Disclaimer

This presentation is for informational purposes only and does not represent professional guidance or advice. Any views and opinions expressed during this presentation are those of the presenters and do not necessarily reflect the views or policies of Janssen Research & Development, LLC, or any other company in the Johnson & Johnson Family of Companies. This presentation may not be reproduced, modified, or copied, in whole or in part, without the express written permission of Janssen Research & Development, LLC

RWD Requirements for Submissions - How Statistical Programmers Play with the RWD

Pan Pan, Lyndi Wex, Qing Ma

November 4, 2022
PhUSE SDE – Shanghai

What We Talk about when Talk about RWD/RWE?
More specifically in submission?

- What are words that popping up when atistical ?

External controlled arm; External database; Missingness; Data cleaning; Data standards; Imputations

Transformation; Mapping; Coding systems; SDTM; ADaM; OMOP CDM; FHIR

- What are Health Authorities guidance saying? Evolving HA Environment

Pragmatic Design; Non-interventional; Externally controlled; Registry; EHR; Medical claims

Fit-in-use; Bias; Data Privacy; Feasibility; patient-level data; Data integrity; Audit trial; replicate

CDISC; Mapping Impact; Data dictionary; Justification; OMOP CDM

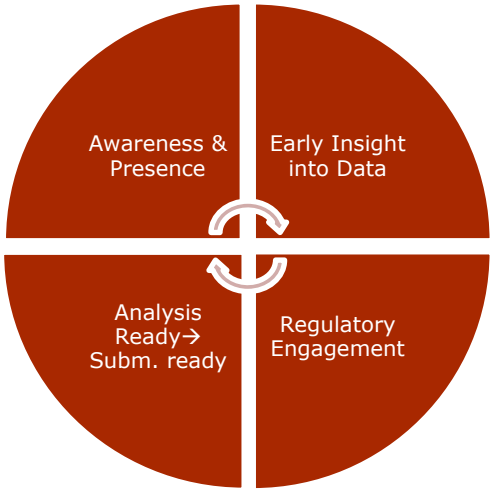
- Existing processes, systems in place for conventional Clinical Trials are not sufficient or entirely relevant when we encounter RWD studies

Why RWD Playbook (for statistical programming)?
- a brief history

Roadblocks/ Opportunities

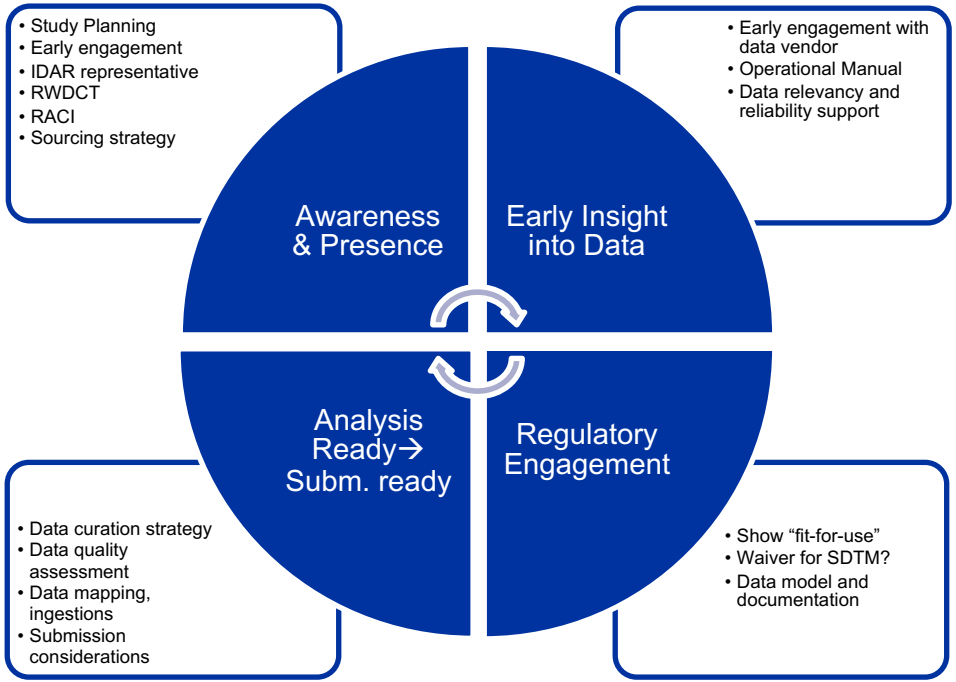
1. Lack of early engagement.
2. Roles & Responsibilities across functions are different
3. Standards of RWD? Data acquisition? Curation? Cleaning? Mapping?
4. Some established processes are not applicable

