

National Cancer Institute SBIR-Technology Transfer (SBIR-TT) Contract Topics 317 and 318 Public Briefing/Webinar

Tuesday September 25, 2010, 1:30PM - 3:00PM

For audio, dial in: 800.369.1726

Passcode: SBIR

For Technical Support, call **800-857-8777** and choose **option 3**

Welcome and Introduction

Jennifer Shieh, Ph.D.

AAAS Science & Technology Policy Fellow

SBIR Development Center
National Cancer institute

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NIH . . . *Turning Discovery Into Health*
U.S. Department of Health and Human Services
National Institutes of Health



Purpose

This is a pre-proposal webinar on funding and licensing opportunities hosted by the NCI SBIR Development Center.

Two Technology Transfer (SBIR-TT) contract topics based on inventions from NCI intramural researchers will be discussed:

Contract Topic 317 - [Wound Healing Preparations Incorporating Nitric Oxide-Releasing Materials](#)

Contract Topic 318 - [Test to Predict Effectiveness of Docetaxel Treatment for Prostate Cancer](#)

Presenters will describe the technical background for these topics and the processes for licensing and/or co-developing these technologies.

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Agenda

Jennifer Shieh, Ph.D. (NCI SBIR) <i>Welcome & Introduction</i>	1:30 pm
Larry Keefer, Ph.D. (NCI CCR Chemical Biology Laboratory) <i>Technical Background, Topic 317: Wound Healing Preparations Incorporating Nitric Oxide-Releasing Materials</i>	1:40 pm
Patricia Weber, Dr.P.H. (NCI SBIR) <i>Topic 317 Contract Deliverables, Q&A</i>	1:50 pm
Tristan Sissung, Ph.D., M.S. (NCI CCR Medical Oncology Branch) <i>Technical Background, Topic 318: Test to Predict Effectiveness of Docetaxel Treatment for Prostate Cancer</i>	2:00 pm
Todd Haim, Ph.D. (NCI SBIR) <i>Topic 318 Contract Deliverables, Q&A</i>	2:10 pm
Sabarni Chatterjee, Ph.D. (NIH Office of Technology Transfer) <i>Overview of License Application Process</i>	2:20 pm
John Hewes, Ph.D. (NCI Technology Transfer Center) <i>Co-Development Research: Collaboration Agreements & CRADAs</i>	2:30 pm
Q&A	2:40 pm
Closing Remarks	2:55 pm

Topic Details:

<http://sbir.cancer.gov/funding/contracts>

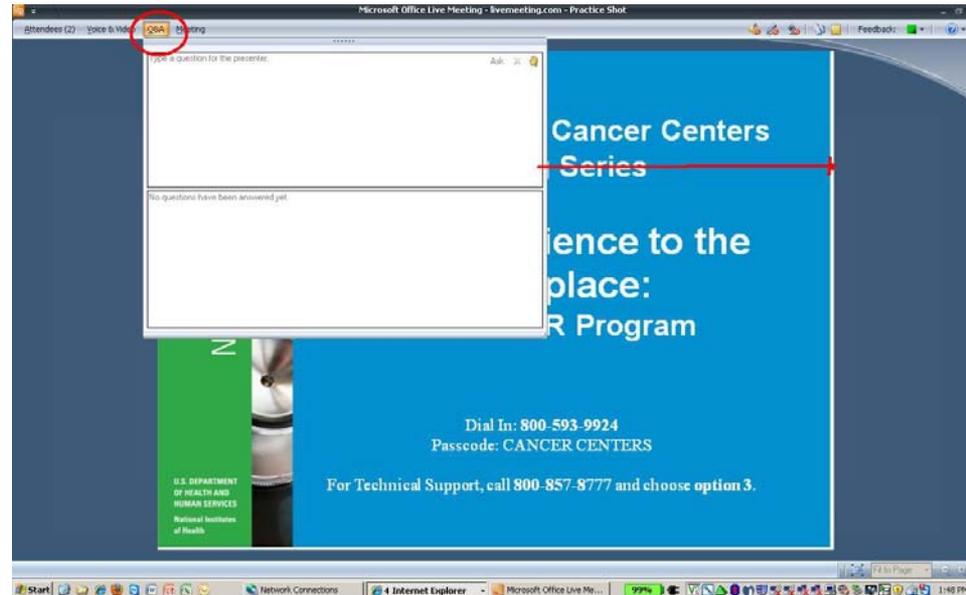
Proposal Deadline:

November 13, 2012 at 5:00PM Eastern Time

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A Quick Guide to Your Screen

- Please submit your question 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 clicking the Q&A on the top navigation panel and dragging it to the right side of your screen.



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Congressionally Mandated Programs

Set-Aside
(FY12)

➤ **Small Business Innovation Research (SBIR)**

Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization

Federal agencies with an extramural R&D budget > \$100M

2.6%

➤ **Small Business Technology Transfer (STTR)**

Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization

Federal agencies with an extramural R&D budget > \$1B

0.35%

~\$115M at the **NCI**

~\$717M at the **NIH**

Multiple Funding Solicitations

- **SBIR & STTR Omnibus Solicitations for Grant Applications**
Release: January
Receipt Dates: April 5, August 5, and December 5
- **Solicitation of the NIH & CDC for SBIR Contract Proposals**
Release: August
Receipt Date: **FY13** – November 13, 2012
- **See the NIH Guide for other Program Announcements (PA's) and Requests for Application (RFA's), i.e. grants**
Release: Weekly
Receipt Dates: Various

<http://grants.nih.gov/grants/guide>

SBIR Contracts vs. Grants

	Funding Solicitations for SBIR Grants	Funding Solicitation for SBIR Contracts
<i>Scope of the proposal</i>	Investigator-defined within the mission of NIH	Defined by the NIH (focused)
<i>Questions during solicitation period?</i>	May speak with any Program Officer	<u>MUST</u> contact the contracting officer
<i>Receipt Dates</i>	3 times/year for Omnibus	Only ONCE per year
<i>Basis for Award</i>	Based on score during peer review	If proposal scores well during peer review, must then negotiate to finalize deliverables with NIH
<i>Reporting</i>	One final report (Phase I); Annual reports (Phase II)	Monthly or quarterly progress reports
<i>Funds set-aside particular areas?</i>	NO	YES

Questions About Contracts?

