



# **Process to Accelerate Translational Science Working Group (PATS WG) report**

Co-chairs

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# Process to Accelerate Translational Science (PATs) Working Group



- A Working Group of CTAC
- Charge: Advise CTAC on the implementation of the TRWG-proposed Translational Research Acceleration Initiative
- CTAC accepted recommendation from March 2009 meeting to pilot process with one pathway before expansion to other pathways
- Met May 10, 2010 to evaluate Immune Response Modifier pilot experience and recommend next steps

# PATS Working Group members



- Lynn Matrisian (Co-chair)
- Ken Cowan (Co-chair)
- Abbruzzesse, James
- Anderson, Kenneth
- Ballard-Barbash, Rachel
- Bertagnolli, Monica
- Bruner, Deborah
- Cairns, Paul
- Cheever, Martin
- Civin, Curt
- Collyer, Deb
- Dorfman, Gary
- Doroshow, James
- Erlichman, Charles
- Gambhir, Sanjiv Sam
- Gilmer, Tona
- Gray, Joe
- Gray, Paulette
- Greenwald, Peter
- Hawk, Ernest
- Hricak, Hedvig
- Lawrence, Theodore
- Leung, K. Gabriel
- Nelson, Bill
- Roach, Nancy
- Schilsky, Richard
- Sellers, Thomas
- Singer, Dinah
- Tepper, Joel
- Tlsty, Thea
- Wilttrout, Robert

# The NCI Translational Research Working Group (TRWG)



- Charged in 2005 to evaluate the current status of NCI's investment in translational research & envision its future in an inclusive, representative & transparent manner
- 63 scientists, clinicians, advocates, and thought leaders from academia, government, and industry
- 150 page report accepted by NCAB 2007: [www.cancer.gov/trwg](http://www.cancer.gov/trwg)



# Defining the Scope of the TRWG:

*The President's Cancer Panel Translational Continuum*



## Basic Science Discovery

- Promising molecule or gene target
- Candidate protein biomarker
- Basic epidemiologic finding

## Early Translation

- Partnerships & collaboration (academia, government, industry)
- Intervention development\*
- Phase I/II trials

## Late Translation

- Phase III trials
- Regulatory approval
- Partnerships
- Production & commercialization
- Phase IV trials – approval for additional uses
- Payment mechanism(s) established to support adoption
- Health services research

## Dissemination

- To community health providers
- To patients & public

## Adoption

- Adoption of advance by providers, patients, public
- Payment mechanism(s) in place to enable adoption

Type 1 Translation

Type 2 Translation

*\*New drug, assay, device, behavioral intervention, educational materials, training*

**Focus of TRWG**

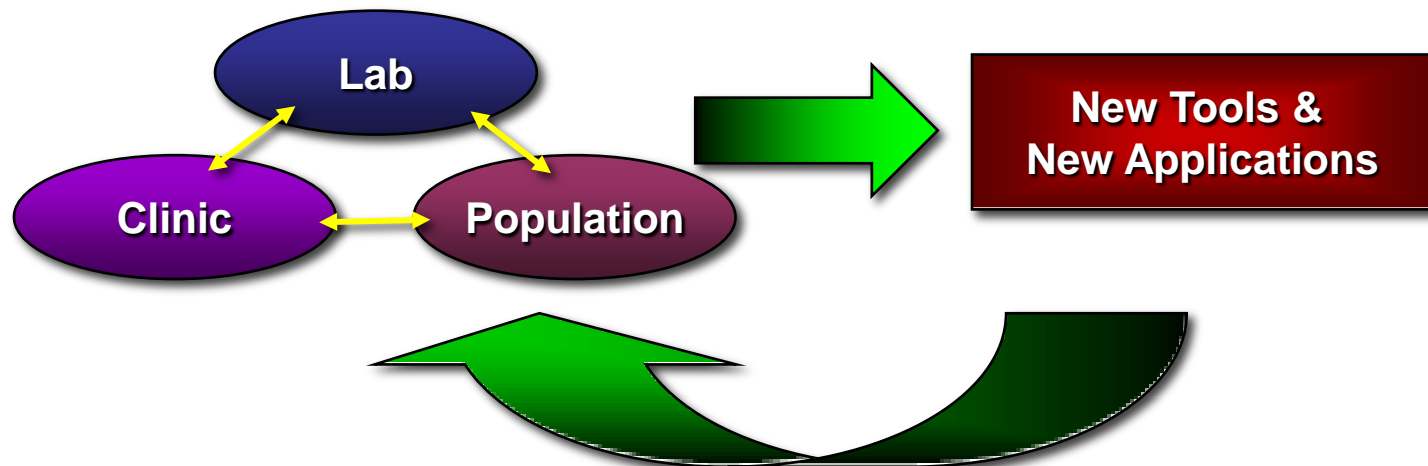
**Interface with Clinical Trials Working Group**

