U.S. FOOD & DRUG ADMINISTRATION

STAGE 3: REVIEW • BIOMARKER QUALIFICATION PROGRAM

FULL QUALIFICATION PACKAGE

Below is a suggested template that submitters may modify to accommodate their submission data, as needed:

1. Executive Summary

2. Background

- Importance of the specified biomarker as a drug development tool
- The background for the disease and/or organ toxicity

3. Proposed Context of Use (COU)

- Proposed COU (Use Statement and Conditions for Qualified Use) to include:
  - Disease area/organ toxicity
  - Targeted population

4. Summary of Supporting Data

- Supportive nonclinical and clinical studies
- Additional evidence from published literature

5. Methodologies

- Performance characteristics and methodologies of the analytically validated biomarker assays used
- Imaging modalities, as applicable
- Chart, graphs, plots, flowcharts etc., as applicable
- Data collection and analysis methodologies such as analysis endpoint/s, baseline data, missing data, sensitivity analysis etc.
- Statistical Analysis Plan
- Codes such as SAS codes used in data analyses, as applicable

6. Results

- Raw data from clinical/nonclinical studies, protocols, testing conditions, populations tested, and the outcome of the performed study
- All data sources, datasets (exploratory, confirmatory etc.), Registry and database(s)
- A report that combines results from all studies, analyses (statistical and modeling) and conclusions
- A conclusion summary that describes key findings from all the studies conducted and discusses how the key findings support the use of the proposed biomarker as a drug development tool

7. Appendices

- Any supporting material such as references, peer-reviewed literature, summaries or statements from other regulatory agencies, academia, consortia, medical boards that may highlight the use of biomarkers
- Upon qualification, reviews of the submitted qualification package and the qualification recommendation will be available on the Biomarker Qualification Program website. Please include a statement acknowledging that you are aware of this plan and do not object to written summary reviews being made publicly available.