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The Best of Both Worlds:
AI and Human-in-the-Loop Processing in TLF Design, Production, and Validation

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Our vision is to transform biometrics from manual, document-based processes to fully autonomous, AI-driven analysis and reporting where **natural language commands generate complete submission-ready outputs**

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Today's Reality: The Clinical Statistics Challenge

Time Burden

Statisticians spend up to 50% of time on coding and formatting instead of analysis

Document Chaos

Critical metadata scattered across PDFs, Word docs, and spreadsheets

Disconnected Workflows

Email-based reviews, version control chaos, manual reconciliation

Scaling Limitations

Growth requires proportional headcount increases

Imagine This Future State...

Statistician

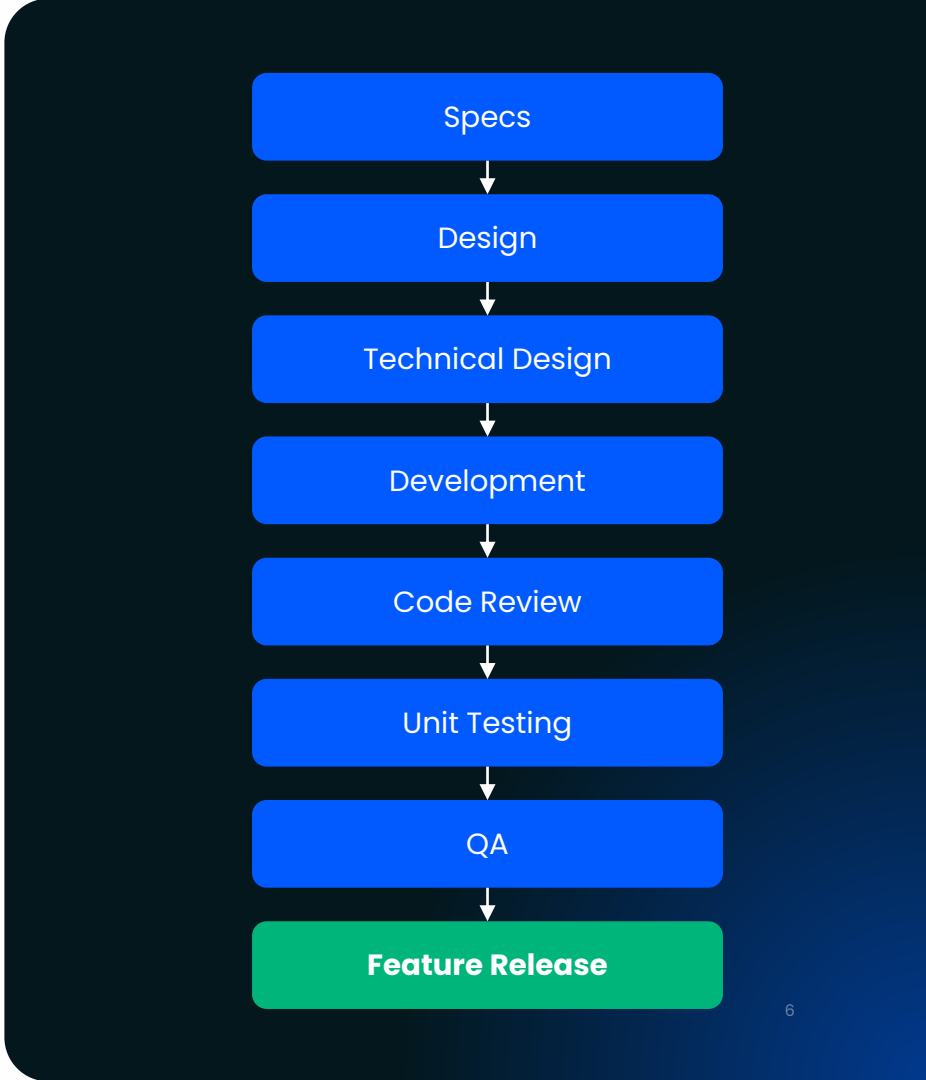
Generate all Phase III efficacy tables for the cardiovascular study, include subgroup analyses by age and gender, format for FDA submission, and create executive summary for the steering committee.

