

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)
- FHIR = 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.

```
Number of fields selected: 31
Source Fields List
                                     Filter:
id (Medical record number)

    Demographics

                  select all | deselect all
   gender (Sex) ?
   name-family (Last name) ?
   name-given (First name) ?
   address-line (Address (street)) ?
   address-city (Address (city)) ?
   address-state (Address (state)) ?
   address-postalCode (Address (postal code))
   address-country (Address (country))
   phone-home (Phone number (home)) ?
   phone-mobile (Phone number (mobile)) ?
   email (Email address) ?
□ Condition
             select all | deselect all
   problem-list (Problem List and health coner

    ■ Medications select all deselect all

   active-medications-list (Active medications
☐ Vital Signs select all deselect all
   ₩ 8480-6 (Systolic blood pressure)
   ≥ 8310-5 (Body temperature) ?

    8867-4 (Heart rate) 
    ?

   9279-1 (Resniratory rate)
```

			Map to REDCap date/time field
External Source Field (StarPanel)	Map to REDCap Field		(Date/time value is used with day offset to construct window of time when searching for source data)
mrn "Medical Record Number" Source Identifier Field	mm "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"	last_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: visit_date "Visit date"
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)





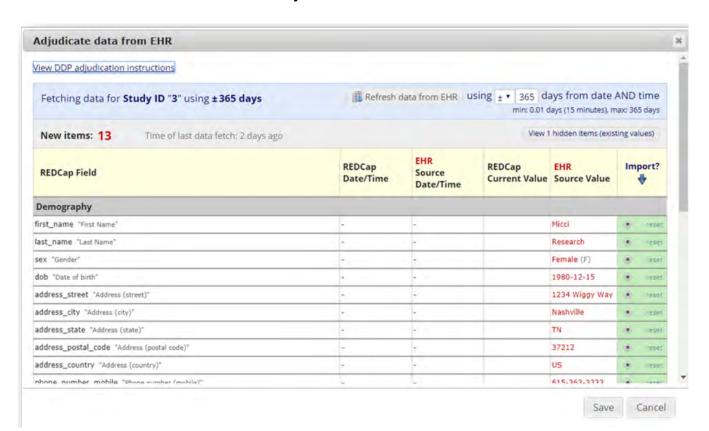
2. Pulling individual patients' data and adjudicating the data

- 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).

Adjudication of EHR data



Labs (Basic Metabolic Panel) new items from source system View Editing existing Study ID 50 50 Study ID Visit date 事 2008-08-14 31 Today Y-M-D * must provide value 萬 Sodium blood (Na) 惠 Potassium blood (K) 1 Chloride blood (CI) 重 Carbon dioxide blood (CO2) Urea nitrogen blood (BUN)

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.

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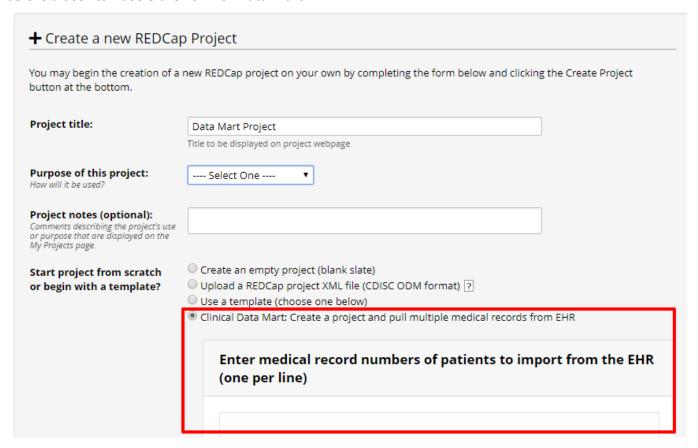


