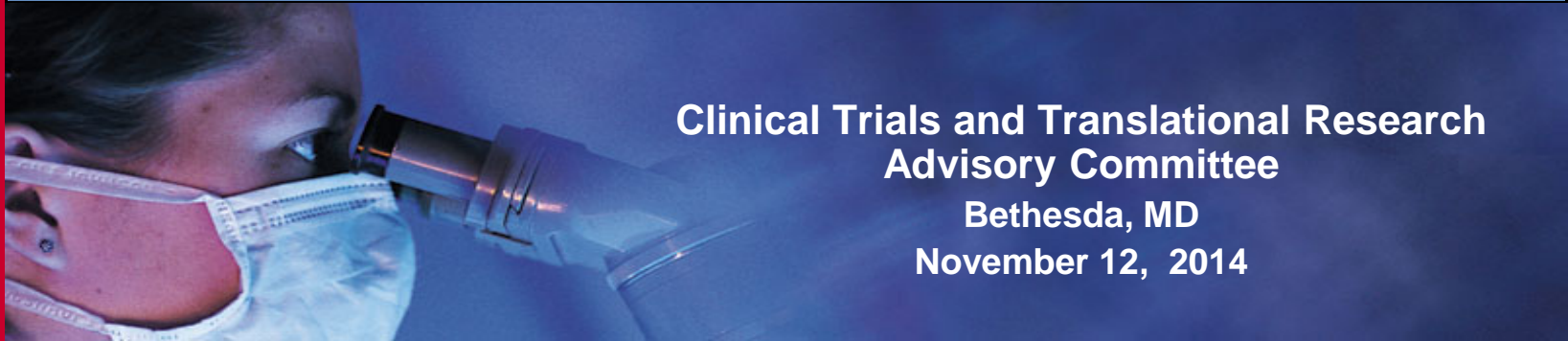




# NCI Update

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National Cancer Institute, NIH



Clinical Trials and Translational Research  
Advisory Committee  
Bethesda, MD  
November 12, 2014

# Topics

- Implementation of the Recalcitrant Cancer Research Act Initiatives
- Redesign of NCI's cancer.gov website
- Cancer Clinical Investigator Team Leadership Awardees for 2014
- Recognition of Retiring CTAC members

# Recalcitrant Cancer Research Act (RCRA) Reporting Requirements

- Initial development of scientific frameworks within 18 months of legislation
  - Pancreatic ductal adenocarcinoma (PDAC); March 2014
  - Small cell lung cancer (SCLC); July 2014
- Review and update the scientific frameworks not later than 5 years after initial development
- Effectiveness of the scientific framework
  - Not later than 6 years after the initial development, submit a report to Congress on the effectiveness of the framework
- NIH Biennial reports:
  - Information on research grants awarded by the NIH for research related to each cancer
  - Assessment of the progress made in improving outcomes for individuals diagnosed with each cancer, including survival rates
  - An update on the activities pertaining to each cancer related to the RCRA activities

# Oversight

- NCI Action Planning Groups (APG)
  - Internally track progress by a small APG for each disease site
  - Provide data on grants and other projects relevant to NCI leadership and extramural working groups
- Extramural Working Groups
  - Plan to convene an **external group of stakeholders** for each disease (CTAC Working Groups) approximately one year after the submission of the relevant framework to discuss progress and identify new scientific opportunities
  - Members will include scientific experts, clinicians, and patient advocates
- CTAC
  - Report implementation progress to CTAC at least annually beginning in 2015

# **Small Cell Lung Cancer Initiatives**

# Recommendation 1: Better Research Tools for Study of SCLC

- Support infrastructure for SCLC specimen collection over the next 3 years
  - Fund collaborative projects across NCI's research networks to expand the generation of PDX and conditionally-reprogrammed cell lines
  - Specimens to be obtained from biopsies of SCLC patients enrolled in clinical trials or for whom detailed clinical information is available
- **Progress:**
  - Supplemental funding has been provided to Cancer Centers and NCORP sites for specimen collection

## Recommendation 2: Comprehensive Genomic Profiling of SCLC

- Characterize the genetic and molecular features of the SCLC specimens that have been collected at diagnosis and relapse over the next 3 to 5 years
- **Progress:**
  - Supplemental funding has been provided to Cancer Centers and NCORP sites for specimen collection

## Recommendation 3: New Diagnostic Approaches for SCLC

- Issue a Program Announcement in the second half of 2015
  - Support studies focused on discovering early molecular changes in histologically normal lung, blood (including circulating DNA), and other relevant tissues that could be applied to subsequent screening studies in high risk populations
- **Progress:**
  - DCP is developing a funding announcement.