RWD Playbook for Statistical Programmers



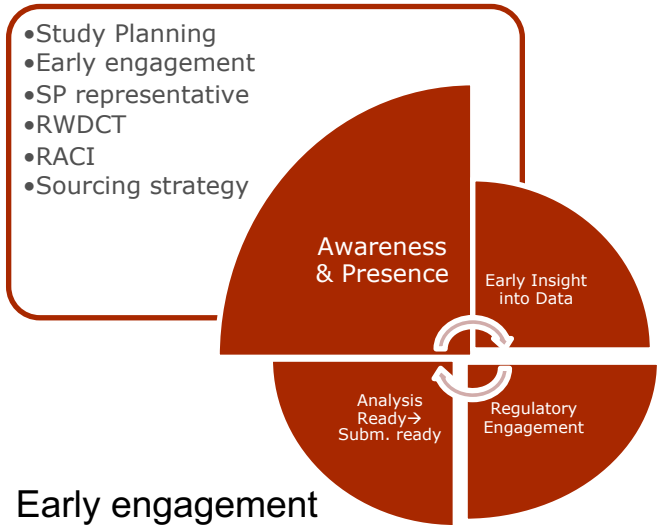
Core Concepts

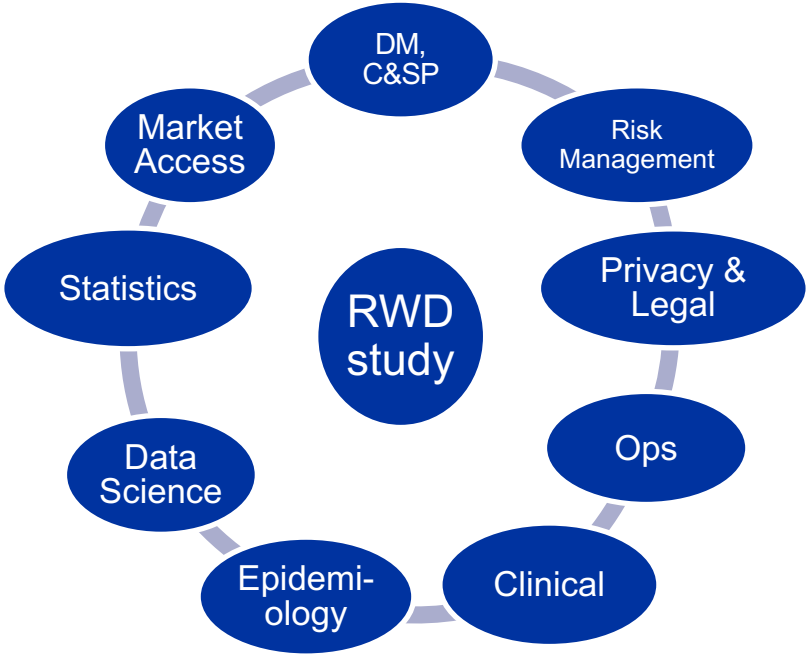
Core Concepts in RWD Playbook – Recommended best practices in RWD activities related to regulatory activities for statistical programmers



Make the RWD Playbook Living and Actionable

Stage Ⅰ: Early Engagement





- Early engagement
- Roles & Responsibilities?

SP: Statistical Programming
RWDCT: Real-world data council team
RACI: R=Responsible, A=accountable, C=Consulted, I=Informed

Make the RWD Playbook Living and Actionable
Stage Ⅰ :Operationalize RWDCT

Real-World Data Council Team (RWDCT)

