U.S. Department of Health and Human Services
National Institutes of Health
National Cancer Institute
SBIR-Technology Transfer (TT)
Contract Topics 298 and 299

Public Briefing/Webinar

NIH Campus
Natcher Building, Room A, Basement Level
Bethesda, MD

Tuesday October 26, 2010, 10 AM-noon

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

U.S. Department of Health and Human Services
National Institutes of Health

National Cancer Institute
SBIR-TT
http://sbir.cancer.gov/funding/contracts/

Dr. Greg Evans (NCI SBIR) 10:00
Welcome and Introduction

Dr. John Hewes (NCI Technology Transfer Center) 10:05
Technology Transfer at the National Cancer Institute

Dr. Murali K. Cherukuri (NCI Radiation Biology Branch) 10:10
Technical background, topic 298 (Low-Field EPR Device)

Dr. Greg Evans (NCI SBIR) 10:20
Phase I contract deliverables, Q&A for topic 298

Dr. Dimiter S. Dimitrov (NCI Nanobiology Program) 10:35
Technical background, topic 299 (HIV Vaccine)

Dr. Greg Evans (NCI SBIR) 10:45
Phase I contract deliverables, Q&A for topic 299

Richard Rodriguez, MBA (NIH Office of Technology Transfer) 11:00
Overview of License Application Process

Q&A Licensing, then open Q&A 11:10

Closing Remarks 11:55

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Welcome and Introduction

Greg Evans, Ph.D.
Project Officer
NCI SBIR Development Center

Welcome and Introduction

- The National Cancer Institute (NCI) and the NIH Office of Technology Transfer (OTT) are formally piloting in fiscal year 2011 the SBIR-Technology Transfer (TT) contract concept
- The concept involves coupling out-licensing with SBIR funding in order to move inventions from intramural NIH out into the marketplace (MOVING SCIENCE TO THE MARKET)
- This pilot is based on the successful program that another federal agency-The National Institute of Standards and Technology (NIST)-has been running for the last 2 years
- If this NCI pilot is successful, we in the NCI SBIR Development Center hope to continue this SBIR-TT program using some of the several hundred other existing employee inventions backed by intellectual property filings

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Welcome and Introduction II

- Purpose of today's event: briefing on technical and licensing aspects of NCI SBIR-TT contract topics 298 and 299
- Proposal receipt deadline is Monday November 8, 5 PM EST
- Frequently asked questions (FAQ) for topics 298 and 299 are on the web: http://sbir.cancer.gov/frequently-asked-questions/
- Q&A from this event will be transcribed and added, along with the slides, to those FAQ already online

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To Ask a Question During this Event

There are 2 options:

- 1-raise your hand (physically, or electronically using the pull-down menu within the Attendee List window on the left side of the Adobe Connect Pro screen)
- 2-send your question in writing via e-mail to Jeff Klein at: kleinjc@mail.nih.gov

During the designated Q&A time slots, we will alternate taking questions in sequence from local versus remote participants.

If you raise your hand, you will be called on to voice your question

If you send your question by e-mail, it will be read aloud by NIH staff.

Technology Transfer at the NCI

John Hewes, Ph.D.
NCI Technology Transfer Center

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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

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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 morefunding (halo effect)
- Publications, patents

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Marketed NCI-Licensed Technologies

Abbott/Others	AIDS Test Kits
Schering AG/Berlex	Fludara®
BMS	Videx ® (ddI)
BMS	Taxol ® (paclitaxel)*
Roche	Hivid ® (ddC)
Millennium	Velcade® *
Cell Therapeutics	Zevalin®
Amgen	Kepivance ®
20/20 GeneSystems	Multi-Replica Blotting Kit*
Molecular Devices	PixCell® Laser Capture Microdissection*
Merck	Gardasil®
Medimmune Oncology	NeuTrexin®
Monogram Biosciences	PhenoSenseTM HIV phenotype tests
Isis	Vitravene®
Ortho Biotech	Prezista®
Biovest/Accentia	BiovaxID™
Squirrel Free Products	Squirrel-free capsaicin-treated birdseed

*Developed under NCI CRADA

NCI has produced important drugs and technologies through collaborations and licensing with the private sector.

