Patient Foundations Guide to Starting a Registry

Know the Purpose of Your Registry

Not all patient registries are the same. Know why you are creating the registry – is it to capture the natural history of the disease, quality of life of patients or caregiver burden, recruit patients for clinical trials, or gather contact information. Assess whether the registry you have in mind is within the scope of what your organization can create. Avoid saying things such as the registry is "to find a cure" as it can introduce false hope.

Involve a Data Advisor from the Start

A data advisor is someone with a technical expertise in clinical data analysis. An appropriate and qualified advisor would provide guidance on selecting patient registry platform, reviewing data dictionary, designing surveys, checking data for completeness and consistency, and analyzing data. Potential educational background to look for: computer science, statistical programming, epidemiology.

Is a Data Dictionary Available?

A data dictionary is a description of the format of the data. It assures the format is one that your foundation can work with. Even if your organization will not do data analysis internally, it is important to understand the data and be able to find information that may be of interest to your community.

Can Raw Data be Exported?

In some cases data is only available within a registry platform without the ability to export it. In this case it is important to understand what virtual environment and tools are available and whether your team has expertise to work within that environment - it is critical to check raw data to make sure it is complete, accurate, and consistent prior to doing analysis.

What Type of Data Do You Plan to Collect?

Know the pros and cons of collecting different data types such as patient-reported data or medical records. If you plan to ask patients to upload medical records, share the purpose of that and know what happens to those records once they're uploaded. Use of validated questionnaires is optimal, however questionnaire should be validated for the specific disease you're collecting data for.

How Do You Plan to Analyze the Data?

Many patient organizations collect data with the hope that it will later be used by researchers, industry, or even regulatory bodies. Unfortunately, this may take a long time or not happen at all, which can be a great disappointment both for the organization and the patients. The most optimal plan is to collect data that your organization can use to raise awareness, share insights, and enable recruitment for clinical trials without depending on external stakeholders.

Governance and Oversight

As with any other project, patient registry requires an appropriate governance framework. Governance may include: scientific and medical advisors, legal guidance, ethics oversight, and patient voice. It is important the governance is shared and well known to the registry participants.

IRB

The Institutional Review Board is an organization that oversees the protection of "human subjects" in research. The IRB needs to be consulted when you are planning a registry; it oversees how you consent participants to the registry and all ethical considerations related to communication and data sharing.

Data Privacy

It's important to understand which privacy laws apply for the registry in the local state, federal (USA) or globally, such as the GDPR and the California Consumer Privacy Act. For example, while HIPAA protects data collected by "covered entities," it does not protect data collected by other entities. Understanding these distinctions is important for being transparent with registry participants.

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