

Biomarker, Imaging, & QOL Studies Funding Program (BIQSFP)

Study Checklist for Randomized Phase 3 Clinical Trials with a Comparator Arm and Cost-Effectiveness Analysis (CEA) Component

INSTRUCTIONS: Please submit a response to each of the elements below and complete the BIQSFP Cost Estimate Worksheet.

1. Describe and justify the perspective of the CEA.
2. Explain the situations in which the outcomes of the clinical trial could substantially change clinical practice.
3. Describe the potential implication(s) of different outcomes of the trial on overall costs to the health care system, in terms of costs saved or costs added.
4. Briefly describe and justify the CEA study terms of:
 - a) Trial population (in relationship to treatment population in community practice)
 - b) Intervention(s) and control therapy selected for the CEA
 - c) Question or hypothesis posed
 - d) Measure(s) of outcome for the CEA
 - e) Method of estimating costs
 - f) Modeling approach proposed (if appropriate)
 - g) Approach to characterizing uncertainty analysis
 - h) The time horizon and discount rates of the CEA. If the time horizon of the CEA exceeds that of the trial, describe the extrapolation or modeling approach that will be used
5. Describe any threats to the external validity of the study in relation to community practice.