



Droice Labs

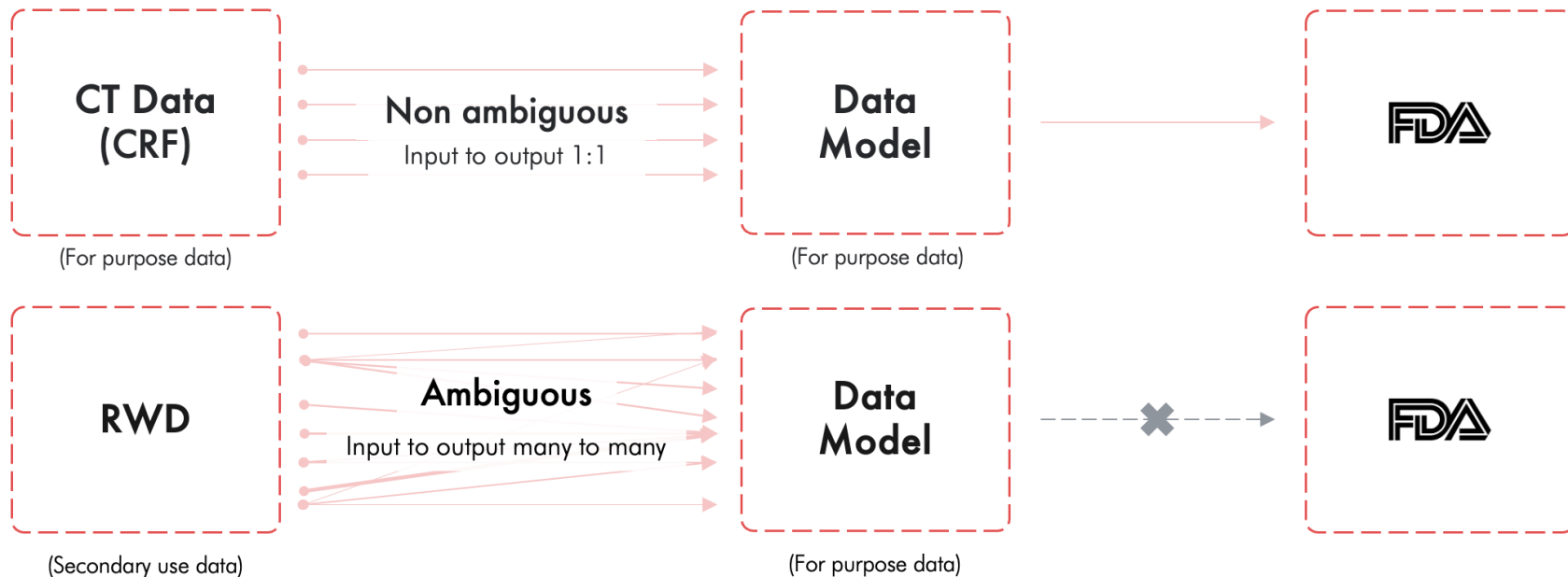
Transforming RWD for Regulatory Submissions: How to Use SDTM for RWD

