Presagen Recognized for

2021

Product Leadership

Global AI-Enhanced
Healthcare Industry
Excellence in Best Practices

FROST *&* SULLIVAN

Strategic Imperatives

Frost & Sullivan identifies three key strategic imperatives that impact the life sciences industry: geopolitical chaos, disruptive technologies, and internal challenges. Every company that is competing in the life sciences space is obligated to address these imperatives proactively; failing to do so will almost certainly lead to stagnation or decline. Successful companies overcome the challenges posed by these imperatives and leverage them to drive innovation and growth. Frost & Sullivan's recognition of Presagen is a reflection of how well it is performing against the backdrop of these imperatives.

SI8

GEOPOLITICAL CHAOS	DISRUPTIVE TECHNOLOGIES	INTERNAL CHALLENGES

Why

GEOPOLITICAL CHAOS	DISRUPTIVE TECHNOLOGIES	INTERNAL CHALLENGES
• Supply chain stability, manufacturing capabilities, and residual healthcare budgets will dictate the industry's growth trajectory despite the nondiscretionary nature of pharma products in the COVID-19 scenario. • Supply chain resilience will continue to be tested as companies scramble to reallocate and ramp up manufacturing to address supply shortages and tackle government protectionism measures. • COVID-19 will likely result in higher demand for access to remote treatment solutions and methods.	• The global life sciences industry has benefited from a combination of novel technologies, including artificial intelligence (AI) platforms, the Internet of medical things, and blockchain. • Adoption of advanced analytics, automation, and cloud solutions results in increased productivity and better decision-making. • Life sciences firms are digitizing operations to address inefficiencies and create patient-centricity and personalized, value-based healthcare solutions.	• Fragmented channels in customer communication, lower margins, and intensifying competition challenge the life sciences industry. • Companies are seeking to shift focus to from existing therapeutic portfolios to COVID-19- related developments and treatments. • Mergers and acquisitions are directly impacting central pharma and instrument developers by exerting cost pressures and mandating consolidation to achieve economies of scale and operational synergies.

When

GEOPOLITICAL CHAOS	DISRUPTIVE TECHNOLOGIES	INTERNAL CHALLENGES
• Healthcare organizations will accelerate innovation to respond to the COVID-19 crisis while rethinking post-pandemic care delivery and financing. • Government-funded COVID-19 testing initiatives will boost revenues in the next 1 to 3 years. • Pharma companies will experiment with new point-of-care (POC) testing, digital supply chain tools, and patient-doctor connectivity programs based on digital platforms. • The pandemic will drive new digital-tech adoption in drug discovery and testing services, and federal funding will encourage deeper product pipelines and inventory.	• The revenue from AI solutions used in drug discovery is expected to grow 26.3% and reach $455 million by 2020. New technologies such as augmented reality will be incorporated into labs, processing lines, and drug manufacturing sites to increase safety, reliability, and efficiency. • In addition to reinventing R&D through technology-enabled drug discovery and clinical trials, digital transformation will improve commercial and supply chain processes during the next 5 years. • Significant growth opportunities await in sensor development for medical instruments and equipment management for connected labs, which will enable remote monitoring and controlling.	• The challenge of economically scaling-up manufacturing will remain a major impediment to advancing therapies from the lab to clinics in the short term. • Big Pharma companies will decentralize and outsource the manufacturing of novel cell and gene therapies to contract development and manufacturing organizations. • Companies must pursue acquisitions of digital solution targets to leverage data monetization opportunities and drive growth in precision medicine. • Pharma companies must aggressively invest in improving last-mile connectivity with patients and focus on improving overall health outcomes.

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. Presagen excels in many of the criteria in the AI-Enhanced healthcare space.

