

COSA Dataset-JSON Hackathon II Results

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Agenda

- 1. Hackathon objectives and background
- 2. API specification development
- 3. Next steps

Hackathon Objectives and Background



Problem Statement



- <u>Primary objective</u>: Create a draft REST API specification for Dataset-JSON
- <u>Secondary objective</u>: Proof-of-concept implementations to demonstrate and test the API specification
- Virtual hackathon
 - The team worked collaboratively to develop and test the draft specification
 - Approximately 100 people registered to participate
 - Results communicated at the 2023 US Interchange
- Dates: Sept. 1 October 13, 2023



What do we plan to do with the draft API specification?

The draft API specification is available for review and comments

The API draft specification will be delivered to the Dataset-JSON Team for eventual review, refinement, and publication

API Spec will be communicated to the Dataset-JSON Pilot teams

Implement prototypes to demonstrate and test the API specification



What are the goals of the pilot?

Milestone 1: Short Term

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- Pilot 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

PHUSE/CDISC/FDA Dataset-JSON as an alternative transport format for regulatory submissions pilot



Collaborative Work



- GitHub repository created to develop the API spec collaboratively
 - <u>https://github.com/cdisc-org/DataExchange-DatasetJson-API</u>
 - OpenAPI 3.1 is used as the standard for the machine-readable spec
 - Project communication took place in Slack and GitHub discussions
- An OpenAPI Specification schema is available to aid in development
 - <u>https://github.com/OAI/OpenAPI-Specification</u>
- Numerous tools, including many free ones, work with OpenAPI
 - <u>https://openapi.tools/</u>
 - Code generators, editors, data validators, and many other tools
- Demonstration API implementations will be available

API Specification Development

Dataset-JSON API draft specification development during the hackathon



API Scope & Assumptions

Focused on data exchange

Support the basics with the intention that this becomes a standard

Based on the same version of Dataset-JSON used in the pilot

May use compression and/or pagination to support larger datasets

Supports a broad range of data exchange scenarios beyond submissions



API draft documentation generated from specification

GET /about Get About the API
GET /studies Get the list of studies
POST /studies Create a new study
GET /studies/{studyOID} Get a study
PUT /studies/{studyOID} Update a study
DELETE /studies/{studyOID} Delete a study
GET /studies/{studyOID}/datasets Get the list of datasets for a study
POST /studies/{studyOID}/datasets Create a new dataset
GET /studies/{studyOID}/datasets/{datasetOID} Get a dataset
PUT /studies/{studyOID}/datasets/{datasetOID} Update a dataset
<pre>PATCH /studies/{studyOID}/datasets/{datasetOID} Append records to a dataset</pre>
DELETE /studies/{studyOID}/datasets/{datasetOID} Delete a dataset

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API draft documentation details

Request

GET	/studies/{studyOID}/datasets Get the list of datasets for a study	
Parameter	s	
Name	Description	
<pre>studyOID * required string (path)</pre>	studyOID	
standard (query)	standard	
if-modified since (header)	Default value :	
(neuver)	if-modified-since	

Response

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de	Description
)	List of datasets for a study
	Media type application/json Controls Accept header. Example Value Schema
	<pre>[{ "oid": "string", "name": "string", "label": "string", "type": "string", "records": 0, "href": "string", "filename": "string" }]</pre>

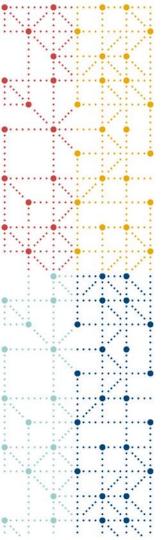


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Dataset Compression and Pagination

GET /st	<pre>udies/{studyOID}/datasets/{datasetOID} Get a dataset</pre>
Parameters	
Name	Description
<pre>studyOID * required string (path)</pre>	studyOID
<pre>datasetOID * required string (path)</pre>	datasetOID
metadataonly (query)	Default value : false
	metadataonly

offset 'query)	Default value : 0	
	offset	
imit 'query)	Default value : 0	
	limit	
accept- encoding 'header)	Default value :	
includer y	accept-encoding	
f-modified- since 'header)	Default value :	
	if-modified-since	



Next Steps



Next Steps

- Complete the PHUSE/CDISC/FDA Dataset-JSON as an alternative transport format for regulatory submissions pilot
 - Read out of the final report scheduled for the PHUSE CSS conference June 3-5
- Make Dataset-JSON API prototype available to try
 - Planned for Q2 2024
- Develop Dataset-JSON v1.1 as a standalone standard
 - · Updates include the findings based on the pilot
 - Plan to schedule a public review of Dataset-JSON v1.1 for Q4 2024
 - Call for volunteers was distributed last week
- Plan to publish the Dataset-JSON API shortly after publishing Dataset-JSON v1.1
 - The API is essential to data exchange using Dataset-JSON
 - Comments on the draft API specification welcome



Additional Resources

Resources

- Dataset-JSON API draft specification
 - <u>https://github.com/cdisc-org/DataExchange-DatasetJson-API</u>
- Dataset-JSON specification
 - https://www.cdisc.org/dataset-json
 - <u>https://wiki.cdisc.org/display/PUB/Dataset-JSON</u>
- Dataset-JSON GitHub repository
 - <u>https://github.com/cdisc-org/DataExchange-DatasetJson</u>
- Dataset-JSON v1.1 wiki
 - https://wiki.cdisc.org/display/DSJSON1DOT1/Dataset-JSON+v1.1
- COSA Directory Dataset-JSON Hackathon I projects
 - <u>https://cosa.cdisc.org/hackathons/datasetJson</u>



Thank You!

Questions?

Interested in volunteering for Dataset-JSON v1.1?

https://www.cdisc.org/volunteer/form

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https://www.linkedin.com/in/sam-hume-dsc

