

Abstract



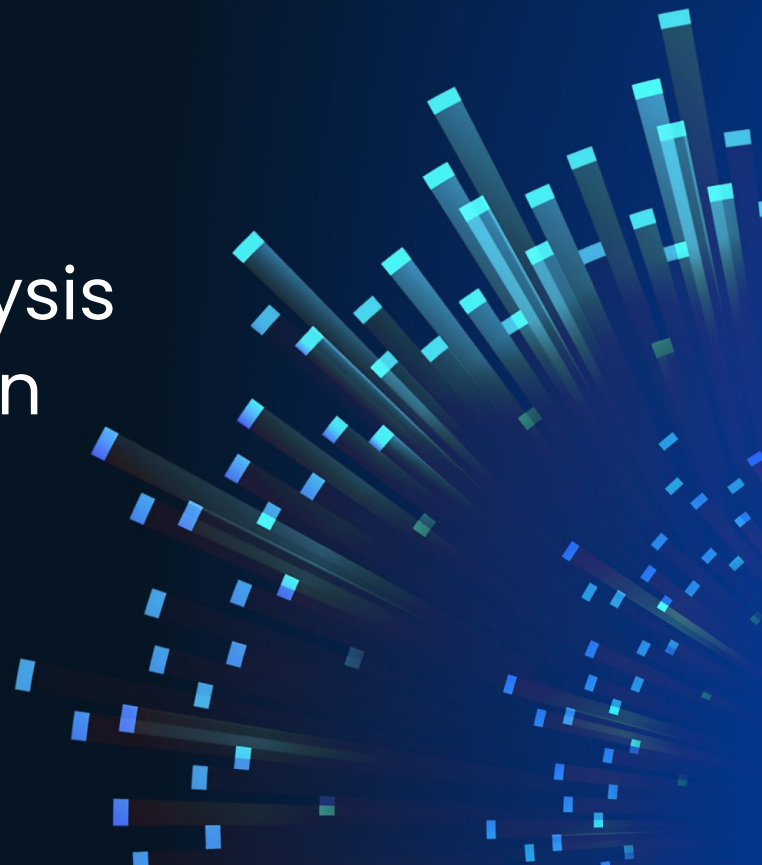
Current models driving the generation, delivery, and reuse of statistical analyses are ill-equipped to maximize the full strategic value of the insights generated in tables, listings, and figures (TLFs). Static displays lock value in the highly variable, non-standard structures of PDFs, RTFs, HTMLs, and other proprietary output formats, when a more structured storage approach would yield far greater returns on investment. Statistical output rendered into standardized, machine-readable formats allows for applications to more fully exploit the value generated in the statistical analysis phase of clinical trials. This paper explores practical implementations of AI-driven table analysis, standardized metadata frameworks, and automated generation capabilities that demonstrate measurable improvements in efficiency, traceability, and analytical reusability. Each of these applications promises reduction in study startup time, greater efficiency through automation and standardization, and resource optimization through Write Once, Read Many methodologies.

TT10

From static archives to analytical intelligence: Transforming statistical analysis value through standardization

Ilan Carmeli / Beaconcure Co-Founder & COO
Achinoam Ravet Perel / Head of Customer Success

November 18, 2025



Agenda

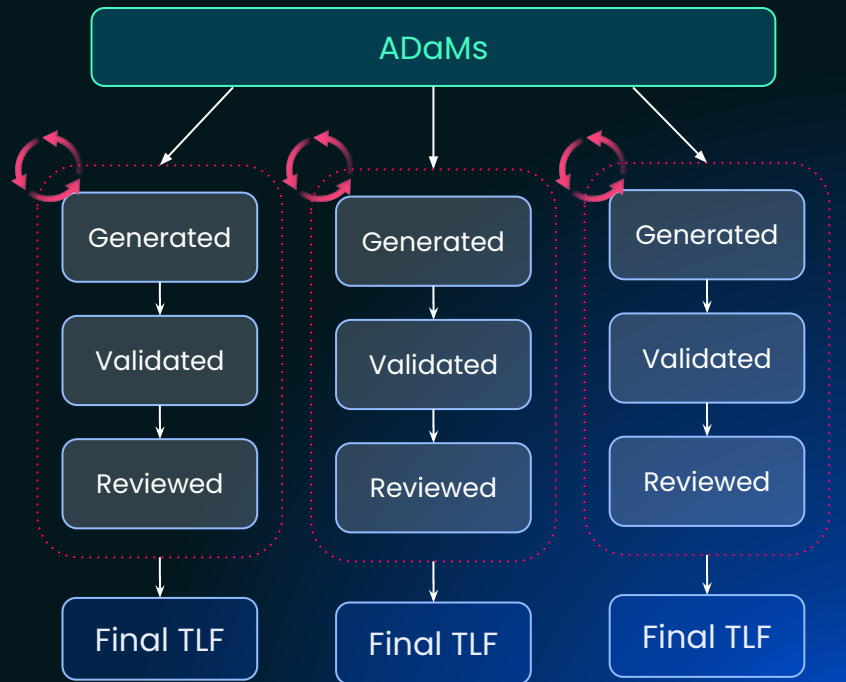
- Current Development Landscape: Limits of Static Displays
- Transformation from Static Documents to Analytical Intelligence
- Real World Implementations
 - Automated Validation Checks
 - Automated Output Generation & Traceability
 - Compatibility with Standards
- Summary
- Q & A

