LMI | Legemiddelindustrien

7th Conference on Clinical Trials in the Nordic Countries 2019

Program
Monday, November 18

09.00	Registration
09.30	Welcome to the Conference *Monica Larsen*, The Association of the Pharmaceutical Industry in Norway, Oslo
	Implementation of the EU Clinical Trial Regulation (no. 536/2014) and the EU portal **Chair: *Outi Konttinen*, National Committee on Medical Research Ethics, Finland**
09.40	Commission´s role in implementing the regulation *Edit Szepessy*, Policy Officer, European Commission, Brussels, Belgium
10.30	Functioning of the EU portal and database *Ana Rodriguez Sanchez Beato*, Head of Clinical and Non-Clinical Compliance, European Medicines Agency
11.20	Coffee Break
	The Clinical Trial Regulation will come into application – what is the latest status? **Chair: *Philip Lange Møller*, Møller & Juhl IVS Denmark**
11.55	Latest update and status from the National Medicines Agencies *Ingvild Aaløkken*, Senior advisor, Norwegian Medicines Agency, Oslo; *Lene Grejs Petersen,* Senior advisor, Danish Medicines Agency; Copenhagen; *Pirjo Inki,* Head of Section, Finnish Medicines Agency, Turku; *Gunilla Andrew Nielsen*, Head of Clinical Trials, Swedish Medical Products Agency, Uppsala
12.55	Lunch
14.10	Is industry ready for the regulation? Latest status. *Nick Sykes*, Director, European Regulatory Policy, Pfizer, Canterbury, UK
14.25	Is academia ready for the regulation? Latest status. *Annette Jørgensen*, Head of Department at GCP-unit, Aarhus University Hospital, Denmark
14.40	Panel discussion: user perspectives – how to get ready *Nick Sykes*, EFPIA/Pfizer, *Annette Jørgensen*, Aarhus University Hospital, *Marie Moores*, Executive Vice President Operations Link Medical Research, Nordic competent Authority representatives
15.10	Coffee Break
	Interplay between GDPR and CTR **Chair: *Helena Lomberg,* BCT Consulting, Sweden**
15.45	GDPR implementation and its impact on the conduct of clinical trials in the Nordic region *Alan Yeomans*, Quality Manager, Viedoc, Uppsala, Sweden
16.15	Secondary use of health data and EFPIA responsible transparency *Brendan Barnes*, Director Data Protection and IP, The European Federation of Pharmaceutical Industries and Associations, Brussels, Belgium
16.45	QA *Alan Yeomans*, Viedoc, Brendan Barnes, EFPIA *et al*
17.30	End
19.00	Dinner

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	Recent and future updates on the international ICH guidelines documents **Chair: *Philip Lange Møller,* Møller & Juhl IVS Denmark**
08.45	Learnings and findings implementation ICH GCP E6 addendum *Martha Colban*, Special adviser, Oslo University Hospital, Norway
09.10	Ongoing trials and ICH GCP R2 and how about Regulation 536/2014 (Serious Breaches and Inspection reports) *Philip Lange Møller,* Møller & Juhl IVS, Denmark
09.25	Regulators expectation on computer validation and data integrity *Ib Alstrup*, GXP Inspector, Danish Medicines Agency, Copenhagen, Denmark
	The Future of Clinical Trials **Chair: *Mia Bengtström*, Pharma Industry Finland**
09.55	TransCelerate – an overview of current initiatives to improve the execution of clinical trials *Catharina Östberg*, Head Clinical Operations GSK, Stockholm, Sweden
10.15	Coffee Break
10.50	How to provide incentives for clinical trials in the hospitals and the White Paper on Health Industry *Marianne van der Wel*, senior advisor and *Nils Olav Refsdal*, senior advisor, Norweigian Ministry of Health and Care Services, Oslo, Norway
11.10	Finnish big data lakes for better healthcare and research – from discovery to feasibility studies *Samu Kurki*, Senior data scientist, Auria Biobank, Turku, Finland
11.30	Lunch
	The Future of Clinical Trials **Chair: *Kristin Løseth*, Director, Medical Information, Patient Safety & Ethics, AstraZeneca AS, Oslo**
12.45	Complex clinical trial design: a review of the Clinical trial landscape *Nick Sykes*, Director, European Regulatory Policy, Pfizer, Canterbury, UK
13.15	New EU recommendations on complex clinical trials *Ditte Zerland Christensen*, Senior Regulatory Assesor, Danish Medicines Agency, Copenhagen, Denmark
13.45	Coffee Break
14.20	Biomarker Assays in Clinical Trials *Tricia Carrigan*, Associate Vice President, Translational Biomarkers and Companion Diagnostics, MSD/EFPIA
14.50	Big data and the use in drug development *Steinar Thoresen*, Strategic Lead Oncology The Nordics and Netherland, Merck Group
15.20-15.30	Wrap up *Monica Larsen*, The Association of the Pharmaceutical Industry in Norway, Oslo

Host
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Organiser
Läkemedelsakademin
Swedish Academy of Pharmaceutical Sciences

In co-operation
LÄKEMEDELSVERKET SWEDISH MEDICAL PRODUCTS AGENCY
LääketeollisuusPharma Industry Finland
LIF The research-based pharmaceutical industry