



Dataset-JSON Uncovered

Standard, FDA Pilot,
Hackathons and Tooling

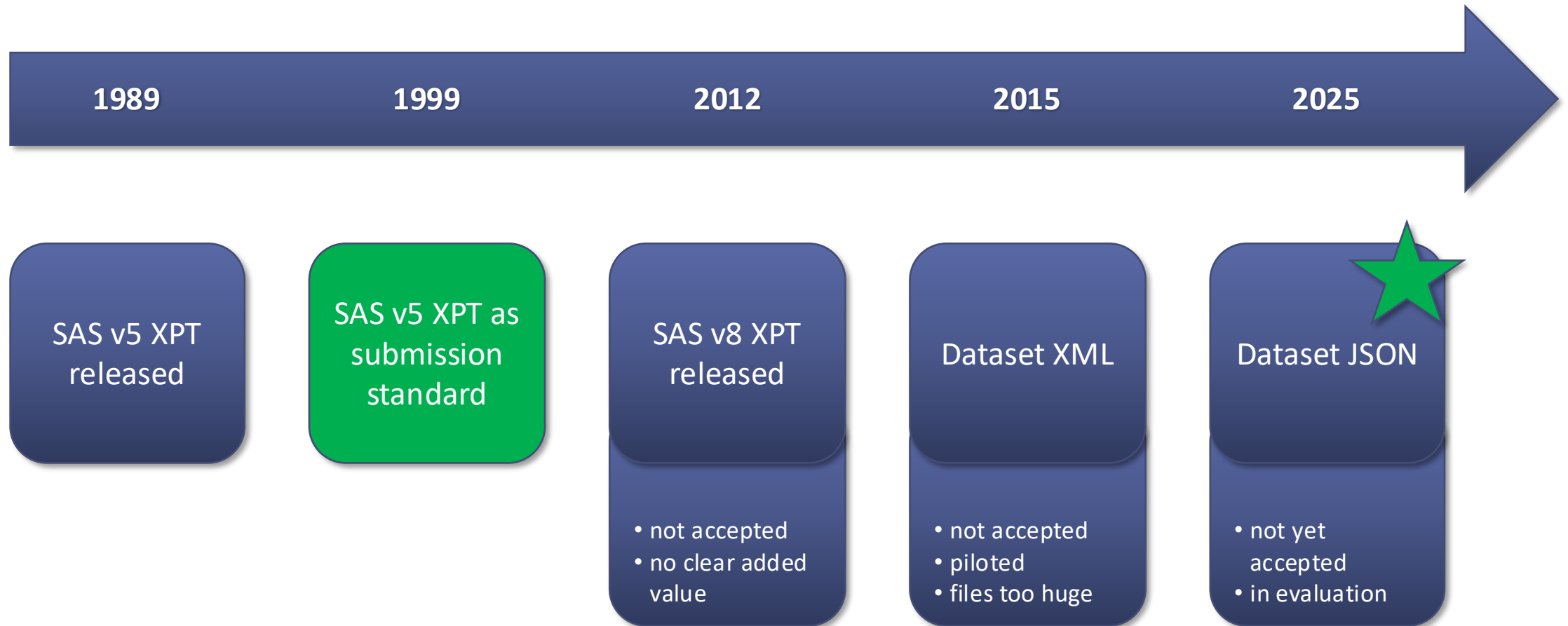


Agenda

- The Standard
 - From Theory to Practice
 - Tech & Tooling
 - Summary
-



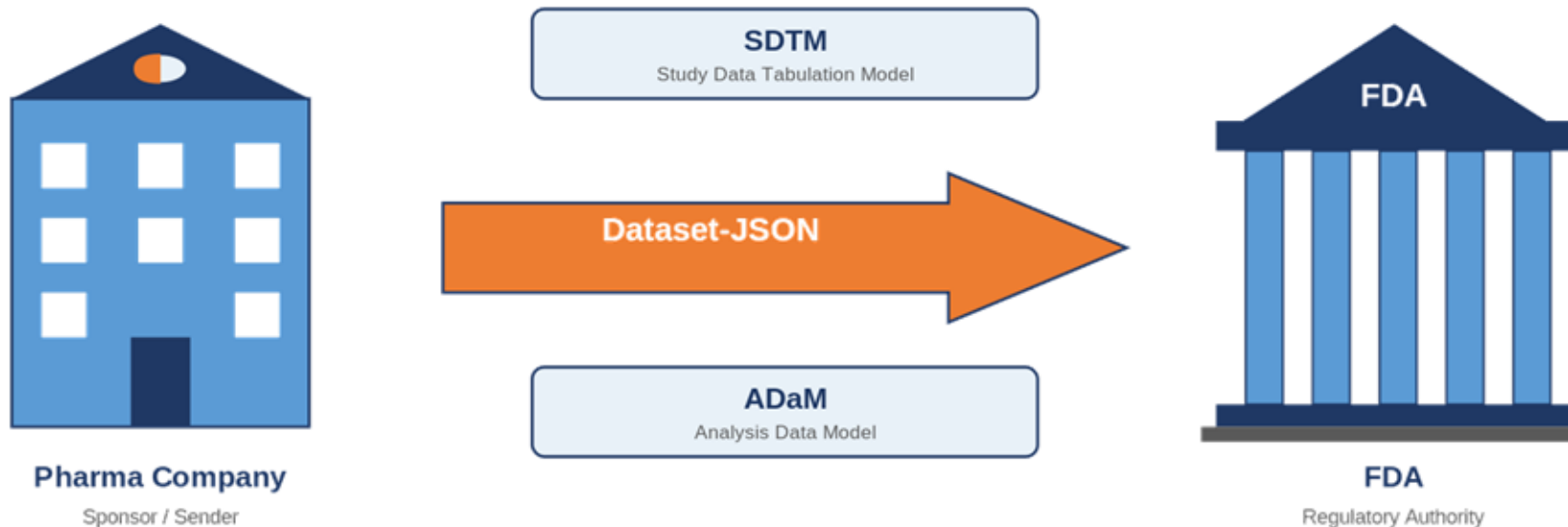
Submission Standards for FDA



What is Dataset-JSON?



Dataset-JSON: A CDISC dataset exchange standard for exchanging tabular data



What is Dataset-JSON?



➤ Key characteristics:

- Part of the ODM v2.0 standard
- Open-source with MIT license
- Truly human readable