Current Landscape

Static Displays Limit Automation and Reuse

- Valuable insights locked in static formats
- Highly variable, non-standard structures across sponsors and teams
- Redundant efforts: same stats generated, validated, reviewed multiple times, for various functional units
- Inconsistent structure and terminology of protocols, SAP, and TLF specs hinder linkage of study objectives, analytical approaches, and output specifications
- Limited traceability to source data, specs, and analytical decisions
- Difficult to rapidly adjust outputs for new data, formats, or study requirements

Current Stats & Programming Development Model



Iterate until completed



Static display of statistics



Transformation from Static Documents to Analytical Intelligence

AI-Enabled Conversion of Static Files into a Robust Structured Database

- Parsing files: Deconstructing down to the cell level, categorizing and linking objects
- TLF metadata is extracted and clustered to facilitate standardized validation checks and automated analysis
- Enables connections between table sets and:
 - Standards – search and compare
 - Multiple places within a table or table set
 - Table sets across studies
- AI model improves over time as more data are incorporated, and is easily adapted to new data, such as new formats and new logical groupings

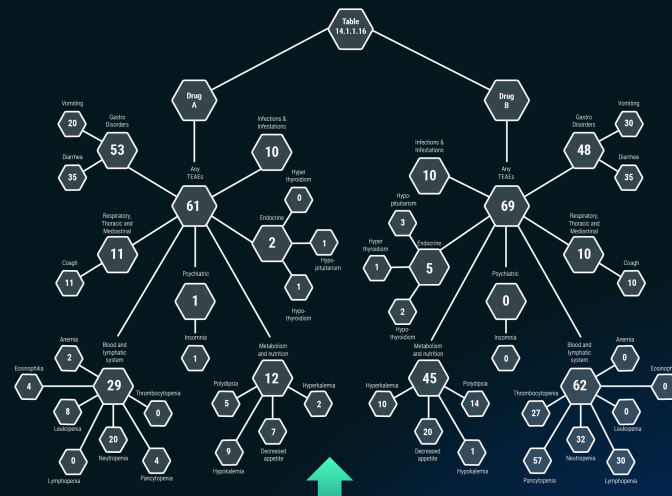
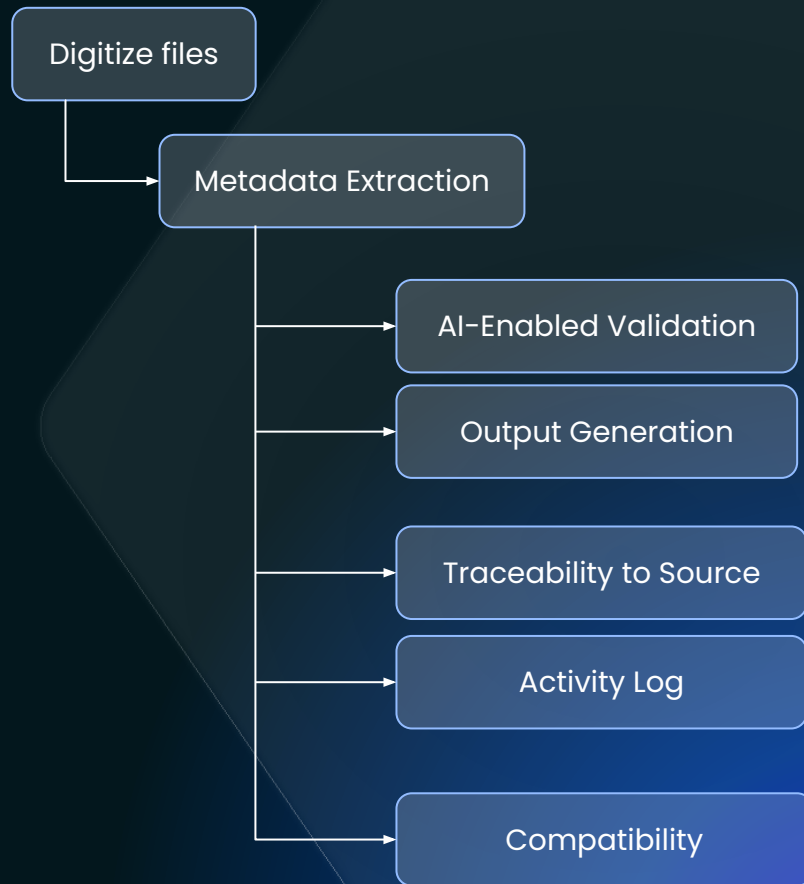


Table 14.1.1.16
TEAE Occurring in >5% of Subjects in at least One Treatment Group in Study by System Organ Class and Preferred Term (Safety Population)

