

CDISC Analysis Results Standards:

Overview with Examples and Implementation Use Cases

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Analysis Results Current State

- Static results created for Clinical Study Report
- May be hundreds of tables in PDF format, often difficult to navigate
- No or limited traceability (e.g., to protocol, SAP, ADaM data)
- Expensive to generate and only used once, no or limited reusability
- ARM v1.0 describes metadata about displays (PDF) and results (at high level), no formal analysis and results model or results data.
- Lack of features to drive automation
- Limited regulatory use cases

Analysis Results Standard



Analysis Results Metadata Technical Specification (ARM-TS), to support automation, traceability, and creation of data displays



Define an Analysis Results Data (ARD) structure, to support reuse and reproducibility of results data



Illustrate and exercise ARD and ARM-TS with a set of common safety data displays

Analysis Results Desired Future State

- Formal model for describing and results as data
- Facilitate automated generation of results
- From electronic (PDF) to machine readable results, with context and metadata to source
- Improved navigation and reusability of results
- Support storage, access, processing and reproducibility of results
- Traceability to Protocol/SAP and to input ADaM data
- Open-source tools to design, specify, build and generate analysis results

ADaM Dataset

Row	STUDYID	USUBJID	MIDS	CEDECOD	WASAEYN	ASTDTM
1	XYZ	000001	HYP0 1	Hypoglycemia	Y	07Sep2012 22:29:00
2	XYZ	000001	HYP0 2	Hypoglycemia	N	10Sep2012 09:12:00
3	XYZ	000001	HYP0 3	Hypoglycemia	N	10Sep2012 23:05:00
4	XYZ	000001	HYP0 4	Hypoglycemia	N	11Sep2012 15:24:00
5	XYZ	000001	HYP0 5	Hypoglycemia	N	18Sep2012 11:39:00
6	XYZ	000002	HYP0 1	Hypoglycemia	N	22Oct2012 13:28:00
7	XYZ	000002	HYP0 2	Hypoglycemia	N	25Oct2012 13:59:00
8	XYZ	000002	HYP0 3	Hypoglycemia	N	17Nov2012 05:01:00

