Call for sponsors of benchmarking of measures of gait using sensors

The use of sensors and wearables for health monitoring outside of the clinic has opened new opportunities for data collection to improve disease management and assess efficacy of interventions. These opportunities include the use of digital measures as endpoints in clinical trials to assess drug efficacy, monitoring measures associated with functional ability and quality of life, and of toxicities and/or response to long-term exposures.

Although digital endpoints are of interest to regulatory agencies such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and are starting to be integrated as primary endpoints into clinical trials[1,2], adoption is slow. In part, this is due to difficulties in quantifying the accuracy of measures when they are collected under free-living conditions in the home and community setting. Indeed, the ability to develop robust measures that are reliably accurate requires both an expanded validation plan designed to pressure-test the digital measure across a range of conditions (e.g. diseases, devices, sensing modalities, body locations) and a good understanding of the impact that variations in daily life can have on data quality.

We propose a collaborative effort to benchmark measures of gait by establishing a collaborative DREAM benchmarking challenge. DREAM Challenges crowdsource solutions to important research problems in the biomedical and bioinformatics fields, and evaluate those solutions in an objective, unbiased fashion to identify the best one. To do so, a challenge presents solvers with training datasets on which to build their algorithms, and an independent benchmarking dataset for evaluation of these algorithms. These challenges provide a blueprint for establishing a broader catalogue of independently benchmarked algorithms for use as outcomes.

We are seeking 3-6 sponsors to join us as partners in developing this collaborative benchmarking effort for measures of Gait. In doing so, these sponsors will be recognized not only for making the gait challenge possible, but also laying the foundation for the catalogue of independently benchmarked algorithms for use as endpoints in industry sponsored clinical trials.

Why Gait?

Walking is the primary means by which most people accomplish activities during their daily lives. Disease, trauma, and aging can cause disruptions to normal walking leading to irregular, arrhythmic, slowed, or otherwise disrupted gait. As a result, assessment of gait has become a common diagnostic and prognostic tool for neurological conditions (e.g. stroke[3,4], cerebral palsy[5], Parkinson's Disease[6], Traumatic Brain Injury[7], Multiple Sclerosis[8], and partial paralysis[9]), a general assessment of aging[10,11], as well as a proxy for assessing cognition[12–14].

Gait assessment is not limited to the detection of disease and is often called the 'sixth vital sign'. Gait patterns can tell a social story about a person, their lifestyle, or their environmental conditions. For example, an oft-cited study has found that average gait speed is highly correlated with the size of the city where people live[15]. As such, gait is a broad indicator of health that has the potential to be of high scientific value, relatively low participant burden, and can be measured broadly.

Deliverables

The goal is to provide a diverse, evolving and accessible dataset that can be used for development and benchmarking of methods for deriving physiological measurements of gait using data from wearable devices. We expect to attract talented data scientists who will participate in this challenge and produce state-of-the-art algorithms that will work on data from multiple devices and patient populations. This dataset and collection of benchmarked algorithms will also serve as the first component of a broader community hub for the indexing and distribution of open source algorithms and supporting data sharing.

Budget and Timeline

The Open Wearables Initiative is calling for 3-6 sponsors at $50,000-$100,000 each to help fund this initiative. The sponsors will have the opportunity to influence key elements of the scope and focus of the initiative. In addition, they will be recognized for their contribution to the industry on the owear.org website and in public communications throughout this project. If interested, please contact Larsson Omberg larsson.omberg@sagebionetworks.org for more information.

The overall direct cost of challenge 1 of this project is $278,500. These funds cover the organization of the challenge, curation of data, cloud computing and engineering support.

	Cost
Challenge organization	$150,000
Outreach and Marketing	$20,000
Data curation	$25,000
Cloud compute	$50,000
Governance and Legal	$30,000
Travel Expenses for winners	$3,500
Total	**$278,500**

References

1. Omberg, L., Neto, E. C. & Mangravite, L. M. Data Science Approaches for Effective Use of Mobile Device–Based Collection of Real-World Data. *Clinical Pharmacology & Therapeutics* (2020) doi:10.1002/cpt.1781.
2. Goldsack, J. *et al.* Digital endpoints library can aid clinical trials for new medicines - STAT. *STAT* https://www.statnews.com/2019/11/06/digital-endpoints-library-clinical-trials-drug-development/ (2019).
3. Cunha, I. T. *et al.* Performance-based gait tests for acute stroke patients. *Am. J. Phys. Med. Rehabil.* **81**, 848–856 (2002).
4. Flansbjer, U.-B., Holmbäck, A. M., Downham, D., Patten, C. & Lexell, J. Reliability of gait performance tests in men and women with hemiparesis after stroke. *J. Rehabil. Med.* **37**, 75–82 (2005).
5. Gage, J. R. Gait analysis. An essential tool in the treatment of cerebral palsy. *Clin. Orthop. Relat. Res.* 126–134 (1993).
6. Sofuwa, O. *et al.* Quantitative gait analysis in Parkinson's disease: comparison with a healthy control group. *Arch. Phys. Med. Rehabil.* **86**, 1007–1013 (2005).
7. Basford, J. R. *et al.* An assessment of gait and balance deficits after traumatic brain injury. *Arch. Phys. Med. Rehabil.* **84**, 343–349 (2003).
8. Corporaal, S. H. A. *et al.* Balance control in multiple sclerosis: correlations of trunk sway during stance and gait tests with disease severity. *Gait Posture* **37**, 55–60 (2013).
9. Holden, M. K., Gill, K. M., Magliozzi, M. R., Nathan, J. & Piehl-Baker, L. Clinical Gait Assessment in the Neurologically ImpairedReliability and Meaningfulness. *Phys. Ther.* **64**, 35–40 (1984).
10. Maki, B. E. Gait Changes in Older Adults: Predictors of Falls or Indicators of Fear? *J. Am. Geriatr. Soc.* **45**, 313–320 (1997).
11. Ashton-Miller, J. Age-Associated Changes in the Biomechanics of Gait and Gait-Related Falls in Older Adults. in *Neurological Disease and Therapy* 63–100 (2005).
12. Rosso, A. L. *et al.* DUAL-TASK WALKING AS A PREDICTOR FOR LATER COGNITIVE IMPAIRMENT. *Alzheimers. Dement.* **13**, P1417–P1418 (2017).
13. Springer, S. *et al.* Dual-tasking effects on gait variability: The role of aging, falls, and executive function. *Mov. Disord.* **21**, 950–957 (2006).
14. Yogev, G. *et al.* Dual tasking, gait rhythmicity, and Parkinson's disease: which aspects of gait are attention demanding? *Eur. J. Neurosci.* **22**, 1248–1256 (2005).
15. Bornstein, M. H. & Bornstein, H. G. The pace of life. *Nature* **259**, 557–559 (1976).