	Drug A (N=118)	Drug B (N=117)
Any TEAEs	61 (51.3%)	69 (59.0%)
Gastro Disorders	53 (32.8%)	48 (41.0%)
Diarrhea	25 (21.0%)	35 (29.9%)
Vomiting	28 (16.4%)	30 (25.6%)
Infections & Infestations	10 (8.4%)	10 (8.5%)
Respiratory, Thoracic and Mediastinal Disorders	11 (9.2%)	10 (8.5%)
Cough	11 (9.2%)	10 (8.5%)
Blood and lymphatic system disorders	29 (24.4%)	62 (53%)
Anemia	2 (1.7%)	0
Eosinophilia	4 (3.4%)	0
Leukopenia	8 (6.8%)	0
Lymphopenia	0	30 (25.6%)
Neutropenia	20 (16.9%)	32 (27.4%)
Pancytopenia	4 (3.4%)	57 (48.7%)
Thrombocytopenia	0	27 (23.1%)
Endocrine disorders	2 (1.7%)	5 (4.3%)
Hypothyroidism	0	1 (0.8%)
Hypoparathyroidism	1 (0.8%)	2 (1.7%)
Metabolism and nutrition disorders	12 (10.1%)	45 (38.5%)
Hyperkalemia	2 (1.7%)	10 (8.5%)
Polydipsia	5 (4.2%)	14 (12.0%)
Decreased appetite	7 (5.9%)	20 (17.1%)
Hypokalemia	9 (7.6%)	1 (0.8%)
Psychiatric disorders	1 (0.8%)	0
Insomnia	1 (0.8%)	0

Real-World Implementations

- **Automated validation** checks
- **Automated output generation**
 - Review metadata alignment between table entities and ADaM
 - Alignment saved and applied to subsequent checks and analyses
- **Traceability**
 - Automated traceability from outputs to ADaM
 - Activity Log records changes
- **Compatibility** with standards such as CDISC ARS framework





Real-World Implementation

Automated Validation Checks

Run Automated Validation Checks

Summary Table

Table 14.1.1.19
Summary of Treatment Emergent Adverse Events & Serious Adverse Events
(Safety Population)

	Drug A (N=119)	Drug B (N=117)	Total (N=236)
Any TEAEs	67 (51.3%)	69 (59.0%)	130 (55.1%)
TEAE Causing Death	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe TEAEs	5 (4.2%)	3 (0.9%)	6 (2.5%)
Treatment-Related TEAE	6 (5.0%)	19 (16.2%)	25 (10.6%)
Discontinued due to TEAEs	5 (4.2%)	6 (5.1%)	11 (4.7%)
Serious Adverse Events	3 (2.5%)	1 (0.9%)	4 (1.7%)
Treatment-Related Serious Adverse Events	1 (0.8%)	0 (0.0%)	1 (0.4%)

N = number of subjects in the specified group, or the total sample.
This value is the denominator for the percentage calculations.

BEACONCURE CONFIDENTIAL SDTM Creation: 08OCT2021 (00:55) Source Data:
advs Table Generation: 09OCT2021

Overall AE Table

Table 14.1.1.11
Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

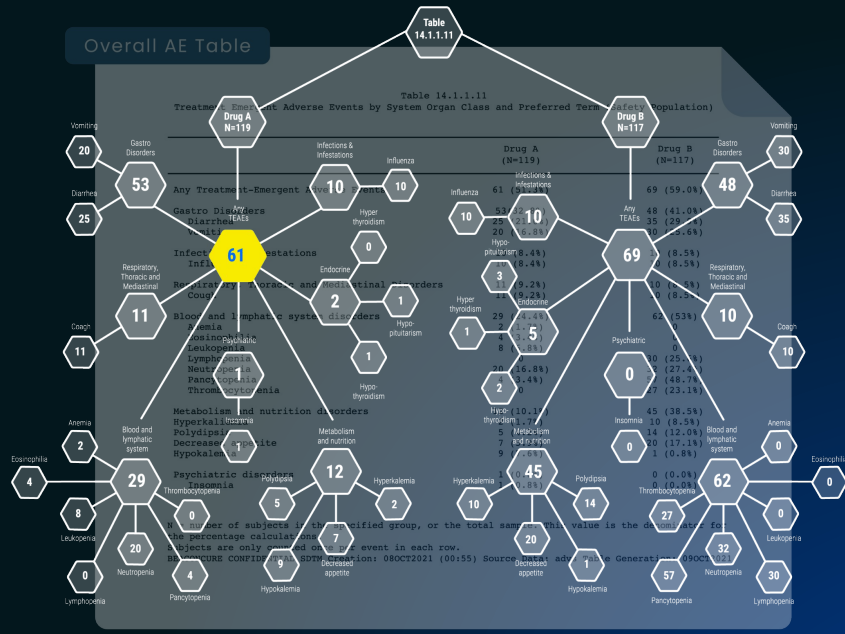
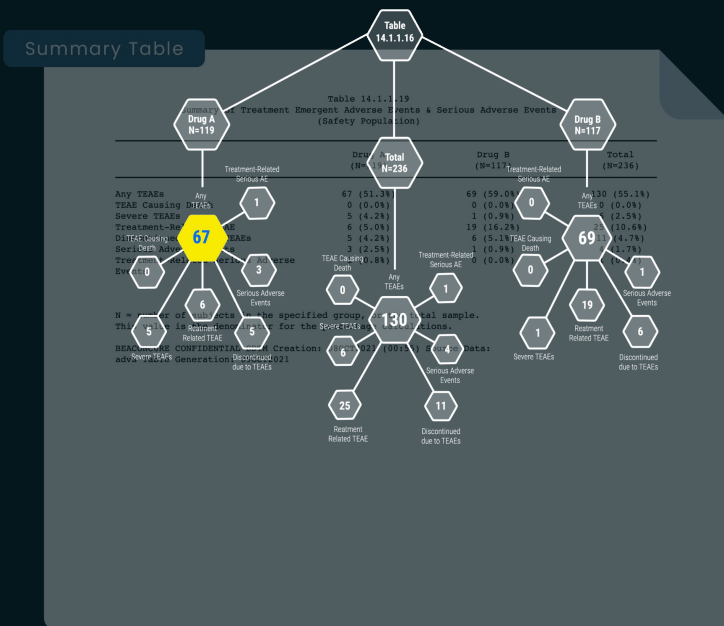
	Drug A (N=119)	Drug B (N=117)
Any Treatment-Emergent Adverse Events	61 (51.3%)	69 (59.0%)
Gastro Disorders	53 (32.8%)	48 (41.0%)
Diarrhea	25 (21.0%)	35 (29.9%)
Vomiting	20 (16.8%)	30 (25.6%)
Infections & Infestations	10 (8.4%)	10 (8.5%)
Influenza	10 (8.4%)	10 (8.5%)
Respiratory, Thoracic and Mediastinal Disorders	11 (9.2%)	10 (8.5%)
Cough	11 (9.2%)	10 (8.5%)
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Anemia	2 (1.7%)	0
Eosinophilia	4 (3.4%)	0
Leukopenia	8 (6.8%)	0
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Polydipsia	5 (4.2%)	14 (12.0%)
Decreased appetite	7 (5.9%)	20 (17.1%)
Hypokalemia	9 (7.6%)	1 (0.8%)
Psychiatric disorders	1 (0.8%)	0 (0.0%)
Insomnia	1 (0.8%)	0 (0.0%)

