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Developing Translational Research Gap Fund Programs

Welcoming remarks will begin at
11:55 a.m. Eastern Time.

The formal presentation will begin at Noon Eastern

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Developing Translational Research Gap Fund Programs

Speakers:

Sharon Krueger, *University of Virginia School of Medicine*

Jacob Johnson, *innovosource*

October 21, 2015



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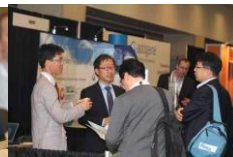
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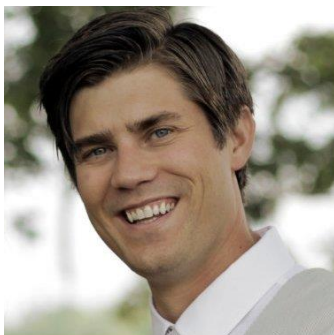


Sharon A. Krueger,
*University of Virginia School of
Medicine*



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Jacob Johnson,
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**Translational Research Gap Funds: Insights from
Mind the Gap Report**

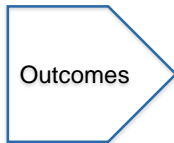
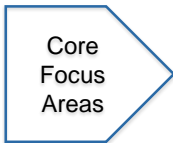
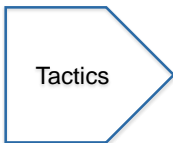
Jacob Johnson
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IMPACTING THE RESEARCH ENVIRONMENT

GENERATING TECH COMMERCIALIZATION IMPACT



Operational tactics must be aligned with and motivate the development of multiple core focus areas

Success in developing these core areas will result in outcomes with real impact to the research environment

RESEARCH INSTITUTION GOALS

RESEARCH

EDUCATION

SOCIETAL BENEFIT





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COMMERCIALIZATION OUTCOMES

Successful outcomes support institutional mission and goals

Expected Time from Initial Investment

Immediate	Nearterm	Midterm	Longterm
	1-3 Years	3-5 Years	5 +Years

Catalyzing the Commercialization Process

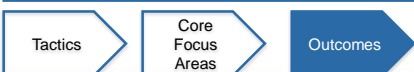
Growing a Community of Innovation

Building Businesses and Creating Jobs

Attracting Capital and Expertise

GENERATING TECH COMMERCIALIZATION IMPACT

Returning Capital



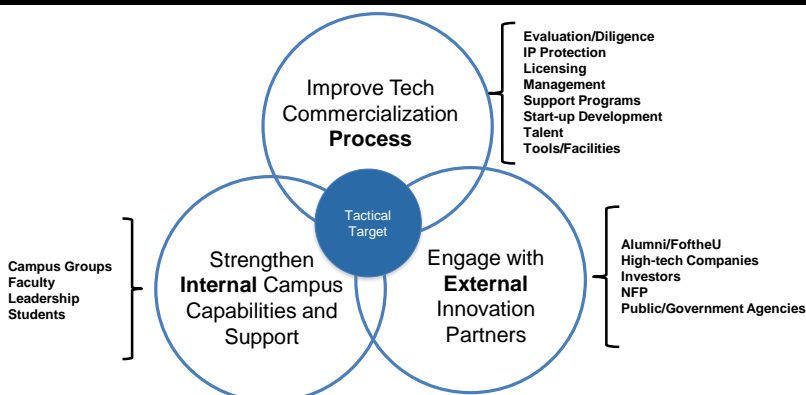
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CORE FOCUS AREAS



GENERATING TECH COMMERCIALIZATION IMPACT



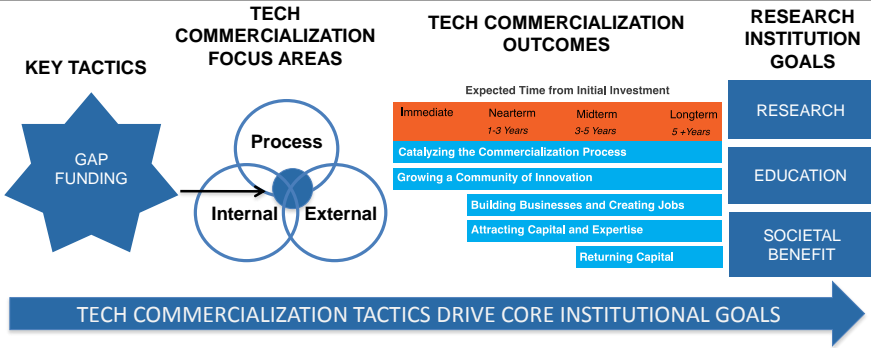
Tactics would ideally positively impact/improve **all three** core areas

