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Abstract

Digital biomarkers are consumer-generated physiological and behavioral measures collected through connected digital tools, such as portables, wearables, implantables, and digestibles, without interfering with a patient's daily lifestyle.

Data collected through digital tools becomes a digital biomarker when a relationship is drawn to a health-related outcome. These digital biomarkers can potentially improve a patient's quality of life, but the practice of passive data collection requires specialized consideration for regulatory clinical submission.

PHUSE’s **Emerging Trends & Technologies - Digital Biomarkers in Clinical Submissions** project explores the current state and future impact of digital biomarkers in the clinical sector.

Digital vs. Traditional Biomarkers

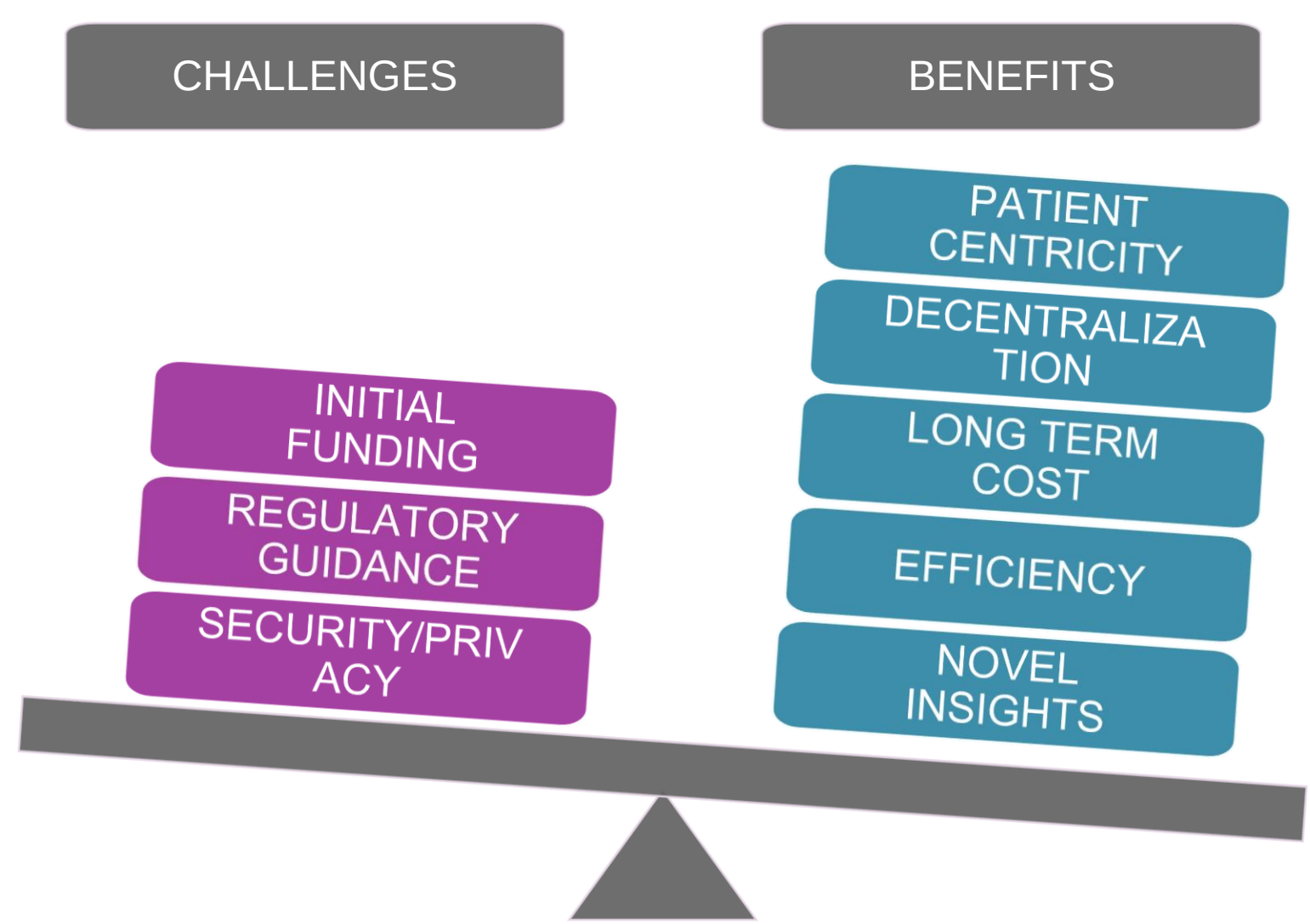
Similarities

- Measure indicators of normal biological or pathogenic processes or responses to exposures or interventions
- Categorized based on clinical goal
- Quantitative and qualitative results
- Accurate and reproducible

Differences

- **Events Measured** Digital allows continuous monitoring, while traditional measures singular, distinct events
- **Assessments Validated** Significantly more investment in validation of traditional biomarkers. Out of the >20 biomarkers approved by FDA and EMA, two are digital¹

