

Welcome to Today's Event

Thanks for joining us!

Today's Topic:

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices, Final Guidance

February 18, 2026

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices, Final Guidance

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U.S. Food and Drug Administration

Final Guidance

- **Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices:** www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices
- 60-Day transition period allowed FDA and sponsors to perform activities to operationalize the recommendations in this guidance
- Beginning on February 17, 2026, FDA generally anticipates that sponsors should be ready to include the newly recommended information outlined in the guidance in their submissions
- Revised electronic Submission Template and Resource (eSTAR) content is now available

Learning Objectives

- Describe purpose of the RWE Guidance update
- Identify scope
- Discuss considerations (such as relevance and reliability and methodological considerations) for use of RWD and the documentation recommended to support its use in regulatory submissions
- Describe updates made to eSTAR forms

Key Terms

- RWD = Real-World Data
- RWE = Real-World Evidence
- IDE = Investigational Device Exemption
- PMA = Premarket Approval Applications
- HDE = Humanitarian Device Exemption
- EUA = Emergency Use Authorization
- TPLC = Total Product Life Cycle
- MDUFA = Medical Device User Fee Amendments
- FDORA = Food Drug and Omnibus Reform Act of 2022

RWE Guidance Timeline

2017 Guidance published

Updated Guidance drafted



Draft Guidance published
December 19, 2023



Public comments received, incorporated into final guidance



Final Guidance published
December 18, 2025



February 17, 2026



RWE Guidance External Webinar-
February 18, 2026

Background on 2025 Revisions to 2017 RWE Guidance

Contains Nonbinding Recommendations

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 18, 2025.

The draft of this document was issued on December 19, 2023.

This document supersedes “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,” issued on August 31, 2017.

For questions about this document regarding CDRH-regulated devices, contact the Office of Clinical Evidence and Analysis at CDRHClinicalEvidence@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 800-835-4709 or 240-402-8010, or by email at industry.biologics@fda.hhs.gov.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

- Section 3629 of FDORA directs FDA to issue or revise existing guidance on considerations for use of RWD and RWE to support regulatory decision-making
- Also fulfills MDUFA V Commitment
 - Least burdensome general expectations
 - Methodologies and best practices
- Guidance revisions based on FDA’s experience with RWD/RWE since 2017
- 2025 Guidance supersedes 2017 Guidance

2025 RWE Guidance compared to 2017 Guidance

Expanded Sections



- General Considerations for the use of RWE
- Application of IDE Requirements in 21 CFR 812 to Clinical Studies Using RWD
- Assessing Data Relevance and Reliability
- Appendix: List of generalized examples of RWE use to support regulatory decision making

Contains Nonbinding Recommendations

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

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New Sections



- Application of RWD from devices authorized under EUAs
- Considerations for Methodologies for Collection and Analysis of RWD to Generate RWE
- Documentation for FDA Review
- Appendix: Recommended Elements for Documentation and FDA Review

Background and Regulatory Context

Definitions (FDA-Wide) (Section I)

Real-World Data (RWD) are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.

Real-World Evidence (RWE) is the clinical evidence regarding the usage, and potential benefits or risks, of a medical product derived from analysis of RWD.



Some Potential Benefits of using RWD (Section II)



Obtaining information from broader clinical experiences than usually represented in traditional clinical studies



Evaluating outcomes that may not be feasible in traditional clinical studies



Capturing data generated over a longer period of time than would be practical in a traditional clinical study



Providing new insights into the performance of a device



Facilitating more timely completion of postmarket requirements and commitments

Guidance Scope (Section III)

Applies to regulatory submissions including

- IDE
- PMA
- 510(k)
- HDE
- Submissions related to post-approval study requirements or postmarket surveillance
- Clinical Laboratory Improvement Amendments (CLIA) Waiver by Applications (CW)
- De Novo classification request
- Dual De Novo/510(k) and CW Submissions (Duals))

