

MCDC Speed Networking Session

Day 1 Afternoon Session





MCDC

Whitespace Enterprises Corporation



MCDC Member Information	Member Capabilities relevant to MCDC and MCM
<p>Whitespace Enterprises Corporation Phoenix, AZ</p> <p>Key POC(s): Dr. Frederic Zenhausern, fzenhaus@email.arizona.edu Tom Miller, tom@wsecorp.com</p> <p>Business Class: Small</p> <p>Trad/Nontrad Status: Nontraditional</p> <p>Member since: March, 2018</p>	<ol style="list-style-type: none"> 1. Contract Development <ul style="list-style-type: none"> • Medical Devices & Immunoassays • ELISA, LFI, VFI 2. Proprietary Medical Device Platforms <ul style="list-style-type: none"> • VERIFAST™ Vertical Flow Immunoassay • NUCLEAIR™ (Numerous Capillaries Lancet Emergency Assays for In-Route processing) • Health Logistics (In-transit Pre-processing) • POC Drug Testing; CBRN; forensics (MiDAS™) 3. CLIA-based DNA Extraction & Quantification
MCDC Project Awards/Other MCM Relevant Efforts	Desired Teaming Areas
<p>Pending OTA submission in response to MCDC-RPP-18-04 DET-18-04-09; Multiplex Vertical Flow Paper-based Immunoassay (VPI) Diagnostic System</p>	<ul style="list-style-type: none"> • Biomarkers Panel Selection & Validation • Assay Development & Validation • Advanced Development & Manufacturing • Logistics and CBRN Threats



ANBM @ University of Arizona



MCDC Member Information	Member Capabilities
<p>Center for Applied NanoBioscience and Medicine (ANBM) at the University of Arizona & College of Medicine Phoenix Phoenix, AZ</p> <p>Key POC(s): Dr. Frederic Zenhausern; fzenhaus@email.Arizona.edu ; T: +(602)-827-2051</p> <p>Business Class: Academic</p> <p>Status: Nontraditional</p> <p>Member since: March 2018</p>	<ol style="list-style-type: none"> Research & Development <ul style="list-style-type: none"> Medical Devices, Assay Chemistries, Biomarkers Discovery, Bioengineering Translational Genomics Rapid Prototyping, Electronics, Instrumentation Product Development Platforms <ul style="list-style-type: none"> Plastic manufacturing (e.g. injection molding) CMOS nanofabrication; Nanoimprinting Lithography Compliance & Regulatory Studies (GLP, FDA...) Clinical studies (Phase 1 &2) Engineering Services (BSL-2; Cleanroom 100)
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<ol style="list-style-type: none"> 1) MCDC-RPP-18-04 DET-18-04-09; Multiplex Vertical Flow Paper-based Immunoassay (VPI) Diagnostic System; pending OTA; 2) HDTRA1-16-C-0026; Vertical Flow Assay / Tier 1 pathogens 3) BARDA HHS0100201000001C - HT Biodosimetry 	<ul style="list-style-type: none"> Biomarkers Panel Selection & Validation Assay Development & Validation Advanced Development & Manufacturing Logistics and CBRN Threats



MCDC Member Info

GigaGen, South San Francisco, CA

Key POC(s): Sheila Keating, PhD

Business Class: Small

Status: Nontraditional

Member since: June, 2018

GigaGen Surge Technology for Ab Therapeutics

Isolate B cells

Generate & screen
scFv library

Make antibody

A. Trianni humanized mouse (immunized)



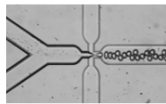
B. Human vaccinee



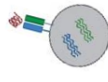
C. Human survivor



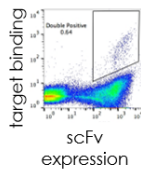
1. Single B cells —
millions isolated by
microfluidics



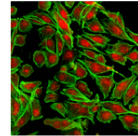
2. Millions-diverse
library of scFv
expressed on
yeast cell surfaces



3. High-affinity
scFv binders
to target
enriched by
flow sorting



1. Directed genome
integration



2. Standard
bioproduction



Member Capabilities

- From antigen to full length antibody production in 3 months
- Rapid development of mAb and pAb therapeutics

Desired Teaming Areas

- Antigen discovery and vaccine development groups
- In vitro neutralization assays
- Animal efficacy models
- Regulatory and CMC
- Large scale production

MCDC Project Interest

- Rapid response to biological threats
- Development of fully-human mAb and pAb therapeutics for pre-exposure prophylaxis and post-exposure therapeutics

Emergent BioSolutions

Gaithersburg, MD

Veronica Hall, HallV@ebsi.com

Traditional DoD Contractor, Member since 2015

Awarded: Development of a dual drug delivery device (autoinjector)

Desired Teaming Areas

- Manufacturing Partnerships
- Development Partnerships
- Companies with Novel Technologies

10 MARKETED PRODUCTS	BIOLOGICAL THREATS							
	BioThrax® ANTHRAX VACCINE	ACAM2000® SMALLPOX VACCINE	Raxibacumab ANTHRAX THERAPEUTIC	Anthrasil® ANTHRAX THERAPEUTIC	VIGIV SMALLPOX VAC THERAPEUTIC	BAT® BOTULISM THERAPEUTIC		
	CHEMICAL THREATS		PUBLIC HEALTH THREATS					
	RSDL® REACTIVE SKIN DECON LOTION	Trobigard™ NERVE AGENT AUTO-INJECTOR	Vivotif® ORAL TYPHOID VACCINE	Vaxchora® ORAL CHOLERA VACCINE				
9 GMP FACILITIES	MANUFACTURING EXPERTISE							
	CLINICAL AND COMMERCIAL SCALE	PROCESS DEVELOPMENT	ANALYTICAL & LABORATORY SERVICES	cGMP BULK DRUG SUBSTANCE	cGMP FINAL DRUG PRODUCT	FILL / FINISH LABEL / PACK DISTRIBUTE	VIRAL BULK MANUFACTUR- ING & VIRAL FILL / FINISH	LYOPHILIZA- TION, CAPSULATION
4 BUSINESS UNITS	R&D AND COMMERCIAL EXPERTISE				11+ CBRN/EID PIPELINE CANDIDATES	6 PROPRIETARY PLATFORMS & TECHNOLOGIES		
	VACCINES & ANTI-INFECTIVES	ANTIBODY THERAPEUTICS	DEVICES	CONTRACT DEVELOPMENT & MANUFACTURING				



MCDC

Microbiotix, Inc.

MICROBIOTIX
Inc.

MCDC Member Information	Member Capabilities
<p><u>Microbiotix, Inc.</u> Worcester, MA</p> <p><u>Key POC(s):</u> Terry Bowlin, Ph.D., tbowlin@microbiotix.com; Kim Kapteyn, kkapteyn@microbiotix.com</p> <p><u>Business Class:</u> Small</p> <p><u>Status:</u> Nontraditional</p> <p><u>Member since:</u> December, 2017</p>	<ul style="list-style-type: none"> • <u>Antimicrobial drug discovery & development</u>, from hit identification → clinical development; • Biodefense – Category A, B and C Priority Pathogens • MDR/XDR - CDC/WHO Priority Pathogens – CARB-X • Medicinal chemistry • Assay development; HTS >200K compd. library • Microbiology (antibacterial, antifungal, antiviral) • ADMET (<i>in vitro</i>) • Strategy, design and oversight of manufacturing, nonclinical and clinical development (Ph. 2 currently) • Quality assurance – GMP, GLP, GCP audits • Regulatory - IND/NDA submission requirements/prep.
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>Defense Threat Reduction Agency (#HDTRA-06-C-0042) - preclinical development of a novel class of broad spectrum antibacterial agents (Category A and B Priority Pathogens) for the warfighter. Established relationship with USAMRIID, Walter Reed</p>	<p>Discovery and development of anti-infective biodefense/ medical countermeasures against Category A, B and C Priority Pathogens, emerging infectious diseases/ pathogens, Traditional and Non-Traditional Agents, as well as MDR/XDR pathogens.</p>



MCDC

Flow Pharma, Inc.



MCDC Member Information	Member Capabilities
<p>Flow Pharma, Inc. Newark, California</p> <p><u>Key POC(s):</u> Reid Rubsamen, M.D. rrubsamen@flowpharma.com</p> <p><u>Business Class:</u> Small</p> <p><u>Status:</u> Nontraditional</p> <p><u>Member since:</u> 2017</p>	<ul style="list-style-type: none"> • We are developing the FlowVax synthetic, adjuvanted microparticle peptide vaccine platform • We have developed FlowVax Ebola, a prototype Ebola vaccine providing 100% protection against morbidity and mortality 14 days after a single injection in Ebola-challenged mice (work done at GNL). • We are developing FlowVaxAIR to allow vaccination using a pocket inhaler • Both FlowVax (for injection) and FlowVaxAir (for inhalation) use room temperature stable, dry powder formulations.
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<ul style="list-style-type: none"> • Viral Disease Countermeasures • Awarded DOD STTR Phase I for Marburg Countermeasure 	<p>Ebola Countermeasure</p>



MCDC

Flow Pharma Desired Teaming Areas

- Flow Pharma is currently developing prototype vaccines for filovirus.
- Flow Pharma's vaccines are designed to produce a killer T-cell response.
- The Company recently received a DOD Phase I STTR award for FlowVax Marburg.
- Flow Pharma is developing FlowVaxAir to allow adjuvanted microsphere vaccination by pocket inhaler.
- Flow Pharma's FlowVax and FlowVaxAir vaccines under development are made using adjuvanted microspheres as dry powders and are room temperature stable, not requiring refrigeration.
- Flow Pharma is seeking to team up for development of FlowVax Ebola and FlowVaxAir Ebola for prevention and possible treatment of Ebola infection.



