CONNECTS Common Data Elements Manual

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This document describes recommended data elements for all therapeutic clinical trials for COVID-19. With the multitude of COVID-19 research being conducted, a common set of data elements is essential for efficiency in the study design process, increased power for discovery through aggregated data, and improved accountability for generalizability and reproducibility. This set of data common data elements (CDEs) is being developed in collaboration with the NHLBI-CONNECTS Study Design Core, a University of Pittsburgh team, and NHLBI-funded research networks such as SIREN and PETAL. Trials funded through NHLBI-CONNECTS will implement these CDEs and make their data available through NHLBI's BioData Catalyst data access and compute environment.

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Overview

Why are COVID-19 Trial Common Data Elements Needed?

The COVID-19 pandemic presents a new challenge to clinical researchers. Many therapeutic agents need to be studied and trials need to be launched rapidly to address the ongoing crisis. A lack of data standardization across trials will make comparisons between therapeutic agents difficult and could hinder the identification of optimal treatments.

CDEs address these challenges in the following ways:

- **Effective study design**
    - Allows researchers to choose appropriate therapeutics and controls based on data from previous studies.
    - Enables more accurate estimate of priors in new studies.
- **Efficient study implementation**
    - Allows for reuse of case report forms (CRFs) across studies, lessening work required for trials to launch.
    - Simplifies comprehension through familiarity for regulators, decreasing DSMB and IRB review time.
    - Promotes the inclusion of variables that may otherwise be dropped for expediency, but which are known to be important in disease progression.
    - Facilitates standardized processes for data and specimen collection and the sharing of best practices across centers.
    - Does not restrict collection of other informative data. Instead, because the core data elements are already well established, it allows researchers to focus on selecting additional data that have maximum information content.
- **Discovery from data aggregation**
    - Obviates the need to try and draw inferences from studies that have different outcomes measured in different ways even if treatments are similar.
    - Enables the combination of smaller trials to produce meaningful findings.
    - Ensures that key covariates are measured similarly so merging and comparison of studies can occur.
    - Improves data integration with other NIH COVID-19 studies such as Accelerating Covid-19 Therapeutic Interventions and Vaccines (ACTIV) trials and National COVID Cohort Collaborative (N3C).
- **Evaluation of reproducibility and generalizability**

- Allows for control groups in studies of different therapies yet common outcomes to be shared to boost understanding of effect sizes.
- Enables comparison of generalizability of trial populations and outcomes.
- Improves the interpretability of a body of literature.

Attributes of a good set of Common Data Elements

To achieve the benefits outlined above, the Data Standardization Core (DSC) followed the following principals for designing the NHLBI-CONNECTS CDE (CCDE).

- **Build on existing trials**

Several trials studying COVID-19 therapeutics have already been conducted or are in progress. The DSC's primary guiding principle's is not to "reinvent the wheel" when it comes to data elements. Wherever possible data elements from previous studies were included in CCDE. This also enables NHLBI-CONNECTS to map data collected in these existing studies to CCDE for comparison with future studies.

- **Build on existing standards and NIH CDE resources**

The DSC sought to use existing data standards wherever possible for CRF language and data coding. Using existing standards enables linking to other data sources such as electronic health records, registries, and epidemiological datasets. DSC referenced widely used standards for clinical trials data and real-world clinical data including CDISC, LOINC, and HPO, as well as NIH CDE resources such as the PhenX and trans-NIH COVID Data Elements.

- **Allow room for innovation**

The DSC recognizes that CRFs are often long and complex. Additionally, all studies will have to collect data elements that are unique to a given study. Our goal is to maximize the number of data elements that COVID-19 therapeutic trials would normally collect and minimize the number of data elements required to enable cross-study analysis.

- **Enable multiple types of analysis**

One of the primary charges of NHLBI-CONNECTS is to maximize the value of COVID-19 trials through data standardization, aggregation, and sharing. Through these CDEs, NHLBI seeks to enable cross-trial and epidemiological studies that would not be possible with any single trial. NHLBI is particularly interested in the influence of social determinants of health on COVID-19 outcomes and identifying remedies to these outcome disparities.

Procedure for CDE curation

In keeping with these guiding principles for CDE design, the DSC adhered to the following procedure for curating CDEs.

