Pioneer's Perspective

DTxDM EAST

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The Digital Therapeutics industry is attracting more attention now than ever before - why is this?

We're seeing a trend towards value-based care that is helping to open minds around what medicine is and what it could be. Human Data Science as a discipline is providing better, faster, and cheaper means of generating evidence of effectiveness in areas like virtual trials, pragmatic studies, and enriched studies. These can all amend drug development timelines and investments positively.

In addition, as the science around digital medicine improves, as does acceptance of what it is capable of. Traditional "gatekeepers" of healthcare: organizations like the FDA, clinical guideline writers like the American Diabetes Association, and payers like the U.K.'s National Health Service—they are all acknowledging the evidence of digital therapeutics by providing regulatory clearances, efficacy labels, standard of care endorsements, and market access.

How should the healthcare system adapt to this emerging industry?

In the recent IQVIA Institute for Human Data Science report "*The Growing Value of Digital Health*," we explored how the healthcare industry is at an inflection point between stakeholders—Digital Therapeutics developers have demonstrated the value of their products and the pressure is now shifting to the rest of the healthcare ecosystem to provide the regulatory, market access, and uptake infrastructure required to get these products to patients. To the extent that leaders across the healthcare system see the value, they need to be moving towards providing coverage commensurate with that clinical and economic value. To the extent that other stakeholders may still have doubts, they should make these concerns explicit so that the industry can address them.

What evidence needs to be demonstrated by digital therapeutic companies to increase adoption and implementation?

There seems to be a consensus *inside* the digital therapeutics industry that payers will cover and physicians will prescribe digital therapeutics if they have (1) a best-in-class efficacy profile demonstrated in an RCT and blessed in some way by the FDA and (2) Real-World Evidence (RWE) that suggests clinical and economic value. However, I think some buy-side stakeholders will challenge this consensus on the grounds that efficacy does not mean effectiveness, creating an advantage for "effectiveness first" digital therapeutics companies.

What conversations need to happen now for the Digital Therapeutics industry to move forward?

We need more collaboration between the entire spectrum of stakeholders from developers to payers to physicians, on establishing mutually agreed-upon best practices around what makes for good evidence of effectiveness. Currently, there is little to no formal or informal consensus on the topic leading to different stakeholders looking at the same evidence and viewing it at different ends of the spectrum.

How is IQVIA advancing these conversations with the industry?

IQVIA, as the leader in Human Data Science, is touching the entire spectrum of Digital Health. Murray Aitken, Executive Director of the IQVIA Institute for Human Data Science, and I are actively involved in XCERTIA, an app assessment guidelines organization, with Murray holding a Board Member seat. Our AppScript team has delivered an EMR-integrated digital therapeutics prescribing platform currently embedded in Epic's App Orchard globally as well as in EMIS Web in the UK. We are also focused on how Real-World Data can be used to support outcomes-based contracting.

What are you most looking forward at DTxDM East?

The people! The Digital Therapeutics community is built on the incredible opportunity to improve patient outcomes—as such, the community is visionary, talented and genuine. Looking forward to working and collaborating with others who have dedicated their careers to this industry.