Integrating the Recommendations of the Clinical Trials Working Group & the Translational Research Working Group

A Presentation to the National Cancer Advisory Board

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TRWG Subcommittees

Overall Leadership	Organization & Funding	Core Services Coordination	Prioritization
Hawk, Ernest	Gray, Joe	Cowan, Kenneth	Tlsty, Thea
Matrisian, Lynn	Reid, Brian	Schnall, Mitchell	Schilsky, Richard*
Nelson, Bill	Bast, Robert*	Bigner, Darell	Abbruzzese, James
	Caligiuri, Michael	Buetow, Kenneth	Emanuel, Peter
	Cote, Richard	Doroshow, James	McGrath, Gail
	Dennis, Phillip	DuBois, Raymond	McTiernan, Anne
	Gomez, Jorge	Jacks, Tyler	Mohla, Suresh
	Gritz, Ellen	Look, A. Thomas	Perez-Soler, Roman
	Hait, William	Maslow, David	Rabkin, Charles
	Kerr, David	Schlom, Jeffrey	Weiner, Louis
	Scheinberg, David		
	Simon, Richard		
	Sullivan, Daniel		

Serving on more than one subcommittee, as able
Blue = Co-chairs

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TRWG Subcommittees

Project Management	Training & Workforce	External Integration
Lawrence, Theodore	Lyerly, H. Kim	Courtneidge, Sara
Limburg, Paul	Olopade, Olufunmilayo	Gordon, Gary
Collins, Jerry	Bast, Robert*	Alberts, David
Esserman, Laura	Dubinett, Steven	Anderson, Kenneth
Fenton, Laurie	Hong, Waun Ki	Cheever, Martin
Nichols, Cherie	McLeod, Howard	DiBisceglie, Adrian
Sellers, Thomas	Moore, Ida "Ki"	Downing, Gregory
Sidransky, David	Oberholtzer, John Carl	Gilmer, Tona
Srivastava, Sudhir	Schilsky, Richard*	Lubenow, Anne
		Pazdur, Richard**
		Sigal, Ellen

*Serving on more than one subcommittee, as able
**FDA was represented by various employees
Blue = Co-chairs

Common Themes of TRWG Initiatives

- **A - Coordinated Management**
  - Facilitate TR through a flexible, integrated NCI organizational approach
  - Achieve a shared understanding of the nature and scope of TR activity
  - Set priorities through a systematic and transparent process involving all stakeholders

- **B - Tailored Funding Programs**
  - Refine existing programs to promote translational success
  - Create new programs for prioritized projects and to promote industry collaboration

- **C - Operational Effectiveness**
  - Provide key project management resources
  - Coordinate supporting core services
  - Promote collaborations among NCI, academia, industry and foundations
  - Enhance training and career incentives

Coordinated Management
Recommended Initiatives

Initiative A1. Establish a flexible, integrated organizational approach that coordinates early translational research opportunities across NCI.

Initiative A2. Designate a specific portion of the NCI budget for early translational research.

Initiative A3. Develop a set of codes that accurately captures the nature & scope of NCI's early translational research awards.

Initiative A4. Establish a distinctive prioritization process for early translational research.

Tailored Funding Programs
Recommended Initiatives

Initiative B1. Modify multi-project/collaborative award guidelines & review criteria, as appropriate, to facilitate early translational research.

Initiative B2. Improve processes & mechanisms for funding investigator-initiated early translational research.

Initiative B3. Establish Special Translational Research Acceleration Programs (STRAPs) to advance prioritized early translational research opportunities.

Initiative B4. Establish a funding program for early translational research that requires academic/industry collaboration involving resource sharing and/or co-funding.

Initiative B5. Integrate access to GMP/GLP manufacturing & other preclinical development services more effectively with milestone-driven early translational research projects.

Operational Effectiveness
Recommended Initiatives

Initiative C1. Establish a formal project management structure for early translational research.

Initiative C2. Establish a system to coordinate core services essential for early translational research.

Initiative C3. Enhance quality & accessibility of annotated biospecimen repositories.

