Supplementary Online Content

Supplement 1.

Additional Contributions

Acknowledgement of contributors to the development of the SPIRIT-PRO extension.

eTable 1. Characteristics of the participants in the international stakeholder survey, Delphi survey, and consensus meeting.

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This supplementary material has been provided by the authors to give readers additional information about their work.

Additional Contributions

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Disclaimer: Please note that views of authors, Delphi and stakeholder participants are individual views and may not represent the views of the broader stakeholder group or host institution.

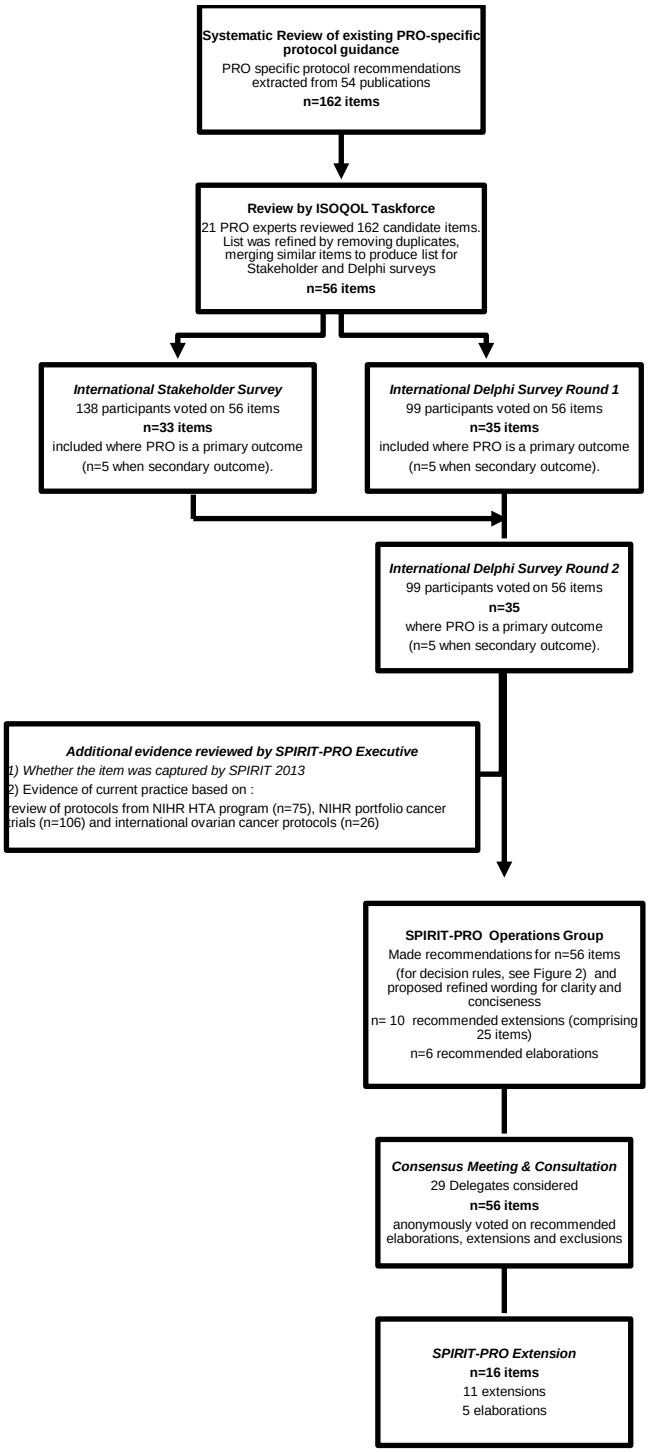
eTable 1. Characteristics of the participants* in the international stakeholder survey, Delphi survey, and consensus meeting.

