DFexplore Transition Training

Welcome to DFexplore

We are excited to introduce to you today DFexplore 5.4.0

❑ It is re-named line of Electronic Data Capture (EDC) products created by DF/net Research.

❑ You are to continue using one tool from this line: DFexplore which previously was referred to as iDataFax.

Introduction to DFexplore

How is it going to affect me?

- ☐ **One Time Action**: You will need to download and install DFexplore tool/app version 5.4.0 on each computer/laptop where you previously used iDataFax.

- ☐ **Ongoing/Moving Forward**: DFexplore tool's user interface is almost identical to iDataFax. The slight differences/updates are covered in the following slides.

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Introduction to DFexplore

How can I prepare?

❑ Download DFexplore 5.4.0 by clicking the link below:
DFexplore 5.4.0 client download

You will be prompted to enter the following information:

❑ Operating system (Windows or MAC)

❑ User ID (Existing iDataFax / DFexplore userID provided by PHRI)

❑ Study (Enter one of the PHRI study names you are participating –
   e.g. ACHIEVE, COMPASS, etc)

❑ Center ID (your 3-digit site number)

Click submit and follow the instructions

Introduction to DFexplore (computer requirements)

What are the computer requirements?

❑ Operating System (Windows 10 and newer macOS 10.14 (Mojave) and newer)
Important note: The Windows client tools have been tested and verified with 64-bit Windows 10. The client tools are not available for any 32-bit Windows OS.

❑ TCP/IP Networking/Internet Connection

❑ Any Client with older OS might need to use Roam AnyWare portal. Contact **PHRI study team** for details

Introduction to DFexplore (FAQ)

Can I still use iDataFax 2014 client?

❑ To access any of PHRI studies you should continue using iDataFax until **transition date TBD**

When can I install DFexplore 5.4.0 client?

❑ You can install DFexplore anytime now

When can I start using DFexplore 5.4.0 client?

❑ You will be able to access any of PHRI studies after upgrade, refer to update on iDataFax landing page and update from coordinating study team for transition date

DFexplore Transition Information

Note: iDataFax/DFexplore will NOT be available during system upgrade

Please save your work and log out of iDataFax prior to the scheduled downtime.

IMPORTANT

If you need to report a SAE/SUSAR, please contact your PHRI study team for further instructions.

Introduction to DFexplore (FAQ cont.)

If I am unable to install DFexplore 5.4.0 client, what should I do?

- ❑ Please visit the _PHRI website_ for troubleshooting tips

- ❑ Contact your organization's IT department

- ❑ Contact your PHRI study team
    - ❑ Contact your NLO/SMC for toll free number

- ❑ Contact PHRI IT department via
    - ❑ Email: PHRI.ICThelpdesk@phri.ca
    - ❑ Help Line US/Canada: 1-866-414-7474
    - ❑ Help Line Direct:1-905-522-3288 X 40444

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Also using iDataFax for Another Non-PHRI Study?

If a site uses a different version of iDataFax for another Study outside of PHRI run trials, they can continue to have multiple versions of iDataFax / DFexplore on the same computer

However – ALL PHRI trials will be using the DFexplore version 5.4.0 after transition date.
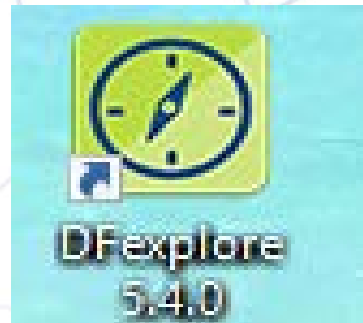
Data Collection Using DFexplore

Electronic Data Capture (EDC)

Sites will still enter data using DFexplore user-interface where:

❑ **SAME** - Data is organized as a set of patient binders with screens that match paper CRFs

❑ **SAME** - Enables users to enter reasons for data values and missing fields, and reply to data queries

❑ **SAME** - Includes other features: lookup tables, range and edit checks, help messages, etc.

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Connecting to the Application

OLD iDataFax Thumbnail
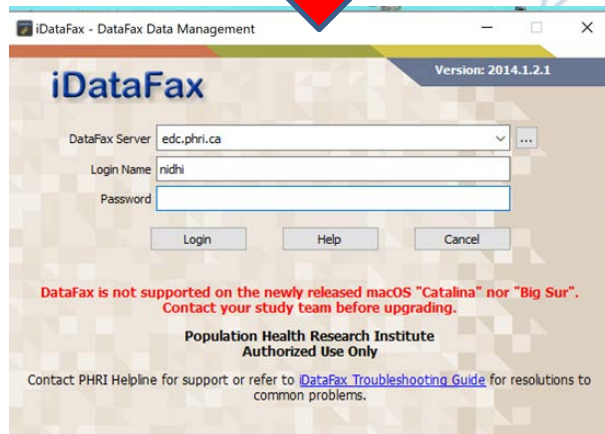
NEW DFexplore Thumbnail
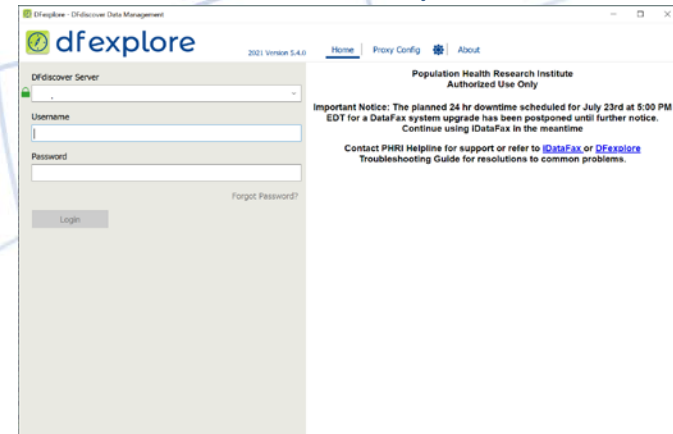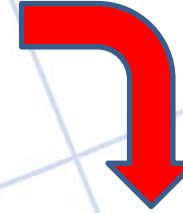
OLD iDataFax Login Screen

