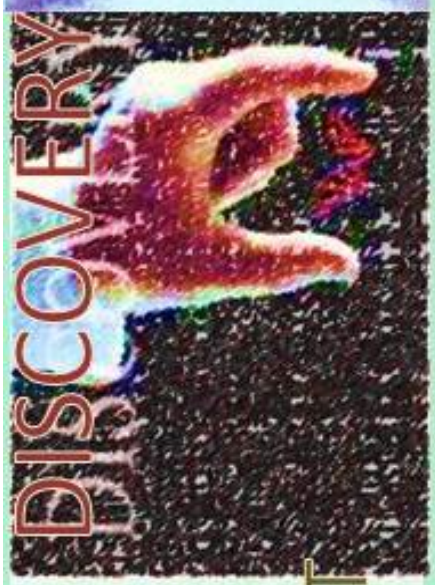

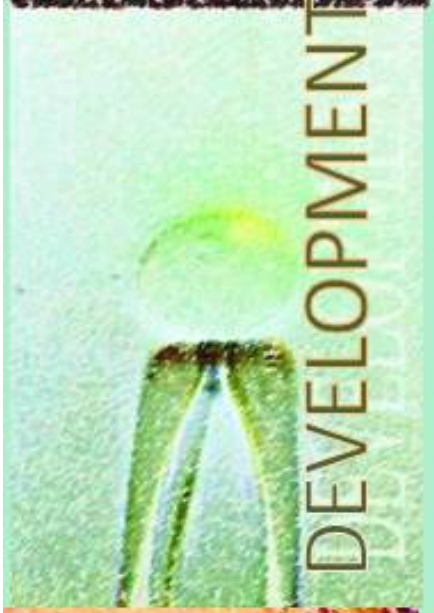

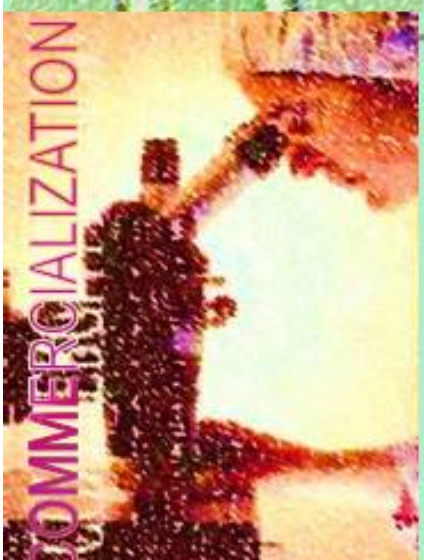

Proceedings of the Workshop on:

FINDING WAYS TO FOSTER SBIR/STTR APPLICANTS FROM IDeA STATES

National Institutes of Health
Building 50, Room 1227/1233
August 21, 2014

Institutional Development Award Program (IDeA)

SBIR/STTR Program

NIGMS, NIH

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WORKSHOP AGENDA:
FINDING WAYS TO FOSTER SBIR/STTR APPLICANTS FROM IDeA STATES
National Institutes of Health, Building 50 Room 1227/1233
August 21, 2014
8:00 a.m. – 3:00 p.m.

Purpose:

1. To understand factors limiting the number of SBIR/STTR applications arising from academic institutions in IDeA states;
2. With identification of limiting factors, suggest reasonable means through which NIGMS/NIH can assist and facilitate IDeA institutions to better foster viable and sustainable small business concerns (SBC).

8:00 – 8:15 **Registration**

8:15 - 8:30 **Welcome and Introductions**
Krishan Arora, Ph.D. and Scott Somers, Ph.D. NIGMS/NIH

8:30 – 8:40 **Introduction to the Workshop, charge to the participants; Introduction of the Workshop Chairs**
Krishan Arora, Ph.D., NIGMS/NIH
(Chairs: William A. Gern, Ph.D., University of Wyoming and Mercedes Rincon, Ph.D. University of Vermont)

8:40 - 9:05 **Overview of the NIH SBIR/STTR Program**
Matthew E. Portnoy, Ph.D., Director, Division of Special Programs, NIH SBIR/STTR Program Manager, OER/ NIH

9:05 - 10:25 **Limiting Factors**
William A. Gern, Ph.D., University of Wyoming and
Mercedes Rincon, Ph.D., University of Vermont

10:25 - 10:35 **Greetings from the Director of NIGMS**
Jon Lorsch, Ph.D., Director, NIGMS/NIH

10:35 – 10:45 Break

10:45 – Noon **Small group discussion of possible ways to address the key bottlenecks identified during the morning with specific emphasis on IDeA States and Programs**

12:10 – 1:00 **Lunch (brought in) and presentations**
#1 – SBIR/STTR success story from Maine
Kevin Strange, Ph.D., MDI Biological Laboratory

#2 – SBIR/STTR success story from Kentucky
Mahendra K. Jain, Ph.D., Kentucky Science and Technology Corporation

1:00 – 2:30 **Re-assemble and summarize breakout discussions**

2:30 – 2:55 **Wrap-Up and Summary of Recommendations to NIH by Workshop Chairs**

2:55 – 3:00 **Closing Remarks**
Fred Taylor, Ph.D., Chief, Research Capacity Branch, Division of Training, Workforce development and Diversity, NIGMS/NIH

Topics to Consider:

1. What career stage offers the best opportunities to expose individuals to entrepreneurial opportunities? Or does it depend entirely on the individual and research project? Are important opportunities lost when undergraduates, graduate students, postdoctoral fellows, or faculty do not know or see the potential to move ideas into the marketplace?
2. Is it possible to balance doing science for the sake of greater understanding with targeting and working towards a tangible (i.e., potentially marketable) end?
3. Is it possible to determine which concepts and/or situations are best for developing as a SBC versus licensing to existing for-profit entities versus remaining as a research enterprise?
4. What expertise is necessary to create a small business concern?
5. What educational training/mentoring and advisory services are needed to generate innovative and quality SBIR/STTR applications?