Does not address

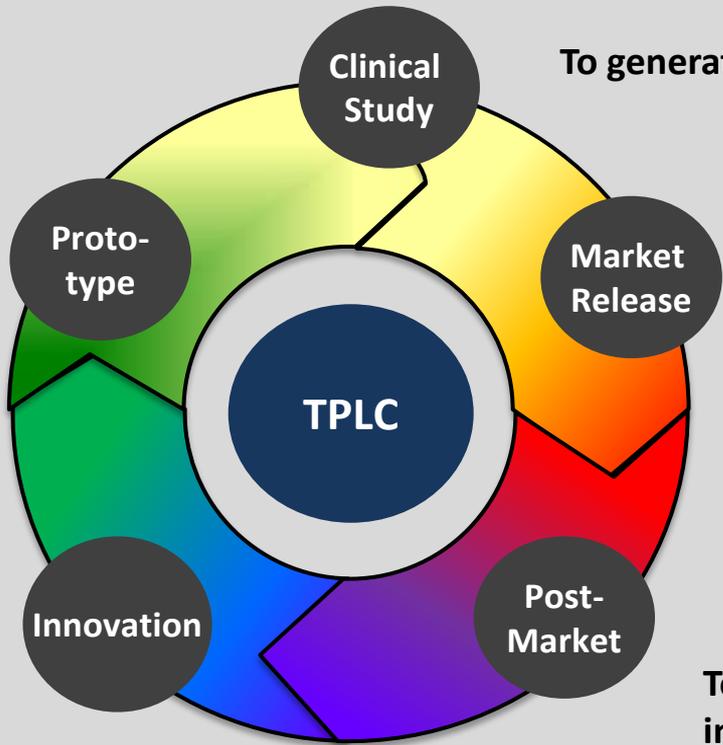
- Use of non-clinical data
- Secondary use of data originally generated from a traditional clinical study
- Systematic literature reviews
- All possible study design/conduct or analytical methodologies

Examples of RWD Sources* (Section IV)



*Published literature may contain clinical data from a variety of sources, including traditional clinical study data and RWD. If a sponsor is proposing to use RWD from published literature to support regulatory decision-making, sponsors should specify the RWD source type (e.g., if a journal article presents a retrospective analysis of EHRs, the RWD source should be specified as EHR).

Examples of RWE Use for TPLC Device Evaluation (Section IV)



To generate hypotheses to be tested in a clinical study

As a concurrent control group or a mechanism for collecting data to support marketing authorization when a registry, EHR, claims data, or some other systematic data collection mechanism exists

To conduct post-approval studies that are imposed as a condition of device approval, as well as to potentially preclude the need for or address postmarket surveillance requirements (i.e., 522 orders and special controls)

To generate evidence for expanding the labeling of a device to include additional indications for use or to update the labeling to include new information on safety and effectiveness

IDEs and EUAs (Section IV)

Added clarifying examples of when an IDE may be required and recommendations on the use of RWD from EUAs

Investigational Device Exemption (IDE):

- Expands on information from 2017 guidance
- If data are being gathered to determine the safety and effectiveness of the device, and the process for gathering the data would influence treatment decisions, an IDE may be required
- Includes 3 hypothetical examples

Emergency Use Authorization (EUA):

- Clinical data routinely collected from the use of a device authorized under an EUA may be considered RWD and may be used to support regulatory decision-making, if determined to be relevant and reliable

Assessing Data Relevance and Reliability

Relevance and Reliability (Sections V and VII)



Recommendations

- **Study Protocol and Analysis Plan** should be:
 - Created prior to analyzing RWD, regardless of whether the RWD are extant or if they are to be collected in the future.
 - Finalized prior to reviewing the outcome data and before performing prespecified analyses.
 - Developed incorporating relevance and reliability concepts
- **Relevance and Reliability Assessment** - included in Study Report:
 - Address RWD source(s), study design, and analytic components of the study.
 - Assess key relevance and reliability factors for the study

Submission Sections

- Study protocol (including analysis plan)
- Study report (for completed studies)
- Additional information (such as case report forms)

Relevance and Reliability – FDA Review



RWE may constitute **valid scientific evidence**, depending on the study question, study design, regulatory decision, data source(s), and design and analysis of the specific dataset derived from RWD source(s).

Submission should provide information to demonstrate:

- Studies were designed to mitigate potential bias.
- Sufficient precautions were considered during study conduct and that appropriate patient protections are in place.
- Data are accurate, as complete as possible, and of adequate data quality to credibly address the question at hand.

