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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

The New Era for Standards: A Blueprint for A Digital-First Clinical Enterprise

Sarah Jamal, Strategic Client Advisor, Oracle

Speakers

Sarah Jamal
Strategic Client Advisor
Oracle

- ✓ Clinical Data Management (CDISC standards)
- ✓ Solutions Consulting
- ✓ Strategy and Customer Engagement

+ representative of Oracle's CDISC platinum membership and E3C member!

Agenda

1. “Putting pen to paper”, but no longer literally

2. What a digital-first clinical enterprise looks like

3. Strategies for the messy reality of running businesses

“Putting pen to paper”, but no longer literally

The transformative shift we are living

“The goal is simple but transformative: make standards executable so they can power automation across the research data life cycle.”

Sam Hume, Principal Consultant, CDISC

13% success rate

Phase 1 to market launch

Learning issue with 87% failure rate

Standards can unlock systematic learning

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What a digital-first clinical enterprise looks like

The journey and the value

From Protocol to Submission

- Secondary data usage

- Protocol
- USDM, Biomedical Concepts

Post-market learnings

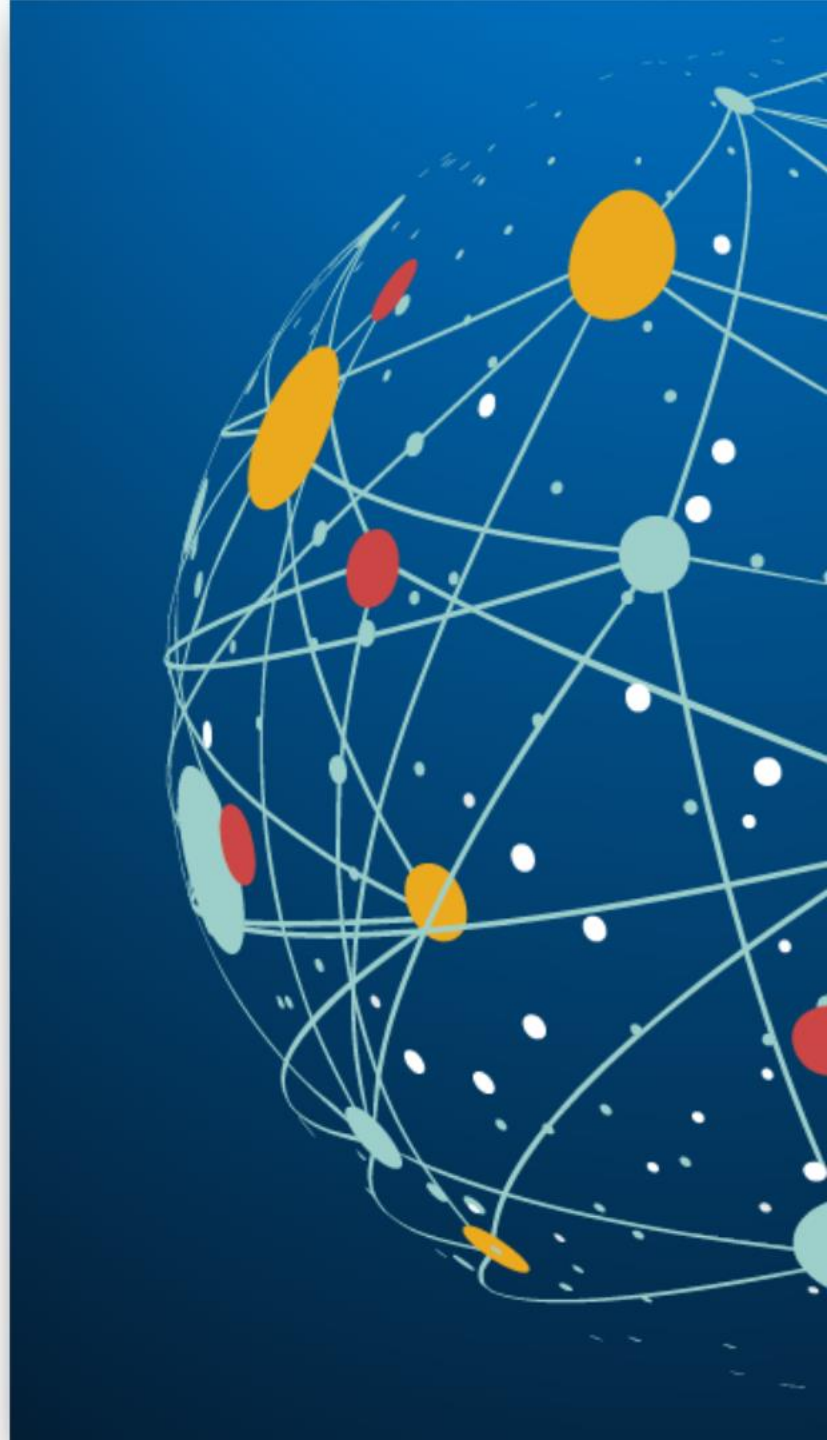
Study Definition

Analysis & Submis-sion

Study Conduct

- **CT, SDTM, aCRF, ADaM, Define-XML**
- ARS, Dataset-JSON
- TLFs & CSR

- CDASH, CORE
- Controlled Terminology (CT)



Digital-first clinical enterprise

Study definition

Study conduct

Analysis & Submission

Human expertise

Defines optimal study design within study protocol

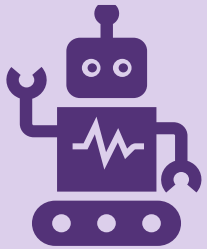
Selects sources of applicable metadata (e.g. corporate standards)

