OMERACT Instrument Selection

Topic: Domain Match

This document provides readers with a guide to various resources on the assessment of domain match using OMERACT Instrument Selection methodology.

A. Background information on domain match A.1. Instrument selection overview whiteboard: https://omeract.org/instrument-selection/ [see 3:10]]

A.2. Domain match video: https://omeract.org/instrument-selection/

A.3. Lesson 1: Definitions need to be detailed video: https://omeract.org/instrument-selection/

A.4. Instrument selection detailed discussion video: https://omeract.org/instrument-selection/ [see 6:33 and 7:30]

B. OMERACT Way



C. Master checklist for instrument selection: Steps 5 & 7

	OMERACT Master Checklist for Instrument Selection Name of Instrument:	
Step #	OMERACT Instrument Selection Process Checklist Item	Mark when complete
Assemb	ly of working group and protocol development	
1	Assemble working group	0
2	Decide on methods protocol for Core Outcome Instrument Set selection	0
3	Deliverable: Submit protocol using Instrument Selection Workbook to Technical Advisory Group [TAG]	0
4	Review and approval of final protocol by TAG	0
Review	of evidence of instrument performance for existing or new instrument	
Part A:	Domain match and Feasibility assessment	
<mark>5</mark>	Obtain Working Group and others assessment of match with the target domain	<mark>o</mark>
6	Obtain Working Group and others assessment of feasibility	0
7	Is the instrument a match with the domain <u>AND</u> feasible? Yes \rightarrow if yes, continue with Part B of checklist below No \rightarrow If no, set instrument aside (find new one or develop new one)	o
Part B: I	Review of evidence of performance of an instrument across key measurement properties	
8	Conduct literature search; create PRISMA diagram; place articles of measurement properties in Summary of Measurement Properties (SOMP) Table	0
9	Conduct COSMIN-OMERACT Good Methods check, add findings into the SOMP Table	0
10	Conduct data extraction, create summary reporting tables, fill in SOMP Table with assessment of adequacy of results	0
11	Conduct synthesis across evidence available for each measurement property	0
12	Decide if any gaps exist in evidence of measurement properties If gaps found, draft protocol for new study to fill gaps If no gaps, finish the SOMP Table with proposed level of endorsement	o
Initial su	ubmission to TAG: literature review findings & protocol for gaps	
13	Deliverable: Submit the Instrument Selection Workbook to TAG	0
14	Receive final response from TAG	0
15	If studies are needed to fill gaps, conduct new measurement property studies, submit to TAG for Good Methods check, add to body of evidence (SOMP) and go back to Step 12 If no studies are needed, put X here:and move to Step 16	o
Final su	bmission to TAG for approval	
16	Obtain agreement on final report	0
17	Set timeline for next review of instrument	0
Ratifica	tion of level of endorsement by OMERACT Community and communication of results	
18	Ratification of level of endorsement by OMERACT Community	0
19	Implement communication and dissemination plan	0

D. OMERACT Filter 2.2. Instrument Selection Algorithm (OFISA): domain match is the first signaling question



E. Where does domain match fit on the Summary of Measurement Properties (SOMP) table?

Domain match is completed by the working group. In the SOMP we are tracking if there is any literature published on domain match. It is acceptable that there is no published literature, and we will move forward with the working group's decision on domain match.

Instrument: ABC Domain: Physical function					Date complet	ed: 2021-02-	11		
Population: rheumatoid arthritis	Intervention(s): drug		Control: placebo/dr	Control: Ty placebo/drug cl		Type of studies: clinical trials			
Author/year	Truth	Feasibility*	Tr	uth		Dis	Discrimination		
	<mark>Domain</mark> match*		Construct validity	Inter-method reliability	Test retest reliability	Long'l construct validity	Clinical trial discrimination	Thresholds of meaning	
Working Group Appraisal (n=20 including 7 PRPs)	+	+							
Tugwell 2005			+/-			+			
Shea 2004						+		+	
Smith 1999									
Beaton 2015							+		
De Wit 2018							+		
Wells 2004			+						
March 2008							+	+/-	
D'Agostino 2011						+/-		+	
Bingham 2018			+		+/-				
Singh 2010			+						
Strand 2015			+/-						
Simon 2011						+		+/-	
New data from Conaghan 2021					+				
Total available studies for each property			5	N/A	3	5	3	4	
Total studies available for synthesis			5	N/A	2	4	3	4	
Synthesis Rating	GREEN From Working group	GREEN From Working group	GREEN	N/A	AMBER	GREEN	GREEN	AMBER	
	Based on the OMERACT algorithm this instrument is:								
OMERACT Endorsement More research needed on test-retest reliability and thresholds of meaning.									

