


POCTRN

INNOVATIVE POINT-OF-CARE TECHNOLOGIES

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IF YOU HAVE A GREAT IDEA FOR THE POINT-OF-CARE, WE'LL HELP YOU MAKE IT A REALITY.

The Boston University Center for Future Technologies in Cancer Care (CFTCC) focuses on the identification, prototyping, and early clinical assessment of innovative point-of-care technologies for the treatment, screening, diagnosis, and monitoring of cancers.

A major aspect of this effort involves assessing early-stage technologies in terms of clinical needs, market demands, and setting appropriateness. We provide seed funding for projects along the translational spectrum. A particular strength of the center is prototyping services that enable next-stage testing of new devices and methodologies.

The center is a member of the NIH Point-of-Care Technologies Research Network (POCTRN), which allows access to the core services of other member centers. This integrated, multidisciplinary team of engineers, clinicians, public health practitioners, and technology transfer experts is currently evaluating technologies in various stages of development for suitability across a range of primary care and nontraditional health care settings.

CFTCC would be pleased to talk with you about your project. You'll find our contact information on the back cover.

ONE OF A KIND

PROTOTYPING Alpha Core

The center facilitates the development of new and innovative technologies to address diagnostic needs in cancer care through the Alpha Prototyping Core. The core enables researchers (in industry, academia, and medicine) from across the country to build rapid prototypes of their devices.



PI Rajan Dewar, PhD, MBBS, *University of Michigan*

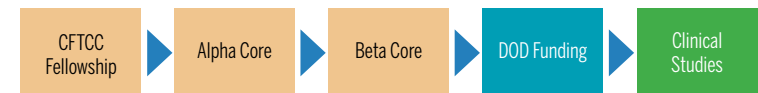
Jane Dx—Paper fluidic HPV screening Jane Diagnostics is in the early stages of developing a device to perform molecular screening for human papillomavirus (HPV), the cause of most cervical cancers, to be used primarily in the developing world. The project started out in the Alpha Core, which provided paper fluidic prototypes for early tests. (Lab Chip. 2016 Feb 21;16(4):753–63)

The success of the initial stage of the project led to new funding, specifically a Center for Integration of Medicine & Innovative Technology (CIMIT) Innovation Grant. The team has now completed the CIMIT CRAASH course in commercialization. Jane Diagnostics incorporated in 2016 to pursue Small Business Innovation Research (SBIR) funding.

ADVANCED PROTOTYPE

PROTOTYPING Beta Core

The Beta Prototyping Core combines the efforts of the CFTCC and the Fraunhofer Center for Manufacturing Innovation. The Beta Core assists projects in gaining insight and design plans for developing a next-generation prototype device suitable for robust clinical use.



PI Darren Roblyer, PhD, *Boston University, College of Engineering*

A new wearable technology for chemotherapy monitoring

There is growing evidence that noninvasive diffuse optical measurements, which use near-infrared (NIR) light to track tumor oxygenation and blood volume, can predict long-term response and resistance to systemic cancer therapies in breast cancer patients. This idea has tremendous potential to change the way almost all cancer patients are treated, providing opportunities to continuously adapt therapeutic regimens using real-time optical feedback, helping to avoid multi-drug resistance, and improve overall survival.

The group is exploring optical signatures of systemic therapy response and resistance in multiple organ sites and cancers including breast and osteosarcoma. They have also identified a growing number of relevant time points during pre-surgical (neoadjuvant) chemotherapy which correlate with long-term pathologic response.



**PATENTS, COPYRIGHTS,
TRADEMARKS, FUNDING,
HOW TO BUILD PROTO-
TYPES...THERE'S A LOT
TO GETTING FROM IDEA
TO IMPLEMENTATION.
THE CENTER OFFERS
PRESENTATIONS AND
WORKSHOPS TO HELP
INNOVATORS NAVIGATE
THE OFTEN-COMPLICATED
PATH OF DEVELOPMENT.**

LEARN HOW

EDUCATION, WORKSHOPS, AND TRAINING

IND/IDE and Reimbursements Workshop

The workshop introduces the basics of filing an Investigational New Drug (IND) Application with the FDA, filing an Investigational Device Exception (IDE) Application with the FDA, and reimbursement (coverage, codes, and payment).