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GAP FUND AS A KEY TACTIC



DISCUSSION THRUST

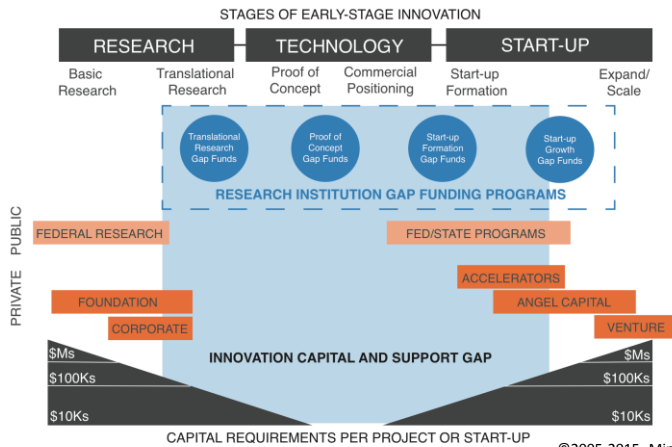
A well-resourced and managed gap funding program has the ability to positively impact the tech commercialization capability in the research environment than any other single institutional tactic

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THE REALITIES OF ES CAPITAL



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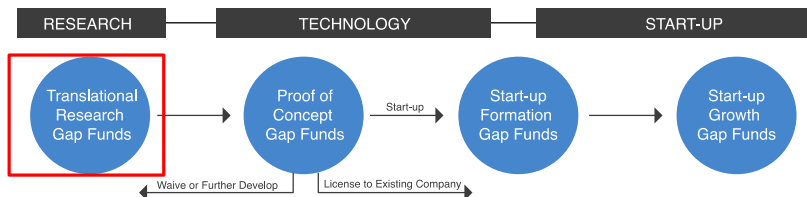
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DEFINING THE GAP



- The “Gap” should be segmented to address special needs of each stage of commercialization
- **Translational Research Gap Funds:** Applied development of a promising research project to a point where it can be properly assessed for commercial potential

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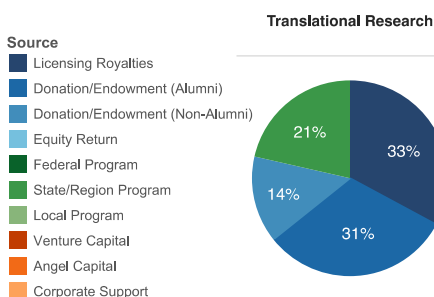
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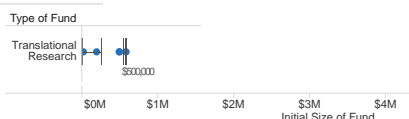
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SOURCE OF TR GAP FUNDS



- 80% supported by institution’s own funding sources
- Increasing support from public and private programs



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FUNDING VEHICLE/REQUIREMENTS

Form of Funding	Financial Expectations	Translational Research
Grant	No Financial Requirements	71%
	Repayment	14%
	Equity	
Investment	No Financial Requirements	14%
	Repayment	
	Convertible loan	
	Equity	

- Mostly Grants
- 86% No Financial Requirements associated with funded projects
- Associated with projected lifetime of fund----budgeted, evergreen, or capped

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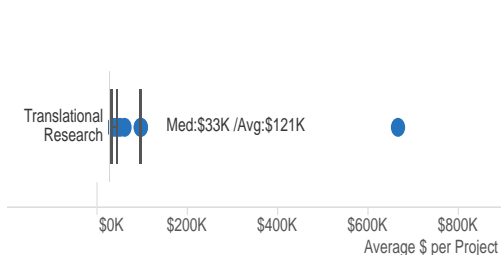
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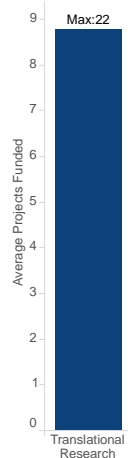
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\$/PROJECT AND NUMBER FUNDED



