

## Interested in partnering with REACHnet to conduct observational research?

Here is some helpful information to get started.

### Data Specifications

Electronic health record data from REACHnet's health system partners is standardized to the PCORnet Common Data Model. For data specifications please see: <https://pcornet.org/data-driven-common-model/>

### Before requesting data, an investigator should:

- Establish clear study aims and research questions that can be answered by the available data.
- Consider requesting a prep-to-research (PTR) query to help determine feasibility of your study. A PTR query provides the number of patients that meet your study's criteria. To request a query, submit a [Query Request Form](#) in [ECO](#).
- Have an identified source of funding or be actively seeking funding for the project.
- Consider how health system partners and patient stakeholders will be engaged in the project.
- Determine clear specifications for the study population, including inclusion and exclusion criteria, time period, and desired data elements along with the appropriate codes (see the [Data Request Form](#) for additional detail).
- Understand the IRB approval process at your institution and be ready to develop the IRB protocol for your study.

### Here is an overview of our process for a data request:

1. Download and complete a Data Request Form, available at [www.reachnet.org/forms](http://www.reachnet.org/forms).
2. Register in [ECO](#) and create a new project to submit your completed request form. A REACHnet representative will confirm receipt and respond with next steps within five business days.
3. If you have not already completed a prep-to-research (PTR) query, our analyst team will work with you to complete one. This will provide you with the count of patients that meet your study's criteria and help determine feasibility.
4. We will review your data request and reach out to you with any questions or clarifications.
5. Once your request form is finalized, we will engage REACHnet's partner health systems to request their participation in your project. If a partner health system agrees to contribute data, they may also identify a co-investigator to work with your study team throughout the project.
  - a. When a requestor is seeking research funding for a proposed study, we may postpone outreach to partner health systems for participation, at the REACHnet Coordinating Center's discretion. However, if the data request is deemed feasible for REACHnet to fulfill pending funding, we will provide a proposal outlining the anticipated scope of work and the fee for our services as well as a letter of support for the funding application, if requested.
6. Once collaborating health systems are identified, we will develop a proposal outlining the anticipated scope of work and the fee for our services. If you already have funding secured for your project, we will provide you with a service contract to be signed by your institution.
7. Once a service contract is in place, REACHnet personnel will work with your study team to meet the regulatory needs for your project. We will develop a Data Sharing and Use Agreement (DSUA) that outlines

the specifications of the dataset to be provided and the terms for data use. The DSUA will be signed by both LPHI (the REACHnet Coordinating Center) and your institution prior to data transfer.

8. We will obtain from you the IRB-approved protocol and IRB approval letter (or exemption) for your study. We will share these materials with the participating health systems so that co-investigators can seek approval (or exemption) through their institutions' IRBs. IRB requirements of the participating health systems must be fulfilled before data transfer.
9. Once all regulatory requirements are fulfilled, our analyst team will create the dataset for your project and coordinate with you for secure delivery. We will issue a Data Receipt Form that includes important guidance and contact information for the co-investigators from REACHnet partner health systems that contributed data for your project.
10. We highly recommend that you review REACHnet's [Dissemination Policy](#) when initiating a project with us. It is an expectation of REACHnet that co-investigators from our partner health systems will be engaged throughout the research process and offered the opportunity to co-author manuscripts and conference abstracts. We will connect you with collaborators at the beginning of the study, but the research team is expected to maintain regular contact with partners for the duration of the project. Further guidance is provided in the Data Receipt Form.
11. Once data are transferred, REACHnet will invoice your institution for payment.
12. REACHnet personnel will check in periodically throughout your project to assess timelines, address concerns, and monitor compliance with the DSUA and REACHnet policies. As you prepare to disseminate results, you should notify REACHnet in advance, as outlined in our Dissemination Policy.
13. It is the responsibility of the study PI to coordinate with co-investigators from the participating health systems to fulfill ongoing IRB requirements, such as continuing review. If IRB fees are incurred after the initial review and approval of the protocol (for which applicable fees are factored into the REACHnet services proposal), the study PI will be responsible for paying those renewal fees.

For additional detail about our process, please review the [Research Participation Policy](#) available on the Resources page.

### **Cost of REACHnet data services**

The fee for REACHnet's data services depends on several factors that vary from study to study, including but not limited to:

- Complexity of the dataset specifications and study population
- Number of REACHnet partner health systems that agree to participate
- Source of funding for the study
- Inclusion of linkage services to match patient records across health systems

Each service proposal is developed on a case by case basis following the process outlined in steps 1-6 above.

### **Changes to Existing Projects:**

The DSUA for your project defines the specifications of your dataset and the terms of use. If you want to make a change to your existing study, please contact REACHnet as soon as possible to discuss the proposed changes. You

should also engage the health system co-investigators to discuss any proposed changes prior to seeking approval through REACHnet. Several common changes are outlined below. Please note that many of the following changes will require an additional fee for services.

**Extension of Term:** extending the study timeline to complete analysis and dissemination activities

- Requires approval of the health systems that contributed data for the study, to be obtained by the REACHnet Coordinating Center
- May require amendment to the IRB protocol, to be handled by the study team and co-investigators from participating health systems
- Amendment to the DSUA to change the end date, to be signed by the study PI's institution and LPHI, the REACHnet Coordinating Center

**Addition of Data Elements:** no change to the research aims, but wish to obtain one or more additional data elements in order to complete the analysis

- Requires approval of the health systems that contributed data for the study, to be obtained by the REACHnet Coordinating Center
- Amendment to the DSUA to update the dataset specifications, to be signed by the study PI's institution and LPHI, the REACHnet Coordinating Center

**Data Refresh:** addition of more recent data with no change to the research aims or included data elements

- Requires approval of the health systems that contributed data for the study, to be obtained by the REACHnet Coordinating Center
- May require amendment to the IRB protocol, to be handled by the study team and co-investigators from participating health systems
- Amendment to the DSUA needed if the timeframe in the dataset specifications needs to be updated or the study end date needs to be extended

**Data Reuse:** use of an existing study dataset for new research questions; no additional data elements can be added, but may include a refresh of the existing dataset, if requested

- Requires approval of the health systems that contributed data for the study, to be obtained by the REACHnet Coordinating Center
- Requires amendment to the IRB protocol, to be handled by the study team and co-investigators from participating health systems
- Amendment to the DSUA to update the Analysis Plan, to be signed by the study PI's institution and LPHI, the REACHnet Coordinating Center

If you wish to add new data elements and new research questions, this requires a new data request and will be reviewed and considered as a new project.