Läkemedelsakademin

Swedish Academy of Pharmaceutical Sciences

The 5th conference on Clinical Trials in the Nordic Countries

15-16 June, 2016, Clarion Sign Hotel, central Stockholm

www.lakemedelsakademin.se/CTNC2016

Time	Preliminary programme
	June 15th , Wednesday
10.00	Welcome, short intro Chairman: Mia Bengtström, Senior advisor, Pharma Industry Finland
	The EU Regulation 536/2014
	Implementation of the Regulation – EMA perspective Ana Rodriguez, Head of Clinical and Non-clinical Compliance, the European Medicines Agency Why regulation instead of directives? Implementation of the regulation from EMA point of view. Overview of the structure of the new database – overview of different working groups and procedures. Overview of the application Procedures
	Implementation of the Regulation – Pharmaceutical industry perspectives. Nick Sykes, Senior Director, Worldwide Safety and Regulatory, Pfizer
	New guidelines under Eudralex volume 10 and upcoming reflection papers Ana Rodriguez, Head of Clinical and Non-clinical Compliance, the European Medicines Agency The Inspectors Working Group at EMA have published a number of reflection papers. What happens to these reflection papers when the new regulation comes in force?
11.50	Lunch
12.55	Chairman: Helena Lomberg, BCT Consulting, the Swedish Society for Clinical Trials
	Implementation of the Regulation in the Nordic countries; local perspectives National Competent Authorities and Ethics Committees representatives from the Nordic Countries will present the current status of the upcoming regulation with focus on local organizational aspects and procedures. What changes are to be expected? Collaboration between EC and CA? Main challenges? Which local laws will be affected? Communication strategy etc? There will be plenty of room for questions and discussions.
	DK: Lene Grejs Petersen, Senior Advisor, the Danish Medicines Agency and Karen Kiilerich, National Ethics Committee
	FI: Johanna Honkalammi, Senior Medical Officer, the Finnish Medicines Agency and Outi Konttinen, General Secretary, National Ethics Committee
	Coffee break
	NO: Ingvild Aaløkken, Head of Unit, the Norwegian Medicines Agency
	SE: Gunilla Andrew-Nielsen, Head of Clinical Trials, the Swedish Medical Products Agency and Peter Höglund, Professor, National Ethics Committee
	Short break
	Panel discussion: Q&A (All speakers day one)
18.00	End of day one
18.30	Conference dinner (separate choice when registering)

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Time	Topic
	June 16th, Wednesday
8.30	Chairman: Monika Larsen, Manager of R&D and Business Development, the Norwegian Association of Pharmaceutical Manufacturers
	Addendum for ICH GCP Guideline; status and changes Ana Rodriguez, Head of Clinical and Non-clinical Compliance, the European Medicines Agency The ICH GCP Guideline has been in force the last 20 years. An ICH Expert Working Group has been working on drafting an addendum to the guideline. What are the changes in the addendum? What is the next steps and when will the addendum be in force?
	Coffee break
	Electronic systems in Clinical Trials, Lisbeth Bregnhøj, Medicines Inspector, the Danish Medicines Agency The expectations when it comes to electronic systems for handling source data, data collection tools, the use of interactive response technologies (IVRS / IWRS / IRT) and trial master files in clinical trials.
	Inspection findings – what can we learn? Philip Lange Møller, GCP Inspector, the Danish Medicines Agency, Helena Lindberg, GCP Inspector, the Swedish Medical Products Agency
11:30	Lunch
12:30	**Panel discussion** (All speakers from session before lunch)
	Chairman: Philip Lange Møller, GCP Inspector, the Danish Medicines Agency
	New initiatives to facilitate clinical trials in the Nordic countries – How are the Nordic countries attractive for clinical trials, and are competitive in a European setting?
	SE: National coordination of clinical studies in Sweden, Håkan Billig, Professor, Chair of Committee
	NO: Action plan for the Norwegian Health&Care 21 strategy, Maiken Engelstad, Assistant Director General , Norweigan Ministry of Health and Care Services
	FI: Secondary use of health data, Pekka Kahri, Director of Information Services, The National Institute for Health and Welfare, Finland
	Coffee break
15.15	**Initiatives for cooperation between the Nordic Countries**
	Nord Ped Med, Pirkko Lepola, University of Tampere
Ca 16.00	End of meeting