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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)  
Oncology Center of Excellence (OCE)**

**June 2021  
Electronic Submissions**

**Revision 2**

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# Providing Regulatory Submissions in Electronic Format — Standardized Study Data Guidance for Industry

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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> |
| May 2021     | <p>Section II.A. For what submission types is an electronic submission of standardized study data required?</p> <ul style="list-style-type: none"> <li>• 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</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 implementation periods for new study standards and version updates, in alignment with the <i>Federal Register</i> 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)</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

7   **I.       INTRODUCTION**  
8

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

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

29  
30   In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to  
31 implement the statutory electronic submission requirements in guidance. Accordingly, as  
32 indicated by the use of the words *must* or *required*, this document is not subject to the usual

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<sup>1</sup> 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).

<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.

33 restrictions in FDA’s good guidance practice regulations, such as the requirement that guidances  
34 not establish legally enforceable responsibilities. See 21 CFR 10.115(d).  
35

36 To comply with the good guidance practice regulations and make sure that regulated entities and  
37 the public understand that guidance documents are nonbinding, FDA guidances ordinarily  
38 contain standard language explaining that guidances should be viewed only as recommendations  
39 unless specific regulatory or statutory requirements are cited. FDA is not including this standard  
40 language in this guidance because it is not an accurate description of the effects of this guidance.  
41 Insofar as this guidance specifies the format for electronic submissions or provides for  
42 exemptions pursuant to section 745A(a) of the FD&C Act, it will have binding effect.  
43

## 44 45 **II. REQUIREMENT TO SUBMIT ELECTRONIC STANDARDIZED STUDY DATA**

### 46 47 **A. For What Submission Types Is an Electronic Submission of Standardized** 48 **Study Data Required?**

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

- 52
- 53 • Certain investigational new drug applications (INDs)<sup>4,5</sup>
- 54 • New drug applications (NDAs)
- 55 • Abbreviated new drug applications (ANDAs)
- 56 • Certain biologics license applications (BLAs)<sup>6</sup>
- 57

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

---

<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 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.

<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*.

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

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

65  
66 Please see the Study Data Technical Conformance Guide (Conformance Guide)<sup>7</sup> for clarification  
67 regarding when electronic standardized study data are required as part of a submission to address  
68 a public health emergency declared by the Secretary of Health and Human Services in  
69 accordance with section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)).

70  
71 **B. What Types of Submissions Are Exempted from the Electronic Submission**  
72 **Requirements for Standardized Study Data?**

73  
74 Section 745A(a) of the FD&C Act allows FDA to establish exemptions from the electronic  
75 submission requirements. Accordingly, FDA has exempted all submissions regarding  
76 noncommercial INDs from the requirements under section 745A(a).<sup>8</sup> For purposes of this  
77 guidance, the term *noncommercial IND* refers to an IND for a product that is not intended for  
78 commercial distribution and includes investigator-sponsored INDs and expanded access INDs  
79 (e.g., emergency use INDs and treatment INDs).<sup>9</sup> Although such submissions will be exempt,  
80 FDA will accept their voluntary submission in a standardized electronic format as described in  
81 this guidance document.

82  
83 **C. What Are the Requirements That Must Be Followed for Electronic**  
84 **Submission of Standardized Study Data?**

85  
86 Under section 745A(a) of the FD&C Act, electronic submissions “shall be submitted in such  
87 electronic format as specified by [FDA].” FDA has determined that study data contained in the  
88 electronic submissions described in section II.A must be in a format that the Agency can process,  
89 review, and archive. Currently, the Agency can process, review, and archive electronic  
90 submissions of clinical and nonclinical study data that use the standards specified in the Data  
91 Standards Catalog (Catalog).<sup>10</sup>

92  
93 The Catalog provides a listing of currently supported<sup>11</sup> and/or required standards, their uses, the  
94 date FDA will begin (or has begun) to support a particular standard, the date such support ends

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

<sup>8</sup> See 745A(a) Implementation Guidance, section III.B.

