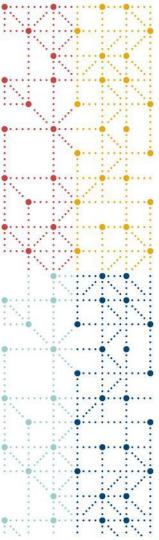


datasetison



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Dmitry Kolosov, Parexel



Agenda

- 1. Dataset-JSON Timeline
- 2. What is Dataset-JSON v1.1?
- 3. Public Review
- 4. COSA Dataset-JSON Viewer Hackathon

Dataset-JSON v1.1 Timeline

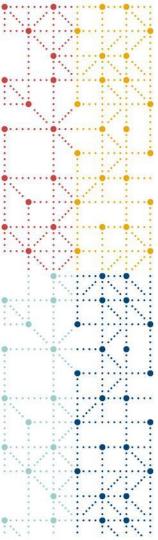




Features to complete

Feature	Due Date
 Review and decide on the solutions to the pilot finding 	✓
Update the standards specification	✓
Author a User's Guide	✓
Update the schema	✓
Update the examples	✓
 Develop an NDJSON version based on the draft 	✓
Update NDJSON examples	✓
Internal Review	✓
Public Review	10 September 2024
 JSONX development - compressed archive of datasets 	TBD
 Review draft API specification 	TBD
 Work with conversion software developers to update tools 	TBD
 Work with viewer software developers to develop/update tools 	TBD





What is Dataset-JSON v1.1

A high-level overview of Dataset-JSON

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 eliminate the limitations of legacy formats

Dataset-JSON is...

- Designed to support a broad range of data exchange scenarios
- Supports API and file-based data exchange
- JSON is simple to implement, very stable, and widely supported
- Open-source schema supports any tabular format
- Extensible to support new metadata and new use cases
- Linked to Define-XML for complete metadata



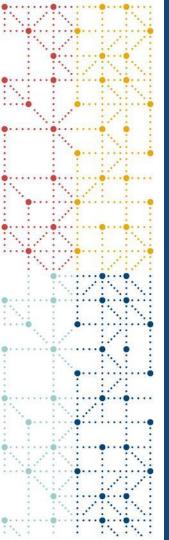
Changes in Dataset-JSON 1.1

Among other changes version 1.1 the main changes are:

- Flattening the overall structure
- Additional datatypes and metadata
- Support for NDJSON
- Converting integer dates to ISO 8601

```
"datasetJSONCreationDateTime": "2023-03-22T11:53:27",
"datasetJSONVersion": "1.1.0",
"fileOID": "www.sponsor.xyz.org.project123.final",
"dbLastModifiedDateTime": "2023-02-15T10:23:15",
"originator": "Sponsor XYZ",
"sourceSystem": {
    "name": "Software ABC",
    "version": "1.0.0"
"studyOID": "xxx",
"metaDataVersionOID": "xxx",
"metaDataRef": "https://metadata.location.org/api.link",
"itemGroupOID": "IG.DM",
"isReferenceData": false,
"records": 100.
"name": "DM",
"label": "Demographics",
"columns": [ ...],
"rows": [ ····
```





Public Review

Public Review

- Public Review started on September 10, 2024
- Public Review lasts 30 days and closes on October 10, 2024
- Reviewers are requested to provide comments via JIRA
- The JIRA project is Dataset-JSON review comments (DSJSONCT) located at:
 - https://jira.cdisc.org/projects/DSJSONCT
- Instructions for Reviewers:
 - https://wiki.cdisc.org/display/DSJSON1DOT1/Instructions+for+Reviewers
- Public Review Webinar recording and slides:
 - https://www.cdisc.org/events/webinar/dataset-json-v1-1-public-review-webinar



Dataset-JSON v1.1 Content to Review

- 1. Dataset-JSON v1.1 Specification
 - https://wiki.cdisc.org/display/DSJSON1DOT1/Dataset-JSON+1.1
- 2. User Guide
 - https://wiki.cdisc.org/display/DSJSON1DOT1/User%27s+Guide
- 3. Schemas and Example Datasets
 - https://github.com/cdisc-org/DataExchange-DatasetJson



CDISC Wiki

Contains the Dataset-JSON v1.1 Specification and a User's Guide with articles



- Pages
- 99 Blog
- Calendars
- Λν Analytics

SPACE SHORTCUTS

Here you can add shortcut links to the most important content for your team or project. Configure sidebar.

