



DTx Integration Guide

Implementing Digital Therapeutics in Practice

Enabling DTx implementation and patient access to this category of medicine



Step 24: DTx Product Implementation and Engagement

This framework provides healthcare decision makers (HCDM) with an industry-level guide to measuring the effectiveness of practices used to implement digital therapeutic (DTx) products in clinical settings. The Digital Therapeutics Alliance does not provide advice on optimal business models or strategies for specific DTx products.

Payors are encouraged to use this framework for all DTx product types, with the recognition that each product has specific considerations to enable end user success.

Check all that apply.

DTx “Engagement Chain”¹

The DTx Engagement Chain comprises five steps for HCDMs and DTx manufacturers to consider in relation to targeting, outreaching to, activating, engaging with, and supporting individual patients.



A. Target

Patient targeting process for this product may include:

- Determine which patient population is most suited for the use of the DTx therapy (Note: this is more selective than simply identifying all patients with a particular condition)
- Analyze patient data to determine greatest product impact and return on investment (ROI)
- Identify and target patients by disease (i.e., disease severity, urgency of medical need)
- Prioritize individuals who will be most successful with treatment

Options to target appropriate patients may include:

- Patient geography
- Disease state and/or comorbidity
- Acuity or severity of disease state
- Demographic parameters
- Social determinants
- Target clinical measures
- Other: _____

Metric: Measured as “n”

Responsible entities: DTx manufacturer may provide initial parameters. HCDM is responsible for population data analysis, patient identification, and prioritization.

¹ The “DTx Engagement Chain” is a registered trademark of Welldoc, Inc. It has been adapted with Welldoc’s permission for use by DTA.



B. Outreach

Patient outreach process for this product may include:

- Determine the outreach modalities to make the target patient population aware of the DTx product
- Undertake targeted education efforts
- Engage patients, and caregivers as appropriate, through marketing activities

Options for patient outreach may include:

- Advertising (i.e., general, social media)
- Enterprise-level awareness campaign (i.e., employer, payor, health system, hospital, clinic)
- Education via a clinician (i.e., in-person or virtual clinical team engagement)
- Targeted direct patient outreach (i.e., phone, email, mail)
- Other: _____

Metric: Measure the “Outreach to Target” ratio, where 100% is perfect outreach

Responsible entities: DTx manufacturer may assist HCDM in conducting awareness campaigns for patients, caregivers, and clinicians.



C. Activate

Patient activation process for this product may include:

- Validate patients who meet criteria for the treatment
- Authorize or prescribe DTx therapy for the patient
- Convert the patient from product authorization
- Deliver product access code and necessary product components to patient
- Ensure DTx product is installed and activated

Degree of direct clinician engagement in this phase may include:

- Clinician needs to be involved in this phase
- Clinician could be involved in this phase
- Clinician does not need to be involved in this phase

Options for patient activation may include:

- Referral or authorization from a clinician, employer, or payor (i.e., non-prescription DTx product)
- Patient self-activation process (i.e., non-prescription DTx product)
- Prescription from a qualified clinician (i.e., prescription DTx product)
- Activation and setup by a clinician, clinical team, or health coach (i.e., non-prescription or prescription DTx product)
- Other: _____

Metric: Measure “Activation to Outreach” ratio, where 100% is perfect activation

Responsible entities: DTx manufacturer is primarily responsible for product activation and enrollment post-product authorization or prescription.



D. Engage

Patient engagement process for this product may include:

- Implement strategy to optimize patient engagement and ongoing utilization with DTx product
- Coordinate shipping date, logistics, and care management
- Identify a care coach for the patient throughout the protocol
- Assess ongoing impact of therapy and patient-specific treatment outcomes

Options for patient engagement may include:

- Ad hoc engagement (i.e., in-product features)
- Programmatic engagement (i.e., enterprise incentives)
- Clinician-guided (i.e., clinical team engagement)
- Other: _____

Metric: Measure “Engagement to Activation” ratio, where 100% is perfect engagement

Responsible entities: DTx products are able to generate patient-specific insights for patients, clinicians, payors, and DTx manufacturers in alignment with privacy and security requirements to assess ongoing engagement and product performance.



