# OPEN FAQs

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

   In order to access OPEN you need to have a CTEP-IAM account. If you do not have one you can log into the CTEP website at [https://eapps-ctep.nci.nih.gov/iam/](https://eapps-ctep.nci.nih.gov/iam/) to request an account. Please allow three business days for processing. If this is an urgent matter please contact the CTSU Help Desk. You will need the ‘registrar’ role on the LPO (Lead Protocol Organization) or a PO (Participating Organization) in order to enroll patients via OPEN. A link to the OPEN Portal is available under the OPEN tab of the CTSU members’ website. Or you may log in using the OPEN url: [https://OPEN.ctsu.org](https://OPEN.ctsu.org)

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 organization, you will need to contact each organization to be sure you are listed on their roster as a ‘registrar’ in order to enroll patients via OPEN.
   You may also view your role on the Lead Protocol Organization (LPO) or Participating Organizations (POs) rosters via the RUMS tab on the CTSU members’ website: [https://www.ctsu.org](https://www.ctsu.org)

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 will have access to a training module and the site user guide.
   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 training module and OPEN user guide are also available in the OPEN tab of the CTSU members’ website.

4. **How do I know whether to use OPEN to enroll patients on a particular study?**

   All NCTN protocols will use OPEN for patient enrollment. To determine which studies are active in OPEN, log onto the CTSU Members’ web site and click on the OPEN tab. You will find the list of studies that are active in OPEN. In addition, if a given study is active in OPEN, the protocol page will display the OPEN logo indicating that enrollments to the study must go through OPEN. You must use OPEN to enroll patients on the specified studies.

5. **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. [https://www.ctsu.org/OPEN_SYSTEM/](https://www.ctsu.org/OPEN_SYSTEM/)

6. **Can you 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.
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## 7. 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. Alternately, detailed site registration status is available by clicking on the Regulatory Tab on the CTSU members’ website [https://www.ctsu.org](https://www.ctsu.org). 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 Lead Protocol Organization or a participating organization.

## 8. 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 organization the site would like to credit for the enrollment, the site will need to choose an investigator who is affiliated with the site and is a member of the Lead Organization or a Participating Organization. The Credit Investigator will receive payment and will have the ultimate responsibility for the patient and audit activities for the study.

## 9. Do I have to choose a Drug Shipment Investigator?

No, the Drug Shipment Investigator is an optional field; however, it may be required for some protocols. Section 2 on the 'Create New' Screen will include protocol specific instructions regarding the requirements for persons associated with the enrollment.

## 10. 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. For errors on the credentialing screen, you must contact the CTSU Help Desk to make changes to the enrollment. For errors on the credentialing or Demography, updates can be made using the OPEN T&UM (for Alliance, ECOG-ACRIN, NRG and SWOG). For other organizations, please contact the CTSU Help Desk.

## 11. 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.

## 12. 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.

## 13. How do I view the enrollments for my site?

From the OPEN Home Page, click on the History Tab. All completed enrollments for your site can be viewed. Click on the Select button next to the enrollment you wish to view.

## 14. 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.
## OPEN FAQs

<table>
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<tr>
<th>Question</th>
<th>Answer</th>
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<tr>
<td>15. Can other staff at my site see the enrollments for our site if they do not enroll patients?</td>
<td>Yes, all site staff with an active CTEP-IAM account may log into 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.</td>
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<td>16. Is the time on the enrollment in Eastern Standard Time?</td>
<td>Yes, the time stamp for enrollments in OPEN will be Eastern Standard Time.</td>
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<td>17. Social Security Numbers (SSN) cannot be given by our site, is this question mandatory in the demography screen?</td>
<td>The Lead Organization for the study will determine which fields in the demographic screen are mandatory. Those fields that are not mandatory will not be required to process an enrollment. Required fields in OPEN are marked with a red asterisk (*).</td>
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<td>18. Can I change my crediting group in between steps?</td>
<td>Yes, sites are allowed to change credited groups between steps or within 7 calendar days of the enrollment.</td>
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<td>19. How are payments made for patient enrollments conducted through the OPEN?</td>
<td>For NCTN trials, NCI per case management funding will be made by the Network Group credited with the accrual or the equivalent will be provided via the NCTN LAPS grant or NCORP Community Site grant directly. For NCORP trials, NCI per case management funding will be made by the Network Group credited with the accrual or the equivalent will be provided via the NCORP Community Site grant directly.</td>
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<td>20. How do I enter funding dates in OPEN?</td>
<td>Click the history tab &amp; 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 sub tab 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.</td>
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