



Process to Accelerate Translational Science (PATs)

March 4, 2009

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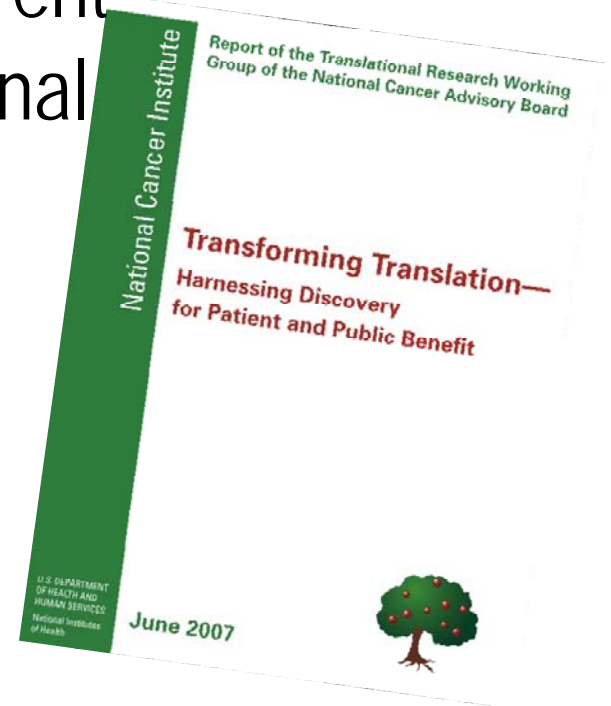
Coordinating Center for Clinical Trials

National Cancer Institute

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



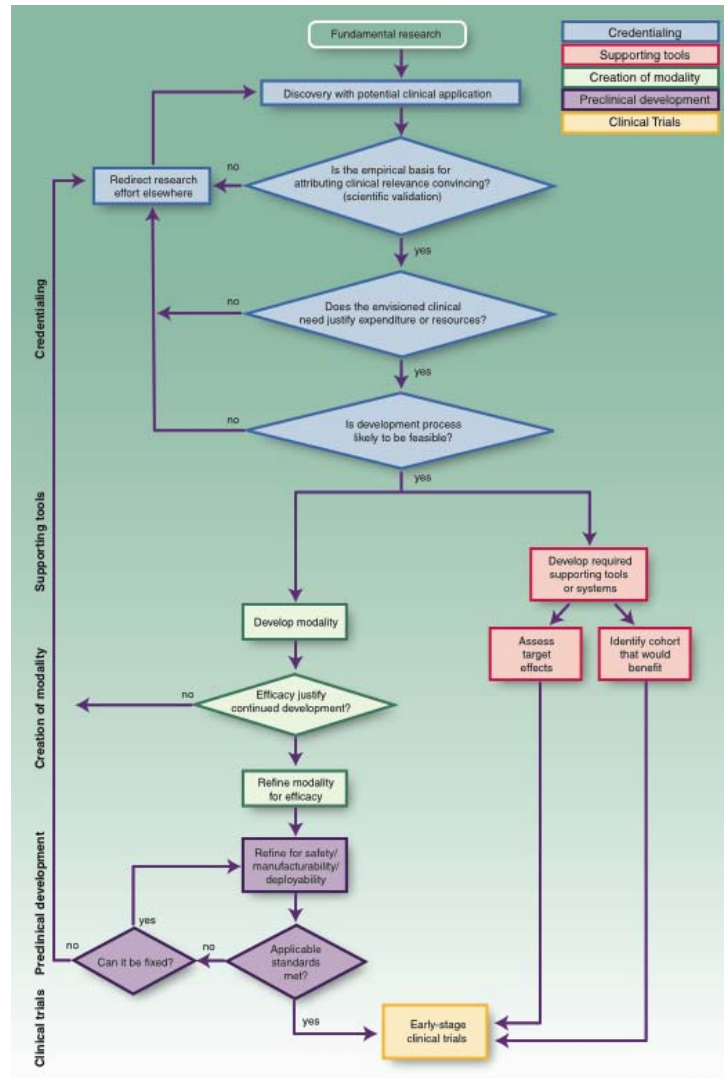
TRWG Pathways to Clinical Goals



clincancerres.aacrjournals.org

CCR 14: 5663-5713 (2008)

The Challenge of Early Translation



How can we best assure that:

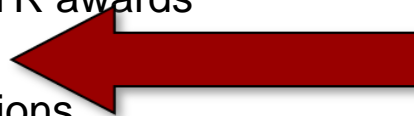
- The most promising concepts enter the developmental pathways?
- Concepts that do enter advance to the clinic or to productive failure?
- Progress is as rapid, efficient and effective as possible?