Tasha Nagamine, MS, Droice Labs

Sam Hume, DSc., CDISC



REQUIREMENTS FOR REGULATORY RWD

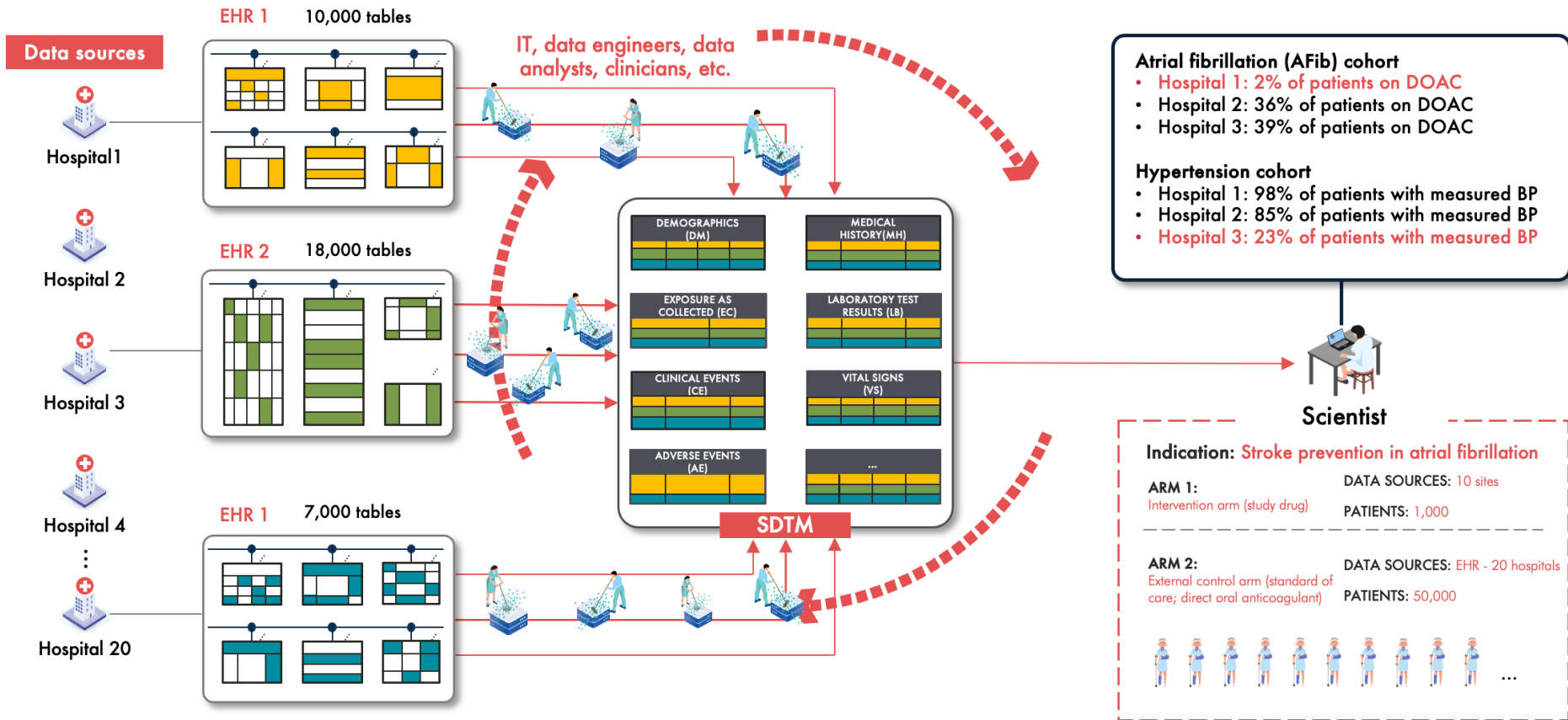


Data Transformation

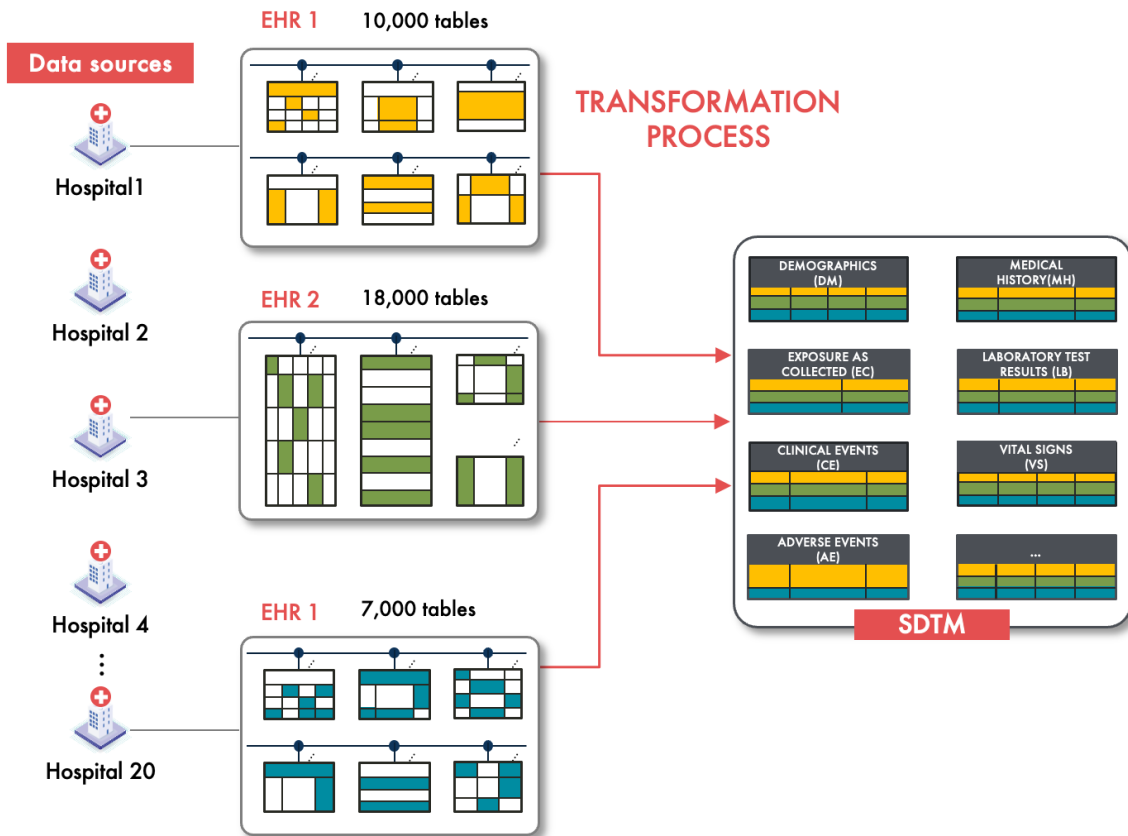
X Data transformation loss

X Data model limitation loss

