Business & Decision Life Sciences

FDA Guidance on Standardized Study Data

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15 October 2014
Today’s Agenda

How are these 3 documents related?

When will they be final?

What do they contain?

What next steps should my organization be taking?
What is the timeframe?

NOW
• All documents are draft

07-May 2014
• Public comment Period ends

FY 2015
• FDA plan to publish final versions
What do they contain?

- Guidance on Submissions in Electronic Format--Submissions under the Federal Food, Drug, and Cosmetic Act
- Guidance on Submissions in Electronic Format--Standardized Study Data
- Study Data Technical Conformance Guide and Data Standards Catalog
Guidance for Industry
Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document contact (CDER) Division of Drug Information at 301-796-3400 or (CBER) Office of Communication, Outreach, and Development at 800-835-4709 or 301-827-1800.

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)

February 2014
Electronic Submissions
What does (and does not) require eSubmission?

- Certain INDs
- NDAs
- ANDAs
- Certain BLAs
- All subsequent amendments, supplements and reports to the above (even if original submission was not electronic)

- Those described in section 561 of FD&C Act
- Devices regulated by CBER as biological
- Other exemptions & waivers will be described in the applicable individual guidance
How will requirements be implemented?

- Posted on FDA’s Drug Guidance page and Vaccines; Blood and Biologics page
- Announced in list of new, revised & withdrawn guidances
- Notice published in Federal Register announcing comment period for draft guidance

- As draft...
- Federal Register will also announce the 'required date'

- As final...
## When will electronic submissions be required?

<table>
<thead>
<tr>
<th>Sponsors will have at least 24 months notice</th>
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<td>Each guidance will specify the exact timetable for specific submissions</td>
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Example 1: New Format (with 24-Month Implementation Period)

FDA issues a draft individual guidance specifying new format(s) for electronic submission of data contained in certain NDAs, ANDAs, BLAs, and INDs, and publishes a Federal Register notice announcing availability of the draft guidance. Following the comment period, FDA finalizes the guidance and publishes another Federal Register notice announcing availability of the final guidance. The Federal Register notice also provides that the specified format(s) will be required 24 months after the date of publication of the notice. After the 24-month implementation period has passed, the guidance will have binding effect and the electronic formats specified in the guidance must be used for the submission types identified in the guidance document.
Example 4: Correction to Required Format

FDA finalizes an individual guidance specifying new format(s) for electronic submission of data contained in certain NDAs, ANDAs, BLAs, and INDs, and the implementation timetable specified in the guidance has passed. The guidance has binding effect and the electronic formats specified in the guidance must be used for the submission types identified in the guidance document. Some time later, FDA announces a correction to one or more of the formats specified in the final guidance. The announcement also provides that the corrected format must be used 2 weeks after the date of the announcement.
What do they contain?

- Guidance on Submissions in Electronic Format--Submissions under the Federal Food, Drug, and Cosmetic Act
- Guidance on Submissions in Electronic Format--Standardized Study Data
- Study Data Technical Conformance Guide and Data Standards Catalog
Guidance for Industry

Providing Regulatory Submissions in Electronic Format — Standardized Study Data

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For questions regarding this draft document contact (CDER) Ron Utzurrum at 301-796-5333, (CBER) Office of Communication, Outreach and Development (OCID) at 301-827-1800 or 1-800-835-4709.

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February 2014
Electronic Submissions
Revision 1
What are the requirements?

- FDA Supported Standard
  - File format standards (PDF, XPT, TXT, XML)
  - Study Data Exchange standards (e.g. SDTM)
  - Analysis Standards (e.g. ADaM, some SDTM datasets)
  - Terminology Standards (e.g. CDISC CT, MedDRA, NDF)
eStudy Guidance: Waivers

No waivers will be granted for submission of data in non-FDA supported study data standard.

Can request waiver to allow a use of a non-current version of a supported standard.

FDA will notify in writing if waiver has been granted.
eStudy Guidance: Timetable

NDAs, ANDAs and certain BLAs
Must follow details in the Data Standards Catalogue for all studies with earliest informed consent date 24 months after Federal Register notice of final guidance availability

Certain INDs
Must use specified formats in studies with earliest informed consent date 36 months after Federal Register notice of availability
eStudy Guidance: Support

**Established Meetings**
- Pre-IND and end-of-Phase II
- Premarketing application meeting is considered too late for these discussions

**e-mail lists**
- Technical questions may be submitted to the appropriate FDA e-mail list

**Conformance Guide**
- Refer to the Draft Study Data Technical Conformance Guide for non-binding details on submitting standardized study data
What do they contain?

Guidance on Submissions in Electronic Format—Submissions under the Federal Food, Drug, and Cosmetic Act

Guidance on Submissions in Electronic Format—Standardized Study Data

Study Data Technical Conformance Guide and Data Standards Catalog
STUDY DATA
TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following Guidance Document(s):

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

For questions regarding this technical specifications document, contact CDER at cdex-ednet@fda.hhs.gov or CBER at obex-ednet@fda.hhs.gov

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February 2014
The document is a mix between the CDER common data issues and new information.
What are the new sections?

A complete data guide
Assist FDA in identifying potential data standardization issues early in the development program.

- Study designs
- Planned data standards
- List of studies
- Non-conformity report

Study Data Standardization Plan
Read documents in detail looking for:

- Requests that contradict SDTM or ADaM
- Processes that will cause your organization difficulties
- Anything that is unclear

Provide Comments

- Important opportunity to comment on the Common Data Standards Issues content
Participate Today!
Submit your comments on proposed regulations and related documents published by the U.S. Federal government. You can also use this site to search and review original regulatory documents as well as comments submitted by others.
Help improve Federal regulations by submitting your comments.

Search for: Rules, Comments, Adjudications or Supporting Documents:

What's Trending

- Presidential Permit Applications: TransCanada Keystone Pipeline, L.P. National Interest Determination
  Closing on Mar 04, 2014
- Requests for Information: Enhancing Agricultural Coexistence; Extension of Comment Period
  Closing on Mar 04, 2014
- Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare...
  Closing on Mar 07, 2014
- Standards of Performance for Greenhouse Gas Emissions from New Stationary Sources: Electric Utility Generating Units

Comments Due Soon
Today (18)
Next 3 Days (94)
Next 7 Days (235)
Next 15 Days (420)
Next 30 Days (807)
Next 90 Days (1,175)

Newly Posted
Today (107)
Last 3 Days (341)
Last 7 Days (651)
Last 15 Days (1,333)
Last 30 Days (2,374)
Last 90 Days (2,065)
5 top tips on commenting

Visit www.regulations.gov

Contact FDA (email) with questions

One well-supported claim can make a difference

Be concise but support your claims

Refer to specific sections or lines in the document
Thank you for your attention.

Join us for a coffee at our stand.

London, United Kingdom, 13 OCT 2014