

The National Cancer Institute at Frederick

National Cancer Advisory Board
November 30, 2006

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



The National Cancer Institute at Frederick

– *Mission* –

Provide a unique national resource for the development and application of advanced technologies to the most urgent and challenging research and development needs of the NCI - and the nation



History of NCI-Frederick

- Established in 1972 by a Presidential directive to convert the former DoD Biological Defense Research Laboratories at Ft. Detrick into a “leading center for cancer research.”
- The Presidential directive stipulated that “operation of NCI-Frederick should be by private contractor to allow the necessary flexibility which would be difficult under direct Government operations.”
- In 1975 the NCI-Frederick was formally designated as a Government-owned, contractor-operated, Federally Funded Research and Development Center (FFRDC).

Selected Other FFRDC Research Centers

- Argonne National Lab (DoE)
- Lawrence Livermore National Lab (DoE)
- Los Alamos National Lab (DoE)
- Brookhaven National Lab (DoE)
- Oak Ridge National Lab (DoE)
- National Defense Research Institute (DoD)
- Jet Propulsion Lab (NASA)

NCI-Frederick is the only FFRDC in DHHS and the only one dedicated solely to biomedical research

Value of the FFRDC to the NCI

- Because of its broad charter and unique acquisition capabilities, the FFRDC provides the NCI with:
 - 1. Enhanced flexibility**
 - 2. Rapid response capability**
 - 3. Increased efficiency**
- In return, the FFRDC designation requires the NCI-Frederick to focus its efforts on meeting the most urgent and difficult-to-achieve needs of the NCI

NCI-Frederick – Responding to the Urgent Need for a Diagnostic AIDS Blood Test

April 1984: NCI requested that NCI-Frederick begin production of a large amount of the AIDS virus. Production of an HIV-1-infected cell bank began the same month

June 1984: 100L of virus-infected cells were produced and provided to each of the 5 companies charged by the NCI with the development of an AIDS blood test

March 1985: FDA approved the first assays to test blood supplies

By 1989 the number of individuals in the US infected via contaminated blood transfusions was reduced to <450.



NCI-Frederick: A Unique National Resource

Meeting the most urgent biomedical research needs of the nation, including:

- **NCI intramural research program**
- **NCI extramural investigators**
- **Other NIH institutes**
- **Other government agencies**
- **NCI corporate partners**



NCI-Frederick AIDS Vaccine Program (AVP): Accelerating the AIDS Research Effort

- **Since 1983 the AVP has produced nearly 100,000L of HIV/SIV products for distribution to >200 investigators. *Many of these products are not commercially available at any price.***
- **20,000 HIV-1 p24 and SIV p27 antigen-capture assay kits provided to >300 investigators. Estimated savings ~ \$7.5M.**
- **~ 3,000 cell-free and cell-associated SIV/SHIV viral load and related assays performed each year, many for NCI/NIH intramural and extramural investigators.**
- **Recombinant wild-type and mutant retroviral nucleocapsid proteins have been provided to >60 different investigators.**
- **Large number of unique HIV and SIV serological reagents shared freely with the NCI/NIH intramural and extramural communities.**



Twelve years ago, when immunologist **Elizabeth Jaffee** was developing vaccines that could shrink tumors in mice, she decided to pursue a bold experiment: testing the **new vaccines on patients with pancreatic cancer.**

Pancreatic tumor vaccines produced by the NCI-Frederick Biopharmaceutical Development Program (BDP)

Jocelyn Kaiser, **SCIENCE** March 31, 2006

NCI-Frederick Biopharmaceutical Development Program (BDP)

1. Established in 1993 to provide cutting-edge development of MoAbs; recombinant proteins; peptide, DNA and virus vaccines; oncolytic virus; gene therapy products; and other biological agents – in support of both intramural and extramural NCI investigators.
2. Provides complete cGMP-compliant support from feasibility testing, through product development and manufacturing, to filing of regulatory documentation.
3. Since inception, the BDP has completed over 100 projects, of which 68 have gone into clinical trials.

