

# Frederick National Laboratory for Cancer Research



## Overview of FNLCR Process, Progress, and Programs

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The Frederick National Laboratory is a federally funded research and development center operated by SAIC-Frederick, Inc., for the National Cancer Institute  
DEPARTMENT OF HEALTH AND HUMAN SERVICES • National Institutes of Health • National Cancer Institute

# Overview of Frederick National Laboratory for Cancer Research

Frederick  
National  
Laboratory  
for Cancer Research

**FNLCR is the only Federally Funded Research and Development Center (FFRDC) dedicated exclusively to biomedical research**

- Proudly operated in the public interest by **Leidos Biomedical Research, Inc** (formerly SAIC-Frederick) on behalf of the National Cancer Institute

**Main campus located on 70 acres at Ft. Detrick, MD**

- Leidos Biomed employees co-located with NCI researchers and other contractors on the NCI Campus at Frederick
- Additional Leidos Biomed scientists at Bethesda and Rockville sites



## ***Mission***

Provide a unique national resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis and treatment of cancer and AIDS.

## FNCLR – Why an FFRDC?

- **The FFRDC provides the NCI unique acquisition and response capabilities, including:**
  - **Flexibility** – due to the broad charter and use of contractor staff
  - **Rapid Response** – new or cutting edge projects can be accomplished more expeditiously.
  - **Increased Efficiency** – due to
    - broad latitude in subcontracting
    - unforeseen work can be added without additional fee, indirect/infrastructure cost, or contract administration or oversight.
- **The FFRDC designation requires FNLCR to meet the NCI's rapidly changing needs that cannot be achieved *as effectively* by other NCI components or through other government mechanisms.**

## Leidos Biomedical Research, Inc.

A wholly-owned subsidiary of **Leidos Holdings, Inc.**, solely dedicated to one mission :



## Frederick National Laboratory for Cancer Research

The *staff* of FNLCR are *employees* of Leidos Biomedical Research, Inc.

# What is Leidos Holdings, Inc.?

## Securing the Future

Helping make our communities, our nation and our world a better place for generations to come.

### National Security

Delivering innovative solutions that help protect freedom in all domains — air, land, sea, space and cyberspace.



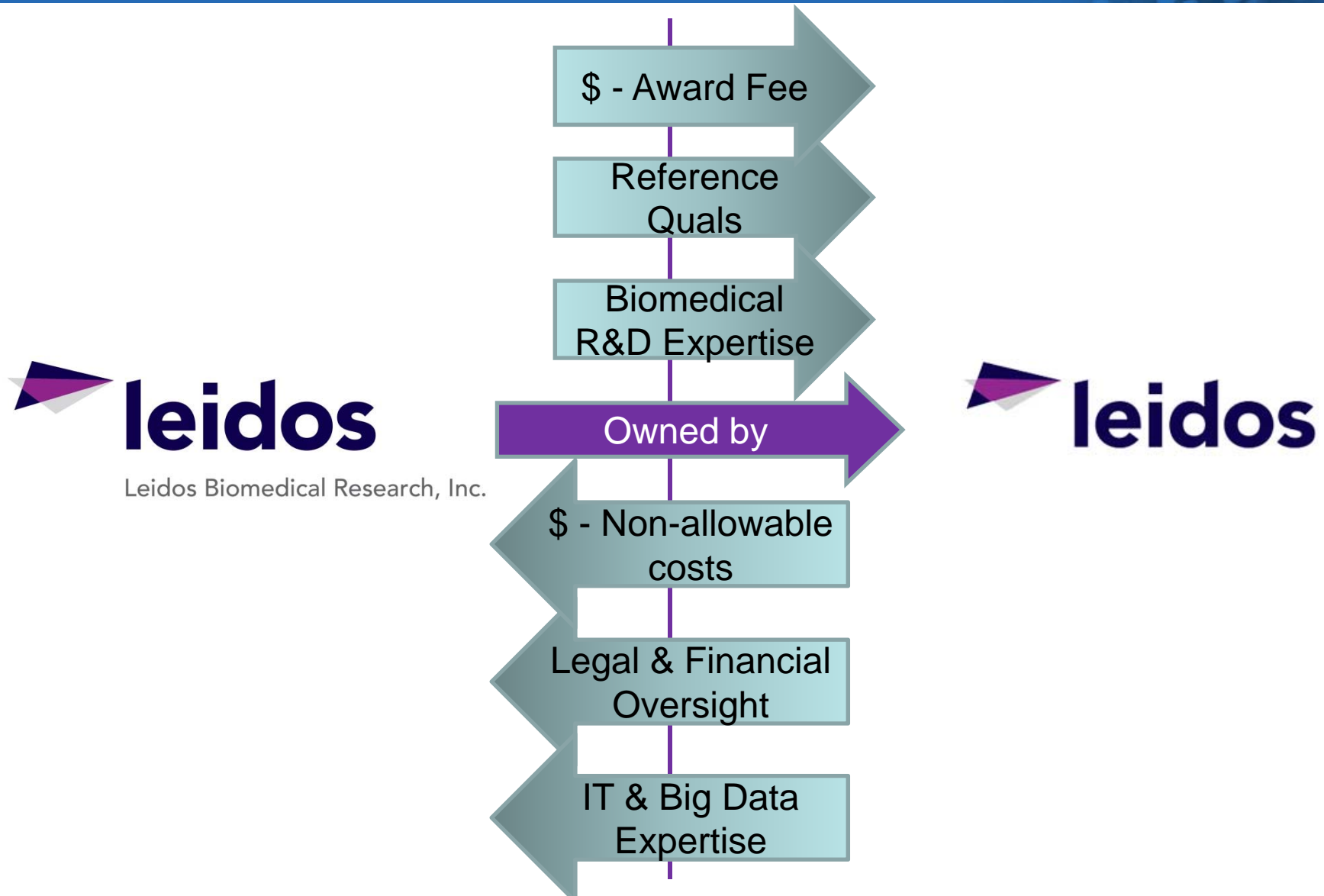
### Health

Advancing health technology to improve patient care, reduce healthcare costs, and enhance public health.

