DIGITAL THERAPEUTICS ALLIANCE

DTx Value Assessment Dossier

DTx Product Evaluation: Regulatory & Security

Step 9: Regulatory Oversight

Digital therapeutics are reviewed and cleared by regulatory bodies as required to support product claims of risk, efficacy, and intended use. Regulatory bodies in different regions and jurisdictions may set forth different levels of regulatory and market authorization requirements for DTx based on the product's intended use and level of risk. DTx manufacturers are required to comply with all local, national, and regional regulatory frameworks and sets of requirements.

Check all that apply.

What form(s) of regulatory oversight does the product require?

☐ Product has completed regulatory reviews and/or received market authorization in:

	Regulatory Status #1	Regulatory Status #2	Regulatory Status #3
Jurisdiction (country or region)			
Regulatory or notified body			
Clearance, certification, or approval date			
Regulatory class* (product classification)			
Product indication			
Other regulatory designations, etc.			

* Regulatory classifications and definitions may differ between regions.

☐ Product is undergoing regulatory and/or market authorization review in the following jurisdiction(s) (including responsible oversight or notified body):

1. _____
2. _____
3. _____

☐ Product does not require regulatory review and is marketed in the following jurisdiction(s):

1. _____
2. _____
3. _____

☐ Product has not officially submitted for review in a regulatory jurisdiction yet

☐ Other: _____

Step 10: Security Best Practices

Digital therapeutics must comply with a variety of international and national security standards. DTx manufacturers and products that adhere to appropriate regulations and laws generally reduce the risk of security breaches, clinician and patient mistrust, and compromised electronic health data.

Check all that apply.

Does the manufacturer have an information security risk management and governance framework in place to account for information security controls, risk management, etc.?

- ☐ Yes, it is validated at the organization level
- ☐ Yes, it is validated at the product level
- ☐ The process is in progress
- ☐ No
- ☐ Other:_____

What cybersecurity certifications and/or accreditations does this manufacturer and/or product maintain?

- ☐ ISO/IEC 27001 (Third-party auditor):_____
- ☐ HITRUST (Number):_____
- ☐ SOC 2 (Number):_____
- ☐ Other:_____

The product has cybersecurity credentials that are: ☐ Self-attested ☐ Externally certified ☐ Neither

Is the scope of the certified company and/or product components appropriate to their purpose?_____

How does the DTx product verify:

Patient authentication (methods to ensure the appropriate patient is accessing the therapy):

_____

Patient authorization (methods to determine if the patient has permission to use the therapy):

_____

Encryption (methods to ensure data are unreadable by unauthorized individuals):

_____

Data access (methods to ensure the appropriate individuals have access to product-generated data):

_____

Therapy access (methods to ensure the appropriate individuals have access to product content and interventions in case of failed login/authentication):_____

_____

Is a protocol in place to address a data breach or other privacy/data security crisis?_____

Does the manufacturer engage in vulnerability testing?_____

What other measures does the manufacturer use to ensure security?_____

_____

Commentary: It is usually not necessary for DTx products to achieve more than a single cybersecurity certification to demonstrate alignment with security best practices. DTx products are also subject to country, region, or product-specific requirements, many of which may not be represented here.

Step 11: Data Privacy and Governance

Patient privacy, governance, and consent processes are critical to the use, trustworthiness, and safety of DTx products. Digital therapeutics must comply with all applicable regional and local electronic Protected Health Information (PHI) and sensitive data regulations.

Check all that apply.

DTx product provides end user with a privacy notice that describes:

- ☐ How the organization collects, uses, and retains end user data
- ☐ Types of data the product obtains
- ☐ Data protection mechanisms
- ☐ Length of data retention
- ☐ How and by whom information is used
- ☐ How relevant data are shared
- ☐ Enables patient opt-out, retraction of data, and/or revocation of consent
- ☐ Other:_____

Patient is able to consent and authorize how personal digital health data are:

☐ Stored ☐ Shared ☐ Saved ☐ Incorporated in digital health records ☐ Other:_____

What types of personally identifiable and sensitive data does the product gather?

_____

_____

_____

What internal company policies and procedures determine how information is collected, protected, and used?

_____

_____

_____

Data are/may be stored on a: ☐ Public cloud ☐ Private cloud ☐ Dedicated server ☐ Other:_____

Data are/may be stored in the following geographic location(s):_____

Does the product include insurance liability coverage? ☐ Yes ☐ No ☐ Other:_____

Other entities involved in DTx product deployment processes, particularly where patient data might be accessible, are held to same standards as the DTx manufacturer: ☐ Yes ☐ No ☐ Other:_____

Policies that govern third-party access and utilization of data:_____

The following types of data may be shared from the DTx product with third-parties:_____

DTx manufacturer procedures in case of a potential data privacy breach include:_____

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.