17th Annual NIH SBIR/STTR Conference

From Washington to Washington: Supporting Small Business Innovation for Health

October 27 - 29, 2015
Bell Harbor International Conference Center, Seattle, WA

Track 1 Session Descriptions
Navigating Through SBIR/STTRs

Administration for Community Living

You thought being selected for an award was difficult, but getting to the market-place can be even more challenging. Biomedical research can take millions of dollars and 10+ years before a product reaches consumer hands. So how are you planning to get over this huge hurdle? NIH offers several assistance programs to help SBIR/STTR awardees strategize how to commercialize their SBIR/STTR developed products. Join this session to find out which program might be available for you and how to become involved.

Diversity, Disability, Re-entry Supplements

NIH staff will describe funding mechanisms used to award Diversity, Disability and Re-entry Supplements. At this session, two small business concerns and individuals who have benefited from these awards will discuss their successes and secrets regarding the process.

Feasibility Planning for Phase I

So you have an idea for a potential product -- now what? It starts with feasibility planning. This session will highlight the preparation needed to put together a development strategy assessing market feasibility, technological feasibility, economic feasibility and potential hurdles and means to circumvent them. Presenters will share their success stories, including hurdles and lessons gleaned, from two unique areas of expertise. Dr. Wermeling will present on his expertise surrounding pharmaceutical drug development, whereas Dr. McMillen will present on her expertise regarding web-based services and mobile applications. An interactive discussion will follow.

Helping Small Businesses Make Sense of the NIH Policies and HHS-Regulatory Requirements on Human Research Protections Workshop

This workshop aims to equip participants with the fundamentals for understanding the NIH policies and HHS-regulatory requirements on human research protections in order that they can better maneuver the process and attain compliance. It will focus on clarifying federal requirements and providing participants with practical tips and instructions to get the job done. Upon completing the workshop, participants will be able to:

- Determine whether, when and how the HHS regulations for human research protections apply to research;
- Understand how to appropriately complete the sections on human research protections and inclusion of women, minorities, and children in an NIH grant application
- Understand and be prepared to navigate through the basic regulatory requirements regarding federalwide assurances (FWAs), institutional review board (IRBs) reviews and informed consent.

Applying and Making Sense of the Regulations on Human Research Protections

This presentation will provide an overview of the role of the HHS Office for Human Research Protections (OHRP), the “Common Rule” and how the HHS regulations on human research protections are applied. Participants will learn about the main differences between these regulations and the FDA’s regulations, how to conduct basic determinations as to whether their research comes under the Common Rule or is exempt, what engagement is about, and when and how to obtain a federalwide assurance (FWA).

Preparing the Human Subjects’ Sections of Your NIH Grant Application

This presentation will help participants determine whether their study meets the definition of human subjects research and walk through completing the ‘Protection of Human Subjects’ section in the NIH grant application. It will provide an overview of the grant review process and discuss in more detail the criteria that reviewers use to determine if the application has included adequate protections for human subjects as well as plans for the inclusion of women, minorities, and children. Case studies will be used for illustration.

Mastering the Regulatory Requirements on IRBs, and Informed Consent

This presentation will instruct participants on what IRBs do, how to go about finding one, and what they could do to facilitate getting their protocols pass reviews. It will also provide an overview on the requirements for informed consent and some of the flexibilities that are available.

How to Get Your Award Faster

Once you know you received a fundable score, we understand that you want to get the award as fast as possible. This presentation goes over Just-In-Time (JIT) materials that the NIH needs prior to award. Typically these are the following:

- Other Support
- IRB/IACUC approvals
- SBIR or STTR Funding Agreement Certification Forms
- Other usual JIT information
- Other information requested by the awarding IC

Knowing what to expect can help you prepare. Good preparation will help assure that you will get your award as soon as possible.

