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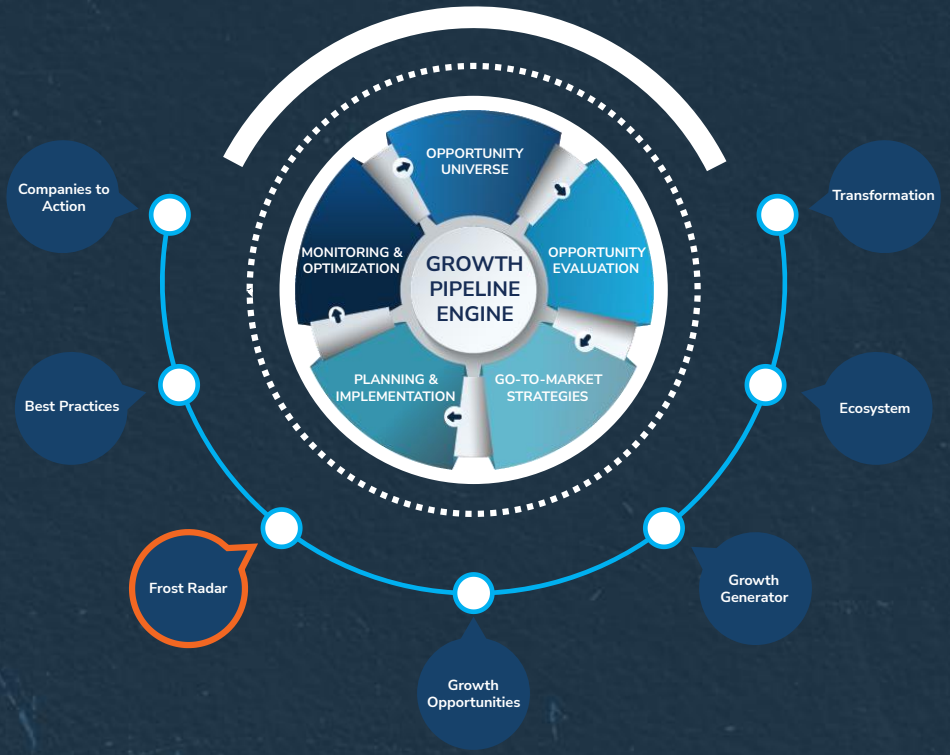
Frost Radar™: Artificial Intelligence-Enabled Clinical Trials, 2026

A Benchmarking System to Spark Companies to Action - Innovation That Fuels New Deal Flow and Growth Pipelines



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Strategic Imperative and Growth Environment

Source: Frost & Sullivan

Strategic Imperative

- The prevalence of cancer, central nervous system (CNS) disorders, and cardiovascular diseases is propelling clinical research, with more than 7,000 molecules in clinical development in all therapy areas, as per Citeline's Annual R&D Review, 2025.
- With surging clinical trial pipelines, the associated challenges pertaining to trial recruitment, patient adherence, and execution are impacting therapeutic outcomes. Technology platforms in the form of AI play an important role in streamlining trial workflows to achieve the desired outcomes.
- AI-based platforms are including cutting-edge solutions, such as digital twins and synthetic and external control arms, to improve trial efficiency and outcomes, especially in oncology trials requiring larger patient sample sizes. AI-powered platforms in clinical trials can improve compliance with trial protocols and the accuracy of endpoint assessment in the next 3 to 5 years.
- The pharmaceutical ecosystem, especially drug development, will continue to expand beyond the traditional sponsor/contract research organization (CRO) relationship with the ingress of technology vendors in the next 2 to 3 years. Cutting-edge AI drug discovery, development, and manufacturing solutions improve trial success rates and cost-effectiveness.
- Small to midsize and virtual biopharmaceutical companies are driving pharmaceutical innovation in the form of targeted therapies, resulting in more competition. Tech-enabled solutions are eliminating the need for lengthy and costly drug development processes through cutting-edge platforms.
- Biopharmaceutical companies will capitalize on AI-driven solutions to support their clinical research activities as trial diversity increases. The industry will witness more partnerships with AI vendors in the next 5 to 7 years, with a focus on improved compliance rates and reduced operational costs for clinical trials.

