

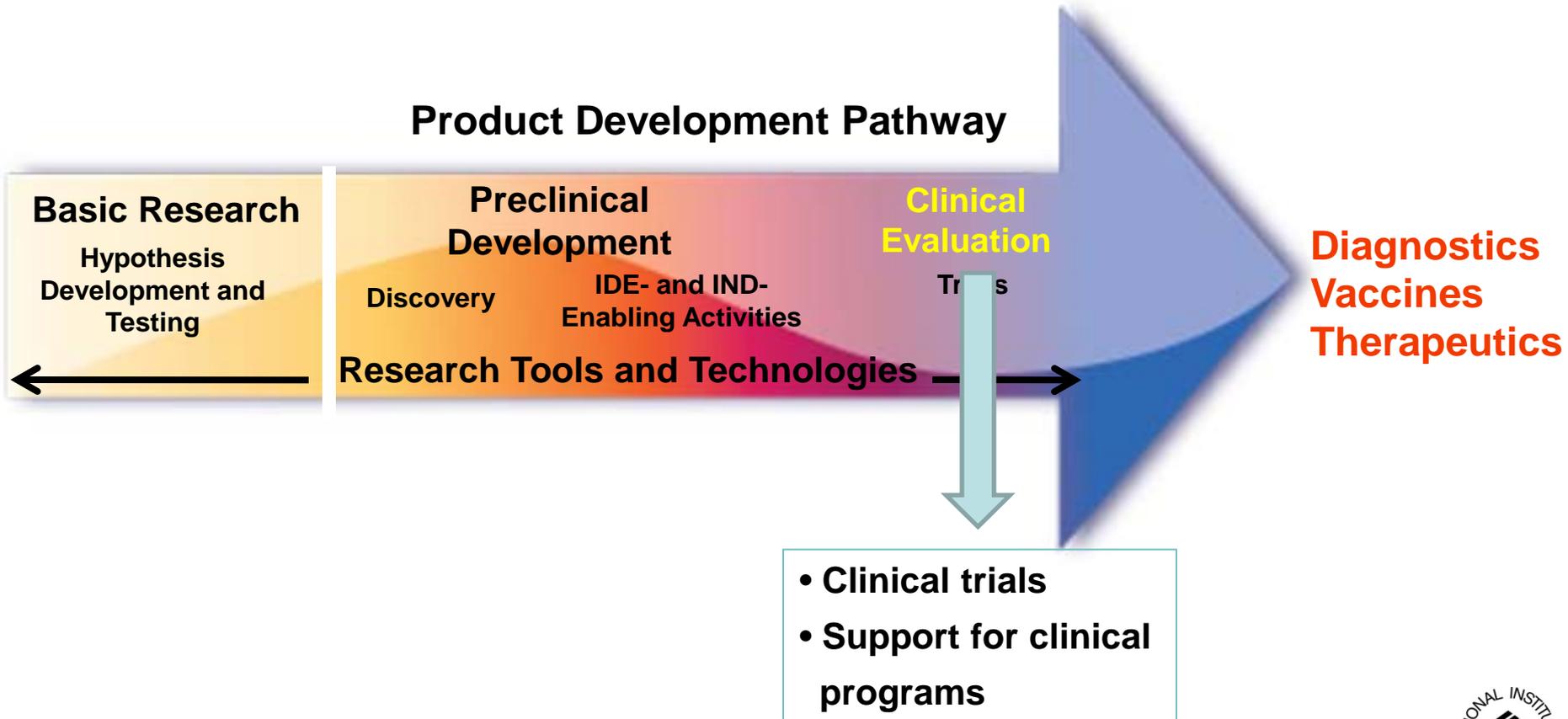
Clinical Resources for the Microbiology and Infectious Diseases Research Community

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December 10, 2012



Clinical Resources to Support Product Development



Clinical Resources

- Broad programs
 - Phase I Clinical Trial Units
 - Vaccine and Therapeutic Evaluation Units (VTEUs)
- Ability to test different types of products:
 - Therapeutics
 - Vaccines
 - Devices
- Access to special populations



