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SD05

Verify:

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

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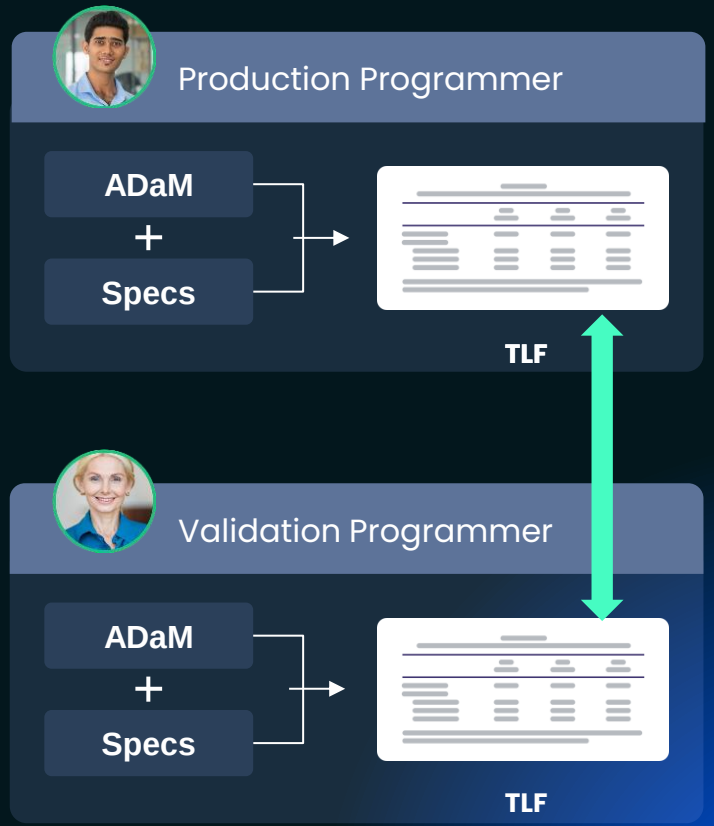
Agenda

- 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



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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- Versioning issues with updating outdated outputs and trackers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

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

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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

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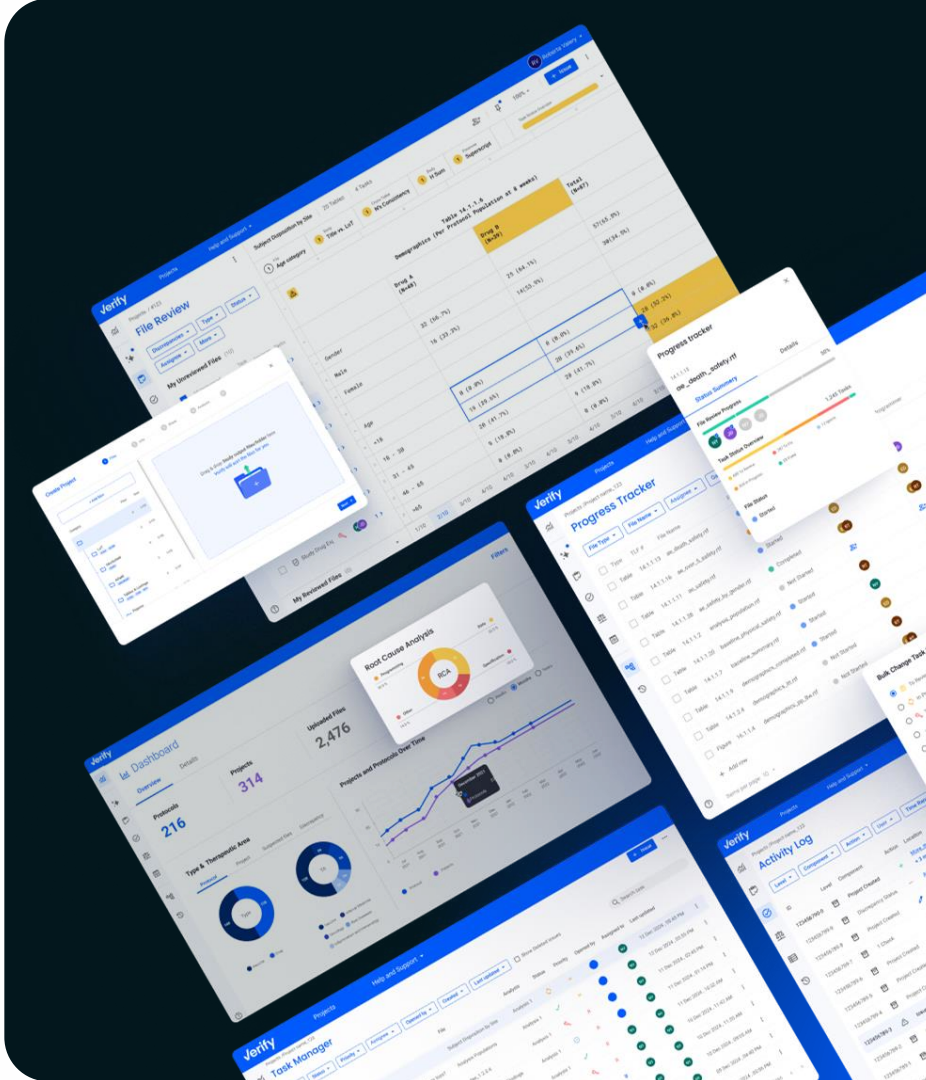
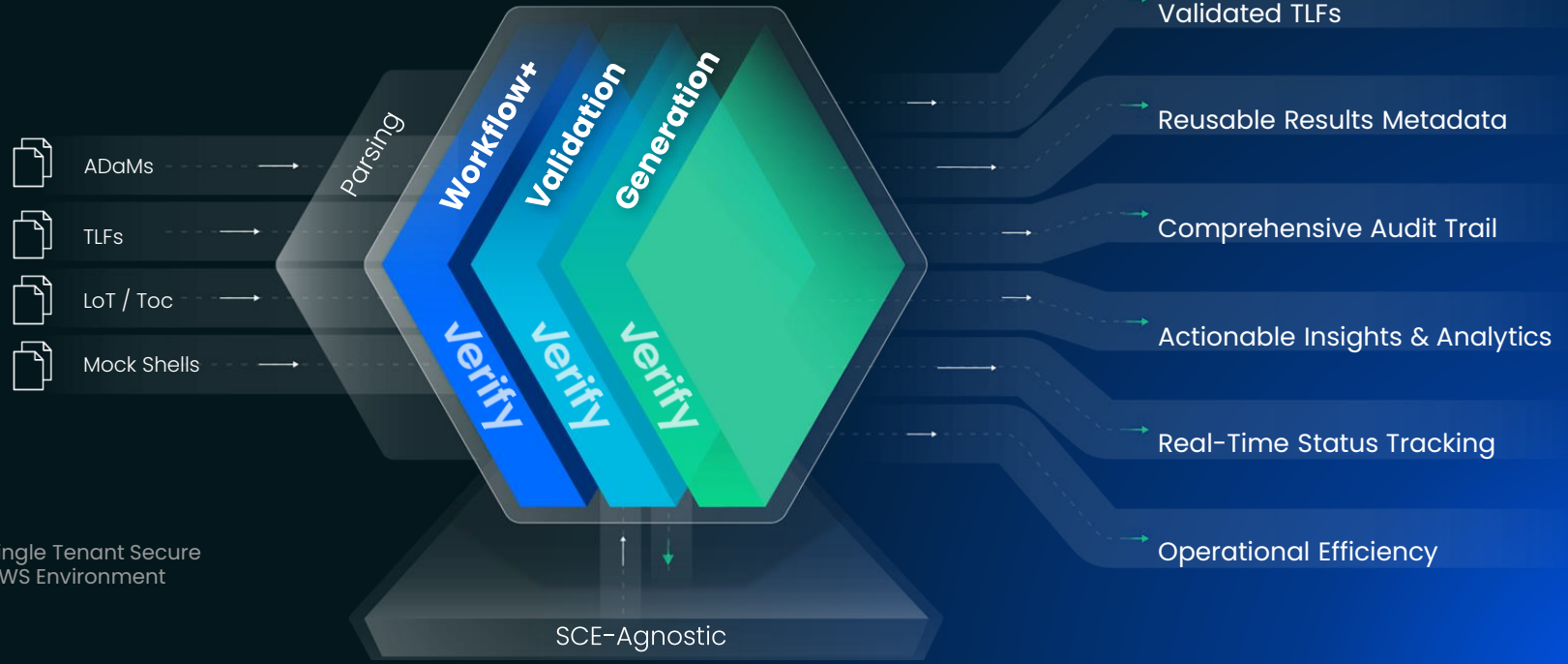


