Appendix 1

Survey instruments and pilot survey details

National Research Nurse Survey

Introduction

Thank you for your interest in this research

What is the purpose of this study?

The aim of this national survey is to gather information on how research nurses deal with quality of life and other patient-reported outcomes in clinical trials. We will donate £2 to Cancer Research UK for each completed survey we receive.

Who is doing this research?

This research is being conducted by the 'Patient-Reported Outcomes Research Group' based in Primary Care Clinical Sciences at the University of Birmingham. The study forms part of a PhD being undertaken by Derek Kyte MSc, supervised by Dr Melanie Calvert PhD, Professor Heather Draper PhD and Dr Jonathan Ives PhD. The West Midlands Research Ethics Committee have favorably reviewed the study (Reference number: 12/WM/0068).

How long will it take?

The questionnaire has 19 questions, expected completion time is 10-15 minutes. During the pilot phase, the average completion time was 11 minutes

How will my data be protected?

All of the data collected from you will be kept anonymous. You will not be asked for any personal information, such as your name, date of birth or contact details, any other potentially identifying data will be kept confidential or anonymised. We will ask you about your work experience, but this information will be analysed at a group level and individual details will not be shared. The results of the questionnaire and any reports derived from it will be securely stored on the computer systems in Primary Care Clinical Sciences at the University of Birmingham for the duration of 10 years. After this period they will be deleted so that they cannot be recovered. Reports derived from the questionnaire results will be published in peer reviewed scientific journals, all data will be anonymous.

Once I agree to take part, can I change my mind?

You can exit the questionnaire at any point prior to submission and your answers will not be analysed. Once you have submitted the completed questionnaire you will not be able to withdraw as there is no way we can retrieve your anonymised answers.

Who can I contact to ask any questions?

Mr Derek Kyte

Phone: 0121 4158502, Email: d.g.kyte@bham.ac.uk

Who can I contact if I wish to make a complaint?

Dr Melanie Calvert

Phone: 0121 4148595, Email: m.calvert@bham.ac.uk

Please note: by advancing to the next page, you are consenting to take part in the study. Anonymity and confidentially will be ensured.

National Research Nurse Survey
DEFINITIONS OF TERMS USED IN THE SURVEY
Patient-reported outcome measures
Patient-Reported Outcome measures ask the patient a series of questions in order to gauge their views on their own health or care, i.e. an outcome directly reported by the patient.
Quality of Life
A Quality of Life measure is a Patient-Reported Outcome which is designed to evaluate the way in which physical, emotional and social well-being are affected by a disease or its treatment.
SECTION 1
The next section asks questions about your experience of the <u>last</u> clinical trial you worked on that used a quality of life or other patent-reported outcome measure. It does not matter is this was a primary or secondary outcome in the trial.
SECTION 1 - Last trial
1. First, some questions about yourself. How long have you been qualified as a nurse?
C Less than 1 year
C 1-3 years
C 4-6 years
C 7-9 years
C 10 years or more
2. How long have you worked as a research nurse in total?
C Less than 1 year
C 1-3 years
C 4-6 years
C 7-9 years
C 10 years or more

National Research Nurse Survey
3. Which of the following age groups do you belong to?
C 25 or younger
C 26-35
C 36-45
C 46-55
C 56 or older
4. Thinking about the <u>last</u> trial you worked on that used a Quality of Life or other Patient-Reported Outcome measure.
Were you employed as a research nurse in primary care or secondary care?
C Primary Care
O Secondary Care
Other (please specify)
5. Which of the following clinical areas did the trial cover? PLEASE TICK ALL THAT
APPLY
General Practice
☐ Orthopaedics
General Medicine
Rheumatology
Cardiovascular
Oncology
☐ Elderly Care
Respiratory
Opthalmology
Obstetrics & Gynaecology
☐ Paediatrics
Neurology
Other(s) (please specify)

National Research Nurse Survey 6. Which of the following Patient-Reported Outcome Measures did the trial use? PLEASE TICK ALL THAT APPLY Eurogol EQ-5D Health Assessment Questionnaire (HAQ) Nottingham Health Profile (NHP) ☐ SF-12® Health Survey or SF-12v2™ Health Survey ☐ SF-36® Health Survey or SF-36v2™ Health Survey Hospital Anxiety and Depression scale (HAD) ☐ Arthritis Impact Measurement Scales (AIMS2) ☐ EORTC QLQ - C30 (Core Questionnaire) Minnesota Living with Heart Failure © Questionnaire (MLHF) Oxford Hip Score (OHS) Oxford Knee Score (OKS) Roland-Morris Disability Questionnaire (RMDQ) ☐ Don't know Can't remember Other(s) (please specify) **SECTION 1 - Last trial** 7. Thinking about the last trial you worked on that used a Quality of Life or other Patient-**Reported Outcome measure.** What assistance did you give to the trial participants during the completion of the questionnaire? PLEASE TICK ALL THAT APPLY ☐ I read the questions out to the participants. ☐ I helped participants to understand the questions. The participants gave me the answers and I filled in the questionnaire. I gave no assistance, the participants filled in their questionnaires independently. Other (please specify)

National Research Nurse Survey
8. During this trial, if the participant had to complete the Quality of Life or other Patient-
Reported Outcome Measure questionnaire <u>in clinic</u> , when did they do so?
C Always before their Consultant/Doctor appointment.
C Always after their Consultant/Doctor appointment.
O Variable, sometimes before and sometimes after their Consultant/Doctor appointment.
○ Not applicable.
Other (please specify)
9. During this trial, which of the following did you do <u>after</u> trial participants had
completed their Quality of Life/Patient-Reported Outcome questionnaires? PLEASE
TICK ALL THAT APPLY
☐ I sent the questionnaire to the data inputting centre without looking at it.
☐ I looked at the completed questionnaire to see if the participant had missed out any questions.
If I discovered missing items, I prompted participants to complete them.
I looked at the completed questionnaire to see if there were any scoring errors (e.g. 2 options selected instead of 1, scoring the wrong way round etc).
☐ If I suspected a scoring error, I prompted participants to look again at some questions, to ensure they had understood them correctly.
You may expand upon your answers here (optional)
SECTION 1 - Last trial

