



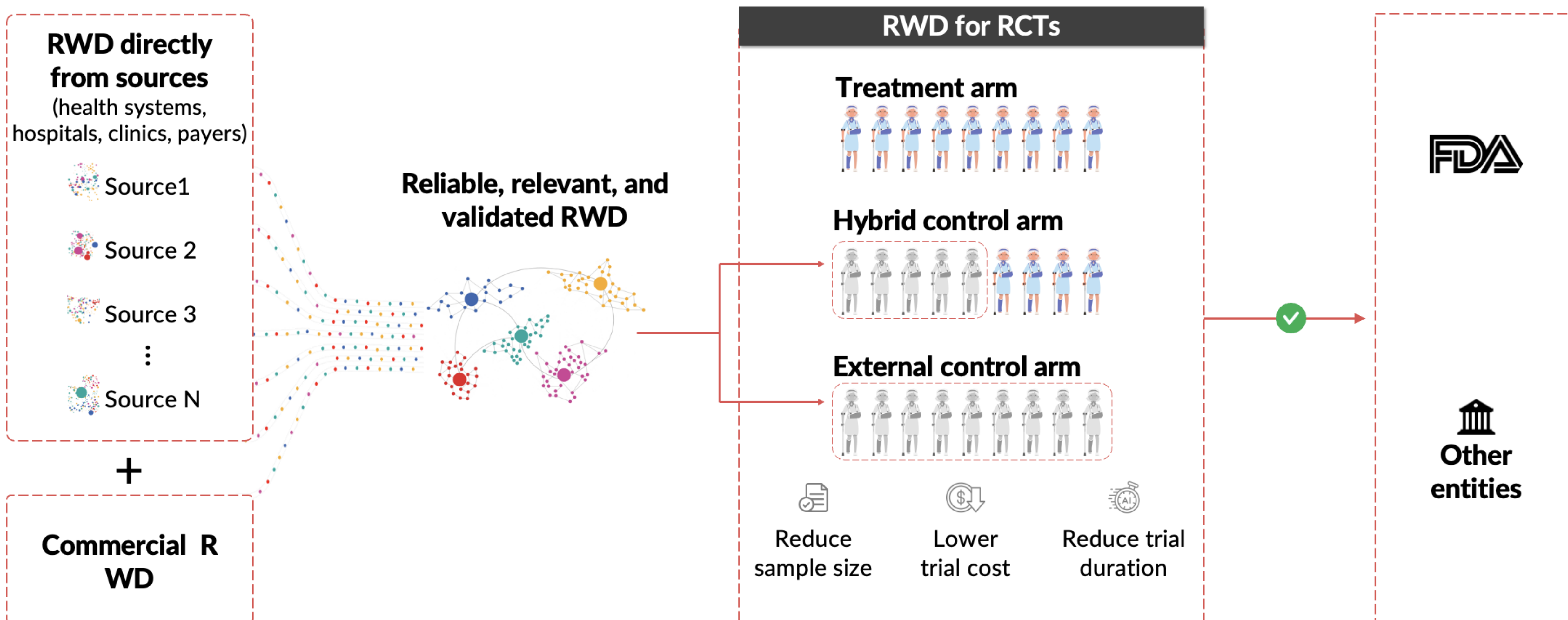
The Role of Quantitative Bias Analysis (QBA) in Ensuring the Reliability of RWD in Regulatory Submissions

