

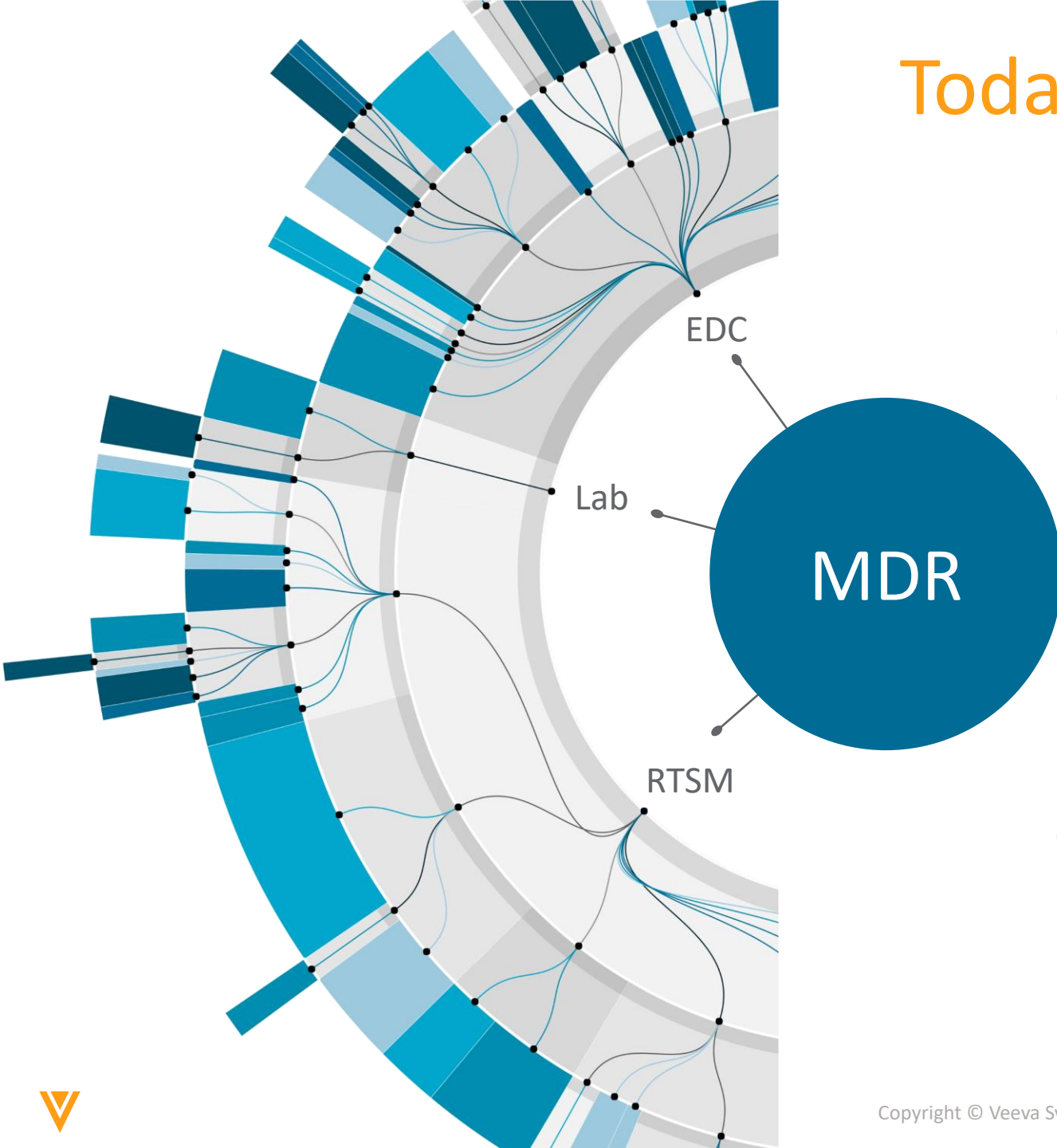


Veeva CDMS

MDR Related Approach and Roadmap

NOTE: The following presentation includes Veeva's current product direction. These plans may change as we learn more.

