Process to Accelerate Translational Science (PATS)

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The NCI Translational Research Working Group (TRWG)

- 63 scientists, clinicians, advocates, and thought leaders from academia, government, and industry
- Charged in 2005 to evaluate the current status of NCI’s investment in translational research & envision its future in an inclusive, representative & transparent manner
- Produced a 150 page report with 15 recommendations accepted by NCAB June 2007: [www.cancer.gov/trwg](http://www.cancer.gov/trwg)
TRWG Pathways to Clinical Goals

cliccancerres.aacrjournals.org

CCR 14: 5663-5713 (2008)
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?
15 Initiatives with Implementation Plans

- **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

Optimize and enhance NCI functions that are critical for translational research.

Develop a new process to accelerate translational cancer research.

www.cancer.gov/trwg
Select several projects/year that are “ripe” for translation

- New Translational Research Acceleration Process DOES:
  - Gather information on translational opportunities
  - Prioritize translational research opportunities
  - Develop a funding & project management plan to accelerate prioritized opportunities

- New Translational Research Acceleration Process DOES NOT:
  - Impact Discovery research
  - Replace existing infrastructure or mechanisms for clinical or translational research
NCI Translates
NCI-wide Translational Science Meeting

- November 7-9, 2008, Washington, DC
- Coordinating Center for Clinical Trials,
  - Sheila Prindiville, M.D., M.P.H.
  - Lynn Matrisian, Ph.D.
- **513 abstracts**
  - Grants/PIs selected by NCI Program Staff
- **800 invited participants**
  - NCI-funded scientists/clinicians
  - Advocates
  - NCI staff

http://ncitranslates.nci.nih.gov
Translational Research Opportunity

• Focuses on a **clinical goal**
  – Develops a modality (drug, device, biomarker, etc) that can be tested in people
  – Identifies the population/cancer type in which it is tested

• Describes **scientific validity**

• Details **clinical need**

• Provides information on **feasibility**
  – Identifies individuals/research groups with projects or capabilities relevant to pathway domains
EXAMPLE: Targeting the Wnt pathway

- Stem cell regulatory network
- Extensive evidence for causal role in CRC and others
- VU-WS30 (anti-helminth) identified in Xenopus egg assay to block Axin degradation & prevent Wnt signaling
- Modifications required to overcome limited systemic access
- Inhibits β-catenin induced proliferation of colon cancer cell lines
- Mouse models of CRC available
- Assays for Wnt signaling needed
- Tox, etc, needed on modified agent
- CRC for initial trials

GI SPORE
Chemistry?
MMHCC
RAID
PHI,II consortia
Translational Research Opportunity Information Guides

- Pathway Specific (6 Information Guides)
- Available at ncitranslates.nci.nih.gov
  - Purpose and Goals tab
- Provides a strawman template for information required for Translational Research Opportunities
CTAC recommended that NCI proceed with establishing a process to accelerate translational cancer research (Dec 08):

- **Call for Opportunities**
  - Summer 09

- **Prioritize**
  - Winter 09/10

- **Fund & Manage**
  - Spring 2010
PATS Working Group

- A Working Group of CTAC
- Charge
  - Determine format for Translational Research Opportunities
  - Determine pathway-specific prioritization criteria
  - Advise on cross-pathway criteria
- Met Feb 16th by webinar
- Met Mar 3rd to initiate criteria setting
PATS Working Group members

- 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
- Wiltrout, Robert
PATS Working Group

Mar 2009

Determine pathway-specific criteria

BM

IRM

LA

Ag

IM

ID

Determine format for pathway-specific criteria

CTAC
Proposed Prioritization Process: tools

Pathway(s) published

Translational Research Opportunity Guideline online

Translational Research Opportunity Template RFI template PATS WG

Pathway-specific criteria and rating scale For prioritization PATS WG
Analytical Hierarchy Process (AHP): A structured technique for complex decision making

- Based on mathematics and human psychology
- Provides a comprehensive framework
  - To structure the problem
  - To represent and quantify key elements
  - To relate those elements to overall goals
  - To evaluate alternative solutions
Analytical Hierarchy Process

NCI Pilot Project: Immunology Pathway (Fall 2008)

Image courtesy of Decision Lens®
Prioritization Process

**Intra-pathway Prioritization**
Pathway-specific criteria determined and weighted

**Inter-pathway Prioritization**
Cross-pathway specific criteria determined and weighted

**Executive Decisions**
NCI leadership
What else is needed?

- Develop customized funding strategies
  - Funding mechanisms and sources depend on project specifics
  - Range from expansion of existing activities to new activities
  - Require extraordinary coordination

- Develop Project Management capabilities
  - Required to link new or existing teams/projects and to facilitate hand-offs between groups
**Special Translational Research Acceleration Project (STRAP)**

- **Requirements:**
  - Goal of completing early stage human studies
  - Project management plan
  - Specific development milestones and timelines
  - Development/commercialization strategy
- **Funds for new and/or expanded projects**
- **Project management would link new or existing teams and projects and facilitate hand-offs between groups**
- **Opportunities to include industry/foundation funding or participation**
PATS Initiative Timeline

- PATS WG constituted Feb 2009
  - Webinar Feb 16th
  - Discussion of strawman Agents criteria Mar 3rd
- Prioritization progress update for CTAC Mar 4th
- Teleconference to review prioritization process recommendation
- Set up Pathway groups to develop pathway specific criteria
- Criteria setting (web-based)

- Call for Opportunities - RFI - summer 2009
- Prioritization – fall 2009
- NCI Translational Science Meeting – Nov 2010
- Call for STRAP proposals – early 2010
- STRAP funding – spring 2010
Gather information:
RFI for Translational Research Opportunities

Prioritize
Intra- and Inter-Pathway Prioritization

Fund & Manage
Special Translational Research Acceleration Projects

Summer 09
Winter 09/10
Spring 2010