F. Excerpt from OMERACT Handbook, Chapter 5, Instrument Selection (Page 14-17) https://omeracthandbook.org/

Part A: Domain match and Feasibility assessment

5. Obtain Working Group and others assessment of match with the target domain

Is it a match with target domain? (Truth)

We begin the assessment of the instrument with the "*Truth*" pillar of the Filter. This addresses whether the instrument appears to be a good match for the target domain, and whether the instrument has the right content for the experience of that domain in the intended target population and study situation.

Essential to this assessment is the definition work done in the domain selection phase. Reviewing the domain definition template (see Figure 5.5) from the broad concept to the specific and focused target domain and its elemental components is important as an initial step to ensure that there is a match of the instrument with the definition previously established. To help you work through this material, we have compiled key references from the literature and have used them to develop sample survey questions (see Instrument Selection workbook). The working group should ask key stakeholders, including patient partners, about the domain match.

Suggested	Template for reporting on the definition of your Domains
This is the one feel you are re will be saved f resource wher domain. Working Grou Target popula	pager for each of your mandatory domains and any important but optional domains you ady to define. It will provide the domain definition in more detail than anywhere else and or future reference by OMERACT. In many situations this has become an invaluable 1, perhaps years later, you are considering an instrument for your p:
Intended use f trials of drugs	for this domain:(e.g., clinical
Core Area	Life Impact
Broad domain	The general of broad domain, like "Pain Impact"
Target Domain	The name you are giving this more specific domain i.e, impact of pain on life activities in all realms of life- physical social and role functioning. This is what we will be focusing on for measurement.
Working definition of target domain	Create a working definition in detail. Don't just repeat the domain name, flesh this out, this is what people will see in your paper. Sometimes this is a definition from another conceptual framework – for example the definition of pain impact should range from periodic interference over the course of one week to inability to do any activities due to this pain.
Domain components	Outline here the components of your domain that are important for a good instrument to capture. e.g., pain impact on ADL's, pain impact on work life, pain impact on social activities. Should nat include pain impact on personality and personal relationships
Qualitative or literature support	Add in some quotes here from the qualitative work you have done. Consider examples of the breadth of the experience of this domain – high levels and low levels. Consider talking in more depth about what is included in this domain and what should NOT be considered part of this domain. This section is particularly important because it is easy to do as you work on your domains, and it will serve you well as a basis for your review of content validity when you start to look at candidate instruments. This definition sheet will be stored on OMERACT's website.
Sources of variability in score.	Please think through sources of variability or contextual factors that might impact the results (scores) when you measure this domain. For example, is there a large difference seen between people gathering the data? Is there a large difference between cultures or continents? Please see paper by confextual factors group Sabrina Nielsen et al, Ann Rheum Dis, 2020, and work on lessons from imaging outcomes lesson #2 (methods working group)

Key sources of information on evaluating domain match and feasibility:

- Auger C. Making sense of pragmatic criteria for the selection of geriatric rehabilitation measures. Ach Geronto and Geriatrics 2006:43;65-83.
- Feinstein AR. The theory and evaluation of sensibility. In Feinstein AR Clinimetrics. Westford MA: Murray Printing Co. 1987:141-166.
- Pakulis PJ. Evaluation physical function in an adolescent bone tumor population, Pediatr Blood Cancer 2005;45:635-643.
- Rowe BH., Oxman AD. An assessment of the sensibility of a quality-of-life instrument. Am J Emerg Med 1992;11(4);374-380.
- Smith M.L. Quality enhancement groups: A qualitative research method for survey instrument development. J Health Behav & Pub Health 2011:1(1);15-22.
- Terwee CB. Qualitative attributes of measurement properties of physical activity questionnaires: a checklist. Sports Med 2010;40(7):525-537.
- Terwee, C.B., Prinsen, C.A.C., Chiarotto, A. et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. Qual Life Res 2018; 27, 1159–1170