10. Thinking about the <u>last</u> tria		that used a Quality of	of Life or other
Patient-Reported Outcome me	asure.		
Please read the following state	ements. In each	case, please answer	'yes', 'no', or 'not
applicable'.			
	Yes	No	Not applicable
The trial protocol included information about Quality of Life/Patient-Reported Outcome measurement.	O	O	O
I felt the trial protocol content covering Quality of Life/Patient-Reported Outcome measurement was adequate for my needs.	0	0	С
I received trial training that included information on Quality of Life/Patient-Reported Outcome measurement.	0	О	О
I felt the trial training I received on Quality of Life/Patient-Reported Outcome measurement was adequate for my needs.	0	0	0
You may expand upon your answers here (option	al)		
			Y

of Life/Patient-Reported Outcome Measure data was being collected in the	ational Research Nurse Si	urvey	
Please read the following statements. In each case, please answer 'yes' or 'no'. Yes No It was explained to me why the Quality Conductione Measure data was being collected in the inial. was confident I could explain to trial varicipants why the Quality of InferPatient-Reported Outcome Measure data was being collected in the trial. Was explained to me why each of the questions in the Quality of Life/Patient-Reported Outcome Measure were included, i.e. how each was of relevance on the trial. was confident I could explain to trial varicipants why each of the questions in the Quality of Life/Patient-Reported Outcome Measure had been included, e. how each was of relevance to the trial. Condition of the questions in the Quality of Life/Patient-Reported Outcome Measure had been included, e. how each was of relevance to the trial. Condition of the questions in the Quality of Life/Patient-Reported Outcome Measure had been included, e. how each was of relevance to the trial. Condition of the questions in the Quality of Life/Patient-Reported Outcome Measures in trials is section will ask about your general thoughts about working with Quality of Life/Patient-Reported Outcome Measures in trials.			d a Quality of Life or other
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tarticipants why the Quality of Cife/Patient-Reported Outcome Measure lata was being collected in the trial. It was explained to me why each of the Questions in the Quality of Life/Patient-Reported Outcome Measure were included, i.e. how each was of relevance to the trial. It was confident I could explain to trial Comparison of the questions in the Quality of Life/Patient-Reported Outcome Measure had been included, e. how each was of relevance to the rial. It was confident I could explain to trial Comparison of the questions in the Quality of Life/Patient-Reported Outcome Measure had been included, e. how each was of relevance to the rial. It was explained to me why each of the questions in the Quality of Life/Patient-Reported Outcome Measure had been included, e. how each was of relevance to the rial. It was explained to me why each of the Quality of Life/Patient-Reported Outcome Measures in trials.	It was <u>explained to me</u> why the Quality of Life/Patient-Reported Outcome Measure data was being collected in the trial.		
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Participants why each of the questions in the Quality of Life/Patient-Reported Dutcome Measure had been included, e. how each was of relevance to the rial. Out may expand upon your answers here (optional) ECTION 2 - General thoughts ECTION 2 is section will ask about your general thoughts about working with Quality of Life/Patient-Reported Outcome Measures in trials.	juestions in the Quality of Life/Patient- Reported Outcome Measure were ncluded, i.e. how each was of relevance	С	О
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is section will ask about your general thoughts about working with Quality of Life/Patient-Reported Outcome Measures in trials.	ECTION 2 - General thoughts	5	
ECTION 2 - General thoughts		ut working with Quality of Life/Patien	t-Reported Outcome Measures in trials.
	ECTION 2 - General thoughts	5	
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ational Research Nurse	.al as	£0114 - £	L!f=/D=4!==4 D	outed A4
12. Thinking about your <u>gener</u> measurement in trials.	<u>'al</u> experienc	e of Quality of	Life/Patient-Repo	orted Outcom
Niconomia de la folloción de 404	4- I			! !- £ 4!
Please read the following state sometimes', 'never'.	ements. In ea	ich case, tick	one option: 'aiwa	ys', 'often',
,				
I feel bad giving the trial participant a	Always	Often	Sometimes	Never
Quality of Life/Patient-Reported Outcome questionnaire to fill in because the content might upset them.	U	U	Ü	U
I feel upset during the administration of a Quality of Life/Patient-Reported Outcome questionnaire, or when I have read the participant's answers.	0	0	0	0
I feel a tension between my role as a nurse and my role as a researcher when dealing with Quality of Life/Patient-Reported Outcome measurement within a trial.	О	O	О	O
You may expand upon your answers here (optio	nal)			
				A
				<u> </u>
ECTION 2 - General thoug	hts			V
13. Some research nurses we Life/Patient-Reported Outcom- concern for the wellbeing of th	have spoker e questionna ne trial partic	ires containin ipant in some	g answers which way.	ı raise
ECTION 2 - General thoughts. 13. Some research nurses we Life/Patient-Reported Outcome concern for the wellbeing of the This information has been term these reports, 'concerning' been particularly extreme que written additional information letter); finally, some nurses reparticipant said to them either	have spoker e questionna ne trial partic med: 'concer Patient-Repo stionnaire so on the quest ported become	ires containin ipant in some rning' Patient-l orted Outcome cores, or some ionnaire whic ming concerne	ng answers which way. Reported Outcome information may times a participath raised concerned by things that t	raise re information simply have nt might have (or attached a
13. Some research nurses we Life/Patient-Reported Outcome concern for the wellbeing of the This information has been term these reports, 'concerning' been particularly extreme que written additional information letter); finally, some nurses re	have spoker e questionna ne trial partic med: 'concer Patient-Repo stionnaire so on the quest ported become	ires containin ipant in some ming' Patient- erted Outcome cores, or some ionnaire which ning concerne ter, the compl	ng answers which way. Reported Outcome information may times a participath raised concerned by things that the fection of the question of the question.	raise re information re simply have nt might have (or attached a the trial tionnaire.
13. Some research nurses we Life/Patient-Reported Outcome concern for the wellbeing of the This information has been term these reports, 'concerning' been particularly extreme que written additional information letter); finally, some nurses reparticipant said to them either Have you ever encountered a	have spoker e questionna ne trial partic med: 'concer Patient-Repo stionnaire so on the quest ported become	ires containin ipant in some ming' Patient- erted Outcome cores, or some ionnaire which ning concerne ter, the compl	ng answers which way. Reported Outcome information may times a participath raised concerned by things that the fection of the question of the question.	raise re information re simply have nt might have (or attached a the trial tionnaire.
13. Some research nurses we Life/Patient-Reported Outcome concern for the wellbeing of the This information has been term of these reports, 'concerning' been particularly extreme que written additional information letter); finally, some nurses reparticipant said to them either thave you ever encountered alwithin a trial?	have spoker e questionna ne trial partic med: 'concer Patient-Repo stionnaire so on the quest ported become	ires containin ipant in some ming' Patient- erted Outcome cores, or some ionnaire which ning concerne ter, the compl	ng answers which way. Reported Outcome information may times a participath raised concerned by things that the fection of the question of the question.	raise re information re simply have nt might have (or attached a the trial tionnaire.

