LMI | Legemiddelindustrien

7th Conference on Clinical Trials in the Nordic Countries 2019

Monday, November 18

09.00	Registration
09.30	Welcome to the Conference *Monica Larsen*, LMI, Oslo, Norway
	Implementation of the EU Clinical Trial Regulation (no. 536/2014) and the EU portal
09.40	The role of the Commission incl Q&A *Edit Szepessy*, Policy Officer, European Commission, Brussels, Belgium
10.30	The role of EMA *Speaker to be announced*
10.20	Coffee Break
	The Clinical Trial Regulation will come into application – what is the latest status?
11.55	Update from the competent Authority representatives *Ingvild Aaløkken*, Senior advisor, Norwegian Medicines Agency, Oslo; *Helle Harder*, Head of Department Clinical Trials, 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	Preparation from Industry /aspects *Nick Sykes*, Director, European Regulatory Policy, Pfizer, Canterbury, UK
14.25	Preparation from Academia *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
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	EFPIA responsible transparency *Brendan Barnes*, Director Data Protection and IP, The European Federation of Pharmaceutical Industries and Associations, Brussels, Belgium
16.45	Panel discussion *Alan Yeomans*, Viedoc, Brendan Barnes, EFPIA *et al*
18.00	End
19.00	Dinner

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	Recent and future updates on the international ICH guidelines documents
08.45	Learnings and findings implementation ICH GCP E6 addendum *Martha Colban*, Special adviser, Oslo University Hospital, Norway
09.25	Updates in efficacy guidelines (E8, E9, E10) *Speaker to be announced*
	The Future of Clinical Trials
09.55	TransCelerate – an overview of current initiatives to improve the execution of clinical trials *Katarina Thor*, Senior Compliance Advisor GCP, Global QA Compliance, Novartis, Uppsala, Sweden
10.15	Coffee Break
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
12.45	Complex clinical trial design: a review of the Clinical trial landscape *Nick Sykes*, Director, European Regulatory Policy, Pfizer, Canterbury, UK
13.15	Complex clinical trial design II *Speaker to be announced*
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	Wrap up
15.30	End

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