

4 Case study examples

Learn how we have
helped our clients
achieve success

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A close-up photograph of several overlapping, colorful lenses or filters in shades of blue, green, and yellow, creating a bokeh effect. The word "Introduction" is overlaid in white text on the upper part of the image.

Introduction

When commissioning research or seeking a new research provider, we understand that you require reassurance that we have relevant experience and proven results. Out of respect for client confidentiality, we are rarely able to provide 'full' case studies, but we really do want to give you a feel for the work we do and the difference we make to our clients.

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 defects 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, it was excluded.

Selecting the right patient reported outcome (PRO) measure

THE CHALLENGE

A key hurdle facing outcome teams as with the entire pharmaceutical industry is non-adherence by patients to medication. This problem is only likely to be surmounted if patients believe that taking medication will lead to immediate benefits through reduction of symptoms, improvement in physiological functioning and quality of life.

Outcome teams are faced with a plethora of PROs, each purporting to measure – often without a sound theoretical or measurement model – a range of health outcomes.

As a consequence, outcome teams often make their choice of a PRO according to whether it has been used in previous studies or its name appears to be appropriate for the intended use. We were approached by an international pharmaceutical company to develop

a workshop for their Outcomes Team to demonstrate that data derived from patient reported outcome (PROs) measures can provide added value in supporting key biomedical endpoints.

THE SOLUTION

A one-day workshop was convened for the Outcome Team, the primary aim of which was to provide them with a practical measurement strategy which would assist in the selection of appropriate PROs for their Phase III & late phase DM studies. The workshop addressed three specific questions posed which were:

1. What is achievable using a PRO?
2. How can we distinguish between the different measured endpoints?
3. How can we understand a PRO score in relation to clinical endpoints?

Selecting the right patient reported outcome (PRO) measure

The workshop was initiated with a comprehensive and interactive overview of the benefits to the outcome team through the patient's perspective using PROs. This was followed by an in-depth exploration of key stages in the development of the strategy.

- Making explicit the expected treatment effects e.g. primary biomedical endpoint(s)
- Linking these – through the articulation of an endpoint model – to outcome domains relevant to the patient and disease from which the most appropriate PRO can be selected
- Differentiation between the different secondary endpoints

The PRO's conceptual framework – the linkage between the PRO's item content and its specific measurement

domains – was emphasised to the team, as was its relationship with the expected primary treatment outcome(s) and study objectives.

OUTCOME

The Outcome Team was able to differentiate more clearly between the endpoints purported to be measured by PROs such as QoL health status, HRQoL, etc. and select the most appropriate for a given purpose. The team also gained a clearer understanding of the importance of developing an explicit endpoint model to ensure a strong link between the PRO's item content, what it should measure and the objectives of the study for identifying potential treatment benefits.

Development of a patient and carer outcome measure for outpatient services

THE CHALLENGE

We were approached by a leading London university hospital to take on the role of project leader and mentor of a project to develop a patient reported outcome (PRO) measure to evaluate the impact of patient care and support on their outcomes.

THE SOLUTION

We initially undertook discussions with the research team to clearly identify the purpose of the PRO and establish how information from its implementation was to be used. This was followed by conducting a carousel group with all staff members to be involved in administering the questionnaire to patients as the first stage in identifying key themes to be covered by the scale. Focus groups were also held with a range of patients and carers to identify areas of

importance to them. Correspondence between staff themes, patients and carers areas of importance was assessed and was found to be very high.

Draft patient and carer questionnaires underwent evaluation through a series of cognitive interviews until a final version of the scales were produced. Questionnaires were fielded in samples of nearly 200 patients and carers to evaluate their psychometric properties. These were found to be satisfactory meeting all but one of the psychometric criteria set.

OUTCOME

A final patient and carer version of the scale each comprising 15-items were developed and are now part of the routine evaluation of patient and carer outcomes in diabetes and cancer outpatient services.



Listening to cancer staff stories

THE CHALLENGE

In an open competition we were selected by a leading cancer charity to undertake a qualitative study to obtain a better understanding of the relationship in a ward setting between patient experience, including involvement in treatment decisions and communication with the clinical team and staff experience as a result of organisational culture and management.

THE SOLUTION

We approached the study first with a series of in-depth interviews with patients having received or currently under treatment across two hospitals in two widely dispersed geographical areas first, to obtain the patients perspective on issues of their

care and secondly, to develop the patient stories as vignettes for use in staff interviews. Face-to-face interviews were conducted with over 30 staff members ranging from administrative through to consultants. Vignettes were used to generate more insights from staff by asking them if or not they identified aspects of these patient stories.

OUTCOME

A number of key themes relating to staff experience and their impact on the delivery of patient care were identified and submitted to the charity as recommendations.

Health Outcomes **Insights**

Getting targeted answers to patient behaviour and outcomes



Health Outcomes Insights is an independent research consultancy serving academia, life science researchers, healthcare agencies and the pharmaceutical industry, across a range of conditions and diseases, get targeted answers to patient behaviour whenever health outcomes are your programme.

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