Frederick National Laboratory
for Cancer Research



Frederick National Laboratory for Cancer Research : New Initiatives

Presentation to the National Cancer Advisory Board

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DEPARTMENT OF HEALTH AND HUMAN SERVICES • National Institutes of Health • National Cancer Institute
Frederick National Laboratory is a Federally Funded Research Center, operated by SAIC-Frederick, Inc., for the National Cancer Institute.

Frederick National Laboratory

Presentation Outline

- Our Identity and Mission
- Exemplifying the impact of Frederick National Laboratory programs
- NCI-Frederick Advisory Committee guidance for the future of Frederick National Laboratory

Overview of Frederick National Laboratory for Cancer Research

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

- Proudly operated by *SAIC-Frederick, Inc*. on behalf of the National Cancer Institute

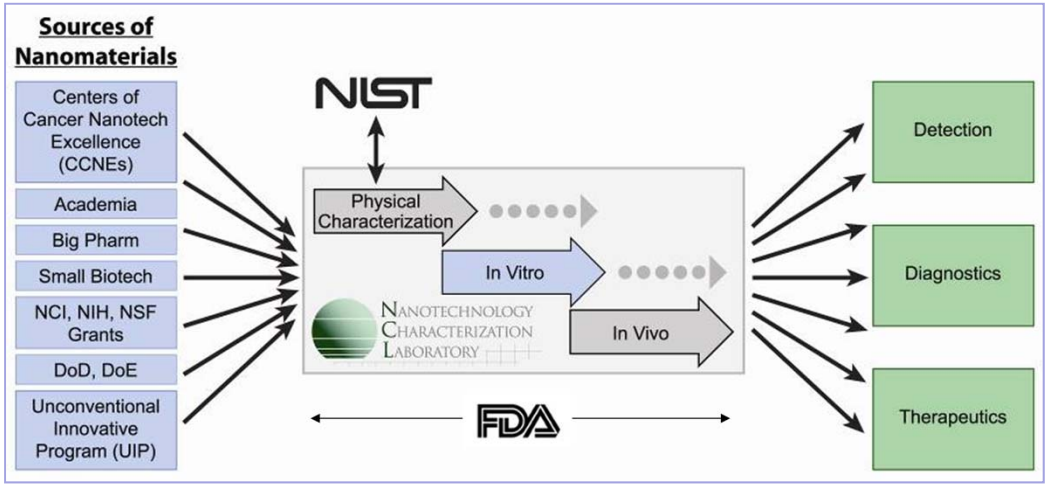
Main campus is on 70 acres at Ft. Detrick, MD

- Co-located with intramural NCI researchers and other NCI activities
- Additional FNLCR scientists at Bethesda and Rockville sites

FFRDC status enables us to nimbly provide advanced integrated biomedical resources and know-how to government, academic, and commercial scientists without competing interest

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



90% of NCL's efforts support the extramural community

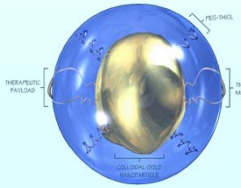
Success Stories:
NCL-aided Submissions to Clinic

AZAYA THERAPEUTICS

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

IND 2009

CYTIMMUNE SCIENCES INC



Phase 1 Completed 2008

- **AurImune®** : PEGylated colloidal gold nanoparticle-TNFα conjugates
- Phase II study in combination with Taxotere to start 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.

