New I-Corps™ Initiative for Small Businesses

July 2, 2014 12:30 – 2:00 pm EST

For audio, dial in: 855-244-8681
Meeting ID: 739 878 799
For Technical Support, call 866-229-3239 and choose option 1

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Submit Your Questions

- Submit your questions any time via the Q&A box on the right-hand side of your screen.

- If you do not see the Q&A box, you can expand it by hovering over the green bar at the top of your screen and clicking the Q&A button.

No audio? Dial 855-244-8681 Meeting ID: 736 514 190
Please submit questions of a general nature via the Q&A Box with no proprietary information.

Please be advised we will not answer questions specific to your project in this webinar.

The webinar slides, audio recording, and Q&A will be published to the website, http://sbir.cancer.gov/icorps

All webinar registrants will be emailed links to access webinar slides, audio recording, and Q&A.
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I-Corps @ NIH Webinar

• Background and overview of I-Corps @ NIH
  • Michael Weingarten, Director of NCI SBIR Program

• The I-Corps Model: How to Make Startups More Successful
  • Steve Blank, Serial Entrepreneur and Developer of the I-Corps/Lean Launchpad methodology

• I-Corps @ NIH Funding Opportunity Announcement and application process
  • Andrew Kurtz, Team Leader and Program Director NCI SBIR Program

• Questions and Answers

Submit your questions through the Q&A chat box
A pilot program that’s a partnership between NSF and NIH.

- 4 participating NIH Institutes
- NCI, NHLBI, NINDS, NCATS

Goal – to accelerate development of biomedical technologies into viable products & services.
I-Corps @ NIH: Format

• A nine-week business strategy boot camp

• Teams are “taught” and guided by a group of experienced faculty (e.g., serial entrepreneurs, venture capitalists, etc.)

• Develop a viable business model around their technology focusing on key questions like their value proposition and revenue model.
I-Corps @ NIH: Format

• Process: gather as much information and insight as possible by conducting 100 interviews with potential customers and partners.

• Adjust business strategy based on direct customer feedback.

• Use of “Business Model Canvas” provides a framework for analyzing information to determine if there is a product/market fit.

Submit your questions through the Q&A chat box

@NCIsbir sbir.cancer.gov/icorps
I-Corps will also help SBIR companies:

- Assess their intellectual property, reimbursement, and regulatory risks before they design and build prototypes
- Evaluate the potential of their product for clinical utility at an early stage
- Identify financing vehicles before they are needed
Since July 2011, NSF has been offering I-Corps to over 300 teams from 100 universities.

NSF’s program has been focused on academic teams at the pre-company phase:
- More than 40% have gone on to start companies.
- Teams have achieved a high success rate when competing for SBIR awards.
Steve Blank

- 21 years / 8 startups
- 13 years @ Berkeley, Columbia, Stanford, & UCSF
- Developed the Lean LaunchPad/NSF I-Corps methodology
I-Corps @ NIH

Keep Calm and Test the Hypothesis

Michael Weingarten – NIH
Steve Blank, Todd Morrill, Karl Handelsman, Allan May
“...accelerate the translation of biomedical research to the marketplace by providing training to NIH-funded SBIR and STTR grantees...”
What It Means

We Know How to Make Startups More Successful
How?

10-week *Entrepreneurial Immersion* course to reduce commercialization risk for Therapeutics, Diagnostics and Devices
Commercialization
Commercialization Insights

• Commercialization efforts have two components
  1. The science/technology
  2. The business model
• Current Commercialization efforts focus on #1
• Successful efforts require the team to do both
Current Thinking about Translational Medicine

Use Outside Consultants

Technology Development Process

- Regulatory
- Intellectual Property
- Product Development
- Project Management
- Mentors
- Business Development

financing

License
Startup
Insight
Add a Formal Path for Commercialization Evidence

Submit your questions through the Q&A chat box
Accelerating Commercialization:
– Requires Parallel Paths

- Technology Progress
- Clinical Trials, etc.