N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.

Subjects are only counted once per event in each row.

BEACONCURE CONFIDENTIAL SDTM Creation: 08OCT2021 (00:55) Source Data: advs Table Generation: 09OCT2021

Run Automated Validation Checks



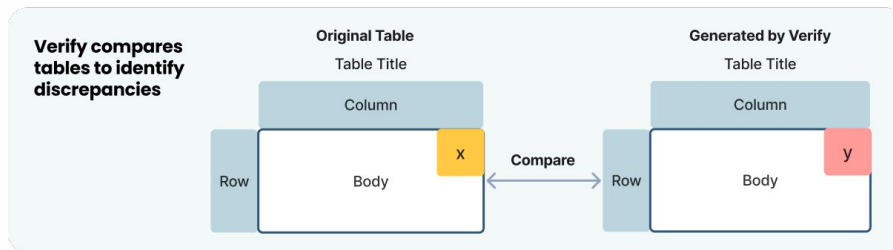
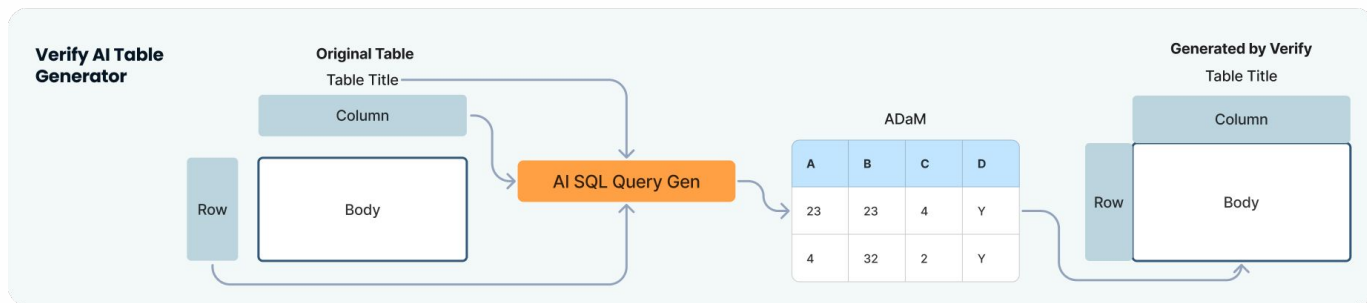
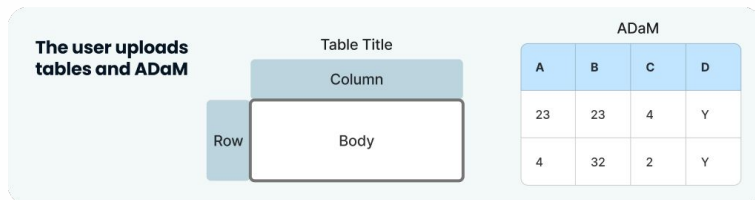
Real-World Implementation

Automated Output Generation & Traceability

Innovative Approach for Output Validation

Within the Verify Platform:

- Dedicated interface to inspect, validate, and flag discrepancies
- Embedded automation to identify mismatches and inconsistencies
- Integrated mechanism for programmers to document and communicate issues