Source: Frost & Sullivan

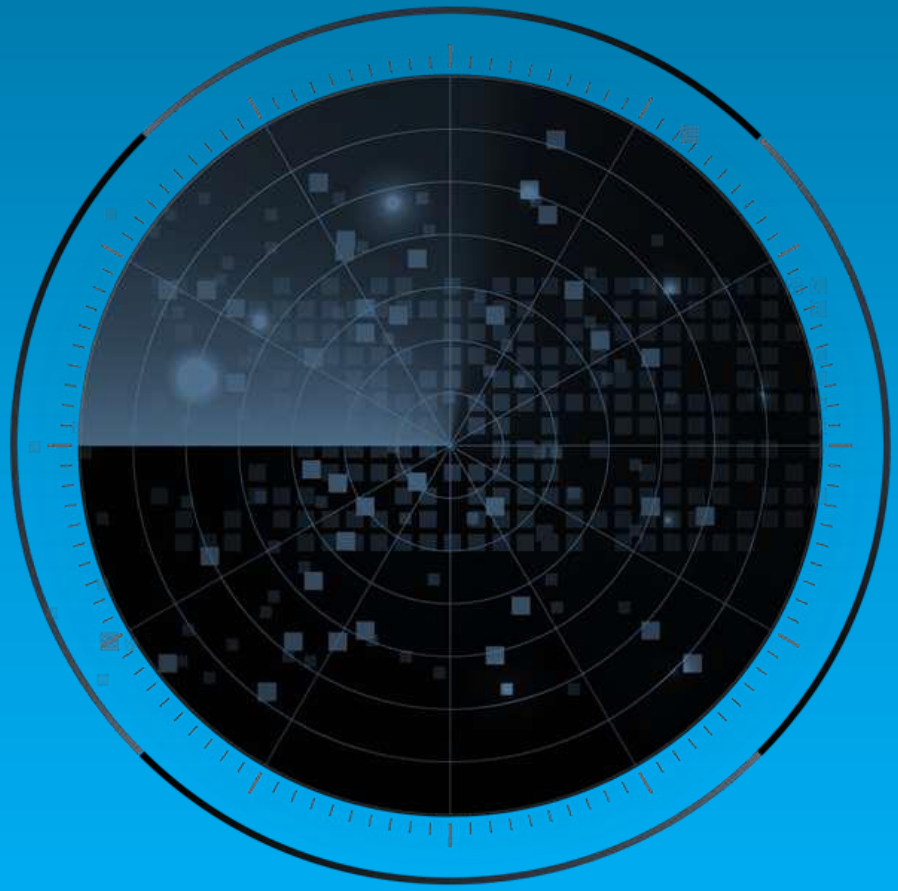
Growth Environment

- The drug development ecosystem is expanding, with the simultaneous reliance on pure-play technology vendors, AI platform providers, and medical device companies that can configure AI algorithms into their devices for clinical trial data collection, analysis, and patient monitoring and engagement. There is a surge in the volume of clinical trials (with more than 300,000 active), supported by developed markets and emerging countries in Asia-Pacific, the Middle East, and Africa that provide a 30 to 40% cost advantage.
- The AI-enabled clinical trials industry is gaining momentum as companies understand the value proposition of implementing technology in clinical research. This Frost Radar™ includes participants from various clinical research industry segments that stand out for their unique AI/ML-enabled platforms. Patient recruitment, regional regulations, and drug development costs are among the major clinical research challenges.
- With the industry focus on precision medicine and precision health, patient centricity has taken center stage, highlighting the importance of patient stratification. AI software identifies the right patient for the right trials through digital biomarkers from historical trials. For efficient trial outcomes, it is imperative to manage trial operations from protocol development and patient enrollment to monitoring and adherence. AI can ensure fewer patient dropouts with synthetic control arms, digital twins, and many other technologies.
- Because data is the core discipline of drug development, electronic medical records (EMRs) and real-world evidence/data (RWE/RWD) also support trial outcomes and improve drug efficiency. AI can create structured databases from disparate and unstructured sources, simplifying data assessment and enhancing trial safety and efficiency. Companies have become more open to new technologies through partnerships with AI vendors, leading to industry convergence and improved trial outcomes.

