

Integrating and Converting Data Across Studies – Clinical Trial Integrated Databases (IDBs)

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ABSTRACT

From the 2012 FDA/PhUSE Computational Science Symposium Working Group 3 Vision Statement: “Data integration has always been a challenge both for industry and the agency.” One approach to address the challenges of integrating and converting data across studies is to build a clinical trial integrated database (IDB). The poster demonstrates how IDBs can provide cost and time savings in supporting many objectives including regulatory submissions, answering customer questions and data mining. Data principles, conversion of legacy data, harnessing the power of CDISC standards and a process to implement and deliver IDBs are discussed.

BACKGROUND

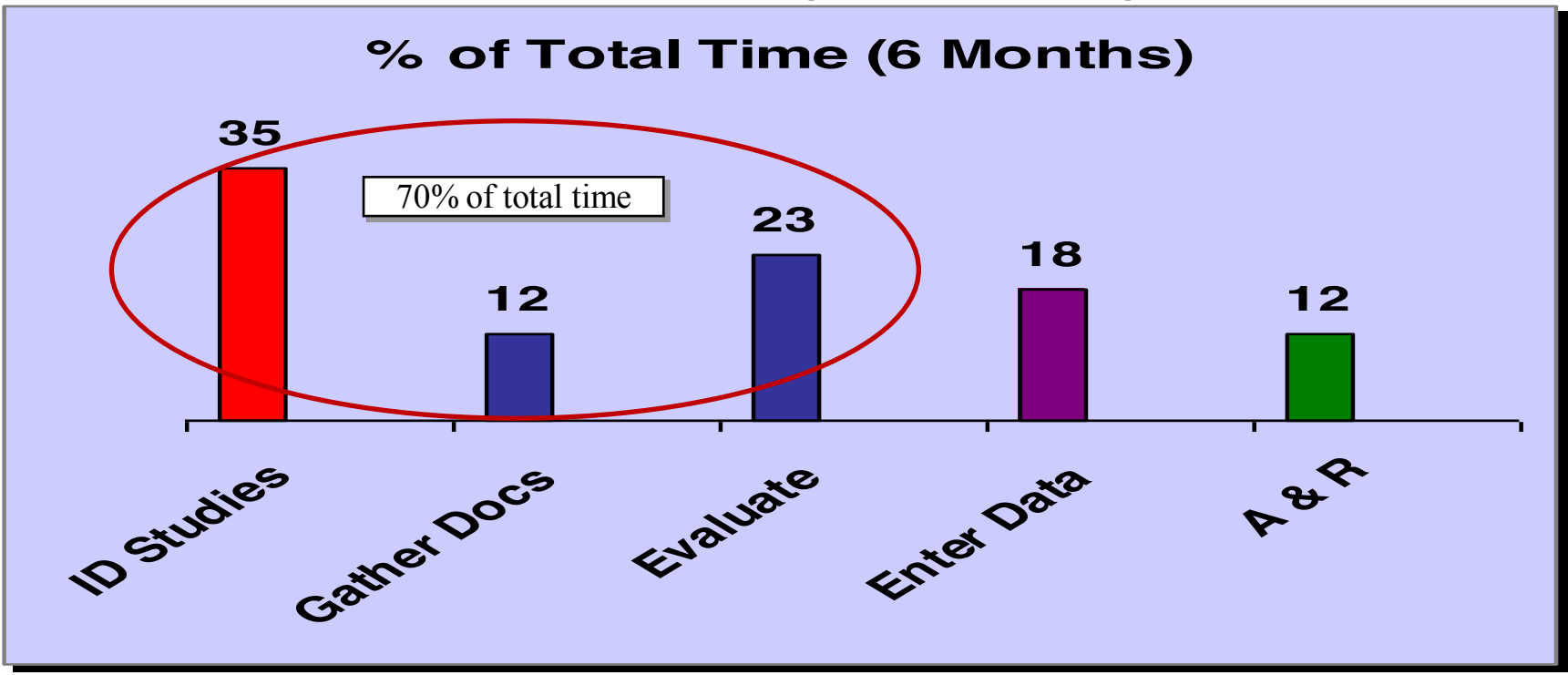
What are IDBs?

IDBs pool together, in a consistent format, all clinical trial patient data (typically Phase II - IV, non-observational trials) for a compound into one database. IDBs support many objectives including regulatory submissions, answering customer questions and data mining.

Why are IDBs so important?

