Clinical data and its analysis are critical to clinical research. Ensuring the overall quality of clinical data is then paramount to ensuring quality care and appropriate decision-making in the medical and healthcare fields.

What constitutes clinical data, what should you look for in that data, and what resources are there to manage data and data analysis and ensure their quality?

Let’s take a look.

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**What is Clinical Data?**

Clinical data is information gathered for the broad purpose of clinical research on the micro-level (patient care) to the macro-level (broad applications within a health system). Clinical data can be collected in a number of different ways:

- **Electronic Health Records:** These records, typically only available within a hospital system, are essentially a patient’s digital history. They include everything from the patient’s last round of diagnostics to any medications they are taking and everything in between.
- **Patient/Disease Registries:** These registries follow specific patient populations based on certain diseases and conditions. Information related to these populations is gathered to then inform further research, and ideally, improve patient outcomes. The National Program of Cancer Registries, for example, gathers data from local entities to allow for a more unified response to cancer research.
- **Clinical Trial Data:** This is data gathered as part of a clinical trial, which is research around new drug applications, treatment methods, device testing, and other applications where data gathering is necessary to determine patient outcomes.

Clinical data has broad applications in the healthcare industry. It’s important to know
What to Look for in Clinical Data

Objectives

Before collecting and reviewing clinical data it is critically important to understand the goal or objective of the data. It must be understood what the data is trying to show and what question the data is trying to answer.

Bias

Once the objective of the data is understood, clinical data must be reviewed for potential biases. Objective evidence is an absolute must in making major decisions pertaining to public health and safety. Biases can come in many forms, and a successful clinical trial is designed in such a way to minimize all potential biases.

A common technique to obtain unbiased data is to blind the study participants as well as the researchers conducting the study. This ensures all data points recorded are objective and no participants or researchers are trying to push any of their own objectives into the data.

Another common technique to obtain unbiased data is to randomize the study participants to receive either the investigational product or to receive the comparator product. This ensures the researchers do not purposely give the investigational product to the healthier subjects with a higher probability of seeing treatment success.

Structure

Data structures are critically important for FDA submissions. Most submissions to the FDA (including NDAs and BLAs) require specific structures of data known as CDISC datasets. CDISC datasets are required for submission to the agency as they allow for a common structure of data across all clinical trials run and across all sponsors conducting clinical trials.

Data Trends

Data trends should be reviewed to ensure the data being collected in the clinical trial are
meaningful and represent real-life expectations. As an example of data trends, a single site within a clinical trial may be responsible for over 75% of all adverse events recorded in the study, despite only enrolling 10% of all study subjects. Noticing a data trend such as this can lead the clinical study teams to review this specific site’s procedures and ensure the study is being conducted correctly.

How Clinical Data Sciences Can Help

Clinical data sciences supports the collection, management, and analysis of clinical data.

What is Clinical Data Science?

Clinical data science links the methods and insights of data science with clinical data. Clinical data scientists then work within clinical trials to ensure sound data management and analysis.

Clinical Data Science is made up of the three following functions:

Biostatistics

The Biostatistician is responsible for the analysis of the clinical trial data. At the end of the day, the FDA speaks the language of statistics and clinical trial results must be conveyed in the form of confidence intervals and p-values. It is the responsibility of the biostatistician to determine which analysis should be conducted, the number of subjects needed to be enrolled to conduct statistically meaningful analyses and how these analysis results should be conveyed to the FDA to meet all regulatory requirements.

Clinical Programming

A clinical programmer on a data science team is responsible for building the programs that will create datasets for further analysis and finding pathways for transferring that data based on the client’s needs. As discussed above, for many applications submitted to the FDA, a special structure of dataset known as CDISC is required. The clinical programming team is responsible for creating these specific data structures to the agency.

Clinical Data Management

The clinical data manager is responsible for the capture and cleaning of the clinical data.
The data manager communicates with both the statisticians and the programming team to ensure the data needed for CDISC datasets and for final analysis is collected in a meaningful and unbiased way.

**How Clinical Data Science Can Benefit Your Project**

ProPharma Group has extensive clinical data experience, including a recent clinical data management project around creating an Electronic Data Capture System (EDC) to capture data, creating CDISC datasets and conducting the final statistical analysis for FDA submission for a midsized pharmaceutical client.

Our data science teams work to support clients with everything from where to begin in their clinical data analysis, to identifying pathways to solutions-based outcomes, to analyzing data with efficacy and efficiency.

[Contact ProPharma Group](#) to see how we can support you with your next clinical management project.