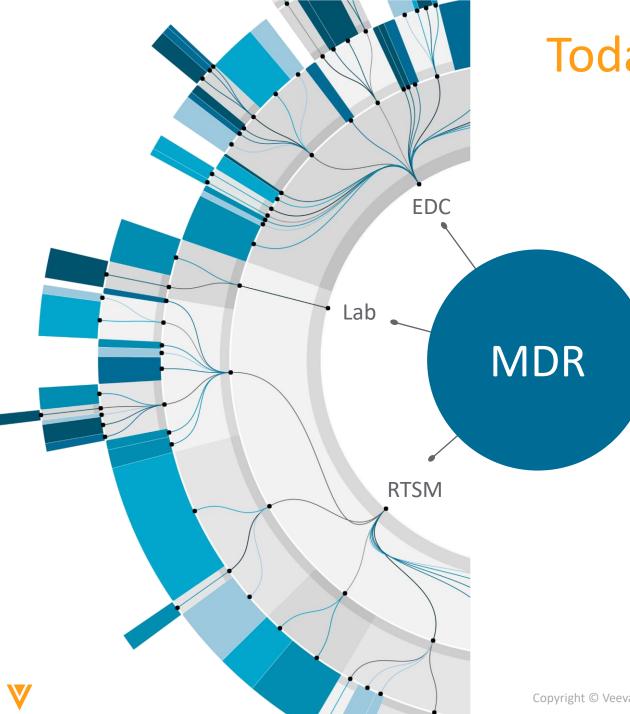


Veeva CDMS MDR Related Approach and Roadmap



Today's Leading MDR Strategy

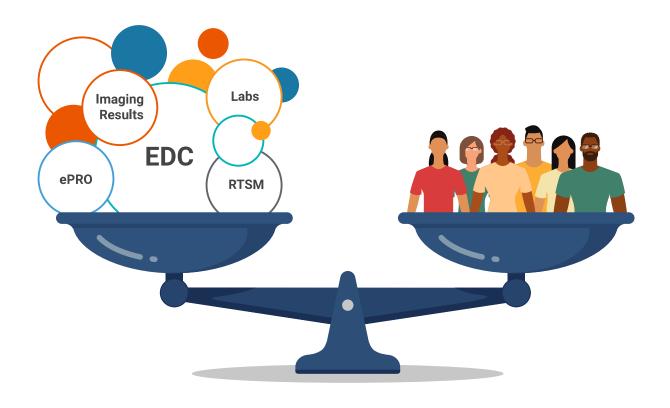
- Design studies with the end in mind (analysis)
- MDR is an important solution to tie together:
 - study design
 - data collection
 - analysis
 - submission
- Study design should start with MDR and through relationships define data collection and analysis
- Data Collection should be as automated as possible
 - MDR should be a repository of all (or as much) data collection metadata to automate collection build



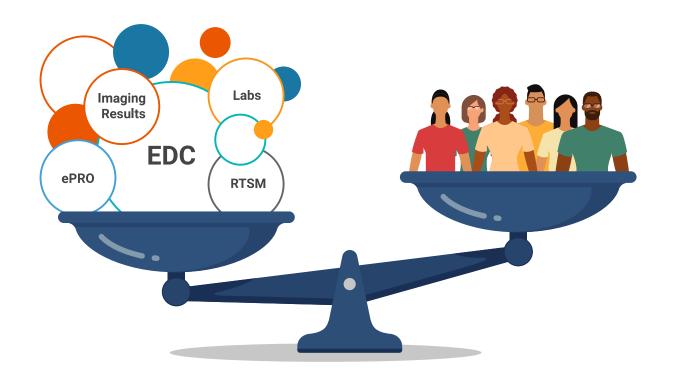














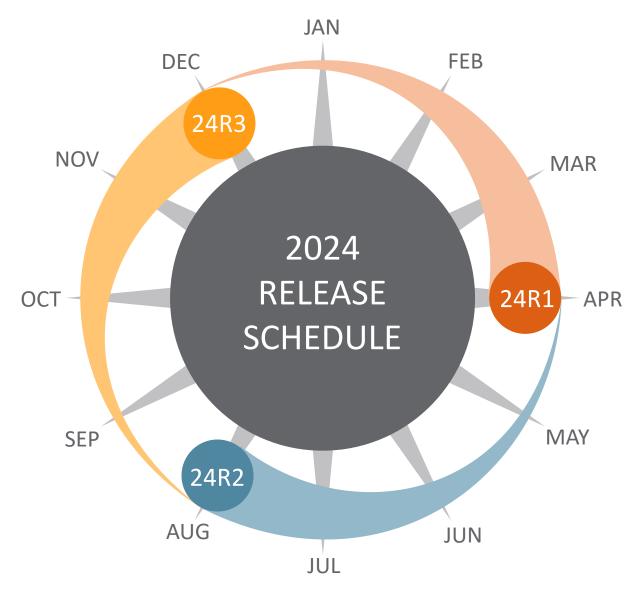
Scalability of Centralized Metadat

 How many unique sources of data today and in the future?