*President's Cancer Panel, 2004-2005 Annual Report*

# The TRWG's Definition of Translational Research



Research that transforms scientific discoveries arising in the lab, clinic, or population into new clinical tools & applications that reduce cancer incidence, morbidity & mortality





# Operational definition of Translational Research: TRWG Pathways



[clincancerres.aacrjournals.org](http://clincancerres.aacrjournals.org)

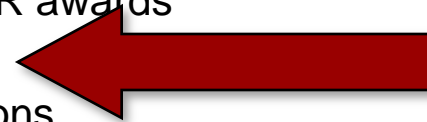
CCR 14: 5663-5713 (2008)

# TRWG report: 15 Initiatives with Implementation Plans



Optimize  
and  
enhance  
NCI  
functions  
that are  
critical for  
translational  
research

- **Coordinated Management**
  - Integrated NCI management
  - Budget designation
  - TR coding
  - Prioritization process
- **Tailored Funding**
  - Modify TR award mechanisms
  - Improve investigator-initiated TR awards
  - STRAP awards
  - Academic/industrial collaborations
- **Operational Effectiveness**
  - Project management
  - Core services coordination
  - Enhance biorepositories
  - Improve IP negotiations
  - Enhance foundation/advocate group collaborations
  - Enhance training/incentives



Translational  
Research  
Acceleration  
Initiative

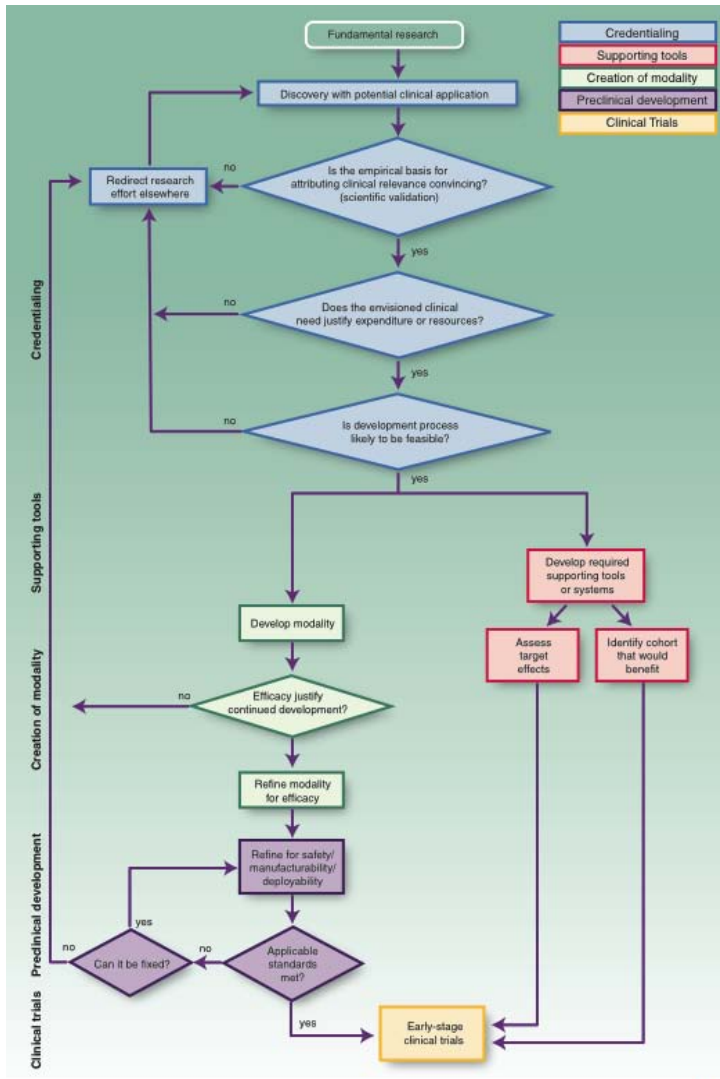


# Designed to address the Challenge of Early Translation



## How can we best assure that:

- The most promising concepts enter the developmental pathways?
- Concepts that do enter advance to the clinic or to productive failure?
- Progress is as rapid, efficient and effective as possible?



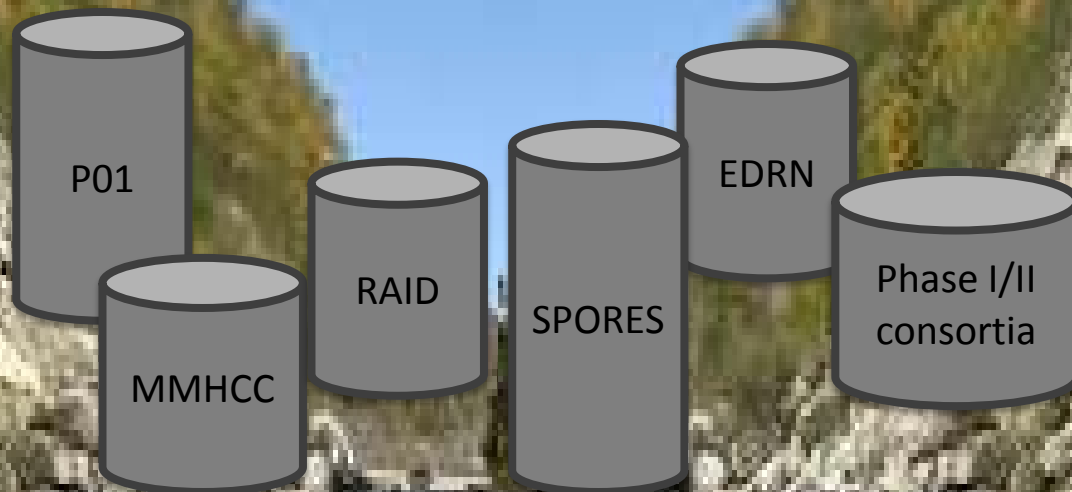
# TRWG vision of the Translational Research Acceleration program

What can the NCI do to get across the “Valley of Death” and accelerate translational research?

