

Industry:

MedTech Human Factors/Usability

Management:

Katia M. Rojas, PhD, Founder & CEO

Ex. Board:

Seeking members

Adv. Board:

Seeking members

Number of Employees:

1

Finance:

Funding to Date:

Founder: \$10,000

Investment Sought: \$1M

For:

Cost of Operating

Mkt & Sales Dev.

Features Development

IP:

Patent-Pending Trademark filed

Vision: Vision:

To become an essential tool for healthcare/MedTech product development to enhance patient safety and product success.

Purpose: Awareness/investment

Business Description / Company Background:

Suabix™ - AI solution strategically designed to empower MedTech product development teams in seamlessly integrating human factors and usability engineering for optimal product success. Human Factors/Usability engineering has been a formal regulatory requirement since 2016 with the goal of reducing tragedies stemming from faulty medical devices. Dr. Rojas, our founder, noticed the high rejection rate of HFE submissions to the FDA (up to 96% of HFE submissions fail due to deficiencies in quality of HF work). Dr. Rojas conducted groundbreaking research and developed the Successful Human Factors 2.0 framework in 2020. This framework optimizes (ensures quality) HFE application in medical devices/combo products, as needed to reduce failed HFE submissions, faulty medical devices, and device recalls. Suabix delivers easy integration of the fit-for-purpose SHF 2.0 framework with advanced AI, enabling device usability excellence at scale.

Market Opportunity / Unmet Need:

Market trends indicate a 41% increased adoption of HFE in MedTech by 2030, due to regulatory demands. Also, AI in Healthcare (US) will reach \$164.10 billion by 2029 (CAGR 42.4%), Thus, with regulatory mandate for HF in MedTech and the need for tools to increase quality in the implementation of HFE, Suabix is poised to become an essential tool for MedTech product development. Market size for usability/HFE tools by 2031: ~\$5 B.

Products / Services – Launched & Pipeline:

Suabix is in the process of launching as beta, already leveraging AI features such as audio/voice transcripts, image analysis, and intuitive chat system to provide real-time guidance in HFE to product development teams to ensure quality and project success. It automates integration of HFE at every phase, by enhancing productivity, deliverables production, device design optimization, risk prediction, accelerating project timelines, and ultimately reducing submission failures, product redesigns, and reputation damaging recalls. We do plan to continue adding innovative features that will further meet the need for automating and streamlining (optimizing) HFE integration process into healthcare product development. Such features are part of the patent application and investment is needed to develop them.

Commercial / Technical Milestones:

MVP for Suabix and filed a provisional patent in year 1 (2023). We are currently in year 2 (2024), focusing on beta-testing and creating market awareness. IP: Deployed early strategies to protect our unique solution, filing for trademark and the provisional patent in year 1 (2023).

Competition / Competitive Advantages / Customer Benefits:

While various usability testing tools exist, Suabix stands apart because of its unique, patent-pending approach: combining a research-based, fit-for-purpose framework with advanced AI, delivering innovative features to *effectively* integrate HFE into healthcare product development. This places us ahead of the competition (either generic or not AI features). Stakeholders include the FDA, pharma/MedTech developers, HF & regulatory consultants, patients, and healthcare providers. Potential clients: MedTech/Pharma developers, HF & regulatory services providers.

Financial Projections & Investment Opportunity: There is potential for SaaS, consulting, and customization revenues, below are initial estimates for SaaS. Assuming investment of at least \$1M in year 2 (2024), prioritizing growth and market penetration over the early years, we predict significant revenues by year 5.

Financial Forecast (Unaudited)

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue	\$28,204	\$56,407	\$112,814	\$225,629	\$564,071
Growth Rate	0%	200%	100%	100%	100%
Gross Profits	(\$270,000)	(\$314,874)	(\$269,749)	(\$134,497)	\$151,257
Gross Margin	-957%	-558%	-239%	-60%	27%