

Featured Solutions from CDISC ARS Hackathon



COSA Quarterly Spotlight - Q4 2023

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Analysis Results Key Objectives

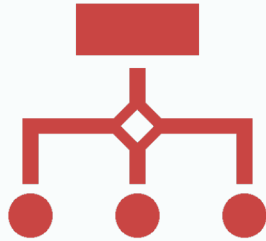


Leverage analysis results metadata to drive the automation of results



Support storage, access, processing, traceability and reproducibility of results

Analysis Results Standards Key Results



Logical model that describes analysis results and associated metadata



User Guide to illustrate and exercise model with common safety displays

Analysis Results Standard Repo on GitHub

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

The screenshot shows the GitHub repository page for 'cdisc-org/analysis-results-standard'. The repository is public and has 65 commits, 4 branches, and 3 tags. The file list includes folders like 'model', 'project', and 'utilities/python', and files like 'README.md', 'LICENSE', and 'CONTRIBUTING.md'. The 'About' section states that this repository will deliver the Analysis Results Standard. The 'Releases' section shows 'ARS Phase 1, Sprint 10' as the latest release. The 'Packages' section indicates no packages are published. The 'Contributors' section lists ASL-rmarshall, bhavinbusa, and drewdisc.

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/>

The screenshot shows the main page of the Analysis Results Standard (ARS) documentation. The header includes the title "Analysis Results Standard (ARS)" and a search bar. A left sidebar lists navigation options: "Analysis Results Standard (ARS)", "Classes", "Slots", "Enumerations", "Types", and "Subsets". The main content area features the title "Analysis Results Standard (ARS)" followed by a description: "DRAFT Logical model to support both the prospective specification of analyses and the fully contextualized representation of the results of the analyses." Below this, the URI is given as "https://www.cdisc.org/ars/1-0 Name: ars_idm". A "Classes" section lists several classes with their descriptions:

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...
AnalysisGroup	A subdivision of the subject population based on a defined factor (e
AnalysisMethod	A set of one or more statistical operations
AnalysisOutputProgrammingCode	Programming statements and/or a reference to the program used to perform a sp...

The screenshot shows the class documentation for "ReportingEvent". It includes a class hierarchy diagram, a table of slots, and identifier/mapping information.

Class: ReportingEvent
A set of analyses and outputs created to meet a sponsor's reporting requirement, such as a CSR or clinical analysis.
URI: ars:ReportingEvent

Inheritance
ReportingEvent is a subclass of ReportingEventBase.

Slots

Name	Cardinality and Range	Description	Inheritance
analysisOutputProgramCode	0..1 Text	A structured list of the analysis output for the reporting event.	class
analysisOutputTable	0..1 Text	An optional structured list of the output defined for the reporting event.	class
analysisOutputText	0..1 Text	The analysis output population defined for the reporting event.	class
analysisOutputTable	0..1 Text	Characteristics used to subdivide the subject population in	class
analysisOutputTable	0..1 Text	Characteristics used to subdivide sites reports in the analysis domain in	class
analysisOutputTable	0..1 Text	Display function	class
analysisOutputTable	0..1 Text	Analysis categorization	class
analysisOutputTable	0..1 Text	The analysis defined for the reporting event.	class
analysisOutputTable	0..1 Text	The defined method used to analyze any analysis results.	class
analysisOutputTable	0..1 Text	Output	class
analysisOutputTable	0..1 Text	Reference to a resource	class
analysisOutputTable	0..1 Text	Any sponsor defined extension to standard terminology.	class
analysisOutputTable	1..1 Text	URI	URI

Identifier and Mapping Information
Schema Source
• Base schema: <https://cdisc.org/ars/1-0>

Mappings

Mapping Type	Mapped Slot
uri	ars:ReportingEvent
uri	ars:ReportingEvent

LinkML Source
Direct
• Direct
Induced
• Direct

User Guide

- <https://wiki.cdisc.org/display/ARSP/Analysis+Results+User+Guide>

1 INTRODUCTION

- 1.1 Background and Purpose
- 1.2 Relationship to Other CDISC Standards
- 1.3 How to Read this Document

