

One MDR, Multiple EDCs



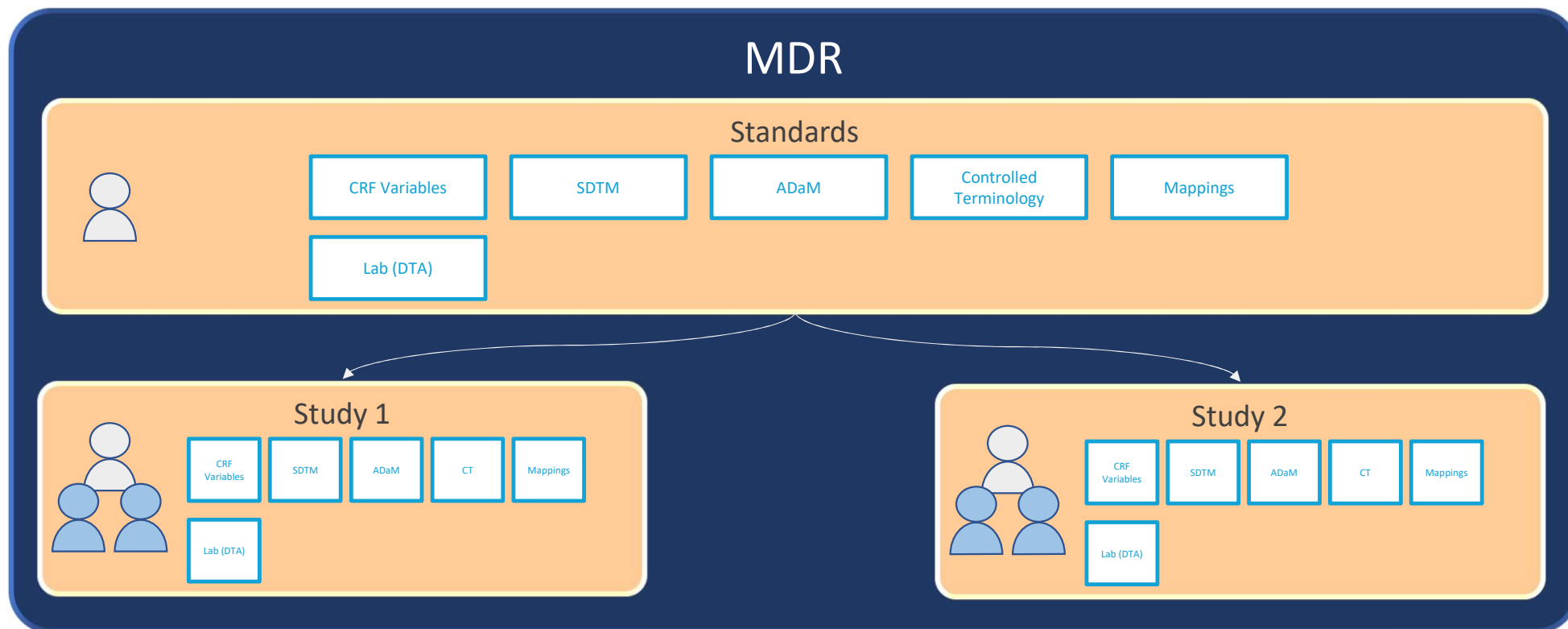
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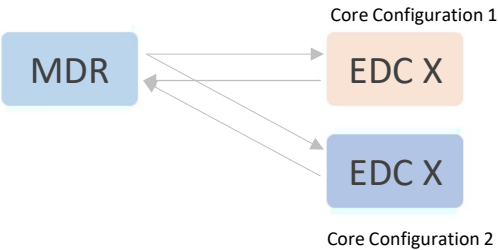
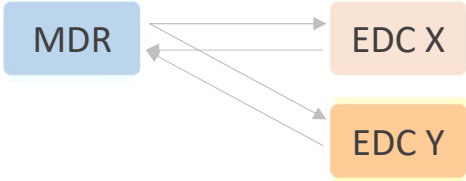
Agenda

- MDR Adoption
- Use Cases
 - Description
 - Design Aspect
- Concepts of EDC Configuration
- Demo
- Outcome