- Schema supporting any tabular format
- Extensible to support new metadata and use cases
- Linked to Define-XML via object identifiers for complete metadata
- UTF-8 support – no name or label length limitations
- One file per dataset, designed for small file sizes



Why should we care?



- Replaces XPT (real shift)
 - Modern workflows (R/Python etc.)
 - Tooling ecosystem emerging
-

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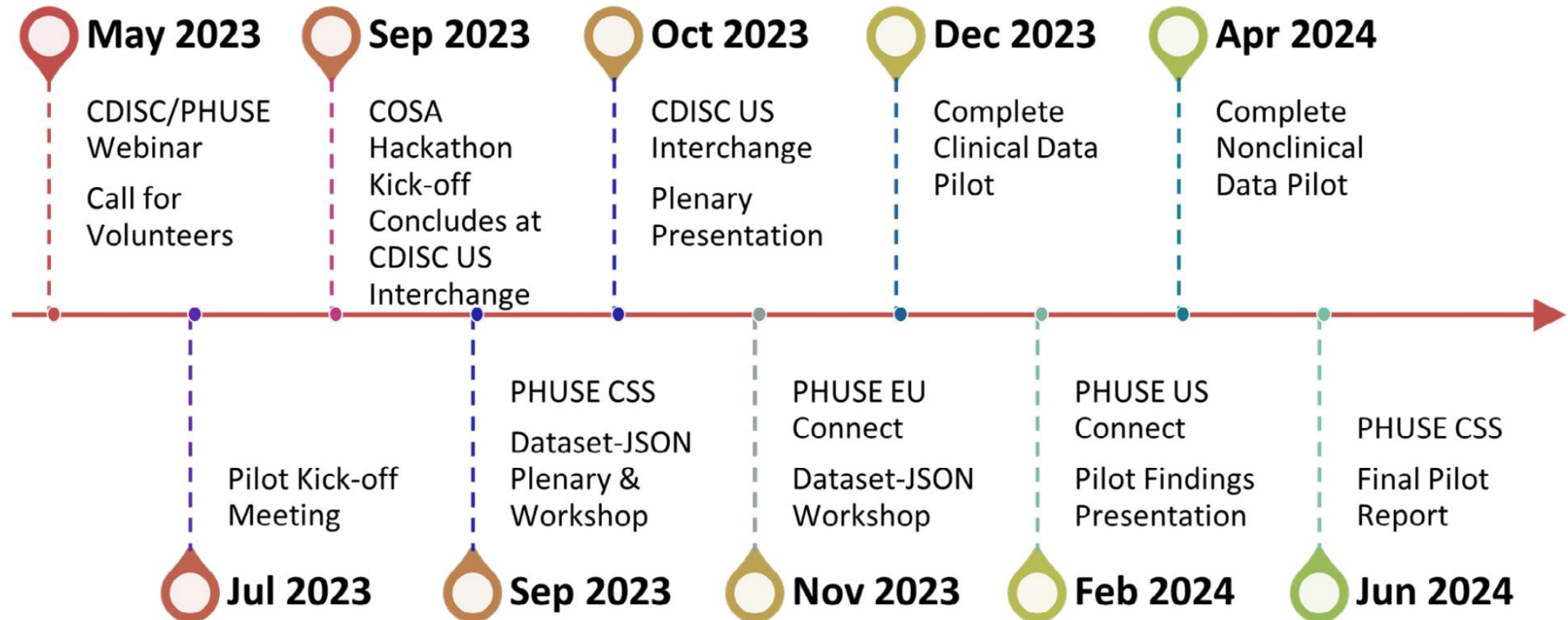
Project Teams