BIND BIOSCIENCES

IND 2011

Nanospectra

- 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

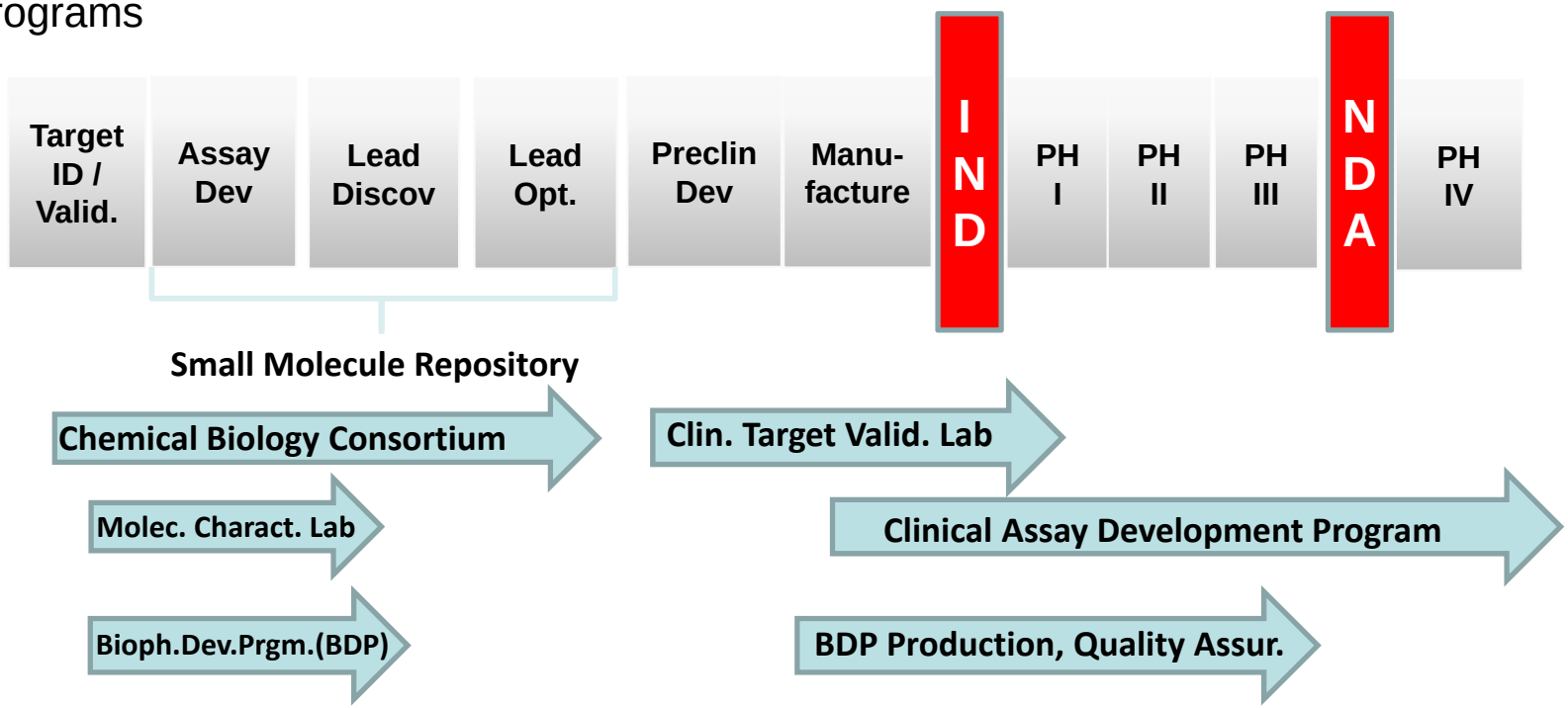
ProNAi

IND 2010

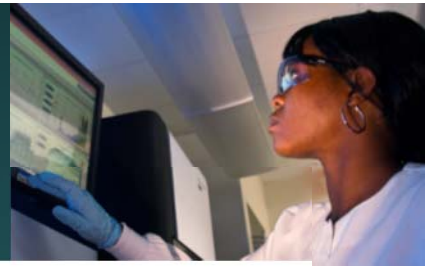
- **PNT2258 :** liposome-encapsulated oligonucleotide for breast and lung cancer.
- Phase I safety study in patients with advanced solid tumors ongoing.

The NCI Experimental Therapeutics Program (NExT)

- 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
- SAIC-F provides operational and dedicated technical support to all phases of NExT programs



NCI-Frederick Advisory Committee
Building for the Future



- **NFAC charge - review the state of research at FNLCR and make recommendations for the best use of its capabilities and infrastructure**
- **15 member committee**

Zachary Hall, Ph.D. Former Director, NINDS Former President; Institute of Regenerative Medicine, UCSF
Emeritus Professor, UCSF

