



Northern California Chapter

EMERGING MARKETS: Clinical Trials in India

THURSDAY JUNE 11, 2009

6:00 -9:00 PM

Genentech, Inc.

**B83, 611 Gateway Boulevard
South San Francisco, CA 94080**

*This program is underwritten in part by
in-kind support from Genentech, Inc.*

TARGET AUDIENCE:

- ✓ Clinical Research Professionals
- ✓ Sponsor Organizations
- ✓ Study Site Investigators & Coordinators
- ✓ Independent Consultants
- ✓ Students of Clinical Research
- ✓ Academic Medical/Clinical Researchers
- ✓ Service Providers/Vendors
- ✓ Institutional Review Boards
- ✓ Quality Assurance

ACRP has approved this program for 1.5 contact hours provider number CBRN XXXXXXXX. These contact hours will be available to those who purchased them at the designated charges.

ACRP mission: Provide global leadership to promote integrity and excellence for the clinical research profession. <http://www.acrpnet.org/>

PROGRAM:

The number of clinical trials conducted in India has been increasing since the 2005 revisions to the clinical trial regulations. While Indian regulations and guidance have been written with ICH standards in mind, there are important differences from ICH. Regulation and enforcement are still evolving in India, leading to some uncertainty about the requirements and the costs of non-compliance. Our guest speaker will explain the requirements and highlight strategies for successful conduct of your clinical trial.

SPEAKER:

Louise C. Johnson is a Senior Regulatory Affairs Consultant with Biologics Consulting Group. She has 30 years experience in the pharmaceutical and biotech industries with US and international regulatory expertise in many therapeutic areas after initial years in discovery research as a pharmacologist. She held significant roles in regulatory strategies for all Phases of filings, negotiation of regulatory approvals, assurance of GCP and regulatory compliance, management of regulatory intelligence, and establishment of Regulatory Affairs within sponsor organizations. She has recently provided regulatory support for Phase 3 and 4 trial and approvals in India, gaining experience with the World Health Organization's GCP guidelines and Prequalification Program for the developing world. She holds an MS in Applied Statistics from Villanova University.

EDUCATIONAL OBJECTIVES:

At the conclusion of this session attendees should be able to describe:

1. The laws and rules governing clinical trials India.
2. The government agencies involved in regulating clinical trials in India.
3. Involvement of the WHO in clinical trials in the developing world.

SCHEDULE:

6:00 – 7:00 PM Registration, Networking,
& Dinner Buffet

7:00 – 7:30 PM Welcome & Announcements

7:30 – 9:00 PM Educational Program

EVENT REGISTRATION before June 8
Register early to assure admission; at event
IF space available (+\$5 nonmembers)
<http://www.acrpnet.org> Northern CA Chapter

NCC ACRP member	Free
ACRP member	\$10
Non - member	\$15

CBRN & ACRP CONTACT HOURS
Available if purchased before June 8,
must sign-in at event and complete online
evaluation after event; contact hours
purchase NOT available at /after event
<http://www.acrpnet.org> Northern CA Chapter

NCC ACRP & ACRP member	\$10
Non -member	\$25

NCC ACRP registration / purchase refund
policy: No refunds.

QUESTIONS: bonnie.miller@comcast.net