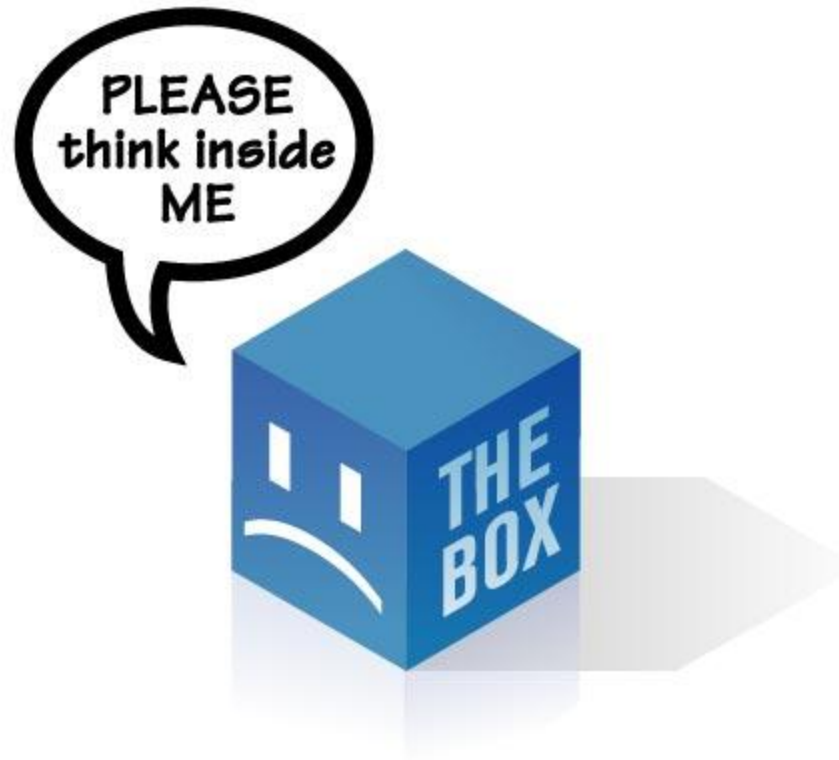


Federal Laboratory Consortium Midatlantic 2011

Let's think outside the box



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"Never, ever, think outside the box."

t h i n k i n g



- What can we do to foster and streamline our relationship with industry
- Samples of different transactions, processes from different agencies
- What's the premise: think about how we can structure our deals better, streamline, and be more efficient.

Communities of Practice

Providing Support for Commercializing DOD Technologies

Barry Datlof

Office of Research and Technology Applications

Medical Research and Materiel Command

United States Army

Fort Detrick, Maryland



FOR people facilitating technology commercialization

WHO need to cooperatively create, modify, store, discuss, present and use information

Matilda is a web-based, **daily portal and social network**

THAT allows multiple authors, editors, and users to share knowledge, Q&As, reference material, slides, feedback and other information;

UNLIKE older methods that have a limited scope of sharing and inherently lead to information sequestration and expiration

Matilda leverages collective wisdom and facilitates ongoing **daily** input and utilization by emphasizing collaborative input, reuse, and personalization

Sponsored by Gaumard

Email

Quick Mail

InfoWeb Topics

- Maternal-fetal medicine
- Reproductive endocrinology
- Reconstructive surgery
- Laparoscopic surgery
- Family planning
- Infertility
- Oncology
- Menopause
- Geriatric
- Military

Upcoming Meetings

ACOG Apr 30-May 4 D.C.

Chat Room

BarryD: CoP's and who can be a part
 ShadD: Can we discuss this at ACOG with Dave?
 DaveB: Can we offer the CoP free or take advertising?

Training

Podcasts & Videos

Jobs

Devices

Drugs

HIPAA

Calendar

InfoWeb

Rolodex

Matilda

Slides

Notes

<Links>

Bookstore

Whitepapers

Chat Room

Google Search

News

Maps

Tools

Ask the expert

Is there an iPad App for this CoP?

Submit

BJOG

AJOG

EJOG

Green

NYT

Post

Placenta Google

NOELLE[®]

Groups/RSS

MOES[™]

PM

4 Sale

Reform

ICD10

Laws

STD

My Audio

My Slides

My Video

Chat

PubMed

Diet

Kids

What is a CoP and Why Form It?

- A group of active practitioners across multiple organizations who share knowledge, contacts, data, tips, best practices, questions, and support for each other.
- Membership is restricted to those actually performing in the field of the CoP.
- CoPs share
 - Knowledge objects (e.g. white papers, ppts, templates, etc.)
 - Knowledge embedded within individuals (e.g. personal approach to a problem)
 - Knowledge embedded in a community (e.g. analyses of members' best practices)
- Benefits for technology development and commercialization
 - Disseminates DOD inventions to broader audience
 - Enhances DOD CoP member's role in the medical community
 - Supports Army licensee's commercialization efforts
 - Increases royalty revenue back to Army from increased sales by Licensee
 - Provides ability for Army to compare its practices and results with outside organizations
 - Provides forum for Medical Technology Transfer licensing personnel to seek input, leads, etc.