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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

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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

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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.

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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)

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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

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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

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How much does it cost?

- Most collaborations involve in-kind exchange
  - Each party responsible for its own costs
- 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

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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 contact 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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Low-Field Electron Paramagnetic Resonance Imaging (EPRI) Device to Optimize Development of Anti-Angiogenic Therapeutics in Cancer Animal Models (NIH/NCI SBIR TT, contract topic 298)

Murali Krishna Cherukuri, Ph.D.
Radiation Biology Branch
Center for Cancer Research, NCI/NIH

Of all small animal imaging techniques, EPRI is the only method which enables,

- Quantitative and non-invasive imaging of tumor pO2.
- Longitudinal (serial) imaging on the same animal.
- Anatomic co-registration with MRI and/or CT.

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EPRI vs MRI/ Probes

MRI:
Images obtained from NMR signals of abundant tissue water protons (1H).

CONTRAST agents increase (T1; Gadolinium) or decrease (T2; iron oxide) image intensity.

EPRI:
No endogenous species with EPR signals in vivo. No anatomic image available.

Exogenous paramagnetic species needed as TRACERS for imaging.

Their EPR spectrum should be simple.

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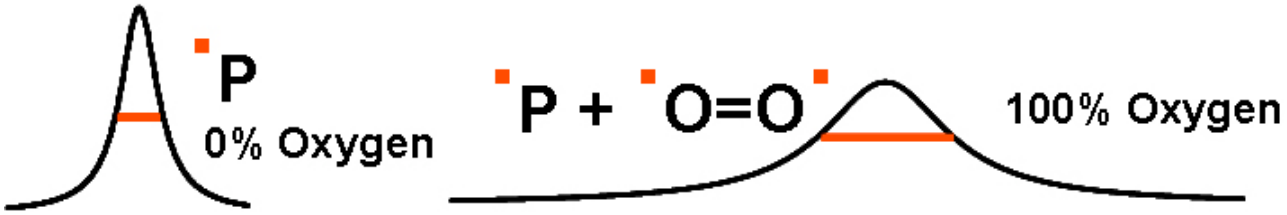
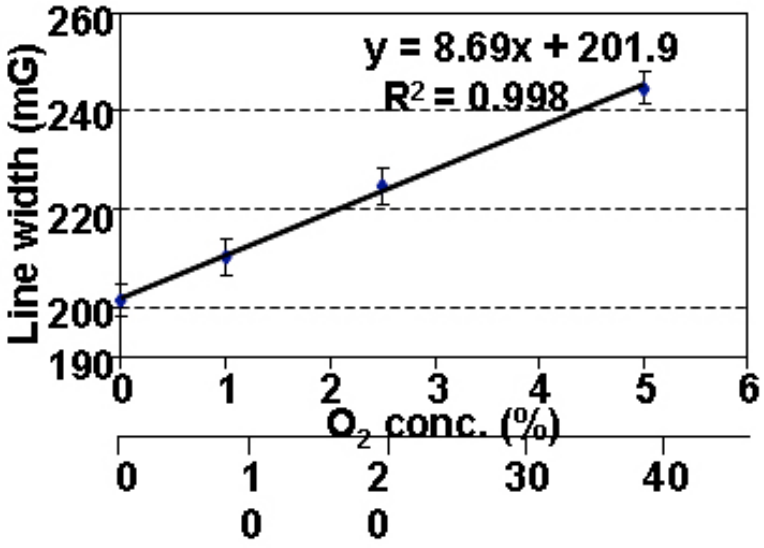
Oxygen Imaging by EPR

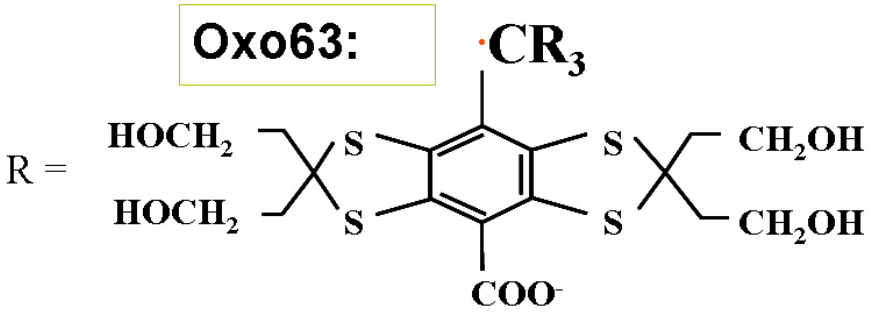
Oxygen Molecule is Paramagnetic (2 unpaired
electrons) and Broadens the EPR Spectrum ofParamagnetic Tracers (.P).



