Towards 360i, or at least 180i: A Validation Perspective

Marcelina Hungria and Allan Hungria, DIcore Group

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Towards 360i, or at least 180i: A Validation Perspective

Presented by:
Marcelina Hungria, DIcore Group, Managing Director / Consultant
Allan Hungria, DIcore Group, Consultant

Meet the Speakers

Marcelina Hungria, MBA

Title: Managing Director / Consultant

Organization: DIcore Group

Marcelina Hungria is a Computer Science graduate, and MBA from Rutgers University, Marcelina has been supporting the pharma/biotech industry with Metadata Repository (MDR) development, CDISC Standards Implementation and Data Submission services for nearly 30 years. She has extensive experience developing and validating software tools, plus overall system testing, using SAS and other programming languages.

CDISC volunteer for 17 years, actively participating on the CDISC Data-Exchange, SDTM and SDTMIG development teams, plus the CDISC CORE initiative. Marcelina is a CDISC authorized Instructor for CDISC Data-Exchange standards.

Allan Hungria, Ph. D.

Title: Consultant

Organization: DIcore Group

Allan Hungria graduated with his doctorate in applied mathematics from the University of Delaware in 2019. His professional interests lie somewhere between numerical computation, programming and teaching. Since 2019, he has worked as a consultant, a data scientist using MATLAB and Mathematica, python, R, PostgreSQL among others, and a professor of mathematics and statistics.

Related to CDISC, Allan has participated in diverse projects for processing of data standards CDASH, SDTM, ADaM and Controlled Terminology, in ODM representation via the CDISC Library API, replication of TLFs for cross-validation of submission data packages, and co-developing DIcore Group's software tools including the Dataset-JSON Viewer and Dataset-JSON Validation.

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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.*

- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*
- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. A high-level glance at CDISC 360
2. 360i: Data exchange Process, Dataset-JSON API - demo
3. 360i: Dataset-JSON Visualization, Integrating Validation Tools in the process - demo
4. 360i Validation: Summary of Challenges and forward steps

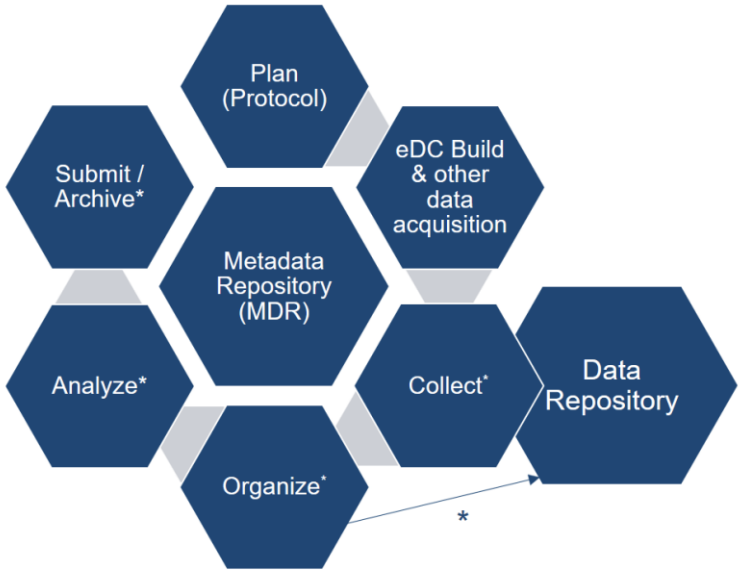
A high-level glance at CDISC 360

Process and Standards

Research Process

Silos vs Integrated approach:

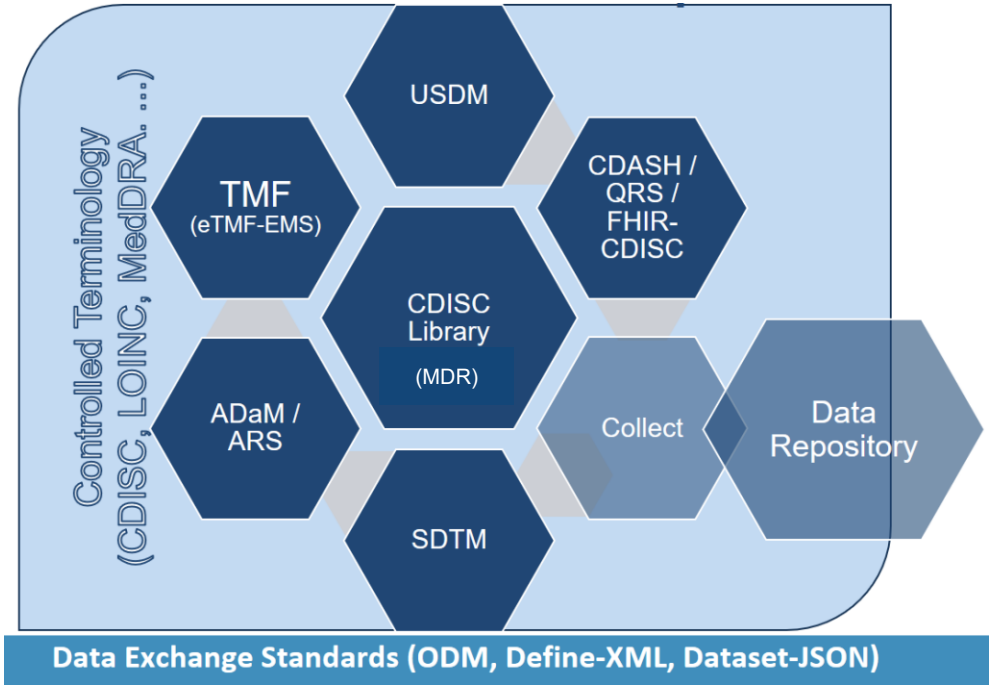
- Process
- Systems



Research Process
CDISC Standards Implementation

Silos vs Integrated approach:

- Disparate systems is a reality.



