



Biomarker Qualification Letter of Intent (LOI) Template

Administrative Information

Requesting Organization

Name: _____

Address: _____

Phone: _____

Website: _____

Primary Contact

Name: _____

Address: _____

Phone: _____

Email: _____

Alternate Contact

Name: _____

Address: _____

Phone: _____

Email: _____

Submission Date (MM/DD/YYYY):

If there is a prior, current, or planned submission to other regulatory agencies, list the agencies and dates as appropriate.

Context of Use

Proposed Context of Use (COU) (limited to 500 characters)

Drug Development Need

Describe the drug development need that the biomarker is intended to address, including (if applicable) the proposed benefit over currently used biomarkers for similar COUs (limited to 1,500 characters).

Biomarker Information

Biomarker name and description. If composite, please list the biomarker components.

Type of Biomarker

- Molecular
- Histologic
- Other (please describe)
- Radiologic
- Physiologic characteristic

Biomarker Information

For molecular biomarkers, please provide a unique ID.

Scheme:

ID:

Matrix (e.g., blood) or modality (e.g., MRI):

Primary biomarker category (see [BEST Glossary](#)):

Describe the mechanistic rationale or biologic plausibility to support the biomarker and its associated COU (limited to 1,500 characters).

If biomarker is an index/scoring system, please provide information on how the index is derived (e.g., algorithm), the biologic rationale for inclusion of each of the components, the rationale for any differential weighting of the elements, and the meaning/interpretation of the index/score (limited to 1,500 characters).

Biomarker Measurement Information

Provide a general description of what aspect of the biomarker is being measured and by what methodology (e.g., radiologic findings such as lesion number, specific measure of organ size, serum level of an analyte, change in the biomarker level relative to a reference such as baseline) (limited to 1,500 characters).

Is the biomarker test/assay currently available for public use? Yes No

Indicate whether the biomarker test/assay is one or more of the following:

- Laboratory Developed Test (LDT)
- Research Use Only (RUO)
- FDA Cleared/Approved. Provide 510(k)/PMA Number:

If the biomarker is qualified, will the test/assay be performed in a [Clinical Laboratory Improvement Amendments \(CLIA\)](#)–certified laboratory? Yes No

Is the biomarker test currently under review by the [Center for Devices and Radiological Health](#) or the [Center for Biologics Evaluation and Research](#)? Yes
 No
 Don't Know

Is there a standard operating procedure (SOP) for sample collection and storage? Yes No

Is there a laboratory SOP for the test/assay methodology? Yes No

Biomarker Measurement Information

Describe the extent of analytical validation that has been performed (e.g., sensitivity, specificity, accuracy, and/or precision of the assay or method) (limited to 1,500 characters).

Additional Considerations for Radiographic Biomarkers

How has the method for image acquisition, analysis, and integration of the data been optimized? (Limited to 1,000 characters.)

Does data currently exist to support the proposed cut point(s), if imaging results are not reported as a continuous variable? Yes No

Provide the name and version of the software package to be used for image acquisition and analysis (limited to 500 characters).

Supporting Information

Please summarize existing preclinical or clinical data to support the biomarker in its COU (e.g., summaries of literature findings, previously conducted studies) (limited to 2,000 characters).

Please summarize any planned studies to support the biomarker and COU. How will these studies address any current knowledge gaps? (Limited to 2,000 characters.)

Previous Regulatory Interactions

- None
- Letter of Support (LOS) issued for this biomarker on date: _____
- Discussed in a Critical Path Innovation Meeting (CPIM) on date: _____
- Previous FDA Qualification given to this biomarker with DDT Tracking Record Number: _____

Attachments

Please provide a list of publications relevant to this biomarker development proposal.

Optional* – If this biomarker development effort is part of a longer-term goal, please summarize your long-term objectives.*

Optional* – If you have other supporting information you would like to provide, please submit as attachment(s).

*Optional information will not be posted publicly.

Please refer to the [Biomarker Qualification Contacts and Submitting Procedures](#) for the mailing address and other important submission-related instructions. If you have any questions about submission procedures, please contact CDERBiomarkerQualificationProgram@fda.hhs.gov.