

Navigating Complexity: Smarter Process for Better Workflows



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Head of customer success



Detours and Wrong Turns

Resultant Workflow Pain Points:

Broken/redundant communications

Extended review cycles

Delayed issue resolution

Limited visibility into ongoing review activities



Difficulty maintaining traceability & Loss of institutional knowledge

Inconsistent implementations

Risk of late-stage errors

Manual Work

Static Displays Limits Automation and Reuse

Resultant Pain Points:

Valuable insights **locked in** static formats

Lack of standardization drives **inconsistency** at scale

Poor traceability weakens confidence and oversight



Redundant efforts – Rework and duplication inflate time, cost, effort

Fragmented documents **prevent end-to-end alignment** from objectives to outputs

Slow, **manual updates** limit responsiveness to change

A Clear Path Forward

The Solution

A Centralized Platform for Seamless Data
Analysis Review Management



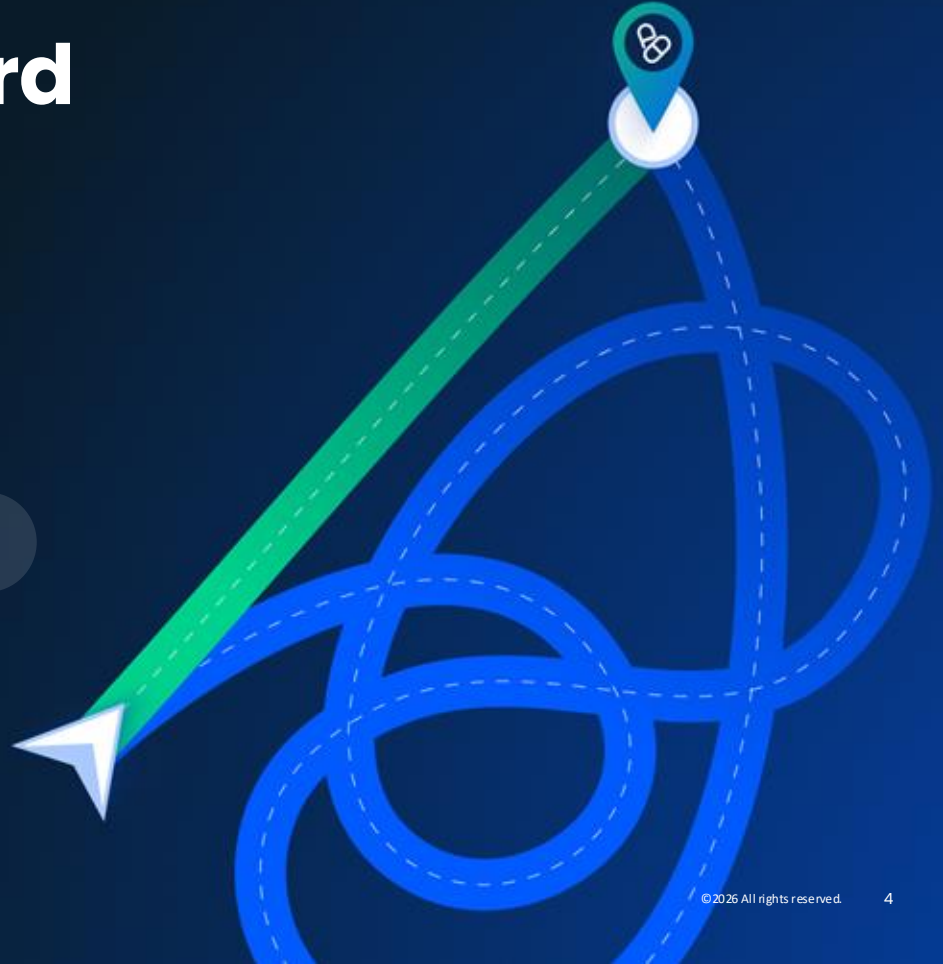
Digitizing documents



GenAI validation

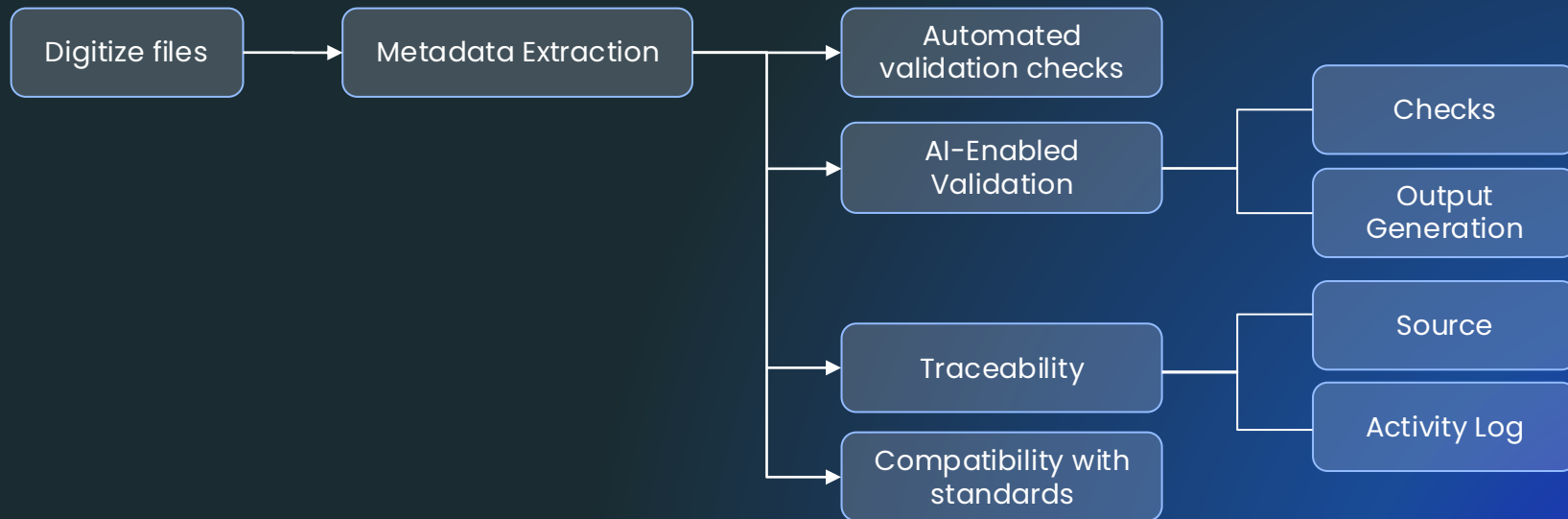


Centralized review & QC tracking



Real-World Implementations

Centralized review platform





Real-World Implementation

Digitizing Documents

Getting a head start

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

The Process

Parsing

Deconstructing to cell level and categorizing

Metadata extraction

structured metadata support standardized checks and automated analysis

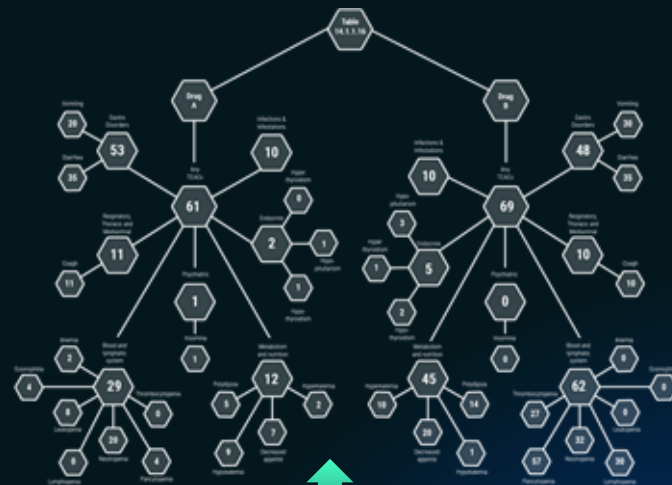
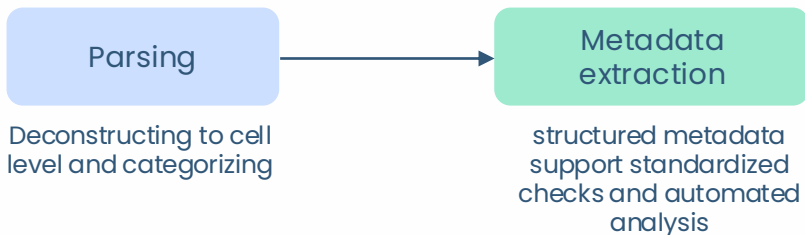


Table 14.1.1-16
TEAE Occurring in ≥5% of Subjects in at Least One Treatment Group in Study by System Organ Class and Preferred Term (Safety Population)