THE INFORMATION LOSS LOOP



SOLUTION: QUANTIFY DATA TRANSFORMATION PERFORMANCE



True positive	False positive
False negative	True negative



Scientist

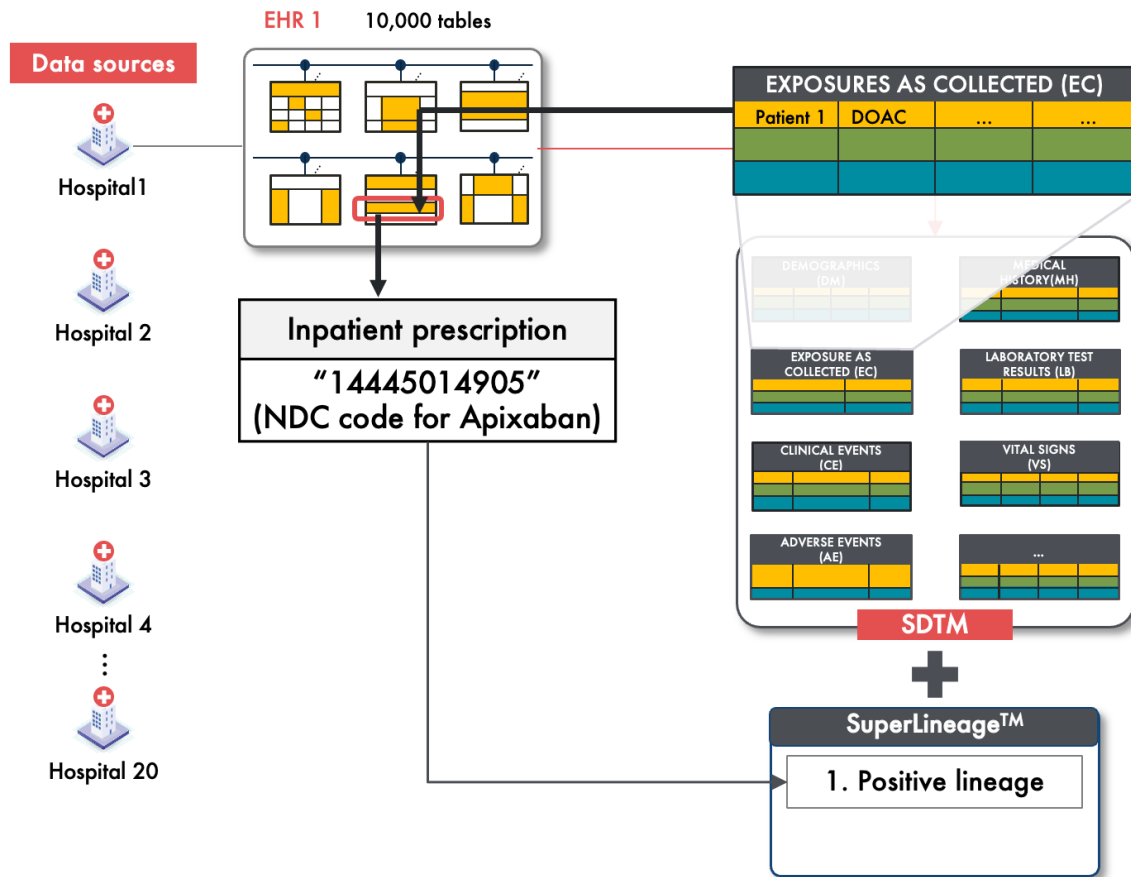
Indication: Stroke prevention in atrial fibrillation