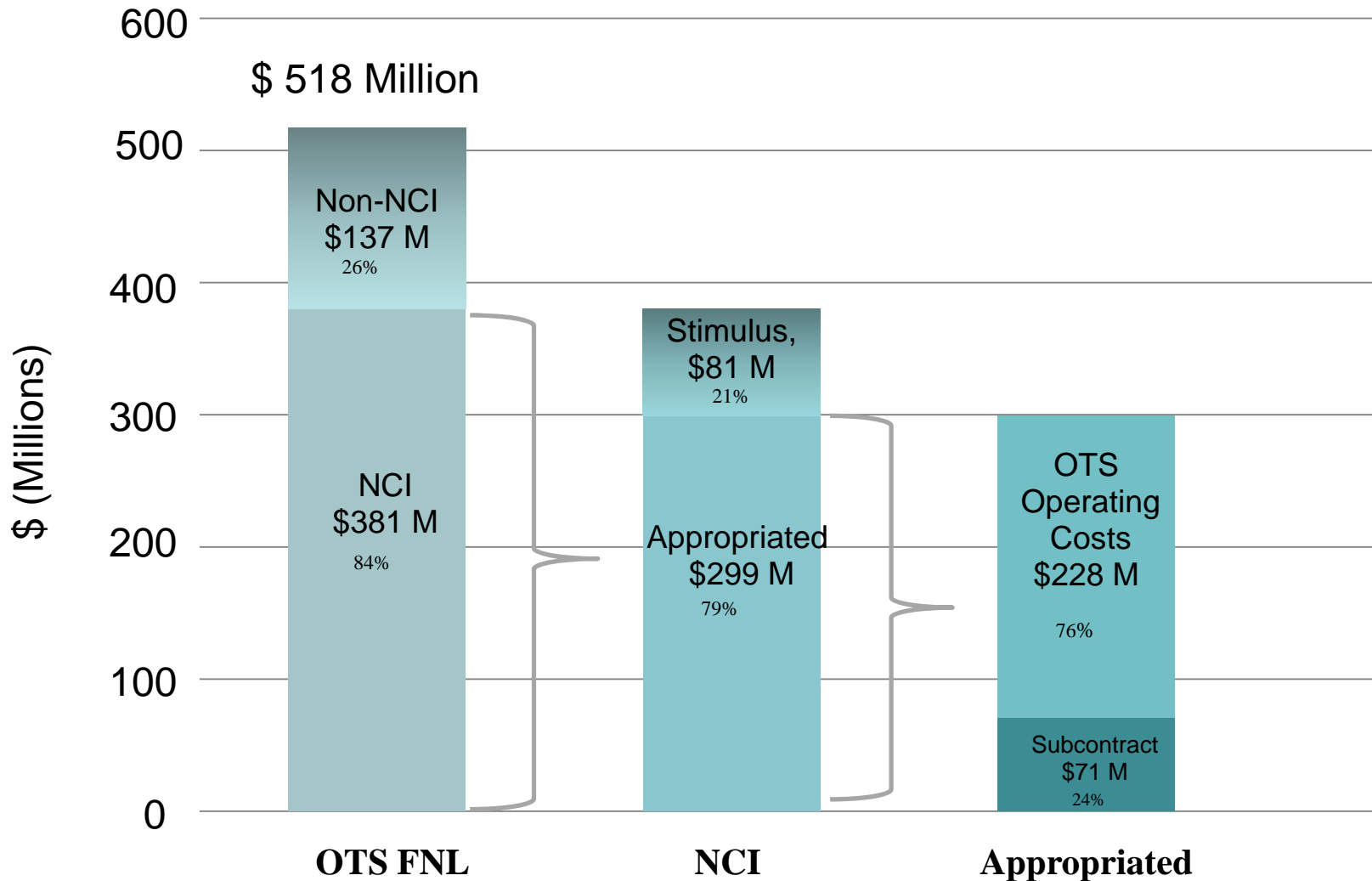
### Engineering

Passionate about protecting our environment and making energy supply and delivery smarter, cleaner, and more reliable.

