REAGAN-UDALL FOUNDATION FOR THE FDA

# Data Standards for Drug and Biological Product Submissions Containing Real-World Data

## Real-World Data Webinar Series

December 3, 2021
1-2 pm Eastern Time

This webinar is part of a series hosted by the Reagan-Udall Foundation for the FDA, in collaboration with the U.S. Food and Drug Administration (FDA). This series is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of $56,097 in federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

REAGAN-UDALL FOUNDATION FOR THE FDA

# Welcome

**Susan C. Winckler, RPh, Esq.**
Reagan-Udall Foundation for the FDA

REAGAN-UDALL FOUNDATION FOR THE FDA

# Thank you for joining

This webinar is being recorded. The slides and video recording will be available after the meeting.

If you'd like to ask a question, you may enter it in the Zoom Q&A. We will get to as many questions as time allows.

Speakers and presenters will not address questions regarding any pending regulatory action.

Submit either electronic or written comments on the draft guidance by January 21, 2022 to Docket Number FDA-2021-D-0548 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

# Agenda

| | |
|---|---|
| 1 pm | **Welcome** |
| 1:05 pm | **Opening Remarks** |
| 1:10 pm | **Overview of Draft Guidance** |
| 1:40 pm | **Question and Answer Panel** |
| 1:55 pm | **Closing Remarks** |
| 2 pm | **Adjourn** |

All times listed in Eastern Time

# Why Are We Here Today?

Provide an overview and address questions from the public about the draft guidance titled *Data Standards for Drug and Biological Product Submissions Containing Real-World Data.*

Submit either electronic or written comments on the draft guidance by January 21, 2022 to Docket Number FDA-2021-D-0548 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance

REAGAN-UDALL FOUNDATION FOR THE FDA

# Opening Remarks

**John Concato, MD, MS, MPH**
Associate Director for Real-World Evidence Analytics, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

