# LETTER OF INTENT TO PROPOSE COA QUALIFICATION

The clinical outcome assessment (COA) letter of intent (LOI) should be accompanied by a cover letter and should include the following information. If literature is cited, please cite using the number assigned to the source in a numbered reference list.

Please note we will not accept LOI submissions that include protocols or study results from qualitative or quantitative research. Please do not leave any sections or subsections blank. If you do not have anything for that section or subsection, please explain the rationale (e.g. does not apply to this COA measure type).

Sections 1-4 will be posted publicly under Section 507. **Sections 1-4 should be stand-alone sections; do not refer to or cross reference any appendices, attachments, or other LOI sections.** Section 507 refers to section 507 of the Federal Food, Drug, and Cosmetic Act [FD&C Act] which was created by Section 3011 of the 21st Century Cures Act.

1. Administrative structure

   Description of the submitter including, but not limited to, principal investigator(s), working group member(s), institutions, and contact information.

2. Concept(s) of interest for meaningful treatment benefit

   a. A description of the meaningful aspect of patient experience that will represent the intended benefit of treatment (e.g., presence/severity of disease-related symptoms, limitations in performance of daily activities)

   b. Provide a conceptual framework for the COA(s)

3. Context of use for COA qualification. Please submit only one context of use per LOI. If there are additional contexts of use, please submit additional LOI(s) as needed.
   a. Targeted study population including a definition of the disease and anticipated selection criteria for clinical trials (e.g., baseline symptom severity, patient demographics, comorbidities, language/culture groups)
   b. Targeted study design and statistical analysis plan (includes the role of the planned clinical outcome assessment in future drug development clinical trials, including the planned set of primary and secondary endpoints with hierarchy, if appropriate)
   c. Applicable study settings for future clinical trials
      i. Geographic location with language/culture groups
      ii. Other study setting specifics (e.g., inpatient versus outpatient)

4. COA type [Patient-reported outcome (PRO), Clinician-reported outcome (ClinRO), Observer-reported outcome (ObsRO), performance outcome (PerfO) measure, or Other]

5. General description of proposed or existing measure. Please submit only one measure per LOI. If there are additional measures, please submit additional LOI(s) as needed.
   a. If an existing measure is being used, include the name and version number and attach a copy of the instrument, scoring of the instrument and user manual in the appendices

6. To the extent available, include a summary of COA development, including documentation that the COA measures the concept of interest in the context of use based on literature review, stakeholder input and qualitative research, if applicable

7. To the extent available, include a summary of COA quantitative measurement properties (i.e., construct validity, test-retest reliability, ability to detect change)

8. Need for the qualified COA
    a. Overview of existing related COAs
    b. Identification of the gap(s) in measurement

9. Indication of whether the Submitter plans to submit the COA to other regulatory agencies for qualification

10. Questions for CDER

11. Appendices

- List of references and copies of only the most important references that submitter feels CDER reviewers may want to review.
- Copy of instrument, scoring guide and user manual for existing instrument

| **Revision History Date** | **Description of Changes** |
|---|---|
| 6.11.20 | Added to Instructions: Please do not leave any sections or subsections blank. If you do not have anything for that section or subsection, please explain the rationale (e.g. does not apply to this COA measure type). |
| 5.28.20 | Initial version |