- More projects, less \$ per
- \$121K average/per project
- ~8 projects per cycle, up to 22



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USE OF FUNDS

Gap Funding Program Support

- Gap Funding Program Improvement
- Marketing/Events
- Mentoring and Education Programs

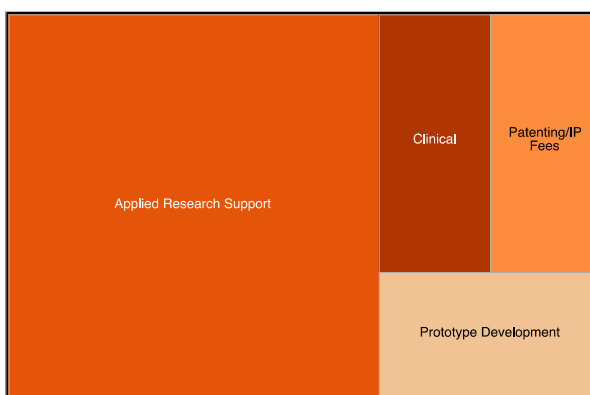
Technology Assessment/Development

- Clinical Validation/Support
- Applied Research Support
- Patenting/IP Fees
- Prototype Development

Commercial Assessment/Development

- Business Planning and Strategy
- Space/Incubator Fees
- Equipment Purchase/Rental
- Management or Talent

Translational Research Gap Funds



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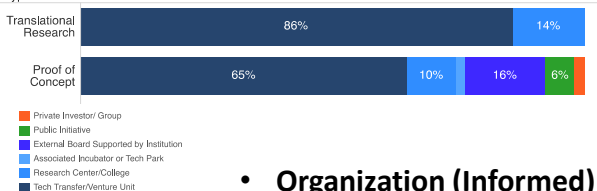


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MANAGEMENT

Type of Fund



- **Organization (Informed):** Sponsoring body and leadership
- **Unit (Accountable/Involved):** Operation that oversees and develops the gap fund program
- **Individual (Responsible):** Professional that manages the day-to-day process of the program

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FUND MANAGER

- Gap Funding Expertise
- Relationship-Builder
- Broad Market Perspective
- Active Managers
- Controlled Communicator

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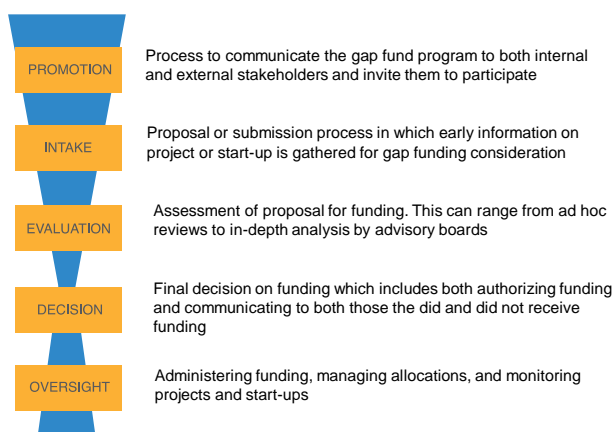
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GAP FUND PROCESS REVIEW



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GAP FUND PROCESS INSIGHTS

- Choose a Promotional (Open vs Targeted) based on fund objectives and resources
- Use the RFP process to demonstrate transparency
- Install a two-tiered evaluation and decision-making process---scorecards, advisory boards
- Create a feedback loop to all projects regardless of funding decision
- Report annually to internal and external stakeholders, but schedule the delivery prior to the institution-wide strategic planning, budgeting process

