Battelle Capabilities & Team Summary

Battelle is a large nonprofit research and development organization, with over 22,000 employees at more than 60 locations globally. A 501(c)(3) charitable trust, Battelle was founded on industrialist Gordon Battelle's vision that business and scientific interests can go hand-in-hand as forces for positive change. Our interests broadly range from energy and environment to health and analytics to national security. Battelle is the largest private U.S. high-containment (BSL-3+ and Chemical Surety labs) contract research organization for complex and trace level sample analysis with ISO 13485:2003 and ISO 9001:2008 certification. Our capabilities relevant to this program are highlighted below.

Bioinformatics / Data Analysis

Battelle has developed several tailored bioinformatic routines for various customers. For example, Battelle is a prime IARPA contractor for Functional Genomic and Computational Assessment of Threats (Fun GCAT) program for rapid classification of threatening DNA sequences using custom analytics and in-house knowledge database for organisms and sequences of concern. As part of this program, **we delivered UltraSEQ (to IARPA)***:* Bioinformatic Software for accurate, science-informed, flexible analysis of genomic datasets. UltraSEQ's base functionality takes input genomic data and efficiently outputs prediction results for taxonomy, biothreat function, and a user-defined rules engine based on alignments and built-in modules. The flexible rules engine is rooted in UltraSEQ's proven prediction capabilities backed by trusted biological data curation practices and allows the flexibility to leverage Battelle's pre-installed models (e.g., genetic engineering signature detection) as well as user-defined models for sequence triage. UltraSEQ was built and is maintained by Battelle's Supporting Infrastructure, which has decades of experience in intelligence and defense applications across various scientific disciplines. ***UltraSEQ provides a logical and modular framework to enable incorporation of additional modules (such as a module developed on the TEI-REX program).***

Additional informatic and data analysis experience is available upon request; a few notable examples include:

- Design & execution of large-scale clinical studies to understand effect of extrinsic & intrinsic factors in microbiome modulation

- Leveraging multi-omics sequencing approaches and cutting-edge computational biology tools to understand complex host-microbe interactions

- Advanced analytics using machine and deep learning for decision making from disparate datasets.

- Multiple regression random forest algorithm and related machine learning techniques to predict the cytotoxic potential of environmental toxins and exposure biomarkers.

- Deep learning algorithms to decode brain activity from a chip implanted in a paralyzed man's motor cortex (NeuroLife™ Neural Bypass Technology).

- Development of bioinformatic tools for easy analysis of peptides and other signatures from LC-MS/MS data.

Forensics / Trace Analysis

For over two decades, Battelle has been a commercial-leading sample analysis and method development partner for the U.S. Government (USG) for complex and trace level sample analysis.

- For approximately the past 10 years, Battelle has used mass-spectrometry-based proteomics for numerous programs, including the identification and quantification of proteins from human hair and touch samples, transgenic crops, virus-like particles, cell cultures, environmental samples, and several other matrices.

- Battelle is also a recognized leader within the forensic DNA community with demonstrated laboratory compliance with the Federal Bureau of Investigation (FBI's) DNA Quality Assurance Standards for Forensic DNA Testing Laboratories. Battelle's DNA forensics programs have resulted in advanced MPS and bioinformatics methods to support human identity, kinship, phenotype, tissue type and ancestral origin applications from internal independent research and development, and external funding.

- Additionally, Battelle has experience in developing methods and materials and in conducting controlled studies to develop a touch DNA recovery capability. For a USG customer, Battelle designed, executed, and delivered methods and hardware specific to recovering and characterizing (STR profiling) touch DNA.

