Case Study

Accelerating Clinical Data Review

Addressing Fragmentation, Improving
Collaboration, and Reducing Review
Cycle Times by 35%

Industry Challenge

Disconnected Review Workflows, Lack of Automation, and Lengthy Data Review Cycles

Clinical data analysis review remains a critical, yet often fragmented, element of the clinical trial process. Many organizations still rely on manual workflows, using email or instant messaging-based feedback loops with marked up spreadsheets in disconnected documentation systems. These traditional approaches can slow down review continuity, increase the risk of errors, and create barriers to clear oversight, particularly in large, multi-stakeholder clinical trials with significant reporting efforts.

Persistent challenges across the industry include:

- Limited visibility into ongoing review activities
- Sequential actions that prolong the turnaround time
- Difficulty maintaining traceability of feedback, decisions, and data changes
- Manual reconciliation of comments and annotations across disparate systems or files
- Rework cycles caused by workflow discontinuities
- Poor documentation of review history when team members or roles shift
- Lack of transparency in cross-company collaborations

These inefficiencies ultimately delay submission timelines and reduce the clarity sponsors need to make informed decisions — slowing the progress of promising treatments.

As the demand for faster, more transparent, and audit-ready clinical reporting operations grows, sponsors are reevaluating how to structure their review processes and CRO interactions. An ongoing collaboration between Beaconcure and Phastar reflects this broader shift to help address these challenges: combining cutting-edge technology with specialist biometrics and data science expertise to rethink how data reporting oversight, documentation review, and communication are handled across clinical trials and across companies.

Solution

A Centralized Platform for Seamless Data Analysis Review Management

To address these operational inefficiencies and enable real-time visibility, Beaconcure developed **Verify,** a centralized platform designed to streamline the review and validation of clinical trial summary tables, listings, and figures (TLFs). The platform provides a unified, structured environment for reviewing outputs and reference documents, improving collaboration, traceability, and overall quality. It is also designed to shorten review times, ultimately accelerating time to submission.

Phastar, a specialist CRO focused on biometrics and data science, partnered with Beaconcure to implement and configure Verify for Phastar's clinical data analyses, TLF reviews, and downstream automations. The goal: to reduce cycle times, improve sponsor visibility, minimize required sponsor effort, and establish cross-company workflow automations for Phastar clients who experience pain points in the current TLF review and post hoc analysis creation cycles.

Features that Deliver the Difference
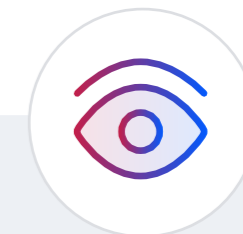
Live Output Interaction
Sponsor reviewers can view parsed TLFs and reference documents directly in Verify, eliminating the inefficiencies of static file reviews and enabling immediate feedback.
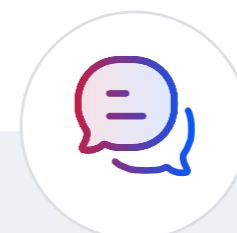
Centralized Feedback & Context Preservation
All comments, annotations, and decisions are tied to specific outputs — preserving reviewer rationale and ensuring a complete, auditable history of changes, even as team members rotate or project phases shift.

Version Tracking & Traceability
File versions, reviewer actions, and comments are automatically logged — making the process traceable and inspection-ready for future regulatory audits.

Layered Workflow Views
Verify provides role-based workflow views for different stakeholders. Whether tracking QC progress, managing file versions, or conducting task-based reviews, each user has a clear view of responsibilities—driving accountability and reducing review cycles.
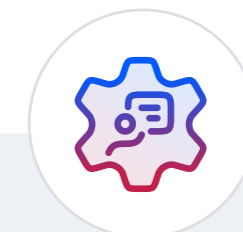
Role-Based Dashboards
Sponsor and internal stakeholders have customized visibility of outstanding tasks, deadlines, and review status — allowing them to focus on what matters most, consolidate feedback, and cut unnecessary follow-ups.

Outcome

Improved Visibility, Over 35% Faster Review Cycles, and Reduced Risk of Rework

Centralizing activities within one platform helps complete tasks faster with fewer iterations, reducing the risk of missed or delayed actions and supporting earlier study milestones. By embedding Verify into core workflows, Phastar has laid the groundwork for faster, more efficient, and fully documented data reporting review — supporting the broader goal of accelerating clinical development timelines and empowering sponsors with the visibility and agility needed to navigate increasingly complex trials.

Key Benefits Delivered

Accelerated Review Timelines

Faster feedback loops and real-time task visibility enable simultaneous actions and proactive planning.

Enhanced Oversight

A centralized dashboard enables ongoing tracking of review status, outstanding tasks, and version history.

Reduced Rework and Cost

Clear documentation and preserved context minimize the need for re-review and manual reconciliation.

Inspection-Readiness Built In

All comments, file versions, and decisions are fully traceable, supporting regulatory compliance.

Taken together, these benefits enable faster decision-making, shorter development timelines, and quicker progression to critical milestones — delivering cost savings and meaningful acceleration in trial execution and team efficiency.

Efficient, Real-Time Review in Practice
Compressing Review Timelines to Deliver Therapies to Patients Faster

In a recent Phase III study for a global top 10 pharma sponsor, Phastar used Verify to manage the internal review of hundreds of files at the Final Analysis stage prior to sponsor handoff. The reviewers — statisticians — created various review tasks and assigned them to the lead statistical programmer for discussion and resolution.

With this centralized, transparent approach, Phastar has reduced review cycle times from 3-5 weeks to less than 2 weeks, achieving over 35% reduction in average clinical data review timelines — supporting accelerated time to submission and faster delivery of therapies.

