DTA Policy Positions

The Digital Therapeutics Alliance's (DTA) vision is to transform global healthcare by advancing digital therapeutics to improve clinical and health economic outcomes. DTA is dedicated to supporting healthcare system, clinician, policymaker, public payor, and private payor efforts to provide patients with appropriate access to high quality, clinically-validated digital therapeutics.

DTA promotes policies that support digital therapeutics' ability to improve:

Patient Access

As healthcare decision makers across the world provide patients with access to digital therapeutics, these therapies can more easily reach high-risk, rural, underserved, and undertreated populations who often lack access to healthcare services even during the best of times, particularly through leveraging digital therapeutics' ability to:

- Be accessible through readily available devices, such as computers, smartphones, or tablets

- Enable flexibility in how, when, and where patients access therapies

- Offer evidenced-based therapy independent of a patient's work, education, childcare, or caregiver schedules

- Create safe and discreet spaces for patients to share sensitive topics

- Provide therapies in a variety of languages and cultural contexts

- Leverage a variety of internet connection types, including intermittent Wi-Fi, sustained basic internet, and broadband internet access, in addition to other forms of telecommunication connectivity

Health Equity

Digital therapeutics have the potential to assist vulnerable patients in accessing on-demand and remote medical care. Decision makers may use DTx therapies to address key gaps in access to treatment for marginalized groups regardless of patient age, language, culture, socioeconomic status, health status, disability, or geography. Due to their software-based nature, DTx therapies are scalable and readily available, ideal for use in underserved and under resourced settings.

Patient Centricity

Patients should be provided with access to DTx therapies that are safe, effective, designed to address specific patient needs, and deliver meaningful insights on personalized treatments, goals, and outcomes. In line with DTx industry standards, product manufacturers are expected to obtain input by individuals representing the targeted patient population through each phase of the product life cycle, from initial design and development stages, to defining beneficial outcomes, and optimizing real-world access and usability.

Mental Health Care Access

A significant proportion of individuals worldwide who require and will benefit from mental health treatment do not have access to mental health care. Present mental health care gaps are exacerbated by various forms of discrimination and stigma, professional staff resource shortages, payor management processes, and disjointed service delivery paradigms.

Digital therapeutics are able to address unmet patient needs and with the support of clinicians, health systems, and governments raising awareness about these new treatment modalities, patients will increasingly use DTx therapies as trustworthy, convenient, and affordable mental health care options. Additionally, clinicians are recognizing the value that mental health-focused DTx therapies can add to their healthcare practices, including, but not limited to, expanding their clinical care reach and improving the allocation of limited resources.

Policymakers and payors should therefore:

- Leverage digital therapeutics to expand the reach, access, and affordability of high-quality evidenced-based mental health care that aligns with clinical best practices

- Seek to lower barriers to care for those with serious mental illness

- Ensure that benefits, benefit levels, cost-sharing, coverage, assessment criteria, review processes, and timeliness of review processes are appropriate for the therapy being reviewed

- Ensure that digital care, human care, and their combinations are reimbursed based on evidence

Healthcare Delivery

To address patient- and population-level gaps in care, policymakers should develop infrastructure for patients, clinicians, and payors that enable seamless delivery of, access to, and use of digital therapeutics in all applicable health delivery settings. This will further enable digital therapeutics' ability to:

- Transform how patients understand, manage, and engage in their healthcare

- Directly impact life and disease state outcomes, validated through clinical studies and real-world data

- Extend clinicians' and community health workers' ability to care for patients

- Support healthcare teams in settings with varying degrees of health care infrastructure

- Enhance health system performance and reduce the overall cost of care

DTA supports policies that promote access to high-quality DTx products, as demonstrated through:

Clinical Evidence

Patients should have access to digital therapeutics that are directly supported by clinical trials and real-world outcomes. Policymakers should prioritize DTx products that have undergone sufficient clinical evaluation to demonstrate product safety and efficacy through published clinical evidence inclusive of clinically meaningful outcomes in peer-reviewed journals. Policies should also account for DTx product

iterations and versioning, potentially utilizing clinical and real-world data to demonstrate ongoing efficacy and impact.

Real-World Insights

Through their data-driven nature, digital therapeutics may have the potential to generate real-world performance data that when used in accordance with data governance requirements, enable actionable insights on therapy impact, clinical outcomes, and product efficacy. These insights may be paired with clinical trial outcomes and other data sets to provide a fuller understanding of product and therapy performance in diverse populations.

