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)

"Real World Data for Clinical Evidence Generation"

To be presented by

Sean Khozin, MD

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Oncology Center for Excellence (OCE) &
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Information Exchange and Data Transformation (INFORMED), US FDA

Thursday, December 6, 2018

Venue: 9366 Gaither Rd. "1st Floor Music Room", Gaithersburg, MD 20877 (CCACC)

6:00 – 6:20 PM – Networking; Pizza/drink
6:20 – 8:50 PM – Program
8:50 – 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, current job-seekers, CCACC volunteers/employees/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, NJTUAADC members, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, DC Leaders Club members, BioTrain volunteers, and all Tai-Chi classes students in Metropolitan DC.

Registration Deadline: Please register by ***Thursday noon, December 6,*** *2018.*
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 8 onto Shady Grove Dr. Drive toward east and turn left onto Gaither Rd. The building is on your left after passing a stop sign.
By Metro rail: Exit at the Red Line Shady Grove Station.

Summary

Conventional cancer clinical trials can be slow and costly, often produce results with limited external validity, and are difficult for patients to participate in. Recent technological advances and a dynamic policy landscape in the United States have created a fertile ground for the use of real-world data (RWD) to improve current methods of clinical evidence generation. Sources of RWD include electronic health records, insurance claims, patient registries, and digital health solutions outside of conventional clinical trials. A definition focused on the original intent of data collected at the point of care can distinguish RWD from conventional clinical trial data.

When the intent of data collection at the point of care is research, RWD can be generated using experimental designs similar to those employed in conventional clinical trials, but with several advantages that include gains in efficient execution of studies with an appropriate balance between internal and external validity. RWD can support active pharmacovigilance, insights into the natural history of disease, and the development of external control arms.

Prospective collection of RWD can enable evidence generation based on pragmatic clinical trials (PCTs) that support randomized study designs and expand clinical research to the point of care. PCTs may help address the growing demands for access to experimental therapies while increasing patient participation in cancer clinical trials. Conducting valid real-world studies requires data quality assurance through auditable data abstraction methods and new incentives to drive electronic capture of clinically relevant data at the point of care.

Speaker

Dr. Sean Khozin is **acting associate director** at the FDA's Oncology Center of Excellence (OCE), and he is the **founding director** of Information Exchange and Data Transformation (INFORMED), an incubator for collaborative regulatory science research focused on supporting innovations that enhance the agency's mission to promote and protect public health. INFORMED is expanding organizational and technical infrastructure for big data analytics and examining modern approaches in evidence generation to support regulatory decisions.

Previously, Khozin was in private practice in New York City, an **attending physician** at St. Vincent's Hospital in Manhattan and an **entrepreneur** specializing in building health information technology systems with virtual patient management and point-of-care data visualization and analytics capabilities. Khozin received the 2017 Charles A. Sanders Life Sciences Award (accepted on behalf of the FDA), the 2017 FDA Commissioner's Group Award for the Naloxone App Challenge, and the 2004 Abraham Lilienfeld Award in biostatistics and advanced analytics.

This event is cosponsored by Chinese Culture and Community Service Center, Inc. (CCACC, www.ccacc-dc.org), NTU Alumni Association DC Chapter (www.ntuaadc.org), and Chinese American Professionals Association of Metropolitan Washington, DC (www.capadc.org).