Summary of FDA Public Listening Session of Oncology Virtual Center of Excellence

Date: April 29th, 2:00 - 3:30PM

Address: FDA White Oak Campus, Silver Spring, MD

Attendees:

FDA: Robert Califf (Commissioner), leaders of the three centers include John Jenkins from CDER, Peter Marks from Biologics, and Jeff Shuren from Device

Societies: Three attendees in person, including ASH (American Society of Hematology), ONS (Oncology Nursing Society), and ISPE (International society of Pharmacoepidemiology). Others on the call including AACR (American Association for Cancer Research), NAACCR (North American Association of Central Cancer Registries), RTI International, etc.

Background:

- This is part of the Cancer Moonshot initiative. FDA plans to establish a virtual Oncology Center of Excellence across CDER, Biologics, and Device, with collaborations with other societies, agencies, academics, and industries.
- This virtual Oncology Center of Excellence will be formed in the next several months, report to Dr. Califf. FDA would also want to break the silo and enhance the collaboration both within and out of FDA
- This is an open discussion session with no presentations. FDA will have two other public hearing sessions with patient advocacy groups and industries.

Key messages:

- Data sharing is one key topic. FDA will create some incentives or culture for different companies or societies to share and pool the data, particularly the NGS (Next Generation Sequencing) data. FDA's role is more like a facilitator
- PMI (Precision Medicine Initiative) is another focus and NGS data is the key. Califf mentioned that there will be some guidance out soon to encourage "Think for Science" and call American to donate biological samples from 1 million subjects. There are three conditions include 1). Ensure subjects' privacy. 2). Science is good 3). Results will go back to patients or subjects.
- FDA encourages each society to consider FDA as one key stakeholder, and think what each can do to help this Oncology Center of Excellence

Other topics:

- Novel study endpoint was mentioned while some such as PROs (Patient Reported Outcomes) may not be oncology specific. FDA encourages having early discussion on these novel endpoints

- FDA realizes the importance using observational data or real-world evidence to compliment clinical trial data, particularly for some small groups such as older adult populations. FDA would like to hear more about it, and has experience such as using the CMS data for influenza vaccine coverage monitoring. Potential to discuss further opportunities to advance methods to optimize use of observational data.
- Price is another topic brought up by FDA. Although FDA will not decide price, FDA is dragged into the discussion sometimes. FDA has worked with CMS in years and does consider the "value" when make decision. FDA helps manage the price through the encouragement of competition (i.e. generic/biosimilars), and streamline the clinical trials to decrease the development cost. One example is whether we can randomize the observation data to save the cost of patient enrollment in clinical trials.
- Dr. Califf mentioned that he had a recent visit to EMA, and EMA is considering using endpoint that meet with the need of both regulatory and reimbursement decisions purposes. He also acknowledged that HTA (health technology assessment) decision varies in different countries.

Follow-up

- For questions or comments about the Virtual Center of Excellence, contact Wei Zhou (wei.zhou2@merck.com) and Jennifer Lund (jennifer.lund@unc.edu) by June 15, 2016.