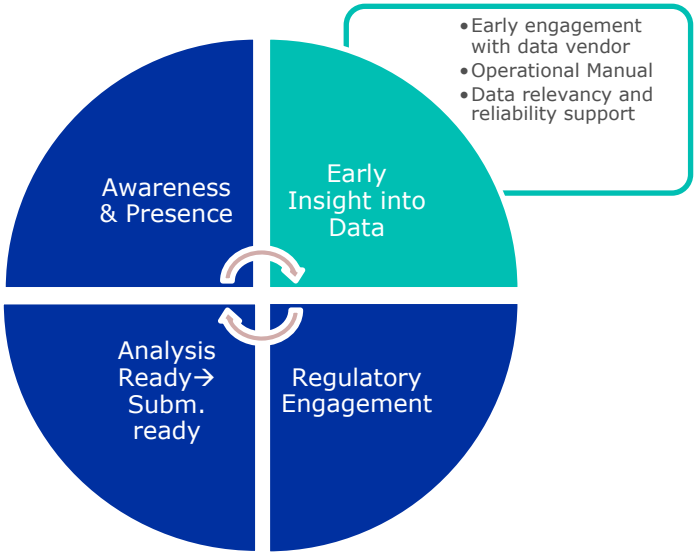
- ✓ Who is the Owner/ Driver?
- ✓ Identify the RWD? And Intent to use?
- ✓ Data vendor contracting?
- ✓ Data privacy?
- ✓ Data Acquisition?
- ✓ Data Transfer Agreement & Data Operational Manual?
- ✓ Fit-in-use assessment?
- ✓ Data standards?

RACI Table (R=Responsible, A=accountable, C=Consulted, I=Informed)

Activity	Integrated Data Analytics Reporting (IDAR)					Non-IDAR Functions		
	CDS	DT	DM	CP	SP&A	SDS	DS/Epi	CS
Responsible for identifying the RWD			I	I	I	R, A	R, A	R, A
Responsible for determining Data Relevancy		I	I	I	C	R	R, A	R, A
Source Data Flows (including vendors, Data Transfer Agreements (DTAs), Business Partner Risk Assessment Process (BPRA))			R, A	C	C	I	I	I
Data Acquisition and Coding			R, A	C	C	I	I	I
Assessment of Data Reliability			R	R	R	R, A	R, A	C
Database Releases			R, A	C	C	C	C	C
Creation of Mapping File			I	R, A	C	C	C	I
Creation of SDTMs			C	R, A	C	I	I	I
Creation of SAP			I	C	C	R, A	I	I
Creation of DPS			I	I	R, A	R	I	I
Creation of ADaMs			I	I	R, A	C	I	I
Data linkage from more than one Databases			I	C	R, A	R	R	R
Data Integrations			I	I	R, A	C	C	C
Standards used			I	R, A	R, A	R, A	R, A	I
Determination of waiver requirement for SDTMs	C		I	R, A	R	C	I	I
Determination of waiver requirement for ADaMs			I	I	R, A	C	I	I
Privacy and Legal Considerations		C	I	I	I	R, I	R, I	R, I

Make the RWD Playbook Living and Actionable

Stage Ⅱ: Data Vendor Communications



EDC, SDTM: Structured and Standard

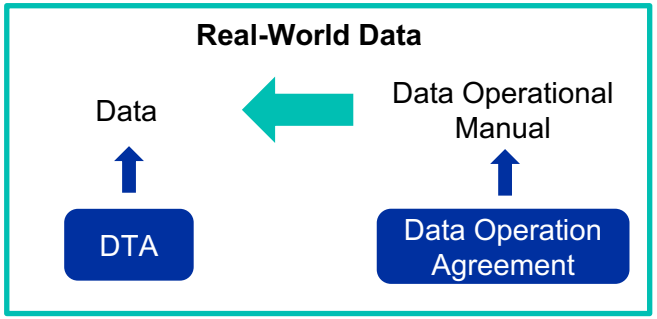
Real-World Data

Data ← Data Operational Manual

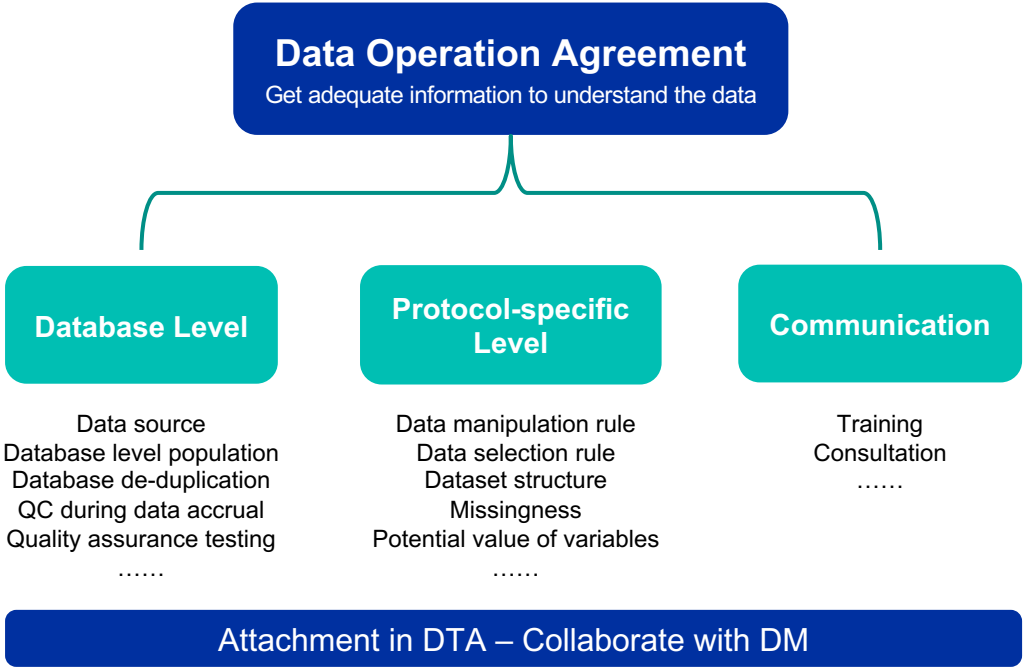
- Supposed to have sufficient information to understand the data
- Fulfill the protocol objectives
- Support fit-in use assessment – Reliability perspective
- Can be further used in SDRG and/or ADRG to explain the data source, the data flows and mapping rules, etc.