AI-Enabled Output Generation

Programmer-Generated Table

N=5

Table 14.3.2.5.2
BE-0552543 Protocol A1234567
Treatment-Emergent Adverse Events by System Organ Class (Treatment Related, Immunogenicity Sub-study Analysis Set)

	Placebo (N=9)	BE-0552543 100mg QD (N=5)	BE-0552543 200mg QD (N=11)
Number of Subjects Evaluable for AEs			
Number (%) of Subjects: by SYSTEM ORGAN CLASS	n (%)	n (%)	n (%)

Verify-Generated Table

N=6

Generate to Verify
Table 14.3.2.5.2
BE-0552543 Protocol A1234567
Treatment-Emergent Adverse Events by System Organ Class (Treatment Related, Immunogenicity Sub-study Analysis Set)

Number of Subjects Evaluable for AEs	Placebo (N=9)	BE-0552543 100mg QD (N=6)	BE-0552543 200mg QD (N=11)
Number (%) of Subjects: by SYSTEM ORGAN CLASS	n (%)	n (%)	n (%)

Compare &
Decide:
Update TLF title or
subset

ADAM Dataset

N=6

Unique Subject Identifier	Full Analysis Set Population Flag	Safety Population Flag	Per-Protocol Population Flag	Completers Population Flag	Randomized Population Flag	Immunogenicity Substudy Analysis Flag	Description of Planned Arm	Planned Arm Code	Description of Actual Arm	Actual Arm Code
USUBJ	FASFL	SAFFL	PPROTFL	COMPLFL	RANFL	ISSFL	ARM	ARMCD	ACTARM	ACTARMCD
A1234567 1001 10015001	Y	Y	Y	Y	Y	Y	BE-0552543 100mg QD	D	BE-0552543 100mg QD	D
A1234567 1001 10015002	N	N	N	N	N	N	SCREEN FAILURE	SCRNFALL	SCREEN FAILURE	SCRNFALL
A1234567 1001 10015003	Y	Y	Y	Y	Y	N	Placebo	A	Placebo	A
A1234567 1001 10015004	Y	Y	Y	Y	Y	Y	BE-0552543 100mg QD	D	BE-0552543 100mg QD	D
A1234567 1001 10015005	Y	Y	Y	Y	Y	Y	BE-0552543 100mg QD	D	BE-0552543 100mg QD	D
A1234567 1001 10015006	Y	Y	Y	Y	Y	Y	BE-0552543 100mg QD	A	BE-0552543 100mg QD	A
A1234567 1001 10015007	Y	Y	Y	Y	Y	Y	BE-0552543 100mg QD	D	BE-0552543 100mg QD	D
A1234567 1001 10015008	Y	Y	Y	Y	Y	Y	BE-0552543 100mg QD	D	BE-0552543 100mg QD	D
A1234567 1001 10015009	Y	Y	Y	Y	Y	Y	BE-0552543 100mg QD	D	BE-0552543 100mg QD	D

Extracting Entities

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Demographics_pp_8w.html 100% + Issue

Comparison Base Table GenAI Table

Metadata Curator

This panel displays the GenAI table metadata, showing the alignment of table entities with their corresponding ADaM columns and values.

Table 14.1.1.6
Basic Results Disclosure for Treatment Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set

Number of Subjects Evaluable for AEs	Placebo (n=96)	Drug A (n=95)	Drug B (n=94)
With Any Adverse Event	42 (43.8)	40 (42.1) 41 (43.1)	50 (53.2) 51 (54.2)
Blood And Lymphatic System Disorders	2 (2.1)	0	0
Eosinophilia	2 (2.1)	0	0
Gastrointestinal Disorders	4 (4.2)	12 (12.6)	22 (23.4)
Abdominal pain	1 (1.0)	1 (1.1)	3 (3.2)
Abdominal pain upper	0	0	4 (4.3)
Diarrhoeas	0	2 (2.1)	1 (1.1)
Lip swelling	2 (2.1)	0 1 (1.1)	0 1 (1.1)

Row Headers
System Organ Class
AESOC
Preferred Term
AEDECOD

Column Headers
Placebo

Calculated Table based on ADaM Datasets

Verify

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100%

+ Issue

Comparison

Base Table

GenAI Table

Generates by Verify

Table 14.1.1.6

Basic Results Disclosure for Treatment Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set

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Abdominal pain upper	0	0	4 (4.3)
Diarrhoeas	0	2 (2.1)	1 (1.1)
Lip swelling	2 (2.1)	1 (1.1)	1 (1.1)

Metadata Curator

This panel displays the Verify-generated GenAI table metadata, which shows the alignment of table entities with their associated ADaM columns and values.

