

# Enhancing the NHLBI SBIR/STTR Program to Navigate the Transition from Discovery to Marketplace

## NHLBI Presentation to the Scientific Management Review Board

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# Re-Engineering the NHLBI SBIR/STTR Program

- The SB set aside is nearly 10% of our competing grant fund
- The omnibus solicitation – laundry list
- Specialized policies and processes are confusing
- The path from discovery to market is:
  - Fragmented
  - Confusing
  - Frustrating
- Scientists are not trained to be entrepreneurs

# Discovery & Development Pipeline



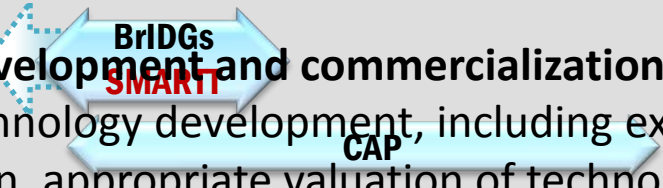
## NIH Resources



• a lack of **knowledge and understanding** about how biomedical technologies are brought to market

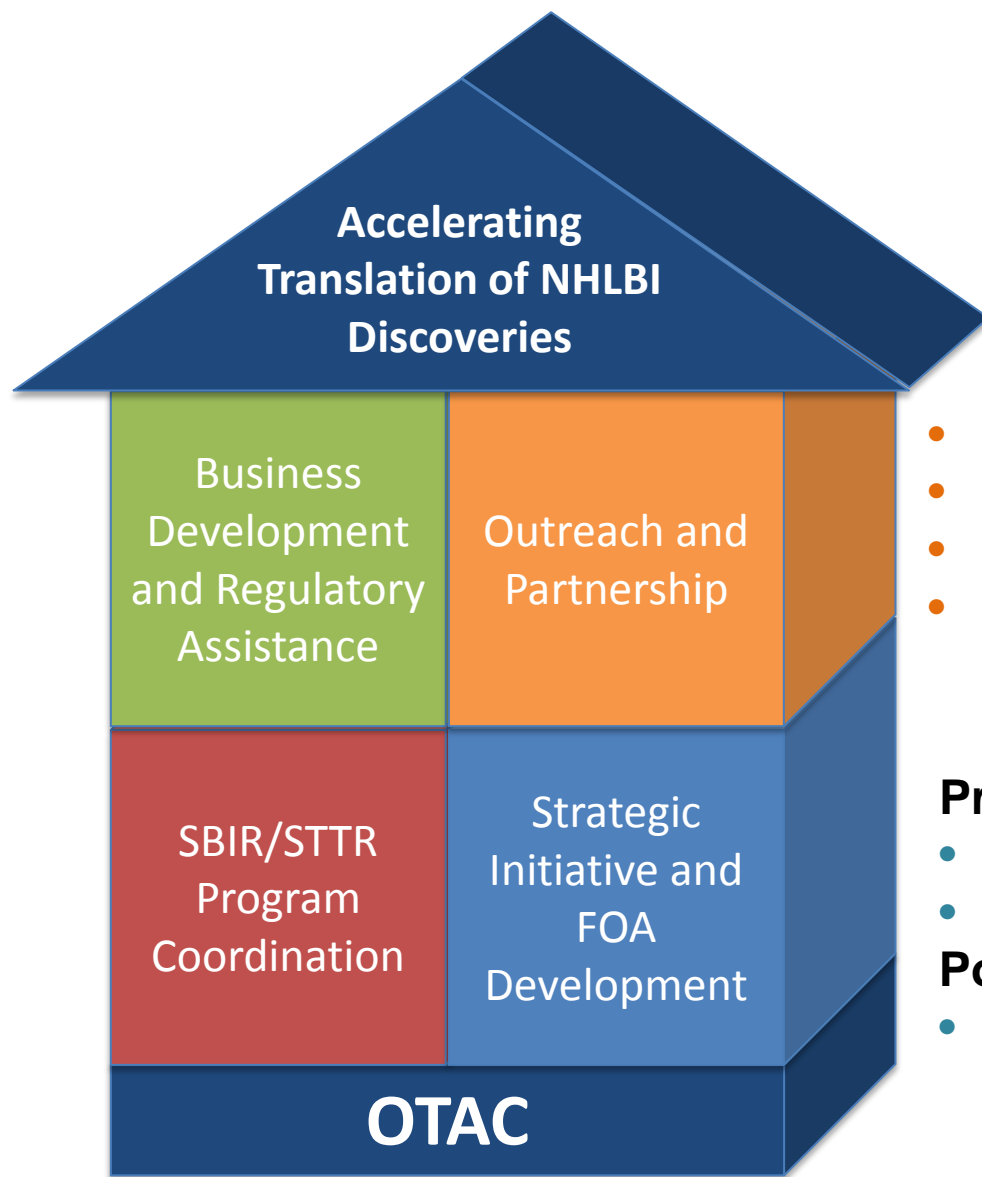
## NIH Assistance

• a lack of sufficient **technology development and commercialization expertise** (e.g. in TTOs) that is required for early stage technology development, including experience in appropriate intellectual property (IP) protection, appropriate valuation of technologies, and company formation.



# Office of Translational Alliances and Coordination

## March 2011



- NHLBI staff engagement
- Topic Review Advisory Committee
- The small business community
- Increased presence at conferences

### **Pre-SBIR**

- Centers for Accelerated Innovations
- SBIR-TT Award

### **Post-SBIR**

- SBIR Bridge Award

# Accelerated Innovations Program Working Group

## AIPWG (November 1-2, 2010)

### Chairs

Barry S. Coller (Rockefeller University)

Leroy Hood (Institute for Systems Biology)

### Members

Robert J. Beall (Cystic Fibrosis Foundation)

Michael Phelps (University of California)

Page Bouchard (Novartis)

Jonathan Sackner-Bernstein (FDA)

Elias Caro (Coulter Foundation)

Ralph Snyderman (Proventys, Inc., Duke University)

Bard J. Geesaman (Accelerator Corporation)

Kenneth Tindall (North Carolina Biotechnology Center)

Robert S. Hillman (Automedics Medical Systems)

Jeff Trent (Van Andel Research Institute, TGEN)

Krisztina Holly (USC)

Phil Weilerstein (National Collegiate Inventors and Innovators Alliance)

