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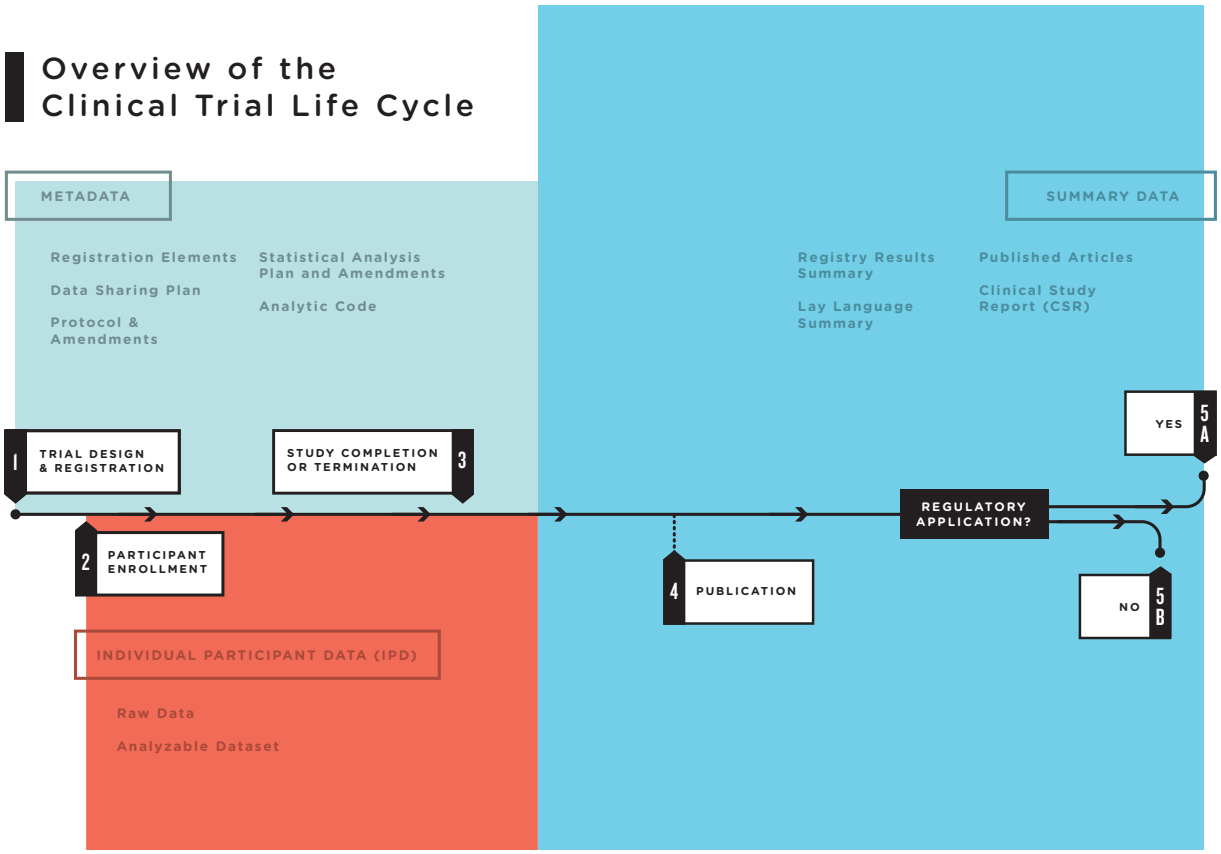
Sharing Clinical Trial Data

