

November Program

WEDNESDAY, NOVEMBER 5, 2003

SPEAKERS:

Stanford S. Jhee, Pharm.D.

Vice President and Research Director, California Clinical Trials

Carl W. Trygstad, MD

Executive Director, Quintiles Japan-Hawaii Pacific Health Alliance

(There might be the third speaker from a pharmaceutical company.)

TOPIC:

Bridging Studies: Strategies and Executions

Recent changes in the Japanese regulatory environment have reduced barriers that historically have made Japan a difficult market for Western pharmaceutical companies to operate in. These changes include Japanese participation in the International Conference on Harmonization (ICH), the acceptance of bridging studies, and the ability to participate in and conduct global clinical trials. These events have helped not only Western pharmaceutical companies but also Japanese global pharmaceutical companies to develop drugs more economically. This program will focus on crucial issues in terms of planning, designing and executing bridging studies.

Dr. Jhee's research focuses on clinical pharmacology in areas such as Phase I drug development, PK/PD modeling, pharmacogenetics and Japanese clinical trials. He also engages in the clinical development of psychiatric and neurologic drugs working with most multi-national pharmaceutical companies. Dr. Jhee has extensive manuscript and book publications on clinical pharmacology and drug development and has lectured at both national and international meetings on these topics.

Dr. Trygstad is in charge of Phase I CNS trials and all pediatric trials at the Medical and Scientific Services Department at Quintiles. He is also responsible for trial aspects in Quintiles' Hawaii operation and supervises the regional CRAs. He is also on the steering committee for studies in Brazil and Peru. Previously he was Clinical Associate at the National Institutes of Health, had faculty positions in Pediatric Nephrology at Indiana University and UCLA, and headed the clinical division of Community and Family Medicine at UCSD where he was the principal investigator for an NIH RO-1 grant for studies in cross cultural medicine.