Tasha Nagamine MS, Droice Labs

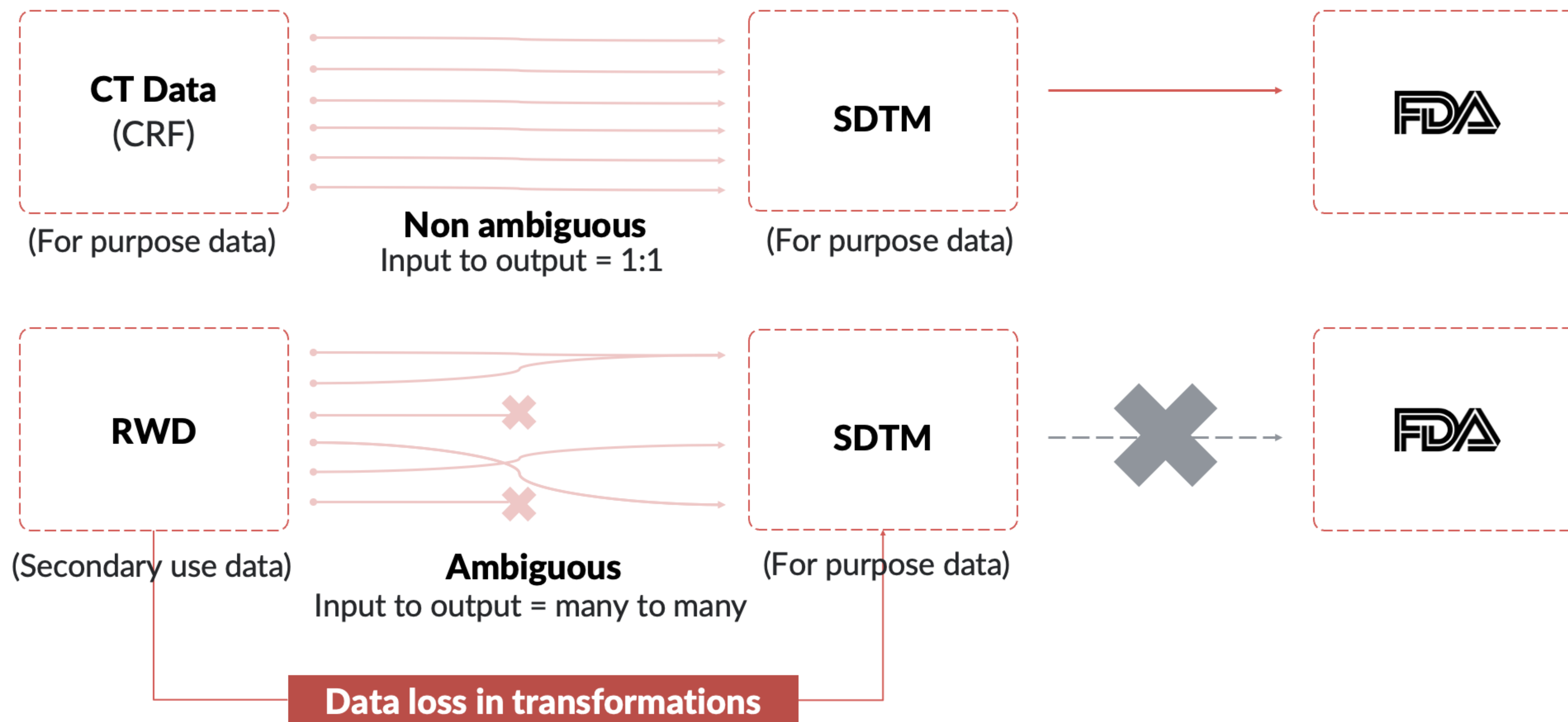
Brian Gillette PhD, Droice Labs



RWD: FASTER, MORE EFFICIENT TRIALS



PROBLEM: RWD $\neq$ RCT DATA



HANDLING BIAS IN RWD THROUGH QUANTITATIVE BIAS ANALYSIS (QBA)



Real-World Data: Assessing
Electronic Health Records and
Medical Claims Data to Support
Regulatory Decision-Making
for Drug and Biological
Products
Guidance for Industry

July 2024

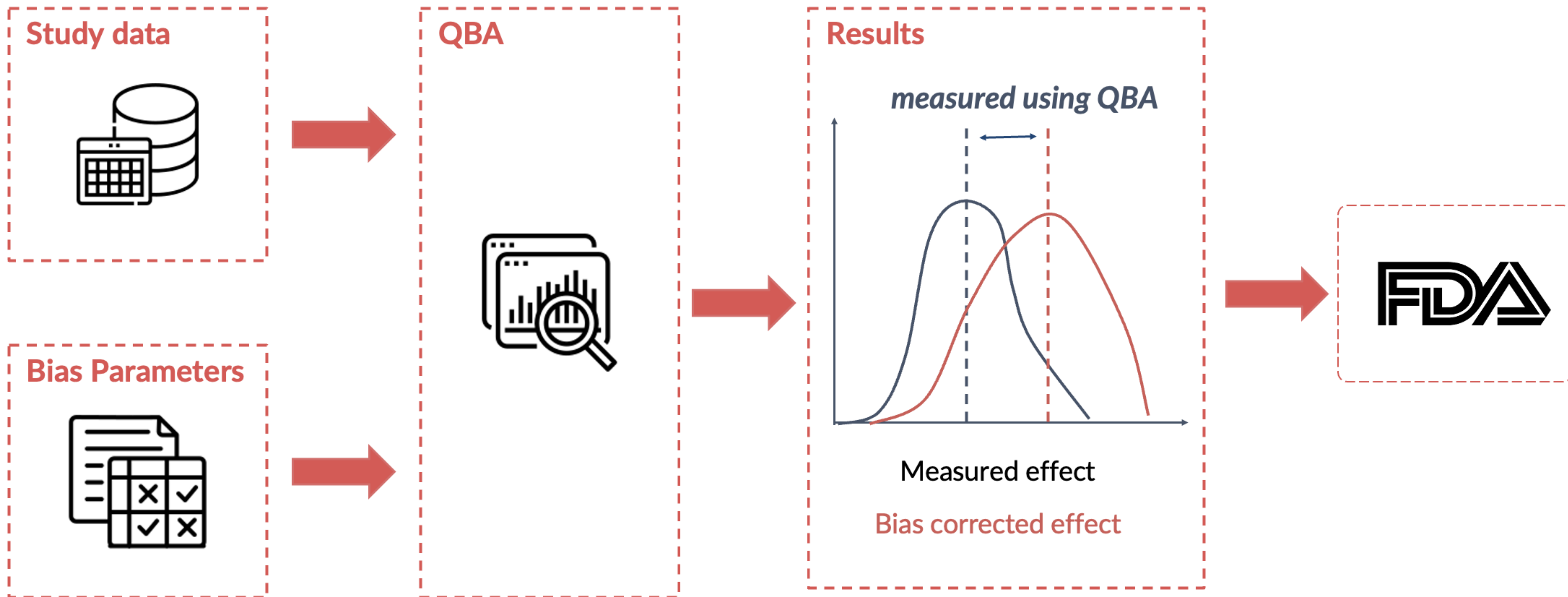
“

FDA also recommends using quantitative approaches, such as quantitative bias analyses... to demonstrate whether and how misclassification, if present, might impact study findings. The protocol should pre-specify the indices (e.g., sensitivity, specificity) that will be used for quantifying bias and describe how the selected indices will be measured during validation.



