Comparison Guide: Patient-Facing Digital Health Technologies (DHTs)

Patient-facing Digital Health Technology (DHT) categories are differentiated based on four key aspects:

1. **Label Claims:** The product's intended use and claimed benefits, including what the product can and cannot do.
2. **Intervention Delivery:** The extent and means by which a product impacts a medical diagnosis or intervention.
3. **Evidence Requirements:** The rigor and type of evidence a product needs to receive regulatory approval.
4. **Regulatory Implications:** The extent to which the product is subject to regulatory oversight.

Patient-Facing DHT Category Comparison Guide

DHT Category	Health & Wellness	Patient Monitoring	Care Support	Digital Diagnostics	Digital Therapeutics
Overview	Disease-agnostic digital health solutions that primarily capture and store general health data and promote healthy living	Digital solutions intended to monitor specific health data, which may be interpreted by a physician for clinical management	Digital solutions intended to help patients better manage their care of a specific disease or medical condition	Validated digital tools and software that deliver a diagnosis or prognosis of a specific disease or medical condition	Health software intended to treat or alleviate a specific disease or medical condition by generating and delivering a medical intervention
Claims	✕ No claims to treat, improve, or diagnose a medical condition	~ May make non-clinical claims to assess patient data	~ May make non-clinical claims to improve health-adjacent measures (i.e., adherence)	✓ Makes a clinical claim to diagnose or assess a specific disease or medical condition	✓ Makes a clinical claim to treat or alleviate a specific disease or medical condition
Intervention Delivery	✕ Does not deliver a medical intervention	~ Collects health data to inform clinician decision making around a medical intervention	~ May recommend actions for patients to better manage care or inform a clinician, but does not deliver a medical intervention	✓ Software drives medical intervention through a formal diagnosis or assessment	✓ Software that generates and delivers a medical intervention

DHT Category	Health & Wellness	Patient Monitoring	Care Support	Digital Diagnostics	Digital Therapeutics
Evidence Requirements	Not required	Non-clinical claims to assess patient data must be validated and meet a regulatory agency's quality requirements	Any non-clinical claims (i.e., adherence) must be validated and meet a regulatory agency's quality requirements	Diagnostic accuracy must be validated and meet a regulatory agency's quality requirements	Efficacy claims must be validated and meet a regulatory agency's quality requirements
Regulatory Implications	No regulatory oversight	May require regulatory approval and labeling	May require regulatory approval and labeling	Regulated product with a label for indication, usage, evidence, and warnings	Regulated product with a label for indication, usage, evidence, and warnings

Patient-facing DHTs are primarily differentiated by their proximity to the patient and their potential to directly impact clinical outcomes. Patient-facing technologies, through marketing and/or labeling, will state a variety of claims on their impacts on outcomes and other measures. It is the presence of these claims, and their specific language, that directly confers a product's potential value and level of risk, in addition to the various regulations they need to meet to legally make such statements.

DHT Clinical Claims

Across patient-facing DHTs, there are three dimension of claims:

- **DHTs without claims** are largely consumer-based products. While these solutions may promote general wellness or patient experience, any clinical outcomes are not attributable to the DHT itself.
- **DHTs with non-clinical claims** may still be used in the context of patient care and reimbursed by payers or health systems since these claims can still provide value to these stakeholders (e.g., improved medication adherence, enable monitoring of key health measures like blood pressure). Since these products do not make explicit claims of clinical improvement, any outcomes are considered indirect and not attributable to the DHT.
- **DHTs with clinical claims** are intended to be used in the context of patient care and are more likely to be reimbursed by payers or health systems due to the value they offer to the patient. Clinical benefits covered in the product claims are directly attributable to the DHT itself.

The method by which DHTs influence care or the delivery of care to generate value directly ties to claims. This not only determines where stakeholders should look to evaluate causality of outcomes, but also where original equipment manufacturers (OEM) can refine their approaches to improve outcomes.

Medical Interventions

Only two categories of products deliver medical interventions—*Digital Therapeutics* and *Digital Diagnostics*—which respectively generate interventions and diagnoses directly through their software. While *Care Support* tools can make clinical recommendations, they do not serve as interventions themselves. Likewise, while *Patient Monitoring* and *Health & Wellness* DHTs can provide patients and/or HCPs with information that can indirectly improve health and well-being, these products do not deliver medical diagnoses or interventions on their own.

- **DHTs that do not impact medical interventions** are largely used in a consumer context and do not aim to deliver health outcomes, but instead aim to provide patients with information about their health and general wellbeing to promote healthier living.
- **DHTs that indirectly impact medical interventions** may be used in the context of patient care to monitor patients or make standard of care recommendations for patients to take, but improved outcomes are delivered indirectly and are dependent on integration with a clinician's clinical practice model and/or a patient taking step to better manage their care.
- **DHTs that serve as medical interventions** inherently improve outcomes through the efficacy of the intervention delivered. Digital Therapeutics are the only category that delivers a medical intervention directly by the software/solution.
- **DHTs that drive medical interventions** are a subset of Digital Therapeutics that directly impact and drive a medical intervention (i.e., real-time diabetes monitoring solution impacting the amount and timing of insulin delivery).

Evidence Requirements

In order to make the claim that DHTs are directly responsible for their outcomes, OEMs must provide evidence in the form of either randomized-controlled clinical trials (RCTs), randomized pragmatic clinical trials (PCT), real-world evidence (RWE), or a combination of the three.

Evidence requirements are regional and set by local regulatory bodies based on the claims made by a DHT. The International Medical Device Regulators Forum (IMDRF) lays out a framework for regulation based on claims and disease severity that has, to date, been in line with the approaches of regulatory bodies across the world. Since evidence requirements directly stem from the claims made by a DHT, those that make no claims require no evidence, while those that make non-clinical and clinical claims must provide evidence to support those claims.[1]

It is also important to note that, while evidence requirements for DHTs represent a baseline regulatory requirement for validation, physicians and payors may impose higher evidence requirements to garner adoption and reimbursement, respectively. Accordingly, OEMs may collect additional layers of evidence to strengthen the value of their DHTs.

[1] International Medical Device Regulators Forum, "'Software as a Medical Device': Possible Framework for Risk Categorization and Corresponding Considerations," September 14, 2014, https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf.