



CONSULTING IN PHARMACOMETRICS MODELING & SIMULATION

BIOTUESDAYS – SEPTEMBER 2018

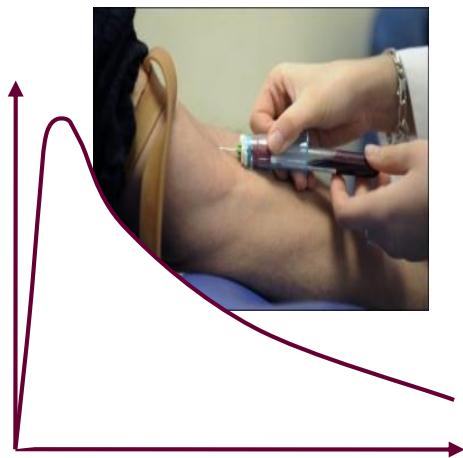
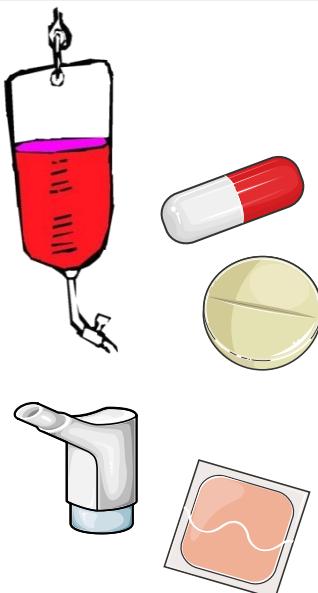
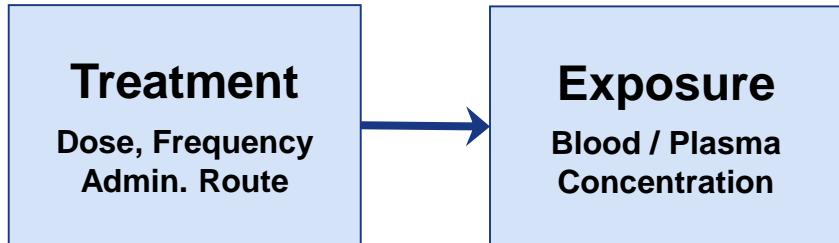


What is Pharmacometrics?

- Science of quantitative pharmacology
 - Pharmacokinetics (PK)
 - Pharmacodynamics (PD)
- Develop mathematical and statistical models to link:
 - Drug administration
 - Blood/plasma exposure
 - Drug effects on efficacy and/or toxicity

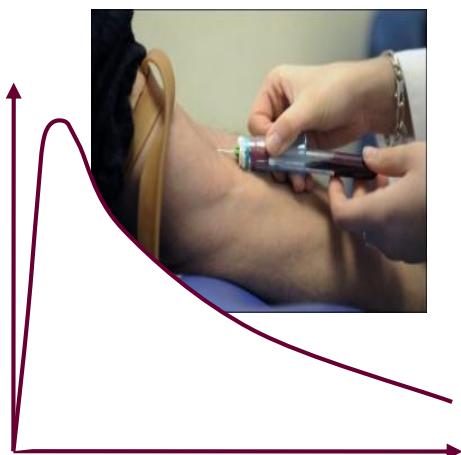
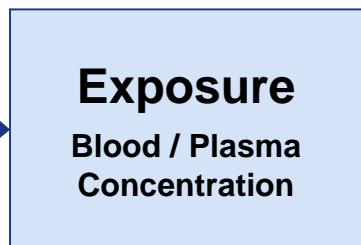
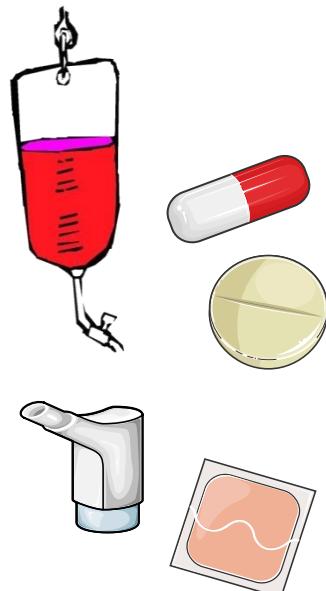
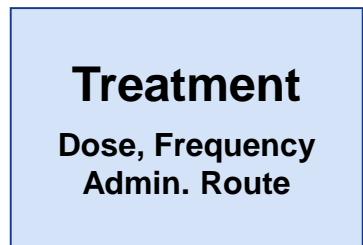
PHARMACOKINETICS (PK)

What the body does to the drug...