	Drug A (N=118)	Drug B (N=117)
Any TEAE	61 (51.7%)	69 (59.0%)
Gastro-Intestinal Disorders	53 (44.9%)	48 (41.0%)
Diarrhea	25 (21.2%)	35 (29.9%)
Vomiting	28 (23.7%)	30 (25.6%)
Infections & Infestations	39 (32.9%)	30 (25.6%)
Respiratory, Thoracic and Mediastinal Disorders	11 (9.3%)	10 (8.5%)
Cough	11 (9.3%)	10 (8.5%)
Blood and Lymphatic system disorders	29 (24.6%)	62 (53%)
Anemia	2 (1.7%)	0
Leukopenia	4 (3.4%)	0
Lymphopenia	0	0
Neutropenia	20 (16.9%)	32 (27.4%)
Pancytopenia	4 (3.4%)	51 (43.6%)
Thrombocytopenia	0	27 (23.1%)
Endocrine disorders	2 (1.7%)	5 (4.3%)
Hypothyroidism	0	5 (4.3%)
Hypoparathyroidism	2 (1.7%)	0
Hypothyroidism	0	2 (1.7%)
Metabolism and nutrition disorders	12 (10.1%)	45 (38.4%)
Hypocalcemia	2 (1.7%)	10 (8.5%)
Hypomagnesemia	5 (4.2%)	14 (11.9%)
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

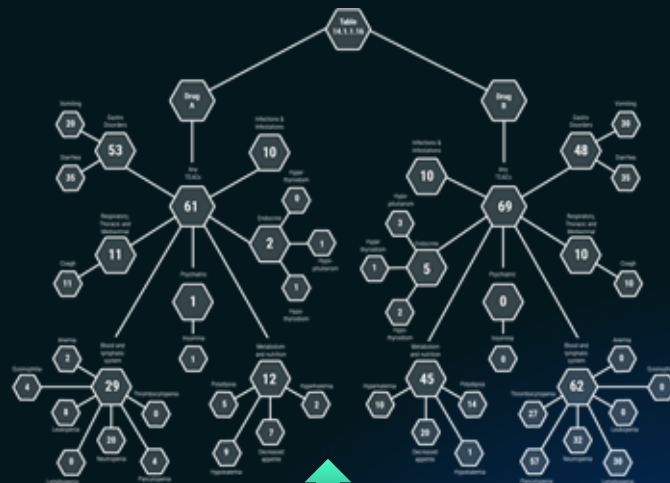
AI-Enabled Conversion of Static Files into a Robust Structured Database

The Process



Benefits:

- Enables connections between table sets and:
 - Standards compliant
 - Multiple places within a table or table set
 - Reuse across studies and programs
- AI model continuously improves with more data and adapts to new formats



YEAR Occurring in 35% of Subjects in at Least One Treatment Group in Study by System Organ Class and Preferred Term (Safety Population)		
	Drug A (N=112)	Drug B (N=117)
Any TRAE	81 (51.2%)	89 (55.6%)
Serious Disorders	53(32.9%)	44 (42.5%)
Diarrhea	25 (21.0%)	35 (29.9%)
Vomiting	20 (16.9%)	22 (25.6%)
Infections & Infestations	35 (6.4%)	30 (8.9%)
Respiratory, Thoracic and Mediastinal Disorders	11 (9.2%)	10 (9.5%)
Cough	10 (8.1%)	10 (8.5%)
Head and Lymphatic system disorders	29 (24.4%)	62 (53.0%)
Anemia	2 (1.7%)	0
Eosinophilia	4 (3.4%)	0
Leukopenia	8 (6.8%)	0
Lymphopenia	0	30 (25.6%)
Neutropenia	20 (16.9%)	22 (27.4%)
Pancytopenia	4 (3.4%)	37 (40.7%)
Thrombocytopenia	0	27 (23.1%)
Endocrine disorders	31(7.7%)	5 (4.3%)
Hypothyroidism	0	2(1.6%)
Hypoparathyroidism	1 (0.8%)	2 (2.4%)
Hypopituitarism	3 (2.6%)	0
Metabolic and nutrition disorders	12 (10.1%)	45 (39.3%)
Hypokalemia	2 (1.7%)	10 (8.5%)
Pyridoxemia	9 (7.4%)	0
Decreased appetite	7 (5.8%)	20 (17.1%)
Hypocalcemia	9 (7.4%)	3 (2.6%)
Psychiatric disorders	1 (0.8%)	0
Insomnia	1 (0.8%)	0