ACRONYMS

ACF	**Administration for Children and Families**
CDC	**US Centers for Disease Control and Prevention**
COBRE	**Center of Biomedical Excellence**
DOD	**Department of Defense**
DOE	**Department of Energy**
EPSCOR	**Experimental program to Stimulate Competitive Research**
FDA	**Food and Drug Administration**
FOA	**Funding Opportunity Announcement**
I-CORPS	**Innovation Corps**
IDeA	**Institutional Development Award**
INBRE	**IDeA Networks of Biomedical Research Excellence**
IND	**Investigational New Drug**
KIN	**Kentucky Innovation Network**
KSTC	**Kentucky Science and Technology Corporation**
MDI-BL	**Mount Desert Island- Biological Laboratory**
NASA	**National Aeronautics and Space Administration**
NCATS	**National Center for Advancing Translational Science**
NCRR	**National Center for Research Resources**
NHLBI	**National Heart, Lung, and Blood Institute**
NIA	**National Institute on Aging**
NIAAA	**National Institute on Alcohol Abuse and Alcoholism**
NIAID	**National Institute of Allergy and Infectious Diseases**
NIDA	**National Institute on Drug Abuse**
NIGMS	**National Institute of General Medical Sciences**
NIH	**National Institutes of Health**
NHGRI	**National Human Genome Research Institute**
NISBRE	**National IDeA Symposium of Biomedical Research**
NLM	**National Library of Medicine**
NSET	**Non-Surgical Embryo Transfer**
NSF	**National Science Foundation**
ORIP	**Office of Research Infrastructure Program**
SBA	**Small Business Administration**
SBC	**Small Business Concern**
SBDC	**Small Business Development Center**
SBIR	**Small Business Innovation Research**
STTR	**Small Business Technology Transfer**
VCOC	**Venture Capital Operating Companies**
WC	**Workers' Compensation**

EXECUTIVE SUMMARY

Section 5168(b) of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112-81) called for action to enhance the coordination between IDeA and SBIR/STTR programs to promote an increase in the participation of entrepreneurs from IDeA states, which usually receive fewer SBIR/STTR awards than do non-IDeA states.

The goal of the workshop entitled "Finding Ways to Foster SBIR/STTR Applicants from IDeA States" was to get greater insight to the types of activities that would provide the most impact for promoting and attracting entrepreneurs from IDeA states into the SBIR/STTR programs and increasing the participation of IDeA states in these programs. The group made three major recommendations.

First and foremost was the *creation of regional networks/hubs*, a consortium to generate infrastructure and build entrepreneurial culture. These regional networks/hubs could support business environments that can facilitate networking and team formation, sharing and transfer of information, best practices and guidelines, and providing assistance and mentoring. These regional networks/hubs could also facilitate sharing of information on state and local resources and programs currently available in the form of commercialization funds or state matching funds – both are excellent incentives.

A second recommendation was in the area of *Education and Training, and Increased Outreach Efforts* facilitated by NIH and IDeA Institutions. NIH could provide training and funding mechanisms for developing educational modules that can train students and research investigators in entrepreneurial skills. NIH could facilitate connections with potential collaborators and Small Business Concern (SBC) partners with academic investigators by developing a virtual portal. NIH could continue and expand efforts to sponsor and facilitate conferences, meetings and webinars that could be used to better disseminate the information and bring SBCs, states' Small Business Development Centers and University scientists together.

Third, a key factor mentioned several times throughout the workshop was *Culture Change* at the IDeA institutions. Culture shift toward acceptance of entrepreneurial activities as a vital adjunct to traditional scholarly pursuits should occur at the IDeA institutions, however, it was recognized by participants that it will be a slow process. It will require efforts both by the NIH and at the institutional level. Leadership at the IDeA institutions needs to encourage entrepreneurial activity among university scientists for innovation and technology development needed to promote commercialization of new products and services, which in turn leads to job creation and local economic development.

Funding to accomplish the recommendations presents challenges, of course, especially for the regional network/hubs. The goal is to use SBIR/STTR funds as a primary source. Through the Authorization Act for FY 2012, Congress allowed NIH the ability to use SBIR funds to support a number of administrative activities, some of which could be directly related to the recommendations of the workshop. This authority ends after FY2015, although an extension may be possible. NIGMS is committed to work with other Federal agencies and non-Federal partners as needed to enhance the IDeA participation with the SBIR/STTR program.

INTRODUCTION

The NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are one of the largest sources of early–stage capital for innovative small companies in the US. While both the programs support small businesses seeking to commercialize up and coming biomedical technologies, the STTR on the other hand, has an additional requirement of formal research collaborations with academic institutions (http://sbir.nih.gov/). These mechanisms facilitate the participation of small businesses in federal research and development (R&D), developing life-saving technologies and therapeutics, while creating jobs, economic growth and public benefit.

Section 5168(b) of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112-81) called for action to enhance the coordination between IDeA and SBIR/STTR programs to promote an increase in the participation of entrepreneurs from IDeA states, which usually receive fewer SBIR/STTR awards than do non-IDeA states.

The NIH initiated the IDeA program to broaden the geographic distribution of funding for biomedical and behavioral research. It builds research capacities in states in which the aggregate success rate for applications to NIH has been historically low (see Appendix 1 for IDeA states).

Data on SBIR and STTR awards show disproportionately fewer applications and awards to many IDeA states. Also, the propensity for university scientists to be engaged in health-related entrepreneurial activities apparently varies considerably among the IDeA states. This could be attributed to the states' extremely variable environment conducive to fostering translation of academic research to commercialization. However, the success rates – based on the total number of applications received - are comparable between IDeA and non-IDeA states. It is thus imperative to better understand the difficulties facing IDeA institution-based investigators who have research projects that could be commercially developed.

The first IDeA SBIR/STTR workshop entitled "Finding Ways to Foster SBIR/STTR Applicants from IDeA States" was held on August 21, 2014 at the National Institutes of Health in Bethesda, Maryland. The goal of the workshop was to get greater insight to the types of activities that would provide the most impact for promoting and attracting entrepreneurs from IDeA states into the SBIR/STTR program and increasing the participation of IDeA States in these programs. In view of this, the specific objectives were:

1) To understand factors limiting the number of SBIR/STTR applications arising from academic institutions in IDeA states, and
2) With the identification of limiting factors, to formulate reasonable recommendations through which NIGMS/NIH can assist and facilitate IDeA institutions to better foster viable and sustainable small business concerns (SBCs).