NEW DFexplore Login Screen

NOTE – the server name is still **edc.phri.ca**

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Accessing DFexplore

❑ **DFdiscover server name**: edc.phri.ca

❑ **Username:** same as you used for iDataFax

❑ **Password:** current one that you used for iDataFax.
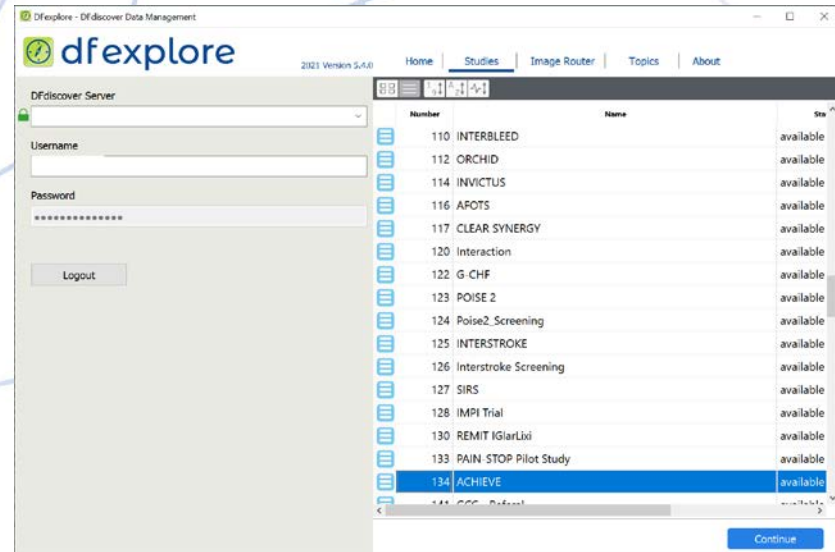
The Launch Screen

OLD iDataFax Launch Screen
Available Studies
❑ Vertical arrangement of available studies

NEW DFexplore Launch Screen
Available Studies
❑ Tabular arrangement of available studies

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The Launch Screen (continued...)

Tabular (Icon) View

List View

Preferences

For each study you can set the preferable auto logout from 5 minutes (by default) up to 30 minutes.
To change auto logout: select from top bar menu:

File ➡ **Preferences**

By using arrows, you can select the number of minutes when you will be log out of DFexplore automatically if you do not use the application.

