

Analysis Results Standard (ARS) – Basic Front End



Driven from ADaM data set JSON files

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Paul Thomas, ASUP Ltd.





Hackathon Target

- Create a basic drag and drop front end that can specify an ARS for a simple table based on an ADaM Dataset-JSON file input
 - ADaM data sets available from Dataset-JSON hackathon
- Understand how to put together a version 1 ARS file
 - What information is required, and how is it stored
 - What information is unlikely to be populated
- Work through the where group structures and their consequences
 - Why are there different type of groups, i.e., Analysis and Data groups
 - What are best ways to use these in a display

Starting point

- Previously developed viewer for Dataset-JSON files
- Written in REACT + TypeScript
- TypeScript interface for cdisc dataset-json
- TypeScript Classes and/or interfaces for implementations of the overall data object, and items

http://localhost:3001/

Data url	https://raw.githubusercontent.com/cdisc-org/DataExchange-DatasetJson/master/examples/adam/adae.json
studyOID	TDF_ADaM.ADaMIG.1.1
metaDataVersionOID	MDV.TDF_ADaM.ADaMIG.1.1
name	ADAE
label	Adverse Events Analysis Dataset <input type="checkbox"/> Show items

Data Search

Record Ide...	Study Iden...	Study Site I...	Unique ...	Actual Trea...	Actual Trea...	Age	Pooled Ag...	Pooled Ag...	Race	Race (N)	Sex	Safety Pop...	Date of
1	CDISCPLOT...	701	01-701-1...	Placebo	0	63	<65	1	WHITE	1	F	Y	19725
2	CDISCPLOT...	701	01-701-1...	Placebo	0	63	<65	1	WHITE	1	F	Y	19725
3	CDISCPLOT...	701	01-701-1...	Placebo	0	63	<65	1	WHITE	1	F	Y	19725
4	CDISCPLOT...	701	01-701-1...	Placebo	0	64	<65	1	WHITE	1	M	Y	19210
5	CDISCPLOT...	701	01-701-1...	Placebo	0	64	<65	1	WHITE	1	M	Y	19210
6	CDISCPLOT...	701	01-701-1...	Placebo	0	64	<65	1	WHITE	1	M	Y	19210
7	CDISCPLOT...	701	01-701-1...	Placebo	0	64	<65	1	WHITE	1	M	Y	19210
8	CDISCPLOT...	701	01-701-1...	Xanomeline ...	81	71	65-80	2	WHITE	1	M	Y	19558
9	CDISCPLOT...	701	01-701-1...	Xanomeline ...	81	71	65-80	2	WHITE	1	M	Y	19558
10	CDISCPLOT...	701	01-701-1...	Xanomeline ...	81	77	65-80	2	WHITE	1	F	Y	19905
11	CDISCPLOT...	701	01-701-1...	Xanomeline ...	81	77	65-80	2	WHITE	1	F	Y	19905
12	CDISCPLOT...	701	01-701-1...	Placebo	0	85	>80	3	WHITE	1	F	Y	19401
13	CDISCPLOT...	701	01-701-1...	Placebo	0	85	>80	3	WHITE	1	F	Y	19401
14	CDISCPLOT...	701	01-701-1...	Placebo	0	85	>80	3	WHITE	1	F	Y	19401
15	CDISCPLOT...	701	01-701-1...	Placebo	0	85	>80	3	WHITE	1	F	Y	19401
16	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724
17	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724
18	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724
19	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724
20	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724
21	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724
22	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724
23	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724
24	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724
25	CDISCPLOT...	701	01-701-1...	Xanomeline ...	54	68	65-80	2	WHITE	1	M	Y	19724

Showing 25 of 1191 rows from 1 row 1

Summary table features – Analysis groups

- Needed to be able to create and manipulate Analysis groups.
 - New summary table pane
 - Add item list from ADaM data set.
 - Add groups list and buttons to create groups
- Drag and drop from the item list to the groups required variables
- Automatically assigned GUID to group ID
 - Have option to update this in a later build
- Include checkbox for initiating Big N (population size) calculation.
 - Although this currently does nothing!

