

ePRO using DFengage

Webinar, 28 May 2020

Speakers:

Lisa Ondrejcek, DF/Net Research, Inc.

Thijs Sondag, Curve Tomorrow

Angela Williams, DF/Net Research, Inc.

Eric Bosch, DF/Net Software, ULC

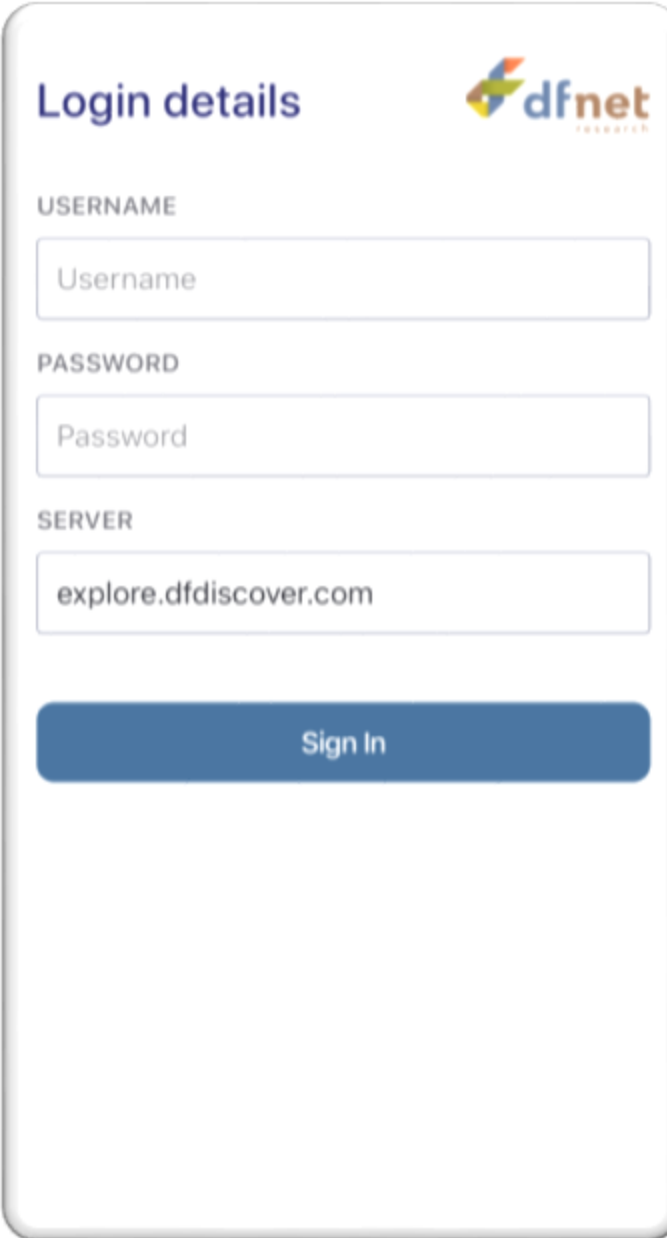
Moderator:

Rebeca Sanz Barriuso, DF/Net Research, Inc.

The screenshot shows a mobile application interface for a 'Quality of Life test'. At the top left is an 'Exit' button. The title is 'Quality of Life test'. Below the title is a progress indicator showing 'Question 2 of 13' with a green bar. The question text is 'In general, would you say your health is'. There are five radio button options: 'Excellent' (selected), 'Very good', 'Good', 'Fair', and 'Poor'. At the bottom, there are two buttons: '← Previous' and 'Next →'.

Agenda

- Introduction
- Demonstration
- DFsetup
- Questions
- Logistics



The image shows a mobile-style login form with a white background and rounded corners. At the top left, it says "Login details" in blue. At the top right is the "dfnet" logo, which consists of a colorful icon followed by the text "dfnet" and "RESEARCH" in smaller letters below it. There are three input fields: "USERNAME" with the placeholder "Username", "PASSWORD" with the placeholder "Password", and "SERVER" with the placeholder "explore.dfdiscover.com". Below these fields is a blue "Sign In" button.

ePRO Presentations at DFUG 2019

Piloting ePRO capabilities in DFexplore

Abigail Isaacson, 26 September 2019

WeGuide: The ePRO App for DFdiscover

Sandy Buchanan, 26th September 2019



Before March 2020: “Nice to Have”