<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-electronic-health-records-and-medical-claims-data-support-regulatory>

HANDLING BIAS IN RWD THROUGH QUANTITATIVE BIAS ANALYSIS (QBA)



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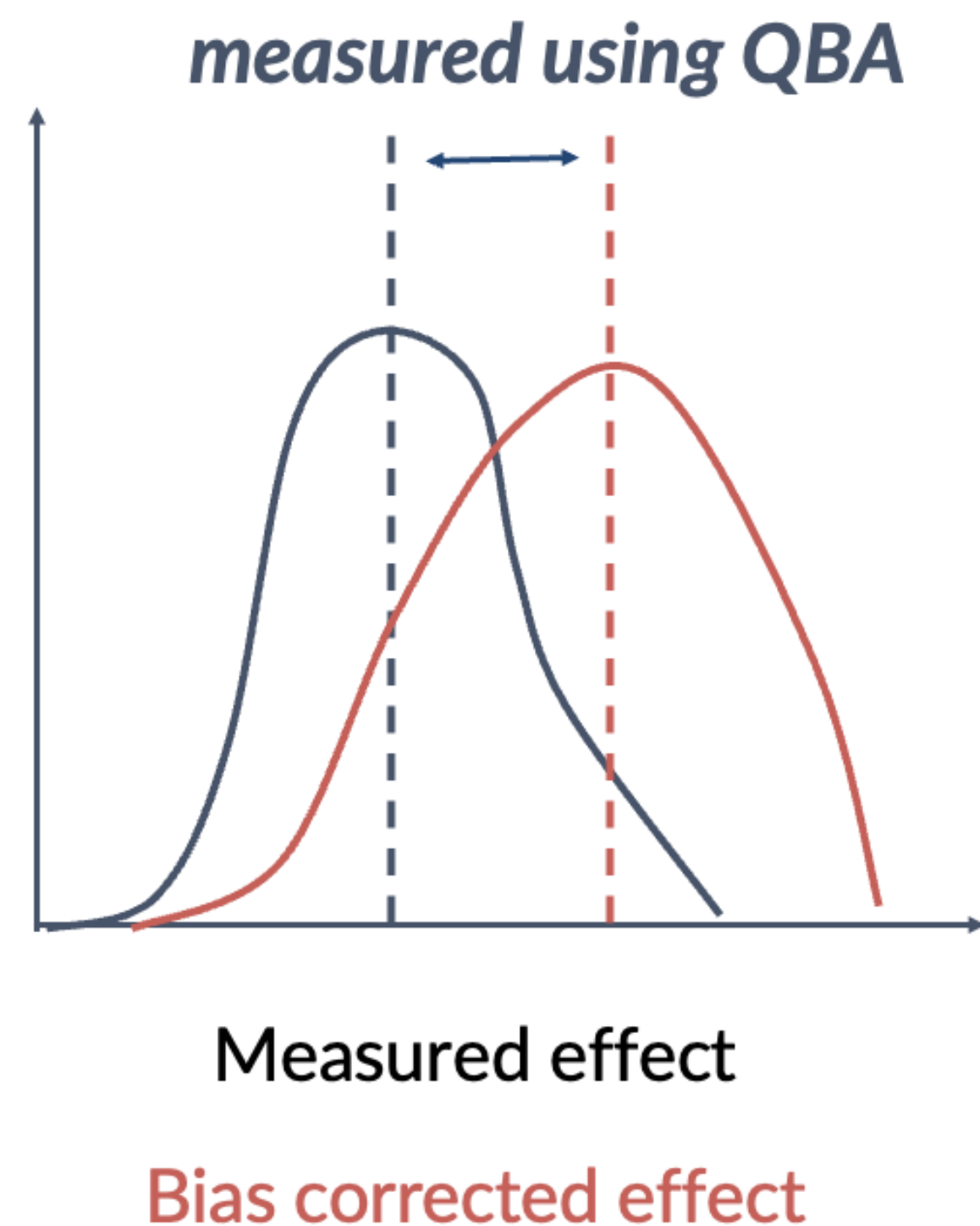
Study data



