

SD05

Verify:

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

Achinoam Ravet Perel / Head of Customer Success

Ilan Carmeli / Co-Founder and Chief Operating Officer

March 18, 2025

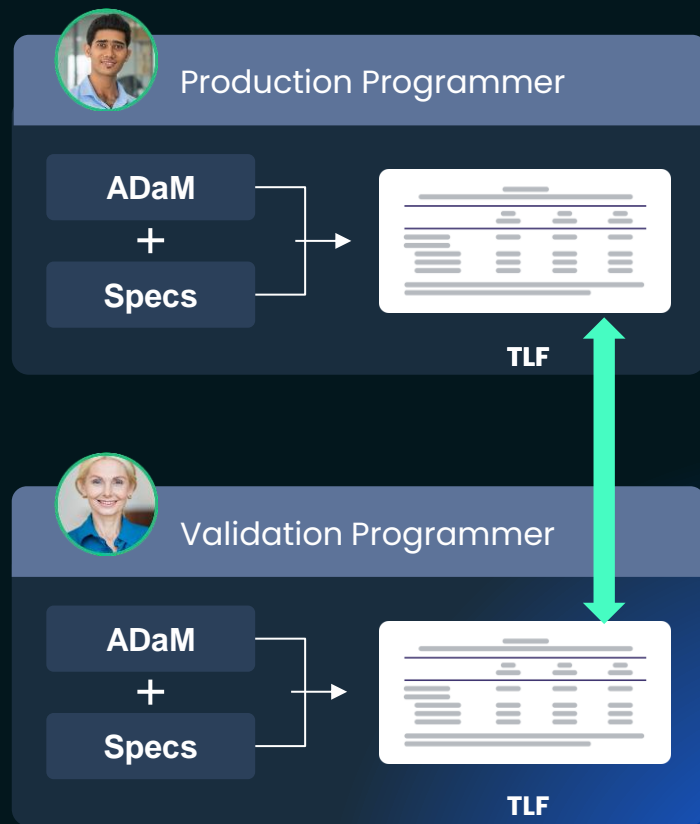
Agenda

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

Current Landscape

The High Cost of Manual TLF Validation

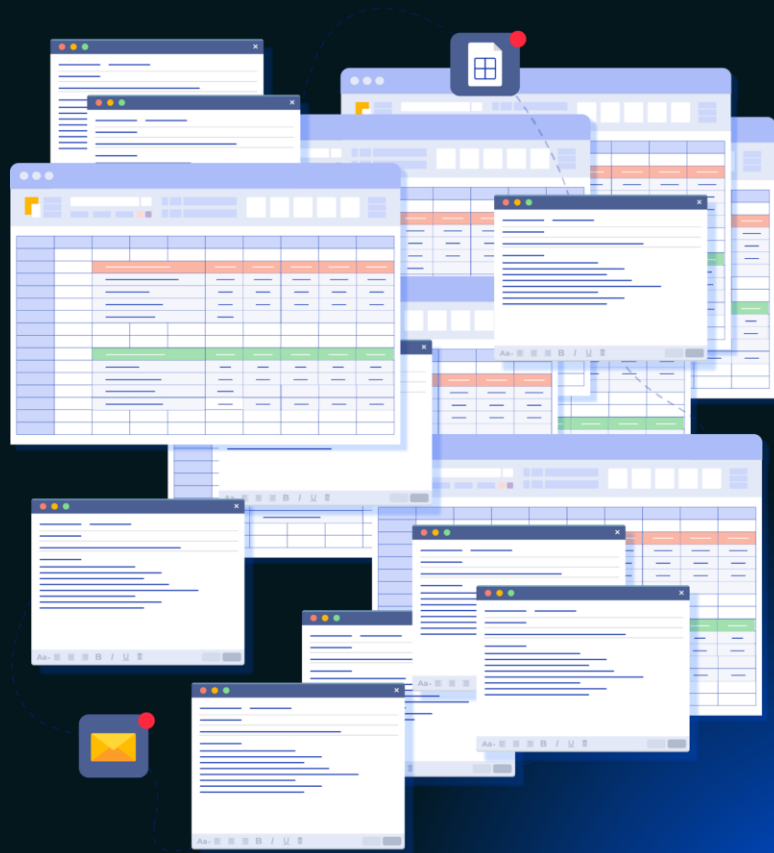
- Large labor footprint: at times duplicative, repetitive, time-consuming, & keeping resources from other necessary tasks
- Customized code
- Study-specific configuration
- As-needed double programming
- Visual review of thousands of pages of outputs
- Decentralized, disjointed reviewer communication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- Versioning issues with updating outdated outputs and trackers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