Figure 5.5 Template for reporting detailed domain definition (see OMERACT Handbook Chapter 4 for further details)

Careful consideration is then given to the domain of the instrument and its global aim of the instrument, as well as the breadth and depth of the elemental components of the instrument; for example, item content in a PRO or what is visible in a specific imaging technique for "inflammation". This appraisal of the match with the target domain covers what is sometimes called *Face and Content Validity*. The assessment should include all perspectives: the patient, clinician and researcher perspective. If the instrument under consideration has different versions or different ways of scoring (for example, individual subscales versus the whole scale), the working group should clearly identify which version they are assessing.

At this stage it is also important to consider the sources of variability. Some of them are things we will talk about later in this chapter when discussing testing of their impact on scores, but some sources of variability should have been integrated into the domain definition itself, and are things that can be assessed at this stage of looking at the instrument. For example, when doing activities of daily living, one can think about doing them with and without the use of assistive devices. That is a source of variability and should be something your group is clear about in the levels of your domain definition. If you want to allow people to use assistive devices, you do not want to choose a questionnaire that forces people to respond without the use of an assistive device. Other examples are: do you allow pain assessment before or after a pain medication is taken? Do you allow people to assist someone in work activities when assessing a worker's productivity? Time of day can also be important if you are trying to measure morning pain or stiffness; you might want that to be measured in the morning if patients tell you that morning pain is the most important to them. You would reject a questionnaire that gathers data on night pain or even average pain rather than pain in

Traffic light scoring

Throughout the instrument selection process, "traffic light" scoring will be offered.

<u>Green</u> always means "good to go"

<u>Amber</u> always means there is a concern, or caution, or weakness but it is good enough to go forward.

<u>**Red</u>** always means stop, do not continue.</u>

<u>White</u> means there is no evidence available

the morning. These are all sources of variability that are identified and hopefully decided upon at the time of the creation of a detailed description of the definition of the target domain (further discussed in Chapter 4, section 6.3). These sources of variability are then carried forward to the instrument selection phase and checked on here under the candidate instrument's "match with target domain". Other sources of variability cannot be addressed by being more focussed in the definition. Things like the fact that two raters will be doing the assessments, or data will be gathered on two different imaging machines. These are likely sources of variability that will need to be tested in the section below called "inter-method reliability".

Example surveys and checklists for Working Groups are available in the instrument selection workbook and groups are encouraged to get multiple inputs – particularly from respondents about the adequacy of the content from the perspectives recommended by COSMIN: comprehensiveness, comprehensibility, and relevance of the content (Terwee et al., 2018).

We also encourage groups to examine some data of their own or from some publications to look at the distribution of responses, patterns of missing items, or floor and ceiling effects – all indicators of potential problems of the fit of the content with the population of interest. For imaging biomarkers, do the techniques (and proposed scoring) capture the intended pathophysiologic feature?

The result of the appraisal of domain match is then scored and recorded in the SOMP in the 'Domain Match' column using the traffic light formula of Green, Amber, or Red. The text box to the side provides the meaning of the traffic light scoring whenever it is used in the instrument selection process.

Example of Evaluation of Content Validity:

At the Patient Perspective Workshop at OMERACT 6, the concept of fatigue was identified by patients as an important outcome which was not included in the current RA core set. Further qualitative and quantitative studies

explored the nature of fatigue as described by patients. Existing fatigue scales were found to omit many aspects of fatigue as reported by patients, and to include questions patients felt were unrelated to their fatigue experience. Therefore, a new fatigue scale, the Bristol Rheumatoid Arthritis Fatigue Multi-Dimensional Questionnaire (BRAF MDQ), was developed from items identified at interviews and focus groups with patients, followed by cognitive interviewing. Through this exercise, items and their wording were developed to cover a range of fatigue severity and impact. "Collaboration with patients enabled development of draft RA fatigue PROMs grounded in the patient data, strengthening face and content validity and ensuring comprehension."

Kirwan J, Hewlett S. Patient Perspective: Reasons and Methods for Measuring Fatigue in RA. J Rheumatol 2007; 34: 1171–3.

