



# Medical Countermeasures Research and Development

Battelle is a global leader in understanding chemical and biological agents and their impact on nations, people, and economies. We conduct secure, state-of-the-art research, development and testing and evaluation using both highly toxic chemicals and highly pathogenic biological agents.

## Approach

Battelle provides efficacy testing and evaluation for FDA-regulated products that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, a naturally occurring disease, or a natural disaster. Through our world-class facilities and high containment operations, we execute the most thorough testing procedures and processes available under stringent quality management systems for providing guiding insights for the most important decisions. Products we test include:

### • Biologics

- Vaccines
- Blood products
- Antibodies (mAb)

### • Drugs

- Antimicrobials
- Antivirals

### • Devices

- Diagnostic tests
- Personal protective equipment

## Animal Models

Battelle has vast experience in developing and characterizing appropriate animal models to evaluate medical countermeasures against biological and chemical threats. We are able to administer challenge agents and test articles to laboratory species via multiple routes of exposure.



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AGENT	 MOUSE	 RAT	 HAMSTER	 GUINEA PIG	 RABBIT	 FERRET	 PIG	 NHP
<b>Bacteria</b>	Tularemia, Anthrax, Plague, Brucellosis, Melioidosis	Tularemia	Anthrax	Anthrax	Anthrax, Tularemia		Pseudomonas aeruginosa	Plague, Tularemia, Anthrax, Brucellosis, TB, Melioidosis, Shigella flexneri, Glanders
<b>Viruses</b>	Influenza, VEE, EEEV, WEEV, Ectromelia, Zika Virus, Coronavirus		West Nile, Pirital, Flexal, other Arenaviruses, Coronavirus		Rabbitpox	Influenza, Coronavirus		Monkeypox, VEE, Influenza, West Nile, Polio, Chikungunya, Zika Virus, Coronavirus
<b>Toxin</b>	Botulinum, Ricin, Aflatoxin, T2, Tetanus			Botulinum, Aflatoxin				Botulinum, Ricin
<b>Chemical</b>	HTMs Vesicant, Nerve Agents, TICs/TIMs			HTMs, Vesicants, Nerve Agents, Opioids	HTMs, Vesicants, Nerve Agents	HTMs, Opioids	HTMs, Vesicants, TICs/TIMs	HTMs, Nerve Agents, Vesicants, Opioids
PARAMETERS/BIOMARKERS								
<b>Clinical Observations</b>	✓	✓	✓	✓	✓	✓	✓	✓
<b>Pulmonary Function</b>	✓			✓	✓	✓	✓	✓
<b>Telemetry</b>	✓		✓	✓	✓		✓	✓
<b>Hematology/Clinical Chemistry</b>	✓		✓	✓	✓	✓	✓	✓
<b>Immune Response Assays</b>	✓			✓	✓	✓		✓
<b>Cytokine Analysis</b>	✓				✓	✓	✓	✓
<b>Transcriptomics/Affymetrix</b>	✓						✓	✓
<b>Gene Expression (Q-PCR)</b>	✓						✓	✓
<b>Proteomics</b>	✓							✓
<b>Pathology</b>	✓		✓	✓	✓	✓	✓	✓

### Drug Approvals

Battelle’s non-clinical studies have supported the successful licensure of multiple medical countermeasure drugs intended for human use under the FDA Animal Rule.

Products Approved by FDA	
Drug	Date
Brincidofovir (Tembexa) - Smallpox Virus Antiviral	June 4, 2021
TPOXX (tecovirimat, ST-246) - Smallpox Virus Antiviral	July, 2018
Anthim - Inhalational Anthrax	March 18, 2016
Biothrax - Inhalation Anthrax	November 23, 2015
Anthrasil - Inhalational Anthrax	March 25, 2015
Ciprofloxacin - Pneumonic Plague	February 2, 2015
h-BAT - Botulinum Neurotoxin	March 22, 2013
Raxibacumab - Inhalational Anthrax	December 12, 2012
Levofloxacin - Pneumonic Plague	April 27, 2012
Cyanokit - Cyanide Poisoning	December 15, 2006
Pyridostigmine bromide - Soman Nerve Gas	February 5, 2003