Standards

USDM provides a standardized way to described the protocol as a digital object

BCs provide a template for the meaning of each clinical observation required per protocol

TAUGs provide disease-specific interpretation of standards



Automation / AI

Ensure the protocol fits into a compliant structure

Reads and interprets digital protocol

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Digital-first clinical enterprise

Study definition

Study conduct

Analysis & Submission

Human expertise

Defines needed integrations between systems

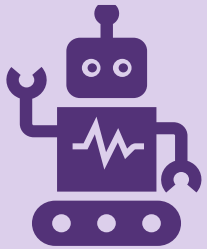
Reviews and validates automated setup

Standards

CDASH standardizes how data is captured in eCRF

BCs provide a template for the meaning of each clinical observation in the eCRF

TAUGs provide disease-specific interpretation of standards



Automation / AI

Translates **USDM** to downstream standards or system specifications, as applicable

Maps CDISC to other standards, e.g. E2BR3, LAB, FHIR

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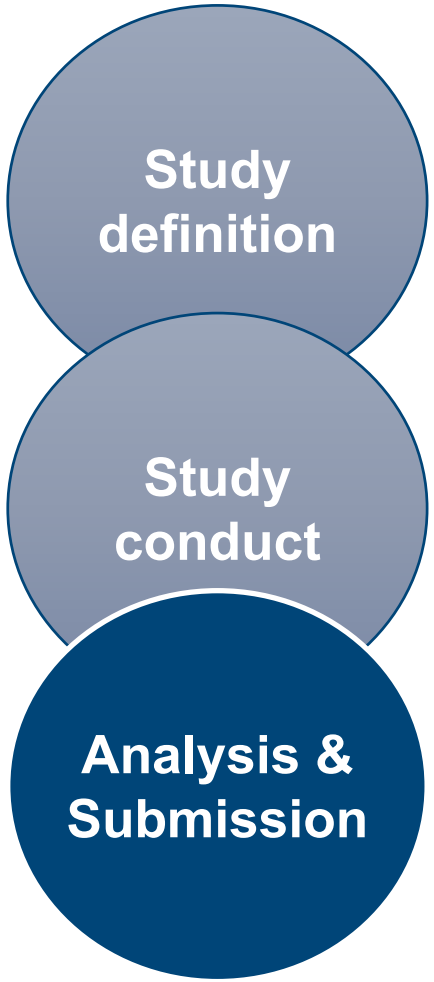
Digital-first clinical enterprise



Human expertise

Selects required outputs

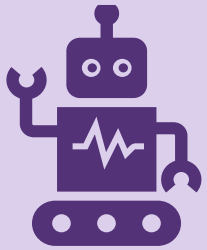
Reviews and validates submission outputs

Standards

SDTM standardizes how collected data is structured for regulatory submission

ADaM standardizes how data is transformed into analysis-ready datasets

define-XML provides machine-readable metadata describing datasets, variables, and their relationships



Automation / AI

Generates compliant submission outputs generated from mapping metadata (shells) and clinical data (final outputs)

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A familiar example – Systolic Blood Pressure (SBP)