QBA



Results



Bias Parameters



sensitivity, specificity



HOW TO GET BIAS PARAMETERS: VALIDATION STUDIES



Real-World Data: Assessing
Electronic Health Records and
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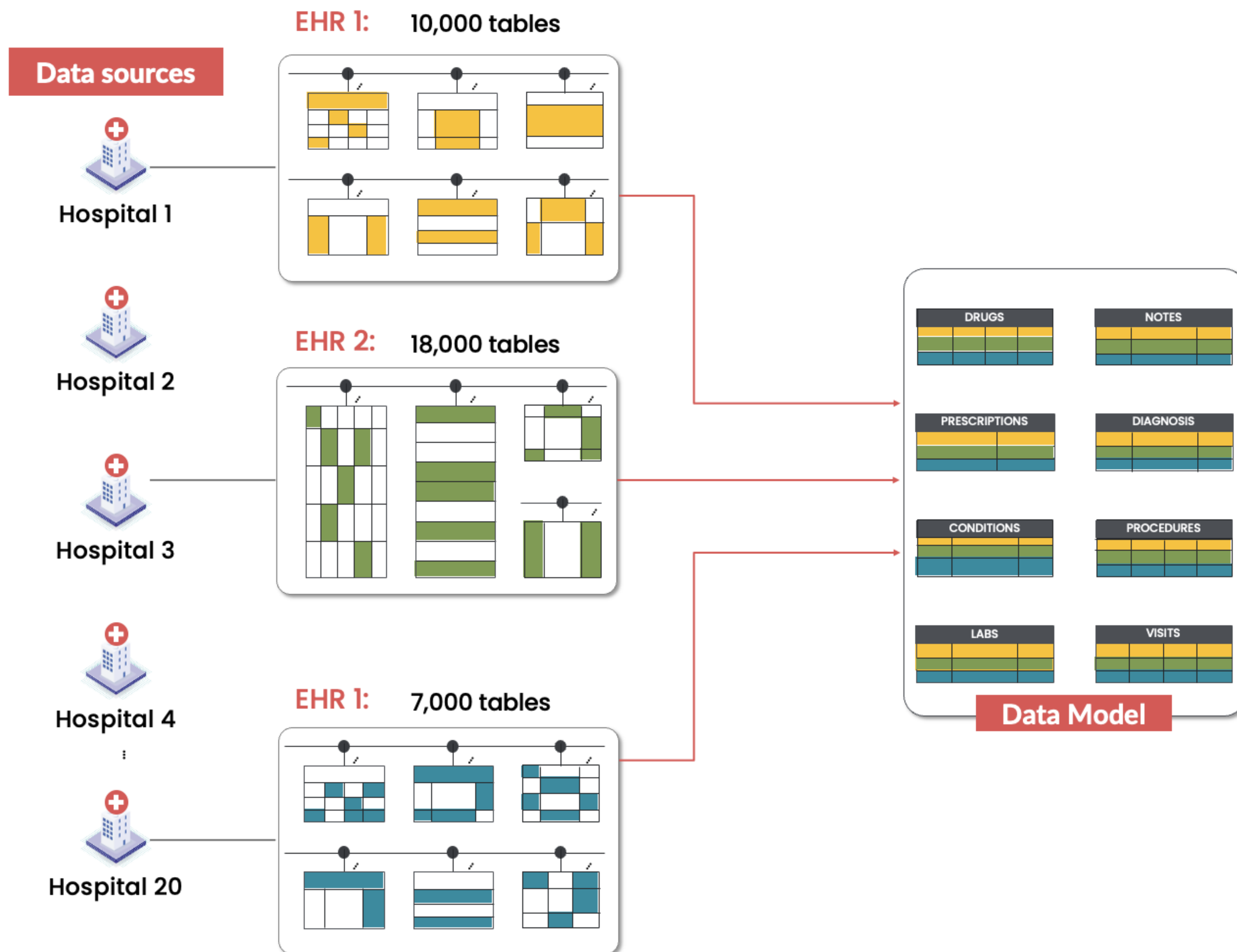
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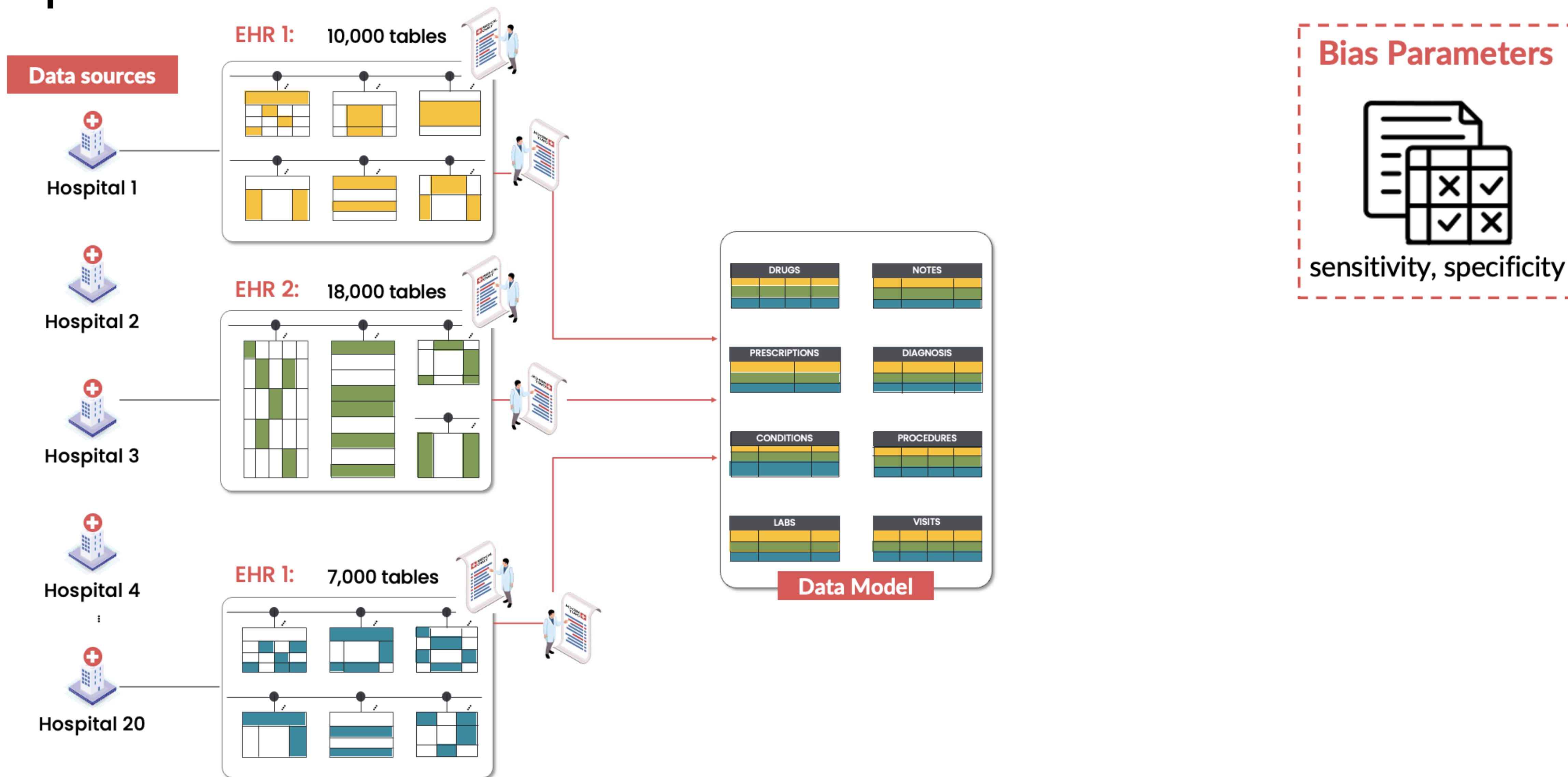


