DTx Industry Code of Ethics

The Digital Therapeutics (DTx) Industry Code of Ethics establishes principles to which every *company* engaged in the design, evaluation, and deployment of digital therapeutics[1] should adhere. This Code of Ethics is complementary to the Core Principles and Best Practices[2] that each DTx *product* should adhere to.

Ethical standards for companies engaged in the design, evaluation, and deployment of digital therapeutics include:

1. **Demonstrate a commitment to patient safety. Do no harm.**
   Emphasize patient safety as a critical factor in all decision-making processes.

2. **Develop interventions that improve the quality of care, clinical outcomes, and quality of life.**
   Develop products that result in a better provision of care and clinical outcomes for patients, caregivers, and the healthcare system.

3. **Protect patients' rights to privacy, consent, and knowledge of data use.**
   Be transparent and accountable about how patient-generated data is being used, stored, and shared. Selling of identified or de-identified patient data without the patient's explicit knowledge and consent is prohibited.

4. **Directly align the product definition, claims, benefits, and risks with all analytical and clinical evaluation outcomes.**
   The product's stated intended use and target clinical association must reflect the evidence generated to develop the product definition. DTx products must not make claims greater than what is supported by analytical and clinical evidence.

5. **Make claims appropriate to product status within each applicable regulatory jurisdiction.**
   Do not make direct or indirect claims that extend beyond regulatory and legal boundaries established by local authorities.

6. **Ensure that credible evidence supporting product claims and outcomes is readily available to patients, caregivers, clinicians, and payors.**
   Make all trial results inclusive of clinically meaningful outcomes on the stated primary endpoint publicly available.

7. **Bring products to market in a responsible way.**
   Respect the end user. Align with DTx Industry Principles and Best Practices. Be forthright about product features, anticipated outcomes, and limitations with relevant stakeholders. Demonstrate a commitment to ongoing testing of product usability, accessibility, sustainability, and reliability.

8. **Verify that products perform as expected and deliver on stated claims.**
   Commit to continuous quality and content improvement through the generation, analysis, and application of real world outcomes, product performance data, and end user feedback.

9. **Ensure that product security, data, and functionality are not compromised.**
   Build an internal culture that prioritizes the protection of data and prevention of security compromise.

10. **Maintain a culture of quality and organizational excellence.**
    Prioritize corporate sustainability and human resources to sustain products through every phase of their lifecycle and create long-term value and stability.

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1 *Digital Therapeutics: Combining Technology and Evidence-based Medicine to Transform Personalized Patient Care.* Digital Therapeutics Alliance. Oct 2018.

2 https://www.dtxalliance.org/aboutdtx/