

DEFINE THE CONCEPT

WORKING GROUP:

1. NAME OF COMPOSITE MEASURE (IF VALIDATING)

2. DEFINING THE CONCEPT BEHIND THE COMPOSITE

What is the central concept your composite measure seeks to represent? Clearly define the core construct (e.g., disease activity, flare, response to treatment, remission). Consider the lived experience, clinical implications, and research importance of this concept. Why is it meaningful to patients, clinicians, and researchers?

MOD-specific prompt: *Does this concept reflect a multi-faceted phenomenon best captured through a continuous score aggregating multiple, interrelated domains within the same individual?*

COD-specific prompt: *Is this concept best characterized by the presence or absence of one or more defined clinical events (e.g., flare, remission)?*

3. IS THIS CONCEPT PART OF AN ENDORSED CORE DOMAIN SET

Yes. If yes please link to endorsed core domain set.

No

4. KEY DOMAINS AND/OR COMPONENTS THAT WILL BE INCLUDED IN THE COMPOSITE MEASURE:

Which domains or components have been selected to operationalize the concept in your composite? List and describe each domain, explaining how they reflect different dimensions of the concept. Why were these specific domains chosen? How do they map onto the lived experience or clinical markers of the concept? How does the combination of these domains create a richer, more accurate picture of the target concept than any domain alone?

MOD-specific prompt: *Explain how each domain contributes to capturing a unified, underlying construct in the same individual.*

COD-specific prompt: *How will the composite be defined?*

All selected domains/components must occur (AND rule)

Presence of any one component is sufficient (OR rule)

A weighted combination of components will be used

5. SOURCES USED TO DEVELOP THE CONCEPTUAL UNDERSTANDING:

Please indicate what sources informed your conceptual definition:

Literature Review

Patient Research Partner (PRP) Input

Delphi or Consensus Process

Other (please specify):

Date of Submission: