

## QC2 Clinical Outcomes Assessment (COA) Consulting Services

Patient Reported Outcomes (PROs), Clinician Reported Outcomes (ClinROs), and Observer Reported Outcomes (ObsROs)



### Questionnaire/Instrument Administration

- Guidelines for Planning Administration
- Feedback on Existing Methodology/Administration Processes



### Questionnaire/Instrument Content

- Item Review & Revision
- Item Development- In-Study and Post-Marketing
- Potential Impact of Items on Outcomes
- Recommendations for PRO Reporting/Write-up



### Data Analysis

- Secondary Data Analyses to Support Quality Assurance (tailored for specific client needs)

### Questionnaire/Instrument Administration

A well-conceived process for obtaining patient-, clinician-, and/or observer-reported outcomes is the foundation for ensuring the integrity of data collected. QC2 can assist with reviewing guidelines, manuals, protocols, Standard Operating Procedures (SOPs), process maps, and other documents and procedures related to administering clinical outcomes assessments. During the planning phase, we can provide guidance on identifying the possible factors influencing questionnaire/instrument administration and how these may in turn affect the quality of data collected from patients. We can also help identify potential issues that may arise during the questionnaire/instrument administration process and provide recommendations and solutions in advance.

### Questionnaire/Instrument Content

QC2 provides services related to reviewing the content of questionnaires/instruments to help ensure that they fully reflect what the study intends to measure. These services can be especially important when validated questionnaires/instruments have been modified due to the omission or addition of items for specific studies. Our services include (but are not limited to) a review of instrument instructions, format, subject identification fields, content, and item wording and ordering. We can also provide guidance and recommendations on the interpretation of results and reporting as they relate to the questionnaire/instrument content.

### Data Analysis

Data analysis services can be tailored to your specific needs. While our services do not include primary analyses of study data for efficacy assessments, we offer data analysis services to support quality assurance practices. This can include secondary analysis of data for clients' specific areas of concern regarding study methodology or site characteristics. We will work closely with you to determine how to best approach and address your needs.