safescimet course 5.1 - Clinical Safety: Pre-Approval

Key Questions Addressed

- Clinical safety: Pre-Approval
- Integrated and translational drug safety
- Signal detection and biomarkers
- Clinical safety with organ focus on: immune system, liver, kidney, lung, cardiovascular, vascular system, neurotoxicity
- Clinical trials methodology and safety issues
- Integrated safety management planning
- Risk benefit assessment, stratification and management
- Risk evaluation, mitigation strategiesle

Feedback from the Previous Course

“The course setup provided a good balance between theory and practical exercises.”

“The number of participants was just right to allow a sufficient amount of time for discussions with the lecturers and among participants.”

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To contact us or to register to our courses visit safescimet@uni-konstanz.de or http://ssm.afww.uni-konstanz.de/safescimetcourses

safescimet is currently supported by Hoffmann-La Roche & Sanofi & Bayer Healthcare AG & Department Human and Environmental Toxicology at the University of Konstanz

About safescimet

safescimet is a unique pan-European network of academia and pharmaceutical industry, which have joined forces to establish a comprehensive modular education and training in Safety Sciences for medicines. The programme covers all aspects of safety in drug development, in order to fulfill the needs of drug safety scientists in the pharmaceutical industry, regulatory authorities and academia. The aim of the programme is to bridge crucial gaps in the education and training of scientists evaluating the safety of drug candidates and new medicines and to ensure that European drug safety scientists are at the forefront of their field.

The course Clinical Safety: Pre-Approval and the other single courses of the safescimet programme provide new opportunities for Continuous Professional Development (CPD) and are part of European Master for Advanced Safety Sciences for Medicines degree at the University of Konstanz. The individual courses are clustered within five separate domains. Each domain deals with one or more specialised topics and contains from two to six single courses. Please visit www.safescimet.eu for details of the full course programme and confirmation of course dates.

Course Objectives

The clinical phase during drug development requires translation of safety information from previous pre-clinical trials of the new compound. Signal detection depends on the understanding of mechanisms of action, preclinical safety findings including histopathology and the monitoring of applicable baseline biomarkers. The translation of animal findings regarding toxicity levels and target organs to human has to ensure a safe First Dose in Man where appropriate risk mitigation strategies play major roles. Therefore the aim of this course is to introduce the principles of translational safety as a tool to bridge preclinical and clinical safety assessments as well as safety management throughout the clinical phase of drug development. Lecturers and students will discuss the strengths and limits of these approaches and will have insight into the overall strategy of clinical safety evaluation prior to drug approval. Case studies from the development of successful new drugs as well as from discontinued compounds are used to illustrate the process of developing safe medicines. Also regulatory requirements from the major target markets are presented and discussed. Upon completion of the course the students will have an overall understanding of integrated drug safety activities, how to approach safety margins during translation from animal to man and the benefit / risk assessment methodology used during drug development.

Key Subjects Covered by the Course

- Integrated and translational drug safety
- Signal detection and biomarkers
- Clinical safety with organ focus on: immune system, liver, kidney, lung, cardiovascular, vascular system, neurotoxicity
- Clinical trials methodology and safety issues
- Integrated safety management planning
- Risk benefit assessment, stratification and management
- Risk evaluation, mitigation strategies

Target Audience

safescimet courses are open to all scientists and students from industry, academia and regulatory authorities, who need a broad comprehensive understanding of the drug development process with particular emphasis on safety. The applicant will normally possess an MSc degree in a Life Science discipline or equivalent. In addition, applicants are expected to have an at least one year working experience in a related discipline.

Why Join the Course

The on-site training of the course consists of four days with lectures, practical exercises, group work and discussions. This setup offers an intense and broad training with leading experts in their field and ample opportunities for lecturer-student interactions. The balance of academic, industry and regulatory teachers provides knowledge directly available to drug safety assessment, including dataset discussions from real case studies.

Learning Outcomes

On successful completion of the course, participants should understand the concepts of clinical safety evaluation prior to drug approval. They should be able to interpret the basic pathways for toxicity in a broader context. More specifically, participants will be able to

- understand integrated drug development and, in parallel, integrated drug safety evaluation
- know and understand translational organ toxicity from animal to man
- appreciate the safety concern in the context with the benefi
- know and understand the prediction and detection of adverse effects during clinical drug development

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- know and understand risk assessment methodology
- apply a risk evaluation and mitigation strategy

Course Programme

The first week of the course consists of four days lectures, practical exercises, group work and discussions, provided by specialists from academia, pharmaceutical industry and regulatory authorities with diverse backgrounds on drug safety aspects.

