

IMAGING STUDY EVALUATION TEMPLATE

Evaluator's Name:

Date of Evaluation:

Concept/BIQSFP ID Number and Title:

Instructions for BIQSFP Evaluators: You have been asked to provide an evaluation of the imaging study associated with the attached phase 2 or phase 3 concept. Your responsibilities consist of evaluating the proposed study and completing this form with your written comments by filling out the fields that follow each review criterion.

Please use the applicant's responses within the *BIQSFP Study Packet, including the Checklist and Budget documents*, in completing your evaluation.

After completing this form, please save it to a new file, attach the form to an e-mail message referencing the concept/BIQSFP number, and forward the email to the NCI/EMMES Program Staff responsible for sending this evaluation. Submit your response at least 3 business days preceding the study evaluation conference call, so that all perspectives may be shared, and your written comments viewed by other evaluators of this study. You will likewise be provided access to the written comments of the other evaluators.

Criteria for Review and Prioritization of Essential Imaging Studies

1. The strength of the preliminary data for feasibility, utility, and performance characteristics

Strengths:

Weaknesses:

2. The potential of the test to change practice and have high impact on patient care (i.e.; the potential impact of the test itself or the potential change of therapy indicated by the results of the trial)

Strengths:

Weaknesses:

3. The ability of the test to yield well defined and validated interpretations that will guide decision-making

Strengths:

Weaknesses:

4. The extent of standardization of the tests as to be transferable to the non-research setting

Strengths:

Weaknesses:

5. The adequacy of the process for image acquisition and processing including feasibility data

Strengths:

Weaknesses:

6. A description of potential cost-sharing approaches that can be developed with entities that would eventually commercialize the test

Strengths:

Weaknesses:

7. Based on the definitions provided and on your evaluation of the study do you consider this test(s) to be **INTEGRAL* or **INTEGRATED* (see * below) to the associated clinical concept and why?

- ***Integral studies** - Defined as imaging tests that must be performed in order for the trial to proceed. Integral studies are inherent to the design of the trial from the onset and must be performed in real time for the conduct of the trial. Studies that will be conducted in the future on stored images are **not** eligible for BIQSFP funding, except if the results are critical to the stated primary or secondary objectives of the trial.

- ***Integrated Studies** – Defined as tests that are clearly identified as part of the clinical trial from the outset and are intended to identify or validate imaging tests that are planned for use in future trials. Integrated studies in general should be designed to test a hypothesis, not simply to generate a hypothesis. The number of integrated tests performed should be sufficient to obtain scientifically valid outcomes during the trial and include complete plans for patient preparation, procedures, analysis, interpretation of results, scoring procedures, expected distribution of the imaging study results in the study population, etc. (see IMAGING STUDY Checklist). One example would be the use of an imaging test to detect biologic modification of the target but where the image is not used as a primary study endpoint.
 - **REAL TIME INTEGRATED ASSAY?** Some integrated studies may require that assays or tests be performed during the trial, for example, imaging tests required during the trial that may be used to test for measuring treatment response.
 - **NON-REAL TIME INTEGRATED ASSAY?** Other integrated studies do not require real time assays/tests or sample collection or processing. Examples of NRT integrated tests include tools to analyze scans collected as part of standard treatment.

8. It is not intended that any priority or particular level of merit be assigned to one of the previous criteria over another. Based on the strength of the information presented and your scientific judgment, is your level of enthusiasm for the study:

<u>High</u>					<u>Mild</u>
1	2	3	4	5	

9. Please comment on the attached Budget and justifications (#8 on the attached IMAGING Study Checklist). Provide recommendations if needed.

It is understood that by agreeing to assist in this evaluation, you have no conflicts of interest with this concept. In addition, all unpublished information, reports, and discussions are strictly confidential.