Overview and 101: Digital Health
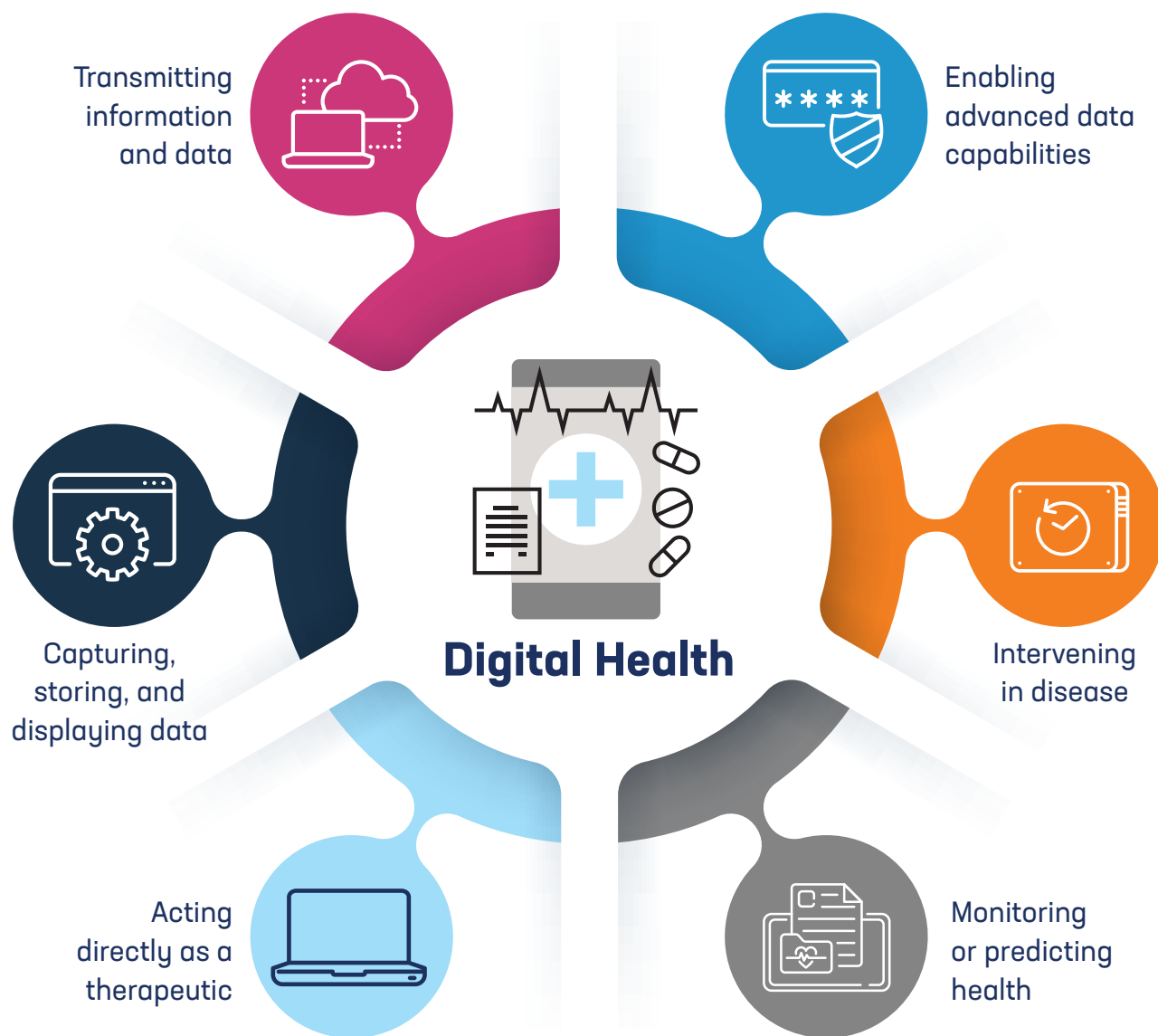
Digital health[1] is transforming nearly every aspect of our healthcare system, such as improving efficiency in drug research and development, shifting how care is delivered, and empowering patients to manage their own care.

Thanks to advancements in science and technology, the biopharmaceutical industry continues to work across the healthcare ecosystem to leverage **digital health tools**[1] to enhance drug research and development and deliver value to patients.

As defined by the Food and Drug Administration, digital health technologies span a wide range of functions and may use computing platforms, connectivity, software, and/or sensors for healthcare treatments or to be used alongside a medicine.[2] **Establishing a common understanding of key terms and use cases is important to better understand how these tools are developed and regulated, the differences in patient access or coverage (if applicable), and how patients use them to achieve better health outcomes.**

Beyond the scope of this overview of use cases—but not beyond the attention of the biopharmaceutical industry—are the many considerations around the security and confidentiality of data and patient privacy when using digital health tools.

Transmitting information and data

Enabling advanced data capabilities

Capturing, storing, and displaying data

Digital Health

Intervening in disease

Acting directly as a therapeutic

Monitoring or predicting health

The types of products and processes that make up digital health vary widely and can include examples of tools that achieve the purposes laid out below.

