

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

2024 TECHNOLOGY INNOVATION LEADER

*IN THE GLOBAL
ORGANOIDS INDUSTRY*

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

2024
BEST
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. HUB Organoids B.V. excels in many of the criteria in the global organoids 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

A Market Snapshot

Pre-clinical studies are an essential part of drug development, where scientists typically use animal models to test how drug molecules work in a living system. However, these studies have come under scrutiny due to concerns over animal welfare, the high cost of maintaining vivariums, sustainability, and the fact that the data obtained may not be accurate compared to human systems.

To address these challenges, Frost & Sullivan highlights the need for reliable and accurate models that can replicate human physiology better to improve drug discovery and development. Owing to recent technological advancements in microfluidics, bioengineering, and life sciences, cutting-edge platforms such as organoid models are transforming drug development. These models allow scientists to create three-dimensional structures with organ-like characteristics that can be used in pre-clinical studies, reducing the need for animal experiments. Pharmaceutical companies can significantly reduce time, costs, and resources by using patient-derived and patient-representative organoids that are more clinically relevant and faster to develop.

Furthermore, the United States Food and Drug Administration Modernization Act, which became law in December 2022, encourages drug developers to use clinical testing platforms and supports the use of pre-clinical drug safety and toxicity assessment data collected from these models. As government policies increasingly promote ethical drug development by validating alternative practices, the adoption of organoids is on the rise.

HUB: Revolutionizing Drug Discovery and Development

Founded in 2013 to commercialize adult stem cell technology, HUB Organoids B.V. (HUB) is a technology intellectual property leader in organoid development. Headquartered in Utrecht, the Netherlands, the company transitioned in 2023 from an independent foundation (originally Hubrecht Organoid Technology) to a private company that offers drug screening services, model and assay development, and clinical trial-in-a-dish capabilities. HUB has state-of-the-art laboratory facilities, and its comprehensive biobank hosts hundreds of patient-derived organoids (PDOs) across multiple disease indications and tissue types. Moreover, HUB's end-to-end service offering positions it as a preferred partner for pre-

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- Unmesh Lal
Global Director: Healthcare & Life Sciences Practice

clinical and clinical drug development. Driven by an innovative team of experts in oncology and immunology, stem cell biology, and inflammatory diseases, HUB actively advances patient-relevant therapeutic solutions.

As PDOs do not require additional reprogramming of stem cells to develop into fully functional mini-organs, they are more representative of the patient's disease state and enhance their predictive value for testing new drugs and therapies. Backed by world-class scientists who developed the first human organoid from intestinal epithelium, HUB has developed a clinical testing platform for patient-relevant drug screenings. The company started with in-house

validation studies in oncology that yielded promising results, and whereafter, it launched High-Throughput Continuous Flow trials. Over the last decade, HUB refined its holistic approach to patient-relevant drug screenings, continuously improving its automated screening platform. It leverages advanced image screening technology, expertise in immunohistochemistry, molecular biology, genetic engineering, and cell and organoid sorting, coupled with an extensive PDO biobank, quality assurance and quality control capabilities, and regulatory compliance to bridge the gap between the laboratory and the clinic. HUB's comprehensive portfolio covers the drug development continuum, including custom model and assay development, drug screening, and patient-derived insights for co-clinical drug development. Additionally, it licenses its technology to pharmaceutical and biotechnology customers in adjacent fields. Its solution suite includes key aspects that ensure efficacy and safety to improve patient benefits:

- **Organoid establishment and characterization** help researchers understand the properties of the target tissue and identify potential therapeutic targets.
- **Target discovery and drug lead selection and optimization** enable scientists to identify and refine potential drug candidates and test them in pre-clinical patient stratification studies.
- **Clinical trial patient selection, mechanism of action, and biomarker identification** are vital to ensure the drug is suitable for the patient population.
- **Post-registration patient clinical data analysis** helps to monitor the drug's performance in real-world applications.

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Education through Innovation and Thought Leadership

As a pioneer and transformational leader who enhances traditional two-dimensional cell cultures or animal drug discovery and development models, HUB's corporate culture revolves around using purpose to drive innovation. Its product roadmap (i.e., planning, development, and implementation strategies) incorporates customer feedback, ensuring its offerings align with customers' dynamic needs. Moreover, the company has invested significant resources in making the platform more accessible, scalable, and user-friendly.

Another challenge was to communicate the value of its unique value proposition to stakeholders who may have different levels of expertise. Over time, HUB recognized the importance of sharing its success stories

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***- Riana Barnard
Best Practice Research Analyst***

to address this concern. For example, HUB demonstrated its patient-relevant screening capabilities in a case study focused on colorectal cancer. The screening technique accelerated lead agent identification, which showed positive outcomes in clinical trials for five head and neck cancer patients. This proof-of-concept study confirmed that using organoids at different stages of the preclinical drug development pipeline can expedite the drug discovery process significantly due to their genetic stability and rapid culturing time.

The company promotes itself at regular events and conferences. For instance, its scientists frequently attend the American Association for Cancer Research's events to present case studies, perform demonstrations, speak with potential clients, and network with relevant partners. By promoting the key

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Furthermore, its subject matter experts participate in regular thought leadership opportunities (e.g., webinars, whitepapers, blogs, and newsletters on relevant market trends and topics) to educate existing and potential clients. These practices demonstrate the value of HUB's products and services. Overall, the company's innovation, success stories, and educational efforts proved to be a winning strategy for increased adoption of its offering.

Strategic Practices Positioning HUB for Future Success

Since its inception, HUB's sterling reputation and customer-centric framework have led to its coveted preferred partner status. Serving as a testament to the company's high client satisfaction rate, it acquires many of its customers through word-of-mouth accolades fueled by its exceptional technological performance.

Frost & Sullivan acknowledges that having a customer-centric strategy is critical for a company's success, and many factors contribute to it. However, implementing and operationalizing the plan requires aligned leadership and staff. The management team at HUB demonstrates a strong commitment to pursuing growth opportunities dynamically. They purposefully expand their sales and marketing capabilities and support best-in-class scientists to participate in these initiatives. This approach enables them to onboard new customers seamlessly to their existing client base, which includes large and medium-sized pharmaceuticals and small biotech firms.

In addition, HUB's presiding patent portfolio creates stiff barriers for existing competitors and new market entrants. With future investments in biobank expansion and diagnostic application development, Frost & Sullivan believes HUB will secure its position as a disruptive market leader.

Conclusion

Technology is a critical success factor for the organoids industry. Yet, with many options available, market stakeholders need to leverage the most appropriate and best technology-based solutions to optimize their market impact. With its drug screening services, model and assay development, and clinical trial-in-a-dish capabilities, supported by its state-of-the-art laboratory facilities and comprehensive biobank hosting hundreds of patient-derived organoids across multiple disease indications and tissue types, HUB Organoids B.V. (HUB) revolutionizes the drug discovery and development landscape. The company stands out from competitors based on its commitment to innovation and creativity, achieving commercial success in advancing patient-relevant therapeutic solutions. Its overall customer-first approach offers immense value to existing clients, while rapid customer acquisition, fueled by word-of-mouth accolades and exceptional technological performance, solidifies HUB's reputation in the market.

With its strong overall performance, HUB Organoids B.V. earns Frost & Sullivan's 2024 Global Technological Innovation Leadership Award in the organoids landscape.

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