*Public Webinar*

# Data Standards for Drug and Biological Product Submissions Containing Real-World Data: Draft Guidance for Industry

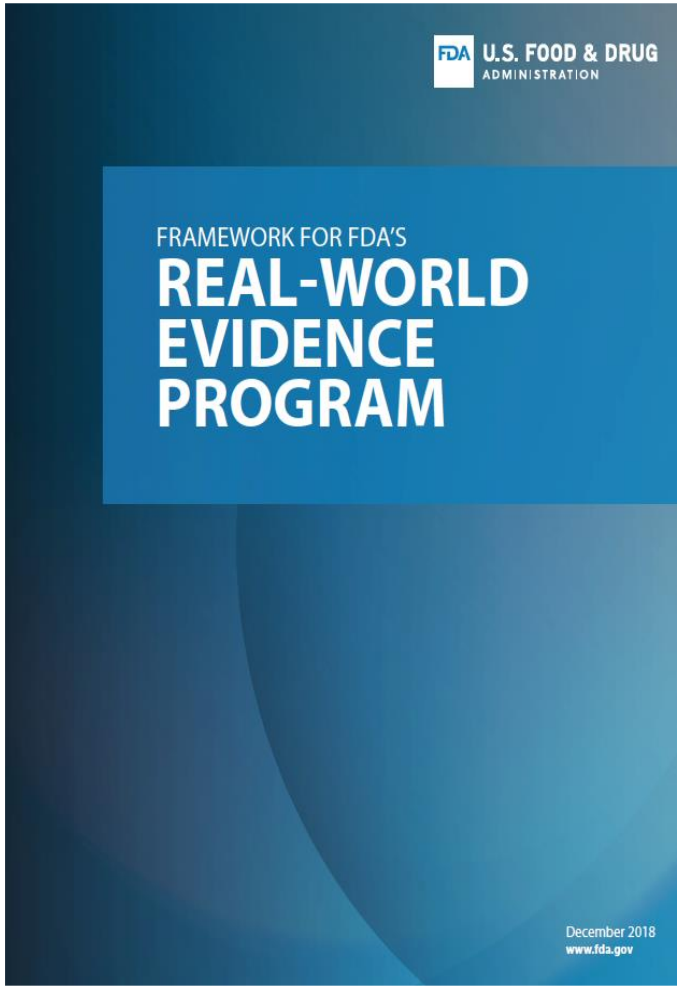
## 3 December 2021

**John Concato, MD, MS, MPH**
**Associate Director for Real-World Evidence Analytics**
**Office of Medical Policy, Center for Drug Evaluation and Research**
**U.S. Food and Drug Administration**

# 21st Century Cures Act of 2016 – *status as of 2021*


- **FDA *has established* a program to evaluate the potential use of real-world evidence (RWE) to:**
  - **Support new indication for a drug approved under section 505(c)**
  - **Satisfy post-approval study requirements**
- **Standard for substantial evidence *remains unchanged*; commitments met under Prescription Drug User Fee Act (PDUFA) VI**
- **Draft framework *issued December 2018***
  - **Describes sources of RWE, challenges, pilot opportunities, etc.**
- **Draft guidance for industry *issued September & October 2021***
  - **'EHR/Claims' guidance; 'Data Standards' guidance**

# FDA RWE Framework (2018)




- **Applies to Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER)**
- **Multifaceted program to implement RWE:**
  - **internal processes**
  - **external stakeholder engagement**
  - **demonstration projects**
  - **guidance development** ←

# CDER-CBER RWE Guidance Series

## CDER Guidance Agenda
## New & Revised Draft Guidance Documents
## Planned for Publication in Calendar Year 2021[1]

### CATEGORY – Real World Data/Real World Evidence (RWD/RWE)[2]

- Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products
- Data Standards for Drug and Biological Product Submissions Containing Real-World Data
- Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products
- Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products

[1] Final guidance documents planned for publication in calendar year 2021 are not included on this list. CDER is not bound by this list of topics, nor required to issue every guidance document on this list. We are not precluded from developing guidance documents on topics not on this list.

[2] New category added since the January 2021 posting

# ‘Data Standards’ Guidance

**G. Scott Gordon, PhD**
Senior Health Informatics Officer, Office of Strategic Programs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

REAGAN-UDALL FOUNDATION FOR THE FDA

# Overview of Draft Guidance

**Massoud Motamed, PhD**
Biology Reviewer, Office of Tissue and Advanced Therapies, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

*Public Webinar*

# Data Standards for Drug and Biological Product Submissions Containing Real-World Data: Draft Guidance for Industry

## 3 December 2021


**G. Scott Gordon, Ph.D.**
Office of Strategic Programs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

**Massoud Motamed, Ph.D.**
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

# Agenda

- Background on 745A(a) and Data Standards Requirements
- Walk-through selective key points of the Draft Guidance
- Question & Answer

# What are we going to talk about?

1. How FDA specifies study data standards requirements for submission
2. Guidance on where real-world data fits into these requirements
3. Guidance on preparing study data obtained from real-world data sources for submission using current study data standards

# REGULATORY BASIS FOR DATA STANDARDS REQUIREMENTS

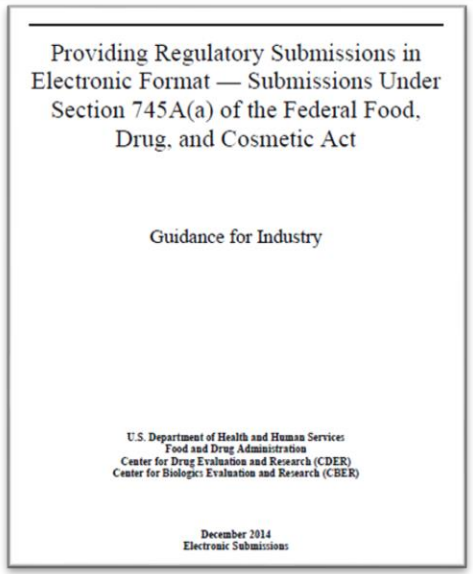
# Regulatory basis for data standards requirements: The Federal Food, Drug, and Cosmetic Act