# Interplay between Leidos Biomedical Research and our Corporate Parent



# FNLCR Operations and Technical Support Contract FY13 Estimated Cost



# FNLCR OTS Contract

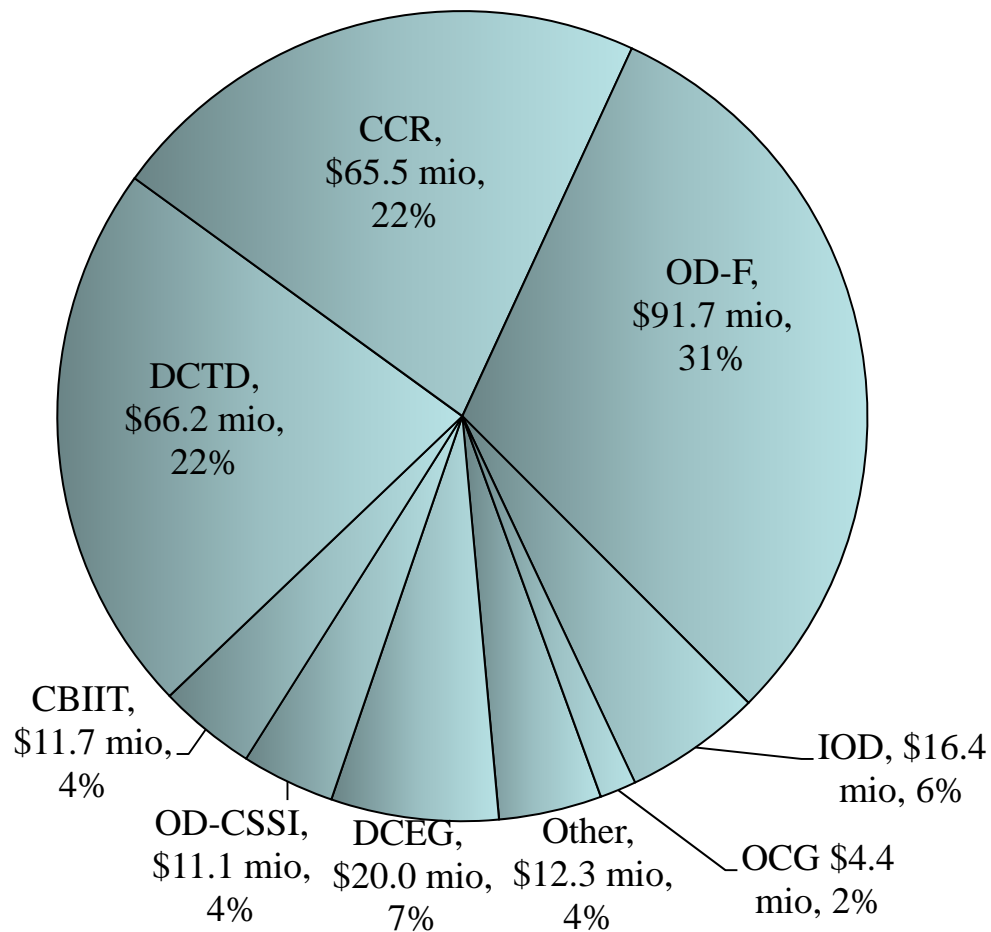
## *Show me the money...*

- **Individual Divisions, Offices, and Centers decide how much of their budgets they want to spend on FNLCR science and services**
  - Infrastructure, management oversight, and shared services are funded by the Office of the Director
  - Virtually all other staff are “dedicated” to the DOC that funds them
- **Changes in work at FNLCR are performed through an electronic approval called a “Yellow Task”**
  - Initiated by a government “customer”, the request is vetted for suitability for FNLCR by the Project Officer and the Contract Officer (both are NCI)
  - The appropriate FNLCR program develops a budget and workplan with the customer
  - Plan and budget are approved by customer and the Administrative Officer (NCI) and the OTS contract is modified to reflect change in funding
- **Yellow Tasks by the numbers (FY13)**
  - 195 YTs submitted by 23 divisions, institutes, and other government agencies
  - Total value of all cost estimates approved - \$243 Million (spanning up to 5 years)
  - Average YT turnaround time : 38 days (range 4 to 160)
  - YT-13-072 – “KRAS Startup Initiative” – Approved Apr 1, 2013 (13 days)



# FNLCR OTS Contract FY13 Estimated Cost

**NCI Appropriated  
Total: \$299.2 Million**



**CBIIT** – Center for Biomedical Informatics and Information Technology

**CCR** – Center for Cancer Research

**DCEG** – Div. of Cancer Epidemiology and Genetics

**DCTD** – Div. of Cancer Treatment and Diagnosis

**IOD** – Immediate Office of the Director

**OCG** – Office of Cancer Genomics

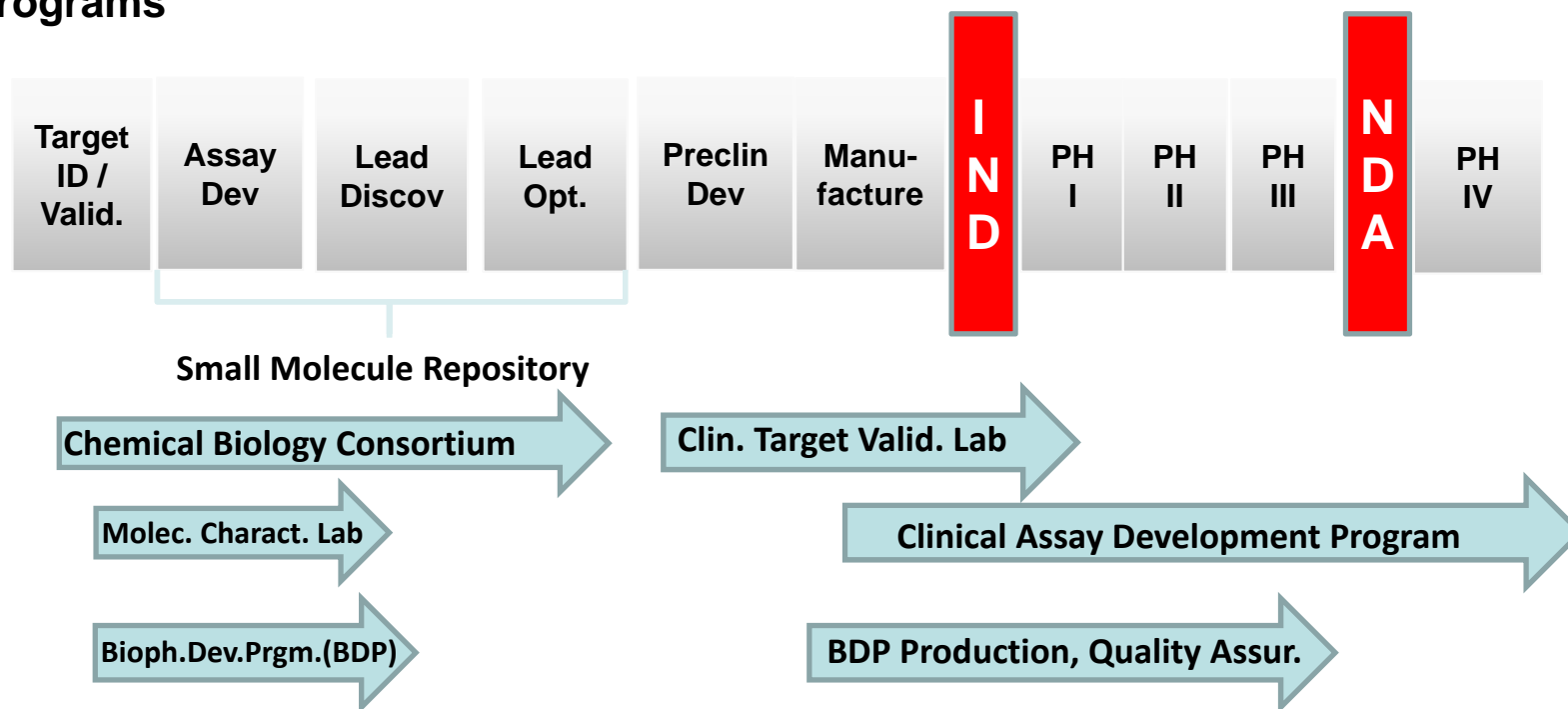
**OD-F** – Office of the Director - Frederick

