

Lab to Market *for Health*

Kurt Marek, PhD
Deputy Director

 @NHLBI_SBIR

Office of Translational Alliances and Coordination
DERA, NHLBI





National Institutes of Health
Turning Discovery Into Health

\$30 Billion

Basic and applied biomedical science

NHLBI is Third-Largest Institute



Health Challenges in the NHLBI Mission

#1
Heart Disease



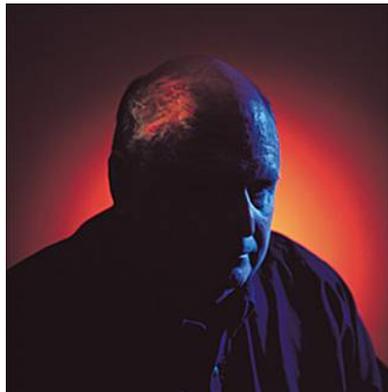
 Disability

#3
Chronic Lung
Disorders



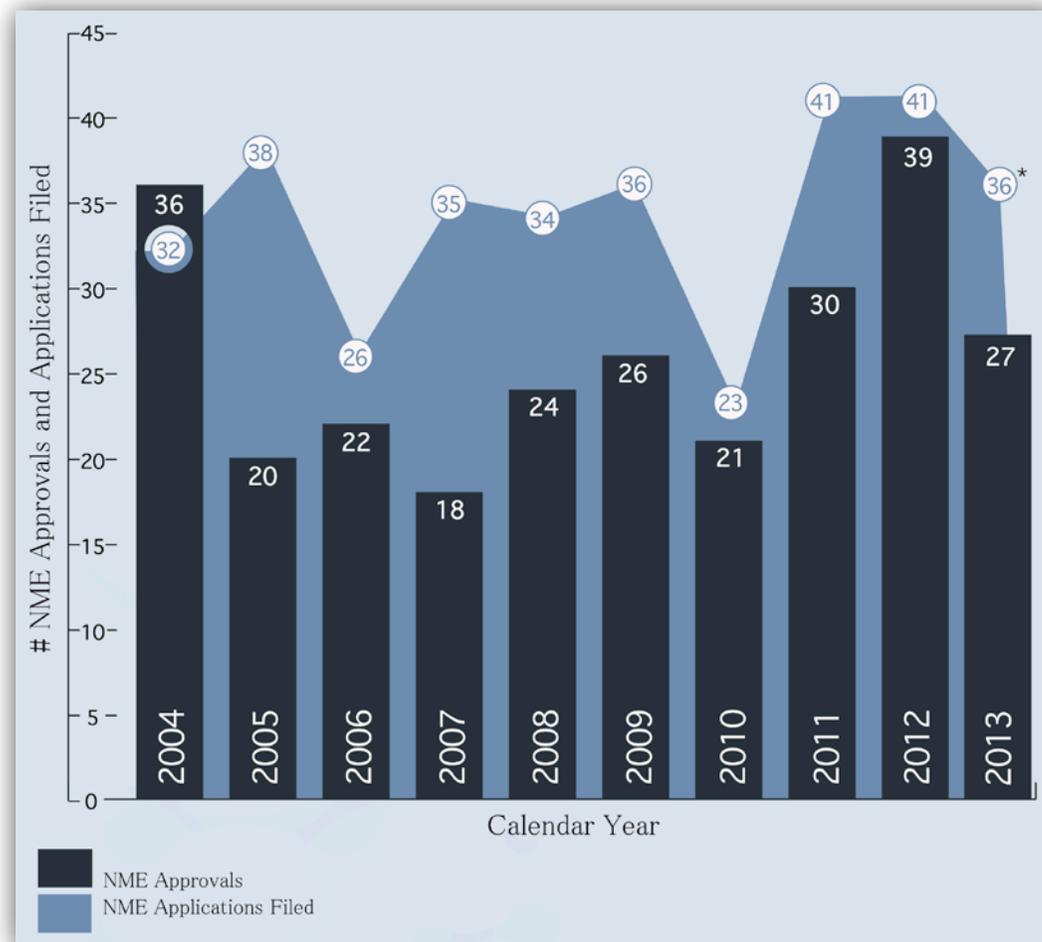
 Quality of life

#4
Stroke



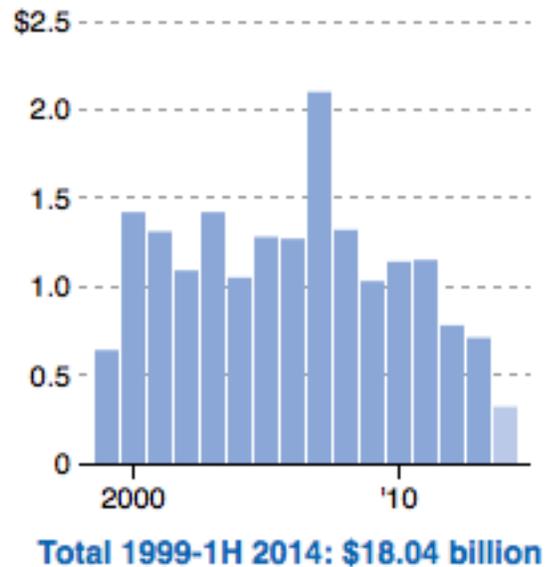