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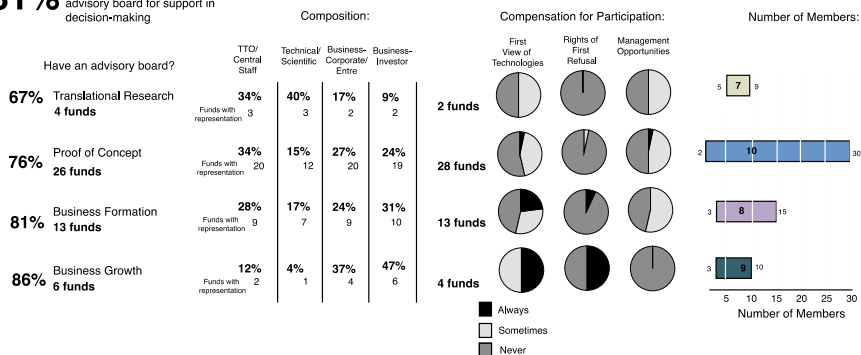
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USE ADVISORY BOARDS

Advisory Board Overview

81% of 63 funds surveyed use an advisory board for support in decision-making



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77% require a signed NDA
of 43 responding funds

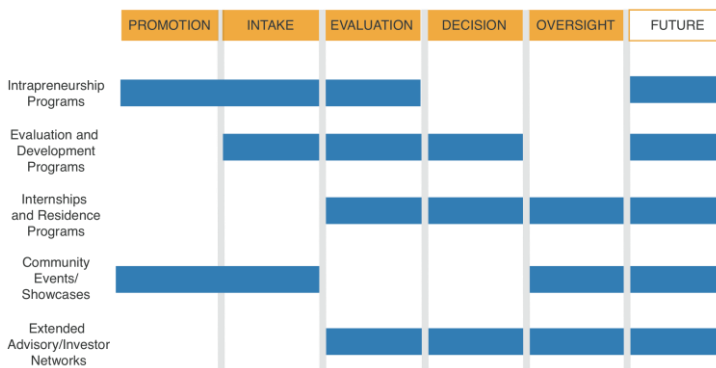
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SUPPORT PROGRAMS



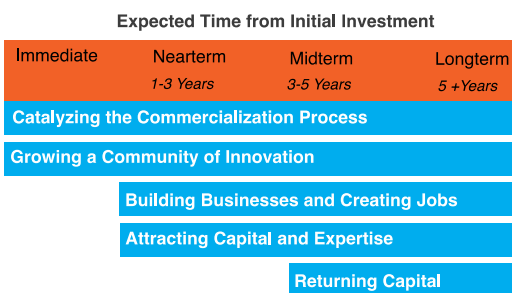
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TR GAP FUND IMPACT



- Catalyzing Commercialization Process:
 - 33% Yield Rate, 42% Commercialized
- Leveraging Capital Government Grants (AVG \$1: 12.5)

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THANK YOU! QUESTIONS

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Mind the Gap: www.gapfunding.org

Developing Translational Research Gap Fund Programs at Research Institutions



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**Developing Translational Research Gap Fund
Programs at Research Institutions**

Sharon Krueger

Director, Translational Research Programs

University of Virginia

School of Medicine

Developing Translational Research Gap Fund Programs at Research Institutions

Why Should Academia support their own Early-Stage Research?

- Funding for research from traditional sources (NIH) has become increasingly competitive to secure (~12% in 2014)
- Industry and cash strapped state governments have not stepped up to fill the funding gap
- This type of research is typically *not* funded by venture and angel investors.
- The number of innovative, early stage start-ups that are based on university technologies has declined, threatening the viability of a key source of medical innovations.

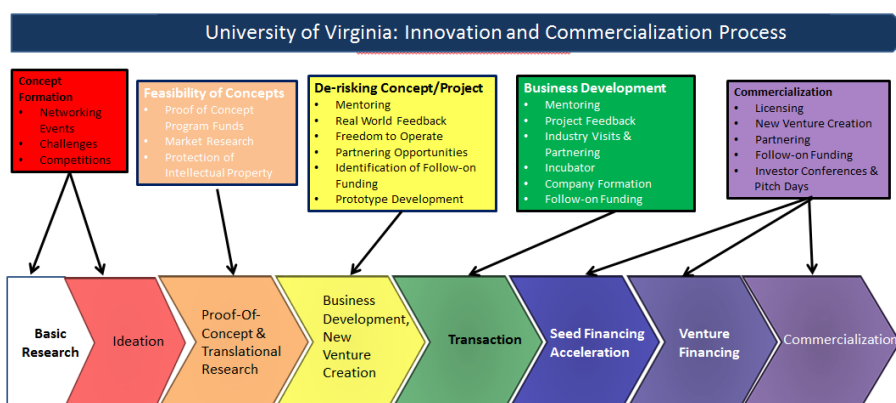
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Additional Reason for Academia to Support Early-Stage Research

