A PARADIGM SHIFT IN CLINICAL DATA PREPARATION

THE POWER OF GRAPHICAL DATA FLOW

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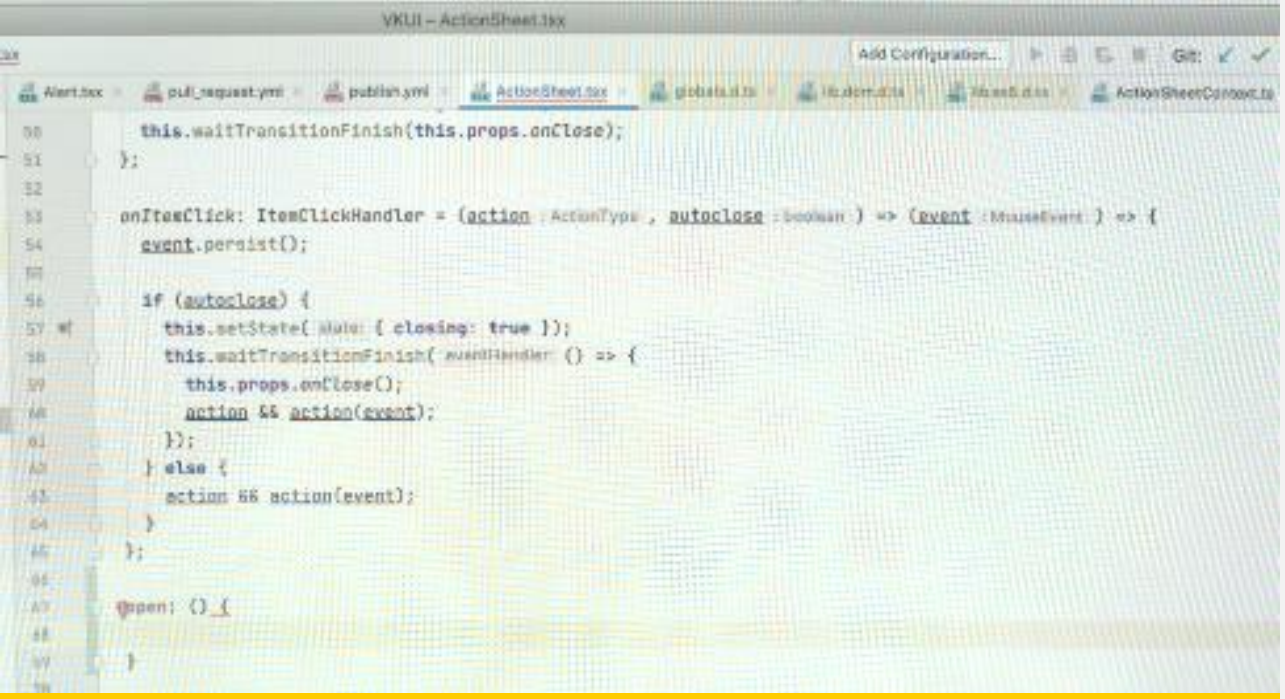
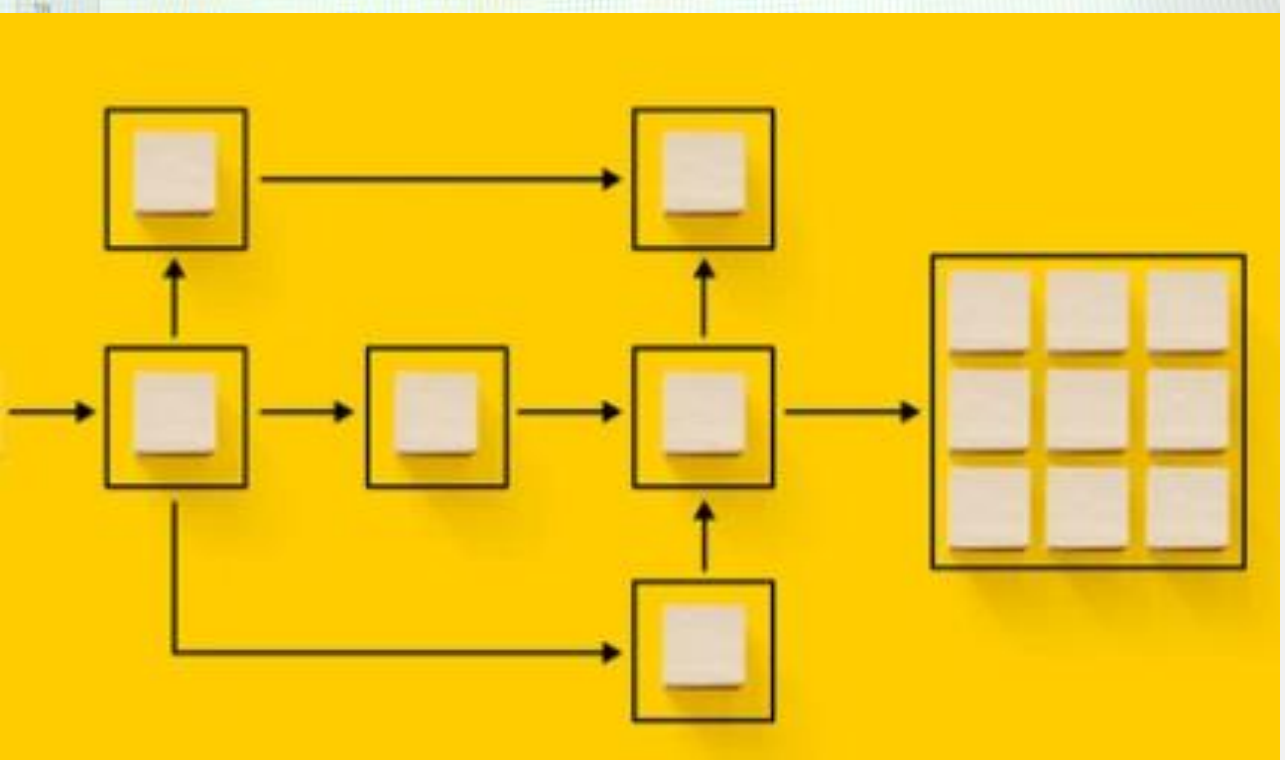
Nimble Clinical Research