Research Process
Metadata and Data repositories

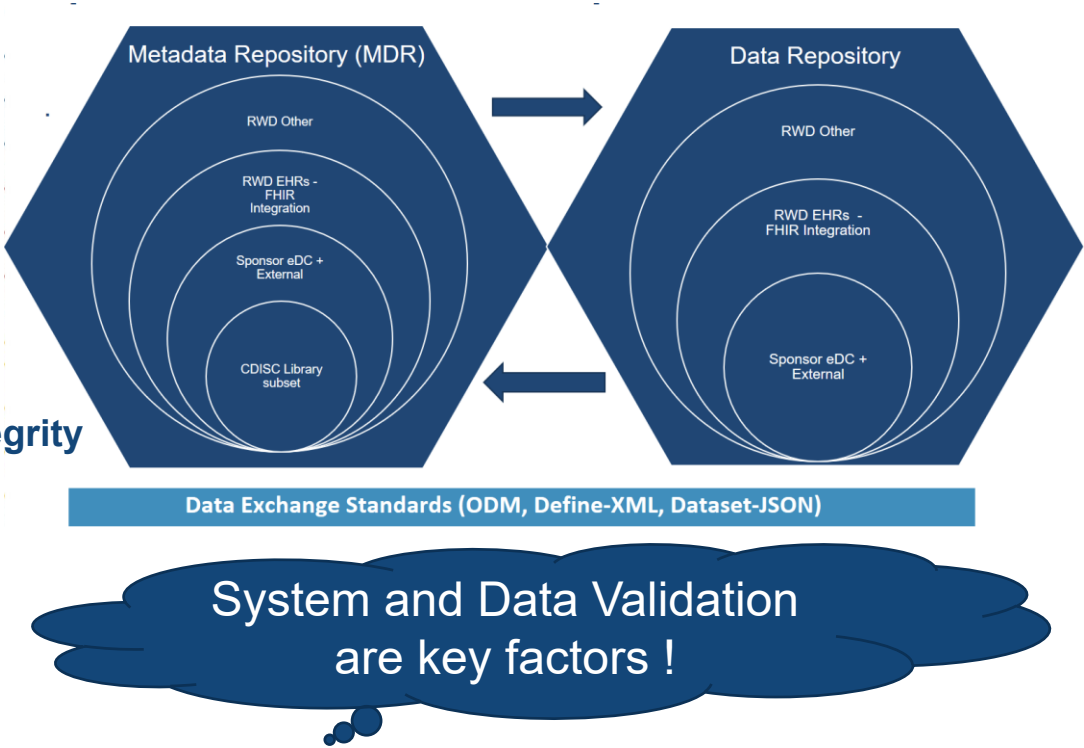
Underlying Infrastructure

- Different Operating systems
- Different programming languages
- Different Software Applications
  - Open source vs proprietary
  - Freely available vs licensed
  - Open source challenges
- Fast-pace technology changes

Focus on Interoperability & Data integrity

Validation:

- Across different systems
- Across different organizations
- Validation at different levels



360i: Data Exchange Process

Summary

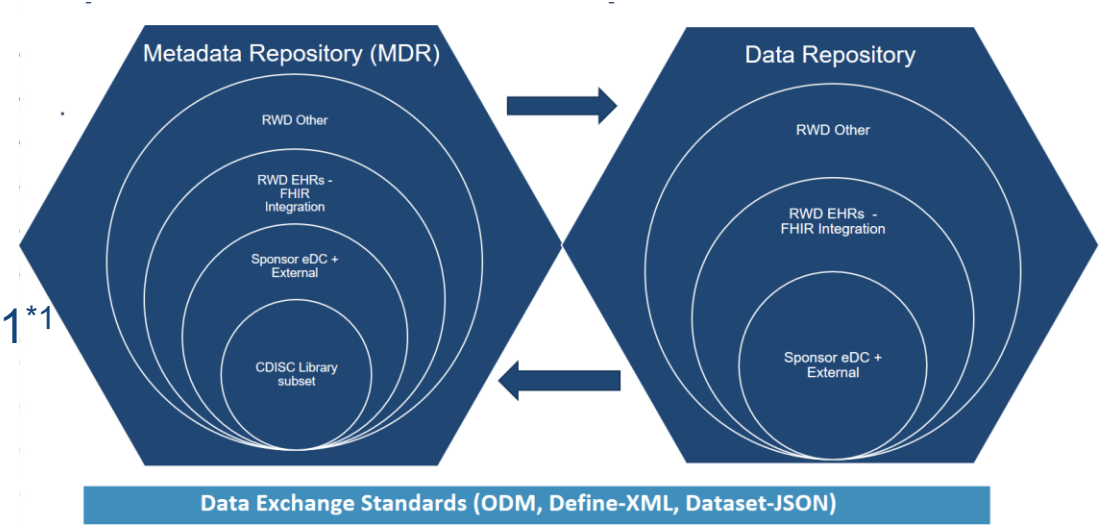
Data Exchange Process

Metadata

- Hierarchical: ODMv2*1 *2
- Tabular: Define-XML*2

Data

- Tabular: Dataset-JSON v1.1*1
- Hierarchical: ODMv2*1 *2



*1 Encouraging adoption of newest CDISC standards

*2 JSON representation is WIP

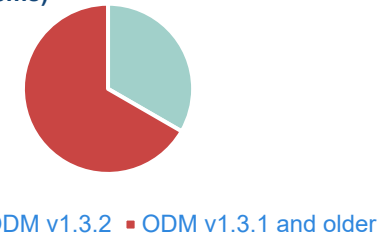
System and Data Validation are key factors !