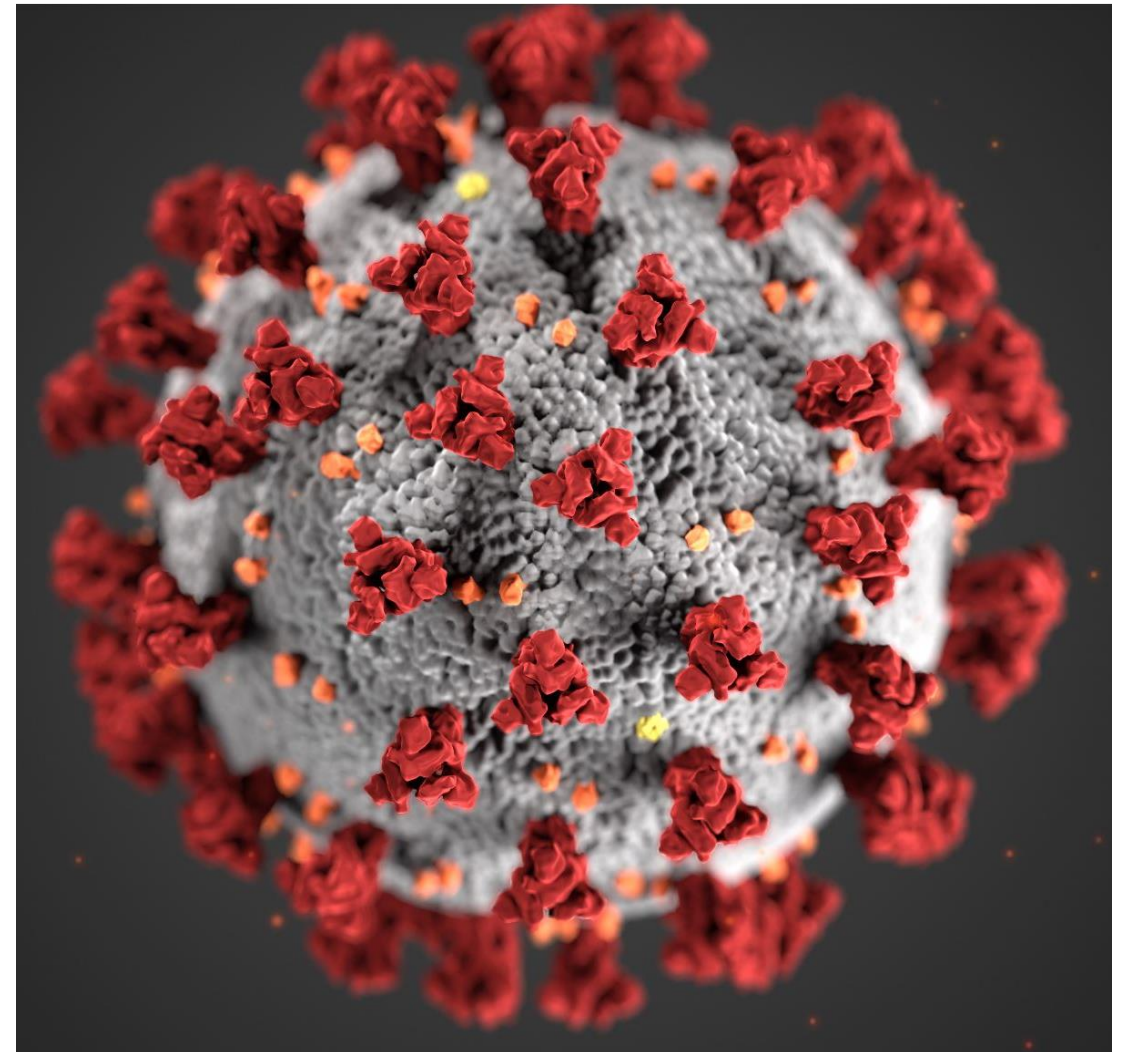
- Who wants to try ePRO? We do!
 - Improve subject engagement and retention
 - Avoid manual data entry by site staff
 - Better quality data
 - Real-time access to data
- But...
 - We don't want to be the first
 - It sounds complicated
 - Easier to keep doing what we're doing

After March 2020: “Must Have”

COVID-19 Safer at Home



- Leave home only for essential work or necessities
- Practice good hygiene: cover coughs and sneezes, don't touch your face, and wash hands often
- Work remotely whenever possible
- Physical distancing of at least 6 feet
- Use cloth face coverings when in public
- Disinfect frequently used items and touched surfaces often



