

FFRDC Business Operations Overview

Intellectual Property, Partnering, and Technology Transfer

Current Determination of Exceptional Circumstances (DEC)

- Under the DEC, the prime FNLCR Contractor assigns inventions to the Government except for c-CRADA Subject Inventions.
- c-CRADA Subject Inventions are conditionally-owned and managed by the FNLCR Contractor
- Subcontractors retain ownership of inventions except in the following circumstances where they assign ownership to the Government or designated third-party:
 - When using third-party proprietary materials or information provided to the NIH
 - When using compounds developed intramurally at NIH or repurposed drugs that are in development towards potential clinical therapeutics

Invention Reporting

- All inventions including those Conditionally-owned by the Contractor are reported to the NCI through designated channels on the current reporting forms.
- The Contractor will cooperate with the Government to provide necessary information to allow appropriate review and patent filing of inventions assigned to the Government.
- The Contractor will deposit invention information into iEdison as appropriate.

Direct Support of the Government's Research Agreements

- Cooperative Research and Development Agreements (CRADA)
- Collaboration Agreements
- Support may include:
 - Personnel
 - Research Services
 - Expertise
- Per the DEC, contractor Inventions are assigned to the Government

Current Contractor Partnering Mechanisms

■ **Collaboration Agreement**

- No exchange of funds
- No advance option to inventions developed by the Contractor
- Inventions assigned to the Government

■ **Contractor-CRADA (c-CRADA)**

- Contractor may offer an advance option to inventions to the c-CRADA Partner and accept CRADA funds
- No direct involvement in the research by Government personnel
- Contractor has conditional ownership of c-CRADA Subject Inventions
- Contractor can manage c-CRADA Subject Inventions and associated patenting, licensing and royalties to benefit the FNLCR

Invention Development Program (IDP)

- Funds preclinical validation projects with the goal of de-risking co-development and in-licensing of NCI Research inventions by private sector organizations.
- The FNLCR Project Manager coordinates with the NCI POC for each project including partnering, project management, financial management, and project-specific reporting.
- Preclinical support provided by the prime contractor or subcontractors as appropriate
- There are approximately six projects ongoing per year.



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Subcontracting, Purchasing & Finance

Government Owned-Contractor Operated (GOCO) responsibilities

Government

- Provides oversight
- Provides infrastructure
- Provides systems
- Provides equipment
- Provides property

Contractor

- Operates facility
- Utilizes in-place systems
- Performs/manages the work
- Ensures required licenses, certifications, and accreditations are maintained

Managing the FFRDC's Research Projects

- To successfully achieve the FNLCR scientific mission – manage and administer a system of internal controls for all business and administrative operations.
 - Integrating common systems of internal controls across the FFRDC and implementing business processes that are risk-based, cross-functional, cost-effective, increase efficiency and enhance productivity
 - Supporting the NCI mission through the identification and application of enterprise-wide processes, throughout the FNLCR Enterprise, to optimize and streamline business practices and administrative functions

Subcontracting and Purchasing Management

- The prime contractor may enter into subcontracts and agreements to execute the work outlined in the Statement of Work (SOW) for the FNLCR.
- Generally terms and conditions of the prime award will flow-down to subcontracts
- Expectation that the prime contractor utilize streamlined acquisition strategy approaches, such as strategic sourcing activities and centralizing for the FNLCR.

Examples of agreements:

*Leases

*Consultant Agreements

*Purchase Orders

*Travel Orders

*Maintenance Agreements

*R/R&D Subcontracts

*Facility Remodeling/Refurbishment Subcontracts

*Service Subcontracts

Financial Management

- All financial aspects of an FFRDC must interact/interoperate
 - Integration of all operational aspects
 - Tracking by fiscal cycle(s)
 - Contractor accounting processes will meet the needs of Government accounting and Government financial systems
 - Streamlined, flexible and transparent financial management/cost reporting system
 - Capable of tracking, evaluating, and projecting financial activities for projects
 - Integrate data from scientific, Facilities Operations and Management, and other Govt. support functions
 - Detailed, accurate and timely reports for cost and scope, and accurate schedule estimates

Financial Management cont.