2 ANALYSIS RESULTS MODEL

- 2.1 ReportingEvent
- 2.2 [Common Components](#)
 - 2.2.1 NestedList
 - 2.2.2 AnalysisOutputCategorization
 - 2.2.3 ReferenceDocument
 - 2.2.3.1 DocumentReference
 - 2.2.4 TerminologyExtension
 - 2.2.4.1 ExtensibleTerminologyTerm
 - 2.2.5 AnalysisOutputProgrammingCode
- 2.3 Analysis Components
 - 2.3.1 WhereClause
 - 2.3.1.1 WhereClauseCondition
 - 2.3.1.2 WhereClauseCompoundExpression
 - 2.3.2 AnalysisSet
 - 2.3.3 DataSubset
 - 2.3.4 GroupingFactor
 - 2.3.4.1 SubjectGroupingFactor
 - 2.3.4.2 DataGroupingFactor
 - 2.3.5 AnalysisMethod
 - 2.3.5.1 Operation
 - 2.3.5.2 AnalysisProgrammingCodeTemplate
 - 2.3.6 Analysis
 - 2.3.6.1 OperationResult

2.4 Output Components

- 2.4.1 GlobalDisplaySection
- 2.4.2 Output
 - 2.4.2.1 OutputDisplay

3 EXAMPLE REPORTING EVENTS

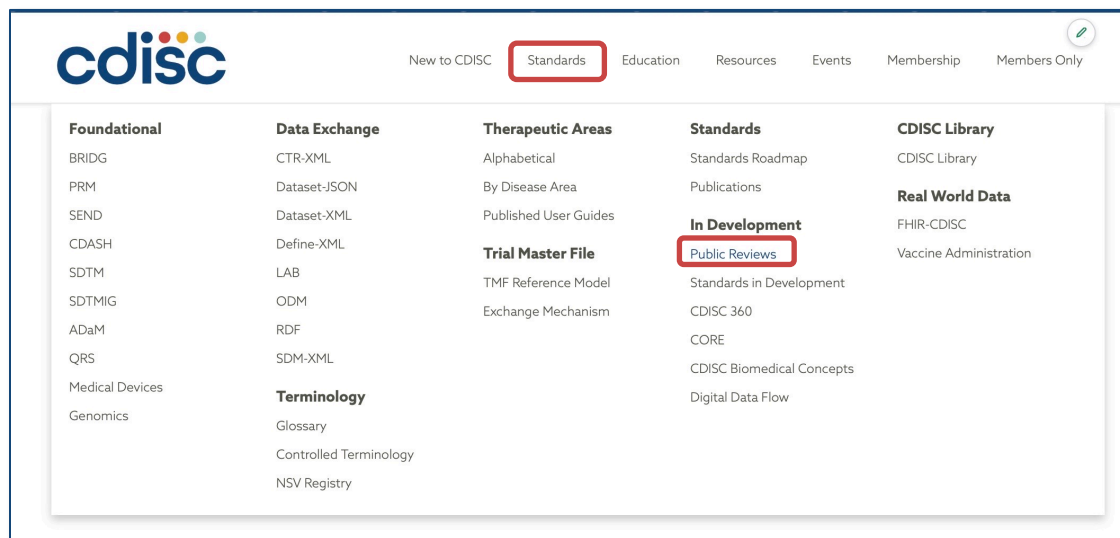
- 3.1 Common Safety Displays
 - 3.1.1 Summary of Demographics
 - 3.1.2 Overall Summary of Treatment-Emergent Adverse Events
 - 3.1.3 Summary of TEAE by System Organ Class and Preferred Term
 - 3.1.4 Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs
 - 3.1.5 Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>
- 3.2 FDA STF
 - 3.2.1 Table 2: Baseline Demographic and Clinical Characteristics, Safety Population

APPENDICES

- Appendix A: Glossary and Abbreviations
- Appendix B: Representations and Warranties, Limitations of Liability, and Disclaimers

Provide Public Review Comments by January 15th!

- <https://www.cdisc.org/public-review/analysis-results-standard-v1-0>



The screenshot shows the CDISC website's navigation menu. The 'Standards' link is highlighted with a red box. Under the 'Standards' section, the 'Public Reviews' link is also highlighted with a red box. The website layout includes the CDISC logo, a navigation bar with links for 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events', 'Membership', and 'Members Only', and a main content area with several columns of links.

