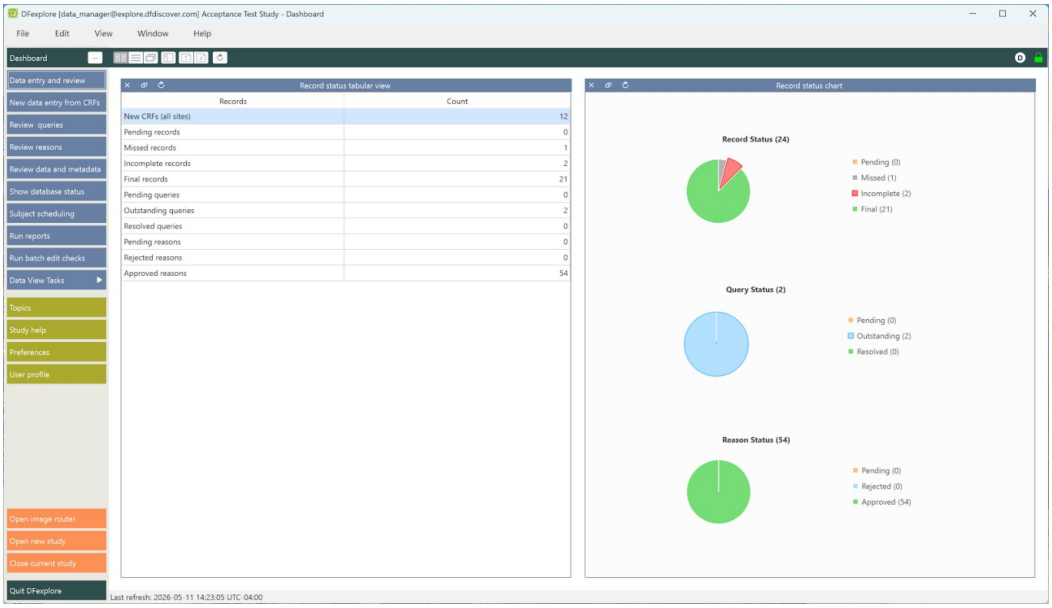


2.4.19. Select View > Status to switch to **Status** View.

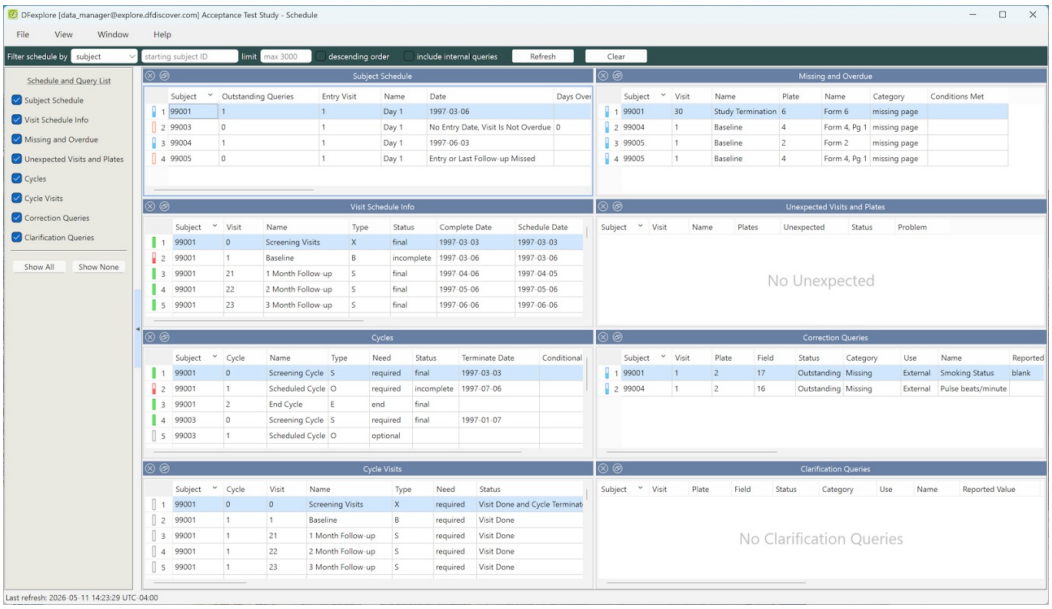


NOTE: Any pages that have been received and which **DFdiscover** could not identify as study CRFs will be found in the Image Router. As a result, the number of **Images awaiting review in Image Router** may differ from what is shown here.

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



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

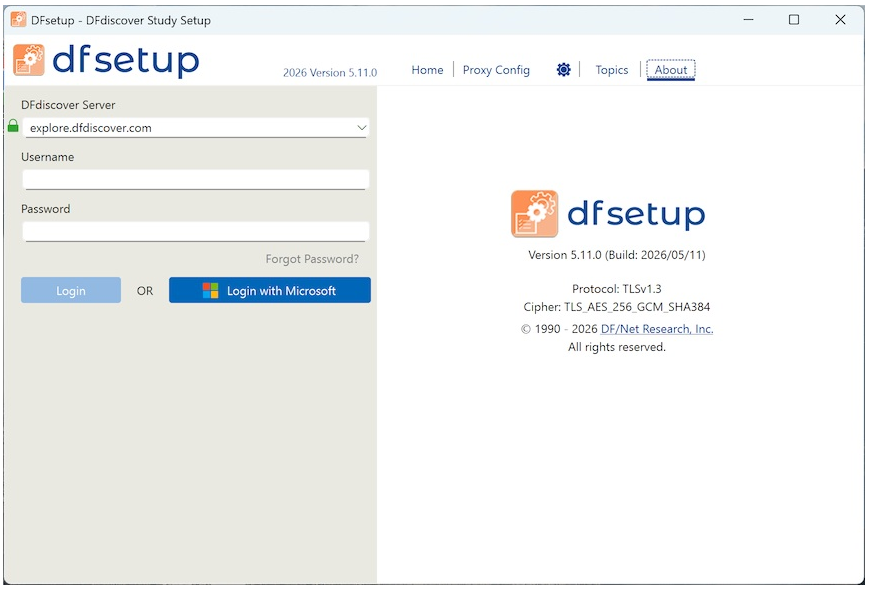


2.4.22. Select File > Exit to exit **DFexplore**.

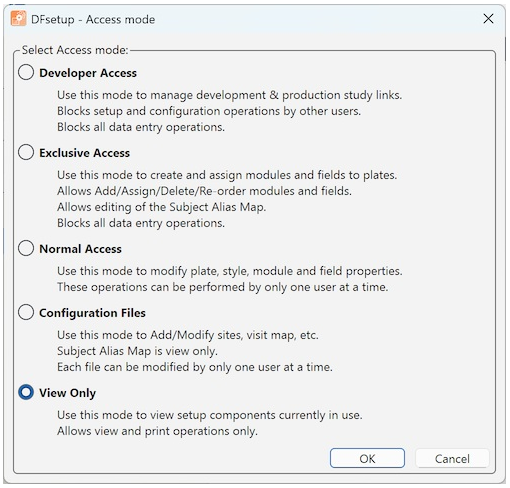
2.5 Start **DFsetup** and verify version information

2.5.1. Start **DFsetup**, login as data_manager as described in "How to start **DFsetup**".

2.5.2. In the login dialog, click About. Confirm that the version information in the dialog matches the installed software Version 5.11.3.

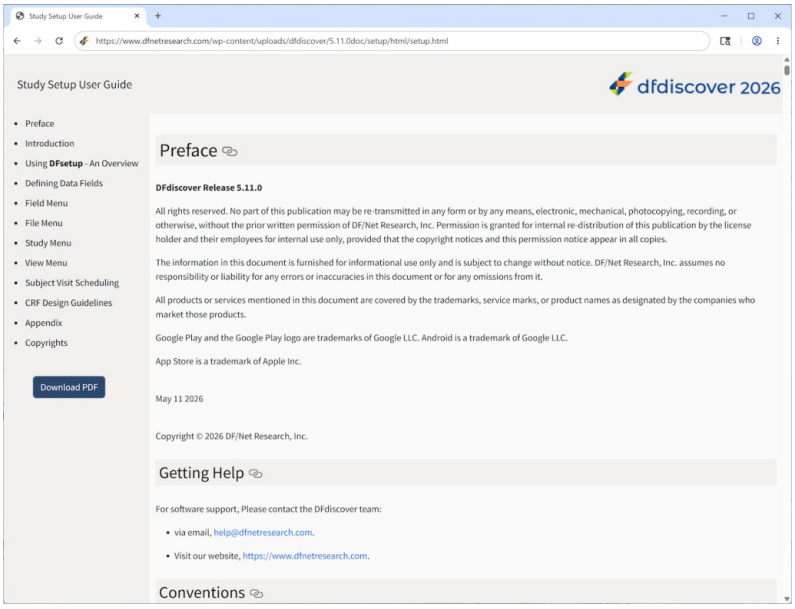


2.5.3. Choose **254 Acceptance Test Study**, select **View Only** and click OK to continue. The main **DFsetup** window opens.



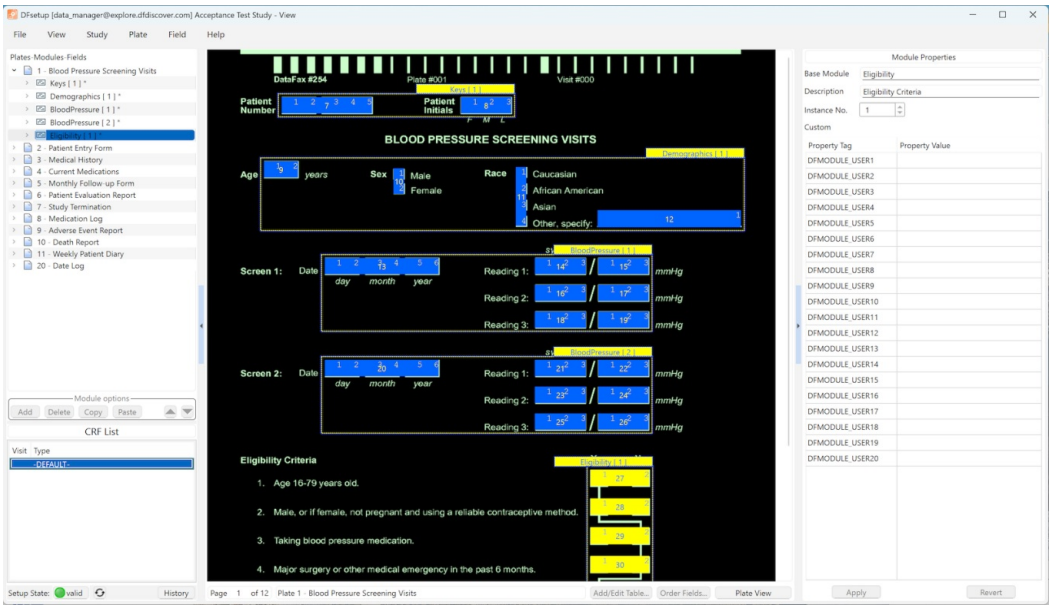
2.6 Verify the online setup documentation. Open the Acceptance Test Study setup and verify the standard **DFsetup** views

2.6.1. Select Help > Topics to access the documentation. In the documentation window click **Preface**, confirm the documentation matches the installed software Version 5.11.3. Select File > Close to dismiss the documentation window.

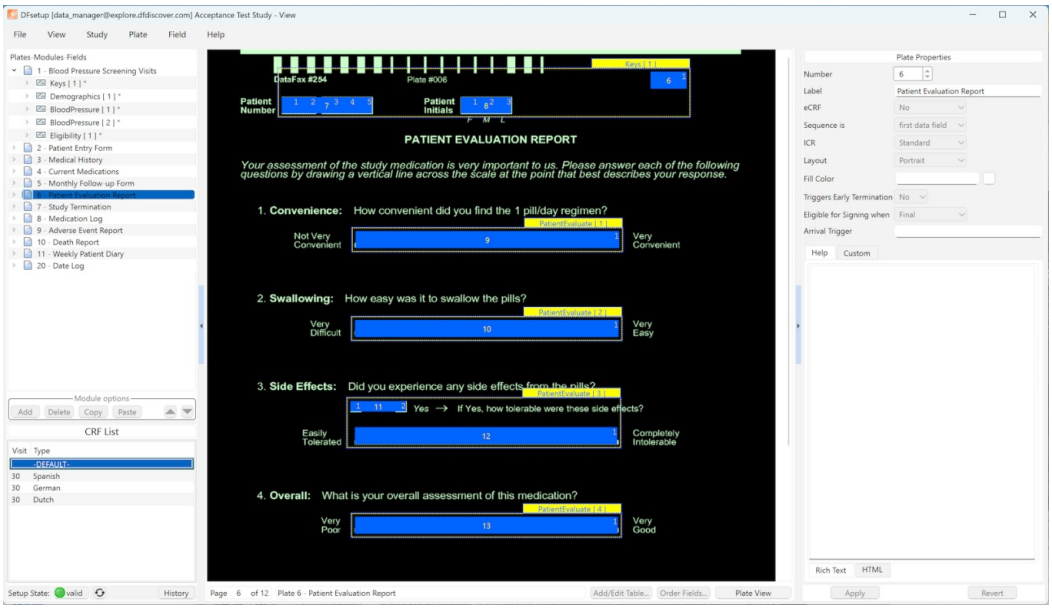


2.6.2. Select any plate entry in the **Plates-Modules-Fields** list panel to make that plate the active plate. The main window is refreshed with the CRF view of the plate definition, which includes widgets for all modules and fields. Click any field widget on the current plate to make that field the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

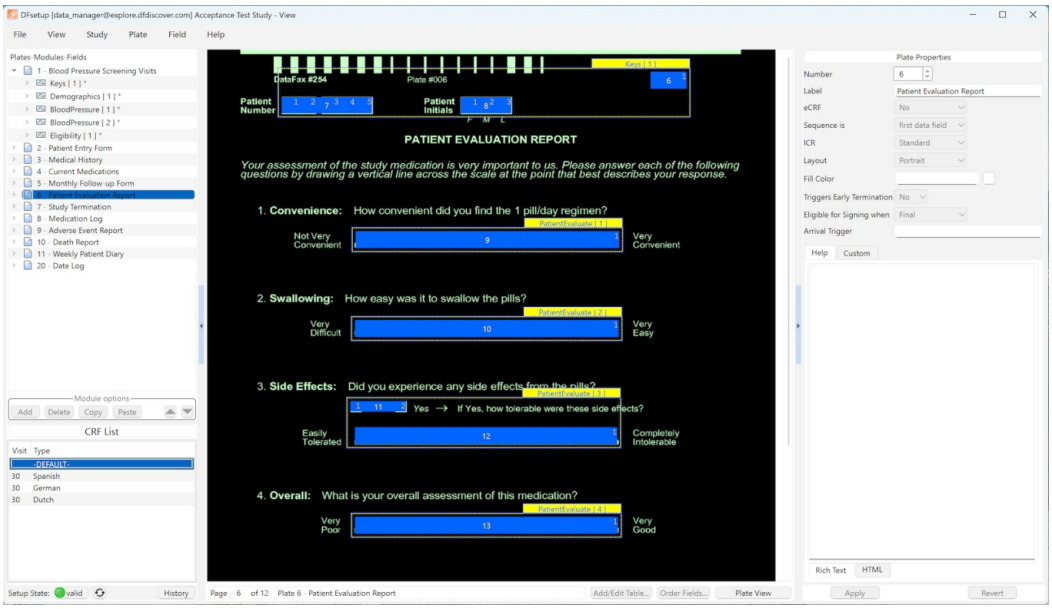
NOTE: **DFsetup** remembers the last active plate from your previous **DFsetup** session so your main **DFsetup** window may display a different plate as the active plate.



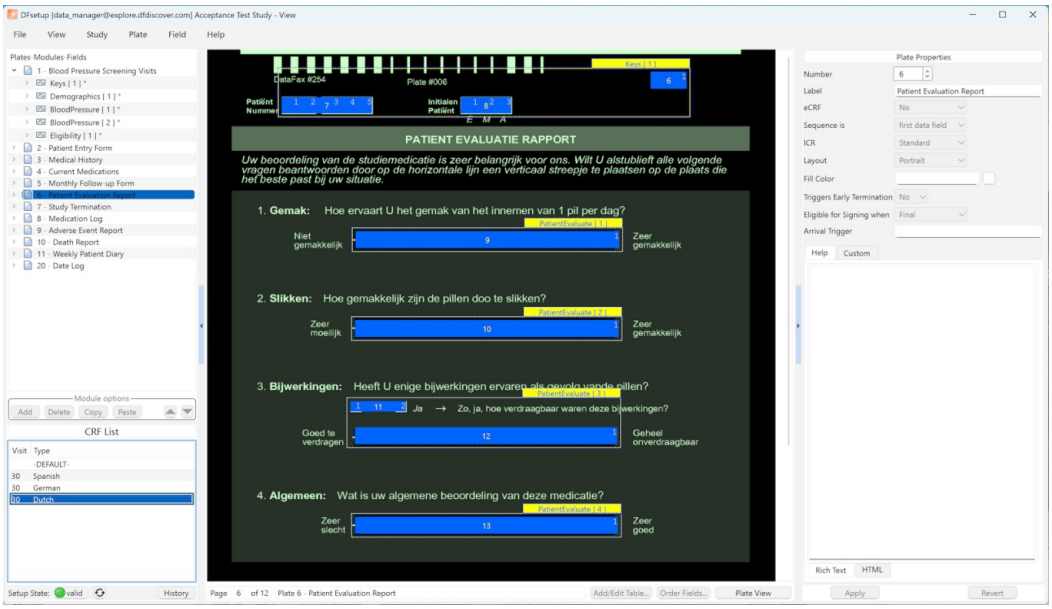
2.6.3. Select the **2 - Patient Entry Form** entry from the list panel to make plate 2 the active plate. Click Plate View > Field List to replace the Plate view with a listing of all **plate 2 fields** and their properties. Click Field List > Plate View to return to the Plate view of plate 2.



2.6.4. 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..

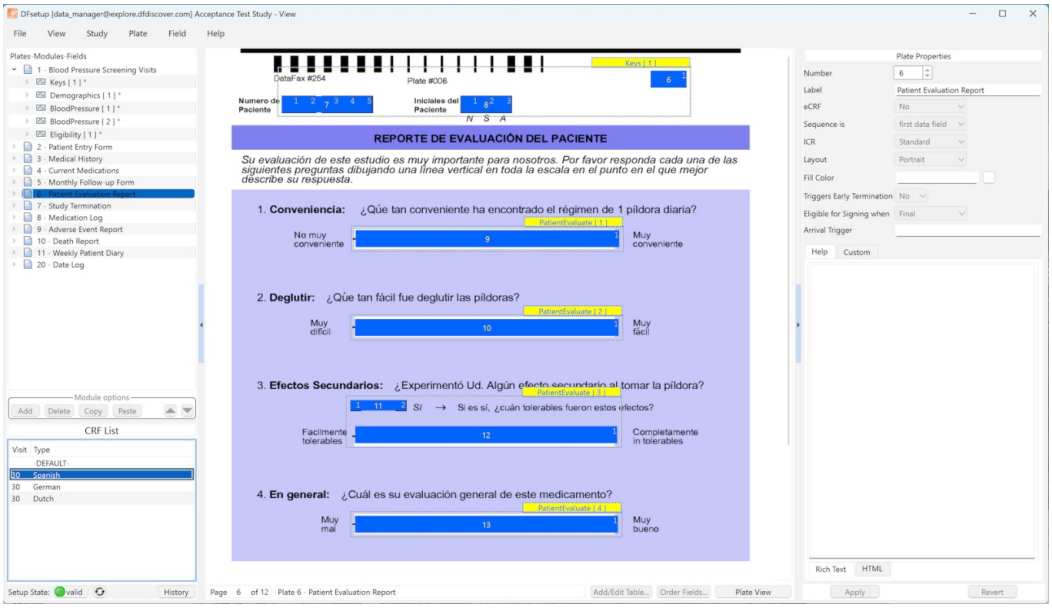


2.6.5. From the CRF List panel, choose the entry **30 Dutch**.

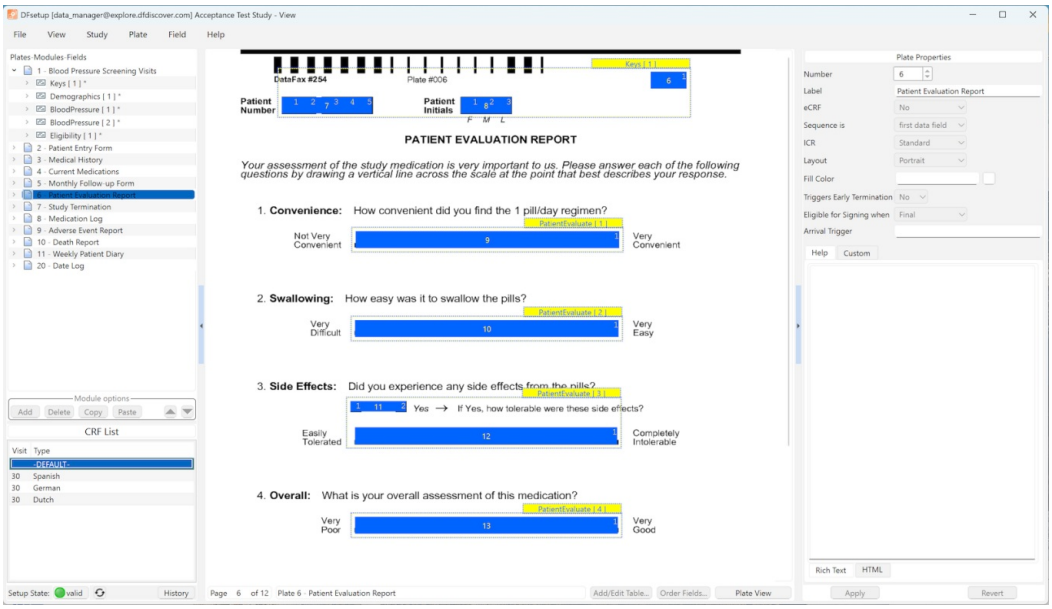


2.6.6. Select File > Preferences. In the **Preferences** dialog, choose **Color** for **Background Color**. Click OK to close the **Preferences** dialog.

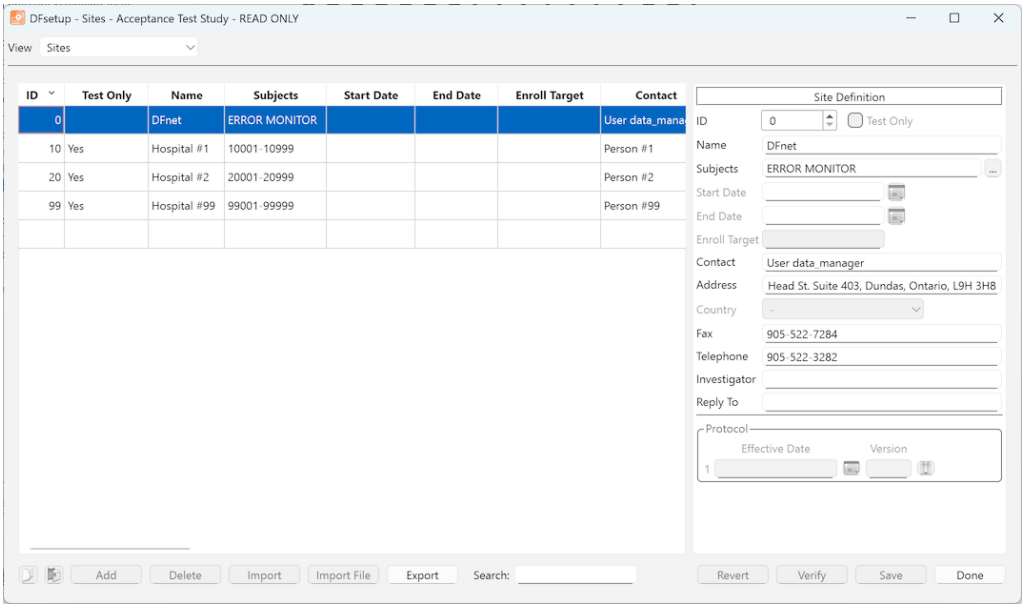
2.6.7. From the CRF List panel, choose the entry **30 Spanish**.



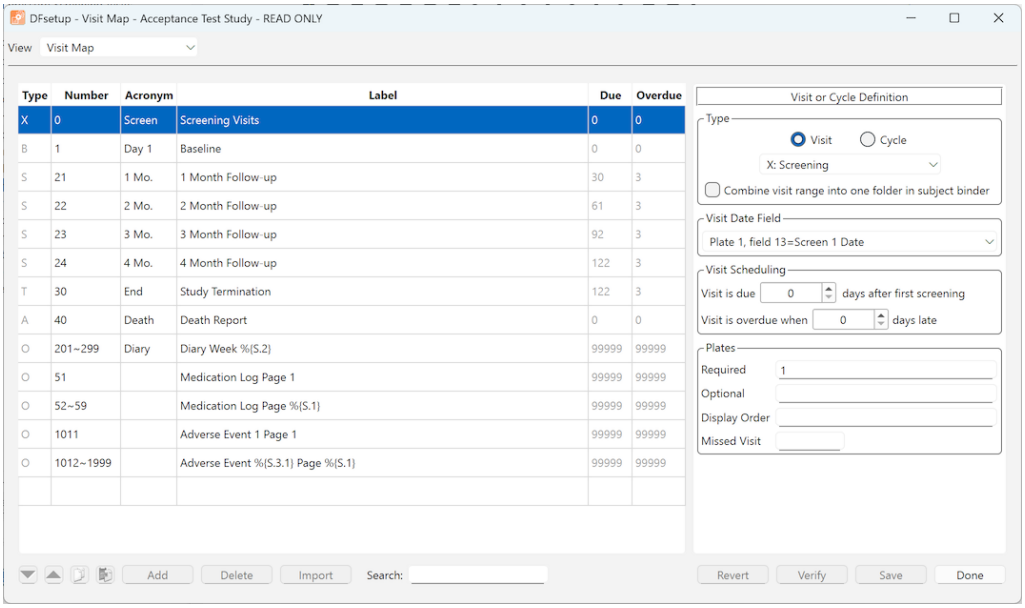
2.6.8. Return to the default (English) CRF background for plate 6 by choosing **DEFAULT** in the CRF List panel.



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



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



2.6.11. 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.

3 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

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

Estimate of Time Required: 20 Minutes

Begin Module 3. Study Setup

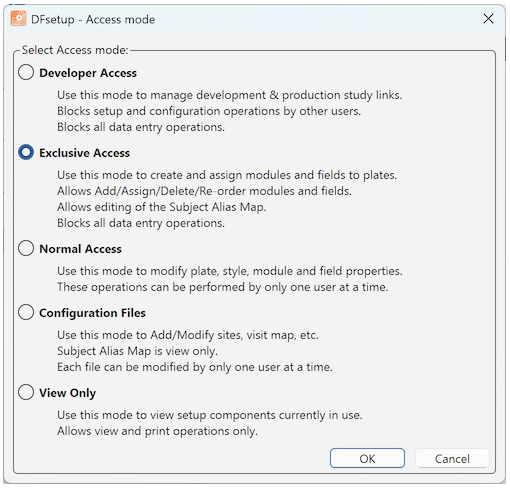
1. Start **DFATK** as described in Module 1 (Installation & Initialization).
2. Click 3. Study Setup followed by Begin to begin this module.

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

3.1.1. 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.

3.1.2. Start **DFsetup**, login as data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFsetup**".

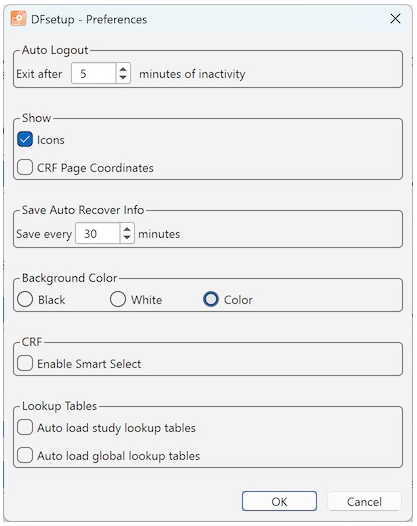
3.1.3. Choose **Exclusive Access** and click OK. **Exclusive Access** allows you to create and modify plates, styles and fields, and to define all setup configuration files.



3.1.4. 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.

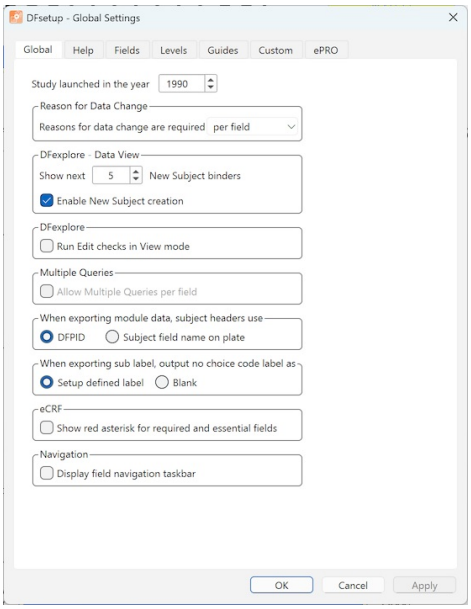


3.2 Define Global study preferences and apply settings to **DFsetup**

3.2.1. 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**

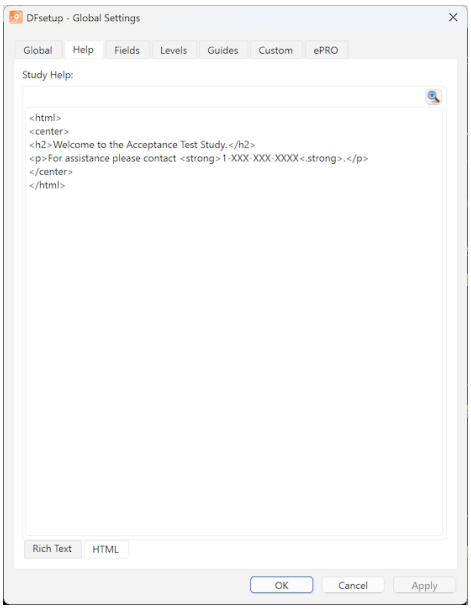
If these options are not set this way, modify them now and click Apply.



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

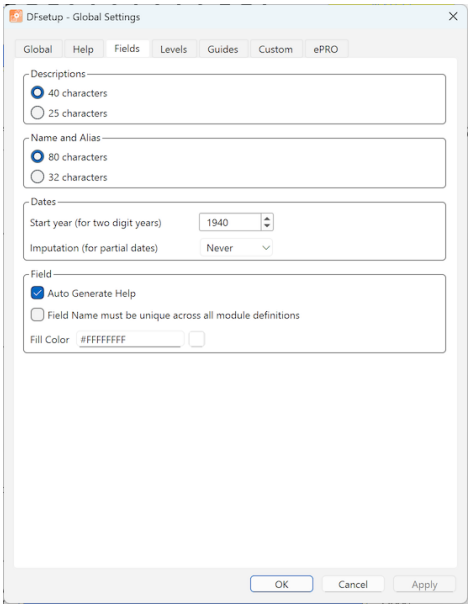
```
<html>
<center>
<h2>Welcome to the Acceptance Test Study.</h2>
<p>For assistance please contact <strong>1-XXX-XXX-XXXX</strong>.</p>
</center>
</html>
```

Click Apply.

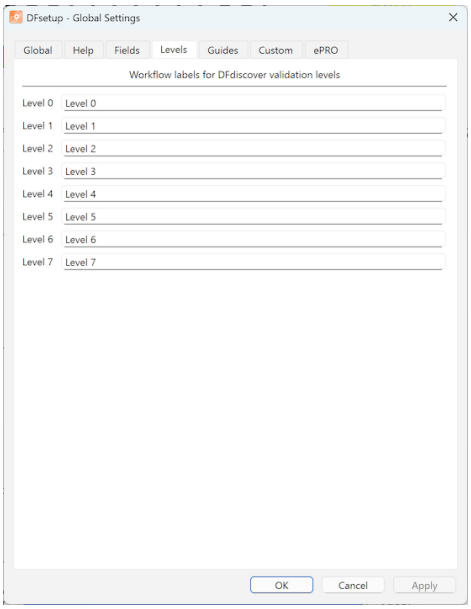


3.2.3. Click **Fields** tab, and set:

- **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**

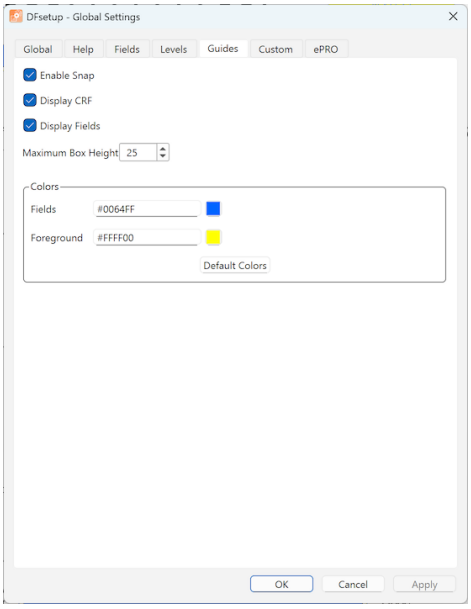


3.2.4. Click **Levels** tab. Confirm that the workflow labels of Level 0, Level 1, and through to Level 7 are used.

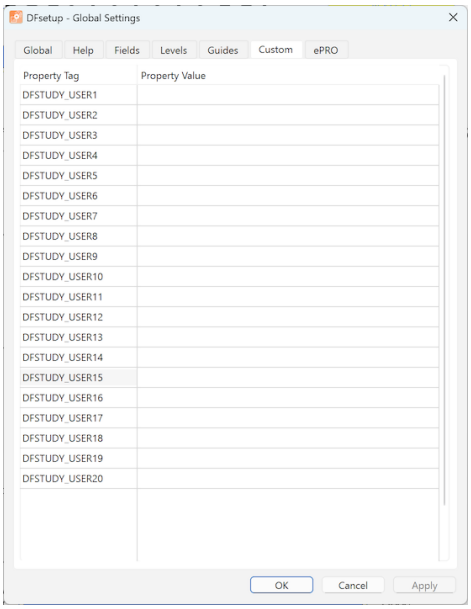


3.2.1. Click **Guides** tab. Confirm/change:

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

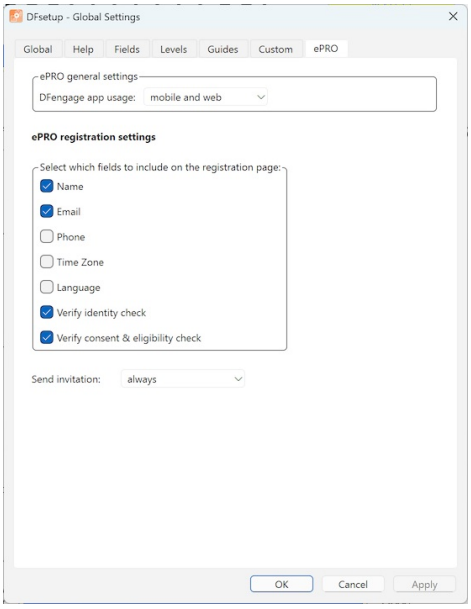


3.2.2. Click **Custom** tab. Confirm that all Property Values are blank.



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

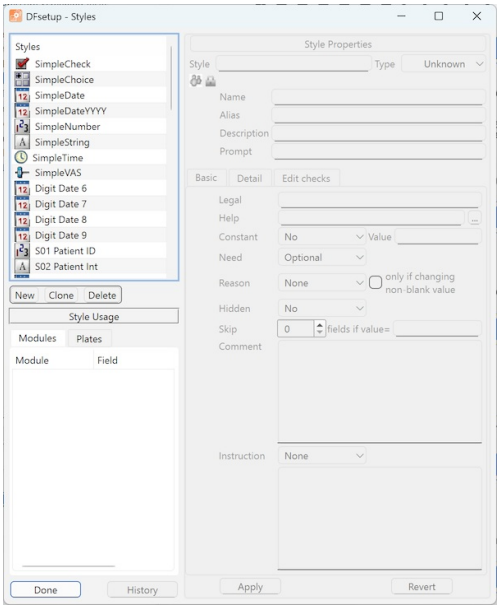
- Checked (enabled) **Name**
- Checked (enabled) **Email**
- Checked (enabled) **Verify identity check**
- Checked (enabled) **Verify consent & eligibility check**
- Send Invitation: **always**



3.2.4. Click OK to save changes and exit the dialog.

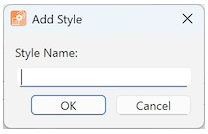
3.3 Create and modify a new style (Comment)

3.3.1. Select View > Styles from the menubar.



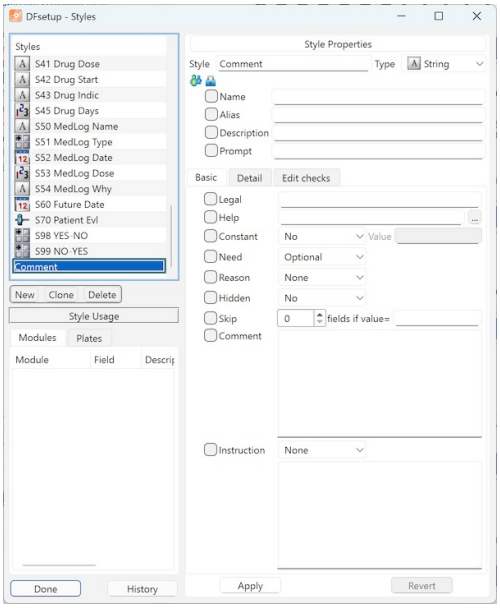
NOTE: The style names and information appearing in your **Styles** dialog may be different from those shown here. You should see the standard **DFdiscover** Simple styles.

3.3.2. 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.



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

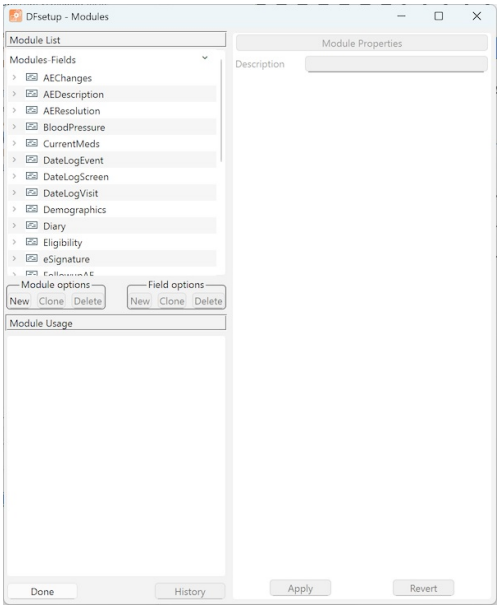
3.3.4. Click **Comment** to make it active, and confirm the **Style Properties Basic** tab displays the style properties as shown.



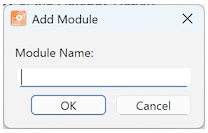
3.3.5. Click **Detail** tab, Change the **Store** property from 1 to 200. Check (enable) the [☑] to the left of the **Store** property to lock this setting in the Comment style. Click Apply to apply the modifications. Click Done to close the **Style Properties** dialog.

3.4 Create and modify a new module (Death)

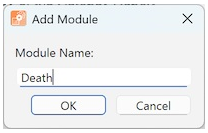
3.4.1. Choose **10 - Death Report** entry from the **Plates-Modules-Fields** list panel to make plate 10 the active plate. Select View > Modules to open the module definition dialog.



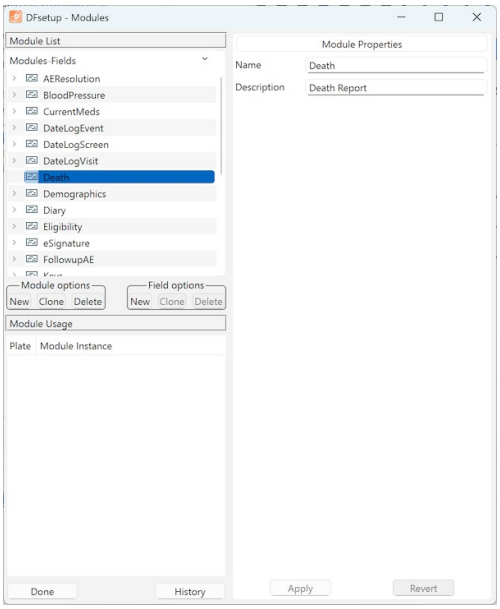
3.4.2. Click **Module options** New.



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

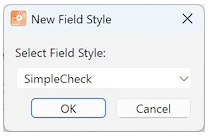


3.4.4. With the **Death** module selected as the active module, confirm that the Name Death appears in the **Module Properties** window. In the **Description** field, enter Death Report. Click Apply.



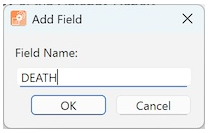
3.5 Assign Field definitions to a newly created module

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

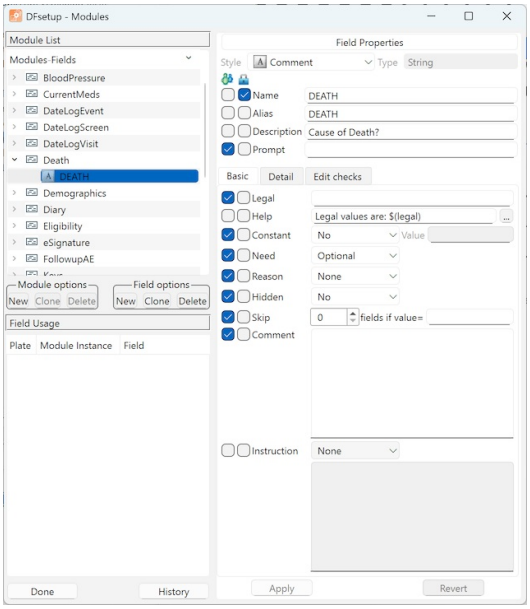


3.5.2. To create a field definition for “Cause of Death”, choose **Comment** from the **Style** pull-down list, click OK.

3.5.3. Enter the name DEATH for the **Field Name:** and click OK.

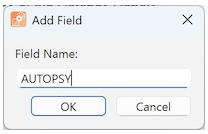


3.5.4. Within the **Field Properties**, enter a **Description** of Cause of Death?. Click Apply.

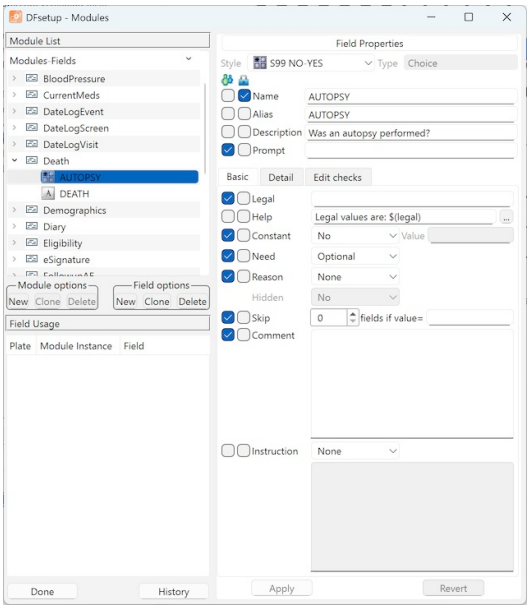


3.5.5. Click **Field options** New. In the resulting **New Field Style** dialog, choose **S99 NO-YES** from the **Styles** pull-down list. Click OK.

3.5.6. Enter the name AUTOPSY for the **Field Name:** and click OK.



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

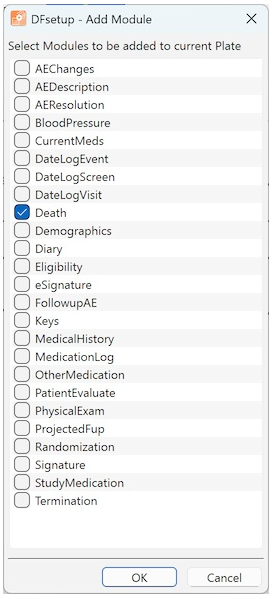


3.5.8. Click Done.

3.6 Assign a module's field definitions to a plate

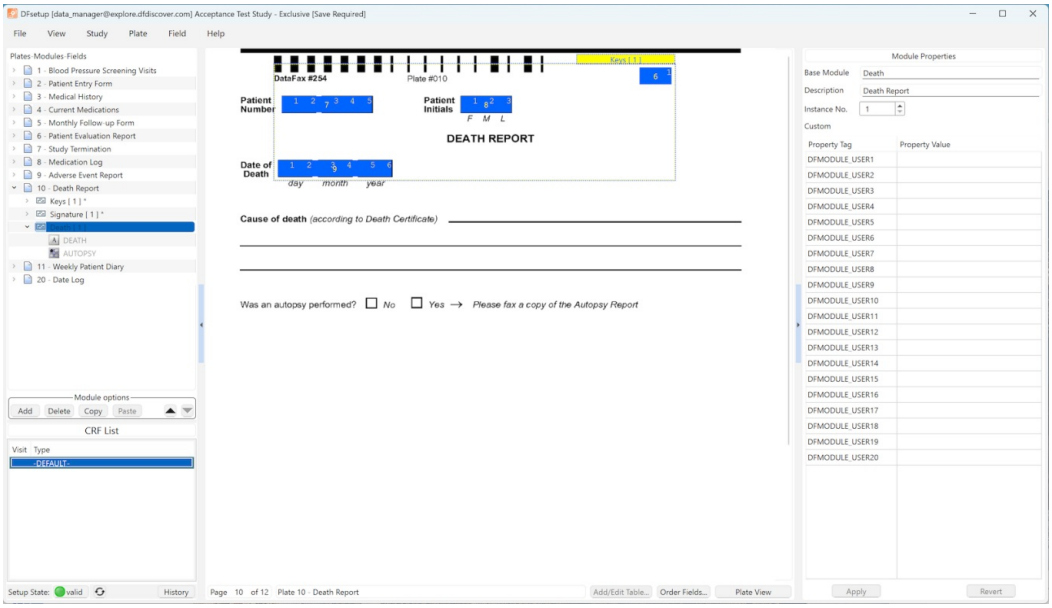
3.6.1. Still with **10 - Death Report** as the active plate, create the field references (layouts) for the **Cause of death** and **autopsy** fields defined in “Assign Field definitions to a newly created module.”. First add the **Death** module to plate **10-Death Report** by clicking Add from the **Module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

modules.

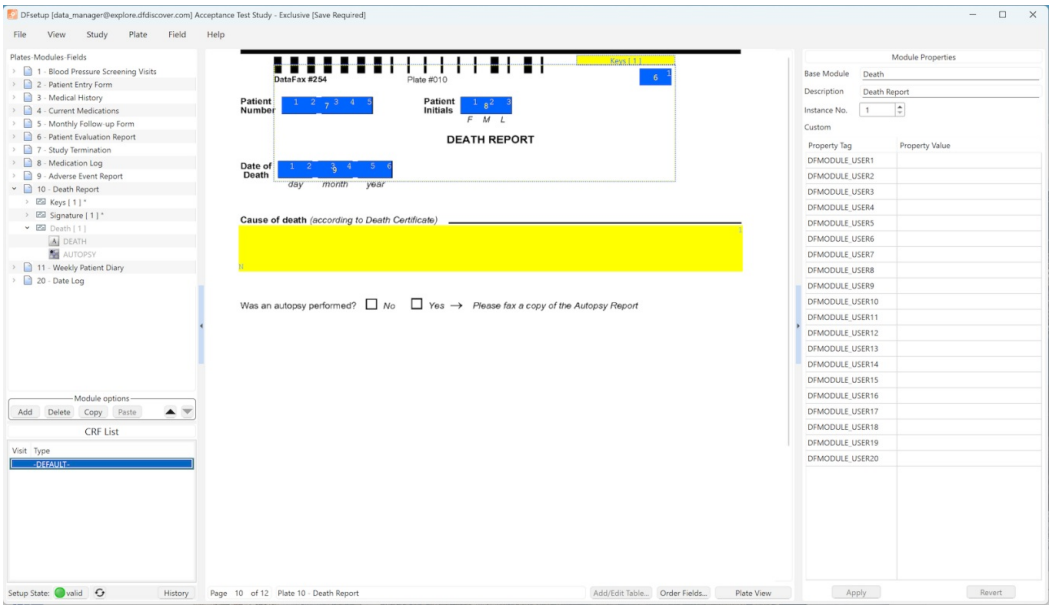


3.6.2. Click [OK] to add the **Death** module to plate **10-Death Report**.

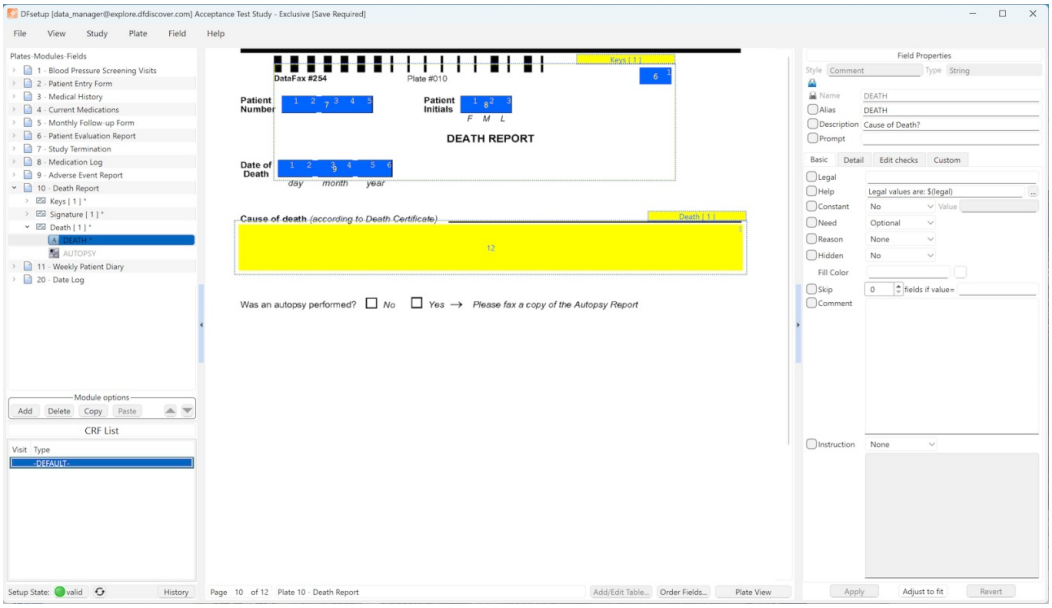
3.6.3. Click [›] to the left of **Death [1]** module entry in the **Plates-Modules-Fields** list to show all field definitions within the **Death [1]** module.



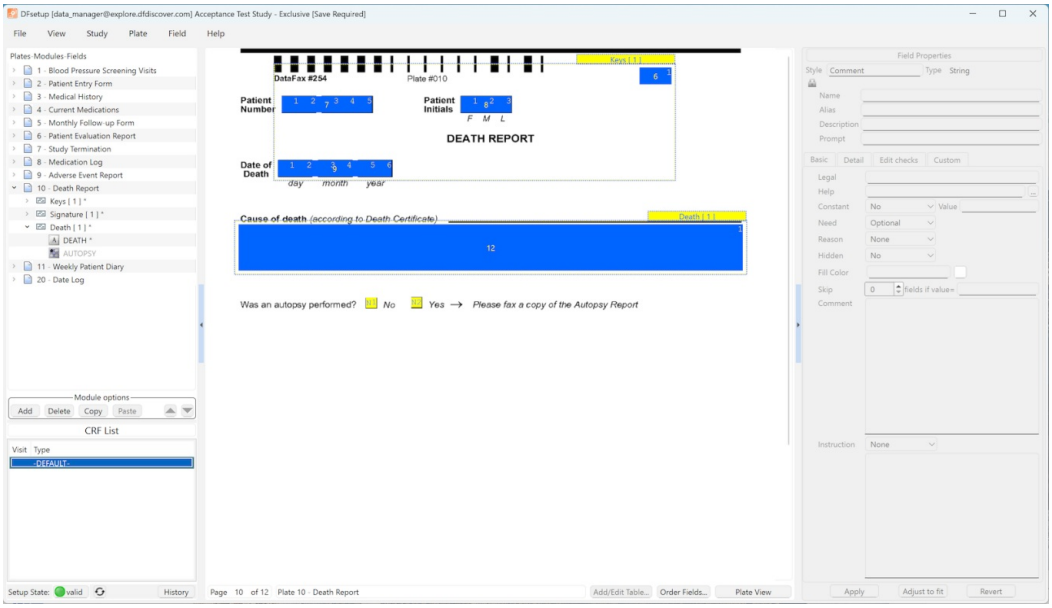
3.6.4. Create a field reference for the **Cause of Death**. Using the mouse, select **Click** the leftmost end of the second longest lines on the plate background. Holding down the **left** mouse key and [Control], drag up and across to the rightmost end of the line. Release the mouse key to create a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



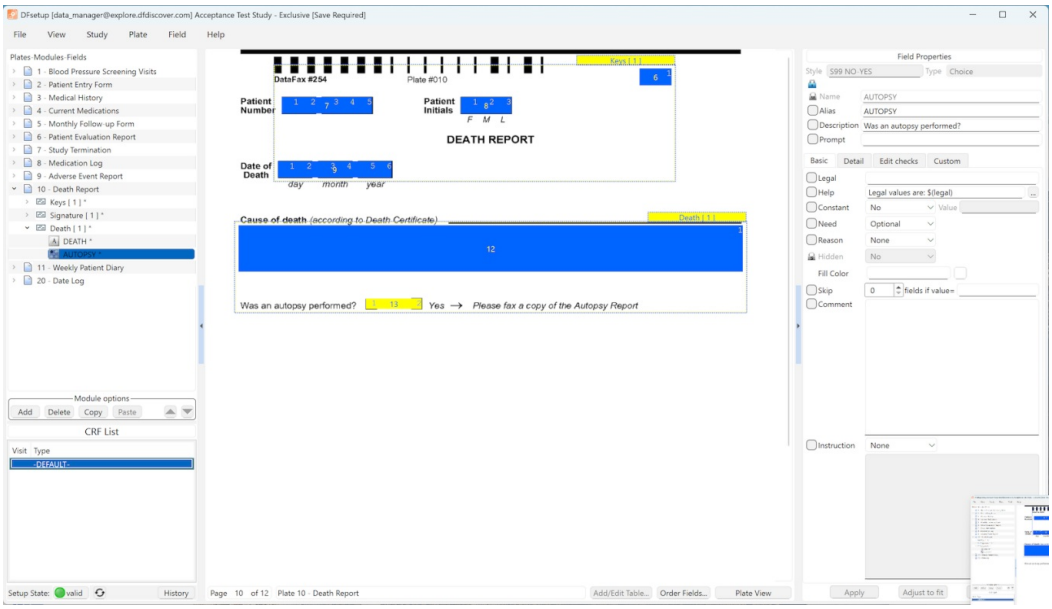
3.6.5. Select the **DEATH** field in the **Plates-Modules-Fields** listing to assign a field definition.



3.6.6. 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.

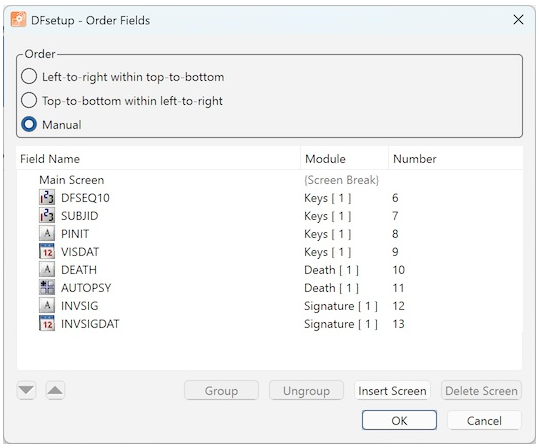


3.6.7. Select the **AUTOPSY** field in the **Plates-Modules-Fields** listing to assign a field definition.

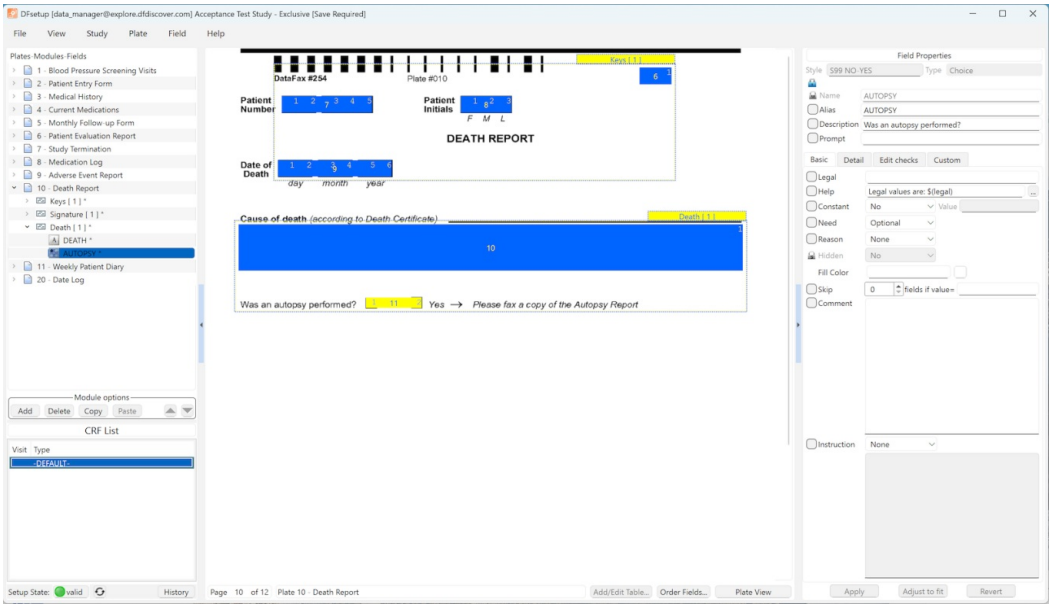


3.7 Correct field ordering on the current plate to set field traversal order for data entry

3.7.1. 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.



3.7.2. Click OK to apply the selected field order.



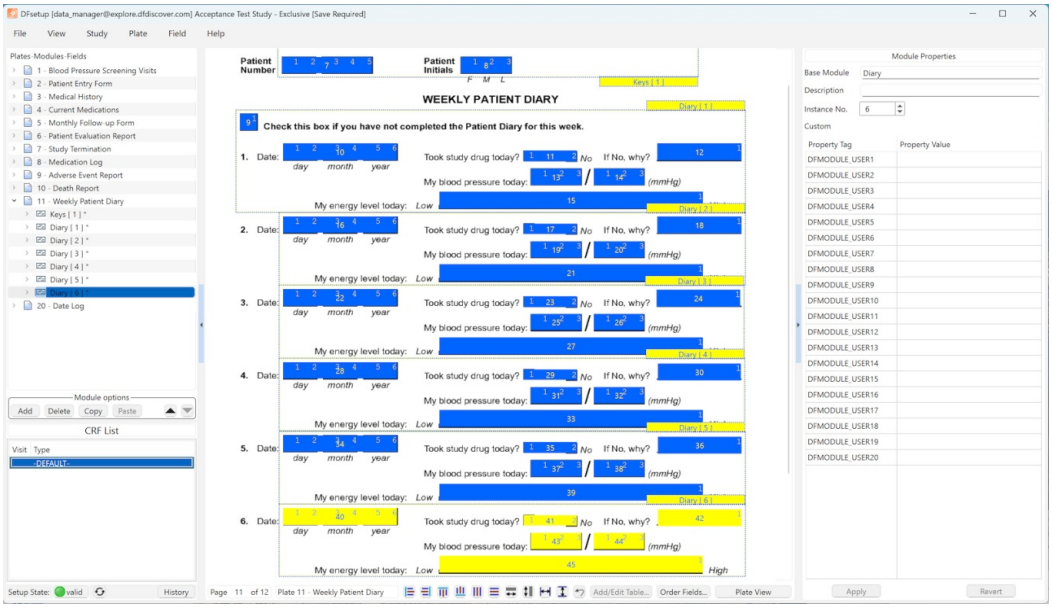
3.7.3. Click [⌄] to the left of **10-Death Report** in the **Plates-Modules-Fields** list to collapse all plate **10 - Death Report** modules.

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

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

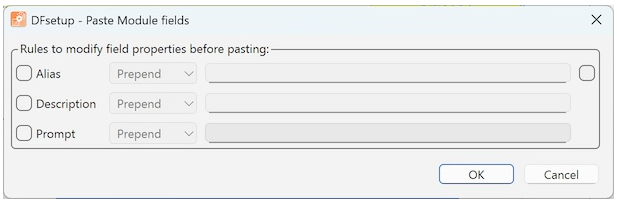


3.8.2. Click [›] to the left of **11-Weekly Patient Diary** to expand the list of modules defined on the current plate. Choose **Diary[6]** from the list.

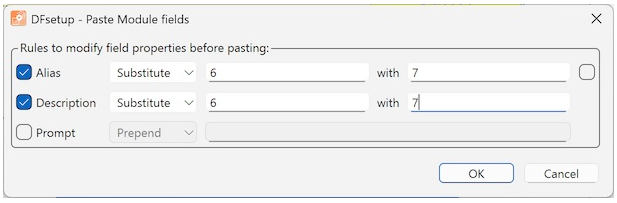


3.8.3. Click Copy from the **Module options**.

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



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



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



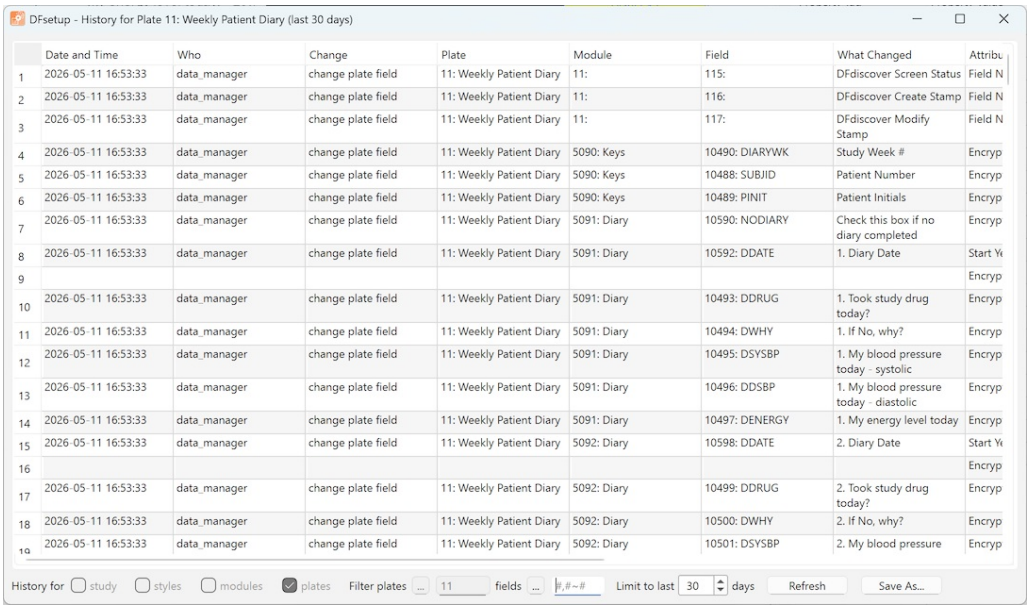
3.8.7. With the block of fields still highlighted, use the mouse to drag the block of field reference widgets and position them over top of their respective field outlines on the plate background. **Click** anywhere on the plate background to release the pasted block.



3.8.8. 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.

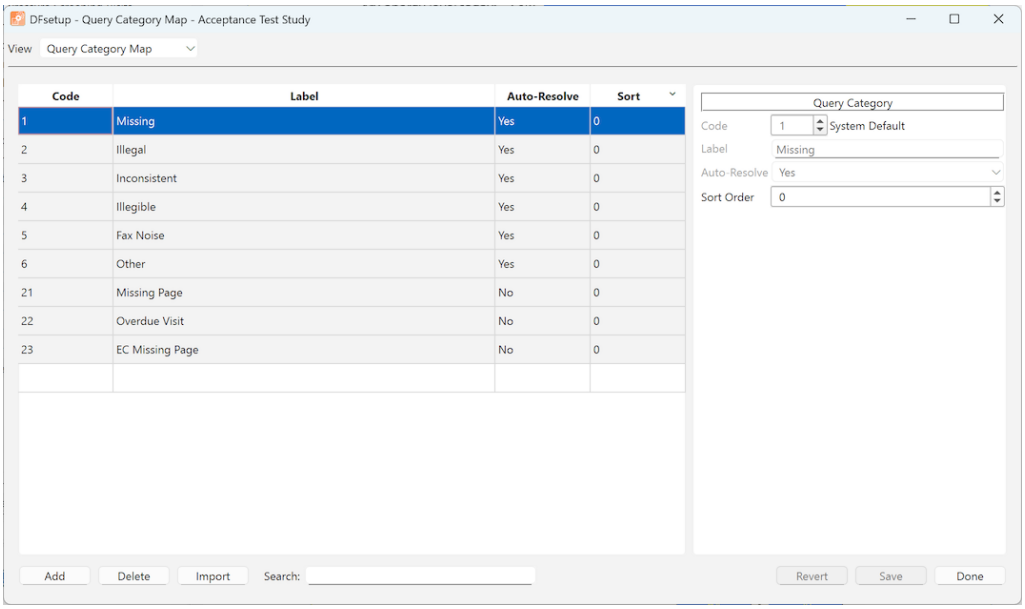
3.8.9. Select File > Save [Required]. Click History. The setup change history is displayed.

3.8.10. 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.

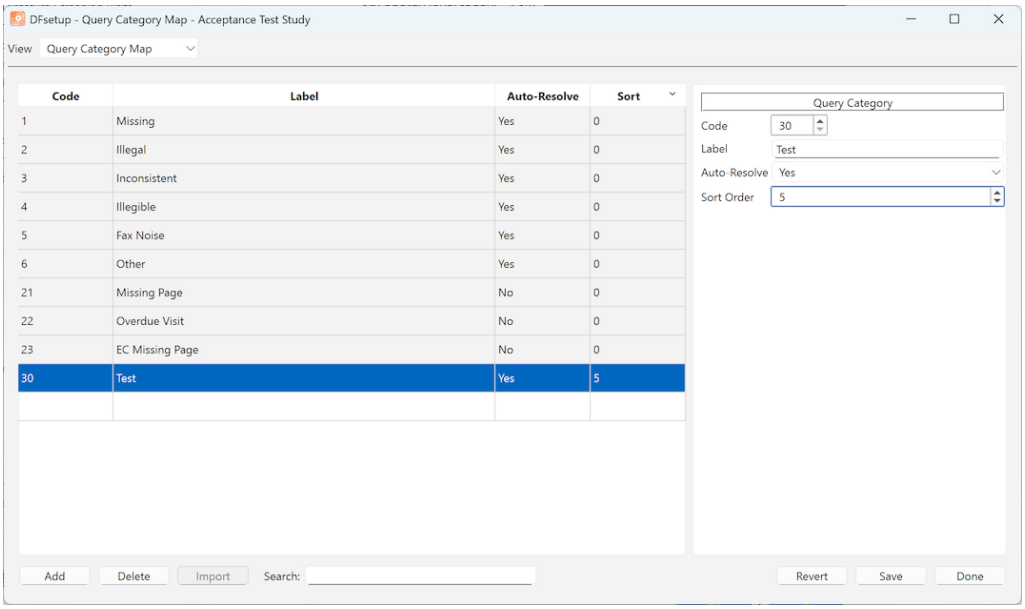


3.9 Create user-defined query category codes

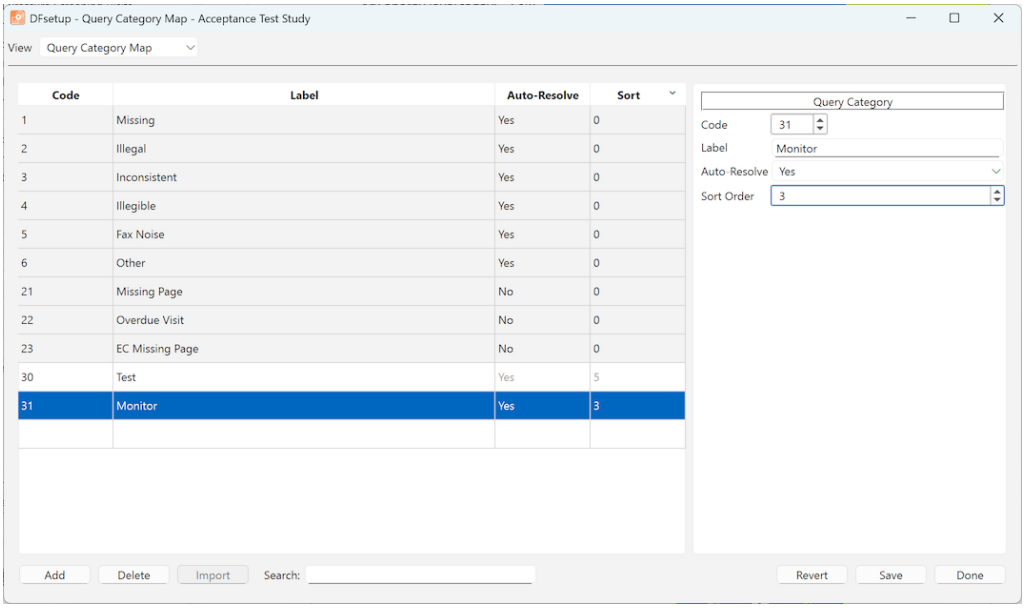
3.9.1. Select View > Query Category Map.



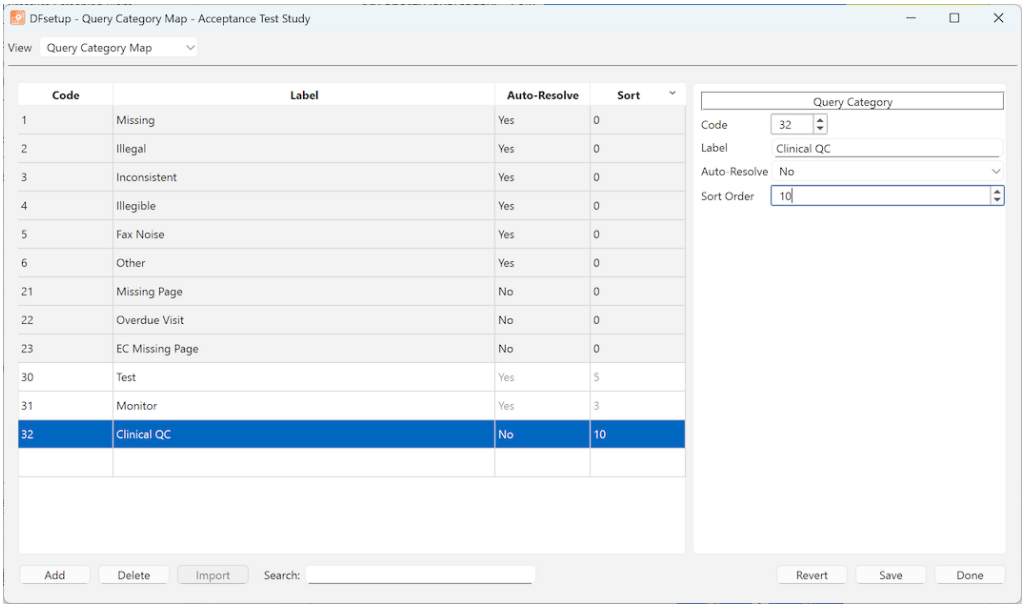
3.9.2. Click Add. The **Code** field is auto-filled with a value of 30. Press Tab to advance to the **Label** field. Enter Test for the **Label** field. Select Yes from the **Auto-Resolve** drop-down. Set **Sort Order** to 5.



3.9.3. 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.

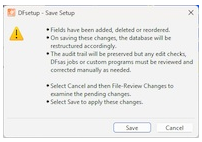


3.9.4. Click Add. Without altering the code number, enter Clinical QC for the **Label** field. Select No from the **Auto-Resolve** drop-down. Set **Sort Order** to 10.



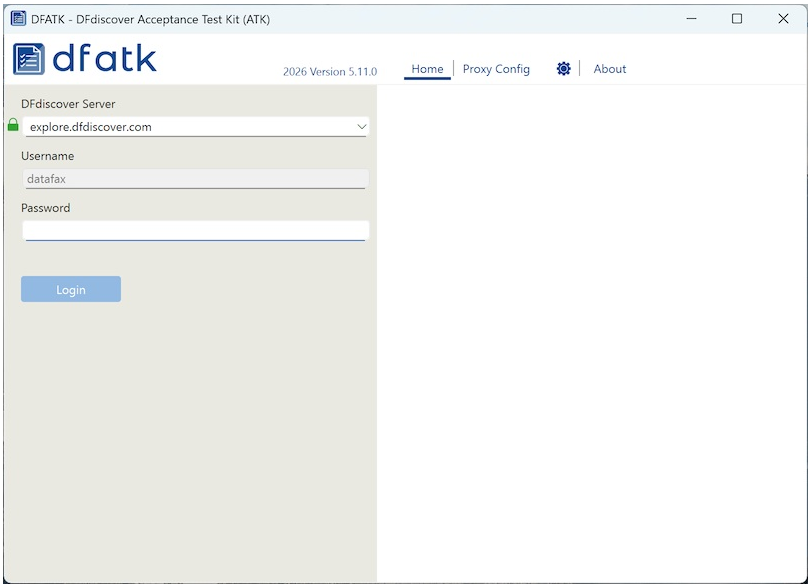
3.9.5. Click Save followed by Done to close the dialog.

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



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

3.10.1. 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).

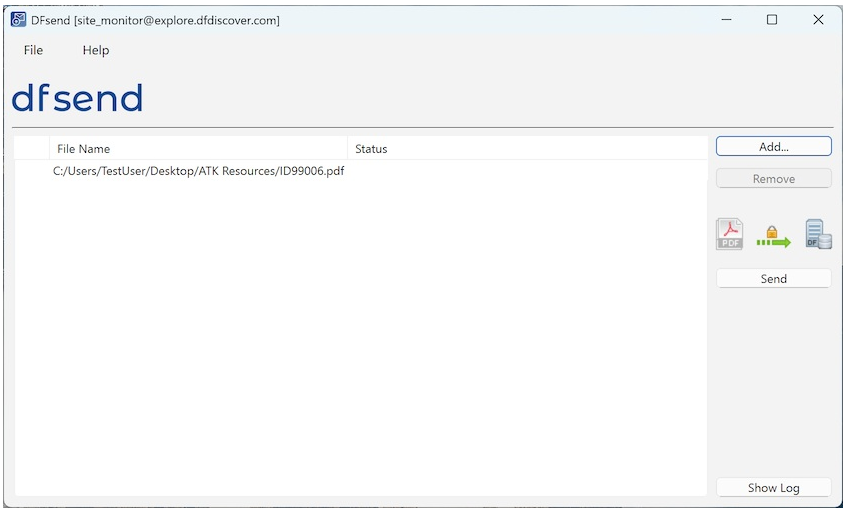


3.10.2. Click Send ID 99006 to email a copy of **ID99006.pdf** to site_monitor. Clicking more than once will result in multiple pages arriving to your email inbox.

> 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.

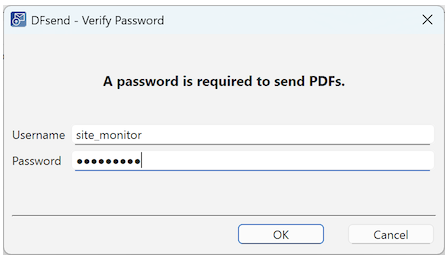
3.10.3. Start **DFsend** and login as user site_monitor, as described in "How to start **DFsend**".

3.10.4. Click Add. From the **Select PDF Files** file selection dialog, locate the previously saved **ID99006.pdf** file. Select the file and click Open.

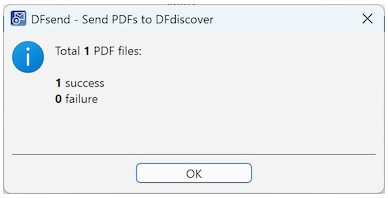


> NOTE: Documents can also be added by dragging-and-dropping the desired PDF files from a local file folder into the list area.

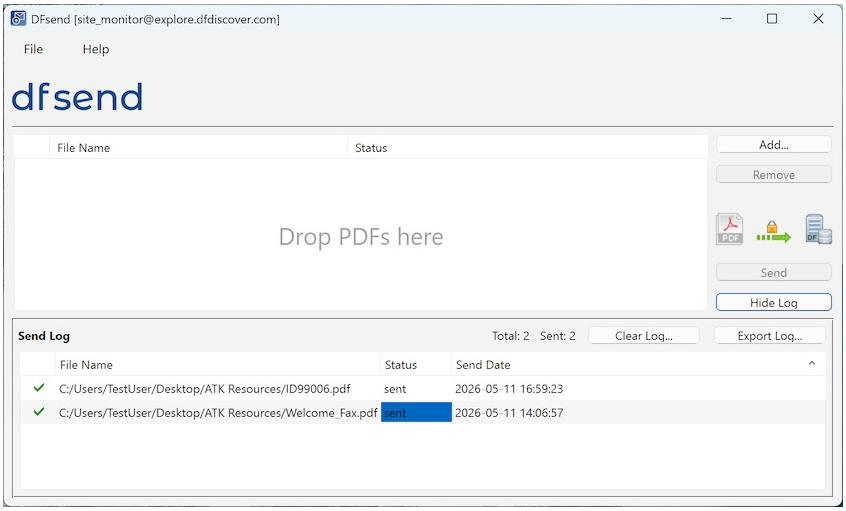
3.10.5. Click Send. In **Verify Password** dialog, enter site_monitor in the **Username** field and the previously assigned password in the **Password** field. Click OK.



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



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

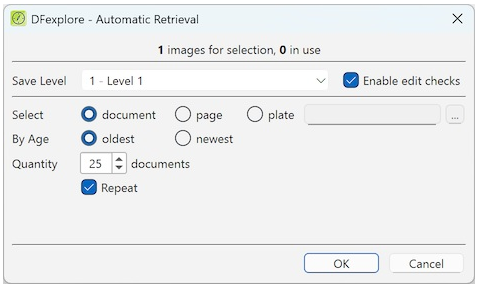


3.10.8. Select File > Exit.

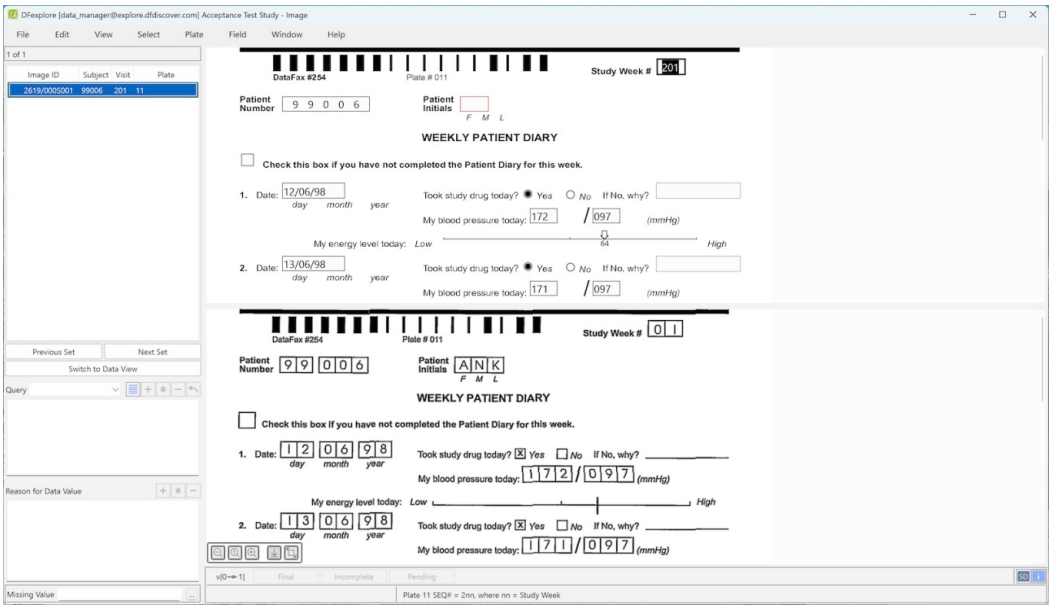
NOTE: Wait 2-3 minutes prior to proceeding to **DFexplore**.

3.10.9. Start **DFexplore**, login as user data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**".

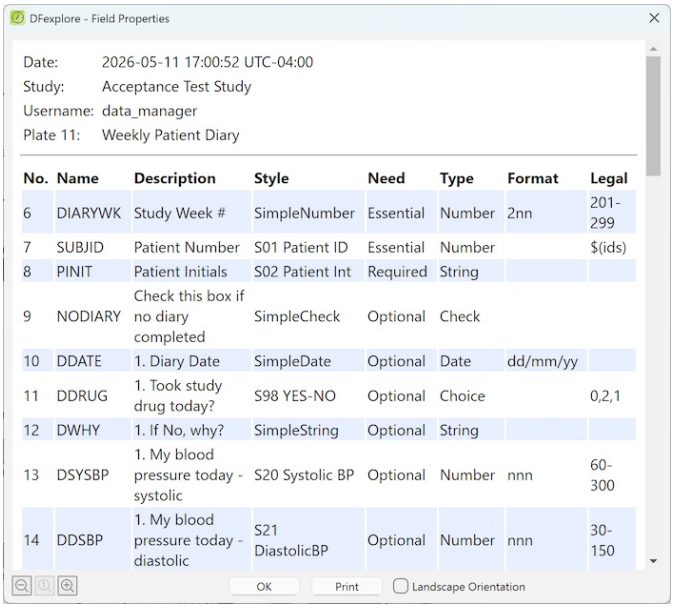
3.10.10. Select View > Image.



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



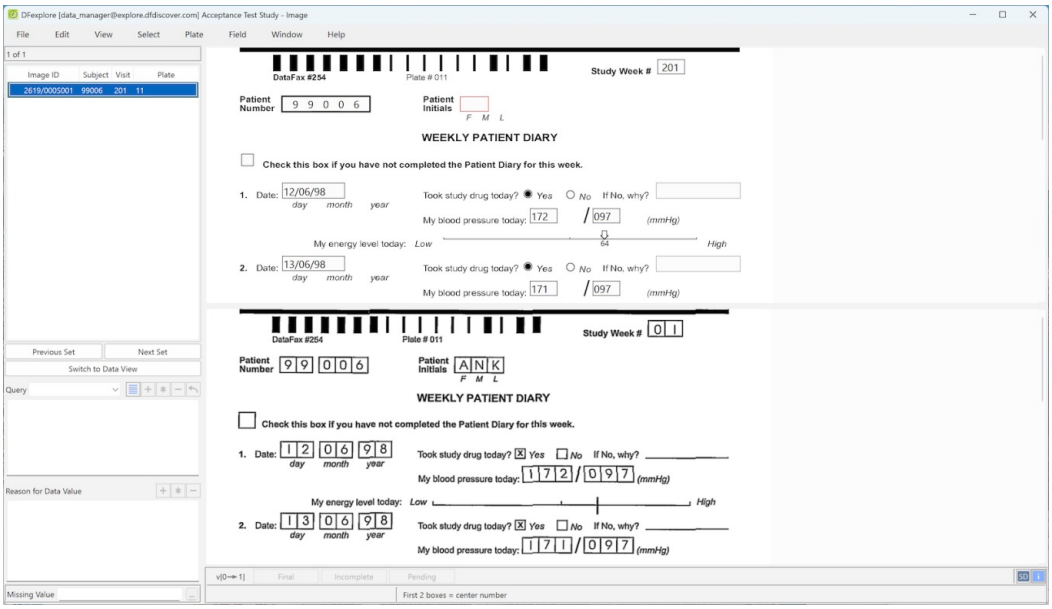
3.10.12. Select Plate > Show Field Properties to display a listing of properties for all fields on the current page. Locate field numbers **46** to **51** that were created in Use copy and paste to create repeating module and field references on a plate.. Verify the settings and click OK.



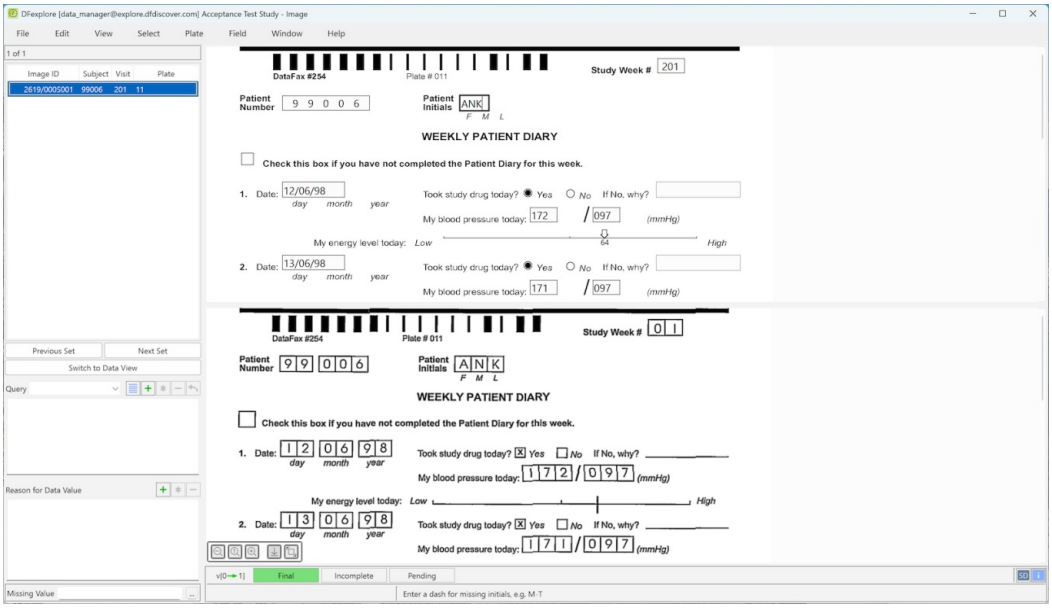
No.	Name	Description	Style	Need	Type	Format	Legal
6	DIARYWK	Study Week #	SimpleNumber	Essential	Number	2nn	201-299
7	SUBJID	Patient Number	S01 Patient ID	Essential	Number		$(ids)
8	PINIT	Patient Initials	S02 Patient Int	Required	String		
9	NODIARY	Check this box if no diary completed	SimpleCheck	Optional	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

3.11 Enter and save all data on the submitted plate 11

3.11.1. 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.

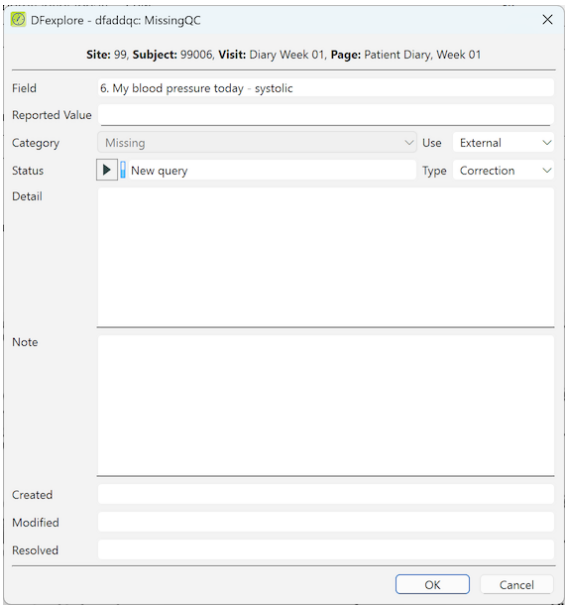


3.11.2. Enter the **Patient Number** as it appears on the CRF image. Press Tab to move to the **Patient Initials** field. Enter ANK as per the CRF image and press Tab to advance to the next field.

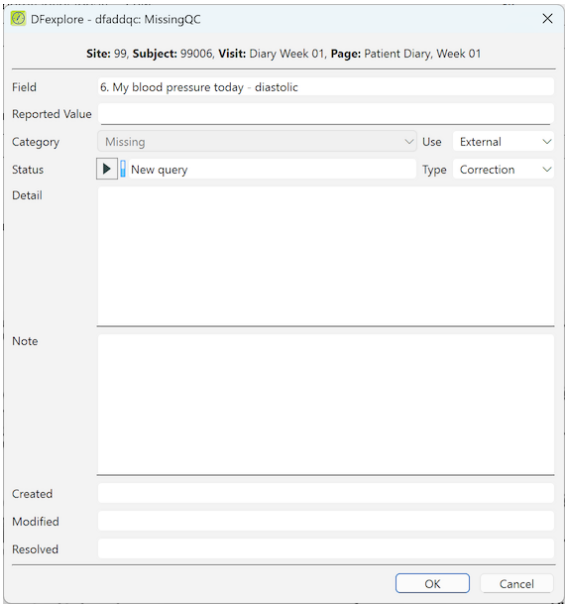


3.11.3. Starting with the **Check this box...** field, enter all data for **11-Weekly Diary Report** as it appears on the CRF image in the lower half of the split-screen window. Press Tab to move from field to field until field **6. My blood pressure today** is the current field. Leave the field blank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



3.11.4. 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.



3.11.5. 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.

3.11.6. With the focus on the save buttons, click Final to save the record to the database with the status Final.



3.11.7. 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.

4 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

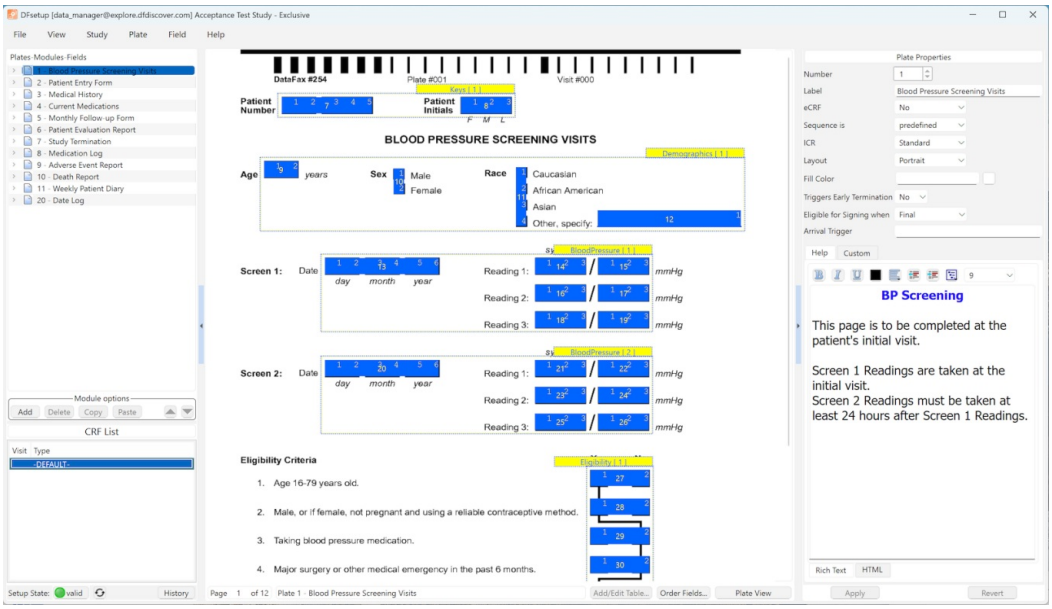
Begin Module 4. eCRF Creation for DFdiscover

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.

4.1 eCRF creation in **DFsetup**

4.1.1. Start **DFsetup**, login as user data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFsetup**"

4.1.2. 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.

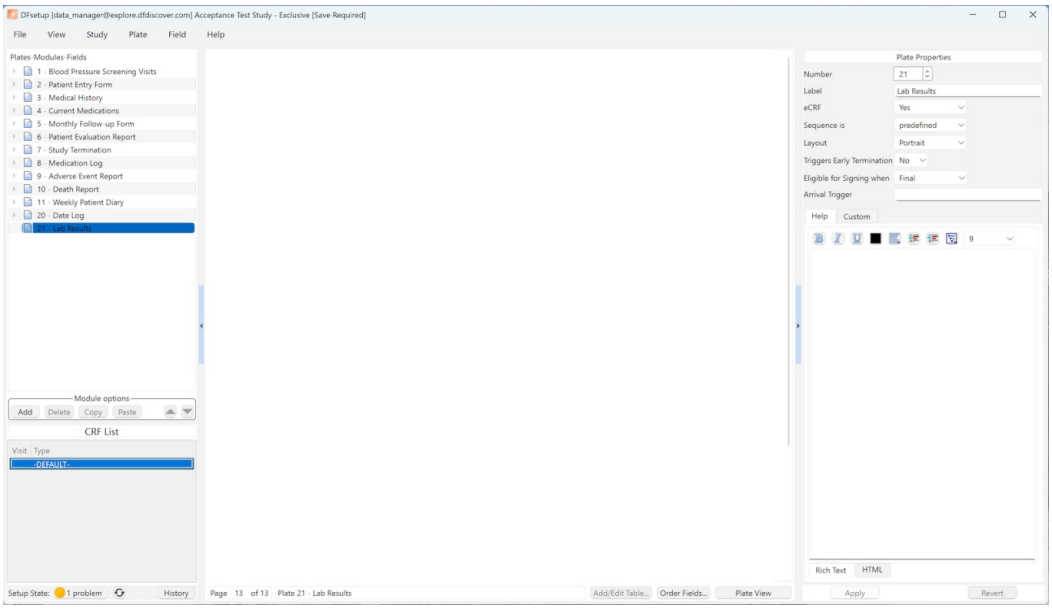
4.1.3. Select Study > Add eCRF Plate. In the **Add eCRF Plate** dialog enter a **New Plate Number** of 21. Click OK.



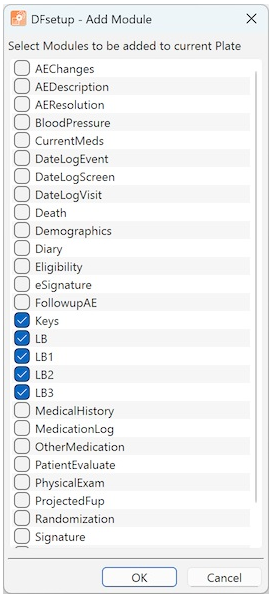
4.1.4. In the **Plate Properties** set:

- **Label** = Lab Results
- **eCRF** = Yes
- **Sequence is** = predefined
- **Triggers Early Termination** = No
- **Layout** = Portrait
- **Eligible for Signing When** = Final

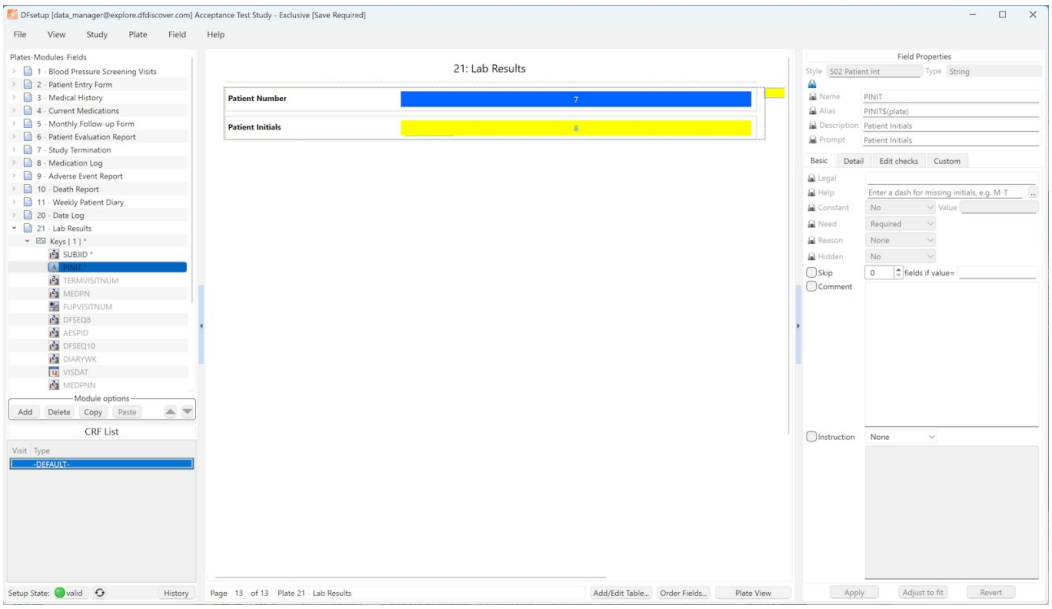
Click Apply.



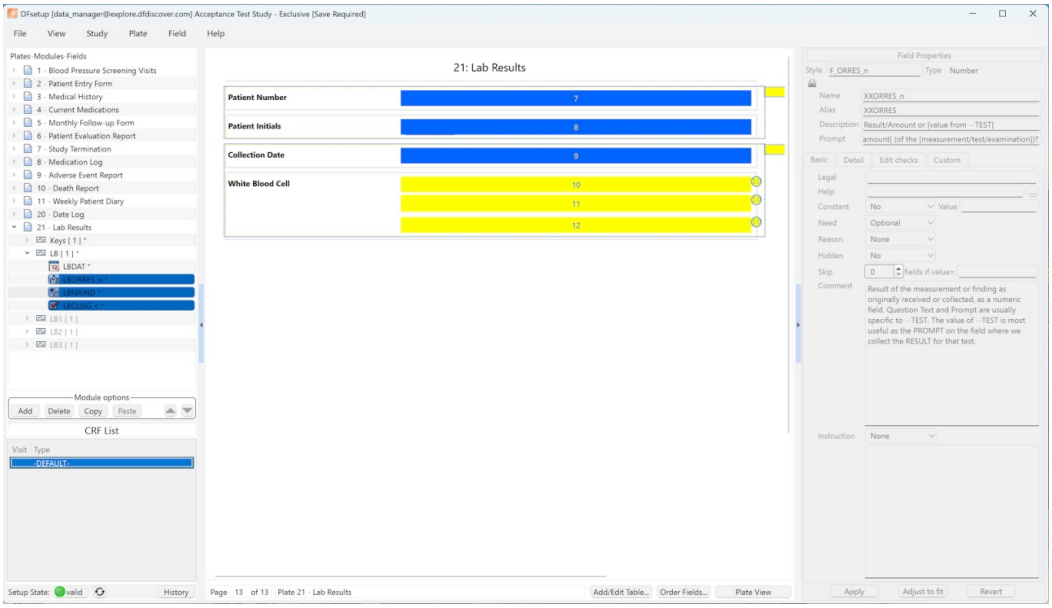
4.1.5. Within **Plates-Modules-Fields Module options** Click Add. Check (enable) **Keys**, **LB**, **LB1**, **LB2**, **LB3** modules, click OK.



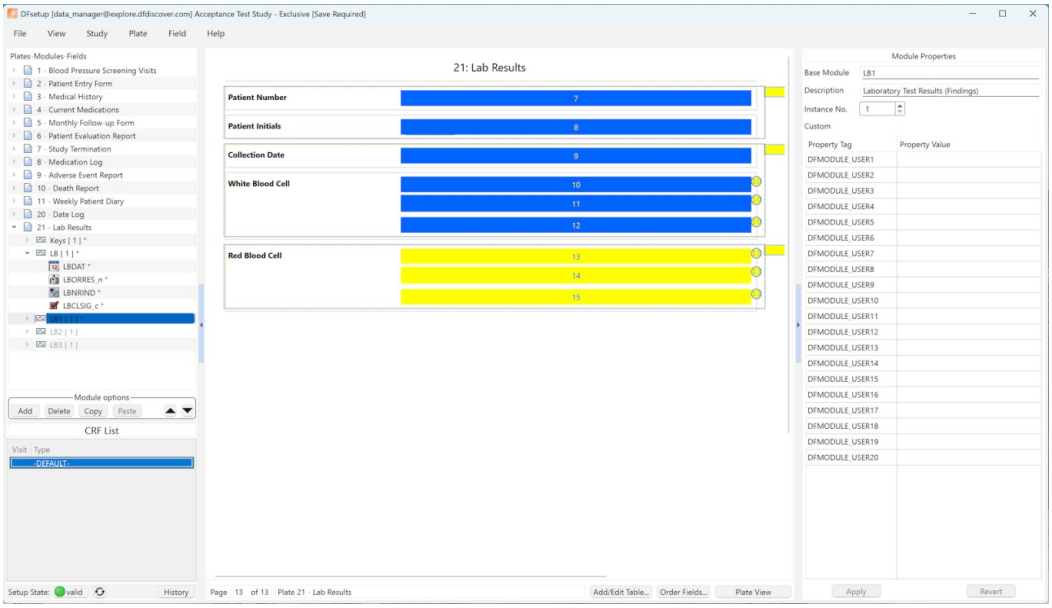
4.1.6. Double-click the **Keys [1]** module to expand the list of fields. Using your mouse, click and drag the **SUBJID** and **PINIT** fields onto the **21: Lab Results** eCRF.



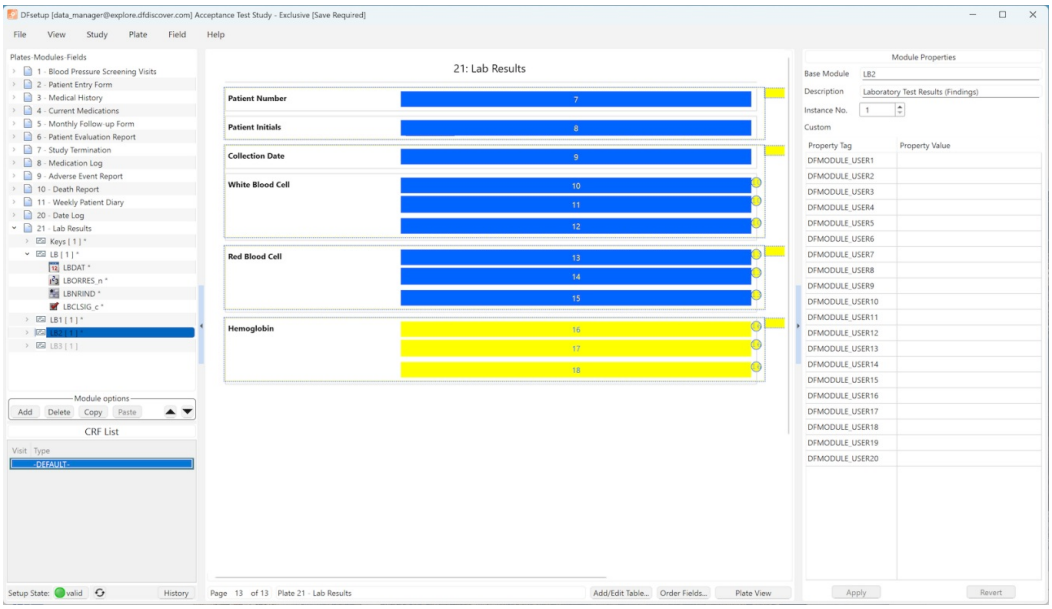
4.1.7. Click **LB [1]** module, drag the module onto the eCRF, select **LBORRES_n**, **LBNRIND** and **LBCLSIG_c** fields by holding Shift and clicking on the fields. Select Field > Group.



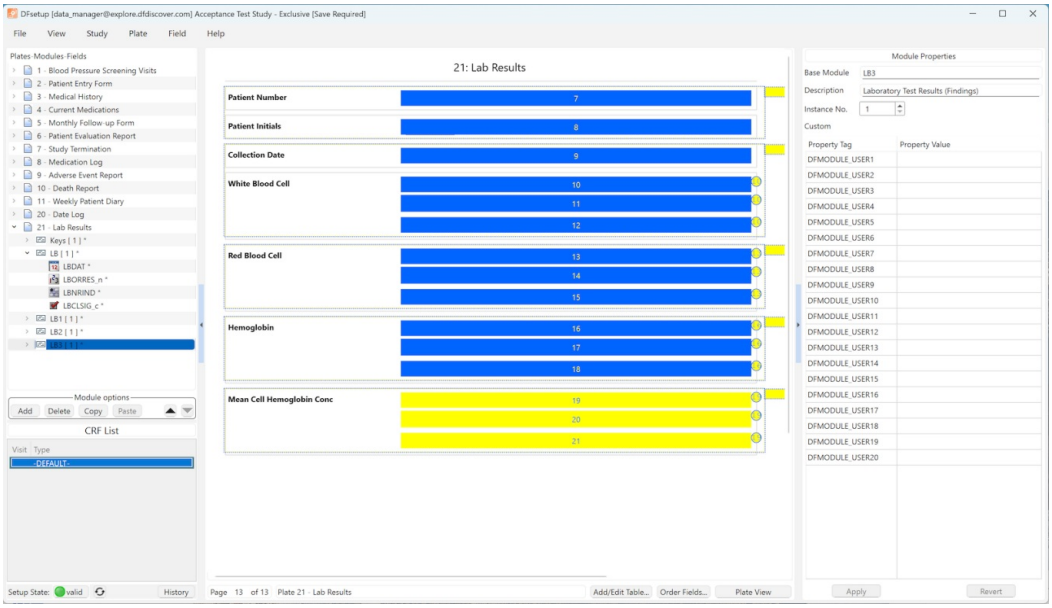
4.1.8. Click **LB1 [1]** Module, drag the module onto the eCRF. Select Field > Group.



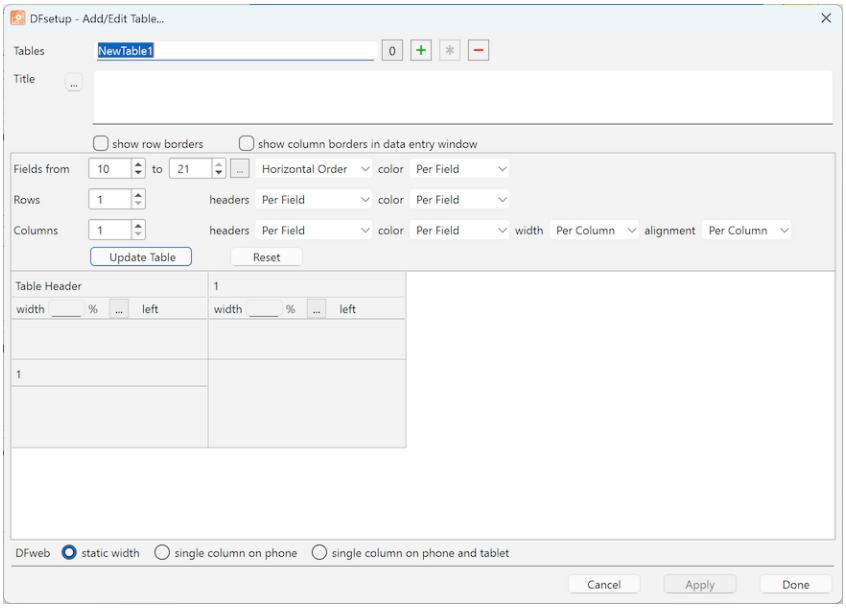
4.1.9. Click **LB2 [1]** Module, drag the module onto the eCRF. Select Field > Group.



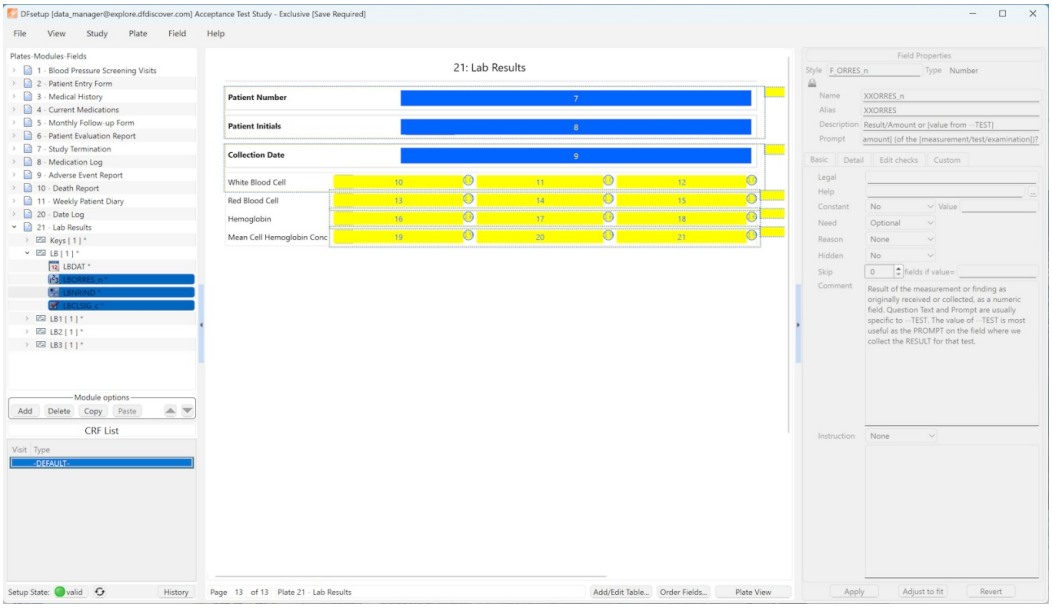
4.1.10. Click **LB3 [1]** Module, drag the module onto the eCRF. Select Field > Group.



