

Verify:

A First-in-Class Review and Validation Platform for Biometrics in Clinical Research

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March 18, 2025

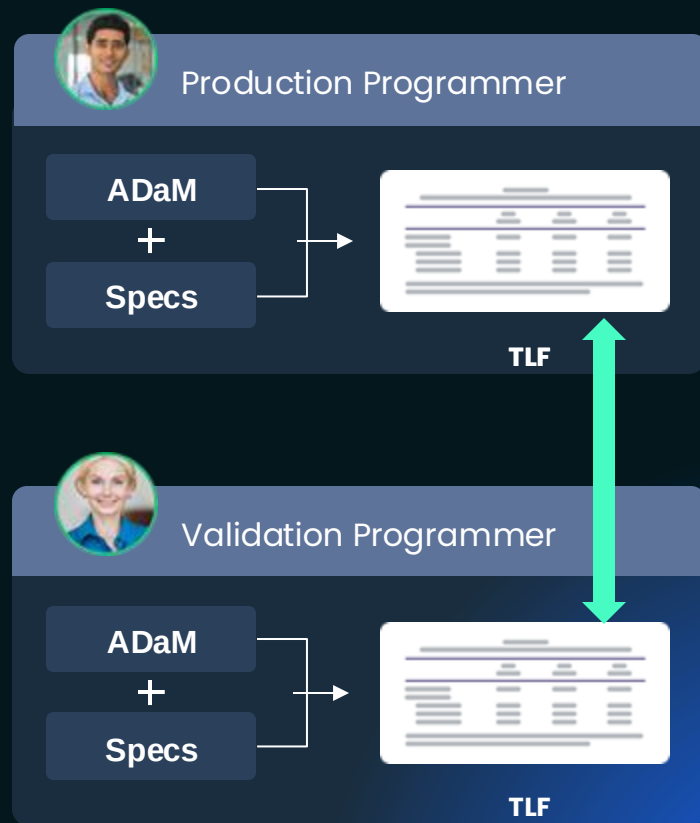
Agenda

- Current Landscape
- Introduction: What is Verify?
- Live Verify Demo
- Vision & Ongoing Development
- Q & A

Current Landscape

The High Cost of Manual TLF Validation

- Large labor footprint: at times duplicative, repetitive, time-consuming, & keeping resources from other necessary tasks
- Customized code
- Study-specific configuration
- As-needed double programming
- Visual review of thousands of pages of outputs
- Decentralized, disjointed reviewer communication and processes



Current Landscape

Siloed Clinical Review Processes

- Inefficient traceability and transparency
 - Multiple emails with varied distribution lists
 - Reviewer comments in marked-up PDFs and spreadsheets
 - Multiple internal & external reviewer spreadsheets and trackers
- Duplicate comments from multiple reviewers
- Versioning issues with updating outdated outputs and trackers
- Maintaining continuity and institutional memory over years of study phases
- Lack of visibility into the status of deliveries





In biometrics, humans are still doing the repetitive, high-volume validation tasks that can be more reliably & efficiently automated with AI

Introducing



AI-Enabled Statistical Analysis Platform

Accelerate TLF validation processes, streamline workflows, and enhance visibility.

Using Verify, biometrics teams can:

- Identify discrepancies in statistical outputs within minutes
- Track deliverable progress in real time
- Prioritize deliverables and resource allocation
- Analyze issue trends and root causes
- Gain a detailed audit trail of all activities
- Manage deliverables with full visibility as a distributed team