Make the RWD Playbook Living and Actionable

Ensure to understand the Data, but How?

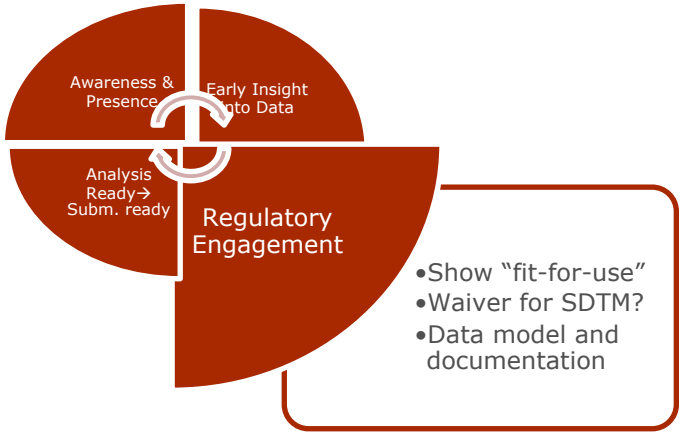


- The data operation agreement aims at **aligning the content of data operational manual to ensure sufficient information**.
- The agreement can be used as an attachment in DTA managed by DM.



Make the RWD Playbook Living and Actionable

Stage Ⅲ: Regulatory Engagement & Fit-in-use Assessment



HA Consultation – Drive by Regulatory Affair

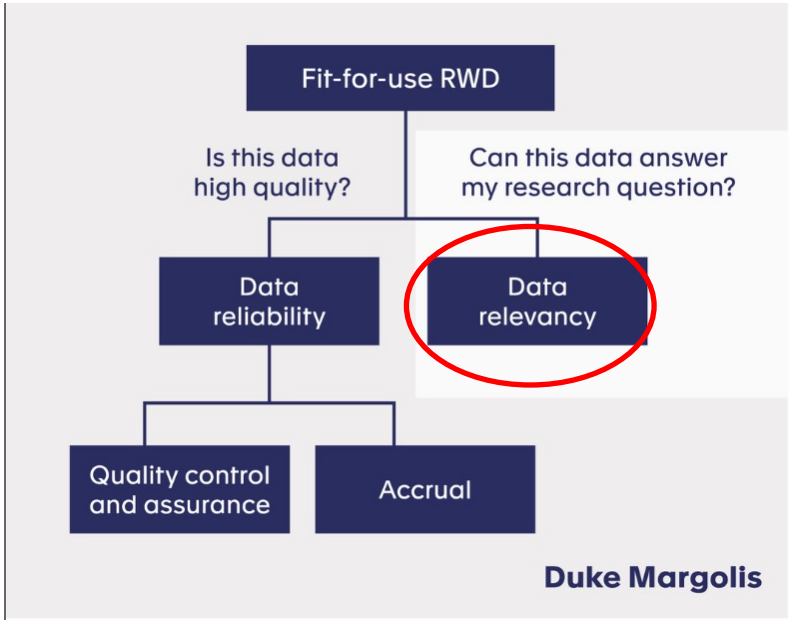
? What data standards can be accepted?

