
# CDISC ODM in the Research Process: end-to-end standardized framework

Presented by Marcelina Hungria, Managing Director, DIcore Group

# Meet the Speaker

## Marcelina Hungria

Title: Owner / Managing Director

Organization: DIcore Group (www.dicoregroup.com)

cdisc Clear Data. Clear Impact. Proud Member

Software Engineer / Developer, MBA, 30 years in Pharma/Biotech.

Extensive experience in System Development and Data Validation, MDR Development, Client support in data standardization from collection, integration, analysis and submission. Software development using SAS and other programming languages

Active member of CDISC Data Exchange Development teams ODM, Define-XML and Dataset-JSON, plus SDTM / SDTMIG teams

CDISC Library, prior CDASH Metadata Curator, SDTM, ADaM and CT support.

CDISC Authorized Instructor: CDISC for Newcomers, ODM, Define-XML, Dataset-JSON

CDISC ODM Vendor Certification, Program Coordination Team

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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author have no real or apparent conflicts of interest to report*

# Agenda

1. The CDISC ODM Standard in the Research Process
2. ODM Metadata & Data Structure
3. ODM Extension Example
4. ODM Use Cases
5. Summary

# The CDISC ODM Standard in the Research Process

# Research process

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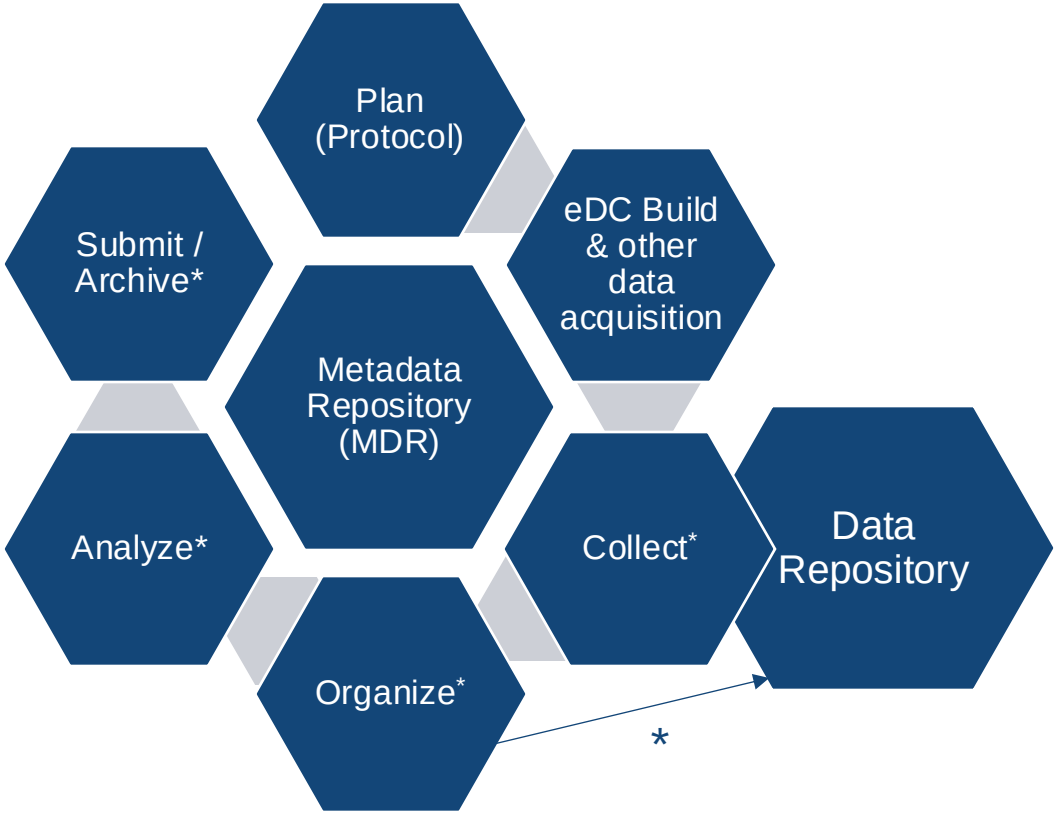
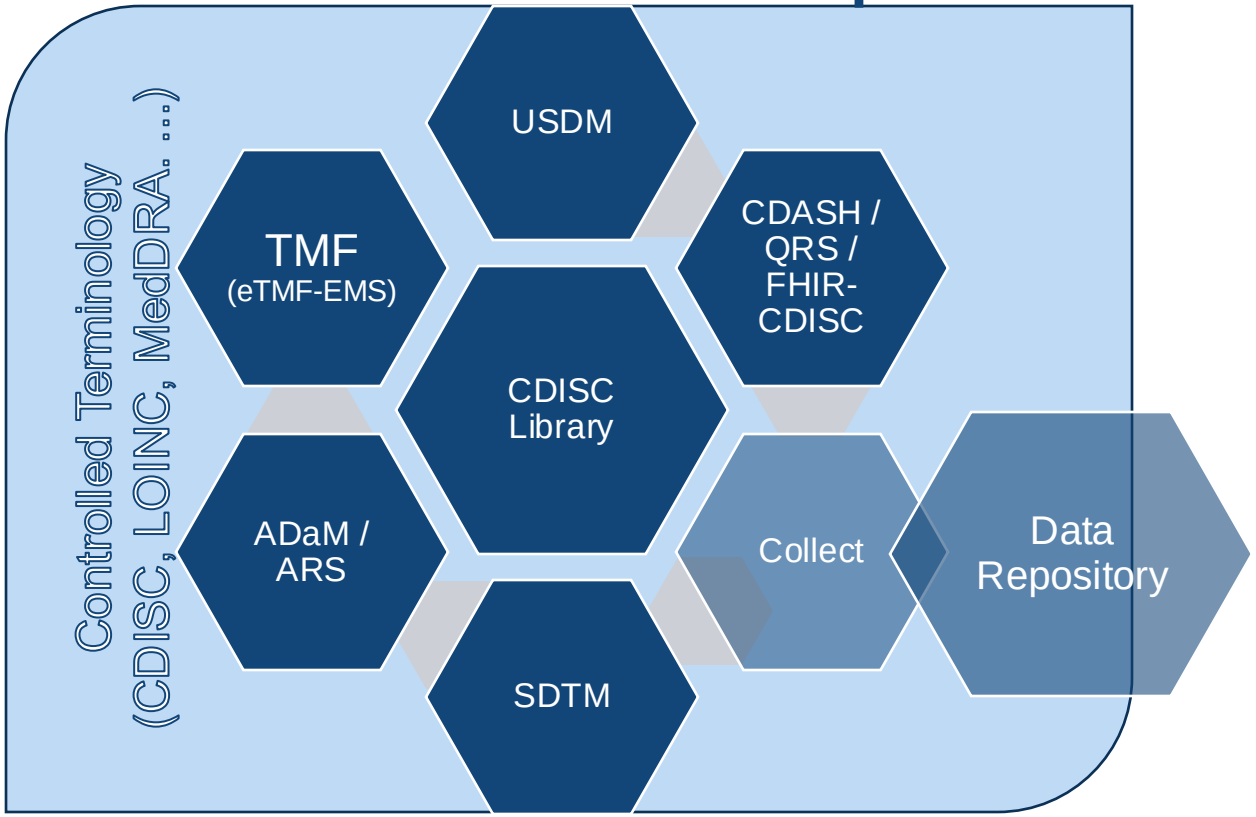
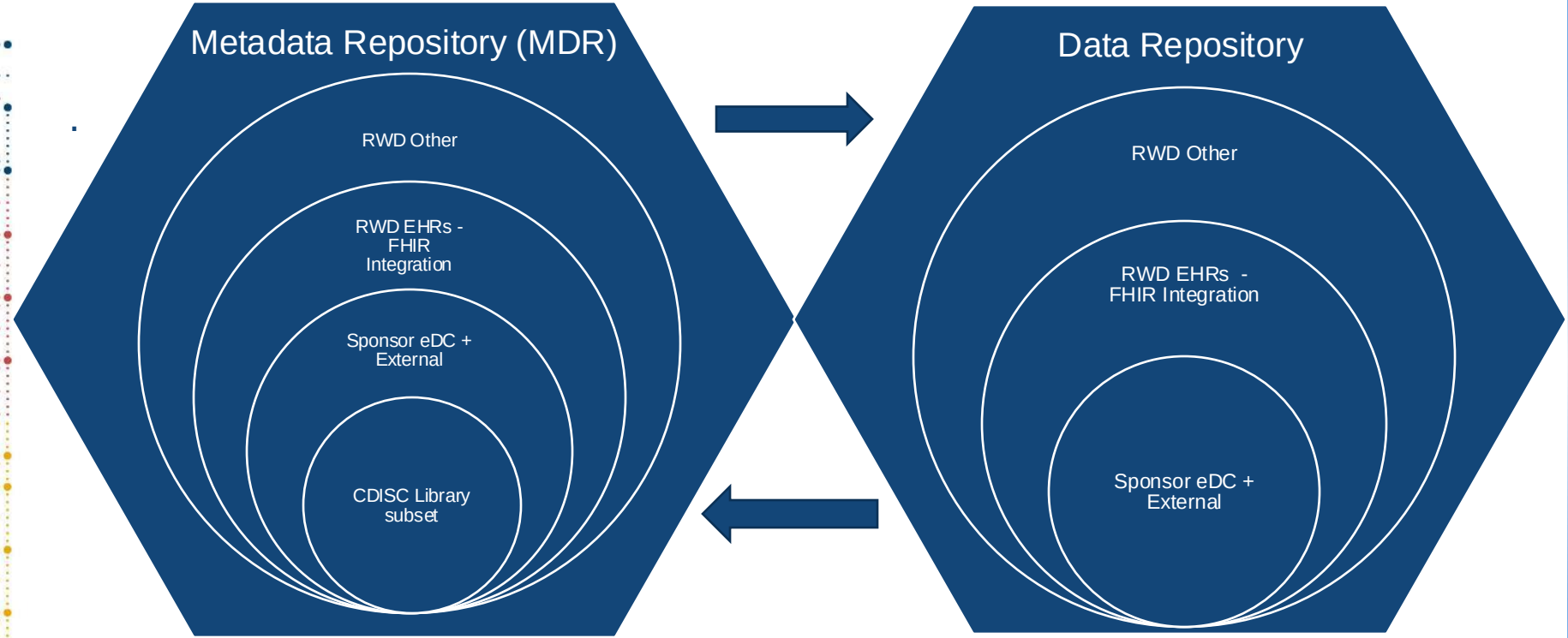