MDR Adoption

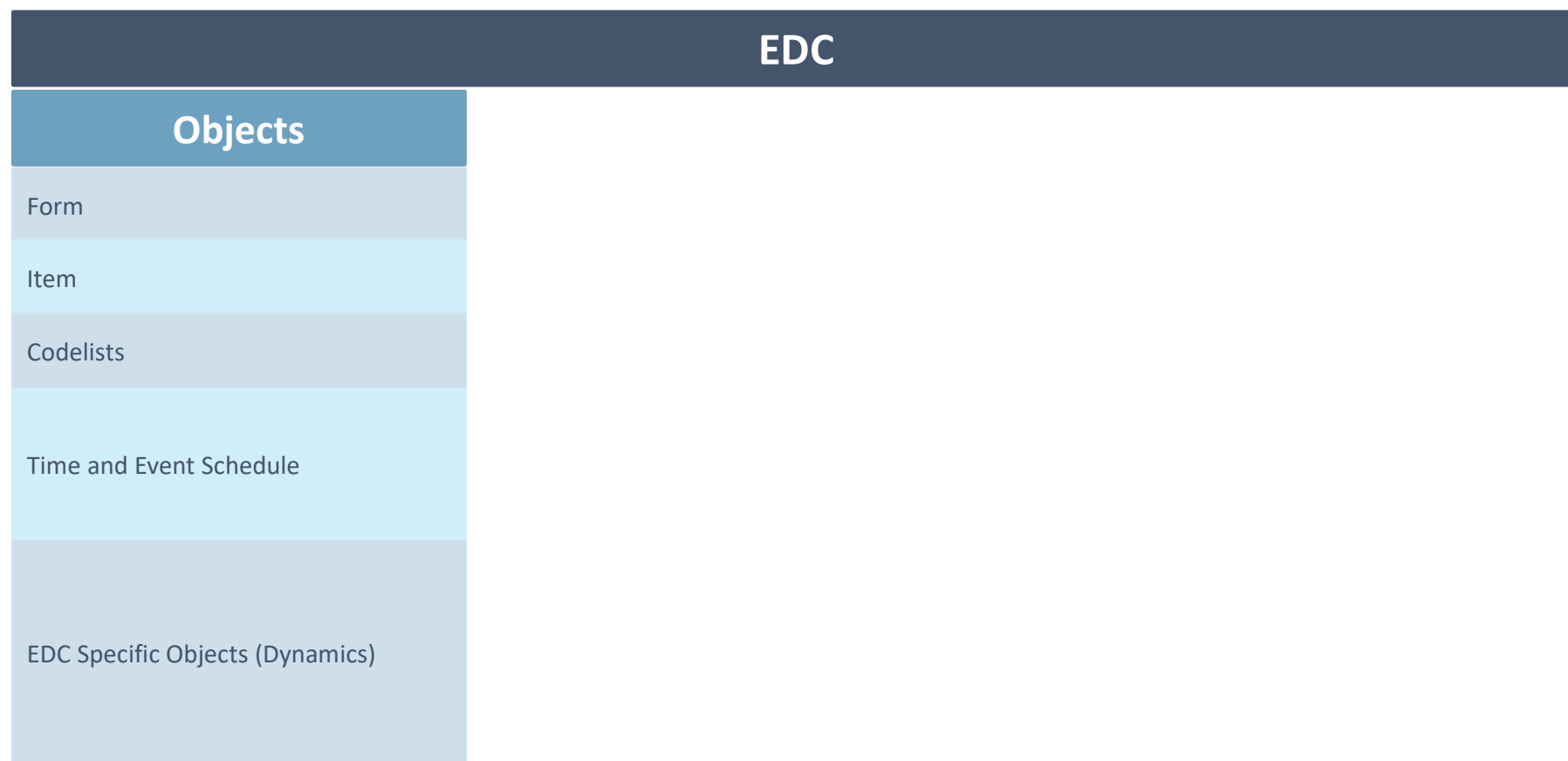


Use Cases

Use Case 1 Bi-Directional Integration	Use Case 2 Multiple Core Configurations	Use Case 3 Multiple EDC Support
Exchange Standard Library and Study Specifications in both directions 	Same EDC with Multiple instances and different Core Configurations 	Different EDCs in use simultaneously by a Sponsor. CROs working with multiple Sponsors using different EDCs 
Medidata Rave - ALS File Veeva - Design Specification File	Allow an Administrator to perform Multiple Core Configurations with minimal	Provide a consistent framework to allow an administrator to onboard a new EDC configuration