- Inclusive of direct and indirect cost breakouts for cost-benefit analysis to determine appropriate level of support function and risk.
- Full transparency of all financial cost reporting systems and reports to allow visibility into program and cost management
 - Contractor and Govt. collaboration to identify and collect common productivity and labor cost data to seek FNLCR-wide solutions
 - As requested, develop additional custom ad hoc reports
- **Contractor financial systems will integrate with Government financial management systems to verify and document financial stewardship.**

*Collection

*Effective Internal Control System for All Expenditures

*Recording and Reporting Financial Activities

Financial Management Support

- The contractor will support Government:
 - Planning
 - Programming
 - Budgeting
 - Evaluate financial status through budgeting system, with real-time reporting capabilities, for the formulation and execution of resource requirements.

Financial Management Electronic Support

- Maintain electronic business/data systems for organizational operations
 - Data collection purposes
 - Data processing
 - Report generation
- Maintain and administer an approved electronic financial management system
 - Budgeting system capable of identifying all resource requirements for projected work
 - Internal financial control system for tracking and expenditure of funds obligated
 - Invoice preparation that is clear and concise, and meets the needs of the Government for providing approval

Property Management and Internal Audits

- Property Management & Accountability
 - Manage, track, and report accountable Government owned property while ensuring safeguarding and disposition when appropriate
- Internal Audits
 - Establish, maintain, and routinely execute audits, reviews, and appraisals



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Scientific Recruitment & Project Management

Human Resources

- Robust recruitment program that promotes and attracts a diverse workforce
- Effective and innovative approaches for hard to fill positions
- Hire and retain highly qualified employees

Human Resources (cont.)

- Constant evaluation of current & future workforce expertise, performance and staffing levels
- Developing appropriate workforce management and transition strategies
- Obtaining additional workforce in real-time as needed
- On-boarding / off-boarding

Project / Program Management & Support (Positions)

- Project / Program Managers (PMs)
- Scientific Project / Program Managers (SPMs)
- Meeting Support
- Writers

Project / Program Management & Support (Activities)

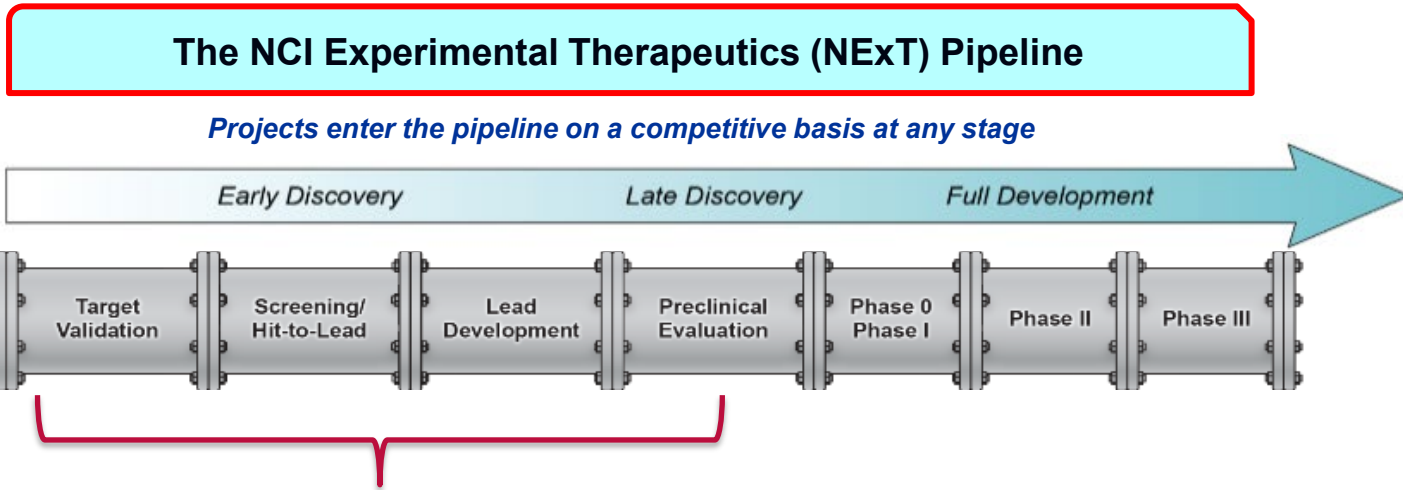
- Planning and oversight of activities
- Logistical, administrative and technical support
- Development, management & reporting of budgets, costs, timelines and performance
- Regular communication with Govt.
- Transparency and responsiveness
- Quick response to needs and ability to adjust to changes

