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# **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)**

**October 2020  
Electronic Submissions**

**Revision 1**

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## Guidance for Industry

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Office of Communications, Division of Drug Information  
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Food and Drug Administration  
10001 New Hampshire Ave., Hillandale Bldg., 4<sup>th</sup> Floor  
Silver Spring, MD 20993  
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353  
Email: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)*

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*Office of Communication, Outreach and Development  
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10903 New Hampshire Ave., Bldg. 71, Room 3128  
Silver Spring, MD 20993  
Phone: 800-835-4709 or 240-402-8010  
Email: [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov)*

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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	<p><b>Updates to Guidance</b></p> <p>Section II.B. What types of submissions are exempted from the electronic submission requirements for standardized study data?</p> <ul style="list-style-type: none"><li>• Updated the term “noncommercial products” to “noncommercial IND” to clarify the products that are exempt from requirements under this guidance.</li></ul> <p>Section II.E. When will electronic submission of standardized study data be required?</p> <ul style="list-style-type: none"><li>• Updated to clarify the information FDA relies on for assessing compliance with study data requirements</li><li>• 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</li></ul>

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1                   **Providing Regulatory Submissions in Electronic Format —**  
2                                   **Standardized Study Data**  
3                                   **Guidance for Industry<sup>1</sup>**  
4  
5

6 **I. INTRODUCTION**  
7

8 Under section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.  
9 379k-1(a)), at least 24 months after the issuance of a final guidance document in which the Food  
10 and Drug Administration (FDA or the Agency) has specified the electronic format for submitting  
11 certain submission types to the Agency, such content must be submitted electronically and in the  
12 format specified by FDA.<sup>2</sup> This guidance and the technical specifications documents it  
13 incorporates by reference describe the requirements for an electronic submission of standardized  
14 clinical and nonclinical study data under section 745A(a) of the FD&C Act. In accordance with  
15 section 745A(a), following the issuance of a final guidance on this topic, study data contained in  
16 the submission types identified in this guidance must be submitted electronically in a format that  
17 FDA can process, review, and archive.  
18

19 This guidance implements the electronic submission requirements of section 745A(a) of the  
20 FD&C Act for study data contained in new drug applications (NDAs), abbreviated new drug  
21 applications (ANDAs), biologics license applications (BLAs), and investigational new drug  
22 applications (INDs) to the Center for Drug Evaluation and Research (CDER) or the Center for  
23 Biologics Evaluation and Research (CBER)<sup>3</sup> by specifying the format for electronic submissions.  
24 Submissions that are not submitted electronically and electronic submissions that are not in a  
25 format that FDA can process, review, and archive will not be filed or received, unless exempt  
26 from the electronic submission requirements or if FDA has granted a waiver (see sections II.B  
27 and II.D).  
28

29 In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to  
30 implement the statutory electronic submission requirements in guidance. Accordingly, as  
31 indicated by the use of the words *must* or *required*, this document is not subject to the usual  
32 restrictions in FDA’s good guidance practice (GGP) regulations, such as the requirement that  
33 guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).  
34

35 To comply with the GGP regulations and make sure that regulated entities and the public  
36 understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard

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<sup>1</sup> This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

<sup>2</sup> 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>.

<sup>3</sup> For purposes of this guidance, quality control or validation data submitted in support of licensure of blood components are not considered study data.

37 language explaining that guidances should be viewed only as recommendations unless specific  
38 regulatory or statutory requirements are cited. FDA is not including this standard language in  
39 this guidance because it is not an accurate description of the effects of this guidance. Insofar as  
40 this guidance specifies the format for electronic submissions, or provides for exemptions  
41 pursuant to section 745A(a) of the FD&C Act, it will have binding effect.  
42  
43

## 44 **II. REQUIREMENT TO SUBMIT ELECTRONIC STANDARDIZED STUDY DATA**

### 45 **A. For what submission types is an electronic submission of standardized study** 46 **data required?**

47  
48  
49 Electronic submissions of standardized study data will be required for the following submission  
50 types:

- 51 • Certain investigational new drug applications (INDs)<sup>4,5</sup>
- 52 • New drug applications (NDAs)
- 53 • Abbreviated new drug applications (ANDAs)
- 54 • Certain biologics license applications (BLAs)<sup>6</sup>

55  
56 This requirement also includes all subsequent submissions, including amendments, supplements,  
57 and reports to one of the submission types identified above. Study data in submissions that are  
58 not submitted electronically will not be filed, unless exempt from the electronic submission  
59 requirements or unless FDA has granted a waiver.  
60

61 Sponsors and applicants must submit study data electronically using the format described in this  
62 guidance for both clinical and nonclinical studies.  
63

### 64 **B. What types of submissions are exempted from the electronic submission** 65 **requirements for standardized study data?**

66

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<sup>4</sup> 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 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) of the FD&C Act. See the final guidance entitled *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.