Real-World Implementation

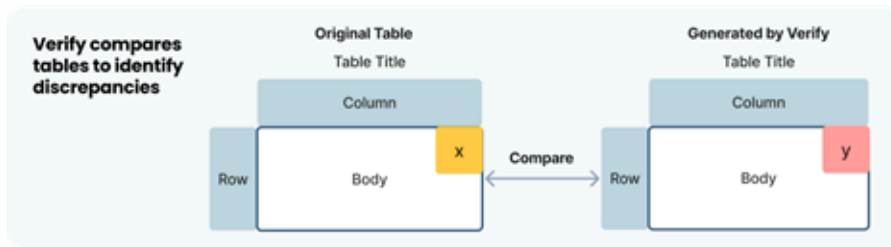
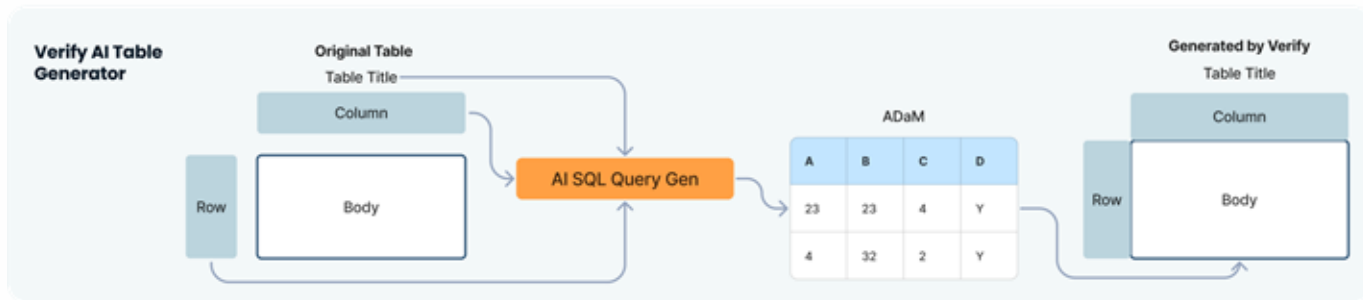
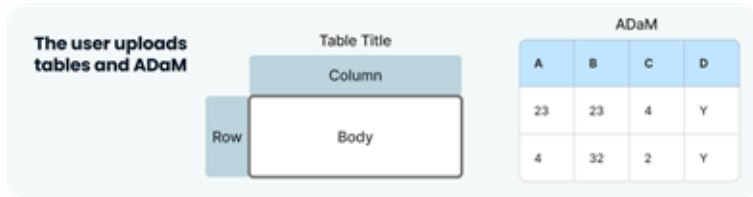
Automated Output Generation & Traceability

Confidence in every step and every output

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)

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

Compare & Decide:
Update TLF title or subset

Verify-Generated Table

N=6

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

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 AE	Planned AE Code	Description of Actual AE	Actual AE Code
USUB	FAISFL	SAISFL	PPISOTFL	COMPLFL	RANISFL	ISOTFL	AEI	AECD	ACTAEI	ACTAECD
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	SCRFNFAIL	SCREEN FAILURE	SCRFNFAIL
A1234567 1001 10015003	Y	Y	Y	Y	Y	N	Placebo	A	Placebo	A
A1234567 1001 10015004	X	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	X	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)

Emergent
Y
N
SAFER
N
Safety Analysis Set
SAFFL
Y
Row Headers
System Organ Class
AESOC
Preferred Term
AEDECOD
Column Headers
Placebo

Calculated Table based on ADaM Datasets

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Demographics_pp_@w.html100% ▾+ Issue⋮

ComparisonBase TableGenAI 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

Number of Subjects Evaluable for AEs	Placebo (n=96) n(%)	Drug A (n=95) n(%)	Drug B (n=94) n(%)
Number (%) of Subjects: by SYSTEM ORGAN CLASS and Preferred Term			
With Any Adverse Event	42 (43.8)	41 (43.1)	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)	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

AEDECO ▾

Column Headers

Placebo

ACTARM ▾Placebo ▾

Traceability

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Demographics_pp_8w.html 100% + + Issue

Comparison Base Table GenAI 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

Number of Subjects Evaluable for AEs	Placebo (n=96) n(%)	Drug A (n=95) n(%)	Drug B (n=94) n(%)
Number (%) of Subjects: by SYSTEM ORGAN CLASS and Preferred Term			
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)
Diarrhoea	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