CFTCC: Introduction to Patents, Copyrights, and Trademarks

Boston University's Technology & Development office leads a conversation on patents, copyrights, and trademarks for groups in academia, industry, and start-ups.

New Directions in Cancer Care for Nonspecialists: Immunotherapy and Resistance to Therapy

The one-day seminar focuses on both synthetic biology approaches to improve the efficacy and safety of adoptive T-cell therapy, and the use of combination anticancer therapies to achieve complete remission and cures for patients with cancer.

Hack Cancer

Calling all hackers, the center supports the development of new and innovative projects with a hack-a-thon focused on cancer care. In addition to hosting our own events, we now also sponsor CAMTech's Global Cancer Innovation Hack-a-thon.

Point-of-Care Technologies Workshop

The workshop provided attendees with a working knowledge and practical skill set to assess and apply metrics of success of point-of-care systems in the spaces of diagnosis, device, and drug delivery systems.



PROOF OF CONCEPT

A NON-ENZYMATIC DNA AMPLIFICATION CIRCUIT FOR CANCER BIOMARKER TESTING

PI Andrew Ellington, PhD, *University of Texas, Austin*

Co-PI Rhoda Alani, MD, *Boston University School of Medicine*

Current molecular cancer diagnostics are not amenable to point-of-care testing. The team is seeking to effectively transition molecular diagnostic testing into a point-of-care setting through the development of an integrated paper fluidic platform that will automate cancer biomarker testing in a manner similar to a classic diagnostic paper test strip. Development will include a handheld electronic reader that further streamlines the already-simple sample analysis and produces a user-readable result that can be wirelessly transmitted. The proposed system will combine extremely novel molecular techniques with mature, robust diagnostic technologies designed for point-of-care testing.

Melanoma is responsible for the majority of deaths from skin cancer, and was the sixth most common cancer in the US in 2010. Histologic examination of early melanoma lesions is difficult and not always predictive for malignant potential. That presents a clinical challenge. Recent studies are encouraging, having identified a panel of robust gene expression biomarkers that can be used to aid melanoma patient care. Using melanoma biomarkers as proofs of principle, the project will address this problem by incorporating gene expression-based and serum-based biomarker detection with an integrated solution for detection in limited-resource settings.





ADVANCED PROTOTYPE

OPTICAL IMAGING FALLOSCOPE FOR OVARIAN CANCER DETECTION

PI Jennifer Barton, PhD, *University of Arizona*

Ovarian cancer is the deadliest female reproductive malignancy, largely due to the lack of early-stage symptoms or effective screening measures. Those who receive the current screening tests are no less likely to die of ovarian cancer. It has been suggested by research that much of the most lethal subtype, high-grade serous ovarian cancer—responsible for 70% of the diagnoses—originates in the distal fallopian tube and migrates to the ovarian epithelium. Therefore, a test that screens both the ovaries and fallopian tubes in high-risk women is needed.

Barton's group has developed a highly flexible, steerable, 0.7 mm-diameter dual-modality endoscope small enough to be introduced transvaginally to screen for ovarian cancer. However, the use of the current prototype would be a challenge for non-specialists. They will develop a second-generation falloscope package for practical use. They will simplify the delivery method to decrease the chances of perforation or other injuries. The final device could then be potentially used as a screening method in primary care OB/GYN settings in addition to specialized centers, vastly increasing patient access to early diagnosis and treatment decision options.





FEASIBILITY TESTING

PERSONAL HEALTH NETWORK TECHNOLOGY FOR CHEMOTHERAPY

PI Katherine Kim, PhD, and Jill Joseph, PhD,
University of California, Davis

Nurse care coordination assists patients navigating complex care and treatment, and improves both the patient experience and health care utilization. This research will explore whether an innovative Personal Health Network (PHN) technology can improve outcomes for cancer chemotherapy patients receiving nursing care coordination, particularly those confronting significant disadvantages in accessing well-coordinated care (e.g., publicly insured patients, rural residents). Little is known regarding how to optimize the value of technology such as we will deploy in supporting cancer patients in this population. Existing funding supports patient recruitment, intervention, and outcome assessment, but provides no opportunity to adequately evaluate and modify, as necessary, the patient-technology interface. The project's overall goal is to ensure that the novel PHN technology meets the needs of disadvantaged cancer patients receiving nursing care coordination.





