EARCO
European Alpha-1 Research Collaboration

CLINICAL REGISTRY SYSTEM
USER GUIDE

Typography

Items displayed in *italics* refer to feature or page labels, for example *Centre Dashboard* or *Header Menu*.

Items displayed in **bold** type refer to clickable actions, for example click **Add New Patient** .

CONTENTS

INTRODUCTION

The OpenApp Clinical Registry System is a user-friendly and intuitive tool used to track patients. A core set of data elements have been included to allow a comprehensive record of a patient's experience.

Patient records are stored in the secure environment used for all OpenApp Registry products.

This User Guide gives a brief introduction to the Registry and instructions on how to use it.

GETTING STARTED

Supported Browsers

The Clinical Registry System is web-based and is accessed using a web-browser. The latest versions of the following browsers are supported:

- Google Chrome – recommended for best experience of all Clinical Registry System features.
- Mozilla Firefox
- Microsoft Edge

Additional Browser Requirements

JavaScript must be enabled in all browsers.

Private/incognito browsing modes should not be used when accessing the Clinical Registry System.

Note The browser version and other settings can be checked by using the **Browser Information** link at the bottom of the Clinical Registry System page, or by going to https://www.whatsmybrowser.org.

Clinical Registry Support

In case of any technical difficulty accessing the Clinical Registry System, general queries or login problems please contact the EARCO Registry Manager: **earco@vhir.org**

Feedback, suggestions, or complaints can also be sent to the EARCO Registry Manager.

Log in to the Clinical Registry System

The Clinical Registry System is protected by a secure authentication mechanism. A username and password will be provided by the EARCO Registry Manager.

1. Navigate to *Secure Login* page for the Clinical Registry System.
   - The URL for the Clinical Registry System is: **earco.vhir.org**
2. Type the **username** in the box provided**.**
3. Type the **password** in the box provided.
4. Click **Secure Login**.

Forgotten Passwords

User passwords are stored in a secure area of the Clinical Registry System and cannot be viewed by the administrator or co-ordinator. If the user has forgotten their password, it must be reset by the user themselves.

1. Click **Forgot password?** below the *Secure Login* button to request a password reset.
    o   The email address provided must match that of a registered user.
    o   An e-mail containing a link to the password reset page will be sent to the user's e-mail address.
2. Click the link in the e-mail to start the reset process.
    o   Follow the instructions on screen to reset the password.

Note   The e-mail should be deleted when the password has been reset by the user.

Request New Account

User accounts are assigned by the EARCO Registry Co-ordinating Centre. A new user account can be requested using an on-line form, which is forwarded to EARCO for processing.

1. Click **New Account?** below the *Secure Login* button to request a new user account.
    o   Complete the form by providing all of the required information.
    o   The email address provided must not be in use by another registered user.
    o   An e-mail containing a link to complete the registration process will be sent to the e-mail address provided.
2. Click the link in the e-mail to complete the user registration.
    o   Follow the instructions on screen to create a password and complete the process.

Note   The e-mail should be deleted when the user has been successfully registered.

Automatic Logout from the Clinical Registry System

If the user leaves the Clinical Registry System idle for more than 30 minutes, they will be automatically logged out.

Notes   To ensure data integrity, unverified data is not saved when the user is automatically logged out of the Clinical Registry System.

*   The idle time limit (timeout) is set by the system administrator.

Manual Logout

When the user is finished using the Clinical Registry System, or when leaving the workstation unattended, they should log out of the system to prevent unauthorised access to patient information.

1. Click **user@centre** details in the *Header Menu*.
2. Click **Logout** in the drop-down menu.

WORKING WITH THE CLINICAL REGISTRY SYSTEM

Once the user has logged in to the Clinical Registry System they will be brought to the *Dashboard* for their Centre. If the user is working in more than one Centre, the *System Home Page* will be displayed instead; this page provides links to their Centres.

A module within the Registry System is a predefined set of security rules, dashboards, forms and reports created for a specific requirement. Each Centre with in the Registry is a separate Module, ensuring the security and segregation of confidential patient data within the Registry.

The data for each Healthcare Provider using the system is isolated within a Centre. Users associated with a particular Centre cannot access the data for other Centres.

The *Centre Dashboard* provides an overview of the activity within a selected Centre and provides access to all of the Centre features.

While working within a Centre, the *Side Menu* provides links to the activities for the Centre. The items available in the *Side Menu* will vary depending on the user's current activity. The user's role within the Centre or Registry will also affect which items are available in the *Side Menu*.

The Header Menu

The *Header Menu* is shown at the top of all pages within the Clinical Registry System and provides quick navigation to the Clinical Registry System features. The items shown will depend on the user's role within the Clinical Registry System.

All of the items in the *Header Menu* are clickable – providing navigation to the *Centre Dashboard* or to other features and modules.
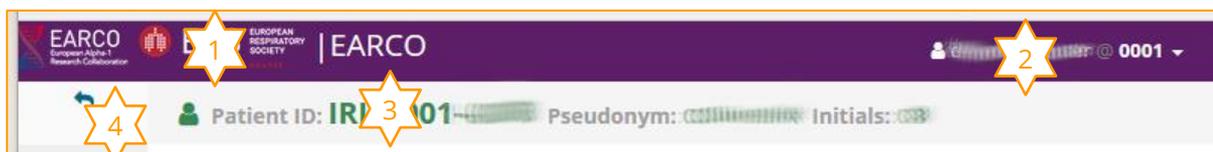

Figure 1 – The Clinical Registry Header Menu (patient view) – see below for details.

1. The Clinical Registry title is shown on the left of the Header bar. Click here to return to the *Centre Dashboard*.
    o If the user is working in more than one Centre this will return to the *System Home Page*.
2. The current user's name and selected Centre are shown at the top right of the Header bar. Click here to open a drop-down menu from where the user can log out of the system. This menu also provides access to other Centres depending on the users profile.
3. The *Context Banner*, displayed below the *Header Menu,*
    o When working within the Patient's pages, details of the currently selected Patient are displayed.
    o When working on the Centre pages, details of the current Centre, User and Role are displayed.
4. When working within the patient's pages, an arrow is shown on the left of the *Context Banner*. Click here to return to the *Centre Dashboard*.

System Home Page

The *System Home Page* provides the user with links to Centres available to them within the system.

Note   Only users that are working in more than one Centre will see this page.

