Dataset-JSON: SAS[©] implementation

Lex Jansen

Senior Director, Data Science Development, CDISC (contractor)





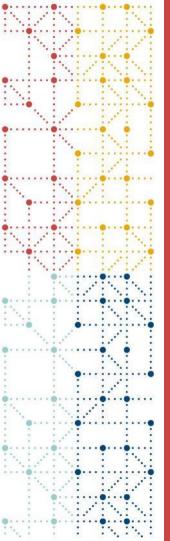


CDISC Q3 COSA Quarterly Spotlight Webinar - 2023-10-05

About your presenter

- 16 years in an IT/Standards role in Biostatistics at Organon
- 4 years as a consultant to help companies implement CDISC
- 11 years at SAS.
 - 8 years as a Principal Software Developer working on SAS Clinical Standards Toolkit (implementing mostly XML based standards (Define-XML, ODM, Dataset-XML)) and SAS Life Science Analytics Framework (Java)
 - 3 years as Principal Solution Consultant at SAS implementing Life Science Analytics Framework
- Since Nov 2021 Senior Director, Data Science Development at CDISC (contractor)
- Core member of the CDISC Data Exchange Standards team since 2008. (co-lead since Nov 2021)
- Core member of the CDISC Define-XML development team.
 - One of the main Define-XML v2 developers.
 - Developer of CDISC/PhUSE Define-XML v2 stylesheet.
 - One of the main developers of the Analysis Results Metadata v1.0 for Define-XML v2.0 extension





Agenda

- 1. Dataset-JSON Document Structure
- 2. SAS and JSON
- 3. Writing Dataset-JSON with SAS
- 4. Reading Dataset-JSON with SAS
- 5. Comparing SAS datasets / Dataset-JSON files
- 6. Validating Dataset-JSON files
- 7. Demo



- Dataset-JSON was adapted from the Dataset-XML specification, but uses JSON format instead of XML
- Each Dataset-JSON file is connected with a Define-XML file, containing detailed metadata
- Each Dataset-JSON files contains basic information about dataset variables, so that it is possible to have a simple view of the contents of a dataset without the need of a Define-XML document
- Dataset-JSON Specification:
 - https://www.cdisc.org/dataset-json
 - https://wiki.cdisc.org/display/PUB/Dataset-JSON
- GitHub repository with JSON Schema and examples: https://github.com/cdisc-org/DataExchange-DatasetJson



- At the top level of the Dataset-JSON object, there are some required attributes (creationDateTime and datasetJSONVersion)*, and one of two optional attributes: clinicalData or referenceData.
- Subject data is stored in clinicalData and non-subject data is stored in referenceData.

```
{
    "creationDateTime": "2023-06-28T15:38:43",
    "datasetJSONVersion": "1.0.0",
    "clinicalData": {
        "studyOID": "cdisc.com/CDISCPILOT01",
        "metaDataVersionOID": "MDV.MSGv2.0.SDTMIG.3.3.SDTM.1.7",
        "itemGroupData": {
        "IG.DM": {
        "IG.DM": {
        "IG.TS": {
        "IG.TS":
```

 studyOID and metaDataVersionOID must match corresponding values in Define-XML



Dataset-JSON Document Structure - top level attributes

Attribute	Usage	Description			
creationDateTime	Required	Time of creation of the file containing the document.			
datasetJSONVersion	Required	Version of Dataset-JSON standard			
fileOID	Optional	A unique identifier for this file.			
asOfDateTime	Optional	The date/time at which the source database was queried in order to create this document.			
originator	Optional	The organization that generated the Dataset-JSON file.			
sourceSystem	Optional	The computer system or database management system that is the source of the information in this file.			
sourceSystemVersion	Optional	The version of the "SourceSystem" above.			
clinicalData	Optional	Contains datasets for clinical data across multiple subjects.			
referenceData	Optional	Contains datasets for non-subject data domains.			



```
"itemGroupData": {
   "IG.DM": {
      "records": 18,
"name": "DM",
      "label": "Demographics",
      ·"items": [ ···
       "itemData": [ ···
```

