#### FROST & SULLIVAN

# TRANSFORMATIONAL GROWTH LEADERSHIP

# Democratizing Real-world Evidence: How 3Aware is Empowering MedTech Innovators

An Exclusive Conversation Featuring



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CEO of 3Aware



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# How is 3Aware pioneering real-world data (RWD) and real-world evidence (RWE) to transform medical device innovation and clinical research?

As the healthcare industry increasingly turns to real-world data to accelerate innovation and regulatory decision-making, medical device companies face unique challenges in harnessing this data effectively. In this exclusive conversation, William Moss, CEO of 3Aware, and Phillip Stoltzfus, Vice President of Marketing and Public Relations, share how their company's deep expertise, collaborative ecosystem, and cutting-edge data analytics position them at the forefront of medical device real-world evidence generation.

# Three Transformative Forces in Real-World Evidence for Medical Devices

Unmesh Lal: Bill, let's start with your perspective on the most significant changes shaping your industry today.

William Moss: There are a few major transformations shaping medical device real-world evidence. First, there's the explosive growth in the volume and variety of RWD we can access — everything from electronic health records and claims data to wearables and patient-reported outcomes. Second, the growing sophistication of Al and machine learning tools that help us extract meaningful insights to support the complete MedTech product life cycle from new product R&D, through launch safety & performance, regulatory certification, marketing authorizations, label expansions, comparative benchmarking and beyond. And third, the evolving regulatory landscape where agencies are increasingly requiring high-quality RWE for both pre-market approvals and post-market recertification. While MedTech manufacturers are facing historically unprecedented margin erosion pressure, they are also in the midst of a digital transformation providing unprecedented capabilities to optimize profitability across their product portfolios.

Phillip Stoltzfus: To add to that, we have seen a shift in expectations among manufacturers. They want data platforms that not only aggregate but also provide actionable intelligence quickly and transparently. It's less about just collecting data and more about deriving meaningful, hypothesis-driven insights that can inform product development, market access, and post-market surveillance.

Frost & Sullivan's Transformational Growth Leadership Program aims to honor visionary business leaders who possess the foresight and leadership acumen to drive positive change within their organizations. The leaders we celebrate hail from diverse sectors and company sizes, yet they all share an unwavering commitment to innovation and excellence.

#### From Niche Beginnings to Market Leader: The 3Aware Vision

**Unmesh Lal:** How do you envision 3Aware evolving over the next five years?

William Moss: Our goal is to be the preeminent real-world evidence partner for medical device manufacturers worldwide. We cover the full spectrum of device categories utilized in a typical care delivery setting with a focus on automating data curation and surfacing critical insights for the clinical scientist to focus on, reducing study durations by as much as 10 times. While extremely valuable across the massive portfolios of world-leading manufacturers, our business model is designed to also make our solutions accessible for smaller and mid-sized companies that have traditionally struggled to leverage this data. Moving forward, we will scale our large cohort, population-level analytics and industrywide benchmarking capabilities and expand our data sources globally with a model that integrates flexible product pricing and subscription structures tailored to various user needs.

At 3Aware, we are not just building a platform—we are enabling the MedTech industry to gain unprecedented understanding of the uses,

performance and outcomes of their products in the real world, leveraging real-world clinical evidence. Our goal is to make longitudinal data access seamless, while maintaining the context of each patient's unique care journey, to support faster learning, safer devices, and smarter innovation. It's about accelerating value, not just compliance"

— William Moss, CEO, 3Aware

Phillip Stoltzfus: We are building on strong foundations — a scrappy, collaborative culture and innovative technology. We aim to deepen partnerships with key institutions like the Mayo Clinic and lead the industry in creating transparent, data-driven insights that support regulatory, clinical, and commercial decision-making.