Ms. Bette Shanahan

eshanahan@mail.nih.gov

301.435.3782

<http://sbir.cancer.gov/funding/contracts/>

Contract Opportunities

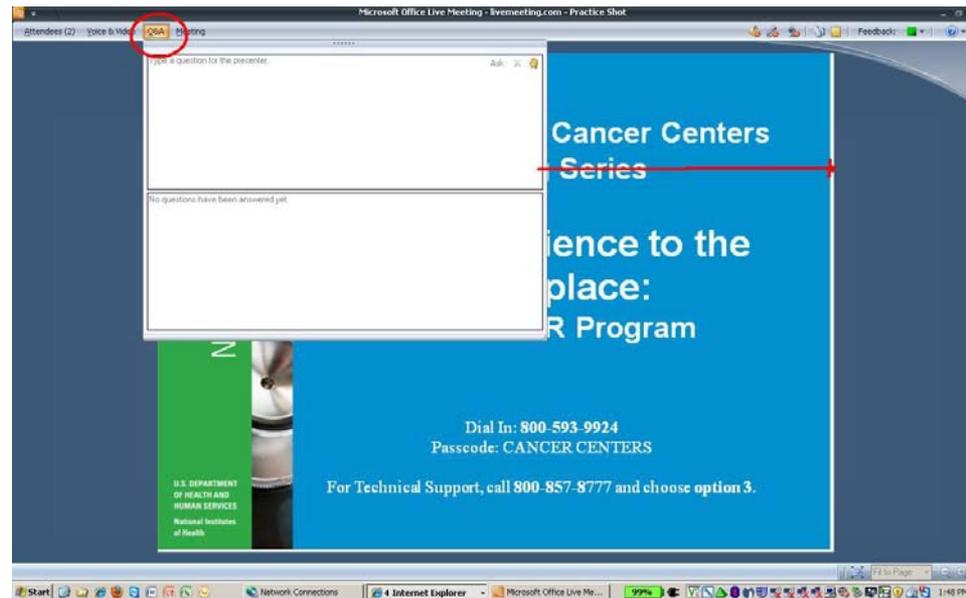
- PHS-2013-1 “Solicitation of NIH and CDC for SBIR Contract Proposals”
- Published August 15, 2012:

Proposals Due: November 13, 2012

- RFP can be found at:
 - <http://grants.nih.gov/grants/funding/SBIRContract/PHS2013-1.pdf>
- More info about NCI’s topic areas:
 - <http://sbir.cancer.gov/funding/contracts/>

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Frequently Asked Questions

Frequently Asked Questions

http://sbir.cancer.gov/funding/contracts/fy2013_faq.asp

After this webinar

Slides and Q&A from this event will be transcribed and added to the website

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Technical Discussion

Topic 317: Wound Healing Preparations Incorporating Nitric Oxide-Releasing Materials

Larry K. Keefer, Ph.D.

Senior Investigator

Chemical Biology Laboratory

Center for Cancer Research

National Cancer Institute

Goal

To develop commercially viable wound-healing preparations exploiting NCI's nitric oxide (NO)-releasing polyacrylonitrile (PAN/NO).

Unmet Need

- 6,500,000 people are affected by chronic wounds.
- 25% of all diabetics will develop a diabetic foot ulcer or wound.
- Wound infections are the principal complications following surgery and are a major source of bacteria that drive infection rates in hospitals.
- Wound infections will become more common with an aging population and increasing prevalence of chronic disease.
- Potential target customers would be the U.S. military, diabetics, wound care centers, and all those with chronic, recurring wounds.
- Competing technologies limited to topical antimicrobials, systemic antibiotics, bandages

Source: (WSJ 4/16/12), JHU School of Medicine)

Wound healing preparations: Global market

- The 2011 global wound-care market was \$16.8 billion and is expected to increase at a compound annual growth rate of 6%.
- The market can be broadly divided into:
 - wound-closure products
 - anti-infectives
 - basic and advanced wound care
 - active wound care therapies.

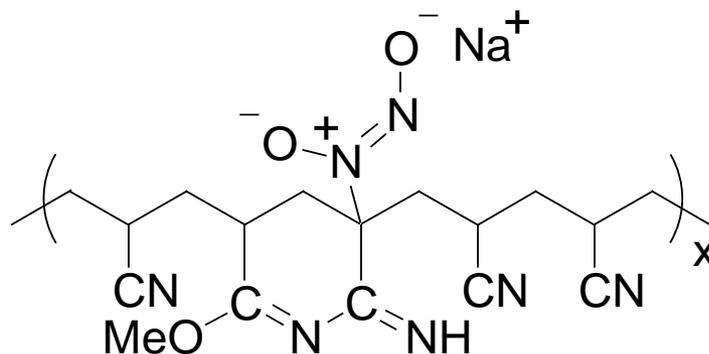
Source: (WSJ 4/16/12), JHU School of Medicine)

Wound healing preparations: Global market

- In addition to providing a barrier to infection and promoting a moist environment, active wound-care products also promote healing.
- This market is, by far, the fastest growing, though it is still in its infancy. Included within the \$1.7 billion active wound-care market are negative pressure wound-therapy (NPWT) devices, artificial skin substitutes, and biological growth factors.
- The active wound-care market is expected to grow at a CAGR of over 11% through 2011.

Invention details

- Synthesized by reacting polyacrylonitrile with NO in presence of base (see structure below).
- Releases NO at pH 7.4 for up to 80 days.
- Promotes wound healing in a vascular surgery model.



DeRosa, et al., *J. Am. Chem. Soc.*, **129**, 3786-3787 (2007)

Invention details (continued)

- Partially soluble in organic solvents such as DMF and DMA.
- Has been stored at 25 °C for months without loss of activity.

Intellectual property

- U.S. Patent No. 7,968,664 (June 28, 2011) covers compositions of matter and contains claims covering a variety of prospective product applications.
- Intellectual property protection until 2025.

Benefits

- Inexpensive, common industrial starting material.
- Nothing introduced systemically.
- Potential for biofilm dispersal in addition to antibacterial effects reduces need for wound manipulation.
- Treatment can potentially be applied by the patient outside a clinical setting.
- Particularly relevant to treatment of non-healing diabetic wounds (known to be NO deficient) that result in numerous amputations yearly.

Guidelines

- Wound healing preparations may utilize any polymer containing a polyacrylonitrile segment.
- Should be protected from heat and moisture until use.
- Chemiluminescence is the preferred method of monitoring NO release.

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NCI Expectations and Deliverables

Topic 317: Wound Healing Preparations Incorporating Nitric Oxide-Releasing Materials

Patricia Weber, DrPH

Project Officer
SBIR Development Center
National Cancer Institute

NCI Expectations and Deliverables, Topic 317: Wound Healing Preparations Incorporating Nitric Oxide-Releasing Materials

- Goal: Develop a wound-healing dressing using NCI-developed NO releasing material technology to alleviate the suffering and costs caused by non-healing wounds in cancer patients as well as other patient populations.
 - Contractor will be granted royalty-free, non-exclusive license but is encouraged to submit an application for a commercialization license to NIH OTT

- Fast-Track proposals allowed: **No**

- Budget: \$200,000 Phase I; \$2,000,000 Phase II; **1 award only**

- Duration: Phase I, 1 year; Phase II, 2 years

Deliverables for Topic 317 Phase I SBIR Contract

- Prepare one or more dressings or other formulations incorporating NO-releasing poly(acrylonitrile) materials
- Produce a prototype product meeting minimum essential characteristics:
 - Quantifiable NO release durations should range from acute time periods (minutes) to 24 hours or longer to support an adequate therapeutic window
 - NO storage and release should be quantified via standard electrochemical or chemiluminescent assays routinely used in characterizing NO-based materials
- Characterize the material's:
 - total NO release potential
 - triggered NO release kinetics

Deliverables for Topic 317 Phase I SBIR Contract (continued)

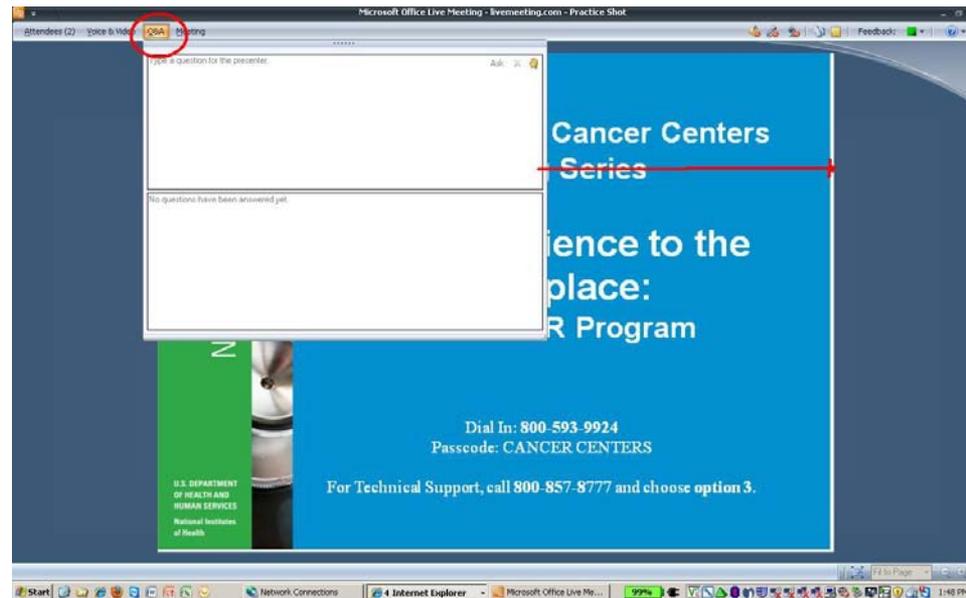
- Conduct proof of concept *in vitro* studies in the appropriate models and environments
- Conduct *in vivo* efficacy studies to demonstrate potential therapeutic benefit of the lead candidate NO-releasing preparation in an appropriate model
- Provide NCI with all data resulting from Phase I Activities and Deliverables

Licensing, and Follow-On Phase II SBIR Contract

- A follow-on Phase II contract can only be submitted after the successful completion of Phase I work
- A Phase II proposal can only be submitted if NIH has granted the Phase I SBIR contractor a commercialization license by that time (exceptions)
- Anticipated Phase II deliverables as listed in published solicitation

Questions?

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Technical Discussion

Topic 318: CYP1B1*3 to Inform Treatment of Castration Resistant Prostate Cancer

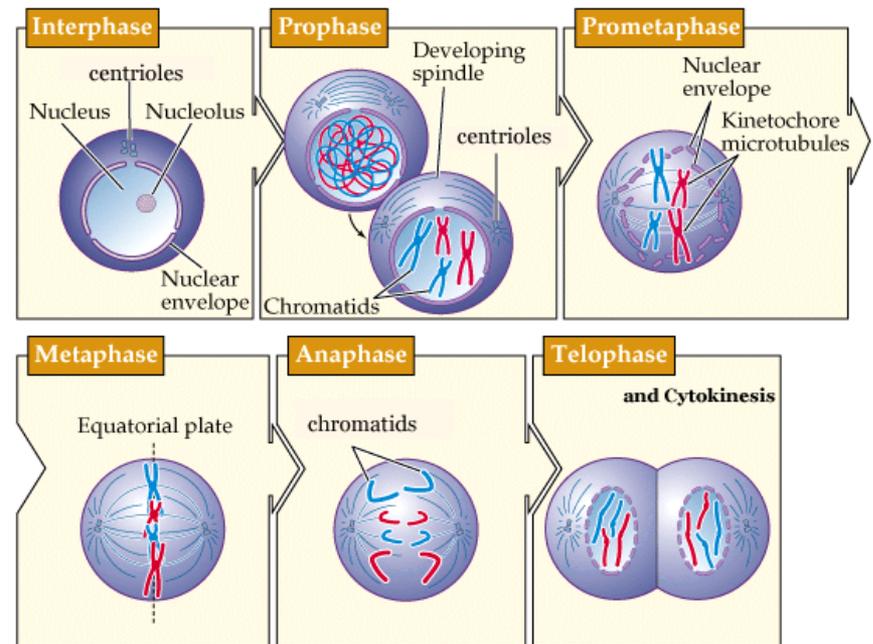
Tristan M. Sissung, Ph.D.
Staff Scientist
Clinical Pharmacology Program
National Cancer Institute

Unmet Need: Prostate Cancer Incidence

- 241,740 men will be diagnosed with prostate cancer in 2012, and 28,170 will die from “castration resistant prostate cancer” (CRPC)
- Docetaxel given to the majority of men with CRPC (~30-40K per year);
 - Newer drugs are being approved (e.g., abiraterone, enzalutamide, provenge, cabazitaxel (2nd line only)).

Taxanes mechanism of action

- Taxanes interfere with tubulin dynamics by stabilizing tubulin during the transition from prophase to anaphase.
- Stabilizing tubulin prevents mitosis from prophase to telophase and is cytotoxic to rapidly dividing cancer cells.



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Extension of Life vs. Toxicity

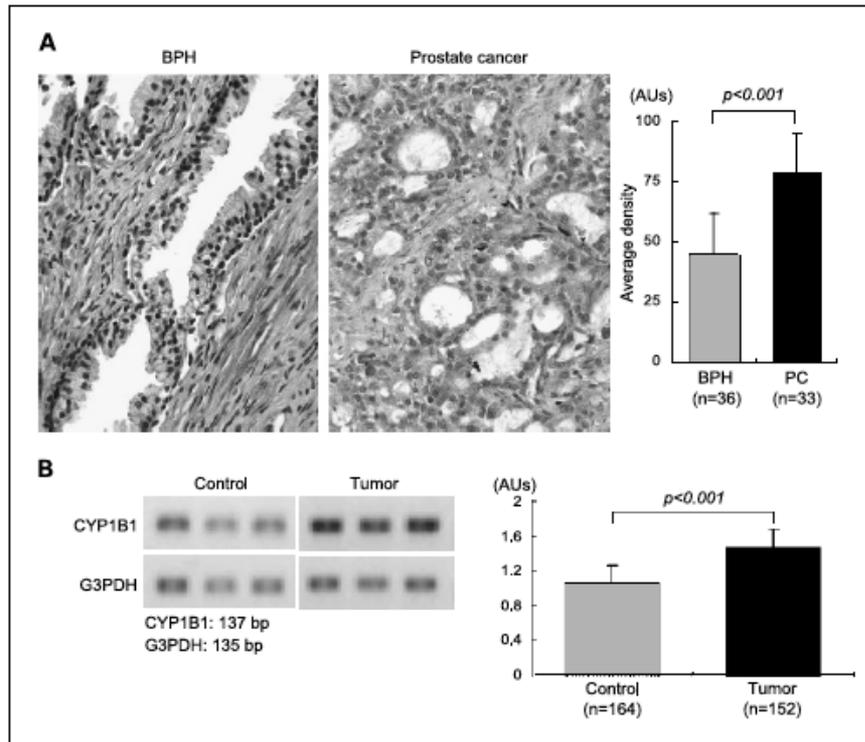
Neutropenia

- Occurs in nearly all patients while grade 4 neutropenia occurs in 85% given 100 mg/m² and 75% given 60 mg/m²
- Severe neurosensory symptoms in ~6% of patients
=> Low benefit, high toxicity

Petrylak et al. NEJM (2004), and docetaxel package insert

Markers that could inform which men will respond would increase benefit and avoid undue harm from docetaxel