Nicklin J, Cramp F, Kirwan J, Urban M, Hewlett S. Collaboration with patients in the design of patient-reported outcome measures: capturing the experience of fatigue in rheumatoid arthritis. Arthritis Care Res 2010; 62: 1552–8

5

Obtain Working Group and others assessment of match with the target domain

0

7. Obtain Working Group decision based on results of domain match & feasibility: Is the instrument a match with the domain AND feasible?

Decision point: Does the Working Group agree that this instrument has passed these first two questions?

We are now at an important decision point in the OMERACT instrument selection process. This decision point is a unique feature to the OMERACT process. If an instrument is not a good match for the target domain or is not feasible to use in the intended setting, it can be set aside by the Working Group. Ongoing attention should focus on only those instruments that have *passed* these two questions with a GREEN or AMBER rating. Many groups have found that a quick check of these first two steps eliminated several instruments that are covering the wrong content for the intended application, or are considered too long, expensive, and/or complex to use. It is best to set them aside and continue only with those that have content/concept match and are feasible to use in the intended application.

	Is the instrument a match with the domain <u>AND</u> feasible?	
7	Yes \rightarrow if yes, continue with Part B of checklist below No \rightarrow If no. set instrument aside (find new one or develop new one)	0

G. Excerpt from Instrument selection workbook (pg. 7, 11-18, Appendix A) <u>https://omeracthandbook.org/workbooks</u>

2.1 Target PICOC of Instrument

Define in detail the PICOC to which the instrument will apply [you will take this from your Core Domain workbook]

Domain Definition Report

This is the one pager for each of your mandatory domains and any important but optional domains you feel you are ready to define. It will provide the domain definition in more detail than anywhere else and will be saved for future reference by OMERACT. In many situations this has become an invaluable resource when, perhaps years later, you are considering an instrument for your domain.

Working Group:		Core Area
Target population		Broad Domain
Intended use for this domain:	(e.g., RCT)	Target Domain
Intervention in trial:		Domain
Comparator in trial:		components

Core Area	Life Impact
Broad domain	The general or broad domain, like "Pain Impact"
Target Domain	The name you are giving this more specific domain i.e, impact of pain on life activities in all realms of life- physical, social and role functioning. This is what we will be focusing on for measurement.
Working definition of target domain	Create a working definition in detail. Don't just repeat the domain name, flesh this out, this is what people will see in your paper. Sometimes this is a definition from another conceptual framework – for example the definition of pain impact should range from periodic interference over the course of one week to inability to do any activities due to this pain.
Domain components	Outline here the components of your domain that are important for a good instrument to capture. e.g., pain impact on ADL's, pain impact on work life, pain impact on social activities. Should not include pain impact on personality and personal relationships
Qualitative or literature support	Add in some quotes here from the qualitative work you have done. Consider examples of the breadth of the experience of this domain – high levels and low levels. Consider talking in more depth about what is included in this domain and what should NOT be considered part of this domain. This section is particularly important because it is easy to do as you work on your domains, and it will serve you well as a basis for your review of content validity when you start to look at candidate instruments. This definition sheet will be stored on OMERACT's website.
Sources of variability in score	Please think through sources of variability or contextual factors that might impact the results (scores) when you measure this domain. For example, is there a large difference seen between people gathering the data? Is there a large difference between cultures or continents? Please see paper by contextual factors group Sabrina Nielsen et al, Ann Rheum Dis, 2020 (<u>https://doi.org/10.1136/annrheumdis-2020-217237</u>), and work on lessons learned from

Part A: Domain match and Feasibility Assessment

5. Obtain Working Group and others assessment of match with the target domain

Is it a match with target domain? (Truth)

To answer this question, there are four tasks to complete:

- 1. Survey of working group members about the content and domain match
- 2. Survey of patients and other key stakeholders about the content and domain match
- 3. Review of raw data for this instrument
- 4. Working group comes to a conclusion about match with target domain and content

5. 1 Survey of working group members about the content and domain match

Sample survey questions are provided in <u>Appendix A</u>. You can use any survey software to obtain this information.