Customer Types

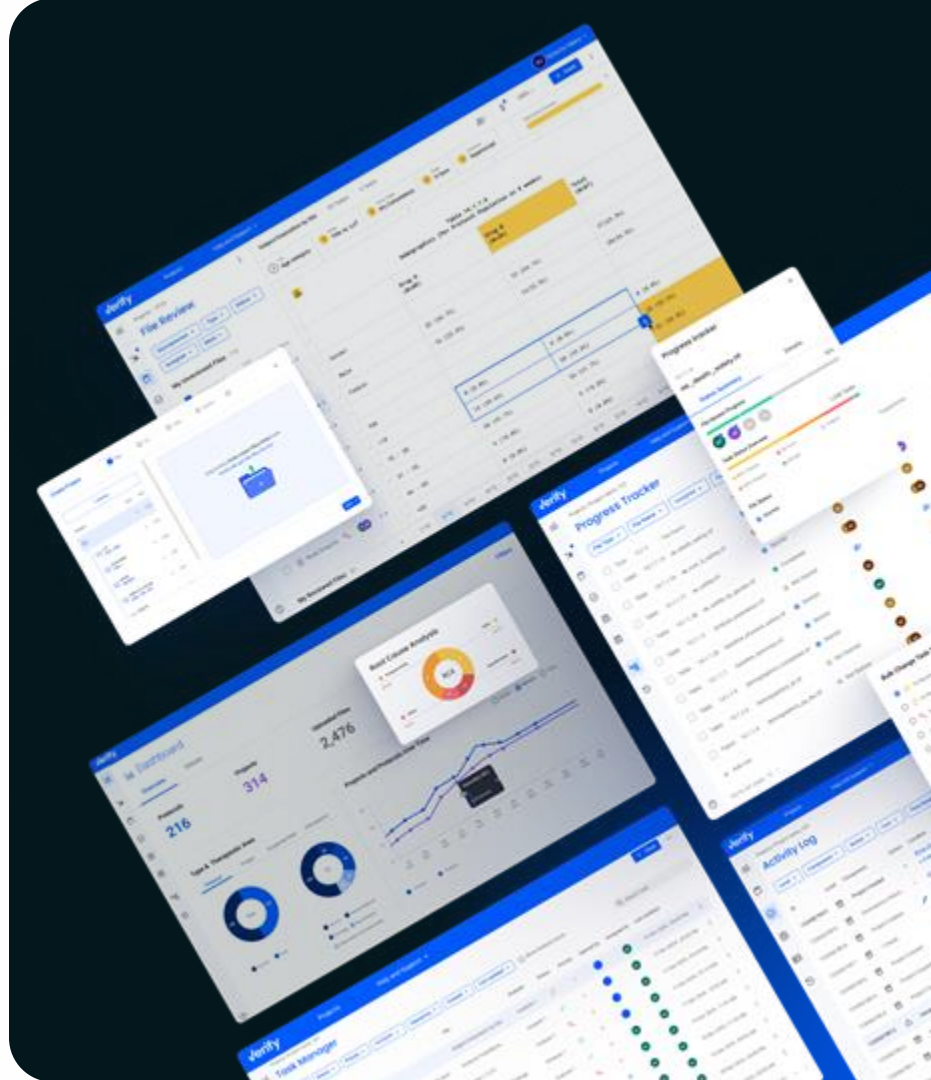


- ✓ Pharma Sponsor
- ✓ CRO
- ✓ Specialty FSP
- ✓ Biotech

Primary Users



- ✓ Statisticians
- ✓ Programmers
- ✓ Clinicians
- ✓ Medical Writers
- ✓ Project Managers



Verify Integrated Application Layer



Source Data



AI-Enabled ingestion



GenAI and Analytics

User Interface

API or Upload



ADaMs



TLFs



LoT / Toc



Mock Shells

Parsing

Workflow+

Validation

Generation

Verify

Verify

Verify

Validated TLFs

Reusable Results Metadata

Comprehensive Audit Trail

Actionable Insights & Analytics

Real-Time Status Tracking

Operational Efficiency

Single Tenant Secure
AWS Environment

SCE-Agnostic



Verify Demo

Output Draft Review in Verify

by Production Programmer

verify

Projects

Help & Support

Projects / #12674 - Demo Video

File Review

Discrepancies

Type

Task Status

Assignees

Advanced

My Unreviewed Files (24)

