FDA – eSource and RWD/RWE: An Update

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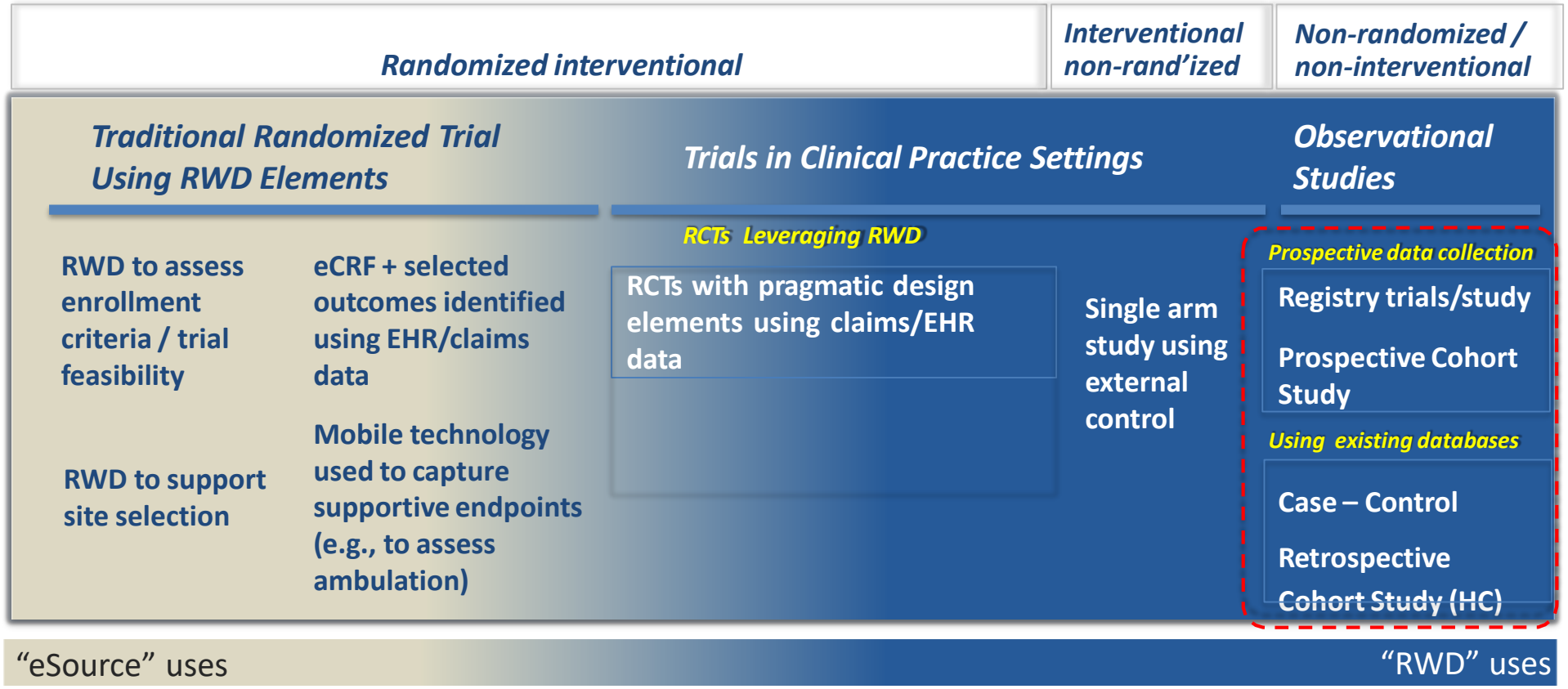
August 20, 2020

