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Apotekarsocieteten

5th Conference on
Clinical Trials in the Nordic Countries

June 15-16, 2016, Sweden

Most welcome to take part in a unique opportunity to meet representatives from the regulatory authorities and other experts within the field of clinical research. Listen to the latest news and currents trends, and network with professional colleagues from the Nordic countries.

Who should attend?

Professionals working with or interested in clinical trials in the Nordic region will benefit from attending the conference. We welcome persons with a more strategic responsibility in their organizations as well as operational professionals. You may work in the following sectors: health care, academia, the biopharmaceutical industry, contract research companies or other service organizations as well as politicians and government officials.

The conference program has been developed in collaboration with:

The Swedish Society for Clinical Trials

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

LMI
LEGEMIDDELINDUSTRIEN
The Association of the Pharmaceutical Industry in Norway

PHARMA INDUSTRY FINLAND

Program

June 15th, Wednesday

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?

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;
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

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June 16th, Wednesday

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?

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 and *Helena Lindberg*, GCP Inspector, the Swedish Medical Products 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

Initiatives for cooperation between the Nordic Countries Nord Ped Med
Pirkko Lepola, University of Tampere

Full program www.lakemedelsakademin.se/CTNC2016

Time and location

The conference is held on June 15-16, 2016 at the Clarion Sign Hotel in central Stockholm. The meeting starts at 10.00 on Wednesday June 15 and ends at approx. 17.00 on Thursday June 16. The Venue is easily reached from Arlanda airport by express train or bus/taxi.

Participation fee, meals and accommodation

The early participation fee is 6.900 SEK and 3.500 SEK for academia/public healthcare participants **(academia/public healthcare should use special coupon code ACPH in the registration form)**.
Late registration, after May 15, is available at 7.900 SEK and 4.500 SEK, academia/public healthcare participants. Lunch and coffee is included in the participation fee. Conference dinner fee on June the 15th is 600 SEK. *All Prices are excl VAT.*

Accommodation is available at the Clarion Sign Hotel, and is not included in the conference fee. Please contact the hotel directly on sales.sign@choice.se and state R583407 when booking a room. For guaranteed accommodation book before May 15. www.clarionsign.se Other nearby hotels include HTL Upplandsgatan, www.htlhotels.com or Scandic Norra bantorget, www.scandichotels.se

For registration and updates on the conference, please visit our web site www.lakemedelsakademin.se/CTNC2016

Further information

For organizational questions please contact Jenny Hagberg, jenny.hagberg@lakemedelsakademin.se, phone: +46 8 723 50 08. For questions regarding the program please contact Anders Pesula, anders.pesula@lakemedelsakademin.se, phone: +46 8 723 50 45.

Register at www.lakemedelsakademin.se
Last date for reduced participation fee, until May 15, 2016.

The Swedish Academy of Pharmaceutical Sciences – part of the Swedish Pharmaceutical Society, a non-profit organisation working for the optimal development and use of medicines.