Technology Transfer Infoweb

Research ← Invention ← Intellectual Property ← Partnerships ← Commercial Development

Funding
Organization
Policies

IP Policies

Patents

Confidential
Disclosure

Marketing

Social
Networking

Laws
&
Regs

Notebooks

Copyrights

Material
Transfer

Licensing

Open
Innovation

Ethics

Invention
Disclosure

Trademarks

Contract
Services

Startups

Portals

Conflict
of
Interest

Invention
Evaluation

Trade
Secrets

Clinical
Trials

Financing

Search

SBIR
STTR

Inventorship

International

Consulting

Incubators

Audio/Visual
Presentation
Tools

Publishing

Interinstitutional
Agreements

PTO

CRADA's
Sponsored
Research

Economic
Development

Software

Special
Projects

Technology
Transfer
Training

Court
Decisions

Software
Intermediary

Tropical
Disease
Vouchers

Communities
of Practice
COPs

Knowledge
Management



**MEDICAL
TECHNOLOGY
TRANSFER**

Panini Contracts



“The First Bite of Eventual Self Service”



Barry Datlof

Office of Research and Technology Applications

Medical Research and Materiel Command

United States Army

Fort Detrick, Maryland

What Are Panini Contracts?

- **Front & Back page contain almost all deal terms**
- **Persona-based contract design**
 - What do our licensees want?
 - Time is of the essence
 - Show me the money
- **Features**
 - Front page identifies the who, what, when, where
 - Back page identifies how much

Integrated Term Sheet



EXCLUSIVE LICENSE AGREEMENT

THIS LICENSE AGREEMENT (**Agreement**), effective as of the Start Date, is made by and between: the U.S. Army [**Choose Lab**] (**Licensor**), as a subordinate laboratory of the United States Army Medical Research and Materiel Command (USAMRMC), having a place of business at [**Choose Address**], and [redacted] (**Licensee**), a [**Choose Type**] corporation, having a principal place of business at [redacted].

RECITALS

WHEREAS, the United States of America, as represented by the Department of the Army of which Licensor is a Federal Laboratory, is the owner by assignment or otherwise of the Licensed Technology; and

WHEREAS, under the authority of 15 United States Code (U.S.C.) 3701 *et seq.*, 35 U.S.C. 200 *et seq.*, and Title 37 of the Code of Federal Regulations (CFR), Chapter IV (together with any amendments and the underlying rules and regulations now or hereafter promulgated collectively), and the Federal Technology Transfer Act, Licensor has custody of inventions described and claimed in, and the right to issue licenses under, the Licensed Technology; and

WHEREAS, Licensor and Licensee desire, in the public interest, that the Licensed Technology be perfected, marketed and practiced so that the benefits are readily available for the widest possible utilization in the shortest time possible; and

WHEREAS, Licensee desires to obtain an exclusive license for the purpose of developing and commercializing the Licensed Technology and has the experience and ability to do so, and Licensee understands and acknowledges that any and all inventions and technology related to or arising out of the Licensed Technology would now and hereafter be subject to and governed by the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the premises noted above, including the above-cited statutory authority, and the mutual promises, covenants, duties and obligations hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Licensor and Licensee, intending to be lawfully bound, do agree as follows:

ARTICLE I: DEFINITIONS

Throughout this Agreement the capitalized terms defined in this Article and other sections have the meanings as set forth herein.

Key Definitions

- 1.1 **Licensed Field of Use** means [redacted] applications or uses for the Licensed Technology.
- 1.2 **Licensed Territory** means [redacted].
- 1.3 **Start Date** means the date [**Choose Start Date**], [of last signature to this Agreement | that the License Execution Fee is received by DFAS]
- 1.4 **Agreement Term** means the period commencing on the Start Date, and continuing in effect until the expiration of the last to expire patent application or Valid Claim of the Licensed Technology, including any extensions granted under the Patent Term Restoration Act or any other statute (as amended), or where Other Intellectual Property is included in the Licensed Technology, until [redacted] years from the

