

Narrative Descriptions of Sessions

Day One

Submission, Policy, Procedures

Overview and Update of the NIH SBIR and STTR Programs

The NIH SBIR and STTR programs offer many opportunities for small companies to do innovative research in the life and health sciences. In this session, Ms. Jo Anne Goodnight, NIH SBIR/STTR Program Coordinator, will provide a general overview of the programs touching on topics such as eligibility requirements, the NIH SBIR/STTR budget, submission, review, when and how to communicate with the NIH staff, Phase III assistance programs, etc. Flexibility is key to the success of NIH's programs and along with that comes many nuances (both programmatically and procedurally) for which applicants must be aware. The times are ever changing and NIH is no exception as it implements new policies and procedures as a result of its

NIH SBIR/STTR Receipt, Referral, and Review Processes

Are you asking yourself questions like: What are critical policies and requirements for submission? How, when, and by whom will my application be reviewed? What criteria will be used when determining the scientific and technical merit of my application? What Institutes/Centers will consider it for funding? Who may I contact for assistance during the review period?" Dr. Suzanne Fisher, Director of the Division of Receipt and Referral of the Center for Scientific Review (CSR) and Dr. Joseph Rudolph, Chief of the Chief, New Emerging Technologies and Training in Neurosciences review group will answer these questions and many more as they methodically step you through the receipt and referral process and the NIH two level peer review process. Insight about what reviewers expect to see for each of the review criteria, samples of reviewers' comments, and some grantsmanship tips from the reviewer's perspective will also be presented.

Preparing a Successful Application in a Competitive Environment

Although this panel includes small companies who have received NIH SBIR and/or STTR awards, not all of their applications have been successful. Some were funded based on their initial submission, others after revising and resubmitting, and others just didn't make it all. Fueled by the economy, competition has become tougher. Take advantage of the tips shared by these panelists about their up-and-down experiences and learn how best to approach the writing of SBIR and STTR grants for NIH evaluation.

Indirect Cost Rates and Accounting Systems Workshop

Don't leave money on the table! A workshop designed to teach participants how to develop basic indirect cost rates; why indirect cost rates are vital to a company's fiscal success; and fundamental accounting system issues that you need to be aware of prior to award.

All You Ever Wanted to Know About the Electronic Submission Process

Every awarded grant starts with a successfully submitted application. NIH requires all applications for the SBIR and STTR grant programs to be submitted through the Federal-wide grants portal known as Grants.gov to the NIH eRA Commons system. Explore the process applicants must follow to prepare, submit, track and verify application submissions. Learn about available support resources and gain valuable tips for success.

Compliance & Stewardship of Federal Funds

NIH is committed to providing its customers (contractors, grantees, and the public) with clear and easy-to-access information on how to comply with federal grants financial and management laws. This information is often referred

to as "compliance assistance," which is a cornerstone of NIH's efforts to strengthen the bond of trust between sponsor (NIH) and recipient (Small Business) and provide stewardship necessary to properly safeguard the Federal investment in America's research enterprise. This session addresses the proper management of Federal funds and the grantee reporting responsibilities inherent when accepting Federal R&D funding.

Identifying NIH SBIR/STTR Funding Opportunities

NIH is a large, complex, yet flexible organization which offers many opportunities for research funding, but how can you identify those of interest to you? This session will address SBIR & STTR grant and contract opportunities, how to find the opportunities, how to determine which opportunities are best for you, and how to stay informed of all research funding opportunities available to small companies.

Using SBIR/STTR for University Technology Spin-out

University technologies can hold great promise but also tend to be very nascent from a commercialization perspective. Therefore the technologies are too early to attract the angel and/or venture capital financing required to take a product to market. SBIR/STTR is an excellent source of financing that can be leveraged to move an idea to a prototype to mitigate some of the early stage risk. This session will demonstrate how one North Carolina business model partners with university inventors to migrate the most promising technologies from university labs to the commercial marketplace. This session will include examples of university technologies that have been commercialized along with input from North Carolina State's Technology Transfer Office on their experiences in working with SBIR/STTR grants.