Disclaimer

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

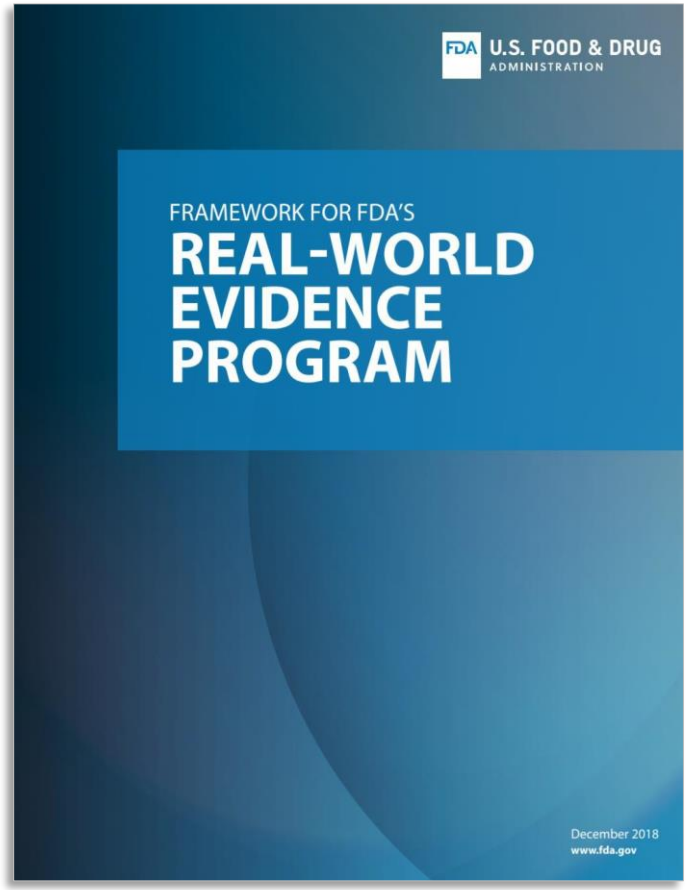
“eSource” to “RWD” – It’s *All* Electronically Captured Health Data!