- How many active versions of those systems?
- How many unique properties/attributes per source system?
- How many property settings per attribute per study?
- What efficiency do you lose in study build by working outside of the system (display logic/rules/etc)?
- What fragility is created by working outside the data collection system off the shelf design environment?
- What is the cycle time that will be necessary to add or more importantly modify external metadata?



Vault Release Cycle – Growth of Value Over Time





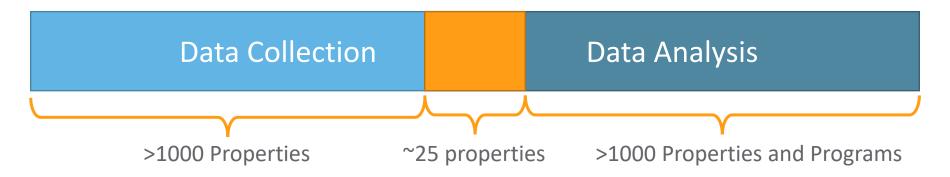
Common Metadata Between Data Collection and Data Analysis

Data Collection

Data Analysis



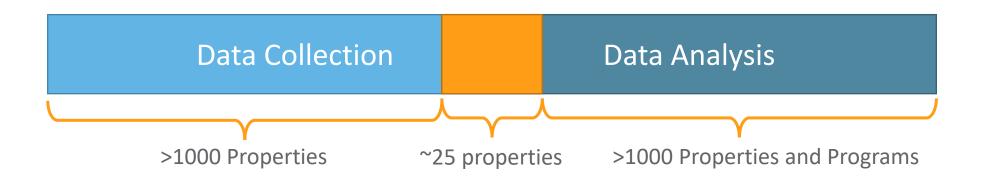
Common Metadata Between Data Collection and Data Analysis



Est. 25 properties of EDC metadata affects downstream programming/analysis



Common Metadata Between Data Collection and Data Analysis



Event

Name
Label
External ID
Type
Repeats

Form

Name Label External ID Repeats

Item Group

Name Label External ID Repeats Default Adds

Item

Name
Label
External ID
Data Type
Length

Codelist

Name External ID Code Decode (Label)

Unit

Name External ID Code Decode (Label)



Terminology For This Discussion

Data Collection Data Analysis

Data Definition

Specific study design metadata that is shared, common, and critical to both DM and Stats



Terminology For This Discussion

Data Definition

Specific study design metadata that is shared, common, and critical to both DM and Stats

Data Standard

Agreed upon standardization of data definitions

Data Collection Standard

additional metadata built upon the Data Standard to maximize value of reuse of EDC or other data collection tool