Latham BioPharm Group, Inc



MCDC Member Information	Member Capabilities relevant to MCDC and MCM
<p>Latham BioPharm Group, Inc Cambridge, MA and Baltimore, MD</p> <p>Key POC(s): Pete Latham, platham@lathambiofarm.com Mike McGinnis, mmcginnis@lathambiofarm.com Pam Duchars, pduchars@lathambiofarm.com</p> <p>Business Class: Small Trad/Nontrad Status: Nontraditional</p> <p>Member since: June 2016</p>	<ul style="list-style-type: none"> • Prime Systems Integrator or Subcontractor • CBRN, Cancer and Gene Therapy Product Development • CMC, Knowledge, Quality and Supply Chain Management and Consulting • Portfolio/Program/Project Management • EVMS • Contract, Subcontractor and Vendor Management • Technical Strategy Development • Proposal Writing and Management
MCDC Project Awards/Other MCM Relevant Efforts	Desired Teaming Areas
<p>Past success as systems integrator for DoD and developed novel platforms for:</p> <ul style="list-style-type: none"> • Accelerated Manufacture of Pharmaceuticals (AMP) • 7-day Biodefense Program • Biologically-Derived Medicines on Demand program (Bio-MOD) • Intercept • Prometheus 	<ul style="list-style-type: none"> • Vaccine Development • Therapeutic Development (Large and Small molecule) • Platform Development • Device Development • All areas in CBRN and Emerging Infectious Disease



MCDC Member Information	Member Capabilities
<p>CritiTech Particle Engineering Solutions Lawrence, Kansas</p> <p>Key POC(s): Matthew McClorey, mmcclorey@crititech.com Neal Gapinski, ngapinski@crititech.com</p> <p>Business Class: Small Business</p> <p>Status: Non-traditional Contractor</p> <p>Member since: May 2017</p>	<ul style="list-style-type: none"> ➤ CRO/CDMO ➤ Experts in Particle Engineering <ul style="list-style-type: none"> • Supercritical Precipitation (SCP) Technology • Spray Drying • Analytical and Characterization Services ➤ SCP Technology Used to Develop Particles/Drugs Ideal for <u>Pulmonary Delivery</u> <ul style="list-style-type: none"> • Higher concentration in lungs • Longer duration of action • Lower systemic exposure • MMAD's for numerous drugs across different drug classes and physiochemical properties are in the "sweet spot" for pulmonary delivery. ➤ Proven track record <ul style="list-style-type: none"> • Team with deep drug development experience (~100 yrs.) • 6 Phase II drugs
<p>Desired Teaming Areas</p>	
<ul style="list-style-type: none"> ➤ MCM Particle Engineering and Characterization ➤ MCM Development & Manufacturing <ul style="list-style-type: none"> • Pre and Post-Exposure • Pulmonary Protectants 	



MCDC Member Information	Member Capabilities
<p><u>Leidos Government Health & Safety Solutions</u> Life Sciences Organization , Frederick, MD</p> <p><u>Key POC(s):</u> Harold Modrow - HAROLD.E.MODROW@leidos.com Brian Roberts - BRIAN.A.ROBERTS@leidos.com</p> <p><u>Business Class:</u> Large</p> <p><u>Status:</u> Traditional</p> <p><u>Member since:</u> February 2017</p>	<ul style="list-style-type: none"> • Prime Integrator • Program/Project Management • Quality Compliance and Management • Regulatory Compliance, Strategy, Submissions • Product Development Plans and Strategy • Manufacturing Oversight • Clinical Oversight and Monitoring
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>MCDC RPP-18-01, TRE-18-03, Development of RAP-103 Peptide as a Chemical Nerve Agent Therapeutic</p>	<p>Preclinical and nonclinical testing Manufacturing Developing MCM: Preclinical and clinical development of Vaccines, Therapeutics, Adjuvants, Prophylactics, Diagnostics</p>



creare[®] INNOVATIVE TECHNOLOGY & PRODUCT DEVELOPMENT

MCDC Member Information	Creare Capabilities
<p>Creare LLC (Founded in 1961) Hanover, NH</p> <p>Key POC(s): Michael Jaeger, mdj@creare.com</p> <p>Business Class: Small</p> <p>Status: Nontraditional</p> <p>Member Since: 6/2016</p>	<p>Contract Engineering R&D</p> <ul style="list-style-type: none"> • Prototype and Technology Development • Laboratory Engineering Testing/Testing Systems • Analysis and Modeling • Software and Electronics Development <p>Technology Areas</p> <ul style="list-style-type: none"> • Fluid and Thermal Systems • Sensors and Controls • Drug/Vaccine Delivery Devices • Biomedical Engineering and Human Systems • Advanced Manufacturing and Materials Processing
MCDC Relevant Efforts	Desired Teaming Areas
<ul style="list-style-type: none"> • Auto-Reconstituting Autoinjector (Recent SBIR) • Low-Cost Dry Powder Drug/Vaccine Delivery Devices (Several SBIRs) • Aerosol Drug/Vaccine Delivery Devices (Several SBIRs) 	<ul style="list-style-type: none"> • Combination Drug/Device Testing • Developing Large-Volume GMP Manufacturing of Combination Devices



SRI International®



MCDC Member Information	Member Capabilities
<p>SRI International Menlo Park, California</p> <p><u>Key POC(s):</u> Michael Gayle, michael.gayle@sri.com</p> <p><u>Business Class:</u> Non-profit</p> <p><u>Status:</u> Non-traditional Defense Contractor</p> <p><u>Member since:</u> June 2016</p>	<ul style="list-style-type: none"> • Discovery Technologies - Candidate Discovery & Delivery • Fully human antibody discovery (FASTclone) • Non-natural polymer affinity reagents (Techneins) • Cell-specific macromolecule delivery platform (FOX3) • Automated design & synthesis platform (SynFini) • Design Technologies/Nonclinical/Clinical Research & Development, Clinical Manufacturing • Platform R&D focus on novel and innovative system development
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>BSD has won 2 projects totaling ~\$4.6M</p> <ul style="list-style-type: none"> * VEE Monovalent VLP Phase I Clinical Study - \$4M Fill/Finish of Venezuelan Equine Encephalitis (VEE) * Virus like particle (VLP) Bulk Drug Product - \$583K * SynFini – Automated Chemical Synthesis Platform; DARPA W911NF-16-C-0051 	<ul style="list-style-type: none"> • Technologies for target identification and production • Manufacturing technologies for monoclonal antibodies • Design technologies for optimization of antibodies and non-natural peptides/polymers • Testing technologies that complement our capabilities • Manufacturing capabilities that compliment our capabilities and discovery technologies



MCDC

Silver Lake Research

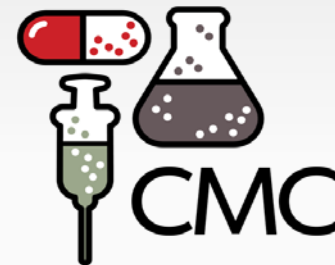


MCDC Member Information	Member Capabilities
<p>Silver Lake Research Corporation Azusa, California</p> <p>Key POC(s): Tom Round, VP Business Development tround@silverlakeresearch.com Mark Geisberg, PhD, Director of R&D mgeisberg@silverlakeresearch.com</p> <p>Business Class: Small Business Status: Nontraditional Member since: 2018</p>	<ul style="list-style-type: none"> • Unique Antibody Generation Technology – the EAP™ System <ul style="list-style-type: none"> • Monoclonal Antibodies to Difficult Targets: Viruses, Bacteria, Toxins, Chemical Agents • <i>No Infectious / Toxic Agents Needed to Generate MABs</i> • Existing MAb Library and New Reagent Development • Patented Lateral Flow Assay (LFA/HHA) Formats <ul style="list-style-type: none"> • Sandwich • Competitive • Nucleic Acid Detection • Easily Multiplexed • Contract Development / Manufacturing of POC/POU Diagnostics
MCDC - Related Efforts	Desired Teaming Areas
<ul style="list-style-type: none"> - First Specific MABs and LFAs for Variola (Smallpox) Virus Detection - MAB panels for Abrin, Ricin, Conotoxins, <i>B. anthracis</i>, other agents 	<p>Chem / Bio Detection Systems Point-of-Use Diagnostics – Immunoassays and Nucleic Acid Detection Critical Reagents Contract Manufacturing - Diagnostics</p>



MCDC

CMC Pharmaceuticals, Inc.



MCDC Member Information

CMC Pharmaceuticals, Inc.