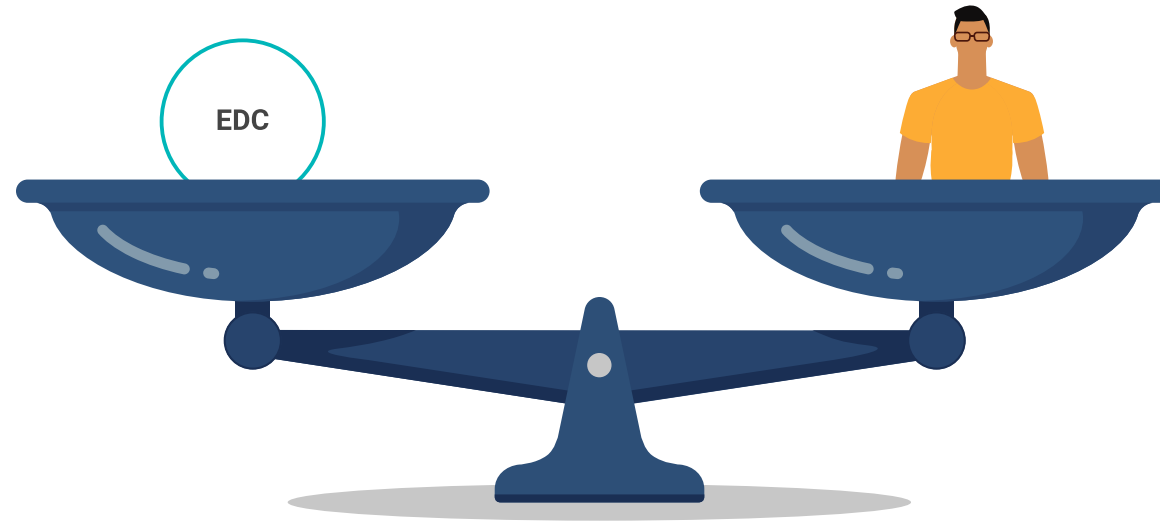
Today's Leading MDR Strategy



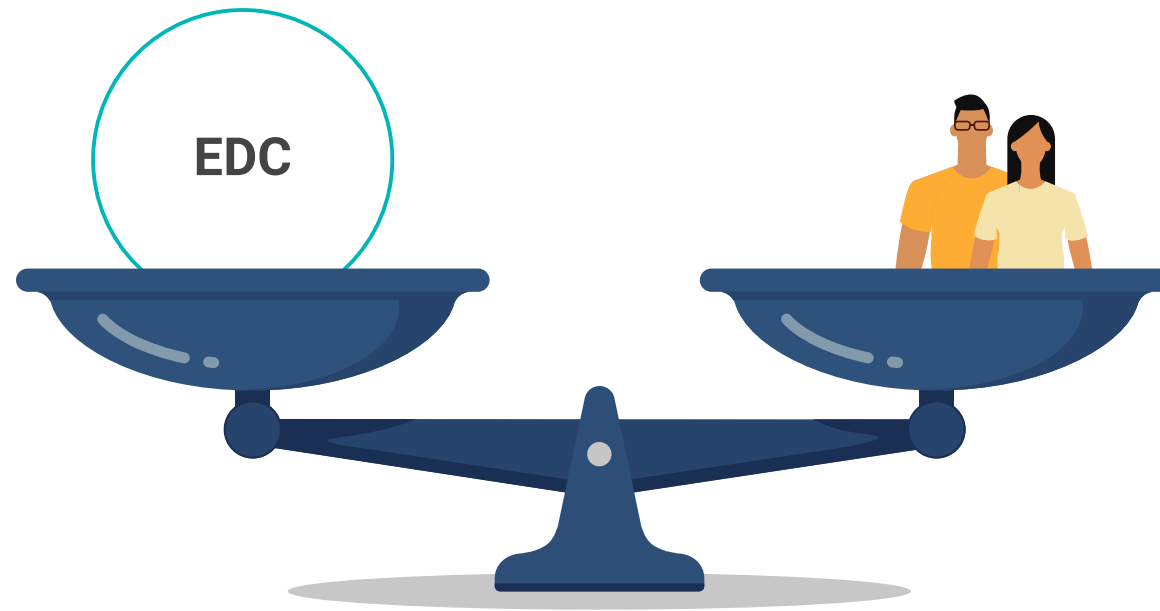
- ✓ Design studies with the end in mind (analysis)
- ✓ MDR is an important solution to tie together:
 - study design
 - data collection
 - analysis
 - submission
- ✓ Study design should start with MDR and through relationships define data collection and analysis
- ✓ Data Collection should be as automated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



