CANCER IMMUNOTHERAPY TRIALS NETWORK (CITN)

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