- itemGroupData is an object with attributes corresponding to individual datasets.
- The attribute name (IG.DM) is the OID of a described dataset, which must be the same as the OID of the corresponding itemGroup in the Define-XML file
- records, name, label: basic dataset information (all required)
- items basic information about variables
- itemData dataset data



```
"items": [
       "OID": "ITEMGROUPDATASEQ",
       "name": "ITEMGROUPDATASEQ",
       "label": "Record Identifier",
       "type": "integer",
       "length": 8
       "OID": "IT.DM.STUDYID",
       "name": "STUDYID",
       "label": "Study Identifier",
       "type": "string",
       "length": 12
       "OID": "IT.DM.DOMAIN",
       "name": "DOMAIN",
       "label": "Domain Abbreviation",
       "type": "string",
       "length": 2
```

- items array of basic information about dataset variables.
- The order of elements in the array must be the same as the order of variables in the described dataset.
- The first element always describes the Record Identifier (ITEMGROUPDATASEQ)

```
"items": [
      "OID": "ITEMGROUPDATASEQ",
       "name": "ITEMGROUPDATASEQ",
       "label": "Record Identifier",
       "type": "integer",
       "length": 8
    --- "OID": "IT.DM.STUDYID",
      "name": "STUDYID",
       "label": "Study Identifier",
       "type": "string",
       "length": 12
     "OID": "IT.DM.DOMAIN",
       "name": "DOMAIN",
       "label": "Domain Abbreviation",
       "type": "string",
       "length": 2
```

- OID OID of a variable (must correspond to the variable OID in the Define-XML file)
- name variable name
- label variable description
- type type of the variable.
 'string', 'integer', 'decimal', 'float', 'double', 'boolean'
- length variable length most useful for the string type
- displayFormat supports data visualization of numeric float and date values
- keySequence indicates that this item is a key variable in the dataset structure

The last 3 attributes are optional

- itemData is an array of records with variables values
- Each record itself is represented as an array of variables values
- The first value is a unique sequence number for each record in the dataset
- Missing values are represented by null in the case of numeric variables, and an empty string in case of character variables:

```
[1, "MyStudy", "", "DM", null]
```





SAS and JSON

SAS and JSON

- Starting in SAS[©] 9.4, you can use PROC JSON to write SAS data sets to JSON files
- Starting in SAS[©] 9.4TS1M4, you can use the **JSON engine** to read JSON files into SAS data sets





- PROC JSON in SAS[©] gives the user control over the JSON output:
 - through the utilization of options
 - through the ability to control containers (objects or arrays)
 - by writing directly to the output file
 - by choosing exactly what to include or not include in the resulting JSON file

```
PROC JSON OUT=fileref | "external-file" <options>;
    EXPORT <libref.>SAS-data-set <(data-set-options)> </options>;
    WRITE VALUES value(s) </options>;
    WRITE OPEN type;
    WRITE CLOSE;
RUN;
```



```
PROC JSON OUT=jsonfout PRETTY;
                                                        "creationDateTime": "2023-06-28T15:38:43",
 WRITE OPEN OBJECT;
                                                        "datasetJSONVersion": "1.0.0",
 WRITE VALUES "creationDateTime" "&CurrentDateTime";
 WRITE VALUES "datasetJSONVersion" "1.0.0";
                                                        "clinicalData": {
 WRITE VALUES "clinicalData";
                                                          "studyOID": "<study OID>",
 WRITE OPEN OBJECT:
                                                          "metaDataVersionOID": "<MDV OID>",
 WRITE VALUES "studyOID" "<study OID>";
                                                          "itemGroupData": {
 WRITE VALUES "metaDataVersionOID" "<MDV OID>";
                                                             "IG.DM": {
 WRITE VALUES "itemGroupData";
 WRITE OPEN OBJECT;
                                                               "records": 18,
 WRITE VALUES "IG.DM";
                                                               "name": "DM",
 WRITE OPEN OBJECT;
                                                               "label": "Demographics",
 WRITE VALUES "records" 18:
                                                               "items": [
 WRITE VALUES "name" "DM";
 WRITE VALUES "label" "Demographics";
                                                                     column metadata
 WRITE VALUES "items";
 WRITE OPEN ARRAY;
   EXPORT work.column metadata / KEYS;
                                                               "itemData": [
 WRITE CLOSE;
 WRITE VALUES "itemData":
                                                                       Column data
 WRITE OPEN ARRAY;
   EXPORT work.column data / NOKEYS;
 WRITE CLOSE;
 WRITE CLOSE;
 WRITE CLOSE:
 WRITE CLOSE;
 WRITE CLOSE:
```