# CDISC Standards in the Research process




**Data Exchange Standards (ODM, Define-XML, Dataset-JSON)**

# Sponsor Metadata and Data repositories




**Data Exchange Standards (ODM, Define-XML, Dataset-JSON)**

# The CDISC ODM Standard

## Metadata and Data Exchange

- XML based
  - Structure: tags or elements, and their attributes
  - Flexible

```
1   <?xml version="1.0" encoding="utf-8" standalone="yes"?>
2   <ODM FileType="Snapshot" Granularity="Metadata"
3       FileOID="www.sponsor_uri/SDTX.1.1.2/2024-04-09:1_vx.0_1"
4       CreationDateTime="2024-06-13T00:08:09Z"
5       AsOfDateTime="2024-02-02T00:08:09Z"
6       ODMVersion="2.0"
7       SourceSystem="xyz" SourceSystemVersion="1.0.0" Originator="Sponsor Study Metadata Team"
8       Description="This is just text to describe the contents of this ODM file.">
9       <Study OID="www.sponsor_uri/STDX"> [496 lines]
506 </ODM>
507
```

# The CDISC ODM Standard

## Metadata and Data Exchange

- XML based
  - Structure: tags or elements, and their attributes
  - Flexible
- Vendor neutral, platform independent format for store, interchange and archive of clinical study data
  - Metadata
  - Administrative data
  - Subject related data
  - Reference data (not-subject related)
- Hierarchical as well as tabular
- Widely used in EDC and CDM systems, plus MDR systems
- Enables **traceability and reusability** in end-to-end systems