Verify Integrated Application Layer

Source Data | AI-Enabled ingestion | GenAI and Analytics | User Interface

API or Upload



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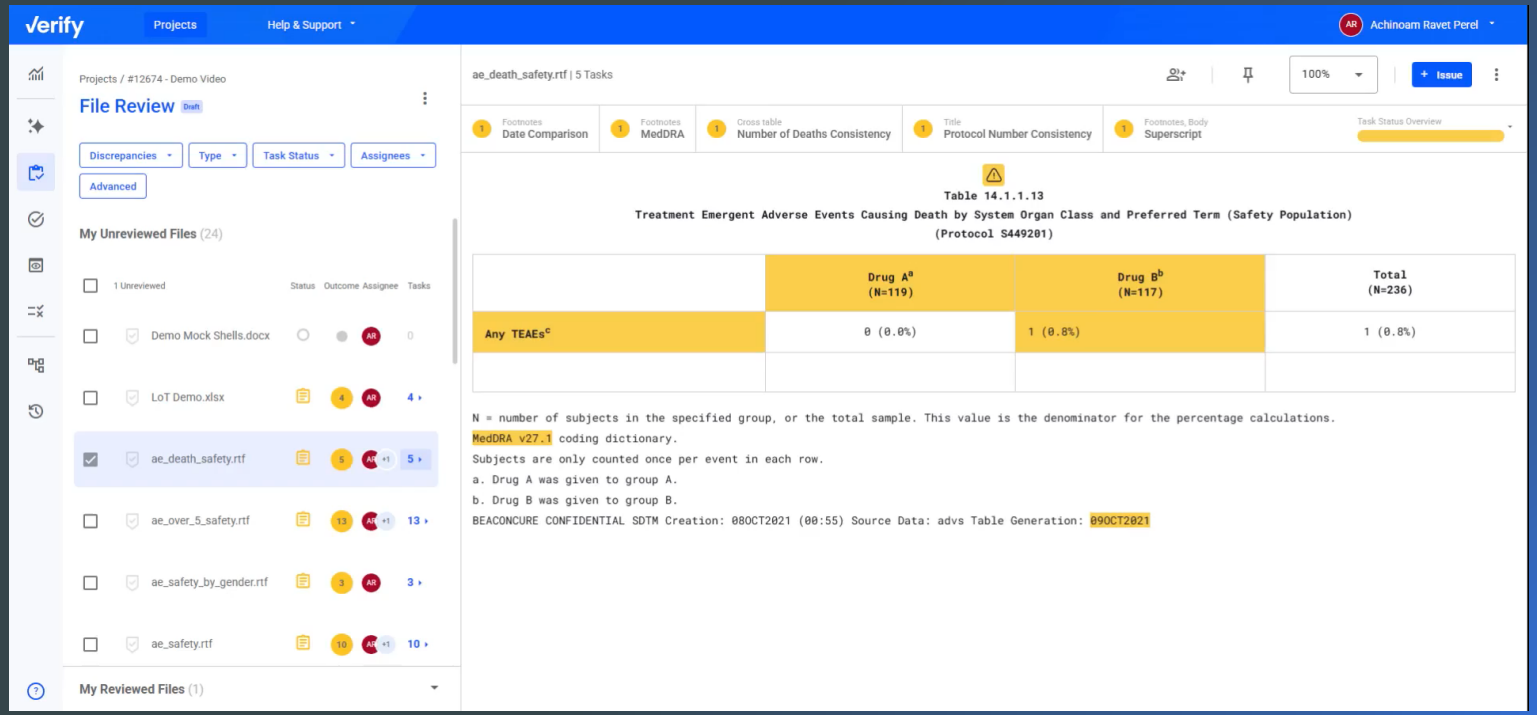
√erify Demo