Project / Program Management & Support (Goals)

- Streamline project support
- Integrate business / administrative processes
- Provide nimble, transparent and responsive support

Examples

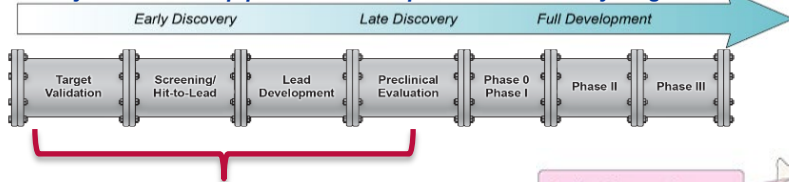
NCI Experimental Therapeutics (NExT) Projects



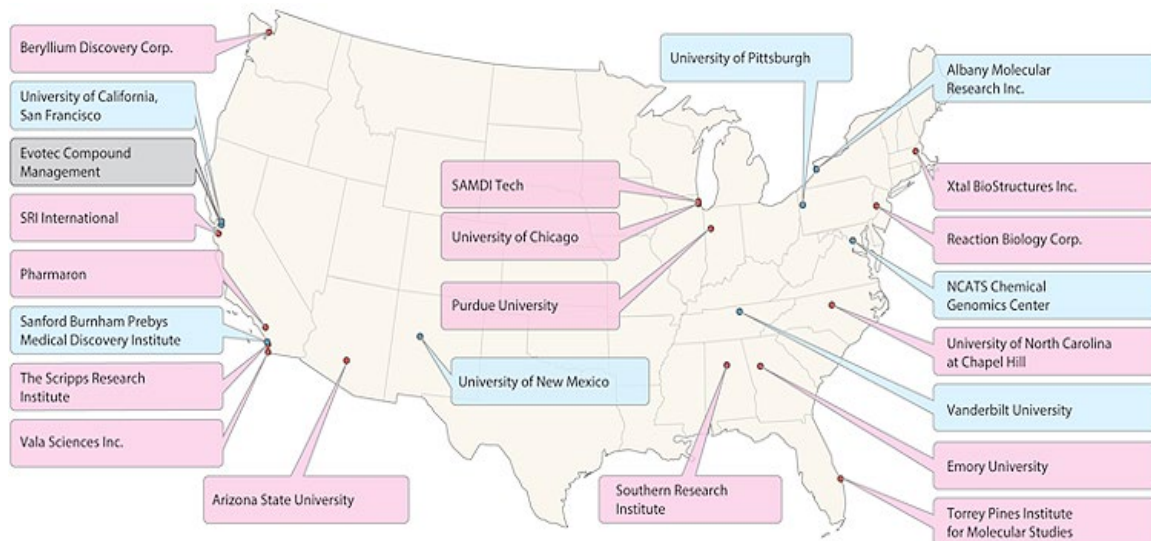
NCI Experimental Therapeutics (NExT) Projects

The NCI Experimental Therapeutics (NExT) Pipeline

Projects enter the pipeline on a competitive basis at any stage



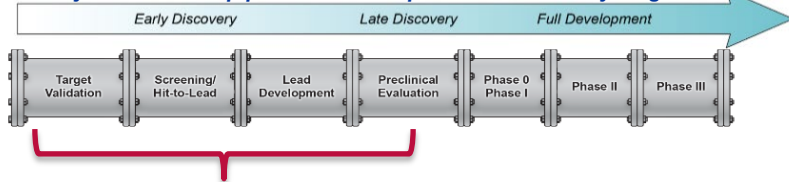
Chemical Biology Consortium (CBC)



