Pre-Congress Symposium 1 (Radiopharmacy / Drug Development)
Saturday, October 13, 09:00-12:00

Session Title
Clinical Trial Regulations

Chairpersons
Clemens Decristoforo (Innsbruck)
Johnny Vercouillie (Tours)

Programme

09:00 - 09:25	Gregor Benedikt Ottawa (Heidelberg): Clinical Trials and GCP
09:25 - 09:50	Iván Peñuelas (Pamplona): Requirements for Radiopharmaceuticals as IMPS in Clinical Trials
09:50 - 10:15	Clemens Decristoforo (Innsbruck): Radiopharmaceuticals and Clinical Trials in Europe: Chances and Challenges
10:15 - 10:45	**Coffee Break**
10:45 - 11:05	Claudio Rossetti (Milan): Regulation of Radiopharmaceutical Preparations for Clinical Trials in EU Countries
11:05 - 11:25	Daniëlle Vugts (Amsterdam): Clinical Trials with Radiopharmaceuticals in Collaboration with Pharma Industry
11:25 - 11:45	Henrike Bergmann (Dresden): Implications of the Updated Clinical Trial Regulation (EU Reg 536/2014) for the Research on Radiopharmaceuticals in a CRO Setting
11:45 - 12:00	Discussion

Educational Objectives
1. General information on clinical trials and GCP
2. Contents of EU regulation 536/2014: what will change?
3. GMP requirements for radiopharmaceuticals today and in the future
4. Interpretation of the Reg. in the different EU member states

Summary
The EU regulation 536/2014 will probably be applicable from 2019 on after successful launch of the EU IT portal. This Pre-Congress symposium will address the implications of the regulation on clinical trials in the field of Nuclear Medicine not only in an academic setting but as well in cooperation with pharma industry and clinical research organizations.
Moreover the interpretation of the regulation in the different member states of the EU will be covered.

Key Words
Clinical trial regulation, GMP, Investigational medicinal product, legislation, radiopharmaceuticals