# FROST & SULLIVAN

# **ZOZZ COMPANY OF THE YEAR**

IN THE GLOBAL AI-FOUNDATIONAL-MODEL PERSONALIZED DRUG SAFETY AND LONGEVITY INDUSTRY





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# **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. Quris-AI excels in many of the criteria in the AI-foundational-model drug safety and longevity space.

AWARD CRITERIA	
Visionary Innovation & Performance	Customer Impact
Addressing Unmet Needs	Price/Performance Value
Visionary Scenarios Through Mega Trends	Customer Purchase Experience
Implementation of Best Practices	Customer Ownership Experience
Leadership Focus	Customer Service Experience
Financial Performance	Brand Equity

## A Market Snapshot

Over the past two years, the power of Generative AI Foundational Models, including Large Language Models (LLMs) like ChatGPT — have transformed our lives, impacting most industries. Quris is now offering a revolutionary BioAI Foundational Model, which may similarly revolutionize healthcare, and has already delivered unmatched drug safety prediction, addressing a trillion-dollar problem.

The pharmaceutical industry is undergoing a transformation, of replacing animal testing with novel approaches that can significantly reduce drug development timelines and costs. These novel approaches include advanced artificial intelligence (AI) foundational models, organ-on-chip (OoC), and stem-cell technologies, offering the potential to solve one of the industry's most persistent challenges: accurately predicting which drug candidates are safe and effective in humans. Frost & Sullivan finds Quris' convergence and integration of these technologies can transform drug safety prediction and development processes and longevity and can further broadly transform healthcare.

The traditional reliance on animal testing for drug safety and efficacy, despite being a standard for over a century, is inadequate, with 92% of drugs that pass these tests ultimately failing in human trials.<sup>1</sup>

This gap, largely due to species-species differences, prompted regulatory changes such as the United

<sup>&</sup>lt;sup>1</sup> Biotechnology Innovation Organization Report (Feb 2021)

States Food and Drug Administration (FDA) Modernization Act 2.0, signed into law in 2022, which promotes modern alternatives to animal studies, including AI, cell-based assays, and OoC models, marking a shift toward more precise human drug testing methods.

Recent advancements in three-dimensional miniaturized organ models - such as organoids, OoCs and

"ChatGPT and other LLM foundational models have transformed our lives, impacting most industries. Quris' BioAI Foundational Model now has the potential to similarly revolutionize longevity and healthcare. Quris differentiates from the competition by integrating AI with its patented patient-on-chip 3D biology into its AI-Foundational-Model for Drug Safety and Longevity, to simulate clinical trials and predict drug candidate safety in humans, and to provide a premium longevity service to consumers. This reduces the need for animal testing and addresses ethical concerns in pre-clinical trials."

- Neeraj Jadhav Senior Industry Analyst, Healthcare micro physiological systems (MPS) – can significantly improve clinical predictability compared to traditional two-dimensional single-cell models. Organoids provide a more accurate representation of organ functions but face challenges in clinical outcome prediction due to variability. OoC models take this a step further by incorporating fluid dynamics and mechanical cues to replicate organ functions more accurately. Multi-OoC models, which connect several organ systems, show great promise in drug development by offering comprehensive and accurate predictions of clinical outcomes, thereby enhancing the process.

Despite these technological advancements, predicting drug safety remains a significant challenge. Many of the current AI and machine learning (ML) platforms, while improving efficiency and cost-effectiveness in drug discovery, have yet to achieve reliable high-

throughput clinical safety predictions. Miniaturized organ technologies, while promising, still face issues with scalability and price. The disconnect between AI-driven approaches and OoC technologies underscore the need for a more integrated system that combines predictive AI power with OoC's modern capabilities.

Frost & Sullivan finds the Bio-AI foundational-model safety approach represents the future of drug safety by integrating AI foundational models with advanced OoC technology to train ML algorithms on data from high-throughput experiments. This methodology aims to enhance the precision of drug safety and efficacy predictions, but its success depends on overcoming challenges like scaling OoC systems and integrating real-time data collection, which are crucial for unlocking AI's full potential in drug discovery and overall well-being.

## **Best Practices Excellence: Quris-Al**

Founded in 2020 and headquartered in Boston, Quris-AI (Quris) is pioneering the integration of AI foundational models and OoC technologies to transform drug development. By mimicking and monitoring human physiological responses to drugs, these advanced organ models generate vast amounts of data that train Quris' algorithms, leading to more predictive and precise drug safety assessments. The company designs its Bio-AI foundational model drug safety platform to reliably forecast drug candidate safety, representing a significant shift away from traditional animal testing. Moreover, the Quris team dedicates its time to expanding its technology to include longevity-focused personalized healthcare for individuals,

rounding out its value proposition and leadership in the market.