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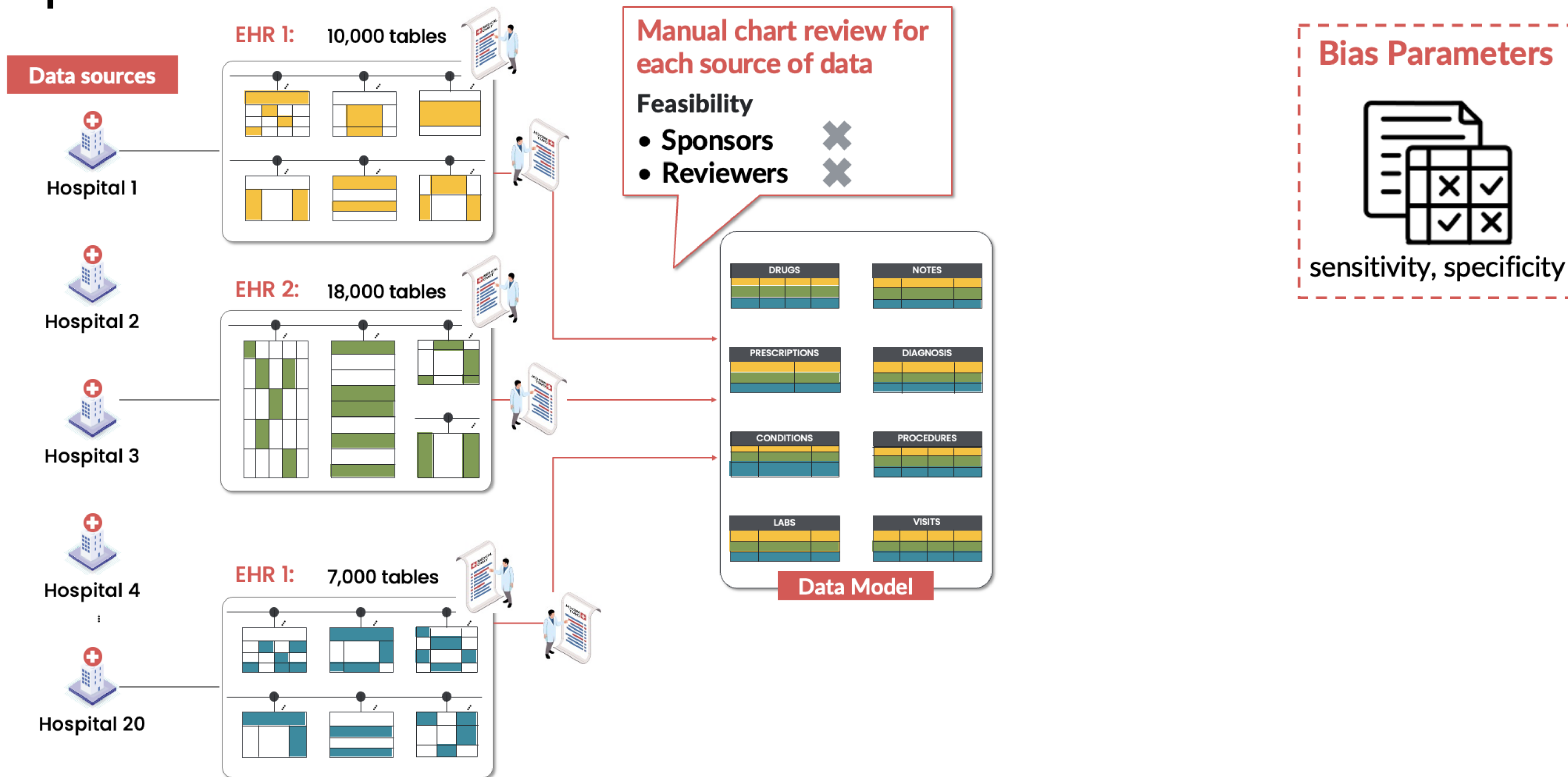
OBTAINING BIAS PARAMETERS FROM RWD IS CHALLENGING