- Mentorship
- Workshops/Webinars
- seed $’s
- physical space & equipment

Commercialization Progress
Answers to Hypotheses are **Outside Your Lab**

- You may be the smartest person in your lab
- But you are not smarter than the collective intelligence of your potential customers, partners, payers and regulators
- You can’t learn this by reading papers or listening to lectures

Need a process for hypotheses testing
• Prevent incisional hernias via wound healing
  – Biocompatible microparticles + fibrin sealant
• Team:
  – Dr. Hobart Harris, UCSF Chief of General Surgery
  – Dr. David Young, UCSF Prof Surgery
  – Cindy Chang, Enzymologist
Video:
“It Saved Us Several Years”
Week 2 – Vitruvian Therapeutics
Student Learning

http://vimeo.com/76660776
Insight
Commercialization Evidence Require Outward Focus
Add Evidence-based Commercialization

Inward-facing
Add Evidence-based Commercialization

Outward-Facing Commercialization Process

Add a parallel

Inward-facing
Add Evidence-based Commercialization

Outward-facing
By the Founding Team

Inward-facing
Commercialization affects your biological and clinical hypotheses

- As you validate the commercial hypotheses you make substantive changes to one or more parts of your initial business model
  - clinical utility, who the customer is, data and quality of data, how reimbursement works, what parts of the product is valuable, roles of partners, etc.
- And this new data on commercialization affects your biological and clinical hypotheses
• Create a magnetic compression anastomosis with improved outcomes

• Team:
  – Michael Harrison, MD, Inventor of Fetal Surgery
  – Elisabeth Leeflang, MD, General Surgery Resident
  – Michael Danty, MS, Business Development
  – Dillon Kwiat, BS, Medical Device Engineer
Video:
“Why PI’s and Founders Need to Get Out of the Building”
Week 6 – Magnamosis, Inc.
Student Learning
http://vimeo.com/79755368
I-Corps Commercialization

• Define clinical utility now, before spending millions
• Understand core customers and the sales and marketing process required for initial clinical sales and downstream commercialization
• Assess IP and regulatory risk before design & build
• Gather data essential to customer partnerships/collaboration/purchases before doing the science
• Identify financing vehicles before you need them
I-Corps @ NIH

class design components
I-Corps @ NIH Teams

• Active NIH SBIR and STTR Phase I grantees

• Teams of 3
  – C-Level (CEO, CTO, COO) Officer
  – Industry Expert
  – PD/PI

Submit your questions through the Q&A chat box
Class Details

• 3-day Course Oct 6-8\textsuperscript{th} in D.C.
• 6 follow-on weekly Webinars
  – team presentations/instructor interactions
• 2 days Lessons-Learned Dec 9-10\textsuperscript{th} in D.C.
• Requires getting out of the lab
  – AT LEAST 15 hours of prep per week
  – Teams contact at least 100 customers/partners/
Class - key design components

- Framework for results
- Experiential
- Evidence-based
- Mentor supported
- Team Teaching
Lean Framework

• Business Model Canvas
  – Articulate initial Hypotheses
  – Weekly Progress Scorecard

• Customer Development
  – Test hypotheses in front of customers
  – Hypothesis > Experiment > Data > Insight

• Agile Development
  – Build Minimum Viable Product
<table>
<thead>
<tr>
<th>Partners</th>
<th>Activities</th>
<th>Product / Service</th>
<th>Get/Keep/Grow</th>
<th>Channel</th>
<th>Customers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Partners</td>
<td>Key Activities</td>
<td>Value Propositions</td>
<td>Customer Relationships</td>
<td>Customer Segments</td>
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<tr>
<td>Key Resources</td>
<td>Channels</td>
<td>Revenue Streams</td>
<td>Cost Structure</td>
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<td>Resources</td>
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<tr>
<td>Revenue</td>
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Experiential

• Getting out of the building – 10-15 hours/weekly

• Formal methodology for customer interaction

• Focus on MVP and Pivots
  – Getting out of the building is a big idea
  – It accelerates speed of translation
Teams Present Results Weekly

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>Experiment</th>
<th>Results</th>
</tr>
</thead>
</table>
| Vitamin manufacturer (partner) | interviews | • They have no pain to drive sales already ("clinical studies" or celebrity promo)  
                              |            | → Go talk to nutritionists....                                            |
| Nutritionist (partner)      | interviews | • Pain: can’t order labs!                                                |
|                             |            | • One-on-one interaction / counseling                                    |
| Yogi (end user)             | interviews | • Very curious and responsive to their own body                           |
|                             |            | • Want multiple test to track over time                                  |
| CrossFit trainer (partner / end user) | interviews | • Like Weight Watchers: proud of their program, no real pain             |
|                             |            | • Looking for quick results, no time for one-on-one interaction          |

