EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies
Clinical Trials Facilitation and Coordination Group
CTFG

EC-DG SANTE/HMA-CTFG/EMA joint training on the Clinical Trials Regulation (EU) 536/2014
March 9-10, 2021

DAY 1 March 9				
Time	Title and summary	Speakers	Chapter in the Clinical Trials Regulation (EU)536/2014	Session chair
9:00-9:10	**Opening**	Pierre Delsaux (Deputy Director General, DG SANTE, European Commission)		

9:10-9:55	**General principles/new concepts (45')** *This presentation will focus on the general principles of the Clinical Trial Regulation, and the differences with the current system. Main topics to be covered: legal form, major differences with the Clinical Trial Directive, key concepts and roles, overview of the authorisation processes, entry into force, the interaction between the different clinical trials expert groups (CTFG, CTEG, CTAG).*	Kristof Bonnarens (European Commission, DG SANTE)		Kristof Bonnarens European Commission, DG SANTE
9:55-10:30	**Normal clinical practice, low-interventional trials, study vs trial, co-sponsorship, legal representative (30')**	Panel discussion: Kristof Bonnarens (European Commission, DG SANTE) Monique Al (Central Committee on Research Involving Human Subjects, CCMO, NL), Stefan Strasser (Austrian Agency for Health and Food Safety (AGES), Institute for Surveillance, AT), María Antonia Serrano Castro	Chapter I, Chapter XI	Kristof Bonnarens European Commission, DG SANTE

		(Spanish Agency of Medicines and Medical Devices, AEMPS, ES)		
10:30-11:00	**Q&A (25')**	As above		
COFFEE BREAK				
11:10-12:40	**Initial application: submission and assessment (60'+ 20' Q&A)** *This section will describe the flow of an initial application from a sponsor to a single or several Member State(-s) Concerned (MSCs) in EU/EEA and the concept of Reporting Member State (RMS) coordinating multinational Part I assessment.* *Alternative initial application submissions will be described – either full (Parts I&II) or partial (Part I only with later Part II) as well as trial expansion into additional MSCs. Background on the application dossier and workflow/timelines for assessing the trial benefit/risk and responsibilities/interaction between MSCs and the RMS will be presented.* *The decision on the trial is taking both Part I and Part II Conclusions into consideration. The authorisation may include conditions, and could in some situations be tacit. Details will also be provided on application resubmission, withdrawal and language requirements.*	Ann Marie Janson Lang (Swedish Medical Products Agency, SE) Greet Musch (Federal Agency for Medicines and Health Products, BE)	Chapters II, IV, annex I	Ann Marie Janson Lang Swedish Medical Products Agency, SE Greet Musch Federal Agency for Medicines and Health Products, BE
12:40-13:30	**LUNCHBREAK**			
13:30-14:50	**Aspects related to ethics (60'+20' Q&A)** *This session will focus on ethical aspects for the protection of subjects participating in clinical trials. Main topics that are covered are the informed consent procedure (general rules, minors, incapacitated subjects, cluster trials and clinical trials in an emergency situation), the assessment criteria for clinical trials in vulnerable subjects (the balance between benefit, risk*	Ethics Committee members, European Commission Clinical Trials Expert Group:	Chapters II (Art 10), V, Annex I, V	Monique Al Central Committee on Research Involving Human Subjects (CCMO, NL)

	and burden, group-relatedness, protection and justification) and the published templates for part II application.	Monique Al (Central Committee on Research Involving Human Subjects, CCMO, NL) Joerg Hasford (chairman, Working group of medical ethics commissions, DE), Katelijne Anciaux (Federal Public Service Health, CT-College, BE)		
14:50-15:00 **COFFEE BREAK**				
15:00-16:30	**Changes to trials (submission and classification) (60'+30')** *In compliance with the CTR, a change to a trial (data-field or document) in the Clinical Trials Portal and Database/CTIS is either (1) a substantial modification (formerly "amendment", art 2.2.13,* a change which likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated*); (2) a change that is not a substantial modification but relevant to the supervision of the trial (art 81.9) or (3) all other changes, which are considered as "non-substantial". The aim of this section is to provide clarification on the classification of the different changes and the different submission routes of these changes to the CTIS. Additional clarifications will be provided on when substantial modifications and Art 81.9 changes can be submitted in*	Edit Szepessy (European Commission, DG SANTE) Stefan Strasser (Austrian Agency for Health and Food Safety (AGES), Institute for Surveillance, AT)	Chapter III, Annex II	Edit Szepessy European Commission, DG SANTE

	different, typical scenarios (e.g. part I/II submissions in Art 5 or Art 11 trials or on an ongoing Art 14 or part II assessment process).	Lene Grejs Petersen (Danish Medicines Agency, DK)		
16:30-17:15	**Union controls (45')** *This session will focus on Union Controls in the Clinical Trials Regulation. An overview of the development of the Union Control process, including the fact-finding studies will be shared. This session will also include responses to questions raised.*	Maria Carlton and Sara Tavares (European Commission, DG SANTE)	Art 79	Maria Carlton European Commission, DG SANTE
17:15-17:30	**Wrap up**			

