

Draft Letter of Support Template

Instructions: LOS Requests should include a draft letter using the template below. Please replace all sections highlighted in yellow with the information requested in the text.

Dear LOS Requester POC:

We are issuing this Letter of Support to GROUP to encourage the further study and use of BIOMARKER DESCRIPTION as an exploratory CLASS OF BIOMARKER (selection, diagnostic, prognostic, predictive, etc. – see BEST [Biomarkers, EndpointS, and other Tools] Resource) for DISEASE OR PURPOSE.

PARAGRAPH STATING WHY BIOMARKER OF IMPORTANCE

- What are the current challenges in the field or area of interest?
- If appropriate, what is the current approach or “gold standard” and how does the biomarker(s) improve the status quo?
- Include citations to relevant documents like existing guidance(s)

We support ORGANIZATION FOLLOWED BY BIOMARKER PROPOSAL DESCRIPTION. SUMMARY DESCRIPTION OF INFORMATION SUBMITTED TO SUPPORT THE LOS REQUEST (literature review, preliminary data, etc.).

- What is the mechanistic rationale or biologic plausibility supporting the proposed biomarker(s)?
- How might the biomarker address the above challenges?
- How might the biomarker affect clinical trial design considerations and/or the data normally collected?
- Include citations to relevant documents like existing guidance(s)

More experience with the use of this biomarker IN WHAT SETTING would be useful to more accurately determine its utility for PROPOSED PURPOSE.

PARAGRAPH SUMMARIZING NONCLINICAL OR CLINICAL INFORMATION SUBMITTED WITH THE LOS REQUEST.

PARAGRAPH SUMMARIZING PLANNED STUDIES OR DATA TO BE COLLECTED WITH THE LOS REQUEST. INCLUDE SPECIAL CONSIDERATIONS OR SPECIFIC INFORMATION THAT SHOULD BE CONSIDERED AS PART OF THE BIOMARKER’S DEVELOPMENT.

IF AND ASSAY OR IMAGING TECHNIQUE IS BEING USED FOR THE BIOMARKER’S ASSESSEMENT, PROVIDE SUMMARY OF CONSIDERATIONS. Strong emphasis on applying good scientific, laboratory, and software development practices for quality control and validation of BIOMARKER DESCRIPTION is imperative. IF APPROPRIATE, INCLUDE SENTENCE OF COLLABORATIVE EFFORTS RELATED TO THE ASSAY AND/OR IMAGING TECHNIQUE.

We encourage exploration BIOMARKER DESCRIPTION AND PROPOSED PURPOSE. We will consider data collection on this biomarker to be exploratory in nature. INCLUDE REFERENCE FOR DATA STANDARDS IF AVAILABLE. We believe data sharing and integrating data across trials can foster an accelerated path for DISEASE OR PURPOSE drug development programs. If sponsors intend to include analyses of this biomarker to support regulatory decision making for a given IND drug development program, they should prospectively discuss the approach to these analyses with the REVIEW DIVISION in CDER.

Any groups (academia, industry, government) that would like to join in this effort or have information or data that may be useful can contact LOS REQUEST POC AND CONTACT INFORMATION or view MENTION WEBSITE IF AVAILABLE.

Signed:

Janet Woodcock

Date

Director, Center for Drug Evaluation and Research (CDER)/FDA