#### A Leader's Path

Traditional drug safety solutions require clinicians to gather information manually with inefficient methods like animal testing, which show an 92% failure rate in determining human outcomes. Multiple innovating AI-Pharma companies, such as DeepMind, Generate, Insitro, Recursion, Valo, and XtalPi have developed AI and ML platforms to offer an improved cost efficiency and reduced timelines of drug discovery (screening, lead selection, optimization, and in-vitro testing) but do not predict safety. AI has significantly evolved in the last ten years. Yet, many of these solutions fall short due to supervised learning requirements and low reliability. Thus, there is an urgent need for developing foundational models to analyze vast data sets to uncover patterns and structures without direct supervision.

Companies like Quris and Recursion are leaders in building powerful AI Foundational Models to accelerate drug development. Quris' unique strength is in its patented BioAI Foundational Model for Drug Safety and Longevity, which integrates AI with its multi-OoC system, so as to simulate clinical trials and predict drug candidate safety in humans, and the potential to broadly impact healthcare.

Quris has augmented its growth and deep-technology by acquisitions and licensing of several synergistic market-leading technologies: It has acquired Nortis, considered the leading Kidney-on-Chip company<sup>2</sup>, vetted by the National Center for Advancing Translational Sciences (NCATS) as part of the National Institutes of Health (NIH) setting new standards for in-vitro drug testing and personalized medicine. It acquired the world's largest micro-physiological (MPS)-data database, a unique dataset with the potential to dramatically advance drug discovery, and will be providing open access to publicly funded data within its MPS database. It has secured exclusive license to MIT-based world-leading iPSC-liver-on-chip technology. And it has in-licensed a unique biobank of over 2-million-patients, providing Quris an unmatched ability to create iPSCs-organoids, so as to conduct clinical-trial-on-chip, for a broad array of diseases and populations.

Backed by the company's strong intellectual property (29 patents, granted and pending), the platform simulates human body reactions for new molecules, reducing the need for animal testing and addressing ethical concerns in pre-clinical trials. The automated, high-throughput system leverages nanosensors to monitor organ responses to drugs continuously, significantly reducing failure rates. Organ-Chip 3D biology systems offer better data safety predictability than conventional 2D biology, but are limited by scalability and expense. Quris demonstrates its innovative prowess by addressing these critical challenges with its AI-Foundational-Model Patient-on-Chip technology. Moreover, accurately predicting novel drug safety significantly increases the speed of drug innovation and time to market, while substantially reducing risks and associated costs.

The company tests drugs on miniaturized, interconnected versions of human organs derived from stem cells, offering a more precise model of drug reactions within the human body. The massive data, including 80 million proprietary real-time sensing data points generated from these tests, train an AI foundational model to predict drug toxicity effectively. The platform is extensively clinically validated. A top pharma

<sup>&</sup>lt;sup>2</sup> Journey of organ on a chip technology, Singh 2022, Applied Surface Science Advances

company recently reported a blinded validation of Quris' platform, in which Quris flagged liver toxicity that current pre-clinical 2D and 3D biology completely missed. Importantly, this included drugs that failed in animal testing, in Phase-I and in Phase-III, where Quris AI foundational model was able to accurately predict their liver toxicity, and hence could have avoided these costly failures.<sup>3</sup> What appeals to the industry is that Quris offers, over time, a broad platform covering the systemic response of the entire body, not just one organ or tissue. The company currently supports the liver, brain, blood-brain barrier, heart, and kidney, with plans to include the intestine in the future. This success translates into coverage of disease entities relevant to these organs, addressing safety and efficacy. The platform's foundational AI model strengthens its capabilities by integrating external data, including research and scientific papers from drug repositories such as DrugBank, and PubChem, into its AI engine. This feature allows Quris to deal effectively with different diseases and organs, offering a comprehensive solution.

The company's patient-on-chip biology provides unmatched insights, including atom-level details and explainability layers. Quris trains its AI-foundational-model on hundreds of stem cell-derived patients-onchip, reflecting broad genomic diversity. The company's collaboration with the New York Stem Cell Foundation, a leader in stem cell automation, bolsters the technology's capabilities. Moreover, Quris' AI technology platform is also designed for exceptional scalability, enabling the execution of thousands, and eventually, millions, of biological patients-on-chip experiments.

