

ACT NOW OpenClinica EDC Training Questionnaire

The following questions are related to the OpenClinica Electronic Data Capture (EDC) System Training required for the ACT NOW Current Experience Study. All data entry personnel, and anyone on the project that will need access to OpenClinica, will need to complete the proper training before being granted access to the system. Several training videos have been made available for newly on-boarded personnel and those that were unable to attend the Investigator and Site Training meetings in March and April. All training videos must be viewed and the EDC Training Questionnaire must be answered correctly, prior to being granted access to the system.

Once training has been completed, please return the EDC Training Questionnaire with your information to the DCOC Site Management Team: askNOW@uams.edu.

By completing this form, you are confirming that you have completed all EDC Training for the ACT NOW Current Experience Study, including the modules below:

- ✓ Access OpenClinica
- ✓ Add a Subject
- ✓ Data Entry Process
- ✓ Notes & Discrepancies during Data Entry
- ✓ Discrepancy Management (Sites)
- ✓ Quality Control Process
- ✓ Site Supplemental Form

To verify that training was completed, please complete the EDC Training Questionnaire provided. Answers to these questions can be found within the training modules.

The DCOC will review your responses and notify you if:

1. There are any outstanding issues or questions that need to be reviewed
2. You have successfully completed all EDC training requirements

Please note: your access to the EDC is contingent on your successful completion of the EDC Training.

Please Complete the EDC Training Questionnaire below:

***** I certify that I have completed EDC Training for the ACT NOW Study. *****

Name: _____

Site: _____

Role: _____

Date: _____

EDC Training Responses:

Please select the appropriate responses by highlighting/circling the correct answer for each question.

1. Where in OpenClinica can you go to find your site number?
 - A. At the top of all OpenClinica screens above the header toolbar next to my site name.
 - B. In the "Other Info" informational box to the left of the screen.
 - C. In the "Notes & Discrepancies" summary statistics table.

2. What is the format for the Study Subject ID for the ACT NOW Data Entry Form?
 - A. Three-digit site number + hyphen + three-digit subject number starting at 001 and incrementing by one for each new case (e.g., 111-001, 111-002, 111-003, ...).
 - B. Three-digit subject number starting at 001 and incrementing by one for each new case + hyphen + three-digit site number (e.g., 001-111, 002-111, 003-111, ...).
 - C. Three-digit site number + three-digit subject number starting at 001 and incrementing by one for each new case (e.g., 111001, 111002, 111003, ...).
 - D. Three-digit subject number starting at 001 and incrementing by one for each new case (e.g., 001, 002, 003, ...).

3. Where do you need to go to add a new subject (or case)?
 - A. Click on the Subject Matrix link at the top of the menu toolbar, which will open up a dialog box for adding a new subject.
 - B. Click on the Subject Matrix link at the top of the menu toolbar and select the "Add New Subject" link at the top of the matrix.
 - C. Click on the Add New Subject link at the top of the menu toolbar, which will open up a dialog box for adding a new subject.
 - D. Both A & C
 - E. Both B & C
 - F. None of the Above

4. Where do you need to go to find a listing of all the discrepancies generated for your site?
 - A. Click on the Subject Matrix link at the top of the menu toolbar to display a summary table of discrepancies.
 - B. View the “Other Info” box on the left side of the screen to display a summary table of discrepancies.
 - C. Click on the Notes & Discrepancies link at the top of the menu toolbar to display a summary table of discrepancies.
 - D. All of the above

5. Which discrepancies (statuses) will your site be responsible for addressing?
(Meaning, which statuses will you need to review and provide resolutions for?)
 - A. New ONLY
 - B. New and Updated ONLY
 - C. New, Updated, Resolution Proposed, and Closed ONLY
 - D. ALL discrepancy statuses (New, Updated, Resolution Proposed, Closed, Not Applicable)

6. What needs to happen in order the case you just entered to be considered complete?
(This is one of the most important things to remember when performing data entry and should be done for ALL forms – Supplemental, Data Entry, and QC.)
 - A. Enter all data and click “Save” on all tabs of the eCRF, then exit the form once saved.
 - B. Select the “Mark CRF Complete” checkbox on the last page/tab of the eCRF and click “Save”.
 - C. Send an email to Site Management with a list of Subject IDs completed by your site.
 - D. Select the “Mark CRF Complete” checkbox on the last page/tab of the eCRF and click “Save”.
 - E. Both A & C
 - F. Both B & D

FOR DCOC STAFF ONLY:

*I certify that I have reviewed the responses to the EDC Training Questionnaire, and that
_____ has successfully completed EDC Training for the ACT NOW Study.*

Name: _____

Role: _____

Date: _____

(The date on which the DCOC has certified training completion will act as the official EDC Training date.)