Benefits and Challenges



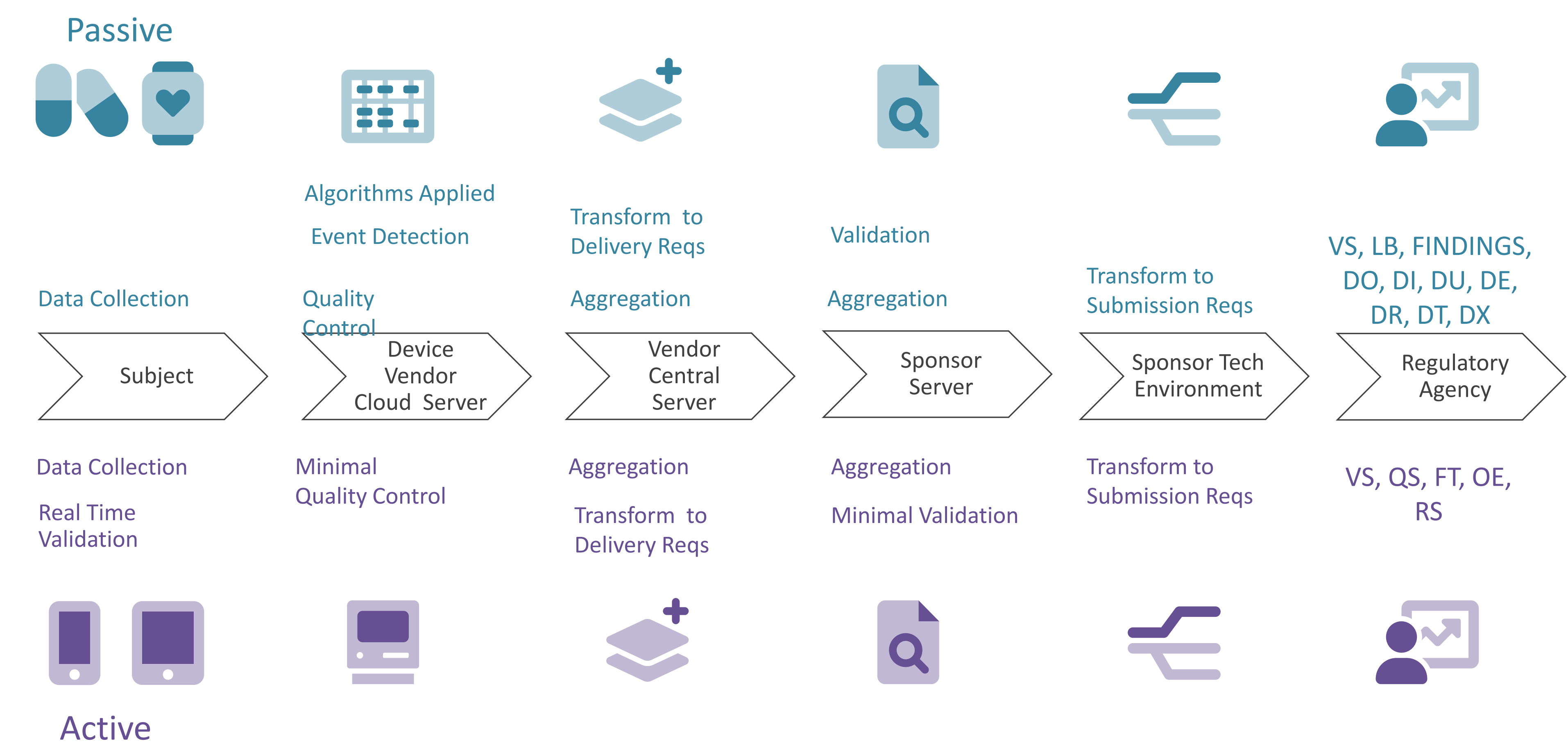
Classification of Digital Biomarkers

Within the healthcare industry, there's a consensus on the utility of digital biomarkers; however, the categorization of these novel tools and terminology is still in debate. Classification criteria may include:

- **Type:** How does the patient interact with the device? Active or passive?
- **Measurement:** On what physiological system is the device used?
- **Application:** How is the biomarker used? Safety monitoring, patient enrollment, medication adherence or clinical efficacy?
- **Feature:** What type of event and population data is collected? Individual or population? Longitudinal or discrete timepoint?
- **FDA device classification:** What regulatory class will be used when seeking approval for the device to be used in health care?
- **Device status relative to clinical insight:** Has the device or the biomarker been validated previously? (see table to right)

The biggest challenge to standardized nomenclature is the wide range of applications and types of devices. Industry and academic cross-functional collaboration are necessary to achieve standardization and wide widespread adoption of digital tools, leading to an increase in regulators confidence in these tools.

Digital Biomarker Data Flow



Want to learn more or join our team? Scan the QR code!