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



Dataset JSON Project Timeline



Hackathon 1 – Conversions & PoCs



- Organized by CDISC Open Source Alliance (COSA)
- Community-driven development of conversion tools
- Solutions in SAS, R, and Python developed collaboratively
- Results directly fed into the FDA pilot

 CDISC Open Source Alliance

DIRECTORY ABOUT EVENTS HACKATHONS APPLICATION OTHER

Hackathons > Dataset-JSON Hackathon



Dates

1 September 2022 - 19 October 2022

Description

Dataset-JSON, a data exchange standard for tabular datasets that uses the JSON format, is part of the ODM v2.0 draft standard and an enhancement to the Dataset-XML v1.0 specification. ODM V2.0 is in Public Review and should be published in March 2023. It is designed to meet the requirements of the regulatory submission use case as well as other data exchange scenarios. As a new standard, it is necessary to provide numerous example implementations of how the Dataset-JSON can be used, in order to speed its adoption.

Dataset-JSON Hackathon

CDISC Over Linked Data (COLD counterpart to FHIR)
Apply 1-line JSON-LD context URL to Dataset-JSON Point it to an explicit JSON-LD manifest/Define API Common data contract No need to include Define-XML files
Single a-priori source of metadata truth for all parties in a 'neutral zone' Acts as standard machine-readable Data Transfer Agreement (DTA) Transforms Dataset-JSON into a graph Applies universally-unique ID to Dataset-JSON content Express Dataset and Define as Linked Open Data on the semantic web Express Dataset and Define as RDF triples / n-quads (to load into a common metamodel e.g. ODM Biomedical Concepts)

Dataset-JSON - Python Implementation
Python module to convert Dataset-JSON to Pandas dataframe, XPT and CSV as well as to convert XPT to Dataset-JSON. Command-line interface is also available.

Dataset-JSON - R package Implementation
Atorus and GSK built a simple R package {xportr} that writes out xpt files, we would like to extend this package to read and write out JSON files. This is a POC for that extension.

<https://cosa.cdisc.org/hackathons/datasetjson>

Hackathon 2 – Viewer



- Focused on building viewers for Dataset-JSON files
- Ensured tooling existed before standard finalization

 CDISC Open Source Alliance

DIRECTORY ABOUT EVENTS HACKATHONS APPLICATION OTHER

Hackathons > Dataset-JSON Viewer Hackathon



Dates

8 October 2024 - 6 January 2025

Description

A virtual hackathon with the primary objective of creating Dataset-JSON Viewer software. This hackathon addresses the significant and broad interest in viewer software for Dataset-JSON, which was a finding from the Dataset-JSON as an Alternative Transport Format for Regulatory Submissions Pilot.

Page

<https://wiki.cdisc.org/display/DSJSONHACK/Hackathon+III%3A+Dataset-JSON+v1.1+Viewer+Projects>

Slides

[Dataset JSON Viewer Hackathon Slides](#)

Dataset-JSON Viewer Hackathon

Dataset-JSON Viewer
A powerful and user-friendly Shiny application for exploring and analyzing JSON datasets with interactive features and comprehensive data visualization capabilities.

