Letter of Support (LOS) Request: Content Elements

Letter of Support Requests should include the four following content elements:

1. **Administrative information**: description of the requestor including, but not limited to:
    - Name of the group or consortia and website information if appropriate
    - Name of the point(s) of contact and contact information

2. **Draft Letter of Support**

3. **Supporting Information:**
    - Clear identification of the biomarker(s), including a concise description of the disease and/or experimental setting in which the biomarker(s) will be used, a brief description of how it is measured or assessed, and the rationale for why the biomarker(s) is useful for drug development
    - Introduction including the current challenges in the field or area of interest, how the proposed biomarker(s) might address, and any currently accepted approaches or "gold standards"
    - High-level summary (5-20 pages in length) of the important current knowledge related to the proposed biomarker(s) including:
        - description of the mechanistic rationale or biologic plausibility supporting the proposed biomarker(s)
        - anticipated benefits of the biomarker(s) should its utility be confirmed in the future
        - potential impact on clinical trial design considerations and/or drug development
        - data overview that supports the proposed LOS content, including strengths or limitations of this data (e.g., comparison with relevant standard approaches when available). For existing studies or preliminary data, please include study synopses (nonclinical and clinical as appropriate) and summary data result tables/figures. Requestors should refrain from simply providing summary statements of conclusions without the accompanying data summary to support those conclusions. The summary should have separate sections for published and unpublished reports if applicable. Inconsistencies in the available data should be highlighted.
    - A brief overview (1-2 pages in length) of the data the requestor plans to obtain from ongoing or future studies to support the further development and understanding of the biomarker's utility in drug development programs. Full study protocols are not expected or necessary.
    - A brief overview (less than a page) describing the methodology for the biomarker's assessment (e.g., assay description and/or imaging approach). If the assessment method is being developed, include the plans and any partnerships related to the development.
    - Indication of where the requestor plans to submit information to other global regulatory agencies
    - Indication and summary, if appropriate, of prior interactions with FDA (Critical Path Innovation Meeting, discussions with CDER or CDRH, etc.)

4. **Appendix:** list of references to support the content of the LOS and most pertinent to the request.