



Partnership Development Update to NCI Frederick Advisory Committee

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May 30, 2012

**Frederick National Laboratory
for Cancer Research**

FNLCR Partnership Development

Presentation Outline



- Priorities
- Processes
- Key Partnering Opportunities
- Status Update : Partnership Development tools
- Discussion

FNLCR Partnership Development Priorities

Types of Partnerships



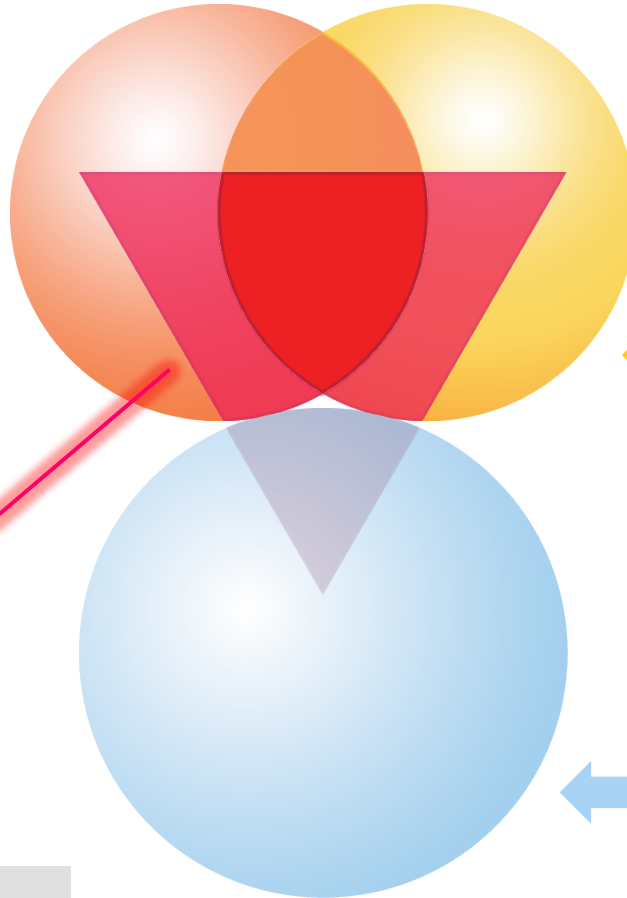
High Profile Partnerships

convey prestige to the NCI and its partnering efforts based on both the partner's name recognition and the goal



Example: big pharma evaluations of development-stage therapeutics in our preclinical models; technology development with major equipment manufacturer

Co-location of scientists at FNLCR boosts value of all partnerships



High Impact Partnerships

are closely aligned with specific strategic, scientific, or operational goals of the NCI, but may lack broad partner name recognition

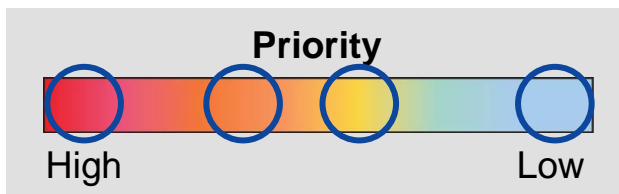


Example: SBIR / STTR recipients, award grantees, etc.

General Partnerships are aligned with broader NCI / government goals, but provide less reciprocal value



Example: collaborations which offset infrastructure costs; simple service agreements



FNLCR Partnership Development Priorities

Focus Areas



Partnering focus in Oncology & AIDS through applied technology programs of the FNLCR:

- Technology Development and Application
 - Genomics, proteomics, Advanced biomedical computing, Biomedical imaging & microscopy, Laboratory animal sciences program, Small animal imaging program
- Preclinical development acceleration
 - Nanotechnology (NCL), Genetically Engineered Mouse Models of cancer (CAPR)
- Clinical development support
 - Clinical Assay Development Center, Biopharmaceutical Development Program
- AIDS Cancer Vaccine Program

Not restricted to Advanced Technology Program or the ATRF

Frederick National Laboratory for Cancer Research Partnering Mechanisms Internal Reference Sheet