Dataset-JSON Visualization
A generic web based Dataset-JSON viewer for visualization of Dataset-JSON v1.1 files in either JSON or NDJSON representations. It works with files compliant with the standard Dataset-JSON v1.1 schema or an extension of it. Implemented in Python.

EDA Dataset-JSON Viewer
Inspired by SAS Universal Viewer. Efficiently fetches requests from our Dataset-JSON API. Try it out: - Back-end <https://api.edacro.com/docs>, - Front-end <https://viewer.edacro.com>

JSON Visualizer

<https://cosa.cdisc.org/hackathons/datasetJsonViewer>

FDA Pilot



- FDA did a **pilot** on the use of Dataset-JSON v1.0
- Results showed **minor issues** related to conversion tools and interoperability testing
- Dataset-JSON is **viable** as the primary transport option"
- FDA's tools **require updates**
- **Dataset-JSON v1.1**, was released in December 2024



FDA Status



- Dataset-JSON - Under FDA Evaluation
 - Federal Register Notice:
published 9 April 2025 (Docket FDA-2025-N-0129)
 - Public Comment Period open through 9 June 2025
 - FDA is "exploring" Dataset-JSON v1.1 as a potential successor to SAS v5 XPT



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Tech & Tooling



- Aligned with define.xml
 - Extra fields like itemGroupOID or itemOID required
 - One file per Data Set
- Three File Types: JSON, NDJSON, DSJC
- Compressed version (DSJC) available
 - Around factor 15 (5GB xpt → 4GB json → 300MB dsjc)
 - No / Less Splitting





- 10 Data Types Supported
 - **String** & **double** –SAS like
integer, *decimal*, float, boolean, *datetime*, *date*, *time*, URI
 - Supports null, but no SAS special missings (._, .A - .Z)
- Special mapping to *targetDataType*
 - Values stored as string and mapped to numerics
 - *decimal* – use dot (.) as decimal separator
comma (,) as thousand separator (optional)
 - *datetime*, *date* and *time* - ISO 8601 strings
 - *DTC → no targetDataType
 - *DTM, *DT, *TM → targetDataType: "integer"



➤ Human Readable?

```
1 {  
2   .... "datasetJSONCreationDateTime": "2024-12-18T15:34:33",  
3   .... "datasetJSONVersion": "1.1.0",  
4   .... "itemGroupOID": "IG.TEST",  
5   .... "records": 4,  
6   .... "name": "TEST",  
7   .... "label": "A test data set in DataSet-JSON-format",  
8   .... "columns": [  
9     .... {"itemOID": "IT.ADTTE.TEXT", "name": "text", "label": "A String", "dataType": "string"},  
10    .... {"itemOID": "IT.ADTTE.NUM", "name": "num", "label": "A number", "dataType": "double"}  
11  ],  
12  .... "rows": [  
13    .... ["This is a text", 17.4],  
14    .... ["This is a second text", 0],  
15    .... ["This is an other text", -45],  
16    .... ["What is this text?", 0.001254],  
17  »  ]  
18 }
```