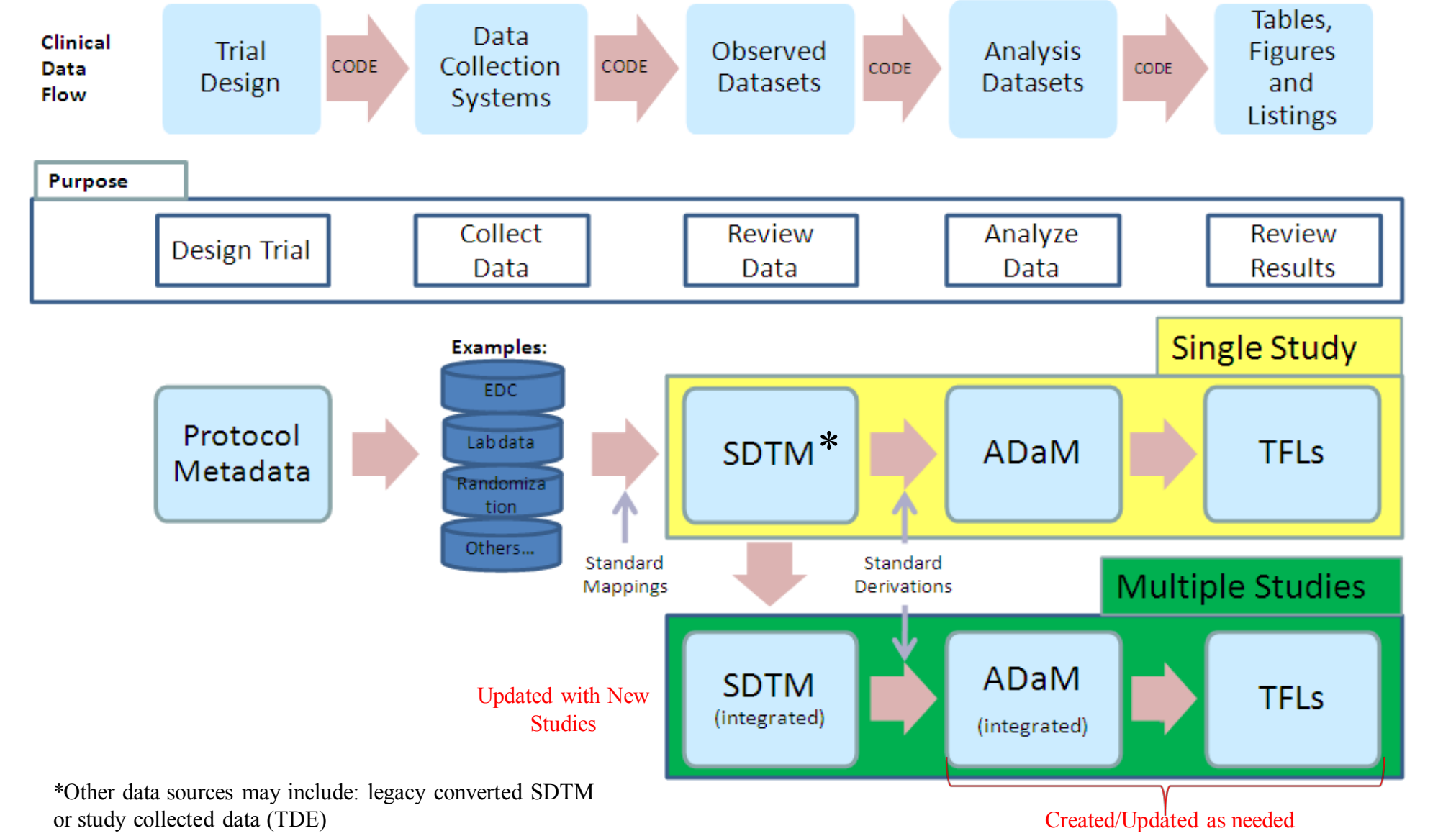
When compound IDBs do not exist, answering questions can be timely and costly.

- Example #1 from company ABC - no compound IDB
 - A regulatory agency question with a 30 day deadline
 - No IDB exists and only 70% studies in the electronic data repository
 - Regulatory agency asked for data from the remaining studies
 - Team created hand generated tables for the remaining studies and was given 30 more days to finish
- Example #2 from company XYZ - no compound IDB
 - Customer question - Response cost millions of dollars and took 6 months
 - 70% of total time spent finding & preparing data



- Example #3 from company PharmaX - compound IDB exists
 - A regulatory agency request - search compound trials for specific terms, per regulatory agency specifications
 - Utilizing the compound IDB, completed the search and validated the results in the required time.

