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Clinical Trials and Manufacturing Task Force

SME and Academia Clinical Trials Information System (CTIS) two-part training webinar

Speaker Bios

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Fergus Sweeney, PhD

Head of Clinical Studies and Manufacturing Task Force
European Medicines Agency, Netherlands

Fergus Sweeney is Head, Clinical Studies and Manufacturing Taskforce at the European Medicines Agency since March 2020, covering Clinical Studies (Clinical Trials Information System), Biological Health Threats and Vaccine Strategy and supports strategy development in manufacturing and personal data protection in health research on medicines. He joined the EMA Inspections Service in 1999 and became Head of Compliance and Inspections (2009) and Head of Division Inspections and Human Medicines Pharmacovigilance in 2013 (including Scientific Committee Services from 2016). He has a BA (Physiology 1979) a Dr de 3eme Cycle (cancer biology 1982), and PhD (Pharmacology 1986). Fergus worked in clinical research mainly in QA from 1982 to 1999.

Pieter Vankeerberghen

Head of Clinical Trials
European Medicines Agency, Netherlands

Pieter Vankeerberghen studied Industrial Pharmacy, obtained a Ph.D. in Pharmaceutical Sciences and holds a master's degree in Informatics. After working for 4 years in R&D, first in Clinical Data Management and later as project manager in human pharmacology, he joined the Belgian authorities in 2000. His roles in sequential order are: business process reengineering project leader, transition manager, followed by coordinating the agency's ICT projects and developments and holding a coordinating role in EU Human/Veterinary e-submissions. From 2016 to July 2020 he led the DG pré R&D department for clinical trials and unmet medical need. In this role he was a Member State Product Owner for the CTIS project. From August 2020 he is head of EMA clinical workstream and CTIS programme manager.

Laura Pioppo

Scientific Administrator, CTIS expert
European Medicines Agency, Netherlands

Laura qualified as pharmacist before joining the EMA in 2009 in the Compliance and Inspection Department where she was responsible for the coordination and follow up of GCP and Pharmacovigilance inspections requested by CHMP. Since 2017 she has been working on the development of the Clinical Trials Information system (CTIS), defining and testing the system functionalities in collaboration with the MS and sponsors product owners and the European Commission.

Fia Westerholm

CTIS Programme Assurance Manager, Change Management Lead
European Medicines Agency, Netherlands

Fia is the Programme Assurance Manager for the Clinical Trials Information System (CTIS) programme that is managed by the European Medicines Agency to enable application of the Clinical Trials Regulation (CTR). Responsibilities include also the lead in CTIS change management including MS and sponsor training programmes and communications for awareness to benefit the preparedness of stakeholders. She has education in veterinary medicine, toxicology and social sciences and holds more than 20+ years of experience in areas of research and development, assessment and regulation of medicines as well as management mostly at EU level but also at national level, encompassing both private and public sector.

Ana Rodriguez Sanchez Beato, PhD

CTIS Deputy Programme Manager/ CTIS Expert
European Medicines Agency, Netherlands

Ana Rodriguez qualified in Pharmacy in 1990 and received her PhD in molecular microbiology in 1995 at Universidad Complutense of Madrid. Since then she has been working in the clinical research field for several years, in the pharmaceutical industry first and then at EMA, after joining the Inspection Sector in September 2003. She became Head of the Clinical and Non-clinical Compliance Service in 2009, with her service involved in the implementation of the Clinical Trials Regulation (CTR) since its publication as well as in the development of CTIS, providing the business perspective. She moved to the Clinical Studies and Manufacturing Taskforce in March 2020, continuing here with her role as CTIS Deputy Programme Manager and CTIS Expert.

Barbara Zajec

CTIS Change Management Trainee
European Medicines Agency, Netherlands

Barbara Zajec joined the CTIS Change Management Team as a trainee in 2020. She is responsible for organising the SME and academia training stream and has been coordinating the CTIS SME and academia 2-part training webinar. She has recently graduated with a MSci from the University of Aberdeen and has a year of experience of working in the pharmaceutical industry in study management.

Stéphanie Kromar

Senior Regulatory Affairs Manager
European Organisation for Research and Treatment of Cancer (EORTC), Belgium

Stéphanie Kromar joined the EORTC in 2013. In 2014, she joined the Regulatory Affairs Department. As Senior Regulatory Affairs Manager, she is responsible for the preparation, submission and follow-up of Clinical Trials Applications from development until the end of trial. She has experience on VHP and recent pilot phases and provides regulatory advice. She is one of the Sponsor Product Owners under the new CTIS delivery model and has been involved in the implementation of the new clinical trials regulation from the firsts UATs till the recent on-site portal testing at EMA.