**OD-CSSI** – Office of the Director - Center for Strategic Scientific Initiatives

# DCTD : The NCI Experimental Therapeutics Program (NExT)

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National  
Laboratory  
for Cancer Research

- NExT is led by the Division of Cancer Treatment and Diagnosis to create a coordinated cancer therapeutics discovery and development pipeline with the external scientific community
  - Projects evaluated by extramural Special Emphasis Panel
- FNLCR provides operational and dedicated technical support to all phases of NExT programs



# DCTD : Biopharmaceutical Development Program (BDP)

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for Cancer Research



- Established in 1993 to provide specialize expertise and service not available in the commercial market



150 L and 500 L Fermentors

- **More than 100 distinct products have been manufactured**
- **More than 60 products have entered clinical trials**

**DCTD** : Biopharmaceutical Development Program (2)  
*Sole Source of Monoclonal Antibody ch14.18*

**Concept** : ch14.18 marks neuroblastomas for killing by the immune system by binding to an overexpressed antigen called GD2

- Due to complexity of process and small market, no commercial vendor would make the antibody

Children's Oncology Group Phase III trial in patients with high-risk neuroblastoma demonstrated clear event-free survival benefit

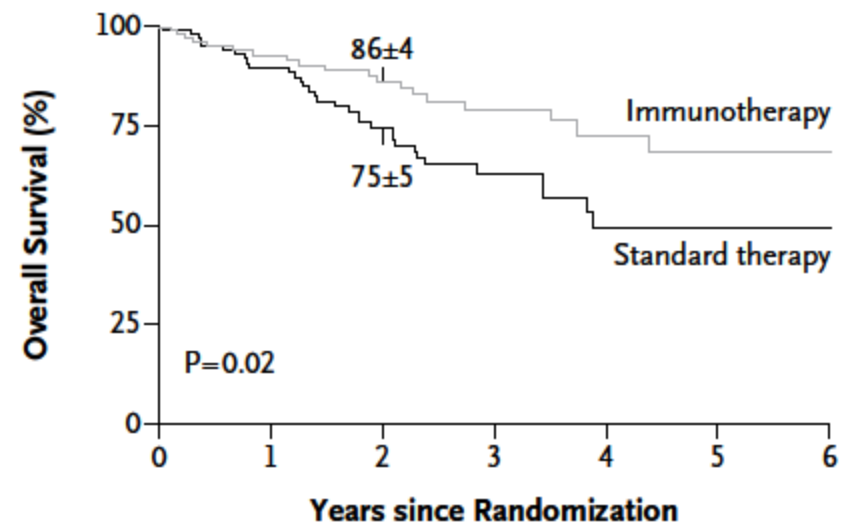
With the success of the trial, a commercial vendor has been found and our process transferred



The NEW ENGLAND JOURNAL of MEDICINE

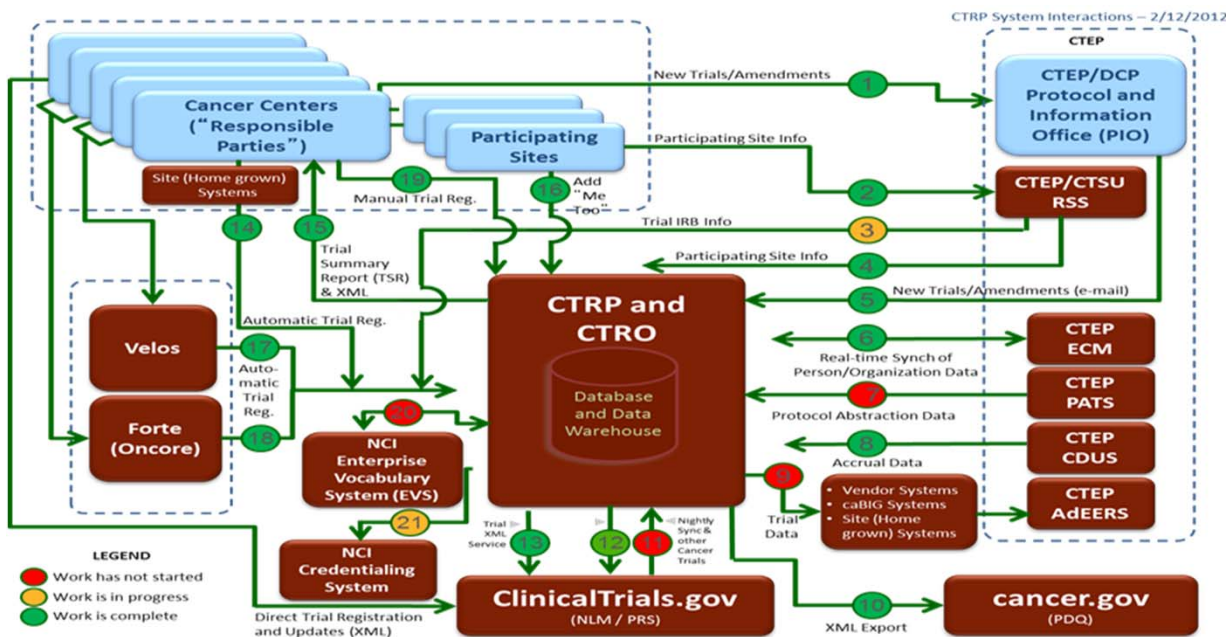
363 1324 (2010)

