



UCB is a global biopharmaceutical company focused on creating value for people living with severe diseases in immunology and neurology now and into the future.



The V3 framework was invaluable in helping UCB and our partners navigate the complexity of building a robust corpus of clinical evidence underpinning the core features and functionality planned for our upcoming smartphone based application.

— **Emily Lewis,**
Global Digital Transformations
Lead, UCB



The Problem

- » We are developing a multi-sided platform for rare disease patients and their HCPs, initially focusing on myasthenia gravis (MG).
- » Recent clinical studies have examined the ability for us to detect ptosis and dysarthria from selfie photos and voice recordings respectively.
- » The first study involved labelling samples and building algorithmic models which have helped us to endophenotype and classify patients who present similarly to see if we can find ways to better treat them.



The Resources

- » We used DiMe's V3 Framework to identify which parts of the clinical evidence strategy we can streamline and shorten:
 - » What features and functionality are "need to have" versus a "nice to have"? What features would push the product to function as Software as a Medical Device (SaMD)?
 - » How we can optimize the order of events to find the most advantageous path to most expeditiously launch the MVP?
- » While an initial study showed model proof of concept, a much larger study is planned to combine both analytical and clinical validation of the models for regulators.



The Impact

- ✓ We had the ability to frame the discussion related to developing and implementing digital clinical measures.
- ✓ We were able to name and, therefore, more precisely discuss the components in the evaluation process.
- ✓ We could prioritize the order in which the steps required to evaluate and implement digital clinical measurements on the platform should occur.