# Advanced courses in pharmacometrics General presentation

### Faculté de Pharmacie de Marseille

Contact director:

florence.gattacceca@univ-amu.fr

January-June 2022



#### **CESU Fundamentals**

Fundamentals for modeling and simulation in pharmacokinetics/pharmacodynamics

New in 2022!

+

**CESU PBPK** 

Advanced course in physiologically-based pharmacokinetic modeling



### **CESU PopPK**

Advanced course in population approaches in pharmacokinetics/pharmacodynamics



#### **DESU PBPK**

Modeling and simulation: physiologically-based pharmacokinetic modelling for pharmacology and toxicology

# **DESU PopPK**

Modeling and simulation: population approaches in pharmacokinetics/pharmacodynamics

### **Admission requirements**

- ✓ Completed master degree or equivalent diploma
- ✓ Student or professional in pharmaceutical, medical, biological or mathematical sciences
- ✓ General knowledge on pharmacokinetics
- ✓ For CESU PBPK and PopPK: validation of CESU fundamentals

### Registration fees for 1 CESU (1 DESU = 2 CESU)

- √ 750 € for students
- √ 1500 € for professionals
- ✓ Possible to attend CESU Fundamentals only

# CESU Fundamentals for modeling and simulation in pharmacokinetics/pharmacodynamics

### Faculté de Pharmacie de Marseille

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10 full days course (2 weeks) *January 10-14 and 24-28, 2022* 



# Lectures (50%)

- √ linear algebra, linear regression, non-linear regression, differential calculus
- ✓ model definition, identifiability, validation
- √ top-down versus bottom-up approaches
- ✓ usual pharmacokinetic and pharmacodynamic models (structure, stochastic, covariate)

### **Hands-ons (50%)**

- ✓ data formatting and analysis with R
- ✓ non-compartmental and compartmental PK analysis with PKanalix
- ✓ usual PK and PD model development and validation with Monolix
- ✓ data simulation with Simulx and R



### **Objective**

being capable of understanding and evaluating pharmacometric studies, and to perform simple PK/PD analysis

# CESU Advanced course in physiologically-based pharmacokinetic modeling

# Contact director: florence.gattacceca@univ-amu.fr

### Faculté de Pharmacie de Marseille

10 full days course (2 weeks) February 28-March 4 and March 14-18, 2022



# Lectures (50%)

- ✓ ADME parameters: evaluation *in vitro* and prediction *in silico*, chemical structure-properties relationships
- ✓ in vitro/in vivo extrapolation
- ✓ model optimization
- ✓ simulation, parameter-sensitivity analysis

# **Hands-ons (50%)**

- ✓ development of a PBPK model with Matlab and Berkeley-Madonna
- ✓ applications of GastroPlus, PKSim, Simcyp in drug development, dosing adjustment, trial simulation



### **Objective**

being capable of accurately developing, applying and evaluating PBPK models

# CESU Advanced course in population approaches in pharmacokinetics/pharmacodynamics

### Faculté de Pharmacie de Marseille

Contact director: florence.gattacceca@univ-amu.fr

10 full days course (2 weeks)

May 2-6 and 16-20, 2022



# Lectures (50%)

- √ statistical inference, algorithms
- ✓ complex pharmacokinetic, pharmacodynamic (efficacy, toxicity) and joint models
- √ advanced functions of population softwares
- ✓ parametric vs non-parametric modeling
- ✓ optimal design, simulations

# Hands-ons (50%)

- ✓ complex population PK, PD, joint models development and validation with Monolix, NONMEM, Phoenix, Pmetrics
- √ application of population models to therapeutic drug monitoring and trial simulation
- ✓ optimal design with PFIM

### **Objective**

being capable of accurately performing, interpreting and evaluating complex PKPD models