CYP1B1

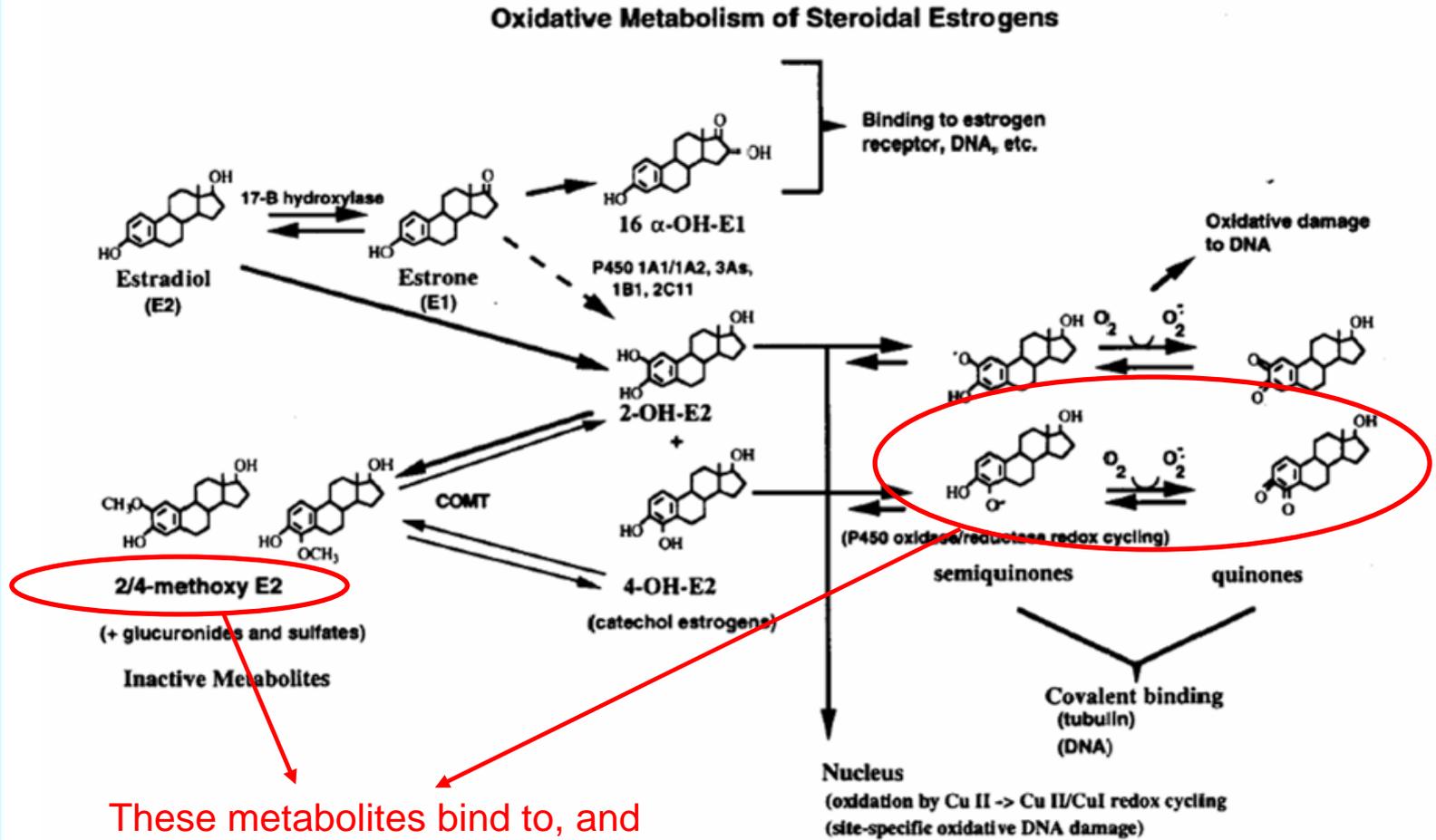


CYP1B1 expression is increased ~2 fold in prostate cancer.

Nearly all prostate tumors express CYP1B1 while matched normal prostate tissues most often do not express detectable levels.

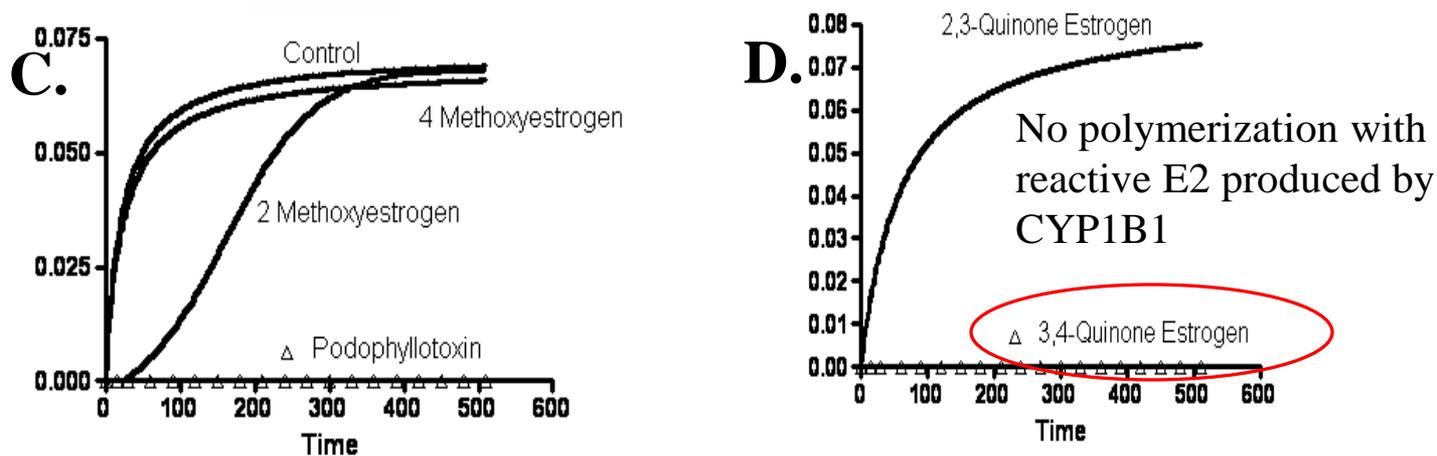
Tokizane et al. (2005) Clin Cancer Res., Sissung (Figg) et al. (2006) Mol Cancer Res.

A Role for the Cytochrome P450 1B1 (CYP1B1) in DOC resistance?



Yager (1996) *Annu Rev Pharmacol Toxicol*: 36; 203-32.