National Research Nurse Survey
SECTION 2 - General thoughts
14. Have you ever taken action in response to 'concerning' Patient-Reported Outcome information you have encountered within a trial, in order to assist a trial participant?
C Yes
Please provide details here of what caused you to become concerned and what actions were taken (optional)
15. Were you able to record <u>all</u> action(s) taken in response to the 'concerning' Patient-Reported Outcome information, in the trial documentation?
O No
O Yes
O Not applicable
You may expand upon your answer here (optional)
SECTION 2 - General thoughts
16. If you were to encounter 'concerning' Patient-Reported Outcome information <u>in a future trial</u> , for example, evidence of anxiety or depression, which of the following might you consider doing? PLEASE TICK ALL THAT APPLY
I would not intervene, it is the responsibility of the trial participant's GP and regular healthcare team to monitor and deal with quality of life related disorders such as anxiety and depression, not the trial staff.
I would discuss the findings with my line manager in the trial, or with the PI.
☐ I would discuss the findings with a colleague.
☐ I would discuss the findings with the participant.
Using my discretion, I would arrange an appointment with the patient's GP or other appropriate healthcare professional.
Other (please specify)

National Research Nurse	Survey		
17. Please read the following s	tatements. In ea	ch case, please ansv	ver 'yes', 'no', or
'unsure'	V	N-	Harris
There is usually specific guidance on dealing with 'concerning' Patient-Reported Outcome information contained in trial protocols .	Yes C	No O	Unsure C
I have usually had trial training on what to do if I encounter 'concerning' Patient-Reported Outcome information.	0	0	O
I feel confident about dealing with 'concerning' Patient-Reported Outcome trial information.	0	O	O
You may expand upon your answers here (option	al)		
			A
SECTION 3 - The future			
This final section will ask about the changes you trials. SECTION 3 - The future	would like to see regardin	g Quality of Life/Patient-Reported	Outcome measurement in future

strongly agree', 'agree', 'ha tatement.	are no opinio	, aisayit	o or strongly	, wijayi 66	TIME
	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
There should be more protocol content and trial training covering Quality of Life/Patient-Reported Outcome measurement, in trials employing such outcomes.	C	O	С	O	C
There should be more Quality of Life/Patient-Reported Outcome measurement guidance contained within other trial documentation, such as site manuals or standard operating procedures, in trials employing such outcomes.	O	0	O	0	O
There should be specific protocol content and trial training on how to deal with 'concerning' Patient-Reported Outcome information, in trials employing such outcomes.	С	О	О	C	О
ou may expand upon your answers here (optional)				<u> </u>
					▼

National Research Nurse Survey

19. Thinking about the future.

What particular Quality of Life/Patient-Reported Outcome guidance should be included the <u>trial protocol</u>, what should be included in <u>trial training</u>, and what should be included in a standard operating procedure? PLEASE TICK ALL THAT APPLY

	Trial Protocol	Trial Training	Standard Operating Procedure
Purpose/Importance of Quality of Life/Patient- Reported Outcome data in trial.	П	Г	
How to administer the questionnaire.			
When to administer the questionnaire.			
When/how to deal with 'concerning' Quality of Life/Patient-Reported Outcome information.		Π	
What to do if participants write additional information on their questionnaires (or attach a letter).	П	П	П
Ethical issues associated with Quality of Life/Patient-Reported Outcome use.			
How to deal with upset patients (communication/counselling skills).		Γ	
Working with non-English language patients.			
How to support the participant to answer sensitive questions.	Π	Π	П
How to collect Quality of Life/Patient-Reported Outcome data without biasing the results.			
Collecting Quality of Life/Patient-Reported Outcome data in different patient groups and/or settings.		Г	
Relevance and reasoning behind individual Quality of Life/Patient-Reported Outcome questions.			
How to deal with difficult situations.			
Other(s) (please specify)			

National Data Manager/Coordinator Survey

Introduction

Thank you for your interest in this research

What is the purpose of this study?

The aim of this national trials unit survey is to gather information on how data coordinators/inputters and data managers deal with quality of life and other patient-reported outcomes in clinical trials. We will donate £2 to Cancer Research UK for each completed survey we receive.

Who is doing this research?

This research is being conducted by the 'Patient-Reported Outcomes Research Group' based in Primary Care Clinical Sciences at the University of Birmingham. The study forms part of a PhD being undertaken by Derek Kyte MSc, supervised by Dr Melanie Calvert PhD, Professor Heather Draper PhD and Dr Jonathan Ives PhD. The West Midlands Research Ethics Committee have favorably reviewed the study (Reference number: 12/WM/0068).

How long will it take?

The questionnaire has 15 questions, expected completion time is 10-15 minutes.

How will my data be protected?

All of the data collected from you will be kept anonymous. You will not be asked for any personal information, such as your name, date of birth or contact details, any other potentially identifying data will be kept confidential or anonymised. We will ask you about your work experience, but this information will be analysed at a group level and individual details will not be shared. The results of the questionnaire will be securely stored on the computer systems in Primary Care Clinical Sciences at the University of Birmingham for the duration of 10 years. After this period they will be deleted so that they cannot be recovered. Reports derived from the questionnaire results will be published in peer reviewed scientific journals, all data will be anonymous.

Once I agree to take part, can I change my mind?

You can exit the questionnaire at any point prior to submission and your answers will not be analysed. Once you have submitted the completed questionnaire you will not be able to withdraw as there is no way we can retrieve your anonymised answers.

Who can I contact to ask any questions?

Mr Derek Kyte

Phone: 0121 4158502, Email: d.g.kyte@bham.ac.uk

Who can I contact if I wish to make a complaint?

Dr Melanie Calvert

Phone: 0121 4148595, Email: m.calvert@bham.ac.uk

Please note: by advancing to the next page, you are consenting to take part in the study. Anonymity and confidentially will be ensured.