Additional details on Relevance and Reliability in Section V, Section VII.C, and Appendix A

Relevance Assessment (Section V.A)



Relevance considerations may include:

Data Availability

- Use of the device
- Outcome(s) of interest in the study population
- Covariates that may impact the exposure or outcomes of interest
- Longitudinality, including longevity (the length of time that data for an individual is captured within the RWD source) and continuity of care

Linkages

- Whether and how data from different sources can be obtained and integrated to address the study question

Timeliness

- Whether the time between data collection and release for research is reasonable and the RWD considered should reflect the current clinical environment

Generalizability

- Whether the study sample is representative of patients in the RWD source that are reflective of the proposed intended use population

Reliability Assessment (Section V.B)



Reliability considerations may include:

Data Accrual

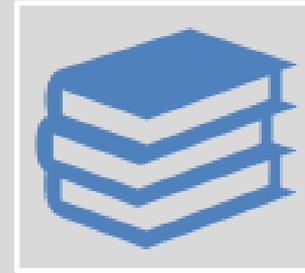
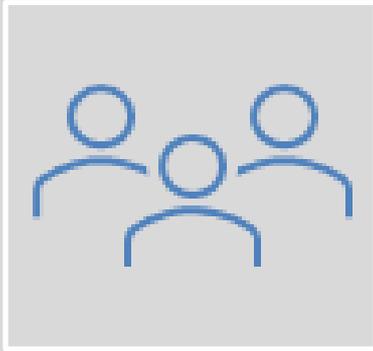
- Adequacy of information and descriptors about data sources provided in the regulatory submission
- Adequacy of information about data accrual methods and procedures provided in the regulatory submission

Data Quality and Integrity

- Quality Control Processes
- Assessment of completeness, accuracy, and consistency across sites and over time
- Establishment and adherence to data collection, recording, and source verification procedures
- Adequate patient protections (such as methods to protect the privacy of individuals' health data and adherence to applicable privacy and ethics standards) established in advance of executing the study protocol
- Prior demonstration of RWE generation from the data source

Methodological Considerations

Considerations for Methodologies for Collection and Analysis of RWD to Generate RWE (Section VI)



Methods for Study Design using RWD (not exhaustive)

Single-arm studies with comparisons to external controls, objective performance criteria, or performance goals

Non-interventional studies (observational studies)

Randomized controlled trials using RWD to supplement one or more study arms

Defining Study Design Elements (not exhaustive)

Study Time, Relative to Index Date

Development of Conceptual and Operational Definitions for the Study Population, Device, Comparator, Outcome, and Covariates

Appropriate Integration of Data Elements within Study Design and Analysis

Documentation for FDA Review

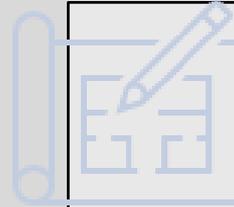
Documentation for FDA Review (Section VII)

- To support the use of RWD in pre-submissions, 510(k)s, PMAs, BLAs, HDEs, De Novos, IDEs, post-approval study PMA supplements, submissions in response to 522 orders, CLIA Waiver by Applications, and applications utilizing the Dual Submission pathway
- Recommendations cover RWD information included in:
 - Regulatory Submission Cover Letters
 - Study Protocol
 - Study Report (including the Relevance and Reliability Assessment)
 - Additional Information (such as Informed consent and IRB documentation, list of investigational sites, as applicable)

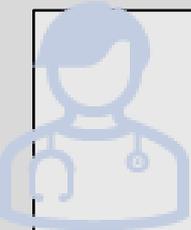
Cover Letter (Section VII.A)



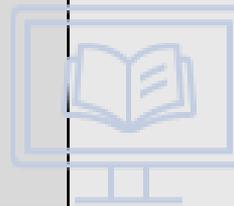
Purpose of Using RWE to support the Submission



Study design using RWD to generate RWE



RWD source(s) used to generate RWE



Specific RWD source(s) and version, including the following, if applicable:

- Data source name
- Data source provider
- Version number
- Date of extraction and range of extracted data

Study Protocol and Study Report (Including R&R Assessment (Sections VII.B and C))



Sponsors should implement relevance and reliability concepts when developing their study protocol

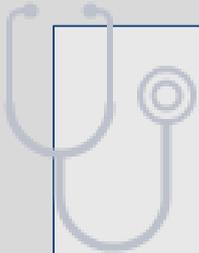


Sponsors should submit the study protocol used to generate RWE and study report for a completed study with RWD