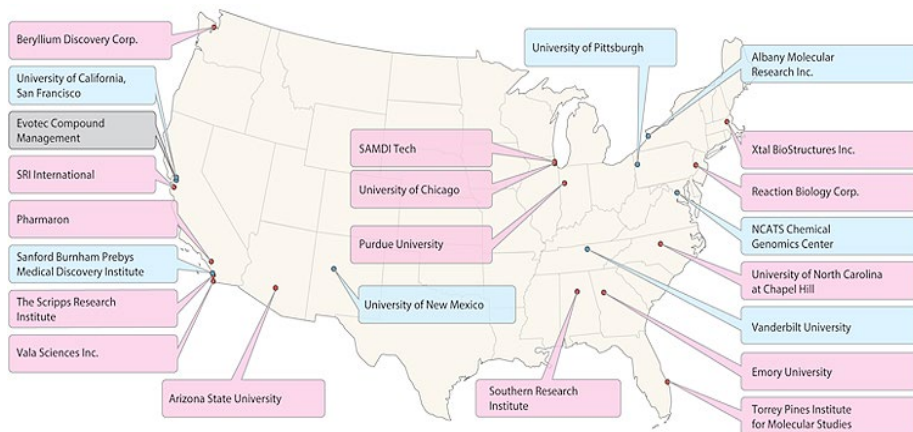
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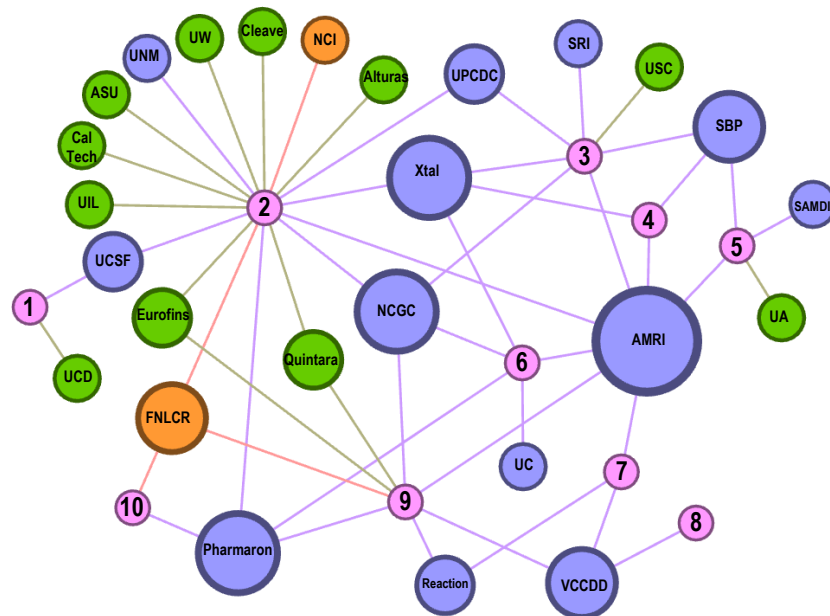
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Chemical Biology Consortium (CBC)



Project Node Map



Canine CTLA4 Therapeutic Ab Development

- Multiple FNLCR Components
 - Biopharmaceutical Development
 - Pharmacokinetic/dynamic Assay Development and Implementation
 - Protein Expression and Purification
- Multiple Coordinated Activities
 - Immunization, hybridoma isolation, chimerization, caninization, mfg
 - Monoclonal antibody screening assay development
 - Expression and purification of immunogen and screening assay proteins

Canine CTLA4 Therapeutic Ab Development

- Multiple Technical Approaches
 - ❖ Immunization of mice and dogs followed by hybridoma screening
 - ❖ Immunization of dogs and plasma cell RNA library screening
 - ❖ Phage-display library screening
 - ❖ *In vitro* booster vaccination

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Summary

- This is an R&D Contract
- Plan for the known unknowns
- Be able to pivot, reallocate resources, adjust staffing in response to the unknown unknowns
 - ✓ Sudden initiatives – ARRA, Cancer Moonshot, Ras
 - ✓ Disease outbreaks – Ebola, SARS-CoV-2
 - ✓ Emerging technologies – CryoEM



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Questions?