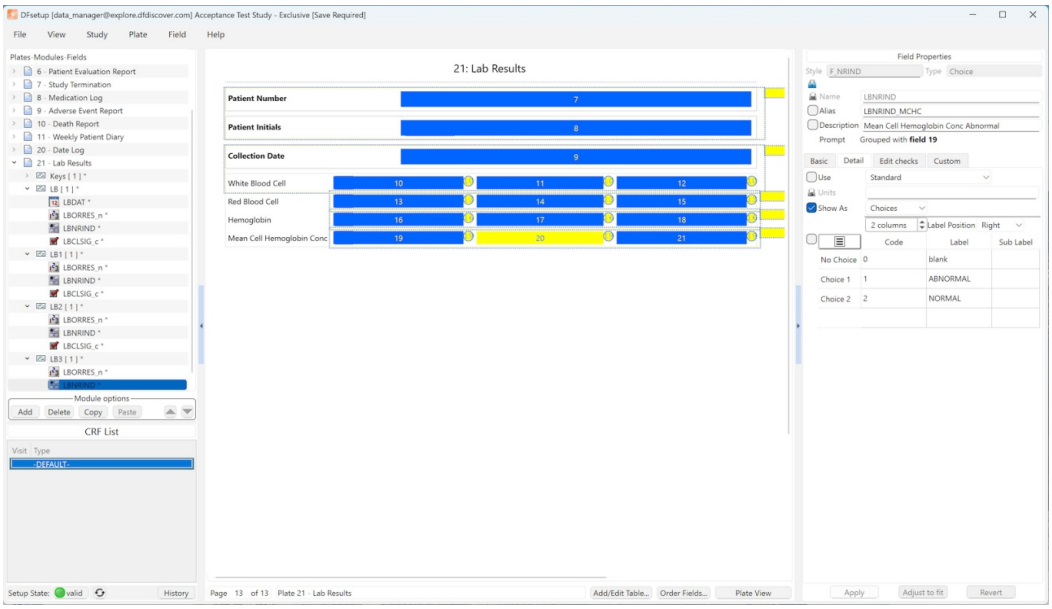
4.1.11. Select fields 10 through 21 by holding Shift and clicking on the fields. Select Field > Add/Edit Table.



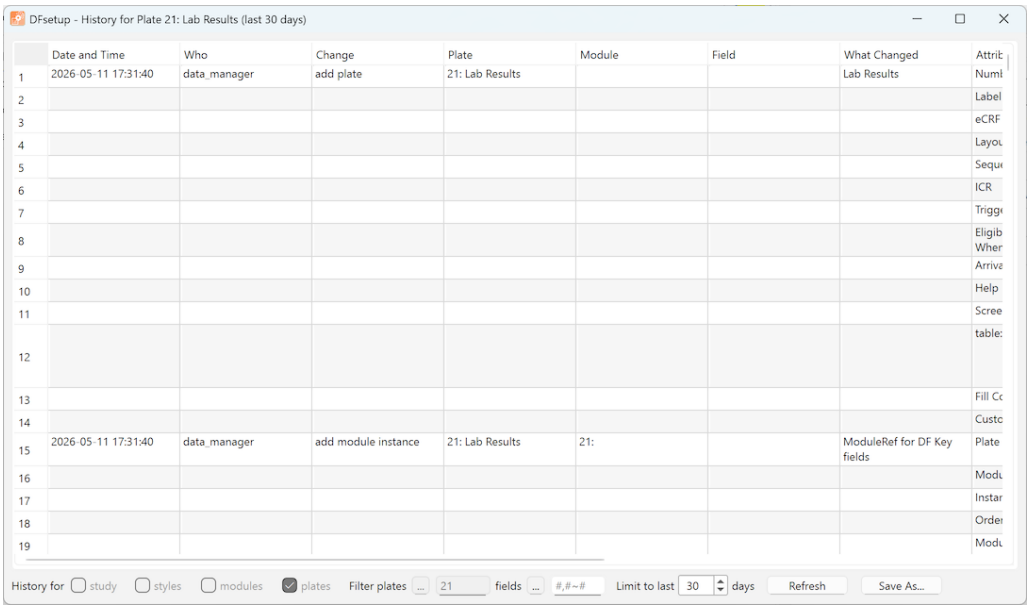
4.1.12. In the Add/Edit Table dialog, specify 4 rows and 3 columns. Under Rows > headers, select **Field Prompt** from the dropdown. Click Update Table. In column 2, select **show coding label** and specify width as 35%. In column 3, select **show coding label**. Under **DFweb**, select **single column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



4.1.13. 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**.



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



4.1.15. 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.

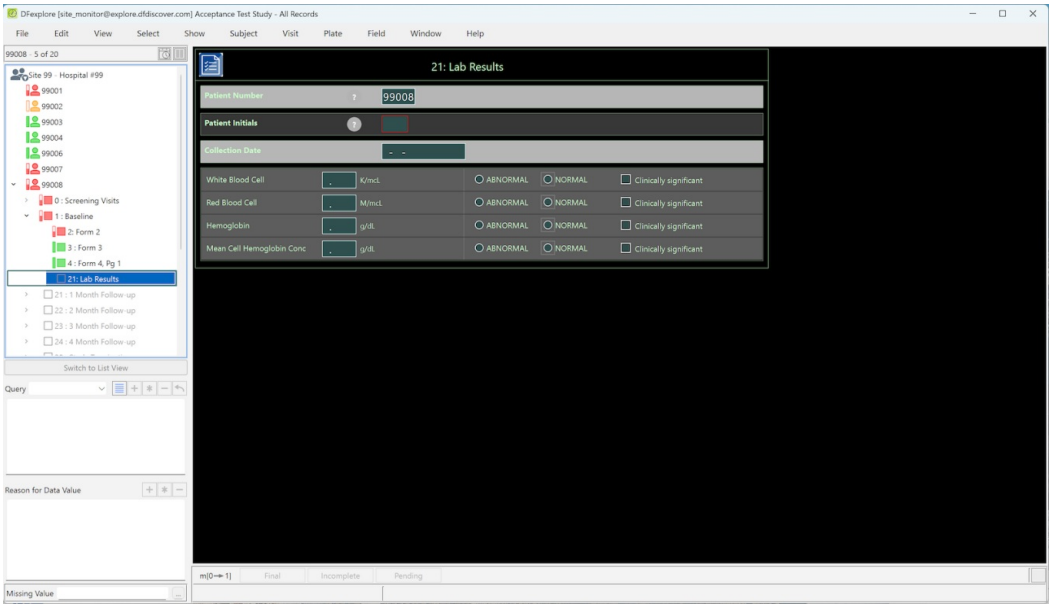
4.1.16. Select File > Exit to close **DFsetup**.

4.2 eCRF background color preferences

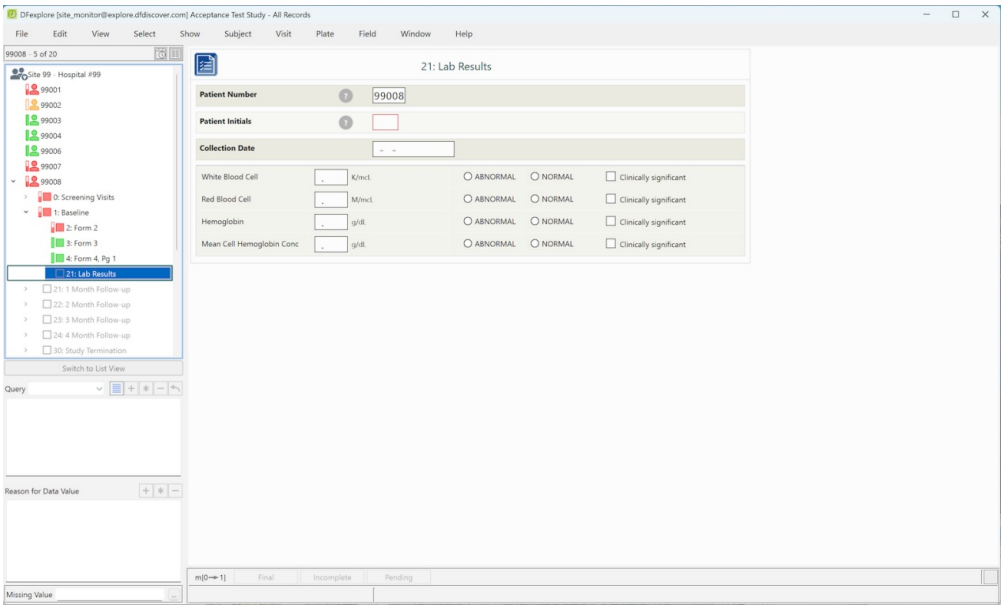
4.2.1. Start **DFexplore**, login as user site_monitor and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**".

4.2.2. Click **Site 99 - Hospital #99** > **99008** > **1: Baseline** > **21: Lab Results** to make it the active page.

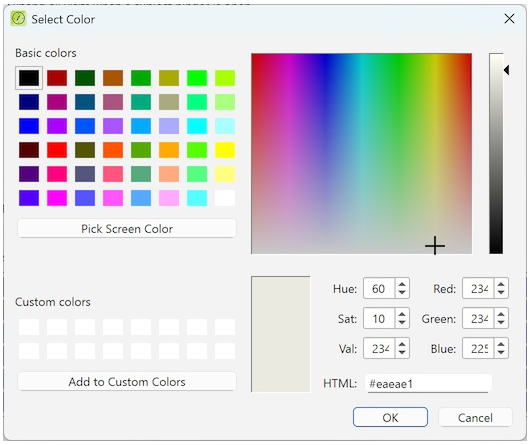
> NOTE: **DFexplore** stores previously defined user preferences. If site_monitor previously used **DFexplore** and modified user preferences, you may see a different background than what is illustrated below.



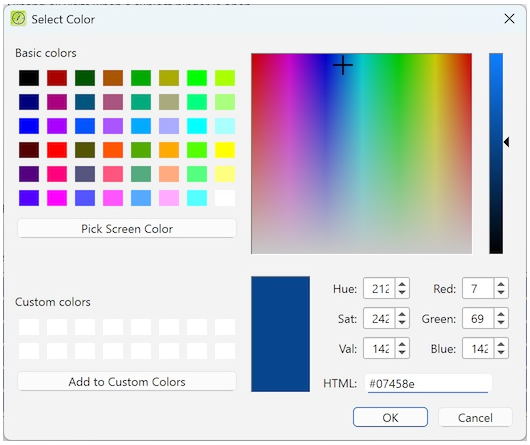
4.2.3. Select File > Preferences, click **Background Options** to expand the preferences. Click **Color** then OK to apply the changes.



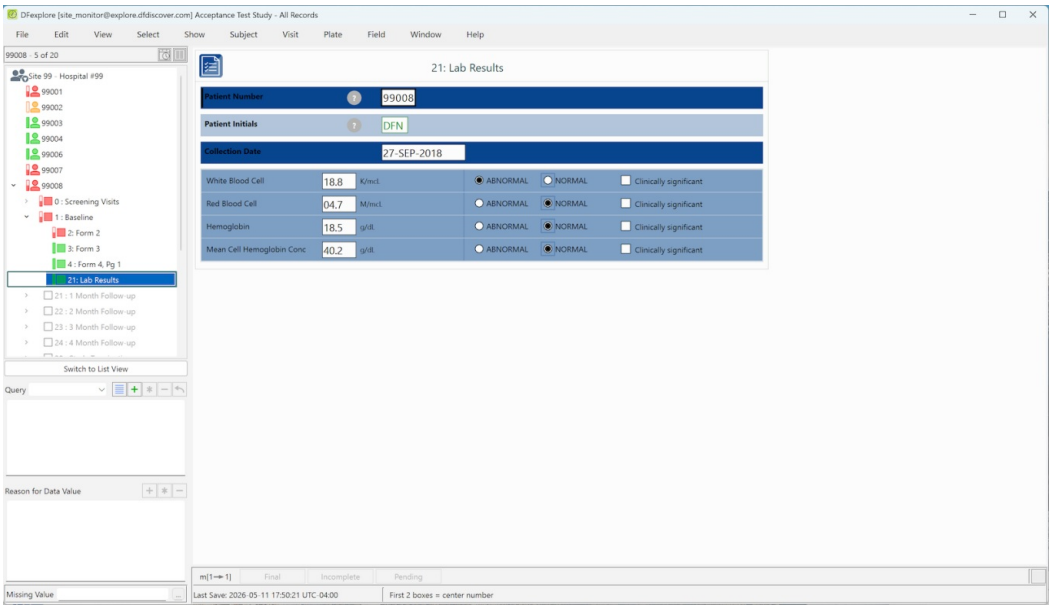
4.2.4. Select File > Preferences > **Data Window**, within **eCRF background color**, click + to open the **Select Color** window.



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

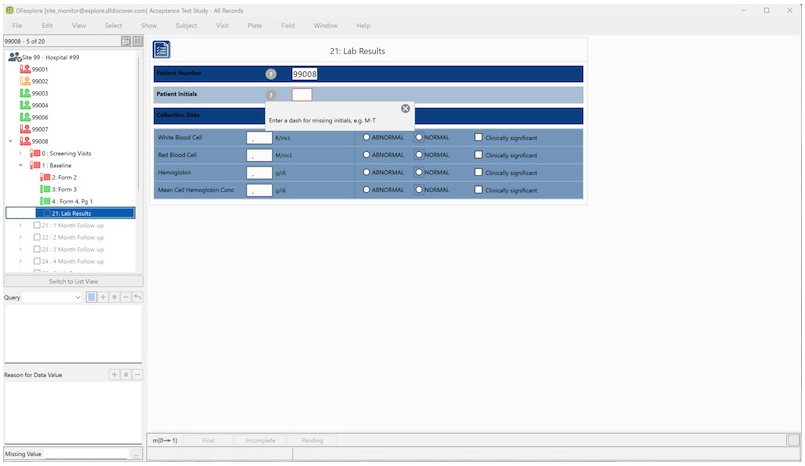


4.2.6. Click OK to close the **Select Color** window, click OK to apply your color preferences.



4.3 Entering eCRF data

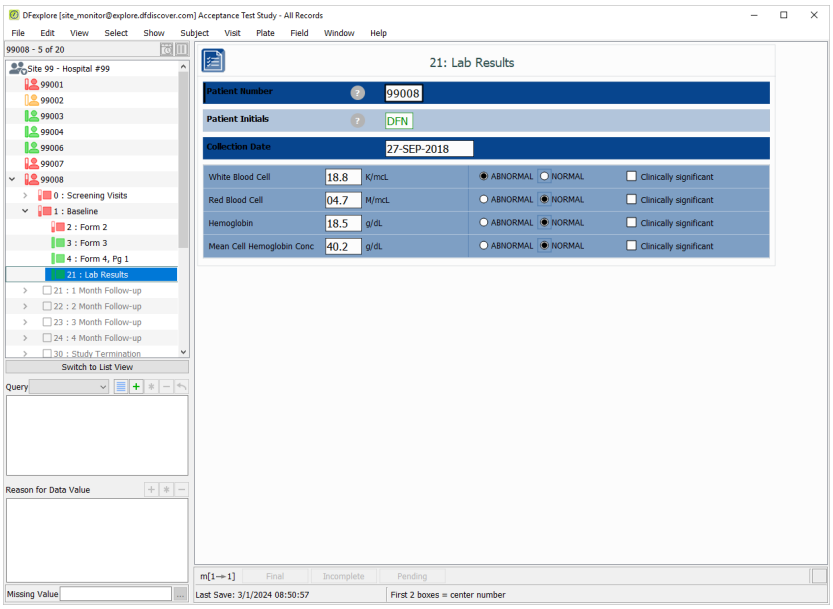
4.3.1. Click ? within the **Patient Initials** field to display the field level help. Click [⊗] to close the help dialog.



4.3.2. 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 SetInitdescribed in Module 8. Image Data Entry. Set:

- **Collection Date** = 27-SEP-2018
- **White Blood Cell** = 18.8, Check (enable) **Abnormal**.
- **Red Blood Cell** = 4.7, Check (enable) **Normal**
- **Hemoglobin** = 18.5, Check (enable) **Normal**
- **Mean Cell Hemoglobin Conc** = 40.2, Check (enable) **Normal**

Click Final to save the data record.



4.3.3. 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.

5 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

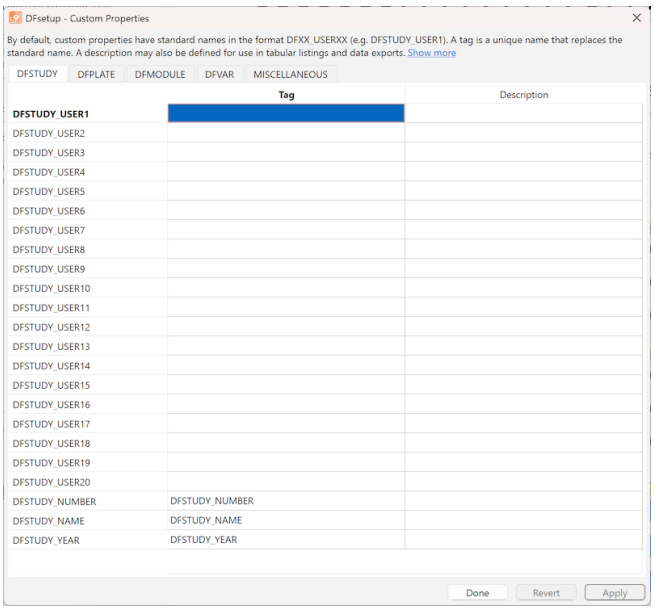
1. Start **DFATK** as described in Module 1 (Installation & Initialization).
2. Click 5. Custom Properties followed by Begin to begin this module.
3. This module requires user data_manager to have exclusive access to the 254 Acceptance Test Study database, the Control Panel must be closed. Click Exit.

5.1 Defining Custom Properties in **DFsetup**

5.1.1. Start **DFsetup**, login as data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFsetup**".

5.1.2. 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.

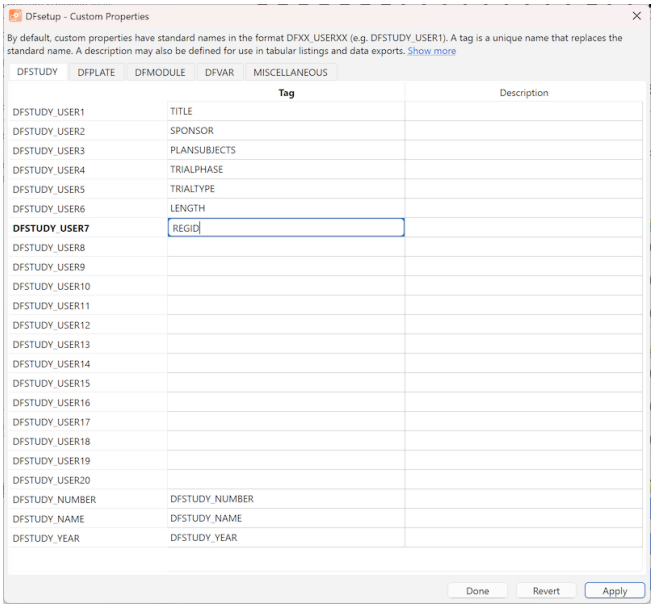
5.1.3. Select Study > Custom Properties.



5.1.4. Click **DFSTUDY** tab, followed by the empty **Tag** cell for **DFSTUDY_USER1** to make it the active field.

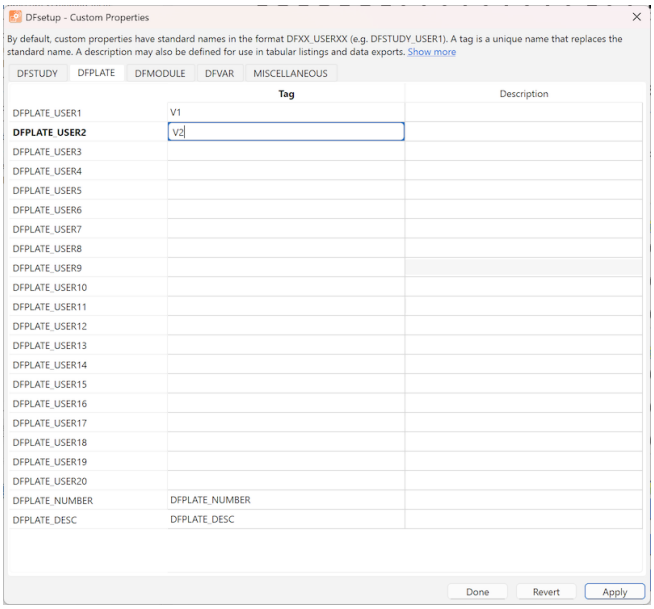
5.1.5. Beginning with **DFSTUDY_USER1** cell. Enter the Custom Properties for **DFSTUDY** as follows:

- **DFSTUDY_USER1** = TITLE
- **DFSTUDY_USER2** = SPONSOR
- **DFSTUDY_USER3** = PLANSUBJECTS
- **DFSTUDY_USER4** = TRIALPHASE
- **DFSTUDY_USER5** = TRIALTYPE
- **DFSTUDY_USER6** = LENGTH
- **DFSTUDY_USER7** = REGID



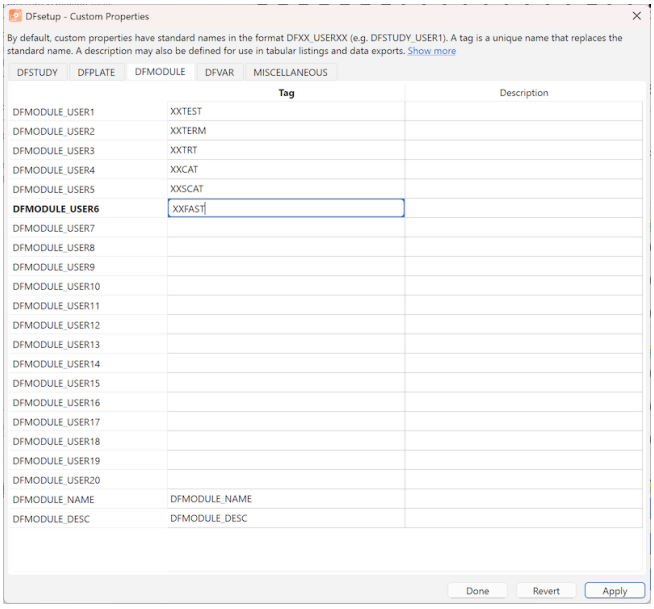
5.1.6. Click **DFPLATE** tab, followed by the empty **Tag** cell for **DFPLATE_USER1**. Enter the Custom Properties for **DFPLATE** as follows:

- **DFPLATE_USER1** = V1
- **DFPLATE_USER2** = V2



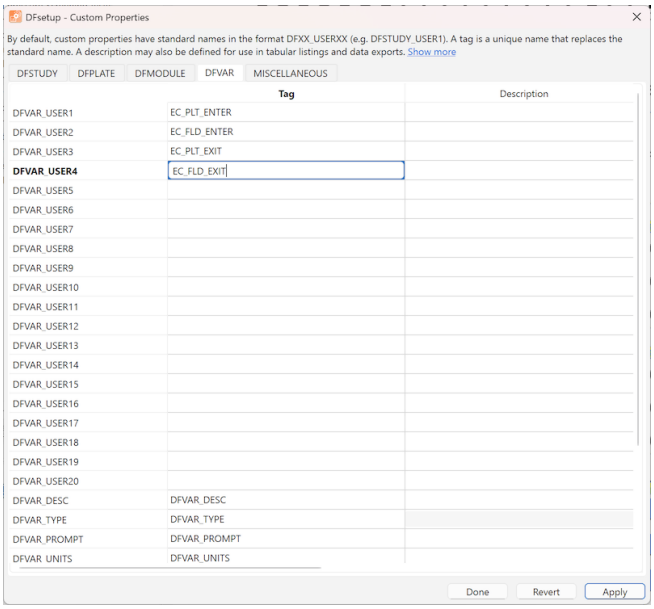
5.1.7. Click **DFMODULE** tab, followed by the empty **Tag** cell for **DFMODULE_USER1**. Enter the Custom Properties for **DFMODULE** as follows:

- **DFMODULE_USER1** = XXTEST
- **DFMODULE_USER2** = XXTERM
- **DFMODULE_USER3** = XXTRT
- **DFMODULE_USER4** = XXCAT
- **DFMODULE_USER5** = XXSCAT
- **DFMODULE_USER6** = XXFAST



5.1.8. Click **DFVAR** tab, followed by the empty cell for **DFVAR_USER1**. Enter the Custom Properties for **DFVAR** as follows:

- **DFVAR_USER1** = EC_PLT_ENTER
- **DFVAR_USER2** = EC_FLD_ENTER
- **DFVAR_USER3** = EC_PLT_EXIT
- **DFVAR_USER4** = EC_FLD_EXIT



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

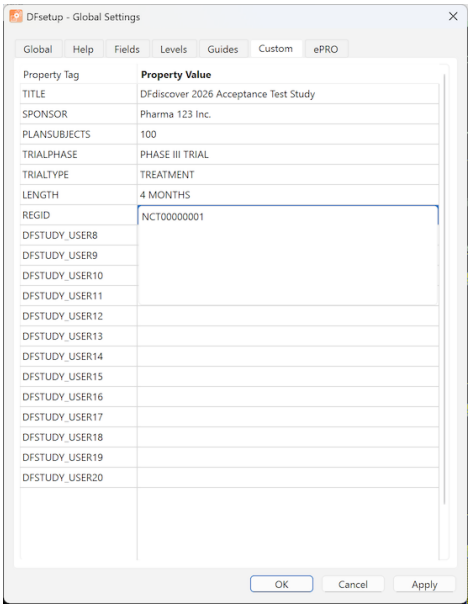
5.2 Adding Global Custom Property values

5.2.1. Select Study > Global Settings>. Click **Custom** tab.

5.2.2. 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.



5.3 Adding Plate, Module and Variable level Custom Property values

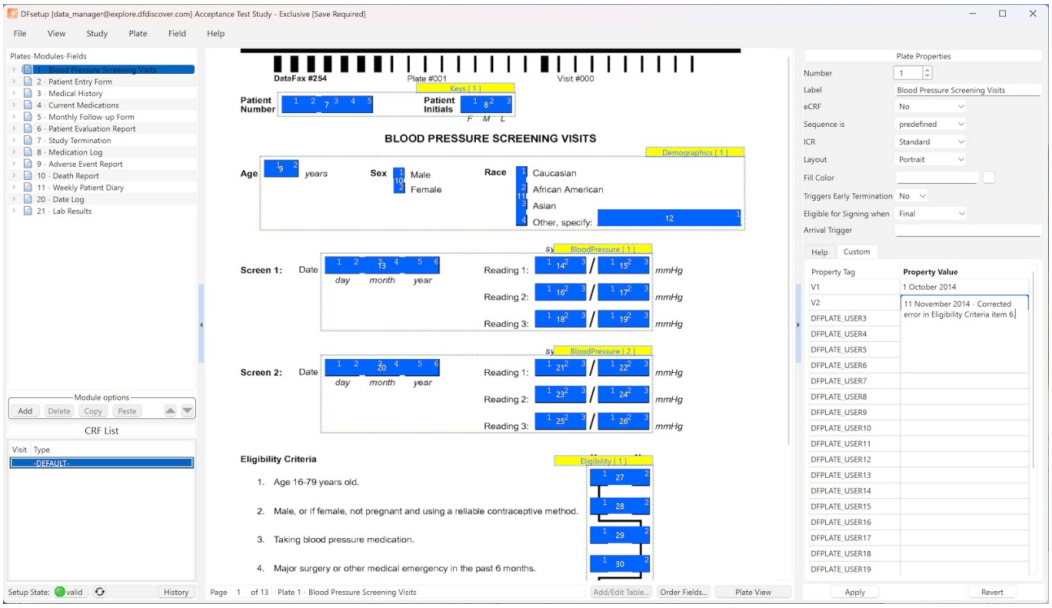
5.3.1. Click **1 - Blood Pressure Screening Visits** to make it the active page. Within the **Plate Properties** window click **Custom** tab.

5.3.2. Enter the **Property Value** tags as follows:

- **V1** = 1 October 2014

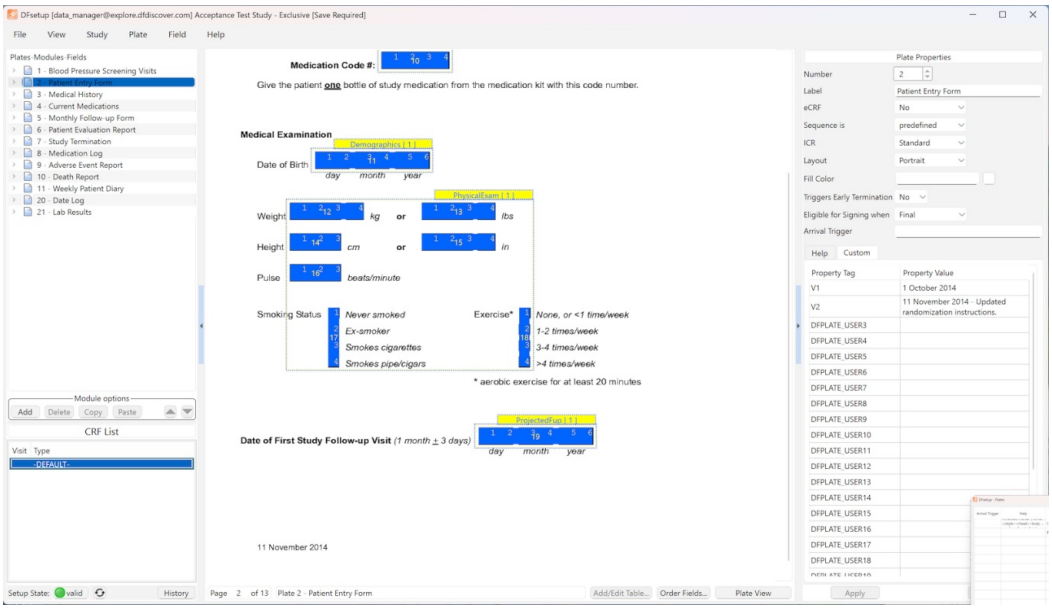
- **V2** = 11 November 2014 - Corrected error in Eligibility Criteria item 6.

Click Apply.



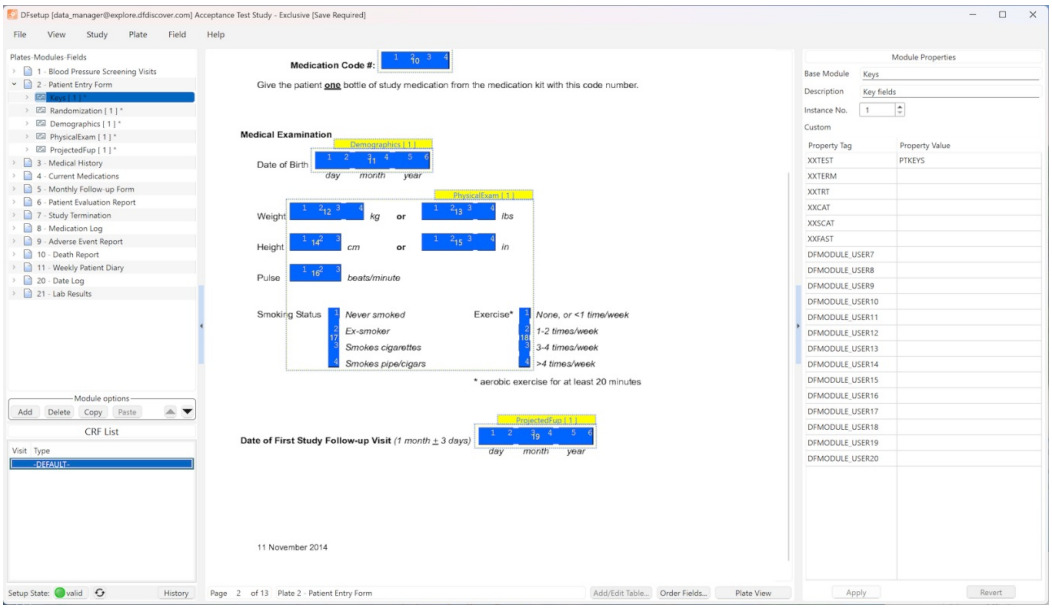
5.3.3. Select View > Plates.

5.3.4. 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.

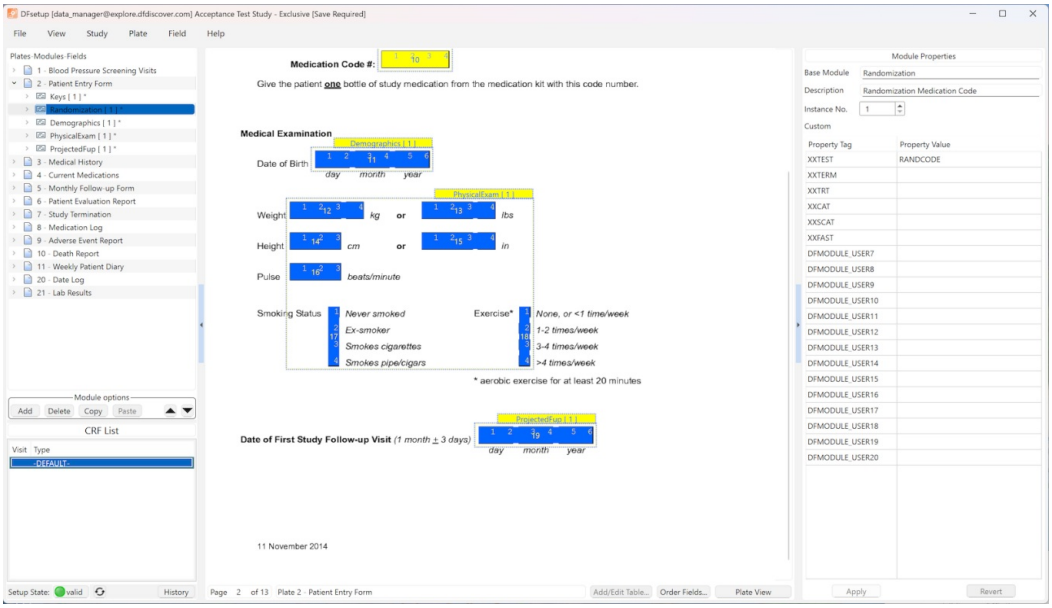


5.3.5. From the **Plates-Modules-Fields** window double-click **2 - Patient Entry Form**. Click **Keys [1]** to make the module active.

5.3.6. In the **Module Properties** window specify PTKEYS for the **XXTEST Property Value**. Click Apply.

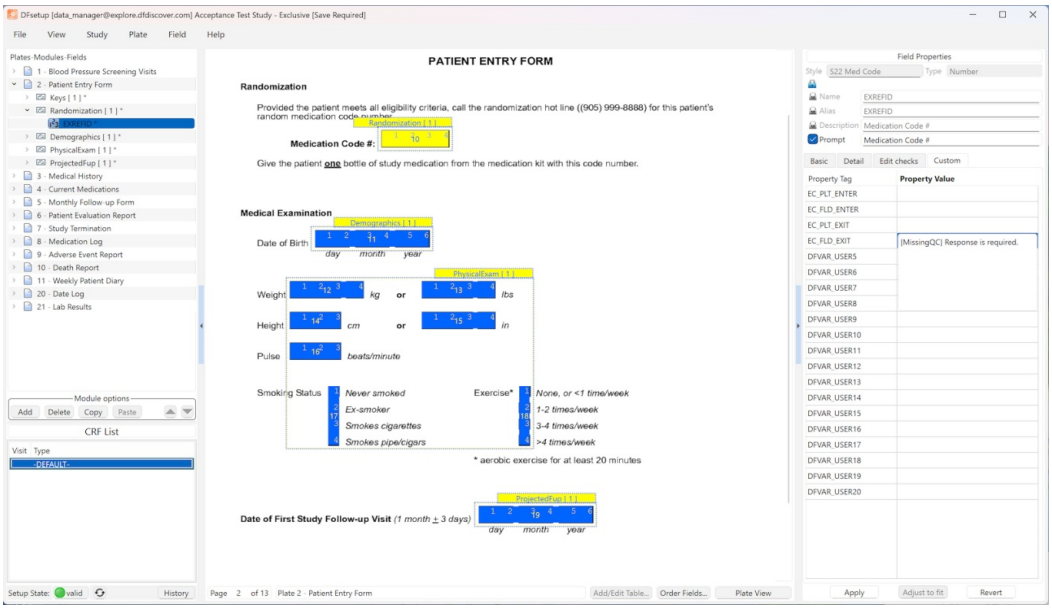


5.3.7. Double-click **Randomization [1]**. In the **Module Properties** window specify RANDCODE for the **XXTEST Property Value**. Click Apply.



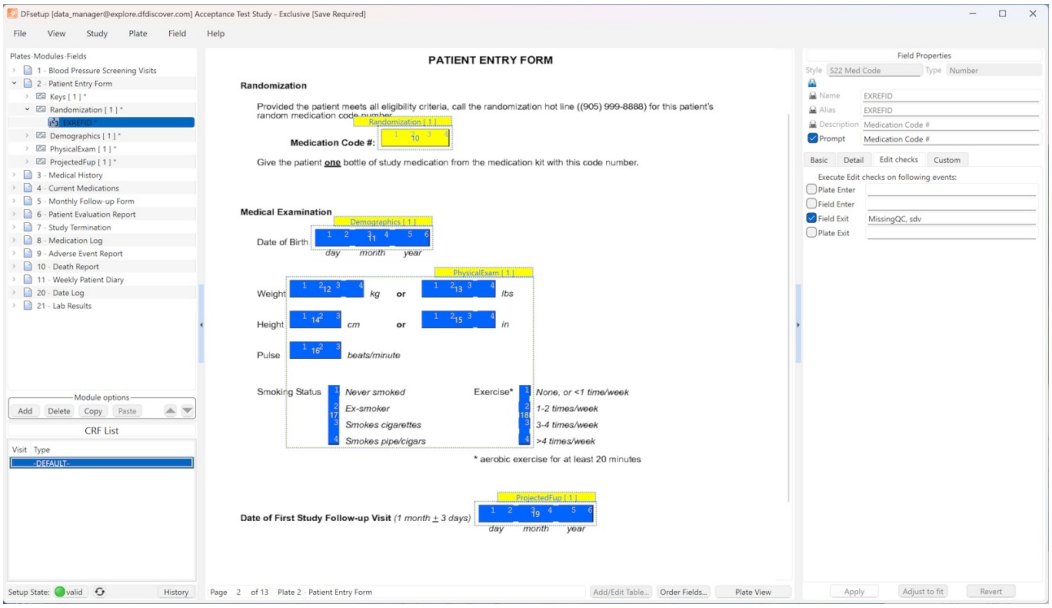
5.3.8. Select **Medication Code #** field. Click **Custom** from the **Field Properties** window.

5.3.9. Enter [MissingQC] Response is required. in the **EC_FLD_EXIT Property Value**.

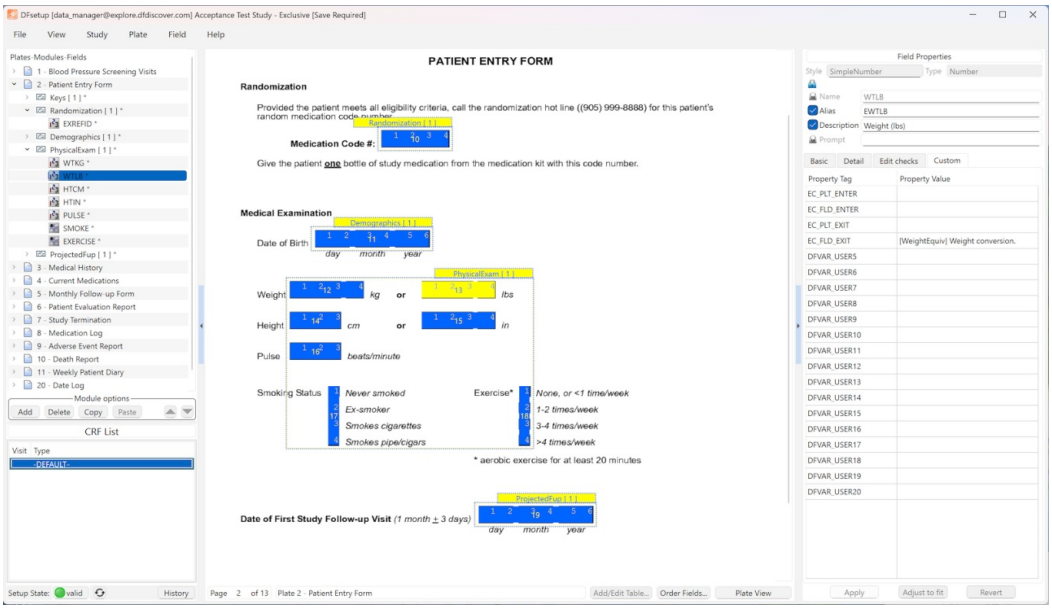


5.3.10. Click **Edit checks** tab within the **Field Properties** window.

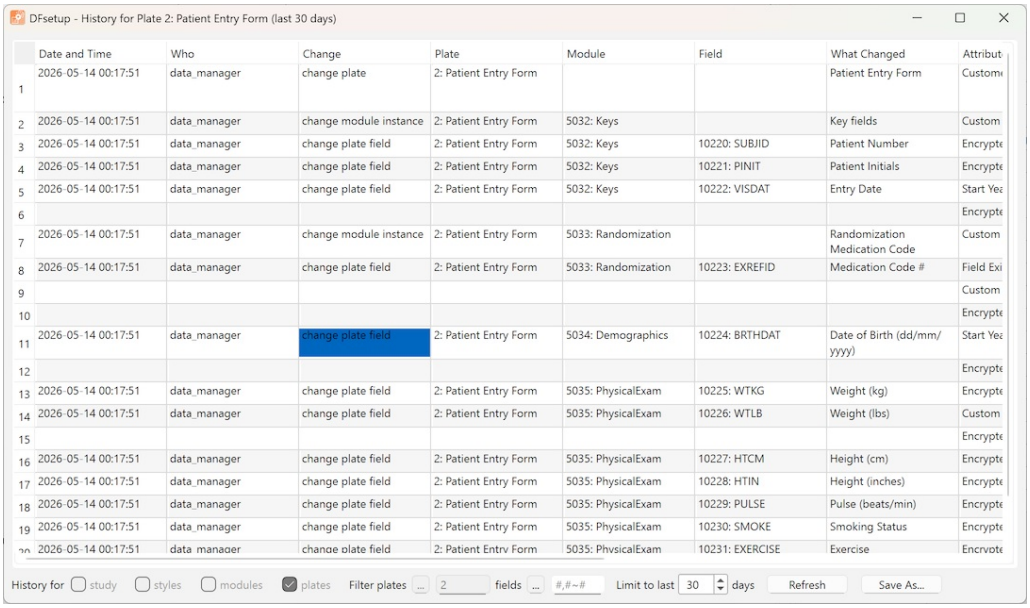
5.3.11. Enter MissingQC, sdv next to **Field Exit**, click Apply.



5.3.12. Click **Weight (lbs)** field, then **Custom**. Enter [WeightEquiv] Weight conversion. in the **EC_FLD_EXIT Property Value**. Click Apply.



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



5.3.1. 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.

5.4 Exporting Custom Properties in **DFsetup**

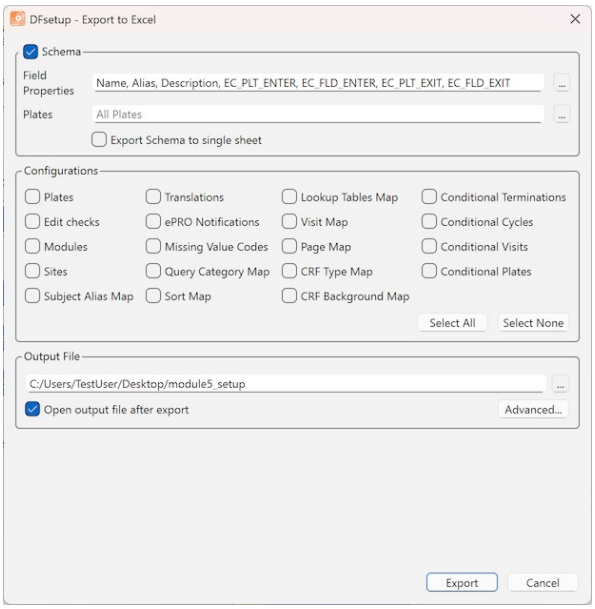
5.4.1. Select File > Export Setup > Excel.

5.4.2. Click **Field Properties** ....

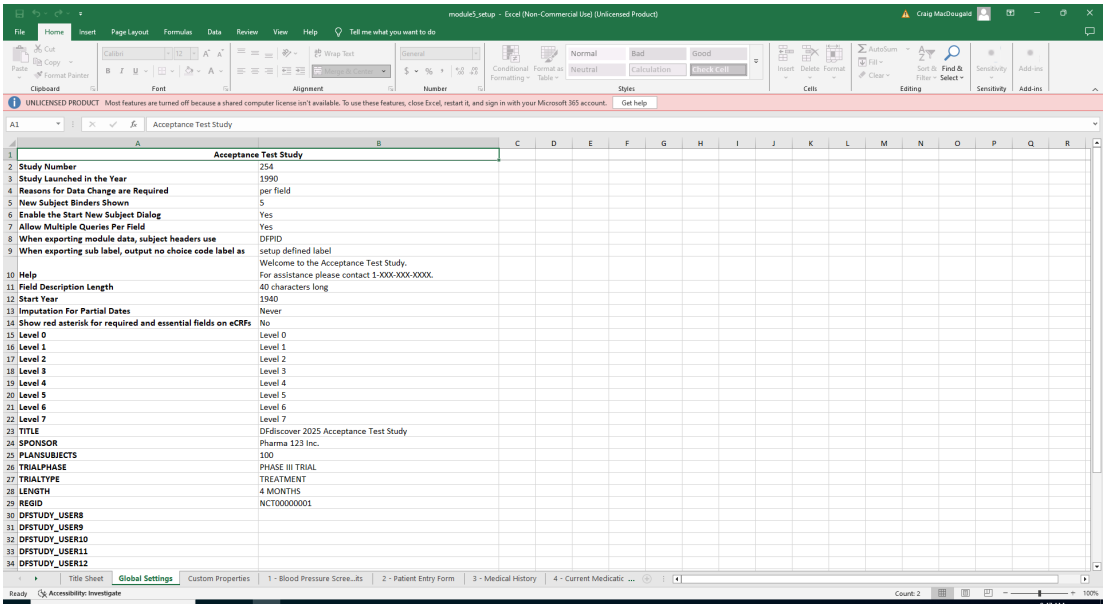
5.4.3. In the resulting dialog, click Select none.

5.4.4. Select **Name**, **Alias**, **Description**, **EC_PLT_ENTER**, **EC_FLD_ENTER**, **EC_PLT_EXIT** and **EC_FLD_EXIT**. Click OK.

5.4.5. Specify module5_setup.xlsx as the **Output File** name, enable (check) **Open output file after export.**. Click Export.

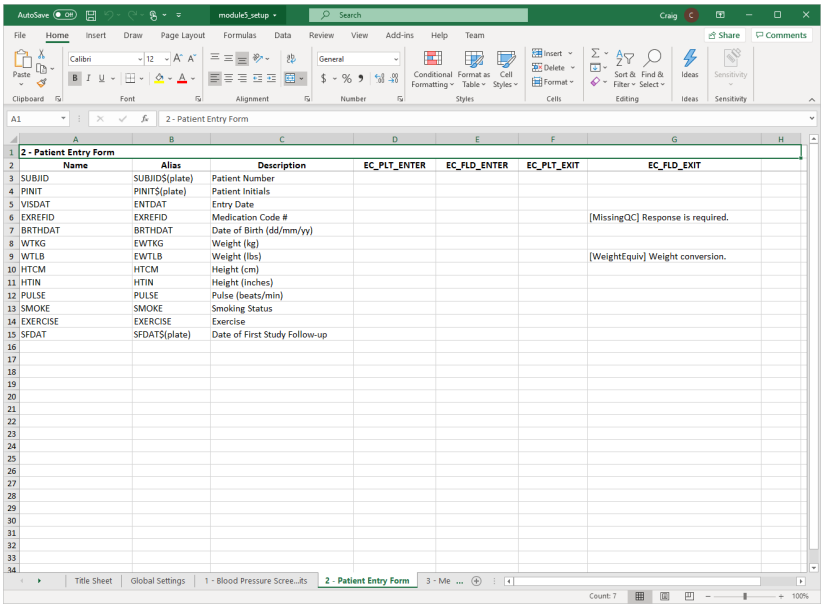


5.4.6. In the exported Excel file open the **Global Settings** tab to view the newly defined Global Property tags.



	A	B
1	**Acceptance Test Study**	
2	**Study Number**	254
3	**Study Launched in the Year**	1990
4	**Reasons for Data Change are Required**	per field
5	**New Subject Binders Shown**	5
6	**Enable the Start New Subject Dialog**	Yes
7	**Allow Multiple Queries Per Field**	Yes
8	**When exporting module data, subject headers use**	DFPID
9	**When exporting sub label, output no choice code label as**	setup defined label
		Welcome to the Acceptance Test Study.
10	**Help**	For assistance please contact 1-XXX-XXX-XXXX.
11	**Field Description Length**	40 characters long
12	**Start Year**	1940
13	**Imputation For Partial Dates**	Never
14	**Show red asterisk for required and essential fields on eCRFs**	No
15	**Level 0**	Level 0
16	**Level 1**	Level 1
17	**Level 2**	Level 2
18	**Level 3**	Level 3
19	**Level 4**	Level 4
20	**Level 5**	Level 5
21	**Level 6**	Level 6
22	**Level 7**	Level 7
23	**TITLE**	DFdiscover 2025 Acceptance Test Study
24	**SPONSOR**	Pharma 123 Inc.
25	**PLANSUBJECTS**	100
26	**TRIALPHASE**	PHASE III TRIAL
27	**TRIALTYPE**	TREATMENT
28	**LENGTH**	4 MONTHS
29	**REGID**	NCT00000001
30	**DFSTUDY_USER8**	
31	**DFSTUDY_USER9**	
32	**DFSTUDY_USER10**	
33	**DFSTUDY_USER11**	
34	**DFSTUDY_USER12**	

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



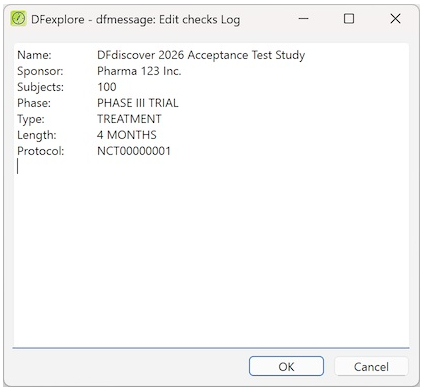
	A	B	C	D	E	F	G	H
1	**2 - Patient Entry Form**							
2	**Name**	**Alias**	**Description**	**EC_PLT_ENTER**	**EC_FLD_ENTER**	**EC_PLT_EXIT**	**EC_FLD_EXIT**	
3	SUBJID	SUBJID$(plate)	Patient Number					
4	PINIT	PINIT$(plate)	Patient Initials					
5	VISDAT	ENTDAT	Entry Date					
6	EXREFID	EXREFID	Medication Code #				[MissingQC] Response is required.	
7	BRTHDAT	BRTHDAT	Date of Birth (dd/mm/yy)					
8	WTKG	EWTKG	Weight (kg)					
9	WTLB	EWTLB	Weight (lbs)				[WeightEquiv] Weight conversion.	
10	HTCM	HTCM	Height (cm)					
11	HTIN	HTIN	Height (inches)					
12	PULSE	PULSE	Pulse (beats/min)					
13	SMOKE	SMOKE	Smoking Status					
14	EXERCISE	EXERCISE	Exercise					
15	SFDAT	SFDAT$(plate)	Date of First Study Follow-up					

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

5.5 Edit checks execution of Custom Properties

5.5.1. 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**.

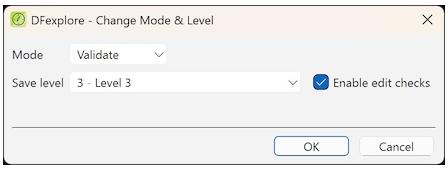


5.5.2. Select File > Preferences, click **Background Options** to expand the preferences. Click **Color** then OK to apply the changes.

5.5.3. Select Select > Change Mode & Level. Set:

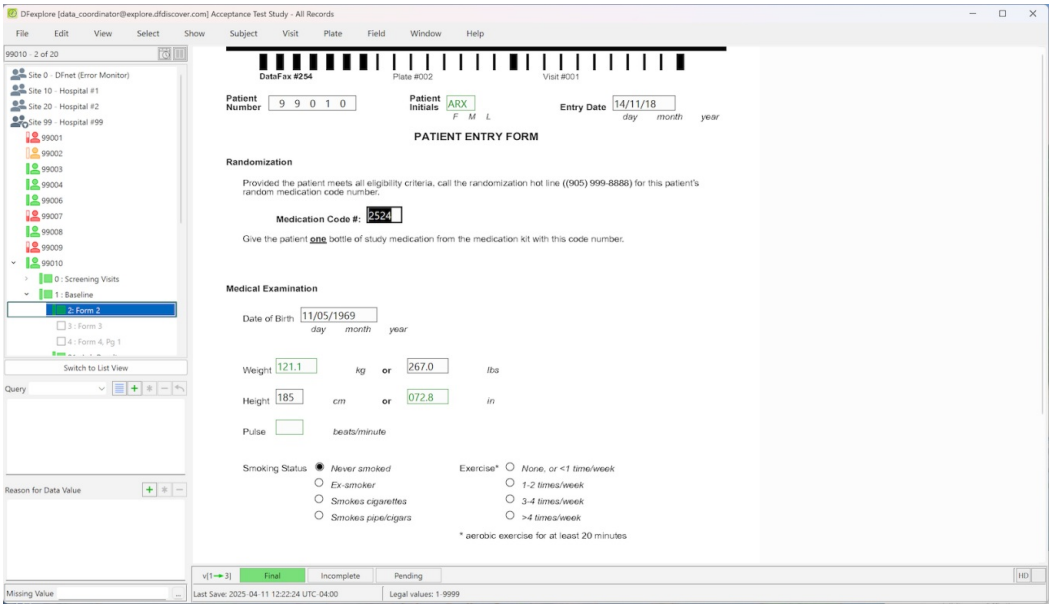
- **Mode** = Validate
- **Save level** = 3 - Level 3
- Check (enable) **Enable edit checks**.

Click OK.

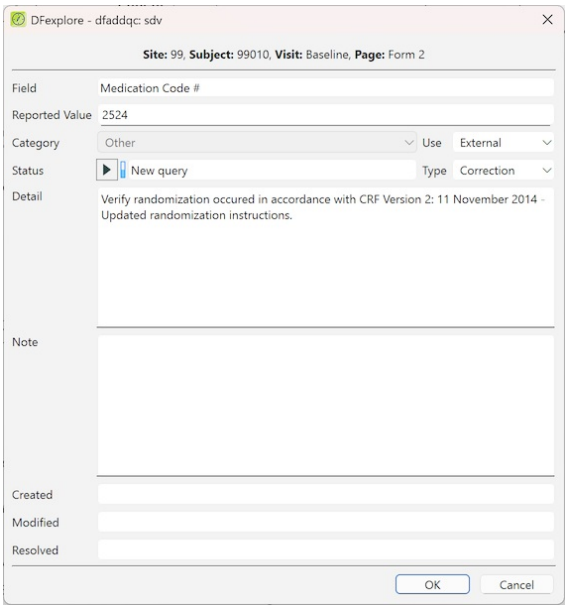


5.5.4. Double-click **Site 99 - Hospital #99** > **99010** > **1 : Baseline** > **2 : Form 2**.

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



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



5.5.7. Click OK to add the edit check containing the **Custom Property Value's** added in "Defining Custom Properties in **DFsetup**.".

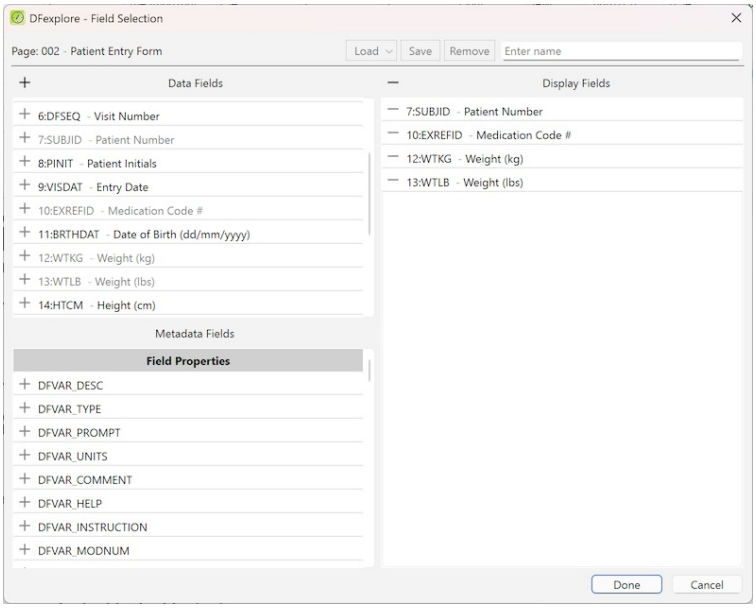
5.5.8. Press Tab to advance through the remainder of the fields on the **Patient Entry Form** page. Verify that the Save information bar at the bottom of the screen indicates that the saved page will be assigned a record **level of 3**. Click Incomplete.

5.6 Creating subject data lists and exporting data views

5.6.1. Select View > List.

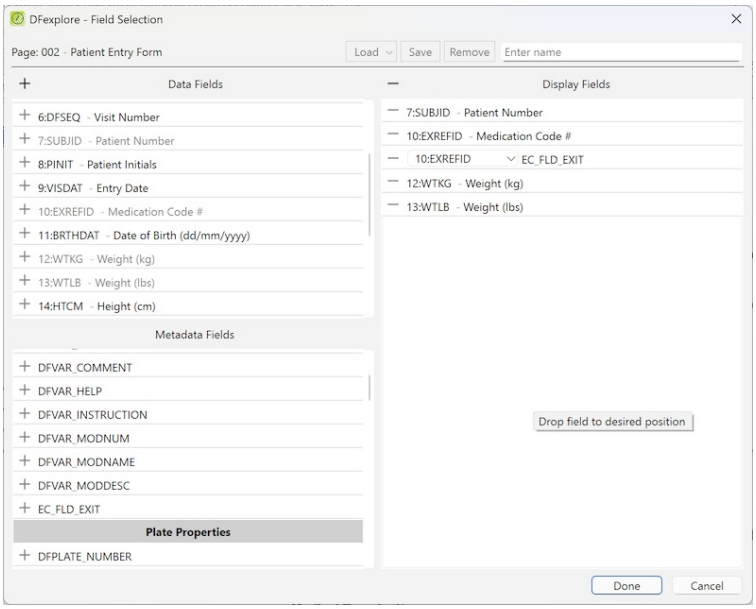
5.6.2. Click **002 - Patient Entry Form**.

5.6.3. 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**.

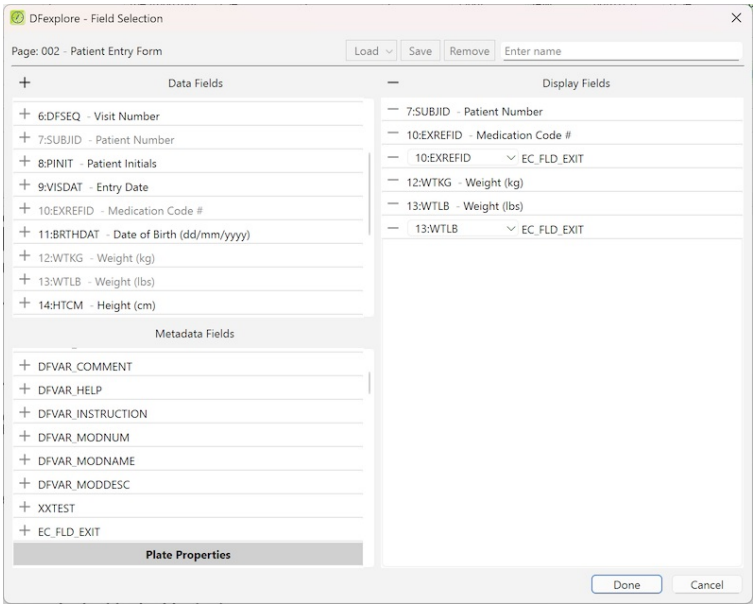


NOTE: Alternatively fields can also be added by dragging-and-dropping the desired fields from the **Data Fields** or **Metadata Fields** windows to the **Display Fields** window.

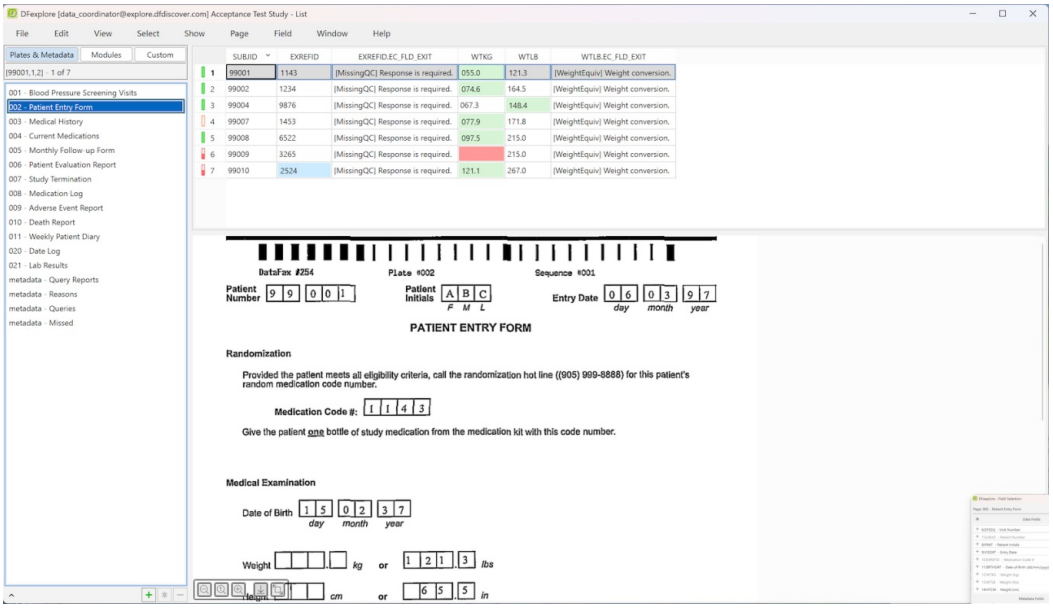
5.6.1. In the **Metadata Fields** window, click ⊞ next to field **EC_FLD_EXIT** to add the field to the **Display Fields window**. From the drop-down select **10:EXREFID**, click and drag the field to be below the **10:EXREFID - Medication Code #** field.



5.6.2. 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**.



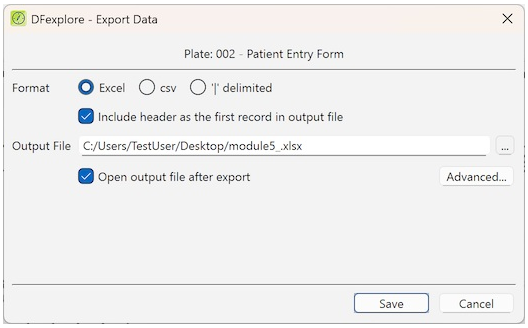
5.6.3. Click Done to apply the field selection criteria and close the dialog.



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

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

5.6.5. 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.

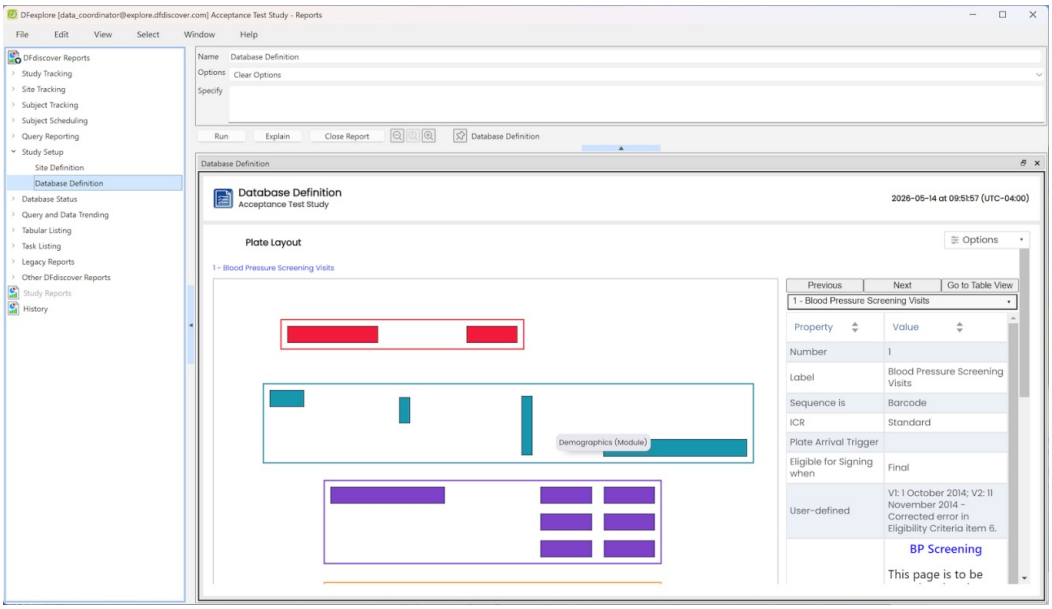


5.7 **DFexplore** Database Definition Report exporting

5.7.1. Select View > Reports.

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

5.7.3. Click Run.



5.7.4. Select File > Save Output as > Excel.

5.7.5. 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.

6 Module 6. Subject Alias

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 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.

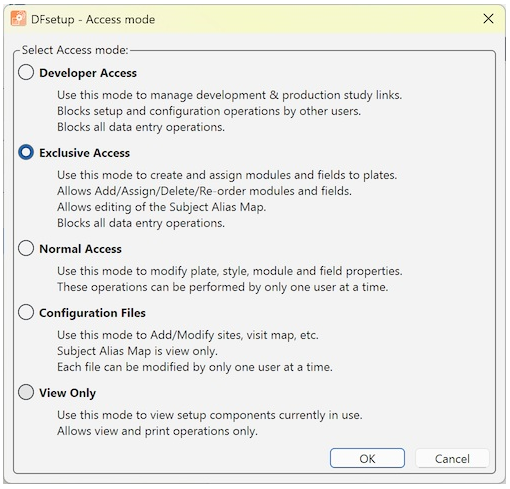
NOTE: Save the **subject_alias_map.csv** file received via email to your local computer. This file is required to complete the remainder of this module. Refer to "Creating user accounts and assigning study permissions." as a valid email address is required for data_manager to receive the module specific 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.

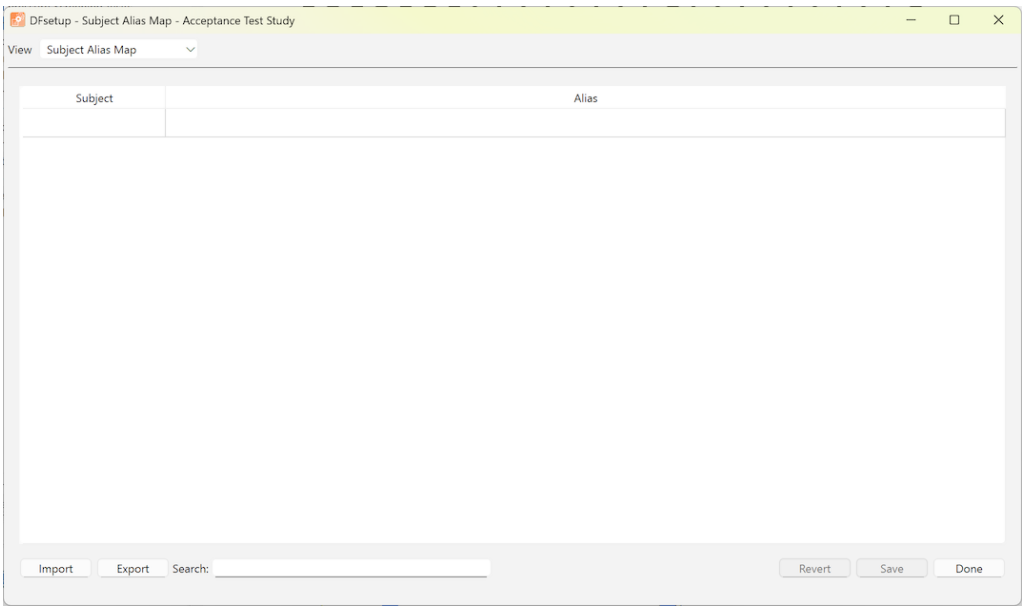
6.1 Importing and Modifying Subject Alias Map using **DFsetup**

6.1.1. Start **DFsetup**, login as user data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFsetup**".

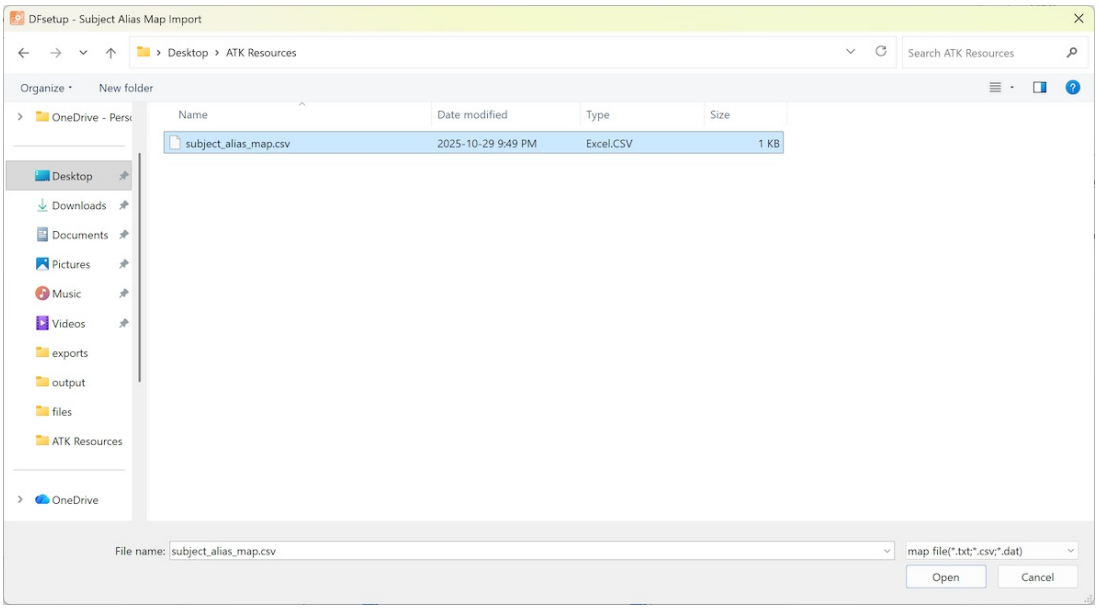
6.1.2. Choose **Exclusive Access** and click OK. **Exclusive Access** allows you to edit the Subject Alias Map.



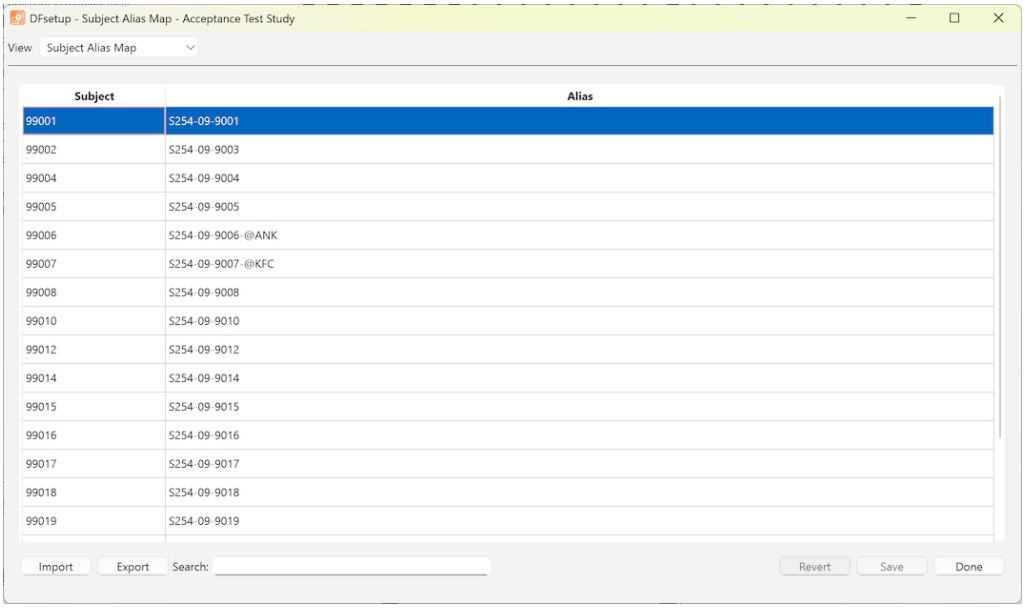
6.1.3. Select View > Subject Alias Map.



6.1.4. Click Import. From the file selection dialog, locate the previously saved subject_alias_map.csv file.



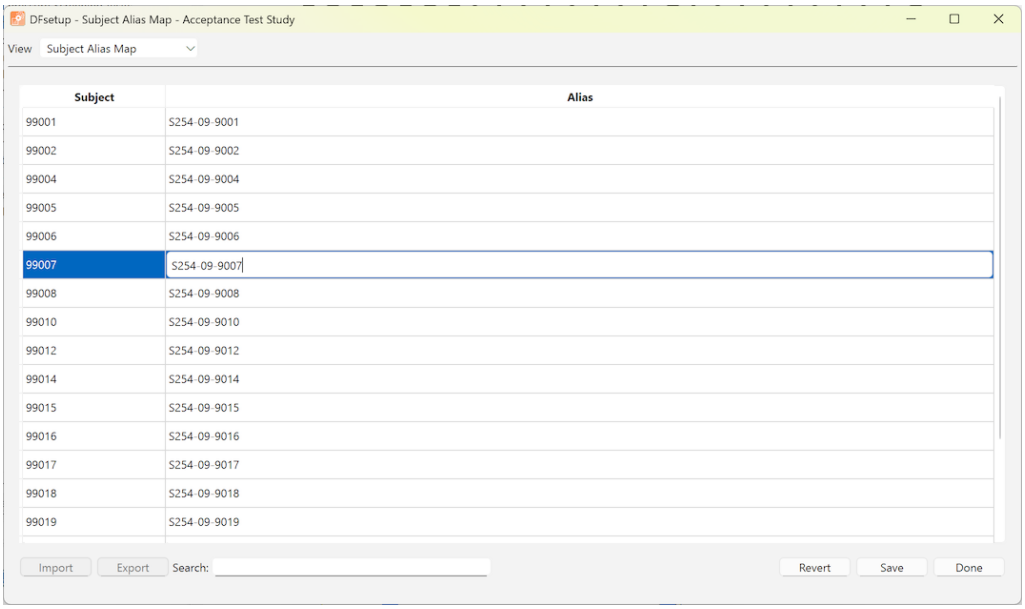
6.1.5. Select the file, click Open, then Save.



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).".

6.1.6. 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



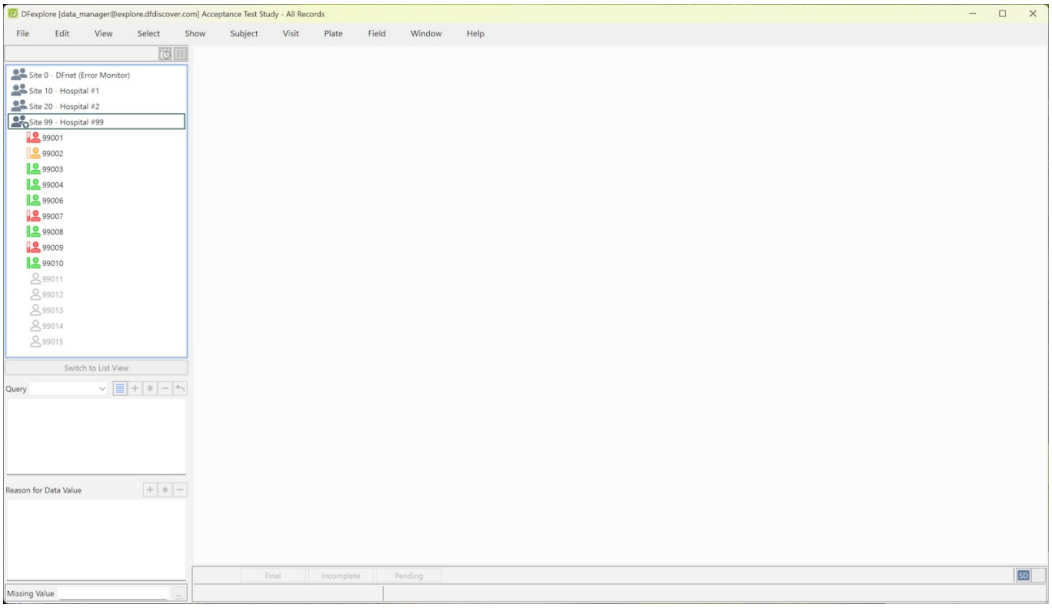
6.1.7. Click Save then Done to apply the modifications to the **Subject Alias Map**.

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

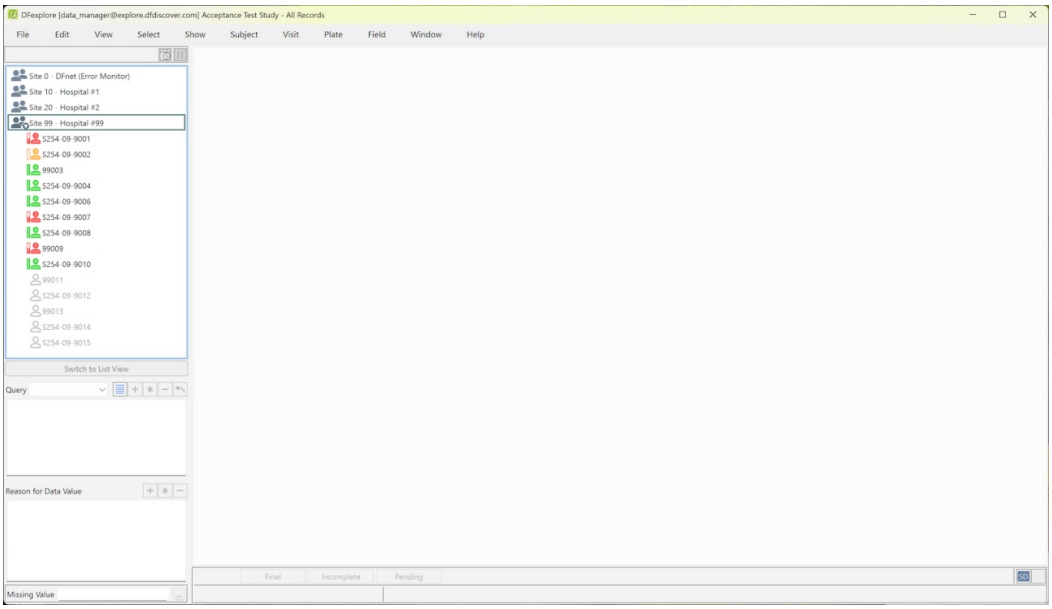
6.2 Creating Subjects using Subject Alias

6.2.1. Start **DFexplore**, login as user data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**".

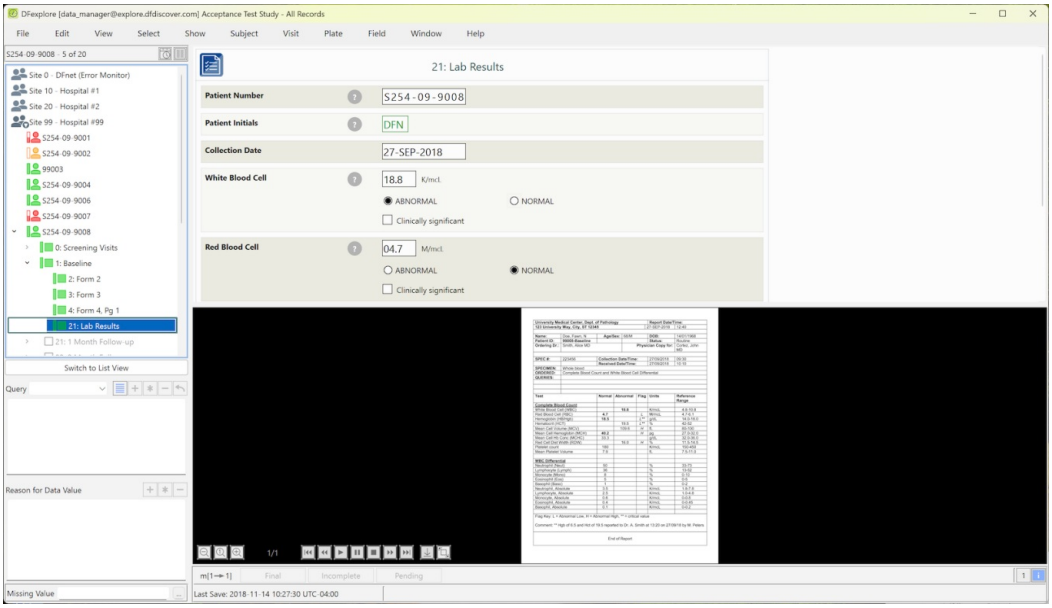
6.2.2. Double-click **Site 99 - Hospital #99** to open the list of available subjects.



6.2.3. Select File > Preferences. Check (enable) **Use subject alias**. Click OK. The Subject ID list now displays the Subject Alias Mapping as defined in **DFsetup**.



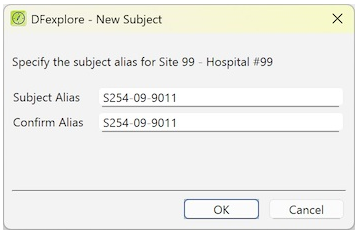
6.2.4. Click **Site 99 - Hospital #99** > **S254-09-9008** > **1: Baseline** > **21: Lab Results** to make it the active page.



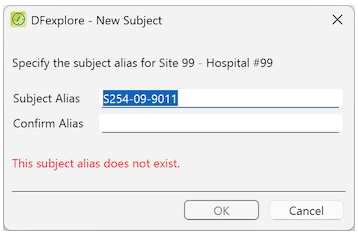
6.2.5. Select Subject > New Subject. Set:

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

Click OK.

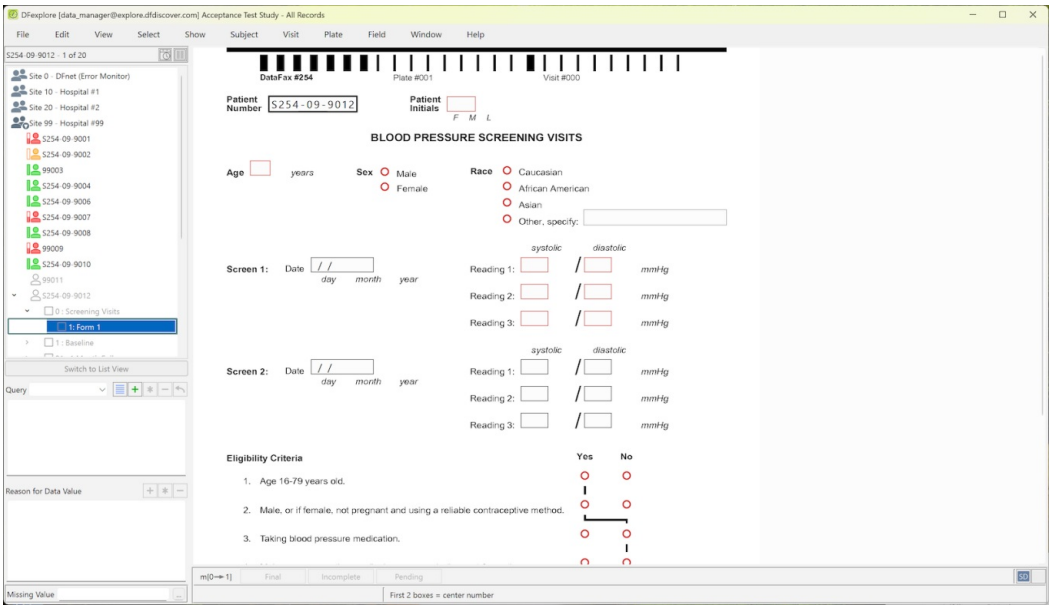


6.2.6. The message **This subject alias does not exist** is displayed. Click Cancel to dismiss the **New Subject** dialog.



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

6.2.7. 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.

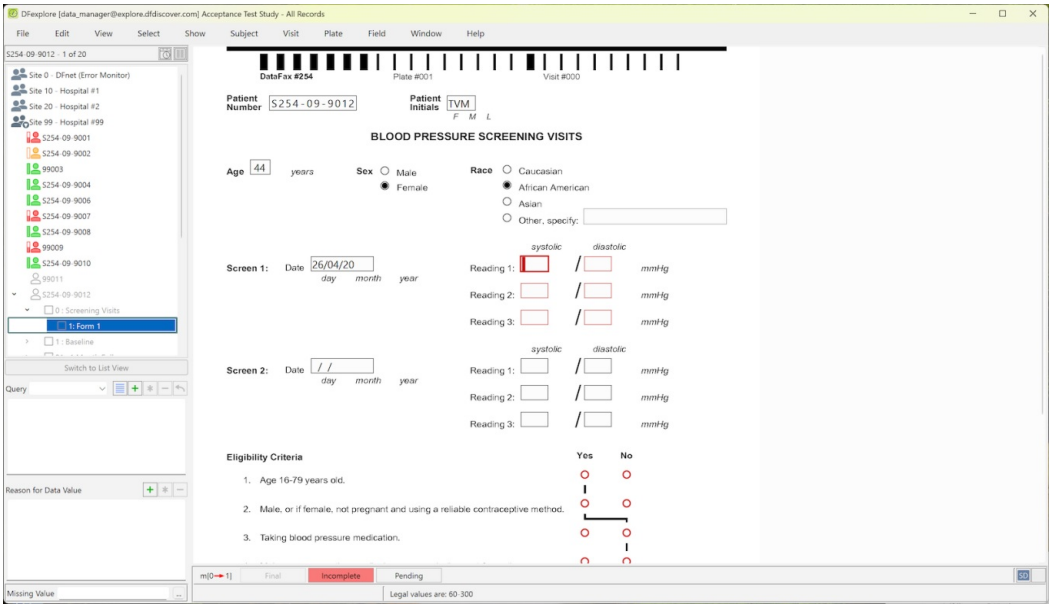


6.2.8. Click anywhere on the plate background - this moves the mouse and keyboard focus to the data window.

6.2.9. 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.

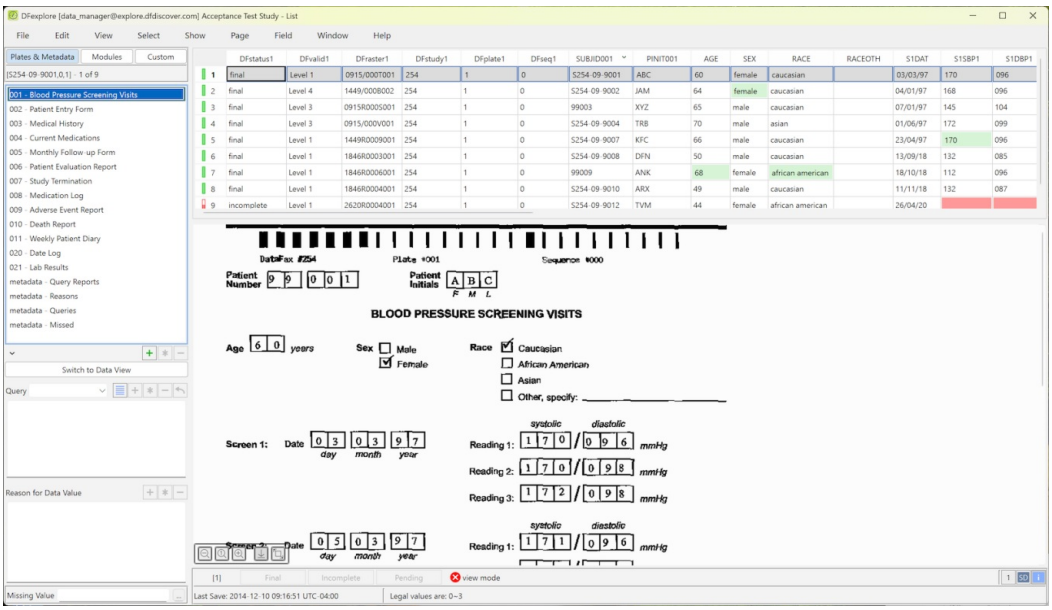
6.2.10. Beginning with the **Age** field set the following values:

- **Age** = 44
- **Sex** = Female
- **Race** = African American
- **Screen 1** = 26/04/20



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

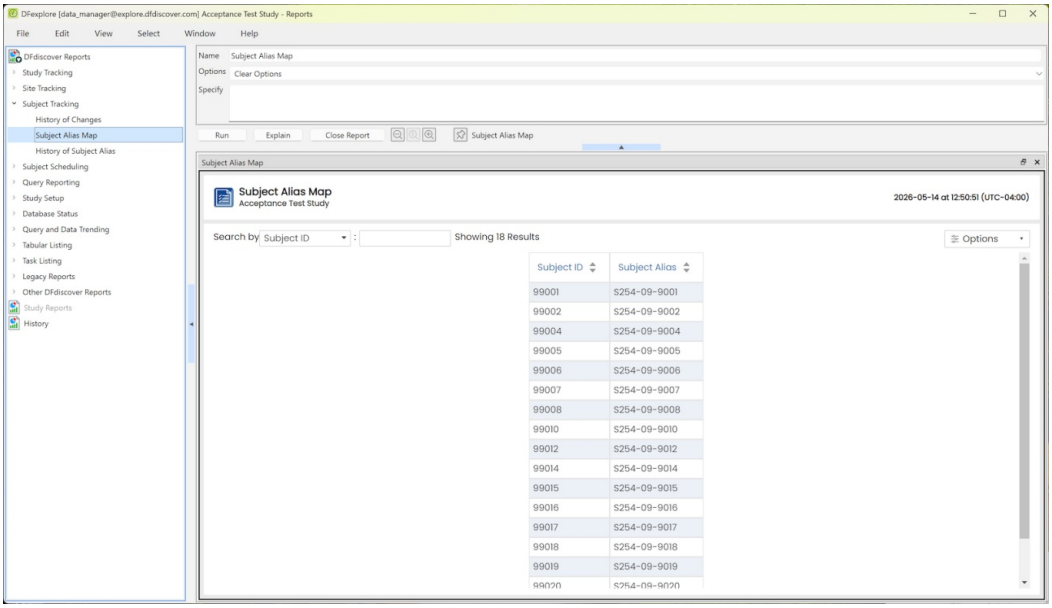
6.2.12. Select View > List. Select **001 - Blood Pressure Screening Visits**.



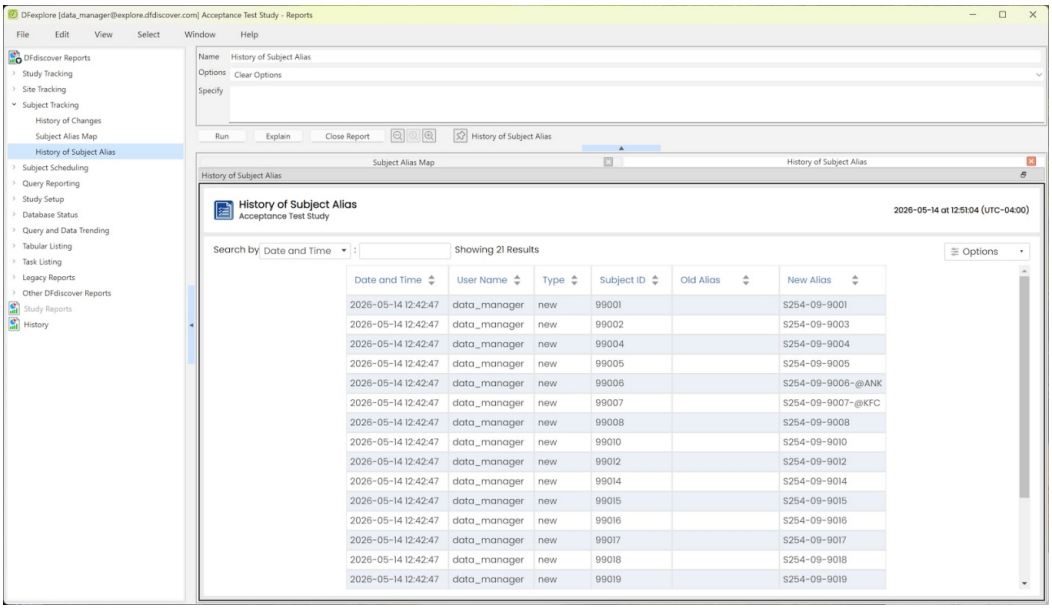
6.2.13. Confirm an entry exists for **S254-09-9012**.

6.3 Subject Alias Tracking (Reports)

6.3.1. 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.



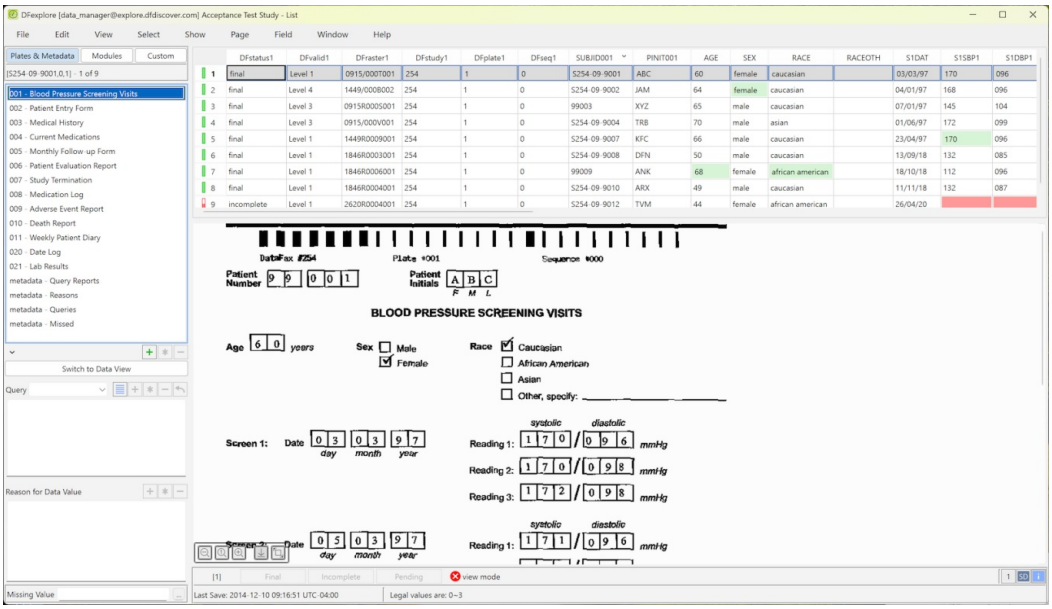
6.3.2. Click **History of Subject Alias** Report then Run.



6.4 Exporting Subject Alias data

6.4.1. Select View > List.

6.4.2. Confirm that **001 - Blood Pressure Screening Visits** is still the active plate.

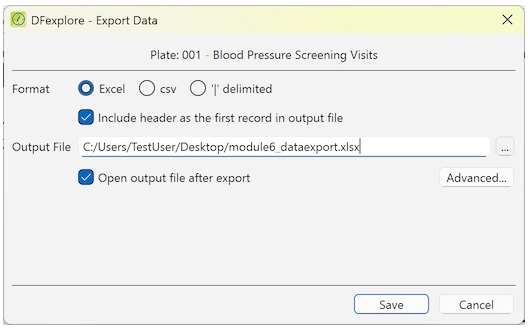


6.4.3. Select File > Export Data.

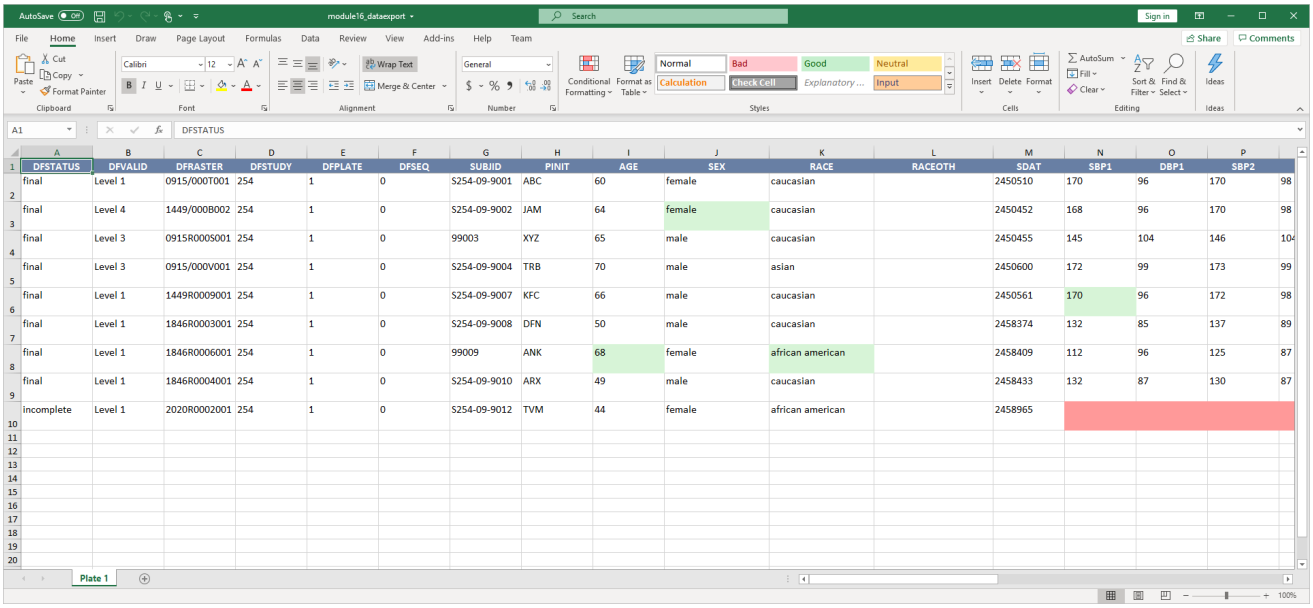
6.4.4. In **Export Data** dialog set:

- **Format** = Excel
- Check (Enable) **Include header as the first record in the output file**.
- Check (enable) **Open output file after export**

6.4.5. 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.



6.4.6. After saving, the file module6_dataexport.xlsx opens. The **SUBJID** displays the Subject Aliases.

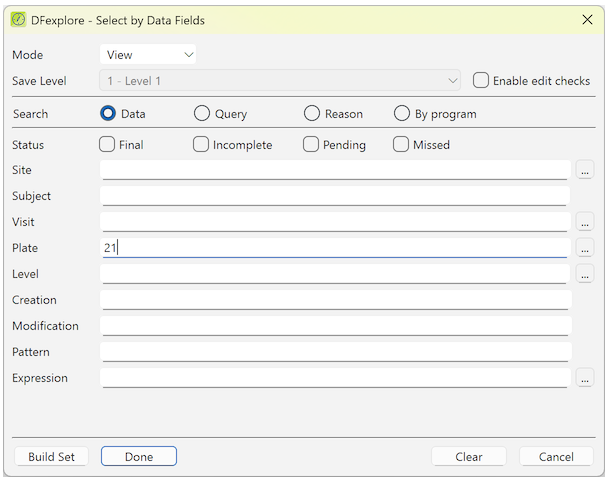


DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	DFSEQ	SUBJID	PINIT	AGE	SEX	RACE	RACEOTH	SDAT	SBP1	DBP1	SBP2	
final	Level 1	0915/000T001	254	1	0	S254-09-9001	ABC	60	female	caucasian		2450510	170	96	170	98
final	Level 4	1449/000B002	254	1	0	S254-09-9002	JAM	64	female	caucasian		2450452	168	96	170	98
final	Level 3	0915R000S001	254	1	0	99003	XYZ	65	male	caucasian		2450455	145	104	146	104
final	Level 3	0915/000V001	254	1	0	S254-09-9004	TRB	70	male	asian		2450600	172	99	173	99
final	Level 1	1449R0009001	254	1	0	S254-09-9007	KFC	66	male	caucasian		2450561	170	96	172	98
final	Level 1	1846R0003001	254	1	0	S254-09-9008	DFN	50	male	caucasian		2458374	132	85	137	89
final	Level 1	1846R0006001	254	1	0	99009	ANK	68	female	african american		2458409	112	96	125	87
final	Level 1	1846R0004001	254	1	0	S254-09-9010	ARX	49	male	caucasian		2458433	132	87	130	87
incomplete	Level 1	2020R0002001	254	1	0	S254-09-9012	TVM	44	female	african american		2458965				

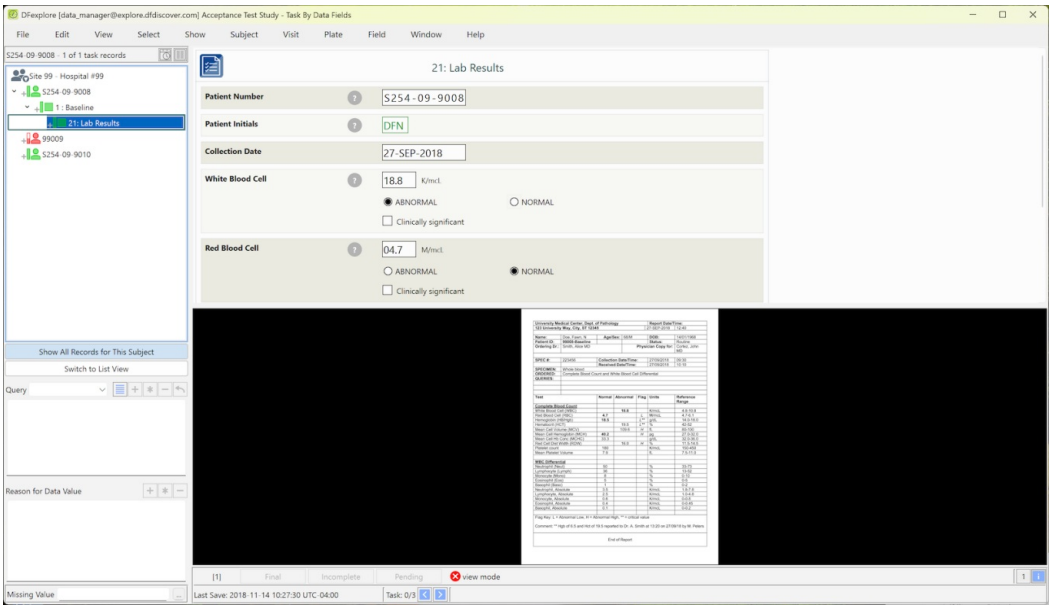
6.4.7. Return to **DFexplore**. Select View > Data.

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

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



6.4.9. Click Done then OK.



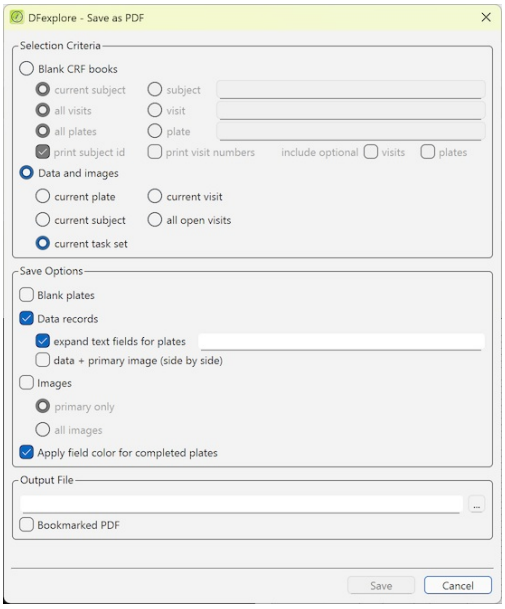
6.4.10. Select File > Save as PDF.

6.4.11. In the **Selection Criteria** panel,

- Select (enable) **Data and images** followed by **current task set**

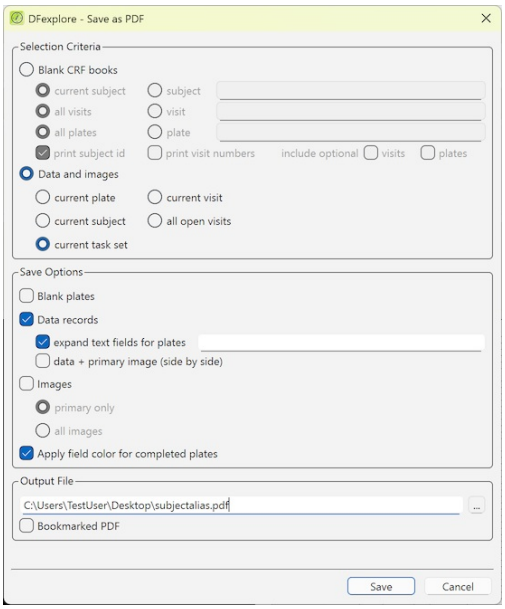
In the **Save Options** panel,

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



6.4.12. 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.

6.4.13. 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.



6.4.14. Locate and open the previously saved subjectalias.pdf file. Confirm the **Patient Number** fields within the PDF are identical to that shown in **DFexplore Data View**.

6.4.15. Select File > Preferences. Uncheck (disable) **Use subject alias**. Click OK.

6.4.16. Select File > Exit to close **DFexplore**.

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.

7 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, DFexplore

Purpose: This module performs tests relating to electronic data capture (EDC) via manual interactive data entry as well as related functions including tasks, queries, and marking/unmarking data as missed.

Tests & Requirements

1. Login to **DFexplore** and inspect the list of sites, subjects and visits 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.

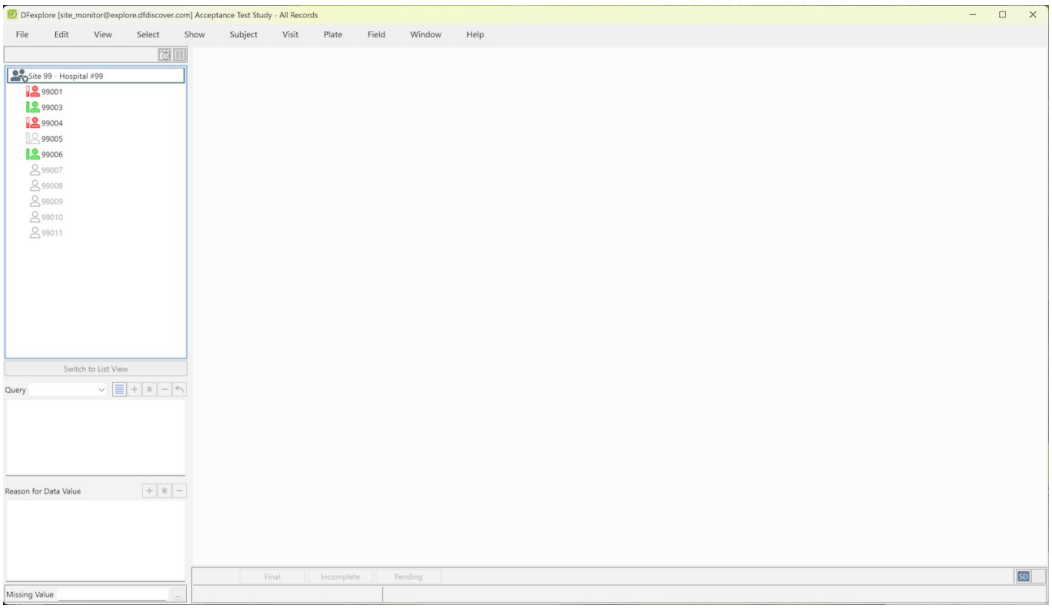
NOTE: Refer to "Creating user accounts and assigning study permissions." as a valid email address is required for site_monitor to receive the module specific PDF files.

