



January 15, 2022

Via Email Submission: BiometricRFI@ostp.eop.gov

Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Re: Notice of Request for Information (RFI) on Public and Private Sector Uses of Biometric Technologies

Dear OSTP Team,

On behalf of the Digital Therapeutics Alliance (DTA), we are glad to submit this response related to the Office of Science and Technology Policy's Request for Information on biometric technologies.

Digital therapeutics (DTx) rely on a broad range of technologies to generate and deliver therapeutic interventions to patients; this includes the use and integration of biometric technologies and data. As DTx products continue to evolve – through novel therapeutic mechanisms of action, technical components, and treatment delivery methods – DTA remains focused on developing foundational principles and frameworks that underpin DTx product integrity and reliability.

To address OSTP's concerns about the use of biometric technologies in digital technologies – from questions about the validity of the underlying science, to differential effectiveness, outcomes, and harms for different demographic groups – DTA provides a brief overview of DTx industry efforts to develop core principles and standards that relate to product development, manufacturing, deployment, and support methods, with the primary aim of serving and protecting patients.

What is a DTx?

DTx products, a new category of medicine, deliver therapeutic interventions directly to patients using scientifically developed, clinically evaluated software to treat, manage, and prevent diseases and disorders. Digital therapeutics address a wide array of health conditions,¹ with products developed for ADHD, anxiety, asthma, cancer side effect management, diabetes, depression, insomnia, migraine, muscle/movement disorders, opioid and substance use disorders, and PTSD — to name a few. DTx products are used independently, alongside medications, and in tandem with clinician-delivered therapy.

Who is DTA?

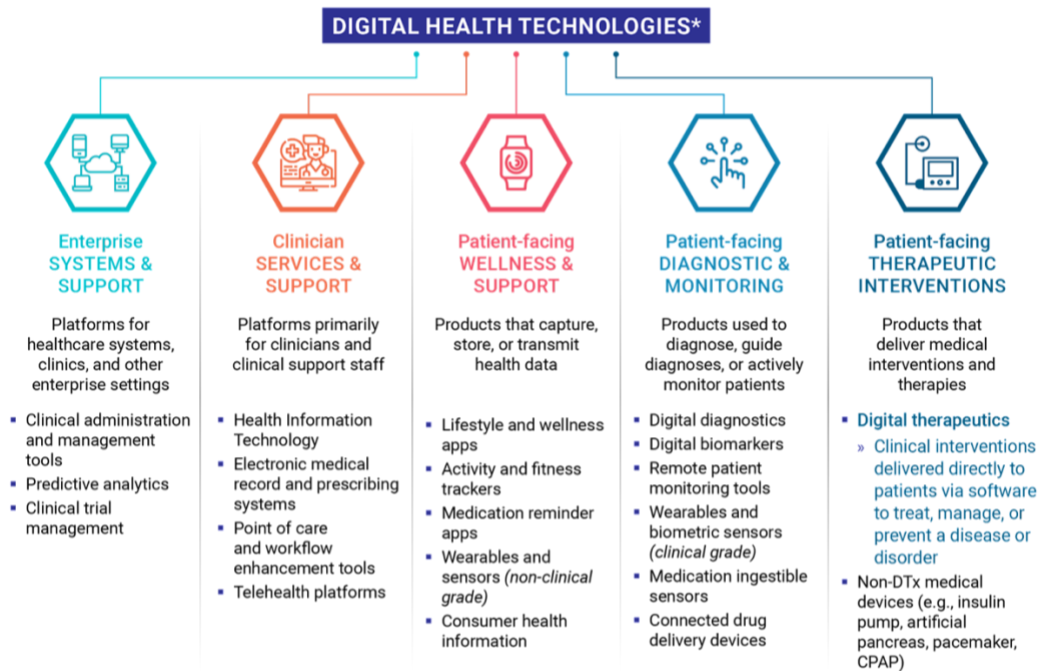
DTA's mission is to help patients, clinicians, payors, and policymakers understand how to identify, assess, and utilize DTx products in everyday settings. As such, DTA works with stakeholders across the healthcare ecosystem to ensure that DTx products are trustworthy and globally accessible care options. Members – including companies across nearly all major healthcare industries and geographic regions – are dedicated

¹ https://dtxalliance.org/wp-content/uploads/2020/03/DTx-Disease-State-Targets_03.20.pdf

to transforming global healthcare by advancing digital therapeutics to improve clinical and health economic outcomes.