\$350 Billion

New Molecular Entities Applications and Approvals

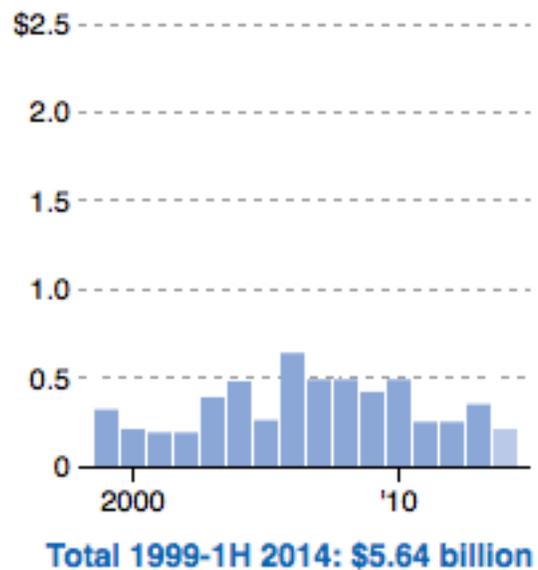


Invested by Venture Capital, in Billions

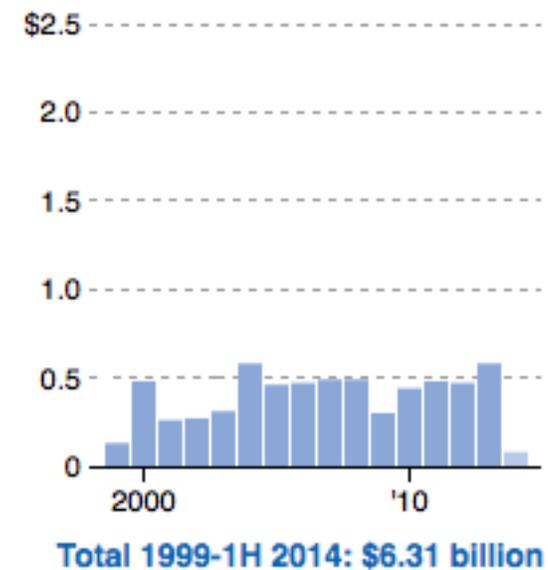
Heart



Lung



Blood

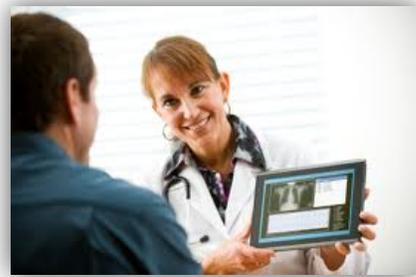
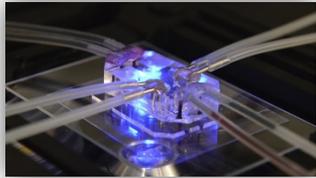


Roadblocks to Translating from Lab to Market



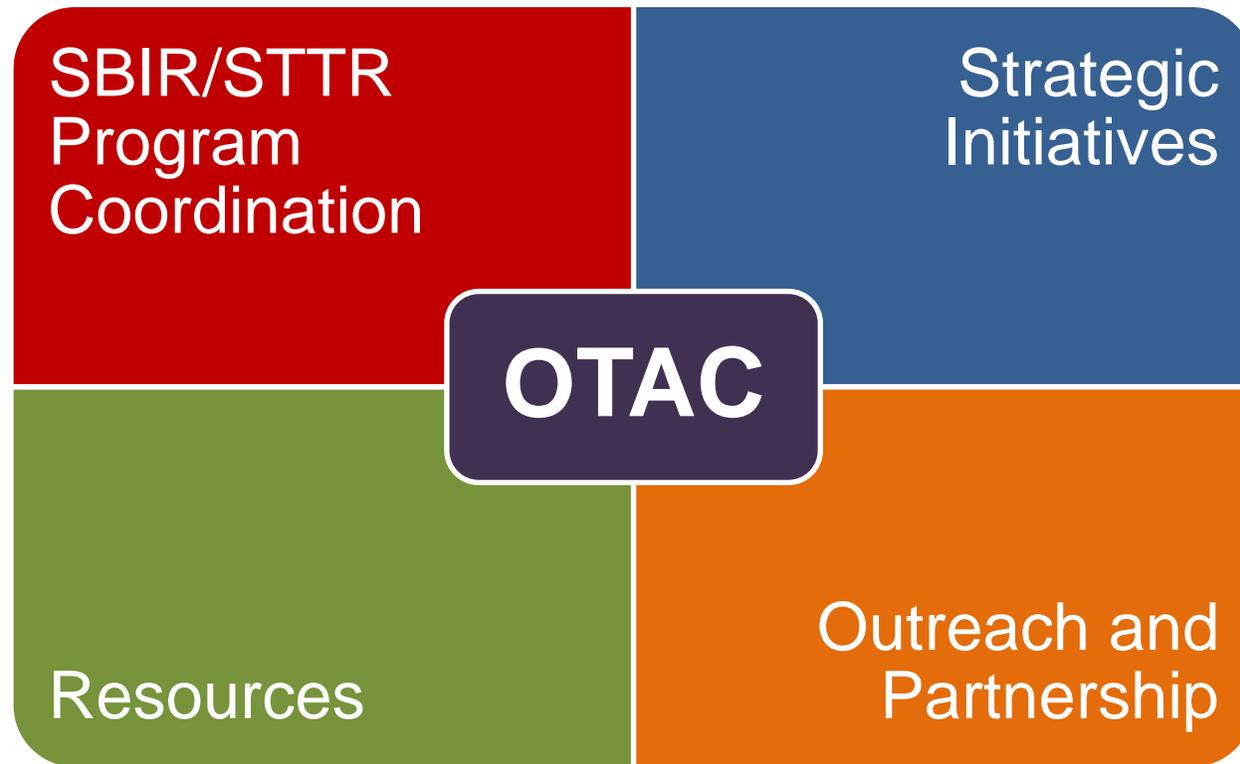
- ✗ Time to market is long and expensive
- ✗ Funding gap
- ✗ Knowledge gap
- ✗ Lack of access to expertise
- ✗ Waning industry and investor interest

