CDISC ARS Hackathon Kickoff

Kick-off Meeting

July 12th, 2023

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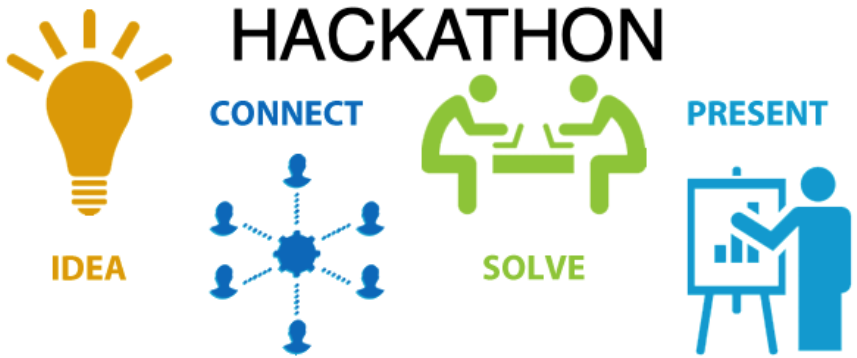
Welcome to CDISC ARS Hackathon!



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

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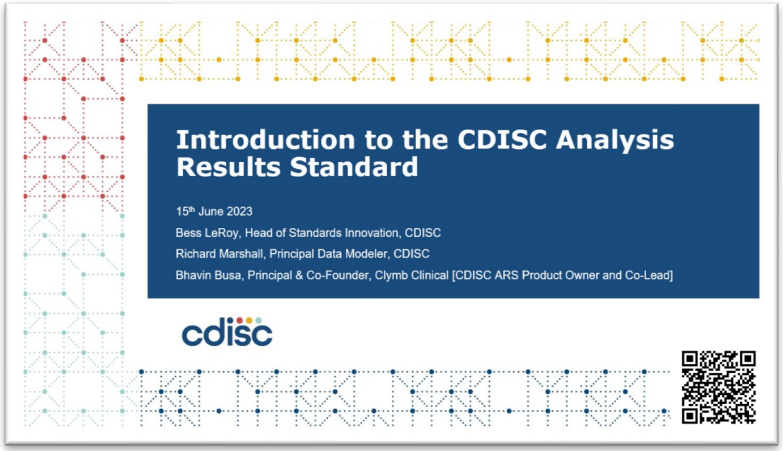
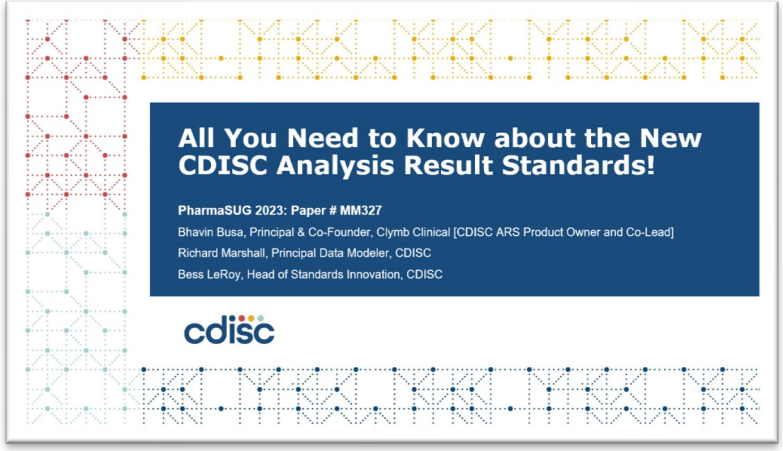
Pre-Read and Reference Materials

CDISC Webinar: 15th June 2023



Slides and video recording available on the CDISC website: Link

Published White Paper: May 2023



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
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 (%)**
≥17 to <65					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 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 (%)

Result Group | Result Variable | Where Clause | Result Statistics

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)

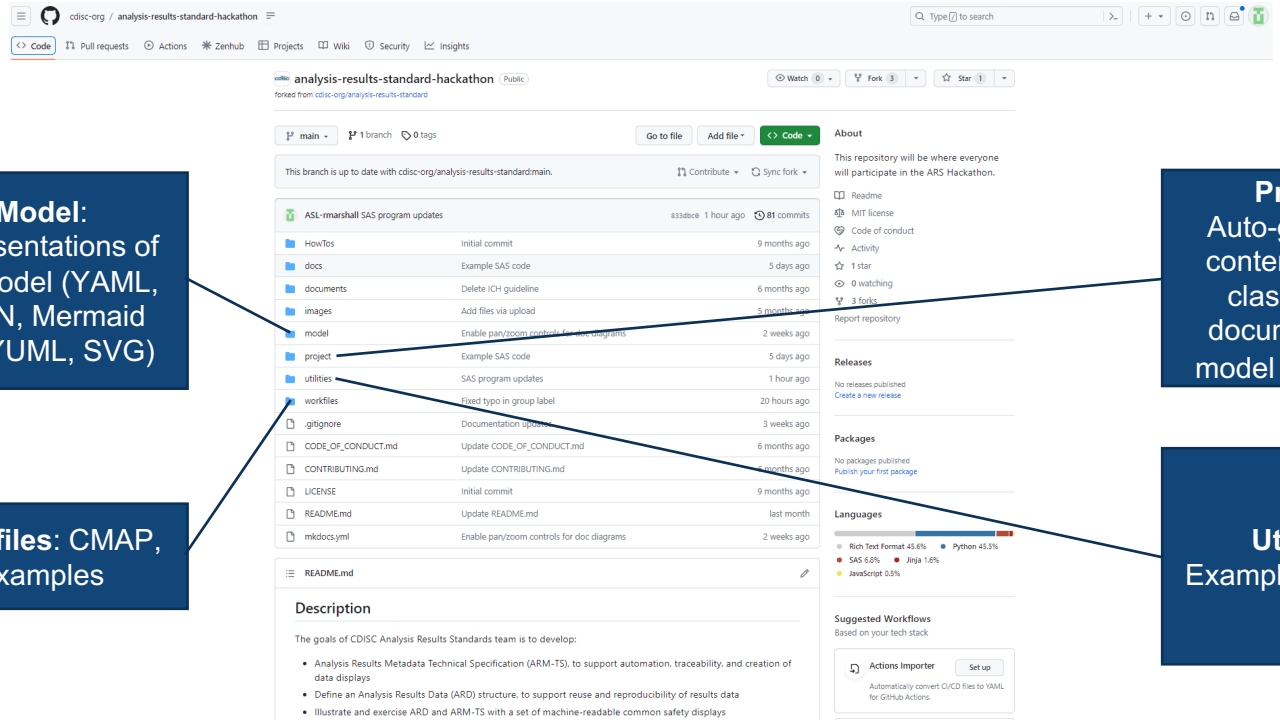
* Pending CDISC Internal Review and Public Review

