



Scale Management Services

United BioSource Corporation (UBC) takes the guesswork out of scale identification and acquisition, translation and distribution for sponsors. Improper scale selection, licensing and translation can have costly effects and scheduling consequences for trial planning. UBC has significant experience in training and assessing raters in the use of clinician-rated scales and other instruments used during clinical trials. In addition to training and education, UBC provides a range of services designed to support use of both clinician-rated and patient-reported scales in clinical research.

Identification & Acquisition: Appropriate Scale Selection & Attainment Services

Many sponsors are confused, frustrated and overwhelmed by the process of identifying and acquiring the appropriate instruments and scale documents required for a trial. UBC is able to assist in the various stages of the process. Initially, scale appropriateness, including version specification, will be analyzed. After scale selection is completed, UBC will determine scale authorship and copyright ownership. The owner(s) of the scale will be contacted and a review of the steps required for use will be conducted. UBC will also ensure all scale use authorizations are meticulously documented with the scale owner and manage all required contracts with copyright holders/publishing houses. Finally, all scale licensing will be performed on behalf of the sponsor by UBC.

Dynamic Translation: Linguistical Validation in Any Language

Without accurate scale translations, clinical trial outcomes can potentially have a significant variance, and ultimately, result in additional costs or setbacks for sponsors. Prior to initiating scale translations, UBC will conduct a search to identify if translated versions of a scale already exist and who is responsible for their distribution. If commercially available translations do not exist, a sponsor may engage UBC to provide scale translations. UBC can translate scales and instruments into any language following the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Principles of Good Practice for translation and validation. Each scale will be tested for language translation, cultural interpretation, as well as forward and backward corroboration by our dependable network of native speaking clinicians. Furthermore, comprehensive translation services may include psychometric and cultural validation.

Distribution: Timely Scale Delivery for Trial Use

Sponsors need not worry about securing and ensuring availability of adequate resources for scale use at all sites. UBC can distribute all relevant source documents (scales, interview manuals, score sheets, etc.) to the sponsor, sites or other designated locations. UBC will determine the number of copies required by site or rater based on study design and estimated rater turnover. UBC will distribute by paper or electronic form according to the sponsors preferences. For electronic distribution, UBC will post source documents on UBC's portal organized by visit, rater or subject therefore allowing for easy access anywhere at any time.

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 includes:

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.