The Centres available to the User are shown in the *Modules/Centres* panel. Click a **Centre** to go to that *Centre Dashboard.*

Depending on the user's role within the Clinical Registry System, additional options may be available on the *System Homepage*.

Centre Dashboard

The *Centre Dashboard* provides an overview of the activity within the user's Centre. From the *Centre Dashboard* the user can view a summary of all patients enrolled, search for a patient, and view recent activity and active queries.
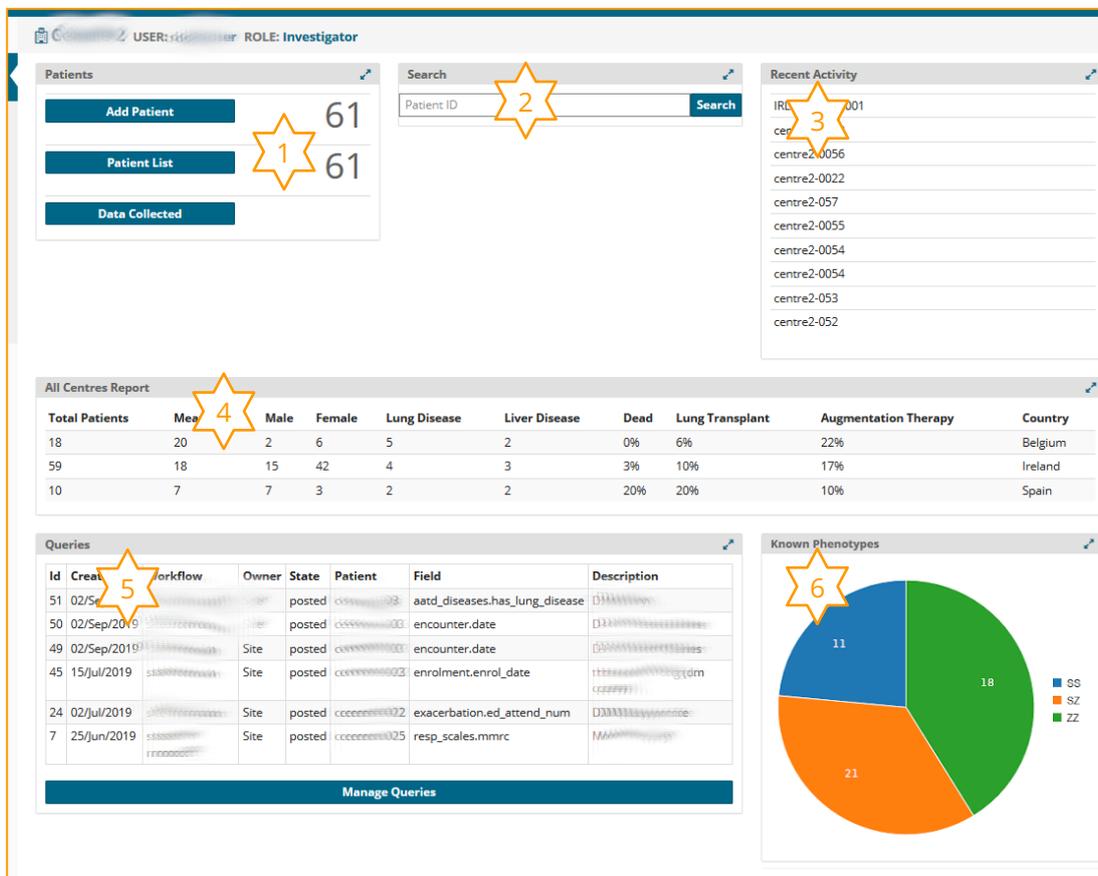

Figure 2 – The Centre Dashboard – see below for details.

1. A summary of patient enrolment is shown at the top left of the page
    o   Click **Add Patient** to open a *Patient Enrolment* form.
    o   Click **Patient List** to open the *Patients* page, from where existing patients can be accessed.
    o   Click **Data Collected** to open the *Forms* page
2. Use the Search tool to quickly locate a specific patient record.
3. A summary of recent activity is shown at the top right of the page – click a **Patient Row** to open the *Patient Summary* Page.
4. The All Centres Report provides a summary of all enrolled patients grouped by country.
5. A summary of the active queries is shown at the bottom left of the page – click **Manage Queries** to open the *Query Management* page.
6. A graph showing a summary of Known Phenotypes recorded for enrolled patients is shown at the bottom left of the page – move the mouse over the graph to see the detail for each segment.

Usually, a user will be associated with only one Centre. However, if they are in more than one Centre, they can select the Centre to work with from the list in the Modules section of the *System Home Page* or from the drop-down list in the *Header Menu*.

The Centre Side Menu

While working within the *Centre Dashboard* and its associated pages, for example while viewing the forms page, the menu displayed on the left of the screen provides access to Centre related features.

1. Use the **Centre** link to return to the *Centre Dashboard.*
2. The currently selected page is highlighted – for example the Forms page.

Figure 3 – The Centre Side Menu – see above for details.

Patient Summary

Once a patient has been selected, the *Patient Summary* page is displayed – it provides an overview of the patient enrolment and baseline details.

The Patient Side Menu

While working within the Patient pages, for example while updating an event, the menu displayed on the left of the screen provides access to Patient related features.

1. Use the **Back Arrow** at the top of the Side Menu to return to the *Centre Dashboard*.
2. The currently selected page is highlighted, e.g. the *Data Collection* page.
3. Use the links to access the other Patient pages.
4. Use the **Queries** link to open the *Manage Queries* report for the selected patient.

Figure 4 – The Patient Side Menu – see above for details.

Clinical Registry Forms

All patient enrolment and recording of baseline and follow-up details within the Clinical Registry System is done using forms.

The forms used to record Baseline and Follow-up events are made up of sections.
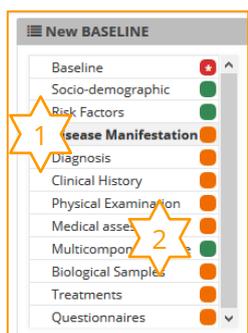
1. The active section is highlighted in bold type with a grey background, e.g., Disease Manifestation.
2. The RAG indicator gives a visual indication of section completion. See Form and Section Validation below for details.

Click a **Section** title to move to that section of the form.