# The CDISC ODM Standard

**Benefits:**

- Provides an industry standard to enable integration of clinical systems
- Promotes interoperability of clinical data applications between organizations and across vendor platforms
- Provides a clinical data archive format compliant with applicable regulatory guidances
  - Supports 21 CRF Part 11 Archive – audit trail
- Facilitates ‘end-to-end’ standardized implementations

# The CDISC ODM Standard Evolution


Can be downloaded or viewed from the CDISC website:

https://www.cdisc.org/standards/data-exchange/odm
Versions and Archive tabs

(1) Its use depends on the parties involved in the exchange
(2) Not backward compatible. Published in the CDISC Wiki and GitHub

# The CDISC ODM Standard Download or View

- https://www.cdisc.org/standards/data-exchange/odm

# ODM Metadata & Data Structures

# ODM Flexible Structures

Design your metadata with goals in mind, plan for reusable definitions.

- Supports the core tasks of data management, including data cleaning
- Supports functionality to include blank CRF as well as SDTM annotated CRF, plus a Data Validation Plan
- Supports functionality to include data views to be used in the mapping of SDTM datasets
- Supports traceability.
  - Recommended to implement the structures that facilitate traceability

The ODM Standard allows extensions to define additional structures

# The CDISC ODM Standard Basic Structure[1] – v1.3.2

- ODM
  - Study
    - MetadataVersion
      - Protocol
        - StudyEvent (i.e., Visit)
          - Form
            - ItemGroup
              - Item
              - …
      - ItemDef
      - CodeList
      - ConditionDef
      - MethodDef
  - AdminData
    - User
    - Location

    (*)
  - ReferenceData
  - ClinicalData

OIDs (Def – Ref)

- ODM
  - ReferenceData
    - ItemGroupData
      - AuditRecord
  - ClinicalData
    - SubjectData
      - InvestigatorRef

      *
      - SiteRef
      - StudyEventData
        - FormData
          - ItemGroupData
            - ItemData
              - AuditRecord

[1]This is just a schematic of concepts. Actual representation in the ODM Specifications

# The CDISC ODM Standard Basic Structure[1] – v2.0

- ODM (added structures)
  - Study
    - MetadataVersion (Workflow, Coding, Define-XML structures))
      - Protocol
        - StudyEvent (i.e., Visit)
          - ItemGroup (Form type)
            - ItemGroup
              - Item
              - …
      - ItemDef (+ properties; i.e., CompletionInstructions)
      - CodeList
      - ConditionDef
      - MethodDef
  - AdminData (Query)
    - User
    - Location

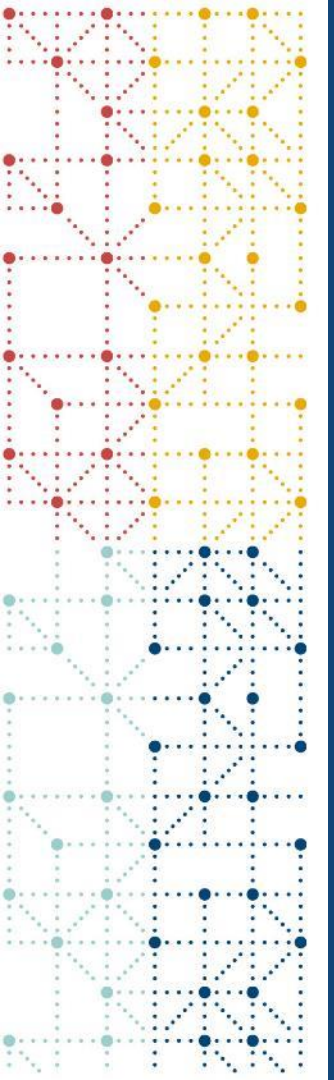
    (*)
  - ReferenceData (Query)
  - ClinicalData (Query)

- ODM
  - ReferenceData
    - ItemGroupData
      - Query
  - ClinicalData
    - SubjectData
      - InvestigatorRef
      - SiteRef

      *
      - StudyEventData
        - FormData
          - ItemGroupData
            - ItemData
              - Query

OIDs (Def – Ref)

[1]This is just a schematic of concepts. Actual representation in the ODM Specifications



# ODM Extension Example

# The CDISC ODM Standard - Extension Example

Define-XML

- Based on ODM v1.3.2
- Only for metadata
- Only for tabular dataset definitions
- Restricts elements or attributes
- Adds elements or attributes