1. Collect CRFs from COVID-19 clinical trials, including several large studies conducted by the PETAL and SIREN networks.
2. Catalog data elements that exist in multiple studies.
3. Harmonize data elements with CDISC CDASH standards.
4. Consult NHLBI-CONNECTS Study Design Core and other domain experts to ensure that necessary outcomes and health disparity variables are collected.

How to use this manual

This manual and accompanying data dictionary are written to assist clinical researchers in designing study data collection instruments that are consistent with CCDEs. This document can also be used to guide harmonization for study data that has already been collected with data from other CONNECTS studies. Each of the following sections covers a CDE domain. Each domain has an accompanying tab in the data dictionary which lists the CCDEs. Additionally, we provide a recommended collection schedule and CRF design guidance in each domain section. This guidance is mandated by CONNECTS but is in place to help researchers mimic and built upon previous CRF designs for clinical trials. We also provide example CRF documents to demonstrate one potential method of implementing the CDEs into CRFs.

CDEs that are labeled as "**Core**" are required for NHLBI-CONNECTS funded trials. Those labeled as "**Recommended**" are strongly encouraged to be included in studies to help further describe variability. "**Optional**" CDEs are listed in this manual to ensure response options and formatting are consistent among studies that do decide to collect those CDEs.

CDE requirement levels are different depending on the type of COVID-19 therapeutic study. In the data dictionary, recommendation levels will be followed by a combination of letters signifying the trials for which that recommendation is expected to apply:

- IP: Admitted patient study
- OP: Outpatient or post-discharge study
- D: Drug intervention
- N: Non-drug intervention

The DSC wants to help remove any barriers to CDE adoption. We are offering consultations for study designers who want guidance on how to structure CRFs to conform with CDE. These services are available at any step of the CRF design process including at the time of study conception up to the time of regulatory approval. The DSC's preference would be to offer suggestions on CRF design as early in the study design process as possible to minimize duplicative work and impact on regulatory approval.

This manual and accompanying data dictionary are living documents. New individual CDEs or domains of CDEs may be incorporated into these documents as the need to do so is identified

in the development of CONNECTS studies. The final spreadsheet in the data dictionary workbook is a change log that documents any modifications to CDEs from version to version.

CONNECTS CDE Domains

Demographics

Demographics comprise most of the typical covariates in clinical trials and epidemiological studies. In addition to typical "Table 1" variables, there are CDEs that enable analysis of disparities in COVID-19 outcomes.

We recommend that these demographics be collected at the time of enrollment when possible. **Some of the data elements in this section are not intended for transfer to BioData Catalyst but are instead needed to link records to other data**. This applies to name and address fields used for Global Unique Identifier (GUID) generation and mapping to US Census data based on geography.

Recommended Collection Schedule

- Baseline visit

CRF Guidance

- Date of birth should not be in the future or before 1/1/1910
    - Age should be calculated from DOB, rather than entered freely
    - For studies using an electronic data capture system, age should be based on date of collection of demographic information and not "today" for systems where that is a calculation option
- Geographic CDEs
    - Country of birth, Country of residence, and State should have a close-ended list for selection or auto-population
    - If not a closed list, country of birth, country, city of birth, and province should have validation to limit character types (e.g., not allowing numbers)
    - Zip code should be limited to between 5 and 10 digits (to allow for international codes to be captured)
- Household size can be restricted to integers between 1 and 20

Medical History / Comorbidities

As with typical clinical trials, medical histories of known conditions should be taken at study enrollment via EHR review if possible and participant self-report if not. Medical histories obtained through EHR review should also be confirmed with participant self-report in case incorrect or incomplete. Core medical history CCDEs are focused on comorbid conditions that are known to affect outcomes of COVID-19. Conditions included in the CONNECTS CDEs use definitions defined by the Charlson Comorbidity Index.

Each protocol should expand upon the list to accommodate medical history elements which are relevant to their trial therapeutics. These elements may be captured as "Other (specify)." Consult the DSC for additional guidance on harmonization.

