Future Clinical Trials – from tomorrow to 2030 – Why choose the Nordics?

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PROGRAM 7.6. (13.00-17.30 EEST/12.00-16.30 CEST)

13.00-13.05 (EEST) Welcome to the conference, *Mia Bengtström, Associate professor, Åbo Akademi University*

Chair for the session: *Jaana Santaholma, Country Medical Director, Novartis Finland Oy*

Looking into the Future – use of data in medicines development

13.05-13.25 (EEST) What have we learned from two decades of digitizing clinical development and where are we headed next? *Kai Langel, Senior Director, Strategy and Innovation, Janssen Global Regulatory Policy and Intelligence*

13.30-14.00 (EEST) Next generation of clinical trials, *Sam Hariry, Global Head Clinical Innovation, Novartis* (virtual)

14.05-14.30 (EEST) Drug Development: the future is today! *Solange Corriol-Rohou, Senior Director Regulatory Affairs & Policy, Europe, AstraZeneca, EFPIA Clinical Research Expert Group* (virtual)

Decentralized Clinical Trials – potential benefit and value for stakeholders

14.35-14.55 (EEST) The promise of decentralized trials: What does industry need to consider, *Nick Sykes, Senior Director, Global Regulatory Policy & Intelligence at Pfizer, Clinical Research Expert Group, EFPIA* (virtual)

15.00-15.15 (EEST) Designing Decentralized Clinical Trials with a Patient-Centric Approach, *Henna Alanko, Global CPA Oncology, Crown CRO and Bayer*

15.20-15.50 (EEST) Coffee break and Networking

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PROGRAM 7.6. (13.00-17.30 EEST/12.00-16.30 CEST)

Short presentations and moderated Panel discussion *Moderator Hege Edvardsen, Senior Manager Research, Development & Innovation, LMI*

15.50-16.10 (EEST) Healthcare view and DCT in Norway, *Kristine Kleivi Sahlberg, Head of Research and Innovation, Vestre Viken, Norway*

16.15-16.30 (EEST) Examples of virtual elements in clinical trials conducted by different sponsors in the Nordic countries. Why is the Nordics a good choice for these kind of studies? *Johanna Hemdahl, Boehringer-Ingelheim, Chair for the Clinical Trial Expert Group, Pharma Industry Finland in collaboration with Nordic colleagues*

16.35-17.00 (EEST)

- DCT activities in Sweden, *Gunilla Andrew-Nielsen, Head of Clinical Trials, Swedish Medical Products Agency*
- DCT in Finland, *Pirjo Inki, Head of section Clinical Trials, Finnish Medicines Agency Fimea*

17.00-17.45 (EEST) Moderated Panel discussion

Panel:

- *Gunilla Andrew-Nielsen, Head of Clinical Trials, MPA*
- *Pirjo Inki, Head of section Clinical Trials, Fimea*
- *Elina Asikanius, Biostatistician Fimea, Member of EMA methodology working part*
- *Solange Corriol-Rohou, Senior Director Regulatory Affairs & Policy, Europe, AstraZeneca*
- *Mia Bengtström, NTA Advisory Board, Pharma Industry Finland*
- *Kristine Kleivi Sahlberg, Head of Research and Innovation, Vestre Viken, Norway*
- *Kicka Lindroos, patient*

17.45 (EEST) Thank you for Day 1 and Welcome to the networking Event, *Mia Bengtström, Associate professor, Åbo Akademi University*

Networking Event
Hima & Sali, Kaapelitehdas, Tallberginkatu 1 C, 00180 Helsinki

PROGRAM 8.6. (09.00-16.00 EEST/08.00-15.00 CEST)

9.00-9.05 (EEST) Welcome to the Day 2, *Mia Bengtström, Associate professor, Åbo Akademi University*

Chair: *Olavi Kilkku, Director, Clinical Operations and Data Science, Orion Pharma R&D*

9.05-9.55 (EEST) Complex clinical trials

Innovation in Clinical Trials: What has been achieved with CCTs and key challenges that need addressing, *Chrissie Fletcher, VP Biostatistics GSK and Lead for Innovation in Clinical Trials Pillar, Clinical Research Expert Group, EFPIA* (virtual)

Regulators view on complex clinical trials, *Elina Asikanius, Biostatistician Fimea, Member of EMA methodology working party*

Pragmatic clinical trials

9.55-10.15 (EEST) Pragmatic clinical trials in vaccine evaluation, *Arto Palmu, Chief Research Officer, Vaccine Research Center Finvac Ltd*

10.20-10.40 (EEST) Pharma perspective on pragmatic trials, *Ola Vedin, Scouting & Innovation Lead, Clinical Development & Operations, Boehringer-Ingelheim*

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PROGRAM 8.6. (09.00-16.00 EEST/08.00-15.00 CEST)

Why choose the Nordic Region for research and trials? Examples of activities in the Nordic countries – ecosystems making the country competitive and role model for the other countries

Feasibility and recruiting tools

10.45-11.00 (EEST) Recruiting subjects to clinical studies fast with modern digital tools, *Petteri Kolehmainen, Managing Director, Healthware International*

11.00-11.15 (EEST) Beyond the Secure Processing Environment: The future of clinical trials and real-world studies, *Erkki Soini, CEO, ESiOR Oy*

11.15-11.30 (EEST) The Finnish Biobank – FinnGenious (TBC)

11.30-12.10 (EEST) Lunch

Chair: *Olavi Kilkku, Director, Clinical Operations and Data Science, Orion Pharma R&D*

Example of activities in the Nordic countries – ecosystems making the country competitive and role model for the other countries

12.10-12.30 (EEST) Trial Nation – A Part Of the Danish Clinical Research Ecosystem, *Marianne Pilgaard, CEO, Trial Nation* (virtual)

The effective use of data and digitalization

12.35-12.55 (EEST) Utilizing Finnish nationwide RWD to create an external control arm to a clinical trial, *Jussi Leinonen, Expert Clinical Data Scientist, Bayer*

13.00-13.30 (EEST) Leveraging technology for better clinical endpoints, Jelena Curcic, Senior Expert in Data Science, Novartis (virtual)

PROGRAM 8.6. (09.00-16.00 EEST/08.00-15.00 CEST)

Chair: *Anssi Linnankivi, Community Lead, Science & Data, Roche Oy*

Why choose the Nordic Region for research and trials? Company examples

13.35 (EEST) Advanced approaches for generating virtual control arms in oncology, *Heidi Loponen, Senior Scientific Consultant, MedEngine Oy*

13.50 (EEST) Virtual control arms – why and how? *Johanna Vikkula, Data Scientist, Medaffcon Oy*

14.05 (EEST) Turning RWD into RWE: External Control Arm for Label Expansion, *Kate Prior, BC Platforms* (virtual)

14.20-14.40 (EEST) Transcelerate, *Joachim Lövin, eTrials Senior System Supporter, NovoNordisk* (virtual)

14.45-15.00 (EEST) Inflames flagship – Collaboration opportunities for Pharma with Åbo Akademi University/Turku University researchers, *Timo Veromaa, Professor of Practice (Drug Development), University of Turku, Finland*

15.00-15.05 (EEST) Closing remarks, *Mia Bengtström, Associate professor, Åbo Akademi University*

15.05-16.00 (EEST) Networking Coffee and Exhibition on Site and Virtually

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