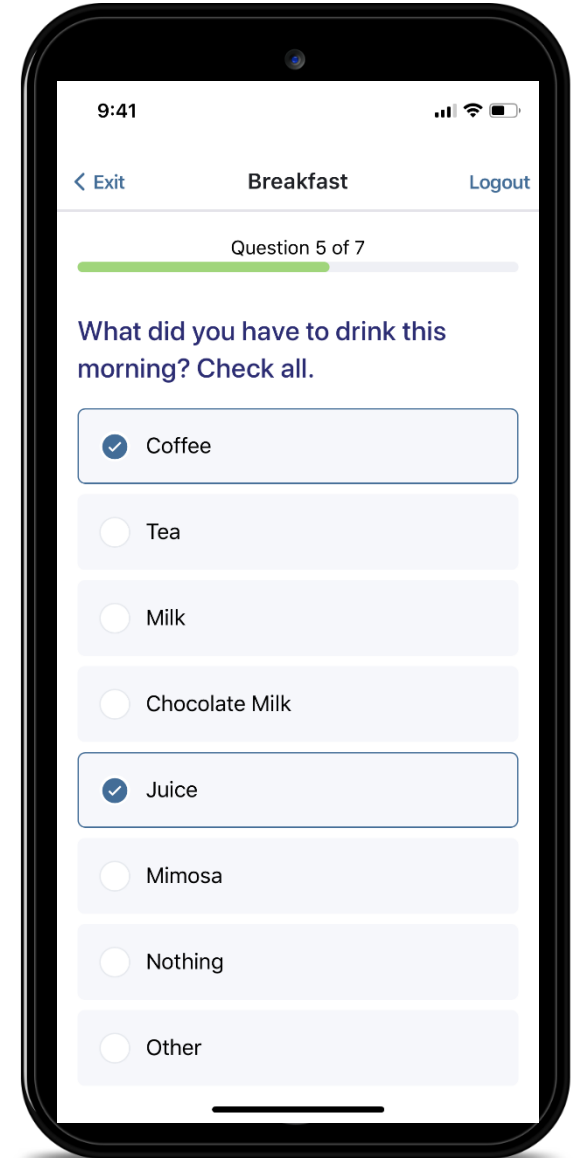
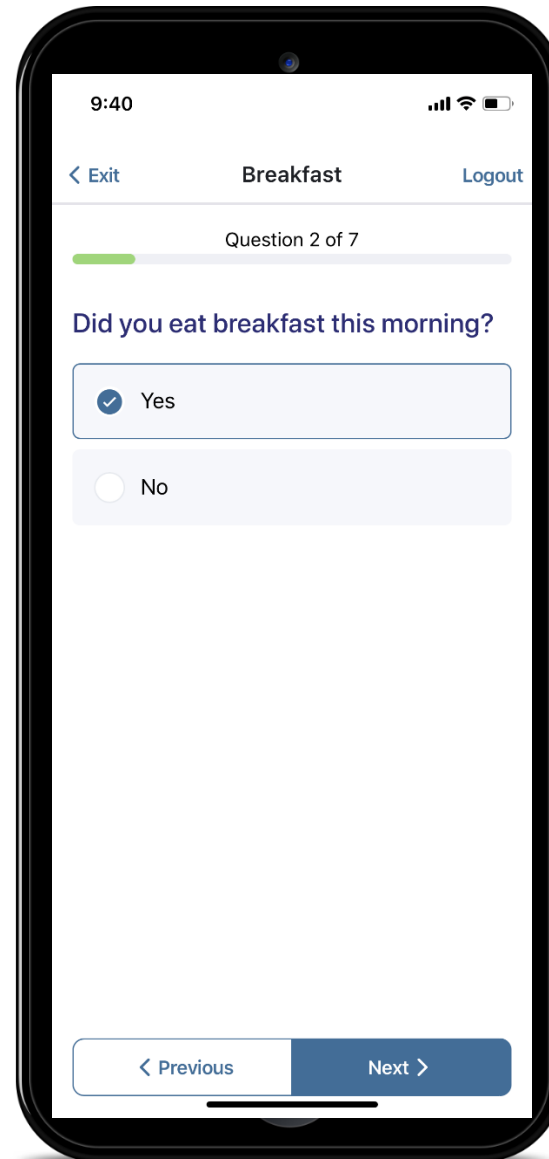
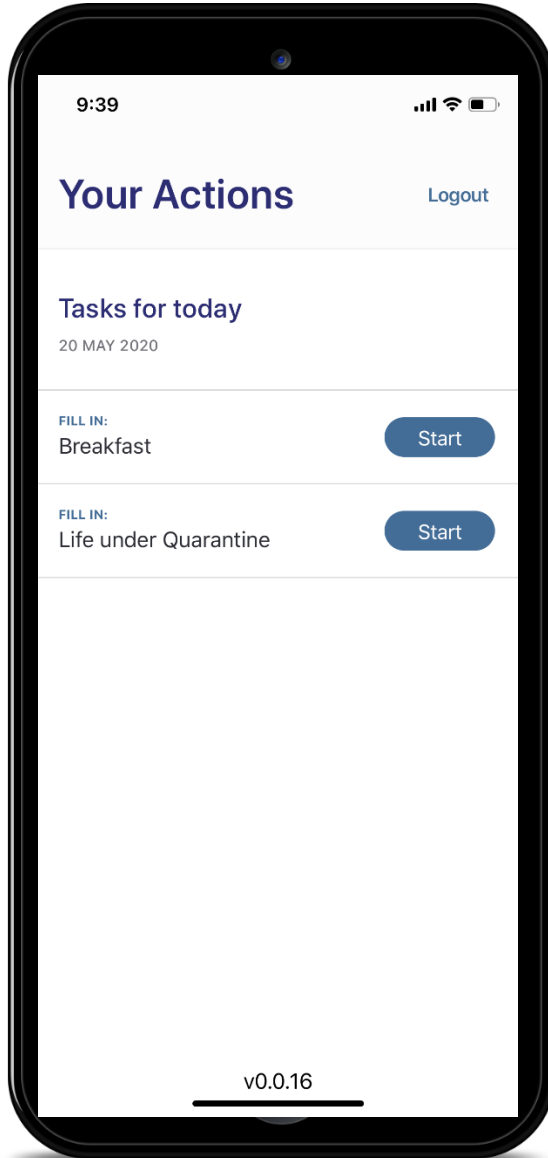
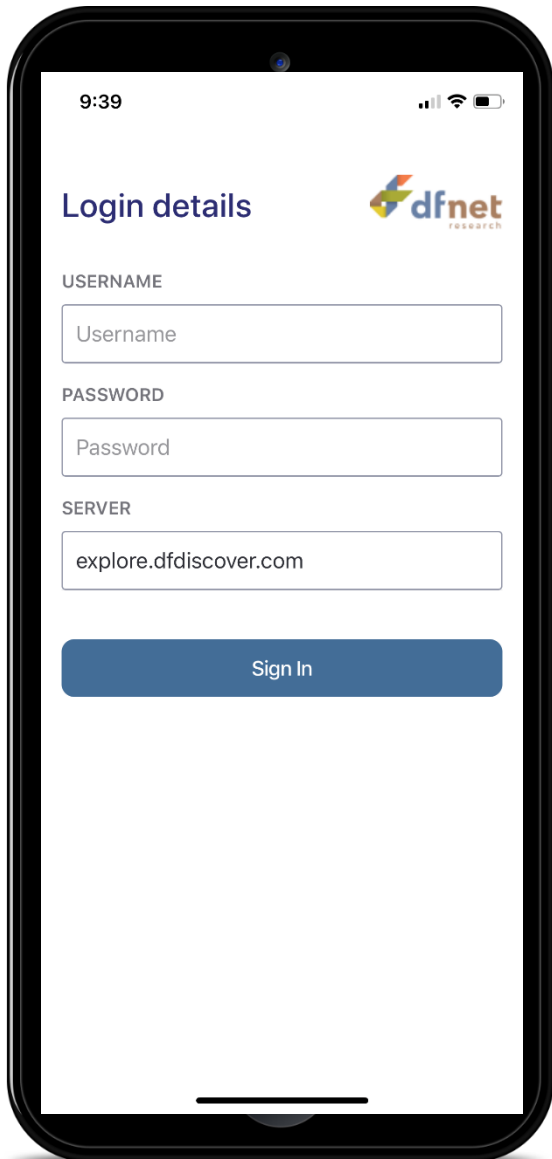
Introducing DFengage

