Genentech

A Member of the Roche Group

Genentech is a very large biotech company with digital focus areas in Oncology, Neuroscience, Inflammation, and Respiratory diseases.

> *The Playbook has helped provide a usable and acceptable framework for discussing the use of digital health technologies with regulators as a primary endpoint.*

— **Thomas Switzer,** Principal Digital Health Scientist, Early Clinical Development Informatics, Genentech

The Problem

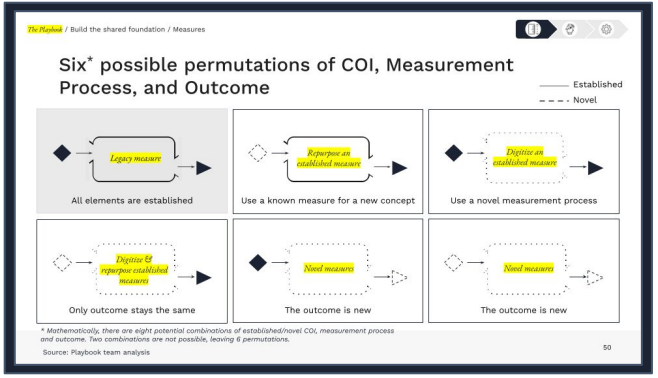
We're exploring early evidence generation in support of digital endpoint or biomarker development. I also consult with other functions and groups within the broader Roche/Genentech organization on the use of digital technologies in clinical development and beyond.

We're trying to solicit some early feedback from regulators regarding using a primary endpoint derived from a digital tool.

The Resource

Diagram on Slide 50. It was used as part of our briefing package for recent interactions with European regulators. We also used other parts of *The Playbook* referencing V3 as part of proposed validation pathway way to elicit early feedback from regulators on endpoint acceptability for later in the molecule pathway.

I've shared *The Playbook* to countless individuals as a core reference when teams are investigating whether to use technologies.



The Impact

✓ Project success ✓ Greater patient centricity ✓ Clear communication internally (team + execs) ✓ Clear communication externally (partners) ✓ Operational efficiencies and/or faster decision making ✓ Team education & cohesion ✓ Refined/improved strategy ✓ More buy-in