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)

December 2014
Electronic Submissions

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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:

http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm

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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), at least 24 months after the issuance of a final guidance document in which the Food and Drug Administration (FDA) 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 exempted from the electronic submission requirements (see section II.B).

In section 745A(a), 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 restrictions in FDA's good guidance practice (GGP) regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

To comply with the GGP 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

[1] This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

[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" (745A(a) Implementation Guidance).

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

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 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.

B. What types of submissions are exempted from the electronic submission requirements for standardized study data?

Section 745A(a) 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).[7] For purposes of this guidance, the term

[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 Act and that also require submission of an IND prior to 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 investigational devices that are used to screen blood donors for certain transfusion-transmissible diseases and to test human cells, tissues, or cellular or tissue-based products (HCT/Ps) to make a donor-eligibility determination. These submissions are subject to the requirements under section 745A(b). See the final guidance entitled *eCopy Program for Medical Device Submissions*, which implements the electronic copy provisions of section 745A(b) 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 Public Health Service Act, including those that do not require submission of an IND prior to the submission of the BLA. Although a discussion of which devices CBER regulates as biological products under Section 351 of the Public Health Service 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). See the final guidance entitled *eCopy Program for Medical Device Submissions*.

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

"noncommercial products" refers to products that are not intended to be distributed commercially and includes investigator-sponsored INDs and expanded access INDs (e.g., emergency use INDs and treatment INDs). 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)[8].

The Catalog provides a listing of currently supported[9] and/or required standards, their uses, the date FDA will begin (or has begun) to support a particular standard, and the date support ends (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).[10] 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).

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[8] Available at http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.

[9] 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.

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

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.

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.[11] 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[12]
- CDISC Controlled Terminology[13]
- Medical Dictionary for Regulatory Activities (MedDRA)[14]

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.

[11] See the Study Data Technical Conformance Guide for a detailed discussion of semantic interoperability. The Study Data Technical Conformance Guide is available at http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.

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

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

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

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. 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 IND, NDA, or ANDA submissions or cber.cdisc@fda.hhs.gov for requests related to BLA 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.[15] 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

[15] 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). 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), http://www.cdisc.org.

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 provided in section II.E.1. After 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 a fixed month and day, March 15, for determining the start date for the implementation timetable (*transition dat*e) before a particular standard will be required in a submission. The *transition date* is the next calendar March 15 date following the publication of a *Federal Register* notice. The transition date does not indicate the date on which the requirement to use a particular commences. Instead, it indicates the beginning date of the implementation period, which will be consistent with the timetables set forth in the 745A(a) Implementation Guidance. 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, 2018, announcing the availability of a new standard. The *transition date* is the next calendar March 15 date, March 15, 2019, 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, 2021, (for NDAs, ANDAs, and certain BLAs) and 36 months (for certain INDs).
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> *Example 2*: A *Federal Register* notice is published on February 14, 2018, announcing the availability of a new standard. The *transition date* is the next calendar March 15 date, March 15, 2018, 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, 2020, (for NDAs, ANDAs, and certain BLAs) and 36 months (for certain INDs).
>
> *Example 3*: A *Federal Register* notice is published on April 6, 2018, announcing the availability of a version update to an existing standard. The *transition date* is the next calendar March 15 date, March 15, 2019, 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, 2020, (for NDAs, ANDAs, and certain BLAs) and 36 months (for certain INDs).

1. Initial Timetable for the Implementation of Electronic Submission Requirements

After the publication of this guidance, all studies with a start date 24 months after the publication date must use the appropriate FDA-supported standards, formats, and terminologies specified in the Catalog (see section II.C) for NDA, ANDA, and certain BLA submissions. Study data contained in certain IND submissions must use the specified formats for electronic submission in studies with a start date 36 months after the publication of this guidance.

An example of a timetable for the initial implementation of the electronic submission requirement is listed below. Table 1 summarizes the timetable.

> *On September 15, 2015, FDA publishes the final "Guidance on Providing Regulatory Submissions in Electronic Format — Standardized Study Data (eStudy Data)." For studies with a start date after September 15, 2017, sponsors or applicants must use the appropriate FDA-supported standards specified in the Catalog for NDA, ANDA, and certain BLA submissions. The Catalog will list September 15, 2017, as the "date requirement begins."*

Table 1: Example of a Timetable for the Initial Implementation of the Electronic Submission Requirement

Initial Requirement	Publication Date (yyyy-mm-dd)	Updated Data Standards Catalog (yyyy-mm-dd)	Date Requirement Begins (yyyy-mm-dd)
Final eStudy Data Guidance Published	2015-09-15	2015-09-15	2017-09-15[16] 2018-09-15[17]

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.

After this guidance is finalized and the 24- and 36-month initial implementation timetables described in section II.E.1 have passed, version updates will be required in submissions for studies with a start date that is no earlier than 12 months after a *Federal Register* notice announcing FDA's determination of the new format as one that it can process, review, and archive.[18] 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.

Examples of version updates to FDA-supported standards are listed below. Table 2 summarizes the timetable associated with these examples.

[16] For NDAs, ANDAs, and certain BLAs. See section II.A.
[17] For certain INDs. See section II.A.
[18] See 745A(a) Implementation Guidance, section III.F (describing the timetable for implementation of revisions and updates).

