

Clinical Data Pull & Clinical Data Mart

Overview

REDCap's "Clinical Data Pull" feature provides the ability to launch a REDCap window while inside an EHR and to quickly and seamlessly import clinical data (one patient at a time) from the EHR into a REDCap project. And REDCap's "Clinical Data Mart" feature provides the ability to import *many* patients' clinical data in bulk into a REDCap project. Both are built-in modules in REDCap that can be enabled by an administrator and work independently for different use cases. Both features utilize REDCap's "Clinical Data Interoperability Services" infrastructure, which can interface with any EHR system that has FHIR web services enabled.

Keywords

- EHR = Electronic Health Record system (e.g., Epic, Cerner; interchangeable with "EMR")
- CDP = Clinical Data Pull (module in REDCap for importing clinical data one patient at a time)
- Data Mart = Clinical Data Mart (module in REDCap for importing bulk clinical data for many patients)
- CDIS = Clinical Data Interoperability Services (the technical infrastructure on which CDP and Data Mart run)
- <u>FHIR</u> = Fast Healthcare Interoperability Resources (standardized data format; pronounced "fire")

Purpose

A major motivation for using the CDP and Data Mart features in REDCap is often the need to re-use clinical data from the EHR, especially for research purposes. If you are performing a research study and collecting data in REDCap, it is typically preferred to have all your data stored and accessible from one single place, and thus it is often more efficient, for both data entry workflow and data analysis purposes, to have all study-centric data stored in REDCap.

The modules transfer structured clinical data in real time from the EHR to REDCap. Each module does this in a slightly different way, which will be explained below. This system-to-system flow of data into REDCap allows users to avoid repeated data entry, which often compromises data quality by creating errors in clinical data values, and it proves to be most efficient while providing the greatest amount of data quality.

How CDP and Data Mart Work

The CDIS infrastructure in REDCap utilizes the "SMART on FHIR" technology stack (sometimes referred to simply as "FHIR services"), which is a set of HTTP web services that can transfer data out of an EHR in a standardized FHIR data format. The FHIR web services utilize OAuth2 for authorization of users in the EHR when exporting data from the EHR into REDCap. Most popular EHR systems have their own implementation of the FHIR web services, thus the setup process on the EHR side may vary from system to system, but the overall technology framework and data format will work essentially the same for all FHIR-enabled EHRs.

From a technical standpoint, the CDIS infrastructure requires that the EHR's server that hosts the FHIR services will communicate securely via HTTPS (i.e., encryption-in-transit) with that institution's REDCap server (and vice versa). In order for the two systems to communicate with each other and operate successfully, some setup will be required both on the REDCap side and on the EHR side. Thus, it is required that you find a contact person on your EHR's technical team to work with them during the setup process and follow the setup instructions carefully.

System-level Installation and Setup

In brief, a contact person on the EHR technical team needs to create a FHIR client/app on the EHR system, in which the app has credentials (e.g., client ID, client secret) in order for REDCap to utilize the FHIR web services for the EHR. (For Epic, creating a FHIR app is not required since REDCap utilizes the Epic "App Orchard".) Part of this requires you to obtain necessary configuration information to enter on the "Clinical Data Interoperability Services" page in REDCap Control Center, and set either of the modules as "Enabled" on that page. The next step (this includes Epic installations as well) is that the EHR contact person must create a launch point (e.g., button, link, or menu item) inside the EHR user interface to launch your FHIR app/client (i.e., to open REDCap as embedded inside the EHR). Once REDCap can be launched from inside the EHR, REDCap will additionally be able to make remote calls to the EHR when users utilize CDP while outside of the EHR interface in REDCap (i.e., in their web browser using REDCap normally).

While the above description is a summarized view of the setup process, **for full detailed instructions regarding the installation of this module, please see the "Setup Instructions" document** from the zip file downloaded on the "Clinical Data Interoperability Services" page in the REDCap Control Center.

The sections below discuss the specific features and setup process of CDP and Data Mart individually.

Clinical Data Pull

Project-level Setup and Field Mapping

In order to use the Clinical Data Pull functionality, a REDCap project must first have the Clinical Data Pull module enabled on the Project Setup page. Only a REDCap administrator may enable the module. Once enabled, any project user with CDP Mapping privileges will be able to navigate to the CDP Mapping page in the project to begin to map EHR data fields to fields in the REDCap project. (Note: It is assumed at this point that the use has already created their data entry forms and fields in the project.) Once the mapping process has been completed, users can then begin to utilize CDP to import data from the EHR into their project.



