



2026 CDISC China Interchange

Building Better Analysis Workflows

CDISC ARS Implementation

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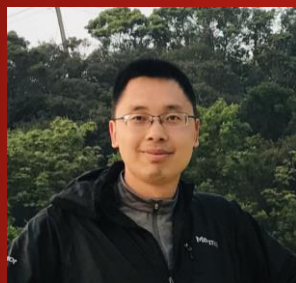


Agenda

1. Analysis Result Standard Instruction
2. ARD Journey
3. ARS ARD Exploration



Speakers



Carlos Pang

Statistical Programmer

Novartis

Over 14 years of experience as statistical programming. Led statistical programming teams in supporting multiple global Phase I–III clinical trials across various therapeutic areas. Pioneered and advanced the application of R programming in clinical trial workflows and regulatory submissions. Developed a range of practical tools to improve programming efficiency and streamline clinical trial workflows.



Analysis Result Standard Instruction

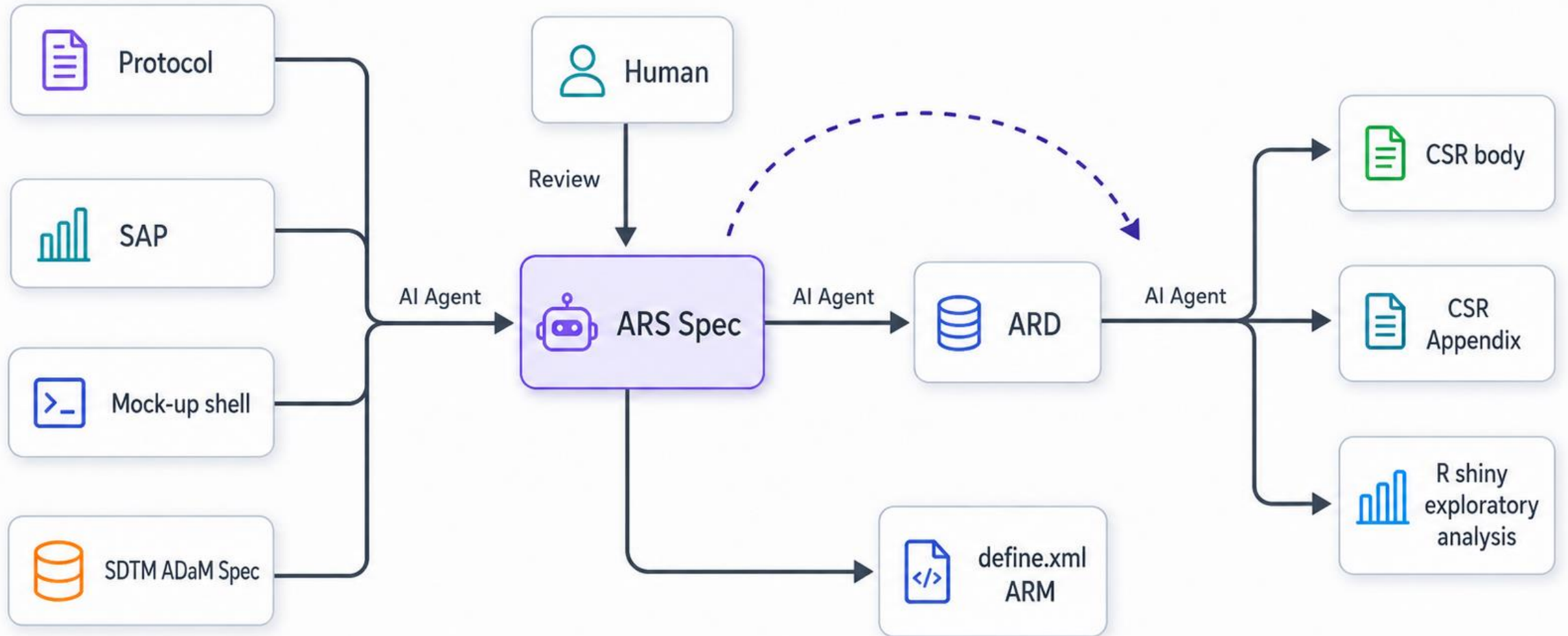


Purpose

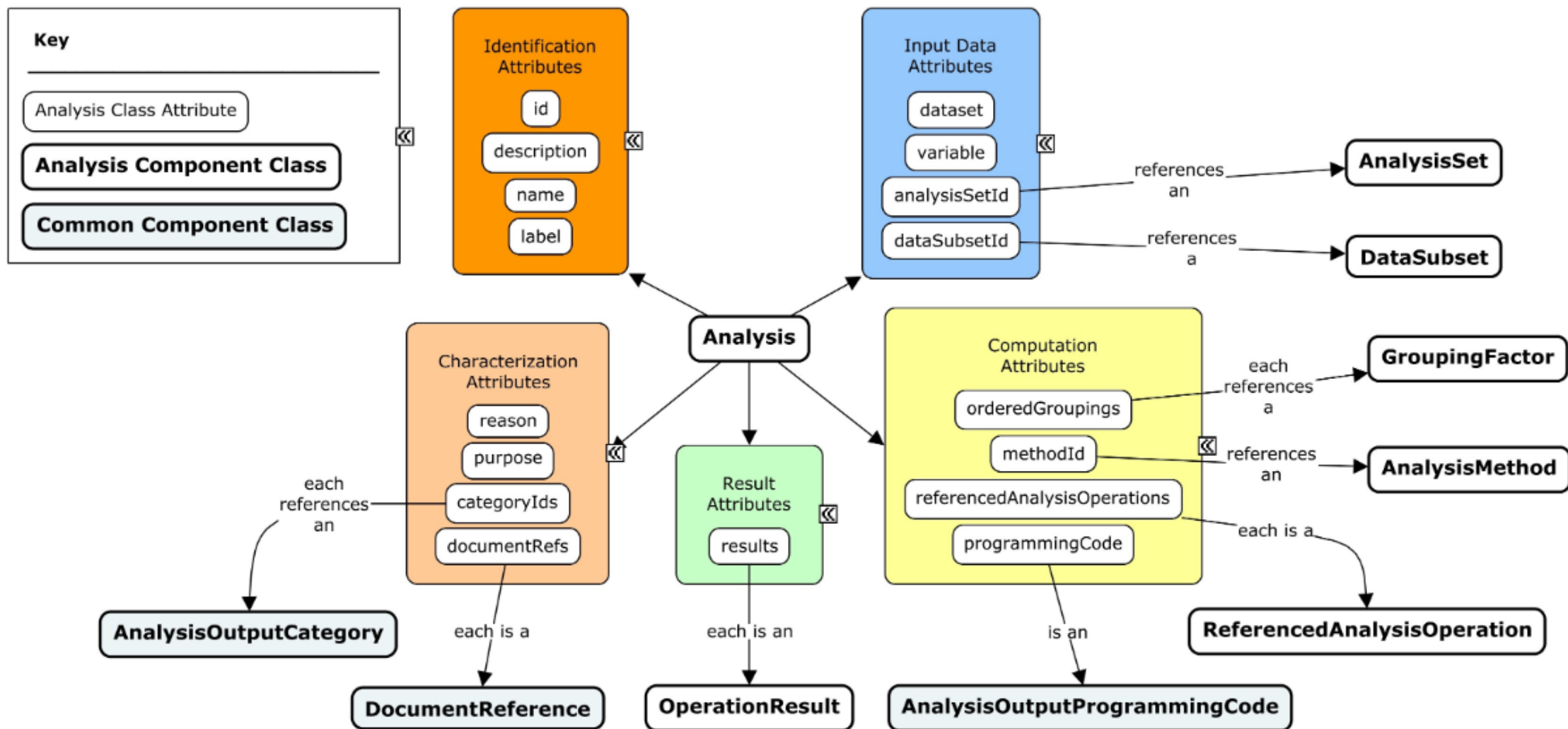


Potential Workflow

Spec-driven development (SDD)



ARS Spec



ARD Definition

id of analysis

the value of the id attribute of the analysis that generated and contains the result

1 row per result value

There is 1 row for each instance of the OperationResult class

operationId

the value of the operationId attribute of the instance of the OperationResult class that is represented on the row

group info

the values of all of the **groupingId**, **groupId**, or **groupValue** attributes that are present in **resultGroups** attribute of the instance of the OperationResult class that is represented on the row.