Parties

Field of Use

Territory

Start Date

Term



Appendix E: License Fees

Payment	Amount	Terms	Due	Other	Additional Terms (as described by the note on the preceding page)
License Execution Fee	\$50,000.00	2 equal payments of \$25,000.00	45 days after Start Date and February 15, 2012	Will be invoiced by Licensor	
Minimum Annual Royalty	5,000.00	Every year unless Earned Royalty is in excess of Minimum Annual Royalty	February 15 th	Prorated in first year; Will be invoiced by Licensor	1
Earned Royalty	5% for Therapeutics 8% for Diagnostics	Percentage amount times Net Sales	February 15 th and July 15 th	-	2
Milestone Payments	\$50,000.00 \$100,000.00 \$250,000.00 \$500,000.00 \$400,000.00	Commence Phase I Clinical Trial Commence Phase II Clinical Trial Commence Phase III Clinical Trial Each FDA Approval First Foreign Approval	45 days after milestone occurs	For each and every Licensed Technology	3
Sale/Merger Milestone	\$50,000.00	Sale/Merger of Licensee according to Clause 15.1	45 days after Sale/Merger completion	-	
Patent Reimbursement	\$66,656.55	3 equal annual payments commencing one year after Effective Date	February 15 th of each year	Will be invoiced by Licensor	
Future Patent Expenses	Ongoing	On an annual basis	February 15 th of each year	Will be invoiced by Licensor	
Patent Enforcement Expenses	As incurred	Proportional to Licensee/Licensor expenses	Semiannually	-	4
Patent Enforcement Proceeds	As awarded	Amount after Patent Enforcement Expenses and credited royalties are recovered;	45 days after Licensee receives payment(s)	-	4
Non-royalty Sublicense Income	25%	As defined in Clause 1.36	45 days after Licensee receives such income		5
License Termination Fee	\$2,000.00	Triggered by Termination by Default of Licensee or Termination at Will by Licensee	45 days after License Termination date	Will be invoiced by Licensor	
Regulatory Voucher Proceeds	24%	3 equal annual payments of 8% each	45 days after the later of the auction conclusion or the receipt of Third Party auction proceeds; and annually thereafter	Payments will be held in escrow until paid	6

Appendix E shall govern in the event of conflict with any terms of Article V





Deals for Compassionate Use

2011 FLC Mid-Atlantic Regional Meeting



A Human Monoclonal Antibody Protects Against Hendra Virus

Mark G. Scher, Ph.D.
Director, Technology Transfer &
Commercialization
The Henry M. Jackson Foundation
for the Advancement of Military Medicine, Inc.



JOTT



Uniformed Services University of the Health Sciences
and

The Henry M. Jackson Foundation
for the Advancement of Military Medicine

Joint Office of Technology Transfer

Protect and commercialize novel technologies developed at USU
by USU and HJF researchers



Hendra and Nipah viruses



- Paramyxoviruses (*Henipavirus*)
- Naturally infects:
 - Fruit Bats** (natural host)
 - Horses → Man
 - Pigs → Man
 - Man (Nipah)
 - Dogs
 - Cats
- BSL-4 restricted, select agents
- Highly pathogenic (**60% - 80% fatality rate in Man**)
 - Widespread multisystem vasculitis
 - Most severe clinical and pathological manifestations
 - brain, lung, spleen
 - Severe respiratory disease and/or acute encephalitis



Hendra and Nipah Viruses Passive Therapeutics



**Human monoclonal antibody m102.4 fully protects
in ferret and monkey models with no side effects**

Dr. Christopher C. Broder

Professor of Microbiology and Immunology
Director, Emerging Infectious Diseases Graduate Program
Department of Microbiology and Immunology
Uniformed Services University

Collaborator – National Institutes of Health

Collaborator - Commonwealth Scientific and Industrial Research
Organisation (Australia)



Hendra Virus Outbreaks

1994 - 2010



Date	Location	Horses, no. cases	Humans, no. cases/no. deaths
1994 Aug	Mackay, QLD	2	1/1
1994 Sep	Hendra, QLD	20	2/1
1999 Jan	Trinity Beach, QLD	1	0/0
2004 Oct	Gordonvale, QLD	1	1/0
2004 Dec	Townsville, QLD	1	0/0
2006 Jun	Peachester, QLD	1	0/0
2006 Oct	Murwillumbah, NSW	1	0/0
2007 Jun	Peachester, QLD	1	0/0
2007 Jul	Clifton Beach, QLD	1	0/0
2008 Jul	Redlands, QLD	5	2/1
2008 Jul	Proserpine, QLD	3	0/0
2009 Jul	Cawarral, QLD	3	1/1
2009 Sep	Bowen, QLD	3	0/0
2010 May	Tewantin, QLD	1	0/0
Total	14 events	44	7/4

Hendra virus...
August 2009/10





Timeline



August 2009

- m102.4 made under laboratory conditions (never used in humans) administered to an infected veterinarian as a treatment of last resort by Queensland Department of Health
- Based upon animal models, timing was too late and dose too low
- However, no adverse issues from administration of antibody
- Veterinarian dies