- X vitamin company
- X CrossFit
- Nutritionists as advocates
Update Business Model Canvas Weekly

**Activities**
- Sample collection
- 510K pre-market oval
- Complete gut flora profile for customer, linked to medical literature

**Value Propositions**
- Tool to perform discovery-based science
- Understand what your diet is really doing for your insides
- Get recommendations from your peers for other diets to try based on your profile
- Be at the cutting-edge of medical research

**Customer Relationships**
- Keep cust: Membership, subscription
- Grow cust. discount on subscription if friends or family member sign up
- Get cust: peer recommendation
- Nutritionist, health coach
- Pharma
- Probiotics manufacturers

**Customer Segments**
- Wealthier women, struggling with weight loss (DIY), 25+
- Food manufacturers purchasing ads
- The ‘feel better’s’: Other types of ‘extreme’ dieters who seek to be healthy and feel good

**Channels**
- Food supplier/health stores
- Consumer-facing ads
- Peer recommendation

**Revenue Streams**
Use Canvas As a Weekly Scorecard

Week 1

Week 2

Week 3
UCSF Class Summary

• 2,355 *in-person* customer interviews
• 952 hypotheses tested
• 423 Pivots
• 26 tremendous teams

Submit your questions through the Q&A chat box
Team Example
Bringing single-cell western blotting to stem cell and cancer research

Interviews: 102

Team: Kelly Gardner, Ph.D.,
Josh Molho, Ph.D.,
Amy E. Herr, Ph.D.

Mentor: Douglas Crawford, Ph.D. (QB3 and Mission Bay Capital)

Existing protein measurement tools are insufficient

1. “Western blotting”
   Average/bulk measurements only

2. Flow Cytometry
   Cell surface proteins only
Zephyrus single cell western blot

1. Cells in suspension
2. Proprietary high margin disposable
3. Instrument (separation & capture)
4. Probe with standard antibodies
5. Fluorescence read-out with existing microarray scanner

Hughes, Spelke, Xu, Kang, Schaffer & Herr (2014), Single Cell Western Blotting. Nature Methods
Testing our hypothesis | Value prop & target customer segment

I wish you could...
speed up creation of transgenic cell lines

Start

PIVOT

1

Zephyrus Biosciences
The Zephyrus Journey…

Not interested!
We can do it with grad students or automation!

PIVOT

Start

1

Scalable Business

www.zephyrusbio.com
The Zephyrus Journey…

We want to be able to measure single-cell protein information in gene expression studies!
The Zephyrus Journey...

Still need to focus!
Pick a target application to start with

Single cell gene expression market exists
**First target market:** stem cell & cancer researchers

**Our Target Market:**
13,000 funded stem cell and cancer laboratories who...
- Have access to a microarray scanner
- Have recent publications highlighting single-cell measurements

**Total Addressable Market:**
52,000 funded stem cell and cancer laboratories globally

**Global stem cell research market:**
>$4B (12% CAGR)

**Global cancer proteomic profiling:**
>$9B (16% CAGR)
The Zephyrus Journey…

Single cell gene expression market exists
The Zephyrus Journey...

Why a BIG tool?
Products with a few $MM in revenue are interesting

Co-marketing?
We would be interested in partnering if you could help us sell microarray scanners
The Zephyrus Journey…

Single cell gene expression market exists
Route to Commercialization

Progress-to-date:
✓ Lab-based prototype established (Nature Methods 2014)
✓ Exclusive option on key UC-owned IP
✓ Customer & business model validation (UCSF Lean Launchpad)
✓ Built out scientific & management team

EARLY ACCESS PROGRAM
Launch: July 2014

6 months

Beta-prototype placement in key labs
Launch: December 2014

Instrument & disposable development

Seed funding

www.zephyrusbio.com
Route to Commercialization

Progress-to-date:
✓ Lab-based prototype established (Nature Methods 2014)
✓ Exclusive option on key UC-owned IP
✓ Customer & business model validation (UCSF Lean Launchpad)
✓ Built out scientific & management team

Instrument & disposable development

Beta-prototype placement in key labs
Launch: December 2014

EARLY ACCESS PROGRAM
Launch: July 2014

Impact of Lean Launchpad:
LLP interviews helped us identify customers for our EARLY ACCESS program where customers can send samples to be analyzed in our company lab.