CAPTURE, STORAGE, AND DISPLAY OF DATA

User-facing technologies[3]	**Mobile health applications** such as lifestyle trackers, fitness apps, nutrition apps, and medication reminders allow patients to capture and track their own health data
	For example, there is a mobile application that connects with a network of blood pressure machines and allows patients to track and trend blood pressure readings[4]
	Consumer health information such as personal health records and patient portals, or digital apps that are integrated with electronic health records that enable patients to see medications, test results, bills, upcoming appointments, and more[5]
Health information technologies[3]	**Electronic health records (EHRs)** serve as a centralized platform to collect and store patient information and allow instant information sharing across a healthcare organization
	For example, there is an EHR that holds information for the majority of patients in the United States with widespread interoperability to connect providers in all aspects of a patient's care[6]
	Electronic prescribing allows healthcare providers to communicate and prescribe medication directly to a pharmacy, such as using a point-of-care prescribing tool that is integrated into provider workflow, to eliminate the manual prescription-writing process[7]

TRANSMISSION OF INFORMATION AND DATA

Telemedicine[1]	**Telemedicine-only platforms** facilitate remote care delivery and professional health-related education through live, on-demand, virtual physician visits to connect patients to medical professionals from numerous specialties via video, audio, or text[8]
	Telemedicine integrated in a one-stop shop platform that provides virtual, on-demand physician visits that diagnose, prescribe, and deliver medications, such as a platform focused specifically on treating chronic migraine[9]
Clinical decision support software[10]	Tools and software that present information for independent clinician review, such as software programs that check drug interactions, calculate drug doses, send preventive care reminders to patients, or track adverse events to medications
Clinical trial support tools[11-13]	Tools such as wearable devices and mobile applications that are utilized to collect, store, transmit, or analyze data, including patient-generated data, captured digitally to help enable decentralized clinical trials[a]
	For example, there are wearable devices that continuously measure gait and sleep in patients in clinical trials that are focused on Parkinson's disease[14]

ADVANCED DATA CAPABILITIES

Artificial intelligence (AI)[1]	Devices or products that can imitate intelligent behavior or mimic human learning and reasoning that are used in identifying and validating drug targets, compound discovery, and safety testing
	For example, there is an AI platform used in research and development that uses an advanced analytical technique called convolutional neural networks to predict binding of small molecules to proteins, facilitating faster discovery of new small molecule medicines[15]
Machine learning (ML)[1]	A subset of AI that can be used to design an algorithm or model without explicit programming but through the use of automated training with data
	For example, there is a tool that applies ML algorithms to models of genetic diseases to determine the difference between healthy and diseased cells and identify drug targets[16]

[a] Decentralized clinical trials leverage technologies such as telemedicine and remote patient monitoring for trial execution.

TRANSLATION OF RAW HEALTH DATA INTO INFORMATION FOR MONITORING OR PREDICTIONS OF ASPECTS OF HEALTH OR A DISEASE[17]

Digital diagnostics[18]	Software-driven connected technologies that are used to detect or confirm the presence of a disease or condition of interest to identify individuals with a subtype of the disease, such as an ML software system used to diagnose diabetic retinopathy[19]
Digital biomarkers[1]	Digital measures of variables that are an indicator of normal biological processes or responses to an exposure or intervention, including therapeutic interventions that can only be or should be measured by a validated digital health technology tool. Examples include a platform that tracks changes in typing cadence, generating a digital biomarker that can be used to monitor brain health and detect neurodegenerative diseases such as Alzheimer's disease, Huntington's disease, and others[20]
Electronic clinical outcomes assessments (eCOAs)[18]	Digital measures used to capture how patients feel, function, or survive, such as a tool that applies AI algorithms to data captured from sensors to predict disease onset/progression and identify key intervention points[21]
Remote patient monitoring[22]	Tools that can be used to collect medical and health data from a patient and securely transmit that information to a healthcare provider for monitoring and intervention purposes For example, there is a tool that monitors the temperature of a person's feet every day for patients with high-risk diabetes to detect diabetic foot ulcers[23]

TRANSLATION OF RAW HEALTH DATA INTO AN INTERVENTION INDEPENDENT OR IN CONCERT WITH OTHER THERAPIES[1]

Digitally integrated products	Tools that are integrated with either a drug or biologic to optimize health outcomes, such as ingestible sensors that can be included in oral tablets to track when a medication is taken in a companion platform[24]
Automatic measurement and intervention tools	Tools that measure and intervene using algorithms to serve a primary function that does not require human intervention. For example, there are artificial pancreas systems that can combine continuous glucose monitoring through a wearable sensor with an insulin pump controlled by a computer-controlled algorithm to automatically deliver insulin[25]

ACT DIRECTLY AS A THERAPEUTIC[18]

Prevention or health improvement tools	Patient-centered tools used to help improve health functions, such as a cognitive behavioral therapy that helps patients with irritable bowel syndrome track symptoms, manage flare-ups, and change unhelpful behaviors and thoughts[26]
Disease management tools	Tools used to help patients and providers manage their disease, such as a platform that engages individuals with type 2 diabetes, hypertension, and obesity—and their providers—to improve self-management and outcomes[27]
Disease treatment tools (prescription required)	Tools prescribed to a patient to treat a disease, such as a sensory stimulus software for the treatment of attention deficit-hyperactivity disorder through a video game experience[28] or a digital therapy used as an adjunct to standard outpatient treatment of opioid use disorder[29]

The regulatory framework applicable to a specific digital health technology depends upon its intended use. Digital health products can range from being unregulated, to being regulated as devices, to being regulated as drugs.