Cleveland, OH

Key POCs:

Mike.radomsky@cmcpfarm.com, President

Casey.loveland@cmcpfarm.com, Business Manager

Lisa.losch@cmcpfarm.com, Special Projects Manager

Business Class: **Small**

Status: **Non-traditional**

Member since: **November 2017**

Relevant Member Capabilities

- **Chemistry, Manufacturing, and Controls** for the development of Pharmaceutical Drug Products
- **Pre-formulation:** Physio-chemical characterization
- **Formulation Development:** Preparation and evaluation of prototype dosage forms including: oral, parenteral, and other route; sterile/non-sterile; hard to solubilize; controlled release/polymers
- **Analytical Development and Characterization:** Drug Product analysis and characterization
- **Stability:** Accelerated, short, and long-term stability studies
- **Supply Chain Management:** Tech transfer and CMO identification

MCDC Projects /Other MCM Efforts

- **Subcontractor:** Formulation and Analytical Development for Auto-injector Use
- **SBIR:** Dual Formulation of Atropine/Scopolamine with Enhanced Stability

Desired Teaming Areas

- **Pre-formulation, formulation and analytical development**
- **Stability, characterization, and compatibility studies**
- **DP/API clinical supply chain management**
- **Drug Product Process Development and Troubleshooting**



MCDC

FORGE Life Science, LLC



MCDC Member Information	Member Capabilities
<p>FORGE Life Science, LLC Doylestown, PA</p> <p><u>Key POC(s):</u> Lillian Chiang, Lillian@forgelifescience.com</p> <p><u>Business Class:</u> Small</p> <p><u>Status:</u> Nontraditional</p> <p><u>Member since:</u> September, 2018</p>	<ul style="list-style-type: none"> • Host-Targeted Antivirals • NME drug discovery • Influenza, SARS, MERS, Respiratory Syncytial Virus, Adenovirus • Cytomegalovirus, Herpes viruses • BKV, JCV, polyoma viruses • HBV, HCV, Hepatitis viruses • Viral Encephalitis • Cancer
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
	<ul style="list-style-type: none"> • Vertebrate Animal Models of Infection including those requiring BSL3/4, especially humanized rodent models • Targeted Delivery technologies, especially liver- or lung-targeting • Patient biomarker detection, especially for metabolomics, viral load and resistance • Combination antiviral treatments



MCDC

EpiVax

EpiVax

MCDC Member Information	Member Capabilities
<p><u>EpiVax</u> Providence, RI</p> <p><u>Key POC(s):</u> Annie De Groot (CEO/CSO), annied@epivax.com Bill Martin (CIO/COO), martinb@epivax.com Lenny Moise (Director, Vaccines), lmoise@epivax.com Leo Einck (Dir. Business Dev.), leinck@epivax.com</p> <p><u>Business Class:</u> Small, Woman-Owned</p> <p><u>Status:</u> Nontraditional</p> <p><u>Member since:</u> May 2017</p>	<p><u>Fee for Service Offerings:</u></p> <ul style="list-style-type: none"> • Contract Vaccine Development Organization • Contract mAb Development Organization <p><u>Tools:</u></p> <ul style="list-style-type: none"> • Immunoinformatics – T cell epitope prediction • Defined process to discover vaccine candidates • Patented process to optimize vaccine candidate immunogenicity and efficacy • Defined process for mAb design • Testing – HLA binding, T cell assays, in vitro immunization (human), in vivo immunization (HLA transgenic mice) <p><u>Platform:</u></p> <ul style="list-style-type: none"> • Computational platform for rapid response to novel and emerging threats • Applications to humoral and cellular protective mechanisms • Delivery platform agnostic
<p>MCDC Projects/Other MCM Efforts</p>	<p>Desired Teaming Areas</p>
<p>Q fever vaccine development 2015-2019 (DTRA) Burkholderia immune evasion 2016-2020 (DTRA) Multi-pathogen vaccine development (NIAID U19) Tularemia vaccine development (NIAID SBIR) Smallpox vaccine development (NIAID SBIR)</p>	<p>Antigen/epitope discovery technologies Vaccine design technologies Monoclonal antibody design technologies</p>



MCDC



CUBRC
Advantage through technology

CUBRC, Inc.
Buffalo, NY

Key POC(s):

Katie Edwards- edwards@cubrc.org
David Mangino- mangino@cubrc.org

Business Class: 501.c.3 Not for Profit
Traditional/Nontraditional Status: Traditional
Member: Since June 2016

Member Capabilities relevant to MCDC and MCM R&D/Products

- Serves as a lead systems integrator for MCM development programs.
- Expertise ranges from early-stage (discovery), mid-stage (IND) to advanced development (NDA and FDA approval).
- Scientific experts lead management of MCM programs.
- Government Compliant Contracting, Financial & Other Supporting Systems
- BSL-2, BSL-3 and Chemical Agent Test Facilities (subsidiary, Avarint, LLC)
- Current Programs: BARDA, NIAID and DTRA; Vaccine & Antibiotic (including Non-Traditional) Development Programs
- Vaccine Platforms/IMPACT Team
 - Vaccine antigen discovery platforms for EID and biothreats
 - Epitope design & engineering to ensure an inclusive, enduring immune response
 - Precedented vaccine backgrounds capable of supporting novel antigenic insertions (e.g. live vectored-viral backgrounds, live vectored-bacterial backgrounds, non-vectored antigen focused backgrounds)
 - Nucleic acid vaccines
 - Validated high throughput in vitro system to evaluate the biological effect of immunotherapies or vaccines on human populations to support more rapid and incisive clinical trials (e.g. “Clinical trial in a test tube”)
 - Manufacturing (platforms, adjuvants/formulation, fill/finish into platforms devices for administration)

Desired Teaming Areas

CUBRC has a number of ongoing programs for vaccine and biomarker discovery and development (e.g. *Burkholderia*) and antibiotic development (e.g. biothreats and AMR public health threats) and are looking to further advance these programs. In addition, CUBRC has assembled a team of developers with platforms that accelerate vaccine development in anticipation of the PRISM RPP release. CUBRC welcomes discussions regarding additional, complimentary technologies.



MCDC

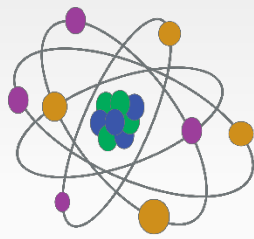
Tiba Biotech



MCDC Member Information	Member Capabilities
<p>Tiba Biotech Cambridge, MA</p> <p>Key POC(s): Karl Ruping, ruping@tiba.bio</p> <p>Business Class: Small</p> <p>Status: Traditional</p> <p>Member since: April, 2018</p>	<ul style="list-style-type: none"> • Fully synthetic, chemically defined nucleic acid delivery materials • Rapid vaccine design, prototyping and pre-clinical production • Specializing in RNA replicon and conventional mRNA vaccines
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>No MCDC Projects, but numerous MCM efforts in collaboration with USAMRIID, including filoviruses (Ebola, Sudan and Marburg virus) and Venezuelan equine encephalitis; and biosecurity for domestic livestock (FMD).</p>	<p>Tiba is a new venture with a unique nucleic acid delivery technology looking for collaborative partners with (1) novel antigen targets or (2) FDA-compliant manufacturing capabilities, to address a range of MCM risks for our Warfighters, Service members and citizens.</p>



MCDC



Tech62
Inc.

Continuing to serve the nation

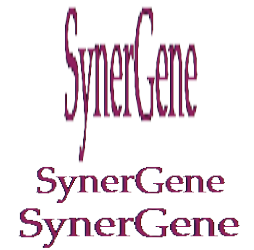


MCDC Member Information	Member Capabilities
<p>Tech62, Inc. Fairfax, VA</p> <p>Key POC(s): Dr. John Mercier, john.mercier@tech62.com</p> <p>Business Class: Small Biz - SDVOSB</p> <p>Status: Nontraditional</p> <p>Member since: April, 2016</p>	<ul style="list-style-type: none"> • Big pharma portfolio management tool customized for MCMs and the FDA Animal Rule • MD and PhD-level MCM strategic advisors • High Performance Computing (HPC) • WMD Casualty Modeling with and w/o MCMs • Human response to WMD insults with probit analysis • TS FCL & TS/SCI staff
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>WMD Casualty Modeling with and w/o MCMs</p>	<p>Open to support prime contractors</p>



MCDC

SynerGene Therapeutics, Inc



MCDC Member Information

SynerGene Therapeutics, Inc.,
Potomac, MD 20854

Key POC:
Joe B. Harford, PhD, President & CEO
harfordj@synergeneus.com

Business Class: Small
Status: Nontraditional
Member since: September 2017

Member Capabilities

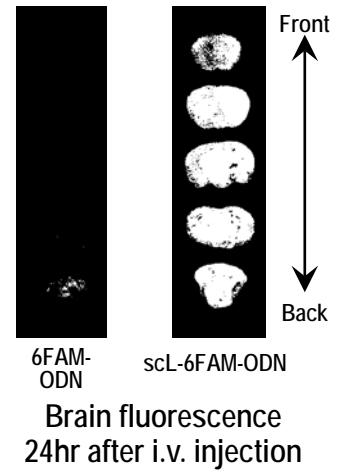
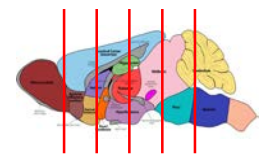
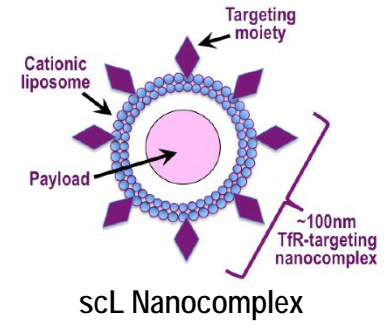
- Translation of basic science to nanomedicines (two therapeutic products now in human trials for cancer with one product in multiple, multisite Phase II trials)
- Creation of novel nanomedicine formulations of payloads for delivery across the blood-brain barrier
- Said payloads can be:
 1. Genes whose expression in the brain would be beneficial;
 2. Oligonucleotides including antisense or siRNA for manipulating endogenous gene expression;
 3. Imaging agents (e.g., gadolinium-based contrast agents for MRI)
 4. Small molecule therapeutics (e.g., TMZ for brain tumors or 2PAM for OPNA exposure)

MCM Efforts

- Under DTRA grant, are developing two OPNA countermeasures:
 1. BChE gene therapy for OPNA prophylaxis
 2. Novel formulation of an oxime (2PAM) for post-exposure treatment
- Developing siRNA-based nanomedicine for mitigation of status epilepticus *via* inhibition of neuroinflammation

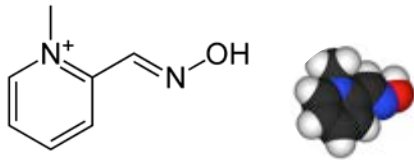
Desired Teaming Areas

- Any project wherein delivery of any entity across the blood-brain barrier would be advantageous.
- Said projects could involve either biological (e.g., neurotropic bacteria, parasites or viruses) or chemical threat agents (e.g., OPNA's).