We are currently accepting customers!
If interested, please contact info@zephyrusbio.com
**Route to Commercialization**

**Progress-to-date:**
- Lab-based prototype established (Nature Methods 2014)
- Exclusive option on key UC-owned IP
- Customer & business model validation (UCSF Lean Launchpad)
- Built out scientific & management team

**EARLY ACCESS PROGRAM**
Launch: July 2014

- **Beta-prototype placement in key labs**
  Launch: December 2014

**Software plug-ins for data analysis**

**Instrument & disposable development**

- Support prototypes
- Expand product capabilities to integrate with FACS

**Seed funding**

**Series A**

**Transfer to manufacturing**

**Full product launch (Q1 2016)**

**Today**

- 6 months
- 6 months
- 9 months+

www.zephyrusbio.com
Progress Update – 6 months since Lean Launchpad

✓ Single-cell western blotting article published in Nature Methods (initially the #1 most emailed article, currently #3 most read article)
✓ Set up company lab at QB3 start-up incubator at UC Berkeley, accepted into prestigious Janssen Lab incubator @953 in San Francisco
✓ Hired R&D engineer
✓ Technology successfully translated into company labs (chip fabrication, assay operation, electrophoresis & blotting on single cells)
✓ On target to launch EARLY ACCESS program next month: first three customers in final negotiations + more in the pipeline
✓ Closing a $1.5M investment round from Angels and VCs (including mentors from the LLP program!)
Teaching Team
Steve Blank
Teaching Team

- 21 years / 8 startups
- 13 years @ Berkeley, Columbia, Stanford, & UCSF
- Developed the Lean LaunchPad/NSF I-Corps methodology
Karl Handelsman
Therapeutics Curriculum Director

- Founder, Cordon Capital
- Previous: General Partner, CMEA Capital
- Specialty: early stage company formation & biotech
Allan May
Devices Curriculum Director

• Founder & Chairman, Life Science Angels
• Managing Partner, Emergent Medical Partners
• Founder, CEO, Board of >30 companies
• >100 investments; 27 exits
Todd Morrill
Diagnostics Curriculum Director

• Managing Director, Venture Management Group
• Former Head, Corp. & Bus. Development, Bio-Rad Labs
• Founder of 3 life science companies
• Instructor, UC Berkeley/Haas, UCSF and NSF
How To Apply?

• Course Description

• Application Info

• Key Dates
  – Webinar: July 2, 2014 12:30 – 2:00pm ET
  – Application Due: Aug 7, 2014
  – Class start: Oct 6, 2014
  – Class end: Dec 10, 2014
I-Corps™ at NIH
Team Training Pilot Program

Application Process & Program Details

July 2, 2014
12:30 - 2:00 PM EDT

Andrew J. Kurtz, PhD
NCI Program Director & Team Leader

Submit your questions through the Q&A chat box
Administrative Supplement Awards (Pilot Cohort)

- NIH will provide administrative supplement awards (up to $25,000) to a pilot cohort of 24 currently-funded SBIR and STTR Phase I grantees to support entrepreneurial training under the I-Corps™ Team Training Pilot Program.

- The program is designed to provide three-member project teams with access to instruction and mentoring to accelerate the translation of technologies currently being developed with NIH SBIR and STTR funding.

- Applications are required and are due by **August 7, 2014**.

- Participants will be selected on a competitive basis and will be notified around mid September 2014.
Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)
National Institutes of Health (NIH)

Components of Participating Organizations
National Cancer Institute (NCI)
National Heart, Lung, and Blood Institute (NHLBI)
National Institute of Neurological Disorders and Stroke (NINDS)
National Center for Advancing Translational Sciences (NCATS)

Funding Opportunity Title
Innovation Corps (I-Corps™) Team Training Pilot Program for NIH Phase I Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grantees (Admin Supp)

Activity Code
Administrative Supplement

Additional funds may be awarded as supplements to parent awards using the following Activity Code(s):