- Translational research/Proof-of-Concept programs connect into Universities strategic plan
 - U.Va. Strategic Cornerstone Plan
 - Advance knowledge and serve the public through research, scholarship, arts and innovation

Importance of Translational Research/Proof-of-Concept Funds

- Bridging the gap between discovery and further technology development.
- De-risking of the technology enables and accelerates acquisition of capital to advance the project
- Demonstrating deal-flow coming out of academia by the increase in launch of new ventures, leading to economic growth





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Background on Coulter Translational Partnership



- TP programs started in 2006 with funding from the Wallace H. Coulter Foundation
- 10 Universities selected: UVA, Duke, Stanford, Michigan, Wisconsin, Drexel, U Washington, Case Western, Boston U and Georgia Tech
- \$1M in funding each year for 5 years, with \$10M endowment if metrics were reached (University had to match the \$10M endowment)
- All the universities met bi-annually and worked together to develop the program process and identify best practices
- 6 additional Universities added in 2011: Columbia, John Hopkins, Louisville, U of Missouri, U of Pittsburgh, U of Southern California



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The Coulter Process

Documented process utilizing industry best practices to accelerate academic innovations to the market to improve patient care by reducing risk and attracting follow-on-funding.



Image Courtesy of the Wallace H. Coulter Foundation



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Coulter Critical Success Factors

- Unmet need: Need statement
- Technology: Feasibility of solving
- Commercialization Analysis: IP, market size, patient impact, provider impact, FDA & reimbursement, unit cost & health care total cost, manufacturing
- Project proposal: Solution, preliminary data, Killer Experiment, milestones, budget & risks, value proposition
- Project selection: Industry and investment input
- Project management: Coaching, regular team reviews and timely feedback
Quarterly Operating Reviews
- Follow-on funding: Proactive & continuous engagement with sources of funding
- (Angels, VCs, Industry, foundations, SBIR, NIH, DOD, etc.) and potential CEOs



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Additional POC programs at U.Va.

- **Ivy Biomedical Innovation Grant:**
 - launched in 2008 (\$250K per year and increased to \$500K per year starting in 2013)
- **LaunchPad for Diabetes:**
 - launched in 2009 (\$250K per year)
- **Clinical Cancer Center Technology Partnership Initiative:**
 - A Public-Private Partnership 2 year pilot launched in 2012 (up to \$1M per year)
- **Virginia Innovation Partnership (VIP):**
 - U.S. Department of Commerce i6 Challenge Grant- \$800K in funding each year in 2012 & 2013 for projects state-wide in all research areas.



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Key POC Program Facts

- **Oversight Review Committee:**
 - Internal: senior research scientists, technology transfer director, senior university leadership.
 - External: early-stage venture capitalists and industry scientists with business development roles.
 - Together they select projects, provide real time real word feedback and mentorship to the funded research projects and have the will to kill projects.
- **Milestone driven proposals, oral presentations and written project reports to the Oversight Review Committee**



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Metrics from U.Va. POC Programs

- Overall internal funding invested from 2006 to date: >\$14.2MM
- Overall proof-of-concept funded projects to date: 131
- Startup companies launched after proof of concept funding: 16
- Technology license deals to industry: 47
- Overall follow on funding to advance the project towards commercialization received from investors, industry, foundations, state and federal sources: \$65MM



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Best Practices from U.Va. Translational Research/Proof-of Concept Programs



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OverSight Review Board Members

- The “right” people are a key component
- External venture capital and industry members serve as an “investment committee” due to their experience and real-world/real-time feedback
- Internal scientific members provide the depth of field expertise
- Internal technology transfer members provide commercialization analysis



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OverSight Review Board Role

- Engaged Review Board that clearly understands it's role with the program
- Mentoring project teams
- Leveraging networks to connect PI's
- External board members that understand early-stage academic research
- Real-time, Real world feedback to the PI's
- Will to kill projects