DEFINITIONS OF TERM	IS USED IN THE SURVEY
Patient-reported outc	ome measures
Patient-Reported Outcome directly report	ome measures ask the patient a series of questions in order to gauge their views on their own health or care, i.e. an ted by the patient.
Quality of Life	
•	ure is a Patient-Reported Outcome which is designed to evaluate the way in which physical, emotional and social well- disease or its treatment.
SECTION 1	
	tions about your experience of the <u>last</u> clinical trial you worked on that used a quality of life or other patient-reported oes not matter if this was a primary or secondary outcome in the trial.
Please be aware that t opinions.	here are no 'right' or 'wrong' answers in this survey. We are simply interested in hearing about your experiences and
*1. Thinking	about the <u>last</u> clinical trial you worked on that used a quality of life or
other patent-r	about the <u>last</u> clinical trial you worked on that used a quality of life or eported outcome measure. Ou describe your role?
other patent-r	eported outcome measure.
other patent-r	eported outcome measure. ou describe your role?
O Data manager	eported outcome measure. ou describe your role?
Other patent-roll How would you Data manager Data coordinate	eported outcome measure. ou describe your role?
How would you Data manager Data coordinate Data inputter	eported outcome measure. ou describe your role?
How would you Data manager Data coordinate Data inputter	eported outcome measure. ou describe your role?
Other patent-r How would ye Data manager Data coordinate Data inputter Other (please specify	eported outcome measure. ou describe your role?
Other patent-r How would ye Data manager Data coordinate Data inputter Other (please specify	eported outcome measure. ou describe your role? ave you worked as a [Q1], in total?
other patent-r How would you Data manager Data coordinate Data inputter Other (please specify 2. How long h	eported outcome measure. ou describe your role? ave you worked as a [Q1], in total?
Other patent-r How would you Data manager Data coordinate Data inputter Other (please specify 2. How long h Less than 1 year	eported outcome measure. ou describe your role? ave you worked as a [Q1], in total?
Other patent-r How would year Data manager Data coordinate Data inputter Other (please specify 2. How long h Less than 1 year C 1-3 years	eported outcome measure. ou describe your role? ave you worked as a [Q1], in total?

National Data Manager/Coordinator Survey
3. To which of the following age groups do you belong?
O 25 or younger
C 26-35
C 36-45
O 46-55
O 56 or older
4. Thinking about the \underline{last} trial you worked on that used a Quality of Life or other Patient-Reported Outcome measure.
Was the trial based in primary care or secondary care?
O Primary Care
O Secondary Care
Other (please specify)
5. Which of the following clinical areas did the trial cover? PLEASE TICK ALL THAT
APPLY
General Practice
Orthopaedics
General Medicine
Rheumatology
Cardiovascular
☐ Oncology
☐ Elderly Care
Respiratory
☐ Opthalmology
☐ Obstetrics & Gynaecology
☐ Paediatrics
□ Neurology
□ DON'T KNOW
Other(s) (please specify)

National Data Manager/Coordinator Survey 6. Which of the following Patient-Reported Outcome Measures did the trial use? PLEASE TICK ALL THAT APPLY Eurogol EQ-5D Health Assessment Questionnaire (HAQ) Nottingham Health Profile (NHP) SF-12® Health Survey or SF-12v2™ Health Survey ☐ SF-36® Health Survey or SF-36v2™ Health Survey Hospital Anxiety and Depression scale (HAD) Arthritis Impact Measurement Scales (AIMS2) ☐ EORTC QLQ - C30 (Core Questionnaire) Minnesota Living with Heart Failure © Questionnaire (MLHF) Oxford Hip Score (OHS) Oxford Knee Score (OKS) Roland-Morris Disability Questionnaire (RMDQ) ☐ Don't know Can't remember Other(s) (please specify) **SECTION 1 - Last trial** 7. Thinking about the last trial you worked on that used a Quality of Life or other Patient-**Reported Outcome measure.** When the Quality of Life/Patient-Reported Outcome questionnaire data were inputted, which of the following occurred? PLEASE TICK ALL THAT APPLY The questionnaire was checked to see if the participant had completed all questions. 🔲 If items were found to be missing, trial participants were followed up in some way (e.g. by post, by phone or via their research nurse) in order to complete the questionnaire. The questionnaire was checked for scoring errors (e.g. two answers given instead of one, or reversed scoring). If scoring errors were detected, trial participants were followed up in some way (e.g. by post, by phone or via their research nurse) in order to correct them. Other (please specify)

Please read the following state know', or 'not applicable'.	ements. In ea	ach case, plea	se answer 'yes',	'no', 'don't
morry or morapphoable i				
The trial wastered included information	Yes	No O	Don't Know	Not applicable
The trial protocol included information about Quality of Life/Patient-Reported Outcome data inputting.			U	· ·
felt the trial protocol content covering Quality of Life/Patient-Reported Outcome data inputting was adequate.	0	0	O	0
received trial training which included nformation on Quality of Life/Patient-Reported Outcome data inputting.	0	0	O	0
felt the trial training I received covering Quality of Life/Patient-Reported Outcome data inputting was adequate.	О	0	O	O
had access to a standard operating procedure which included information on Quality of Life/Patient-Reported Outcome data inputting.	О	0	O	6
felt the standard operating procedure covering Quality of Life/Patient-Reported Outcome data inputting was adequate.	0	0	О	0
ou may expand upon your answers here (optio	nal)			_
				Y
ECTION 2 - General thoug	hts			
• • • • • • • • • • • • • • • • • • • •				
	about working with	Quality of Life/Patient-	Reported Outcome Measu	ires in trials.
is section will ask about your general thoughts	hts			
is section will ask about your general thoughts	hts			
nis section will ask about your general thoughts	hts		-	
nis section will ask about your general thoughts	hts			
nis section will ask about your general thoughts	hts			
ECTION 2 his section will ask about your general thoughts ECTION 2 - General thoug	hts			

