

Improving the patient-reported outcome sections of clinical trial protocols: a mixed methods evaluation of educational workshops

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Online supplement 1: Workshop booklet table of contents and program

PROtocol Checklist Workshop Quality of Life Office

University of Sydney
29-30 May 2014

Workshop Booklet



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Program Outline – Day 1

Thursday 29 May 2014

Time	Session	Speaker
10.30am	Registration and Morning Tea	
10.45	<p>Session 1: Introduction, rationale, objectives and hypotheses</p> <p>Welcome, introductions and house-keeping</p> <p>Patient-Reported Outcomes (PROs) terminology and conceptual model</p> <p>Importance of the protocol</p> <p>Introducing the PROtocol Checklist –plus workshop format and overview</p> <p>The Protocol: Background and Rationale</p> <p>The Protocol: Objectives and Hypotheses</p> <p>Reflect, review, write – small groups or individually</p>	MK
12.30pm	Lunch	
1.00	<p>Session 2: PRO measures</p> <p>Available PRO questionnaires – what’s out there</p> <p>Choosing the best PRO questionnaire(s) to match your Objectives/Hypotheses</p> <p>Psychometric properties required</p> <p>Details of PRO questionnaires to include in your protocol</p> <p>Reflect, review, write – small groups or individually</p>	MK and RMB
3.15	Afternoon tea	
3.30	<p>Session 3: Utility measures</p> <p>Economic evaluation and cost utility analysis (CUA) in clinical trials</p> <p>HRQoL, health utilities and QALYs</p> <p>Commonly used valuation methods – SG, TTO, DCE</p> <p>Multi-attribute utility instruments (MAUIs, e.g. EQ-5D, AQOL)</p>	RV - CREST
5.00	Plenary discussion: Day 1 Q&A	ALL
5.30	End of Day 1	

Program Outline – Day 2

Friday 30 May 2014

Time	Session	Speaker
9.00am	<p>Session 4: PRO questionnaire administration</p> <p>Inclusion and exclusion criteria specific to PRO assessment Administration of PRO questionnaires – place and mode of administration Timing of PRO assessments Reflect, review, write – small groups or individually</p>	MK
11.00	Morning Tea	
11.15	<p>Session 5: Missing data - statistics and logistics</p> <p>The effects of missing data on power The effects of missing data on bias Types of missingness Collection of auxiliary data Elements of prevention Reflect, review, write – small groups or individually</p>	DC and MK
1.00pm	Lunch	
1.30	<p>Session 6: Endpoints and Statistical considerations</p> <p>Endpoints</p> <ul style="list-style-type: none"> • Questionnaire scoring • Methods for deriving PRO endpoints • Analysis metric • Responder definitions <p>Statistical considerations</p> <ul style="list-style-type: none"> • Power/sample size calculations • Minimal important difference • Statistical analysis • Assessment of missing data • Handling missing data • Multiple comparisons <p>Reflect, review, write – small groups or individually</p>	DC
3.00	Afternoon tea	
3.15	<p>Session 7: Interpretation and Clinical significance of PRO results</p> <p>Why PRO results are challenging to interpret Aids to interpretation - Effect sizes, minimally important difference & clinical anchors</p>	MK
3.50	<p>Session 8: Quality assurance, appendices and resources</p> <p>How to get the best quality data – tips and resources</p>	RMB
4.10	<p>Plenary discussion: Day 2 Q&A</p> <p>Workshop evaluation</p>	ALL
4.30	End of Day 2	