Lab to Market *for Health*



- ✓ Office of Translational Alliances and Coordination: *A new approach for NIH*
- ✓ NIH Centers for Accelerated Innovations: *New model for success*
- ✓ Small business program
- ✓ Resources and outreach to support the pipeline: *Connecting people, ideas, and resources*

Lab to Market for Health



OTAC Staff



Jodi Black
Acting Director



Kurt Marek
Deputy Director



Jennifer Shieh
Small Business
Coordinator



Chris Sasiela
Regulatory Specialist



Gary Robinson
Business Development
Specialist



Gautam Prakash
Intellectual Property
Specialist



Ram Aiyar
Entrepreneur-In-
Residence



Steve Flaim
Special Advisor



Eric Padmore
Program Analyst



Jessica Rami
SBIR Program Specialist

Other NHLBI Staff Present Today

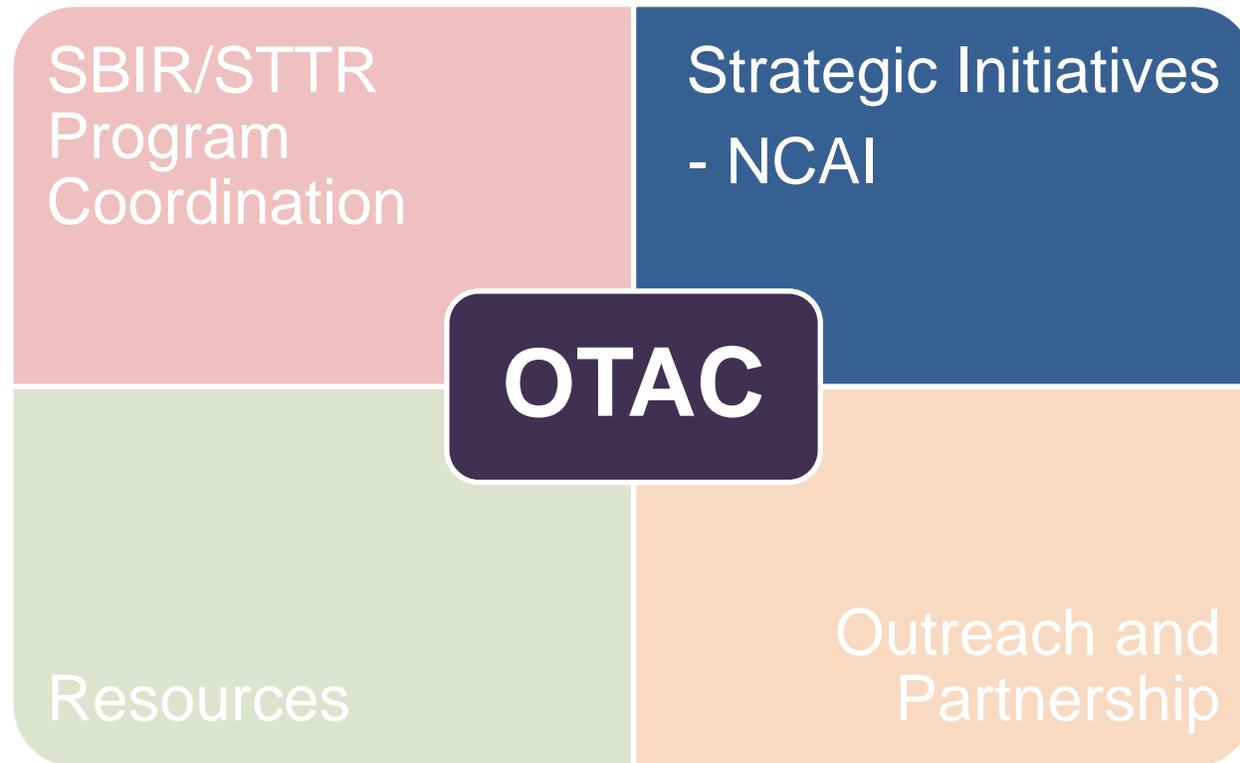


Tony Creazzo
Scientific Review Officer

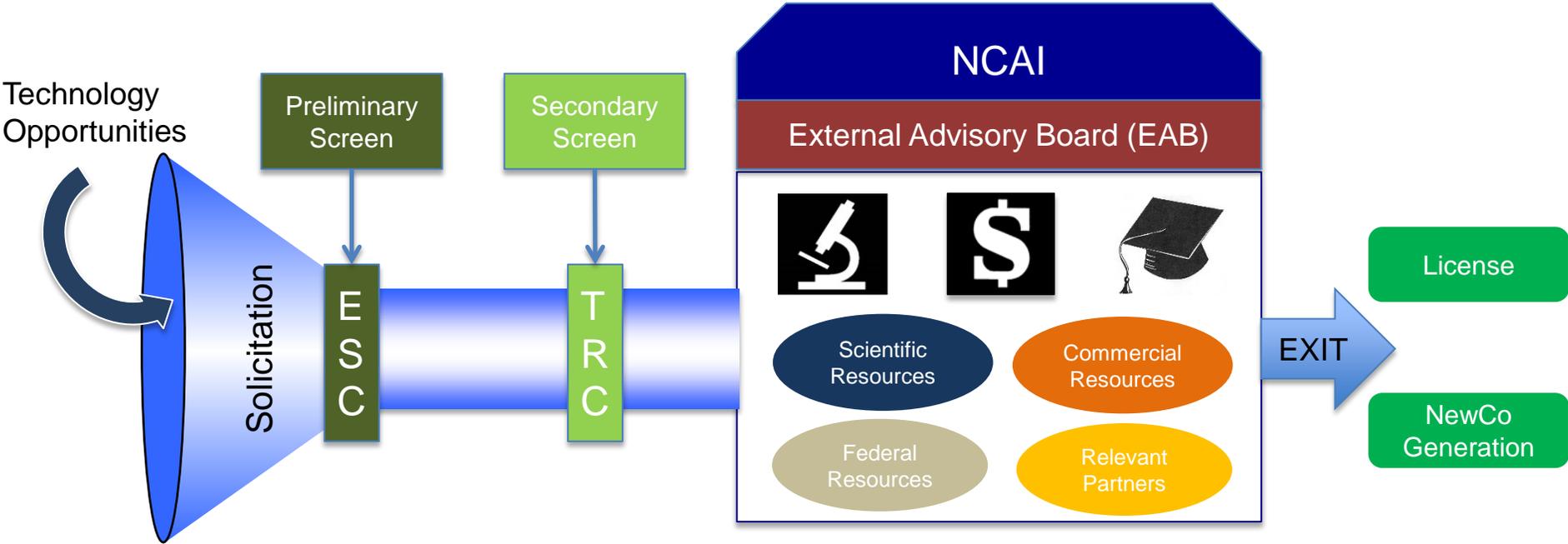


Hubert Walters
Grants Specialist

Office of Translational Alliances and Coordination



Commercially Relevant Technology Sourcing Followed by Milestone-Driven Development