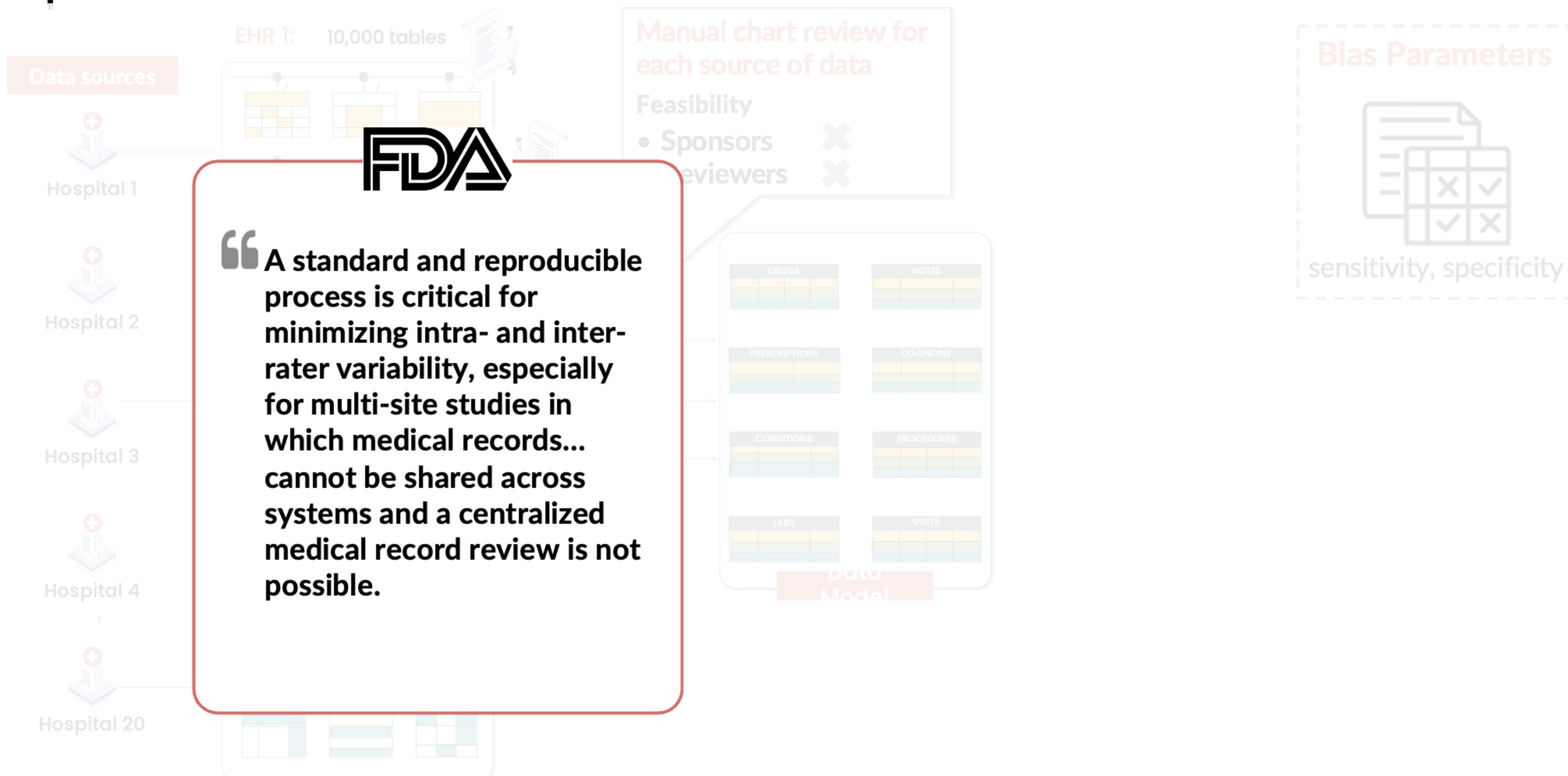
OBTAINING BIAS PARAMETERS FROM RWD IS CHALLENGING