Participants	ISOQOL Taskforce (n=21)	Stakeholder Survey (n=138)	Delphi Survey (n=99)	Consensus meeting (n=29)
Role n(%)				
Clinician	2(10)	40(29)	30(30)	11(38)
Clinical Trialist/health-related academic/researcher	11(52)	85(62)	57(58)	17(59)
Health Economist	0(-)	19(14)	6(6)	1(3)
Statistician	4(19)	27(20)	21(21)	4(14)
Trial Methodologist	5(24)	32(23)	25(25)	12(41)
Trial Manager/coordinator	3(14)	17(12)	5(5)	1(3)
Data manager/coordinator	0(-)	16(12)	2(2)	1(3)
Research Nurse/Therapist	0(-)	8(6)	5(5)	0(0)
Patient Advocate	0(-)	12(9)	15(15)	3(10)
Expert advisor PRO in trials	9(43)	27(20)	34(34)	11(38)
Psychometrician	4(19)	19(14)	23(23)	5(17)
Funder	0(-)	1(1)	6(6)	3(10)
Industry Representative	1(5)	12(9)	3(3)	2(7)
Journal Editor	1(5)	7(5)	18(18)	9(31)
Policy Maker	0(-)	3(2)	10(10)	7(24)
Ethicist/Member of ethical review panel	1(5)	14(10)	15(15)	5(17)
Evidence synthesis researcher	1(5)	21(15)	12(12)	2(7)
Regulator	0(-)	2(1)	7(7)	5(17)
Other	2(10)	17(12)	16(16)	2(7)
Years experience in clinical trials n(%)				
Less than 1 year	0(-)	15(11)	2(2)	0(-)
1 to 5 years	1(7)	30(22)	9(9)	2(7)
6 to 10 years	2(13)	30(22)	12(12)	2(7)
More than 10 years	12(80)	61(45)	74(76)	24(86)
Years experience in PRO protocol development n(%)				
Less than 1 year	1(6)	9(7)	9(10)	3(11)
1 to 5 years	2(13)	45(34)	20(21)	4(14)
6 to 10 years	3(19)	34(26)	14(15)	3(11)
More than 10 years	10(63)	45(34)	52(55)	18(64)
No of clinical trial protocols developed or evaluated n(%)				
Less than 10	2(13)	58(42)	25(26)	5(18)
11 to 20	5(33)	21(15)	17(18)	4(14)
21 to 30	2(13)	21(15)	10(10)	2(7)
More than 30	6(40)	37(27)	45(46)	17(61)
Clinical areas represented by participants n(%)				
Burns and plastics	1(6)	0(0)	1(1)	1(3)
Cardiology	2(13)	10(7)	9(9)	5(17)
Care of the elderly	1(6)	14(10)	9(9)	4(14)
Dementia	1(6)	12(9)	4(4)	2(7)
Dermatology	1(6)	3(2)	5(5)	2(7)
Emergency Medicine/Trauma	1(6)	2(1)	1(1)	0(-)
Endocrinology	2(13)	7(5)	5(5)	0(-)
Gastroenterology	1(6)	10(7)	10(10)	4(14)
General Practice	0(-)	12(9)	6(6)	4(14)

Participants	ISOQOL Taskforce (n=21)	Stakeholder Survey (n=138)	Delphi Survey (n=99)	Consensus meeting (n=29)
Haematology	3(19)	11(8)	12(12)	4(14)
Neonatal Care	0(-)	3(2)	2(2)	0(-)
Neurology	0(-)	20(15)	10(10)	0(-)
Neurosurgery	0(-)	2(1)	3(3)	1(3)
Obstetrics & Gynaecology	0(-)	6(4)	3(3)	1(3)
Oncology	12(75)	61(44)	56(57)	19(66)
Orthopaedics	2(13)	17(12)	4(4)	0(-)
Paediatrics	0(-)	17(12)	8(8)	1(3)
Palliative Care	2(13)	11(8)	16(16)	6(21)
Public Health	0(-)	25(18)	7(7)	2(7)
Rehabilitation	1(6)	16(12)	11(11)	1(3)
Renal Medicine	1(6)	7(5)	1(1)	0(-)
Respiratory Medicine	1(6)	10(7)	7(7)	1(3)
Rheumatology	2(13)	14(10)	17(17)	2(7)
Surgery	4(25)	12(9)	15(15)	7(24)
Sports & exercise Medicine	0(-)	5(4)	2(2)	0(-)
Other	1(6)	31(22)	17(17)	3(10)

*Note participants could have more than one role or area of clinical expertise.

eFigure 1. Flow diagram Methods and participants involved in the development of the SPIRIT-PRO Extension, including the numbers of candidate items considered at each step.



eFigure 2. Decision rules used by the Operations Team to inform proposals at the SPIRIT-PRO international consensus meeting

**One item which Delphi participants noted lacked clarity on wording and >60% scored 1-9 was also considered.*