Manual Protocol
Requires collection of SBP

CRF manual definition
Manual creation of a field for SBP

Data Tabulation into SDTM
Programmer writes code to map SYSBP from EDC into SDTM structure

Data Analysis
Programmer writes code to map SYSBP from SDTM to ADaM and to generate TFLs

Multiple re-interpretations = **duplicated efforts, risks for inconsistency, slower timelines, less trust in data reuse for learnings**

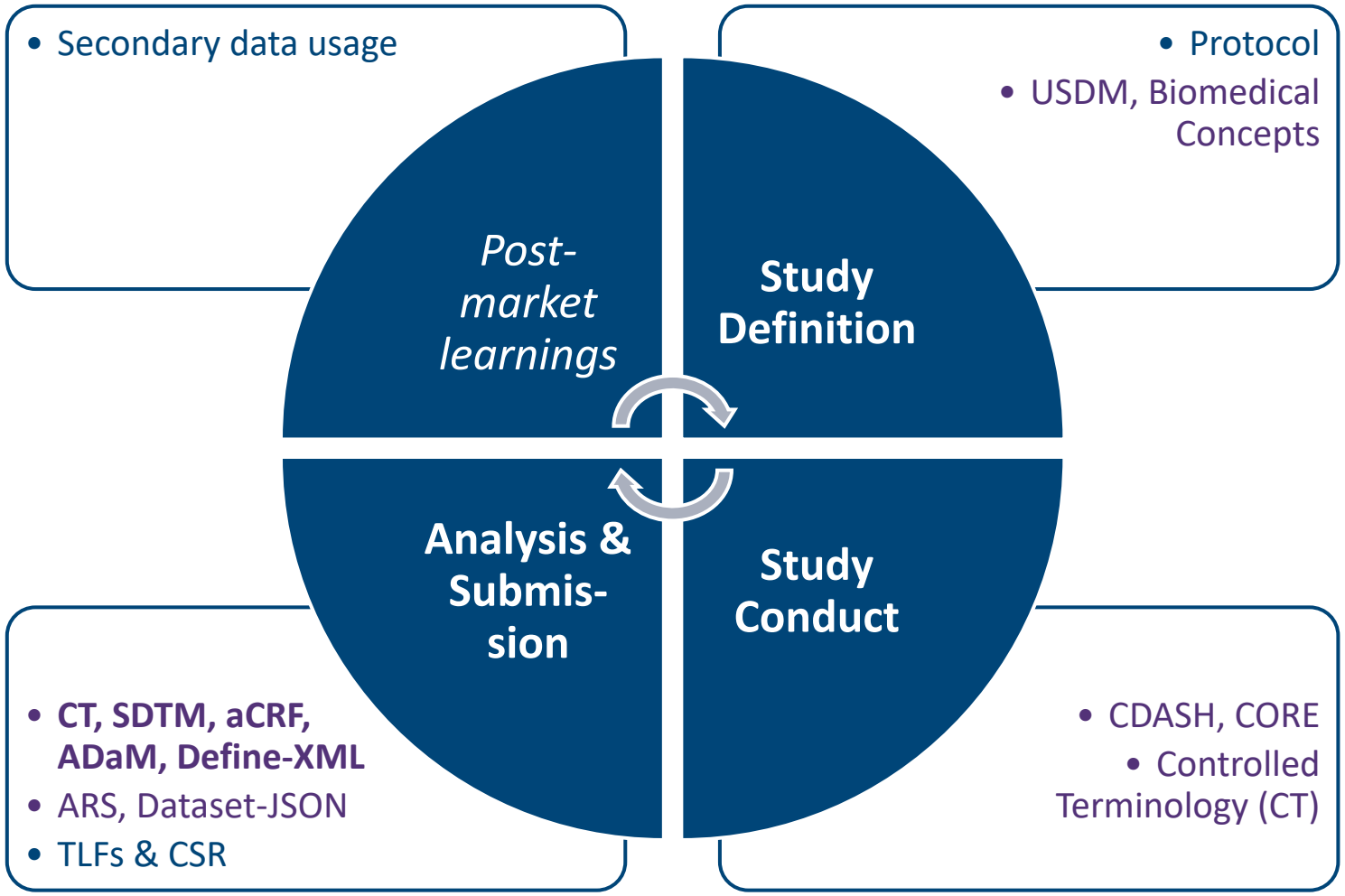
USDM Digital Protocol using Biomedical Concepts
SBP = C25298