RUN;

```
PROC JSON OUT=jsonfout PRETTY;
                                                        "creationDateTime": "2023-06-28T15:38:43",
 WRITE OPEN OBJECT;
                                                        "datasetJSONVersion": "1.0.0",
 WRITE VALUES "creationDateTime" "&CurrentDateTime";
 WRITE VALUES "datasetJSONVersion" "1.0.0";
                                                        "clinicalData": {
 WRITE VALUES "clinicalData";
                                                          "studyOID": "<study OID>",
 WRITE OPEN OBJECT:
                                                          "metaDataVersionOID": "<MDV OID>",
 WRITE VALUES "studyOID" "<study OID>";
                                                          "itemGroupData": {
 WRITE VALUES "metaDataVersionOID" "<MDV OID>";
                                                             "IG.DM": {
 WRITE VALUES "itemGroupData";
 WRITE OPEN OBJECT;
                                                               "records": 18,
 WRITE VALUES "IG.DM":
                                                               "name": "DM",
 WRITE OPEN OBJECT;
                                                               "label": "Demographics",
 WRITE VALUES "records" 18:
                                                               "items": [
 WRITE VALUES "name" "DM";
 WRITE VALUES "label" "Demographics";
                                                                     column metadata
 WRITE VALUES "items";
 WRITE OPEN ARRAY;
   %write json metadata array(work.column metadata);
                                                               "itemData": [
 WRITE CLOSE;
 WRITE VALUES "itemData":
                                                                       Column data
 WRITE OPEN ARRAY;
   EXPORT work.column data / NOKEYS;
 WRITE CLOSE:
 WRITE CLOSE;
 WRITE CLOSE:
 WRITE CLOSE;
 WRITE CLOSE:
RUN;
```



Using Define-XML metadata when creating Dataset-JSON

- Get OIDs from Define-XML when creating Dataset-JSON
- Use pre-specified metadata from Define-XML (label, datatype, length, and KeySequence) for creating Dataset-JSON
- Get variable display formats from Define-XML when creating SAS datasets from Dataset-JSON (especially for numeric date/time variables)
- Important to check that Define-XML is consistent with the data!



```
/* Create metadata from Define-XML for ADaM */
%CreateMetadataFromDefineXML(
   definexml=&root/json/adam/define.xml,
  metadatalib=metaadam
/* Some manual data type updates */
data metaadam.metadata columns;
  set metaadam.metadata columns;
  if xml_datatype='float' and index(name, 'VISIT')
    then json datatype='decimal';
run;
/* Create metadata from Define-XML for SDTM */
%CreateMetadataFromDefineXML(
  definexml=&root/json/sdtm/define.xml,
  metadatalib=metasdtm
/* Some manual data type updates */
data metasdtm.metadata columns;
  set metasdtm.metadata_columns;
  if xml_datatype='float' and name ne 'LBSTRESN'
   then ison datatype='decimal';
run;
```

Writing Dataset-JSON - %write_datasetjson()

```
%write_datasetjson(
```

```
dataset=
                             /* (libname.)memname of the data set
                             /* Path to XPT file
xptpath=,
jsonpath=,
                             /* Path to Dataset-JSON file
usemetadata=N,
                             /* Use Define-XML metadata? (Y/N
metadatalib=,
                             /* Define-XML metadata library
datasetJSONVersion=1.0.0,
fileOID=,
asOfDateTime=,
originator=,
sourceSystem=,
sourceSystemVersion=,
studyOID=,
metaDataVersionOID=,
metaDataRef=,
pretty=NOPRETTY);
```