Example 1: CDISC releases a data standard SDTM 4.1 as a version update to SDTM 4.0 on February 15, 2016. The version update includes domain and variable changes to the standard. Following the release by CDISC, FDA executes an acceptance testing process to determine whether it is able to support the updated version, SDTM 4.1. The acceptance testing process confirms that FDA is able to support the updated version. Accordingly, SDTM 4.1 becomes a format that FDA can process, review, and archive, as described in section II.C. On May 6, 2016, FDA publishes a Federal Register *notice announcing support for the new version, SDTM 4.1, and updates the Catalog. The transition date posted in the* Federal Register *notice is March 15, 2017. Although SDTM version 4.1 is supported by FDA as of May 6, 2016, and sponsors or applicants are encouraged to begin using it as of May 6, 2016, the new version will only be required in submissions for studies that start after March 15, 2018. The Catalog will list March 15, 2018, as the "date requirement begins." When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.*

Example 2: CDISC releases a data standard SEND 2.1.1 as a version update to SEND 2.1 on September 18, 2016. The version update SEND 2.1.1 includes clarifications and corrections to typographical errors in SEND version 2.1, but no new content or structural changes. FDA will determine when it is able to support the updated version, SEND 2.1.1, but generally FDA testing will not be required for version updates for errata. On October 3, 2016, FDA publishes a Federal Register *notice announcing support for the new version, SEND 2.1.1, and updates the Catalog. The transition date posted in the* Federal Register *notice is March 15, 2017. Although the new SEND version 2.1.1 is supported by FDA as of October 3, 2016, and sponsors or applicants are encouraged to begin using it as of that date, the new version will only be required in submissions for studies that start after March 15, 2018. The Catalog will list March 15, 2018, as the "date requirement begins." When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.*

Example 3: On January 15, 2018, the SDO releases the PDF version 2.0 file format as an update to PDF version 1.7. Following the release by the SDO, FDA executes an acceptance testing process to determine whether it is able to support PDF version 2.0 for study data submissions. The acceptance testing process confirms that FDA is able to support the updated version. On June 28, 2018, FDA publishes a Federal Register *notice announcing support for the new version, PDF 2.0, and updates the Catalog. The transition date posted in the* Federal Register *notice is March 15, 2019. Although the new PDF version is supported by FDA and sponsors or applicants are encouraged to begin using it as of June 28, 2018, PDF 2.0 will only be required in submissions for studies that start after March 15, 2020. The Catalog will list March 15, 2020, as the "date requirement begins." When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.*

Table 2: Examples of Version Update Timetables for FDA-Supported Standards

SDO Releases Version Update	Date Released by SDO (yyyy-mm-dd)	FR Notice of FDA Support (yyyy-mm-dd)	Update Data Standards Catalog (yyyy-mm-dd)	Transition Date (yyyy-mm-dd)	Date Requirement Begins (yyyy-mm-dd)
SDTM 4.1	2016-02-15	2016-05-06	2016-05-06	2017-03-15	2018-03-15[19]
SEND 2.1.1	2016-09-18	2016-10-03	2016-10-03	2017-03-15	2018-03-15[20]
PDF 2.0	2018-01-15	2018-06-28	2018-06-28	2019-03-15	2020-03-15[21]

3. New Standards

After this guidance is finalized (and the 24- and 36-month milestones discussed above have been reached), 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 24 months (for NDAs, ANDAs, and certain BLAs) and 36 months (for certain INDs) after the publication of a notice of availability in the *Federal Register*. 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 of a new standard and how it would be implemented. Table 3 summarizes the timetable associated with the example.

> *FDA, with public input, conducts an evaluation and testing of a new study data exchange format standard, DS Exchange version 2.0. On April 22, 2018, FDA publishes a* Federal Register *notice announcing support of the new study data exchange standard, DS Exchange version 2.0, and updates the Catalog. The transition date posted in the* Federal Register *notice is March 15, 2019. Although the new study data transport standard will be supported by FDA as of April 22, 2018, and sponsors or applicants are encouraged to use it, the new standard for study data exchange will only be required in submissions for studies that start after March 15, 2021. The Catalog will list March 15, 2021, as the "date requirement begins."*

[19] Based on an Initial Requirement Date example of 2017-09-15 for NDAs, ANDAs, and certain BLAs (see section II.E.1).
[20] Ibid.
[21] Based on an Initial Requirement Date example of 2017-09-15 for NDAs, ANDAs, and certain BLAs, and 2018-09-15 for certain INDs (see section II.E.1).

Table 3: Example of an Implementation Timetable for a New Standard

SDO Releases New Data Transport	Date Released by SDO (yyyy-mm-dd)	FR Notice of FDA Support (yyyy-mm-dd)	Updated Data Standards Catalog (yyyy-mm-dd)	Transition Date (yyyy-mm-dd)	Date Requirement Begins (yyyy-mm-dd)
DS Exchange 2.0	2017-02-20	2018-04-22	2018-04-22	2019-03-15	2021-03-15[22]

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 prior to 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 Study Data Technical Conformance Guide (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.

[22] Based on the Initial Requirement Date example of 2017-09-15 for NDAs, ANDAs, and certain BLAs and 2018-09-15 for certain INDs (see section II.E.1).

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 pre-submission technical review. The technical staff welcomes any additional feedback or comments regarding the information posted on the Web page.