Data-Exchange Standards Adoption

Standards

- ODM
  - V2 (released Aug-2023)
  - V1.3.2 (released Dec-2013)
- Define-XML (ODMv1.3.2 based)*
  - V2.1 (released Jan-2019)
  - V2.0 (released Mar-2013)
- Dataset-JSON
  - V1.1 (released Dec-2024)
    - FDA requested comments
      - DIcore Group's comments
  - Dataset-JSON API
    - V1.0 (Public Review ends 17-Oct-2025)

- **CDISC ODM Certified Products (mostly EDC Systems)**

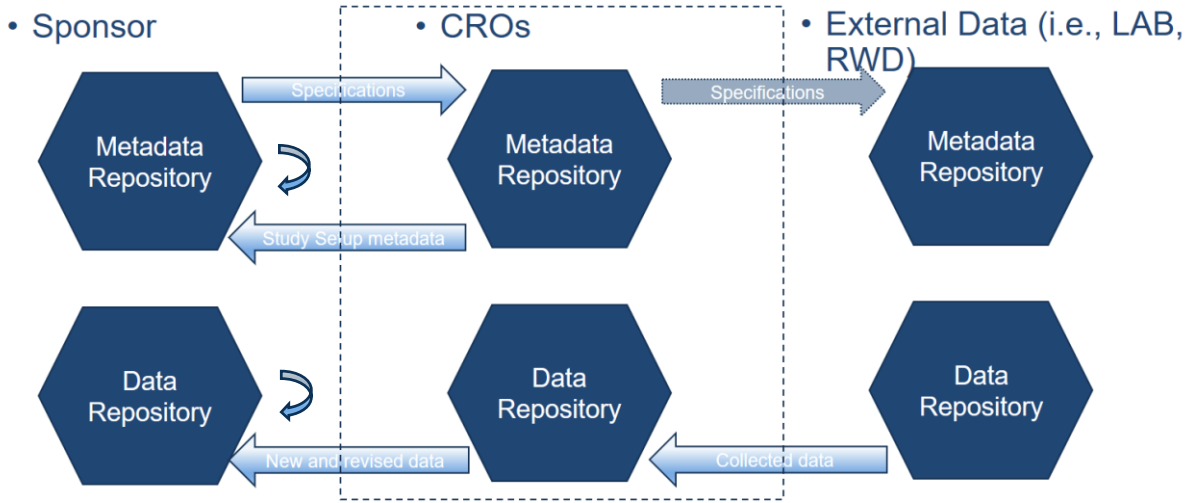


- **No statistics publicly available. V2.1 usage increasing based on comments received during training**
- **At least 10 Dataset-JSON viewers available to the user community**
- **Dataset-JSON API Reference implementation Incorporated in the DIcore Group set of tools and other Dataset-JSON viewers.**

Data-Exchange Process: Acquisition or Transformation

Data Integrity & Validation:

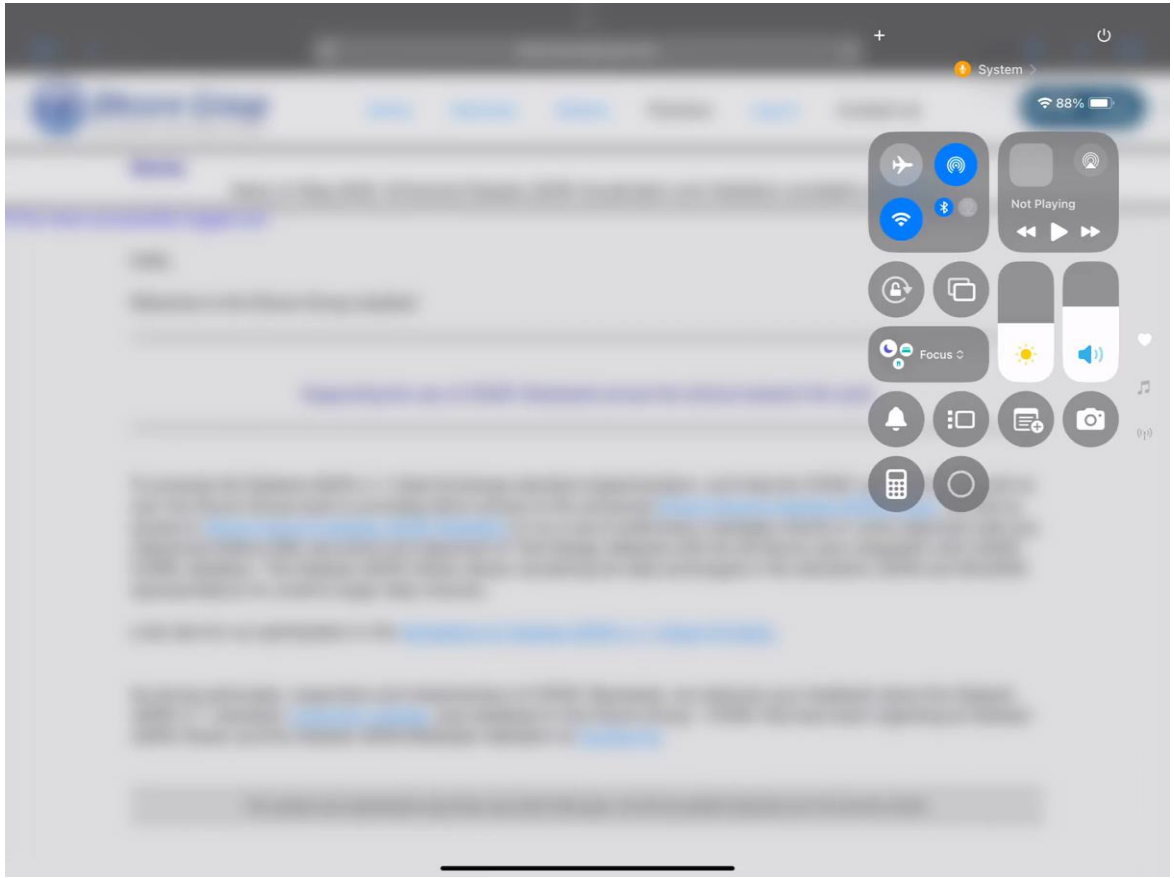
- Specification ~ Data Transfer Agreement (DTA)



Data Exchange Process – Acquisition

Acquiring data

- APIs (cache)
- Other mechanisms
  - i.e.; sftp



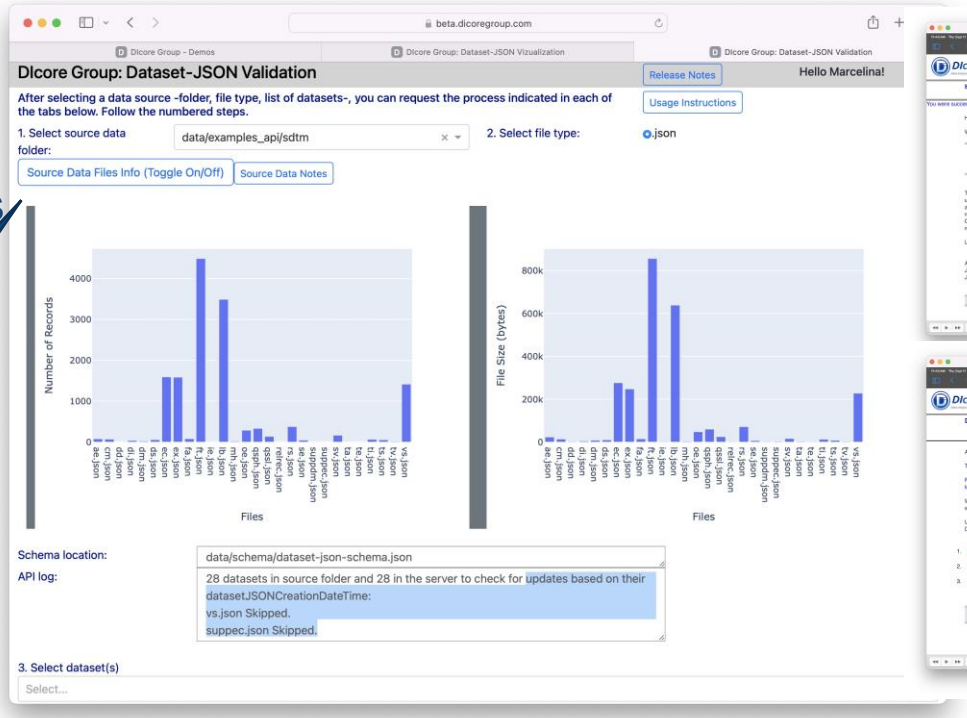
Data Exchange Process – Acquisition

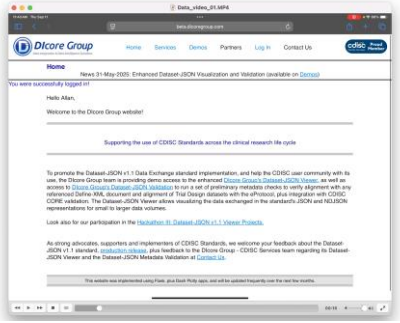
Acquiring data

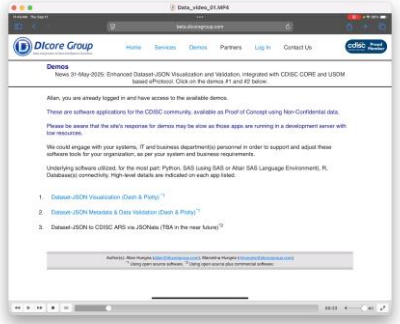
- APIs*1 (cache)
- Other mechanisms
  - i.e.; sftp

DTA

*1 Reference Implementation







Data Exchange Process – Acquisition & Validation

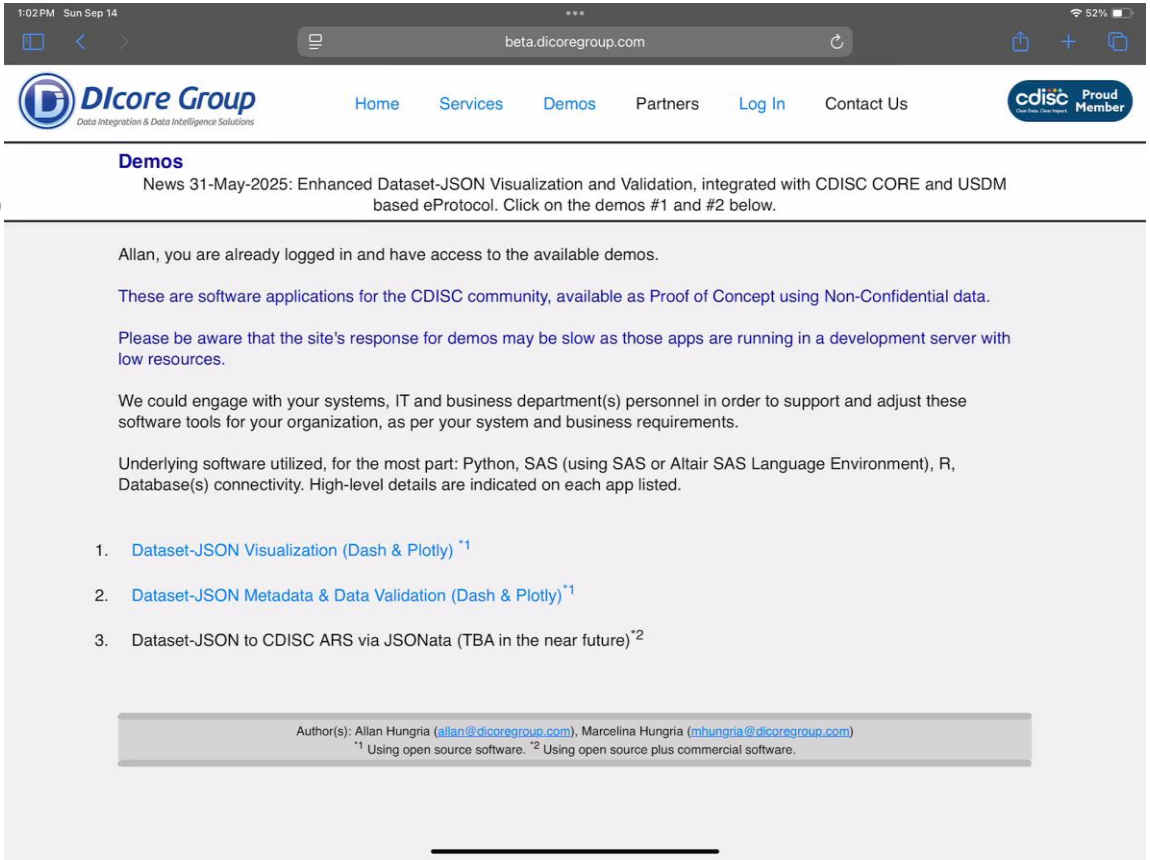
Acquiring data

- APIs (cache)
- Other mechanisms

DTA

Validating data (cache)

- Structural Validation
  - Schema
  - Other
- High-level inspection
  - Source Dataset-JSON
  - Alignment with Define-XML
- Data Validation (CORE Engine)
  - Standard Conformance
  - Custom Rules groups
- Data against e-Protocol
- Data against e-SAP



Data Exchange Process – Acquisition & Validation

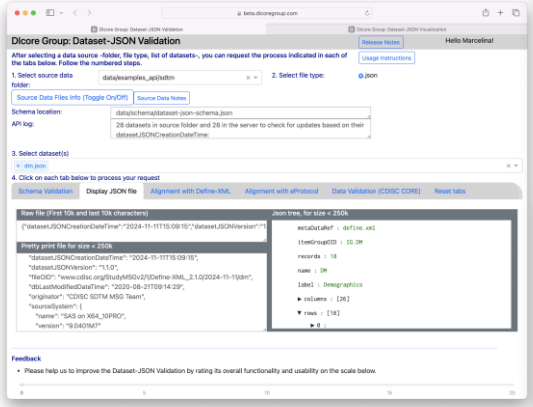
Acquiring data

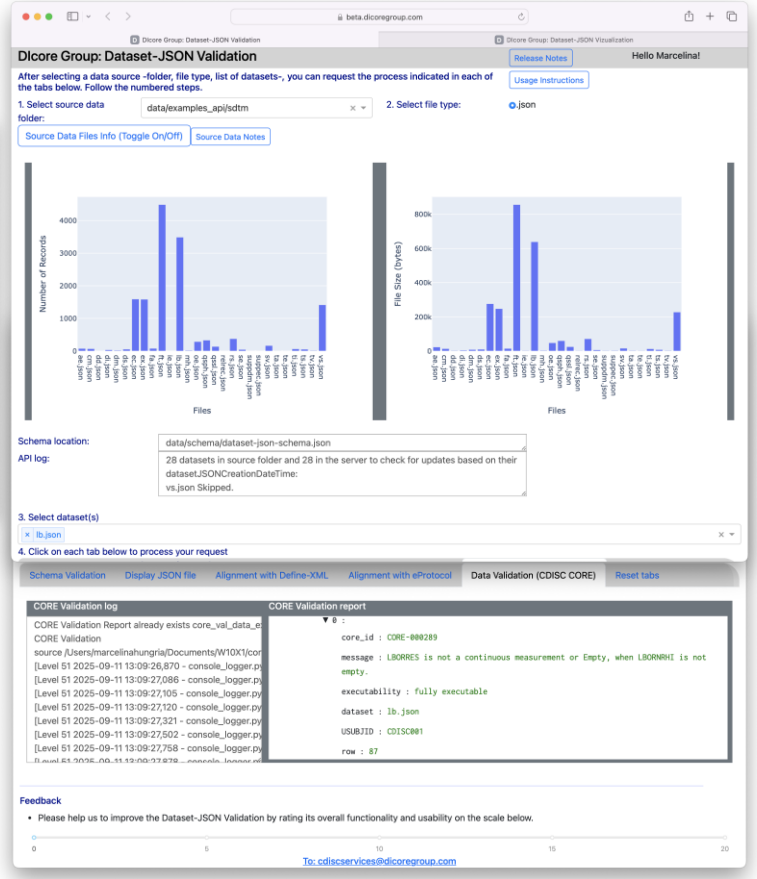
- APIs (cache)
- Other mechanisms

Validating data (cache)

- Structural Validation
  - Schema
  - Other
- High-level inspection
  - Source Dataset-JSON
  - Alignment with Define-XML
- Data Validation (CORE Engine*1)
  - Standard Conformance
  - Custom Rules groups
- Data against e-Protocol
- Data against e-SAP

*1 Reference Implementation





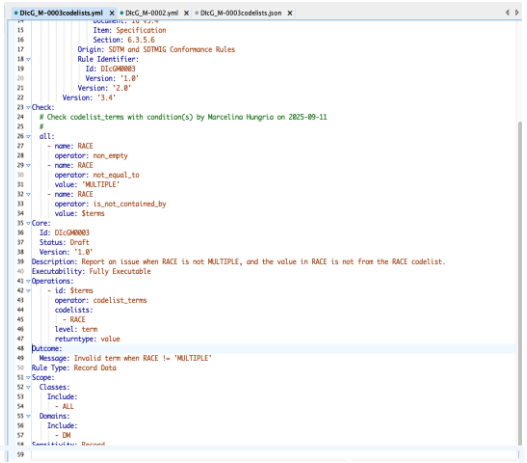
Data Exchange Process – Acquisition & Validation

Acquiring data

- APIs (cache)
- Other mechanisms

Validating data (cache)

- Structural Validation
  - Schema
  - Other
- High-level inspection
  - Source Dataset-JSON
  - Alignment with Define-XML
- Data Validation (CORE Engine)
  - Standard Conformance
  - Regulatory Rules
  - Additional Rules
- Custom Rules groups
- Data against e-Protocol
- Data against e-SAP



Group n (for DTA xyz)

Sponsor / Others (i.e. Sxyz v# & DlcG v1.0 & ...)

