ActiGraph

White Paper

Maximize Your R&D Investment in DHTs Through the Collection and Retention of Raw Sensor Data

Maximize Your R&D Investment in DHTs Through the Collection and Retention of Raw Sensor Data

Advances in sensor technology and data science have revolutionized the ability to remotely obtain and analyze clinically relevant information from individuals. Remote sensor data collected from Digital Health Technologies (DHTs) has the potential to overcome the challenges of suboptimal clinical outcomes in clinical investigation and offer patient-centric, objective clinical outcomes. Sensor-based DHTs, however, involve complex processing steps (algorithms) that can be confusing to clinical trialists who are used to working with patient reported outcomes (PRO) and clinician reported outcomes (ClinRO) collected during intermittent study visits. Through the last 20 years of supporting clinical research, we have learned that one of the key factors when using sensor-based DHTs for clinical investigation is the collection and retention of raw sensor data. In this white paper, we clarify the myths about raw data and discuss why raw data is essential to maximize the clinical insights and the investment made into the clinical trials.

Remote sensor data collected from Digital Health Technologies (DHTs) has the potential to overcome the challenges of suboptimal clinical outcomes in clinical investigation and offer patient-centric, objective clinical outcomes.

In order to make this topic more digestible to non-engineers, we would like to draw an analogy to the use of PRO and/or ClinRO data in clinical investigation.

When using PROs and ClinROs in clinical trials, items in the questionnaires are collected and then summed according to scoring criteria to derive the summary score. The items are the source data and required by regulatory agencies so they

can be reviewed for discrepancies. Furthermore, they can be mined in the future for subcategories or individual items that are parts of the summary score to gain additional insight.

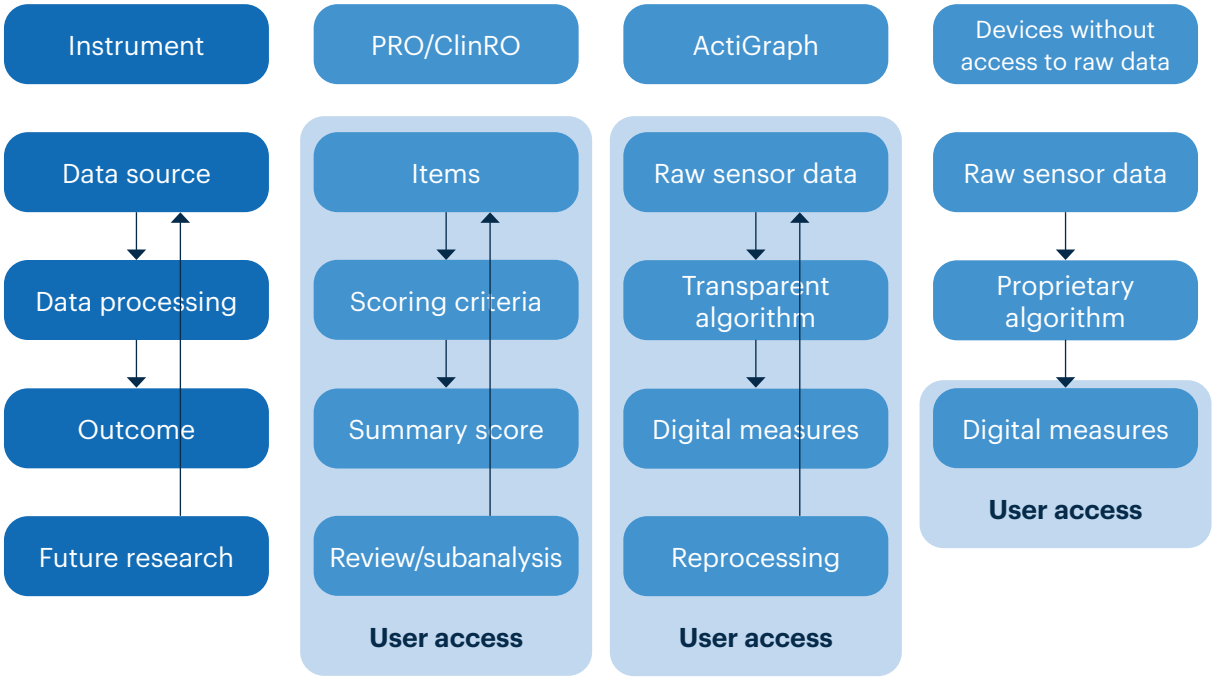
Just like a PRO or ClinRO, the raw sensor data is collected by the wearable device and then processed by algorithms to derive the digital measures of interest (e.g., walking speed or total sleep time). In this case, the raw sensor data is the source data and should be retained for the same reason as in PROs and ClinROs. The algorithms for deriving digital measures are substantially more complex than the scoring criteria, making it even more critical to retain the raw sensor data to optimize the use of DHTs in clinical investigations.