The study report should include an assessment of the key relevance and reliability factors for a study using RWD

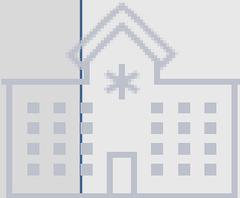
Additional Information (Section VII.D)



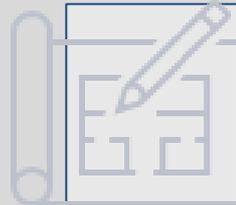
ClinicalTrials.gov National Clinical Trial (NCT) Number, if applicable



Informed consent and IRB documentation, as applicable
-Initial and continuing IRB review and approval, and
-Initial and approved changes to informed consent



List of investigational sites, if any, including mailing address, contact information, and investigator name



Case Report Form templates, as developed by the sponsor, if applicable
-These templates may be helpful if EHR or claims data are not mapped to the dataset from the source

Guidance Appendices

Recommended Relevance and Reliability Elements for Documentation and FDA Review (Appendix A)



Table 1- Recommended RWD Relevance Elements for Submission of RWE

Item (Linked to Section V.)	Information for Sponsors to Document (e.g., to make available for inspection)	Information for Sponsors to Provide to FDA in Submission	Recommended Location in FDA Submission
Determine if the RWD contains sufficient detail to capture data elements and address the study question	x (detailed)	x (rationale)	Protocol (rationale for study question and data element definitions)
Assess longitudinality of data source		x	Protocol
Assess continuity of care in data source		x	Protocol and report
Ensure reasonable time between data collection and release for research		x	Protocol and report
Consider changes in clinical practice/guidelines over time		x	Protocol
Specify timing for RWD updates		x	Protocol and report
Assess whether and how data from different sources can be obtained and integrated, given the potential for heterogeneity in population characteristics, clinical practices, and coding across data sources		x	Protocol
If applicable, use of a predefined linkage methodology that is scientifically valid and accounts for differences in coding and reporting across sources	x (detailed)	x (high level)	Protocol

- Not intended to be a checklist, not one-size fits-all
- Describes locations of relevance and reliability elements (such as in study protocol, report, sponsor internal documentation)
- Serves as a guide to sponsors
- Tables DO NOT need to be included in the submission to FDA

Examples Where RWE is Used in Regulatory Decision-Making (Appendix B)

Example 1: New approval of PMA

An implanted device, available OUS, used RWE as the primary clinical evidence to support the original PMA submitted to FDA. RWD from an OUS registry in one country, which included hundreds of patients with more than two years of follow-up, was compared against performance goals (PG) for device safety and effectiveness. In this example, an IDE application was not required for the clinical study because it was conducted OUS. An IDE application was also not required because the RWD comprised routinely collected extant data from an OUS registry. The PGs were derived from a prospectively defined meta-analysis of published literature and data from a U.S. registry of a comparator device legally marketed in the U.S. The study evaluated routinely collected functional outcome data and patient reported outcome measures. The safety assessment also included a comparison of the serious device-related adverse event rates for the subject device extracted from the OUS registry to rates in the same literature studies used to derive the PG. These analyses served as the primary basis supporting approval of the PMA. Important considerations from FDA's review, supporting the relevance and reliability of the RWD in this submission, included, in part: 1) devices of interest were clearly identified in the OUS registry, 2) data from the OUS registry were generalizable to U.S. patients, and 3) the OUS registry had adequate data capture methods to ensure completeness, accuracy, and consistency across sites of key variables, including covariates of interest and outcome measures.