Can be downloaded from the CDISC website:

https://www.cdisc.org/standards/data-exchange/define-xml
Versions and Archive tabs

# The CDISC ODM Standard Extensibility Example Define-XML – ODM v1.3.2 Extended Structure

- ODM OIDs (Def – Ref)
  - Study
    - MetadataVersion
      - Standards
      - Annotated CRF
      - Supplemental Docs
      - ValueList
        - ItemRef
        - …
      - WhereClause
      - ItemGroup
        - ItemRef
        - …
      - ItemDef
      - CodeList
      - MethodDef
      - CommentDef
      - Leaf

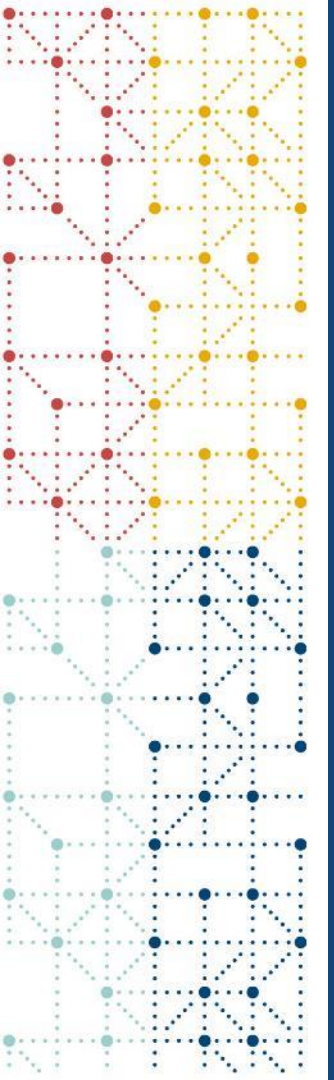
```
<ODM
  xmlns="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:def="http://www.cdisc.org/ns/def/v2.1"

  ODMVersion="1.3.2"
  FileOID="www.cdisc.org/StudyMSGv2/1/Define-XML_2.1.0"
  FileType="Snapshot"
  CreationDateTime="2021-01-24T16:59:33"
  Originator="CDISC MSG Team"
  SourceSystem="M.Hungria-System"
  SourceSystemVersion="2.1-A1"
  def:Context="Submission"
  >
...
<Study OID="cdisc.com/CDISCPILOT01">
  <GlobalVariables>
    <StudyName>CDISCPILOT01</StudyName>
    <StudyDescription>Study Data Tabulation Model Metadata Submission Guidelines Sample Study</StudyDescription>
    <ProtocolName>CDISCPILOT01</ProtocolName>
  </GlobalVariables>
  <MetaDataVersion OID="MDV.MSGv2.0.SDTMIG.3.3.SDTM.1.7"
    Name="Data Definitions for MSGv2.0 SDTM datasets."
    Description="This metadata version contains only a subset of SDTM domains available in the SDTMIG 3.3.
      The data contained do not represent the data which would appear together in an actual regulatory submission."
    def:DefineVersion="2.1.0"
    def:CommentOID="COM.MDV">

      <!-- ********************************************************************** -->
      <!-- Standard Definitions                                                   -->
      <!-- ********************************************************************** -->

  <def:Standards>
      <def:Standard OID="STD.1" Name="STDTMIG" Type="IG" Version="3.3" Status="Final" def:CommentOID="COM.ST1"/>
      <def:Standard OID="STD.2_1" Name="SDTMIG-MD" Type="IG" Version="1.1" Status="Final" def:CommentOID="COM.ST2"/>
      <def:Standard OID="STD.4" Name="CDISC/NCI" Type="CT" PublishingSet="DEFINE-XML" Version="2020-12-18" Status="Final" def:CommentOID="COM.ST4"/>
      <def:Standard OID="STD.3" Name="CDISC/NCI" Type="CT" PublishingSet="SDTM" Version="2020-12-18" Status="Final" def:CommentOID="COM.ST3"/>
  </def:Standards>
```

[1]This is just a schematic of concepts. Actual representation in the Define-XML Specifications



