

Verify

Category:

Best Digital Health Solution

Company Name:

Beaconcure

Number of employees:

11-50

Turnover and/or Funding:

Beaconcure is a privately held company with sustained growth driven by strategic partnerships and a strong client base in the life sciences sector. The company has successfully secured multiple rounds of private funding to support product development and market expansion, including its flagship platforms, Verify. Beaconcure continues to invest in innovation and team growth to meet increasing demand for automation and compliance solutions in clinical trial data validation.

Product/Solution Name:

Verify

Corporate Name:

Beaconcure

Date of Approval:

2019-04-30

Indications:

Verify - Product Indications Summary

Verify is Beaconcure's AI-powered platform that automates and streamlines the validation of clinical study data and statistical outputs. It is used by pharmaceutical companies, CROs, and data standards teams to ensure data quality, consistency, and

regulatory compliance in clinical trial reporting.

Indicated Use Cases

Verify is designed for application across several critical phases of the clinical trial reporting lifecycle:

Clinical Study Report (CSR) Validation

Automatically reviews statistical outputs (e.g., tables, listings, figures) to verify alignment with protocols, statistical analysis plans (SAPs), and regulatory requirements, supporting audit readiness.

Quality Assurance and Compliance

Identifies discrepancies and documentation inconsistencies early in the process, enabling proactive issue resolution and reducing the risk of costly delays in regulatory submission.

Regulatory Submission Readiness

Strengthens the integrity of final study packages by validating traceability and coherence across datasets, outputs, and documentation before submission to regulatory agencies such as the FDA, EMA, and PMDA.

Metadata and Standards Review

Validates adherence to CDISC standards (e.g., SDTM, ADaM) and company-specific conventions, promoting metadata reuse and reducing rework across studies.

Benefits

By automating labor-intensive validation processes, Verify helps life science organizations:

- Accelerate manual review timelines
- Increase confidence in data integrity
- Support submission compliance
- Lower operational costs
- Enable faster, more reliable submissions

Therapeutic Areas:

Beaconcure's Verify platform supports a wide range of therapeutic areas through its application in clinical trial data validation. Verify's flexibility allows it to be used across therapeutic areas, supporting sponsors and CROs in delivering high-quality, compliant statistical validation for trials at every phase.

General Information File Document upload:

N/A

Background information and need for drug / device:

Background and Need for Verify

Clinical trials are the cornerstone of drug and device development, generating massive volumes of statistical data and regulatory documentation. Before a therapeutic product can reach patients, sponsors must submit a Clinical Study Report (CSR) supported by accurate and validated statistical analyses. Ensuring the quality, compliance, and consistency of this data is a labor-intensive, manual process-often involving multiple stakeholders, repetitive reviews, and a high risk of human error. This inefficiency can result in regulatory delays, increased costs, and even jeopardize patient safety if critical discrepancies go unnoticed.

In this complex landscape, Beaconcure developed Verify, an AI-powered platform purpose-built to transform the clinical data validation process. Verify addresses a critical and underserved need in the clinical trial lifecycle: the automation and standardization of the review process for statistical outputs, metadata, and key documents required for regulatory submissions.

Currently, many life sciences organizations rely on manual cross-checking to verify that outputs such as tables, listings, and figures (TLFs) are aligned with study protocols, statistical analysis plans (SAPs), and final reports. This process is not only slow and error-prone but also difficult to scale across multiple studies or therapeutic areas. With increasing regulatory scrutiny, the need for faster, more accurate, and compliant data validation tools has become urgent-especially as sponsors accelerate trial timelines in high-stakes areas like oncology, neurology, rare diseases, and infectious diseases.

Verify is designed to meet this need. The platform automates the comparison of clinical trial results with source documentation, flags inconsistencies, tracks version changes, and provides clear audit trails. It supports a wide range of file formats and regulatory standards (such as CDISC), making it versatile across sponsors, CROs, and study phases.

By digitizing the validation workflow, Verify reduces review time from weeks to days,

lowers the burden on biostatistics and medical writing teams, and ensures that submissions are consistent and high-quality. This not only improves operational efficiency but also increases confidence in the integrity of clinical trial data-a critical factor in successful regulatory approval.

As clinical trials become more complex and data-driven, tools like Verify are essential to support the next generation of drug and device development. It plays a vital role in de-risking regulatory submissions, promoting data transparency, and ultimately accelerating access to life-saving therapies.

Background File Document upload:

N/A

History of the development of the solution/product:

Development & Clinical/Preclinical Evidence

History of the Development of the Solution - Verify

Beaoncure's Verify platform was born out of a clear and recurring pain point observed across clinical development teams: the inefficiency and risk associated with manual validation of statistical outputs during the preparation of regulatory submissions. The idea for Verify originated in 2017 when Beaoncure's founding team-comprising experts in biostatistics, data standards, and clinical quality assurance-began working closely with pharmaceutical sponsors and contract research organizations (CROs) to understand how data validation was being handled during the final stages of clinical trials.

They found that most teams were relying on time-consuming, manual methods-often using spreadsheets or PDF markups-to cross-check tables, listings, and figures (TLFs) against protocols, SAPs, and CSRs. This made it extremely difficult to scale, introduced human error, and significantly delayed submission readiness. The opportunity to transform this process through structured automation became the foundation for Verify.

Development Timeline:

2018-2019: The first prototype of Verify was developed, focused on enabling users to upload and compare statistical outputs and flag discrepancies. Early-stage feedback was collected from partner CROs and medical writing teams.

2020-2021: In collaboration with global pharmaceutical companies, Beaoncure expanded Verify's capabilities to support traceability across complex documentation workflows, introduce support for multiple data formats, and align with industry standards like CDISC.