Twenty three experts including Principal Investigators, innovators, and academic leaders from IDeA states participated in this workshop. Program Staff from eight NIH institutes and centers - NIAID, NHLBI, NIDA, NIA, NIAAA, NLM, ORIP and NCATS were also in attendance, attesting to the significance and timeliness of the workshop.

The workshop was designed to be interactive and stimulate conversations and exchange across extramural stakeholders and the NIH. The breakout sessions were conducted to address the limiting factors for SBIR/STTR applications from IDeA states where participants were encouraged to propose solutions and make recommendations.

DISCUSSION AND FINAL RECOMMENDATIONS

The SBIR/STTR workshop was the first of its kind in the IDeA program that aimed to improve the chances of applications from IDeA states to mechanisms that require entrepreneurship and commercialization of corresponding research outputs. Collective wisdom from participants coming from the IDeA states and the NIH community was called upon to identify the procedural and logistical requirements, access to information and resources, and the identification of challenges and solutions. Success stories were presented so as to provide real examples of how actual needs and challenges were addressed, and practical advice given to the aspiring applicants. The role of NIH, IDeA states and institutions were emphasized and revisited.

1. Limiting Factors:

The group unanimously cited the importance of capacity building as a limiting factor, with challenges emanating from money and space issues. It is critical to acquire and develop the entrepreneurial capability and spirit in researchers and faculty at the IDeA institutions.

A number of limiting factors were identified and discussed in great length that included:

- lack of proactive Office of Technology and Commercialization and/or Small Business Development Center at the universities and academic institutions;
- lack of medical school in the campus and/or state;
- reduced number of existing small businesses within the IDeA states;
- lack of supportive business and entrepreneurial environment and infrastructure;
- less knowledge of SBIR/STTR grants and eligibility; as a follow up to this, SBIR/STTR outreach sessions organized at the National IDeA Symposium, IDeA Regional meetings and NIH Annual SBIR/STTR meeting.
- investigators lack of interest and experience in commercialization and moving innovative ideas to marketplace;
- lack of institutional support both financial and for rewards/incentives/ tenure and promotion potential;
- lack of incubator space on the campus or nearby to facilitate startups or development of early phase ideas;
- difficult to find business collaborators/partners;
- lack of critical mass of entrepreneurial mentoring faculty and expertise;
- lack of appropriate educational courses and modules to foster the entrepreneurial skills at earlier career stages - during undergraduate, graduate and post-doctoral levels;
- lack of knowledge about state and local resources.

2. **Recommendations:**

The group made three major recommendations. The first and foremost was *creation of regional networks/hubs*, a consortium to generate infrastructure and build entrepreneurial culture in the IDeA states. These regional networks/hubs could support business environments that can facilitate networking and team formation, sharing and transfer of information, best practices and guidelines, providing assistance and mentoring. These regional networks/hubs could also facilitate sharing of information on state and local resources and programs currently available in the form of commercialization funds or state matching funds – both are excellent incentives.

NIH received Congressional authorization to create and fund a pilot Phase 0 program with attributes closely matching the regional network/hub concept for the IDeA states raised during the workshop (The NIH Research Evaluation and Commercialization Hub (REACH) Awards; RFA-OD-14-005). No additional funds remain for Phase 0 activities; however, meeting that support of additional programs presents a significant challenge.

The second recommendation made was in the area of *Education and Training and Increased Outreach Efforts* facilitated by NIH and IDeA Institutions.

Education and Training is a multifaceted area with 3 major players: NIH, Institutions, and the IDeA states. NIH could provide training and funding mechanisms that would train researchers in entrepreneurialism. The NIH Innovation Corps (I-Corps™) a pilot project at NIH, in collaboration with NSF is a mechanism to train business-minded biotech researchers such as postdocs and faculty. This is a potential mechanism that NIH could, perhaps with some modifications, make available to IDeA-based investigators.

NIH could facilitate connections with potential collaborators and partners. A new user friendly SBIR website was recently launched (http://sbir.nih.gov); a virtual partner portal is under development that should facilitate access by companies and investors to make connections with academic investigators. This portal when launched should be very useful in creating public/private partnerships, although would require aggressive introduction and promotion to relevant communities (as in Outreach Efforts, see below).

Institutions may need to review tenure and promotion considerations for encouraging entrepreneurial activities. They will also need to encourage mentoring activities at their institutions. Each state also has its Small Business Development Center (SBDC), and the Office of Technology Transfer and Commercialization at the academic institutions should encourage and facilitate sharing these resources and incentives with interested entrepreneurial investigators.

For Outreach Efforts, NIH could sponsor and facilitate conferences, meetings and webinars and bring successful entrepreneurs as speakers to share their best practices. Meetings that currently take place, such as IDeA regional meetings, could be used to better disseminate information related to the SBIR/STTR programs and bring SBCs, SBDCs and scientists together. Outreach efforts by NIH may also include a bus tour to the IDeA states and share information on grantsmanship for developing competitive SBIR/STTR applications.

In addition to the awards made at Biennial National IDeA Symposium on Biomedical Research Excellence (NISBRE) to junior faculty and for mentoring, another award category in entrepreneurship can be included to recognize the contributions of an investigator in the area of Innovation and Commercialization; at NISBRE and also at IDeA regional meetings, a specialized session on SBIR/STTR could be included to promote attendance of interested parties. At these meetings, opportunities and matching programs that IDeA states offer for companies and academic investigators could be emphasized and shared.