O2 conc. (%) vs. line width (mG)



Trityl based Free Radical Tracers for EPR Imaging of Tissue Oxygen



Contrast media developed for other applications by GE Healthcare can be used as tracer in EPRI.
MTD 8 mMol/kg In Vivo Half life: 15 minutes

- Image Spatial Distribution of Paramagnetic Tracers with EPR.
- Use Tissue Oxygen (paramagnetic) for T2 contrast and generate pO2 maps.

Commercial Applications

Areas in which the technology can be applied:
Mouse models of human cancer

- Testing drugs which impact tumor physiology
- Example: Anti-angiogenic drugs, mTOR inhibitors
- Identify treatment schedule of radiation + chemotherapy for synergy

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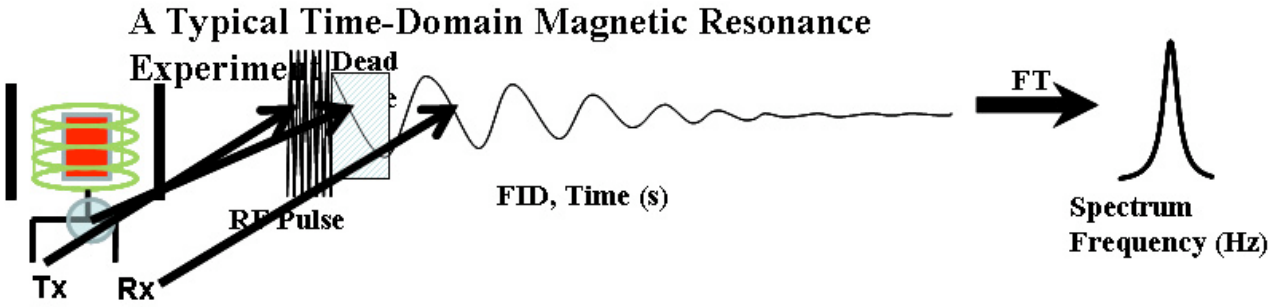
Time-Domain EPR Imaging
A Typical Time-Domain Magnetic Resonance Experiment



NMR versus EPR – Time factors

	NMR	EPR
Dead Time	**5-20 ms**	**200-500 ns**
Signal Persistence **Available Signal**	**Seconds** **(99. 9%)**	**1-5 ms** **(50 – 90 %)**

Major fraction of the initial part of the exponentially decaying signal is lost in dead time.

Signal detection in EPR (nanosecond) is challenging compared to MRI (NMR).

