Education CTU-EOC

Monday, May 9th, 2021
Room A2.08 Campus EST USI
From 08:30 AM to 16:00 PM

Teachers:

Dr. Pietro **Gervasoni**, Managing Director of swissethics
Prof. Silvio **Garattini**, President and Founder of Mario Negri Institute, Milan
Cordula **Landgraf**, PharmD, SCTO Director Communications & Stakeholder Engagement, Swiss Clinical Trial Organisation (SCTO)
Dr. Valter **Torri**, Head of Laboratory, Mario Negri Institute, Milan
Dr. Rita **Banzi,** Center for Health Regulatory Policies, Mario Negri Institute, Milan

PROGRAM

Ethical Issues

The increasing knowledge in molecular biology and the development of the techniques for the evaluation of the biological processes and of their interaction have brought about, in preclinical and clinical research, what is called precision medicine, to select the treatment that works best for an individual.

The development of new therapeutic approaches raises many ethical issues, of which investigators' also and in particular at the preclinical level, should be aware of and take into consideration in their decisions and activities.

The objectives of this course are to increase this awareness of the ethical issues and of their potential impact in the selection and preclinical evaluation of new molecules, in the decision making process, in the care of patients and in the social environment.

In particular,

- in the planning and modalities of activation of clinical studies;
- in the selection of treatment, relationship and care of patients;
- in the collection of data and biological tissues;
- in the analysis, report, publication and sharing of data and results;
- in the active involvement of patients already at the beginning of the clinical project;
- in the registration, selling and marketing of therapeutic compounds in Europe.

ETHICAL ISSUES PROGRAM –May 25th, 2021

TIME	TITLE	CONTENT	TEACHER
8h30-8h45 15'	**Welcome and Introduction**		*Prof. Dr. med. Dr phil. med. Alain Kaelin*
8h45-10h15 1h30'	**Ethics in human research**	1. Basic: Ethics and law Ethical principles Ethical committees Ethical requirements 2. Consent: Informed consent General consent Comprehensibility Biobanks 3. Current challenges Data sharing Digitalisation Genetics Personalised medicine Artificial intelligence	*Dr. Pietro Gervasoni*
10h15-11h00 45'	**Ethical issues in preclinical research (including animal experiments)**	1. Animal experiments are necessary before any new chemical entities will be administered to humans. 2. Ethical issues include the three R: reduction, refinement and replacement. 3. The legislation should support animal experiments.	*Prof. Silvio Garattini*
11h00-11h15	COFFEE BREAK		
11h15-12h00 45'	**Ethical issues in controlled clinical trials**	1. There is a need of comparative studies when more than one drug or vaccine is available. 2. Drugs or vaccines must be compared with the best treatment available. 3. Vaccination should be extended to all Countries.	*Prof. Silvio Garattini*
12h00-12h45 45'	**The ethics of patient and public involvement (PPI) in academic clinical research**	1. The concept of PPI 2. Ethical considerations why patients and the public should be involved in academic clinical research 3. Ethical principles in the performance of PPI	*Mrs. Cordula Landgraf*
12h45-13h45	LUNCH BREAK		
13h45-14h30 45'	**Ethical issues in the statistical analysis of clinical trials**	Ethical implications of statistical planning and analysis in clinical experimentation, Focus on 1. key statistical aspects of design (randomization, choice of control group, use of placebo, type of comparison) 2. Statistical analysis (interim analysis, multiple tests, reporting of results).	*Dr. Valter Torri*
14h30-15h15 45'	**Ethical issues in drug approval and marketing at the European level**	Overview of the role and responsibilities of the European Medicines Agency Ethical aspects in drug development and assessment (i.e., issues in pivotal trials and evaluation criteria) Ethical issues and accountability (i.e., financing, transparency and data sharing, communication and engagement with the public)	*Dr. Rita Banzi*
15h15-15h30 15'	**General discussion with all participants**		*All*
15h30-16h00 30'	**Summary**		*All*