

**FDA/AF OA Drug Development Workshop:  
Assessment of Long-term Benefit  
June 22<sup>nd</sup>, 2021  
Virtual  
Agenda**

**Meeting Goals and Objectives:**

This workshop is an ongoing public stakeholder discussion on the current state of science in the disease of Osteoarthritis (OA) to identify knowledge gaps and ways to address them.

Specific topics include discussion of OA, current approach to assessment of OA therapies, biomarkers in OA drug development, and assessment of disease progression and long-term benefit.

<b>Introduction (15 min)</b>	
10:00-10:05	<b>Opening remarks (5 min)</b> Patrizia Cavazzoni, CDER Director Introduce the goals of the workshop
10:05-10:15	<b>Overview (10 min)</b> Steven Taylor (AF)/Nikolay Nikolov (FDA)
<b>Session 1: Current Approach to Disease of OA (70 min)</b>	
10:15-10:25	<b>Overview of OA and Burden of Disease (10 min)</b> Tuhina Neogi
10:25-10:35	<b>Patient Perspective (10 min)</b> Bill Agee
10:35-10:55	<b>Landscape of OA drug and biologic development: Regulatory perspective (20 min)</b> <ul style="list-style-type: none"> <li>• FDA-CDER-DAAP: Robert Shibuya-10 min</li> <li>• FDA-CBER-OTAT: Elizabeth Hart-10 min</li> </ul> (Current approach to assessment of OA symptoms and function)
10:55-11:25	<b>Panel Discussion and Q/A (30 min)</b> <b>Panelists:</b> The Speakers, Cale Jacobs (AF), Leslie Tive (Industry) <b>Moderators:</b> Larissa Lapteva (FDA) and Tuhina Neogi (Academia)
<b>11:25-12:00 pm BREAK</b>	
<b>Session 2: Biomarkers in OA Drug Development (105 min)</b>	
12:00-12:10 pm	<b>Regulatory Considerations on Biomarkers and Assessment of Long-term Benefit in OA (10 min)</b> Nikolay Nikolov
12:10-12:20 pm	<b>Biochemical Markers in OA (10 mins)</b> Virginia Kraus
12:20-12:40 pm	<b>Imaging Biomarkers in OA (20 mins)</b> <ul style="list-style-type: none"> <li>• MRI vs. X-Ray, Frank Roemer</li> <li>• Quantitative MRI, Sharmila Majumdar</li> </ul>
12:40-12:50 pm	<b>Role of Biomarkers in Drug Development (10 min)</b> Jeffrey Siegel
12:50-1:05 pm	<b>Statistical Considerations on the Use of Surrogate Endpoints (15 min)</b> Tom Fleming
1:05-1:45 pm	<b>Panel Discussion and Q/A (40 min)</b>

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	<b>Panelists:</b> The Speakers, Greg Levin (FDA), Xiaojuan Li (AF), Emily Hunt (Patient), Morten Karsdal (Industry) <b>Moderators:</b> Nikolay Nikolov (FDA) and David Felson (Academia)
<b>1:45-2:00 pm BREAK</b>	
<b>Session 3: Assessment of OA Disease Progression and Long-term Benefit (155 min)</b>	
2:00-2:15 pm	<b>Challenges with Assessment of Disease Progression (15 min): Clinical and Structural</b> Tim McAlindon
2:15-2:35 pm	<b>Lessons Learned from Clinical Programs to Assess Disease Progression (20 min)</b> <ul style="list-style-type: none"> <li>• Sprifermin Case Study, Marc Hochberg</li> <li>• Canakinumab Case Study, Phil Conaghan</li> </ul>
2:35-2:45 pm	<b>Considerations on Assessment of Long-term Pain and Function (10 min)</b> Daniel Clauw
2:45-3:05 pm	<b>Proposed Concept Clinical Endpoints of Long-term Benefit (20 min)</b> Yura Kim
3:05-4:35 pm	<b>Panel Discussion and Q/A (90 min)</b> <b>Panelists:</b> The Speakers, Becky Rothwell, Nikolay Nikolov, (FDA), David Felson (AF), Stephanie Rosado (Patient), Jeymi Tambiah, Angelika Jahreis (Industry) <b>Moderators:</b> Jeff Siegel (FDA) and Ali Mobasher (Academia)
<b>Summary (25 min)</b>	
4:35-4:55 pm	<b>Summary Remarks (20 min)</b> Session Moderators (5-10 minutes Summary of each Session)
4:55-5:00 pm	<b>Closing Remarks (5 min)</b> Larissa Lapteva

Format: Virtual, Zoom Webinar

<https://www.fda.gov/drugs/news-events-human-drugs/fda-arthritis-foundation-osteoarthritis-drug-development-workshop-assessment-long-term-benefit>

Meeting Registration Site: <https://cvent.me/eXw9IG>

Panel discussions: Questions from the audience