Example 2: Expanded indications for use

An implanted device was authorized under a PMA and was subsequently available in the U.S. several years for one indication for use. The sponsor of the original PMA submitted a PMA panel-track supplement seeking to expand the indication for this device, which included a systematic literature review as well as RWD. The systematic literature review served as the primary clinical evidence to support safety and effectiveness of the device for the new use. The RWD comprised information from the sponsor's patient database linked with Medicare claims, and were provided as supplemental clinical evidence to support the safety of the device with the proposed indication. An IDE application was not required for the clinical study using RWD because the clinical data for the subject device were obtained from extant data that had been generated as part of routine clinical care. The RWE characterized the safety profile in patients with the specific condition (i.e., new indication) implanted with the device. A comprehensive review was conducted to identify validated diagnostic (i.e., ICD-CM) codes associated with safety outcomes, and used to assess these outcomes among patients receiving the implant and

- Six (6) new examples
 - New approval of PMA
 - Expanded indications for use
 - Submission in response to a 522 order
 - Control Group
 - Granting of De Novo
 - RWE obtained from use of EUA device

- Each example includes a high-level discussion of some considerations for relevance and reliability

Updates to eSTAR Forms

Overview: eSTAR

- Expected RWD-related documents/information are submitted within existing attachment questions (such as clinical section, cover letter)
 - No separate section for attachment of documents

- New RWD section in eSTAR only includes questions that ask for the citation of the attachment and page number of where RWD information is found (similar to Reprocessing, Electromagnetic Compatibility (EMC), etc.)

Cover Letter Updates (all eSTARs)

Cover Letter / Letters of Reference

- [Add Attachment](#) Attach your Cover Letter ?
- [Add Attachment](#) Attach any Letters of Reference ?

Updated help text:

- Lists recommended RWD information to include in submission cover letter
- Option to directly open RWE Guidance

Warning: JavaScript Window -

Section VII of the Real-World Evidence (RWE) Guidance describes the documentation recommended to support the use of RWD for generating RWE for regulatory purposes. Per Section VIIA of the RWE Guidance, FDA recommends that you include the following in the cover letter for each study:

- Purpose of using RWE to support the submission (see list of examples in Section IVA of RWE Guidance);
- Study design (i.e., type of study) using RWD to generate RWE (see list of examples in Section VIA of RWE Guidance);
- RWD source(s) used to generate RWE (see list of examples in Section IVA of RWE Guidance); and
- Specific RWD source(s) and version, including the following information, if applicable:
 - Data source name,
 - Data source provider,
 - Version number, and
 - Date of extraction and date range of data extracted.

Do you want to open the RWE guidance?

IMDRF CH1.01----- ↑ Common Content ↓ Regional Content -----

If this is a premarket notification, the cover letter should include your preference for continued confidentiality (21 CFR 807.95). For all premarket submissions, if the device was marketed under an EUA or enforcement policy guidance during the COVID-19 public health emergency, include the EUA number or guidance information.

If your submission contains Real-World Data (RWD) for pre or post-market use, click the "RWD Cover Letter Information" link below.

Resources

[21 CFR 807.95](#) [RWD Cover Letter Information](#)

Files attached to this question will be removed if the jurisdiction is changed.

Warning: JavaScript Window

RWD Section (Marketing Submission eSTAR)

- New RWD Section in non-IVD and IVD eSTAR

- If submitter answers “No” to first question:
 - Subsequent section not displayed

- If submitter answers “Yes” to first question:
 - Subsequent fields must be completed
 - Indicate attachment(s) and/or page number(s) of previously uploaded document where each element of recommended information has been included

- Help text corresponds to specific information recommended to be included in each respective document

Real-World Data (RWD)	
Does your clinical evidence include RWD or Real-World Evidence (RWE)?	Yes, includes RWD/RWE ?
Please cite the page number(s) of the cover letter that contains RWD related information.	? ?
Please specifically cite the attachment(s) and page number(s) of any information provided related to the RWD study protocol.	? ?
Please specifically cite the attachment(s) and page number(s) of any information provided related to the RWD Study Report (including the relevance and reliability assessment).	? ?
Please specifically cite the attachment(s) and page number(s) of any Additional RWD Information for the review. Type "N/A" if not applicable.	? ?

Post-Market Study Plan Section Help Text (PMA eSTAR)

Post-Market Study (PMS) Plans

Based on the answer provided in the Application/Submission Type section, PMS information is needed.

PMS Information ?

Identify the number of PMSs agreed upon as part of the conditions to market the device(s). ?

Add Attachment Please attach detailed documentation (e.g., study protocols, statistical analysis, milestones, design, etc.) pertaining to each Post-Market Study. If no PMS is identified, please attach a rationale explaining why PMS is not necessary. ?