E. Support

Patient support process for this product may include:

- Support patient use of DTx product
- Conduct patient follow up inquiries
- Track long-term data accumulation, trends, and impact

Options for patient support may include:

- In-product support
- Remote customer care services
- Clinical team support
- HCDM follow up
- Other: _____

Metrics: Measure traditional metrics, such as call center performance (i.e., inbound calls, issue resolution) and patient satisfaction

Responsible entities: Depending on the specific product and settings of use, DTx manufacturer and HCDMs share responsibility for ongoing patient support and data outcomes tracking.

Step 25: Determining Full-Scale Launch vs. an Implementation Pilot Study

An implementation pilot study is a limited-scale test of processes and procedures particularly focused on the feasibility and acceptability of an approach to be used in practice. Implementation studies do not answer the question, “Does this intervention work?,” nor do they always reflect the exact impact the intervention is going to have with wider adoption of the tested protocol. Phased or full-scale integration may be preferable to conducting a post-market implementation study.

Check all that apply.

When is it appropriate to conduct an implementation study for this product?

Potential questions to answer through a post-market implementation study may include:

- What method will optimize adoption and access to the DTx product for a specific population?
- In a specific setting, what is the best way to identify, engage with, and maintain patient adherence to therapy?
- How does this product impact a specific aspect of the patient journey?
- What additional factors may assist end users in following therapy requirements?
- Which product utilization and target population adoption success measures should be tied to contractual agreements?
- What is the acceptability and feasibility of this product in specific real-world settings?
- Other: _____

Setting-specific questions for a post-market implementation study may include:

- Health plans:* How does the product impact clinicians' workflow and ability to care for patients?
- Employers:* What impacts does the product have on subsets of employee presenteeism, absenteeism, retention, and performance?
- HTA evaluators:* What country-specific tactics may be required to scale the product across target populations?
- Other: _____

When is it NOT appropriate to do an implementation study for this product?

The most common misuses of post-market implementation studies include:

- Attempting to assess baseline safety and efficacy of the DTx therapy.
- Undertaking a pilot when a phased or full implementation is an appropriate next step.
- Assuming that limited-scale results may be substituted for collecting and analyzing real-world data (RWD) outcomes in a full-scale on-the-market environment.
- Evaluating a product that is still in its initial development phase.
- Other: _____

Commentary: HCDMs face a difficult decision when determining whether to undertake a pilot study or implement a product at full-scale.

- » As a first step, HCDMs should identify DTx product(s) that demonstrate strong clinical impact via high-quality studies (i.e., randomized control trial [RCT]).
- » Implementation studies should be focused and are most appropriate to assess how to integrate a product within a specific environment.
- » Not all product launches in a new healthcare setting require an implementation pilot to ensure a successful rollout.

Step 26: Clinical Team Engagement

Digital therapeutics provide clinicians with multiple benefits, including expanded therapeutic options for patient care and access to actionable data insights. DTx products are able to integrate into existing workflows, expand clinicians' ability to actively treat patients, and optimize information available for making clinical decisions.

DTx-generated insights may be leveraged by clinicians to:

- Assess impact of therapy toward patient goals
- Apply actionable insights to optimize, adjust, recommend, escalate, or de-escalate therapy
- Use targeted data sets to help with challenging patient cases
- Detect adverse events and/or non-optimal outcomes
- Develop a better understanding of medication usage
- Provide ongoing monitoring and/or measurement
- Other: _____

Degree of clinician involvement in the use of the DTx product (in-person or virtual):

- Independent product use by patient, without clinician involvement
- Independent product use by patient, following a clinician's recommendation, authorization, or prescription
- Intermittent clinician assessment and therapy adjustment
- Recommended clinician engagement, monitoring, and therapy adjustment
- Required ongoing clinician engagement, monitoring, and therapy adjustment
- Other: _____

The following clinicians, (i.e., diabetes educator, dietitian, dentist, nurse, nurse practitioner, occupational therapist, pharmacist, physical therapist, physician, physician's assistant, psychiatrist, psychologist, speech and language pathologist):

- Engage with the DTx therapy in some capacity: _____
- Are able to authorize use of the DTx therapy: _____

Following initial DTx product authorization, subsequent clinician requirements may include:

- Periodic review of patient-specific outcomes during therapy
- Review of final patient-specific therapy outcomes at the conclusion of therapy
- No follow-up steps are necessary for this product once the therapy is initiated
- Other: _____

Clinical support services provided by the DTx manufacturer, if applicable, include:

- One-time engagement with a clinician who may authorize qualifying patients' use of the product
- Health coaching services (ad hoc services)
- Health coaching services (built-in component of therapy)
- Other: _____

Entities potentially involved in the various phases of DTx-related care include (check all boxes that may apply):

	Advisory Team	Product Evaluation Team	Payor Entity	Compliance Team	Product Access Team	Authorizing Clinician	Clinical Support Team	Other
Initial assessment of the product's intended use, safety, and efficacy	<input type="checkbox"/>							
Product authorization for patient access (i.e., prescription, non-prescription DTx)	<input type="checkbox"/>							
Dispensing or distributing DTx product (i.e., access code, affiliated components)	<input type="checkbox"/>							
Patient education related to product purpose and anticipated outcomes	<input type="checkbox"/>							
Product integration with IT and other technology systems	<input type="checkbox"/>							
Product onboarding (i.e., logistical product use considerations)	<input type="checkbox"/>							
Review and assessment of patient-specific data and outcomes	<input type="checkbox"/>							
Therapy optimization following an evaluation of clinical outcomes	<input type="checkbox"/>							
Product maintenance or support	<input type="checkbox"/>							
Other: _____	<input type="checkbox"/>							
Other: _____	<input type="checkbox"/>							
Other: _____	<input type="checkbox"/>							

- » Advisory team (i.e., patient advisory board, caregivers, practicing care team members)
- » Product evaluation team (i.e., Health Technology Assessment [HTA] body, Pharmacy & Therapeutics [P&T] committee, formulary developers, innovation divisions)
- » Payor entity (i.e., payor, employer, health plan strategy and budgetary approval teams)
- » Compliance team (i.e., legal, regulatory, privacy, security teams)
- » Product access team (i.e., technical infrastructure, implementation, support teams)
- » Authorizing clinician (i.e., clinician qualified to authorize patient use of the product)
- » Clinical support team (i.e., administrative representatives, clinical practice implementation teams)

Step 27: Payment Codes

Depending on which country or region a DTx product will be used within, HCDMs have access to multiple coding options that enable them to quantify and be reimbursed for use of the product, affiliated services, and/or clinician engagement.

The following codes may apply to this particular DTx product:

Therapy Indication:

Target Disease State/Indication	Code Set (i.e., ICD, SNOMED)	Specific Code(s)

DTx Product Codes:

	Relevant Code Set (i.e., Unique Device Identifier, HCPCS, Durable Medical Equipment)	Specific Code(s)
DTx product: _____		
Affiliated DTx product components: _____		
Services provided by the DTx product: _____		
Other: _____		
Other: _____		

Clinician-Specific Codes:

Clinician	Relevant Code Set (i.e., CPT Codes)	Specific Code(s)
Assessment of the product		
Authorization of the product		
Time spent with patient related to the product		
Services provided related to the product		
Resources utilized related to the product		
Other: _____		

Step 28: Ensuring Quality Data Sets

Digital therapeutics produce a variety of data sets. Various subsets of this data are processed via clinically validated algorithms and subject to ongoing data accuracy and reproducibility validation processes.

DTx manufacturers use numerous mechanisms to prevent patients and clinicians from receiving incomplete, inaccurate, or biased results. As such, data generated by DTx products that meet industry core principles and standards should be reliable, accurate, and integrable with complimentary systems.