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

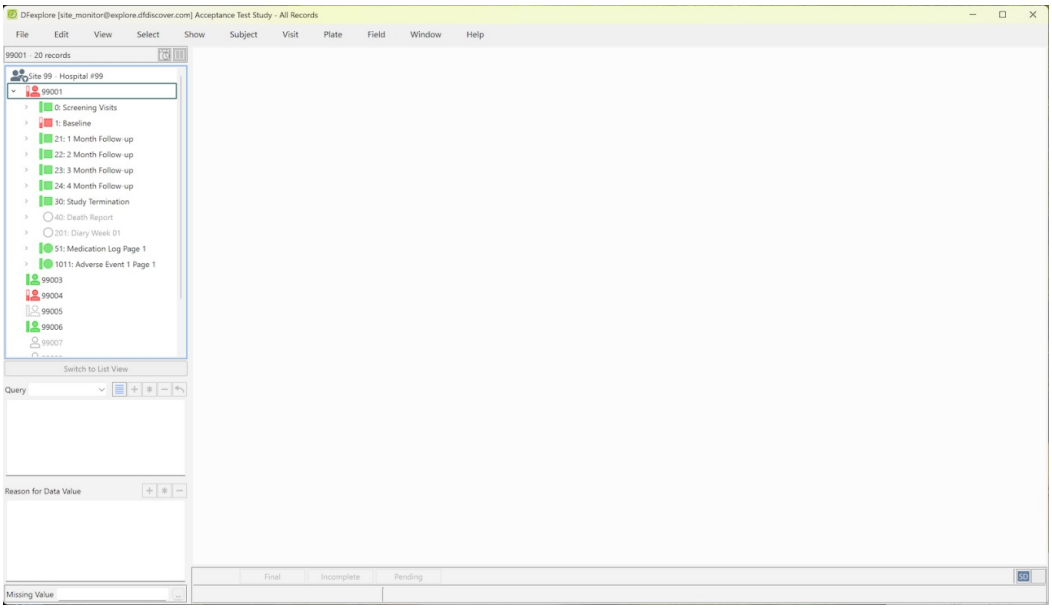
7.1 Login to **DFexplore** and inspect the list of sites, subjects and visits in the record list window

7.1.1. Start **DFexplore**, login as site_monitor and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

7.1.2. Confirm that only **Site 99 - Hospital #99** is available.



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



7.1.4. Double-click entry for the highlighted **1 : Baseline** visit to display the list of pages belonging to the visit.

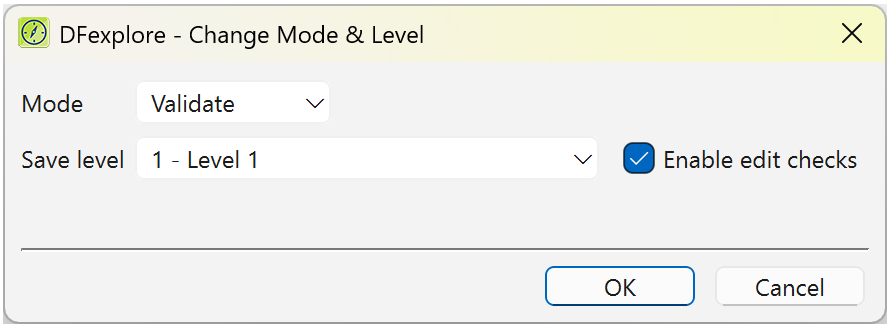
7.1.5. Close the subject binder for Subject 99001 by double-clicking **Site 99 - Hospital #99** in the record list panel.

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

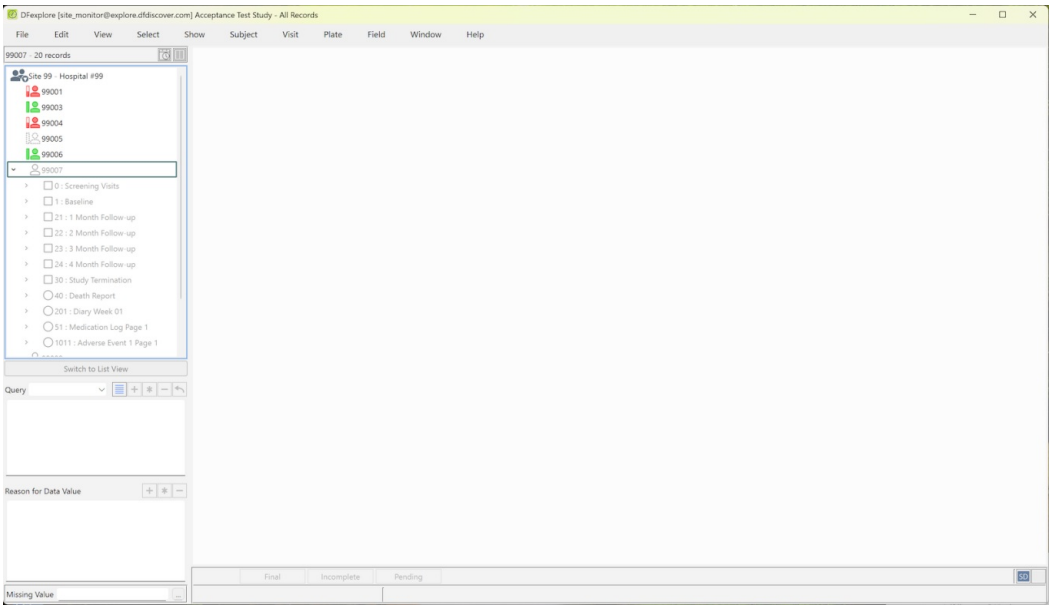
7.2.1. Using the paper CRFs that were printed or emailed at the beginning of this module (Step 2). Select Select > Change Mode & Level to set the working mode and data entry level. In the dialog, set:

- **Mode** = Validate
- **Save level** = 1 - Level 1
- Check **Enable edit checks**

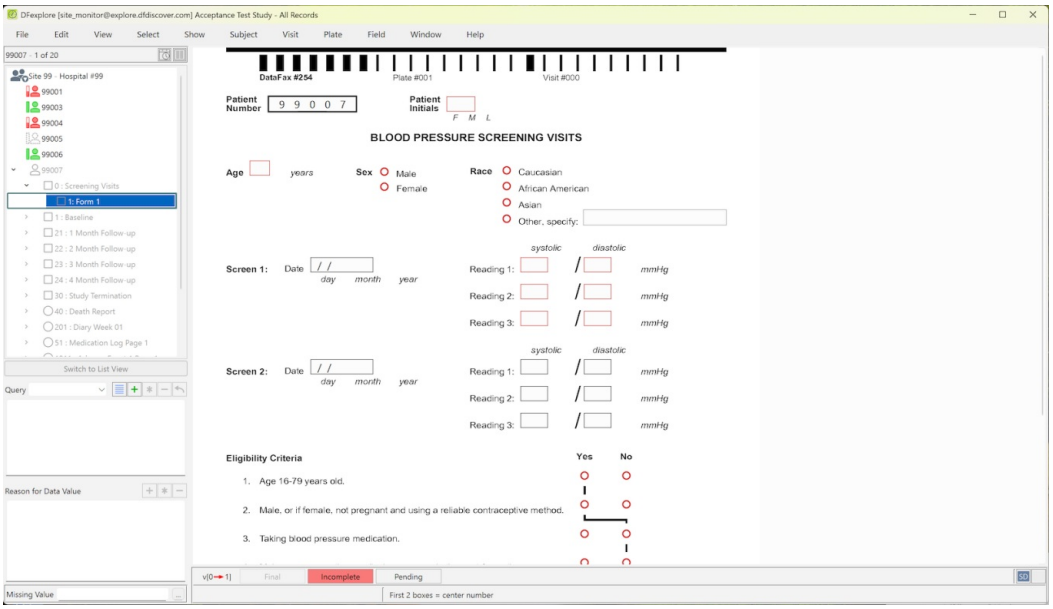
Click OK.



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



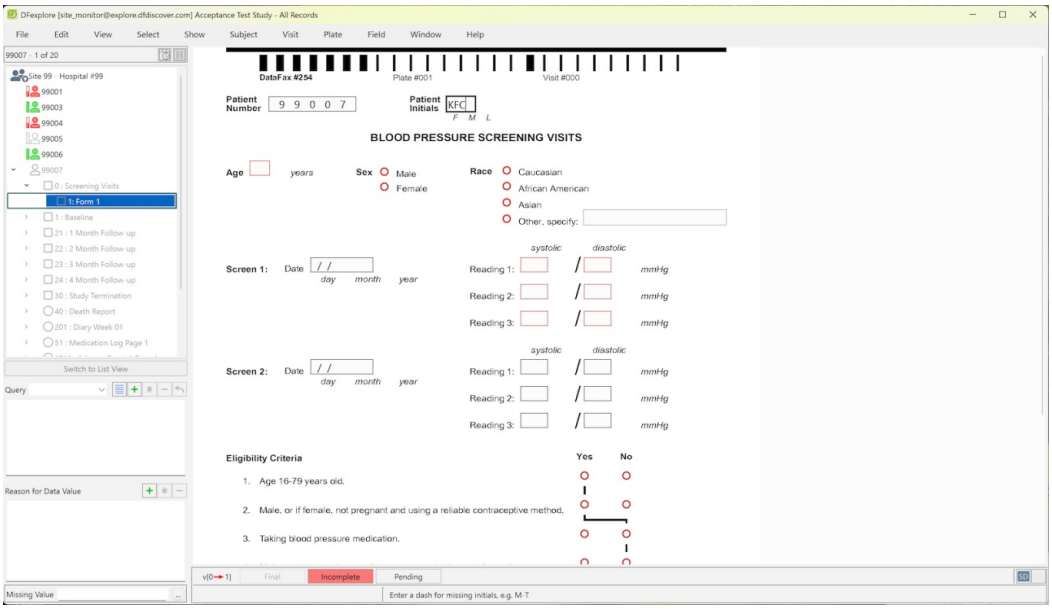
7.2.3. Double-click the **0 : Screening Visits** entry to display all pages belonging to the visit.



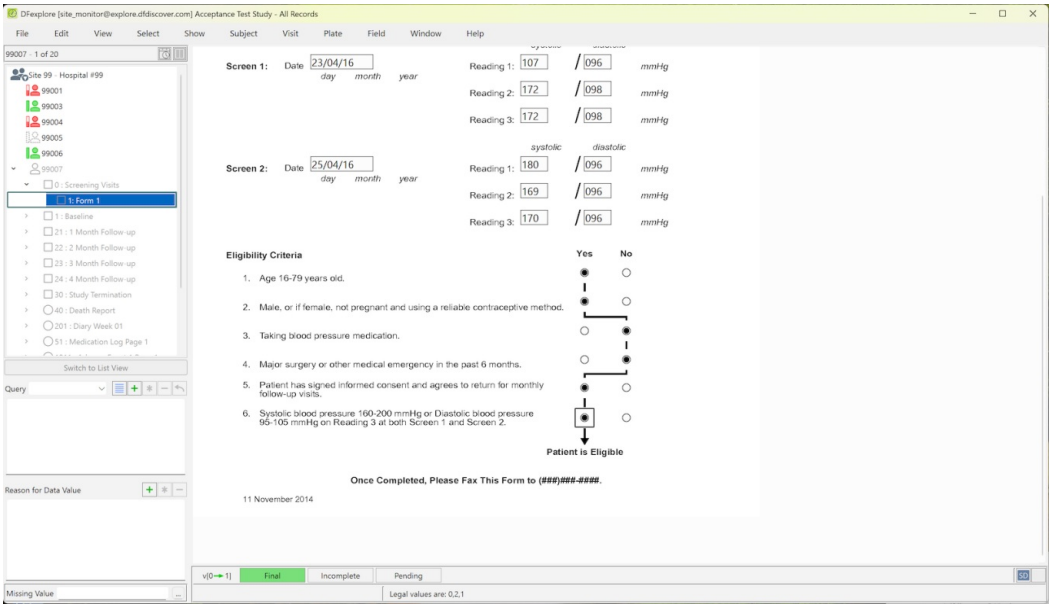
7.2.4. 1 : Form 1 becomes the active page. The data window redraws with the plate background and related data entry fields.

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

7.2.6. 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.



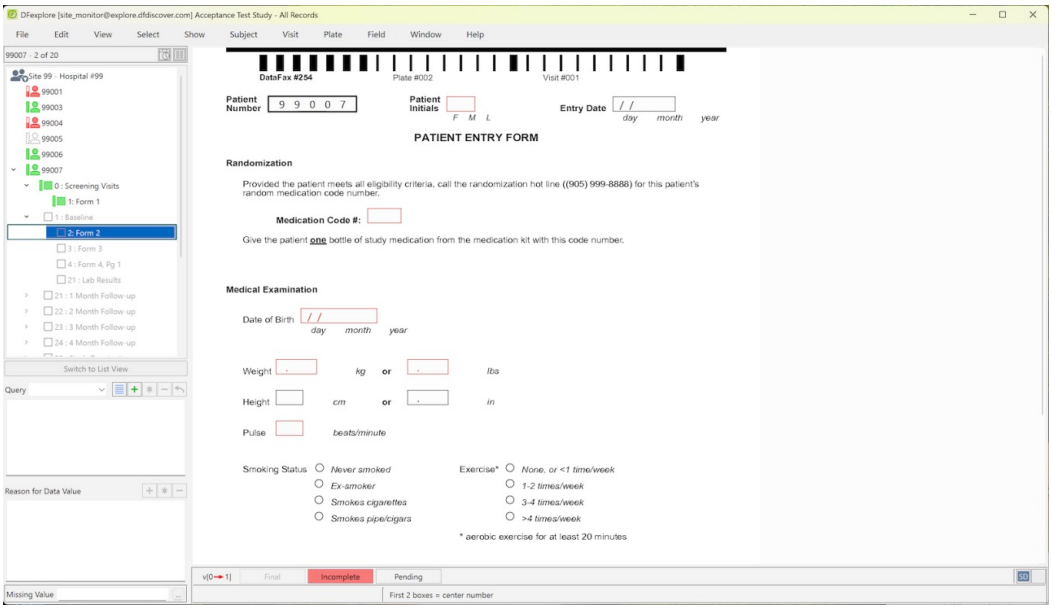
7.2.7. Continuing from the **Age** field, press Tab to advance through the fields individually. Enter all remaining data as it appears on the printed CRF. Although leading zeros may not always appear on the paper CRF, be sure to enter leading zeros where necessary. After entering the **Eligibility Criteria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



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

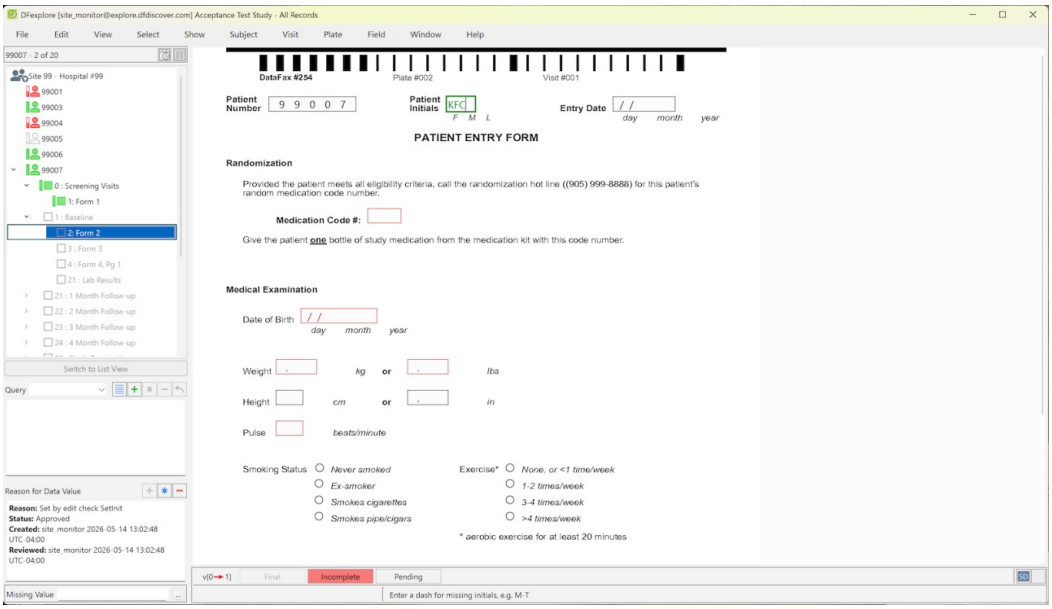
7.3 Add reasons to explain entered data values

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



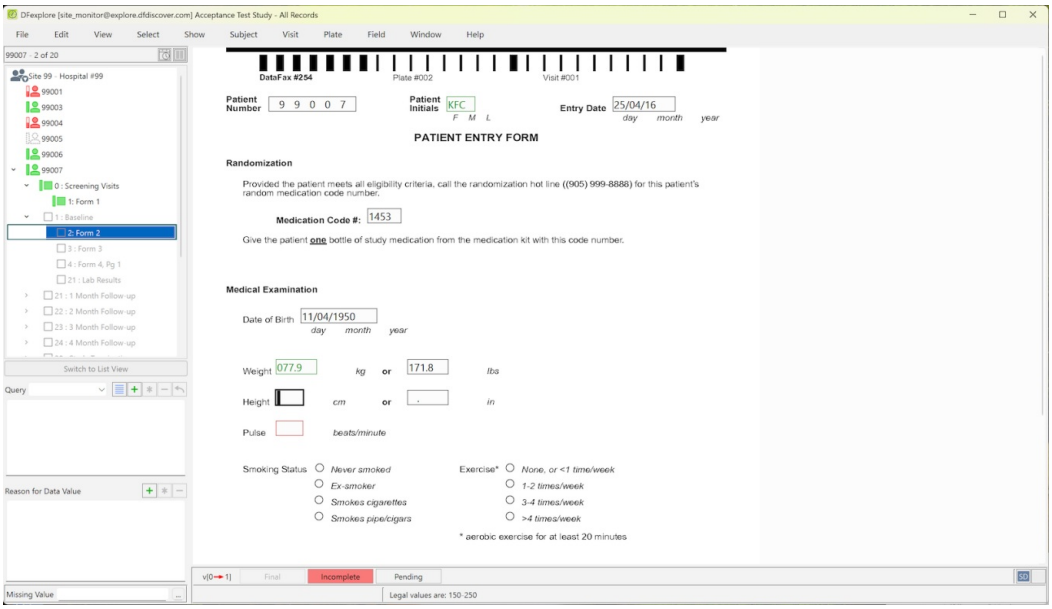
7.3.2. Click anywhere on the plate background - this moves the mouse and keyboard focus to the data window.

7.3.3. 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 SetInit 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.

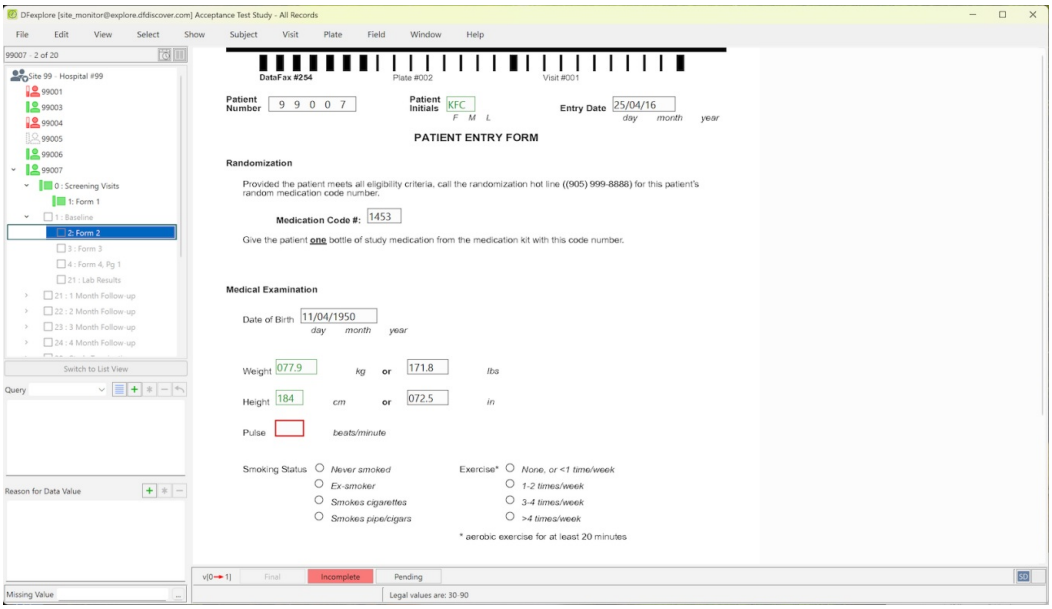


7.3.4. Press Tab to advance through each field and enter the data as it appears on the printed CRF, up to and including **Weight (lbs)**. Press Tab to exit the **Weight (lbs)** field and execute the WeightEquiv edit check. The WeightEquiv edit check calculates and enters the equivalent value in the blank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

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



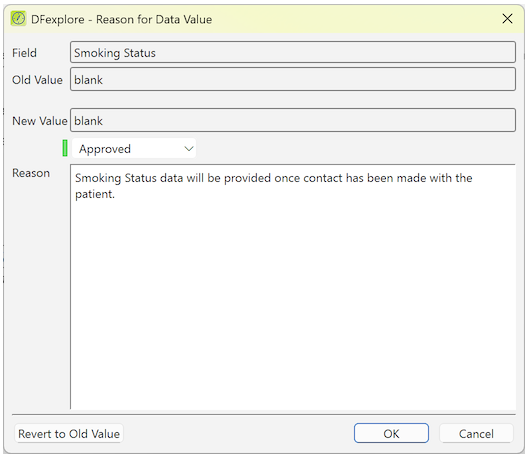
7.3.5. The HeightEquiv edit check is similar to the WeightEquiv edit check. If only one of the two height values are entered, the edit check calculates and enters the equivalent value for the blank field. Press Tab to exit the **Height (in)** field and enter the value as it appears on the printed CRF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



7.3.6. Enter the value of the **Pulse** field as it appears on the printed CRF. Press Tab to advance to the **Smoking Status** field.

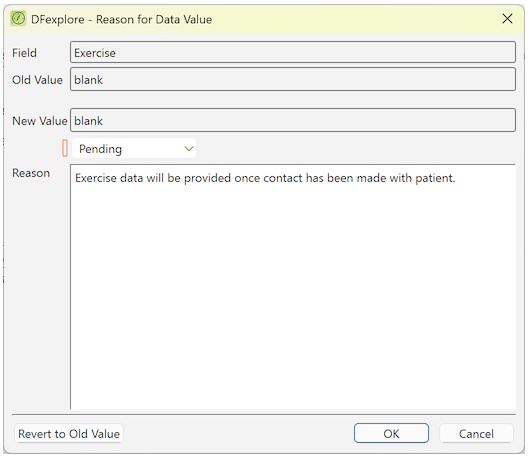
7.3.7. Select Field Add Reason For Data Value or click + in the **Reason for Data Value** window. In the resulting dialog, choose **Approved** from the pull-down list.

7.3.8. 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.



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

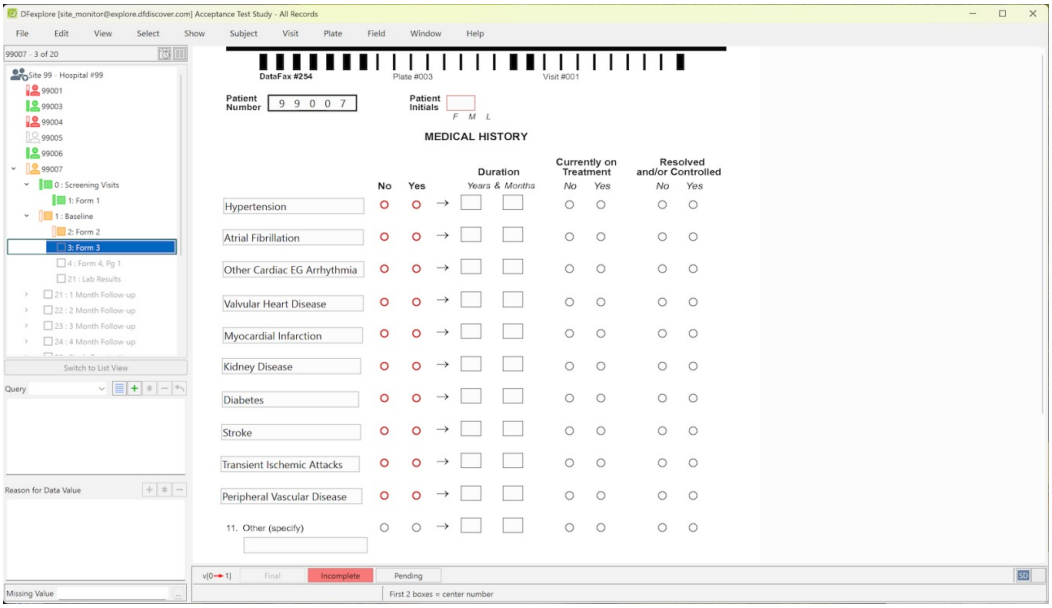
7.3.10. Enter the text Exercise data will be provided once contact has been made with patient. for the **Reason** property. Click OK, press Tab to advance to the **Date of First Study Follow-up Visit** field.



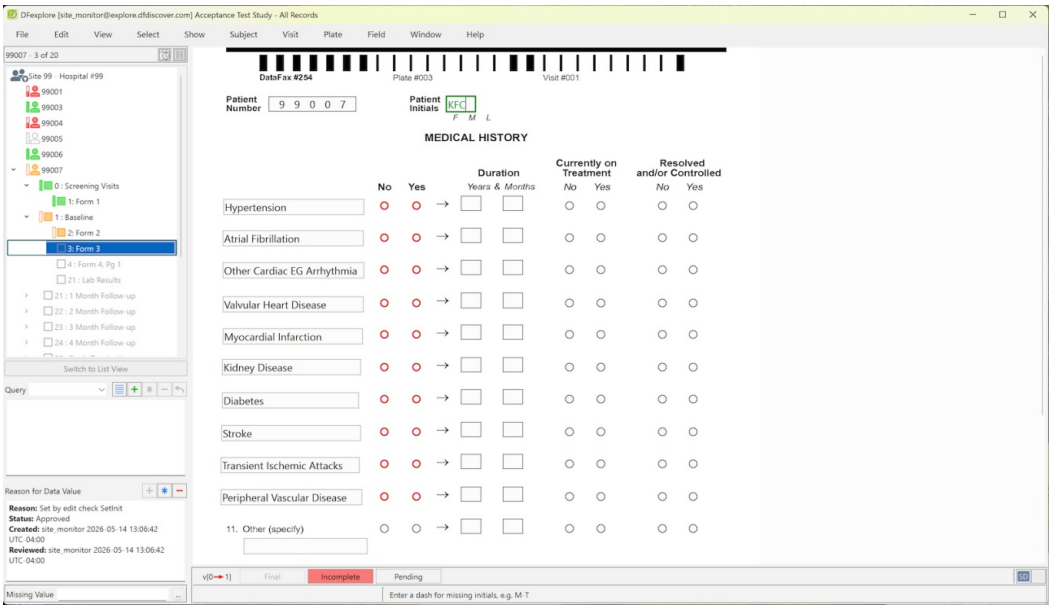
7.3.11. Enter the **Date of First Study Follow-up Visit** and press Tab to advance to the save field. Verify that Final is highlighted. Do not save the page with this status as the **Smoking Status** and **Exercise** fields have yet to be completed. Click Pending.

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

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



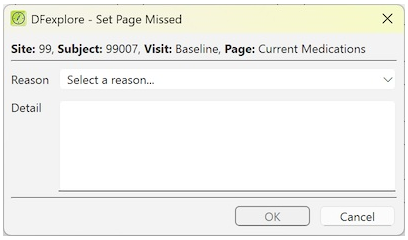
7.4.2. Starting at the **Patient Number** field, press Tab to advance to the **Patient Initials** field. The SetInit edit check executes upon entry to the field.



7.4.3. 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**.

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

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

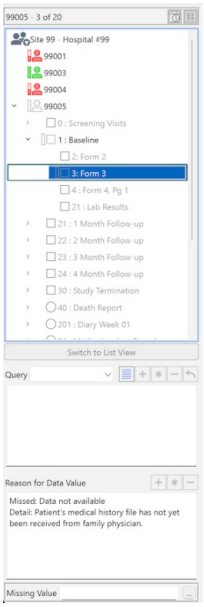


7.5.2. In the dialog, choose **Data not available** value from the **Reason** pull-down list. Enter Medication information is missing from patient's chart. as the **Detail**.

7.5.3. Click OK to register the page as missed.

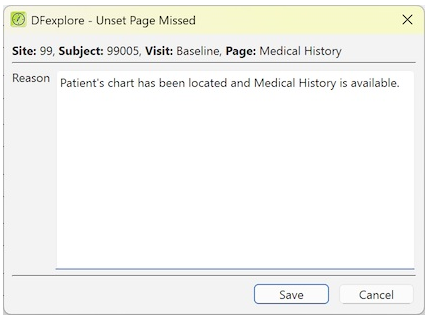
7.5.4. Double-click Subject **99005** in the record list. From the now open list of visits for that subject, double-click the **1 : Baseline** visit.

7.5.5. All pages for that visit are displayed.



7.5.6. Choose **3 : Form 3**. Select Plate > Unset Page Missed.

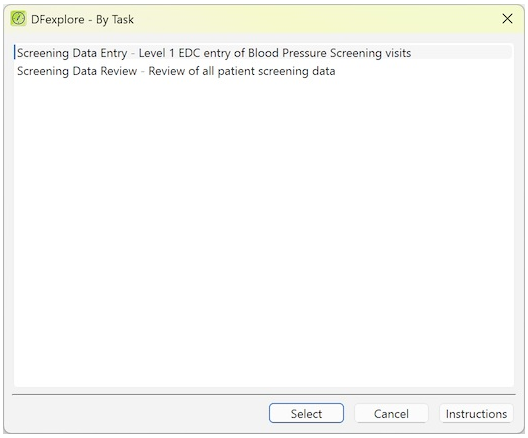
7.5.7. Enter the text Patient's chart has been located and Medical History is available. in the **Reason** field. Click Save to unset **3: Form 3** as missed.



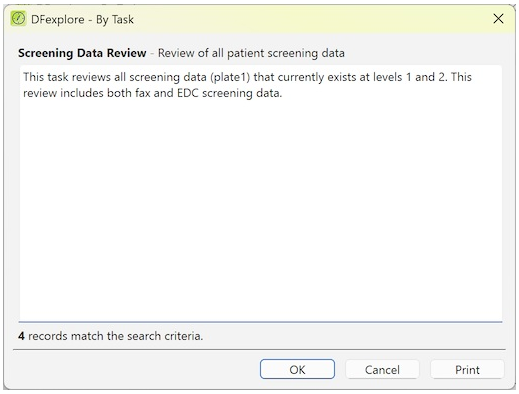
7.5.8. Double-click **Site 99 - Hospital #99** entry in the record list. This closes all open subject binders for **Site 99 - Hospital #99**.

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

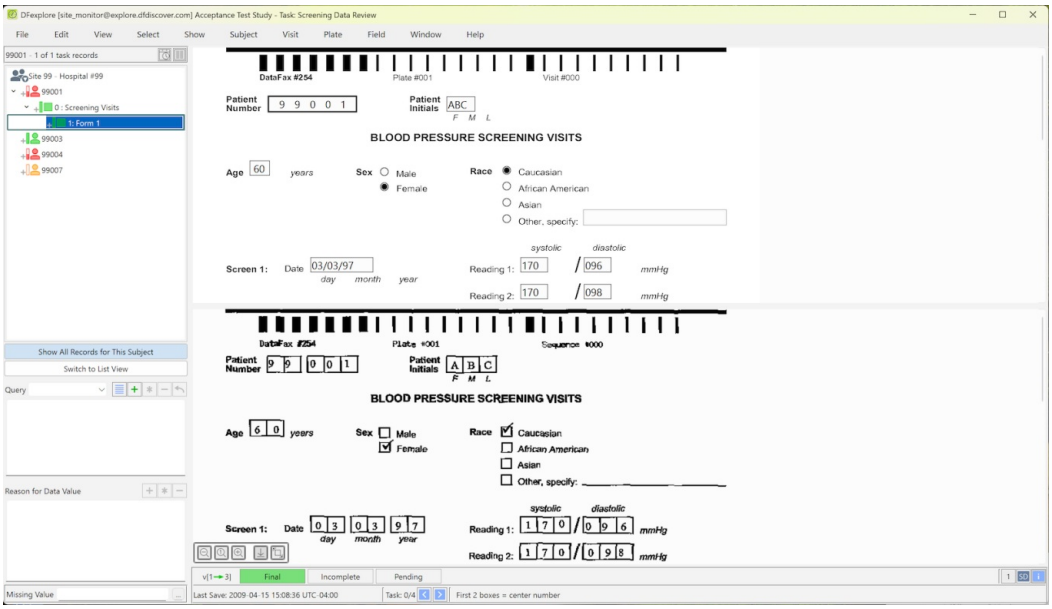
7.6.1. Select Select > By Task to view the list of predefined data entry and data management tasks.



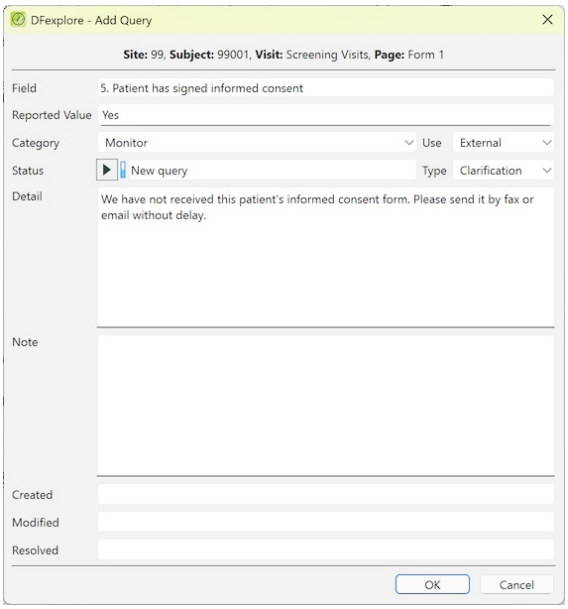
7.6.2. Click **Screening Data Review** from the list, then Select to load the task and its selection criteria. This task is used to review all screening plate 1s that exist at level 1 or 2 and save them to level 3. Examine the lower left of the dialog to determine the number of records that match the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



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

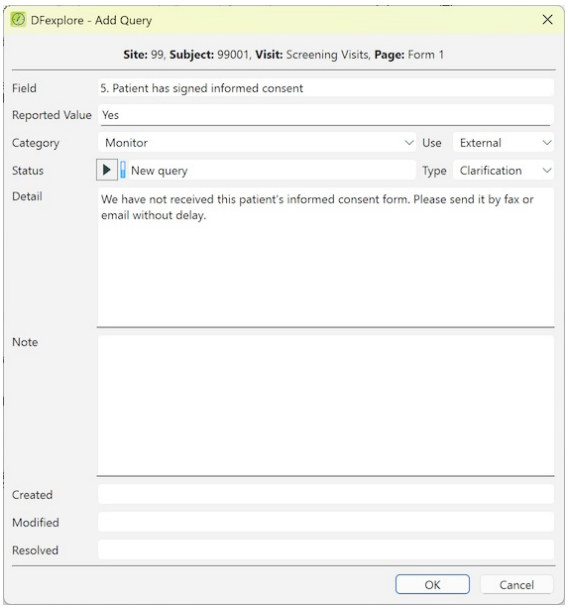


7.6.4. Beginning with the first task record for Subject **99001**, press Tab to advance through all fields on the page, comparing their values to those on the CRF image in the image window. When **Eligibility Criteria #5** is the current field, Select Field > Add Query or click + in the **Query** window.



7.6.5. 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.



7.6.6. Click OK to apply the query.

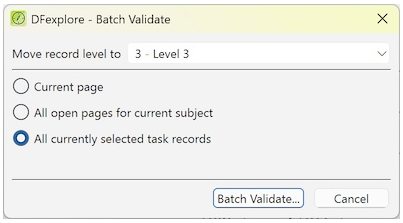
7.6.7. Press Tab to advance through the remaining fields on the page. Once all fields have been traversed, press Tab to make the save buttons active.

7.6.8. Click Incomplete to save the current task record to the database at level 3.

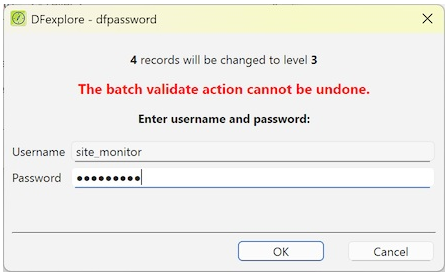
7.6.9. Batch validate the remaining records in the task list to raise their level to level 3. Select Select > Batch Validate. In the dialog, set:

- **Move record level to** = 3 - Level 3
- Choose **All currently selected task records**

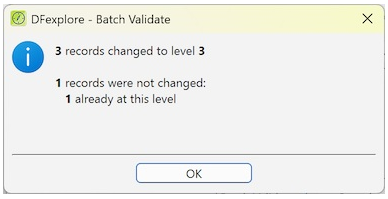
Click Batch Validate.



7.6.10. 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.



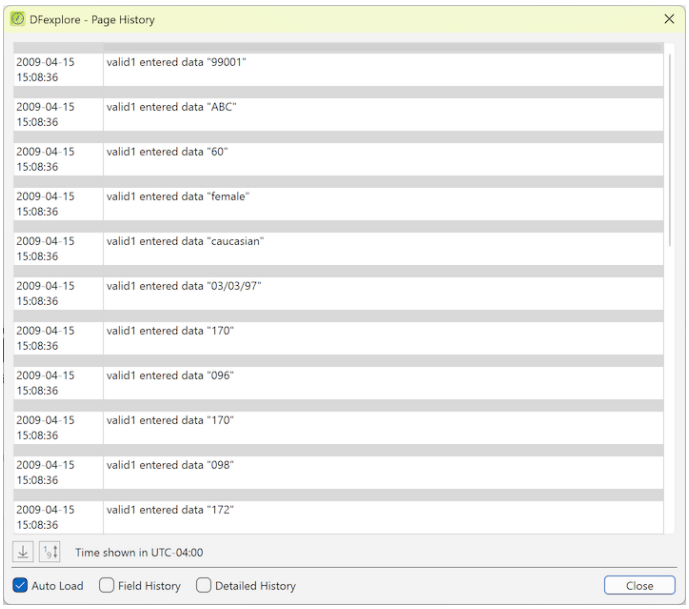
7.6.11. Review the details in the summary dialog. Click OK to close the summary dialog and complete the batch validation operation.



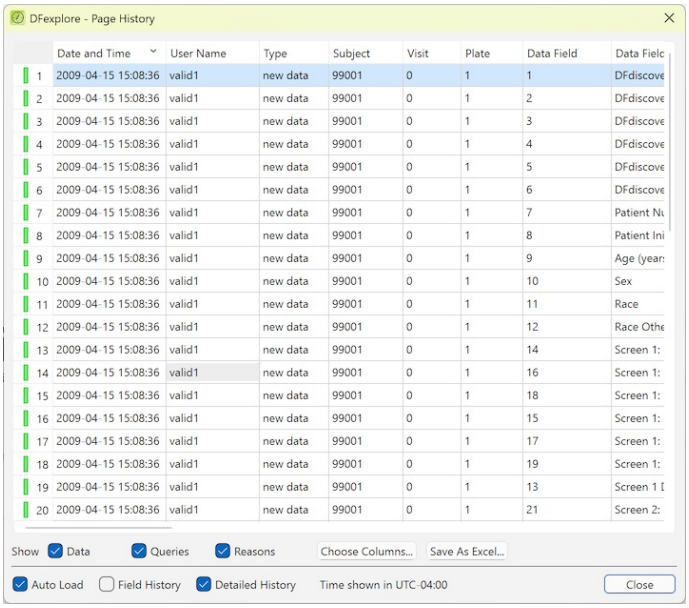
7.7 Confirm audit trail information for entered and modified data

7.7.1. Return to Subject **99001** > **0 : Screening Visits** > **1 : Form 1**.

7.7.2. Select Plate > List History of All Changes on This Page to display the current record's history. The default page history dialog is displayed.



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



7.7.4. 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.

7.7.5. 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.

8 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

Client Tools Used: DFATK, DFexplore, DFsend

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.

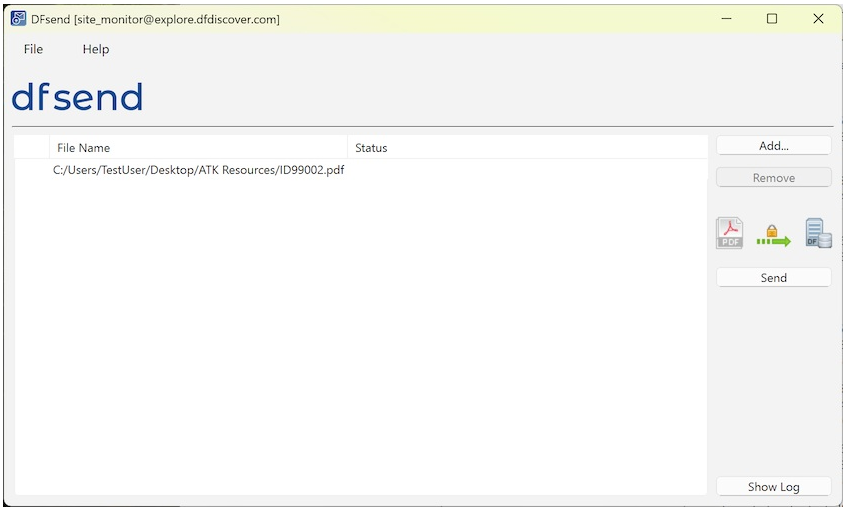
8.1 Send PDF images to DFexplore

8.1.1. 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.

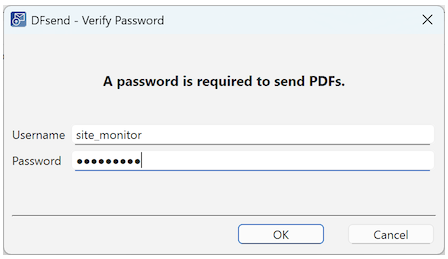
8.1.1. Start **DFsend** as described in "How to start **DFsend**".

8.1.2. Click Add. From the **Select PDF Files** file selection dialog. Locate the previously saved **ID99002.pdf** file. Select the file. Click Open.

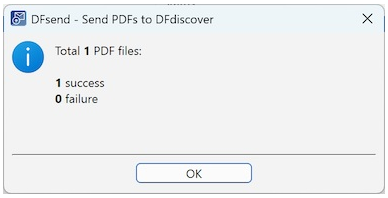


NOTE: Documents can also be added by dragging-and-dropping the desired PDF files from a local file folder directly into the list area.

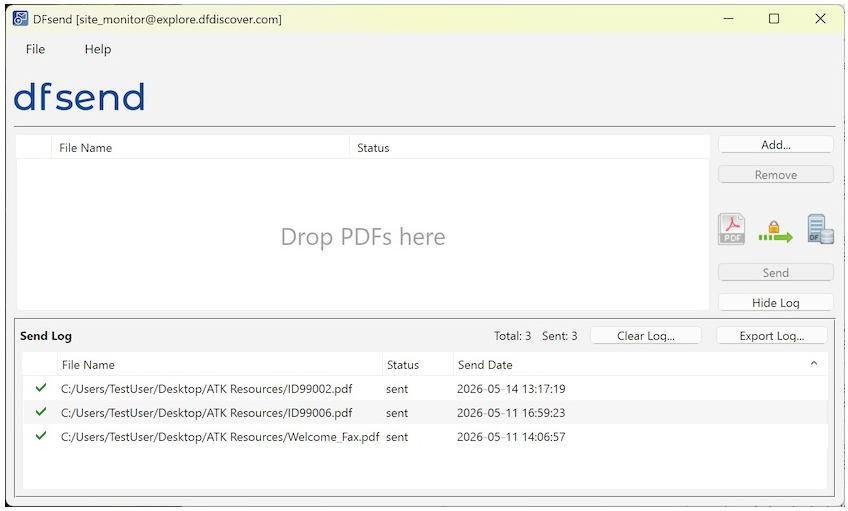
8.1.3. Click Send. In **Verify Password** dialog, enter site_monitor in the **Username** field and the previously assigned password in the **Password** field. Click OK.



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



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



8.1.6. Select File > Exit.

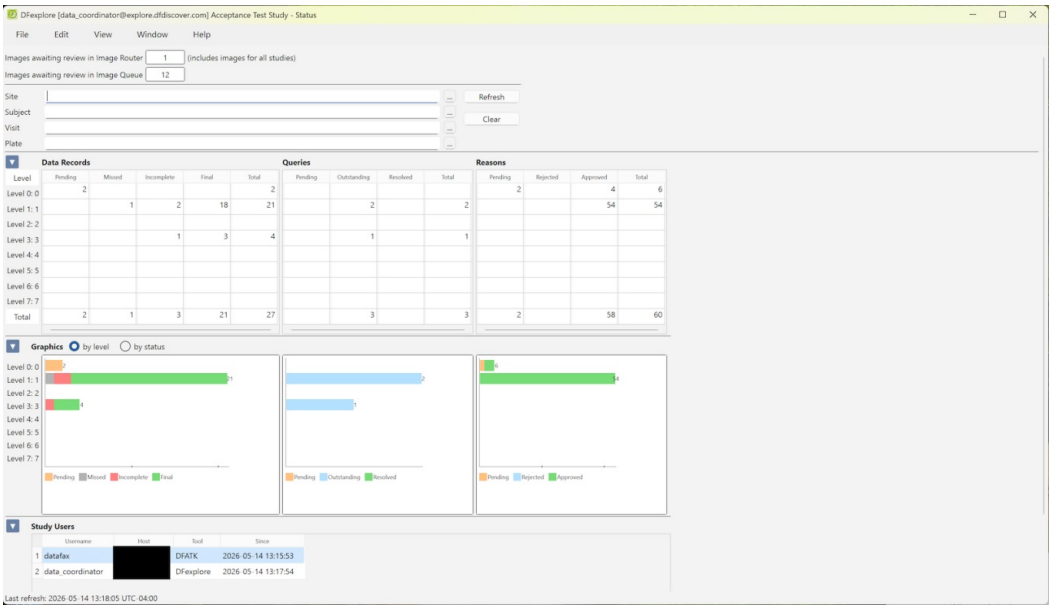
NOTE: Wait 2-3 minutes prior to proceeding to **DFexplore**.

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

8.2.1. 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**.

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

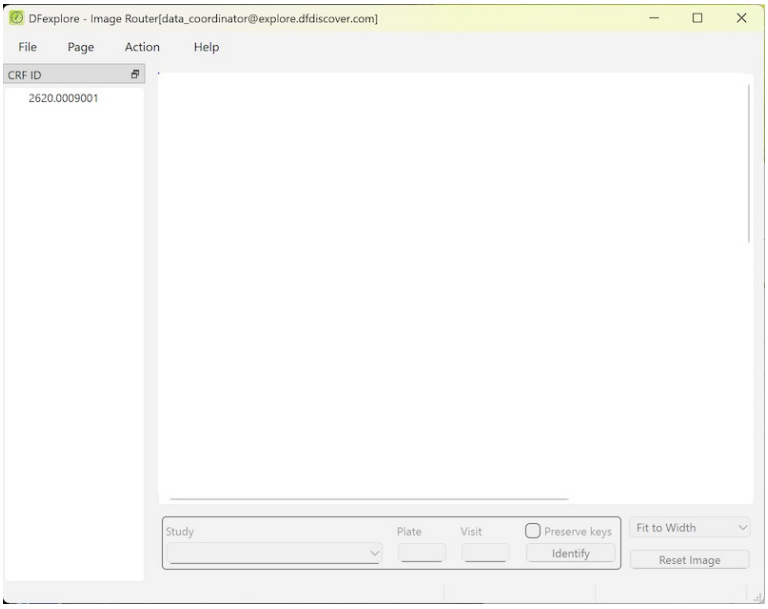


NOTE: Although 13 records were submitted, only 12 will be awaiting validation. The first page in the document has an unreadable barcode. As the barcode could not be identified for the page, it has been routed to the **Image Router** instead of to 254 Acceptance Test Study.

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

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

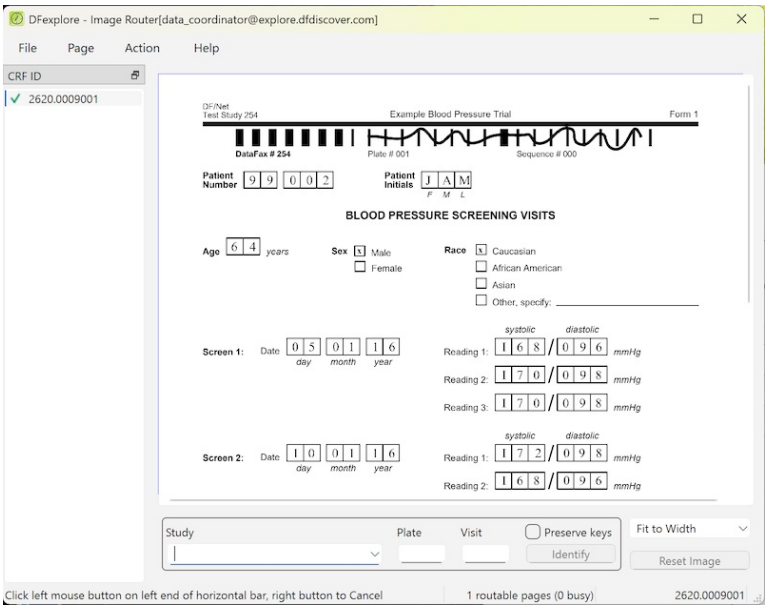
8.3.1. In the **DFexplore** login dialog, click Image Router to open the **Image Router**.



8.3.2. 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.

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



8.3.4. Click leftmost end of the horizontal barcode line. Drag the cross-hairs across the solid barcode line then click rightmost end of the line.

8.3.5. Select **254 - Acceptance Test Study** from the Study drop-down list. Enter **Plate** and **Visit** numbers, as illustrated. Click Identify to identify the record.

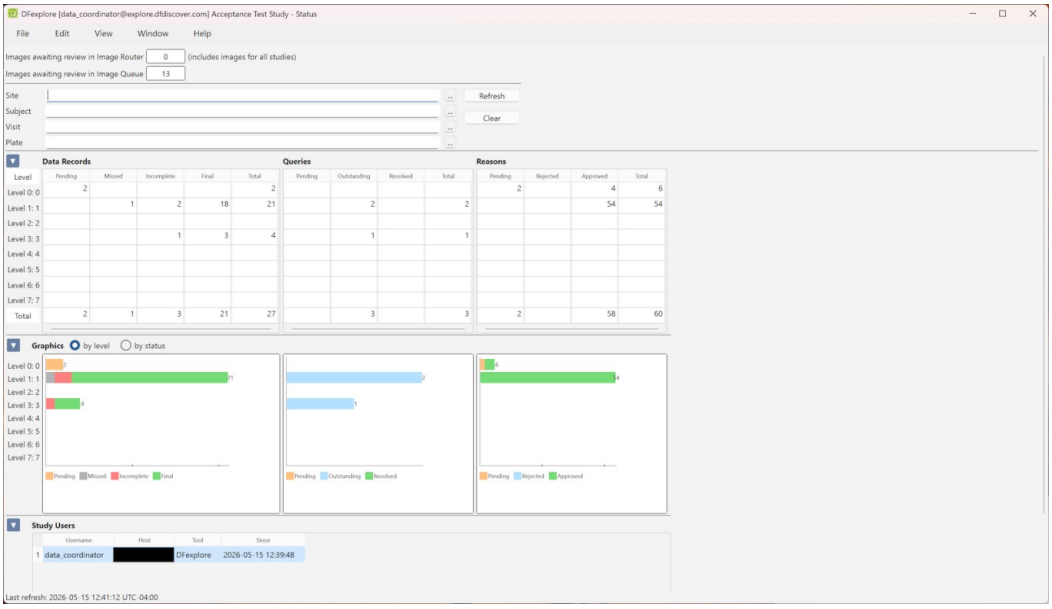


8.3.6. Select File > Close Image Router to exit the **Image Router** and return to the **DFexplore** login dialog.

8.4 Login to **DFexplore** and confirm receipt of the routed page in the Status View

8.4.1. 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.

8.4.2. 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.

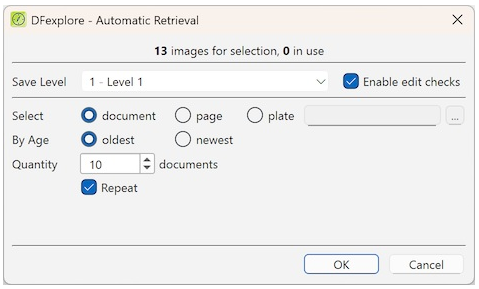


8.5 Retrieve new images in **DFexplore** Image View

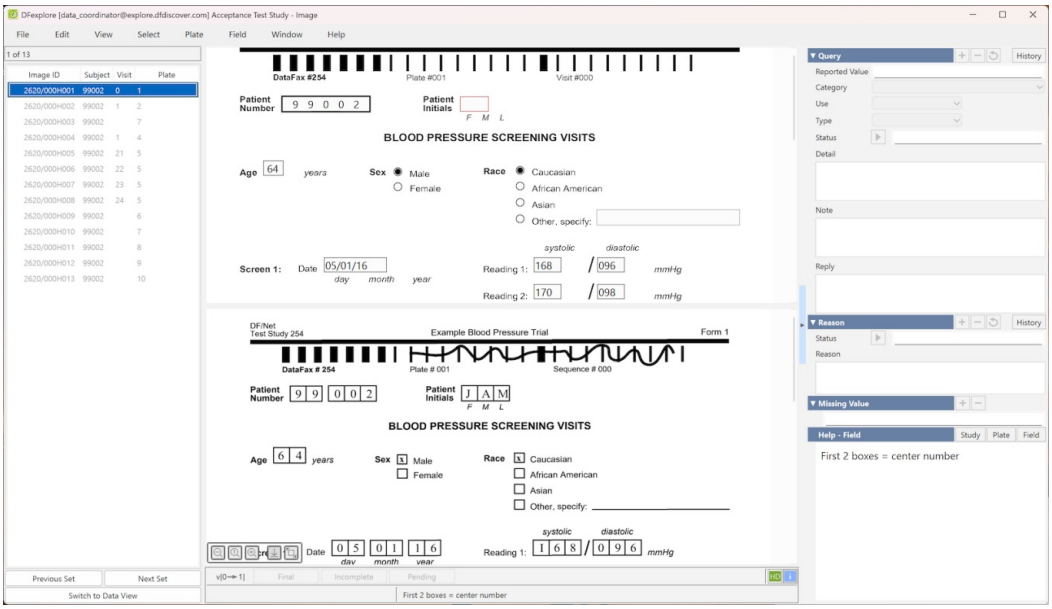
8.5.1. Select View > Image. In the **Automatic Retrieval** dialog,

- Set **Save level** = 1 - Level 1
- Check (enable) **Enable Edit Checks**
- **Select** = document
- **By Age** = oldest
- **Quantity __ documents** = 10

- Check (enable) **Repeat**



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



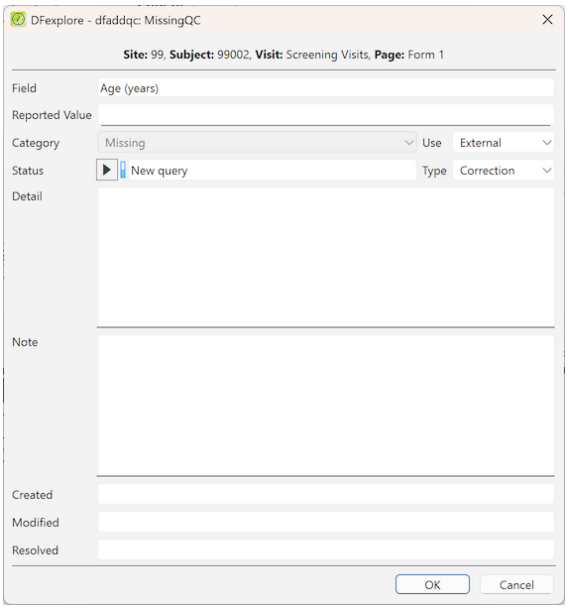
8.6 Enter Plate 1 (Form 1) for Subject 99002

8.6.1. 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.

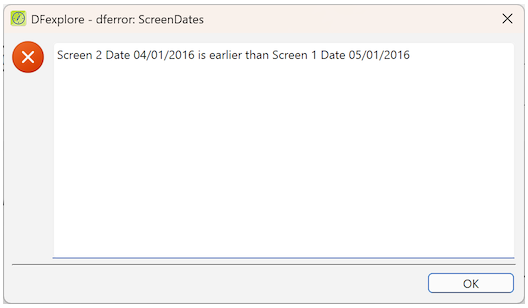
8.6.2. Correctly enter **Patient Number** and **Patient Initials** as per the CRF image. Press Tab to advance to the **Age** field.

8.6.3. 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.



8.6.4. 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.

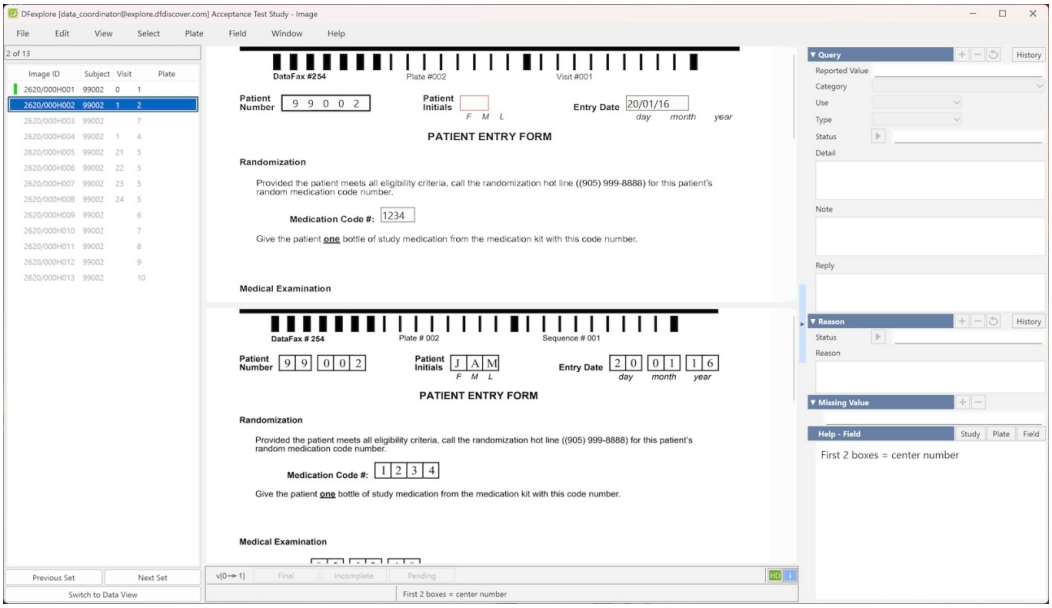
8.6.5. The ScreenDates edit check is executed on exit from the **Screen 2 Date** field. It checks that the **Screen 2** Date follows the **Screen 1** Date by at least one day. Enter a **Screen 2 Date** of 04/01/16, which precedes the **Screen 1 Date** of 05/01/16, then press Tab to exit the field. After verifying the message in the confirmation dialog, click OK.



8.6.6. 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.

8.6.7. 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.

8.6.8. 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.

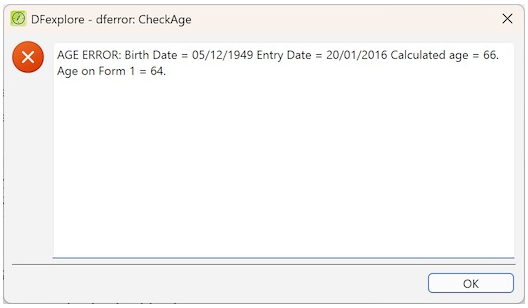


8.7 Enter Plate 2 (Form 2) for Subject 99002

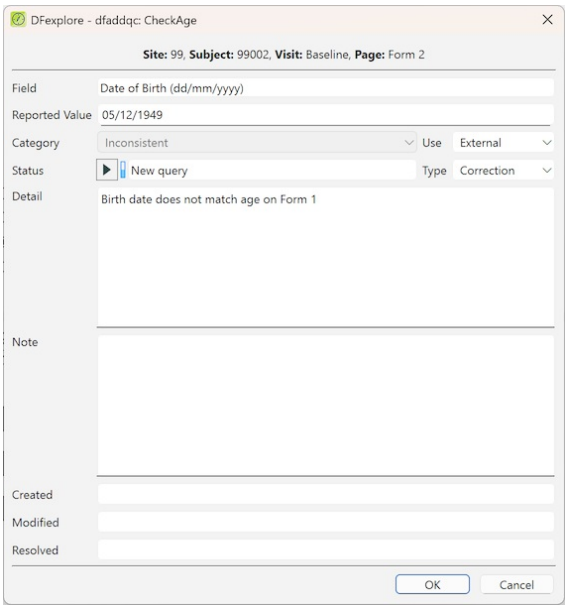
8.7.1. Correctly enter **Patient Number** per the CRF image. Press Tab to advance to the **Patient Initials** field. The SetInitedit check automatically completes the **Patient Initials** field if the initials are available on the **Screening Form (Plate 1)**.

> NOTE: The **Patient Number** must be entered correctly on the data record for the SetInitedit 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.

8.7.2. 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.



8.7.3. 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.

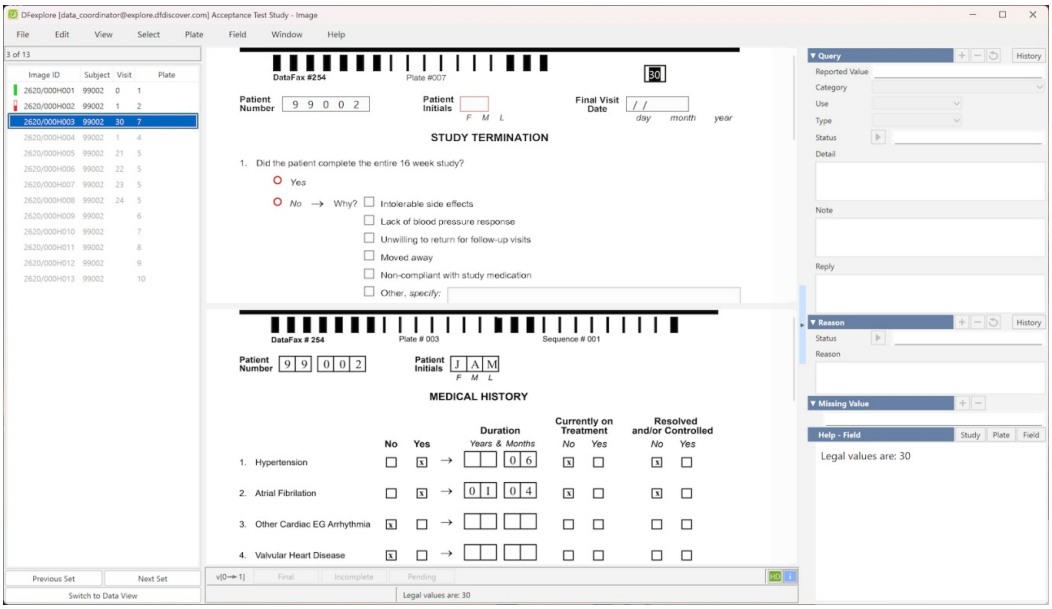


8.7.4. Press Tab to advance to the **Weight (kg)** field. Do not enter a value as the corresponding field on the CRF image is blank. Continue on to the **Weight (lbs)** field and enter the value that appears on the CRF image. If only one of the 2 weight fields are completed, the WeightEquiv edit check calculates and enters the equivalent value for the blank Weight field. Press Tab to exit the **Weight (lbs)** field executing the WeightEquiv edit check.

8.7.5. 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.

8.7.6. 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.

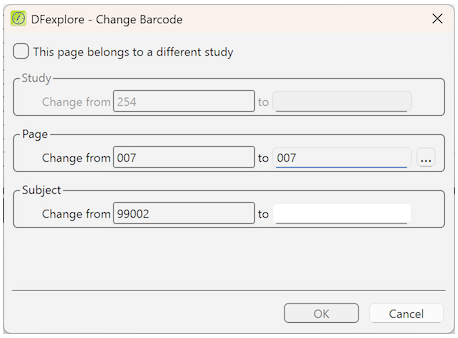
8.7.7. As an outstanding query exists on the **Date of Birth** field, the page must be saved to the database with a status of **Incomplete**. Click Incomplete with the mouse or by pressing the space bar.



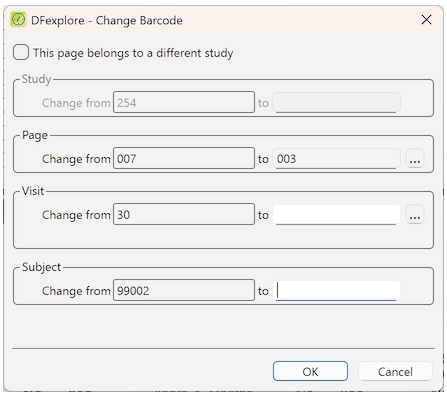
NOTE: If outstanding queries and/or illegal values exist on a data record, **DFdiscover** will never allow the record to be assigned the status **Final**.

8.8 Enter Plate 3 (Form 3) for Subject 99002

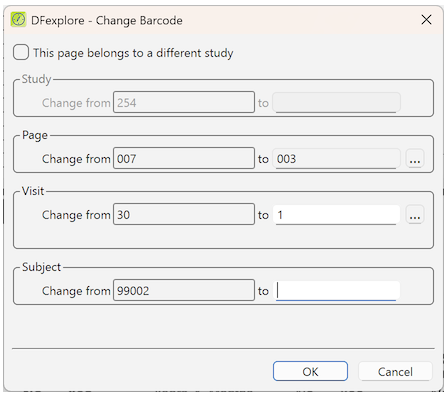
8.8.1. **Plate 3** has been incorrectly identified by **DFdiscover** as **Plate 7** (the data record and CRF image do not match). Before data entry can begin, the record must first be correctly identified by correcting the barcode. To do this, Select Plate > Change Barcode.



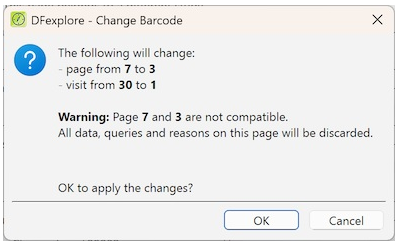
8.8.2. In the **Change Barcode** dialog, set the **Page** to **003**. Do this by clicking ... to display a listing of all defined study plates, then select the entry **003 - Medical History** from the list. Click OK to close the dialog.



8.8.3. 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.



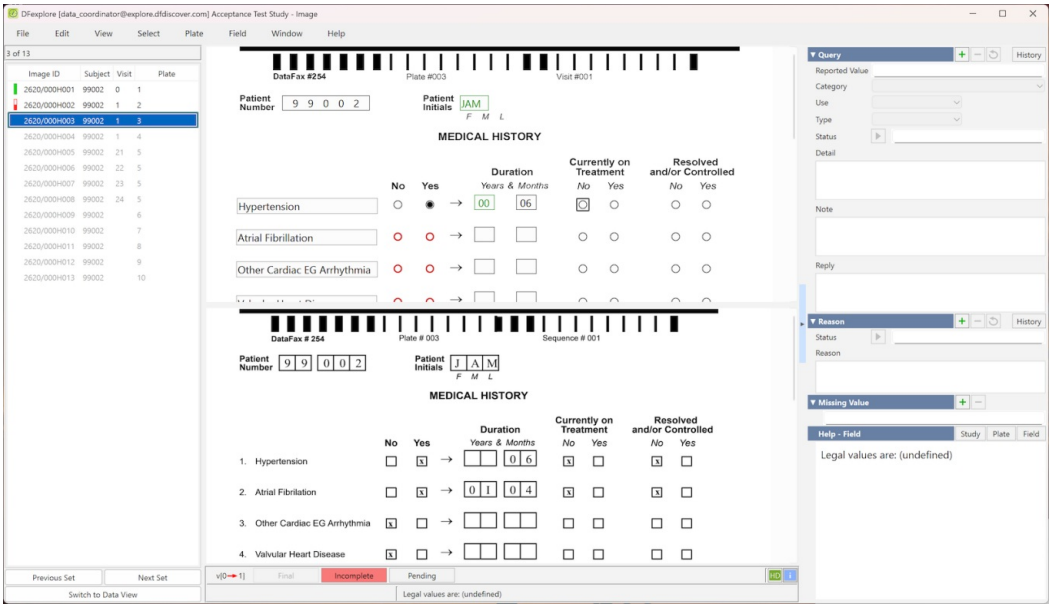
8.8.4. Confirm the change to the barcode by clicking OK in the warning dialog.



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.

8.8.5. 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.".

8.8.6. 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.



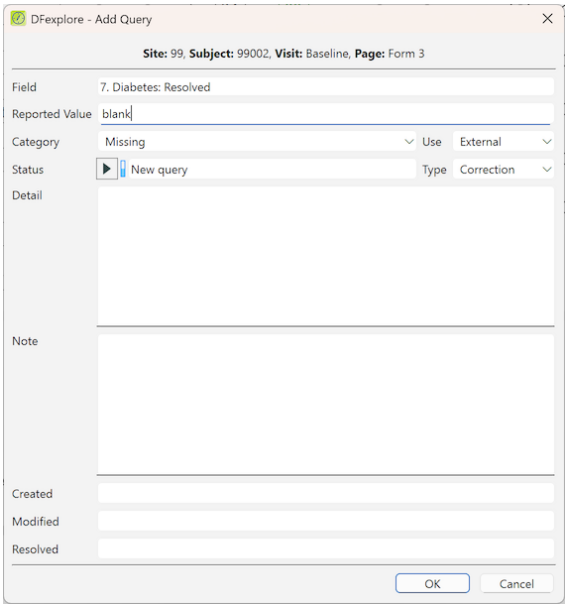
8.8.7. Enter the remaining values for **1. Hypertension** and enter all fields for **2. Atrial Fibrillation**. Press Tab to advance to the first No/Yes field for **3. Other Cardiac EG Arrhythmia**.

8.8.8. 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.

8.8.9. 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:

- **Category** = Missing
- **Status** = New query
- **Use** = External
- **Type** = Correction

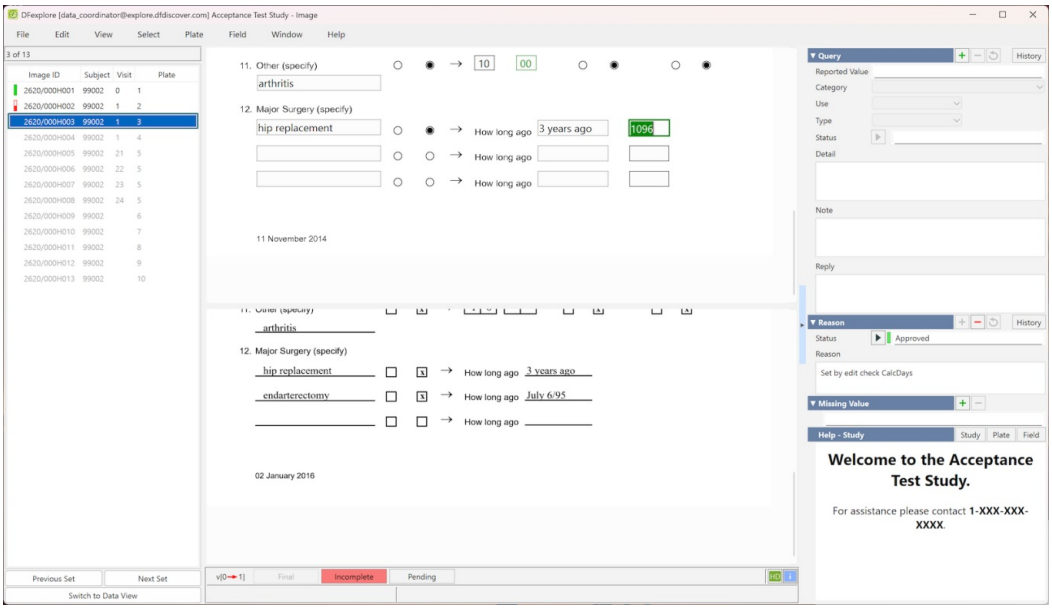
Click OK.



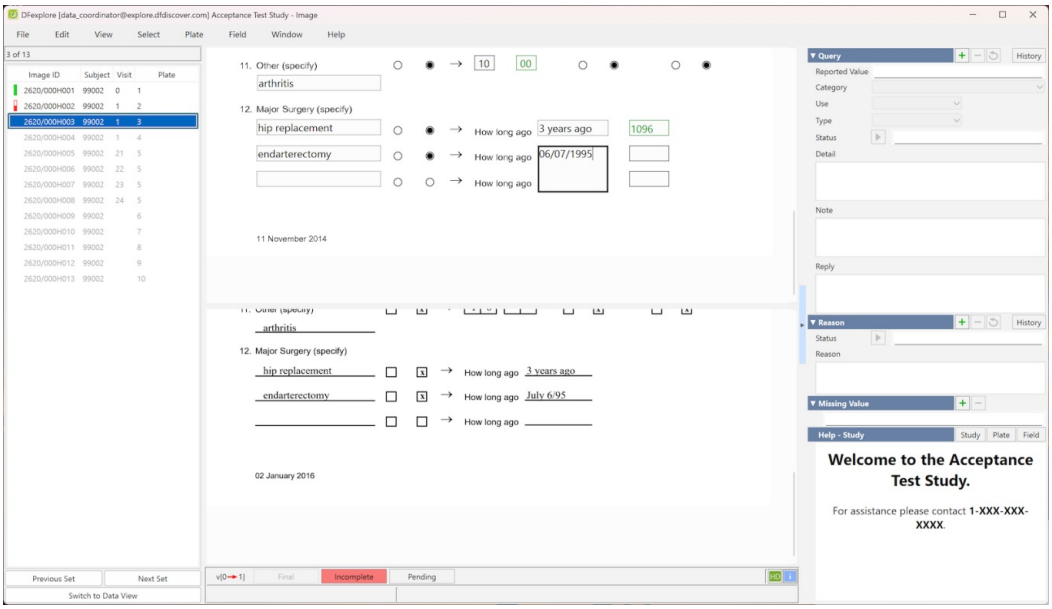
NOTE: **DFexplore** attempts to infer the **Category**, **Status**, **Use** and **Type** information when a query is being added. It is important to verify the query settings and correct them if necessary, before applying the query to the data field.

8.8.10. 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.

8.8.11. 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.

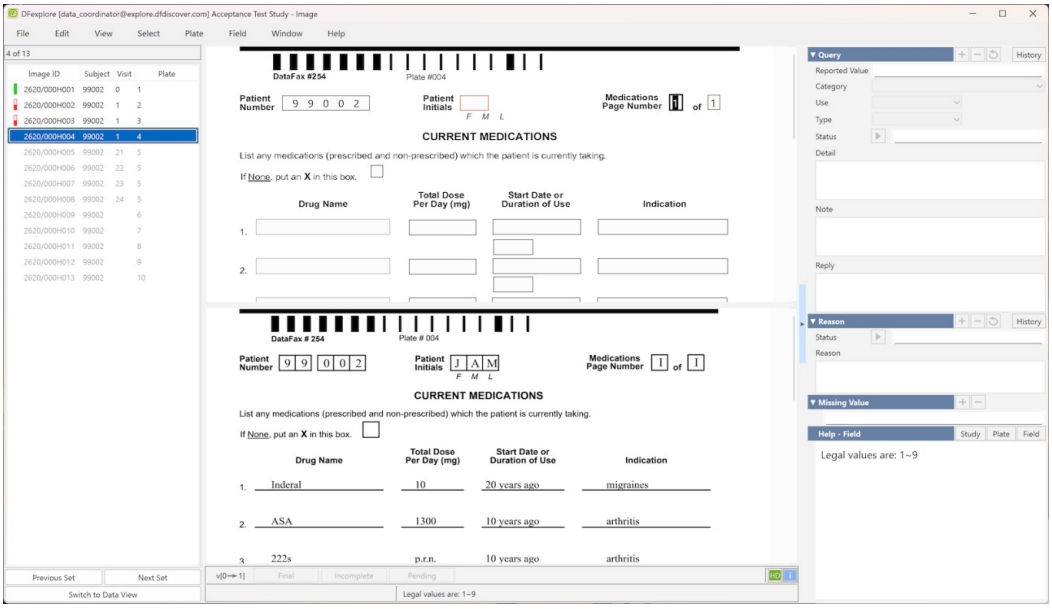


8.8.12. Press Tab to advance to the 2nd Major Surgery item. Input endarterectomy and perform the same steps as in Step 11. Enter the date 06/07/1995 for July 6/95 in the **How long ago** field.



8.8.13. 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 the field to make the save buttons at the bottom of the data entry window active.

8.8.14. 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**.

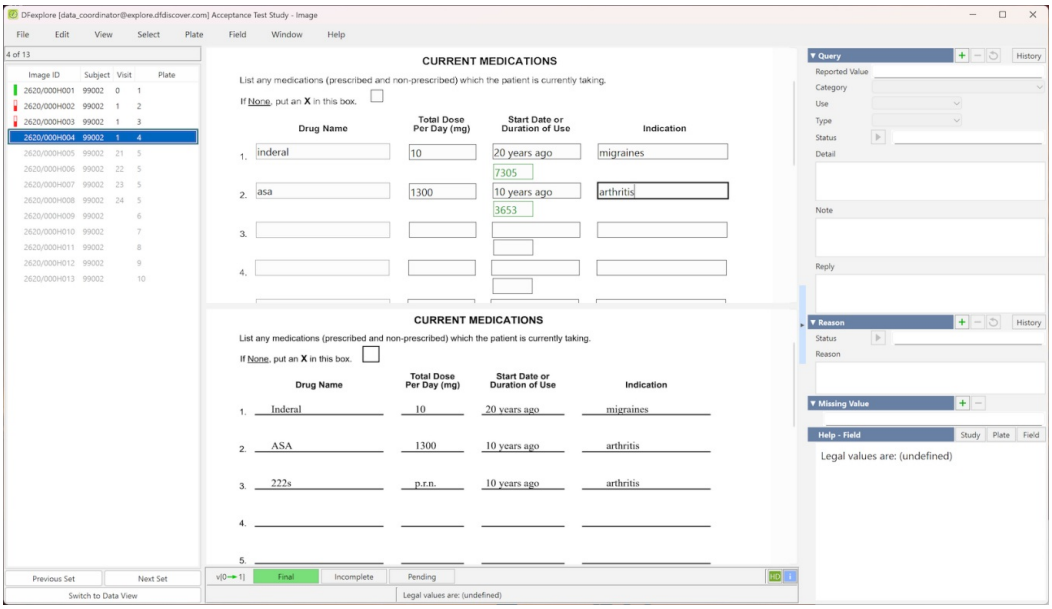


8.9 Enter Plate 4 (Form 4) for Subject 99002

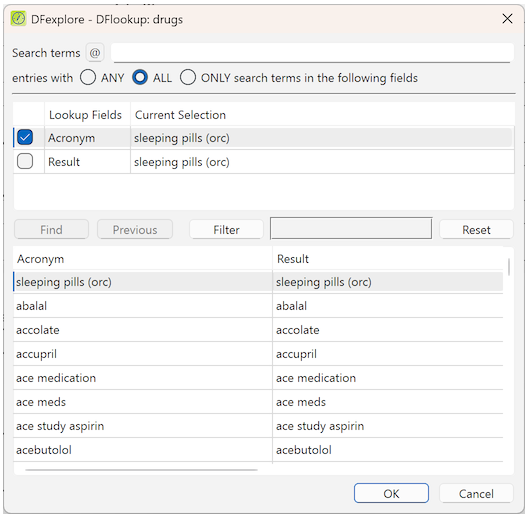
8.9.1. Correctly enter **Patient Number**, **Patient Initials** and both **Medications Page Number** fields per the CRF image. As for the previous pages, the SetInitedit check automatically completes the **Patient Initials** field. Press Tab to advance to the **1. Drug Name** field.

8.9.2. 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.

8.9.3. 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.



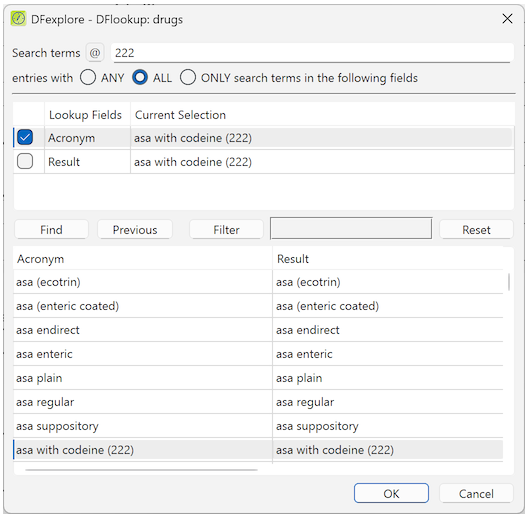
8.9.4. Press Tab to advance to the **3. Drug Name** field. An edit check, DrugLookup, has been programmed to match the entered drug text with an entry in a lookup table. Enter the 3rd drug name 222s and press Tab to exit the field executing DrugLookup edit check. (If an entry can not be found in the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



8.9.5. In the search dialog,

- Check (enable) **Acronym**
- Uncheck (disable) **Result**
- Input (enter) 222 in the **Search terms**

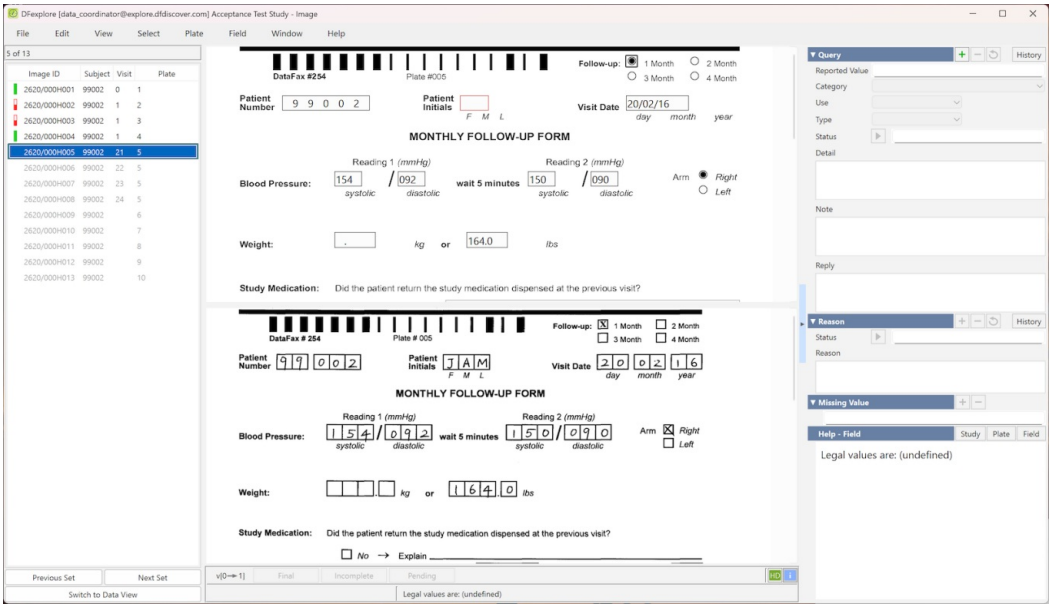
Click Find. Once the match **asa with codeine (222)** is found, click OK.



8.9.6. 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.

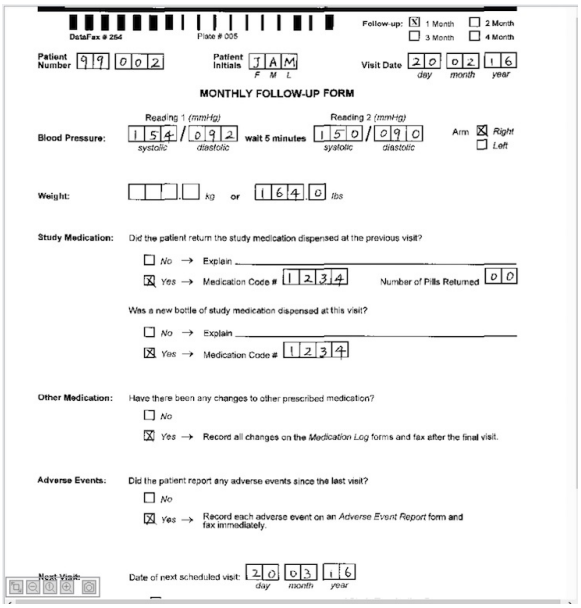
8.9.7. Step 1 to Step 6 test specific data fields. Any field that has not been entered (by you or the **DFdiscover** ICR) is now completed by entering the values as they appear on the CRF image. After entering the last data field, press Tab to exit the field and make the save buttons at the bottom of the data entry window active.

8.9.8. 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 or by pressing the space bar.



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

8.10.1. 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.".

8.10.2. 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.

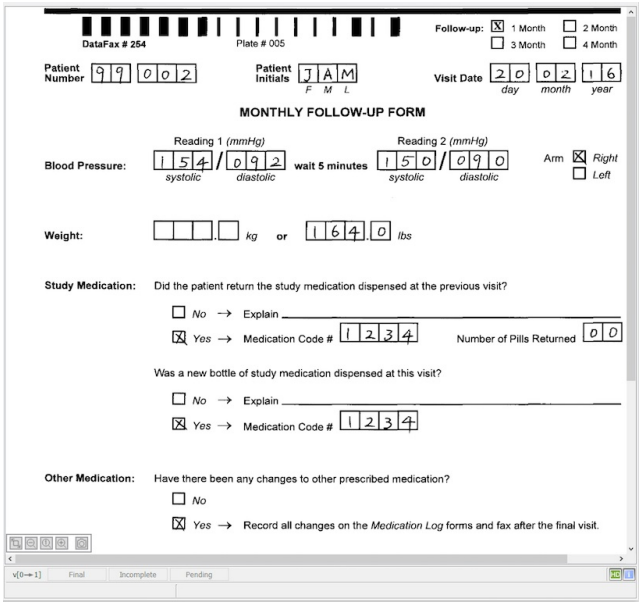
8.10.3. Click until the image reaches its maximum size. Examine the enlarged SD image.



8.10.4. 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.

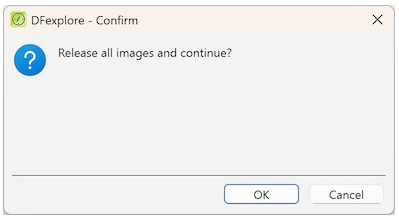


8.10.5. Examine the HD image. Verify that the HD image is clearly visible and there is a noticeable difference between the HD image and the previous SD image.

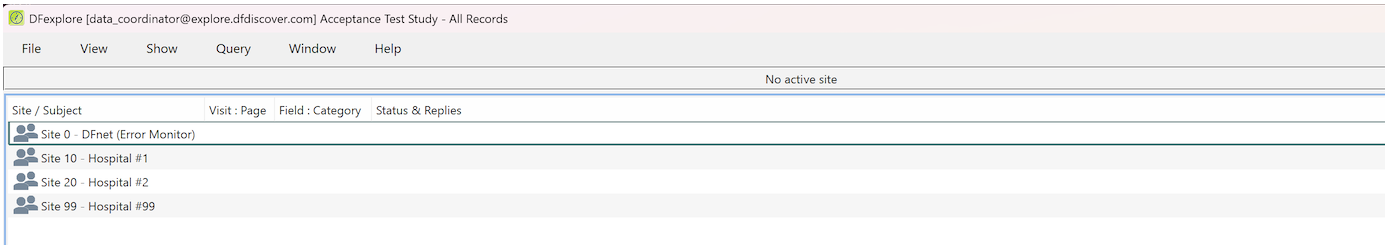


8.11 Edit an existing query

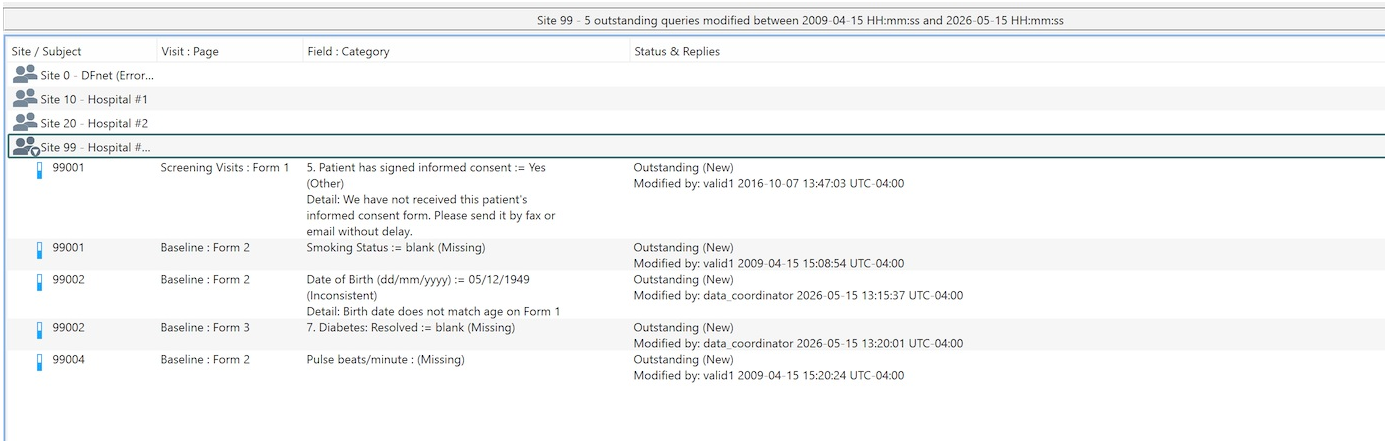
8.11.1. Select View > Queries to change from Image View to Queries View.



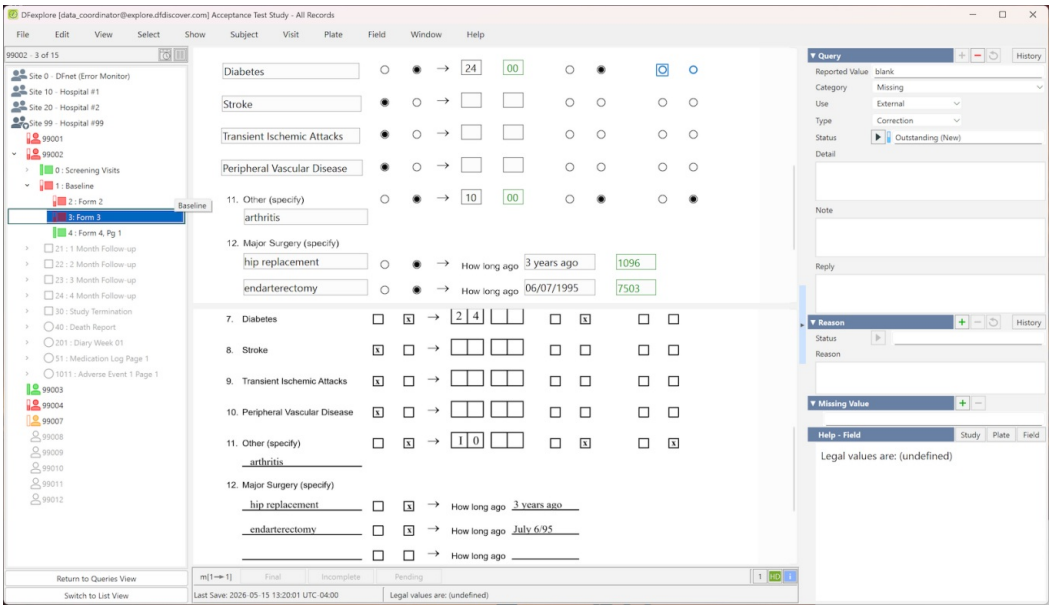
8.11.2. Click OK in the confirmation dialog to release the Image View records and open Queries View.



8.11.3. 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**.



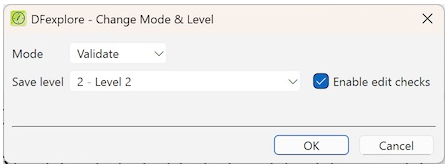
8.11.4. Locate the query for Subject **99002**, **Baseline : Form 3**. This is the query that was added to the field **7. Diabetes, Resolved and/or Controlled** in "Enter Plate 3 (Form 3) for Subject 99002.". Double-click the query to be taken directly to the page and queried field.



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

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

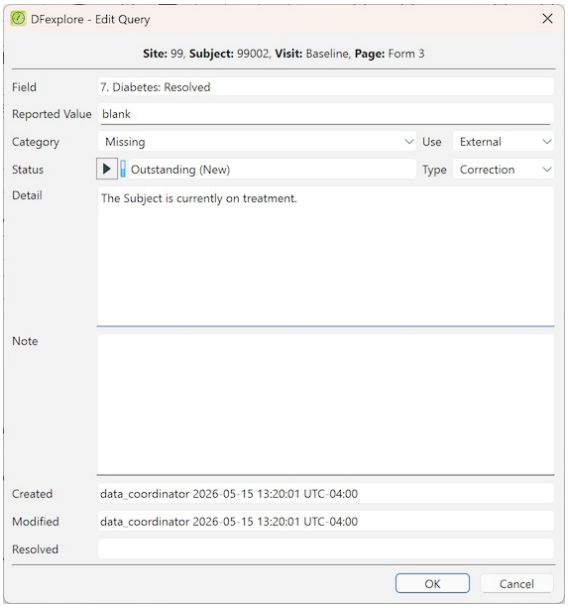
Click OK to apply the changes.



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

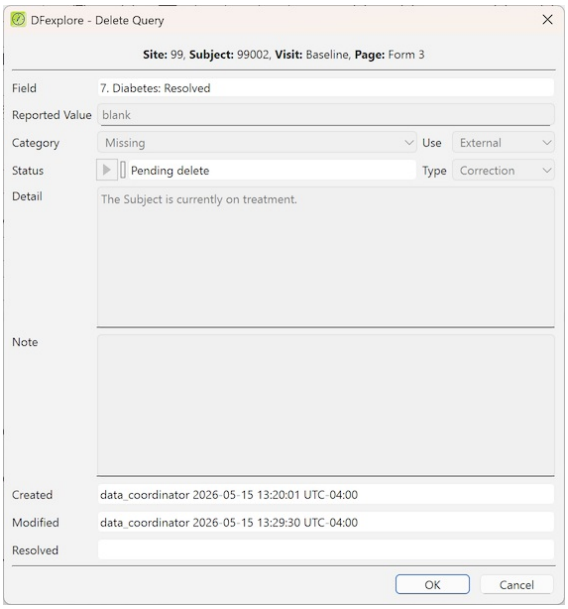
- **Status** = Resolved NA from the pull-down list.
- Enter The Subject is currently on treatment. in the **Detail** field

Click OK to apply the edits.

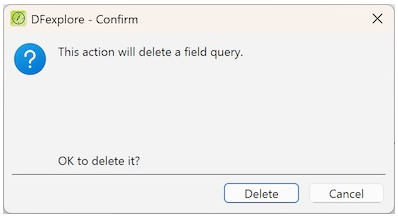


8.12 Delete an existing query

8.12.1. 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 −.



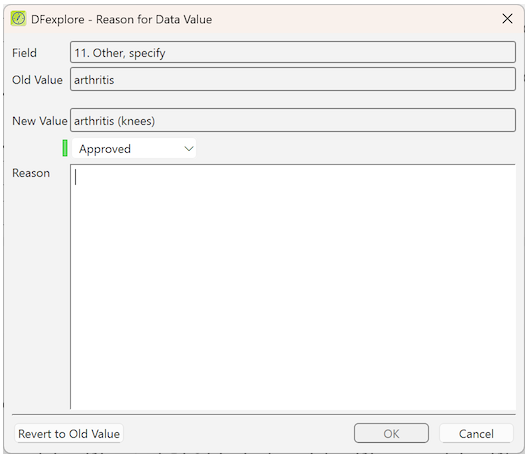
8.12.2. Click OK to perform the query deletion.



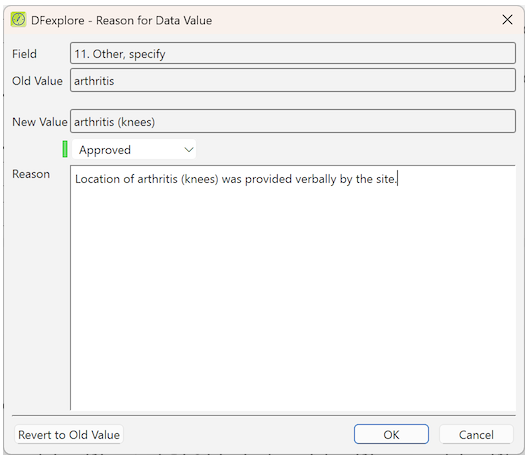
8.12.3. Click Delete in the confirmation dialog.

8.13 Change data and record a reason for data change

8.13.1. 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 +.



8.13.2. 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.

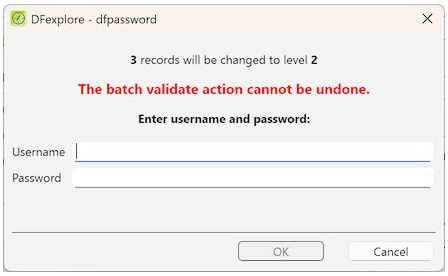


8.13.3. Press Tab to advance through the remaining fields on the **Medical History** page until the save buttons at the bottom of the screen become active. Click Final to save the modified page to the database at level 2.

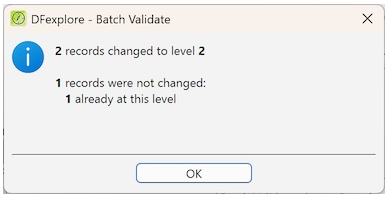
8.14 Batch validate all opened pages for Subject 99002 to level 2

8.14.1. 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.

8.14.2. 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.



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

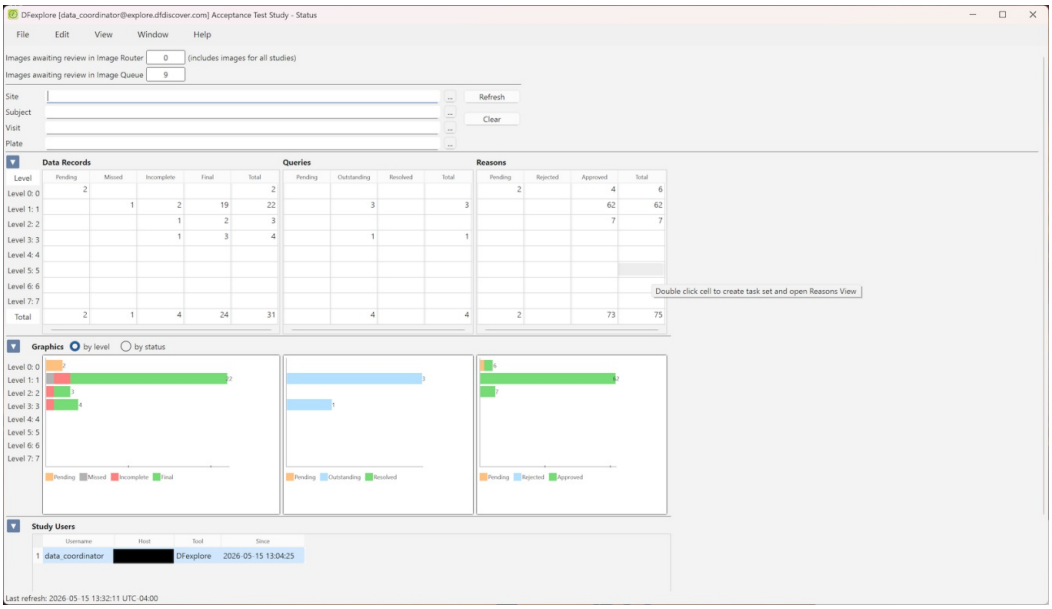


8.14.4. Click OK to close the summary dialog and complete the batch validation operation.

8.15 Confirm the status of entered pages in Status View

8.15.1. Select View > Status to close Image view and release all pages in the record list and open **Status** view.

8.15.2. Confirm that the number of images awaiting review is now 9.



8.15.3. 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.

9 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

1. Retrieve an existing data record in **DFexplore**.
2. Apply a user-defined Category query.
3. Add a reason for Data Value to explain entered data.
4. Edit an existing query.
5. Delete a user-defined Query Category that is used by an existing query.
6. Delete a user-defined Category query.

Estimate of Time Required: 30 Minutes

Begin Module 9. User-defined Query Category Types

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

9.1 Retrieve an existing data record in **DFexplore**

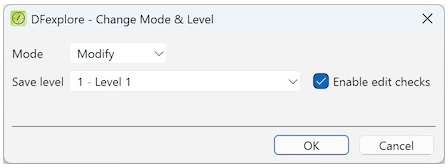
9.1.1. Start **DFexplore**, login as data_coordinator and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

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

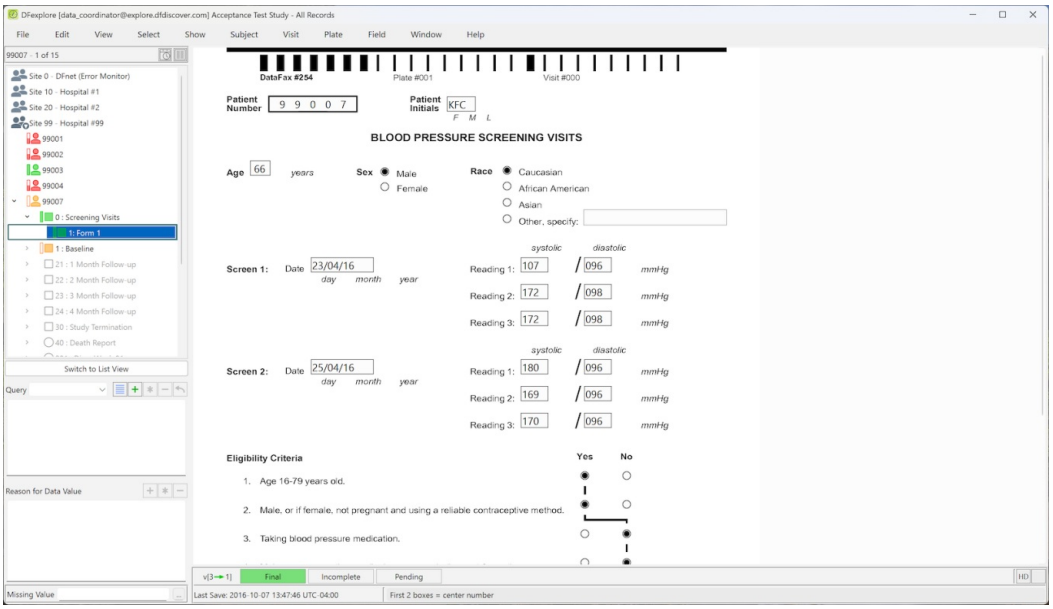
9.1.1. Select Select > Change Mode & Level. Within the dialog, set:

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

Click OK to apply these settings.



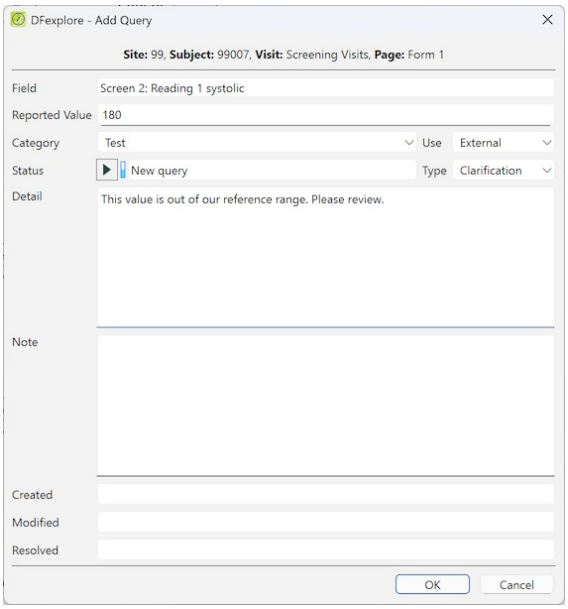
9.1.2. Double-click the folder for **Site 99** and then double-click subject **99007** to open the subject binder. Locate **0: Screening Visits** in the list of visits for subject **99007**, and double-click this entry to open task records for this subject. Press Tab to advance through the fields until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



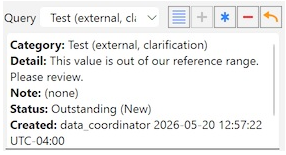
9.2 Apply a user-defined Category query

9.2.1. 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:

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



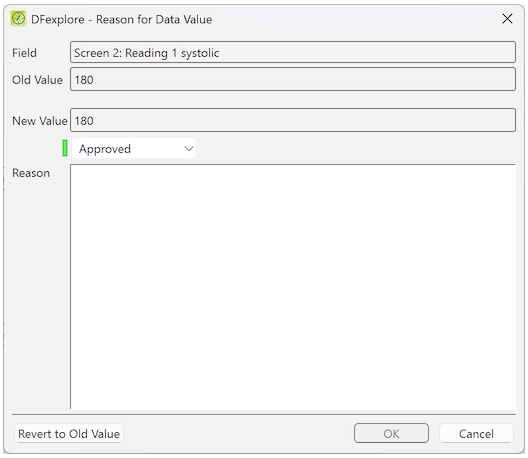
9.2.2. Click OK to apply the query to the **Screen 2, Reading 1 systolic blood pressure** field. Note that the field becomes blue. Examine the details in the **Query** window that appears near the bottom left of the screen.



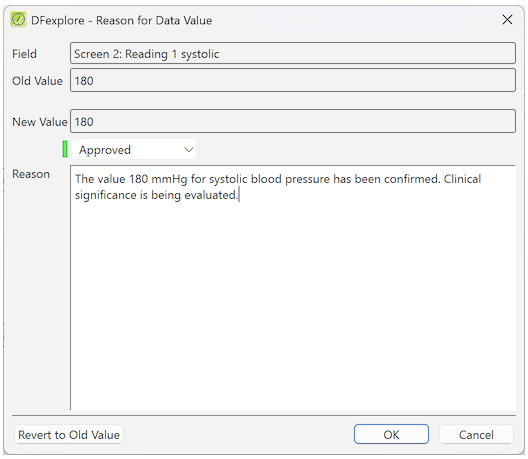
9.2.3. Press Tab to advance through the remaining fields on the page without making any changes. Press Tab to advance to the save buttons at the bottom of the data screen. Click Incomplete to save the page.

9.3 Add a reason for Data Value to explain entered data

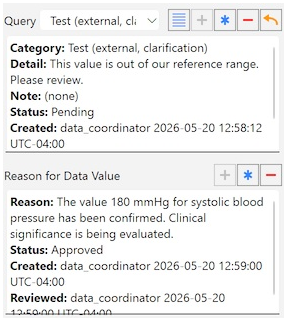
9.3.1. With **BLOOD PRESSURE SCREENING VISITS** as the active page, press Tab to advance through the fields until **Screen 2, Reading 1 systolic blood pressure** becomes the current field. Select Field > Add Reason For Data Value or click [+] to open Reason for Data Value dialog.



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



9.3.3. 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.

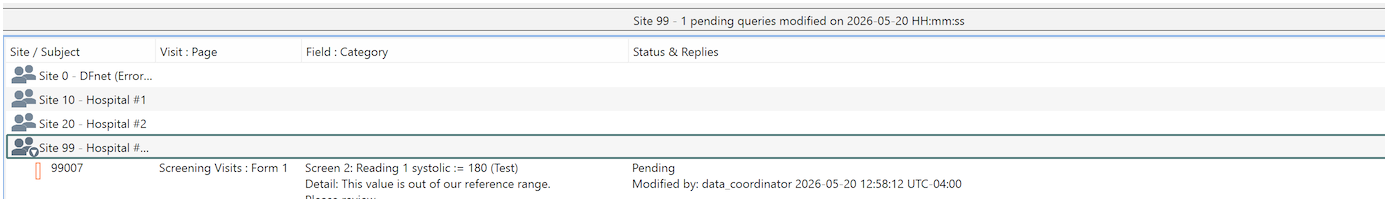


NOTE: If a user-defined Category Code is defined with auto-resolution in **DFsetup**, adding a reason to a field that has a query with such a category will change the query status from outstanding to pending.