DHT is a fast evolving field. We are still learning best practices for using them in clinical development. The conversions from raw sensor data to digital measures (algorithms) are one of the key factors in determining if the DHT is validated and fit for use. It can be altered by firmware updates and hence impact the consistency of digital measures derived during the trial. Furthermore, algorithms have been improved by the advance of data science at a much faster pace than clinical development.

Imagine the following scenario: A sponsor collected DHT data during a 2-year Phase 2 study, and a new algorithm that is more accurate and/or fit-for-use than the original becomes available as they prepare to analyze the study data. This new algorithm may even be recommended by the regulator. The sponsor will only be able to take advantage of this improved algorithm if raw sensor data has been retained.

Another likely scenario: A sponsor uses wearables to examine step counts in a study on people with multiple sclerosis (MS). Two years later, research findings show that gait speed is a meaningful aspect of health for people living with MS. If the sponsor has raw sensor data retained from the earlier study, they could have applied

algorithms for gait speed to that raw data and generate valuable clinical evidence that might support these measures for their late-phase studies or other programs in MS. But if raw data was not collected or retained, this would not have been an option.



Therefore, we strongly advocate the collection and retention of raw sensor data for clinical investigation. This is the best practice to ensure data quality and traceability when using digital endpoints in regulated clinical trials.[1] Furthermore, in this rapidly-evolving field, the retention of raw data allows the sponsors to keep pace with the state-of-the-art digital science techniques, ensure compatibility across studies[2] and thus maximizing the scientific impact.

What is considered "raw data?"

Raw sensor data refers to data existing in an early stage of signal processing and considered a direct representation of the original analog signal produced by the sensor and sampled by the analog-to-digital converter (ADC).[3] Raw data corresponds to the values provided by the ADC with no or minimal processing necessary for calibration. In the case of an accelerometer, the raw data is a representation of gravity (G) values across three axes (i.e., X, Y and Z axis) sampled at a specific frequency (e.g., 30 Hz). In the case of a photoplethysmography (PPG), raw data is a representation of the optical measures directly captured from the photodetector sampled at a specific frequency (e.g., 50 Hz).

To learn more about how your clinical program can benefit from using DHTs, please contact us to schedule a meeting with a member of our Science team.

References

1. U.S Food and Drug Administration. Center for Drug Evaluation and Research. Digital Health Technologies for Remote Data Acquisition in Clinical Investigations. U.S. Food and Drug Administration. Published January 24, 2022. Accessed May 5, 2022. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations

2. On behalf of the Determinants of Diet and Physical Activity knowledge hub (DEDIPAC); International Children's Accelerometry Database (ICAD) Collaborators, IDEFICS Consortium and HELENA Consortium, Steene-Johannessen J, Hansen BH, et al. Variations in accelerometry measured physical activity and sedentary time across Europe – harmonized analyses of 47,497 children and adolescents. Int J Behav Nutr Phys Act. 2020;17(1):38. doi:10.1186/s12966-020-00930-x

3. Goldsack, Jennifer C., Andrea Coravos, Jessie P. Bakker, Brinnae Bent, Ariel V. Dowling, Cheryl Fitzer-Attas, Alan Godfrey, et al. "Verification, Analytical Validation, and Clinical Validation (V3): The Foundation of Determining Fit-for-Purpose for Biometric Monitoring Technologies (BioMeTs)." Npj Digital Medicine 3, no. 1 (April 14, 2020): 1–15. https://doi.org/10/gjjdgk

ActiGraph's mission is to bring life to digital data. Built on 20 years of remote data capture expertise, ActiGraph's medical-grade wearable technology platform has been used to capture real-world, continuous digital measures for over 200 industry-sponsored clinical trials. Appearing in more than 20,000 published scientific papers to date, ActiGraph is the most experienced and trusted technology partner in the industry.