

Single Day Event

Digital Specifications

Enabling the next generation of clinical trials

Nekzad Shroff - VP, Head of Clinical Solutions

Rebecca Bates - Sr Director, Biostatistics

Saama Inc



Clinical Trial Specifications Today

- Spreadsheets
- Manually created and managed
- Hard to read, interpret
- Human effort intensive
- Cannot enable process automation

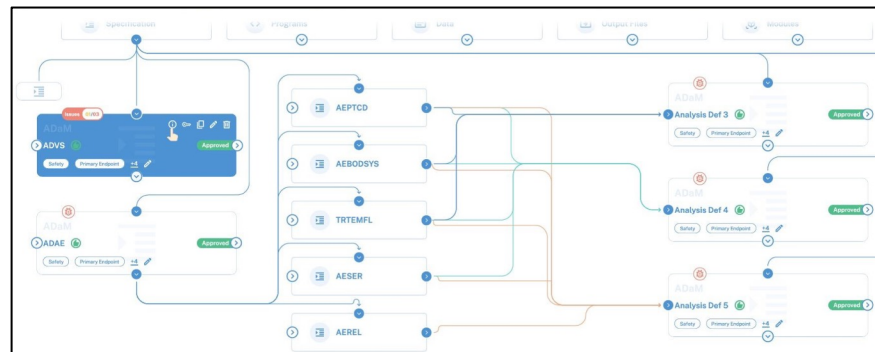
	A	B	C	D	E	F
1	Order	Dataset	Variable	Label	Data Type	Length
2	1	ADQSADAS	STUDYID	Study Identifier	text	12
3	2	ADQSADAS	SITEID	Study Site Identifier	text	3
4	3	ADQSADAS	SITEGR1	Pooled Site Group 1	text	3
5	4	ADQSADAS	USUBJID	Unique Subject Identifier	text	11
6	5	ADQSADAS	TRTSDT	Date of First Exposure to Treatment	integer	8
7	6	ADQSADAS	TRTEDT	Date of Last Exposure to Treatment	integer	8
8	7	ADQSADAS	TRTP	Planned Treatment	text	20
9	8	ADQSADAS	TRTPN	Planned Treatment (N)	integer	8
10	9	ADQSADAS	AGE	Age	integer	8
11	10	ADQSADAS	AGEGR1	Pooled Age Group 1	text	5
12	11	ADQSADAS	AGEGR1N	Pooled Age Group 1 (N)	integer	8
13	12	ADQSADAS	RACE	Race	text	32
14	13	ADQSADAS	RACEN	Race (N)	integer	6
15	14	ADQSADAS	SEX	Sex	text	1
16	15	ADQSADAS	ITFL	Intent-to-Treat Population Flag	text	1
17	16	ADQSADAS	EFFFL	Efficacy Population Flag	text	1
18	17	ADQSADAS	COMP24FL	Completers of Week 24 Population Flag	text	1
19	18	ADQSADAS	AVISIT	Analysis Visit	text	8
20	19	ADQSADAS	AVISITN	Analysis Visit (N)	integer	8
21	20	ADQSADAS	VISIT	Visit Name	text	17
22	21	ADQSADAS	VISITNUM	Visit Number	integer	8
23	22	ADQSADAS	ADY	Analysis Relative Day	integer	6



