

4.00 credits

19.0 h + 10.0 h

Q1



This learning unit is not open to incoming exchange students!

Teacher(s)	. SOMEBODY ;Elens Laure (coordinator) ;
Language :	English
Place of the course	Bruxelles Woluwe
Main themes	This course on simulation covers various types of simulations, including deterministic and probabilistic approaches, and addresses parameter uncertainty. It explores practical, technical, and clinical aspects related to simulation outcomes, guiding students from initial questions to clinical solutions. The course includes creating virtual patient datasets, clinical trial simulations, model-based meta-analysis, designing first-in-human (FIH) studies, and power calculations. It emphasizes decision-making using simulation results for drug development, repurposing, and precision dosing, and provides insights into reporting simulation results and using simulation software tools.
Learning outcomes	
Evaluation methods	Type: Exam during the examination period Assessment method: Oral, Practical exam, Written The evaluation is based on a team project, for which a report will be prepared, to be submitted before the oral exam. The oral exam will take place during the examination period. At the oral exam, students will individually present and defend their project. Questions will be asked for clarification about techniques used, statements made, and conclusions drawn in the report and presentation. Project: max. score 8/20 Oral exam: max. score 12/20 The project counts for the full 8 points only if at least 6/12 is obtained on the oral exam. In case the score on the oral exam is less than 6/12, the score on the report is reduced to at most 4/8. If the score for the oral part is less than 3/12, the score for the report is reduced to at most 2/8. This is to encourage active participation in the teamwork. Timely submission of the report is a necessary condition to take part in the exam. In case the deadline has not been met, the score for this course will be NA.
Teaching methods	Lectures Hands on Seminars
Content	The aim of this course is to gain proficiency in understanding the theory and hands-on expertise in the application of nonlinear mixed-effects models for simulations to inform trial design, drug development, drug repurposing, dose finding, and personalized medicine (including precision dosing). Furthermore, students will learn how to communicate simulation results effectively. • Simulation • Clinical trial simulation • Model-informed drug development • Model-informed drug repurposing • Model-informed precision dosing • Hands-on exercises • Industry experience • Regulatory perspective • Hospital experience
Inline resources	Slide decks on Toledo
Other infos	KULeuven course K0P04A
Faculty or entity in charge	FARM

Programmes containing this learning unit (UE)				
Program title	Acronym	Credits	Prerequisite	Learning outcomes
Advanced master in pharmacometrics	PMTX2MC	4		