AWARD CRITERIA

Product Portfolio Attributes	Business Impact
Match to Needs	Financial Performance
Reliability and Quality	Customer Acquisition
Product/Service Value	Operational Efficiency
Positioning	Growth Potential
Design	Human Capital

Applying Artificial Intelligence to Improve IVF Success Rate and Time-to-Pregnancy

Headquartered in Australia and with offices in San Francisco and London, Presagen, an artificial intelligence (AI) healthcare company, applies scalable machine learning (ML) to address challenges in the women's health tech space. The company designs innovative solutions usable by patients and clinics globally for the fertility market. Its flagship product, Life Whisperer, is a one-of-its-kind cloud-based AI-powered software solution to improve the outcomes for patients undergoing fertility treatment or in vitro fertilization (IVF).

> *"Life Whisperer allows physicians to identify the most viable embryos for implantation, leading to decreased time-to-pregnancy by an average of 15%. It exhibits a 25% accuracy improvement for objectively assessing embryo viability and tracks embryo development over time, a market-disruptive capability providing a competitive advantage over manual selection processes."*
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> *- Supriya Lala Kundu, Best Practices Research Analyst*

Life Whisperer properly leverages Presagen's image-based medical diagnostics platform and ML. It determines healthy embryos for implantation automatically, unlike the traditional error-prone manual approach involving lab-based fertilization followed by embryologists' visual assessment under the microscope to select the most viable embryos. The company's non-invasive embryo selection technique implements key algorithms that recognize morphological features to grade the embryo's quality.

Women's rising age to become mothers results in declining fertility worldwide. According to the United

States (US) Department of Health and Human Services, 12 to 13 out of every 100 couples in the US have trouble becoming pregnant.

Fertility and other female reproductive system issues account for one-third of the cases.[1] Additionally, IVF treatments have low success rates for patients over 35 years. The chances of delivering a single full-term baby of normal birth weight are 24% in women aged 35 to 37 years and 6% in women aged 38 to 40 years, with an average cost of $12,400 per cycle in the US.[2]

With its AI-enabled solution, Presagen aims to boost IVF's success rates, thereby lowering costs, improving access for patients, and enabling them to start a family sooner. Life Whisperer allows physicians to identify the most viable embryos for implantation, leading to decreased time-to-pregnancy by an average of 15%. It exhibits a 25% accuracy improvement for objectively assessing embryo viability and tracks embryo development over time, a market-disruptive capability providing a competitive advantage over manual selection processes.

Life Whisperer utilizes standard imaging equipment (a standard camera attached to the microscope) and evaluates the embryologist's captured embryo images using computer vision algorithms. It does not require additional hardware, thus remaining affordable for patients and clinics. Cloud-based, it is simple to set up (within minutes), cost-effective, and scalable to clinics globally, in contrast to hardware-dependent competing technologies that rely on expensive time-lapse imaging systems (which can be unaffordable by small clinics and limiting scalability).

Technology

Presagen leverages Pytorch on Amazon Web Services (AWS) for deep learning and Amazon Elastic Compute Cloud for AI Training and AWS Fargate for inferencing to design and build Life Whisperer's algorithms. These algorithms are trained using thousands of actual historical IVF case images (both successful and unsuccessful) extracted from the company's globally linked clinical data platform in the AWS cloud. The algorithms classify the embryo's most significant features, invisible to the human eye, in determining viability. The platform then returns the report in real-time (within 10 to 15 seconds). The information helps the physician select the most viable embryos for implantation based on a score; the higher the score, the better the chance of pregnancy. The report also provides intuitive insights to the patients about their treatment process.

With the respective regulatory authorization, the product is commercially available in two-thirds (more than 60%) of the world's IVF market, including Europe, Japan, South-East Asia, Australia, New Zealand, Canada, and India.

In December 2020, Life Whisperer successfully delivered the first IVF baby supported by AI and applied to medical imaging. Identified within the cohort, the embryo demonstrated the highest likelihood of a successful clinical pregnancy, thus transferred to the mother's uterus in the IVF cycle, and culminating in a baby.