Initiative C4. Develop enhanced approaches for negotiation of intellectual property agreements & agent access.

Initiative C5. Enhance interactions & collaborations with foundations & advocacy groups to advance early translational research.

Initiative C6. Enhance training & career incentives for early translational research.

TRWG Integration with CTWG – Transforming 15 Initiatives into 6 Activities

- Integrating NCI management
- Establishing a refined TR coding system
- Implementing STRAP awards
- Modifying/coordinating TR awards
- Establishing a project management system
- Coordinating activities with external constituents (foundations, advocates)

Integrated NCI Management
(A1, A2)

- CCCT professional staff recruitment (immediate)

- 12-month detailee or IPA to manage start-up activities (immediate)

- TROC - January 2008
  - To oversee & coordinate TR portfolio

- CTAC – March 2008
  - Expand mission & membership to address TR

Translational Research Award Coding
(A3)

- Essential foundation to identify & manage TR portfolio & decisions

- Coding methodology developed by RAEB/CCCT with input from program staff & extramural TRWG members (as needed)

- Coding implemented by RAEB for FY09 awards

- Proposed TRWG FY09 budget includes new RAEB staff for coding effort

STRAP Implementation
(A4, B3)

- Comprehensive, annual prioritization of 2-3 specific TR opportunities

- Prioritization process led by CTAC-WG
  - Extramural researchers
  - NCI staff
  - Patient advocates
  - Industry/foundation representatives

STRAP Implementation (cont.)
(A4, B3)

- First round of prioritization initiation July 2008

- STRAP RFA based on first set of priorities
  - Release target date - October 2009
  - Award target date - July 2010

- Intended to fund focused, closely managed, collaborative, development projects (industry model)

Translational Research Award Modification/Coordination
(B1, B2, B5, C2, C3, C6)

- Guideline modification for multi-project collaborative TR awards (initiation early 2008)
  – Essential to incentivize translational progress
  – Current guidelines are heterogeneous & often focus on discovery more than translation

- Coordination of TR core services for enhanced efficiency (initiation mid-2008)

Translational Research Award Modification/Coordination (cont.)
(B1, B2, B5, C2, C3, C6)

- Integration of projects that are funding early stages of TR (e.g., SPORE, P01, STRAP, etc.) with preclinical development resources (e.g., RAID and RAPID) (initiation late 2008)

- Development of improved approaches for TR training (initiation early 2009)

Project Management System
(C1)

- Success depends on 3 factors
  - Accurate identification of TR awards through new codes
  - Guideline modifications to reward milestone-driven progress
  - Analysis of existing core services & other resources

- Implementation delayed until 2009 to permit time to complete new coding, guideline modifications, and core services/resource analyses
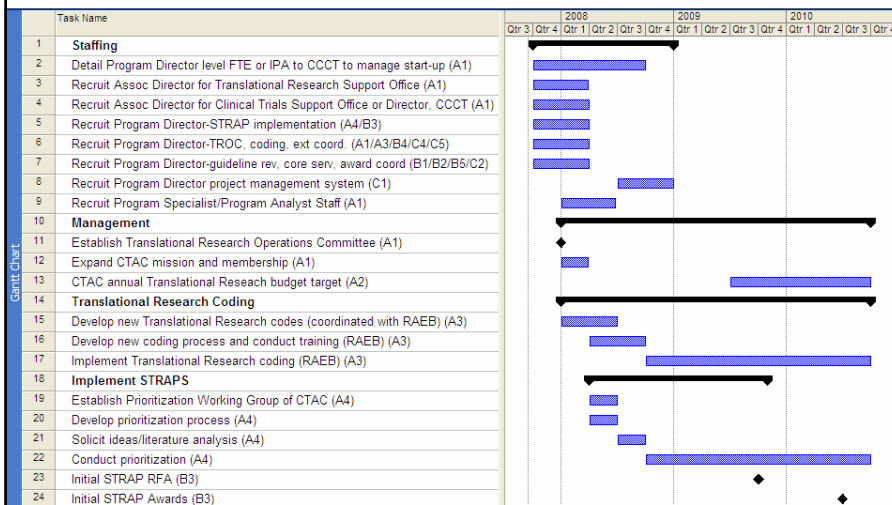
External Coordination
(B4, C4, C5)