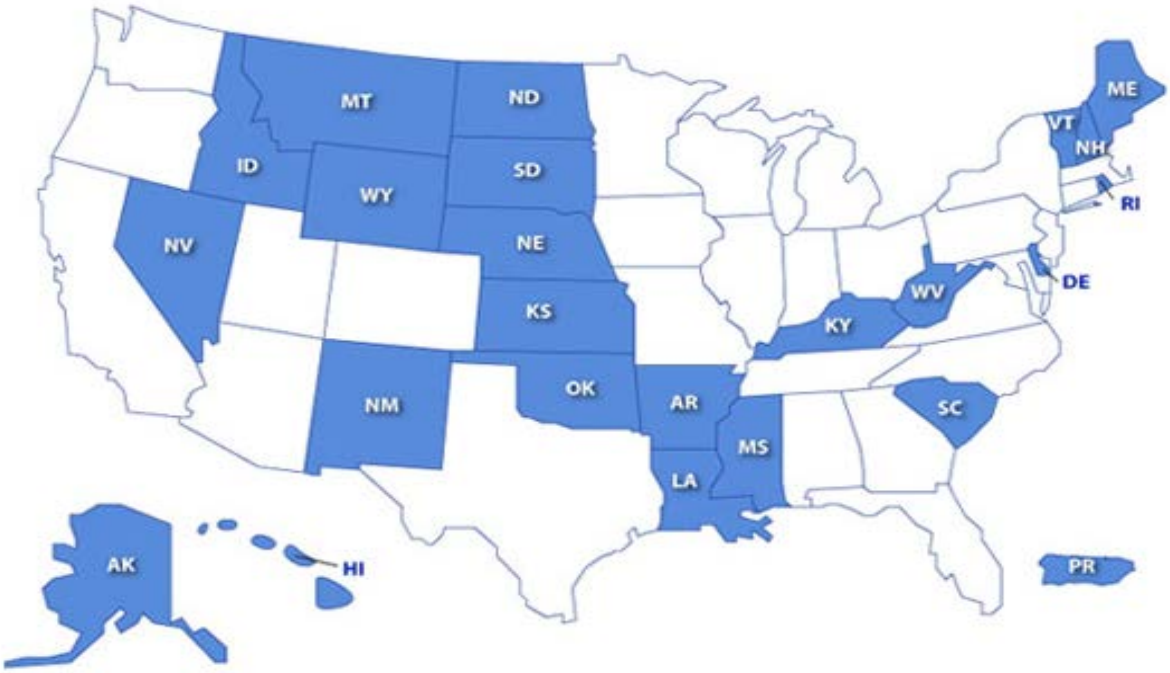
Third, a key factor mentioned several times throughout the workshop was *Culture Change* at the IDeA institutions. Culture shift toward acceptance of entrepreneurial activities as an vital adjunct to traditional scholarly pursuits should occur at the IDeA institutions, however, it was recognized by the workshop participants that it will be a slow process as seen by the outcomes of IDeA Center of Biomedical Research Excellence (COBRE) and IDeA Networks of Biomedical Research Excellence (INBRE) programs. It will require efforts both by the NIH and at the institutional level. Leadership at the IDeA institutions needs to encourage entrepreneurial activity among university scientists for innovation and technology development needed to promote commercialization of new products and services, which in turn leads to job creation and local economic development.

Funding to accomplish the recommendations presents challenges of course, especially for the regional network/hubs. The goal is to use SBIR/STTR funds as a primary source. Through the Authorization Act for FY 2012, Congress allowed NIH the ability to use SBIR funds to support a number of administrative activities, some of which could be directly related to the recommendations of the workshop. This authority ends after FY2015, although an extension may be possible. NIGMS is committed to work with other Federal agencies and non-Federal partners as needed to enhance the IDeA participation with the SBIR/STTR program.

APPENDIX

APPENDIX 1: US Map highlighting IDeA States

There are 23 states and Puerto Rico - shaded states that are eligible for IDeA.



APPENDIX 2. TRANSCRIPTS OF PRESENTATIONS

2.1 Overview of the NIH SBIR/STTR Program

Matthew Portnoy

The SBIR/STTR program office at the NIH works closely with the Small Business Administration (SBA) and 10 other agencies. Aided by the Defense Authorization Act, with vital interests from Congress, the White House and SBA, the program will increase the participation in underrepresented areas such as IDeA states for NIH, for EPSCOR states for other agencies, and also in women and minorities.

The SBIR programs specifically aims to: a) stimulate technological innovation, b) use small business to meet Federal R&D needs, c) foster and encourage participation by minorities and disadvantaged persons in technological innovation, and d) increase private-sector commercialization innovations derived from Federal R&D. For STTR, the objectives are: a) to stimulate and foster scientific and technological innovation through cooperative research and development carried out between small business concerns and research institutions, and b) to foster technology transfer between small business concerns and research institutions.

SBIR accounts for 2.8% and STTR 0.4% of the NIH budget, respectively. The SBIR/STTR landscape is broad, with NIH, one of 11 institutions accounting for 30% or a third of the pie. Altogether, the FY 2013 allocation across all agencies was $2.3B, with NIH, DOE, NSF, NASA and DOD in the top 5. These agencies make up 95% of the programs by dollars, and have both STTR and SBIR programs. DOD had the most allocation at $1B while NIH received $697M for 2013: $ 663M for SBIR and $95M for STTR. For the current fiscal year, NIH SBIR and STTR allocation is $758M, with the $60 M increase set-aside by law, and the restoration of budget sequestration cut from prior year. These funds were distributed to all institutes in proportion to their budget. The overall average success rates for 2012 and 2013 for the programs at the NIH are: for Phase 1, 15-20%, Phase 2, 30-40%%, Fast Track (combined phases 1 and 2) 10% of overall rewards and are comparable to Phase 1 rewards. These numbers are comparable to the numbers in other agencies. For the IDeA states, success rates for the SBIR/STTR programs are comparable to those in non-IDeA states: 11% for Phase 1, 30% for Phase 2, and 14% overall.

A new SBIR/STTR NIH website will be launched (sbir.nih.gov), redesigned and easy to access for applicants, with useful resources and links, and infographics for the process.

For solicitations and due dates, in addition to the parent FOAs (Omnibus) for SBIR (PA-14-071) and STTR (PA-14-072), a new SBIR Direct to Phase II FOA (PA-14-088) is available for companies that have done a lot of preliminary data. SBIR Contract Solicitation (NIH, CDC) dates are as follows: release is August and close date is November 2014. NIH Guide for Grants and Contracts is released weekly and receipt dates are specified in each FOA (http://grants.nih.gov/grants/guide/index.html). There are 80 other SBIR/STTR funding opportunities onscreen and on the Omnibus that IDeA states and other institutions can take part in.