Verify Agent

- ✔ Analyze 47 protocol-defined endpoints across 3,247 patients
- ✔ Generate 23 efficacy tables with automated subgroup stratification
- ✔ Apply FDA formatting standards
- ✔ Create executive dashboard with key findings
- ✔ All outputs ready for review in 12 minutes
- ✔ Steering committee summary highlights 15% relative risk reduction ($p<0.001$)

How?

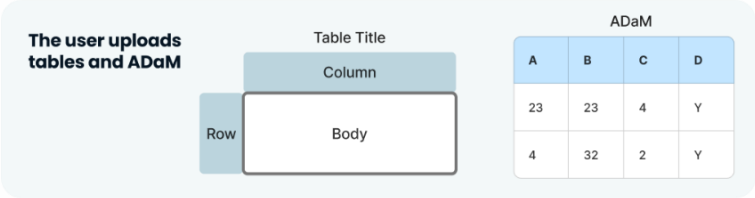
Following the same **procedures** of the software development space with some adaptations.

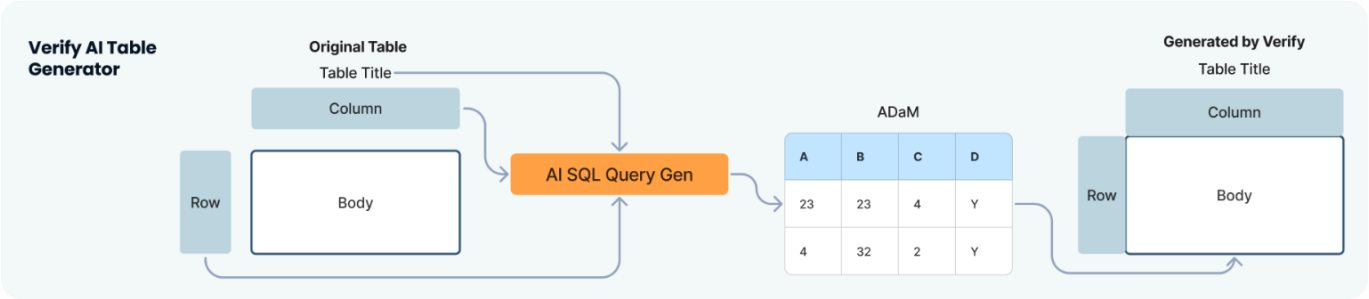


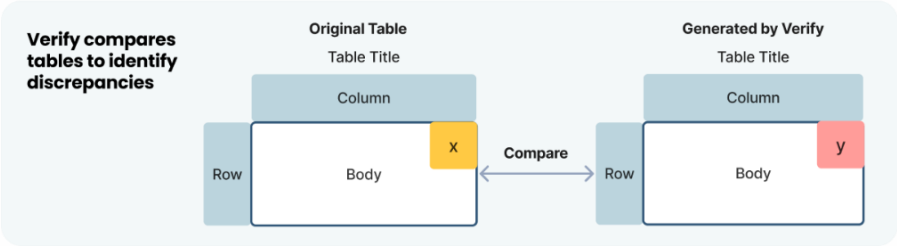
Innovative Approach for Output Validation

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







How can we leverage and reuse the metadata acquired in one trial many times over?

What Should the Human-Machine Partnership Look Like?