Andrea Seidel-Glaetzer, MA, RN

Head of Project Management and Member of the Executive Board
Coordination Centre For Clinical Trials Heidelberg (KKS), Germany

Prior to joining the University Hospital Heidelberg (KKS) 10 years ago, she gained some years' experience in the pharmaceutical industry. KKS acts with more than 80 staff members as a kind of CRO and provides services to support mainly investigator initiated clinical trials in academic institutions, but also for smaller industries. Since March 2020 Andrea joins EMA's Clinical Trials Information System testing as a representative of the academia on behalf of the German KKS-Network. This is an association of 26 clinical trial centres, all located at medical faculties and university hospitals with the common task to strengthen activities in clinical trials.

Kristof Bonnarens

Policy Officer - Pharmaceuticals, Directorate-General for Health and Food Safety
DG SANTE, European Commission, Belgium

Kristof is an industrial pharmacist. Being a Belgian national, he started working for the Belgian Federal Agency of Medicines and Health Products in 2005, and in 2009 he took up the responsibility for the Research and Development division, in charge of clinical trial applications. He was the Belgian member and secretary of the Clinical Trial Facilitation Group, and the Belgian representative in the European Commission's Clinical Trial Expert Group. He was also part of the negotiations of the Clinical Trial Regulation in 2013 and 2014. After a brief period working for the association of the Belgian pharmaceutical industry from 2016 onwards, he joined the EU Commission in 2019.

Edit Szepessy

Policy Officer - Pharmaceuticals, Directorate-General for Health and Food Safety
DG SANTE, European Commission, Belgium

Edit is a board-certified pathologist with a Ph.D. in cell and molecular biology. Before joining the European Commission in 2016, she worked as a postdoctoral fellow at the Diabetes Research Center of the Vrije Universiteit Brussel (VUB) and then as a translational research physician at the European Organisation for Research and Treatment of Cancer (EORTC). Edit joined the clinical trials team in DG SANTE in 2018, where she is responsible for the timely and adequate implementation of the Clinical Trials Regulation.

Agnès Mathieu-Mendes

Deputy Head of Unit – Medical products: quality, safety, innovation
DG SANTE, European Commission, Belgium

Agnès Mathieu-Mendes is deputy Head of the unit dealing with the quality, safety and innovation of medicinal products in the Directorate General on Health and food safety in the European Commission. Her responsibilities include the implementation of the Falsified Medicines Directive, the Clinical Trials Regulation, good manufacturing practices, good distribution practices and mutual recognition agreements on GMP with third countries. She has been working for many years in the pharmaceutical field such as in the authorisation process of medicinal products or orphan medicinal products.

Agnès Mathieu-Mendes joined the European Commission in 2006 to work on the Better Regulation agenda of the Directorate General for Enterprise and Industry. She is a pharmacist by training and has a diploma in pharmaceutical engineering and industrial technology. Prior to the European Commission, Agnès Mathieu-Mendes held a position in the pharmaceutical industry and in the Council of Europe.

Fátima Simões Sousa Pimentel

Senior Clinical Trials Manager/Coordinator
INFARMED, I.P., Portugal

Fátima Pimentel studied Industrial Pharmacy and obtained a pos-degree in Clinical trials Monitoring. Working in INFARMED since 2005 in the Clinical Trials Unit, her roles have been as a senior Clinical trials coordinator, especially in the VHP procedure, Coordinator for technical and regulatory support to Academic trials submissions, Participant in the Portuguese Regulatory and scientific advice for Clinical Trials discussions, Coordinator of the Portuguese national electronic platform for clinical trials submissions (RNEC). She is also a member of CTFG since 2008 and has joined the CTIS project almost since the beginning, having a role as a Member State Product Owner for the CTIS project, an expert for the EMA training team and a role as a Master Trainer for PT. She has been active in several communications and trainings related with Clinical trials submissions.

Ann Marie Janson Lang, MD, PhD,

Associate Professor, Co-Chair of CTFG, Clinical Trials Facilitation and Coordination Group
Swedish Medical Products Agency, Sweden

Ann Marie obtained her MD and PhD at the Karolinska Institute, Sweden. Dr Janson Lang started her own research group at the Dept of Neuroscience at the Karolinska Institute and was Principal Investigator for numerous Swedish and international research projects. Dr Janson Lang is inventor of two patents and co-founded the Swedish biotech company NeuroNova AB in 1998. Dr Janson Lang also worked as physician and investigator in clinical trials, served in the board of the Swedish Movement Disorder Society (SWEMODIS, Swedish associate of the international Movement Disorder Society) and was co-founder of the Swedish Parkinson's Disease Registry (SWEPAR).

In 2009 Dr Janson Lang was appointed Clinical Assessor and later was employed as Expert by the Swedish Medical Products Agency (MPA). She represents the Swedish MPA in the Expert group on Clinical Trials of the European Commission since 2011. Since 2012, Dr Janson Lang represents Sweden in the Clinical Trials Facilitation Group and was elected Co-Chair in 2018, re-elected in 2020. She is also a Member State Product Owner of the Clinical Trials Information System.