INSTRUCTIONS

PRINT

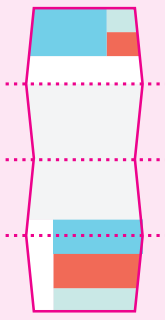
Insert 11″x17″ paper and print these two pages double-sided.

CUT

Once printed, cut carefully along the solid magenta line.

FOLD

Fold the document “accordion style” as shown below:



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)

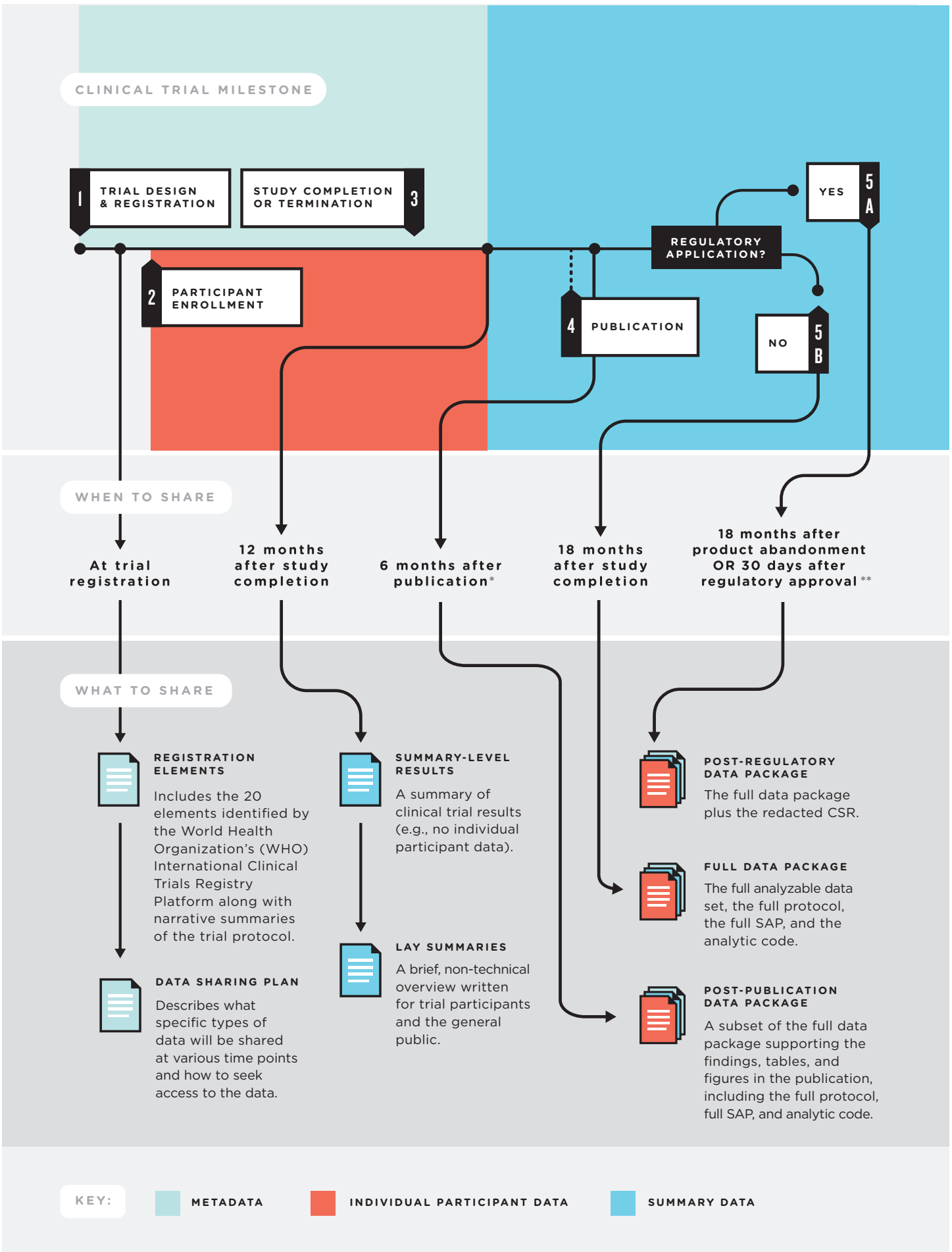
Data that are collected from participants (e.g., the raw data) and then cleaned, abstracted, coded, and transcribed to become the analyzable data

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.



* No later than 6 months after publication applies to all studies, whether intended and 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.*

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