Source: Frost & Sullivan

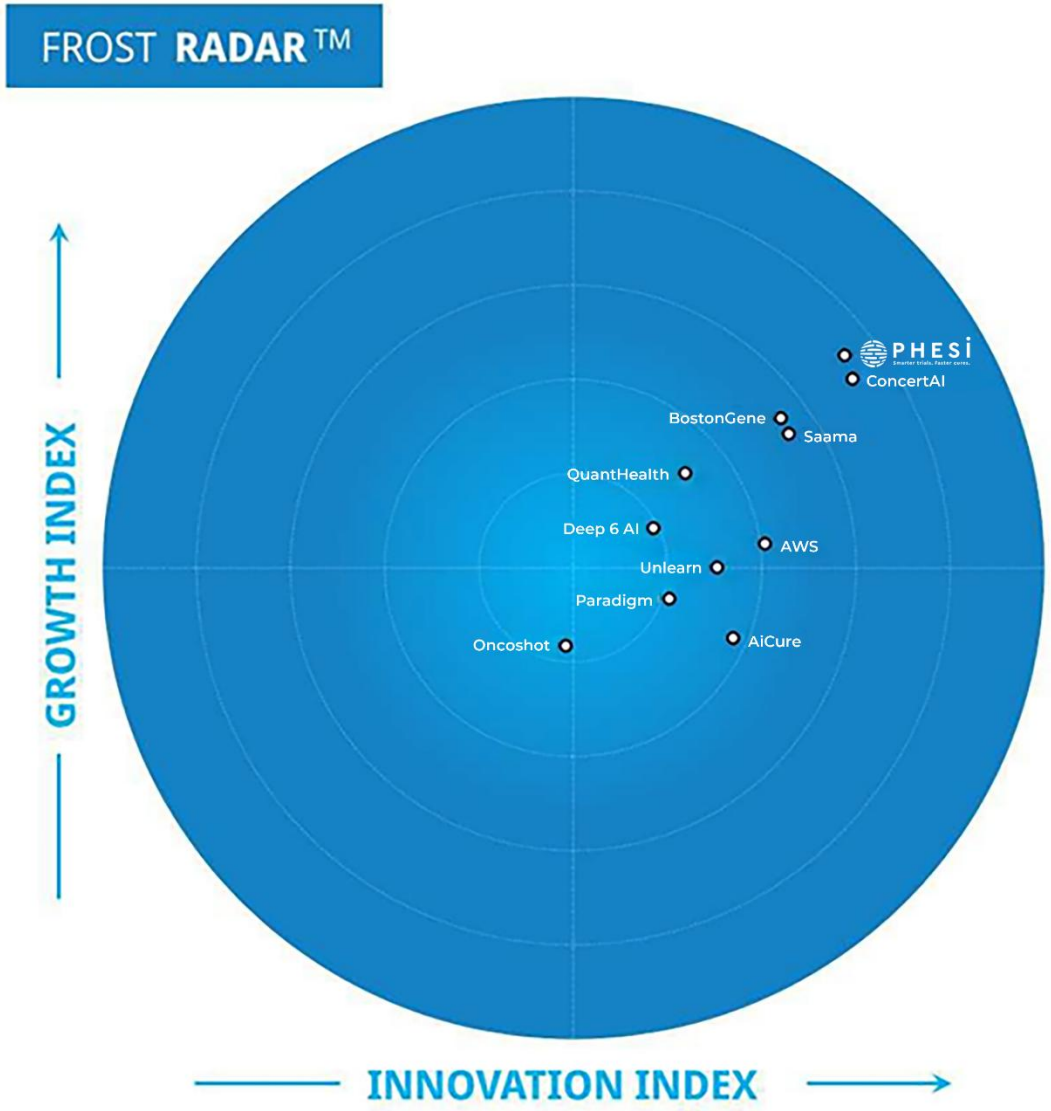
Frost Radar™

Artificial Intelligence-Enabled Clinical Trials



Source: Frost & Sullivan

Frost Radar™: Artificial Intelligence-Enabled Clinical Trials



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Source: Frost & Sullivan

Frost Radar™ Competitive Environment

- AI has been revolutionizing the technology-enabled drug discovery and development landscape. In clinical research, AI has been gaining traction across site selection, trial design and protocol optimization, and patient recruitment and management. With 80% of clinical trials not attaining the required patient recruitment and trial start-up delays, sophisticated generative and agentic AI-based technologies and real-world data and copilot-based large language models (LLMs) have been creating a stir across the landscape, providing real-time database access to target the right patient to the right clinical trial.
- To be considered for this Frost Radar™, companies had to meet following inclusion criteria:
  - A focus on integrating sophisticated AI technologies into the clinical trial stages, including patient identification, recruitment, site selection, protocol optimization, and many more.
  - Presence across at least 2 regions
  - Active partnerships with pharma/biopharma sponsors, CROs, and/or academic organizations
  - Revenue from the AI-based clinical trial platform licensing/subscription
