REDCap CDIS (Clinical Data Interoperability Services)

REDCap and Epic

Enterprise REDCap users have the ability to access the Encompass Epic EMR environment from inside of their REDCap projects in order to map and pull data from fields in the EMR to fields in their REDCap project design. This offers a faster and more efficient way for importing data from the EMR into a REDCap project using secure and built-in functionality. Reducing the effort on researchers to enter this same data manually.

CDIS services in REDCap currently consist of two items: Clinical Data Pull (CDP) and Clinical Data Mart (CDM). Both services effectively serve the same purpose of setting up the automated pulling of data from the EMR and into REDCap. A full outline of both CDP and CDM, including setup and use can be found below.

Checklist of Requirements before you can use CDIS

- o Have active and valid access to Epic Encompass EMR (User managed)
- o Complete LiftCap request for CDP or CDM functionality in your project (Admin enabled)
- o Have User Rights capabilities in the project to use CDIS features (Admin enabled, user managed)

CDP vs. CDM

Clinical Data Pull (CDP)

To utilize the Clinical Data Pull (CDP) for a REDCap project, please contact your REDCap administrator regarding the process entailed and procedures required in order to have the CDP enabled for the project and also for an individual to be given authorization to use the CDP.

What is 'Clinical Data Pull' (CDP)?

Clinical Data Pull is a special feature for importing data into REDCap from an EHR (electronic health record system), such as Epic, Cerner, etc. It provides an adjudication process whereby REDCap users can approve all incoming data from the EHR before it is officially saved in their REDCap project. Clinical Data Pull can only be enabled by a REDCap Administrator, so you should contact them if you wish to utilize Clinical Data Pull for this project.

How 'Clinical Data Pull' works

Clinical Data Pull has the ability to fetch data from the EHR system both manually in real time and automatically at a regular interval. From the EHR interface, Clinical Data Pull can create new records in a CDP-enabled REDCap project. Additionally, if a user knows the patient identifier (e.g. medical record

number), then they could optionally enter the MRN for a record in a CDP-enabled REDCap project, after which it will then go and immediately retrieve the patient data from the EHR in real time.

Enabling the Feature

After a REDCap administrator has enabled the CDP for your REDCap project, the administrator can then give any user in the project access to the CDP (assuming the user has been authorized to access source system data), in which the user can be given user privileges to perform the mapping/setup process and/or to adjudicate/import data from the source system. Only an administrator can grant individuals access to begin utilizing the CDP. After being granted access to the CDP, the user will then see the CDP step on the Project Setup page where they can navigate to the CDP mapping/setup page, which allows the user to map fields already created in their REDCap project to fields from the external source system. This mapping allows REDCap to know how where to put the data when importing it from the external system.

The Field Mapping Process

A user on the mapping/setup page can choose any available fields from the external source system to map to one of their REDCap project fields. (Note: This assumes that the user has already created their data collection instruments and fields in their project.) There are two types of fields that may be mapped: 1) one-time data fields, and 2) temporal data fields. One-time data fields are those where data will only be stored one time in the source system, such as demography data. Conversely, temporal data fields are those where data may be collected many times over a period of time (e.g., labs, vitals, any kind of longitudinal data). When mapping temporal fields, you must also specify a REDCap date/datetime field that will be used for determining the window of time in which it should look when fetching data from the source system. It will determine the window of time in conjunction with the day offset value defined on the mapping page. For example, if the value of the mapped REDCap date/datetime field is 2001-11-29 and the day offset is 1 day, it will query the source system and return only data saved for the field from 2001-11-28 until 2001-11-30. Any source data outside of that range will be ignored during the adjudication process. It is important to note that the source data for a temporal field will NOT be fetched from the external source system UNLESS its associated REDCap date/datetime field has a value. Once a value is entered for the associated date/datetime field, source data will then be fetched for that temporal field.

There are a few demography fields (race, sex, and ethnicity) that, if used in a project, are required to have their choices coded a very specific way. You can find these codes in the LOINC code spreadsheet list as well as in REDCap from your Project Setup page (see "Tell Me More"):

On the mapping/setup page, you may choose up to 5 source fields to be used as 'preview fields'. Preview fields are optional and are typically used to confirm that the record identifier (e.g. medical record number) that was entered is correct by displaying other contextual data from the source system. For example, if you have 'last name' and 'date of birth' as source fields, you may choose them to be preview fields in your project, and thus when a value is entered in REDCap as the record identifier, if will then fetch and display the last name and date of birth of the person to validate their identity. If preview fields are not utilized, it is possible that incorrect source data is imported. Thus preview fields are not required but are recommended for data quality purposes.

The Adjudication Process

After the mapping process has been completed, data from the external source system will not be imported automatically into the REDCap project, but instead it requires that a person view and adjudicate each data item from the source system before being imported into the project. The adjudication screen can be accessed from either of two places: 1) on the Record Status Dashboard, and 2) on the data entry form when viewing a record. The Record Status Dashboard will display a new table column with a count of any new items from the source system for each record displayed. Clicking on the count will open the adjudication screen for that record. Alternatively, when viewing a record on a data entry form, the count of new items from the source system will be displayed at the top of the page in red box, in which clicking the View button will open the adjudication screen. On the adjudication screen, it will display all data from the source system that has not been adjudicated yet. If only a single source value has been returned for a REDCap field, it will automatically pre-select that item for you. If the field is a temporal data field that has multiple values returned, it will automatically pre-select the data value *ONLY IF* that value is the only value returned that occurs on the exact same calendar date as the REDCap date/datetime value (that is, unless a pre-selection option - e.g., Minimum value, Latest value - has already been set for that field on the mapping page). The user must view all the items on the adjudication screen and select the radio button next to each to denote the source value they wish to import. Once all values have been selected, clicking the Save button will import the value into the project. If some items were left and were not adjudicated, the user can return at any time to adjudicate them in the future.