DAY 2 March 10				
9:00-10:20	**Safety reporting and assessment (60'+20' Q&A)** *The training session on 'Safety reporting and assessment' will introduce to the member states cooperation in safety assessment and relevant guidance documents as well as the planned Implementing Regulation on cooperation in safety. The principle of a safety assessing member state (saMS) will be presented as well as guidance on workshare procedures like annual safety report (ASR), suspected unexpected serious adverse reaction (SUSAR), safety-related notifications and information. In addition, information on requirements on reference safety information by CTR will be given.*	Elke Stahl (Federal Institute for Drugs and Medical Devices, BfArM, DE) Sandra Bright (Health Products Regulatory Authority, HPRA, IE) Elena Prokofyeva (Federal Agency for Medicines and	Chapter VII, Annex III	Elke Stahl Federal Institute for Drugs and Medical Devices, BfArM, DE

		Health Products, BE) Edit Szepessy (European Commission, DG SANTE)		
10:30- 11:30	**Member State preparedness and national aspects (30'+30' Q&A)** *The CTR provides very detailed definitions and processes for clinical trial authorisation and supervision. However, several aspects remain within the national remit of the Member States to regulate. These include not only the process for the single decision between National Competent Authority/ies and Ethics Committee(s), but also typical national aspects like fees, penalties, damage compensation and insurance. For most Member States this also concerns the technical aspects of interaction with the EU Clinical Trials Information System (CTIS) and integration in their current national IT system(s). This session will provide an overview over relevant national aspects, the readiness of Member States for the implementation of the CTR and examples of national solutions by different Member States.*	Member State National Competent Authorities and Ethics Committees from the Clinical Trials Expert Group and Clinical Trials Facilitation and Coordination Group: Stefan Strasser (Austrian Agency for Health and Food Safety (AGES), Institute for Surveillance, AT) Elke Stahl (Federal Institute for Drugs and Medical Devices BfArM, DE)		Stefan Strasser Austrian Agency for Health and Food Safety (AGES), Institute for Surveillance, AT

		Inki Pirjo (Finnish National Agency of Medicines, FIMEA, FI) Pierre-Henri Bertoye (French National Commission on Human Research, MoH, FR)		
COFFEE BREAK				
11:40-12:25	**GCP aspects (15')** **Manufacturing/importation and labelling (15')** *This session will provide an overview on GCP and GMP-related aspects under the Regulation (EU) No 536/2014 including the conduct of a clinical trial, the supervision by the sponsor, training and experience of individuals involved in conducting the clinical trial as well as the use of auxiliary medicinal products and will highlight differences to the current system(s).* Q&A 15'	Good Clinical Practice Working Group: Kim Pietsch (Paul-Ehrlich-Institut, PEI, DE) Quality assessor: Giulia Praticò (Italian Medicines Agency, AIFA, IT)	Chapter VIII and X Chapter IX, X Annex VI	Kim Pietsch Paul-Ehrlich-Institut, PEI, DE
12:25-13:20	**Transparency rules, publication (incl. deferral and publication of the assessment report, inspection reports, 35'+20')** *The session will provide a description of the transparency rules available in the secure and public domain of CTIS, to*	Laura Pioppo (European Medicines Agency)	Chapter XIV, Art 81(4) EMA Transparency annex	Laura Pioppo European Medicines Agency

	facilitate users' understanding of the implemented mechanism that will enable the publication of data and documents via CTIS.			
13:20-14:20	**LUNCHBREAK**			
14:20-15:20	**GDPR/CTR (DG SANTE 40', Q&A 20')** *Data protection aspects of clinical trials. Applicable legal framework and legal basis for processing of health data. Controller and its obligations. International transfers.*	Dalibor Vojta (European Commission, DG SANTE)	EDPB Q&A	Dalibor Vojta Data Protection Coordinator European Commission, DG SANTE
15:20-16:00	**MS Preparedness for the use of CTIS *(20'+20' Q&A)*** *This session intends to provide guidance on the need to identify the MS organizations that will use CTIS and the distribution of responsibilities among them for the assessment and supervision of CTAs as well as the CTIS users and related roles within each organization and the training required according to the users profile/needs.*	Ana Rodriguez (European Medicines Agency) Fátima Simoes, (National Authority of Medicines and Health Products, INFARMED, PT)	Chapter XIV, Art 81	Ana Rodriguez European Medicines Agency
16:00-16:10 **COFFEE BREAK**				
16:10-17:00	**Transition (30'+30' Q&A)** *This section explains transition measures with regards to trial authorisation, safety assessment and the voluntary harmonisation process (VHP)*	Agnès Mathieu-Mendes (European Commission, DG SANTE) Hartmut Krafft, (Paul Ehrlich Institut, DE) Elke Stahl,	Chapter XIX	Chair: Agnès Mathieu-Mendes European Commission, DG SANTE

		(BfArM DE)		
17:15-18:00	**Cooperation between MS and the European Commission (30'+30' Q&A)** *This section explains the role and interaction of the Clinical Trials Coordination and Advisory Group, Clinical Trials Expert Group, national contact points and the Clinical Trials Facilitation and Coordination Group, Heads of Medicines*	Agnès Mathieu-Mendes (European Commission, DG SANTE) Ann Marie Janson Lang (Swedish Medical Products Agency, SE)	Chapter XV	Agnès Mathieu-Mendes European Commission, DG SANTE
18:00-18:10	**Closing of the training**	Andrzej Jan Rys, Director, Directorate for Health systems, medical products and innovation, European Commission, DG SANTE		