# Recommendations 4 & 5: Therapeutic Development Efforts

- Issue a Program Announcement in the second half of 2015
- Support studies focused on understanding the unique features of SCLC that could be used to develop new therapeutics
  - 1) Molecular vulnerabilities that could be used to develop target agent combinations
  - 2) High rate of initial response and rapid development of clinical resistance to drug and radiation therapy
- **Progress:**
  - DCTD is developing a funding announcement.

# **Pancreatic Ductal Adenocarcinoma Initiatives**

## Recommendation 1: Relationship between PDAC and Diabetes Mellitus

- June 2013 – NIDDK-NCI Pancreatitis-Diabetes-Pancreatic Cancer Workshop held
  - Recommended NCI-NIDDK develop a funding opportunity announcement for expanding research in the critical areas identified by the workshop.
- **Progress:**
  - NIDDK-NCI issued a joint RFA for a consortium for the study of chronic pancreatitis, diabetes, and pancreatic cancer (RFA-DK-028) in October, 2014

## Recommendation 2: Biomarkers for Early Detection of PDAC and Its Precursors

- Issue a Program Announcement over the next year focusing on the development of novel methods to obtain and interrogate pancreatic tissues containing pre-neoplastic lesions to stimulate studies in this area.
- **Progress:**
  - DCP is developing a program announcement funding opportunity.

## Recommendation 3: New therapeutic approaches in immunotherapy

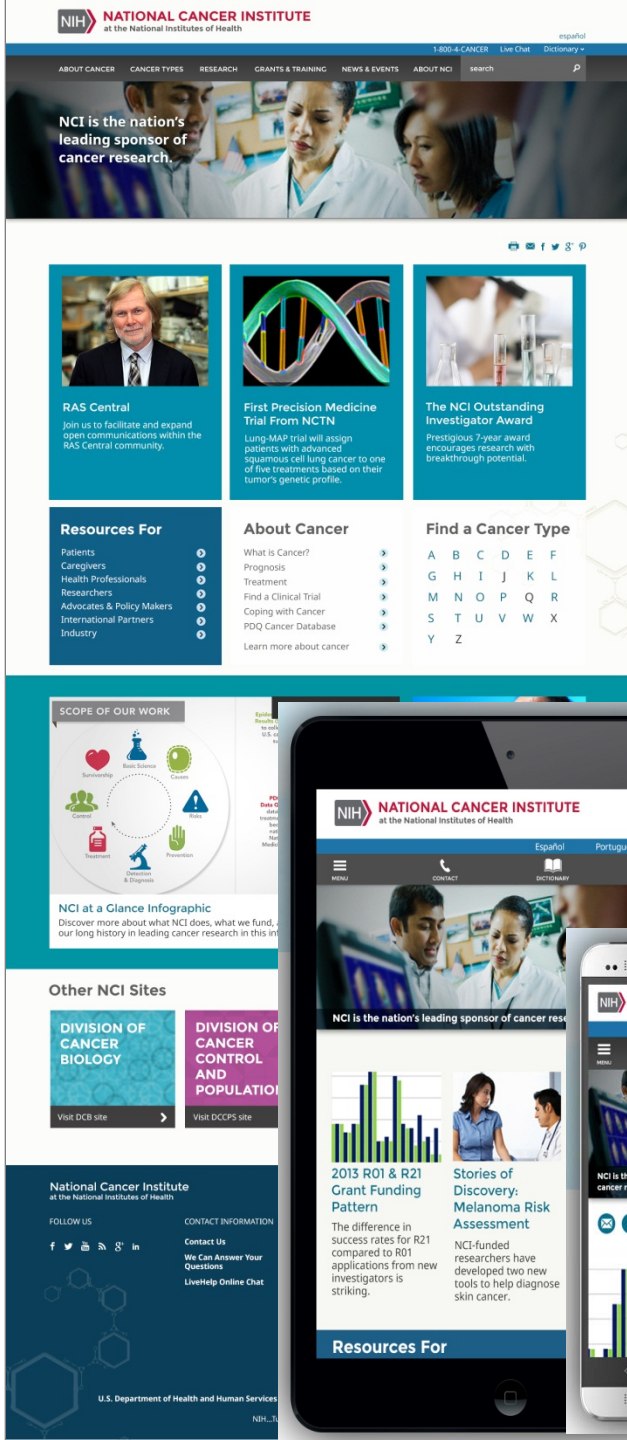
- Progress in pancreatic cancer immunotherapy will include:
  - support of grants dealing with the discovery and validation of new immunotherapy targets
  - rational combination of immune modifiers in preclinical and clinical studies,
  - production of immune-modulatory molecules at the NCI Frederick to facilitate the initiation of early phase PDAC immunotherapy trials
- The Cancer Immunotherapy Trials Network will design and conduct therapy trials with the most promising immunotherapy agents