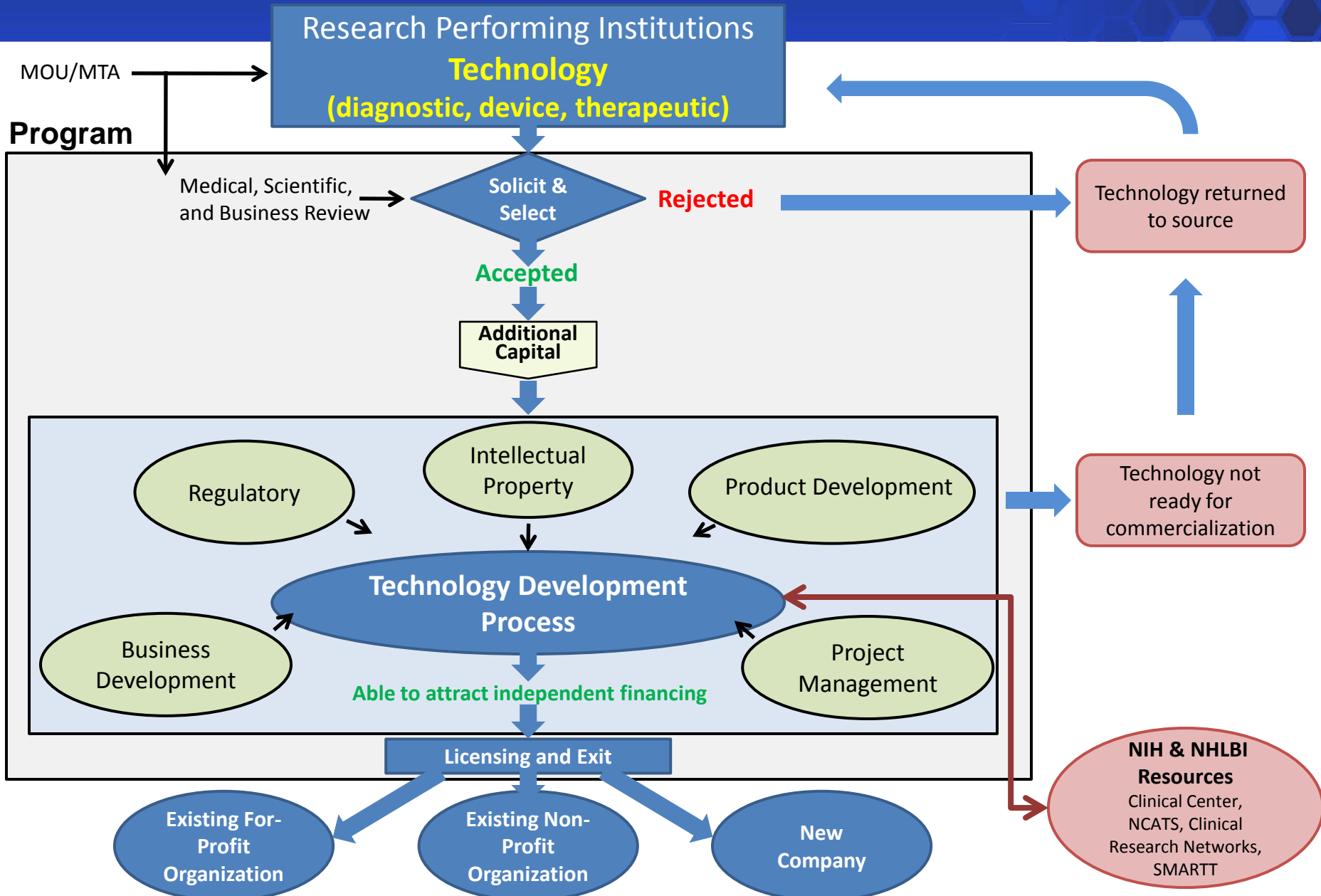
Ron King (BioAccel)

Alastair J.J. Wood (Symphony Capital, LLC)

Bruce Oberhardt (NanoVector, Inc.)