*/

*/

Writing Dataset-JSON - %write_datasetjson() - loop

```
data null;
  length datasetname $64 isonpath $512 fileoid $128 code $2048;
  set work.dirtree adam;
   datasetname=scan(filename, 1, ".");
   jsonpath=cats("&project folder/json out/adam/", datasetname, ".json");
   fileoid=cats("& fileOID", "/", "%sysfunc(date(), is8601da.)", "/", datasetname);
    code=cats('%nrstr(%write datasetjson('
      , 'dataset=dataadam.', datasetname, ','
      /* , 'xptpath=', fullpath,',' */
      , 'jsonpath=', jsonpath, ','
      , 'usemetadata=N,'
      . 'metadatalib=metaadam.'
      , "fileOID=", fileoid, ","
      , "asOfDateTime=2023-05-31T00:00:00, "
      , "originator=CDISC ADaM MSG Team", ","
      , "sourceSystem=Sponsor System,"
      , "sourceSystemVersion=1.0,"
      , "studyOID=& studyOID,"
        "metaDataVersionOID=& metaDataVersionOID,"
      , "metaDataRef=define.xml"
    ,');)');
   call execute(code);
```



run:

Writing Dataset-JSON - %write_datasetjson() - loop

```
data null;
 length datasetname $64 isonpath $512 fileoid $128 code $2048;
  set dirtree sdtm:
    datasetname=scan(filename, 1, ".");
    jsonpath=cats("&project folder/json out/sdtm/", datasetname, ".json");
    fileoid=cats("& fileOID", "/", "%sysfunc(date(), is8601da.)", "/", datasetname);
    code=cats('%nrstr(%write datasetjson('
     /* , 'dataset=datasdtm.', name, ',' */
      , 'xptpath=', fullpath,','
      , 'jsonpath=', jsonpath, ','
        'usemetadata=Y,'
       'metadatalib=metasdtm.'
      . "fileOID=", fileoid, ","
       "asOfDateTime=2023-05-31T00:00:00, "
        "originator=CDISC SDTM MSG Team,"
       "sourceSystem=Sponsor System,"
       "sourceSvstemVersion=1.0."
        "studyOID=& studyOID,"
        "metaDataVersionOID=& metaDataVersionOID,"
      . "metaDataRef=define.xml"
    ,');)');
    call execute(code);
```



run:



- Starting in SAS[©] 9.4TS1M4, you can use the **JSON engine** to read JSON files into SAS data sets
- A JSON map is a file that the JSON engine uses to define the data set structures that are created when reading JSON





```
"creationDateTime": "<yyyy-mm-ddThh:mm:ss>",
"datasetJSONVersion": "1.0.0",
"clinicalData": {
 "studyOID": "<study OID>",
 "metaDataVersionOID": "<MDV OID>",
 "itemGroupData": {
   "IG.DM": {
      "records": 18,
     "name": "DM",
      "label": "Demographics",
      "items": [
             column metadata
      "itemData": [
                column data
```

Creates 6 data sets:

- ALLDATA
- CLINICALDATA
 - studyOID, metaDataVersionOID
- ITEMGROUPDATA IG DM
 - records, name, label
- IG_DM_ITEMS
 - contains column metadata (OID, name, label, type, length, displayFormat, keySequence)
- IG DM ITEMDATA
 - contains column data (element1, element2, element3, ...)
- ROOT
 - contains creationDateTime, datasetJSONVersion

