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

1 Validate & evaluate digital endpoints

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