- From more than 25 companies in the space, Frost & Sullivan selected 11 standouts that reflect a sharp focus on innovative AI technologies for clinical trial support and RWE generation and access and a goal to overcome the key challenges across the highly mature clinical trials industry.
- Five companies emerged as Innovation and Growth Index leaders (scored out of 5), reflecting their disruption potential with innovative platforms, active R&D investments, extensive pipelines and partnership landscapes, and widespread adoption.

Source: Frost & Sullivan

Frost Radar™ Competitive Environment (continued)

- Phesi's AI-driven clinical development solutions focus on protocol design, site and country selection, and trial feasibility, supported by institutional and strategic investors. By leveraging a unique digital patient profile-driven analysis of program and protocol design, combined with an integrated, AI-powered data science approach to strategic and operational feasibility, the company enables precise and efficient analysis of clinical trial data. It also seamlessly supports disease modeling by indication, biomarker, treatment modality, inclusion/exclusion criteria, and outcomes in over 4,000 diseases across 195 countries, supporting regulatory approval of key assets and significantly reducing time and costs.

™

Source: Frost & Sullivan

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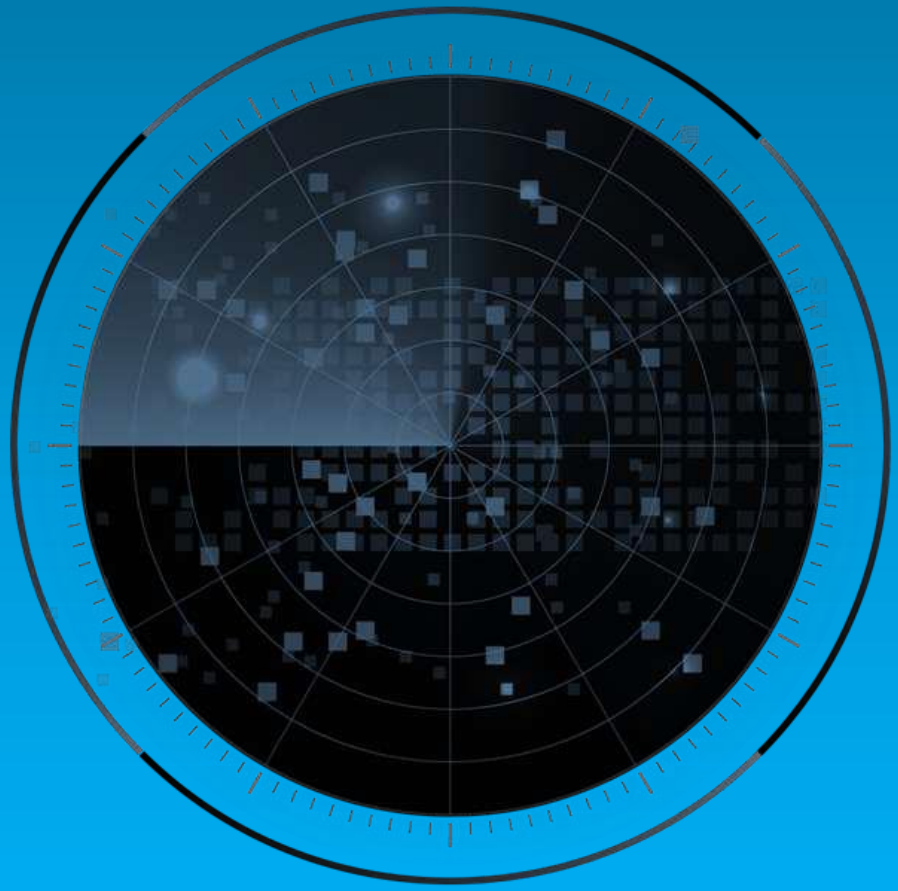
Companies to Action