PAGE TREE

- · Instructions for Reviewers
- Specification
- Dataset-JSON 1.1
- ▼ User's Guide
 - · Alignment of Dataset-JSON with
 - . Character Encoding and Escaping
 - · Dataset-JSON Extensions
 - · Precision and Rounding
- · Representing Dataset-JSON as N
- · Representing Numeric Dates
- Use of sourceSystem

Pages / Dataset-JSON v1.1 / Specification 🚡 🖉









Dataset-JSON 1.1

Created by Omar Garcia Calderon, last modified by Lex Jansen on Aug 28, 2024

DRAFT

Title	CDISC Dataset-JSON Specification			
Version	1.1			
Prepared by	CDISC Data Exchange Standards Team			
Notes to Readers	This is the specification for Version 1.1 of CDISC Dataset-JSON.			
Revision History	Date	Version	Summary of Changes	
	2024-09-06	1.1	Draft	
	2023-08-23	1.0	Final	

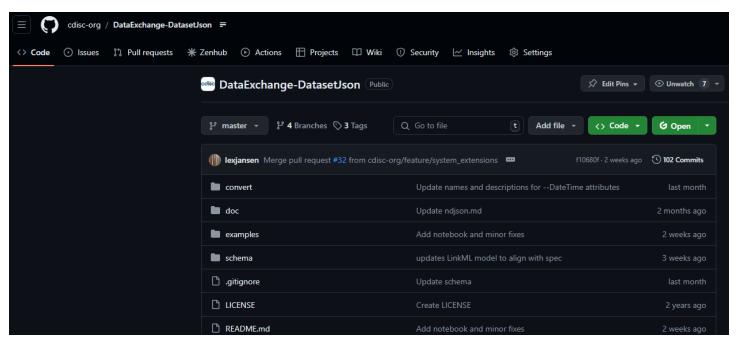
- Introduction
- · Top-level Metadata Attributes
- Column Metadata
 - Supported Column Data Type Combinations
 - Date/Time Variables
 - Decimal Variables
- Row Data
- · A Full Example of a Dataset-JSON File
- NDJSON Representation of Dataset-JSON
- A Full Example of an NDJSON Dataset-JSON File



GitHub: JSON Schema and Examples

 The JSON schema, both for JSON and NDJSON representations, and examples can be found at the GitHub repository for the Dataset-JSON Version 1.1 standard:

https://github.com/cdisc-org/DataExchange-DatasetJson







COSA Dataset-JSON Viewer Hackathon

CDISC Open-Source Alliance (COSA)

COSA Mission: The CDISC Open-Source Alliance (COSA) supports, promotes, and sometimes sponsors open-source and free software development projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community.



- Dataset-JSON Hackathon solutions may apply to be included in the COSA Repository Directory
 - Projects from the first Dataset-JSON Hackathon: https://cosa.cdisc.org/hackathons/datasetJson
- Requires an open-source license
- · Requires a public repository
- There will be opportunities to demonstrate your viewer software
 - COSA Webinar to demo solutions



Previous Dataset-JSON Hackathons



- COSA has hosted several hackathons
 - Dataset-JSON Hackathon I (July October 2022)
 Goal: Develop open-source software tools for working with Dataset-JSON
 - Result: 21 solutions for Dataset-JSON 1.0 available in COSA directory
 - Dataset-JSON Hackathon II (September October 2023)

Goal: Develop API specification for Dataset-JSON **Result**: GitHub repository with the API specification

Language	Solutions
R	5
SAS	4
Python	5
JavaScript	4
Java	1
Swift	1
XSLT	1



COSA Dataset-JSON Viewer Hackathon



- Primary objective: Create Dataset-JSON Viewer software
 - Projects can be new or extensions to existing software
- Significant and broad interest in viewer software for Dataset-JSON
 - A finding from the Dataset-JSON as an Alternative Transport Format for Regulatory Submissions Pilot
- Virtual hackathon
 - Individuals or teams will work virtually
 - Periodic meetings will be scheduled to discuss progress and answer questions
 - · Project demonstrations will be scheduled for a COSA Spotlight Webinar
- Dates: Oct. 8th Jan. 6th
 - More details will be made available before the start of the hackathon
 - Let us know if you may be interested in participating



Thank You!

Questions?

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