

SESSIONS

DAY 1 – APRIL 26, 2021 - 26/04/2021

Software as a Medical Device Digital Week

26 - 27 April 2021
2-Day Webcast Series

The Legislative Proposal for a European Approach on AI by the European Commission

09:00 - 10:00

- Background and rationale of the EU regulatory framework on AI
- Main elements of the regulatory framework on AI
- Interlink with existing EU legislation on medical devices

Participants

Gabriele Mazzini - Legal and Policy Officer, European Commission

Salvatore Scalzo - Policy and Legal Officer, AI, European Commission

Medical Device Software, Regulatory requirements and the MDR

10:00 - 11:00

- Introduction, What is medical device software?
- MDCG Guidance on Software
- Software qualification and classification
- General Safety and Performance Requirements
- State of the Art and AI

Participants

Dr Fiona Dunn - Senior Technical Specialist & Scheme Manager, Active Devices, Medical Devices, BSI

Dr Aris Tzavaras - Technical Specialist & Scheme Manager, Active Devices, Medical Devices, BSI

SCHEDULE

DAY 1 – APRIL 26, 2021 - 26/04/2021

Software as a Medical Device Digital Week

26 - 27 April 2021
2-Day Webcast Series

TIME	
09:00	09:00 - The Legislative Proposal for a European Approach on AI by the European Commission
10:00	10:00 - Medical Device Software, Regulatory requirements and the MDR

How to Make a Profit with Data while Complying with the GDPR?

09:00 - 10:00

- General Data Protection Regulation review related to software and AI
- Creating value with data, AI and the re-identification of anonymized datasets
- Where does the line cross for things like heart rate monitoring (ie. data re-use to improve services, data disclosures to third parties etc.)?
- What are the rules around CE marking for these companies?

Participants

Jan Dhont - Partner, Privacy and Cybersecurity Wilson, Sonsini, Goodrich & Rosati

Nikolaos Theodorakis - Of Counsel, Goodrich & Rosati

Laura Brodahl - Associate, Goodrich & Rosati

The Persuasive Power of Data Visualization Across the Clinical Trial Management Spectrum

10:00 - 11:00

Data plays the fundamental role in a clinical trial. As medical technologies continue to advance, the sources of data collection are expanding past just one clinical trial database. Methods including but not limited to wearables, mobile applications, eDiaries, real-world evidence, outcome assessments, imaging, EHRs and EMRs are all sources for data collection and can be housed in different places. It's critical for companies to successfully manage and identify meaningful, actionable insights that impact a trial. By using an intuitive data visualization tool, large amounts of sensitive trial data from various sources can be translated into meaningful information in just one application. Join us to learn more about how data visualization increases efficiency in the incredibly complicated clinical trial process.

- Why: Benefits and Advantages of Data Visualization Technologies in Clinical Trials
- What: Power BI Dashboard and Reporting Tool
- How: Using Data Pooling and Automation to Visualize Real-Time Clinical Study Data
- Case Studies: Successful Uses of Power BI Visualization in Clinical Trials Today

Participants

Mark McIlduff - General Manager, U.S. Operations, Avania

Hailey Jannetty - Sr. Data Analyst, Avania

SCHEDULE

DAY 2 – APRIL 27, 2021 - 27/04/2021

Software as a Medical Device Digital Week

26 - 27 April 2021
2-Day Webcast Series

TIME	
09:00	09:00 - How to Make a Profit with Data while Complying with the GDPR?
10:00	10:00 - The Persuasive Power of Data Visualization Across the Clinical Trial Management Spectrum