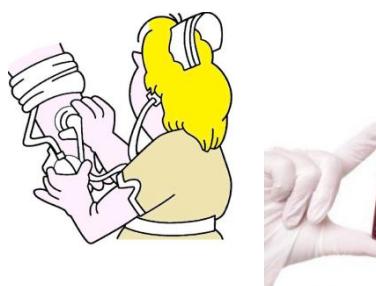
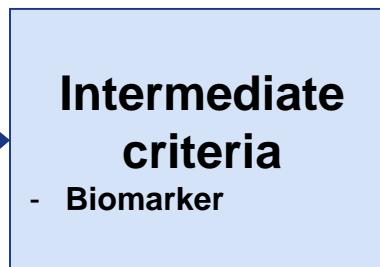
PHARMACOKINETICS (PK)

What the body does to the drug...



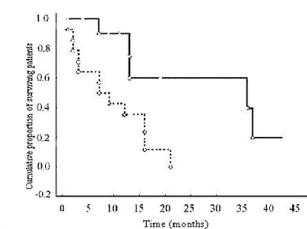
PHARMACODYNAMICS (PD)

What the drug does to the body...



Efficacy

Toxicity

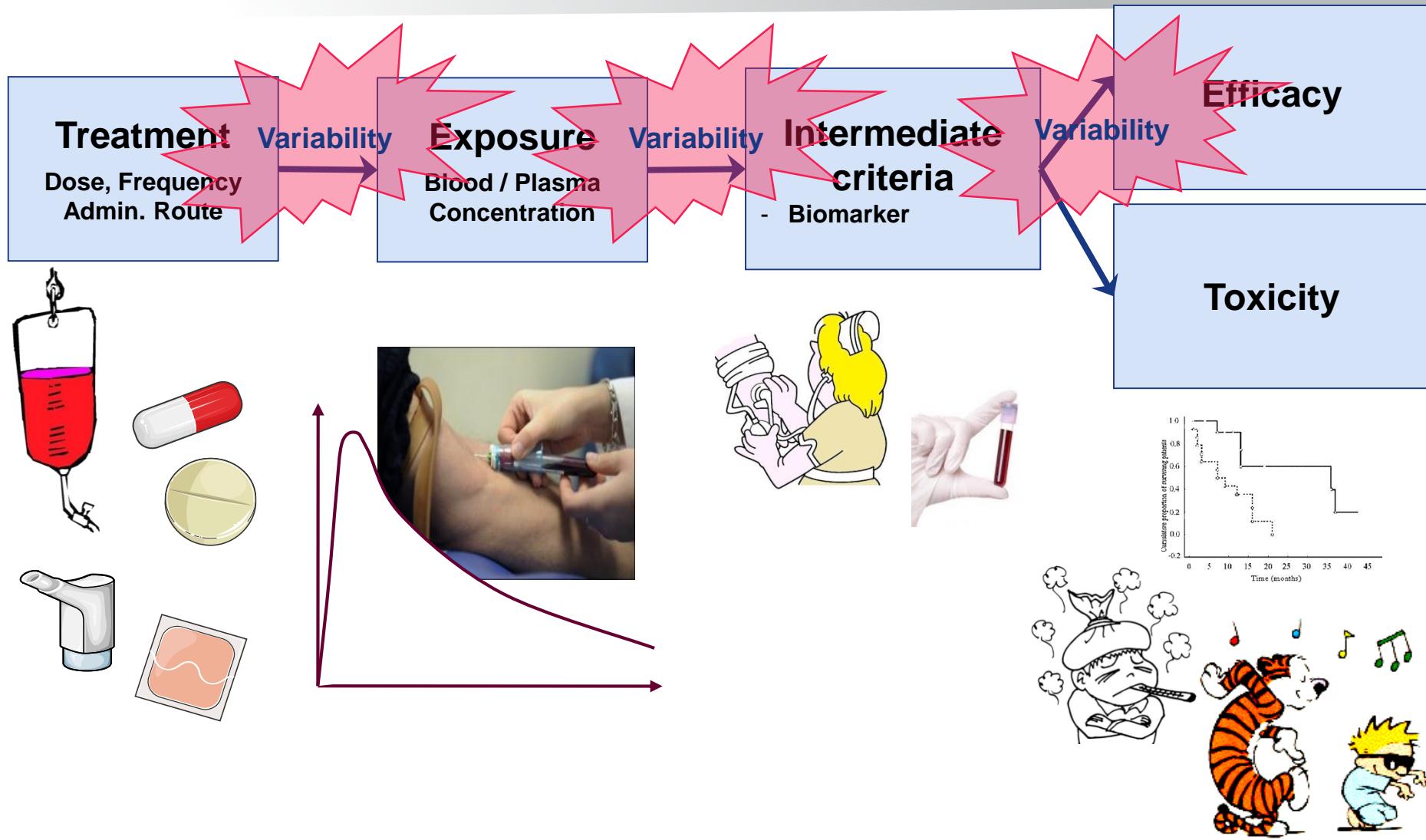


PHARMACOKINETICS (PK)

What the body does to the drug...