Tools for Identifying Research Funding Beyond SBIR

Elizabeth Allen, GrantSource Librarian at UNC-Chapel Hill, will provide tips for conducting a funding search outside of NIH SBIR/STTR for your research and technology development. You will learn how to make the most effective use of federal, agency and commercial databases; set up funding alerts; and research awards made by funding agencies.

Leveraging State Resources

Unbeknown to many, a wealth of SBIR/STTR information and support is often available right in your own backyard. Many state organizations are available and interested in assisting you with applying for an SBIR or STTR grants/contract, and some actually have funding available to help defer the costs of preparing an application. Join this group to learn specifically about the various resources available in North Carolina and other states, and where to look for opportunities in your state.

A Peek Into the NIH, CDC: Special Programs and Resources

The "Peek Into the NIH and CDC" sessions will highlight the scientific priority areas for SBIR/STTR for fifteen NIH institutes and centers (ICs), as well as the CDC and then expand upon opportunities and research resources available to small businesses beyond the SBIR/STTR program. Topics of discussion will include programs that encourage collaborating with SBIR/STTR communities, non-SBIR/STTR funding opportunities/mechanisms, NIH and CDC resources available to the extramural research community, and NIH collaboration mechanisms.

Protecting Your SBIR/STTR Intellectual Property Rights Through iEdison Invention Reporting

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.

NIH SBIR Contracting Opportunities

As federal agencies that provide funding to assist innovative researchers with the development of their research ideas (a.k.a. investigator-initiated research), the majority of the NIH and CDC SBIR awards are made as grants. But did you know that both of these agencies also offer contract opportunities? The NIH/CDC SBIR contract solicitation is issued annually in the summer with proposals due in early November and includes narrowly-focused scientific/technical topics to which small companies may propose. Join this session to learn about the differences between grants and contracts, which might be best for you, and how to proceed with submitting a proposal.

Day 2

Transitioning to the Market

Strategies for Commercialization: Building a Business Roadmap to Success

Are you a researcher who is having difficulty with entrepreneurial thinking? Are you struggling with how to start, finance, and build your business? Should you be pouring in more “sweat equity” into your company or should you perhaps consider obtaining venture capital, angel, or corporate investors? Is licensing a viable option? Understanding the current commercialization environment of your specific industry sector and your personal vision for the technology and your company’s growth affects the decisions you’ll make with bringing your SBIR/STTR-developed innovation to the marketplace. Attend this session to begin to design your “business roadmap to success.”

Raising Follow-on Capital: Beyond SBIR

In today’s life sciences environment, as small businesses look for much needed capital financing for their sometimes risky ventures, venture capital presents an opportunity for small businesses to access early and late stage investment from venture funds that focus on life science and biomedical innovations. Panelists will discuss venture capital and angel investor criteria and hurdles required for investment in early stage biotech opportunities. They will also discuss how to prepare for valuation, raising risk capital, differences in stages of investment and the due diligence process.

Online Market Research Tools at Low to No Cost

This session will provide information about resources which can be searched to provide data for market research. Tools discussed will include government databases, library resources, and other data resources hidden in the Deep Web.

Building Corporate Alliances & Partnerships

Building alliances to help commercialize biotechnology and health-related products can be more difficult than obtaining the funding to do the research, especially in these economic hard times. It's almost impossible to go it alone. This session will equip small businesses with the knowledge on building their phase III strategies for bringing their technologies to the marketplace through building alliances and partnerships with corporate partners. Topics will include how to start the relationship-building process and when, advantages and challenges of partnerships including issues that need to be considered when transferring technologies through testing, licensing, partnering, consulting, and overall business development strategies for effective partnering.

Incubator Programs in North Carolina

Business incubation is a business support process that accelerates the successful development of start-up and fledgling companies by providing entrepreneurs with an array of targeted resources and services. Business incubators nurture the development of entrepreneurial companies, helping them survive and grow during the start-up period, when they are most vulnerable. The most common goals of incubation programs are creating jobs in a community, enhancing a community's entrepreneurial climate, retaining businesses in a community, building or accelerating growth in a local industry, and diversifying local economies while producing successful firms that will leave the program financially viable and freestanding. This session will discuss best practices in business incubation and the critical factors for success for biotech based companies.