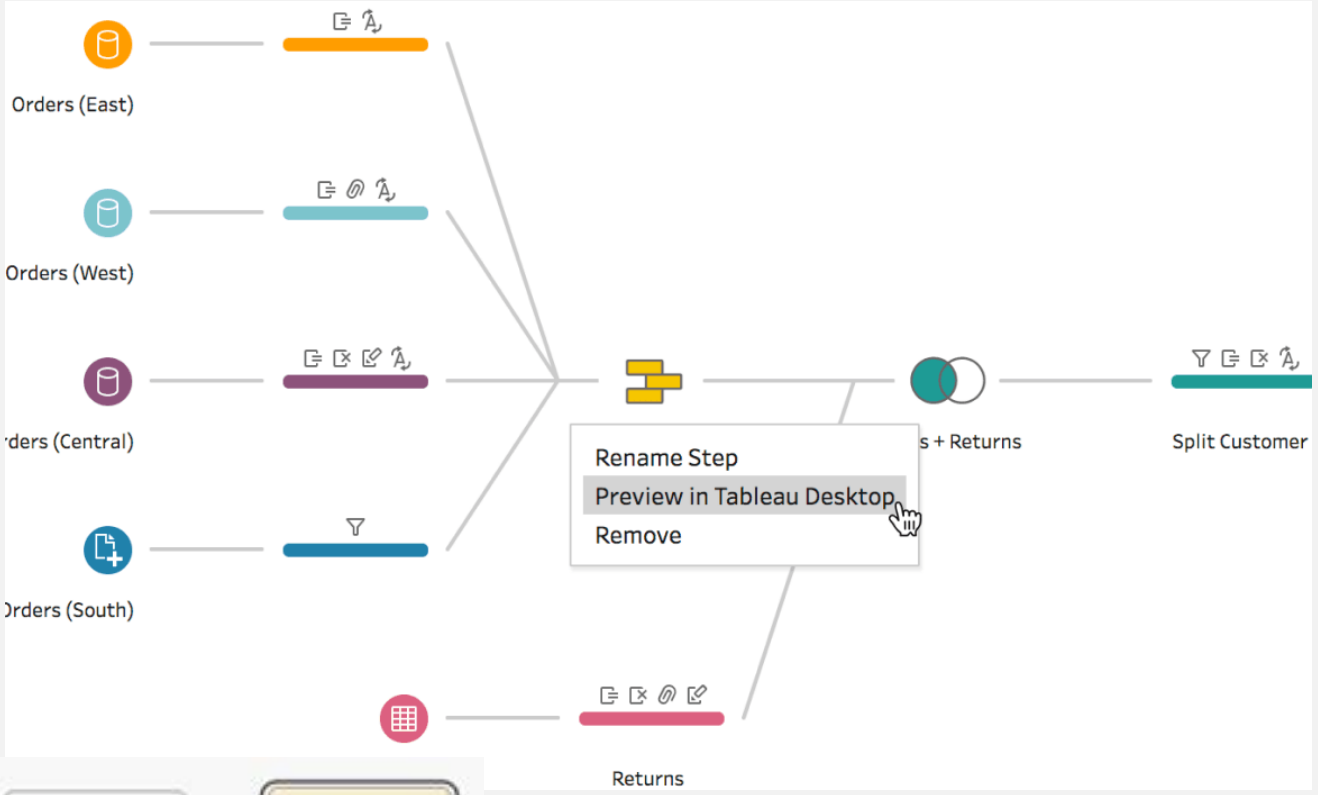


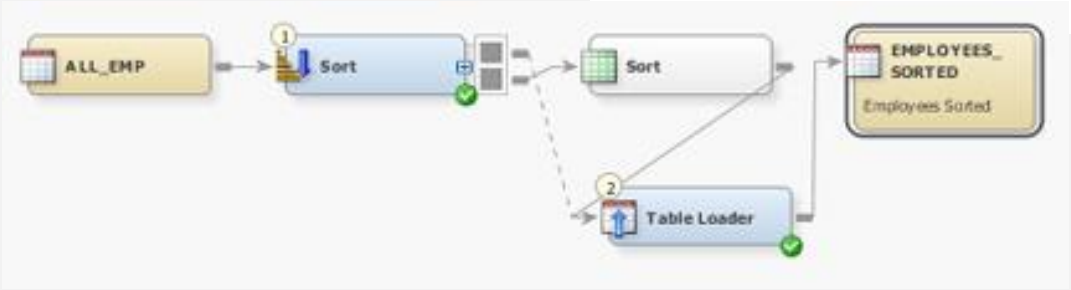
INTRODUCTION

- **Traditional Statistical Programming**: Tedious, & error-prone
- **Graphical Data Flow**: A visual approach to data integration and transformation that is intuitive and efficient
- **The Imperative**: With the changing technology landscape, and the demand for real-time insights, there's an opportunity for change.

CURRENT OPTIONS

- **Tableau Prep**: Interactive platform for data cleansing and preparation with a drag-and-drop interface.
- **Alteryx Designer**: End-to-end platform offering data blending, analytics, and visualization capabilities.
