

# **4th Annual Countermeasures Against Chemical Threats (CounterACT) Network Research Symposium June 22-24, 2010, San Francisco, CA**

The overarching goal of the NIH CounterACT Network research program is to enhance the current medical response capabilities of the nation in preparation for a chemical emergency event. To achieve this goal, the National Institutes of Health has developed a comprehensive trans-NIH initiative in translational research comprised of a network of research centers of excellence, individual research projects, small business innovation research projects, contracts and inter-agency agreements with other federal entities. This program is managed across seven NIH Institutes under the leadership of the National Institute of Neurological Disorders and Stroke.

## **Purpose of the Meeting**

The primary objective of this meeting was to afford CounterACT scientists the opportunity to foster and/or strengthen new and existing collaborations among fellow researchers in the chemical defense field. Network scientists presented their latest research findings from the fourth project year of their parent awards for the purpose of sharing this information among CounterACT investigators and Program Officials at the NIH.

## **Highlights**

The meeting was held June 22-24, 2010 at the Intercontinental Mark Hopkins Hotel in San Francisco, CA. Scientific presentations were grouped by topic into one of eight breakout sessions (see agenda). Several poster sessions were included in the agenda to allow for maximal interaction among investigators. Several working lunches gave investigators the opportunity to engage in interactive discussions with representatives from industry and across several federal agencies.

A highlight of this year's meeting was a Drug Development Symposium at the CounterACT Preclinical Development Facility at SRI International in Menlo Park, CA on June 21, 2010. The pre-meeting symposium "An Overview of the Preclinical Development Process: From 'Idea to IND' in One Day" was presented by scientists and staff from SRI International. This course was attended by almost half of all CounterACT meeting attendees, including 50 principal investigators and their collaborators, 14 young investigator travel awardees, and 12 members of various federal agencies. Other satellite meetings included a workshop on the status of research on cyanide medical countermeasures sponsored by the NIAID, and several advisory committee meetings associated with the CounterACT Research Centers of Excellence.

Another highlight of the meeting was the effort to make the meeting "Green". The principles of Reduce, Reuse, & Recycle were practiced in partnership with the Mark Hopkins Hotel staff.

## **Attendees**

Among the approximately 200 participants were over 100 CounterACT Principal Investigators (PIs), co-investigators (Co-PIs), and their research staff, along with 25 CounterACT Junior Scientist Travel Awardees, whose attendances were supported through the 2010 CounterACT Travel Award Program. Also in attendance were scientists from industry and many federal agencies interested in medical countermeasure development, including the Department of Defense, HHS Office for Public Health Emergency Preparedness, Biomedical Advanced Research and Development Authority, Department of Homeland Security, Centers for Disease Control, National Institutes of Health, and the Food and Drug Administration.

# AN OVERVIEW OF THE PRECLINICAL DEVELOPMENT PROCESS: FROM “IDEA TO IND”™ IN ONE DAY

*Presented by:*

**Carol Green**, Senior Director of Toxicology and Pharmacokinetics

**Mary Tanga**, Senior Director of Medicinal Chemistry

**Lalitha Iyer**, Director of Drug Metabolism and Pharmacokinetics

**Gita Shankar**, Director of Formulation

**Helen Parish**, Senior Director of Pharmaceutical Sciences

**Jon Mirsalis**, Executive Director of Preclinical Development

This course will provide an overview of all the steps needed to move a candidate therapeutic product from the early discovery stage through to the filing of an Investigational New Drug (IND) application. Topics will include medicinal chemistry, pharmacokinetics and metabolism, formulation, clinical manufacturing, analytical chemistry, and toxicology. The tentative agenda and key topic points are outlined below.

9:00 Introduction to Preclinical Development and the IND Process (Carol Green)

- Overview of the IND process
- What you need to enter development
- Plans, costs, and schedules
- Phase 0 vs. Phase I clinical trials
- 10 Things That Can Go Wrong (and probably will!)

9:45 Medicinal Chemistry (Mary Tanga)

- The Art and Science of Drug Design
- Lead optimization in drug discovery
- mg to kg: Scale up of drug synthesis
- Issues in radiolabeled drug synthesis

10:30 BREAK

10:45 Pharmacokinetics and Metabolism (Lalitha Iyer)

- Principles of Pharmacokinetics and Toxicokinetics
- Basics of Bioanalytical Chemistry
- Predictive ADMET for discovery research
- Overview of Drug Metabolism

11:30 Formulation (Gita Shankar)

- Overview of routes of administration
- Introduction to Preformulation
- Overcoming solubility and permeability problems
- Case Studies of Dosage Forms

12:15 Working LUNCH

1:15 IND Section 7: CMC Section (Helen Parish)

