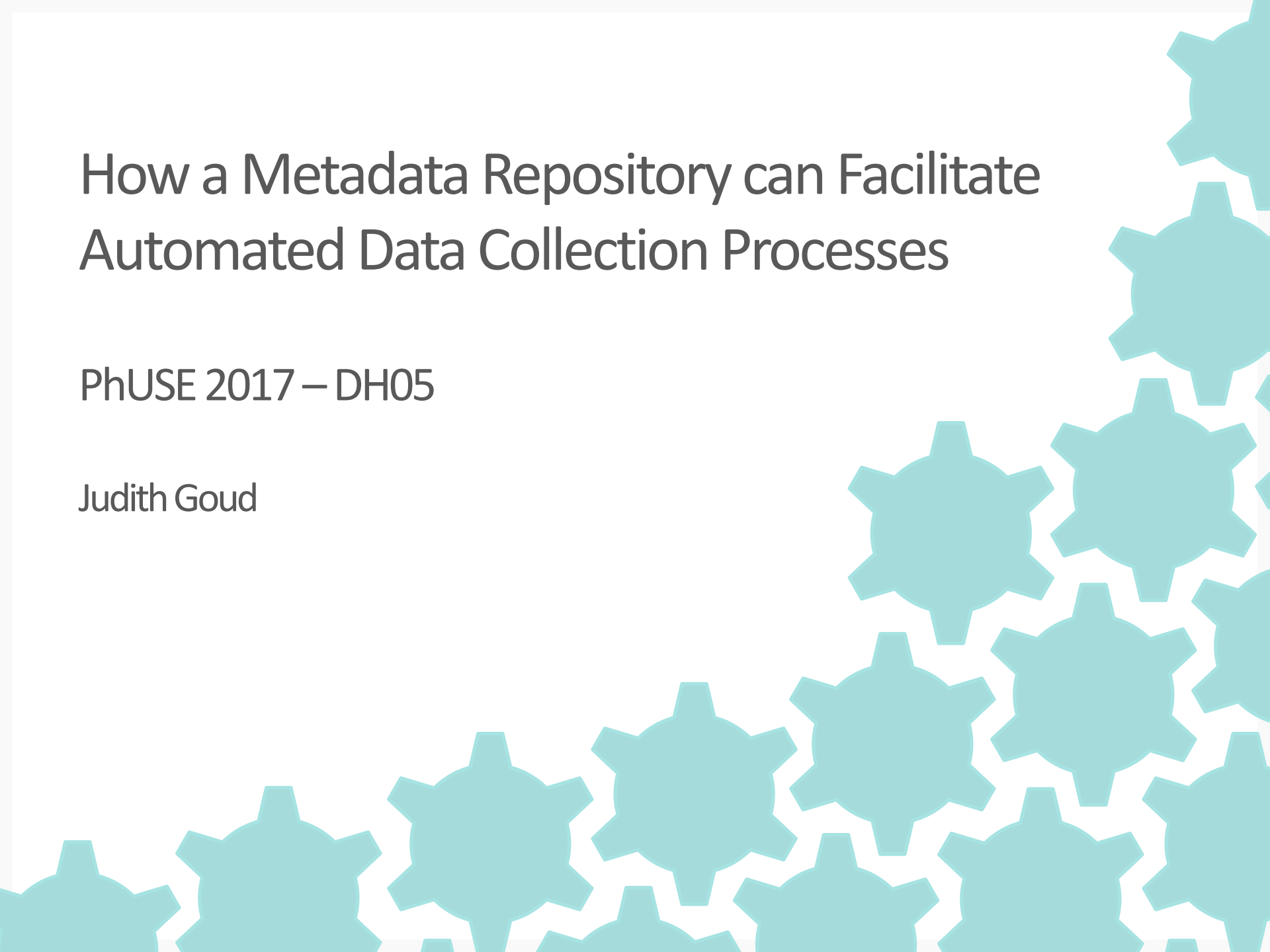


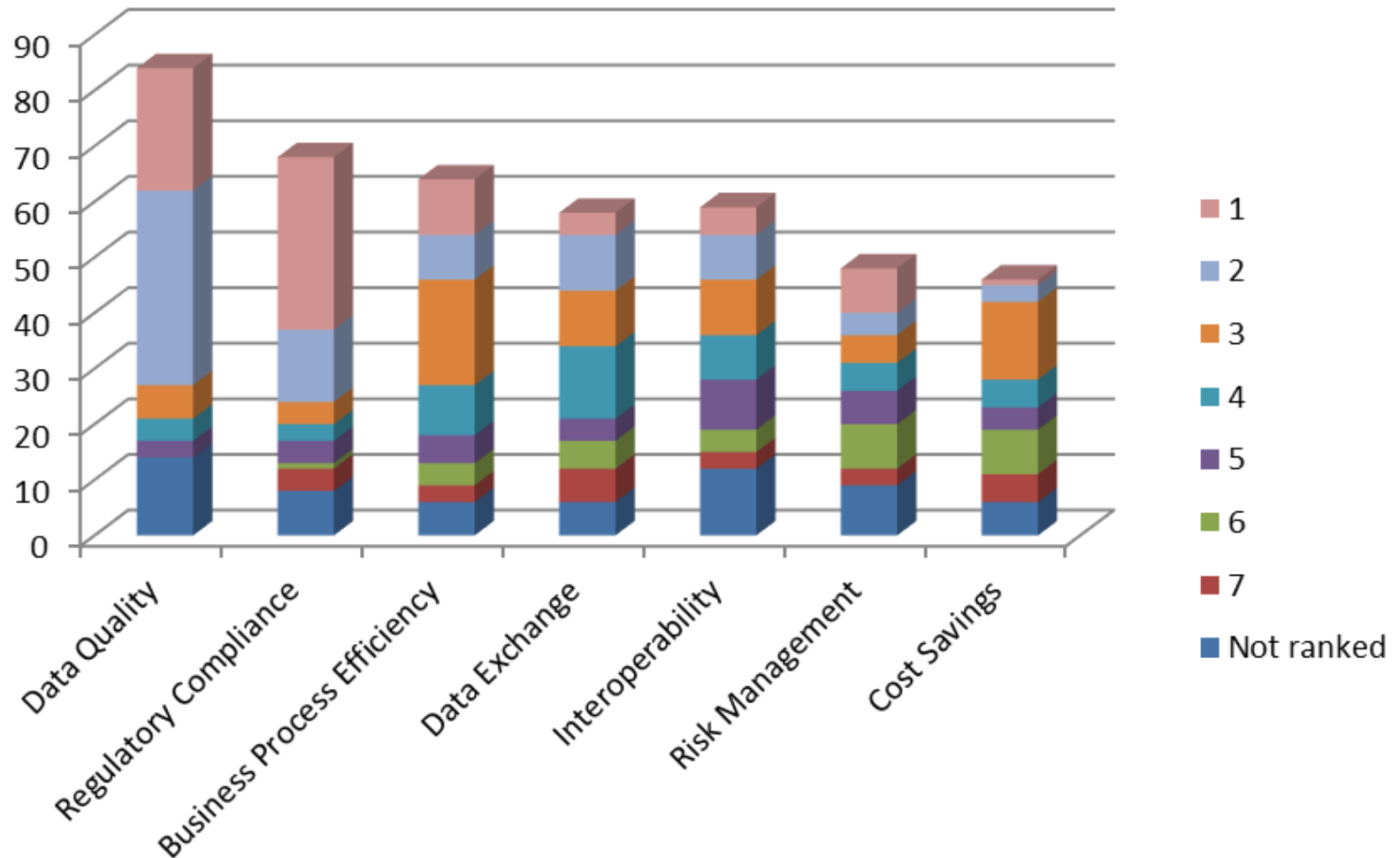
How a Metadata Repository can Facilitate Automated Data Collection Processes

PhUSE 2017 – DH05

Judith Goud



Drivers for Metadata Management



Clinical Development Lifecycle



- Study Design
- Protocol Development
- CRF Development
- DB Structure/Validation
- Edit Checks/Validation
- External Data Specs
- Site/PI Identification
- Patient Recruitment Plan
- Critical Documents
- IRB Approvals
- Statistical Analysis Plan

- Patient Recruitment
- Data Acquisition
- Data Exchange
- SD Verification
- Site Monitoring
- Transfer of External Data
- Database QA & Lock
- Analysis & Programming
- Initial Stat Tables
- Study Closeout