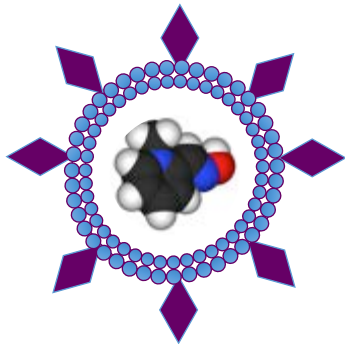
scL-2PAM Given During Cholinergic Crisis Induced by Paraoxon (5 X LD₅₀) is More Effective Than Free 2PAM in Rescuing Mice

Oxime:



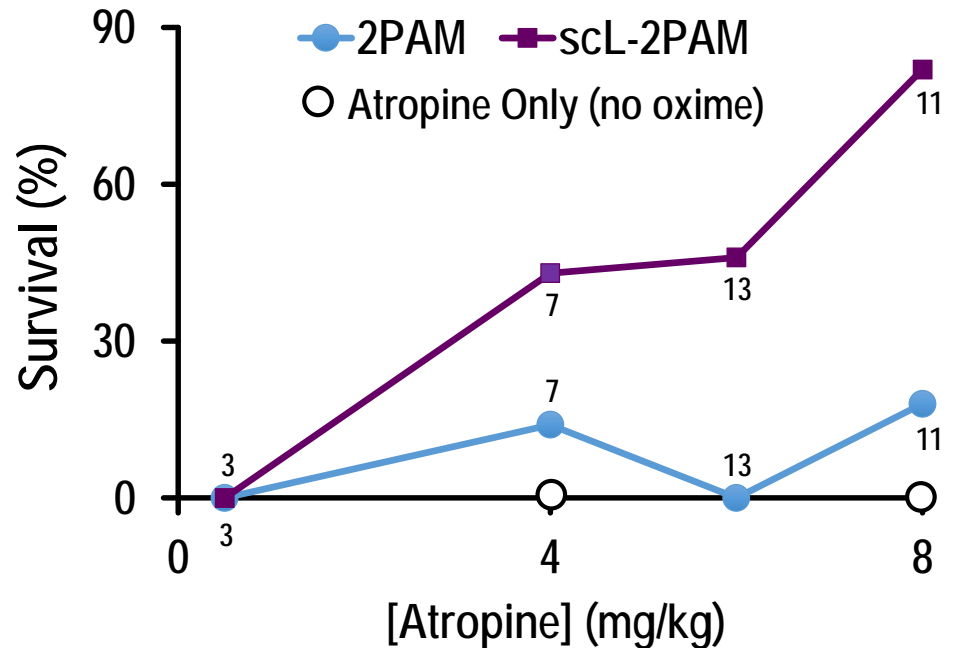
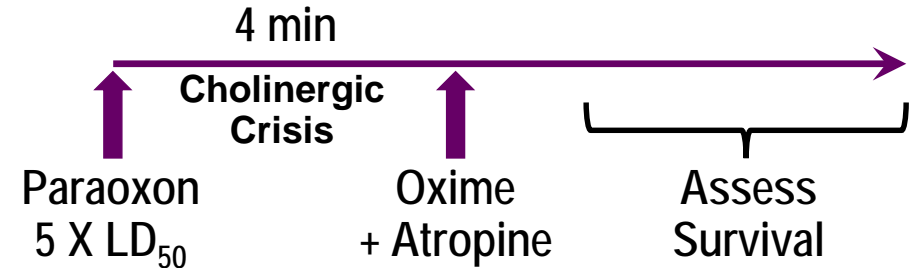
2PAM

(MW = 137 but does not cross BBB effectively)



scL-2PAM

Carries the oxime 2PAM
(actively crosses BBB *via* TfR-mediated transcytosis)



[Paraoxon] = 12.5 mg/kg (5 X LD₅₀)

[Oxime] = 30 mg/kg

[Atropine] = 0.5 - 8 mg/kg





MCDC

Southern Research



MCDC Member Information	Member Capabilities
<p>Southern Research Birmingham, AL and Frederick, MD</p> <p>Key POC: Michelle Wright Valderas, PhD mvalderas@southernresearch.org</p> <p>Business Class: N/P</p> <p>Status: Nontraditional</p> <p>Member since: May 2018</p>	<ul style="list-style-type: none"> • Contract Research Organization (CRO) • Infectious disease, biodefense countermeasures, drug discovery, translational research, animal model development/testing, AALAC accredited • Animal model expertise in: Dengue, Zika, Monkeypox, Rabbitpox, Chikungunya, Anthrax, Equine encephalitis (VEE, EEE, WEE), West Nile, Yellow Fever, Influenza (Seasonal/HPAI) • Toxicological testing (IND-enabling studies) and Infectious disease efficacy testing of vaccines and therapeutics • Non-clinical drug development and clinical trial sample analysis in support of FDA drug and vaccine licensure • BSL1-3, ABSL1-3, Tier 1 select agent registered • Small and large animal testing
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>If desired</p>	<ul style="list-style-type: none"> • Vaccine and therapeutic development companies



MCDC



Duke Human Vaccine Institute

Duke University School of Medicine

MCDC Member Information	Member Capabilities
<p>Duke Human Vaccine Institute, Duke University Durham, North Carolina</p> <p>Key POC(s): Thomas Denny, thomas.denny@duke.edu Matthew Johnson, matthew.r.johnson@duke.edu Greg Sempowski, greg.sempowski@duke.edu</p> <p>Business Class: Academic Status: Traditional, Non-Profit</p> <p>Member Since: March, 2018</p>	<ul style="list-style-type: none"> • DHVI RBL: State-of-the-art high-containment (BSL3) facility for lab and small animal pre-clinical studies • DHVI P3: Innovative/Rapid platform to isolate Abs against BSL2/3 and Select Agent human pathogens <ul style="list-style-type: none"> • Over 10,000 mAbs isolated and characterized • DHVI cGMP: In-house process development, production, quality testing and product release <ul style="list-style-type: none"> • Flexible facility to produce protein and mRNA • DHVI DVTU: Physician-scientists conducting Phase 1-4 clinical trials to control/prevent infectious disease <ul style="list-style-type: none"> • Early Phase Clinical Trial Isolation Unit (Duke Hospital) • 100+ trials and over 7,000 participants (15 Open Trials) • DHVI GLP: CLIA/CAP/ISO – accredited GCLP end-point monitoring laboratories (immunology/virology)
<p>MCDC Projects/Other MCM Efforts</p> <ul style="list-style-type: none"> • DoD/DARPA - Pandemic Prevention Platform • DoD - Center for Long Term Follow-up of the Late Effects of Acute Radiation Exposure in Primates • DHHS/NIH - Radiation Countermeasures Center of Research Excellence 	<p>Desired Teaming Areas</p> <p>Open to teaming partnerships to provide biocontainment services, Ab countermeasure development, Phase-1 manufacturing, clinical trials with pediatric to geriatric and special populations and GLP end-point monitoring</p>



MCDC

**GLOBAL INFECTIOUS DISEASES
INSTITUTE**

MCDC Member Information	Member Capabilities
<p><u><University of Virginia-Global Infectious Diseases Institutes (GIDI)></u> <Charlottesville, Virginia></p> <p>Key POC(s): <Alison Criss akc2r@Virginia.edu; Linda Columbus Columbus@Virginia.edu; David Garcia dgarcia@Virginia.edu></p> <p>Business Class: < Academic Institute></p> <p>Status: <Nontraditional></p> <p>Member since: <October, 2017-UVA></p>	<ul style="list-style-type: none"> • Internationally recognized experts in diarrheal diseases, structural biology of infectious agents that cause outbreaks and epidemics, molecular epidemiology of antimicrobial resistance, and culture-independent diagnostics for all of the above. • Longstanding collaborations with researchers in resource-limited settings around the world for investigating infectious diseases and running clinical trials for interventions. • Over 100 cross-disciplinary, motivated faculty members from 9 different on-Grounds entities, from public policy to social science to STEM.
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>No projects funded to date</p>	



