DIGITAL THERAPEUTICS ALLIANCE

Proposing a Harmonized Multi-Functional DHT Approach

It is important for Healthcare Decision Makers (HCDM) to understand whether Digital Health Technologies (DHT) are multi-functional or standalone to best evaluate the effectiveness and impact of a specific product. While certain DHT products have only one function, an increasing number of DHTs are incorporating multiple components and functions into a single product. Given the impact this has on patient care, it is critical for end users, clinicians, policymakers, and payors to clearly understand the types of components that are embedded in multi-functional DHTs and the anticipated impacts of each function.

Proposal: HCDMs are encouraged to adopt a multi-functional approach for evaluating and assessing DHTs.

Approach In Practice

Movement toward a harmonized multi-functional DHT approach would enable the:

- Development of a harmonized list of the types of functions that may be incorporated into a DHT (i.e., therapeutic, diagnostic, decision support, etc.).

- Establishment of consistent definitions and expectations related to the function of each product component, aligned with globally recognized standards and guidelines (i.e., HL7, IEC, IEEE, ISO).

- Global adoption of function-level definitions, requirements, and expectations across national jurisdictions to enable product and process harmonization and scalability.

- Common understanding of DHT product functions by clinicians, patients, and caregivers.

Corollary to Pharmaceuticals

HCDMs and end users expect to know if a pharmaceutical product contains more than one active ingredient or function (i.e., a medication that treats high blood pressure and chest pain, in addition to lowering high cholesterol levels). It is therefore equally important for HCDMs to know if DHTs have more than one function (i.e., monitoring patient digital biomarkers, in addition to treating post-traumatic stress disorder).

Hypothetical DHT Product Examples

The figure on the next page depicts six hypothetical multi-functional products and their DHT Category designation (Health System Clinical Software, Health & Wellness, Patient Monitoring, Care Support, Digital Diagnostic, or Digital Therapeutic). Each product depicted contains multiple functions, with the highest risk function determining the DHT Category. The levels of regulatory review and clinical evidence needed to ensure the product is safe and effective will vary based on each product's respective functions and requirements.

Hypothetical DHT Product Examples

Digital Functions *(Not Exhaustive)*	Product #1	Product #2	Product #3	Product #4	Product #5	Product #6
Therapeutic *(Higher Regulatory Scrutiny)*						✔
Diagnostic					✔	
Decision Support	✔					
Clinical Analytic	✔			✔		✔
Patient Health Data Storage			✔	✔	✔	✔
Patient Monitoring			✔	✔		✔
Clinical/ Standard of Care Recommendations				✔		✔
Clinical Education				✔		✔
Non-Clinical Analytic		✔				
Operational *(Lower Scrutiny)*	✔					
Communication (real-time)	✔					
Communication (asynchronous)	✔					✔
Guided Wellness Exercises		✔				
DHT Category	**Health System Clinical Software**	**Health & Wellness**	**Patient Monitoring**	**Care Support**	**Digital Diagnostics**	**Digital Therapeutics**
	HCP-Facing	Patient-Facing				

Higher Regulatory Scrutiny → Lower Scrutiny

Note: *Further work is necessary to standardize the list of potential functions that may be incorporated into DHTs, in addition to the respective standards and expectations affiliated with each function.*

Aligning With Existing National DHT Nomenclatures

Existing national pathways used to categorize and evaluate DHTs vary between countries and include a variety of labels such as: digital health technology (DHT), digital medical device (DMD), digitale gesundheitsanwendungen (DiGA), dispositifs médicaux numériques (DMN), medical device, mHealth, software as a medical device (SaMD), software in a medical device (SiMD), etc.

Adopting a multi-functional approach will not change existing DHT regulatory or market access pathways. DHTs will continue to be subject to existing pathways and be required to meet all necessary requirements for market entry to ensure patient safety, data privacy, legal compliance, etc. The approach intends to provide more clarity within and across national and local evaluation pathways.

Increasing Clarity and Value

Clearly defining and identifying individual DHT functions across regulatory jurisdictions and healthcare settings can provide:

- **Policymakers and payors with:**
  - A harmonized list of the functions that may be incorporated into a DHT.
  - Consistent definitions and requirements for product function.
  - Ability to maintain existing national DHT nomenclatures and pathways.
  - Greater clarity and specificity in post-market surveillance.

- **Health systems and clinicians with:**
  - DHT clinical evidence and regulatory oversight requirements.
  - Clearer understanding of the products clinicians prescribe to patients.
  - Ability to attribute therapy outcomes to specific product functions.
  - More efficient DHT evaluation and dissemination in patient care settings.

- **Patients and caregivers with:**
  - Increased clarity on DHT product functions and anticipated clinical impacts.
  - Ability to differentiate between various DHTs on the market.
  - Ability to use the proper DHTs for the right time and purpose.

- **Product developers and manufacturers with:**
  - Clarity on the necessary quality and evidentiary requirements for products with specific functions within and across national jurisdictions.
  - Greater ability to scale across jurisdictions and streamline evidence generation.

Conclusion

This approach will provide a structured understanding of the essential functions within digital health products. It enables clarity for HCDMs and end users, promotes interoperability, and supports patient-centered care. Embracing ongoing collaboration and flexibility will allow the framework to adapt to future advancements and meet the evolving needs of the digital health ecosystem. By embracing this multi-functional evaluation approach, it is possible to unlock the full potential of DHTs and drive positive transformation in healthcare delivery.

Note from Megan Coder: *As a next step, this proposed approach will be presented to DTA and DTx Policy Coalition members for review and discussion.*