Regulatory (FDA x or PMDA y or ...)

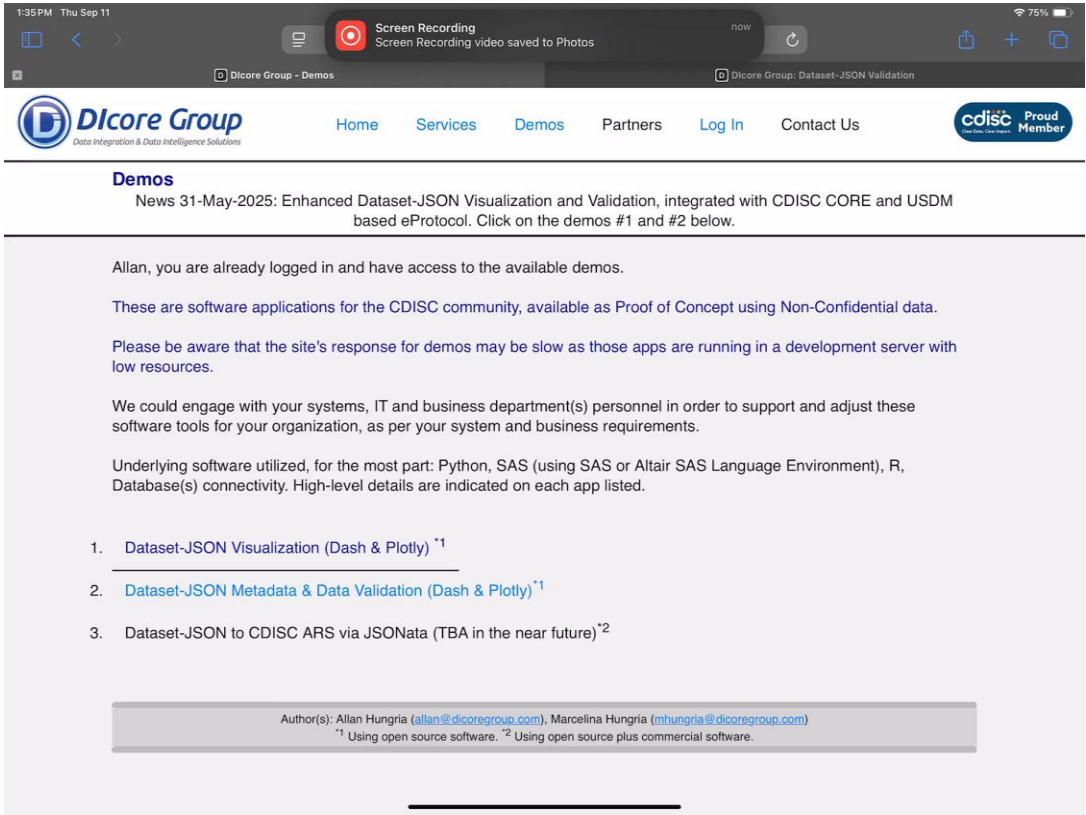
Standard Conformance (i.e, (SDTMIG 3.4 & SDTMIGMD 1.0), (ADaMIG 1.3 & related), USDM v4.0), ...

Data Exchange Process –Visualization

After Structural Validation

- High-level inspection
  - Metadata
  - Data summary / statistics (cache)
  - Data details
    - Default view
      - data sample for large volumes
    - Selective view
      - Data streaming