The Ins and Outs of SBIR Contracts & Grants

As federal agencies that provide funding to innovative research with the development of their research ideas (a.k.a. investigator-initiated research), the majority of the NIH SBIR awards are made grants. But did you know that NIH, and other federal agencies also offer contract opportunities thru the SBIR mechanism? The NIH SBIR contract solicitation is issued annually in the summer with proposals due in early November and includes topics identified by program staff aimed at soliciting research in targeted scientific/technical area. In this session, you will learn:

- What differentiates SBIR contract from SBIR/STTR grants
- How to hear about and submit proposals in response to SBIR contract solicitations
- Some of the unique requirements of contracts vs. grants, such as reporting and OMB requirements

Mastering Research Involving Animals

Are you considering using live vertebrate animals in your research? Are you aware that the policies and regulations regarding research animals are different than those involving human subjects? This session provides information on

- The requirements for using animals
- Appropriate completion of the Vertebrate Animal Section of the grant application and peer review considerations
- The functions of an Institutional Animal Care and Use Committee
- Details on the various Assurance documents including which type is required if your institution does not have its own animal facility
- The consequences of what happens when animal activities become noncompliant.

Phase 1 SBIR/STTR Proposal Development

You've got a great idea. It will change the world! All you need to do is write the proposal to get your project launched with SBIR/STTR funding. But writing the proposal is pretty difficult. Or is it? Join us in this Phase I Proposal Development session where we will develop the framework to help you prove the following hypothesis - "A clear understanding of the review criteria combined with comprehensive strategic planning and sufficient time will make proposal development the easy part."

Resolving SBIR/STTR Allegations of Waste, Fraud, and Abuse to Promote Program Integrity

Learn about the roles and responsibilities of the Division of Program Integrity (DPI) and find out how their work is an important component of NIH efforts to oversee, detect, and prevent fraud, waste, and abuse. Know what to do if your company is involved in a DPI review. DPI in the Office of Management Assessment is the component of the NIH that conducts reviews of non-criminal allegations of misuse of NIH grant and contract funds; NIH grantee and contractor conflict of interest; violations of grant or contract laws, regulations, or policies; and issues referred to NIH by HHS Office of Inspector General (OIG) when prosecution or civil action has been declined or when OIG plans no further investigation. DPI is also responsible for reporting to OIG allegations that are or appear to be violations of criminal law.

SBA – Seattle District Office

Description TBD

Successfully Submitting a Small Business Grant Application to NIH using ASSIST

Until recently, grant applicants had to use Grants.gov's downloadable forms or procure the services of a commercial system-to-system service provider to prepare and submit a grant application to NIH. Now there is another option – ASSIST. NIH's Application Submission System & Interface for Submission Tracking (ASSIST) is a secure, web-based option for the preparation and submission of grant applications through Grants.gov to NIH. Among the many benefits of ASSIST are the ability to check your application against NIH business rules and preview your application in the NIH format prior to submission. This session provides an overview of the NIH grant application process and basic ASSIST features.

Using RePORT to Your Advantage

NIH makes an abundance of grant and funding data – including analyses of who and what we fund – available to the public through a resource called RePORT. Learn how to use this resource to find information to help target your grant application, find key NIH staff and grantee contacts, and more.

Track 2 Session Descriptions
Circumventing the Hurdles

CDC – Small Business Innovation Research Program: Translating Innovation for Practical Solutions

This session will provide participants with an introduction to CDC and its global public health mission. We will describe current CDC priorities and identify areas of need where the SBIR Program can have significant impact in real world public health settings. Examples of past and current projects will be provided to demonstrate how the CDC SBIR Program has helped create practical solutions to public health problems worldwide.

Compliance and Stewardship of Federal Funds

NIH and its grant recipients share responsibility for compliance and oversight to ensure proper stewardship of Federal funds. To fulfill this administrative partnership, the NIH provides "compliance assistance" that consists of clear and easy-to-access information on federal grants financial and management requirements for contractors, grantees, and the public. Compliance assistance is crucial to the successful administration and fiscal management of grant awards and it safeguards the Federal investment in America's R&D efforts. This session will address the administrative requirements, cost principles, and audit requirements applicable to SBIR/STTR grants.

FDA – Overview of U.S. Regulatory Requirements: Pharmaceuticals

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. The mission of CDER's Small Business and Industry Assistance (SBIA) Program is to promote productive interaction with regulated domestic and international small pharmaceutical business and industry by providing timely and accurate information relating to development and regulation of human drug products. This presentation will address the CDER SBIA program, the new drug approval process, financial incentives for small pharmaceutical business.

