NIAID Biodefense Research Agenda

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Princeton University
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Overview

- NIAID Biodefense Research Agenda
- Biodefense Research Pathway
- 2003 initiatives
- 2004 opportunities
NIH Biodefense Research Funding, FY 2000-2004

Dollars in Millions

<table>
<thead>
<tr>
<th>Year</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>$0</td>
</tr>
<tr>
<td>2001</td>
<td>$0</td>
</tr>
<tr>
<td>2002</td>
<td>$274.5M</td>
</tr>
<tr>
<td>2003</td>
<td>$1.497B</td>
</tr>
<tr>
<td>2004</td>
<td>$1.625B</td>
</tr>
</tbody>
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(Budget Appropriation) (P.B.)
Biodefense Research Priorities and FY03 NIH Budget

- Basic Research (including Genomics) $297M
- Diagnostics $27M
- Vaccines $337M
- Expansion of Research Capacity $746M
- Therapeutics $90M

$1.497 Total

NIAID Biodefense Research
http://biodefense.niaid.nih.gov
FY 2004 President’s Budget - NIAID

- AIDS: $1.407B (32.4%), +4.6%
- Biodefense: $1.611B (37.2%), +45.0%
- Non-AIDS Non-Biodefense: $1.317B (30.4%), +3.3%

Total: $4.335B

NIAID Biodefense Research
http://biodefense.niaid.nih.gov
Biodefense Research: A Delicate Balance

Investigator - Initiated Scientific Concepts

Programmatic Direction to Guide Countermeasures Development
Research Target Areas

- Basic Research
- Countermeasures
- Research Resources
- Involvement of Industry
Basic Research in Biodefense: Progress and Priorities

Basic Research

- Pathogenesis
- Microbial Physiology and Ecology
- Genomics/Proteomics
- Host Defenses
- Animal Models

NIAID Biodefense Research

http://biodefense.niaid.nih.gov
Countermeasures

- Therapeutics
- Improved Vaccines
- New/Novel Vaccines
- Diagnostics
NIAID Scientific Accomplishments in Biodefense: Therapeutics

- Identified new targets sites for anthrax toxin
- Prepared and submitted treatment IND for cidofovir
- Developed new encephalitis animal model for testing of drugs against flaviviruses
- Evaluating currently licensed antibiotics against Category A bacteria (plague, anthrax)
- Screened 650 antiviral compounds against 9 orthopoxvirus targets
NIAID Biodefense Vaccine Development Recent Progress

- **Anthrax**
  - Accelerated development of recombinant protective antigen (rPA)
  - Supported development of next generation vaccine candidate

- **Ebola**
  - Developed an adenoviral vector vaccine for Ebola that protected monkeys against virus challenge

- **Smallpox**
  - Accelerated development of Modified Vaccinia Ankara (MVA) as a component of a safer smallpox vaccine
  - Developing non-human primate animal challenge model
### Genomic Sequencing of Potential Bioterror Agents: Selected NIH Projects Completed or Nearing Completion

<table>
<thead>
<tr>
<th>Agent</th>
<th>Diseases</th>
<th>NIAID Category</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus anthracis</em> (multiple strains)</td>
<td>Anthrax</td>
<td>A</td>
</tr>
<tr>
<td><em>Brucella suis</em></td>
<td>Brucellosis</td>
<td>B</td>
</tr>
<tr>
<td><em>Burkholderia mallei</em></td>
<td>Glanders</td>
<td>B</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em></td>
<td>Gas gangrene</td>
<td>B</td>
</tr>
<tr>
<td><em>Coxiella burnetii</em></td>
<td>Q fever</td>
<td>B</td>
</tr>
<tr>
<td><em>E coli 0157:H7</em></td>
<td>Hemolytic uremic syndrome</td>
<td>B</td>
</tr>
<tr>
<td><em>Mycobacterium tuberculosis</em></td>
<td>Tuberculosis</td>
<td>C</td>
</tr>
<tr>
<td><em>Rickettsia typhi</em></td>
<td>Typhus</td>
<td>C</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>Bacteremia, endocarditis</td>
<td>B</td>
</tr>
<tr>
<td><em>Yersinia pestis</em></td>
<td>Plague</td>
<td>A</td>
</tr>
<tr>
<td><em>Variola major</em></td>
<td>Smallpox</td>
<td>A</td>
</tr>
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Research Resources

- Animal Model Development
- Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research
- National Biocontainment Laboratories/Regional Biocontainment Laboratories
- Biodefense and Emerging Infections Research Resources Repository
Models for Partnering with Industry on Biodefense Research

- Partnerships For Biodefense
- Collaborative Research for Drugs, Diagnostics, Immunotherapeutics, Vaccines and Adjuvants
- SBIRs
- Research Resources (e.g. RCEs, Repositories, Animal Models)
- Vaccine Production Contracts
  - rPA
  - MVA
Project BioShield

Three-pronged program:

- Increase authorities and flexibility for NIH to expedite research and development of critical biomedical countermeasures
- Establish secure funding source for purchase of critical biomedical countermeasures
- Establish a FDA Emergency Use Authorization for critical biomedical countermeasures
Currently Available Opportunities for FY 2004
NIAID Investigator-Initiated Small Research Grants

PA-03-108, through April 2006

- Small research projects that can be carried out in a short period of time, with limited resources.
- Up to two years, up to $50,000 (direct costs) per year. Not renewable.
- R03 mechanism, ongoing, standard receipt dates.
Biodefense Partnerships: Vaccines, Adjuvants, Therapeutics, Diagnostics, and Resources

RFA being planned

The objective of this grant program is to assist the private sector in the further development of high priority products for biodefense including specific vaccines, adjuvants and immunostimulants, therapeutics, diagnostics, and clinical resources.

Funding mechanism: U01
Small Business Biodefense Program

PAS-02-149

Because of the need to advance research involving biodefense and concern that the time and cost of these projects may exceed that routinely awarded for SBIR and STTR grants, NIAID will entertain well-justified applications focused on NIAID high priority biodefense products with expanded duration and award limits compared to standard SBIR and STTR grants.

Funding mechanism: SBIR-R43/R44 and STTR-R41/R42

Ongoing
NIAID recognizes the need to establish a cadre of investigators skilled and knowledgeable in the area of biodefense and emerging infectious diseases, so it is encouraging the submission of training and career development grant applications in these areas.

Funding mechanisms: T32, T35, F32, F31, and K Ongoing
Other 2004 Initiatives

Decreases in funds or changes in priorities could eliminate or limit these initiatives.

How to Participate

- Follow the websites for information
  - grants
  - contracts
- Contract the appropriate program officer to discuss your ideas and how they might fit
- Make sure your application suits the goals of the initiative
- Look for practical approaches to meet the goals of the Biodefense agenda
- Explore new and different options for contributing
URLs

- NIH Guide to Grants and Contracts

- NIAID contracts RFP site
  http://www.niaid.nih.gov/cgi-shl/cmb/rfps.cfm

- NIAID Biodefense website
  http://www.niaid.nih.gov/biodefense