



ActiGraph provides an end-to-end solution to utilize wearable devices into clinical trials. This include study design, operations, logistics, and data analysis to provide evidence of clinical benefits during these trials.

*“Tools like **The Playbook** are being adopted by companies of all sizes. It provides a framework allowing you to understand how regulators, sponsors, and vendors can collaborate on the use of novel methods in clinical trials.”*

— **Matt Biggs**, VP of Applied Science, ActiGraph

The Problem

We were assisting in a phase 2 RCT for a rare disease. This led to multiple meetings between the sponsor and regulatory agencies.

We needed help in trying to understand the reasoning behind questions received by regulatory agencies and address the key points which would allow them to understand new endpoints and increase their trust in these new digital endpoints.

The Impact

- ✓ Project success
- ✓ Clear comms w/ ext partners
- ✓ Team education & cohesion
- ✓ Refined/improved strategy

The Resource

Using tools like the Pre-Mortem from *The Playbook* allowed us to better understand the questions being asked by the regulatory agencies to address the different perceived risks.

The [Pre-Mortem Use Case](#) allows for an objective and methodical approach to evaluating risks. This allowed us to provide the clear, core information around data quality, operations, safety, etc. to allow the agencies to accept and understand these endpoints.

EVALUATING RISKS

Risks of trial failure due to the inclusion of a digital endpoint fall into four categories:

- Tech, vendor, and/or partner selection
- Study design
- Data quality and data management
- Operations and maintenance

These are supported and fueled by likelihood of occurrence and severity of impact on trial.

TOP RISKS ACROSS THE FOUR CATEGORIES

YOUR QUICK REFERENCE GUIDE TO INFORM A RISK-BASED APPROACH TO TWEAKING THE SUCCESSFUL INCLUSION OF DIGITAL ENDPOINTS

Risk Category	Impact	Severity	Mitigation Strategy
Missing/Incomplete Endpoint
Missing Data
Data Integration
Data Transfer/Integration
Missing/Incomplete Data
Missing/Incomplete Data

WANT TO GO DEEPER?

You can view the individual working articles by clicking the full discussions from the pre-mortem process:

- See Tech Deep Dive: [Tech Deep Dive](#)
- See Operations Deep Dive: [Operations Deep Dive](#)
- See Data Quality Management Deep Dive: [Data Quality Management Deep Dive](#)
- See Vendor Partner Selection Deep Dive: [Vendor Partner Selection Deep Dive](#)

The Playbook
Driving Adoption
a DIME, Tour of Duty