The Digitization Opportunity

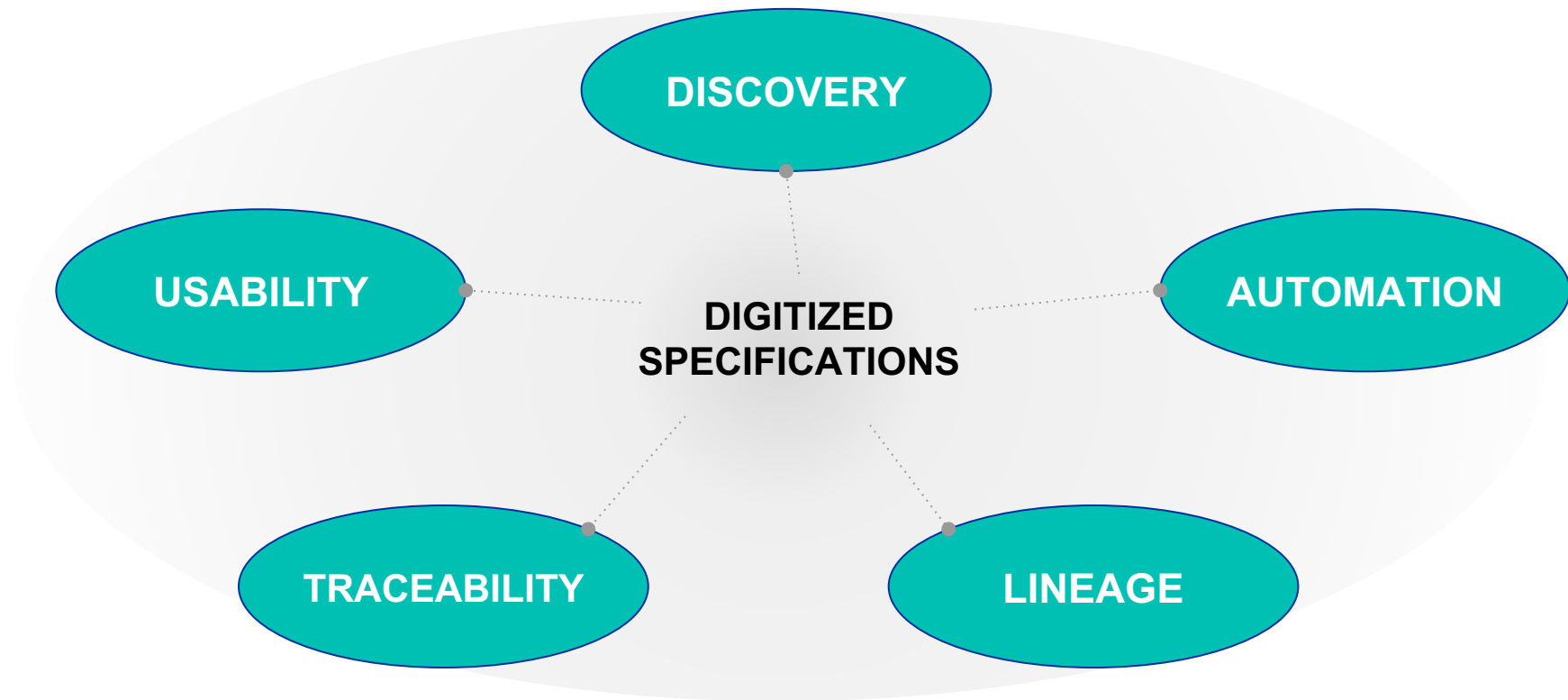
What do we refer to as digitization?

- Specifications managed in a knowledge graph
- Easily rendered for human interpretation
- Platform for automation
- CDISC 360 Foundation





The Power of Digitization - 5 ways

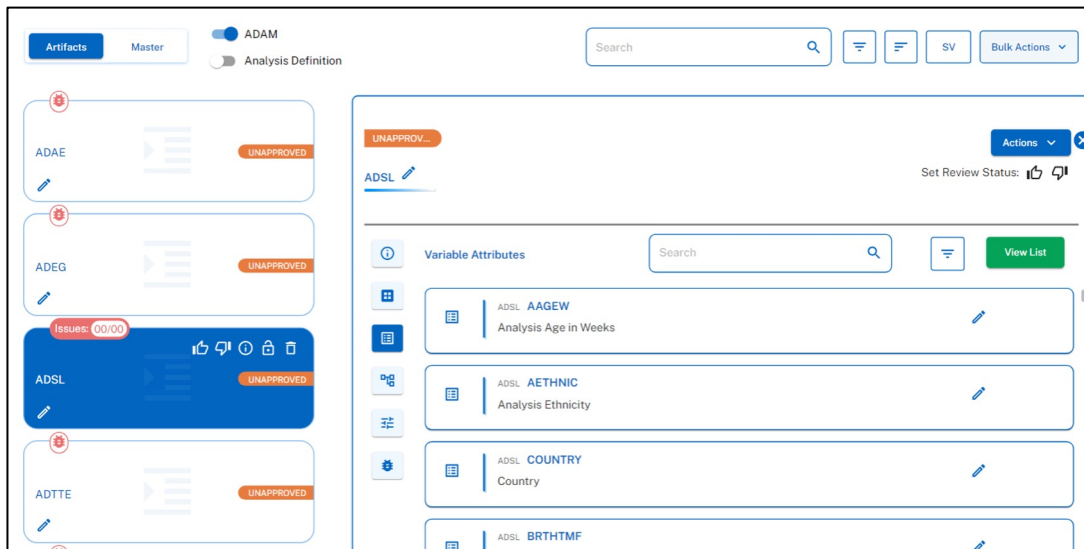




1. Enhanced Discovery

Digitization enables contextual search which is very powerful way to track and find assets

- Remove “tribal knowledge” dependency
- Search across studies - Bust the folder siloes
- Search within specs
- Easily identify relevant assets without reading cumbersome documents



2. Improved Usability

Digitizing specifications with an intuitive interface enables easy management for improved usability

- Eliminate data duplication and typical spreadsheet-inherent errors
- Huge improvement over hunting across spreadsheet tabs to interpret
- Rationalize - single common definition of a variable in one place
- Linkages make it easy to see the impact of changes to a variable

The screenshot displays the Phuse system interface. At the top, a navigation bar includes tabs for 'Base Attributes', 'Where Clauses (2)', 'CodeLists (0)', 'Derivation Methods (2)', 'Comments (0)', 'Documents (0)', and 'Dictionary(0)'. The 'Derivation Methods (2)' tab is active. Below the navigation bar, the 'Derivation Method' section features a search bar and two entries:

- Algorithm: Average Triplicate Values**
Average the triplicate values
Linked To: ADEG.AVISIT EQ Baseline
- Algorithm: Post Baseline LOCF**
LOCF values only using post baseline values
Linked To: ADEG.AVISIT NE Baseline