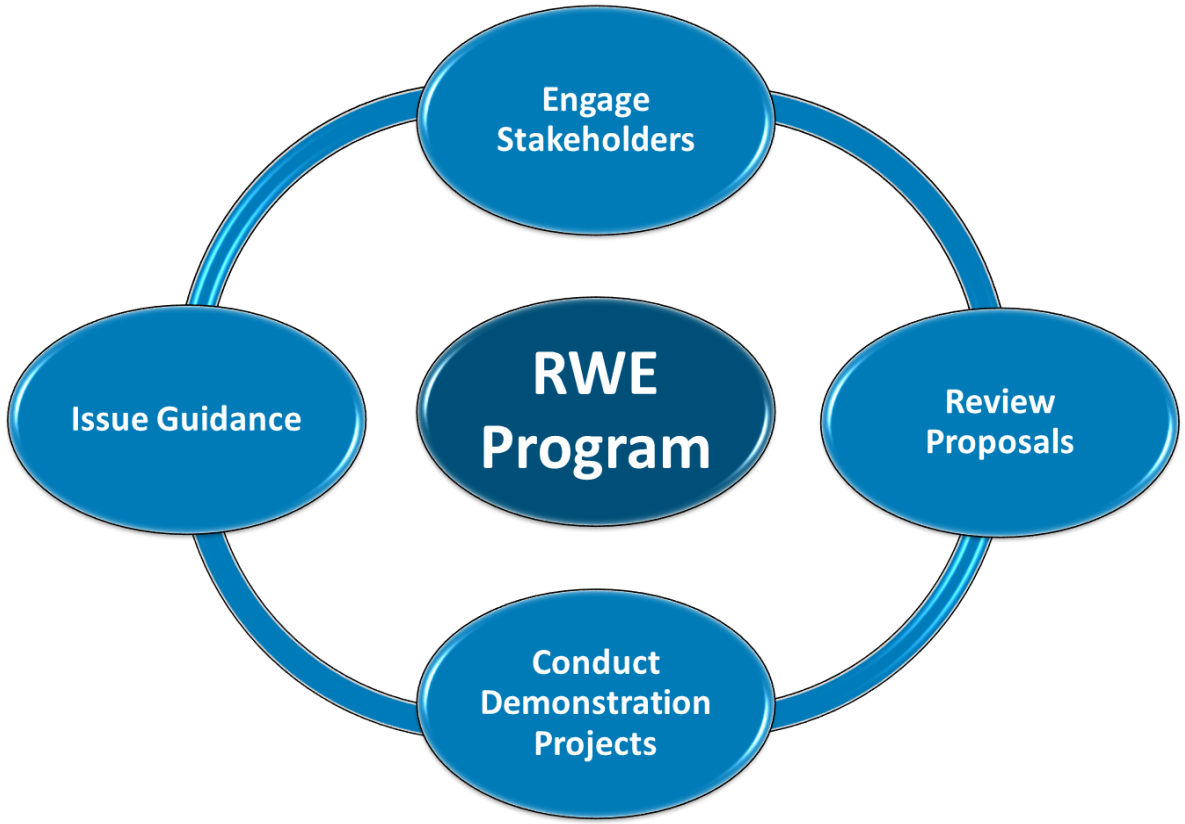


Why Expand RWD/E Use?

