14/06/2021
EMA/336518/2021
Clinical Trials and Manufacturing Task Force

Clinical Trials Information System (CTIS) July Info Event

Speaker Bios

Fergus Sweeney

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. 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 holds a Ph.D. in Pharmaceutical Sciences and a master's degree in Informatics. After working in R&D, he joined the Belgian authorities in 2000. There he worked as a business process reengineering project leader, transition manager, ICT projects and developments coordinator and held 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.

Sylvain Giraud

Head of Unit
DG SANTE, European Commission (EC), Belgium

Sylvain Giraud is the Head of Unit "Medical products: quality, safety and innovation" in the Directorate General for Health and Food Safety of the European Commission (DG SANTE). The unit is in charge of EU level policy developments on quality, availability and affordability of medicines and supervises important aspects of the implementation of EU legislation, the implementation of the Pharmaceutical Strategy for Europe and the coordination of international cooperation on medicines policy. In previous Head of Unit positions in DG SANTE in the last 10 years Sylvain has been dealing with Health Systems, global health and EU health policy coordination.

Ana Rodriguez Sanchez Beato, PhD

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

Ana Rodriguez 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. 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) 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.

Sarah Scales

CTIS Change Management Officer
European Medicines Agency, Netherlands

Sarah is a Change Management Officer for the Clinical Trials Information System (CTIS). She is responsible for communications planning, the CTIS user personas, and leading sponsor organisation modelling for CTIS from the EMA perspective. Sarah has previous experience in technology projects and change management from her time as a software product manager for an AI-based legal technology application. Prior to joining EMA, Sarah worked as a consultant on new technology projects for the European Commission and various EU agencies.

Maria Elgaard Sørensen

Special Adviser and Project Manager
Danish Medicines Ageny, Denmark

Maria Elgaard is a special adviser and project manager at the Danish Medicines Agency. 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 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 includes 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 to educate and guide end users in the changed solutions.

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. 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 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.

Trine Birgitte Moulvad

VP Regulatory, PV & Medical Writing Zealand Pharma A/S, Denmark

Trine Birgitte Moulvad is an experienced drug and drug-device developer and has been a leader in small, medium and large sized pharmaceutical companies. She is specialised within Regulatory Affairs and Patient Safety and has gained experience in the complex global regulatory environment in which organisations develop and obtain approvals for drug and drug-device combination products. She has a proven record of successful regulatory agency interactions and negotiations enabling efficient global drug approvals.

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, Andrea gained some years' experience in the pharmaceutical industry. KKS acts as a kind of CRO and supports mainly 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 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.

Rose-Marie Swallow

Senior Manager in EU Regulatory Policy & Intelligence, Bayer

Rose-Marie joined Bayer in July 2013 and is a Senior Manager in EU Regulatory Policy & Intelligence, with special responsibility for Clinical Trial Regulation implementation within the company. She represents Bayer on the EFPIA Clinical Research Expert Group. Rose-Marie came to Bayer with over 20 years EU regulatory experience in both the prescription and non-prescription healthcare sectors gained within a number of large research based Pharmaceutical Companies. She has also worked as a Senior Regulatory Consultant in a small CRO. Rose-Marie has a BSc in Chemistry and Biochemistry.