9.3.4. 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.

9.4 Edit an existing query

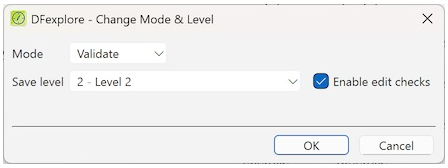
9.4.1. Select View > Queries. Select Show > Pending Queries to display all pending queries for **Site 99 - Hospital #99**.



9.4.2. Double-click entry for subject **99007, Screening Visits: Form 1** to be taken directly to the page and the pending field.

9.4.3. In Data View, Select Select > Change Mode & Level. In the dialog, set:

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

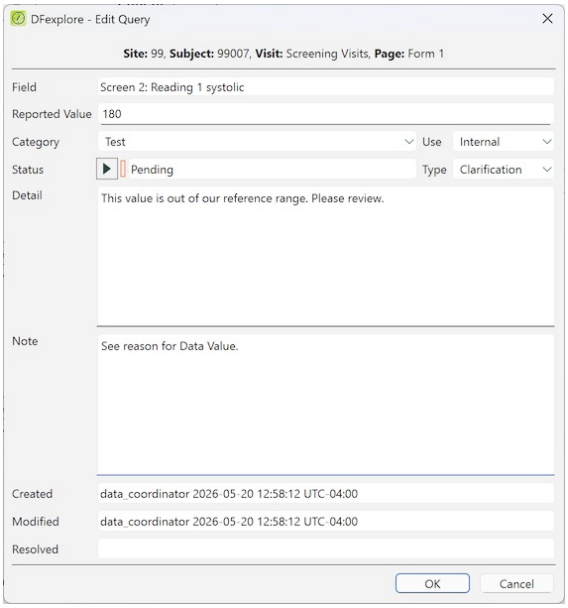


9.4.4. Click OK to apply and close the **Change Mode & Level** dialog. The current field is **Screen 2, Reading 1 systolic blood pressure**.

9.4.5. 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.



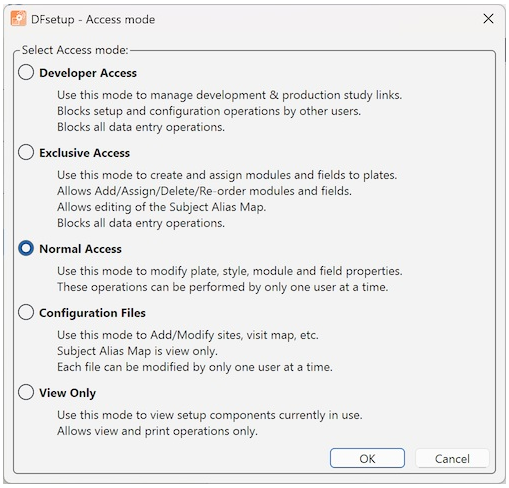
9.4.6. From the **Screen 2, Reading 1 systolic blood pressure** field, press Tab to advance through the remaining fields on the page without making any changes. Press Tab to advance to the save buttons at the bottom of the data screen to make them active. Click Final.

9.4.7. Select File > Exit to close and exit **DFexplore**.

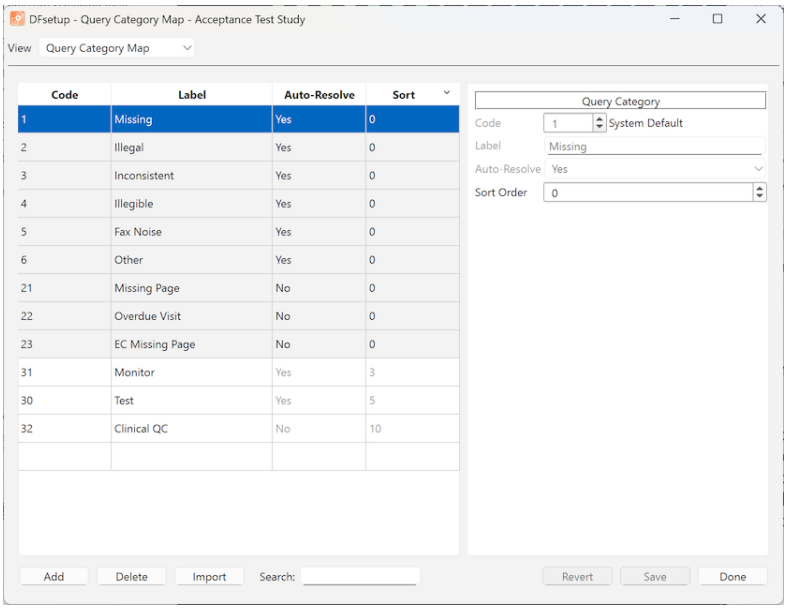
9.5 Delete a user-defined Query Category that is used by an existing query

9.5.1. Start **DFsetup**, login as data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFsetup**".

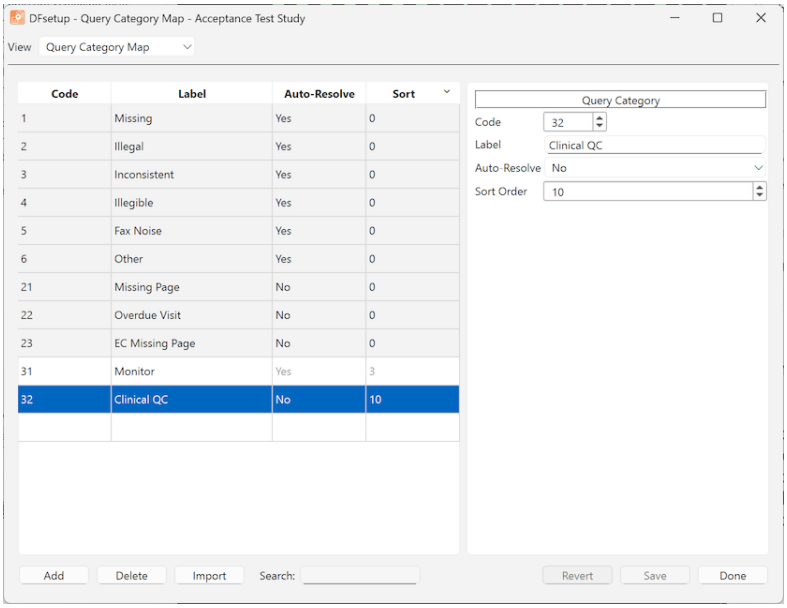
9.5.2. Choose **Normal Access** and click OK.



9.5.3. Select View > Query Category Map.



9.5.4. 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.



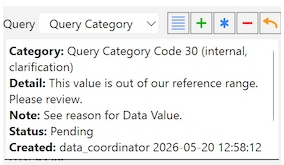
9.5.5. Select File > Exit to close **DFsetup**.

9.6 Delete a user-defined Category query

9.6.1. Start **DFexplore**, login as data_coordinator and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

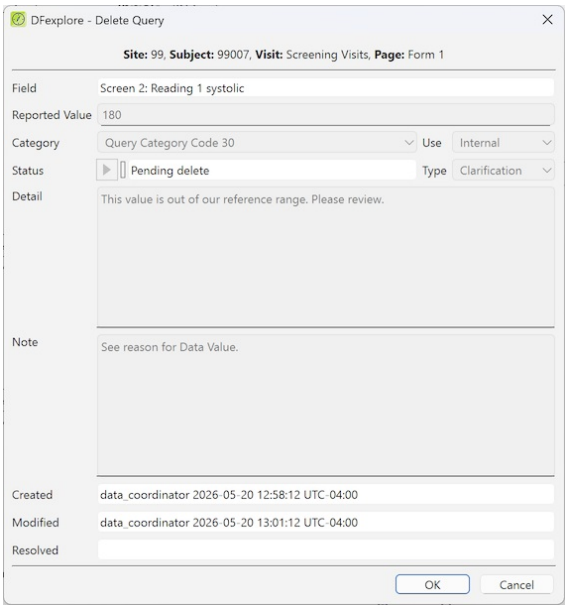
NOTE: If data_coordinator has been set up for 2-factor authentication with Azure SMS, you may need to wait for a 1-time code to arrive at the phone number as defined in **DFadmin**.

9.6.1. 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**.

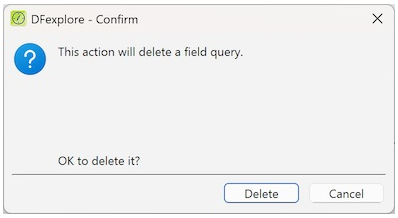


9.6.2. Select Field > Delete Query or click [−].

9.6.3. Click OK to perform the query deletion.



9.6.4. Click Delete in the confirmation dialog.



9.6.5. 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.

9.6.6. 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.

10 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

1. Submit PDF images to DFdiscover.
2. Enable multiple queries per field in **DFsetup**.
3. Retrieve submitted CRF in **DFexplore** Image View.
4. Enter Plate 9 for Subject 99002.
5. Apply multiple queries to a field.
6. 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.

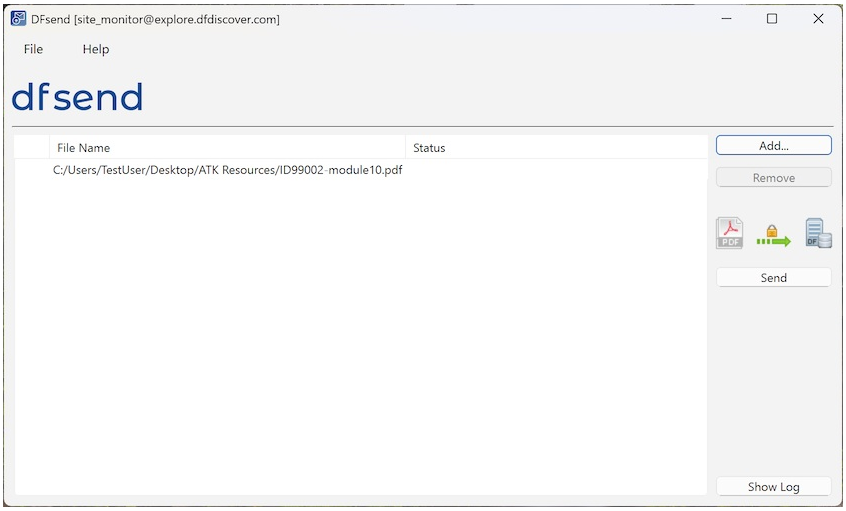
NOTE: Save the **ID99002-module10.pdf** file received via email to your local computer. This file is required to complete the remainder of this module. Refer to "Creating user accounts and assigning study permissions." as a valid email address is required for site_monitor to receive the module specific 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.

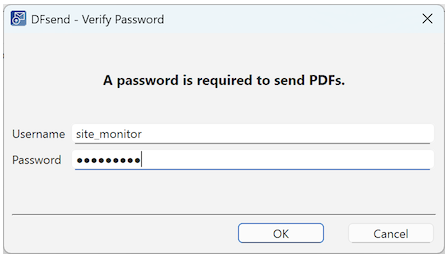
10.1 Submit PDF images to DFdiscover

10.1.1. Start **DFsend**, login as user site_monitor as described in "How to start **DFsend**".

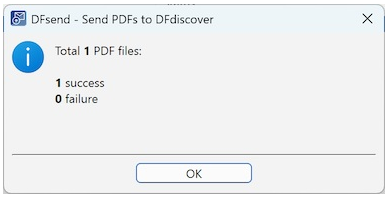
10.1.2. Click Add. From the **Select PDF Files** file selection dialog, locate the previously saved **ID99002-module10.pdf** file. Select the file, click Open.



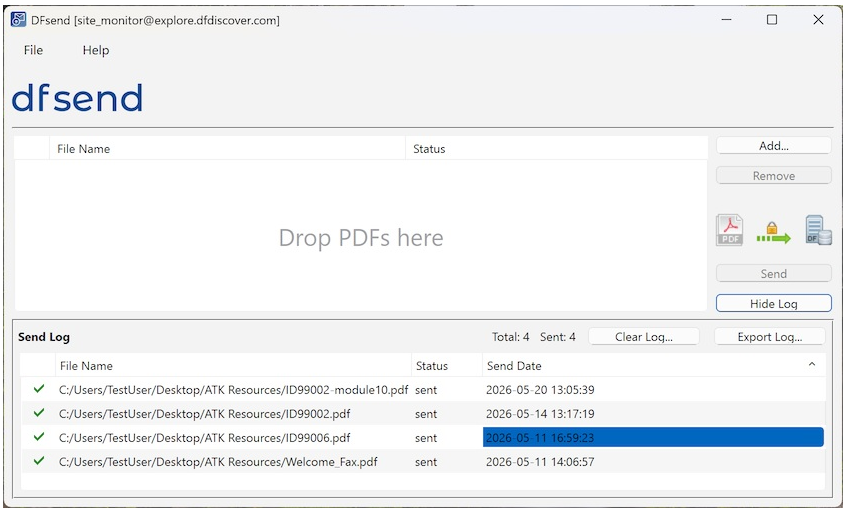
10.1.3. Click Send, enter site_monitor in the **Username** field and the previously assigned password in the **Password** field. Click OK.



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



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

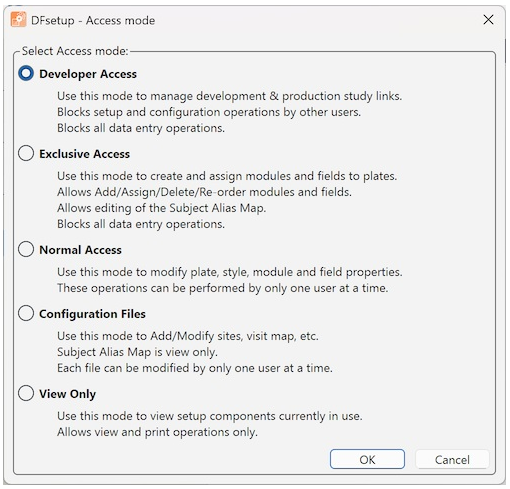


10.1.6. Select File > Exit.

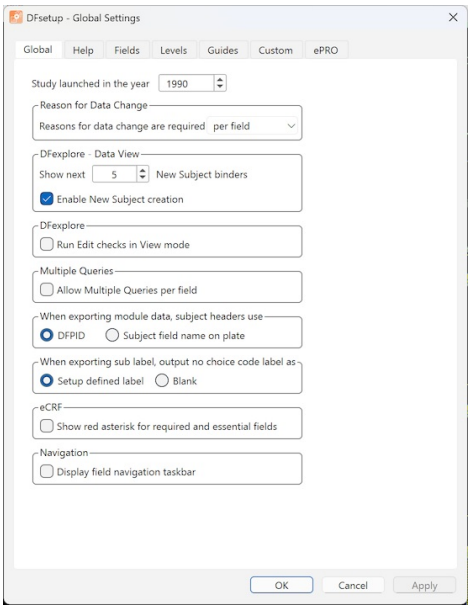
10.2 Enable multiple queries per field in DFsetup

10.2.1. Start **DFsetup**, login as user data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFsetup**".

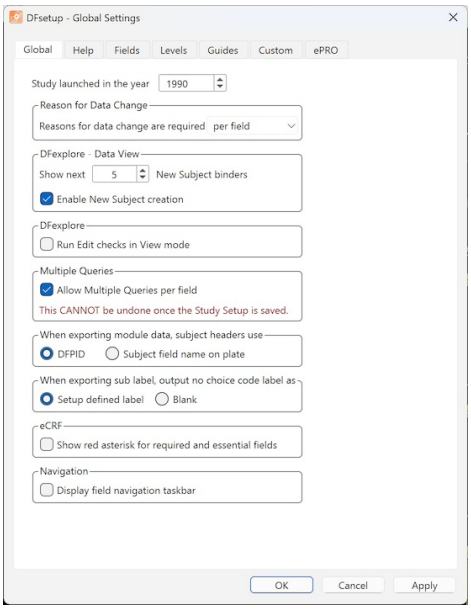
10.2.2. Choose **Developer Access** in the **Access mode** dialog, click OK.



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



10.2.4. 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.



10.2.5. Click OK to close the **Global Settings** dialog.

10.2.6. Select File > Save [Required], followed by File > Exit.

10.3 Retrieve submitted CRF in **DFexplore** Image View

10.3.1. 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**.

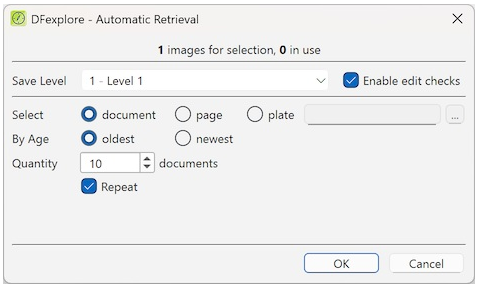
10.3.1. The main window for **DFexplore** is displayed. Select View > Image.

10.3.2. In the **Automatic Retrieval** dialog, set:

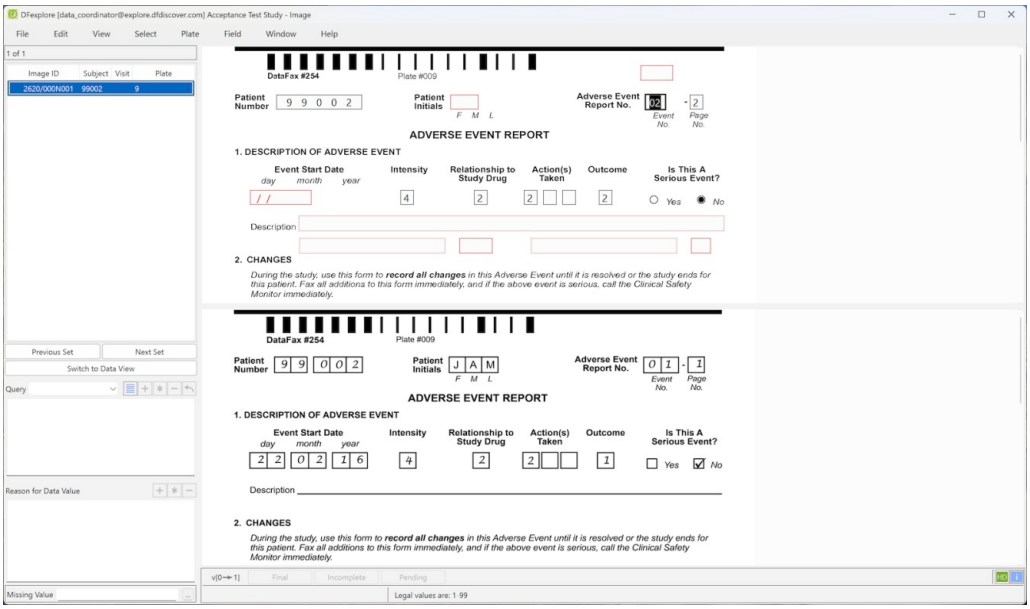
- **Save level** = **1 - Level 1**
- Check (enable) **Enable Edit Checks**
- **Select** = **document**
- **By Age** = **Oldest**
- **Quantity __ documents** = **10**
- Check (enable) **Repeat**

Confirm the settings.

Click OK.

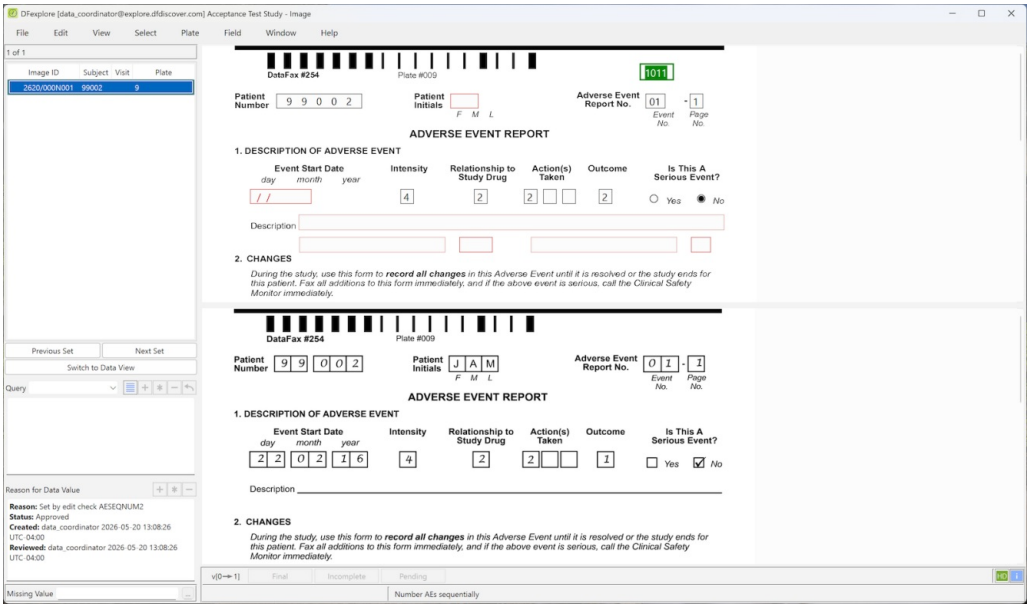


10.3.3. The first image retrieved is the **Adverse Event Report** CRF.



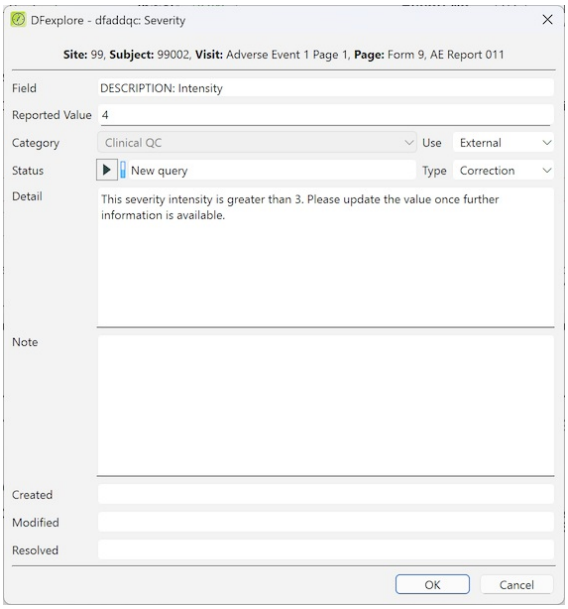
10.4 Enter Plate 9 for Subject 99002

10.4.1. 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.



10.4.2. Press Tab to advance to the **Patient Number** field.

10.4.3. 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.

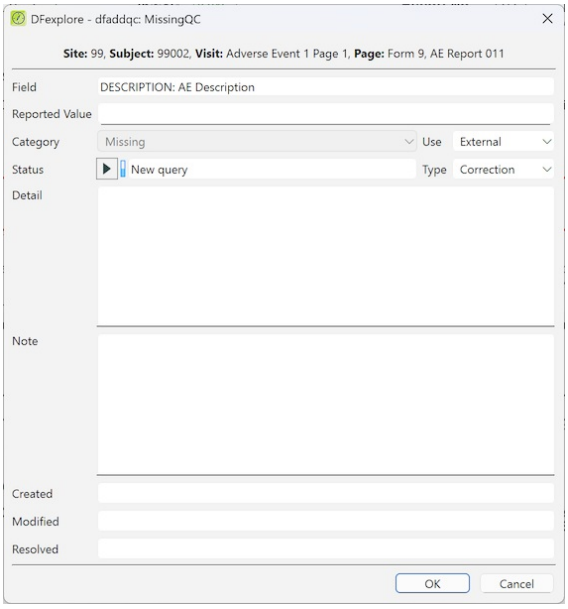


10.4.4. Click OK to apply the edit check. The field becomes blue, and the next field **Relationship to Study Drug** becomes the current field.

10.4.5. 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.

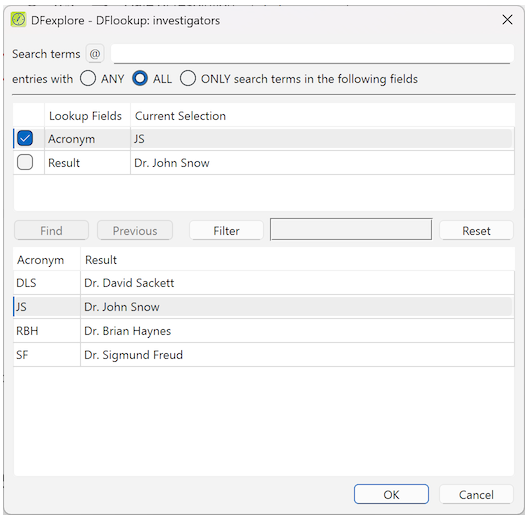
Confirm that **Missing** is displayed in the **Category** field.



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

10.4.7. 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.



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

10.5 Apply multiple queries to a field

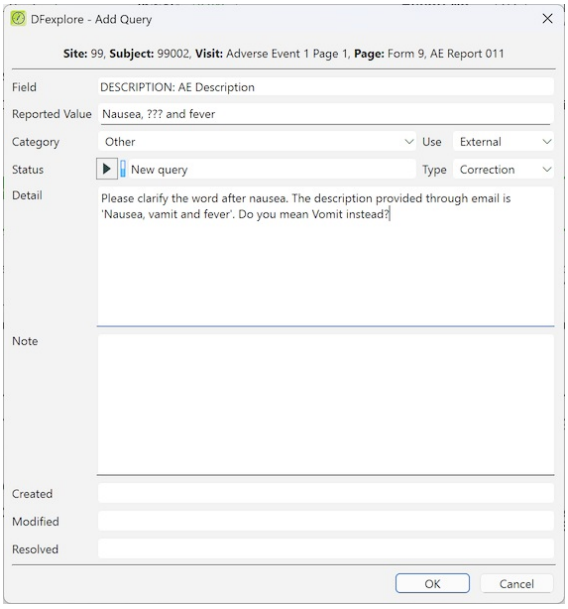
10.5.1. With the **Adverse Event Report** displayed as the current page, make the page active by clicking anywhere on the page background using the mouse. Press Tab to advance through the fields until **Description** becomes the current field. Note that the **Description** field is blank and has an unresolved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



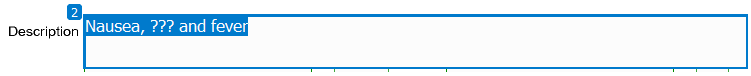
10.5.2. Select Field > Add Query or click +. In the dialog, confirm **Category** type **Missing** is disabled. Set:

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

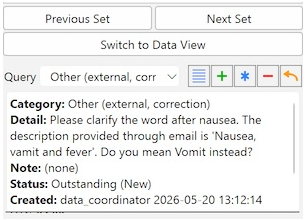
NOTE: Multiple queries can be added to a single field, but each query must have a unique Query Category type. Therefore, a Category will be disabled if it has been previously used on the same field where a new query is to be added.



10.5.3. 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.

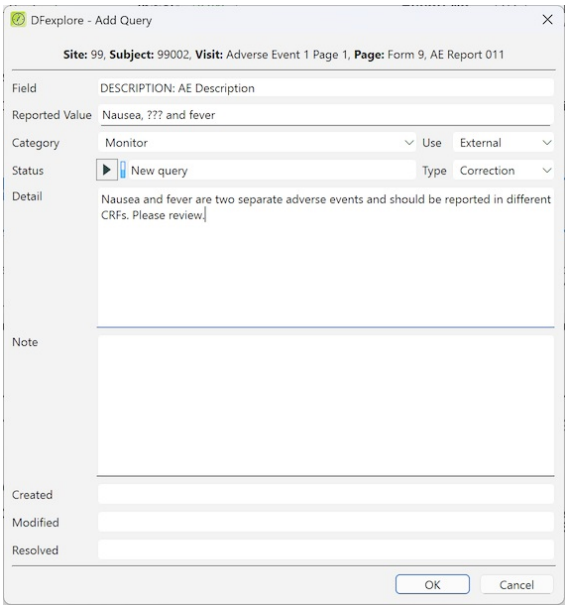


10.5.4. With the focus still on the **Description** field, examine the details in the **Query** window that appears at the bottom left corner of the main data entry screen.



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

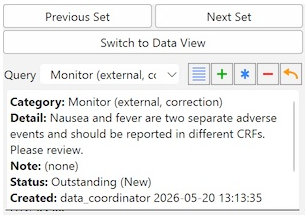
- **Category** = Monitor
- **Use** = External
- **Type** = Correction
- **Status** = New query
- **Detail** = Nausea and fever are two separate adverse events and should be reported in different CRFs. Please review.



10.5.6. 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.

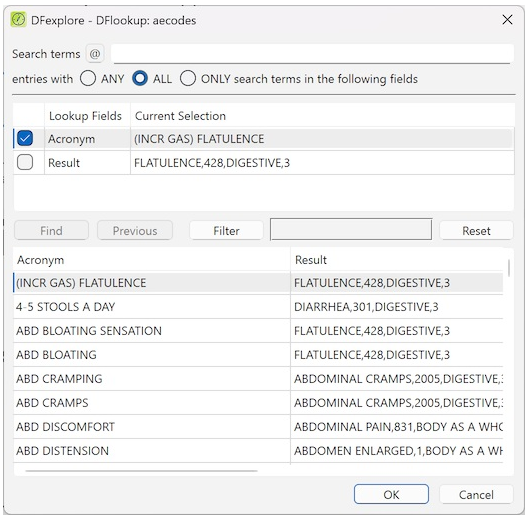


10.5.7. With the focus still on the **Description** field, examine the details in the **Query** window that appears at the bottom left corner of the main data entry screen.



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

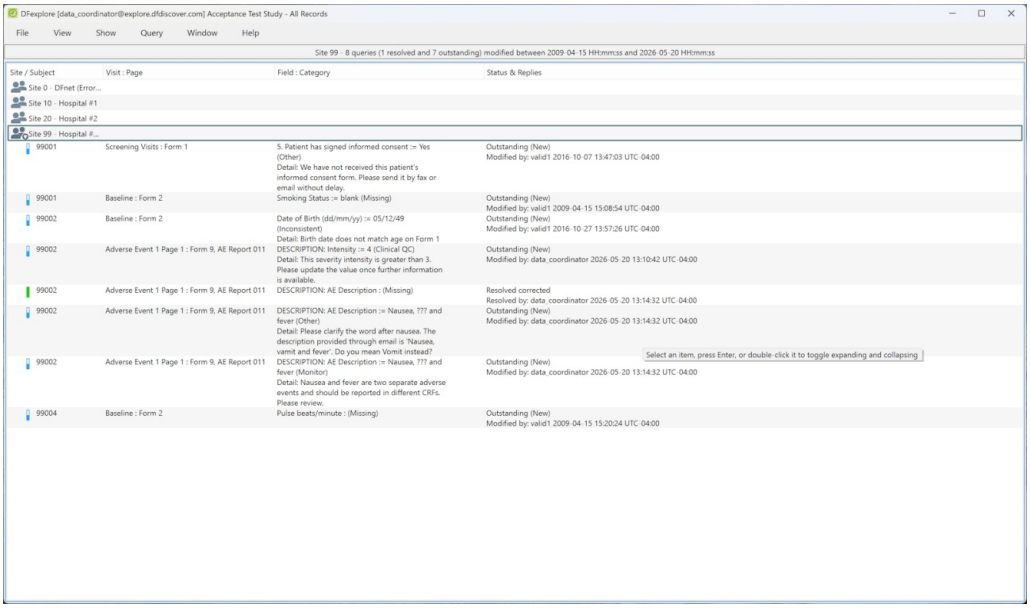
10.5.8. Press Tab to exit the **Description** field, the DFlookup: aecodes window appears. Click Cancel in the window to close the dialog. The next field **AECOTERM** becomes the current field.



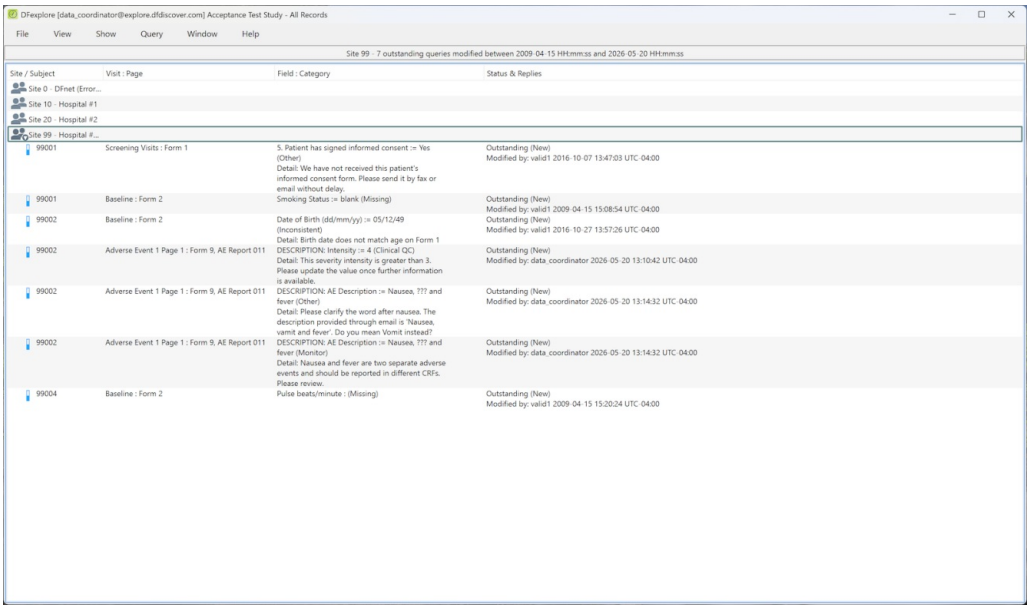
10.5.9. Press Tab to advance through the remaining fields on the page without making any changes. Press Tab to advance to the save buttons at the bottom of the data screen to make them active. Click Incomplete.

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

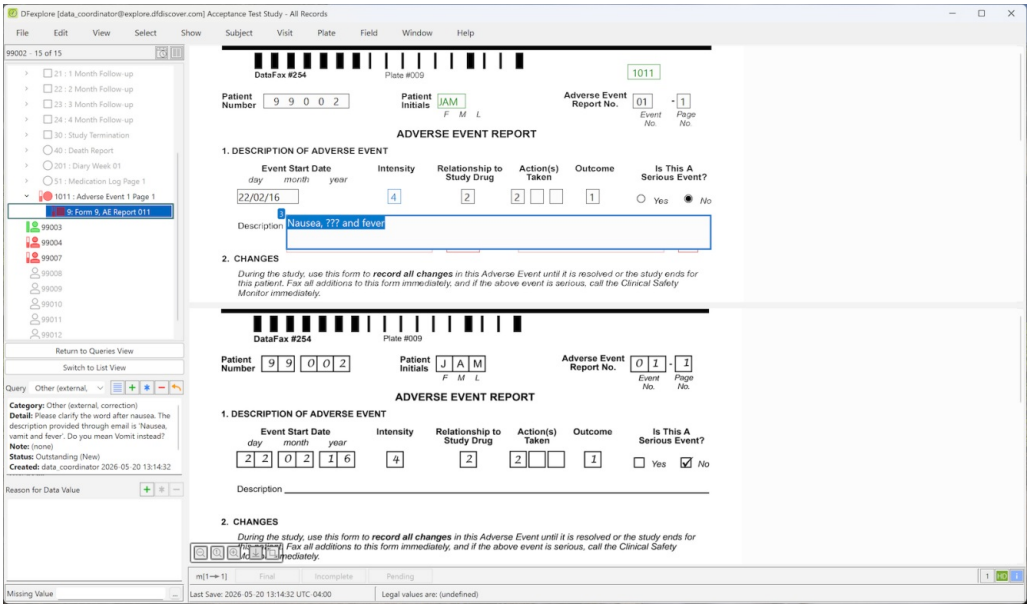
10.6.1. With the **Adverse Event Report** page still active, Select View > Queries to open the **Queries** View window. In the resulting confirmation dialog, click OK to release all Image records. Select Show > All Queries. Double-click **Site 99 - Hospital #99**. Locate and confirm that the Queries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



10.6.2. 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.



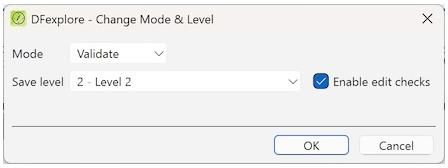
10.6.3. Double-click entry containing the query category **Other** in the **Description** field of Subject **99002, Adverse Event 1 Page 1: Form 9, AE Report 011**.



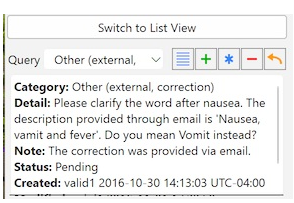
10.6.4. Select Select > Change Mode & Level. In the dialog, set:

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

Click OK to apply the changes.



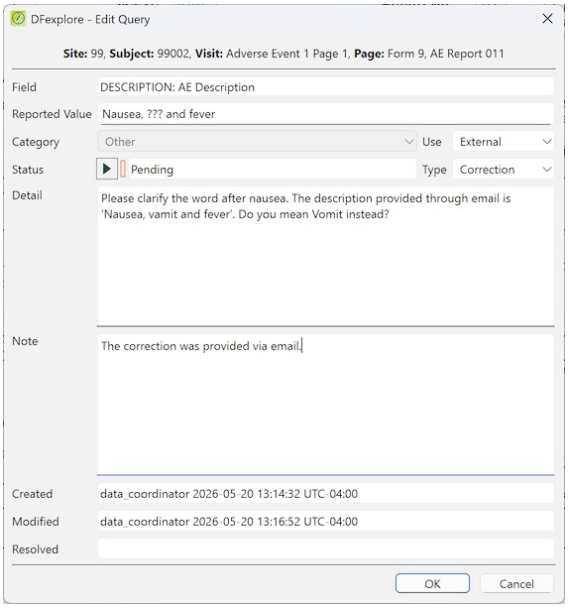
10.6.5. Delete the text ??? in the description field and enter vomiting instead. Examine the query window. From the **Query** drop-down choose **Other (external, correction)** query in the query list.



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

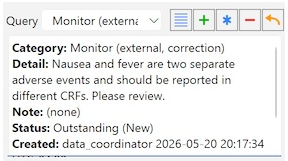
- Select **Pending** from the **Status** pull-down.
- Enter The correction was provided via email. in the **Note** field.

Click OK to apply the edits.

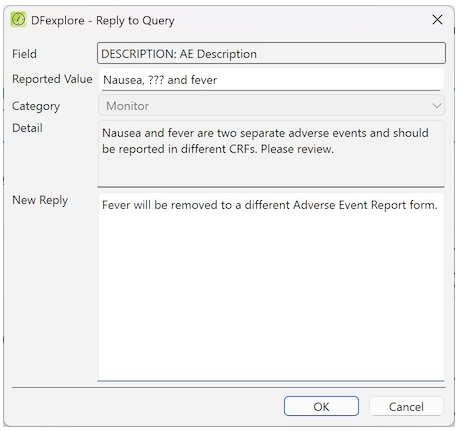


10.7 Select and reply to an existing query in a field that has multiple queries

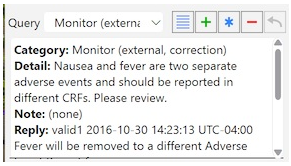
10.7.1. Select **Monitor (external correction)** from the **Query** pull-down to make the query active.



10.7.2. 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.

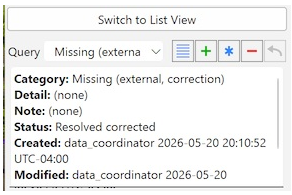


10.7.3. Click OK to close the dialog. Examine the information present in the **Query** window.

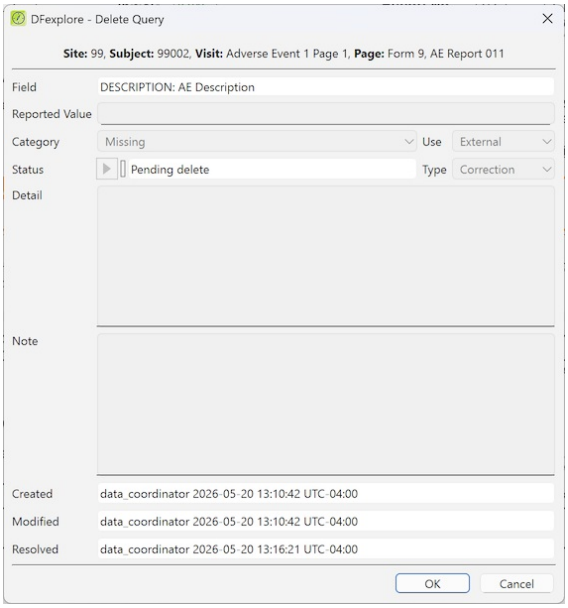


10.8 Select and delete an existing query in a field that has multiple queries

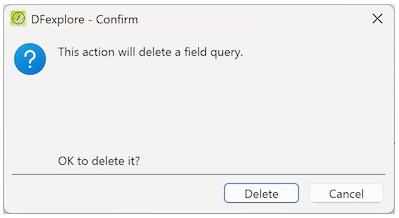
10.8.1. Choose **Missing (external, correction)** from the **Query** pull-down list. The query list in the query window displays the **Missing (external, correction)** query. Confirm that the first query is defined with **Category: Missing (external, correction)** and a **Status: Resolved corrected**.



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



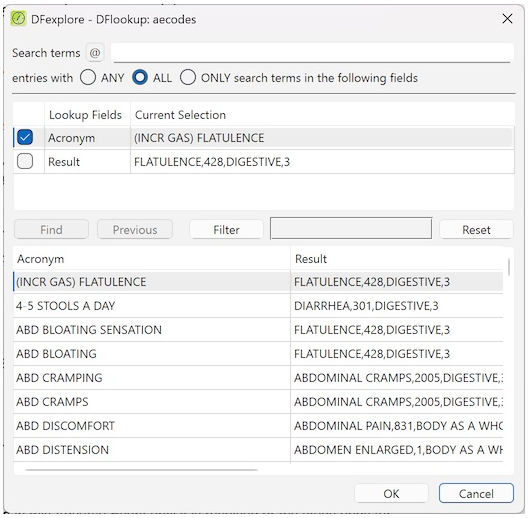
10.8.3. Click OK to perform the query deletion.



10.8.4. 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.



10.8.5. 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.



10.8.6. 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.

10.8.7. 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.

11 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
- Ensure **Use subject alias** setting is disabled in **DFexplore** under File > Preferences.

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.

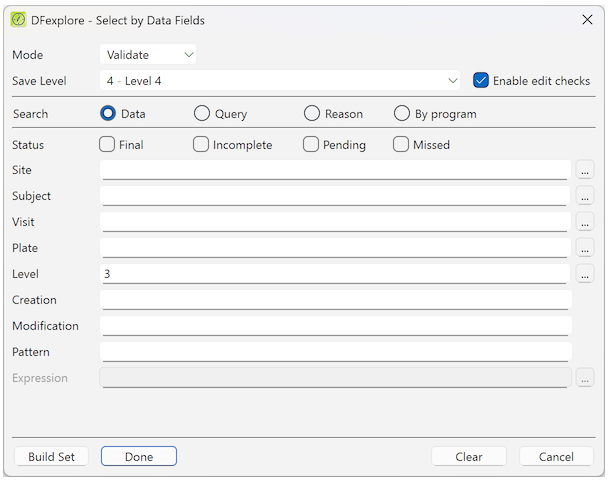
> NOTE: Refer to "Creating user accounts and assigning study permissions." as a valid email address is required for site_monitor to receive the module specific PDF files.

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

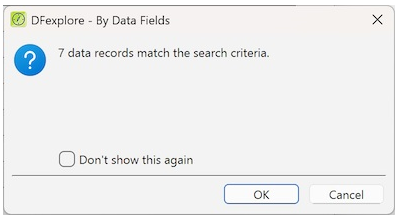
11.1.1. Start **DFexplore**, login as user data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

11.1.2. Select Select > By Data Fields from the menubar to open the **Select By Data Fields** retrieval dialog. In the dialog, set:

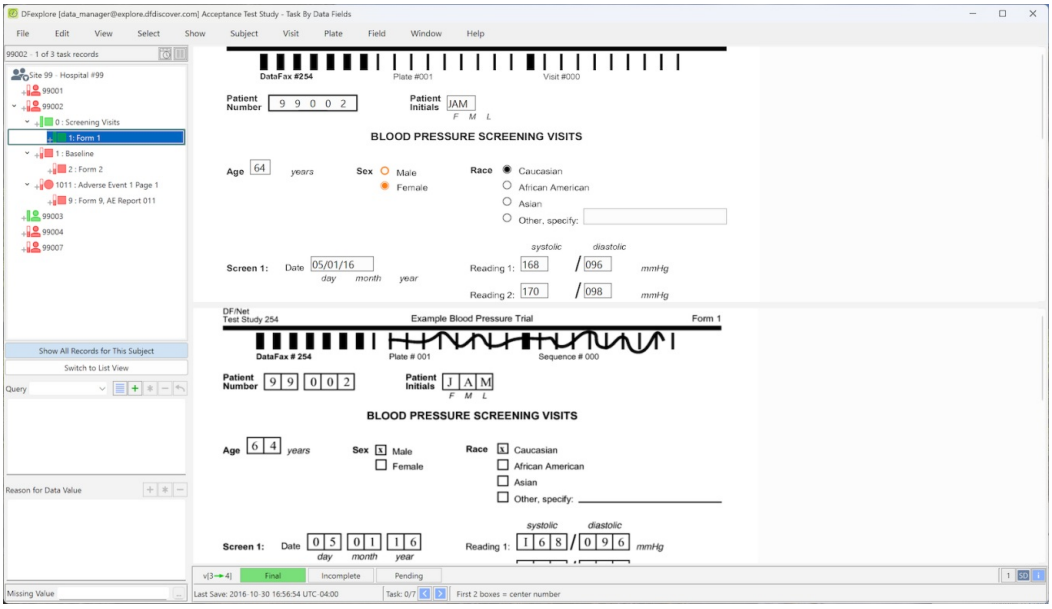
- **Mode** = Validate
- **Save level** = 4 - Level 4
- **Search** = Data
- **Level** = 3
- Check (enable) **Enable edit checks**



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

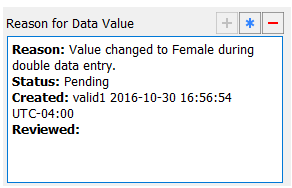


11.1.4. Double-click entry for Subject **99002** to open the subject binder.

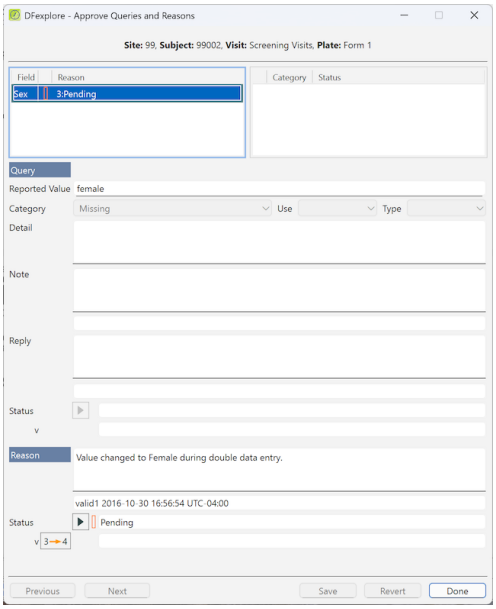


11.2 Review and approve a pending reason for data value, and approve a selected query in a field that has multiple queries

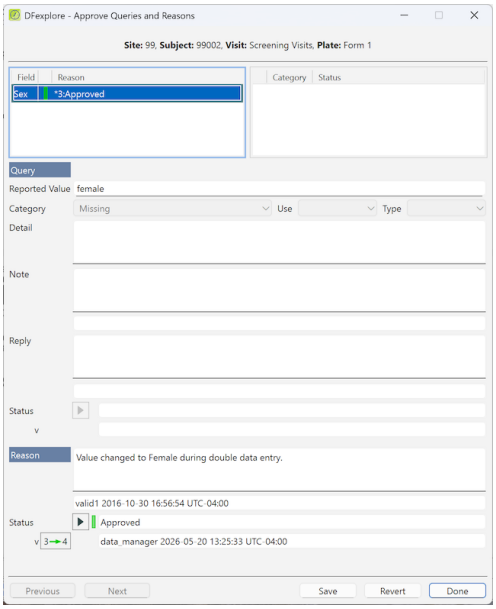
11.2.1. 1: Form 1 (BLOOD PRESSURE SCREENING VISITS) for Subject **99002** is the active page. Press Tab to advance to the **Sex** field. Examine the information in the **Reason for Data Value** window.



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



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

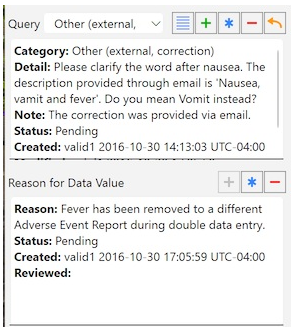


11.2.4. Click Save and Done to close the dialog.

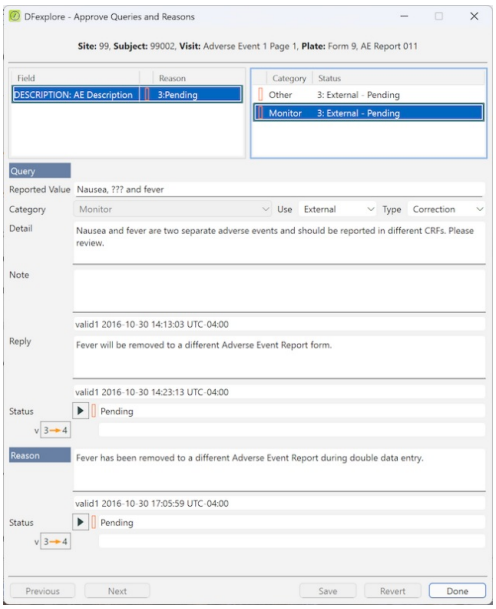
11.2.5. Do not make any other changes to the data on the current page and press Tab to advance to the save buttons. Click Final to save the page and its reason at level 4.

11.2.6. Click **9: Form 9, AE Report 011**.

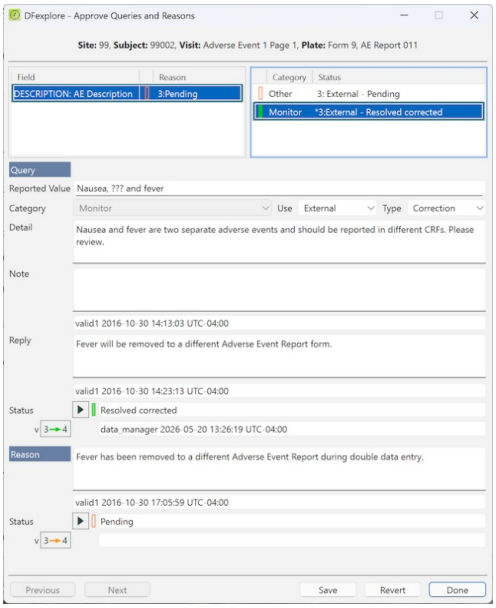
11.2.7. Click anywhere on the page background to make the fields active. Press Tab to advance to the **Description** field. Examine the information displayed in this field and the information in the corresponding **Query** window.



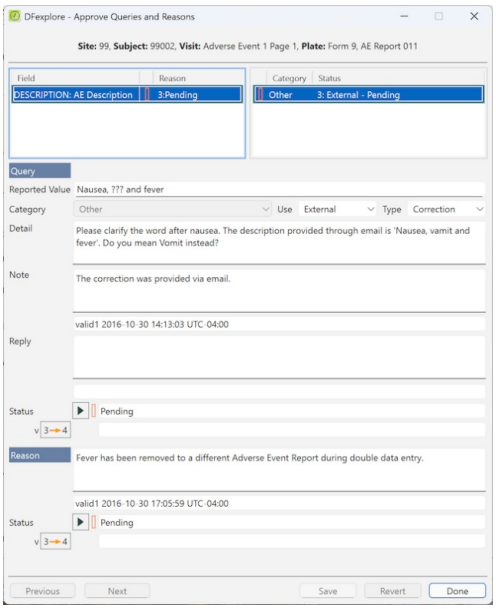
11.2.8. Select Field > Approve Queries and Reasons. Select the **Monitor** query. Examine the information in the dialog.



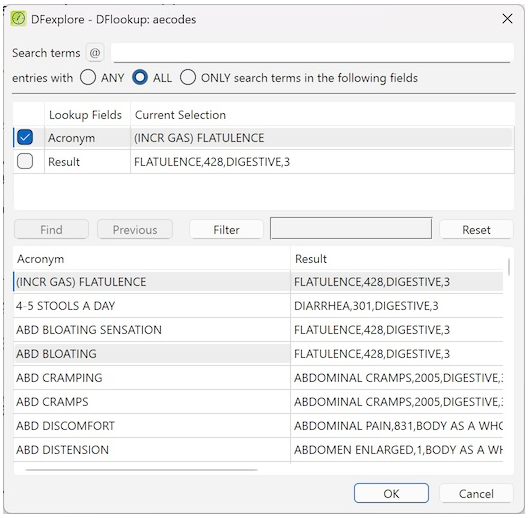
11.2.9. Select **Resolved corrected** from the **Status** in the **Query** section. Confirm that the CRF will be moved from level v 3→4, and **Status** from **Pending** to **Resolved corrected**.



11.2.10. 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.



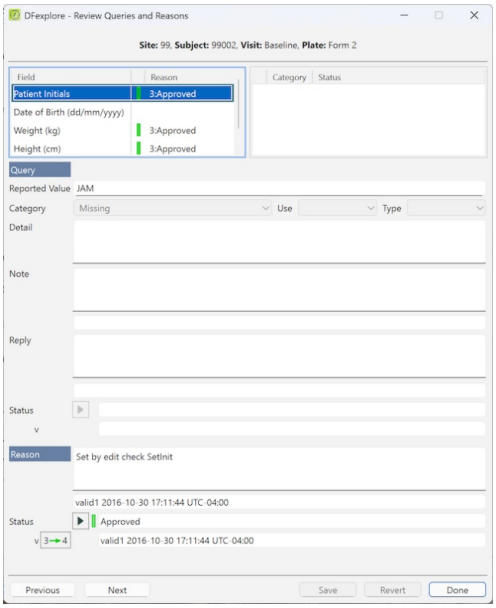
11.2.11. Press Tab to exit the **Description** field. Upon leaving the field, the DrugLookup edit check is executed and the **DFlookup:AECODES** dialog appears. Click Cancel.



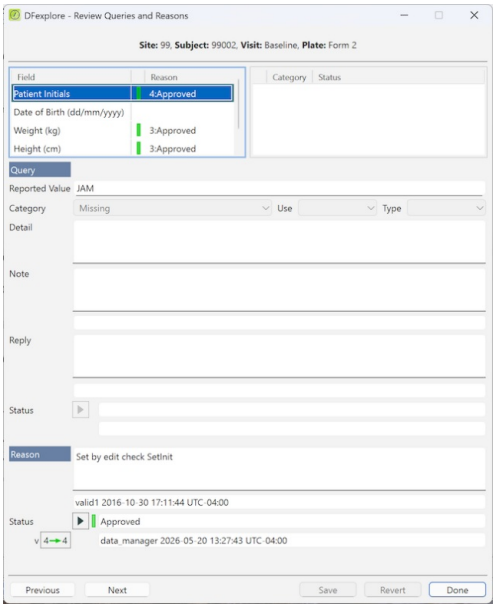
11.2.12. Do not make any other changes to the data and press Tab to advance to the save buttons. Click Incomplete to save the page at level 4.

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

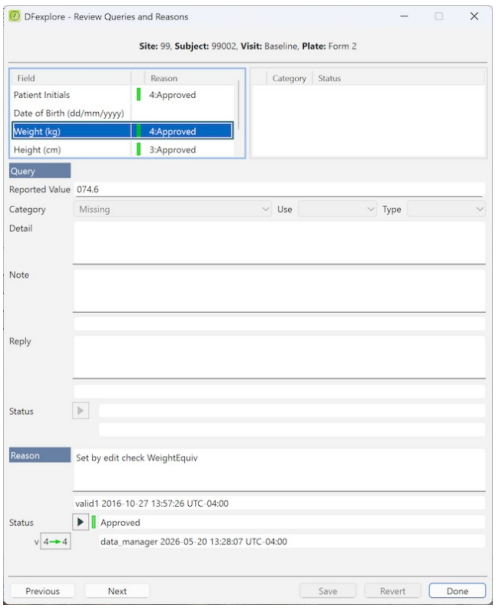
11.3.1. Double-click Subject **99002**. Select entry for **2 : Form 2**. Select Field > Review Queries and Reasons to review all queries and reasons that are present on the page.



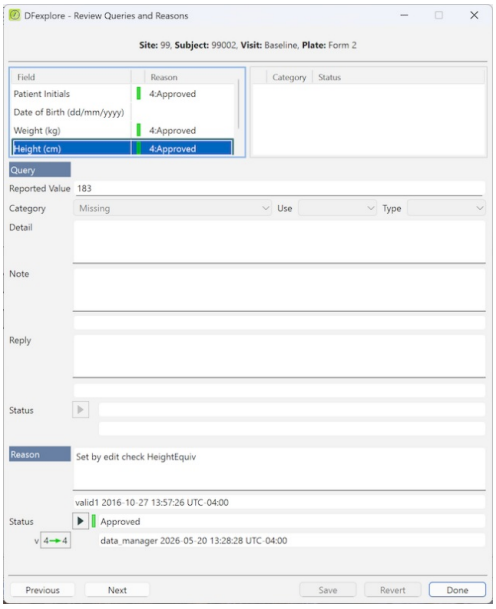
11.3.2. Working with the highlighted entry for **Patient Initials**, confirm that the **Status** is set to **Approved** and the level button displays 3→4. Click 3→4 to move the approved reason from level 3 to level 4 without making any other modifications.



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



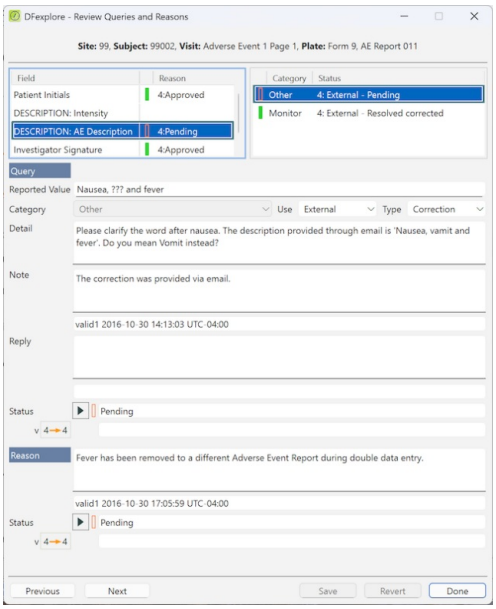
11.3.4. Select the 4th Reason entry **Height (cm)**. Confirm that the **Status** is set to **Approved** and v 3→4 is displayed. Click v 3→4 to move the approved reason from level 3 to level 4 without making any other modifications.



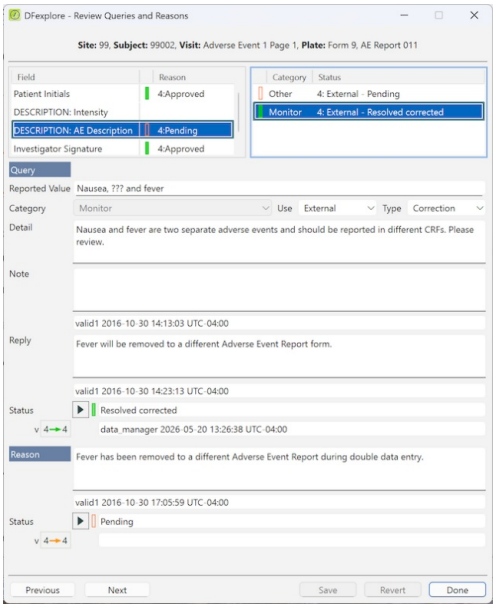
11.3.5. Once each of the 3 approved reasons have been reviewed, click Done.

11.3.6. As an outstanding query remains on the **Date of Birth** field, click Incomplete to save.

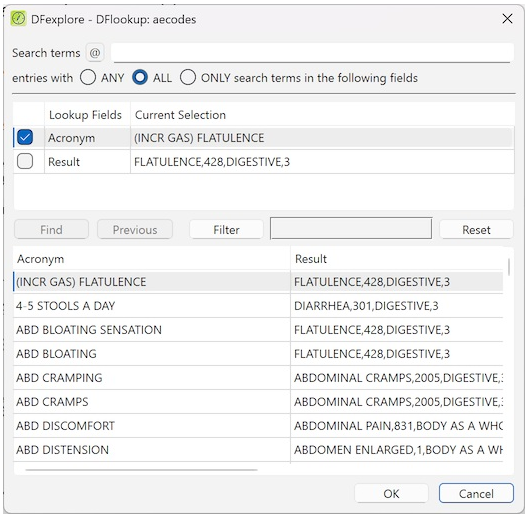
11.3.7. Continuing with the **ADVERSE EVENT REPORT** as the current page, click anywhere in the data entry screen to make the page active. Press Tab to advance though the fields until the **Description** field becomes the current field. Select Field > Review Queries and Reasons. Examine the information in the dialog.



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



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



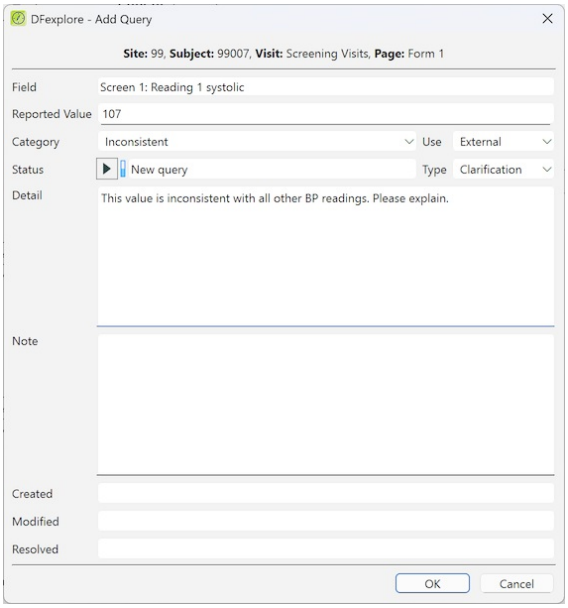
11.3.10. Do not make any other changes to the data on the current page and press Tab to advance to the save buttons. Click Incomplete.

11.4 Data review and add a query to inconsistent data

11.4.1. 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.

11.4.2. Select Field > Add Query or click + to open the **Add Query** dialog. In the dialog, set:

- **Category** = Inconsistent
- **Use** = External
- **Type** = Clarification
- **Status** = New query
- Enter This value is inconsistent with all other BP readings. Please explain. in the **Detail** field.



11.4.3. Click OK to apply the query.

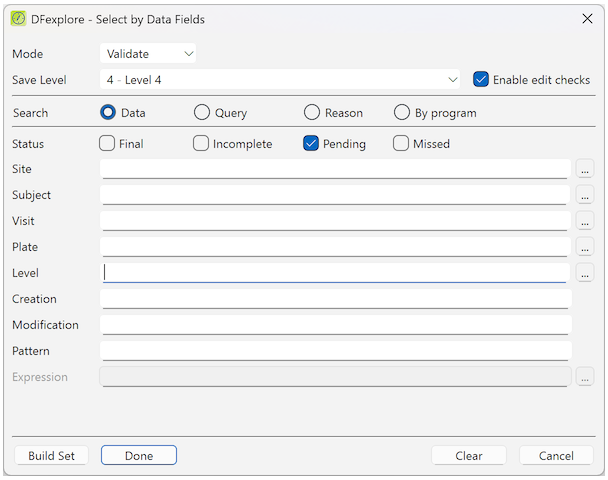
11.4.4. Press Tab to advance through the remaining fields on the page until the save buttons become active. Click Incomplete to save the page.

11.5 Review and complete pending data for Subject 99007

11.5.1. 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:

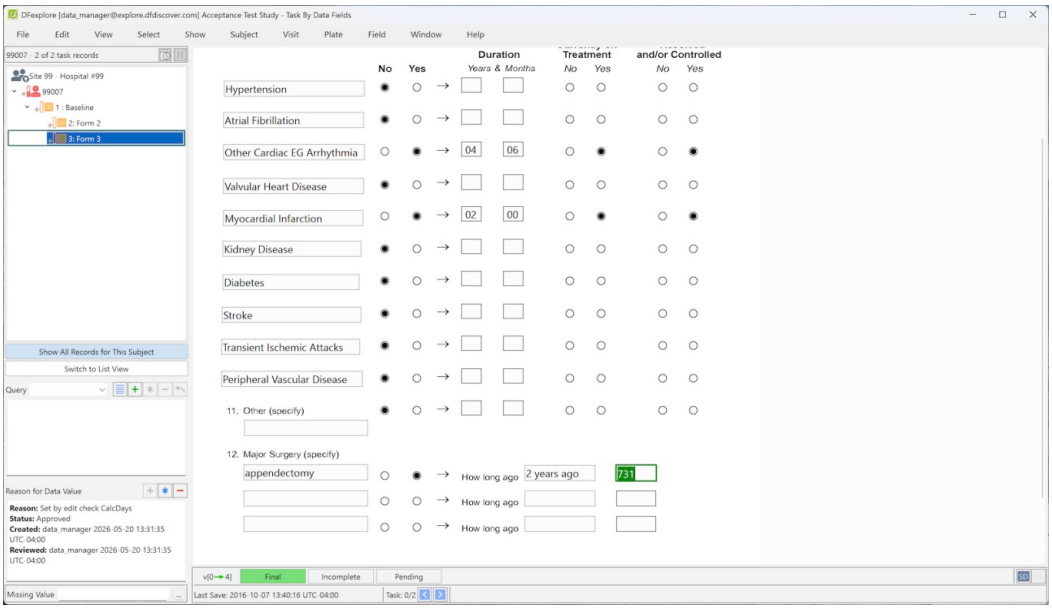
- **Mode** = Validate
- **Save level** = 4 - Level 4
- **Search** = Data
- **Status** = Pending

Leave the retrieval **Level** field blank.



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

11.5.3. 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.

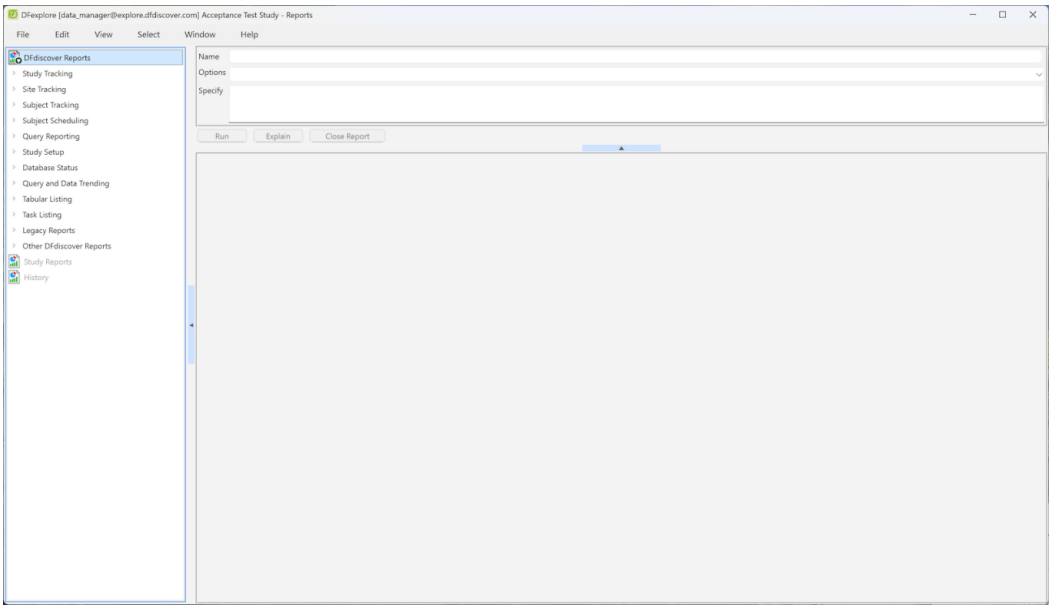


11.5.4. As there are no outstanding problems on the page and the data is now complete, click Final to change the page status from **Pending** to **Final** at level 4.

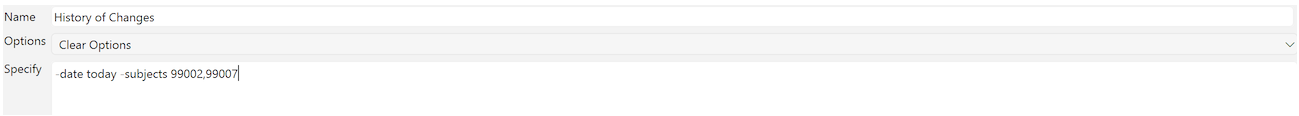
11.5.5. Select Select > All Records to release all task records from the current set. Click OK in the dialog to clear the main **Data View** window.

11.6 Confirm audit trail information for reviewed and modified data

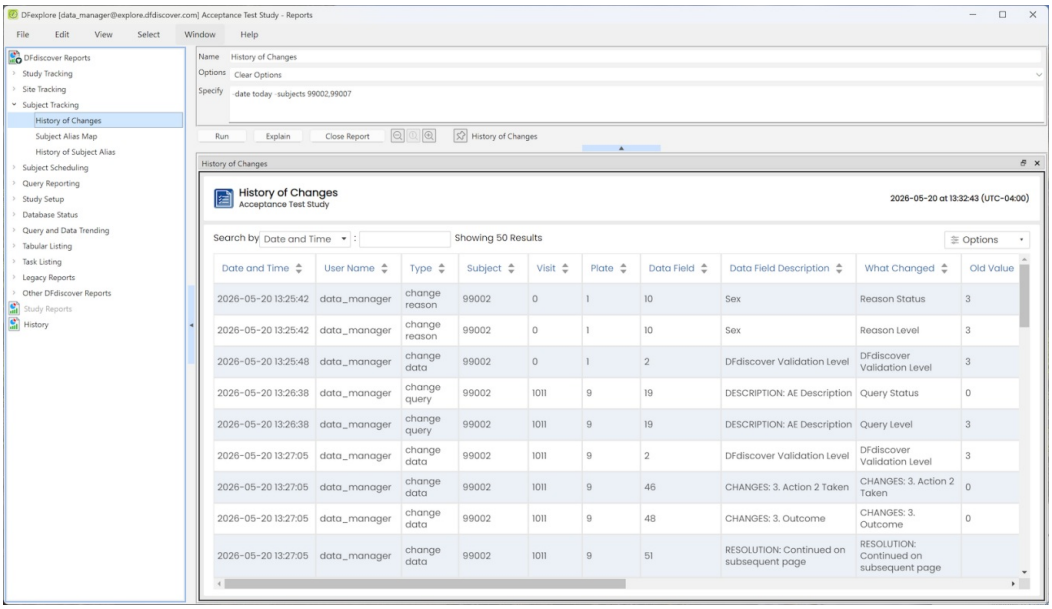
11.6.1. Select View > Reports. **Reports View** becomes the current view.



11.6.2. 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.

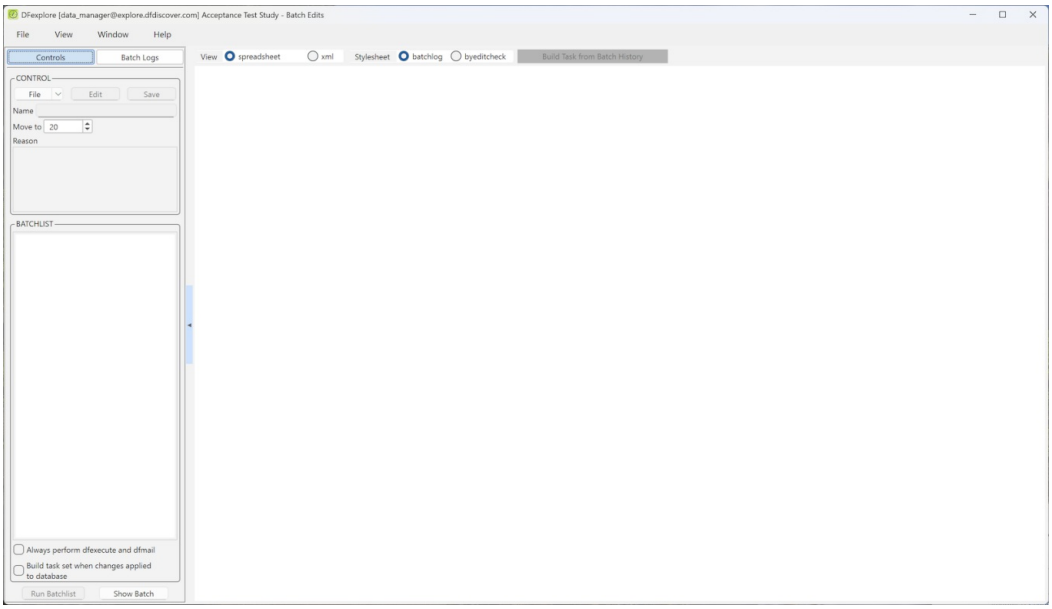


11.6.3. Click Run to execute the **History of Changes** report. Examine the output.

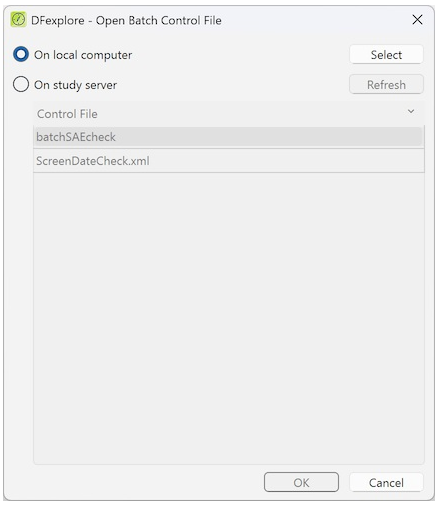


11.7 Run batch edit checks to verify data integrity

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

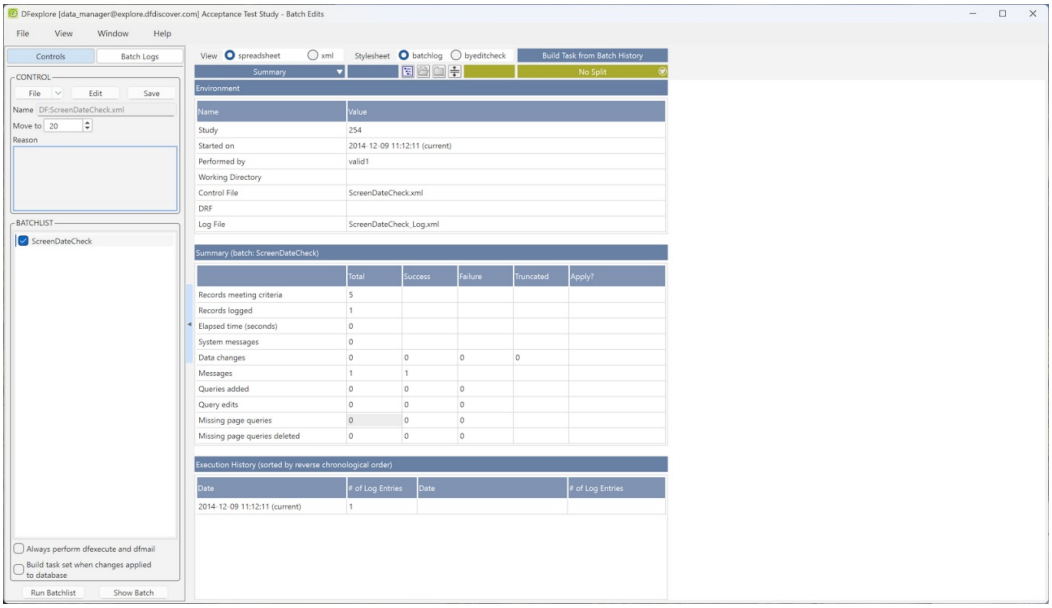


11.7.2. With the **Controls** tab as the current view. Click File > Open Control File from the drop-down list.



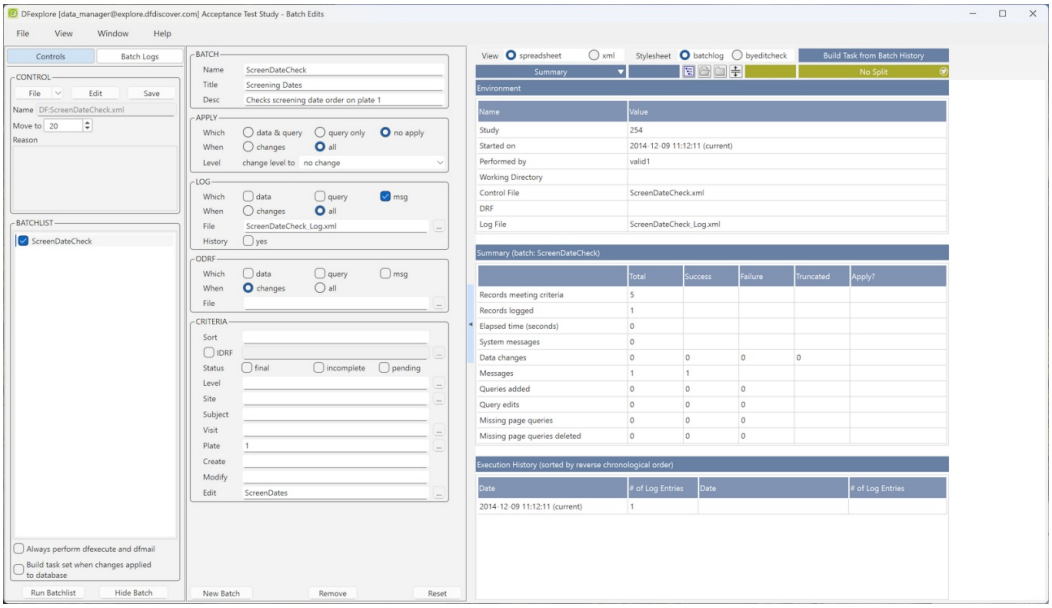
11.7.3. In the **Open Batch Control File** dialog, select (enable) the **On study server** option to display a list of available control files that are located on the study server for the 254

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



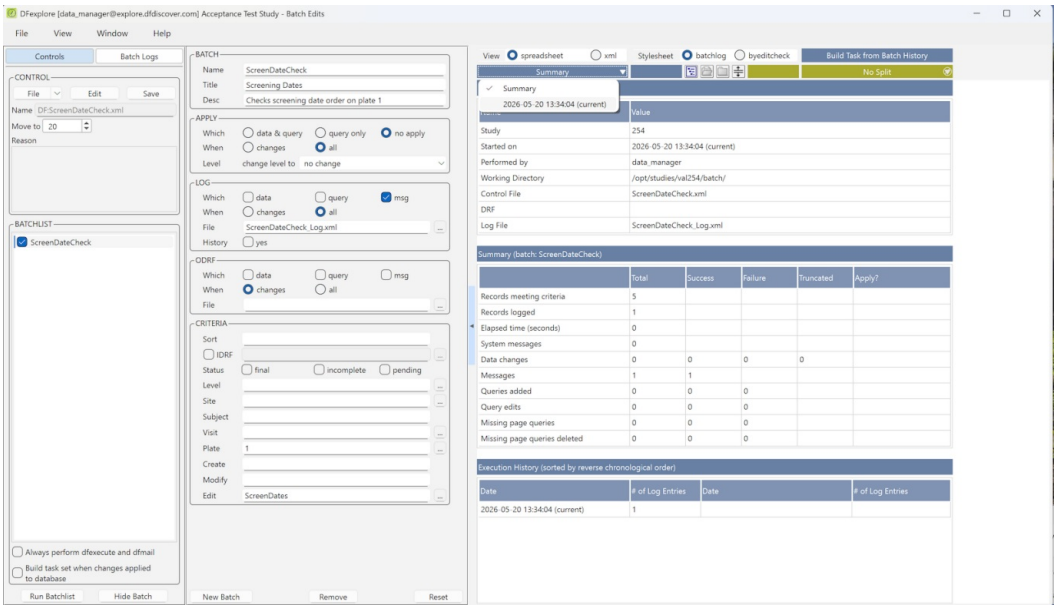
11.7.4. Click Show Batch to ensure the settings are as shown below. Click Hide Batch to hide the settings.

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.

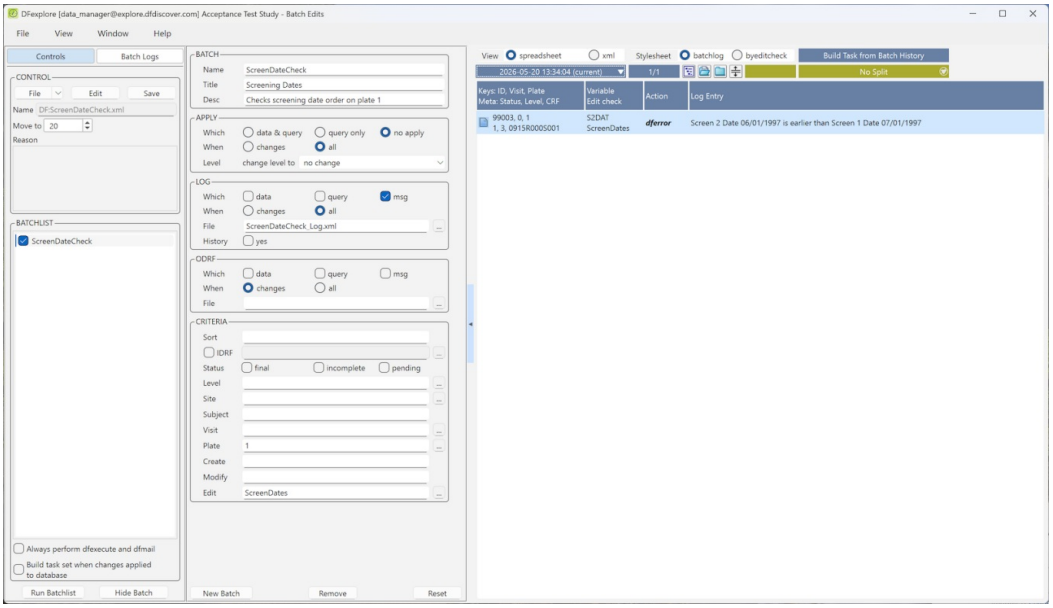


11.7.5. Click Run Batchlist to run the current batch program. Click Run in the confirmation dialog.

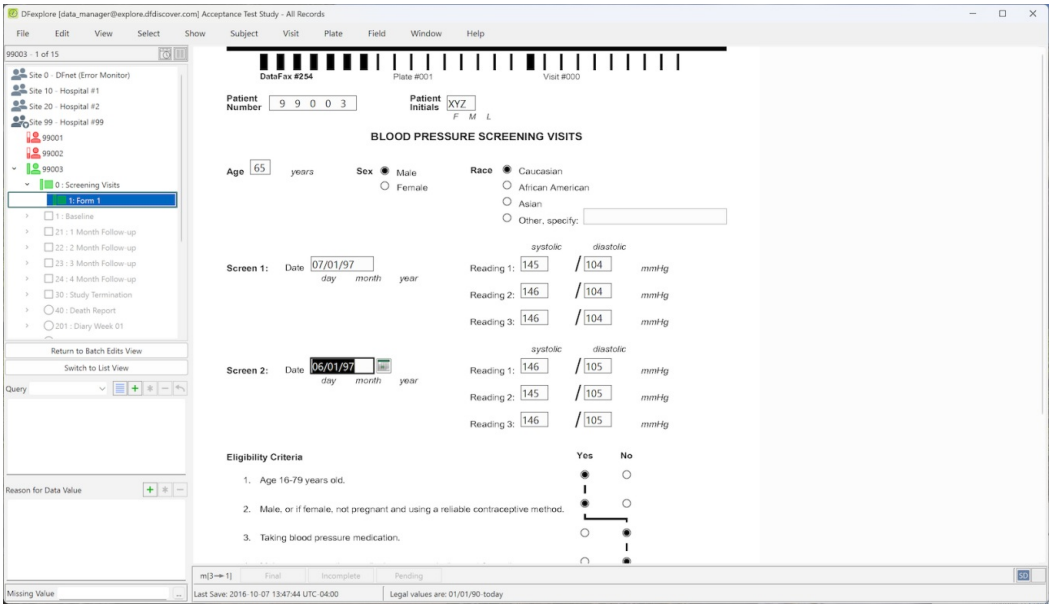
11.7.6. From the **Summary** drop-down list, choose the item identified as '(current)'.



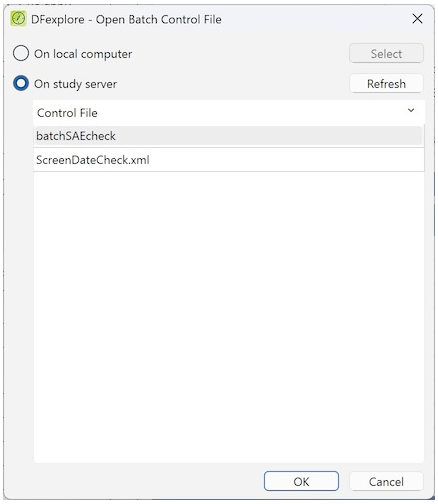
11.7.7. The edit check ScreenDates checks the Screen 1 and Screen 2 dates on Form 1 (plate 1) and determines if they are out of sequence. Examine the log entry message.



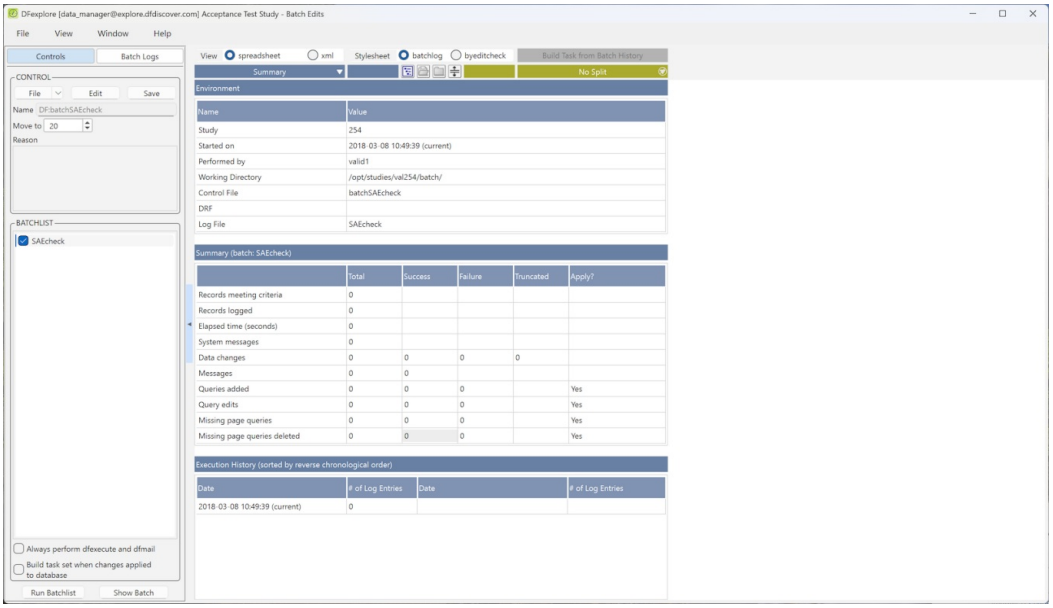
11.7.8. Double click the entry to be taken to **Data** View. Examine the values in the **Screen 1** and **Screen 2** date fields.



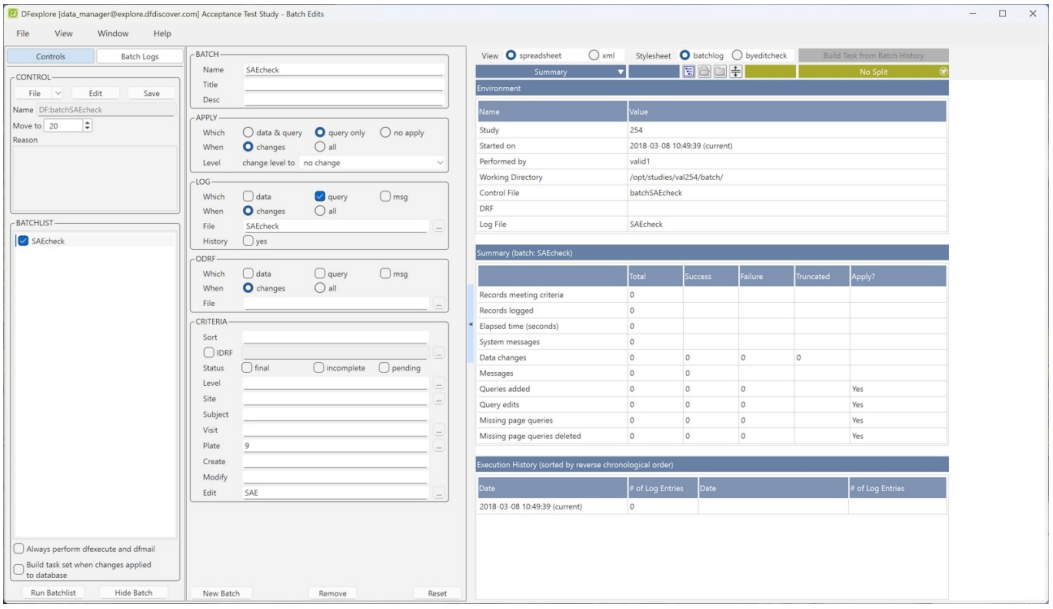
11.7.9. Select View > Batch Edits. With the **Controls** tab as the current view, click File > Open Control File from the drop-down list.



11.7.10. 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.

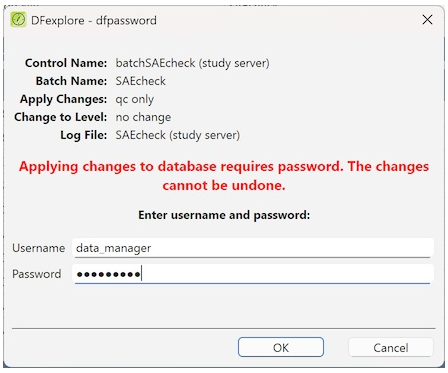


11.7.11. Click Show Batch to ensure the settings are as shown below. Click Hide Batch to hide the settings.

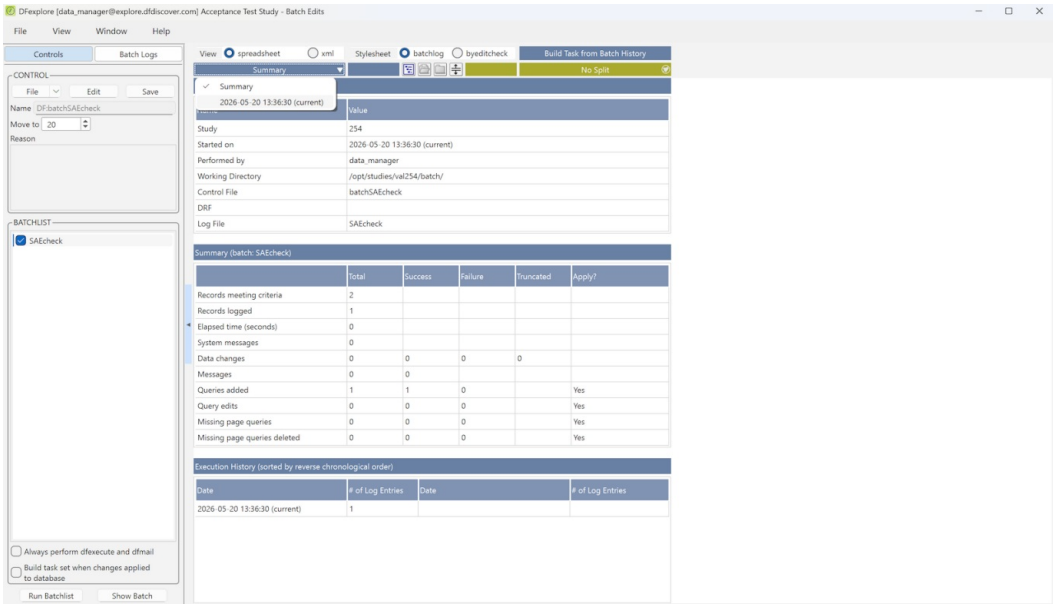


NOTE: The batchSAEcheck.xml control file applies a query to **Is This A Serious Event** field on plate 009 when the response to this field is inconsistent with the value in the **Intensity** field of the same plate.

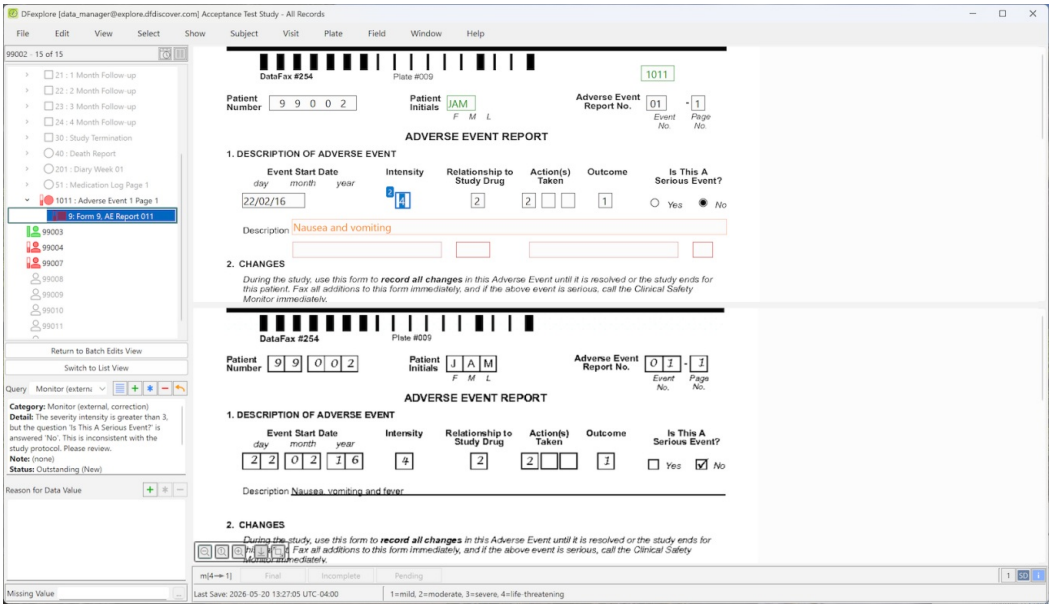
11.7.12. Click Run Batchlist to run the current batch program. Enter the Username and Password of the current user, click OK.



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

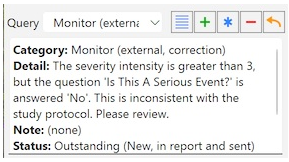


11.7.14. Double-click the entry to be taken to **Data View**.



11.7.15. 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.

11.7.16. 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.



NOTE: The query list is presented in accordance with the query sort order defined in Module 3.9 Create user-defined query category codes.

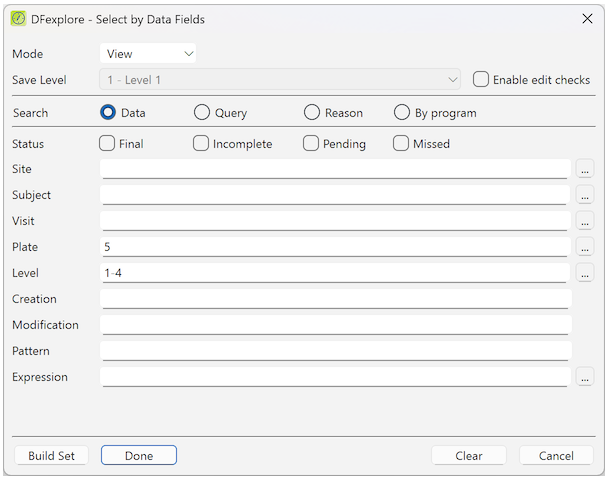
11.7.17. Double-click **Site 99 - Hospital #99** entry to close all subject binders.

11.8 Use a data expression to retrieve specific subject information

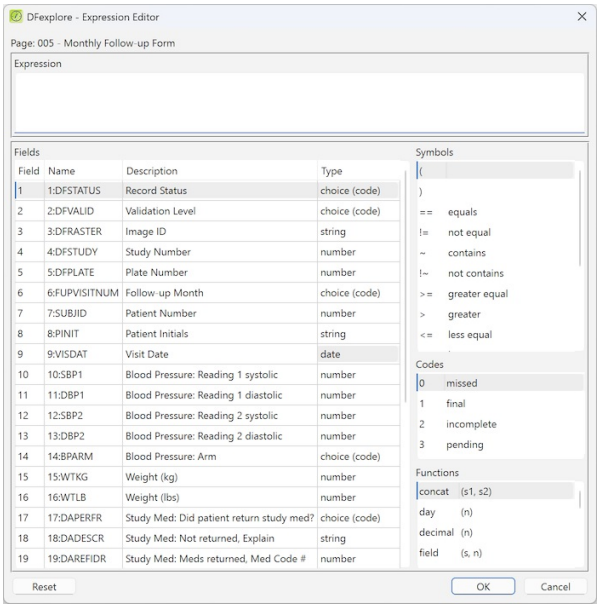
11.8.1. Still in **Data** View, determine which subjects have had adverse events. Do this by selecting Select > By Data Fields to open the **Select by Data Fields** window. In the dialog, set:

- **Mode** = View
- **Plate** = 5
- **Level** = 1-4

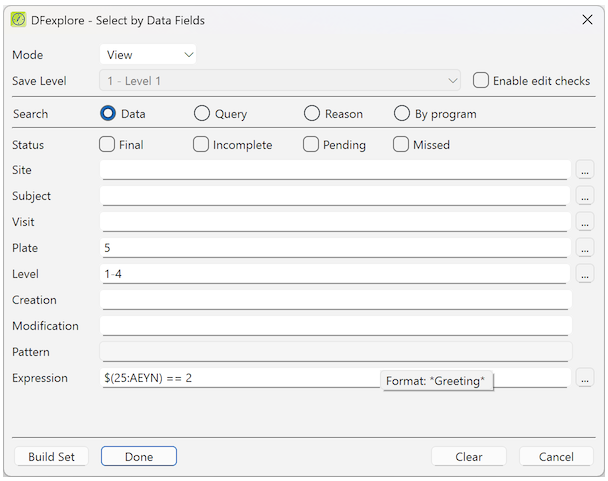
Do not select any Status check box.



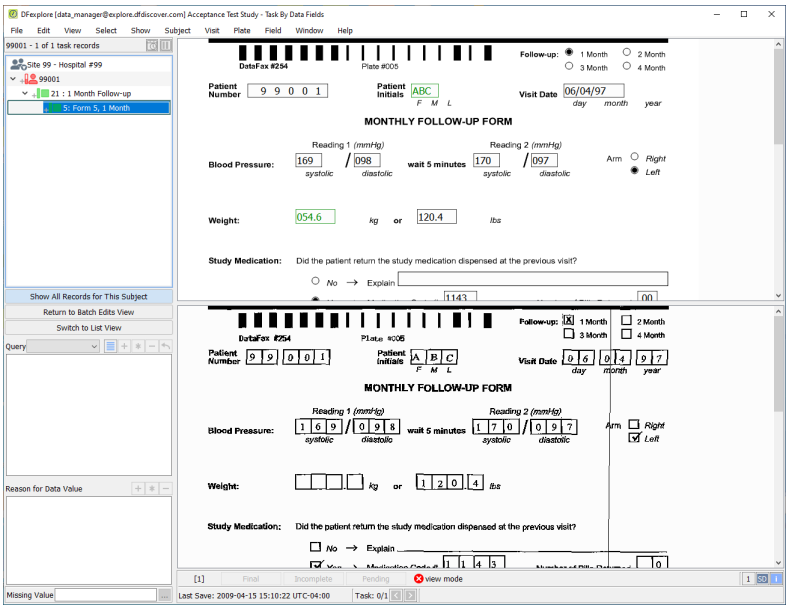
11.8.2. Click **Expression** ... to open the **Expression Editor** dialog.



11.8.3. 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.

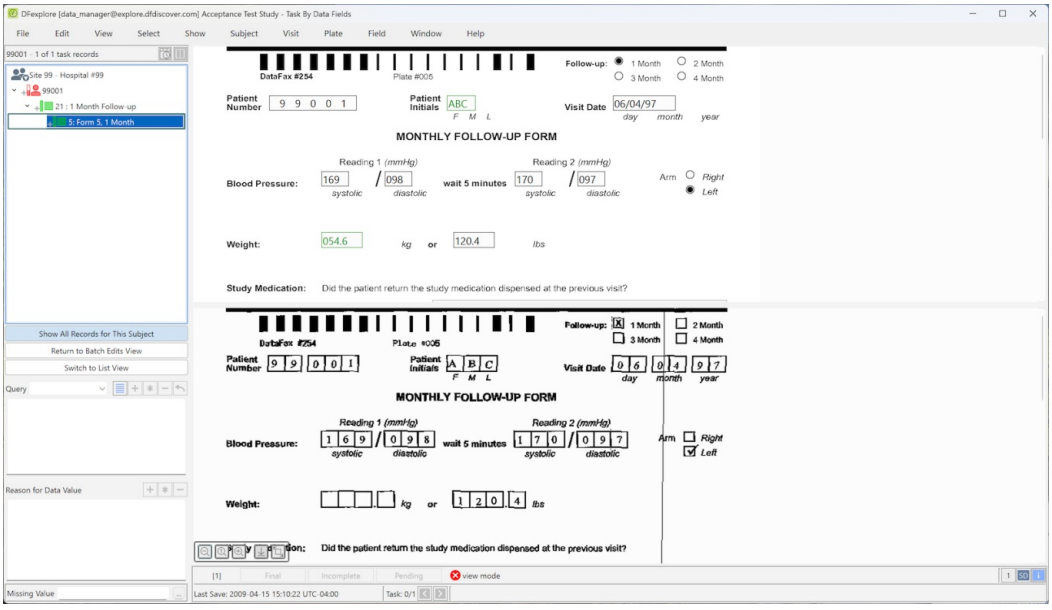


11.8.4. Click Done to apply the settings. Click OK in the confirmation dialog to retrieve the 1 data record that matches the expression and retrieval criteria.



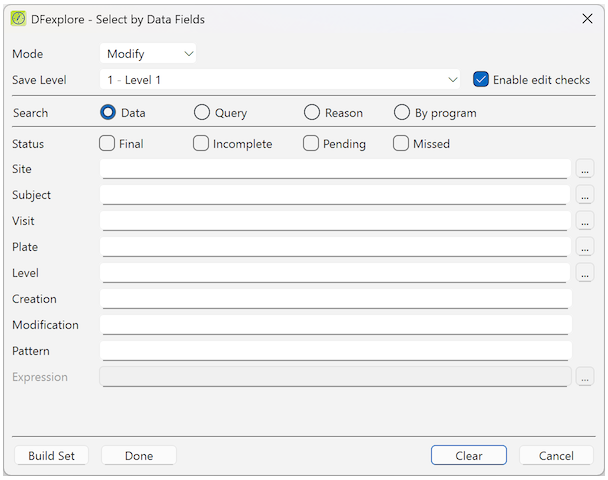
11.8.5. Scroll down the current page for Subject **99001** to locate the adverse event question. Confirm that the **Yes** choice has been entered in response to the question **Did the patient report any adverse events since the last visit?**.

11.8.6. 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**.

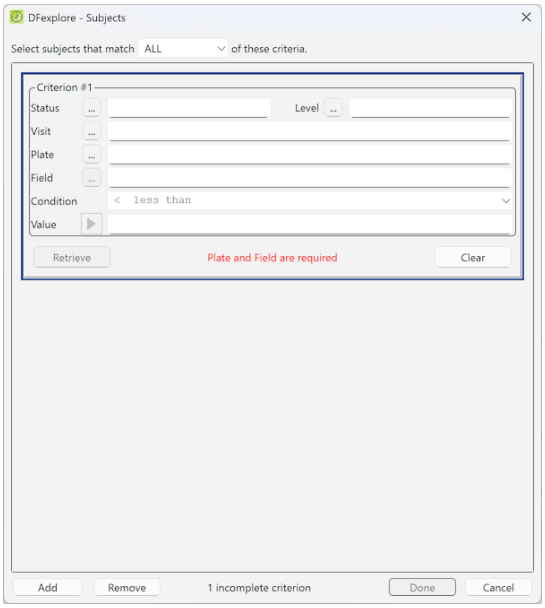


11.9 Use cross-plate data criteria to retrieve specific subject information

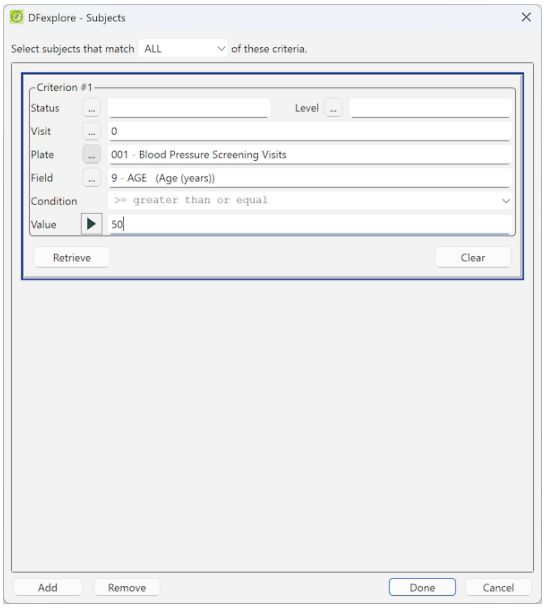
11.9.1. Select Select > All Records to release all task records from the previous test. Click OK in the resulting confirmation dialog. Select Select > By Data Fields to open the **Select by Data Fields** dialog, click Clear to clear the previous retrieval specifications and reset the dialog.



11.9.2. The steps that follow search for and retrieve all patients in the database that are >=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**.

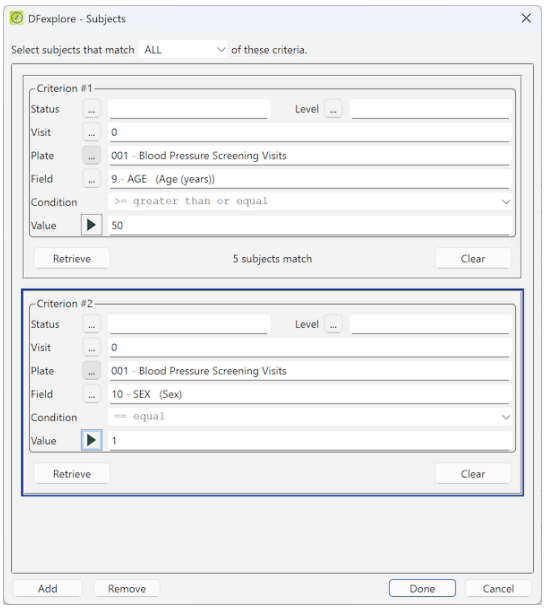


11.9.3. Begin by building an expression for the first subject criterion of Age. Working in the **Criterion #1** block, specify **Visit** = 0. Click ... next to **Plate** to open a list of study plates. In the list double-click entry **001 - Blood Pressure Screening Visits** to populate the **Plate** 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 **>= greater than or equal** to assign a retrieval Condition. Finally, specify 50 in **Value**.



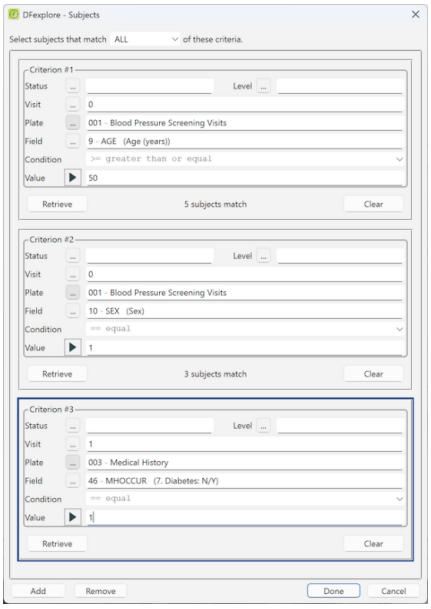
11.9.4. Click Retrieve to retrieve the number of subjects that match the specified Age criterion. Click Add to add a new criterion block in preparation for the specification of the 2nd retrieval criterion (Male).

11.9.5. 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.



11.9.6. 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).

11.9.7. 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.