- ePRO app that's fully integrated with other DFdiscover tools
- Built on the WeGuide platform, a proven ePRO solution for over 10 years
- Android and iOS compatible
 - Available for download on Google Play or the Apple Store
- One database definition in DFsetup
 - Changes can be immediately pushed to all devices

Introducing DFengage

- Questionnaires are triggered at set times on the device
- Reminders and notifications
- Works online or offline
 - When connectivity is available, automatically syncs back
- DFengage sends data directly back to DFdiscover
- Data is immediately available for site, monitor, and data management review





Deployment for COVID-19 trials: WeGuide



Could BCG, a 100-year-old vaccine for tuberculosis, protect against coronavirus?

Deployment for COVID-19 trials: DF/Net



SP-PA-COV-202

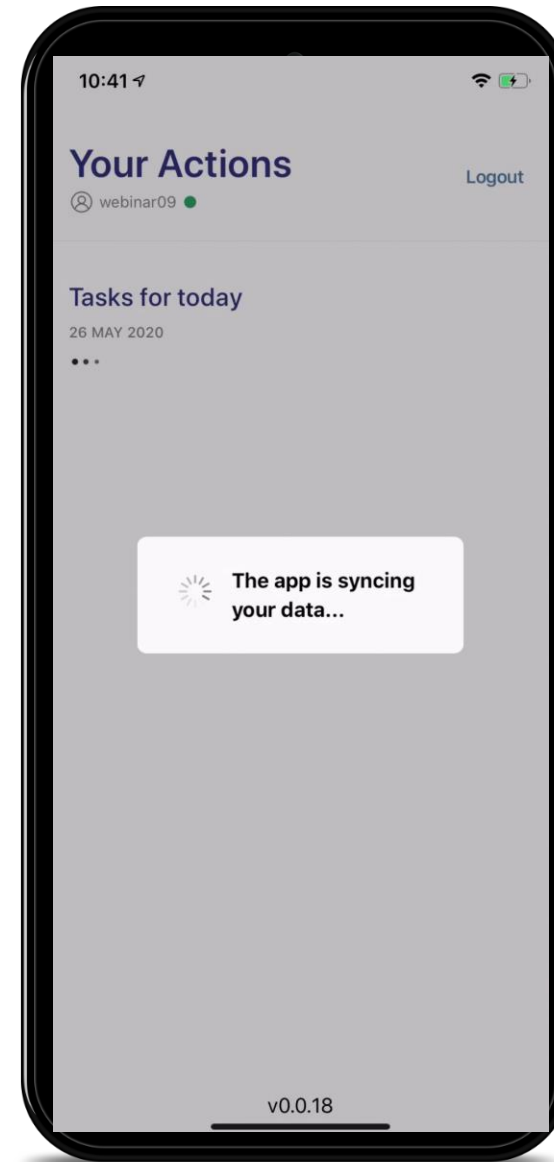
CLINICAL STUDY PROTOCOL

A single center, randomized, open label, adaptive clinical trial to compare the safety and efficacy of five different experimental drug regimens to standard of care for the treatment of symptomatic outpatients with COVID-19



Demonstration

- Login as a participant



Demonstration

- Listening to the visit map

The screenshot displays two overlapping windows from a clinical trial management system. The background window, titled "DFsetup [TSondag@explore.dfdiscover.com] ePRO Webinar - View", shows a "Visit Map" for "Plate 15 - Life under Quarantine". The map lists visits from 8 to 31, with questions such as "Please answer the following questions about life under quarantine. Ready?", "Have your sleep patterns changed?", and "How have your sleep patterns changed?". A "Visit or Cycle Definition" dialog box is open, showing settings for a "Visit" type, scheduled date field, and scheduling parameters. The foreground window, titled "Movie Recording", shows a mobile app interface with "Your Actions" and "Tasks for today" sections. A task for "Breakfast Questionnaire: Day 2" is visible with a "Start" button. A recording control bar at the bottom of the mobile app shows a red recording indicator and "Zero KB" of data recorded.

v0.0.18

Demonstration

- Showing what's expected

The image displays two views of a clinical trial interface. The left view is a desktop browser window showing a questionnaire titled "15: Life under Quarantine". The right view is a mobile app interface showing "Your Actions" and "Tasks for today".