May - June 2010

- Request to USU from Queensland Government for m102.4 to be administered for compassionate use to mother and daughter whose horse died of Hendra virus
- m102.4 administered, no adverse issues
- Mother and daughter are doing well, follow-up tests continue
- Queensland Government requests m102.4 cell line to produce m102.4 under GMP to stockpile for future compassionate use
 - Queensland Government accepts all liabilities



“The drug has successfully prevented Hendra virus in animals when given before symptoms develop and was flown in from the United States”. (7pm TV News QLD)

Human monoclonal antibody m102.4

Authorities seek supply of Hendra antiserum June 1, 2010

A mother and daughter who opted to take an experimental drug to ward off the deadly hendra virus are being monitored by their local hospital as authorities make longer-term plans to combat the virus. Queensland health authorities are negotiating to buy a supply of the antiserum taken by Rebecca Day and her daughter, Mollie, 12.

Authorities want supplies on hand for other cases of potential exposure that may arise.





Hendra Virus Outbreaks

2011



2011 Outbreaks	Location	Horses, no. cases	Humans, no. cases/no. deaths
26-Jun	Kerry, QLD	1	0
28-Jun	Loganlea, QLD	1	0
30-Jun	Wollongbar, NSW	2	0
June-July	Mt Alford, QLD	3	0
3-Jul	Macksville, NSW	1	0
4-Jul	Park Ridge, QLD	1	0
11-Jul	Kuranda, QLD	1	0
13-Jul	Hervey Bay, QLD	1	0
14-Jul	Lismore, NSW	1	0
15-Jul	Boondall, QLD	1	0
22-Jul	Chinchilla, QLD	1	0
24-Jul	Mullumbimby, NSW	1	0
15-Aug	Newrybar, NSW	1	0
18-Aug	South Ballina, NSW	2	0
18-Aug	Mullumbimby, NSW	1	0
23-Aug	Currumbin Valley, QLD	1	0
28-Aug	North Ballina, NSW	1	0
Total	17 events	21	0

“Inverse Umbrella CRADA”

Courtney Silverthorn, PhD

SAIC-Frederick Inc.

FLC Mid-Atlantic Regional Meeting

October 5th, 2011

Standard Umbrella CRADA vs. 'Inverse' Umbrella CRADA

- Standard Umbrella CRADA
 - **Brings materials into NIH** for diverse projects across laboratories
 - One outside party
 - Multiple government/contractor investigators
 - One original CRADA followed by individual research plans
 - No transfer of funds
- 'Inverse' Umbrella CRADA
 - **Allows greater access to unique government resources**
 - Many outside parties
 - One government/contractor investigator
 - Each outside party signs a pre-approved M-CRADA template with a single research plan and an individualized "transfer document" appendix
 - Funds based on a per quantity basis

A New M-CRADA Model

- “Theory, not practice”
- Another way to streamline CRADA negotiations for specific projects
- Increase collaborations with both industry and academia, providing valuable data while increasing the strength and capability of the analysis being provided to the collaborator

Potential Applications

- Initially conceived by NCI for increasing outside party access to SAIC-Frederick's AIDS and Cancer Virus Program viral assay capabilities
- Also investigated as a measure to bring in funds for distribution of samples to third party requestors in the original model of the Cancer Human Biobank (caHUB)

VA's Blue Button

Maryam Azarion

**Department of Veterans Affairs
Office of General Counsel**

VA's Blue Button Trademark



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VA's Blue Button Trademark

- Demographic Information
- Emergency contact information
- Health care providers
- Health insurance
- Treatment
- Facilities
- Medical conditions and personal medical history
- Medications, herbals, supplements, allergies and adverse reactions
- Lab and test results, immunizations
- Vitals and readings
- Family health history (self and relatives), military health history
- Health data (blood sugar, blood pressure, weight, etc)
- Other health-related information the Veteran feels a doctor or hospital might need to know

Application for the Trademark License

- Apply online:
 - <http://www.va.gov/bluebutton/apps/license/index.cfm>
- Non-exclusive license
- Royalty fee licenses

America Competes Act

- “America Competes Reauthorization Act of 2010” or “America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Reauthorization Reauthorization Act of 2010.” (Public Law 111-358; Jan 4, 2011)
- Sec 105. Prize Competition – amends The Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq*).
- Permits the heads of agencies to carry out competitions to advance the mission of the respective agency.

VA Blue Button and America Competes Act *tie the knot*

- Award of \$50,000
- First team that builds a Personal Health Record (PHR)
- Use Blue Button TM
- Arrange to have PHR on the website of 25,000 physicians
- Software and systems permit download of individually identifiable information
- Comply with HIPAA
- Apply online
- License: nonexclusive and royalty free