1. Describe the target population and conceptualize treatment benefit and potential context of use (COU)

2. Identify aspects of health affected by the disease that are meaningful to patients and clinically relevant

3. Identify the concepts of interest (COI)

4a. Select the measurement(s) that is the best reflection of the concept of interest

4b. Assess potential digital health technology for data capture

5. Describe the context for which the measurement and technology will be used (determine COU)

6. Select candidate digital health technology for data capture and assess existing evidence supporting its use

Validate the Measurement (In the context of use)
- Define meaningful change that can be interpreted as treatment benefit
- Demonstrate that the measurement is effective in detecting meaningful change
- Evaluate the extent to which the measurement reflects the intended concept of interest
- Determine measurement approaches and endpoint definition (sampling frequency and duration, scoring algorithm, thresholds)

Validate the Technology* (Overall system-hardware & software)
- USABILITY ASSESSMENT
  - Establish tolerability and acceptability of the technology by participants
- VALIDATION
  - Demonstrate that the system produces measures that are accurate, reliable, reproducible, and validated against a reference standard in a representative population
- VERIFICATION
  - Verify the system outputs are acceptable at the bench in terms of its measurement errors, and other relevant performance characteristics

*Leveraging prior evidence where appropriate
**Validating the measure and validating the technology may be performed in an integrated manner

Once all steps are complete (confirm with regulators)

ENDPOINT IS READY FOR USE

Stakeholders should engage with regulators early and often throughout the process of developing novel endpoints

See Detailed Steps Chart for more information