It is critical to advance regulatory frameworks and coverage and reimbursement policies that enable access with a modern and strategic approach. Such an approach should facilitate transparency, promote active collaboration with stakeholders, and function as a review process that is efficient and predictable.

References: 1. PhRMA. Biopharmaceutical Digital Health Lexicon. Accessed April 1, 2022. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Digital-Health-Lexicon.pdf **2.** US Food & Drug Administration. What is digital health? Published September 22, 2020. Accessed January 27, 2022. https://www.fda. gov/medical-devices/digital-health-center-excellence/what-digital-health **3.** World Health Organization. Classification of digital health interventions. 2018. WHO/RHR/18.06. Accessed January 27, 2022. https://apps.who.int/iris/bitstream/handle/10665/260480/WHO-RHR-18.06-eng.pdf **4.** Higi. Accessed January 27, 2022. https://www.higi.com/higiplatform **5.** MyChart. Accessed January 27, 2022. https://www.mychart.com/ **6.** Epic. Accessed January 27, 2022. https://www.epic.com/about **7.** Surescripts. Accessed January 27, 2022. https://surescripts.com/enhance-prescribing/e-prescribing **8.** Amwell. Accessed January 27, 2022. https://business.amwell.com/ **9.** Cove. Accessed January 27, 2022. https://www.withcove.com/ **10.** US Food & Drug Administration. Clinical decision support software: draft guidance for industry and Food and Drug Administration staff. Published September 27, 2019. Accessed January 27, 2022. https://www.fda.gov/media/109618/download **11.** Clinical Trials Transformative Initiative. Advancing the use of mobile technologies for data capture & improved clinical trials. Accessed January 27, 2022. https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_Digital_Health_Technologies_Recs.pdf **12.** Clinical Trials Transformative Initiative. Developing novel endpoints generated by mobile technology for use in clinical trials. Accessed January 27, 2022. https://dcricollab.dcri.duke.edu/sites/NIHKR/KR/GR-Slides-07-20-18.pdf **13.** Clinical Trials Transformative Initiative. Decentralized clinical trials. September 2018. Accessed January 27, 2022. https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_DCT_Recs. pdf **14.** Miseta E. AbbVie goes all-in on wearables and digital technologies. August 2019. Accessed February 2, 2022. https://www.clinicalleader.com/doc/abbvie-goes-all-in-on-wearables-and-digital-technologies-0003 **15.** Atomwise. Accessed January 27, 2022. https://www.atomwise.com/our- technology/ **16.** Insitro. Accessed January 27, 2022. https://insitro.com/approach **17.** Coravos A, Goldsack JC, Karlin DR, et al. Digital medicine: a primer on management. *Digit Biomark*. 2019;3(2):31-71. **18.** Digital Therapeutics Alliance. Digital health industry categorization. Published November 2019. Accessed January 27, 2022. https://dtxalliance.org/wp-content/uploads/2019/11/DTA_Digital-Industry-Categorization_Nov19.pdf **19.** Abràmoff MD, et al. Improved automated detection of diabetic retinopathy on a publicly available dataset through integration of deep learning. *Invest Ophthalmol Vis Sci*. 2016;57(13):5200. **20.** NeuraMetrix. Accessed January 27, 2022. https://neurametrix.com **21.** Evidation. Accessed January 27, 2022. https://evidation.com/ **22.** Center for Connected Health Policy. Remote patient monitoring. Accessed January 27, 2022. https://www.cchpca.org/about/about-telehealth/remote-patient-monitoring-rpm **23.** Podimetrics. Accessed January 27, 2022. https://podimetrics.com/ **24.** Miliard M. FDA approves first digital pill, a drug that comes with ingestible sensor. Published November 14, 2017. Accessed January 27, 2022. https://www.healthcareitnews.com/news/fda-approves-first-digital-pill-drug-comes-ingestible-sensor **25.** National Institute of Diabetes and Digestive and Kidney Diseases. Artificial pancreas. Updated October 2021. Accessed January 27, 2022. https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/artificial-pancreas **26.** Mahana Therapeutics. Accessed January 27, 2022. https://www.mahanatx.com/ **27.** Welldoc. Accessed January 27, 2022. https://www.welldoc.com/ **28.** Akili. Accessed January 27, 2022. https://www.endeavorrx.com/ **29.** Pear Therapeutics. reSET-O. Recovery is a round-the-clock process. Accessed March 28, 2022. https://www.resetforrecovery.com/