MCDC



MCDC Member Information	Member Capabilities
<p>VenatoRx Pharmaceuticals, Inc. Malvern, PA</p> <p><u>Key POC(s):</u> Ezra Felker, Chief Operating Officer</p> <p><u>Business Class:</u> Small Business</p> <p><u>Status:</u> Nontraditional</p> <p><u>Member since:</u> July, 2018</p>	<ul style="list-style-type: none"> • Discovery and development of novel anti-infectives to treat MDR bacterial infections and emerging viral diseases • Platform-based automated high throughput screening facilities • Random diversified library of 200k drug-like small-molecule compounds • Biological expertise and capabilities to support full range of development for anti-bacterial and antiviral projects • Medicinal chemistry expertise, infrastructure and capabilities to drive compound advancement from hit-to-lead through lead optimization to candidate selection • Pre-clinical expertise to support exploratory ADME, pharmacokinetic, efficacy, PK/PD and safety studies for candidate selection • Integrated network of CROs and academic collaborators
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<ul style="list-style-type: none"> • HHS/NIAID: Therapeutic Medical Countermeasures for Biodefense and Emerging Infectious Diseases (BL/BLI combination; CRE, CRPA, <i>Burkholderia</i> spp.) • DTRA: New PBP Inhibitors Impervious to Beta-Lactamases (<i>Burkholderia</i> spp., <i>Yersinia pestis</i>, and <i>Francisella tularensis</i>) 	<ul style="list-style-type: none"> • Development of animal models for bacterial Biodefense targets (<i>Burkholderia</i> spp., <i>Acinetobacter</i> spp., etc.) • Prospective targets and expertise (disease areas/biology/models) to support antiviral projects



MCDC



MCDC Member Information	Member Capabilities
<p>BDO USA, LLP Washington, DC</p> <p>Key POC(s): Steve Morris, smorris@bdo.com Andrew Stiles, astiles@bdo.com</p> <p>Business Class: Large</p> <p>Status: Nontraditional</p> <p>Member since: 2018</p>	<p style="text-align: center;">AWARD MANAGEMENT</p> <ul style="list-style-type: none">• Strategic Pricing – maximize funding and cost recovery while limiting compliance risk exposure• Financial Management & Contract Administration<ul style="list-style-type: none">➤ Cost Accounting System Design and Implementation➤ Monthly Job Costing and Invoicing➤ Budget Monitoring and Forecasting➤ Indirect Rate Optimization and Monitoring➤ Subcontractor Financial Management• Program/Project Management<ul style="list-style-type: none">➤ Government/Prime Communication➤ Team Management➤ Required Reporting and Schedule Updates➤ Meeting Coordination and Documentation Management• Regulatory Compliance<ul style="list-style-type: none">➤ FAR, CAS, and 2 CFR 200 (OMB Uniform Guidance)➤ Government Audit Support – DCAA, DCMA, DFAS, and HHS➤ Internal Controls for Adequate Business Systems



MCDC

BIOHYBRID

s o l u t i o n s

MCDC Member Information	Member Capabilities
<p>BioHybrid Solutions LLC Pittsburgh, PA</p> <p>Key POC(s): Tonia Simakova, tonia@biohybridsolutions.com</p> <p>Business Class: Small Business</p> <p>Status: Nontraditional</p> <p>Member since: February, 2018</p>	<ul style="list-style-type: none"> • Biotechnology R&D firm • Protein stabilization for therapeutic and biocatalytic applications • Application of polymer science in biotechnology
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>If desired</p>	<p>Protein/Enzyme manufacturers, biosensors, smart materials, bioactive coatings, pharmaceuticals (proteins and small molecules) producers</p>



MCDC



MCDC Member Information	Member Capabilities
<p>Antigen Discovery Inc. Irvine, California</p> <p>Key POC(s):</p> <p>Xiaowu Liang, CEO xliang@antigen-discovery.com</p> <p>Angela Yee, COO ayee@antigen-discovery.com</p> <p>Business Class: Small Status: Nontraditional Member since: Sept 2018</p>	<ul style="list-style-type: none"> ▪ CRO specialized in genome-wide immune profiling ▪ Rapid generation of whole proteome microarrays ▪ 60,000+ biomarker candidates from 40 infectious agents ▪ Identify target antigens for diagnostics, vaccines & therapeutics ▪ Small sample volume (e.g. ~5µL) and diverse biological specimens, e.g. serum, saliva, fecal, milk, etc. ▪ Therapeutic antibody target validation ▪ Clinical trial immune monitoring and efficacy evaluation
MCDC Projects/MCM Efforts	Desired Teaming Areas
<p>New member</p>	<ul style="list-style-type: none"> ▪ Diagnostic test developers and device manufacturers ▪ Vaccine and therapeutic antibody developers ▪ Biobanks and sample providers



MCDC



BioFactura

MCDC Member Information	Member Capabilities
<p>BioFactura, Inc. Frederick, Maryland</p> <p>Key POC(s): Darryl Sampey, Ph.D., CEO dsampey@biofactura.com</p> <p>Business Class: Small</p> <p>Status: Nontraditional</p> <p>Member since: May 2017</p>	<ul style="list-style-type: none"> • Protein Design and Optimization • Mammalian Cell Line Development (NS0, CHO, other) • Upstream/Downstream Bioprocess Development • Analytical Characterization (LC-MS/MS, other) • Process Scale-Up and Engineering/Tox Campaigns • Phase I cGMP Manufacturing <ul style="list-style-type: none"> ○ Up to 500L Single-Use Bioreactor Scale ○ All Disposable Single-Use Downstream ○ Rapid Setup and Changeover
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<ul style="list-style-type: none"> • <i>Smallpox Therapeutic Development (mAb cocktail)</i> • <i>Improved Production of VEE VRP Vaccines</i> • <i>Antibody-based Therapies Against Sudan ebolavirus</i> • <i>Antibody-based Therapy Against Marburgvirus</i> 	<ul style="list-style-type: none"> • Biologic MCM Development (cell culture derived) • MS-based Characterization/Analytics • Bioprocess Development • Phase I cGMP Manufacturing



MCDC

Windgap Medical, Inc.



MCDC Member Information	Member Capabilities
<p><u>Windgap Medical, Inc.</u> Watertown, MA</p> <p><u>Key POC(s):</u> Adam Standley astandley@windgapmedical.com</p> <p><u>Business Class:</u> Small Business</p> <p><u>Status:</u> Non-traditional</p> <p><u>Member since:</u> July, 2018</p>	<ul style="list-style-type: none"> • Dual-chamber autoinjector development <ul style="list-style-type: none"> • 0.3mL dosage: validated device ready for prototyping with your drug • Other dosages: We can develop a combination product, leveraging our expertise in rapid prototyping, molding, filling, and assembly development to prototype new therapies • Powder and Liquid filling development <ul style="list-style-type: none"> • GMP and non-GMP lines available to conduct fill trials • Device testing (ISO 11608 & MIL STD 810G) • Regulatory strategy & FDA filing prep
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>Our Epinephrine Autoinjector, AndiPen[®], was recently licensed to publicly traded pharmaceutical company and will be on-market 2020.</p>	<p>Seeking collaborators to develop new therapies & medical countermeasures to meet expanding needs of the US Military. Contact us if you have innovative drugs or biologics that can benefit from use in a dual-chamber autoinjector by improving drug-stability or ease-of-use.</p>



MCDC



MCDC Member Information	Member Capabilities relevant to MCDC and MCM
<p>SciTech Services, Inc. 2129 Pulaski Highway, Suite 100 Havre de Grace, MD 21078 Phone: 443.303.3623 Email: info@scitechinc.com www.scitechinc.com</p> <p>David H. Moore, DVM, PhD President dmoore@scitechinc.com 443-303-3623</p> <p>Business Class: Small Business Nontraditional</p> <p>Original MCDC Member / Executive Committee Member</p>	<p>List all relevant capabilities:</p> <ul style="list-style-type: none"> • Working with the Government • Working with the DoD • Working in the DoD Chem Bio Defense Program • Working with the JPEO-CBD • Understanding Requirements • Quality Proposal Preparation • DoD Contract Program Management • DELTEK Cost Point Government approved accounting system • Experience in OTA Program management (DOTC) • Working with prime and subcontractor partners • 28 years of successful operations
<p>MCDC Project MCDC-18-04-002; Development of Alternative Large Animal Models for OP-NA Countermeasure Evaluations</p>	<p>Desired Teaming Areas; Program/project management for non-traditional team projects</p>