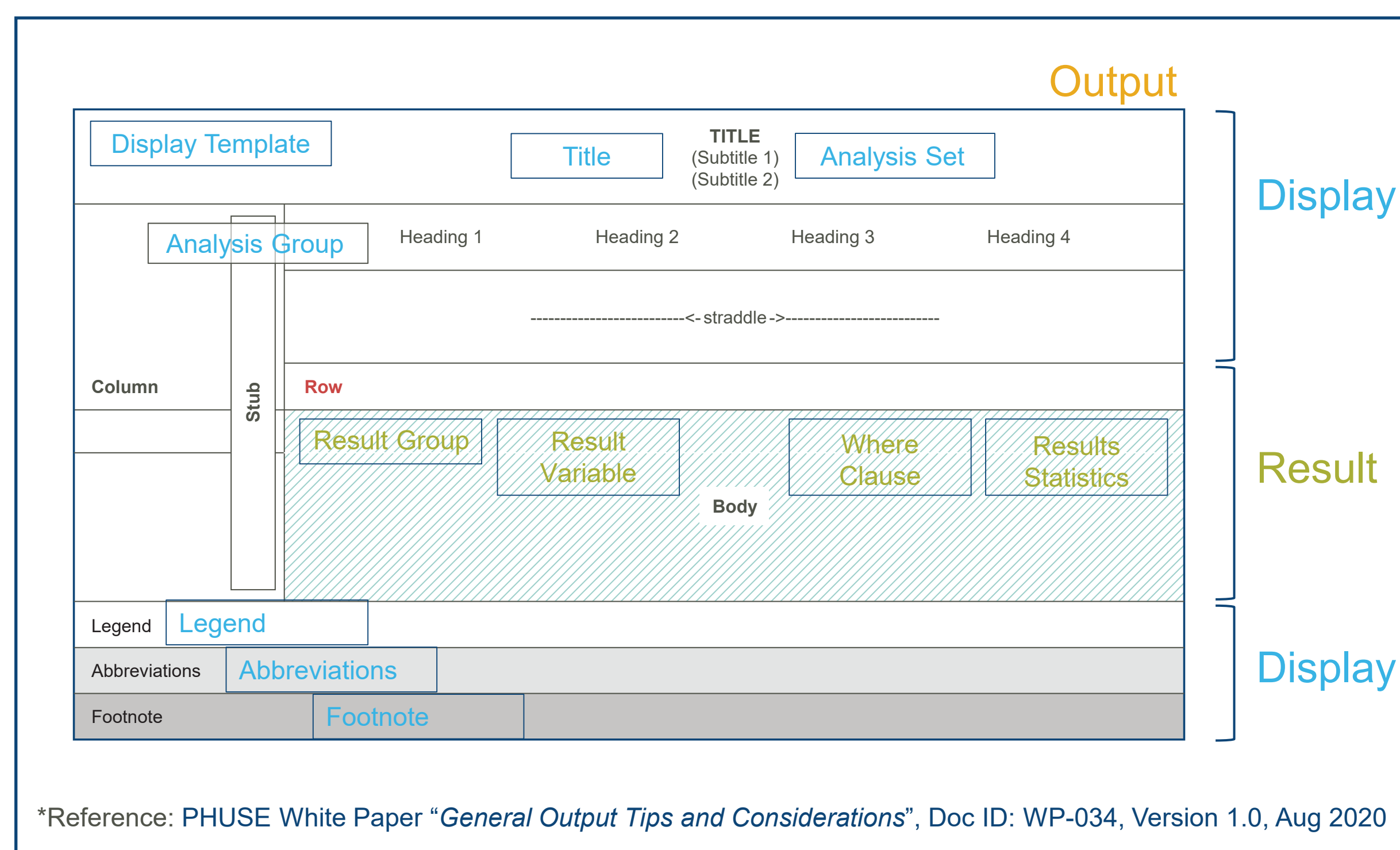
Analysis Results

Baseline	IBAL	Mean (SD)	95% CI	95% CI Lower	95% CI Upper
Baseline	IBAL	Mean (SD)	95% CI	95% CI Lower	95% CI Upper
Week 4	IBAL	Mean (SD)	95% CI	95% CI Lower	95% CI Upper
Week 12	IBAL	Mean (SD)	95% CI	95% CI Lower	95% CI Upper

ARM for define.xml

Display Identifier	Display Name	Result Identifier	Parameter	Analysis Variable	Analysis Reason	Analysis Purpose	Analysis Dataset
IBAL	Mean Change from Baseline to Week 4	IBAL	Mean Change from Baseline to Week 4	IBAL	Mean Change from Baseline to Week 4	Mean Change from Baseline to Week 4	IBAL