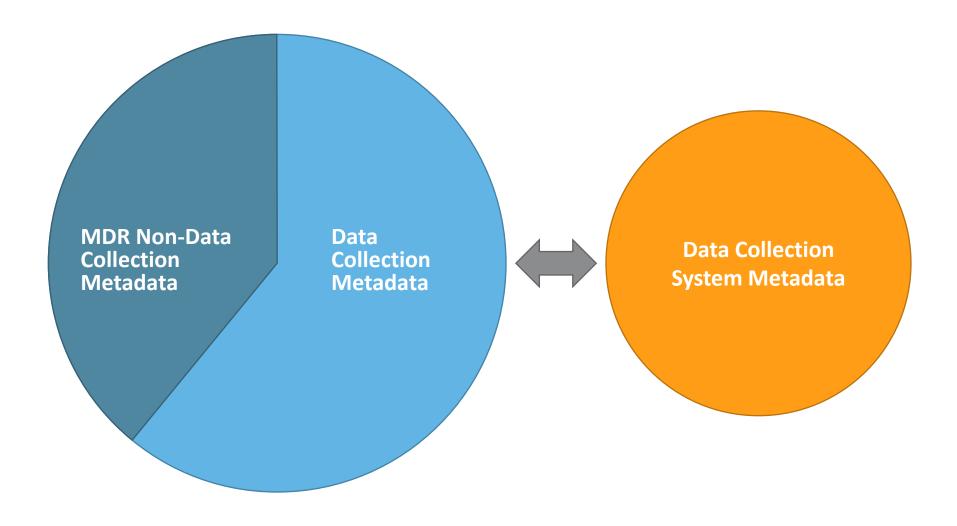


Goal: Enabling Stats and DM Parallel Flow



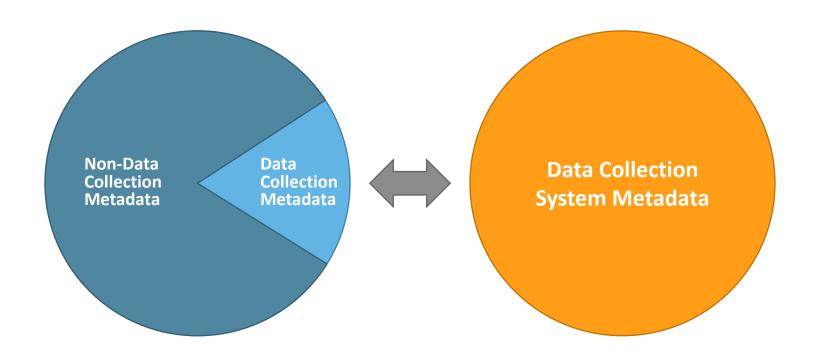


Relative Scale of Metadata



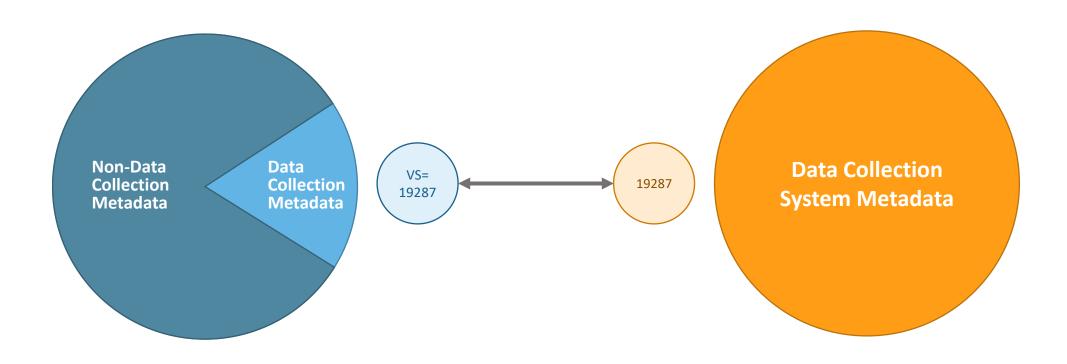


Relative Scale of Metadata



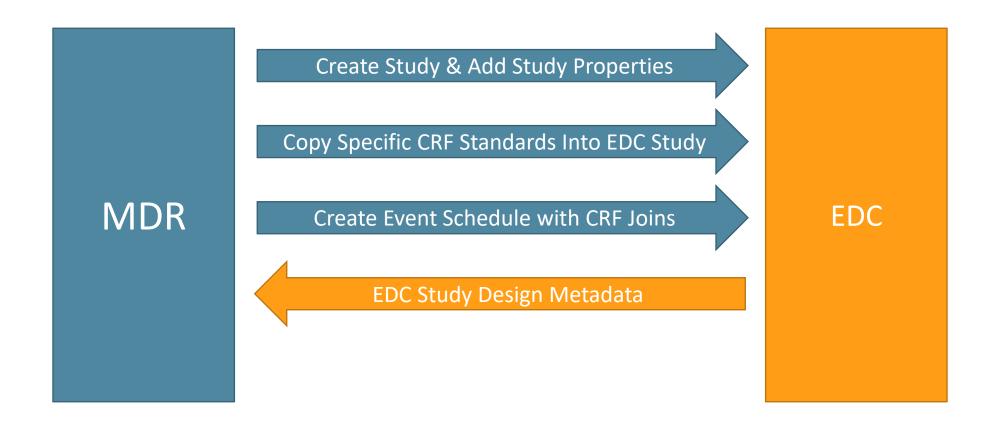


How to Automate Governance and Compliance to Data Standard and Definition?