- Data Analysis
- Safety Assessment
- Analysis Table Preparation
- Clinical Assessments
- Report Generation

- ISS/ISE Preparation
- Clinical-Statistical Integrated Report
- Datasets, Listings & Tabulations
- eCTD File Structure Modules (2-5)

Clinical Development Lifecycle



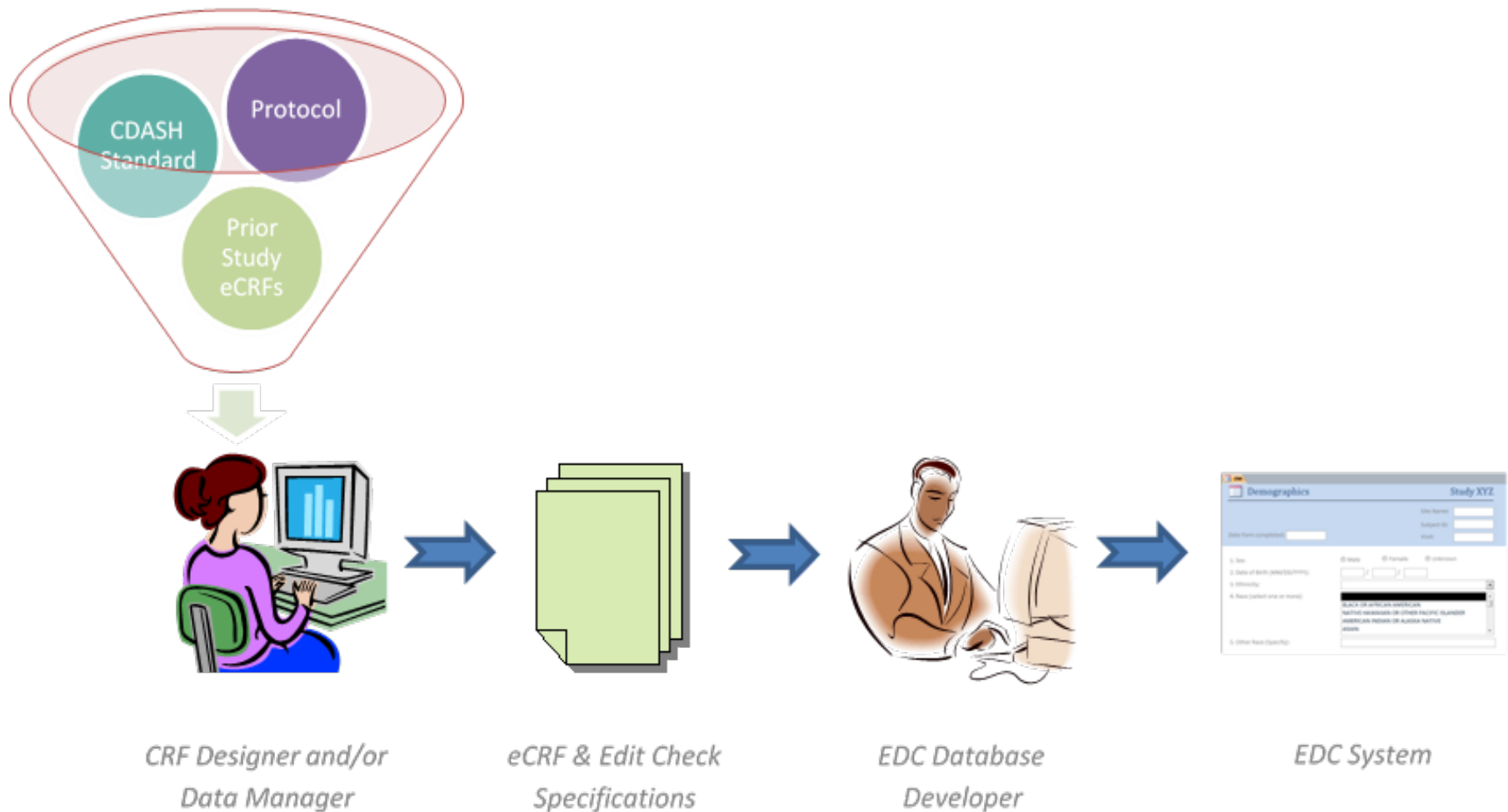
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