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[1] "Women's Reproductive Health." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 28 Apr. 2020, www.cdc.gov/reproductivehealth/womensrh/index.htm.
[2] Growth Insights on the US In vitro Fertilization Services Market, 2018, (*Frost & Sullivan, May 2019*)

Frost & Sullivan appreciates that Presagen offers new hope to millions of would-be parents worldwide by enabling IVF clinics globally to utilize Life Whisperer and leverage AI to help patients conceive quickly and cost-effectively.

"We [Presagen] are so overwhelmed with joy to see our world-first Life Whisperer baby born and the wonderful impact it has had in helping this couple start a family."

Dr. Michelle Perugini, Chief Executive Officer, Presagen

Developing a Spectrum of Femtech Products Leveraging Market-leading AI Platform Trained on Federated Learning Technique

In addition to Life Whisperer, Presagen has several Femtech products in its pipeline focused on improving fertility and women's health outcomes. The company's AI-based solutions aim to change the way the global medical data is connected to deliver affordable, accessible, AI-enabled native health care products. Its platform connects to clinical networks worldwide, with diverse medical data representing distinct clinical environments and patient demographics, to create scalable and unbiased AI products.

"Besides saving patients' time and money and eliminating repeat cycle anxieties, the company's low-cost screening technology creates efficiencies and improves standardization within clinics. Due to improved success rates that eliminate repeat cycles, clinics can treat more patients and increase revenue. In turn, this heightens the clinic's brand equity and demand from patients."

- Supriya Lala Kundu, Best Practices Research Analyst

Presagen designed a novel Federated Learning technique that enables its AI algorithms to train using globally distributed data without centralizing it, thus complying with data privacy and security protocols. The decentralized AI training approach minimizes the risk of private patient information movement. Still, it accesses the data locked in clinics to create a secure, reliable, and easily accessible high-performing AI solution - a market-disruptive computing power compared to conventional centralized training approaches.

Frost & Sullivan concurs that the Presagen platform's unique learning approach properly addresses the challenges of building massively scalable AI products globally while abiding by data privacy laws, nicely providing a competitive advantage to the company.

Presagen's second AI-based product, Life Whisperer Genetics, focuses on non-invasively assessing the embryo to determine genetic abnormalities likelihood, such as Down syndrome. It can potentially become the gold standard in embryo quality pre-screening, assessing for both viability and genetic (euploidy) enrichment.

A US-based retrospective study showed that when Life Whisperer Genetics was used to rank embryos, the top-ranked embryo was genetically normal in 82% of the time. Furthermore, 96% of embryo cohorts had at least one genetically normal embryo in the top two Life Whisperer Genetics ranked embryos. The solution has the potential to eliminate the conventional invasive, expensive procedures of conducting a biopsy on the growing embryo for preimplantation genetic testing. Presagen's second product was launched and recieved CE-Mark approval in May 2021, where it is authorized for use in Europe, UK,

Canada, India, Southeast Asia, Australia and New Zealand, with approvals pending for the USA.

Thirdly, Presagen seeks US and European partnerships for oocyte quality assessment, as high-quality oocytes selection is critical to a better quality embryo and improving pregnancy chances. Additionally, for applications in the egg freezing market, the company focuses on egg quality assessment so that patients can ascertain a viable pregnancy in the future. It can help guide patients in making critical decisions such as the number o**f** eggs to freeze and the optimal duration threshold and, subsequently, evaluate their chances of becoming pregnant. Presagen also collaborates with US, European and Australian researchers to initiate a project to determine endometriosis early, concentrated on the femtech market with application in obstetrics and gynecology.

Providing Affordable Solution for Patients and Creating Cost and Workflow Efficiency for Clinics Heightening Brand Equity and Demand

Presagen's business model includes demonstrating its platform's value proposition. The company collects data for clinical validation and clinical testing through its global cloud AI platform. By leveraging its collaborative clinical network, it also plans to develop a product pipeline using the existing, proven infrastructure. Moreover, Presagen can sell these easily accessible products through the clinic networks cost-effectively.