VALIDATION

LATERAL FLOW HPV TEST FOR CERVICAL CANCER SCREENING IN LOW-RESOURCE SETTINGS

PI Rebecca Richards-Kortum, PhD, *Rice University*

Cervical cancer is a leading cause of cancer death among women in the developing world. Screening programs to detect HPV, the cause of cervical cancer, have reduced the incidence and mortality of cervical cancer in the developed world. However, these screening programs are not appropriate for low-resource settings due to their high cost and need for infrastructure and trained personnel. To enable global cervical cancer prevention efforts, Richards-Kortum's team proposes to develop an inexpensive (<\$2), robust, and rapid (<60 min.) HPV DNA test that does not require lab equipment and is as simple to use as a rapid HIV test.

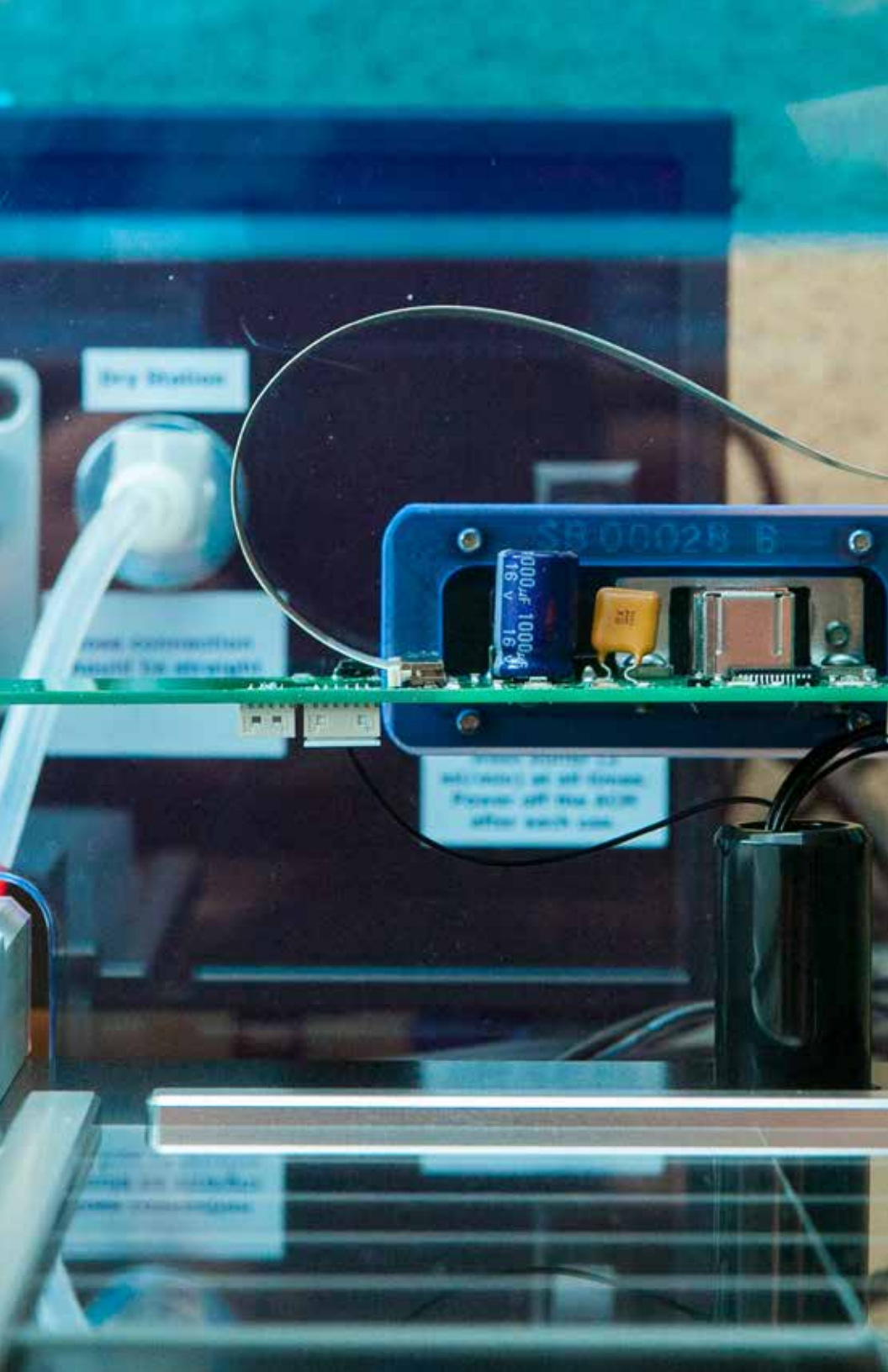
Their approach is based on a sensitive lateral flow test to detect high-risk HPV DNA. They hypothesize that their lateral flow HPV DNA test can be performed by community health care workers with sensitivity and specificity similar to commercially available hybrid capture HPV DNA tests.

