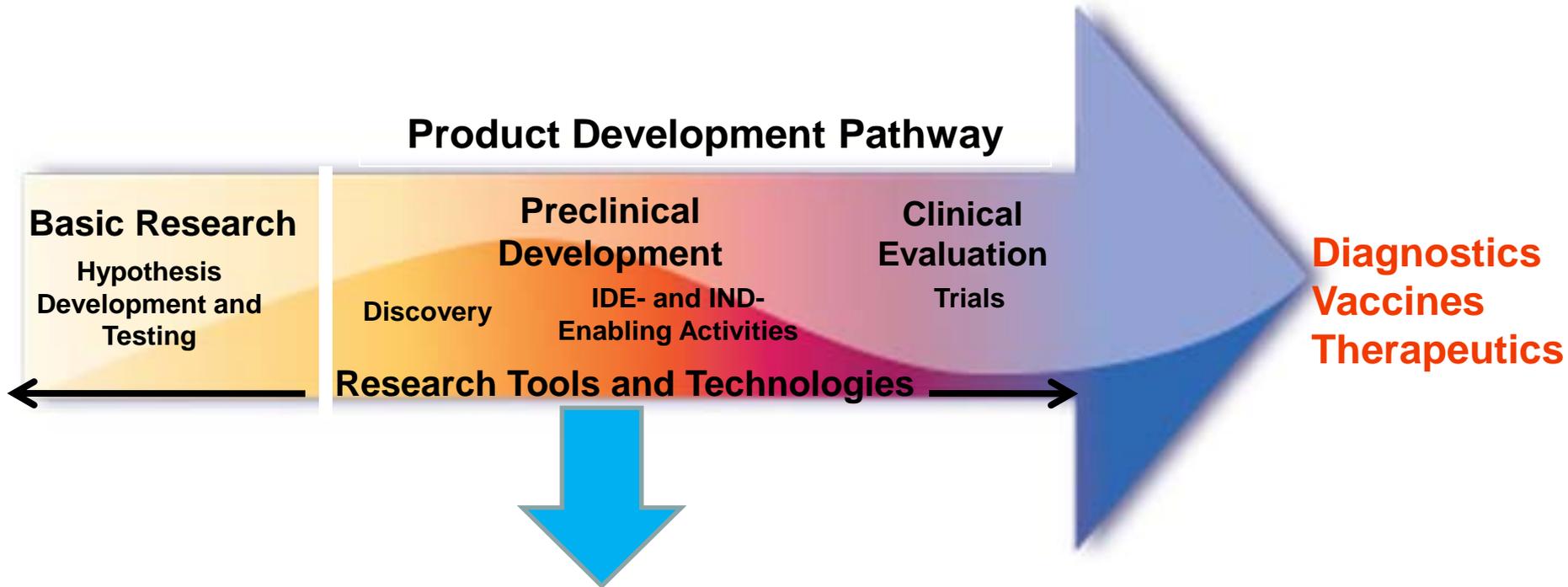


Development of Antimicrobials and Broad-Spectrum Activity: Antibiotics

Rosemarie Aurigemma, PhD
Chief, Biodefense Drug Development Section
Office of Biodefense Research Affairs
Division of Microbiology and Infectious Diseases
NIAID, NIH, DHHS
December 10, 2012

