

# Transforming Biopharmaceutical Research and Development Through Digital Health

Digital health is transforming nearly every aspect of our health care system, improving efficiency, expanding access to treatments and technologies and ushering increased development of personalized medicine.

Applying digital health to biopharmaceutical research and development and the FDA-regulated lifecycle of a product, which we refer to as **digital R&D**, is beginning to positively disrupt biopharmaceutical development. Thanks to advancements in science and technology, the biopharmaceutical industry is leveraging the potential of digital R&D to improve drug development and deliver greater value to patients. Unfortunately, large scale benefits from digital technologies have been restrained due to the inability of the current regulatory and policy landscape to keep pace with the rapidly evolving, scientific and technological aspects of digital R&D.

A modern vision and regulatory framework, supported by better tools for assessing how digital technologies can be best used in R&D, are needed to unlock the full potential of digital R&D for the benefit of patients.

## INCREASING APPLICATION OF DIGITAL R&D

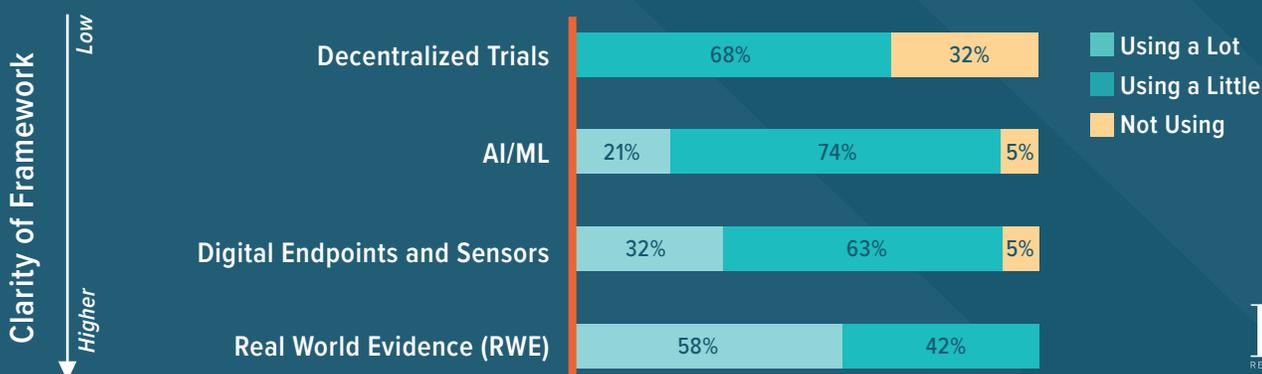
Digital R&D is a rapidly evolving ecosystem with the potential to reduce barriers to innovation and expand the market for novel medical products and therapeutics.

Artificial intelligence/machine learning (AI/ML) and connected devices and sensors represent the most commonly leveraged technologies for digital R&D.

The area with the most promise is in the field of clinical trials—spanning the full spectrum of trial design, trial operation and data collection—but those technologies are also being used in the discovery R&D processes and in manufacturing and life cycle management.

(Table 1)

### How heavily are digital R&D applications being used by biopharmaceutical manufacturers?



As understanding of science and digital technology advances, the regulatory uncertainty and need for a modern flexible regulatory approach is increasing. Survey feedback from biopharmaceutical manufacturers highlights this relationship between a predictable framework and the expanded use of digital technologies, as shown. For example, nearly every PhRMA member surveyed reported use of AI/ML and real-world evidence (RWE). Of those, nearly three times as many manufacturers reported a higher frequency of the use of RWE versus the use of AI/ML, where the regulatory framework is less defined.

While rapid integration of digital technologies is occurring, there is an opportunity to expedite and increase use of digital R&D throughout the medical product lifecycle by addressing regulatory uncertainty. This includes addressing validation of technologies and the acceptance by regulators of digitally derived data and present barriers to advancing application of digital technology solutions.

See Table 1 on previous page

## LOOKING AHEAD: UNLOCKING THE POTENTIAL OF DIGITAL R&D

The increasing adoption of digital R&D presents an opportunity to increase efforts to develop and advance a framework for digital R&D. Among these opportunities are:

- Developing a common lexicon to facilitate the further adoption of digital R&D tools and technologies.
- Establishing a flexible and scalable global regulatory framework for digital technology development, validation and usage in R&D.
- Convening regular forums to gather digital technology experts across biopharmaceutical industry to collaborate on issues, emerging trends, validation approaches, etc. when developing recommendations for FDA.
- Ensuring there is a consistent regulatory approach to digital R&D across all the FDA centers.

### SNAPSHOT: MODERNIZING CLINICAL TRIALS

The area of R&D where PhRMA members are currently the most active in the application of digital technologies is clinical trials.

Specifically, PhRMA members are applying digital technologies in clinical trials to:

- use electronic diaries and wearables as exploratory endpoints
- leverage mobile apps and cleared medical devices that use mobile apps
- use predictive analytics for patient and site selection
- capture real world evidence (RWE) alongside clinical trial data
- develop capability for fully decentralized (virtual) clinical trials
- improve digital recording of patient recorded outcomes (PROs)

### SNAPSHOT: ARTIFICIAL INTELLIGENCE (AI)/ MACHINE LEARNING (ML)

One example of a digital technology identified by a majority of PhRMA members as an area of high interest is Artificial Intelligence (AI)/Machine Learning (ML).

Examples of the ways in which PhRMA members are applying AI/ML include:

- the discovery of new drugs
- algorithm development for patient identification and patient risk detection
- identification and prediction of rare adverse events
- designing and running clinical trials
- pharmacovigilance
- investigating and implementing digital approaches to automate lab activities with the potential for fully automated labs
- exploring the use of cloud infrastructure needed for wider AI/ML adoption.