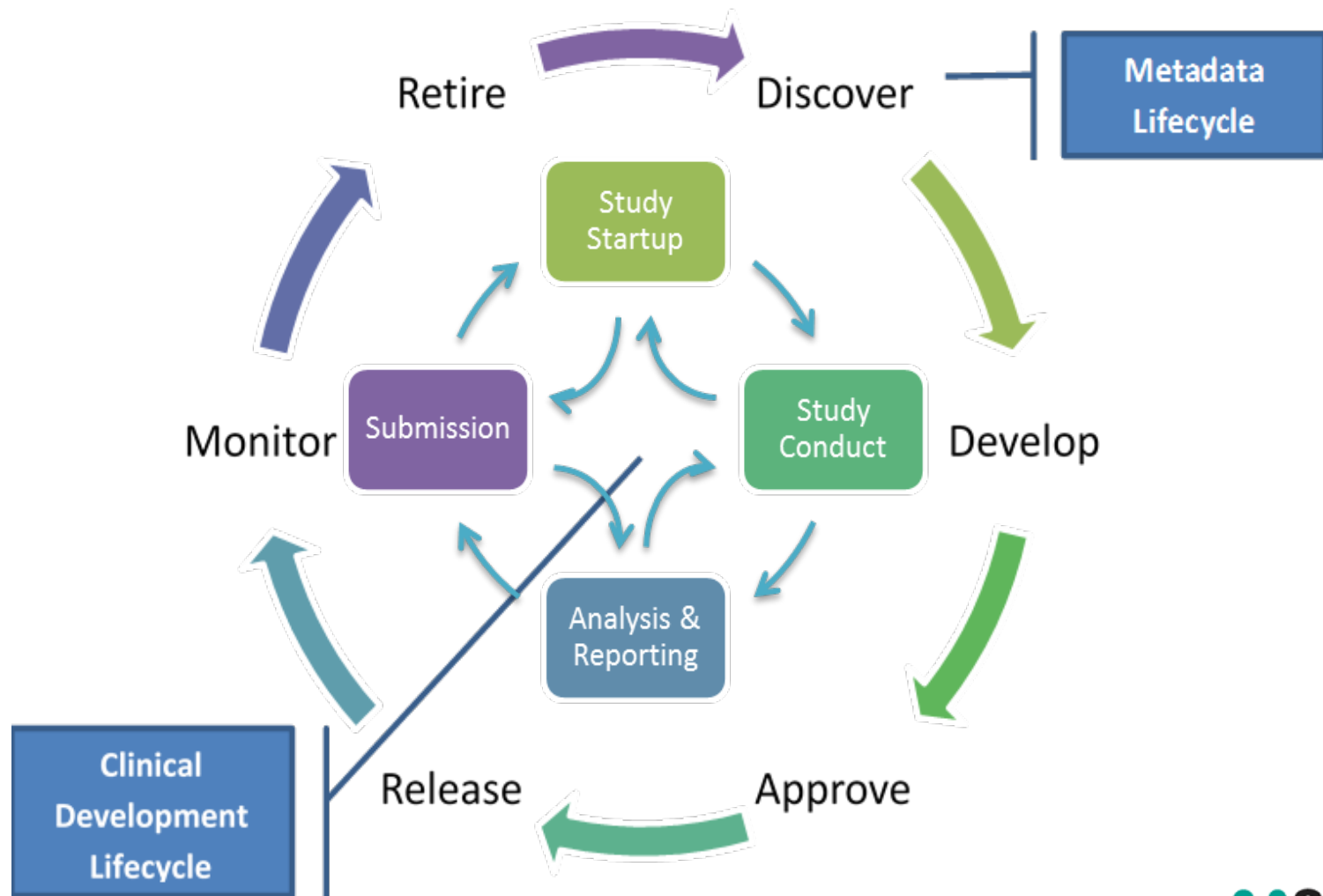
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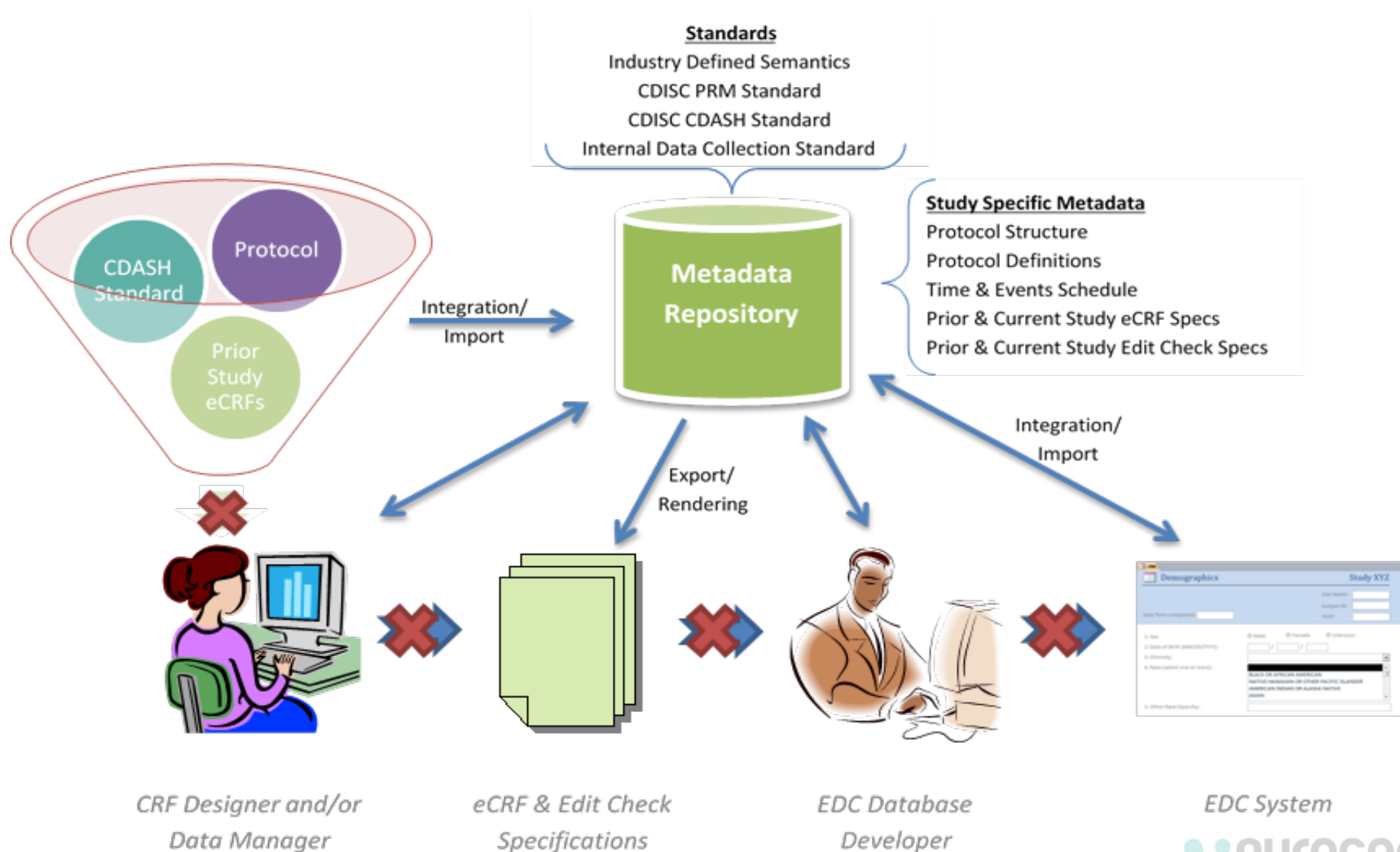
Traditional EDC System Development