01

Output Draft Review in Verify

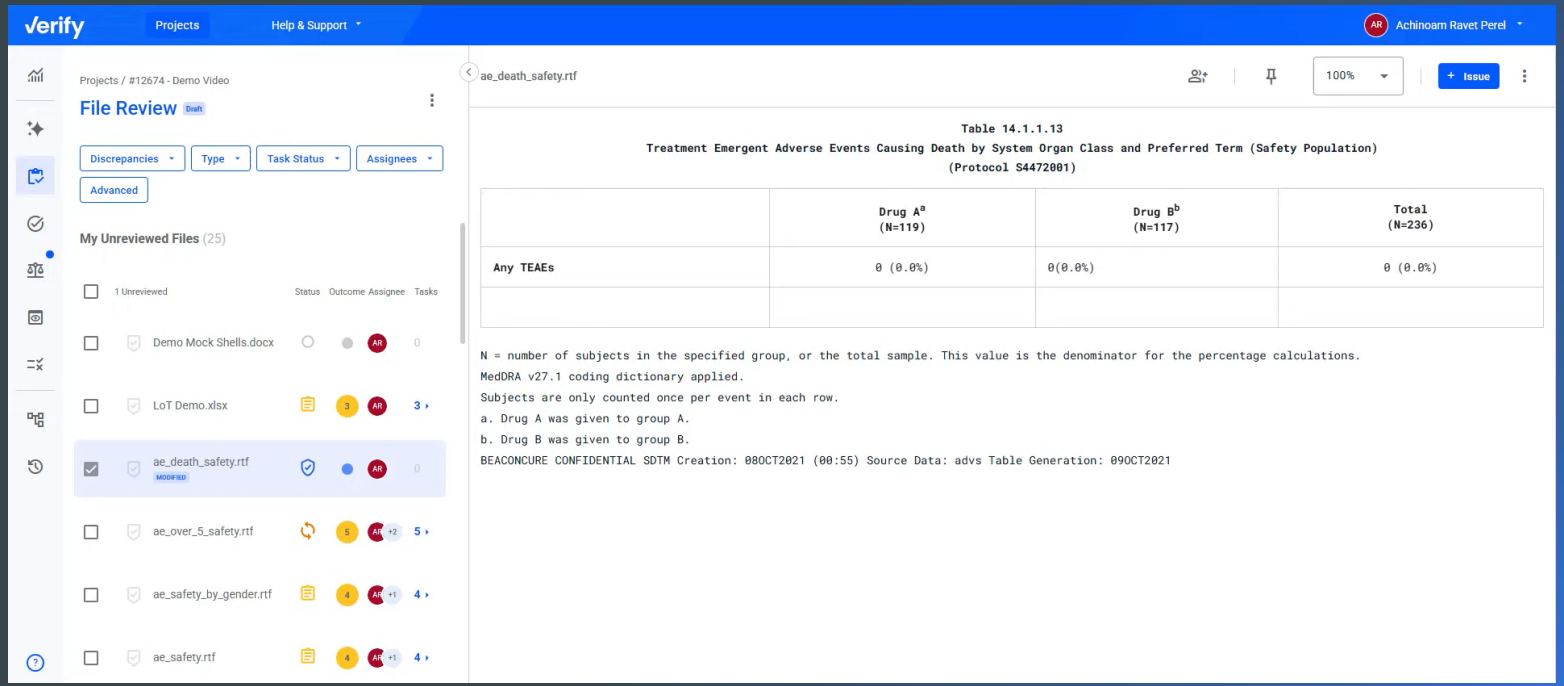
by Production Programmer



02

Output Review Iteration in Verify

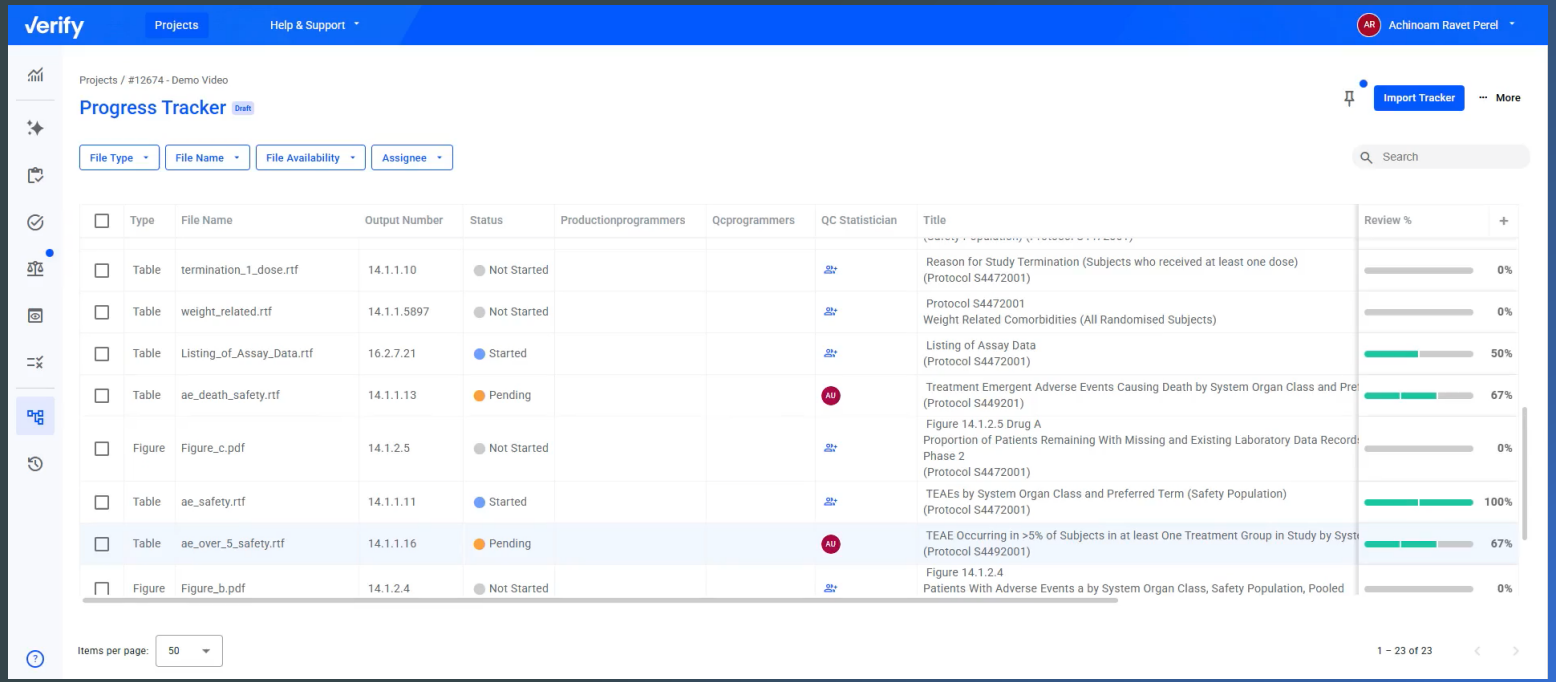
by Validation Programmer



03

Real-Time Management and Tracking in Verify