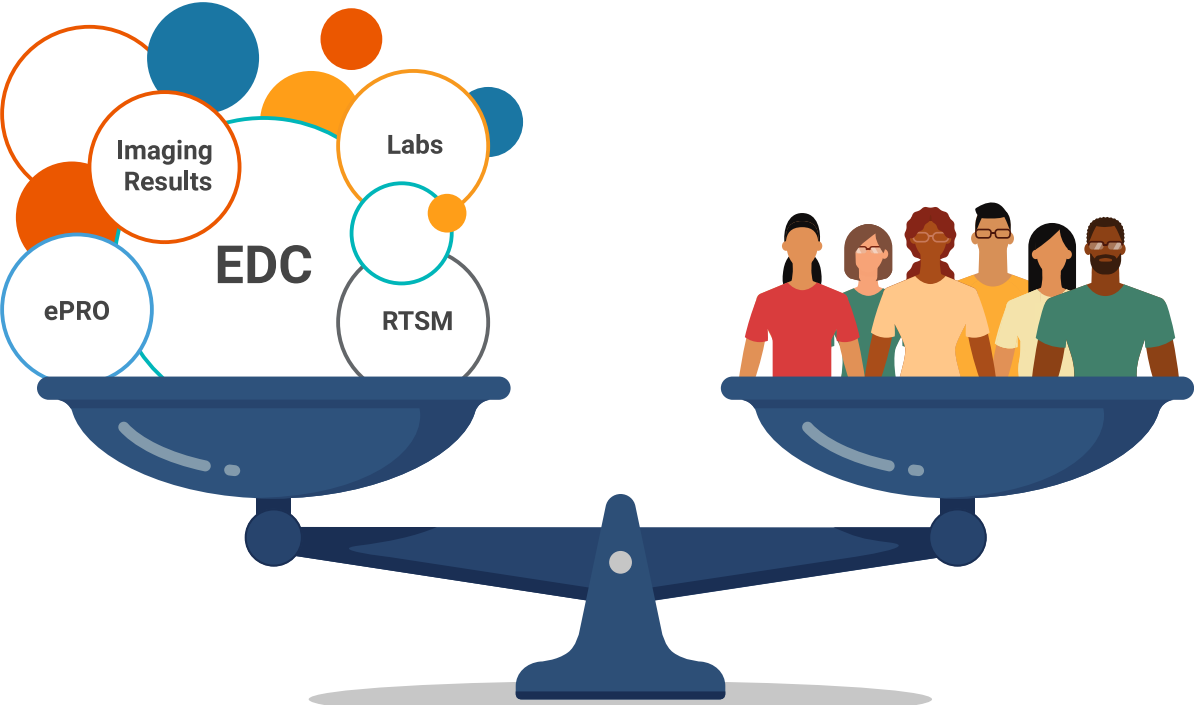
The Data Source Tipping Point



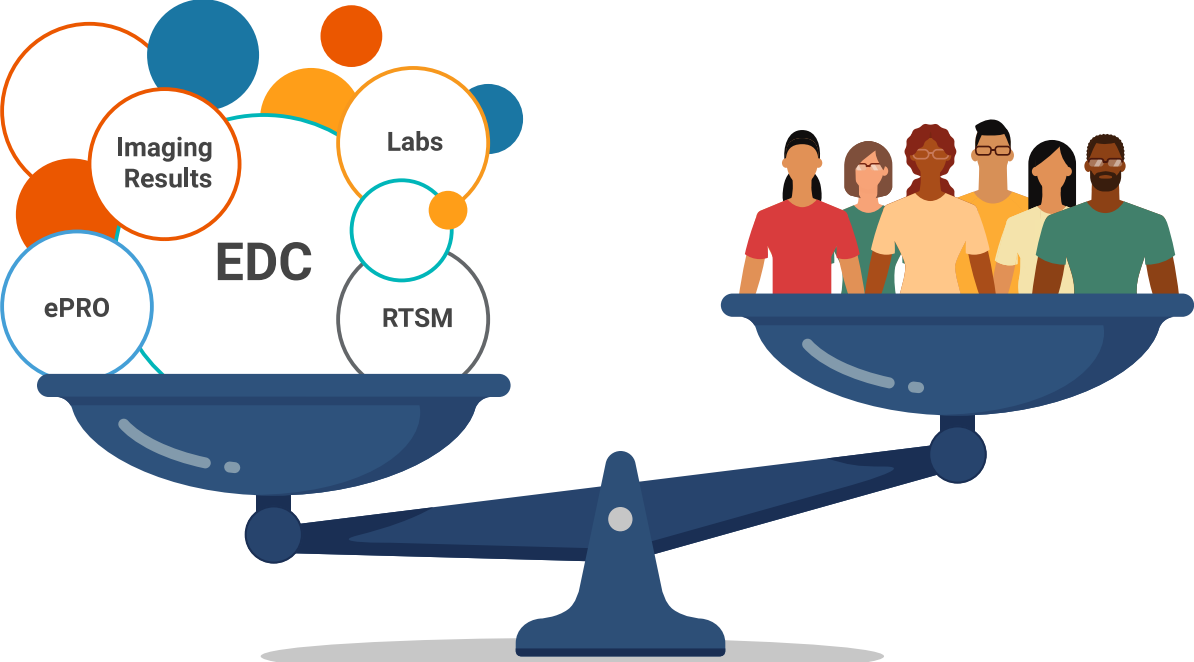
The Data Source Tipping Point



The Data Source Tipping Point



The Data Source Tipping Point



Scalability of Centralized Metadata Management

- 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



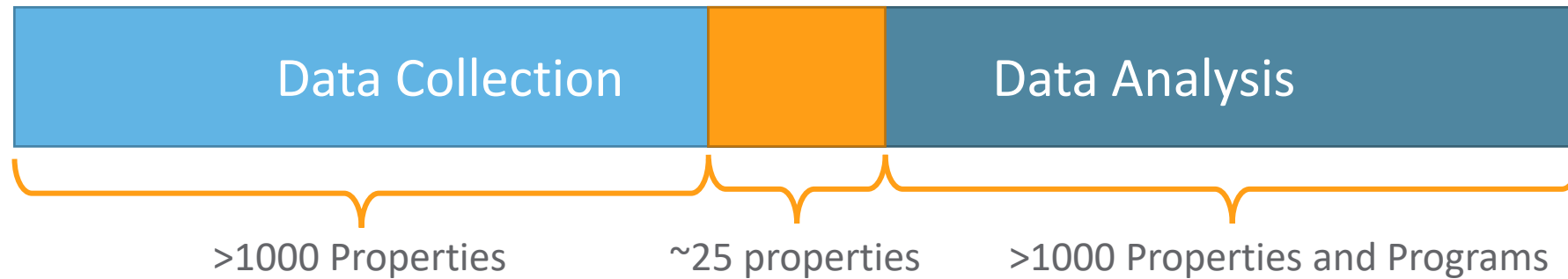
Common Metadata Between Data Collection and Data Analysis

Data Collection

Data Analysis

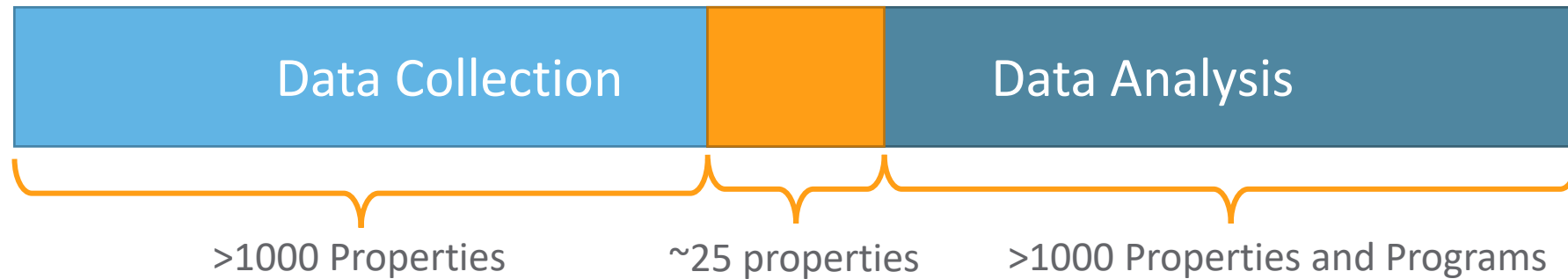


Common Metadata Between Data Collection and Data Analysis



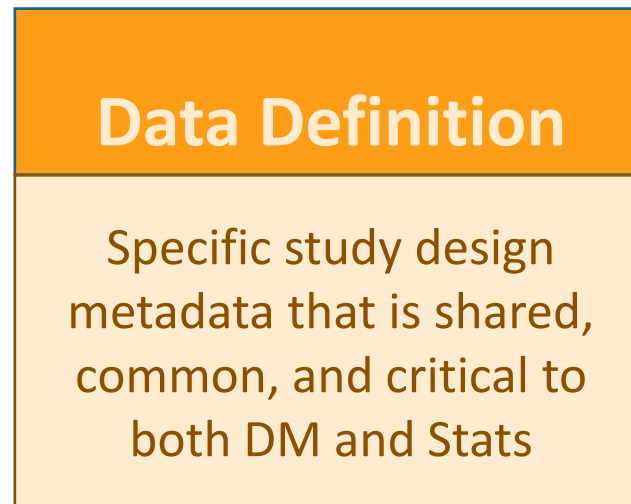
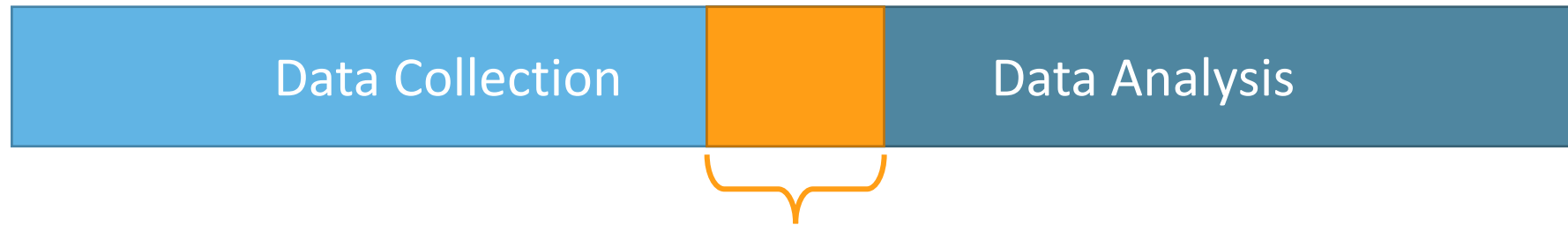
Est. 25 properties of EDC metadata affects downstream programming/analysis