Verify

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

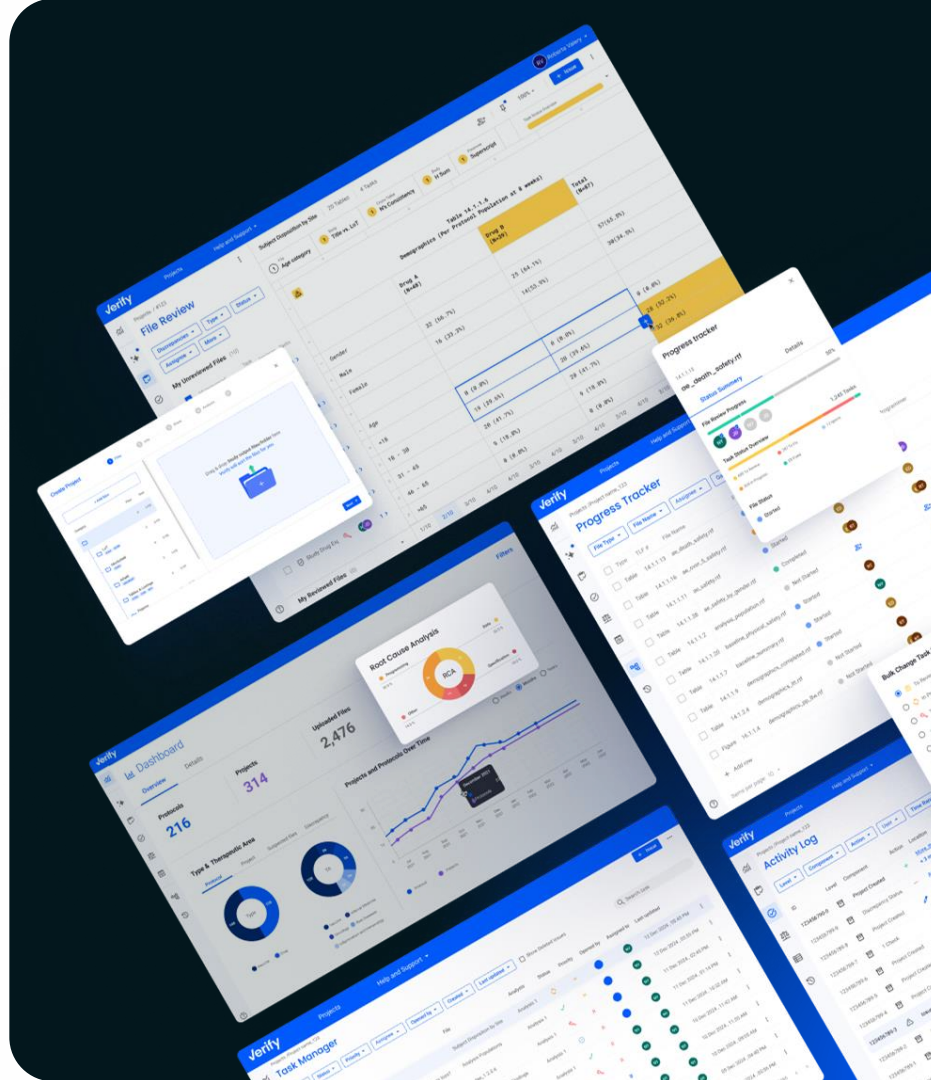


- ✓ Pharma Sponsor
- ✓ CRO
- ✓ Specialty FSP
- ✓ Biotech

Primary Users



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



Verify Integrated Application Layer



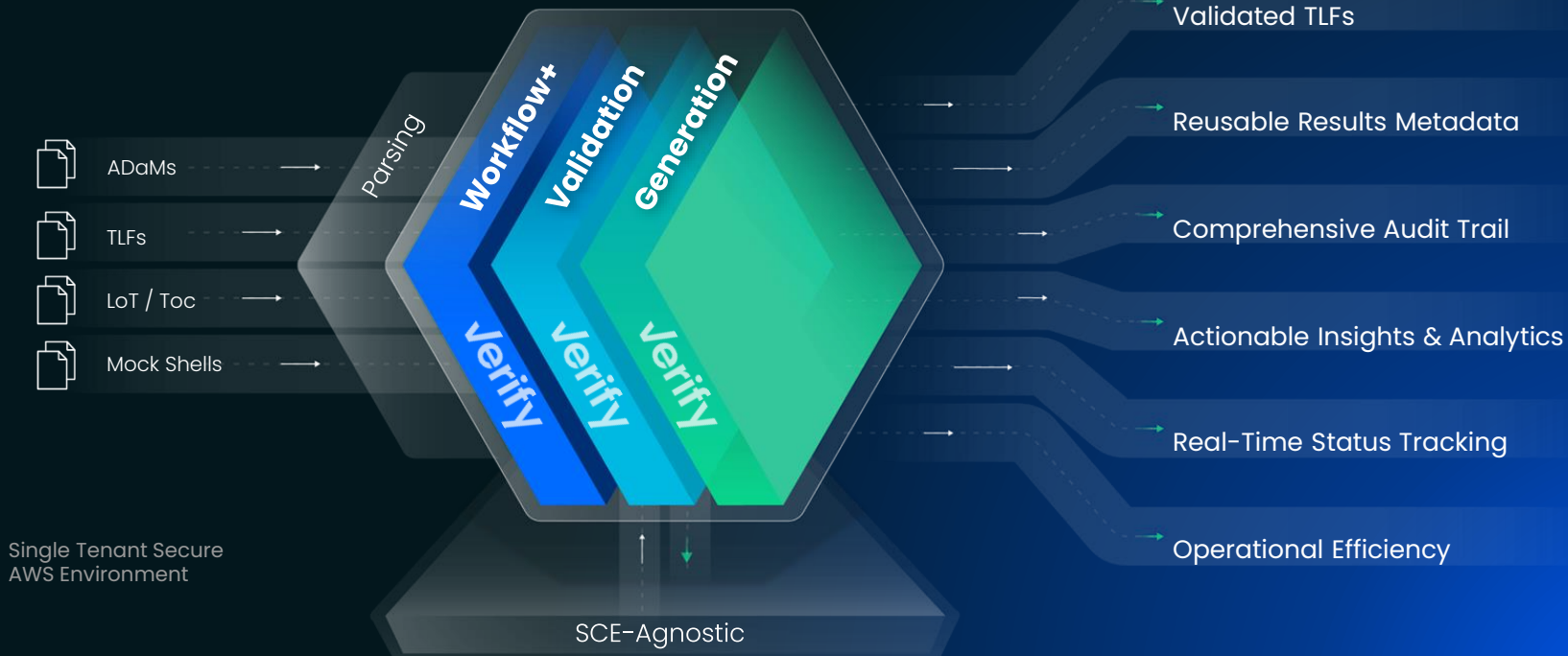
Source Data

AI-Enabled ingestion

GenAI and Analytics

User Interface

API or Upload





Verify Demo

Output Draft Review in Verify

by Production Programmer

verify Projects Help & Support Achinoam Ravet Perel

Projects / #12674 - Demo Video

File Review Book

Discrepancies Type Task Status Assignees Advanced

My Unreviewed Files (24)