PHARMACODYNAMICS (PD)

What the drug does to the body...





EXAMPLE OF APPLIED PHARMACOMETRICS

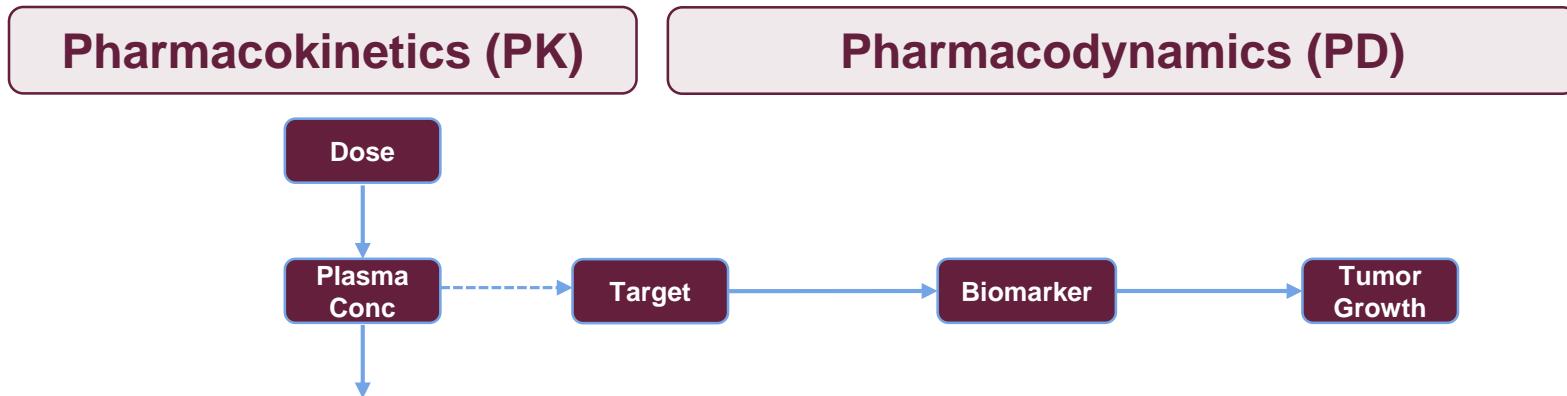
TRANSLATIONAL RESEARCH: ANTICIPATION OF PHASE I