**B Overall Survival**



# CBIIT - Clinical Trials Reporting Program

- Develop a system to provide accurate and objective monitoring of trials and accruals by NCI-designated Cancer Centers (Coordinating Center for Clinical Trials)
- FNLCR provides project planning and management, software development and quality assurance.
- Built on an enterprise-wide platform that supports the Cancer Therapy Evaluation Program (CTEP), the Division of Cancer Prevention (DCP), ClinicalTrials.gov, credentialing, automated patient-trial matching and the capture of key data elements in emerging clinical trials, such as biomarkers.



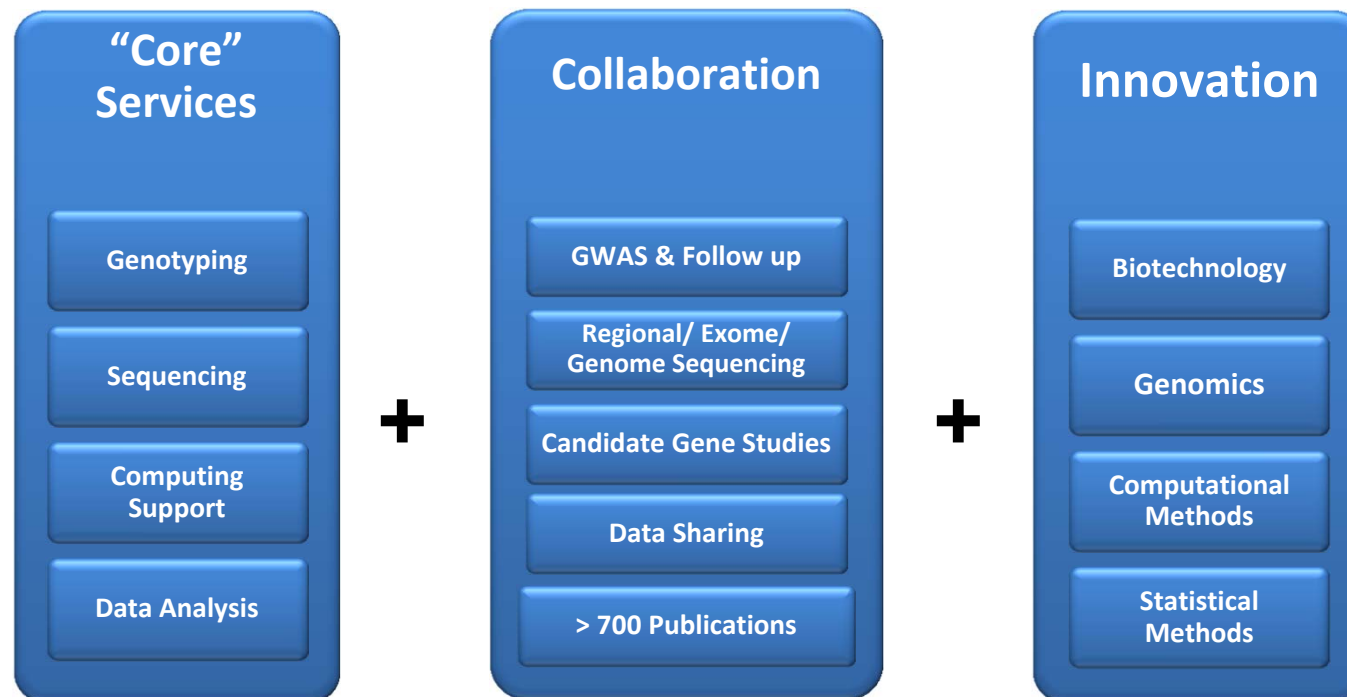
2013 Completed  
Roadmap in green

# DCEG – Cancer Genomics Research Lab

*“The Human Genetics Lab of DCEG”*

Frederick  
National  
Laboratory  
for Cancer Research

- **Conduct high quality molecular epidemiology studies of cancers and related traits**
- **Provide expertise for all aspects of genetic analyses**



# DCEG – Cancer Genomics Research Lab (2)

## Evolutionary Dynamics of the Human NADPH Oxidase Genes *CYBB*, *CYBA*, *NCF2*, and *NCF4*: Functional Implications

Eduardo Tarazona-Santos,<sup>1,\*,1,2</sup> Moara Machado,<sup>1,2</sup> Wagner C.S. Magalhães,<sup>2</sup> Renee Chen,<sup>1</sup> Fernanda Lyon,<sup>2</sup> Laurie Burdett,<sup>3,4</sup> Andrew Crenshaw,<sup>3,4</sup> Cristina Fabbri,<sup>5</sup> Latife Pereira,<sup>2</sup> Laelia Pinto,<sup>2</sup> Rodrigo A.F. Redondo,<sup>6</sup> Ben Sestanovich,<sup>1</sup> Meredith Yeager,<sup>3,4</sup> and Stephen J. Chanock<sup>\*,1</sup>