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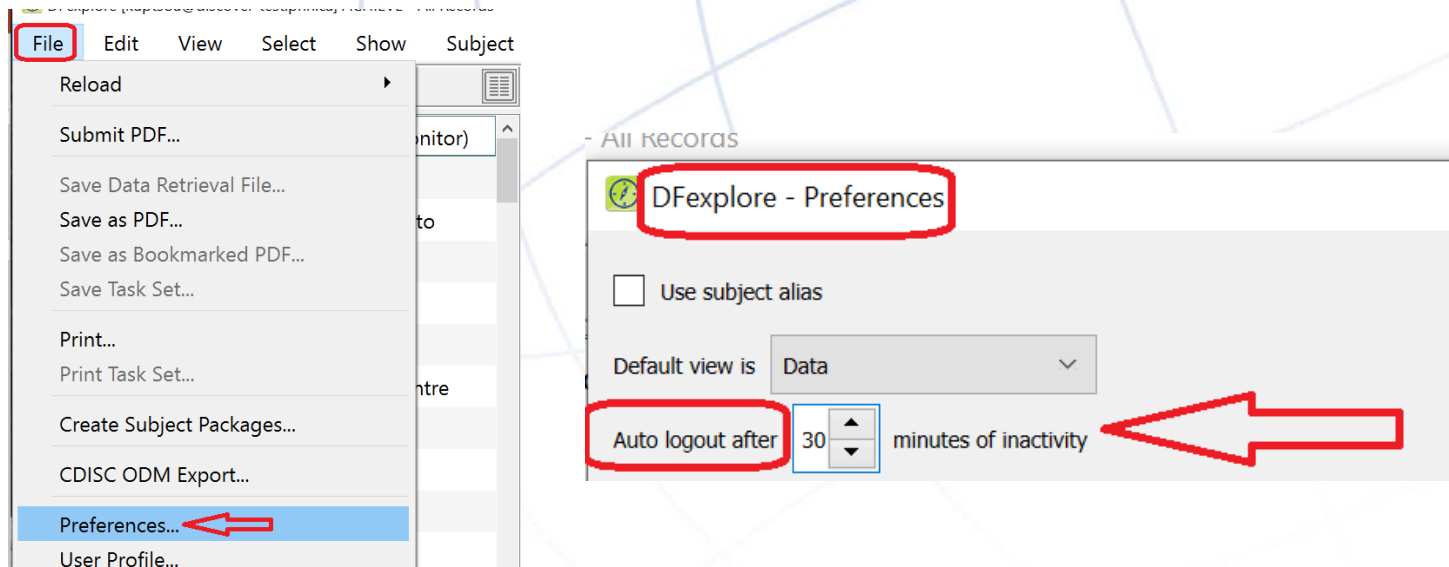
Subject Binders and Save Button
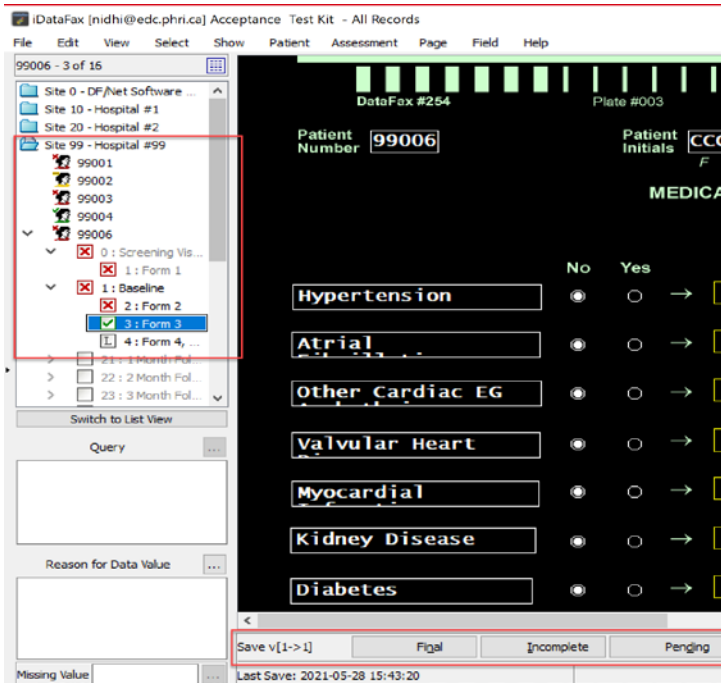
OLD iDataFax Main Screen

- ❑ Participant "Faces"
- ❑ Black background for text fields
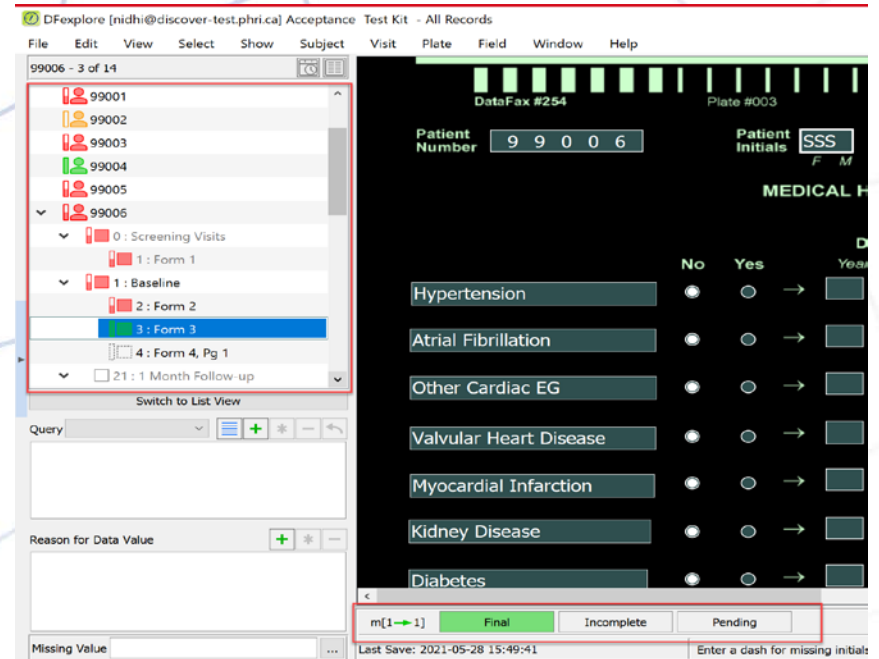
NEW DFexplore Main Screen

