



CARDIOCARE

An Interdisciplinary Approach for the Management of the Elderly Multimorbid Patient with Breast Cancer Therapy Induced Cardiac Toxicity

Workshop: Navigating the regulatory landscape in Cardiovascular Health

European Society of Cardiology, Brussels

[10:00-16:00]

Speakers from CARDIOCARE partners

- Prof. Konstantinos Marias, FORTH (CARDIOCARE partner)
- Dr. Costanza Conti, IMS
- Anca Bucur, PHILIPS

Moderator

- Prof. Dimitrios I. Fotiadis (UOI)

AGENDA:

Introduction

- Welcome and opening remarks & Overview of CARDIOCARE project – **Prof. Dimitrios I. Fotiadis (UOI)**
- Key-note speech on the evolving regulatory framework in Europe - **Prof. Piotr Szymanski (Chair, ESC Regulatory Affairs Committee)**
- Brief introduction to the regulatory aspects in Cardiovascular Health - **Costanza Conti (IMS)**

Tele-health Systems and Risk Stratification

- Current regulatory framework in EU: challenges and prospects
Prof. Enrico Gianluca Caiani, FESC at ESC
- Tele-health Systems and Risk Stratification in CARDIOCARE - **Prof. Konstantinos Marias, FORTH (CARDIOCARE partner)**

Medical devices in Cardiovascular Health

- Medical devices, update on the implementation of MDR - **Prof. Alan Fraser, FESC at ESC**
- Focus on the harmonized approach to Early Feasibility Studies for medical devices in the EU (HEU-EFS) - **Dr. Giuditta Callea**
- Medical devices in Cardiovascular Health in CARDIOCARE - **Dr. Costanza Conti, IMS (CARDIOCARE partner)**

Utilising Big Data for Patient Profiling/Monitoring & Artificial Intelligence, and the AI Act

- Current challenges and opportunities for using healthcare data in clinical research - **Folkert Asselbergs, ESC expert on AI and data**
- Access Potential Applications of Big Data in Health - **Dr. Sara Marceglia**
- Requirements adopting AI: safety, robustness, frameworks, explainability - **Prof Frank Rademakers**
- Big Data, Artificial Intelligence, and the AI Act in CARDIOCARE - **Anca Bucur, PHILIPS (CARDIOCARE partner)**

Wrap up session & closing remarks

- **Prof. Dimitrios I. Fotiadis (UOI)**
- **Costanza Conti (IMS)**