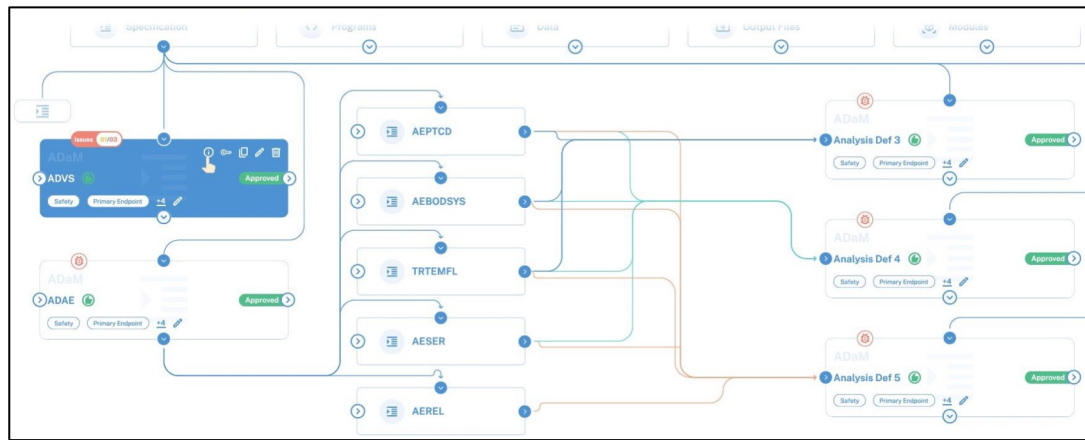
To the right, the 'Attributes' section displays a table with the following data:

Derivation Methods ID	Type	Expression Context
MD-ab0aa896426247d8b...	Computation	..
Expression Code	Document	Pages
..	SAP	29

3. Seamless Traceability

Digitization enables clear linkages between variables, analysis definitions, code and outputs in a Network View

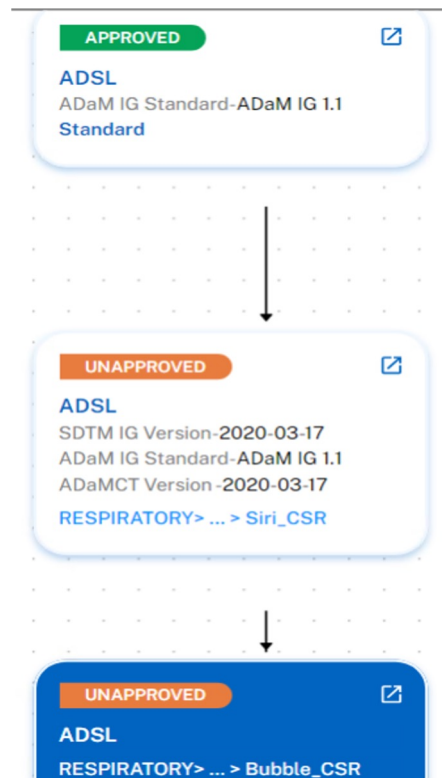
- Understanding the big picture of the analysis - which data led to what outcome and which variables were involved - ALL IN ONE PLACE - for:
- **New programmers** re-using prior work
- **Primary / QC programmers** trying to validate analysis
- **Biostatisticians** verifying the analysis or replicating it



4. Lineage and Dependencies

Digitization simplifies versioning of specifications by providing clear lineage and history

- Audit trails easy to manage and access, since all changes and versions are tracked in the system in digitized form
- With the knowledge graph visualization, interpreting of complex lineage and related dependencies becomes very intuitive

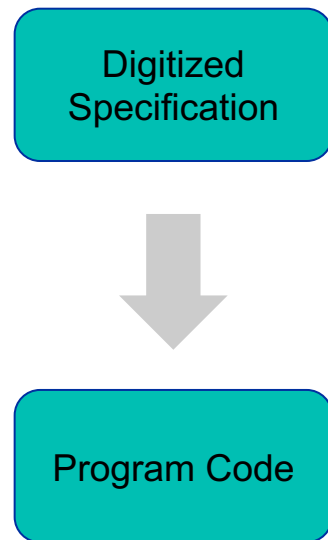




5. Platform for Automation

Digitized specs is foundational for future machine automation of coding and spec generation

- Standardization of datasets and specifications enables us to leverage modern technologies to auto-generate code which implements the specification
- Significant productivity boost from being able to auto generate the base version of the code quickly; the programmer can be much more productive
- Safety analyses in particular are much more standardized and can be auto-driven using the metadata available in specs





The Global Healthcare Data Science Community

Contact Channels

UK +44 1843 609600
office@phuse.global
phuse.global

Social Media

@phusetwit
/phusebook
/phusetube
/company/phuse

Nekzad Shroff
VP, Head of Clinical Solutions
Saama
nekzad.shroff@saama.com



Rebecca Bates
Sr Director, Biostatistics
Saama
rebecca.bates@saama.com

