



# RARE DISEASE REGISTRIES: ADVANCING DISEASE UNDERSTANDING, TREATMENTS, AND CURES

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## Introduction: Nothing is Impossible

The call for help came out of the blue in 2010 when one mother living in Texas suddenly telephoned another mother living in Northern Virginia. The two women were strangers, but shared a common bond. Both are the parents of children diagnosed with Phelan-McDermid syndrome, a rare, genetic disorder known to cause developmental delays, impaired speech, seizures, and intellectual disabilities.

Geraldine Bliss, a rare disease advocate with the **Phelan-McDermid Syndrome Foundation** (<http://22q13.org/j15/>) in Houston and mother to Charles, then 9, was on the hunt for someone to attend a Washington, D.C. conference—a boot camp of sorts—on how to create a rare disease registry. Megan O’Boyle, at the time a stressed-out working professional, mother to then 10-year-old Shannon, and one of the only candidates living near the nation’s capital, fit the bill.

“I did not want to do it,” said Megan. “I didn’t know much about the disease. I had no background in science, no background in medicine, and no background in research. I wasn’t even a volunteer with an advocacy group. But Geraldine convinced me, and I figured: how hard could it be?”

Megan, now the principal investigator for the Phelan McDermid Syndrome International Registry, is not one to mince words. She described some of the more difficult tasks required to establish a registry as “worse than childbirth.”

“The moral to the story?” she asked. “My naivety paid off. If I knew then what I know now, I would have said, ‘this is impossible.’ But I was driven as a parent who thinks nothing is impossible.”

This toolkit is designed to help rare disease patients, advocates and advocacy organizations understand and navigate the trials and tribulations of creating a rare disease registry. By all accounts it is a difficult, complicated, sometimes tedious, frequently time consuming, and often an expensive endeavor.

While establishing a registry is challenging, at the same time, medical researchers believe it is through the growing network of patients identified and tracked by disease registries that scientists may one day develop a drug or medical device to treat any one of the roughly 7,000 already identified rare diseases and disorders, a number that continues to grow.

# SECTION 1:

## UNDERSTANDING REGISTRIES



A rare disease patient registry is an online database set up to collect, store, retrieve, analyze, and disseminate information on individuals—both children and adults—diagnosed with a specific rare disease or genetic disorder. A rare disease is defined by the National Institutes of Health as one that affects fewer than 200,000 Americans.

The registry serves as an organized, interactive system, based on uniformly formatted information obtained directly from patients, families, a treating physician, or healthcare professional. Laboratory and/or genetic test results, and even the collection of biomaterials, are increasingly added to or accompany the individual patient file.

### Registries vs. Clinical Trials

One of the primary qualities of a registry, compared to a clinical trial, is that a clinical trial normally requires a specific hypothesis or intervention that is being tested, such as a drug or therapy.

By contrast, a registry is normally “observational” in nature, which means it collects data on a voluntary basis in the normal course of a physician’s or patient’s actual experience and does not set any particular obligation to participate, schedule, or undergo treatment.

### Registry Designs

There are many different types of registries, according to Catherine Olson, Director of CoRDS (<http://www.sanfordresearch.org>), or the Coordination of Rare

Diseases at Sanford, a not-for-profit research institution based in Sioux Falls, SD.

“Some registries track 50 people over a specific amount of time, and others track thousands of people for as long as they will let you,” she said. “There are registries involved with collecting samples for bio banks or tracking a drug treatment, and there are registries created to find donors that would agree to provide blood or other biomaterial.”

Government researchers report that less than one-fifth of the 7,000 known rare diseases have an established registry set up to follow the progression of a disease. Many rare registries are operated by patient advocacy organizations, often through a partner institution; by scientific researchers working in academia; or by a pharmaceutical or biotechnology company focused on drug development.

### Geographic Scope

Typically registries are country specific, but in rare disease the need for a global approach can be a key factor to avoid multiple registry efforts that split the efforts to collect meaningful data. Many successful rare international registries have been developed, particularly when a registry has yet to be initiated or when a treatment comes to market that focuses the community on a single registry. Increasingly, government health officials around the world are working to establish both uniform research tools and open, web-based software designed to build global disease registries.