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Projects / Project name_123

Activity Log

LevelComponentActionUserTime 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	NY
Table	Entity	✎	File_name.rtf	ADaM Column: ACT	ADaM Column: SUBJID	The Value for Population	Analysis1	May 14th 2024 10:00 PM	NY
Table	Entity	+	File_name.rtf		Saftey Population		Analysis1	May 14th 2024 10:00 PM	NY
Table	Entity	−	File_name.rtf	ACT		ADaM Column: X ..	Analysis1	May 14th 2024 10:00 PM	NY
Table	Metadata	👍	File_name.rtf			The table metadata has I	Analysis1	May 14th 2024 10:00 PM	NY

Comparison to Base Table

verify

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Demographics_pp_8w.html100%+ Issue

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

Number of Subjects Evaluable for AEs	Placebo (n=96) n(%)	Drug A (n=95) n(%)	Drug B (n=94) n(%)
Number (%) of Subjects: by SYSTEM ORGAN CLASS and Preferred Term			
With Any Adverse Event	42 (43.8)	48 (42.1) 41 (43.1)	58 (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)

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
TRTEMPL Y

Non-Serious
AESER N

Safety Analysis Set
SAFPL Y

Row Headers
System Organ Class
AESOC

Preferred Term
AEDECOD

Column Headers
Placebo
ACTARM Placebo

Verify Agent

verify Projects Help and Support

Demographics_pp_8w.html 100% + Issue

Comparison Base Table GenAI 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

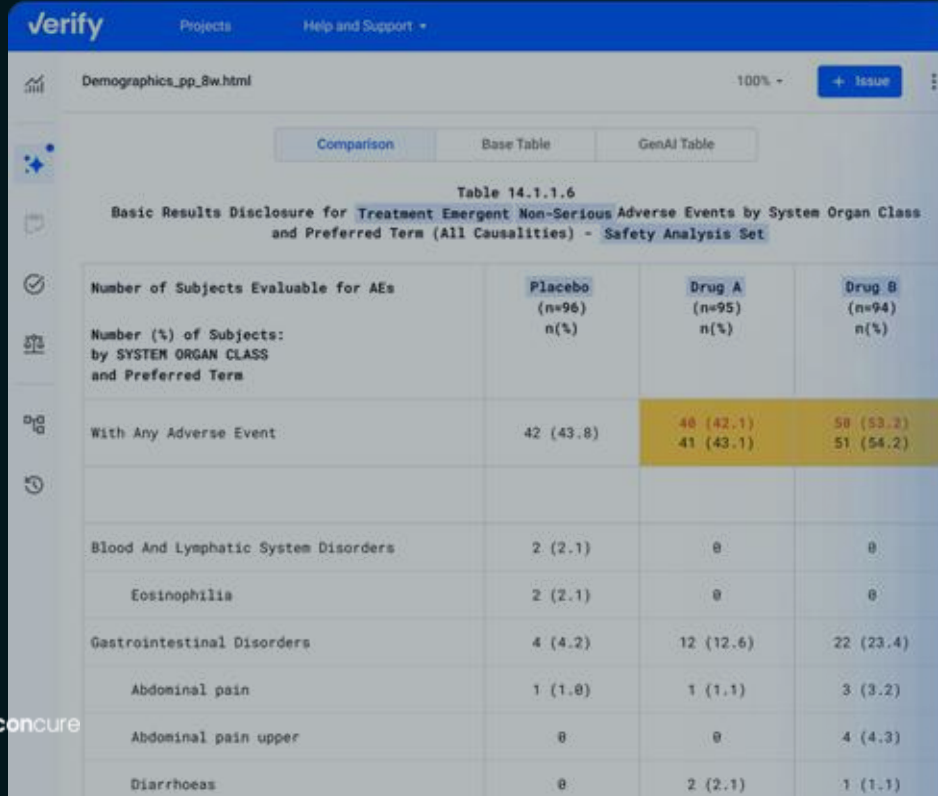
Number of Subjects Evaluable for AEs	Placebo (n=96) n(%)	Drug A (n=95) n(%)	Drug B (n=94) n(%)
Number (%) of Subjects: by SYSTEM ORGAN CLASS and Preferred Term			
With Any Adverse Event	42 (43.8)	48 (42.1) 41 (43.1)	58 (53.2) 51 (54.2)
Blood And Lymphatic System Disorders	2 (2.1)	0	0
Eosinophilia	2 (2.1)	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)

Verify Assistant

What can I help with?