Desktop View: 15: Life under Quarantine

Main Screen

What is the visit number?	6
What is the subject identifier?	7
Today's date	8
Please answer the following questions about life under quarantine. Ready?	9

Sleep

Have your sleep patterns changed?	10
How have your sleep patterns changed?	11
	12
	13
	14
	15
	16
	17
Specify other sleep pattern changes:	18

Work

Have your work patterns changed?	19
How have your work patterns changed?	20
	21
	22
	23
Specify other work pattern changes:	24
On average, how many video conference calls do you attend each week?	25
Of those calls, how many are non-work related (e.g. family, book club)?	26

Mobile View: Your Actions

10:41

webinar09

Logout

Tasks for today

26 MAY 2020

FILL IN:
Life Under Quarantine

Start

Demonstration

■ User friendly data entering

The screenshot displays a mobile application interface for data entry. The left pane shows a tree view of modules, including '15 - Life under Quarantine' and 'Webinar' items. The main area displays a questionnaire with questions about sleep and work patterns, numbered 8 through 27. The right pane shows a mobile view of 'Question 12 of 22' with the question 'Which video conference systems have you used?' and a list of options: Zoom, Teams, WebEx, GoToMeeting, Skype, BlueJeans, FaceTime, and WhatsApp.

Question	Number
Today's date	8
Please answer the following questions about life under quarantine. Ready?	9
Have your sleep patterns changed?	10
How have your sleep patterns changed?	11
	12
	13
	14
	15
	16
	17
Specify other sleep pattern changes:	18
Have your work patterns changed?	19
How have your work patterns changed?	20
	21
	22
	23
Specify other work pattern changes:	24
On average, how many video conference calls do you attend each week?	25
Of those calls, how many are non-work related (e.g. family, book club)?	26
What has been the largest number of attendees on one of the video calls?	27

Question 12 of 22

Which video conference systems have you used?

- Zoom
- Teams
- WebEx
- GoToMeeting
- Skype
- BlueJeans
- FaceTime
- WhatsApp

Demonstration

- Notify and automatically remind based on visit map

DFsetup - Visit Map - ePRO Webinar - READ ONLY

View: Visit Map

Type	Number	Acronym	Label	Due	Overdue
C	1		Questionnaire Cycle	0	0
B	0	BSL	Day 1 Visit	0	0
S	10	D0	Day 1 - participant rep...	0	0
S	20	D1	Day 2 - participant rep...	1	1
S	30	D2	Day 3 - participant rep...	2	1
T	40	D3	Term Survey	4	4

Visit or Cycle Definition

Type: Visit Cycle

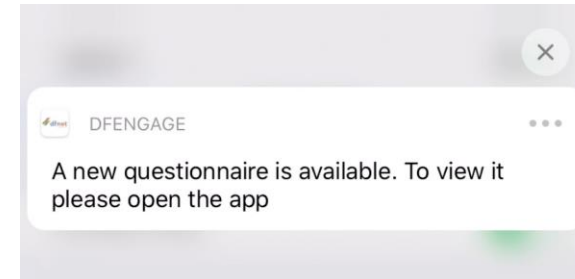
S: Scheduled

Visit Date Field: Plate 10, field 8=Visit Date

Visit Scheduling: Visit is due 1 days after baseline, Visit is overdue when 1 days late

