

F R O S T & S U L L I V A N

2024 TECHNOLOGY INNOVATION LEADER

*IN THE NORTH
AMERICAN INTEGRATED
CLINICAL TRIAL
OPTIMIZATION INDUSTRY*

F R O S T & S U L L I V A N

BEST
2024 PRACTICES
AWARD



Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Clinion excels in many of the criteria in the integrated clinical trial optimization space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Business Impact</i>
Commitment to Innovation	Financial Performance
Commitment to Creativity	Customer Acquisition
Stage Gate Efficiency	Operational Efficiency
Commercialization Success	Growth Potential
Application Diversity	Human Capital

Decentralized Clinical Trials and Cloud-based Platforms Drive Growth

eClinical solutions significantly enhance the management of clinical trials, driving clinical development towards cost-efficiency, regulatory compliance, and sustainability. However, over 30% of trial sites still only dabble in the early stages of digital transformation, primarily utilizing digital tools for basic data collection and the coordination of product commercialization rather than optimizing clinical trials.¹

Frost & Sullivan pinpoints several obstacles that hinder the rapid adoption of eClinical solutions:

- The industry lacks a comprehensive definition and a mature regulatory framework for clinical IT solutions on a global scale, exposing the market to technological, legal, and geopolitical uncertainties.
- Concerns about data privacy, security, and ownership persist, especially for remote patient monitoring and telehealth essential for virtual trials.
- The limited availability of industry expertise and skilled resources to analyze novel digital endpoints and biomarkers for specific clinical study requirements limits broader adoption across various therapy areas.

¹ *Global eClinical Solutions Growth Opportunities: Decentralized Clinical Trials, Rising Mobile Health Adoption, and Cloud-based Platforms Lower Costs and Enhance Efficiency* (Frost & Sullivan, March 2022)

- Challenges in integrating multiple data management and eClinical solutions and managing and reconciling trial information pose significant hurdles for most sponsors. They also prioritize improving tracking and reporting mechanisms.
- Fragmented clinical information technology (IT) systems impede interoperability, slowing the adoption of clinical IT solutions that leverage data-centric workflows for innovative trial designs.
- High implementation costs, budget constraints, and a lack of skilled research professionals to operate digital solutions present significant barriers for small and medium-sized sponsors.

Furthermore, Frost & Sullivan's independent research finds that non-traditional players are entering the market with technology solutions that promote cost optimization and enhanced accessibility through interoperability and continuous engagement. Cloud-based electronic data capture (EDC), randomization and trial supply management (RTSM), interactive response technology, and integrated platforms offer biopharmaceutical sponsors a unified view of trial workflows, thus improving efficiency.

"The company refined its holistic approach to eClinical solutions, continuously building its platform to bridge industry gaps. For example, the company distinguishes itself from its competitors by directly integrating AI functionality into its platform instead of offering it as an add-on service. This strategic approach enables Clinion to eliminate manual and automated processes within its system and replace them with AI components, thus providing complete end-to-end support for its clients."

- Aarti Chitale
Senior Industry Analyst: Health and Life Sciences

Moreover, digital health tools that capture high-quality patient data in natural settings (Real World Evidence) are advancing trial operations and boosting the efficiency of clinical development programs. Lastly, innovative partnerships among pharmaceutical companies, contract research organizations (CROs), and technology providers are crafting an ecosystem that supports using eClinical tools for hybrid, virtual, and decentralized trials.

In this evolving landscape, clinical trial IT vendors are seizing the opportunity to design intelligent, connected solutions that focus on decentralized and virtual hybrid trials. As a result, remote patient recruitment and monitoring applications are experiencing significant growth, covering everything from patient recruitment and engagement to real-world evidence collection and reporting.

The United States remains the dominant market for eClinical solutions, with pharmaceutical companies investing heavily in clinical development and new product launches. The presence of several prominent vendors and startups addressing emerging areas, such as decentralized trials and mobile health tools, supports this growth. Consequently, Frost & Sullivan expects the revenue in this region to increase at a compound annual growth rate of 14.8% from 2021 to 2026.²

² Global eClinical Solutions Growth Opportunities: Decentralized Clinical Trials, Rising Mobile Health Adoption, and Cloud-based Platforms Lower Costs and Enhance Efficiency (Frost & Sullivan, March 2022)

Clinion: Trailblazing the Clinical Trial Space

Founded in 2010, Clinion is an innovator in the clinical trial and data management space. The company simplifies clinical trial management by sharing consistent trial data, leading to accelerated clinical development, reduced trial costs, increased compliance, and faster market entry. This technology supports large clientele, including small and medium-sized CROs and pharmaceutical companies within the broader life science sector. Its cloud-based eClinical platform employs advanced automation technologies, such as artificial intelligence (AI), machine learning (ML), and generative AI, to speed up clinical study timelines and enhance visibility into all aspects of the process.

Clinion's solution portfolio includes EDC, RTSM, Clinical Trial Management System (CTMS), electronic Clinical Outcome Assessment (eCOA), and document automation solutions. Its user-friendly design ensures an optimal user experience while providing easy access to complex functionality at an affordable price. The company has actively managed 500+ trials, and its ePRO mobile platform has supported 20,000+ users. With operations spanning over 15 countries and involving 300,000 subjects, Clinion engages in numerous regulatory-approved studies and has contributed to 70+ COVID-19 studies.