DTx in the Digital Health Landscape

It is increasingly clear to healthcare decision makers that products across the digital health ecosystem serve different, but complementary purposes. Depending on a product’s intended use and risk, it is subject to increasing degrees of clinical evaluation, regulatory oversight, and real-world data requirements.



*Categorizations of the digital health technology ecosystem will continue to evolve. This is a select representation of a broad, diverse ecosystem.

Industry Principles

Considering DTx products’ technical nature and direct engagement in patient care (including the generation and utilization of patient-generated data), DTx manufacturers have aligned on rigorous patient-centered core principles (*below*),² an industry code of ethics,³ and product development best practices.⁴ As part of their membership with DTA, DTx manufacturers attest to aligning with the following industry principles. Each DTx product must:

1. Prevent, manage, or treat a medical disorder or disease
2. Produce a medical intervention that is driven by software
3. Incorporate design, manufacture, and quality best practices
4. Engage end users in product development and usability processes
5. Incorporate patient privacy and security protections

² https://dtxalliance.org/wp-content/uploads/2019/11/DTA_DTx-Definition-and-Core-Principles.pdf

³ https://dtxalliance.org/wp-content/uploads/2019/11/DTA_DTx-Industry-Code-of-Ethics_11.11.19.pdf

⁴ https://dtxalliance.org/wp-content/uploads/2019/11/DTA_DTx-Product-Best-Practices_11.11.19.pdf



6. Apply product deployment, management, and maintenance best practices
7. Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals
8. Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use
9. Make claims appropriate to clinical evaluation and regulatory status
10. Collect, analyze, and apply real world evidence and/or product performance data

International Efforts

The International Organization for Standardization (ISO) is an independent, non-governmental international organization with a membership of 165 national standards bodies. Through its members, ISO brings together experts to develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

A DTx-specific Technical Report (TR) will cement an internationally recognized definition of a digital therapeutic, in addition to addressing key standards that DTx products should incorporate to ensure data protection, algorithm integrity, technical rigor, appropriate clinical impact, etc.

This effort will likely build onto another ISO standard published in 2021: [ISO/TS 82304-2:2021](#) *Health software — Part 2: Health and wellness apps — Quality and reliability*. This particular standard provides quality requirements for health apps and defines a health app quality label in order to visualize the quality and reliability of health apps. Covering the entire life cycle of a product, it is intended for use by app manufacturers as well as app assessment organizations in order to communicate the quality and reliability of a health app. Consumers, patients, carers, healthcare professionals and their organizations, health authorities, health insurers and the wider public can use the health app quality label and report when recommending or selecting a health app for use, or for adoption in care guidelines, care pathways and care contracts. Adding a DTx perspective will further improve on this standard.

DTx Industry Efforts

Lastly, DTA is currently working on a *DTx Value Assessment & Integration Guide*, which provides healthcare decision makers with a framework to evaluate the value of and enable the implementation of digital therapeutics in clinical practice. This Guide aims to provide consistent assessment criteria that enhance and refine DTx assessment processes within existing health systems, and includes product evaluation questions related to patient privacy, product security, data governance and storage, regulatory oversight, clinical validation, and real-world implementation.

Thank you for the opportunity to provide commentary on this process. We will be glad to share updates on our international and industry efforts as they further evolve and look forward to any further conversations with your team regarding this and other related efforts.

Sincerely,
Megan Coder, PharmD, MBA
Chief Policy Officer