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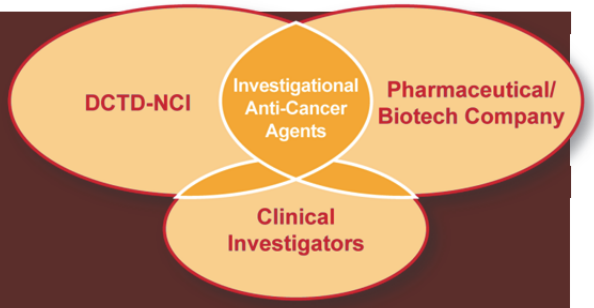

RAB News

A Biennial Digest of CTEP Regulatory Affairs Branch Activities of Interest to Pharmaceutical Collaborators and Investigators

Welcome to the first issue of the NCI CTEP Regulatory Affairs Branch's *RAB News*. By posting this newsletter, we hope to bring you news of our most recent activities and accomplishments and enhance our communications with industry, investigators and other interested parties. We welcome your comments and suggestions. Email us at: RABNews@mail.nih.gov.

To learn more about our mission and staff, visit the CTEP and RAB main website at: http://ctep.cancer.gov.

RAB's Mission

The Regulatory Affairs Branch (RAB) ensures that CTEP meets its regulatory responsibilities as the sponsor of Investigational New Drug Applications (INDs) and that the Program fosters partnerships with industry and academics by implementing collaborative agreements.

RAB, headed by *Branch Chief Jan Casadei, PhD,* is comprised of two complementary groups to accomplish our mission:

Drug Regulatory Group (DRG)
Led by *Associate Branch Chief Rita Misra, PhD, MPH*, and staffed by 3 Regulatory Affairs Professionals, the DRG provides IND support and acts as liaison to the FDA for CTEP, DCTD.

Agreement Coordination Group (ACG)
Led by *Associate Branch Chief Sherry Ansher, PhD,* and staffed by 2 Research & Development Agreements Specialists, the ACG fosters pharmaceutical collaboration in evaluating new anticancer agents, through the implementation of appropriate agreements.

CTEP by the Numbers

Number of DCTD INDs supported by RAB:	**109**
Number of treatment clinical trials supported by CTEP:	**~800**
Number of patients enrolled in DCTD-supported clinical trials:	**~30,000**
Number of INDs filed last 8 months (September 2012 – April 2013), including	**13**
Single-agent:	**7**
Combination:	**3**
Indication-specific:	**3**
Number of CRADAs executed over last 8 months (September 2012 – April 2013):	**5**
CRADAs with new agents:	**2**
Total number of active agreements (CTAs, CRADAs, M-CRADAS,) supported by RAB:	**86**

See tables below for details of recent single-agent INDs filed and CRADAs for new agents.

RAB is CTEP's primary interface with CTEP's collaborators and with the FDA, coordinates a monthly FDA-NCI meeting with the FDA Oncology Director and staff, and supports end-of-phase 2 meeting requests and other communications with the FDA.

INDs for New Agents Filed in the Last 6 Months: 6 *(September 2012 – February 2013)*

IND Title/Agent Name(s)	Target/MOA	Collaborator
MK-1775	Wee1 inhibitor	Merck & Co.
MLN8237	Aurora kinase inhibitor	Millennium
MK-8776 (SCH 900776)	Chk1 inhibitor	Merck & Co.
Brentuximab Vedotin (SGN-35)	Anti-CD30 antibody-drug conjugate	Seattle Genetics
Ibrutinib (PCI-32765)	BTK inhibitor	Pharmacyclics
Dabrafenib Mesylate (GSK 2118436B)	BRAF kinase inhibitor	GlaxoSmithKline

CRADAs for New Agents Executed in the Last 6 Months: 1 *(September 2012 – February 2013)*		
Agent(s)	**Collaborator(s)**	**Activation Date**
Pomalidomide (CC-4047) (NSC 767909)	Celgene	9/7/12

For a list of all CTEP Agreements and Agents available, please see:
http://ctep.cancer.gov/industryCollaborations2/default.htm#agreements_and_agents.

New CTEP-specific CRADA Template

In April 2011, a revision to the Intellectual Property (IP) Option to Collaborator was finalized and posted on the CTEP website. The new IP option categorizes inventions as either agent-related (Section A) or biomarker- or assay-related (Section B) and provides different options to collaborators depending on the invention category. This new IP option addresses use of human specimens and clinical data, important areas that were not addressed previously.

New 6-month Timeline for CRADA Negotiation

As part of CTEP's initiatives to decrease the interval of time between Senior Advisory Committee (SAC) approval and execution of the CRADA for the development of an agent, CTEP has created a CTEP-specific model CRADA that eliminates or minimizes the need for negotiation of much of the agreement. The absolute deadline of 6 months from approval to execution has been met 100% of the time.

During 2011-2012, the average time from SAC approval to CRADA execution was 160 days compared to an average of 495 days for the 10 CRADAs executed from 2008-2011, prior to the establishment of the Alternate Technology Development Coordinator (TDC) and implementation of the 6-month deadline.

The establishment of an Alternate TDC for CTEP within DCTD has markedly enhanced the ability to expedite the execution of agreements for CTEP. For 2011-2012:

- New CRADAs: 16
- CRADA Amendments: 13
- CTA Amendments: 8
- New MTAs: 162
- New CDAs: 26

Check out our new IP option and CRADA template here:
http://ctep.cancer.gov/industryCollaborations2/default.htm
(Guidelines for Collaborations with Industry).

OEWG Implementation and Results

In March 2010, the Operational Efficiency Working Group (OEWG) recommended strategies to decrease the activation time for NCI-sponsored clinical trials. A major element of the recommendations was the establishment of target timelines (210 days for Phase 1and 2, 300 days for Phase 3) and absolute deadlines (540 days for Phase I and II, 730 days for Phase III; updated in April 2012 to 450 days and 540 days, respectively) for studies to go from LOI or concept submission to trial activation (i.e., open to patient enrollment). Each target timeline is broken into three stages with interim targets (LOI/Concept approval, Protocol submission, and Protocol approval and activation).

Since April 1, 2010, 16 Phase 3 Cooperative Group trials have activated, with a median of 372 days and average of 376 days from submission to activation. There have been 28 Phase 2 Cooperative Group trials starting as Concepts with a median of 400 days and average of 375 days from submission to activation. In addition, 40 Cooperative Group early phase trials starting as LOIs that have activated in a median of 392 days and an average of 397 days. Finally, 99 non-Cooperative Group early phase trials have activated with a median of 408 days and average of 403 days from submission to activation.

More information on the OEWG goals and results will be covered in the next issue of *RAB News.*