National Data Manager/Coordinator Survey
9. Some data managers/inputters we have spoken to have reported encountering
Quality of Life/Patient-Reported Outcome data which raised concern for the wellbeing
of the trial participant in some way.
This information has been termed: 'concerning' Patient-Reported Outcome information.
In these reports, 'concerning' Patient-Reported Outcome information may have been
extreme questionnaire scores, or sometimes a participant might have written additional
information on the questionnaire which raised concern (or attached a letter).
Thinking about your <u>general</u> experience. Have you ever encountered any 'concerning' Patient-Reported Outcome information within a trial?
O No
C Yes
C Don't know
SECTION 2 - General thoughts
· · · · · · · · · · · · · · · · · · ·
SECTION 2 - General thoughts 10. Have you ever taken action in response to 'concerning' Patient-Reported Outcome information you have encountered within a trial, in order to assist a trial participant?
10. Have you ever taken action in response to 'concerning' Patient-Reported Outcome
10. Have you ever taken action in response to 'concerning' Patient-Reported Outcome information you have encountered within a trial, in order to assist a trial participant?
10. Have you ever taken action in response to 'concerning' Patient-Reported Outcome information you have encountered within a trial, in order to assist a trial participant? No
10. Have you ever taken action in response to 'concerning' Patient-Reported Outcome information you have encountered within a trial, in order to assist a trial participant? O No O Yes
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13. Please read the following statements. In each case, please answer 'yes', 'no', or don't know'. Yes No Don't know There is usually specific guidance on dealing with 'concerning' Patient-Reported Outcome information contained in trial protocols. I usually receive training on what to do if OOO Concerning' Patient-Reported Outcome information. I feel confident about dealing with OOO Concerning' Patient-Reported Outcome trial information. You may expand upon your answers here (optional) ECTION 3 - The future ECTION 3 This final section will ask about the changes you would like to see regarding Quality of Life/Patient-Reported Outcome measurement in future rials.	lational Data Manager/Co	pordinator Su	rvey	
I would not intervene, there is nothing I could do. I would not intervene, it is the responsibility of the trial participant's GP and regular healthcare team to monitor and deal with quality of life related disorders such as anxiety and depression, not the trial staff. I would discuss the findings with my line manager in the trial, or with the PI. I would discuss the findings with the participants research nurse. I would discuss the findings with a data manager/inputter colleague.	12. If you were to encounter 'co	oncerning' Patie	nt-Reported Outcom	e information <u>in a</u>
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Other (please specify) 13. Please read the following statements. In each case, please answer 'yes', 'no', or don't know'. Yes No Don't know There is usually specific guidance on C C C dealing with 'concerning' Patient- Reported Outcome information contained in trial protocols. I usually receive training on what to do if C C I encounter 'concerning' Patient- Reported Outcome information. I feel confident about dealing with C C C 'concerning' Patient-Reported Outcome trial information. You may expand upon your answers here (optional) ECTION 3 - The future ECTION 3 his final section will ask about the changes you would like to see regarding Quality of Life/Patient-Reported Outcome measurement in future rials.	$\hfill \square$ I would discuss the findings with the particip	pants research nurse.		
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don't know'. Yes No Don't know There is usually specific guidance on C C C C C C C C C C C C C C C C C C	Other (please specify)			
There is usually specific guidance on C C C C C dealing with 'concerning' Patient-Reported Outcome information contained in trial protocols. I usually receive training on what to do if C C C C C C C C C C C C C C C C C C	13. Please read the following sidon't know'.	tatements. In ea	ch case, please ansv	ver 'yes', 'no', or
dealing with 'concerning' Patient- Reported Outcome information contained in trial protocols. I usually receive training on what to do if C C I encounter 'concerning' Patient- Reported Outcome information. I feel confident about dealing with C C 'concerning' Patient-Reported Outcome trial information. You may expand upon your answers here (optional) ECCTION 3 - The future ECCTION 3 his final section will ask about the changes you would like to see regarding Quality of Life/Patient-Reported Outcome measurement in future rials.		Yes	No	Don't know
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rials.	SECTION 3			
ECTION 3 - The future	his final section will ask about the changes you virials.	would like to see regarding	Quality of Life/Patient-Reported	Outcome measurement in future
	ECTION 3 - The future			

4. Thinking about the <u>futu</u>	<u></u> .				
lease read the following s					_
strongly agree', 'agree', ha	ve 'no opinio	n', 'disagre	ee' or 'strongly	y disagree'	with the
tatement.					
	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
There should be more protocol content and trial training for data nanagers/inputters, covering Quality of ife/Patient-Reported Outcome neasurement.	C	C	С	О	C
there should be site manuals or standard operating procedures vailable to data mangers/inputters that include information on Quality of ife/Patient-Reported Outcome dministration in the trial.	O	0	0	0	O
There should be specific protocol ontent and trial training for data nanagers/inputters on how to deal with concerning' Patient-Reported Outcome information in trials.	О	O	б	C	O
ou may expand upon your answers here (optional)				
					Y

_			your job well, and should training, and what shoul
	·	edure? PLEASE TICK	- '
	Trial Protocol	Trial Training	Standard Operating Procedure
ow to input Quality of fe/Patient-Reported utcome data into the atabase.			L
hat to do if there is issing data.			
That to do in the event of coring errors (e.g. two nawers instead of one, or eversed scoring).	П	Π	Π
that to do if participants rite additional formation on their uestionnaires (or attach a tter).			
/hen action should be ken in the event of ktreme questionnaire cores.	П		Π
Tho to speak to if there is oncern about a articipants Quality of fe/Patient-Reported utcome data.			
her(s) (please specify)			A
			Y

Introduction

Thank you for your interest in this research

What is the purpose of this study?

The aim of this national survey is to gather information on how trial managers coordinate quality of life and other patient-reported outcome measurement in clinical trials. We will donate £2 to Cancer Research UK for each completed survey we receive.

Who is doing this research?

This research is being conducted by the 'Patient-Reported Outcomes Research Group' based in Primary Care Clinical Sciences at the University of Birmingham. The study forms part of a PhD being undertaken by Derek Kyte MSc, supervised by Dr Melanie Calvert PhD, Professor Heather Draper PhD and Dr Jonathan Ives PhD. The West Midlands Research Ethics Committee have favorably reviewed the study (Reference number: 12/WM/0068).

How long will it take?

The questionnaire has 14 questions, expected completion time is less than 10 minutes.

How will my data be protected?

All of the data collected from you will be kept anonymous. You will not be asked for any personal information, such as your name, date of birth or contact details, any other potentially identifying data will be kept confidential or anonymised. We will ask you about your work experience, but this information will be analysed at a group level and individual details will not be shared. The results of the questionnaire and any reports derived from it will be securely stored on the computer systems in Primary Care Clinical Sciences at the University of Birmingham for the duration of 10 years. After this period they will be deleted so that they cannot be recovered. Reports derived from the questionnaire results will be published in peer reviewed scientific journals, all data will be anonymous.

Once I agree to take part, can I change my mind?

You can exit the questionnaire at any point prior to submission and your answers will not be analysed. Once you have submitted the completed questionnaire you will not be able to withdraw as there is no way we can retrieve your anonymised answers.

Who can I contact to ask any questions?

Mr Derek Kyte

Phone: 0121 4158502, Email: d.g.kyte@bham.ac.uk

Who can I contact if I wish to make a complaint?