When DTx-generated data are multi-directional, data from this DTx product may:

- Be incorporated into existing healthcare systems and interfaces (i.e., electronic health records [EHR], order entry systems, clinical decision support systems)
- Receive data inputs from external devices and systems (i.e., sensors, EHRs)
- Other: _____

To ensure data integrity and consistency at the system level when integrating DTx data sets into existing systems, the following considerations should be taken into account:

- Matching the appropriate patient identifiers between the DTx product and IT system
- Tracing data provenance during product use, including key inputs, sources, entities, systems, and processes that influence data set of interest
- Ongoing evaluation processes to ensure integrity and accuracy of any newly combined data sets
- Identification of data limitations or potential holes in combined data sets
- Specifying the timing of when data points were generated within separate sets and determining potential implications on clinical assessment decisions
- Cleaning combined data sets prior to patient, clinician, or payor display
- Other: _____

Preventive measures to ensure data integrity may be necessary if:

- Unstructured data from other systems mixes with DTx-generated data
- Data sources via unapproved sensors or inputs are introduced into DTx systems and factored into outcomes generation
- Other: _____

Commentary: DTx products may be used in alignment with pre-established protocols for other software-based medical devices. With the proper protocols and processes, data integrity can be fully preserved throughout the product use and life cycle.

Step 29: Access to DTx Product Outcomes

Clinical data generated by digital therapeutics are processed by clinically validated algorithms and are therefore clinically actionable and able to be used in direct care delivery and optimization. Data generated by DTx products are subject to interoperability standards and are governed by national and regional privacy standards and regulations (i.e., privacy notices, access to personal data, right to erasure, restriction of use, and consent).

How is data access enabled?

DTx product uses the following interoperability standards and processes:

- Fast Healthcare Interoperability Resources (FHIR): An HL7 standard for exchanging healthcare information electronically
- Standardized Application Programming Interfaces (APIs)
- International standards (i.e., ISO/IEEE 11073) to ensure the product is interoperable with all applicable hardware, software, service, and/or drug components
- Health information exchange(s) (HIE) to exchange health-related information among entities according to nationally recognized standards
- Other: _____

How is data protected?

Data may be:

- De-identified
- Encrypted
- Provided to HCDMs in aggregate form at the population level
- Subject to “appropriate permissions”
- Stored in secure servers
- Other: _____

Given the appropriate authorization, data sharing is possible with:

- Primary or authorizing clinician
- Additional healthcare team members
- Patient
- Caregiver
- Employer, payor, or other authorizing entity
- Other: _____

Where may end users, clinicians, and payors access relevant data?

- In-product interface (i.e., via patient device)
- Standalone portal and/or dashboard
- EHR portal
- Embedded in clinical decision support pathways
- Delivered via fax, email, or PDF
- Other: _____

Where may caregivers access data outcomes?

- In-product interface (i.e., via patient/caregiver device)
- Standalone portal and/or dashboard
- EHR portal
- Delivered via fax, email, or PDF
- Other: _____

What forms of rights do end users have?

- Privacy notice (i.e., covering data processing, use, and disclosure of personal details)
- Access to personal data (i.e., correcting, removing, or limiting data, and portability)
- Right to erasure (i.e., forgotten, deleted, or anonymized)
- Restriction of use (i.e., data for archives only)
- Consent (i.e., offering degrees of control to the individual)
- Other: _____

Step 30: Product Integration

When digital therapeutics are integrated into health systems, products are granted access to clinical information from sources within and outside of the system and use that information to provide direct clinical care. Product integration and interoperability requirements differ based on the intended practice setting of use (i.e., inpatient health system, outpatient clinic, patient home environment).

Integration considerations for this product include:

	Product Offerings to Enable Integration (including DTx manufacturer and third-party offerings)	Requirements for the Health System	Additional Considerations	Not Applicable
Include DTx product in electronic formulary and/or prescribing systems				
Connect DTx product to EHR				
Incorporate product into the prescription dispensing system				
Send data from the DTx product to the health system (i.e., EHR, dashboards)				
Write data from the health system into the DTx product				
Connect product to relevant third-party vendors				
Port relevant data from DTx product into payor systems				
Connect DTx product with payor billing modules				
Deliver product access to the patient				
Send data to patient portal				
Other: _____ _____				
Other: _____ _____				

Digital Therapeutics Alliance

Founded in 2017, the Digital Therapeutics Alliance (DTA) is a non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics. As the leading international organization on digital therapeutic thought leadership and education, DTA provides patients, clinicians, payors, and policy makers with the necessary tools to evaluate and utilize DTx products.

DTA's members—including organizations dedicated to manufacturing, evaluating, supporting, and utilizing DTx products—work to transform global healthcare by advancing high-quality, clinically validated digital therapeutics to improve clinical and health economic outcomes.