Humans

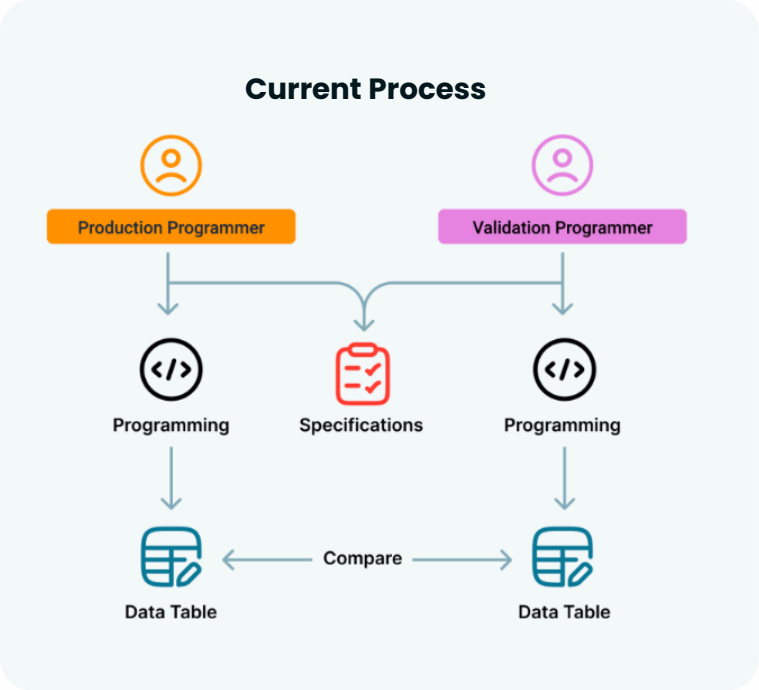
- **Endpoint definition,** characterization
- Study conceptualization and design
- **Review, coalesce, interpret**
- Drive **continuous process improvement** for AI algorithms

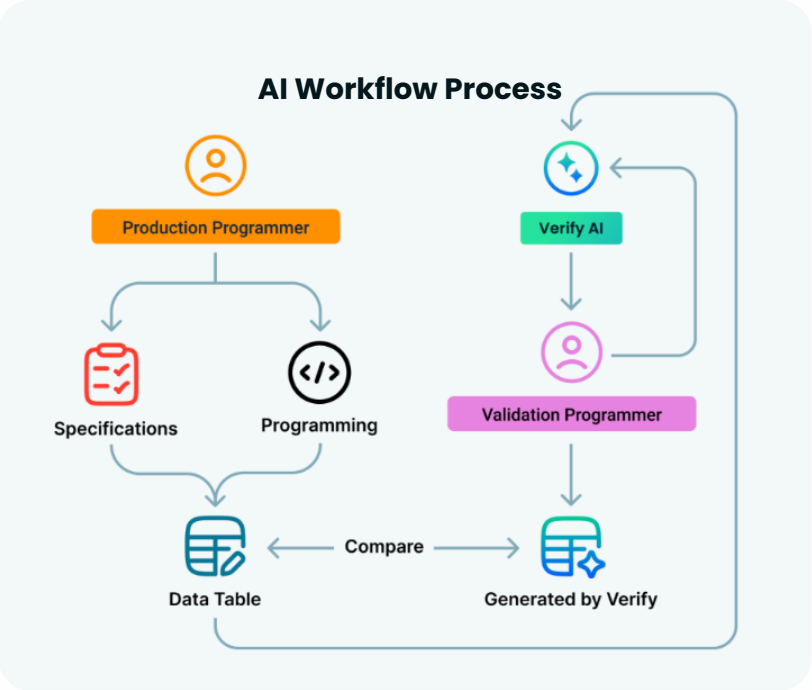
Verify AI

- **Parse and understand** multiple document types
- **Automate review** with NLP, NER, RAG
- **Generate TLFs automatically** with HITL
- **Continually self-improve** AI models and algorithms

AI & Human Interaction

Verify empowers validation programmers with a **metadata-driven** solution to efficiently validate TLFs, significantly reducing time, costs, and errors in validation processes of clinical outputs





SAS Output | Beaconcure Explain TLF

localhost:8501

Deploy

Show Table Schema

Schema not available. Please load a file first.