Vaccine and Treatment Evaluation Units and Phase I Clinical Trial Units



Clinical Resources

- Types of trials conducted include:
 - First in human
 - QTc trials
 - Trials with novel anti-microbial therapeutics
 - Multiple trials with biodefense agents including smallpox and anthrax vaccines
 - Flu vaccine trials in pediatric and elderly populations



Support for Clinical Evaluation

- Clinical Agents and Specimen Repository
- Clinical Research and Operations Management Support (CROMS)
- Regulatory Affairs Support
- Statistics and Data Coordinating Center for Clinical Research (SDCC)



Clinical Resources Eligibility Criteria

- Concept proposals may be submitted to the concept approval committee by
 - Investigational site Principal Investigators
 - DMID staff



Clinical Resources Application Process

- Consultation with relevant Program Staff
 - Assessment of ‘readiness’
 - Availability of product for clinical use
 - Adequate non-clinical data available
 - Programmatic priorities
 - Budgetary constraints
 - Filling an important gap based in overall product development plan



Clinical Resources Approval Process

- Prioritized by DMID VTEU and Phase I Clinical Trials Concept Approval Committee based on:
 - Public health significance
 - Appropriateness and feasibility of study design
 - Capacity of proposed clinical sites
 - Proposed personnel



Clinical Resources Assurances Provided

- Materials Transfer Agreement (MTA)
- Clinical Trial Agreement (CTA)
- Safety oversight, clinical monitoring, data management and regulatory management, as needed



Clinical Resources

Requirements for Users

- Clinical site investigators are expected to publish results:
 - Expectations and requirements detailed in CTA/MTA
- Manuscripts, abstracts and presentations provided to DMID and the company for review and comment prior to release



DMID Resources for Researchers

Resources for Researchers

DMID Resources for Researchers

[Animal Models of Infectious Disease](#)

[BEI Resources Repository](#)

[Bioinformatics Resource Centers](#)

[Biosafety Laboratories](#)

[Clinical Agents and Specimen Repository](#)

[Clinical Laboratory Diagnostics for Invasive Aspergillosis](#)

[Clinical Proteomics Centers](#)

[Clinical Research Operations and Management Support](#)

[Filariasis Research Reagent Resource Center](#)

[Genome Sequencing Centers](#)

[International Clinical Sciences Support Center](#)

[In Vitro Assessment](#)

[Malaria Vaccine Production Services](#)

[Network on Antimicrobial Resistance in Staphylococcus aureus \(NARSA\)](#)

[Pathogen Functional Genomics Resource Center](#)

[Phase I Clinical Trial Units for Therapeutics](#)

[Regulatory Affairs Support](#)

[Schistosomiasis Resource Center](#)

[Statistics and Data Coordinating Center](#)

Resources for Researchers

Microbiology and Infectious Diseases Resources

The Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all human infectious agents except HIV.

Funding Opportunities

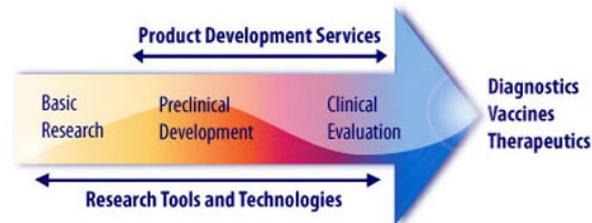
Apply for grants and contracts to conduct basic research, preclinical development, or clinical evaluation.

- [NIH-Wide Funding Opportunity Announcements](#)
- [NIAID Funding Opportunity Announcements and Requests for Proposals](#)

Product Development Services and Research Tools and Technologies

Request development by DMID-funded contractors of critical information needed to move a product through the product development pathway. Note: Services are contingent upon availability of required preliminary data.

Click on labels below to view services for [diagnostics](#), [vaccines](#), and [therapeutics](#); and for [basic research](#), [preclinical development](#), and [clinical evaluation](#).



Click on [research tools and technologies](#) above for:

- [Biological research resources](#) (organisms and reagents)
- [Microbial sequencing, genotyping, and protein biomarker discovery](#)
- [Data, databases, and bioinformatics tools](#)
- [Biocontainment facilities](#)

Website Tools

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