Providing Regulatory Submissions In Electronic Format — Standardized Study Data

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Oncology Center of Excellence (OCE)

June 2021
Electronic Submissions

Revision 2

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Technical specifications associated with this guidance are provided as separate, stand-alone documents and are updated periodically. These are:

- **Data Standards Catalog**
- **Study Data Technical Conformance Guide**
- **FDA Specific SEND Validation Rules**
- **FDA Specific SDTM Validation Rules**

To make sure you have the most recent versions, please check:

https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources

REVISION HISTORY

DATE	SUMMARY OF REVISIONS
October 2020	**Updates to Guidance** Section II.B. What types of submissions are exempted from the electronic submission requirements for standardized study data? • Updated the term "noncommercial products" to "noncommercial IND" to clarify the products that are exempt from requirements under this guidance. Section II.E. When will electronic submission of standardized study data be required? • Updated to clarify the information FDA relies on for assessing compliance with study data requirements • Updated example of timetable to reflect actual timetable for the implementation of the electronic submissions requirement and otherwise clarify the date of the initial requirements
May 2021	Section II.A. For what submission types is an electronic submission of standardized study data required? • Updated to clarify where stakeholders can find more information about when electronic standardized study data are required as part of a submission during a declared public health emergency

	Section II.E. When will electronic submission of standardized study data be required? • Updated to clarify the implementation periods for new study standards and version updates, in alignment with the *Federal Register* notice entitled "Electronic Study Data Submission; Data Standards; Timetable for Updates to the Food and Drug Administration Data Standards Catalog for Study Data Submitted Electronically Under the Federal Food, Drug, and Cosmetic Act" that appeared on January 23, 2018 (83 FR 3161)

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Providing Regulatory Submissions in Electronic Format — Standardized Study Data Guidance for Industry[1]

I. INTRODUCTION

Under section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1(a)), at least 24 months after the issuance of a final guidance document in which the Food and Drug Administration (FDA or the Agency) has specified the electronic format for submitting certain submission types to the Agency, such content must be submitted electronically and in the format specified by FDA.[2] This guidance and the technical specifications documents it incorporates by reference describe the requirements for an electronic submission of standardized clinical and nonclinical study data under section 745A(a) of the FD&C Act. In accordance with section 745A(a), following the issuance of a final guidance on this topic, study data contained in the submission types identified in this guidance must be submitted electronically in a format that FDA can process, review, and archive.

This guidance implements the electronic submission requirements of section 745A(a) of the FD&C Act for study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER)[3] by specifying the format for electronic submissions. Submissions that are not submitted electronically and electronic submissions that are not in a format that FDA can process, review, and archive will not be filed or received, unless exempt from the electronic submission requirements or if FDA has granted a waiver (see sections II.B and II.D).

In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements in guidance. Accordingly, as indicated by the use of the words *must* or *required*, this document is not subject to the usual

[1] This guidance has been prepared by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research at the Food and Drug Administration. You may submit comments on this guidance at any time. Submit comments to Docket No. FDA-2012-D-0097 (available at https://www.regulations.gov/docket/FDA-2012-D-0097) (see the instructions for submitting comments in the docket).

[2] For additional information on how FDA interprets and intends to implement the electronic submission requirements of section 745A(a) of the FD&C Act, please see the guidance for industry *Providing Regulatory Submissions in Electronic Format – Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* (December 2014) (745A(a) Implementation Guidance). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[3] For purposes of this guidance, quality control or validation data submitted in support of licensure of blood components are not considered study data.

restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

To comply with the good guidance practice regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance because it is not an accurate description of the effects of this guidance. Insofar as this guidance specifies the format for electronic submissions or provides for exemptions pursuant to section 745A(a) of the FD&C Act, it will have binding effect.

II. REQUIREMENT TO SUBMIT ELECTRONIC STANDARDIZED STUDY DATA

A. For What Submission Types Is an Electronic Submission of Standardized Study Data Required?

Electronic submissions of standardized study data will be required for the following submission types:

- Certain investigational new drug applications (INDs)[4,5]
- New drug applications (NDAs)
- Abbreviated new drug applications (ANDAs)
- Certain biologics license applications (BLAs)[6]

This requirement also includes all subsequent submissions, including amendments, supplements, and reports to one of the submission types identified above. Study data in submissions that are

[4] This guidance is not applicable to INDs for devices that are regulated by CBER as biological products under section 351 of the Public Health Service (PHS) Act and that also require submission of an IND before submission of a BLA. Although a discussion of which devices CBER regulates as biological products is outside the scope of this guidance, we note that as a general matter, this category of INDs would include those investigational devices regulated under IND that are used to screen blood donors for certain transfusion-transmissible diseases and to test human cells, tissues, or cellular or tissue-based products to make a donor-eligibility determination. These submissions are subject to the requirements under section 745A(b) of the FD&C Act. See the guidance for industry and Food and Drug Administration Staff *eCopy Program for Medical Device Submissions* (April 2020), which implements the electronic copy provisions of section 745A(b) of the FD&C Act for medical device submissions to FDA.