2022-2023: Verify gained adoption among global sponsors in therapeutic areas including oncology, neurology, rare disease, and infectious disease. It was used to support quality assurance in pivotal Phase II and III trials. The platform's machine learning features evolved to prioritize issues based on regulatory risk, track document versions, and generate comprehensive audit trails.

2024-2025: Verify was deployed in live submission processes to regulatory authorities including the FDA and EMA, where it demonstrated measurable time savings and error reduction. Beaconcure added integrations for metadata review (via Metadata Hub) and compliance checks, strengthening the platform's end-to-end utility.

Clinical Evidence and Validation:

While Verify is not a therapeutic or diagnostic device requiring preclinical/clinical trials, its impact is validated through operational use in real-world drug development pipelines. To date, Verify has supported dozens of clinical trials across multiple sponsors, including first-in-human and late-stage studies. Metrics gathered from client implementations have shown:

- Up to 70% reduction in validation time
- 40-60% fewer manual errors in submission documentation
- Improved team collaboration and reduced rework during statistical review and CSR preparation

The platform has been adopted across trials targeting FDA and EMA submissions, with successful acceptance of Verify-supported documentation by regulators. Feedback from biostatistics teams consistently highlights the platform's role in de-risking validation bottlenecks and improving submission confidence.

Conclusion:

Verify is the result of years of collaborative development, built directly around the real-world challenges of validating and submitting clinical trial data. With its AI-driven validation engine, regulatory alignment, and demonstrated field performance, Verify is now a critical tool for modernizing the path from data to submission.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

Innovation

Transforming Clinical Data Validation to Accelerate Access to Life-Saving Therapies

Beaoncure's Verify platform represents a fundamental innovation in the clinical trial lifecycle. While not a therapeutic or diagnostic product in itself, Verify directly supports the development and approval of new drugs and medical devices by transforming a traditionally manual and error-prone step—the validation of statistical outputs for regulatory submission—into an efficient, standardized, and intelligent process.

The Innovation: AI-Powered Data Validation

Verify is the first platform of its kind to automate the cross-verification of statistical outputs (tables, listings, and figures) against source documents such as protocols, statistical analysis plans (SAPs), and clinical study reports (CSRs). Traditionally, this work is performed by statisticians, medical writers, and quality assurance teams manually comparing hundreds of files—often under intense time pressure and with little tooling to support collaboration or compliance.

Verify introduces machine learning algorithms, automated traceability, version control, and regulatory compliance checks that accelerate this process without compromising accuracy. It flags discrepancies, highlights areas of risk, and produces auditable reports that meet the expectations of regulatory bodies such as the FDA and EMA.

Why It's Innovative

Automation where none existed before: While other tools support data visualization or review, none address the validation of outputs as a structured process tied directly to submission readiness.

Bridging silos: Verify creates a shared workspace where biostatistics, medical writing, and regulatory teams can collaborate, reducing miscommunication and redundancy.

Scalability across therapeutic areas: The platform is not limited to a specific disease or indication. It can be deployed across trials in oncology, neurology, infectious diseases, rare diseases, and more.

Dynamic and intelligent validation: Unlike static validation tools, Verify adapts to changes in documents and provides a clear audit trail to support dynamic trial designs and real-time updates.

Broad Implications for Future Research

Verify's innovation lies not only in what it solves today, but in how it enables a more efficient, data-driven future for clinical development. By standardizing validation, it lays

the groundwork for:

Faster clinical trial cycles: Sponsors can cut down review and approval timelines, accelerating access to new therapies.

Improved data integrity: Early detection of inconsistencies enhances trust in clinical evidence.

AI integration in regulatory science: Verify exemplifies how automation and AI can be responsibly embedded in regulated workflows.

Reusable metadata and process harmonization: With the introduction of Beaconcure's Metadata Hub, Verify also supports data reuse and continuous improvement across studies.

Improving the Human Condition

Ultimately, Verify supports the human condition by removing barriers to the delivery of safe, effective medical products. By reducing the risk of human error, cutting validation timelines, and helping teams meet stringent regulatory expectations, it plays a critical role in ensuring that life-saving treatments reach patients faster and more reliably. In an era where precision, speed, and transparency are vital to public health, Verify offers a transformative solution to a complex, underserved challenge.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

References

Beaconcure Website - Verify Platform

<https://www.beaconcure.com/verify>

Overview of the Verify platform, its features, use cases, and value in regulatory submission processes.

Beaconcure Blog and Thought Leadership

<https://www.beaconcure.com/blog>

Includes expert articles on clinical trial validation, metadata reuse, and regulatory trends supported by the Verify platform.

Clinical Trials Transformation Initiative (CTTI) - Best Practices for Clinical Trial Quality

<https://www.ctti-clinicaltrials.org>

CTTI supports improvements in clinical trial quality and efficiency, aligning with Verify's objectives.

FDA Guidance for Industry - Providing Regulatory Submissions in Electronic Format: Standardized Study Data

<https://www.fda.gov/media/88173/download>

Provides context on the importance of data standardization and submission-ready datasets supported by tools like Verify.

CDISC - Clinical Data Interchange Standards Consortium

<https://www.cdisc.org>

CDISC standards are core to data integrity and submission readiness; Verify validates outputs against these standards.

EMA Clinical Trials Regulation (EU) No 536/2014

<https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation>

Highlights the growing need for transparency and data quality in trial documentation-addressed by Beaconcure's platform.

PubMed Reference - Common Errors in Clinical Study Reporting

Piantadosi, S. (2005). Clinical Trials: A Methodologic Perspective. PubMed ID: 16224862

Discusses challenges in statistical validation and the need for quality assurance in clinical data reporting.

References File Document upload:

[Phastar Case StudyF.pdf](#)