Please provide a summary of your working group's input regarding the <u>Domain Match</u> of the selected instrument. Below are samples of the types of questions we need you to address; you can use these or similar questions but please provide a summary of your working group's responses at this level of detail. This example is geared towards PROs; we offer a table with suggestions of how to ask similar types of questions of imaging outcomes, other biomarkers and composite outcomes in <u>Appendix A</u>.

SUMMARY OF DOMAIN MATCH (IF NECESSARY, REPLACE & PROVIDE YOUR RESULTS HERE):

Instrument: Click here to enter text.

Date: Click here to enter a date.

Question	Working Group's sur	nmary response
Is this instrument (think about items, response, domain capture for	□Yes	N (%)
PROs; for imaging, think about match with domain components)	Uncertain	N (%)
measuring what YOU want to measure? Are the items relevant to your	□No	N (%)
concept, as experienced by your targeted patients' experiences and for		
the intended application? Consider sources of variability you identified,		
are any of those criteria that were considered in the definition of the		
domain? For example, is using assistive devices permitted in your		
concept of independence in ADL functioning? Or do you want to specify		
a particular time of day when you define your concept of pain intensity		
– night pain, or morning pain for example?		
Comments:		
Click here to enter text.		

Have all important the elements	of the target domain for this	□Yes	N (%)
population, and intended application	□Uncertain	N (%)	
and depth needed)?		□No	N (%)
Comments:			
Click he	re to enter text.		
Is the instrument free of redund	ant, unnecessary, or potentially	□Yes	N (%)
inappropriate or sensitive items		□Uncertain	N (%)
Comments:		□No	N (%)
Click he	re to enter text.		
Are the items phrased in a clear	and understandable way?		N (%)
Comments:	· · · · · · · · · · · · · · · · · · ·		N (%)
Click he	re to enter text.		N (%)
Are the items written at a level t	hat will be understood by the target	□Yes	N (%)
population?		□Uncertain	N (%)
Comments:		□No	N (%)
Click he	re to enter text.		
Are the instructions for completi	ng items and selecting responses for	□Yes	N (%)
the items clear?		□Uncertain	N (%)
Comments:		□No	N (%)
Click he	re to enter text.		
Are the response options clear a	nd appropriate for each item (consider	□Yes	N (%)
match with the question, ordering	ng of responses)?	Uncertain	N (%)
Comments:		□No	N (%)
Click he	re to enter text.		
Is the recall period in the instrun	nent appropriate given the population,	□Yes	N (%)
domain and intended application	n, i.e, over the past week, last 24 hours	Uncertain	N (%)
(if applicable)?	-	□No	N (%)
Comments:		Not applicable	
Click he	re to enter text.		
Is the method of scoring approp	iate (consider any weighted		N (%)
responses)?	late (consider any weighted		N (%)
Comments: Click here to enter te	vt		N (%)
comments. enex here to enter te	At.		N (70)
Final decision based or	n working group data(check)	one):	1
Good to go		- /	
\square some cautions but o	kay		
not right for this or	nlication		
i in not right for this ap	plication		

5.2 Survey of patients and other key stakeholders about the content and domain match

Sample survey questions are provided in <u>Appendix A</u>. We set up the survey for respondents to assess <u>both</u> domain match and information needed for the next section on feasibility. We have put them together for the practicality of handing patients and others one form to complete. In order to be able to do this well, the respondents will need to know the target domain and its definition from the detailed definition report (part of the core domain set), as well as the intended application (population, setting). Please make sure you let them know this information.

Please use the responses to the part of the survey addressing "domain match" to provide the summary results. You can use any survey software to obtain this information.

PLACE YOUR SUMMARY RESULTS HERE:

Working Group's conclusion on respondents' data (check one): Good to go some cautions but okay not right for this application

5.3 Review of Raw Data

You now need to look at some data on responses to the scale from either a published paper with existing data or from a pilot project the working group undertakes. We encourage working groups to examine data of their own or from publications to look at the distribution of responses, patterns of missing items, or floor and ceiling effects – all indicators of potential problems of the fit of the item content with the population of interest.