On-site Training

Day 1	Introduction; Minimal pre-clinical safety package; Extrapolation of animal findings to human ; PK/PD modelling; Signal detection (QT prolongation)
Day 2	Phase 1 trials: First Dose in Man; Dose escalation; DDI and Impact on sub population; TQT study; Integrated cardiac safety
Day 3	Concept of clinical safety pre-approval; signal prediction and detection; integrated safety management plan; integrate safety summary; HAs approaches to submissions; risk management plans; causality assessment
Day 4	Epidemiology, comparative benefit risks, statistics

Individual Home Assignments

After the week of on-site training, students will receive an individual 38 hours home assignment consisting of written questions and a case study. These individual assignments are to be completed through a frequent exchange with the SafeSciMET teachers using distance learning approach. Written individual assignments are to be completed and submitted via Moodle within 6 weeks after the on-site training and will then be approved by the course leader.

Course Credits

Participants attending the on-site training week only, without completing the exam and/or the home assignment, will be given a certificate of attendance confirming completion of a Continuing Professional Development (CPD) course.

In order to receive the full 3 ECTS credits for a successfully completed course, participants need to pass the written exam of the on-site training week as well as to have successfully completed the home assignment.

Syllabus

The syllabus contains lecture hand outs, list of abbreviations and list of reading materials and will be provided by the course leaders 14 days prior to the course. The information and the material for the individual home assignment will be provided during the first week of the course.

Assessment

The assessment is based on a 2-hour written examination on the last day of the first course week and on the evaluation of the home assignment.

Type	- The purpose of the examination is to test that the examinee has aquired a broad knowledge and comprehension of the course subjects during the lectures. - The percentage of items on the test devoted to a particular topic will roughly correspond to the emphasis given on the topic during the course. - Experimental Design: 5% - Pre-clinical: 5% - Clinical: 40% - Translational: 50%
Assessors	Course leaders
Exam aids	All written exam aids are allowed, especially the provided material: lecture hand outs, list of abbreviations and case studies.

Contact Person

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Course Leaders

Prof. Daniel Dietrich - Professor of Human and Environmental Toxicology, Faculty of Biology, University of Konstanz
Dr Lucette Doessegger - Consultant, Formerly F. Hoffmann-La Roche Ltd, Pharma Division, Basel, Switzerland

Practical Information

Course credits	3 ECTS credits
Level	Master's level (second cycle higher education)
Location	Messeturm Bau 657, Messeplatz 10, 4058 Basel Switzerland
Teaching methods	Lectures, case reports, demonstrations and home assignments.
Student workload	- Preparation: 12 hours - Course: 38 hours - Assignment: 38 hours - Examination: 2 hours - Total: 90 hours
Course fee	Please visit on www.safescimet.eu **Fees** and **How to apply** for more information.
Course capacity	20 participants
Language	- The official language of the course is English. - No simultaneous translations will be provided.
Course notes	Complete course notes, except for the textbook, will be available for all the participants.
Course accreditation	- safescimet courses meet the criteria for Continuous Professional Development (CPD) diplomas, and are part of Master programme Advanced Safety for Medicines. - When registering for one or several "Stand Alone"courses of our programme, this course provides CPD credits for your individual CPD portfolio. Each course is credited with 38 contact hours. - The course setup is already consistent with the requirements of the Bologna process. Tha full Master programme is undergoing evaluation for being accredited and certified as a regular postgraduate MSc degree at the University of Constance/Germany.

Accommodation

Hotel rooms can be arranged individually and on own expenses. Hotel reccomendations have been named as reccomendations have been named as: Swissotel Le Plaza (Messeplatz 25, 4005 Basel, +41 (0)61 555 33 33, www.swissotel.com/hotels/basel), Hotel Nomad (Brunngässlein 8, 4052 Basel, +41 (0)61 690 91 60, www.nomad.ch).

Transport

The course will take place in F. Hoffmann-La Roche, Ltd, Main Campus, Panorama Building 67, Grenzacherstrasse 124, Basel, Switzerland, easily accessible by bus from Basel SBB Railway Station or Basel German Railway Station. Bus transportation is also available from airport.

Registration

To apply please visit www.safescimet.eu. Your application needs your registration on www.safescimet.eu.

Cancellation

For our cancellation policy please visit **How to Apply/Terms and Conditions** on www.safescimet.eu.