Figure 5 – The Baseline Form section selector – see above for details.

Save/Cancel

On all pages within the Clinical Registry System where data can be entered (forms), any changes or new data must be saved to record the information in the system.
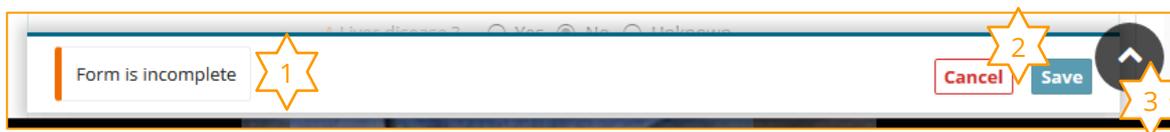

Figure 6 – The Form Action Bar – see below for details.

1. The form will be flagged as missing data until all of the required data has been correctly entered. See Data Integrity Checks below for details of data requirements.
2. Use the **Save** button on the form to record the information.
   o In all data entry/update forms, the **Close/Cancel** button shown with the Save button can be used to leave the form without saving the changes or new data being entered.
   o Confirmation of the action may be required.
3. Longer forms include a *back-to-top* button at the bottom of the page. Click the **arrow** to return to the top of the form.

Note   It is recommended that users regularly use the **Save** button to ensure that data is not accidentally lost.

Save As Complete

On all Clinical Registry forms the option to flag the data recorded as complete will be provided to prevent accidental changes to the data.

The **Save as Complete** button will be displayed on the form View and Edit pages when all Required (*) and Expected (Δ) data has been provided and all queries have been Responded to and Closed or Cancelled.

Forms marked as Complete do not have an Edit button.

See Data Integrity Checks below for details of Required (*) and Expected (Δ) fields. See Working with Queries below for details of Responding to Queries.

Revert to Edit

A form that has been flagged as Complete can be re-opened if data changes are required.

The **Revert to Edit** displayed on the form View pages can be used to enable the Edit button on a Completed form.

Data Entry

Throughout the Clinical Registry System, data is entered using a variety of methods:

- **Text boxes** allow the user to enter free-text to describe a symptom, action, etc. There is no limit to the amount of text allowed. Depending on the user's browser, spelling errors will be indicated.
- **Drop-down lists** allow the user to scroll through a list – click an item in the list to select it.
- **Auto-complete selection lists** are used to allow the user to filter a long list – start typing the required text and click an item in the list to select it. The magnifier to the right of the field will open a *Data Picker* page where the user can browse the full range of options for selection.
- **Check boxes** allow the user to select more than one option from a list – click as many options as required to select them.

- **Radio buttons** allow the user to select a single option from a list – click an option to select it. The previous selection will be removed.
- **Date pickers** are used to select a date from a calendar. Most date fields also allow the user to type the date. Some date fields do not require an exact date, for example a month and year may be sufficient.
- **Repeating fields** allow for multiple entries of similar data to be recorded within a section or form. A button will be displayed in the form section to allow the first and multiple entries.

> The **i** symbol is displayed beside fields that require complex or specific data. Click the **i** symbol to view an explanation of the data requirements.

Progressive Disclosure and Dynamic Fields

Progressive disclosure is used within the Clinical Registry System indicate the most important fields within a section of a form. Once this first field has been completed, additional (dynamic) fields are made available to complete the section.

Slow Changing Data

Slow changing data is logged during an event and maintained on the forms for subsequent events. For example, patient medication can be flagged to remain until the course is stopped.

The *Ongoing* option must be set to **Yes** for the medication/therapy data to carry forward to the next event.

Repeating Data

Repeating data fields allow more than one entry per form.

For example, more than one ambulatory exacerbation or emergency hospital admission may be recorded on the patient event forms.

Data Integrity Checks

The Clinical Registry system uses Red/Amber/Green (RAG) colouring to indicate data validity and completion status.

All data on a form is checked and validated by the system as it entered by the user. There are three particular checks carried out on an active form.

The form data validation status will be indicated in the *Action Bar* at the bottom of the form.

The **Save** button for the form will not activate until all required data has been entered and is valid.

The **Save as Complete** button for the form will not activate until all required data and all expected data has been entered and is valid.

Required/Expected/Optional Data

Required data fields (also referred to as mandatory or compulsory) must be entered before a form can be saved. A red asterisk (*) is shown beside a field name to indicate that data must be entered in the field.

The status of the form data will be indicated in the *Action Bar* at the bottom of the form and the **Save** button for the form will not activate until all required data on the form has been entered.

Example: While adding a Patient's Baseline record, the **Save** button will not be active until the Baseline Date has been filled in.

Expected data fields are normally expected to be filled in, but the form can be saved if the fields are empty. An amber triangle (△) is shown beside the field name.

This will allow a user to save a form if they do not have sufficient information for a data field and it would be impractical to prevent the other data on the form being saved.

Example: When adding a Patient's Baseline record, the risk factors and disease manifestation must be recorded. If some or all of this data has not been entered, the form **Save** button is active.

Optional data fields (also referred to as permitted or voluntary) do not have any completion requirement. No symbol is applied to these data fields. These data fields do not prevent the form being saved, or marked as complete, if they have not been filled.

Example: On a patients Baseline form, when recording the Smoking Status, the Other Inhaled Exposure data is optional. Empty options will not prevent the form being saved. The **Save** button is active. The **Save as Complete** button will be active when all Required and Expected data is filled in.

Data Validity

When entering data on forms, the system compares the values entered with required values that are set within the Clinical Registry System. These comparisons can be either "Hard Check" or "Soft Check".

If there is an error when entering data, the system will display a message, describing the value that it did not expect and may ask for the correct value to be entered. The field will be highlighted with a coloured border.

Empty fields are treated in the same way as fields that contain data.

Hard Check **Red** **Validation Error**	The field contains invalid data. Missing data for a required field is considered as invalid data by the system. For example, when entering a Date of Encounter in the future, the system displays "At time of entry, date was in the future. Please correct.". The relevant field is highlighted in red and the RAG indicator on the section/form is set to red. The form cannot be saved until the error has been corrected. Required fields are treated as *invalid* if they are empty.

Soft Amber Validation Warning	The field contains unexpected data. For example, when entering 20 where the expected value should be below 10, the system displays "The value is outside of the expected range. Please correct or clarify". The relevant field is highlighted in amber, and the RAG indicator on the section/form is set to amber. The entry in the field may be changed, or if the value is correct the form can be saved with the errors included. Expected and Optional fields are treated as *valid* if they are empty.