*All questions must be entered
into the Webex chat*

OVERVIEW OF PROCUREMENT PROCESS

Procurement Process Authority

- Only a warranted Contracting Officer with the appropriate, delegated authority may bind the Government
- Discussions you may have today are for information only (past and current activities)
- Procurement Sensitive Information **MUST NOT** be discussed (future activities)
 - Questions regarding this acquisition should be directed to the Contracting Officer via FNLCR_ACQinfo@nih.gov
 - To do otherwise could put your organization at risk for being excluded from the competition
- Official Government requirements will be set forth in the solicitation
- A formal Questions and Answers process will be discussed later

General Background

- The NCI contemplates a new contract will be awarded with an ordering period of 10 years.
 - Anticipate an Indefinite Delivery – Indefinite Quantity (IDIQ) contract with both severable and non-severable Task Orders. Options may be included.
 - Anticipate most, but not all, work will be cost reimbursement in nature with a negotiated fee if applicable.
 - Ceiling for the new award is to be determined; anticipated ceiling will be above \$15B.
 - The ceiling is a maximum contract value that cannot be exceeded by the total of all combined Task Orders awarded under the contract.
 - The ceiling is NOT a direct funding level.

General Background – (cont'd)

- NCI contemplates the source selection process utilized will reflect a best value process with the potential for an award to other than the lowest priced offeror.
- All evaluation factors and significant sub-factors and their relative importance will be clearly stated in the solicitation.
 - Technical capability will be of paramount importance in this acquisition
 - Subcontracting plan will be a critical evaluation factor
- Additional information concerning the competitive process will be announced on the Government-wide point of entry, Beta Sam at <https://beta.sam.gov/>, as well as at the FNLCR Acquisition Portal at <https://www.cancer.gov/about-nci/contracts/fnlcr-acquisitions>.
- **Information posted on Beta Sam takes precedence over information provided elsewhere.**

The Statement of Work

- Objectives and activities of the FFRDC are dynamic and subject to continuing evolution
- The Statement of Work must *not* be all-inclusive or restrictive and must encompass a wide range of scientific disciplines
- This model has been used by other FFRDCs and allows for a broad scope that is further defined by specific Task Order
- It is intended to provide a broad framework for the work to be performed at the FNLCR during the contract term
- The RFI which contains the draft Statement of Work is available on the FNLCR Acquisition Portal at <http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents> or on Beta Sam

The RFP

- The NCI contemplates the following general schedule (subject to change)
 - Draft RFP Issuance 3rd Quarter FY21
 - RFP Issuance 1st Quarter FY22
 - Receipt of Proposals 3rd Quarter FY22

 - Contract Award is planned in Fall 2023, subject to change.
 - The Government expects to provide 150 days for proposal response.

Questions and Answers

- Question for the Q&A Session immediately following these presentations must be submitted in the “Chat Box” in Webex.
- For questions following Industry Day, these questions must be submitted to the FNLCR_ACQinfo@nih.gov
 - A clear subject line indicating “QUESTIONS”
 - Email box is continuously monitored
 - Responses will not be provided via email
- All responses to questions received will be published on Beta Sam and the FNLCR ACQ Portal
- The FNLCR Acquisition Portal will maintain a comprehensive list of all questions and responses
- The Government expects to publish questions and answers weekly

Additional Information

- For more background information on the FFRDC please visit the following sites:
 - Frederick National Laboratory for Cancer Research (FNLCR)
<http://frederick.cancer.gov>
 - National Cancer Advisory Board (NCAB)
<http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm>
 - Frederick National Laboratory Advisory Committee (FNLAC)
<http://deainfo.nci.nih.gov/advisory/fac/fac.htm>
- **Send all questions via email to: FNLCR_ACQinfo@nih.gov (FNLCR_ACQinfo@nih.gov).**



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THANK YOU

- Breakout Sessions
 - All questions must be submitted into the Webex chat box
 - Any questions not answered during the breakout session will be posted on beta.sam.gov in a Q&A format
- Subsequent questions submitted to FNLCR_ACQinfo@mail.nih.gov
- Closing Remarks