The proposed work will allow the team to optimize sample preparation methods, fully characterize test performance in the lab, and assess usability of the device in a point-of-care setting. Results of this work will enable efficient identification and resolve any in-field challenges before proceeding to subsequent field evaluation studies.

CFTCC
Funding



Validation
Testing



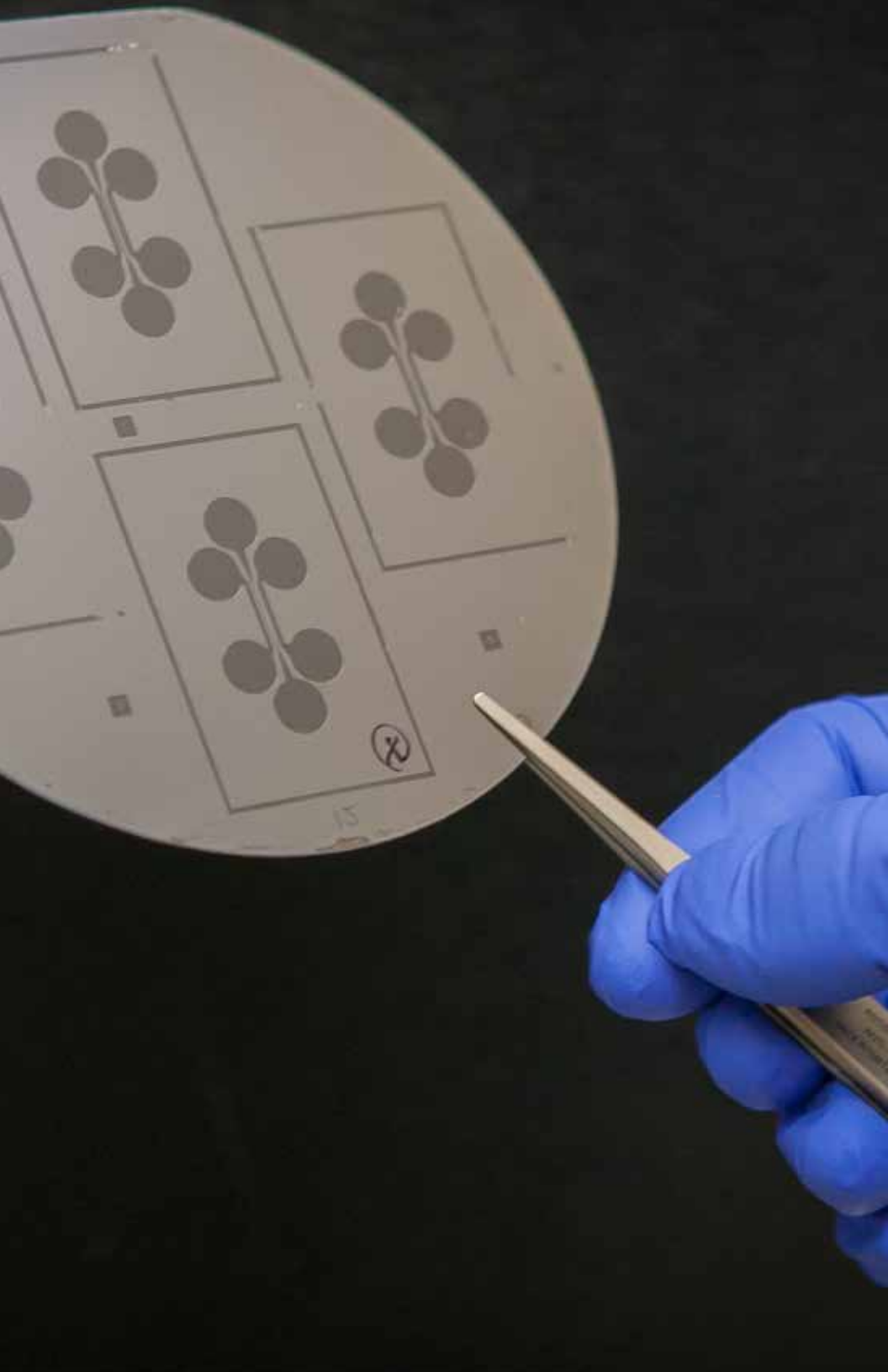
NEW IDEAS WELCOME

CLINICAL NEEDS OUTREACH

The center aims to engage clinicians, patients, and patient advocates at all stages of technology development. At any time, clinicians can bring new ideas or clinical needs to center leadership, who will then act to connect clinical partners with appropriate resources and expertise in the engineering and product development space. The center also frequently reaches out to clinical partners to define and refine major clinical needs in cancer care, which inform our competitive grant-making programs. Another major function of the center is bringing clinicians, scientists, and engineers together in a variety of venues to look for opportunities to improve patient care throughout the continuum of care.

The Clinical Needs Assessment (CNA) Core In alliance with BU-BMC Cancer Center, CNA Core seeks to identify and define clinical needs in cancer care that can be effectively addressed by point-of-care technologies. The core transforms insight from practicing surgical and medical oncologists into tangible concepts and specifications for future technologies that are used to inform technology development solicitations. A steering committee of clinicians and other leaders in diagnostics and medical devices serve on the Clinical Advisory Board.