Ask or feedback on SQL

Verify Agent



The screenshot shows the Verify Assistant interface. On the left, a table titled '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' is displayed. The table has four columns: 'Number of Subjects Evaluable for AEs', 'Placebo (n=96) n(%)', 'Drug A (n=95) n(%)', and 'Drug B (n=94) n(%)'. The first row shows 'With Any Adverse Event' with values 42 (43.8), 48 (42.1) / 41 (43.1), and 58 (53.2) / 51 (54.2). The second row shows 'Blood And Lymphatic System Disorders' with values 2 (2.1), 0, and 0. The third row shows 'Eosinophilia' with values 2 (2.1), 0, and 0. The fourth row shows 'Gastrointestinal Disorders' with values 4 (4.2), 12 (12.6), and 22 (23.4). The fifth row shows 'Abdominal pain' with values 1 (1.0), 1 (1.1), and 3 (3.2). The sixth row shows 'Abdominal pain upper' with values 0, 0, and 4 (4.3). The seventh row shows 'Diarrhoeas' with values 0, 2 (2.1), and 1 (1.1). On the right, a chat window titled 'Verify Assistant' is open. It contains a message from the user: 'What could cause the miscount of abdominal pain AE in Placebo for safety population?' and a response from the assistant: '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).'

Number of Subjects Evaluable for AEs	Placebo (n=96) n(%)	Drug A (n=95) n(%)	Drug B (n=94) n(%)
With Any Adverse Event	42 (43.8)	48 (42.1) 41 (43.1)	58 (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)

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



Metadata Curator: Study-Specific Support

The screenshot displays the Verify Metadata Curator interface. The main panel shows a comparison table for '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'. The table compares Placebo (n=96), Drug A (n=95), and Drug B (n=94) across various adverse events. The 'With Any Adverse Event' row is highlighted in orange. The 'Metadata Curator' panel on the right shows the alignment of table entities with their associated ADaM columns and values. A dropdown menu for 'Variable2' is open, showing a list of variables. A blue button labeled 'Validation programmer' is visible in the bottom right corner of the Metadata Curator panel.

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) n(%)	Drug A (n=95) n(%)	Drug B (n=94) n(%)
With Any Adverse Event	42 (43.8)	49 (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)

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

TRTEMPL Y

Search Variable

Variable1

Variable2

Variable3

Variable4

Variable3

Variable4

Variable4

AEDECOD

Validation programmer

Column Headers

Placebo

From Manual Navigation to Human-AI Co-Piloting



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



Real-World Implementation

Automated Workflow

Knowing where you are, and what's ahead

Converting Findings to Tasks

Verify detect and route all tasks through a single “navigation system”:

1. GENAI
2. Validations checks
3. Human review

All findings captured in one place for coordinated action:

- Easily prioritized, assigned, tracked, and resolved
- Fully controlled with clear ownership and status
- Bulk actions and consistent editing for efficient management at scale

