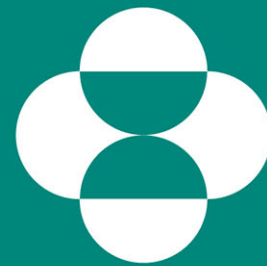


MERCK METADATA REPOSITORY:

BUSINESS-BASED VALUE IN AN MDR



MERCK

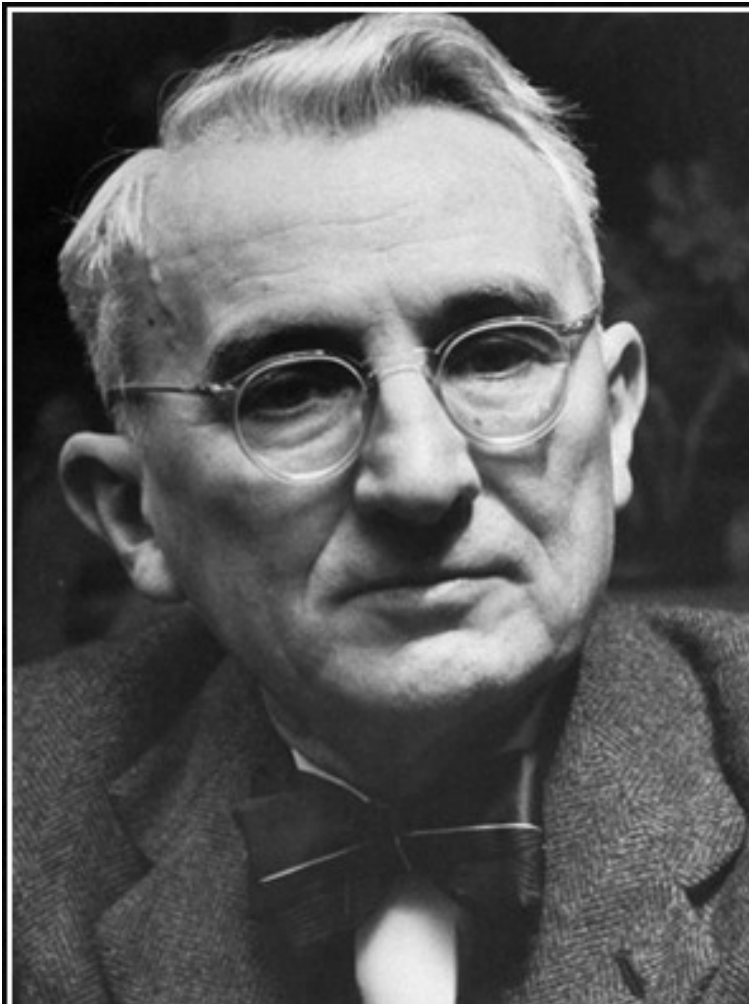
INVENTING FOR LIFE

A. Brooke Hinkson

Manori Turmel

Karl Konrad

PhUSE Connect Conference, Raleigh NC, 4-6 June 2018



Keep your mind open to change all the time. Welcome it. Court it. It is only by examining and reexamining your opinions and ideas that you can progress.

— Dale Carnegie —

AZ QUOTES

Business Problems to Address

Current information management practices are not sufficient or scalable

My Wish List:

Technology-enabled information management business processes

- Enable informed business decision making capabilities regarding the definition, use, maintenance and sharing of clinical info.

Standards and flexibility

- Leverage industry standards to implement well-defined data definitions that are harmonized across the clinical lifecycle
- Apply “fit for purpose” data definitions into a trial