<sup>5</sup> This guidance is not applicable to noncommercial INDs. See section II.B.

<sup>6</sup> 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*.

67 Section 745A(a) of the FD&C Act allows FDA to establish exemptions from the electronic  
68 submission requirements. Accordingly, FDA has exempted all submissions regarding  
69 noncommercial INDs from the requirements under section 745A(a).<sup>7</sup> For purposes of this  
70 guidance, the term “noncommercial IND” refers to an IND for a product that is not intended for  
71 commercial distribution and includes investigator-sponsored INDs and expanded access INDs  
72 (e.g., emergency use INDs and treatment INDs).<sup>8</sup> Although such submissions will be exempt,  
73 FDA will accept their voluntary submission in a standardized electronic format as described in  
74 this guidance document.  
75

76 **C. What are the requirements that must be followed for electronic submission of**  
77 **standardized study data?**  
78

79 Under section 745A(a) of the FD&C Act, electronic submissions “shall be submitted in such  
80 electronic format as specified by [FDA].” FDA has determined that study data contained in the  
81 electronic submissions described in section II.A must be in a format that the Agency can process,  
82 review, and archive. Currently, the Agency can process, review, and archive electronic  
83 submissions of clinical and nonclinical study data that use the standards specified in the Data  
84 Standards Catalog (Catalog).<sup>9</sup>  
85

86 The Catalog provides a listing of currently supported<sup>10</sup> and/or required standards, their uses, the  
87 date FDA will begin (or has begun) to support a particular standard, the date such support ends  
88 (or will end), the date the requirement to use a particular standard will begin (or has begun), the  
89 date such requirement ends (or will end), and other pertinent information. The Agency may  
90 refuse to file (RTF) for NDAs and BLAs, or refuse to receive (RTR) for ANDAs, an electronic  
91 submission that does not have study data in conformance to the required standards specified in  
92 the Catalog.  
93

94 When planning a study (including the design of case report forms, data management systems,  
95 and statistical analysis plans), the sponsor or applicant must determine which FDA-supported  
96 standards to use or request a waiver of those requirements as described in section II.D. There  
97 may be versions of a standard available that are not yet supported by FDA (e.g., specific SDTM  
98 or ADaM versions) or there may be FDA-supported standards that, currently, have only specific  
99 components developed (e.g., SEND study types).<sup>11</sup> See section III for additional support on data  
100 standards questions or issues. FDA-supported standards listed in the Catalog are categorized as  
101 follows:  
102

103 *1. Exchange Format Standards*  
104

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<sup>7</sup> See 745A(a) Implementation Guidance, section III.B.

<sup>8</sup> The previous version of this guidance used the term “noncommercial products” rather than “noncommercial INDs.” This change was made to clarify our meaning.

<sup>9</sup> Available at <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>.

<sup>10</sup> 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.

<sup>11</sup> Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM), Standard for Exchange of Nonclinical Data (SEND), available at [www.cdisc.org](http://www.cdisc.org).

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

111

## 112 *2. Study Data Standard*

113

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

120

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

124

## 125 *3. Controlled Terminology Standard*

126

127 The use of controlled terminology standards, also known as vocabularies, is an important  
128 component of study data standardization and is a critical component of achieving semantically  
129 interoperable data exchange.<sup>12</sup> Controlled terminology standards specify the key concepts that  
130 are represented as preferred terms, definitions, synonyms, codes, and code systems. Controlled  
131 terminology standards are maintained by external organizations (i.e., external to the sponsor or  
132 applicant). Sponsor- or applicant-defined custom terms are not considered controlled  
133 terminologies. However, some controlled terminologies are extensible and permit additions to  
134 existing codelists. It is the expectation that sponsors or applicants will use the controlled  
135 terminologies maintained by external organizations as the standard. Examples of controlled  
136 terminology standards include:

137

138 • The National Drug File (NDF) — Reference Terminology for drug classifications<sup>13</sup>

139 • CDISC Controlled Terminology<sup>14</sup>

140 • Medical Dictionary for Regulatory Activities (MedDRA)<sup>15</sup>

141

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<sup>12</sup> See the Study Data Technical Conformance Guide for a detailed discussion of semantic interoperability. The Study Data Technical Conformance Guide is available at <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>.