| MAP SOURCE FIELDS TO REDCAP FIELDS | | | | | |
|---|--|---|--|--|--|
| External Source Field (StarPanel) | Map to REDCap Field | Map to REDCap date/time field (Date/time value is used with day offset to construct window of time when searching for source data) | | | |
| mrn "Medical Record Number" | mrn "Medical record number" | | | | |
| Demographics | | | | | |
| dob "Date of Birth" | dob "Date of birth" | | | | |
| ethnicity "Ethnicity" | ethnicity "Ethnicity" | | | | |
| firstName "First Name" | first_name "First Name" | | | | |
| gender "Gender" | sex "Gender" | | | | |
| lastName "Last Name" | Iast_name "Last Name" | | | | |
| race "Race" | race "Race" | | | | |
| Labs | | | | | |
| AN-GAP "ANION GAP" | angap "Anion gap (AN-GAP)" | Date/time field: visit_date "Visit_date" | | | |
| Use same mapping for other source field | Map other REDCap field | Preselect a value (optional): | | | |
| BUN "UREA NITROGEN BLOOD" | bun "Urea nitrogen blood (BUN)" | Date/time field: | | | |
| Use same mapping for other source field | Map other REDCap field | Preselect a value (optional): | | | |
| CO2 "CARBON DIOXIDE BLOOD" | co2 "Carbon dioxide blood (CO2)" | Date/time field: visit_date "Visit date" | | | |

Importing Clinical Data into REDCap using CDP

The "Clinical Data Pull" functionality may be utilized in both of the ways described below.

- 1. EHR Launch
 - a. "EHR Launch" refers to launching a REDCap window from inside the EHR interface. This window provides a patient-level context so that the patient currently being viewed in the EHR may have their clinical data imported into a REDCap project.
 - b. Displayed in the window will be a list of REDCap projects that are CDP enabled, in which the user may choose to view the patient's record inside a given project or (if not yet added) may add the patient to a project. This is easily done just by clicking the "Add patient" button next to the project name.
 - c. If non-temporal CDP fields (e.g., demographics) have been mapped in the project, then data for those fields will be immediately fetched from the EHR and added to the project when the "Add patient" button is clicked.
 - d. If the user navigates inside a project, the patient record may be viewed via the Record Home Page and via data entry forms in the project in typical REDCap fashion. Data may be entered in this view, and CDP data may be adjudicated and imported into the project, if desired. Thus, once inside a project, the user may perform typical data entry operations as they normally would in REDCap.
 - e. Note: The EHR Launch must always be the first step before using "Clinical Data Pull" because the launch itself initiates a user's authorization for the FHIR services on the REDCap side. Once a user has been authorized by simply performing the EHR Launch once, they can use CDP either from inside the EHR launch window or from the REDCap side (outside the EHR).

EHR Launch (REDCap embedded in a window in the EHR)

| eChart View | Research, Brad | MRN: 204250 PCP: | Chart: Sex: Male [2] |
|---|--------------------------|--|----------------------------|
| Select Chart Quick View Activities Activities | REDCap MRN 204250 - Res | earch, Brad (DOB 1986-06-06) | |
| AbL Admission/General Obs. Behaviors | EHR / REDCap Porta | I select o | ne of your existing REDCap |
| ethia ethia ethia tab Benuts | + Add patient to project | DDP Test Project | |
| Radiology Results MD Notes Medical Devices | View patient in project | Epic Test Project | |
| Messages Orders Prain Management Progress Notes Restrictive Device Risk Assessment Skin & Wound Social Services | Wiew patient in project | DDP Demo Project (FHIR) new DDP items to adjudicate | |
| Complete Assessment Complete Assessment Distance Immunications & Tests Observations Ventilator Check Custom Assessment | | | |

| eChart View | Research, Brad | MRN: 204250 PCP: | Chart: Sex: Male [2] |
|--|--|---|--|
| Select Chart Quick View Activities Activities | REDCap MRN 204250 - Resea My Projects Project: Epic Test Project: | rch, Brad (DOB 1986-06-06) s <mark>ject</mark> | |
| ADL ADL ADL ADL ADL Admission/General Obs. Behavior Cpge Plan effilt effilt effilt Etablishe Addology Results Radiology Results MD Notes Medical Devices Medical Devices | The grid below displays the form-by- currently selected record. You may cl access that form/event. | form progress of data entered for the ick on the colored status icons to | Legend for statu Incomplete Unverified Complete |
| Orden Pain Management Dograph Notes | Data Collection Instrument | Status | |
| Restrictive Device Risk Assessment | Demographics | • | |
| Sion & Wound Social Services | Baseline Data | 0 | |
| Complete Assessment | Month 1 Data | 0 | |
| Dietary Immunizations & Tests Observations Monthater Charle | Month 2 Data | (c) | |
| | Month 3 Data | 0 | |
| Custom Assessment | Completion Data | O | |