FDA – Seattle District Office

Description TBA

Indirect Cost Rates and Accounting System Workshop

Who needs to negotiate rates? SBIR/STTR phases and indirect cost (IDC) negotiations "What you need to know about -- when to negotiate versus no need to negotiate." SBIR/STTR guidelines and specific rules to know in regard to IDC. Special IDC costs you need to know: IR&D and Executive bonuses per the Department of Health and Human

Services Acquisition Regulation (HHSAR) and NIH policy. The what / when / who / how of the IDC submission duration, contents, frequency, types, contracts, status, etc. IDC rate calculations and helpful resources leading to preparing an adequate IDC submission. Indirect rate structure One-Tier, Two-Tier, Three-Tier and more. IDC pitfalls to avoid and lessons learned.

Institutional Development Award (IDeA) Program

The National Institute of General Medical Sciences (NIGMS) Institutional Development Award (IDeA) Program increases the biomedical and behavioral research capacity at institutions located in states with historically small number of grant awards from the NIH. Currently, 23 states and Puerto Rico are eligible for this program. NIH is especially interested in promoting participation of IDeA states and programs in its small business programs, including SBIR/STTR, in order to advance scientific research and discovery, technological innovation and economic growth in these states. This session will discuss NIH small business opportunities and how to forge partnerships between the academics who know the problems and the companies that make the technologies. The session will also provide information on technical assistance for small businesses in IDeA states, sharing of best practices and leveraging resources across IDeA and non-IDeA states.

NIH Resources for Small Business Success

While the NIH is the major agency providing funding for biomedical research, did you know that it also provides resources to the biomedical community that can help accelerate research? Come to this session to learn about some of the resources available including the Therapeutics for Rare and Neglected Diseases (TRND), the Bridging Interventional Development Gaps program (BrIDG), and the Human Tissues and Organs Resource for Research (HTOR). Hear how small businesses have used these opportunities to help leverage their research and development programs. Note: these examples are illustrative of opportunities available at NIH. In addition, individual institutes may have other resources available. For information on these institute-specific resource opportunities for small businesses, visit the one-on-one sessions.

Opportunities for Eliminating Health Disparities

What are health disparities? What makes eliminating health disparities challenging? This session will showcase the ongoing search of the National Institute on Minority Health and Health Disparities (NIMHD) to identify, attract, and support small business innovations designed to reduce or eliminate health disparities. The NIMHD envisions an America in which all How can your small business contribute to this vision? What populations are considered "health disparity populations"? These and many other questions will be answered during this session and examples of innovative SBIR and STTR awards supported by NIMHD will be presented.

Phase II SBIR/STTR Proposal Development

You've made it through the first hurdle – getting your Phase I funded. You've achieved your aims. You've demonstrated feasibility. You're ready to write and submit your Phase II proposal. Or are you?? In this session we'll explore the key considerations for the Phase II proposal with specific emphasis on commercialization. We'll provide the framework for a strong commercialization plan, discuss key activities that you can initiate while still working on your Phase I project, and review the overall attributes of a strong and well-crafted proposal.

Protecting Your Intellectual Property

Inventions made under a federal research award can be a company's most valuable asset if properly identified and managed. But while many may embark upon the road to commercialization, the successful journey needs a roadmap to avoid any roadblocks and potholes along the way. Effective and timely protection of intellectual property rights is of paramount importance for ensuring marketing and commercialization success. Practical information about protecting and commercializing those rights will be provided.

Research Integrity and the Handling of Research Misconduct Allegations at the NIH

Participants will gain a basic understanding of the policies and regulations concerning research misconduct in NIH-funded activities. Upon completion of this session, attendees should be conversant and understand the elements of research misconduct, the assurance requirements for NIH grant applications, and the roles of the HHS Office of Research Integrity (ORI) and the NIH in promoting research integrityAs federal agencies that provide funding to innovative research with the development of their research ideas (a.k.a. investigator-initiated research), the majority of the NIH SBIR awards are made grants. But did you know that NIH, and other federal agencies also offer contract opportunities thru the SBIR mechanism? The NIH SBIR contract solicitation is issued annually in the summer with

proposals due in early November and includes topics identified by program staff aimed at soliciting research in targeted scientific/technical area. In this session, you will learn:

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Writing your Type II Commercialization Plan

Lifesaving innovations do not benefit the public unless they reach the market, but achieving this task requires strategic planning and business savvy leadership. Attend this session for an in-depth discussion of what your commercialization plan should include to impress NIH reviewers. NHLBI's entrepreneur-in-residence Gary Robinson, who brings a wealth of expertise in the development and commercialization of new life science technologies, will provide suggestions about the structure and organization of your plan, and ways to articulate the value proposition and market appetite of your technology. You'll also hear examples of state and local based resources that can help small businesses build their commercialization plan and other insightful tips to jumpstart your application to achieve commercial success.

Track 3 Session Descriptions
Path to Commercialization

Beyond SBIR/STTR: Non-dilutive Capital Sources

Not ready for equity funding yet? There are a variety of non-dilutive capital options available, but procuring this type of funding can be challenging. This panel will feature presentations from people intimately familiar with non-dilutive capital sources, including state granting funds, foundations, academic institutional funds and friends and family.

Data Management Under Federal Awards

On February 22, 2013, the White House Office of Science & Technology Policy (OSTP) released a memorandum entitled "Increasing Access to the Results of Federally Funded Scientific Research." In this memorandum, OSTP Director John Holdren directed U.S. Federal agencies with more than $100M in R&D expenditures to develop plans to make the published results of federally funded research freely available to the public within one year of publication and requiring researchers to better account for and manage the digital data resulting from federally funded scientific research. The OSTP's final policy reflects substantial inputs from scientists and scientific organizations, publishers, members of Congress, and other members of the public—over 65 thousand of whom recently signed a We the People petition asking for expanded public access to the results of taxpayer-funded research. Federal agencies are expected to implement their respective public access plans. This session will provide an overview of the development of the NIH Public Access Plan (released February 2015), and it should help the community and researchers prepare for addressing data management/sharing as part of their federal funding applications as appropriate.

Finding Lab Space When There is No Vacancy

Are you looking for lab space? Do you already have lab space but need more? Hear from real estate and regional incubator leaders from Washington state's no vacancy market, as they discuss how to secure, and develop laboratory space, as well as new models for sharing space.

Networking and Partnership

Diverse areas of science require various levels of technological expertise. Depending on how far advanced a tool or technology is, there is a potential for consultative networking, collaboration and/or more formal partnerships. For example, proof-of-concept ventures are more likely to require less formalized consultative or collaborative 'seed-like' input to optimize potential, whereas SBCs w/ more developed technologies require more formalized partnerships and commercial investment. This session will help to elucidate ecosystems that enhance your businesses' stage-specific development via appropriate networking and partnerships strategies

NIH Technical Assistance: Niche Assessment Program & Commercialization Assistance Program

You thought being selected for an award was difficult, but getting to the market-place can be even more challenging. Biomedical research can take millions of dollars and 10+ years before a product reaches consumer hands. So how

are you planning to get over this huge hurdle? NIH offers several assistance programs to help SBIR/STTR awardees strategize how to commercialize their SBIR/STTR developed products. Join this session to find out which program might be available for you and how to become involved.

Planning for Phase III

The SBIR funding mechanism is unique in many ways. But it is the only mechanism that "requires" post-funding actions. Publications, graduate course and thesis completion, and training events or curricula may be expected from other NIH grant mechanisms. Meanwhile, SBIR funds Phases I and II but has built into the funding mechanism a Phase III for commercialization of the products developed in the earlier phases. SBIR grantees treat this 3rd phase with widely divergent levels of enthusiasm and planned activity. It could be argued that Phase III, which includes no funding from NIH, is the most important phase. For SBIR to be successful, products with proven efficacy need to get out-to-market for public use.

In this session, early-stage and longer-term Phase III SBIR grantees will share:

- The strategies and challenges faced in Phase III.
- Lessons they have learned about starting early in planning for Phase III; what can be done in Phases I and II to increase the likelihood of Phase III success?
- Recommendations for new and experienced SBIR grantees in planning for Phase III.