- ❑ Subject "Silhouettes"
- ❑ Grey background for text fields

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Subject Binders and Save Button
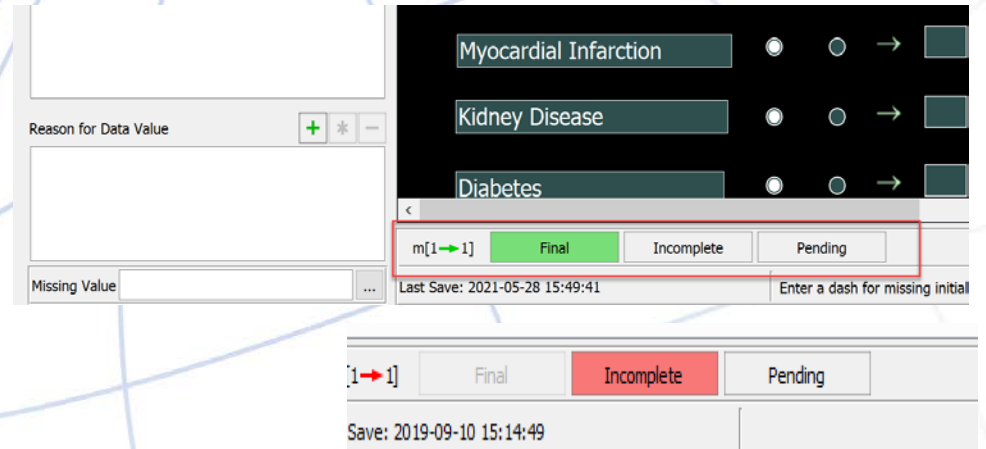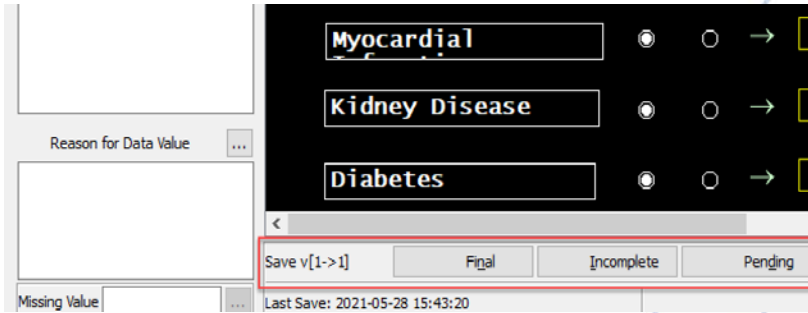
OLD iDataFax Main Screen

- ☐ Final Save button **– Grey**
- ☐ Save as Incomplete button
  - Grey

NEW DFexplore Main Screen

- ☐ Final Save button **– Green**
- ☐ Save as Incomplete button
  - Red

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What do the Colours and Icons Represent?

Different icons and colors indicate the status of participants, assessments and pages

Empty Head – New participant not yet started

Green Head – No problems, all pages entered so far are complete. ***NEW*** Thermometer – Fully complete
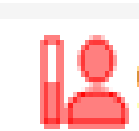
Red Head – One or more pages are incomplete or queried. ***NEW*** Thermometer – Half full

Yellow Head – One or more pages are pending, and no pages are incomplete. ***NEW*** - Thermometer - Empty

'L' Head – All pages within assessment have been marked lost (i.e., unavailable)

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Password Resets – Forgotten

Click on "Forgot Password" to reset

Password Resets – Compromised Password

Click on File ➡ User Profile ➡ Change Password

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Updated Terminology

OLD iDataFax	NEW DFexplore
DataFax	**DFdiscover**
iDataFax	**DFexplore**
Fax	Image
Centre	Site
Lost record	Missed Record
Problem	Category
Sign-off	Save
QC	Query
Login name	Username
Patient / Participant	Subject