- **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**

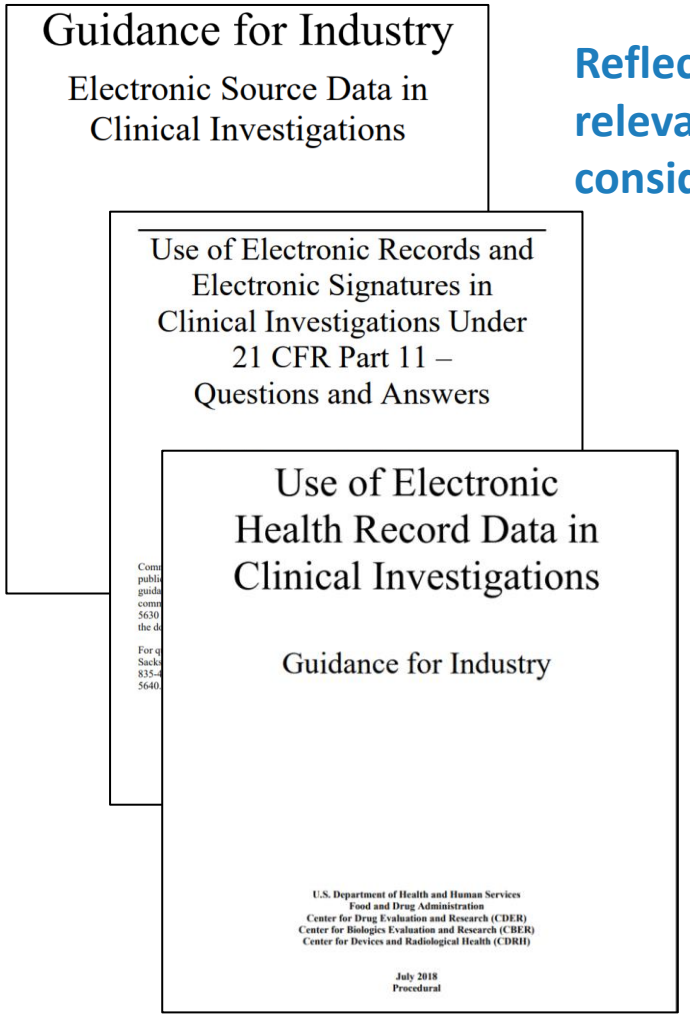
FDA's Real-World Evidence Program





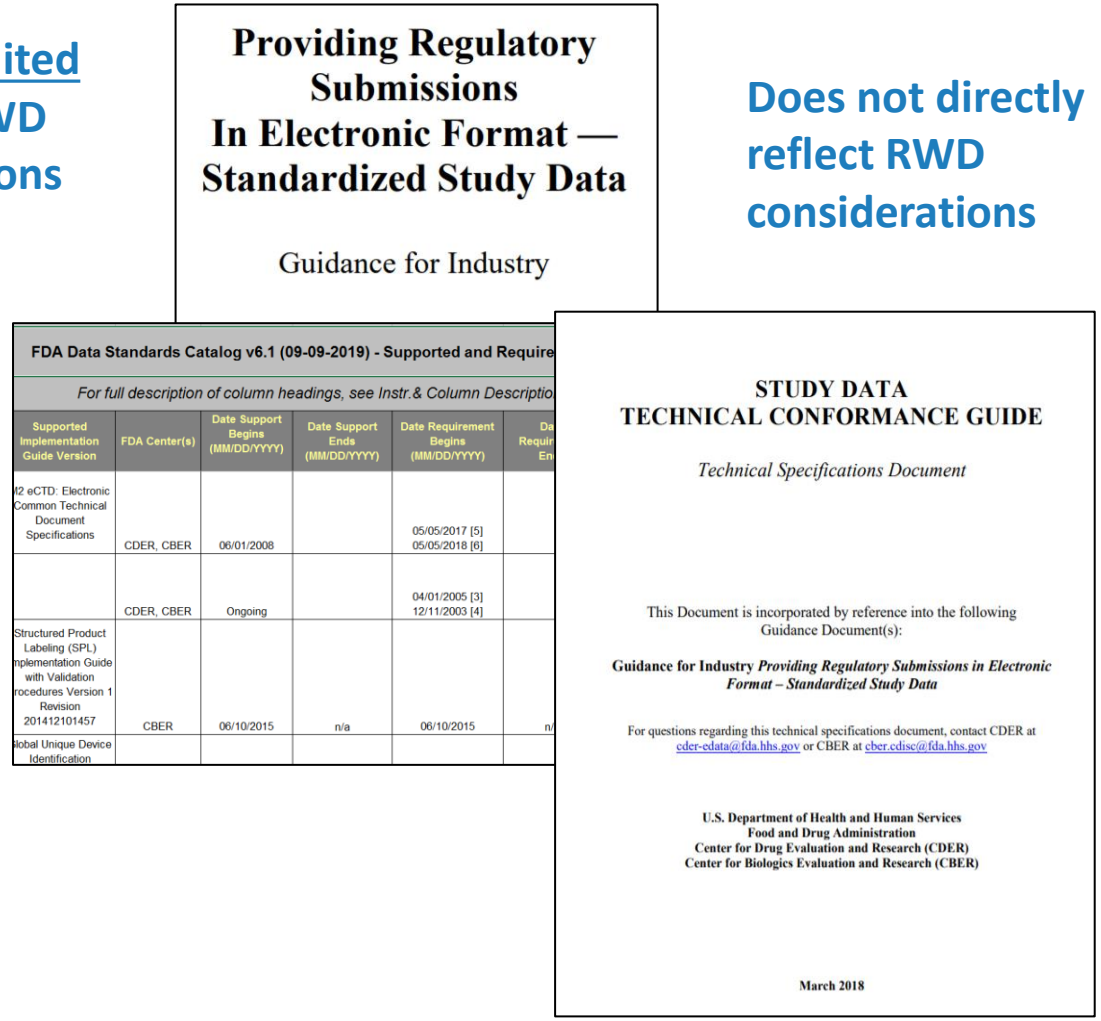
https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

Today - Limited Existing FDA Guidance



Reflects limited relevant RWD considerations

What does FDA recommend?



Does not directly reflect RWD considerations

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!

CERSI UCSF-Stanford

I-SPY TRIALs

OneSource

VULCAN HL7 FHIR

SCDM Society for Clinical Data Management DATA DRIVEN

TransCelerate BIOPHARMA INC. ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

eSource Implementation Consortium

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

FRIENDS of CANCER RESEARCH

COVID-19 Evidence Accelerator

National COVID Cohort Collaborative (N3C)

FDA U.S. FOOD & DRUG ADMINISTRATION

NIH National Institutes of Health

cdisc

Pfizer

UAMS University of Arkansas for Medical Sciences

The Office of the National Coordinator for Health Information Technology

eSource for Clinical Trials