Case study

CLARIO.

Opal wearable sensors (APDM, a Clario Company) in the Library of Digital Measurement Products

About Clario

Clario's Precision Motion solutions, including the Opal V2® wearable sensor system featured in DiMe's Library of Digital Measurement Products, are at the forefront of digital outcome development. The *Opal* V2® system is designed to capture crucial data on gait, balance, tremor, bradykinesia, and physical activity in Parkinson's disease (PD), showcasing the library's commitment to cutting-edge tools.

The opportunity

- Enable researchers and clinicians to collect meaningful mobility health outcomes, contributing to the impact of the Library of Digital Measurement Products
- Accelerate access to more precise and comprehensive insights into therapeutic efficacy
- Optimize clinical trial efficiency by reducing required sample sizes

The challenge

- Progress in PD trials is hindered by a lack of sensitive measures of disease progression, failing to capture subtle changes, and limiting the ability to assess therapeutic efficacy early on
- Conventional clinical rating scales lack precision to measure early changes in PD, which delays early intervention opportunities
- Early intervention in PD requires sensitive measures before clinically observable

The approach

- Precision Motion's movement scientists play a key role in guiding clients through the selection of the most appropriate instrumented assessments and digital health outcomes tailored to the unique needs of each study.
- The Opal wearable sensor system provides a robust software interface specifically designed for clinical trials. This system streams data to a laptop in real-time, ensuring precise and accurate testing while offering dependable reporting of outcomes.

- For PD clinical trials, science-backed recommendations include a comprehensive set of assessments designed to capture key aspects of mobility and motor function. These tests include the 2-minute walk test, 30-second balance test, and assessments for tremor and bradykinesia in both clinical and research settings.
- DiMe's Library of Digital Measurement Products offers complementary tools for evaluating gait quality and physical activity in real-world environments, ensuring that data collection extends beyond the clinic and reflects daily life activities.

The impact

- ✔ Opal wearable sensors capture digital motor signs of PD, offering high sensitivity to both disease severity and the effects of interventions, directly linking to patient-reported outcomes
- ✔ Opal sensors, from the 1-6 series, quantify both early and late-stage PD motor signatures, including critical symptoms like arm swing reduction, foot shuffling, and turning impairments
- ✔ With the application of machine learning algorithms to Opal outcomes, motor progression is detected with significantly higher accuracy, identifying changes 15 months into the disease
- ✔ By incorporating DiMe's Library of Digital Measurement Products, which includes the Opal system, along other cutting-edge tools, researchers and clinicians can access a suite of validated instruments designed to enhance the precision of PD clinical trials

> "Opal technology is quick, easy to use, and provides many objective nuanced and comprehensive measures of Parkinson's disease."
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> **— Dr. Fay Horak**
> *Chief Scientist, Clario*