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iDataFax Data View – Old Screen
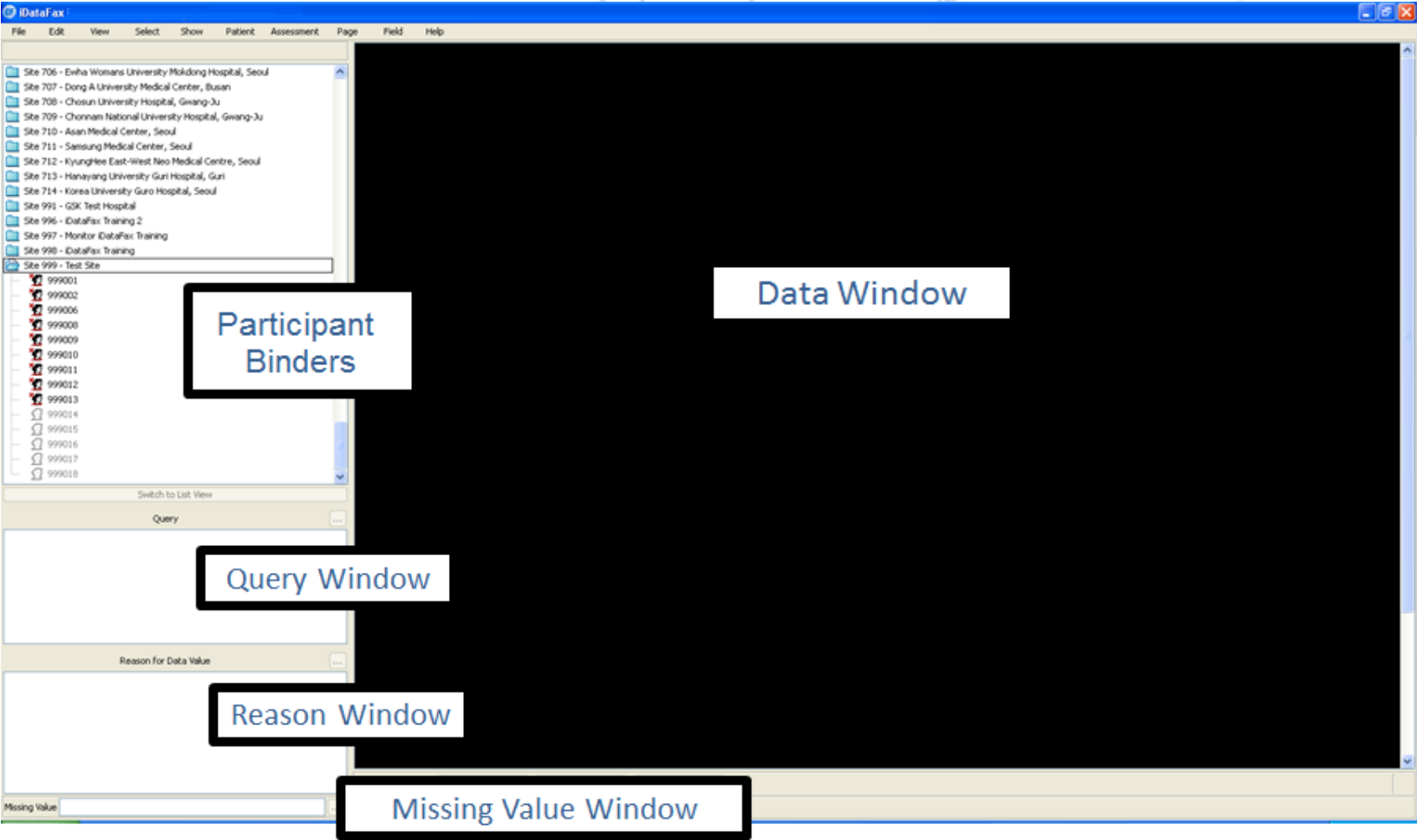
DFexplore Data View – New Screen

New Date Picker Using Calendar Widget

New Date Picker using Calendar – Default setting

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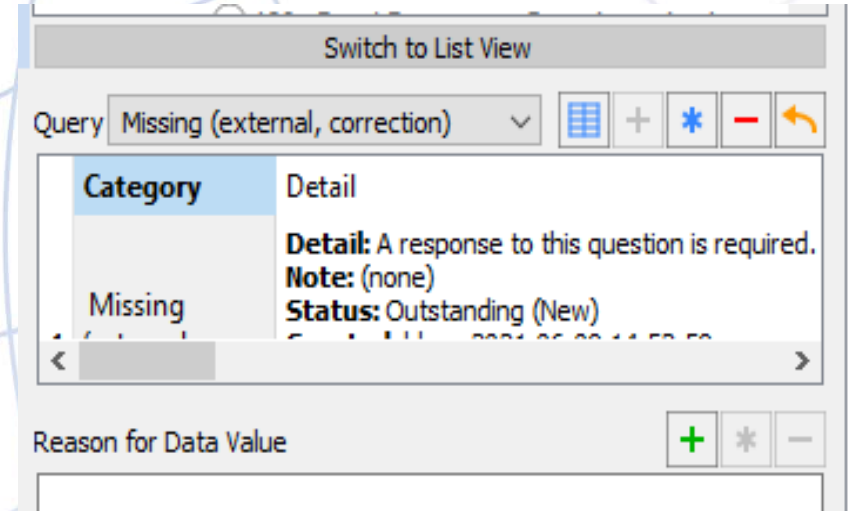
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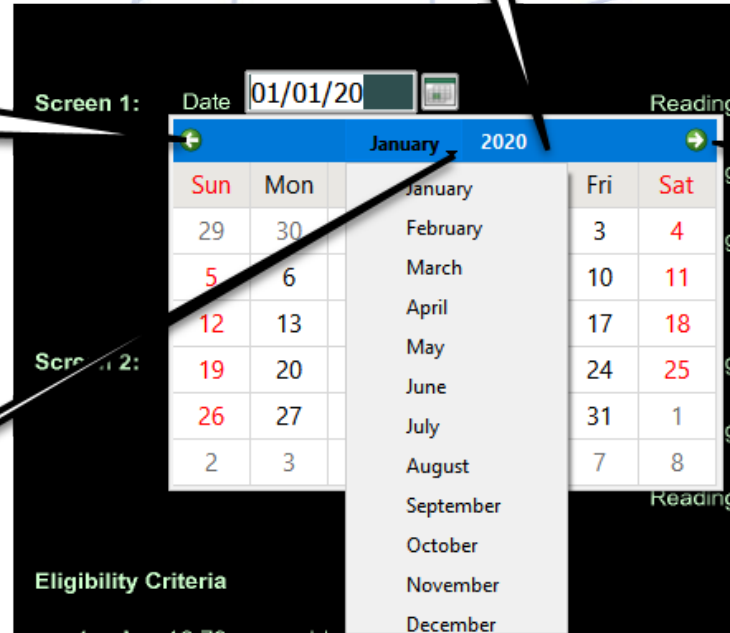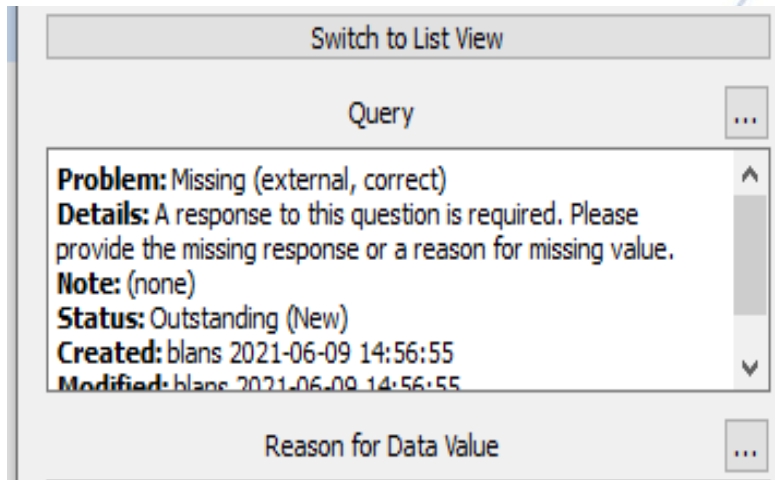
Query Window

