19 January 2023
EMA/33990/2023
TDA

Speaker bios by session

Event name: CTIS Event on 20 January 2023: Readiness for Mandatory CTR use from 31 January 2023

Event date and time: 20 January 2023, 10:00 – 13:00

Chairs

Dr. Peter Arlett

Head Data Analytics and Methods Task Force
European Medicines Agency, Netherlands

Education: Medical Degree, University College London 1991; Member, Royal College of Physicians (MRCP) of London 1994; Fellow of the Faculty of Pharmaceutical Medicine (FFPM) of the Royal College of Physicians of London 2007; Fellow of the Royal College of Physicians of Edinburg 2017; Honorary Professor, London School of Hygiene and Tropic Medicine (2020). Career to date: Head of Pharmacovigilance and Epidemiology Department, EMA 2008 – 2020; Principal Administrator, Pharmaceuticals Unit, European Commission 2003-2008; UK MHRA 1996-2003; Hospital Physician, Oxford and London, UK NHS 1991-1996.

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 and CTCG chair. 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.

Opening remarks

Björn Eriksson, MD, PhD,

Director General

Swedish Medical Products Agency, MPA

Björn Eriksson serves as Director General of the Swedish Medical Products Agency, MPA, since 2021. He has served as a member of the management board of the MPA since 2018. Earned his medical degree with a specialty in Cardiology and a PhD in Cardiology and Clinical physiology from Karolinska Institute. He has held clinical and research positions at Karolinska University hospital (1996-2005) and he has been working with clinical research in the pharmaceutical industry (2005-2010).
Managerial experience includes being head of clinical departments in Östersund and at Akademiska University hospital in Uppsala. In 2013 he was appointed Regional County Director for Region Jämtland-Härjedalen and thereafter Hospital Director for Skåne University Hospital, Lund and Malmö. During the first year of SARS Covid-19 pandemic, he served as Health Care Director in Stockholm. In the EU regulatory network, he is a member of the EMA Management Board and a member of the HMA Management Group where he has special responsibilities- for clinical trials.

Ms Emer Cooke

Executive Director

European Medicines Agency, Netherlands

Emer Cooke is as of 16 November 2020 the new Executive Director of the European Medicines Agency, based in Amsterdam.
She also takes the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA).
She was the Director responsible for all medical product-related regulatory activities at the World Health Organization in Geneva between November 2016 and November 2020. In this role, Ms Cooke was responsible for leading WHO's global work on the regulation of health technologies (medicines, vaccines, diagnostics, vector control products and devices), coordinating the regulatory teams (Prequalification, Regulatory Systems Strengthening, and Safety), and working with member states and international partners to assure the quality, safety and efficacy of appropriate health technologies.
Ms Cooke is a pharmacist with Master's degrees in Science and Business Administration from Trinity College Dublin. She has over 30 years' of experience in international regulatory affairs and spent 14 years (2002 to 2016) in management positions at the European Medicines Agency as Head of Inspections and Head of International Affairs respectively. From September 1998 to July 2002, she worked in the Pharmaceuticals unit of the European Commission.

Session 1

Laura Pioppo

Scientific Administrator, CTIS expert

European Medicines Agency, Netherlands

Laura qualified as pharmacist and obtained a master degree in pharmacovigilance before joining the EMA Inspection Department where she was responsible for the coordination and follow up of GCP and Pharmacovigilance inspections. 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 and is now leading one of the CTIS workstream with focus on CTR implementation and transparency aspects, the involvement of caseworkers and also educating and guiding end users in the changed solutions.

Maria Elgaard Sørensen

Special Adviser and Project Manager
Team Manager in the Clinical Trials Unit
Danish Medicines Agency, Denmark

Maria Elgaard is a special adviser and project manager at the Danish Medicines Agency. Her educational background is MPharm and she has been working as an assessor of clinical trials application for several years. As of 2016, she has been increasingly engaged in the CTIS project currently as MSPO and master trainer Nationally she has been appointed as a business specialist in both the European and the Danish IT solutions for handling clinical trials and other national systems with interaction to the clinical trials area.

Responsibilities include implementation of new or adapted IT solutions used in the CT unit including analysing and improving business processes with the involvement of caseworkers and also educating and guiding end users in the changed solutions.

Karina Griffiths

Senior Director, Head, Clinical Trial Regulatory Operations & Co-implementation lead for EUCTR Pfizer

Leads a Global function that provides Strategic and Operational Expertise & Leadership across Clinical Trial Applications & Central Ethics submissions, facilitating the operational execution of the Global Regulatory core packages & In-Country Dossiers.

With over 20 Years of Pharma and CRO experience has built and led cross-functional teams, in Clinical Operations, Study Startup and Regulatory as well as implemented multiple global change management programmes partnering with internal and external experts in clinical trials.

Andrea Seidel-Glaetzer, MA, RN

Head of Project Management

Coordination Centre for Clinical Trials Heidelberg (KKS), Germany

Andrea joined the Coordination Centre for Clinical Trials at University Hospital Heidelberg (KKS) as a Project Manager more than 10 years ago. Before, she gained some years of experience in the pharmaceutical industry and a CRO.

The KKS acts as a kind of CRO and mainly supports investigator-initiated clinical trials in academic institutions and smaller industries. Since March 2020 Andrea joins EMA's Clinical Trials Information System testing as a representative of the academia on behalf of ECRIN.

Session 2

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.

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 positions 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.

Anna Herks Vitézová

Project Manager

European Medicines Agency, Netherlands

Anna Herks Vitézová started at the EMA in 2021 as project manager supporting Data Analytics and Methods Task Force. She is a pharmacist and holds a PhD in epidemiology. In the past she worked for clinical research organisations and on development of a medical software. Currently she is supporting CTIS team with project management activities and matters related to service desk user experience.

Noémie Manent

Principal Scientific Administrator

European Medicines Agency, Netherlands

Noémie Manent joined the European Medicines Agency EMA in March 2011 as a Principal Scientific Administrator in the Compliance and Inspection Sector. Today, she is a member of the Data Analytics and Methods Task Force and is leading the operation workstream for the Clinical Trial Information System (CTIS) enabling the application of the Clinical Trial Regulation.