<sup>9</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>10</sup> Available at <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>.

<sup>11</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.

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

100  
101 When planning a study (including the design of case report forms, data management systems,  
102 and statistical analysis plans), the sponsor or applicant must determine which FDA-supported  
103 standards to use or request a waiver of those requirements as described in section II.D. There  
104 may be versions of a standard available that are not yet supported by FDA (e.g., specific SDTM  
105 or ADaM versions) or there may be FDA-supported standards that, currently, have only specific  
106 components developed (e.g., SEND study types).<sup>12</sup> See section III for additional support on data  
107 standards questions or issues. FDA-supported standards listed in the Catalog are categorized as  
108 follows:

109  
110 *1. Exchange Format Standards*

111  
112 An exchange format standard specifies a particular way that information is encoded in a  
113 computer file. Specifications for a format permit the file to be written according to a standard,  
114 opened for use or alteration, and written back to a storage medium for later access. Some  
115 exchange formats in widespread use are proprietary; others are open source. Examples of format  
116 standards currently supported by FDA include: Adobe Portable Document Format (pdf), SAS  
117 Institute Transport File format (xpt), and Extensible Markup Language (xml).

118  
119 *2. Study Data Standard*

120  
121 Study data standards describe a standard way of exchanging study data between computer  
122 systems. Study data standards may describe the data elements and relationships necessary to  
123 achieve the unambiguous exchange of information between disparate information systems. The  
124 Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model  
125 (SDTM) and Standard Exchange for Nonclinical Data (SEND) are examples of study data  
126 standards for tabulations data.

127  
128 Analysis standards describe a standard data structure intended to support analysis. Analysis  
129 standards include extraction, transformation, and derivations of the original data. The CDISC  
130 Analysis Data Model (ADaM) is an example of a study data standard for analysis data.

131  

---

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

132 3. *Controlled Terminology Standard*

133  
134 The use of controlled terminology standards, also known as vocabularies, is an important  
135 component of study data standardization and is a critical component of achieving semantically  
136 interoperable data exchange.<sup>13</sup> Controlled terminology standards specify the key concepts that  
137 are represented as preferred terms, definitions, synonyms, codes, and code systems. Controlled  
138 terminology standards are maintained by external organizations (i.e., external to the sponsor or  
139 applicant). Sponsor- or applicant-defined custom terms are not considered controlled  
140 terminologies. However, some controlled terminologies are extensible and permit additions to  
141 existing codelists. It is the expectation that sponsors or applicants will use the controlled  
142 terminologies maintained by external organizations as the standard. Examples of controlled  
143 terminology standards include:

- 145 • The National Drug File (NDF) — Reference Terminology for drug classifications<sup>14</sup>
- 146 • CDISC Controlled Terminology<sup>15</sup>
- 147 • Medical Dictionary for Regulatory Activities (MedDRA)<sup>16</sup>

148  
149 **D. Will FDA Issue Waivers of the Electronic Submission Requirements for**  
150 **Standardized Study Data?**

151  
152 Electronic submissions of study data must be in a format that FDA can review, process, and  
153 archive. Currently, the Agency can process, review, and archive electronic submissions of study  
154 data that use the standards specified in the Catalog posted to the FDA’s Study Data Standards  
155 Resources web page.<sup>17</sup>

156  
157 FDA will not provide waivers to submit data that do not conform to any FDA-supported study  
158 data standard. However, sponsors or applicants may apply for a waiver from the requirement to  
159 use specific versions of FDA-supported standards for the submission of study data. Generally, a  
160 waiver will enable a sponsor or applicant to submit study data electronically using a version of a  
161 standard that was previously supported by FDA.

162  
163 To apply for a waiver from the requirement to submit study data using a version of a standard  
164 that is not supported as set forth in the Catalog, an email request must be sent to the FDA  
165 technical staff at [cdcr-edata@fda.hhs.gov](mailto:cdcr-edata@fda.hhs.gov) for requests related to CDER-regulated submissions

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<sup>13</sup> See the Study Data Technical Conformance Guide for a detailed discussion of semantic interoperability.