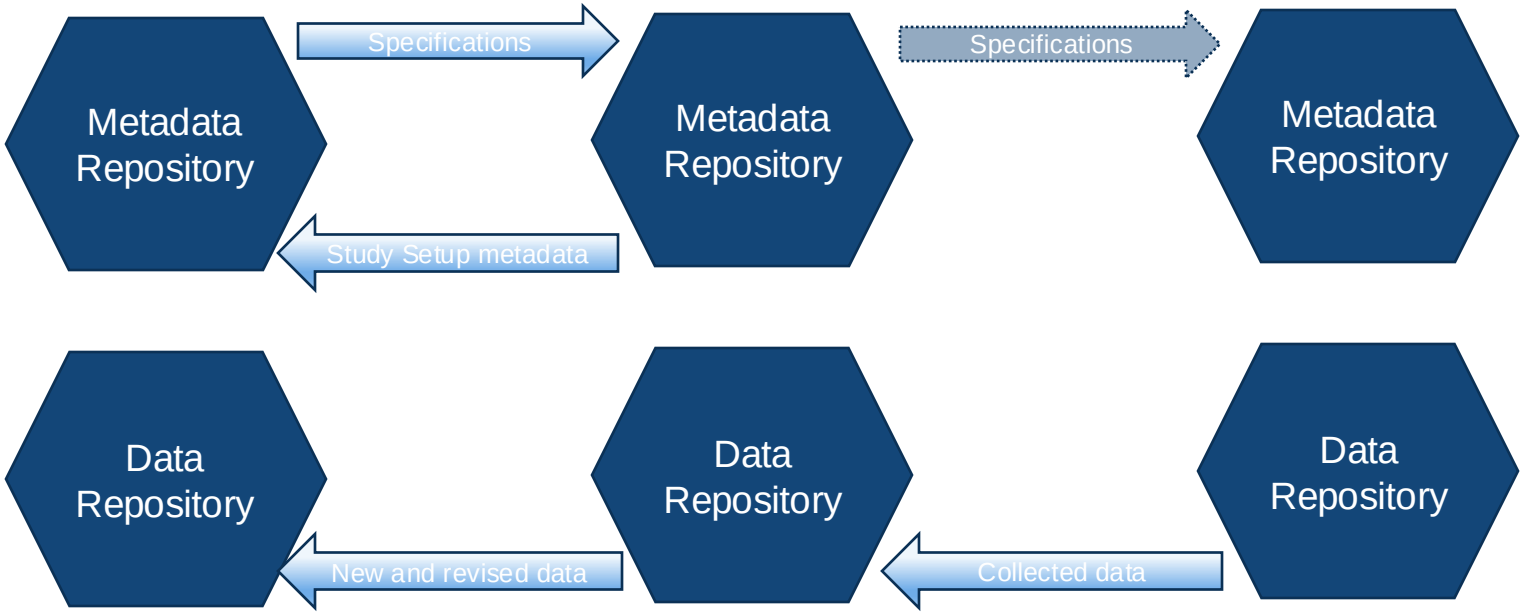
# ODM Use Cases

# ODM Use Cases

- Automated set up of EDC / CDM systems
- Data transmission from 3rd party data providers (CROs, EDC vendors) to sponsors
- Clinical data archiving
- Clinical data standards metadata repositories
- Submission of SDTM and ADaM metadata
- Electronic Health Record Integration

