Programs to Accelerate the Development of Diagnostics for Bacterial ID Plus AMR or AST Characterization

Office of Biodefense, Research Resources, and Translational Research (OBRRTR)
Division of Microbiology and Infectious Diseases (DMID)

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NIAID

National Institute of Allergy and Infectious Diseases

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Division of Microbiology and Infectious Diseases

…supports extramural basic through applied research to control and prevent diseases caused by virtually all human infectious agents except HIV

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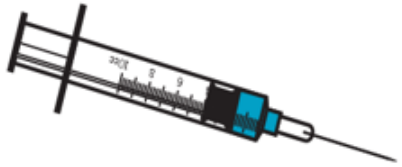
Programs to Accelerate Development of ID, AMR, AST

- DMID Concept Acceleration Program for Diagnostics
- NIAID supports CARB-X Diagnostics, Therapeutics, and Preventives
- DMID Omnibus Broad Agency Announcement for Diagnostics proposals
- NIAID Diagnostics Pre-Clinical Services
- NIAID Research Resources for IVD developers

Concept Acceleration Program (CAP)

- Actively engage entrepreneurs / industry
- Focus on innovative technologies/platforms
- Provide strategic advice to help shepherd candidate products through the R&D and regulatory processes via, e.g., **CARB-X**, FIND
- Identify promising early research & help translation into IVD projects suitable for advanced development via the **Omnibus BAA**
- Leverage **Pre-Clinical Services** (PCS) to address critical “gap-filling” needs
- Alignment with current regulatory guidance for faster clearances and commercial success and sustainability

Diagnostics



Vaccines

Therapeutics

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CARB-X Accelerator for Early Development

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https://carb-x.org/apply/before-you-apply/

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DMID Omnibus Broad Agency Announcement (BAA)

- Annual solicitation for proposals to combat antimicrobial resistance
- Current Objectives:
  - Faster bacterial ID direct from whole blood, < 4 hr
  - AST from PBC or bacterial isolate in < 2 hr
  - Combined bacterial ID and predictive AMR or AST in < 7 hr
  - Improved performance in nucleic acid sequencing, mass spec sensitivity, protein sequencing, antigen or toxin capture and detection

Structure of BAA Contract Awards

- Awards will be made as milestone-driven periods of performance (Base + Options) based on a negotiated Statement of Work
- Options will only be exercised when milestones defined in the Statement of Work are achieved
- NIAID estimates a total FY23 budget of up to $12.8 million for the non-severable base work (combined direct and indirect costs) for contracts awarded across multiple Research Areas, depending on the number of technically meritorious proposals, agency priorities, and availability of funds.
- The total performance period comprising the Base and any Options proposed by an Offeror shall not exceed five (5) years.

Contract Awards Will NOT Support Development of:

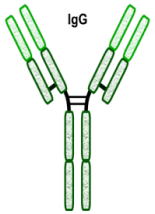
- Diagnostic tests for pathogen ID from culture or isolate (bacterial plate).
- Diagnostics that rely solely on the detection of host-response proteins.
- Basic research and discovery of new host-based diagnostic targets.
- Diagnostic efforts that will require significant hardware development

Why Diagnostics Pre-Clinical Services?

- Lower the risk for product developers; encourages commitment to product development to reduce the burden of infectious diseases
- Expertise/capability in product development
- Help accelerate promising discoveries along the product development pathway
- Gap-filling, not intended as full development program
- Agreements assure confidentiality, maintain intellectual property (IP) of product developer, and encourage publication

Pre-Clinical Services Scope of Support

In-Scope Services



- Specimen acquisition
- Reagents and Assays
- Product development support

Out-of-Scope Services

- Dx testing in animal samples
  - Usually not part of IVD development
    - —CDRH has no Animal Rule for Diagnostics, unlike CDER
    - —IVD testing is usually non-invasive
- Instrument and Consumables Development
  - Usually an albatross around PD timelines and budgets