#### Building Trust through Innovation and a Customer-centric Approach

Quris emphasizes collaboration across teams to enable rapid testing and refinement, ensuring stage-gate efficiency before presenting solutions to clients. The company maintains strong communication with pharmaceutical partners, actively listening to their needs and tailoring its technology based on feedback. Quris' exceptional leadership team includes a Nobel laureate Prof. Aaron Ciechanover, Moderna co-founder and former Chair of FDA's Science Board Prof. Robert Langer, and former CEO of Pfizer Dr. Henry McKinnel, and former CEO of Biogen Dr. Michel Vounatsos, who bring deep scientific and pharmaceutical expertise. These leaders are instrumental in aligning the company's innovation with market needs, ensuring the solutions effectively meet industry requirements.

Modern technology is advancing personalized healthcare insights by emphasizing the uniqueness of human health. Quris is harnessing unique, innovative technologies, to focus on wellness and longevity, aligning its mission with personalized health. Quris' Bio-AI approach leverages its patient-on-chip technology, to train its AI foundational model, with data from multiple individuals, so as to revolutionize healthcare.

Quris' Consumer Longevity Services solution offers a personalized approach to healthcare and longevity by leveraging advanced biotechnology and AI. The process begins with the consumer providing a blood sample, from which Quris generates induced pluripotent stem cells, storing them for future use. The company then creates tiny versions of the patient's organs, starting with the liver, to test the effects of medicines and supplements.

<sup>&</sup>lt;sup>3</sup> Bioconvergence at Merck: how AI and advanced 3D cell models are improving hepatotoxicity predictions, Phil Hewitt, CAMS 2024 Alternative Approaches for Human-Relevant Toxicity Assessment.

Additionally, patients can leverage these stored stem cells for future personalized therapies, such as self-transplanting, offering the ultimate 'biological insurance' and a proactive approach to long-term health.

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- Samantha Fisher Best Practices Research Analyst The platform is a sandbox that allows companies to explore drug repurposing, tweak existing drugs, and make modifications. Additionally, the solution achieved a significant breakthrough in 2024. Quris' Bio-Al foundational model analyzes a drug's molecular structure, providing a safety score and identifying specific atoms within the molecule that affect its safety and efficacy. This capability enables the creation of new molecular entities by tweaking the structure to overcome issues, opening new opportunities for developing novel chemical compounds.

More importantly, a critical element of Quris' focus is the aging process. This model is in the early stages of understanding the aging process in cells, with a primary focus on drug safety and later efficacy. This approach is crucial for longevity, as different individuals respond uniquely to medications due to variations in their organs and metabolism. For example, when different people take the same medication, the drug levels in their bloodstream can vary significantly, leading to potential health risks. By creating tiny, bioengineered organs on a chip, the platform allows for personalized testing of drugs, helping to identify which medications are optimal for each individual and avoiding those that could be harmful.

# A Foot in the Present and an Eye on the Future

Quris is currently in the proof-of-product stage, focused on automating and scaling its platform to enhance its capabilities. The company aims to expand its technology from predicting drug safety to assessing efficacy, enabling the launch of its AI-Enabled-IND service. By forming strategic alliances with top pharmaceutical companies and gaining access to valuable data, Quris is positioning itself to drive innovation in drug development. Additionally, the company's wellness service targets the growing consumer interest in personalized health solutions. With these initiatives, Quris is on a clear path to generate over \$103 million in annual recurring revenue within 5 years.

Quris-AI demonstrates high-growth potential. The company is well-positioned in the market, with an industry-leading product that provides tremendous value in high-demand sectors and reflects the industry's demand for solutions that simplify and enhance clinical trial efficiency. The company works with major pharmaceutical companies, such as Merck, AstraZeneca BVH, and academic partners, advancing drug capabilities like the one for Fragile X Syndrome (i.e., a genetic disorder that makes X chromosomes abnormally susceptible to damage). Quris is currently raising a \$100 million Series A funding, which will assist the company in positioning itself to address the tailwinds of the proposed Modernization Act 3.0 proposed in February 2024. This bill requires the FDA to update its regulations within six months of the bill's enactment, to approve non-animal drug testing methods that improve safety, efficacy, or speed. This legislation aims to reduce or replace animal testing in nonclinical research, improve predictability for

nonclinical testing, and potentially reduce development times for drugs. Quris seems to be the only company that is squarely focused on using AI-foundational model together with patient-on-chip biology, to address this bill, and the drug-safety challenge.