ARD

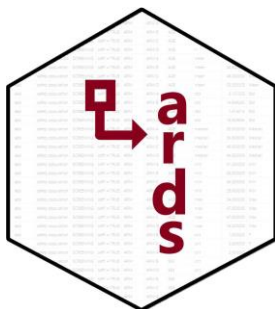
Instances of the OperationResult class are represented in a tabular format



ARD Journey



R Packages to create ARD



cards

- Handles both simple and complex summaries
- Composable and extensible API via cardx
- Integrates with the wider pharmaverse ecosystem
 - ARDs produced can be consumed by packages such as gtsummary and tfrmt

ards

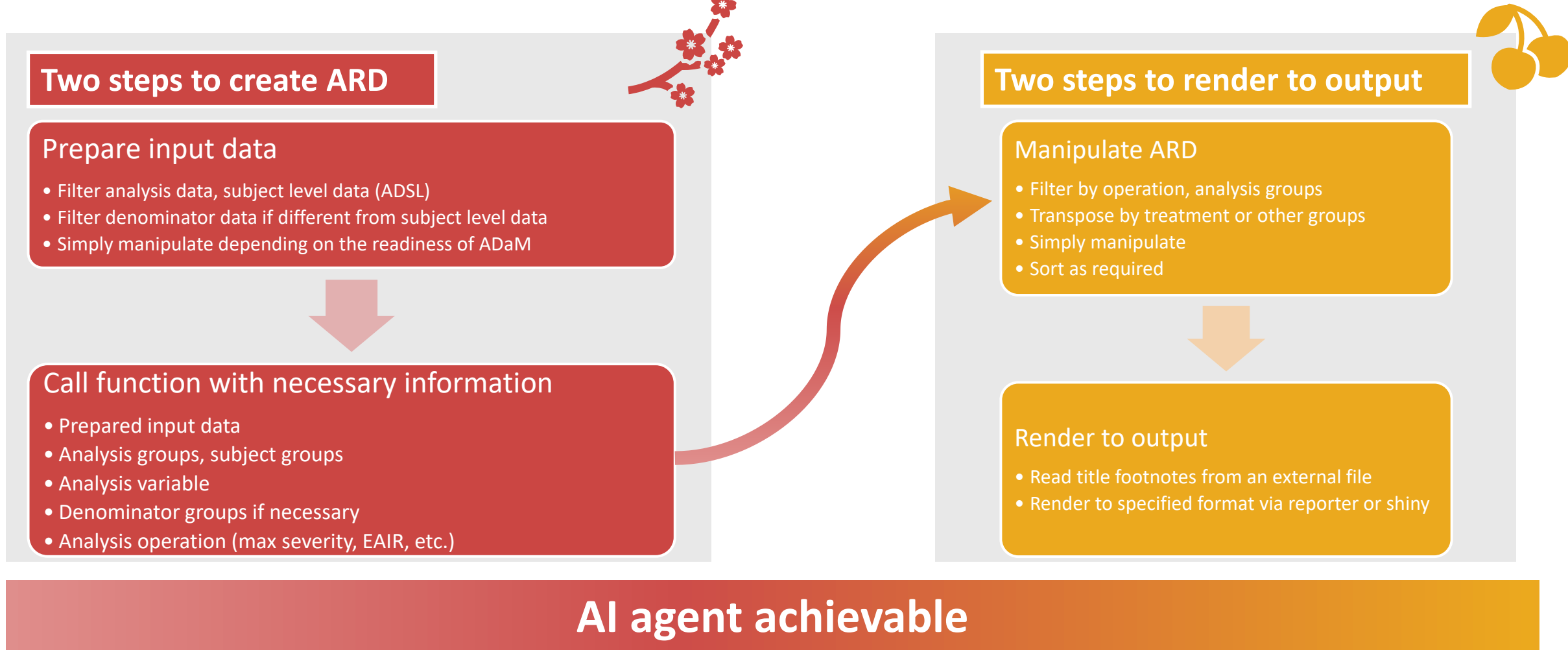
- Designed to add calculated analysis result into ARD

Customize package

- Precisely align with the analysis and layout requirements
- Maximize workload reduction before and after ARD creation

Automation with ARD - AwARD

Workflow





Automation with ARD - AwARD

Example - Frequency Table

```
indata |>
  create_ard_freq(
    subj_indata,
    grp_var="aebodsys aeDecod",
    subj_grp_id="trt_a1",
    operation='n_percent eair'
  )
```