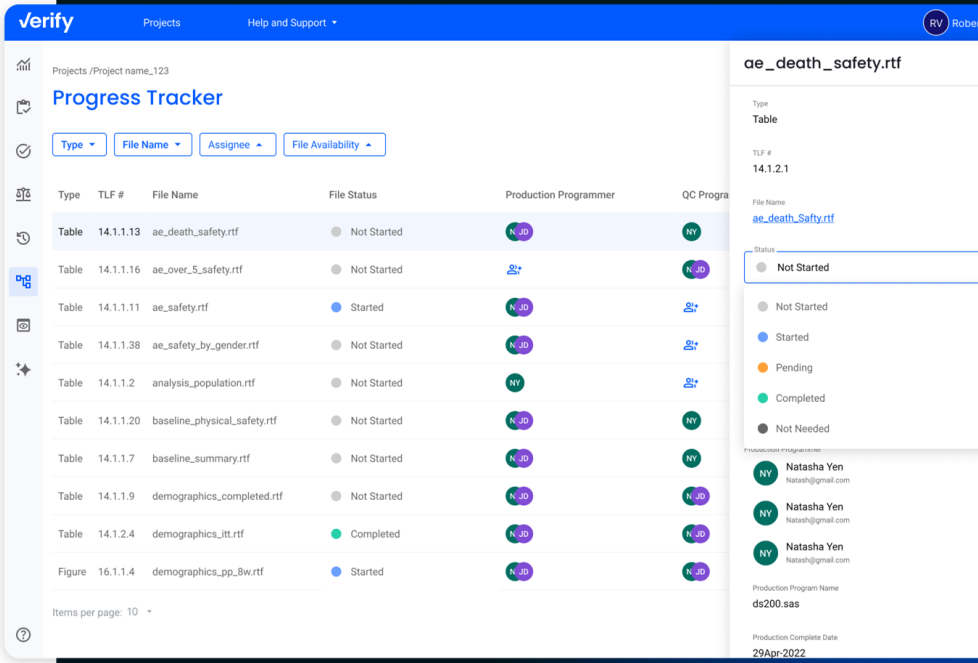
by PM or Lead Programmer



Progress Tracker

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



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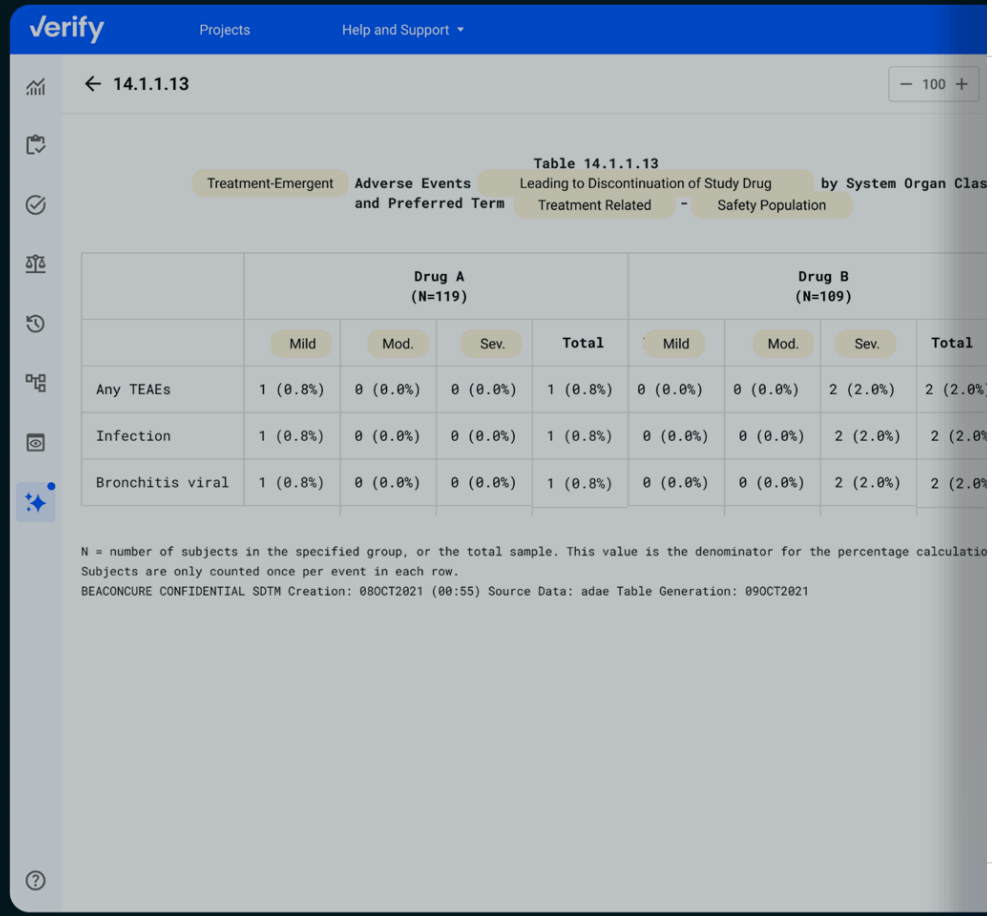