ARM 1: Intervention arm (study drug)
DATA SOURCES: 10 sites
PATIENTS: 1,000

ARM 2: External control arm (standard of care; direct oral anticoagulant)
DATA SOURCES: EHR - 20 hospitals
PATIENTS: 50,000



SOLUTION: QUANTIFY DATA TRANSFORMATION PERFORMANCE



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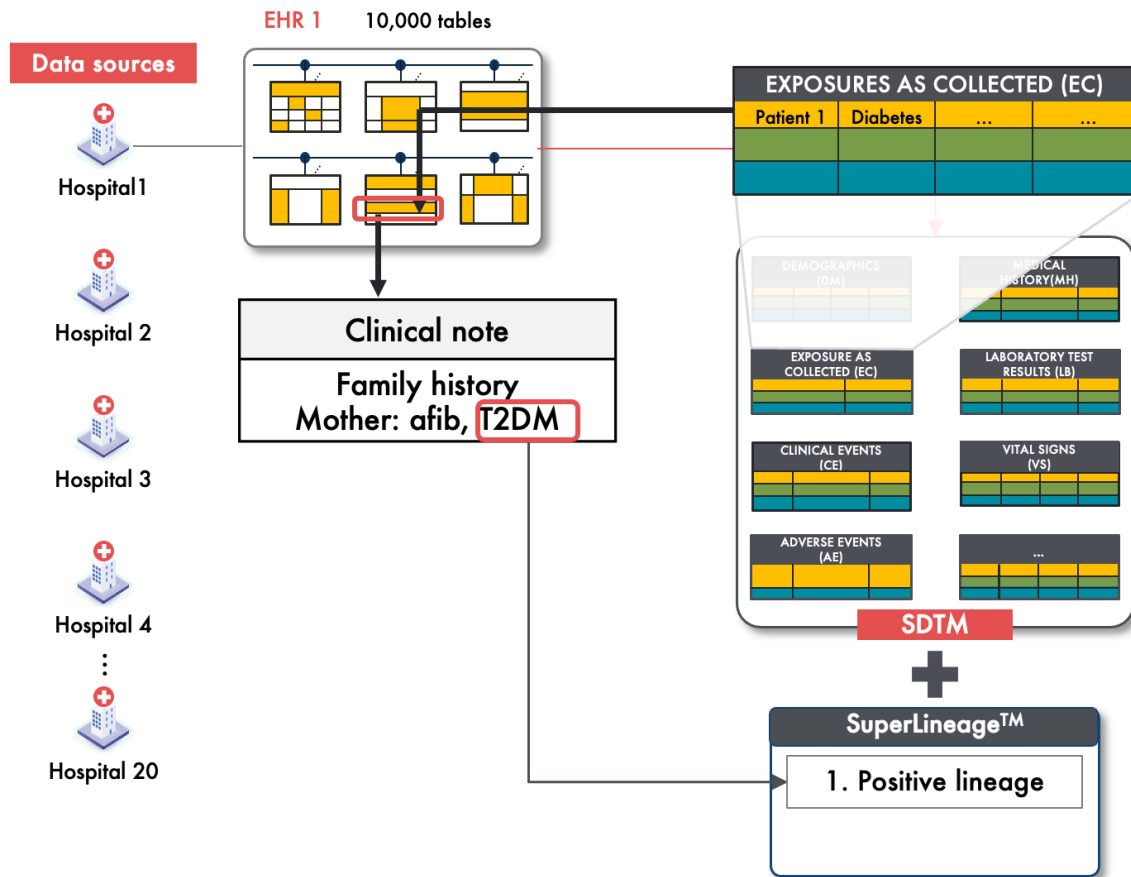
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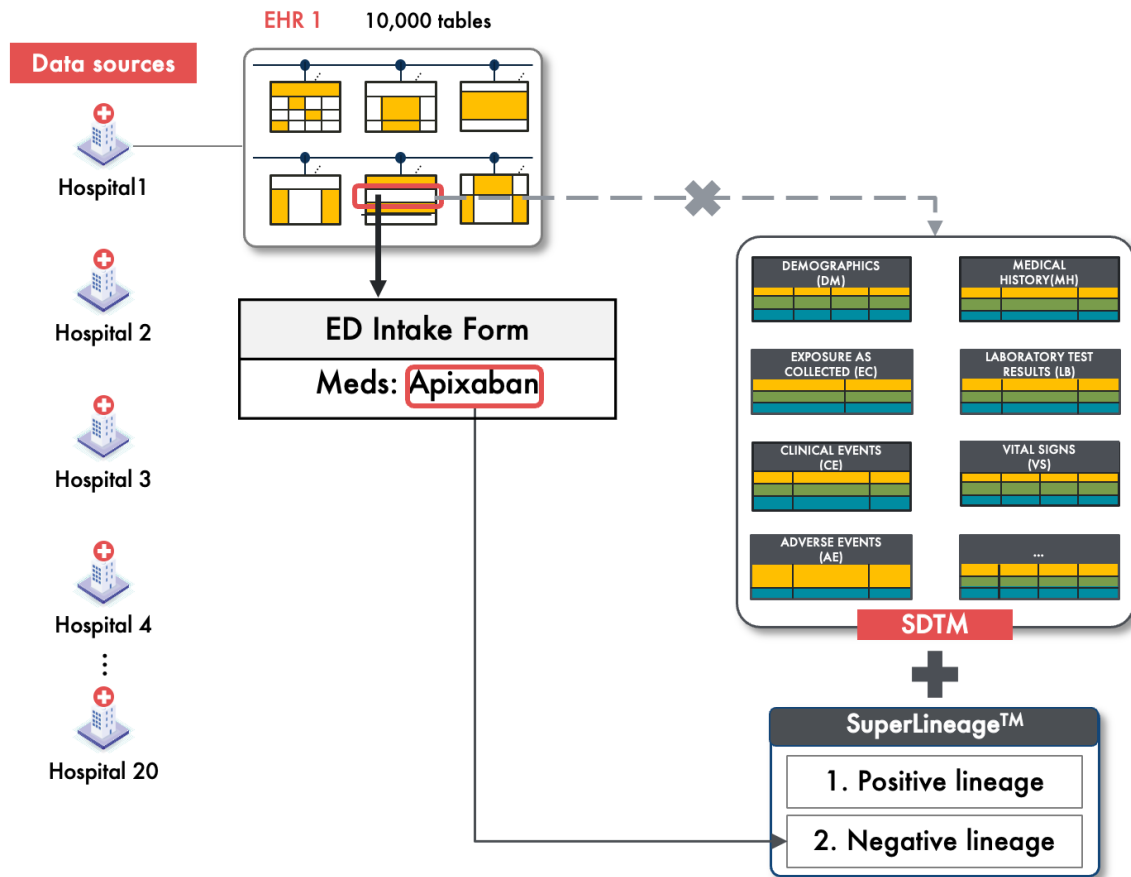