## SECTION 2: THE PURPOSE OF A REGISTRY



Registries can be different things to different people and organizations. Families may see a registry as an educational tool to better understand symptoms making their child sick. Research institutes and universities may see registry data as a way to validate animal studies, or to establish once overlooked disease endpoints for further clinical research. Pharmaceutical or biotechnology companies might want to establish disease progression or burden, or supplement data of the necessarily small clinical trials. Regulators such as the FDA are now accepting registries as part of the marketing approval requirements.

“I think of a rare disease registry as a tool for research,” said Catherine with CoRDS, looking at the big picture of why registries matter. “Part of the reason for a rare disease registry in the early stage of research is proof of concept. An advocacy group is able to demonstrate to a clinical researcher that it has a legitimate population, and carefully collected data and consent from patients to review their data, among other benefits. The registry essentially provides evidentiary material and justification for a research study.”

### What Value Do You Seek from the Data?

On a day-to-day basis, the purpose of a registry is to follow the progress of participants over time, with an eye toward tracking and documenting the prevalence, progression, and trajectory of a disease.

Over several years, the data can paint a picture, a natural history, showing how a rare disease or disorder evolves as people age, thereby providing valuable information not only about the onset of a disease, but insight into how symptoms change as individuals age. Thinking upfront about what use, analyses, or value you hope to obtain from the registry is critical to designing the registry and planning its scope and goals over time.

For example:

- Patients may create insights they had not known were common;
- A registry might need to focus on natural history in its early stages that may help with pivotal clinical trials for a treatment; or
- A rare disease registry might create a long term history for every patient and become a valuable tool for disease management for both physicians and patients.
- The various goals and insights from a registry can vary across the multiple stakeholders, particularly patients, researchers, and biopharma companies.

## SECTION 2: THE PURPOSE OF A REGISTRY

### Patient Insights on Registries

Insights from registries may result in new approaches to research by uncovering common traits, behaviors, and symptoms that may guide researchers into areas that they had not previously considered. These insights may also change the standard of care for patients. For instance, if we know that many people with a certain rare disease are struggling with a previously unrecognized condition that can be presented to medical specialists and change the standard of care for that disease.

Families grappling with a rare disease understand that registries are a crucial step toward finding drug treatments and cures, adds Megan of the Phelan-McDermid Syndrome Data Network registry. They also know they may not live to reap the long-term benefit. That's why she likes to remind rare disease advocacy organizations, patients, and families that registries also serve a valuable purpose in the here and now.

It also enables families to be better advocates for a child or loved one. For instance, Megan notes that through Phelan-McDermid Syndrome Foundation's registry, families have learned that 40 percent of the kids have funky toenails. Eighty percent have a sensory disorder that prevents them from feeling pain. The information is not necessarily useful to researchers, but it is of great value to parents because they know they are not alone.

*"The registry provides us with vital ammunition in the ongoing battle with medical professionals unfamiliar with rare disorders, or with the 'powers that be' in the local school system where educators often refuse to provide one-on-one assistance," Megan said. "Suddenly you are not some crazy mom making outrageous demands for extra care or special education services or one-on-one supervisory assistance. Instead, you are a concerned parent communicating undeniable research findings."*

### Researcher Insights on Patient Registries

Researchers in a rare disease often are starting from a point of limited or no data collected, limited published literature on a disease, and a challenge of identifying patients for ongoing clinical trials.

As a result, researchers in both academia and industry have a mutual interest in seeing a rare disease registry created. Often researchers may start one locally within their own set of patients, and this may be as simple as starting a database file.

In comparison with the real life patient experience that patients find the most significant (e.g. Can a patient go to work? Walk? Perform daily activities?), clinical researchers that have successfully studied animal models want to begin to understand the disease progress from various perspectives including molecular, genetic, and clinical.

In the early stages of research, a disease registry can provide a vehicle to potentially assist with all of these questions. In planning a registry, it is important to consider the role of both patient reported experience and the complex clinical data required for research physicians and biostatisticians to study and publish on the clinical data as quickly as possible. Creating a registry that speeds this process is a critical foundation for establishing the baseline understandings needed for treatment development.

As research and treatment options progress, the registry can evolve to start evaluating treatment outcomes across a disease population.

## SECTION 2: THE PURPOSE OF A REGISTRY

### Industry Insights on Patient Registries

Many rare disease companies sponsor, operate, and publish analyses from registries. There are numerous examples where a company working to develop and approve a treatment will create and sponsor a registry for all the same reasons as academic researchers.