Eligibility for Support Services

- Academia, start-ups, non-profit organizations, industry, and government
- Domestic or ex-U.S. entities
- Do not need to have NIH funding
- Simple request process: available year-round
- Support based on: Priority, Significance, Innovation, Preliminary Data, Value, Product Development Plan

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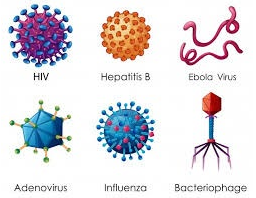
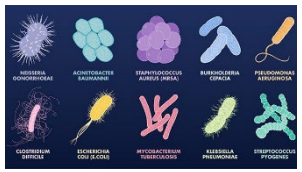
Research Tools and Biological Materials

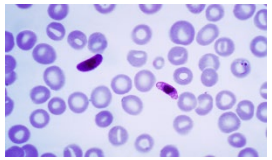
- Biological research resources (organisms and reagents)
- Basic, bioinformatics, and ‘omics research resources
- Structure determination of proteins
- Biocontainment facilities

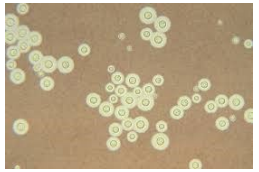
Research Resources Section

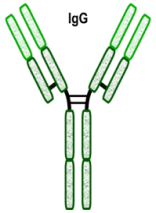
MID-BRR Repository











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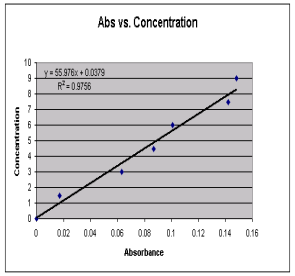
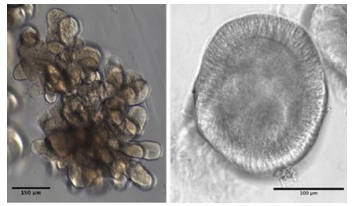
SUPPORTING INFECTIOUS DISEASE RESEARCH

In Vitro Assessment of Antimicrobial Activity



Pre-Clinical models of Infectious Diseases



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Systems Biology for Infectious Diseases Research

- Develop and validate predictive models of host/pathogen interaction networks to reveal potential biomarkers that predict disease onset, severity, progression and response to therapeutics
- Generate software packages and tools for visualization and integration of large-scale experimental, biological, and clinical datasets
- Generate publicly available datasets, computational models, experimental protocols and reagents
- Provide training on systems biology approaches to broader scientific community

https://www.niaid.nih.gov/research/systems-biology-infectious-diseases-research

Bioinformatics Resource Centers (BRCs)

- Provide open access and user-friendly interfaces to integrated research data sets and bioinformatics tools for pathogens and pathogen host interactions
- Store, update, integrate, and display various data types and associated metadata as genomic and systems biology data
- Provide analytical resources, bioinformatics services, and hands-on and web-based trainings to support the scientific community
- Promote interoperability and collaboration among BRCs, NIAID-funded programs and the scientific community

https://www.niaid.nih.gov/research/bioinformatics-resource-centers

Genomic Centers for Infectious Diseases

- Develop and use next-generation sequencing and related genomic technologies such as transcriptomics and metagenomics
- Provide genome sequencing of microorganisms, vectors, and hosts and host microbiomes
- Provide comparative genomic sequencing, single-nucleotide polymorphism identification, genotyping and gene expression
- Provide bioinformatics software tools and analyses and methods and protocols to scientific community

https://www.niaid.nih.gov/research/genomic-centers-infectious-diseases

Functional Genomics Program

- Determine the biochemical functions of hypothetical genes, unknown open reading frames, and noncoding RNAs
- Provide the foundation for developing potentially new diagnostics, therapeutics and vaccines
- Generate publically available data, software tools, experimental protocols and reagents