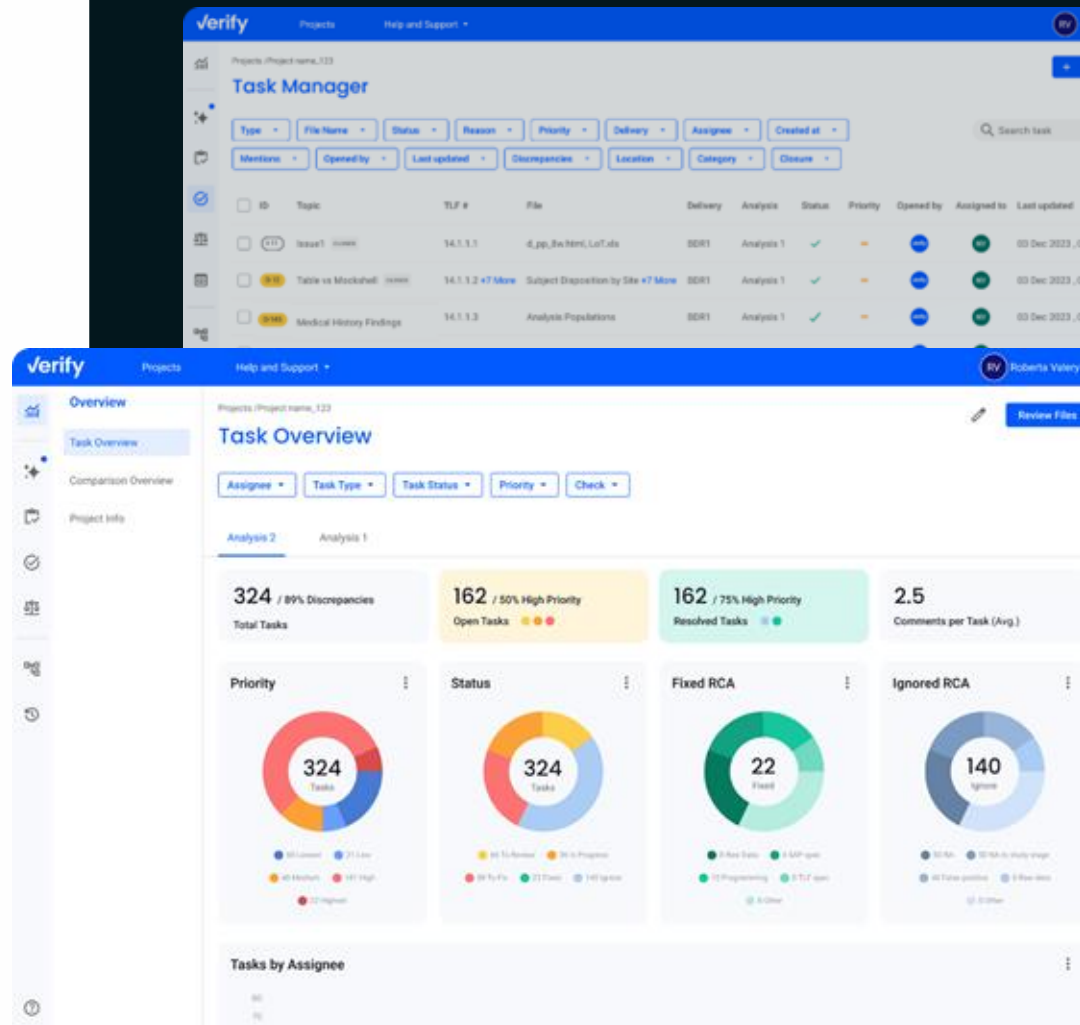
The screenshot displays the Verify application interface. The main panel shows a table titled "Table 14.1.1.6 Basic Results Disclosure for Treatment Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set". The table compares data for Placebo (n=96), Drug A (n=95), and Drug B (n=94). The table is divided into two sections: "Number of Subjects Evaluable for AEs" and "Number (%) of Subjects by SYSTEM ORGAN CLASS and Preferred Term".

	Placebo (n=96) n(%)	Drug A (n=95) n(%)	Drug B (n=94) n(%)
With Any Adverse Event	42 (43.8)	48 (42.1) 41 (43.1)	58 (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)

The right panel shows a "Tasks" section with a "GenAI Validation" task. The task description states: "unequal values. Base table value = 0. Generated table value = 1 (3.1)". The task is currently in a "To Review" status.

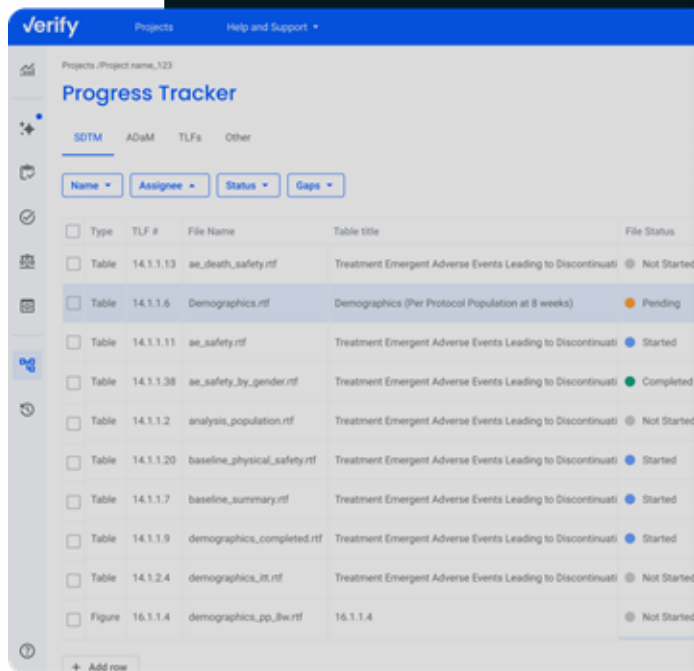
Tasks Dashboard & Task Manager

- Acts as a **traffic control center** for all review and validation activities
- **Centralized visibility** and ownership of all review activities
- **Early risk identification** for delays, rework, or misalignment
- **Data-driven insights** into throughput, cycle time, and bottlenecks
- **Built-in traceability** for documentation and institutional memory for audit readiness