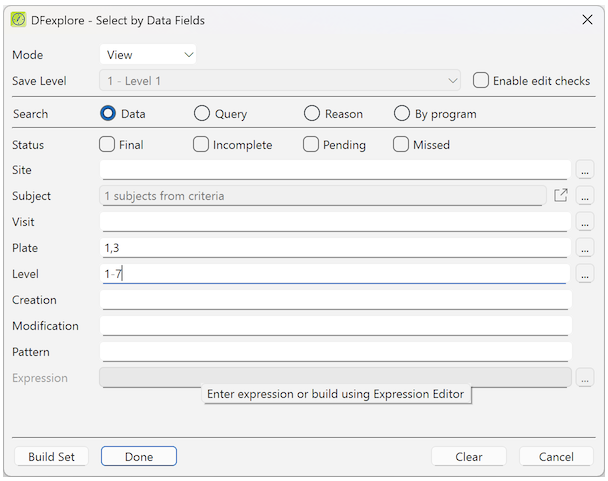


11.9.8. Click Retrieve to retrieve the number of subjects that match the specified Diabetes history criteria. Click Done to find the subjects that match ALL three of the criteria specifications and close the Subject Criteria dialog.

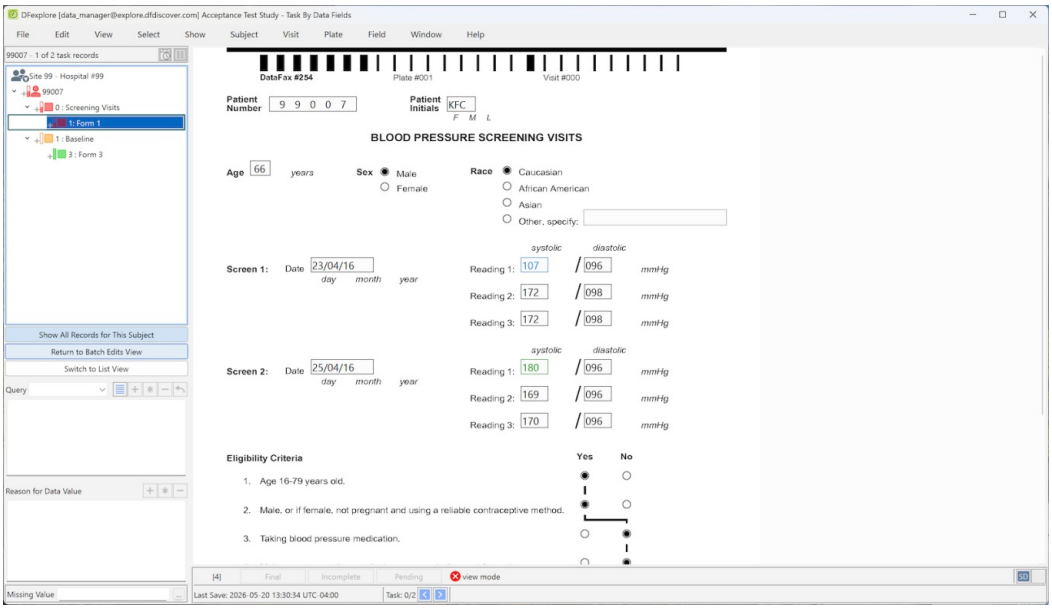
11.9.9. In the **Select by Data Fields** dialog, set:

- **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.



11.9.10. 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.



11.9.11. 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 >= 50** and **Sex=male**.

11.9.12. 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'.

11.9.13. 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.

12 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

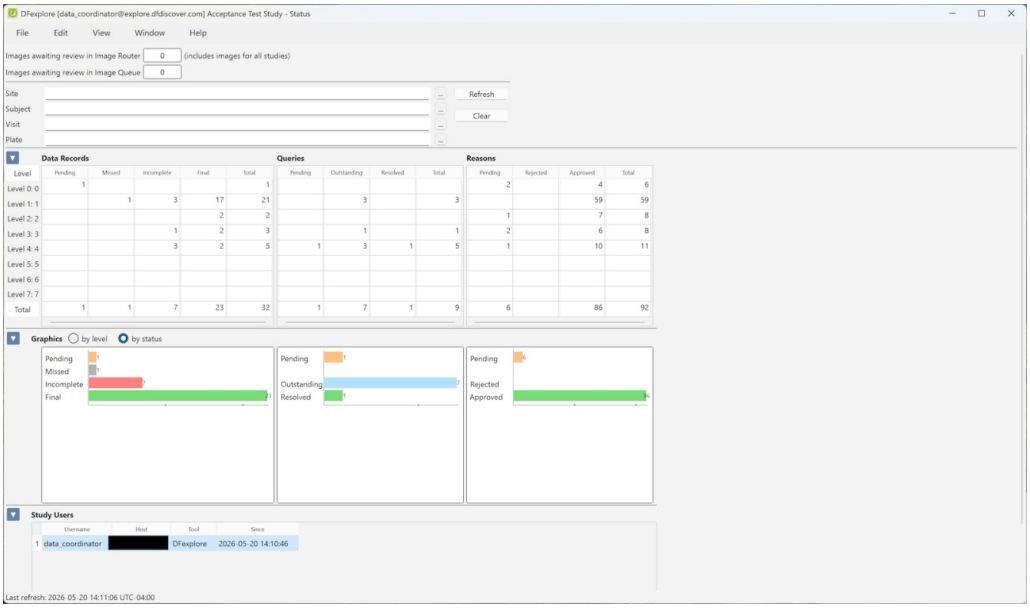
1. Start **DFATK** as described in Module 1 (Installation & Initialization).
2. Click 12. External Query Reports followed by Begin to begin this module.

12.1 Obtain database query metrics and details using Status and List Views to review all outstanding queries prior to query report creation

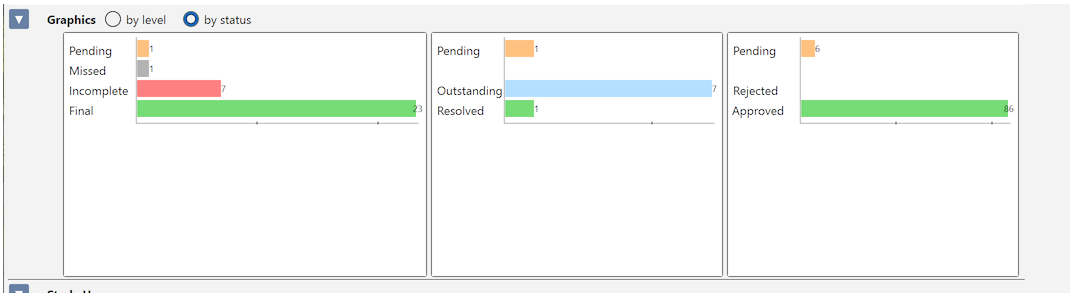
12.1.1. Start **DFexplore**, login as user data_coordinator and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

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**.

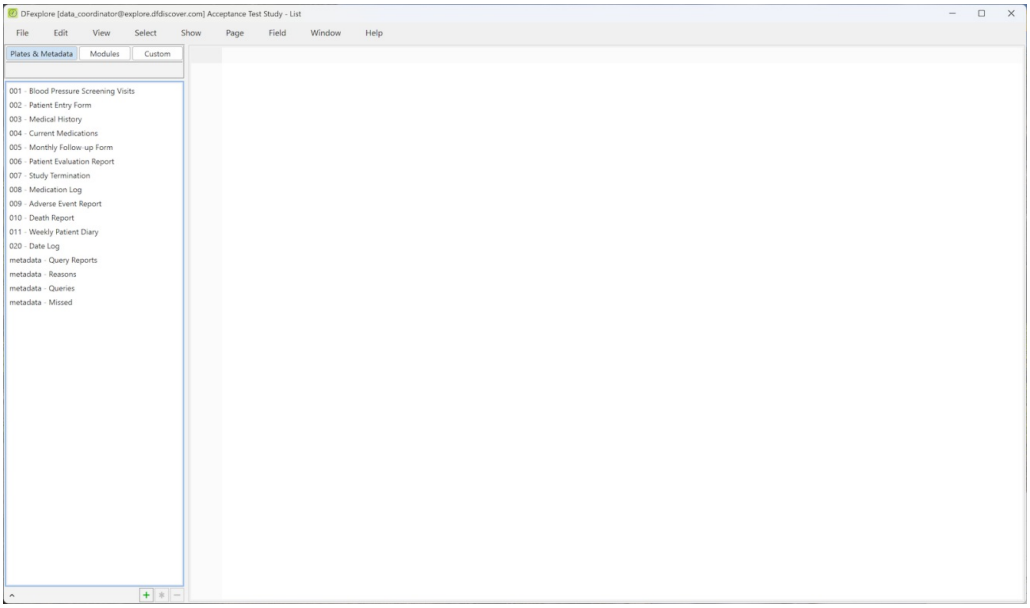
12.1.1. Select View > Status. Examine the **Queries** table to view the status and count of all queries in the database.



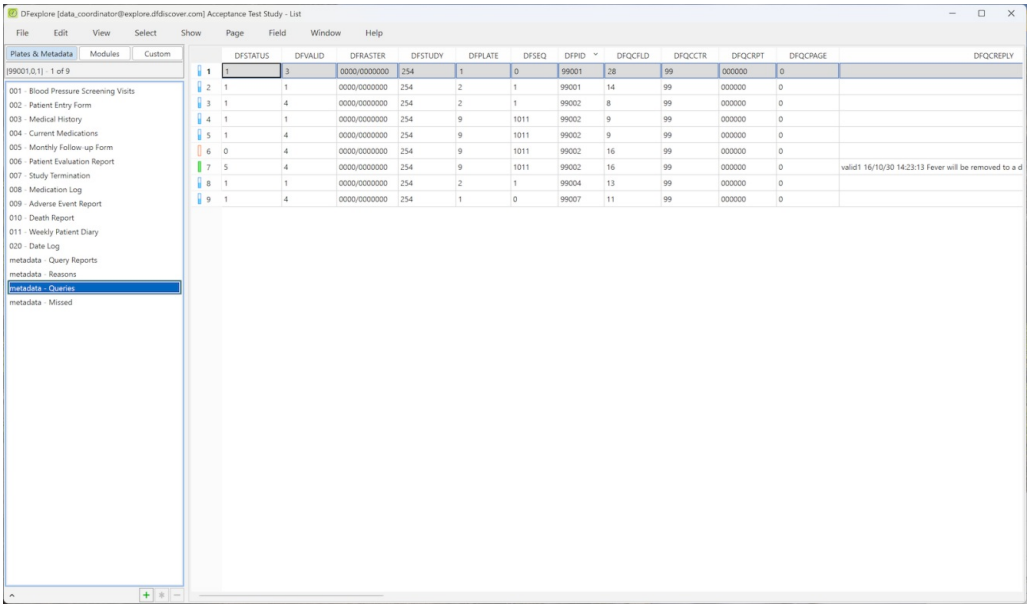
12.1.2. Open the **Graphics** section and select the toggle button for **by status**. Confirm the count of Pending and Outstanding queries.



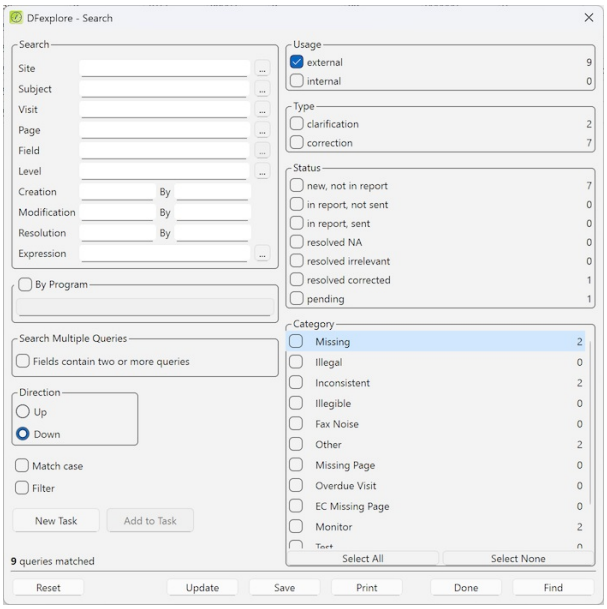
12.1.3. Select View > List. Select the **Plates & Metadata** tab.



12.1.4. Click **metadata - Queries** to display information about database queries.



12.1.5. 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.

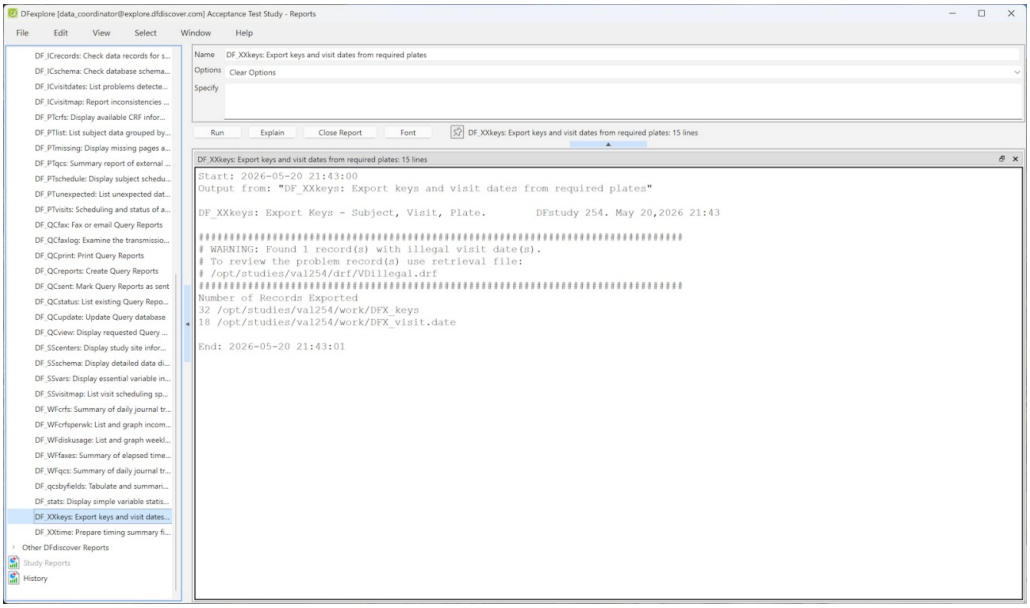


12.1.6. Click Done to close the Search dialog.

12.2 Run database integrity check report DF_XXkeys to export all key fields and visit dates from required plates in the database

12.2.1. Select View > Reports to change from List View to **Reports** View.

12.2.2. 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.

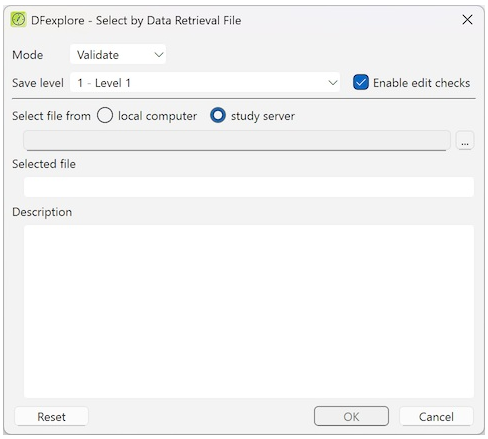


12.2.3. In Step 2, DF_XXkeys detected an illegal visit date. As indicated by the message in the reports window, a data retrieval file called VDillegal.drf was created. This file contains the plate(s) on which the illegal visit date was detected, and can be reviewed and edited in **Data** View. Click Close Report to close the report output window. Select View > Data to change to **Data** View.

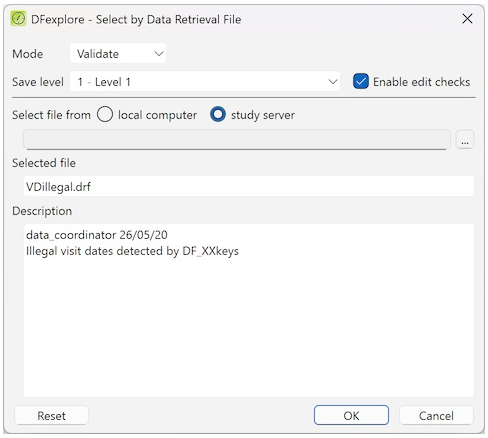
12.3 Use Data View to check, and if necessary correct, illegal visit dates by retrieving the problems keys identified by DF_XXkeys

12.3.1. To review the data retrieval file created in Step 2, select Select > By Data Retrieval File. In the retrieval file dialog, set:

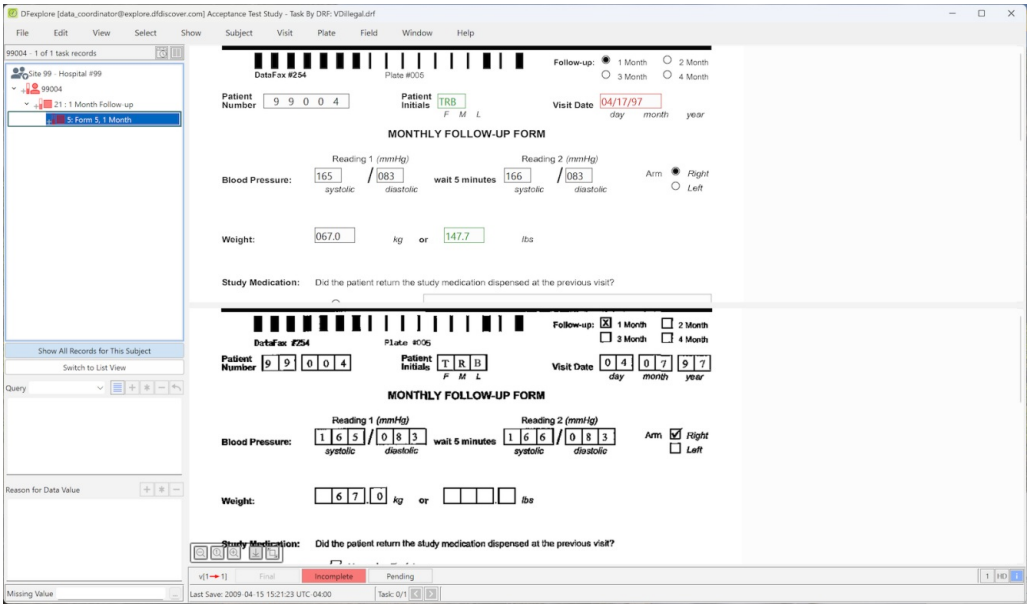
- **Mode** = Validate
- **Save level** = 1 - Level 1
- Check (enable) **Enable edit checks**
- **Select file from** = study server



12.3.2. 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.



12.3.3. Click OK in the dialog. Click OK in the resulting confirmation dialog to retrieve all data records having illegal visit dates.

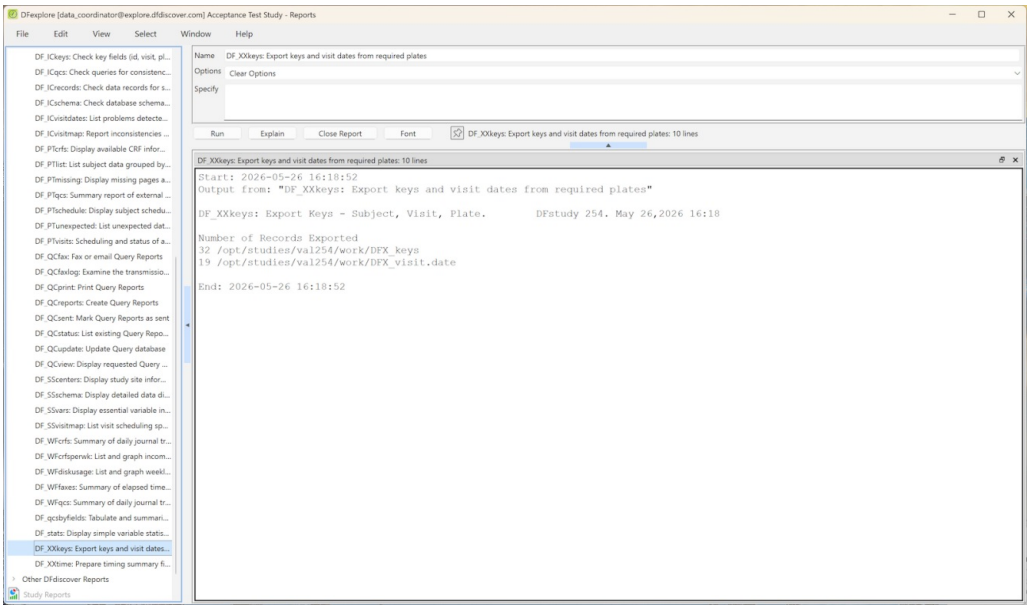


12.3.4. Click anywhere in the page to make it active for data entry. Starting with the **Follow-up** choice field, press Tab to advance to the **Visit Date**. The Visit Date value has been entered as 04/17/97 (an illegal date), rather than 04/07/97 as shown on the CRF image. Enter the correct date and press Tab to exit the field.

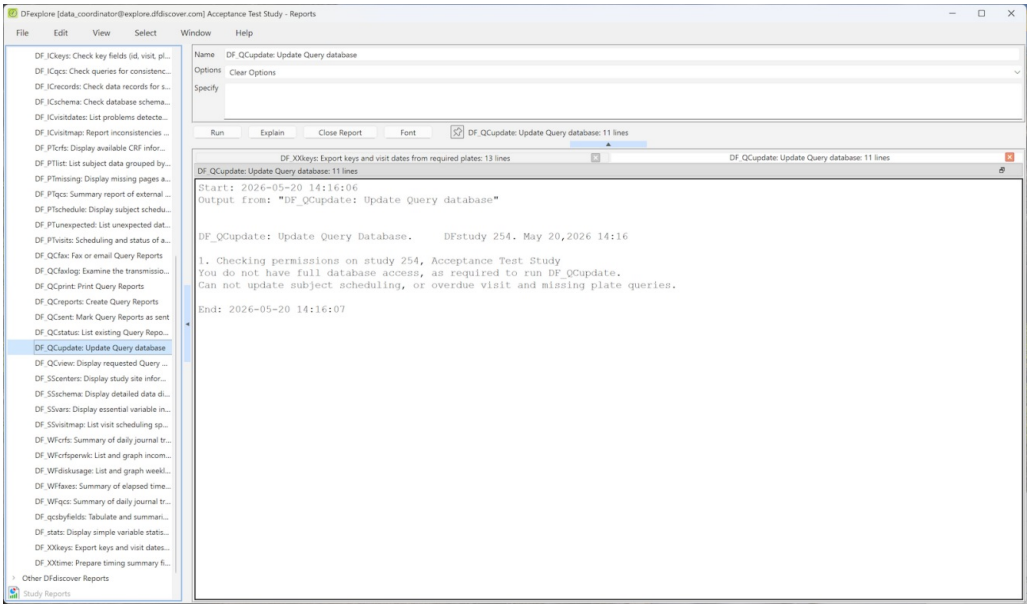
12.3.5. As problems no longer exist on the corrected page, the page can be saved with a status of **Final**. Click Final to save the page.

12.4 Execute DF_QCupdate to update the query database and lock all records for query report generation

12.4.1. 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.



12.4.2. 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.

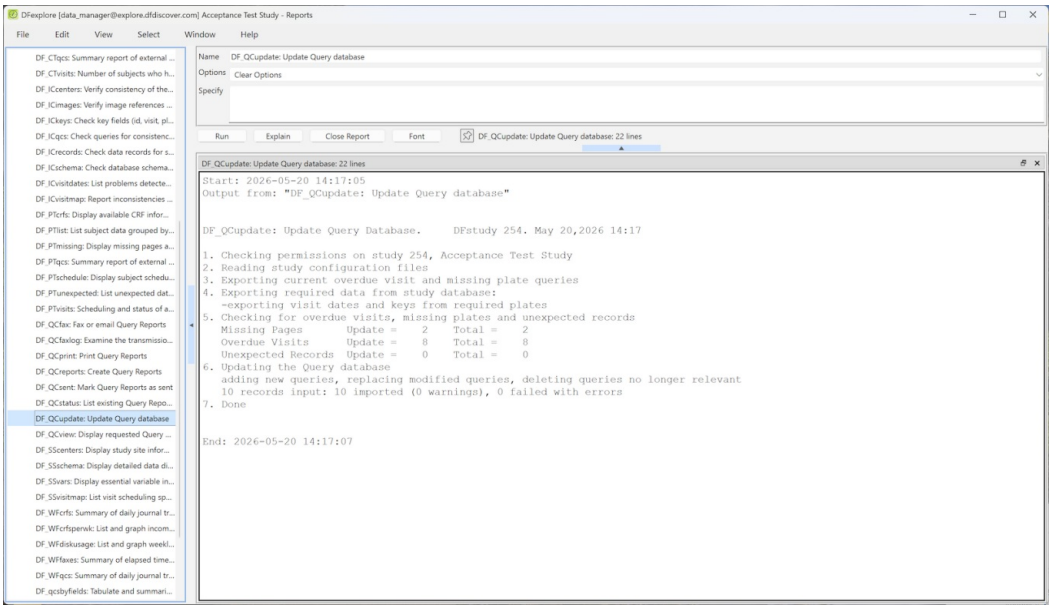


12.4.3. A user requires unrestricted permissions to execute **DF_QCupdate**. As user data_coordinator is restricted to database Modify and Write levels of 0-4 (as set in Module 1. Installation and Initialization), it is not possible to execute **DF_QCupdate** successfully. Click File > Exit to close **DFexplore**.

12.4.4. 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.".

12.4.5. Select View > Reports.

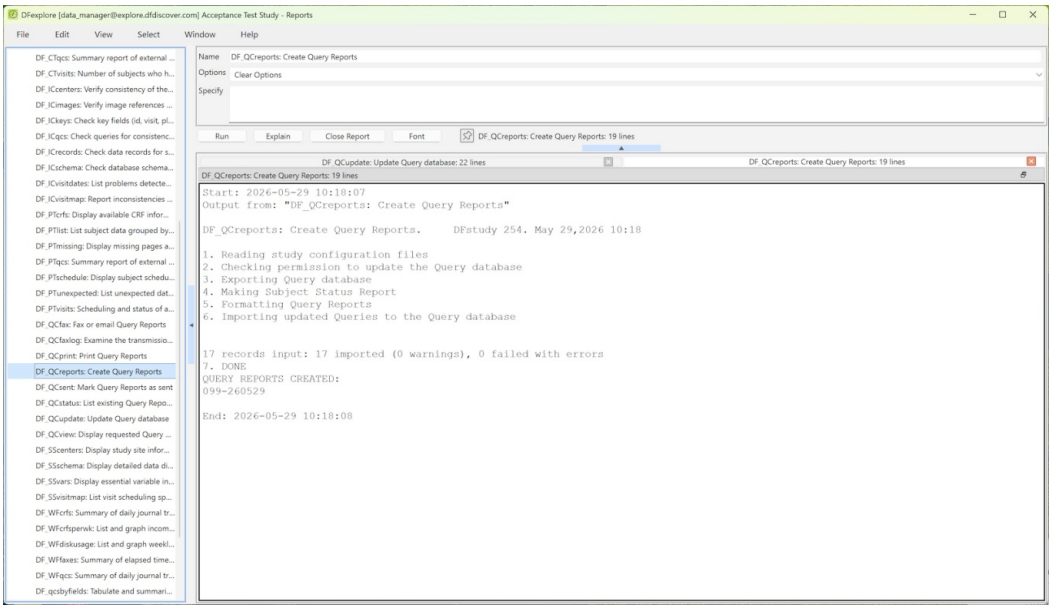
12.4.6. Double-click **DFdiscover Reports**, expand **Legacy Reports** by clicking ›. Choose **DF_QCupdate** from the list of reports. Click Run to execute **DF_QCupdate** with the correct permissions.



12.5 Execute DF_QCreports to create a standard, 3-part external query report for a study site

12.5.1. Choose **DF_QCreports** from the list of **Legacy Reports** and click Explain to view a report description.

12.5.2. Do not enter any options in the Specify field so that a complete query report is generated. Click Run to execute **DF_QCreports**.

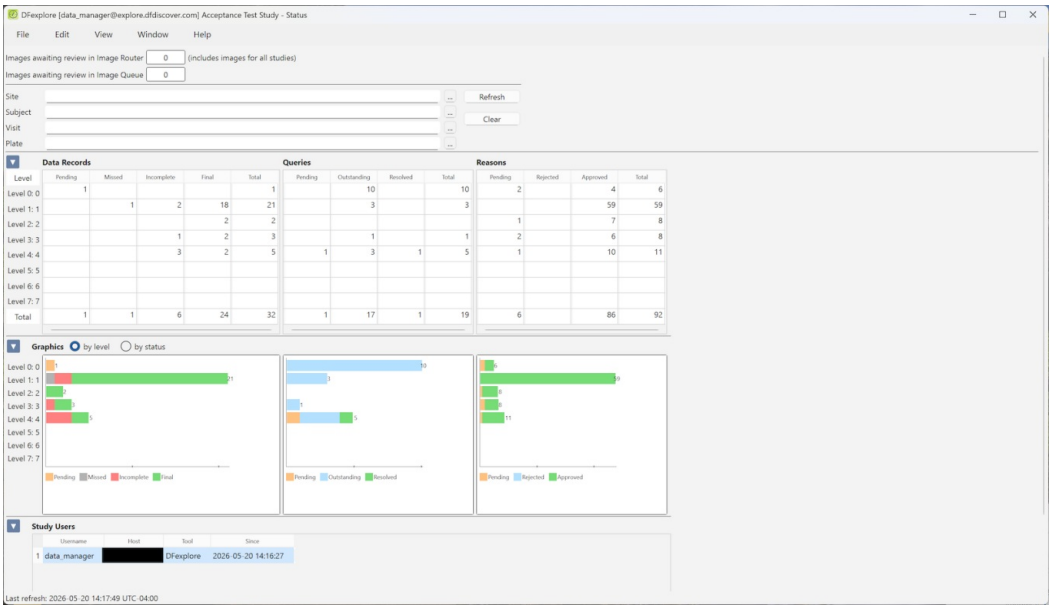


NOTE: **DFdiscover** report numbers are comprised of a site number followed by the date of report creation (as yy/mm/dd). The two are separated by a hyphen. Your Query report has been created for Site 99 and the date of creation is the date on which DF_QCreports was executed (i.e.today).

12.5.3. 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.

12.6 Confirm the status of external queries following query report creation

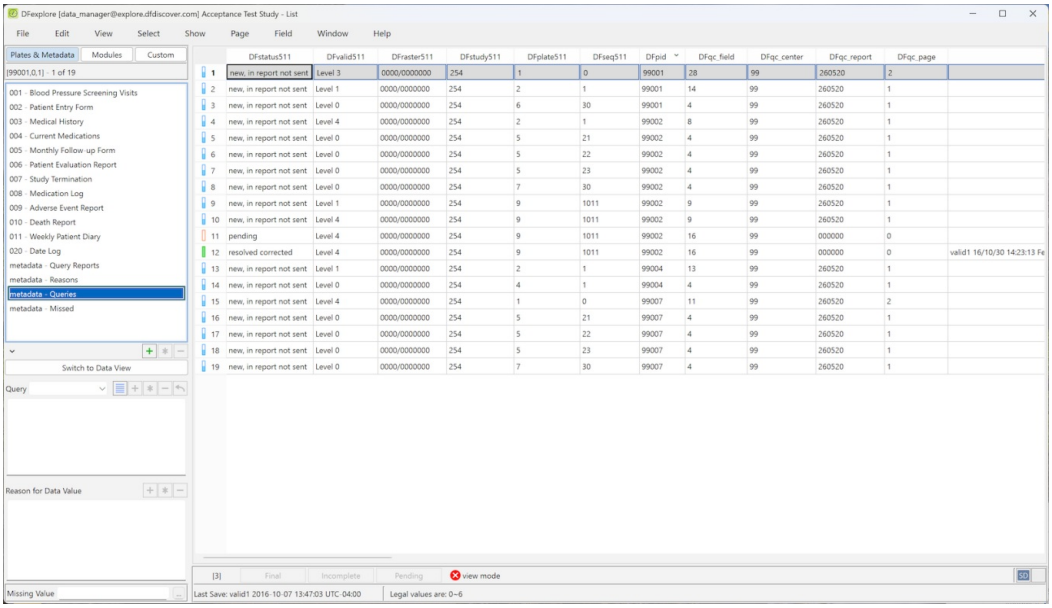
12.6.1. Select View > Status. Click Refresh to update the database counts. Examine the **Queries** table to view the status and count of all queries in the database.



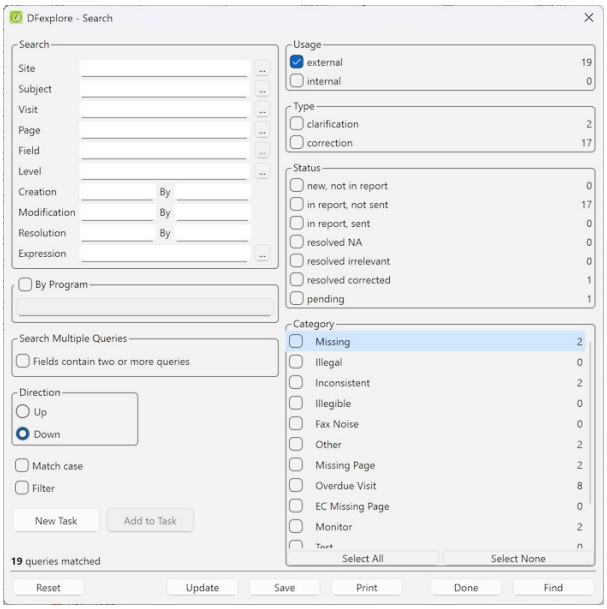
NOTE: The counts in the Queries table have changed because the query database has been updated by the running of the report **DF_QCupdate** in "Execute DF_QCupdate to update the query database and lock all records for query report generation.". If applicable, DF_QCupdate will create new queries for missing pages and overdue visits based on the study scheduling information present in the study visit map files.

12.6.2. Select View > List.

12.6.3. Click **metadata - Queries** to display information about database queries.



12.6.4. 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.

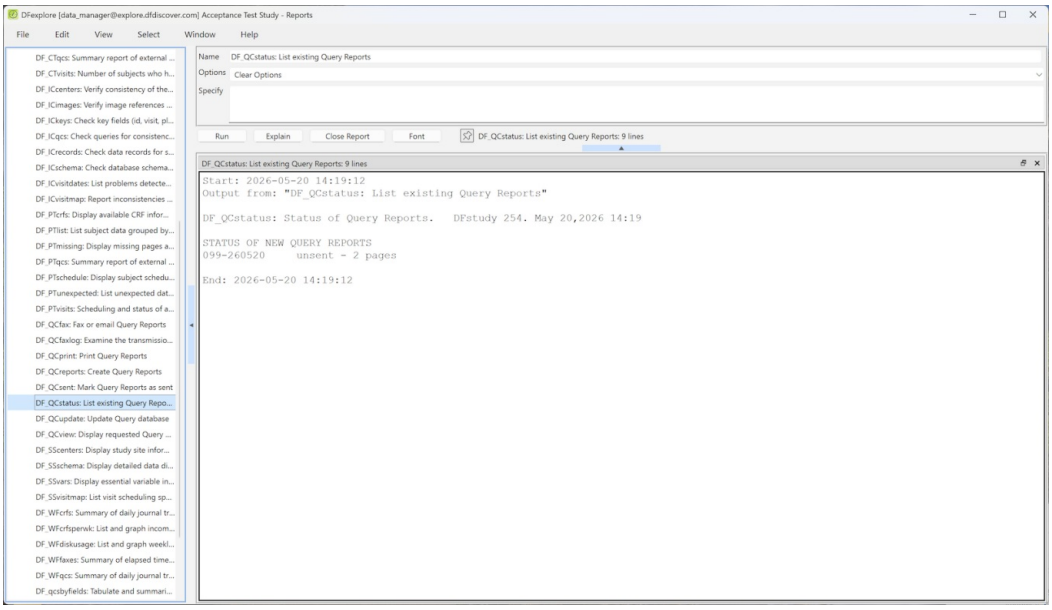


12.6.5. Click Done to close the dialog.

12.7 Execute DF_QCstatus to verify that a new query report was created by listing all reports in the QC/NEW directory

12.7.1. Select View > Reports.

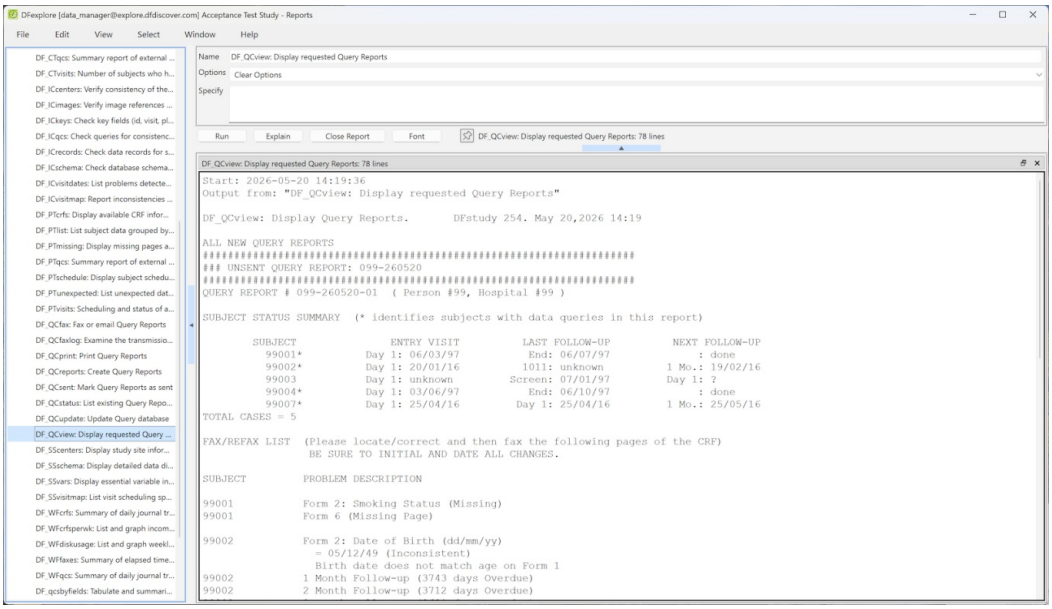
12.7.2. From the list of **Legacy Reports**, select **DF_QCstatus** and click Explain to view a report description. As a query report was created but not sent, click Run to obtain the status of all query reports currently in the study QC/NEW directory.



12.7.3. Click Close Report to close the report output window.

12.8 Execute DF_QCview to display the newly created query report

12.8.1. 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**.



12.8.2. Click Close Report to close the report output window.

12.9 Execute DF_QCprint to print the query report from the QC/NEW directory

12.9.1. 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.

12.9.2. Click Close Report to close the report output window.

12.10 Comparing several examples from the printed query report against their corresponding queries in the study database

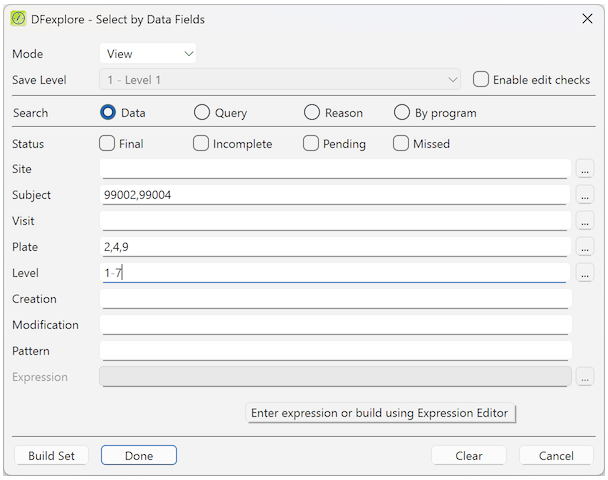
NOTE: For this test you will need to reference the query report printed in "Execute DF_QCprint to print the query report from the QC/NEW directory." to verify the information contained in the report against the study database. Three examples of queries will be verified in this test. You may choose to check the remainder of the queries yourself.

12.10.1. 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.

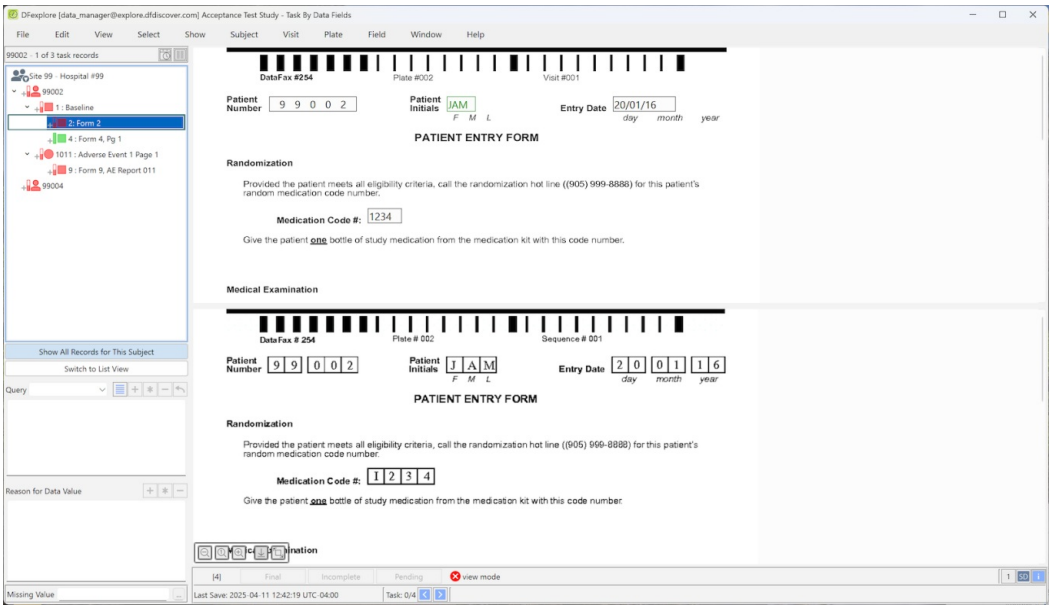
12.10.2. Select View > Data.

12.10.3. Select Select > By Data Fields. In the dialog, set:

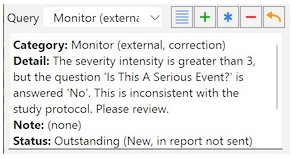
- **Mode** = View.
- **Subject** = 99002,99004
- **Plate** = 2,4,9
- **Level** = 1-7



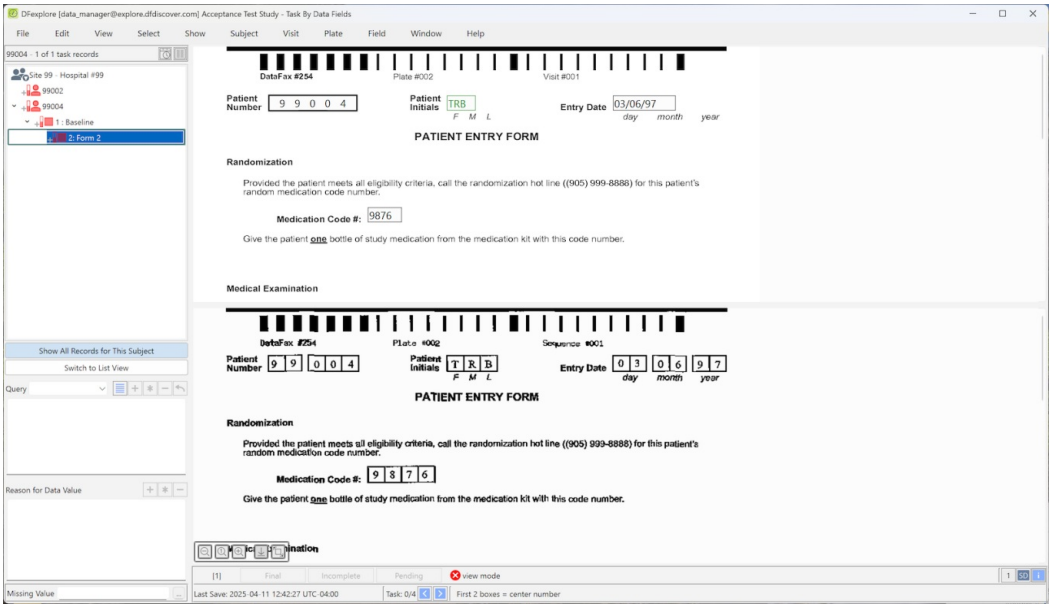
12.10.4. Click Done then OK to apply the record selection criteria and retrieve the applicable pages.



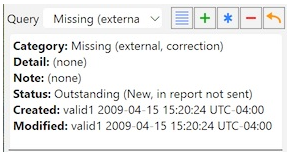
12.10.5. Highlight the **9: Form 9, AE Report 011** page in the record list. Press Tab to advance through the fields until **Intensity** becomes the current field. Confirm that this field is blue and the query count "2" is displayed on the field widget. Examine the **Query** window to view the details of the queries. Verify that the information in the **Query** window is consistent with the corresponding printed Query report.



12.10.6. In the record list, double-click entry for subject **99004**.



12.10.7. 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.



12.10.8. Examine the record list for the entry for **Form 4** for Subject **99004** (identified as a **Missing Page** on the query report).

12.10.9. Select Select > All Records. Confirm the settings:

- **Mode** = Modify
- **Save level**= 1 - Level 1

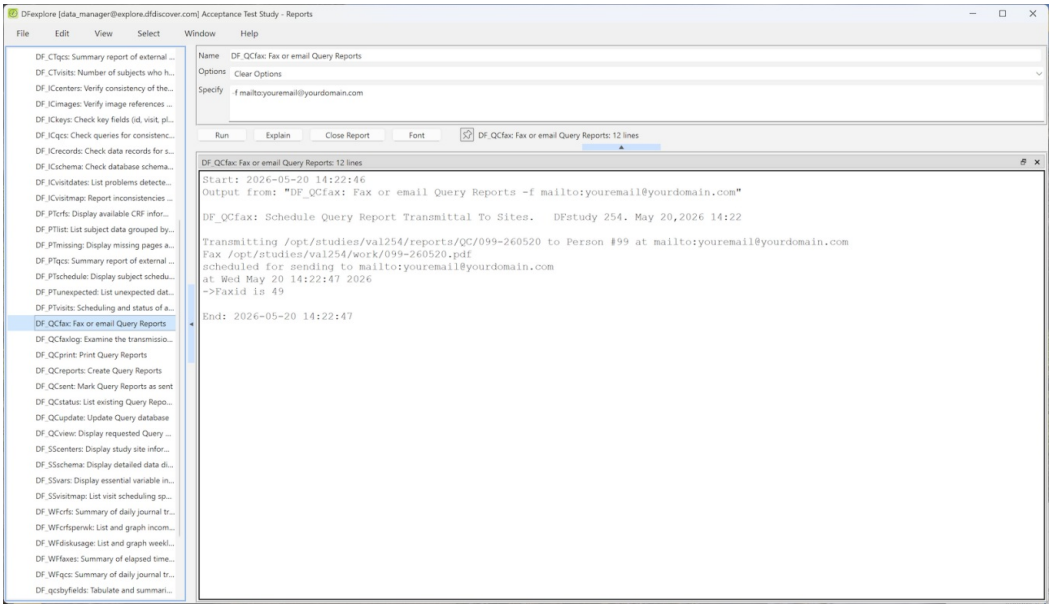
- Enable (check) edit checks

Click OK to release the task set and display all records in the database.

12.11 Execute DF_QCfax to email the query report to a valid email account

12.11.1. Select View > Reports.

12.11.2. 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**.



12.11.3. 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.

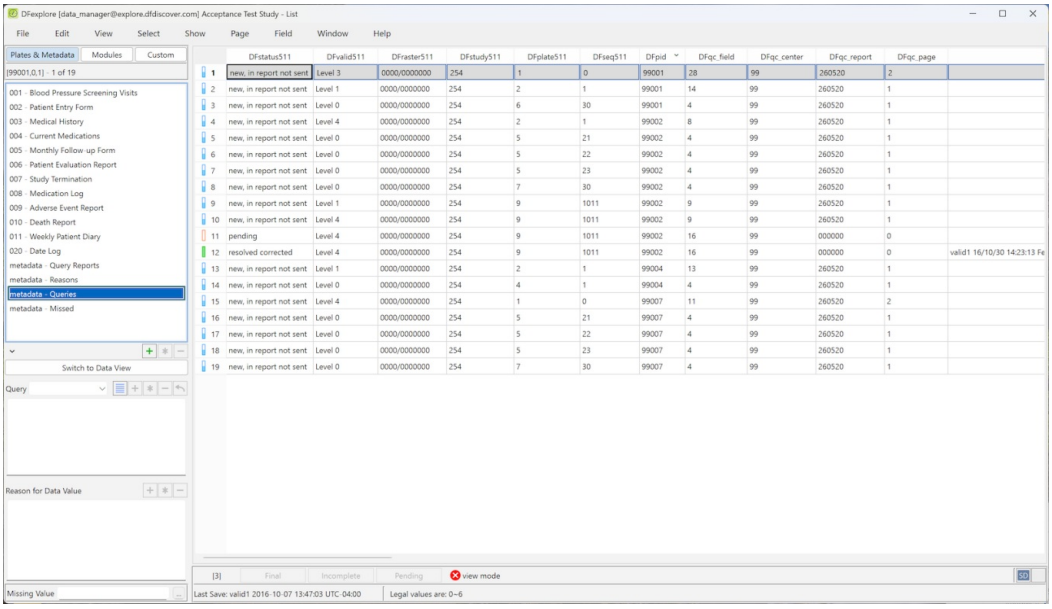
12.12 Verify the status of the queries in the sent report

12.12.1. 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.

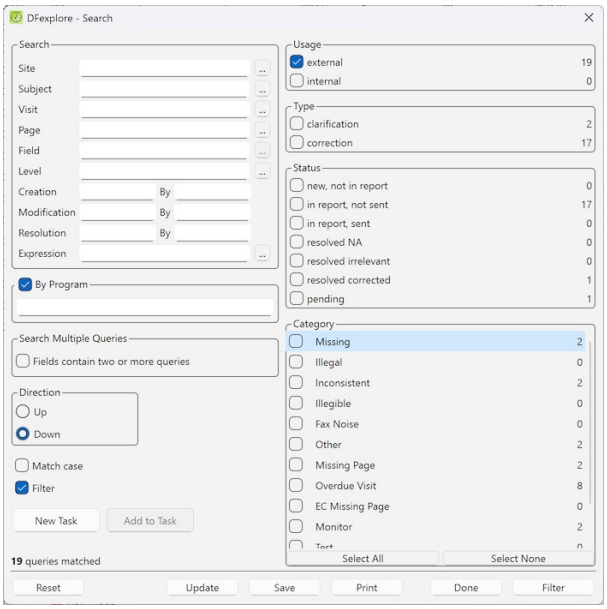
> NOTE: The counts in the **Queries** table are the same as those in Step 1 because queries have been sent to the site but not resolved.

12.12.2. Select View > List, and click **Plates & Metadata**.

12.12.3. 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**.



12.12.4. 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.



12.12.5. Click Done to close the Search dialog.

12.12.6. 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.

13 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

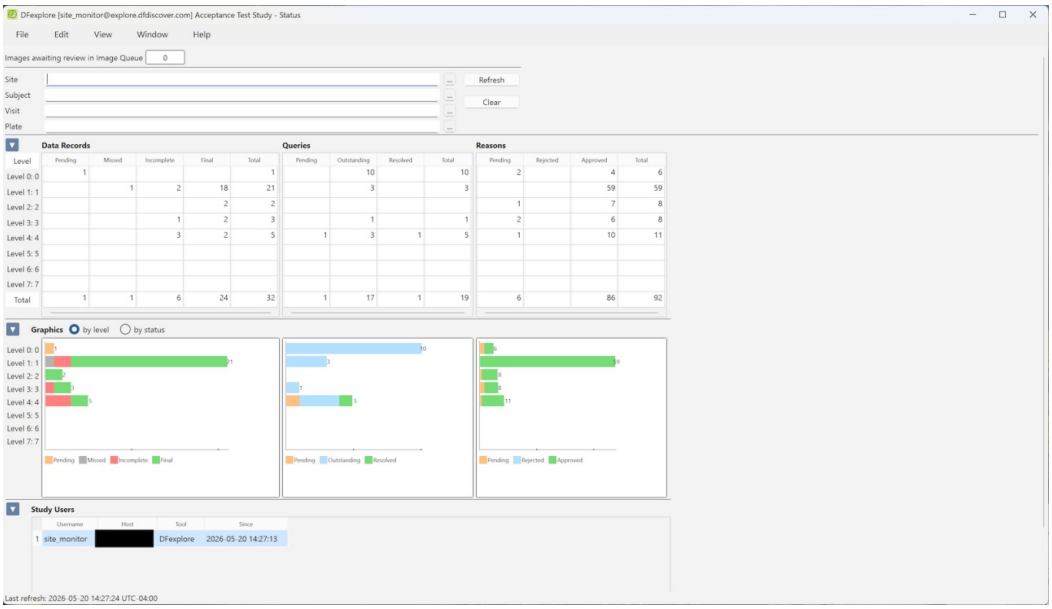
Begin Module 13. Replying to EDC Queries, eSignatures

1. Start **DFATK** as described in Module 1 (Installation & Initialization) .
2. Click 13. Replying to EDC Queries followed by Begin to begin this module.

13.1 Determine a count of outstanding queries in Status View

13.1.1. Start **DFexplore**, login as site_monitor and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**".

13.1.2. Select View > Status. Examine the **Queries** table to view the status and count of all queries.

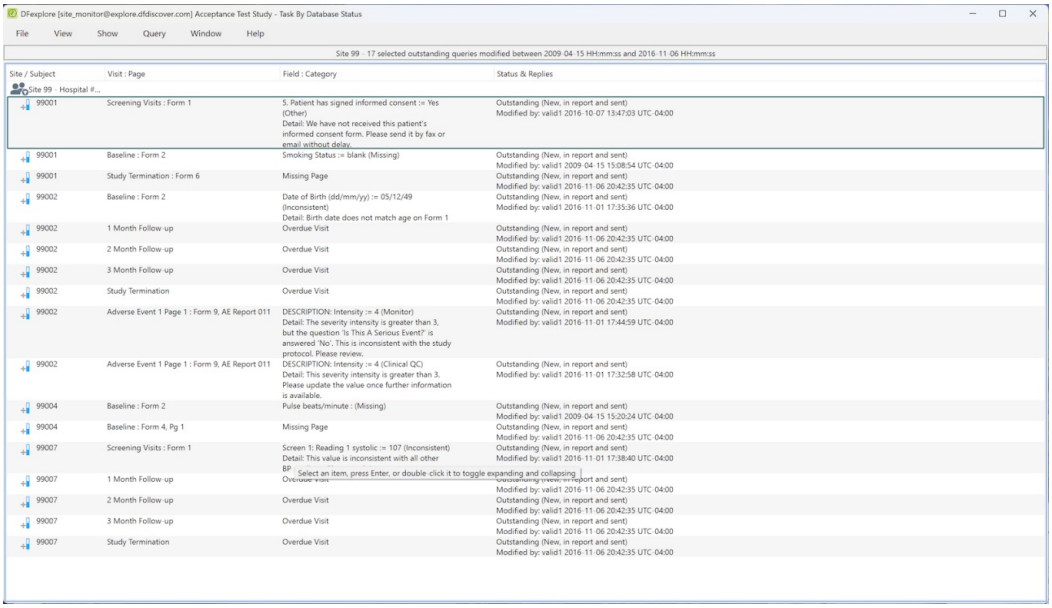


13.1.3. Locate the **Outstanding** column that displays a count of 17 in the Total row. Double-click 17 to retrieve the records containing the 17 outstanding queries.

13.1.4. In the Database Status task Specification dialog set:

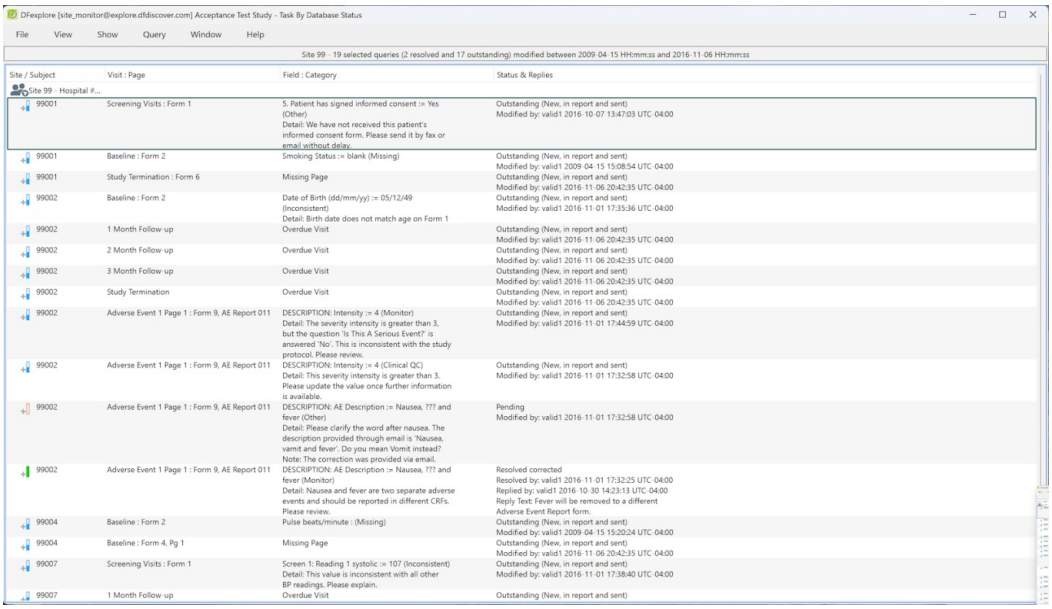
- **Mode** = Validate
- **Save level** = 1 - Level 1
- Check (enable) **Enable Edit checks**
- **Search queries and open** check (enable) **Queries View?**

Click Yes to display a dialog confirming the retrieval. In the confirmation dialog, click OK to open **Queries View** .



13.2 Review outstanding queries in Queries View

13.2.1. Select Show > Outstanding Queries to verify that you are seeing only outstanding queries for subjects in **Site 99 - Hospital #99**.

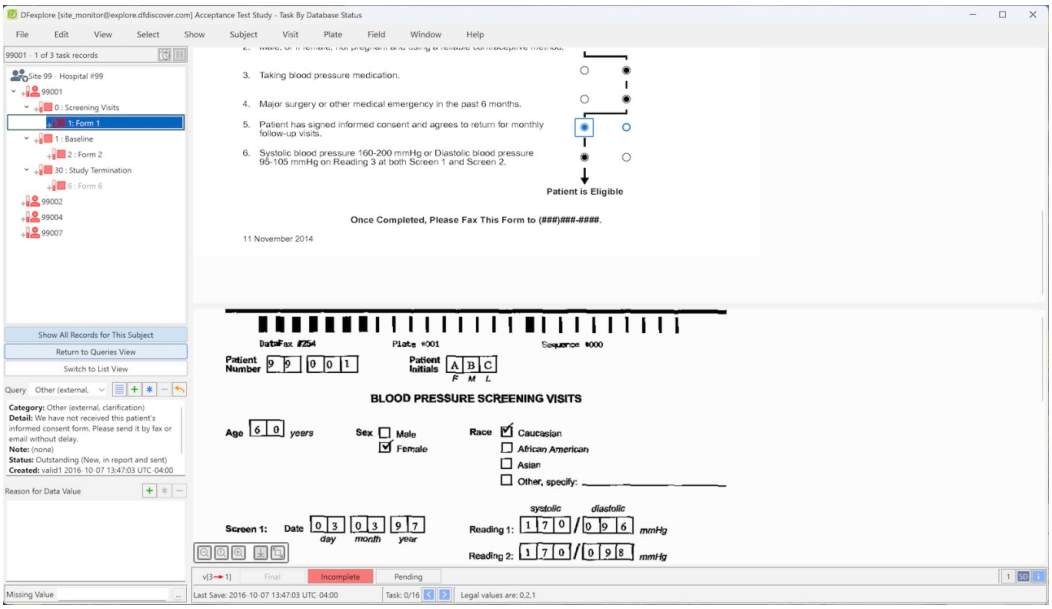


13.2.2. Examine **Queries View** to confirm:

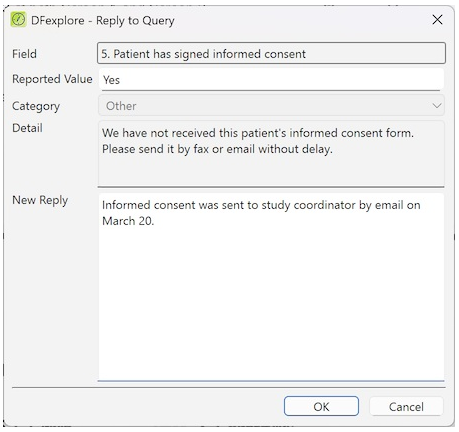
- The **Status & Replies** column displays **Outstanding (New, in report and sent)** for all queries.
- An entry exists for Subject **99001** , Screening Visits Form 1, 5. Patient has signed informed consent.
- An entry exists for Subject **99007** , Screening Visits Form 1, Screen 1 Reading 1 systolic.

13.3 Using EDC, locate and reply to outstanding clarification queries

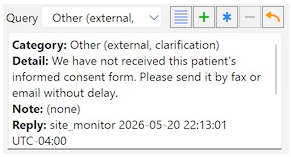
13.3.1. Locate the entry for Subject **99001, Screening Visits Form 1, 5. Patient has signed informed consent**. Double-click the query to switch to **Data View** and make the queried page and field active. Examine the information present in the **Query** window.



13.3.2. 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.

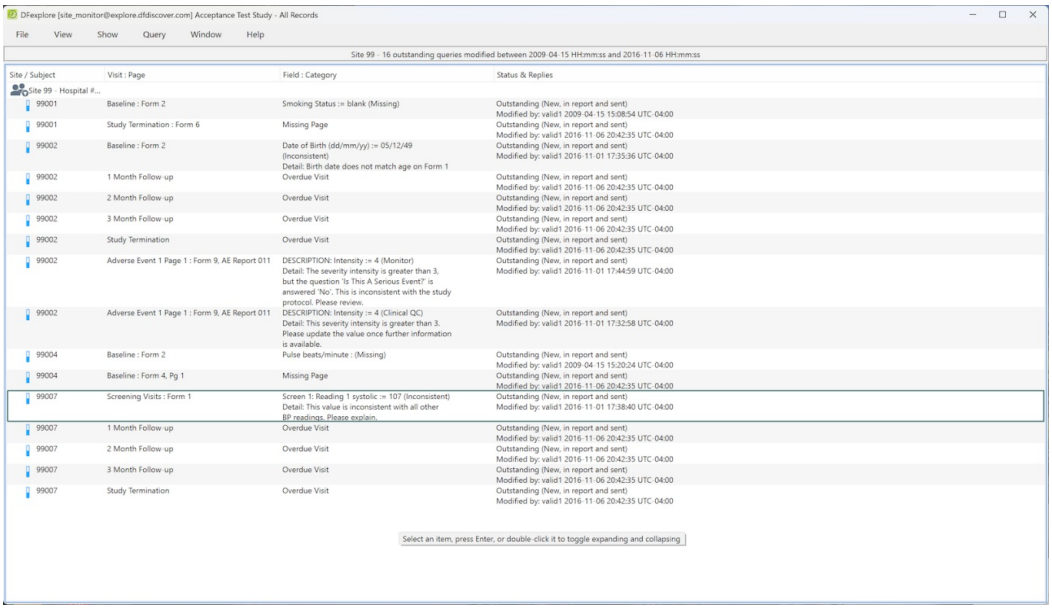


13.3.3. Click OK to apply the reply to the queried field. Examine the information present in the **Query** window.

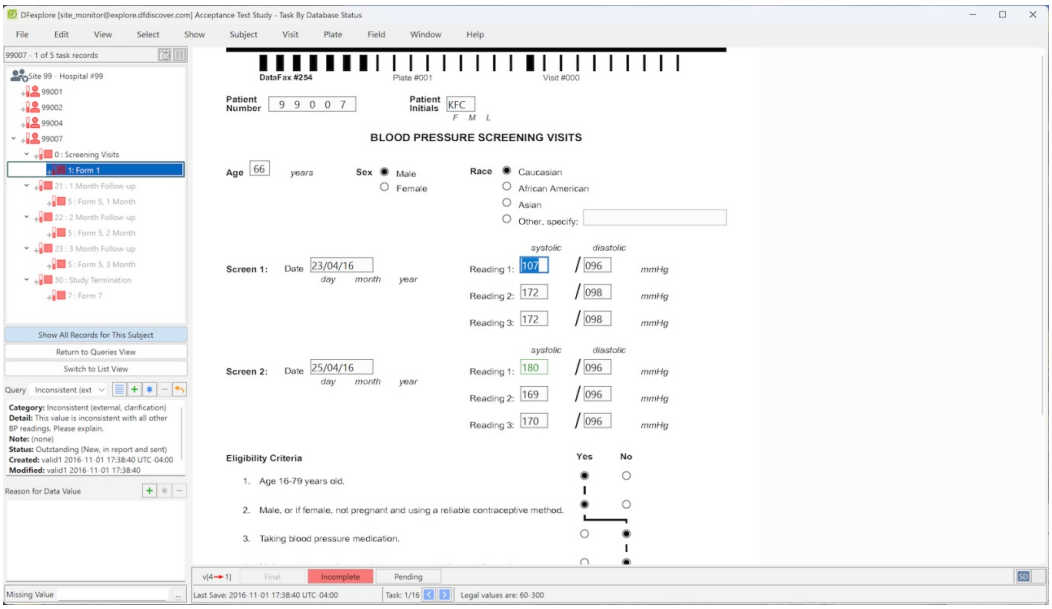


13.3.4. Do not enter or change data in any of the remaining fields on the current page. Click Final to save the current page and the query reply to the database.

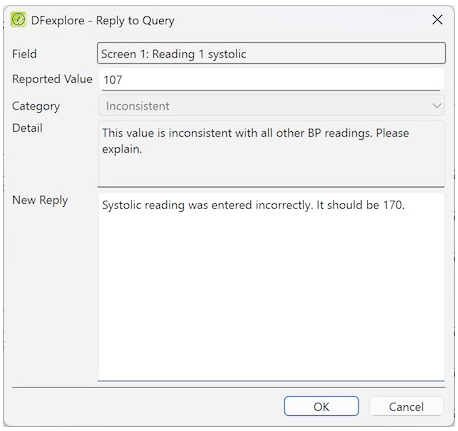
13.3.5. From the record list window, click Return to Queries View. Examine the list of queries.



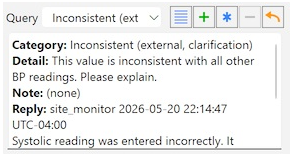
13.3.6. Locate the entry for Subject **99007, Screening Visits: Form 1, Screen 1: Reading 1 systolic.** Double-click the systolic blood pressure query to switch to **Data View** and make the queried page and field active. Examine the information present in the **Query** window.



13.3.7. 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.



13.3.8. Click OK in the **Reply to Query** dialog to apply the reply to the queried field. Examine the information present in the **Query** window.



13.3.9. Click Final to save the current page and the query reply to the database.

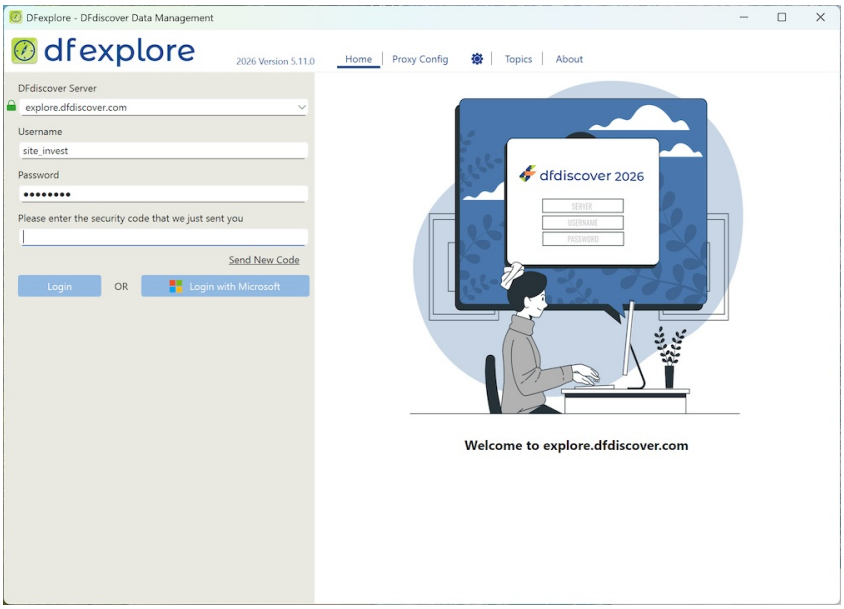
13.3.10. Select File > Exit to close and exit **DFexplore**.

13.4 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.

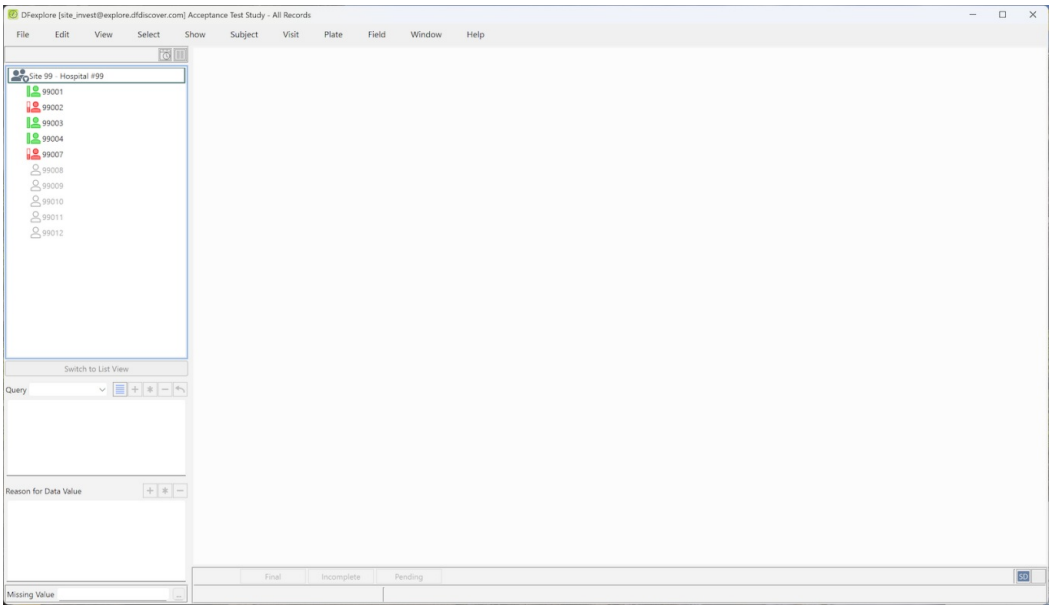
13.4.1. Start **DFexplore**, login as user site_invest and open the **254 Acceptance Test Study** as described in ("How to start **DFexplore**").

13.4.2. As user site_invest has 2FA enabled, enter security code received by email or SMS as previously defined.



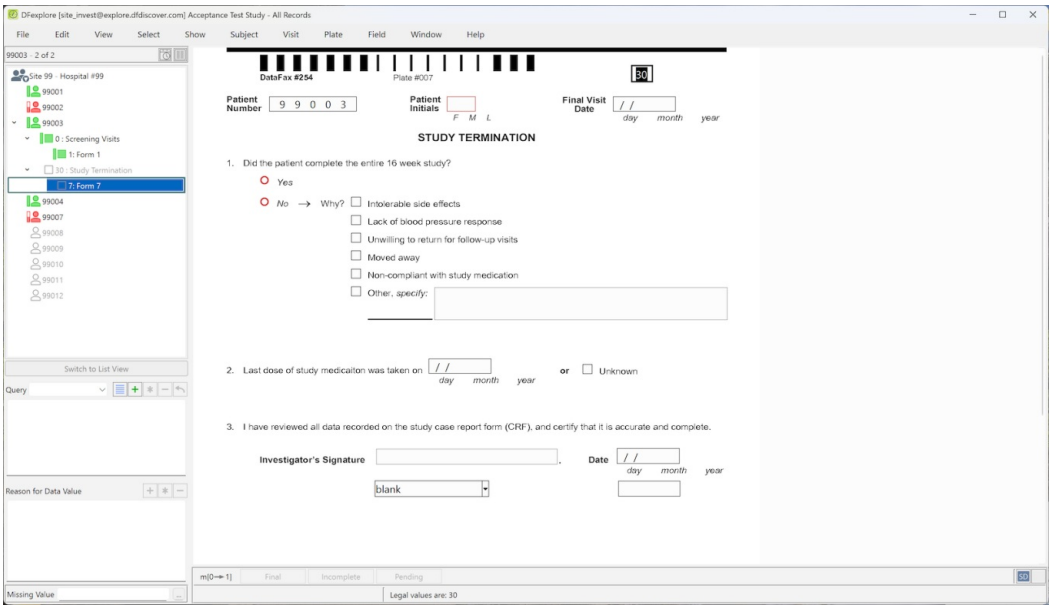
NOTE: Refer to "Creating user accounts and assigning study permissions." as a valid email address or phone number is required for site_invest to receive 2FA codes.

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

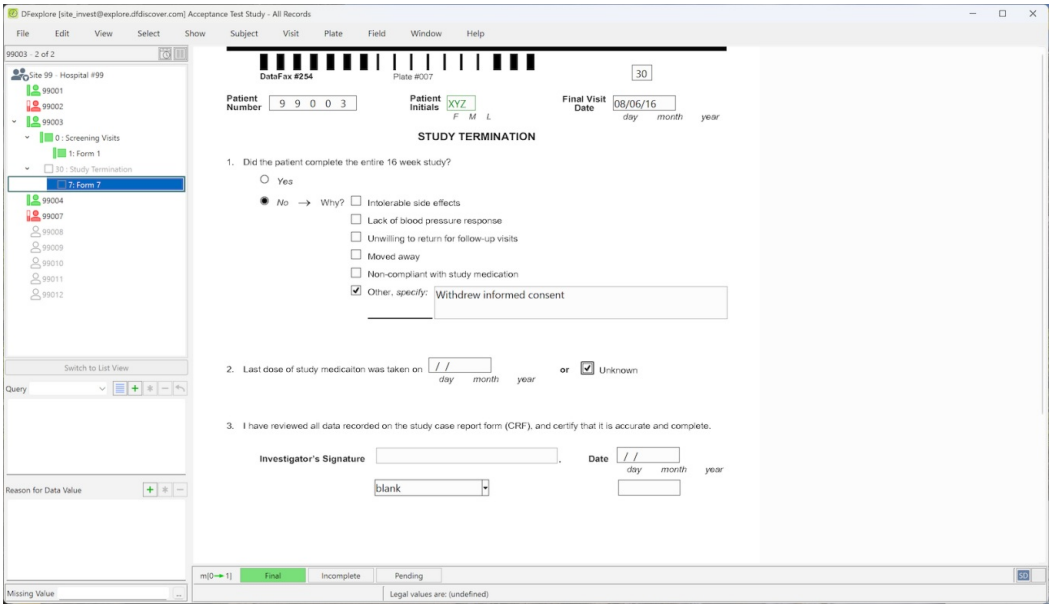


13.4.4. Locate subject **99003** , double-click its entry to expand a list of visits for Subject **99003**.

13.4.5. Double-click **30 : Study Termination** . Select **7: Form 7** to open a new **STUDY TERMINATION** form.



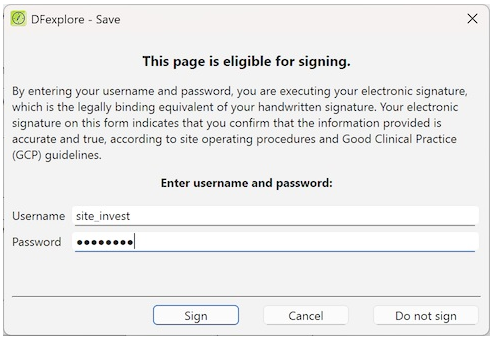
13.4.6. Click anywhere in the screen background to begin data entry. Enter the form data as shown below:



13.4.7. 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.

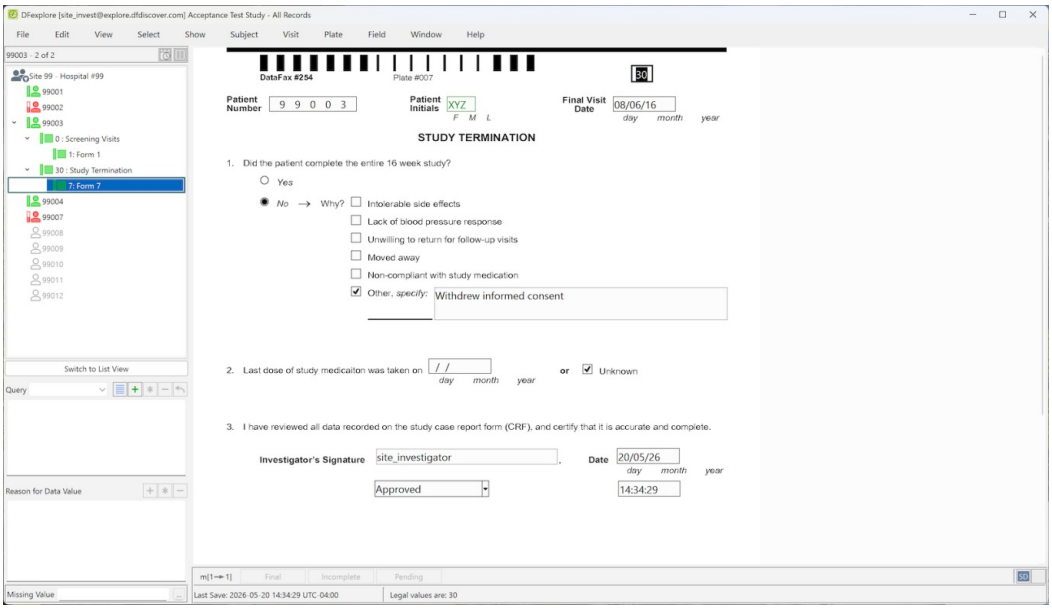
13.4.8. Press Tab to advance to the remaining 2 eSignature fields. Again attempt to manually enter data into each of these fields. Press Tab to exit the last field on the page (**eSignature Time**) to make the save buttons active.

13.4.9. Click Final to save and eSign the **STUDY TERMINATION** form.



13.4.10. 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.

13.4.11. In the **DFexplore - eSignature Reason** dialog select **Approved** from the dropdown, click OK.



13.4.12. Examine the 4 eSignature fields at the bottom of the page.

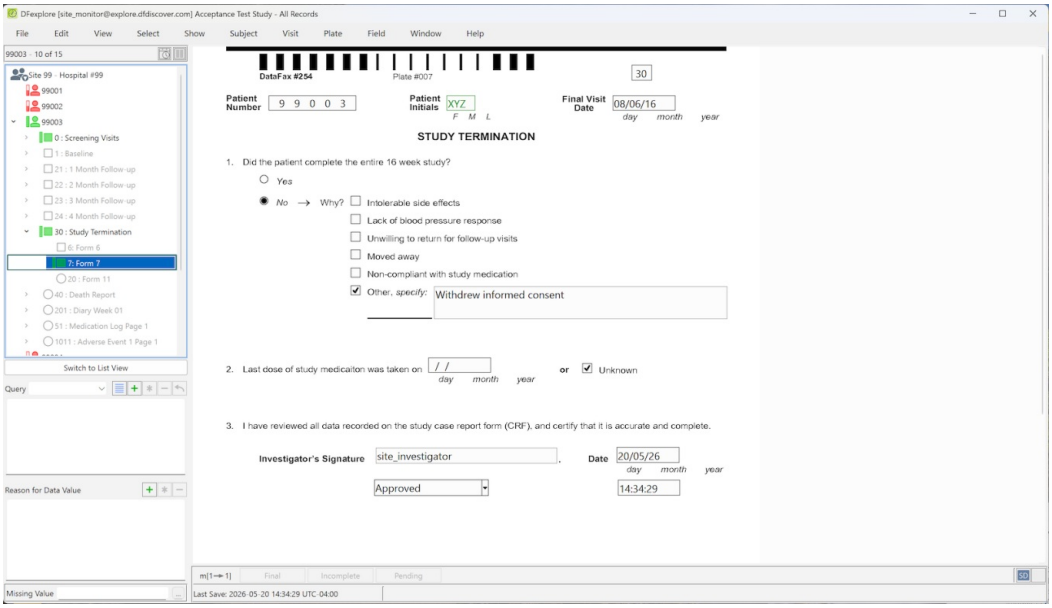
13.4.13. Select File > Exit to close and exit **DFexplore**.

13.5 Verify removal and re-application of eSignatures

13.5.1. Start **DFexplore**, login as user site_monitor and open the **254 Acceptance Test Study** as described in ("How to start **DFexplore**").

13.5.2. Locate subject **99003** , double-click its entry to expand a list of visits for Subject **99003** .

13.5.3. Double-click **30 : Study Termination** . Select **7: Form 7** to open the **STUDY TERMINATION** form.

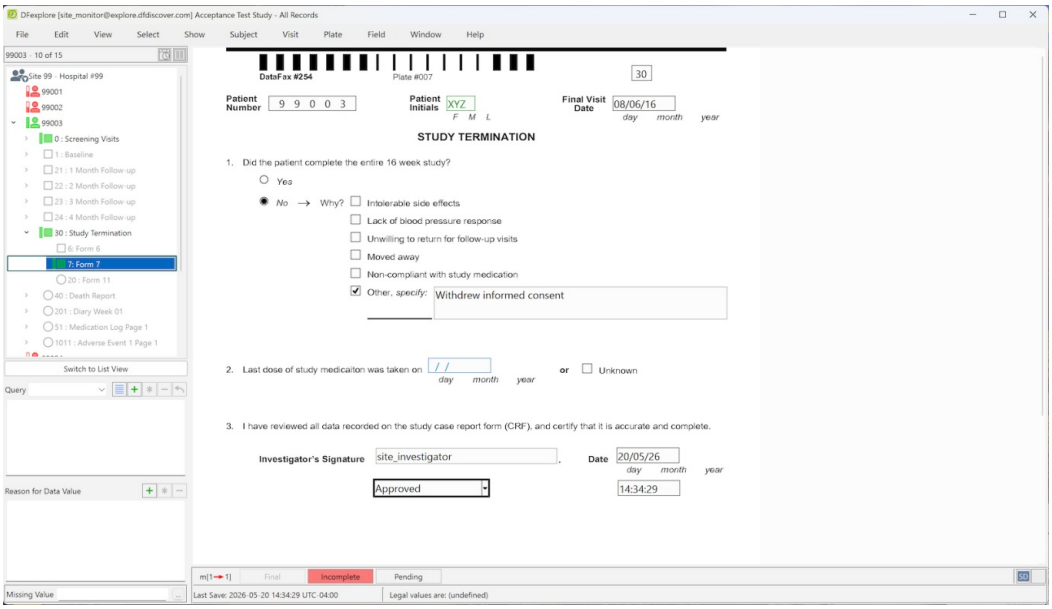


13.5.4. Click **2. Last dose of study medication was taken on** field. Select Field > Add Query or click + to open the **Add Query** dialog. In the dialog, set:

- **Category** = Monitor
- **Use** = External
- **Type** = Clarification
- **Status** = New query
- Enter Investigator to confirm last dose taken with subject during clinic visit. in the **Note** field.

13.5.5. Click OK to apply the query.

13.5.6. Press Tab to advance to the **Unknown** field. Un-check (disable) the checkbox.



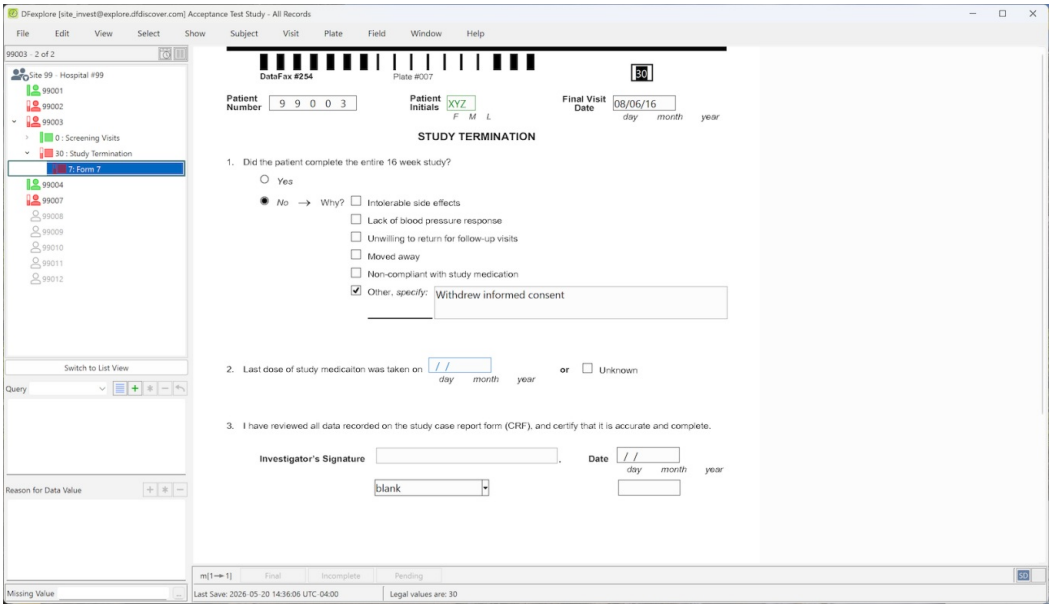
13.5.7. Press Tab to advance through the remaining fields on the page until the save buttons become active. Click Incomplete to save the page.

13.5.8. Select File > Exit to close and exit **DFexplore**.

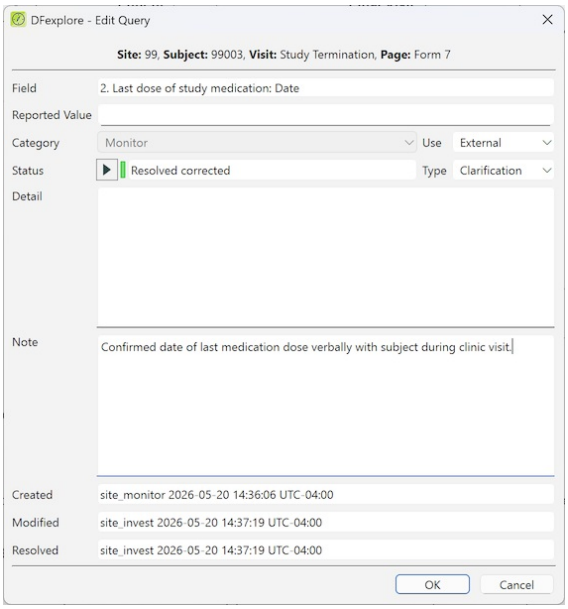
13.5.9. Start **DFexplore**, login as user site_invest and open the **254 Acceptance Test Study** as described in ("How to start **DFexplore**").

13.5.10. Locate subject **99003** , double-click its entry to expand a list of visits for Subject **99003** .

13.5.11. Double-click **30 : Study Termination** . Select **7: Form 7** to open the **STUDY TERMINATION** form.



13.5.12. 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.



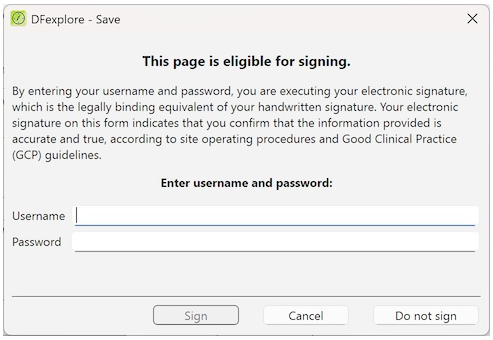
13.5.13. Click OK to close the dialog.

13.5.14. Enter the **2. Last dose of study medication was taken on** date as 02/06/16 .

13.5.15. 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.

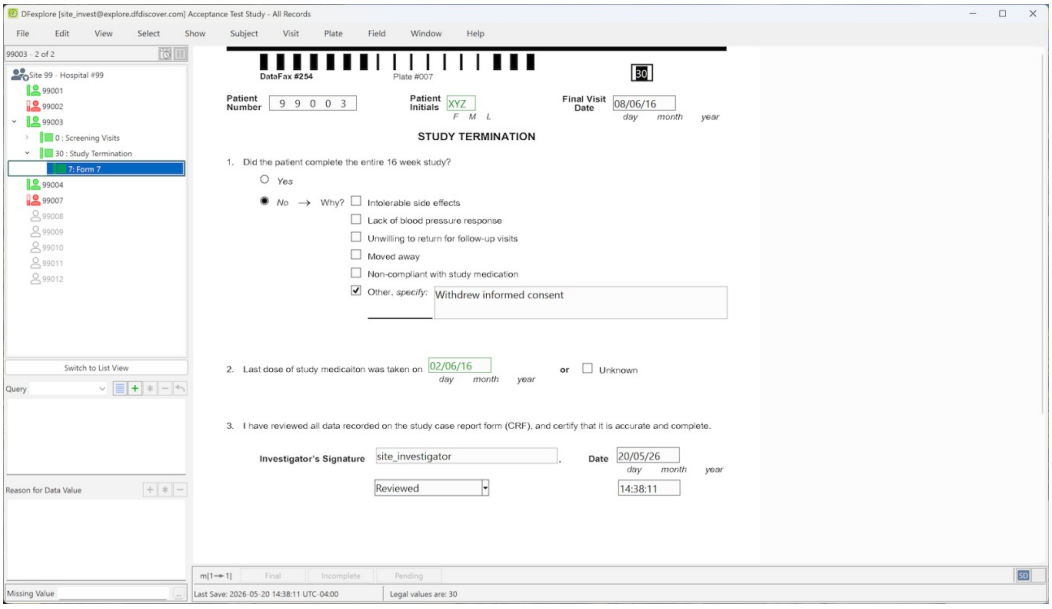
13.5.16. Press Tab to advance to the remaining 2 eSignature fields. Again attempt to manually enter data into each of these fields. Press Tab to exit the last field on the page (**eSignature Time**) to make the save buttons active.

13.5.17. Click Final to save and eSign the **STUDY TERMINATION** form.



13.5.18. 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.

13.5.19. In the **DFexplore - eSignature Reason** dialog select **Reviewed** from the dropdown, click OK.



13.5.20. Examine the 4 eSignature fields at the bottom of the page.

13.5.21. 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.

14 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

1. Submit PDF images to DFdiscover.
2. Verify that all CRFs have arrived successfully in Image view.
3. Retrieve submitted CRFs using **DFexplore** Image View.
4. Enter Form 2, Subject 99001, resolve outstanding queries, and save the corrected CRF to the database.
5. Enter Form 2, Subject 99002, resolve outstanding queries, and save the corrected CRF to the database.
6. Enter Form 4, Subject 99004.
7. Enter Form 2, Subject 99004, resolve outstanding queries, and save the corrected CRF to the database.
8. Select and resolve a query in a field that has multiple queries.
9. Review and approve a pending query reply for Form 1 for Subject 99002.
10. Review, correct and approve a pending query reply for Form 1, Subject 99007.
11. Confirm query resolution by examining the database status.

Estimate of Time Required: 30 Minutes

Begin Module 14. Re-submitting Query Corrections

1. Start **DFATK** as described in Module 1 (Installation & Initialization).
2. Click 14. Re-submitting Query Corrections followed by Begin to begin this module.

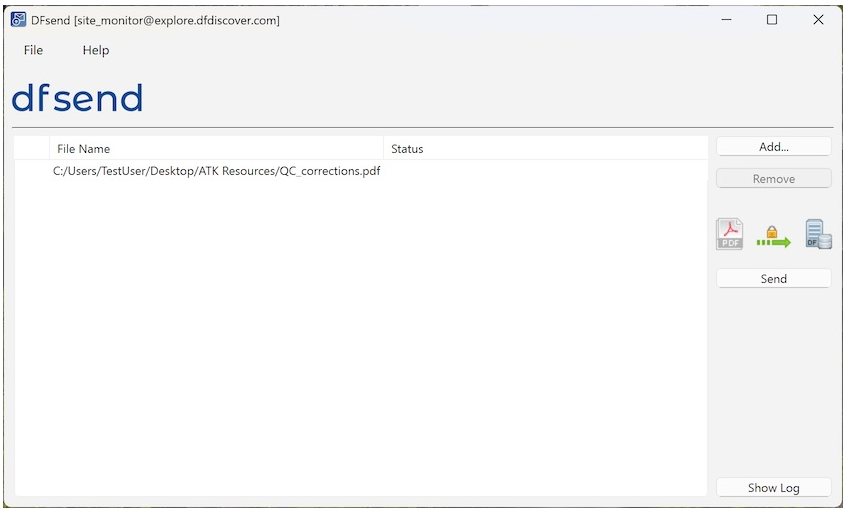
14.1 Submit PDF images to DFdiscover

14.1.1. 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.

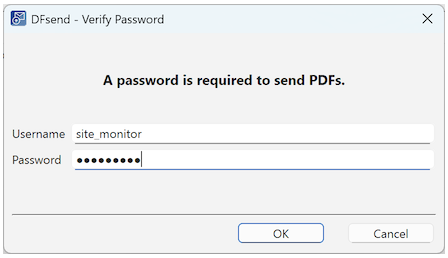
14.1.1. Start **DFsend**, login as user site_monitor as described in "How to start **DFsend**".

14.1.2. Click Add. From the **Select PDF Files** file selection dialog, locate the previously saved **QC_corrections.pdf** file. Select the file, Click Open.

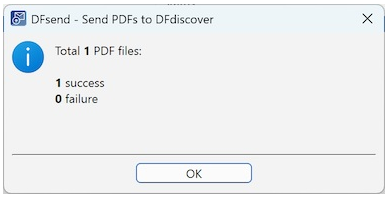


NOTE: Documents can also be added by dragging-and-dropping the desired PDF files from a local file folder directly into the list area.

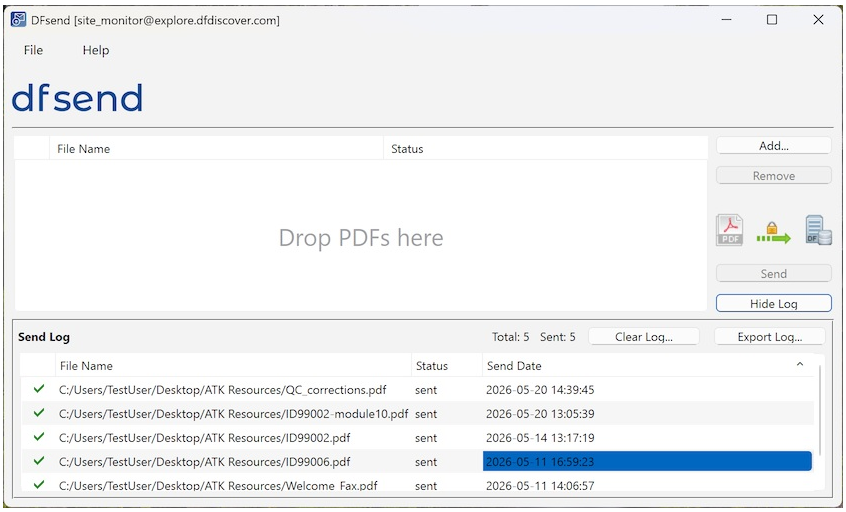
14.1.1. Click Send, enter site_monitor in the **Username** field and the previously assigned password in the **Password** field. Click OK.



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



14.1.3. Click Show Log to confirm successful transmission of the **QC_corrections.pdf** file to **DFdiscover**.



14.1.4. Select File > Exit.

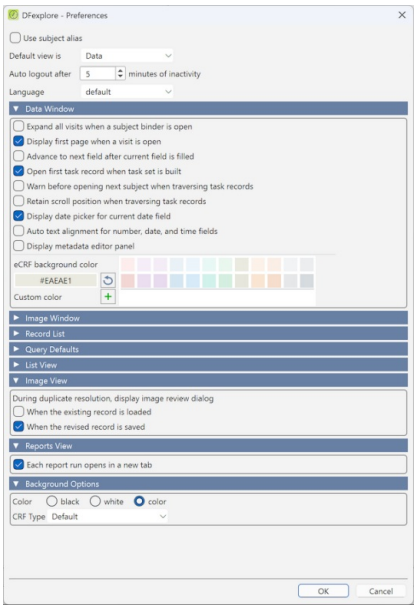
NOTE: Wait 2-3 minutes prior to proceeding to **DFexplore**.

14.2 Verify that all CRFs have arrived successfully in Image view

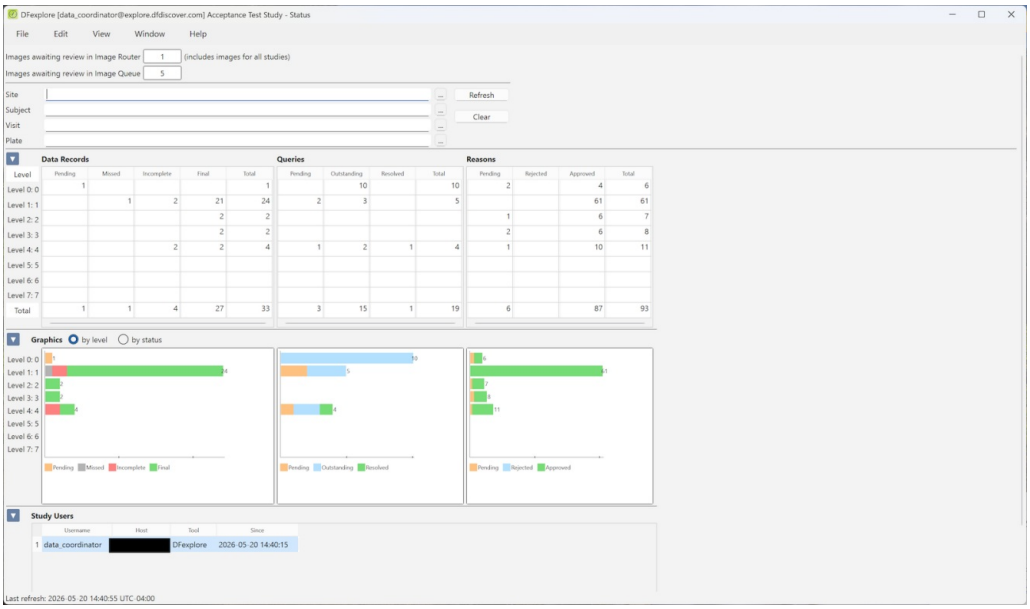
14.2.1. Start **DFexplore**, login as user data_coordinator and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

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**.

14.2.1. 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.



14.2.2. Select View > Status. Examine the information displayed for the Images awaiting review in Image Queue, **Data Records** and **Queries** tables.

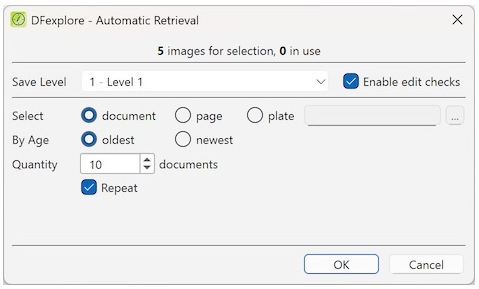


NOTE: The number of pages awaiting review in the Image Router may be different from that shown here as this number includes pages for all studies on the **DFdiscover** server, not only those that belong to the 254 Acceptance Test Study.

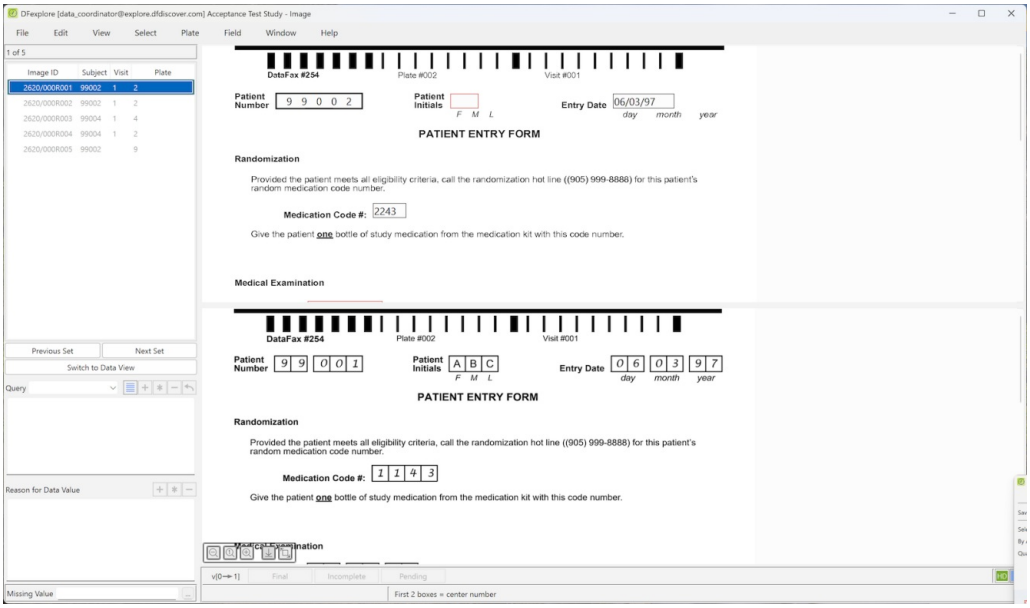
14.3 Retrieve submitted CRFs using **DFexplore** Image View

14.3.1. 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

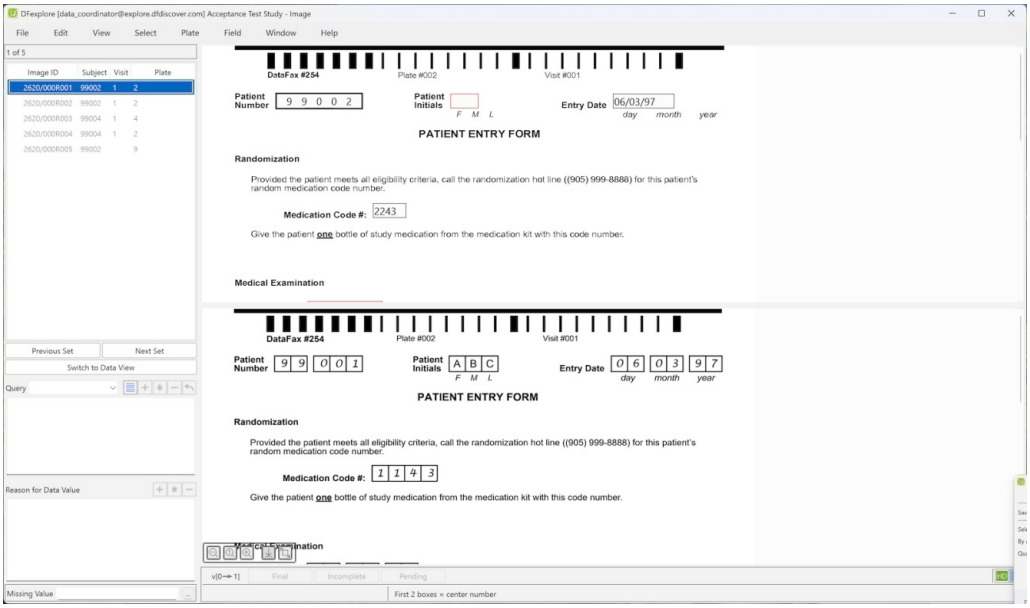


14.3.2. Click OK to bring forward all new images awaiting data entry.



14.4 Enter Form 2, Subject 99001, resolve outstanding queries, and save the corrected CRF to the database

14.4.1. 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.

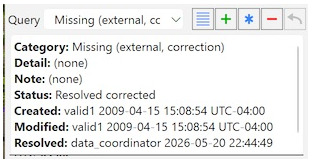


NOTE: In your normal image entry process, you must always pay careful attention to the accuracy of the ICR data. You will need to do the same here. It is possible that the new pages contain ICR errors that you will need to correct during entry. In particular, it is important that you correct any key 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.

14.4.2. Click OK to load the data from the existing subject **99001, PATIENT ENTRY FORM**.

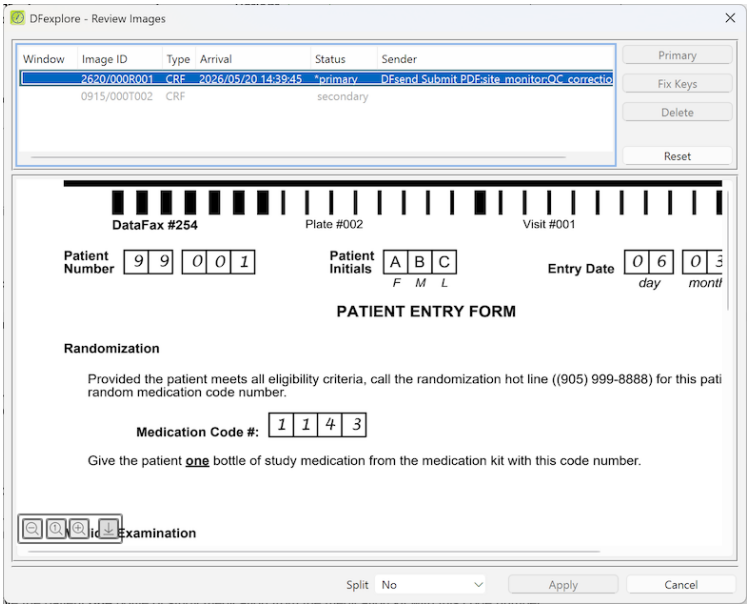


14.4.3. Press Tab to advance from field to field, and verify that data is the same as that found on the CRF image. Note that some fields may contain values that have been assigned by edit checks. Stop when the **Smoking Status** field becomes the current field. Examine the details in the **Query** window. Enter the data as it appears on the image.

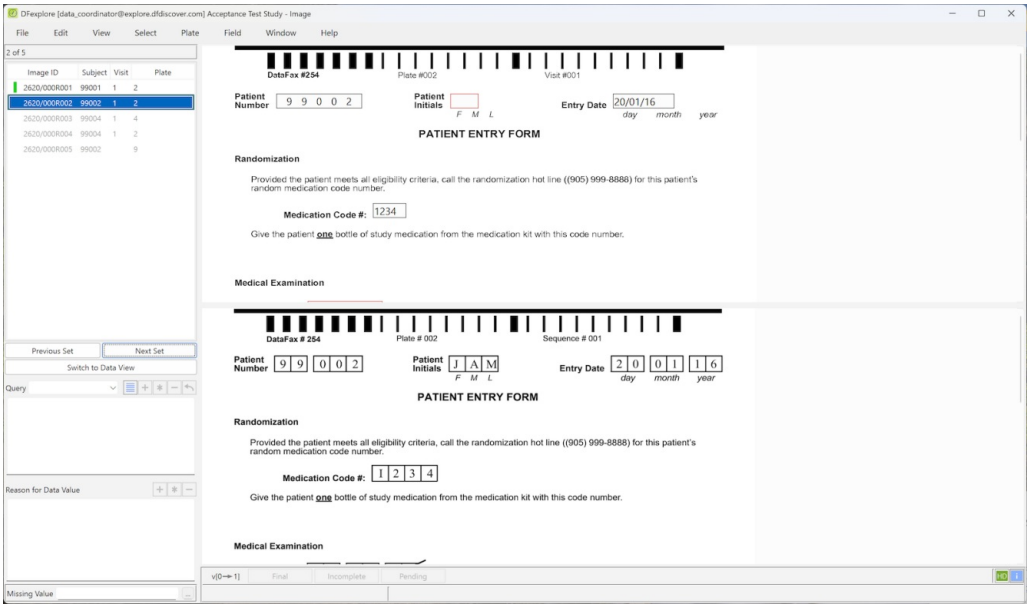


NOTE: When data is entered into a field that contains an outstanding missing value query of type **Correction**, the query is automatically resolved by **DFdiscover** as the missing data has now been provided. The color green indicates that the query has been resolved.

14.4.4. 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.



14.4.5. 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.



14.4.6. 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.