For general information use only

Acronym	Type of Agreement	Who can execute?		Can both participate?	Can NCI or FFRDC receive \$\$?	IP Promise	Which type of customer can engage?
		NCI/TTC	FFRDC/OTS				
CDA	Confidential Disclosure Agreement	yes	yes	yes	no	no	all
MTA	Material Transfer Agreement	yes	yes	yes	no	no	1,2,3,5
CTA	Clinical Trial Agreement	yes	no	yes	no	no	all
CA	Collaboration Agreement	yes	yes	yes	no	no	all
	Beta Testing Agreement	yes	yes	yes	no	no	all
TSA	Technical Services Agreement	no	yes	no	yes (FFRDC)	no	2,3,4,5
c-CRADA	Contractor CRADA	no	yes	no	yes (FFRDC)	yes	2,3,4,5
NCI CRADA	Cooperative R&D Agreement	yes	no	yes	yes	yes	3,4,5
-u-CRADA	-- Umbrella CRADA	yes	no	no	yes	yes	3,4,5
	-- Clinical Trial CRADA	yes	no	yes	yes	yes	all
-m-CRADA	-- Materials CRADA	yes	no	no	yes	yes	3,4,5
IAA or IAG	Interagency Agreement	yes	no	no	yes	n/a	2

Yellow indicates new offering

Types of Customers

- 1 NIH Researcher (includes NCI)
- 2 Other Federal researcher (i.e., CDC, DHS, USAMRIID) →
- 3 Academic researcher (may be a grant recipient) →
- 4 Researcher employed by a commercial entity →
- 5 Non-Federal government funded researcher, i.e., state university →

All can use TSA and
c-CRADA

FNLCR Partnership Development Processes

Contractor agreements



Technical Service Agreement (TSA)

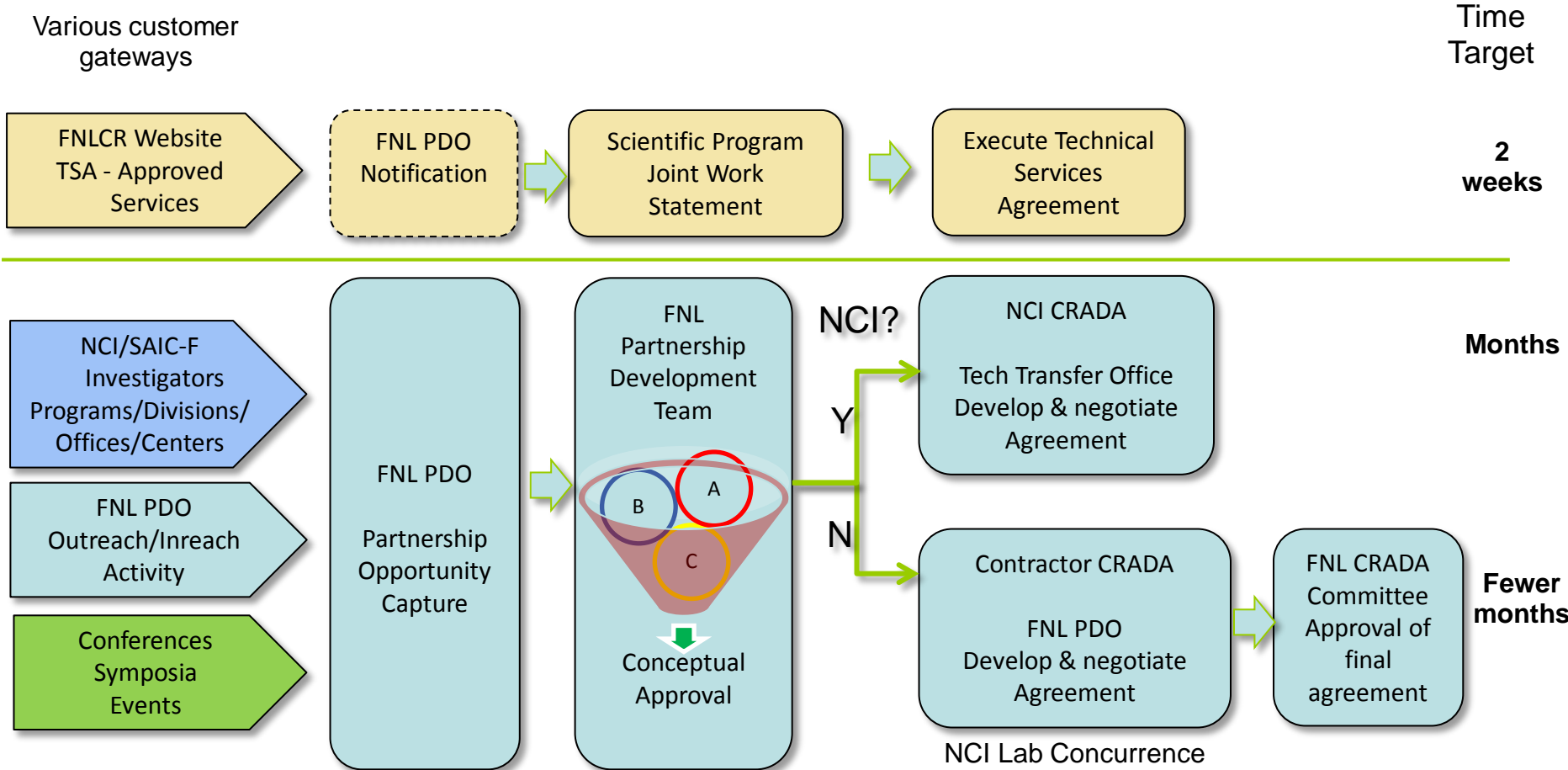
- Pre-approved services (under final review May 2012)
- Requires
 - Cost Estimate
 - Signed Agreement by the Outside Party and SAIC-Frederick CEO
 - Receipt of Funds Prior to Beginning Work