Dr Melanie Calvert

Phone: 0121 4148595, Email: m.calvert@bham.ac.uk

Please note: by advancing to the next page, you are consenting to take part in the study. Anonymity and confidentially will be ensured.

	onal Trial Manager Survey
atie	nt-reported outcome measures
	nt-Reported Outcome measures ask the patient a series of questions in order to gauge their views on their own health or care, i.e. an me directly reported by the patient.
Quali	y of Life
	ality of Life measure is a Patient-Reported Outcome which is designed to evaluate the way in which physical, emotional and social wel are affected by a disease or its treatment.
he nutco	ext section asks questions about your experience of the <u>last</u> clinical trial you worked on that used a quality of life or other patent-report me measure. It does not matter is this was a primary or secondary outcome in the trial. TION 1 - Last trial
TEO	ext section asks questions about your experience of the last clinical trial you worked on that used a quality of life or other patent-repor me measure. It does not matter is this was a primary or secondary outcome in the trial.
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	Which of the following clinical areas did the trial cover? PLEASE TICK ALL THAT APPLY			
	General Practice			
	Orthopaedics			
	General Medicine			
	Rheumatology			
	Cardiovascular			
	Oncology			
	Elderly Care			
	Respiratory			
	Opthalmology			
	Obstetrics & Gynaecology			
	Paediatrics			
	Neurology			
Other	(s) (please specify)			
	las the trial based in primary or secondary care?			
0	Secondary Care			
Other	(please specify)			

5. \	onal Trial Manager Survey
	Which of the following Patient-Reported Outcome Measures did the trial use?
PL	EASE TICK ALL THAT APPLY
	Euroqol EQ-5D
	Health Assessment Questionnaire (HAQ)
	Nottingham Health Profile (NHP)
	SF-12® Health Survey <u>or</u> SF-12v2™ Health Survey
	SF-36® Health Survey <u>or</u> SF-36v2™ Health Survey
	Hospital Anxiety and Depression scale (HAD)
	Arthritis Impact Measurement Scales (AIMS2)
	EORTC QLQ - C30 (Core Questionnaire)
	Minnesota Living with Heart Failure © Questionnaire (MLHF)
	Oxford Hip Score (OHS)
	Oxford Knee Score (OKS)
	Roland-Morris Disability Questionnaire (RMDQ)
	Don't know
	Can't remember
Oth	er(s) (please specify)
6. I	
-	During the trial, were the staff involved in data collection given instructions on how to
	Ouring the trial, were the staff involved in data collection given instructions on how to ninister the quality of life/patient-reported outcome questionnaire?
	-
adı O	ninister the quality of life/patient-reported outcome questionnaire?
adı O	ninister the quality of life/patient-reported outcome questionnaire?
adı o	ninister the quality of life/patient-reported outcome questionnaire?
adı o	ninister the quality of life/patient-reported outcome questionnaire? No Yes
o You	ninister the quality of life/patient-reported outcome questionnaire? No Yes
o You	ninister the quality of life/patient-reported outcome questionnaire? No Yes may expand upon your answer here (optional)
o You	ninister the quality of life/patient-reported outcome questionnaire? No Yes may expand upon your answer here (optional)
o You	ninister the quality of life/patient-reported outcome questionnaire? No Yes may expand upon your answer here (optional)
o You	ninister the quality of life/patient-reported outcome questionnaire? No Yes may expand upon your answer here (optional)
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o You	ninister the quality of life/patient-reported outcome questionnaire? No Yes may expand upon your answer here (optional)
o You	ninister the quality of life/patient-reported outcome questionnaire? No Yes may expand upon your answer here (optional)

7. Again, thinking about the same trial. What particular information on Quality of Life/Patient-Reported Outcome measurement was given to the data collection staff? Please read the options below and in each case select either 'included in trial protocol, training or SOP', or 'not included'.

C C
O O
0
0
O
0
A

This section will ask about your **general** thoughts about working with Quality of Life/Patient-Reported Outcome Measures in trials.

SECTION 2 - General thoughts

8. Some research nurses/data mangers we have spoken to have reported encountering Quality of Life/Patient-Reported Outcome questionnaires containing answers which raise concern for the wellbeing of the trial participant in some way.

This information has been termed: 'concerning' Patient-Reported Outcome information.

In these reports, 'concerning' Patient-Reported Outcome information may simply have been particularly extreme questionnaire scores, or sometimes a participant might have written additional information on the questionnaire which raised concern (or attached a letter); finally, some research nurses reported becoming concerned by things that the trial participant said to them either during, or after, the completion of the questionnaire.

Have you ever encountered/been made aware of any 'concerning' Patient-Reported Outcome information within a trial?

0	No
0	Yes
0	Don't know

SECTION 2 - General thoughts

9. Have you ever taken action in response to 'concerning' Patient-Reported Outcome
information you have encountered/been made aware of within a trial, in order to assist a
trial participant?

	∪ No	
	C Yes	
١	You may provide details about the action taken here (optional)	
		<u> </u>
		7

National Trial Manager Survey
10. Was there a mechanism in place to record <u>all</u> action(s) taken in response to the
'concerning' Patient-Reported Outcome information, in the trial documentation?
C No
C Yes
Not applicable
You may expand upon your answer here (optional)
SECTION 2 - General thoughts
11. If your data collection staff were to encounter 'concerning' Patient-Reported Outcome information in a future trial, for example, evidence of anxiety or depression, which of the following would you expect them to do? PLEASE TICK ALL THAT APPLY
Not to intervene, it is the responsibility of the trial participant's GP and regular healthcare team to monitor and deal with quality of life related disorders such as anxiety and depression, not the trial staff.
To discuss the findings with their line manager in the trial, or with the PI.
To discuss the findings with a colleague.
☐ To discuss the findings with the participant.
Using their discretion, arrange an appointment with the patient's GP or other appropriate healthcare professional.
Other (please specify)
SECTION 3 - The future
SECTION 3
This final section will ask about the changes you would like to see regarding Quality of Life/Patient-Reported Outcome measurement in future trials .
SECTION 3 - The future

12. Thinking about the future.

Please read the following statements. In each case, please indicate whether you 'strongly agree', 'agree', 'have no opinion', 'disagree' or 'strongly disagree' with the statement.