- **Section 745A(a)(1) of the FD&C Act describes the general scope of section 745A(a) and provides that submissions under NDAs, ANDAs, certain BLAs, and certain INDs must be in electronic format specified in FDA guidance:**
  - **Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act shall be submitted in such electronic format as specified by the Secretary in such guidance.**

- **Section 745A(a)(2) states that the guidance issued by FDA may provide a timetable for future standards and criteria for waivers and exemptions:**
  - **In the guidance under paragraph (1), the Secretary may (A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and (B) set forth criteria for waivers of and exemptions from the requirements of this subsection.**

# How the FDA communicates technical requirements for submitting study data

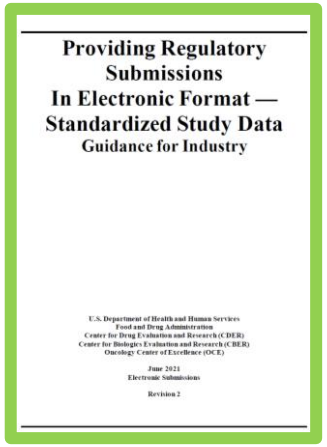
*Study data* standards describe a standard way of exchanging study data between computer systems.


Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

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)

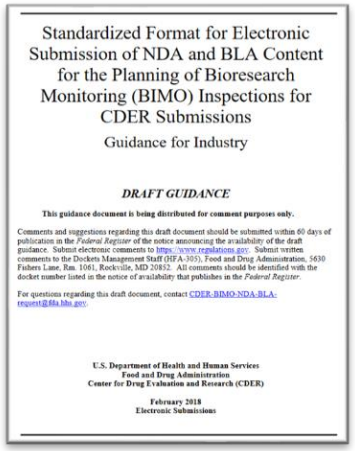
December 2014
Electronic Submissions


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


Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions

Guidance for Industry

*DRAFT GUIDANCE*

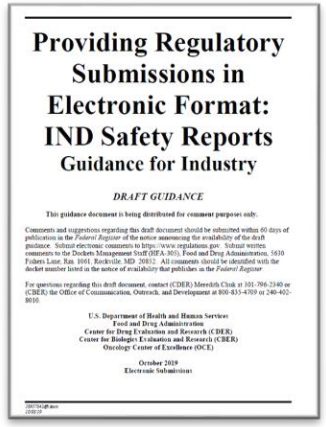
This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (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-BIMO-NDA-BLA-request@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

February 2018
Electronic Submissions


Providing Regulatory Submissions in Electronic Format: IND Safety Reports
Guidance for Industry

*DRAFT GUIDANCE*

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (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*.