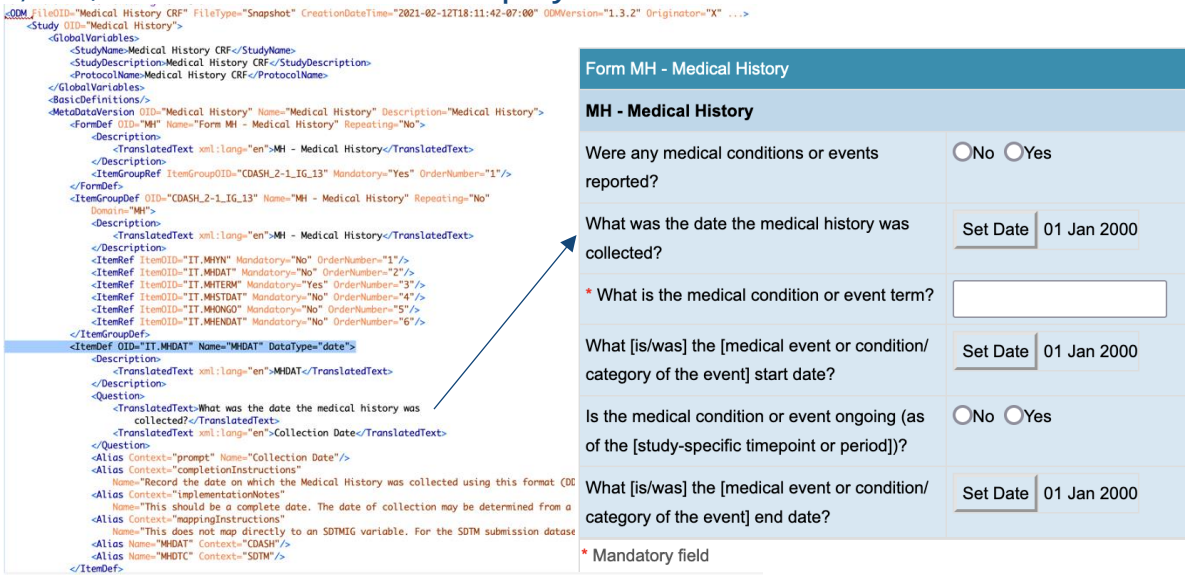
# ODM Use Cases:
# Automated set up of EDC / CDM systems - Process

- Sponsor
- CROs
- External Data (i.e., LAB)



# ODM Use Cases - Automated set up of EDC / CDM systems - Details

- Different EDC systems could render a UI interface in different ways; however, the interpretation of the ODM metadata in an ODM file should remain consistent with the metadata specified by the Originator.
  - No presentation elements; i.e., vertical or horizontal display
  - Extensions can be used



# ODM Use Cases - Automated set up of EDC / CDM systems – cont.

- Different EDC systems could render an annotated CRF in different ways; however, the interpretation of the ODM metadata in an ODM file should remain consistent with the metadata specified by the Originator.
  - No presentation elements; i.e., color or position of annotations
  - Extensions can be used

CDASH or SDTM annotations ?

```
<ODM FileOID="Medical History CRF" FileType="Snapshot" CreationDateTime="2021-02-12T18:11:42-07:00" ODMVersion="1.3.2" Originator="X" ...>
  <Study OID="Medical History">
    <GlobalVariables>
      <StudyName>Medical History CRF</StudyName>
      <StudyDescription>Medical History CRF</StudyDescription>
      <ProtocolName>Medical History CRF</ProtocolName>
    </GlobalVariables>
    <BasicDefinitions/>
    <MetaDataVersion OID="Medical History" Name="Medical History" Description="Mec
      <FormDef OID="MH" Name="Form MH - Medical History" Repeating="No">
        <Description>
          <TranslatedText xml:lang="en">MH - Medical History</TranslatedText
        </Description>
        <ItemGroupRef ItemGroupOID="CDASH_2-1_IG_13" Mandatory="Yes" OrderNumb
      </FormDef>
      <ItemGroupDef OID="CDASH_2-1_IG_13" Name="MH - Medical History" Repeating=
        Domain="MH">
        <Description>
          <TranslatedText xml:lang="en">MH - Medical History</TranslatedText
        </Description>
        <ItemRef ItemOID="IT.MHYN" Mandatory="No" OrderNumber="1"/>
        <ItemRef ItemOID="IT.MHDAT" Mandatory="No" OrderNumber="2"/>
        <ItemRef ItemOID="IT.MHTERM" Mandatory="Yes" OrderNumber="3"/>
        <ItemRef ItemOID="IT.MHSTDAT" Mandatory="No" OrderNumber="4"/>
        <ItemRef ItemOID="IT.MHONGO" Mandatory="No" OrderNumber="5"/>
        <ItemRef ItemOID="IT.MHENDAT" Mandatory="No" OrderNumber="6"/>
      </ItemGroupDef>
      <ItemDef OID="IT.MHDAT" Name="MHDAT" DataType="date">
        <Description>
          <TranslatedText xml:lang="en">MHDAT</TranslatedText>
        </Description>
        <Question>
          <TranslatedText>What was the date the medical history was
            collected?</TranslatedText>
          <TranslatedText xml:lang="en">Collection Date</TranslatedText>
        </Question>
        <Alias Context="prompt" Name="Collection Date"/>
        <Alias Context="completionInstructions"
          Name="Record the date on which the Medical History was collected
        <Alias Context="implementationNotes"
          Name="This should be a complete date. The date of collection may
        <Alias Context="mappingInstructions"
          Name="This does not map directly to an SDTMIG variable. For the SD
        <Alias Name="MHDAT" Context="CDASH"/>
        <Alias Name="MHDTC" Context="SDTM"/>
      </ItemDef>
```

