U.S. FOOD & DRUG ADMINISTRATION

STUDY DATA STANDARDS: WHAT YOU NEED TO KNOW

Study Data Standards

Study data standards describe a standard way to exchange clinical and nonclinical research data between computer systems. These standards provide a consistent general framework for organizing study data, including templates for datasets, standard names for variables, and standard ways of doing calculations with common variables.

Having standard, uniform study data enables FDA scientists to explore many new research questions by combining data from multiple studies. Data standards also help FDA receive, process, review, and archive submissions more efficiently and effectively.

Study data standards are required for most study data submitted to FDA's Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER). FDA may refuse to file (for NDAs and BLAs) or refuse to receive (for ANDAs) an electronic submission that does not have study data in conformance with the required standards specified in the FDA Data Standards Catalog.

Study data is information about a person in a clinical trial. It includes demographic information, details of medical treatment, descriptions of the participant's progress, and other relevant information. In early studies, this same information is captured for animals and is referred to as nonclinical data.

Study data standards apply to the following types of submissions to CBER and CDER:

- Commercial Investigational New Drug (IND) applications (for products that are intended to be distributed commercially)
- New Drug Applications (NDAs)
- Abbreviated New Drug Applications (ANDAs)
- Biologics License Applications (BLAs)
- All subsequent submissions to these types of applications, including amendments, supplements, and reports, even if the original submission was filed before the requirements went into effect

For exemptions, please see *Providing Regulatory Submissions in Electronic Format—Standardized Study Data: Guidance for Industry* at www.fda.gov/eStudyResources.

Deadlines

- Sponsors whose studies started after **Dec. 17, 2016,** must submit data in the data formats supported by FDA and listed in the FDA Data Standards Catalog. This applies to NDAs, BLAs, ANDAs, and subsequent submissions to these types of applications.
- For INDs, the requirement starts after **Dec. 17, 2017.**

Additional information

- FDA will periodically publish its intent to begin supporting new standards and new versions of current standards. FDA will give at least a year's notice before the new version is required. For entirely new standards, the notice will be at least two years in advance.
- For the definition of study start date, see FDA's guidance on study data standards at www.fda.gov/eStudyResources.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES/U.S. FOOD & DRUG ADMINISTRATION
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These study data standards were developed as part of a collaboration between FDA, the nonprofit Clinical Data Interchange Standards Consortium (CDISC), and other stakeholders.

Current study data standards

- CDISC Standard for Exchange of Nonclinical Data (SEND) for nonclinical data
- CDISC Study Data Tabulation Model (SDTM) for clinical data
- CDISC Analysis Data Model (ADaM) for analysis of clinical data
- CDISC Case Report Tabulation Data Definition Specification (Define-XML) for the metadata that accompany SEND, SDTM, and ADaM datasets

FDA is supporting efforts to develop clinical terminology standards for particular therapeutic areas within SDTM. SDTM will be updated periodically to include new and revised standards for specific therapeutic area extensions.

For the updated list of data standards supported at FDA, including all deadlines, see the FDA Data Standards Catalog.

Main resources and FDA guidance documents

For the most recent versions of FDA's study data guidance and technical specifications, check FDA's Study Data Standards Resources page at www.fda.gov/eStudyResources. This page includes:

- FDA's December 2014 guidance on study data standards, *Providing Regulatory Submissions in Electronic Format—Standardized Study Data: Guidance for Industry*
- Relevant technical specifications:
  - FDA Data Standards Catalog
  - Study Data Technical Conformance Guide
  - FDA-Specific Study Data Business Rules

For additional questions, please contact **cber.cdisc@fda.hhs.gov** (CBER) or **cder-edata@fda.hhs.gov** (CDER).