☐ 1 Unreviewed

Status Outcome Assignee Tasks

☐ Demo Mock Shells.docx

AR

0

☐ LoT Demo.xlsx

4

AR

4

☒ ae_death_safety.rtf

5

AR

5

☐ ae_over_5_safety.rtf

13

AR

13

☐ ae_safety_by_gender.rtf

3

AR

3

☐ ae_safety.rtf

10

AR

10

My Reviewed Files (1)

ae_death_safety.rtf | 5 Tasks

1 Footnotes Date Comparison

1 Footnotes MedDRA

1 Cross table Number of Deaths Consistency

1 Title Protocol Number Consistency

1 Footnotes_Body Superscript

Task Status Overview

Table 14.1.1.13

Treatment Emergent Adverse Events Causing Death by System Organ Class and Preferred Term (Safety Population) (Protocol S449201)

	Drug A ^a (N=119)	Drug B ^b (N=117)	Total (N=236)
Any TEAEs ^c	0 (0.0%)	1 (0.8%)	1 (0.8%)

N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
MedDRA v27.1 coding dictionary.
 Subjects are only counted once per event in each row.
 a. Drug A was given to group A.
 b. Drug B was given to group B.
 BEACONCURE CONFIDENTIAL SDTM Creation: 08OCT2021 (00:55) Source Data: advs Table Generation: **09OCT2021**

Output Review Iteration in Verify

by Validation Programmer

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Projects / #12674 - Demo Video

File Review Book

Discrepancies Type Task Status Assignees

Advanced

My Unreviewed Files (25)

	Status	Outcome	Assignee	Tasks
☐ 1 Unreviewed				
☐ Demo Mock Shells.docx				AR 0
☐ LoT Demo.xlsx				3 AR 3
☒ ae_death_safety.rtf				AR 0
☐ ae_over_5_safety.rtf				5 AR +2 5
☐ ae_safety_by_gender.rtf				4 AR +1 4
☐ ae_safety.rtf				4 AR +1 4

ae_death_safety.rtf

100% + Issue

Table 14.1.1.13

Treatment Emergent Adverse Events Causing Death by System Organ Class and Preferred Term (Safety Population)
(Protocol S4472001)

	Drug A ^a (N=119)	Drug B ^b (N=117)	Total (N=236)
Any TEAEs	0 (0.0%)	0 (0.0%)	0 (0.0%)

N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
MedDRA v27.1 coding dictionary applied.
Subjects are only counted once per event in each row.
a. Drug A was given to group A.
b. Drug B was given to group B.

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



Real-Time Management and Tracking in Verify

by PM or Lead Programmer

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Progress Tracker Draft

File Type File Name File Availability Assignee

Search

☐	Type	File Name	Output Number	Status	Productionprogrammers	QCprogrammers	QC Statistician	Title	Review %	+
☐	Table	termination_1_dose.rtf	14.1.1.10	Not Started				Reason for Study Termination (Subjects who received at least one dose) (Protocol S4472001)	0%	
☐	Table	weight_related.rtf	14.1.1.5897	Not Started				Protocol S4472001 Weight Related Comorbidities (All Randomised Subjects)	0%	
☐	Table	Listing_of_Assay_Data.rtf	16.2.7.21	Started				Listing of Assay Data (Protocol S4472001)	50%	
☐	Table	ae_death_safety.rtf	14.1.1.13	Pending				Treatment Emergent Adverse Events Causing Death by System Organ Class and Preferred Term (Protocol S4492001)	67%	
☐	Figure	Figure_c.pdf	14.1.2.5	Not Started				Figure 14.1.2.5 Drug A Proportion of Patients Remaining With Missing and Existing Laboratory Data Records Phase 2 (Protocol S4472001)	0%	
☐	Table	ae_safety.rtf	14.1.1.11	Started				TEAEs by System Organ Class and Preferred Term (Safety Population) (Protocol S4472001)	100%	
☐	Table	ae_over_5_safety.rtf	14.1.1.16	Pending				TEAE Occurring in >5% of Subjects in at least One Treatment Group in Study by System Organ Class (Protocol S4492001)	67%	
☐	Figure	Figure_b.pdf	14.1.2.4	Not Started				Figure 14.1.2.4 Patients With Adverse Events a by System Organ Class, Safety Population, Pooled	0%	

