

Summer Institute of Advanced Epidemiology and Preventive Medicine
Summer 2014

Course Syllabus

Pharmacoepidemiology and Pharmacovigilance: Vaccines & Therapeutics

Course number: 0158.1156

2 Academic Credits

June 29th - July 3rd 2014, 14:00-18:30

Room 215, Sackler Medical Faculty Building, Tel Aviv University

Course Instructors

Raz Gross (TAU), Myron Levine (UMB), Herve Le Louet (UPEC), Elizabeth Miller (PHE-LSHTM), Gaby Chodik (TAU), Irene Fermont (ISOP Israel), Hedva Voliovitch (Teva), Jacob Atsmon (TAU), and Dani Cohen (TAU)

[TAU - Tel Aviv University, UMB - University of Maryland, PHE-LSHTM – Public Health England & London School of Hygiene and Tropical Medicine, UPEC- University Paris-Est Creteil, ISOP – International Society of Pharmacovigilance]

Course Assistant:

Dr. Tomer Ziv- zivtome@post.tau.ac.il

Course location and schedule:

All classes will take place at the [Sackler Medical Faculty building](#) - room 215.

Day	Time	Lecturer	Topic
Sun 29 th June	14:00-15:30	Raz Gross	Principles and methodology of drug effect measurement. The role of pharmacoepidemiology.
	16:00-16:45	Raz Gross	Multiple approaches in addressing effectiveness or safety issues.
	17:00-18:30	Myron Levine	Vaccines in historical perspective; Characteristics of the current licensed vaccines; Delivery routes and adjuvants; Next generation of vaccines.
Mon 30 th	14:00-15:30	Myron Levine Dani Cohen	Clinical development of vaccines (phase 1, 2 and 3 studies); Safety, immunogenicity and protective efficacy evaluation.
	16:00-17:30	Herve Le Louet	From pharmacovigilance to risk management. Examples from the European strategy .
	17:45-18:30	Herve Le Louet	From pharmacovigilance to risk management (cont.)
Tue 1 st July	14:00-15:30	Elizabeth Miller	Post-licensure evaluation of vaccines; Signal detection of adverse events. Risk benefit analysis (rational and methods of risk-benefit calculations).
	16:00-16:45	Elizabeth Miller	Post-licensure evaluation of vaccines (cont.)
	17:00-18:30	Gaby Chodik	Pharmacoepidemiology and Pharmacovigilance using megadata analysis: Strengths and limitations
Wed 2 nd	14:00-14:30	Irene Fermont	Introduction to Pharmacovigilance regulation-EMA/Europe
	14:30-15:30	Hedva Voliovitch	Risk management Program: Identification of risks.
	16:00-17:30	Hedva Voliovitch Irene Fermont	Risk minimization
	17:45-18:30	Irene Fermont	Risk communication
Thu 3 rd	14:00-17:00	Jacob Atsmon, Hedva Voliovitch, Irene Fermont	Exercises (in groups): Development of risk management plan for selected therapeutics and vaccines
	17:30-18:30	and others	Group presentations
Fri, 4 th	09:00-11:00		Final exam

I. Course prerequisites:

- Basic course in Epidemiology
- Basic course in Biostatistics

II. Final exam

Course participants, who wish to receive academic credits for the course, must pass the final exam with a grade of at least 60 (D-).

Participants who will chose not take the exam or will receive grade below 60 (F) - will receive a participation diploma only.

**The final exam will take place on Friday, July 4th, at 09:00-11:00, room 215.
An additional date for the exam will be scheduled if required.**