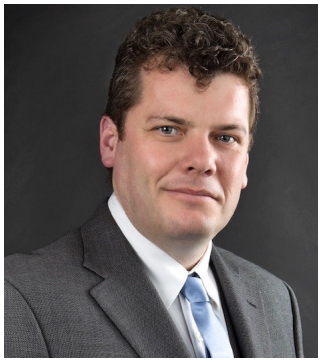

"Ask the Expert"
About Digital Therapeutics

Mike Ryan, EVP
Europe & Asia Pacific

Q1:

WHY DID EVERSANA DECIDE TO APPLY THEIR EXPERTISE TO DIGITAL THERAPEUTICS?

A:

We recognized the opportunity to set a commercialization standard in the digital therapeutics market that meets customer need, works with regulators and payors, and defines how we bring these products to a global market. Advancements in digital medicine will take us into a new frontier, but only if the infrastructure exists to dispense and measure these therapies. This nascent industry needs a commercial model that not only is valuable to payors, providers and patients, but that is also innovative and nimble. Our integrated commercial platform provides the solutions payors demand to successfully launch a product: from HEOR and market access, to pricing to regulatory expertise. It is the perfect combination – the industry needs to commercialize these digital products, and our mission is to advance healthcare.

Q2:

WHAT CHALLENGES ARE YOU EXPECTING WHEN COMMERCIALIZING DIGITAL THERAPEUTICS?

A:

Whether in the US or EU, payors are challenged with supporting the real time benefits for digital therapies vs. pharma. This is a big hurdle to commercialization and the industry is realizing that in order for patients to benefit from the potential of these products, change is needed. As a catalyst for change, we are working with a number of organizations like the National Council for Prescription Drug Programs (NCPDP), to standardize reimbursement and coding for digital therapeutics.

Q3:

EVERSANA IS WORKING WITH COGNOA. WHAT IS THE VISION FOR THIS RELATIONSHIP?

A:

It is our vision to advance the commercialization standard for prescription digital medicines: how they will be ordered, dispensed, and covered by insurance and payors. By developing digital medicine solutions, Cognoa is working to solve a critical unmet need in behavioral healthcare by enabling earlier interventions and more personalized, accessible care. As EVERSANA's CEO Jim Lang stated when the partnership was announced, "It's our privilege to ensure that Cognoa's prescription digital medicines are available to every physician, so that any child can get access earlier when those innovations have the greatest impact."

Cognoa has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for the first digital diagnostic and first digital therapeutic device for autism, the company's first area of therapeutic focus. These devices utilize Cognoa's AI-powered digital medicine platform, designed to support earlier identification and treatment of pediatric behavioral health conditions.

EVERSANA will develop and manage a go-to-market strategy that ensures comprehensive market access; deploys highly trained sales and clinical field force to reach and educate providers; and effectively supports the patient journey through prescription and intake, benefits verification, distribution, and adherence through personalized Hub and specialty pharmacy services. Our extensive payor contracts will support the routine ordering and reimbursement of prescription digital medicines. By leveraging existing healthcare infrastructures utilized by pharmaceutical companies and medical device manufacturers, EVERSANA will ease adoption by physicians, payors and patients at commercial launch of Cognoa's prescription digital medicines.

Q4:

HOW DO YOU EXPECT THE LEARNINGS FROM THIS PARTNERSHIP TO IMPACT THE REST OF THE DIGITAL THERAPEUTICS INDUSTRY?

A:

These therapies are so promising it is a shame that patients do not have access as quickly as we all would like due to challenges, for example, like reimbursement coding in the US. We are paving the way for faster commercialization because, as the industry grows, so does the demand for innovative product commercialization and pricing models. By sharing best practices as a single commercialization partner who can engage all stakeholders, we hopefully are solving industry challenges – regulatory, clinical evidence, market access, distribution, specialty pharmacy – and because of our solutions, help other companies get these therapies to patients faster. Cognoa's CEO Brent Vaughan stated when the partnership was announced, "EVERSANA is helping us – as an industry – to unleash the potential of digital medicine."

Q5:

WHAT ARE THE REGULATORY REQUIREMENTS AROUND DIGITAL MEDICINES?

A:

Across the globe, digital medicines are most commonly regulated under the Software as a Medical Device (SaMD) framework, developed by the International Medical Device Regulators Forum (IMDRF). The IMDRF defines products, categorizes risk, sets quality standards and establishes clinical evaluation criteria for digital medicine. Key to the level of regulatory scrutiny and associated evidence required, is the intended use of the digital medicine. Products that simply inform treatment

require far less evidence in relation to efficacy and safety than those that either treat or diagnose critical illness. For companies entering the digital medicine arena, the need to generate evidence can be seen as being burdensome. However, in addition to its regulatory role, it is also a differentiator of quality and commitment – companies that are not willing to invest in evidence generation quickly drop out, thereby protecting end-users from poor products.

Organizations such as the Digital Therapeutics Alliance work closely with regulatory agencies to establish approval pathways that meet both regulatory needs and that of the manufacturer. Furthermore, in some countries, specific guidance has been issued; for example, the German Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) issued regulations in July 2019 that digital health apps that are certified as medical products and fulfill criteria of data security, quality and functionality can be offered as care, making them eligible for reimbursement by public health insurers.

Q6:

WHAT ARE YOU MOST LOOKING FORWARD TO IN THE FUTURE OF DIGITAL THERAPEUTICS?

A:

Commercializing digital therapies is no longer a brilliant idea on a piece of paper. It's no longer a local phenomenon. It's global. And it holds the promise to materially change the way diseases are managed. It is critical that the industry comes together to collaborate and solve the challenges that prevent these therapies from reaching patients. EVERSANA is invested in better understanding the challenges the global community shares, and in working to provide the solutions to move forward successfully. We are looking forward to meeting the innovators in this space that share the same patient-centric, value-driven vision of healthcare as we do.

Need help commercializing your digital medicines? Talk with our experts to learn more about how EVERSANA's fully integrated commercial services platform can help you engage the right stakeholders to ensure comprehensive market access for your digital medicines.