# Leading Innovation in Medical Device Data Analytics

**Unmesh Lal:** What key areas of innovation are driving your growth?

William Moss: One of our core values is – Innovation through collaborative thought-leadership. Our roadmap is highly influenced by world-leading key opinion leaders in Medtech, healthcare and regulatory affairs. Right now, a huge focus is on refining population-level analyses that can identify patient cohorts, safety signals, and efficacy trends in real-world settings. We're also investing in Al tools that automate data curation, score encounter outcomes and accelerate the determination of a wide array of study endpoints. Another exciting avenue

may be integrating genomics and other omics data to provide deeper clinical context for devices, especially implantables and diagnostics.

#### Moving Beyond the Hype: Al in Real-world Evidence

**Unmesh Lal:** Al is a buzzword, but how is 3Aware putting it to practical use?

William Moss: The real value comes from "boring but powerful" applied AI, the practical application of various artificial intelligence techniques to solve real-world problems and improve existing systems. We believe that we are bridging the gap between theoretical AI concepts and their tangible implementation, to automate data normalization, optimize study protocol development, reduce manual chart review, and accelerate mission critical insights across large populations, enabling clinical scientists to operate at the very top of their license. We work to ensure our tools and methods are scalable, compliant with regulatory standards and protect the privacy of all those involved.

#### Precision Medicine and Population-Level Insights

**Unmesh Lal:** Where do you see the future of precision health intersecting with RWE?

William Moss: Precision medicine is about understanding which patients will benefit most from which device or therapy delivered at the right time, and why. By combining RWE with advanced analytics, we can identify subpopulations based on genetics, comorbidities, and device usage patterns. This approach not only supports personalized treatment but also helps in designing smarter clinical trials and other clinical studies.

## Overcoming Challenges in a Complex Regulatory Environment

**Unmesh Lal:** What are the biggest hurdles you face?

William Moss: One challenge is balancing data accessibility with privacy and compliance across different regions. Another is managing the expectations of various stakeholders — from manufacturers, regulators and payers to providers and patients. We will remain vigilant, while continuing to innovate while maintaining the highest data quality, security/privacy controls and transparency, to earn trust.

Phillip Stoltzfus: Geopolitical factors are increasingly influencing where and how clinical data can be used. We are constantly adapting our strategies to ensure our clients can navigate these complexities without disrupting their operations or research timelines.

# **Growth Strategy: Organic Expansion and Strategic Partnerships**

**Unmesh Lal:** Is 3Aware's growth mostly organic, or are acquisitions part of your strategy?

William Moss: It's a mix. We have grown organically by deepening our product capabilities and expanding our customer base, but strategic partnerships and acquisitions will play a critical role in broadening our data assets and technical expertise. Our focus is always on integrating complementary technologies and services that enhance the value we deliver.

#### Culture and Brand Identity: The "Scrappy" Edge

**Unmesh Lal:** How would you describe 3Aware's culture and brand?

William Moss: We describe our team as "scrappy" — resourceful, resilient, and collaborative. This culture enables us to be nimble and innovative in a complex, rapidly evolving industry. Our brand stands for transparency, partnership, and collaborative thought leadership. We want clients to see us not just as a vendor, but as an extension of their team.



# Client Engagement: Beyond Transactional Relationships

#### **Unmesh Lal:** How do you ensure a superior client experience?

William Moss: We embed ourselves deeply with client teams, assigning executive sponsors and regularly gathering feedback at key project milestones. Our goal is to be proactive, anticipating challenges and opportunities rather than simply reacting. Clients often tell us that working with 3Aware feels like working with an internal group rather than an external service provider.

#### **Innovation Mindset: Fail Fast, Learn Faster**

#### **Unmesh Lal:** How do you foster continuous innovation?

William Moss: We run multiple internal pilot projects — everything from Al automation to new data visualization tools. We embrace a "fail fast" mentality: if something isn't delivering value quickly, we pivot or stop it. The challenge is letting go of ideas you care about, but staying focused on impact keeps us sharp and competitive.

## Future Outlook: Real-world Evidence as a Strategic Asset

# **Unmesh Lal:** Looking ahead, what excites you most — and what keeps you up at night?

William Moss: : I am excited by the growing recognition that RWE is not just a compliance checkbox, but a strategic asset that can drive innovation, efficiency, profitability and — most importantly — improve patient outcomes, across the full product life cycle. The challenge is scaling this effectively while navigating evolving regulations, ensuring data privacy, and meeting diverse stakeholder needs. But the pace of change and the collaborative spirit in our industry give me confidence we will get there.

