NCI Alliance for Nanotechnology in Cancer

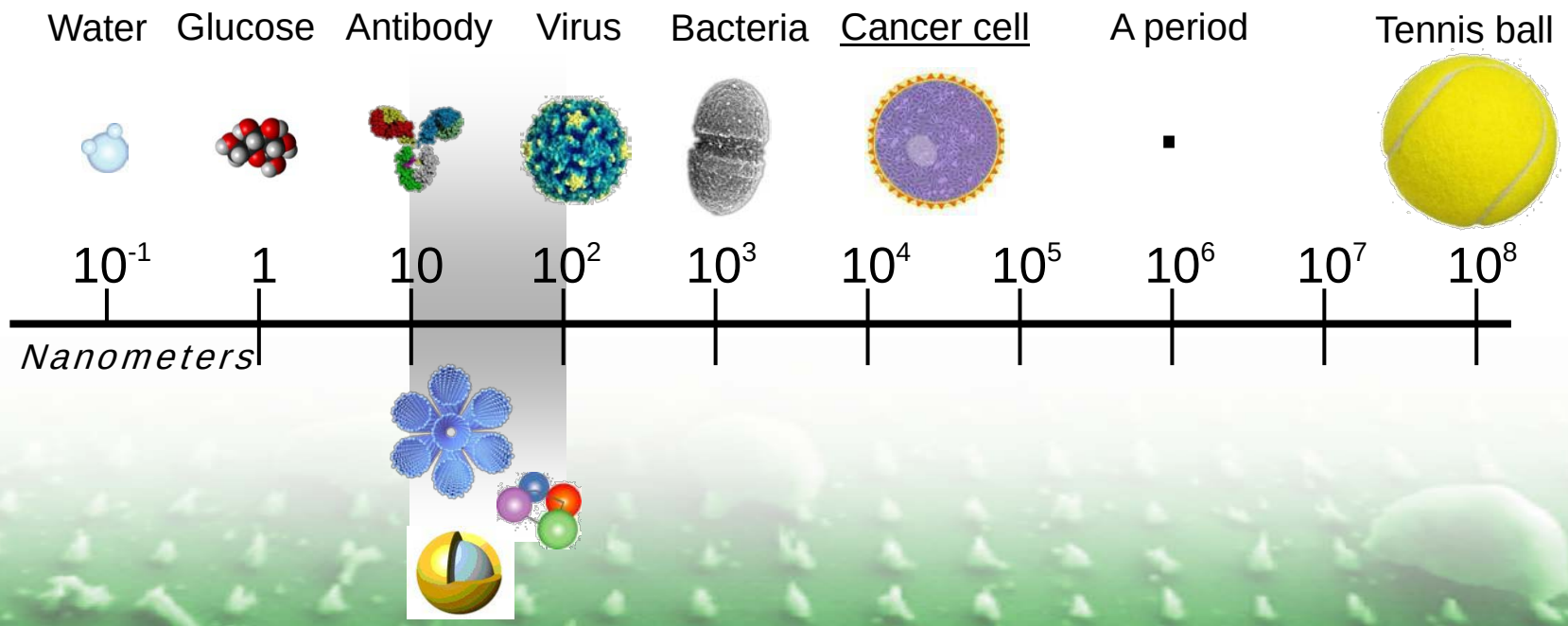
Pre-application Meeting
RFA-CA-09-012
Centers of Cancer Nanotechnology Excellence (CCNEs)

Piotr Grodzinski, Ph.D.
Director, NCI Nanotechnology Alliance
National Cancer Institute