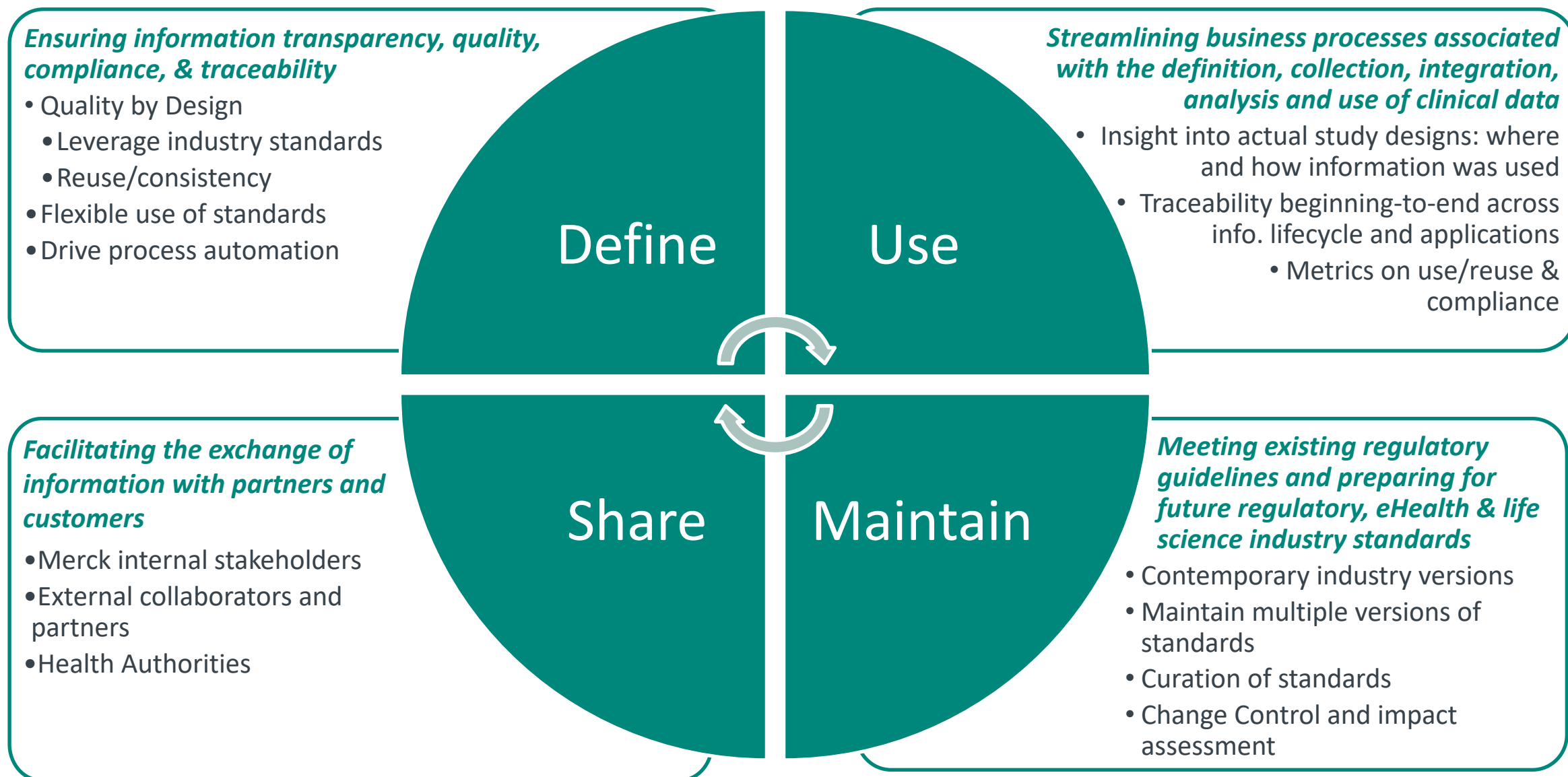
Model driven information management

- Information is modeled, shared, and used to drive automation of processes

A foundation on which future processes & technologies can be applied

- Enabling a true collaboration between machines and subject matter experts

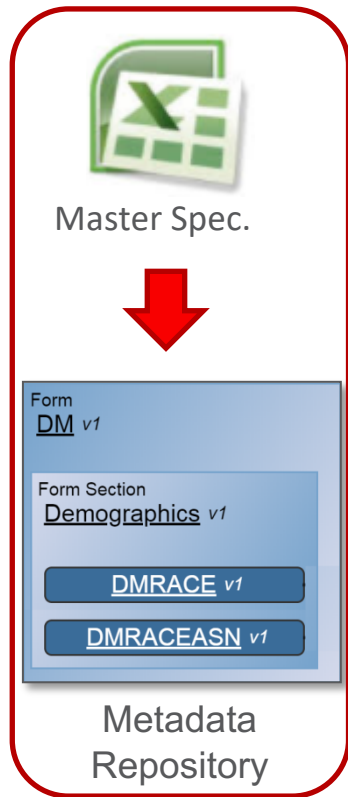
Consistently define, use, and reuse information globally through the use of standards to achieve process and scientific excellence by:



Transition from spreadsheets to managing data definitions within a semantic-based metadata repository (MDR)

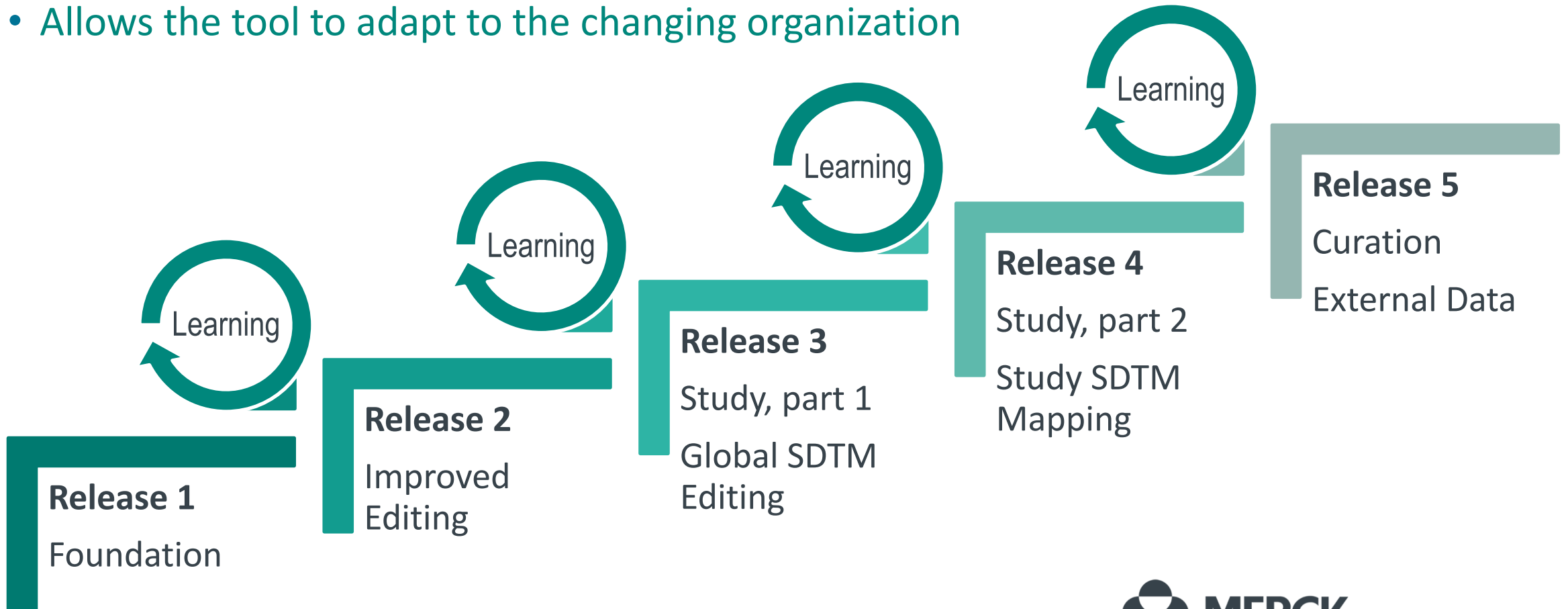
“Master Specification” Context

- **Scope:** Basic data collection information to support EDC build, SDTM mappings (for multiple IG versions), and data definitions to support the generation of our Data Management Workbench (DMW) review models
- **Includes:**
 - Within a workbook: A minimum of 8 worksheets; number increases with each form version
 - Within a worksheet: Numerous columns (e.g., Columns A – CG) and rows (e.g., over 550)
- **The Master Specification represents one data definition spreadsheet**
 - One Master Specification for each unique eCRF
 - Over 20 standard components today
 - 11 spreadsheets representing different information have to be harmonized and fed into DMW
 - Will reduce the number of standard components as we transition info. into the MDR