Title

Treatment Emergent

TRTEMFL

Y

Non-Serious

AESER

N

Safety Analysis Set

SAFFL

Y

Row Headers

System Organ Class

AESOC

Preferred Term

AEDECOD

Column Headers

Placebo

ACTARM

Placebo

Traceability

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Demographics_pp_8w.html 100% + Issue

Comparison Base Table GenAI Table

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Abdominal pain	1 (1.0)	1 (1.1)	3 (3.2)
Abdominal pain upper	0	0	4 (4.3)
Diarrhea	0	2 (2.1)	1 (1.1)

SQL

This panel displays the Verify-generated SQL used to produce the GenAI table.

```
1 SELECT
2 CASE
3 WHEN GROUPING(AESOC) = 1
4 THEN 'With Any Adverse Event'
5 WHEN GROUPING(AEDECOD) = 1
6 THEN AESOC /* Show top-level group field */
7 ELSE ' ' || AEDECOD /* Indent subgroups
8 */
9 END AS "Number of Subjects Evaluable for AEs
10 Number (%) of Subjects: by SYSTEM ORGAN CLASS and
11 Preferred Term",
12 COUNT(DISTINCT CASE WHEN ACTARM = 'Placebo' THEN
13 USUBJID END) AS "Placebo (N=96) n(%)",
14 COUNT(DISTINCT CASE WHEN ACTARM = 'DRUG A' THEN
15 USUBJID END) AS "DRUG A (N=95) n(%)",
16 COUNT(DISTINCT CASE WHEN ACTARM = 'DRUG B' THEN
17 USUBJID END) AS "DRUG B (N=94) n(%)
18 FROM ADAE
19 WHERE
20 TRTEMFL = 'Y' AND AESER = 'N' AND SAFFL = 'Y'
21 GROUP BY
22 ROLLUP (
```

Traceability

Verify

Projects

Help and Support ▾

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Projects /Project name_123

Activity Log



Level ▾

Component ▾

Action ▾

User ▾

Time Range ▾

🔍 Search Activity

Level	Component	Action	Location	Pre Value	New Value	Details	Analysis	Date	User
Table	Generation	✓	File_name... + 3 More			3 tables reprocess succe	Analysis1	May 14th 2024 10:00 PM	
Table	Entity		File_name.rtf	ADaM Column: ACT	ADaM Column: SUBJID	The Value for Population	Analysis1	May 14th 2024 10:00 PM	
Table	Entity	+	File_name.rtf		Safte Population		Analysis1	May 14th 2024 10:00 PM	
Table	Entity	-	File_name.rtf	ACT		ADaM Column: X ..	Analysis1	May 14th 2024 10:00 PM	
Table	Metadata		File_name.rtf			The table metadata has l	Analysis1	May 14th 2024 10:00 PM	



Items per page: 10 ▾ 1 Page out of 1

Comparison to Base Table

verify

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ComparisonBase TableGenAI Table

Table 14.1.1.6

Basic Results Disclosure for Treatment Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set

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Abdominal pain	1 (1.0)	1 (1.1)	3 (3.2)
Abdominal pain upper	0	0	4 (4.3)
Diarrhoeas	0	2 (2.1)	1 (1.1)
Lip swelling	2 (2.1)	0 1 (1.1)	0 1 (1.1)

Metadata Curator

This panel displays the GenAI table metadata, showing the alignment of table entities with their corresponding ADaM columns and values.

Title

Treatment Emergent

TRTEMFLY

Non-Serious

AESERN

Safety Analysis Set

SAFFLY

Row Headers

System Organ Class

AESOC

Preferred Term

AEDECOD

Column Headers

Placebo

ACTARMPlacebo

Verify Agent

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Comparison Base Table GenAI Table

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Abdominal pain	1 (1.0)	1 (1.1)	3 (3.2)
Abdominal pain upper	0	0	4 (4.3)
Diarrhoeas	0	2 (2.1)	1 (1.1)

Verify Assistant

What can I help with?

Ask or feedback on SQL

Verify Agent

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Comparison Base Table GenAI Table

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Basic Results Disclosure for Treatment Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set

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Abdominal pain upper	0	0	4 (4.3)
Diarrhoeas	0	2 (2.1)	1 (1.1)

Verify Assistant

What could cause the miscount of abdominal pain AE in Placebo for safety population?

10/24/2025 10:02

Verify Assistant

Share

According to the metadata of the base table, the SAE flag (AESER) was not used. Therefore, the base table value includes all TEAE (2), not only Non-Serious TEAE (1).

