CLINICAL TRIALS

INSTRUMENT DEVELOPMENT & VALIDATION

Qualitative and quantitative instrument development and validation to support global labeling claims for PRO/ ePRO and ObsRO/ eObsRO; ClinRO/ eClinRO and PerfO/ ePerfO; and Diary/eDiary.

WHY SPRIM PRO

PATH TO LABELING CLAIMS FOR COA AND eCOA

Concept elicitation, cognitive debriefing, usability, conceptual equivalence (migration), equivalence and psychometric validation testing and analysis with submission ready reports

PATH TO LABELING CLAIMS FOR MEDICAL DEVICES AND DIGITAL THERAPEUTICS

Human factors usability testing, device validation and digital product training for patients and healthcare providers with submission ready reports; and complete CRO services for clinical validation

REGULATORY SUPPORT

Regulatory experts deliver strategic submissions and meeting support for COA/ eCOA and device approvals

INSTRUMENT DEVELOPMENT & VALIDATION

SPECIALIZED SERVICES

NEXT GENERATION ePRO AND eObsRO

Develop and validate instruments that patients and caregivers can use from their smartphones to provide images, audio and video to central expert raters for scoring

FIT-FOR-PURPOSE WEARABLES AND BIOSENSORS

Identify clinical-trial grade wearables and biosensors to ensure high quality data and intuitive user experience

PRODUCT TESTING

Conduct product testing to acquire insights from consumers through surveys, focus groups and 1-on-1 interviews