Form and Section Validation

Form and Section validation is dependent on the fields they contain.

Red Validation Error	Required but missing or invalid: required (mandatory) information in this form or section is required. The form cannot be saved until valid data has been entered in all fields on the form or section.
Amber Validation Warning	Expected but missing: more information in this form or section is expected but has not been entered. The form can be saved but will be flagged to indicate that it is missing data.
Green Validation Success	Optional: all required information in this form or section has been entered. The form is saved and is flagged to indicate that all data has been entered and is valid.

Note   As a form cannot be saved while required data is missing or invalid, the form will never show a Validation Error (Red) status.

The Cascading Effect

Field to Section

Within Clinical Registry, the validation state of a Section is dependent on the fields in that Section. As the fields in a Section may have a mix of validation states, the Section validation state is determined by the most serious field validation error.

For example:

- If a Section contains any fields with a Red/Error validation state, the Section border and heading will be red and the indicator in the *Section Selector* will be Red/Error.
- If a Section contains no fields with a Red/Error validation state but one or more fields with an Amber/Warning validation state, the Section border and heading and the indicator in the *Section Selector* will be Amber/Warning.
- If a Section contains no fields with a Red/Error or Amber/Warning validation state the Section border and heading and the indicator in the *Section Selector* will be Green/Success.

Section to Form

Within Clinical Registry, the validation state of a Form is dependent on the data on the form. The form validation state is determined by the most serious Section validation state.

As the Form cannot be saved while it contains sections with a Red/Error validation state, the form itself will never show as Red.

If the Form includes any Expected fields that have been left empty or contain invalid data the form validation status will be Amber/Warning.
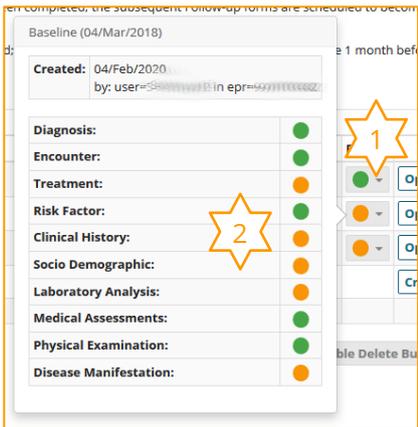
1. The form RAG indicator will be Amber/Warning until all of the required and expected data has been entered.
2. The data validation status of the Sections indicates the Sections requiring attention.

Figure 7 – The Form Data Validation Status – see above for details. ?? Awaiting image – sections wrong ??

Navigating the Clinical Registry System

Below are some instructions for quick access to key areas of the Clinical Registry System.

View the Centre Dashboard

When working within the patient pages,

- Click **the arrow** at the right of the *Context Banner.*
- Click the **Clinical Registry** title, in the *Header Menu*.

View the Centre Queries Report

- Go to the *Centre Dashboard* page.
- Click **Queries** in the *Side Menu*.

View the Centre Patient List

- Go to the *Centre Dashboard* page.
- Click **Patient List** in the *Side Menu*.

View a Patient Summary Page

- Go to the *Centre Dashboard* page.
- Click **Patient List** in the *Side Menu*.
- Click anywhere on the **Patient Row**.

View a Patient Data Collection Page

- Go to the *Centre Dashboard* page.
- Click the **Patient ID** in the *Recent Activity* list.

WORKING WITH PATIENT DATA
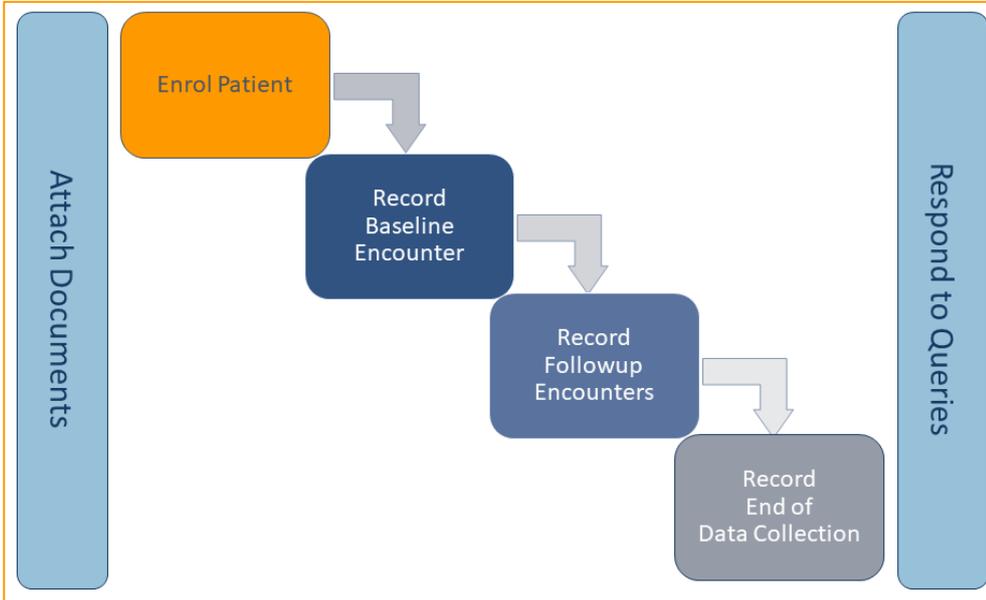
The Registry Workflow

Figure 8 – The Clinical Registry Workflow.

The diagram above shows the Clinical Registry Workflow.

Once the patient has been enrolled, the Baseline data should be recorded as soon as possible.

Follow-up events are added to the Patients record annually.

Queries posted by the data manager can be responded to at any time.

Documents, such as Patient report documents and images, may be attached to the Patient record at any time.