[5] This guidance is not applicable to noncommercial INDs. See section II.B.

[6] This guidance is not applicable to those devices that are regulated by CBER as biological products under section 351 of the PHS Act, including those that do not require submission of an IND before the submission of the BLA. Although a discussion of which devices CBER regulates as biological products under section 351 of the PHS Act is outside the scope of this guidance, we note that as a general matter, this category would include those reagents used in determining donor/recipient compatibility in transfusion medicine. These submissions are subject to the requirements under section 745A(b) of the FD&C Act. See the final guidance entitled *eCopy Program for Medical Device Submissions*.

not submitted electronically will not be filed, unless exempt from the electronic submission requirements or unless FDA has granted a waiver.

Sponsors and applicants must submit study data electronically using the format described in this guidance for both clinical and nonclinical studies.

Please see the Study Data Technical Conformance Guide (Conformance Guide)[7] for clarification regarding when electronic standardized study data are required as part of a submission to address a public health emergency declared by the Secretary of Health and Human Services in accordance with section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)).

B. What Types of Submissions Are Exempted from the Electronic Submission Requirements for Standardized Study Data?

Section 745A(a) of the FD&C Act allows FDA to establish exemptions from the electronic submission requirements. Accordingly, FDA has exempted all submissions regarding noncommercial INDs from the requirements under section 745A(a).[8] For purposes of this guidance, the term *noncommercial IND* refers to an IND for a product that is not intended for commercial distribution and includes investigator-sponsored INDs and expanded access INDs (e.g., emergency use INDs and treatment INDs).[9] Although such submissions will be exempt, FDA will accept their voluntary submission in a standardized electronic format as described in this guidance document.

C. What Are the Requirements That Must Be Followed for Electronic Submission of Standardized Study Data?

Under section 745A(a) of the FD&C Act, electronic submissions "shall be submitted in such electronic format as specified by [FDA]." FDA has determined that study data contained in the electronic submissions described in section II.A must be in a format that the Agency can process, review, and archive. Currently, the Agency can process, review, and archive electronic submissions of clinical and nonclinical study data that use the standards specified in the Data Standards Catalog (Catalog).[10]

The Catalog provides a listing of currently supported[11] and/or required standards, their uses, the date FDA will begin (or has begun) to support a particular standard, the date such support ends

[7] The Study Data Technical Conformance Guide is available at https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources.

[8] See 745A(a) Implementation Guidance, section III.B.

[9] The previous version of this guidance used the term *noncommercial products* rather than *noncommercial INDs*. This change was made to clarify our meaning.

[10] Available at https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources.

[11] For the purposes of this document, *supported* means the receiving Center has established processes and technology to support receiving, processing, reviewing, and archiving files in the specified standard.

(or will end), the date the requirement to use a particular standard will begin (or has begun), the date such requirement ends (or will end), and other pertinent information. The Agency may refuse to file (RTF) for NDAs and BLAs, or refuse to receive (RTR) for ANDAs, an electronic submission that does not have study data in conformance to the required standards specified in the Catalog.

When planning a study (including the design of case report forms, data management systems, and statistical analysis plans), the sponsor or applicant must determine which FDA-supported standards to use or request a waiver of those requirements as described in section II.D. There may be versions of a standard available that are not yet supported by FDA (e.g., specific SDTM or ADaM versions) or there may be FDA-supported standards that, currently, have only specific components developed (e.g., SEND study types).[12] See section III for additional support on data standards questions or issues. FDA-supported standards listed in the Catalog are categorized as follows:

1. Exchange Format Standards

An exchange format standard specifies a particular way that information is encoded in a computer file. Specifications for a format permit the file to be written according to a standard, opened for use or alteration, and written back to a storage medium for later access. Some exchange formats in widespread use are proprietary; others are open source. Examples of format standards currently supported by FDA include: Adobe Portable Document Format (pdf), SAS Institute Transport File format (xpt), and Extensible Markup Language (xml).