The key rationale from the industry and regulatory perspective is two-fold:

First, rarity necessitates unusually small numbers of patients in the Phase 2 and Phase 3 trials; and

Second, most promising rare disease treatments will file their regulatory applications for “accelerated approval” due to the urgent, life threatening impacts on patients.

This is considered a known risk-benefit in rare disease treatment development. As a result, a vital question will remain, even after a full Phase 1, 2, and 3 clinical program: “What will the impact of this treatment be on the rest of the community that was not part of the clinical trials?”

The answer to that is to study and monitor the entire disease community. Thus the disease registry used in the early days to help basic research and locate patients now evolves into a critical component of treatment approval for a sponsoring company.

This situation then leads to regulatory authorities requiring “Post Marketing Commitments” to be monitored and studied for long-range time periods (a decade or more in many cases), and companies agreeing to create, support, or extend a disease registry.

In this context, regulatory authorities recognize that registries are excellent vehicles for companies to study the long-term outcomes and safety of a product after the Phase 3 trial has been submitted and the product approved for commercial use.

# SECTION 3: DESIGNING A REGISTRY: NO NEED TO REINVENT THE WHEEL



Professional stakeholders in the rare disease community have developed something of a mantra when instructing advocacy organizations on how to build a registry: do not reinvent the wheel.

That means the first step is to perform due diligence when exploring whether to create a rare disease registry to determine what's out there.

There is no single place to find a comprehensive list of existing rare disease advocacy organizations or registries, although government officials recognize the need for a consolidated resource.

Still, due diligence has to start somewhere and the **National Organization for Rare Disorders (NORD)** is a good place to begin when exploring options in the United States. (<http://rarediseases.org/for-patients-and-families/information-resources/rare-disease-information/>).

It also is essential to look beyond U.S. borders because rare diseases have no boundaries and because rarity usually requires a global approach to establish a meaningful data set. To get started internationally, check a report released in January 2015 by the Internet-based reference portal Orphanet, operated by a 40-country consortium and sponsored by **The French National Institutes of Health and Medical Research**. (<http://www.orpha.net/orphacom/cahiers/docs/GB/Registries.pdf>)

Patient advocacy organizations can go at it alone or partner with a registry partner, typically non-profit organizations that serve as a registry incubator, often providing access to scientific advisory boards, vetted research protocols, and informed consent forms. Most importantly, vendors provide web-based technology platforms/portals, through which a rare disease advocacy organization can build its own branded registry. Specialized hosts save time and money, eliminating the high cost of building Internet infrastructure.

The main decisions a rare disease advocacy organization has to consider are whether they want a registry partner and which one to choose. Registry specialists suggest identifying the services offered by different providers to see which host is the best match to suit the organization's needs.

## SECTION 3: DESIGNING A REGISTRY: NO NEED TO REINVENT THE WHEEL

Hosted vendor registries can be for-profit or non-profit; focus on a single rare disease/disorder; or serve any and all diseases under one platform. Some registries, even if hosted, are owned by pharmaceutical or biotechnology companies. Others are run by rare disease advocacy organizations.

Following are some of the largest host platforms based in the United States working in rare disease registries. Each one has pros and cons, commonalities, or offerings that may include institutional review boards, vetted questionnaires, study protocols, technology oversight/system maintenance, and access to clinical trials.

“Most of the groups we talk to are patient advocates in the process of interviewing different hosts,” said Catherine, CoRDS. “They want to know what we have to offer, what we do not offer, whether there is a charge and how to apply. I believe this is a perfect and sensible approach. Patient groups need to make informed decisions. Shopping around makes sense. It is what any smart consumer does to get the right product or service.



## SECTION 4: DEVELOPING THE REGISTRY



Registry specialists agree that there is a progression and series of tasks to complete before launching a registry. Many decisions must be made well in advance of inviting registrants.

