Working with patients

Contents

Roadmap: Adding patients to a study

Typically, only users assigned to a role with the View Protected Health Information right can enroll patients.

You can enroll patients only one at a time. If a patient does not provide all the required information, enrollment cannot proceed. However, if you must stop the enrollment process before it is complete, the information already entered is saved.

Step	Action	Description
1	Create the patient.	The patient reports to a site. 1 Select **Create Patient** (). 2 Click **Yes, Create a new patient**. 3 Fill in the fields as necessary. 4 Click **Submit**. The Patient Status Summary table on the Dashboard tracks the number of patients with each enrollment status.
2	View or view and sign any Informed Consent Documents (ICDs).	1 Create the patient. 2 Select **Patients** (). 3 Click the **Summary** link for the patient. 4 The patient views and signs any ICDs. 5 If required, a site user and an observer also sign the ICD. 6 Click **Sign/Accept**.
3	Complete any required screening forms to determine whether the patient is eligible to participate.	The patient is assigned to a site, visits are scheduled, and visits are populated with the required forms. Site users: • Complete any EDC forms for screening. • If a patient fails screening, a site user with the appropriate rights must discontinue or re-enroll the patient. Patients: • Depending on the study configuration, patients who enter data on ePRO forms may be notified through email that they have forms to complete. • Complete any required ePRO forms for screening.

Step	Action	Description
4	Complete any required forms for enrollment.	Typically, a site user completes any required EDC forms for enrollment. The patient completes any required ePRO forms for enrollment. The patient status becomes Enrolled when the EDC forms and ePRO forms required for enrollment are complete.

Roadmap: Managing a patient

Step	Action	Procedure
1	Upload the ICDs.	A sponsor user can upload the ICDs for the site. 1 Select **Administration** ( ). Click **Manage ICDs**. 2 Fill in the fields as necessary. 3 Browse for the ICD file to upload. 4 Click **Add**.
2	Create, screen, and enroll the patient.	1 Select **Create Patient** ( ) to create the patient. 2 Sign any ICDs. 3 From the Visit Landing page, complete any EDC forms required for screening and enrollment. 4 Have the patient complete any ePRO forms required for screening and enrollment.
3	Discontinue or re-enroll the patient if the patient does not complete enrollment.	• To discontinue the patient, from the Visit Landing page, click **Discontinue**. • To re-enroll the patient, obtain the missing information and complete the enrollment process.
4	Track the status of the patient.	1 Select **Patients** ( ). The Patient List page appears. 2 View the status of the patient in the Status column.
5	Manage the patient.	Perform the following procedures as needed.
	Search for the patient.	1 On the Patient List page, enter search criteria. 2 To the right of the drop-down list, click **Submit** ( ).
	View and edit the patient profile.	1 On the Patient List page, click the **Profile** link for the patient. The Patient Profile page appears. 2 Edit the fields as necessary. 3 Click **Submit**.
	Reset the patient password.	• On the Patient List page, select the radio button for the patient and click **Reset Password**.
	Set a temporary password for the patient.	• On the Patient List page, select the radio button for the patient and click **Set Temporary Password**.

Step	Action	Procedure
	View the audit trail for the patient.	• On the Patient Profile page, click the **Audit Trail** button (**A**).
	Transfer the patient,	1 On the Patient List page, click the radio button of the patient to transfer. 2 Click the **Transfer** button.
6	Manage the ICDs.	Perform the following procedures as needed.
	Add an ICD.	On the ICD Management page: • Fill in the fields as necessary. For more information, see ICD Management page.
	Edit or add a new version of an ICD.	1 On the ICD Management page, click the **Details** link for the ICD. The Edit ICD page appears. 2 Edit the fields as necessary. 3 Click **Update**.
	Add new languages for an ICD.	1 On the Edit ICD page, click **Add New Language** ( ). 2 From the **Language** drop-down list, select the language of the ICD. 3 Specify the ICD to upload. 4 Click **Upload**. 5 Click **Update**.

Roadmap: Transferring a patient from one site to another

When a patient requires a transfer to a new site, a user with the right to transfer patients from the originating site begins the process by selecting the patient in the Patient List and clicking the **Transfer** button.

Step	Action	Description
1	Select the patient.	1 Select **Patients** (). 2 Search by Status, Patient List, Site Name, or patient ID.
2	Start the transfer.	1 Click the radio button of the patient to transfer. 2 Click the **Transfer** button.
3	Review the Patient Transfer affidavit and statuses.	Observe the color associated with Signature Status, Query Status, and Source Verification Status. • If the status is black, no action is required. • If red, attention is required. Incomplete statuses of these items do not prevent the patient transfer, but you may want to cancel the transfer, complete these activities, and reinitiate the transfer.
4	Select the destination site.	1 From the **Destination Site** drop-down list, select the site to which to transfer the patient. 2 From the **Reason For Transfer** drop-down list, select the reason for the transfer.
5	Conclude the transfer and create the archive.	• Click **Submit**. Because the archive contains the entire patient record generated to a PDF file, archive creation can take time. During that time, do not update the patient record.
6	View the PDF archive.	1 On the Patient List page, click the **Patient Transfer History** tab. 2 Click the **View** link for the patient.

Patient status

A list of patient statuses appears in the Patient Status section on the Dashboard along with the number of patients with each status. The statuses track the patient through the enrollment process. The Patient Status section also includes the number of Active patients (total number of patients minus patients with a Completed or Discontinued status).

The following statuses are standard with the OutcomeLogix application. Study designers can create additional, study-specific statuses. A patient can have only one status at a time.

Status	Description
Prescreened	Patient has been created but not enrolled.
Created	Patient details were submitted. The first visit with an expected date is created for the patient.
Withdrawn	Patient withdrew from the study or declined the ICD form. The trigger for this status is study-specific.
Consented	Patient signed the ICD.
Screening	Patient completed the EDC and ePRO forms required for screening. The patient met all the inclusion criteria and none of the exclusion criteria.
Screen-Failed	Patient started the screening process and then failed for one or more reasons; for example, the patient selected **No** on the Site Inclusion form and, therefore, cannot be included in the study.
Opt Out	Patient declined to sign the ICD.
Enrolled	Patient completed the EDC and ePRO forms required for enrollment.
Randomized	Patient was randomized in the study.
Discontinued	Patient was enrolled, but was discontinued for one or more reasons.
Lost to follow-up	Patient was enrolled in the study but never returned or cannot be contacted after repeated efforts. The trigger for this status is study-specific.
Completed	Patient completed the last protocol-specified event (visit, web, or telephone contact).