We suggest you review responses to the instrument from about 30 persons who are similar to your target population. Frequency distributions for each element/item and for each total score can be examined. Gathering data in a sample similar to your target population allows for examination of ceiling (% of respondents with perfect scores) or floor (% at lowest score) that are indicators of missing content range for the respondents. The distribution of the total score in the target population will give a sense of the degree to which it can be treated as a continuous score using parametric statistics (means, t test) rather than non-parametric statistics (medians, ranks). Missing data can indicate sensitive or misunderstood content. Similar features could be examined for each aspect of a composite outcome measure or clinical score or biomarker.

This data can inform your decision about the suitability of the content and coverage of the concept. Use the data to really get a sense of what the scale or index is saying. Groups might choose to use a table like the sample table below to summarize responses and provide more detail on the pattern of responses on a multi-item (reflective) scale. The same could be adapted for key features of a composite index. Below is a sample table for presenting this data.

Modify the sample table below to fill in your results.

Item #	Item label	Missing (n)	0	1	2	3	Mean (0-3) item score
			No difficulty	Some difficulty	A lot of difficulty	Not able to do	
1	Reach	1	148	83	17	1	0.48
2	Sit	0	127	105	16	1	0.56
3	Lift	1	117	101	28	2	0.66
4	work	3	75	105	57	9	1.00
5	Carry	2	49	121	70	7	1.14
6	Pain	3	102	111	33	0	0.72
7	Dress	4	37	94	80	34	1.45
8	Transport	2	127	93	26	1	0.60
9	Walk	1	175	63	10	0	0.33
10	Run	5	153	78	13	0	0.43
11	Sports	2	130	96	21	0	0.56
			Ins	strument: XXXXX			
		Mean S	Score:	SD	_ Median		
			Cronbachs Alphs i	in this data:			

Review of Raw Data Form

Feature	Criterion	Score
Check that your data has a good	>80% of people answered, less than 20% drop out	□Yes
completion rate	OR evidence that the responders were similar to	
	the target sample.	
		□No
	Working Group Comments:	
	Click here to enter text.	
Missing data	a) Amount of missing data/responses	🗆 Yes
	b) Pattern of missing – was there any pattern?	□Uncertain
	Working Group Comments:	
	Click here to enter text.	
Floor and Ceiling	Both less than 15%?	□ Yes
		□Uncertain
	Working Group Comments: Click here to enter text.	□ No
Perceived completion time	Is it reasonable for intended study?	□ Yes
		□Uncertain
	Working Group Comments:	□ No
	Click here to enter text.	
Normality of distribution in target	Is it reasonable for intended study?	□ Yes
Population	Working Group Comments:	□Uncertain
	Click here to enter text	
1		

	🗆 No
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Results: Domain Match

Based on the Results above (working group survey, respondent's survey, data review), complete the Working Group's assessment of whether the instrument is a match with the target domain.

Red flag (stop, do not continue): Am	ome cautions, but continue):	Greer	n (good to go):
	No Information Available	Red Amber Flag Flag	Green Flag
Is it a match with target domain? (,	R 💧	G

7. Obtain working group decision based on synthesis of overall ratings of domain match and feasibility

Working Group's vote: you should now do a vote across your own working group members and record how you feel about this instrument based on the assessments of domain match and feasibility. This vote is important, and the result should be recorded in this workbook. Groups should achieve at least 70% agreement that this instrument can move forward (that is either a GREEN or AMBER vote). If less than that, the instrument should be set aside.

It is common, and a very good practice, to put instruments that are not doing well aside at this point. There is no way to repair or retest a mismatch with the target domain, or a lack of feasibility in using the tool. These instruments should not continue and as shown in the OMERACT Instrument Selection Algorithm they will land in the "STOP" area and not be considered further. This will save you a lot of time, so think this through carefully.

Result of Working Group Vote:

Date:	Agree it is a domain match & feasible (%)	Do not agree it is a domain match & feasible (%)
Working Group (N=)		

Based on the Results above, complete the Working Group's final assessment of whether the instrument matches the target domain and is feasible to use.

Green (good to go): _____ Amber (some cautions, but continue): _____ Red flag (stop, do not continue): _____

Complete step 7 on the Instrument Selection checklist. If the decision is to continue to assess the measurement properties of the instrument selection, move on the next section in the workbook, Part B. If the decision is to put the instrument aside, stop here in the workbook. Submit the workbook to <u>admin@omeract.org</u> to be kept on file.