Animal Testing and Radiobiology

- 200,000+ ft^2 laboratory space that includes animal facilities:
    - ABSL-3 containment area with 15 animal rooms and 22 ABSL-3 laboratories; 2 ABSL-2 animal rooms and 8 ABSL-2 laboratories.
    - Aerosol Exposure Laboratory – Specialized laboratories for generating aerosol exposure challenges of ABSL-2 and -3 threat organisms and highly toxic materials.
    - Highly Toxic Materials Laboratory –29 ABSL-2 animal rooms; 15 laboratory areas with 144 linear feet of filtered chemical fume hoods for working with neat (pure) chemical warfare agents.
- Many staff are enrolled in biological/ chemical Personnel Reliability Programs. Additional certifications include CDC/ UDA Select Agent; ISO 9001-2008; American Association for Accreditation of Laboratory Animal Care (AAALAC) accreditation; Office of Laboratory Animal Welfare (OLAW) assurance compliance; USDA Class R Research Facility under the Animal Welfare Act; FDA for work according to Good Laboratory Practices (GLP).
- As part of Battelle's Environment, Safety & Health (ES&H) organization, Battelle's Radiation Safety implements all components of Battelle's radiation safety program, including managing radioactive material licensing activities. Services include radiation consulting services for both safety purposes and specialized research capability augmentation; guiding and promulgating radiation safety practices; and providing operational oversight of activities that use or generate ionizing radiation. Radiation Safety also manages Battelle's internal chemical and radiological remediation projects. Battelle facilities have the ability to test the following:
    - Delivery of low doses of alpha and beta radiations: α / β / γ (or x-ray) / (γ + neutron)); localized or whole (animal) body; larger animals may be limited and partners would be needed for those.

Battelle Genomics Facilities

Battelle genomics facilities are equipped with the latest instrumentation to meet the needs of the program, and teaming agreements in place with other area research facilities that enable us to gain access to additional equipment and services as needed. The Battelle Omics Laboratory Suite incorporates top of the line instrumentation with established unidirectional workflows that reduce contamination to ensure clean, reproducible results. Our Omics facility design includes separate DNA and RNA extraction laboratories, as well as designated pre-amplification and post-amplification laboratories for sequencing library preparations. These laboratories are equipped with all equipment necessary for performing extractions, library preparations, sequencing, nucleic acid quantification and quality control including: QIAcube, PCR and qPCR instruments, Agilent Bioanalyzer, Covaris, spectrophotometric (Nanodrop) and fluorometric (Quantus, Qubit) DNA and RNA quantification instruments, and benchtop sequencers including a MinION, NextSeq550, MiSeq, and MiSeqDx. Furthermore, Battelle constantly grows our omics capabilities through capital equipment purchases which are determined based on evaluation of equipment updates or needs to better serve our clients.

Key Personnel in Proposed Battelle Team

Chiranjit Mukherjee, Ph.D. Dr Mukherjee has over 7 years of experience in computational biology related to host-microbiome studies, specializing in applying advanced data analytics to solve biological questions related to microbial community structure and function. He has extensive background in biotechnology, molecular biology, microbiology, and bioinformatics, with advanced degrees in Microbiology and Biomedical Sciences - focusing on microbiome data analysis. Prior to joining Battelle in 2021, Dr. Mukherjee worked as a Bioinformatics Scientist at Second Genome Inc. where he was involved in utilizing multi-omics methods to better understand relationship between systemic diseases and the human gut microbiome.

Craig Bartling, Ph.D. Dr. Bartling has a Ph.D. in Biochemistry, with 18+ years of research experience in the life sciences, including the past 5 years dedicated to biosecurity, threat assessment, and forensic intelligence. Dr. Bartling is currently the PI for the IARPA FunGCAT Program as well as data curation lead for Battelle's ThreatSEQ Web Service; in these roles, he provides technical guidance and leadership to a multi-discipline team, effectively facilitating productive communications between data scientists, software developers, and biological scientists.

Danielle Huk, Ph.D. Dr. Huk holds advanced degrees in Toxicology and Molecular and Cellular Pharmacology and serves as a Genomics Lead Scientist at Battelle. She has served as principal investigator or task lead for several programs in molecular biology assay development, omics-based diagnostic capability development, metagenomics-based ecological observation, and toxicogenomic analysis of drug compounds.

Bryan Gemler Brian is a computational biologist at Battelle Memorial Institute, serving as bioinformatics and biological data science task leads for several programs in the biosecurity, environmental, and toxicology spaces, including the Battelle ThreatSeq web service and IARPA FunGCAT Program. His areas of expertise include deep scientific programming, state of the art genomics and transcriptomics bioinformatic tools and techniques, and building/deploying big data analysis pipelines.

Patrick Fullerton – Patrick has a Bachelor's Degree in Physics, with several years of research experience. He serves as a software research scientist at Battelle where he supports the FunGCAT Program. He is responsible for generating and collecting data from Battelle's UltraSEQ software. He curates, cleans, and creates databases, and performs statistical, exploratory, and regression analysis on large datasets.