Regulatory Overview on Real World Data

Recently Published FDA RWE Guidances

Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products
Draft Guidance for Industry, September 2021

Data Standards for Drug and Biological Product Submissions Containing Real-World Data
Draft Guidance for Industry, October 2021

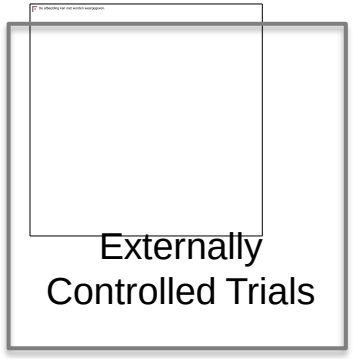
Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry
Draft Guidance for Industry, November 2021

Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products
Draft Guidance for Industry, December 2021

Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products
Guidance for Industry, *September 2022*

Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products
Draft Guidance for Industry
February 2023

Novel Designs in Oncology



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Example RWD Challenges

- Early RWD proposals lack basic elements of the study design and insufficient characterization to facilitate substantive review
- Lack of pre-specified protocol and SAP
- Data Source not fit-for-purpose or appropriate to answer the study question
  - Covariate and outcome ascertainment
  - Confounding: Concerns with measured, unmeasured, and residual confounding
- ECTs → Index Date Selection and Immortal Time Bias