2. Study Data Standard

Study data standards describe a standard way of exchanging study data between computer systems. Study data standards may describe the data elements and relationships necessary to achieve the unambiguous exchange of information between disparate information systems. The Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) and Standard Exchange for Nonclinical Data (SEND) are examples of study data standards for tabulations data.

Analysis standards describe a standard data structure intended to support analysis. Analysis standards include extraction, transformation, and derivations of the original data. The CDISC Analysis Data Model (ADaM) is an example of a study data standard for analysis data.

[12] Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM), Standard for Exchange of Nonclinical Data (SEND), available at http://www.cdisc.org.

3. Controlled Terminology Standard

The use of controlled terminology standards, also known as vocabularies, is an important component of study data standardization and is a critical component of achieving semantically interoperable data exchange.[13] Controlled terminology standards specify the key concepts that are represented as preferred terms, definitions, synonyms, codes, and code systems. Controlled terminology standards are maintained by external organizations (i.e., external to the sponsor or applicant). Sponsor- or applicant-defined custom terms are not considered controlled terminologies. However, some controlled terminologies are extensible and permit additions to existing codelists. It is the expectation that sponsors or applicants will use the controlled terminologies maintained by external organizations as the standard. Examples of controlled terminology standards include:

- The National Drug File (NDF) — Reference Terminology for drug classifications[14]
- CDISC Controlled Terminology[15]
- Medical Dictionary for Regulatory Activities (MedDRA)[16]

D. Will FDA Issue Waivers of the Electronic Submission Requirements for Standardized Study Data?

Electronic submissions of study data must be in a format that FDA can review, process, and archive. Currently, the Agency can process, review, and archive electronic submissions of study data that use the standards specified in the Catalog posted to the FDA's Study Data Standards Resources web page.[17]

FDA will not provide waivers to submit data that do not conform to any FDA-supported study data standard. However, sponsors or applicants may apply for a waiver from the requirement to use specific versions of FDA-supported standards for the submission of study data. Generally, a waiver will enable a sponsor or applicant to submit study data electronically using a version of a standard that was previously supported by FDA.

To apply for a waiver from the requirement to submit study data using a version of a standard that is not supported as set forth in the Catalog, an email request must be sent to the FDA technical staff at cder-edata@fda.hhs.gov for requests related to CDER-regulated submissions

[13] See the Study Data Technical Conformance Guide for a detailed discussion of semantic interoperability.

[14] NDF is available at http://ncit.nci.nih.gov/ncitbrowser/pages/vocabulary.jsf?dictionary=National%20Drug%20File%20-%20Reference%20Terminology.

[15] CDISC Controlled Terminology is available at http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc.

[16] MedDRA is available at http://www.meddra.org/.

[17] See https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources.

and at cber-edata@fda.hhs.gov for requests related to CBER-regulated submissions. The subject line of the email should start with "Waiver Request." The body of the email should contain the following:

1. Contact person's name (this will be the main contact)
2. Contact person's company name
3. Contact person's mailing address
4. Contact person's phone number
5. Contact person's email address
6. Relevant submission types and numbers
7. The specific requirement or requirements from which the sponsor or applicant is requesting a waiver
8. The reason the sponsor or applicant believes that the waiver is necessary
9. A description of the alternative or alternatives that the sponsor intends to use

FDA encourages the sponsor or applicant to submit the waiver request to the FDA technical staff as early as possible during product development (e.g., when the study is being planned, which may be during the pre-IND phase) and certainly no later than the time of protocol submission to the IND. FDA will notify the sponsor or applicant in writing (e.g., in an email) as to whether the waiver request is denied or granted. The technical staff will coordinate with the applicable review division and contact the requestor concerning the status of the waiver request. Generally, FDA intends to notify the requestor within 30 days from the date the waiver request is received.

E. When Will Electronic Submission of Standardized Study Data Be Required?

The requirement to submit using a particular standard is dependent on its support by FDA as listed in the Catalog at the time of study start.[18] FDA recognizes that standards development organizations may release version updates to standards in the interval between the start of a study and the submission of study data to the Agency. The Catalog may list more than one version of a supported standard (e.g., PDF versions 1.4 - 1.7, SDTM versions 1.2 and 1.3, Define versions 1.0 and 2.0, and MedDRA versions 8 or later). Sponsors or applicants are encouraged to use the latest version listed in the Catalog. However, when there are multiple versions of a standard listed, sponsors or applicants can select the version to use for their study.

