CME 8 (Radionuclide Therapy/Radiopharmacy/Dosimetry)
Monday, October 23, 16:30-18:00

Session Title
Clinical Trial Design for Radionuclide Therapy

Chairs
Clemens Decristoforo (Innsbruck)
Jonathan Gear (London)

Programme

16:30 - 17:00 Andreas Kluge (Dresden): General Aspects of Clinical Trial Design

17:00 - 17:30 Clemens Decristoforo (Innsbruck): Regulatory Affairs in Radiopharmacy

17:30 - 18:00 Rebecca Gregory (London): Dosimetry for Clinical Trials

Educational Objectives
1. Learn how to design a clinical trial in radionuclide therapy and understand the different phases of clinical trials.
2. Acknowledge how to choose primary and secondary end points with regard to the trial design.
3. Acknowledge that there is the possibility of phase 0 studies in radionuclide therapy.
4. Get familiar with specific regulatory aspects in radiopharmacy.
5. Acknowledge that in radionuclide therapy we have the possibility to perform dosimetry which will influence the trial design and which has the potential to foresee or to prevent toxicity.

Summary
Radionuclide therapy is a very dynamic field. Numerous new radiopharmaceuticals are about to enter the field. In order to prove the effectiveness of new radiopharmaceuticals and in order to get a compound registered specific clinical trials are needed. Basically they can be conducted in an analogous manner as e.g in chemotherapy. However the unique properties of radiopharmaceuticals allow to perform dosimetry which in turn allows us to conduce phase 0 trials. Additionally dosimetry can help to foresee and avoid toxicity. With regard to regulatory affairs radiopharmaceutical feature some particularities as well which will be highlighted in this session.

Key Words
Radionuclide therapy, clinical trial design, radiopharmacy, dosimetry