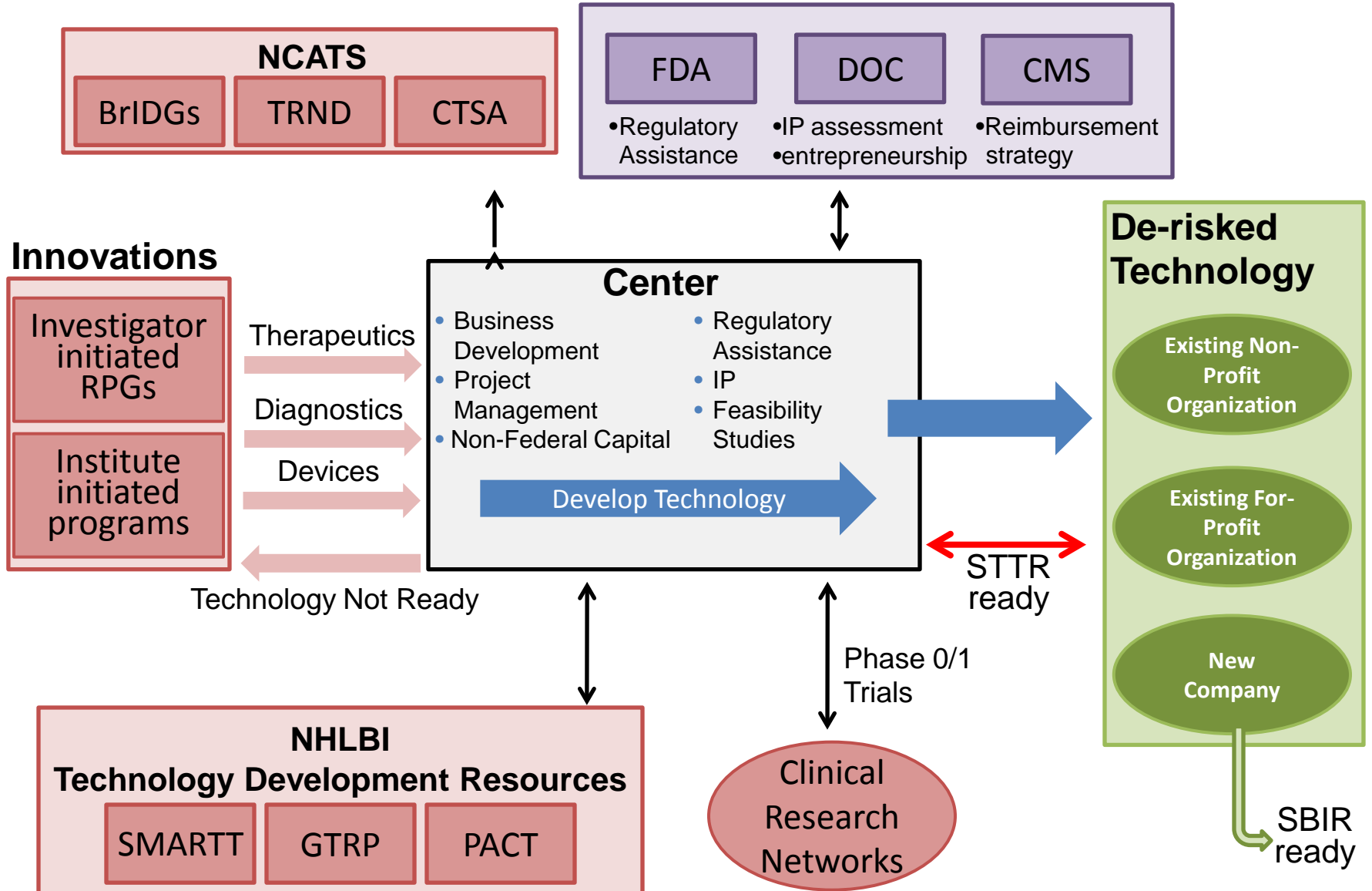
**Device expertise:** Paul Yock, Rick Anderson, Tom Fogarty, Aaron Kaplan

# NIH Centers for Accelerated Innovations



# NIH Centers for Accelerated Innovations

## Integration with Federal Programs/Resources



# Benefits of the Centers for Accelerated Innovations program

The Centers program offers the potential to benefit public health by identifying, accelerating, and increasing the number of highly innovative scientific discoveries that are translated into marketable products. The Centers:

- address critical bottlenecks and gaps
- will decrease the time from discovery to product
- will increase the chance of success
- will encourage public-private partnerships with an integrated environment of resources
- foster a culture needed for sustained technology development



# A New Opportunity?

- The CAI is a pre-company Proof of Concept (POC) program.
- Historically, SBIR/STTR funds could not be used to support pre-company POC activities
- The recent SBIR/STTR reauthorization permits NIH to use \$5 million of STTR funding to support pre-company POC activities
- The CAI and STTR POC goals are identical and the language used in the bill is nearly identical to that in the CAI FOA
- This funding would enable the CAI to be a trans-NIH program

# Trans-NIH Participation Benefits

- The potential to enhance participation of other ICs at reduced costs, increase efficiency and economies of scale
- The potential to increase the number and geographic diversity of Center locations
- The potential to enhance outcomes and provide a broader basis for effective program evaluation
- Ready access to NHLBI infrastructure in place for Centers program management (OTAC)
- A trans-NIH vibrant network to share experiences, develop best practices, and enhance culture change
- Opportunities to conduct technology development process research across a broader scope of technologies
- Opportunities to conduct regulatory science research

# NHLBI Issues and Challenges

- Budget caps affect IC funding flexibility
  - 83% of the NHLBI Phase II portfolio develops technologies that require FDA approval
  - NIH relies on the private sector for Phase III
  - Waivers need to be simple and broad
- Administrative funds
- Commercialization outcomes - inability to evaluate
- Peer review