Need-based Innovation Strategy

Backed by world-class subject matter experts, Clinion developed its system over the last decade. The company refined its holistic approach to eClinical solutions, continuously building its platform to bridge industry gaps. For example, the company distinguishes itself from its competitors by directly integrating AI functionality into its platform instead of offering it as an add-on service. This strategic approach enables Clinion to eliminate manual and automated processes within its system and replace them with AI components, thus providing complete end-to-end support for its clients. Specifically, Clinion offers advanced AI-enabled features that complement its current EDC capabilities:

- **eProtocol Automation** offers effortless protocol creation, modification, and deployment through an intuitive interface powered by generative AI suggestions.
- **Global Libraries**, a centralized repository for study-specific data elements, forms, and designs, allows users to copy forms, edit checks, and skip logic checks to set up the study in days.
- **AI Medical Coding** replaces the complex and time-consuming manual process with a high-accuracy automated function, which ensures improved data quality and coding insights for adept decision-making. The tool cuts medical coding time from weeks to a few days, with a 100% match rate and 80% accuracy.³
- **Remote Source Data Verification Automation** handles source data verification remotely, saving time and resources by eliminating on-site visits.
- **Clinical Study Reports (CSR) Automation** utilizes AI-driven statistical analysis and ML models to simplify clinical study reports' creation, management, and submission process. For instance, this feature uses inputs from both the protocol and the analysis report and employs generative AI to accurately change the report's tense from future (as seen in the protocol) to past (required for the CSR).

³ Interview with Frost & Sullivan (21 March 2024)

Frost & Sullivan lauds Clinion for prioritizing efficiency and ease of use. Recently, the company launched a Food and Drug Administration phase II biotech study in just 12 days, surpassing the industry standard of six to eight weeks.⁴

Always striving for simplicity and speed, the company pays close attention to user needs. Therefore, it offers an easy-to-understand and implementable pricing model. Depending on the client's preference, it bases its service costs on a per-study-per-month basis or on an annual basis. Clinion applies a flat fee for its services, adopting a pay-as-you-go approach that relies on the usage duration. Most clients with a set study duration find this approach helpful in managing their budgets more effectively. Clinion is willing to negotiate a more flexible pricing plan for studies that span multiple years, particularly for those extending beyond three or five years. Nevertheless, the pricing structure remains simple without hidden fees.

Clinion's eClinical platform is agile and scalable, meeting the requirements of single-site trials or complex multi-arm global studies. To ensure data safety and integrity, it complies with regulatory standards, such as FDA 21CFR Part11, ISO9001, ISO27001, the General Data Protection Regulation (GDPR), and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice (ICH GCP) along with data standards such as HIPAA and Annex 11.

“Clinion demonstrates high growth potential and positions itself strategically in the market with an industry-leading product that provides tremendous value in high-demand sectors. In 2023, the company managed to double its client base and is now planning to expand into Europe, following its success in North America and India.”

- Riana Barnard
Best Practice Research Analyst

Frost & Sullivan identifies Clinion's platform as a groundbreaking, innovative technology.

A Proven Track Record

Clinion's executive team drives technological innovation (focusing on AI/ML), investing over 50% of revenues in research and development. Experienced advisors assist in crafting the technology strategy, while subject matter experts form the core of the sales team.

The company's round-the-clock support team highly emphasizes exceptional customer service quality, prioritizing human interaction over automated processes. The team responds rapidly to all tickets and resolves critical issues within four hours (per the service level agreement). Clinion's chief executive officer reviews tickets bi-weekly to ensure the team meets high customer service standards. In addition, the product development team focuses on simplifying and improving system usability to enhance customer experience. Ultimately, Clinion aims to make its system easy to deploy and use, ensuring repeat business.

Clinion's marketing strategy focuses on enhancing its search engine optimization performance and delivering valuable content to establish its leadership in the industry. The company produces high-quality blogs, engages in social media activities, and participates in events to showcase its expertise.

Clinion's emphasis on creating meaningful content drives brand recognition, attracts organic traffic, and positions it as a top choice in clinical trials. The company's sales office in Austin, Texas, generates inbound

⁴ Interview with Frost & Sullivan (21 March 2024)

interest through effective marketing activities. Clinion's multi-pronged approach strengthens its market position and advances its goals.

Clinion demonstrates high growth potential and positions itself strategically in the market with an industry-leading product that offers tremendous value in high-demand sectors. In 2023, the company doubled its client base and is planning to expand into Europe, following its success in North America and India.

Conclusion

Technology is a critical success factor for the eClinical solutions industry. Yet, with many options available, market stakeholders need to leverage the most appropriate and best technology-based solutions to optimize their market impact. Clinion's solution streamlines clinical trial management by covering all phases of the trial process. Its platform serves as a centralized hub for all trial requirements, including laboratory data, electronic data capture, and electronic patient-reported outcomes, to provide improved visibility and control while eliminating the need for multiple systems, reducing data silos, and minimizing manual labor.

Clinion stands out from competitors based on its commitment to innovation and creativity while achieving commercial success. Always striving for simplicity and speed, the company exceeds user demands and expectations. It successfully doubled its client base in 2023 and plans to expand into Europe.

Clinion earns Frost & Sullivan's 2024 North American Technology Innovation Leadership Award for its strong overall performance in the integrated clinical trial optimization space.

What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation Leadership Award recognizes the company that has introduced the best underlying technology for achieving remarkable product and customer success while driving future business value.

Best Practices Award Analysis

For the Technology Innovation Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization Success: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at <http://www.frost.com>.

The Growth Pipeline Engine™

Frost & Sullivan’s proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.

[Learn more.](#)

Key Impacts:

- **Growth Pipeline:** Continuous Flow of Growth Opportunities
- **Growth Strategies:** Proven Best Practices
- **Innovation Culture:** Optimized Customer Experience
- **ROI & Margin:** Implementation Excellence
- **Transformational Growth:** Industry Leadership



The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**