c-Cooperative Research and Development Agreement (c-CRADA)

- Requires
 - Completion of a Concept Approval Form for review by the FNL Partnership Development Team
 - Approval by the NCI Program
 - Approval by the NCI Management Operations and Support Branch (MOSB)
 - Receipt of Funds (Milestone Payment) Prior to Beginning Work

FNLCR Partnership Development Processes

Opportunity Capture, Concept Approval, Agreements



FNL PDO = Frederick National Laboratory Partnership Development office
 TSA = Technical Services Agreement (Contractor M-CRADA)

FNLCR Partnership Development Processes

Test Exercises



NCI “customers” submitted virtual partnership project requests:

- TSA request ; SIV qPCR/RT-PCR assays in AIDS Cancer Vaccine Program (ACVP)
- Therapeutic agent testing in Nanotechnology Characterization Laboratory (NCL)
- Contractor CRADA : Transgenic mouse development platform development with Laboratory Animal Sciences Program (LASP)
- Contractor CRADA : Evaluation of HDAC inhibitors for HIV (ACVP)
- Contractor CRADA : Develop therapeutic delivery system using virus-like particles (PEL)





Lessons learned and “tune-ups” in progress:

- TSA: Goal of 10 business day process turnaround; achieved 17 days
 - Cost estimate forms have been streamlined; report formats tuned-up
- CRADA (LASP): Process through FNL Partnership Development Team went smoothly; clarifications needed for conceptual approval; PDO to engage program sooner
- NCL: Projects declined due to poor strategic fit with program mission



FNLCR Partnership Development Opportunities

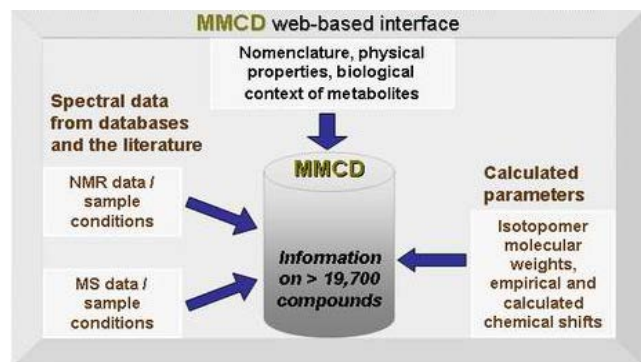
Sample Market Segments and Scenarios

Partner	Segment	FNLCR Lab/Program Alignment	Project/Mechanism
	Pharma	Center for Advanced Preclinical Research Cancer therapeutics development	Lung cancer GEM model novel kinase inhibitors NCI CRADA
	Biotech	Laboratory of Proteomics & Analytical Technologies (LPAT) Technology development	Develop Metabolomics Discovery Center/ Potential Contr. CRADA
	Information Technology	Advanced Biomedical Computing Center Technology development	Bioinformatics cloud computing workflows/ Potential Contr. CRADA
	Non-profit Research Inst.	HPV Immunology Laboratory Assay development and validation	HPV vaccine studies/ NCI CRADA or Ctr CRADA
	Academia	Electron Microscopy Laboratory Advanced imaging techniques & assays	3-D EM tomography Potential Contr. TSAs

Scientific partnerships benefit FNLCR laboratories and partnering organizations by making personnel, services, facilities, expertise, material, and equipment accessible to both partners.

