Education CTU-EOC

Planning and Conducting Biomedical Research

Monday 7 and 14 November 2022

Room A1.03 Campus Est USI, Lugano
From 9 AM to 5 PM

The new course "planning and conducting biomedical research", which is part of the PhD program, wants to offer a comprehensive discussion of the aims, activities and methodological aspects (including statistical principles and applications) of biomedical research, from the preclinical to the advanced clinical development stage in different pathological entities. The last section deals with the special issues faced by preclinical and clinical researchers working in the field of rare disease. A more detailed description of aims and content can be found in the syllabus. The course is the first one in this field, and is of interest for researchers, clinical scientists and clinical investigators in the translational field to understand their role and input for a mutual productive interaction.

Teachers:

Dr. Valter **Torri**, Lab. Metodologia per la Ricerca Clinica, Mario Negri Milano
Prof. Cristiana **Sessa**, IOSI Bellinzona

Objectives:

To understand the statistical and methodological concepts to help in planning and implementing preclinical and clinical research and to interpret their findings. The course will include practical examples and case discussion, mainly in the field of oncology and neurosciences relevant for the clinical counterpart of some of the participants.

PART 1 – MONDAY 7 NOVEMBER 2022			
TIME	**TITLES**	**CONTENT**	
9h00-9h30	**Introduction to the course**		V. Torri C. Sessa
9h30-10h45	**Preclinical phase, principles of methodology**	• Objectives and pathways • What is a preclinical model? *In silico*, *in vitro* and *in vivo* models. Models in systems biology • Preclinical endpoints	V. Torri
10h45-11h00	**BREAK**		
11h00-12h30	**Statistical principles for experimental design**	• Methodological issues • Designs of preclinical experiments • Statistical inference, basic concepts	V. Torri
12h30-13h30	**LUNCH**		
13h30-15h15	**Clinical phase, methodology of early development**	• First in human, dose finding studies. Relationships between dose, safety and activity of an experimental compound	C. Sessa
15h15-15h30	**BREAK**		
15h30-16h30	**Clinical phase, methodology of early development**	• Presentation and discussion of articles of early development study in cancer, cardiovascular and neuroscience diseases	V. Torri C. Sessa

PART 2 – MONDAY 14 NOVEMBER 2022			
TIME	**TITLES**	**CONTENT**	
9h00-10h45	**Clinical phase, methodology of middle development**	• Objectives and endpoints in phase II studies • Review of actual and future biomarkers for phase II trials • Discussion and examples	V. Torri C. Sessa
10h45-11h00	**BREAK**		
11h00-12h30	**Methodology of translational research**	• Statistical challenges in the analysis of biological data • Multiple comparisons issues • High dimensionality • Clustering • Resampling methods	V. Torri
12h30-13h30	**LUNCH**		
13h30-15h15	**Clinical phase, methodology of advanced development**	• Phase III trials • Clinical endpoints, choosing the right summary, adaptive designs, statistical monitoring • Surrogate endpoints • Statistical methods for multiple endpoints	V. Torri C. Sessa
15h15-15h30	**BREAK**		
15h30-16h30	**Clinical phase, methodology of rare diseases**	• Rare diseases, definition • Useful statistical designs for small trials • Useful statistics for small trials	V. Torri