Common Metadata Between Data Collection and Data Analysis

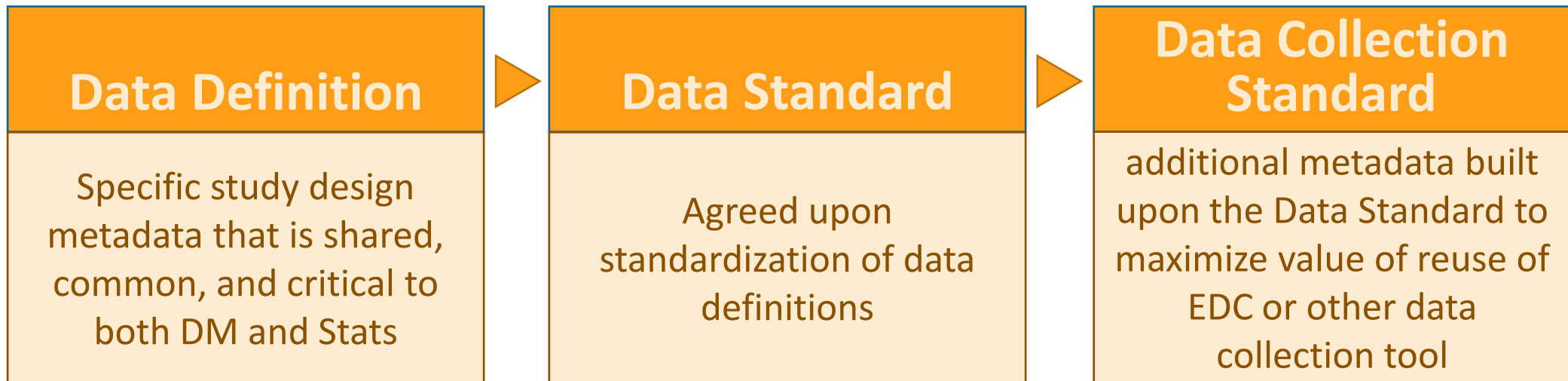


Event	Form	Item Group	Item	Codelist	Unit
Name Label External ID Type Repeats	Name Label External ID Repeats	Name Label External ID Repeats Default Adds	Name Label External ID Data Type Length	Name External ID Code Decode (Label)	Name External ID Code Decode (Label)