Discovery  
Research

Phase III  
trials

NCI has programs that fulfill translational research needs



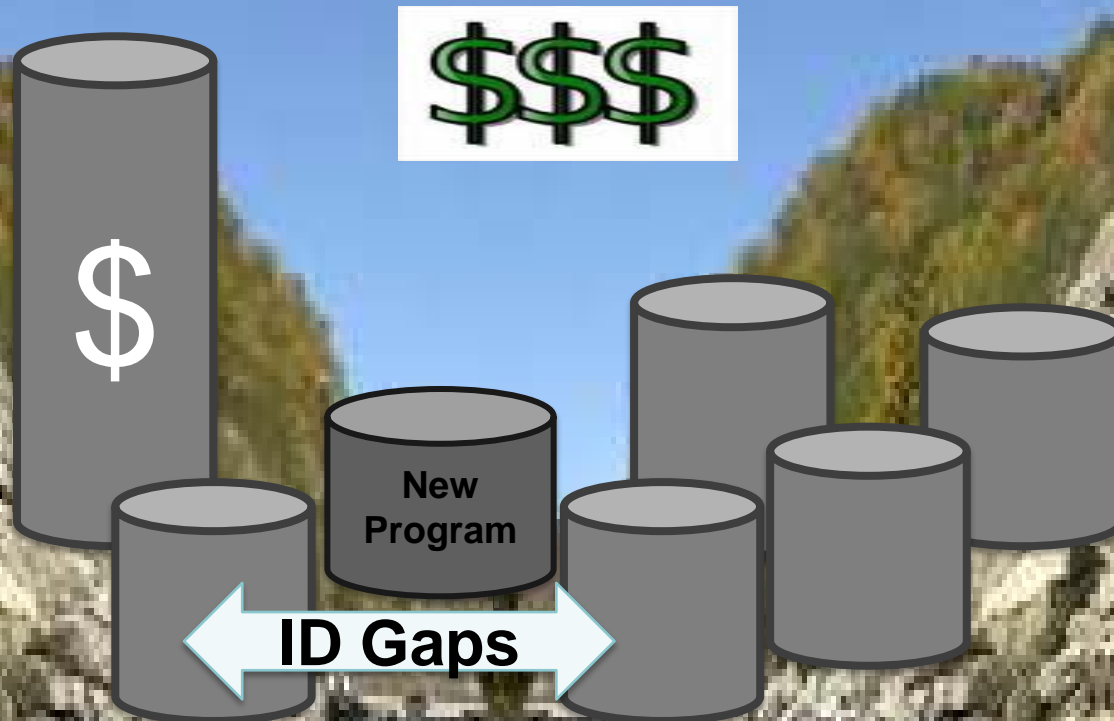
# An obvious solution:

- increase the funding in translational research programs
- identify gaps and generate new programs as needed

Discovery  
Research

Phase III  
trials

May be necessary, but not sufficient



# The Translational Research Acceleration Initiative approach

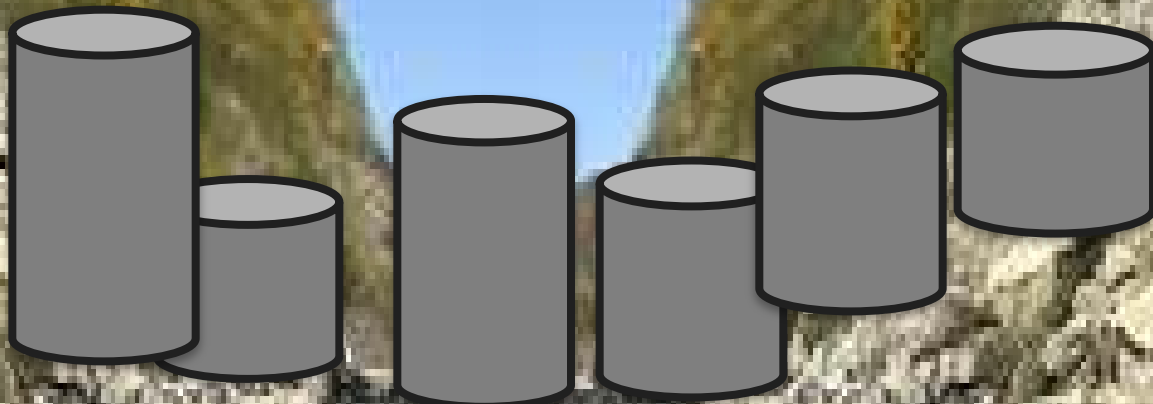
- Focus on a few highly meritorious projects each year