Product assessment bodies are encouraged to leverage real-world insights generated by digital therapeutics to optimize outcomes at the individual and population levels related to patient use and clinical impact. This includes patient-centric measures, such as clinical outcomes, therapy efficacy, standardized patient assessments, physiologic data via associated sensors; patient and clinician utilization, such as patient utilization and engagement, product onboarding metrics, clinician prescribing parameters, patient-reported outcomes; and product functionality, such as product performance, analytics, quality measures.

At the individual patient level, in alignment with privacy and data governance requirements, DTx products may provide patients, caregivers, and clinicians with meaningful, actionable clinical information. At the de-identified population level, data generated by DTx products may be aggregated to track progress or compare aggregate outcomes based upon disease state, level of acuity, geographic location, age, gender, etc. This data is used to iterate and improve DTx product impact and effectiveness over time.

Product Usability

To ensure that a DTx product's full therapeutic value is delivered to the patient, clinical decision makers assess product appropriateness and usability. Policymakers should therefore support efforts designed to optimize patient access to DTx products that are user-centric and demonstrate ongoing impact through real-world outcomes. This can support clinicians' ability to provide the appropriate therapy for the appropriate patient, at the appropriate time, and with the appropriate usability and accessibility. Clinical entities are now

able to deliver care through digital therapeutics to populations that have previously been outside the reach of traditional care—either due to geographic limitations, cultural and language boundaries, disparities, or health condition severity. Correctly identifying patient populations who will benefit from a DTx therapy and ensuring that all necessary technical requirements are accounted for will increase the likelihood of successful clinical outcomes and reduce costs.

Data Governance

Patient privacy, data governance, and consent processes that include the scope and extent of data use are central to the utilization, trustworthiness, and safety of DTx products. Digital therapeutics should comply with all applicable electronic Protected Health Information (PHI) and sensitive data regulations to protect patient data, such as the Data Protection Act (DPA) in the United Kingdom, General Data Protection Regulation (GDPR) in Europe, and Health Insurance Portability and Accountability Act (HIPAA) regulation in the United States. Where possible, DTA supports harmonized local, national, and regional privacy standards.

Additionally, policymakers are encouraged to support harmonized standards for open patient information exchanges. Individual patient health information should be safeguarded in the process of developing and supporting exchanges where deidentified, aggregate data sets are made available for research and education purposes. Patients deserve transparency and clarity in how their data is used—even if the data is deidentified—and by whom, and be assured that data is used responsibly, for purposes such as research or education.

Cybersecurity

Digital therapeutics are expected to comply with a variety of national and international security standards, such as receiving cybersecurity certification to demonstrate alignment with security best practices. DTx products are also subject to country, region, or product-specific requirements. Where possible, DTA supports harmonized security standards. Products that adhere to appropriate regulations and laws generally reduce the risk of security breaches, clinician and patient mistrust, and compromised electronic health data.

DTA supports policies that enable optimized DTx product use through:

Harmonized Regulatory Pathways

As more healthcare decision makers across the world review, assess, approve, and implement DTx products, it is important for policymakers, payors, and clinicians to have access to reliable frameworks that enable more consistent evaluation of DTx products across local, national, and regional settings. Regulatory environments should enable DTx therapy delivery models that are easily accessible, understandable, and efficient. To prevent a patchwork of differing requirements and enable scalable patient access of digital therapeutics to improve patient care, DTA advocates for the use of harmonized criteria in new and existing DTx evaluation and implementation pathways.

Ecosystem Interoperability

Policymakers developing and implementing interoperability guidelines and regulations should further enable digital therapeutic interoperability with data systems, networks, electronic health records, devices, and other platforms to provide, extract, and appropriately leverage data for the direct benefit of patient care. This will enable DTx product scalability locally, nationally, and regionally. Increased interoperability can improve care access and quality.

Clinician Support: Authorization & Therapy Delivery

To expand access to digital therapeutics, policymakers should recognize that many digital therapeutics may be furnished or supported by physicians and non-physician practitioners where legally enabled, such as physician's assistants, nurse practitioners, pharmacists, and clinical psychologists. Many digital therapeutics include self-directed mechanisms for clinicians who can prescribe digital therapeutics and clinical care team members who may view patient use of the digital therapy, clinical responses and outcomes, or patient-reported health status. This allows other clinical care team members to exercise medical judgment even though the digital therapy may have been prescribed by another member of the care team.

Reimbursement & Funding

DTx therapies bridge the access divide by putting treatment into the hands of patients wherever they may be. Digital therapeutics have the unique

capability of allowing clinician monitoring of treatment adherence and shared decision making, even when patients and clinicians are separated by time and distance. DTx products should be adequately described and categorized in payor, employer, and healthcare delivery system formularies, medical policies, clinical coverage policies, and treatment guidelines. Individual product coding is vital for health care practitioners, systems, claims administrators, safety monitoring, and real-world data verification for digital therapies.