- Highlighted validation issues
  - At a data item level
    - i.e., DM

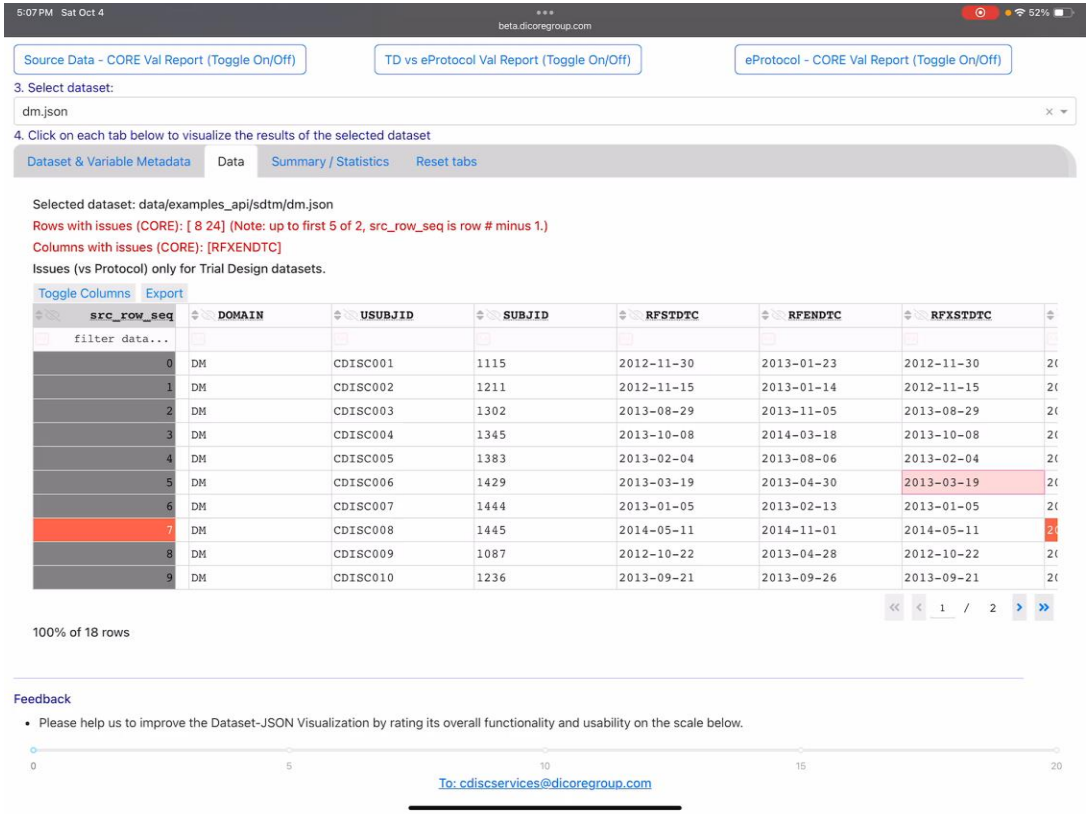


Data Exchange Process –Visualization, cont.

After Structural Validation

- High-level inspection
  - Metadata
  - Data summary / statistics (cache)
  - Data details
    - Default view
      - data sample for large volumes
    - Selective view
      - Data streaming

- Highlighted validation issues
  - At a data item level
    - i.e., LB

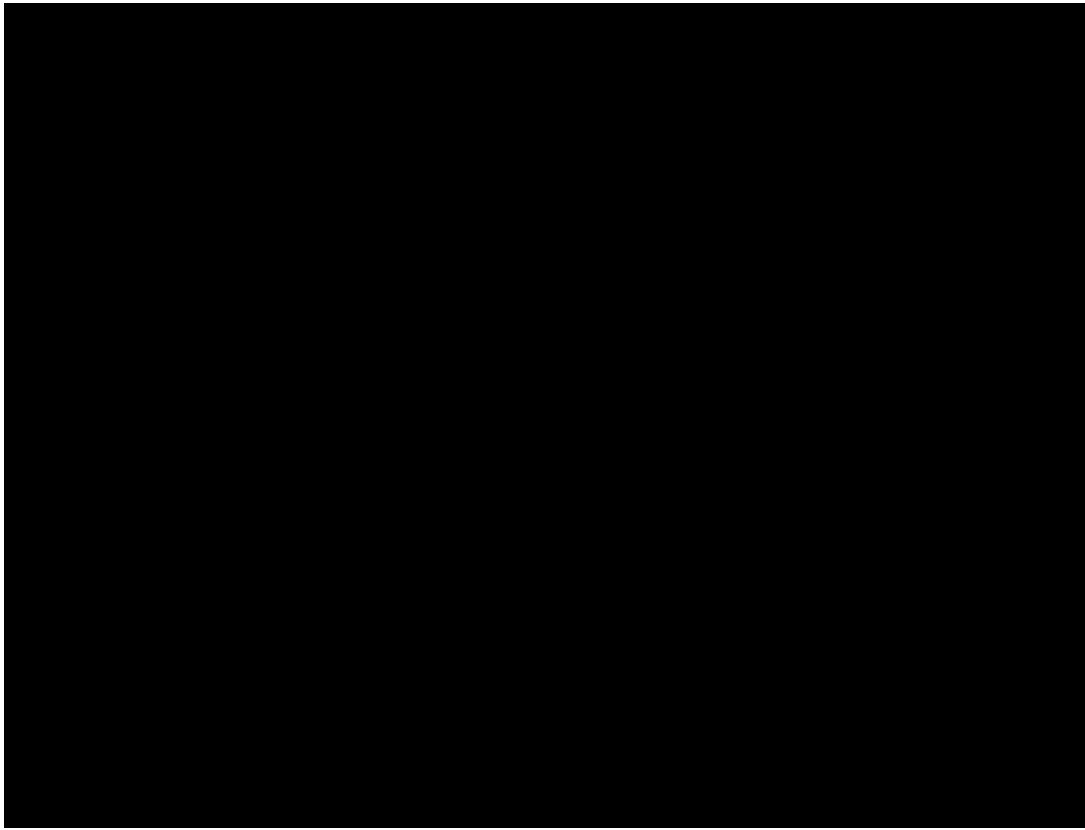


Data Exchange Process –Visualization, cont.

After Structural Validation

- High-level inspection
  - Metadata
  - Data summary / statistics (cache)
  - Data details
    - Default view
      - data sample for large volumes
    - Selective view
      - Data streaming

- Highlighted validation issues
  - At a data item level
    - i.e., TV (against the e-Protocol)



Data Exchange Process –Visualization, cont..

After Structural Validation

- High-level inspection
  - Metadata
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- Highlighted validation issues
  - At a data item level

