Development of the Programmable Bio-Nano-Chip: Bridging the Commercialization Gaps

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Today there are about 7B mobile phones worldwide and about 50,000 mobile health applications actively changing the landscape of how healthcare will be delivered in the next few years. While numerous physical MEMS-based sensors (MEMS accelerometers, MEMS autofocus, MEMS gyroscopes, etc.) are already integrated into smart phones, the linkage to chemical sensors remains largely untapped. Currently, 60 to 70% of medical decisions are made using diagnostic tests. New medical microdevice technologies derived from micro/nano activities provide potential solutions to bridge this significant clinical gap. However, today there are four major inhibitors to the successful commercialization of micro/nano-based medical diagnostic products: 1) First, adaptation of micro/nano sensors for use at the point-of-care has been challanging; 2) Second, current micro/nano sensors systems fail to compete with remote laboratory testing, both from cost and performance vantage points; 3) Third, micro/nano sensors systems typically lack new content that is not already available through remote labortories; and 4) Forth, the multiple phases of regulatory approval that traditionally take a decade to complete, slow the migration of new tests to these potentially portable platforms.

To help overcome these significant barriers, the McDevitt laboratory and SensoDx recently have developed the Programmable Bio-Nano-Chip (p-BNC) system. This platform technology combines unique chem- and biosensing capabilities with powerful machine learning algorithms to provide novel and intuitive single-valued indices across several major diseases. This presentation will feature the commercialization challenges faced in moving this versatile platform technology from the laboratory bench to the patient's bedside. Major challenges to be discussed here will include development of new methods to prototype devices, the integration of the subcomponents into functional devices, materials choices that mitigate problems with nonspecific biological interations, development of mass-scalable manufacturing methods, development of methods to stabilize labile bioreagents, optimization of bioassays so as to compete with gold standard tests and validation of multimarker panels through completion of large-scale clinical trials. Overcoming these barriers has paved the way for first in kind insights related to early disease detection for cardiac heart disease and oral cancer.

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