OLD iDataFax Query Window

❑ Query type called Problem

❑ Respond to Query using

NEW DFexplore Query Window

❑ Query type called Category

❑ Respond to Query using

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Assessment Icons

Assessment and page icons use the same colors, with the same meaning, but they come in different shapes to indicate whether they are required or optional:

OLD iDataFax icon   **NEW DFexplore icon**

Square – a required assessment or page

Circle – an optional assessment or page

Diamond – an unexpected assessment or page

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Electronic Data Entry

DFexplore will still allow you to:

- ❑ Tab across the e-CRF to show you where you need to enter data
- ❑ Click on fields where you would like to enter data
- ❑ Complete Auto-calculations (where applicable)
- ❑ Utilize signature look up tables (where applicable)
- ❑ Execute digital signatures, compliant with 21 CRF Part 11
- ❑ View and reply to Queries
- ❑ Receive QC reports
- ❑ Provide Reasons for Data Value

Electronic Signatures

The e-signature feature continues to be **21 CFR Part 11 compliant**

The e-signature is a combination of the DFexplore user name and password, and is to be provided at the end of the eCRF page or visit assessment.

An electronic signature (e-signature) is the legally binding equivalent to a hand written signature which indicates the user confirms the data reported within the eCRF.
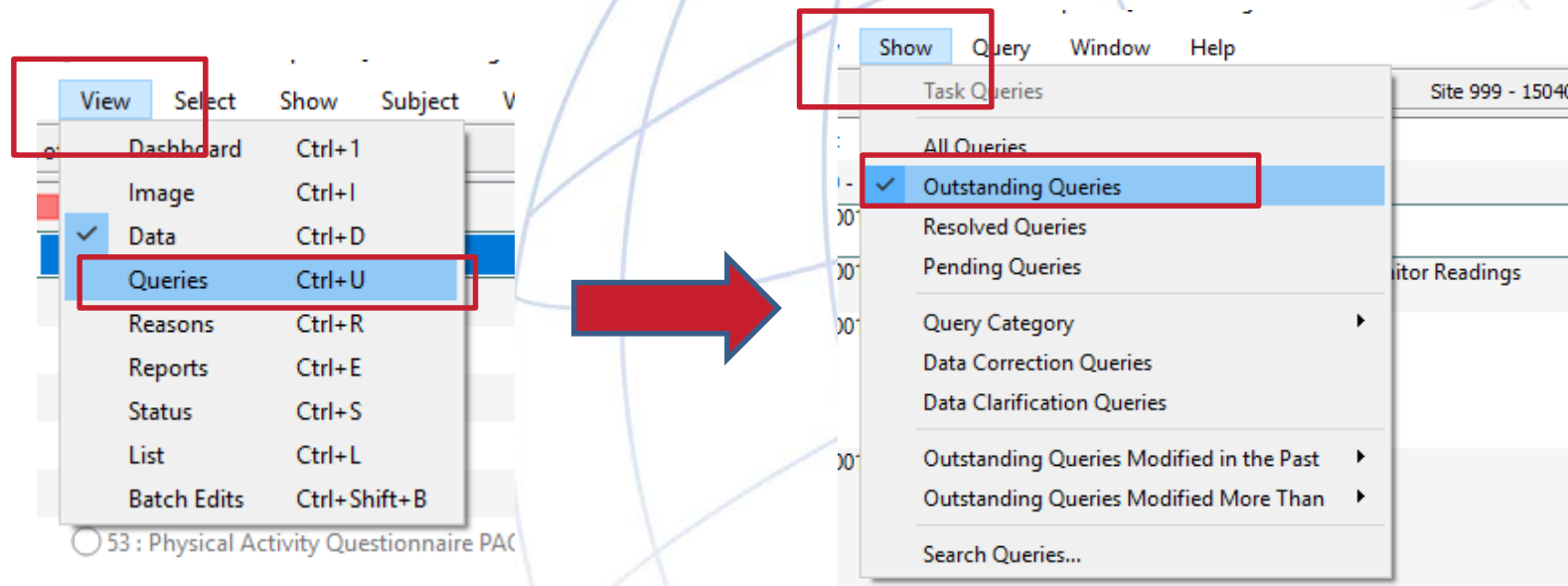