Show Relevant ADaM Data

Instructions

Uploading SAS7BDAT Files

1. Enter the ADaM file type (e.g., ADSL, ADAE, ADTTE)
2. **Specify relevant ADaM columns** that are important for your analysis
3. If on Windows and encountering issues, check "Specify temporary folder" and provide a path
4. Click the 'Browse files' button to select your SAS7BDAT file
5. Once selected, click 'Load Selected File' to load the data

Running Queries

Manual SQL Query

1. Enter your SQL query in the text area
2. Click 'Execute Query' to see the results

Natural Language Query (TLF Explanation)

Beaconcure Explain TLF demo

Step 1: Upload ADaM File

Enter ADaM file type (e.g., ADSL, ADAE, ADTTE)

ADAE

Relevant ADaM Columns

Enter relevant ADaM column names as a Python list:

["USUBJID", "TRT01P", "AGE", "SEX", "RACE", "SAFFL", "ITTFL"]

Specify temporary folder (helpful for Windows issues)

Upload a SAS7BDAT file

Drag and drop file here

Limit 200MB per file • SAS7BDAT

Browse files

Step 2: Execute SQL Query

Chat about your SQL query and TLF creation

Enter the SQL query you want to understand:

SELECT TRT01P, COUNT(*) as N FROM ADSL WHERE SAFFL='Y' GROUP BY TRT01P

Set SQL Query Context

No relevant ADaM data available. Please specify relevant columns when loading the file.

Execute & Show TLF

Chat with LLM

Ask your question:

e.g., How does this query create the patient counts by treatment group?