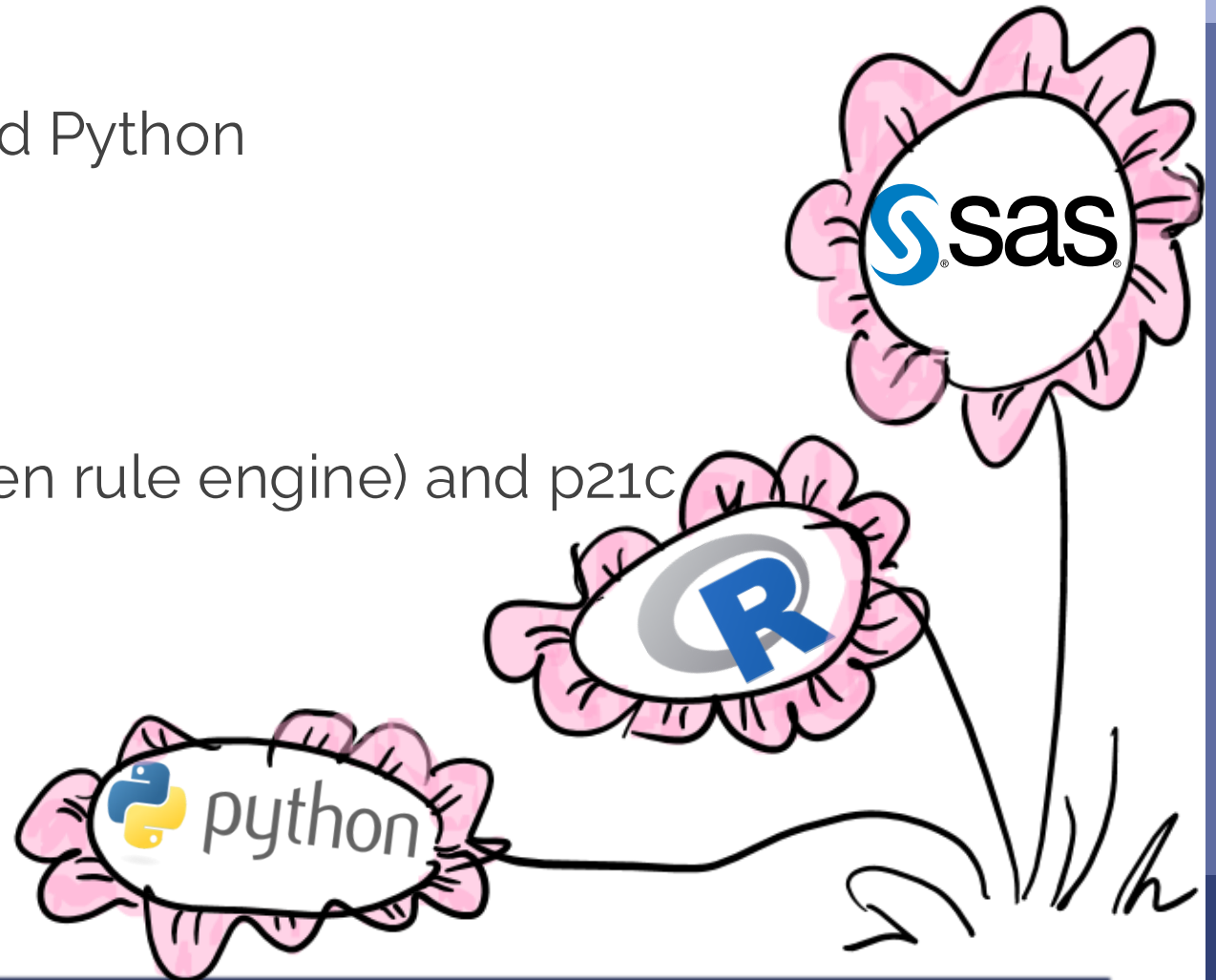

```

datasetJSONCreationDateTime": "2024-11-11T15:09:13", "datasetJSONVersion": "1.1.0", "fileOID": "www.cdisc.org/StudyMSGv1/Define-XML_2.1.0/2024-11-11/adsl", "dbLastModifiedDateTime": "2022-04-16T20:09:03", "originator": "CDISC ADAM MSG Te
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```

Tech & Tooling



- Tools already available for:
 - Reading + Writing in SAS, R and Python
 - Display and Convert
 - Supported by CORE (cdisc open rule engine) and p21c





➤ Reading + Writing in SAS

github.com/lexjansen/dataset-json-sas

```
%write_datasetjson(dataset = adam.adsl,  
                    jsonpath = &outdir./adsl.json,  
                    ...)
```

github.com/Morioka-Yutaka/sas_dataset_json

```
%m_sas_to_json1_1(outpath = &outdir.,  
                  library = adam,  
                  dataset = adsl)
```



➤ Reading + Writing in R

github.com/atorus-research/datasetjson

```
ds_json <- dataset_json(adsl, ...)  
write_dataset_json(ds_json, file = "./adsl.json")  
ds_adsl <- read_dataset_json("./adsl.json")
```

github.com/i-akiya/R4DSJSON

```
f_js <- system.file("tdt", "dm.json", package="R4DSJSON")  
df_dm <- R4DSJSON::read.dataset.json(file = f_js)  
write.dataset.json(file="dm.json", dataframe= df_dm, ...)
```



➤ Reading + Writing in Python

github.com/satish-ghadigaonkar/pydsjson