Recommended Collection Schedule

- Baseline visit

CRF Guidance

- If medical history information is unavailable or unknown, please consult with the DSC to discuss potential alternatives for collection
- Substance abuse
    - Synonyms for each response option for substance abuse type in case studies wish to incorporate in response options
        - Cannabis (e.g., Marijuana, Hash/Hashish, Synthetics [K2, Kush, Spice])
        - Cocaine (including Crack)
        - Opioids (e.g., Heroin, Methadone, Rx Opiates)
        - Stimulants (e.g., Amphetamines, other stimulants aside from Cocaine and Crack)
        - Sedatives (e.g., Tranquilizers, Valium, Zanax)
        - Other (e.g. Hallucinogens, Dissociatives, Inhalants)
    - Allow substance type and frequency to repeat as needed to capture all substance forms, if included. These have been delineated as separate variables for capture in the Data Dictionary, but their structure is flexible to allow for a variety of CRF capture formats, including use of tables, check boxes, etc.
- For several medication variables, it is critical to get an affirmative "no" that a study participant is not taking certain types of medication related to the treatment of COVID-19 at baseline. These yes/no gating questions have been added to the Medical History assessment to capture that information. If a participant answers "yes" to any of the included questions, a concomitant medication form should be completed.
- Although the CDE data structure is event-style, the Medical History terms may be prepopulated on the CRF to reduce data entry burden. This may also be done for custom pre-specified Medical History terms that will be documented as Other-specify in the harmonized data.

Environmental and Social COVID-19 Risk Factors

As COVID-19 is a contagious disease, patient exposure to specific environmental and social risk factors could be directly related to how and when they contracted the disease. These elements are reflective of established common potential sources of transmission. All data elements in this domain are recommended but not core.

Recommended Collection Schedule

- Baseline visit

CRF Guidance

- None noted

Outcomes – Inpatient

Inpatient outcomes are important to standardize across COVID-19 studies. Study staff may need to contact admitting hospitals or otherwise be able to reference participant EHR records to obtain detail about a participant's worst state on each day of an inpatient stay. These measures should be included in all outpatient trials, as these participants may still be hospitalized at some point during the trial.

Recommended Collection Schedule

- Baseline visit
- Daily while patients are admitted. These data are recorded in electronic health records. Therefore, retrospective chart review at regular intervals, discharge, or study conclusion may be preferrable where possible. Study staff should record the participant's outcomes in 24-hour intervals starting at the same time each day.
- For Outpatient studies, where the participant is admitted to an Inpatient setting, these variables should also be collected in the same 24-hour interval format as for participants in Inpatient studies.

CRF Guidance

- Recommend collection in a repeated daily assessment form; will likely be able to be captured in the same form as Healthcare Encounters – Inpatient, as well as Vitals and Clinical Labs (see Appendix A: CRF Data Collection Schedule and Associated CDE Domains).
- For daily assessment of oxygen support, recommend capturing the "worst" or most invasive form of oxygen support used in a given 24-hour period.

Outcomes – Outpatient

Outpatient studies, or studies recruiting patients not admitted to a hospital or acute care facility who can live independently, should capture participant symptom burden via in-person exam, coordinator phone calls, or electronic patient surveys. Studies can choose to perform data collection daily or allow patients to recollect their symptom severity for days between assessments.

Required outcomes include (1) symptom burden, as specified by collection of the COVID-related symptoms including fever, cough, chest pain, abdominal pain, nausea, vomiting, diarrhea, muscle or body aches, chills, headache, sore throat, upper respiratory (nose/sinus/throat) congestion, loss of sense of taste, loss of sense of smell, confusion (change in ability to think, change in ability to interact with other people), and other symptoms, (2) fatigue, (3) dyspnea, and (4) functional status.

Recommended Collection Schedule

- Baseline visit
- At each protocol-specified collection point
- Recommended days for collection: Day 1, 3, 5, 7, 14, 21, 28

CRF Guidance

- One form per follow-up visit/call/electronic survey
- Recommend collection through repeated daily assessment form on each protocol-specified collection day.
- For "Other COVID-related symptoms," CRF structure should allow for the capture of multiple "other" symptoms. For each additional symptom specified, they should be captured in a new variable in the structure indicated; for example, 3 "other" symptoms should be captured in variables SYMOTHERSP1, SYMOTHERSP2 and SYMOTHERSP3, etc.
- Will likely be able to be captured in the same form as Healthcare Encounters – Outpatient, as well as Vitals and Clinical Labs, if they occur outside of an inpatient admission (see Appendix A: CRF Data Collection Schedule and Associated CDE Domains).

