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US

INTERCHANGE

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Dataset-JSON as Alternative Transport Format for Regulatory Submissions

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Meet the Speakers

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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.

Agenda

1. Pilot Background
2. Preliminary OCS Pilot Results
3. Executing the Pilot
4. Why you should get involved!

Background

Introducing Dataset-JSON

What is Dataset-JSON?
A dataset exchange standard for exchanging tabular data leveraging JSON designed to meet the regulatory submission needs and eliminating limitations of legacy formats

Dataset-JSON is…

- Part of the ODM v2.0 standard and based on the JSON standard
- Open-source and truly human readable
- Schema supporting any tabular format
- Extensible to support new metadata and new use cases
- Linked to Define-XML for complete metadata
- Created to be used as stand-alone datasets with smaller file sizes

What are the goals of the pilot?

Milestone 1: Short Term

- Pilot submissions using JSON format with existing XPT ingress/egress to carry the same data
- Same content, different suitcase, no disruption to business process on either side
- Allow FDA to evaluate how internal tools can support JSON format

➔ **Success Criteria: Demonstrate that Dataset-JSON can transport information with no disruption to business**

Milestone 2: Development of future strategy

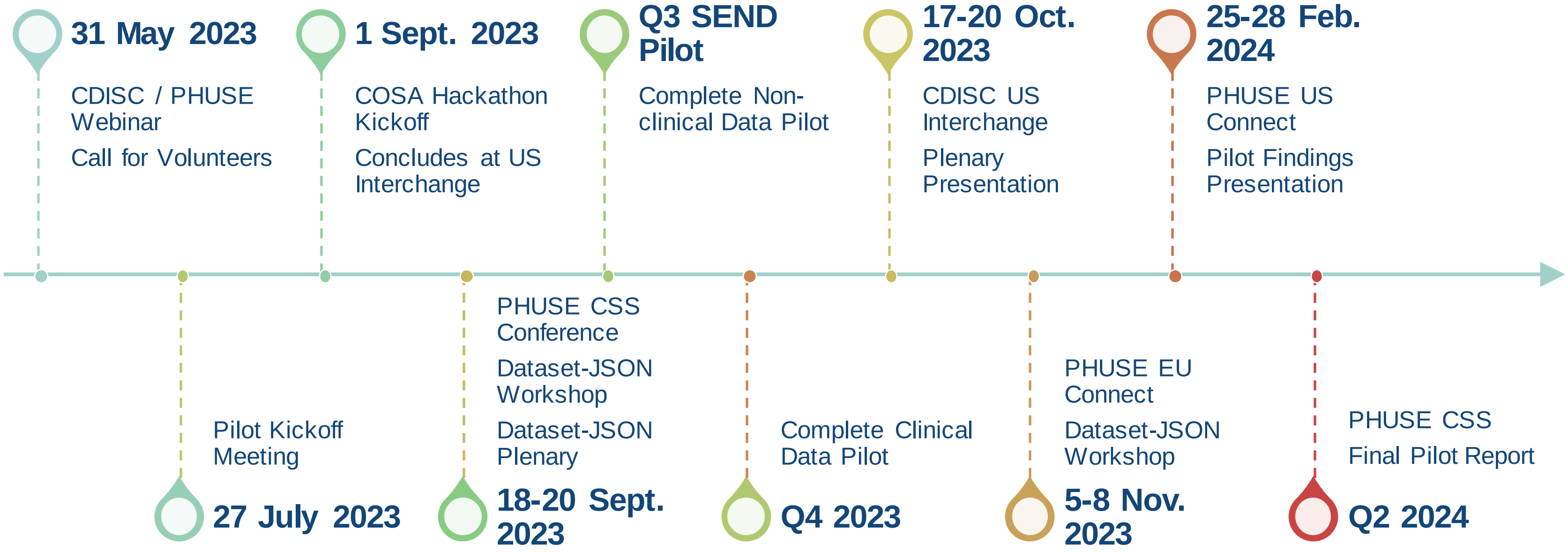
- Evaluate how current and future industry standards can benefit without XPT limitations
  e.g., Variable names > 8, labels > 40, data > 200
- Evaluate combining metadata with data
  e.g., Define-XML / Define-JSON based
- Enhanced conformance rules
- FDA to utilize findings to evaluate tool redevelopment plan to natively consume files in JSON format

➔ **Success Criteria: Demonstrate the viability of Dataset-JSON as the primary transport option**

Pilot Subteams

1. Pilot Submissions Report
2. The Dataset-JSON Business Case
3. Technical Implementation
4. Strategy for Future Development