Concepts of EDC

EDC Objects



EDC Objects -

Rave EDC		
Objects	Rave Objects	Rave Object Attributes
Form	Form	OID, Name, LogDirection, ViewRestrictions, ...
Item	Field	OID, Name, Pretext, ViewRestrictions, ...
Codelists	Data Dictionaries	DataDictionary
Time and Event Schedule	Folders	FolderOID, Name, TargetDays, AcceptableDays, ...
	Matrices	MatrixOID, Name, IsReusable , ...
EDC Specific Objects (Dynamics)	Edit Checks	CheckName, InFix, BypassDuringMigration , ...
	Derivations	DerivationName, Form, Field,...
	Custom Functions	Name, Code, Language , ...

EDC Objects - Veeva

Veeva EDC		
Objects	Veeva Objects	Veeva Object Attributes
Form	Form	Form Name, Form Label, Form Short Label, Status, Linked Form(s), Linked Form(s) Warn When Empty...
Item	Item	Item Name, External ID, Label, Data Type, Required, Codelist, ...
Codelists	Codelists	Name, Status, ExternalID, Hidden
Time and Event Schedule	Event Group	Event Group, Event Group Name
	Event	Event, Event Name,, ...
EDC Specific Objects (Dynamics)	Rules	Name, Action, Query Text, Rule Syntax, Description...
	Date Comparisons	Comparison to various objects ,...
	Casebook Variables	Name, Label, Data Type, Event Group, Event, ...

Concepts of EDC Configuration in MDR

Rave Implementation in MDR		
The Objects and the Attributes are called as Metadata Model (Meta Model) Our MDR allows to define the Meta Model , i.e. - Objects - Object Attributes	Rave Objects	Rave Object Attributes
	Form	OID, Name, LogDirection, ViewRestrictions, ...
	Field	OID, Name, Pretext, ViewRestrictions, ...
	Data Dictionaries	DataDictionary
	Folders	FolderOID, Name, TargetDays, AcceptableDays, ...
	Matrices	MatrixOID, Name, IsReusable , ...
	Edit Checks	CheckName, InFix, BypassDuringMigration , ...
	Derivations	DerivationName, Form, Field,...
	Custom Functions	Name, Code, Language , ...

EDC Objects – Object Oriented Design Approach

Rave Implementation in MDR		
Our MDR allows to define the Meta Model i.e. - Objects - Object Attributes General Design Approach - Core Objects - Objects commonly used across EDCs are made Core Objects. The attributes are extended for these Objects (Forms, Field, Data Dictionaries, Folders Matrices, Edit Checks) - EDC Specific Objects - EDC specific objects unique to an EDC implementation are extended in the EDC Configuration (Derivations, Custom Functions, LabVariableMappings, Rules, Date Comparisons)	Rave Objects	Rave Object Attributes
	Form	Core Objects
	Field	
	Data Dictionaries	
	Folders	
	Matrices	EDC Specific Objects
	Edit Checks	
	Derivations	
	Custom Functions	

Demo – Use Case 1



- For a Study conducted in Rave, import ALS file and ensure the study can manage all ALS objects. After checking conformance with Standards, export the ALS to synchronize the study in Rave.
- System Features
 - Apply Rave EDC Configuration
 - Import ALS
 - Check Conformance and AutoMap
 - Export ALS

Demo – Use Case 2



- For a Standard Library managed across multiple EDC instances (URLs), extend the Core Configurations for each instance.
- System Features
 - Apply Core Configurations for multiple instance of an EDC to a Standards Library

Core Configurations in Rave across URL - Example

	URL 1	URL 2
Item.AnalyteName	RBC WBC	RBC WBC Sodium Potassium
Item.CodingDictionary	WhoDrug	WhoDrug MedDRA
EDC Roles (Forms and Items) - ViewRestrictions - EntryRestrictions	Reviewer Auditor Investigator	Reviewer Auditor Investigator CRA
Item.ReviewGroups	Data Manager	Data Manager
Marking Groups (Check Actions)	Site from System Site from DM	Site from System

Demo – Use Case 3



- An Organization having an EDC is adopting a new EDC. The Standards Team wants to re-use the standard CRFs Library across multiple EDCs.
- System Features
 - Apply Multiple EDC Configuration to a Standards Library

Q & A

Thank You

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