Hum Genet (2013) 132:1153–1163  
DOI 10.1007/s00439-013-1321-4

ORIGINAL INVESTIGATION

## The new sequencer on the block: comparison of Life Technology's Proton sequencer to an Illumina HiSeq for whole-exome sequencing

Joseph F. Boland · Charles C. Chung · David Roberson · Jason Mitchell · Xijun Zhang · Kate M. Im · Ji He · Stephen J. Chanock · Meredith Yeager · Michael Dean

LETTERS

nature  
genetics

## Meta-analysis identifies four new loci associated with testicular germ cell tumor

Charles C Chung<sup>1,2,19</sup>, Peter A Kanetsky<sup>3,4,19</sup>, Zhaoming Wang<sup>1,2,19</sup>, Michelle A T Hildebrandt<sup>5,19</sup>, Roelof Koster<sup>6,19</sup>, Rolf I Skotheim<sup>7,8,19</sup>, Christian P Kratz<sup>1,18,19</sup>, Clare Turnbull<sup>9,19</sup>, Victoria K Cortesiss<sup>10,19</sup>, Anne C Bakken<sup>7,8</sup>, D Timothy Bishop<sup>11</sup>, Michael B Cook<sup>1</sup>, R Loren Erickson<sup>12</sup>, Sophie D Fossá<sup>13</sup>, Kevin B Jacobs<sup>1,2</sup>, Larissa A Korde<sup>1,14</sup>, Sigrid M Kraggerud<sup>7,8</sup>, Ragnhild A Lothe<sup>7,8</sup>, Jennifer T Loud<sup>1</sup>, Nazneen Rahman<sup>9</sup>, Eila C Skinner<sup>15</sup>, Duncan C Thomas<sup>10</sup>, Xifeng Wu<sup>5</sup>, Meredith Yeager<sup>1,2</sup>, Fredrick R Schumacher<sup>10</sup>, Mark H Greene<sup>1</sup>, Stephen M Schwartz<sup>16,17</sup>, Katherine A McGlynn<sup>1</sup>, Stephen J Chanock<sup>1,20</sup> & Katherine L Nathanson<sup>3,6,20</sup>

LETTERS

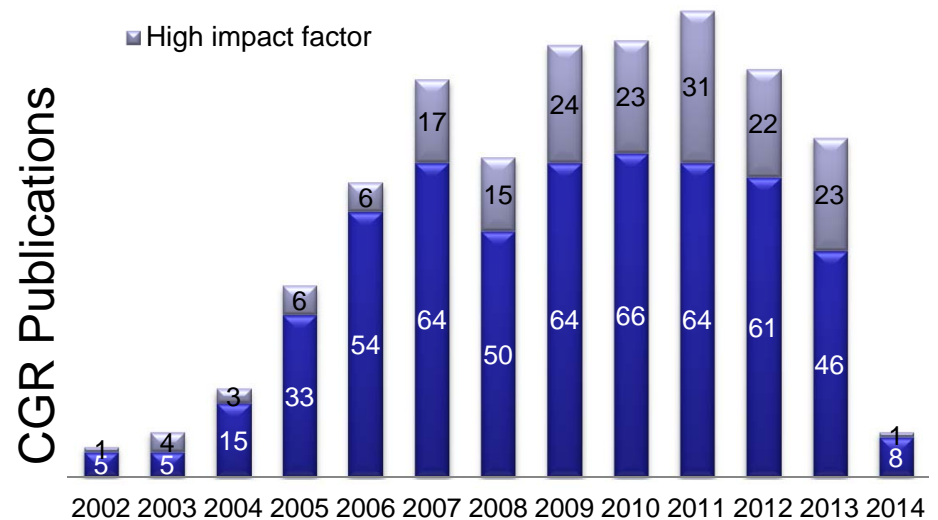
nature  
genetics

## Genome-wide association analysis identifies new lung cancer susceptibility loci in never-smoking women in Asia

Qing Lan<sup>1,68</sup>, Chao A Hsiung<sup>2,68</sup>, Keitaro Matsuo<sup>3,68</sup>, Yun-Chul Hong<sup>4,68</sup>, Adeline Seow<sup>5,68</sup>, Zhaoming Wang<sup>6,68</sup>, H Dean Hosgood III<sup>1,7,68</sup>, Kexin Chen<sup>8,68</sup>, Jiu-Cun Wang<sup>9,10,68</sup>, Nilanjana Chatterjee<sup>1</sup>, Wei Hu<sup>1</sup>, Maria Pik Wong<sup>11</sup>,

## Comprehensive resequence analysis of a 123kb region of chromosome 11q13 associated with prostate cancer

Charles C Chung<sup>1</sup>, Joseph Boland<sup>1,2</sup>, Meredith Yeager<sup>1,2</sup>, Kevin B Jacobs<sup>1,2</sup>, Xijun Zhang<sup>1,2</sup>, Zuoming Deng<sup>1,2</sup>, Casey Matthews<sup>1,2</sup>, Sonja I. Berndt<sup>1</sup>, and Stephen J Chanock<sup>1</sup>



ARTICLES

nature  
genetics

## Detectable clonal mosaicism and its relationship to aging and cancer

Human Molecular Genetics, 2012, Vol. 21, No. 9 2132–2141  
doi:10.1093/hmg/dd029  
Advance Access published on February 8, 2012