Dataset-JSON Pilot: Timeline



31 May 2023

CDISC / PHUSE Webinar

Call for Volunteers

27 July 2023

Pilot Kickoff Meeting

1 Sept. 2023

COSA Hackathon Kickoff

Concludes at US Interchange

18-20 Sept. 2023

PHUSE CSS Conference

Dataset-JSON Workshop

Dataset-JSON Plenary

Q3 SEND Pilot

Complete Non-clinical Data Pilot

Q4 2023

Complete Clinical Data Pilot

17-20 Oct. 2023

CDISC US Interchange

Plenary Presentation

5-8 Nov. 2023

PHUSE EU Connect

Dataset-JSON Workshop

25-28 Feb. 2024

PHUSE US Connect

Pilot Findings Presentation

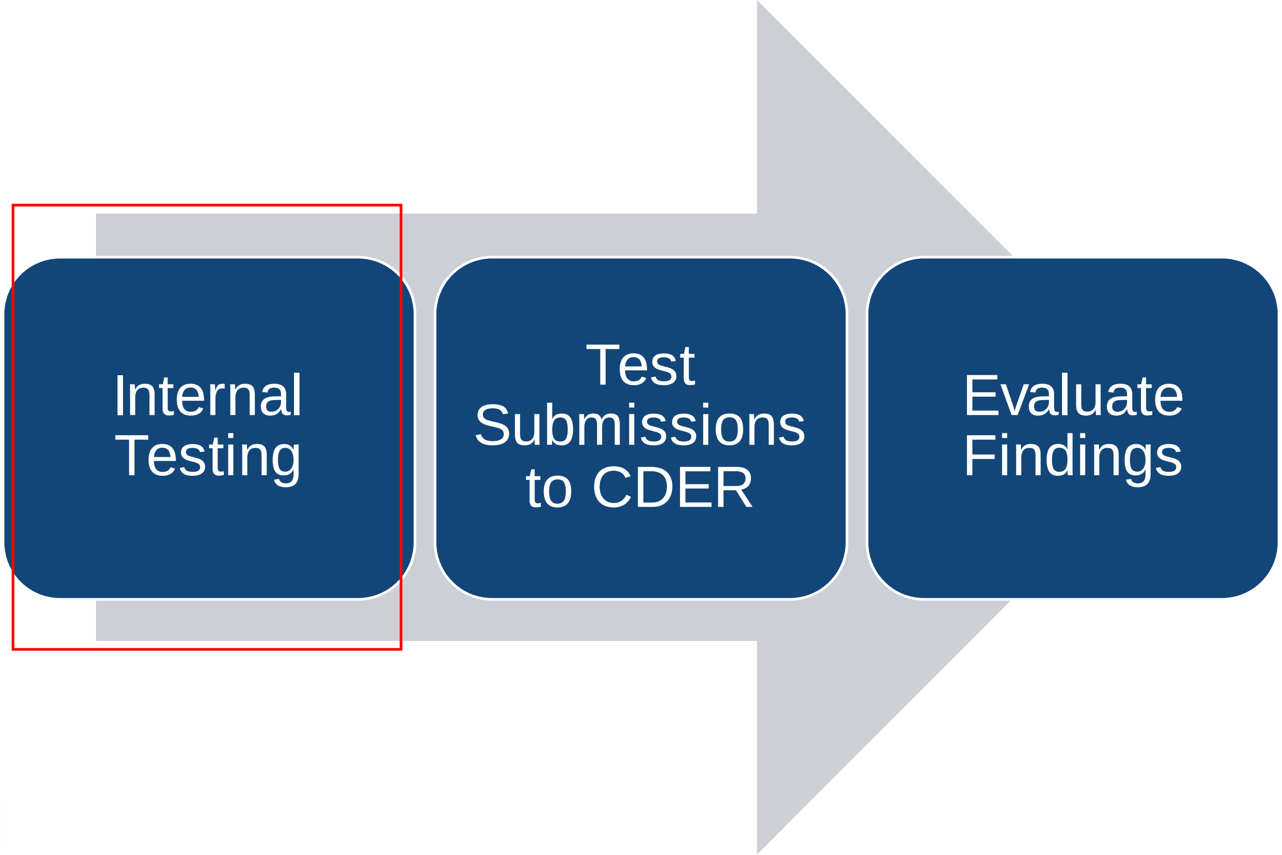
Q2 2024

PHUSE CSS

Final Pilot Report

Preliminary OCS Pilot Results

Overall Pilot Strategy



Pilot Strategy

Goal: Confirm data integrity within nonclinical test data submissions

Utilized Python Hackathon Solution

Reviewed CDISC Dataset-JSON specifications

Converted Datasets from XPT to JSON and back

Performed Validation Checks

Preliminary Results

- Successes:
  - Minimal effort for conversion utilizing Python
  - Data integrity maintained throughout conversions
- Opportunities to improve:
  - JSON files larger than XPT files
  - Date issues identified