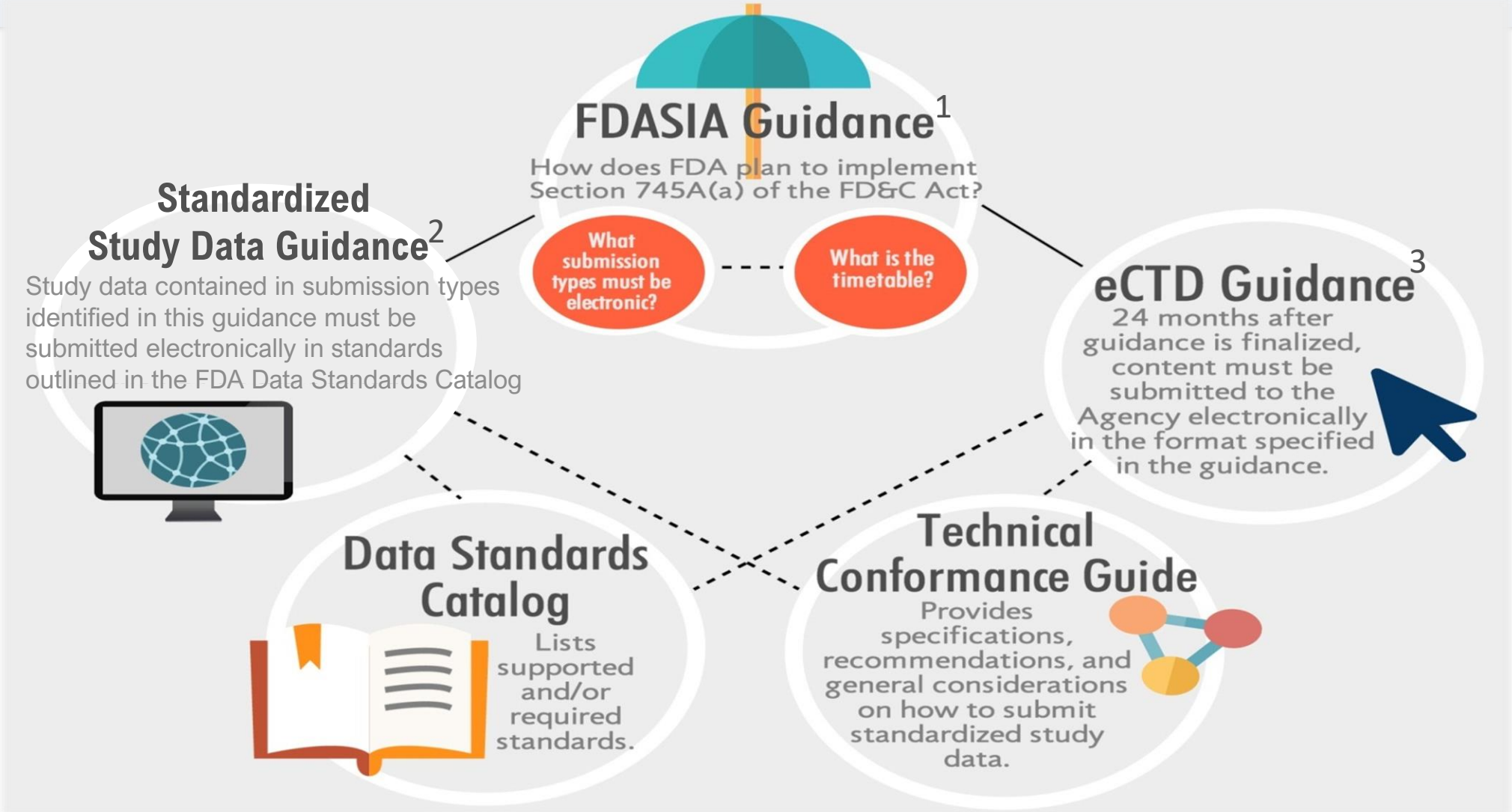
For questions regarding this draft document, contact (CDER) Meredith Clink at 301-796-2140 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

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)

October 2019
Electronic Submissions

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

# Electronic study data standards resources




1 *Providing Regulatory Submissions in Electronic Format - Submissions Under Section 745A(a) of the FD&C Act: Guidance for Industry (Dec. 2014)*
2 *Providing Regulatory Submissions in Electronic Format - Standardized Study Data: Guidance for Industry (June 2021)*
3 *Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*