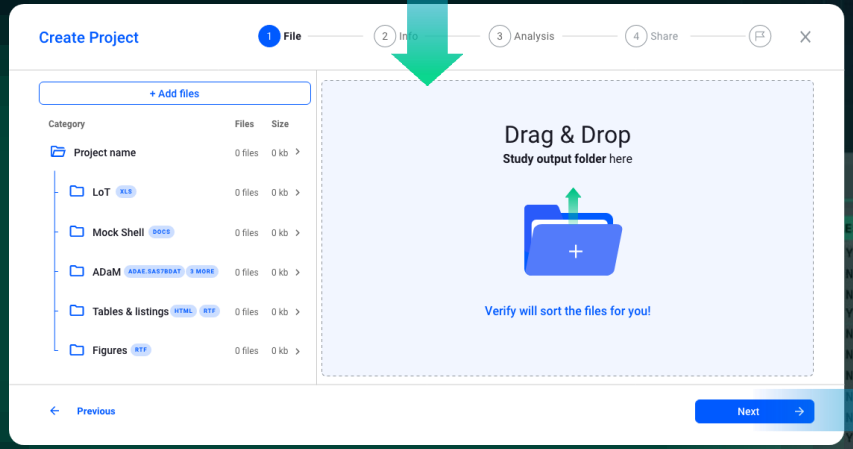
Send Message

Clear Chat

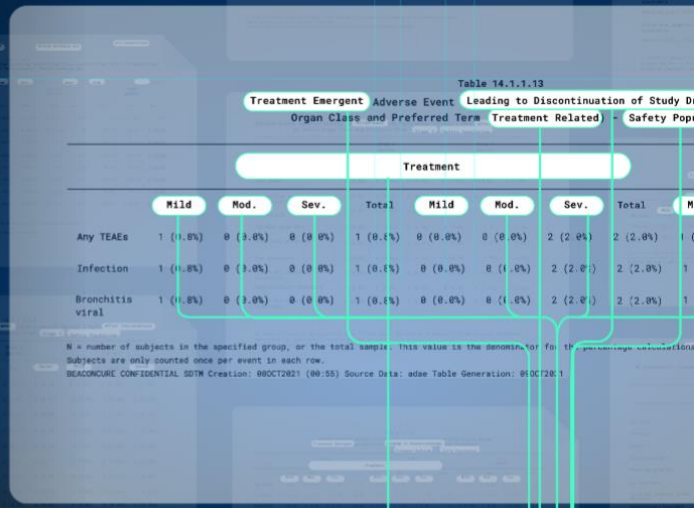
Verify's Parsing

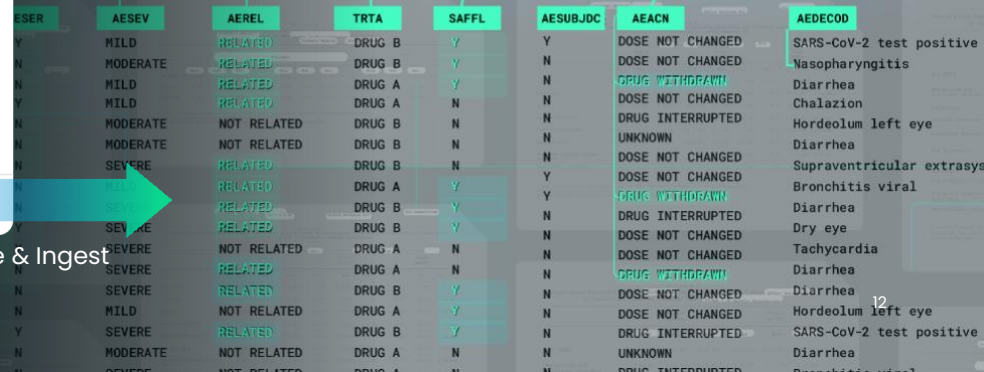
AI-Enabled Parsing and Results Metadata Extraction

Drag & Drop



Parse & Ingest





Best of Both Worlds Use Case

AI-Enabled Output Generation with HITL Feedback

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 Evaluable for ABs	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