As Life Whisperer reduces the time-to-pregnancy by decreasing treatment cycles, it allows the doctor to select the healthiest embryo the first time, thus saving patients thousands of dollars from repeat IVF treatment cycles. Besides saving patients' time and money and eliminating repeat cycle anxieties, the company's low-cost screening technology creates efficiencies within clinics. Due to improved success rates that eliminate repeat cycles, clinics can treat more patients and increase revenue. In turn, this heightens the clinic's brand equity and demand from patients.

From a revenue model standpoint, Presagen applies the social media model, and refers to itself as the Social Network for Healthcare. Users of the platform are clinics, which can freely access the platform's suite of AI products on-demand to service their patients. Where social media companies typically generate revenue from advertisers, Presagen revenue is derived from patients (or payers) who pay for the use of the AI product, in a pay-per-use model, that is delivered by the clinic. Similar to YouTube where content providers of videos receive royalties on views, clinics that contribute medical data back into the platform, which allows Presagen to build new AI products that are globally accessible and affordable, receive royalties on global product sales. Presagen's commercial success is shifting from the typical high fee small market model to low fee mass-global market model, which benefits clinics, patients, and investors alike.

As an additional value proposition to patients, the company nicely bridges the transparency gap between patients and the doctors who provide them with clinical guidance and insights on embryo selection.

As it broadens its clinic network, Presagen expands its research collaborators simultaneously and conducts collaborative clinical trials with fertility providers and clinics using Life Whisperer to establish the clinical utility and promote brand awareness for subsequent products. The royalty owners of the products they market (to patients) incentivize the clinics to contribute the medical data, remain involved in product development, and provide a medium to disseminate those products to patients.

The company presents at all notable global scientific congresses, patient forums, and healthcare conferences, building its brand and positioning its product as a cost-effective solution to upscale customers' labs with the latest technology and significantly improving patient outcomes. Besides forging new partnerships in the US, India, Southeast Asia, and Europe, Presagen is working with its clinical partners to design the product requirements for US Food & Drug Administration approval.

Conclusion

Presagen's market-leading artificial intelligence (AI)-based platform allows accessing diverse datasets from its global clinical network adhering to data privacy laws and building massively scalable products catering to women's fertility and the femtech market. Its flagship cloud and web-based product, Life Whisperer, leverages non-invasive AI to grade and rank the most viable embryos automatically by identifying complex correlations in different parts of the image with approximately 25% greater accuracy than visual grading by embryologist alone. As such, the product heightens in vitro fertilization cycle's success rates, accelerates time-to-pregnancy, eliminates repeat cycles, and lowers the patients' financial and emotional burden. It enables clinics to service more patients, improve efficiency, and enhance revenue.

The company has also developed an AI-based solution to evaluate the genetic integrity of embryos non-invasively. Other AI-enabled applications in the femtech market include products to evaluate oocytes for freezing and ascertain future viable pregnancy options and potential solutions catering to broader women's health issues - such as early endometriosis detection. Frost & Sullivan's industry benchmarking research finds Presagen's AI-based innovative, efficient, scalable, and cost-effective solutions to be quite game-changing, pioneering digital technology adoption in the women's global healthcare space.

With its strong overall performance, Presagen earns the 2021 Frost & Sullivan Global Product Leadership Award in the AI-Enhanced healthcare market.

What You Need to Know about the Product Leadership Recognition

Frost & Sullivan's Product Leadership Award recognizes the company that offers a product or solution with attributes that deliver the best quality, reliability, and performance in the industry.

Best Practices Award Analysis

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

Product Portfolio Attributes

Match to Needs: Customer needs directly influence and inspire the product portfolio's design and positioning

Reliability and Quality: Products consistently meet or exceed customer expectations for performance and length of service

Product/Service Value: Products or services offer the best value for the price compared to similar market offerings

Positioning: Products serve a unique, unmet need that competitors cannot easily replicate

Design: Products feature innovative designs, enhancing both visual appeal and ease of use

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 on-going growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.

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 six 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)**