Automated CRF setup using CDASH + Mapping clinical data from EHR (FHIR) to EDC (CDASH)
SBP has a universal label, units and metadata (C25298)

Auto-generated SDTM mapping
SBP = C25298 is auto-mapped into SDTM (VSTESTCD = SYSBP, VSTEST = Systolic Blood Pressure)

Auto-generated ADaM and ARS mapping
SDTM VS domain flows to ADVS, where BC can specify "change from Baseline" derivation
ARS Vital Signs shell inserts value associated to C25298

From Protocol to Submission



Business impact

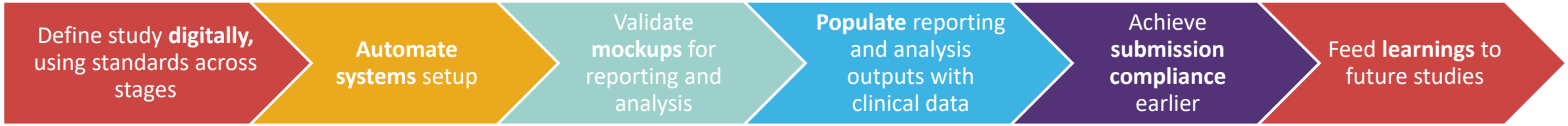
- ✓ Automated systems setup
- ✓ Reduced manual handoffs and human-error
- ✓ Consistency and reusability
- ✓ …

Increase the probability of success

Strategies for the messy reality of running businesses

Building the plane while flying it

The optimal journey (greenfield)



The current reality (modernization)

Pilots driving incremental efficiencies, but only on the 'edges'

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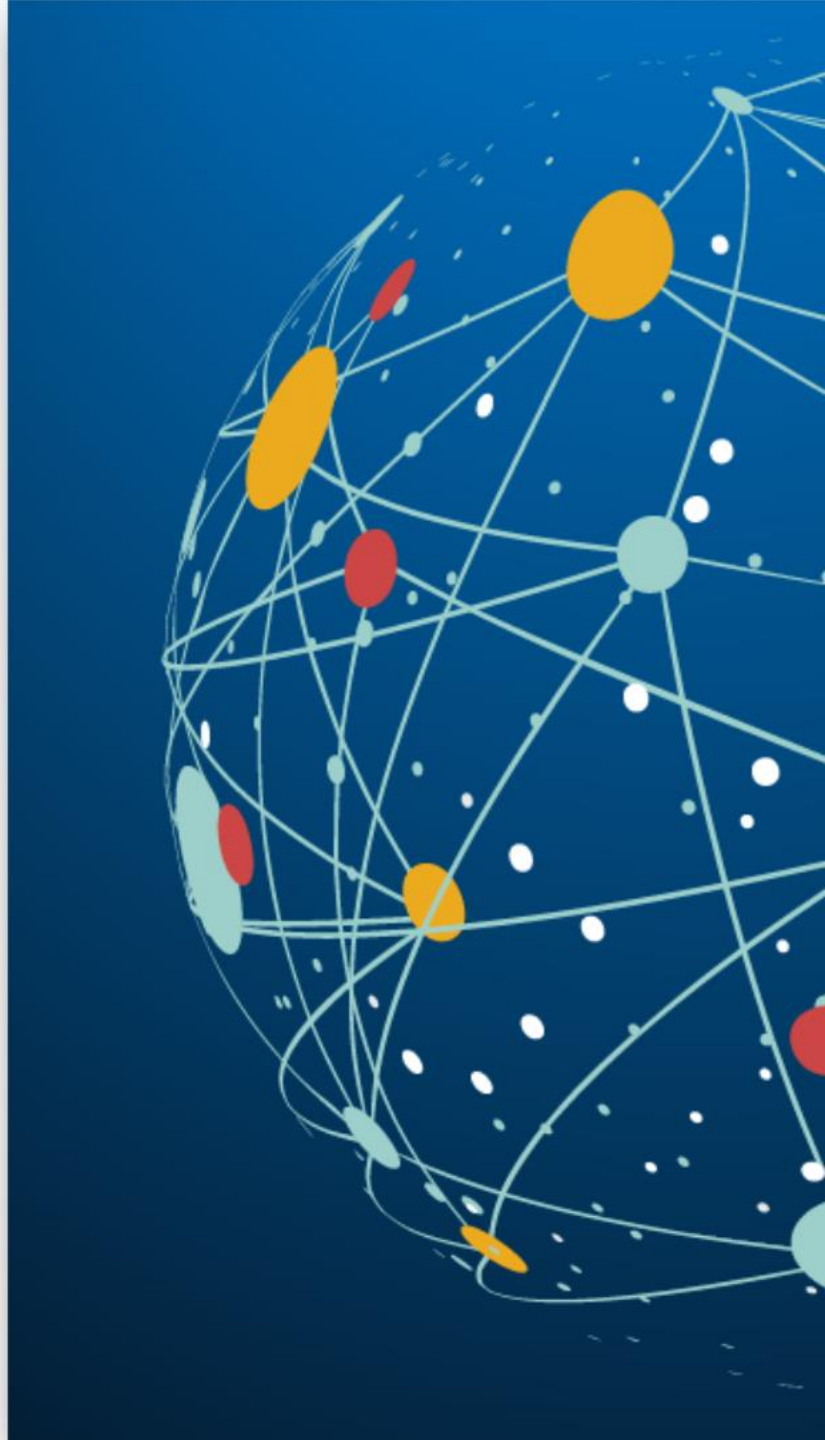
Operational reality requires phased strategy with consistent metadata layer and orchestrated workflows