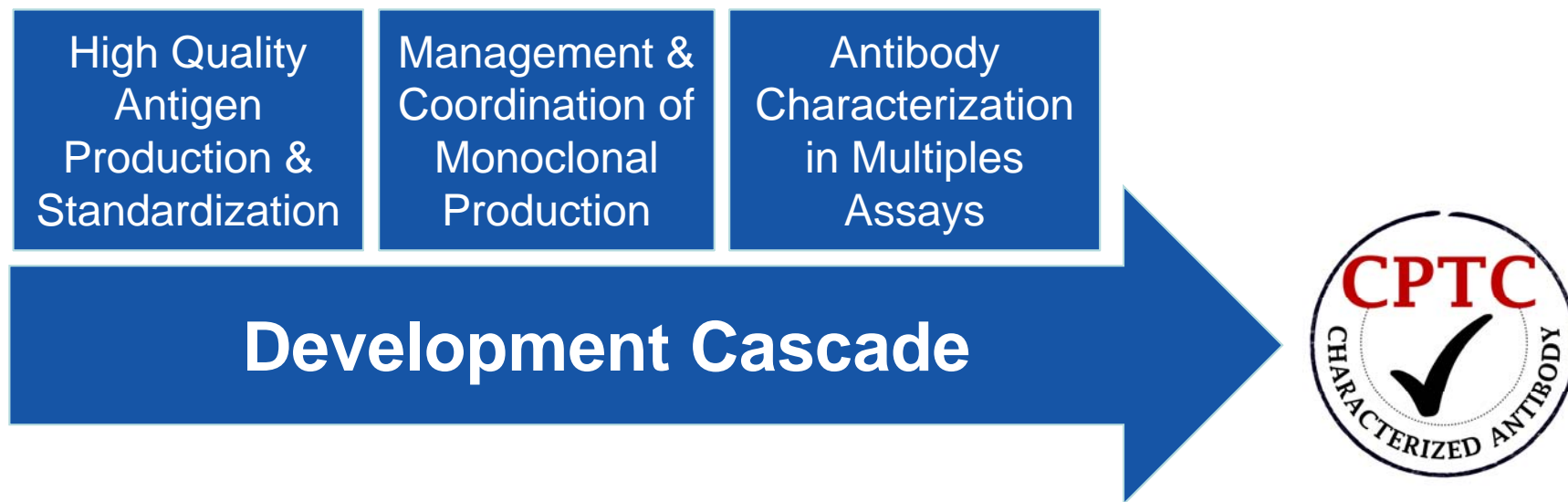
## Genotypic variants at 2q33 and risk of esophageal squamous cell carcinoma in China: a meta-analysis of genome-wide association studies

Christian C. Abnet<sup>1,\*</sup>, Zhaoming Wang<sup>1,3,1</sup>, Xin Song<sup>4,5,1</sup>, Nan Hu<sup>1,1</sup>, Fu-You Zhou<sup>7,1</sup>,

CORRESPONDENCE

## Improved imputation of common and uncommon SNPs with a new reference set

**“The biomedical research community spends \$2 billion per year on antibodies, half of which do not work” \***



Visit: <http://antibodies.cancer.gov>



## OD-F - Facilities Maintenance and Engineering

- Project delivery
  - Management
  - Engineering
  - Controls
- Facilities maintenance
  - ~2 Million ft<sup>2</sup>
  - 9000 trouble calls / yr
- Facilities operations
  - Custodial Services
  - Special assists