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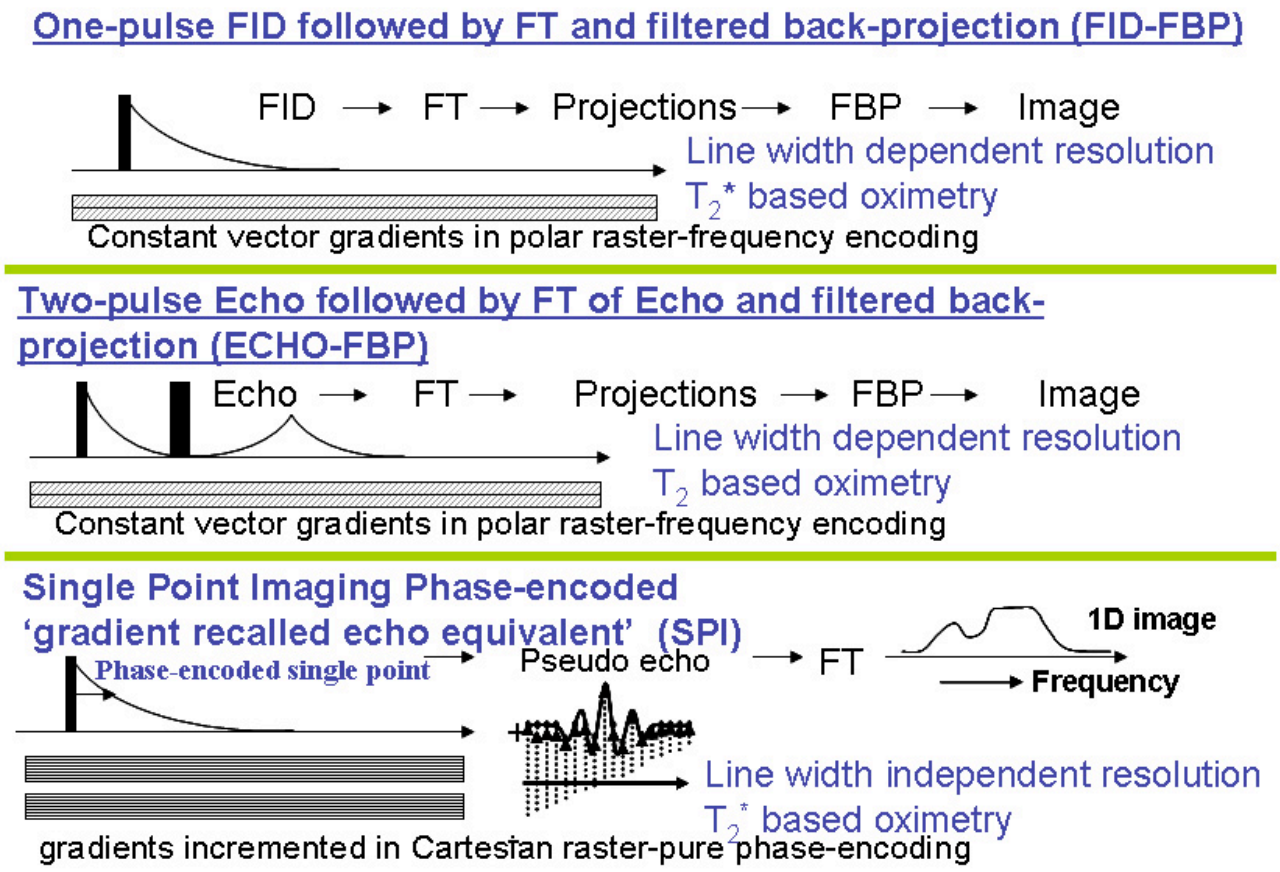
Status Quo/EPRI



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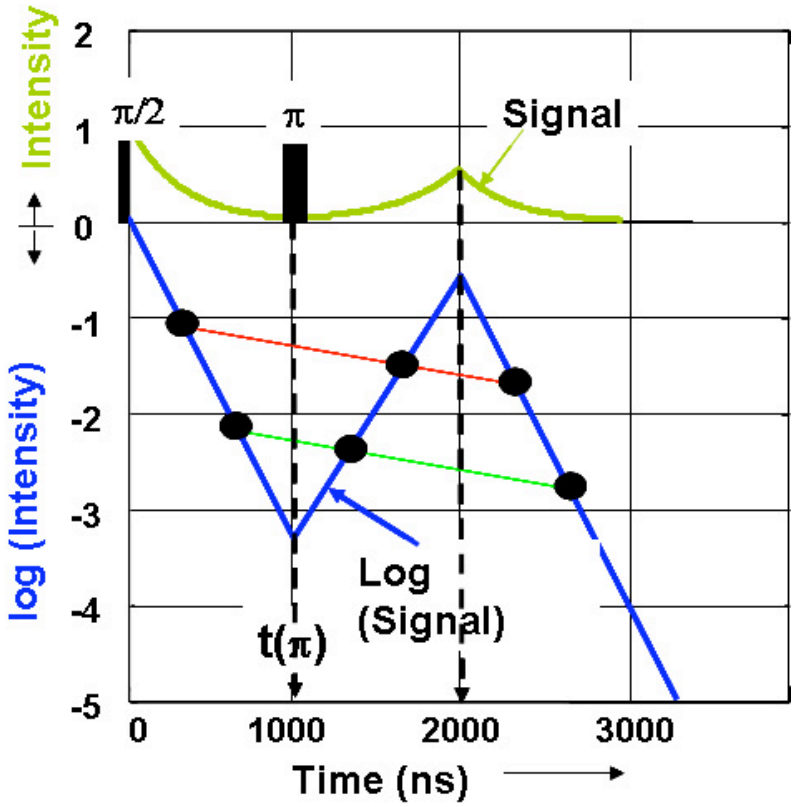
Technology