- **Identify Population and Registry Goals:** Rare disease advocacy organizations first need to identify the target population. Will the registry accept any patient with the disorder regardless of etiology, establish subgroups or impose geographic limits? Different goals may require different questionnaires or documentation. Thinking ahead avoids disqualification, for example, from drug research or funding.
- **Scientific Advisory Committees:** Expert oversight is desirable for registries, regardless of the purpose or sponsor. They provide strategic and research guidance as independent advisory and experts in a disease. Committee members should be representative of stakeholders or specialists such as epidemiologists, patient physicians, disease foundations, advocacy organization members, with one person responsible for decision-making.
- **Data Collection and Inquiry Tools:** Will data be collected only online or also through participant meetings? Will physicians have access for data entry? Will the registry accept biomaterial samples and/or genetic tests, and how will they be submitted? Specialists should supervise all decisions about data collection.

Chris Jones, a registry consultant in Boston, MA who spent 10 years at Genzyme and helped lead the redesign of their rare disease registries, said the most successful rare disease registries are those that are constantly aligning their goals with operations. This requires forethought to anticipate what stakeholders believe is critical and what they may need in the future.

“The most important thing is knowing what the research goals are. If there are holes in the data collected toward those goals, then researchers may not be able to analyze results. If the FDA does not view the collected information as quality data and the data fails to paint a picture but instead just looks like a random group of unrelated dots on a chart, it can render the data useless,” Chris said. “These kinds of information gaps are all a function of how the registry is set up and how case report forms or patient questionnaires are developed. That means patient advocates as registry sponsors need cover as many bases as possible from the beginning and try to roadmap how they see the registry evolving over years.”

## SECTION 4: DEVELOPING THE REGISTRY

### Documentation Required

It's been said that if it's worth doing, it's worth documenting. Registry specialists urge rare disease advocacy organizations to seek professional advice or collaboration on creating carefully worded documents, especially when it comes to questionnaires and consent forms.

There is a science to developing a questionnaire and a science to what kind of wording is most acceptable or best suited to get useful objective answers. The goal is to develop questions that result in answers that will help advance research. To ensure that, rare disease advocacy organizations should work with someone with the necessary experience and understanding to help them achieve that.

*"You will be working with clinicians who know and understand the disease but they typically know nothing about bioinformatics, collecting data, or how to ask the right questions so that the data is useful to researchers in the future," said Liz Horn, co-principal investigator with the Phelan-McDermid Syndrome (PMS) Data Network. "This is most often a question of design."*

As for consent forms, Liz believes it's important to cover every possible angle including whether the patient can be contacted again and whether they are interested in research opportunities. "Sometimes it's not possible to think of everything on the front end," she said. "Sometimes things change and you have to

go back and make adjustments to the consent form."

She notes this happened with the PMS registry because new opportunities emerged in 2014 that did not exist before, but there was no way the organizations could have foreseen asking a question to cover the unknown.

Here are some documents that registries must have on file:

### Statement of Protocol

The Protocol Statement is a description of all the steps taken to establish the registry, from due diligence to ultimate goal. It includes an explanation of defined participants, the topic of study, and why a study is needed. The protocol also typically discusses whether the registry has an advisory board, institutional review board, established consent forms, and details on data submission and method of analysis. It clarifies whether physicians and clinical researchers have access to data, along with policy statements regarding confidentiality, withdrawal from the registry, funding sources, and clarification of who owns the data, to name a few elements. Think of it as the table of contents with a chapter-by-chapter summary of how the patient advocacy organization got from A to Z.

### Consent Forms

A written, voluntarily signed agreement stating that an individual understands and agrees to participate in all aspects of a registry along with subsequent research or use of data. Informed consent is a federally regulated, legal requirement for clinical trials, or studies involving human subjects. See the **Informed Consent Toolkit** for more information (<https://globalgenes.org/toolkits/informedconsent/introduction/>).

## SECTION 4: DEVELOPING THE REGISTRY

### Assent Forms

Similar to consent forms, the document pertains to people who are too young or too impaired to provide knowing consent. It typically requires oversight/signature from a parent or guardian.

### Participant Survey/Questionnaire

These data-gathering tools must include specific elements to address patient history, patient conditions, family history, symptoms, setbacks, medications, as well as questions designed to track the progression of the disease/disorder.

Additionally, the questionnaires must be designed to protect privacy (de-identification) while making sure a participant's identity can be tracked across studies without duplication. Questionnaire design must consider the following:

- **Common Data Elements:** The National Institutes of Health, National Center for Advancing Translational Science defines common data elements as a set of common question that can be used across diseases or registries. They are important because they facilitate consistency in data capture.
- **Global Unique Identifiers:** The National Institutes of Health and academic researchers established the Global Unique Identifiers system in 2010. It enables researchers to assign a unique identifier to study participants, not only to track a participant's enrollment in different studies but also to prevent data duplication that would invalidate or skew study results.