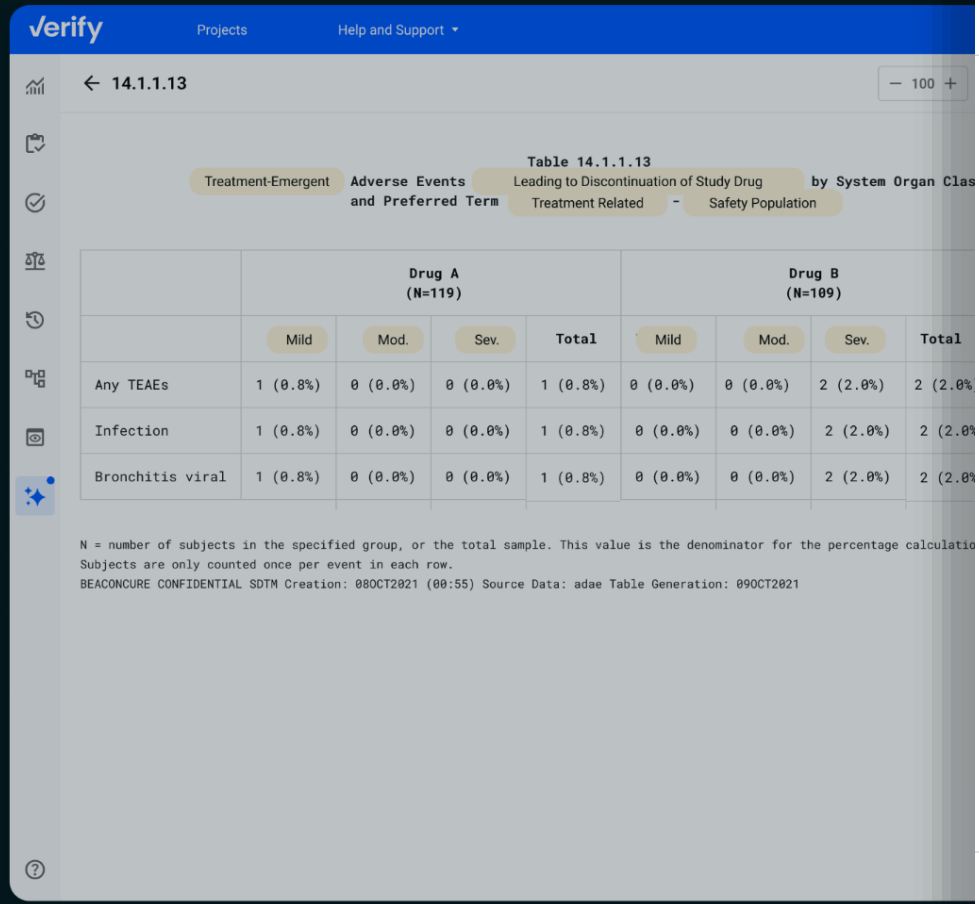
Verify-Generated Table

N=6

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
USUB.	FASFL	SAFFL	PPROTFL	COMPLFL	RANDFL	ISSFL	ARM	ARMCD	ACTARM	ACTARMSD
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	SCRNFAIL	SCREEN FAILURE	SCRNFAIL
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



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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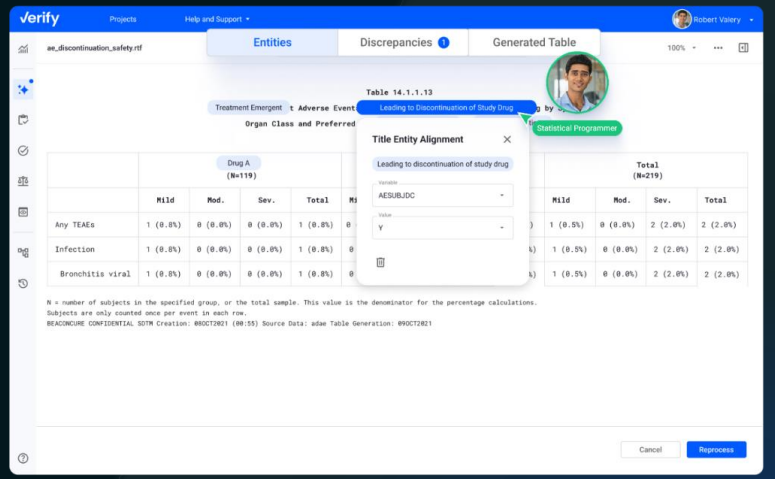
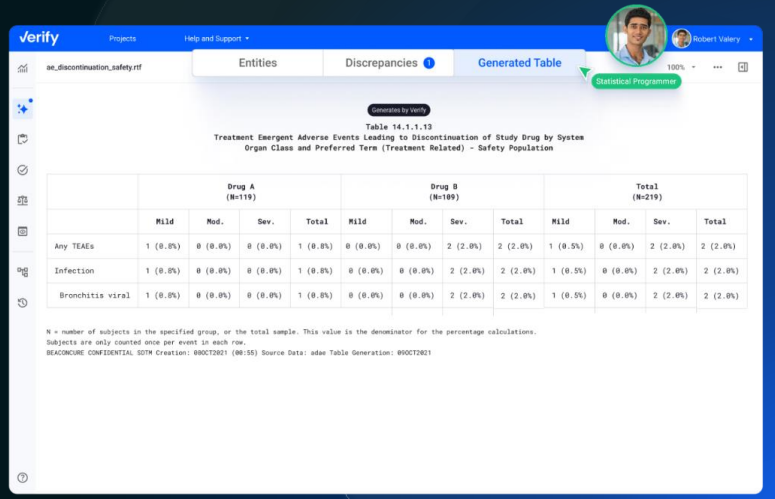
Automate Reuse of Context-Rich Results Metadata

- **Human-in-the-loop (HITL) feedback**
  - Modify metadata alignment between table entities and ADaM
  - Alignment saved and applied to subsequent checks and analyses
- **Compatibility with CDISC ARS** framework
- Basis for **automated output generation**
- **Activity Log** automatically records changes
- Automated traceability from outputs to ADaM





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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

Verify Benefits and Outcomes

Speed

- Shorter Review Cycles
- Reduced Review Effort
- Enhanced Accuracy

Efficiency

- Reduced Spreadsheet Maintenance
- Fewer Email Chains
- Scalable Growth

Visibility

- Centralized Management
- Enhanced Executive Oversight
- Transparent Audit Trail

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Thank You!

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