Center for Future Technologies in Cancer Care: Request for Applications 2015

We are looking for big translational ideas for point of care technologies!

- Can you create a blood test that could replace the mammogram?
- Can you create a test to predict the onset of resistance to therapy?
- Do you have a bioreactor technology that could reduce the cost and complication of personalized treatments like T cell therapy?
- Have you designed a mobile app that could get significant numbers of at risk people to quit smoking?

The questions above are examples of the kinds of breakthrough technologies in point of care that could revolutionize the way that cancer is diagnosed and treated.

The Center for Future Technologies in Cancer Care (CFTCC) seeks innovative proposals that focus on translational technologies that meet a need in contemporary cancer care. This is our third solicitation. A clear articulation of the potential impact of a successful demonstration of the proposed technology must be given. Proposals that could impact significant numbers of people will be prioritized.

We plan to fund 2-3 projects for one year starting in July 2016. Budgets of up to $200,000 in direct costs may be requested.

Proposals can focus on needs in the areas of screening, diagnosis or treatment. Diagnosis includes staging of both new and recurrent disease. Treatment can include improved treatment mechanisms (e.g. drug delivery methods), treatment monitoring methods, and/or quality of life interventions for patients in treatment.

Background on the Center for Future Technologies in Cancer Care

The CFTCC is a member of the NIH Point of Care Technology Network (POCRTN, www.poctrn.org)

Cancer care is a continuous process from prevention, screening, diagnosis, and treatment to survivorship. Broad and general barriers to cancer care can be grouped into three categories: patient barriers, provider barriers, and system barriers. Innovative point-of-care (POC) technologies seek to increase the capacity of providers to care for more patients without decreasing the quality of care, increasing burden, or interrupting workflow. New technologies have the potential to reduce the turnaround time from testing to results and allow for more efficient patient triage, treatment, discharge and monitoring.

The POC can be a home, primary care office, clinic, or other location, provided that the technology enables a task to shift from a more to a less sophisticated setting. Cost reduction is one metric on
which technologies will be judged, but an increase in positive patient outcomes and/or quality of life should be paramount.

Technologies that are in the basic research stage will not be considered responsive. While clinical data is not required to be competitive, a clear plan toward generating pre-clinical data is required. Projects should be milestone driven, and a statement of how the grant funds would be used to advance the project over the 12 month project period must be given.

General Design Characteristics for Point-of-Care Technologies in Cancer Care

Cancer care is defined as treatment, monitoring, diagnosis, screening, staging or technologies to improve patient quality of life. Described below are general design features for an ideal POC technology for use in cancer care settings. Although the design should incorporate as many of these features as possible, it is recognized that technology constraints may preclude incorporation of some of these features.

**Footprint:** POC technologies should be designed to have as small a footprint as possible. Small bench top or handheld devices are optimal.

**Analytical Performance:** POC technologies for use in cancer care may produce either quantitative or qualitative results. In the vast majority of cases the same tests are offered on more automated instrument platforms in the central clinical laboratory. As a general rule, the point of care devices should perform equally to state of the art instruments with regard to analytical accuracy, reportable range and imprecision. Exceptions where lesser degrees of analytical performance may be acceptable include devices designed as screening tests (to be followed up by confirmation in a central laboratory), devices for monitoring a changing status in a patient or devices that produce unique test results that are not available in a central laboratory or using other technology. Analytical time should be kept to a minimum.

**Information connectivity:** All instrumented POC technologies should be capable of being interfaced directly to an electronic medical record system. Several companies offer open architecture POC data management systems designed for this purpose. Industry standards specifying the appropriate connectivity architecture have been developed and are available from the Clinical Laboratory Standards Institute. The ability to transmit data using a bidirectional wireless interface is most optimal.

**Ease-of-Use:** Ease-of-use is essential to successful implementation of POC technologies. In the case of instrumented devices the user interface with the device should be designed to ensure regulatory compliance under the clinical laboratory improvement amendment (CLIA-88) with minimal requirements for intervention by the operator. Results readout must not be subjective but easy to read using color change readout, digital or graphic formats. The use of required fields including operator identification, patient identification, date and time of the test, confirmation that quality control has been performed and confirmation that reagents are within their expiration date should
be embedded in the user interface. The use of barcode scanners, RFID chips and touch screen technology should be employed to facilitate data transfer and to ensure accuracy of the information entered. Ideally the device would be interfaced to the institutional ADT system to cross check accuracy. Of course, devices that are not monitoring or diagnostic devices will not be held to this standard.

**Sample types:** Whole blood or other unprocessed samples are the most optimal choices for POC. The use of serum or plasma that must be processed before analysis is to be avoided. Ideally instruments can perform primary tube sampling without the need for de-capping and pipetting samples. Where possible, samples that do not require a trained phlebotomist should be used such as capillary finger-stick whole blood or saliva.

**Reducing Operator errors:** The device should have built in software safeguards to ensure proper operation and reduce common errors such as lock-out of untrained operators, lock-out for failed quality control (or failure to perform quality control) and lock-out of expired reagents. The device software ensures that the quality control values are within acceptable range before testing can be performed.

**Storage of Consumables:** The shelf life should be minimally 6 months to 1 year

**Pre-Proposal Guidelines:**

- Pre-proposals are to be completed on this template, filling in application sections in the below section headings in the relevant blocks.
- Pre-proposal length limit is 2 pages, including figures and graphics. Please leave margins and font size as is.
- Pre-proposals submission format should be Word .doc file (preferred) or as a .pdf.
- Files should be saved locally for your records, and then attached to email. File naming should follow the convention PILastName_CFTCCPreProposal_Year.doc (i.e. Smith_CFTCCPreProposal_2015.doc). If you are submitting multiple pre-proposals, please name them differently.
- **Pre-proposals are due by 11:59pm (midnight) on 15 December 2015 to hfawcett@bu.edu.**
- Announcement of applications selected for full proposals will be on 21 December 2015 via e-mail to the contact PI.
- Full proposals will be due on 29 January 2016.
- Awards will be announced in April 2016.
- Project starts will be on 1 July 2016 for a 12 month period.

Best Regards,
More information about the CFTCC is at www.bu.edu/cftcc

Please address questions to Helen Fawcett at hfawcett@bu.edu