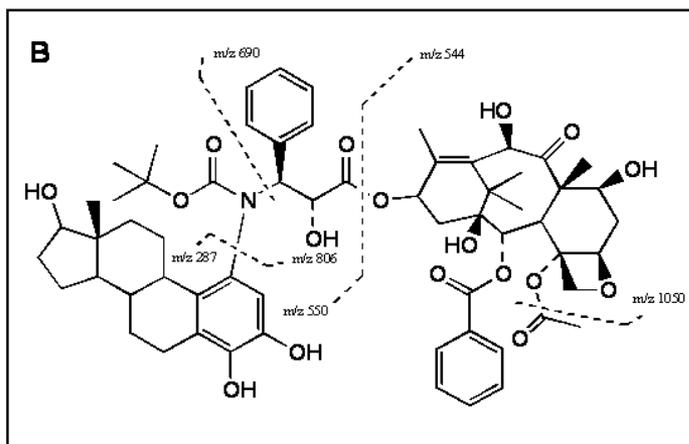
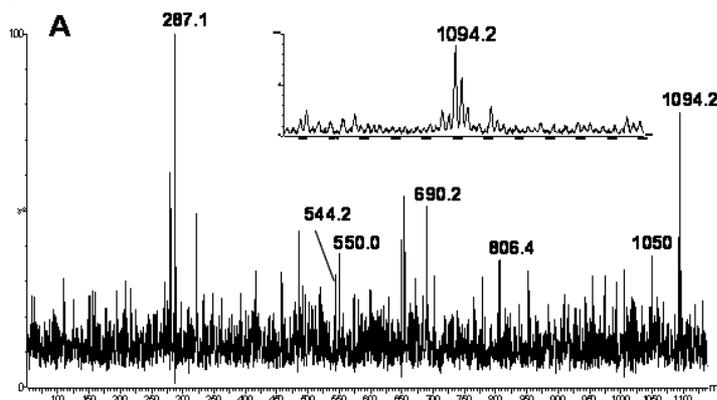
CYP1B1 estrogen metabolites interfere with tubulin polymerization by taxanes



The major estrogenic metabolite of CYP1B1, that is more prevalent in those carrying *CYP1B1**3, is responsible for completely inhibiting docetaxel-induced polymerization of tubulin.

Sissung (Figg) et al. (2008) Mol Cancer Res.

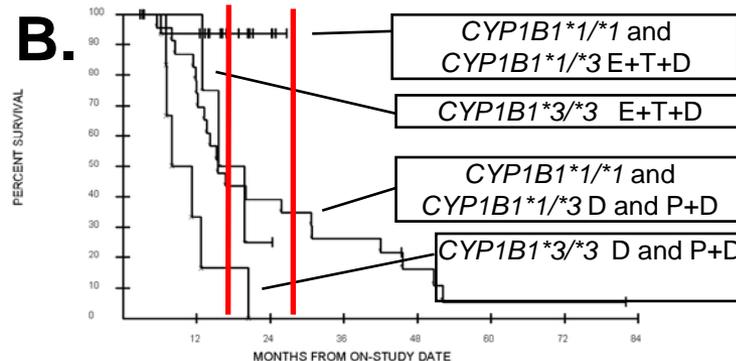
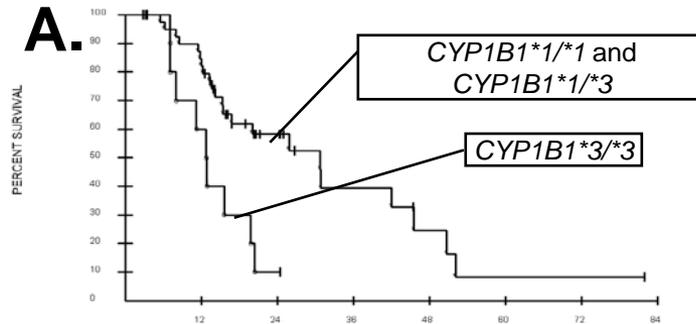
Estrogen-docetaxel adduct



The major estrogenic metabolite of CYP1B1, which is more prevalent in those carrying *CYP1B1**3, is ALSO responsible for covalently binding docetaxel and presumably reducing potency.

Sissung (Figg) et al. (2008) Mol Cancer Res.

CYP1B1 polymorphisms are related to survival following docetaxel



Median OS = Doc (~16mos) E+T+D (~25mos)

CRPC survival –

A) ~2 fold survival difference between *1 carriers vs. those that only carry *3.

B) Broken down by trial - CYP1B1*3 status marks 5/6 patients who likely did not experience life-prolongation by docetaxel.

Sissung (Figg) et al. (2008) Mol Cancer Res.

CYP1B1 polymorphisms are related to survival following docetaxel and paclitaxel

0290-9556/02/3011-1149-1152\$7.00
 DRUG METABOLISM AND DISTRIBUTION
 Copyright © 2002 by The American Society for Pharmacology and Experimental Therapeutics
 DMD 30:1149-1152, 2002

Vol. 30, No. 11
 745/1013351
 Printed in U.S.A.

1.

Short Communication

DOCETAXEL (TAXOTERE) IS NOT METABOLIZED BY RECOMBINANT HUMAN CYP1B1 IN VITRO, BUT ACTS AS AN EFFECTOR OF THIS ISOZYME.

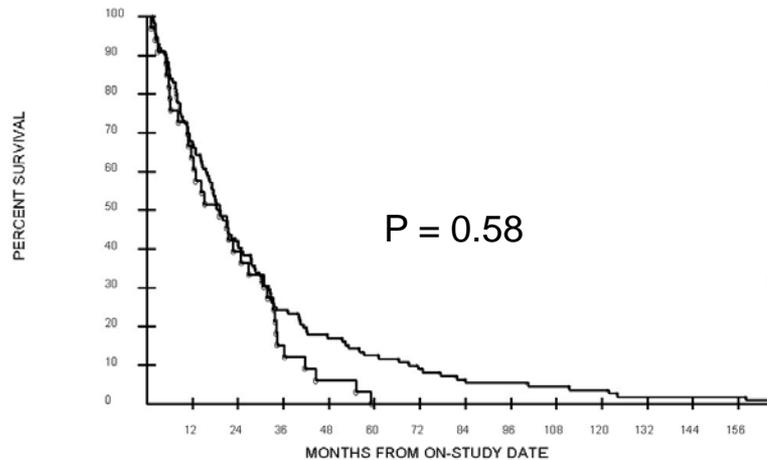
(Received March 20, 2002; accepted July 22, 2002)

This article is available online at <http://dmd.aspetjournals.org>

Bournique et al. (2002) Drug Metabolism and Distribution; 30(11): 1149-52.

2.

SURAMIN and THALIDOMIDE-- ALL STUDIES SURVIVAL



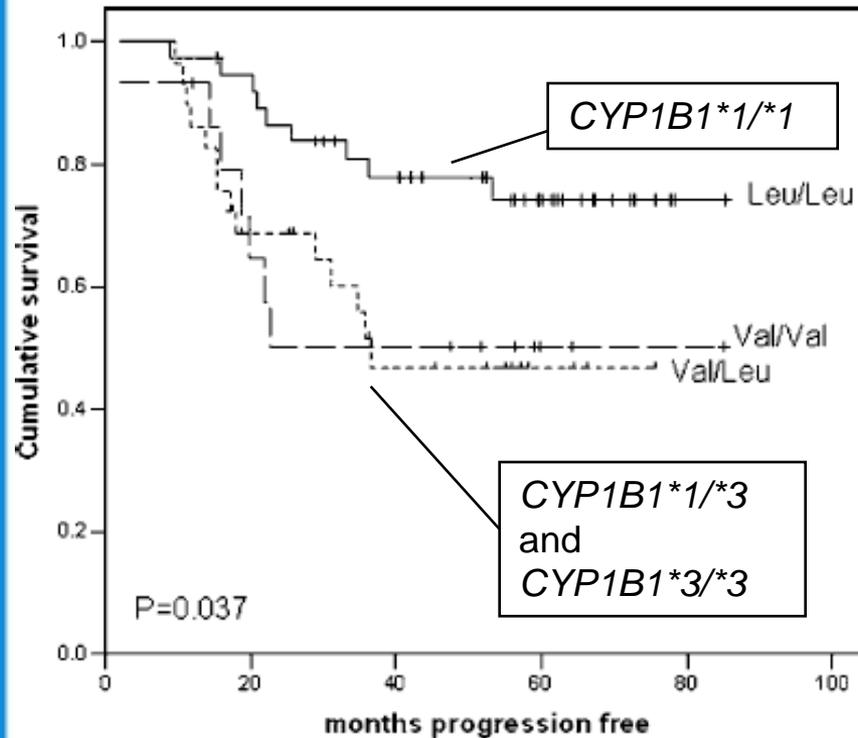
Legend * ANY SUR: LL, LV o ANY SUR: VV

112/112 failed 33/33 failed

While long-term survival might be related to *CYP1B1**3 status, there is no relationship between a similar cohort of men treated with different drugs.