New Help text:

- If Post-Market Study plan proposes to use RWD, recommends sponsors refer to Section VII of RWE Guidance for information to include in cover letter, study protocol, etc.
- Includes link to RWE Guidance

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Post-Market Study Plans

Post-Market Study Plans may include clinical or nonclinical study plans. The documentation provided here will not include final reports and analysis, and instead includes study plan information only. This may include:

- a) Study Objectives,
- b) Study Design,
- c) Subjects and Sites Information,
- d) Endpoints (primary and secondary),
- e) Summary of Data Analysis plan, and
- f) Length and frequency of follow-up

Post-Market Non-Clinical or Clinical Data from one region provided during the pre-market phase to a second region would be considered non-clinical or clinical data for the second region and would reside in the respective non-clinical or clinical section.

IMDRF CH2.07..... ↑ Common Content ↓ Regional Content

Please note that a post-approval study may be a clinical or non-clinical study required in the PMA approval order and is intended to gather specific information to address questions about the postmarket performance of or experience with an approved medical device.

If your post-market study plan(s) propose(s) to include RWD, please refer to Section VII of the RWE Guidance for recommended information to be included in documentation submitted to FDA (e.g., cover letter, study protocol, additional information).

Resources

[RWE Guidance](#)

Warning: JavaScript Window

RWD Section (IDE PreSTAR)



Investigational Plan ?	
Study Purpose	
Please provide the purpose of your study, including the name and intended use of the device, the objectives of the investigation, and the duration of the investigation (specified in months and years).	
Clinical Protocol ?	
Add Attachment	Attach a written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound. ?
How many subjects will be enrolled in the study?	<input type="text"/>
How many investigational sites will be enrolled in the study?	<input type="text"/>
What is the planned study follow-up (in months)?	<input type="text"/> ?
Real-World Data (RWD)	
Does your clinical protocol include RWD or Real-World Evidence (RWE)?	Yes, includes RWD/RWE ?
Please cite the page number(s) of the cover letter that contains RWD related information.	<input type="text"/> ?
Please specifically cite the attachment(s) and page number(s) of any information provided related to the RWD study protocol.	<input type="text"/> ?
Please specifically cite the attachment(s) and page number(s) of any Additional RWD Information for the review. Type "N/A" if not applicable	<input type="text"/> ?

- New RWD Section under “Investigational Plan”
- Same as marketing submission RWD section, except no prompt for study report (including relevance and reliability assessment), as that is not applicable for an investigational plan

RWD/RWE Topic Category (PreSTAR for Q-Submissions)

Submission Characteristics

Submission Purpose

Provide the overall purpose of the Q-Sub, including goals for the outcome of the interaction with FDA.

Relating to the feedback being requested, which type of submission do you plan to submit in the future? Pre-Submission ?

Select up to a maximum of four (4) topic categories that are applicable to this submission. ?

<input type="checkbox"/> Animal Study	<input type="checkbox"/> Benchtop Performance Testing
<input type="checkbox"/> Biocompatibility	<input type="checkbox"/> CLIA Waiver Study Design
<input type="checkbox"/> Clinical Study	<input type="checkbox"/> COA, PRO, and/or PPI
<input type="checkbox"/> Cybersecurity	<input type="checkbox"/> Device Description or New Technology
<input type="checkbox"/> EMC & Electrical/Mechanical/Thermal Safety	<input type="checkbox"/> Human Factors
<input type="checkbox"/> Indications for Use/Intended Use	<input type="checkbox"/> Interoperability
<input type="checkbox"/> Labeling	<input type="checkbox"/> Predetermined Change Control Plan (PCCP)
<input type="checkbox"/> Real-World Data/Real-World Evidence	<input type="checkbox"/> Regulatory Strategy
<input type="checkbox"/> Reprocessing	<input type="checkbox"/> Software/Firmware
<input type="checkbox"/> Statistics	<input type="checkbox"/> Sterility and Shelf Life
<input type="checkbox"/> Wireless Technology	<input type="checkbox"/> Not Listed (Applicant Specified)

New Category
for RWD/RWE

Help Text (PreSTAR for Q-Submissions)

Pre-Submission Questions ?

Please include clear, specific questions related to the selected topic category. The Topic Category dropdown list is populated by the selected choices in the Submission Characteristics section. To better inform FDA review, you may describe your perspective for each submitted question.