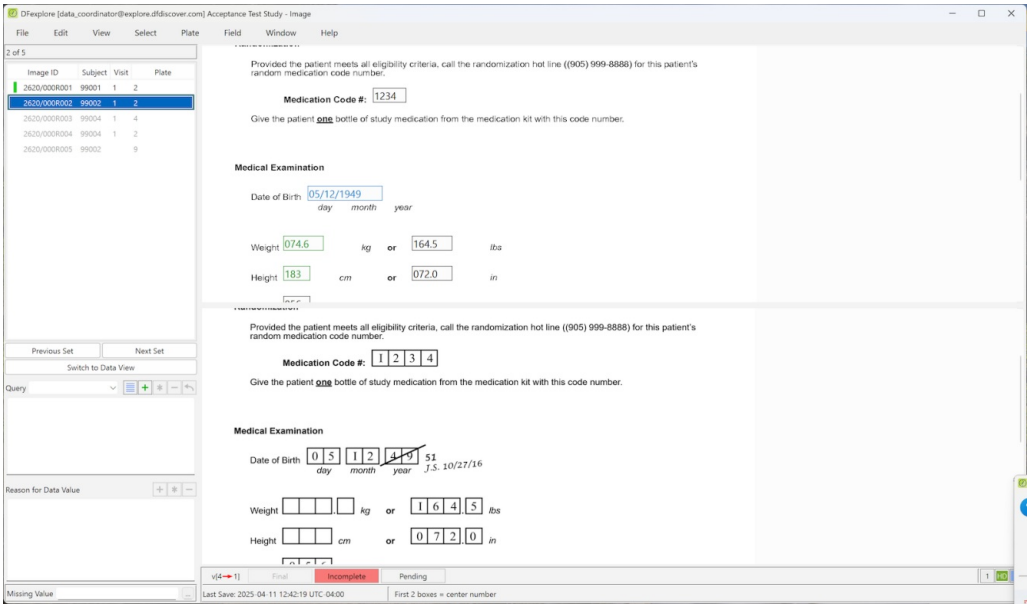


14.5 Enter Form 2, Subject 99002, resolve outstanding queries, and save the corrected CRF to the database

14.5.1. 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.

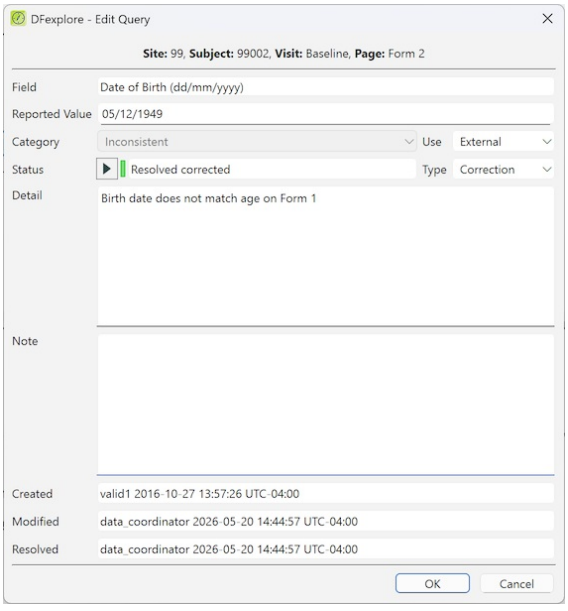


14.5.2. Click OK to load the data from the existing Subject **99002**, **PATIENT ENTRY FORM**.

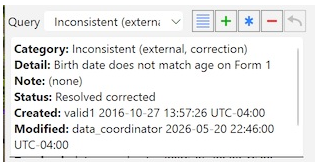


14.5.3. Press Tab to advance from field to field, and verify that data is the same as that found on the CRF image. Stop when the **Date of Birth** field becomes the current field. Examine the details in the **Query** window.

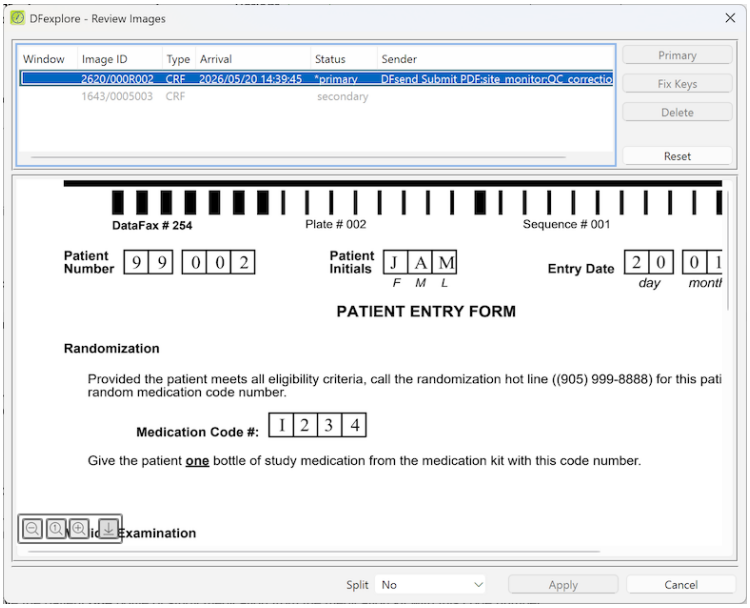
14.5.4. Enter the corrected date value 05/12/1951, as it appears on the image of the CRF. With **Date of Birth** as the current field, select Field > Edit Query or click *.



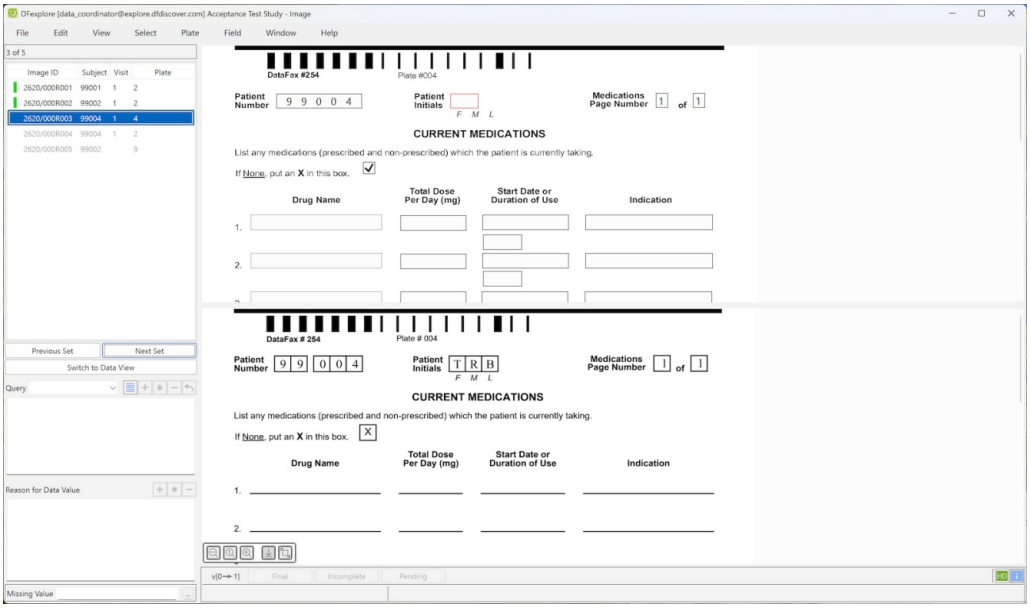
14.5.5. Select **Resolved corrected** from the **Status** pull-down. Click OK to apply the change to the query status. Examine the Query window.



14.5.6. 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.



14.5.7. 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.

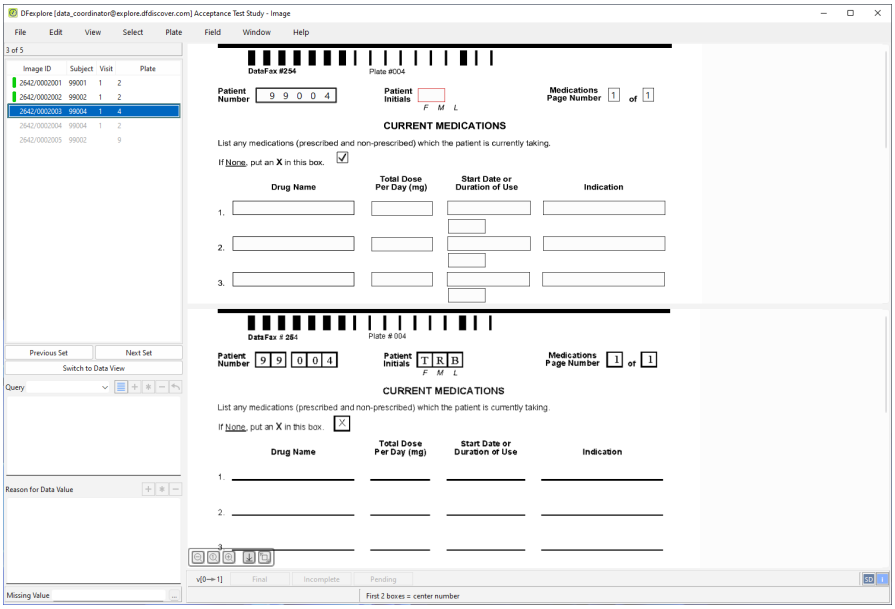


14.6 Enter Form 4, Subject 99004

14.6.1. 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.

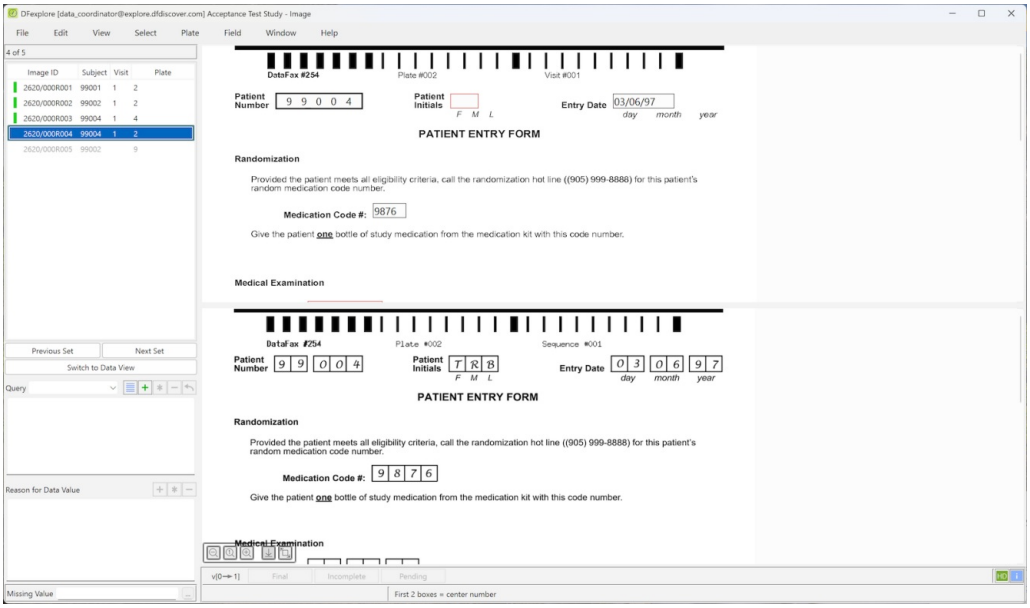
14.6.1. Enter all fields on the data record as they appear on the CRF image. Once the save buttons at bottom of the record become active, click Final to save the entered page.



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.

14.7 Enter Form 2, Subject 99004, resolve outstanding queries, and save the corrected CRF to the database

14.7.1. 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.

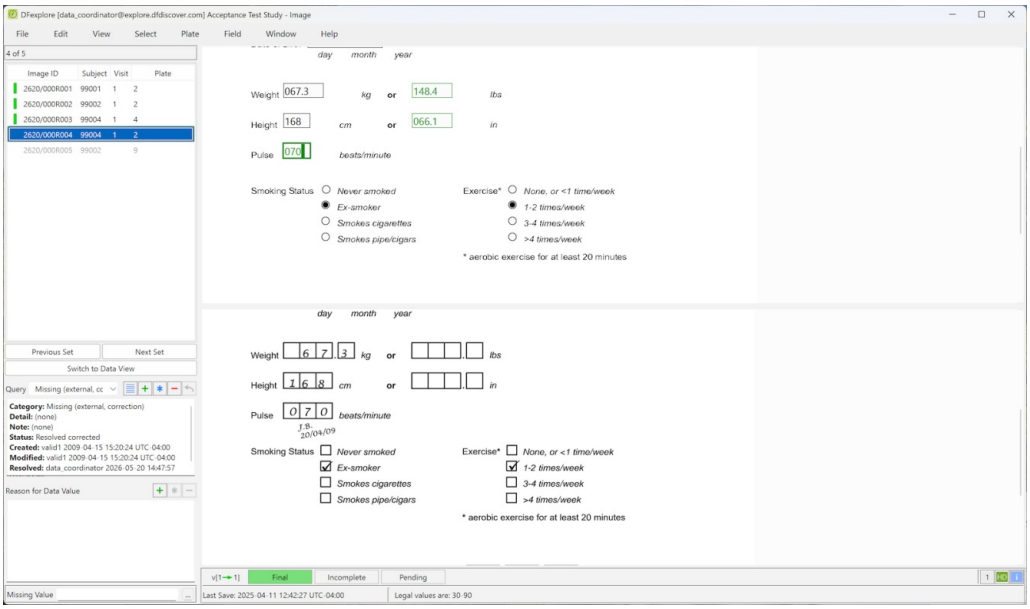


14.7.2. Click OK to load the data from the existing Subject **99004**, **PATIENT ENTRY FORM**.



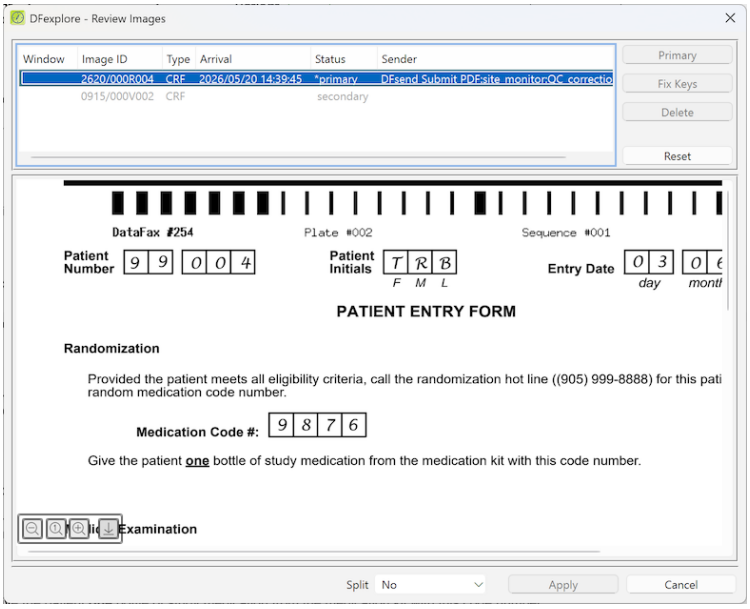
14.7.3. Press Tab to advance from field to field, and verify that data is the same as that found on the CRF image. Note that some fields may contain values assigned by edit checks. Stop when the queried **Pulse** field becomes the current field. Examine the details in the **Query** window.

14.7.4. 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.



14.7.5. 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.

14.7.6. 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.

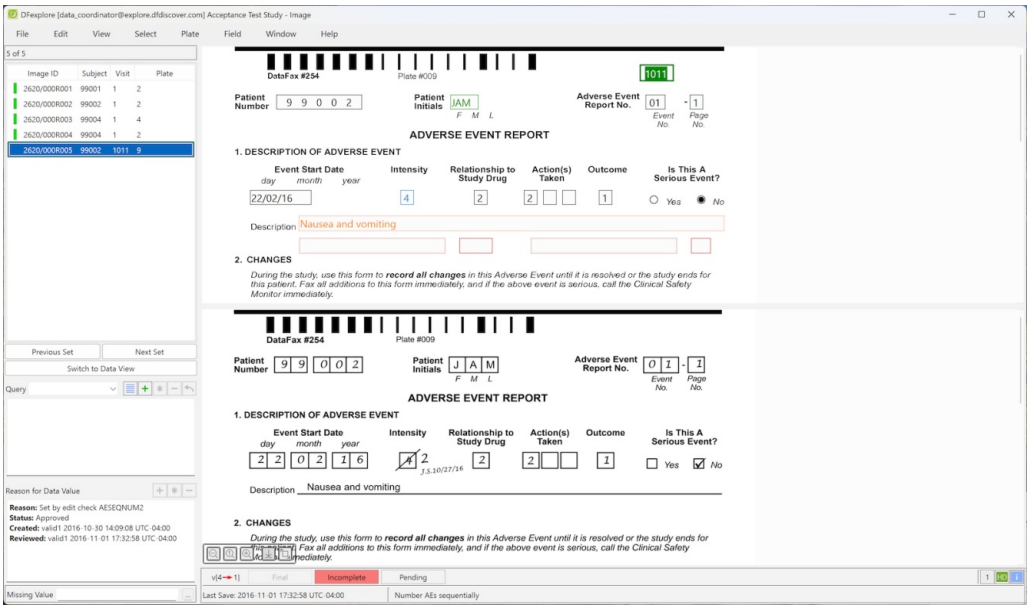


14.8 Select and resolve a query in a field that has multiple queries

14.8.1. 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.

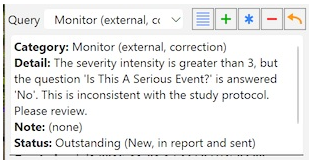


14.8.2. Click OK to load the data from the existing Subject **99002, ADVERSE EVENT REPORT FORM**.

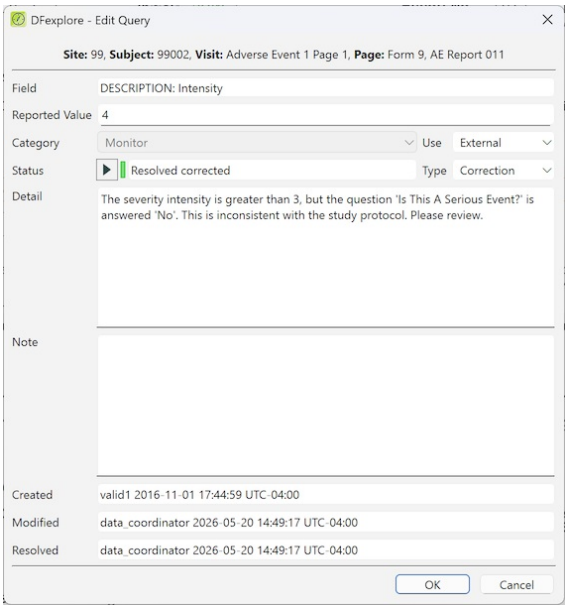


14.8.3. Correctly enter each data field on the page per the CRF image, up to the **Intensity** field. Confirm that the Intensity field has a value of 4, and contains 2 unresolved queries.

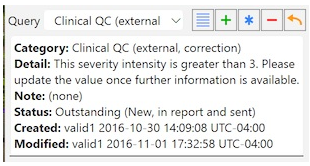
14.8.4. Enter the correct value 2 for **Intensity** field per the CRF image. Examine the details in the **Query** window.



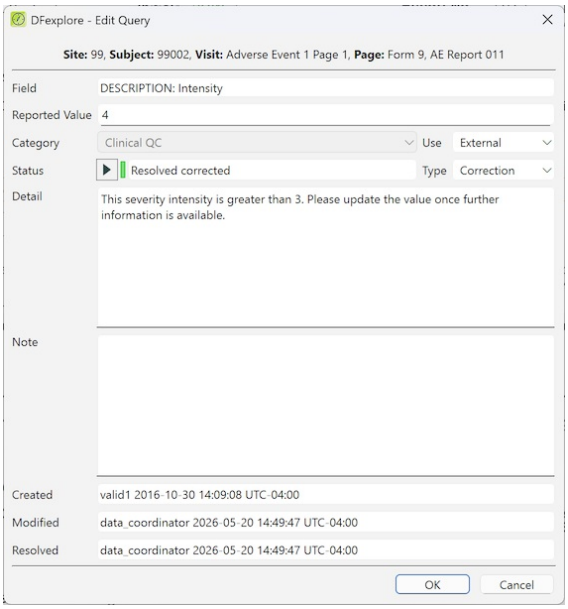
14.8.5. Select Field > Edit Query or click *. Choose **Resolved corrected** from the **Status** pull-down. Click OK to apply the edits.



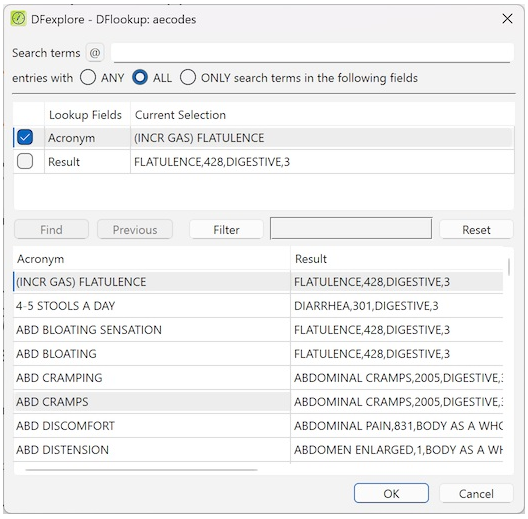
14.8.6. With the focus still on the **Intensity** field, examine the details in the **Query** window. Select the **Clinical QC** query from the **Query** drop-down, and examine its details.



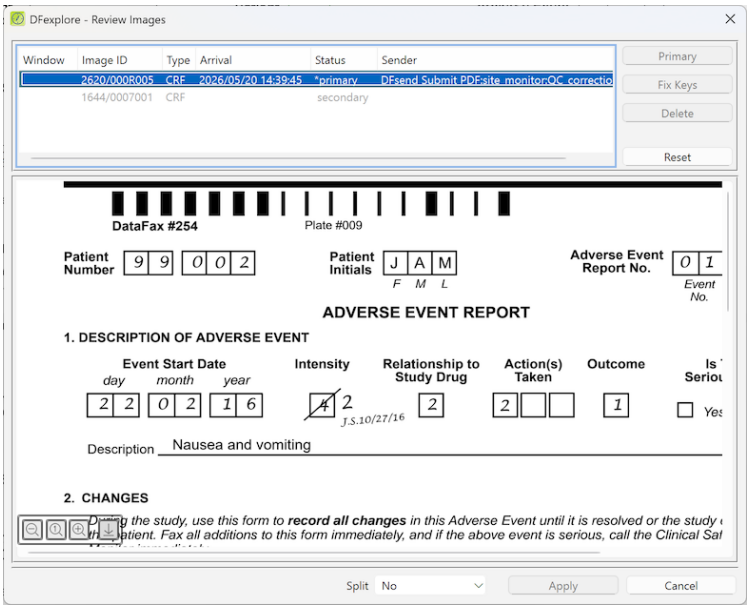
14.8.7. Select Field > Edit Query or click * in the dialog, choose **Resolved corrected** from the **Status** pull-down. Click OK to apply the edits.



14.8.8. 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.

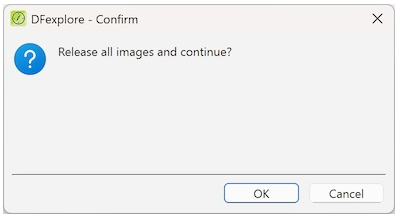


14.8.9. Continue tabbing through the remaining fields on the page and verify that the data in the fields is the same as the CRF image. Once the save buttons become active at the bottom of the record, click Incomplete to save the corrected page to the database. Upon clicking Incomplete, the **Review Images** dialog appears. Click Cancel to close the **Review Images** window.



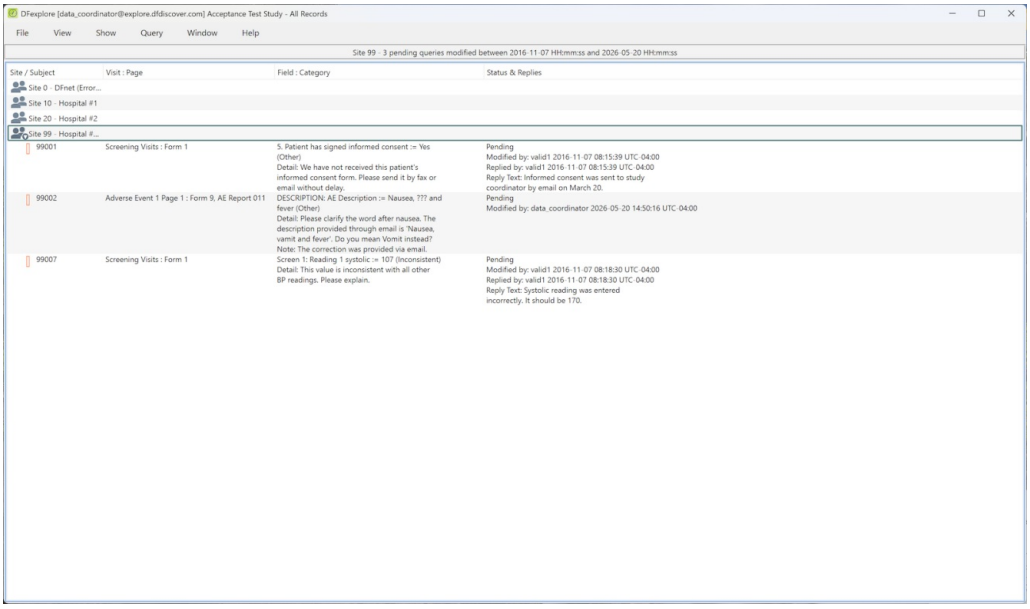
14.9 Review and approve a pending query reply for Form 1 for Subject 99002

14.9.1. Select View > Queries.

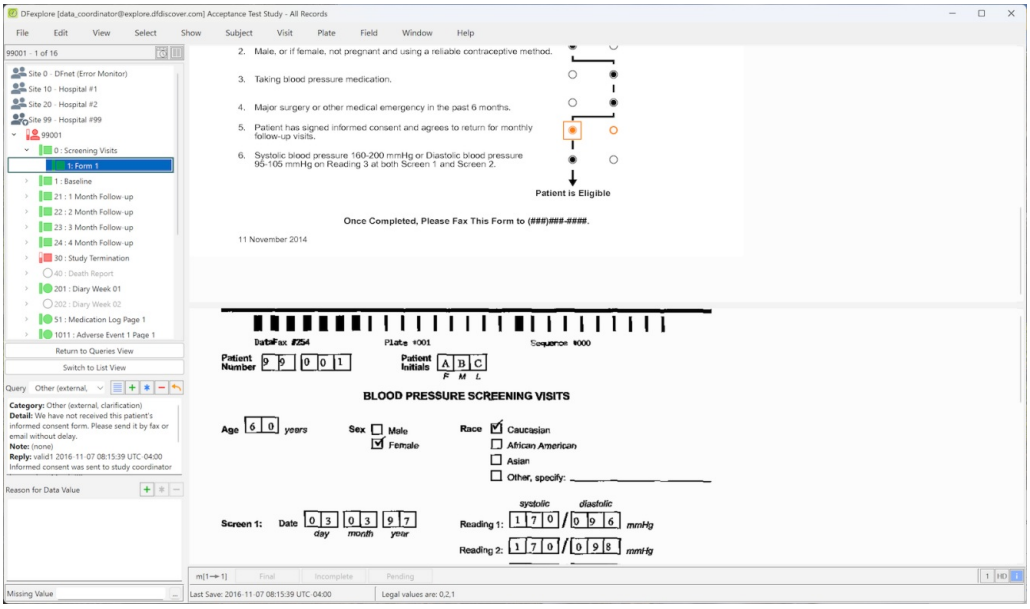


14.9.2. Click OK in the confirmation dialog to release the **Image View** records and open **Queries View**.

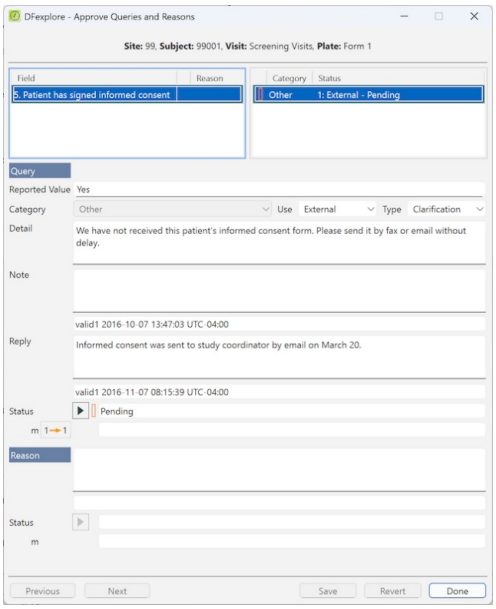
14.9.3. Select Show > Pending Queries to display only queries for which a resolution is pending. Double-click **Site 99 - Hospital #99** entry to display all pending queries.



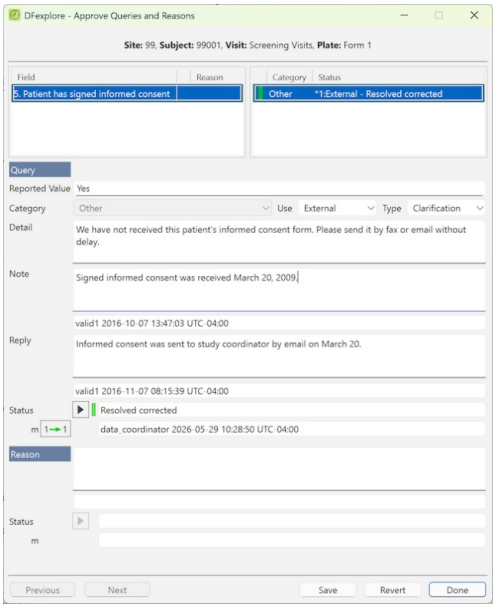
14.9.4. Locate the pending query for Subject **99001, 5. Patient has signed informed consent**. Double-click the query to make the queried field and page the current page. Examine the information in the **Query** window.



14.9.5. Select Field > Approve Queries and Reasons to review all queries and reasons that are present on the current page.



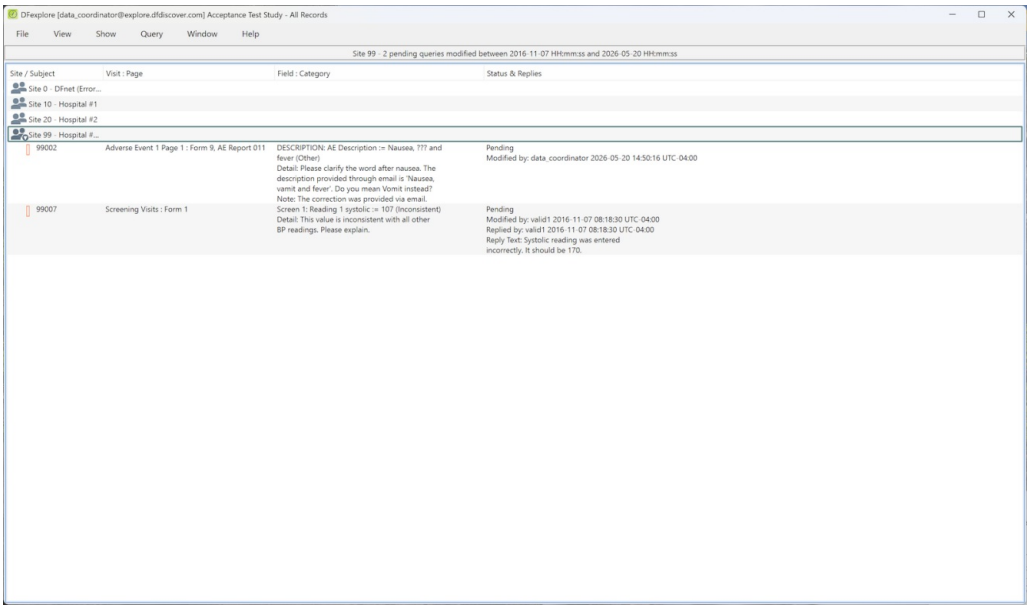
14.9.6. Choose **Resolved corrected** from the **Status** pull-down. Enter Signed informed consent was received March 20, 2009. in the **Note** field.



14.9.7. Click Save to apply the **Resolved corrected** status to the query. Click Done to close the **Approve Queries and Reasons** dialog.

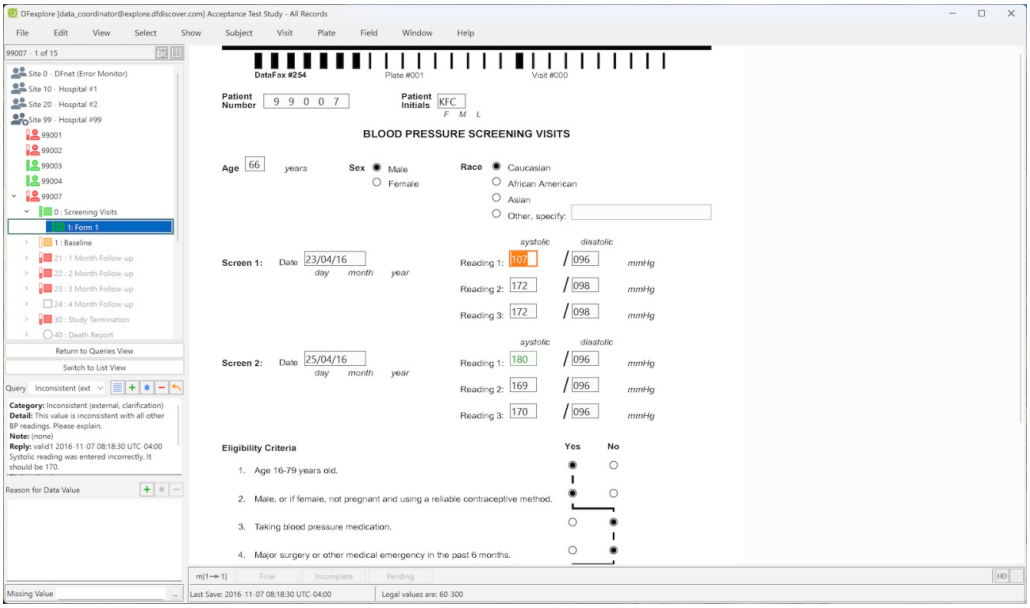
14.9.8. Do not change any other data or metadata on the **0 : Screening Visits** page for Subject **99001**. Make the save buttons at the bottom of the screen active and click Final to save the data record and query to the database.

14.9.9. In the record list window, click **Return to Queries View** to return to Queries View to process the pending query for Subject **99007**.

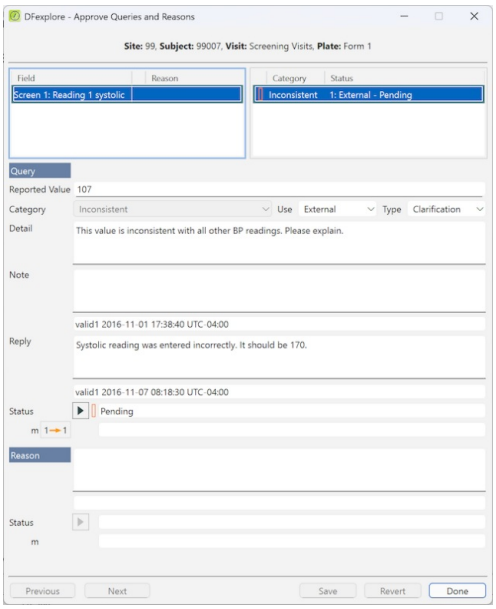


14.10 Review, correct and approve a pending query reply for Form 1, Subject 99007

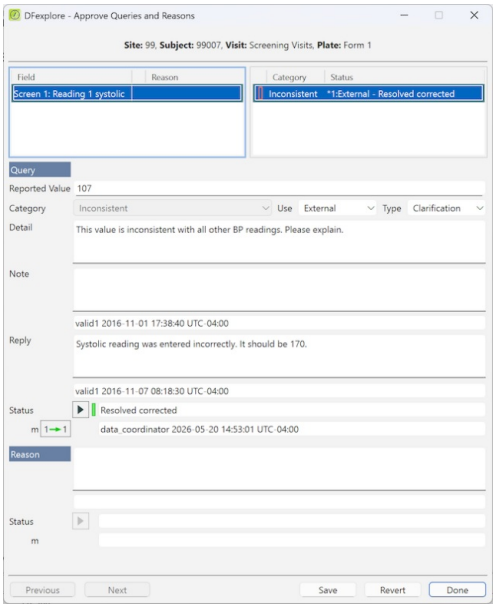
14.10.1. Locate the pending query for Subject **99007, Screen 1: Reading 1 systolic**. Double-click the query to make the queried field and page current. Examine the information in the Query window.



14.10.2. Select Field > Approve Queries and Reasons to review all queries and reasons that are present on the current page.



14.10.3. Choose **Resolved corrected** from the **Status** pull-down.

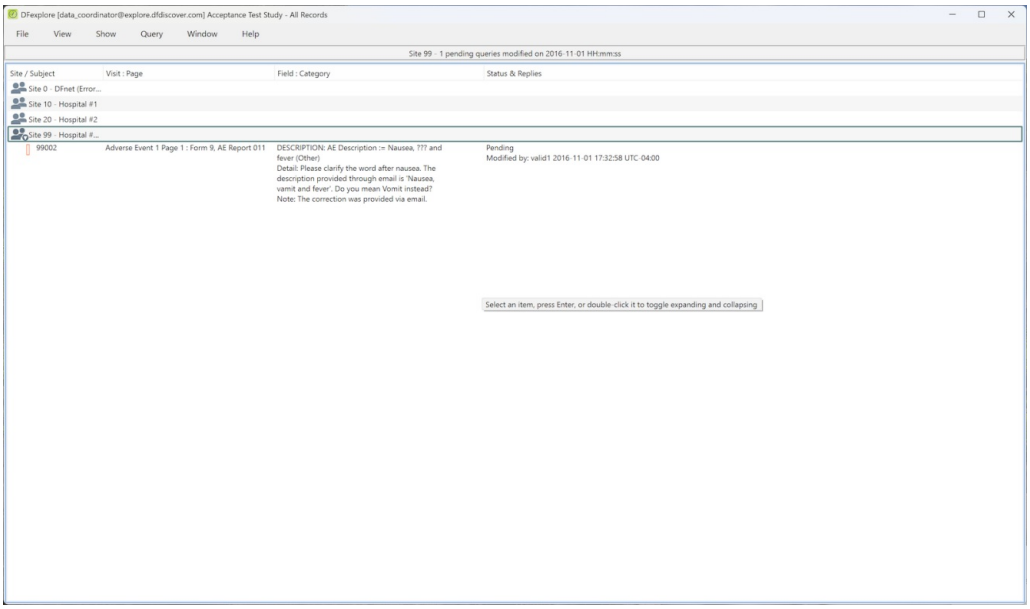


14.10.4. Click Save to apply the **Resolved corrected** status to the query. Click Done to close the **Approve Queries and Reasons** dialog.

14.10.5. 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.

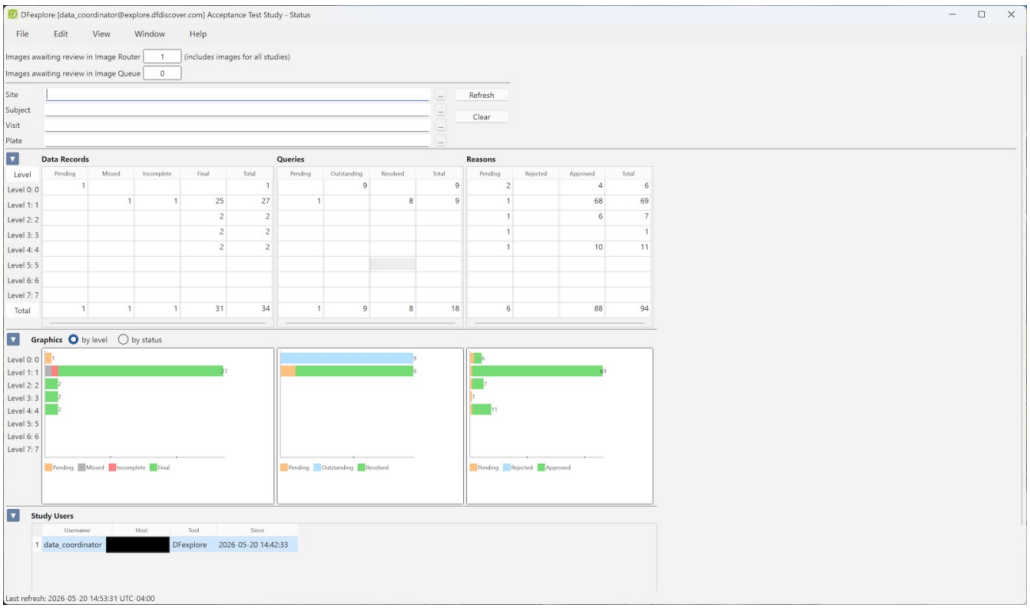
14.10.6. Click Final to save the data record and query to the database.

14.10.7. In the record list window, click Return to Queries View to return to Queries View.



14.11 Confirm query resolution by examining the database status

14.11.1. Select View > Status. Examine the information displayed for the Image Queue, Data Records and Queries tables.



14.11.2. 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.

15 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.

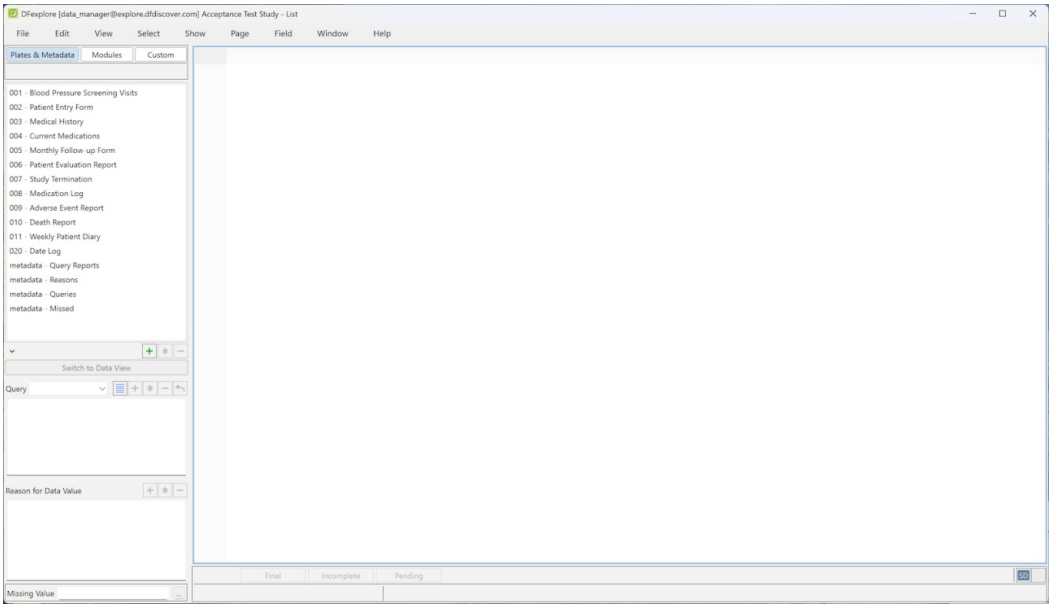
> NOTE: Refer to "Creating user accounts and assigning study permissions." as a valid email address is required for data_manager to receive the module specific PDF files. Wait 2-3 minutes prior to proceeding to **DFexplore**.

15.1 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**.

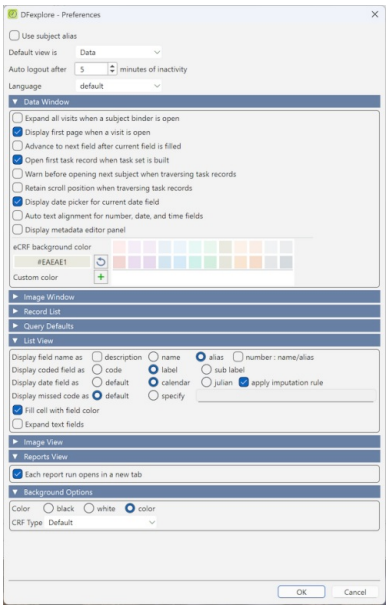
15.1.1. Start **DFexplore**, login as user data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

15.1.2. Select View > List.



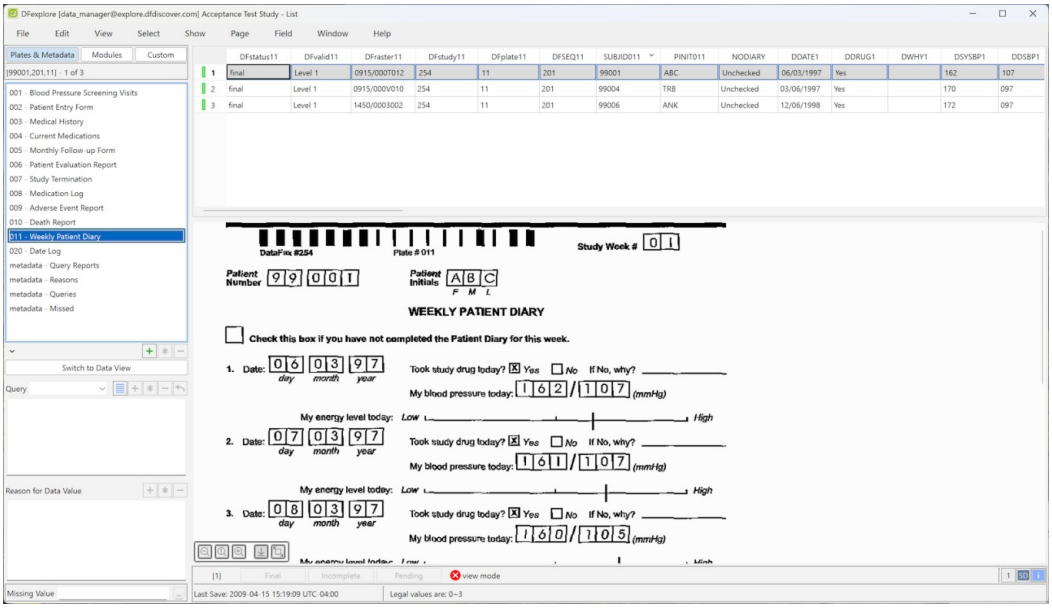
15.1.3. Select File > Preferences. In the dialog, locate the **List View** panel. Click [▼] and enter the **List View** settings as follows:

- **Display field name as** = alias
- **Display coded field as** = label
- **Display date field as** = calendar
- Check (enable) **apply imputation rule**
- **Display missed code as** = default
- Check (enable) **Fill cell with field color**
- Uncheck (disable) **Expand text fields**



15.1.4. Click OK to close the dialog.

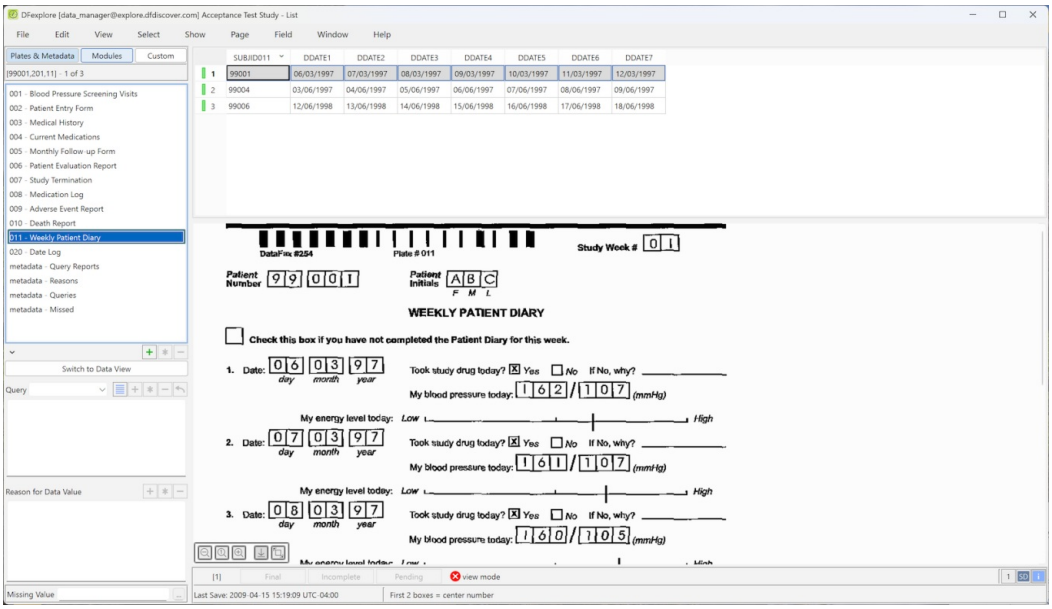
15.1.5. In the main **List View** window, **Plates & Metadata** panel, click **011 - Weekly Patient Diary**.



15.1.6. 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.

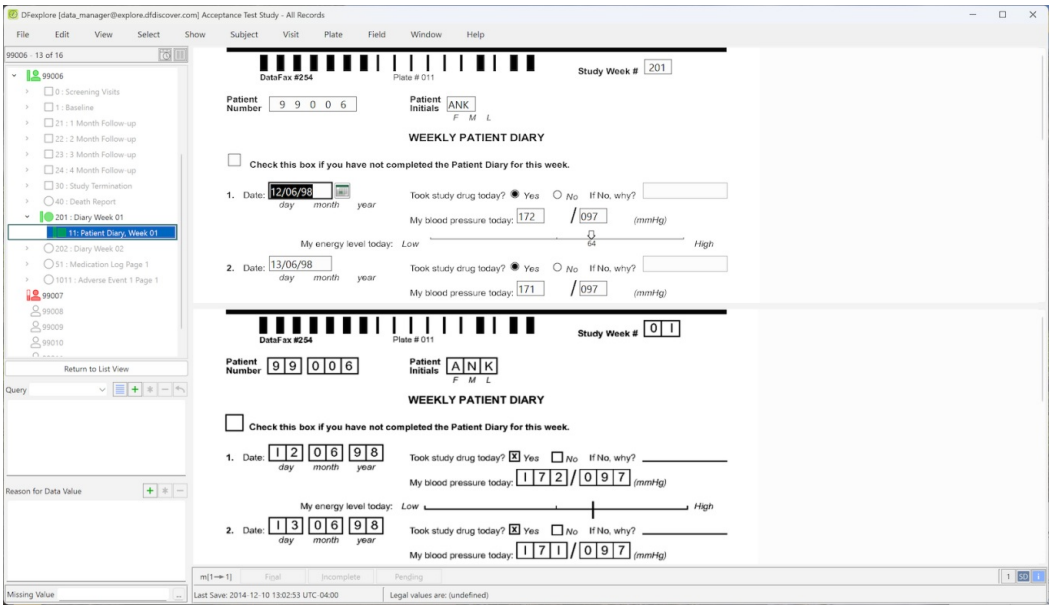
NOTE: Alternatively fields can also be added by dragging-and-dropping the desired fields from the **Data Fields** or **Metadata Fields** windows to the **Display Fields** window.

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



15.1.2. 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.

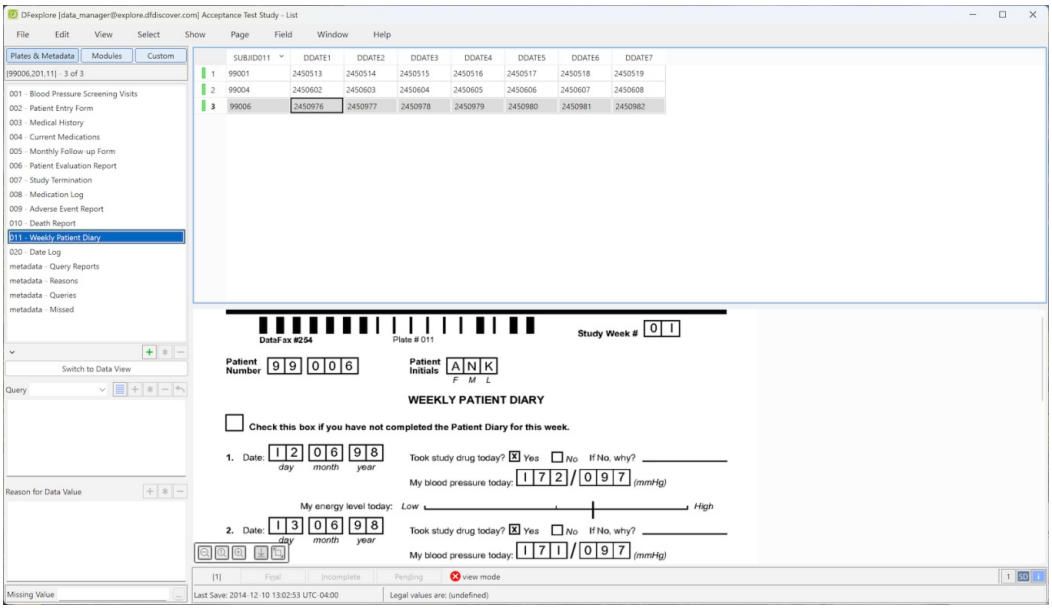
15.1.3. Double-click **DDATE1** cell for ID 99006 in the table. This takes you to the corresponding date field in the **WEEKLY PATIENT DIARY** page in **Data View**. Confirm that the date values are the same as those on the printed **WEEKLY PATIENT DIARY** for Subject 99006.



15.1.4. 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.

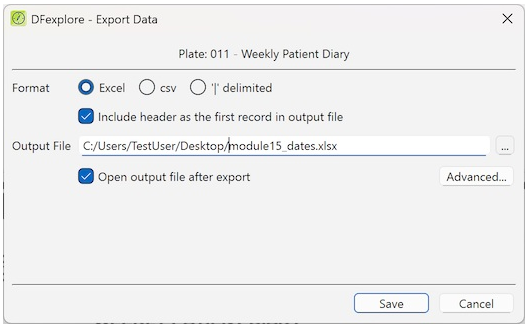
15.2 Export date values from the database and save the exported data to a file on the local computer

15.2.1. 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.

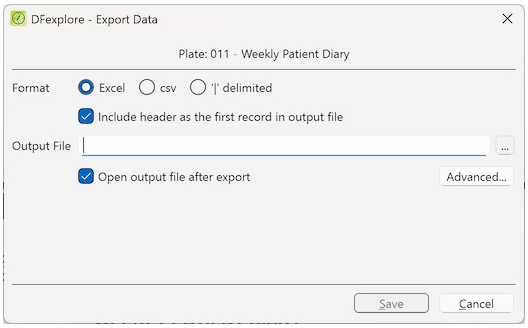


15.2.2. Select File > Export Data to save the dates to a local file. In the dialog, set:

- **Format** = Excel
- Check (enable) **Include header as the first record in output file**
- Check (enable) **Open output file after export**



15.2.3. 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.



15.2.4. 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

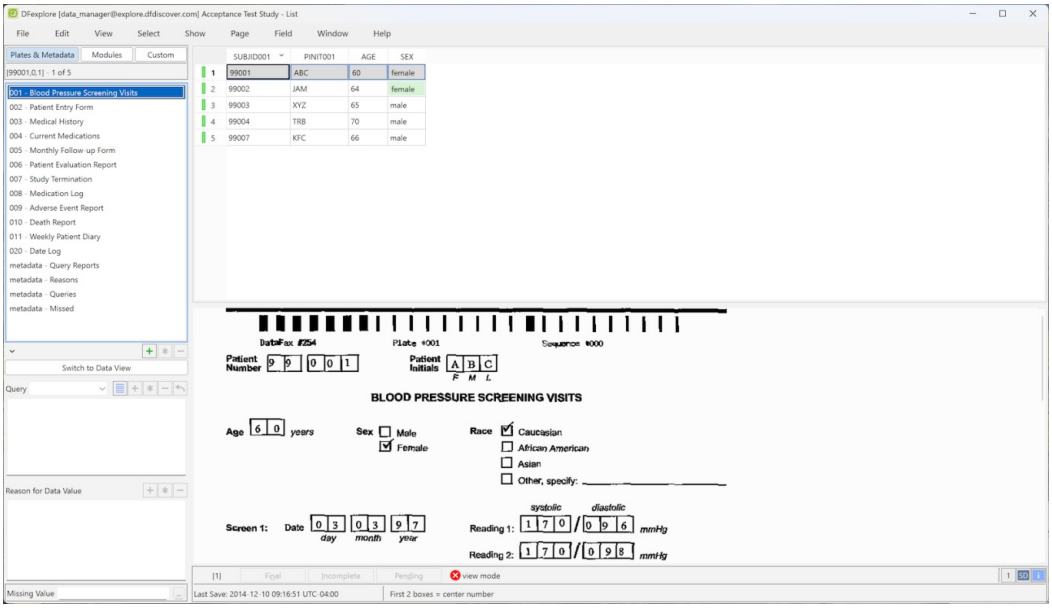
15.3 Examining data values according to user-specified criteria

15.3.1. From the list of plates, select plate **001 - Blood Pressure Screening Visits** to make it current.

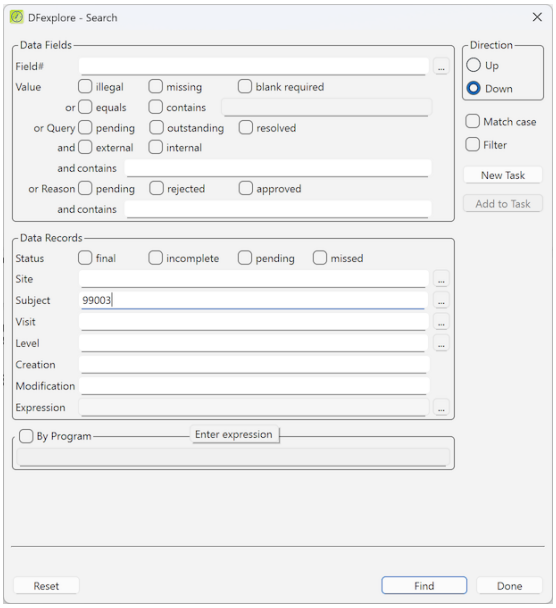
15.3.2. Select Select > Field Selection. In the **Data Fields** window, click [+] next to fields **7:SUBJID001**,**8:PINIT001**,**9:AGE**,**10:SEX**. The fields are added to the **Display Fields** window.

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.

15.3.1. Click Done to apply the field selection criteria and close the dialog. Examine each of the data fields.



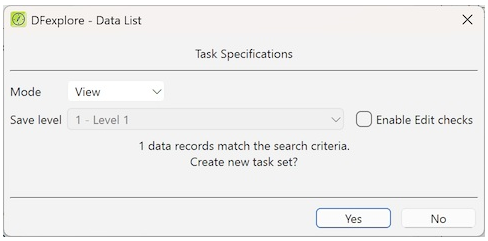
15.3.2. To search for specific subject data, Select Select > Search. Enter 99003 in the **Subject** field.



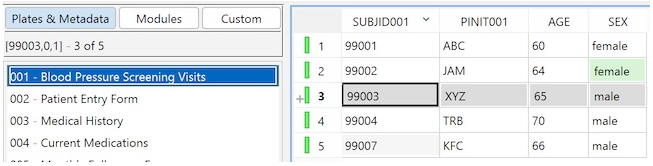
15.3.3. Click Find to start the search. Examine the message in the bottom-left corner of the dialog as well as the highlighted entry in the **List View** table.

15.3.4. Click Find Next to locate a 2nd match (if one exists) in the **List View** table.

15.3.5. Click New Task to create a task set of records that match the search criteria. In the resulting dialog, change the **Mode** to **View**.



15.3.6. 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.



15.3.7. 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

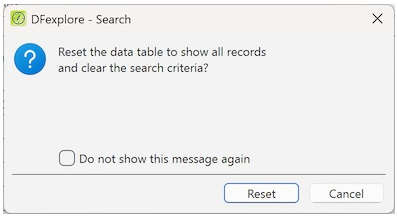
99003 is displayed. Click Return to List View.

15.4 Query the database for specific data values

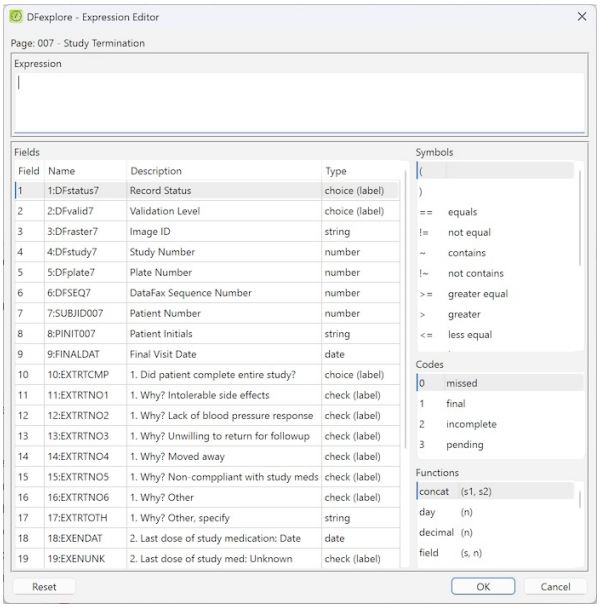
15.4.1. Select File > Preferences. In the dialog, locate the **List View** panel. Choose **default** for **Display date field as**. Click OK to save the setting and close the dialog.

15.4.2. Click **007 - Study Termination** to make it the current page. Select Select > Search to open the **Search** dialog.

15.4.3. Click Reset and Reset in the resulting dialogs to clear all previously specified search criteria.



15.4.4. Click ... next to the **Expression** field. The **Expression Editor** opens.



15.4.5. 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.



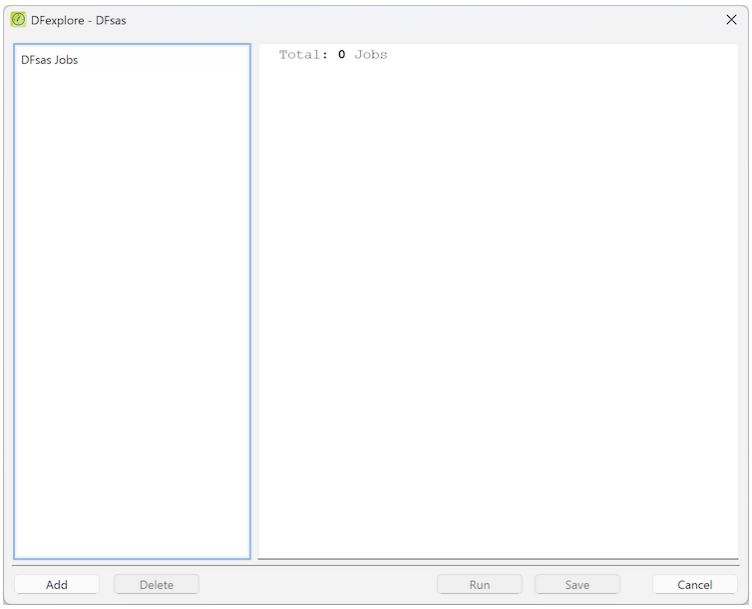
15.4.6. Click Find to locate all subjects that have study termination dates that match the specified search expression.

15.4.7. Click Find Next to locate the next match.

15.4.8. Do not continue the search and click Done to close the **Search** dialog.

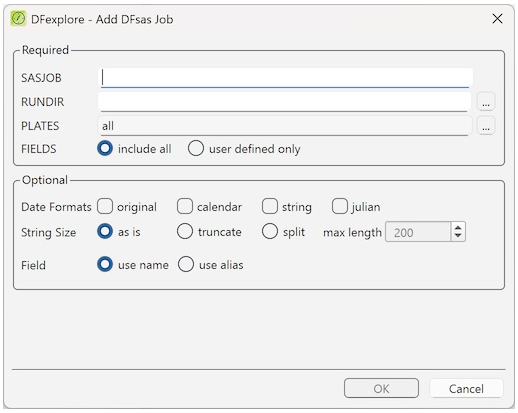
15.5 Create a DFsas job file according to user-specified criteria

15.5.1. Select File > DFsas. The **DFsas** dialog opens.

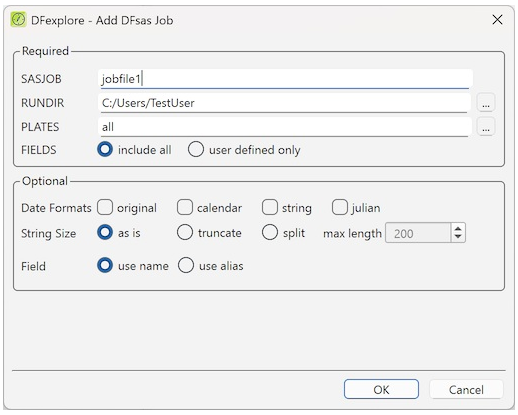


NOTE: If you have previously executed this module as data_manager, the **DFsas Jobs** panel may display **jobfile1** and possibly other files. If **jobfile1** is already in the list, highlight **jobfile1** and click Delete before continuing with this module.

15.5.1. Click Add to create a new **DFsas** job.

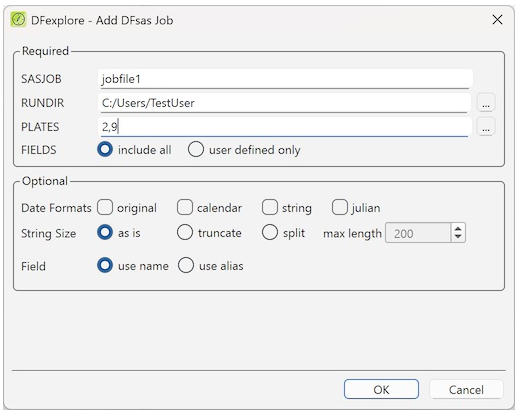


15.5.2. Enter **SASJOB** = jobfile1. Click **RUNDIR** ... to display the file selection dialog. Choose a directory to save "jobfile1" and click Open.



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**.

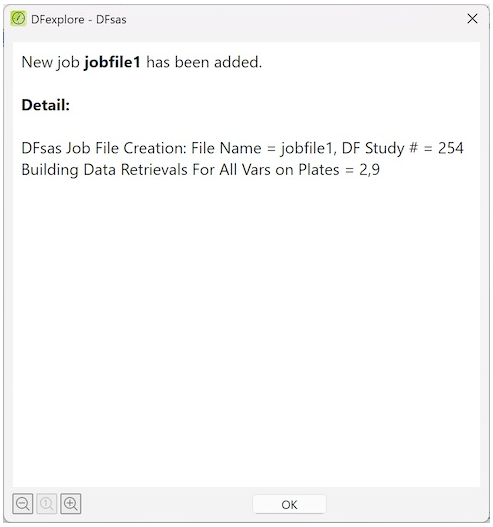
15.5.1. Click **PLATES** ... to view all defined study plates. From the list, hold Control key (Command on macOS) and click the entries for **002 - Patient Entry Form** and **009 - Adverse Event Report** to highlight them. Click OK. Choose **FIELDS** = include all.



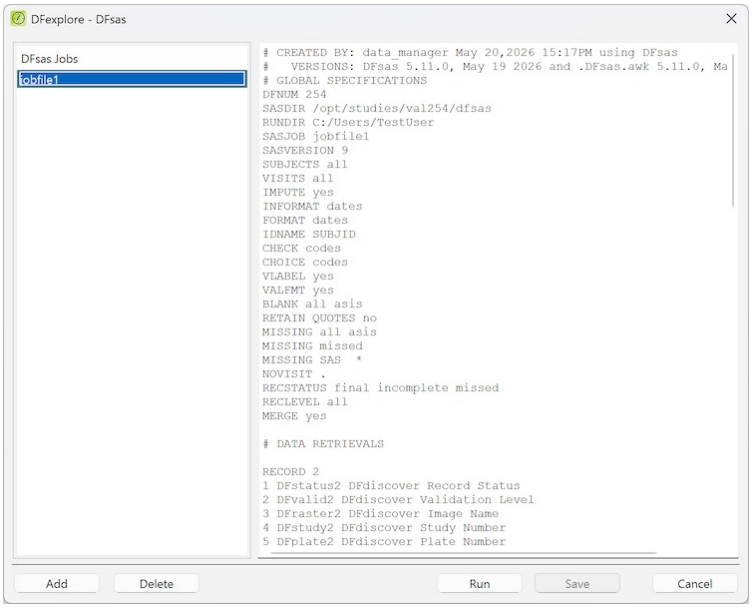
15.5.2. In the **Optional** panel set:

- Check (enable) only **calendar** for **Date Formats**
- **String Size** = as is
- **Field** = use alias

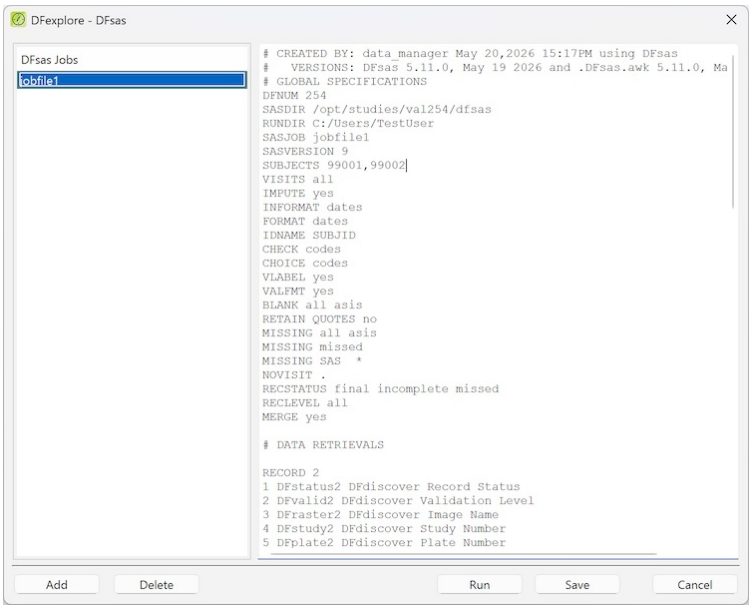
Click OK to create and add jobfile1.



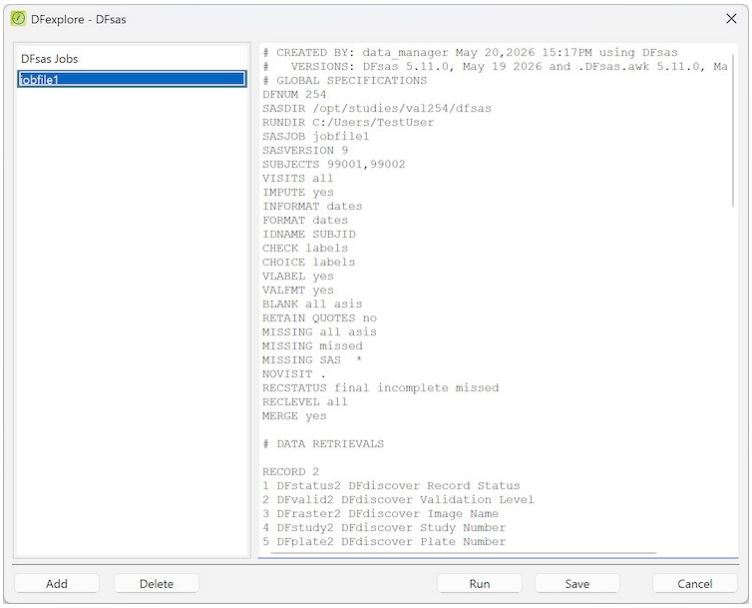
15.5.3. Click OK in the summary confirmation dialog.



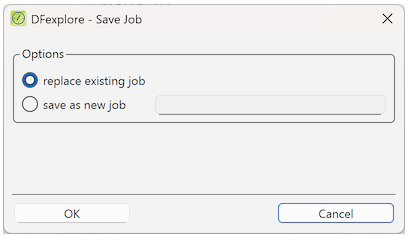
15.5.4. Edit the **SUBJECTS** global specification in the new jobfile1 by selecting it from **DFsas Jobs** panel. In the main window, change the text SUBJECTS all to SUBJECTS 99001,99002. This will limit the created SAS data files to subjects 99001 and 99002 only.



15.5.5. Locate the global specifications for **CHECK** and **CHOICE**. Change CHECK codes to CHECK labels and CHOICE codes to CHOICE labels.

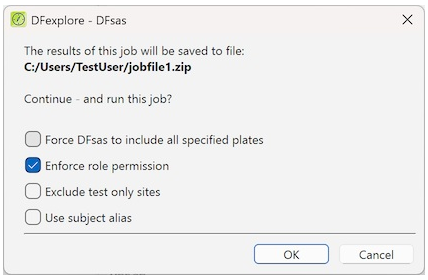


15.5.6. Click Save to save the changes. In the resulting confirmation dialog, choose **replace existing job** and click OK.

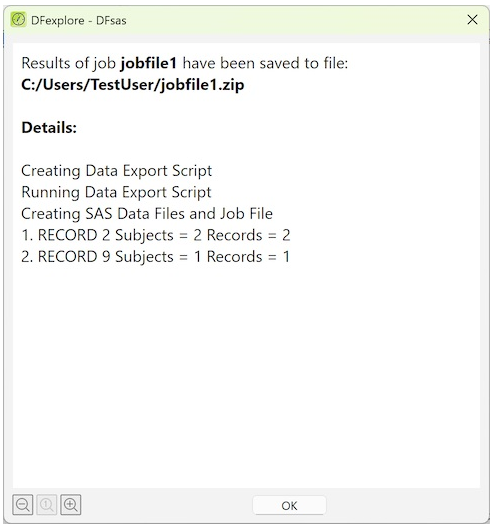


15.6 Create a SAS job file and data files using the DFsas job file criteria

15.6.1. In the **DFsas** window, highlight jobfile1. Click Run to create SAS job and data files.



15.6.2. 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.



15.6.3. 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.

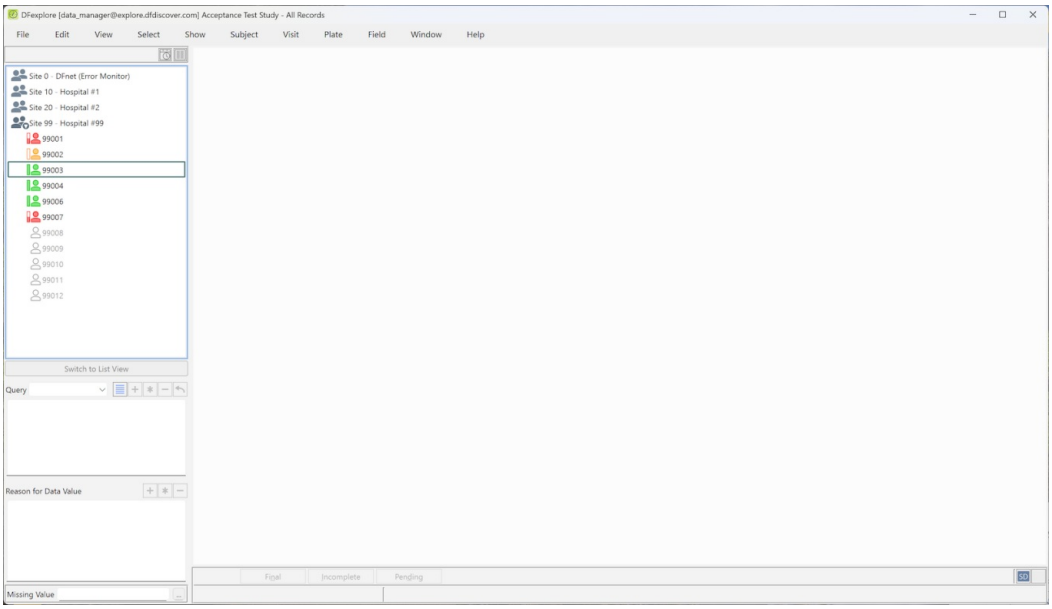
15.6.4. With a text editor, open the data file jobfile1.d01. Examine the contents and confirm that it contains 2 data records - one for each of subjects 99001 and 99002. Print the file (you will need to reference this printed output in "Compare the contents of SAS data files with the actual data in the database." and then close the text editor application.

15.6.5. 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.

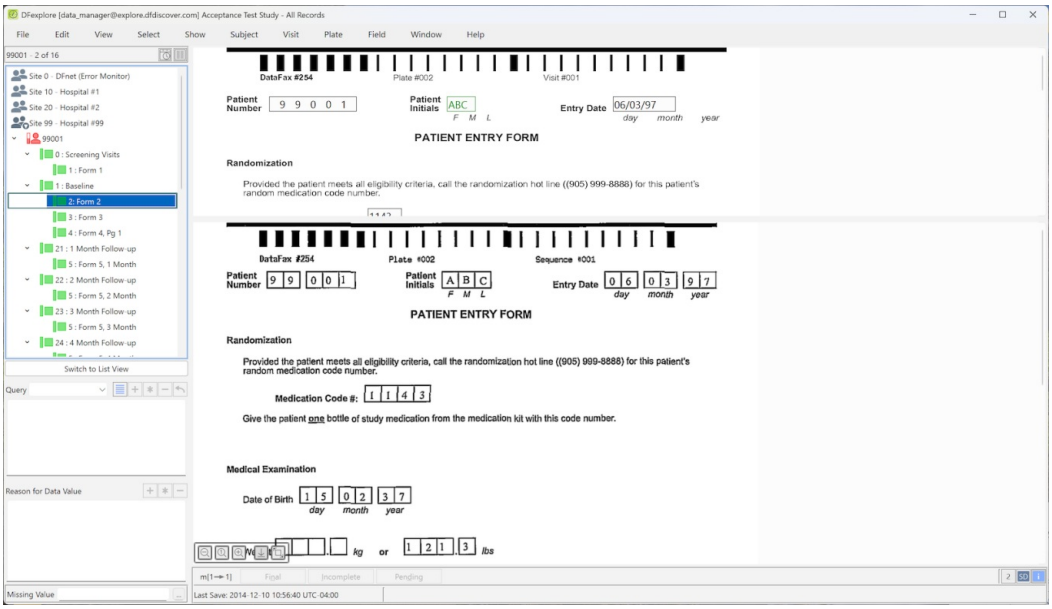
15.7 Compare the contents of SAS data files with the actual data in the database

15.7.1. Click Cancel to dismiss the **DFsas** dialog. Select Select > All Records. Without changing any settings, click OK.

15.7.2. 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**.

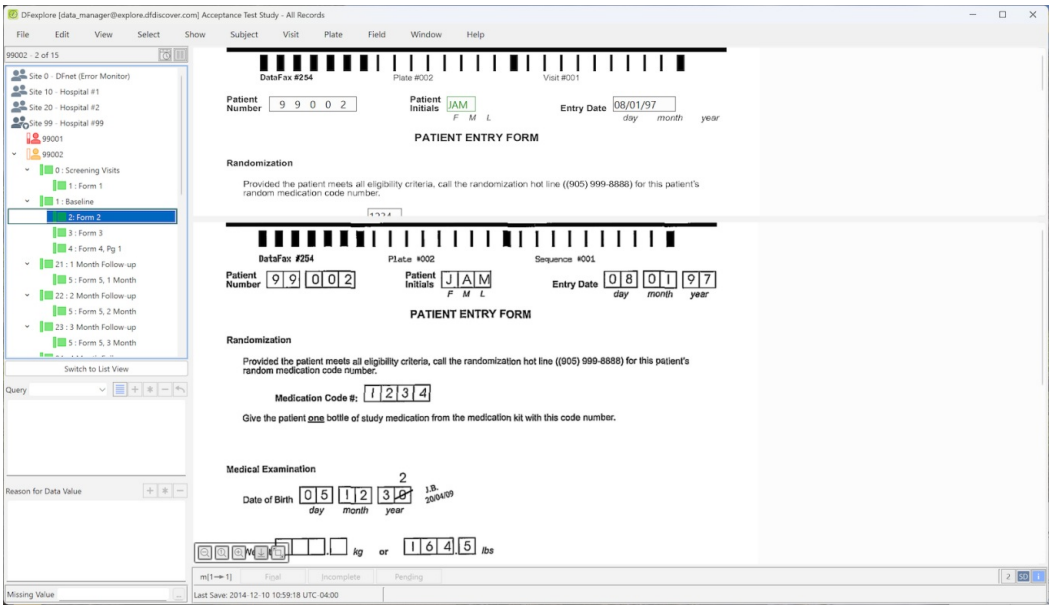


15.7.3. Double-click Subject **99001**. Select Subject > Expand All Visits. Locate the entry for **2: Form 2** within the **1 : Baseline** visit and select it from the list to open the data record.



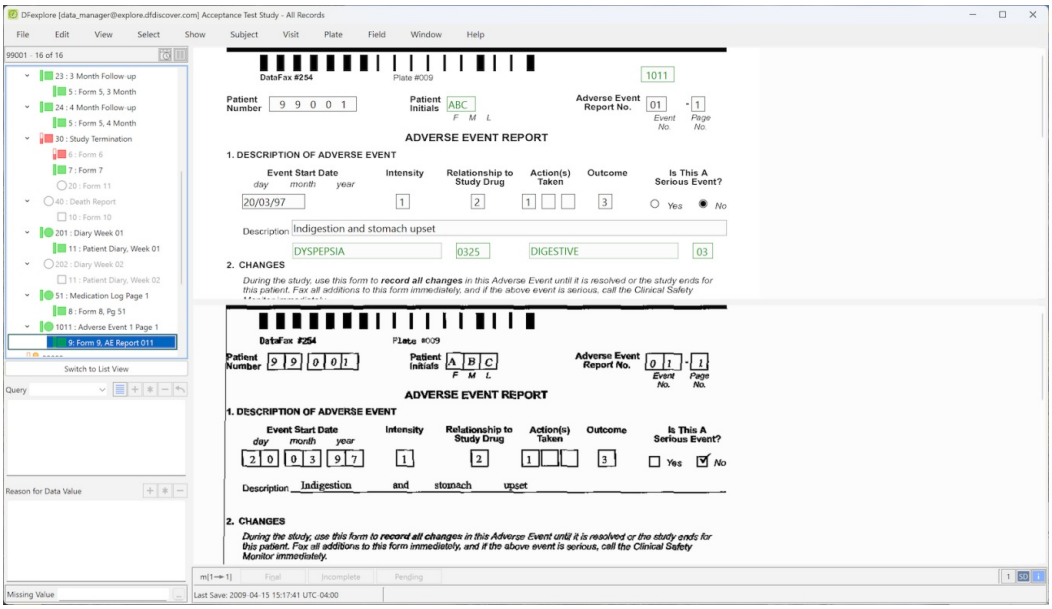
15.7.4. Compare the values in each field of the data record with those values in the printout of the data file jobfile1.d01.

15.7.5. 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.



15.7.6. 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.

15.7.7. 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.



15.7.8. Compare the values in each field of the data record in **DFexplore** with those values in the printout of the data file jobfile1.d02.

15.7.9. 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.

16 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.

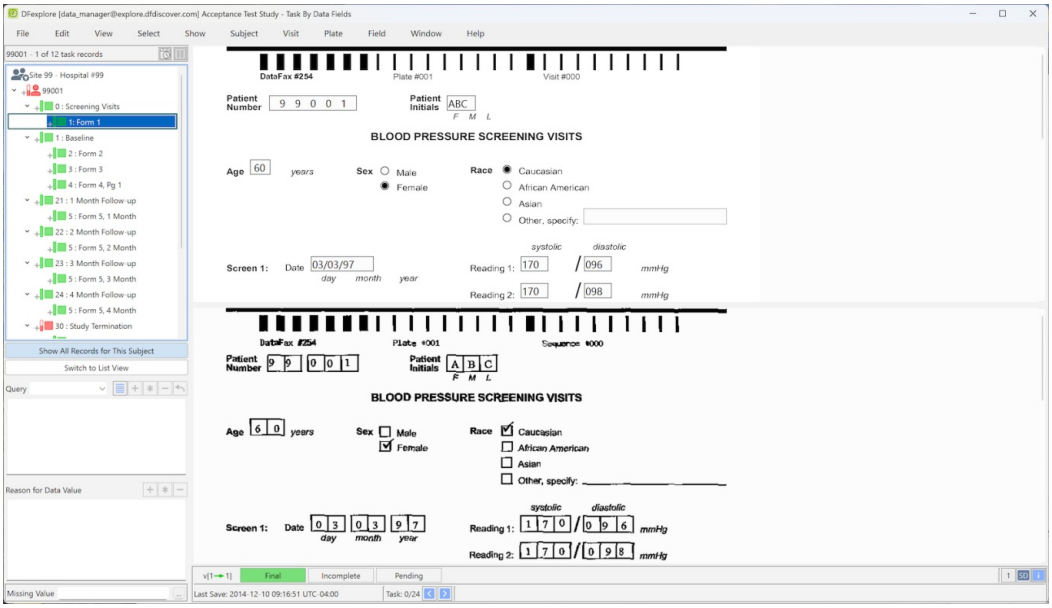
16.1 Retrieve existing data according to user-specified criteria

16.1.1. Start **DFexplore**, login as user data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

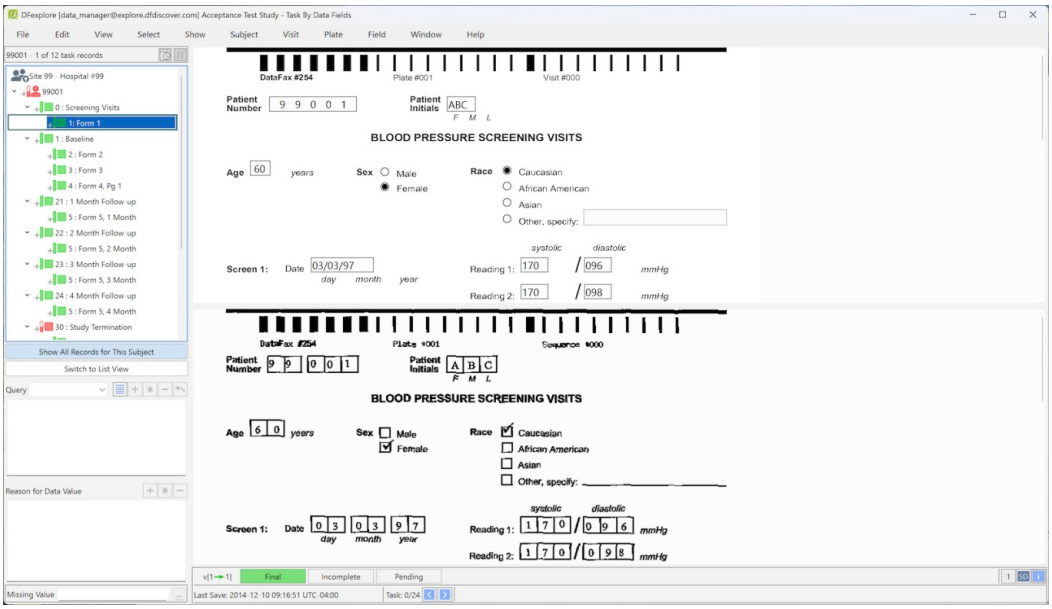
16.1.2. Select Select > By Data Fields. Set retrieval criteria as follows:

- **Mode** = Validate
- **Save level** = 1 - Level 1

- **Search** = Data
- **Subject** = 99001,99002
- **Level** = 1-4



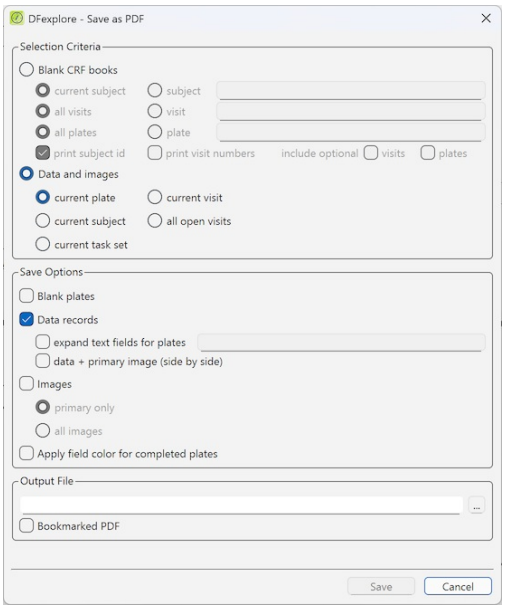
16.1.3. Click Build Set to retrieve all data records that match the specified criteria. Click OK in the confirmation dialog, and finally click Done to create a task set of the retrieved data.



16.1.4. 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.

16.2 Saving DFexplore data to a standard PDF document

16.2.1. Select File > Save as PDF.

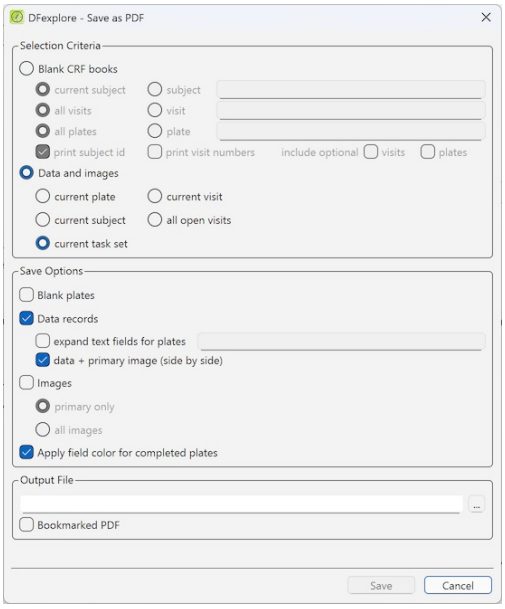


16.2.2. In the **Selection Criteria** panel,

- 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**



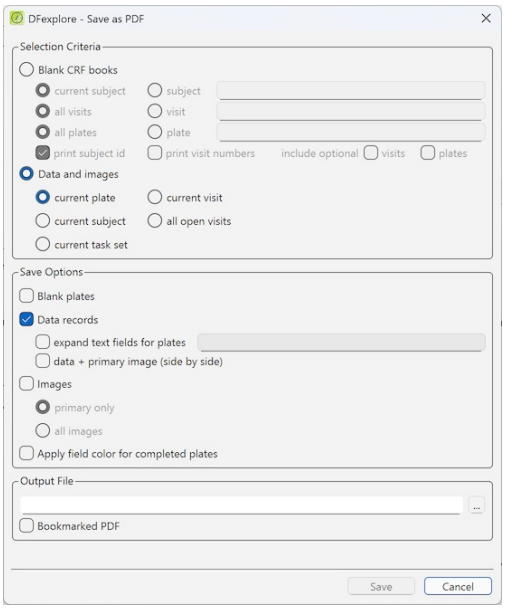
16.2.3. Click **Output File** ... . In the file selection dialog, choose a directory in which to save the PDF file. Once a directory has been chosen, append the file name subjects.pdf to the directory name. Click Save.

16.2.4. 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.

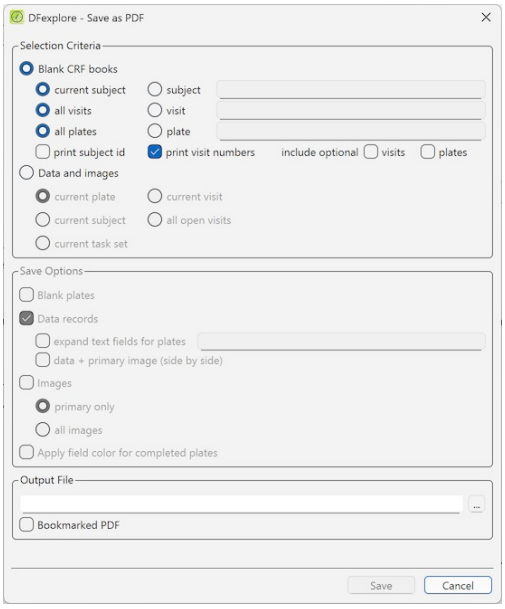
16.3 Saving DFexplore blank CRF books to a standard PDF document

16.3.1. Select File > Save as PDF.



16.3.2. In the **Selection Criteria** panel,

- Select (enable) **Blank CRF books**, followed by **all visits**, **all plates**.
- Un-check (disable) **print subject id**
- Check (enable) **print visit numbers**



16.3.3. 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 blanksubject.pdf to the directory name. Click Save.

16.3.4. 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.

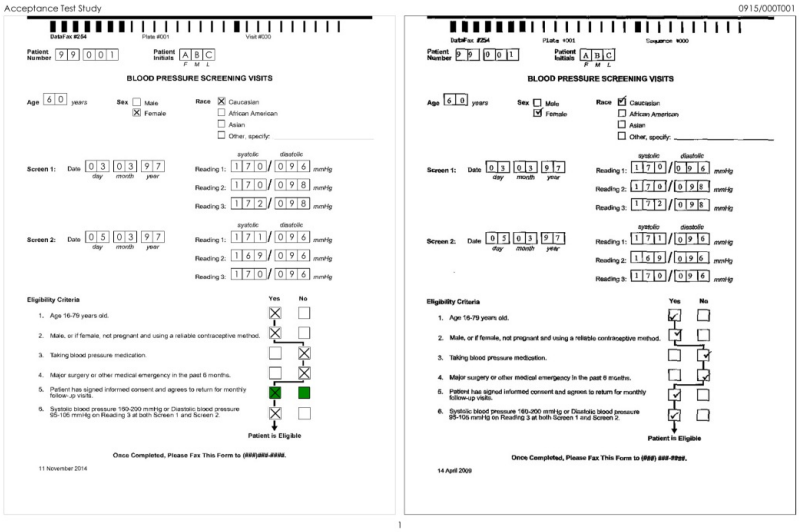
NOTE: The save directory in this test was chosen to be C:\Users\Public. Your save directory may be different.

16.4 Viewing a standard PDF data file using a PDF viewer application

16.4.1. 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.

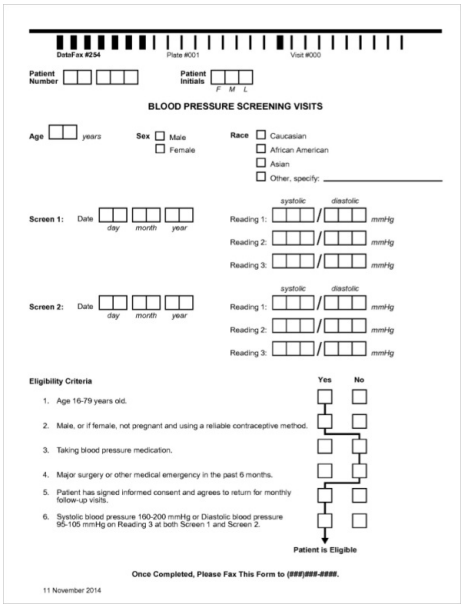
NOTE: All PDF files opened in this test and in the remainder of this module are illustrated using **Acrobat Reader**. If you are using a different PDF viewer application, the appearance of your document may differ from that shown here. It may also be necessary to rotate the PDF image so that it is displayed in landscape format.

16.4.1. Examine the PDF document.



16.4.2. 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.

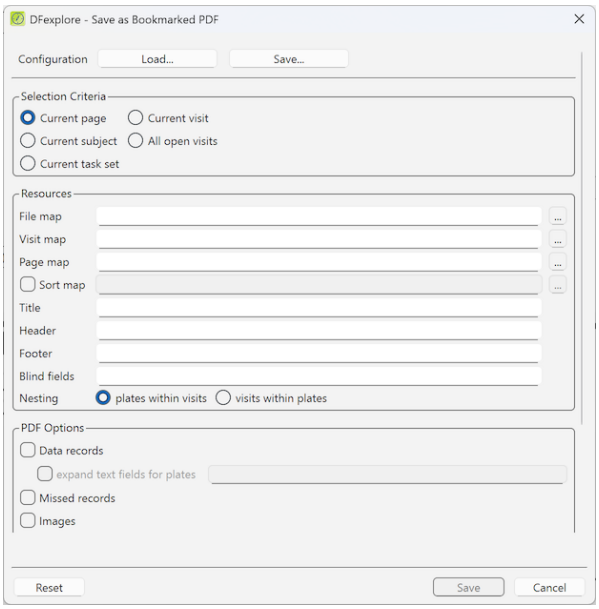
16.4.3. Examine the PDF document. Confirm the PDF document was printed without the presence of Subject ID numbers.



16.4.4. Exit the PDF viewer application.

16.5 Saving **DFexplore** data to an encrypted bookmarked PDF file

16.5.1. 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.



16.5.2. In the **Selection Criteria** panel,

- Select (enable) **Current subject**

In the **Resources** panel,

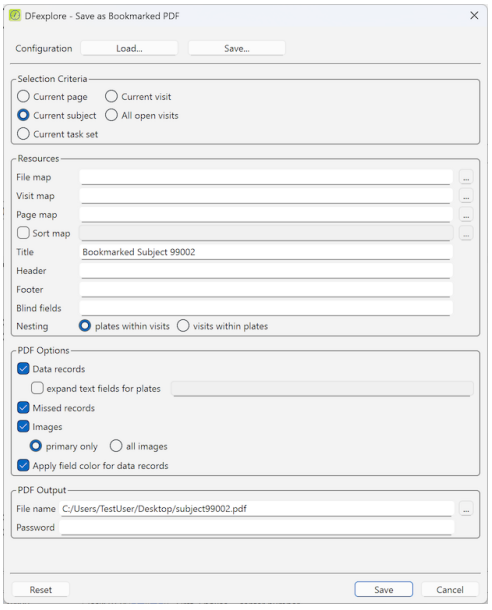
- Enter a **Title** of Bookmarked Subject 99002
- Use the default Nesting **plates within visits**

In the **PDF Options** panel,

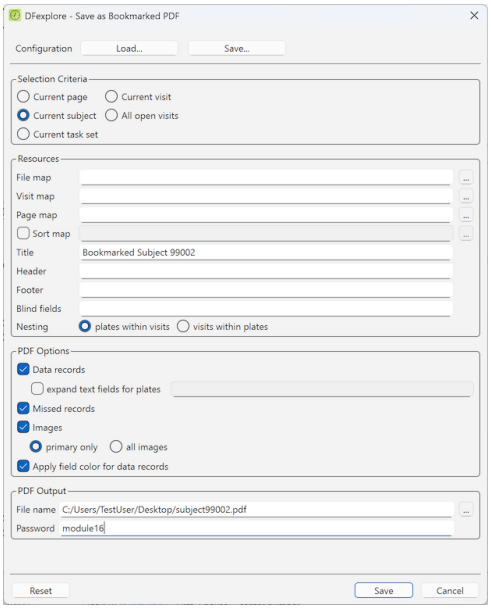
- Check (enable) **Data records**
- Check (enable) **Missed records**
- Check (enable) **Images** and select (enable) **primary only**
- Check (enable) **Apply field color for data records**

In the **PDF Output** panel,

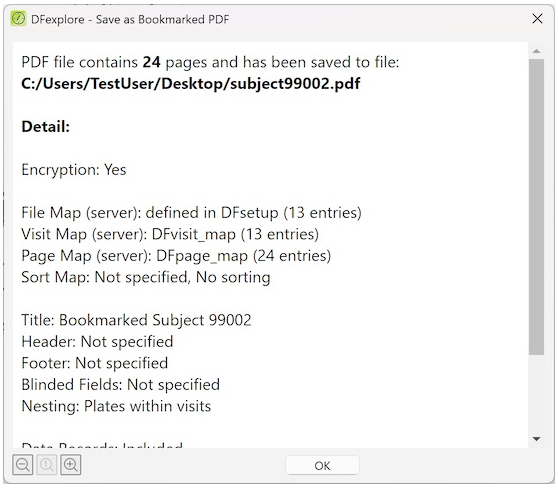
- Select an **Output File** directory using the file selection dialog and set the file name to subject99002.pdf.



16.5.3. Enter module16 as the value for **Password**.



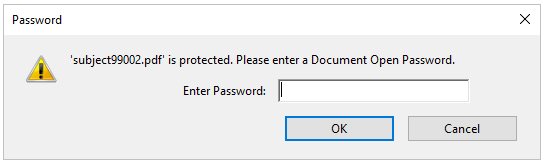
16.5.4. Click Save to create a password encrypted PDF file of completed data pages and primary images for Subject 99002.



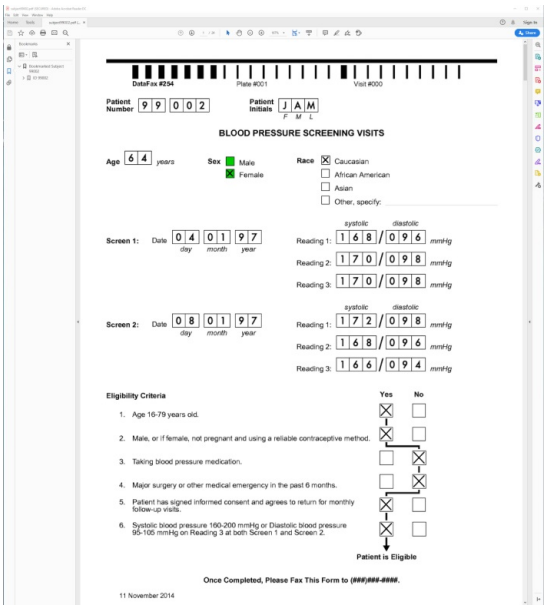
16.5.5. Click OK to close the dialog.

16.6 Open and view an encrypted bookmarked PDF file using a PDF viewer application

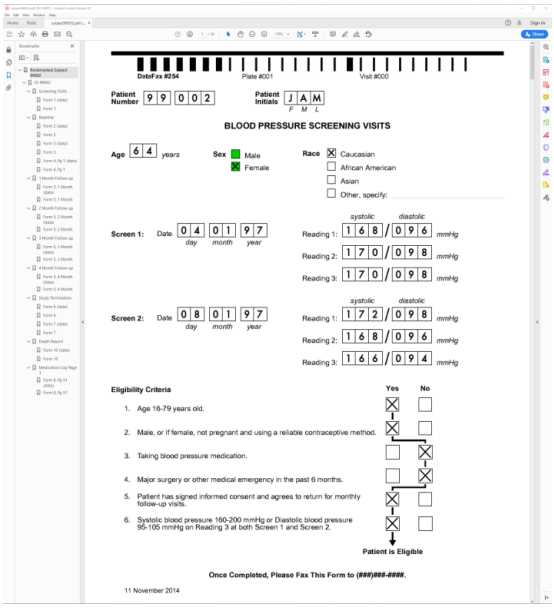
16.6.1. A PDF viewer application is required for this test. Start the PDF viewer application. Locate the directory created in "Saving DFexplore data to an encrypted bookmarked PDF file.". Locate and open subject99002.pdf.



16.6.2. In the **Password** dialog enter module16 as the password. This matches the password that was specified at file creation in "Saving DFexplore data to an encrypted bookmarked PDF file.". Once the password has been entered, the PDF file opens.



16.6.3. Open all bookmarks for Subject 99002.

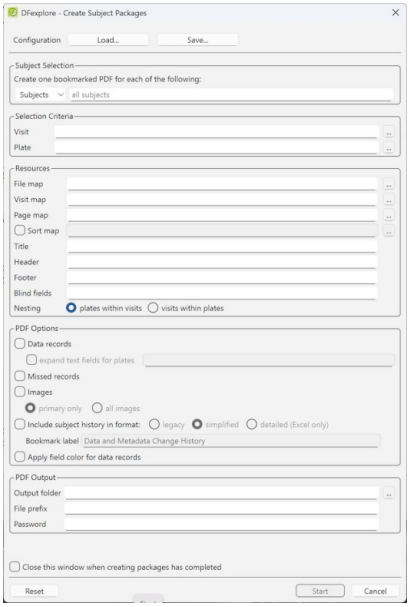


16.6.4. In the bookmark panel, each data record is represented by the suffix **(data)** to distinguish it from the primary CRF image. Click entry **Form 2 (data)** to make the Form 2 data record the active page. Click entry **Form 2** to make the Form 2 primary CRF image the active page.

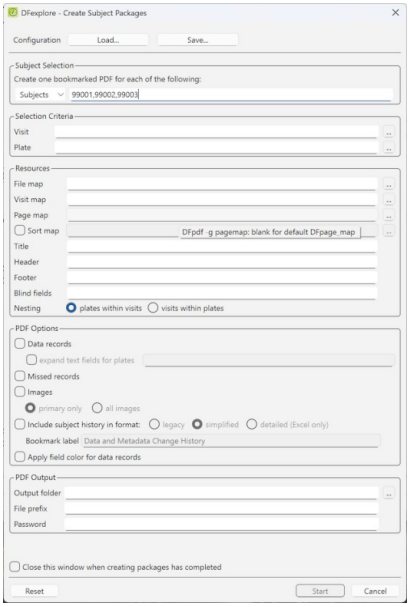
16.6.5. Exit the PDF viewer application. In **DFexplore**, select View > Data. Then, select Select > All Records. This will release the task set of records for Subjects 99001 and 99002. Click OK in the resulting dialog to retain the default settings.

16.7 Create a complete subject package PDF file that includes data records, CRF images and audit trail

16.7.1. Select File > Create Subject Packages.

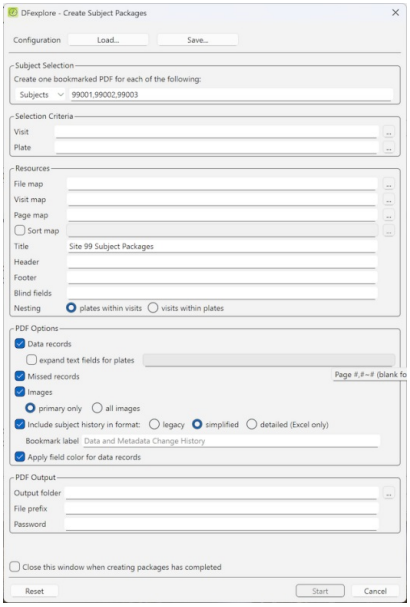


16.7.2. In the **Subject Selection** section, choose **Subjects** from the drop-down and enter 99001,99002,99003 to create complete subject packages for Subjects 99001, 99002 and 99003.



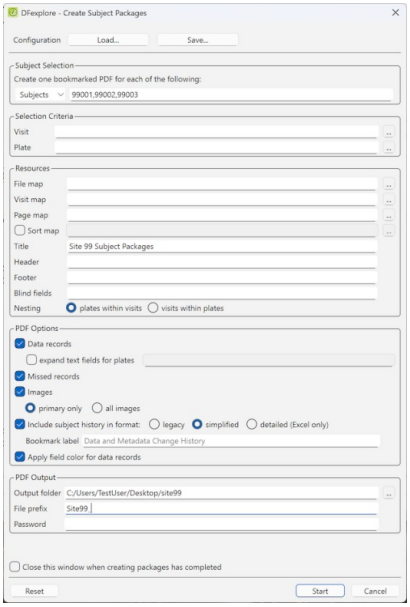
16.7.3. In the remainder of the dialog specify the following settings:

- **Title** = Site 99 Subject Packages
- Check (enable) **Data records**
- Check (enable) **Missed records**
- Check (enable) **Images**
- Check (enable) **primary only**
- Check (enable) **Include subject history in format** and **simplified**
- Check (enable) **Apply field color for data records**

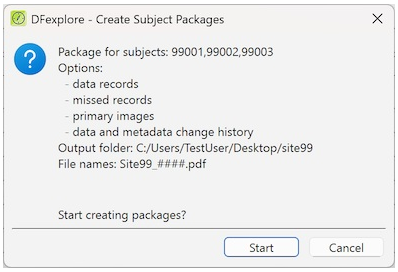


16.7.4. Specify a PDF output folder by first clicking **Output folder** [...] to view the directory structure for the local computer. Select a directory in which to save the subject package PDF files.

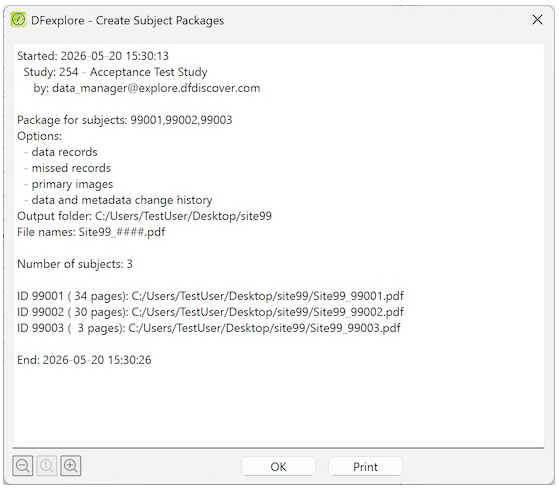
16.7.5. Specify a file prefix to be prepended to each subject package created. Enter Site99_ in the **File prefix** field.



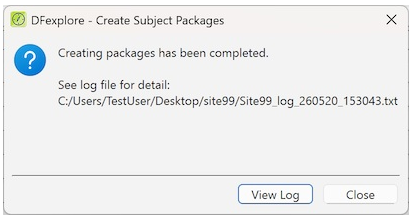
16.7.6. Do not encrypt the subject packages to be generated by leaving the **Password** field empty. Click [Start] to begin generating a complete subject package for each of the specified subjects 99001, 99002 and 99003.



16.7.7. Verify that the output in the confirmation dialog specifies packages for subjects 99001, 99002 and 99003. Click [Start] to start package creation.



16.7.8. In the confirmation dialog, click View Log. Review the output. Click OK to close the log.



16.7.9. The main **Create Subject Packages** dialog is displayed. Click Cancel to close this dialog.

16.8 Open and view a PDF subject package using a PDF viewer application

16.8.1. 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.

16.8.2. Open the subject package for Site99_99001.pdf.

16.8.3. Open all bookmarks for Subject 99001.

16.8.4. 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.