- **KNIME**: Open-source analytics platform, harnessing data through modular workflows.
- **Talend**: Cloud-based tool focusing on big data integration and management through a visual approach.
- **SAS Based Solutions:**
  - Data Integration Studio
  - SAS Enterprise Guide
  - SAS Studio





CHALLENGES

Complex Logic & Custom Code

- Graphical interfaces might not capture the nuances or allow for highly customized code.
- May not support SAS or R

Lack of Targeted tools

- Lack of tools targeting CDISC standards and Clinical Data needs

Performance & Scalability

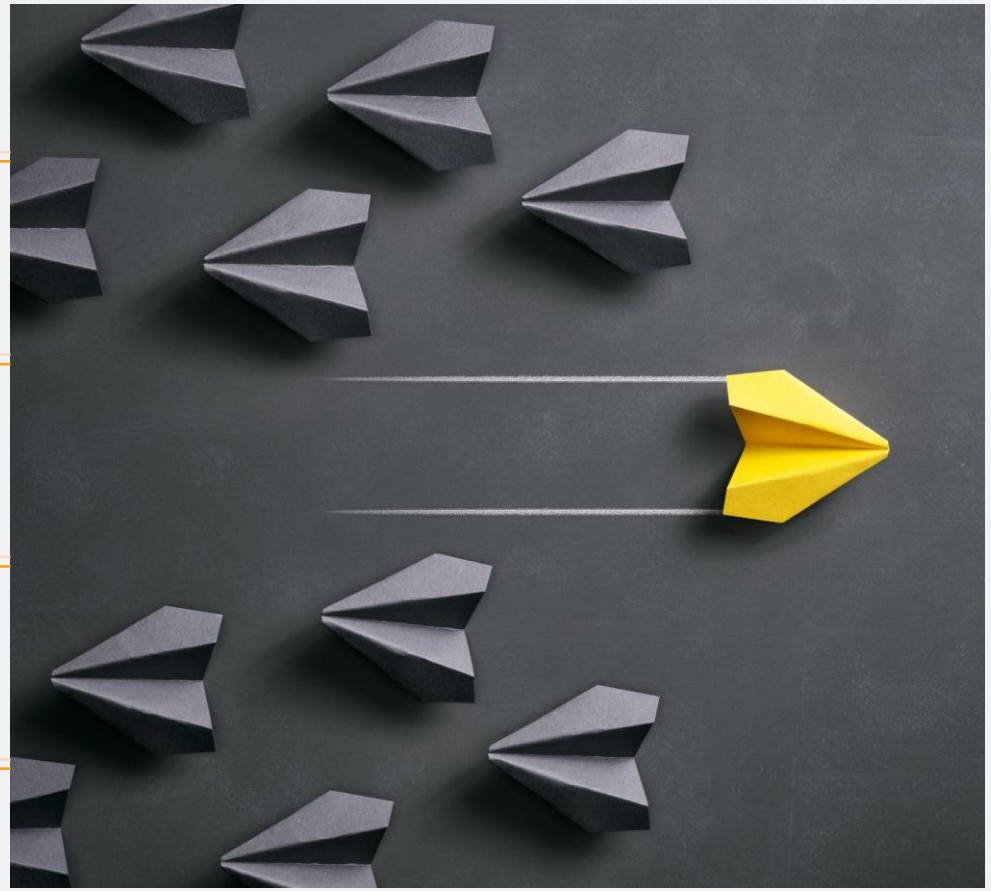
- For large datasets and complex operations, concerns about the performance and scalability