	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
Data collection staff in trials need more information on Quality of Life/Patient-Reported Outcome measurement - in the trial protocol.	C	C	С	O	C
Data collection staff in trials need more information on Quality of Life/Patient-Reported Outcome measurement - in other trial documentation, such as SOPs.	О	0	О	0	О
Data collection staff in trials need more information on Quality of Life/Patient-Reported Outcome measurement - delivered in the form of trial training.	O	O	O	0	O
There should be specific <u>protocol</u> <u>content and trial training</u> for data collection staff on how to deal with 'concerning' Patient-Reported Outcome information .	O	O	O	O	0
It is important to explain to data collection staff, the purpose and Importance of Quality of Life/Patient-Reported Outcome data to the trial.	О	О	O	0	О
It is important to explain to data collection staff, the relevance and reasoning behind individual Quality of Life/Patient-Reported Outcome questions.	О	0	О	O	0
ou may expand upon your answers here (optional)				_
					<u>^</u>

13. Thinking about the <u>future</u>.

What particular Quality of Life/Patient-Reported Outcome guidance should be included the <u>trial protocol</u>, what should be included in <u>trial training</u>, what should be included in a <u>standard operating procedure</u>, and what guidance should <u>not be included</u> in any of the above? PLEASE TICK ALL THAT APPLY

	Trial Protocol	Trial Training	Standard Operating Procedure	None
Purpose/Importance of Quality of Life/Patient- Reported Outcome data in trial.	П	П	Г	П
How to administer the questionnaire.				
When to administer the questionnaire.				
When/how to deal with 'concerning' Quality of Life/Patient-Reported Outcome information.				
What to do if participants write additional information on their questionnaires (or attach a letter).		П	П	
Ethical issues associated with Quality of Life/Patient-Reported Outcome use.				
How to deal with upset patients (communication/counselling skills).	П	П	П	Г
Working with non-English language patients.				
How to support the participant to answer sensitive questions.		П		П
How to collect Quality of Life/Patient-Reported Outcome data without biasing the results.				
Collecting Quality of Life/Patient-Reported Outcome data in different patient groups and/or settings.	Π	Γ		
Relevance and reasoning behind individual Quality of Life/Patient-Reported Outcome questions.				
How to deal with difficult situations.		П		

er(s) (please specify	()			
l Has compl	eting this question	naire changed the	way you will man	ane quality of
	orted outcome mea			age quanty or
o No				
◯ Yes				
ou may expand upor	your answer here (optional)			
				<u></u>
				7

Introduction

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Dr Melanie Calvert

Phone: 0121 4148595, Email: m.calvert@bham.ac.uk

Please note: by advancing to the next page, you are consenting to take part in the study. Anonymity and confidentially will be ensured.

DEFINITIONS OF TERMS USED IN THE SURVEY

Patient-reported outcome measures

Patient-Reported Outcome measures ask the patient a series of questions in order to gauge their views on their own health or care, i.e. an outcome directly reported by the patient.

Quality of Life

A Quality of Life measure is a Patient-Reported Outcome which is designed to evaluate the way in which physical, emotional and social well-being are affected by a disease or its treatment.

Chief Investigator

The Chief Investigator (CI) is defined as the lead investigator for a single site study, or in relation to a study conducted at more than one site, the investigator who takes primary responsibility for the conduct of the study across all sites.

Principal Investigator

The Principal Investigator (PI) is defined as the authorised health professional responsible for the conduct of that study at a study site, and if a team of authorised health professionals at a study site conducts the study, the Principal Investigator is the leader responsible for that team.

SECTION 1

The next section asks questions about your experience of the <u>last</u> clinical trial you worked on that used a quality of life or other patent-reported outcome measure. It does not matter is this was a primary or secondary outcome in the trial.

SECTION 1 - Last trial

	1. First, some questions about yourself. How much experience in total have you had as a CI/PI?				
0	Less than 1 year				
0	1-3 years				
0	4-6 years				
0	7-9 years				
0	10 years or more				

National CTU CI/PI Survey
2. Which of the following age groups do you belong to?
C 25 or younger
C 26-35
C 36.45
C 46-55
O 56 or older
3. Thinking about the <u>last</u> trial you worked on that used a Quality of Life or other Patient-Reported Outcome measure.
Which of the following clinical areas did the trial cover? PLEASE TICK ALL THAT APPLY
General Practice
☐ Orthopaedics
☐ General Medicine
Rheumatology
Cardiovascular
☐ Oncology
☐ Elderly Care
Respiratory
☐ Opthalmology
Obstetrics & Gynaecology
☐ Paediatrics
☐ Neurology
Other(s) (please specify)
4. Was the trial based in primary or secondary care?
C Primary Care
© Secondary Care
Other (please specify)

National CTU CI/PI Survey
5. In the study, Were you a CI or PI?
O CI
O PI
Other (please specify)
6. Which of the following Patient-Reported Outcome Measures did the trial use?
PLEASE TICK ALL THAT APPLY
☐ Euroqol EQ-5D
Health Assessment Questionnaire (HAQ)
Nottingham Health Profile (NHP)
☐ SF-12® Health Survey or SF-12v2™ Health Survey
☐ SF-36® Health Survey or SF-36v2™ Health Survey
☐ Hospital Anxiety and Depression scale (HAD)
☐ Arthritis Impact Measurement Scales (AIMS2)
☐ EORTC QLQ - C30 (Core Questionnaire)
☐ Minnesota Living with Heart Failure © Questionnaire (MLHF)
Oxford Hip Score (OHS)
Oxford Knee Score (OKS)
Roland-Morris Disability Questionnaire (RMDQ)
□ Don't know
☐ Can't remember
Other(s) (please specify)
SECTION 1 - Last trial
7. At what stage of the trial design phase was the quality of life/patient-reported
outcome element first discussed?
C From the start
C Part way through the process
C At the end of the process
You may expand upon your answer here (optional)
A.
▼
_

B. Was a qu he trial?	uality of	f life/pation	ent-repor	ted outco	omes exp	ert invol	ed in the	e desig	n phase of
O No									
O Yes									
You may expand	d upon your	answer here (optional)						<u> </u>
									7
). In your o	-		=	-	-	=	_	_	- ·
vhat level	-			_	ement gro	oup view	the quali	ty of life	e/patient
eported or	utcome	e(s) Withir	i the tria	lí					
mportant at	2	3	4	5	6	7	8	9	10 (extremely important)
all)	0	0	0	0	0	0	0	0	0
ou may expand	l upon your	answer here (optional)						
									A
_		•				_			s on how
o administ		•				_			s on how
o administ		•				_			s on how
O No O Yes	ter the (quality of	life/patio			_			s on how
O Administ	ter the (quality of	life/patio			_			s on how
C No C Yes You may expand	ter the (quality of	life/patio			_			s on how
C No C Yes You may expand	ter the (quality of	life/patio			_			s on how
O administ O No O Yes You may expand	ter the (quality of	life/patio			_			s on how
O administ O No O Yes You may expand	ter the (quality of	life/patio			_			s on how
C No C Yes You may expand	ter the (quality of	life/patio			_			s on how
C No C Yes You may expand	ter the (quality of	life/patio			_			s on how
- 110	ter the (quality of	life/patio			_			s on how
C No C Yes You may expand	ter the (quality of	life/patio			_			s on how
C No C Yes You may expand	ter the (quality of	life/patio			_			s on how
O administ O No O Yes You may expand	ter the (quality of	life/patio			_			s on how

11. Again, thinking about the same trial. What particular information on Quality of Life/Patient-Reported Outcome measurement was given to the data collection staff? Please read the option below and in each case select either 'included in trial protocol, training or SOP', or 'not included'.