MCDC



MCDC Member Information	Member Capabilities relevant to MCDC and MCM
<p>MRIGlobal: Kansas City, MO; Gaithersburg, MD; Palm Bay, FL, Charlottesville, VA</p> <p>Key POC: Robert Casillas, PhD; rcasillas@mriglobal.org</p> <p>Business Class: 501c3 (N/P)</p> <p>Trad/Nontrad Status: Traditional</p> <p>Member since: April 2016</p>	<ul style="list-style-type: none"> • Chemical Surety and ABSL-3 High Containment • Animal studies conducted IAW 21 CFR Part 58 and FDA’s “Animal Rule” in species ranging from rodent to NHPs • Non-GLP/GLP (IND/NDA-Enabling) • Relevant Routes of Exposure (Ocular/Pulmonary/Dermal) • Clinical in vitro diagnostics, molecular and immunoassay biodetection, and FDA 510k validation
MCDC Project Awards/Other MCM Relevant Efforts	Desired Teaming Areas
<ul style="list-style-type: none"> • DET-17-05 (Awarded; Man-Portable Dx System) • DET-17-08 (In Negotiation; Chem Exposure In Vitro Dx) • TRE-18-04 (In Basket; Large Animal OPNA Model) • HDTRA1-17-C-0011 (NHP presymptomatic biomarkers to distinguish bacterial from viral infections) • HDTRA1-16-0028 (NHP F. tularensis vaccine studies) • HHS0100201700001C - BARDA (NHP PK studies) • DTRA Sample to Sequence Platform Programs • BARDA Anthrax & Biodosimetry PCR assay for FDA 510k 	<ul style="list-style-type: none"> • Pre-/Nonclinical MCM studies against Chem/Bio agents <ul style="list-style-type: none"> ○ Toxicology, Analytical & Bioanalytical (R&D and GLP) ○ Dose-Ranging, Formulation Optimization ○ Sample Stability & Storage, Custom Synthesis • Natural History and Pre-Qualified Small/Large animal models • Biomarkers of the host immune response • Prototype Chem or Bio Agent Dx Systems • Clinical research collaborators and partners needing in vitro diagnostic and biodetection support



Battelle Memorial Institute

<p>MCDC Member Information</p> <p>Battelle Memorial Institute: Columbus OH</p> <p>Key POC(s): COL (Ret) Russell Coleman, 240-815-0741, colemanr@battelle.org</p> <p>Mark Huller, huller@battelle.org</p> <p>Business Class: Non-Profit</p> <p>Status: Traditional</p> <p>Member since: “The beginning”</p>	<p>Member Capabilities</p> <ul style="list-style-type: none"> • World’s largest non-profit CRO with >80 years supporting DOD; • Decades supporting MCM development, to include 14 of 19 products approved under the FDA “animal rule;” • Chemical and Biological Agent “surety” and “personal reliability” programs, to include TS-SCI capability; • World’s largest privately-owned BSL-3 laboratory, with extensive IND-enabling and pivotal toxicology and Test & Evaluation capabilities; • Animal-model development, to include FDA validation/qualification; • Proof-of-concept and pivotal (GLP) efficacy testing in a wide range of animal models up to NHP/large animal; • Full array of validated assays to support FDA-regulated non-clinical and clinical testing; • Comprehensive medical device development capabilities (systems integration, human factors engineering, cybersecurity, materials and formulations, ISO 13485, developmental engineering, etc.);
<p>MCDC Projects/MCM Efforts</p> <ul style="list-style-type: none"> • Prime on 1 “about-to-be-awarded” MCDC OTA and a sub on multiple MCDC OTA. • The premier CRO supporting MCM development! 	<p>Desired Teaming Areas</p> <p>Our incredibly broad and deep capabilities can be used to support the development of a range of medical countermeasures to CBRN threats, either as a Prime or a Sub. Partnering with Battelle can be your road-map to success!</p>



MCDC

AktiVax, Inc.

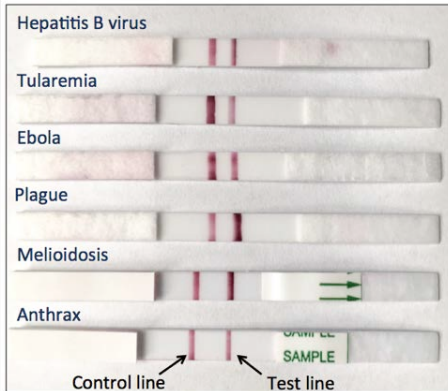


MCDC Member Information	Member Capabilities
<p>Aktivax, Inc. 100 Technology Drive, Suite 300C Broomfield, CO 80021</p> <p>Key POC(s): Amir Genosar, CEO amir@aktivax.com Arik Eisenkraft MD., Medical Dir. arik@aktivax.com</p> <p>Business Class: Small business</p> <p>Status: Non-traditional</p> <p>Member since: 2016</p>	<ul style="list-style-type: none"> • Specialty Pharma • Proprietary prefilled drug delivery devices • Prefilled syringes • Broad range of auto-injectors <ul style="list-style-type: none"> • Glass free • Wet, wet-wet, wet-dry • Up to 5 ml dose • Up to 3 simultaneous injections • Nasal, oral, and topical dispensers • Successful track record of partnering and collaborations: DoD-MCS, BARDA, NIH, BMGF, leading pharma and biotech, development stage companies • GMP Manufacturing capability ready by end of 2019
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>BARDA staged contract to establish GMP manufacturing capability and advance up to 4 treatments in ARAI to FDA approval</p> <p>DoD-MCS contract to develop 6 treatments in ARAI</p>	<p>AktiVax is looking to partner with drug programs where our capabilities can enable or enhance the product development and commercialization</p>



**DIAGNOSTICS
DISCOVERY**
LABORATORY

- melioidosis
- glanders
- plague
- tularemia
- anthrax
- Ebola
- Lassa fever
- hantavirus
- HBV
- VEEV
- opioids



- University startup
- Antibody-based diagnostics & therapeutics
- Whooping cough, Lyme disease & patient sample enrichment/concentration

MCDC Member Information

Department of Microbiology and Immunology
University of Nevada, Reno School of Medicine

Key POC(s):

David AuCoin, PhD; daucoin@med.unr.edu
Chair, Microbiology and Immunology

Paul Brett, PhD; pbrett@med.unr.edu

Mary Burtnick, PhD; mburtnick@med.unr.edu

Business Class: Academic; Dx/D small business

Status: Nontraditional

Member since: December, 2017

Member Capabilities

- Platforms for biomarker discovery – identification of shed/secreted antigens in patient samples (BSL3)
- Production of libraries of mAbs to microbial targets
- Purification (grams) & affinity calculations (SPR)
- Immunoassay construction – ELISA & lateral flow
- Diagnostic prototypes – Biodot equipment
- Brett/Burtnick laboratory
 - ultrapure carbohydrates from *Burkholderia* species
 - synthesis of glycoconjugate vaccines
 - bacteria-host cell interaction studies

MCDC Projects/Other MCM Efforts

Multiple NIH, DTRA, DHS funded contracts/grants for diagnostic development, antibody production, vaccine development

Desired Teaming Areas

Biotech partners that have a focus in:
Antigen capture immunoassay platforms
Therapeutic antibodies
GMP manufacturing of glycoconjugate vaccines



MCDC

Polo Custom Products



MCDC Member Information	Member Capabilities
<p>Polo Custom Products Topeka, Kansas</p> <p>Key POC(s): Wayne Hiegert, Mary Phelan whiegert@polocustomproducts.com mphelan@polocustomproducts.com</p> <p>Business Class: Small; HUBZone approved</p> <p>Status: Nontraditional</p> <p>Member since: August 2018</p>	<ul style="list-style-type: none"> • Design and manufacture custom sewn, sealed, and thermoformed products • Product development team and engineering team in-house for concept through manufacturing phases • Original manufacturer of the Chemical Protective Patient Wrap • Prototyped Contaminated Human Remains Pouch • Concepts for an Isolation Wrap, CBRN Poncho • ISO 9001:2015, ITAR/JCP certified • Additional information and brochures available at www.polocustomproducts.com
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>New member</p>	<p>Desired areas are custom sewing, sealing or thermoforming items using high end, complex CBRN materials</p>



