

CDISC ARS Hackathon Kickoff



Kick-off Meeting

July 12th, 2023

Bhavin Busa, Bess LeRoy, Richard Marshall



Welcome to CDISC ARS Hackathon!



IDEA

HACKATHON

CONNECT



SOLVE

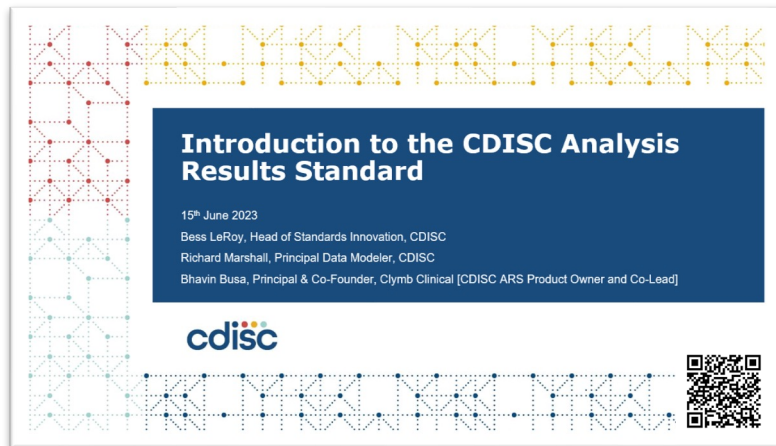
PRESENT



- ✓ Help operationalize CDISC Analysis Results Model!
 - ✓ Be an Early Adopter and Gain a Head Start!

Pre-Read and Reference Materials


CDISC Webinar: 15th June 2023



Introduction to the CDISC Analysis Results Standard

15th June 2023
Bess LeRoy, Head of Standards Innovation, CDISC
Richard Marshall, Principal Data Modeler, CDISC
Bhavin Busa, Principal & Co-Founder, Clymb Clinical [CDISC ARS Product Owner and Co-Lead]

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Slides and video recording available on the CDISC website: [Link](#)

Published White Paper: May 2023



All You Need to Know about the New CDISC Analysis Result Standards!

PharmaSUG 2023: Paper # MM327
Bhavin Busa, Principal & Co-Founder, Clymb Clinical [CDISC ARS Product Owner and Co-Lead]
Richard Marshall, Principal Data Modeler, CDISC
Bess LeRoy, Head of Standards Innovation, CDISC

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White Paper available on the PharmaSUG website: [Link](#)



ARS Model - Training Video

Release date: 7/14/2023

Check ARS Hackathon Slack channel for update



Analysis Results Standards Key Results



Develop a technical specification to prospectively leverage Analysis Results Metadata to drive automation



Develop a structure to represent Analysis Results as data



Develop a logical model to support a technical specification and an analysis results dataset



Illustrate and exercise with a set of common data displays

Demographics Analysis Results and Metadata

Display Template

Title

Analysis Set

Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)

Characteristic	Analysis Group	Drug Name Dosage X N = XXX	Drug Name Dosage Y N = XXX	Placebo N = XXX	Active Control N = XXX	Total Population N = XXX
		n (%)	n (%)	n (%)	n (%)	n (%)
Sex, n (%)		n (%)	n (%)	n (%)	n (%)	n (%)
Male		n (%)	n (%)	n (%)	n (%)	n (%)
Female		n (%)	n (%)	n (%)	n (%)	n (%)
Age, years		X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)
Mean (SD)		X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)
Median (min, max)		X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)
Age groups (years), n (%)		n (%)	n (%)	n (%)	n (%)	n (%)
≥17 to <65	Result Group		Result Variable	Where Clause	Result Statistics	n (%)
≥65						n (%)
≥65 to <75						n (%)
≥75		n (%)	n (%)	n (%)	n (%)	n (%)
Race, n (%)		n (%)	n (%)	n (%)	n (%)	n (%)
American Indian or Alaska Native		n (%)	n (%)	n (%)	n (%)	n (%)
Asian		n (%)	n (%)	n (%)	n (%)	n (%)
Black or African American		n (%)	n (%)	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander		n (%)	n (%)	n (%)	n (%)	n (%)
White		n (%)	n (%)	n (%)	n (%)	n (%)
Other		n (%)	n (%)	n (%)	n (%)	n (%)

Source: [include Applicant source, datasets and/or software tools used].