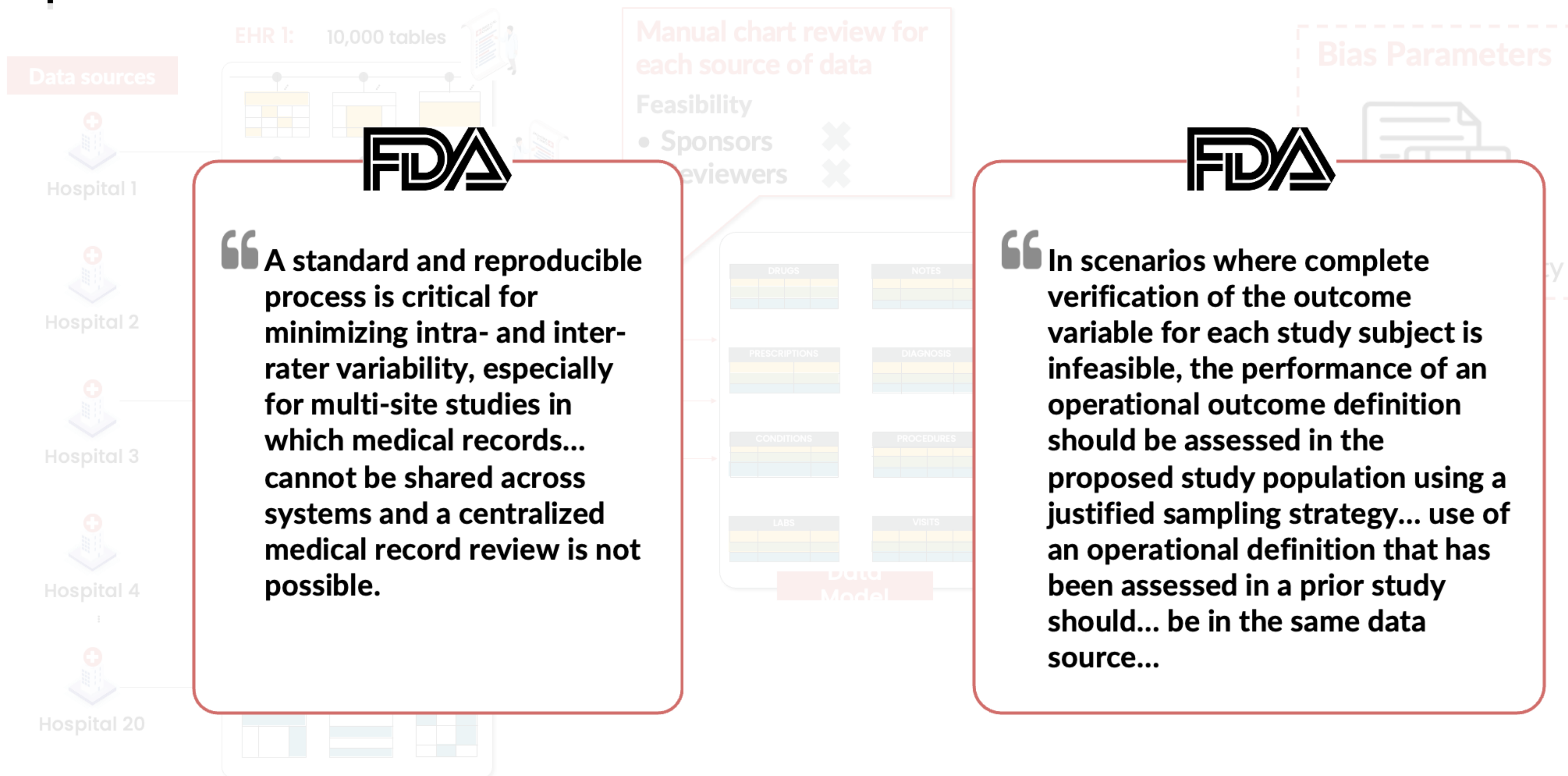
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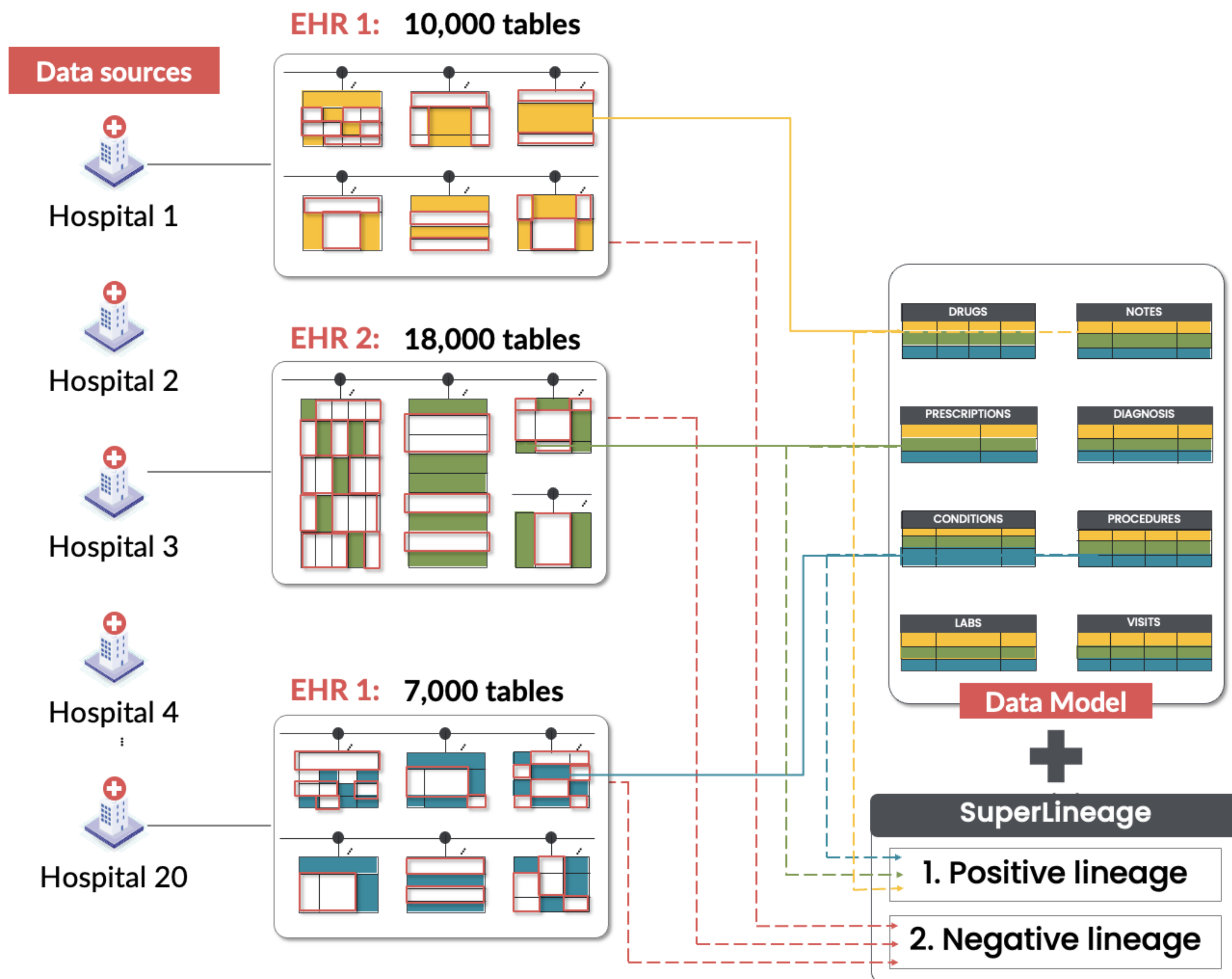
FDA GUIDANCE ON RWD VALIDATION STUDIES



