Monique Al

Special advisor CCMO

Central Committee on Research Involving Human Subjects (CCMO)

Monique Al obtained her degree in Human Nutrition at Wageningen University & Research, The Netherlands. Subsequently she received a PhD in Human Biology in September 1994 at the Maastricht University. After that she worked for several nutritional and pharmaceutical companies in the field of clinical research. In 2001 she started as a scientific staff member at the Central Committee on Research Involving Human Subjects (CCMO) in The Netherlands. Currently she is an coordinating advisor specialized in clinical trials and clinical investigations at the CCMO.

Linda Abdelall

Policy Officer, DG Santé, European Commission

Linda Abdelall works on Clinical Trials at the European Commission, DG SANTE since April 2022. She coordinates the Clinical Trials Coordination and Advisory Group (CTAG) and the European Commission's Clinical Trial Expert Group (CTEG). She is a pharmacist by training and has a MSc degree in Governance and Leadership in European Public Health from Maastricht University.

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Associate Director, Global Regulatory Policy
Bristol Myers Squibb

Caroline is Associate Director in Global Regulatory Policy at Bristol Myers Squibb, based in Switzerland. She holds a Masters Degree in Political Sciences from Sciences Po Paris with a specialization in European Law. She has been working in the pharmaceutical industry for the past ten years. She has been working on preparing her organization and the industry in general for the implementation of the Clinical Trials Regulation since 2017. In particular, she has been leading the industry's efforts relevant to transitioning clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation since 2021, through cross-trade associations (representing big and small companies, commercial & academic sponsors) advocacy activities.

Scott Feiner

Senior Manager, Clinical Records Management, Strategic Clinical Operations
AbbVie

Scott has over a decade of experience with clinical trial disclosure, initially working for smaller sponsors as a one-person clinical trial disclosure department, to later operating in larger organizations, serving as an expert in summary results reporting and clinical document redaction/anonymization for public disclosure. As part of implementation planning for the EU Clinical Trials Regulation, Scott is AbbVie’s representative in the EMA CTIS sponsor master trainer programme.

Maria Elena García Méndez

Pharmacist, member of the Technical Secretariat of the Ethics Committee

Universitary Hospital La Paz

Elena García Méndez is a Pharmacist, with post-graduate courses for a PhD program in Microbiology and a Master's Degree in Clinical Bioethics. She has an extensive experience in clinical research with drugs and advanced therapies in different therapeutic areas and in all phases of clinical development. She worked for 30 years in the Clinical Research/Operations department of a multinational pharmaceutical company holding different positions with increasing responsibility (from CRA to Head of Clinical Operations). She joined the Technical Secretariat of the Ethics Committee for the Research with Medicinal Products of Universitary Hospital La Paz - Hospital Cantoblanco - Hospital Carlos III in March 2021.

Laura Lavin de Juan

Head of Service in the Clinical Trials Division

Spanish Agency of Medicines and Medical Devices (AEMPS)

Laura is a Clinical assessor in the Clinical Trials Division of the Spanish Agency for Medicines and Medical Devices since January 2021. During the last two years, her focus was primarily on facilitation of the implementation of the Clinical Trials Regulation (CTR) and the Clinical Trials Information System (CTIS) in Spain. Laura was appointed Master Trainer in Spain in November 2021, and manages everything related with the CTR and CTIS since then.

Marianne Lunzer

Assessor, Dept of Clinical Trials, Federal Office for Safety in Health Care

AGES

Marianne is a medical doctor by training and joined AGES in 2008 as a pharmacovigilance assessor. She was an alternate PRAC member between 2015 and 2017. In 2017, she joined the clinical trial unit at AGES as a safety assessor and has since been part of the Clinical Trials Facilitation and Coordination Group (CTFG) group. Since 2022 she is chairing the group now called Clinical trials coordination group (CTCG). Marianne contributed to the CTFG best practice guidelines for safety assessors for clinical trials and is a member of the drafting team for the Commission implementing regulation for the cooperation in safety assessment of clinical trials.

Noemie Manent

TDA-CTT Operations Workstream Lead

European Medicines Agency

Noémie Manent is the Operations Lead in the Clinical Trial Transformation team at the European Medicines Agency, facilitating change management for member states and sponsors with the implementation of the clinical trial Regulation. She has played an essential role in the set up of structured summary results for clinical trials. Also, she has experience in the coordination of inspections for marketing authorisation application. Noemie has more than 15 years experience working in clinical R&D for small and medium enterprises in industry and academia mainly in France and the United Kingdom.

Leonard van den Berg

University Medical Center Utrecht (UMC)

Leonard H. van den Berg is a professor of neurology who holds a chair in neurology focused on Motor Neuron Disorders at the University Medical Center Utrecht in the Netherlands.

He is founder and director of the Netherlands ALS Center,and chair of the European Network to Cure ALS (ENCALS), a network of the European ALS Centres, and of TRICALS, a European Trial Consortium.

As a practicing neurologist specializing in neuromuscular diseases, a major emphasis of his research has been in ALS and other motor neuron disorders, and he has been a principle investigator on numerous drug trials concerning treatment options for these diseases. He is author of over 650 peer reviewed publications.