

# Frederick National Laboratory for Cancer Research



## Introduction to a new National Laboratory

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**CTO, Frederick National Laboratory, SAIC-F**

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## The Frederick National Laboratory (FNL) is

- The only Federally Funded Research and Development Center (FFRDC) dedicated exclusively to biomedical research
- A strategic technology and applied research center for the **National Cancer Institute**
- Proudly operated in the public interest by *SAIC-Frederick, Inc.* on behalf of the National Cancer Institute

### *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.

# An R&D center for Cancer Research

Frederick  
National  
Laboratory  
for Cancer Research



New Advanced  
Technology  
Research Facility

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

- 1800 FNL employees co-located with NCI researchers and other functions on the NCI Campus at Frederick
- Additional FNL scientists at NCI Bethesda and Rockville sites



# Advanced Technology Research Facility (ATRF) opened in June 2012

Frederick  
National  
Laboratory  
for Cancer Research

Designed for Collaborative Teamwork on Mission Objectives



Strategic Applications of Advanced Technology for Cancer Research

330,000 sq. ft

*Includes lab space for National Missions, Partnering, Training*

# Essential Guides, a sampling

- **The Frederick National Laboratory for Cancer Research**  
<http://frederick.cancer.gov/>
- **FNL / ACL Antibody Characterization Lab**  
<http://antibodies.cancer.gov>
- **FNL / NCL Nanotechnology Characterization Lab**  
<http://ncl.cancer.gov/>
- **FNL Advanced Technology and the ATRF**  
[http://ncifrederick.cancer.gov/About/ThePoster/Media/Documents/Sep12\\_POSTER.pdf](http://ncifrederick.cancer.gov/About/ThePoster/Media/Documents/Sep12_POSTER.pdf)
- **FNL Partnership Development Office**  
<http://frederick.cancer.gov/Partnerships/>

# FNL: Antibody Characterization Laboratory (ACL)

Develops and characterizes monoclonal antibodies using advanced methods and provides data for distribution to the cancer research community on behalf of the **NCI Office of Cancer Clinical Proteomics Research (OCCPR)**

Example  
Partnership:

CLINICAL PROTEOMIC  
TUMOR ANALYSIS CONSORTIUM

High Quality  
Antigen  
Production &  
Standardization

Management &  
Coordination of  
Monoclonal  
Production

Antibody  
Characterization  
in Multiple  
Assays

**Development Cascade**

Antibodies &  
Performance  
Data Made  
Available to the  
Public

# Process to Request Antibodies

- **Target requests (intramural and extramural)**
  - Two target requests completed to date (annual)
  - Targets received are full-length domains or peptides
    - Vetted by Antibody Scientific Committee
    - Monoclonal antibodies are produced, screened, and extensively characterized at no cost
    - Antigen must be provided by requester
    - Investigators can participate in the screening process
    - All antibodies are characterized for all methods, regardless of intended final use
- **All antibodies are made available to the public once characterization is completed**
- **More information can be found at:**  
[http://antibodies.cancer.gov/apps/site/reagent\\_opportunities](http://antibodies.cancer.gov/apps/site/reagent_opportunities)