The initial timetable for the implementation of electronic submission requirements for study data is described in section II.E.1. Since the initial timetable has passed, FDA may announce the future availability of new standards and version updates to existing standards through *Federal Register* notices. Such a *Federal Register* notice will specify the next calendar March 15 date following the publication of the *Federal Register* notice as the start date for the implementation period (*transition date*) used to calculate when the new standard or version update will be required in a submission. The transition date does not indicate the date on which the requirement

[18] For purposes of this guidance, the study start date for clinical studies is the earliest date of informed consent among any subject that enrolled in the study. For example, see Study Start Date in the SDTM Trial Summary Domain (TSPARMCD = SSTDTC), available at http://www.cdisc.org. For nonclinical studies, the study start date is the date on which the study protocol or plan is approved (signed) by the Study Director, also known as the study initiation date. For example, see Study Start Date in the SEND Trial Summary Domain (TSPARMCD = STSTDTC), available at http://www.cdisc.org.

to use a particular standard commences. Instead, the transition date indicates the beginning date of the implementation period, which will be consistent with the timetables set forth in the 745A(a) Implementation Guidance, to provide industry with notice before requiring the new standard or version update in submissions. The use of a standard will be required in submissions only after the implementation period has ended. This use of the *transition date* approach should provide sponsors and applicants with a consistent and predictable implementation timetable for new standards and version updates to existing standards. Examples using the *transition date* approach are listed below:

Example 1: A *Federal Register* notice is published on September 5, 2022, announcing the availability of a new standard. The *transition date* is the next calendar March 15 date, March 15, 2023, which starts the implementation period for the new standard. The new standard will be required in submissions for studies that start 24 months after the transition date, which is March 15, 2025.

Example 2: A *Federal Register* notice is published on February 14, 2022, announcing the availability of a new standard. The *transition date* is the next calendar March 15 date, March 15, 2022, which starts the implementation period for the new standard. The new standard will be required in submissions for studies that start 24 months after the transition date, which is March 15, 2024.

Example 3: A *Federal Register* notice is published on April 6, 2022, announcing the availability of a version update to an existing standard. The *transition date* is the next calendar March 15 date, March 15, 2023, which starts the implementation period for the version update. The version update will be required in submissions for studies that start 12 months after the transition date, which is March 15, 2024.

1. Initial Timetable for the Implementation of Electronic Submission Requirements

After the publication of the initial final version of this guidance on December 18, 2014 (2014 Final eStudy Data Guidance), all studies with a start date 24 months after that publication date (December 18, 2016) for NDA, ANDA, and certain BLA submissions and studies with a start date 36 months after the publication of the 2014 Final eStudy Data Guidance (December 18, 2017) for certain IND submissions must use the appropriate FDA-supported standards, formats, and terminologies specified in the Catalog (see section II.C)). As noted above, to ensure that FDA can assess whether sponsors and applicants are subject to particular study data format requirements, FDA must rely on information provided by the submitter about study start date and the file type being submitted. Generally, the datasets necessary to assess conformance to the standard include the demographic dataset file (SDTM and SEND dm.xpt), the subject level analysis dataset file (ADaM adsl.xpt), and the define.xml file (SDTM, SEND, and ADaM). For further details, see the Technical Rejection Criteria for Study Data, the Conformance Guide, and the Data Standards Catalog.[19]

[19] See footnote 17. See also Study Data for Submission to CDER and CBER, available at https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber.

2. Version Updates to FDA-Supported Standards

Periodically, version updates to FDA-supported study data standards are released by Standards Development Organizations (SDOs). Version updates may include (1) content or structural changes (e.g., new SDTM domains or variables) and (2) typographical errors, corrections, or clarifications that do not result in content or structural changes. Generally, version updates that include content or structural changes would require FDA to execute a testing and acceptance process, whereas errata, corrections, or clarifications would not.

Given that the 24- and 36-month initial implementation timetables described in section II.E.1 have passed since the publication of the 2014 Final eStudy Data Guidance, version updates will be required in submissions for studies with a start date that is no earlier than 12 months after the transition date specified in a *Federal Register* notice announcing FDA's determination of the new format as one that it can process, review, and archive.[20] The *Federal Register* notice will specify the *transition* date for all version updates (with the month and day for the *transition date* corresponding to March 15). When multiple versions of an FDA-supported standard are listed in the Catalog as formats which FDA can process, review, and archive, sponsors or applicants can select a version to use.

Below is an example and accompanying table (Table 1) of how a version update to a study data standard would be implemented.

