

FDA Public Workshop – Orthopaedic Sensing, Measuring and Advanced Reporting Technology (SMART) Devices

Monday, April 30, 2018



Agenda – Morning

- 8:00 – Keynotes
- 8:40 – Break
- 8:45 – Engineering and Technology Considerations
- 10:25 – Break
- 10:40 – Clinical and Patient Perspective
- 1:05 – Lunch



Agenda – Afternoon


- 1:05 – Lunch
- 1:50 – Cybersecurity in Healthcare
- 3:05 – Break
- 3:20 – Regulatory Considerations
- 5:00 – Closing Remarks

Please Provide Feedback!

To leave a comment,

- Go to www.regulations.gov
 - Search for [FDA-2018-N-0235](#)
 - Click on 

Alternatively,

- Go to the Federal Register notice
 - Click on 
- Comment period closes May 29



Archived Content

Go to:

<https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm595401.htm>

- Webcast
- Presentations
- Transcripts



Internet Access

Network: FDA-Public
Password: publicaccess

Break – 8:40 to 8:45

Next Up: Engineering and Technology Considerations

8:45	Current Landscape of SMART Technology in Orthopaedics	Mark Allen, PhD
9:00	Utilization of SMART Technology: Passive Monitoring, Diagnostics, Automated Treatment	Shuvo Roy, PhD
9:15	Industry Perspective on Market Considerations for SMART Technology	Lisa Ferrara, PhD
9:30	Future Applications for SMART Technology	Michel Maharbiz, PhD
9:45	Panel Discussion	Anton Dmitriev, PhD Vijay Goel, PhD

Internet

- Network: FDA-Public
- Password: publicaccess

Feedback

- Go to: www.regulations.gov
- Search for: [FDA-2018-N-0235](#)

Break – 10:25 to 10:40

Next Up: Clinical and Patient Perspective

10:40	Clinician Welcome, Purpose, and Introduction to Clinical and Patient Panel Session	Joseph Kvedar, MD
11:00	Clinical Impact of SMART Technology	Aenor Sawyer, MD
11:15	SMART Technology in the Hands of a Surgeon: What Information Would Benefit Your Practice?	Stefano Bini, MD
11:30	Utility of SMART Technology in Clinical Studies	Mark Froimson, MD
11:45	Advancing Osseointegrated Amputee Care Through SMART Technology: Clinical and Patient Perspective	Rickard Brånemark, MD, PhD
12:00	Fireside Chat with Patients	
12:20	Panel Discussion	Steve Weber, MD Adolph J. Yates Jr., MD

Internet

- Network: FDA-Public
- Password: publicaccess

Feedback

- Go to: www.regulations.gov
- Search for: [FDA-2018-N-0235](https://www.fda.gov/oc/2018-02-23)

Lunch – 1:05 to 1:50

Next Up: Cybersecurity Considerations

1:50	Cybersecurity in Healthcare	Salwa Rafee, MS
2:05	Healthcare / SMART Data Management Considerations	Darren Lacey, JD
2:20	Cybersecurity Regulatory Considerations	Seth Carmody, PhD
2:35	Panel Discussion	Linda Ricci Beau Woods

Internet

- Network: FDA-Public
- Password: publicaccess

Feedback

- Go to: www.regulations.gov
- Search for: [FDA-2018-N-0235](#)

Break – 3:15 to 3:30

Next Up: Regulatory Considerations

3:30	Regulatory Overview and Pathways	Michael Owens, MS
3:45	Clinical Trial Innovation	Joshua Chetta, PhD
4:00	Digital Health Initiatives	Bakul Patel, MS, MBA
4:15	Orthopaedic SMART Device Evaluation	Colin O'Neill, MS
4:30	Panel Discussion	Constance Soves, PhD Janice Hogan, JD

Internet

- Network: FDA-Public
- Password: publicaccess

Feedback


- Go to: www.regulations.gov
- Search for: [FDA-2018-N-0235](https://www.fda.gov/oc/2018/n0235)

Adjourn

To leave a comment,

- Go to www.regulations.gov
 - Search for [FDA-2018-N-0235](#)
 - Click on A dark blue button with the text "Comment Now!" in white.

Alternatively,

- Go to the Federal Register notice
 - Click on A green button with the text "SUBMIT A FORMAL COMMENT" in white.
- Comment period closes May 29