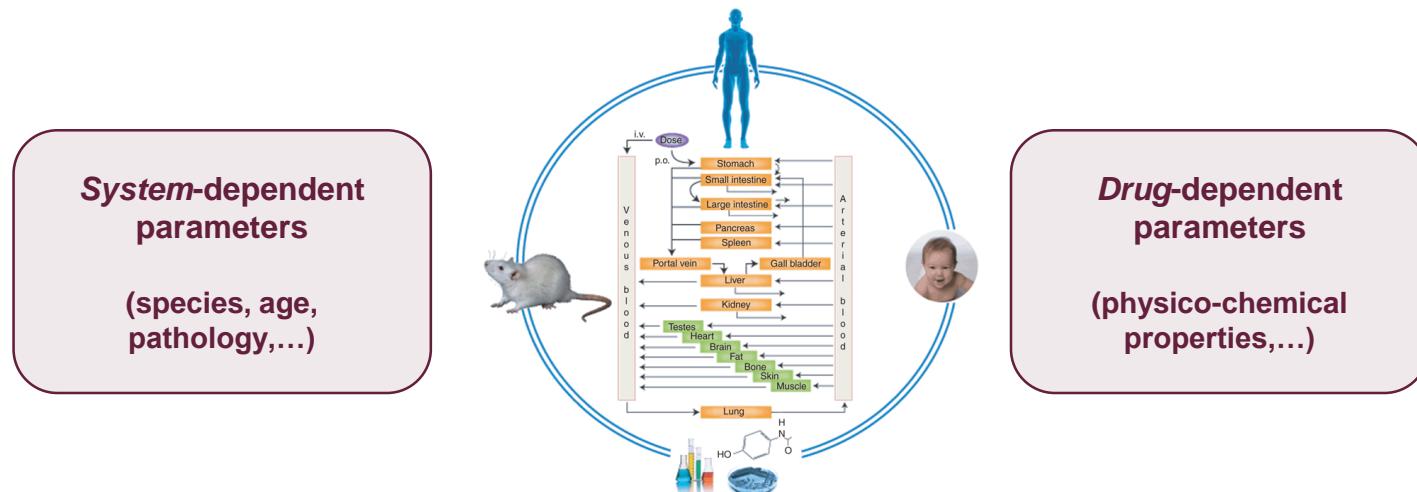
PK-PD Modeling in xenograft mice



- Semi-mechanistic PK-PD modeling



- PBPK (Physiologically-based Pharmacokinetics) modeling



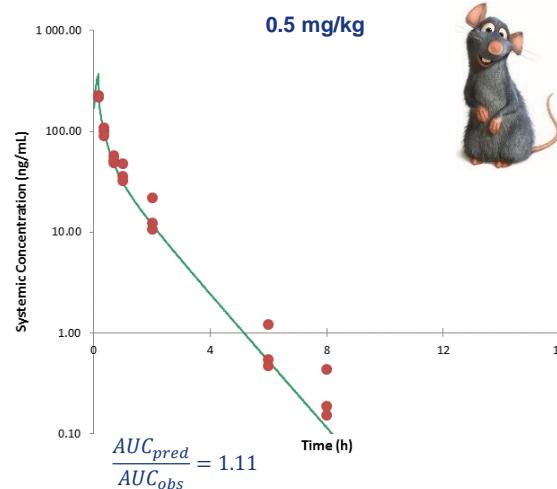
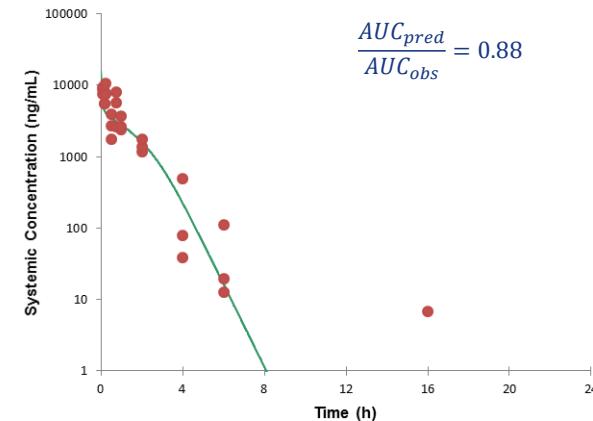


Extrapolation from mice...

- PBPK Model development in xenograft mice



- Extrapolation to other pre-clinical species
 - PBPK model in mice
 - Replacing the *system*-dependent parameters