The End of Data Collection records the end of a patient's participation in the Clinical Registry.
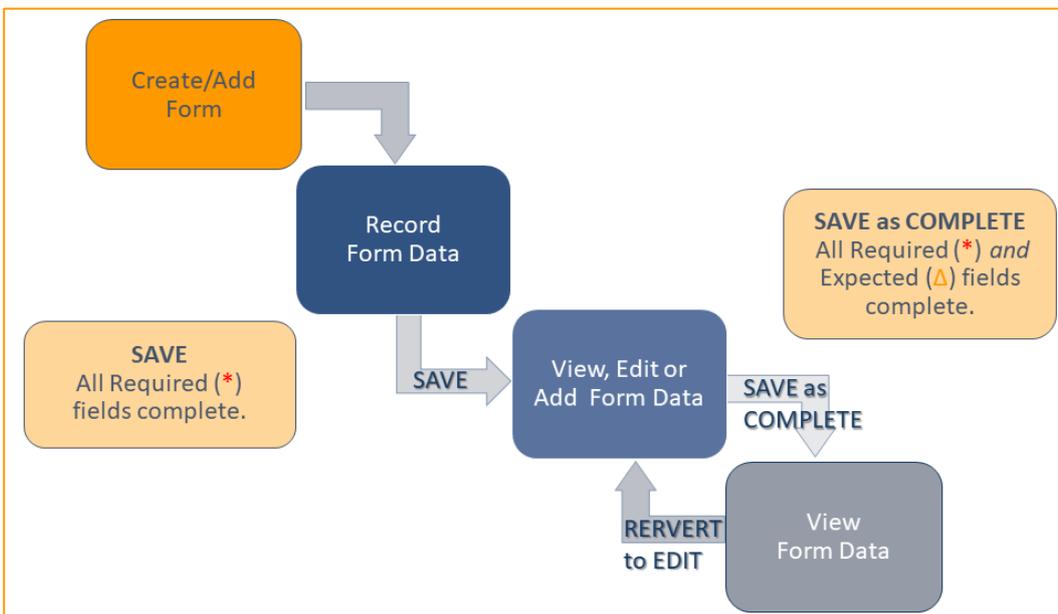
The EARCO Document Workflow

Figure 9 – The EARCO Document Workflow

Events (Forms) added to the patient record can be Saved before all data has been provided to allow for interruptions, or incomplete data, at the time of data entry.

The data for Required (*) fields must be provided before the form can be Saved. Expected (Δ) and Optional fields may be left blank when Saving the form. Remember, Required (*) fields may be Dynamic, i.e., become active depending data provided in another field.

Once the data for all Required (*) and Expected (Δ) fields has been provided, and all Queries have been responded to and closed or cancelled, the form can be Saved as Complete to prevent further editing.

If further optional data becomes available, or changes to existing data are required, the Revert to Edit option can be used to allow data editing.

See Progressive Disclosure and Dynamic Fields and Data Integrity Checks above for details of Dynamic, Required (*) and Expected (Δ) fields.

See Working with Queries below for details of Responding to Queries.

Note It is recommended that users regularly use the **Save** button to ensure that data is not accidentally lost.

Enrol a Patient in the Registry

The first task in the Clinical Registry process is the enrolling of patients. The Clinical Registry Enrolment form is made up of two sections; all data on both parts of the form must be entered to complete the enrolment.

1. Navigate to the *Centre Dashboard*.
2. Click the **Add Patient** button to open the *Enrolment* form.
    o   A unique *Patient ID* is automatically assigned.
    o   All fields marked on the *Identifying data* section of the form are Required.
3. Complete the Consents section of the form.
    o   Consent to be added to register must be provided.
4. When all of the information has been entered, click **Enrol** to save the patient enrolment details.
    o   The record cannot be saved until all required information has been correctly provided.
    o   If a patient with same details already exists on the Registry a warning will be displayed to help avoid duplication. Click **OK** to continue if the patient being enrolled is correctly identified.

Note On completion on enrolment, the Baseline form is automatically opened. See Create the Baseline Data below for details.

The Importance of Consent

The patient or their Carer must give consent to be enrolled in the system. The overall consent is noted with the date of the signed form.

The Patient's Consent is recorded as part of the enrolment process. The options are:

*   Consent to added to the Register is *required* for enrolment on the EARCO Registry system.
*   Agreement to be contacted for research purposes is *optional* for enrolment on the EARCO Registry system.
*   Agreement for data transfer to national registry is *optional* for enrolment on the EARCO Registry system.

Notes If a patient withdraws their consent for inclusion in the Registry, an *End of Data Collection* form must be completed to record the reason for withdrawal of consent. See End of Data Collection below for details.

• A patient may request that their data is removed from the Clinical Registry when they withdraw consent – See Wipe Patient Data below for details.

Wipe Patient Data

A patient or their carer may request that their data is removed from the Registry.

1. Navigate to the patient's *Summary* page.
2. Click the **Wipe this patient's data** button to start clearing the patient's data.
3. Tick the confirmation box in the Wipe Patient's Data pop-up and note the date or reason:
   o If the patient has requested the deletion the date must be recorded.
   o If the action was not requested by the patient the reason must be recorded.
4. Click **Wipe Record** to remove the Patient identifying data and all data collected and return to the *Centre Dashboard*.

Note This action cannot be reversed, wiped data cannot be recovered.

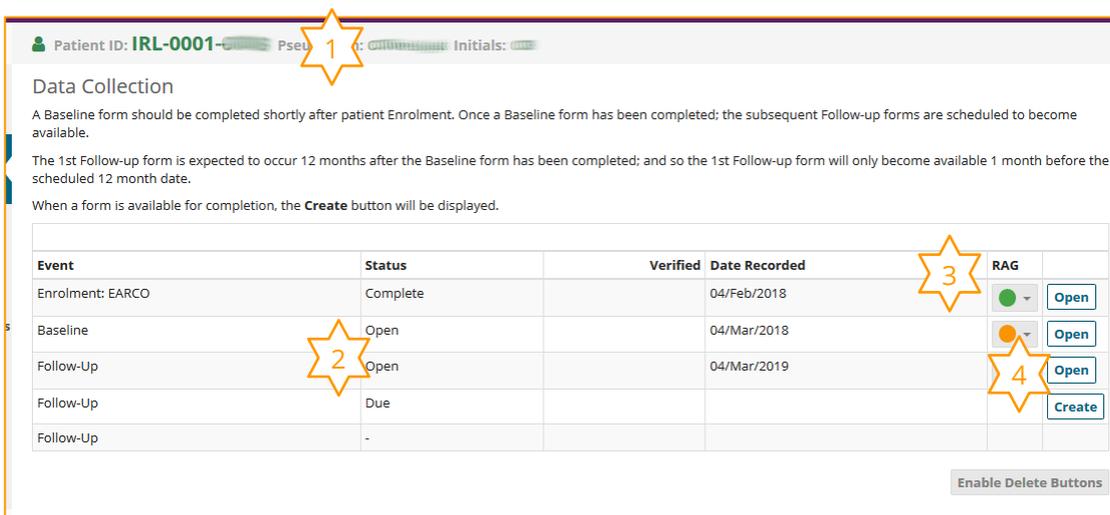## View the Patient Data Collection Record

The patient's *Data Collection* page is created as the patient's enrolment details are saved.