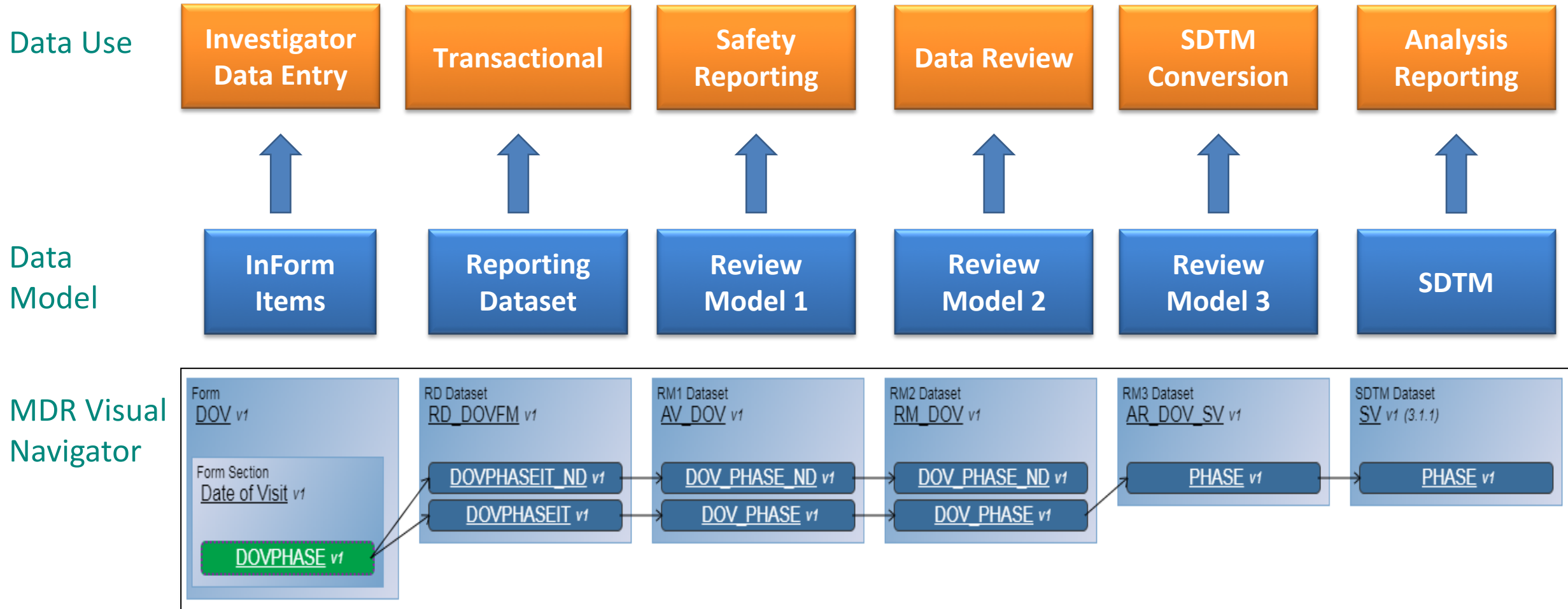


Implementation - Release Strategy

- Frequent, Incremental improvement with each release
- Allows the organization to grow with the features of the tool
- Allows the tool to adapt to the changing organization



