CDISC ARS Hackathon Kickoff

Kick-off Meeting
Jul 12th, 2023
Bhavin Busa, Bess LeRoy, Richard Marshall
Welcome to CDISC ARS Hackathon!

- 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, Cymb Clinical [CDISC ARS Product Owner and Co-Lead]

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 # MM37
Bhavin Busa, Principal & Co-Founder, Cymb Clinical [CDISC ARS Product Owner and Co-Lead]
Richard Marshall, Principal Data Modeler, CDISC
Bess LeRoy, Head of Standards Innovation, CDISC

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

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Drug Name Dosage X N = XXX</th>
<th>Drug Name Dosage Y N = XXX</th>
<th>Placebo N = XXX</th>
<th>Active Control N = XXX</th>
<th>Total Population N = XXX</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Analysis Group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Male</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Female</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Age, years</td>
<td>X.X (Y.Y)</td>
<td>X.X (Y.Y)</td>
<td>X.X (Y.Y)</td>
<td>X.X (Y.Y)</td>
<td>X.X (Y.Y)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>X.X (Y.Y)</td>
<td>X.X (Y.Y)</td>
<td>X.X (Y.Y)</td>
<td>X.X (Y.Y)</td>
<td>X.X (Y.Y)</td>
</tr>
<tr>
<td>Median (min, max)</td>
<td>X.X (Y.Y, Z)</td>
<td>X.X (Y.Y, Z)</td>
<td>X.X (Y.Y, Z)</td>
<td>X.X (Y.Y, Z)</td>
<td>X.X (Y.Y, Z)</td>
</tr>
<tr>
<td>Age groups (years), n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>≥17 to &lt;65</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>≥65</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>≥65 to &lt;75</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>≥75</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>American Indian or Alaska Native Asian</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>White</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Other</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
</tbody>
</table>

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
## Analysis Results and Associated Metadata Example

<table>
<thead>
<tr>
<th>Identifiers</th>
<th>Analysis Group</th>
<th>Result Variable</th>
<th>Results Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Title</td>
<td>Dataset</td>
<td>Variable</td>
</tr>
<tr>
<td>Table 2</td>
<td>Baseline Demographics and Clinical Characteristics, Safety Population</td>
<td>ADSL</td>
<td>TR01X</td>
</tr>
<tr>
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<td>TR01X</td>
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</tbody>
</table>
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/](https://cdisc-org.github.io/analysis-results-standard/)
Analysis Results Standard Application Programming Interface (API)

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

ARS API

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/
ARS Model Supported Workflow and Entry Points

Reporting Event (CSR, DSUR, IB, etc.)

Analyses of Interest

Analysis Results Metadata (Technical Specs)

Analysis Results Data (ARD)

Outputs / Displays

Design & Specify

Machine-readable!

SAP / Mock-up shells

Standard TFL Templates

Machine-readable!

CSR Publishing

RTF/PDF/HTML

Data Visualization

Results along with Metadata

Automation Engine

Data Visualization

Specs Ingestion

JSON, SAS, R, YAML, etc.

Machine-readable!

Prospective!

ADaM Specs & Programming

SAS / R / Python

ADaM

Automation Engine

SAS / R / Python

Automation Engine

CSR Publishing
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

15 June
Announcement: Webinar June 15th

11 July
Send out Welcome letter to participants

15 June – 7 July
Registration

19 July
Team Formation (participants driven)

12 July
Kick off TC: July 12\textsuperscript{th} (recorded)

31 Aug*
Share Results: Slides due Aug 31st

20 July – 30 Aug*
Team Weekly Check-in: Wed 10AM EST

18–19 Oct.
Presentation of Results: US Interchange Oct. 18-19

Webinar Demonstrations

* 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

Bhavin Busa
ARS Product Owner & Co-Lead
bhavin@clymbclinical.com

Richard Marshall
Principal Data Modeler
rmarshall@accuratesystems.co.uk

Bess LeRoy
Head of Standards Innovation, CDISC
bleroy@cdisc.org