Using evidence from digital endpoints to demonstrate the value of a new drug: Considerations and recommendations

Recommendations for Pharma

Throughout drug development process

1. Engage with payers alongside regulators as soon as the decision to include a digital endpoint is made.
2. Prep to bridge knowledge gaps & requirements to demonstrate acceptability & value of digital endpoints to all stakeholders.
3. Build your IEP before starting your clinical trials.

During digital endpoint selection/development

2. Investigate relationship between digital measures & endpoints with long term outcomes & events.
3. Include study design elements that allow for estimation of MCID.
4. Engage early with national healthcare standards bodies, payers, & regulators.
5. Develop evidence of acceptability & usefulness.
6. Select endpoint(s) that are scalable & fit-for-purpose.

During digital endpoint deployment

1. Prioritize collection of confirmatory evidence that shows scalability of new evidence & the relationship to accepted endpoints in clinical development.
2. Include outcomes that matter to payers in trials (e.g. medical cost usage, hospitalization).
3. Collect more RWE, in parallel with digital endpoints, earlier in clinical development.

Full resource available here.