16.8.5. In the bookmark list click the entry for **Data and Metadata Change History** to display the complete audit trail report for Subject 99001.

16.8.6. Exit the PDF viewer application to close both the file Site99_99001.pdf and PDF viewer.

16.8.7. 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.

17 Module 17. DFweb Data Entry

Overview

Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- DFws 5.11.3 installed and properly configured on DFws server
- DFweb 5.11.3 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

Client Tools Used: DFATK, DFexplore, DFweb

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. Resetting a user login password.
2. Verify **DFweb** version information, logging into **DFweb** and **DFweb** site certificate verification.
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.

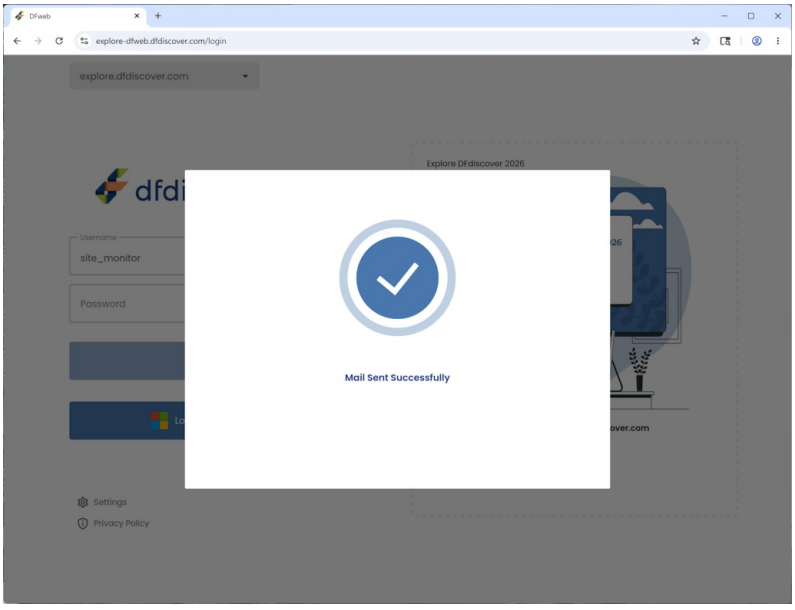
NOTE: Save the labreport99008_module17.pdf file received via email to your local computer. This file is required to complete Adding, reviewing and downloading subject documents.. Refer to Creating user accounts and assigning study permissions. as a valid email address is required for data_coordinator, data_manager, site_monitor or site_invest to receive the module specific PDF files.

17.1 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.

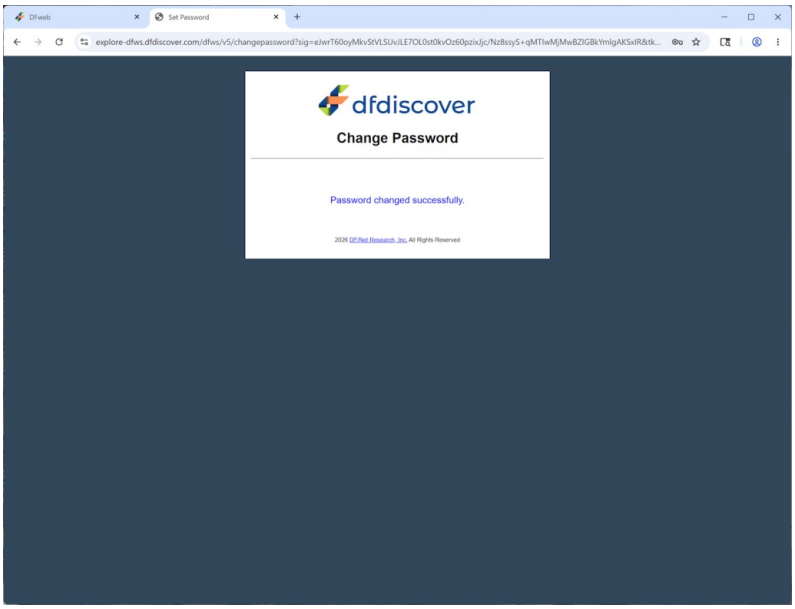
17.1.1. Open a web browser and navigate to https://dfweb.dfdiscover.com/login or the **DFweb** URL provided by your administrator, In the **DFweb** login dialog, enter the **DFdiscover Server** name that has been provided by your administrator. Click Continue. enter site_monitor in the Username field of the login dialog, and click Forgot Password?.

17.1.2. 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.**



17.1.3. Open the password reset email from your **DFdiscover** server and click the provided link to reset the site_monitor password.

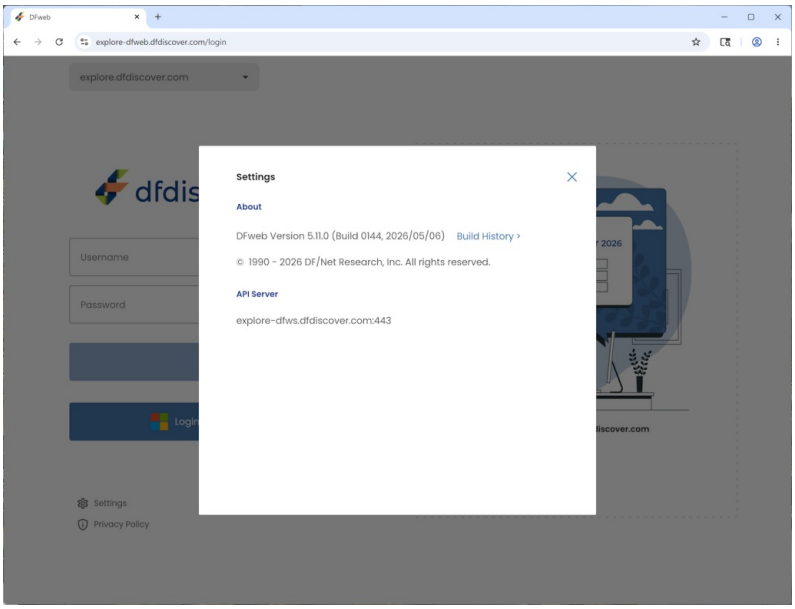
17.1.4. Enter and confirm a new password, then click Update.



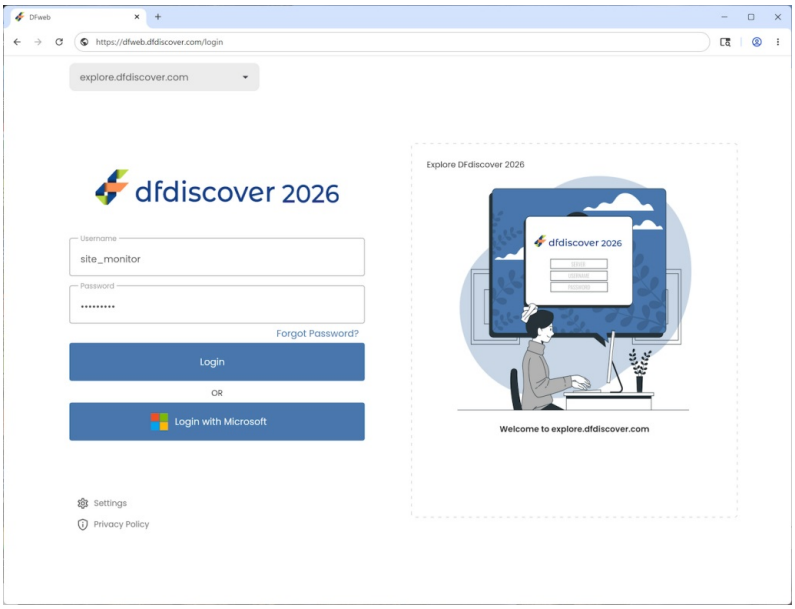
17.1.5. A message confirming **Password changed successfully.** is displayed in your browser, and a notification email is sent to the address associated with the site_monitor account.

17.2 Verify **DFweb** version information, logging into **DFweb** and **DFweb** site certificate verification

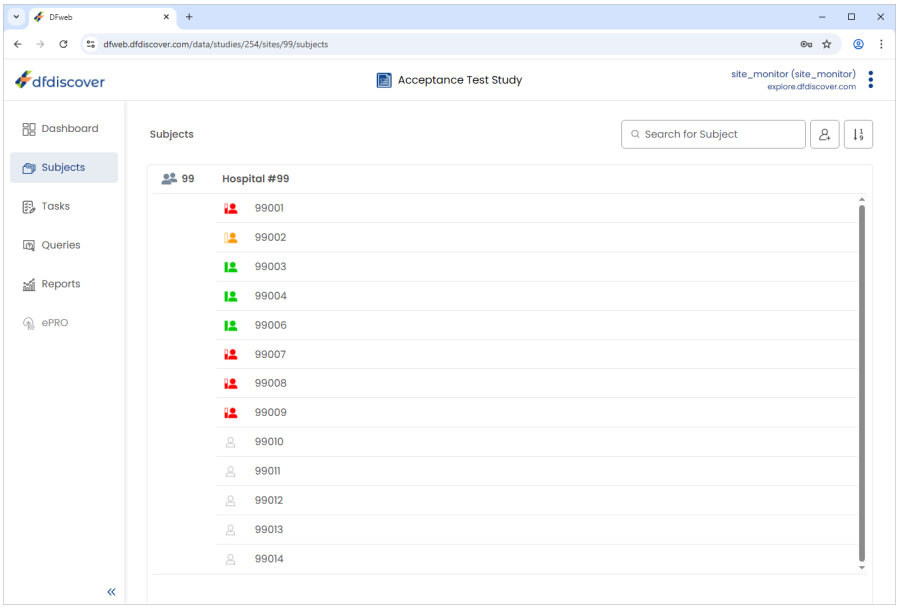
17.2.1. Open a web browser and navigate to https://dfweb.dfdiscover.com/login or the **DFweb** URL provided by your administrator, Click ⚙ Settings, verify the version information: **DFweb Version 5.11.3** is displayed.



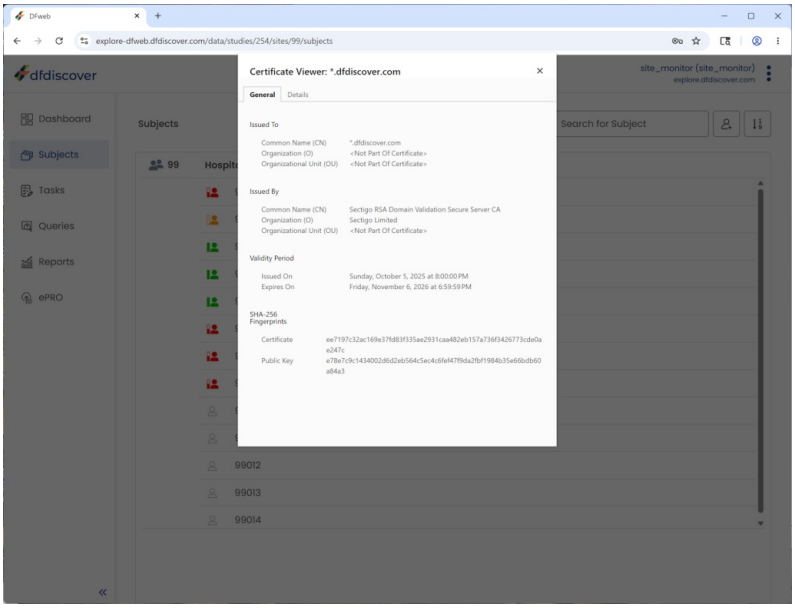
17.2.2. Enter site_monitor in the **Username** field and the previously assigned password in the **Password** field. Click Login to login.



17.2.3. A list of subjects for **Hospital #99** is displayed.



17.2.4. 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.



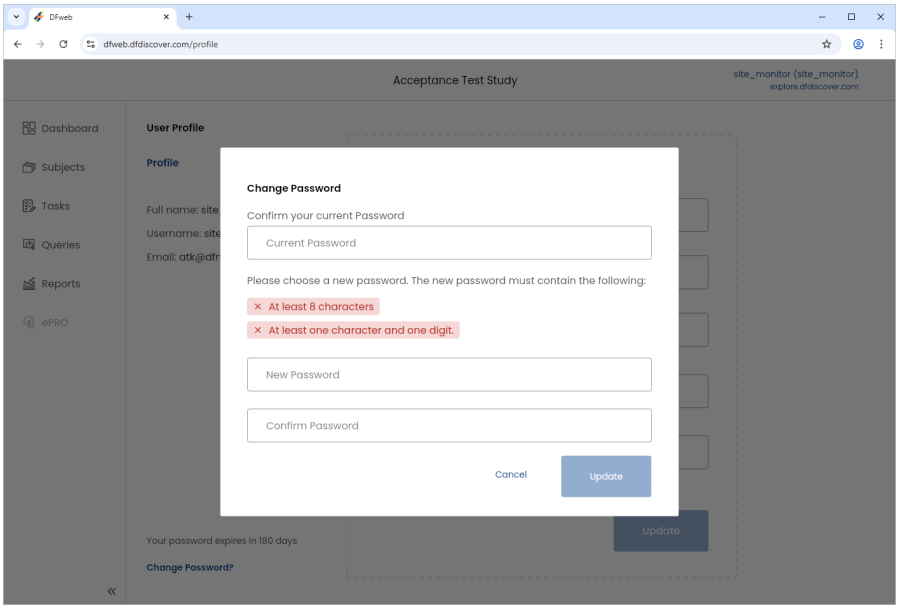
17.3 Copying URL and changing user passwords

17.3.1. From the **Subjects** list, click Subject **99002** to open the **0: Screening Visits 1:Form 1** page.

17.3.2. Copy the **DFweb** URL by clicking ⋮ > Copy URL.

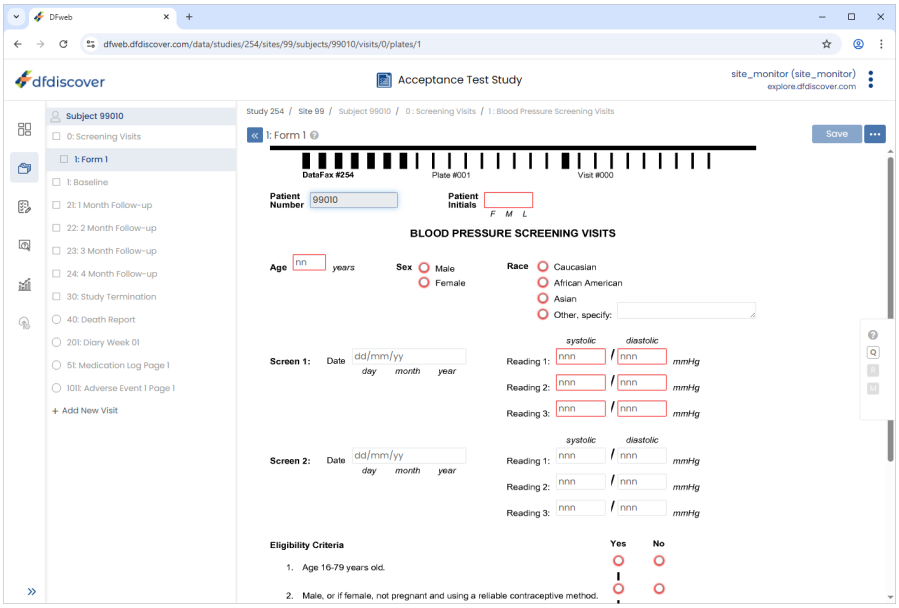
17.3.3. Open a new browser tab, paste the copied URL into the new browser tab, click Enter. The pasted URL in the new tab re-directs you to the **DFweb** login page. Login again using site_monitor credentials, upon logging in confirm you are taken to the same subject data record as the previous web browser tab. Close the web browser tab.

17.3.4. Click ⋮ > User Profile > Change Password to view the **Change Password** window. Click Cancel.



17.4 Creating a new subject, entering subject data

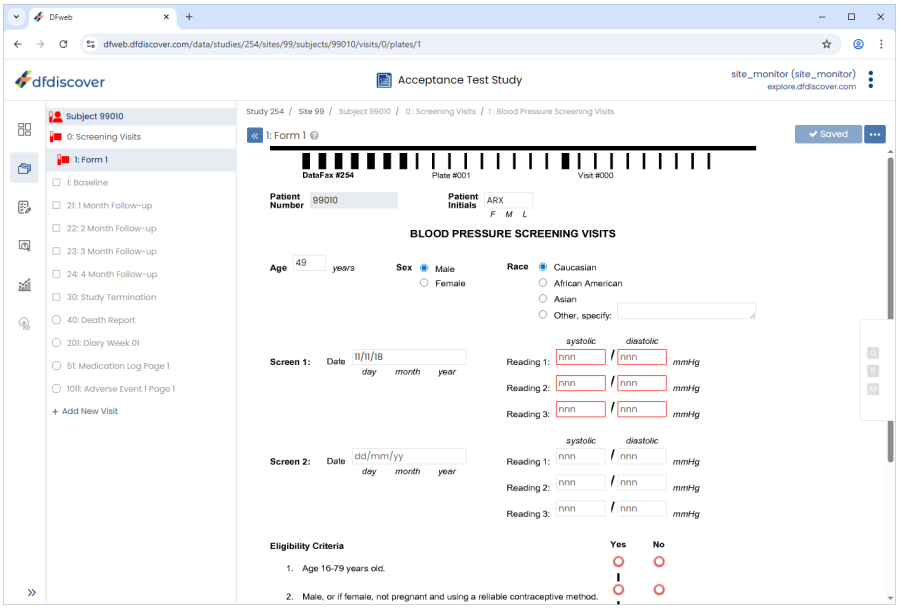
17.4.1. Click **Subjects** , select **99010** to open the **0: Screening Visits 1:Form 1** page.



17.4.2. Click **Patient Initials** enter ARX, Set:

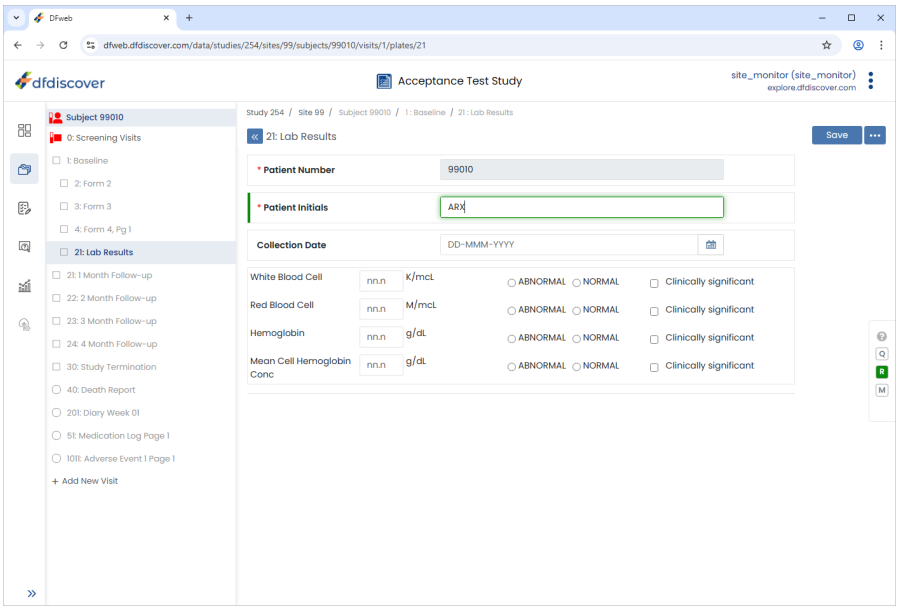
- **Age (years)** = 49
- **Sex** = male
- **Race** = caucasian
- **Screen 1 Date** = Click icon, select 11-Nov-2018

Click SAVE.



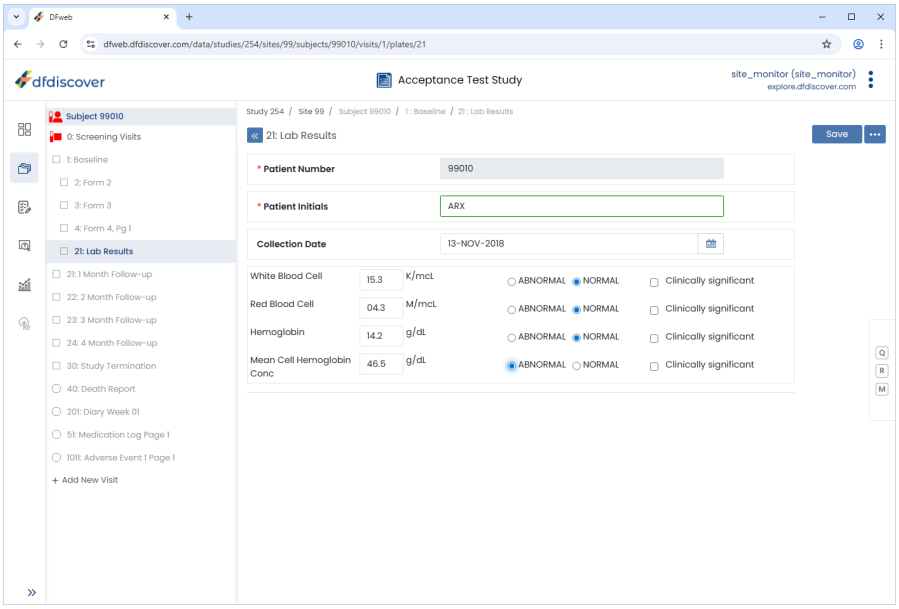
17.4.3. Select **1:Baseline** > **21:Lab Results** page. Click **Patient Initials** field.

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.

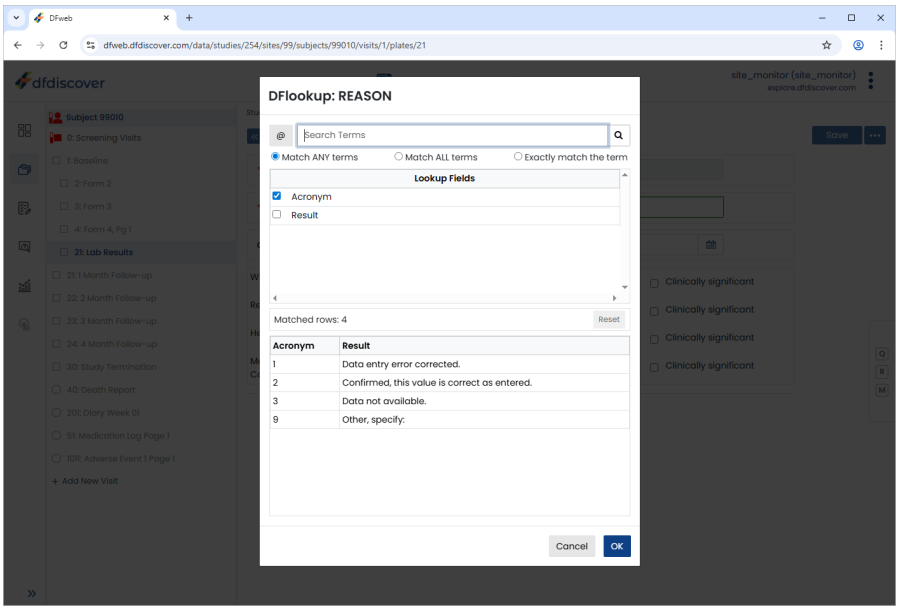


17.4.4. Set the remaining fields within the **21: Lab Results** form as follows:

- **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**



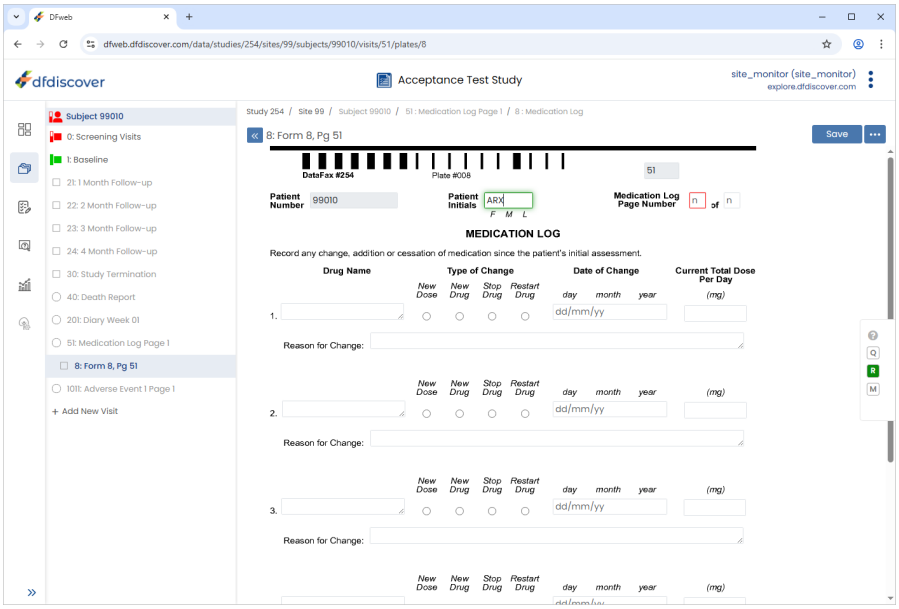
17.4.5. Click [R] to open the **Reason for Data Value** dialog. Click [...] next to **Reason**. The **DFlookup: REASON** dialog is displayed.



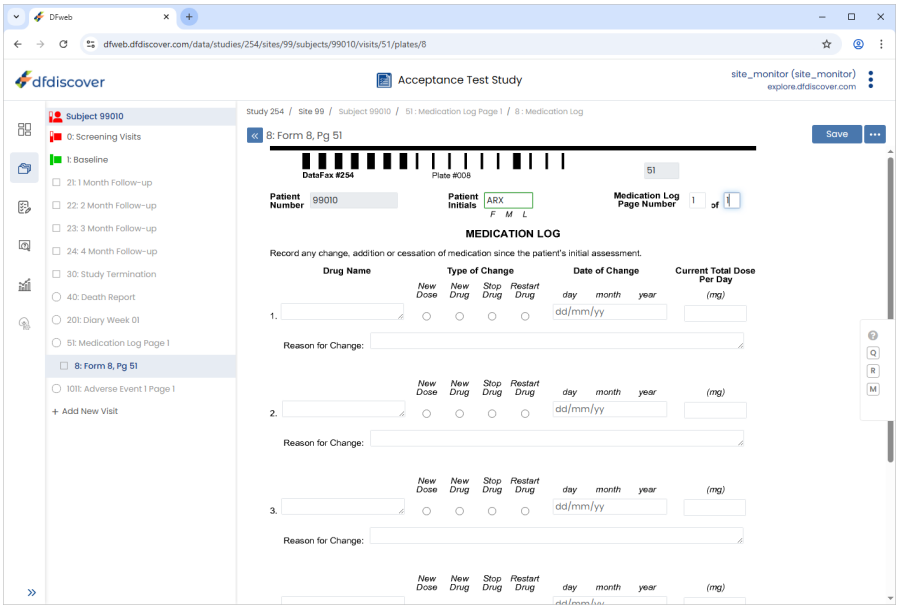
17.4.6. Select the **Result** of Confirmed, this value is correct as entered., Click [OK], followed by [Apply] then [SAVE].

17.4.7. Select **51: Medication Log Page 1** > **8: Form 8, Pg 51** page. Click **Patient Initials** field.

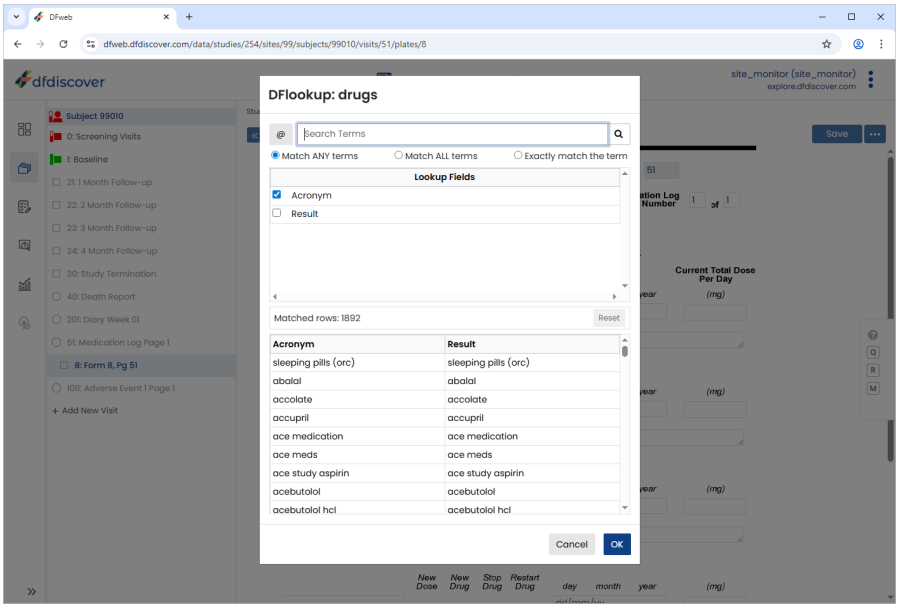
NOTE: The SetInitedit check executes upon entry to the field. If the initials are available on **1 : Form 1** (previously entered), they are retrieved and populate the **Patient Initials** field.



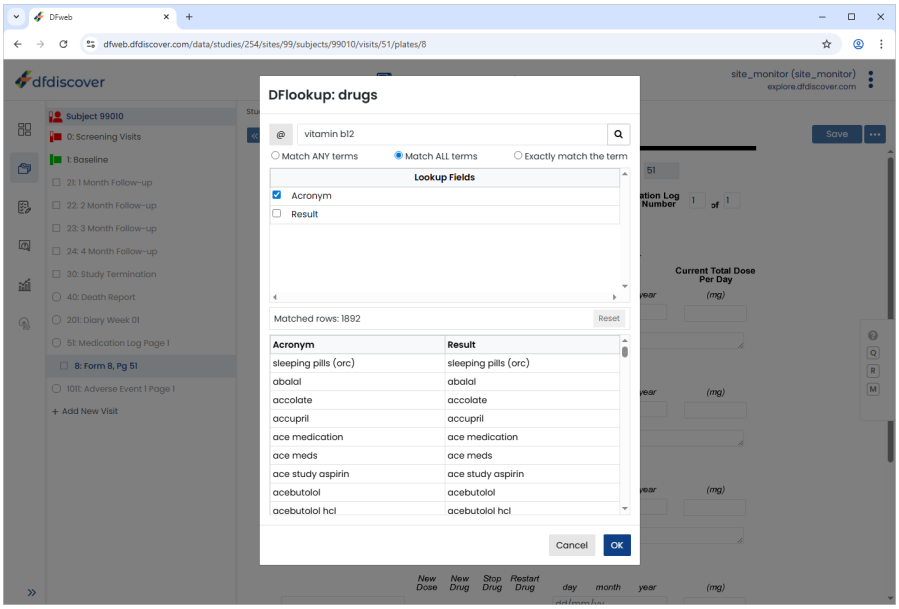
17.4.1. Press Tab. In the **Medication Log Page Number** field, enter values 1 of 1.



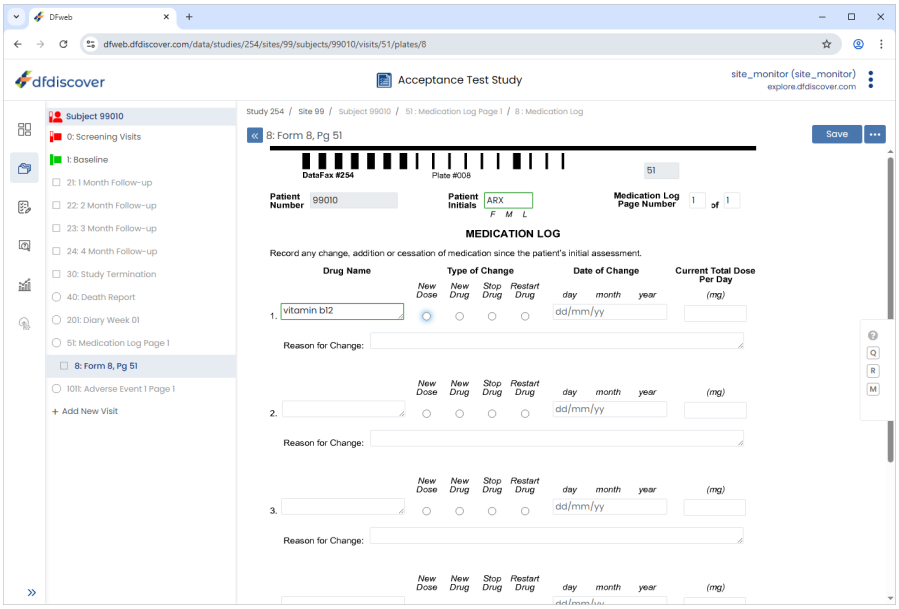
17.4.2. Press Tab to advance to **1. Drug Name** field. Enter Vitamin B-12 in the **1. Drug Name** text field, press Tab. Upon leaving the field, an edit check is executed and **DFlookup: drugs** dialog appears.



17.4.3. Enter vitamin b12 in the **Search Terms**, Check **Match ALL terms** and click 🔍 to filter the results.



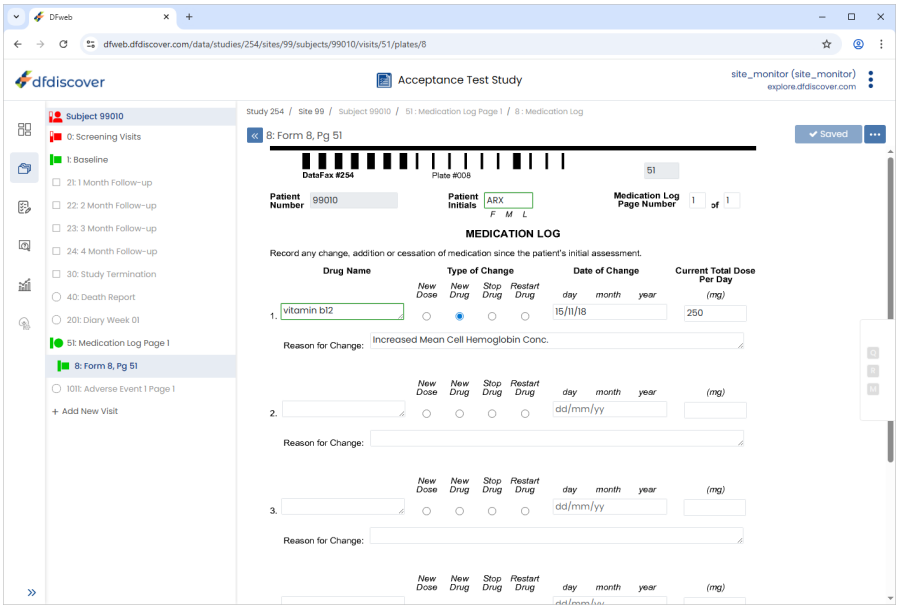
17.4.4. Select the result of **vitamin b12** from the table. Click OK. The **1. Drug Name** field becomes auto-populated with vitamin b12 result.



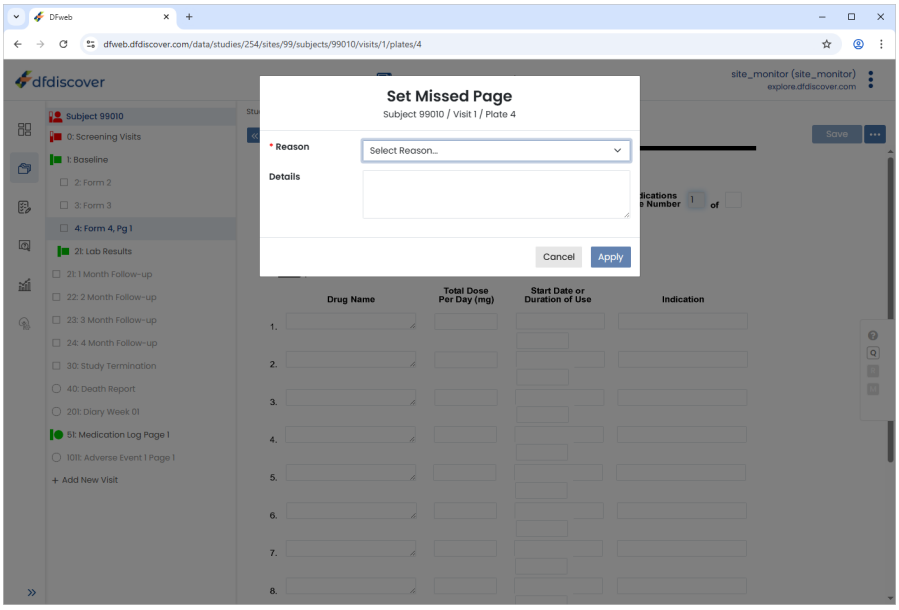
17.4.5. Beginning with the **Type of Change** field complete the remaining data fields as follows:

- **Type of Change** = Select **New Drug**
- **Date of Change** = Select 15/11/18
- **Current Total Dose Per Day** = 250
- **Reason for Change** = Increased Mean Cell Hemoglobin Conc.

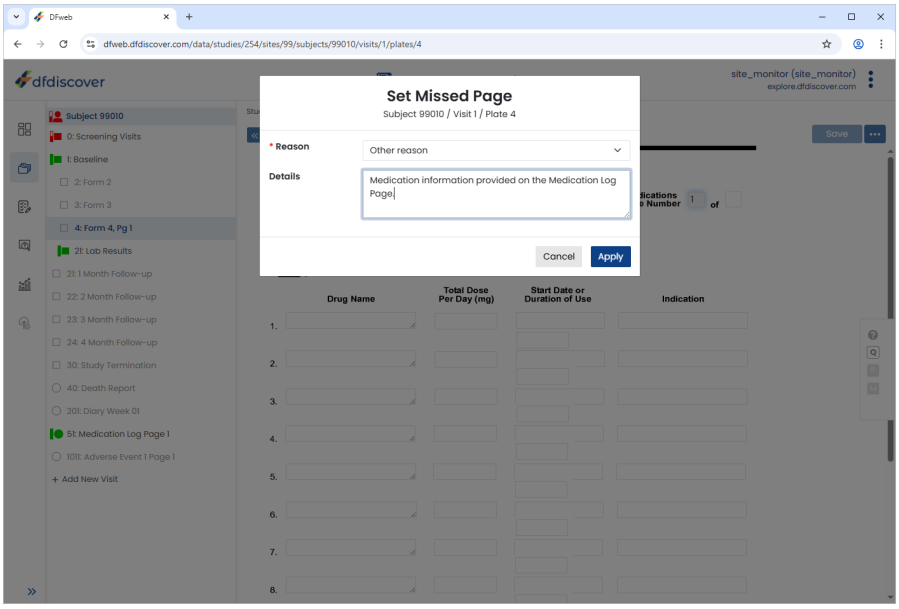
Click SAVE.



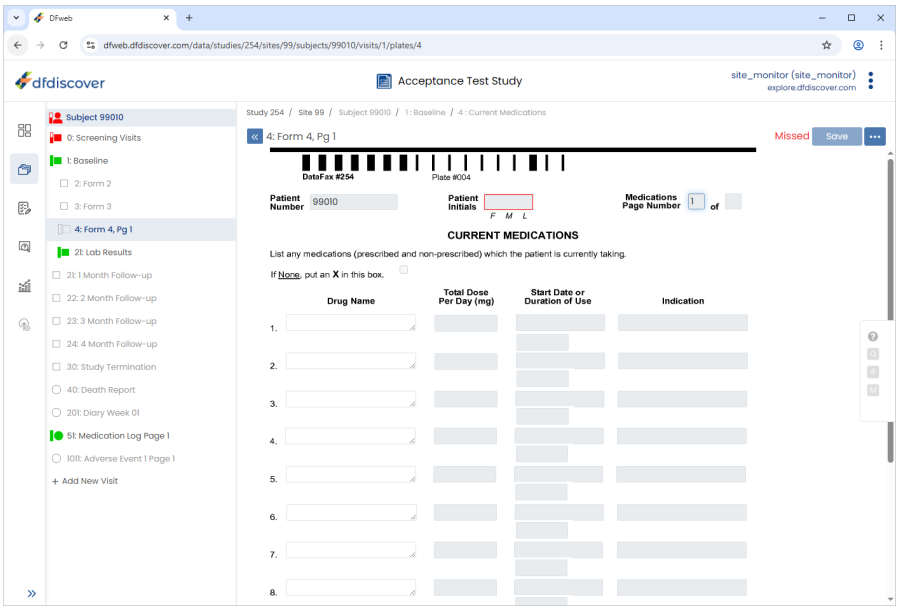
17.4.6. Select **1: Baseline** > **4 : Form 4, Pg 1**. Click ··· > **Set Page Missed** to open the **Set Page Missed** dialog.



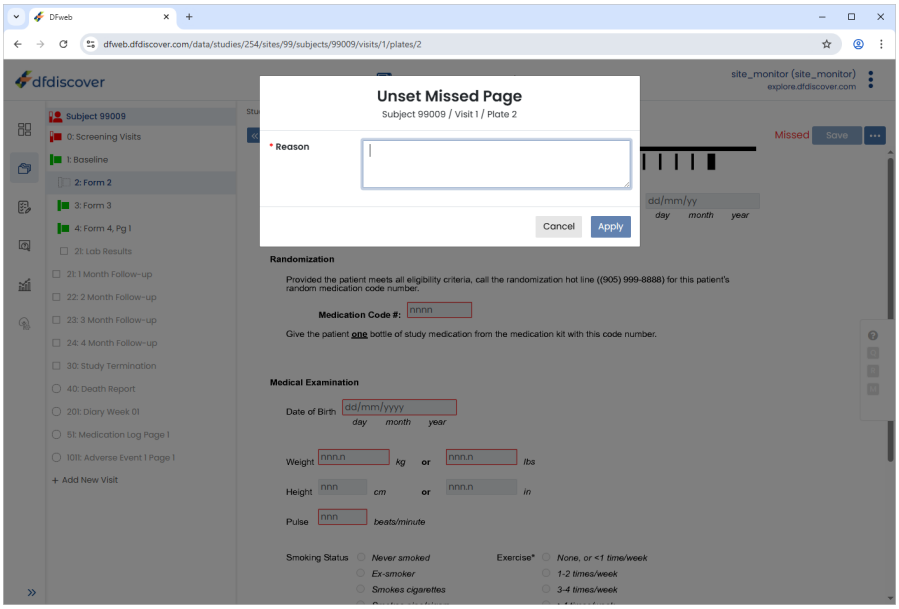
17.4.7. In the dialog, choose **Other Reason** value from the **Reason** pull-down list. Enter Medication information provided on the Medication Log Page. as the **Detail**.



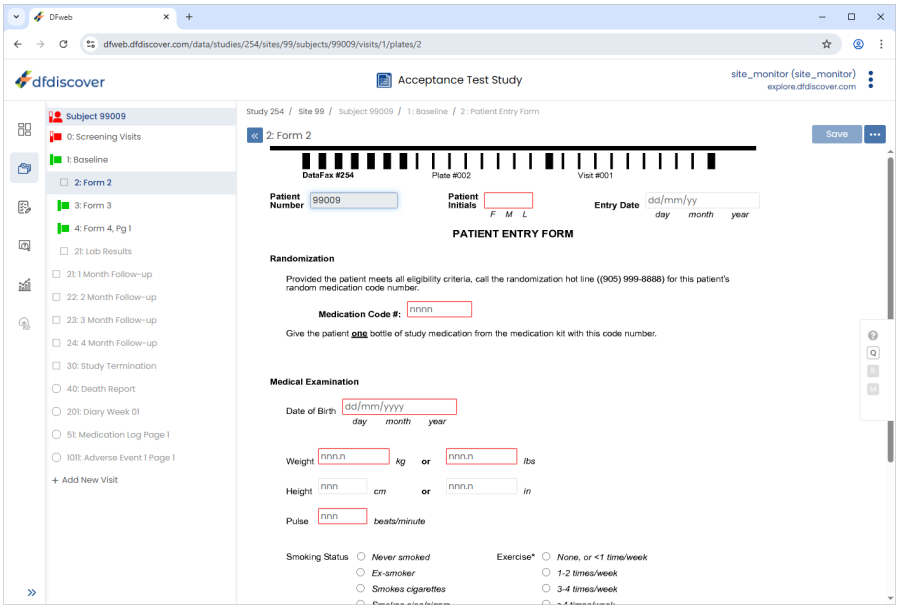
17.4.8. Click Apply to register the page as missed.



17.4.9. Click **Subjects** , select **99009** > **1: Baseline** > **2: Form 2**. Click ··· > **Unset Page Missed** to open the **Unset Missed Page** dialog.

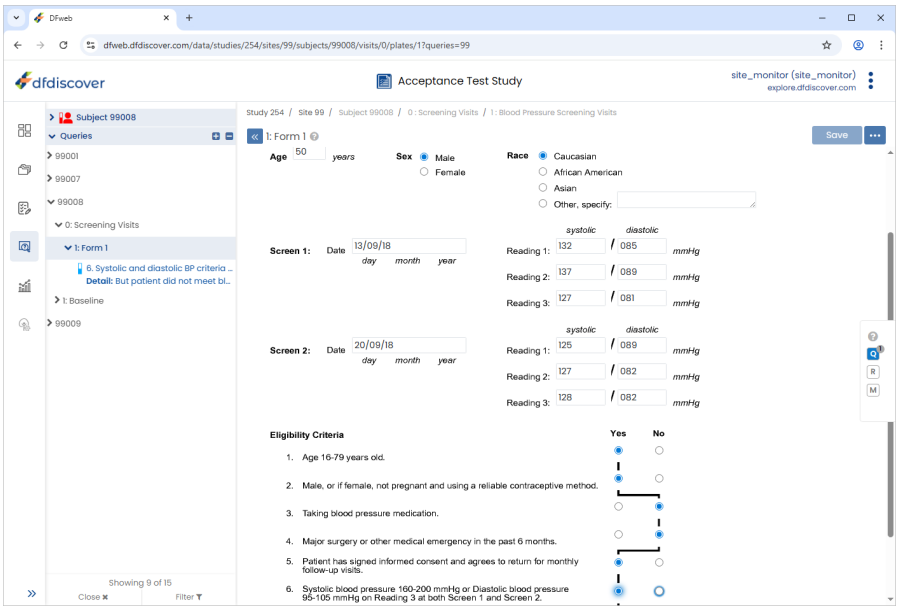


17.4.10. Enter a reason of Data to be captured during chart review.. Click Apply

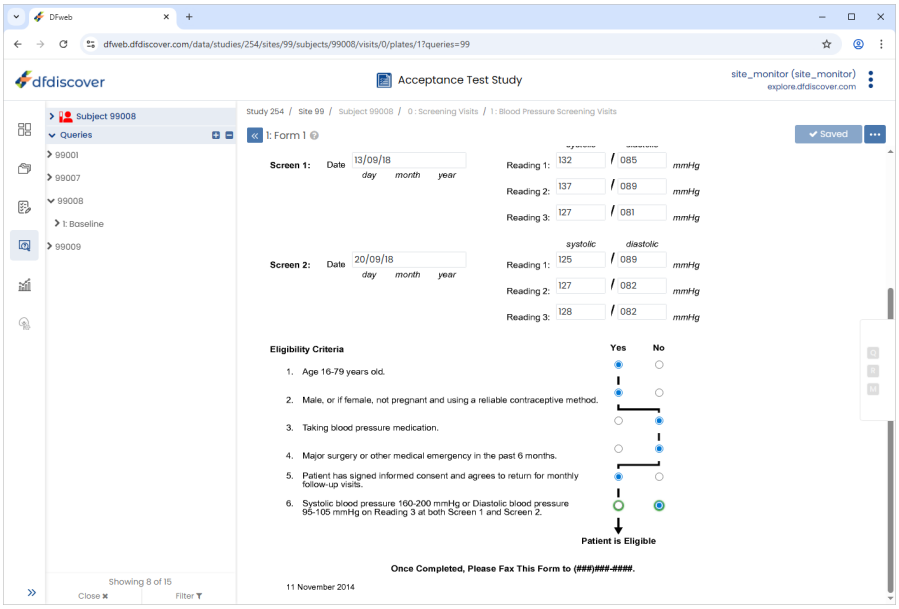


17.5 Adding, modifying and resolving queries

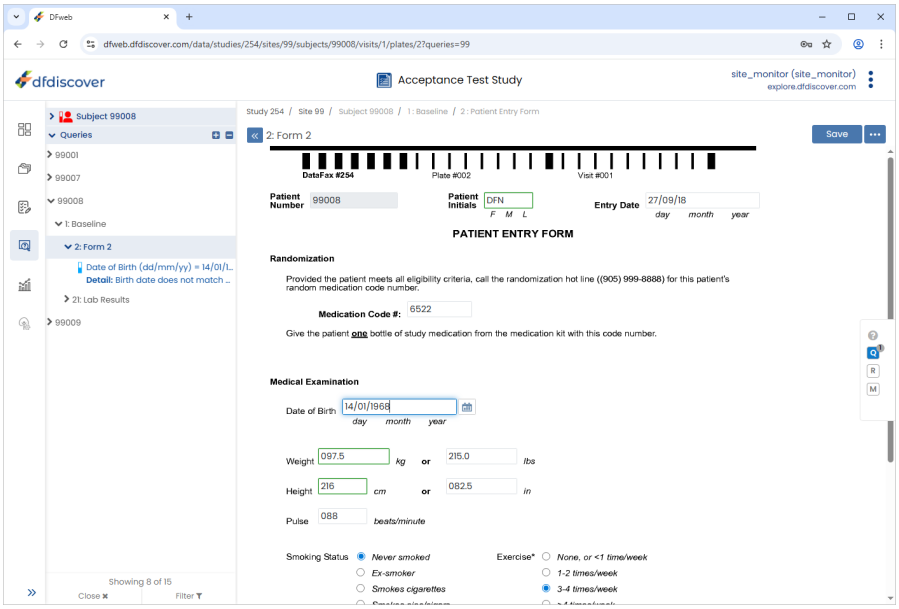
17.5.1. From the sidebar bar, Click . Locate and select the outstanding query for Subject **99008** > **0:Screening Visits** > **1:Form 1**.



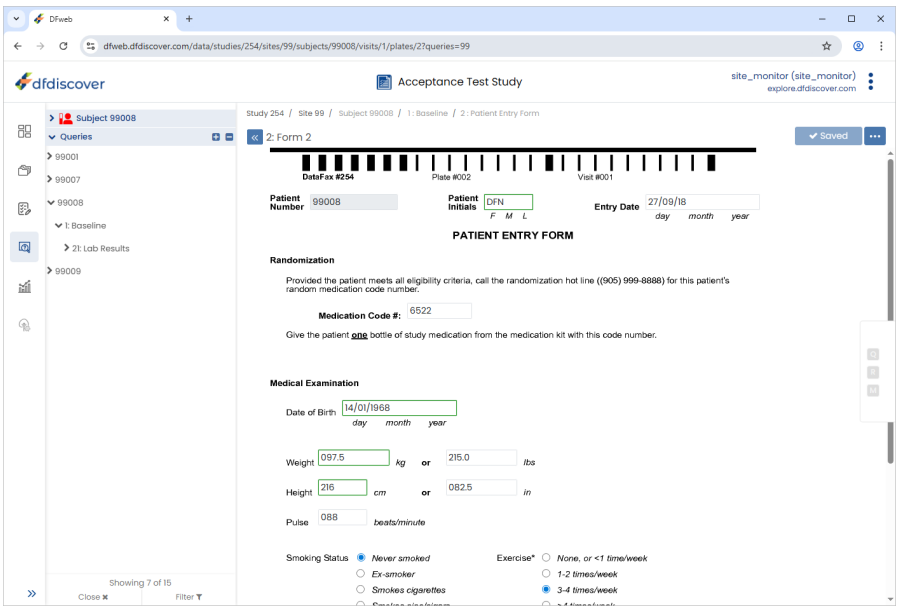
17.5.2. Change **6. Systolic and diastolic BP criteria** from 'Yes' to 'No', Click then *, select **Resolved** from the **Status** drop-down list. Click Apply > Close and SAVE to save the data record changes.



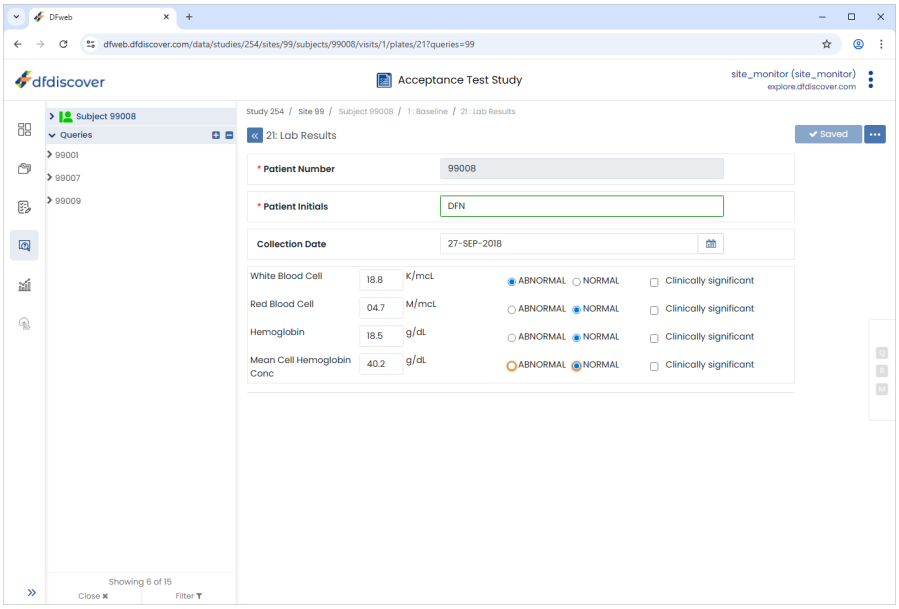
17.5.3. Click **99008** > **1:Baseline** > **2: Form 2**. Select **Date of Birth (dd/mm/yyyy)** query. Correct **Date of Birth (dd/mm/yyyy)** to 14/01/1968.



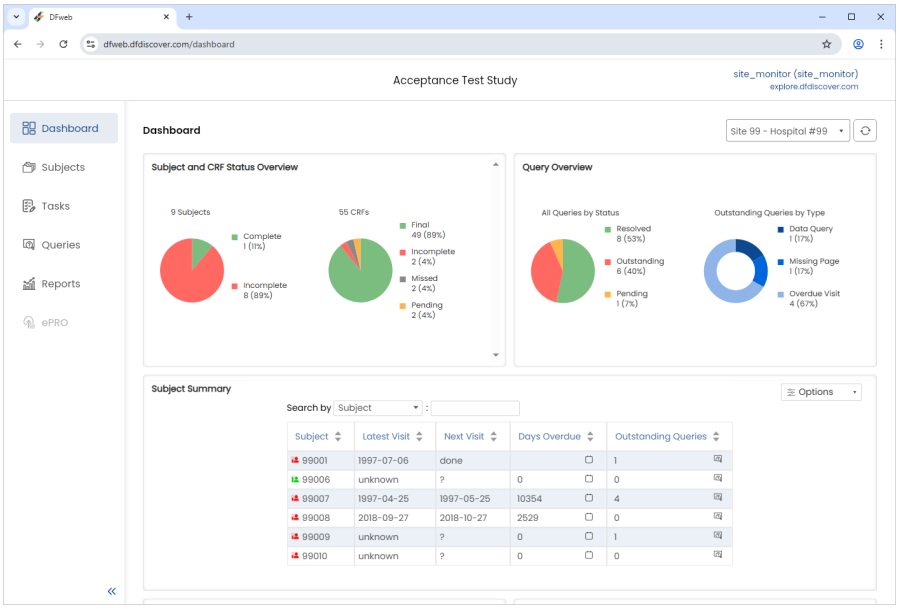
17.5.4. Click Q then *, select **Resolved** from the **Status** drop-down list. Click Apply > Close to save the query changes. Click SAVE.



17.5.5. 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.



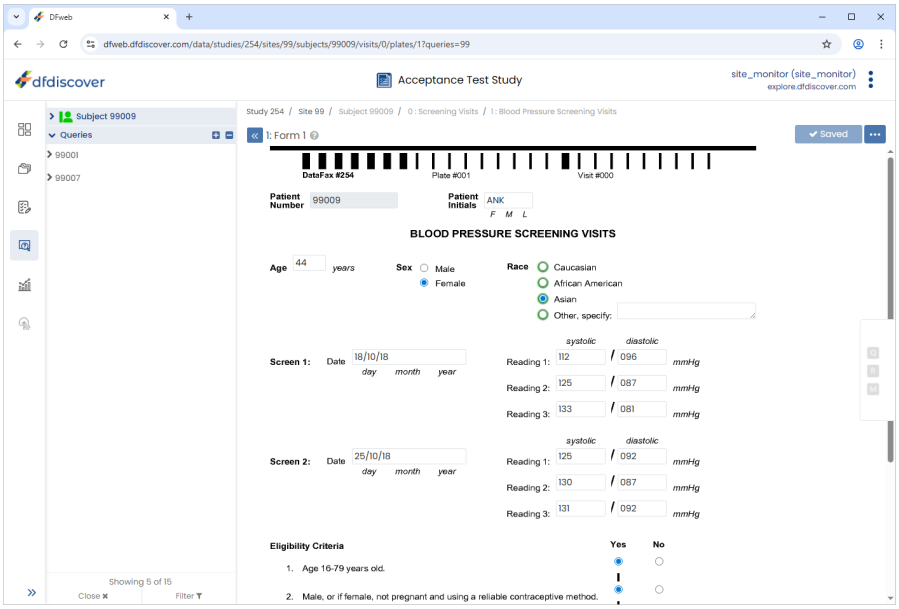
17.5.6. Click .



17.5.7. 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.

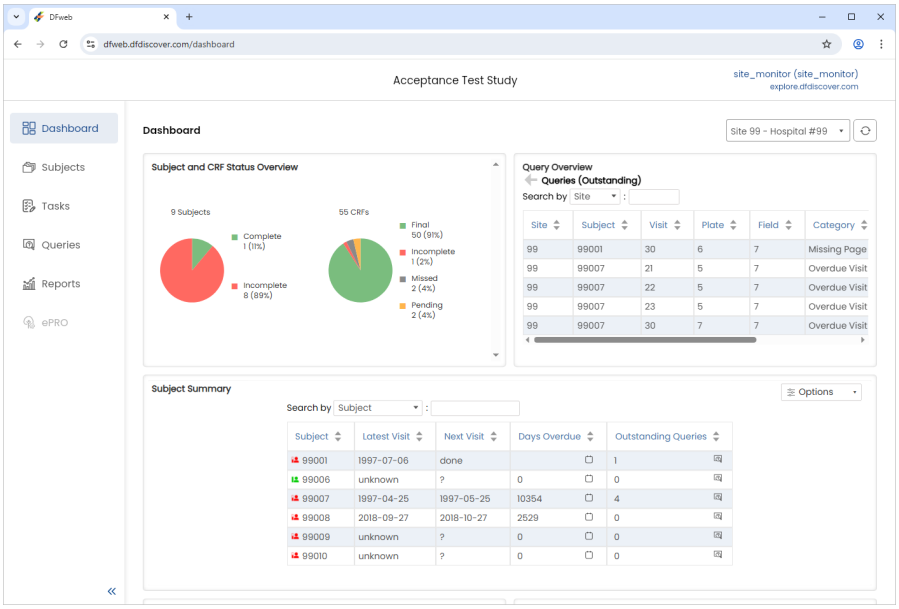
17.5.8. In the **Queries Overview** table locate and select the outstanding query for subject **99009**.

17.5.9. Select **Asian** in the **Race** field. Click Save.



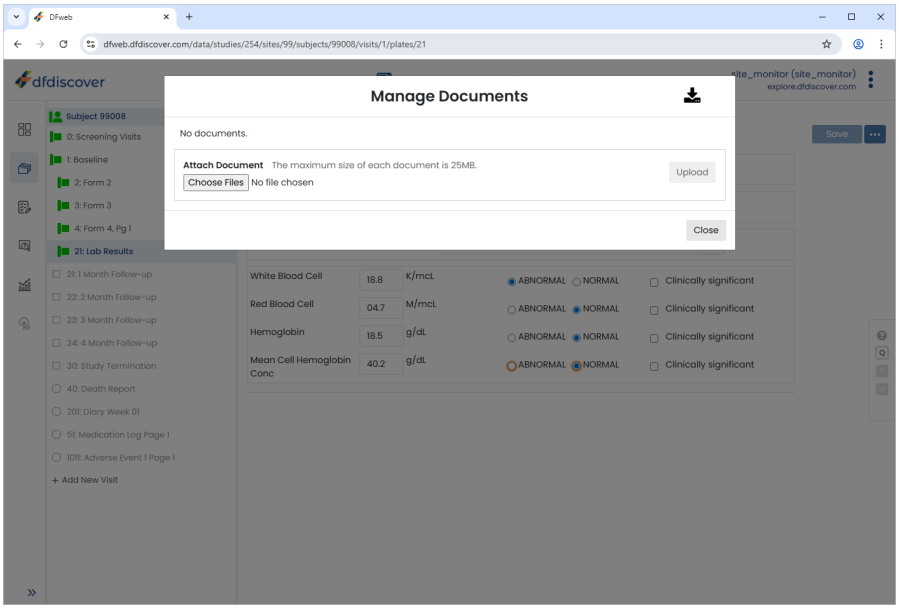
17.5.10. Return to the **Dashboard** page by Clicking .

17.5.11. 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.

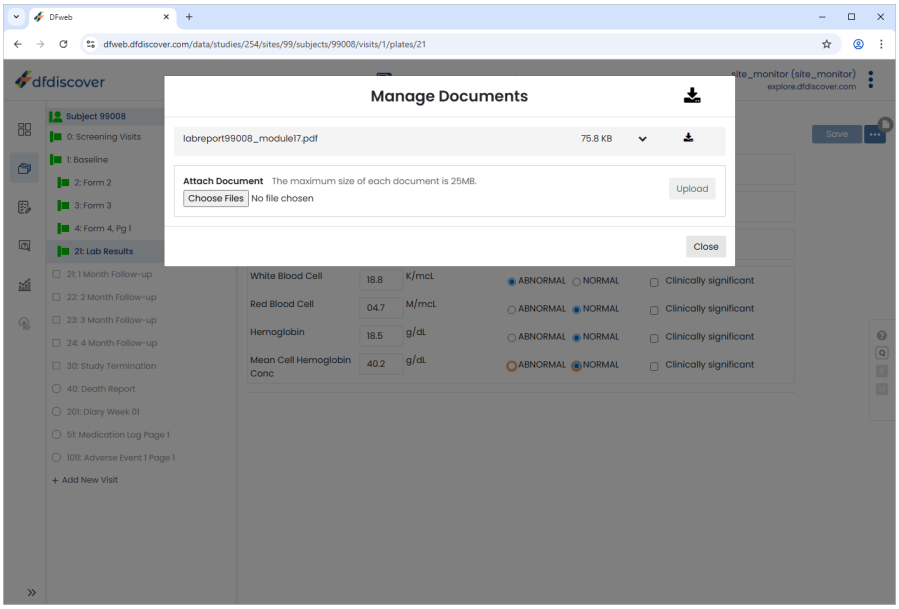


17.6 Adding, reviewing and downloading subject documents

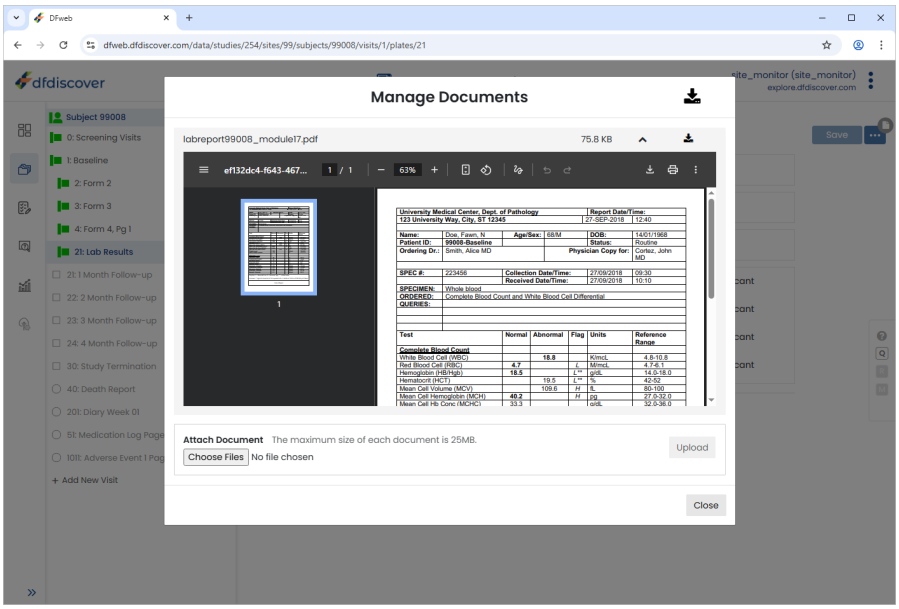
17.6.1. From the sidebar, select **Subjects** > **99008** > **1: Baseline** > **21: Lab Results**. Click > **Manage documents** to open the **Manage documents** window.



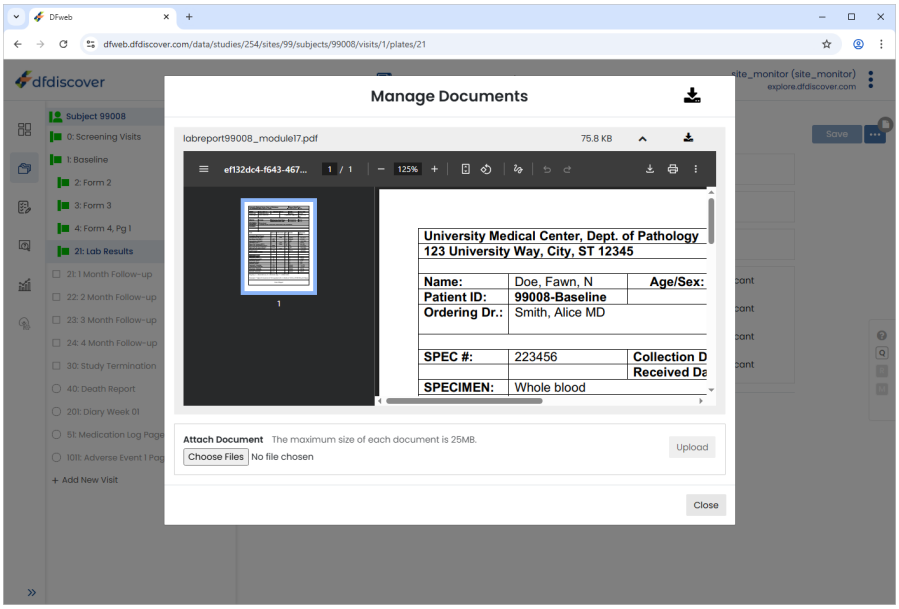
17.6.2. Click Choose Files, select the previously saved labreport99008_module17.pdf (Refer to Step 2). Click Open > Upload to upload the document.



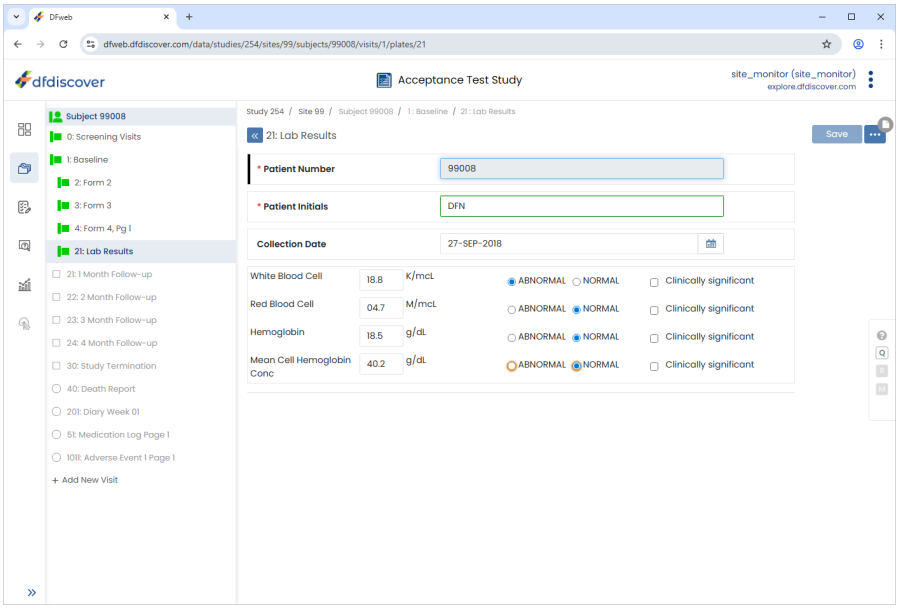
17.6.3. Click ⌄ to view the newly uploaded document.



17.6.4. The document can be zoomed in/out by using the navigation buttons within the document window.



17.6.5. Click Close to close the **Manage Documents** window. Notice the ··· icon has now changed to ··· indicating the data record now has associated documents.



17.6.6. Click ⋮ > Logout to exit **DFweb**.

17.7 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.

17.7.1. 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.

17.7.2. As user site_invest has 2FA enabled, enter security code received by email or SMS as previously defined.

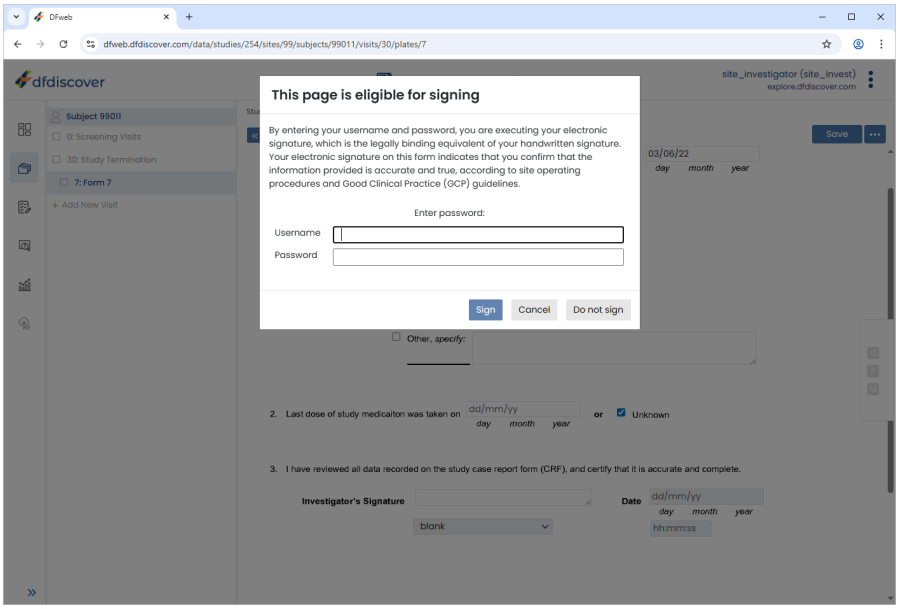
NOTE: Refer to Creating user accounts and assigning study permissions. as a valid email address or phone number is required for site_invest to receive 2FA codes.

17.7.3. From the **Subjects** list, click Subject **99011** > **30: Study Termination** > **7: Form 7**.

17.7.4. Click **Patient Initials** enter SIG, Set:

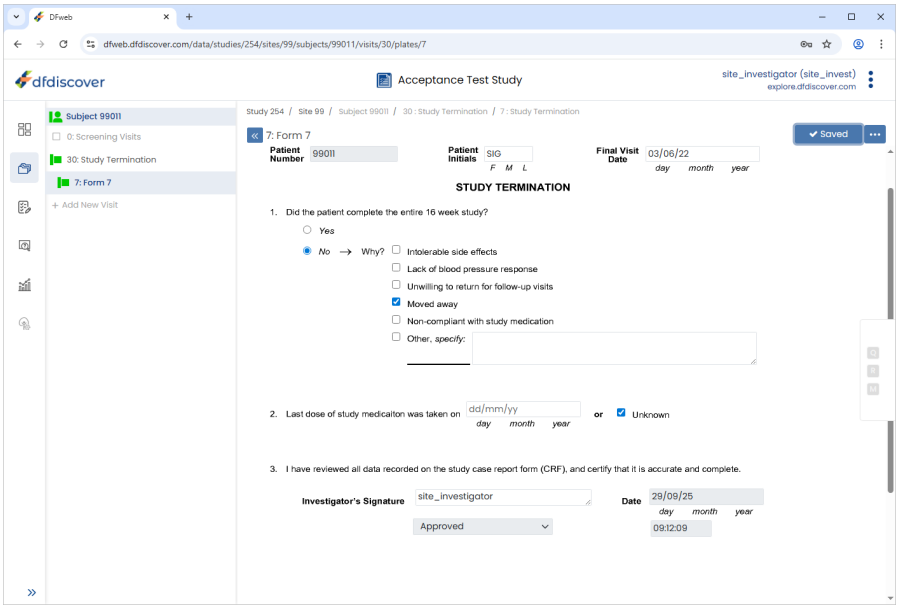
- **Final Visit Date** = 03/06/22
- **1. Did the patient complete the entire 16 week study?** = **No**
- Check (enable) **Moved away**
- **2. Last dose of study medication was taken on** = Check (enable) **Unknown**

Click SAVE to save and eSign the **Study Termination** form.



17.7.5. 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.

17.7.6. In the **DFexplore - eSignature Reason** dialog select **Approved** from the dropdown, click OK.



17.7.1. Examine the 4 eSignature fields at the bottom of the page.

17.7.2. Click ⋮ > Logout to exit **DFweb**.

17.8 Verify removal and re-application of eSignatures

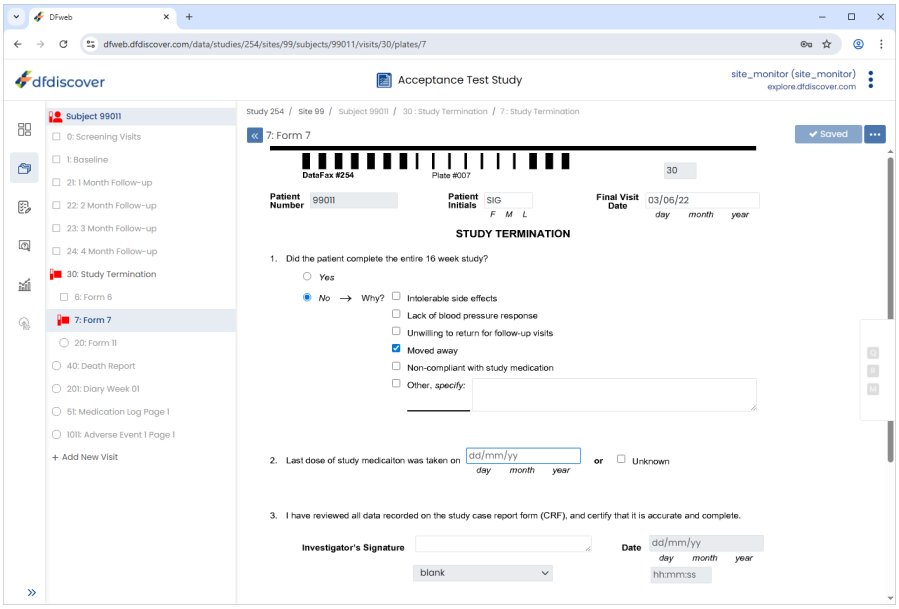
17.8.1. In the **DFweb** login dialog, enter site_monitor in the **Username** field and the previously assigned password in the **Password** field. Click Login to login.

17.8.2. From the **Subjects** list, click Subject **99011** > **30: Study Termination** > **7: Form 7**.

17.8.3. 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.

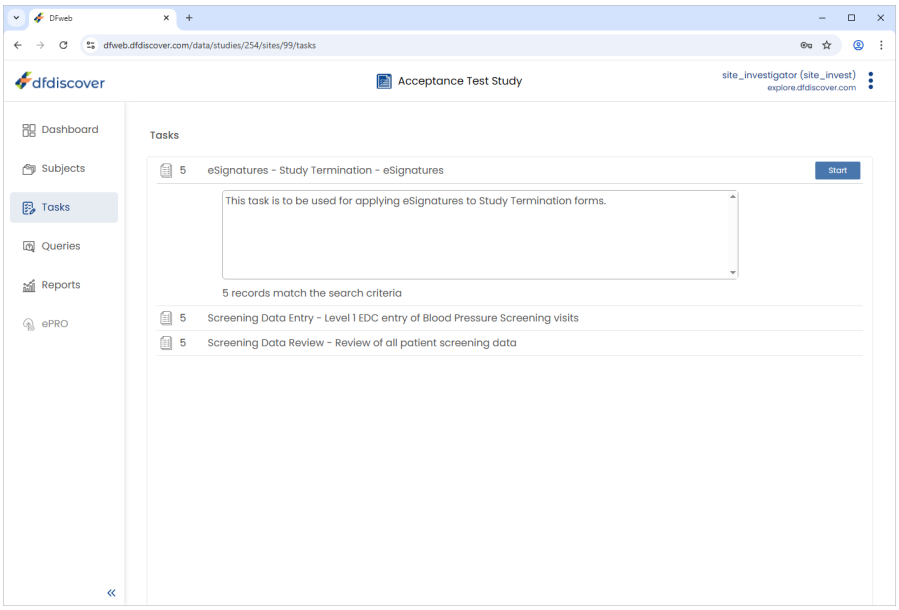
17.8.4. Press Tab to advance to the **Unknown** field. Un-check (disable) the checkbox. Click SAVE.



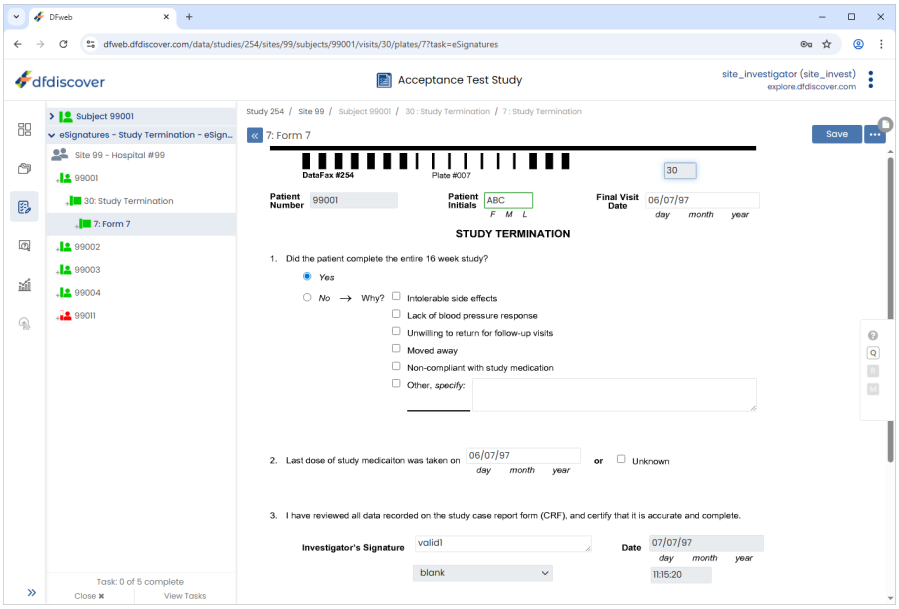
17.8.5. Click ⋮ > Logout to exit **DFweb**.

17.8.6. 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.

17.8.7. From the sidebar, Click **Tasks**.

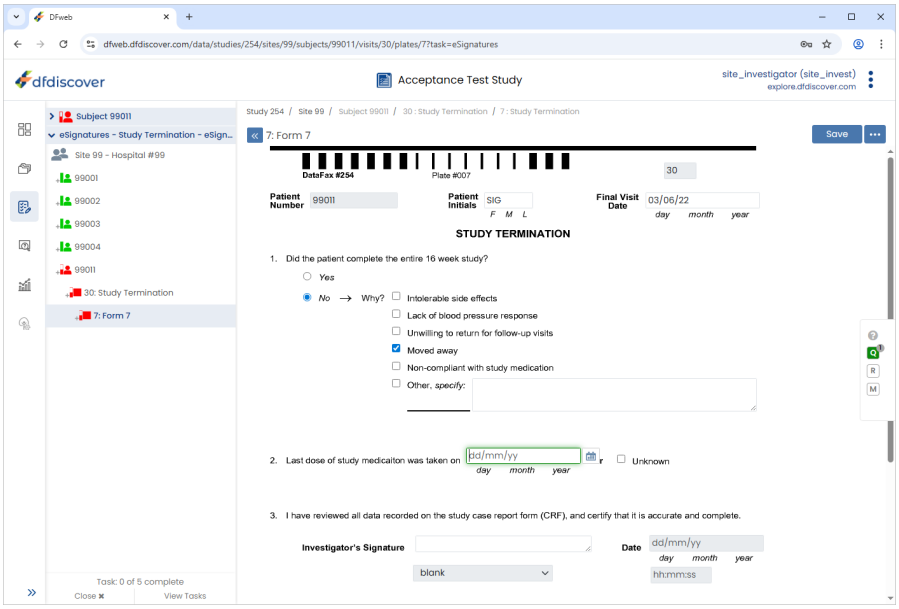


17.8.8. Locate the **eSignatures - Study Termination - eSignatures** task. Click Start.



17.8.9. From the **Subjects** list, click Subject **99011** > **30: Study Termination** > **7: Form 7**.

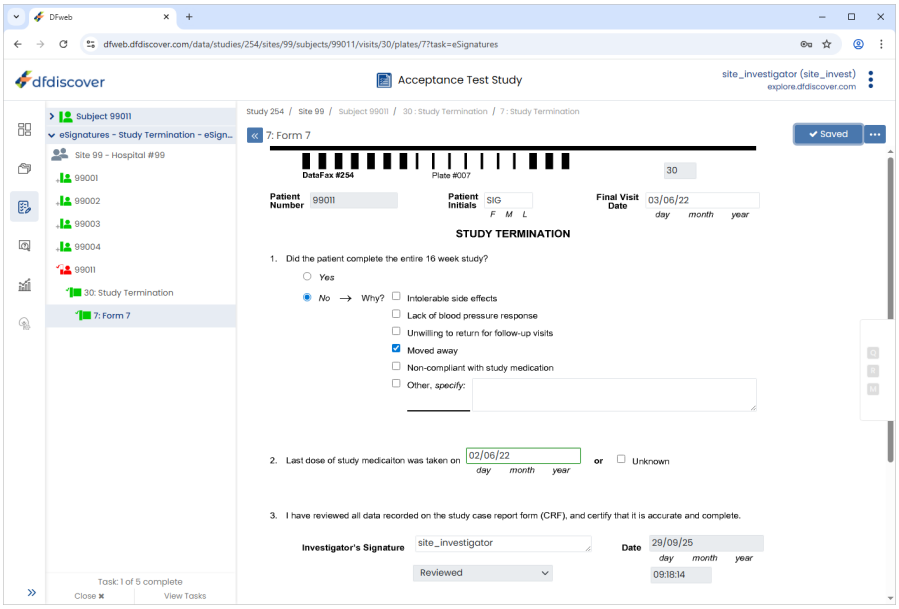
17.8.10. Click the **2. Last dose of study medication was taken on** field. Click Q then *. Select **Resolved** from the **Status** drop-down list. Enter Confirmed date of last medication dose verbally with subject during clinic visit. in the **Note** field. Click Apply > Close.



17.8.11. Enter the **2. Last dose of study medication was taken on** date as 02/06/22. Click SAVE.

17.8.12. 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.

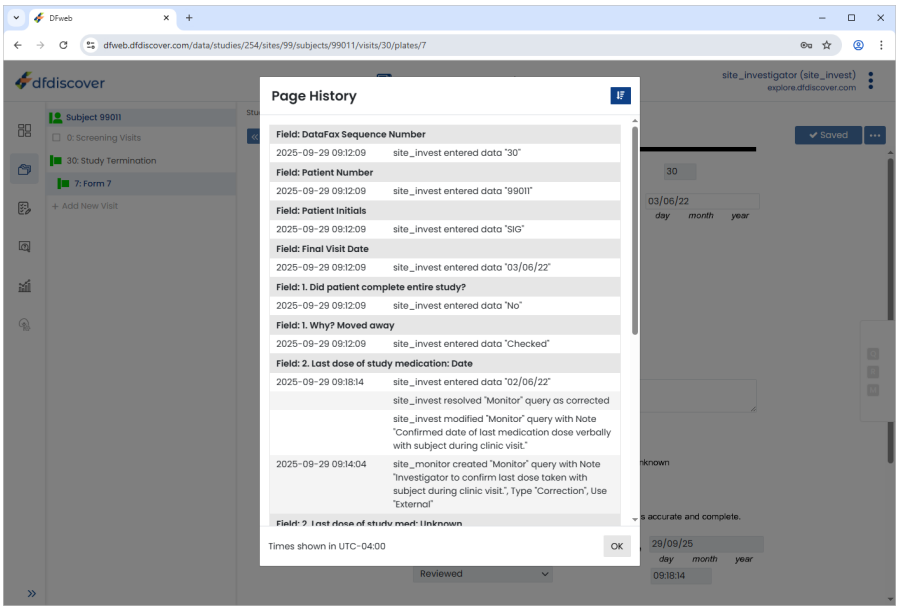
17.8.13. In the **DFexplore - eSignature Reason** dialog select **Reviewed** from the dropdown, click OK.



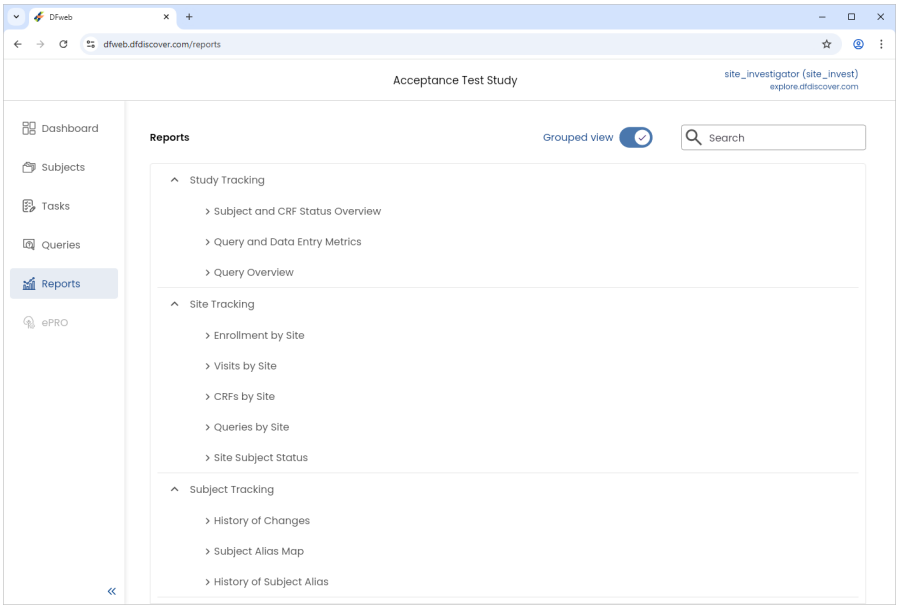
17.8.14. Examine the 4 eSignature fields at the bottom of the page.

17.8.15. Click Close x to close **Tasks** view. In the resulting warning dialog click Continue.

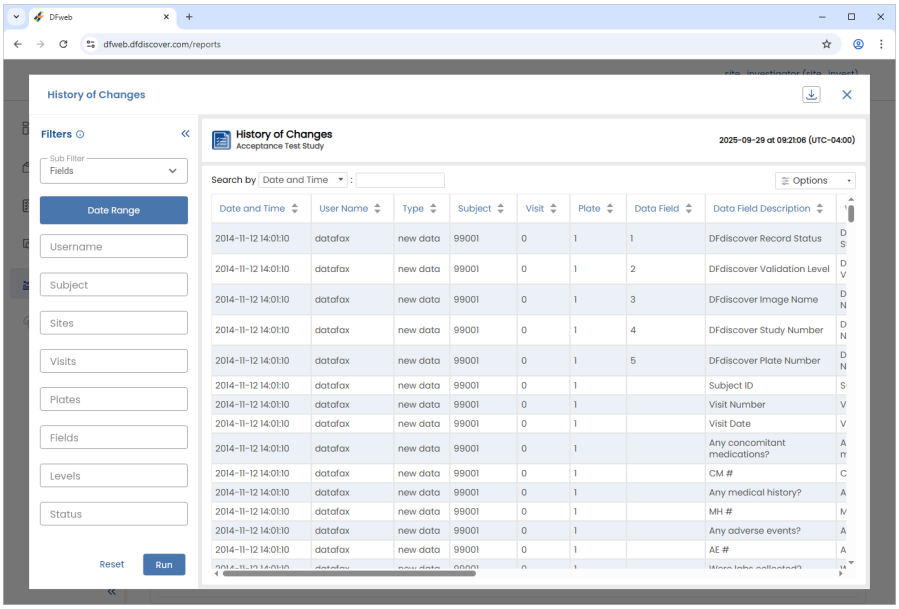
17.8.16. Click ··· > View Page History to open the **Page History** window. The **Page History** is displayed, Click OK to close the window.



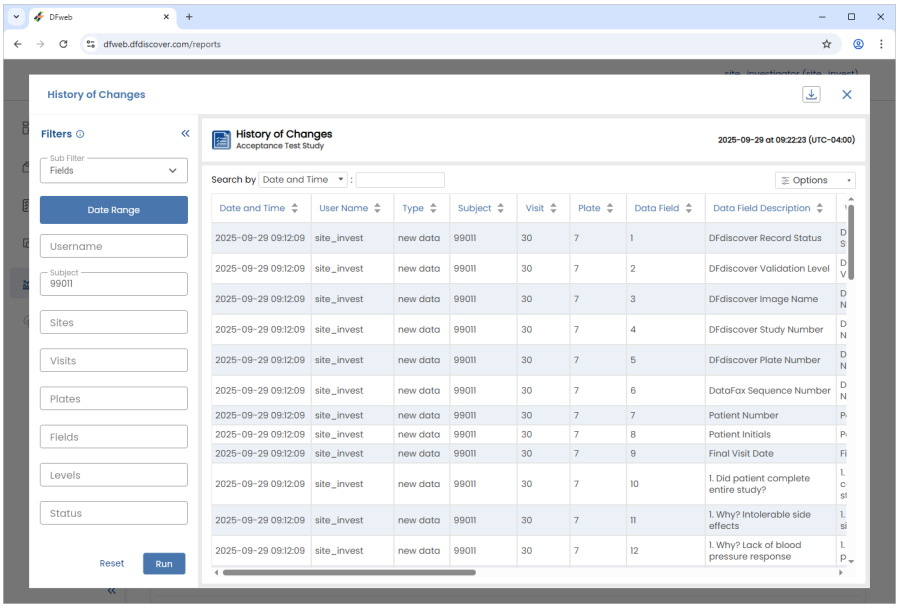
17.8.17. Click **Reports**, enable (toggle on) **Grouped View**.



17.8.18. Select **History of Changes** under the **Subject Tracking** reports list.



17.8.19. 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.

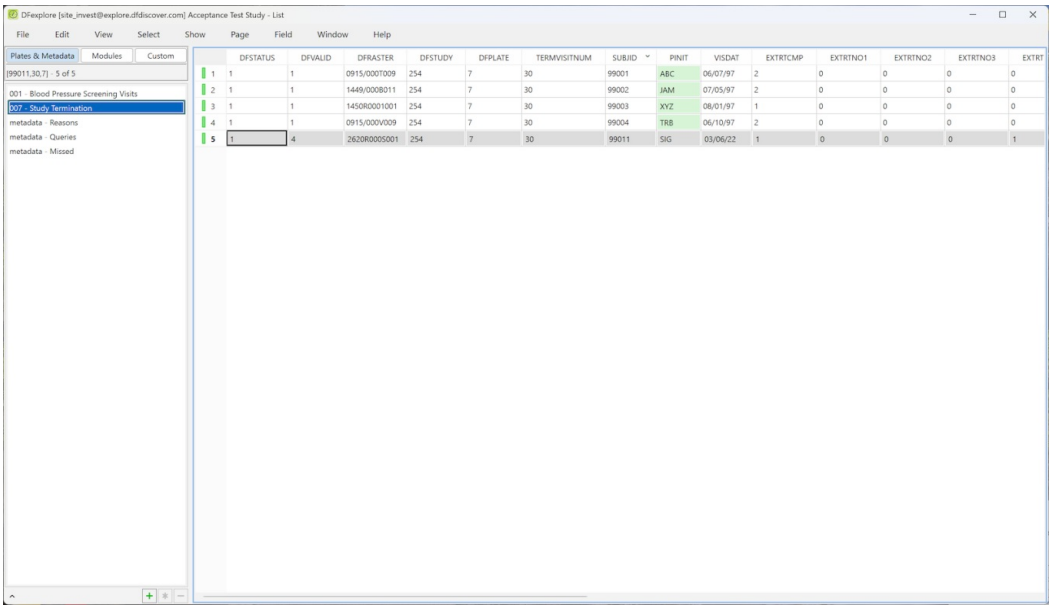


17.8.20. Click ⋮ > Logout to exit **DFweb**.

17.9 Verify **DFweb** saves eSignature task data to the specified save level

17.9.1. Start **DFexplore**, login as data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

17.9.2. Select **View** List. Click **007 - Study Termination**. Confirm **DFVALID** displays as "4" for subject **99011**.



17.9.3. 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**.

18 Module 18. DFcollect Mobile Data Collection

Overview

Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- DFws 5.11.3 installed and properly configured on DFws server
- Valid DFdiscover license with DFWS and DFCOLLECT license features on DFdiscover server
- Mobile Device with DFcollect 5.11.3 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

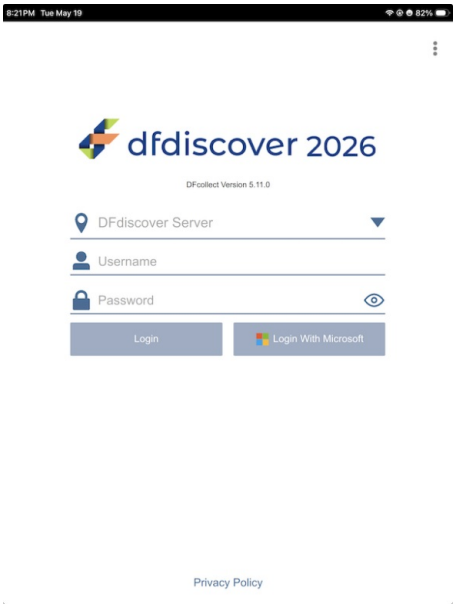
Begin Module 18. DFcollect Mobile Data Collection

1. Start **DFATK** as described in Module 1 (Installation & Initialization).
2. Click 18. DFcollect Mobile Data Collection followed by Begin to begin this module.

18.1 Installation and App preferences

18.1.1. 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.

18.1.2. Open **DFcollect**.

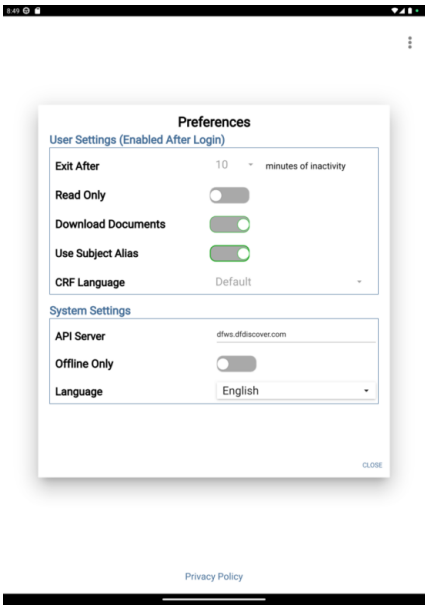


18.1.3. Click ⋮ > Preferences. Set:

System Setting

- **API Server** = your API servername
- **Offline Only** = Disabled (greyed out)

Click Close to apply settings.



18.1.4. Click ⋮ > About DFcollect Confirm that the version information in the about dialog matches the installed **DFcollect** Version 5.11.3. Click Close to return to the **DFcollect** login screen.



18.2 Resetting a user login password

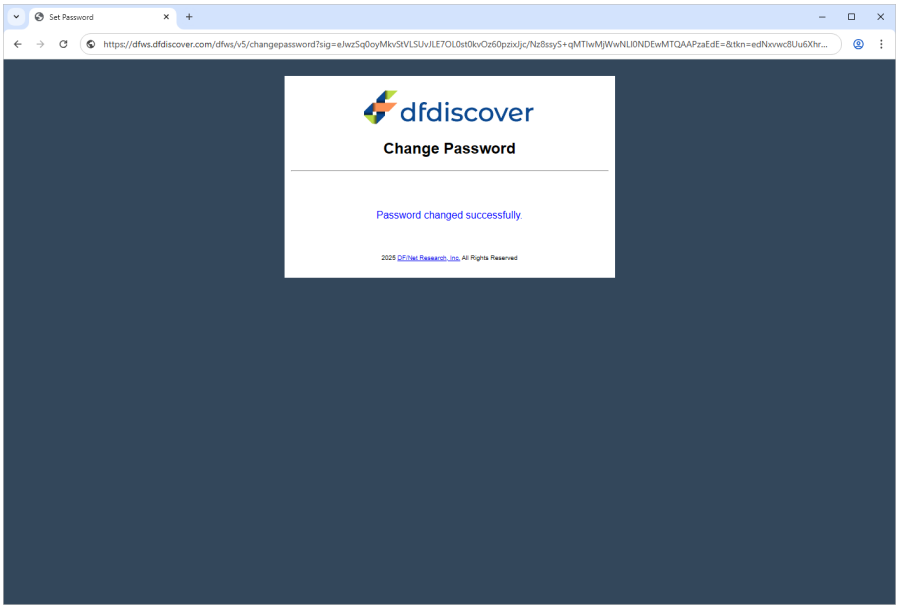
18.2.1. Click ⋮ > Forgot Password?.

18.2.2. 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.**



18.2.3. Open the password reset email from your **DFdiscover** server and click the provided link to reset the site_monitor password.

18.2.4. Enter and confirm a new password, then click Update.



18.2.5. 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.

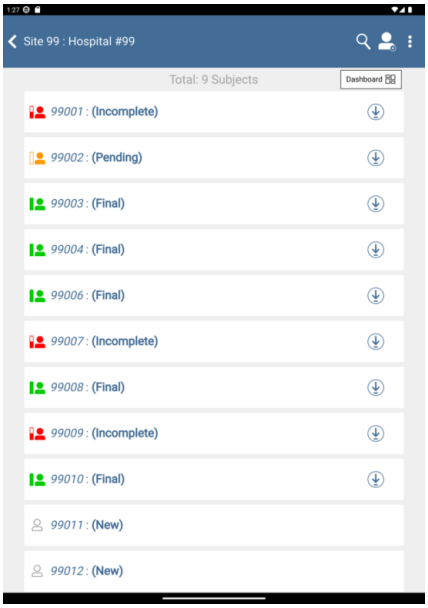
18.3 Online data record creation

18.3.1. 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.

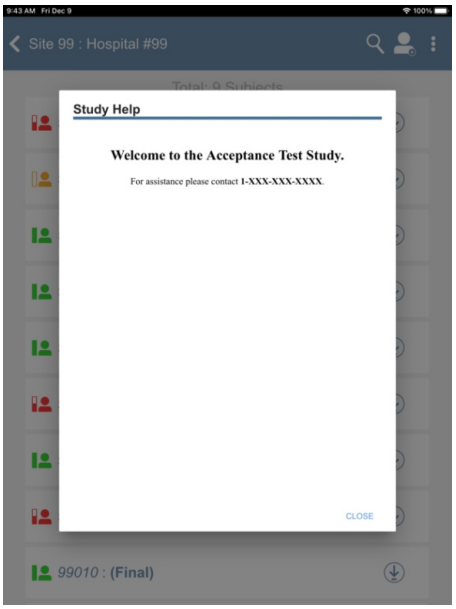


18.3.2. From the list of available studies, click **254 Acceptance Test Study**, if not already opened.

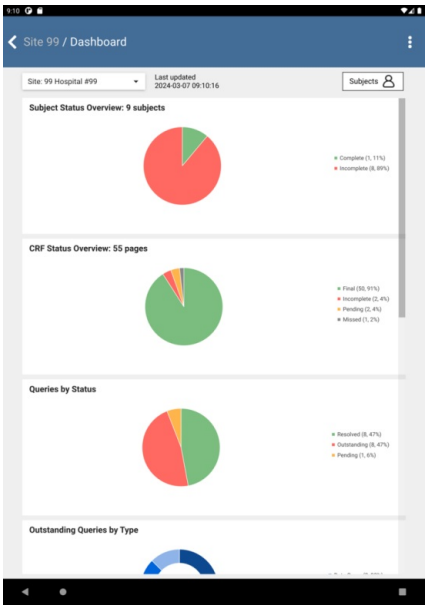
18.3.3. Click **99: Hospital #99** to display a list of available subjects.



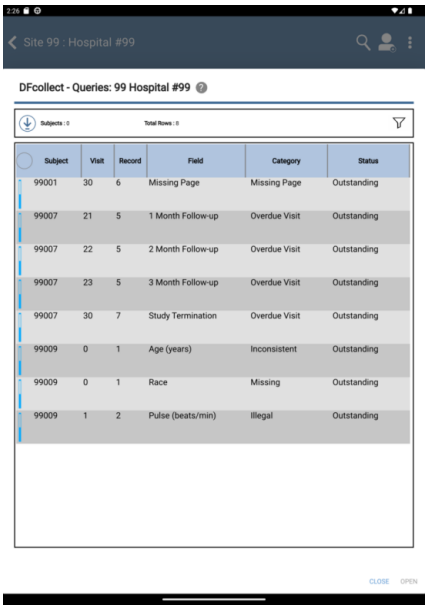
18.3.4. Click ⋮ > Study Help to view any study related help messages. Click Close to close the Study Help window.



18.3.5. Click ⊞ to open **Dashboard** view.

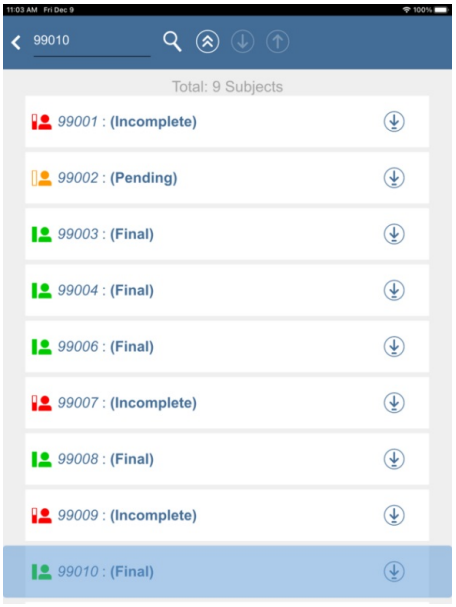


18.3.6. Click **View Outstanding Queries** located under**Outstanding Queries by Type** to view all outstanding queries.

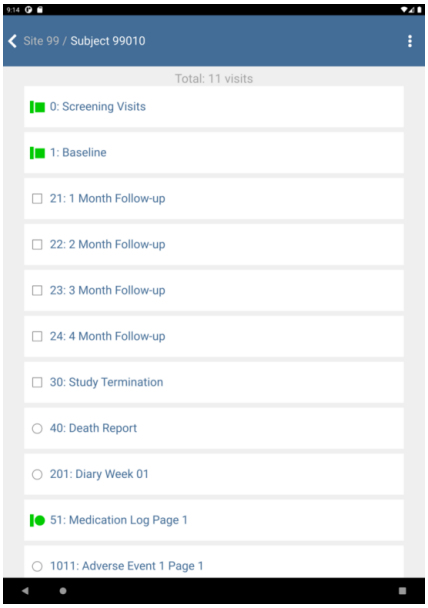


18.3.7. Click Close to return to the subject listing.

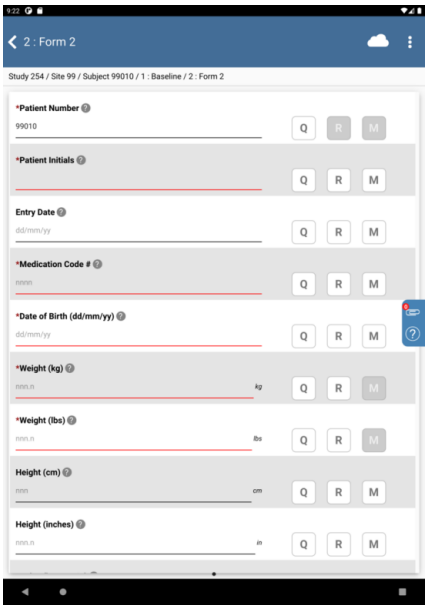
18.3.8. Click to search for a subject ID number, enter 99010. Click , subject **99010 : (Final)** gains the focus.



18.3.9. Click subject **99010 : (Final)** to view the list of study visits.



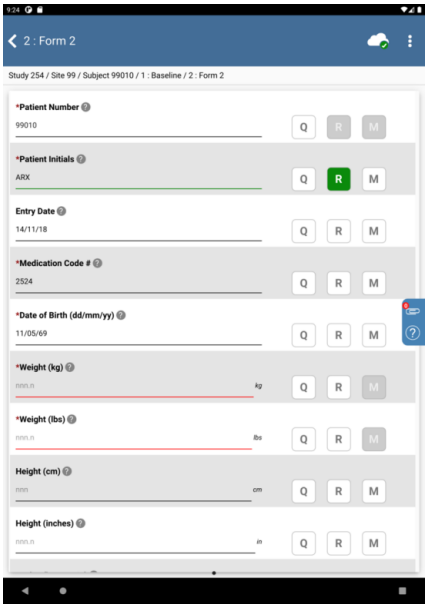
18.3.10. Click **1: Baseline** > **2: Form 2**. **Plate Form 2** becomes the active page.



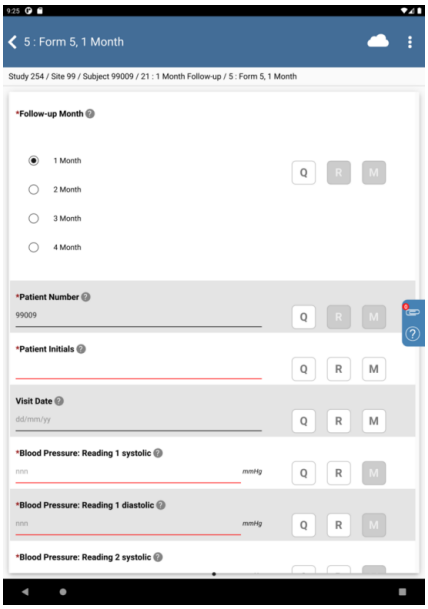
18.3.11. Click **Patient Initials**. The initials automatically populate this field as a result of the edit check SetInitdescribed in Module 8. Image Data Entry. Set:

- **Entry Date** = Click , select 14/11/18.
- **Medication Code #** = 2524
- **Date of Birth** = Click , select 11/05/1969.

Click .



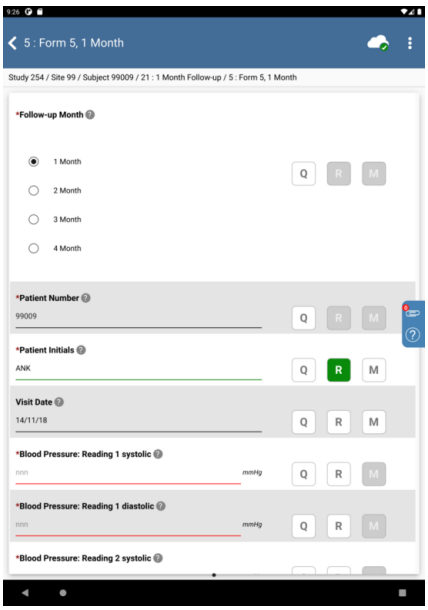
18.3.12. Click > > **99009 : (Incomplete)** > **21: 1 Month Follow-up** > **5: Form 5, 1 Month**.



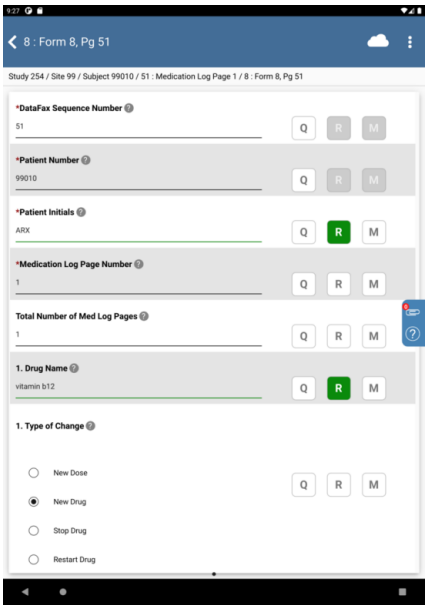
18.3.13. Click **Patient Initials**. The initials automatically populate this field as a result of the edit check SetInitdescribed in Module 8. Image Data Entry. Set:

- **Visit Date** = Click , select 14/11/18.