2. Pulling individual patients' data and adjudicating the data

- a. "Clinical Data Pull" refers to the process of importing and adjudicating EHR data into a REDCap project. As noted above, once a user has been authorized via the EHR Launch, they can use CDP either from inside the EHR launch window or from the REDCap side (outside the EHR). Either way is legitimate and is to the user's discretion as to which way they might prefer to access the patient's record in REDCap. To see a demonstration of CDP in action, you may view a 5-minute video of the CDP module.
- b. Adjudication "Adjudication" refers to the process in which EHR data is manually reviewed and approved by a user before it is officially saved and stored in the REDCap project. The adjudication process is done for data quality purposes to ensure that the correct data values get imported. In many cases, extraneous data points may be pulled

into REDCap from the EHR, but only some of them may be the desired data to be imported. Thus, a user is needed to adjudicate this data inside an adjudication popup window in the project to confirm that the correct data gets stored. The adjudication process can be done either within the EHR launch window and/or on the REDCap side in a browser.

- c. If accessing REDCap from within the EHR launch window, then the patient is already known, so you will be taken to the patient's Record Home Page if you navigate into a project. On the Record Home Page, you may adjudicate any data that has been imported from the EHR, or you may enter more data inside a data entry form.
- d. If accessing a patient record on the REDCap side (outside the EHR), then you will have to choose the record from the record list in the REDCap project. If the patient does not exist in the project yet, you may add a new patient by first creating a record and then entering the patient's MRN (medical record number) into the REDCap field that has been mapped as the MRN field, after which REDCap will immediately begin pulling the patient's data from the EHR in real time.
- e. If temporal data fields have been mapped (i.e., fields with an associated date/time of service), such as labs or vitals, then those values will only be retrieved from the EHR after their associated temporal field has been entered (often a "visit date" field or similar).

| Adjudicate data from EHR | | | | | | |
|--|---------------------|----------------------------|-------------------------|-----------------------|-------------|------|
| iew DDP adjudication instructions | | | | | | |
| Fetching data for Study ID " 3 " using ± 365 days using ± • 365 days from date AND time min: 0.01 days (15 minutes), max: 365 days | | | | | | |
| New items: 13 Time of last data fetch: 2 days ago | | | View 1 | I hidden items (exist | ting values | 5) |
| REDCap Field | REDCap Date/Time | EHR Source Date/Time | REDCap Current Value | EHR Source Value | Impor | t? |
| Demography | | | | | | |
| irst_name "First Name" | - | - | | Micci | • re | eset |
| ast_name "Last Name" | - | - | | Research | • re | eset |
| ex "Gender" | - | - | | Female (F) | • re | eset |
| lob "Date of birth" | - | - | | 1980-12-15 | • re | eset |
| ddress_street "Address (street)" | - | - | | 1234 Wiggy Way | • re | eset |
| ddress_city "Address (city)" | - | - | | Nashville |) re | eset |
| ddress_state "Address (state)" | - | - | | TN | • re | eset |
| ddress_postal_code "Address (postal code)" | - | - | | 37212 | • re | eset |
| ddress_country "Address (country)" | - | - | | US | • re | eset |
| ahona number mohila "Ohona number (mohila)" | | _ | | 615.262.2223 | | |

Adjudication of EHR data

Save Cancel

📃 Labs (Basic Metabolic Panel)

| Editing existing Study ID 50 | new items from source system View |
|---------------------------------|-----------------------------------|
| Study ID | 50 |
| Visit date * must provide value | H 2008-08-14 Today Y-M-D |
| Sodium blood (Na) | |
| Potassium blood (K) | |
| Chloride blood (CI) | H |
| Carbon dioxide blood (CO2) | |
| Urea nitrogen blood (BUN) | |
| djudicate data from StarPanel | |

Adjudicate data from StarPanel

Displayed below is the data fetched from the external source system. It will display all the mapped REDCap fields that have source data returned. To import the source data values into REDCap, select the source value by clicking the radio button for the desired value in the row. Some fields may have multiple values returned, so you must choose the best or most correct value. Once you made all your selections, press the Save button below to save the source values into REDCap.

