



Training for Patient-Reported Outcomes

Consistent Training: Dependable Effectiveness

Effective training from United BioSource Corporation (UBC), applied consistently to raters across a wide range of rating instruments, has been shown to increase scoring standardization and precision with clinician-rated scales. This translates into successful study design and effective study implementation. UBC's consistent training approach is equally as effective when dealing with Patient-Reported Outcome (PRO) instruments.

Standardized Training: Quality Evidence

PRO instruments can be used as effective endpoints in clinical research. The amount and type of evidence required by the FDA to support labeling claims measured by PRO instruments is not different than any other endpoint, so inter-patient variability, like inter-rater variability, must be minimized.

According to the *Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims*, the FDA indicates that increased training for both clinicians and patients will be critical to ensure the effective use and application of PRO assessments. The FDA suggests that study quality can be optimized through standardized instruction for investigators, standardized training and instruction for patients and standardized interviewer training and training format.

Multimedia Training: Comprehensive Materials

A sample training program designed by UBC to satisfy the draft Guidance might include: Disease specific didactic training for investigators and site personnel regarding the influence of the targeted disease on patient comprehension and PRO reporting; protocol-specific didactic training for clinicians regarding the instruments; and comprehensive patient education materials delivered not only at study initiation, but available throughout the duration of a subject's participation.

Patient Starter Toolkits – Consisting of multimedia patient education materials highlighting the disease, PRO completion guidelines, background information on reporting symptoms and communications reminding patients of the protocol schedule.

Trainer Toolkits – Designed to standardize patient education across all sites participating in a trial. The toolkits include all materials from the Patient Starter Toolkit as well as training materials on conducting effective patient education, patient assessment quizzes to confirm understanding and patient reminders to distribute.

UBC accelerates the generation, analysis and communication of real-world evidence.

Our training and education content includes:

For Investigators:

- Differential diagnosis
- Procedure administration
- Scoring ability
- Interview skills
- Disease/symptom education
- Device instruction
- GCP training
- Safety guidance
- Protocol preparation

For Patients:

- Informed consent
- Clinical trial conduct
- Disease education
- PRO self-administration
- Diary completion
- Device instruction
- Visit reminders
- Procedure training

Our training and education services include:

For Investigators:

- Online, self-paced training
- Web-based, live meetings
- Live demonstrations
- Interactive workshops
- Validated assessments
- Certification programs
- Guidelines and manuals
- Multimedia training materials
- Multi-lingual program delivery

For Patients:

- Patient retention programs
- Patient compliance programs
- Multimedia training materials
- Translated materials
- Data collection device instruction

For more information about UBC's specialty clinical solutions, call us in the U.S. at +1 610 225 5900 or in the E.U. at +420 221 001 740. Or email us at training@unitedbiosource.com.