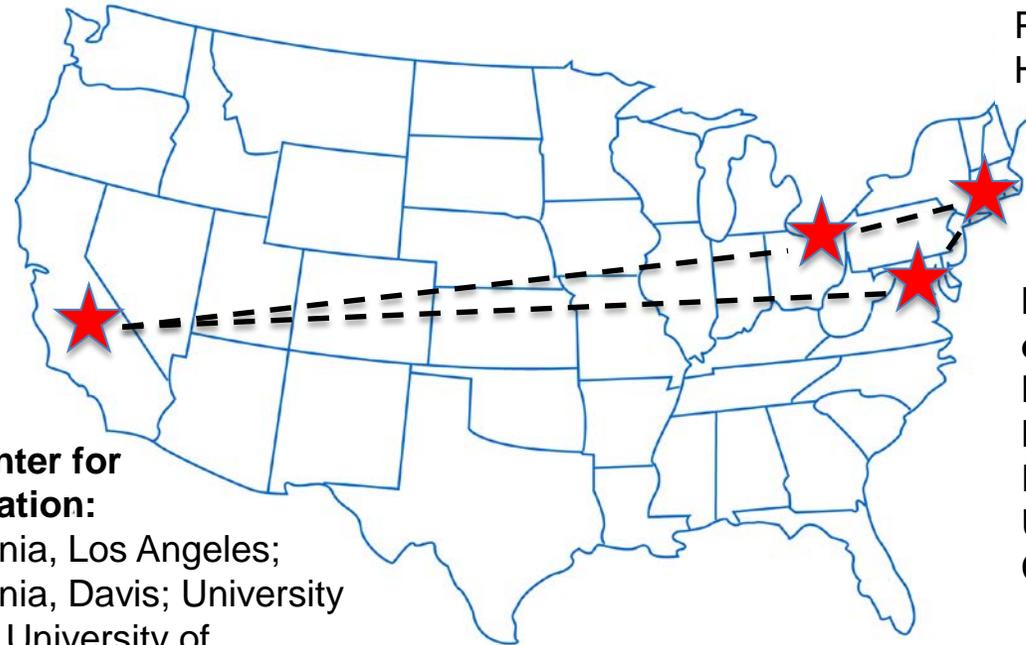
NCAI: *Catalyzing Academic Innovation*

The Cleveland Clinic Innovation

Center: The Cleveland Clinic Lerner College of Medicine, Case Western Reserve University, Cincinnati Children's Hospital, The Ohio State University, and University of Cincinnati

The Boston Biomedical Innovation Center:

Brigham and Women's Hospital, Boston Children's Hospital, Massachusetts General Hospital, and President and Fellows of Harvard College



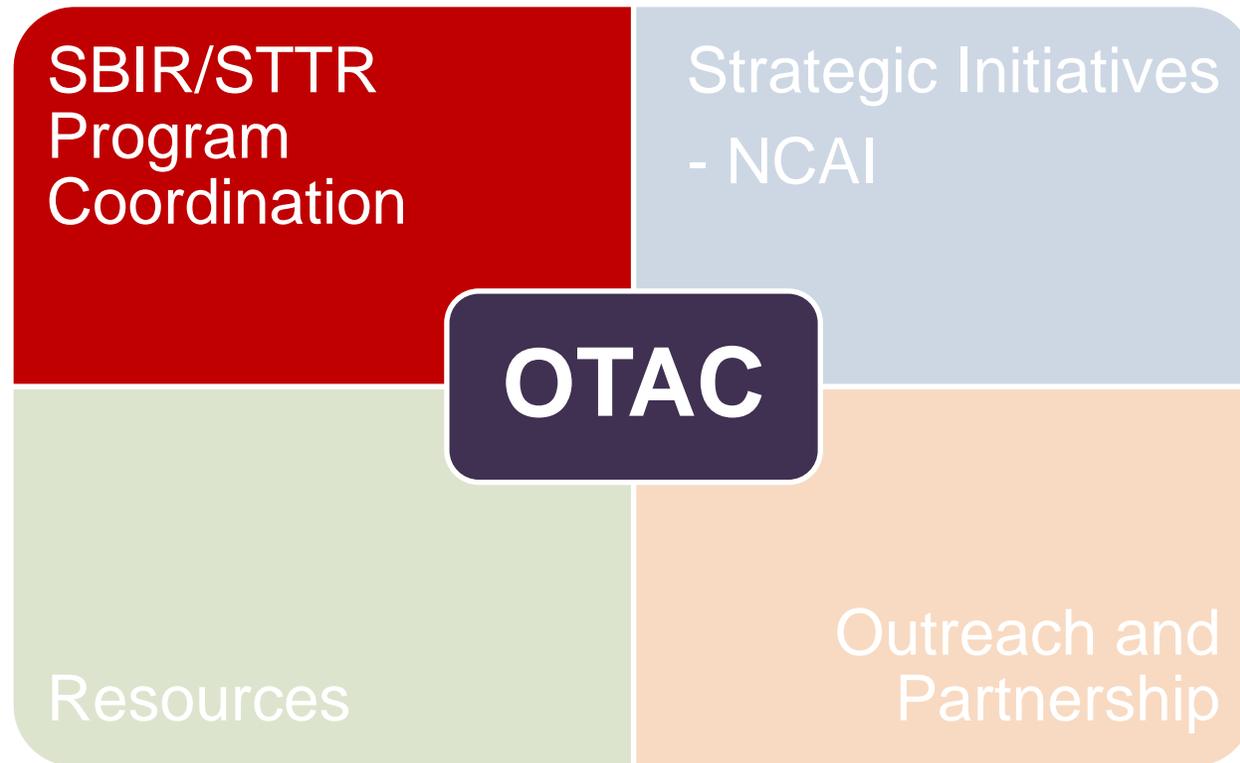
The UC BRAID Center for Accelerated Innovation:

University of California, Los Angeles; University of California, Davis; University of California, Irvine; University of California, San Diego; and University of California, San Francisco