Sissung (Figg) et al. (2008) Mol Cancer Res.

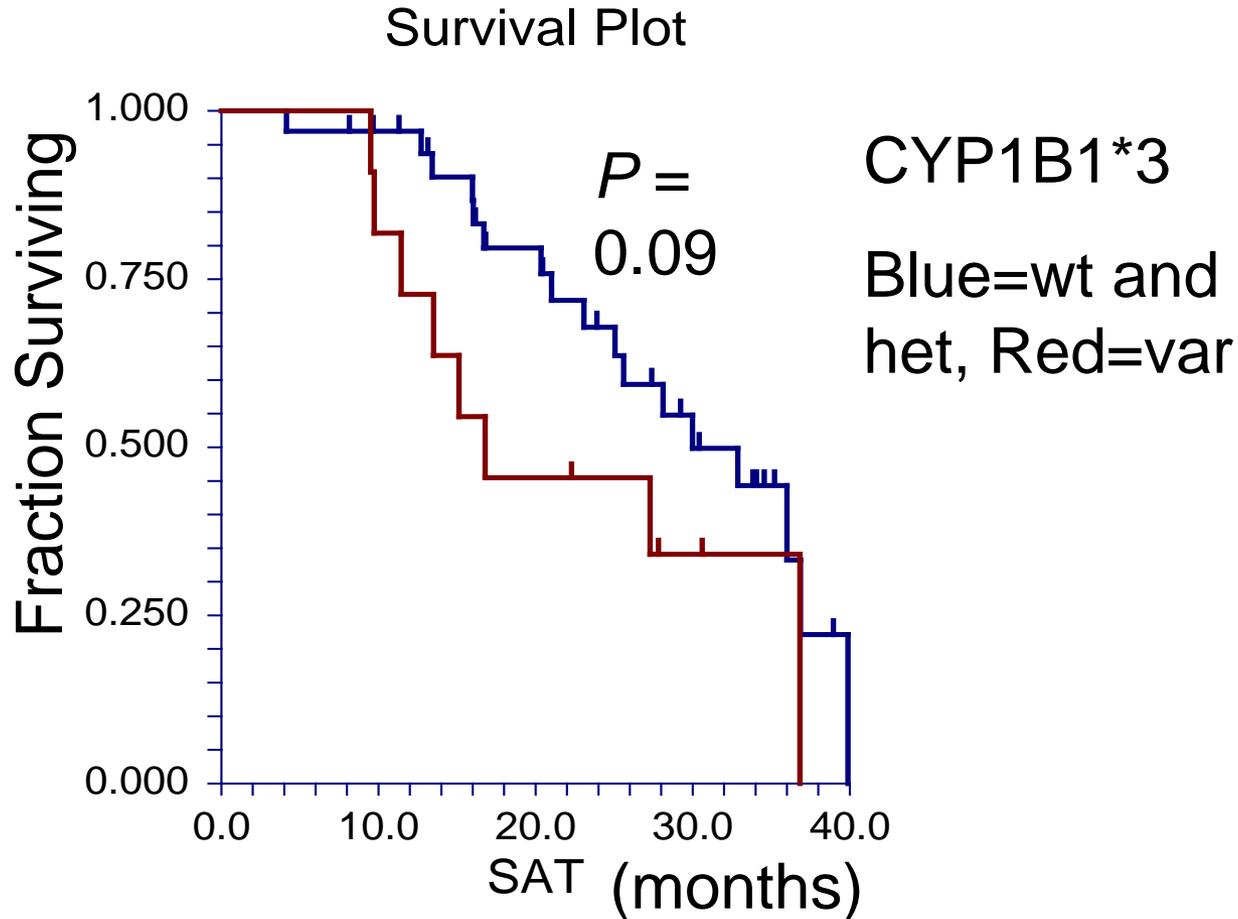
This effect has also been observed in women treated with paclitaxel



CYP1B1 is also greatly upregulated in ovarian cancer where paclitaxel is an accepted treatment option.

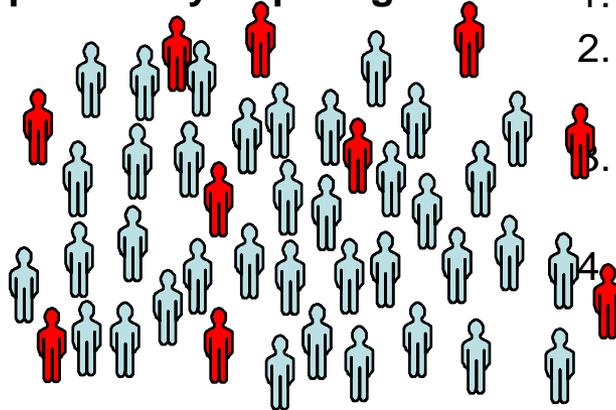
Marsh S, et al. (2007) *The Pharmacogenetics Journal*; 7, 362-5.

CYP1B1*3 in bevacizumab thalidomide and docetaxel for CRPC



Clinical Application

General CRPC patient population potentially requiring docetaxel



Putative CYP1B1 Non-Responders (~20%)

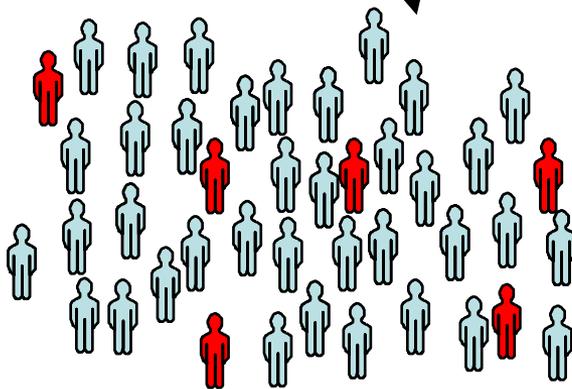
1. Consider other treatments (e.g. abiraterone)
2. Develop CYP1B1 inhibitors that can reduce CYP1B1-docetaxel interaction
3. Evaluate CYP1B1-estrogen metabolites prior to and during treatment
4. Segregate small number of responders based on other markers



CYP1B1*3/*3



CYP1B1*1/*1 & CYP1B1*1/*3



Putative Responders (~80%)

1. Treat with docetaxel
2. Rely on other markers to distinguish other non responders (~30% of remaining individuals)

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NCI Expectations and Deliverables

Topic 318: Test to Predict Effectiveness of Docetaxel Treatment for Prostate Cancer

Todd Haim, Ph.D.