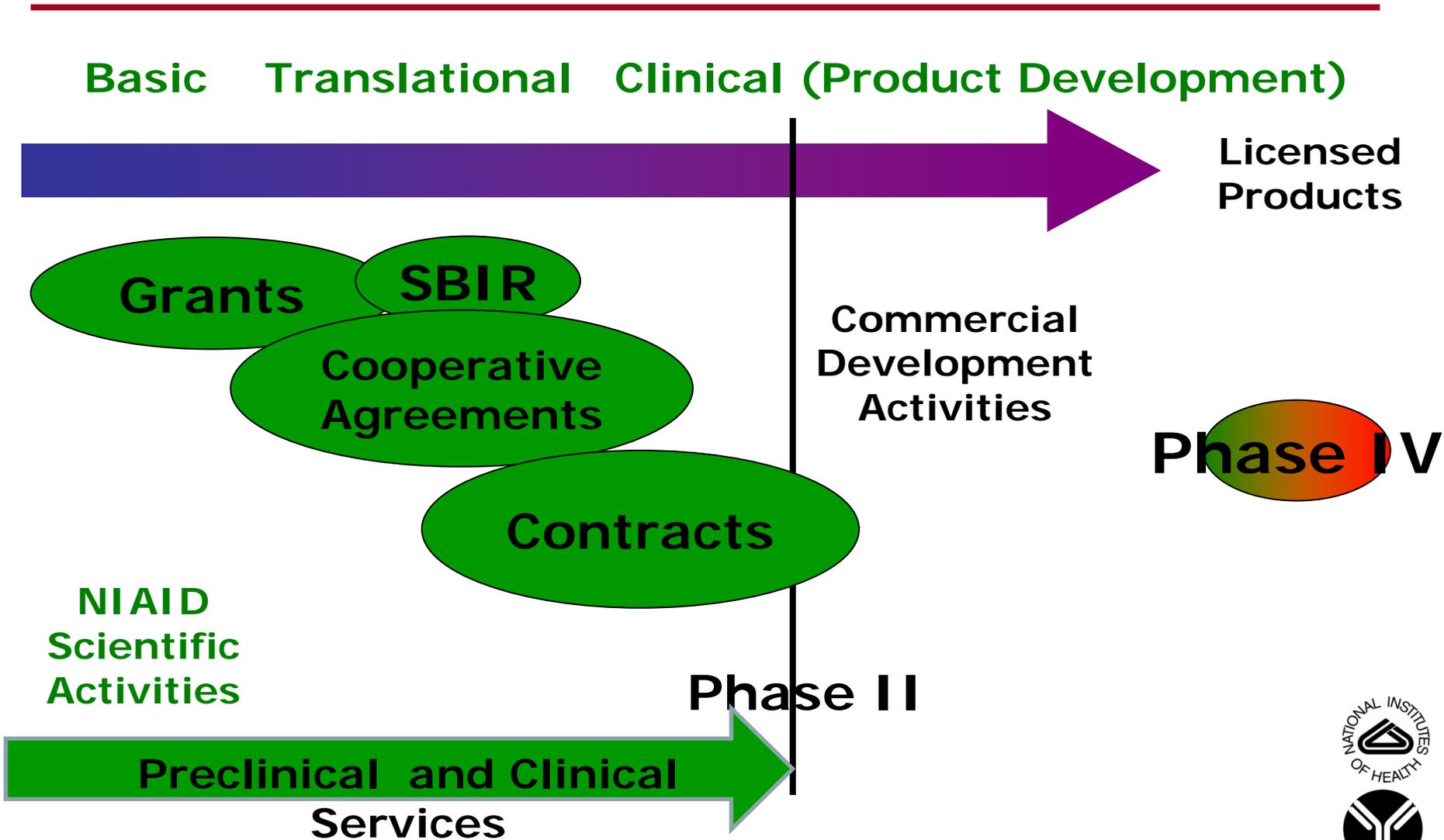


Continuous Support for Product Development

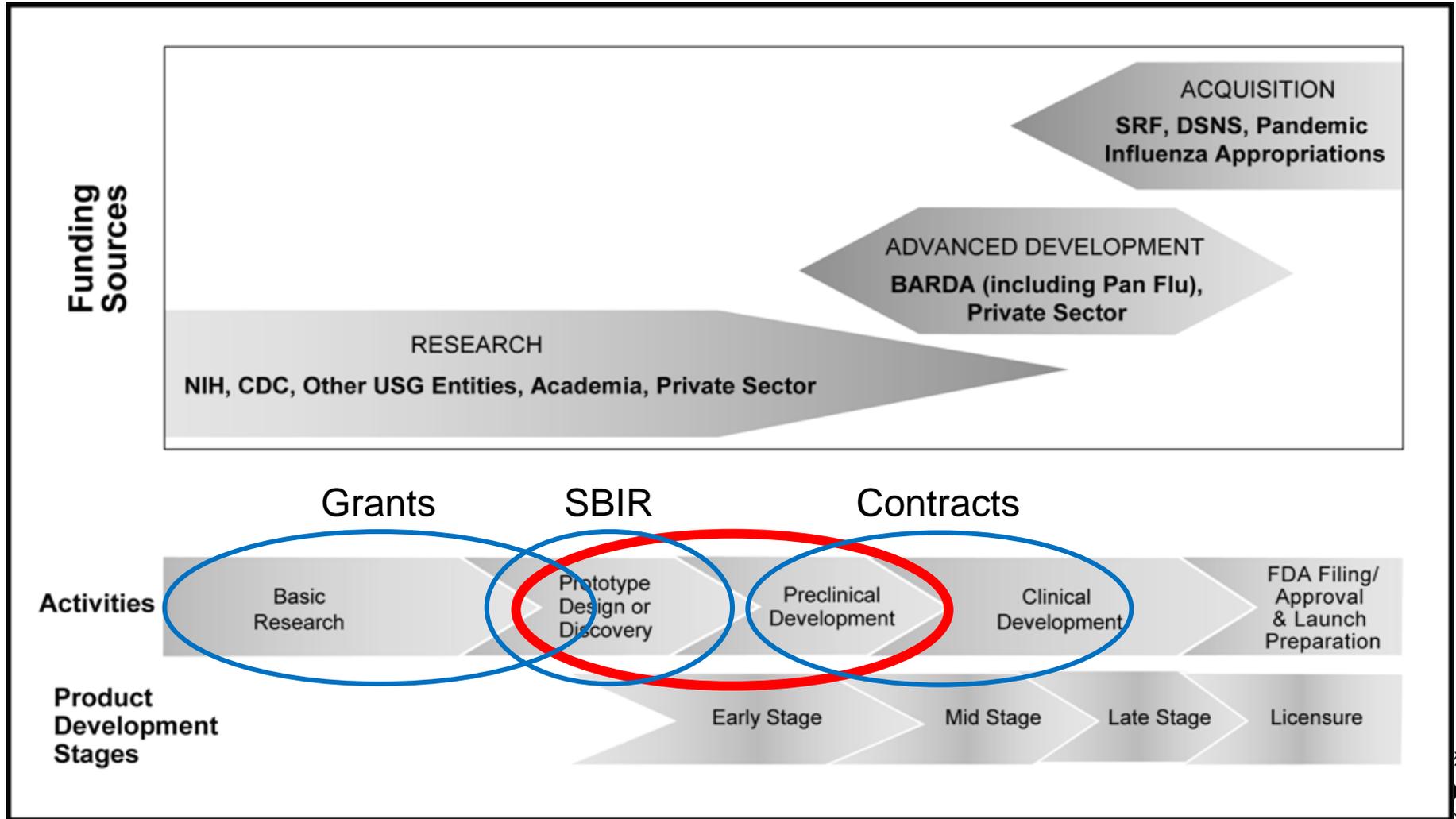


- Preclinical development support for small molecules and biopharmaceuticals
- Product development support through Phase I clinical trials

Overlapping Support for Product Development



Grants: Biodefense Partnerships



Contracts:

Broad Agency Announcement

- Office of Acquisitions conducts solicitation/award
- Proposal process:
 - Letter of Intent (no white paper)
 - Finite time to submit, proposals due within 45-90 days
 - Communication only with OA officials
 - Responses provided via BAA amendments
 - No contact with program staff during ‘open’ period
- Scientific Review Program conducts peer review
- Programmatic review based on portfolio balance, funding
- OA handles SOW negotiation; base + options structure



Finding information regarding Support Opportunities



National Institute of Allergy and Infectious Diseases

Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases.