```
ds = pydsjson.dsjson.ReadDatasetJson(  
    filepath=r".\examples\source\adlbc.json",  
    item_group_prefix="")  
df = ds.to_df(ds_name="ADLBC")
```

Tech & Tooling



➤ Display and Convert

➤ COSA Dataset Viewer Hackathon

➤ cosa.cdisc.org/hackathons/datasetJsonViewer

➤ Mostly web based Apps

➤ github.com/KatjaGlassConsulting/dataset-json-react-demo

➤ github.com/sbarcelo777/Dataset-JSON-hackathon

➤ github.com/explore-eda/dataset-json-viewer

➤ www.dicoregroup.com/demos

➤ Local Apps:

➤ github.com/defineEditor/vde-dataset-viewer

➤ www.xml4pharma.com/Smart_Submission_Dataset_Viewer

➤ NEW Cumba Data Browser



VDE Dataset Viewer

ae [Icons]

	AESOC A	AESOCED A	AESOV A	AESER A	AECAN A	AEREL A	
13			MILD	N	DOSE NOT CHANGED	POSSIBLY RELATED	NOT RE
14			MILD	N	DOSE NOT CHANGED	POSSIBLY RELATED	NOT RE
15			MILD	N	DOSE NOT CHANGED	NOT RELATED	NOT RE
16			MODERATE	N	DOSE NOT CHANGED	UNLIKELY RELATED	NOT RE
17			MILD	N	DOSE NOT CHANGED	POSSIBLY RELATED	NOT RE
18			MILD	N	DOSE NOT CHANGED	NOT RELATED	NOT RE
19			MILD	N	DOSE NOT CHANGED	NOT RELATED	NOT RE
20			MODERATE	N	DOSE NOT CHANGED	UNLIKELY RELATED	RECOV
21			MILD	N	DOSE NOT CHANGED	POSSIBLY RELATED	NOT RE
22			MILD	N	DOSE NOT CHANGED	UNLIKELY RELATED	RECOV
23			MILD	N	DOSE NOT CHANGED	NOT RELATED	NOT RE
24			MILD	Y	DOSE NOT CHANGED	UNLIKELY RELATED	NOT RE
25			MILD	N	DOSE NOT CHANGED	RELATED	NOT RE
26			MILD	N	DOSE NOT CHANGED	NOT RELATED	NOT RE

CORE-000266: If AESER = "N" then none of the seriousness criteria (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD, AESMIE) could be equal to "Y".

SUPPDM X SUPPEC X LB X AE X

Smart Submission Dataset Viewer



Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

File Tools View Search Options

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC			
Rec.#	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTCT	RFENDTCT	RFXSTDTCT	RFXENDTCT	RFICDTCT	RFPENDTCT	DTHDTCT	DTH
1	CDISCPIL...	DM	CDISC001	1115	2012-11-30	2013-01-23	2012-11-30	2013-01-23	2012-11-23	2013-05-20		
2	CDISCPIL...	DM	CDISC002	1211	2012-11-15	2013-01-14	2012-11-15	2013-01-12	2012-10-30	2013-01-14	2013-01-14	Y
3	CDISCPIL...	DM	CDISC003	1302	2013-08-29	2013-11-05	2013-08-29	2013-11-05	2013-08-20	2014-02-13		
4	CDISCPIL...	DM	CDISC004	1345	2013-10-08	2014-03-18	2013-10-08	2014-03-18	2013-10-01	2014-03-18		
5	CDISCPIL...	DM	CDISC005	1383	2013-02-04	2013-08-06	2013-02-04	2013-08-06	2013-01-22	2013-08-06		
6	CDISCPIL...	DM	CDISC006	1429	2013-03-19	2013-04-30	2013-03-19	2013-04-30	2013-02-25	2013-04-30		
7	CDISCPIL...	DM	CDISC007	1444	2013-01-05	2013-02-13	2013-01-05	2013-02-12	2012-12-31	2013-06-20		
8	CDISCPIL...	DM	CDISC008	1445	2014-05-11	2014-11-01	2014-05-11	2014-11-01	2014-05-01	2014-11-01	2014-11-01	Y
9	CDISCPIL...	DM	CDISC009	1087	2012-10-22	2013-04-28	2012-10-22	2013-04-28	2012-10-06	2013-04-28		
10	CDISCPIL...	DM	CDISC010	1236	2013-09-21	2013-09-26	2013-09-21	2013-09-21	2013-09-08	2013-09-26		
11	CDISCPIL...	DM	CDISC011	1336	2012-12-07	2013-06-05	2012-12-07	2013-06-05	2012-11-21	2013-07-05		
12	CDISCPIL...	DM	CDISC012	1378	2013-09-03	2014-01-28	2013-09-03	2014-01-28	2013-08-24	2014-01-28		
13	CDISCPIL...	DM	CDISC013	1083	2013-07-22	2013-08-03	2013-07-22	2013-08-01	2013-07-09	2013-08-03	2013-08-03	Y
14	CDISCPIL...	DM	CDISC014	1012	2013-04-03	2013-05-02	2013-04-03	2013-04-29	2013-03-20	2013-09-18		
15	CDISCPIL...	DM	CDISC015	1022					2014-03-17	2014-03-17		
16	CDISCPIL...	DM	CDISC016	1143	2013-04-03	2013-06-01	2013-04-03	2013-05-30	2013-03-30	2013-09-22		
17	CDISCPIL...	DM	CDISC017	1250	2013-09-21	2014-02-08	2013-09-21	2014-01-31	2013-08-21	2014-03-08		
18	CDISCPIL...	DM	CDISC018	1427	2012-12-17	2013-02-18	2012-12-17	2013-02-11	2012-12-13	2013-06-03		

Cumba Data Browser



- To be released soon
- DataSet-JSON support
- Formats from Define.xml
- Extended Filter + Sorting
