SPIRIT-PRO Extension Stakeholder Survey Invitation

Invitation

On behalf of the SPIRIT-PRO executive, ISOQOL PROtocol Checklist Taskforce and our international partners, we would like to invite you to complete a survey to establish which items relating to patient-reported outcomes (PROs) you feel should be included in clinical trial protocols (when PROs are a primary or key secondary outcome).

What is the purpose of the survey?

We are currently in the process of developing PRO specific guidance for trial protocol writers in the form of an official SPIRIT-PRO extension. This guidance is needed because currently many protocols lack this information, resulting in poor quality PRO data/reporting which limits the use of these data informing patient care, clinical guidelines and health policy. This survey will help ensure that that the final guidance reflects stakeholder views.

Where are we now?

A number of tasks have already been completed:

- Our previous systematic review of existing PRO-specific guidance for trial and health related research protocol writers identified 162 unique PRO-specific recommendations (1).
- An International Society for Quality of Life Research (ISOQOL) expert taskforce was convened to review these 162 items. Redundant items were removed and where possible similar items were merged, as a result the number of recommendations was reduced to 56 (2).
- These 56 items form the basis of the stakeholder survey.

Why are you contacting me?

You have been contacted as a member of a group who have experience in developing, implementing or reviewing clinical trial protocols and we would like you to participate in the stakeholder survey. This will help us establish views on which PRO-specific items should be included in future clinical trial protocols and supporting trial documentation. Members of the stake holder groups being asked to complete the survey include: clinical trialists, academics/researchers, health economists, methodologists, trial personnel, patient user representatives and advocates, PRO experts, psychometricians, funders, industry representatives, journal editors, policy makers, ethicists and researchers. This will allow us to gain a broad range of opinions on the perceived suitability of each of the 56 items for inclusion in the final SPIRIT-PRO extension. You are receiving this email as you have been identified as someone with that experience.

What does it involve?

If you choose to complete the survey you will be asked to review each of the 56 candidate items and assess how important each item is to include in the SPIRIT-PRO extension checklist. Following this, participants will indicate whether certain checklist items should be included in other trial documentation, such as guidance for trial staff, guidance for study participants, the PRO statistical analysis plan and/or other trial documentation.

What happens then?

Anonymised data from this stakeholder survey will be included in a Delphi exercise. Delphi panel members will complete the same survey, and compare their results with anonymised data from the

stakeholder survey. They will then complete the survey again. This exercise will be repeated until a general consensus across the Delphi panel is reached on which items should be included in the protocol. A consensus meeting will then take place to finalise the guidelines and develop a knowledge transfer strategy. You will only be asked to complete the stakeholder survey once.

What do I need to do now?

If you feel you have the relevant experience as outlined above we would like you to take part in the stakeholder survey. The survey will take approximately 20–30 minutes to complete.

Please click on the following link to complete the stakeholder survey:

SPIRIT-PRO Extension Stakeholder Survey Link

Can I withdraw my data?

Once you have submitted the survey online it will not be possible to withdraw your data as all information collected on the stakeholder survey is anonymised and we are unable to retrieve your information. However, your responses will be anonymised and you will not be identified in any publications or survey results.

We hope you will feel able to contribute to this important exercise and we thank you for your time.

Contacts

If you wish to discuss the project or your responses please contact the principal investigator of the research team directly: Prof M. Calvert m.calvert@bham.ac.uk

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