Terminology For This Discussion



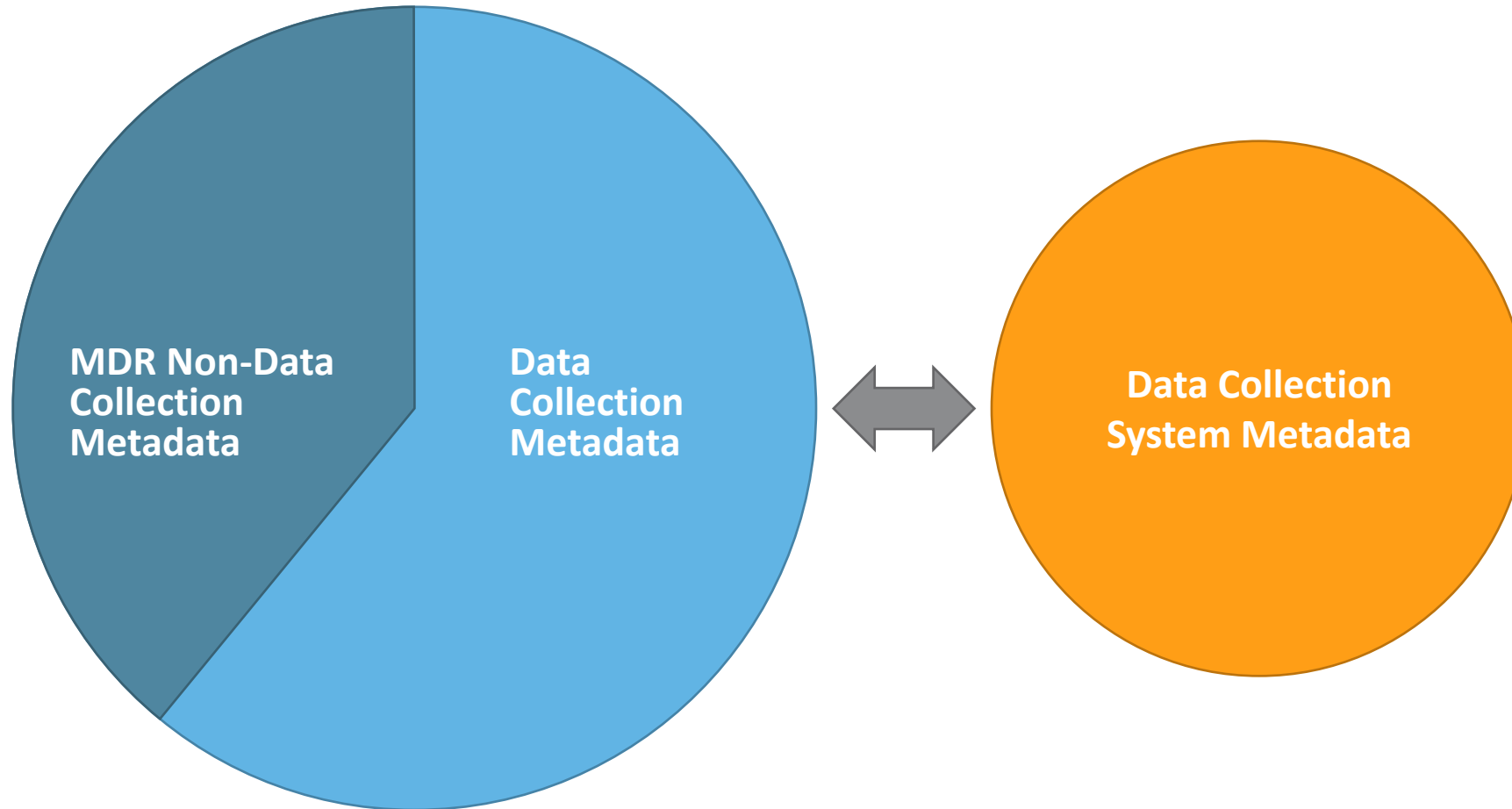
Terminology For This Discussion



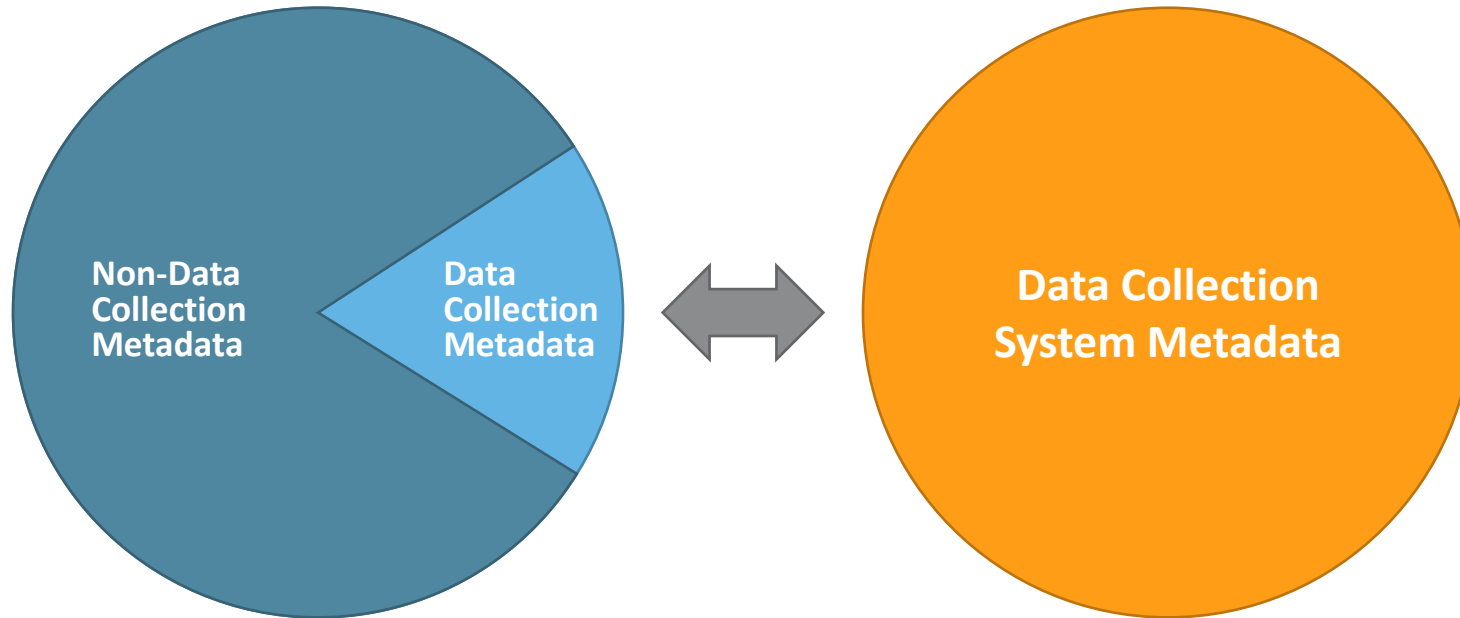
Goal: Enabling Stats and DM Parallel Flow