Nanotechnology and Cancer

NCI Alliance for Nanotechnology in Cancer

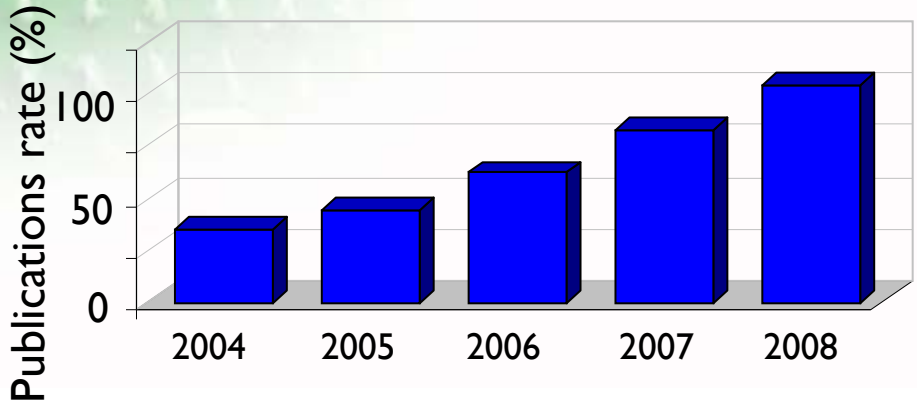
Nanotechnology is a "disruptive technology" which <u>drives</u> a new generation of cancer preventive, diagnostic, and therapeutic products, resulting in dramatically improved cancer outcomes



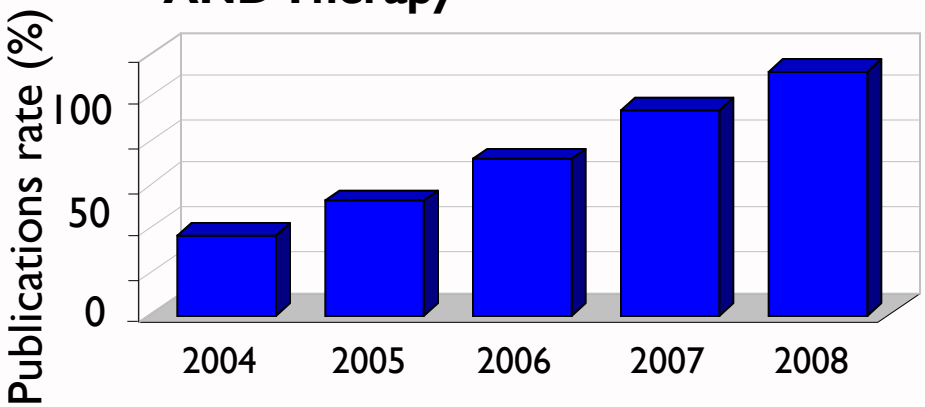
Cancer Nanotechnology – New Field of Research
PubMed Search with Selected Keywords

NCI Alliance for Nanotechnology in Cancer

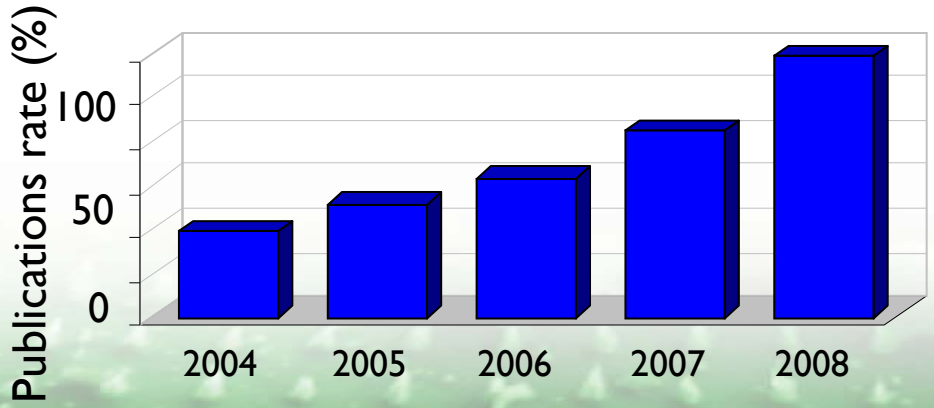
Cancer AND Nanotechnology



Cancer AND Nanotechnology AND Therapy



Cancer AND Nanotechnology AND Diagnosis



- Cancer nanotechnology has emerged as a dynamic, new research area
- Strong representation in diagnostic tools and therapeutic development
- An opportunity – leverage cancer preventive schemes based on nanotechnology – not explored to date:

↓

Cancer AND Nanotechnology AND Prevention : only **29** publ.

