Unlocking the Value of Digital Measures in Drug Development

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By embracing digital measures, pharma can accelerate drug development, improve patient outcomes. Pharma can and will continue to compete on assets, but should not compete on (digital) endpoints. We require industry collaborations in order to usher in a new era of medicine.

Digital measures have the potential to revolutionise drug development. However, pharma has been slow to fully utilise these measures due to their high costs and lack of standardised applications across therapeutic areas.

This report presents an expert-led analysis of the state of digital measures in drug development. More specifically, the report delves into:

- Defining digital measures and the need for standardisation
- Benefits and challenges of digital measures in drug development
- Current and future adoption of digital measures in drug development
- How pharmaceutical companies can drive the adoption of digital measures

Download the report to learn what our HealthXL community experts believe is in store for the future of digital measures in drug development and how best to prepare for it.

Most investigated health concepts using digital endpoints:*

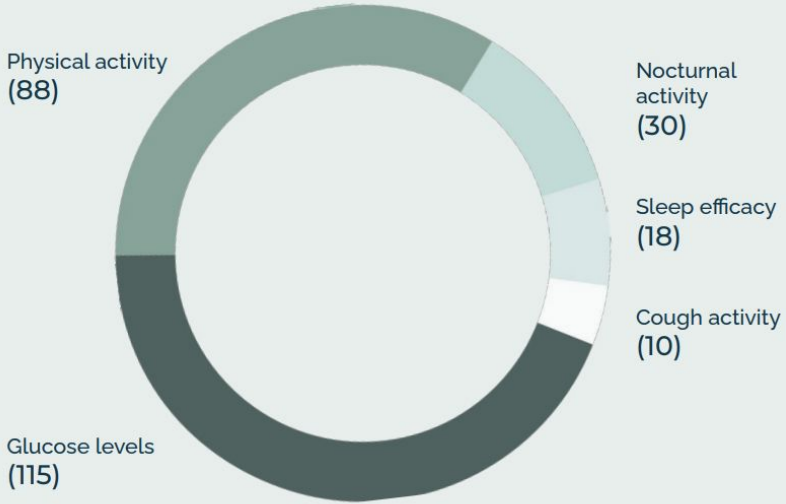

Figure 4.2: Frequency of health concepts investigated as digital endpoints

Digital endpoint use across study phase:*

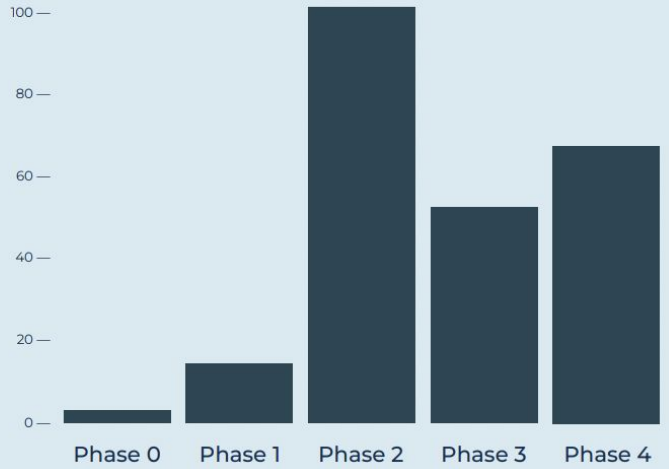

Figure 4.3: Frequency distribution of digital endpoints investigated by study phase

*Analysis on DiME library of Digital Endpoints (version 24 July 2023) performed by HealthXL (August 2023).

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Industry experts interviewed for this report have expressed concerns about the catch-all use of words such as digital biomarkers. Regulatory experts are also calling for a more consistent usage of definitions of digital biomarkers and COAs. This would suggest that the digital measures space as a whole is still maturing.

Experts in digital R&D from pharmaceutical organizations are taking the lead from regulators, with many converging towards the FDA's definition of a digital biomarker in particular (Figure 2.2).

81% of experts surveyed for this report said that they themselves, or their organization, have adopted the FDA's definition of a digital biomarker, with the remaining respondents leaning on definitions authored by the EMA and DiMe.

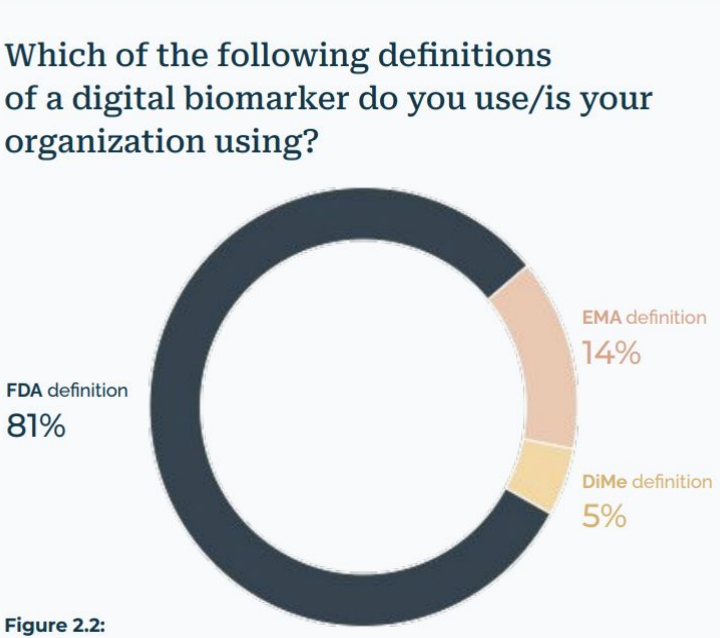

Figure 2.2:
Survey results for experts polled on **"Which of the following definitions of a digital biomarker do you use/is your organization using?"** (n=21)

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What Digital Endpoints Are Being Used?

The Digital Medicine Society (DiMe) has curated a crowdsourced database of 430 digitally-collected endpoints, used in industry-sponsored studies throughout the period September 2005 to July 2023.

Our analysis of DiMe's data revealed that activity monitors, continuous glucose monitors and smartphone apps were the most frequently deployed DHTs for endpoints collection. According to this analysis, Novo Nordisk followed by Pfizer and Novartis had registered the most digital endpoints (Figure 4.1).

Glucose levels and physical activity were the health concepts most frequently investigated through digital means (Figure 4.2). Digital endpoints were most frequently used in Phase 2 as well as Phase 4 trials (Figure 4.3).

Figure 4.1: Digital endpoints in clinical trial trends (includes digital biomarkers and eCOAs)

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