Echo-based Single Point imaging – Pure phase encoding pairs or triplets of single points in a two-pulse echo scheme produces line width independent images which are T2 - weighted – both resolution and oximetry are superior



Current Specs

Resonator type: Patented parallel coil resonator
Resonator dim.: 25-50 mm dia. and length
Resonator Q: 15-20
Dead-time: 300 ns at 200 W
Bandwidth: 15-20 MHz
RF pulse: 70-ns at 300 MHz
Transmit power: 200 W (nominal)
Digitizer speed: 200 Ms/s (Max 1Gs/s)
Spin Probe: Trityl-based [Oxo63]
TR inter pulse delay: 6-7 ms.
Dose for imaging: 1.125 mmol/kg body weight (Oxo63)
Image resolution: 1-1.2 mm
Oxygen resolution: ±2 mm (Hg)
FIDs summed: 1000 – 4000 per grad. setting

3D imaging time: 2 min. (21x21x21 grad. steps)
3D oxygen mapping: 6 min for 3D

Staff and Collaborators

James Mitchell
Sankaran Subramanian
Nallathamby Devasahayam
John Cook
Anastasia Sowers
Frank Harrington
(Workshop) Ram
Murugesan
Atsuko Matsumoto
Ken-ichiro Matsumoto
Fuminori Hyodo
Shingo Matsumoto
Hironobu Yasui
Keita Saito
Emi Furasato
Murali C Krishna
CCR/NCI/NIH
Rolf Tschudin (LCP/NIDDK/NIH)
Calvin Johnson (CIT/NIH)
Tom Pohida (CIT/NIH)
Randall Pursley (CIT/NIH)
Salem Ghadi (CIT/NIH)

Overview and Deliverables
Topic 298 (Preclinical EPR Device)

Greg Evans, Ph.D.
Project Officer
NCI SBIR Development Center

- Goal: perform commercially directed research and development with this imaging technology developed in intramural NCI, and independently, to seek a commercialization license from the NIH Office of Technology Transfer
- Fast-Track proposals allowed: No
- Budget: $200,000 Phase I; $1,000,000 Phase II; 1 award only
- Duration: Phase I 9 months, Phase II 2 years

Deliverables for Topic 298 Phase I SBIR Contract

- Build a transmit channel capable of pulsed excitation with 10-100 nanosecond pulses to provide broad band excitation of an object the size of a mouse.
- Build a resonator having short recovery time after an input power at 300 MHz sufficient to study a mouse in a 25 x 25 mm coil.
- Build a receive system comprising a preamplifier and digitizer/averager module.
- Assemble the transmit channel, resonator, and receive system into a prototype.
- Perform phantom testing on the prototype with an external magnet, evaluate the sensitivity and resolution of the images generated, and test oximetry.

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Follow-On Phase II SBIR Contract

- Phase I contract period will be approx Sept 30, 2011 thru June 30, 2012 (9 months)
- A Phase II contract invitation can in principle be issued within 2 months of the successful completion of Phase I work
- An invitation will generally only be issued if NIH has granted the Phase I SBIR contractor a commercialization license by that time (exceptions)
- Timing of license application (coordination of funding/licensing)
- Anticipated Phase II deliverables as listed in published solicitation

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Q&A for Topic 298

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A New Type of Vaccine for Prevention of HIV Infection and HIV-Associated Cancers
NIH/NCI SBIR-TT, contract topic 299

Broadly Neutralizing Antibodies against HIV-1: How to Elicit them?