Discovery  
Research



Phase III  
trials

Prioritization

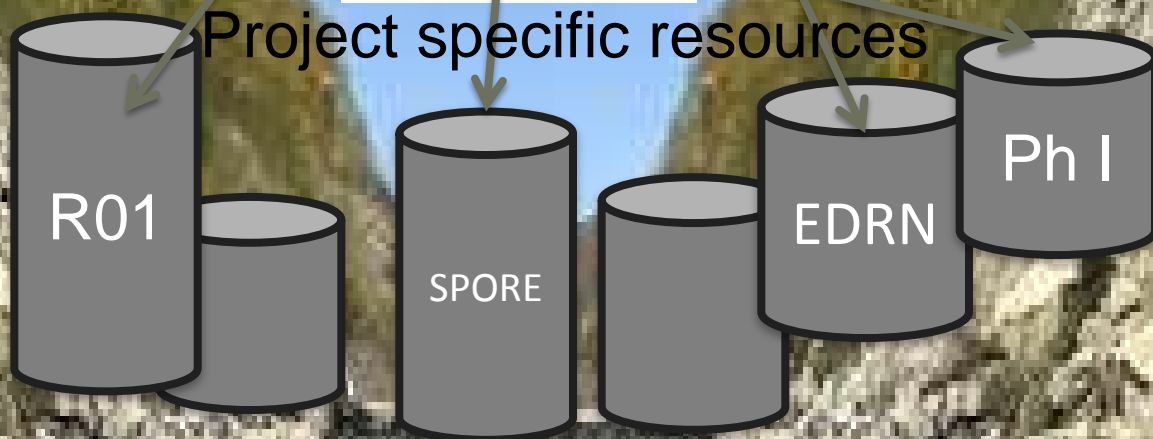
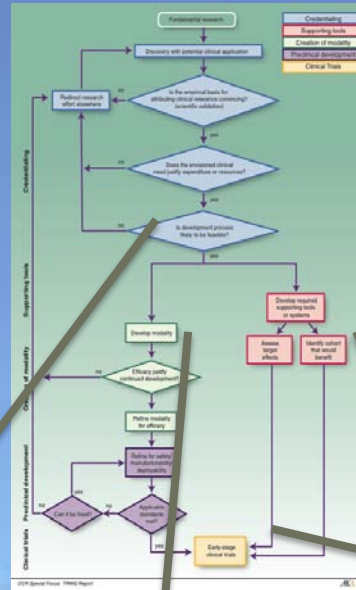


# The Translational Research Acceleration Initiative approach

- Identify existing resources that when linked accomplish a specific goal

Discovery Research

Phase III trials



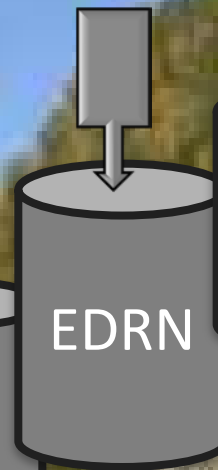
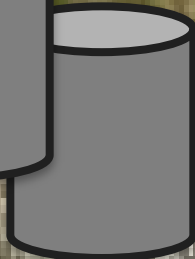
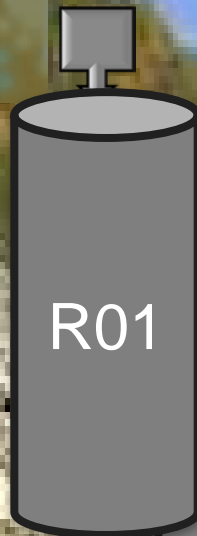
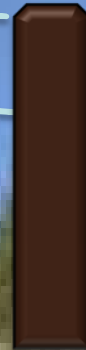


# The Translational Research Acceleration Initiative approach

- Provide additional resources and project management to leverage resources

Discovery  
Research

Phase III  
trials



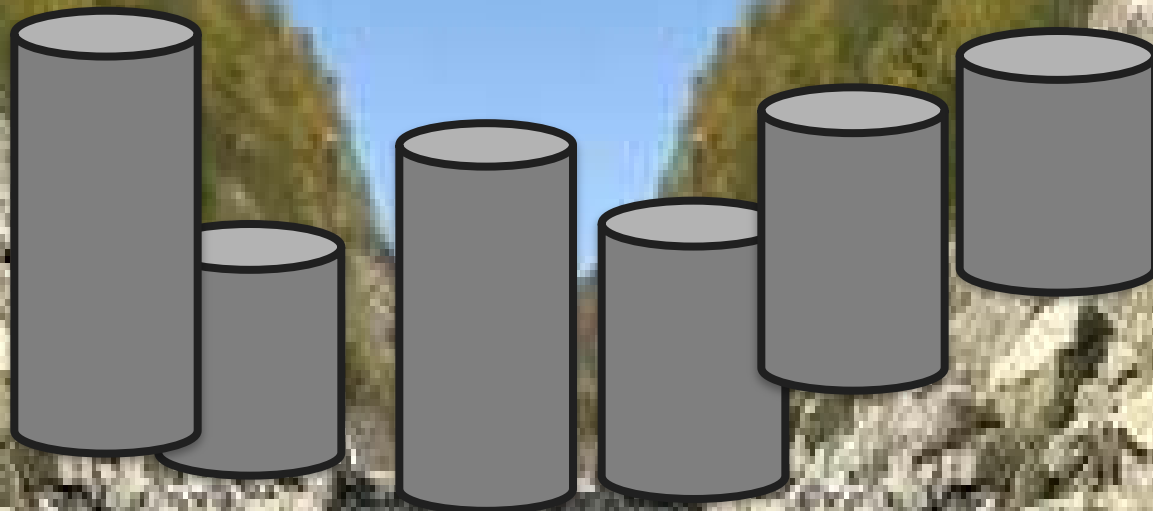
# The Translational Research Acceleration Initiative approach

