Sharing Clinical Trial Data

MAXIMIZING BENEFITS, MINIMIZING RISK

Recommendation at a Glance: When to Share Data

Rationale for Responsible Sharing of Clinical Trial Data

Clinical trials play a crucial role in advancing medical innovation and represent a significant investment from all involved — including trial participants, sponsors, and researchers. Data are generated throughout the clinical trial lifecycle, but results are often not published in a timely manner, and many data are not shared beyond the original investigators.

Data sharing could advance scientific discovery and improve clinical care by maximizing knowledge gained from data collected in trials, stimulating new ideas for research, and avoiding unnecessarily duplicative trials; however, to reduce potential harms, policies are needed to protect the privacy and consent of participants, the validity of analyses, the investment of funders and sponsors, and the academic recognition of investigators.

To answer this need, an Institute of Medicine consensus study recommends guiding principles and a practical framework to enhance clinical trial data sharing, the practice of making data from scientific research available—with or without restrictions—for secondary uses, which include re-analyses, new analyses and meta-analyses. This brochure focuses exclusively on the committee’s recommendation for when to share specific types of data.

There are three types of data that should be shared:

**SUMMARY DATA**

Data commonly generated based on analysis of the individual participant data from a clinical trial (e.g., summary-level results posted on registries, lay summaries, publications, and clinical study reports (CSRs) used for regulatory application)

**INDIVIDUAL PARTICIPANT DATA (IPD)**

Data that are collected from participants (e.g., the raw data) and then cleaned, abstracted, coded, and transcribed to become the analyzable data

**METADATA**

“Data about the data” (e.g., protocol, statistical analysis plan (SAP), and analytic code)
What data should be shared and when during the clinical trial lifecycle in order to help amplify scientific knowledge worldwide while minimizing risk?

The following chart outlines the major stages of the clinical trial lifecycle and recommends when to share specific data packages in common scenarios.

**REGISTRATION ELEMENTS**
Includes the 20 elements identified by the World Health Organization’s (WHO) International Clinical Trials Registry Platform along with narrative summaries of the trial protocol.

**DATA SHARING PLAN**
Describes what specific types of data will be shared at various time points and how to seek access to the data.

**SUMMARY-LEVEL RESULTS**
A summary of clinical trial results (e.g., no individual participant data).

**LAY SUMMARIES**
A brief, non-technical overview written for trial participants and the general public.

**POST-REGULATORY DATA PACKAGE**
The full data package plus the redacted CSR.

**FULL DATA PACKAGE**
The full analyzable data set, the full protocol, the full SAP, and the analytic code.

**POST-PUBLICATION DATA PACKAGE**
A subset of the full data package supporting the findings, tables, and figures in the publication, including the full protocol, full SAP, and analytic code.

**KEY:**
- METADATA
- INDIVIDUAL PARTICIPANT DATA
- SUMMARY DATA

* No later than 6 months after publication applies to all studies, whether intended or not intended to support regulatory applications and regardless of the timing of publication relative to study completion, although publication is most likely to occur after study completion.

** Sharing of the post-regulatory data package should occur: 30 days after approval or 18 months after study completion, whichever is later; 18 months after abandonment of the product or indication. This applies to all studies intended and to support regulatory applications, even if abandonment occurs prior to actual regulatory application.

Download the full report at www.iom.edu/datasharing.