



American Society for Quality (www.asq.org) – Washington D.C. and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting

“Clinical Trials”

To be presented by

Sue-Jane Wang, PhD (Suejane.Wang@fda.hhs.gov)

Associate Director, Pharmacogenomics and Adaptive Design
&
Biostatistics Lead, CDER Biomarker Qualification Program

Office of Biostatistics
Office of Translational Sciences
Center for Drug Evaluation and Research (CDER), US FDA

Thursday, May 24, 2012

6:00 – 6:20 PM – Networking; Pizza/drink

6:20 – 8:30 PM – Program

8:30 – 8:45 PM – Door-prizes drawing; Networking

Online Registration site: <http://www.asq509.org/ht/d/DoSurvey/i/35817>

Open to Public –

\$5 for non-ASQ members to cover pizza/drink cost;

Free: [ASQ Members](#), [veterans](#), [senior citizens](#), [students](#), [local interns](#), [residents](#), [postdocs](#), [FDA Commissioner’s Fellows](#), and [current job-seekers](#)

Location: [Kelly’s Deli Conference Center, 7519 Standish Place, Rockville, MD 20855](#)

Registration Deadline: Please register by **Thursday noon, May 24, 2012.**

Question: Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; gchang2008@yahoo.com or 240-793-8425 (cell).

Driving directions: **By Car:** From **I-270** (N or S bound): Take Exit 9A and exit from the **FIRST** right exit; turn left (east) onto Shady Grove Dr.; turn right (south) onto Rockville Pike (**Route 355**); turn left (east) onto East Gude Dr.; turn left (north) immediately onto Crabb’s Branch Dr.; turn left (west) immediately onto Standish Place. The first building on your right side is 7519 Standish Place; open parking). [The venue is on the first floor with its entrance opposite to the left side of building main entrance.](#) **By Metro train:** Off from Red Line **Shady Grove Station**, and take RideOn **Route 59 TOWARD ROCKVILLE** and get off from “**Calhoun Place**” stop. Standish Place is next to the Bus stop. Our venue is within 2 min of walking distance from the stop.

Summary: **Clinical Trials**

This presentation gives an overview of drug development. This includes **introduction** of clinical trials, key elements for **study design** consideration in trial planning, the **types** of clinical trials for early versus later phase drug development and **scientific principles**.

Presenter's Bio: **Sue-Jane Wang, PhD**

Sue-Jane Wang, Ph.D. is currently **Associate Director** for Pharmacogenomics and Adaptive Design, and **Biostatistics Lead** for the CDER Biomarker Qualification Program in the Office of Biostatistics under the Office of Translational Sciences, Center for Drug Evaluation and Research, U.S. FDA. In her current role, Dr. Wang oversees regulatory submissions on the topics of adaptive design, pharmacogenomics and biomarker qualification. Dr. Wang has focused her recent research on those topics and has published more than 80 peer reviewed articles in clinical trials and pharmacogenomics, mostly supported by regulatory science research grants.

Dr. Wang is a **guest editor** for special issues, e.g., Biometrical Journal, and is the first statistician recipient receiving the FDA individual level Scientific Achievement Award on Excellence in Analytical Science for a sustained record of published regulatory research in statistical design and methodology advancing complex and emerging clinical trial designs and analysis that support regulatory guidance, policies and review in 2010. Last year, Dr. Wang was the recipient of DIA Thomas Steal award for excellence in statistics publishing.

Dr. Wang is a **fellow** of American Statistical Association.