Next Steps

Internal	External
• Continue testing with additional study types • Test additional use cases with clinical datasets	• Receive test submissions from industry and perform testing • Evaluate findings from test submissions

Executing the Pilot

Open-Source Conversion Software Tools

SAS

The SAS conversion software by Lex Jansen

Dataset-JSON example files are included in the repository

Includes a macro for comparing libraries with SAS datasets

Documentation is included

R

R conversion package by Atorus Research and Johnson & Johnson

Documentation is included

Python

Python conversion software by Pierre Dostie

Pilot will focus on SAS and R, but any conversion tool can be used

High-level Process Overview

1. Select the software conversion tool(s) to use (one or more)

2. Select study datasets and convert them to Dataset-JSON

3. Convert Dataset-JSON datasets into a native dataset form

4. Compare the native datasets back to the original format and ensure there are no unexpected changes in converted dataset

5. Optionally, test other conversion scenarios (e.g., interoperability tests)

6. Complete the on-line questionnaire to record your findings

Example Conversion Scenarios

Pilot Conversion Scenarios

1. SAS dataset -> Dataset-JSON -> SAS dataset
2. R dataframe -> Dataset-JSON -> R dataframe
3. Dataset-JSON -> native format -> Dataset-JSON

Complete at least 1 scenario from the list above or use your own scenario

Example Interoperability Scenarios

Interoperability Conversion Scenarios

1. SAS dataset -> Dataset-JSON -> R dataframe
2. R dataframe -> Dataset-JSON -> SAS dataset

Interoperability scenarios are optional and may be tested in addition to the Pilot Conversion Scenarios. Improved interoperability is a benefit of Dataset-JSON.

Technical Implementation Observations

Date representations

- Highlights new interoperability requirements
- Date epochs are different for SAS (1/1/1960) and R (1/1/1970)

Numbers and precision

- Additional testing and documentation

Processing large datasets

- Splitting, Streaming, Compression, Partitioning, Paging

Structural simplifications

- Considering 2 minor structural simplifications

Minimal effort to build Dataset-JSON software tools

File Size Observations from Initial Testing

		SAS v5 XPT	Dataset-XML	Dataset-JSON
SDTM	FT	5,917	4,287	858
	LB	2,699	4,104	640
	VS	784	1,372	229
ADaM	ADLBC	33,441	145,575	24,942
	ADQSNPIX	12,840	61,561	8,404
	ADVS	13,313	51,646	8,257

- These are numbers about uncompressed files
- These are exchange formats, not operational formats
- File sizes are in KB
- CDISC pilot datasets were used for the comparison

Dataset-JSON Hackathon II

- Primary objective: Create a draft REST API specification for Dataset-JSON

- Secondary objective: Proof-of-concept implementations to demonstrate and test the API specification

- Virtual hackathon
  - https://github.com/cdisc-org/DataExchange-DatasetJson-API

- Draft API specification will be used as an input to:
  - Dataset-JSON Pilot future strategy and business case teams
  - ODM v2.x API development

Why you should get involved!

Or what we overheard on the elevator

PHUSE Business Case Sub-Team Elevator Pitch

Dataset-JSON is a widely accepted data format that will streamline data exchange between organizations. Moving to Dataset-JSON will prepare us for the current digital world and will enable our company to more accurately, completely, and efficiently represent our clinical research data, allowing us to better serve our patients/customers. It supports current data standards but also allows for standards to evolve and removes current limitations imposed by XPT format. Dataset-JSON will save time, hardware cost, increase performance, and is easily transferable between systems. All this will save cost and time.

Thank You!

Questions?

Interested in Participating?

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Open-Source Conversion Software Tools

- SAS
  - https://github.com/lexjansen/dataset-json-sas
  - The SAS conversion software by Lex Jansen
  - Dataset-JSON example files are included in the repository
  - Includes a macro for comparing libraries with SAS datasets
  - Includes a Python script for validating Dataset-JSON
  - Documentation is included
- R
  - https://github.com/atorus-research/datasetjson
  - https://atorus-research.github.io/datasetjson/index.html
  - https://cran.r-project.org/web/packages/datasetjson/index.html
  - R conversion package by Atorus Research and Johnson & Johnson
  - Documentation is included
- Python
  - https://github.com/dostiep/Dataset-JSON-Python (submit issues)
  - Python conversion software by Pierre Dostie
  - We will not cover the Python tooling in the workshop
  - The Dataset-JSON Pilot will focus on SAS and R, but any conversion tool can be used