**The Problem**

As a startup in the DCT space, we are accelerating innovation using more connected digital infrastructure which can capture RWD for participants in clinical trials who need to be continuous ambient monitoring. For this we needed to build processes that would help us:

- Benchmark; the current standard of care lacks sensitive or objective measures, and benchmarking a score across multiple independent data sets builds confidence that what we are measuring is a clinically meaningful benefit to patients and/or caregivers.

- Better understand how digital biomarkers can help set criteria for inclusion/exclusion, treatment allocation and evaluate treatment response, in particular because our platform will complement current standard of clinical trial processes.

- Consider ethical and privacy concerns after reading the *The Playbook*, which allowed us to revise our vision and make it patient-first in this data-first digital era.

**The Resource**

We used the following pages from *The Playbook* to address these challenges directly:

- Page 216: Benchmarking can identify the best measure when there are multiple approaches to measuring the same concept.

- Page 259: Should I use an eCOA or a digital biomarker as my endpoint?

- Page 188: Fundamentals for clinicians / Redefining patient safety / Ethics: Ethical considerations in technology selection

**The Impact**

- Project success
- Greater patient centricity
- Operational efficiencies and/or faster decision making
- Team education and cohesion
- Refined/improved strategy
- Area knowledge/subject matter