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

# OVERVIEW OF DRAFT GUIDANCE KEY MESSAGES

# Sections of Draft Guidance



**October 2021**
**Real-World Data/Real-World Evidence (RWD/RWE)**

***Contains Nonbinding Recommendations***

*Draft — Not for Implementation*

# Regulatory background and central message of guidance

Section II

Guidance Pages 2-3

## II. REGULATORY BACKGROUND

Under section 745A(a) of the FD&C Act, at least 24 months after the issuance of a final guidance document in which 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.[8] The guidance for industry, *Providing Regulatory Submissions In Electronic Format — Standardized Study Data* (Study Data Guidance), and the technical specifications referenced therein describe electronic submission requirements under section 745A(a) of the FD&C Act for clinical and nonclinical study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs) submitted to the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research.[9] Given that these electronic submission requirements apply to study data submitted in the covered application types, they apply to RWD that is submitted as study data in such applications. That is, RWD submitted as study data to NDAs, ANDAs, certain BLAs, and certain INDs, as further described in section II.A of the Study Data Guidance, must be in an electronic format that the Agency can process, review, and archive, unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver.[10] Currently, as stated in the Study Data Guidance, the Agency can process, review, and archive electronic submissions of clinical and nonclinical study data (including those derived from RWD sources) that use the standards specified in the Data Standards Catalog (Catalog).[11] As that guidance explains, the Catalog provides a listing of currently supported[12] and/or required standards, their uses, the date FDA will begin (or has begun) to support a particular standard, the date such 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. FDA is issuing this guidance to provide recommendations to sponsors for complying with section 745A(a) of the FD&C Act using standards specified in the Catalog when submitting study data derived from RWD sources in applicable drug submissions.

# Regulatory background and central message of guidance – 1 of 3

Section II

Guidance Page 2

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**FDA specifies the data standards that must be used for submission of study data**

# Regulatory background and central message of guidance – 2 of 3

**Section II**

**Guidance Page 2**

Given that these electronic submission requirements apply to study data submitted in the covered application types, they apply to RWD that is submitted as study data in such applications. That is, RWD submitted as study data to NDAs, ANDAs, certain BLAs, and certain INDs, as further described in section II.A of the Study Data Guidance, must be in an electronic format that the Agency can process, review, and archive, unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver.[10]

**FDA specifies the data standards that must be used for submission of study data**

**Study data standards requirements apply to RWD submitted as study data**

# Regulatory background and central message of guidance – 3 of 3

**Section II**

**Guidance Page 3**

Currently, as stated in the Study Data Guidance, the Agency can process, review, and archive electronic submissions of clinical and nonclinical study data (including those derived from RWD sources) that use the standards specified in the Data Standards Catalog (Catalog).[11] As that guidance explains, the Catalog provides a listing of currently supported[12] and/or required standards, their uses, the date FDA will begin (or has begun) to support a particular standard, the date such 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. FDA is issuing this guidance to provide recommendations to sponsors for complying with section 745A(a) of the FD&C Act using standards specified in the Catalog when submitting study data derived from RWD sources in applicable drug submissions.

**FDA specifies the data standards that must be used for submission of study data**

**Study data standards requirements apply to RWD submitted as study data**

**Current allowable study data standards are found in the Data Standards Catalog**

# FDA recognizes many challenges in use of RWD for regulatory submissions

Section III.A.

Guidance Page 3

## III. APPLYING CURRENTLY SUPPORTED DATA STANDARDS TO STUDY DATA DERIVED FROM REAL-WORLD DATA SOURCES

### A. Challenges in Real-World Data Standardization

FDA recognizes the challenges involved in standardizing study data derived from RWD sources for inclusion in applicable drug submissions. These challenges include but are not limited to: (1) the variety of RWD sources and their inconsistent formats (e.g., EHR, registry); (2) the differences in ***source data*** captured regionally and globally using different standards, ***terminologies***, and ***exchange formats*** for the representation of the same or similar data elements[13]; (3) a wide range of methods and algorithms used to create datasets intended to aggregate data; and (4) the many aspects of health care data that can affect the overall quality of the data, including business processes and database structure, inconsistent vocabularies and coding systems, and de-identification methodologies used to protect patient data when shared.