We recommend carefully considering the number of questions and the extent of feedback requested to ensure that FDA has sufficient time to provide an in-depth response to each question and to enable focused meetings.

Question 1 Topic Category: Real-World Data/Real-World Evidence

Add Attachment If applicable, attach supporting documentation related to the question posed above.

Add Question **Delete Question**

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Due to resource constraints, please be aware that you may be contacted interactively to discuss the scope and nature of the questions submitted. Examples of questions that lead to productive Pre-Sub interactions are provided in Appendix 2 of the Q-Sub guidance.

Additional guidance regarding common types of questions submitted in Pre-Subs is provided below:

Study Protocols: Resource constraints do not permit FDA to prepare or design study plans. If requesting feedback on a protocol, please submit a proposed outline with a rationale for the chosen approach. If the Pre-Sub is for a non-significant risk device study, IDE exempt device, CW, Dual, or a study to be conducted outside the US (OUS) to support a marketing submission, please consider submitting the entire protocol through the Pre-Sub process prior to initiating the study.

Review of Data: Requests for a pre-review of data are generally not appropriate for the Pre-Sub program. However, if the data and conclusions are difficult to interpret, it may be appropriate to ask a specific question regarding the interpretation of preliminary results or the planned approach for addressing the results within the upcoming submission.

Regulatory Approach: Under the Pre-Sub program, FDA can provide feedback on regulatory strategy and approach (e.g., if a cleared 510(k) or granted De Novo device has potential to serve as a predicate). A formal written request for device classification and indications for use requires a 513(g) Request for Information. See Section III.G of the Q-Sub guidance for information on procedures for when classification of a medical product is unclear or in dispute.

Real-World Data (RWD): FDA can provide feedback on specific aspects of using RWD in a particular regulatory submission (e.g., questions regarding the study protocol (see Section VII.B of RWE Guidance) and/or the sponsor's approach to their relevance and reliability assessment (see Section V of RWE Guidance)).

Resources

- [Q-Submission Guidance](#)
- [RWE Guidance](#)

Warning: JavaScript Window

New Help text:

- Notes that FDA can provide feedback on specific aspects of RWD in a submission
- Includes link to RWE Guidance

Resources

Slide Number	Cited Resource	URL
4	RWE Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices
N/A	Examples of RWE use in Regulatory Submissions	www.fda.gov/media/146258/download

RWE Policy Questions

Email: CDRHClinicalEvidence@fda.hhs.gov

Pre-Submissions can be helpful!

- We encourage manufacturers to engage early with FDA by submitting a Pre-Sub to discuss RWD use in their regulatory submission
- Pre-Subs can be a helpful way to obtain feedback on:
 - Proposed study protocol
 - Suitability of RWD source to address a study question
 - Approach to addressing human subject protections for RWD

Summary

- RWE Guidance was updated to address the FDORA legislation requirements, MDUFA V Commitment, and FDA's experience with RWD since 2017
- Assessment of Relevance and Reliability is key to determine if RWD is suitable for regulatory decision-making, and guidance includes recommendations for information to be included in regulatory submissions to FDA
- eSTAR forms have been updated to correspond to guidance update



Additional Panelists

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Chief Epidemiologist

Office of Clinical Evidence and Analysis
Office of Product Evaluation and Quality

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**Center for Devices and Radiological Health
U.S. Food and Drug Administration**

Panel Discussion

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**

- www.fda.gov/Training/CDRHLearn

- **Additional questions about today's webinar**

- Email: DICE@fda.hhs.gov

- **Upcoming Webinars**

- www.fda.gov/CDRHEvents



Start Here/The Basics! (Updated 10/3/2024) DUFA Small Business Program, Registration and Listing	▼
How to Study and Market Your Device - (Updated module 9/11/24) 510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification	▼
Postmarket Activities (New module 10/7/24) Quality System, QMSR, Exporting, Device Recalls, MDR, Inspection - Global Harmonization	▼
In Vitro Diagnostics - (Updated 9/27/24) IVD Development, CLIA, and Virtual Town Hall Series	▼
Unique Device Identification (UDI) System	▼
Specialty Technical Topics - (Updated 10/8/24)	▼
Radiation-Emitting Products	▼
510(k) Third Party Review Program (for Third Party Review Organizations)	▼
Industry Basics Workshop Series	▼



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