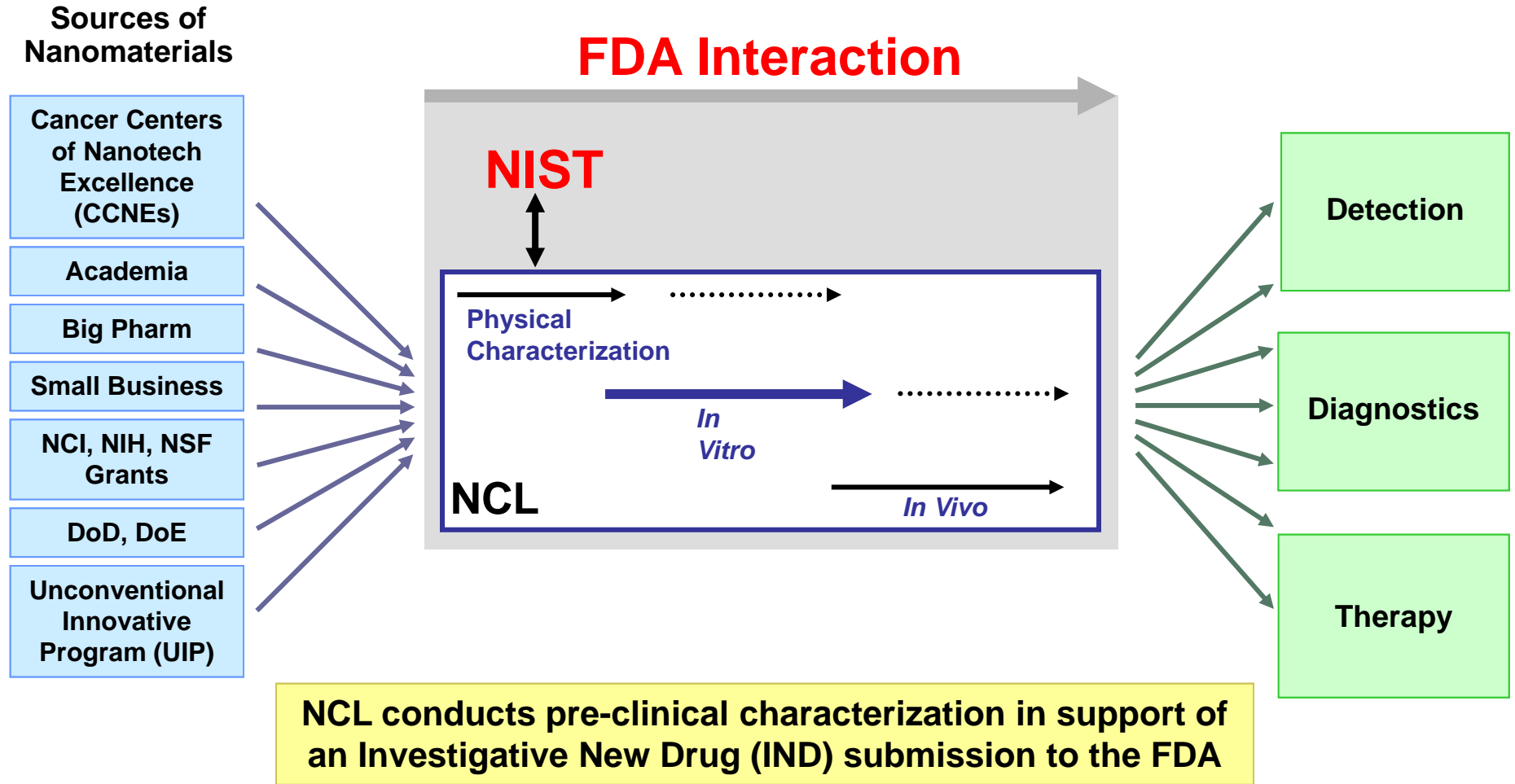


NCI-Frederick Nanotechnology Characterization Laboratory (NCL)

Objectives of the NCL:

1. Create an environment for the confluence of nanotechnology disciplines (e.g. physics, chemistry, engineering, mathematics) with the biosciences (e.g. biotechnology, pharmacology, and experimental therapeutics).
2. In collaboration with NIST, develop robust protocols for product validation, comparison, and evaluation.
3. In collaboration with FDA, develop a rigorous but accelerated pathway toward clinical translation of new nanotechnology products.

Nanotechnology Characterization Laboratory (NCL) Concept of Operations



Vaccine Pilot Plant (VPP)

In support of NIAID's Vaccine Research Center

- **Addresses an urgent request from the White House and Congress to NIAID**
- **Completed by the NCI-Frederick on schedule, under budget, and in just 36 months (from lease to delivery of the first cGMP product)**



Characteristics of the VPP

- **State-of-the-art multiproduct facility for the production of biological products from prokaryotic or eukaryotic cells**
- **Four independent production suites (2 X 100L, 400L, & 2,000L)**
- **Two aseptic filling suites (up to 50,000 units/run)**
- **GMP warehouse for the storage and distribution of clinical materials**
- **Integrated quality control and assay development laboratories**
- **A unique and flexible quality assurance framework for ensuring cGMP compliance in a multiproduct/product development environment**
- **State-of-the-art systems to support manufacturing cGMP compliance through Phase III clinical trial**

The result – a significant increase in NIAID’s capacity to produce vaccines for HIV and other emerging infectious diseases (e.g. avian flu, SARS, Ebola, and West Nile encephalitis)

NCI-Frederick - Meeting the Needs of the Nation

During the past five years, NCI-Frederick:

- Provided basic and clinical research services to 25 of the 28 NIH institutes, centers, and NIH-OD
- Published over 4,000 peer-reviewed research articles
- Executed 3,067 Material Transfer Agreements and 77 collaborative research agreements with numerous universities and industry collaborators
- Cited by *The Scientist* as a top ten (#7) “Best Places to Work” for U.S. research institutions
- Cited by *The Scientist* as a top ten (#3) “Best Places to Work for Postdoctoral Fellows”

NCI-Frederick - Meeting the Needs of the Nation in 2005/2006

- Provided advanced technology expertise and support to the DHS, DoD, FDA and USDA
- Produced over 40 novel biopharmaceutical products and vaccines through our two cGMP manufacturing programs
- Supported over 300 NIH-sponsored clinical trials to test innovative cancer and AIDS treatments
- Acquired or stored over 1.5 million clinical samples in support of cancer and AIDS clinical trials world-wide

NCI-Frederick - Meeting the Needs of the Nation in 2005/2006

- Provided over 1 million novel research animals to over 1,100 investigators at more than 200 U.S. institutions
- The NCI-Frederick Preclinical Repository acquired, produced and/or distributed over \$10M in quality biological research reagents at no cost to investigators
- Provided advanced biomedical computing expertise and support to over 1,800 users from the world's largest high-performance computer resource dedicated solely to biomedical research

Summary

With its unique FFRDC authorities, versatility, and advanced technologies the NCI-Frederick is meeting the most urgent and challenging needs of NCI's intramural and extramural investigators, NIH institutes, Government agencies, and NCI's corporate partners.