14.1.1.16.sql

924 kb



Metadata Curator: Study-Specific Support

verify

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Demographics_pp_8w.html

100%

+ Issue

Comparison

Base Table

GenAI Table

Table 14.1.1.6

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Metadata Curator

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Title

Treatment Emergent

TRTEMFL

Y

N

Y

Variable1

Variable2

Variable3

Variable4

Variable3

Variable4

Variable4

AEDECOD

Validation programmer

Column Headers

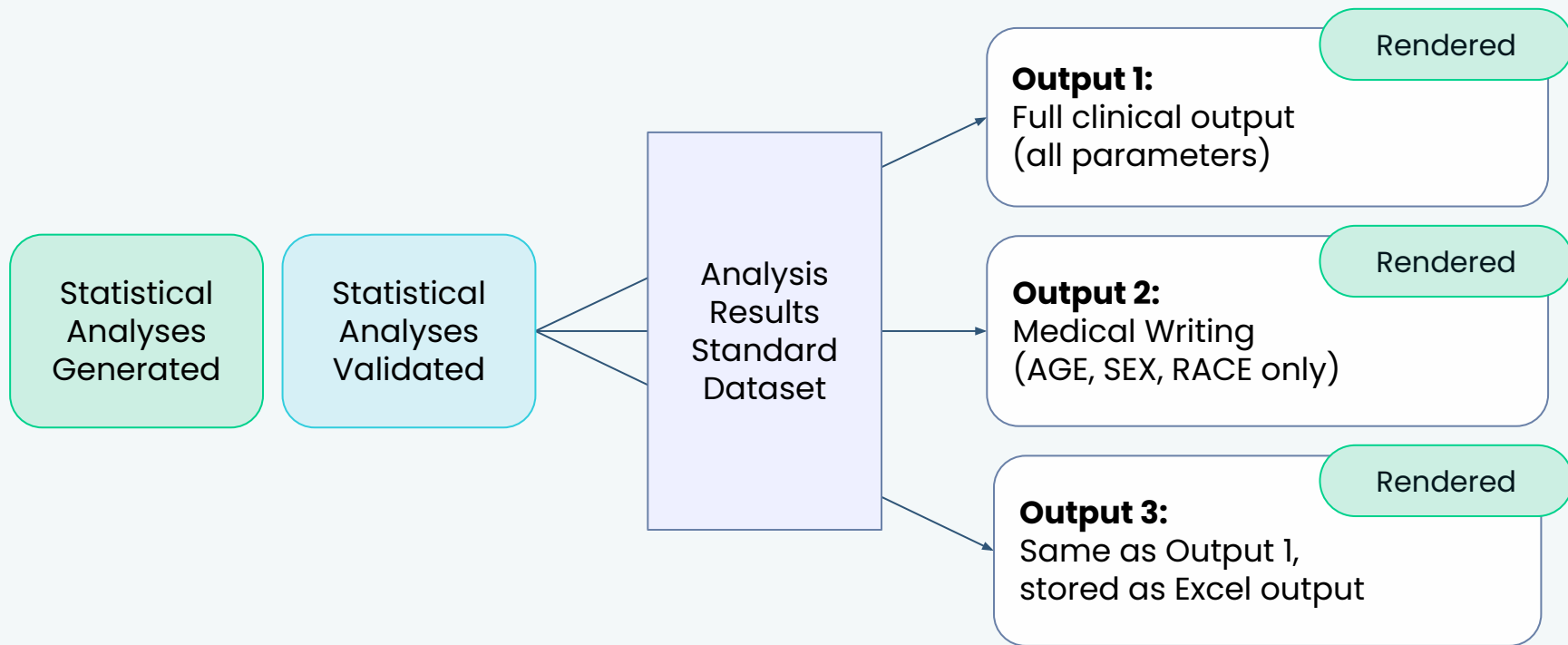
Placebo



Real-World Implementation

Compatibility with Standards

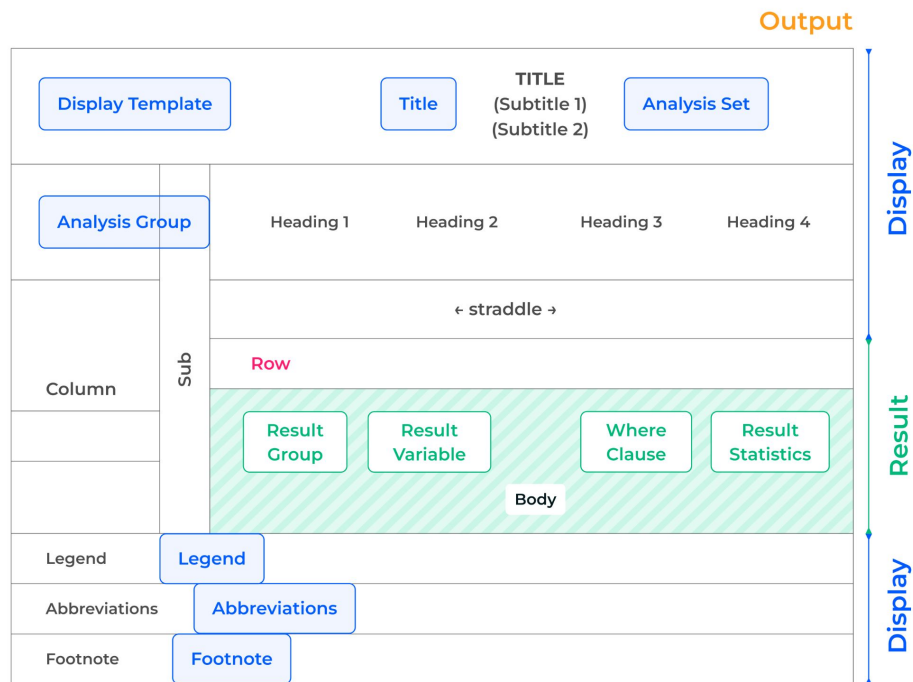
Write Once, Read Many (WORM) Programming Model



Compatibility with CDISC ARS

- CDISC ARS provides a **standard structure** to represent analysis results and qualifying metadata to support traceability, reproducibility, reusability and quality
- Verify parses outputs, identifies **key metadata elements** of a table, and represents outputs in **standard format**
- This standard format (Verify ARS) is used as the underlying metadata structure for the metadata repository
- It is often used when organizations already have TFL but want to standardize **post hoc** using ARS principles, or Enables back-standardization of **legacy studies** and outputs.