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Program Director Responsibilities

- Manages logistics and process for the program
- Ranging from internal program marketing for soliciting applications, proposal preparation, project selection, project oversight and reporting
- To coaching/mentoring the funded investigators, outreach to industry and investors for follow-on funding opportunities



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University Technology Transfer Office

- Supports proposals by providing:
 - An initial assessment of possible intellectual property protection
 - Market/commercialization prospects for the proposed project
 - Communication of this information to the program director and the Review Board
- Works with funded project team and program director to draft a commercialization strategy plan during the course of project funding



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Project Selection Process

- Submitted proposals are triaged and selected for oral presentation by the OverSight Review Board using the following criteria:
 - Research stage
 - Research plan/Science
 - Clinical Impact
 - Collaborations
 - Intellectual Property
 - Commercialization
 - Regulatory/Clinical Pathway
- Feedback is provided by the Program Director after triage and oral presentations phases to all projects: funded & unfunded



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Lessons Learned from U.Va. Translational Research/ Proof-of-Concept Programs



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Overall Lessons Learned:

- Clearly defined “Proof-of-Concept”
- Clearly written RFA
- Provide funding for project diligence
- Dedicated program director with administrative support
- Virginia Innovation Partnership had engaged point of contacts at each university



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A Change in Culture

- Need to educate faculty and administration on the translational research process
 - Milestone driven research and commercialization vs. the NIH aim driven research
 - Project funding may be tranced to milestones or killed for lack for progress
- Importance of match-making and networking events to foster collaboration for proposals
- Need to educate faculty on the technology transfer process



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The Funded Project

- Project diligence:
 - Regulatory pathway, reimbursement pathway, manufacturability, marketability and competition should be analyzed to identify possible roadblocks
- Funding to advance the project:
 - Program Director and funded teams should have a clear understanding of how the project should proceed through the different funding mechanisms before it would be ready for industry or VC funding



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Enhance the Visibility of the Program

- Increases faculty involvement
- Higher quality of applications
- Networking/collaboration events at specific universities/areas in the Commonwealth
- PR on the program and project successes at the highest level within the University and the State



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Translational Research Proof-of-Concept Program Challenges



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Program Challenges

- Level of buy-in and support from Senior Leadership (President, Provost, Dean's, Department Chair's)
- Understanding of your university's entrepreneurial culture
- How is innovation & entrepreneurship recognized in the Promotion and Tenure process
- Appreciation of the constraints on academic early-stage researchers (teaching, advising students, grant & paper writing, committee work)



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Measuring Impact & Success

- Traditional hard metrics:
 - IP: disclosures, PCT filed, patents issued
 - Follow-on Funding received to advance the project from: internal, state, federal, industry, investors
 - License deals
 - Start-up companies launched
 - Prototype and/or FDA stage



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Measuring Impact & Success

- Soft but valuable metrics
 - Collaborations formed to advance the project
 - Connections made to advance the project
 - Presentations given on the project
 - Publications
 - Number of faculty and departments involved in the program
 - PR on the projects/program: print articles, interviews, web sites, etc.



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In Closing

- Translational research/Proof-of-Concept funding is critical in facilitating the transfer of innovative academic research into commercial applications
- OverSight Review Board members provide real-time, real-world feedback, mentorship and networking opportunities to academic researchers
- Entrepreneurial faculty teach, mentor and provide opportunities for the next generation of entrepreneurial students



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Questions? Comments?



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Discussion and Q&A

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 Need to Know Basics of Technology Transfer for Support Staff
 Negotiation of License Agreements
 Nuts and Bolts for Compliance Under Federal Funding Awards
 The Basics of Open Source Licensing
 Tips for Managing MTAs
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Milwaukee, WI USA



AUTM Eastern Region Meeting

Sept. 29 – 30, 2016
The Westin Philadelphia
Philadelphia, PA

Registration Open Soon!



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AUTM Business Development

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Get Involved

We need your help. The Online Professional Development Committee is seeking professionals interested in joining their committee.



Interested? Please contact Melinda Briggs – mbriggs@autm.net



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AUTM Annual Meeting



AUTM 2016 Annual Meeting

Feb. 14 – 17
San Diego, CA USA