Several informative surveys conducted in conjunction with the Dana-Farber Cancer Institute revealed that precision diagnostics and point-of-care technologies are often not familiar to those working in clinical settings. Through consultation with our Clinical Advisory Board, External Advisory Board, and the other POCTRN members, the CNA Core works with oncologists at the three POCTRN network locations (Boston Medical Center, Johns Hopkins, and Mass General Hospital) to promote the use and development of point-of-care technologies.



POINT-OF-CARE TECHNOLOGIES RESEARCH NETWORK (POCTRN)

In our evolving health care system, primary care physicians and nurses are assuming more significant roles, with the patient more involved in decision-making and self-care. These changes require the development of inexpensive and easy-to-use medical devices and information-sharing tools that provide timely health status information at the point of care.

To meet that challenge, the National Institute of Biomedical Imaging and Bioengineering (NIBIB) created the Point-of-Care Technologies Research Network in 2007. The Boston University Center for Future Technologies in Cancer Care is a member. POCTRN drives development of point-of-care diagnostic technologies through collaborative efforts that merge scientific and technological capabilities with clinical need. Find opportunities for collaboration with member centers at www.poctrn.org/engagements or contact Tiffani Lash at baileyti@mail.nih.gov or 301-451-4778.

Other POCTRN Centers

CIMIT Point-of-Care Technology Research Center in Primary Care
cimitcolab.org/web/cimit-poctr/home

Johns Hopkins University Center for Point-of-Care Tests for Sexually Transmitted Diseases
hopkinsmedicine.org/medicine/std/

WANT TO WORK WITH CFTCC, OR WANT MORE INFORMATION?

If you have an idea for cancer care and need help turning it into reality, or if you'd just like to learn more about CFTCC, visit our website: bu.edu/cftcc.

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