FDA GUIDANCE ON RWD VALIDATION STUDIES



STANDARDIZED AND SCALABLE RWD VALIDATION



Bias Parameters



sensitivity, specificity

yahoo/finance Search for news, symbols or companies

Droice Labs Discusses SuperLineage for Real-World Data Traceability at FDA Listening Session

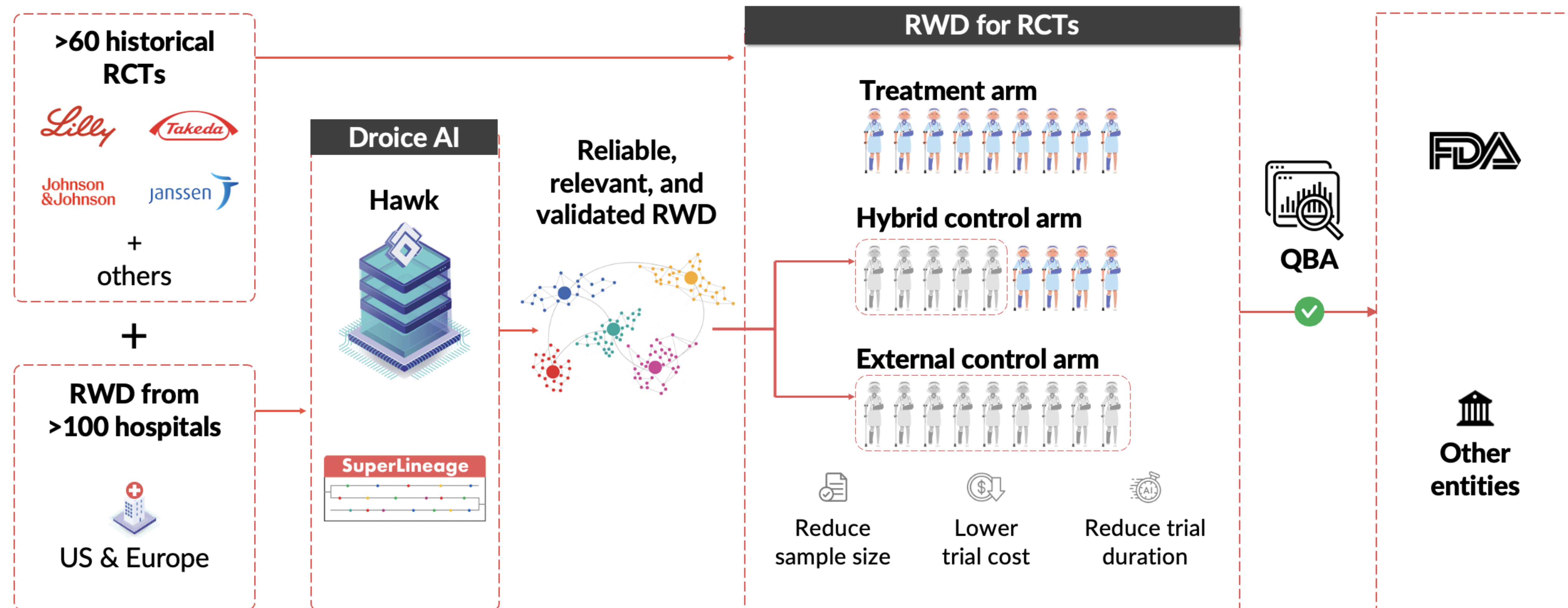
Droice Labs
Tue, Feb 27, 2024 • 3 min read

NEW YORK, NY / ACCESSWIRE / February 27, 2024 / Droice Labs met with the Food and Drug Administration's Real-World Evidence Subcommittee in a listening session held on Feb. 2, 2024. The topic of this session was **SuperLineage™**, a standardized format and approach, developed by Droice, that stores element-level data lineage and traceability to enable trust and reliability in real-world patient data (RWD) for regulatory decision-making.

SuperLineage:
Traceability for Reliable RWD

<https://finance.yahoo.com/news/droice-labs-discusses-superlineage-real-150000597.html>

RWD: FASTER, MORE EFFICIENT TRIALS





Thank you
