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.