| 1 Unreviewed | Status | Outcome | Assignee | Tasks |
|---|-----------------------|-----------------------|----------|-------|
| <input type="checkbox"/> Demo Mock Shells.docx | <input type="radio"/> | <input type="radio"/> | AR | 0 |
| <input type="checkbox"/> LoT Demo.xlsx | <input type="radio"/> | <input type="radio"/> | 4 AR | 4 |
| <input checked="" type="checkbox"/> ae_death_safety.rtf | <input type="radio"/> | <input type="radio"/> | 5 AR | 5 |
| <input type="checkbox"/> ae_over_5_safety.rtf | <input type="radio"/> | <input type="radio"/> | 13 AR | 13 |
| <input type="checkbox"/> ae_safety_by_gender.rtf | <input type="radio"/> | <input type="radio"/> | 3 AR | 3 |
| <input type="checkbox"/> ae_safety.rtf | <input type="radio"/> | <input type="radio"/> | 10 AR | 10 |

My Reviewed Files (1)

ae_death_safety.rtf | 5 Tasks

Footnotes Date Comparison | Footnotes MedDRA | Cross table Number of Deaths Consistency | Title Protocol Number Consistency | 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

verify Projects Help & Support AR Achinoam Ravet Perel

Projects / #12674 - Demo Video

ae_death_safety.rtf 100% + Issue

File Review

Discrepancies Type Task Status Assignees Advanced

My Unreviewed Files (25)

| File | Status | Outcome | Assignee | Tasks |
|-------------------------|--------|---------|----------|-------|
| 1 Unreviewed | | | | |
| Demo Mock Shells.docx | ✓ | | AR | 0 |
| LoT Demo.xlsx | ✓ | 3 | AR | 3 |
| ae_death_safety.rtf | ✓ | 0 | 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 |

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



03

Real-Time Management and Tracking in Verify

by PM or Lead Programmer

verify Projects Help & Support AR Achinoam Ravet Perel

Projects / #12674 - Demo Video

Progress Tracker Draft

File Type File Name File Availability Assignee

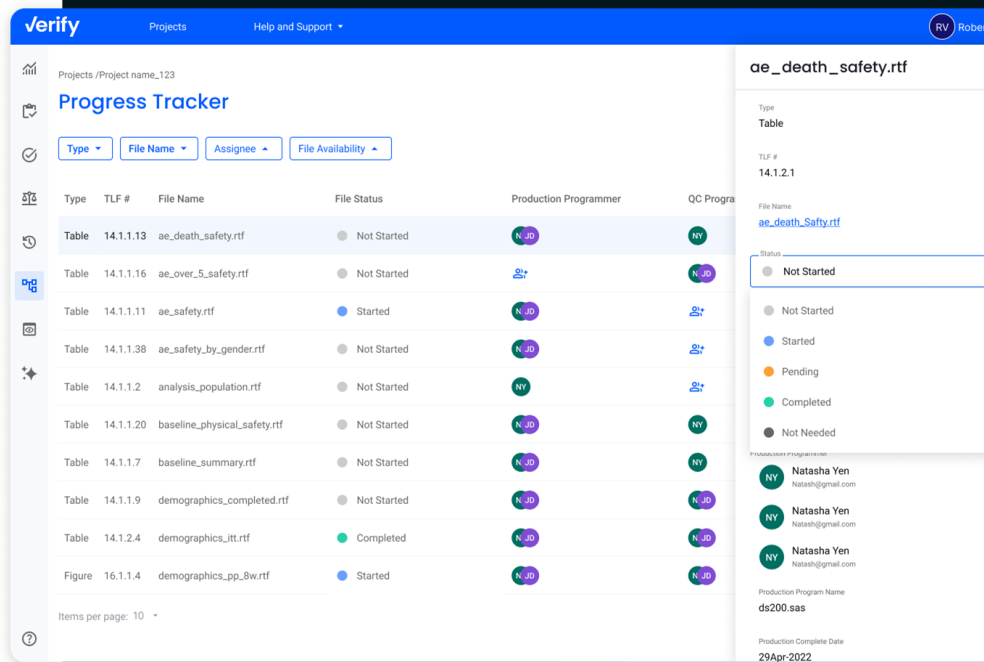
| <input type="checkbox"/> | Type | File Name | Output Number | Status | Productionprogrammers | Qcprogrammers | QC Statistician | Title | Review % | + |
|--------------------------|--------|---------------------------|---------------|-------------|-----------------------|---------------|-----------------|--|----------|---|
| <input type="checkbox"/> | 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% | |
| <input type="checkbox"/> | Table | weight_related.rtf | 14.1.1.5897 | Not Started | | | | Protocol S4472001 Weight Related Comorbidities (All Randomised Subjects) | 0% | |
| <input type="checkbox"/> | Table | Listing_of_Assay_Data.rtf | 16.2.7.21 | Started | | | | Listing of Assay Data (Protocol S4472001) | 50% | |
| <input type="checkbox"/> | Table | ae_death_safety.rtf | 14.1.1.13 | Pending | | | AU | Treatment Emergent Adverse Events Causing Death by System Organ Class and Preferred Term (Protocol S449201) | 67% | |
| <input type="checkbox"/> | 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% | |
| <input type="checkbox"/> | Table | ae_safety.rtf | 14.1.1.11 | Started | | | | TEAEs by System Organ Class and Preferred Term (Safety Population) (Protocol S4472001) | 100% | |
| <input type="checkbox"/> | Table | ae_over_5_safety.rtf | 14.1.1.16 | Pending | | | AU | TEAE Occurring in >5% of Subjects in at least One Treatment Group in Study by System Organ Class and Preferred Term (Protocol S449201) | 67% | |
| <input type="checkbox"/> | 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 - 100 +

