Supplementary File 2: Round one survey

Demographic questions

Question	Response option
Which is your nationality? If you have more than one, please indicate all your nationalities	[Free text]
What is your gender?	Male Female
What is your age?	___ years
What is the highest level of education you have completed?	Graduated from Primary School Graduated from High School Graduated from College/University Post-graduate Degree (e.g. MSc, PhD) Other (please specify)
Were you invited to take part in this survey because you have been a patient with a shoulder disorder?	Yes No
The following questions are only asked to patients	
Have you ever experienced one of the following shoulder conditions: rotator cuff disease (e.g. rotator cuff tears, tendinitis, and impingement), adhesive capsulitis (frozen shoulder), shoulder instability, osteoarthritis in the shoulder joints, dislocation of the shoulder, proximal humeral fractures or non-specific shoulder pain?	Yes No
Have you ever sought health care for a shoulder condition? *This question is asked only to people who answered that they have experienced a shoulder condition*	Yes No
Do you have a shoulder condition at the moment? *This question is asked only to people who answered that they have experienced a shoulder condition*	Yes No
How long have you had your current shoulder condition? *This question is asked only to people who answered that they have a shoulder condition at the moment*	Less than 6 weeks Between 6-12 weeks More than 3 months Recurrent
The following questions are only asked to clinicians/scientists	
In which country do you work at the moment? If you work in more than one country, please indicate all the countries where you work	[Free text]
Which of the following options best describe your current job function? Please tick all options that apply to your current job function.	Health Care Provider Health Care Researcher Other (please specify)
Which of the following options best describe the field in which you are currently working? Please tick all options that apply to the field in which you are currently working.	General practice/family medicineOrthopaedics Epidemiology Physiotherapy

Question	Response option
	Anesthesiology
	Rheumatology
	Human Movement Science
	Neurosurgery
	Osteopathy
	Statistics
	Psychology
	Chiropractic/manipulative therapy
	Other (please specify)
How many years have you been working in this field?	___ years
Have you ever taken part in the design, conduct and/or analysis of clinical trials for shoulder conditions?	Yes (if so, please specify the number of trials ___) No
Have you ever conducted a systematic review of clinical trials for shoulder conditions?	Yes, (if so, please specify the number of systematic reviews ___) No
Have you ever conducted a study on the development or testing of a measurement instrument applicable to patients with a shoulder condition?	Yes, (if so, please specify the number of studies ___) No
Have you ever participated in the development of a core outcome measurement set for any health condition?	Yes (if so, please specify the number of core outcome sets ___) No

Domain questions

Question	Response option
Core Area: Life Impact	
Is the domain **'Overall Pain Intensity'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Overall Pain Intensity' is defined here as: 'how much a person's shoulder hurts overall, reflecting the general magnitude of the pain experience'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Temporal Aspects of Pain'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Temporal Aspects of Pain' is defined here as: 'variability of shoulder pain over time, namely frequency and duration of pain episodes'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Rest Pain Intensity'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Rest Pain Intensity' is defined here as: 'how much a person's shoulder hurts while resting/not making any shoulder movement'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Intensity of Pain With Activity'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Intensity of Pain With Activity' is defined here as: 'how much a person's shoulder hurts after performing any movement which involves use of the shoulder (e.g. reaching for an object on a high shelf)'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Intensity of Pain On Resisted Movement'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Intensity of Pain On Resisted Movement' is defined here as: 'how much a person's shoulder hurts when they move the shoulder against resistance (e.g. pushing the shoulder away from the body with someone pushing it in the opposite direction)'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Day Pain Intensity'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Day Pain Intensity' is defined here as: 'how much a person's shoulder hurts during the day time'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Night Pain Intensity'** important enough to	Yes

Question	Response option
be included in a core domain set for clinical trials of shoulder conditions? 'Night Pain Intensity' is defined here as: 'how much a person's shoulder hurts during the night time'.	No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Analgesic Use'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Analgesic use' is defined here as: 'the amount of prescription and over the counter analgesic medication a person takes for their shoulder condition.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Physical Functioning'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Physical Functioning' is defined here as: ' a person's ability to carry out daily physical activities required to meet basic needs, ranging from self-care (e.g. bathing, combing hair) to more complex activities that require a combination of skills (e.g. driving a car)'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Health-Related Quality of Life'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Health-Related Quality of Life' is defined here as: 'the physical, psychological and social domains of health, taken together, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations and perceptions'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Social Functioning'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Social Functioning' is defined here as: ' a person's ability to interact with people in a contextually and socially appropriate manner (e.g. showing consideration and esteem when appropriate, responding to the feeling of others), to create and maintain close relationships with others (excluding members of the family), to engage in desired aspects of community social life (e.g. charitable organizations, service clubs or professional social organizations)'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Recreation and Leisure Activity'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Recreation and Leisure Activity' is defined here as: ' a person's ability to engage in any form of play, recreational or leisure activity acts (e.g. sports of any kind or levels)'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Work Ability'** important enough to be	Yes