Administrative supplement requests may be submitted electronically for the following activity codes:

- R41 Small Business Technology Transfer (STTR) Grant - Phase I only
- R42 Small Business Innovation Research (SBIR) Grant - Phase I only

Announcement Type
New

Related Notices
None

Funding Opportunity Announcement (FOA) Number
PAR-14-261
I-Corps™ at NIH

sbir.cancer.gov/icorps

Coming Soon: Course Syllabus
Eligibility (Pilot Cohort)

- Small businesses supported by currently funded NIH SBIR or STTR Phase I grant awards from one of the four participating Institutes and Centers (NCI, NHLBI, NINDS, NCATS)
- Predicate grant award must extend (at least) through December 31, 2014, and should have remaining budget and R&D activities that extend at least until that date
- SBIR contractors are not eligible to apply
- SBIR/STTR Fast-Track grantees are eligible to apply, provided that the grantee is currently completing the Phase I portion of the award
Frequently Asked Question (FAQ #1):
May I apply for a no-cost extension to meet the eligibility requirements?

**ANSWER**
Grantees should **not** request an extension solely for the purpose of participating in the I-Corps™ program. Grantees should only request a no-cost extension if additional time is needed to expend the grant budget and complete R&D activities.
Frequently Asked Question (FAQ #2):
Is the I-Corps™ training program only for new companies and/or inexperienced teams?

**ANSWER**

No, not necessarily. The pilot program is intended to instruct teams developing early stage (Phase I) projects to help inform next steps. Although teams with limited commercialization experience may benefit the most, **all teams will take away valuable general lessons, as well as specific insights around their particular technology and/or innovation.**
Three-Member Project Teams

- **C-Level Corporate Officer**
  - “Chief” Executive Officer (CEO), “Chief” Operating Officer (COO), etc.
  - Relevant knowledge of the technology
  - Deep commitment to investigate the commercial landscape
  - Substantial decision-making authority within the company

- **Industry Expert**
  - Experience in translating technologies to the marketplace
  - Can be someone that has an established relationship with the company OR someone selected as a third-party resource

- **PD/PI**
  - PD/PI on the SBIR/STTR Phase I award
Time Commitment

• Each team member should plan to spend at least **10-15 hours per week** on I-Corps™ activities and learning exercises for the full duration of the program.

• Participants are required to get “out of the lab” and gather information by conducting a large number of interviews (i.e., 100+ interviews), with potential customers, strategic partners, and other third-party stakeholders.

➤ This level of commitment is absolutely required to reap the benefits of the I-Corps™ training program!
Frequently Asked Question (FAQ #3):
Who makes a good Industry Expert?

**ANSWER**

- Someone with the right “rolodex” that has industry contacts in your area of commercialization
  - *Critical for getting out of the lab and setting up interviews!*
- Someone who has entrepreneurial experience
- Someone who has business expertise in your sector
Frequently Asked Question (FAQ #4):
Is there flexibility in how the three required roles are filled on the I-Corps™ Team?

**ANSWER**

Yes, for example, if the PD/PI is also the CEO, then you may designate an alternate C-Level Corporate Officer to lead the team. In other cases, it might be more appropriate to select a different senior level scientist to serve in the PD/PI role. All teams should include three members and should be led by someone with decision-making authority within the company. NIH program staff can help advise.
I-Corps™ at NIH

NIH Program Contacts

Christie Canaria, PhD
National Cancer Institute (NCI)
Telephone: 240-276-5720
Email: canariaca@mail.nih.gov

Jenifer Shieh, PhD
National Heart, Lung, and Blood Institute (NHLBI)
Telephone: 301-443-8785
Email: jennifer.shieh@nih.gov

Stephanie Fertig, MBA
National Institute of Neurological Disorders and Stroke (NINDS)
Telephone: 301-496-1779
Email: fertigs@ninds.nih.gov

Lili Portilla, MPA
National Center for Advancing Translational Sciences (NCATS)
Telephone: 301-217-2589
Email: portilll@mail.nih.gov

Submit your questions through the Q&A chat box
Research Strategy Section (6 pages)

- **Summary of the Predicate SBIR/STTR Phase I Grant**
  - Description of project aims and a summary of progress achieved (to date)