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: 08OCT2021 (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 WI... |
| 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 14.3.1.13
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) | | | | |
|------------------|-----------|----------|----------|----------|----------|----------|----------|---------------|----------|----------|----------|----------|
| | Mild | Mod. | Sev. | Total | Mild | Mod. | Sev. | Total | Mild | Mod. | Sev. | Total |
| Any TEAEs | 1 (0.5%) | 0 (0.0%) | 0 (0.0%) | 1 (0.5%) | 0 (0.0%) | 0 (0.0%) | 2 (2.0%) | 2 (2.0%) | 1 (0.5%) | 0 (0.0%) | 2 (0.9%) | 3 (1.4%) |
| Infection | 1 (0.5%) | 0 (0.0%) | 0 (0.0%) | 1 (0.5%) | 0 (0.0%) | 0 (0.0%) | 2 (2.0%) | 2 (2.0%) | 1 (0.5%) | 0 (0.0%) | 2 (0.9%) | 3 (1.4%) |
| Bronchitis viral | 1 (0.5%) | 0 (0.0%) | 0 (0.0%) | 1 (0.5%) | 0 (0.0%) | 0 (0.0%) | 2 (2.0%) | 2 (2.0%) | 1 (0.5%) | 0 (0.0%) | 2 (0.9%) | 3 (1.4%) |

N = number of subjects in the specified group, or the total number that occur in the denominator for percentage calculations. Subjects are only counted once per event in each row.
BEACONCHEM CONFIDENTIAL. BSM Creation: 08/07/2023 (08:55) Source Data: adae Table Generation: 01/07/2024

| SUBJID | TRTENFL | AESER | AESEV | AEREL | TRTA | SAFFL | AESUBJDC | AEACN | AEDECOD | AEDECOD1 ₁ | AESOC | AEBODSYS ₁ |
|---------|---------|-------|----------|-------------|--------|-------|----------|------------------|--------------------------------|--------------------------------|-----------------------------|-----------------------------|
| 1003201 | Y | Y | MILD | RESA00 | DRUG B | / | Y | DOSE NOT CHANGED | SARS-CoV-2 test positive | Investigations | Investigations | Investigations |
| 1003201 | Y | N | MODERATE | RESA00 | DRUG B | Y | N | DOSE NOT CHANGED | Nasopharyngitis | Investigations | Infections and infestations | Infections and infestations |
| 1003204 | Y | N | MILD | RESA00 | DRUG A | Y | N | DOSE NOT CHANGED | Diarrhea | Diarrhoea (excl infective) | Infections and infestations | Infections and infestations |
| 1003204 | Y | Y | MILD | RESA00 | 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 | Diarrhoea (excl infective) | Gastrointestinal Disorder | Gastrointestinal Disorder |
| 1003205 | Y | N | SEVERE | RESA00 | DRUG R | 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