Budget guidelines are $150M for Phase 1 and $1M for Phase 2, with hard caps at 50% above these levels: $225,000 for Phase I and $1,500,000 for Phase II. Reauthorization requires that agencies (not applicants) applying for funds above the hard caps apply for waiver from SBA, based on an approved list (http://1.usa.gov/1iUa5Kh). The approval is good for the 2014 SBIR/STTR Omnibus, and any FOA that falls on the topic list, including the Direct Phase II FOA.

There are three important reauthorization updates on 1) majority–owned venture capital provision, 2) switching between SBIR and STTR, and 3) SBIR Direct Phase II (http://grants.nih.gov/grants/funding/sbir/reauthorization.htm). Small business concerns that are majority-owned by multiple venture capital operating companies (VCOCs), hedge funds and/or private equity firms are now eligible to apply (NIH SBIR only). See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-071.html for details, and http://grants.nih.gov/grants/forms.htm#sbir, for forms. Applicants planning to switch from NIH SBIR/STTR Phase II or Phase IIB to any active NIH SBIR or STTR solicitation can now apply (http://grants.nih.gov/grants/funding/sbirsttr1/2014-2_SBIR-STTR-topics.pdf). It is strongly suggested that program rules must be adhered to while in consultation with their program officers. The Direct to Phase II SBIR FOA (PAR-14-088) is IC specific and not equivalent to Phase IIB. It permits bypass of Phase 1, where the SBC must have a technology prototype, with completed Phase-1-type R&D that can transition directly into Phase 2. This new FOA is not available to the STTR program and CDC, FDA, and ACF SBIR programs. It must be emphasized that this is different from the Fast Track where applications for both Phases 1 and 2 are submitted and reviewed together to eliminate funding gap. The review process for the new FOA goes through standard protocol where it is assigned to the small business study section (http://1.usa.gov/1eL6koM).

Coordination between IDeA and SBIR is being set in motion through the following:

a. Planning sessions among staff members
b. Utilization of IDeA listservs for SBIR information dissemination
c. Hiring of a dedicated NIH SBIR outreach coordinator
d. Conduct of SBIR outreach to IDeA states during annual and regional conferences
e. Conduct targeted outreach to IDeA states via coordination with state economic development offices to the extent allowed under reduced travel restrictions
f. Monitor SBIR applications from IDeA states
g. Hold the annual NIH SBIR conference in an IDeA state as feasible and coordinate the conference program/agenda with IDeA institutions in that state (2012 Kentucky, 2013 South Dakota, 2014 New Mexico)

Other agencies' involvement includes: coordination at SBA and SBIR agency level, drafting Outreach report clearance, possible SBIR bus tour through underrepresented states, and holding National SBIR Conference in Austin, TX in November 2014, in proximity with a number IDeA states.

During the open forum, the definition of venture-capital-company was raised. This is in the purview of the SBA that sets all definitions and eligibility. It sets the ownership to no more than 50% and allows multiple ownership.

2.2 Limiting Factors

a. Session 1

Mercedes Rincon

Following Limiting Factors were identified and discussed:

i. *Lack of proactive Office of Technology and Commercialization at the Universities*
IDeA institution needs an office with expertise in technology transfer to facilitate submitting small business applications. It was recommended that a facilitatory rather than proactive Office of Technology with properly trained staff should be in place. In addition, the facilitation should be done through the Office of Research since the technology transfer office staff may not have the expertise and networking capability. Since technology transfer officers are trained very differently from researchers, it will be very helpful if the IDeA states can have a regional office with individuals to understand both sides. It is thus reasonable to expect, that each institution must have the expertise. To foster more innovation, commercialization success gauged through patents and technology transfers may be included one of the criteria for tenure promotion. It was further suggested that there should be a regional mechanism to attain a homogeneous way of handling technology transfer and commercialization. Are there Developmental Offices in the institutions? Can GM help to develop a regional office to help investigators working on SBIR applications?

ii. *Lack of medical school in the campus and/ or state*
Medical schools provide infrastructure and a culture of facilitation. However, not having the schools was not considered a limiting factor per se or a disadvantage for SBIR. Their presence provides a clinical champion that requires collaboration, fostering networking with basic scientists and medical practitioners, thereby increasing facilitation and availability of resources. This results in an increase in critical mass of experts which will otherwise be distributed in several departments.

iii. *Reduced number of existing small businesses (e.g. biotechs) within the IDeA states and/or limited information about existing small businesses in those states*
People who would like to develop small businesses such as venture capitalist prefers an environment where the development is found. They should be made aware of where the leadership for such is located, where success indicators can be tracked. With a limited information in each area, having a network of collaborators is an enabling mechanism, and will thus, be very useful. Are investigators knowledgeable or familiar with small businesses in their state?

iv. *Lack of knowledge about what SBIR and STTR grants are and whether investigators can apply or not.*
Awareness is low; thus, mentoring is needed for developing SBIR/STTR applications. It was recommended that a COBRE-like program will be very helpful. It typically promotes R01 mechanisms and assists individuals to get engaged. Finding partners in universities and small businesses is a challenge, to put together a team, or consortium,

in creating an environment as groundwork for product development. A program that links researcher and company is needed.

v. *Insufficient exposure to training/education regarding commercialization (e.g. workshops on patents, startups, VC, how to make a good pitch etc.). The case of SPARK-VT.*
Education should start early in career development. However, it may be disadvantageous for young investigators to work on this type of research as they may not be able to publish their work.

vi. *Lack of interest in commercialization and/or in moving forward with the ideas from investigators (entrepreneurial spirit)*
A reward structure must be in place to encourage people to participate.