The Task Manager view within Verify allows stakeholders to gain immediate visibility into project tasks, including status, priority, and assignment. In addition to Phastar reviewers, sponsor reviewer roles include sponsor study team members, statisticians, programmers, data managers, and medical writers — enabling coordinated communication across functions and organizations.

Each file review task within Verify enables context-specific communication directly on digitized output files, without the need for additional trackers or annotated PDFs. This allows a traceable, real-time interactions about output structure, data, versions, management tasks, and any other submission-related issues, with the full history automatically preserved.

The Impact
Faster Reviews, Enhanced Oversight, Measurable Results

Using the Verify platform has transformed Phastar's review operations, demonstrating measurable impact across live studies:

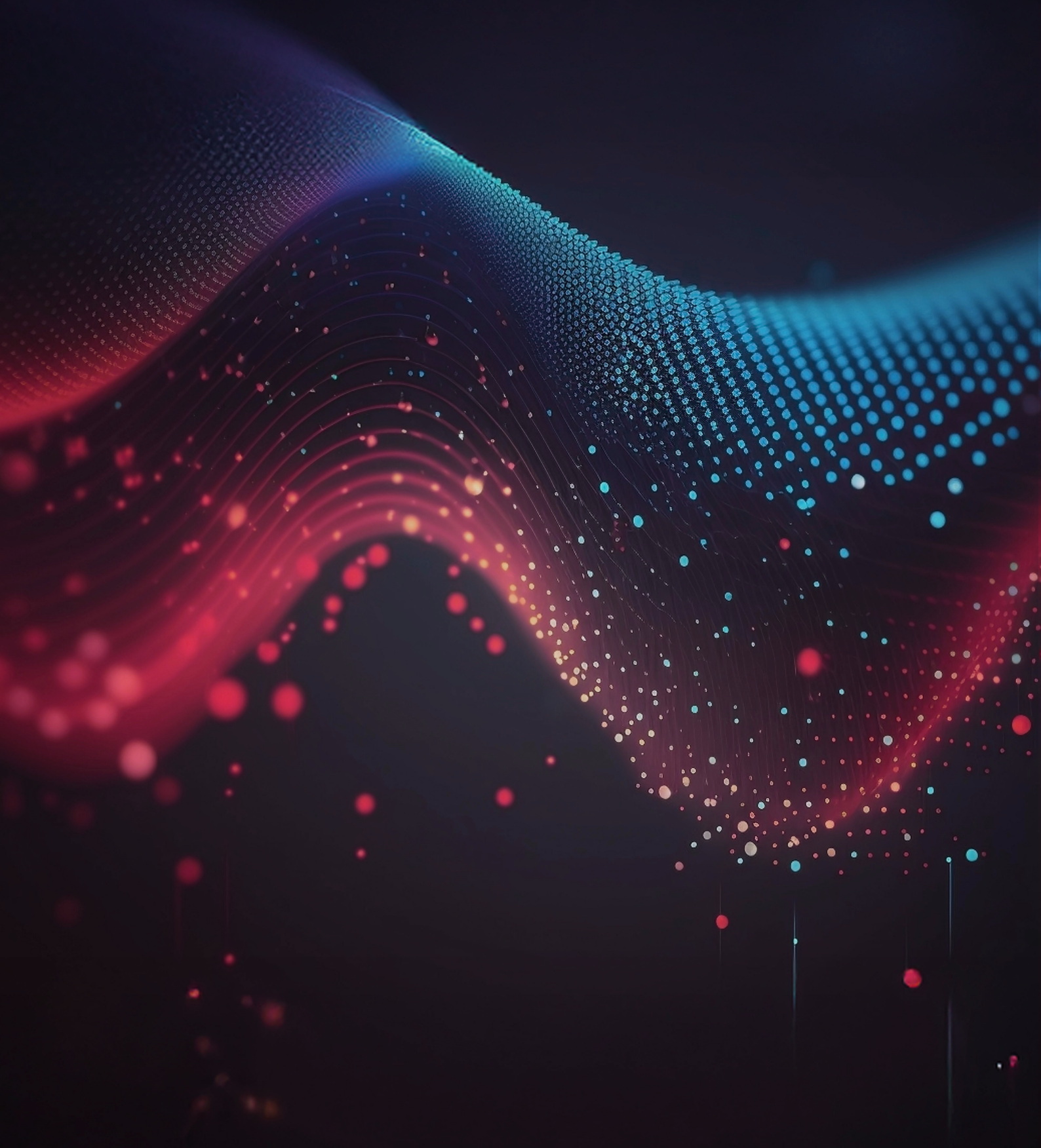| Metric	Before	After	Result
Review cycle duration	3-5 weeks	<2 weeks	**>35%** Faster reviews
Review traceability	Manual, fragmented	Fully centralized	**Audit-ready documentation**
Feedback loop coordination	Email and static files	Structured workflows	**Fewer rework cycles**
Sponsor visibility	Low	Real-time	**Improved planning and confidence**

Conclusion

Building Data Review Processes for the Future

The collaboration between Beaconcure and Phastar illustrates a broader movement across clinical data review: rethinking how we efficiently manage data oversight, documentation, and traceable communication.

With increasing trial complexity and growing regulatory expectations, there's an urgent need to replace fragmented processes with systems that are better suited to today's clinical landscape, and offer transparency, accountability, and adaptability.

The Verify platform — and a robust partnership between technology providers and specialist biometrics and data science experts — play a key role in that transformation.

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