Outcomes - Adverse Events

CONNECTS considers adverse events as core safety outcomes. Each protocol may specify what qualifies as an adverse event, and/or identify specific adverse events of interest. Adverse events should be collected on an ongoing basis and recorded regardless of whether they occur on a designated collection day. Adverse events should be recorded with the date and time that the event occurred and followed through resolution or end of study. Adverse events for CONNECTS follow CTCAE definitions for determination of grading, with Grade 3 or Grade 4 adverse events considered serious (SAEs).

CONNECTS adverse events CDEs conform to CDISC formatting. For ongoing AEs and SAEs, each change in severity as measured by Grade will be captured as a new AE.

Recommended Collection Schedule

- Continuous monitoring for new events and changes to ongoing events (from time of randomization through end of study).

CRF Guidance

- Add a prompt to the inpatient and outpatient outcome CRFs as a reminder to update the Adverse Event log.
- Start and End times are optional and should only be recorded if time is known.
- If only a partial date is known, record a partial date (i.e. month and year without day). Do not enter a generic placeholder. For the inpatient setting, complete dates are expected.
- Adverse events should be categorized according to Medical Dictionary for Regulatory Activities (MedDRA) event terms.

Concomitant Medications

A record of concomitant medications is essential to identify potential confounding effects or reactions with the therapeutic agents being tested. The CDEs list core, recommended, and optional medications of interest that are commonly taken by individuals infected with COVID-

19. Each protocol should expand upon the list to address known or suspected medication-interactions which are relevant to their trial therapeutics. Medications not specified as CDEs should be captured as the medication name.

All prespecified concomitant medications should be assessed at baseline as Yes/No/Unknown current use. For CONNECTS, "current" concomitant medications is defined as the participant taking or receiving the medication in question on a routine basis (with or without prescription) within the 3 weeks prior to randomization. Specifically, vasopressors are identified as core and are necessary elements for inpatient studies (I, D, N).

After randomization and through the end of the study, new medications or changes to existing medications should be reported. There is no need to capture No/Unknown use after the baseline assessment. Each medication series should be followed through the end of the dosing schedule or end of study, whichever comes first. Changes to the dose or dose frequency qualify as a new concomitant medication records with start/end dates and times corresponding to the change in dosing schedule.

Please note – the study intervention drug must **NOT** be captured on the concomitant medications log. Study drug dosing details are captured elsewhere.

Recommended Collection Schedule

- Baseline visit (to assess routine medications within 3 weeks prior to randomization).
- Continuous monitoring for new medications and changes to baseline medications (from time of randomization through end of study).

CRF Guidance

- If only a partial date is known, record a partial date – do not enter a generic placeholder. For the inpatient setting, complete dates are expected.
- For data accountability, consider adding an "unknown" option for the start and end day/month fields; however, this "unknown" selection will not be transferred to BioData Catalyst.
- Start and End times are optional and should only be recorded if time is known.
- Help text should be added on how to complete start dates. Coordinators should only provide the level of granularity which is relatively certain, rather than providing an estimated month and/or day when only the year is available. The focus should be on year for any medications the participant has been taking for several years.
- Recommend a gate question for vasopressors; recommend in CRF, then which one received (but gate question not included in manual)
- Medications should be entered each time a series starts/stops, so multiple entries for new medications within a single day should be permitted.
- Capturing dose information is optional, as noted in the Data Dictionary; however, **if studies choose to capture dose information, for CDISC compliance purposes, each change in dose becomes a new concomitant medication**. For this reason, the DSC

recommends only capturing dose information to high-risk concomitant medications or those specifically identified in the study protocol.

Vitals

Vital signs are routinely collected as part of the baseline visit to determine eligibility to participate in a trial, to serve as a reference point to select vitals which may be trended during the trial, and to reveal indicators of severity and risk. The DSC encourages researchers to supplement this list with other vital signs as dictated by specific criteria in their individual trials. Vitals is a CDISC-modified domain. As such, please consult the DSC for guidance on how to best capture new vital signs. Element variable names and labels are based on the SDTM VSTESTCD and VSTEST controlled terminology list, respectively. The Vital Signs domain includes elements that map to many CDISC forms but are grouped together in this domain due to shared subject matter. To accommodate this structure, numerical vital results are recommended to be captured as "Char" variable type instead of "Num"; this structure only applies to the VS domain, and the DSC should be consulted for assistance with data transformation for CDISC compliance.

Some vital signs are necessary elements for inpatient studies (I, D, N) to calculate core inpatient outcomes and are therefore listed as "core" variables for collection here. To facilitate complete tracking of core outcome scale, it is required to collect these elements at baseline.