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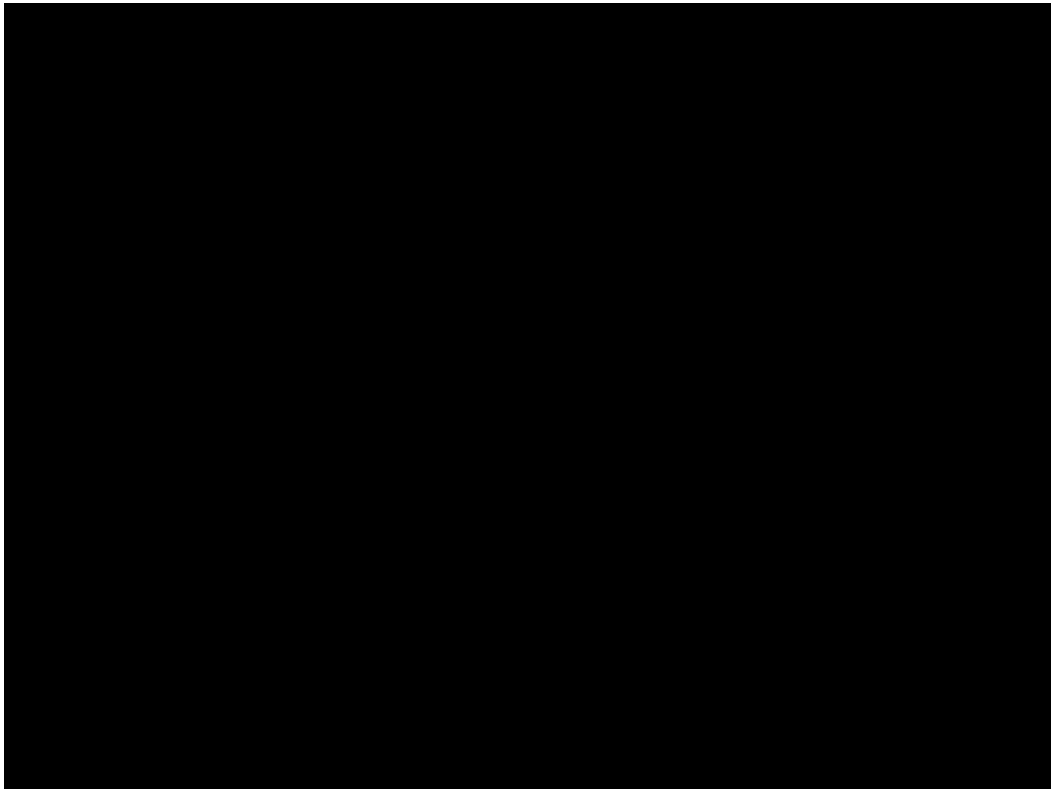

Data Exchange Process –Visualization

After Structural Validation

- High-level inspection
  - Metadata
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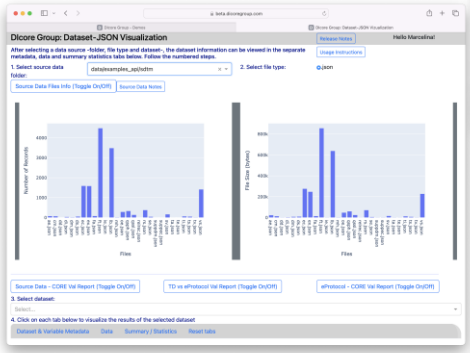
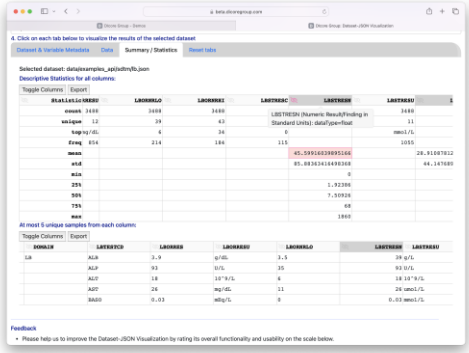
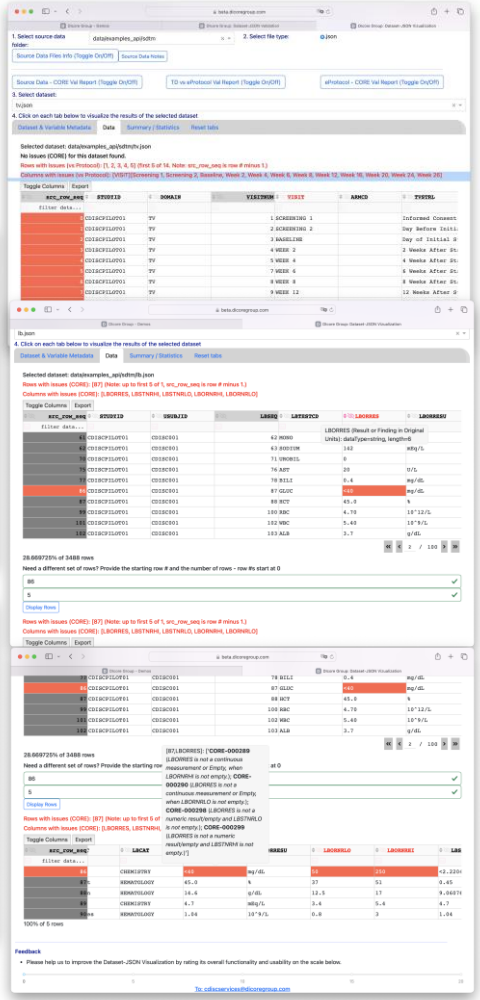
  - Data details
    - Default view
      - data sample for large volumes
    - Selective view
      - Data streaming
- Highlighted validation issues
  - At a data item level
    - Reported using the CORE engine
    - Reported using different mechanism







360i Validation: Summary of Challenges and Forward Steps

Process and Tools

Fact: there are different groups in each organization and different software tools available to the user community.

- Determining and prioritizing validation points
  - Different use cases
- Understanding different standards.
  - Different schemas
    - Different versions
- Parsing different sources and outputs
  - Different systems
  - Different programming languages
- CDISC initiatives evolving; i.e., CDISC CORE
  - Engine re-work undergoing
  - Improvements to implementation and usability of rules; i.e., capability to provide detailed location of issue(s) reported

Encourage building common ground for data exchange

- Create/support infrastructure where diverse software tools be dynamically and programmatically invoked and their output consumed
  - Take advantage of available resources
    - Willingness to test ideas
  - Managed / validated infrastructure
- Gradually incorporate more validation and integration points
  - i.e., incorporate Dataset-JSON Alignment of Metadata with the Define-XML and the e-Protocol as CORE custom rules; Alignment vs BC specializations, e-SAPand Validation of Analysis Results,

Thank You!

Questions?

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