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



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

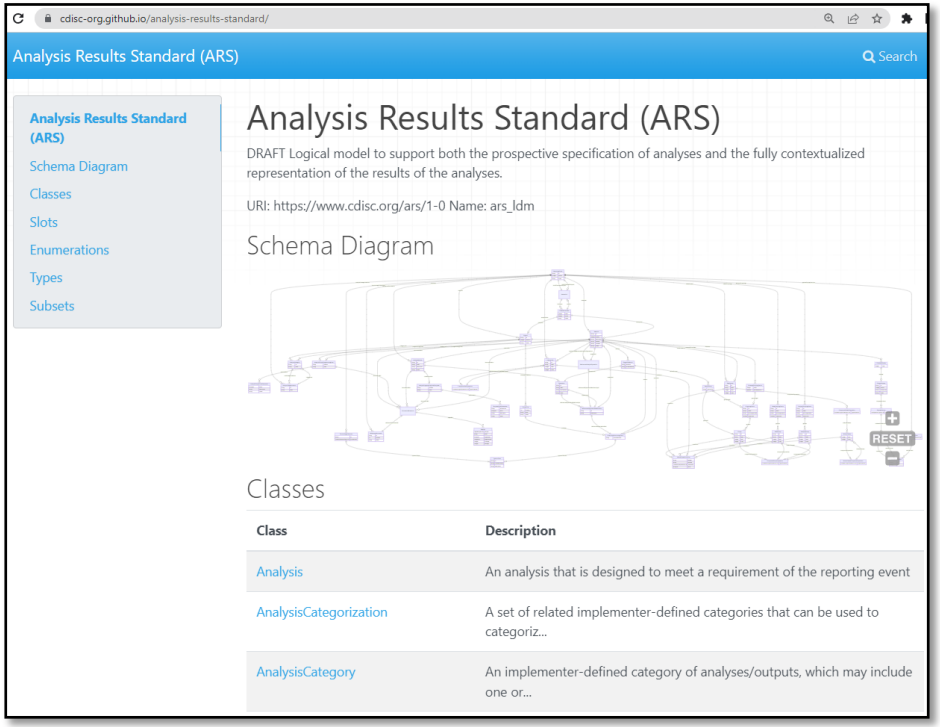
Workfiles: CMAP, examples

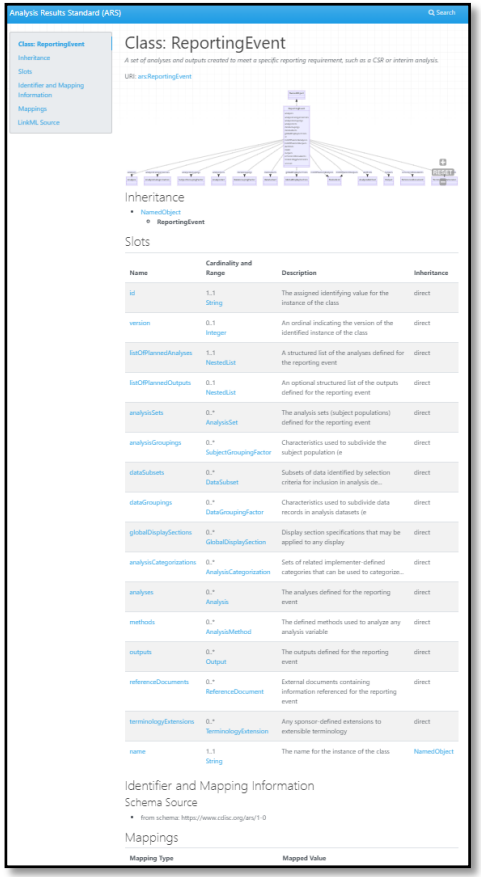
Project: Auto-generated content (Python classes/API, documentation, model structures)

Utilities: Example programs

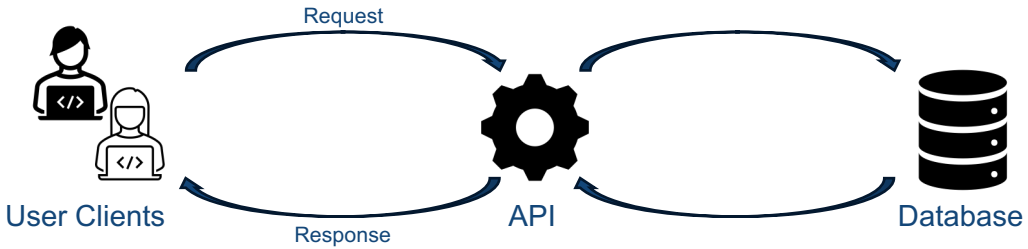
Analysis Results Standard Model Documentation

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





Analysis Results Standard 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

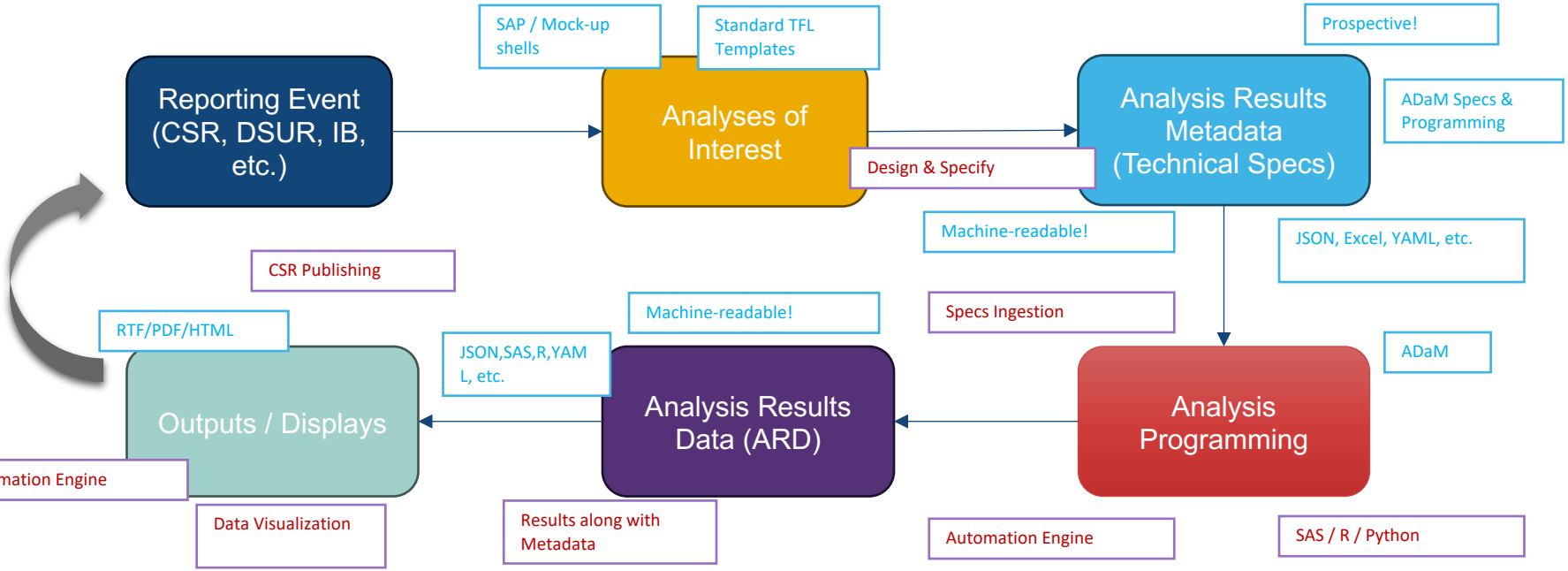
```
http://ars-hackathon-dev.azurewebsites.net/mdr/ars/reportingevents/CSD/
```

Server response

Code	Details
200	Response body


```
{
  "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"
```

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

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* Subject to change

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!

Contact Details

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