[NIAID Home](#)

[Health & Research A to Z](#)

[Labs & Scientific Resources](#)

[Funding](#)

[About NIAID](#)

[NIAID > Research Funding > Advisory Council > Concepts Cleared](#)

Research Funding

[Newsletter and Blog](#)

[Opportunities and Announcements](#)

[Paylines and Funding](#)

[Grants](#)

[Contracts](#)

[Training and Career](#)

[International Awards](#)

[Small Business Awards](#)

[Science Policy Areas](#)

[Standard Operating Procedures](#)

[Questions and Answers](#)

[Advisory Council](#)

[Biographical Sketches](#)

[Concepts Cleared](#)

[Minutes](#)

[Operating Procedures](#)

[What Council Does](#)

[Glossary](#)

[Find It! A-Z](#)

[Latest Funding Updates](#)

Concepts: Potential Opportunities

Concepts represent early planning stages for initiatives: program announcements, requests for applications, and solicitations.

Approval of a concept by NIAID's advisory Council does **not** guarantee it will become an initiative. We make that decision based on scientific and programmatic priorities and the availability of funds.

Concepts reveal possible initiatives or give you ideas for an investigator-initiated application. Read more in [Concepts May Turn Into Initiatives](#) and [Choose Approach and Find FOAs](#) in Part 2 of our [Strategy for NIH Funding](#).

Below we post the concepts Council approves a few weeks after each advisory Council meeting—go to the [Advisory Council](#) portal for the schedule. To get an email alert when we post new concepts, sign up at [NIAID Funding Newsletter and Email Alerts Subscription Center](#) and pick Concepts, Potential Funding Opportunities as a topic of interest.

DAIDS	DAIT	DMID
May 2012	May 2012	May 2012
January 2012	January 2012	January 2012
September 2011	September 2011	September 2011
May 2011	May 2011	May 2011
February 2011	February 2011	February 2011
September 2010	September 2010	September 2010



Recent BAA solicitation for FY2013

The screenshot shows the FedBizOpps.gov website. The header includes the logo and text "FEDBIZOPPS.GOV Federal Business Opportunities". A navigation menu has "Opportunities" highlighted. The main content area displays a solicitation from the National Institutes of Health (NIH) for the "Development of Therapeutics Medical Countermeasures for Biodefense and Emerging Infectious Diseases". The solicitation number is BAA-NIAID-DMID-NIHAI2012149. The agency is the Department of Health and Human Services, Office of National Institutes of Health, located at the National Institute of Allergy and Infectious Diseases. There are buttons for "Notice Details" and "Packages", and a "Print" icon.

Complete View

[Return To Opportunities List](#)

[Watch This Opportunity](#)

[Add Me To Interested Vendors](#)

[Original Synopsis](#)

Combined

Synopsis/Solicitation

11/17/2012

Solicitation Number:

BAA-NIAID-DMID-NIHAI2012149

Notice Type:

Combined Synopsis/Solicitation



Product Development Contracts: Therapeutics (2003-present)



Product Development BAA: Broad Spectrum Therapeutics

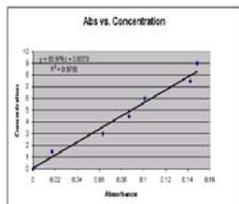
Company	Product	BioD Indication	Public Health Indication
Achaogen	Novel Aminoglycoside	i.v. Rx for: <i>Y. pestis</i> , <i>F. tularensis</i>	Gram neg. (<i>Klebsiella</i> , <i>Acetobacter</i> , <i>Pseudomonas</i>)
Trius	Small molecule dual targeted inhibitor of DNA synthesis	i.v. Rx for: <i>Y.pestis</i> , <i>F.tularensis</i> , <i>B.pseudomallei</i>	Gram neg. and gram pos. CAP and UTI
Enanta	Bicycolide (macrolide)	i.v. and oral Rx for: <i>B.anthraxis</i>	Gram pos. CABP, MRSA
CUBRC/ Tetrphase	Novel Tetracycline	i.v. and oral Rx for: <i>Y. pestis</i> , <i>F.tularensis</i> , <i>B.</i> <i>anthracis</i>	Gram pos. and gram neg. CABP
Crucell	Monoclonal antibodies	i.v. Rx for: influenza A	B.S. against influenza A; co- formulate with MAb against influenza B for prophylaxis
NexBio, Inc.	BS, host-targeted recombinant protein enzyme	Inhalation Rx for influenza A	B.S. activity against influenza A, B and parainfluenza
Unither Virology, Inc.	BS, host-targeted iminosugar antiviral	i.v. and oral Rx for: Dengue	i.v. and oral for: Influenza