Inserting Metadata Lifecycle in CDLC



New Approach to EDC System Development



EDC System

Metadata Repository Integration with EDC

Metadata Repository

- Industry (CDISC) standards
- Internal global standards
- Internal TA/Product standards
- Business rules/policies
- Transformation logic
- Domain terminologies
- Robust data types
- Industry domain models

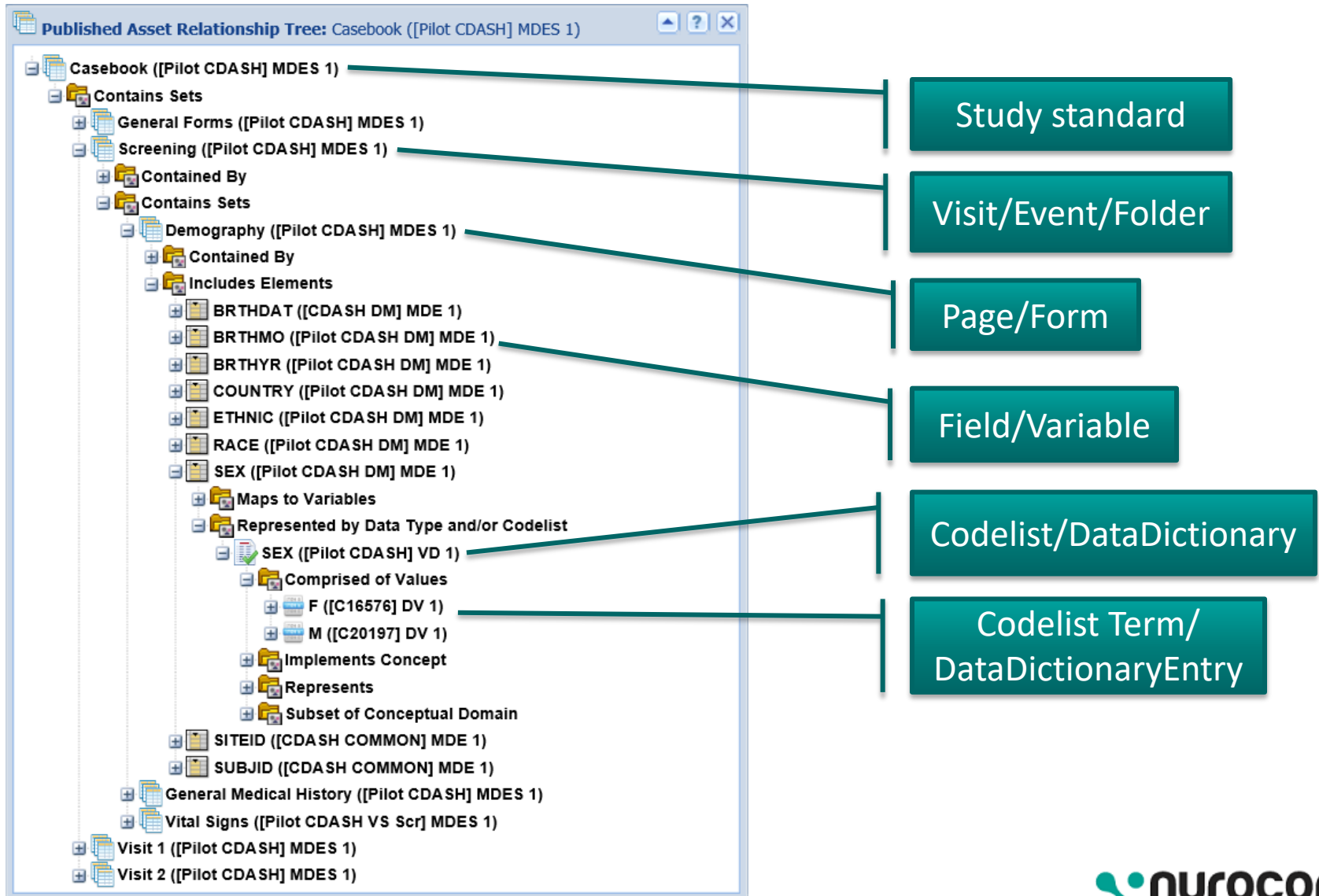
- Study Definition
- Visit Schedule
- Visits
- eCRF Forms
- Fields
- Codelists/Values
- Edit Checks
- Functions & Derivations

ODM export with extensions or other export, via API or WebServices

EDC

Study DB

EDC Metadata Structure in MDR



EDC Layout Metadata in MDR

Relationship
Properties in
context of eCRF

ETHNIC ([Pilot CDASH DM] MDE 1)

Relationship Properties

Origin: CRF
Page Number within Document: 1
Is Visible on CRF?: true
Nest Level: 1
Question Text: What is the ethnicity of the subject?
Control Type: Radio button
Prompt: Ethnicity
Is Required?: true
Ordinal: 3