# Documentation of all actions taken with data from source to submitted data

**Section III.B.**

**Guidance Page 3**

## B. Documentation of Processes for Managing Real-World Data

During ***data curation*** and ***data transformation***, adequate processes should be in place to increase confidence in the resultant data. Documentation of these processes may include but are not limited to electronic documentation (i.e., metadata-driven audit trails, quality control procedures, etc.) of data additions, deletions, or alterations from the source data system to the final study analytic data set(s). Sponsors should also document in their applicable drug submission changes to data to conform to the current FDA-supported data standards, and the potential impacts of these changes.

# Further updates in the future

**Section III.C.**

**Guidance Pages 3-4**

## C. Considerations for Conforming Real-World Data to Currently Supported FDA Study Data Standards

FDA plans to issue further guidance and/or to update the Catalog with standards for study data that are derived from RWD sources. Currently, and absent a waiver, sponsors submitting clinical and nonclinical study data (including those derived from RWD sources) in submissions subject to section 745A(a) of the FD&C Act are required to use the formats described in the Study Data Guidance and the supported study data standards listed in the Catalog. Sponsors should refer to the specifications, recommendations, and general considerations provided in the *Study Data Technical Conformance Guide*[14] when submitting study data in an applicable drug submission to FDA. When seeking to conform RWD to data standards supported by FDA, sponsors should consider the relevant data transformations, conversions, or ***mappings*** that may be needed to produce study datasets in the required format in an applicable drug submission.

# Further updates in the future

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# Consider what is needed to make RWD conform to existing data standards requirements

**Section III.C.**

**Guidance Page 4**

When seeking to conform RWD to data standards supported by FDA, sponsors should consider the relevant data transformations, conversions, or ***mappings*** that may be needed to produce study datasets in the required format in an applicable drug submission.

Sponsors should discuss early, with the appropriate FDA review division, any planned submission of study data derived from RWD sources in an applicable drug submission and their approaches for transforming the data to the current FDA-supported data standards. Sponsors should describe these approaches, including in the protocol, data management plan, and/or final study reports.

FDA recognizes that a range of approaches may be used to apply currently supported data standards (e.g., Clinical Data Interchange Standards Consortium's (CDISC's) Study Data Tabulation Model (SDTM)) to RWD sources such as EHR or claims data.

With adequate documentation of the conformance methods used and their rationale, study data derived from RWD can be transformed to SDTM datasets and submitted to FDA in an applicable drug submission.

# Consider what is needed to make RWD conform to existing data standards requirements

**Section III.C.**

**Guidance Page 4**

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**Section III.C.**

**Guidance Page 4**

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With adequate documentation of the conformance methods used and their rationale, study data derived from RWD can be transformed to SDTM datasets and submitted to FDA in an applicable drug submission.

# Deeper-dive: Example of challenges in conceptual mapping from RWD to submission data standards

**Section III.D.**

**Guidance Page 4**

## D. Considerations for Mapping Real-World Data to Study Data Submission Standards

FDA is aware that, for nearly every ***data domain***, there is wide divergence in the terminologies used and their precise meaning between RWD sources and FDA-supported data standards. Examples range from the meaning and specific terms used for race/ethnicity, terminology systems for medications, and interpretation of health care records for vital measurements. Even for seemingly identically recorded variables (e.g., male/female), there can be differences in the way these variables are defined between RWD sources and FDA-supported data standards. For example, sex as a variable may be codified in CDISC's terminology as a concept based on physical characteristics, whereas EHRs may use gender identity. In such cases, sponsors should document the potential impact of mapping the sex variable or other variables to CDISC's terminology on the study findings.

# Reiteration: Documentation is key; guidance on *what* information should be put *where* in submission

**Section III.D.**

**Guidance Pages 4-5**

Documentation of the sponsor's rationale for choosing particular CDISC data elements for RWD and documentation of the differences between the two is critical. The sponsor should provide a description of the general approach and anticipated impact of data mapping as a part of or in an appendix to the ***Study Data Reviewer's Guide*** to highlight the domains involved. Furthermore, the sponsor should include a data dictionary that documents the definition of every data element used and all relevant information about the element, such as its relationships to other data, origin, usage, and format. The technical details, best not included in the Study Data Reviewer's Guide, can be referenced by guiding the reviewers to the detailed mappings in the ***Define-XML*** file (see the Appendix) and relevant dataset/domains.