### Participant Communications/Reports

Documents in this category include letters, emails, telephone transcripts, doctor's notes, or comments and copies of medical assessments, laboratory reports/results or other written communications pertaining to the patient's condition.

### Proof of Oversight/Funding

Written evidence documenting the nature of both an advisory board and Institutional Review Board, with biographies of members. Additionally, the documentation should include a list of all funding sources, regularly updated to keep the list of financing current.

### Governing Registry Activities

Patient registries typically are governed by Scientific Advisory Boards comprising recognized experts or leaders in the field of any given rare disease. The board provides objective, outside advice and oversight of registry activities ranging from constructive criticism, input on scientific procedures, or trouble-shooting when complicated issues and problems arise. The scientific advisory board (SAB) may also serve to elevate the status or visibility of a registry.

Scientific advisory board members may come from academia, the non-profit sector, hospital treatment facilities, clinical research institutions, families living with the disease, or from pharmaceutical and biotechnology companies developing drugs and treatments. The SAB is represented by a principal investigator tasked with making final decisions and serving as the voice of the registry. Most principal investigators are physicians or clinical researchers, but self-taught disease experts from a rare disease advocacy organization are equally acceptable.

## SECTION 4: DEVELOPING THE REGISTRY

Scientific advisory board member input may stem from informal contact, casual inquiries or off-the-cuff discussions, but regular board meetings with a formal agenda and recorded minutes are expected. Registry experts suggest keeping the scientific advisory board to a core group of five-to-seven members serving for a one- to two-year term of service.

Rare disease advocacy organizations that partner with host vendors have the benefit of an existing scientific advisory board already assembled by the established sponsor. But it is acceptable to create an independent registry governed by a newly established scientific advisory board.

### Approval and Review of Registry Documents and Research

Rare disease advocacy organizations are sometimes told there is no need for an institutional review board. This is not advisable and not always true. The simple collection of data on a rare disease may not require an institutional review board, but federal law requires institutional review board review and oversight of all biomedical research involving human subjects to “assure the protection of the rights and welfare of human subjects.”

Therefore, if an organization hopes that the registry data may one day contribute to research studies, or even qualify for government funding to support research involving human subjects, the institutional review board is essential. The laws pertain to human subject research to study investigational drugs/devices/procedures, off-label use of an FDA approved drug, research data intended for publication and case reports on biomaterials.

Most registry partner organizations already have an institutional review board in place. By law, the institutional review board must conduct regular and continuing reviews of research involving human subjects “at intervals appropriate to the degree of risk, but not less than once per year.” Institutional review boards are especially interested in the process of informed consent and the wording of written consent forms.

Institutional review board activities are outlined under various federal regulations including laws that fall under the jurisdiction of the National Institutes of Health, the Food and Drug Administration and the federal Health Insurance Portability and Accountability Act. **A free guidebook** published by the U.S. Department of Health and Human Services, Office for Human Research Protection, outlines regulatory policies, the institutional review board mission and other guidance ([http://www.hhs.gov/ohrp/archive/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm)).



## SECTION 5: ENSURING A SUCCESSFUL REGISTRY LAUNCH AND SUSTAINABILITY

Communicating regularly with patient advocacy organization members and families is vital to the success of a patient registry. Staying in touch with group members and keeping them informed in the age of the Internet eases the burden. Social media websites like Facebook, Twitter, LinkedIn, and others, along with establishing a user friendly website for the advocacy organization, are good tools. Newsletters via email or regular mail, along with social gatherings, also serve to strengthen communication.

Registry experts also suggest partnering with other groups to share information as well as attending conferences and meetings that target the rare disease community.

Consider The Rare Epilepsy Network, a collaboration among the Epilepsy Foundation and multiple organizations with research interest in rare epilepsies. The collaboration is funded through an award from the Patient-Centered Outcomes Research Institute. The goal of the Rare Epilepsy Network is to build a patient/caregiver-centered database designed to increase research opportunities for patients and caregivers. It provides patients affected by a rare epilepsy and their families the opportunity to participate in studies that may facilitate observational studies, clinical trials, and comparative effectiveness research. The network will establish a registry of these patients, which includes patient- or caregiver-reported data that address patient information, medical history, diagnosis, and treatment. This research will be in the form of natural history studies and completion of surveys. The registry will also create the infrastructure for future research, such as clinical trials. All of the research will be patient-centered, which means it will address research questions and topics that are important to the patients and caregivers with the ultimate goal of having patients and caregivers better able to participate in healthcare decisions.