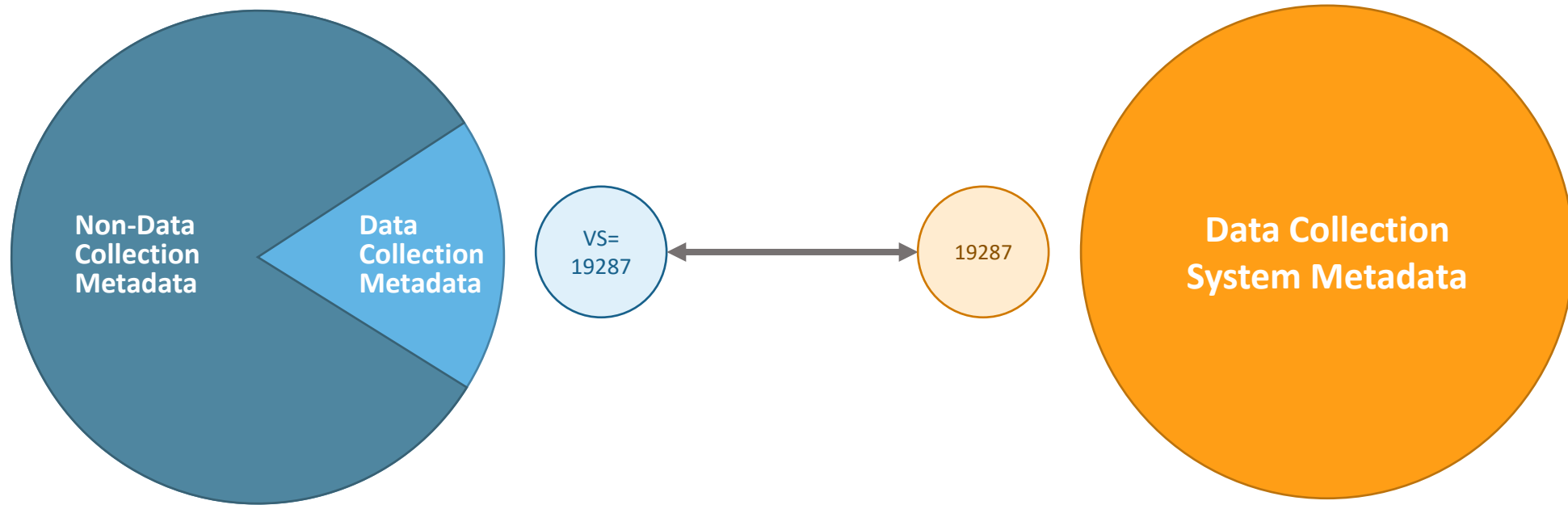
Relative Scale of Metadata



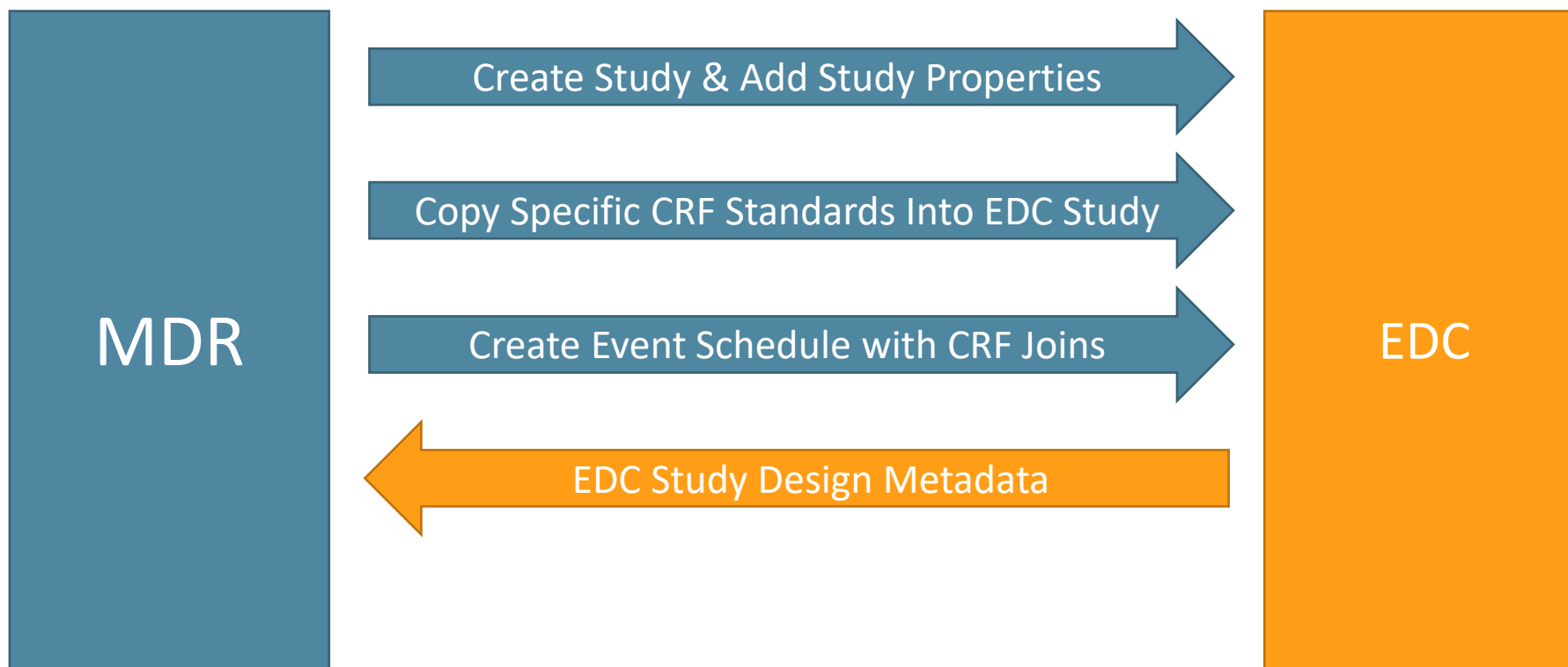
Relative Scale of Metadata



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

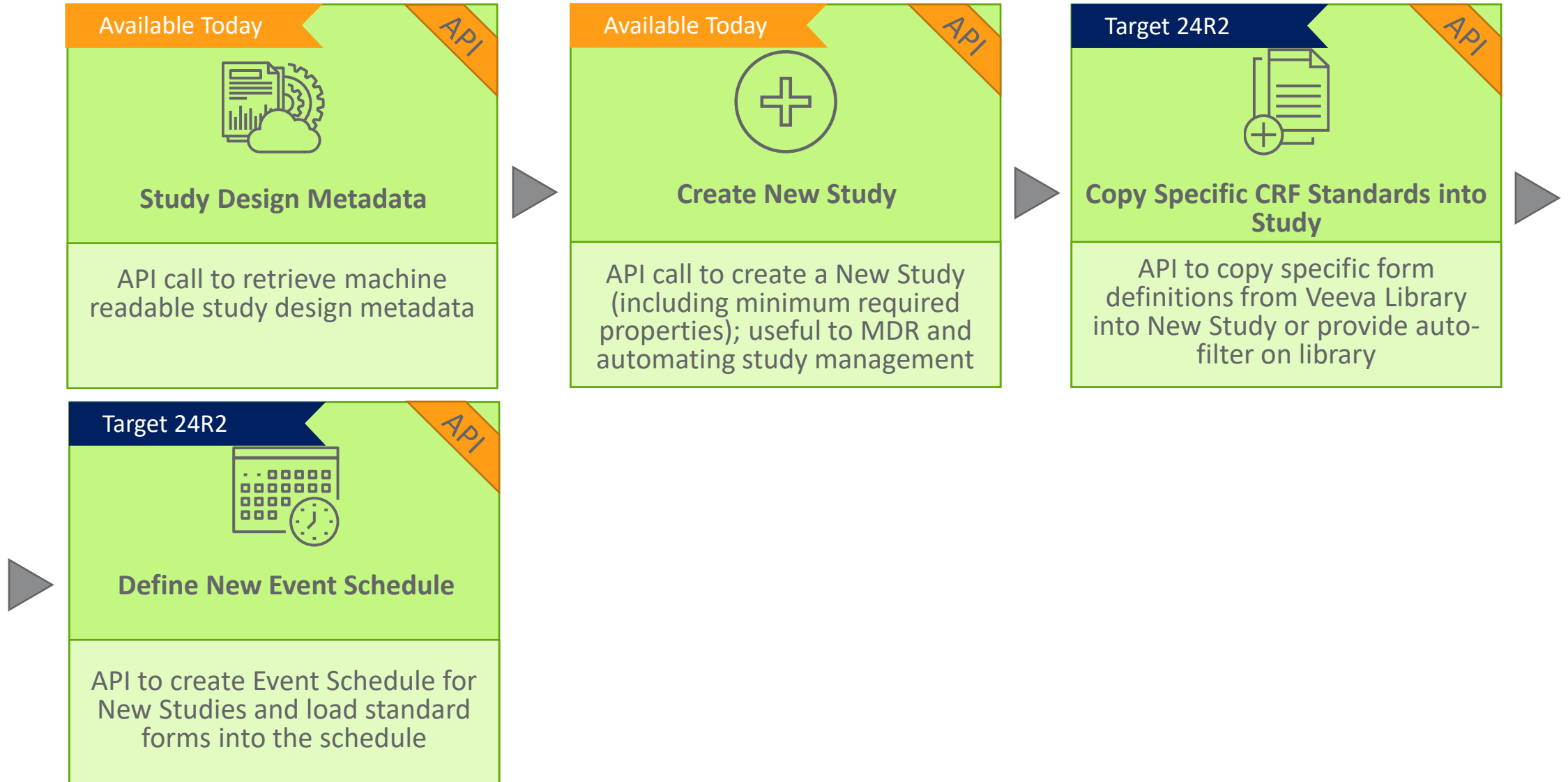