	Included in trial protocol, training or SOP	Not included
The purpose and/or Importance of Quality of Life/Patient-Reported Outcome data to the trial.	0	С
Relevance and reasoning behind individual Quality of Life/Patient-Reported Outcome questions.	С	C
When to administer the questionnaire (time points).	C	С
When to administer the questionnaire during the clinic appointment (before/during/after the consultation).	O	0
How much assistance to give the participant during questionnaire completion.	С	С
How to check for, and deal with, missing Quality of Life/Patient-Reported Outcome data.	С	О
How to deal with Quality of Life/Patient-Reported Outcome information that raises concern for the wellbeing of the trial participant (e.g. a questionnaire indicating severe anxiety or depression).	c	C
What to do if participants write additional information on their questionnaires (or attach a letter).	0	0
You may expand upon your ans	swers here (optional)	
		Δ.

SECTION 2 - General thoughts

SECTION 2

 $This \ section \ will \ ask \ about \ your \ \underline{\textbf{general}} \ thoughts \ about \ working \ with \ Quality \ of \ Life/Patient-Reported \ Outcome \ Measures \ in \ trials.$

SECTION 2 - General thoughts

12. Some research nurses we have spoken to have reported encountering Quality of Life/Patient-Reported Outcome questionnaires containing answers which raise concern for the wellbeing of the trial participant in some way.

This information has been termed: 'concerning' Patient-Reported Outcome information.

In these reports, 'concerning' Patient-Reported Outcome information may simply have been particularly extreme questionnaire scores, or sometimes a participant might have written additional information on the questionnaire which raised concern (or attached a letter); finally, some nurses reported becoming concerned by things that the trial participant said to them either during, or after, the completion of the questionnaire.

Have you ever encountered/been made aware of any 'concerning' Patient-Reported Outcome information within a trial?

0	No
0	Yes
0	Don't know

O No

SECTION 2 - General thoughts

13. Have you ever taken action in response to 'concerning' Patient-Reported Outcome information you have encountered/been made aware of within a trial, in order to assist a trial participant?

O Yes	
You may provide details here (optional)	
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	V

National CTU CI/PI Survey
14. Was there a mechanism in place to record <u>all</u> action(s) taken in response to the
'concerning' Patient-Reported Outcome information, in the trial documentation?
C No
C Yes
Not applicable
You may expand upon your answer here (optional)
SECTION 2 - General thoughts
15. If your data collection staff were to encounter 'concerning' Patient-Reported Outcome information in a future trial, for example, evidence of anxiety or depression, which of the following would you expect them to do? PLEASE TICK ALL THAT APPLY
Not to intervene, it is the responsibility of the trial participant's GP and regular healthcare team to monitor and deal with quality of life related disorders such as anxiety and depression, not the trial staff.
To discuss the findings with their line manager in the trial, or with the PI.
To discuss the findings with a colleague.
To discuss the findings with the participant.
Using their discretion, arrange an appointment with the patient's GP or other appropriate healthcare professional.
Other (please specify)
SECTION 3 - The future
SECTION 3
This final section will ask about the changes you would like to see regarding Quality of Life/Patient-Reported Outcome measurement in future trials .
SECTION 3 - The future

16. Thinking about the future.

Please read the following statements. In each case, please indicate whether you 'strongly agree', 'agree', 'have no opinion', 'disagree' or 'strongly disagree' with the statement.

	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
Data collection staff in trials need more information on Quality of Life/Patient-Reported Outcome measurement - in the trial protocol.	C	C	С	C	C
Data collection staff in trials need more information on Quality of Life/Patient-Reported Outcome measurement - in other trial documentation, such as SOPs.	О	0	O	0	О
Data collection staff in trials need more information on Quality of Life/Patient-Reported Outcome measurement - delivered in the form of trial training.	0	O	O	0	0
There should be specific <u>protocol</u> <u>content and trial training</u> for data collection staff on how to deal with 'concerning' Patient-Reported Outcome information .	O	O	O	O	0
It is important to explain to data collection staff, the purpose and Importance of Quality of Life/Patient-Reported Outcome data to the trial.	О	О	О	0	О
It is important to explain to data collection staff, the relevance and reasoning behind individual Quality of Life/Patient-Reported Outcome questions.	O	0	O	O	0
ou may expand upon your answers here (optional)				
					<u>*</u>

17. Thinking about the <u>future</u>.

What particular Quality of Life/Patient-Reported Outcome guidance should be included the <u>trial protocol</u>, what should be included in <u>trial training</u>, what should be included in a <u>standard operating procedure</u>, and what guidance should <u>not be included</u> in any of the above? PLEASE TICK ALL THAT APPLY

	Trial Protocol	Trial Training	Standard Operating Procedure	None
Purpose/Importance of Quality of Life/Patient- Reported Outcome data in trial.	П	П	Г	П
How to administer the questionnaire.				
When to administer the questionnaire.				
When/how to deal with 'concerning' Quality of Life/Patient-Reported Outcome information.				
What to do if participants write additional information on their questionnaires (or attach a letter).	П		П	
Ethical issues associated with Quality of Life/Patient-Reported Outcome use.				
How to deal with upset patients (communication/counselling skills).	П	П	П	П
Working with non-English language patients.				
How to support the participant to answer sensitive questions.		П		П
How to collect Quality of Life/Patient-Reported Outcome data without biasing the results.				
Collecting Quality of Life/Patient-Reported Outcome data in different patient groups and/or settings.	П	П	П	П
Relevance and reasoning behind individual Quality of Life/Patient-Reported Outcome questions.				
How to deal with difficult situations.				

		ed the way you will mar	nage quality of
	tcome measurement in	ı future trials?	
O No			
○ Yes			
ou may expand upon your answer	here (optional)		A
			▼