Recommended Collection Schedule

- Baseline visit
- For inpatient studies, study sites should provide any core vitals data that are collected for routine monitoring of participants. Vitals should be collected daily while patients are admitted. These data are recorded in electronic health records. Therefore, retrospective chart review at regular intervals, discharge, or study conclusion may be preferrable where possible. Study staff should record the participant's outcomes in 24-hour intervals starting at the same time each day.
- For inpatient studies, if data collection occurs more often than once daily, the "worst" instance should be used, or data collection at a pre-specified time point, depending on the study protocol.
- For outpatient studies, core vitals data elements should be taken with any in-person assessments. If a participant in an outpatient study is admitted, the DSC recommends collecting according to the inpatient frequency through the electronic health record for the duration of the admission. However, the reference time period for vitals should be a 24-hour clock to allow for consistency across studies.

CRF Guidance

- All elements should be captured in original units, accompanied by the original unit of measure. Common unit options may be prepopulated in the electronic data capture system to reduce data entry burden (e.g., fixed/no choice or limited choice).
- For planned vitals collection timepoint (VSTPT), many studies will collect vitals at a specific point in time (e.g., time closest to 8:00 am daily) or the "worst" instance of vitals in a day, depending on study needs. This variable should be based on the collection

schedule in the study protocol and should not differ across vitals. If a different collection schedule is used, the "other" option should be selected.

Clinical Labs

Similar to vital signs, a variety of laboratory test values are captured as part of the baseline visit to determine eligibility to participate in a trial, to serve as a reference point to select labs which may be trended during the trial, and to reveal potential indicators of severity and risk. The CDEs include clinical labs regularly taken during triage, some which are of specific interest in COVID-19 patients. The DSC encourages researchers to supplement this list with other labs which are relevant to their trial therapeutics. This is a CDISC-complaint domain, as such, please consult the DSC for guidance on how to best capture new laboratory test.

Some clinical labs are necessary elements for inpatient studies (IP, D, N) in order to calculate core outcomes and are therefore listed as "core" variables for collection here. These elements are required at baseline.

Recommended Collection Schedule

- Baseline visit
- The DSC is not currently recommending frequency for documentation of specific clinical labs. Study sites should provide any core lab data that are collected for routine monitoring of participants, which will vary between outpatient and inpatient settings. However, the reference time period for labs should be a 24-hour clock to allow for consistency across studies.
- For outpatient studies, core clinical labs data elements should be documented with any in-person assessments, as available. If a participant in an outpatient study is admitted, the DSC recommends collecting according to the inpatient frequency through the electronic health record for the duration of the admission. However, the reference time period for labs should be a 24-hour clock to allow for consistency across studies.

CRF Guidance

- Several CDEs should **not** be collected on the CRF, and instead should be entered directly by the data coordinating center. These elements may be programmed into the electronic data capture system or applied to the dataset post-collection. These elements include
    - Category of Lab Test (LBCAT)
    - Subcategory of Lab Test (LBSCAT)
    - Lab Ref Range Lower Limit (LBORNRLO)
    - Lab Ref Range Upper Limit (LBORNRHI)
    - Lab Reference Range Indicator (LBNRIND)
- For the lab tests identified as CDEs, if your laboratory provides results in a different unit than what is specified in the data dictionary, please report the original lab result with original unit of measurement. The Lower and Upper Limit reference ranges will need to be adjusted accordingly.

COVID-19 Testing

An active COVID-19 infection, regardless of severity, is expected to be an inclusion criterion in all trials. The DSC proposes a small set of standardized data elements to characterize the confirmation of this active infection and recognizes that studies may wish to capture additional details on COVID diagnosis not outlined here. The primary test of interest for studies to collect is the COVID test that confirms the patient has tested positive for COVID-19 to qualify for the study.

Recommended Collection Schedule

- Baseline visit
- Refer to study protocol for additional COVID-19 testing documentation requirements

CRF Guidance

- Should allow ability to repeat/add instances of testing details if extended COVID testing history is desired
- Whether the patient has a qualifying positive COVID test should be assessed at baseline; though currently included in "medical history", studies are free to structure their forms to capture this information alongside other COVID testing details.
- If studies wish to capture additional positive tests, the COVID test information should be completed for each subsequent test. Sample collection date/time elements can be used to identify the "qualifying" test vs. subsequent tests post-hoc, if needed. However, only one test will count as the "qualifying" test, which is associated with the positive response to the COVID test question asked at baseline.