<sup>13</sup> NDF is available at

<http://ncit.nci.nih.gov/ncitbrowser/pages/vocabulary.jsf?dictionary=National%20Drug%20File%20-%20Reference%20Terminology>.

<sup>14</sup> CDISC Controlled Terminology is available at

<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>.

<sup>15</sup> MedDRA is available at <http://www.meddra.org/>.



142 **D. Will FDA issue waivers of the electronic submission requirements for**  
143 **standardized study data?**  
144

145 Electronic submissions of study data must be in a format that FDA can review, process, and  
146 archive. Currently, the Agency can process, review, and archive electronic submissions of study  
147 data that use the standards specified in the Catalog posted to the FDA’s Study Data Standards  
148 Resources Web page.<sup>16</sup>  
149

150 FDA will not provide waivers to submit data that do not conform to any FDA-supported study  
151 data standard. However, sponsors or applicants may apply for a waiver from the requirement to  
152 use specific versions of FDA-supported standards for the submission of study data. Generally, a  
153 waiver will enable a sponsor or applicant to submit study data electronically using a version of a  
154 standard that was previously supported by FDA.  
155

156 To apply for a waiver from the requirement to submit study data using a version of a standard  
157 that is not supported as set forth in the Catalog, an email request must be sent to the FDA  
158 technical staff at [cdcr-edata@fda.hhs.gov](mailto:cdcr-edata@fda.hhs.gov) for requests related to CDER-regulated submissions  
159 and [cber-edata@fda.hhs.gov](mailto:cber-edata@fda.hhs.gov) for requests related to CBER-regulated submissions. The subject  
160 line of the email should start with “Waiver Request.” The body of the email should contain the  
161 following:

- 162 1. Contact person’s name (this will be the main contact)
- 163 2. Contact person’s company name
- 164 3. Contact person’s mailing address
- 165 4. Contact person’s phone number
- 166 5. Contact person’s email address
- 167 6. Relevant submission types and numbers
- 168 7. The specific requirement or requirements from which the sponsor or applicant is  
169 requesting a waiver
- 170 8. The reason the sponsor or applicant believes that the waiver is necessary
- 171 9. A description of the alternative or alternatives that the sponsor intends to use  
172

173 FDA encourages the sponsor or applicant to submit the waiver request to the FDA technical staff  
174 as early as possible during product development (e.g., when the study is being planned, which  
175 may be during the pre-IND phase) and certainly no later than the time of protocol submission to  
176 the IND. FDA will notify the sponsor or applicant in writing (e.g., in an email) as to whether the  
177 waiver request is denied or granted. The technical staff will coordinate with the applicable  
178 review division and contact the requestor concerning the status of the waiver request. Generally,  
179 FDA intends to notify the requestor within 30 days from the date the waiver request is received.  
180

181 **E. When will electronic submission of standardized study data be required?**  
182  
183

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<sup>16</sup> See <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>.

184 The requirement to submit using a particular standard is dependent on its support by FDA as  
185 listed in the Catalog at the time of study start.<sup>17</sup> FDA recognizes that standards development  
186 organizations may release version updates to standards in the interval between the start of a study  
187 and the submission of study data to the Agency. The Catalog may list more than one version of a  
188 supported standard (e.g., PDF versions 1.4 - 1.7, SDTM versions 1.2 and 1.3, Define versions 1.0  
189 and 2.0, and MedDRA versions 8 or later). Sponsors or applicants are encouraged to use the  
190 latest version listed in the Catalog. However, when there are multiple versions of a standard  
191 listed, sponsors or applicants can select the version to use for their study.

