

Biomarkers and Imaging Discovery and Development Committee (BIDD)

Supplementary Terms of Reference

- 1 **Remit:** the Biomarkers and Imaging Discovery and Development Committee (BIDD) is a sub-committee of the Clinical and Translational Research Committee (CTRC), with a remit to review, fund and manage research in all types of biomarkers (predisposition¹, screening, diagnostic, prognostic, predictive, pharmacological and surrogate response) using invasive (i.e. tissue and blood samples) and non invasive (i.e. imaging) technologies. In fulfilment of this, BIDD will:
 - Work with the Clinical and Translational Research Committee (CTRC), the Clinical Trials Advisory and Awards Committee (CTAAC), the Biological Sciences Committee (BSC), the Scientific Executive Board (SEB) and the other funding committees to ensure co-ordination of activities.
 - Advise SEB and CTCR on opportunities for promoting and improving the quality of biomarker and imaging research.
- 2 **Additional Terms:**
 - 2.1 BIDD will review and fund biomarker and imaging research of the following types:
 - I. Biomarker discovery projects using human samples². In broad terms, these include:
 - a. Discovery of biomarkers using hypothesis or non hypothesis (i.e. –omic) driven approaches
 - b. Definition of biomarker distribution in a limited number of specimens
 - c. Retrospective study of the relationship between the biomarker and clinical outcome.
 - II. Biomarker assay development projects. These might be performed at different stages from the original assay set-up at discovery stage to the validation of the assay for use on clinical material. Cell lines could be used at initial stages but it is expected that the assay will be transferred to human samples during the life of the project. The inclusion of assay development projects will provide increased assurance that biomarker research using clinical samples is being performed to the highest standards.
 - III. Biomarker qualification projects. These include the prospective study of the correlation between the biomarker and clinical outcome. Biomarker qualification projects where the biomarker is used as a primary endpoint in a clinical trial or where the biomarker is used to define randomization will

¹ Except for Genome Wide Association Studies (GWAS)

² Preclinical assay development using cell lines and/or animal models will be considered for pharmacological biomarkers.

remain the responsibility of the relevant clinical trials Committee (NAC, PRC, CTAAC).

- IV. Imaging discovery and evaluation projects. These include all imaging biomarker studies used in whole body imaging, development of imaging agents, and imaging technologies. Research in this area might be expected to include screening, diagnostic, prognostic, predictive and pharmacological biomarker research. Clinical imaging research involving first-in-human studies or the use of unregistered imaging agents where clinical trial sponsorship is required will remain within the remit of NAC.
- 2.2 BIDD will review outline applications for 2.1 I, III, and IV to provide feedback on the proposal that can be used by applicants to improve the quality of the biomarker and/or imaging research study.
- 2.3 BIDD will receive annual reports on the progress of the biomarker/imaging research and the sample accrual (where appropriate), and terminate funding where objectives are not being achieved.
- 2.4 BIDD will consider and have in place mechanisms for the dissemination of information both internally and externally on the implications of study outcomes.

3 Membership:

- Members will be drawn to ensure that the committee has standing expertise in areas pertinent to biomarker and imaging research, including molecular pathology, pharmacology, biostatistics, molecular genetics, oncology and functional imaging.
- An international panel of experts will review applications.

4. Meetings: the Committee will normally meet three times a year.