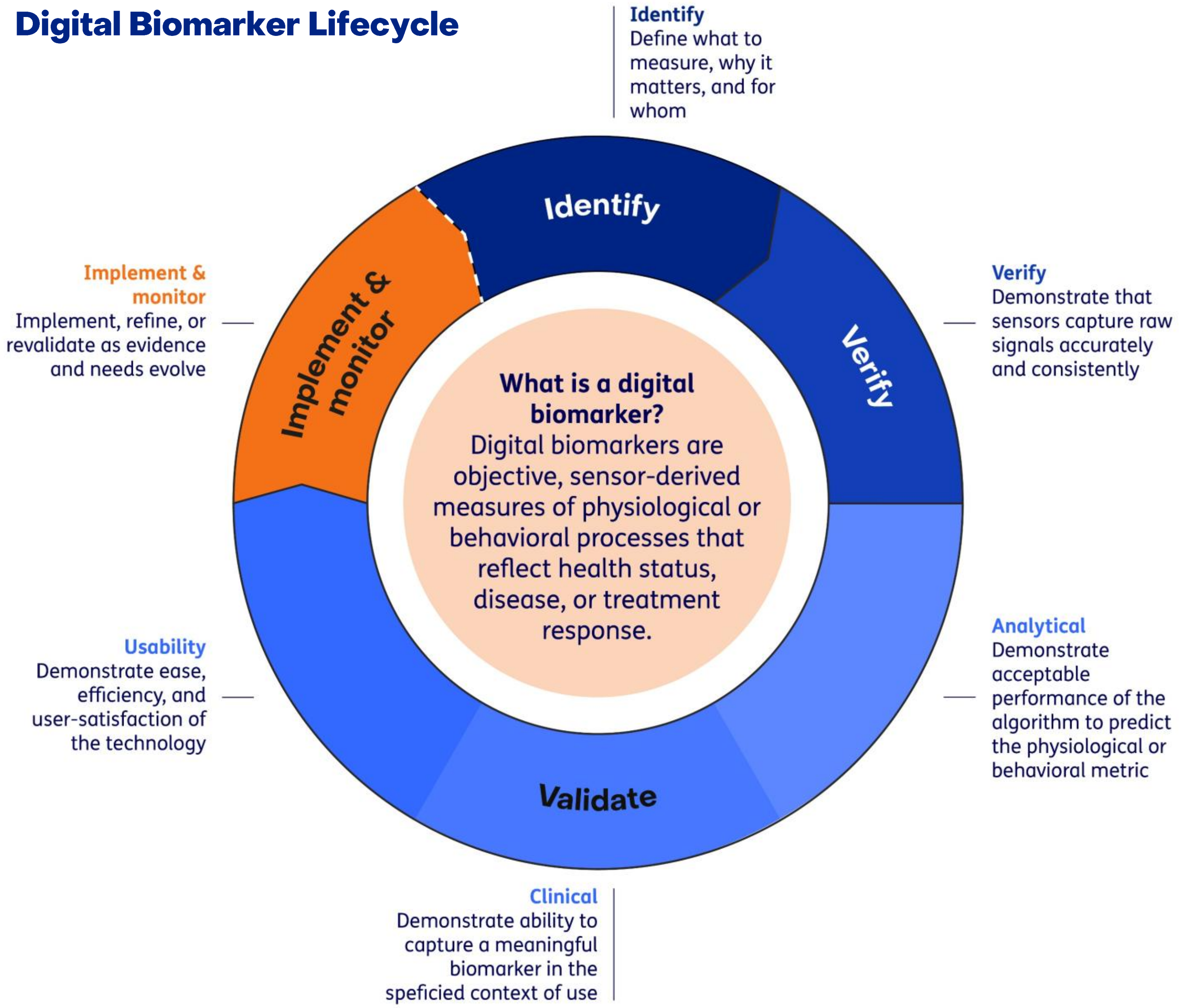
What is a digital biomarker?

Digital biomarkers are objective, quantifiable physiological or behavioural measures collected using sensor-based digital health technologies to assess normal biological processes, disease states, or responses to treatment. Unlike traditional clinical assessments, digital biomarkers can capture health continuously and in real-world settings, providing insight into how people function and feel in their daily lives.

Digital biomarkers are derived from **digital measures**, which are raw sensor-based outputs without intrinsic clinical meaning, and are transformed into digital biomarkers once they are interpreted and validated for their clinical relevance.

To ensure this transformation and that digital biomarkers are fit for purpose, their development and evaluation can be structured using established frameworks such as the Digital Medicine Society's (DiMe) V3+ framework for verification and validation, together with the Digital Measures That Matter framework, which anchors measurement selection in patient-meaningful aspects of health.

Digital Biomarker Lifecycle



Digital Biomarker Lifecycle *explained*

Identify
The first step is to define what should be measured, why it matters, and for whom. This involves linking patient-meaningful aspects of health to a clearly specified digital biomarker, including its intended role (e.g. monitoring or prognostic) and context of use. Grounding measurement selection in what matters to patients helps ensure that digital biomarkers address relevant clinical or functional questions rather than replicating low-value traditional assessments.

Verify
Verification establishes that the sensor and data capture technology perform as intended. This step focuses on confirming that raw signals are captured accurately, precisely, and consistently across devices and conditions of use. Verification is independent of disease or clinical outcome and provides the technical foundation required before any algorithmic processing or interpretation can be considered reliable.

Validate: analytical
Analytical validation evaluates whether the algorithm correctly transforms raw sensor data into the intended digital measure. This includes assessing accuracy, precision, robustness, and consistency of the digital measures against appropriate reference standards. Analytical validation demonstrates that the physiological or behavioral metric behaves as expected across datasets, environments, and relevant subpopulations.

Validate: clinical
Clinical validation demonstrates that the digital biomarker is meaningfully associated with clinical states, outcomes, or experiences in the target population and context of use. This step assesses whether the measure reflects relevant aspects of health, discriminates between meaningful states, or responds to change where change is expected. Clinical validation is essential to establish that a digital biomarker is fit for its intended decision-making purpose.

Validate: usability
Usability validation evaluates whether the digital health technology can be used correctly, consistently, and acceptably by real users in real settings. This includes assessing ease of use, efficiency, user-satisfaction, potential use-related errors, and the impact of user interaction on data quality and adherence. Usability is a critical extension of validation, recognising that even technically robust measures can fail if they are not usable in practice.

Implement & monitor
Following validation, digital biomarkers are implemented in clinical studies, real-world evidence generation, or care pathways. Ongoing monitoring is required to ensure that performance, usability, and relevance are maintained as technologies, populations, or contexts of use evolve. Digital biomarkers may require refinement or revalidation over time to remain fit for purpose across their lifecycle.