¹ Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).

Abbreviations: N, number of patients in treatment arm; n, number of patients with given characteristic; SD, standard deviation

Footnote

Abbreviations

Legend

Analysis Results and Associated Metadata Example

Identifiers		Analysis Group			Result Variable			Results Statistic		
Name	Title	Dataset	Variable	Value	Variable	Value	Label	Value	Name	Label
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	53	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	61.6	Percent	%
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	33	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	38.4	Percent	%

Hackathon Objectives



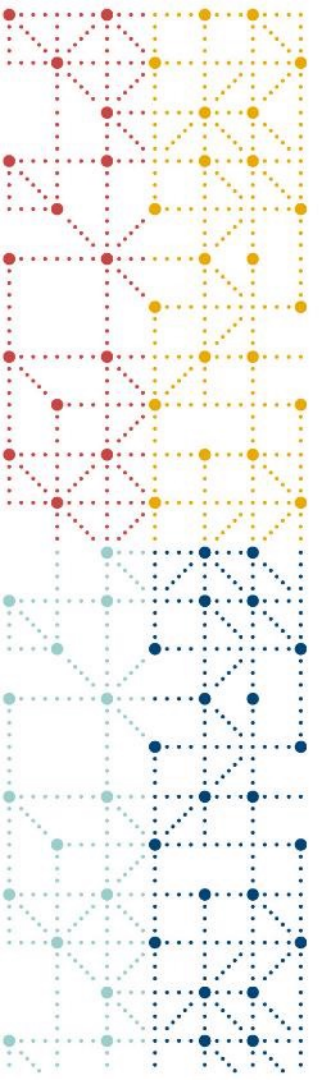
Drive adoption of
CDISC Analysis
Results Standard



Foster open-source
software tools for
operationalization



Leveraging hackathon
learnings to enhance
the standards



Hackathon Welcome Letter

Email sent to all participants: 7/12/2023



Hackathon Resources on GitHub



CDISC ARS model files*



CDISC ARS model documentation



Examples and utilities (sample programming code)



CDISC ARS API



[CDISC Pilot Study](#) (CRF, SDTM, ADaM, SAP and CSR)



Common Safety Displays (mock-up displays)

* Pending CDISC Internal Review and Public Review

Communication Channels



- **Slack** Workspace to exchange information and get questions answered
- **GitHub** CDISC ARS Hackathon Repo for reporting issues
- **Zoom** for Weekly Check-in: Every Wednesday 10:00AM EST [Invite will be sent out to all participants]

ARS Hackathon Repo on GitHub

- <https://github.com/cdisc-org/analysis-results-standard-hackathon>

The screenshot shows the GitHub repository page for 'analysis-results-standard-hackathon'. The repository is public and forked from 'cdisc-org/analysis-results-standard'. The main branch is 'main'. The repository contains a file tree with folders like 'ASL-marshall SAS program updates', 'HowTos', 'docs', 'documents', 'images', 'model', 'project', 'utilities', and 'workfiles'. The 'model' folder is highlighted. The 'README.md' file is open, showing the project's goals and a list of tasks.