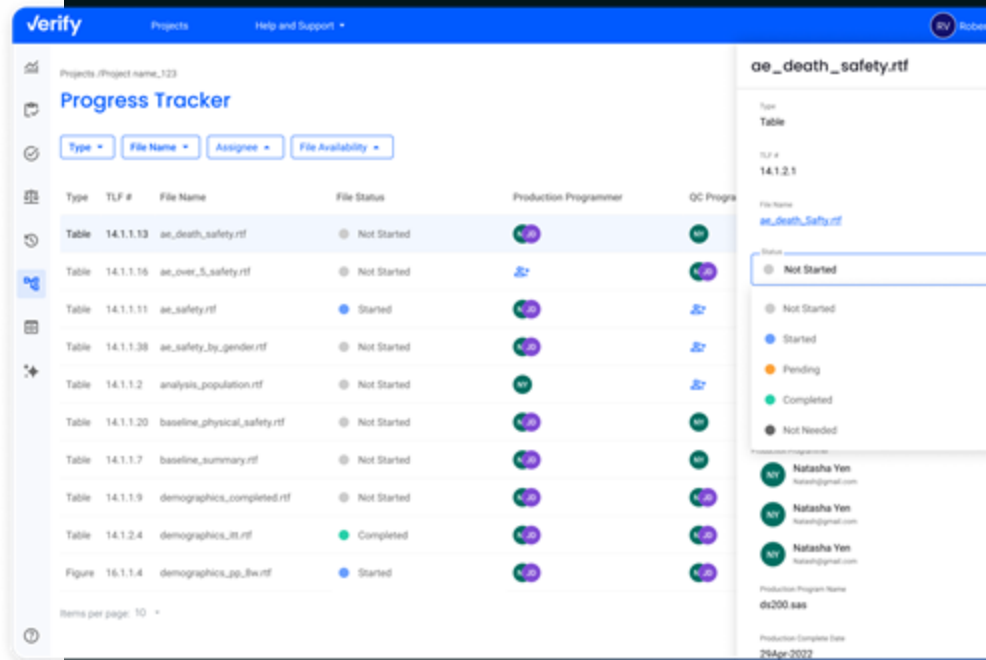
Items per page: 50

1 - 23 of 23



End-to-End QC Management

- Centralized online management of overall QC progress for entire TLF delivery
 - Save time by eliminating manual updates of offline QC trackers
 - Real-time visibility of tasks and status
- Upload Excel tracker containing full TLF list, assignees, dates, etc. Verify automatically:
 - Assigns project files to users
 - Clearly labels missing project files
- Users quickly find their assigned files & tasks
- Update assignees, set dates, change status, add free text, apply quick filters
- Automatic synchronization with File Review, Task Manager, and Activity Log



verify Projects Help and Support

← 14.1.1.13

Table 14.1.1.13
Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by System Organ Class and Preferred Term Treatment Related - Safety Population

	Drug A (N=119)				Drug B (N=109)			
	Mild	Mod.	Sev.	Total	Mild	Mod.	Sev.	Total
Any TEAEs	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
Infection	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
Bronchitis viral	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	2 (2.0%)	2 (2.0%)

N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculation. Subjects are only counted once per event in each row.
BEACONCURE CONFIDENTIAL SDTM Creation: 09OCT2021 (00:55) Source Data: adae Table Generation: 09OCT2021

Metadata Alignment

Review the current alignment between **table entity** and ADaM column and values. Revise if necessary.

Table Entity ADaM Column ADaM Value(s)

Title

Treatment-Emergent

TRTEMFL

Y

Leading to Discont...

AEACN

DRUG WIL...

