



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

Biomed/Biotech Special Interest Group (SIG) Meeting
(<http://www.asq509.org/ht/d/sp/i/31557/pid/31557>)

“Overview of FDA’s Expedited Programs with a Case Study of Immunotherapy in Renal Cell Carcinoma”

To be presented by

James Xunhai Xu, MD

(james.xu@fda.hhs.gov)

Medical Officer, Division of Oncology Products 1
Office of Hematology and Oncology Products, Office of New Drugs
Center for Drug Evaluation and Review (CDER), US FDA

Thursday, August 25, 2016

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

6:20 – 8:45 PM – Program

8:45 – 9:00 PM – Door-prizes drawing; Networking

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

Open to Public –

\$5: [non-ASQ members](#) to cover pizza/drink cost;

Free: ASQ members, veterans, senior citizens, past speakers, US PHS Commissioned Corp officers, teachers, students, interns, residents, postdocs, FDA Commissioner’s Fellows, MJ-DC members, NTUAADC members, CAPA members, NTMUADC members, CKUAADC members, NTHUAADC members, CCACC volunteers/employees, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, and current job-seekers

Location: [Kelly’s Deli Conference Center, 7529 Standish Place, Rockville \(Derwood, for GPS users\), MD 20855](#)

Registration Deadline: Please register by ***Thursday noon, August 25, 2016.***

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 Cars: 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 of 7529 Building with its external entrance opposite to the left side of 7519 building main entrance.](#) **By Metro trains:** 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

Dr. James Xu will discuss the FDA's expedited review program for Fast Track, Breakthrough Therapy Designation, Priority Review, and Accelerated Approval. Dr. Xu will also present a case study for nivolumab's breakthrough therapy designation and regular approval for the treatment of renal cell carcinoma. He plans also help audience to understand some medical terms commonly used in oncology and clinical trials.

Speaker's Bio: James Xunhai Xu, MD



Dr. James Xunhai Xu is a **medical officer** with FDA/CDER/OND/OHOP's genitourinary cancer products review team. He received his Bachelor of Science degree in chemical engineering with a minor in mathematics from Brigham Young University and his M.D. degree from University of Minnesota. He completed his internal medicine residency at the Yale-New Haven Hospital of Yale University in New Haven, CT, and his hematology and medical oncology fellowship at the New York-Presbyterian Hospital of Columbia University in New York City. Because of his unique background in semiconductor process engineering, programming algorithm development, and medicine, Dr. Xu is the **recipient** of the prestigious ASCO (American Society of Clinical Oncology)-Conquer Cancer Foundation Young Investigator Award in 2011 and Merit Award in 2012.

Dr. Xu is the first to have proposed and preliminarily confirmed the feasibility of using deep sequencing technology to detect genetic mutation in rare cell samples such as circulating tumor cells (CTC) from patients' peripheral blood. He has published in peer-reviewed journals in lung, breast, and pancreatic cancers. Dr. Xu is board certified in internal medicine, hematology, and medical oncology. Dr. Xu also serves as a **physician staff member** at the Center for Cancer and Blood Disorder in Bethesda, Maryland, treating patients with all types of malignancy and hematological diseases.

This event is cosponsored by NTU Alumni Association DC Chapter (www.ntuaadc.org), Chinese American Professional Association DC Chapter (www.capadc.org), and Association of Chinese American Physician Mid-Atlantic Chapter (ACAP-MAC).