How is APDM Unique?

- Quality not quantity, we are not a Fitbit
- Strong scientific foundation and validation (over 25,000 citations)
- Over 500 clinical researchers worldwide using technology
- Experience in PH0, PHI, and PHII clinical trials
- Full stack engineering: hardware, software, algorithm
- Experts in neuroscience and movement disorders
- Strong patent portfolio
- Non-dilutable federal funding ($7MM 2017-2019, +$14MM since 2007)
- Real-time audit ready (DCAA and Federal Uniform Guidance)

Matthew Johnson, Biometric Monitoring Device Workshop, May 9, 2017
<table>
<thead>
<tr>
<th>Ortho</th>
<th>Research &amp; Development</th>
<th>Scientific Validation</th>
<th>Market Deployment</th>
<th>Mature Product</th>
<th>Gold Standard</th>
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<td>Orthopedic</td>
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<td>Biofeedback</td>
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<td>Fall Risk</td>
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</table>
Clinical Endpoints

- Stride Length
- Gait Speed
- Step Time Variability
- Foot Clearance
- Arm Swing Range of Motion
- Trunk Range of Motion
- Sit-to-Stand Lean Angle
- Turn Speed
- Steps per Turn
- Postural Sway
Mobility Lab Video

https://www.youtube.com/watch?v=JxmZpQ62mg4&t=23s
Two Paths for Our Solution

Wearable Technology for Movement Disorders

In-Clinic

At-Home

Research  •  •  •  Trials  •  •  •  Practice

Validated Populations

✓ Parkinson’s Disease
✓ Multiple Sclerosis
✓ Ataxia
✓ Huntington’s Disease
✓ Cerebral Palsy
✓ Fall Risk
✓ Oncology
✓ Traumatic Brain Injury
✓ Orthopedic
✓ Stroke

Matthew Johnson, Biometric Monitoring Device Workshop, May 9, 2017
In-Clinic Monitoring

**Current State-of-the-Art**
- 10+ years of validated endpoints
- Fits within clinical trial paradigm
- Battery life not an issue
- Form factor is good enough
- Training professional staff >> patients
- Data is big, but not BIG!

**Roadmap (1-3 years)**
- Technology in current state is deployable
- PHII & PHIII trials ongoing
- Primary Endpoints submittable to FDA

At-Home Monitoring

**Current State-of-the-Art**
- Limited validation completed
- New clinical trial paradigm
- Battery life is not a full day
- Patients are aware they are wearing device
- Patients will wear it incorrectly
- >1Gb of data/patient/day

**Roadmap (5-7 years)**
- More scientific validation (and funding!)
- Hardware and form factor updates
- PHO clinical trials are necessary
- Industry + Regulators + Patient Advocacy
- Data transfer standards must be created

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Clinical Trial Use Cases

In-Clinic Monitoring

Research & PH0 Clinical Trials
- Huntington’s, Parkinson’s, & Multiple Scler.
- NIH, Pfizer, and Vertex
- Average Trial: 5 Sites, 50 subjects, domestic
- Objective: Select primary outcomes

PHI & PHII Clinical Trials
- Parkinson’s Disease and Ataxia
- Biogen, Axovant, and Takeda
- 50+ Sites, international
- Primary outcomes submitted to FDA

At-Home Monitoring

Research Trials
- NIH funded projects
- 3 years of data collection
- Form factor redesign, fabric
- 150 subjects analyzed +1 week

PHI-III & Post Market Potential
- Decrease duration & number of patients
- Quicker Yes or No answer in earlier Phases
- More sensitive and relevant outcomes
- Efficacy tracking in post-market
- Fuel for “precision medicine”
- 7-10 year time horizon

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• Not all wearables are the same, make sure scientific and clinical validation has occurred
  • Typically takes 3-7 years for rigorous internal/external validation
  • Just because it’s made by Apple or Intel doesn’t mean that it’s appropriate for a clinical trial

• Don’t forget about using technology in the clinic
  • We tend to immediately jump to at-home monitoring
  • Changing an entire industry’s operating procedures is a huge undertaking
  • Objective outcomes from technology in the clinic >> current state-of-the-art

• Wearables do more than count steps
  • Postural transitions are more sensitive to early disease progression than gait
  • Variability of gait speed and stride length sensitive to PD, MS, and fall risk patients

• Sensor placement is extremely important
  • A sensor on the wrist cannot measure gait accurately in affected populations
  • Multi-sensors arrays are the future

• Medical device industry moves slow
  • Asymmetric product development cycles compared with Silicon Valley
  • By the time wearables are fully accepted in clinical trials, we will have new technology
  • It’s okay that the medical industry moves slow, it should.

Matthew Johnson, Biometric Monitoring Device Workshop, May 9, 2017
• Simoes. “Feasibility of Wearable Sensors to Determine Gait Parameters.” University of South Florida. 2011
• Balasubramanian. “Age Related Changes in Balance and Gait.” Arizona State University. 2014
• Curtze, et al. “Lеводopa is a Double Edged Sword for Balance and Gait in People with Parkinson’s Disease.” Movement Disorders. 2015
• Mancini, et al. “Continuous Monitoring of Turning in Parkinson’s Disease: Rehabilitation Potential.” NeuroRehabilitation. 2015

https://www.dropbox.com/sh/zqyjl7q4evd1xcp/AABBt9OoWTfmlrwc6dCcVOZa?dl=0

Matthew Johnson, Biometric Monitoring Device Workshop, May 9, 2017
“APDM is the only company that showed us what THEY HAVE DONE, as opposed to what they could do.”

-Biogen executive

Matthew Johnson, matt@apdm.com
<table>
<thead>
<tr>
<th>CONSIDERATION</th>
<th>ATTRIBUTE</th>
<th>GAP</th>
<th>COMMENTS</th>
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</thead>
<tbody>
<tr>
<td>510K Compliant</td>
<td>No</td>
<td>Quality System</td>
<td>Early 2018</td>
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<tr>
<td>FDA Cleared for Specific Use Case</td>
<td>No</td>
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<td>Submitting Primary Outcome measures for Parkinson’s Disease</td>
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<td>Time Stamp of Data Acquisition</td>
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<td>US Patent 8,647,287: Wireless synchronized movement monitoring apparatus and system</td>
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<td>Analytical Validation</td>
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<td>Clinical Validation</td>
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<td>Secure Data Transfer</td>
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<td>GCP Compliant for Audit Trail</td>
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<td>Pursuing Use Case in Other Patient Populations</td>
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<td>Parkinson’s, Multiple Sclerosis, Ataxia, Huntington’s Disease, mTBI, Cerebral Palsy, Fall Risk, Total Knee and Hip Replacement</td>
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