

# CLINICAL TRIAL – DATA MANAGEMENT

Revised June 9, 2025

## OVERVIEW – DATA MANAGEMENT FOR CLINICAL TRIALS

- a. **Description:** This manual describes the importance of data management, which is to outline the procedures and guidelines for accurate and timely data entry into the various electronic medical records and data capture systems required for clinical trials and data management (i.e. CareConnect, Oncore, Medidata, etc.). Ensuring accurate and timely data entry is essential for the success of the clinical trials.
- b. **When is information put into CareConnect and OnCore?** Information is inputted into CareConnect during the patient visits and acts as the electronic case report form (eCRF) for data capturing. While Oncore acts as clinical trial management system which maintains and manages performing and reporting functions at the study and subject level.
- c. **Timeline:** All data must be entered into the systems (CareConnect, Oncore, Medidata, etc.) in a timely manner, following the specified timelines outline in the study protocol. (ie., 2-5 business days)

## ACTION ITEMS

1. Data Entry Procedures
  - a. **Training & Access:** Ensure that personnel involved in data entry are adequately trained on the data entry system(s) used for the study and the delegated staff has the necessary access. Confirm with management that all department required training has been completed. Access to these systems should open immediately after completed required courses. For sponsor systems, request access from the Clinical Trial Manager or Clinical Research Associate.
  - b. **Data Collection:** Collect data from study participants using electronic or paper case report forms (CRFs) or electronic data capture (EDC) systems required by the sponsor of the trial. (i.e. Medidata, RedCAP, etc.) Be sure to verify with sponsor if source documents are paper or electronic.
  - c. **Verification:** Verify the accuracy and completeness of data before entering it into the system.
  - d. **Quality Control:** Implement quality control measures to identify and correct errors in data entry promptly. More information can be found [here](#).
  - e. **Documentation:** Maintain detailed documentation of all data entry activities, including any corrections or modifications made to the data. (for example: when DOA log must be updated, an initial and the date of signing is required to prove modifications were made and verified)
  - f. **Audit Trail:** Ensure that the data entry system(s) used for the study have an audit trail feature to track any changes made to the data. (Medidata, Clario, CareConnect etc.)
  - g. **Data Security:** Adhere to strict data security protocols to protect the confidentiality and integrity of study data. More information can be found [here](#).
2. Importance of Accurate and Timely Data Entry
  - a. Accurate and timely data entry is critical for the success of clinical trials and data management for the following reasons:
    - i. **Validity of Study Results:** Inaccurate or incomplete data can compromise the validity and reliability of study results, leading to incorrect conclusions.
    - ii. **Patient Safety:** Timely data entry ensures that patient safety is maintained by allowing for prompt identification and resolution of adverse events.

- iii. Regulatory Compliance: Regulatory authorities require accurate and complete data for compliance with regulations and guidelines governing clinical trials.
- iv. Study Integrity: Data integrity is essential for maintaining the overall integrity of the study and ensuring that it meets its objectives.

### 3. Reporting and Escalation

- a. Reporting: Report any issues or discrepancies identified during the data entry process to the appropriate personnel, such as the Data Manager or Principal Investigator.
- b. Escalation: Escalate any significant data entry issues or concerns to the relevant stakeholders for resolution.