Dimiter S. Dimitrov, Ph.D.
Protein Interactions Group
Nanobiology Program
Center for Cancer Research
NCI-Frederick, NIH

Commercial Applications

- HIV is a major killer, there is an acute need for a vaccine
- ~ 60 million people have been infected
- ~ 25 million have died of HIV-related causes
- ~ 2.7 million were newly infected in 2008

http://www.unaids.org/en/KnowledgeCentre/HIVData/EpiUpdate/EpiUpdArchive/2009/default.asp

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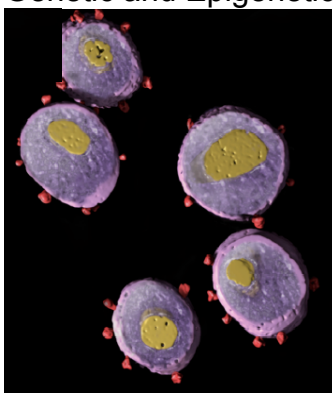
HIV Heterogeneity as a Major Problem for Development of Efficacious AIDS

Genetic and Epigenetic Alterations to Heterogeneity



HIV virions
Subramaniam, S.
(NCI)

Possible Solutions

- Vaccines eliciting antibodies targeting conserved epitopes
- Understanding mechanisms used by HIV to evade neutralizing antibody responses and developing novel strategies to overcome them

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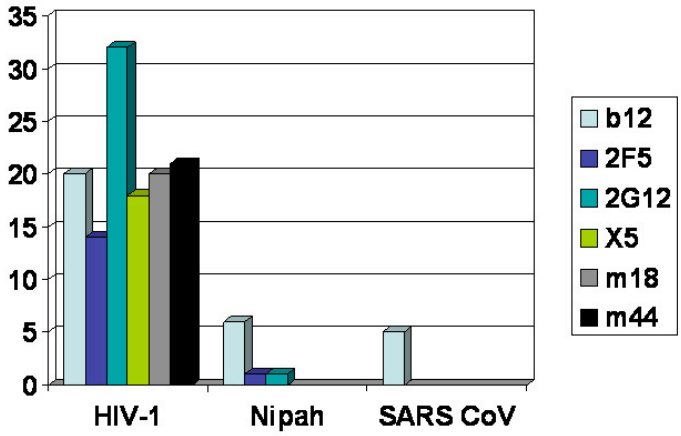
Germline Predecessors of bnAbs Neglected Partners of Vaccine Immunogens

- All known bnAbs -highly divergent from germline
- Do germline predecessors of bnAbs bind Env?
- Primary immunogens binding to germline BCR
  - help guiding antibody responses through complex maturation pathways?

Extensive Somatic Mutational Diversification of Cross-Reactive Neutralizing Antibodies against HIV-1 but not against Nipah, Hendra, SARS CoV



Can Human Germline Antibodies Recognize Epitopes of bnAbs?

- Generation of germline-like antibodies corresponding to known bnAbs and testing for binding to Envs (Xiao et al BBRC 2009; Xiao et al Viruses 2009)
- Panning of naive IgM phage libraries from adults against Envs by sequential antigen panning – only non-neutralizing or enhancing isolate specific relatively low-affinity antibodies of low mutational diversification found (Chen et al Viruses 2010)
- Generation and panning of naive IgM phage libraries from cord blood against Envs by sequential antigen panning – high-affinity Abs against SARS CoV and Hendra virus found but not HIV-1-specific Abs (Chen et al unpublished)

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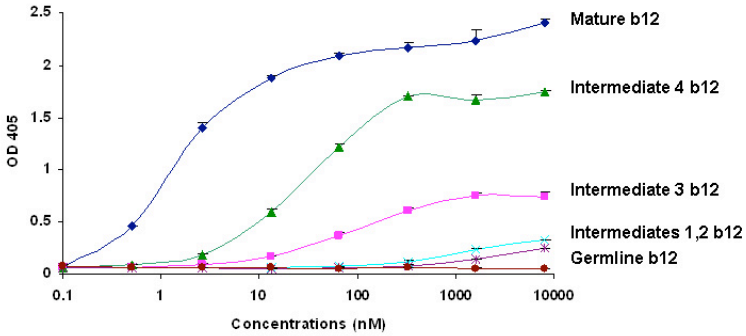
Lack of Measurable Binding of Germline-like Putative Predecessors of bnAbs Including m66.6