- **grpX, operation** are required in CDISC ARD
- **grpXn** to store frequency for descending sorting
- **display1** to store indented groups for table presentation
- **valc** also contains combination of n and %
- **indata_link** (optional) drills down to patient level data

grp1_var	grp1n	grp1	grp2_var	grp2n	grp2	display1	display2	subj_grp1_id	subj_grp1n	subj_grp1	method	operation	val	valc
aebodsys		Infections and infestations	aeDecod		#Total	Infections and infestation	Infections and infest	trt_a1	2	ACTIVE2	frequency	nsubj		
aebodsys		Infections and infestations	aeDecod		#Total	Infections and infestation	Infections and infest	trt_a1	2	ACTIVE2	frequency	n_percent		
aebodsys		Infections and infestations	aeDecod		Upper respirato	Upper respiratory trac	Infections and infest	trt_a1	2	ACTIVE2	frequency	nsubj		
aebodsys		Infections and infestations	aeDecod		Upper respirato	Upper respiratory trac	Infections and infest	trt_a1	2	ACTIVE2	frequency	n_percent		
aebodsys		Infections and infestations	aeDecod		Urinary tract inf	Urinary tract infection	Infections and infest	trt_a1	2	ACTIVE2	frequency	nsubj		
aebodsys		Infections and infestations	aeDecod		Urinary tract inf	Urinary tract infection	Infections and infest	trt_a1	2	ACTIVE2	frequency	n_percent		
aebodsys		Infections and infestations	aeDecod		Nasopharyngitis	Nasopharyngitis	Infections and infest	trt_a1	2	ACTIVE2	frequency	nsubj		
aebodsys		Infections and infestations	aeDecod		Nasopharyngitis	Nasopharyngitis	Infections and infest	trt_a1	2	ACTIVE2	frequency	n_percent		
aebodsys		Infections and infestations	aeDecod		Respiratory trac	Respiratory tract infect	Infections and infest	trt_a1	2	ACTIVE2	frequency	nsubj		
aebodsys		Infections and infestations	aeDecod		Respiratory trac	Respiratory tract infect	Infections and infest	trt_a1	2	ACTIVE2	frequency	n_percent		
aebodsys		Infections and infestations	aeDecod		Pneumonia	Pneumonia	Infections and infest	trt_a1	2	ACTIVE2	frequency	nsubj		
aebodsys		Infections and infestations	aeDecod		Pneumonia	Pneumonia	Infections and infest	trt_a1	2	ACTIVE2	frequency	n_percent		



Automation with ARD - AwARD

Function Overview

create_ard_freq

- Different types of frequency analysis by simple level and hierarchical levels
- Combined analysis results for post processing workload reduction
- *Supports specified analysis such as EAIR, EAOR*
- *Handles specified data rules, such as max severity, different denominators*
- Provide option to drill down to patient level data