Plates: Required 10, Optional, Display Order, Missed Visit

Buttons: Add, Delete, Import, Search, Revert, Verify, Save, Done

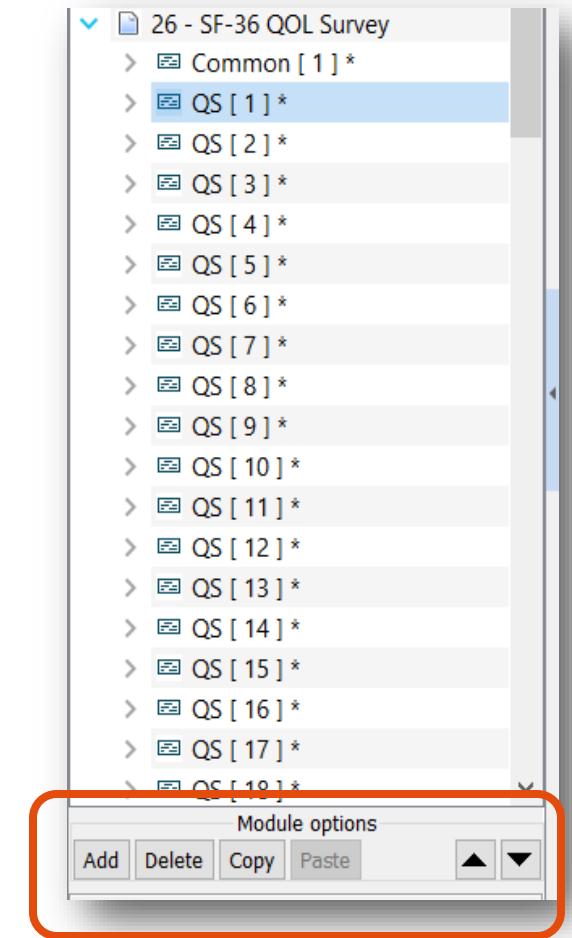
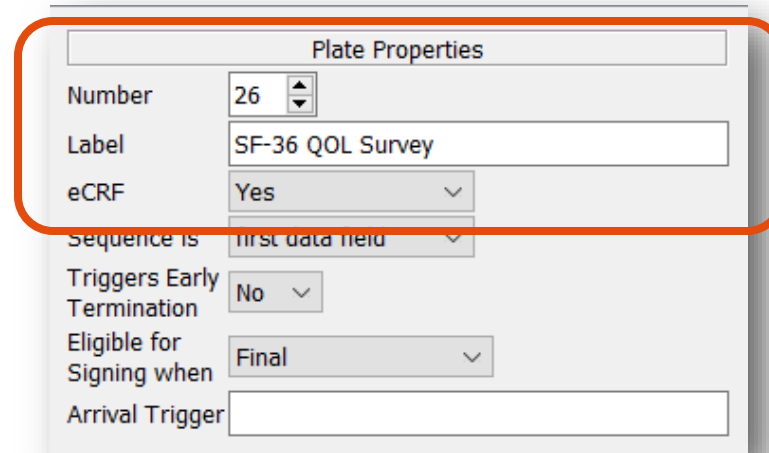
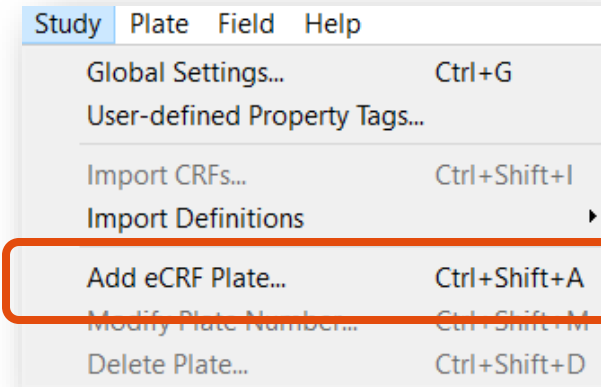


How to ...

- Create ePRO plate in DFsetup
- Assign ePRO plates in visit map
- Define and assign ePRO role in DFadmin

How to *create* ePRO plate in DFsetup (1)

1. Add CRF/eCRF to study
2. In Plate Properties, define Plate Number and Label
3. Add/copy Modules to plate



How to *create* ePRO plate in DFsetup (2)

4. For any ePRO plate, all questions/pages must be combined into one plate

CRF: QOL-1 (020) Subject ID Visit Code

SF-36 Quality of Life Survey, page 1 of 6

Choose one option for each questionnaire item.

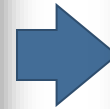
1. In general, would you say your health is: Excellent
 Very good
 Good
 Fair
 Poor

2. Compared to one year ago, how would you rate your health in general now?
 Much better now than one year ago
 Somewhat better now than one year ago
 About the same
 Somewhat worse now than one year ago
 Much worse now than one year ago

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?
 Yes, limited a lot
 Yes, limited a little
 No, not limited at all

4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
 Yes, limited a lot
 Yes, limited a little
 No, not limited at all



26: SF-36 QOL Survey

What is the visit number?

What is the subject identifier?

In general, would you say your health is: Excellent Very Good Good
 Fair Poor

Compared to one year ago, how would you rate your health in general now?
 Much better now than ... Somewhat better now... About the same
 Somewhat worse than... Much worse than one ...

Vigorous Activities, such as running, lifting heavy objects, participating in strenuous sports?
 Yes, limited a lot Yes, limited a little No, not limited at all

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
 Yes, limited a lot Yes, limited a little No, not limited at all

Lifting or carrying groceries? Yes, limited a lot Yes, limited a little No, not limited at all

Climbing several flights of stairs? Yes, limited a lot Yes, limited a little No, not limited at all

Climbing one flight of stairs? Yes, limited a lot Yes, limited a little No, not limited at all

Bending, kneeling, stooping? Yes, limited a lot Yes, limited a little No, not limited at all

Walking more than a mile? Yes, limited a lot Yes, limited a little No, not limited at all

Walking several blocks? Yes, limited a lot Yes, limited a little No, not limited at all

Walking one block (about 100 meters)? Yes, limited a lot Yes, limited a little No, not limited at all

Bathing or dressing yourself? Yes, limited a lot Yes, limited a little No, not limited at all

How to *create* ePRO plate in DFsetup (3)

- Questions appear in DFengage based on module order and the order of the questions within the modules

The screenshot displays the DFsetup interface for configuring a survey. The main window shows a list of questions for the '26: SF-36 QOL Survey' module. Each question is represented by a blue bar with its ID number and a yellow bar indicating its type. The questions are:

