EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Data Publication (Policy 0070) re-launch - EMA webinar

16th May 2023
Virtual meeting

In line with the Final Programming Document 2023-2025 and as reported during the Management Board meeting in December 2022, the European Medicines Agency will gradually resume the Clinical Data Publication (Policy 0070) activities (beyond COVID-19 medicines) in September 2023.

The webinar will focus on the background and scope of the re-start, while also providing guidance for applicants and industry stakeholders, including small and medium-sized enterprises intending to submit clinical data for publication.

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Chaired by Anne-Sophie Henry-Eude (EMA)

15:15 Joining and technical checks

15:30 Welcome and opening speech

Welcome **5'**
Melanie Carr (EMA)

Introduction by the Chair **5'**
Anne-Sophie Henry-Eude (EMA)

15:40 Phased implementation of the Policy 0070

Step I - Scope and updates **15'**
Karen Quigley (EMA)

Timelines **10'**
David Fernandez Lopez (EMA)

Guidance and new Q&A document **10'**
Silvia Garrido-Lestache (EMA)

Anonymisation Report template **15'**
Radu Popescu (EMA)

16:30 Q&A

16:55 Closing remarks

Wrap up **5'**
Anne-Sophie Henry-Eude (EMA)

About the speakers

Melanie Carr

Head of the Stakeholders and Communication Division and a member of the Executive Board at the European Medicines Agency (EMA).

Melanie Carr joined EMA in 1996 and has held various roles in pharmacovigilance, the centralised procedure for marketing authorisation, orphan medicines, the SME office and corporate stakeholders department. In her current role she is responsible for stakeholder relations management, communication, and crisis management. She has a degree in Pharmacy from the University of Nottingham in the UK and worked as a regulatory professional in the pharmaceutical industry prior to joining EMA.

Anne-Sophie Henry-Eude

Head of Document Access and Publication Department at the European Medicines Agency (EMA).

Anne-Sophie Henry-Eude has a degree in pharmacy from the University of Lille in France and postgraduate degrees in Regulatory Affairs and in Pharmacovigilance & Pharmacoepidemiology. She worked in the pharmaceutical industry before joining EMA as product team leader for anti-infectives and later as paediatric coordinator in the HIV and vaccines field. In 2013 she put in place a Service to centralise activities linked to access to documents (Policy 0043) and later Clinical Data Publication (Policy 0070). Since 2021, she has been Head of the Document Access and Publication Department, which manages transparency activities at EMA.

Karen Quigley

Clinical Data Publication Specialist at the European Medicines Agency (EMA)

Karen Quigley has a degree in pharmacy from Trinity College Dublin and a postgraduate Masters in Science degree from the same university specialising in the field of controlled drug delivery and rheology. She subsequently obtained her PhD from the Faculty of Medicine, University of London. Karen joined the EMA 20 years ago and has worked in different areas including mutual recognition, scientific advice, veterinary medicines authorisation, availability of medicines and oncology. In 2016 she joined the Clinical Data Publication team working on Policy 0070. Prior to joining the Agency, she worked at the Council of Europe in Strasbourg and with the Health Products Regulatory Agency in Dublin.

David Fernández López

Clinical Data Publication Specialist at the European Medicines Agency (EMA)

David Fernández López joined the European Medicines Agency as a Clinical Data Publication Specialist in November 2021. He received his bachelor's degree in Neurobiology from the Complutense University of Madrid (Spain) in 2003 and his PhD in Pharmacology and Human Therapeutics from the same institution in 2009. He performed basic and translational academic research in Neuroscience and Pharmacology in several institutions in Europe and the United States for over ten years and worked as a Scientific Officer in the biotech start-up AptaTargets for two years. He then joined the Medical Affairs team at Novartis Pharma, where he spent 4 years (2017-2021) performing his duties as Medical Scientific Liaison and Medical Advisor in the Neuroscience Therapeutic Area.

Silvia Garrido-Lestache

Clinical Data Publication Specialist at the European Medicines Agency (EMA)

Silvia Garrido-Lestache is a Clinical Data Publication Specialist at the EMA. She started work in Glaxo Wellcome as clinical trial monitor before moving into international clinical development research as clinical research manager in GSK. Since joining EMA in 2002, she has fulfilled several positions, initially as project manager for centralised marketing authorisation applications in a wide range of therapeutic areas. Thereafter, she served as Access to Documents manager. She is a graduate in Biological Sciences from the University of Alcala de Henares, Madrid (Spain) and completed a MSc in Human Nutrition at Aberdeen University, Scotland (United Kingdom).

Radu Popescu

Clinical Data Publication Specialist at the European Medicines Agency (EMA)

Radu Popescu has been with the European Medicines Agency (EMA) for more than 12 years. Following the completion of his medical training he familiarised himself with clinical research. He worked in clinical operations for several CROs before joining the EMA. He held various scientific administrator positions within the EMA before deciding to join the Document Access and Publication Department. In his current role he utilises his multidisciplinary experience and knowledge in support of the EMA transparency activities.