

# DTx East 2022 Conference Recap, September 27-29th, 2022

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## DTx industry is hitting its stride

The [5<sup>th</sup> Annual DTx East conference](#), held September 27-29<sup>th</sup> in Boston, brought together industry experts and stakeholders in the digital therapeutics (DTx) space to discuss key challenges and opportunities around reimbursement, regulation, physician adoption, patient engagement, and more. The 3-day conference was attended by over 400 delegates, roughly doubling attendance at prior events, with representation from leading DTx companies, biopharma, payers, providers, government policy makers, and others.

As a knowledge partner sponsor for the event, IQVIA delivered the presentation *A Global to Local Pulse on Key DTx Trends and Emerging Evidence Standards*, and moderated the panel discussion '*Cracking the Code*' on Patient Engagement.

Below is a recap of the conference's three focus areas and **seven key themes**:

### The most optimal ways to commercialize DTx are still to be determined.

- **Business models for commercializing DTx are still evolving.**

- Consensus sentiment is that digital health solution go-to-market strategies and engagement models for both DTx companies and biopharma companies remain in flux even today, and going forward, there will be no one-sized fits all approach to commercialization.
- Some companies with sufficient capital will still take a direct-to-patient approach. Others are pursuing employer- and provider-based models as an initial point of entry. Direct-to-payer coverage is also an option for those who have the right evidence, albeit commercialization is still a challenge. Each of these channels pose complex challenges, and for some companies, multiple channels may be needed over the product lifecycle.

- **Biopharma has finally come to the DTx table.**

- Biopharma is now more actively engaged in the DTx space than ever before, making strategic decisions to bring stand-alone digital therapeutics, companion digital health solutions to support traditional drug assets, as well as combination solutions.
- Biopharma partnerships with DTx companies are also expanding beyond co-promotion and commercialization into real world data and evidence generation partnerships, as well as joint product development initiatives, as demonstrated by the recent \$30m USD Sanofi and Dario Health partnership.

## DTx and biopharma are shifting from building solutions to finding the best ways to derive value from them.

### • Regulatory clarity is emerging across markets.

- In the U.S., a new Digital Health Policy Navigator was recently released on the FDA [website](#), which is a tool to help developers determine whether their products and software functions will necessitate FDA oversight and what pathways are available.
- In Europe, the Germany Digital Health Applications (DiGA) Fast Track process has laid the groundwork for more clear regulatory and reimbursement pathways for digital therapeutics, of which other markets are looking to incorporate some aspects, including anticipated updates to the French guidelines for DTx later this Fall.

### • Reimbursement is still a major hurdle.

- In the U.S., commercial payers have no consensus whether and how to cover DTx, as a pharmacy benefit with National Drug Code (NDC) codes or as a medical benefit. Decisions are typically made on a case-by-case basis. In Congress, the Access to Digital Therapeutics Act is pending, but if approved, could define a clear coverage pathway and benefit category within CMS. For remote patient monitoring (RPM) and remote therapeutic monitoring (RTM), CMS is proposing expanding upon the Current Procedural Terminology (CPT) codes introduced in early 2022, with a new set of RTM codes intended for use by non-physician practitioners and non-physician qualified health professionals, though some confusion exists on pre-requisites for billing.
- Although the payer pathway cannot be guaranteed, the success of Sleepio and Daylight solutions getting on the Evernorth PBM formulary demonstrates some potential; Evernorth is leveraging its claims data to identify potential patients and is sending them texts/emails with QR codes to streamline the sign-up process.

### • More evidence is needed.

- There was continued acknowledgement that evidence is key to DTx commercialization. In addition to clinical efficacy, payers are also seeking health economics, patient engagement, and real world data, which are all reasons why DTx companies are pursuing innovative pilots with health systems. Examples highlighted during the conference included Aetion and Cognio partnering to leverage Aetion's neutral, anonymized data platform and predictive modeling to identify and engage populations at risk of Alzheimers. Happify is also conducting trials that look at current populations prospectively and track effects.
- As much as more evidence is necessary, the question remains how much and at what level of risk. In one case, for a German mental health DiGA product, a sham app comparator was reported to have similar or better results than the actual product. The lesson learned is that trial design is critically important to optimize outcomes and mitigate risk.

### • Physicians are also key stakeholders for adoption and integration of Digital Health solutions.

- It is increasingly clear that prescribing digital applications and their use need to fit into clinical workflows, considering the amount of work already on physicians' plates and the risk of burnout. An example of the integration of clinical decision support to ensure uptake was cited in reference to Xealth's integration into Epic, allowing providers to easily prescribe and keep track of DTx prescriptions via the EHR.
- The panel discussion on patient engagement revealed the importance of product design based on a true understanding of patient needs and their journey, further accelerating clinician buy-in.

**Looking forward, equal access to DTx will be a major focus of industry to keep a pulse on.**

• **Equity considerations need to be at the forefront of digital health realizing its promise.**

- Now more than ever, developers, payers, and health systems are looking towards more appropriateness for underserved populations in regards to DTx. There is increased discussion in the community on securing equity by leveraging data and modeling to ensure that the patient populations most likely to benefit from these solutions that treat their respective diseases are actually receiving them.
- One company that presented an example of establishing an internal working group and conducting ratio modeling to ensure equitable coverage was Akilli. This company mentioned these practices are now reviewed on a regular basis by its C-suite.

Overall, the conference generated a lot of excitement in the DTx sector, and the industry is poised to carry this momentum forward to continue realizing the benefits DTx can play in delivering positive patient outcomes.

Almost all companies today have a digital mandate and focus. IQVIA is equipped with the digital experts, data, tools, and technology to help achieve your business goals. Please contact us to discuss how we can deliver the best of IQVIA's capabilities to support you and your stakeholders.

**CONTACT:** Kate Bennet, Sr. Principal, EU ([kate.bennet@iqvia.com](mailto:kate.bennet@iqvia.com))  
**CONTACT:** Nick Mageras, Principal, U.S. ([nicholas.mageras@iqvia.com](mailto:nicholas.mageras@iqvia.com))