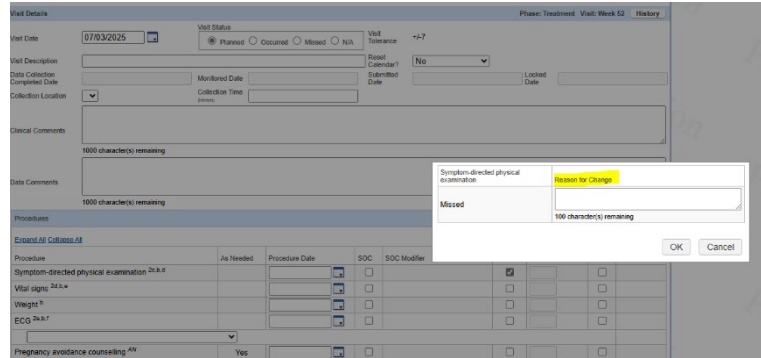
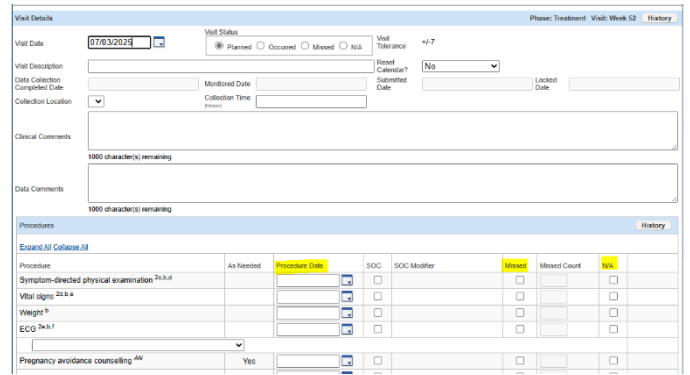
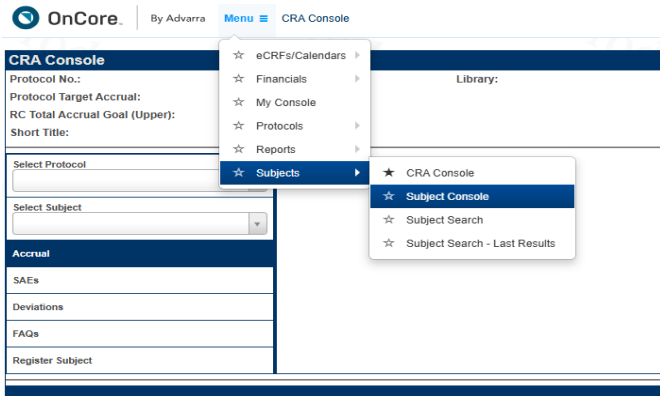
### 4. Query Resolution

- a. Most queries are opened due to the original submission not having the correct details, or there is missing or ambiguous information. When submitting a query, it is necessary to clarify all details for the CRA. If there are certain questions pertaining to lab results or patient history, it is best to revert to the PI for further details.
- b. Queries should be answered promptly to avoid overdue queries with your CRA or Sponsor.
- c. How do you know if a query is overdue?
  - a. CRCs will receive an email from their CRAs explaining that the study has a certain number of queries open and when they should be answered by.

## Data Entry Procedures for UCLA

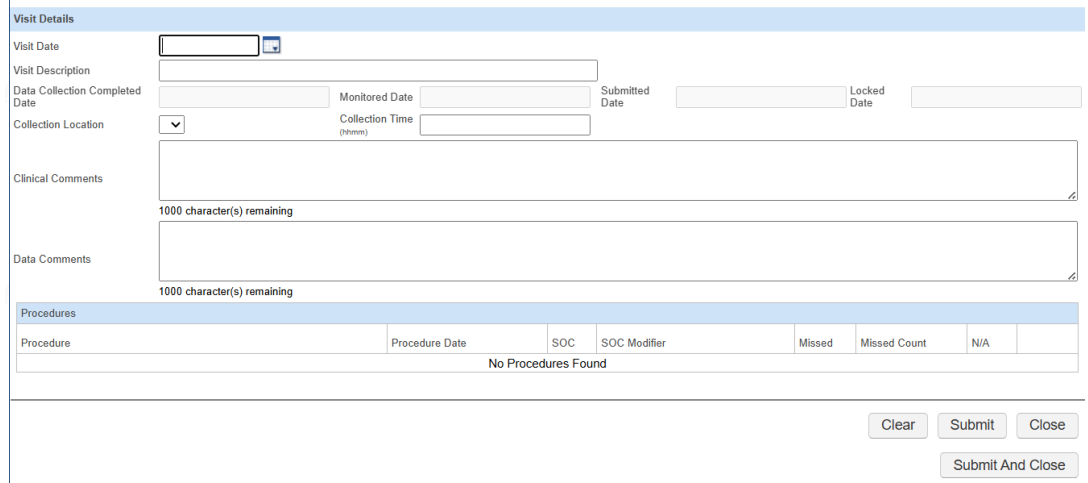
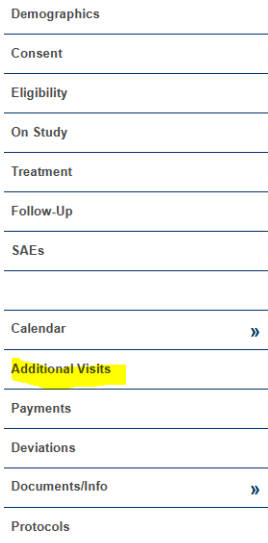
### 5. [Oncore](#)