Source: Frost & Sullivan

Phesi, Inc.

INNOVATION

- Phesi, a patient-centric data analytics solutions provider, has developed the AI-driven Trial Accelerator ™ platform that focuses on four modules: Patient View, Trial View, Country View, and Investigator Site View. The Trial Accelerator ™ leverages the largest contextualized patient and clinical trial database and functions on the central premise of patient centricity in design (patient profiling by indication/biomarker, trial phase, and treatment modality) and operations. In January 2025, the company announced the upgraded version 2.0 of the Trial Accelerator ™ with enhanced AI capabilities and new features for clinical trial sponsors. The company also launched a self-service Investigator Site Profile solution
- Phesi has a unique, curated patient database of more than 465,000 clinical trials across 195 countries and territories, strongly positioning it to optimize trial design and execution across any therapy area at an indication and biomarker level and trial phase, including rare diseases, thereby reducing protocol amendments and non-active, non-enrolling sites.
- The company stands out in terms of generating RWD supporting clinical research. Using data from more than 300 million patients spanning trial sites across 195 countries and 4,000 indications, especially focusing on rare and ultrarare indications, the platform seamlessly creates digital patient profiles with the digital twins aiding in protocol design, patient identification to reduce amendments and patient burden, enrollment forecasts, and identification of the highest-performing countries and investigator sites.
- Other key applications of Phesi's platforms include inclusion/exclusion criteria and outcomes optimization, DE&I planning that ensures diversity and inclusion in trials, as well as country and site feasibility that helps identify leading enrolling countries and investigator sites to accelerate enrollment by specific patient genotype and phenotype, owing to its vast, patient-specific databases.

Phesi, Inc. (continued)

GROWTH

- Phesi has been one of the leading vendors across the AI-enabled clinical trials industry, serving pharma companies of all sizes, including top 5 pharma companies. Its formidable market focus and business model ensure consistent growth year on year with the majority of revenue contributed by protocol optimization, while the Digital Patient Profile (DPP) segment, which enables the digital twin analysis, is expected to showcase over 50% growth in 2025.
- The company's strong industry positioning is exemplified with its recent feature in Nature review journal that highlights the potential of digital twins in transforming clinical trials with their ability to replace external control arms in clinical trials.
- Phesi is also adept in promoting its capabilities and building investor and potential client interest by means of participating in events, such as ASCO and ASCO GI to showcase its capabilities in conducting oncology clinical trials and other complex diseases, SCOPE Summit, CNS Summit, D-PHARM to highlight its Trial Accelerator Platform, and JP Morgan Healthcare Conference for building credibility and brand equity among leading pharma biopharma sponsors as well as potential investors.
- In addition to its diligent focus on oncology and rare diseases, the company has been focusing on GLP1 therapies, considering its recent analysis suggesting more than 100 diseases are being studied for the use of GLP1 therapies that include direct interventions as well as multiple comorbidities and modulatory effects. The company seamlessly provides its RWD using its Trial Accelerator ™ platform and the DPP of GLP-1 patients. These areas will generate additional revenue streams.

