Leiden University
Medical Center

Welcome

Network of Orthopaedic Registries of Europe

NIMAC SYMPOSIUM
Brussels, April 6th 2018

www.EFORT.org/NORE

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NORE Network of Orthopaedic Registries of Europe

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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

Leiden University Medical Center

Network of Orthopaedic Registries of Europe

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 2nd 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	**Chairspersons:** **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

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The political and patient safety picture

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Chairpersons:

Tom Melvin and Per Kjaersgaard-Andersen

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coffee break

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The new EU Medical Device Regulations

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Initiatives on quality and safety for future patients

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Take Home Messages