## Recommendation 4: Ras-Specific Therapeutics

- Five high priority projects for the focus of the NCI's large-scale program on RAS at the Frederick National Laboratory for Cancer Research have been identified:
  1. Pursuing allele specific compounds for those RAS alleles most prevalent in human cancer (e.g., KRAS G12D and G12V in pancreatic cancer)
  2. Developing KRAS selective binding compounds for KRAS ablation without allele specificity
  3. Developing imaging methods and screens to identify and disrupt KRAS complexes in cells and to monitor their disruption
  4. Mapping the surface of KRAS cancer cells and identifying epitopes that could be targeted by immunotherapy and proteins that could be targeted for drug delivery by nanoparticles
  5. Developing and conducting next-generation synthetic lethality screens and engineering mice to facilitate these screens
- Progress as the project relates to PDAC will be measured by periodic reports, publications, and presentations

# Topics

- Implementation of the Recalcitrant Cancer Research Act Initiatives
- Redesign of NCI's [cancer.gov](http://cancer.gov) website
- Cancer Clinical Investigator Team Leadership Awardees for 2014
- Recognition of Retiring CTAC members



# NCI's Cancer.gov Website Re-design

- Modern, responsive design
- Logical navigation
- User-friendly
- Viewable in all formats
  - Desktop
  - Smart phone
  - Tablet



# Emphasizing Clinical Trials on the Next Version of Cancer.gov

The screenshot displays the Cancer.gov website interface. The top navigation bar includes links for ABOUT CANCER, CANCER TYPES, RESEARCH, GRANTS & TRAINING, NEWS & EVENTS, ABOUT NCI, and a search function. A left sidebar lists various cancer-related topics, with 'Clinical Trials' highlighted in a teal arrow. The main content area features a circular diagram titled 'CANCER RESEARCH LIFECYCLE' with four segments: BASIC RESEARCH, PRECLINICAL/TRANSLATIONAL RESEARCH, CLINICAL TRIALS (Phase 0, I, II, III), and EVALUATION/APPROVAL. To the right of the diagram is a 'On This Page' section with four bullet points. Below the diagram is a featured article titled 'Why Clinical Trials Are Critical to Progress Against Cancer' with a 'SHARE' button. The article text discusses the importance of clinical trials in cancer research and treatment.

ABOUT CANCER CANCER TYPES RESEARCH GRANTS & TRAINING NEWS & EVENTS ABOUT NCI search

Cancer Genomics  
Causes of Cancer  
Cancer Screening & Prevention  
Cancer Diagnosis & Treatment  
**Clinical Trials**  
Cancer & Public Health  
Global Health  
Cancer Health Disparities  
Intramural Research  
Research Infrastructure