Clinical Data Mart (CDM)

The Data Mart feature is used for importing patient data in bulk into a REDCap project. While CDP is meant for pulling one patient at a time, Data Mart can pull dozens or hundreds of patients' data into REDCap all at once. Like CDP, Data Mart is using the CDIS infrastructure connection to Epic.

To use the Data Mart feature and create a Data Mart project, you must be given explicit permissions for this by a REDCap administrator. Once you have been given permissions, you can navigate to the Create New Project page in REDCap to see a new option to create a Clinical Data Mart project. Note: If you have not yet logged into the EHR, you will be asked to first do so before proceeding. This must be done because connecting your user account and session with Epic is always the first step before you can use either CDP or CDM.

Once the project has been created, the whole structure of the project (i.e., the fields and forms) will be pre-defined. To begin pulling clinical data from the EHR, you must navigate to the Clinical Data Mart page using the link on the left-hand project menu. On that page, you may request changes to your existing Data Mart configuration (if you wish to add new MRNs, new fields, or modify the date range) and/or pull data from the EHR using the "Fetch clinical data" button near the top of the page. By default, you will only be able to pull data just one time and will not be able to modify the Data Mart configuration after initially being set when the project is created. However, an administrator can change these settings on the Project Setup page so that you may pull data as often as you wish or to allow you to make configuration changes when needed.

Key differences between Clinical Data Pull (CDP) and Clinical Data Mart (CDM)

While both CDP and Data Mart utilize the CDIS infrastructure and the FHIR web services to pull data from the HER into a REDCap project, there are very distinct differences between the two features. Listed in the table below are comparisons of these two features to help delineate their key differences and to understand when one might be more appropriate than the other for specific use cases.

	CDP	CDM
Common Uses	• Real time data collection • Prospective clinical studies/trials • Longitudinal and/or multi arm studies	• Registries • Prospective or retrospective clinical studies/trials • Searching for specific lab values or diagnosis codes for a cohort of patients over a set time period
Data Mapping to HER fields	• Field mapping must be set up prior to data pull by a user with CDP Setup/Mapping privileges in the project. This is completed via the CDP mapping page (accessed via the Project Setup page). • Mapping can be adjusted at any time in a CDP project, and it can be complex when mapping EHR fields to REDCap fields (allows for one to many, many to one, or many to many mapping). • Temporal data (e.g., vital signs and labs) must have an accompanying date or date/time field (e.g., visit date) for determining the window of time in which to pull data (using the ± day offset). Temporal data can be mapped to fields in a classic project, to events in a longitudinal project, or to repeating instruments/events. • All values for Allergies, Medications, and Problem List will be merged	• Mapping is not required since the project structure/instruments are pre-defined when the project is created. Demographics is created as a single data collection form, and the following forms are created as repeating instruments: Vital Signs, Labs, Allergies, Medications, and Problem List. Each data value on the repeating instruments are represented as a separate repeating instance of the form. • User defines the data pull configuration when creating the project e.g., chooses specific MRNs, date range, and data fields from the EHR. • Project level settings control whether or not users in the project can 1) fetch data just one time or as often as they wish, and 2) modify the data pull configuration or not. These settings may be changed only by a REDCap administrator.

	together for each category and each saved in its own a Notes/Paragraph field (if mapped).	
Activation Process	• LiftCap request submission required • REDCap administrator must enable CDP for the project on the project's Project Setup page.	• LiftCap request submission required • Project is first created by a user, but each revision of the data pull configuration will go through an audit process and approved by a REDCap administrator (if the project level setting has been enabled to allow configuration changes).
User Privileges	• Project users can set up field mapping and adjudicate data from REDCap if they have project level rights to do so.	• A user's REDCap account must be given Data Mart privileges by a REDCap administrator, after which the user will be able to create a Data Mart project and pull EHR data. (Note: This is not a project level user right but a REDCap user account privilege.) • Users with Project Setup/Design Users with Project Setup/Design rights in a Data Mart project will be able to request changes to the data pull configuration (if needed and if the project--level setting has been enabled).
Usage	• Users must launch a patient in the REDCap window inside the EHR user interface, and will be able to add the patient to any CDP enabled REDCap project to which they have access. Once the patient is in a project, the user can manually pull data from the EHR for the patient. • Data pulled from the EHR is not saved immediately in the project but is stored temporarily in a cache, in which users must first review/adjudicate all data values before being saved in the project. • Once a patient has been added to a project, CDP will automatically continue to look for any new data added to the EHR for up to 7 days.	• Data Mart will only pull data from the EHR when a user with appropriate privileges clicks the "Fetch clinical data" button. There is no function to pull any new data at other times automatically. • To pull new data values in the EHR, a user must manually click the Fetch button again (assuming the project level setting is enabled to allow more than one data pull). • Extra instruments or events may be added to the Data Mart Project, but if any of the pre-defined fields or instruments are modified, it may prevent the data pull from working successfully thereafter.