The Baseline record is automatically added, and should be created as soon as possible after enrolment.

Follow-up events are scheduled to occur every 12 months after the baseline has been recorded. Records will be automatically added one month before the due date.

An End of Data Collection record must be added if a patient withdraws consent or ends participation in the Registry.

Figure 10 – The Data Collection page – see below for details.

1. The currently selected patient is shown in the *context banner* below the *Header Menu*.
2. Details of all scheduled events with the patient are displayed.
3. The RAG indicator gives a visual indictor of the event form completion. Click the button to view details of the form completion status. See Form and Section Validation above for details.
4. Click the button to the right of the event to create or view the form details.

To access the patient's *Data Collection* page:

1. Navigate to the *Centre Dashboard*.
2. Click the **Patient List** link in the *Side Menu* to open the *Patients* page.
3. Click the **patient row** to open that patient's *Patient Summary* page.
   - The patients Summary details are shown.
4. Click the **Data Collection** link in the Side Menu to open that patient's *Data Collection* page.

Delete/Restore a Form

Forms can be removed from a Patient's Data Collection record; they are retained, but marked "deleted", on the Clinical Registry System for data integrity reasons and can be restored at any time.

1. Navigate to the patient's *Data Collection* page.
2. Click the **Enable Delete Buttons** button at the bottom of the list of documents to replace the *Open* buttons with *Delete* or *Replace* buttons as appropriate.
   - Deleted forms will be displayed with a line through the details.
3. Click the **Delete** button to the right of the document to remove it from the list.

OR

3. Click the **Restore** button to the right of the document to restore it to the list.
4. Click the **Hide Delete Buttons** button at the bottom of the list of documents to return to the default view.

Create the Baseline Data

The first task after enrolling a patient on the Registry is the completion of the Baseline data. The baseline form records all details of the patient's socio-demographics, risk factors, diagnosis, treatments etc.

The Patient's Baseline form is automatically opened on completion of the patient enrolment.

The Patient's Baseline details should be gathered as soon as possible after enrolment on the Registry, ideally within 3 months. The option to create a Baseline remains active until a record for a Baseline event within the schedule has been added.

1. Navigate to the patient's *Data Collection* page.
2. Click the **Create** button to right of the Baseline event to open the Baseline form.
3. Type the **Baseline date** in the box provided.
   - This is a required field; the form cannot be saved without a valid entry in this field.
4. Complete all sections of the form.
5. Click **Save** to update the form information.
   - Most fields/sections are Expected, allowing the Baseline to be saved without all of the data.
   - Empty Fields or Sections are saved with a form. The Baseline form can be edited as data becomes available. See Update Existing Form Data below for details.
   - The *Save* button will not be activated if Required information is missing.
   - The *Cancel* button will change to *Close* when the data has been saved.
6. When all information is complete click **Close** to return to the patient's *Data Collection* page.

See Data Integrity Checks above for details of Required and Expected fields and completion status indicators.

Create Follow-up Event

Follow-up forms will be added to the patient's Data Collection page one month before the scheduled date. The follow-up form should be created as close as possible to the scheduled date. The Follow-up form contains fewer sections than the Baseline form.

1. Navigate to the patient's *Data Collection* page.
2. Click the **Create** button to the right of the form in the list to open a new *Follow-up Event* form.
3. Type the **Assessment date** in the box provided.
    - This is a required field; the form cannot be saved without a valid entry in this field.
4. Click the **Section Title** to move to that section and record the data.
    - Additional fields may be displayed depending on the values entered, e.g., if Yes is selected for any of the fields in Medical Assessments, Liver Assessment, further details will be required.
5. Click **Save** to update the form information.
    - Empty Fields or Sections are saved with a form. The form can be edited as new/additional data becomes available. See Update Existing Form Data below for details.
    - The *Save* button will not be activated if Required information is missing.
    - The *Cancel* button will change to *Close* when the data has been saved.
6. When all information is complete click **Close** to return to the patient's *Data Collection* page.

View Existing Form Data

The data recorded on forms can be viewed at any time.

1. Navigate to the patient's *Data Collection* page.
2. Click the **Open** button to the right of the Event to view full details of the Event.
    - The date the Event was recorded and edited are shown in the *Form Details Bar* at the top of the page.
    - A Complete status indicator or an Edit button will be displayed in the *Form Details Bar*.
    - All sections and fields on the form are displayed, with flags indicating fields that have had queries posted.
3. Click **PDF** in the *Form Details Bar* to export the form data as a PDF file.
4. Click **Edit** in the *Form Details Bar* to open the form data for editing. See Update Existing Form Data below for details.
5. Click **Save as Complete** in the *Form Action Bar* to mark the form as Complete.
    - Forms flagged as Complete cannot be edited.
6. Click **Revert to Edit** in the *Form Action Bar* to re-open the form for further editing.
    - The Edit button will be made available in in the *Form Details Bar* at the top of the page.
7. Click **Close** in the *Form Action Bar* to return to the patient's *Data Collection* page.

The symbols below may be displayed to the right of the form data to indicate the status of data. The symbols shown will depend on the users Role within the Registry. All symbols are clickable.

i	The **i** symbol is displayed beside fields requiring complex or specific data. Click the **i** symbol to view an explanation of the data requirements.
🔗	The 🔗 symbol beside a field indicates a chained data item. The data in that field is linked to other forms. Click the 🔗 symbol to view and open the related forms.

Note   Flags are also displayed on the form view indicating the status of any Queries raised – See Working with Queries section below for details.

Update Existing Form Data

All data recorded on existing forms can be updated at any time, for example to correct errors made during data entry, record a change in the patient's circumstances or because additional information has become available.