Near-Term Roadmap: Proposed Study Design Flow

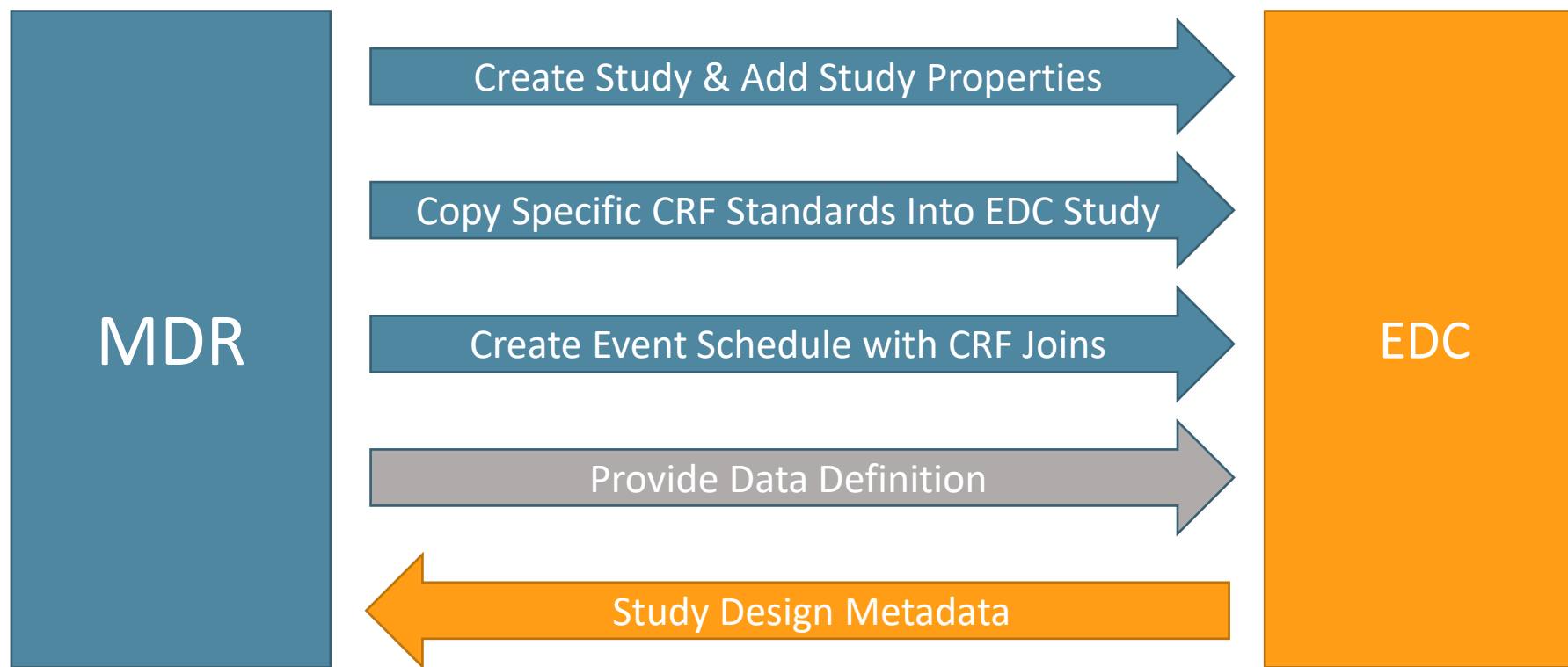


Study Design APIs: Automating EDC Design

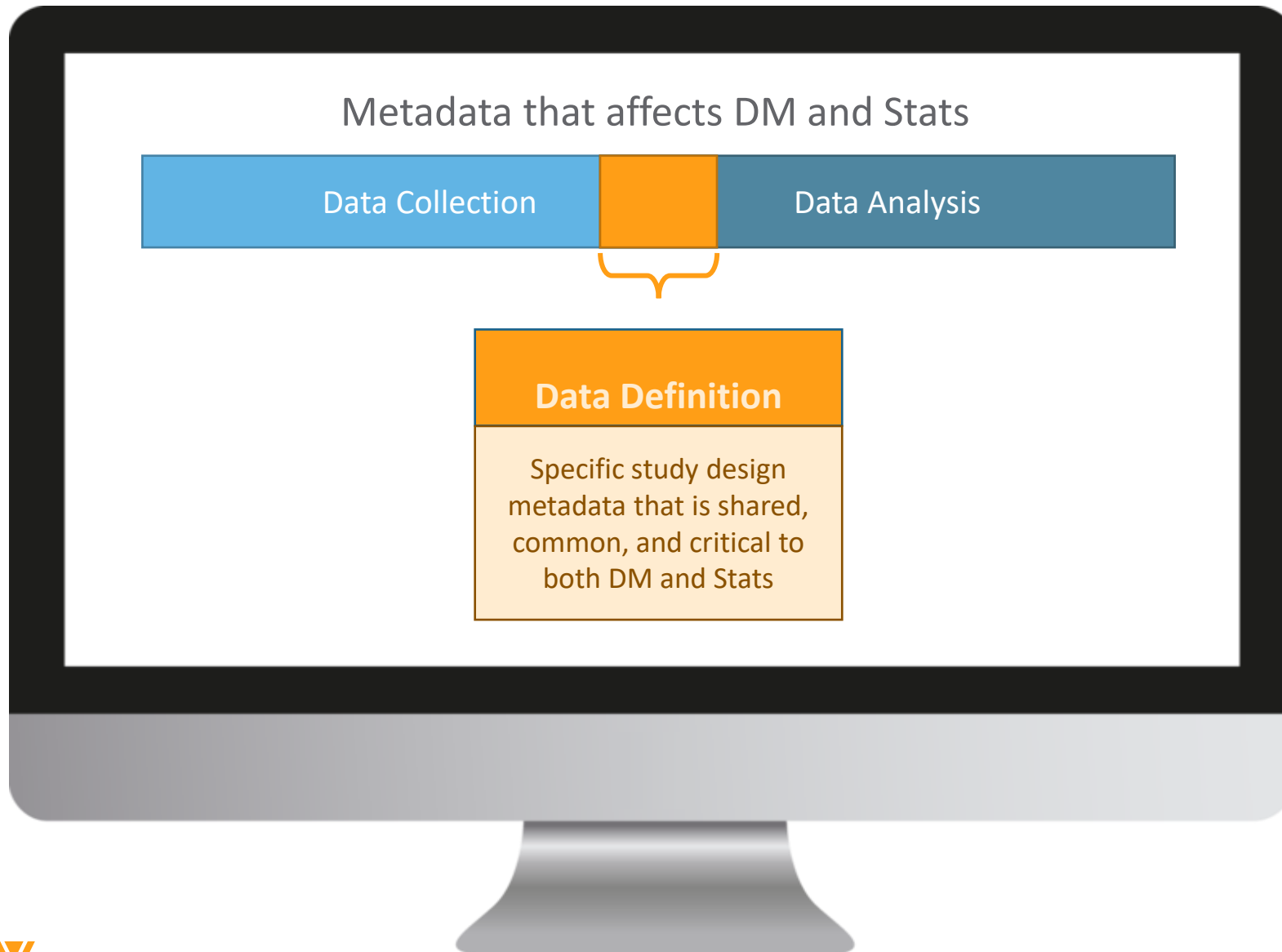
External Automation



Long-Term Roadmap: Proposed Study Design Flow



