

CANCER IMMUNOTHERAPY TRIALS NETWORK (CITN)

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NCI's Growing Support for Cancer Immunotherapy

- NCI's intramural program has broad expertise in cancer immunology and immunotherapy
- NCI Biologics Resources Branch has provided a large number of biologics for clinical trials through the RAID program
- Investigational Drug Steering Committee Immunotherapy Task Force provides input to CTEP for development of anti-cancer IT agents
- Early 2006: a joint DCTD and DCB committee
 - Recognized need to translate new findings in basic tumor immunology including functions of novel IT agents
 - Proposed workshop to identify and prioritize IT agents that currently not in clinic but urgently should be made available for translation to clinical trials



A Series of Meetings and Workshops Drove Development of a New Immunotherapy Network

- ❑ Summer, 2007: Workshop of extramural investigators identified and prioritized 20 novel IT agents needed for translation
- ❑ Summer, 2008: NCI Cancer Antigen Pilot Prioritization Project: to determine criteria to define an “ideal” cancer antigen for additional translational funding: 20 antigens were top candidates
- ❑ 2008-2009: Immune Response Modifiers (IRM) as the first pathway to obtain “STRAP” funding, and the IRM Working Group refined list of 20 agents and developed criteria for selecting combination agents
- ❑ 2008: AACR/AAI joint immunology steering committee formulated plan to generate specific interest at NCI in a large network in cancer immunotherapy
- ❑ A directive from the NCI’s CTWG and TRWG for increased focus on coordinated networks of investigators to accomplish translational goals through close collaboration between basic, translational and clinical investigators
- ❑ Interest by the NCI director led to directive to develop concept for a small consortium/network in immunotherapy

Development of the RFA

- ▣ Concept written Fall 2008 for RFA for 6-8 self-forming clinical IT sites (multi-PI) to formulate Phase I and II IT trials for IT agents in combination with standardized immunomonitoring: approved by NCI senior leadership and BSA, March 2009
- ▣ Summer and Fall, 2009: after push-back from IT community, RFA reformulated for funding of a single central operations Center (PI site) with large number of subcontract clinical sites; RFA released late 2009

RFA-CA-10-007

- ❑ Funds the Central Operations and Statistical Center (COSC) to provide overall leadership and coordination for the CITN
- ❑ Member clinical sites as subcontracts to COSC site, with funding only based on accrual to trials (up to 25 sites)
- ❑ Laboratory sites to be associated with clinical sites for immunomonitoring, biomarker, and correlative science studies linked to the trials
- ❑ NCI/CTEP Clinical Trials Support Unit (CTSU) as integral for regulatory support and data management services
- ❑ Member Sites chosen based on CTEP-organized peer review and in consultation with PI for final site selections
- ❑ 4 applications received February 2010; reviewed in NCI/DEA in June, 2010



FHCRC as the CITN COSC Membership in the CITN

- ▣ Fred Hutchinson Cancer Research Center (“Mac” Cheever, PI); approved by NCI senior leadership and second level NCAB review
- ▣ Sept. 24 release of NOTICE (NOT-CA-10-034) on NIH funding opportunities website:
NCI CITN Seeks Member Clinical Sites
- ▣ Specific instructions for application on the CTEP website (<http://www.ctep.info.gov>)



Timeline of Member Site Involvement in the CITN

- ▣ Letters of Intent due Oct 15
- ▣ Applications due Nov 15
- ▣ Review of applications mid-December
- ▣ Formulation of CITN with Member Sites: early 2011