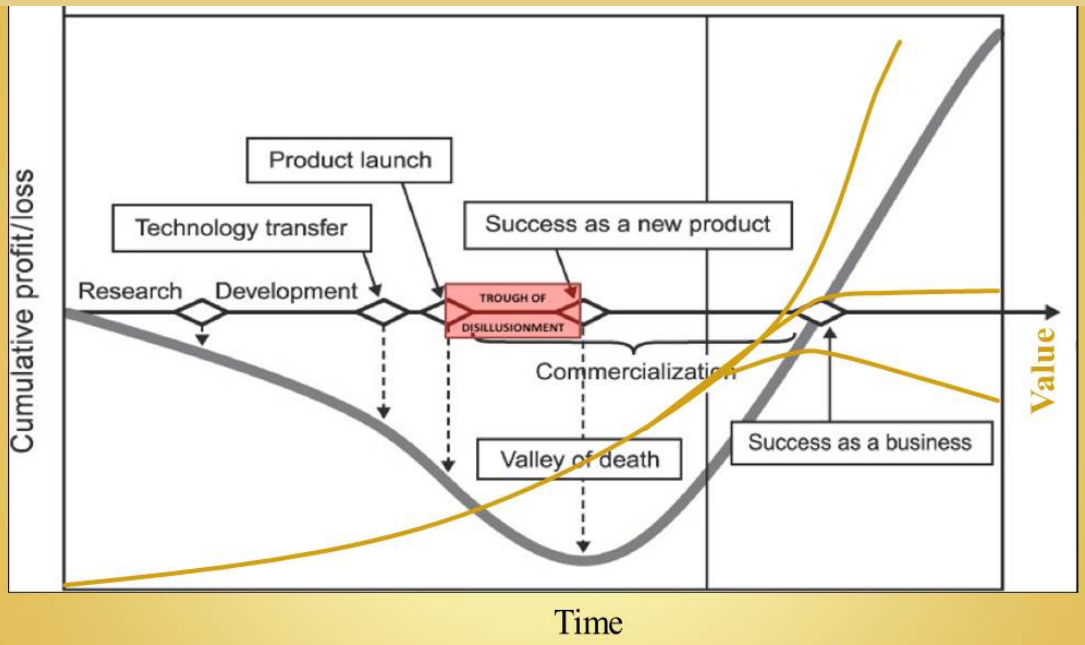
vii. *Lack of internal funding to support some of the entrepreneurial ideas within the universities.*
There is a constitutional barrier that makes it challenging to access state support. This may vary from state to state. However, some states may provide a forgivable loan. It was emphasized that there should be no mistakes in early stages.

b. Session 2
William A. Gern

Biopharma Industry Data: Dr. Gern presented some data on the biopharma industry for 2012 showing the analysis on companies and employment for 2012. A data sheet was also presented on the population, federal funded R&D dollars for 2011 and the number of medical schools. There are 6 states, all IDeA, that do not have medical schools: ME, DE, WY, AK, ID and MT. The last 4 share a medical program with University of Washington called WWAMI. The venture capital dollars for 2008-13 was also shown. California is on top of the list at $14.7B, followed by Massachusetts at $3.1B. Fifty percent of venture capital is in CA, with 80 % found in the San Francisco Bay area. IDeA states' contribution amounted to 2% of the total venture capital dollars at $585M, with the most investments located in North Dakota at $24 M, the only IDeA state in the top 10. Federal R&D in IDeA and EPSCOR states is less than 0.75%, signifying its implication on the number of investible business. Population apparently, is not a factor in the distribution of venture capital.

The Death Chart-Model of Commercialization Phases: This chart shows the cash flow as a function of development stage (time). The large grey line traces the cash flow for small businesses as it moves through R&D, technology transfer, product launch, and commercialization. The transition from research and preclinical development to the clinic is often described as very risky, if not perilous; hence the description, Valley of Death. This represents the trough of disillusionment, a period between product launch and commercialization.

Figure 1. Valley of Death-Model of Commercialization Phases



Osawa, Y. and Miyazaki, K., 2006. "An Empirical Analysis of the Valley of Death: Large-scale R&D Project Performance in a Japanese Diversified Company." Asian journal of technology innovation 14, 2, 93-116.
Modified with Value line by William Gern, Office of Research & Economic Development, University of Wyoming

As traced by the large grey line, value that accumulates through time beyond the Valley of Death may have multiple outcomes. Venture capitalist comes in after the risk is eliminated, as the business has negotiated beyond the Valley of Death. An example was presented in the case of the basics of clinical drug development for neurodegenerative disease indications, where an NIH STTR and other grants were especially useful in providing support through the Valley of Death phase. Angel investors, startup-company, foundations or early stage venture capitalist come in next. Later, big pharma, public and private partnerships take over, for product development, partnerships and infusion of venture capital during early commercialization.

2.3 Remarks from the Director of NIGMS

Jon Lorsch

Dr. Jon Lorsch enumerated the charge of the workshop: identify and address the challenges and barriers to SBIR and STTR funding, and in a greater sense, increase the economic activity in IDeA states. How a grantee is allowed to use SBIR/STTR funds is one challenge that needs to be addressed, while following prescribed guidelines. He ascribed the importance of working together as a goal that can be achieved through regional efforts. This could be used to leverage the entire IDeA community regionally or even nationally, by synergies that will allow to have things done, that would not have been accomplished individually.

2.4 Working Towards SBIR/ STTR Success Stories in Maine

Kevin Strange

MDI Biological Laboratory was founded in 1898 as a seasonal marine research institute in South Harps well, Maine, which later moved to Mount Desert Island in1921. It was in 1926 when Dr. E. K. Marshall established the focus to biomedical research using marine fishes to understand excretory mechanism of human liver. In 2000, the organization became a research institution, where a full time director was hired in 2009.

Dr. Strange cited the challenges of MDI Biological Laboratory in terms of its location, relatively unknown stature, overshadowed by larger neighbors and the financial hurdles of the period: great recession, federal deficit, NIH focus shifting to translational science. Raising awareness and changing perception at all levels was very critical in addressing the challenges. That establishing a human health research focus, coupled with recruitment of outstanding faculty in a culture of basic discovery and translational science, were key to the success of MDI Biological Laboratory. From basic research to drug development in regenerative medicine and aging biology, MDI-BL, operated on 4 tenets: no silos, no bureaucracy, being small but nimble, and innovation. These propelled them out of the valley of death path and created opportunities for success, beginning with a the discovery of ZF143, a small molecule that stimulates tissue repair in zebra fish, a readily synthesized natural compound that was designed based on the genetic inhibition of target protein in mice, speeding tissue repair and slowing tissue degeneration. This led to the establishment of their first company, Novo Biosciences. Working with the state government led to the Maine Technology Institute, where lessons learned included increasing the understanding for R in R&D, difficulty of establishing a relationship with academic institutions, and the vigilance to work with them. On November 4, 2014, the organization will receive $3M for infrastructure to support workforce training and drug discovery, LD 1223. Partnerships built the foundation for the bioengineering collaboration with the University of Maine. In another development, MDI Biological Laboratory also partnered with Foundation for Blood Research and Bigelow Laboratory for Ocean Sciences, to establish Maine Life Sciences Group to provide R&D expertise, leadership, and strategic planning to state government and the establishment of real accountability and transparency standards for R&D state funding. LSG Biotech Collaborative provides comprehensive resources for growing life sciences businesses.