Question	Response option
included in a core domain set for clinical trials of shoulder conditions? 'Work Ability' is defined here as 'a worker's ability to meet physical and/or psychological demands of work'.	No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Psychological Functioning: Depression'** important enough to be included in a core domain set for clinical trials of shoulder conditions? Depression refers to negative mood, loss of self-confidence, loss of motivation and enjoyment.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Psychological Functioning: Anxiety'** important enough to be included in a core domain set for clinical trials of shoulder conditions? Anxiety refers to fear, extreme worrying and hyperarousal symptoms.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Psychological Functioning: Fear avoidance beliefs'** important enough to be included in a core domain set for clinical trials of shoulder conditions? Fear avoidance beliefs refers to the belief that any shoulder movements that result in pain need to be avoided.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Sleep Functioning'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Sleep Functioning' is defined here as: 'sleep functions like onset, maintenance, quality, amount of sleep, and functions involving the sleep cycle. This domain also includes the impact on perceptions of alertness and sleepiness during usual waking hours'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Fatigue'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Fatigue' is defined here as: 'fatigue, ranging from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that it is likely to decrease one's ability to carry out daily activities (including work activities) and to function at one's usual levels in family or social roles'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Satisfaction with Treatment Services'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Satisfaction with Treatment Services' is defined here as: '	Yes No Unsure/I do not know

Question	Response option
a person's satisfaction with care received, including treatment and care providers'.	Please provide any comments you wish to justify your response to the above question
Is the domain **'Global assessment of treatment success'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Global assessment of treatment success' is defined here as: 'a person's assessment of their recovery or degree of improvement'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Severity of the Main Complaint'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Severity of the Main Complaint' is defined here as an unavoidable painful or limited functional activity during daily life in which the shoulder is chiefly involved. It is a person-specific individualized approach for measuring limitation of shoulder function during daily activities'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
In your opinion, are there any domains in this core area that have too large conceptual overlap? If yes, please mention them in the space provided below.	Yes (please specify) No
Are there any additional suggestions that you would like to make about the wording of terms and definitions of domains within this core area?	[Free text]
Core Area: Resource use/economical impact	
Is the domain **'Work Productivity'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Work Productivity' is defined here as: 'economical impact on paid or unpaid job employment due to shoulder condition, including absenteeism and presenteeism'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Health Care Services'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Health Care Services' is defined here as: 'utilization of health care services within the formal health care system for treating shoulder conditions, including: visits, laboratory tests, imaging, days of admission to a hospital, medications'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Non-health Care Services'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Non-health Care Services' is defined here as: 'utilization of health care services not included in the formal health care system for treating shoulder conditions, including for example: visits to professionals of alternative medicine, over-the-counter medications, patient's time and travel	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question

Question	Response option
expenses'.	
Is the domain **'Requiring Re-operation or Revision Surgery'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Requiring Re-operation or Revision Surgery' is defined here as: 'utilization of additional surgical procedures following the failure of the first attempt'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
In your opinion, are there any domains in this core area that have too large conceptual overlap? If yes, please mention them in the space provided below.	Yes (please specify) No
Are there any suggestions that you would like to make about the wording of terms and definitions of domains within this core area?	[Free text]
Core Area: Pathophysiological Manifestations	
Is the domain **'Range of Motion'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Range of Motion' is defined here as: 'the distance and direction that the shoulder is able to move, either when initiated by the person with shoulder pain or when guided by the care provider (e.g. amount of shoulder flexion, abduction, external rotation, internal rotation)'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Muscle Strength'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Muscle Strength' is defined here as: 'force generated by the contraction of a muscle or of a group of muscles of the shoulder and/or of other adjacent body parts'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Muscle Tone'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Muscle Tone' is defined here as: 'a slight tension or firmness present in the resting muscles (i.e. a slight resistance offered when trying to move them passively) of the shoulder and/or of other adjacent body parts'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Pain on Palpation'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Pain on palpation' is defined here as: 'pain following palpation of muscle, tendon and bony prominences of the shoulder region, where patients are instructed to say 'yes' at the moment when they start to feel pain or discomfort'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Testing Positive on Specific Tests During Physical Examination'** important enough to be included	Yes No