Name of Authorized Person Completing CRF:

Electronic Signature:
(Legally binding equivalent t

year   month   day   Time   24 hr clock

ARTESiA Baseline CRFs. Final Version 1.0 2014-12-03

Viewing Queries

To View Queries, Click:
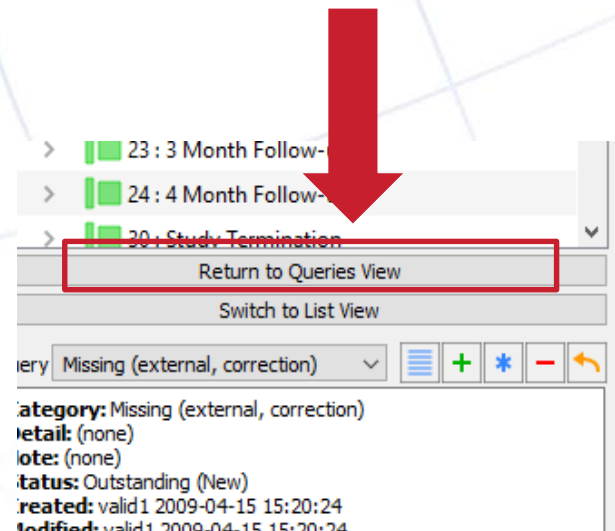
VIEW ➝ QUERIES ➝ SHOW ➝ OUTSTANDING QUERIES

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Query View

□ **Double-click on the query to go to the exact field with the QC you want to fix**

□ **Click on "Return to Query View" to return to listing of outstanding Queries**

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Submitting Source Documents

☐ Source documents for Patient Personnel Information

☐ Scan / Save the document to PDF (multiple pages can be saved in one file)

☐ Open the needed CRF (eg. Consent/ Shuttle Form/ Baseline etc.)

☐ From the "**Menu**" bar under the **"Subject"** tab > **Import Subject CRFs** and open the PDF file through a browser window