Change Management - Stakeholders

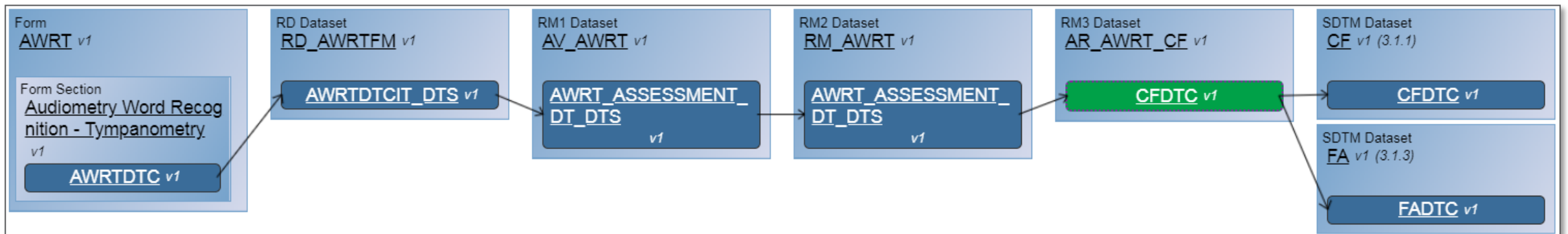


Change Management - Communication



Visualize Information Flow: SDTM Up-versioning Example

- When comparing the SDTM definitions across two different SDTM versions, it's not obvious to see what has changed
- Once information is loaded in an MDR, the data traceability is clear
 - This is represented across 4 worksheets in the Master Spec
- In the example below, the Date/Time of assessment is collected on the eCRF, goes through several data transformations, and in SDTM v3.1.1, it goes to the CF domain, while in SDTM v3.1.3, it goes to the FA domain

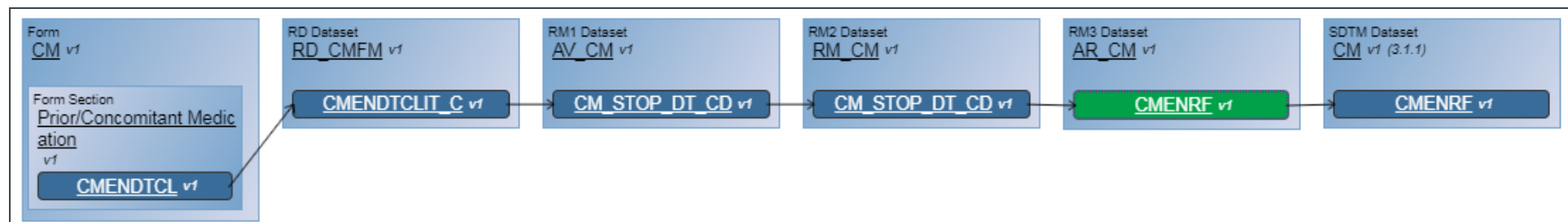


Visual Navigator - CMENDTCL

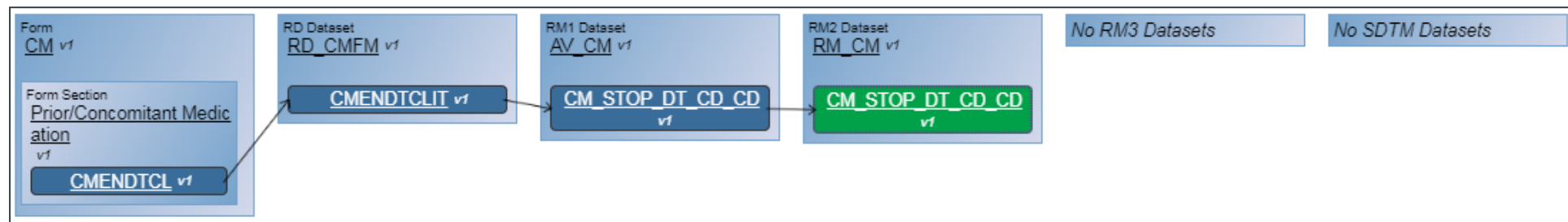
Start at SDTM 3.1.3
Item:



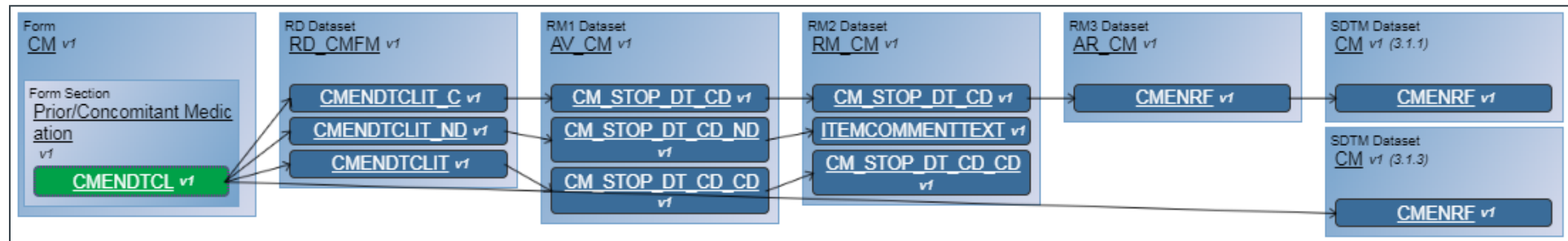
Start at RM3
Item:



Start at RM2
Item:

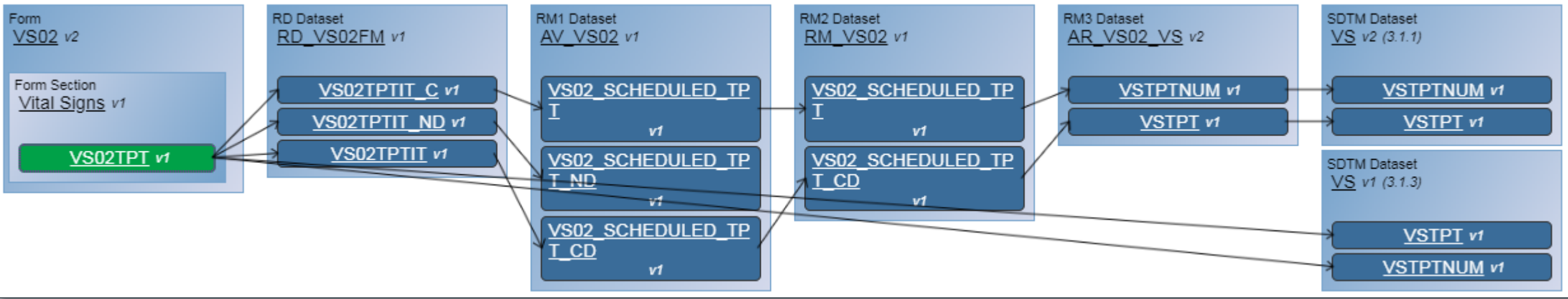


Start at Form
Item:



Semantic Links: Library Migration “Integrated”(Legacy) to “PDAM”(Next-Gen)

PDAM Data Flow for VS02TPT:



Library	Item Name	Question	Responses
Integrated	VSTPT02ESDE	Scheduled Time	Predose 1 hour post dose 2 hours post dose 5 hours post dose 12 hours post dose
PDAM	VS02TPT	Scheduled Time	Predose 1 hour post dose 2 hours post dose 5 hours post dose 12 hours post dose

Semantically, VS02TPT and VSTPT02ESDE are equivalent. Thus, the data flow of the migrated Integrated variable is the same as the PDAM variable, and you can re-use the data flow to VSTPT and VSTPTNUM in SDTM.

Near-term Business Value

- **Cross-company collaborations**
 - Understand similarities, and be able to link related items between the two companies
 - Once a link is established, then the data can be better understood by using the existing relationships, programs, etc.
- **Metadata Access for All**
 - Utilize a Data connector to reach into the MDR from other tools
- **Coordinate metadata handoffs to downstream systems**
 - SDTM programming is not performed in the MDR
 - Mapping definitions are described in the MDR
 - Utilize the versioning and mapping instructions in MDR to select which standard programs to execute for SDTM programming
- **Coordinated Roadmap Discussions**
 - Seems to be an endless number of expectations for an MDR
 - By using smaller, more frequent releases, the MDR can adapt to the current business need

THANK YOU