



## Course 6.3 Stratification: Pharmacogenetics and drug safety

27 – 31 August 2012

Section of Pharmacogenetics, Dept. Physiology and Pharmacology  
Karolinska Institutet, Stockholm, Sweden

3 – 7 September 2012

Home Assignment (Case Studies and Course questions)

## Pharmacogenetics and Drug Safety Course:

Key questions to be tackled by the course

- ⌚ Drug metabolizing enzymes and drug transporters – important genetic polymorphisms
- ⌚ Whole genome scan strategy and technology
- ⌚ Pharmacogenomics in important therapy areas
- ⌚ Variation in the HLA locus and the functional consequences related to adverse drug reactions
- ⌚ Epigenetics of drug response and adverse drug reactions
- ⌚ Pharmacogenomic biomarkers for prediction of adverse drug reactions
- ⌚ Pharmacogenetics in drug development
- ⌚ Pharmacogenomics in post marketing surveillance
- ⌚ Establishment of biobanks
- ⌚ Ethical issues in pharmacogenetics
- ⌚ Personalized medicine, vision for the future

## Introduction

Pharmacogenetics is rapidly growing partly as a result of the very rapid development in techniques for studies of the human genome and genome function. The aim is e.g. to find pharmacogenomic biomarkers which can predict drug response and drug toxicity. In addition, drugs aimed for genetically defined populations have become a reality.

## Why join the course in “Pharmacogenetics and drug safety”?

Knowledge about drug action requires information about the involvement of polymorphic genes encoding e.g. drug metabolising enzymes, drug transporters, drug targets and human leukocyte antigens. Pharmacogenetics is now an integrated part in drug development. Already today we know about specific genomic biomarkers that effectively predict ADRs and this development is expected to continue in the future. The regulatory agencies now require pharmacogenomic aspects to be integrated into all different phases of drug development. Pharmacogenetic knowledge can also help to identify novel drug targets as well as to understand the bases for interindividual variation in drug response. IN addition, there are examples where drugs have been rescued based on novel pharmacogenetic information.

## Course Objectives

This course will provide participants with an overview of the current knowledge in pharmacogenetics with functional importance for adverse drug reactions. This involves the basics of genomics as well as methods for optimal use of pharmacogenetic information.

### *Key areas covered by this course*

- *Human genome and web accessible databases*
- *Methods to identify mutations and to study their functionality*
- *Clinical important genetic polymorphism of drug metabolizing enzymes*
- *Clinical important genetic polymorphism of drug transporters*
- *Pharmacogenetics of importance for therapy of different types of diseases*
- *Association between certain HLA alleles and adverse drug reactions*
- *Useful pharmacogenomic biomarkers for prediction of adverse reactions*
- *Regulatory guidelines for pharmacogenetics in drug development*
- *Ethical issues in pharmacogenetics and the use of material from biobanks*
- *Personalized medicine in the future*

## Target Group

SafeSciMET students, academics and workers in the pharmaceutical industry and regulatory authorities who need a broad comprehensive understanding of the drug development process with particular emphasis on safety.

## Learning outcomes

On successful completion of the course, participants should have a good understanding for the mechanisms behind associations between pharmacogenetics and risk for adverse drug reactions and also be familiar with technology for studying these types of associations.

More specifically, participants will be able to:

- To be aware of technology and methods for identifying mutations and for assessing functional consequences of mutations
- Know and understand how genetic polymorphisms of drug metabolizing enzymes and drug transporters can be associated with increased risk of adverse drug reactions
- Be able to relate to important examples of useful pharmacogenetic biomarkers for prediction of adverse drug reactions
- Know and understand the regulatory guidelines for pharmacogenetics in drug development
- Be aware of ethical issues in pharmacogenetics
- Properly apply knowledge in the field of pharmacogenetics for future personalized medicine



# Course Programme

## The Syllabus

A syllabus containing an introductory chapter, lecture hand outs, list of abbreviations, definitions and reading materials will be provided by the course leader 14 days prior to the course. The material for the 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 course and on the evaluation of the home assessment

**Type** The purpose of the examination is to test that the examinee has a broad knowledge and comprehension of the drug development process as a whole. The percentage of items on the test devoted to a particular topic will roughly correspond to the emphasis given the topic in teaching of the course:  
Experimental Design: 5%  
Pre-clinical : 55%  
Clinical : 25%  
Translational : 15%

**Assessors(s)** Course Directors

**Exam aids** All written exam aids are allowed.

**Course administrator:** Inger Johansson, Dr.  
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# Practical Information

**Course Credits:** 3 ECTS credits  
**Level:** Master's level (second cycle higher education)  
**Course Dates:** 27 – 31 August 2012  
**Location:** Dept of Physiology and Pharmacology  
Nanna Svartz väg 2  
Karolinska Institutet  
SE-171 77 Stockholm, Sweden

**Teaching methods:** Lectures, case workgroup discussions, presentations and discussions. In order to emphasize the flow of the process, the course is to a large extent based on the use of cases in both lectures and assignments.

**Student Workload:** Preparation: 15 hours  
Course: 38 hours  
Assignment: 45  
Examination: 2 hours  
Total: 90

**Course Fee:** 2,500 Euro—750 Euro (dependant on category of student) (please visit [www.SafeSciMET.eu](http://www.SafeSciMET.eu). **How to apply for more information**)

**Application deadline:** **June 15<sup>th</sup> 2012**

**Course Capacity:** 36

**Language:** The official language of the course is English. No simultaneous translations will be provided

**Course notes:** Complete course notes will be available for all the participants.

**Course accreditation:** The course meets the criteria for continuous professional Development (CPD) diplomas, and it will be part of a (forthcoming European) Masters of advanced Safety Sciences degree.  
More information can be obtained through our website: <http://www.SafeSciMET.eu>

## Course Leaders

Magnus Ingelman- Sundberg, Professor  
Section of Pharmacogenetics, Department of Physiology and  
Pharmacology, Karolinska Institutet, SE-171 77 Stockholm, Sweden

Barry C. Jones, Dr.  
Pfizer Global Resaerch & Development, Sandwich Laboratories  
Phizer Limited, Sandwich, Kent CT13 9NJ, UK

### Lecturers (tentative list)

Tommy B. Andersson, Prof.	AstraZeneca, Sweden
Magnus Ingelman-Sundberg, Prof	Karolinska Institutet, Sweden
Inger Johansson, Dr.	Karolinska Institutet, Sweden
Geoff Johnston	Pfizer Global Research, UK
Barry C Jones, Dr.	Pfizer Global Research, UK
Duncan McHale	AstraZeneca, UK
Ian White, Dr.	UCB Pharma S.A.



## REGISTRATION

Please visit [www.safescimet.eu](http://www.safescimet.eu) to register. On the homepage, please go to **How to Apply** and sign up:

[For MSc of Advanced Safety Courses](#)

[For Continuing Professional Development \(CPD\)](#)

[For Single courses](#)

You will be notified that your registration fee has been received

**The closing date to register for this course is June 15<sup>th</sup> 2012**

Please note that the number of participants is limited to 36. It is highly advisable to send in your registration form as soon as possible. Registration will be made on a **first come first served** basis

## TRANSPORT

The course takes place in Karolinska Institutet, Stockholm, Sweden, 3 km from the central train station and 35 km from Arlanda Airport.

## ACCOMMODATION

Hotels can be arranged individually e.g. via <http://booking.com/stockholm>

## CANCELLATION

July 15<sup>th</sup> 2012. Before that date the Course fee will be refunded except for an administrative fee of EUR 75,- After that date, no refunds can be made for cancellations