Chair

C. Barrett

D. Botstein

L. Garraway

J. Gray

B. Hahn

M. Justice

T. Look

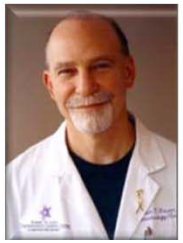
L. Marnett

J. Mesirov

G. Nolan

K. Olden

J. Pietenpol



S. Rosen

C. Willman

Expanding the Partnering Base

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

- **Enables SAIC-Frederick to partner directly with extramural scientists and organizations for access to our science and technology know-how**
- **Use full CRADA authority under CRADA statutes**
  - c-CRADAs for Research, Development, and Testing collaborations
  - “Technical Service Agreement” for tactical evaluation of proprietary partner materials, SIV assays, etc.
- **Intellectual property rights**
  - SAIC-F is the custodian of joint or sole IP emerging from the CRADA
  - SAIC-F can provide an advanced understanding of IP / Commercialization rights
  - Any royalty streams support FFRDC R&D efforts
- **Processes**
  - Focus on speed
  - Local government review and approval with external input as appropriate

New Partnering Initiatives

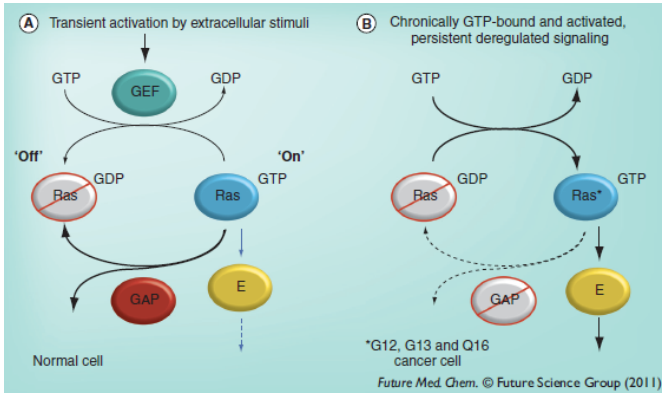
Expanding access to FNLCR Resources

- **Contractor Cooperative Research and Development Agreements (cCRADA)**
  - Four partnerships received initial concept approval
  - Five additional agreements in development
- **Technical Service Agreement (TSA)**
  - Seven distinct assays approved for external offering
  - Three additional assays submitted for approval, 11 in preparation
  - One agreement signed with UCSF, 4 in progress
- **External-facing FNLCR website operational and evolving**
  - http://frederick.cancer.gov/

FNLCR New Initiatives: “Big Ideas”

Fulfill the “National Laboratory” vision

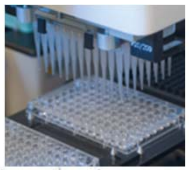
- Ideas contributed by NCI, FNLCR, and external workgroups
  - **Ras Therapeutics** (*Dr. Varmus*)
    - Identify and validate new therapeutic approaches targeting oncogenic Ras



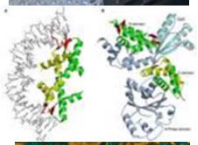
  - **Preclinical models** (*Drs. Doroshow and Wiltrout*)
    - Systematic comparison of the constellation of preclinical efficacy models to develop robust standards and improve predictive utility

Implementing the “Big Ideas” at FNLCR

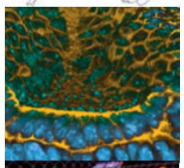
We have essential needs…



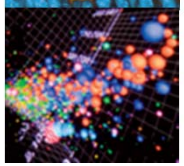
Genetics and Genomics



Proteins and Proteomics



Imaging and Nanotechnology

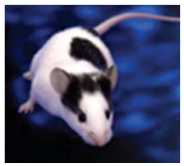


Advanced Biomedical Computing

Lab Space

…integrated into a brand new state-of-the-art Research Facility

Advanced Technology Research Facility
Opened June 2012



Integrated *in vivo* support at Frederick & Bethesda

Implementing the “Big Ideas” at FNLCR

- **Leadership**
  - Appointment of NCI FNLCR Laboratory Director to work with SAIC-Frederick leadership
- **Scientists**
  - “Hub-and-spoke” model – FNLCR, academia, industry
    - Redirect some FNLCR scientists supporting intramural core services
    - Dedicated laboratory space at new Advanced Technology Research Facility
- **Support**
  - Redirect necessary support from current FNLCR budget
    - “In-kind” personnel, plus contracts
- **Timing**
  - As soon as the scientific workplan for each project is developed

Conclusions

- **Frederick National Laboratory for Cancer Research** is a unique resource within the national biomedical research community
- **Program partnerships** facilitate basic and translational research achievements
- **New partnering opportunities** expand the impact of FNLCR science
- **New "big idea" research programs** will strengthen the identity and impact of FNLCR as a National Laboratory