Treatment Related

AEREL

RELATED

Safety Population

SAFFL

Y

Column/Row Headers

Major (Treatment)

TRTA

Minor (Severity)

AESEV

Cancel

Save

AI-identified linkages between table entities and ADaM

Table 16.5.5.12
Treatment Emergent Adverse Event Leading to Discontinuation of Study Drug by System Organ Class and Preferred Term Treatment Related Safety Population

	Treatment								Total (N=219)			
	#ILD	Mod.	Sev.	Total	#ILD	Mod.	Sev.	Total	#ILD	Mod.	Sev.	Total
Any TEAE	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.4%)
Infection	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.4%)
Bronchitis (viral)	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.4%)

N = number of subjects in the specified group, or the total number, then based on the denominator. For TEAEs, subjects are only counted once per event in each row.
Statistical comparison with baseline: 95% CI: 0.00-0.01 Source Data: Adverse Event Discontinuation: 0.00-0.01

SUBJID	TRTEMPL	AESER	AESV	AEREL	TWTA	SAFPL	AESUBJOC	AEACN	AEDCCO	AEDCCO1j1	AESOC	AEROSYS SYS
1003201	Y	Y	MILD	0.000000	DRUG B	/	Y	DOSE NOT CHANGED	SARS-CoV-2 test positive	SARS-CoV-2 test positive	Investigations	Investigations
1003201	Y	N	MODERATE	0.000000	DRUG B	/	N	DOSE NOT CHANGED	Nasopharyngitis	Nasopharyngitis	Infections and infestations	Infections and infestations
1003204	Y	N	MILD	0.000000	DRUG A	/	N	DOSE NOT CHANGED	Diarrhea	Diarrhea (excl infective)	Gastrointestinal Disorder	Gastrointestinal Disorder
1003204	Y	Y	MILD	0.000000	DRUG A	N	N	DOSE NOT CHANGED	Chalazion	Chalazion	Eye disorders	Eye disorders
1003205	N	N	MODERATE	NOT RELATED	DRUG B	N	N	DRUG INTERRUPTED	Hordeolum left eye	Hordeolum	Infections and infestations	Infections and infestations
1003205	N	N	MODERATE	NOT RELATED	DRUG B	N	N	UNKNOWN	Diarrhea	Diarrhea (excl infective)	Gastrointestinal Disorder	Gastrointestinal Disorder
1003205	Y	N	SEVERE	0.000000	DRUG B	N	N	DOSE NOT CHANGED	Supraventricular extrasystoles	Supraventricular extrasystoles	Cardiac disorders	Cardiac disorders

Modified by human-in-the-loop feedback Increase validation accuracy and speed

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ae_discontinuation_safety.rtf Entities Discrepancies 1 Generated Table 100% ***

Table 14.1.1.13
Leading to Discontinuation of Study Drug by System

Treatment Emergent Adverse Event
Organ Class and Preferred

Drug A
(N=119)

	Mild	Mod.	Sev.	Total	Mi
Any TEAEs	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0
Infection	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0
Bronchitis viral	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0

Title Entity Alignment

Leading to discontinuation of study drug

Variable
AESUBJDC

Value
Y

Statistical Programmer

Total
(N=219)

	Mild	Mod.	Sev.	Total
	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)

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.
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Modified by human-in-the-loop feedback

Increase validation accuracy and speed

verify

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EntitiesDiscrepanciesGenerated Table

100%

Table 14.1.1.13

Treatment Emergent Adverse Event Leading to Discontinuation of Study Drug by System

Organ Class and Preferred

Drug A
(N=119)

	Mild	Mod.	Sev.	Total	Mi
Any TEAEs	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0
Infection	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0
Bronchitis viral	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0

Table 14.1.1.13

Treatment Emergent Adverse Event Leading to Discontinuation of Study Drug by System

Organ Class and Preferred

Total
(N=219)

	Mild	Mod.	Sev.	Total
Any TEAEs	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
Infection	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
Bronchitis viral	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)

Title Entity Alignment

Leading to discontinuation of study drug

Variable

AESUBJDC

Search Columns

AESUBJDC

AEACN

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.