Source: Frost & Sullivan

Phesi, Inc. (continued)

FROST PERSPECTIVE

- Connecticut-based Phesi is an AI-powered company providing patient-centric clinical trial solutions. The Phesi Trial Accelerator ™ is fully aligned with industry megatrends on AI-led trial design and patient recruitment transformation with the launch of version 2.0. The company must now leverage its uniquely integrated digital twin-based patient profile, protocol design, and investigator site selection analytics capabilities as well as the DE&I offerings to transform development and grow its market share.
- The company stands out in its focus across more than 4,000 indications that include rare and ultrarare diseases as well as specific cancer biomarkers, such as PIK3CA, EGFR, KRAS G12C, and G12D in gastric, colorectal, pancreatic, prostate, breast, and lung cancer patients. This is highlighted through peer-reviewed digital twin articles in CAR T CRS, KRAS G12 mutated NSCLC patients, and chronic GvHD in primary settings that showcase Phesi's capabilities in disease modeling and the prediction of safety and efficacy outcomes. The company must promote these studies and use cases at global events, such as ASCO, SCOPE Summit, DPHARM, and JP Morgan Healthcare conference, to build further brand equity and credibility.
- With only a few companies supporting trial rescue, Phesi must also promote its capabilities across trial rescue services that assess trial protocols as well as countries and investigator sites for pharmaceutical sponsors, evaluating the potential success or failure of the trial and providing an opportunity to enhance trial design and country and investigator site selection before trial initiation.

Source: Frost & Sullivan

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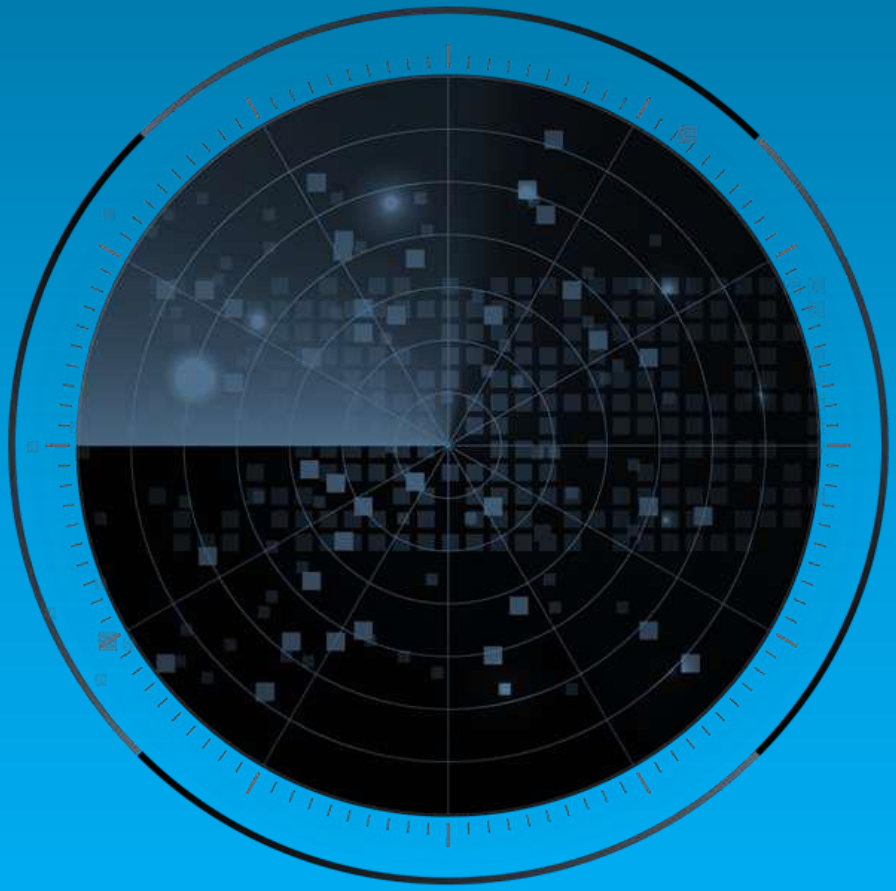
Best Practices & Growth Opportunities