create_ard_summary

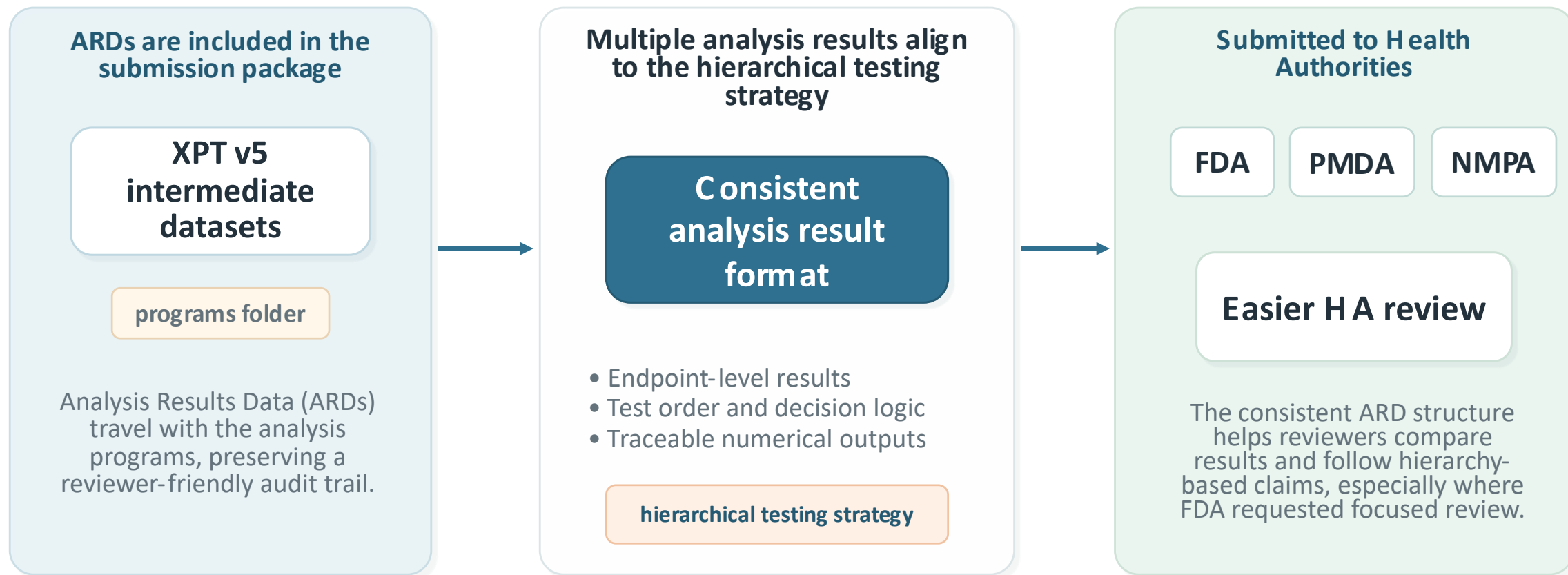
- Different types of descriptive statistics summary
- Combined analysis results for post processing workload reduction
- *Supports specified decimal precision*
- Provide option to drill down to patient level data

format_ard_mix

- An easy solution to combine frequency analysis results and descriptive statistics summary, such as for demographics analysis
- Well-fitted ARD structure for post processing workload reduction

use_template

Health Authority Submission



Submission-ready ARDs turn program outputs into a consistent, traceable review layer for HAs.