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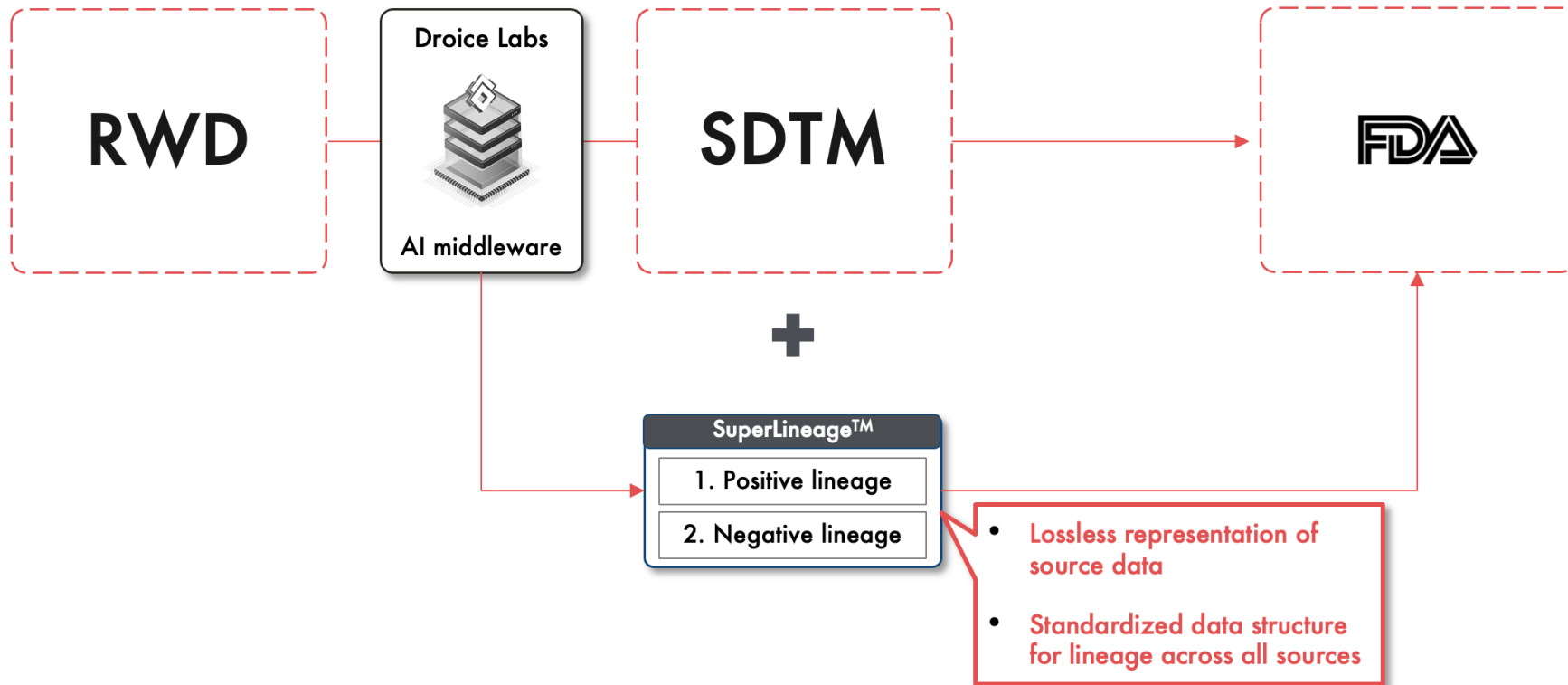


(standards expertise)



Droice Labs

(AI middleware)





Thank you

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