15 Initiatives with Implementation Plans



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



Develop a new process to accelerate translational cancer research

TRWG Recommended Process for Accelerating Translational Research



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

Step 1: Figure out how to gather information



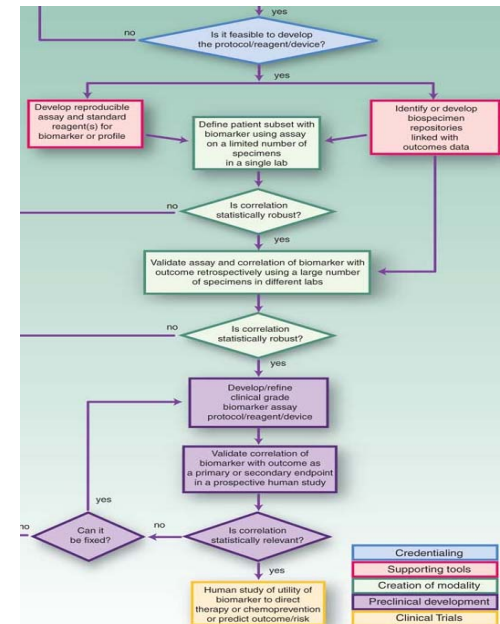
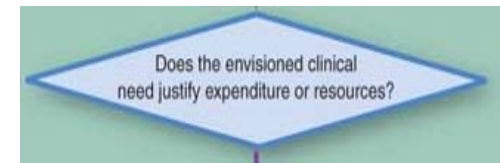
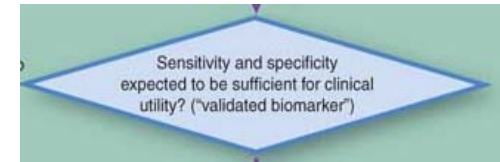
NCI Translates *NCI-wide Translational Science Meeting*