Source: Frost & Sullivan

Best Practices

1. AI-based platforms are developing cutting-edge solutions, such as digital twins and synthetic and external control arms, to improve trial efficiency and outcomes, especially in oncology trials requiring greater patient sample sizes. Leveraging AI-powered platforms in clinical trials can improve compliance with trial protocols and the accuracy of endpoint assessments.

2. The pharmaceutical ecosystem, especially drug development, will continue to expand beyond the traditional sponsor/CRO relationship, with the ingress of technology vendors. AI vendors are creating a strong position with cutting-edge drug discovery, development, and manufacturing solutions, improving trial success rates and cost-effectiveness.

3. Biopharmaceutical companies will continue to capitalize on AI-driven solutions to support their clinical research activities as the diversity in trials increases. Tech-enabled solutions are eliminating the need for lengthy and costly drug development processes through cutting-edge platforms. The industry will witness more partnerships with AI vendors, with a focus on improved trial compliance and reduced operational costs.

Source: Frost & Sullivan

Growth Opportunities

1. As the number of clinical trials increases year over year, tremendous amounts of patient data in the form of EMRs are being generated. AI vendors with in-house LLM platforms must partner with local hospitals, clinical sites, diagnostic labs, and other provider networks to build patient databases. Small and midsize companies can partner with larger tech vendors to support in-house technology expansion.

2. AI vendors have developed LLM-based platforms for data sourcing, patient screening and identification, and recruitment so that companies can easily increase the geographic scope for patient identification based on phenotypes, genotypes, or cohorts.

3. Oncology trial cohort sizes, especially in the late stages, include thousands of patients in experimental and control groups. With companies moving toward adaptive trial designs, RWE-based endpoints provide a comprehensive evaluation of treatment benefits. AI vendors can partner with local and regional diagnostic and imaging centers, community networks, and central labs to build patient databases, and with RWE vendors for more specific patient genotypic and phenotypic databases.

Source: Frost & Sullivan

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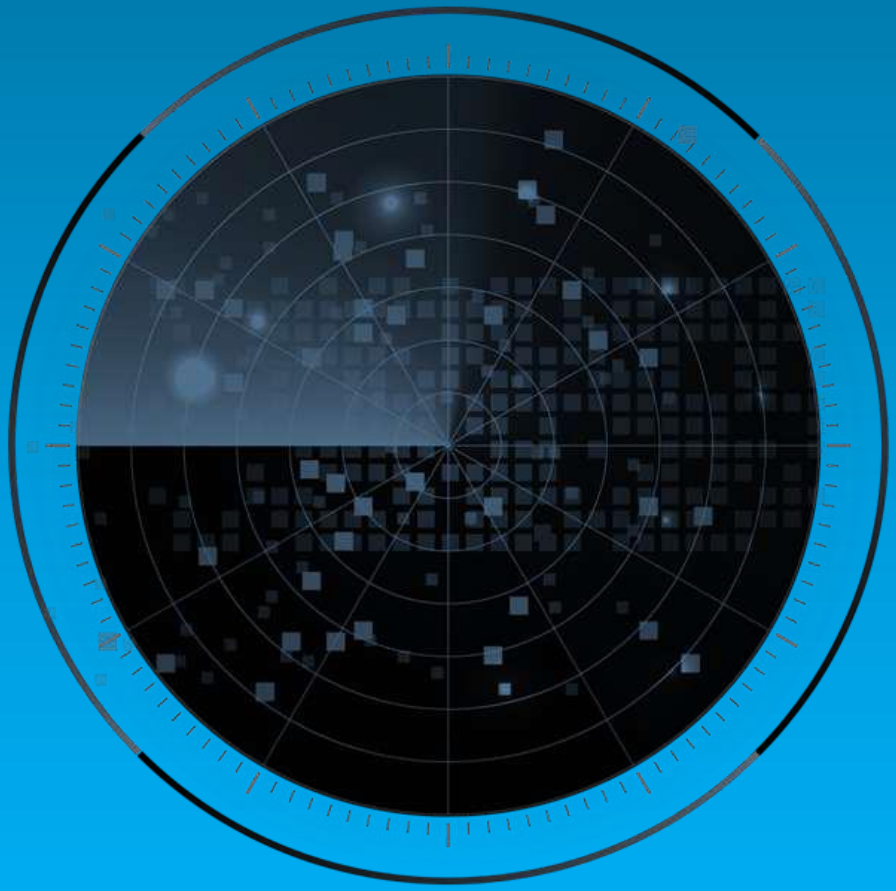
Frost Radar™ Analytics