- Adopt “define once” paradigm, *i.e. build the metadata backbone*
- Aim to connect what already exists before replacing anything
- Orchestrate workflows across systems, *i.e. aim for end-to-end value*

AI without standards optimizes tasks

Standards + metadata enable AI to optimize the system

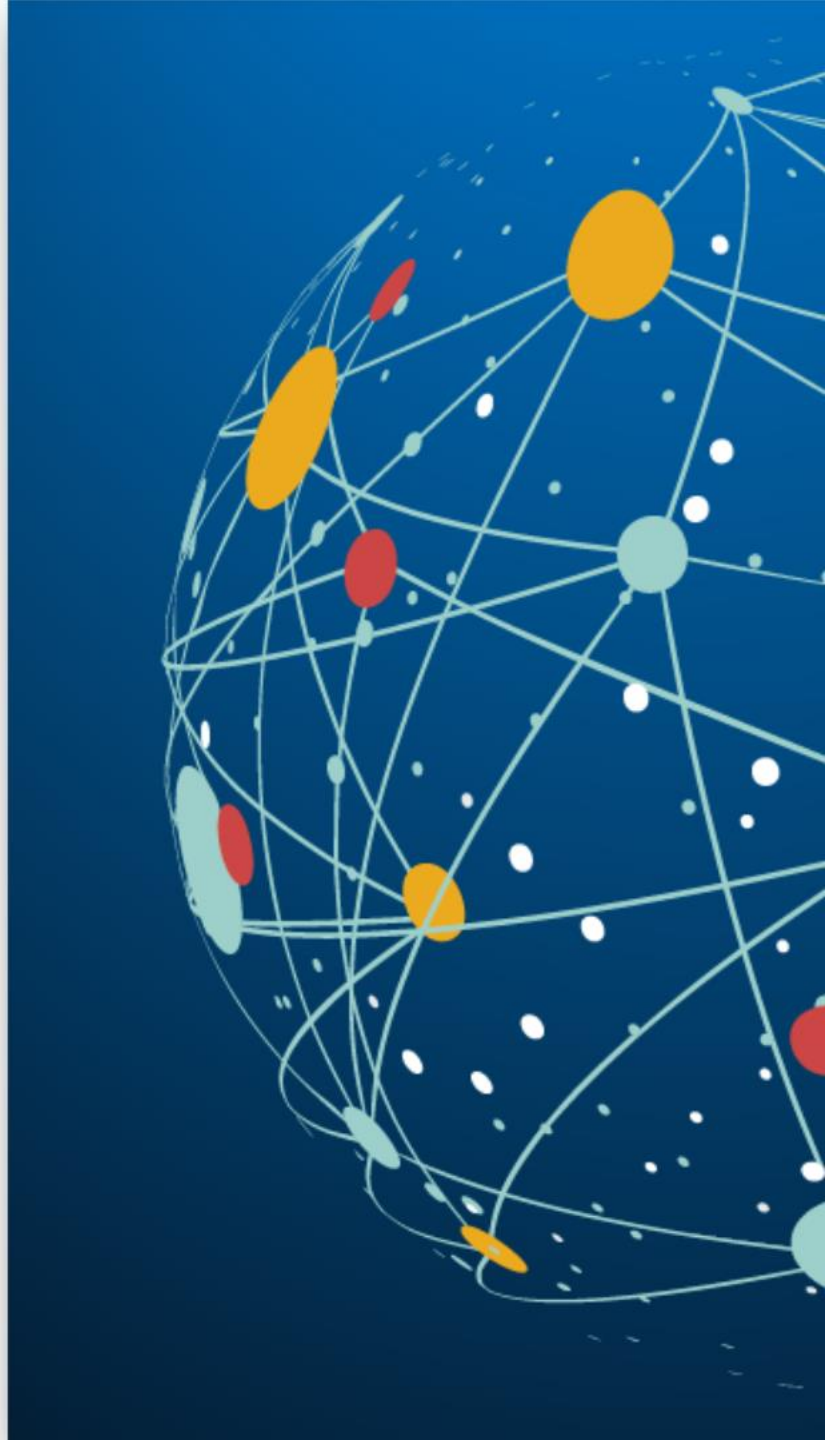


Where to start?

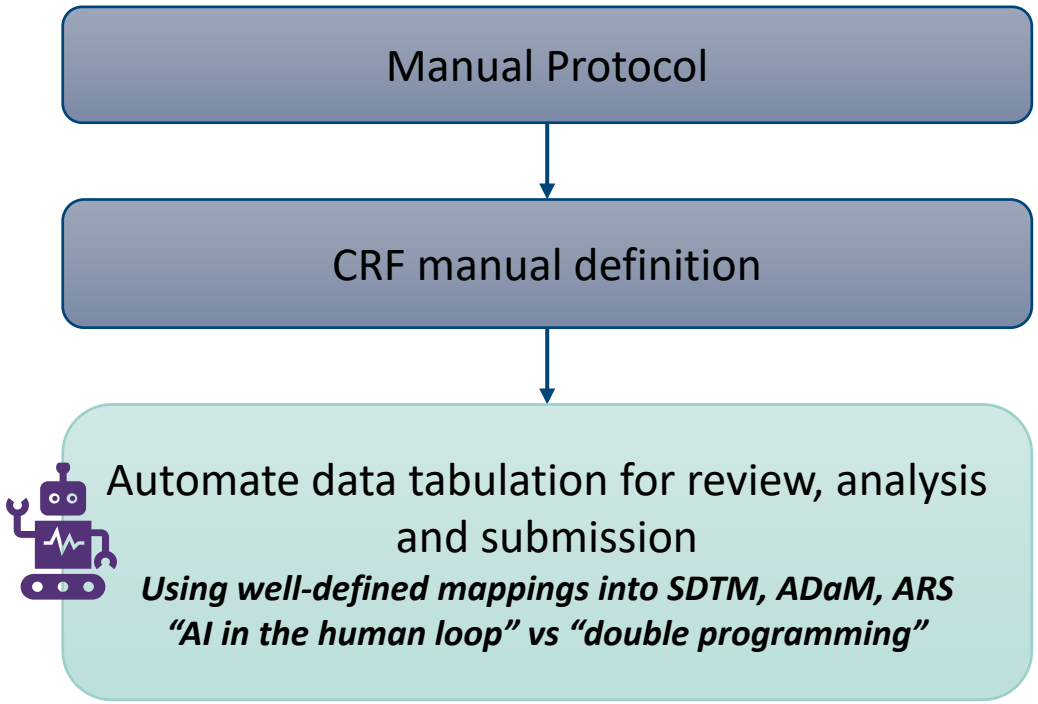
'Not-so-secret' secrets to successful adoption

1. Segment your portfolio
2. Use metadata layer alongside existing processes to enable cross-study view & reuse (study pooling)
3. Pick a chronological entry point:
    1. test and prove value on 1–2 studies;
    2. gradually expand footprint.

Transform how studies are done *over time*



A downstream example – data tabulation & analysis



- Use metadata to automate tabulation and analysis outputs
- Change management mainly on process
- Minimize human intervention
- Measure proof points to justify ROI
- Move upstream by connecting workflows
- *'Side-effect' benefits*

Takeaways

Key Takeaways

1. Standards are key to learn systematically
2. Benefits range from reduction in cycle times to lower operational costs and AI-ready data
3. Start from metadata consistency

Standards are not a constraint.

They are your **strategic lever** for speed, scale, AI and smarter trials.

Thank You!

Questions?