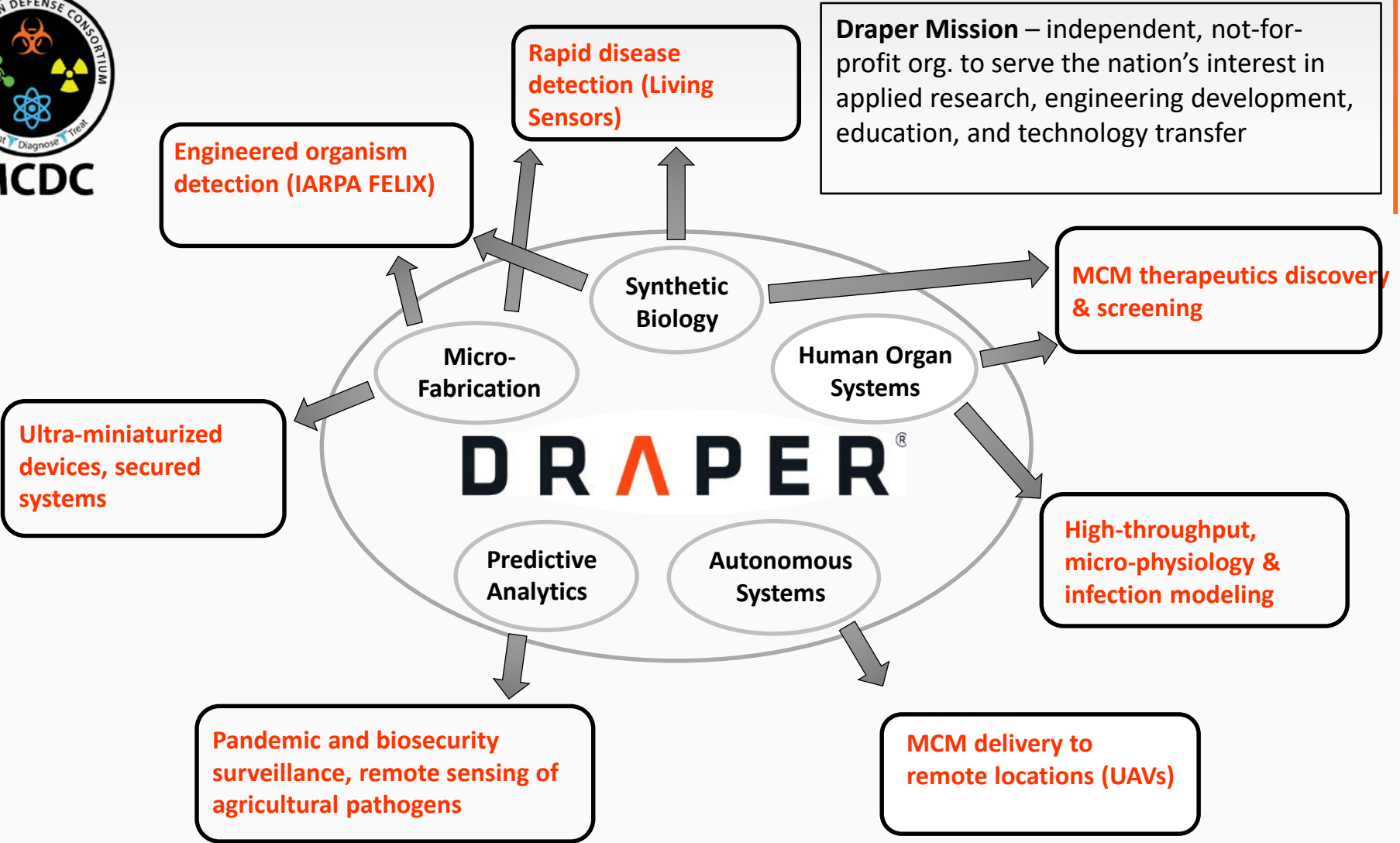
MCDC

Q-LINEA 

MCDC Member Information	Member Capabilities
<p>JGW Group Reston, VA</p> <p>Q-Linea Uppsala, Sweden</p> <p>Key POC(s): Jack O'Neil, joneil@jgwgroup.com</p> <p>Business Class: Small</p> <p>Status: Nontraditional</p> <p>Member since: <October, 2016></p>	<ul style="list-style-type: none"> The JGW Group has been supporting CBRNE and Military/Government requirements since 1979. JGW has been involved in the development and commercialization of PCR based BWA detection technology for Homeland Security and Military users. JGW currently has access to global medical countermeasure and diagnostics technologies including novel delivery and diagnostic platforms.
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<ol style="list-style-type: none"> Submitted to DET-18-01: Rapid Single-molecule-based Diagnostic Platform Assessment of Pathogen Susceptibility to Anti-microbial Agent Tracking Next Generation Diagnostic System Increment 2 Platform Component Development 	<p>JGW are considered a "Nontraditional Defense Contractor" and are happy for any teaming opportunities with may be available from other NCBDC Members.</p>



Draper Mission – independent, not-for-profit org. to serve the nation’s interest in applied research, engineering development, education, and technology transfer

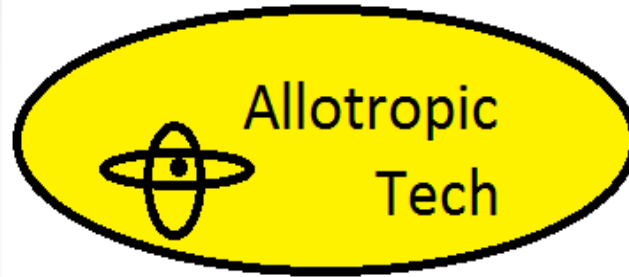


The Charles Stark Draper Laboratory, Inc.
 HQ- Cambridge, MA; Reston, VA; Washington, DC; St Petersburg, FL
Business Class: Large, Not-for-Profit Corp
Status: Traditional (joined MCDC in 2018)

Key POC(s)
 Timothy Petrie, tpetrie@draper.com, 617-258-3636
 Roger Odegard, r.odegard@draper.com, 703-935-5114
 Robert Larsen, rob@draper.com, 617-258-1863



MCDC



MCDC Member Information	Member Capabilities
<p>Allotropic Tech Halethorpe, MD</p> <p>Key POC(s): Bob Balcerzak, bob.b@allotropictech.com</p> <p>Business Class: Biotech – Small Business</p> <p>Status: Nontraditional</p> <p>Member since: July, 2018</p>	<ul style="list-style-type: none"> • CDMO specializing in expression and recovery of “hard to express” recombinant proteins • Capabilities include design, expression, purification , QC • Unique expression system combining traditional baculovirus with whole insect larvae (<i>Trichoplusia ni</i>) • Advantages include: <ul style="list-style-type: none"> * no optimization needed * ability to screen mutations quickly * rapid scale up * improved post-translational modifications
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
	<p>Chemical Weapons Defense, sub-unit protein vaccine development, protein discovery and characterization and development research.</p>



MCDC



MCDC Member Information	Member Capabilities								
<p>Allotropic Tech Halethorpe, MD</p> <p>Key POC(s): Bob Balcerzak, bob.b@allotropictech.com</p> <p>Business Class: Biotech - Small Business</p> <p>Status: Nontraditional</p> <p>Member since: July, 2018</p>	<ul style="list-style-type: none"> Experienced supplier to USAMRICD and NIH Over 300 proteins/enzymes produced using baculovirus/larvae expression system Select Examples of protein/enzymes produced include: <table data-bbox="1000 739 1767 971"> <tr> <td>Acetylcholinesterase,</td> <td>Butyrylcholinesterase</td> </tr> <tr> <td>Paraoxonase 1 (PON1),</td> <td>Prolidases</td> </tr> <tr> <td>Variola Viral Antigens</td> <td>Hemagglutinin (Influenza)</td> </tr> <tr> <td>Ebola Glycoprotein</td> <td>SARS (Spike Protein)</td> </tr> </table> Capability to design and express native, fusion, mutation and VLP proteins. 	Acetylcholinesterase,	Butyrylcholinesterase	Paraoxonase 1 (PON1),	Prolidases	Variola Viral Antigens	Hemagglutinin (Influenza)	Ebola Glycoprotein	SARS (Spike Protein)
Acetylcholinesterase,	Butyrylcholinesterase								
Paraoxonase 1 (PON1),	Prolidases								
Variola Viral Antigens	Hemagglutinin (Influenza)								
Ebola Glycoprotein	SARS (Spike Protein)								
MCDC Projects/Other MCM Efforts	Desired Teaming Areas								
	Chemical Weapons Defense, sub-unit protein vaccine development, protein discovery and characterization and development research.								



MCDC



Chenega Support Services, LLC

5726 W. Hausman Road, Suite 100, San Antonio, TX 78249
 Phone: 210-424-2094 · FAX: 210-694-5454

MCDC Member Information	Member Capabilities
<p><u>Chenega Corporation</u> San Antonio, TX</p> <p><u>Key POC(s):</u> Dr. George Gisin - george.gisinjr@chenegars.com Kevin Walter Smith - kevin.walter.smith.qcstechllc.com</p> <p><u>Business Class:</u> Small Business, Subsidiary of ANC</p> <p><u>Status:</u> Traditional <u>Member since:</u> December 2017</p>	<ul style="list-style-type: none"> • Contract Development & Manufacturing • Large-Scale Contract Procurement & Management (i.e. Equipment, Materials) • Program & Personnel Management • Modeling & Simulation • Prototype Development • SMEs & Teaming Partners specializing in: • CBRN Pathogen Development • BWA/CWA Countermeasure Development • CBRN Medical Diagnostics Platform Design & Implementation
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>JE-RDAP (W911QY-18-D-0036) TATRC USAISR CDC - NCIRD</p>	<p>JPM-MCS Medical Diagnostics Platform Technologies & Systems BWA/CWA Detection & MCM Development Vaccine Development against Biothreat Agents (BSL3)</p>



Southwest Research Institute®

San Antonio, Texas



MCDC Member Information	Member Capabilities relevant to MCDC and MCM	
<p>Company name Southwest Research Institute</p> <p>Key POC(s): Joe McDonough, jmcdonough@swri.org Mike MacNaughton, mmacnaughton@swri.org</p> <p>Business Class: Nonprofit Trad/Nontrad Status: Exempt from cost-share, Traditional Contractor</p> <p>Member since: February 2016</p>	<ul style="list-style-type: none"> • FDA-inspected cGMP class 1000 operations for clinical and preclinical supplies of drug and finished dosage. • Safe Robust drug candidates supported by proprietary Rhodium™ modeling platform. • Encapsulation-based and conventional formulation development for stabilization and any route of delivery. • Translational development experienced from discovery through IND submission. • Approved Chemical Surety and DEA Schedule 1-5 handling license. 	
MCDC Project Awards/Other MCM Relevant Efforts	Desired Teaming Areas	
<p>WMD MCM, pharmaceuticals, medical devices</p> <ul style="list-style-type: none"> - CNS active OP antidotes - MMB4, HLo7, and stable autoinjectable formulations - Cyanide antidotes and formulations - New antivirals - Anti infectives 	<p><u>We offer-</u></p> <ul style="list-style-type: none"> Opioid countermeasures Nerve agent antidotes CMC & Regulatory exp. Autoinjectable formulation & other routes of admin. cGMP Manufacturing & Medical devices QC and ICH Stability 	<p><u>We desire</u></p> <ul style="list-style-type: none"> Partnerships Regulatory Lead candidates Clinical