Metadata Alignment

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

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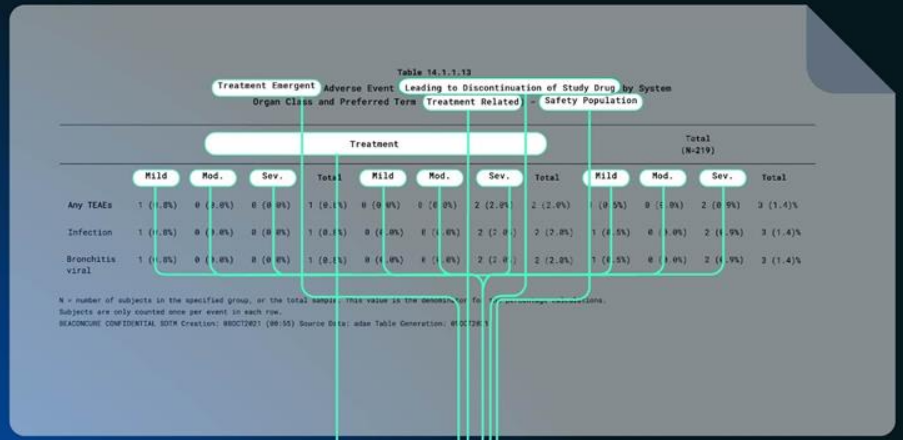
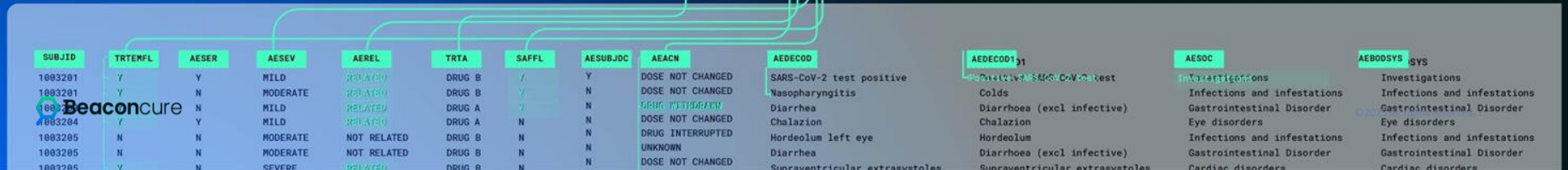
AI-identified linkages between table entities and ADaM





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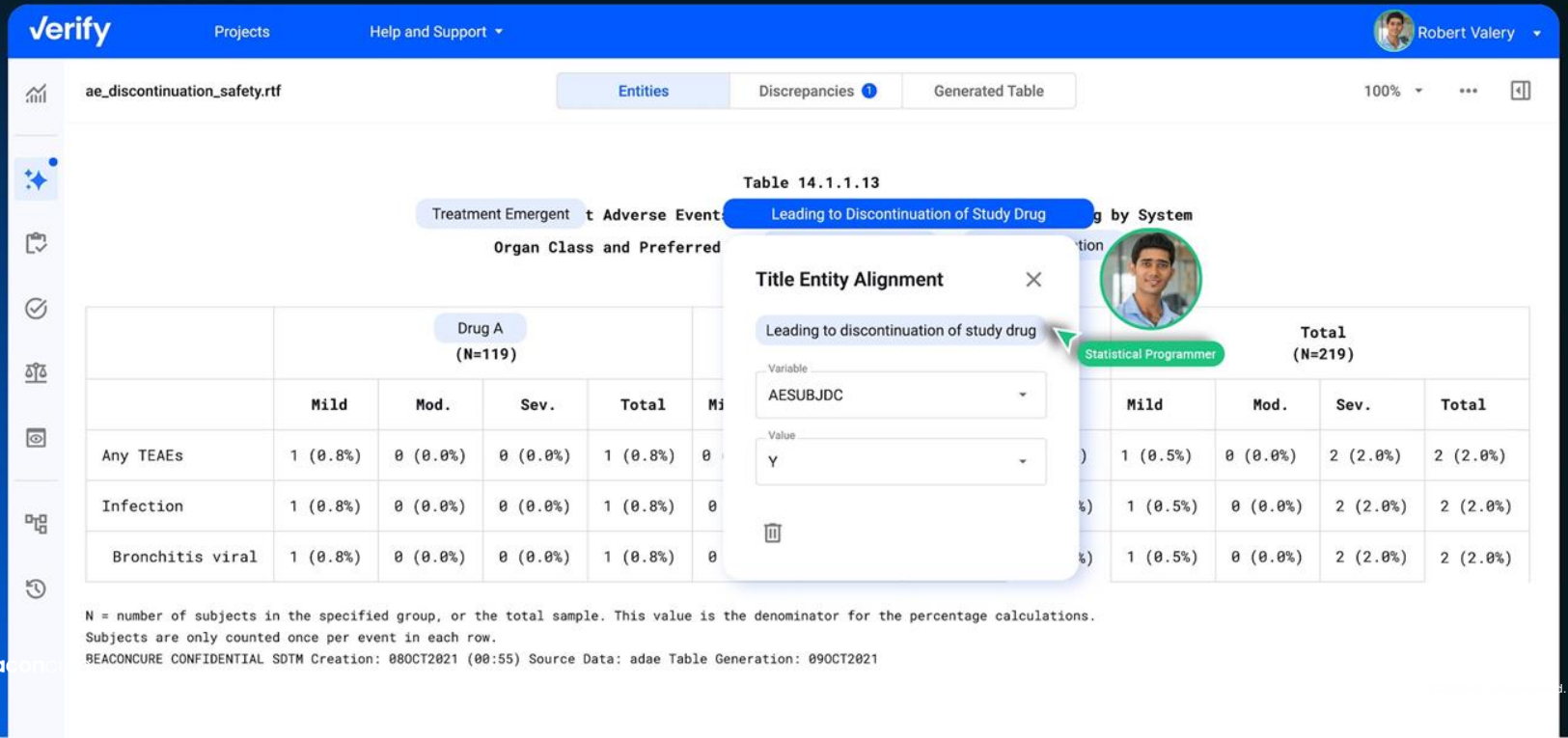
Modified by human-in-the-loop feedback
Increase validation accuracy and speed