ITEMGROUPDATA_IG_DM

	records	name	label
1	18	DM	Demographics

IG_DM_ITEMS

	OID	name	label	type	length	keySequence
1	ITEMGROUPDATASEQ	ITEMGROUPDATASEQ	Record Identifier	integer		
2	IT.DM.STUDYID	STUDYID	Study Identifier	string	12	1
3	IT.DM.DOMAIN	DOMAIN	Domain Abbreviation	string	2	
4	IT.DM.USUBJID	USUBJID	Unique Subject Identifier	string	8	2
5	IT.DM.SUBJID	SUBJID	Subject Identifier for the Study	string	4	
6	IT.DM.RFSTDTC	RFSTDTC	Subject Reference Start Date/Time	string		
7	IT.DM.RFENDTC	RFENDTC	Subject Reference End Date/Time	string		
8	IT.DM.RFXSTDTC	RFXSTDTC	Date/Time of First Study Treatment	string		
9	IT.DM.RFXENDTC	RFXENDTC	Date/Time of Last Study Treatment	string		
10	IT DM DEICDTC	DEICDTC	Date /Time of Informed Comment	-1-1		

IG_DM_ITEMDATA

		element1	element2	element3	element4	element5	element6	element7	element8
	1	1	CDISCPILOT01	DM	CDISC001	1115	2012-11-30	2013-01-23	2012-11-30
١	2	2	CDISCPILOT01	DM	CDISC002	1211	2012-11-15	2013-01-14	2012-11-15
	3	3	CDISCPILOT01	DM	CDISC003	1302	2013-08-29	2013-11-05	2013-08-29
	4	4	CDISCPILOT01	DM	CDISC004	1345	2013-10-08	2014-03-18	2013-10-08
	5	5	CDISCPILOT01	DM	CDISC005	1383	2013-02-04	2013-08-06	2013-02-04
	6	6	CDISCPILOT01	DM	CDISC006	1429	2013-03-19	2013-04-30	2013-03-19
	7	7	CDISCPILOT01	DM	CDISC007	1444	2013-01-05	2013-02-13	2013-01-05
	8	8	CDISCPILOT01	DM	CDISC008	1445	2014-05-11	2014-11-01	2014-05-11

2012-10-22



Reading Dataset-JSON - %read_datasetjson()



Reading Dataset-JSON - %read_datasetjson() - loop

```
%util gettree(
  dir=&project folder/json out/adam,
  outds=work.dirtree adam,
 where=%str(ext="json" and dir=0)
);
data null;
  length code $2048;
  set work.dirtree adam;
    code=cats('%nrstr(%read datasetjson(',
                'jsonpath=', fullpath, ', ',
                'datalib=outadam, ',
                'dropseqvar=Y, ',
                'savemetadata=Y, ',
                'metadatalib=metainad',
              ');)');
    call execute(code);
run;
```





Comparing SAS datasets / Dataset-JSON files

Comparing SAS datasets

- Compare results in a summary
- Details for datasets that had differences

```
%macro util_comparedata(
  baselib=,
  complib=,
  dsname=,
  compareoptions=%str(listall criterion=0.00000001 method=absolute),
  resultds=,
  detailall=N
  );
```