NCI Alliance for Nanotechnology in Cancer
Phase 1: 2005 – 2009
Achievements

NCI Alliance for Nanotechnology in Cancer

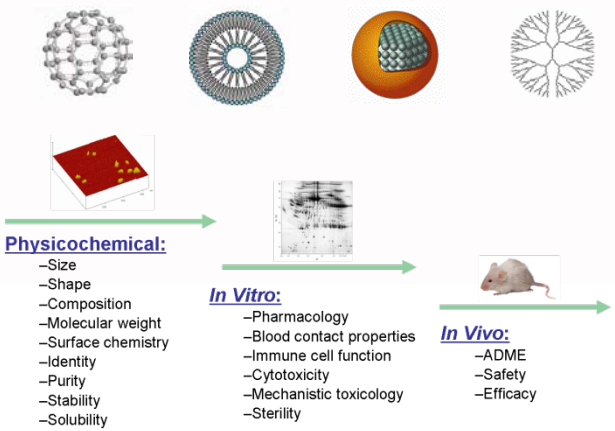
- **Building the community** – established well operating multi-disciplinary teams around scientific focus areas of the program
  - Met or exceeded program goals outlined in Cancer Nanotechnology Plan
  - Established Nanotech Characterization Lab (NCL) as a major hub for nano-materials characterization
  - Established ties to the divisions to support current and future scientific needs of the investigators and the cancer nanotechnology field
  - Held 3 Strategic Nanotechnology Workshops to outline needs of the field for next 5-10 years
- **Scientific output** – over 600 peer-reviewed journal papers published with average impact factor ~7. Strong evidence of establishing joint projects.
- **Clinical translation** – 50 companies associated with the program in the space of diagnostics and therapy; 24 were formed in last 4 years. Developing strong intellectual property portfolio – over 200 disclosures and patents filed
  - 8-10 clinical trials are associated with program projects
  - 4 companies are in pre-IND discussions with FDA
  - 17 IRB protocols for work with patients and human samples are in place
- **Leveraged funding** – investigators received numerous additional grants from peer-reviewed government sources, philanthropy, industry, and venture investors.

Nanotechnology Characterization Laboratory (NCL)

NCI Alliance for Nanotechnology in Cancer

FDA NIST

- Interagency collaboration with FDA and NIST to develop and standardize characterization methodology for nanomaterials
- NCL achieved prominent standing in nanotechnology community and is used as a model for establishing efforts in academia and industry
- Serving as a bridge to bring NCI and Alliance nanotech investigators to the FDA



Achievement:

- More than 165 individual nanoparticles undergoing characterization
  - 50 Active collaborations (MTAs)
  - In 2008, 14 new MTAs, 13 CDAs, 1 CRADA with GE
  - 45 animal studies to date

NCI Alliance for Nanotechnology in Cancer – Phase II - Organizational Structure

NCI Alliance for Nanotechnology in Cancer

- Centers for Cancer Nanotechnology Excellence (CCNE) U54 Cooperative Agr.
- Multi-disciplinary Training K99/R00 Awards, R25 Awards
- Cancer Nanotechnology Platform Partnerships U01 Cooperative Agr.
- Nanotechnology Characterization Laboratory

- Coordination and Governance Committee
- Industrial Advisory Committee
- Clinical Advisory Committee
- NIH Cancer Nanotechnology Working Group

