

# Clario Precision Motion: scientific consulting services

Expert guidance on generating the richest clinical evidence by capturing precise and meaningful aspects of mobility in clinical trials

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Creating protocols that optimize the collection of digital mobility endpoints can be a challenge. Not only is this a time-consuming task, but it also requires specialized clinical and technical knowledge to achieve study goals and objectives. Clario's Precision Motion Scientific Consulting Services provide proactive guidance throughout the study lifecycle, ensuring you can generate the richest evidence at every step.

## Accelerate trial timelines with tailored advice

Clario's Precision Motion scientists offer a range of consulting services that help you accomplish more in less time. Working alongside our clients, our scientific advisors have the expertise needed to analyze data, interpret results, and even develop novel instrumented tests and endpoint measurements, across therapeutic areas and trial formats.

#### Precision Motion scientific consulting overview

Our scientific experts work as extended team members to sponsors in meeting study objectives by providing scientific expertise, evidence and experience.

Precision Motion solutions for clinical trials

Movement-specific protocol development, digital mobility endpoint selection and evaluation

Precision Motion instrumented test selection, configuration and implementation

Custom development of novel tests, analytics and endpoint measurement related to: human movement, neuroscience, movement disorders, gait and balance, physical therapy, rehabilitation and biomechanics

# Opal® V2C system for precision motion measurement — a purpose-built solution to assess meaningful aspects of mobility in clinical trials

Clario's Opal V2C system for motion measurement has been studied and deployed in clinical trials, including but not limited to:

- Parkinson's Disease (PD)
- Multiple Sclerosis (MS)
- Spinocerebellar Ataxia (SCA)
- Friedreich's Ataxia (FA)
- Essential Tremor (ET)
- Multiple System Atrophy (MSA)
- Huntington's Disease (HD)
- Progressive Supranuclear Palsy (PSP)
- Genetic and rare diseases
- Cardiovascular and metabolic diseases

## Clario's Precision Motion scientific consulting services

Whether your trial is a clinic-based, decentralized or hybrid format, Clario's experts can help you optimize your digital mobility endpoint strategy.

#### **Standard offerings:**

# Preparation of a Precision Motion protocol synopsis

The Precision Motion scientific consultant will build an Opal V2C-instrumented protocol synopsis from the ground up after consulting with the client on the goals and objectives of the study.

#### Protocol review and commentary

The Precision Motion scientific consultant with expertise in Opal wearables and human movement will:

- Review draft protocol provided by the client
- Provide guidance on Opal V2Cinstrumented test selection, order and frequency
- 3. Advise on digital mobility endpoint selection

# Custom Opal V2C — instrumented tests and/or instruction design

The Precision Motion scientific consultant will provide custom Opal V2C-instrumented test design and/or standard instrumented test instruction modification.

Note: Feasibility and timelines must be scoped for both items. Novel instrumented tests do not include algorithm development or modification and only raw inertial data will be provided.

# Literature review and summary report

The Precision Motion scientific consultant will provide scientific evidence from the literature to support the use of Opal V2C-instrumented tests and digital mobility endpoints for the specified study.

#### **Data interpretation**

The Precision Motion scientific consultant will assess and interpret the significance and implications of Opal V2C digital mobility endpoint results.

#### **Meeting attendance**

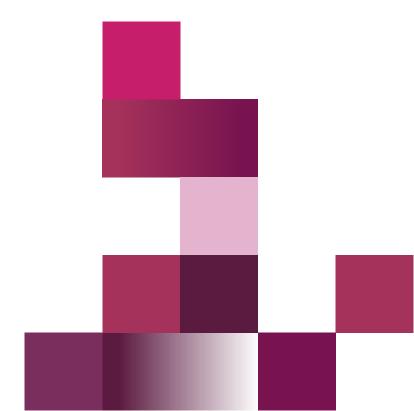
The Precision Motion scientific consultant will attend third-party meetings on behalf of the client.

#### Hourly KOL consulting

The Precision Motion scientific consultant will provide scientific advisory services pertaining to Opal V2C wearables and human movement charged at an hourly rate.

# Preparation of a precision motion statistical analysis plan

The Precision Motion scientific team member will prepare a statistical analysis plan based on the key study endpoints (study phase dependent), utilizing the commercially available Opal V2C system digital mobility endpoints.



# Precision Motion statistical analysis package

The Precision Motion scientific team member will develop a statistical analysis package based upon the key study endpoints (study phase dependent) utilizing the commercially available Opal V2C-instrumented tests and digital mobility endpoints. Key deliverables include:

- Execution of a statistical analysis plan throughout the study
- 2. Preparation of reports, graphs and tables to support the data analysis
- Interpretation of results to help determine the most useful movement performance mobility endpoints based upon the study objectives

#### Hourly data analysis

The Precision Motion data scientist team member will perform data analyses of Opal V2C System digital mobility endpoints on an hourly basis.