Moreover, the company is positioning its platform to play a significant role in personalized medicine and healthcare. For example, in the near future, technologies like Quris will assist physicians and caregivers in making more informed decisions about treatments, surgeries, and medications tailored to individual needs. In health insurance, current practices are rudimentary, often relying on broad, generic factors to determine premiums. However, with Quris' technology, which enables detailed exploration of individual health data, insurers can assess risk more accurately and adjust premiums accordingly. This capability is already being utilized through the company's longevity platform, allowing individuals to receive personalized medication recommendations and dosage adjustments based on their specific health profiles.

Looking forward, Quris-AI aims to continue revolutionizing the drug discovery process, focusing on the urgent need for more efficient, accurate, and humane methods as the industry evolves. The company will develop its AI-foundational-model platform further, expand its drug pipeline, and secure additional partnerships. Moreover, as Quris-AI cements more industry collaborations and continues its mission to modernize drug discovery and development, it will play a pivotal role in reducing the reliance on animal testing and bringing safer, more effective drugs to market faster.

Modern technology is advancing on various fronts, including emphasizing human health uniqueness. Quris focuses on wellness and longevity, aligning its mission with the personalized health concept. By using its unique Bio-AI approach, Quris is integrating AI with patient-on-chip technology, to train its AI foundational model with data from multiple individuals to revolutionize healthcare.

# Conclusion

Over the past two years, the power of Generative AI Foundational Models, including Large Language Models (LLMs) like ChatGPT — have transformed our lives, impacting most industries. Quris is now offering a revolutionary BioAI Foundational Model, which may similarly revolutionize longevity and healthcare, and has already been validated by top pharma companies, delivering unmatched drug safety prediction.

Traditional drug development methodologies, which depend heavily on tissue culture and animal testing, face significant limitations. These approaches often struggle to predict accurate drug behavior in humans; as a result, 92% of drug candidates fail in clinical trials. Overall, Quris-AI (Quris) addresses this critical need with a strong leadership focus that incorporates customer-centric strategies and exemplifies best practice implementation.

Helmed by exceptional leadership comprising Nobel laureate, former Chair of FDA's Science Board and Moderna co-founder, and former CEOs of Pfizer and Biogen, Quris leverages its best-in-class AI patienton-chip technology to create miniaturized versions of human organs on microfluidic chips to simulate their biological functions. This approach offers a more accurate representation of human physiology compared to traditional approaches, leading to better predictions of drug interactions with human biology. When combined with AI, the company's platform allows researchers to conduct thousands to millions of experiments simultaneously, generating high-throughput data that trains its powerful AI-foundational-model to achieve high effectiveness in predicting drug safety and efficacy. Moreover, Quris is expanding its focus to leveraging its AI-foundational-model to address personalized medicine with the goal of becoming the standard in healthcare. The company remains a trusted partner, earning a reputation for offering the overall best in the industry.

With its strong overall performance, Quris earns Frost & Sullivan's 2024 Global Company of the Year Award in the AI-foundational-model drug safety and longevity industry.

# What You Need to Know about the Company of the Year Recognition

Frost & Sullivan's Company of the Year Award is its top honor and recognizes the market participant that exemplifies visionary innovation, market-leading performance, and unmatched customer care.

# **Best Practices Award Analysis**

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

# Visionary Innovation & Performance

Addressing Unmet Needs: Customers' unmet or under-served needs are unearthed and addressed by a robust solution development process

Visionary Scenarios Through Megatrends: Long-range, macro-level scenarios are incorporated into the innovation strategy through the use of Mega Trends, thereby enabling first-to-market solutions and new growth opportunities

Leadership Focus: Company focuses on building a leadership position in core markets and on creating stiff barriers to entry for new competitors

**Best Practices Implementation**: Best-in-class implementation is characterized by processes, tools, or activities that generate a consistent and repeatable level of success

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

# **Customer Impact**

**Price/Performance Value**: Products or services provide the best value for the price compared to similar market offerings

**Customer Purchase Experience**: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

**Customer Ownership Experience**: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

**Customer Service Experience**: Customer service is accessible, fast, stress-free, and high quality

**Brand Equity**: Customers perceive the brand positively and exhibit high brand loyalty

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Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator<sup>™</sup>. 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)