- a. Why is Oncore used at UCLA, and what is it used for?
  - a. The use of Oncore is to manage all clinical trials in clinical research, this system is used to keep track of all research studies and participants. This includes deadlines, study plans, and patients' personal information.
- b. It is highly recommended that a patient visit be documented within 1-3 business days of the study visit occurring. This is helpful for research administrations billing reconciliation.
- c. Why is it important to have patient visits documented within 1-3 business days?
  - a. By setting a 1-3 business day limit, records are kept as up to date as possible without losing any information. This also keeps the chain of command organized as well, since any delays to patient visits could affect timelines for charge reviews.
- d. Steps to **enter a patient visit**
  - i. Log into Oncore > Locate **subject console** > **Select Protocol and Select Subject** > **Calendar** > Click on the blue hyperlink > change visit status to "Occurred" and update the visit date as necessary > enter "procedure date" for the procedures that were completed > click Submit & Close
  - ii. NOTE: if a procedure was **missed** or not applicable (**NA**), enter in an explanation



e. Steps to enter an **unscheduled visit**

- iii. Subject console > click subject MRN > **additional visits** > enter visit information > Submit and Close



f. Why do studies have unscheduled visits and what warrants an unscheduled visit?

- i. Unscheduled visits occur with patients who may come in with an AE, missed visit procedures, or has returned upon the PIs request for more tests and/or conversations about their previous study visit.

g. Steps to enter in a **monitoring visit**

- a. Go to CRA Console > select protocol > click **monitoring visit**> Select which visit dates for the subjects were monitored > enter the monitored date > Submit

- h. Why is it important for monitoring visits to be entered in?
  - a. Monitoring visits are specialized visits from the sponsors to make sure the study site is following all rules and regulations through the duration of the study. These visits occur over the course of the study. It is important to keep track of monitoring visits and keep track of any changes or deviations that were created during that visit. Study sites are also required to keep the monitoring visit log on hand as well to track which CRA and CRC were present during the monitoring visit, and when each CRA came to visit the site.