RFAs for CCNEs and CNPPs published on May 29
Receipt date – October 14

Training RFAs to be published – August

Purpose of RFA-CA-09-012

NCI Alliance for Nanotechnology in Cancer

Support an integrated network of multi-disciplinary centers to develop cancer-oriented techniques and tools with clinical relevance using nanotechnology innovation

From Concept to Clinical Translation

NCI Alliance for Nanotechnology in Cancer

- Research and development of cancer-oriented techniques and tools with practical clinical applications and based on nanotechnology
- All CCNEs must be strongly committed to and *capable* of *translation* of the technologies/tools under development
- Work scope includes the completion of the pre-clinical stage of the development of nanotechnology-based solutions to the clinically relevant cancer problems. Even though *clinical trials are beyond the scope* of this RFA, *in vitro studies* that employ *clinical biospecimens and early clinical investigations* are within the scope

CCNE

Concept/Technology Identification → Technology Proof-of-Concept → Animal Models → Clinical Samples → Clinical Trials

CNPP

Alliance program

Phase 1 → Phase 2

Increasing emphasis on technology development and translation

Budgets and Timeline

NCI Alliance for Nanotechnology in Cancer

- Budget: $20M - $27M dollars for FY 2010
- Total cost budget/ application: $3.2M
- Six to ten awards for five years are anticipated

- Letter-of-intent: September 14
- Application receipt date: October 14
- Peer Review Date: February/March 2010
- Council Review Date: May 2010
- Anticipated Start Date: September 2010

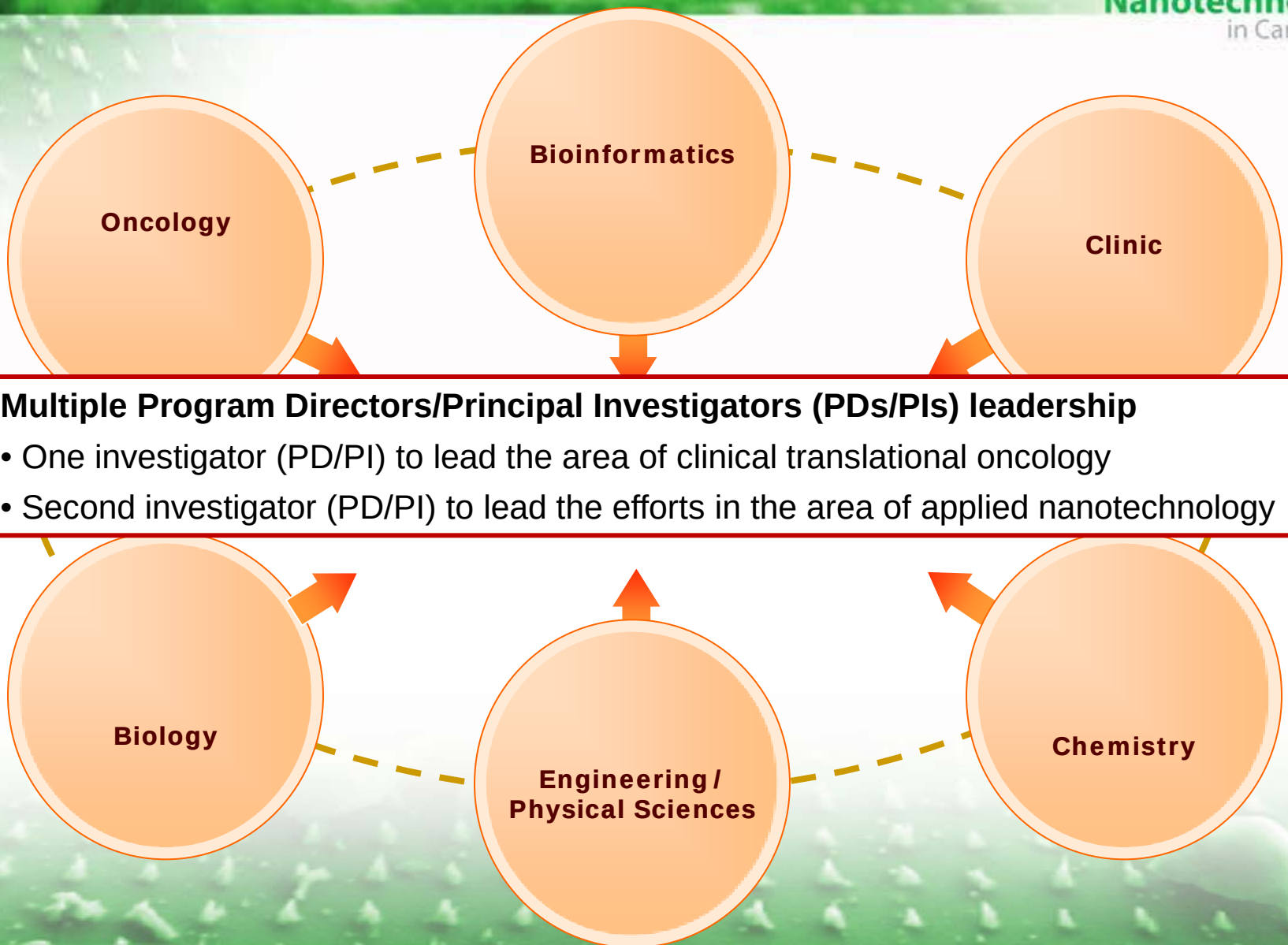
Definition of Nanotechnology in the Context of this RFA

