

**The problem:** Bioweapons and naturally occurring emerging infectious pathogens that cause major outbreaks are unbounded by borders and pose a significant threat to national security. The ability to detect, track, investigate, and respond to viral pathogens affecting human, animal, and plant health is paramount to the safety and well-being of Americans. **However, current methods are not able to detect novel and emerging viral threats in a timeframe needed to effectively respond to biothreats.**

**What do we do and who we do it for:** Our mission is to commercialize hardware and software pathogen detection tools to find, stop, and prevent infectious diseases. Our primary customers are the Directors of public health and epidemiology laboratories within the Departments of Defense and of Health and Human Services, including the CDC, USAMRIID, Armed Forces Health Surveillance Branch, and the FDA. With support from the National Science Foundation Innovation-Corps National Program, Incelera conducted over 300 customer interviews to understand their workflow and current challenges. Laboratory directors are responsible for developing and operating biosurveillance networks to identify and track biological threats. Current surveillance methods use next generation sequencing technologies to detect emerging pathogens and map their genomes. Genomic datasets are manually annotated and analyzed by lab personnel to design rapid, field-deployable targeted molecular assays. However, major challenges still remain on creating robust software solutions to analyze such data. As a consequence, the cycle from detecting a new pathogen to developing targeted tests takes months, causing tremendous loss of government resources.

**To address these challenges, Incelera is commercializing a software suite called Systems for Emerging Natural Threat Recognition & Identification (SENTRI).** SENTRI automatically and accurately classifies viruses and reconstruct genomes, even when viruses are in low concentrations. These capabilities are critical for surveillance to detect viruses from sequence data and provide candidate targets for molecular assays to support epidemic surveillance. SENTRI enables customers to achieve i) earlier identification of intentional or natural emerging infectious disease ii) expedient public health threat and risk assessment (situational awareness in theater and States-side); iii) accelerate the deployment of effective medical countermeasures. Importantly, the software correctly assigns taxonomic identity at the genotype/serotype level of viruses, even at low concentrations. With this analytic pipeline, the team was able to demonstrate unparalleled capabilities to classify viruses and provide genomic reconstruction for the viruses detected. **These technological capabilities align strongly with the proposed Army Modernization Priorities of Network Infrastructure (Intelligence, Surveillance, and Reconnaissance) and Soldier Lethality (field medical care) to provide resilient mission command and exploit the technological superiority against a peer adversary.**

**How we do it:** SENTRI is based on an algorithm that maximizes viral information recovery to provide the highest level of taxonomic resolution possible (genotype/serotype). It operates independent of sequencing platform and coverage depth. This algorithm was created out of the necessity to accurately define viral taxonomies from clinical and environmental samples which lacked closely related database entries. This technology and other products being developed at Incelera were developed with \$500k from DARPA and funds from the Alkek Center for Metagenomics and Microbiome Research (CMMR) at the Baylor College of Medicine (BCM). We have already completed proof-of-concept studies with clinical collaborators, which was recently accepted for publication in Nature Communications. These data demonstrate that this new tool offers unprecedented capabilities in detecting and classify viruses, even in the most diverse microbial communities. SENTRI offers a major advancement over existing viral

classification pipelines in the accurate detection and identification of viral sequences and by providing the user with reconstructions of viral genomes for targeted-assay design. In summary, this pipeline provides a unique methodology for viral detection and classification with relevance in clinical virology, viral surveillance, and molecular epidemiology. Of particular relevance to military operations, our software provides a means for classifying unknown viruses or mutant strains without prior knowledge of the target. In effect, the system is a building a dynamic database on the fly so that emerging threats are not missed.

**Who we are:** Incelera was spun out of the CMMR in 2017. Currently there are four members: **Nadim Ajami, PhD (CSO)** was an Assistant Professor of Molecular Virology and Microbiology at BCM where he built the CMMR, a microbiome center that currently supports over 500 projects. Dr. Ajami also co-founded Diversigen, Inc., a microbiome sequencing company spun out of BCM in 2012.

**Lorenzo D'Amico, PhD (CEO/CTO);** was a research biomedical engineer at CMMR and led the technology development effort under DARPA project and was the entrepreneurial lead during customer discovery NSF project.

**Matthew Wong, BS (Lead Software Developer),** was a senior bioinformatic programmer at the CMMR. Matthew co-authored a publication with Dr. Ajami describing the SENTRI algorithm.

**Jill Thompson, BS (Head of Business Development)** was the Senior VP of Business Development at OraSure Technologies. Jill joined the team as Industry Mentor for the NSF project, and has a track record working medical device and diagnostic startups and has closed nearly \$1B in business dealings.

**Next steps are to demonstrate integration with customer operations**

We are already working closely with collaborators in different parts of the world to apply this SENTRI for molecular epidemiology and biosurveillance. We are currently raising capital to conduct proof-of-feasibility studies with partners and potential customers at CDC Puerto Rico Division for Arboviruses, FDA Center for Food Safety and Applied Nutrition, the clinical institutions at the Texas Medical Center, UCLA Health, and the Children's Hospital of Philadelphia. In addition, we plan to work with the Armed Forces Health Surveillance Branch to conduct pilot studies. Overall the goal of these studies are to generate key data from real-world use-cases. In addition, we are working with the American Type Culture Collection (ATCC), which is currently developing new viral standards, to differentiate Incelera in the market as having the most comprehensive and high-quality genomic databases.

***Desired Technology Pitch location:*** Austin, TX.

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