Biomanufacturing: Navigating the Road from Discovery to Market

This session will present the activities required to move a new biomolecule or biomaterial intended for use in humans from the laboratory to the global marketplace. It will highlight the milestones and procedures required to meet the regulatory expectations of the United States Food & Drug Administration (FDA) and other boards of health. These regulatory bodies have strict guidelines for the data required to initiate the use of the biomolecule or biomaterial in humans. They also have established the current Good Manufacturing Practice (cGMP) regulations that dictate the biomanufacturing methods required to manufacture and distribute the final product. Fortunately, there are several options available to companies looking to introduce new products to the market. It is important to evaluate these options and develop a strategy for an accelerated transfer early in the transfer cycle, perhaps even before discovery. These options, as well as advantages and disadvantages of each, will be reviewed. After attending this presentation, attendees should be able to conduct their own evaluation and develop a strategy that meets their objectives.

Selling Your SBIR/STTR-developed Technology to Federal Agencies

Did you know that by having been selected as an SBIR or STTR awardee you may sell your SBIR/STTR-developed product/service back to any agency of the Federal government without having to compete (again) for the sale? Well you can. The competition for SBIR Phase I and Phase II awards satisfies the competition requirements of the Armed Services Procurement Act resulting in a Federal agency having the ability to procure your SBIR-STTR developed products as sole-source procurements. The Department of Defense procures more products and services than any other federal agency so attend this session to learn how you too might penetrate this large complex agency and interest them in your SBIR-STTR technology.

Overview of Regulatory Requirements: Medical Devices

FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH

regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions. This presentation will primarily address FDA's medical device rules and regulations. Mr. William M. Sutton, Deputy Director, Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at CDRH will present the basic regulatory requirements that manufacturers of medical devices must comply with in order to legally market a medical device in the United State. This includes a discussion on the definition of a medical device; medical device classification, establishment registration and listing; premarket applications [510(k) and PMA]; as well as postmarketing activities. Mr. Sutton will also provide valuable resources that will assist small manufacturers on how to comply with FDA's medical device regulations.

Commercializing Your Healthcare/IT/Media Product

Each year thousands of healthcare-related products are created but only some of them become commercial successes; almost all of the ones that make it to the market, get sold, and are ultimately deployed have some common characteristics. Shahid will describe some of those characteristics and help you find ways of getting the attention of your customers, explaining your product to them in a concise and meaningful way, devising pricing and partnering strategies, and finally figuring out how to get paid for what you've created. It's difficult to have your product's messaging make it through the noise in an ordinary market – but, of course we're not living in ordinary times so things are even harder. Shahid will help you devise the right strategies so that you can rise above the herd and get noticed in the marketplace.

Overview of 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. This work covers more than just medicines. For example, fluoride toothpaste, antiperspirants, dandruff shampoos and sunscreens are all considered "drugs." The presentation by the Division of Drug Information, CDER, will address the regulatory requirements for the approval of new drugs; generic drug approval process; overview of over-the-the counter drugs; listing and registration of product and companies with the agency; and small business assistance programs and resources for information.

NIH Technical Assistance Programs

You thought being selected for an award was difficult, well getting to the marketplace is 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 awardees strategize how to commercialize their SBIR-developed products. Join this session to find out what opportunities might be available for you and how to become involved.

Interactive Multi-Media Panel: Commercialization of Behavioral Services, Interventions and Products

During this panel session, successful SBIR social-behavioral grantees will explain how they 1) found and engaged potential backers BEFORE submitting a Phase II application, 2) collaborated with potential end-users about production, distribution, and marketing during their research, 3) sold products to specific markets when users felt they should be free, 4) addressed barriers to marketing and sealed a deal, and 5) tracked the success of their product in the marketplace.