NCI Alliance for Nanotechnology in Cancer

- Devices or base materials must be smaller than 1000 nm in size although the assembly, synthesis, and/or fabrication of components of these final structures at dimensions less than 300 nm should be demonstrated
- Devices/materials used and/or proposed to be developed must be either (a) synthetic materials or (b) biomaterials engineered to provide novel properties or modified functions based on nanoscale size, i.e., nanomaterials

Multi- PD/PI Center Leadership

NCI Alliance for Nanotechnology in Cancer



Multiple Program Directors/Principal Investigators (PDs/PIs) leadership

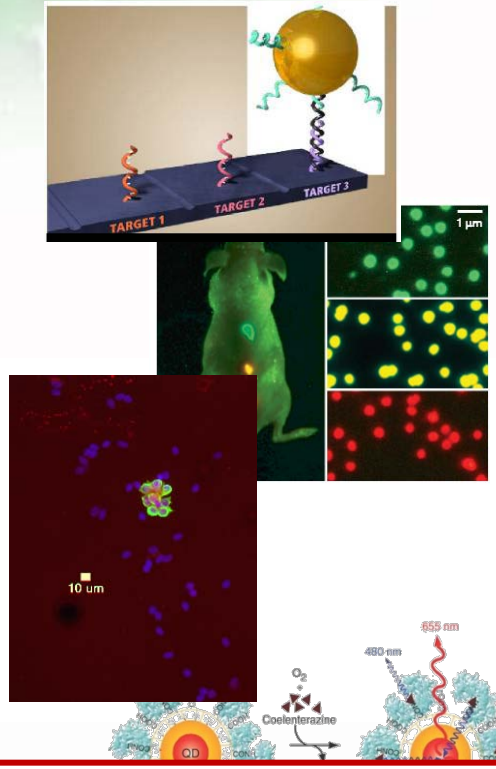
- One investigator (PD/PI) to lead the area of clinical translational oncology
- Second investigator (PD/PI) to lead the efforts in the area of applied nanotechnology