- Contents of the “Chemistry, Manufacturing and Controls” section
- Quality control testing
- Stability assessments
- Clinical packaging and labeling

2:00 IND Section 8: Toxicology and Pharmacology (Jon Mirsalis)

- Selection of species
- Non-GLP and GLP study designs
- Genetic Toxicology & Safety Pharmacology
- Special considerations for biologics and pediatric medications

2:45 Q&A

3:00 Adjourn

## 4th Annual CounterACT Network Research Symposium - Agenda Overview

### DAY 1 Tuesday, June 22, 2010

TIME	EVENT	ROOM
8:00 am - 5:00 pm	<b>REGISTRATION</b>	
8:30 am - 8:35 am	Introduction and Goals Dr. David A. Jett, NINDS	Peacock Court
8:35 am - 9:10 am	<b>Medical Countermeasures Research in the United Kingdom</b> Dr. David Russell, WHO Collaborating Centre & Health Protection Agency, United Kingdom	Peacock Court
9:20 am - 12:00pm	<b>Concurrent Breakout Sessions</b>	<b>Session 1A: Nerve Agents-Cholinesterase: Peacock Court</b> <b>Session 1B: Pulmonary: The Six Continents</b> <b>Session 1C: Diagnostic Technologies: California</b>
12:00 pm - 12:20 pm	Break	
12:20 pm - 1:00 pm	Working Lunch: Q&A with NIH and other Federal Officials	Peacock Court
1:00 pm - 2:00 pm	<b>Poster Session #1</b>	<b>Room of the Dons, Garden-Florentine</b>
2:00 pm - 4:00 pm	<b>Concurrent Breakout Sessions</b>	<b>Session 1A: Nerve Agents-Cholinesterase: Peacock Court</b> <b>Session 1B: Pulmonary: The Six Continents</b> <b>Session 1C: Diagnostic Technologies: California</b>
4:00 pm - 4:10 pm	Break	
4:10 pm - 5:30 pm	<b>Concurrent Breakout Sessions</b>	<b>Session 1A: Nerve Agents-Cholinesterase: Peacock Court</b> <b>Session 1B: Pulmonary: The Six Continents</b> <b>Session 1C: Diagnostic Technologies: California</b>
5:30 pm - 6:30 pm	<b>Poster Session #2</b>	<b>Room of the Dons, Garden-Florentine</b>

### DAY 2 Wednesday, June 23, 2010

9:00 am - 10:00 am	<b>Intellectual Property 101</b> Melanye K. Johnson, J.D., Senior Attorney, HHS Office of the General Counsel (OGC)	Peacock Court
10:00 am - 10:30 am	<b>CounterACT Preclinical Development Facility</b> Dr. Carol Green, SRI International	Peacock Court
10:40 am - 12:00pm	<b>Concurrent Breakout Sessions</b>	<b>Session 2A: Nerve Agents-Cholinesterase: Peacock Court</b> <b>Session 2B: Pulmonary: The Six Continents</b> <b>Session 2C: Cyanide: California</b>
12:00 pm - 1:00 pm	Lunch (Provided)	Top of the Mark
1:00 pm - 2:00 pm	<b>Poster Session #3</b>	<b>Room of the Dons, Garden-Florentine</b>
2:00 pm - 5:20 pm	<b>Concurrent Breakout Sessions</b>	<b>Session 2A: Nerve Agents: Peacock Court</b> <b>Session 2B: Mustard: The Six Continents</b> <b>Session 2C: Cyanide: California</b>
5:30 pm - 6:30 pm	<b>Poster Session #4</b>	<b>Room of the Dons, Garden-Florentine</b>

### DAY 3 Thursday, June 24, 2010

8:30 am - 10:30 am	<b>Concurrent Breakout Sessions</b>	<b>Session 3A: Nerve Agents-Seizures: Peacock Court</b> <b>Session 3B: Mustard: The Six Continents</b>
10:30 am - 10:40 am	Break	
10:40 am - 12:00 pm	<b>Concurrent Breakout Sessions</b>	<b>Session 3A: Nerve Agents-Seizures: Peacock Court</b> <b>Session 3B: Mustard: The Six Continents</b>
12:00 pm - 12:20 pm	Break	
12:20 pm - 1:00 pm	Working Lunch: Introduction to DTRA'S Medical Science & Technology Program for Chemical Agent Countermeasure Development Defense Dr. Jeffrey Yourick, DTRA	Peacock Court
1:00 pm - 2:00 pm	<b>Poster Session #5</b>	<b>Room of the Dons, Garden-Florentine</b>
2:00 pm - 4:00 pm	<b>Concurrent Breakout Sessions</b>	<b>Session 3A: Nerve Agents-Seizures: Peacock Court</b> <b>Session 3B: Mustard: The Six Continents</b>