File/Folder	Commit	Author	Time Ago
ASL-marshall SAS program updates	Initial commit	5338ca	1 hour ago
HowTos	Initial commit		9 months ago
docs	Example SAS code		5 days ago
documents	Delete ICH guideline		6 months ago
images	Add files via upload		5 months ago
model	Enable pan/zoom controls for doc diagrams		2 weeks ago
project	Example SAS code		5 days ago
utilities	SAS program updates		1 hour ago
workfiles	Fixed typo in group label		20 hours ago
.gitignore	Documentation updates		3 weeks ago
CODE_OF_CONDUCT.md	Update CODE_OF_CONDUCT.md		6 months ago
CONTRIBUTING.md	Update CONTRIBUTING.md		6 months ago
LICENSE	Initial commit		9 months ago
README.md	Update README.md		last month
mkl0cs.yml	Enable pan/zoom controls for doc diagrams		2 weeks ago

Model: representations of the model (YAML, JSON, Mermaid ER, YUML, SVG)

Workfiles: CMAP, examples

Project: Auto-generated content (Python classes/API, documentation, model structures)

Utilities: Example programs

Analysis Results Standard Model Documentation

- <https://cdisc-org.github.io/analysis-results-standard/>

Analysis Results Standard (ARS)

DRAFT Logical model to support both the prospective specification of analyses and the fully contextualized representation of the results of the analyses.

URL: <https://www.cdisc.org/ars/1-0> Name: ars_ldm

Schema Diagram

Classes

Class	Description
Analysis	An analysis that is designed to meet a requirement of the reporting event
AnalysisCategorization	A set of related implementer-defined categories that can be used to categoriz...
AnalysisCategory	An implementer-defined category of analyses/outputs, which may include one or...

Class: ReportingEvent

A set of analyses and events created to meet a specific reporting requirement, such as a CSR or interim analysis.

URL: [ars:ReportingEvent](#)

Inheritance

- NamedObject
- ReportingEvent

Slots

Name	Cardinality and Range	Description	Inheritance
id	1..1 String	The assigned identifying value for the instance of the class	direct
version	0..1 Integer	An ordinal indicating the version of the identified instance of the class	direct
isaOfPlannedAnalysis	1..1 NestedList	A structured list of the analyses defined for the reporting event	direct
isaOfPlannedOutputs	0..1 NestedList	An optional structured list of the outputs defined for the reporting event	direct
analysisSets	0..* AnalysisSet	The analysis sets (subject populations) defined for the reporting event	direct
analysisGroupings	0..* SubjectGroupingFactor	Characteristics used to subdivide the subject population (e	direct
dataSubsets	0..* DataSubset	Subsets of data identified by selection criteria for inclusion in analysis de...	direct
dataGroupings	0..* DataGroupingFactor	Characteristics used to subdivide data records in analysis datasets (e	direct
globalDisplaySections	0..* GlobalDisplaySection	Display section specifications that may be applied to any display	direct
analysisCategorizations	0..* AnalysisCategorization	Sets of related implementer-defined categories that can be used to categoriz...	direct
analyses	0..* Analysis	The analyses defined for the reporting event	direct
methods	0..* AnalysisMethod	The defined methods used to analyze any analysis variable	direct
outputs	0..* Output	The outputs defined for the reporting event	direct
referenceDocuments	0..* ReferenceDocument	External documents containing information referenced for the reporting event	direct
terminologyExtensions	0..* TerminologyExtension	Any sponsor-defined extensions to extensible terminology	direct
name	1..1 String	The name for the instance of the class	NamedObject

Identifier and Mapping Information

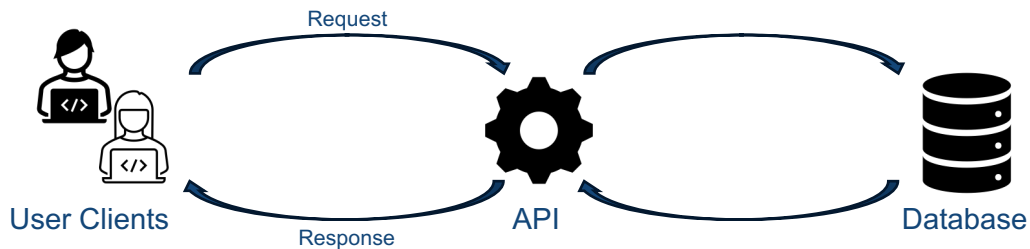
Schema Source

- from schema: <https://www.cdisc.org/ars/1-0>

Mappings

Mapping Type	Mapped Value
--------------	--------------

Analysis Results Standard Application Programming Interface (API)