Post Affordable Care Act: What You Should Know about the Changing Healthcare Landscape

The Affordable Care Act is quickly changing our health landscape. Hear from Washington State regional leaders on what your company needs to know about the changing health landscape from your future customers.

Raising Capital: The Entrepreneur's Perspective

Hear from entrepreneurs who have successfully raised capital from a variety of sources – non-dilutive and dilutive. Among the topics this panel will discuss are: fitting the funding to your business plan; identifying appropriate sources of capital; timing and sequencing of capital; do's and don'ts in raising capital and lessons learned.

Technology Transfer

The focal point for U.S. Government investment in innovative healthcare research and development has been the NIH. The intramural research program itself at the NIH has led to a huge variety of novel basic and clinical research discoveries - all of which require commercial partners in order to develop them into products for hospital, physician or patient use. With over half of new NIH license agreements granted to small firms and over 600 products (including 24 FDA-approved drugs and vaccines) launched by NIH licensees, working with technologies from the intramural NIH and FDA research programs cannot be overlooked as part of any long-term growth strategy for biomedical firms. This session will discuss ways in which SBIR/STTR firms can partner with NIH.

Tracking the Web Session I: Leveraging SBIR to Build a Healthcare Software Company

In this first of a two-session series, industry veterans and SBIR awardees will share their experience turning ideas for digital health innovations into proven products. The healthcare industry provides many opportunities for solutions, such as mobile apps, e-health portals, point-of-care systems, diagnostic aids, remote reminders, and patient education. These product and service needs are driven by the need for efficient outreach, education, reimbursement or patient-reported outcomes to make health care more transparent and more engaging. This panel will explore the challenges inherent in the product development cycle and market validation process, through the experiences of two successful company leaders. A moderator will introduce the issues, followed by comments and "tales from the trenches" from the two leaders. The panel will also include an opportunity for interactive discussion between panelists and the audience. What is a good idea? How do you test it? How do you build it? How do you price it? How do you recruit and motivate a core team with limited resources? These and other questions will be addressed in a dynamic exchange.

Tracking the Web II: Growing Your Company Into a Profitable, Sustainable Businesses

In this second of a two-session series, industry veterans and SBIR awardees will share their experience turning innovative products into successful operational companies. How do you build on the SBIR pilot and advance to the next stage of growing your company? How do you position your products and sales strategy for accelerated growth? How can you minimize the notoriously long sales cycle in healthcare? What are some tried-and-true strategies for leveraging the SBIR program for continued expansion? How does one go about fundraising for a growth-stage digital

health company? Small businesses developing solutions in healthcare experience the same commercialization challenges confronting innovators in a highly fragmented market. This panel will explore these challenges through the experiences of two successful company leaders. A moderator will introduce the issues, followed by comments and "tales from the trenches" from the two leaders. The panel will also include an opportunity for interactive discussion between panelists and the audience.

Washington State Peer to Peer Panel

Description TBD

Women-Owned and Socially, Economically Disadvantaged Business Applicant Workshop

As changes take place in the economy, going from idea to commercial product has become increasingly difficult. While this applicant workshop is open to all attendees, women owned businesses and socially, economically disadvantaged businesses are particularly encouraged to attend. Applicants will receive guidance from program staff, applicants, and potential partners through highly interactive sessions designed to provide additional assistance to companies.

Lessons Learned from Successful Applicants: Navigating the Application Process

During this session you will hear from a panel of NIH investigators, including those from women owned and socially, economically disadvantaged businesses, who have received NIH SBIR and/or STTR awards. Take advantage of the tips shared by these panelists about their up-and-down experiences, including how to recover from rejection and successfully resubmit.

Advice from Potential Funding Partners

This session will feature speakers with experience in angel investment, venture capital and large pharmaceutical partnering. Learn how best to partner with different groups to get your product to market with this open and honest discussion

Lessons Learned from Successful Companies: Navigating Commercialization

This is a unique opportunity to hear from a panel of NIH funded investigators, including those from women owned and socially, economically disadvantaged businesses, who have successful navigated the commercialization process. Panelists will share their experiences and the lessons learned from getting their technology to market.