- What is the visit number? (ID 6, Common [1])
- What is the subject identifier? (ID 7, Common [1])
- In general, would you say your health is: (ID 8, QS [1])
- Compared to one year ago, how would you rate your health in general now? (ID 9, QS [2])
- Vigorous Activities, such as running, lifting heavy objects, participating in strenuous sports? (ID 10, QS [3])
- Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf? (ID 11, QS [4])
- Lifting or carrying groceries? (ID 12, QS [5])
- Climbing several flights of stairs? (ID 13, QS [6])

The 'Field Properties' panel on the right shows the configuration for a 'SimpleChoice' field. The field is named 'QSORRES_C' and has an alias 'QSORRES_5'. The description is 'SF-36 Question 5' and the prompt is 'Lifting or carrying groceries?'. The field is set to 'Standard' style and '3 columns' width. The 'Label Position' is set to 'Right'. The 'Choices' table is as follows:

Code	Label
No Choice 0	Blank
Choice 1 1	Yes, limited a lot
Choice 2 2	Yes, limited a little
Choice 3 3	No, not limited a...

How to *create* ePRO plate in DFsetup (4)

- Questions can be set up as choice fields, check box, string field, date, number, etc. as usual
- In field properties, use 'Prompt' to record question/text that will appear as the prompt in DFengage
- Set up choice codes/labels in field properties; these will appear in same order for participant in app

Field Properties

Style: SimpleChoice Type: Choice

Name: QSORRES_C

Alias: QSORRES_1

Description: SF-36 Question 1

Prompt: In general, would you say your health is:

Basic Detail Edit checks User-defined

Use: Standard

Units:

Show As: Choices

3 columns Label Position: Right

	Code	Label
No Choice	0	Blank
Choice 1	1	Excellent
Choice 2	2	Very Good
Choice 3	3	Good
Choice 4	4	Fair
Choice 5	5	Poor

2:04

< Exit SF-36 QOL Survey Logout

Question 1 of 36

In general, would you say your health is:

Excellent

Very Good

Good

Fair

Poor

< Previous Next >

How to *create* ePRO plate in DFsetup (5)

9. Skip patterns perform same role

A screenshot of the DFsetup application's 'Basic' tab. The 'Skip' checkbox is checked, and the configuration is set to '5' fields if the value is '2'. The 'Skip' row is highlighted with an orange border.

Basic	Detail	Edit checks	User-defined
<input type="checkbox"/> Legal			
<input type="checkbox"/> Help			...
<input type="checkbox"/> Constant	No	Value	
<input type="checkbox"/> Need	Optional		
<input type="checkbox"/> Hidden	No		
<input checked="" type="checkbox"/> Skip	5	fields if value=	2
<input type="checkbox"/> Comment			

10. Character display/length may be defined

A screenshot of the DFsetup application's 'Basic' tab. The 'Display' field is set to 4, 'Store' is checked and set to 4, and 'Format' is set to 'nnnn'.

Basic	Detail	Edit checks	User-defined
Display	4		
<input checked="" type="checkbox"/> Store	4		
<input checked="" type="checkbox"/> Format	nnnn		

11. Field Need may be defined as optional, required or essential

A screenshot of the DFsetup application's 'Basic' tab. The 'Need' checkbox is checked, and the dropdown menu is open, showing 'Required' selected. The 'Need' row and dropdown are highlighted with an orange border.

Basic	Detail	Edit checks
<input checked="" type="checkbox"/> Prompt	Temperature	
<input type="checkbox"/> Legal		
<input checked="" type="checkbox"/> Help	ture today.	
<input type="checkbox"/> Constant	No	
<input checked="" type="checkbox"/> Need	Required	
<input type="checkbox"/> Hidden	Optional	
<input type="checkbox"/> Skip	Required	
<input type="checkbox"/> Comment	Essential	

A screenshot of a mobile ePRO application. The screen displays 'Subject Diary Card' for 'Temperature'. At the bottom, there are navigation buttons for '< Previous' and 'Next >'. A red arrow points from the 'Need' dropdown in the previous screenshot to the 'Next >' button.

3:01

< Exit Subject Diary Card Logout

Question 2 of 26

Temperature

< Previous Next >

How to *assign* ePRO plates to visit map

- In visit map, patient-reporting 'visits' are created as scheduled visits in relation to Baseline visit

View Visit Map

Type	Number	Acronym	Label	Due	Overdue
C	0		SCR	0	0
X	99	SCR	Screening	0	0
C	1		1st Injection	60	0
B	0	BSL	Day 0	0	0
S	01	D0	Day 0 - patient reporting	0	0
O	02-09		Unscheduled Visit 0.%(S.1.1)	0	0
S	10	D1	Day 1 - patient reporting	1	1
S	20	D2	Day 2 - patient reporting	2	1
S	30	D3	Day 3 - patient reporting	3	1
S	31	D3-1	Day 3	3	1

