



U.S. FOOD & DRUG
ADMINISTRATION

FDA – eSource and RWD/RWE: An Update

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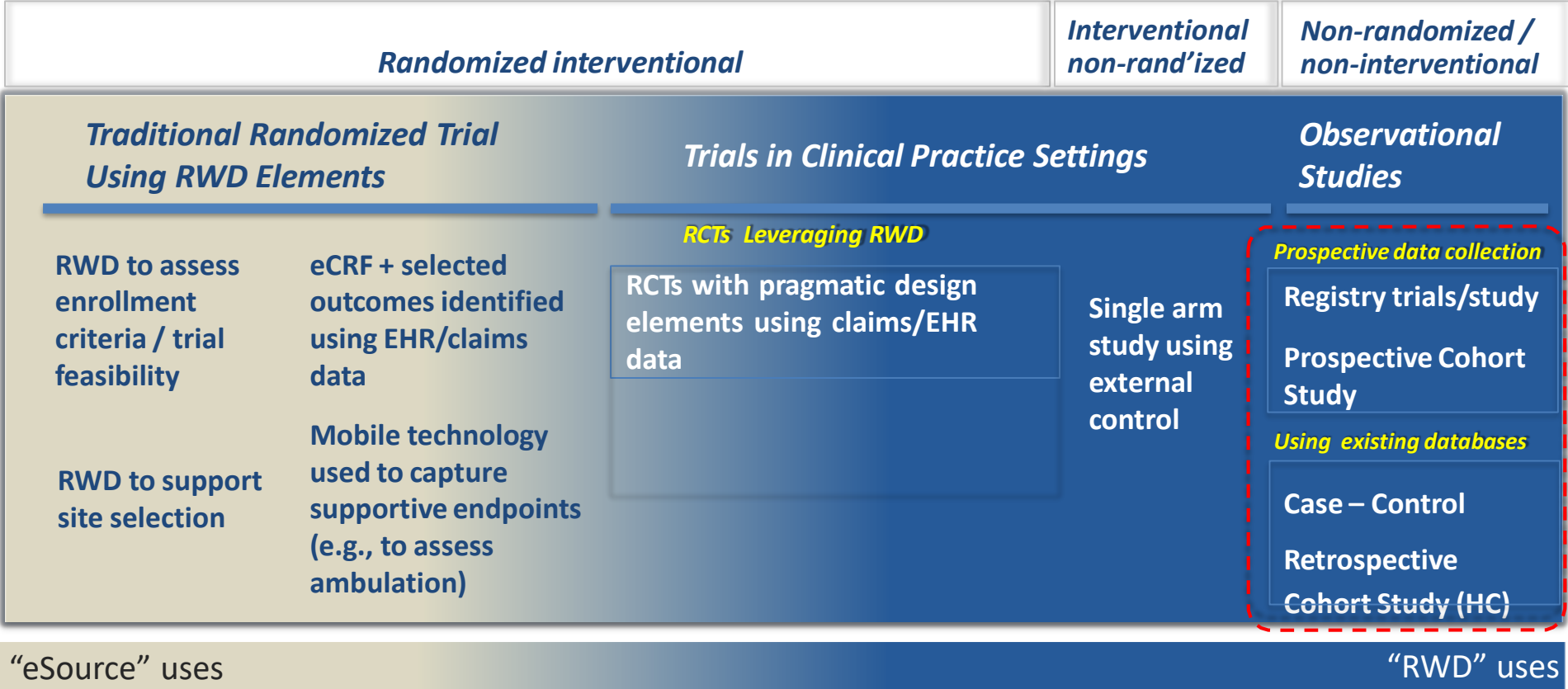
Food and Drug Administration

August 20, 2020

Disclaimer

The views and opinions expressed in the following slides are those of the individual presenter and should not be attributed to the FDA.

“eSource” to “RWD” – It’s *All* Electronically Captured Health Data!



Why Expand RWD/E Use?

- **Provide new opportunities to close the divide between research and clinical care**
 - **Additional settings, access to more diverse populations, larger data sets**
- **Big data – potential for detection of infrequent events, long-term but infrequent outcomes**
- **Lower resource intensity – more questions answered**
- **Understand how medications are used in practice and value**

FDA's Real-World Evidence Program



Today - Limited Existing FDA Guidance

Guidance for Industry
Electronic Source Data in
Clinical Investigations

Reflects limited
relevant RWD
considerations

**Providing Regulatory
Submissions
In Electronic Format —
Standardized Study Data**

Guidance for Industry

Does not directly
reflect RWD
considerations

Use of Electronic Records and
Electronic Signatures in
Clinical Investigations Under
21 CFR Part 11 –
Questions and Answers

Use of Electronic
Health Record Data in
Clinical Investigations

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)
Center for Devices and Radiological Health (CDRH)

July 2018
Procedural

FDA Data Standards Catalog v6.1 (09-09-2019) - Supported and Required

For full description of column headings, see Instr. & Column Description

Supported Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends (MM/DD/YYYY)
12 eCTD: Electronic Common Technical Document Specifications	CDER, CBER	06/01/2008		05/05/2017 [5] 05/05/2018 [6]	
	CDER, CBER	Ongoing		04/01/2005 [3] 12/11/2003 [4]	
Structured Product Labeling (SPL) Implementation Guide with Validation Procedures Version 1 Revision 201412101457	CBER	06/10/2015	n/a	06/10/2015	n/a
Global Unique Device Identification					

**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
cdcr-edata@fda.hhs.gov or CBER at cber.edisc@fda.hhs.gov

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)

March 2018

What does FDA recommend?

How does FDA currently request it?

What's Underway?

- Scan for relevant data standards for EHR and Claims data – “what exists”
- RWE requirements in FDA – “what must be true”
- Line of sight of FDA requirements across existing (CDISC and HL7) standards – “where's the opportunity”

Objective:

A Roadmap to a future state of standards that support RWD capture to regulatory submissions

Coordinate, Collaborate And Leverage!



OneSource



TransCelerate
BIOPHARMA INC.

ACCELERATING THE DEVELOPMENT OF NEW MEDICINES



Society for Clinical Data Management
DATA DRIVEN

eSource
Implementation
Consortium



COVID-19 Evidence Accelerator

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National COVID
Cohort Collaborative
(N3C)



National Institutes
of Health



eSource for Clinical Trials

The Office of the National Coordinator for
Health Information Technology