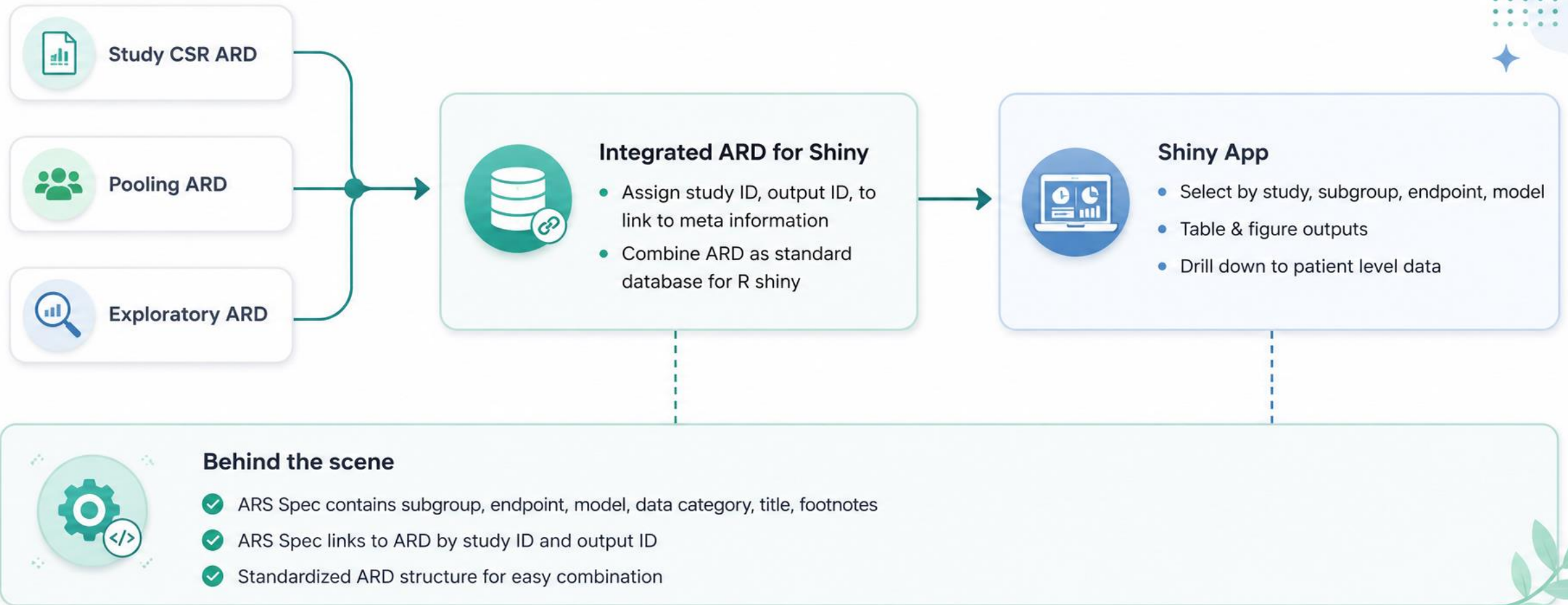


ARS ARD Exploration



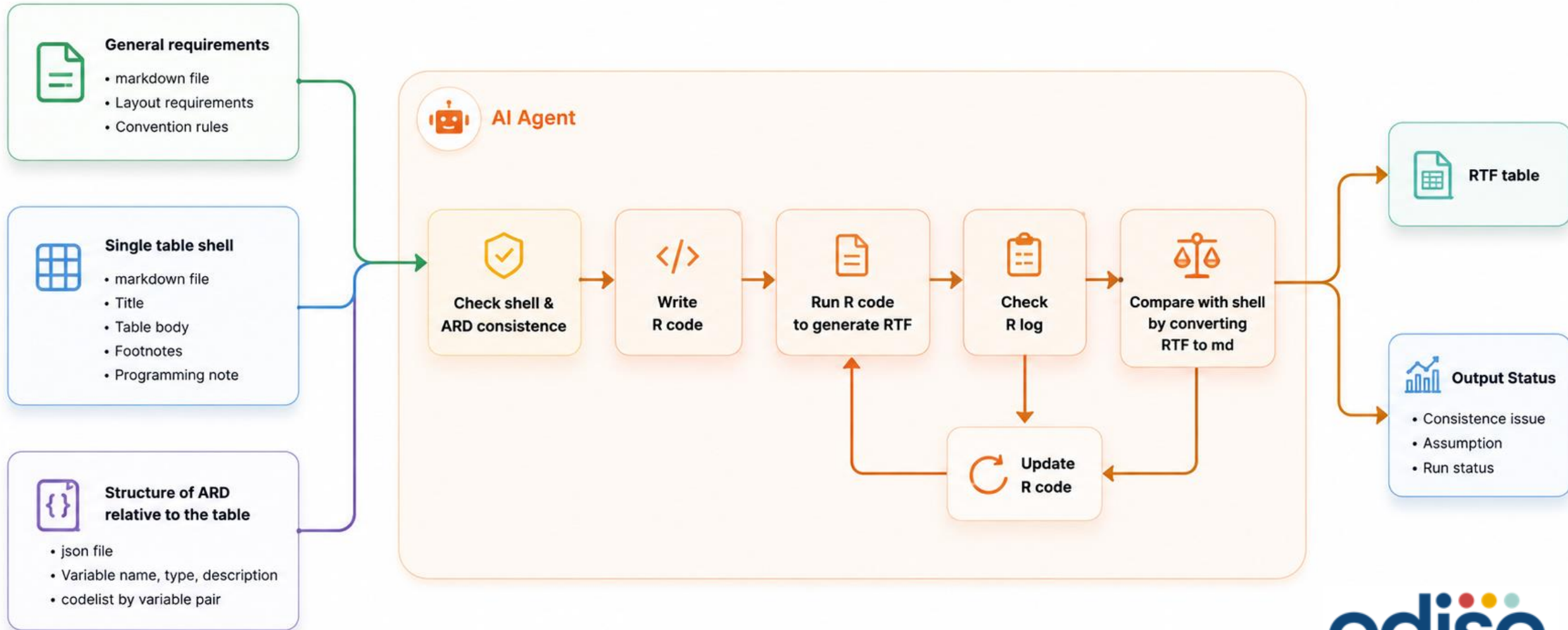
ARS-based R Shiny App

Workflow

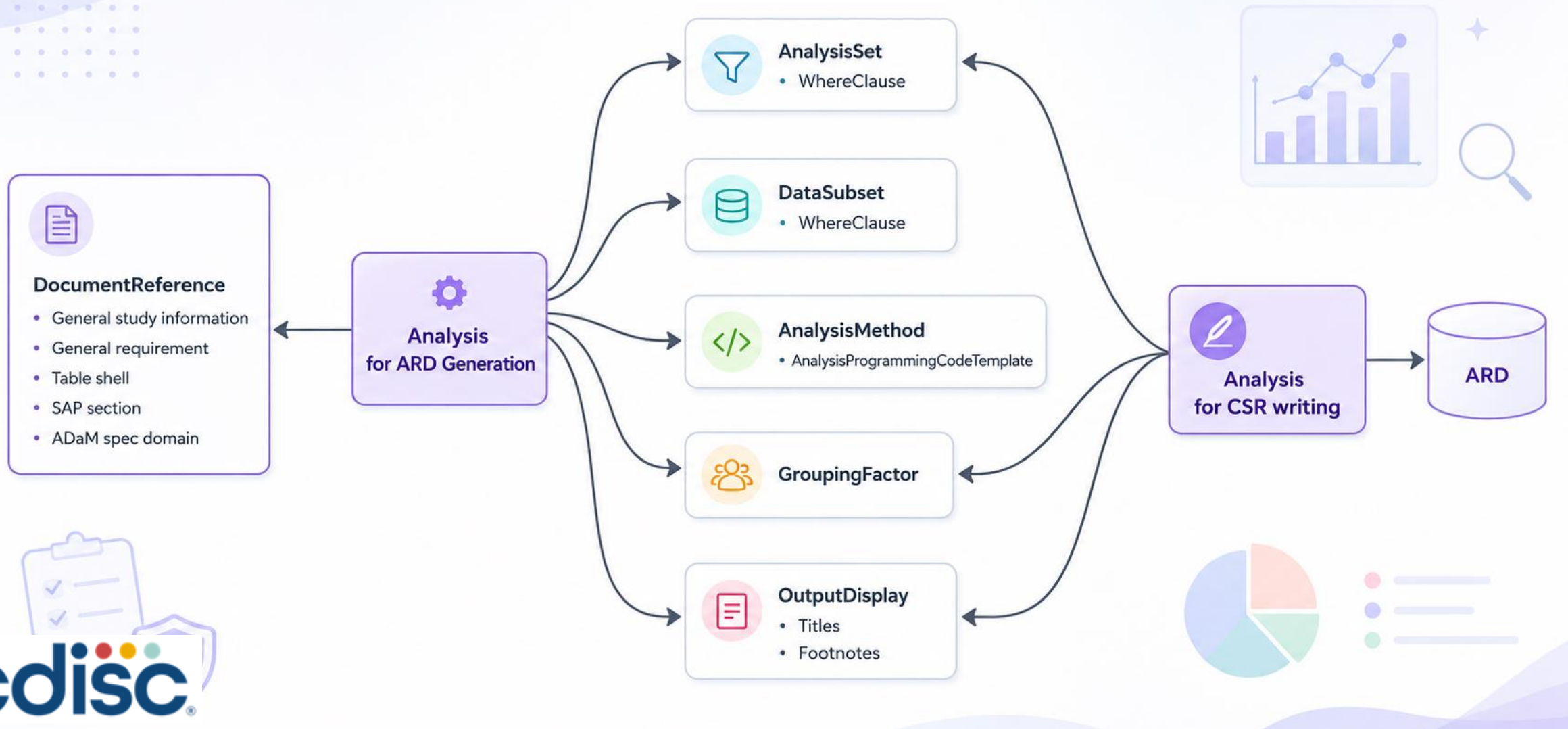


AI Agent – TFL Generation

Render ARD to table



AI Agent – ARS Spec



Key Takeaways and Future Direction

- CDISC ARS provides a strong conceptual framework
- A well-designed ARS should support multiple purposes
- The most useful solution is usually the one that balances structure, traceability, and maintainability.
- Starting with automation, evolving into AI Agent, and ultimately building an enterprise-level database to enable ARS submission.



*Building on Today
Shaping the Future*

