

## CONSIDERATIONS FOR MODIFYING DOMAIN MATCH AND FEASIBILITY QUESTIONS ACROSS PROS, COMPOSITES, IMAGING OUTCOMES, AND BIOMARKERS

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