

Pathways for Successful Translation of New Imaging Agents and Modalities: Phase III Studies

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| 9:00 - 9:20 AM | Background and goals Lalitha Shankar, NCI |
| 9:20 - 9:45 AM | FDA, current view Phillip Davis, Senior Medical Officer Pathways to Successful Translation: regulatory innovations in cancer imaging development |
| 9:45 - 9:55 AM | Questions from Audience |
| 9:55 - 10:15 AM | Previous PET agent approval processes: Lessons learned Terri Wilson, Blue Earth Diagnostics |
| 10:15 - 10:25 AM | Questions from Audience |
| 10:25 – 10:40 AM | Coffee Break |
| 10:40 - 11:05 AM | CMS, current view Rosemarie Hakim, Coverage and Analysis Group |
| 11:05 – 11:15 AM | Questions from Audience |
| 11:15 AM – 3:30 PM 11:15 AM-12:00 PM | Case studies <i>PSMA target PET probe for prostate cancer</i> Thomas Hope, Asst. Professor, Abdominal Imaging and Nuclear Medicine, UCSF Munir Ghesani, Asst. Prof. of Radiology, NYU School of Medicine, NYU Langone Medical Center |
| 12:00 – 12:15 PM | Panel Discussion: Sanjiv Sam Gambhir, Nushin Todd, Phillip Davis, Rosemarie Hakim |
| 12:15 - 1:15 PM | LUNCH |

- 1:15 – 2:00 PM *Optical probe for image guided surgery*
Eben Rosenthal, Prof. Of Otolaryngology and of Radiology, Stanford University
James P. Basilion, Prof. of Radiology and of Biomedical Engineering, Case Western Reserve University
- 2:00 – 2:15 PM Panel Discussion: Sanjiv Sam Gambhir, Betsy Ballard, Rosemarie Hakim
- 2:15 – 2:30 PM PM Coffee Break**
- 2:30 – 3:15 PM *Ultrasound with Microbubbles*
Sanjiv Sam Gambhir, Prof. and Chair of Dept. of Radiology, Stanford University
- 3:15 – 3:30 PM Panel Discussion: Sanjiv Sam Gambhir, Louis Marzella, Rosemarie Hakim
- 3:30 – 5:00 PM Discussion**
3:30 – 3:50 PM *Clinical Trial Design, CED, and CMS Reimbursement*
Moderator: Johannes Czernin
Panel: Barry Siegel, Brian Carey, Anthony Fotenos (FDA), Laurence Clark (CMD CMS), Constantine Gatsonis (ECOG-ACRIN),
- 3:50 – 4:10 PM *Funding Imaging Clinical Trials*
Moderator: Mitchell D. Schnall
Panel: Lalitha Shankar (NCI), Bonnie Clarke (SNMMI), Jonathan Sorger (Intuitive Surgical)
- 4:10 – 5:00 PM Discussion and Next Steps**