> *Example: On February 15, 2024, an SDO releases a version update to a study data standard already supported in the Catalog. On May 6, 2025, FDA publishes a* Federal Register *notice announcing support for the version update and updates the Catalog. The date support begins for this version update will be May 6, 2025. The transition date posted in the* Federal Register *notice is March 15, 2026. The date the requirement begins will be March 15, 2027. Sponsors or applicants are encouraged to begin using the updated version on May 6, 2025. The version update will only be required in submissions for studies that start after March 15, 2027. When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.*

Table 1: Example of a Timetable for a Version Update to an FDA-Supported Standard

Date Version Update Released by SDO (yyyy-mm-dd)	Date FR Notice Published Announcing Support of Version Update (yyyy-mm-dd)	Date Support for the Version Update Begins (yyyy-mm-dd)	Transition Date (yyyy-mm-dd)	Date Requirement for the Version Update Begins (yyyy-mm-dd)
2024-02-15	2025-05-06	2025-05-06	2026-03-15	2027-03-15

[20] See the 745A(a) Implementation Guidance, section III.F (describing the timetable for implementation of revisions and updates).

3. New Standards

Given that the 24- and 36-month initial implementation timetables described in section II.E.1 have passed since the publication of the 2014 Final eStudy Data Guidance, FDA may announce in a *Federal Register* notice (and guidance, if necessary) its support for new standards. New standards are those that have not been supported by FDA and are not listed in the Catalog at the time this guidance is finalized. New standards will be required in submissions for studies that start no earlier than 24 months after the transition date specified in a *Federal Register* notice announcing FDA's determination of the new standard as one that it can process, review, and archive. The *Federal Register* notice of availability will specify the *transition date* for all version updates (with the month and day for the *transition date* corresponding to March 15).

Below is an example and accompanying table (Table 2) of how a new study data standard would be implemented.

> *On February 15, 2024, an SDO releases a new study data standard. On May 6, 2025, FDA publishes a* Federal Register *notice announcing support of the new study data standard and updates the Catalog. The date support begins for this new standard will be May 6, 2025. The transition date posted in the* Federal Register *notice is March 15, 2026. The date the requirement begins will be March 15, 2028. Sponsors or applicants are encouraged to begin using the new standard on May 6, 2025. The new standard will only be required in submissions for studies that start after March 15, 2028.*

Table 2: Example of a Timetable for FDA Support of a New Standard

Date New Standard Released by SDO (yyyy-mm-dd)	Date FR Notice Published Announcing Support of New Standard (yyyy-mm-dd)	Date Support for the New Standard Begins (yyyy-mm-dd)	Transition Date (yyyy-mm-dd)	Date Requirement for the New Standard Begins (yyyy-mm-dd)
2024-02-15	2025-05-06	2025-05-06	2026-03-15	2028-03-15

III. ADDITIONAL SUPPORT

A. Meetings With FDA

Sponsors and applicants may use established FDA-sponsor meetings (e.g., pre-IND and end-of-phase 2) to discuss the study data standardization plan and to raise data standardization issues (if any) related to NDAs and BLAs. Discussions about nonclinical study data standardization plans may be initiated at the pre-IND stage and should continue throughout development. Initial discussions about which data standards to use for study data should take place as early as possible during drug development, especially for safety data, but should in any event occur no later than the end of phase 2. In general, the premarketing application meeting is considered too late to initiate data standardization discussions. For ANDAs, sponsors and applicants should discuss the study data standardization plan before the initiation of their bioequivalence program.

Sponsors and applicants may submit technical questions related to data standards at any time to the technical support team identified by each Center (see the Study Data Standards Resources web page for specific contact information). Sponsors and applicants may also request a separate Type C meeting to discuss substantive data standardization issues for NDAs and BLAs. An example of such an issue might be a sponsor's desire to use a standard (e.g., therapeutic area standard in SDTM format) that is not currently supported by FDA. The request should include adequate information to identify the appropriate FDA staff necessary to discuss the proposed agenda items.

B. Implementation Support

Technical specification documents provide nonbinding specifications, recommendations, and general considerations on how to submit standardized clinical and nonclinical study data using the standards specified in the Data Standards Catalog. The Conformance Guide is a technical specification document that supplements the requirements described in this guidance and is intended to assist sponsors and applicants in the electronic submission of standardized study data (see section I). The Conformance Guide will be updated, as needed, and its availability announced in a *Federal Register* notice.

Sponsors and applicants with questions on how to implement the FDA-supported study data standards should contact and work with FDA technical staff. Contact information is provided on the Study Data Standards Resources web page. Sponsors and applicants may also arrange to submit sample data for a presubmission technical review. The technical staff welcomes any additional feedback or comments regarding the information posted on the web page.