- Success will lead to hand off to Phase III trial, not renewal of funding

**Discovery  
Research**



**Phase III  
trials**

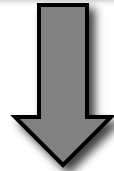


# Translational Research Acceleration Initiative

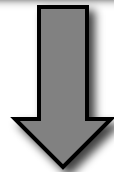


*Select several projects/year that are “ripe” for translation*

**Gather information**



**Prioritize**



**Fund & Manage**

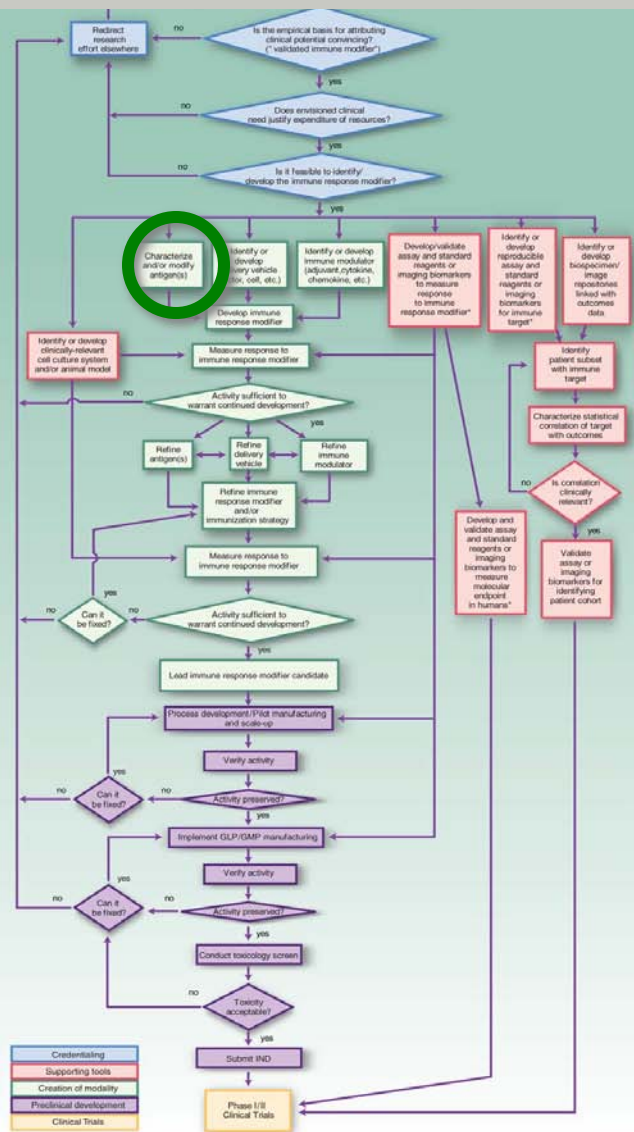
- Does not impact discovery research
- Leverages existing translational programs

Special Translational Research Acceleration projects  
(STRAP)

