

## Key Terms

### Artificial Intelligence (AI)

Digital systems able to perform tasks and make predictions and recommendations to solve problems in an "intelligent" manner. "Intelligent" initially was benchmarked against human capacities, but that comparison has proved limited; AI is being applied to problems that human processing capabilities cannot address. At the same time, AI also struggles at many tasks that are simple for most humans.

### Machine Learning (ML)

A type of AI trained to make judgments without being explicitly programmed, imitating the way humans learn and gradually improve performance through experience.

Digital health, inclusive of electronic health data, shared data platforms, and artificial intelligence, is opening new horizons for every phase of health and biomedical research & development. The ways in which digital health data can be generated, shared, and analyzed are all redefining what is possible in research today.

## New Avenues for Research & Collaboration

The ability to capture, share, and rapidly interpret electronic health data – including sequenced genomes, electronic health records, and data from wearable devices – is transforming the research landscape in remarkable ways.

New research collaborations, new insights from huge data sets, and the ability for researchers to rapidly mine those data sets to access meaningful data creates far-reaching potential for rapid-pace medical and public health progress.

- The [NIH All of Us](#) centralized precision medicine database – which has participant-provided information, including data from surveys, wearables, physical assessments, and electronic health records – has been accessed by nearly 4,000 researchers across career stages from research institutions small and large.
- Sharing information from genetic databases across multiple research institutions has helped create a large pool of data from which researchers can conduct genome-wide association studies. These studies have greatly enhanced our understanding of the genetic risk factors of multiple diseases, including Alzheimer's disease.

## Empowering Cost- and Time-Efficient Biomedical R&D

It can take up to 10 years and hundreds of millions of dollars for a drug to go from the preclinical research stage to being approved for treating disease. Advances in ML are streamlining drug screening and making the drug discovery pipeline more efficient.

- There are billions of potential small molecules, but only a fraction will demonstrate medical benefit. Traditionally, researchers would have to physically test molecules of interest at the bench. AI can be used to simulate molecular interactions to radically narrow down the target list, improve the odds of success, and accelerate the speed of testing for new therapeutic interventions.
- Research at the NIH and the [National Center for Advancing Translational Sciences](#) uses ML to develop models that simulate screening of new drugs without actually producing them in a lab. After this initial screening, a shorter list of potential drugs can be tested in real life – saving time and dollars.
- Researchers at the University of Toronto leveraged an [AI-powered protein structure database](#) to identify a new target treatment for hepatocellular carcinoma (HCC), design the treatment, and synthesize it without the conventional trial-and-error method.

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## Digital Health Technologies (DHTs)

DHTs refer to an ever-growing array of digital technologies – including telehealth, sensors, electronic databases, artificial intelligence, and the list goes on – used to collect, share, and integrate data to improve individual and population health.

## Omics

Omics research is the high-volume characterization and quantification of biological molecules (e.g. the genome, proteins, etc.) to better understand their structure and function.

Advances in data storage and AI have made omics research mainstream in biomedical and clinical studies and have paved the way for precision medicine.



## Expanding the Horizons of Clinical Research

The flexibility and functionality of digital health technologies can support a wide range of goals, such as increasing clinical trial diversity, maximizing the number of enrollees for rare disease research, and creating a personalized medicine experience for clinical trial participants.

### Remote clinical trials

- Remote trials are conducted away from a traditional trial site. Patients may hear about the trial from their primary care physician but sign up online using electronic consent (eConsent).
- Once enrolled, patients can use telehealth technologies, including video conferencing or mobile texting, to check in with trial personnel from home.
- Data from participants can be acquired automatically from wearable devices, which continuously track parameters such as heart rate, oxygen saturation, step count, and sleep activity and relay the data directly to trial personnel in real-time.
- Patient-reported data can also be actively collected from participants from external devices, like blood pressure cuffs, or through self-reported clinical electronic patient reported outcomes (ePROs).
- Remote automatic and patient-reported data collection can paint a holistic picture of patient health in a real-world setting, outside of a conventional trial site.
- Barriers like time, distance, or cost might be removed for patients who could otherwise not participate in on-site clinical research.

### Precision medicine and clinical research

Precision medicine (a.k.a. "personalized medicine") – and precision medicine research – cannot exist without digital health. Precision medicine incorporates a person's genetics, environment, and lifestyle into their health care. Advances in DHTs, including large-scale patient and omics databases, AI algorithms, and telehealth have brought precision medicine to clinical research.

- AI can consolidate large data sets such as electronic health records, wearable devices, omics information, and environmental factors from a single patient to evaluate their disease risk factors, etiology, and treatment.

- Precision medicine can make single patient research studies meaningful and are instrumental to developing "n-of-1" patient-centered treatments.
- The same digital health tools underlying precision medicine are being used in broader kinds of clinical trials as well, including the National Human Genome Institute's Implementing Genomics in Practice (IGNITE) program, which combines genomic precision medicine with pragmatic clinical trials to study genotype-guided therapies.

## Real-time Impact on Public Health

Conducting research in real time allows public health practitioners to make decisions as data are collected and analyzed. There are many public health functions that can be enhanced and supported with digital health tools.

- High quality data visualization tools, such as COVID-19 maps and dashboards, make real-time analysis and research more accessible and provide public health authorities with the information needed to make data-grounded decisions more quickly.
- Surveillance and decision-making in response to outbreaks or epidemic-level challenges is increasingly being guided by big-data decision support.
- Programs as simple as text message reminders and population alert systems that utilize digital communications and use information captured or analyzed via digital health are being incorporated into public health research.
- The Digital Engagement and Tracking for Early Control and Treatment (DETECT) trial is expanding on this concept by analyzing data generated from wearables and self-report surveys to detect for fast-spreading illnesses such as influenza and COVID-19.
- Digital health can also enhance environmental monitoring and evaluation, such as wastewater tracking, so that health departments can track the spread and prevalence of infectious diseases.

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A recent global survey of physicians showed **34% view precision medicine as the health care treatment innovation they are most looking forward to in 2023.**



**A single sample of wastewater can show infection status of millions of people 4 to 6 days before clinical trends are observed.**