<https://ars-hackathon-dev.azurewebsites.net/docs>

ARS API 0.1.0 OAS 3.1

/openapi.json

default

GET	/mdr/ars/reportingevents/	Get All Ars Packages
GET	/mdr/ars/reportingevents/{reportingevent_id}/	Get Reporting Event

<https://ars-hackathon-dev.azurewebsites.net/mdr/ars/reportingevents/>
<https://ars-hackathon-dev.azurewebsites.net/mdr/ars/reportingevents/FDASTF/>

Curl

```
curl -X 'GET' \
  'http://ars-hackathon-dev.azurewebsites.net/mdr/ars/reportingevents/CSD/' \
  -H 'accept: application/json' \
  -H 'x-token: ' .
```

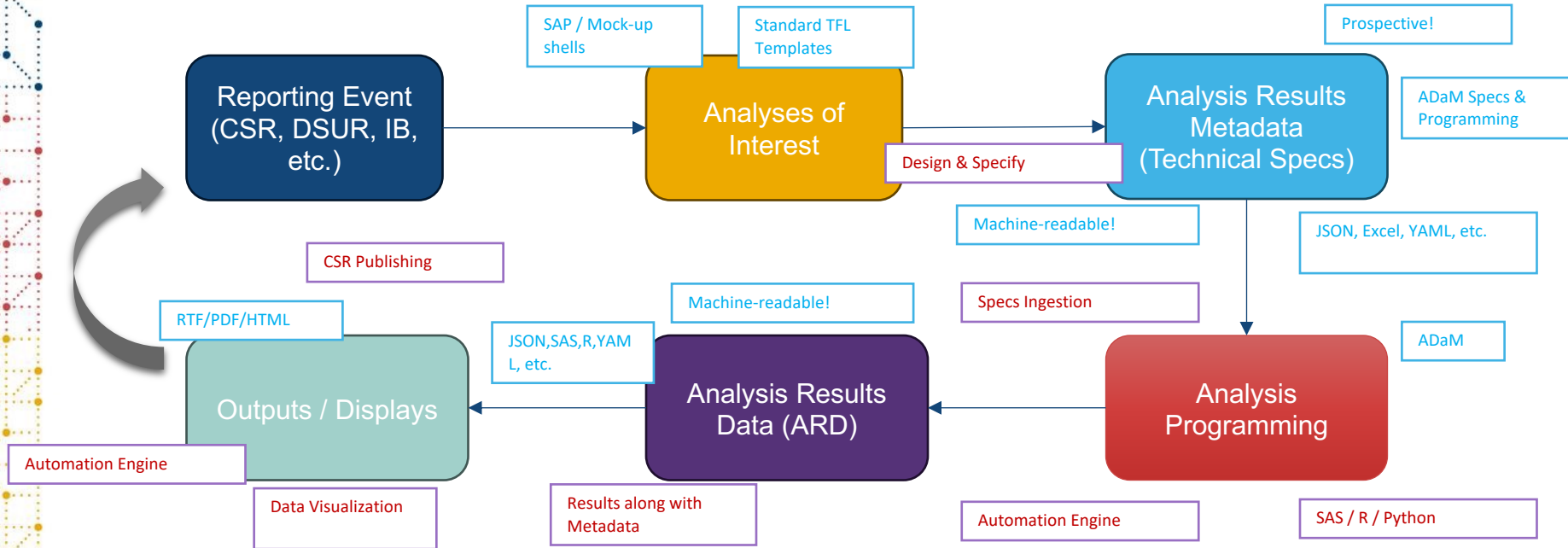
Request URL

```
http://ars-hackathon-dev.azurewebsites.net/mdr/ars/reportingevents/CSD/
```