Abs	Germline-like putative predecessor binding	Broad neutralization by mature IgG1
m44	+	modest
m46	+	weak
X5	+++	modest
2G12	-	high
b12	-	high
2F5	-	high
m66.6	-?	high

Putative Intermediate b12 Antibodies Bind Env with Varying Affinities



Xiao X et al Viruses 2009

New Cross-reactive HIV-1-neutralizing mAbs (m66, m66.6): Relatively Low Divergence from Closest Germline V Genes

Antibodies	VH			VL		
	CDR3 Length	V mutations	Germline	CDR3 Length	V mutations	Germline
m65	17	10	IGHV5-51*01	8	2	IGKV3-20*01
m66	23	8	IGHV5-51*01	9	3	IGKV1-39*01
m66.6	same	same	same as m66	same	10	same as m66
2F5	24	14	IGHV2-5*10	9	14	IGKV1-13*02
4E10	20	17	IGHV1-69*10	9	10	IGKV3-20*01

m65 was selected as m66 but did not neutralize
m66.6 was derived from m66 by shuffling of antibody light chains from the same patient (SC44)

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Targeted Vaccines: Epitope-targeting Vaccines and Ab-targeting Vaccines (Jamie Scott in Microbiol Mol Biol Rev 2008)

How to Design a Vaccine that Can Elicit Known mAbs, e.g., m66.6?

A Hypothesis

- A mechanism to evade immune responses to highly conserved Env structures – lack or relatively weak binding to germline antibodies
- HIV-1-specific bnAbs -highly divergent from germline compared to known bnAbs against some other infectious agents -may require long times for elicitation
- Efficient elicitation of known bnAbs against HIV-1 may require initiation of immune responses by primary immunogens that could be different from the Env or Env variants and completion of maturation by Env-based immunogens

Chen W et al AIDS Vaccine Meeting Seattle 2007; Cape Town 2008; Xiao X et al Paris 2009, BBRC 2009; Xiao X et al Viruses 2009; Dimitrov DS mAbs 2010

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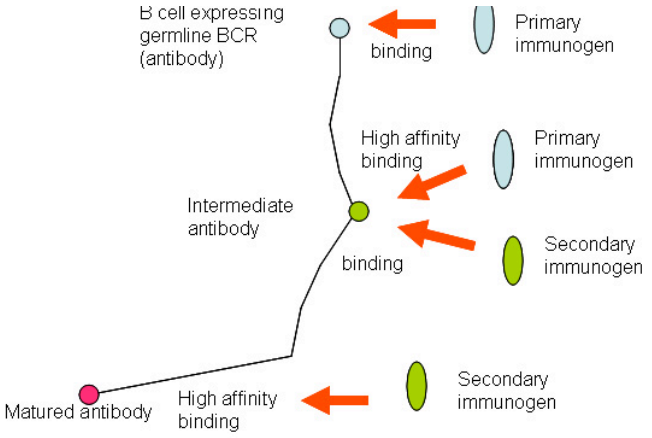
Elicitation of Known bnmAbs by Using Primary and Secondary Immunogens A Hypothesis – Proof of Concept?



Dimitrov DS SAB Meeting Durham 2008; Xiao X et al Viruses 2009; Dimitrov DS mAbs 2010

Current Research and Future Plans

- Synthesize, express and characterize putative primary immunogens, predecessors and intermediates of m66.6
- Identify novel putative primary immunogens by panning and screening of phage displayed libraries of peptides and proteins
- Evaluate combinations of primary immunogens and Envs as potential candidate vaccines in vitro and in animal models including mice with human germline antibody genes

Available Resources

- Germline-like predecessors of known bnAbs
- Two putative primary immunogens
- Envelope glycoproteins as secondary immunogens
- Antibody libraries, phage and yeast display, 454 sequencing – 1.5 mln antibody sequences, and other antibody/antigen-related reagents

Staff and Collaborators

NCI-Frederick
Z Zhu
W Chen
Y Feng
R Gong
M Zhang
P Prabakaran
J Owens
E Streaker
Y Wang
Q Zhao
H Qin
X Xiao
D Dimitrov