Areas of Research Focus

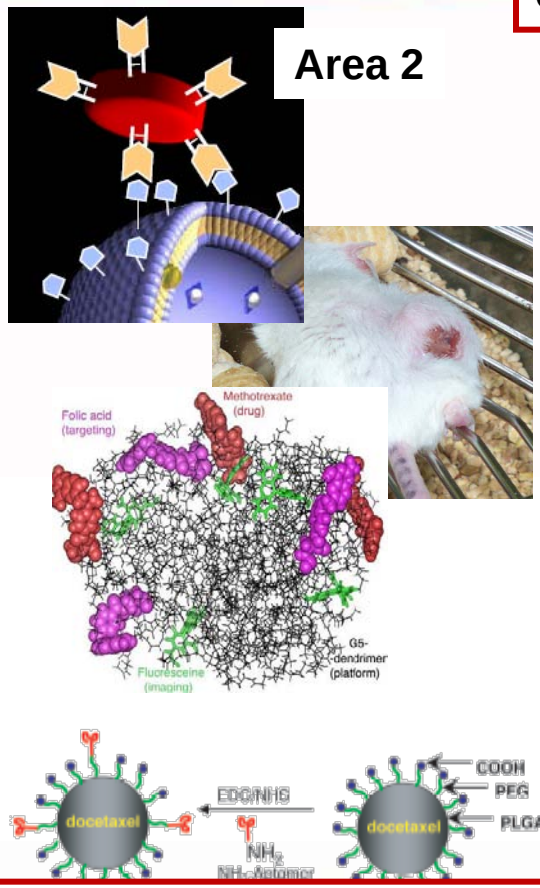
NOT-CA-09-029

CCNE application can focus on one or any combination of two or three research areas

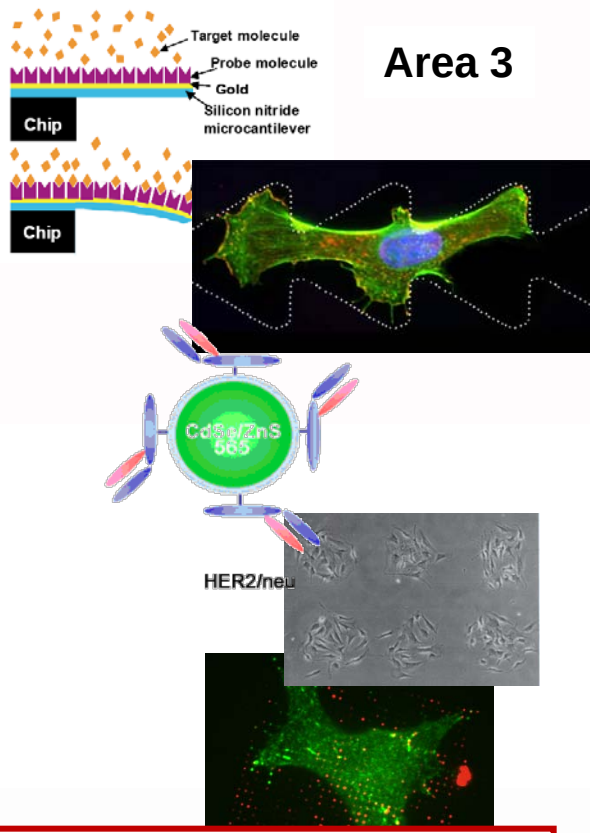
Area 1



Area 2



Area 3



Area 1. Early diagnosis using *in vitro* assays and devices or *in vivo* imaging techniques

Area 2. Multifunctional nano-therapeutics and post-therapy monitoring tools

Area 3. Devices and techniques for cancer prevention and control.