Project Officer
Development Center
NCI SBIR

NCI Expectations and Deliverables, Topic 318: Test to Predict Effectiveness of Docetaxel Treatment for Prostate Cancer

- Goal: The focus of this topic is to advance development of this genetic test which would provide rapid and useful *a priori* predictions of the clinical outcome of docetaxel patients and guide the therapeutic strategy for each patient. The short-term goals of this project are to:
 - i. develop a rapid and reproducible assay for the CYP1B1*3 variant
 - ii. provide additional preclinical evidence necessary for carrying the CYP1B1*3 genotype test into the clinical setting
 - iii. determine if cabazitaxel activity is related to the CYP1B1*3 allele and reactive estrogen species
- Fast-Track proposals allowed: **No**
- Budget: \$300,000 Phase I; \$2,000,000 Phase II; **1 award only**
- Duration: Phase I, 9 months; Phase II, 2 years

Deliverables for Topic 318

Phase I SBIR Contract

- Develop a simple array-based genotyping technique for CYP1B1*3 in which a genotype call is conferred to the patient within two days following the receipt of a blood sample
- Extend the proof-of-concept that CYP1B1*3 interferes with docetaxel activity via formation of estrogen quinones using cellular assays and/or tumor-bearing mice
- Validate that the genotype is related to survival in retrospective samples obtained from patients with CRPC undergoing therapy with docetaxel (The NCI intramural laboratory can aid in getting samples)

Deliverables for Topic 318 Phase I SBIR Contract (continued)

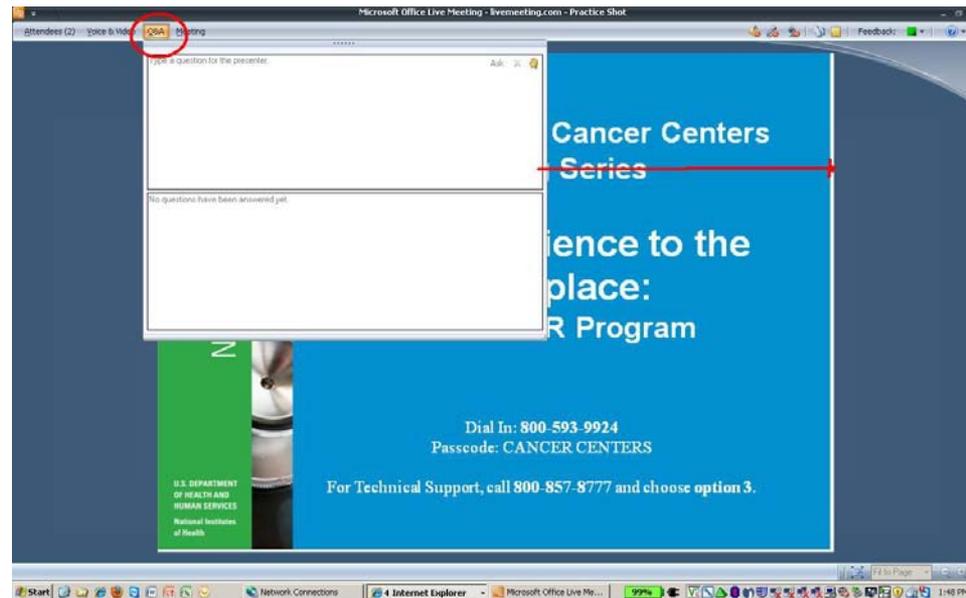
- Identify the percentage of patient samples with the CYP1B1*3 variant
- Determine if cabazitaxel is subject to the same interaction with E2-3,4Q
 - The NCI intramural laboratory has synthesized frozen E2-3,4Q and can provide some of the quinone estrogen species; it is unlikely that the NCI laboratory could provide any retrospective samples
- Deliver data to the NCI

Licensing, and Follow-On Phase II SBIR Contract

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- Anticipated Phase II deliverables as listed in published solicitation

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No audio? Dial 800.369.1726, Passcode: SBIR

Licensing

NCI SBIR-TT Public Briefing

Sabarni K. Chatterjee, Ph.D., M.B.A.

Licensing and Patenting Manager, Cancer Branch
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Three Important NIH Offices for an SBIR-TT Contractor

- 1) NCI Office of Acquisitions
 - Awards SBIR-TT Contracts.

- 2) NCI Technology Transfer Center
 - Coordinates collaborative interactions with the Topic inventor(s).

- 3) NIH Office of Technology Transfer
 - Coordinates the Topic licenses.

The NIH Office of Technology Transfer (NIH OTT)

- The NIH OTT is the centralized office that manages inventions that arise from intramural NIH and FDA research.
 - The NIH OTT serves as the bridge that connects these inventive discoveries to commercial partners that develop these technologies into products and services to benefit public health.
 - In FY 2011
 - Managed ~1,300 active agreements
 - \$1B sales
 - \$96.9M in royalties

Patents and Licenses

Q: Why are licenses relevant to an SBIR-TT contractor?

A: Because issued and pending patents exist for the SBIR-TT Topic background inventions.

- For development and commercialization of these inventions, licenses must be in place.
 - There are two relevant types of licenses and we will walk you through both of them.

The Internal Use License

- The SBIR-TT contractor is automatically awarded a “royalty-free, non-exclusive” internal use license concurrent with the SBIR-TT contract.
 - This internal use license allows the SBIR-TT contractor to complete their research without worrying about possibly infringing any existing NIH patents.
 - This internal use license is automatic and royalty-free.

The Commercialization License (Part 1)

- The internal use license allows the SBIR-TT contractor to complete internal research and development using the invention, but it does not allow an SBIR-TT contractor to actually make, use, or sell the final commercial product.
- The goal of the SBIR-TT funding mechanism is to enable an SBIR-TT contractor to develop an NIH invention into a commercial product that benefits the public.
 - For commercialization rights, we require (issued claims) and/or request (pending claims) that an SBIR-TT contractor obtain a commercialization license.

The Commercialization License (Part 2)

- Because commercialization is a critical component of SBIR-TT, we have included a commercialization license requirement into each Topic.
 - “A Phase II proposal will typically/generally only be invited by NCI if the Phase I contractor has been granted a commercialization license via the NIH license application process.”
- *Correction from 9/25/12 webinar: Phase II competition will not require an invitation. However, applying for a commercialization license is strongly encouraged.*

The Timing of the Commercialization License

- Because the time required to obtain a commercialization license can vary, SBIR-TT offerors are strongly encouraged to apply for a commercialization license at the same time that they submit an SBIR-TT contract proposal.
 - We want to help you to obtain a commercialization license before the SBIR-TT Phase II proposals are solicited.

The Negotiation of the Commercialization License

Q: Can we negotiate the terms of the commercialization license?

A: Yes. Many of the terms within the license are negotiable.

- We will help you to design the license that will best fit your commercialization plans.

How Do I Obtain a Commercialization License?

- Contact the responsible Licensing and Patenting Manager (LPM) in the NIH OTT.
 - For Topic 317, the responsible LPM is Betty Tong, tongb@mail.nih.gov
 - For Topic 318, the responsible LPM is Sabarni Chatterjee, chatterjeesa@mail.nih.gov
 - Betty and Sabarni will walk you through the licensing process.