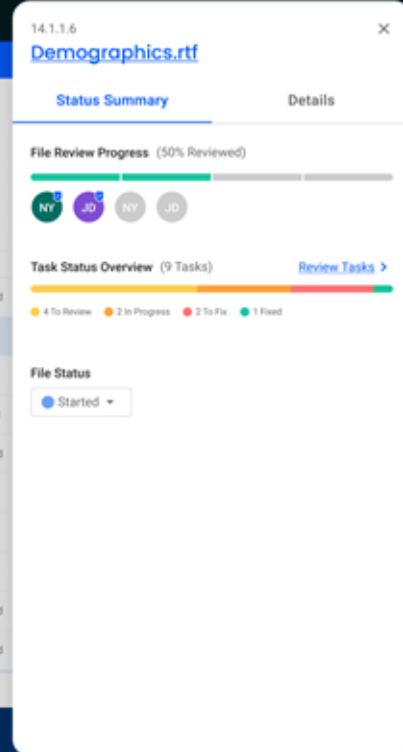
Progress Tracker

- Provides a real-time map of progress and status with clear ownership and dependencies across all deliverables
 - Review progress
 - Automatic tracker maintenance
 - Bulk actions and consistent editing
- Shows readiness for submission as the final destination approaches



The screenshot shows the 'verify' Progress Tracker interface. It features a sidebar with navigation icons and a main table of deliverables. The table has columns for checkboxes, Type, TLF #, File Name, Table title, and File Status. The 'Demographics.rtf' file is highlighted in blue and marked as 'Pending'.

	Type	TLF #	File Name	Table title	File Status
☐	Table	14.1.1.13	ae_death_safety.rtf	Treatment Emergent Adverse Events Leading to Discontinuation	Not Started
☒	Table	14.1.1.6	Demographics.rtf	Demographics (Per Protocol Population at 8 weeks)	Pending
☐	Table	14.1.1.11	ae_safety.rtf	Treatment Emergent Adverse Events Leading to Discontinuation	Started
☐	Table	14.1.1.38	ae_safety_by_gender.rtf	Treatment Emergent Adverse Events Leading to Discontinuation	Completed
☐	Table	14.1.1.2	analysis_population.rtf	Treatment Emergent Adverse Events Leading to Discontinuation	Not Started
☐	Table	14.1.1.20	baseline_physical_safety.rtf	Treatment Emergent Adverse Events Leading to Discontinuation	Started
☐	Table	14.1.1.7	baseline_summary.rtf	Treatment Emergent Adverse Events Leading to Discontinuation	Started
☐	Table	14.1.1.9	demographics_completed.rtf	Treatment Emergent Adverse Events Leading to Discontinuation	Started
☐	Table	14.1.2.4	demographics_rit.rtf	Treatment Emergent Adverse Events Leading to Discontinuation	Not Started
☐	Figure	16.1.1.4	demographics_pp_8w.rtf	16.1.1.4	Not Started



The details panel for 'Demographics.rtf' (14.1.1.6) shows a 'Status Summary' and 'Details' tab. It includes a 'File Review Progress' bar at 50% (Reviewed), a 'Task Status Overview' for 9 tasks (4 To Review, 2 In Progress, 2 To Fix, 1 Fixed), and a 'File Status' dropdown set to 'Started'.

14.1.1.6
[Demographics.rtf](#)

Status Summary Details

File Review Progress (50% Reviewed)

Task Status Overview (9 Tasks) [Review Tasks >](#)

File Status
Started

Verify Automated Workflow

A Single Platform That Sees Everything, Guides Every step, & keeps sponsors and CROs on the fastest, safest path to submission



Streamlined Collaboration and Review

- Add comments directly on digitized TLFs
- Compress issue adjudication timelines
- Trace CRO-Sponsor handoffs and requests



Centralized End-to-End QC Management

- Unify QC activities with a synchronized online tracker
- Automate task assignment
- Track status progress to quickly address gaps and open issues



Real-Time Oversight of Deliverables

- Monitor deliverable status with full visibility
- Preserve institutional memory
- Enable fast, informed decision-making

Automated Activity Log generates immutable records of all actions and decisions

The difference between **reacting to problems** & **navigating through** **them with confidence**



Speed

- Shorter Review Cycles
- Reduced Review Effort
- Enhanced Accuracy



Efficiency

- Reduced Spreadsheet
- Free resource
- Scalable Growth



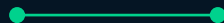
Visibility

- Centralized Management
- Enhanced Executive Oversight
- Transparent Audit Trail

✓**verify**: Deliver faster with confidence



Thank You



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