Interoperability & Integration

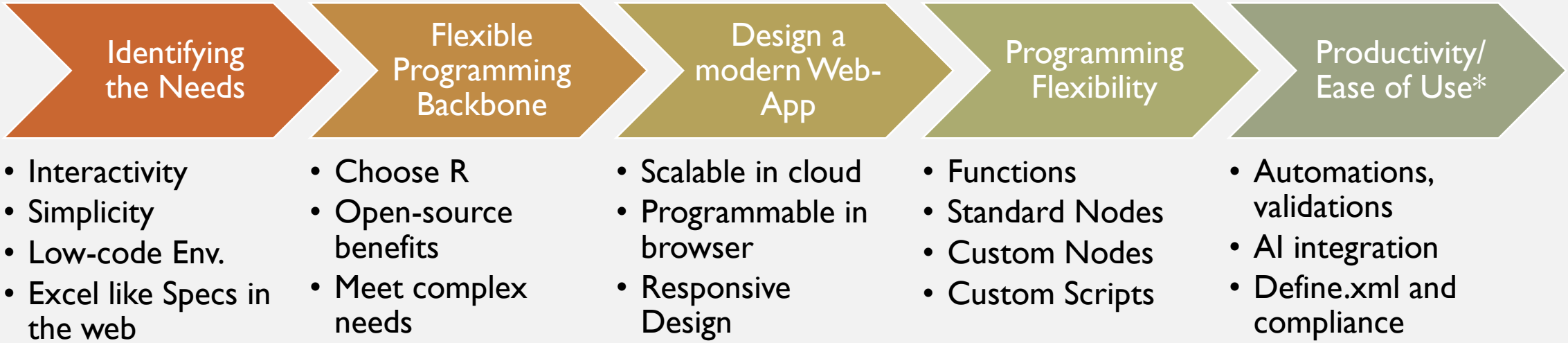
- Integration with existing workflow may be challenging.

WHY NOW IS THE TIME FOR CHANGE?

Evolving Technology Landscape	Shift towards R & cloud, with integration capabilities with powerful open-source technology solutions making graphical data flow viable.
Industry Pressures for Efficiency	With increasing pressures for faster drug development and data analysis, efficiencies in data management become critical.
Collaboration	As pharma becomes more interdisciplinary, tools that can bridge the knowledge gap and provide self-service capabilities in demand.
Demand for Real-time Analysis	The need for instant insights and real-time data analysis drives the adoption of more intuitive tools.
Integration of AI/ML Capabilities	Web based platforms increasingly offer AI/ML integration