Duke University
H Liao
G Fouda
R Schutte
X Shen
M Alam
A Moody
S Munshaw
T Kepler
G Kelsoe
D Montefiori
G Tomaras
B Haynes

VRC
G Ofek
P Kwong

USUHS
Y Feng
G Quinnan
C Broder

NIH
N Longo

Overview and Deliverables
Topic 299 (HIV Vaccine)

Greg Evans, Ph.D.
Project Officer
NCI SBIR Development Center

- Goal: perform commercially directed research and development with this vaccine development technology from intramural NCI, and independently, to seek a commercialization license from the NIH Office of Tech Transfer
- Fast-Track proposals allowed: No
- Budget: $300,000 Phase I; $2,500,000 Phase II; 1 award only
- Duration: Phase I 9 months, Phase II 2 years

Deliverables for Topic 299 Phase I SBIR Contract

- Characterize in vitro the already identified putative primary immunogen for binding to human germline antibodies.
- Identify novel potential primary immunogens of bnAbs against HIV using putative germline predecessors of bnAbs.
- Perform in vitro characterization of the newly identified primary immunogens for binding to human germline antibodies.
- Obtain or generate and maintain mice that carry human germline antibody genes and that can be used as an in vivo model, e.g., can elicit high-affinity human antibodies by immunization.

Follow-On Phase II SBIR Contract

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Q&A for Topic 299

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If you send your question by e-mail, it will be read aloud by NIH staff.
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Overview of License Application Process

Richard U. Rodriguez, M.B.A.
Director, 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 managesinventions that arise from intramural NIH and FDA research. The NIH OTT serves as the bridge that connects these inventive discoveries to commercial partners that developthese technologies into products and services to benefit public health.
- In FY09
  - Managed ~1,300 active agreements
  - $1B sales
  - $91.2M 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 though 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 theinvention, 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 acommercial product that benefits the public.

- For commercialization rights, we require (issued claims) and/orrequest (pending claims) that an SBIR-TT contractor obtain a commercialization license.

U.S. Department of Health and Human Services
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http://sbir.cancer.gov/funding/contracts/

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."

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 invited.

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 298, the responsible LPM is Michael Shmilovich, shmilovm@mail.nih.gov
  - For Topic 299, the responsible LPM is Sally Hu, hus@mail.nih.gov
  - Michael and Sally will walk you through the licensing process.

For Further Questions

- Please see the SBIR-TT FAQ at: http://sbir.cancer.gov/frequently-asked-questions/
- 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 Anita Hughes, Contract Specialist, NCI Office of Acquisitions, anita.hughes@nih.gov.

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

Q&A for Licensing, Then for Any Topic

There are 2 options

- 1-raise your hand (physically, or electronically using the pull-down menu within the Attendee List window on the left side of the Adobe Connect Pro screen)
- 2-send your question in writing via e-mail to Jeff Klein at: kleinjc@mail.nih.gov

During the designated Q&A time slots, we will alternate taking questions in sequence from local versus remote participants.

If you raise your hand, you will be called on to voice your question

If you send your question by e-mail, it will be read aloud by NIH staff.

Closing Remarks

Greg Evans, Ph.D.
NCI SBIR Development Center

- Thanks to the presenters and audience (remote and local)
- Special Thanks to Cara Chrisman, NCI SBIR
- Content from this event to be posted on the NCI SBIR website within 1 week (proposal receipt date is 2 weeks away)

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

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National Institutes of Health

Important Information for Proposal Submission

PROPOSAL RECEIPT DEADLINE IS MONDAY NOVEMBER 8, 5 PM EASTERN TIME
http://sbir.cancer.gov/funding/contracts/
-see topics 298 and 299

http://grants.nih.gov/grants/funding/SBIRContract/PHS2011-1.pdf
-see pages 57-62

All technical inquiries from companies must be sent to:
Ms. Anita Hughes
Phone: (301) 435-3805
Fax: (301) 480-0309
Email: anita.hughes@nih.gov

Proposals to the NCI, if mailed through the U.S. Postal Service, must be addressed as follows:
Ms. Anita Hughes
Contract Specialist
Office of Acquisitions
National Cancer Institute
6120 Executive Blvd., EPS, Room 6038
Bethesda, MD 20892-7193