Frost Radar™: Benchmarking Future Growth Potential 2 Major Indices, 10 Analytical Ingredients, 1 Platform

Growth Index

Growth Index (GI) is a measure of a company's growth performance and track record, along with its ability to develop and execute a fully aligned growth strategy and vision; a robust growth pipeline system; and effective market, competitor, and end-user focused sales and marketing strategies.

GI1

MARKET SHARE (PREVIOUS 3 YEARS)
This is a comparison of a company's market share relative to its competitors in a given market space for the previous 3 years.

GI2

REVENUE GROWTH (PREVIOUS 3 YEARS)
This is a look at a company's revenue growth rate for the previous 3 years in the market/industry/category that forms the context for the given Frost Radar.

GI3

GROWTH PIPELINE
This is an evaluation of the strength and leverage of a company's growth pipeline system to continuously capture, analyze, and prioritize its universe of growth opportunities.

GI4

VISION AND STRATEGY
This is an assessment of how well a company's growth strategy is aligned with its vision. Are the investments that a company is making in new products and markets consistent with the stated vision?

GI5

SALES AND MARKETING
This is a measure of the effectiveness of a company's sales and marketing efforts in helping it drive demand and achieve its growth objectives.

Source: Frost & Sullivan

Frost Radar™: Benchmarking Future Growth Potential 2 Major Indices, 10 Analytical Ingredients, 1 Platform

Innovation Index

Innovation Index (II) is a measure of a company's ability to develop products/ services/ solutions (with a clear understanding of disruptive megatrends) that are globally applicable, are able to evolve and expand to serve multiple markets and are aligned to customers' changing needs.

INNOVATION SCALABILITY
This determines whether an organization's innovations are globally scalable and applicable in both developing and mature markets, and also in adjacent and non-adjacent industry verticals.

RESEARCH AND DEVELOPMENT
This is a measure of the efficacy of a company's R&D strategy, as determined by the size of its R&D investment and how it feeds the innovation pipeline.

PRODUCT PORTFOLIO
This is a measure of a company's product portfolio, focusing on the relative contribution of new products to its annual revenue.

MEGATRENDS LEVERAGE
This is an assessment of a company's proactive leverage of evolving, long-term opportunities and new business models, as the foundation of its innovation pipeline. An explanation of megatrends can be found here.

CUSTOMER ALIGNMENT
This evaluates the applicability of a company's products/services/solutions to current and potential customers, as well as how its innovation strategy is influenced by evolving customer needs.

Source: Frost & Sullivan

Next Steps

JOIN:
Growth Council

APPLY:
Companies to Action

ENGAGE:
Growth Dialog

PARTICIPATE:
Growth Council Think Tank

Does your current system support rapid adaptation to emerging opportunities?

Source: Frost & Sullivan

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