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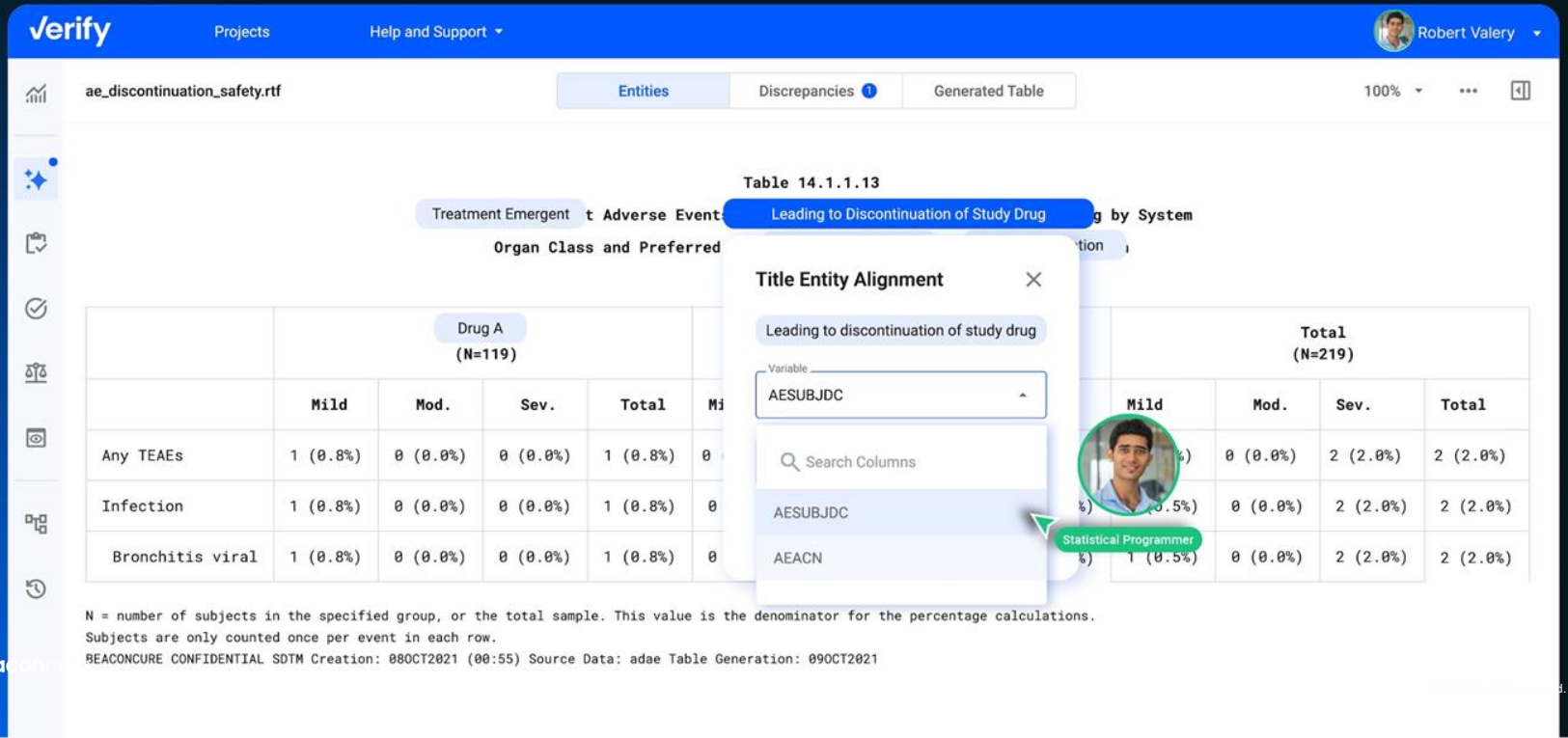