# ACL Characterization and the CPTC\* Seal



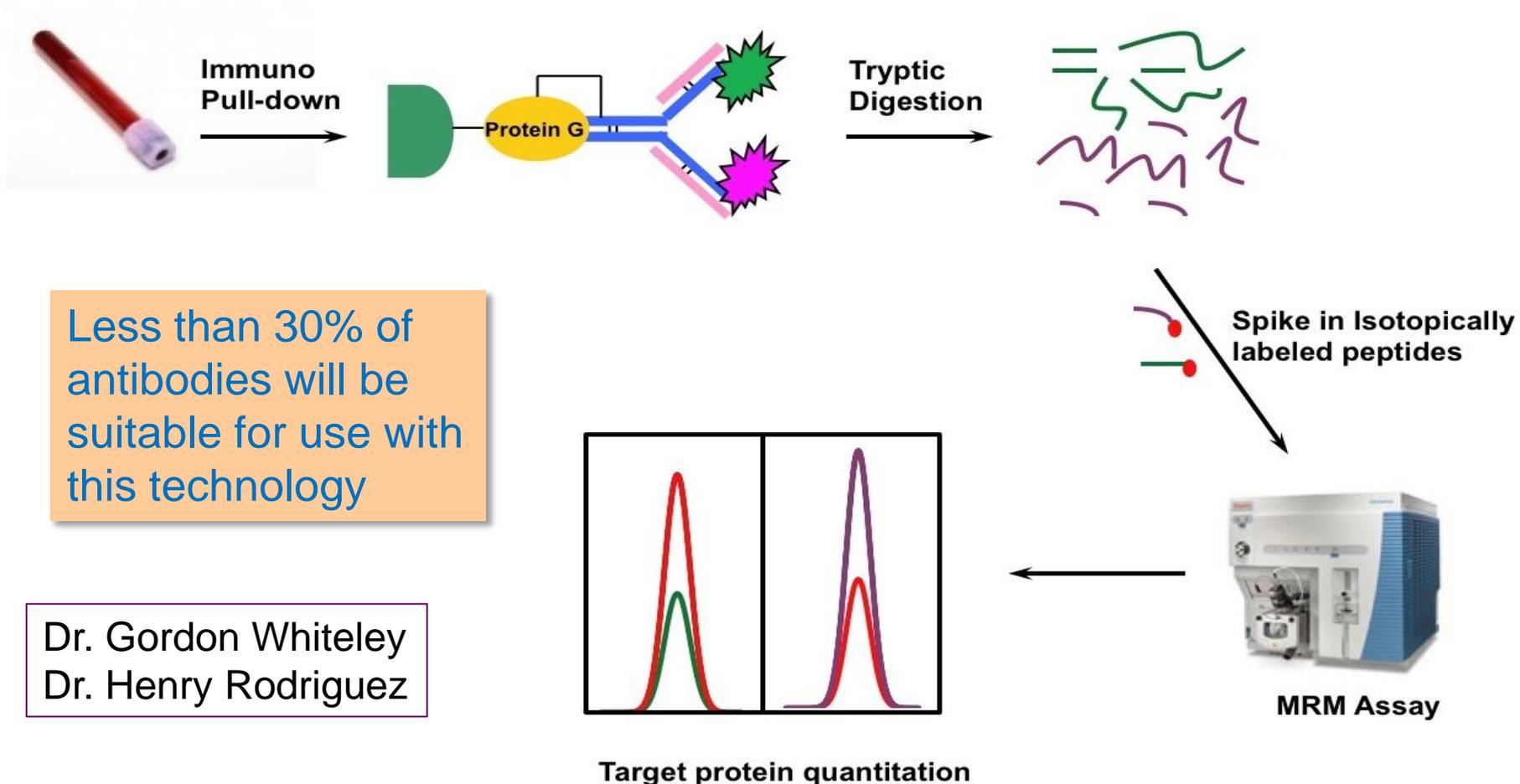
These antibodies with the term “CPTC” have been thoroughly characterized through a standardized process, and the data from this analysis is publicly available through the National Cancer Institute.

<http://antibodies.cancer.gov>

\*Clinical Proteomics Technologies for Cancer

# Priority Themes include: Specialized Antibody for Clinical Biomarker assays

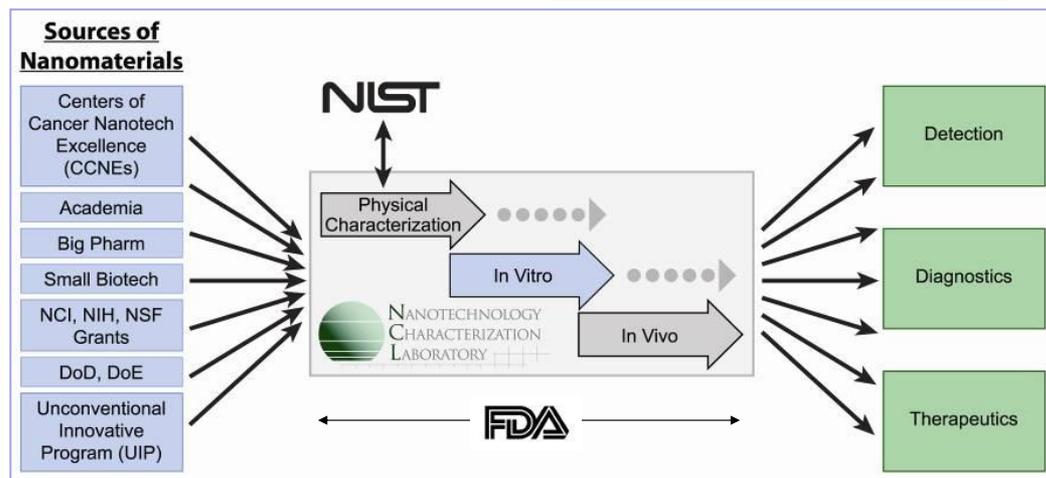
## Immuno-MRM assay antibodies



# FNL: Nanotechnology Characterization Laboratory (NCL)

- **NCL was established in 2004 as an interagency collaboration among NCI, NIST, and FDA. The lab's mission is to accelerate the translation of promising nanotech cancer drugs and diagnostics**
- **NCL performs preclinical characterization of nanomaterials, including:**
  - physicochemical characterization
  - in vitro experiments
  - in vivo testing for safety and efficacy