National Institutes of Health

NHLBI
NSF
FDA
USPTO
CMS, Kaiser

Office of Translational Alliances and Coordination





MedImmune

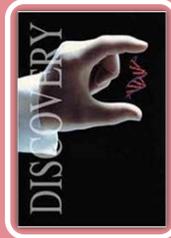


\$85 million

NON-DILUTIVE INVESTMENTS
IN INNOVATION ANNUALLY



SBIR/STTR: Phased Development



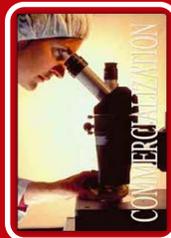
PHASE I

- Feasibility Study
- \$225K for 6-12 months



PHASE II

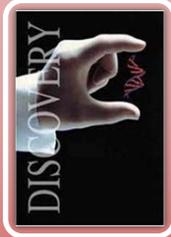
- Full Research/R&D
- \$1.5M for 2 years
- Commercialization plan required



PHASE III

- Commercialization Stage
- Use of non-SBIR/STTR Funds

SBIR/STTR: FastTrack



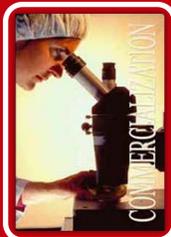
PHASE I

- Feasibility Study
- \$225K for 6-12 months



PHASE II

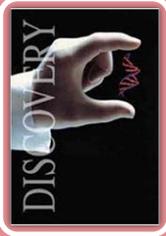
- Full Research/R&D
- \$1.5M for 2 years
- Commercialization plan required



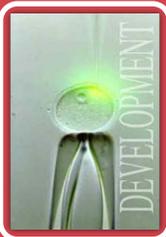
PHASE III

- Commercialization Stage
- Use of non-SBIR/STTR Funds

SBIR/STTR: Direct to Phase II

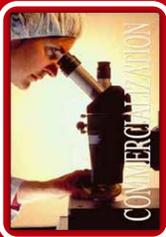


PHASE I Equivalence



PHASE II

- Full Research/R&D
- \$1.5M for 2 years
- Commercialization plan required



PHASE III

- Commercialization Stage
- Use of non-SBIR/STTR Funds

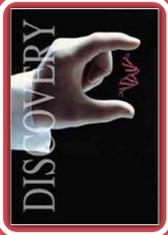
Investigator Initiated Grants

- Omnibus Solicitations (Phase I, Phase II, FastTrack)
 - [PA-14-071](#) (SBIR) and [PA-14-072](#) (STTR)
- Direct to Phase II Solicitation
 - [PAR-14-088](#) (SBIR only)

**We encourage applications for any topic
within the NIH mission**

Due December 5, 2014

Phase IIB Bridge and Small Market Awards



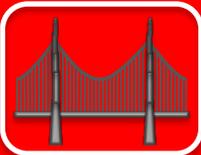
PHASE I – R41, R43

- Feasibility Study
- \$225K for 6-12 months



PHASE II – R42, R44

- Full Research/R&D
- \$1.5M for 2 years



Bridge and Small Market Awards

- \$1 million per year for 3 years
- Supports products requiring FDA clearance/approval



- Use of non-SBIR/STTR Funds

Small Market Awards

- [RFA-HL-14-012](#)
- Rare diseases, pediatric populations

Bridge Awards

- [RFA-HL-13-016](#)

Targeted Funding Opportunities

Topic	Receipt Date	FOA
Bioreactors for Reparative Medicine	10/10/14	RFA-HL-15-004 , RFA-HL-15-008
Onsite Tools and Technologies for Clinical Research Point-of-Care	10/15/14	RFA-HL-14-011 , RFA-HL-14-017
Technologies To Assess Sleep Health Status	11/14/14	RFA-HL-14-013
Assessment of Tissue Oxygenation	11/16/15 - Direct Ph II	RFA-HL-15-019
Microfluidic Platform for Blood Testing in Neonatal and Pediatric Patients	2/10/15 – Ph II	RFA-HL-14-026
Point-of-Care Device for the Diagnosis of Sickle Cell Disease in Low Resource Settings	10/23/15 – Ph II	RFA-HL-14-010

Annual Contract Topics (PHS2015-1)

- Transcatheter Cerclage Mitral Annuloplasty (SBIR-TT)
- Closure Devices for Transcaval Access to the Abdominal Aorta
- In-bore Defibrillation for Invasive MRI Cardiology Procedures
- Devices to Close Ductus Arteriosus in Premature Infants
- Therapeutic Delivery of ADP-ribosylarginine Hydrolase
- Selective Silencing of Stat3 Signaling to Treat Relapsed Disease after Transplantation
- Cellular Immunotherapy after Stem Cell Transplantation