| New items: 9 Time of last data fetch: just now Display all items (all forms) Display only this form's items View 6 hidden items (existing values) REDCap Field REDCap Date/Time StarPanel Source Date/Time REDCap Current Value StarPanel Source Value Import? na "Sodium blood (Na)" 2008-08-14 (00:00) 2008-08-14 11:16 140 Import? k "Potassium blood (K)" 2008-08-14 (00:00) 2008-08-14 11:16 135 Import? k "Potassium blood (K)" 2008-08-14 (00:00) 2008-08-14 11:16 3.5 Import? d "Chloride blood (CI)" 2008-08-14 (00:00) 2008-08-14 11:16 3.5 Import? co2 "Carbon dioxide blood (CO2)" 2008-08-14 (00:00) 2008-08-14 11:16 104 Import? co2 "Carbon dioxide blood (CO2)" 2008-08-14 (00:00) 2008-08-14 11:16 104 Import co2 "Carbon dioxide blood (CO2)" 2008-08-14 (00:00) 2008-08-14 11:16 24 Import | Fetching data for S | Study ID "50" using ±30 days | | Refresh d | lata from StarPanel | using ± \$ 30 min: 0 | days from date .01 days (15 minutes), r | AND max: 365 | time 5 days |
|---|---------------------------|-----------------------------------|---|--|-------------------------------|-------------------------|--|-----------------|----------------|
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| | | | | | 2008-08-14 11:16 | | 25 | \bigcirc | reset |
| | | | | | | | ~ . | \frown | |

Clinical Data Mart

Introduction

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, so it only needs to be set up once, after which both CDP and Data Mart will utilize it.

To use the Data Mart feature and create a Data Mart project, a user must be given explicit permissions for this by a REDCap administrator on the Browse Users page in the Control Center. Once they have been given permissions, they can navigate to the Create New Project page in REDCap to see a new option to create a Clinical Data Mart project (see screenshot below). Note: If they have not yet launched the REDCap window from inside their EHR, it will inform them that they must first do so before proceeding. This must be done because launching the REDCap window inside the EHR, which is always the first step before a user can use either CDP or Data Mart.

| Data Mart Project |
|---|
| Title to be displayed on project webpage |
| Select One 🔻 |
| |
| O Create an empty project (blank slate) |
| Upload a REDCap project XML file (CDISC ODM format) ? |
| O Use a template (choose one below) |
| Clinical Data Mart: Create a project and pull multiple medical records from EHR |
| Enter medical record numbers of patients to import from the EHR (one per line) |
| |

| If pulling time-based data, select the range of time from which to pull data (optional) | | |
|---|-----------------------------------|--------------------------|
| from | in to | |
| Choose fields i | n FHR for which to pull data | |
| choose heras i | | |
| Source Fields | List Filter: search se | ource fields by keywords |
| 🗹 id (Medical rec | ord number) | |
| + Demographics 13/13 selected | | deselect all |
| - Condition 0/1 selected | | select all |
| problem-list | (Problem list and health conerns) | |
| - Medications 0/1 selected | | select all |

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, the user must navigate to the Clinical Data Mart page using the link on the left-hand project menu. On that page, they may request changes to their existing Data Mart configuration (if they 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, users 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 (see below) on the Project Setup page so that they may pull data as often as they wish or to allow them to make configuration changes when needed.

| | 🐂 Clinical Data Mart settings for this project (Administrators only) |
|----------|---|
| Optional | By default, users using the Data Mart can only pull EHR data one time, and they cannot modify their initial Data Mart configuration. As an administrator, by clicking the buttons below you may grant project users the privilege to fetch EHR data multiple times and also the privilege to submit changes (i.e., as new revisions) to their existing Data Mart configuration, in which each revision of the configuration must be approved by an administrator in the To-Do List. |
| | Enable Ousers can request changes to their Data Mart configuration |
| | Enable Ousers can fetch EHR data multiple times (after the initial fetch) |

Below is a screenshot of the Clinical Data Mart page in a project.



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.

| | Clinical Data Pull | Clinical Data Mart |
|------------------------|---|--|
| Most 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 EHR 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 together for each category and each saved in its own a Notes/Paragraph field (if mapped). | 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. |
|----------------------------------|--|---|
| Activation process | The local institution may have a formal process to evaluate the users/project prior to approval (recommended) - e.g., check IRB status, check users' EHR access. REDCap administrator must enable CDP for the project on the project's Project Setup page. | The local institution may have a formal process to evaluate the users/project prior to approval (recommended) - e.g., check IRB status, check users' EHR access. 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 via the To-Do List (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 the EHR if they have project-level rights to do so. In order to adjudicate data from the EHR, users must have access to the EHR and must have launched at least one patient in the REDCap window inside the EHR user interface. REDCap administrator and team can optionally create a User Access Web Service to further control user access during adjudication (info documented on this page). | A user's REDCap account must be given Data Mart privileges by a REDCap administrator on the Browse Users page in the Control Center, 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.) Also, there is no optional User Access Web Service as there is with CDP to further control user access for pulling data. |

| | | In order to pull data from the EHR, users must have access to the EHR and must have launched at least one patient in the REDCap window inside the EHR user interface. 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 (via a cron job) continue to look for any new data added to the EHR for up to X days, in which X is the value of the setting "Time of inactivity after which REDCap will stop checking for new data" (info documented on this page). | Data Mart will only pull data from the EHR when a user with appropriate privileges clicks the "Fetch clinical data" button. There is no cron job 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. |