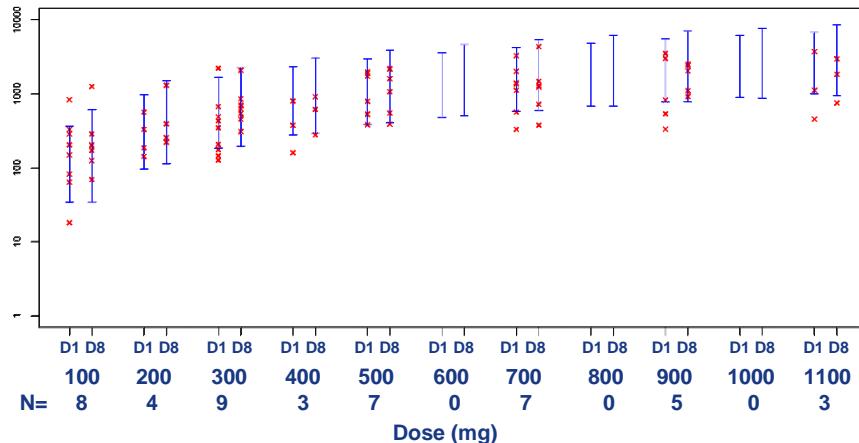




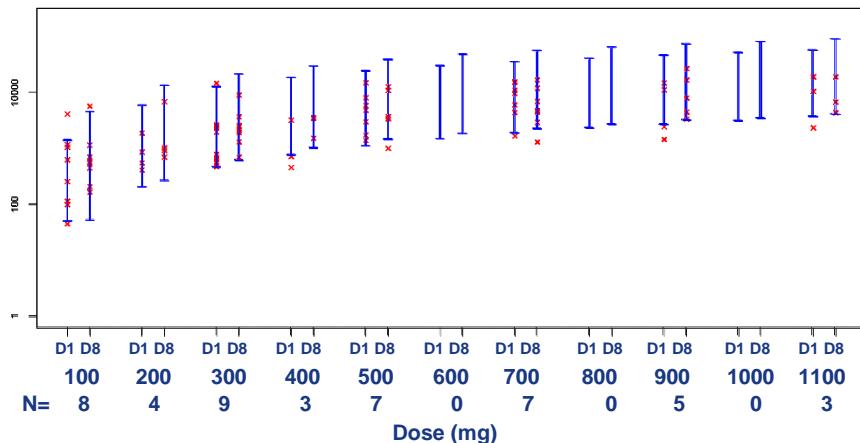
... to patients (ongoing Phase I study)

- PK parameters

C_{max}

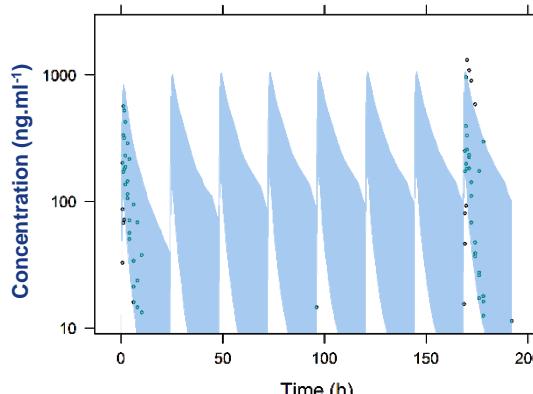


AUC

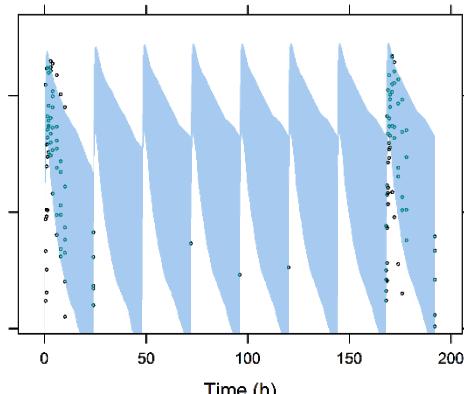


- PK profile

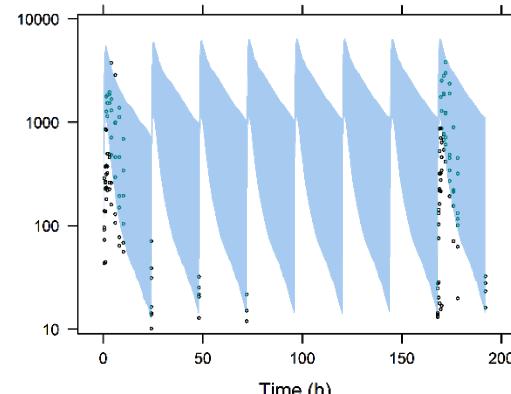
200 mg



500 mg



1100 mg





CALVAGONE, IN FEW WORDS



Created in 2015, we are now 4 consultants!

Background in pharmacy,
pharmacology, bio-physics,
bio-mathematics/statistics

Home-based offices,
located in Lyon, Beaujolais,
Paris and the Netherlands

Expertise in
pharmacometrics and
clinical pharmacology

Clients from academia and
biotechs to big Pharma,
located all over Europe, in
Australia, Asia and USA

Different therapeutic areas:

Oncology, Infectiology, Endocrinology,
Immunology, Hematology, Pediatrics, CNS,
Orphan diseases, ...

Different questions:

PK and PK-PD data analysis, Clinical Trial
simulations, Translational research (animal
to human, adult to child), Study design,
FDA and EMA submission...





Calvagone services in Pharmacometrics

- Data analysis, Modeling & Simulation
 - Data management, creation of PK-PD databases
 - Non-compartmental analysis (NCA)
 - Population PK and PK-PD modeling (NONMEM, Monolix)
 - Identification of influential predictive factors
 - Clinical trial simulation
 - Quality control (QC)
- Support in drug development
 - Support in study design
 - Preparation of package for Dossier submission (FDA, EMA, ...)
 - Pediatric Investigation Plan (PIP)
 - General consulting
- Organisation of dedicated trainings



Wishing to build long-term relationships of trust



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WWW.CALVAGONE.COM



Any question?