- **I-Corps™ Team**
  - Rationale for the selected team members (e.g., expertise, experience)
  - Statements to indicate a strong commitment to the time-intensive program
  - Discuss willingness to “pivot” based on knowledge gained during the program

- **Potential Commercial Impact**
  - Provide a brief profile of a typical customer
  - Describe the customer need(s) that will be met by the proposed innovation
  - Discuss how the customer currently meets those needs, and describe the value proposition that is offered by the product/innovation

- **Project Plan**
  - Describe the stage of development for the SBIR/STTR Phase I project
  - Explain the proof-of-concept that will be demonstrated by the end of Phase I
  - Discuss next steps to advance the project closer to commercialization
Frequently Asked Question (FAQ #5):
What should be included in the budget?

**ANSWER**

- **Direct costs** associated with completing the I-Corps™ program
  - $1,500 per team member to cover registration ($4,500)
  - Travel costs for two trips to the course site for the entire team
  - Travel costs to conduct interviews with customers, partners, etc.
  - Personnel time

**NOT ALLOWED**

- Indirect costs
- R&D costs
Applications Reviewed in Two Stages

1. NIH staff will evaluate the *written application* to consider whether the team's participation in the I-Corps™ program will increase the parent award’s overall impact

   ➢ See the review criteria under Section V.1 in PAR-14-261, and be sure to address the key points in the written application

2. The most responsive and best qualified candidates will be contacted to provide NIH staff with clarification on the written application **AND** to provide responses to additional questions

   ➢ See a list of typical questions under Section V.1 in PAR-14-261, and consider your responses as you are drafting your application
## Class Schedule (Pilot Cohort)

- **Class Length:** Oct 6 – Dec 10 (11 class sessions)
- **Opening Class:** Oct 6 – 8
- **On-line Class:** Tuesdays (Oct 14, 21, 28 & Nov 4, 11, 18)
- **Final Presentations:** Dec 9 – 10
- **Location:** Microsoft Corporation  
  5404 Wisconsin Ave  
  Chevy Chase, MD 20815

Submit your questions through the Q&A chat box.
Online Curriculum

- During the program, online content will be hosted by the NIH (or designee) to track the progress of the teams
- The team’s progress will be shared with the entire cohort of I-Corps™ teams to facilitate group learning

Teaching Philosophy

- A key part of this class is seeing how various teams solve similar problems through listening to the instructors coach and critique
- The success of the team is less about the original idea and more about the learning, discovery, and execution
- The I-Corps™ training program is intended to provide a forum for participants to “bounce” ideas off their peers
Frequently Asked Question (FAQ #6):
Will my Intellectual Property (IP) rights be protected when I discuss my ideas with the class?

**ANSWER**

Customer discovery does not require that you share the **specifics** of your IP. However, you will be sharing with the class what you learned on a weekly basis about reimbursement, regulation, customers, partners, etc. All of your presentations, customer discovery and validation notes, and your business model canvas, will be shared with the teaching team. **If you have specific legal questions, you should consult an IP attorney.**
Expected Outcomes

- Enhanced understanding of the Business Model Canvas
- Significantly refined commercialization plans, and well-informed “pivots” in the overall commercialization strategy
- Stronger Phase II SBIR & STTR applications

Outcomes Evaluation

- Outcomes from the pilot program will be carefully evaluated before the NIH considers possible continuation of this program
- The NIH will seek to collect outcomes data from participating teams immediately following the course, which may include customer evaluation surveys, interviews, and/or other data

➢ Feedback from the pilot cohort will be critical
I-Corps™ at NIH

sbir.cancer.gov/icorps

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National Cancer Institute (NCI)
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Email: canariaca@mail.nih.gov

Jenifer Shieh, PhD
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Email: jennifer.shieh@nih.gov

Stephanie Fertig, MBA
National Institute of Neurological Disorders and Stroke (NINDS)
Telephone: 301-496-1779
Email: fertigs@ninds.nih.gov

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The NCI SBIR Development Center

http://sbir.cancer.gov
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PLEASE PARTICIPATE IN OUR POLL
NCI SBIR Development Center
NCIsbir@mail.nih.gov
Phone: 240.276.5300

http://sbir.cancer.gov
Sign up for updates!

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LinkedIn
http://www.linkedin.com/company/nci-sbir-development-center

Thank You!