

National Eye Institute SBIR/STTR Program

Initiatives and Issues: A Program Officer's Perspective

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Preview

- **Mission of the NEI**
- **How We have Managed our Program**
- **Some Issues & Challenges**
- **New Initiative for Navigating FDA Regulatory Pathway**

National Eye Institute

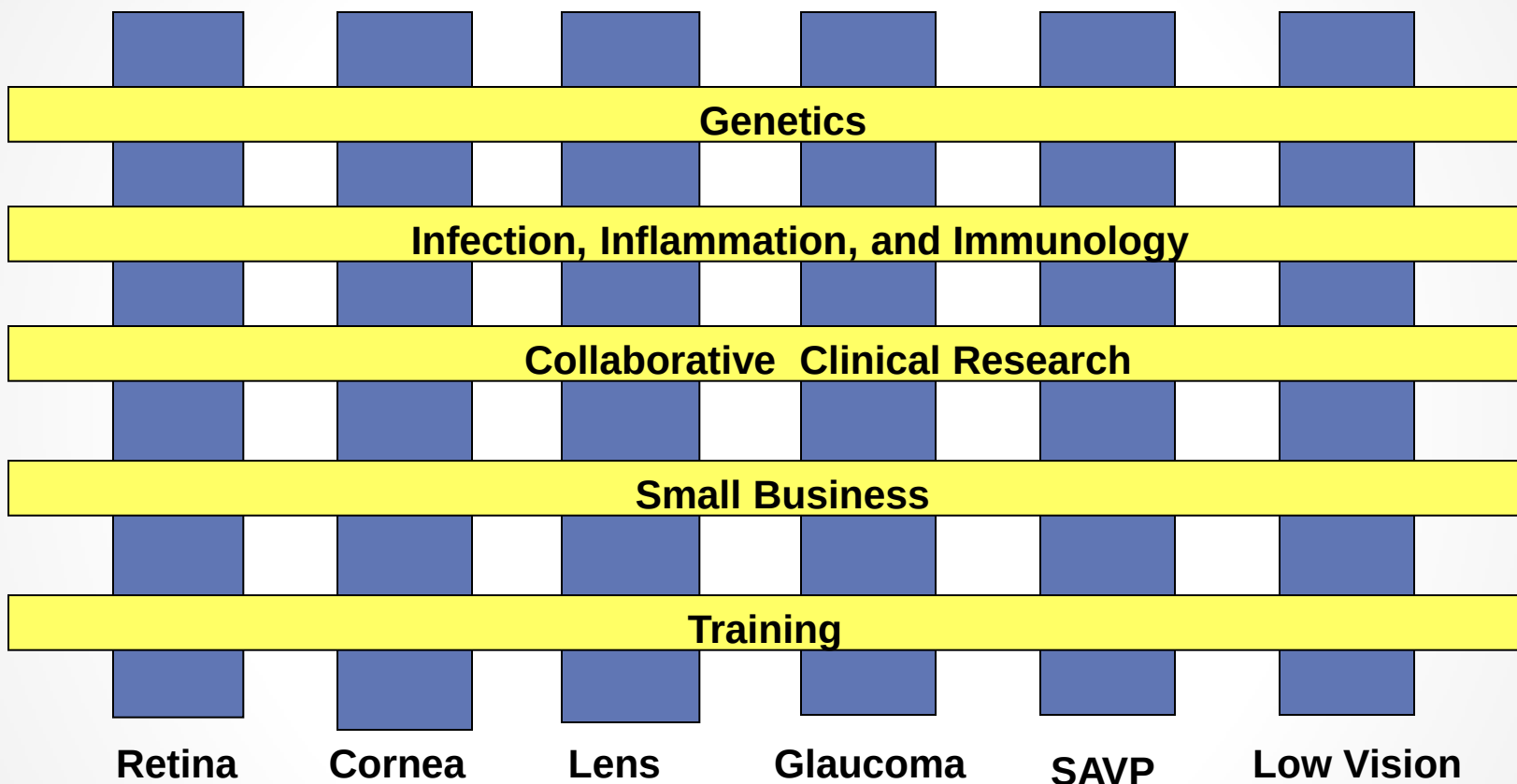
MISSION:

- **“...conduct and support of research for new treatment and cures and training relating to blinding eye diseases and visual disorders, including research and training in the special health problems and requirements of the blind and in the basic and clinical sciences relating to the mechanism of the visual function and preservation of sight.”**

NEI Management Model

- ***Clinically Oriented, Medium-sized Institute***
 - ***Eye Diseases and Visual Disorders***
 - ***Blindness and Low Vision***
- ***Committed to Investigator-Initiated Research***
 - ***Scientists and Clinicians***
 - ***Managed to a High Award Rate***
- ***Cross-Cutting Management Organization***

NEI Division of Extramural Research



NEI Management Model

SBIR/STTR Program

- **Originally, Managed by Many Program Officers**
 - Small Subset of Portfolio
 - Research Expertise in their Portfolio
 - Little Industry Experience
- **Now, Consolidated under one Program Officer**
 - Small Business is Primary Focus
 - Knowledge of SBIR/STTR Regulations & Policies
 - Experience in Small Business

Issues and Challenges

- **Tracking Commercialization Success**
 - Long Time Frame
 - Acquisitions and Partnerships
- **Abundance of High Quality Applications**
 - Vision Research Amenable to Commercialization
 - Therapeutics, Diagnostics, Assistive Devices, etc.
- **Peer Review**
 - Commercialization Expertise needed
 - Challenges in Resubmission
- **Access to Product Development Resources**
 - Pharmacokinetics, Toxicology, Formulation, etc.
 - FDA Regulatory Expertise

NEI New Initiative Regulatory Assistance Program

- ***Pilot Program for Active SBIR & STTR Grantees***
 - *Help Navigating the Federal Regulatory Pathway*
 - *Both Therapeutics & Medical Devices*
 - *Competitive Application Process*
- ***Single Regulatory Consultant Company***
 - *Initial Meeting – Questions, Goals, etc.*
 - *Develop a Comprehensive Regulatory Strategy*
 - *Follow-up and Progress Review*
- ***Outcomes?***

Thank You!