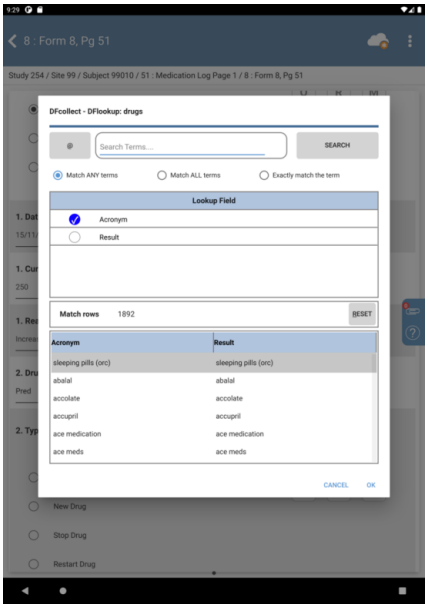
Click .



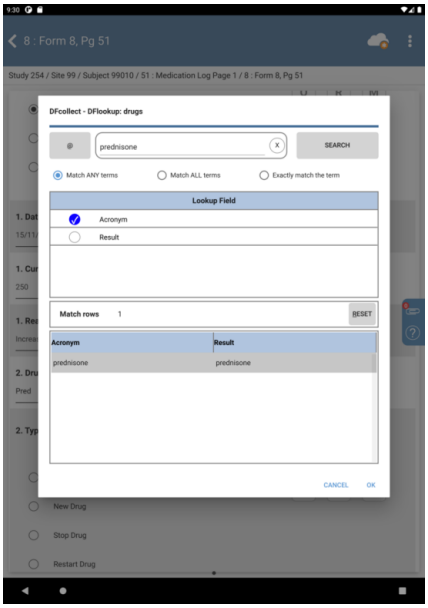
18.3.14. Click > > **99010 : (Incomplete) 51: Medication Log Page 1** > **8: Form 8, Pg 51**.



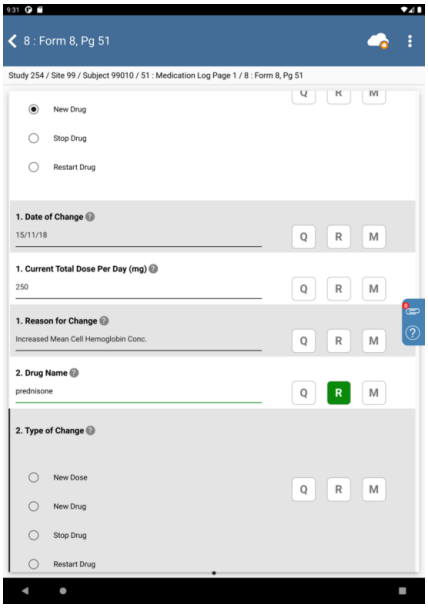
18.3.15. Enter Pred in the **2. Drug Name** text field, select the **Type of Change** field. Upon leaving the field, an edit check is executed and **DFlookup: drugs** dialog appears.



18.3.16. Enter prednisone in the **Search Terms**, Check **Match ANY terms**. Click Search to filter results.



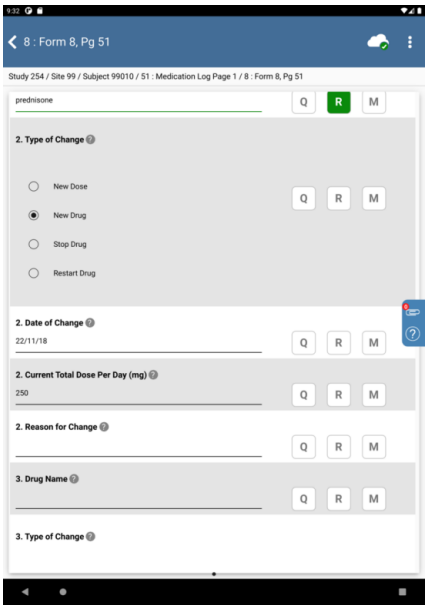
18.3.17. Locate the entry for **prednisone** in the results table. Double-click the entry to auto-populate the field. The **2. Drug Name** field is auto-populated with prednisone, the field contains a **Reason for Data Value** and **Type of Change** field gains focus.



18.3.18. Beginning with the **Type of Change** field complete the remaining data fields as follows:

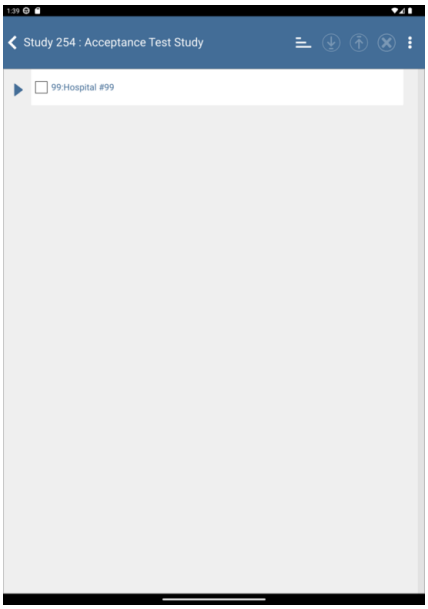
- **Type of Change** = Select **New Drug**
- **Date of Change** = Select 22/11/18
- **Current Total Dose Per Day** = 250

Click .

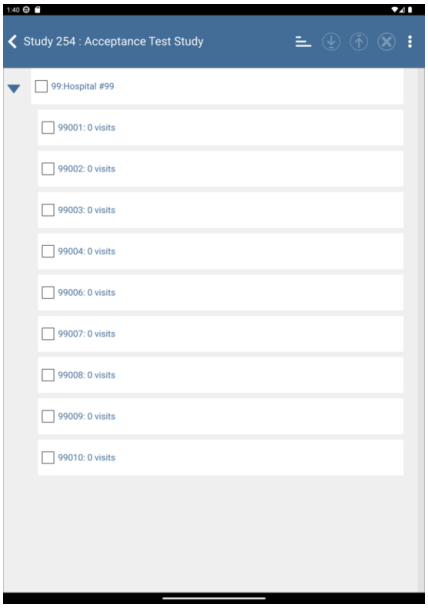


18.4 Download subject data for offline use

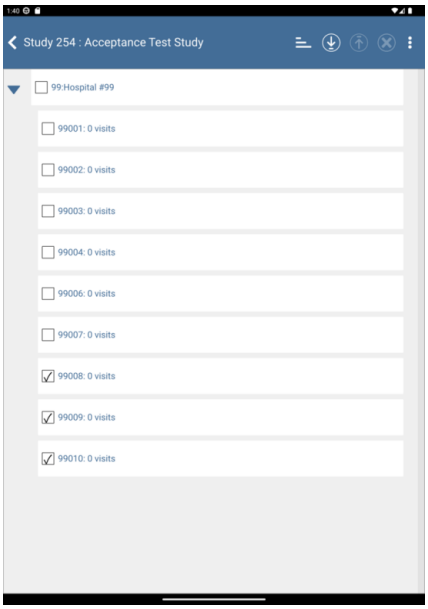
18.4.1. Click > Storage & Syncing.



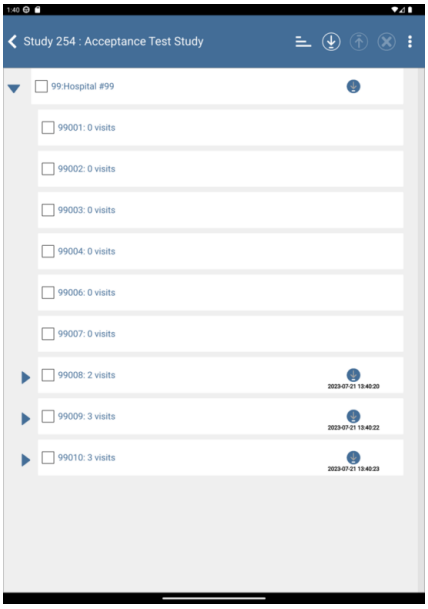
18.4.2. Click ▶ to show the subject listing for **99: Hospital #99**.



18.4.3. Check (enable) subjects **99008: 0 visits**, **99009: 0 visits** and **99010: 0 visits**.



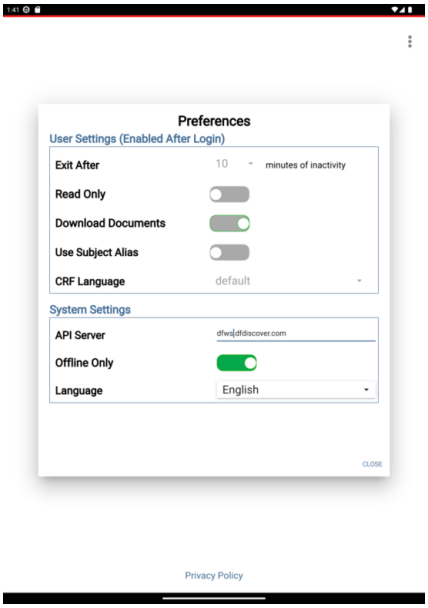
18.4.4. Click to download the subjects. After completion, click OK to dismiss the **Download Progress: Data** window. Upon successful download there is an icon showing the date and time the download was performed.



18.4.5. Click ⋮ > Logout to logout of **DFcollect**.

18.5 Create data records in offline mode, query resolution and adding reasons for data values

18.5.1. Click ⋮ > **Preferences** > **Offline Only** toggle button to enable Offline Only mode (becomes green). Click Close.



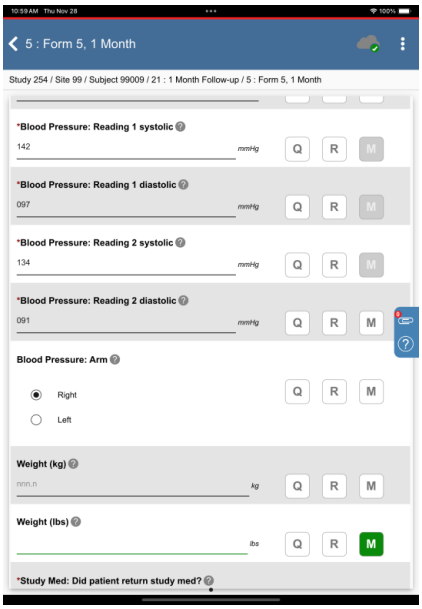
18.5.2. In the **DFcollect** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. Enter site_monitor in the **Username** field and the previously assigned password in the **Password** field. Click Login to login.



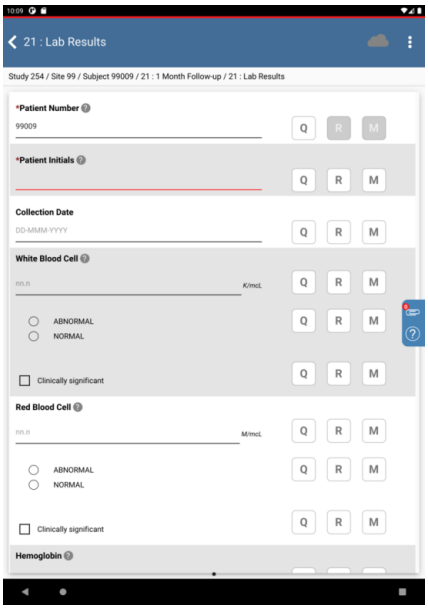
18.5.3. Click **99: Hospital #99** > **99009 : (incomplete)** > **21: 1 Month Follow-up** > **5: Form 5, 1 Month**. Set:

- **Blood Pressure: Reading 1: systolic** = 142, **diastolic** = 097
- **Blood Pressure: Reading 2: systolic** = 134, **diastolic** = 091
- **Blood Pressure: Arm** = Right
- **Weight (lbs)** = Click M, select **Missing Value** from the **Code** drop-down list. Click Apply.

Click . Click Cancel in the resulting **Add Query** dialog.

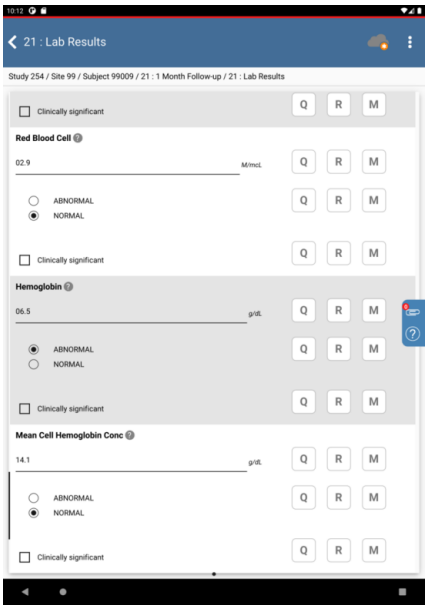


18.5.4. Click > **21: Lab Results**.



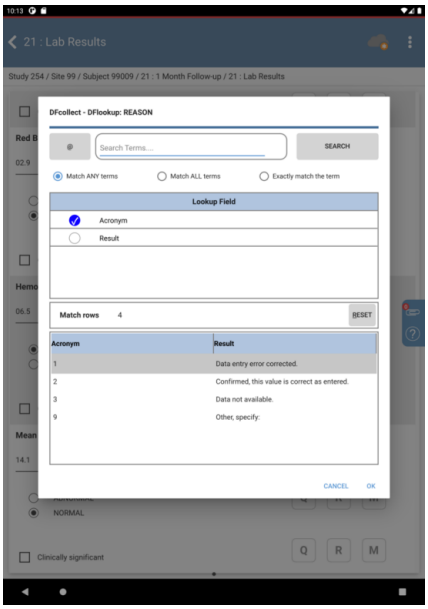
18.5.5. Click **Patient Initials**. The initials automatically populate this field as a result of the edit check SetInitdescribed in Module 8. Image Data Entry, Set:

- **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**

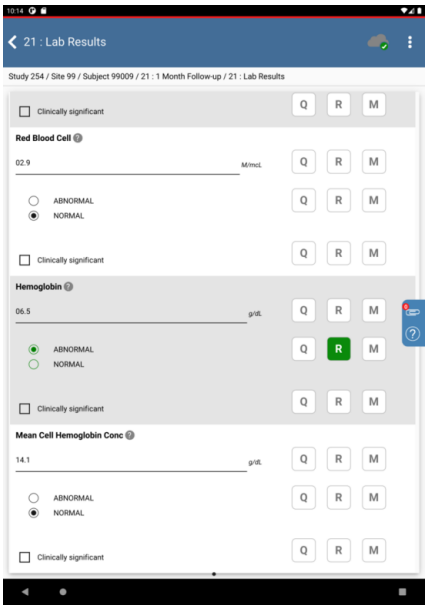


18.5.6. Click R, to the right of the **Hemoglobin** "[ABNORMAL/NORMAL]" field.

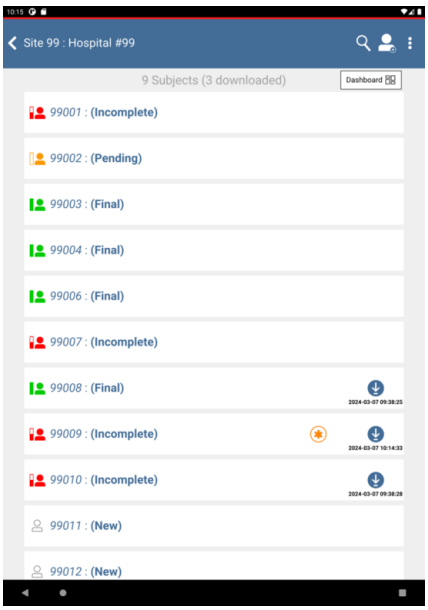
18.5.7. Click ... next to **Reason**. The **DFlookup: REASON** dialog is displayed.



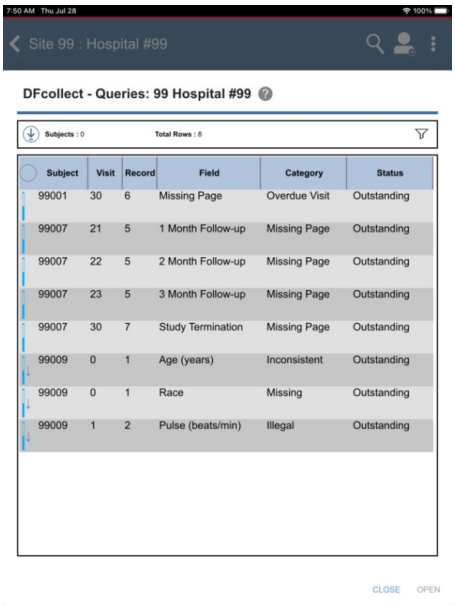
18.5.8. Select the **Result** of **Confirmed, this value is correct as entered.**, Click OK, followed by Apply then Click .



18.5.9. Return to the subject listing for **99: Hospital #99** by clicking > .

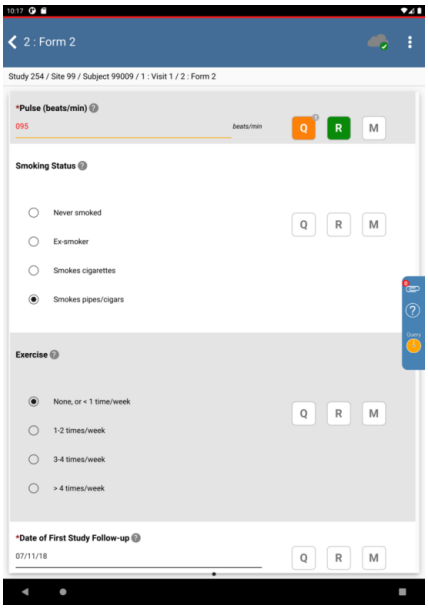


18.5.10. Click ⋮ > Query View to view outstanding queries.

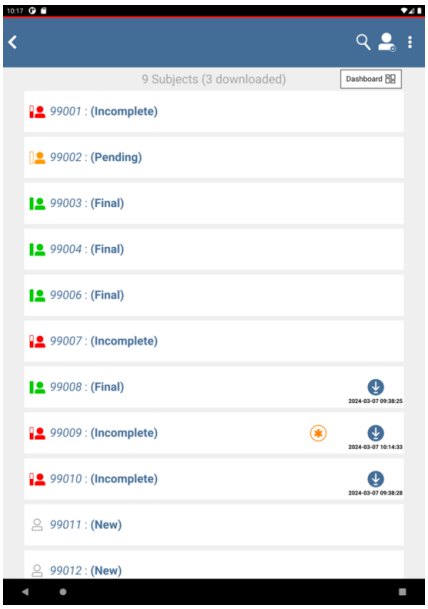


18.5.11. Locate and select the outstanding query for subject **99009** > **Pulse(beats/min)** field. Click Open. The **Pulse(beats/min)** field gains focus.

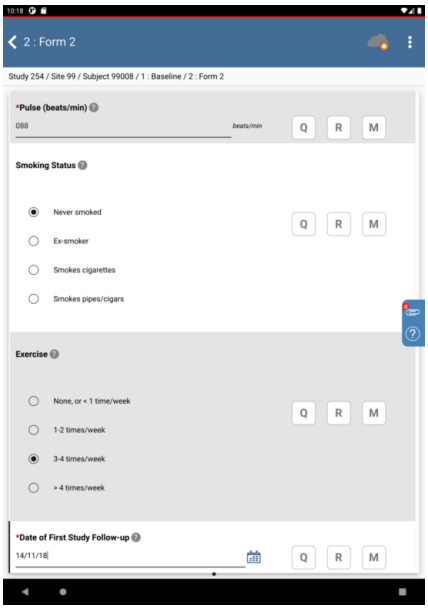
18.5.12. Click R next to the **Pulse** field. In the **Reason** field specify Value of 95 for pulse is confirmed.. Click Apply > .



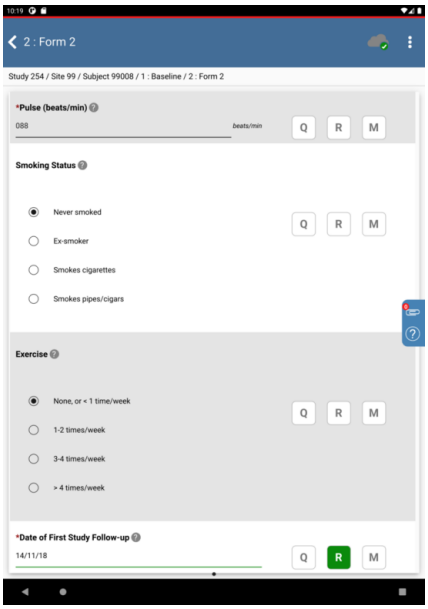
18.5.13. Click to return to **Query View**. Confirm the outstanding query for **99009** > **Pulse(beats/min)** field is no longer present. Click Close.



18.5.14. Click **99008 : (Final)** > **1: Baseline** > **2: Form 2**. In the **Date of First Study Follow-up** field click , select 14/11/18.



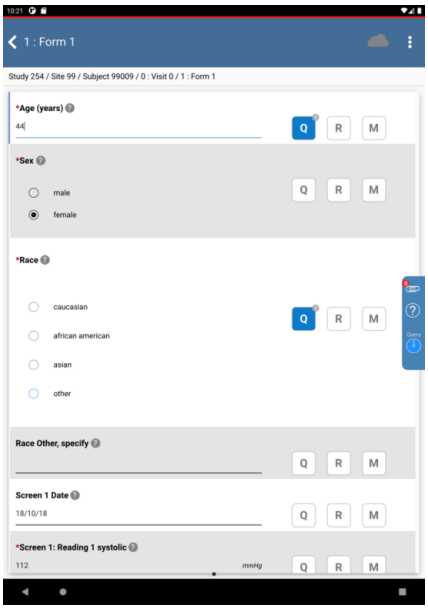
18.5.15. Click R. In the **Reason** field specify Subject has to reschedule due to conflict.. Click Apply > .



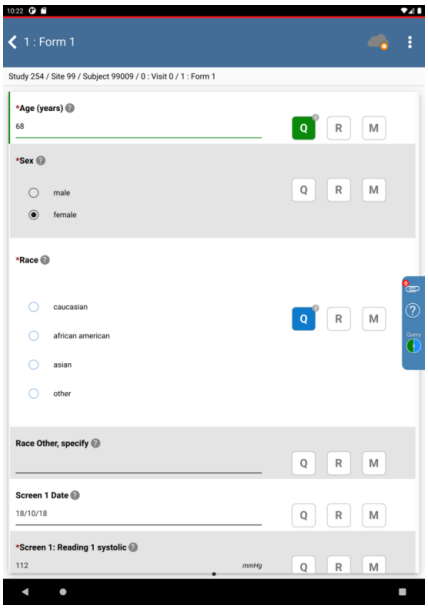
18.5.16. Return to the subject listing for **99: Hospital #99** by clicking < > <. Re-open **Query View** by clicking ⋮ > Query View.



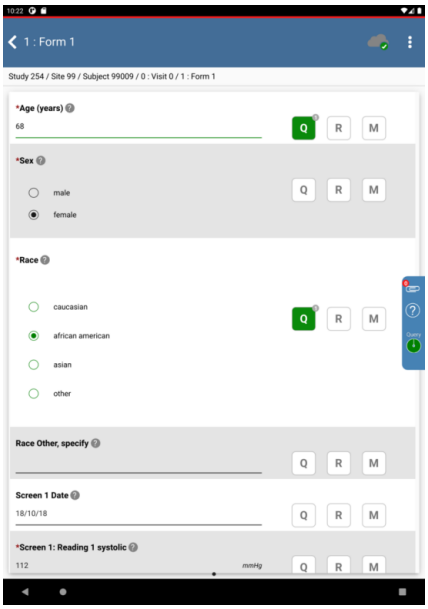
18.5.17. Locate and select the outstanding query for subject **99009** > **Age (years)**. Click Open. The **Age (years)** field gains focus.



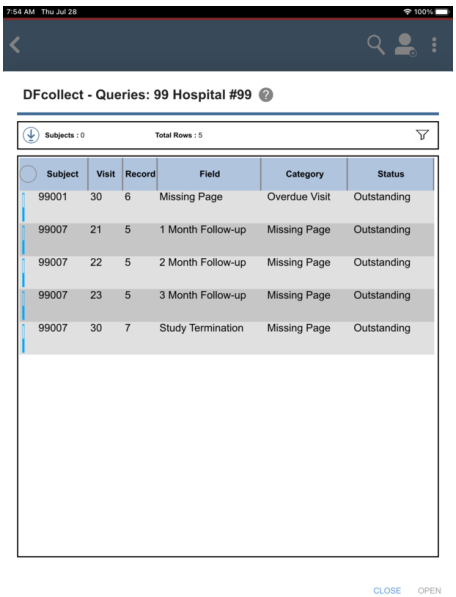
18.5.18. Correct **Age (years)** from 44 to 68. Click Q > *, select **Resolved** from the **Status** drop-down list. Click Apply > Close.



18.5.19. Click **Race**. Select **african american**, the query box changes from outstanding to resolved. Click .



18.5.20. Click to return to **Query View**. Confirm the outstanding query for **99009** > **Age (years)** and **Race** fields are no longer present. Click Close.

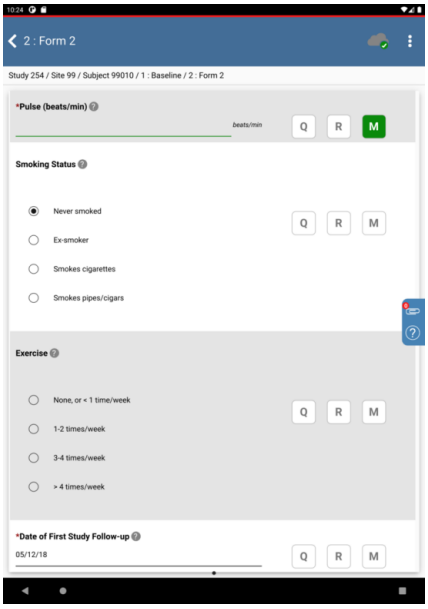


18.5.21. Click **99010 : (Incomplete)** > **1: Baseline** > **2: Form 2**. Set:

- **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 .

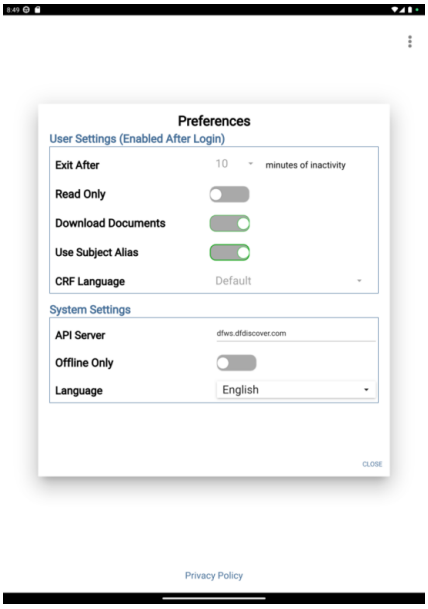
NOTE: The **Weight (kgs)** and **Height (cm)** fields are auto-populated as a result of edit checks.



18.5.22. Click > Logout, to logout of **DFcollect**.

18.6 Sync data collected offline to your **DFdiscover** server

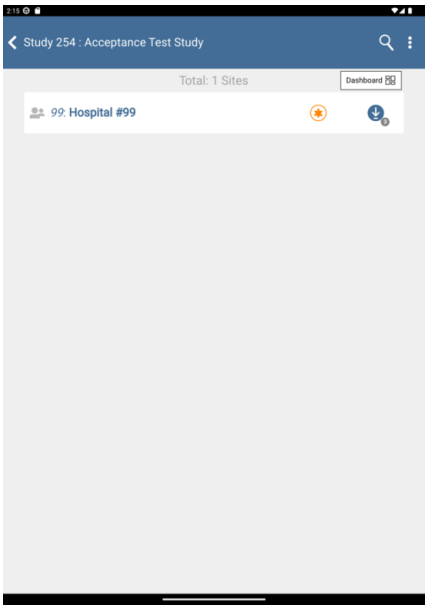
18.6.1. Click > **Preferences** > **Offline Only** toggle button to disable the Offline Only mode (becomes greyed out). Click Close.



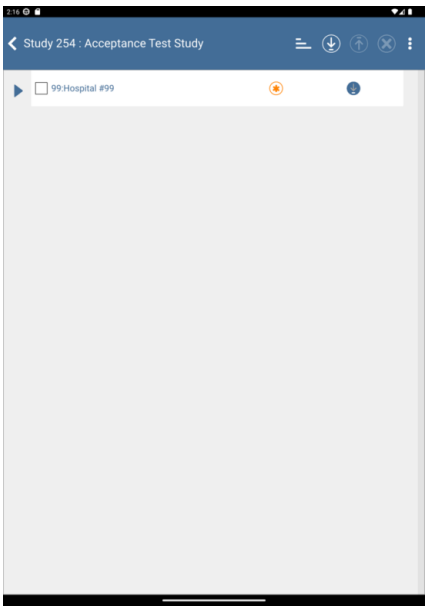
18.6.2. In the **DFcollect** login dialog, enter the name for **DFdiscover Server** that has been provided by your administrator. Enter site_monitor in the **Username** field and the previously assigned password in the **Password** field. Click Login to login.



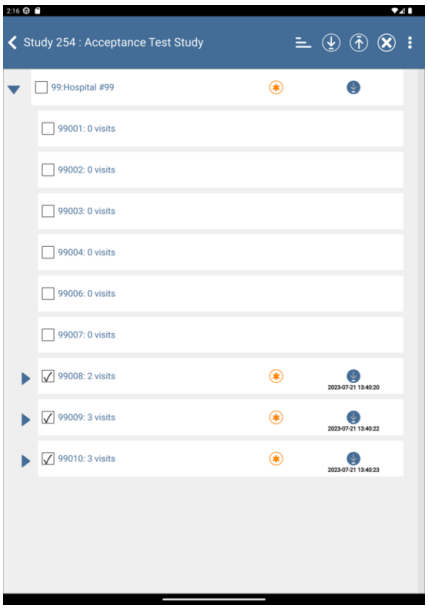
18.6.3. Upon logging into **DFcollect**, the ✱ icon is displayed next to **99: Hospital #99** indicating there are cached changes in **DFcollect** that have not been saved to the database.



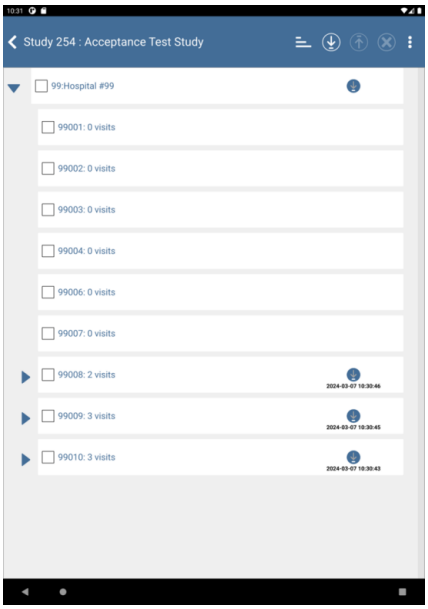
18.6.4. Click ⋮ > Storage & Syncing.



18.6.5. Click ▶ to expand list of subjects. Check (enable) subjects **99008: 2 Visits**, **99009: 3 visits** and **99010: 3 visits**.

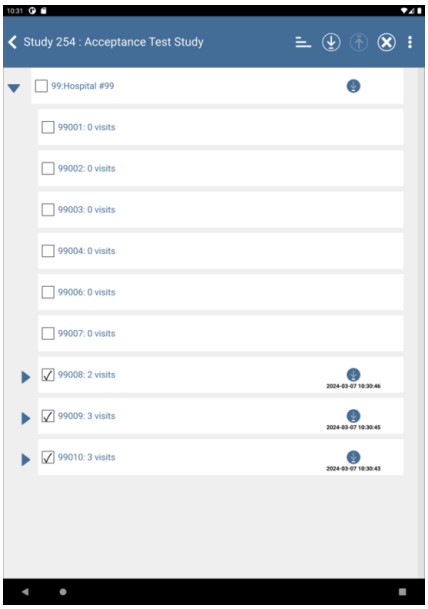


18.6.6. Click ⬆ to upload the previously entered subject data. When the upload is complete, click OK to dismiss the **Upload Progress** window. The ℹ icon shows the date and time of successful upload.

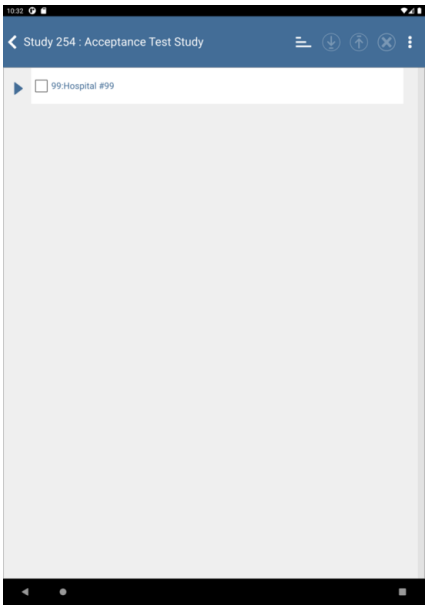


18.7 Clearing DFcollect cache

18.7.1. Check (enable) subjects **99008: 2 visits** , **99009: 3 visits** and **99010: 3 visits**.

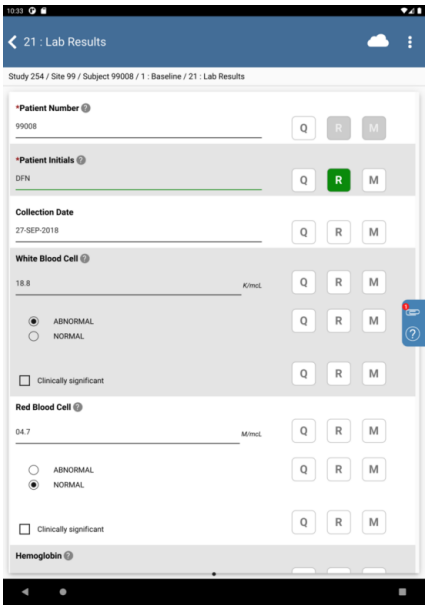


18.7.1. Click then Apply within the **Delete Records from Storage** dialog. The icon showing the date and time are cleared.

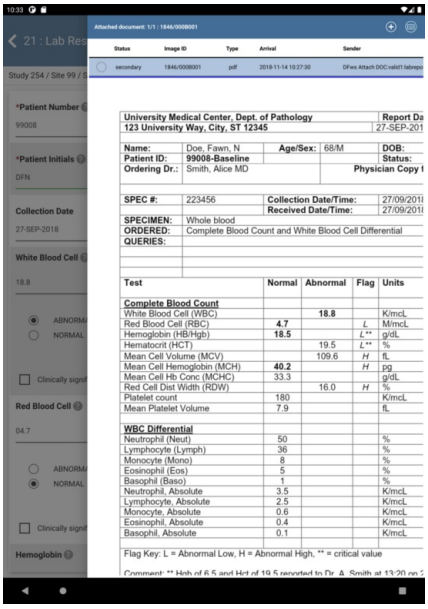


18.8 Adding, reviewing and downloading subject documents

18.8.1. Click > **99008 : (Final)** > **1: Baseline** > **21: Lab Results**.



18.8.2. Click to view the attached documents.



18.8.3. Click ⋮ > Logout.

18.9 Confirming data sent to the server using **DFexplore**

18.9.1. Start **DFexplore**, login as data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

18.9.2. Select **Site 99: Hospital #99** > subject **99009** > **0: Screening Visits** > **1: Form 1**. Verify and review the data uploaded is correct.

- **Age (years)** = 68 with a resolved corrected query.
- **Race** = 2 (african american) with a resolved corrected query.

18.9.3. Select **File** > Exit to close **DFexplore**.

18.10 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.

18.10.1. 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.

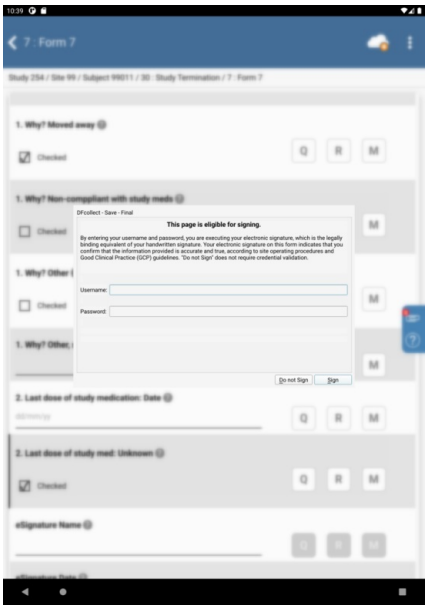
18.10.2. As user site_invest has 2FA enabled, enter security code received by email or SMS as previously defined.

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.

18.10.1. From the **Subjects** list, click Subject **99011** > **30: Study Termination** > **7: Form 7**.

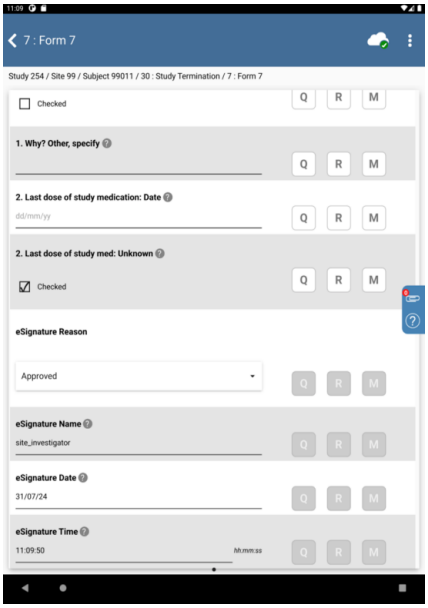
18.10.2. Click **Patient Initials** enter SIG, Set:

- **Final Visit Date** = 03/06/22
- **1. Did patient complete the entire study?** = **No**
- Check (enable) **Why? Moved away**
- Check (enable) **2. Last dose of study medication: Unknown**
- Click . to save and eSign the **Study Termination** form.



18.10.3. 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.

18.10.4. In the **DFcollect - eSignature Reason** dialog select **Approved** from the dropdown, click OK.



18.10.5. Examine the 4 eSignature fields at the bottom of the page.

18.10.6. Click ⋮ > Logout to exit **DFcollect**.

18.11 Verify removal and re-application of eSignatures

18.11.1. 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.

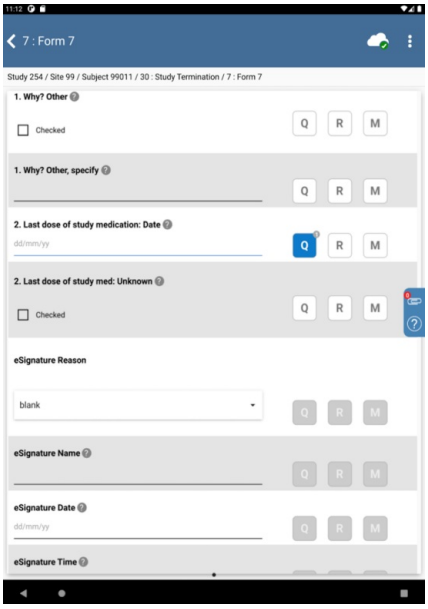
18.11.2. From the **Subjects** list, click Subject **99011** > **30: Study Termination** > **7: Form 7**.

18.11.3. Click **2. Last dose of study medication: Date** 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 to apply the query.

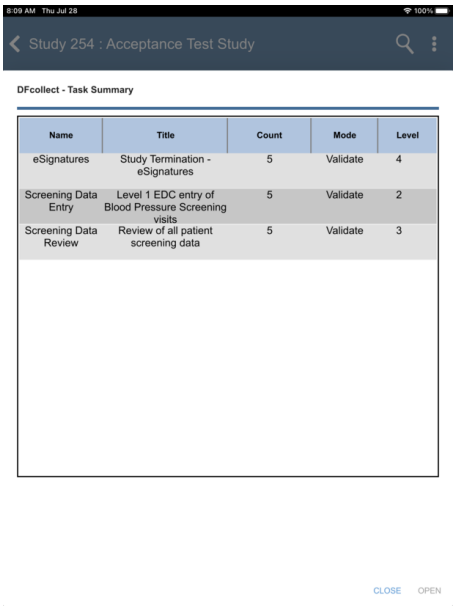
18.11.4. Advance to the **2. Last dose of study med: Unknown** field. Un-check (disable) the checkbox. Click .



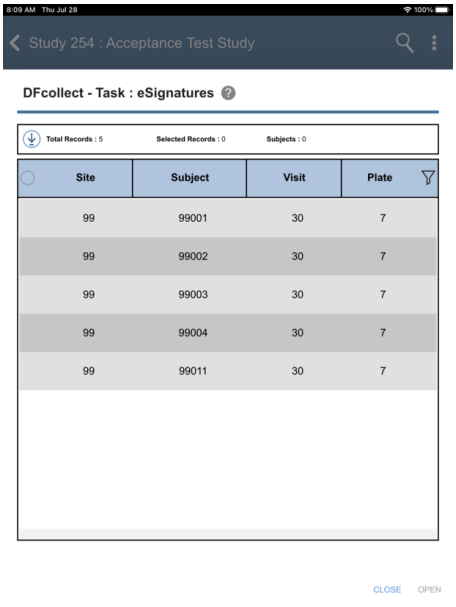
18.11.5. Click > Logout to exit **DFcollect**.

18.11.6. 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.

18.11.7. Click > Task listing.

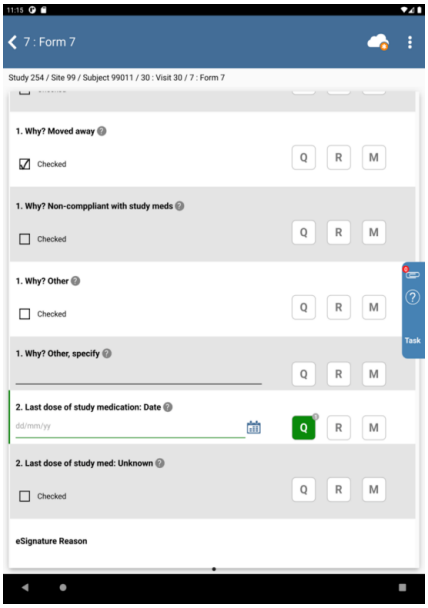


18.11.8. Locate the **eSignatures - Study Termination - eSignatures** task. Click Open.



18.11.9. From the **Subjects** list, select subject **99011** > **30: Study Termination** > **7: Form 7**. Click Open

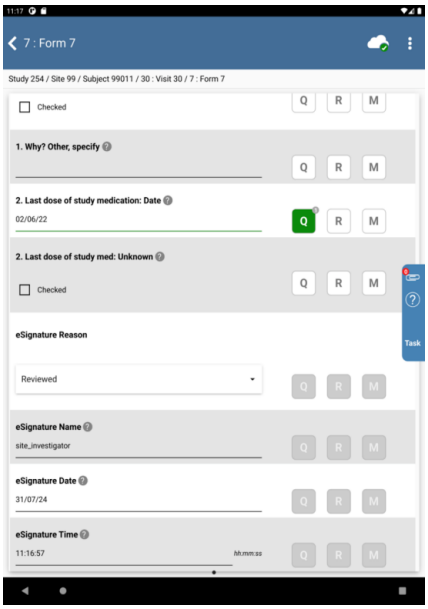
18.11.10. Click the **2. Last dose of study medication: Date** field. Click then *. Select **Resolved** from the **Status** drop-down list. Enter Confirmed date of last medication dose verbally with subject during clinic visit. in the **Note** field. Click Apply, Close.



18.11.11. Enter the **2. Last dose of study medication: Date** as 02/06/22. Click .

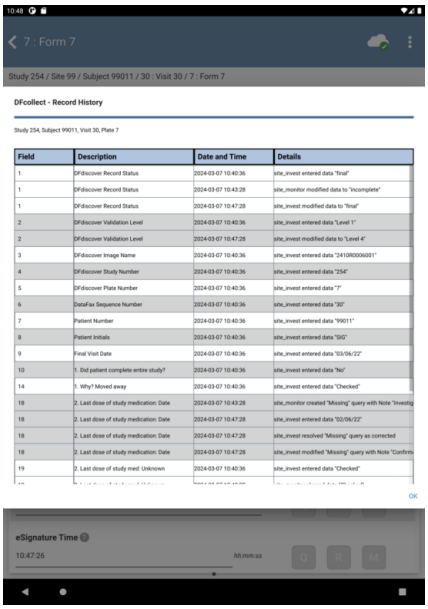
18.11.12. In the **dfpassword** confirmation dialog enter the user name site_invest and the corresponding password used for login in "Add an Electronic Signature (eSign) to a set of completed subject records.". Click Sign to apply the electronic signature to the current page.

18.11.13. In the **DFcollect - eSignature Reason** dialog select **Reviewed** from the dropdown, click OK.



18.11.14. Examine the 4 eSignature fields at the bottom of the page.

18.11.15. Click ⋮ > Page History to open the **Page History** window. The **Page History** is displayed, Click OK to close the window.

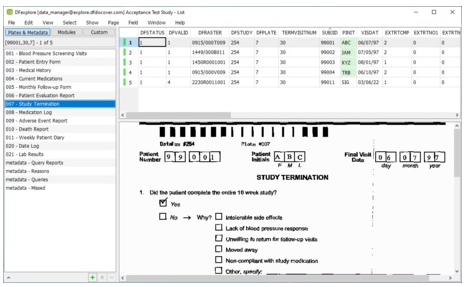


18.11.16. Click ⋮ > Logout to exit **DFcollect**.

18.12 Verify **DFcollect** saves eSignature task data to the specified level

18.12.1. Start **DFexplore**, login as data_manager and choose **254 Acceptance Test Study** as described in "How to start **DFexplore**"

18.12.2. Select View > List. Click **007 - Study Termination**. Confirm **DFVALID** displays as "4" for subject **99011**.



18.12.3. Select File > Exit to close **DFexplore**.

18.13 Verify no saved data remains upon uninstallation and reinstallation of **DFcollect**.

18.13.1. 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 assigned password in the **Password** field. Click Login to login.



18.13.2. Click ⋮ > Storage & Syncing.

18.13.3. Click ▶ to show the subject listing for **99: Hospital #99**.

18.13.4. 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.

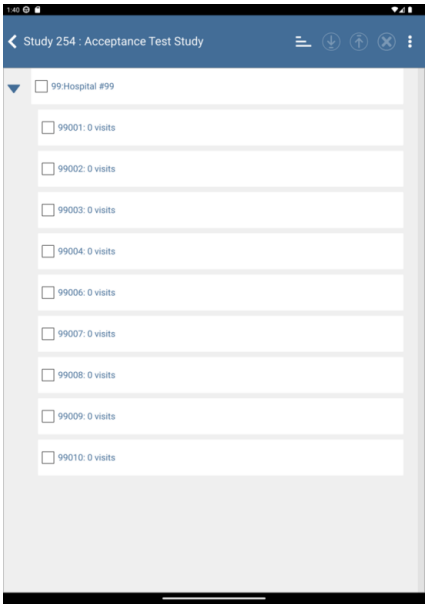
18.13.5. Click ⋮ > Logout to logout of **DFcollect**. Then, close the application.

18.13.6. Using your mobile device's normal unistallation tools, uninstall/remove **DFcollect** from the device.

18.13.7. 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.

18.13.8. Click ⋮ > Storage & Syncing, then ▶ to show the subject listing for **99: Hospital #99**.

18.13.9. 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.



18.13.10. 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.

19 Module 19. DFengage ePRO Data Entry

Overview

Prerequisites:

- Completion of module 1 of Acceptance Test Kit
- DFws 5.11.3 installed and properly configured on DFws server
- DFweb 5.11.3 installed and properly configured on DFweb server
- DFengage 2.6 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 15.0 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

Primary Component: 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 Language can be changed.
11. Confirm logout of **DFengage** application clears data history.
12. 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).

   Expected Result: DFATK starts successfully.

2. Click 19. DFengage ePRO Data Entry followed by Begin.

   Expected Result: Module 19 begins.

19.1 Create **DFengage** users role in **DFadmin**

19.1.1. Start **DFadmin**.

a. Specify the **DFdiscover** Server provided by your administrator.

b. Specify the **Username** as datafax and enter the assigned user password in the **Password** field.

c. Click Login to complete login and continue.

Expected Result: Login is successful.

19.1.2. Open the **Roles** tab. Within the list of studies, select **254 Acceptance Test Study**.

a. Click New to add a new user role.

b. In the dialog, enter the role name ePROdata.

c. Click Create.

Expected Result: The ePROdata role is created.

19.1.3. Select the ePROdata role and enter ePROdata user permissions in the **Description** field.

19.1.4. In the **Tools & Reports** tab, below the **Description** field, set the following:

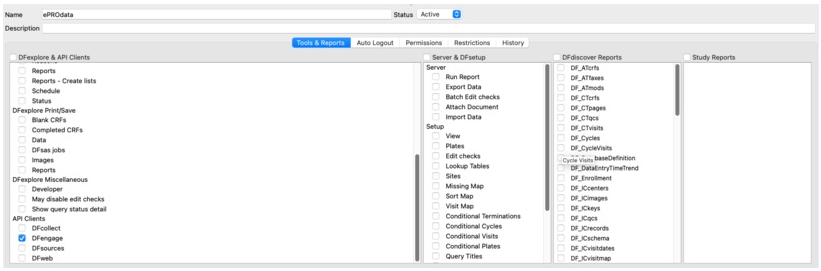
In the **DFexplore & API Clients** panel,

a. Check (Enable) **Data** within **DFexplore Views**

b. Check (Enable) **DFengage** and **DFweb** within **API Clients**

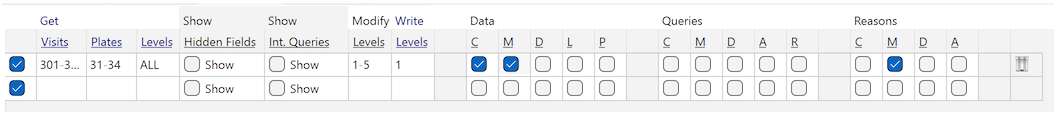
In the **Server & DFsetup** panel,

c. Check (Enable) **View** within **Setup**



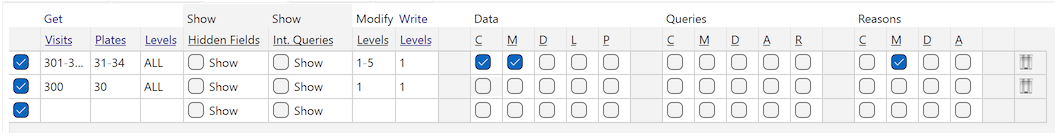
19.1.5. Click the **Permissions** tab. Set plates 31-34 data permissions as follows:

- **Visits** = 301-303,310-319
- **Plates** = 31-34
- **Levels** = ALL
- **Modify** = 1-5
- **Write Levels** = 1
- **Data** = Check (enable) CM (Create, Modify)
- **Reasons** = Check (enable) M (Modify)



19.1.6. Set plate 30 data permissions as follows. Then Select File > Save or click Save.

- **Visits** = 300
- **Plates** = 30
- **Levels** = ALL
- **Modify** = 1
- **Write Levels** = 1



Expected Result: The updated ePROdata role is saved with the above criteria.

19.1.7. Open the **Users** tab. Select site_monitor to make it the active user. Enter the details as instructed below:

a. Click **ePRO Admin Permissions**.

b. 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 **ePRO Admin permissions** as follows and then select File > Save or click Save.

- **Type** = Admin
- **Sites** = 99

Expected Result: The site_monitor admin permissions are saved.

19.1.8. Select dfeproagent to make it the active user.

a. Click the **Permissions** tab and add a row for the ATK study with the following values. Then select File > Save or click Save.
- **Study** = 254 Acceptance Test Study
- **Sites** = ALL
- **Subjects** = ALL
- **Role Name** = **ePROdata**

Expected Result: The dfeproagent permissions are saved.

19.2 Add bulk **DFengage** users accounts to **DFadmin**

19.2.1. Still as datafax and with the **DFadmin** application open, click **Users** tab to open the user definition window.

a. Click Add Bulk Users.

b. Set the following:

- **Study** = **254 Acceptance Test Study**
- **Role** = **ePROdata**
- **Username Prefix** = atk_
- **Subjects Range** = 99001-99015

c. Check (enable) **Preview usernames**

d. Set an **Initial Password** by entering a password of your choice.

e. Click Add 15 user accounts, in the resulting confirmation dialog click Yes to add the defined user accounts.

f. Click Close.

Expected Result: 15 users (atk_99001 - atk_99015) with the **ePROdata** role are created.

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

19.2.2. Select user **atk_99015**.

a. Click **Permissions** tab.

b. Confirm the following permissions are set:

- **Study** = **254 Acceptance Test Study**
- **Sites** = 99
- **Subjects** = 99015
- **Role Name** = **ePROdata**

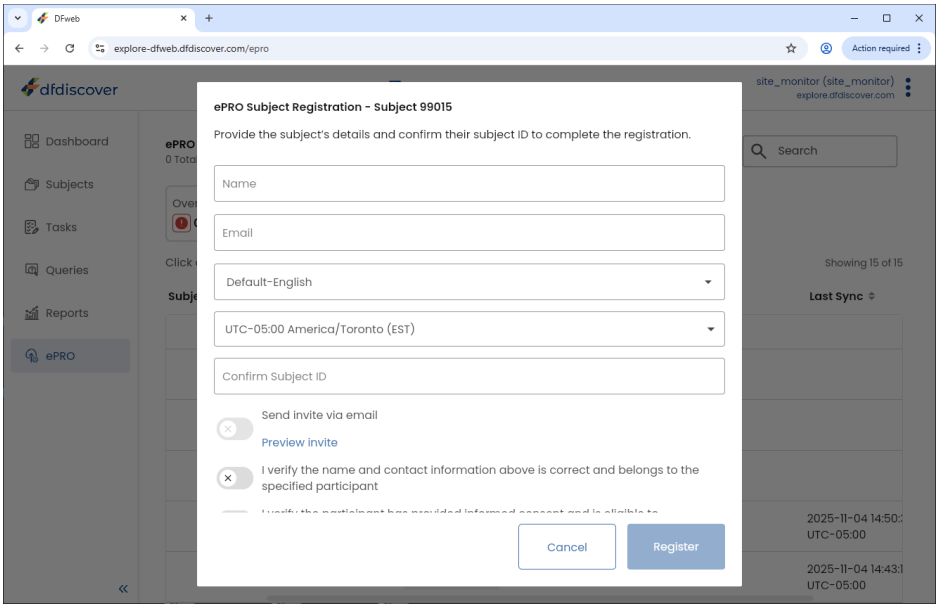
Expected Result: Permissions for user **atk_99015** are as specified above.

19.2.3. Select File > Save > Exit to close **DFadmin**.

19.2.4. 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.

Expected Result: Login to **DFweb** is successful.

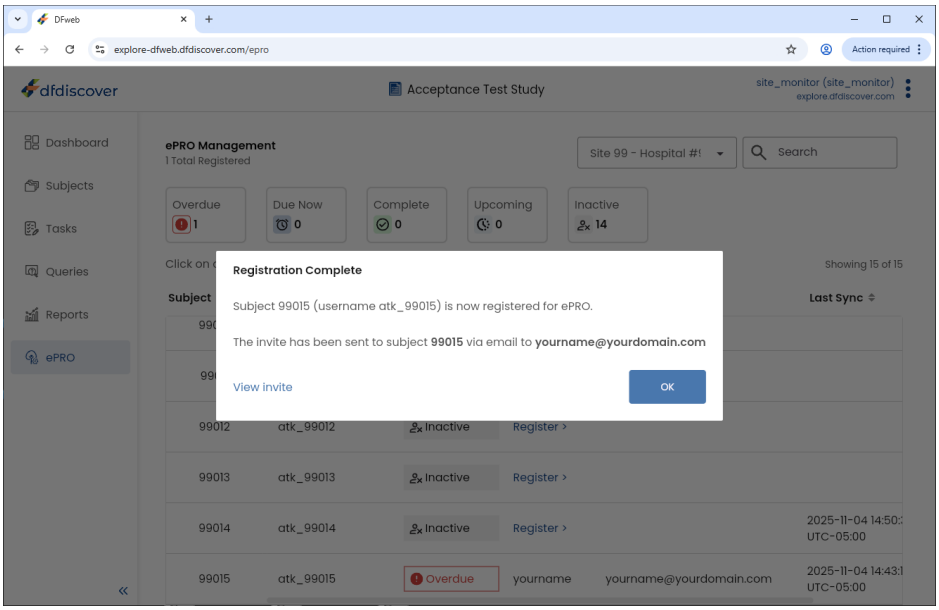
19.2.5. From the sidebar, Click **ePRO**. Locate the subject 99015 with username atk_99015. Click **Register**.



a. 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

b. Click Register > OK.



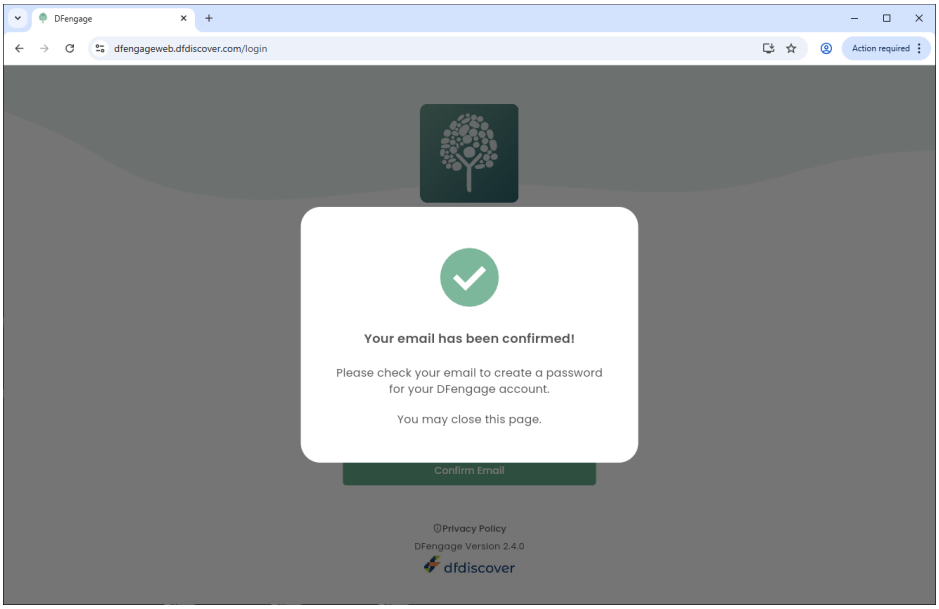
Expected Result: ePRO registration for user **atk_99015** is completed.

19.2.6. Click View invitation to 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.

Expected Result: The invitation is received by email and the invite link opens DFengage login screen with the server and username displayed with a message '*Please confirm your email address*'.

19.2.7. Enter the email address specified during the **ePRO Subject Registration** process. Click Confirm Email.

Expected Result: A confirmation dialog is displayed noting your email has been confirmed.



19.2.8. Close the **DFengage** web browser window.

19.3 Installation and initial DFengage login

19.3.1. Open a web browser and navigate to https://dfweb.dfdiscover.com/?server=explore.dfdiscover.com&api=dfws.dfdiscover.com or the DFengage web URL provided by your administrator.

a. Enter site_monitor in the Username field of the login dialog and the previously assigned password in the **Password** field.

b. Click Login.

Expected Result: Login to **DFweb** is successful.

19.3.2. From the sidebar, Click **ePRO**. Select subject 99015 with username atk_99015 to open the **ePRO Subject Details** dialog.

a. Click **Get link/QR code** and under the Login Link section use the link or QR code to install **DFengage**.

b. Once it's installed click the link or scan the QR code again to auto-fill the server, API, and username.

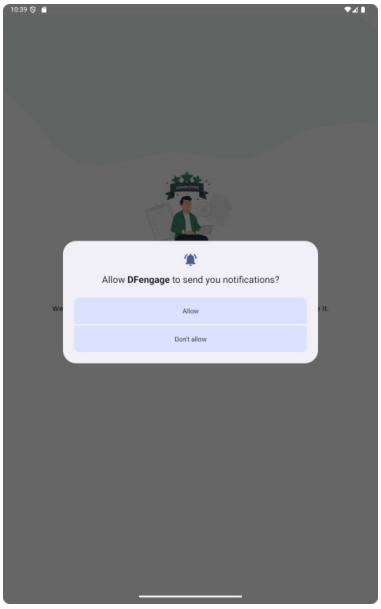
c. Open **DFengage**.

Expected Result: DFengage opens successfully.

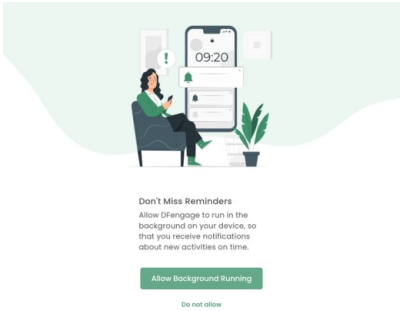
19.3.3. Click Get Started. Enter the previously assigned password in the **Password** field. Click Login to login. The change password dialog is presented. Enter a password of your choice and click Set new password.

19.3.4. The **Pincode setup** dialog is presented. Enter any 4-digit numeric pincode. Click Continue.

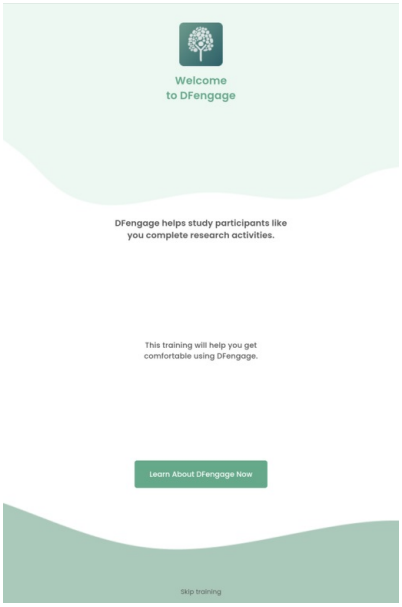
19.3.5. **DFengage** may ask to enable notifications. Click Allow or follow your device's instructions to enable notifications. If no such prompt appears, proceed to Language selection.



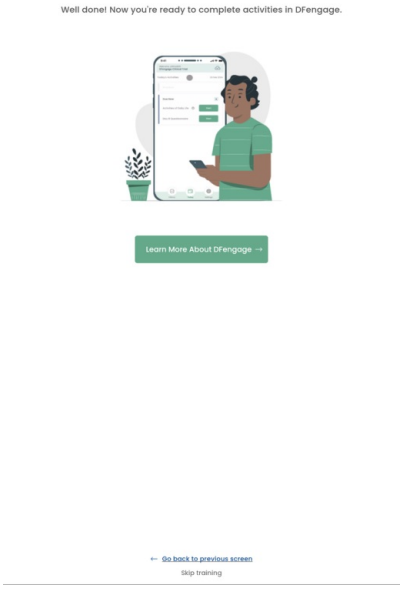
19.3.6. **DFengage** may ask to run in the background. Click Allow Background Running and follow any steps needed to enable background running. If no such prompt appears, proceed to Language selection.



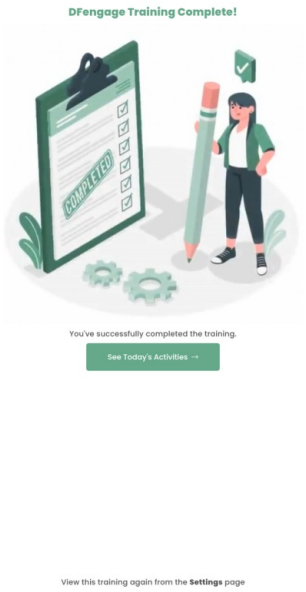
19.3.7. Select **default** from the **Pick Your Language** dropdown and click Continue. The **DFengage** training prompt is displayed. Click Learn about DFengage now.



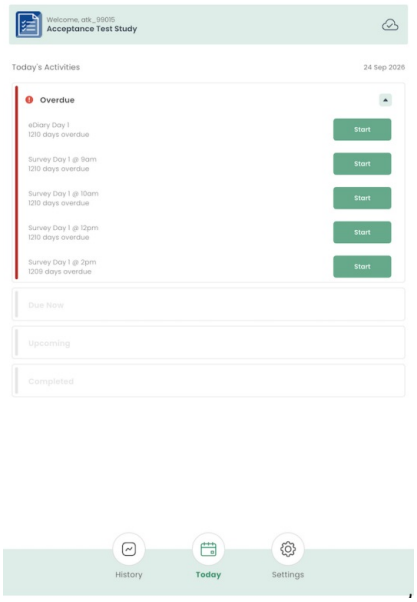
19.3.8. Proceed through the tutorial by clicking Next until you reach the end of the first section. Click Learn More About DFengage to continue to the second section of the tutorial.



19.3.9. Click Next to proceed until all training slides are complete. Click See Today's Activities to proceed to the main activity page.



Expected Result: The Today's Activities page shows the logo for the ATK alongside the ATK study name and a welcome for **atk_99015**.



19.4 Complete a task in online mode

19.4.1. Click Start next to **eDiary Day 1**.

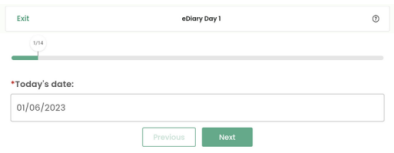
19.4.2. Click **Today's date**.

a. Select a date of 01 Jun 2023.

b. Click OK.

c. Click Next.

Expected Result: The date field is displayed as 01/06/2023 and user is navigated to next question



19.4.3. Complete the remaining **eDiary Day 1** questions. For **What time is it?**, enter 14:45. Click OK and then click Next.

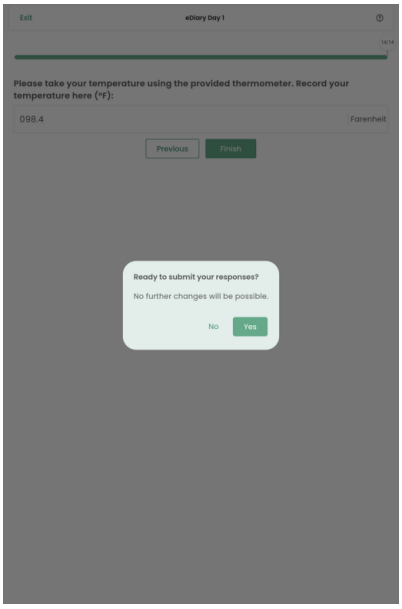
Expected Result: The time field is displayed as 14:45:00 and user is navigated to next question.

19.4.4. Continue entering the following and clicking Next on each screen. Once entered, click Finish. Then click Yes.

- **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
- **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)

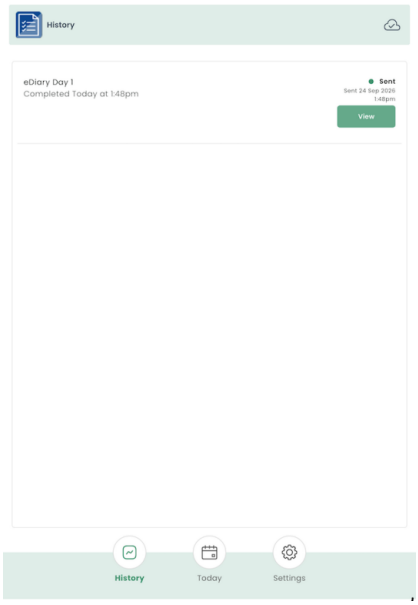
- **On a scale of 1 to 10, with 1 being the least and 10 being the worst pain imaginable , how severe were your symptoms today?** = 7
- **Please take your temperature using the provided thermometer. Record your temperature here (degrees F)** = 98.4



Expected Result: Data is saved and user is navigated back to **Today's Activities**.

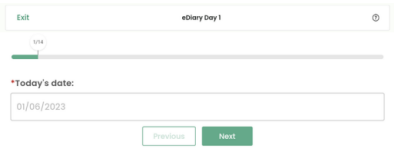
19.4.5. Click the History button to open the history page.

Expected Result: The completed **eDiary Day 1** displays as **Sent** with the date and time sent.



19.4.6. Click View for the sent **eDiary Day 1** entry.

Expected Result: The fields are unable to be changed.

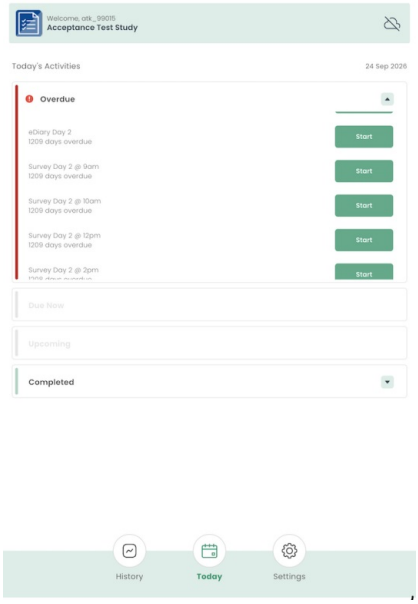


19.4.7. Close the **DFengage** application.

19.5 Complete a task in offline mode

19.5.1. Switch your device to airplane mode or otherwise disconnect from the internet.

19.5.2. Open **DFengage**. Login with your pincode. Click Start next to **eDiary Day 2**.



19.5.3. Click **Today's date**.

a. Select a date of 02 Jun 2023.

b. Click OK.

c. Click Next.

Expected Result: The date is displayed as 02/06/2023 and the user is navigated to the next question.

19.5.4. What time is it?

a. Enter 17:30

b. Click OK.

c. Click Next.

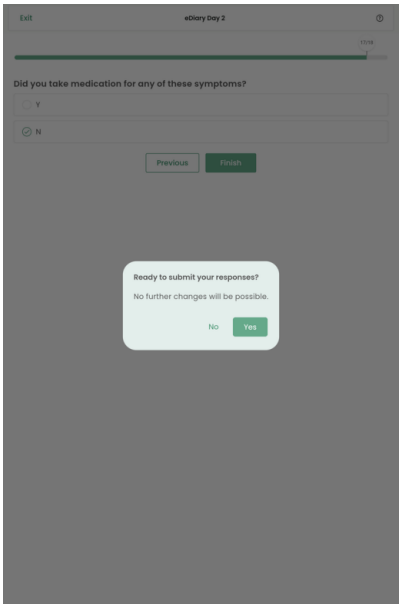
Expected Result: The time field shows as 17:30:00 and the user is navigated to the next question.

19.5.5. Confirm you have reviewed the instructions by checking (enabling) **Read and Understood (Continue to next screen)**.

a. Complete the remaining **eDiary Day 2** questions by entering the following and clicking Next on each screen. Once entered, click Finish > Yes.

- **Pain** = Quite a bit

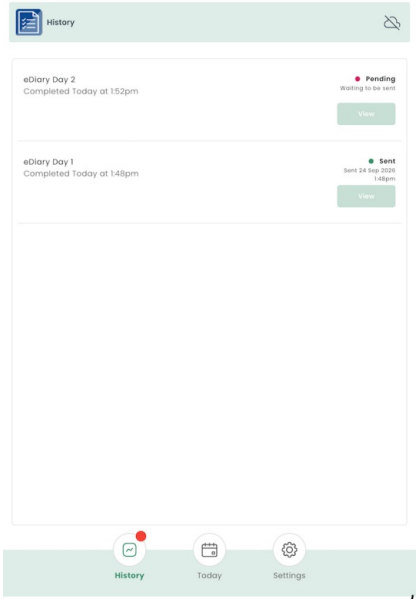
- **Redness** = Not at all
- **Swelling** = A little bit
- **Itching** = A little bit
- **Nausea/Vomiting** = Not at all
- **Headache** = Not at all
- **Fatigue** = Very Much
- **General feeling unwell** = Quite a bit
- **Joint aches** = Not at all
- **Muscle aches** = A little bit
- **Other Symptoms?** = N
- **Did you take medication for any of these symptoms?** = N



Expected Result: Questionnaire successfully saved and user is navigated back to **Today's Activities**.

19.5.6. Click History.

Expected Result: eDiary Day 2 is marked as **Pending** with the current date and time of completion and **eDiary day 1** is synced (displayed as **Sent**).



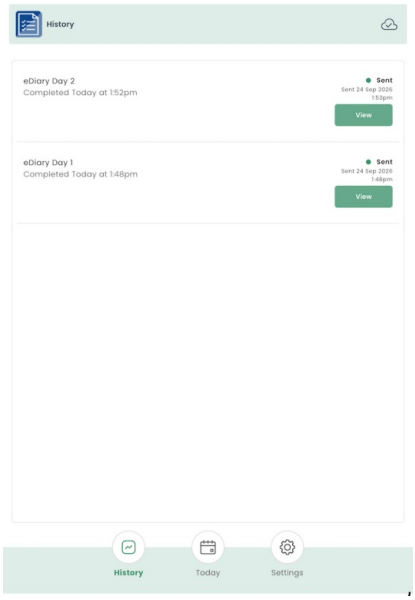
19.5.7. Close **DFengage** application.

19.6 Sync data collected offline to your **DFdiscover** server

19.6.1. Switch off airplane mode on your device or otherwise re-connect to the internet.

19.6.2. 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.

Expected Result: eDiary Day 2 is shown as **sent** with the expected date and time of sync.



19.6.3. Close **DFengage** application.

19.7 Resetting a user login password

19.7.1. 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.

19.7.2. Enter a **Username** of atk_99015. Click the Forgot Password link on the login page.

a. In the **Forgot Password** dialog enter the email address associated with the atk_99015 account.

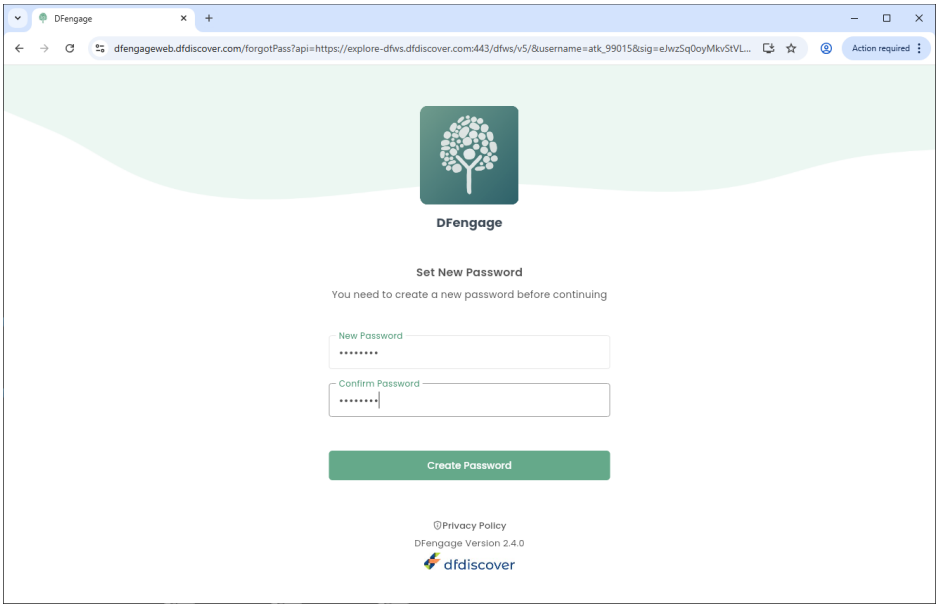
b. Click OK.

Expected Result: A confirmation message, '*Email Sent*', is displayed.

19.7.3. Open the password reset email from your **DFdiscover** server and click the provided link to reset the atk_99015 password.

a. Enter and confirm a new password.

b. Click Create Password.



Expected Result: 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.

19.7.4. Return to **DFweb**, login as user site_monitor and Click **ePRO**. Select subject 99015 with username atk_99015 to open the details dialog. Under **View logs**, click **ePRO account log** and then click **Back**>.

Expected Result: Registration audit trail can be seen.

19.7.5. Also under **View logs**, click **ePRO access log** and then click **Back**.

Expected Result: Login, start and submit activity can be seen.

19.7.6. Under **Login support**, click **Get link/QR code**. Under **Login Link**, click **Copy Link**.

Expected Result: Link is copied for next step.

19.8 Enter data in DFengage Web

19.8.1. Open a web browser and paste the previously copied login link into the address bar.

a. In the **DFengage** login dialog, enter the assigned password in the **Password** field.

b. Click Login.

c. Select **default** from the list of **Available Languages**. Click Continue.

Expected Result: DFengage 2.6.0 is opened and **default** language is selected.

19.8.2. Click Next to proceed through all training slides.

Expected Result: Training is complete.

19.8.3. Click See Today's Activities to continue to the main activity page.

Expected Result: Main activity page is open.

19.8.4. Open the activity labeled **eDiary Day 7**.

Expected Result: Activity opens to the first question, a date field.

19.8.5. Click the date selector icon and verify a future date cannot be selected. Select a date of 10 Oct 2025. Click OK and then Next.

Expected Result: The date field is displayed as 10/10/2025 and user is navigated to next question.

19.8.6. In the time dialog, select 13:20. Click OK and then Next.

Expected Result: The time field is displayed as 13:20:00 and user is navigated to next question.

19.8.7. The first set of questions relate to reactions at or around the site of vaccination. Complete as follows:

- **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?** = 100

Expected Result: A warning message appears to note the number you have selected is out of the defined range.

19.8.8. Enter the number 49, a number defined in the legal range.

Expected Result: Number is accepted with no warning message.

19.8.9. Continue completing the fields as follows. Once entered, click Finish > Yes.

- **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

Expected Result: Questionnaire successfully saved and user is navigated back to **Today's Activities**.

19.8.10. Click History to open the history page.

Expected Result: eDiary Day 7 is marked as **Sent** with correct date and time.

19.8.11. Click Logout to exit the **DFengage web** application.

19.9 Configure and receive DFengage notifications

19.9.1. Start **DFsetup**, login as data_manager, and choose **254 Acceptance Test Study** in normal access mode as described in "How to start **DFsetup**". Click View > ePRO Notifications in the file menu to open the ePRO Notifications dialog.

Expected Result: The ePRO Notifications dialog is displayed.

19.9.2. Select the Generic New Activity Reminder notification entry with **ID** 1.

Expected Result: The following details will be displayed:

Days = 0

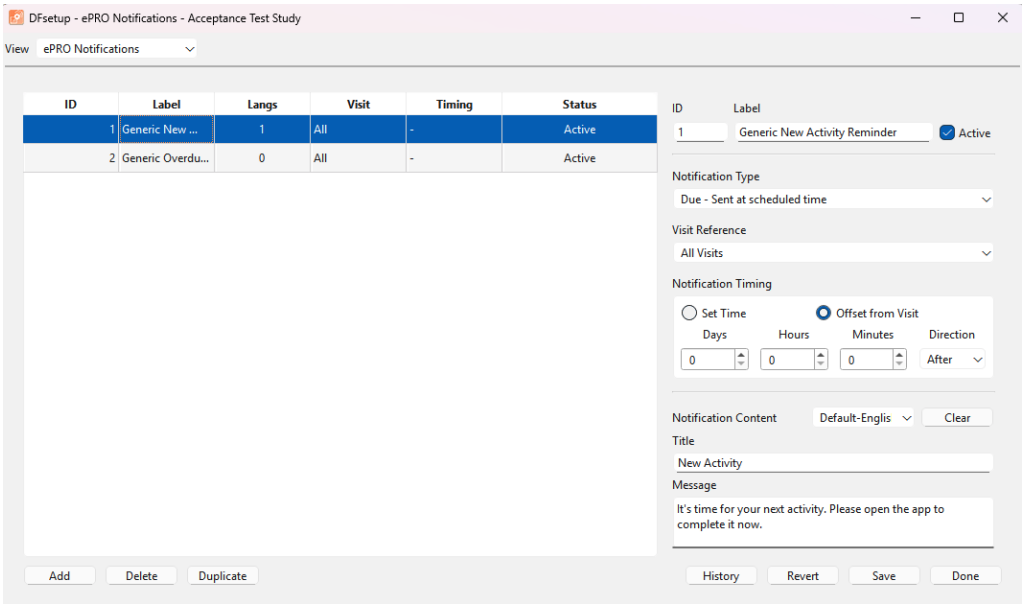
Hours = 0

Minutes = 0

Direction = After

Title = New Activity

Message = It's time for your next activity. Please open the app to complete it now.



19.9.3. Click the Generic Overdue Activity Reminder notification with **ID** 2.

Expected Result: The following details will be displayed:

Days = 0

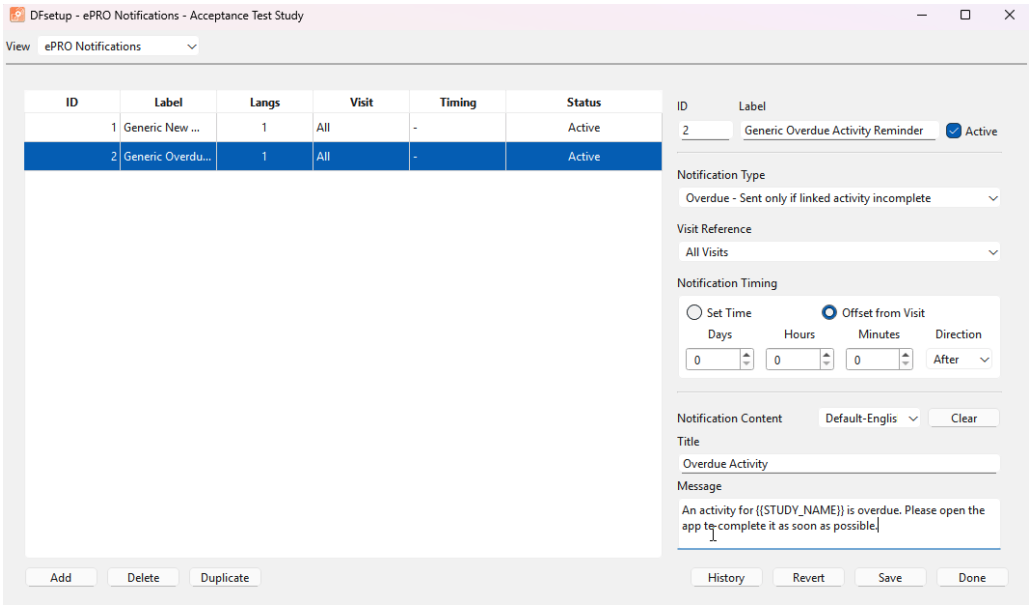
Hours = 0

Minutes = 0

Direction = After

Title = Overdue Activity

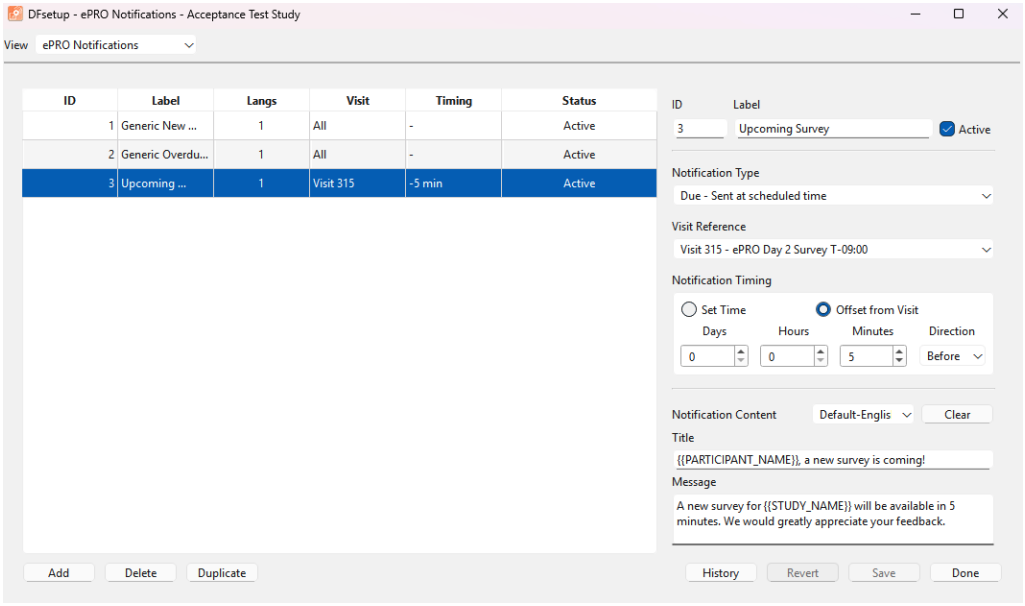
Message = Oops, you missed your last activity. Let's get back on track now.



19.9.4. 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.

- **Label** = Upcoming Survey 9am
- **Active** = Checked (enabled)
- **Notification Type** = Due - Sent at scheduled time
- **Visit Reference** = Visit 315 - ePRO Day 2 Survey T-09:00
- **Notification Timing**
  - **Offset from Visit** = Checked (selected)
  - **Days** = 0
  - **Hours** = 0
  - **Minutes** = 5
  - **Direction** = Before
- **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.

Expected Result: ID 3 properties are defined and saved.



19.9.5. For each of the remaining ePRO Day 2 Survey visits outlined in the visit map:

Visit 316 - ePRO Day 2 Survey T-10:00

Visit 317 - ePRO Day 2 Survey T-12:00

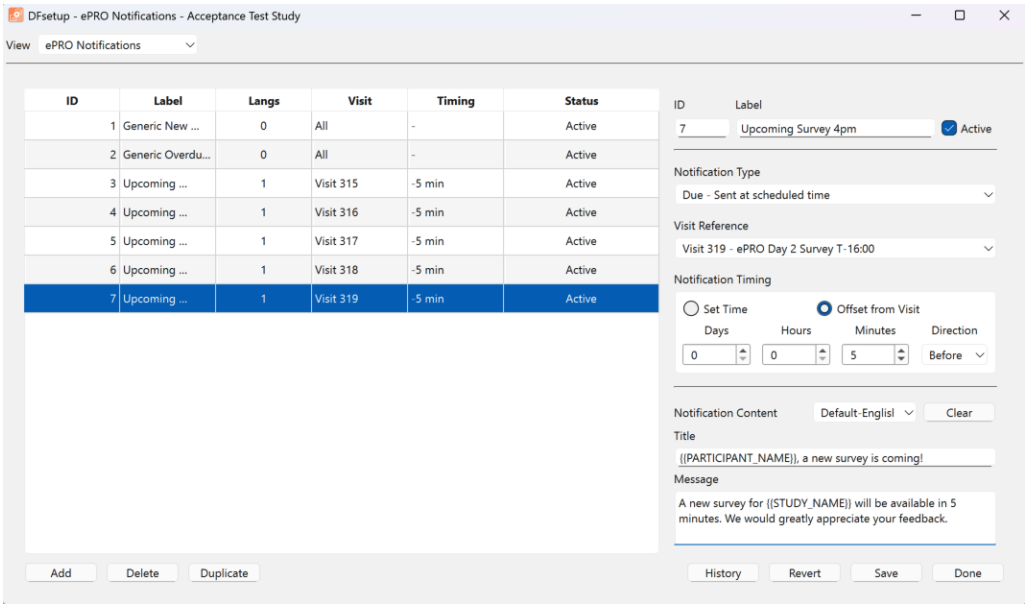
Visit 318 - ePRO Day 2 Survey T-14:00

Visit 319 - ePRO Day 2 Survey T-16:00

a. 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**).

b. Click Save to save changes to the notifications and then Done to close the ePRO notifications dialog.

Expected Result: Four new notifications saved.

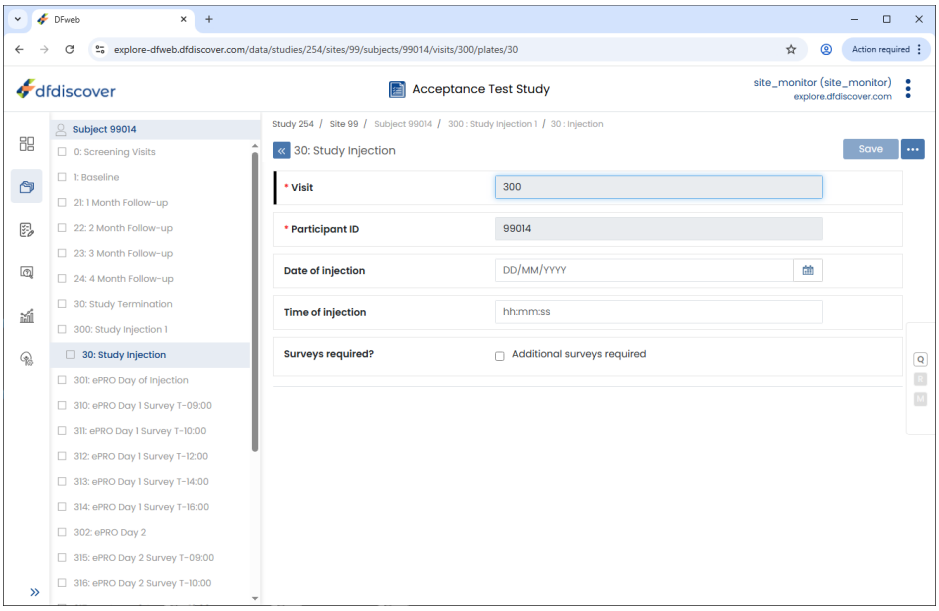


19.9.6. Click File > Exit to quit **DFsetup**.

19.9.7. 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.

Expected Result: Login to **DFweb** is successful.

19.9.8. Click **Subjects** , select **99014** > **300: Study Injection 1** to open the **30: Study Injection** page.



19.9.9. Enter the following data on the **Study Injection** page and click Save. Then Click ⋮ > Logout to exit **DFweb**.

- **Date of Injection** = Yesterday's date
- **Time of Injection** = 10:00:00
- **Surveys required?** = Check (enable) **Additional surveys required**

Expected Result: Data has been saved and user is successfully logged out of **DFweb**.

19.9.10. Open the **DFengage** mobile application. Login as user atk_99014 (See: DFengage Login). Select **default** from the **Pick Your Language** dropdown, click Continue.

19.9.11. Close **DFengage** on the device and await the time designated for one of the custom notifications defined in step 4 and step 5(**9am, 10am, 12pm, 2pm, 4pm**).

Expected Result: The expected custom notification arrives on your device 5 minutes before the generic notification arrives.

> NOTE: as the date of injection was already set to Yesterday's date in step 9, 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.

19.9.12. Wait for an additional 5 minutes until scheduled notification time.

Expected Result: Two notifications are received on your device at the expected time: one for the **overdue survey on Day 1**, one for the **new survey on Day 2**.

19.9.13. Click either of the notifications to open **DFengage** and enter PIN to login.

19.9.14. Click Start next to the **Survey Day 1 @9am**. Provide answers as follows, clicking Next to navigate to the next question. Once all are entered, click Finish then Yes.

a. Click **Today's date**, Select a date of 04 Nov 2025. Click OK.

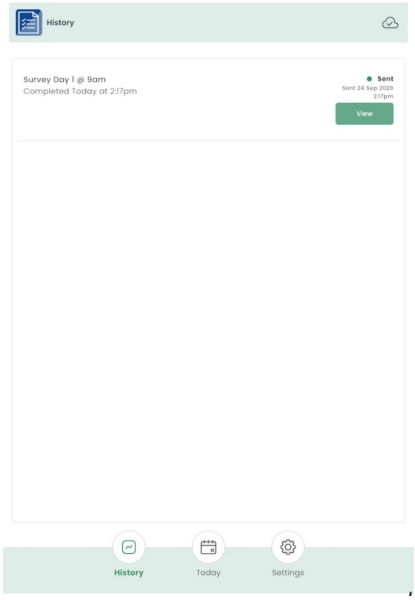
b. For **Please indicate on the scale how your health is TODAY**, enter 74.

c. For **How would you rate your pain on average**, enter 6.

Expected Result: Questionnaire successfully saved and user is navigated back to **Today's Activities**.

19.9.15. Click **History**

Expected Result: Survey Day 1 @9am is displayed as Sent.



19.10 Confirm Language can be changed

19.10.1. Switch to the **Settings** page. Open the **Language** dropdown.

a. Change the language to **French**.

19.10.2. Return to the **Today's Activities** page.

Expected Result: The questionnaire descriptions are in **French**.

19.10.3. Locate **Journal électronique Jour 1**, click Start.

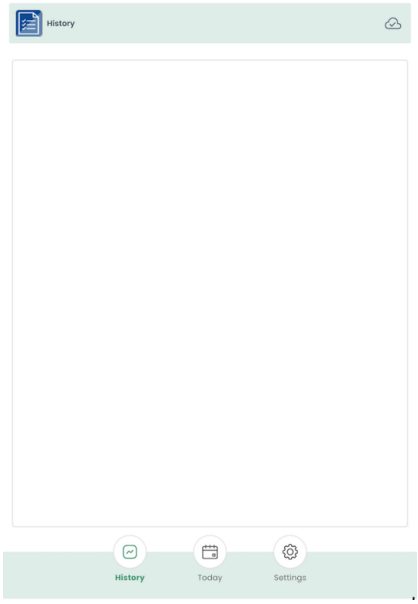
Expected Result: Today's date is displayed as **Date du jour :**.

19.10.4. Click Exit to close the activity.

19.11 Confirm logout of **DFengage** application clears data history

19.11.1. Click **Settings** > Logout > Logout. Then log in again as user atk_99014 (See DFengage Login). Select the default language again, and when you arrive at the **Today's Activities** page, click **History**.

Expected Result: No entries exist on the **History** Page.



19.11.2. Click **Settings** > Logout > Logout.

19.12 Confirm data sent to the server using **DFexplore**

19.12.1. Login to **DFexplore**, Open subject **99015** > **301: ePRO Date of Injection** > **31: eDiary Day 1**.

Expected Result: The data previously entered now appears in **DFexplore**.

19.12.2. Select **Page** > **List History of Changes on This Page**, check (enable) **Detailed History**.

Expected Result: 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
☐ Pass ☐ Fail	1. Confirm version information can be obtained for DFdiscover.
☐ Pass ☐ Fail	2. Obtain super-user privileges and remove older Acceptance Test Study, if one exists.
☐ Pass ☐ Fail	3. Install the Acceptance Test Study.
☐ Pass ☐ Fail	4. Define Acceptance Test Study to the DFdiscover server.
☐ Pass ☐ Fail	5. Create a role and permissions for datafax.
☐ Pass ☐ Fail	6. Creating study roles and permissions.
☐ Pass ☐ Fail	7. Creating user accounts and assigning study permissions.
☐ Pass ☐ Fail	8. Enable high definition imaging.
☐ Pass ☐ Fail	9. Start the Acceptance Test Study Control Panel application.
DFdiscover RPM & Build Date	
Server FQDN & OS	
Server Azure SMS Config & Region	
DFdiscover Tools Build Version & Date	
Completed By (Print name)	
Title	
Date	
Signature	

Module 2. DFdiscover Client Applications

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Send PDF images to **DFexplore**
☐ Pass ☐ Fail	2. Resetting a user login password.
☐ Pass ☐ Fail	3. Verify the online user documentation. Open the Image Router and verify the appearance of the Welcome Image.
☐ Pass ☐ Fail	4. Open the Acceptance Test Study and verify the standard **DFexplore** views.
☐ Pass ☐ Fail	5. Start **DFsetup** and verify version information.
☐ Pass ☐ Fail	6. Verify the online setup documentation. Open the Acceptance Test Study setup and verify the standard **DFsetup** views.
DFdiscover Tools Build Version & Date	
Completed By (Print name)	
Title	
Date	
Signature	

Module 3. Study Setup

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Permitted users can gain exclusive access to **DFsetup** to modify a study setup.
☐ Pass ☐ Fail	2. Define Global study preferences and apply settings to **DFsetup**.
☐ Pass ☐ Fail	3. Create and modify a new style (Comment).
☐ Pass ☐ Fail	4. Create and modify a new module (Death).
☐ Pass ☐ Fail	5. Assign Field definitions to a newly created module.
☐ Pass ☐ Fail	6. Assign a module's field definitions to a plate.
☐ Pass ☐ Fail	7. Correct field ordering on the current plate to set field traversal order for data entry.
☐ Pass ☐ Fail	8. Use copy and paste to create repeating module and field references on a plate.
☐ Pass ☐ Fail	9. Create user-defined query category codes.
☐ Pass ☐ Fail	10. Submit a copy of the newly defined Plate 11 into the study database and retrieve the page in **DFexplore** Image View.
☐ Pass ☐ Fail	11. Enter and save all data on the submitted plate 11.
Completed By (Print name)	
Title	
Date	
Signature	

Module 4. eCRF Creation for DFdiscover

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. eCRF creation in **DFsetup**.
☐ Pass ☐ Fail	2. eCRF background color preferences.
☐ Pass ☐ Fail	3. Entering eCRF data.
Completed By (Print name)	
Title	
Date	
Signature	

Module 5. Custom Properties

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Defining Custom Properties in **DFsetup**.
☐ Pass ☐ Fail	2. Adding Global Custom Property values.
☐ Pass ☐ Fail	3. Adding Plate, Module and Variable level Custom Property values.
☐ Pass ☐ Fail	4. Exporting Custom Properties in **DFsetup**.
☐ Pass ☐ Fail	5. Edit checks execution of Custom Properties.
☐ Pass ☐ Fail	6. Creating subject data lists and exporting data views.
☐ Pass ☐ Fail	7. **DFexplore** Database Definition Report exporting.
Completed By (Print name)	
Title	
Date	
Signature	

Module 6. Subject Alias

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Importing and Modifying Subject Alias Map using **DFsetup**.
☐ Pass ☐ Fail	2. Creating Subjects using Subject Alias.
☐ Pass ☐ Fail	3. Subject Alias Tracking (Reports).
☐ Pass ☐ Fail	4. Exporting Subject Alias data.
Completed By (Print name)	
Title	
Date	
Signature	

Module 7. EDC Data Entry

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Login to **DFexplore** and inspect the list of sites, subjects and visits in the record list window.
☐ Pass ☐ Fail	2. Enter and save new data using EDC data entry for Subject 99007.
☐ Pass ☐ Fail	3. Add reasons to explain entered data values.
☐ Pass ☐ Fail	4. Enter and save Plate 3, Subject 99007 as a pending record.
☐ Pass ☐ Fail	5. Mark and save unavailable data as missed. Unmark available data as missed.
☐ Pass ☐ Fail	6. Retrieve and modify existing data using a predefined task and save modifications to the database.
☐ Pass ☐ Fail	7. Confirm audit trail information for entered and modified data.
Completed By (Print name)	
Title	
Date	
Signature	

Module 8. Image Data Entry

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

Module 9. User-defined Query Category Types

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Retrieve an existing data record in **DFexplore**.
☐ Pass ☐ Fail	2. Apply a user-defined Category query.
☐ Pass ☐ Fail	3. Add a reason for Data Value to explain entered data.
☐ Pass ☐ Fail	4. Edit an existing query.
☐ Pass ☐ Fail	5. Delete a user-defined Query Category that is used by an existing query.
☐ Pass ☐ Fail	6. Delete a user-defined Category query.
Completed By (Print name)	
Title	
Date	
Signature	

Module 10. Multiple Queries Per Field

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Submit PDF images to DFdiscover.
☐ Pass ☐ Fail	2. Enable multiple queries per field in **DFsetup**.
☐ Pass ☐ Fail	3. Retrieve submitted CRF in **DFexplore** Image View.
☐ Pass ☐ Fail	4. Enter Plate 9 for Subject 99002.
☐ Pass ☐ Fail	5. Apply multiple queries to a field.
☐ Pass ☐ Fail	6. Select and edit an existing query in a field that has multiple queries.
☐ Pass ☐ Fail	7. Select and reply to an existing query in a field that has multiple queries.
☐ Pass ☐ Fail	8. Select and delete an existing query in a field that has multiple queries.
Completed By (Print name)	
Title	
Date	
Signature	

Module 11. Data Review

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Retrieve all data for Site 99 that exists at level 3.
☐ Pass ☐ Fail	2. Review and approve a pending reason for data value, and approve a selected query in a field that has multiple queries.
☐ Pass ☐ 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.
☐ Pass ☐ Fail	4. Data review and add a query to inconsistent data.
☐ Pass ☐ Fail	5. Review and complete pending data for Subject 99007.
☐ Pass ☐ Fail	6. Confirm audit trail information for reviewed and modified data.
☐ Pass ☐ Fail	7. Run batch edit checks to verify data integrity.
☐ Pass ☐ Fail	8. Use a data expression to retrieve specific subject information.
☐ Pass ☐ Fail	9. Use cross-plate data criteria to retrieve specific subject information.
Completed By (Print name)	
Title	
Date	
Signature	

Module 12. External Query Reports

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Obtain database query metrics and details using Status and List Views to review all outstanding queries prior to query report creation.
☐ Pass ☐ Fail	2. Run database integrity check report DF_XXkeys to export all key fields and visit dates from required plates in the database.
☐ Pass ☐ Fail	3. Use Data View to check, and if necessary correct, illegal visit dates by retrieving the problems keys identified by DF_XXkeys.
☐ Pass ☐ Fail	4. Execute DF_QCupdate to update the query database and lock all records for query report generation.
☐ Pass ☐ Fail	5. Execute DF_QCreports to create a standard, 3-part external query report for a study site.
☐ Pass ☐ Fail	6. Confirm the status of external queries following query report creation.
☐ Pass ☐ Fail	7. Execute DF_QCstatus to verify that a new query report was created by listing all reports in the QC/NEW directory.
☐ Pass ☐ Fail	8. Execute DF_QCview to display the newly created query report.
☐ Pass ☐ Fail	9. Execute DF_QCprint to print the query report from the QC/NEW directory.
☐ Pass ☐ Fail	10. Comparing several examples from the printed query report against their corresponding queries in the study database.
☐ Pass ☐ Fail	11. Execute DF_QCfax to email the query report to a valid email account.
☐ Pass ☐ Fail	12. Verify the status of the queries in the sent report.
Completed By (Print name)	
Title	
Date	
Signature	

Module 13. Replying to EDC Queries, eSignatures

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Determine a count of outstanding queries in Status View.
☐ Pass ☐ Fail	2. Review outstanding queries in Queries View.
☐ Pass ☐ Fail	3. Using EDC, locate and reply to outstanding clarification queries.
☐ Pass ☐ Fail	4. Add an Electronic Signature (eSign) to a set of completed subject records.
☐ Pass ☐ Fail	5. Verify removal and re-application of eSignatures.
Completed By (Print name)	
Title	
Date	
Signature	

Module 14. Re-submitting Query Corrections

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Submit PDF images to DFdiscover.
☐ Pass ☐ Fail	2. Verify that all CRFs have arrived successfully in Image view.
☐ Pass ☐ Fail	3. Retrieve submitted CRFs using **DFexplore** Image View.
☐ Pass ☐ Fail	4. Enter Form 2, Subject 99001, resolve outstanding queries, and save the corrected CRF to the database.
☐ Pass ☐ Fail	5. Enter Form 2, Subject 99002, resolve outstanding queries, and save the corrected CRF to the database.
☐ Pass ☐ Fail	6. Enter Form 4, Subject 99004.
☐ Pass ☐ Fail	7. Enter Form 2, Subject 99004, resolve outstanding queries, and save the corrected CRF to the database.
☐ Pass ☐ Fail	8. Select and resolve a query in a field that has multiple queries.
☐ Pass ☐ Fail	9. Review and approve a pending query reply for Form 1 for Subject 99002.
☐ Pass ☐ Fail	10. Review, correct and approve a pending query reply for Form 1, Subject 99007.
☐ Pass ☐ Fail	11. Confirm query resolution by examining the database status.
Completed By (Print name)	
Title	
Date	
Signature	

Module 15. Data Export and DFsas

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Export date values in calendar format and save the exported data to a file on the local computer.
☐ Pass ☐ Fail	2. Export date values from the database and save the exported data to a file on the local computer.
☐ Pass ☐ Fail	3. Examining data values according to user-specified criteria.
☐ Pass ☐ Fail	4. Query the database for specific data values.
☐ Pass ☐ Fail	5. Create a DFsas job file according to user-specified criteria.
☐ Pass ☐ Fail	6. Create a SAS job file and data files using the DFsas job file criteria.
☐ Pass ☐ Fail	7. Compare the contents of SAS data files with the actual data in the database.
Completed By (Print name)	
Title	
Date	
Signature	

Module 16. PDF File Creation

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Retrieve existing data according to user-specified criteria.
☐ Pass ☐ Fail	2. Saving **DFexplore** data to a standard PDF document.
☐ Pass ☐ Fail	3. Saving **DFexplore** blank CRF books to a standard PDF document.
☐ Pass ☐ Fail	4. Viewing a standard PDF data file using a PDF viewer application.
☐ Pass ☐ Fail	5. Saving **DFexplore** data to an encrypted bookmarked PDF file.
☐ Pass ☐ Fail	6. Open and view an encrypted bookmarked PDF file using a PDF viewer application.
☐ Pass ☐ Fail	7. Create a complete subject package PDF file that includes data records, CRF images and audit trail.
☐ Pass ☐ Fail	8. Open and view a PDF subject package using a PDF viewer application.
Completed By (Print name)	
Title	
Date	
Signature	

Module 17. DFweb Data Entry

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Resetting a user login password.
☐ Pass ☐ Fail	2. Verify **DFweb** version information, logging into **DFweb** and **DFweb** site certificate verification.
☐ Pass ☐ Fail	3. Copying URL and changing user passwords.
☐ Pass ☐ Fail	4. Creating a new subject, entering subject data.
☐ Pass ☐ Fail	5. Adding, modifying and resolving queries.
☐ Pass ☐ Fail	6. Adding, reviewing and downloading subject documents.
☐ Pass ☐ Fail	7. Add an Electronic Signature (eSign) to a set of completed subject records.
☐ Pass ☐ Fail	8. Verify removal and re-application of eSignatures.
☐ Pass ☐ Fail	9. Verify **DFweb** saves eSignature task data to the specified save level.
DFweb URL used for testing	
DFweb Version & Build Date	
Completed By (Print name)	
Title	
Date	
Signature	

Module 18. DFcollect Mobile Data Collection

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Installation and App preferences.
☐ Pass ☐ Fail	2. Resetting a user login password.
☐ Pass ☐ Fail	3. Online data record creation.
☐ Pass ☐ Fail	4. Download subject data for offline use.
☐ Pass ☐ Fail	5. Create data records in offline mode, query resolution and adding reasons for data values.
☐ Pass ☐ Fail	6. Sync data collected offline to your **DFdiscover** server.
☐ Pass ☐ Fail	7. Clearing **DFcollect** cache.
☐ Pass ☐ Fail	8. Adding, reviewing and downloading subject documents.
☐ Pass ☐ Fail	9. Confirming data sent to the server using **DFexplore**.
☐ Pass ☐ Fail	10. Add an Electronic Signature (eSign) to a set of completed subject records.
☐ Pass ☐ Fail	11. Verify removal and re-application of eSignatures.
☐ Pass ☐ Fail	12. Verify **DFcollect** saves eSignature task data to the specified level.
☐ Pass ☐ Fail	13. Verify no saved data remains upon uninstallation and reinstallation of **DFcollect**.
DFws API used for testing	
DFcollect Version & Build Date	
Completed By (Print name)	
Title	
Date	
Signature	

Module 19. DFengage ePRO Data Entry

Pass/Fail	Testing step
☐ Pass ☐ Fail	1. Create **DFengage** users role in **DFadmin**.
☐ Pass ☐ Fail	2. Add bulk **DFengage** users accounts to **DFadmin**.
☐ Pass ☐ Fail	3. Installation and initial **DFengage** login.
☐ Pass ☐ Fail	4. Complete a task in online mode.
☐ Pass ☐ Fail	5. Complete a task in offline mode.
☐ Pass ☐ Fail	6. Sync data collected offline to your **DFdiscover** server.
☐ Pass ☐ Fail	7. Resetting a user login password.
☐ Pass ☐ Fail	8. Enter data in **DFengage** web.
☐ Pass ☐ Fail	9. Configure and receive **DFengage** notifications.
☐ Pass ☐ Fail	10. Confirm Language can be changed
☐ Pass ☐ Fail	11. Confirm logout of **DFengage** application clears data history.
☐ Pass ☐ Fail	12. Confirm data sent to the server using **DFexplore**.
DFws API used for testing	
DFengage Web URL used for testing	
DFengage Version & Build Date	
Completed By (Print name)	
Title	
Date	
Signature	

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., 5.11.3), 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. 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	
DFdiscover Release	
Server Operating System and Version	
Problem	
Immediate Workaround	
Problem Resolution	

Signature and Date

Completed By (Print name)	
Title	
Date	
Signature	

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mpack/munpack

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c3.js

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jwt-cpp

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QXlsx

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