**CANCER RESEARCH LIFECYCLE**

- BASIC RESEARCH
- PRECLINICAL/TRANSLATIONAL RESEARCH
- CLINICAL TRIALS (Phase 0, I, II, III)
- EVALUATION/APPROVAL

**On This Page**

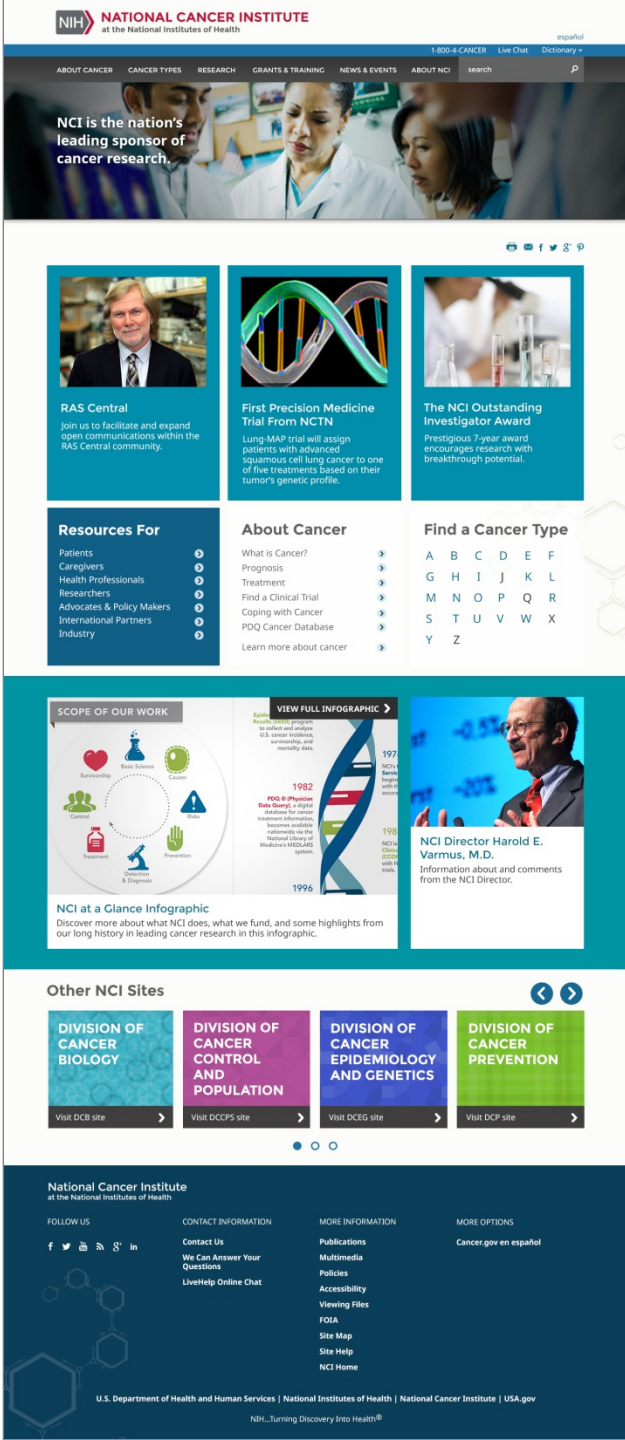
- Why Clinical Trials Are Critical to Progress Against Cancer
- How New Knowledge about Cancer Is Changing Clinical Trials
- How NCI Programs Make a Difference
- How NCI Is Supporting Cutting-Edge Clinical Trials

**Why Clinical Trials Are Critical to Progress Against Cancer** [SHARE](#)

Clinical trials are essential for moving new methods of preventing, diagnosing, and treating cancer from the laboratory to the physician's offices and other clinical settings.

In clinical trials, researchers carefully and methodically test drugs, medical devices, screening approaches, behavioral modifications, and other interventions. Trials are used to answer many different clinical questions relevant to all aspects of health care, such as whether a treatment can prevent cancer in people at increased risk, whether a new drug can extend the lives of patients with advanced cancer, or whether specific treatment approaches can improve patients' quality of life. The Food and Drug Administration (FDA) typically requires proof of safety and effectiveness of a new anticancer drug in a large clinical trial before it can be used broadly in patient care.

In addition to testing new interventions, clinical trials can help determine the best use of existing interventions, test new approaches for increasing the number of people who seek follow-up care after a positive cancer screening test, and test ways to improve end-of-life care for patients.



# Designed with key audiences in mind

- Patients & families
- Health professionals
- Researchers
- Advocates
- Industry

# Embarking on “usability testing” with these groups

# Topics

- **Implementation of the Recalcitrant Cancer Research Act Initiatives**
- **Redesign of NCI's cancer.gov website**
- **Cancer Clinical Investigator Team Leadership Awardees for 2014**
- **Recognition of Retiring CTAC members**

## Award Purpose

- **Recognize and support outstanding mid-level clinical investigators at NCI-designated Cancer Centers participating extensively in NCI-funded collaborative clinical trials whose participation and activities promote a culture of successful clinical research**
- **Promote the retention of clinical investigators in academic clinical research careers**