Foundational	Data Exchange	Therapeutic Areas	Standards	CDISC Library
BRIDG	CTR-XML	Alphabetical	Standards Roadmap	CDISC Library
PRM	Dataset-JSON	By Disease Area	Publications	Real World Data
SEND	Dataset-XML	Published User Guides	In Development	FHIR-CDISC
CDASH	Define-XML	Trial Master File	Public Reviews	Vaccine Administration
SDTM	LAB	TMF Reference Model	Standards in Development	
SDTMIG	ODM	Exchange Mechanism	CDISC 360	
ADaM	RDF		CORE	
QRS	SDM-XML		CDISC Biomedical Concepts	
Medical Devices	Terminology		Digital Data Flow	
Genomics	Glossary			
	Controlled Terminology			
	NSV Registry			



CDISC ARS Hackathon!



IDEA

HACKATHON

CONNECT



SOLVE

PRESENT



Hackathon Objectives



Drive adoption of
CDISC Analysis
Results Standard



Foster open-source
software tools for
operationalization

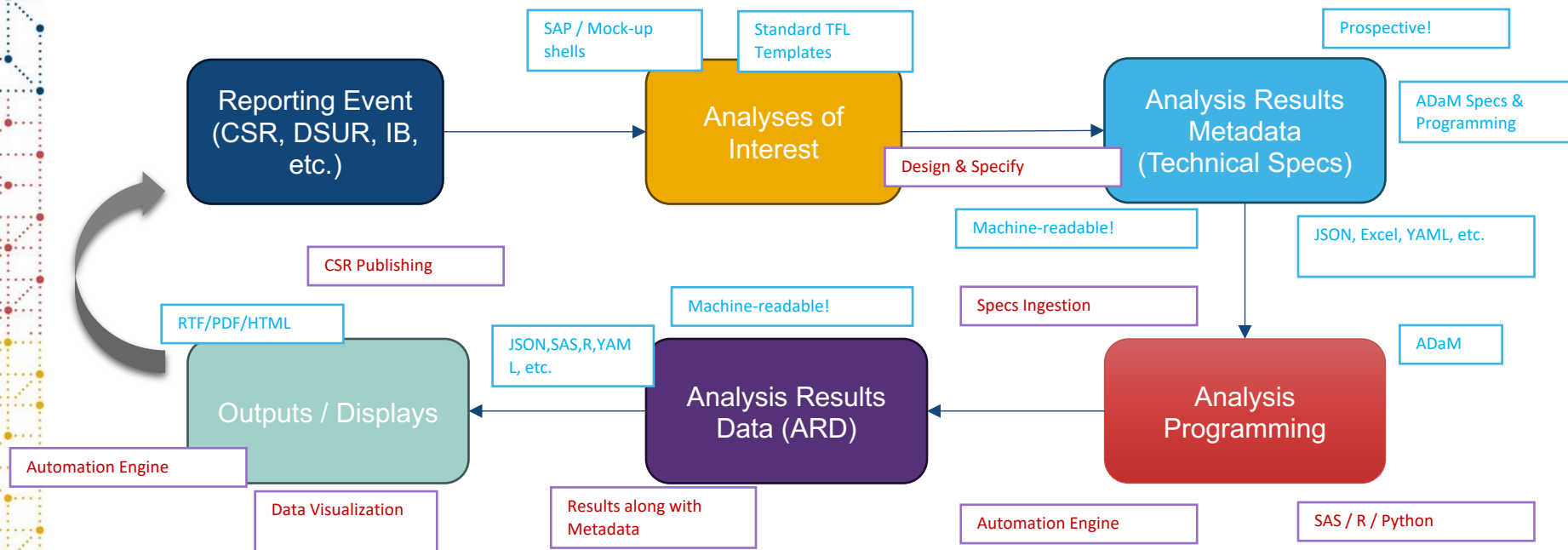


Leveraging hackathon
learnings to enhance
the standards

Hackathon Timeline



ARS Model Supported Workflow and Entry Points





Featured Solutions

ARD Generator by Karl Wallendszus: A SAS-based tool for streamlined data analysis using ARS metadata. **15 mins**

{cards} R Package by Daniel D. Sjoberg: An automated approach to enhance result generation and traceability. **15 mins**

ARS Specification by Paul Thomas: A REACT + TypeScript Basic Front-End for simplified ARS specification. **15 mins**

ARS in Action by Malan Bosman: Demonstrating the real-world potential of the ARS model. **15 mins**

Combined Q & A Session **15 mins**

* At the end of each presentation, we will have a short 2-3 mins Q&A session



Contact Details

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