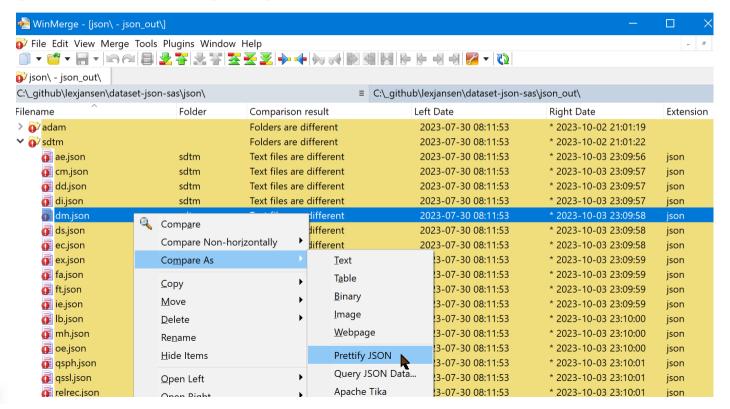
Compare results for dataset ADADAS The COMPARE Procedure Comparison of DATAADAM.ADADAS with OUTADAM.ADADAS (Method=ABSOLUTE, Criterion=1.0E-08) resultc DSLABEL/LENGTH/LABEL Data Set Summary Dataset Created Modified NVar NObs Label DSI ABEL/LABEL DATAADAM.ADADAS 020CT23:22:29:17 020CT23:22:29:17 40 12463 ADAS-COG Analysis Dataset OUTADAM.ADADAS 030CT23:23:04:27 030CT23:23:04:27 40 12463 ADAS-Cog Analysis DSI ABEL/FORMAT/LABEL DSI ABEL/LENGTH Variables Summary Number of Variables in Common: 40. DSI ABEL/LENGTH Number of Variables with Differing Attributes: 8. DSLABEL/LENGTH DSI ABEL/LENGTH Listing of Common Variables with Differing Attributes DSI ABEL/LENGTH Variable Dataset Type Length Label ITTFL DATAADAM.ADADAS Char 1 Intent-To-Treat Population Flag DSLABEL/LENGTH/LABEL 1 Intent-to-Treat Population Flag OUTADAM.ADADAS Char AVISIT DATAADAM.ADADAS Char 8 Analysis Visit OUTADAM.ADADAS Char 16 Analysis Visit VISIT DATAADAM.ADADAS Char 17 Visit Name 31

10 Vicit Namo

OUTADAM ADADAC Chan

Comparing JSON files

WinMerge (https://winmerge.org) can compare JSON files in 'pretty' mode







Validating Dataset-JSON files

Validating Dataset-JSON files

```
ison_validate.py X
 scripts > 🏓 json_validate.py > 🗘 validate_json
        import argparse
        from os import listdir, getenv
        from os.path import isfile, join
        import ison
        import jsonschema as JSD
        def validate json(json data, schema file):
            Validates a Dataset-JSON file against a defined ison schema, given a schema file
            Arguments:
                ison data: The resulting Dataset-JSON file to validate
                schema_file: Path to a schema file defining dataset-JSON schema
                with open(schema file) as f:
                    schema = json.load(f)
                JSD.validate(json_data, schema=schema)
                print(" Ok!")
                return True
            except Exception as e:

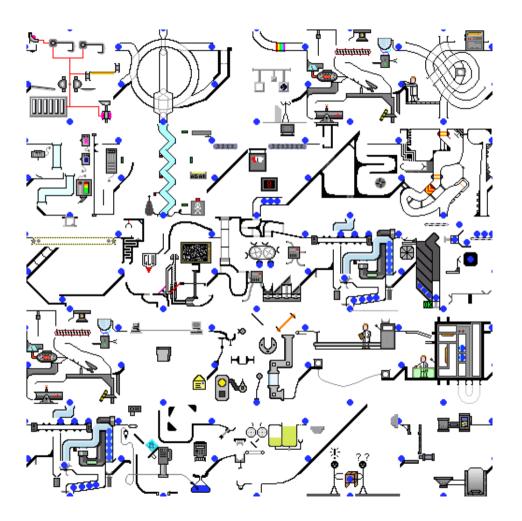
    □ pwsh - scripts + ∨ □ 
    □ ··· ^ ×

(venv) PS C:\_github\lexjansen\dataset-json-sas\scripts> python .\json_validate.py -d ..\json_out\sdtm -s ..\schema\dataset.schema.json
 Validating against schemafile ..\schema\dataset.schema.json
 Validating ..\json out\sdtm\ae.json
 Validating ..\json out\sdtm\cm.json
 Validating ..\json_out\sdtm\dd.json
```



python .\json_validate.py -d <folder> -s ..\schema\dataset.schema.json

Demo





GitHub: https://github.com/lexjansen/dataset-json-sas

open issues at: https://github.com/lexjansen/dataset-json-sas/issues

Email: <u>ljansen@cdisc.org</u>

lexjansen@gmail.com

Web: https://www.lexjansen.com

LinkedIn: https://www.linkedin.com/in/lexjansen/