## Funding

- **First awards made in 2009 with 68 recipients to date**
- **~ 10 to 12 new awards per year**
- **Award duration is two years with funding of \$50,000 total costs per year**
- **Awardee must devote at least 15% effort to the activities associated with this award and the sponsoring institution must protect the awardee's time for these activities**

# Supported Activities

## **Include, but not limited to:**

- Organizing courses, lecture/seminar series, educational sessions, or workshops
- Attending courses, seminars, meetings, conferences, or workshops
- Engaging fellows and new faculty in collaborative clinical research efforts
- Mentoring junior staff/fellows/trainees
- Participating on a particular cancer center committee
- Developing a clinical trial concept and/or protocol
- Designing and implementing initiatives to better coordinate, support and integrate a clinical trials culture at the institution
- Developing streamlined processes for the awardees' institution's (IRB), Data Safety Monitoring Board (DSMB), or Scientific Review Committees
- Resolving activation or accrual issues

# Eligibility

- **Nominated by Cancer Center Director**
- **One application per Cancer Center**
- **Engaged in the conduct of NCI-funded cancer clinical trials**
- **Currently practicing in the oncology clinical setting; board certified**
- **Full-time faculty member, assistant or associate professor level**
- **Physician or oncology nurse, clinical psychologist, or similarly qualified clinician with a doctoral degree**
- **Practicing at least 3 years but no more than 10 years post-fellowship**

# Application Evaluation Criteria

- **Training and experience**
- **Leadership experience in clinical research activities/clinical trials**
- **Extent of participation in clinical trials and related activities**
- **Nominee's planned activities to promote a successful clinical research culture at his/her institution**
- **Clear institutional commitment to allow at least 15% effort for activities proposed in the application**
- **Appropriate level of institutional commitment to the career development of the nominee**



# 2014 CCITLA Awardees



**Neeraj Agarwal, M.D.**  
**University of Utah Huntsman Cancer Institute**



**Robert Chen, M.D.**  
**City of Hope Comprehensive Cancer Center**



**Michael Gibson, M.D., Ph.D., F.A.C.P.**  
**Case Comprehensive Cancer Center**  
**Case Western Reserve University**

## 2014 CCITLA Awardees



Theodore Hong, M.D.  
Dana-Farber/Harvard Cancer Center



R. Kate Kelley, M.D.  
UCSF Helen Diller Family Comprehensive Cancer Center



Araz Marachelian, M.D., M.S.  
USC Norris Comprehensive Cancer Center

# 2014 CCITLA Awardees



**Stergios Moschos, M.D.**  
**UNC Lineberger Comprehensive Cancer Center**



**Rita Nanda, M.D.**  
**University of Chicago Medicine  
Comprehensive Cancer Center**



**Daniel Persky, M.D.**  
**University of Arizona Cancer Center**

# 2014 CCITLA Awardees



**Erin Reid, M.D., M.S.**  
**UC San Diego Moores Cancer Center**



**Teresa Rutledge, M.D.**  
**University of New Mexico Cancer Center**

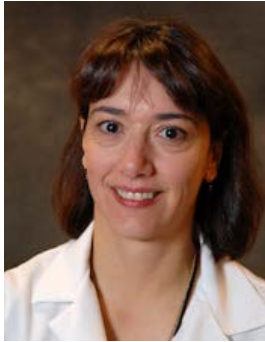
# Congratulations to the 2014 NCI Cancer Clinical Investigator Team Leadership Award Recipients



# Topics

- **Implementation of the Recalcitrant Cancer Research Act Initiatives**
- **Redesign of NCI's cancer.gov website**
- **Cancer Clinical Investigator Team Leadership Awardees for 2014**
- **Recognition of Retiring CTAC members**

# Retiring CTAC Members



**Monica Bertagnolli, M.D.**  
**Dana Farber Cancer Center**



**Lisa Newman, M.D., M.P.H., F.A.C.S.**  
**University of Michigan Cancer Center**



**Frank Torti, M.D.**  
**University of Connecticut School of Medicine**





## CTAC Working Groups

- **Propose the formation of a Small Cell Lung Cancer (SCLC) and a Pancreatic Ductal Adenocarcinoma (PDAC) Working Groups**
- **Review the progress of the implementation of the Recalcitrant Cancer Research Act scientific frameworks and identify any new opportunities**
- **Members will include scientific experts, clinicians, and patient advocates**
- **Working Groups will report progress to CTAC**