Key Metadata Elements of a Table



Linked Analysis Results & Associated Metadata

→ Steps:

1. Extract metadata from TFL, TLF shells, or specifications
2. Map TFL content to standardized ARD fields
3. Generate ARM metadata
4. Reconstruct ARD datasets

→ Example:

Results Statistic (blue) linked to how to get the statistics: “for ADSL variable SEX, count distinct USUBJID grouped by TR01X”

Analysis Results and Associated Metadata Example

Identifiers		Analysis Group			Result Variable			Result Statistic		
Name	Title	Dataset	Variable	Value	Variable	Value	Label	Value	Name	Label
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	53	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	61.6	Percent	%
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	33	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	38.4	Percent	%

Evolution of Clinical Research Analytics:

Human-AI Integration



AI Processing Pipeline

- Document parsing
- Entity extraction
- Relationship mapping
- Automated validation checks
- Discrepancy identification



Human Review Interface

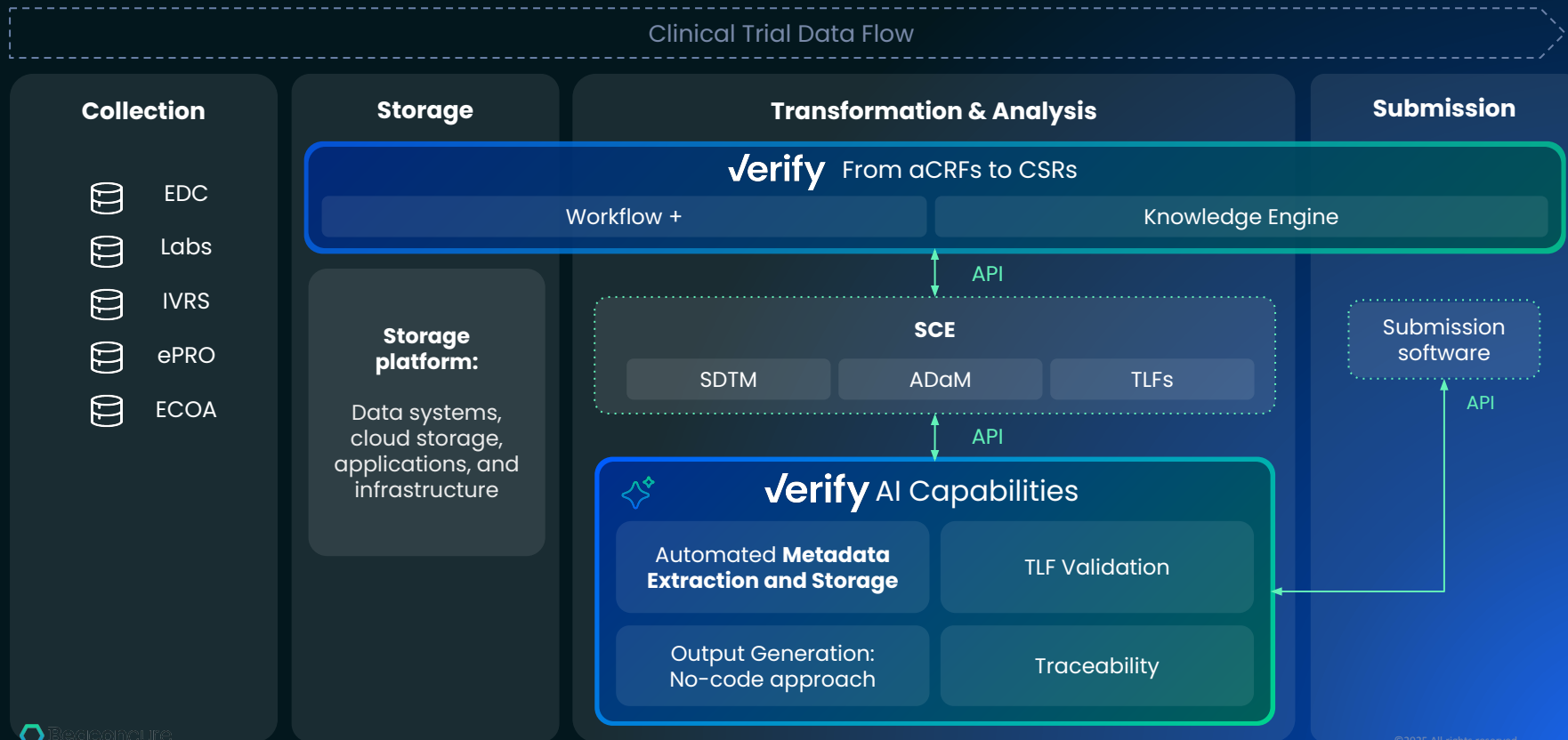
- Clear presentation of AI-identified elements
- Intuitive tools for reviewing and modifying metadata
- Feedback capture mechanisms
- Activity logging for audit trails



Learning Loop

- Capture of human decisions and corrections
- Integration of feedback into training data
- Continuous model improvement
- Performance monitoring and metrics

How Verify Fits into Clinical Workflows



Q&A

Thank You!

achinoam@beaconcure.com