CCNE Application - Characteristics

NCI Alliance for Nanotechnology in Cancer

Open competition, not a renewal

- Multiple (four) institutional entities drawing funds from the grant
  - Higher number of institutions will require strong justification
- Development and participation of for-profit entities to enable clinical translation encouraged
- 3-5 integrated research projects
  - At least one project focused on late discovery/early development
  - At least one project focused on clinical translation
- Applications of technology involve investigation of 2 different tumor types
  - Suggest diseases characterized by particularly low survival rates (brain, lung, ovary, and pancreas cancer)
  - Clear path for clinical translation of the investigative studies
- 3 cores (Bioinformatics recommended)
- Education/Training and Outreach Programs
- Developmental (Pilot) Projects
- Trans-Alliance Challenge Projects

Application and Submission Process

NCI Alliance for Nanotechnology in Cancer

- **Letter of Intent (LOI) – due September 14**
  - **Strongly recommended but not required**
  - **Non-binding**

- **RFA-CA-09-012 will be submitted in paper form**
  - **Use forms from most current PHS 398 instructions**
  - **http://grants.nih.gov/grants/funding/phs398/phs398.html**

CCNE Application Structure

NCI Alliance for Nanotechnology in Cancer

N1. Overview of the Proposed CCNE and Its Area of Focus

N2. Research Team, Center Org. and Infrastructure (Admin. Core)

N3. Research Projects

N4. Shared Research Support Resources (Cores)

N5. Education/Training and Outreach Programs

N6. Developmental Projects and Trans-Alliance Activities

Research Team and Research Capabilities

NCI Alliance for Nanotechnology in Cancer

- **Research Team and Capabilities**
  - **Capabilities, expertise, and experience of the team and the PIs in areas of research focus**
  - **Demonstrate clinical utility of proposed technologies**

- **Translational Potential and Resources**
  - **Development and participation of for-profit entities to enable clinical translation encouraged**
  - **Nanomaterials production scale-up**
  - **Animal study and toxicology evaluation resources**
    - **Nanotechnology Characterization Lab, http://ncl.cancer.gov**
  - **Bioinformatics capabilities and resources**
    - **NCI Center for Bioinformatics: http://ncicb.nci.nih.gov/**

Research Projects

NCI Alliance for Nanotechnology in Cancer

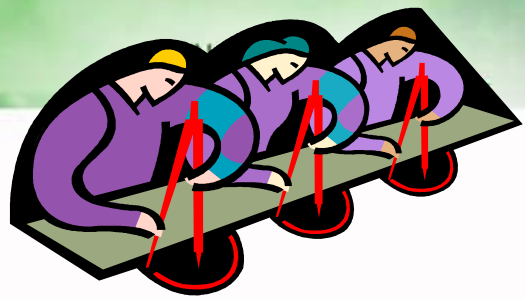
- 3-5 component research projects in areas of research focus
  - Integrate projects to build a bigger whole and draw on each other
  - At least <u>one</u> project focused on late discovery/early development project
  - At least <u>one</u> project focused on clinical translation
- Projects will be judged on scientific merit
  - Provide sufficient detail to enable review
- Research Plan
  - Milestones
    - Research projects must include a specific section labeled "Milestones". Milestones should be scientifically justified and well-defined for each year of the project. Milestones should provide quantitative benchmarks for comprehensively assessing the annual progress of the projects, for example:
      - Detect one cancer cell in 10^6 normal blood cells
      - Enable the visualization of tumors consisting of <1000 cells

Education/Training and Outreach Programs

NCI Alliance for Nanotechnology in Cancer

- **At the Center**
  - **Integrative training for multi-disciplinary researchers**
  - **Physical science approaches applied to cancer research**
  - **Graduate programs, fellowships, certifications, courses**
- **Within the Alliance**
  - **Programs for personnel exchange among CCNEs**
  - **Data sharing plan**
- **Outreach activities**
  - **Publish CCNE results and advertise capabilities**
  - **External seminar series, workshops**
- Required set aside $60K/yr, direct cost

Developmental Projects and Trans-Alliance Activities



- **Discuss strategies and mechanisms**
  - **Do not propose specific projects**

- **Plan for development of *Pilot Projects*** – set aside $70K/yr, direct cost
  - **Exploratory research, short term projects**
  - **Conducted within the Center**

- **Plan for participation in *Alliance Challenge Projects*** – set aside $110K/yr, direct cost
  - **Collaboration with other Alliance awardees**

