MRC Confidence in Concept (CiC) University of Manchester Allocation 2017

Diagnostics Guidance

General Guidance

Proposals for CiC funding for diagnostics should meet the following criteria:

- Project should be early stage translational research to generate pilot data that, if positive, would support submission of a proposal for external funding to a translational research scheme (e.g. MRC Developmental Pathway Funding Scheme (DPFS)
- Demonstrate a clear unmet medical need in a defined patient population
- Clear rationale how diagnostic could improve healthcare e.g.
    - Improved outcomes through earlier diagnosis
    - Better patient stratification to inform treatment selection
    - Improved outcomes through better monitoring
    - Improved outcomes through avoidance of adverse events
- Studies may incorporate one or more existing diagnostic technologies or development of new technologies
- Studies may focus on single biomarkers or development of multi-parameter biomarker signatures
- Proposals that incorporate new methods of data analysis and/or computational modelling to identify signatures of different disease strata are encouraged
- Proposals should discuss the repeatability, reproducibility and robustness of the biomarker(s) from a relevant patient population both in the research setting and in the real-world setting, and where practical these should be investigated within the project
- Describe a brief plan for how the findings could be progressed into clinical practice and over what timescale

The funding will not support:

- Investigative studies of biomarkers without clear path to patient stratification and improvement of treatment paradigms (i.e. “fishing exercises”)
- Biomarkers which are unlikely to be robust and cost-effective in real-world healthcare (e.g. methodology not appropriate for severity of disease, timecourse of disease or healthcare setting). Applicants are encouraged to speak to the contacts listed below who can advise on this.

Molecular Diagnostics

Molecular diagnostics-related applications which use the MRCfunded infrastructure (namely Manchester Molecular Pathology Innovation Centre and Stoller Biomarker Discovery Centre) are particularly encouraged.

The Stoller Biomarker Discovery Centre (SBDC; £13M MRC capital award) uses advanced mass spectrometry to measure many proteins within a single sample (such as blood, urine, or from tissue such as a tumour biopsy) within a much shorter time than has ever been possible before. The £10million of equipment available mean that throughput of samples is high, suiting clinical research projects. Furthermore validation and verification procedures with GCP compliance allow candidate biomarkers to be developed swiftly on follow up samples. Such approaches are of huge benefit to clinical researchers as it allows them to develop diagnostic approaches – this can give insights into how that disease develops and, importantly, how it might be treated. In addition, by examining the differences in the levels of particular marker proteins from patients who respond to a drug compared to those who don't respond, doctors will be able to identify which drug is the best treatment for individual patients.

The Manchester Molecular Pathology Innovation Centre (MMPathIC; a £3M MRC/ EPRC Molecular Pathology node) has an infrastructure of staff to build a pipeline which will facilitate the translation of markers (from all the 'omics technologies) from discovery research, through to implementation of novel pathology tests to enable the expansion of stratified medicine in the clinic. Depending on the specific requirements of the project, MMPathIC is able to provide support via the node infrastructure (health economics, GCLP validation/ verification labs, text mining and health informatics) and linkage to NHS clinical expertise and pathology laboratories.

The Stoller Biomarker Discovery Centre and the Manchester Molecular Pathology Innovation Centre have been deliberately co-located in a bespoke £3million complex in Citylabs funded by MRC, providing a full translational pathway from discovery through to the clinic.

We encourage CiC applications in the precision medicine, novel diagnostics and molecular pathology areas which may link into the infrastructure developed across MMPathIC and Stoller Centre.

Applicants are encouraged to make contact to discuss the needs of a particular project in the first instance:

- Dr Katherine Boylan (MMPathIC Director of Operations) Katherine.Boylan@manchester.ac.uk
- Dr Julie Brazzatti (SBDC Centre Manager) Julie.Brazzatti@manchester.ac.uk

PET/MR Imaging

We encourage funding applications for imaging studies that utilise the new PET/MR scanner in St Mary's Hospital, Central Manchester NHS Foundation Trust.

The University has been awarded £5.3m from the Dementias Platform UK (DPUK) initiative via the MRC to buy and install the North West's first PET/MR scanner. The GE Healthcare SIGNA PET/MR is a fully integrated 3T PET/MR system and a patient 60cm single bore. The system is fully capable of simultaneous PET/MR in the same field of view, at the same time and presented as co-localised datasets. Although the scanner has been funded for primarily dementia-based research, it can also be used for non-dementia studies.

The scanner is housed in a dedicated scanner suite within the Nuclear Medicine Department of St Mary's Hospital, Central Manchester NHS Foundation Trust. The suite has three treatment rooms (two

of which have bedhead services), a research office, consulting room and a fully-equipped radiopharmacy room for the drawing up of radiotracers. It will be staffed by University radiographers and physicists covering both imaging modalities.

The installation is now complete and testing is now underway, with the scanner expected to be operational from June 2017. CMFT was chosen as the ideal location for the scanner due to its central Manchester location and close proximity to the main University campus, the co-location of the suite adjacent to the clinical PET/CT scanner at CMFT and the opportunity to take research into clinical practice.

The price of using the scanner has been set at £1,550 per hour. This figure does not include the price of the radiotracer which could either be supplied by an external organisation or manufactured at the Wolfson Molecular Imaging Centre. When costing time on the scanner, colleagues should include the time taken to prepare the patient on the scanner bed and also for time after the scan. We recommend for each hour of scanning, an additional 30 minutes is included for this preparation and follow-up time.

For more information on costing, radiotracers and accessing the scanner, please contact Denise Ogden, Senior Project Manager, on x 50017 or by email at denise.ogden@manchester.ac.uk. Denise is also the main contact for signposting colleagues to appropriate research and clinician colleagues in the study design process.