cdisc

Site Number

Subject Number

**Form MH - Medical History**

| | | | |
|---|---|---|---|
| **1 MH - Medical History** | | | |
| 1.1 | Were any medical conditions or events reported? | ○ No ○ Yes | ***MHYN*** |
| 1.2 | Collection Date (DD-MMM-YYYY) | | ***MHDAT*** |
| 1.3 | Medical History Term | | ***MHTERM*** |
| 1.4 | Start Date (DD-MMM-YYYY) | | ***MHSTDAT*** |
| 1.5 | Ongoing | ○ No ○ Yes | ***MHONGO*** |
| 1.6 | End Date (DD-MMM-YYYY) | | ***MHENDAT*** |

MHDTC

# ODM Use Cases
# Automated set up of EDC / CDM systems – cont.

- If starting developing system from scratch, evaluate ODM v2.0 vs v1.3.2
- If system already using ODM v1.3.2, you may consider upgrading to v2.0
  - It would allow additional end-to-end functionality

- ODM v2.0 enhancements over v1.3.2.
  - Additional structures added reduce the need for extensions

# The CDISC ODM Standard

## Examples and Useful References on the CDISC Knowledge Base

https://www.cdisc.org/kb

- CDISC eCRF portal[(1)]: https://www.cdisc.org/kb/ecrf
  - Ready-to-use examples, CDASH-compliant, annotated eCRFs, available in PDF, HTML and XML, to use as is or import to an EDC system for customization.
- CDISC Articles:
  - https://www.cdisc.org/kb/articles/magic-happens-between-cdash-and-sdtm
- CDISC Examples:
  - https://www.cdisc.org/kb/examples

(1) Some screenshots included in this presentation

# The CDISC eCRF Portal
# View & download

https://www.cdisc.org/kb/ecrf

# The CDISC ODM Standard Summary

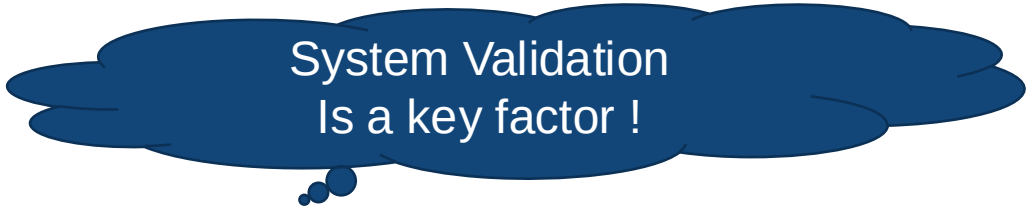
end-to-end Clinical (and Non-Clinical) Research framework

- ODM can be leveraged at every stage in the process
- Manage metadata from the start
  - Plan with the end in mind
  - Plan for Traceability
  - Plan for Reusability
- Augment metadata as new information becomes available
- Validate systems and data at every stage in the process

# CDISC ODM Vendor Certification Program

## Formal process for assessing ODM compliance for vendor system

- Provides assurance that ODM-capable products are able to process ODM files with a high level of conformity to the published specifications





https://www.cdisc.org/resources/odm-products/odm-product-certification

# Thank You!

## Questions?

mhungria@dicoregroup.com

www.linkedin.com/in/marcelinahungriadicoregroup

www.linkedin.com/in/marcelinahungria

www.dicoregroup.com

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