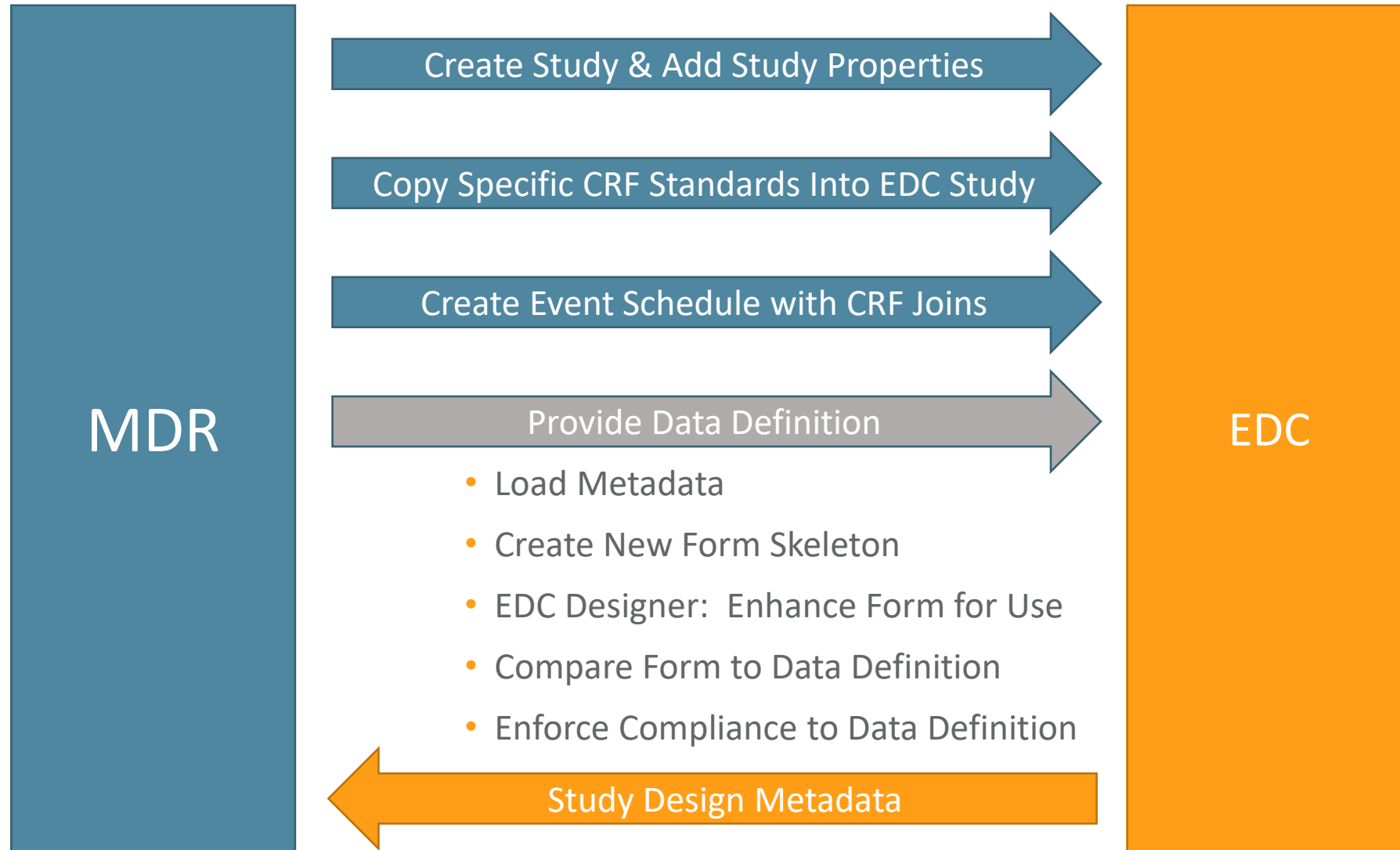
Data Definition Diff. Report: Protecting Downstream



Data Definition Diff Report

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

Looking Ahead: Proposed Study Design Flow





Questions