192  
193 The initial timetable for the implementation of electronic submission requirements for study data  
194 is provided in section II.E.1. Since the initial timetable has passed, FDA may announce the  
195 future availability of new standards and version updates to existing standards through *Federal*  
196 *Register* notices. Such a *Federal Register* notice will specify a fixed month and day, March 15,  
197 for determining the start date for the implementation timetable (*transition date*) before a  
198 particular standard will be required in a submission. The *transition date* is the next calendar  
199 March 15 date following the publication of a *Federal Register* notice. The transition date does  
200 not indicate the date on which the requirement to use a particular standard commences. Instead,  
201 it indicates the beginning date of the implementation period, which will be consistent with the  
202 timetables set forth in the 745A(a) Implementation Guidance. The use of a standard will be  
203 required in submissions only after the implementation period has ended. This use of the  
204 *transition date* approach should provide sponsors and applicants with a consistent and  
205 predictable implementation timetable for new standards and version updates to existing  
206 standards. Examples using the *transition date* approach are listed below:

207  
208 *Example 1:* A *Federal Register* notice is published on September 5, 2018, announcing the  
209 availability of a new standard. The *transition date* is the next calendar March 15 date,  
210 March 15, 2019, which starts the implementation period for the new standard. The new  
211 standard will be required in submissions for studies that start 24 months after the  
212 transition date, which is March 15, 2021, (for NDAs, ANDAs, and certain BLAs) and 36  
213 months (for certain INDs).

214  
215 *Example 2:* A *Federal Register* notice is published on February 14, 2018, announcing the  
216 availability of a new standard. The *transition date* is the next calendar March 15 date,  
217 March 15, 2018, which starts the implementation period for the new standard. The new  
218 standard will be required in submissions for studies that start 24 months after the  
219 transition date, which is March 15, 2020, (for NDAs, ANDAs, and certain BLAs) and 36  
220 months (for certain INDs).

221  
222 *Example 3:* A *Federal Register* notice is published on April 6, 2018, announcing the  
223 availability of a version update to an existing standard. The *transition date* is the next

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<sup>17</sup> 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), <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), <http://www.cdisc.org>.

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 certain INDs).

### 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) 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 the 2014 Final eStudy Data Guidance (December 18, 2017). 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 and the Data Standards Catalog.<sup>18</sup>

Table 1 summarizes the timetable for the initial implementation of the electronic submission requirement.

Table 1: 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)
2014 Final eStudy Data Guidance Published	2014-12-18	2014-12-18	2016-12-18 <sup>19</sup> 2017-12-18 <sup>20</sup>

### 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

<sup>18</sup> See Study Data for Submission to CDER and CBER: <https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber>.

<sup>19</sup> For NDAs, ANDAs, and certain BLAs. See section II.A.

<sup>20</sup> For certain INDs. See section II.A.

260 include content or structural changes would require FDA to execute a testing and acceptance  
261 process, whereas errata, corrections, or clarifications would not.

262  
263 Given that the 24- and 36-month initial implementation timetables described in section II.E.1  
264 have passed since the publication of the 2014 Final eStudy Data Guidance, version updates will  
265 be required in submissions for studies with a start date that is no earlier than 12 months after a  
266 *Federal Register* notice announcing FDA’s determination of the new format as one that it can  
267 process, review, and archive.<sup>21</sup> The *Federal Register* notice will specify the *transition date* for  
268 all version updates (with the month and day for the *transition date* corresponding to March 15).  
269 When multiple versions of an FDA-supported standard are listed in the Catalog as formats which  
270 FDA can process, review, and archive, sponsors or applicants can select a version to use.

271  
272 Examples of version updates to FDA-supported standards are listed below. Table 2 summarizes  
273 the timetable associated with these examples:

274 *Example 1: CDISC releases a data standard SDTM 4.1 as a version update to SDTM 4.0*  
275 *on February 15, 2016. The version update includes domain and variable changes to the*  
276 *standard. Following the release by CDISC, FDA executes an acceptance testing process*  
277 *to determine whether it is able to support the updated version, SDTM 4.1. The*  
278 *acceptance testing process confirms that FDA is able to support the updated version.*  
279 *Accordingly, SDTM 4.1 becomes a format that FDA can process, review, and archive, as*  
280 *described in section II.C. On May 6, 2016, FDA publishes a Federal Register notice*  
281 *announcing support for the new version, SDTM 4.1, and updates the Catalog. The*  
282 *transition date posted in the Federal Register notice is March 15, 2017. Although SDTM*  
283 *version 4.1 is supported by FDA as of May 6, 2016, and sponsors or applicants are*  
284 *encouraged to begin using it as of May 6, 2016, the new version will only be required in*  
285 *submissions for studies that start after March 15, 2018. The Catalog will list March 15,*  
286 *2018, as the “date requirement begins.” When multiple versions of an FDA-supported*  
287 *standard are listed in the Catalog, sponsors or applicants can select a version to use.*