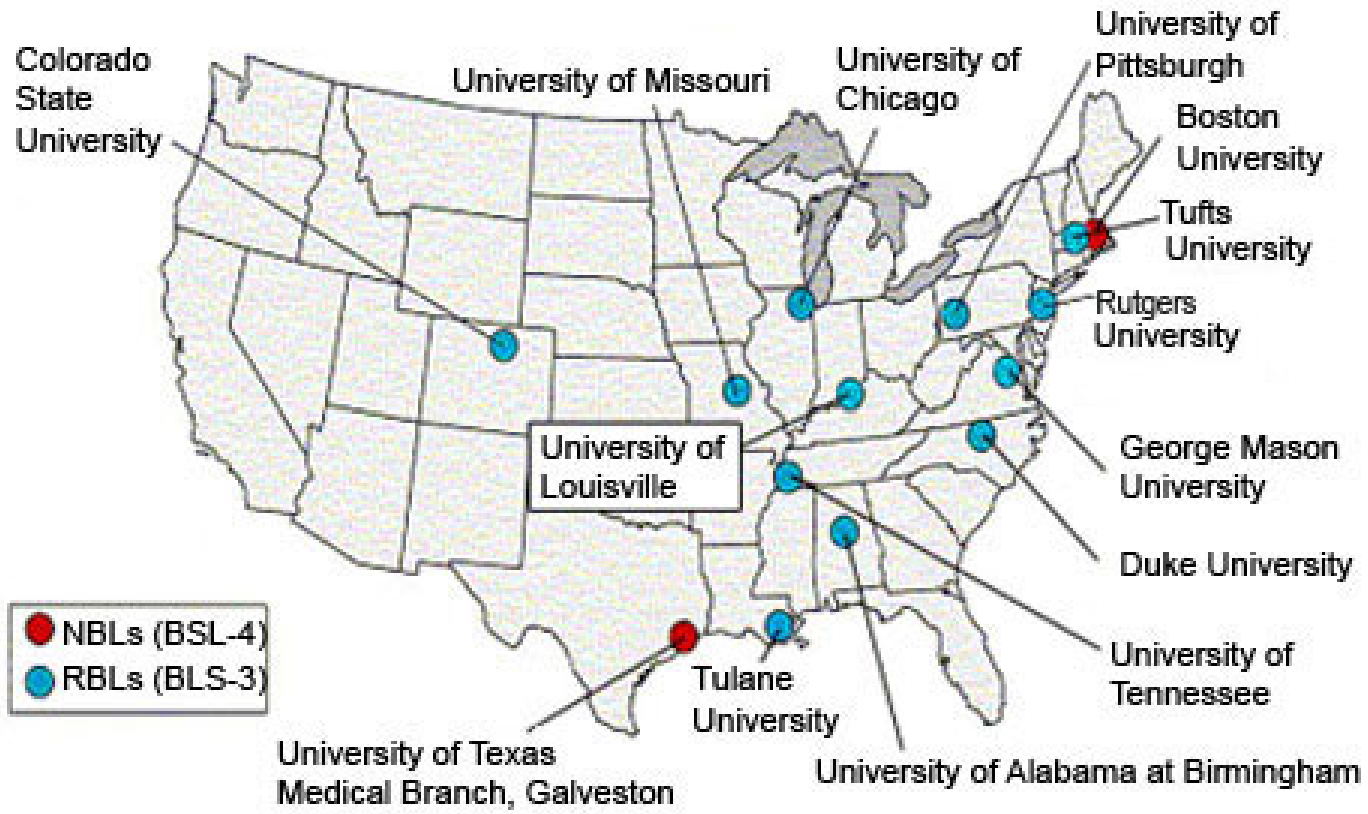
https://www.niaid.nih.gov/research/functional-genomics-program

Structural Genomics for Infectious Diseases

- For NIAID targeted pathogens and organisms causing emerging and re-emerging infectious diseases, providing the research community with:
  - Experimental three-dimensional atomic structures of targeted proteins (including structures requested from the scientific community).
  - Sequence-verified expression clones, and purified proteins made available through the centers.
  - Functional characterization of selected high value targets.
  - Structure-guided vaccine design and drug discovery efforts.

https://www.niaid.nih.gov/research/structural-genomics-centers

Biocontainment Facilities



Questions?

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