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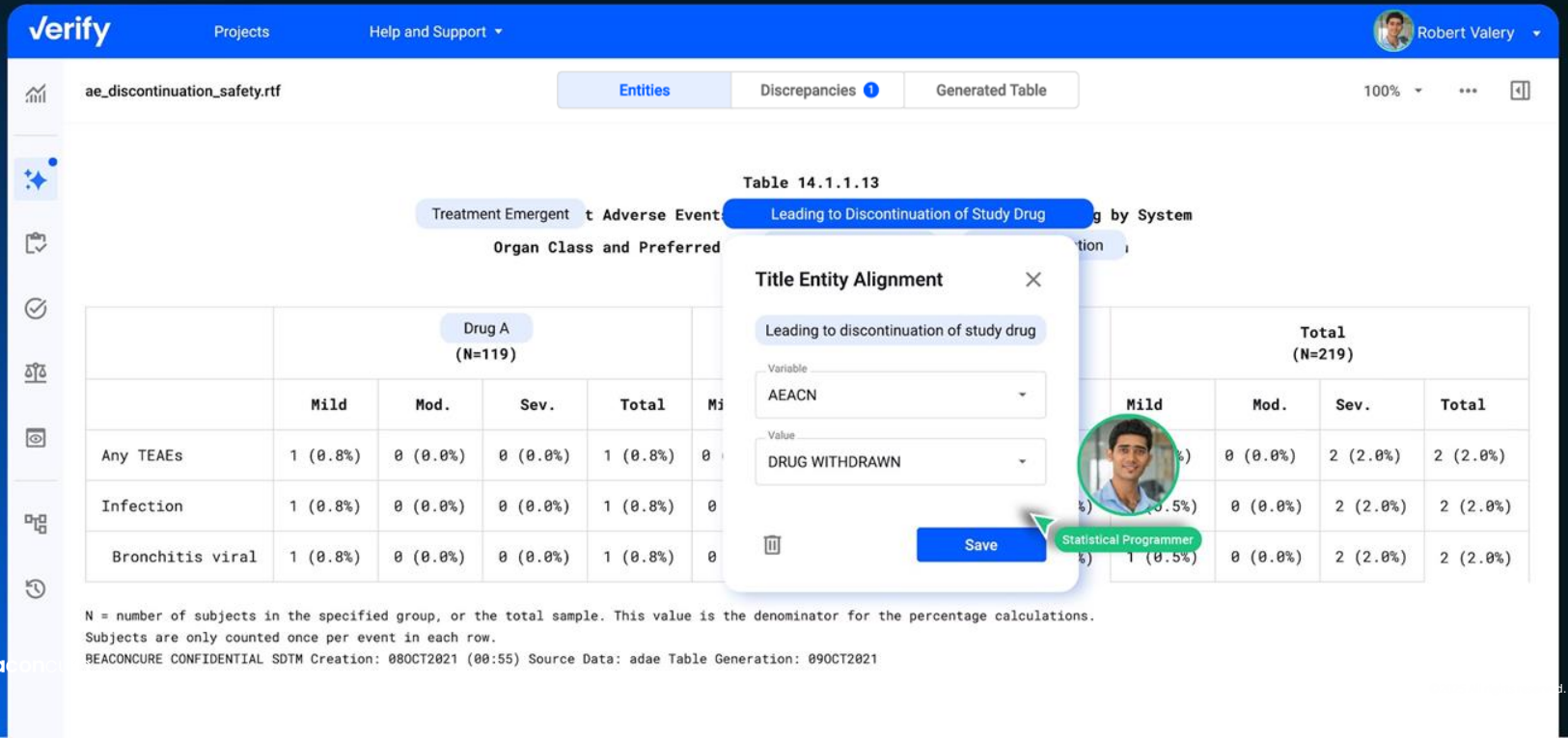