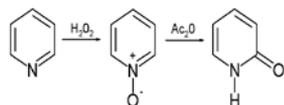
Preclinical Product Development Services

Therapeutics

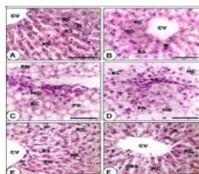
In Vitro Assessment of Antimicrobial Activity



Interventional Agent



ADM



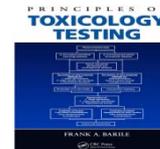
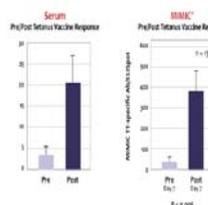
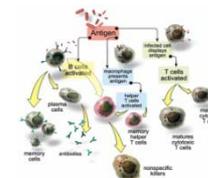
Biopharmaceutical Products



Chemistry, Manufacturing, and Controls (CMC) Documentation for IND

Vaccines

Testing



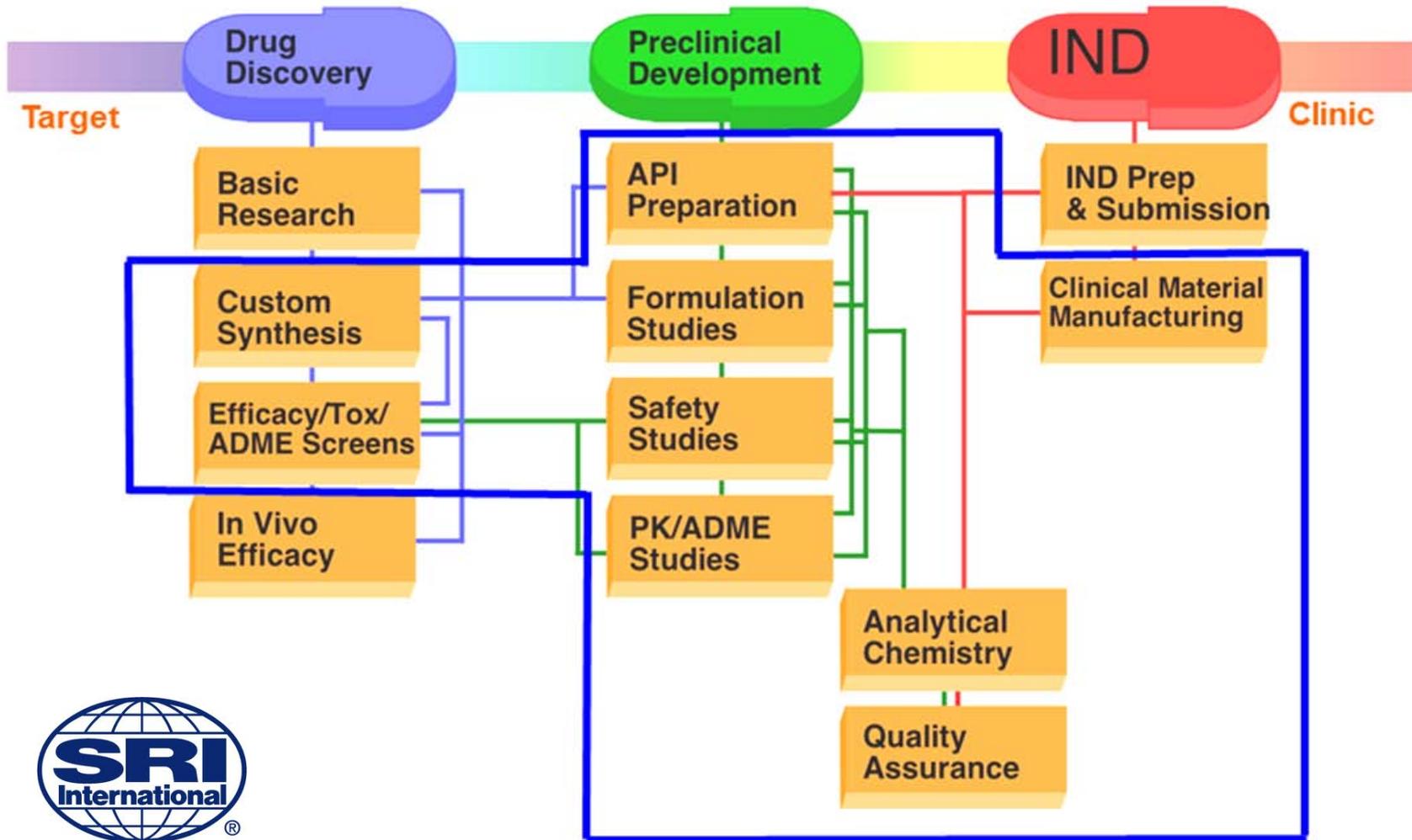
Manufacturing



Animal Models



Development of Interventional Agents: suite of services



Example: Clinical Formulation Development

- Developed a preliminary human clinical formulation
- Mock clinical capsules prepared and subjected to stability testing
- At accelerated temp/humidity (i.e., typical Brazil day), capsules with compound turned darker



Mutyam et al., AAPS Journal, 11, S2, #1425, 2009



Example: Data to Support BAA Proposal



UNITED THERAPEUTICS SUBSIDIARY ENTERS INTO CONTRACT WITH NATIONAL INSTITUTES OF HEALTH FOR AWARD OF UP TO \$45 MILLION TO SUPPORT GLYCOBIOLOGY ANTIVIRAL PROGRAM

SILVER SPRING, Md., Oct. 10, 2011 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) announced that its subsidiary, Unither Virology, LLC, has been awarded a contract for up to approximately \$45 million under a Broad Agency Announcement from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), for studies directed at the development of a broad-spectrum antiviral drug based on its glycobiochemistry antiviral platform. Based

NIAID supported:

- Drug candidate synthesis to identify a lead
- Toxicity studies to establish preliminary safety



Development of Biopharmaceutical Products: suite of services

- Services available in 5 major areas
 - Feasibility assessments
 - Assay Development
 - Process Development