Maximizing Benefits, Minimizing Risk

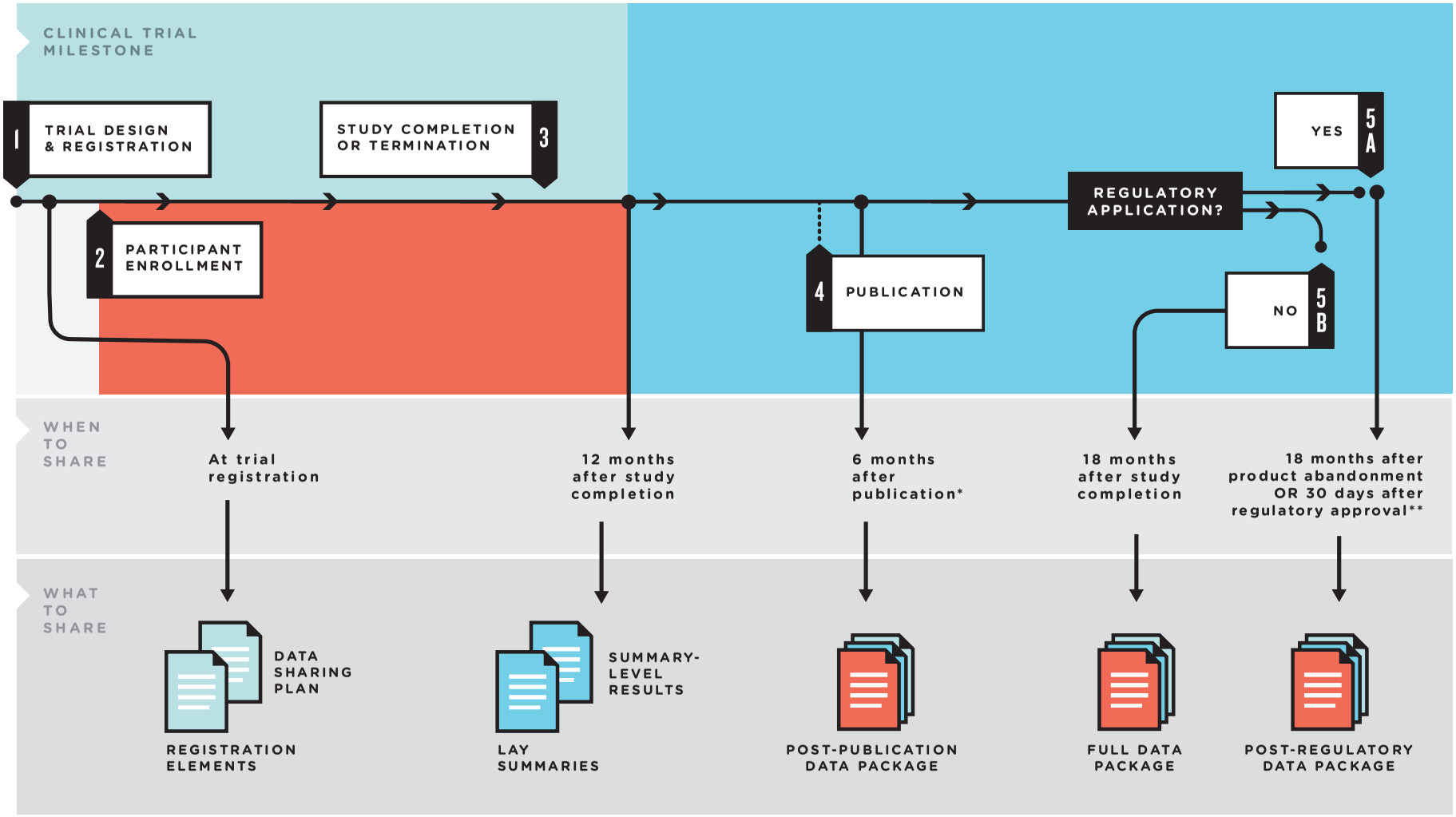
Key Figures

Data sharing could advance scientific discovery and improve clinical care by maximizing the knowledge gained from data collected in trials, stimulating new ideas for research, and avoiding unnecessarily duplicative trials. But data sharing also entails significant risks, burdens, and challenges. In *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*, an expert committee provides guiding principles and a practical framework for the responsible sharing of clinical trial data, including what types of data are available at different stages of a trial and the optimal times to share them. Key figures from the report appear below.

Overview of the Clinical Trial Life Cycle



Clinical Trial Life Cycle: When To Share Data



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 publication timing relative to study completion, though publication is most likely to occur after study completion.

** **Sharing 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.