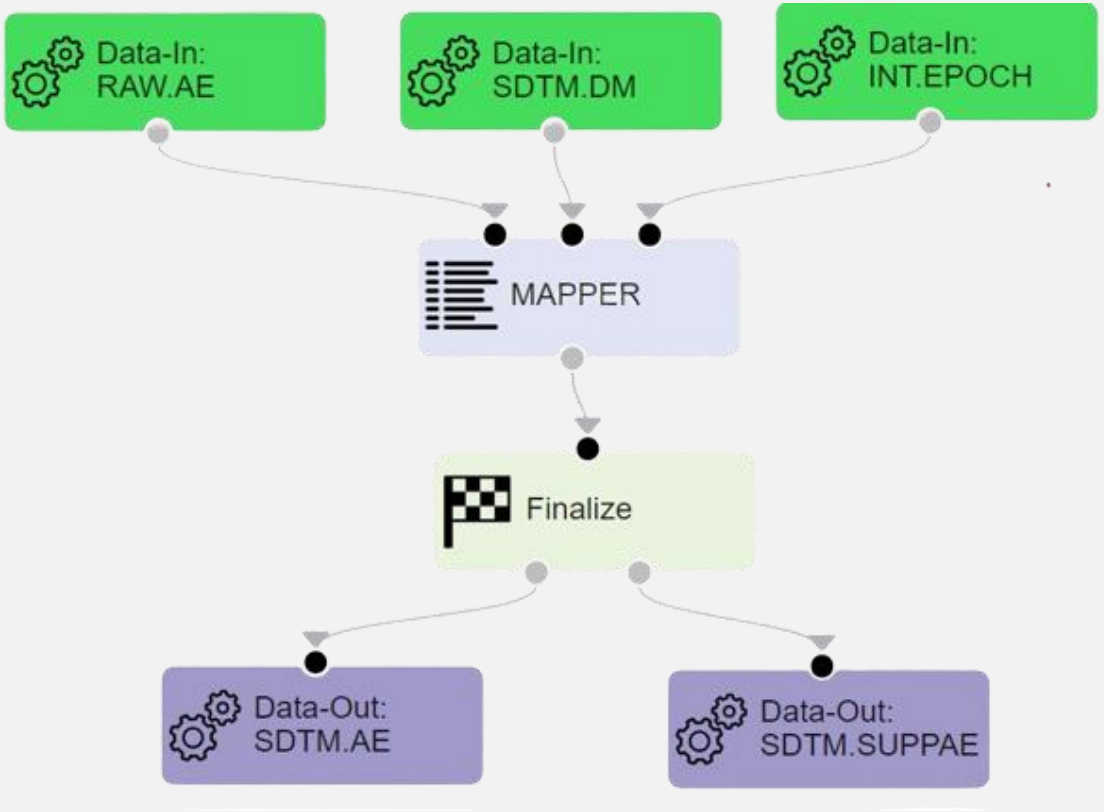


OUR JOURNEY: EMBRACING THE GRAPHICAL APPROACH



*To be ready by end of 2023

USE CASE: SDTM

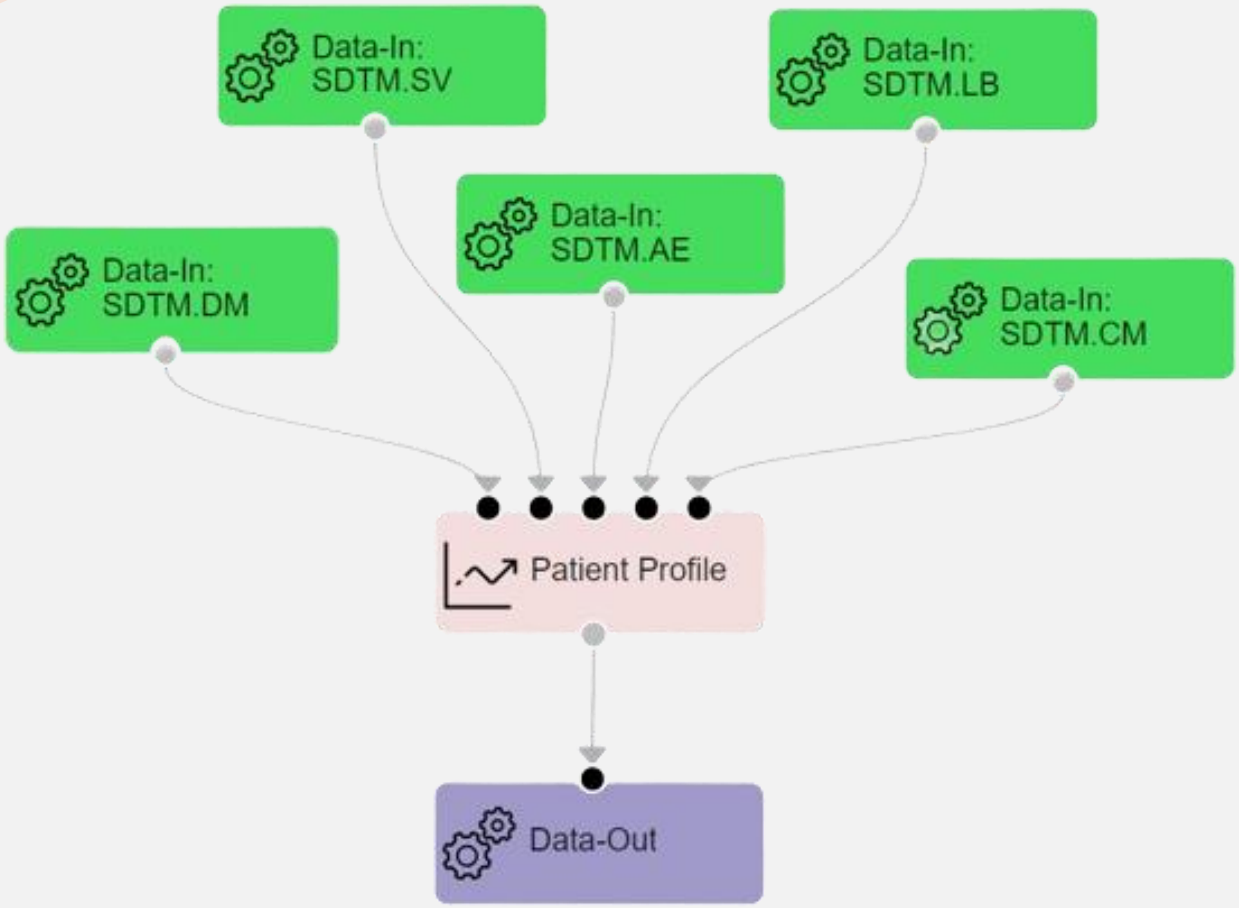


Data In	Read Source Data
Mapper	Map variable, test-level, & value-level data in an excel like structure, embedded with R-code snippets for granular mapping control
Finalize	Split, names, labels, sort, order variables, trim, basic checks per CDISC expectation
Data Out	Save datasets to target data libraries

USE CASE: SDTM SPECIFICATIONS

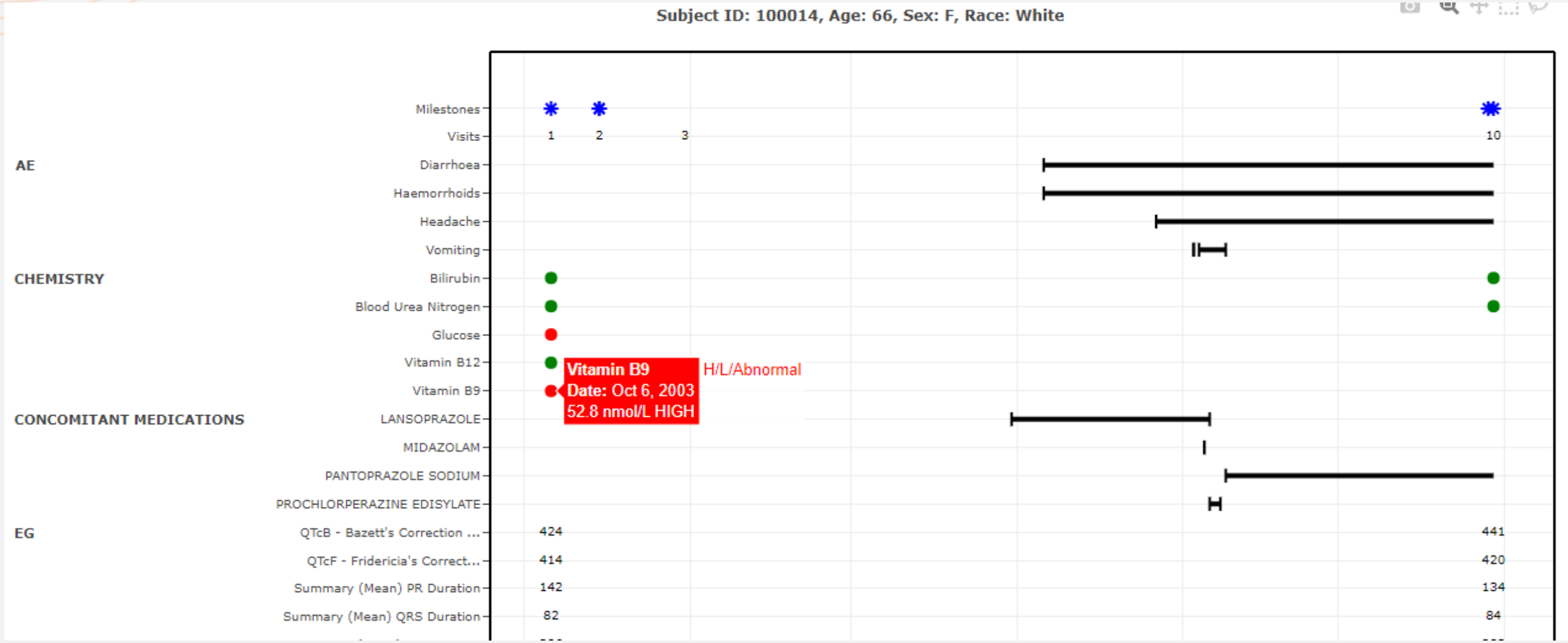
Dataset	Source	Target	Destinatio	ID Variable	Function	Params	Label	Type	Map Name
VS1	CNO	CNO	SUPP	VISITNUM					
VS1	F_STATUS	STATUS	SUPP	VSDTC			Status		
VS1	PAG_NAME	PAGE	CO						
VS1	PATNO		NA						
VS1	PNO		NA						
VS1	REC_ID		NA						
VS1	R_DRUG		NA						
VS1	SCTRY		NA						
VS1	TAREA		NA						
VS1	VSDAT	VSDTC			conv2DTC	"sasdt":"df$VSDAT","sastm":"df$VSTIM"	Date/Time of Measurements	C	ISO 8601
VS1	EVENT_ID	VISITNUM			unschVisit	"date" : "df$VSDTC"	Visit Number	N	VISITNUM
VS1		VSDY					Study Day of Vital Signs	N	
VS1	VSTIM		NA						
VS1	VSYN		NA						NY
VS1		STUDYID			Value	"code": "'NIM-01'"	Study Identifier	C	
VS1		DOMAIN			Default		Domain Abbreviation	C	DOMAIN
VS1		USUBJID			Value	"code": "paste('NIM-01', dfCNO, dfPATNO, sep =\"-\")"	Unique Subject Identifier	C	
VS1		VSSEQ			Default		Sequence Number	N	
VS1	VSTEST	VSTESTCD			Default		Vital Signs Test Short Nan	C	
VS1	VSTESTCD		NA						
VS1		VSTEST			Default		Vital Signs Test Name	C	
VS1	VSORRES	VSORRES					Result or Finding in Origi	C	

