21st Century Active Surveillance: Focus on Methodology

June 1, 2016 – FDA White Oak Campus, Building 31, Great Room 1503 A

AGENDA

7:30-8:00 **Continental Breakfast**

8:00-8:15 **Opening Remarks**

Program Leaders:
Sharon-Lise Normand, Harvard
Frederic Resnic, Lahey
Danica Marinac-Dabic, FDA

8:15-9:30 **Plenary Session: Harnessing Real World Evidence for Active Surveillance**:
Moderators: Kathleen Hewitt, ACC and Ben Moscovitch, Pew

Electronic Patient Data Linkage to EHR – Harlan Krumholz, Yale (30 min)

Legal Environment – Robert Portman, Powers, Pyles, Sutter & Verville (30 min)

Audience Questions (15 min)

09:30-10:50 **Session 1: Envisioning Active Surveillance**
This session will describe what is meant by active surveillance today for devices and what it should include in the future.
Moderator: Joseph Ross, Yale

1) **Regulatory Perspective**: Thomas Gross, FDA (15 min)
2) **Small company perspective** : Jeff Dunkel, Titan Spine (15 min)
3) **Large company perspective:** Richard Kuntz, Medtronic (15 min)
4) **Public Health Perspective**: Dale Nordenberg, Novasano Health & Science (15 min)

Audience Discussion: Led by Moderator (20 min)

10:50-11:05 **Break**

11:05-12:20 **Session 2: Case Studies in Medical Device Surveillance: Today**
This session will focus on understanding specific examples of medical device surveillance. Each example to be a focused presentation including goal, approach, findings, and lessons learned.
Moderator: Michael Matheny, Vanderbilt

Example 1: Device surveillance using national registries – Frederic Resnic, Lahey (15 min)
Example 2: Device surveillance using integrated health care delivery system – Guy Cafri, Kaiser (15 min)
Example 3: Canadian Pilot – Mark Roche, ONC (15 min)

Audience Discussion: Led by Moderator (30 min)

12:20-13:20 **Lunch Break**

13:20-14:55 **Session 3: Device Surveillance Methodology Efforts Today: Where are the Gaps?**
This session will identify the gaps by discussing strengths and weaknesses in the Session 2 Case studies (including scalability, sustainability, methodological consensus, alert/signal communication (to regulators, manufacturers, providers, patients) and operational control.
Moderators: Sharon-Lise Normand, Harvard and Jesse Berlin, J&J

Panel Members: Roseann White - Duke, Vahan Simonyan - FDA, Myoung Kim - J&J, Daniel Caños - CMS

14:55-15:10 **Break**

15:10–16:10 **Session 4: Prioritizing Methodology Developments**
This session will begin development of recommendations regarding the intersecting priorities of specific surveillance models.
Moderators: Danica Marinac-Dabic, FDA and Harlan Krumholz, Yale

Panel Members: Theodore Lystig - Medtronic, Libbe Englander - Pharm3r, Liz Paxton - Kaiser, Michael Matheny - Vanderbilt, Patient representative (TBA)

16:10-16:45 **Closing Remarks**: Sharon-Lise Normand, Harvard, Frederic Resnic, Lahey and Danica Marinac-Dabic, FDA

1) Review key next steps,
2) Identify authorship teams for white papers,
3) Announce next meeting and timeline.