Thank you

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301-496-2149

<http://www.nhlbi.nih.gov/sbir>

 @NHLBI_SBIR

NHLBI Resources

Resources for NHLBI-funded Companies

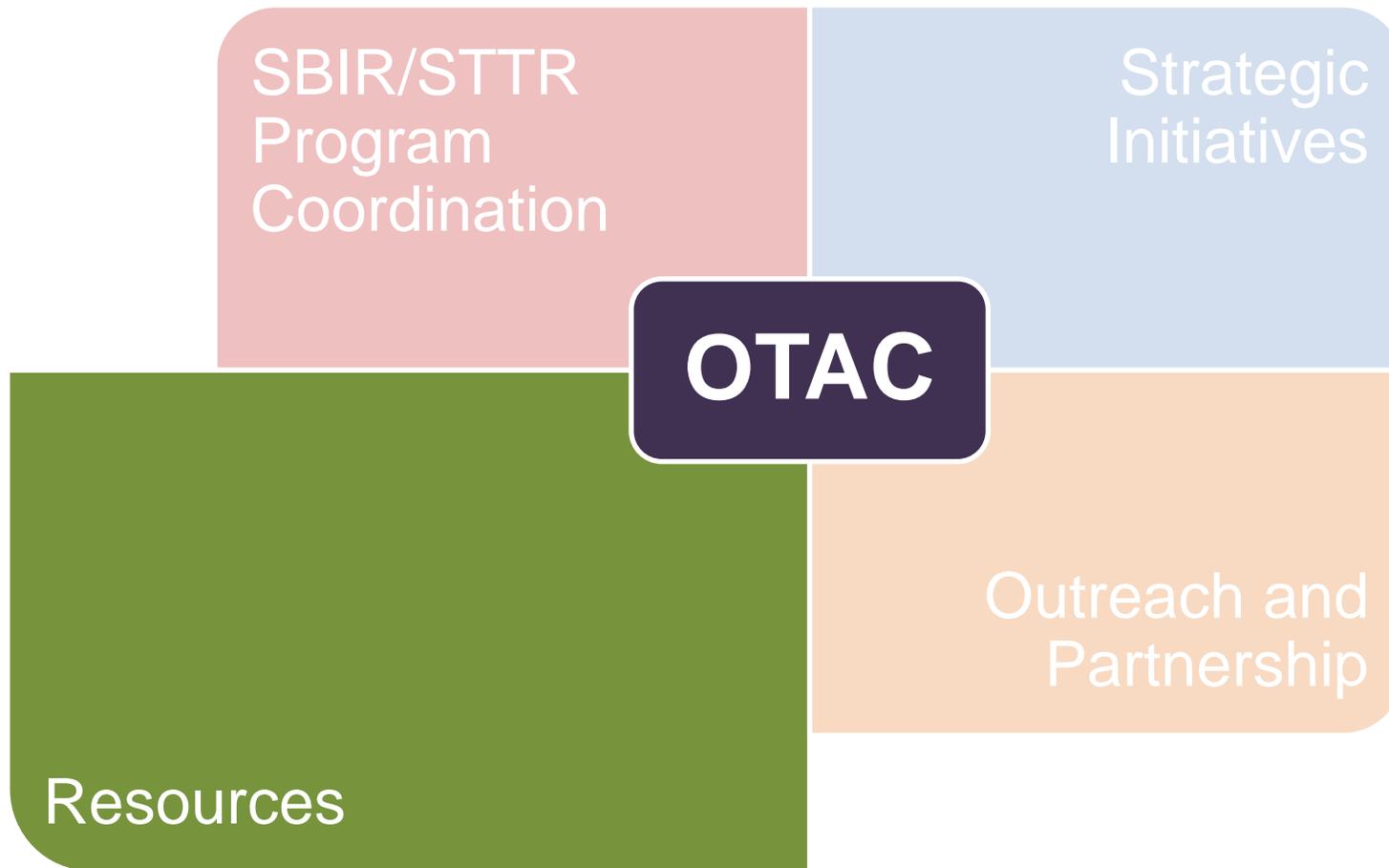
Chris Sasiela, PhD, RAC
Regulatory Specialist

 @NHLBI_SBIR

Office of Translational Alliances and Coordination
DERA, NHLBI



Office of Translational Alliances and Coordination



Not your standard NIH Office



Jennifer Shieh

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Chris Sasiela

Regulatory Specialist
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Gautam Prakash

Intellectual Property Specialist
gautam.prakash@nih.gov



Ram Aiyar

Entrepreneur-In-Residence
ram.aiyar@nih.gov



Steve Flaim

Special Advisor
stephen.flaim@nih.gov

- **Clinical Specimen and Data Repository**

 **BioLINCC** biolincc.nhlbi.nih.gov

- **IND-Enabling Programs**

 **Gene Therapy Resource Program** gtrp.org

 **SMARTT** nhlbismartt.org

- **Lead Discovery and Optimization**
 - Molecular Libraries Program
 - Assay Development/HTS

- **IND-Enabling**
 - Therapeutics for Rare and Neglected Diseases
 - Bridging Interventional Development Gaps
 - Annual application cycle (Nov-Jan)

