



## How to improve your Clinical Outcome Assessment (COA) data quality

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# We offer something different in COA development and evaluation

## OUR APPROACH

**While we follow regulatory guidance for clinical outcome assessment (COA) instrument development (FDA 2009), at Health Outcomes Insights we build on this by bringing the latest research and thinking in both offline and online COA design and evaluation that will enhance the quality of data collected with your COA.**

Achieving satisfactory psychometric properties of a COA is an essential element in its development, however, it should not be the sole arbiter of the quality of the data collected.

Satisfactory psychometric properties of a COA can mask a multitude of COA poor design issues that can lead to poor-quality data, high question breakoff and lowered response rates.

**In combination with QuestReview™ our award winning evidenced-based COA evaluation platform and our multimethod analytical approach, we evaluate your COA and advise you on how to improve the design of the instrument so you can achieve maximum value from your research. We advise you on a range of key issues including:**

- Correspondence between your COA content and concept of interest
- Overall design of your COA design e.g. question/item wording
- Differences in mobile, desktop and paper respondent behaviour and how this will impact on response rates to your COA
- Appropriateness of question/item and response formats for the specific mode of administration of your COA
- Question/item layout and its affect on respondents' answers

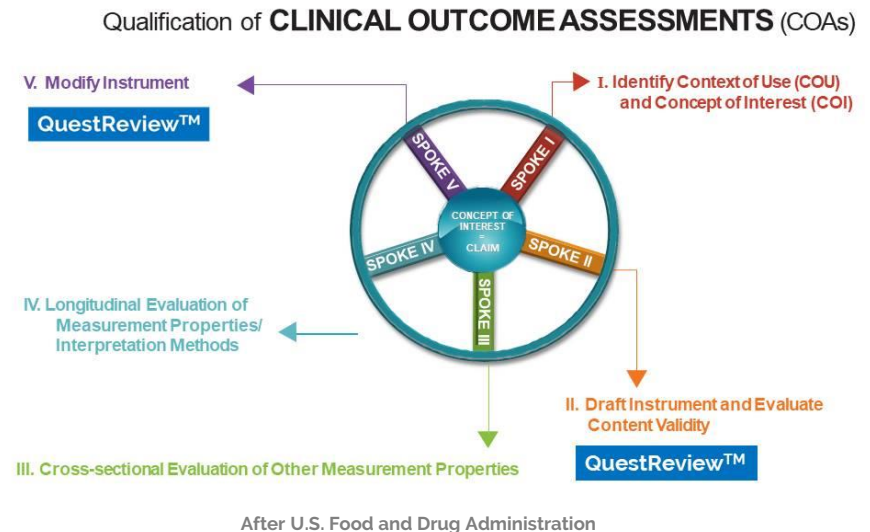
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## OUR APPROACH TO COA EVALUATION

With QuestReview™ our COA evaluation platform and within the framework of *concept of interest* and *context of use*, we identify at key stages in the COA development and evaluation process, design weaknesses including, item wording, respondent comprehension, response options and layout etc.

At Health Outcomes Insights we are aware that different evaluation methodologies identify different problems, so where necessary we combine QuestReview™ with a range of methodologies to ensure your COA is comprehensively evaluated. These include:

- Cognitive interviews (Think aloud/retrospective recall)
- Behaviour coding
- Focus groups
- Respondent debriefing
- Expert groups



# How QuestReview™ can help you

## Questionnaire Pretesting/Piloting

Form and content problems  
identified and rectified prior to pretesting  
Reduced testing time and costs.

## Pre-translatability assessment

Leads to Increased equivalence  
between source questionnaire and  
subsequent translations.

## Pre-Cognitive Interviews (CI)

Reduced CI rounds due to form and  
content problems identified and  
rectified prior to CI.

## Value dossier development

Ensures your COA aligns with industry  
and best practice guidelines.

# A case study: Evaluation of a chronic condition symptom scale prior to translatability assessment

## THE CHALLENGE

To undertake an evaluation of the content of a chronic condition symptom frequency scale prior to pre-translatability assessment and inclusion in a clinical trial.

## THE SOLUTION

The scale was evaluated using QuestReview™ which is an evidenced-based expert review diagnostic tool which benchmarks a questionnaire against 32 design parameters of questionnaire design good practice. The 32 parameters include, word length, ambiguity, wording and bias etc. Each parameter is rated using a traffic light system: No defects identified, Revision suggested, Major defects identified.

Fifty percent of questions were identified requiring revision including instructions on how to complete the questionnaire..

A total of 10 major design weaknesses and 13 suggested revisions were identified across 5 questions.

Questionnaire overall performance included, completion time, mean number of words per question, reading ease, reading grade.

## OUTCOME

Based on our feedback the client decided to remove the questionnaire from the trial as the quality of data was of concern and in relation to the cost of retaining the questionnaire in the trial.



Health Outcomes Insights helps healthcare agencies, life science researchers, academia and the pharmaceutical industry across a range of diseases and conditions, get targeted answers to patient behaviour and experiences whenever health outcomes are part of the programme.

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