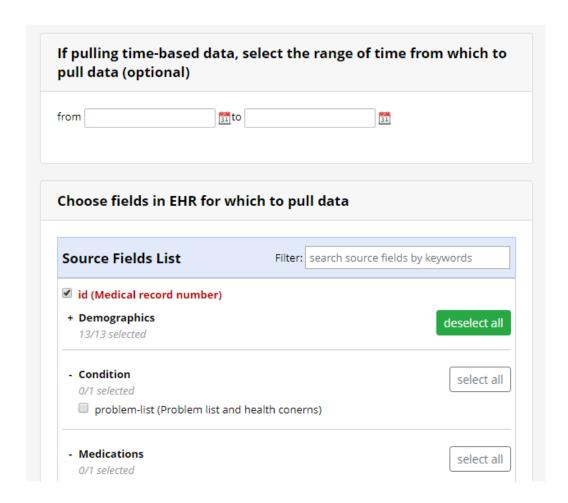
Clinical Data Mart

Introduction

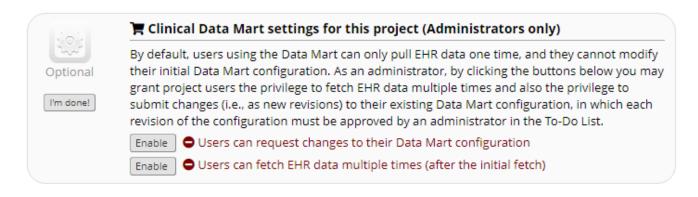
The Data Mart feature is used for importing patient data in bulk into a REDCap project. While CDP is meant for pulling one patient at a time, Data Mart can pull dozens or hundreds of patients' data into REDCap all at once. Like CDP, Data Mart is using the CDIS infrastructure, so it only needs to be set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





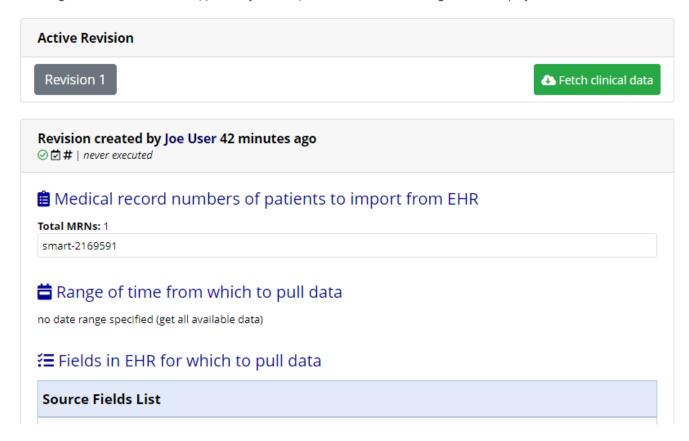
Once the project has been created, the whole structure of the project (i.e., the fields and forms) will be pre-defined. To begin pulling clinical data from the EHR, the user must navigate to the Clinical Data Mart page using the link on the left-hand project menu. On that page, they may request changes 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.



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

📜 Clinical Data Mart

Listed below is the current Data Mart configuration for this project. If you have appropriate privileges, you may run the "Fetch clinical data" button to retrieve data from the EHR. When fetching, any existing patients will have new data added to their record in the project, and those not yet in the project will be created as new records. If you have permission to create new revisions of the current Data Mart configuration, you will see a "Request a configuration change" button at the bottom of the page. When submitted, all configuration revisions must be approved by a REDCap administrator before taking effect in the 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 Field mapping must be set up prior to data Mapping is not required since the mapping to pull by a user with CDP Setup/Mapping project structure/instruments are **EHR fields** privileges in the project. This is completed pre-defined when the project is via the CDP mapping page (accessed via created. Demographics is created as the Project Setup page). a single data collection form, and Mapping can be adjusted at any time in a the following forms are created as CDP project, and it can be complex when repeating instruments: Vital Signs, Labs, Allergies, Medications, and mapping EHR fields to REDCap fields (allows for one-to-many, many-to-one, or Problem List. Each data value on the many-to-many mapping). repeating instruments are Temporal data (e.g., vital signs and labs) represented as a separate repeating must have an accompanying date or instance of the form. date/time field (e.g., visit date) for User defines the data pull determining the window of time in which configuration when creating the to pull data (using the ± day offset). project - e.g., chooses specific MRNs, date range, and data fields Temporal data can be mapped to fields in a classic project, to events in a longitudinal from the EHR. project, or to repeating Project-level settings control instruments/events. whether or not users in the project All values for Allergies, Medications, and can 1) fetch data just one time or as Problem List will be merged together for often as they wish, and 2) modify each category and each saved in its own a the data pull configuration or not. Notes/Paragraph field (if mapped). These settings may be changed only by a REDCap administrator. **Activation** The local institution may have a formal The local institution may have a process process to evaluate the users/project prior formal process to evaluate the to approval (recommended) - e.g., check users/project prior to approval IRB status, check users' EHR access. (recommended) - e.g., check IRB REDCap administrator must enable CDP for status, check users' EHR access. the project on the project's Project Setup Project is first created by a user, but each revision of the data pull page. 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 Project users can set up field mapping and A user's REDCap account must be privileges adjudicate data from the EHR if they have given Data Mart privileges by a project-level rights to do so. In order to REDCap administrator on the adjudicate data from the EHR, users must Browse Users page in the Control have access to the EHR and must have Center, after which the user will be launched at least one patient in the able to create a Data Mart project REDCap window inside the EHR user and pull EHR data. (Note: This is not interface. a project-level user right but a REDCap user account privilege.) REDCap administrator and team can optionally create a User Access Web Also, there is no optional User Service to further control user access Access Web Service as there is with during adjudication (info documented on CDP to further control user access this page). 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 projectlevel 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.