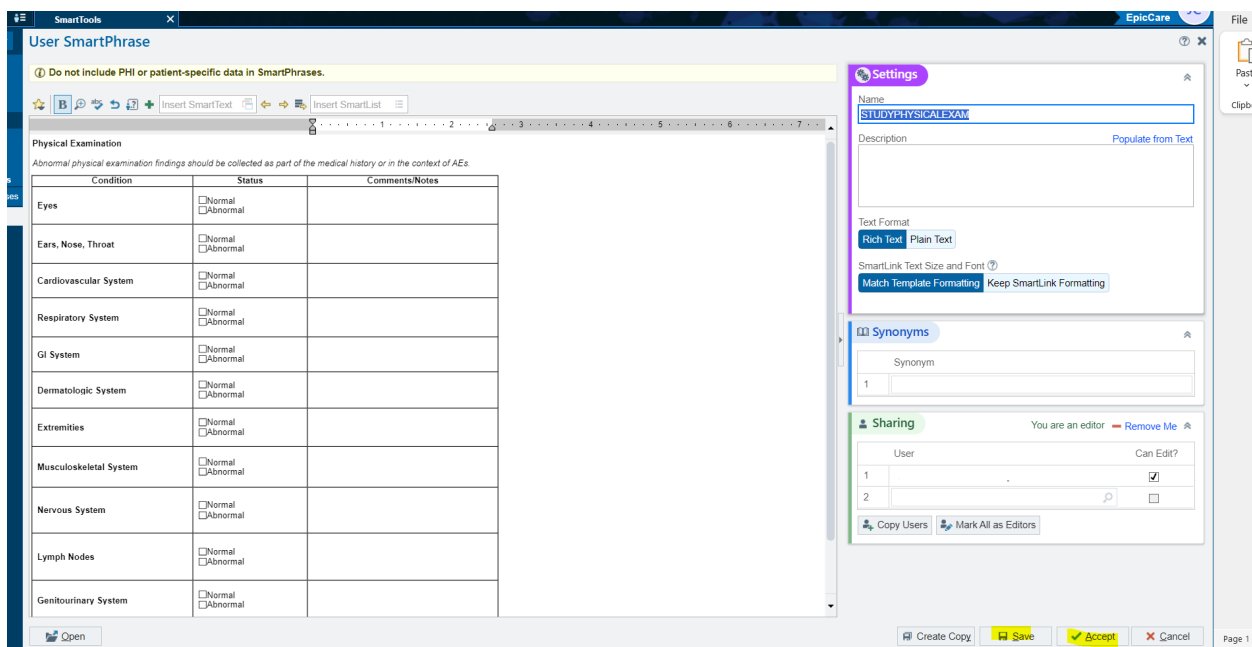
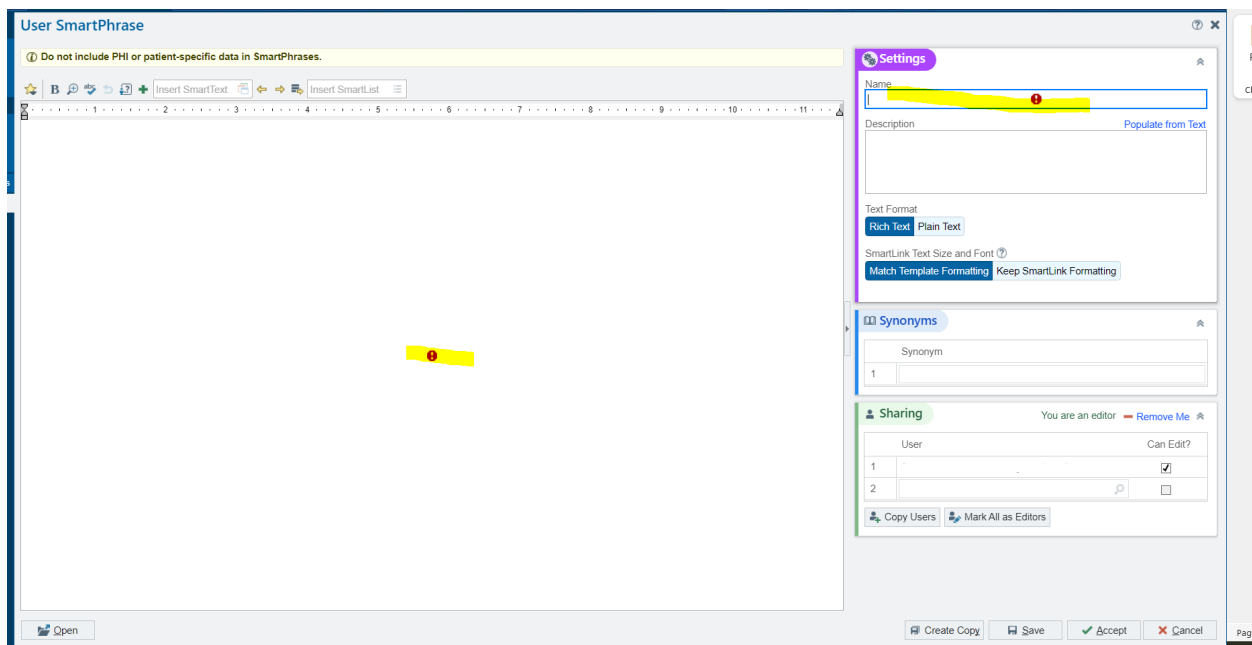
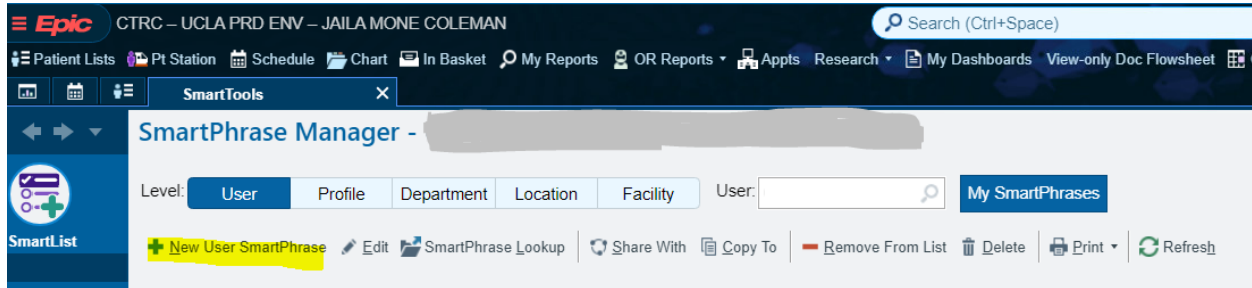
- i. Upload the Signed ICF to [OnCore](#)
  - a. Go to CRA Console > select protocol > click subject ID > documents/info > attachments > add > document type > select **“signed treatment consent”** and input version date > either Attach a File or URL > Submit