Lessons learned for stimulating science commercialization in Maine are as follows:

a. *Create a culture of entrepreneurship, but don't try to convert the disbelievers*
b. *Select for the right people and provide them training, mentoring, resources and incentives*
c. *Get to the students and postdocs early*
d. *Work with state government*
e. *There is strength in numbers: form unique collaborative efforts with likeminded people*

2.5 SBIR/STTR Success Story from Kentucky

Mahendra Jain

The Kentucky Science and Technology Corporation (KSTC) is an independent and non-profit

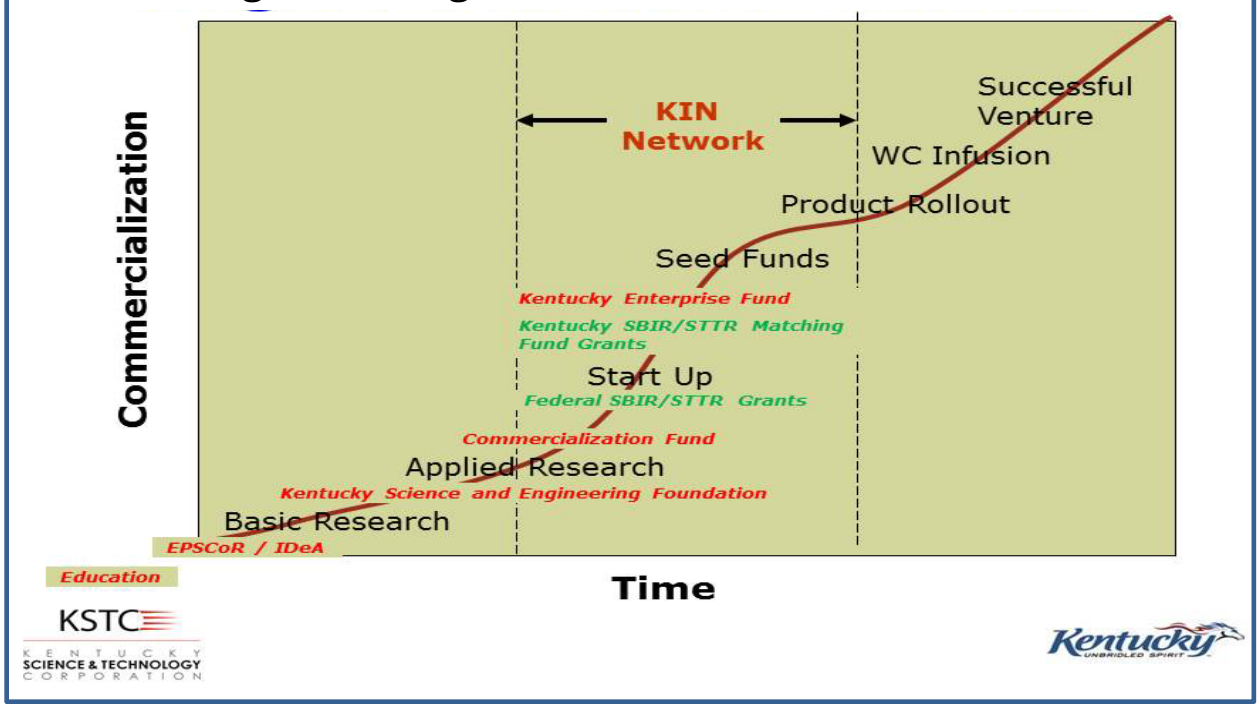
company founded in 1987, with a mission to strengthen the capacity of people, companies and organizations, to develop and apply science and technology, and compete responsibly in the global marketplace. KSTC administers several state-funded programs including the Kentucky SBIR/STTR Matching Funds Program created and funded by the Cabinet for Economic Development, Office for Entrepreneurship. The program has boosted Kentucky's national ranking in receiving SBIR/STTR grants from 44th in 2002 to 28th in 2012. For the 2013 State Entrepreneurship Index, Kentucky ranked fourth. Businesses leveraged $82,125,204 in Federal SBIR/STTR grants with $46,665,654 in Kentucky SBIR/STTR. In addition, 195 matching fund grants were obtained for 96 companies. This has resulted in the creation 0f 460+ high technology jobs, filing of 125+ Patents, 12+ licensing arrangements, products sold and $10M+ (two companies acquired) in private capital investments.

Examples of the companies are:

a. *AntiOp, Inc*. This company developed naloxone nasal spray (ready-to-use, unit-dose) for the treatment of suspected opioid overdose, and is in clinical development stage with an active IND with FDA; final FDA approval is expected soon. A spin off from the University of Kentucky, the company received NIH-NIDA $3,450,564 grant, plus KY SBIR Matching funds of $650,000.
b. *Transposagen Biopharmaceuticals, Inc*. This company develops unique animal models, cell lines, stem cells and research tools to improve drug discovery and development. SBIR funding coming from the following ICs NIH-NCI, NCRR, NIGMS, NIHGRI is $4,733,497 plus Kentucky SBIR Matching funds of $2,199,936. Original investment was $700,000 in private capital. They are marketing genetically modified (single gene knockout) families of rat to research institutions and organizations such as Genentech, Amgen, Merck, Novartis, Genzyme, AstraZeneca and Amylin.
c. *ParaTechs Corporation*. Products include: baculovirus expression vector system for producing human therapeutic proteins at higher titer, non-surgical embryo transfer device for mice, a biological method for treatment of chronic wounds, and a nitrate reductor device for measuring nitrate as nitrite in physiological fluids. A spin off of University of Kentucky in 2004, the SBIR funding from NIGMS, NCRR, NIAID, and OD was $4,305,737 plus Kentucky SBIR matching funds of $1,494,146. Company is currently selling Non-Surgical Embryo Transfer (NSET) device in USA, and has licensed distributors in United Kingdom and Australia
d. *NaugaNeedles, LLC.* A spin off of University of Louisville in 2007, it received a Vogt award of $120K, and SBIR $1,239,700 funding from NIH, including $575,758 in Kentucky Matching funds. The company is enabling mass-production of AFM probes (nanoneedles 1-100um L/25-100 nm D) for cell scanning and probing in cellular biology
e. *Four Tigers, LLC*. A company formed in 2004, in STTR with University of Kentucky, College of Dentistry, SBIR funding from NIH-NIDCR is at $731,324, including Kentucky SBIR matching funds of $417,040. The company is developing blackberry extract (anti-oxidant, anti-inflammatory, anti-bacterial, and anti-viral properties) delivered via chewing gum for oral hygiene (reduce gingivitis) in Blackberry Farm, Paris, KY. Five products are in the pipeline: gum, energy gum, chewable tablet, lozenge, cold sore ointment, thin-film composite.