Reduce reliance on double programming

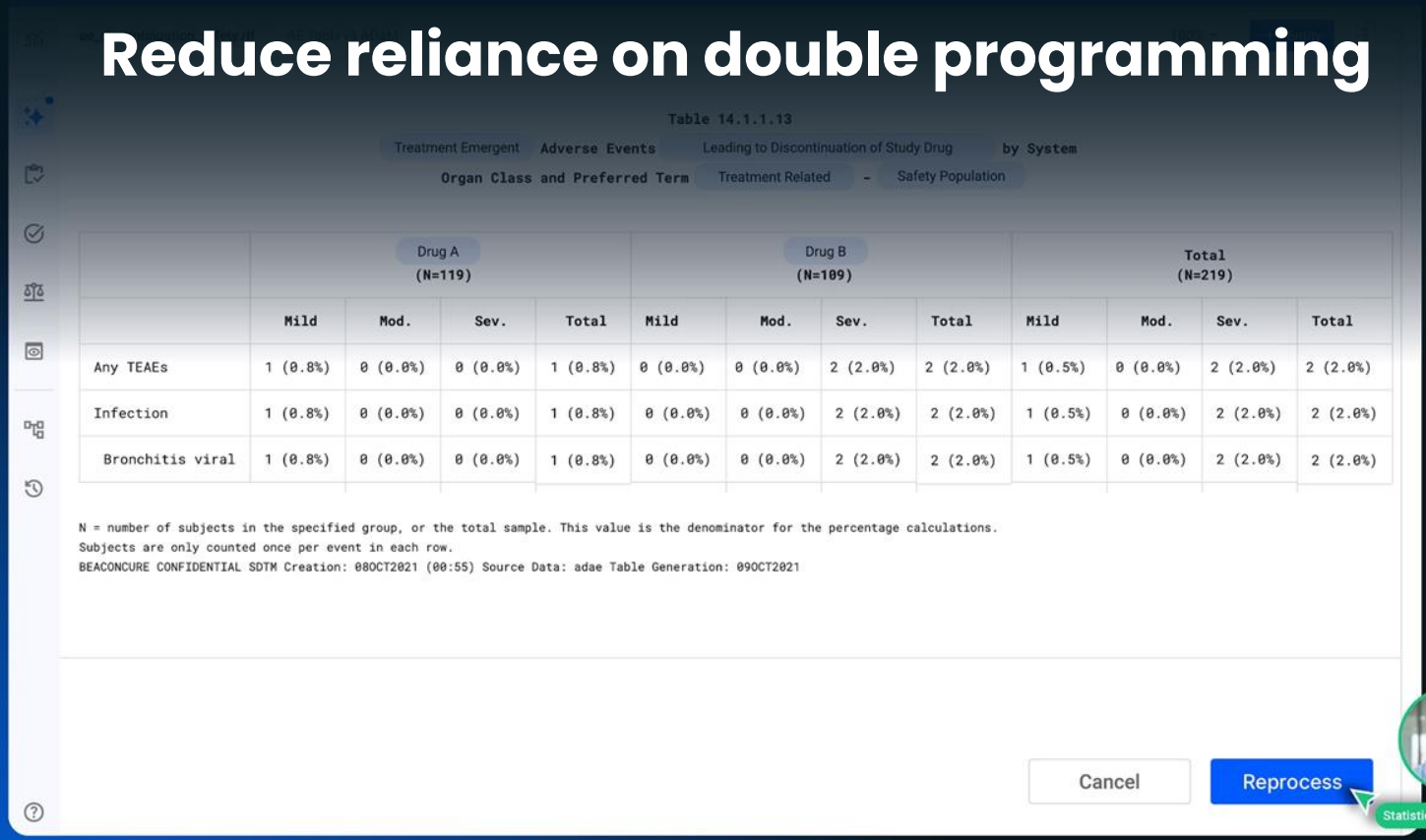

Table 14.1.1.13

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

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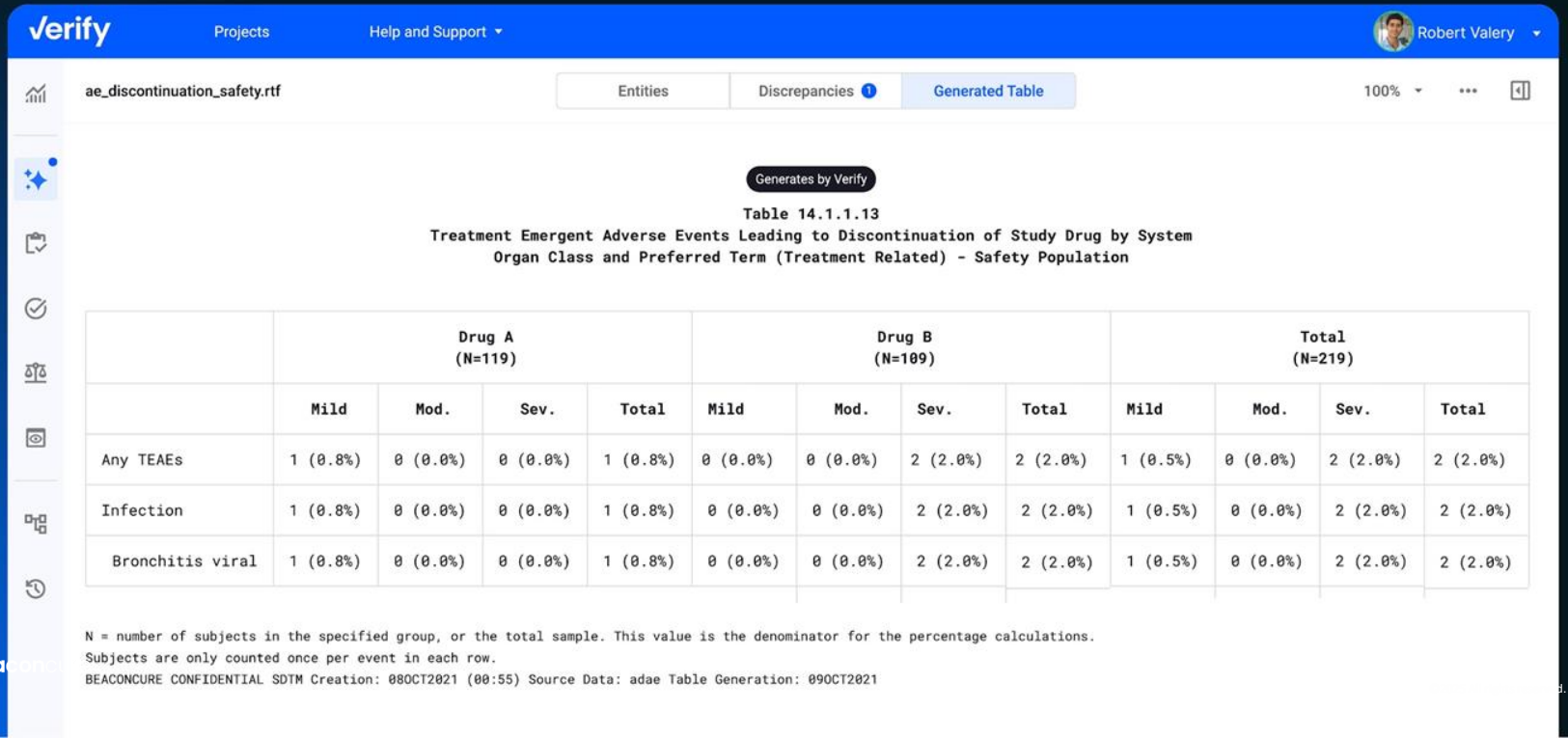
Enable AI-powered table generation



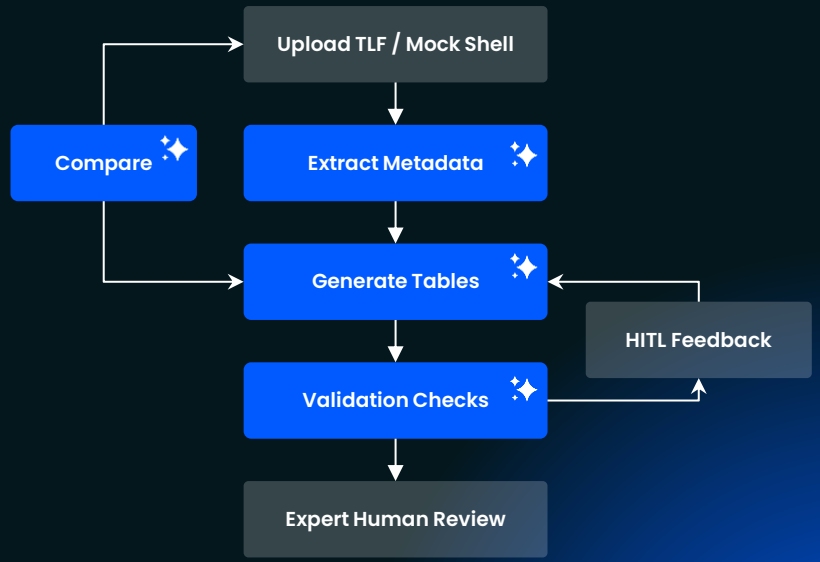
Right-to-Left Coverage

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



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Q & A

Thanks for participating!

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