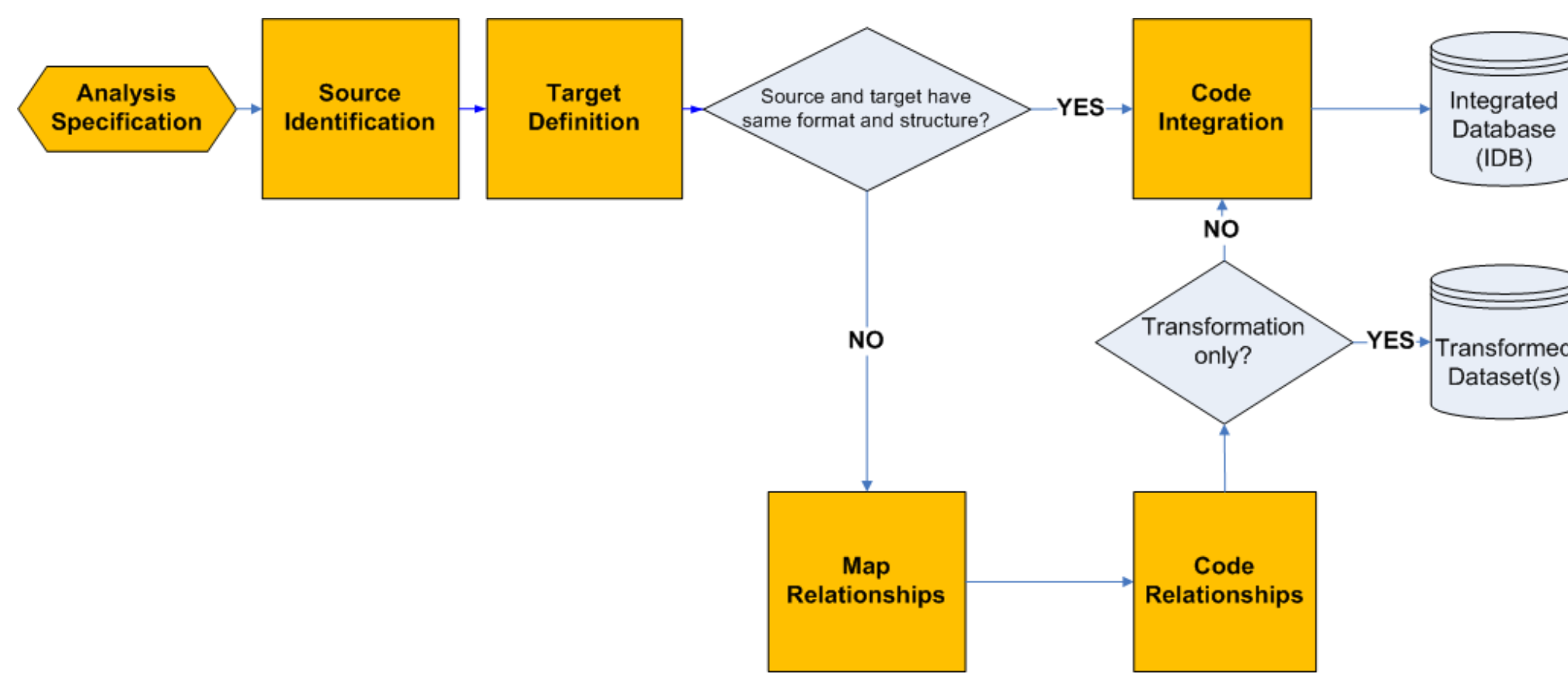
Clinical Data Flow



IDB Strategy - format change

- Clinical data flow will change to deliver industry formatted datasets in flow and will take advantage of metadata to automate data transformations.
- The current clinical data integration (IDB) process will take advantage of the available metadata and align with the new data flow.
- IDB format will align with strategy for Trial Level Data:
 - Observed data in SDTM format
 - Reporting and Analysis data in ADaM format
- Most current IDBs are in company proprietary format. Each compound team will follow and complete a transition plan discussion that will determine IDB format. The transition plan should take into account many factors, including where the compound is in its life cycle.

IDB Creation Process



Data Integration Principles to Consider

- Principle 1: Integrated Databases (IDBs) should include all data points (safety, efficacy, and study metadata) for patients, (excluding observational studies), across all indications for the compound.
- Principle 2: Data could be integrated for a compound when two or more studies have been locked.
- Principle 3: IDBs should remain current throughout the lifecycle of the compound.

IDBs and Submissions – Best Practices

- Create and maintain the compound’s IDB per clinical development plan.
- Comply with the Data Integration Principles and build your IDB as early as possible. Do not procrastinate!
- One source for all integrated analyses.
- IDB as source for compound level safety reviews prior to first submission. Gain experience prior to first submission!

CONCLUSION

Goal – Compounds have an IDB that aligns with the data integration principles per their compound transition plan.

By following data integration principles, compounds are positioned to answer regulatory and customer questions in a timely and cost effective manner.