# OD-F – Advanced Technology Program...

Shared

Protein Expression  
Lab

Protein Chemistry  
Lab

Proteomics and  
AnalyticalTech

Molecular  
Technology

Optical Microscopy  
and Analysis Lab

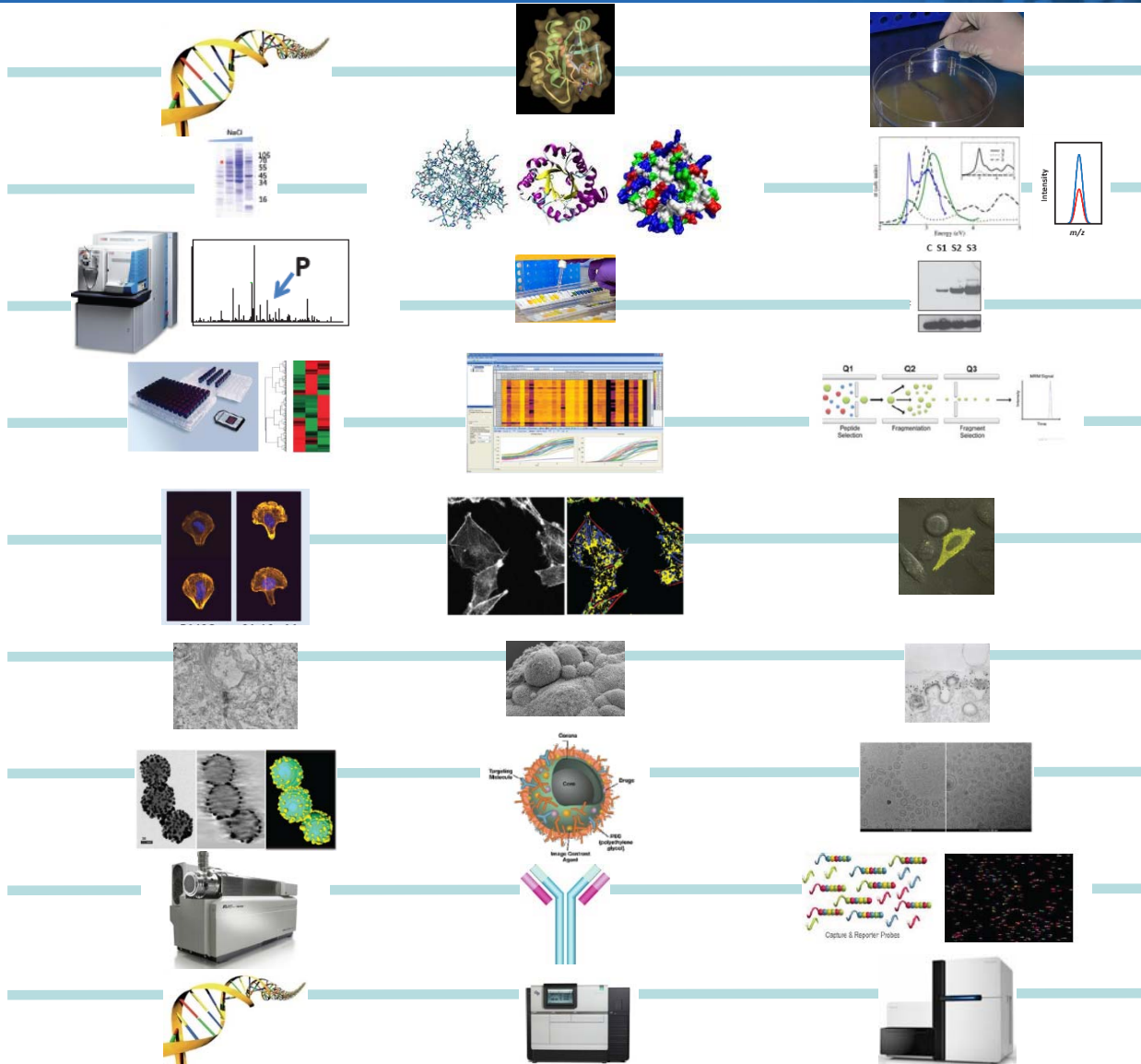
Electron Microscopy  
Lab

Nanotechnology  
Characterization Lab

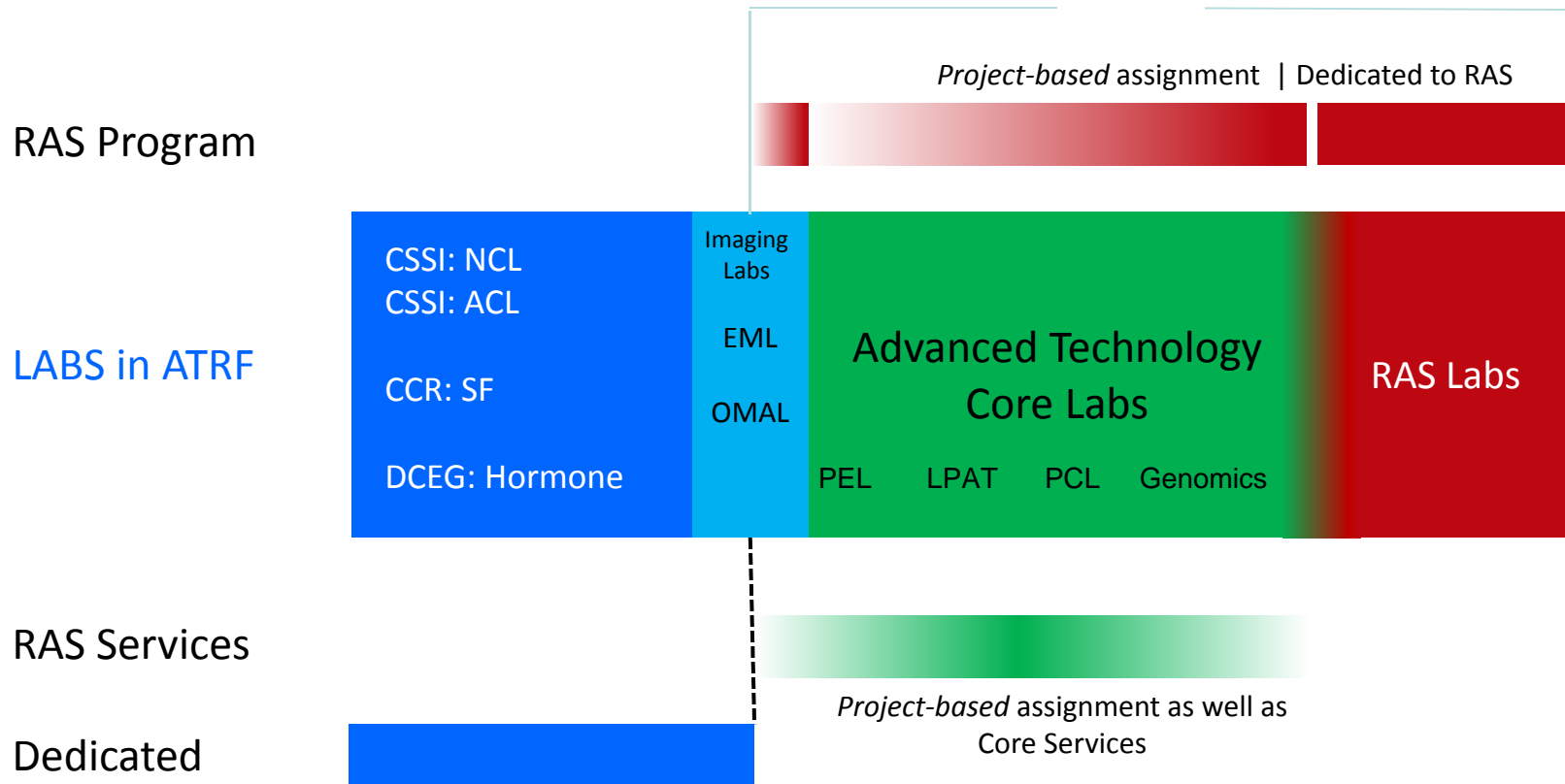
Antibody  
Characterization Lab

CCR Sequencing  
Facility

Dedicated



# ...pivots to IOD – Cancer Research Technology Program *and* RAS



# Conclusions

- **Leidos Biomedical Research, Inc. is owned by Leidos Holdings, Inc., and operates FNLCR for the NCI in the Public Interest**
- **Most NCI Appropriated funding comes from individual Divisions, Offices, and Centers to support their specific objectives**
- **FNLCR staff drive NCI program objectives by integrating technical, operational, and contracting expertise**