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Bea

16

Modified by human-in-the-loop feedback

Increase validation accuracy and speed

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ae_discontinuation_safety.rtf Entities Discrepancies 1 Generated Table 100% ***

Table 14.1.1.13
Leading to Discontinuation of Study Drug by System

Treatment Emergent Adverse Event Organ Class and Preferred Drug A (N=119)

	Mild	Mod.	Sev.	Total	M
Any TEAEs	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0
Infection	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0
Bronchitis viral	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0

Total (N=219)

	Mild	Mod.	Sev.	Total
	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)

Title Entity Alignment

Leading to discontinuation of study drug

Variable: AEACN

Value: DRUG WITHDRAWN

Save

Statistical Programmer

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.

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Reduce reliance on double programming

Table 14.1.1.12

Treatment Emergent Adverse Events Leading to Discontinuation of Study Drug by System

Organ Class and Preferred Term Treatment Related - Safety Population

	Drug A (N=119)				Drug B (N=199)				Total (N=219)			
	Mild	Mod.	Sev.	Total	Mild	Mod.	Sev.	Total	Mild	Mod.	Sev.	Total
Any TEAEs	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	2 (2.0%)	2 (2.0%)	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
Infection	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	2 (2.0%)	2 (2.0%)	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
Bronchitis viral	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	2 (2.0%)	2 (2.0%)	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)

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: sdsc Table Generation: 09OCT2021

Cancel Reprocess

Statistical Programmer

Enable AI-powered table generation

verify

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ae_discontinuation_safety.rtf

EntitiesDiscrepancies 3Generated Table

100% ***

Generates by Verify

Table 14.1.1.13
Treatment Emergent Adverse Events Leading to Discontinuation of Study Drug by System Organ Class and Preferred Term (Treatment Related) - Safety Population

	Drug A (N=119)				Drug B (N=109)				Total (N=219)			
	Mild	Mod.	Sev.	Total	Mild	Mod.	Sev.	Total	Mild	Mod.	Sev.	Total
Any TEAEs	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	2 (2.0%)	2 (2.0%)	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
Infection	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	2 (2.0%)	2 (2.0%)	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)
Bronchitis viral	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	2 (2.0%)	2 (2.0%)	1 (0.5%)	0 (0.0%)	2 (2.0%)	2 (2.0%)

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.

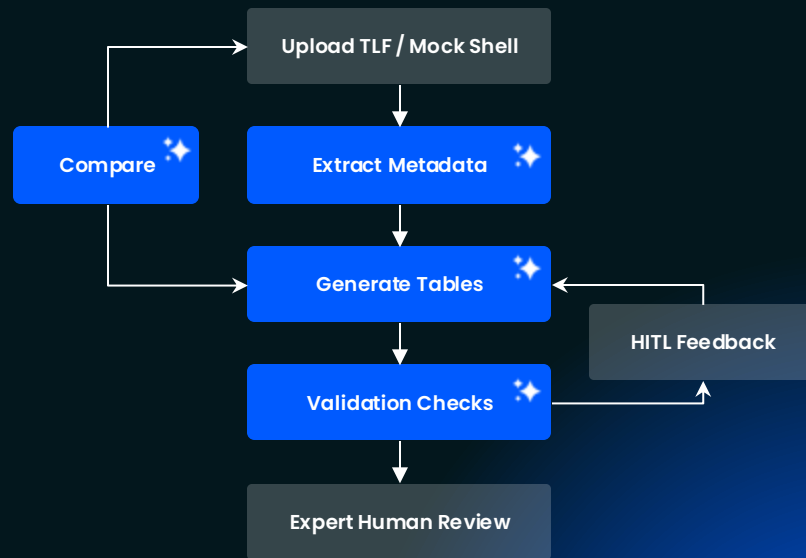
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Innovative Approach to TLF Validation

AI processes reverse engineer TLFs and automate metadata management, with human expertise providing key feedback

1. AI-enabled metadata extraction from final TLFs, instead of relying on human metadata updates
2. Verify generates tables based on extracted metadata
3. SMEs provide human-in-the-loop (HITL) feedback, to ensure accurate metadata alignment
4. AI-enabled validation checks identify errors missed at earlier stages
5. SMEs review and address issues

Beaconcure introduces an **industry-transforming** methodology to produce validated TLFs



Q & A

Thanks for participating!

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