Agilent: HP / HI / Co-location Opportunity

Metabolomics Discovery Lab



- Agilent and FNLCR will develop a combined MS/NMR center to identify metabolite biomarkers of cancers
- Initial studies will utilize a unique mouse model of ovarian cancer in which tumor development is tightly controlled
- Metabolomic data will be combined with genomic and proteomic data from same mouse models to distinguish disease-related changes from background variation
- Discoveries made using the mouse model will be validated in both mouse and human diseases



Successful outcomes are strengthened through the hardware and software capabilities afforded through Agilent Technologies, cancer models available within the NCI, and metabolomics expertise at the FNLCR

Contractor CRADA Management Status



- ✓ CRADA and TSA template agreement documents finalized
- ✓ CRADA Concept Approval Forms finalized
- ✓ Management process mapped
- ✓ Management process training completed for ATP, LASP, ACVP laboratories/programs
- ✓ External FNLCR Website (TSA services)—usability/functionality testing complete

Items in final stages of completion


- Approved list of TSA services (May 2012)
- Pilot CRADA scenario test runs
- Deviated FAR clauses review and approval (TBD)
- Contract Modification (TBD)

FNLCR Website: Functionality Testing Completed

View of Services Landing Page



Frederick National Laboratory for Cancer Research

 For Our Staff

Enter search term



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Home: Products and Services

Products and Services

The Frederick National Laboratory for Cancer Research translates basic research findings into new technologies and treatments for patients with cancer and AIDS.



▶ Animal Sciences

Providing cutting-edge animal services through highly developed expertise and technologies.



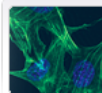
▶ Nucleic Acid Technologies

Developing the tools and assays to define the molecular signatures of cancer and HIV/AIDS.



▶ HIV/SIV

The AIDS and Cancer Virus Program is an integrated, multidisciplinary program that pursues basic and applied studies.



▶ Imaging/Microscopy

Providing a broad range of training and support, including image acquisition and quantitative analysis.



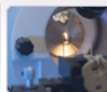
▶ Pre-clinical & Clinical Assays

The Frederick National Lab has expertise covering a broad spectrum of testing and clinical trial support.



▶ Biopharmaceuticals

Product Development, GMP Manufacturing Resources and Preclinical Reagent Repository



▶ Proteins & Proteomics

Protein expression, detection, and characterization technologies that define complex interactions leading to cancer.



▶ Tumor Repository

Transplantable in vivo-derived tumors and in vitro-established tumor cell lines from various species.



▶ Still need help?

For general questions, please e-mail our Project Officers at ncifoso@nih.gov or call 301-846-1108.

FNLCR Partnership Development

Recruiting New Leadership



Chief Technical Officer, SAIC-Frederick

- Atsuo Kuki, Ph.D. will join SAIC-Frederick July 9
 - BS Chemistry (Yale); PhD Biophysics (Stanford)
 - Joined Chemistry faculty at Cornell, followed by 15 years drug discovery experience in Biotech and Pharma in Chemistry and Discovery Technologies
- Recruiting and candidate evaluation assisted by interviews with local NCI leadership and external search committee



FNLCR Partnership Development

Advanced Technology Research Facility



Ceremonial Ribbon Cutting on May 21, 2012

- Concurrent with Frederick County Chamber of Commerce Centennial celebration
- 700 state and local business leaders, politicians, and dignitaries

Substantive completion mid-June

Scientist moves begin immediately thereafter



Frederick National Laboratory for Cancer Research

FNL Partnership Development

Conclusions



- Top priority for new partnerships will be with high-profile partners seeking co-location at FNL for scientific collaborations providing substantive and durable benefit to the AIDS and cancer research community
- Management processes for review, approval, and management of FNL contractor partnering opportunities have been established
 - Require real-world validation
- Sustained outreach activities have identified a number of potential opportunities
 - No deals signed yet
- Elements of Contractor CRADA authority still await government approval

Questions & Comments?