1. Navigate to the patient's *Data Collection* page.
2. Click the **Open** button to right of the Event to view full details of the Event.
3. Click the **Edit** button in the *Form Details Bar* to open the form data for editing.
4. Edit the data of the form as required.
5. Click **Save** to update the form information.
    o   The form will not be saved if required information is missing; a message will be displayed at the bottom of the form indicating the fields to be completed.
6. When all information has been entered, click **Close** to return to the patient's *Data Collection* page.

End of Data Collection

Occasionally patients withdraw their consent for inclusion in the Registry, become lost to follow up or die after their inclusion in the Registry. In any of these cases, the End of Data Collection form must be used to record the reason for end of participation.

Record End of Data Collection Details

If no End of Data Collection details have been recorded, they should be added using the End of Data Collection option in the patients *Side Menu*.

1. Navigate to the patient's *Patient Summary* or *Data Collection* page.
2. Click the **End of Data Collection** link in the *Side Menu* to open the End of Data Collection form.
    o   If the End of Data Collection recorded exists, the details will be displayed with the usual form view options. See View Existing Form Data above for details.
    o   Complete the details on the form.
    o   If the patient has died, the date and cause of death should be recorded.
3. If participation has ended for a reason not shown on the form, the **Other** option should be selected and a note of the reason for must be recorded – the form cannot be saved without this information.
4. Click **Save** or **Save as Complete** to record the form information.
    o   The form will not be saved if required information is missing.
    o   The *Cancel* button will change to *Close* when changes have been saved.
5. When all information has been entered click **Close** to return to the patient's *Data Collection* page.

Note   Once the *End of Data Collection* form has been saved it will be included on the patients *Data Collection* page and can be accessed in the same way as other forms.

•   A patient may request that their data is removed from the Clinical Registry when they withdraw consent – see Wipe Patient Data above for details.

View/Edit End of Data Collection Details

The patient's End of Data Collection form can be edited in the same way as other forms on the patient's *Data Collection* page. See View Existing Form Data above for details.

Attachments

Patient report documents and images may be attached to a patient's record. Once attached they can be viewed using the built-in attachment viewer.

PDF and MS Word documents and PNG and JPEG image files are accepted as attachments.

Patient-Identifying Data

The OpenApp system does not attempt to modify the documents to remove Patient-Identifying data. It is the user's responsibility to ensure that all patient identifying information is removed before any files are uploaded to the OpenApp system.

Attach a File

1. Navigate to the patient's *Data Collection* page.
2. Click the **Attachments** link in the *Side Menu* to open Patient's *Attachments* page.
3. Click the **Attach File** button at the top of the page to start the file upload.
4. Before uploading the file, the user must confirm that no patient identifying data is present in the file to be uploaded.
5. Drag the file to be uploaded into the box provided.
   - Click on the box to open a browser to search for and select the file.
   - Only one file should be uploaded at a time.
6. Edit the **Label** to change the attachment name from the default of the file name.
7. Depending on the file type, the viewer may be chosen.
8. Select which **Study Enrolment** the attachment relates to.
   - If the patient is enrolled in only one Study, their Patient ID will be displayed.
9. Click **Attach** to upload and attach to the patient record.

The Built-in Attachment Viewer

The built-in Attachment Viewer opens in a popup page. Once the *Attachment Viewer* is open, all attachments for the selected patient can be viewed using the left-hand navigation bar.

1. Navigate to the patient's *Data Collection* page.
2. Click the **Attachments** link in the *Side Menu* to open Patient's *Attachments* page.
3. Click on the ⦙ **menu** link to the right of the attachment and select **View** from the menu.
4. The Attachment will open in the *Attachment Viewer* popup.
5. Other attachments of the same type will be listed in the left-hand navigation bar – click an **attachment** title to switch between attachments.
6. Click the **arrow** at the top of the left-hand navigation bar to switch between attachment types.
7. Click the **Download** button at the top of the page to download the attachment for use locally.
8. Click the **Expand** button at the top of the page to hide the left-hand navigation bar.
9. Use the **Close** button at the top the *Attachment Viewer* page to return to the Patient's *Attachments* page.

Note: Microsoft Word documents cannot be viewed using the built-in viewer. A download option is provided for these files.

Rename an Attachment

1. Navigate to the patient's *Data Collection* page.
2. Click the **Attachments** link in the *Side Menu* to open Patient's *Attachments* page.
3. Click on the ⦙ **menu** link to the right of the attachment and select **Rename** from the menu.
4. Type the **new name** in the box proved and click **Rename** to save the change.

Delete an Attachment

1. Navigate to the patient's *Data Collection* page.
2. Click the **Attachments** link in the *Side Menu* to open Patient's *Attachments* page.
3. Click on the ⦙ **menu** link to the right of the attachment and select **Delete** from the menu.

Note   There is no confirmation of this action – it cannot be reversed.

Studies

The patient's *Studies* page can be used to view the details of the patient's Study enrolment.

Consents

The patient's *Consents* page can be used to view the Consents that the patient or their Carer given.

Details of each consent is shown.

Queries

The patient's *Queries* page can be used to view a report of all Queries raised across all of the selected patient's forms.

See the Working with Queries section below for details on working with Queries.

FORMS

The Forms page allows the user to view a summary of form completion within the Registry.

The list of forms to be displayed is selected using the dropdown boxes at the top of the page.

1. Navigate to the *Centre Dashboard*
2. Click the **Forms** link in the *Side Menu* to open the *Forms* page.
3. Select a **Form** to view using the dropdown list at the top of the page.
   o The **Date from** and **Date to** selectors can be used to narrow the list of forms displayed.

The columns on the Forms page provide details of the creation and update as well as the Form state, Verification and Frozen status for the form is shown and an overall completion of the form sections is indicated using Red/Amber/Green indicators. See Data Integrity Checks above.

Direct access to the patient's summary or the individual form is provided from the list.
- Click the **Patient ID** to open the *Patient Summary* page.
- Click the **Event Date** to open the Event Form.

WORKING WITH QUERIES

Queries can be posted by the Registry Data Manager at any time. Queries are associated with specific fields and can be posted for any field on any form within the Clinical Registry System.

?
Queries

A report on all queries for a Centre or the selected Patient can be accessed from the *Side Menu*. See View the Queries report below for details.

When working with a Patient's record, fields with queries posted are flagged on the event forms. A report of queries for the selected Patient can be accessed from the *Patient Side Menu*.