Dr. Scott McNeil  
Dr. Piotr Grodzinski



Open themes across nanocancer field, and free.  
Any Nanoformulation whose process is sufficiently advanced  
to be at the doorstep of the IND

# NCL Capabilities: An Assemblage of FNL Resources



Laboratory  
for Cancer Research



## In Vivo Screening

- ADME-Toxicity
- Efficacy
- Pharmacokinetics
- Drug Metabolism
- Immunotoxicity

## Reformulation

## In Vitro Screening

- Blood contact properties
- Toxicity
- Immune cell functions



## Clinical Support Lab

## Analysis of Clinical Samples

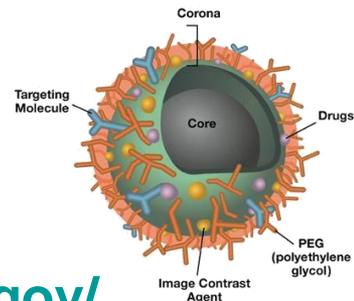
## Scale-Up Assistance

- Batch-to-batch consistency
- Process design and optimization
- Quality control
- Developing methods for in-process testing

## Chemistry

- Size
- Composition
- Surface functionality
- Compatibility in biological matrices

FREDERICK NATIONAL LABORATORY



<http://ncl.cancer.gov/>

Frederick National Laboratory  
for Cancer Research

# Success Stories: NCL-aided Submissions to Clinic



*IND 2009*

- **ATI-1123** : PEGylated nanoliposomal formulation of docetaxel
- Phase I safety study in patients with advanced solid tumors complete in 2012.

- **BIND-014** : docetaxel-encapsulated PLGA nanoparticle-aptamer conjugates
- Binds PSMA expressed on prostate cancer cells
- Phase I safety study in patients with advanced or metastatic cancer ongoing.

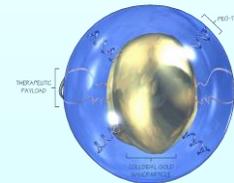


*IND 2011*

- Silica-core gold-shell particle for photothermal ablation with NIR irradiation
- Pilot safety study in head and neck cancers ongoing; efficacy study in lung tumors to start in 2012.



*IDE 2008*



*Phase 1  
Completed 2008*

- **AurImune®** : PEGylated colloidal gold nanoparticle-TNF $\alpha$  conjugates
- Phase II study in combination with Taxotere to start in 2012.



*IND 2010*

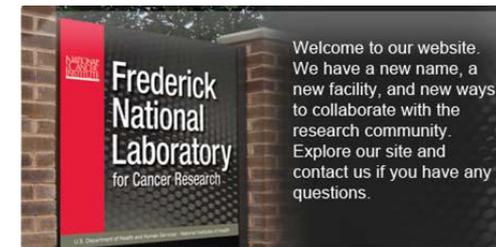
- **PNT2258** : liposome-encapsulated oligonucleotide for breast and lung cancer.
- Phase I safety study in patients with advanced solid tumors ongoing.

# New Partnering Initiatives

*Expanding access to FNL Resources*

- **Contractor Cooperative Research and Development Agreements (cCRADA)**

- Ten partnerships received initial concept approval to date
- Additional agreements in development
- Examples:
  - Discovery and Validation of Proteomic Biomarkers
  - Immunogenicity testing for a Phase 1 Trial of a novel Vaccine
  - Evaluating Strategies to uncover reservoirs of HIV post-antiretroviral treatment



<http://frederick.cancer.gov/Partnerships/>

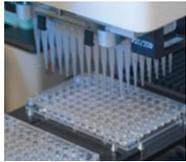
- **Technical Service Agreement (TSA)**

- Fifteen distinct assays approved for external offering
- Access to Discrete Specialized Capabilities

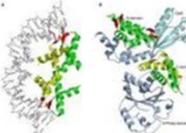
# In 2012, the RAS-driven tumors program was selected by the NCI as the first National Mission for the FNL

## Technological Capabilities

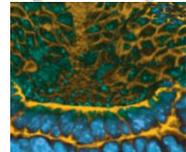
Genetics and Genomics



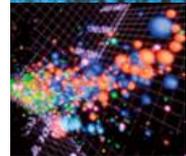
Proteins and Proteomics



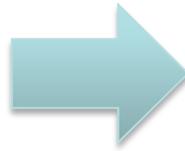
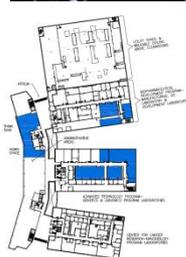
Imaging and Nanotechnology



Advanced Biomedical Computing



Lab Space



**Killing RAS-driven cancers ...  
deploy FNL resources on a unified  
and coherent national objective**



Advanced Technology Research Facility  
Opened June 2012



Integrated *in vivo* support at  
Frederick & Bethesda

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