	Obtain working group decision based on synthesis of overall ratings of domain match and feasibility: Is the instrument a match with the domain <u>AND</u> feasible? [Select Yes or No]	
7	Yes $ ightarrow$ if yes, continue with Part B of checklist below	0
	No $ ightarrow$ If no, set instrument aside (find new one or develop new one)	

Appendix A: Sample survey questions for surveying patients/other respondents on domain match and feasibility

The sample questions below are based on assessing domain match and feasibility of a PRO. They can be modified for use with other types of instruments using the considerations in this table:

PRO's	Composites	Imaging Outcome Instrument (scoring	Other biomarkers (e.g. ESR, CRP)
		system)	
Match to domain	Is there a clear match	Does it capture the	Is this biomarker a
definition	with each domain to	target domain?	good match to the
	the target of the		domain definition?
	composite (i.e., disease		
	activity?)		
Framing of the domain.	Does the questionnaire	Does the imaging	Does the instrument
Do the instructions for	specify how to manage	technique description	offer specific directions
the instrument orient	things like assistance,	offer choices to avoid	that help to avoid
the respondent/	assistive devices, or	specific sources of	variability in scores?
observer as to how to	coping strategies when	variability? i.e., T2	For example, blood
consider important	answering?	weighting in MRI, or	pressure can vary by
sources of variability?		specific angle used for	time of day, examiner,
		an Xray examination.	and environmental
			factors.
Do items cover the	Coverage of key	Coverage of the	Is it capturing all the
essential elements of	elements of the target	elements of that	essential elements as
the domain from	composite domain in	domain	described in the
detailed definition	the parts of the		domain definition?
template?	composite		
Response options	Scoring of each of the	Scoring of each	How is it quantified
	parts of the composite	element appropriate?	and is that
	(remember inherent		standardized?
	weighting given by the		
	scaling of each domain)		

Weighting of items into	How are elements	How the scoring	How is it scored
score	weighted in the	system weights the	compared to norms?
	composite scoring	elemental components	
	system?	in the score?	

Feedback from <u>respondents</u> to instrument:

Is it a match with target domain? (Truth) & Is it practical to use? (Feasibility)

Instrument: Click here to enter text.

Date:Click here to enter a date.

questions/items in the instrument, based on experience of this domain. answer Are the items in this instrument relevant to you and your experience? \Box Yes Comments: Click here to enter text. \Box No Do you think there should be any additional items (i.e., were there things that were missed)? \Box Yes \Box Uncertain Comments: Click here to enter text. \Box No \Box Yes Do you think that there should be any items taken out of the instrument? \Box Yes \Box Uncertain Do you think that there should be any items taken out of the instrument? \Box Yes \Box Uncertain Comments: Click here to enter text. \Box No \Box Ves Were there overlapping, sensitive, or embarrassing items? \Box Yes \Box Uncertain Comments: Click here to enter text. \Box No \Box Ves Does the instrument overall reflect your experience of your [domain]? \Box Yes \Box Uncertain Did you find that all the items were easy to read? If not, which items \Box Yes \Box Uncertain Did you feel that all the items were clear and understandable? Could you understand what all the questions were trying to ask? If not, which items \Box Yes Did you think that the response options were clear and understandable? <t< th=""><th>Match to Domain: Thinking about the content of the actual</th><th>Respondents</th></t<>	Match to Domain: Thinking about the content of the actual	Respondents
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Comments:	Were the instructions for answering the items clear?	
	Comments:	□Uncertain

Click here to enter text.	□No
Does the timing of the recall period seem reasonable to you (e.g. over the past week, last 24 hours) (if applicable)? Comments: Click here to enter text.	☐Yes ☐Uncertain ☐No ☐Not applicable
Feasibility: Questions about the practical considerations about this instrument.	Respondents answer
Was it easy enough to complete? Comments:	□Yes □Uncertain
Click here to enter text.	
Did it take a reasonable amount of time to complete?	□Yes
Comments:	□Uncertain
Click here to enter text.	□No
Did the format seem appropriate (how it looked on the page, font size,	□Yes
how items and responses were organized)?	□Uncertain
	□No
Do you think there was too much equipment and training needed before	□Yes
you could be able to respond to this instrument?	□Uncertain
Comments:	□No
Click here to enter text.	