#### Final Thoughts: Collaborating to Transform Healthcare

Phillip Stoltzfus: We see ourselves as partners to innovators across the medical device ecosystem. The future belongs to those who can combine data, technology, and clinical insight into actionable strategies. It's an exciting time, and we are proud to help shape that future.

William Moss: Absolutely. Our commitment to collaborative thought leadership and our evolving ecosystem is what will keep us — and our clients — ahead in this transformative era.





#### William Moss | CEO of 3Aware

William (Bill) Moss is CEO of 3Aware, a fit-for-purpose real-world evidence analytics SaaS provider for MedTech. Since joining in 2023, he leverages extensive experience in health and life sciences, with a strong record of growing ventures to market leadership. Previously, he was CEO of Seven Bridges Genomics, leading its acquisition by Summa Equity in 2022. He has also held executive roles at several companies that were strategically acquired. Moss holds a BS in Mechanical Engineering from Lehigh University and a JD from Rutgers University School of Law. He serves on the Board of the Lea's Foundation for Leukemia Research.



#### Phillip Stoltzfus | VP of Marketing & Public Relations

Phil Stoltzfus is Vice President of Marketing & Public Relations at 3Aware, creator of aiSurveillance, a clinical data solution serving the real-world evidence needs of MedTech device manufacturers, regulatory bodies and other healthcare entities. Phil has a BBA in Marketing from Temple University and 20+ years of experience in academic medicine, community-based health care as well as HealthTech supporting biopharma and MedTech. He has supported the launches of three start-ups offering first-of-its-kind solutions in their respective markets. Phil is passionate about precision medicine, real-world data access and transparency; and effectiveness and efficiency of medical treatments and their resulting clinical, scientific and economic learnings



#### **Unmesh Lal | Vice President, Frost & Sullivan**

**Unmesh Lal** brings over 20 years of experience in healthcare strategy and consulting, with a focus on global life sciences and precision health. He specializes in identifying transformative technologies, innovative business models, and growth opportunities across pharmaceutical contract services. A recognized thought leader, Unmesh has authored key industry insights and presented at leading global events including J.P. Morgan, Bio-Asia, and Bio-IT World. He holds a master's degree in biomedical engineering from the University of Michigan—Ann Arbor.

#### Join the Movement: Advancing Real-World Evidence with Purpose

At Frost & Sullivan, we invite healthcare leaders to join the conversation and co-create the future of real-world evidence and medical device innovation.

#### Connect with us to:

- ▶ Subscribe to our ICT Growth Opportunity Newsletter.
- ▶ Join the Growth Council—an exclusive community for innovators.
- ▶ Share your transformation journey with a global audience.
- ▶ Engage with our growth experts to explore new growth opportunities.

#### **Annexure: Redefining RWE Innovation in MedTech**

For a deeper understanding of how real-world evidence, Al, and regulatory transformation are reshaping the healthcare landscape, explore these Frost & Sullivan thought leadership pieces aligned with 3Aware's mission:

- ► Frost Radar<sup>TM</sup>: Life Sciences Real-World Evidence Solutions, 2025
- ► Clinical Decision Support System Market, Global, 2024–2030
- ► Frost Radar™: Clinical Decision Support Systems in North America, 2025
- ► Frost Radar™: US Population Health Management, 2024
- ▶ Population Health Management Sector, Global, 2024–2029

Each analysis provides actionable intelligence for real-world evidence leaders, regulatory professionals, and digital health innovators navigating a fast-evolving post-market environment.

#### YOUR TRANSFORMATIONAL GROWTH JOURNEY STARTS HERE

Frost & Sullivan's Growth Pipeline Engine, transformational strategies and best-practice models drive the generation, evaluation, and implementation of powerful growth opportunities.

Is your company prepared to survive and thrive through the coming transformation?

Join the journey.