- **Vision for other Trans-Alliance Activities**

- **Describe interface with NCL and caNanoLab**

Collaborative Alliance Challenge Projects

NCI Alliance for Nanotechnology in Cancer

- **$110K/yr direct cost set aside for Challenge Projects**
- **CCNEs and CCNE – CNPP collaborative projects proposed for 12-18 months duration**
- **CGC and Advisory Committees select projects and manage funds**

CCNE and CNPP research teams

↓

Sciences, medicine, and engineering
Competition and collaboration
Synergy and difference

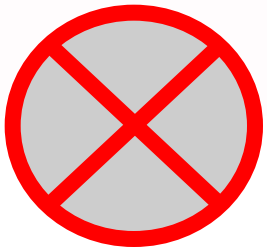
↓

Can we build a <u>bigger whole</u>?

Applying to Different RFAs of the Alliance - PD/PI Eligibility

NCI Alliance for Nanotechnology in Cancer

- **PDs/PIs submitting a U54 application in response to the CCNE RFA-CA-09-012 are NOT eligible to apply for the U01 CNPP award under RFA-CA-09-013 or CNTC award under RFA-CA-09-014 as PDs/PIs**



Frequently Asked Questions

NCI Alliance for Nanotechnology in Cancer

- **Q - How many areas of focus, I can choose within the application?**
- **A - The selection of one, or combination of two, or all three areas are allowed**

- **Q - How many institutions can be involved in the application?**
- **A - We recommend up to <u>four</u> institutional entities drawing funds to be involved in the application. Higher number will require strong justification**

- **Q - What tumor types and how many of them should be included?**
- **A - We require technology application in clinical care in <u>two different tumor types</u> with a preference for those organs in which the disease is characterized by particularly low survival rates (brain, lung, ovary, and pancreas). Other tumor types are also allowed**

- **Q - Are clinical trials covered by this RFA?**
- **A - No, this RFA will not support clinical trials. However, *in vitro studies* of *clinical biospecimens* are supported, and investigators are encouraged to seek funding from alternate sources to conduct *in vivo* trials in parallel with the CCNE award.**

- **Q- Are gene therapy studies covered by this RFA?**
- **A- Projects focused on genetic engineering or design of gene therapies (e.g., DNA sequencing or gene vector methods) are not appropriate for this RFA. However, gene therapy through the use of nanoparticle vehicles for the delivery of genetic vectors is within the scope**

Agency Contacts

NCI Alliance for Nanotechnology in Cancer

1. Scientific/Research Contacts:

Piotr Grodzinski, Ph.D.
Center for Strategic Scientific Initiatives
Office of the Director
National Cancer Institute
31 Center Drive, Room 10A52, MSC 2580
Bethesda, MD 20892
Telephone: (301) 594-4177
FAX: (301) 496-7807
Email: grodzinp@mail.nih.gov

Dorothy Farrell, Ph.D.
Center for Strategic Scientific Initiatives
Office of the Director
National Cancer Institute
31 Center Drive, Room 10A52, MSC 2580
Bethesda, MD 20892
Telephone: (301) 496-5652
FAX: (301) 496-7807
Email: farrelld@mail.nih.gov

Agency Contacts

NCI Alliance for Nanotechnology in Cancer

2. Peer Review Contacts:

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Blvd, Rm 8041, MSC 8329
Bethesda, MD 20892-8329
Telephone: (301) 496-3428
FAX: (301) 402-0275
Email: ncirefof@dea.nci.nih.gov

3. Financial/Grants Management:

Emily Linde
Office of Grants Administration
National Cancer Institute
EPS, 6120 Executive Blvd, suite 243
Rockville, MD 20892-7150
Phone: (301) 496-8784
FAX: (301) 496-8601
E-mail: lindee@mail.nih.gov

NCI Alliance for Nanotechnology in Cancer

Questions?

Submit by email: farrelld@mail.nih.gov