DIGITAL THERAPEUTICS ALLIANCE

DTx Value Assessment Dossier

DTx Product Benchmark Questions

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The following ten questions:

- Provide Healthcare Decision Makers (HCDM) with a high-level understanding of a digital therapeutic (DTx) product's stage of development and real-world use
- Do not substitute for a full product evaluation, as outlined in the remainder of the full Dossier
- Enable HCDMs to more easily conduct a side-by-side comparison of multiple products

DTx manufacturers may provide further insights related to these topics in other steps of the Dossier to provide HCDMs with a fuller understanding of the product's abilities and impact.

1. What is the DTx product's current stage of development?

- ☐ Product is in technical and pre-clinical development phase
- ☐ Product is in clinical development phase
- ☐ Product is undergoing regulatory review
- ☐ Product has met all necessary clinical and regulatory requirements in one or more jurisdictions

*Please see **Step 1** in the Dossier for more detailed product evaluation criteria.*

2. What level of evidence has the product generated? *[select the most rigorous study design completed]*

- ☐ Product has completed one or more observational studies (i.e., real-world use)
- ☐ Product has completed a non-controlled experimental/interventional study (i.e., prospective single arm trial, open label trial, head-to-head comparative trial)
- ☐ Product has completed a non-randomized experimental/interventional study (i.e., non-randomized controlled trial, self-controlled study, crossover study)
- ☐ Product has completed one or more randomized controlled trials (RCTs) or pragmatic RCTs

*Please see **Step 13** in the Dossier for more detailed product evaluation criteria.*

3. What is the product's clinical intended use?

- ☐ Product produces a behavioral change
- ☐ Product produces a physiologic change
- ☐ Product is used for disease and/or condition management

*Please see **Step 2** in the Dossier for more detailed product evaluation criteria.*

4. How is patient use of the product primarily authorized?

- ☐ Product access is provided to a patient without clinician, payor, employer, or third-party involvement
- ☐ Product access is provided via a clinically validated screening tool that patients use to determine qualification for therapy
- ☐ Product access is provided via an authorized clinical protocol that states criteria for automatic patient qualification
- ☐ Product access is provided via a non-prescription recommendation by a clinician, payor, employer, or other qualified entity
- ☐ Product access is provided via a formal prescription from a qualified clinician (in-person or virtually) or other qualified entity

*Please see **Step 3** in the Dossier for more detailed product evaluation criteria.*

5. **What is the product's regulatory status in the target jurisdiction of use?**
   - ☐ Product has not determined its regulatory pathway yet
   - ☐ Product does not require regulatory review and is not required to list or register
   - ☐ Product does not require regulatory review, but is required to list or register and meets health authority requirements for software development
   - ☐ Product is undergoing regulatory and/or market authorization review
   - ☐ Product has completed regulatory review and received market authorization in at least one jurisdiction

   *Please see **Step 9** in the Dossier for more detailed product evaluation criteria.*

6. **What is the product's current level of security?**
   - ☐ Product does not have an information security risk management and governance framework in place
   - ☐ Product has an information security risk management and governance framework in place
   - ☐ Product has self-attested cybersecurity credentials
   - ☐ Product actively holds a third-party security certification

   *Please see **Step 10** in the Dossier for more detailed product evaluation criteria.*

7. **What is the product's current level of privacy?**
   - ☐ Product does not have a privacy protocol in place
   - ☐ Product provides end users with a privacy notice
   - ☐ Product enables end users to consent and authorize how data are stored, shared, saved, and used
   - ☐ Product fulfills the previous criteria and meets all national requirements for privacy (i.e., GDPR, HIPAA)

   *Please see **Step 11** in the Dossier for more detailed product evaluation criteria.*

8. **What forms of economic assessment related to the target jurisdiction has the product undergone?**
   - ☐ Product has not undergone an economic analysis
   - ☐ Product has undergone a population- or setting-specific economic outcomes evaluation
   - ☐ Product has undergone an economic outcomes evaluation that accounts for multiple populations
   - ☐ Product has undergone a formal economic review process conducted by a third-party

   *Please see **Steps 19–23** in the Dossier for more detailed product evaluation criteria.*

9. **What is the product's current stage of commercialization in the target jurisdiction of use?**
   - ☐ Product is not commercially available to patients
   - ☐ Product is available to select patients who are engaged in pre-market studies
   - ☐ Product is available to limited patient populations via pilot studies
   - ☐ Product is commercially available to patients

   *Please see **Step 1** in the Dossier for more detailed product evaluation criteria.*

10. **What is the product's stage of reimbursement in this or other jurisdictions?**
    - ☐ Product is in pre-coverage phase
    - ☐ Product is undergoing initial coverage decision evaluations
    - ☐ Product is being paid for by patients and other end users
    - ☐ Product is covered by one or more payor entities

    *Please see **Step 1** in the Dossier for more detailed product evaluation criteria.*

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.