? Fit-in-use plan

FDA: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products (Draft, Sep 2021)

Fit-in-use assessment

– Driven by Statistician or Data Science

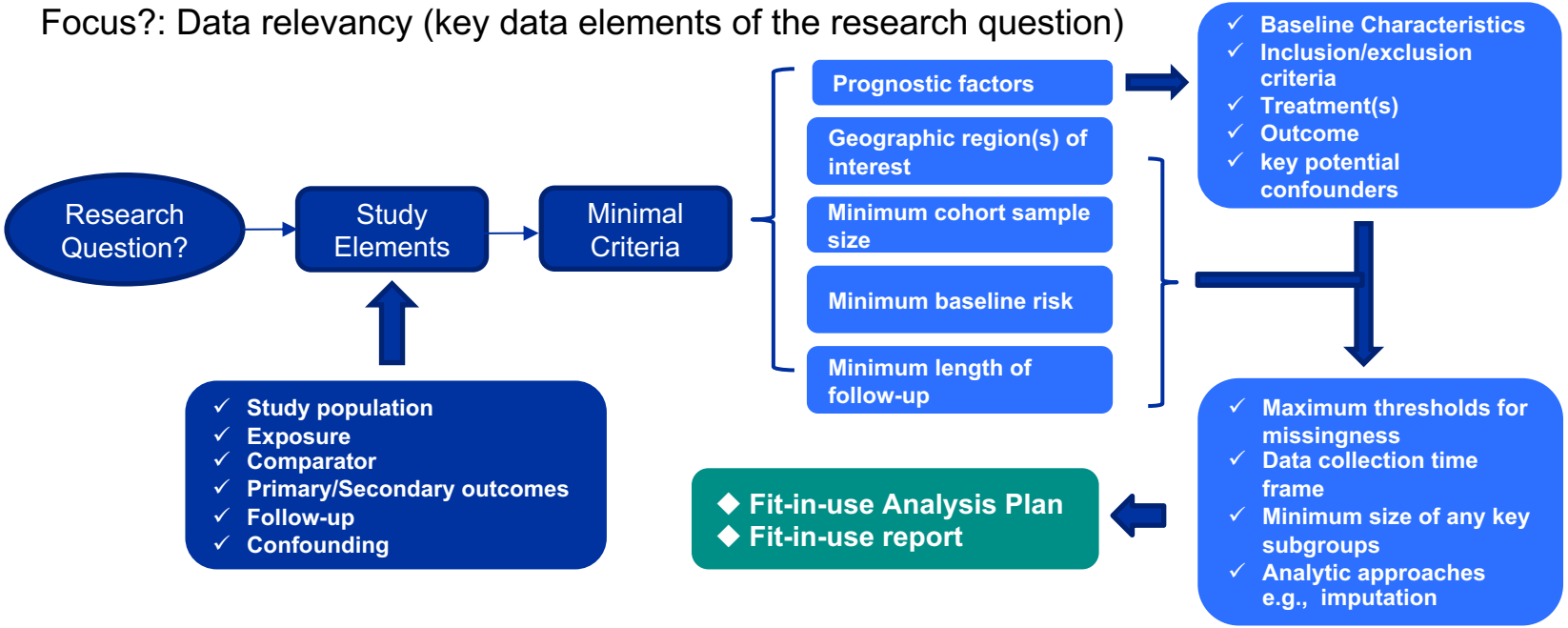


Make the RWD Playbook Living and Actionable

Stage Ⅲ: Fit-in-use Assessment

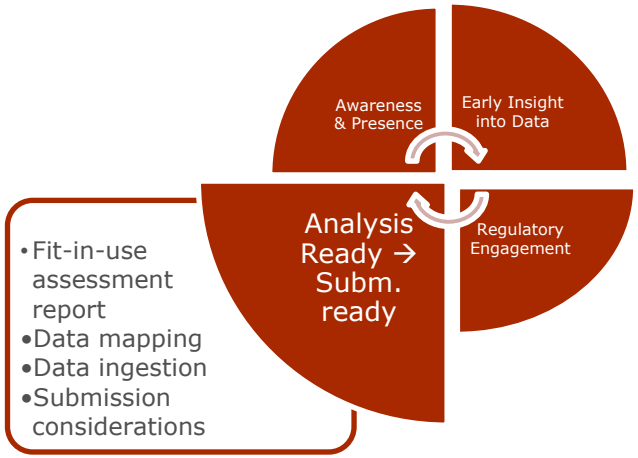
When?: Secondary use of data or hybrid data sources that merge secondary data with primary data collection.