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

<sup>15</sup> CDISC Controlled Terminology is available at  
<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>.

<sup>16</sup> MedDRA is available at <http://www.meddra.org/>.

<sup>17</sup> See <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>.

166 and at [cber-edata@fda.hhs.gov](mailto:cber-edata@fda.hhs.gov) for requests related to CBER-regulated submissions. The subject  
167 line of the email should start with “Waiver Request.” The body of the email should contain the  
168 following:

- 169 1. Contact person’s name (this will be the main contact)
- 170 2. Contact person’s company name
- 171 3. Contact person’s mailing address
- 172 4. Contact person’s phone number
- 173 5. Contact person’s email address
- 174 6. Relevant submission types and numbers
- 175 7. The specific requirement or requirements from which the sponsor or applicant is requesting a  
176 waiver
- 177 8. The reason the sponsor or applicant believes that the waiver is necessary
- 178 9. A description of the alternative or alternatives that the sponsor intends to use
- 179

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

#### 188 189 **E. When Will Electronic Submission of Standardized Study Data Be Required?**

190  
191 The requirement to submit using a particular standard is dependent on its support by FDA as  
192 listed in the Catalog at the time of study start.<sup>18</sup> FDA recognizes that standards development  
193 organizations may release version updates to standards in the interval between the start of a study  
194 and the submission of study data to the Agency. The Catalog may list more than one version of a  
195 supported standard (e.g., PDF versions 1.4 - 1.7, SDTM versions 1.2 and 1.3, Define versions 1.0  
196 and 2.0, and MedDRA versions 8 or later). Sponsors or applicants are encouraged to use the  
197 latest version listed in the Catalog. However, when there are multiple versions of a standard  
198 listed, sponsors or applicants can select the version to use for their study.

199  
200 The initial timetable for the implementation of electronic submission requirements for study data  
201 is described in section II.E.1. Since the initial timetable has passed, FDA may announce the  
202 future availability of new standards and version updates to existing standards through *Federal*  
203 *Register* notices. Such a *Federal Register* notice will specify the next calendar March 15 date  
204 following the publication of the *Federal Register* notice as the start date for the implementation  
205 period (*transition date*) used to calculate when the new standard or version update will be  
206 required in a submission. The transition date does not indicate the date on which the requirement

---

<sup>18</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), 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>.

207 to use a particular standard commences. Instead, the transition date indicates the beginning date  
208 of the implementation period, which will be consistent with the timetables set forth in the  
209 745A(a) Implementation Guidance, to provide industry with notice before requiring the new  
210 standard or version update in submissions. The use of a standard will be required in submissions  
211 only after the implementation period has ended. This use of the *transition date* approach should  
212 provide sponsors and applicants with a consistent and predictable implementation timetable for  
213 new standards and version updates to existing standards. Examples using the *transition date*  
214 approach are listed below:

215  
216 *Example 1:* A *Federal Register* notice is published on September 5, 2022, announcing the  
217 availability of a new standard. The *transition date* is the next calendar March 15 date, March  
218 15, 2023, which starts the implementation period for the new standard. The new standard  
219 will be required in submissions for studies that start 24 months after the transition date,  
220 which is March 15, 2025.

221  
222 *Example 2:* A *Federal Register* notice is published on February 14, 2022, announcing the  
223 availability of a new standard. The *transition date* is the next calendar March 15 date, March  
224 15, 2022, which starts the implementation period for the new standard. The new standard  
225 will be required in submissions for studies that start 24 months after the transition date,  
226 which is March 15, 2024.

227  
228 *Example 3:* A *Federal Register* notice is published on April 6, 2022, announcing the  
229 availability of a version update to an existing standard. The *transition date* is the next  
230 calendar March 15 date, March 15, 2023, which starts the implementation period for the  
231 version update. The version update will be required in submissions for studies that start 12  
232 months after the transition date, which is March 15, 2024.