verify Projects Help and Support Robert Valery

ae_discontinuation_safety.rtf Entities Discrepancies 1 Generated 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 | Total (N=219) | | | |
|------------------|----------------|----------|----------|----------|----------|---------------|----------|----------|----------|
| | 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%) | 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%) | 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%) | 1 (0.5%) | 0 (0.0%) | 2 (2.0%) | 2 (2.0%) |

Title Entity Alignment

Leading to discontinuation of study drug

Variable: AESUBJDC

Value: Y

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

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

verify Projects Help and Support Robert Valery

ae_discontinuation_safety.rtf Entities Discrepancies 1 Generated 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 | Total (N=219) | | | |
|------------------|----------------|----------|----------|----------|----------|---------------|----------|----------|-------|
| | 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%) | |

Title Entity Alignment

Leading to discontinuation of study drug

Variable
AESUBJDC

Search Columns

AESUBJDC

AEACN

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

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

verify Projects Help and Support Robert Valery

ae_discontinuation_safety.rtf Entities Discrepancies 1 Generated Table 100%

Table 14.1.1.13
Treatment Emergent Adverse Event Leading to Discontinuation of Study Drug by System
Organ Class and Preferred Term

| | Drug A (N=119) | | | | Total (N=219) | | | |
|------------------|-------------------|----------|----------|----------|------------------|----------|----------|----------|
| | Mild | Mod. | Sev. | Total | Mild | Mod. | Sev. | Total |
| Any TEAEs | 1 (0.8%) | 0 (0.0%) | 0 (0.0%) | 1 (0.8%) | 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%) | 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%) | 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.

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

Reduce reliance on double programming

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.

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

Cancel

Reprocess



Statistical Programmer

Enable AI-powered table generation

verify Projects Help and Support Robert Valery

ae_discontinuation_safety.rtf Entities Discrepancies 1 Generated 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.

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

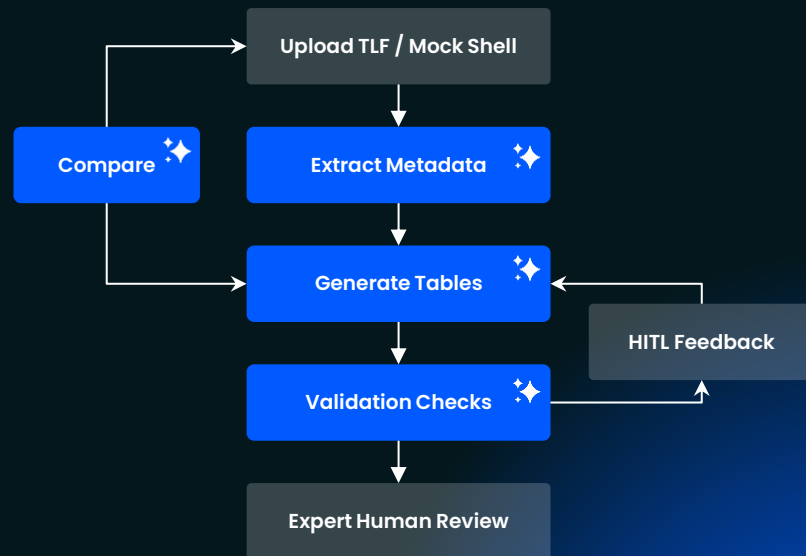
Right-to-Left Coverage

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!

llan@beaconcure.com
Achinoam@beaconcure.com