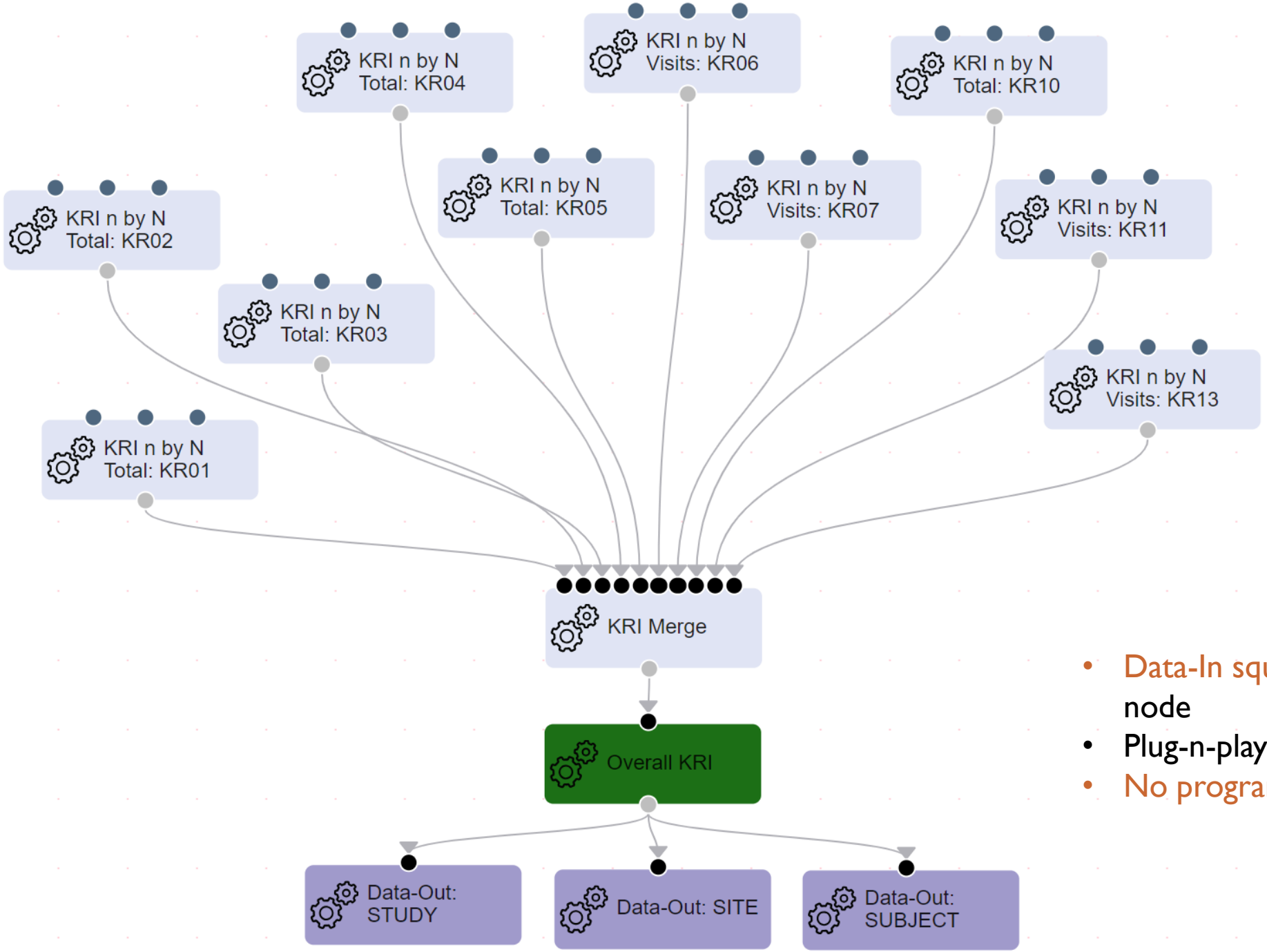
USE CASE: GRAPHICAL PATIENT PROFILE



- Plug-n-play: Plug a SDTM dataset to feed into graphical patient profiles
- No programming background needed
- The output dataset, feeds into graphical patient profile