Based on Mappings
to SDTM

Study Code: Casebook

Site number:

Subject number:

Screening

Study Design: Demographics [DM]

Demography

1.* Birth date

Birth Year

Birth Month

2.* Sex

- ☐ Male
☐ Female

3.* Ethnicity

- ☐ HISPANIC OR LATINO
☐ NOT HISPANIC OR LATINO
☐ NOT REPORTED
☐ UNKNOWN

4.* Race

- ☐ NATIVE HAWAIIAN OR OTHER ISLANDER
☐ ASIAN
☐ AMERICAN INDIAN OR ALASKA
☐ BLACK OR AFRICAN AMERICA
☐ WHITE

Key: [*] = Item is required

EDC Metadata from MDR to EDC

```
<?xml version="1.0" encoding="UTF-8"?>
- <ODM xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.3 ODM1-3-2.xsd" SourceSystemVersion="1.0 (7.1.5.108)"
SourceSystem="SHARE" Originator="CDISC" ODMVersion="1.3.2" FileType="Snapshot"
FileOID="Semantics.Manager.ODM_1.3.2_Casebook_1.0_1478897301772979722371" CreationDateTime="2017-01-
10T09:37:59" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xlink="http://www.w3.org/1999/xlink" xmlns="http://www.cdisc.org/ns/odm/v1.3">
- <Study OID="Study.Casebook.[Pilot_CDASH]_MDES_1">
+ <GlobalVariables>
- <MetaDataVersion OID="MDV.Casebook.2017-01-10_09:37:59" Name="Casebook MDV" Description="Casebook
[Pilot_CDASH]_MDES_1">
+ <ItemGroupDef OID="IG.MDES.Screening.[Pilot_CDASH]_MDES_1" Name="Screening" Repeating="Yes"
Domain="Screening">
- <ItemGroupDef OID="IG.MDES.Demography.[Pilot_CDASH]_MDES_1" Name="DM" Repeating="No"
Domain="Demography">
- <Description>
<TranslatedText xml:lang="en">Demographics</TranslatedText>
</Description>
<ItemRef OrderNumber="2" Mandatory="No" ItemOID="IT.MDE.SEX.[Pilot_CDASH_DM]_MDE_1"/>
<ItemRef OrderNumber="4" Mandatory="No" ItemOID="IT.MDE.RACE.[Pilot_CDASH_DM]_MDE_1"/>
<ItemRef OrderNumber="1.2" Mandatory="No" ItemOID="IT.MDE.BRTHMO.[Pilot_CDASH_DM]_MDE_1"/>
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<ItemRef OrderNumber="3" Mandatory="No" ItemOID="IT.MDE.ETHNIC.[Pilot_CDASH_DM]_MDE_1"/>
<ItemRef OrderNumber="1" Mandatory="No" ItemOID="IT.MDE.BRTHDAT.[CDASH_DM]_MDE_1"/>
<ItemRef OrderNumber="2" Mandatory="No" ItemOID="IT.MDE.SITEID.[CDASH_COMMON]_MDE_1"/>
<ItemRef OrderNumber="3" Mandatory="No" ItemOID="IT.MDE.SUBJID.[CDASH_COMMON]_MDE_1"/>
<ItemRef OrderNumber="1" Mandatory="No" ItemOID="IT.MDE.COUNTRY.[Pilot_CDASH_DM]_MDE_1"/>
</ItemGroupDef>
- <ItemGroupDef OID="IG.MDES.General_Medical_History.[Pilot_CDASH]_MDES_1" Name="MH" Repeating="Yes"
Domain="General Medical History">
```

EDC Metadata in EDC



Study XYZ ▪ Screening - Demographics - General Medical History - Vital Signs ▪ Visit 1 - Laboratory Tests - Vital Signs ▪ Visit 2 - Laboratory Tests - Vital Signs ▪ General Forms - Adverse Events - Concomitant Medication - Discontinuation	Subject	010-001	
	Visit	Screening	
	Page	Demographics	
	Birth Date	Birth Year ...	
		Birth Month ...	
	Sex	☐ Male ☐ Female	
Ethnicity	...		
Race	...		

Q&A and Contact

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