- j. Why is it recommended to upload consents into OnCore?
  - a. Uploading signed consent forms to OnCore can act as another secure place to store an electronic copy of documents, especially if the study is using paper consent forms.

## 6. [Care Connect](#)

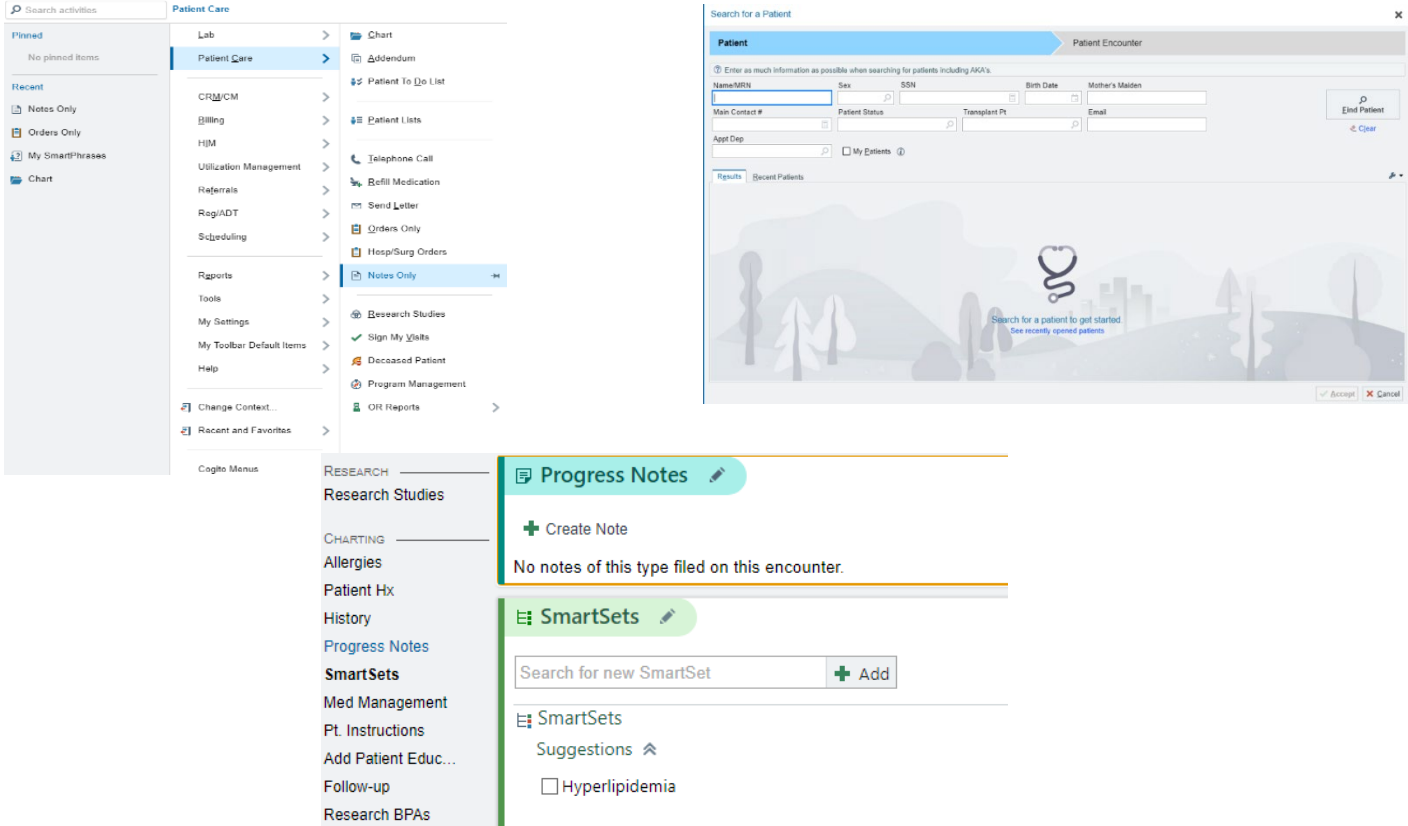
- a. Documenting in Care Connect should act as your electronic case report form (eCRF)
- b. Why is CareConnect important? Who uses it and what information is stored there?
  - i. CareConnect is a patient charting system that is used by CRCs, PIs, and other members of the study team at UCLA. All patient information is stored on CareConnect including previous medical history.
  - ii. Tip: Create a draft eCRF into Word. Which can then be transferred into Care Connect as your smart phrase.