Question	Response option
in a core domain set for clinical trials of shoulder conditions? In some clinical trials, tests are used for diagnostic purposes to decide if the person is eligible for the trial (e.g. 'painful arc test' or 'Neer impingement test' or 'empty can test' for rotator cuff disease; 'apprehension test' or 'relocation test' for shoulder instability). In some trials, these examinations are repeated post-treatment to assess whether or not the test is still positive, which suggests that the shoulder condition is still present. An example of an examination is presented here: http://www.physio-pedia.com/Painful_Arc	Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Shoulder Instability'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Shoulder Instability' is defined here as: 'loosening of connective tissue surrounding the shoulder joint which enables the bones forming the joint to move excessively on each other. In some cases the upper arm bone (humerus) may move partially or completely out of the socket during certain arm movements (i.e. subluxation or dislocation)'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Scapular Dysfunction'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Scapular Dysfunction' is defined here as 'problems with rotating the scapular (the two wing shaped bones on the upper back) or poor motor control of the scapular'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Proprioception'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Proprioception' is defined here as: 'the person's sense of the position and movement of the shoulder and/or of other adjacent body parts'.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Weakness on Movement'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Weakness on Movement' is defined here as: 'the person's sense that more effort than normal is required to move the shoulder	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Shoulder swelling'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Shoulder Swelling' is defined here as: 'abnormal enlargement of an area of the shoulder that is caused by accumulation of fluid in the shoulder joint'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above

Question	Response option
	question
Is the domain **'Shoulder Posture'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Shoulder Posture' is defined here as: 'the position in which the shoulder is held upright against gravity while standing, sitting or lying down. Good posture places the least strain on supporting muscles and ligaments during movement'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain '**Radiographic Outcomes'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Radiographic Outcomes' are defined here as: 'any measure of the structure of the bones/joints/tendons measured via imaging (e.g. x-ray, MRI or ultrasound to measure anterior subluxations, acromiohumeral distance reduction success, tendon thickness)'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Failure of Surgery'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Failure of Surgery' is defined here as 'failure of the surgery to correct a specific structural problem (e.g. malunion of a fracture after surgery)'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Surgical Process Outcomes'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Surgical Process Outcomes' are defined here as: 'measures of the implementation of a surgical intervention (e.g. length of time of the surgery, reduction manoeuvre time, number of reduction attempts)'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
Is the domain **'Haemodynamic Variables'** important enough to be included in a core domain set for clinical trials of shoulder conditions? 'Haemodynamic Variables' are defined here as: 'any measure of blood flow, such as blood pressure or heart rate. Such outcomes are sometimes measured in trials of surgical interventions for shoulder conditions'	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
In your opinion, are there any domains in this core area that have too large conceptual overlap? If yes, please mention them in the space provided below	Yes (please specify) No
Are there any suggestions that you would like to make about the wording of terms and definitions of domains within this core area?	[Free text]
Core Area: Mortality	
Is the domain **'Number of Deaths'** important enough to be included in a core domain set for clinical trials of shoulder conditions?	Yes No Unsure/I do not know

Question	Response option
'Number of Deaths' is defined here as: 'reporting of the number of deaths that occurred within a clinical trial'. Deaths very rarely occur in shoulder condition clinical trials, however, if occurring they would be very relevant outcomes. For this reason, this domain is presented here for judging its importance for inclusion in the core domain set. When no deaths occur in a clinical trial, a simple sentence stating that "no deaths occurred in this trial" could cover this domain. If deaths occur, an attempt to assess the likelihood that these deaths are treatment-related or not could be reported.	Please provide any comments you wish to justify your response to the above question
Are there any suggestions that you would like to make about the wording of terms and definitions of domains within this core area?	[Free text]
General comments	
In your opinion, are there any domains that should be added to the list presented in this survey? If yes, please mention them in the space provided below.	[Free text]
If you have experienced a shoulder condition, are there any considerations that you would like to make about the domains included in this survey? For example, you may wish to suggest some domains that, according to your opinion, should absolutely be included in this core domain set.	[Free text]
Are there any other considerations that you would like to make about the domains included in this survey?	[Free text]
Are there any general considerations that you would like to make about this survey?	[Free text]
Ideally, how many domains would you include in this core domain set for clinical trials of shoulder conditions? Please try to answer this question regardless of your rating during this survey.	Number: ___ (please specify why)
The presence (or not) of adverse events should always be reported in all clinical trials. Following OMERACT guidance, a recommendation for the reporting of adverse events should be included in every core outcome set. For this core outcome set, we propose an approach that demands a conceptual separation between adverse events and core domains. This means that a measured adverse event would only be defined as an adverse event if belongs to a different domain than one of the core domains. The following hypothetical example is provided for illustrative purposes. Suppose that this core domain set has already been defined and "Pain Intensity", "Physical Functioning" and "Work Productivity" are the core domains included. In this case a patient with an increase in pain intensity due to treatment cannot be defined as an adverse event because it belongs to one of the core domains (i.e. Pain Intensity). In fact, this increase in pain intensity would be summarized within the group results	Yes No (please specify why) Not my expertise

Question	Response option
for that domain. However, people who report symptoms such as dizziness or nausea (or any other bad event or outcome following treatment would be defined as adverse events. Do you agree with this approach to defining adverse events?	
Different aspects should be taken into account when reporting the presence of adverse events. Examples of these aspects are: distinction between serious and non-serious adverse events, adverse events that can be intervention- specific, adverse events that can be treatment-related or not. Do you have any suggestion on how adverse events should be reported in shoulder condition clinical trials?	[Free text]