288  
289 *Example 2: CDISC releases a data standard SEND 2.1.1 as a version update to SEND*  
290 *2.1 on September 18, 2016. The version update SEND 2.1.1 includes clarifications and*  
291 *corrections to typographical errors in SEND version 2.1, but no new content or*  
292 *structural changes. FDA will determine when it is able to support the updated version,*  
293 *SEND 2.1.1, but generally FDA testing will not be required for version updates for*  
294 *errata. On October 3, 2016, FDA publishes a Federal Register notice announcing*  
295 *support for the new version, SEND 2.1.1, and updates the Catalog. The transition date*  
296 *posted in the Federal Register notice is March 15, 2017. Although the new SEND version*  
297 *2.1.1 is supported by FDA as of October 3, 2016, and sponsors or applicants are*  
298 *encouraged to begin using it as of that date, the new version will only be required in*  
299 *submissions for studies that start after March 15, 2018. The Catalog will list March 15,*  
300 *2018, as the “date requirement begins.” When multiple versions of an FDA-supported*  
301 *standard are listed in the Catalog, sponsors or applicants can select a version to use.*

302

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<sup>21</sup> See 745A(a) Implementation Guidance, section III.F (describing the timetable for implementation of revisions and updates).

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
SEND 2.1.1	2016-09-18	2016-10-03	2016-10-03	2017-03-15	2018-03-15
PDF 2.0	2018-01-15	2018-06-28	2018-06-28	2019-03-15	2020-03-15

### 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 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* 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 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*

349 *be supported by FDA as of April 22, 2018, and sponsors or applicants are encouraged to*  
 350 *use it, the new standard for study data exchange will only be required in submissions for*  
 351 *studies that start after March 15, 2021 (for NDAs, ANDAs, and certain BLAs) and March*  
 352 *15, 2022 (for certain INDs). The Catalog will list March 15, 2021, as the “date*  
 353 *requirement begins” for NDAs, ANDAs and certain BLAs and March 15, 2022, as the*  
 354 *“date the requirement begins” for certain INDs.*  
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358 Table 3: Example of an Implementation Timetable for a New Standard  
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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 <sup>22</sup> 2022-03-15 <sup>23</sup>

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 369 **III. ADDITIONAL SUPPORT**

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 371 **A. Meetings With FDA**  
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373 Sponsors and applicants may use established FDA-sponsor meetings (e.g., pre-IND and end-of-  
 374 phase 2) to discuss the study data standardization plan and to raise data standardization issues (if  
 375 any) related to NDAs and BLAs. Discussions about nonclinical study data standardization plans  
 376 may be initiated at the pre-IND stage and should continue throughout development. Initial  
 377 discussions about which data standards to use for study data should take place as early as  
 378 possible during drug development, especially for safety data, but should in any event occur no  
 379 later than the end of phase 2. In general, the premarketing application meeting is considered too  
 380 late to initiate data standardization discussions. For ANDAs, sponsors and applicants should  
 381 discuss the study data standardization plan before the initiation of their bioequivalence program.  
 382

383 Sponsors and applicants may submit technical questions related to data standards at any time to  
 384 the technical support team identified by each Center (see the Study Data Standards Resources  
 385 Web page for specific contact information). Sponsors and applicants may also request a separate  
 386 Type C meeting to discuss substantive data standardization issues for NDAs and BLAs. An  
 387 example of such an issue might be a sponsor’s desire to use a standard (e.g., therapeutic area  
 388 standard in SDTM format) that is not currently supported by FDA. The request should include  
 389 adequate information to identify the appropriate FDA staff necessary to discuss the proposed  
 390 agenda items.  
 391

<sup>22</sup> For NDAs, ANDAs, and certain BLAs. See section II.A.

<sup>23</sup> For certain INDs. See section II.A.

392           **B. Implementation Support**  
393

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

401  
402   Sponsors and applicants with questions on how to implement the FDA-supported study data  
403   standards should contact and work with FDA technical staff. Contact information is provided on  
404   the Study Data Standards Resources Web page. Sponsors and applicants may also arrange to  
405   submit sample data for a pre-submission technical review. The technical staff welcomes any  
406   additional feedback or comments regarding the information posted on the Web page.