

OPEN Frequently Asked Questions (FAQs)

1. What do I need to be able to enroll a patient in OPEN?

Site staff must have an active [NCI CTEP IAM](#) account linked with an ID.me account to access OPEN. All persons enrolling patients in OPEN must have an active Investigator (IVR), Non-Physician Investigator (NPIVR), Non-Investigational New Drug/Non-Treatment (NINT) or Associate Plus (AP) registration type within CTEP's Registration and Credential Repository (RCR). If this is an urgent matter, contact the CTSU Help Desk. You must have the *Registrar* role on the Lead Protocol Organization (LPO) or a Participating Organization (PO) roster in order to enroll patients via OPEN. If you do not have the *registrar* role or are registered as an Associate you will have view only access. If a Delegation of Task Log (DTL) is required for a trial, the enrolling person, treating investigator, and credit investigator, must be listed on the DTL in order to be associated with an enrollment in OPEN.

2. How can I check if I am on my Group roster as a registrar?

If your institution is a member of one or more Network Group, you will need to contact each Network Group to be sure you are listed on their roster as a *registrar* in order to enroll patients in OPEN. You may also view your role on the LPO POs rosters using Roster Update Management (RUMS) section on the [CTSU members' website](#).

3. What training is available for OPEN?

OPEN is user-friendly and intuitive, however, a number of training tools have been developed to assist users in navigating through the system. On all of the OPEN screens, users have access to multiple site user guides. OPEN has a practice mode feature, where users can perform practice enrollments to familiarize themselves with the application and enrollment forms prior to actually enrolling patients. The OPEN user guides are also available in the OPEN section of the CTSU members' website and on the OPEN login page.

4. How do I access OPEN to enroll patients?

A link to the OPEN Portal is available under the OPEN tab on the CTSU members' website or you can access it through your browser at <https://open.ctsu.org/open/home.open>.

5. Can I complete a registration that was initiated by another user?

Yes, all individuals with enrollment privileges for their site may complete any enrollments that are "in progress" for their site.

6. Why is the protocol I want to enroll a patient on not in the drop-down list for my site?

- Your site may not have regulatory approval to participate on the protocol. To check your approval status, click on the *Site Status List* on the *Create New Screen* in OPEN to view details on each of the protocols that are associated with your institution. Detailed site registration status is also available by clicking on the [Regulatory Link](#) on the CTSU members' website.
- Your site may not be a member of a participating organization on the protocol. Check the cover page of the protocol to see if your site is a member of the LPO or a PO.
- If the protocol has a DTL, check to see if you are listed with the OPEN Registrar task on the DTL in order to enroll patients on the protocol.

7. What is the difference between the Treating Investigator and the Credit Investigator?

The Treating Investigator is the investigator who will have contact with the patient throughout the course of the study. When the Treating Investigator is not a member of the Network Group which the site would like to give credit to, the site will need to choose an investigator who is affiliated with the site and is a member of the LPO or a PO. Refer to the [CTSU-OPEN-Person Types and Business Rules](#). The Credit Investigator will receive payment and will have the ultimate responsibility for the patient and audit activities for the study.

8. Can I fix an error on a completed enrollment?

Errors to the eligibility checklist for completed enrollments cannot be made in OPEN, you must contact the LPO and the CTSU Help Desk. Credentialing or demography updates can be made using the OPEN Transfer & Update Module (T&UM). For ETCTN trials, please contact the CTSU Help Desk.

9. How long will the OPEN screen remain idle before it times out?

The OPEN screen will time out after 30 minutes with no activity. You will then have to log in with your username and password.

10. What is the difference between *New* and *Incomplete* statuses for a registration?

A registration has the status of *New* when the registration is saved for the first time (the demography or eligibility checklist has not been started). A status of *Incomplete* is assigned after the corresponding checklist form has been started but has not been submitted for registration or has validation errors.

11. How do I view the enrollments for my site?

From the OPEN Home Page, click on the History Tab. There are two enrollment browsers, one for patient enrollments and one for non-patient enrollments. The non-patient browser will only be available for NCORP sites with non-patient enrollments. Click on the patient browser to view the patient enrollments at the site(s) you are affiliated with. Click on the non-patient browser to view the non-patient enrollments at the site(s) you are affiliated with.

12. Will I be able to view data from our affiliate sites?

Yes, you will be able to view the enrollments for all of the sites with which you are affiliated and listed on the roster.

13. Can other staff at my site see the enrollments for our site if they do not enroll patients?

Yes, all site staff with an active CTEP-IAM account linked with an ID.me account may log in to OPEN and see all of the completed enrollments for the sites with which they are affiliated. However, they will not be able to view enrollments that are incomplete if they do not have a *registrar* role.

14. Is the time on the enrollment in Eastern Standard Time?

Yes, the time stamp for enrollments in OPEN will be Eastern Standard Time.

15. How do I enter funding dates in OPEN?

Click the history tab and search for the Patient ID (PID) associated with the enrollment. Enrollments with funding requiring completion dates in OPEN will have a \$ icon next to the protocol number. Click on *select* next to the patient enrollment with the required PID. The summary screen will be displayed. Click on the Funding subtab at the top of the screen. The enrollment data will be displayed at the top of the screen and a funding table will be populated with each of the funding types available.

16. I am at a NCORP site, how do I enroll a non-patient to a Cancer Care Delivery Research (CCDR) protocol?

Click on the Enroll screen as you would for a patient enrollment. Once you select the protocol and step a field for 'Registration Type' will appear. Select 'non-patient'. The Non-Patient Type field will appear, select the type of non-patient you are enrolling (Caregiver, Other Professional Discipline, Providers, or Practice, or Other). Continue with the enrollment entering the demography (except for 'Practice' registration type) and eligibility checklist data.