 - cGMP manufacturing
 - Regulatory Documentation Support



Gap-filling 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

- [Email this page](#)
- [Print this page](#)
- [Get email updates](#)
- [Order publications](#)
- [Bookmark & share](#)

Stay Connected



Find more ways to stay connected to NIAID

Contact Info

dmidresources@niaid.nih.gov

Opportunities to Ease the Development Path



National Institute of Allergy and Infectious Diseases

Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases.

Bridging the Gap –
Overcoming Bottlenecks in
Development of
Therapeutics for Infectious
Diseases

Agenda

Logistics

Overcoming Bottlenecks in the Development of Therapeutics for Infectious Diseases



Bridging the Gap – Overcoming Bottlenecks in the Development of Therapeutics for Infectious Diseases

August 9-10, 2012
Rockville, MD

The Division of Microbiology and Infectious Diseases (DMID) at NIAID is committed to helping advance new therapeutics for infectious diseases through the product development pipeline. The three key objectives for this workshop are:

- Review the current state of the translational research enterprise from the perspective of all stakeholders
- Enable interaction between seasoned translational researchers and investigators who are new to product development and encourage new collaborations
- Brainstorm on innovative ways to address bottlenecks in product development and consider new ways to capitalize on existing resources

Website Tools

- [Email this page](#)
- [Print this page](#)

Stay Connected



[Social media privacy policy and disclaimers.](#)



Resources for Researchers

Microbiology and Infectious Diseases Resources

<http://www.niaid.nih.gov/labsandresources/resources/dmi/d/Pages/default.aspx>

THANK YOU!

Rose Aurigemma: aurigemr@niaid.nih.gov

