Quality and Pre-clinical assessment of IMPs under ECTR.

Room:	**Jan Willem Schaapfoyer**
Time:	**Monday 11:00 to 12:30**
Chair(s):	**Joop van Gerven**
Organizing FIGON partner(s):	**CCMO**

The European Clinical Trial Regulation No 536/2014 (ECTR) will become effective on 31 January 2022. This will have a substantial impact on the procedural aspects in the applications and assessment of clinical trials in the Netherlands. The ECTR will lead to further international harmonisation. Multinational clinical trials will be assessed in cooperation with all concerned member states (MSc) and one MS in the lead (reporting MS). The assessment of protocol, IB and IMPD by the Medical Research Ethics Committee (MREC) and CCMO has to be laid down in an assessment report with focus on pre-clinical, quality, clinical and statistical aspects. Consequently, it is necessary to increase the awareness of the recommendations and requirements of relevant EMA and ICH guidelines for quality and risk identification and mitigation of Investigational Medicinal Products (IMPs) in clinical trials*.
In particular, for the approval of clinical trial protocols, a thorough assessment of the non-clinical part in risk analysis and study design is essential. This is particularly the case for First-in-Human studies (Phase 1 trials), but the relevance of the IB for study protocols for later phases also needs to be determined.
For the quality part, more emphasis is likely to be given on the active substance, and its manufacturing process and control, in line with European regulatory standards. Experts from the Medicines Evaluation Board (CBG) are involved on behalf of MRECs and CCMO in the assessment of selected IMPDs. Currently a similar approach is under investigation for the assessment of IBs. The aim is a better (international) alignment of assessments of the IMPD and the IB in clinical trials, with requirements for a further development toward a Marketing Authorisation Application, allowing a faster availability for patients.
CCMO, CBG and MREC BEBO will highlight some practical aspects of the CTR and relevant nonclinical and quality aspects for the investigators and assessors in order to get prepared for the ECTR.

* Scientific guidelines | European Medicines Agency (europa.eu)

Invited lectures:

11:00 – 11:15	**EU clinical trial regulation and CTIS – what you need to know.** *Dr. Monique Al – Head of National Clinical Trial Office, CCMO*
11:15 – 12.00	**Preclinical assessment of (early phase) trials from MREC and Regulatory viewpoints** *Prof. Dr. Frank Jansman, Clinical Pharmacologist, MREC BEBO and University Groningen* *Dr. Jan Willem van der Laan – Senior assessor pharmacology and toxicology, Medicines Evaluation Board, Chair Safety Working Party, EMA/CHMP*
12:00 – 12:30	**Quality Assessment of IMPDs under ECTR** *Dr. Bastiaan Nuijen, Hospital Pharmacist at CCMO and Antoni van Leeuwenhoek Hospital* *Dr. Martijn van der Plas, Senior Assessor Quality, Medicines Evaluation Board*

Indicated speaker time includes 5-10 minutes for discussion