USE CASE: GRAPHICAL PATIENT PROFILE

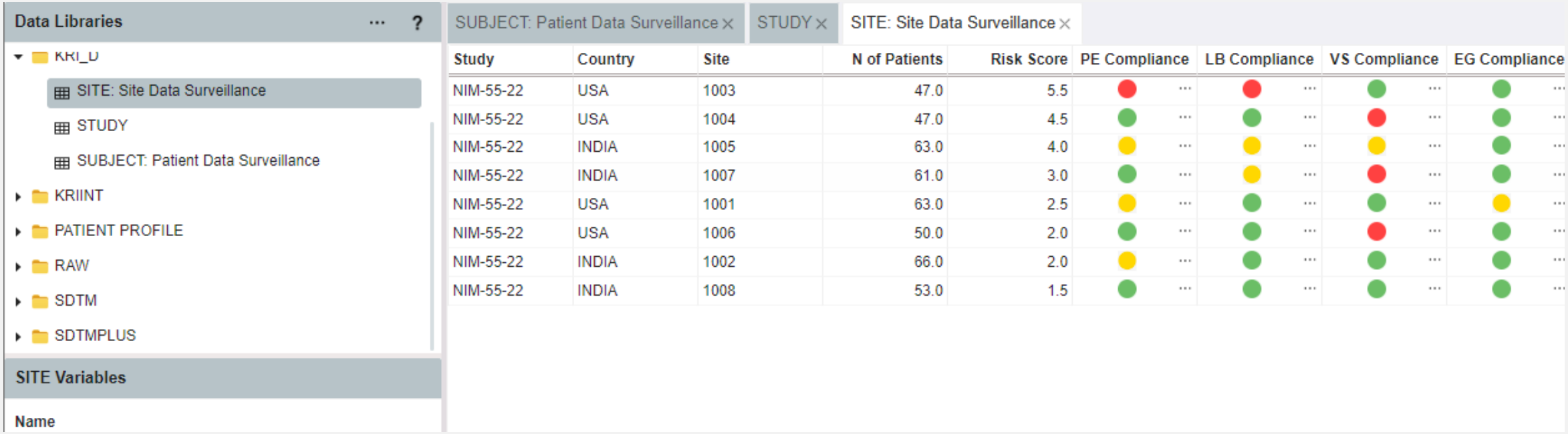




USE CASE: RBQM

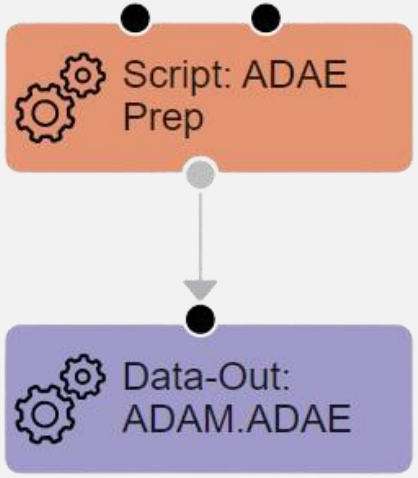
- Data-In squeezed into * icon on top of node
- Plug-n-play KRIs design
- No programming background needed

USE CASE: RBQM



Study	Country	Site	N of Patients	Risk Score	PE Compliance	LB Compliance	VS Compliance	EG Compliance
NIM-55-22	USA	1003	47.0	5.5				
NIM-55-22	USA	1004	47.0	4.5				
NIM-55-22	INDIA	1005	63.0	4.0				
NIM-55-22	INDIA	1007	61.0	3.0				
NIM-55-22	USA	1001	63.0	2.5				
NIM-55-22	USA	1006	50.0	2.0				
NIM-55-22	INDIA	1002	66.0	2.0				
NIM-55-22	INDIA	1008	53.0	1.5				

USE CASE: ADAM CREATION



- ADaM programming harder to standardize
- For now, all the ADAE programming in a single node
- For efficiency, code can be created offline and pasted in the web

CONCLUSION

One will not turn to graphical data flow for show,
but for the promise of better workflow!

- Lower-level nodes in other applications such as join, sort and so on… are not convenient to meet complex clinical data analysis needs

- Flexible Scripting node needed for complex custom programming

- Sophisticated high-level nodes can facilitate:
  - Low code environment
  - Plug-n-play solutions
  - Self-service environment
  - Rapid Prototyping

THANK YOU

Q & A

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