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Select pages for upload

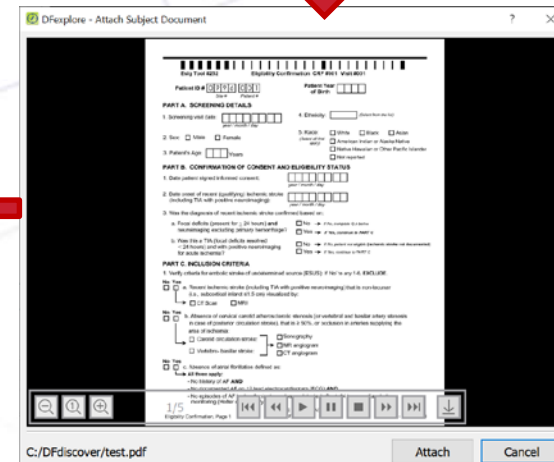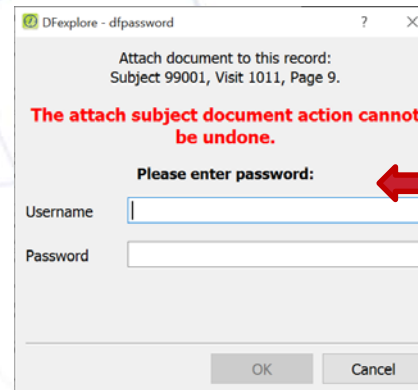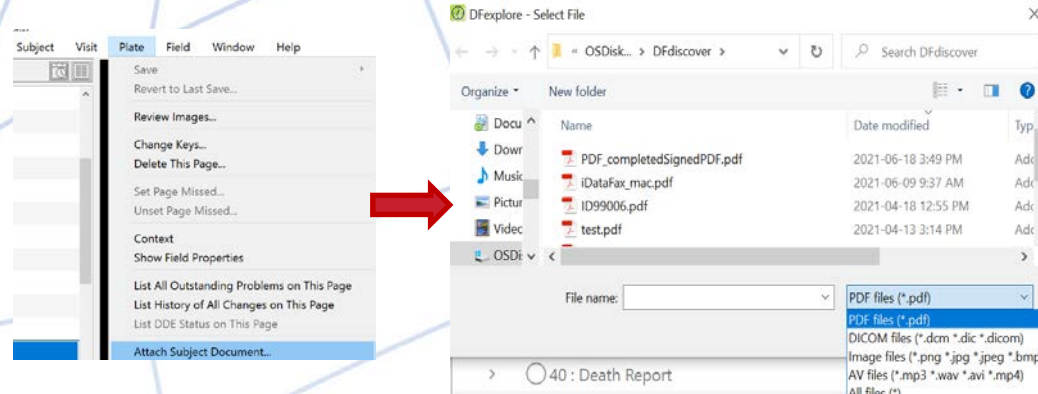Once the documentation has been selected click on "Import"
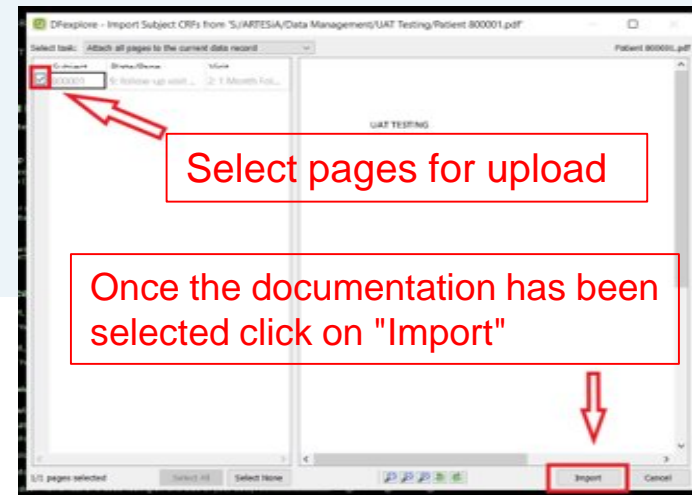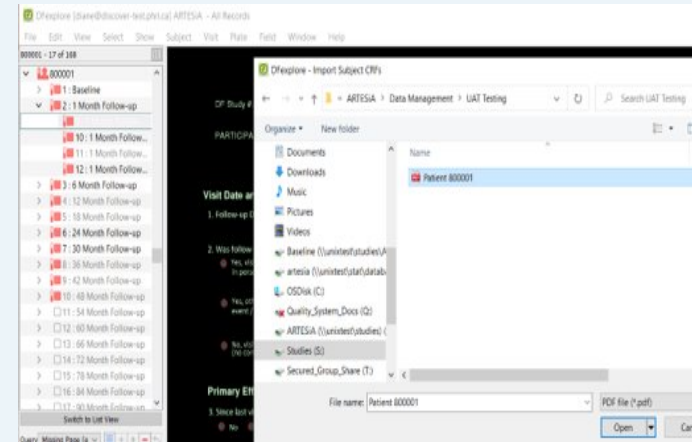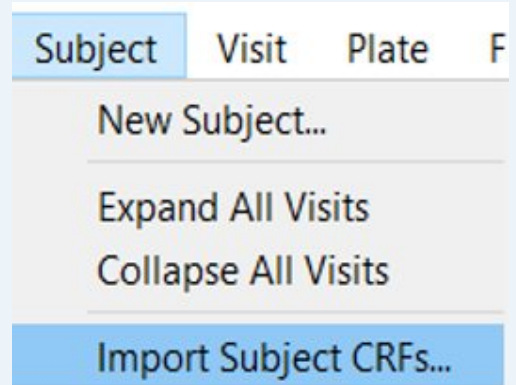
Uploading Other Source Documents

To **Attach** additional Source Images (such as ECGs, DICOM, etc)

Use **Plate** ➡ **Attach Patient Document** to attach the documents to the current record as a supporting document. Documents can be reviewed later with the review images dialog attached

Limitations:

- Attached files must be less than 25MB in size.

- Supported formats:
  - ❑ PDF
  - ❑ DICOM (dcm, dic, dicom),
  - ❑ image (png, jpg, jpeg, bmp)
  - ❑ AV(mp3, wav,mp4)

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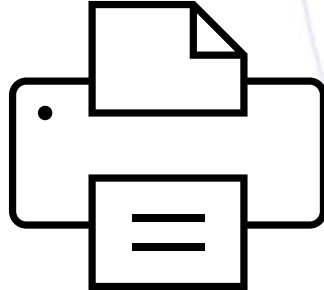
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Submitting Source Documents - Fax

Sites can continue to Fax Subject Source Documents Via

- ❑ **Fax Number:** 1-800-268-2370
- ❑ (Contact your NLO/SMC for local toll free fax number)
- ❑ **Email:** datafax@phri.ca

Faxes are now called **Images**

DataFax #148   Plate #091

Inclusion Criteria
Shuttle Report No. 7 0 1

Participant ID# 9 9 9 0 0 0 1   Initials A A A
Centre #   Participant #   F M L

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Thank you

If you have any further questions please contact your Project Office Study Team