Key Metadata Elements of a Table*



Extended ARM Elements

Output

- Identifiers
- Study ID
- Task
- Type
- Style
- File

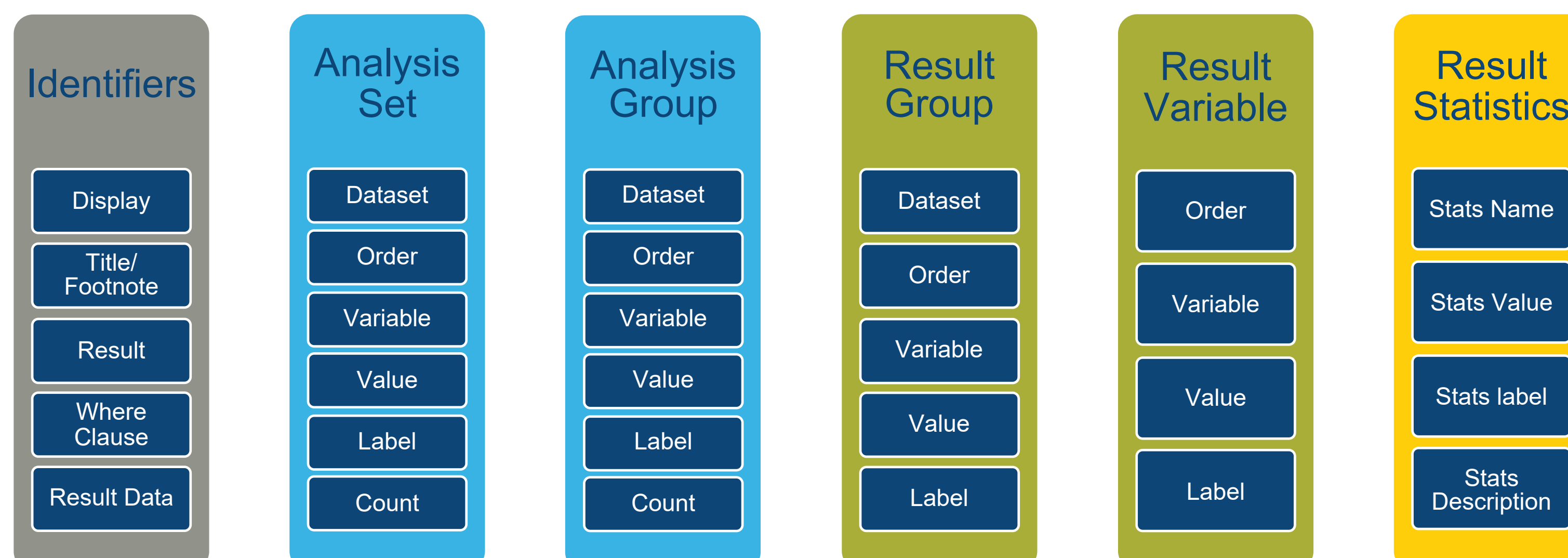
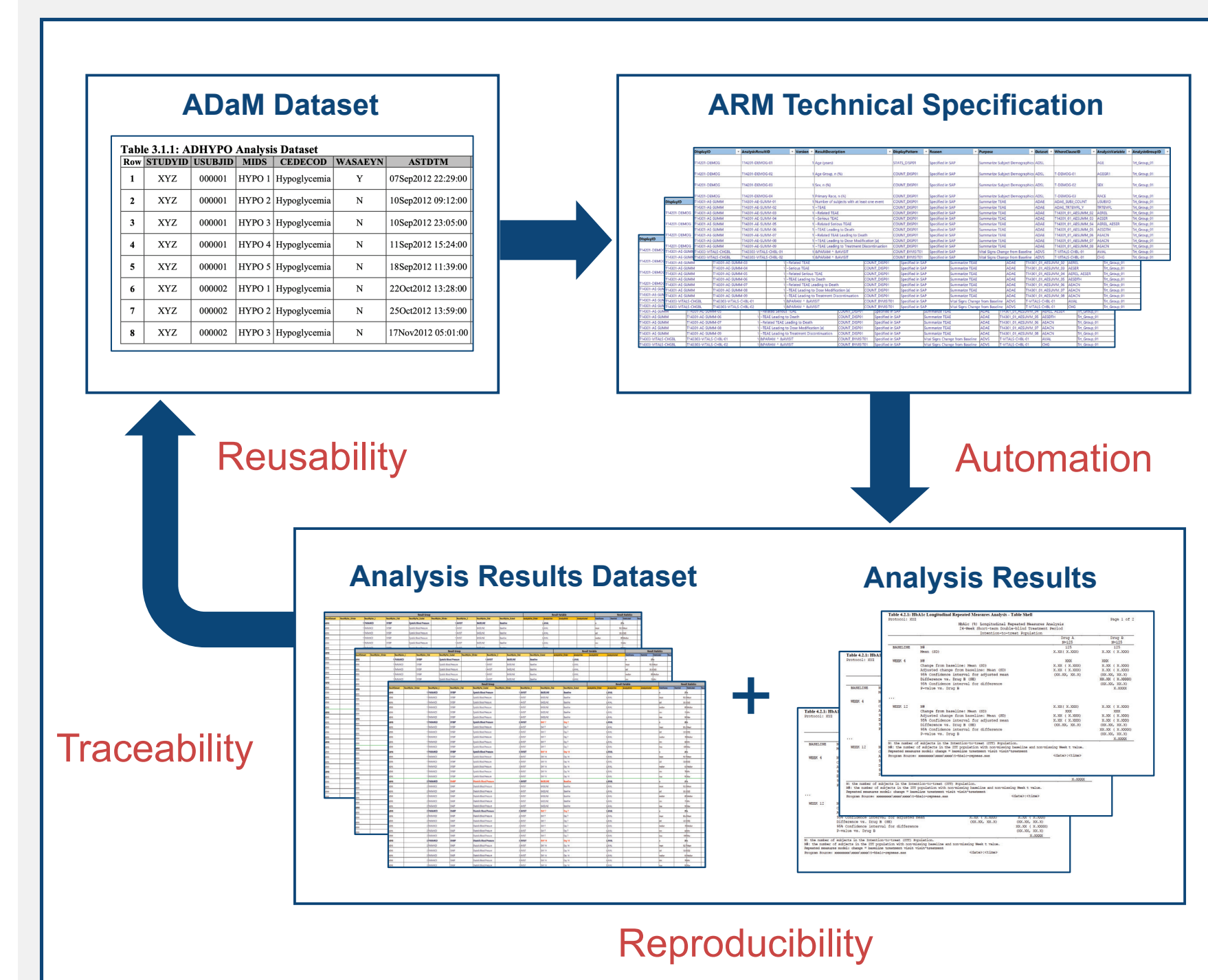
Display

- Identifiers
- Display Template
- Title/Footnote
- Analysis Set
- Analysis Group

Results

- Identifiers
- Result Group
- Result Variable
- Where Clause
- Results Statistics
- Prog. Code Ref

Analysis Results Dataset Model - Key Elements



Analysis Results Standards Deliverables

- Content Scope: Common Safety Analyses
- Machine readable mock displays made accessible through an "eTFL portal"
- ARM Technical Specification
- New Model and Implementation Guide to represent analysis results
- Terminology
- Identification of Conformance Rules

Review target
Q4, 2022