## SECTION 6: CONCLUSION



Rare disease registries can play a vital role in providing researchers new insights into rare diseases that can help lead to earlier diagnosis, improved care, and new therapies. But building a rare disease registry represents a commitment not only of time and effort, but of money.

The cost of a rare disease registry will vary depending on several factors. Experts say it can carry significant costs, or very little, depending on whether an organization decides to rely on its own technology and people to manage and update the data, perform outreach, and ensure participants update and answer questions, or rely on another organization to handle these functions.

Organizations have options to outsource any and all functions of a registry, to partner with other organizations to share costs, or rely on existing registries that may be available at no cost. The answer may ultimately depend on the resources an organization can bring to bear and what they are hoping to accomplish.

Beyond the question of affordability, organizations will also need to consider questions of control. While it may be a financially attractive alternative to work with an existing registry where a drug company or well-financed organization provides oversight and financial support, it will be important to determine whether access to the data is restricted by the registry creator and whether providers of data will have access to it and under what conditions.

“One big question is, ‘Who owns the data and who has access to the data? Drug companies can give you money to create a disease registry, but it’s important to understand whether patients have access,’” said Phelan-McDermid Syndrome Data Network’s Liz Horn. “Drug companies can be very helpful partners. The downside is if a drug company decides to kill a project, or if a project for some reason is stopped, you are left hanging and the data is lost. If you want access, make sure the platform or institution you choose gives you access.”

Critical to determining the correct path for any organization is to understand what the organization hopes to do with the data. In reality, not every group should have a standalone registry. Small organizations with limited budgets and no relationships with clinicians simply may not be ready to build a registry.

Before moving forward, find similar groups that have gone through the process of building a registry and talk to them. Find out what worked and what didn’t in their effort to build a registry. Find out what they would do differently knowing what they know now.

“Most groups aren’t ready to jump right in. It’s hard to tell people who want to run that they have to walk first,” said Liz. “It’s especially hard because they have a sick child or family member, and they are desperate to find help.”

# RESOURCE GUIDE



**The Rare Diseases Clinical Research Network** is designed to advance medical research on rare diseases by providing support for clinical studies and facilitating collaboration, study enrollment and data sharing. Through the RDCRN consortia, physician scientists and their multidisciplinary teams work together with patient advocacy groups to study more than 200 rare diseases at sites across the nation. <https://www.rarediseasesnetwork.org>

### **Global Genes Understanding Rare Disease Registries Webinar Series**

Global Genes presented a two-part webinar series entitled “Understanding Rare Disease Registries,” which covered the topics that every organization involved in planning a registry should consider. <https://globalgenes.org>

### **Orphanet: Rare Disease Registries in Europe**

<http://www.orpha.net/orphacom/cahiers/docs/GB/Registries.pdf>

### **Eurodis Policy Fact Sheet on Patient Registries**

[http://www.eurordis.org/sites/default/files/publications/Factsheet\\_registries.pdf](http://www.eurordis.org/sites/default/files/publications/Factsheet_registries.pdf)

### **PCORnet**

The National Patient-Centered Clinical Research Network is an initiative of the **Patient-Centered Outcomes Research Institute (PCORI)**. PCORnet aims to transform clinical research by engaging patients, care providers and health systems in collaborative partnerships that leverage health data to advance medical knowledge and improve health care.

<http://www.pcornet.org/>

#### **Non-Profit**

- CoRDS Sanford Research – Sioux Falls, SD
- Genetic Alliance Reg4All – Washington, D.C.
- NORD/DRDR/ORDR National Organization for Rare Disorders – Washington, D.C.

#### **Academic**

- RDCRN Rare Disease Clinical Research Network and the NCATS National Center for Advancing Translational Sciences – Washington, D.C.

#### **Commercial**

- Patient Crossroads CONNECT – San Mateo, CA
- Digital Infuzion – Washington, D.C.
- Quintiles Outcomes – Cambridge, MA

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