Queries are managed using the *Query Modal* pop-up. The *Query Modal* opens on top of the page from which it was opened allowing the user to work with the Query.

Query IDs

All queries within the Clinical Registry system are identified with a unique ID as they are created.

Queries are associated with a Centre within a Study.   As there are many Centres and may be more than one Study in the system and because there may be more than user working at the same time, there may be gaps in the ID sequence as they are allocated to other Centres.

Query Status Indicators

Fields with queries posted are flagged on the patient event forms. These indicators are clickable, opening the *Query Modal* to allow the user to work with the Query.

🏳	**Query Create Flag** A white flag beside a field indicates that no queries have been posted to the data. This flag is shown beside fields on a form saved with errors (with warnings). Click the flag to Create (post) a query.
🚩	**Query Owned Flag** A red flag beside a field indicates that a query has been posted for that field **AND** that it is the responsibility of the current User. Click the flag to view and respond to the query.
🚩🔗	**Query Not Owned Flag** An orange flag with a link beside a field indicates that a query has been posted for that field **AND** that another User is currently responsible for the Query. Click the flag to view the query details.
✔	**Query Closed/Cancelled Flag** A green flag with a tick beside a field indicates that a query for that field has been closed (answer accepted) or cancelled. Click the flag to view the query details.

View the Queries report

The Centre Queries report lists all queries posted for the selected Centre, while the Patients Queries report lists all queries posted for the selected Patient.

1. Navigate to the *Centre Dashboard* or the patient's *Summary* page.
2. Click the **Queries** link in the *Side Menu* to open the *Queries* report.

- All posted or answered queries that are the responsibility of the current user are displayed, with the most recent queries at the top of the list.
  - The current owner of the query is shown in the Holder column.
  - The update date indicates the date the query was answered.
  - More than one query may be posted for a field.
3. Click the **Query ID** to open the query modal or click the **Form Title** to open the associated form.

The report can be filtered using the drop-down menus at the top of the page. See Reports below for details on all options when viewing the *Queries* report.

View and Respond to a Query

The *Query modal* can be opened from the *Queries Report* or from a *Patient Data Collection* form. These instructions assume the user is working on a Form.

1. Click the **Query flag** to the right of the field to open the *Query Modal* and view details of all queries posted for that field.
   - If the Query is opened from a report the Query Modal will open with the selected Query opened.
2. Click the **Query summary** to view the query details and all its responses.
   - If the query has not been responded to, a form allowing a response to be recorded is opened, otherwise the query and its response will be shown.
3. Type a **Response** in the box provided.
4. Click **Answer query** below the box to save the response and mark the Query as Answered.

OR

4. Click **Leave as posted** below the box to save the response and leave the Query as Posted to allow further responses.
5. Click **Close Modal** when all changes have been saved to return to the original page.

Note   **Close Modal** will close the response page without saving the changes, so it is important to click either **Answer query** or **Leave as posted** before closing the Query Modal.

- A form cannot be Saved as Complete until all Queries have been responded to and Accepted or Cancelled.

Query Modal Options

When working in the *Query Modal* the buttons at the bottom of the modal can be used to work with the Queries for the selected form.
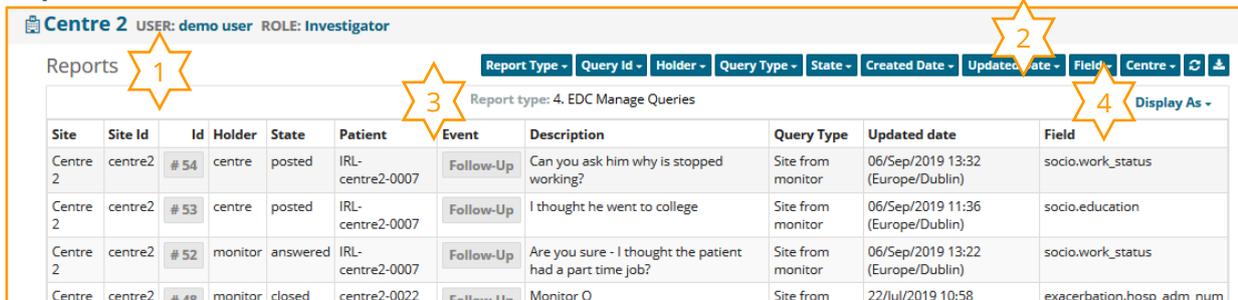
All Queries	Displays all queries posted for the selected Patient Event form.
Queries for: (field name)	Displays only the queries for the originally selected query field.
Close Modal	Closes the modal and returns to the original page.

REPORTS

All reports within the Clinical Registry System are built using the OpenApp Query Builder and are presented in the same format and have the same filtering, sorting and layout options.

The reports are available depend on a user's role within a Centre.

Report Structure

Figure 11 – OpenApp Report Layout – see below for details.

1. The page title is shown at the top left of the page.
2. The reports can be filtered using the drop-down menus at the top of the page. The other options at the top of the page are:

   The reports are based on real-time data. Use the **Refresh** button to update the report to show the latest available data.

   Use the **Download** button to export the data from the report in .CSV format for use in MS Excel for example.

3. The report title and currently selected filter are shown above the details.
4. The reports open in *Table* view by default, use the **Display As** drop-down menu to select an alternative view.

Table View

- Table view displays 10 rows per page.
- The current location is shown at the bottom left of the page.
- Navigation buttons are shown at the bottom right of the page.

Grid View

- Grid view display all selected records on a single, scrolling, page.
- The columns on the grid can be sorted, or hidden using the drop-down menu in the column header.
- Hidden columns can be made visible using the Columns drop-down menu to the right of the column headers.

Chart View

- Chart view facilitates the display of the report data in a graph. This view is only suitable for statistical type reports.
- Once selected the graph type and details must be configured before the graph can be displayed.
- The graph settings are not stored, but remain while the user is working in the current Centre. Use the browser refresh button to clear the settings and configure another graph.

FAQ – FREQUENTLY ASKED QUESTIONS

The FAQ page provides answers to common questions. The Data Manager will put entries on the list to assist users in recording data or using the system.

The questions are listed alphabetically – the answer to the first question will displayed when the page is opened.

1. Navigate to the *Centre Dashboard*.
2. Click the **FAQ** link in the Side Menu to open the *Frequently Asked Questions* page.
3. Click a **Question** to view the associated answer.

FIGURES