Summary table for: ADSL

▼ Items

- ITEMGROUPTASEQ
- STUDYID
- USUBJID
- SUBJID
- SITEID
- SITEGR1
- ARM
- TRT01P

▼ Groups

Id: d880639c-5ec4-45... (x)

Label: Treatment

Values from: TRT01A

Order by: TRT01AN

Big N?

Show levels

⊕ data ⊕ analysis

Summary table features – Analysis groups

- Add dialog for manipulating levels within the analysis group
 - Do not cater for data driven groups – add a button that will query the data and create levels
 - Add buttons for creating and removing levels
 - Each row is an ordered and labelled WhereClause.

Order by

Big N?

Show levels

Treatment Levels

<input type="button" value="⊖ 0"/>	<input type="text" value="Placebo"/>	<input type="text" value="TRT01A"/>	<input type="text" value="Equals"/>	<input type="text" value="Placebo"/>
<input type="button" value="⊖ 54"/>	<input type="text" value="Xanomeline Low Dose"/>	<input type="text" value="TRT01A"/>	<input type="text" value="Equals"/>	<input type="text" value="Xanomeline Low Dose"/>
<input type="button" value="⊖ 81"/>	<input type="text" value="Xanomeline High Dose"/>	<input type="text" value="TRT01A"/>	<input type="text" value="Equals"/>	<input type="text" value="Xanomeline High Dose"/>

Summary table features – Analysis groups

- With added Total group

Order by

Big N?

Show levels

Treatment Levels ×

<input type="radio"/>	<input type="text" value="0"/>	<input type="text" value="Placebo"/>	<input type="text" value="TRT01A"/>	<input type="text" value="Equals"/>	<input type="text" value="Placebo"/>
<input type="radio"/>	<input type="text" value="54"/>	<input type="text" value="Xanomeline Low Dose"/>	<input type="text" value="TRT01A"/>	<input type="text" value="Equals"/>	<input type="text" value="Xanomeline Low Dose"/>
<input type="radio"/>	<input type="text" value="81"/>	<input type="text" value="Xanomeline High Dose"/>	<input type="text" value="TRT01A"/>	<input type="text" value="Equals"/>	<input type="text" value="Xanomeline High Dose"/>
<input type="radio"/>	<input type="text" value="99"/>	<input type="text" value="Total"/>	<input type="text" value="TRT01A"/>	<input type="text" value="In"/>	<input type="text" value="Placebo
Xanomeline Low Dose
Xanomeline High Dose"/>

Summary table features – Column headers

- Can now add table headers by dragging the Analysis group id onto the table
 - Headers are taken from the current analysis group levels

The screenshot displays a software interface with a configuration panel on the left and a table area on the right. The configuration panel is titled "Groups" and contains the following fields:

- Id:** ab6a7e7e-5580-44... (with a close button 'x')
- Label:** Treatment
- Values from:** TRT01A
- Order by:** TRT01AN
- Big N?:**
- Show levels:** (button)

Below the configuration panel is a tab labeled "Treatment Levels" with a close button 'x'. The table area on the right is currently empty and displays "0 filters applied...". A small square icon is visible in the top right corner of the table area.

Summary table features – Row variable + Stats

- Add row variables by dragging from the item list
 - Automatically add some default statistics.
 - Automatically add formula for cell contents

Summary table for: ADSL

Load Save [Down Arrow] AF

0 filters applied...

▼ Groups

id: ab6a7e7e-5580-44... (x)

Label: Treatment

Values from: TRT01A

Order by: TRT01AN

Big N?

Show levels

[+ data] [+ analysis]

	Placebo	Xanomeline Low Dose	Xanomeline High Dose	Total
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Summary table features – ARS file

- Clicking on the ARS button shows JSON contents
 - Save button to download the file

Summary table for: ADSL

Load Save [Down Arrow] ARS

0 filters applied...

