

Verify:

Facilitating End-to-End Automation of
Clinical Validation Processes Using AI
Algorithms and Dynamic Collaboration



Ilan Carmeli / Co-Founder and Chief Operating Officer
Achinoam Ravet Perel / Head of Product Delivery

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Agenda

- Introduction: What is Verify?
- Current Landscape
- Verify Use Cases
- Live Verify Demo
- Summary
- Q & A

Introducing **Verify**

AI-Enabled Statistical Analysis Workspace

A unified workspace to upload and QC statistical outputs and manage processes, reducing cost, manual review, and errors.

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

3 Key Pillars

Digitize

AI-enabled conversion of outputs and datasets into a machine readable dynamic data store



Validate

Use AI analysis and automation to perform standardized review of table sets



Collaborate

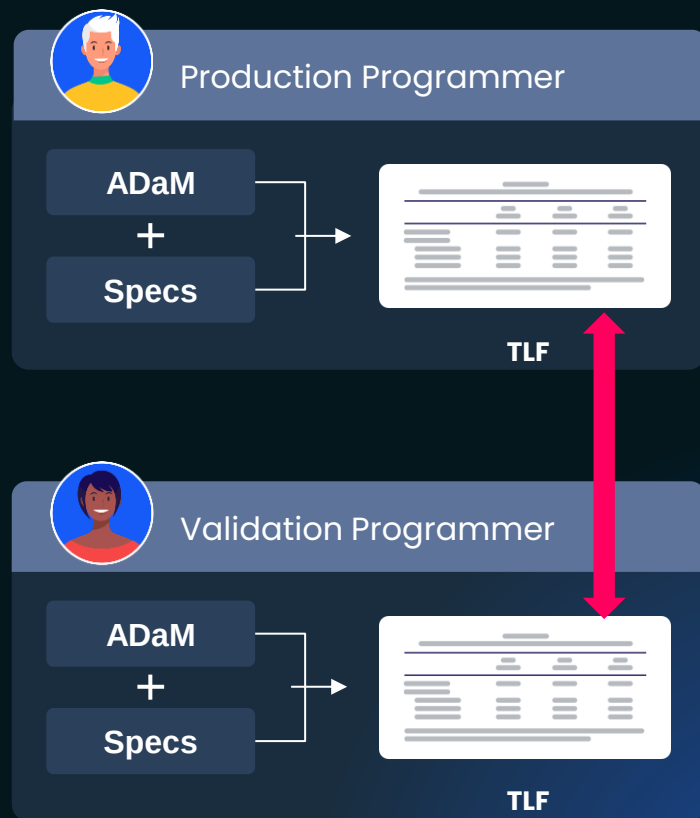
Manage review and validation workflows within a centralized, secure platform



Current Landscape

The High Cost of Manual TLF Validation

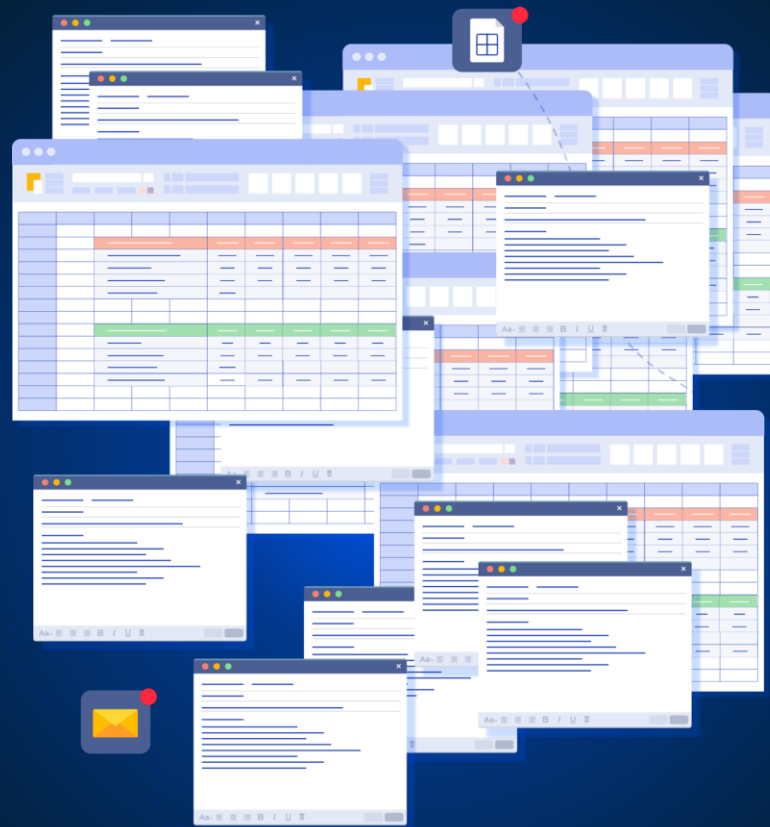
- Large labor footprint: at times duplicative, repetitive, time-consuming, & keeping resources from other necessary tasks
- Customized code
- Study-specific configuration
- As-needed double programming
- Visual review of thousands of pages of outputs
- Decentralized, disjointed reviewer communication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- Versioning issues with updating outdated outputs and trackers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

Who Uses Verify?

End-to-end users

Use Verify often and throughout study validation, such as: DSMB meeting, interim analysis, dry run, final

Roles typically include:

- Statisticians
- Validation Programmers
- Clinical Programmers
- FSP programmers

Role-specific users

Involved at specific key stages, such as: DMCs, format reviews, interim analyses, Final CSR

Roles typically include:

- Clinical SMEs
- Clinicians/Medical Monitoring
- Medical Writers
- Pharmacists
- Pharmacovigilance/Drug Safety
- Pharmacokineticists
- Quality Assurance
- **Anyone who reviews TLF sets!**

Full, unified teams all collaborate within the Verify platform

Live Demo



Summary

- AI-enabled processes for validation and review play to the strengths of human and machine, enabling fewer manual hours spent on reviews and more time to focus on critical data
- An AI model trained on your data saves time and improves validation process quality by standardizing processes and reducing time spent on formatting and visual review
- Centralized collaboration cuts coordination delays and boosts productivity with real-time communication across stakeholders
- Traceable audit trail delivers full visibility, with all data and comments tracked in one place
- Real-time visibility of review progress and feedback support informed decision-making

Q & A

Thanks for participating!

Ilan@beaconcure.com
Achinoam@beaconcure.com