# Pilot Project: Immune Response Modifier Pathway



- Why IRM?
  - Most complex of the Pathways
  - Previous prioritization of Immune Response Modifiers (summer 2007)
    - <http://dcb.nci.nih.gov/ImmunAgentWork>
  - A group of committed immunologists/immunotherapists could be identified (Mac Cheever, Fred Hutchinson Cancer Center)
- Phase I: Focused on Antigen development (Cheever et al, CCR 15, 5323, 2009)
- Phase II: Expanded to entire IRM Pathway (IRMP WG report, approved by CTAC Nov 2009)



# Recommendations from the IRM Prioritization Working Group



NCI  
provides:  
Immune  
Response  
Modifier:

T cell factors  
*and/or*  
T cell checkpoint  
factors  
*and*  
Adjuvant



Extramural competition:  
Target and regimen

*and/or*

Cellular or viral  
antigens  
for **vaccine**  
therapy  
regimen

T-cell  
therapy  
targets  
for **adoptive**  
therapy  
regimen

Existing  
**antibody**  
regimen

Short list of High Priority targets

Required  
Components:

Formulation

Rationale for  
combination

Response assay

Patient selection  
assay

Clinical trials



# TRWG vision of STRAPs



- **S** is for Special
  - Not possible through regular R, P, U, etc mechanisms
  - High probability of significantly advancing field
- **TR** is for Translational Research
  - Follows TRWG pathway to early stage clinical trials
  - Includes assessment modalities
- **A** is for Acceleration
  - Fast, Facile, and Flexible
- **P** is for Project
  - Project Management
  - Timelines and Milestones

# IRM STRAP



## **Administrative Supplements to Advance Special Translational Research Acceleration Projects on Immune Response Modifiers Currently Funded by the National Cancer Institute (NCI)**

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**Notice Number:** NOT-CA-10-025

### **Key Dates**

Release Date: May 27, 2010

Request Receipt Date: July 15, 2010

Earliest Anticipated Start Date for Supplement Awards: September 1, 2010

### **Issued by**

National Cancer Institute (NCI) (<http://cancer.gov/>)

### **Purpose**

The National Cancer Institute (NCI) announces the opportunity for grantees to seek **supplemental funding for existing NCI-funded grants**. The purpose of this initiative is to accelerate translational **research focused on immune response modifiers (IRMs)**.

\$2M for one project

IRM Pathway milestones (at least up to clinical trials)

# May 10<sup>th</sup>, 2010 PATS WG meeting



- Are TRWG fundamental assumptions still true? *Yes*
- Is the process used in the pilot project for identifying candidate STRAP projects useful?  
*Needs improvement*
- What standing programs and infrastructure is available to leverage for STRAP projects?  
*Lots, including NExT*
- Is the prioritization process used for the pilot useful for the other pathways? *Maybe, maybe not*
- What funding strategies are useful for STRAPs?  
*Must be flexible*

# PATS WG report recommendations:



- **UMBRELLA STRAP SOLICITATION**

- Broad solicitation for “ripe” translational projects
- Must get to human testing – TRWG Pathways as guidelines
- Link and leverage existing projects/funding mechanisms, most likely from multiple institutions/programs
- 1-3 page concept review based on scientific validity, clinical need, feasibility, and suitability for NCI investment
- Project can be enhanced by NCI or expert committee
- Project implementation and handoff to advanced trials is actively managed (NCI-based project coordinator)
- Agents Pathway with therapeutic intent should use NExT at least for initial cycles.

# PATS WG report recommendations:



- **PRIORITIZATION**

- PATS WG members representing Biomarkers, Imaging, Devices, and Lifestyle pathways consulted on information gathering and prioritization within pathway
- Pathway specific subgroups
  - Prioritize opportunities to inform NCI in general
  - Prioritize for STRAP applications under Umbrella Program
  - Set criteria
  - Advise on infrastructure available/needed
  - Ambassadors to investigator community



# PATS WG report recommendations:



- **TIMELINE**

- Start Umbrella STRAP solicitation process immediately
- Initiate Prioritization process for other pathways and incorporate into STRAP solicitation as appropriate and feasible

- **SCOPE**

- 2-3 STRAP projects funded/year
- \$2-3M/STRAP project
- STRAP projects for 3-5 year time period
  - milestone driven

# PATS WG report recommendations:



- Discussion
- Does CTAC accept the PATS WG report?