# Deeper-dive: Example of challenges in transformation from RWD following proposed mappings

**Section III.E.**

**Guidance Page 5**

## E. Considerations for Data Transformations

Sponsors may encounter challenges when transforming RWD into data that are consistent with FDA-supported data standards. Examples of these challenges include (but are not limited to) management of semantic concepts (terms) that are present at multiple locations in a health record (such as medication information), inconsistent coding or miscoding of concepts (e.g., drugs or diagnoses), changes in data collection or coding practices (e.g., International Classification of Diseases-9 (ICD-9) and ICD-10 codes) that occurred during the study, or missing information (either because information is not typically recorded in health care settings or due to inconsistent data entry).

# Re-reiteration: Documentation is key; guidance on *what* information should be put *where* in submission

**Section III.E.**

**Guidance Page 5**

Sponsors should document data challenges encountered during transformation to an FDA-supported data standard and a justification of their approach to enable the application of an FDA-supported data standard. Mapping of standards and terminologies can be handled using the Define-XML (see the Appendix) and domain data files. Given that describing the rationale and justification for approaches used to reconcile any challenges in the source data are likely to require free-text description, in addition, a narrative should be presented in the Study Data Reviewer's Guide, either in the body or as an appendix, with appropriate directions for reviewers to the Define-XML and dataset/domains for more detail, if needed.

# EXAMPLES: Possible ways to approach RWD-to-CDER/CBER study data standards

**Appendix**

**Guidance Page 8**

## APPENDIX: EXAMPLES OF MAPPING HEALTH CARE DATA TO CDISC SDTM

Differences in the coding systems used between real-world data (RWD) and traditional clinical trial data can usually be addressed using the Define-XML file, which is included in all standard Study Data Tabulation Model (SDTM) submissions. The Define-XML file, along with the appropriate use of *Decode* or *Alias* data elements, provides a mechanism for communicating the transformation of external coding systems to the appropriate SDTM controlled terminology.

# EXAMPLES: Possible ways to approach RWD-to-CDER/CBER study data standards – 1 of 3

**Appendix**

**Guidance Page 8**

An example of this approach involves race/ethnicity data, where the Food and Drug administration (FDA) anticipates both heterogeneity among electronic health records (EHRs) as well as between EHR and Clinical Data Interchange Standards Consortium (CDISC) terminologies. In the guidance for industry *Collection of Race and Ethnicity Data in Clinical Trials* (October 2016), FDA recommends that a minimum of five specific categories be used to define race:

(1) American Indian or Alaska Native
(2) Asian
(3) Black or African American
(4) Native Hawaiian or Other Pacific Islander
(5) White

RWD sources, however, may not follow the same system of coding. Given that FDA recommends using the race and ethnicity categorization outlined in the October 2016 guidance mentioned above, a sponsor should map the RWD terminology system to the relevant SDTM terminology. To achieve this objective, the *Decode* or *Alias* elements in Define-XML file can be used to document the conversions to a single nomenclature while ensuring ***traceability***.