# Advanced scientific consulting with R&D support: custom algorithm and novel digital mobility endpoint development

The Precision Motion scientific consultant will assess and determine customer needs for custom Opal V2C-instrumented tests, requiring algorithm development to produce novel digital mobility endpoints.

The Precision Motion R&D scientific team member will perform an analysis of raw inertial Opal V2C data for the development and validation of novel algorithms and digital mobility endpoints.

# Our Precision Motion scientific consulting services team lead

Dr. Sowalsky leads the scientific consulting services for Precision Motion at Clario. With an advanced background in applied neuromechanics, kinesiology and exercise science, including six years as a provider in clinical practice, she consults with clinicians, researchers and product technologists providing scientific evidence and advice to sponsors on meeting clinical trial study objectives.

Dr. Sowalsky's academic achievements include a B.S. in kinesiology and exercise science from Appalachian State University, Doctor of Chiropractic from Logan University, and a Ph.D. in applied neuromechanics, from the University of Florida. Passionate about improving the lives of patients and their families, Dr. Sowalsky continues to build the body of evidence for Precision Motion monitoring measures to capture meaningful digital mobility outcomes to inform therapeutic innovation and development.



**Kristen Sowalsky, Ph.D., D.C.**Director, Clinical Science and Consulting

#### **Precision Motion scientific services team**



Fay Horak, Ph.D., P.T. Chief Scientist, Consulting



**James McNames, Ph.D.** Chief Scientist, R&D



Mahmoud El-Gohary, Ph.D. Senior Scientist, R&D



Christopher Gomez, M.D., Ph.D. Expert Consultant, Ataxia, Consulting



Martina Mancini, Ph.D. Expert Consultant, Parkinson's Disease, Consulting



**Vrutangkumar Shah, Ph.D.** Lead Biostatistician, Consulting



Adam Jagodinsky, Ph.D. Scientific Advisor, Consulting



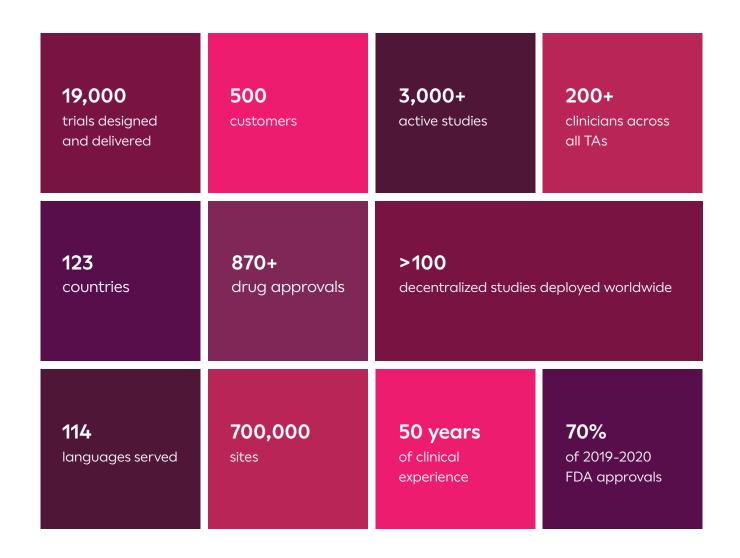
**Daniel Muzyka, M.S.**Biostatistician, Consulting

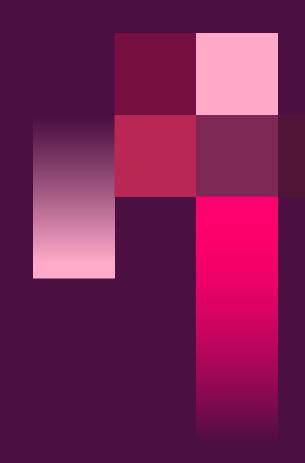


Rebecca Bonaker, M.S. Clinical Science Associate, Consulting

#### Why choose Clario?

Clario brings together the best of ERT and Bioclinica to offer the broadest endpoint technology platform. Our Precision Motion solutions and team members are unparalleled in the industry. For the past 10 years, more than 1,000 researchers worldwide have used Opal technology to evaluate human movement and patient functional mobility. Our Opal technology has been studied and cited in over 500 scientific publications. Our expert science team has generated a body of evidence with over 45,000 scientific citations.





#### About Clario

Clario generates the richest clinical evidence. Fusing our deep scientific expertise and global scale into the broadest endpoint technology platform, we empower our partners to transform lives.

