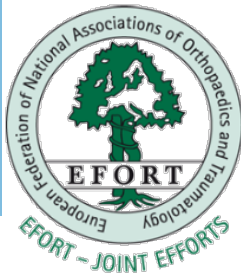


Welcome



NIMAC SYMPOSIUM
Brussels, April 6th 2018





EFORTnet

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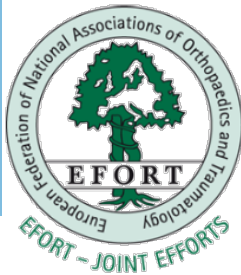
- Mission and vision
- What we offer
- How we work
- Membership & Network
- History of EFORT
- Statutes
- EFORT Annual Reports
- Ethical Orthopaedics
- Network of Orthopaedic Registries of Europe (NORE)
 - Research & Publications
 - Meetings & Events
 - Projects & Activities

NORE Network of Orthopaedic Registries of Europe



About NORE	Research & Publications	Events, Presentations & Meetings	Projects & Activities
Who We Are	NORE Charter	NORE Advisory Board & Organisation	Contact NORE

NORE, the Network of Orthopaedic Registries of Europe, is an international registry network built up as a standing committee of EFORT and founded in 2015. The network is organised as an EFORT standing



Engaging with the new EU regulatory landscape for medical devices - Challenges and Opportunities



Agenda

10.30 – 10.35	Welcome & Introductions	Rob Nelissen
10.35 – 12.00	SESSION 1:	
	The political and patient safety picture – Involving Regulators, scientists, industry and Clinicians in the EU decision making process	Chairpersons: Tom Melvin and Per Kjaersgaard-Andersen
10.35	Where we stand in EFORT	Per Kjaersgaard-Andersen
10.45	The Life of a TJR; the stages of regulating and monitoring a total joint replacement now and the future	Keith Tucker and Amie Smirthwaite
11.05	Major Proposals from the new Medical Devices Regulations	Tom Melvin
11.20	Impact on Industry of new regulations for medical devices	Oliver Bisazza
11.35	Patient Safety: the Regulatory Perspective and the Impact of the new MDR	Mark Grumbridge
11.50	Expert engagement in policies for scientific research and innovation in the EU	Rob Nelissen

Agenda

12.00 - 12.15	Coffee break	Foyer 2 nd floor
12.15 – 13.15	SESSION 2:	
	The new EU Medical Device Regulations	Chairpersons: Amie Smirthwaite and Rob Nelissen
12.15	Shifting paradigms for high-risk devices – the objectives of the new regulations Orthopaedics – lessons learned from the past	Jörg Lützner and Per Kjaersgaard-Andersen
12.30	Rational minimum requirements for evidence of medical devices	Christine Quinton
12.45	Minimum requirements, clinical practice and lessons learned from the past	Tim Wilton
13.00	Discussion and Review of the morning's presentations	All
13.15- 14.00	Lunchbreak	Restaurant with a view 9th floor

Agenda

14.00 – 14.15	Questions and answers on morning session	Chair: Rob Nelissen
14.15 – 15.15	SESSION 3:	
	What to do next, quality and safety for future patients	Chairpersons: Christine Quinton and Oliver Bisazza
14.30	Monitoring by registries or do we still need clinical trials? The Pros and Cons	Sion Glyn Jones
14.45	Post-market clinical follow-up and registries, the example of the Dutch Arthroplasty, LROI	Rob Nelissen
15.00	The future from the eyes of a surgeon who is also connected to a manufacturer	Luca Orlandini
15.15 – 15.30	Coffee break	Foyer 2nd floor
15.30 – 16.15	SESSION 4:	
	Initiatives on quality and safety for future patients	Chairpersons: Luca Orlandini and Tim Wilton
15.30	Pre-market approval guidelines and the new MD regulations	Amie Smirthwaite
15.45	NIMAC What could it say to Brussels?	Keith Tucker
16.00	Review of presentations, Summary and Conclusions An opportunity for each presenter to add a comment to what they originally said or change their mind! Your THM (Take home message)!!	Rob Nelissen

WELCOME & INTRODUCTION

Rob Nelissen
Orthopaedic Surgeon, Chair Dutch
Arthroplasty Register ([LROI](#)) and
Chair of NORE

SESSION 1:

The political and patient safety picture

Involving Regulators, scientists, industry and Clinicians in the EU decision making process

Chairpersons:

Tom Melvin and Per Kjaersgaard-Andersen



coffee break

SESSION 2:

The new EU Medical Device Regulations

Chairspersons:

Amie Smirthwaite and Rob Nelissen

TIME FOR
LUNCH



SESSION 3:

What to do next, quality and safety for future patients

Chairpersons:

Christine Quinton and Oliver Bisazza



coffee break

SESSION 4:

Initiatives on quality and safety for future patients

Chairpersons:

Luca Orlandini and Tim Wilton

Take Home Messages