For Further Questions

- Please see the SBIR-TT FAQ at <http://1.usa.gov/S9Hzph>
- For licensing questions, please contact the Licensing and Patenting Manager responsible for the Topic that interests you.
- For all other SBIR-TT questions, please contact Elizabeth Shanahan, Contract Specialist, NCI Office of Acquisitions, eshanahan@mail.nih.gov

Agenda

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Research Collaborations and Co-Development

John Hewes, Ph.D.
Technology Transfer Center
National Cancer Institute

How to Partner with NIH

- Grants (<http://www.grants.gov>)
- Contracts (<https://www.fbo.gov>)
- Public Private Partnerships
- Research Collaborations
- Licensing Technologies
- Materials/Services
- **Now...SBIR-TT**

Why Collaborate with the NIH?

NIH and Company Perspectives:

For NIH

- Extensive scientific expertise and regulatory at Company
- Access to proprietary materials
- No ability to commercialize
- Access to additional funds
- Technology transfer builds the U.S. economy
- Publications

For Company

- Opportunity to collaborate with top scientists
- Access to unique data, technologies, and materials
- May be able to license NIH inventions for commercial use or research
- Right to use data for regulatory filings
- Signing an Agreement may help Company obtain more funding (halo effect)
- Publications, patents

Many ways to collaborate

- Confidential Disclosure Agreement
 - Initial discussions with researcher(s)
- Material Transfer Agreement
 - transfer of tangible research materials between two or more organizations
- Collaboration Agreement
 - Basic, pre-clinical or clinical research collaboration
- Clinical Trial Agreement
 - NCI clinical trial of company agent or device
- Cooperative Research and Development Agreement (CRADA)
 - License option on forward IP
 - NCI's efforts compensated by company

NCI Collaboration Agreement

- Defined research project
- No license option
- Data and material sharing
- Confidentiality
- Publications
- No funding exchange
- Anticipated to be the agreement of choice for the SBIR-TT program initially.
- Can expand into CRADA as project dictates

CRADAs:

Legal Requirements and NIH Policies

- Law:
 - Provide option to exclusive license in specified field of use
 - Government can receive (but not provide) funding*
 - Consistent with missions of the Federal laboratory
 - NIH CRADA policies
 - Intellectual contribution by NIH and Collaborator
 - Dissemination of research results
 - Conflict of interest review
 - Focused CRADA research plan
 - License option balanced with research tools policy
- * Except when funds are provided by the same Federal Lab.

CRADA Inventions

- Reported in about 10% of CRADAs
- Collaborator may exercise option and license (royalty-bearing)
- If Collaborator declines option for exclusive license, NIH may license to others
- NIH does not provide assignment (ownership) of government inventions made under the CRADA to the company
- NIH does not provide royalty-free commercial sales licenses (except for combination study inventions)

Negotiation of CRADAs

- Determine CRADA is best agreement type
- Appendix A: Research Plan
 - Focused
 - Responsibilities of each party
- Appendix B: Financial/Materials
- Appendix C: Modifications to NIH model
- Route for clearance
- Review by NIH CRADA subcommittee
- Agreement execution

The structure of the collaboration is flexible

- NCI/NIH models
 - Modified if needed to address company's concerns
- Company models
 - For any agreement type, except CRADA
 - Modified if needed to address NIH concerns

How much does it cost?

- Most collaborations involve in-kind exchange
 - Each party responsible for its own cost
- CRADAs only permit NCI to receive funds to offset NCI costs for CRADA research. However, in the context of SBIR recipients. NCI cannot receive funding that was provided to the Collaborator from an NCI grant or contract.*
- NCI cannot provide funding to Company under any of these agreements

*This policy may change due to updates from the SBIR/STTR Reauthorization Act of 2011

Collaboration on SBIR-TT Contracts

- ✓ NIH labs can collaborate under many different formats, depending on the need;
- ✓ Company can exchange knowledge with the NCI researcher;
- ✓ Company can utilize fixed asset resources at NCI and NCI-Frederick;
- ✗ Company cannot contact NCI researchers prior to contract award;
- ✗ Company cannot rely on the NCI lab to perform the majority of the effort being proposed for the SBIR contract;
- ✗ Company cannot fund work in NCI lab using SBIR money under a CRADA.*

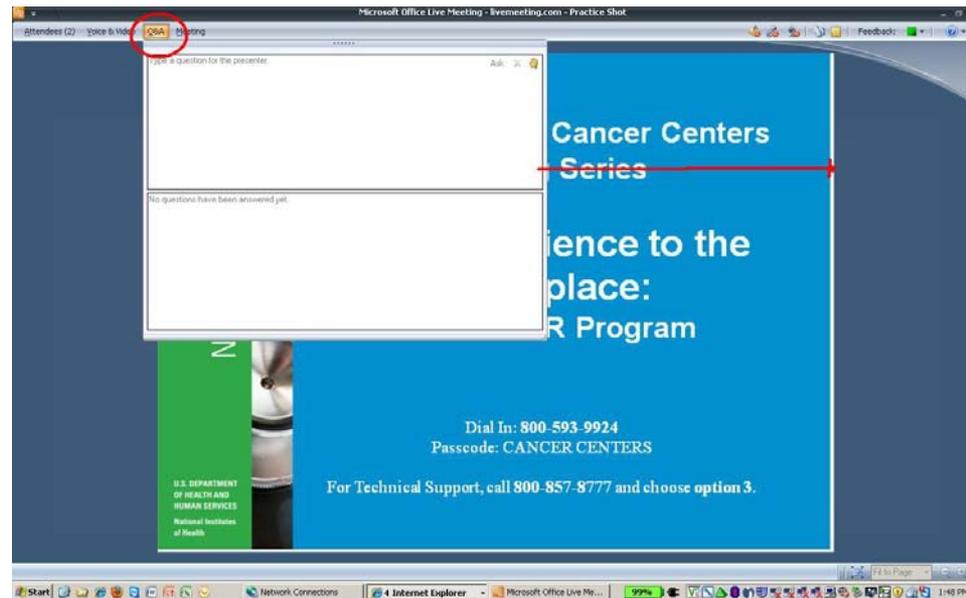
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Questions?

- Please submit your question 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 clicking the Q&A on the top navigation panel and dragging it to the right side of your screen.



Closing Remarks

Jennifer Shieh, Ph.D.
NCI SBIR Development Center

- Thanks to the presenters and remote audience
- Content from this event to be posted on the NCI SBIR website within 2 weeks (proposal receipt date is ~6 weeks away)

Important Information for Proposal Submission

PROPOSAL RECEIPT DEADLINE: TUESDAY NOVEMBER 13, 5:00 PM EASTERN TIME

<http://sbir.cancer.gov/funding/contracts/>

- see topics 317 and 318

<http://grants.nih.gov/grants/funding/SBIRContract/PHS2013-1.pdf>

- see pages 49-53

All technical inquiries from companies must be sent to:

Ms. Bette Shanahan

Phone: (301) 435-3782

Fax: (301) 480-6699

Email : eshanahan@mail.nih.gov

Proposals to the NCI, if mailed through the US Postal service, must be addressed:

Bette Shanahan

Office of Acquisitions

National Cancer Institute

6120 Executive Blvd, #6054

Bethesda, MD 20892-7193*

**Change city to Rockville and zip code to 20852 if hand-delivered or delivered by an overnight service to NCI*