Visit or Cycle Definition

Type
 Visit Cycle
S: Scheduled

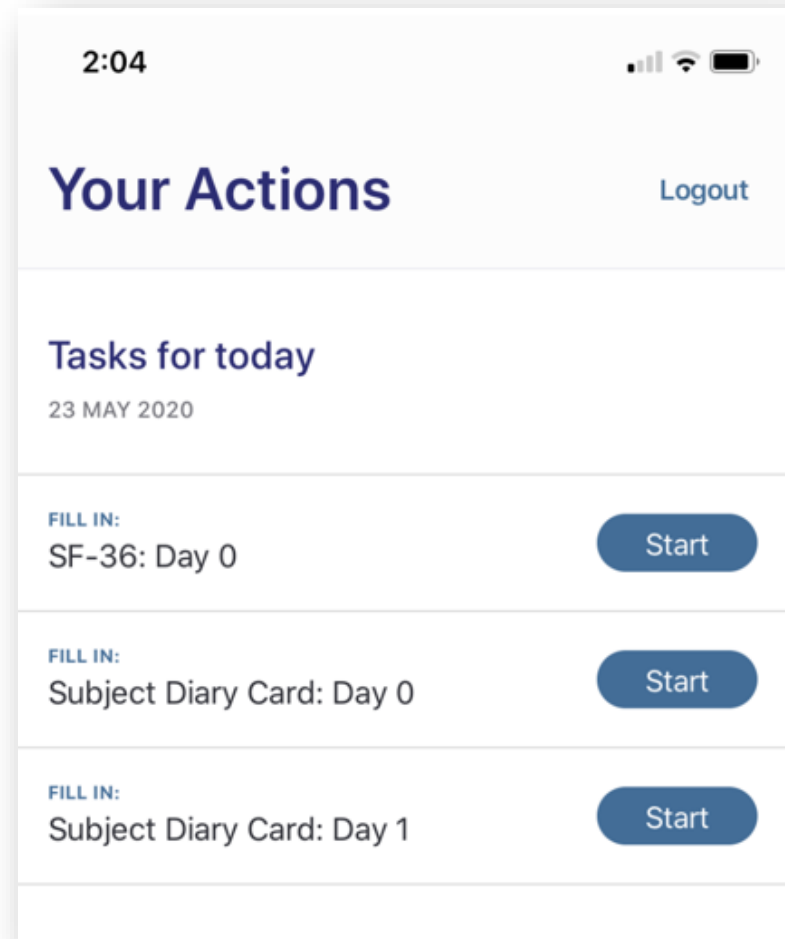
Visit Date Field
(none)

Visit Scheduling
Visit is due 1 days after baseline
Visit is overdue when 1 days late

Plates
Required 26,40
Optional
Display Order
Missed Visit

How to *assign* ePRO plates to visit map

- Patient-reporting 'visits' appear as "Tasks" when the subject logs in to DFengage after baseline visit has been completed



How to *define* ePRO role in DFadmin

- Create a role (ePROdata shown) that allows view access to study setup and visit map, and allows writing data (only); no other permissions are needed.

Tools & Reports | Auto Logout | Permissions

DFExplore

Server & DFsetup

Views

- Batch Edits
- Dashboard
- Data
- Data - Attach subject document
- Data - Import subject CRFs
- Data - Submit PDF
- Data - with Select
- Image
- Image - Create tasks
- Image - Delete new records
- Image - Raw data entry
- List
- List - Create views
- List - Import Data
- Queries

- View
- Plates
- Edit checks
- Lookup Tables
- Sites
- Missing Map
- Sort Map
- Visit Map
- Conditional Terminations
- Conditional Cycles
- Conditional Visits
- Conditional Plates
- Query Titles
- Query Covers
- Query Messages
- CRF Type Map

How to *define* ePRO role in DFadmin

- Restrict to include only the visits and plates needed for ePRO data collection.

Name: Status:

Description:

Tools & Reports | Auto Logout | **Permissions**

	Get		Show	Show	Modify	Write		Data					Queries					Reasons				
	Visits	Plates	Levels	Hidden Fields	Int. Queries	Levels	Levels	<u>C</u>	<u>M</u>	<u>D</u>	<u>L</u>	<u>P</u>	<u>C</u>	<u>M</u>	<u>D</u>	<u>A</u>	<u>R</u>	<u>C</u>	<u>M</u>	<u>D</u>	<u>A</u>	
<input checked="" type="checkbox"/>	0, 10, 20, 30, 40	1, 10, 15	0-1	<input type="checkbox"/> Show	<input type="checkbox"/> Show	1	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>				<input type="checkbox"/> Show	<input type="checkbox"/> Show			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

How to *assign* ePRO role in DFadmin

- Create users, following standard procedure, with two notable differences
 - User must be assigned a permanent password; one-time passwords are not yet supported
 - Assign a single subject ID (their subject ID in the trial) to the user

The screenshot displays the user management interface in DFadmin. At the top, a list of users is shown with columns for user name, creation date, role, and status. Below this, the details for user 'webinar17' are shown, including their status (Active) and a 'New Password' button. The 'Permissions' tab is selected, showing the user is assigned the role of 'Study or DFdiscover Administrator' with a value of 'None'. A table titled 'Study Roles' lists the roles assigned to the user, with the first role being '809 ePRO Webinar' with 1 site and 1017 subjects, and the role name 'ePROdata'.

	Study	Sites	Subjects	Role Name
<input checked="" type="checkbox"/>	809 ePRO Webinar	1	1017	ePROdata
<input checked="" type="checkbox"/>				



Questions?

Email us at help@dfnetresearch.com

Visit our website at dfnetresearch.com

Ready to engage?

- Email beta@dfnetresearch.com
- You'll receive two different questionnaires
 - Life During Quarantine: Day 1
 - Breakfast Questionnaire: Days 2, 3
- Feedback is appreciated

Thank you!