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Clinical Trials Information System (CTIS) - Demonstration for CTIS stakeholders

Virtual Event 20 January 2022

Speaker Bios

Fergus Sweeney

Head, Clinical Studies and Manufacturing Task Force

European Medicines Agency, Netherlands

Fergus Sweeney is Head, Clinical Studies and Manufacturing Taskforce at the European Medicines Agency. 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.

Xavier de Cuyper

Xavier De Cuyper is the CEO of FAMHP, the Belgian Federal Agency for Medicines and Health Products for 15 years and as such one of the experienced members of the Management Board. He is a strong entrepreneurship professional with a proven track of working in government administration. He is the mentor of Clinical Trials within the HMA (in the EU).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Kristof Bonnarens

Team leader, 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. Kristof 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. Kristof has worked on the CTIS project and has been closely involved in the CTIS governance, the independent audit and the Commission decision on full functionality.

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 Laura 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.

Melis Koyuncuogullari

Business Analyst

NTTData

Melis has 5 years of experience in IT consultancy and has been working in the CTIS project as a part of Business Analyst team for 2 years. She has been involved in the Analysis & Design of the many modules in the system and participated testing activities.

Olga Álvarez

Business Analyst Team lead

NTTData

Olga has 8 years of experience in IT consultancy sector, 6 of them working in IT product definition and delivery. She has been working in CTIS project for 3 years and a half, since NTTData took over, and during this period she has been participating in the definition of the solution from a functional point of view, Quality Assurance and coordination of the delivery and validation activities in preparation for the Go-Live.

Marianne Lunzer

Safety assessor

Agency for Health and Food Safety (AGES), Austria

Marianne is a Medical Doctor currently working as a safety assessor in the clinical trials department at AGES. She has been a CTFG alternate since 2017 and a CTIS MS PO since 2019. Marianne also served as pharmacovigilance assessor (2008-2017) and was an alternate member of the PRAC.

Ruediger Pankow

Principal Consultant | Regulatory Affairs

Parexel International GmbH, Germany

Ruediger is a Molecular Biologist by profession and Principal Consultant Regulatory Affairs at Parexel, where he has 14 years CRO experience in global clinical trials management and regulatory consulting. Representing ACRO for the EU Scientific and Regulatory Committee he has been continuously involved since 2016 in various European Medicines Agency stakeholder activities for the EU Clinical Trial Information System (CTIS) development, specifically since 2019 as sponsor product owner for the EMA CTIS delivery model and as CTIS expert for EMA CTIS training modules validation.

Ana Rodriguez Sanchez Beato

CTIS Deputy Programme Manager/CTIS Expert

European Medicines Agency, Netherlands

Ana holds a PhD in molecular microbiology in 1995. She has worked in the pharmaceutical industry and at EMA, joining the Inspection Sector in September 2003. Ana 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) and 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.

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 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 leading various projects. From 2016 he led their R&D department for clinical trials and unmet medical need. In this role he was a Member State Product Owner for the CTIS project. Since August 2020, he is head of EMA clinical workstream and CTIS programme manager.

Petri Paakkonen

Head of Human Medicines Information Management

European Medicines Agency, Netherlands

Petri Paakkonen is Head of Human Medicines Information Management. He joined the EMA Information Management in 2018 as Head of Project Assurance and Management, prior to joining the Agency Petri has held multiple position in Business and IT-development in the private sector and at the Finnish Medicines Agency. Currently Petri is also responsible for the IT delivery within the CTIS programme.

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). She leads on CTIS change management and this includes MS and sponsor training programmes and communications to benefit the preparedness of stakeholders. Her educational background is in veterinary medicine, toxicology and social sciences and her experience is from years at EU and national levels in research and development, assessment and regulation of medicines as well as management.

Steven Le Meur, EMA

Service Delivery Manager

European Medicines Agency, Netherlands

Steven worked as a clinical data manager in the pharmaceutical industry before joining the EMA where he was involved in data management, business intelligence and data analysis activities for the EudraVigilance system. He is now service delivery manager for the business intelligence platform.