The Kentucky SBIR/STTR Program has a support system that provides pre-application assistance via one on one consultation, seminars and workshops, Phase Zero Grants ($4K) and Phase Double Zero Grants ($4K). The Kentucky SBIR/STTR Matching Grants and the review of comments served as the post-award assistance. Faculty members are also allowed entrepreneurial leave at the university of Louisville and University of Kentucky. The figure below shows the stages of innovation and investment at KSTC where IDeA and EPSCOR grants provide the groundbreaking support for basic research.

Figure 2. Stages of Innovation and Investment



Kentucky Science and Engineering Foundation, the Kentucky Commercialization Fund, SBIR/STTR funds, Kentucky SBIR/STTR Matching Funds and the KIN Network usher the work into the applied field, start up, seed funds, product rollout, WC infusion, and the successful venture.

APPENDIX 3. SMALL GROUP DISCUSSION OF POSSIBLE WAYS TO ADDRESS THE KEY BOTTLENECKS IDENTIFIED DURING THE MORNING SESSION WITH SPECIFIC EMPHASIS ON IDEA STATES AND PROGRAMS

3.1 Reports from the Breakout Sessions

a. Breakout Session I

The first group cited the importance of capacity building as a limiting factor, with challenges emanating from money and space issues. Acquiring and developing the entrepreneurial spirit in researchers need to be emphasized. There were three suggestions on how to increase capacity:

i. Focus on specific thematic areas: choose a specific area for development.
ii. Engagement of faculty. Developing an environment of mentor to mentor training will be very desirable and useful. For tenure and promotion considerations, patents and building companies should be included.
iii. For pilot commercialization programs, flexibility can be explored with the outsourcing of work (contract organization).

b. Breakout Session II

The second group ascribed to the requirement for a program that must have the following:

i. Faculty development that will increase capability towards entrepreneurship should be strongly encouraged. Very few faculty members have history of entrepreneurship and are therefore not trained in submission and being evaluated by a different type of review panel.
ii. Networking or team formation across the region should be promoted. There was a strong recommendation for regional consortium/hubs to increase the critical mass of entrepreneurs.
iii. Access to expertise and capital must be provided.

c. Breakout Session III

The third group echoed the proposal for the creation of regional networks, a consortium that can facilitate sharing and transfer of information and guidelines, providing assistance and mentoring. The following approaches were suggested:

i. Sharing of best practices with better information flow is recommended at the regional networks and through mentoring.
ii. Tap into what are available in the State, in the form of commercialization funds or state matching funds. Both are excellent incentives.
iii. Proactively searching for companies via: sbir.nih.gov, NIH REPORTeR (search the publicly available database for key words).

3.2 Recommendations by the Group

Culture Change is Key! Cultural shift should occur towards entrepreneurship. Institutions will have to work on this, which entail time. NIH may help but a lot of factors will not be in the purview of the NIH.

Four major issues and potential solutions were highlighted:

a. ***Regionalization.*** The concept of having regional hubs to provide the information and assistance needed is important. The use of SBIR/STTR funds is challenging and with administrative funds committed through 2015, the ability to include the budget of a new NIH mechanism is formidable. Whether SBA can allow the use of administrative funds in the future remains to be seen.

b. ***Education and Training.*** This is a multifaceted area with 3 major players: NIH, Institutions and the state.

i. NIH provides training and funding mechanisms that can train people in the entrepreneurial mindset. These are potentially flexible to look at multiple levels of education but not below the undergraduate level. The I-Corps pilot project at NIH, in collaboration with NSF is a mechanism to train business-minded biotech researchers such as postdocs and faculty. This is a potential mechanism that in the future, NIH could perhaps with some modifications, be made available for IDeA institutions. NIGMS's Innovative Programs to Enhance Research Training (IPERT) (R25) program is another option.
Each IC may have their different and specific mechanisms.

ii. Institutions: Granting tenure is an important consideration and is an institutional thing.

iii. States have various ways of dealing with the issues but NIH is limited in extending assistance.

c. Facilitation by NIH

i. A new website, a virtual partner portal, will be launched for access by companies, investors to make connections. This will be very useful in creating public/private partnerships.

ii. Sponsored conferences and meetings can bring sponsors and scientists together. This can also be a part of education and training.

d. ***Increase Outreach Efforts.*** Several suggestions were put forward:

i. Use the circuit writer concept.

ii. Schedule bus tours cited by NIH using administrative funds and staff time.

iii. Get more IC representation at IDeA regional and national meetings.

iv. Leverage existing IDeA infrastructure for dissemination of information via the use of listservs.

v. Provide webinars on SBIR/STTR grantsmanship.

vi. Start a new award category. In addition to awards made at NISBRE to junior faculty and for mentoring, another award category in entrepreneurship can be

included to recognize the innovative efforts; and also a specialized session on SBIR/STTR can be included to promote attendance of interested parties.

vii. Emphasize IDeA opportunities at national workshops/meetings, citing matching programs. Check matching programs that different states have for companies for consideration.

APPENDIX 4. ROSTER OF PARTICIPANTS

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