Expedited Clinical Programs and Study Designs for Osteoarthritis Structure Modifying Therapies
May 16, 2019
Washington, DC

Draft Program Agenda

9:00 – 9:15 AM   Welcome & Overview
Joel Block, MD

9:15 – 9:45 AM   Panel Discussion: Impact of OA
Prevalence, risk factors, societal burden, unmet need
Leigh Callahan, PhD; Tuhina Neogi, MD, PhD; patient representative

9:45 – 10:00 AM   Group Discussion
Moderator: Jeffrey Katz, MD

10:00 – 10:15 AM  Break

10:15 – 10:45 AM  Disease progression
Current status of imaging biomarkers
Philip Conaghan, MD, PhD

10:45 – 11:00 AM  Current status of soluble biomarkers for OA
Virginia Kraus, MD

11:00 – 11:30 AM  Group Discussion
Panel: Philip Conaghan, MD; Virginia Kraus, MD
Moderator: Joel Block, MD

11:30 AM – 12:00 PM Applying biomarkers for accelerated approval of OA structure modifying drugs
Nikolay Nikolov, MD
Food and Drug Administration (FDA)

12:00 – 12:30 PM  Group Discussion
Moderator: Marc Hochberg, MD, MPH

12:30 – 1:15 PM  Lunch

1:15 – 2:15 PM  Post approval study designs for drugs approved on the basis of a surrogate endpoint in OA
Lee Simon, MD

2:15 – 3:30 PM  Group Discussion
Moderator: Philip Conaghan, MD, PhD

3:30 – 3:45 PM  Final comments
Joel Block, MD