

HOW TO CHOOSE THE RIGHT MEASURE

Clinical outcome assessments (COAs) measure how an individual feels, functions, or survives. There are several types of COAs, including patient-reported outcomes (PROs) and clinician-reported outcomes (ClinROs). In drug development, selecting the appropriate COA is crucial for obtaining meaningful results.

5 Key considerations for an optimal COA strategy include:



01 APPROPRIATENESS

Choose measures that accurately capture the concept of interest in the study. If no suitable measure exists, consider developing a bespoke instrument.

The [FDA's guidance](#) on patient-focused drug development emphasizes a patient-centered approach, encouraging meaningful patient input to ensure assessments capture outcomes that matter most to them.

In some cases, disease-specific regulatory guidance may outline requirements, and occasionally identify suitable measures.



02 SUITABLE MEASUREMENT PROPERTIES

Ensure the measure has the necessary properties for accurate decision making:

- **Reliability**
Demonstrates good measurement/psychometric properties (e.g., sensitivity, test-retest reliability).
- **Validity**
Evidence supports that the measure assesses the intended concept.
- **Responsiveness**
Sensitive enough to detect meaningful change when it exists.
- **Precision**
Provides numerical accuracy using appropriately granular response scales.
- **Interpretability**
The degree of change that is meaningful to patients is understood.

Often, the evidence supporting the measurement properties of a COA are available from the instrument author, but Signant Health scientists can help provide this.



03 ACCEPTABILITY

Ensure the measure is acceptable to the target population. Consider the time needed for completion, the completion environment, typical compliance rates, the ease of cultural adaptability of the measure, and ease of use.

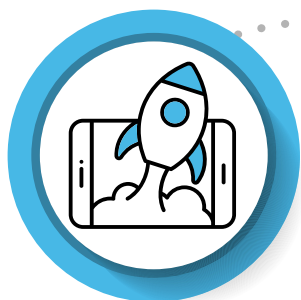
CULTURAL ADAPTATION

When translating a COA into another language, a word-for-word translation may not be sufficient. Questions such as asking patients if they can walk a block, climb stairs, or lift a gallon of milk may not be relevant or easily understood in different cultural contexts. Cultural adaptation is necessary to ensure the measure is used effectively in another country.



04 FEASIBILITY

Assess the ease of administering and completing the COA within the context of the study protocol. Consider any hardware, software, or country-specific requirements or restrictions.



05 IMPLEMENTATION CONSIDERATIONS

Ensure you know which version of the COA you want to use and have a license in place to use it. If you are adapting a COA from paper to electronic, make sure you choose a vendor that follows best practices to ensure the COA's properties remain unchanged.

Consult with Signant Health's dedicated science and scale management teams for guidance on scale selection, management, and implementation.

DISCUSS PROTOCOL →

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