<http://www.ncats.nih.gov/>

- **Phase 1 awardees**

- Niche Assessment Program

- <http://grants.nih.gov/grants/funding/nap.htm>

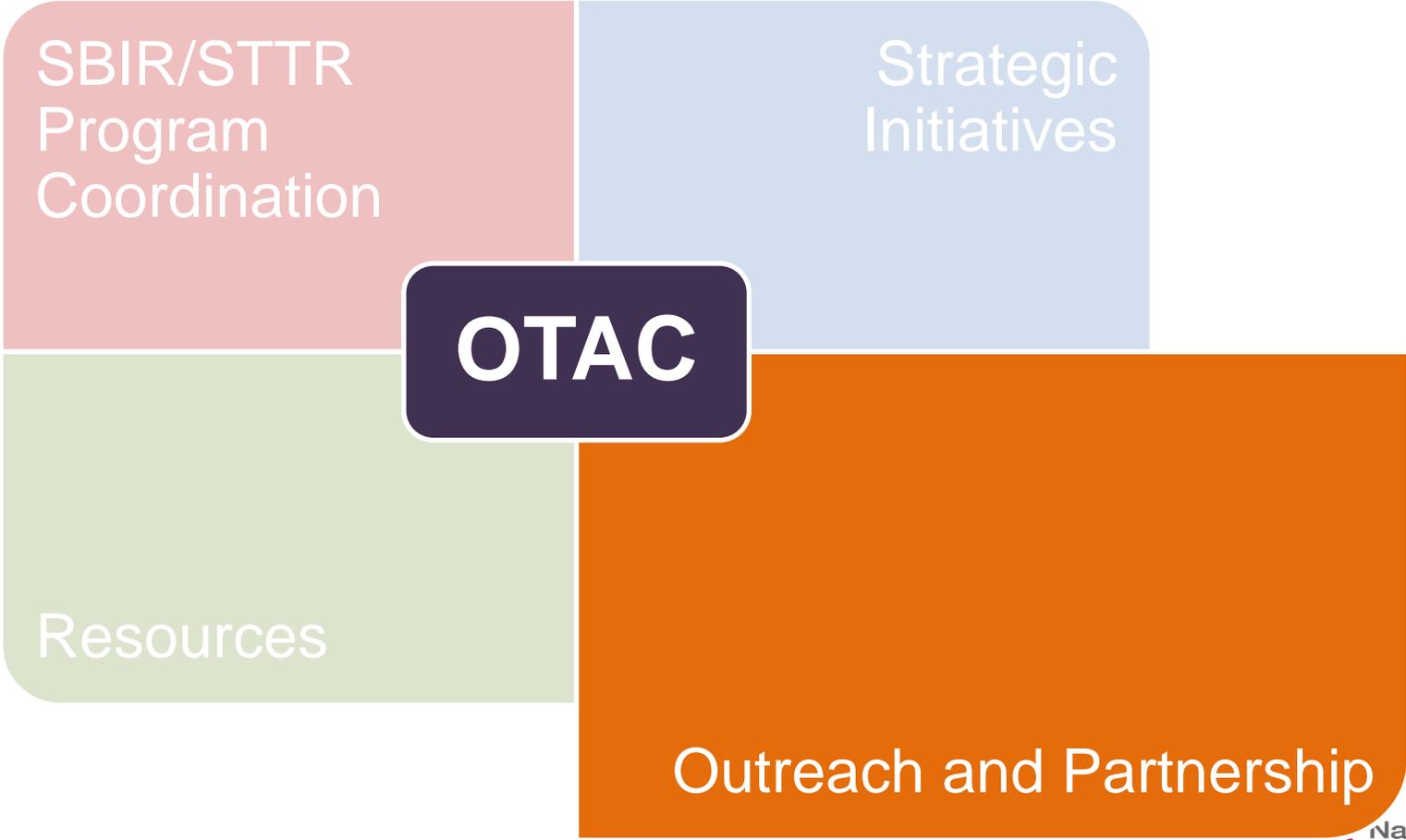
- **Phase 2 awardees**

- Commercialization Assistance Program

- Commercialization Training Program
 - Accelerated Commercialization Track
 - Regulatory Training Track ***NEW***

- <http://grants.nih.gov/grants/funding/cap/>

Office of Translational Alliances and Coordination



Stakeholder Engagement

- Face-to-Face

- Association of University Technology Managers
- State Science and Technology Institute
- Biotech Showcase; Angel Capital Association
- Brookings Forum on Medical Device Innovation; AdvaMed; BIO
- SBIR/STTR Meetings (National, NIH Annual, Regional)

- Virtual

-  @NHLBI_SBIR
- Website: www.nhlbi.nih.gov/otac
- Listserve: www.nhlbi.nih.gov/sbir
- Email: nhlbi_sbir@mail.nih.gov

Navigating the FDA Website

 bit.ly/QYjYeB



C. Sasiela, Ph.D., RAC

First Contact with FDA

 bit.ly/UqFRo7



J. Shah, Ph.D.



A. Swearingen, RAC

Medical Device Regulation

 Offline



L. Weaver-Huffman, RAC

Drug and Biologics Regulation

Dec 16 2pm EST



M. Gaido, Ph.D., RAC



Pairing Companies with Investors

NHLBI Regional Innovation Conferences Trade Organization Meetings



Thank you

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