Server response

Code	Details
200	<p>Response body</p> <pre>{ "name": "Common Safety Displays", "id": "CSD", "listOfPlannedAnalyses": { "listItems": [{ "name": "Summary of Demographics", "level": 1, "order": 1, "sublist": { "listItems": [{ "name": "Summary of Subjects by Treatment", "level": 2, "order": 1, "analysisId": "An01_05_SAF_Summ_ByTrt" }, { "name": "Age", "level": 2, "order": 2, "sublist": { "listItems": [{ "name": "Summary by Treatment", "level": 3, "order": 1, "analysisId": "An03_01_Age_Summ_ByTrt" }] } }] } }] } }</pre>

ARS Model Supported Workflow and Entry Points





Examples of Hackathon Artifacts

- An open-source solution to:
 - prospectively generate analysis results metadata (technical specification) per the ARS model
 - ingest analysis results metadata to automate generation of the code (“meta-programming”)
 - ingest analysis results metadata to automate generation of analysis results data (ARD)
 - make use of the metadata and ARD to generate displays in RTF or PDF formats

Note: This hackathon does not restrict the types of software tools developed but does explicitly seeks tools to operationalize draft CDISC ARS



Poll Question

- Please provide at least one user story from your perspective on how you plan to operationalize CDISC ARS in the text box below

*A **user story** is a short, simple description of a feature told from the perspective of the person who desires the new capability, usually a user or customer of the system. User stories typically follow a simple template:*

As a < type of user >, I want < some goal > so that < some reason >



User Story (Example)

- *As a Biostats/Stats Prog, I want to use a design tool to prospectively generate machine-readable analysis results metadata for downstream programming activities.*



Individual and Team Participation

- Registered as individuals for the hackathon
- Some registrants are working together as a team
- Team collaboration opportunities
 - Those interested in joining or forming a team can let others know via Slack
 - Look for project handoff and work streams opportunities

Hackathon Timeline





Rewards for Participants

- Each solution that can be demoed will receive:
 - Exposure for their tool during the US Interchange
 - Demo their tool during a CDISC webinar after the US Interchange
 - Completed open-source projects will be offered a place on the COSA directory
 - Promote their tool in future COSA events
 - COSA Hackathon certificate
- Every person or team that completes at least an MVP tool that can be demoed is considered a winner

ARS Hackathon Subject Matter Experts to Help

- Anthony Chow
- Bess LeRoy
- Bhavin Busa
- Charles Shadle
- Drew Mills
- Jared Schreibman
- Richard Marshall



- Please use Slack Workspace to exchange information and get questions answered & GitHub CDISC ARS Hackathon Repo for reporting issues

Get Hacking!

```
or object to mirror
mirror_mod.mirror_object
operation == "MIRROR_X":
mirror_mod.use_x = True
mirror_mod.use_y = False
mirror_mod.use_z = False
operation == "MIRROR_Y":
mirror_mod.use_x = False
mirror_mod.use_y = True
mirror_mod.use_z = False
operation == "MIRROR_Z":
mirror_mod.use_x = False
mirror_mod.use_y = False
mirror_mod.use_z = True
```

```
selection at the end - 1
mirror_ob.select = 1
mirror_ob.select = 1
context = bpy.context
context.selected_objects.append(mirror_ob)
print("Selected object modified")
mirror_ob.select = 0
bpy.context.selected_objects.remove(mirror_ob)
data.objects[one.name].select = 0
print("please select exactly one object")
```

```
-- OPERATOR CLASSES -----
class MirrorOperator(bpy.types.Operator):
    """Mirror selected object to the selected mirror X"""
    bl_idname = "mirror_mirror_x"
    bl_label = "Mirror X"
```



Contact Details

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