Vaccination

As vaccines for COVID-19 are approved and administered, it is critical to know the vaccination status of CONNECTS study participants to contextualize outcomes and, potentially, other events during the study.

Recommended Collection Schedule

- Baseline visit
- Ask about changes to the participant's COVID-19 vaccination history at each scheduled outpatient data collection. Only collect data when a new vaccination has occurred.

CRF Guidance

- None noted

Disposition

Disposition data elements capture key timepoints and status indicators for study participants that occur only once during a study. As these are key in analyses, particularly in cases where study data must be de-identified.

Recommended Collection Schedule

- Study disposition CDEs should be collected for each participant at key study time points: a portion of the form related to study inception (e.g., enrollment, randomization, screening, consent) should be completed at the beginning of study participation.
- CDEs related to termination of study participation should be completed upon study exit for all participants, whether due to study completion or early exit from the study for any reason, including withdrawal of consent or death.

CRF Guidance

- CDEs regarding death details are included in this domain. These elements should be left blank unless Discharge Status = "Died".
- A collection of common ICD-10 coded Cause of Death response options have been provided.

Presentation

In the inpatient setting, studies may wish to collect additional information regarding patient presentation to the hospital at time of admission. None of these elements are required "core" CDEs. If studies choose to collect this information, they should follow the formatting specified in the data dictionary.

Recommended Collection Schedule

- Presentation CDEs should be collected upon inpatient admission. If a patient is admitted multiple times throughout the course of a study, presentation CDEs should be completed for each admission.

CRF Guidance

- One repeated form per hospital admission.
- If only a partial date is known, record a partial date – do not enter a generic placeholder.

Healthcare Encounters – Inpatient

Over the course of a study, a participant may have one or more healthcare encounters indicative of or related to an adverse event, change in clinical status, or both. These encounters and associated details should be captured to help show the progression of participant status and provide a measure of hospital utilization. Inpatient encounter data elements are captured daily while a patient is admitted to ascertain whether a patient was in a general hospital bed or ICU.

Recommended Collection Schedule

- Daily assessment while admitted

CRF Guidance

- Recommend collection alongside other variables needed for daily assessment in inpatient setting, including inpatient organ support outcomes.
- If only a partial date is known, record a partial date – do not enter a generic placeholder. For the inpatient setting, complete dates are expected.

Healthcare Encounters – Outpatient

For outpatient studies, patients may have one or more encounters with a healthcare provider, such as a primary care provider. This information can be obtained during regularly scheduled study collection dates. If the healthcare encounter results in an inpatient admission, then information from the "Healthcare Encounters – Inpatient" section should be collected.

Recommended Collection Schedule

- During regular study collection dates (e.g., since your last study check-in, have you had any unplanned healthcare encounters?).

CRF Guidance

- One repeated form per outpatient encounter

Appendix A: CRF Data Collection Schedule and Associated CDE Domains

Baseline Data Collection

- Collected once, will not change:
  - Disposition – part 1 (DS; consent, screening, enrollment)
  - Demographics (DM)
  - Medical History (MH)
  - Environmental Risk Factors (RSK)
- Establish baseline, may be repeated:
  - ConMeds (CM) – current
  - COVID-19 Testing (COVID) – prior
  - COVID-19 Vaccines (VAC) – prior
  - Vital Signs (VS)
  - Laboratory Tests (LB)
  - Presentation (PRS) – inpatient studies only

Routine Data Collection (Enrollment – Discharge)

- Daily assessments
  - Outcomes – inpatient/outpatient
  - Healthcare Encounters – inpatient/outpatient
  - Vital Signs – as specified by protocol
  - Clinical Labs – as specified by protocol
- Update as needed
  - Adverse Events (AE) – updates only
  - ConMeds (CM) – updates only
  - Presentation (PRS) – if newly admitted
  - COVID-19 (COVID) – updates only; where applicable
  - Vaccines (VAC) – updates only; where applicable

Study Discharge

- Close out log forms
  - Adverse Events (AE) – updates only
  - ConMeds (CM) – updates only
- Close out disposition form
  - Disposition – part 2 (DS; study discharge and death details if applicable)