- c. **Creating Smart Phrase:** Login to CareConnect > EPIC > Tools > MySmartPhrases > **"New User SmartPhrase"** > copy and paste draft case report form into the box on the left and enter in a title for the phrase under *Settings* > Save > Accept
  - i. **Note:** the title of the smartphrase is the dot phrase (i.e., **.STUDYPHYSICALEXAM**)
  - ii. **Tip:** Share the SmartPhrase to members on the study team that will need to utilize the phrase



- d. **Utilizing SmartPhrase:** EPIC > Patient Care > Notes Only > Select Patient Chart > Progress Notes > **Create Note** > Use “dot phrase” > Accept > Sign Encounter

- i. **Tip:** If the PI or sub-I needs to review or sign the eCRF, check the co-signer box



7. Uploading Research Consent Form to CareConnect

- a. Why should the research informed consent be uploaded to the patient’s chart?
- i. Ensuring the ICF is listed in the patient’s chart allows providers not a part of the research study to review the type of research the patient is participating in, as well as allowing ancillary departments such as CTRC and pharmacy to confirm that the patient has consented to the study,
- b. How to upload the Informed Consent to CareConnect
- i. Email the consent form to [ehims](mailto:ehims@mednet.ucla.edu), including the following information in your email:
    1. Research Consent Coversheet
    2. Main ICF, Bill of Rights, and HIPAA
    3. Sub-study consent form (if applicable)
    4. Each must be labeled with the patient’s name and MRN in the top right-hand corner

**CONTACTS AND RESOURCES**

- OnCore
  - CRIS or CRBP (for OnCore assistance and building the calendar) – [CRISAdmin@mednet.ucla.edu](mailto:CRISAdmin@mednet.ucla.edu) or [CRBP@mednet.ucla.edu](mailto:CRBP@mednet.ucla.edu)
  - New Subject [Registration](#)
- CareConnect
  - [Progress Notes in CareConnect](#)
  - [Co-Signer to Note](#)
  - [Consent Form into CareConnect](#)

- DOMCTP ([DOMCTP@mednet.ucla.edu](mailto:DOMCTP@mednet.ucla.edu))
- [ResearchGo](#)
- Contact Sponsor or CRA for study related questions and access
- UCLA: Guidance on the proper handling of information technology, including personal information, can be found in the [UCLA Institute for Digital Research and Education](#)