- **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

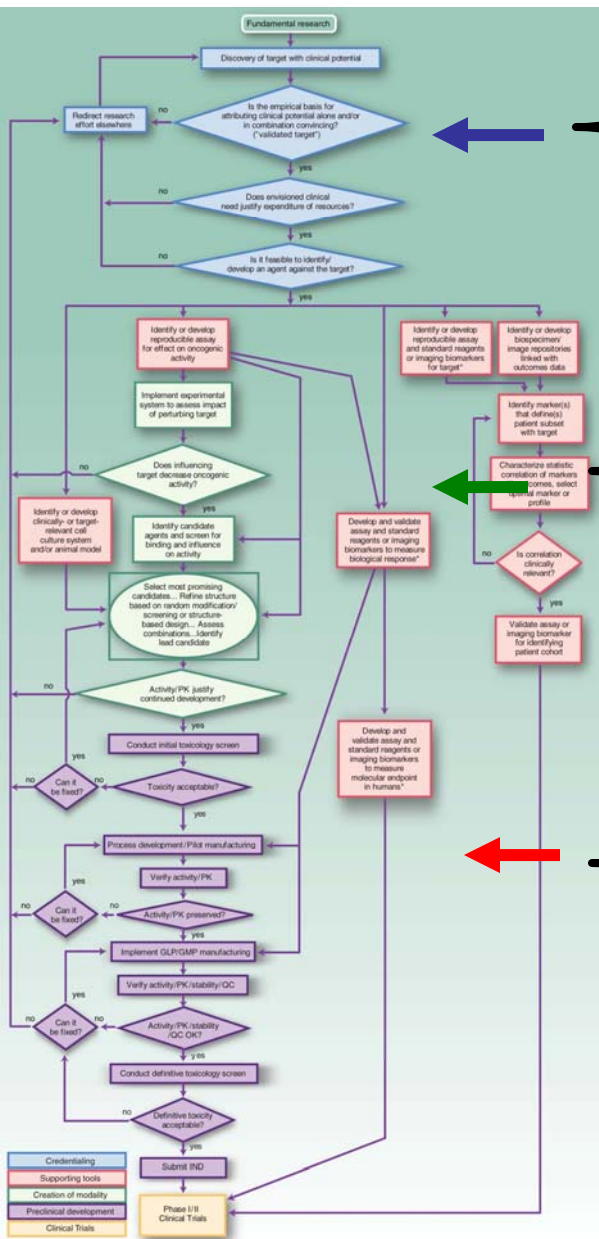
Translational Research Opportunity



- 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 *GI SPORE*
- VU-WS30 (anti-helminth) identified in *Xenopus* egg assay to block Axin degradation & prevent Wnt signaling
- Modifications required to overcome limited systemic access *Chemistry?*
- Inhibits β -catenin induced proliferation of colon cancer cell lines *MMHCC*
- Mouse models of CRC available
- Assays for Wnt signaling needed *RAID*
- Tox, etc, needed on modified agent
- CRC for initial trials *PHI, II consortia*

Information Guide to Translational Research Opportunities



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

PATS Implementation



CTAC recommended that NCI proceed with establishing a process to accelerate translational cancer research (Dec 08):