# EXAMPLES: Possible ways to approach RWD-to-CDER/CBER study data standards – 2 of 3

**Appendix**

**Guidance Page 9**

**Table 1: Approach to Using Define-XML to Indicate Decision Involved in Transforming Non-Standardized Data (Race Data) to Standardized Data (i.e., SDTM and ADaM)**

*Illustrative example of an approach to representing cross-mapping of coding systems, in this case for Race data, to CDISC coding in the Define-XML file. This table does not recommend **how** to map coding systems to CDISC terminology, only how to represent the mapping choices made.*

| Race [RACE, C74457] | |
|---|---|
| **Permitted Value (Code)*** | **Display Value (Decode)**** |
| AMERICAN INDIAN OR ALASKA NATIVE [*C41259*] | American Indian or Alaska Native, Native American, Native of Alaska |
| ASIAN [*C41260*] | Asian, Chinese |
| BLACK OR AFRICAN AMERICAN [*C16352*] | Black or African American, Black |
| NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER [*C41219*] | Native Hawaiian or Other Pacific Islander, Samoan |
| OTHER [*] | Other |
| WHITE [*C41261*] | White, Mexican |

*Permitted Value (Code): vocabulary that is provided in the study data tabulations and conformant with controlled terminologies.

**Display Value (Decode): vocabulary that was used in the original data set (i.e., EHR value). Code/Decode: Respective CDISC elements.

# EXAMPLES: Possible ways to approach RWD-to-CDER/CBER study data standards – 3 of 3

**Appendix**

**Guidance Page 9**

Various approaches can be applied to permit the use of RWD in applicable drug submissions. Examples of potential approaches are: 1) translating the codes to their mapped structured definitions with subsequent mapping to appropriate CDISC controlled terminologies, which provides the most detail but is labor-intensive; or, alternatively 2) mapping all original codes to the least granular analogous codes, and then mapping those to CDISC controlled terminologies, which is less labor-intensive yet necessitates that detail of a more specific categorization will not be represented in the submitted, standardized dataset. It is up to the sponsors to determine the best approach to mediating data transformation, as well as to document and justify their approach accordingly. However, if details that are essential to the consideration of the safety and effectiveness of a drug are absent, the latter approach may not be appropriate. Whatever approach is used, the application of *Decode* to achieve CDISC standard controlled terminology is one mechanism to document the normalization of nomenclature into a format developed by CDISC.

# What we talked about – 1 of 3

1. How FDA specifies study data standards requirements for submission

   - FDA specifies the data standards that must be used for submission of study data
   - FDA requirements apply to RWD submitted as study data in submissions subject to section 745A(a) of the FD&C Act
   - Current allowable study data standards are found in the Data Standards Catalog

# What we talked about – 2 of 3

## 2. Guidance on where RWD fits into these requirements

- FDA recognizes challenges in using data standards not optimized for RWD sources
- FDA plans to issue further guidance and/or to update the Catalog with standards for study data that are derived from RWD
- Until then, current Catalog study data standards apply to submissions subject to section 745A(a) of the FD&C Act

# What we talked about – 3 of 3

## 3. Guidance on preparing study data with RWD for submission using current study data standards

- FDA recognizes there is no "one size fits all" approach to using current data standards for study data derived from RWD sources
- Sponsors should discuss possible approaches with FDA as early as possible
- All data transformations, mappings, etc., should be documented
- Examples provided in the guidance Appendix are purely illustrative

# Take-Home Messages for RWD and Submissions to FDA

- **Current study data standards apply to study data derived from RWD sources**
- **Talk to FDA early**
- **“Document, document, document”**

# Acknowledgments

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**FDA Center for Devices and Radiological Health**


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# Question and Answer

REAGAN-UDALL FOUNDATION FOR THE FDA

**Moderated by**

Susan C. Winckler, RPh, Esq.

**Panelists**

John Concato, MD, MS, MPH

G. Scott Gordon, PhD

Massoud Motamed, PhD

# Next Steps

Submit either electronic or written comments on the draft guidance by January 21, 2022, to Docket Number FDA-2021-D-0548 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance

# Next Steps

- Please watch for registration information on the third webinar in our series on FDA-issued draft guidance on Real-World Data.
- The next webinar will discuss the draft guidance of Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry.
- Docket No. FDA-2021-D-1146
- Registration information for that event will be located on the FDA Foundation website, www.reaganudall.org

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# Thank you!