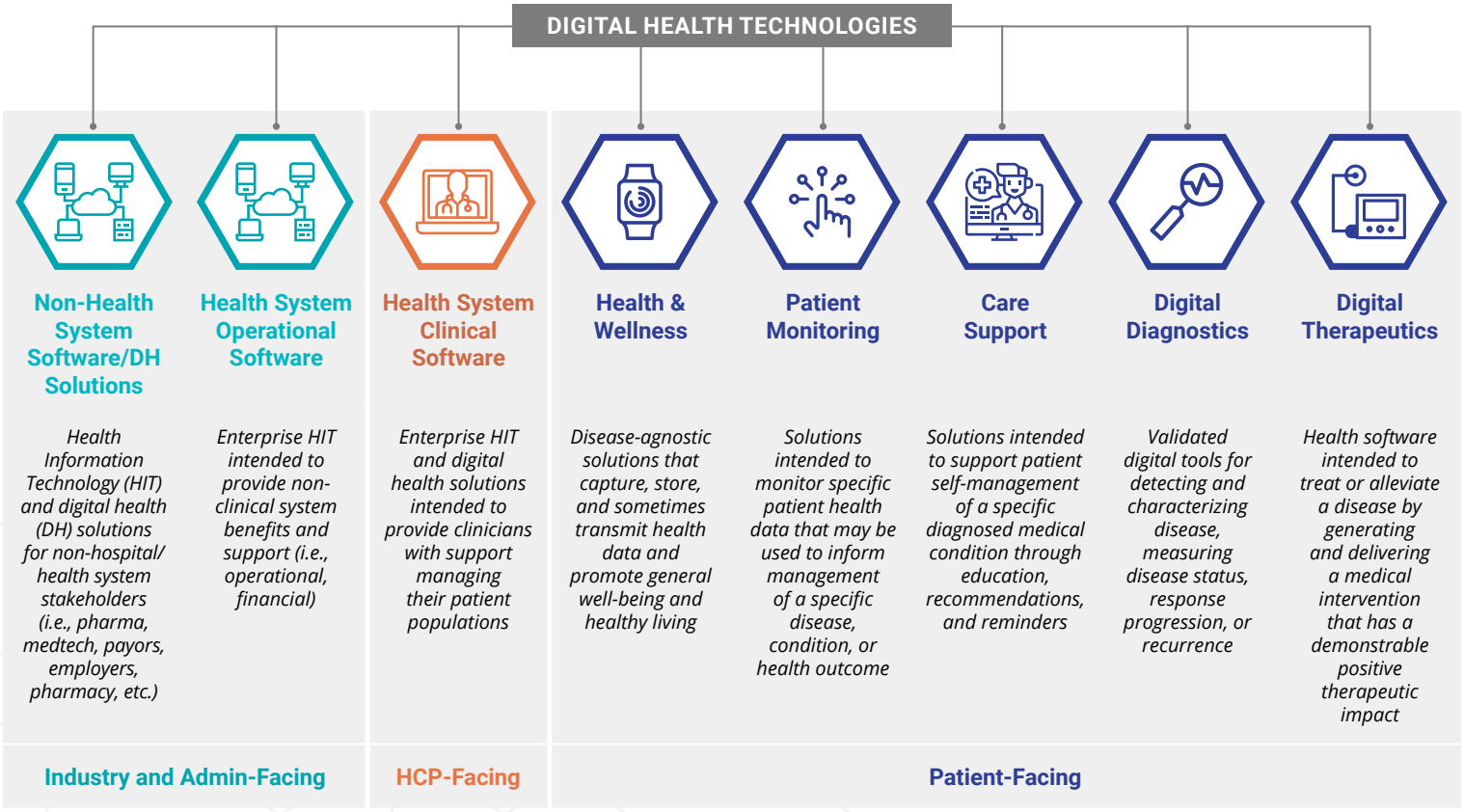
Digital Health Technology Ecosystem Categorization

What Are Digital Health Technologies?

Digital Health Technologies (DHTs) are defined by the US FDA as "computing platforms, connectivity, software, and sensors [used] for health care and related uses."[1] The definition is broad and can include technologies that serve a variety of purposes, including facilitating low-acuity patient wellness, operationalizing patient data, and even delivering a standalone intervention.

DHT Categorization

Digital Health Technology categories include:



The three categories on the left side primarily serve non-patient stakeholders, including healthcare providers (HCP), health system and hospital administration, and other stakeholders in the healthcare industry (i.e., original equipment manufacturers, biopharmaceutical companies, employers, and payors). While these solutions may contain patient-facing elements (i.e., Electronic Medical Record (EMR) patient portals), the majority are more akin to enterprise software since they are often centrally adopted and indirectly impact patient care.

[1] U.S. Food and Drug Administration, "What Is Digital Health?," September 22, 2020, https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health.

The five patient-facing categories on the right side are solutions primarily intended for a patient to use and have patient-facing features (i.e., mobile app, computer software, wearable), even though these products can also incorporate features that are physician-, payer-, or health system-facing. This subset of solutions is presented from left to right in order of increasing impact on clinical management, which is a core orienting principle for how DHTs are evaluated, regulated, and paid for. Along with increased impact on clinical management comes a higher bar for evidence required for adoption, greater regulatory scrutiny, and increased stakeholder willingness to pay.

Five differentiation criteria were used to develop this DHT categorization, including product:

- End users/beneficiaries
- Intended benefits/claims
- Level of regulatory scrutiny
- Strength of evidence
- Intervention type

This categorization is therefore broad enough to encompass the vast array of solutions on the market today, as well as descriptive enough to enable the categories to be actionable (i.e., consistent coverage and review policies applied to specific categories). Further insights are provided in the document, *Guidance to Industry: Classification of Digital Health Technologies (DHT).*