	Placebo	Xanomeline Low Dose	Xanomeline High Dose	Total
BMIBL				

ARS Output

```
{
  "listOfPlannedOutputs": { "...": 1 item },
  "analysisGroupings": [ 1 item ],
  "groups": [ 4 items ],
  "0": { 5 items },
    "id": "string \"ab6a7e7e-5580-440f-871a-47ece69324d5\"",
    "dataDriven": "bool false",
    "label": "string \"Treatment\"",
    "groupingVariable": "string \"TRT01A\"",
    "groups": [ 4 items ],
      "0": { 5 items },
        "level": "int 1",
        "order": "int 0",
        "id": "string \"5028e9e6-c470-43fc-aef1-f3ee109e7ec9\"",
        "label": "string \"Placebo\"",
        "condition": { 4 items },
          "dataset": "string \"ADSL\"",
          "variable": "string \"TRT01A\"",
          "comparator": "string \"eq\"",
          "value": [ 1 item ],
            "0": "string \"Placebo\""
          ]
        }
      ]
    }
  ]
}
```

Summary table features – ARS file

- ARS file includes hard coded sections for
 - listOfPlannedAnalysis
 - listOfPlannedOutputs
 - methods

```
ARS.json X
C:\Users > P_d_T > OneDrive > Office > 052. Presentations > {} ARS.json > [ ] analysisGroupings
1
2 {
3   "id": "ARS",
4   "version": 0.1,
5   "name": "Analysis Results Standard, Exploring the Holistic Overview in a Localhost Example",
6   "listOfPlannedAnalyses": { ...
7   },
8   "listOfPlannedOutputs": { ...
9   },
10  "analysisGroupings": [ ...
11  ],
12  "methods": [
13  {
14    "name": "Summary of by group of a continuous variable",
15    "id": "M_GRP_SUM_CONTIN",
16    "label": "Summarise continuous variable",
17    "description": "Standard summary statistics for a continuous variable",
18    "documentRefs": [],
19    "operations": [
20    {
21      "id": "M_GRP_SUM_CONTIN_N",
22      "label": "n",
23      "name": "n",
24      "resultPattern": "3sf"
25    },
26    { ...
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```

Summary table features – ARS file

- Dynamically generated
 - analysisGroupings
 - analysis
 - outputs

```
35 "analysisGroupings": [  
36   {  
37     "id": "ab6a7e7e-5589-440f-871a-47ece69324d5",  
38     "dataDriven": false,  
39     "label": "Treatment",  
40     "groupingVariable": "TRT01A",  
41     "groups": [  
42       {  
43         "level": 1,  
44         "order": 0,  
45         "id": "5028e9e6-c470-43fc-ae1f-f3ee109e7ec9",  
46         "label": "Placebo",  
47         "condition": {  
48           "dataset": "ADSL",  
49           "variable": "TRT01A",  
50           "comparator": "eq",  
51           "value": [  
52             "Placebo"  
53           ]  
54         },  
55       },  
56       {  
57         "level": 1,  
58         "order": 54,  
59         "id": "fc0f1e44-bc4d-4947-be65-6b25cd4e5fc6",  
60         "label": "Xanomline Low Dose",  
61         "condition": {  
62           "dataset": "ADSL",  
63           "variable": "TRT01A",  
64           "comparator": "eq",  
65           "value": [  
66             "Xanomline Low Dose"  
67           ]  
68         },  
69       }  
70     ]  
71   }  
72 ]
```

```
204 "analyses": [  
205   {  
206     "id": "BMIBL_TREATMENT_CONT",  
207     "reason": {},  
208     "purpose": {},  
209     "analysisSetId": "ab6a7e7e-5580-440f-871a-47ece69324d5",  
210     "dataset": "ADSL",  
211     "variable": "BMIBL",  
212     "methodId": "M_GRP_SUM_CONTIN",  
213     "name": "Summary of BMIBL by Treatment",  
214     "level": 2,  
215     "order": 1  
216   }  
217 ],  
218 > "outputs": [
```

```
"outputs": [  
  {  
    "name": "Local example table",  
    "id": "TAB_1",  
    "version": 1,  
    "displays": [  
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        "display": {  
          "name": "Example",  
          "id": "DISP_1",  
          "version": 1,  
          "displayTitle": "Example display",  
          "displaySections": [  
            {  
              "sectionType": "Column Headers",  
              "orderedSubSections": [  
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                  "order": 0,  
                  "text": "Placebo"  
                },  
                {  
                  "order": 1,  
                  "text": "Xanomline Low Dose"  
                }  
              ]  
            }  
          ]  
        }  
      }  
    ]  
  }  
]
```

```
18 "outputs": [  
19   {  
20     "name": "Local example table",  
21     "id": "TAB_1",  
22     "version": 1,  
23     "displays": [  
24       {  
25         "order": 1,  
26         "display": {  
27           "name": "Example",  
28           "id": "DISP_1",  
29           "version": 1,  
30           "displayTitle": "Example display",  
31           "displaySections": [  
32             {  
33               "order": 1,  
34               "text": "n"  
35             },  
36             {  
37               "sectionType": "Row Header",  
38               "orderedSubSections": [  
39                 {  
40                   "order": 1,  
41                   "id": "DISPLAY_BMIBL",  
42                   "text": "BMIBL"  
43                 },  
44                 {  
45                   "order": 1,  
46                   "id": "DISPLAY_BMIBL-n",  
47                   "text": "n"  
48                 },  
49                 {  
50                   "order": 1.01,  
51                   "id": "DISPLAY_BMIBL-pct",  
52                   "text": "pct"  
53                 },  
54                 {  
55                   "order": 1.02,  
56                   "id": "DISPLAY_BMIBL-mean",  
57                   "text": "mean"  
58                 }  
59               ]  
60             }  
61           ]  
62         }  
63       }  
64     ]  
65   }  
66 ]
```

Minor Summary table features

- Add buttons for Loading/Saving the current state to local browser storage
- Developer feature - add information button to see the current data state in the browser

Data url: <https://raw.githubusercontent.com/cdisc-org/DataExchange-DatasetJson/master/examples/adam/adsl.json>

studyOID: TDF_ADaM.ADaMIG.1.1

metaDataVersionOID: MDV.TDF_ADaM.ADaMIG.1.1

name: ADSL

label: Subject-Level Analysis

Show Items Data Summary table

Summary table for: ADSL

Load Save ⓘ ARS

0 filters applied...

	Placebo	Xanomeline Low Dose	Xanomeline High Dose	Total
BMIBL				
n	n(Baseline BMI (kg/m ²) x Treatment["Placebo"])	n(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	n(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	n(Baseline BMI (kg/m ²) x Treatment["Total"])
pct	pct(Baseline BMI (kg/m ²) x Treatment["Placebo"])	pct(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	pct(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	pct(Baseline BMI (kg/m ²) x Treatment["Total"])
mean	mean(Baseline BMI (kg/m ²) x Treatment["Placebo"])	mean(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	mean(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	mean(Baseline BMI (kg/m ²) x Treatment["Total"])
sd	sd(Baseline BMI (kg/m ²) x Treatment["Placebo"])	sd(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	sd(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	sd(Baseline BMI (kg/m ²) x Treatment["Total"])
p0	p0(Baseline BMI (kg/m ²) x Treatment["Placebo"])	p0(Baseline BMI (kg/m ²) x Treatment["Xanomeline Low Dose"])	p0(Baseline BMI (kg/m ²) x Treatment["Xanomeline High Dose"])	p0(Baseline BMI (kg/m ²) x Treatment["Total"])



Further development

- Enable Big N
- Enable data groups
 - Does this just effectively mean a where clause at table level?
- Allow groups to be added rows
- Allow statistics to be moved to columns
- Allow nesting of groups at row/column level
 - Potentially affecting display metadata within the ARS
- Add formatting information for displays
 - Need to work on the best representation – potentially some form of markdown
- Add more complex analysis methods
 - Do these require extra metadata to be added to the model?



Summary

- Met most of my objectives from the hackathon
 - Front end completed, and published
 - Enhanced by understanding of the ARS model
 - Missed out on using Data groups
- I see the ARS model as a valid solution for describing analysis that needs to be performed on a study
- I think it will be possible to fill the known gap around the details of presenting data within the context of the model – but I'm not sure this is necessary.
- Needs to be stress tested on a large study



Contact Details

Paul Thomas,
Independent contractor, currently working with AstraZeneca
ASUP Ltd.

paul@asup.co.uk

Live project demo: <https://www.asup.uk/ars-hackathon/#summary>

Git repository: <https://github.com/PaulDThomas/dataset-json-handler>