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

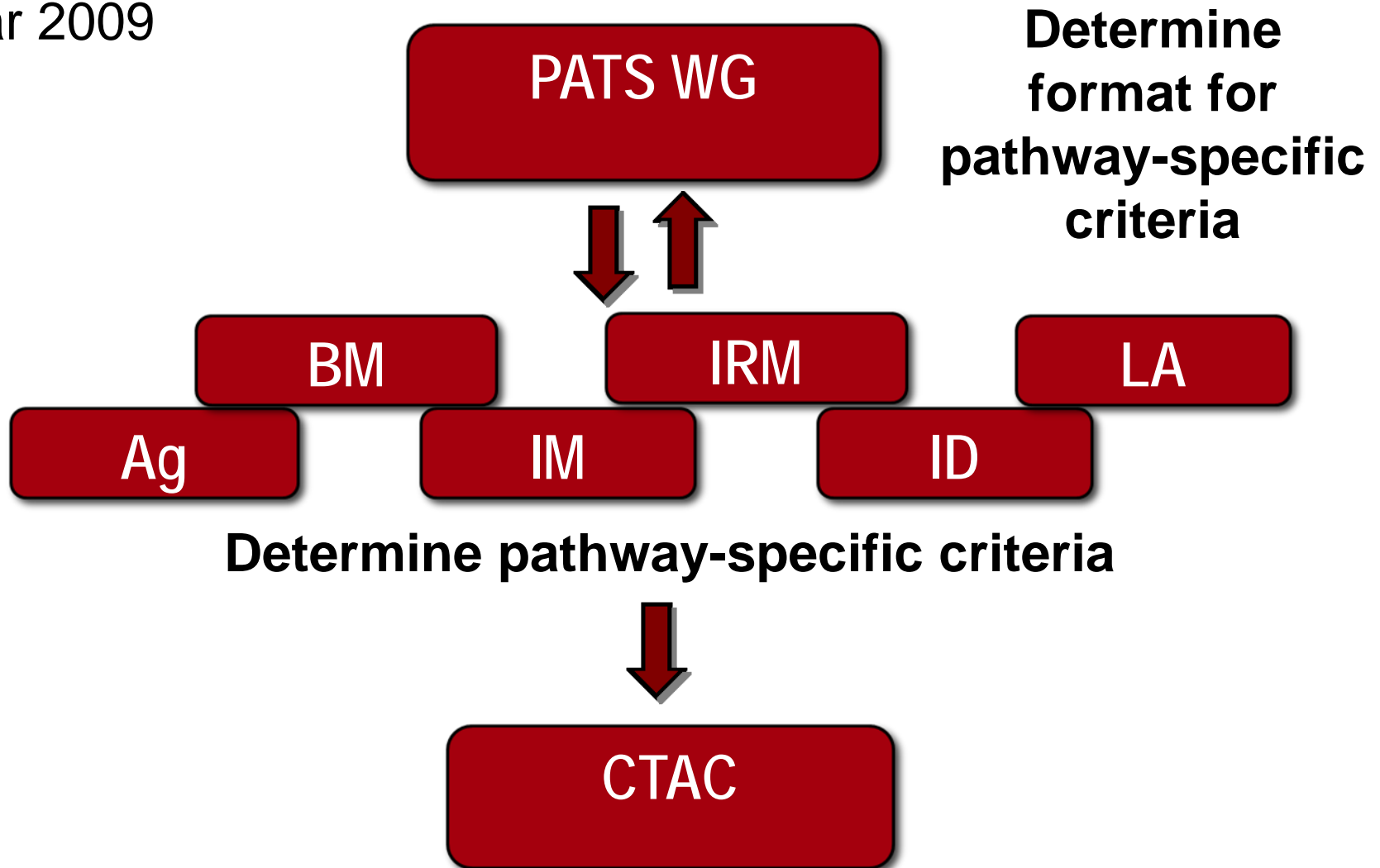


- Ken Cowan (Co-chair)
- Abbruzzesse, James
- Anderson, Kenneth
- Ballard-Barbash, Rachel
- Bertagnolli, Monica
- Bruner, Deborah
- Cairns, Paul
- Cheever, Martin
- Civin, Curt
- Collyer, Deb
- Dorfman, Gary
- Doroshow, James
- Erlichman, Charles
- Gambhir, Sanjiv Sam
- Gilmer, Tona
- Gray, Joe
- Gray, 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



Proposed Prioritization Process: tools



Pathway(s)

published



Translational Research Opportunity Guideline

on line



Translational Research Opportunity Template

RFI template



Pathway-specific criteria and rating scale

For prioritization



Proposed Prioritization Tool



Analytical Hierarchy Process (AHP):

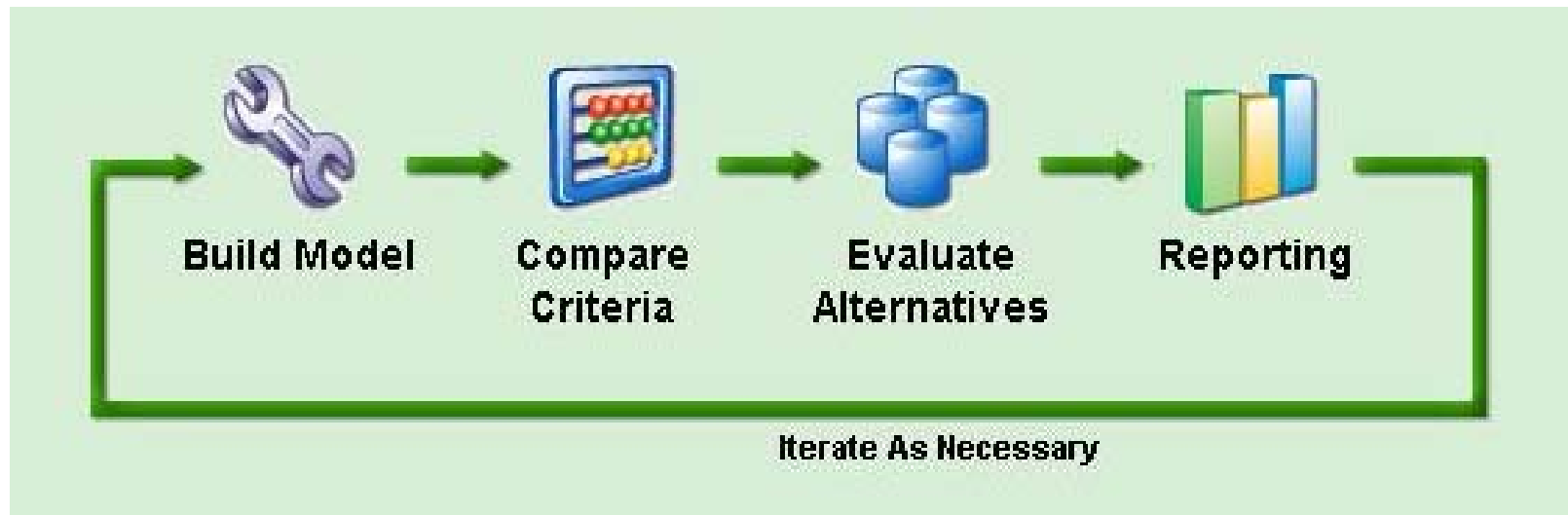
A structured technique for complex decision making

- 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)



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?



NCI CTROC

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

NCI CCCT

- **Develop Project Management capabilities**
 - Required to link new or existing teams/projects and to facilitate hand-offs between groups

Proposed New Funding Strategy



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

Summary