Near-Term Roadmap: Proposed Study Design Flow

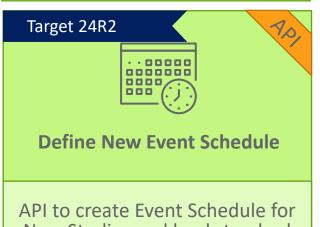




Study Design APIs: Automating EDC Design

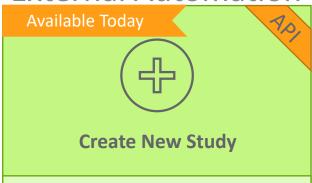
Study Design Metadata

API call to retrieve machine readable study design metadata

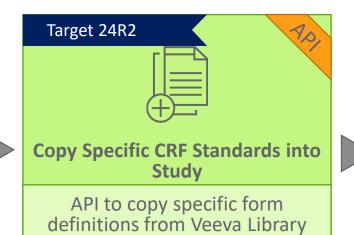


forms into the schedule

External Automation

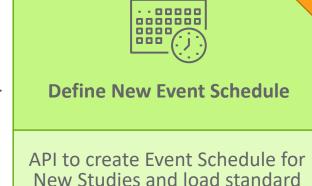


API call to create a New Study (including minimum required properties); useful to MDR and automating study management



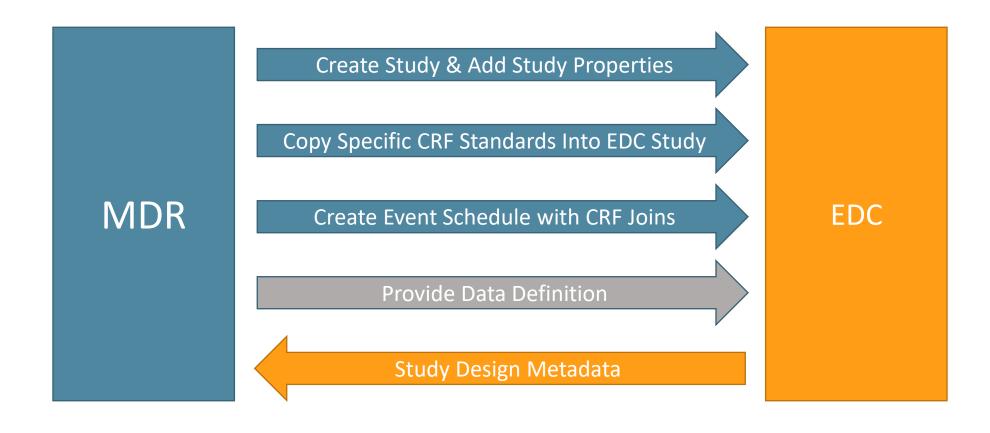
into New Study or provide auto-

filter on library



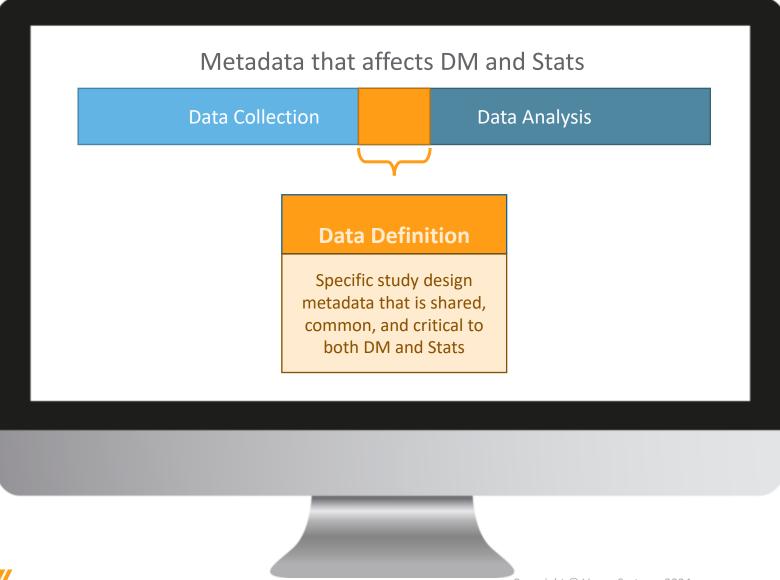


Long-Term Roadmap: Proposed Study Design Flow





Data Definition Diff. Report: Protecting Downstream



Data Definition Diff Report

 Focused detection of any study design changes that may impact downstream standards or programs



Looking Ahead: Proposed Study Design Flow

Create Study & Add Study Properties Copy Specific CRF Standards Into EDC Study Create Event Schedule with CRF Joins **MDR** Provide Data Definition **EDC** Load Metadata Create New Form Skeleton EDC Designer: Enhance Form for Use Compare Form to Data Definition Enforce Compliance to Data Definition Study Design Metadata





Questions