#### 233 234 1. *Initial Timetable for the Implementation of Electronic Submission Requirements*

235  
236 After the publication of the initial final version of this guidance on December 18, 2014 (2014  
237 Final eStudy Data Guidance), all studies with a start date 24 months after that publication date  
238 (December 18, 2016) for NDA, ANDA, and certain BLA submissions and studies with a start  
239 date 36 months after the publication of the 2014 Final eStudy Data Guidance (December 18,  
240 2017) for certain IND submissions must use the appropriate FDA-supported standards, formats,  
241 and terminologies specified in the Catalog (see section II.C)). As noted above, to ensure that  
242 FDA can assess whether sponsors and applicants are subject to particular study data format  
243 requirements, FDA must rely on information provided by the submitter about study start date and  
244 the file type being submitted. Generally, the datasets necessary to assess conformance to the  
245 standard include the demographic dataset file (SDTM and SEND dm.xpt), the subject level  
246 analysis dataset file (ADaM adsl.xpt), and the define.xml file (SDTM, SEND, and ADaM). For  
247 further details, see the Technical Rejection Criteria for Study Data, the Conformance Guide, and  
248 the Data Standards Catalog.<sup>19</sup>  
249

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<sup>19</sup> 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.<sup>20</sup> 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  |

<sup>20</sup> See the 745A(a) Implementation Guidance, section III.F (describing the timetable for implementation of revisions and updates).

284 3. *New Standards*

285  
286 Given that the 24- and 36-month initial implementation timetables described in section II.E.1  
287 have passed since the publication of the 2014 Final eStudy Data Guidance, FDA may announce  
288 in a *Federal Register* notice (and guidance, if necessary) its support for new standards. New  
289 standards are those that have not been supported by FDA and are not listed in the Catalog at the  
290 time this guidance is finalized. New standards will be required in submissions for studies that  
291 start no earlier than 24 months after the transition date specified in a *Federal Register* notice  
292 announcing FDA’s determination of the new standard as one that it can process, review, and  
293 archive. The *Federal Register* notice of availability will specify the *transition date* for all  
294 version updates (with the month and day for the *transition date* corresponding to March 15).  
295

296 Below is an example and accompanying table (Table 2) of how a new study data standard would  
297 be implemented.  
298

299 *On February 15, 2024, an SDO releases a new study data standard. On May 6, 2025, FDA*  
300 *publishes a Federal Register notice announcing support of the new study data standard and*  
301 *updates the Catalog. The date support begins for this new standard will be May 6, 2025.*  
302 *The transition date posted in the Federal Register notice is March 15, 2026. The date the*  
303 *requirement begins will be March 15, 2028. Sponsors or applicants are encouraged to begin*  
304 *using the new standard on May 6, 2025. The new standard will only be required in*  
305 *submissions for studies that start after March 15, 2028.*  
306

307 **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  |

308  
309 **III. ADDITIONAL SUPPORT**

310 **A. Meetings With FDA**

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312  
313 Sponsors and applicants may use established FDA-sponsor meetings (e.g., pre-IND and end-of-  
314 phase 2) to discuss the study data standardization plan and to raise data standardization issues (if  
315 any) related to NDAs and BLAs. Discussions about nonclinical study data standardization plans  
316 may be initiated at the pre-IND stage and should continue throughout development. Initial  
317 discussions about which data standards to use for study data should take place as early as  
318 possible during drug development, especially for safety data, but should in any event occur no  
319 later than the end of phase 2. In general, the premarketing application meeting is considered too  
320 late to initiate data standardization discussions. For ANDAs, sponsors and applicants should  
321 discuss the study data standardization plan before the initiation of their bioequivalence program.  
322  
323

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

## 332 **B. Implementation Support**

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

340 Sponsors and applicants with questions on how to implement the FDA-supported study data  
341 standards should contact and work with FDA technical staff. Contact information is provided on  
342 the Study Data Standards Resources web page. Sponsors and applicants may also arrange to  
343 submit sample data for a presubmission technical review. The technical staff welcomes any  
344 additional feedback or comments regarding the information posted on the web page.  
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347