DynPort Vaccine Company

MCDC Member Information	Member Capabilities
<p><u>DynPort Vaccine Company</u> Frederick, MD</p> <p><u>Key POC(s):</u> Gary Nabors, gary.nabors@gdit.com Mary Kate Hart, marykate.hart@gdit.com</p> <p><u>Business Class:</u> Large</p> <p><u>Status:</u> Traditional</p> <p><u>Member since:</u> September 2016</p>	<ul style="list-style-type: none"> • DVC is a systems integrator capable of managing all aspects of medical product development. Our internal expertise includes SMEs in manufacturing, test development, nonclinical studies, clinical trials, biostatistics, regulatory affairs, quality systems, earned value management, contracts/subcontracts management and project management. • DVC has subcontracted a wide variety of services in order to build teams to meet government requirements. Major subcontracted services include process development, cGMP manufacturing and validation, test development and validation, nonclinical studies and clinical trials.
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>Current: Botulinum vaccine, plague vaccine, butyrylcholinesterase bioscavenger, small molecule anti-infectives, monoclonal Abs</p> <p>Past: Vaccines and therapeutics for biodefense and influenza indications</p>	<p>Partnering to develop products including vaccines, biologic therapeutics, small molecule therapeutics, monoclonal antibodies, and other medical solutions.</p>



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Advanced Technology Systems Company



MCDC Member Information	Member Capabilities
<p>Advanced Technology Systems Company McLean, Virginia Key POC(s): Bill Pramenko, Bpramenko@ATSCVA.com Vice President, Program Development and Marketing 703-556-0557</p> <p>Business Class: Small Business</p> <p>Status: Non Traditional</p> <p>Member since: <month, year></p>	<ul style="list-style-type: none"> • Logistics • FMS • FSR • Integration • R&D support • Engineering • Developmental engineering • Subtractive and Additive manufacturing
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>Building of a NEPMU</p>	<p>Manufacturing/assembly of FRP Communications/Logistics/OCONUS/FMS</p>



Universal Stabilization Technologies, Inc.



MCDC

MCDC Member Information	Member Capabilities
<p>Company name: Universal Stabilization Technologies, Inc. San Diego, CA</p> <p>Key POC(s): Dr. Victor Bronshtein victorb@vitrilife.com 858-245-9323</p> <p>Business Class: Small Business</p> <p>Status: Nontraditional</p> <p>Member since: December, 2017</p>	<ul style="list-style-type: none"> - Preservation of fragile biologics, such as vaccines, for long-term stability in the dry state at high ambient temperatures. - Development of dissolvable, needle-free delivery devices for mucosal and transdermal administration of thermostable biologics. <p><u>Contract Service and Production Capabilities:</u></p> <ul style="list-style-type: none"> • Scalable production by foam drying of thermostable vaccines and biologics in the dry state, in unit dose or bulk formats. <ul style="list-style-type: none"> • Vials, bottles, bags, trays, syringes, cartridges • Process development for particle size reduction of foam to powder. <ul style="list-style-type: none"> • Ball milling, jet milling, blending • Delivery methods/devices preparation: dissolvable polymeric films, dissolvable microneedle patches, enteric coated capsules, tablets, wafers, creams/ointments, blister packs • Physicochemical analysis of dried materials and devices
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
	<p>Provide stabilization and delivery technologies to collaborators for production of thermostable vaccines for mucosal and transdermal delivery.</p>



MCDC



Lauren
SCIENCES LLC

Lauren Sciences LLC

V-Smart[®] Nanomedicines

Non-Invasive Targeted Brain Therapeutics

MCDC Member Information	Member Capabilities
<p>Lauren Sciences LLC New York, New York</p> <p>Susan Rosenbaum, JD, Founder, Chair, CEO Irwin Hollander, PhD, VP of R&D</p> <p>Small Biotechnology Company</p> <p>Nontraditional</p> <p>October 2018</p>	<p>Lauren Sciences is New York biotech that solves greatest medical challenge in treatment of brain diseases -- that most therapeutic agents, including biologicals, do not cross blood brain barrier (BBB) -- with its breakthrough V-Smart[®] technology from Israel and its innovative V-Smart[®] targeted drug delivery platform.</p> <p>Lauren Sciences develops transformative V-Smart[®] Nanomedicines for CNS/neurological indications. V-Smart[®] Nanomedicines are proven to: encapsulate non-brain penetrant therapeutic agents, cross BBB, deliver to brain ("macro target"), target and deliver to specific brain sites ("micro target"), selectively release at target sites, be administered systemically (non-invasively), be safe and effective (pre-clinical).</p> <p>V-Smart[®] Nanomedicines are presently in pre-clinical development for: PD, ALS, Neuro-HIV, AD, GBM, and are supported with 12 foundation grant awards.</p>
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
	<p>Lauren Sciences now seeks to use its breakthrough V-Smart[®] enabling technology to develop V-Smart[®] Nanomedicines for Medical Countermeasures (MCM) to Chemical Biological Radiological and Nuclear (CBRN) threats, with V-Smart[®] and Chemical and Biological Defense (CBD) Agents for virus (antiviral e.g., antibodies, siRNA, small molecules, IgG), fungi, bacteria (anti-fungal, anti bacterial e.g., amphotericin B, antibiotics), nerve agents (anti-nerve agent e.g., oximes), opioid overdose, addiction (e.g., LAUR-004, developed with enkephalin), seizures (e.g., clonazepam).</p>



MCDC

Consegna Pharma Inc.



MCDC Member Information	Member Capabilities
<p>Consegna Pharma Inc. Pittsburgh PA</p> <p><u>Key POC(s):</u> Larry Zana, CEO, lzana@consegnapharma.com</p> <p><u>Business Class:</u> Small</p> <p><u>Status:</u> Nontraditional</p> <p><u>Member since:</u> April 2018</p>	<ul style="list-style-type: none"> Design and development of long-acting injectable formulations using Computational Drug Delivery™ software.
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<ul style="list-style-type: none"> 24 hr naloxone to address renarcotization 7-day naloxone prophylaxis 20-day butyrylcholinesterase suitable for autoinjector Fixed dose combination to treat TBI 	<p>Development of long-acting injectable formulations for medical countermeasures.</p> <ul style="list-style-type: none"> Synthetic opioids Nerve agents TBI



MCDC

MURTECH

MCDC Member Information	Member Capabilities
<p>Murtech, Inc Glen Burnie, MD</p> <p>Key POC(s): Paul Diaz pdiaz@Murtech.us</p> <p>Business Class: Veteran Owned Small Business</p> <p>Status: Non-Traditional</p> <p>Member since: April 2016</p>	<ul style="list-style-type: none"> • Program Management • CBRN Defense • Systems Management • Systems Engineering • Evaluation & Testing • Integrated Asset Management • Supply Chain Management • ITAR Registered • TS Facility Clearance
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<p>Department of Defense (DoD) Critical Reagents Program (CRP)</p>	<p>Based on set of Core Capabilities we are interested in Teaming Opportunities that span the spectrum of functional areas within the MCDC Consortium</p>



MCDC



Altimmune, Inc. (NASDAQ: ALT)

MCDC Member Information	Member Capabilities
<p>Altimmune, Inc. (NASDAQ: ALT) (formerly Vaxin Inc., Immune Targeting Systems & Pharmathene, Inc.) Gaithersburg, Maryland USA</p> <p>Key POC(s): Scot Roberts, CSO – sroberts@altimmune.com José Ochoa, CBO – jochoa@altimmune.com Sybil Tasker, CMO – stasker@altimmune.com</p> <p>Business Class: Small</p> <p>Status: Nontraditional</p> <p>Member since: October 2018</p>	<p>Altimmune is clinical stage vaccine and immuno-therapeutic company developing rationally designed products that harness the immune system to prevent and cure infections. Altimmune develops vaccine candidates through its RespirVec platform, which is a replication-deficient adenoviral vector-based vaccine platform that (i) is delivered intranasally for easy administration greatly simplifying logistics in MCM deployment, (ii) provides broad activation of the immune system including humoral, cellular, mucosal and innate immune responses, (iii) has a robust stability profile that eliminates cold chain requirements during deployment, (iv) has potential for rapid development from sequence to Phase 1 study commencement in 4 months, and (v) has proven activity in the face of pre-existing anti-vector immunity.</p>
MCDC Projects/Other MCM Efforts	Desired Teaming Areas
<ul style="list-style-type: none"> - NasoShield (anthrax) - SparVax-L (anthrax) - NasoVAX (pandemic) - RespirVec (emerging diseases) 	<ul style="list-style-type: none"> • Vaccines, Biologics, Immunotherapy • manufacturing and clinical studies

IIT Research Institute

Capabilities and Scientific Expertise



About Us

- Who we are
 - Mid-sized CRO
 - Founded in 1936 as the research arm of the Illinois Institute of Technology
 - Operates as an independent, not-for-profit preclinical contract research organization and research institute
 - Since 2002, entire operational focus is on biomedical research
 - >2500 GLP-compliant studies completed for >200 different sponsors
- Areas of specialization
 - Preclinical safety and toxicology (GLP studies since 1979)
 - Biodefense and infectious disease
 - Inhalation toxicology
 - Cancer prevention and therapeutics
- Who are our sponsors?
 - Commercial, government and academic sponsors