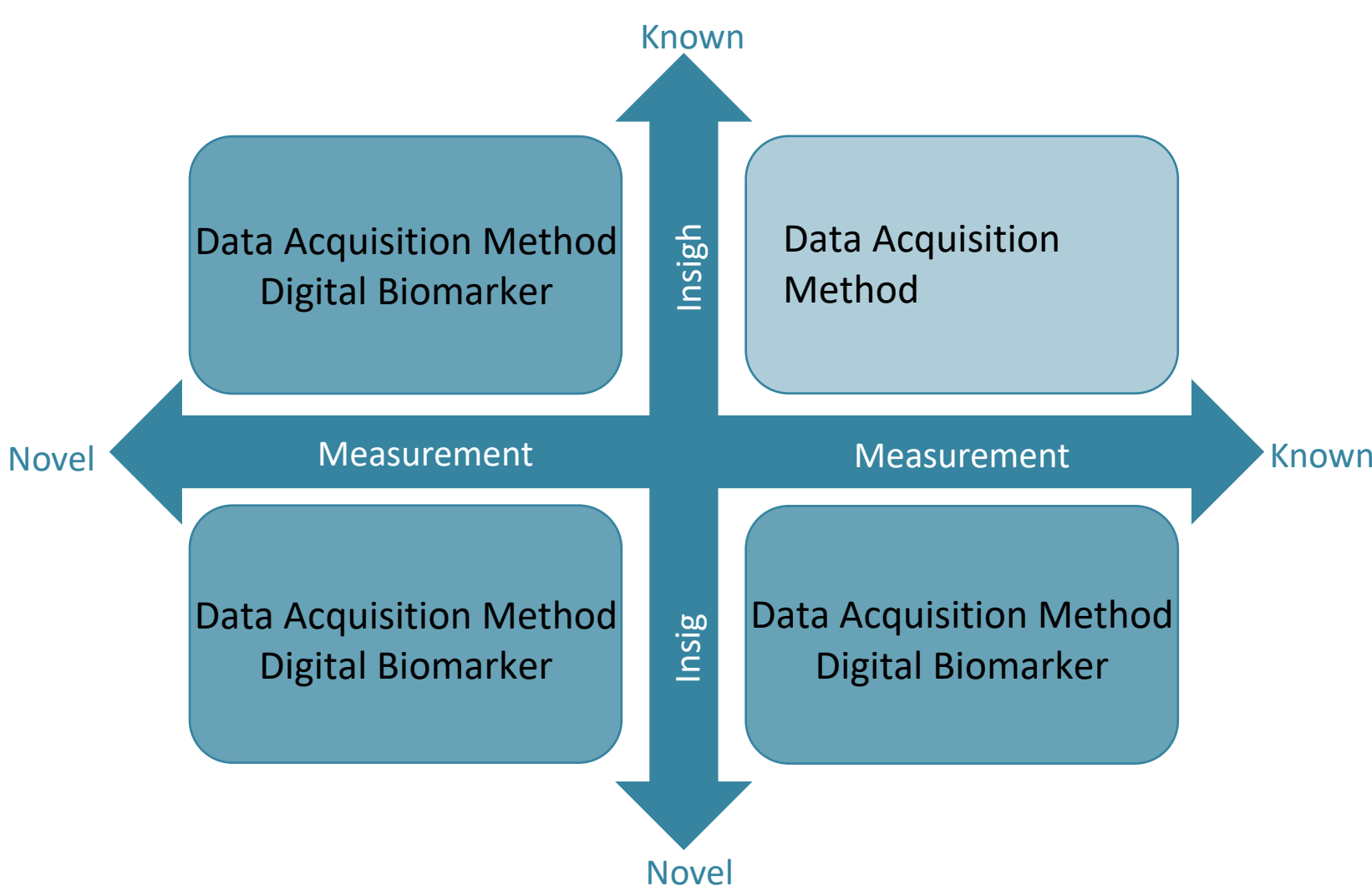
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Digital Biomarkers vs. eCOA

Recent FDA draft guidance for Digital Health Technologies (DHT) states that novel endpoint development using digital technology should follow same principles as traditional biomarkers. Endpoints must be well-defined and justified.²

Validation requirements depend on the combination of novel/known methods and assessment endpoints as described below.³



Novel Endpoints and Devices

Electronic clinical outcome assessments (eCOA) indicate how an individual feels, functions or survives. A digital measurement can be an eCOA or a digital biomarker depending on the usage. For example, gait speed can be used as an eCOA to directly measure how a patient functions in day to day life. When it is used to reflect pathogenic disease progress and has been shown to have a relationship with survival in older adults, gait speed is considered as a digital biomarker.⁴

Case Studies

- Deep dives into case studies using digital biomarkers for novel endpoints , platforms, software, and devices
- Platforms** for conducting, monitoring, analyzing data
- Hugo Health, RADAR-Base, Koneksa, Evidation Health
- Digital Therapeutics** studies using decentralized clinical trial model to evaluate Primary and secondary outcome measures
- Pear Therapeutics’ Somryst, reSET

Acknowledgements:

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