- CORE Integration
- SQL Integration
- Statistics
- Charts
- ...



Cumba Clinical Data Browser - 0.5.0.2229-SNAPSHO

File Edit Display Columns Sort Filter Tools Help

library ADLBC

	RTP anned atment	TRTPN Planned Treatment (N)	TRTA Actual Treatment	TRTAN Actual Treatment (N)	TRTSDT Date of First Exposure to Treatment	TRTEDT Date of Last Exposure to Treatment
	(F)	(F)(N)	(F)	(F)(N)	(F)(N)	(F)(N)
52	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014
88	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014
124	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014
160	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014
196	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
232	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
268	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
319	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
376	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
16	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
320	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
41	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
77	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
113	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
149	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
185	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
221	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
257	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
297	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
365	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
5	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
298	ebo	0 - PI			19725 - 02JAN2014	19906 - 02JUL2014
43	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014
79	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014
115	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014
151	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014
187	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014
223	ebo	0 - Placebo	Placebo	0 - Placebo	19725 - 02JAN2014	19906 - 02JUL2014

Library

- sdtm
 - FORMATS
 - AE - Adverse Events
 - CM - Concomitant Medications
 - DM - Demographics
 - DS - Disposition
 - EX - Exposure
 - LB - Laboratory Tests Results
 - MH - Medical History
 - QS - Questionnaires
 - RELREC - Related Records
 - SC - Subject Characteristics
 - SE - Subject Elements
 - SUPPAE - Supplemental Qualifiers for AE
 - SUPPDM - Supplemental Qualifiers for DS
 - SUPPDS - Supplemental Qualifiers for DS
 - SUPPLB - Supplemental Qualifiers for LB
 - SV - Subject Visits
 - TA - Trial Arms
 - TE - Trial Elements
 - TI - Trial Inclusion/ Exclusion Criteria
 - TS - Trial Summary
 - TV - Trial Visits
 - VS - Vital Signs
- adam
 - FORMATS
 - ADAE - Adverse Events Analysis Dataset
 - ADLBC - Analysis Dataset Lab Blood Chem
 - ADLBH - Analysis Dataset Lab Hematolog

Value: 0.0
Formatted: Placebo
Name: TRTPN
Label: Planned Treatment (N)
Type: DOUBLE (double)
Format: ARMN.
Origin: Derived
Comment: ADSL.TRT01PN
OrderNumber: 5
Mandatory: No
dataType: DOUBLE
targetDataType: UNKNOWN
KeySequence: -1
itemOID: TRTPN

Press F2 to focus!

Agenda

- The Standard
 - From Theory to Practice
 - Tech & Tooling
 - Summary
-



Summary



- **Dataset-JSON is a modern, open successor to XPT**
 - Human-readable, extensible, technology-friendly
 - **The FDA pilot confirmed viability**
 - No show-stoppers; data integrity maintained
 - Findings incorporated into v1.1
 - **Community-driven development works**
 - Hackathons ensured tooling existed before finalization
 - Open-source tools available for SAS, R, and Python
 - **Organizations should start preparing now**
 - Evaluate tools, build internal processes, **contribute to community**
 - **The shift from XPT to JSON is closer than we think**
 - There is no reason to wait
-



Questions?



Thank you!