- Foundation/advocacy group outreach on TR issues initiated by OLA/DCLG in October 2007

- TRWG initiatives involving industry collaboration under auspices of existing CTAC Public/Private Partnership Subcommittee (implementation in 2008)

Requested FY08 Budget for TRWG Implementation

Incremental CCCT staff & expenses	$700,000
Incremental CTAC expenses	$ 50,000
Prioritization process	$400,000
Core Services analysis	$100,000
IP licensing agreement analysis	$100,000
Evaluation process design	+ $200,000
Total	**$1,550,000**

Initiatives by Category

	Task Name	2008	2009	2010
		Qtr 3 Qtr 4 Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4
1	**Staffing**			
2	Detail Program Director level FTE or IPA to CCCT to manage start-up (A1)			
3	Recruit Assoc Director for Translational Research Support Office (A1)			
4	Recruit Assoc Director for Clinical Trials Support Office or Director, CCCT (A1)			
5	Recruit Program Director-STRAP implementation (A4/B3)			
6	Recruit Program Director-TROC, coding, ext coord. (A1/A3/B4/C4/C5)			
7	Recruit Program Director-guideline rev, core serv, award coord (B1/B2/B5/C2)			
8	Recruit Program Director project management system (C1)			
9	Recruit Program Specialist/Program Analyst Staff (A1)			
10	**Management**			
11	Establish Translational Research Operations Committee (A1)			
12	Expand CTAC mission and membership (A1)			
13	CTAC annual Translational Reseach budget target (A2)			
14	**Translational Research Coding**			
15	Develop new Translational Research codes (coordinated with RAEB) (A3)			
16	Develop new coding process and conduct training (RAEB) (A3)			
17	Implement Translational Research coding (RAEB) (A3)			
18	**Implement STRAPS**			
19	Establish Prioritization Working Group of CTAC (A4)			
20	Develop prioritization process (A4)			
21	Solicit ideas/literature analysis (A4)			
22	Conduct prioritization (A4)			
23	Initial STRAP RFA (B3)			
24	Initial STRAP Awards (B3)			

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Initiatives by Category (cont.)

	Task Name	2008		2009	2010
		Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4	Qtr 1 Qtr 2 Qtr 3 Qtr 4
24	**Award Modification/Coordination**				
25	Revise Translational Research award guidelines (B1)				
26	Collaborative efforts to enahnce biospecimen repositories (C3)				
27	Implement Core Services analysis/coordination (C2)				
28	Develop process for integrating of TR awards with RAID/RAPID resources (B5)				
29	Implement integration of TR awards with RAID/RAPID resources (B5)				
30	Training Working Group of CTAC (C6)				
31	Improve investigator-initiated Translational Research award mechanisms (B2)				
32	**Project Management**				
33	Recruit Divisional Project Managers (C1)				
34	Develop resource inventory (C1)				
35	Implement Project Management system (C1)				
36	**Foundation/Advocacy Group Collaboration (led by OLA/DCLG)**				
37	Begin planning enhanced outreach/collaboration (C5)				
38	Implement regular interactions focused on Translational Research (C5)				
39	Implement funding partnerships for Translational Research (C5)				
40	Implement outreach for tissue donation (C5)				
41	**Industry Collaboration**				
42	Expand mission of CTAC Public/Private Partnership Subcommittee (B4/C4)				
43	Develop standard intellectual property licensing terms (C4)				
44	Initiate academic/industry collaboration awards (B4)				
45	**Evaluation**				
46	Design Evaluation Process				

Issues Under Active Discussion

- Accelerated implementation of a STRAP-like mechanism to fuel the most compelling translational advances (i.e., pilot testing)

- Facilitation of relationships with foundations & advocacy organizations in a new way
  - Higher level
  - More frequent
  - More systematic

- Greater interaction between intra- and extramural programs focused on translational progress