

Session No	Day 1	min
1	Introduction & Refresh of regulatory requirements for performing clinical studies with radiopharmaceutical with special focus on diagnostic radiopharmaceuticals & Particularities of first-in-human and phase II studies with radiopharmaceuticals	20
2	Ethical & medical considerations for first-in-human and phase II studies with radiopharmaceutical	20
3	Ethical & medical considerations for first-in-human and phase II studies with radiopharmaceutical in vulnerable populations	20
4	Preparing the protocol for first-in-human and phase II studies with radiopharmaceutical (template, mandatory requirements...) Patient information and informed consent: mandatory requirements	20
5	Objectives, endpoints and outcome measures of first-in-human phase studies with radiopharmaceuticals & Practical examples (Patient selection & inclusion/non-inclusion criteria) practical examples)	20
6	Objectives, endpoints and outcome measures of phase II studies with radiopharmaceuticals & Practical examples (+Patient selection & inclusion/non-inclusion criteria)	20
7	Standard of truth, Comparator, superiority/non-inferiority/equivalence(?) studies) & practical examples, Randomisation?	20
8	Q&A / online quiz	20
9	Wrap-up of Day 1	5

	Day 2	min
10	Administration of investigational medicinal product & its posology, duration of participation in the study	20
11	Performing first-in-human study, data collection & analysis, reporting results, including practical examples	20
12	Performing phase II study, data collection & analysis, reporting results, including practical examples	20
13	Assessment of safety in first-in-human and phase II study	20
14	Statistical considerations phase I/II and phase II studies with radiopharmaceuticals	
15	Estimation of number of subjects to be enrolled and reason for choice of sample size	20
16	identification of typical clinical situations of phase II studies and choice of optimal statistical method to test established hypothesis (superiority/non-inferiority/equivalence(?) studies, predictive value, other?)examples with real? Hypothetical? Tracers?	20 +20
17	Q&A / online quiz	20
18	Wrap-up of the day 1&2	10