Focus?: Data relevancy (key data elements of the research question)



Make the RWD Playbook Living and Actionable

Stage IV: Mapping Your RWD



Why Mapping:

1. Serve the submission readiness.
2. Serve the analysis defined in protocol/ SAP.

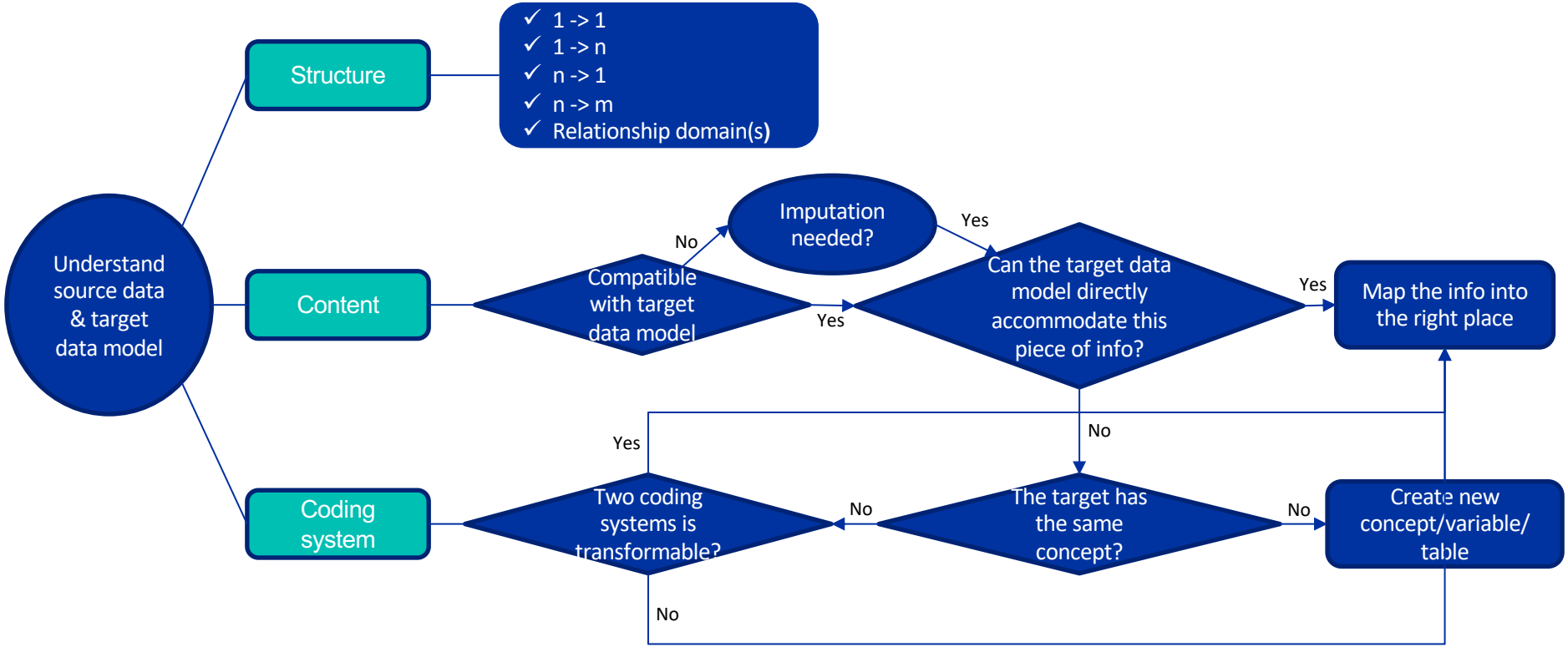
Challenges on Mapping

1. Various real-world data models
2. Un-structured values
3. Different coding systems and controlled terminology

FDA: Data Standards for Drug and Biological Product Submissions Containing Real-World Data Guidance for Industry (Draft, Oct 2021)
EMA: European Medicines Regulatory Network Data Standardization Strategy (Dec 2021)
PMDA: FAQs on Electronic Study Data Submission (Jun 2022)

Make the RWD Playbook Living and Actionable

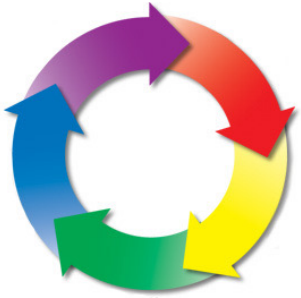
Stage Ⅳ: Mapping Your RWD



In Summary

Visibility

Cross-Functional Council



Whole life cycle Engagement

Thank You!