



CONSULTING IN PHARMACOMETRICS MODELING & SIMULATION

BIOTUESDAYS – SEPTEMBER 2018



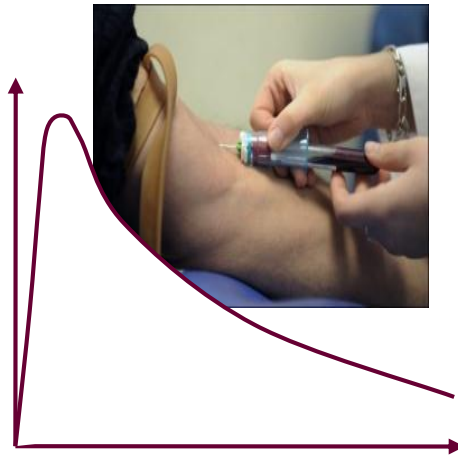
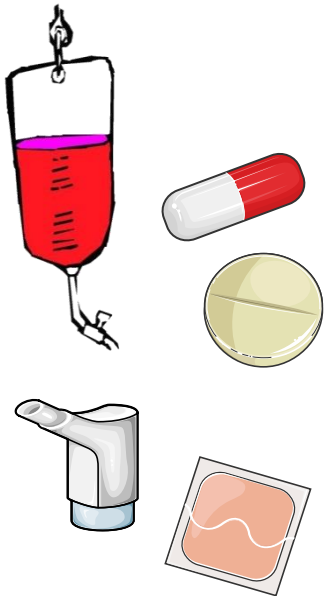
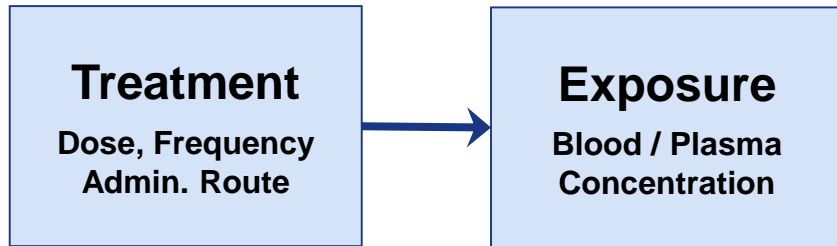
What is Pharmacometrics?

- 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...

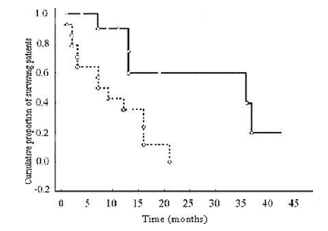
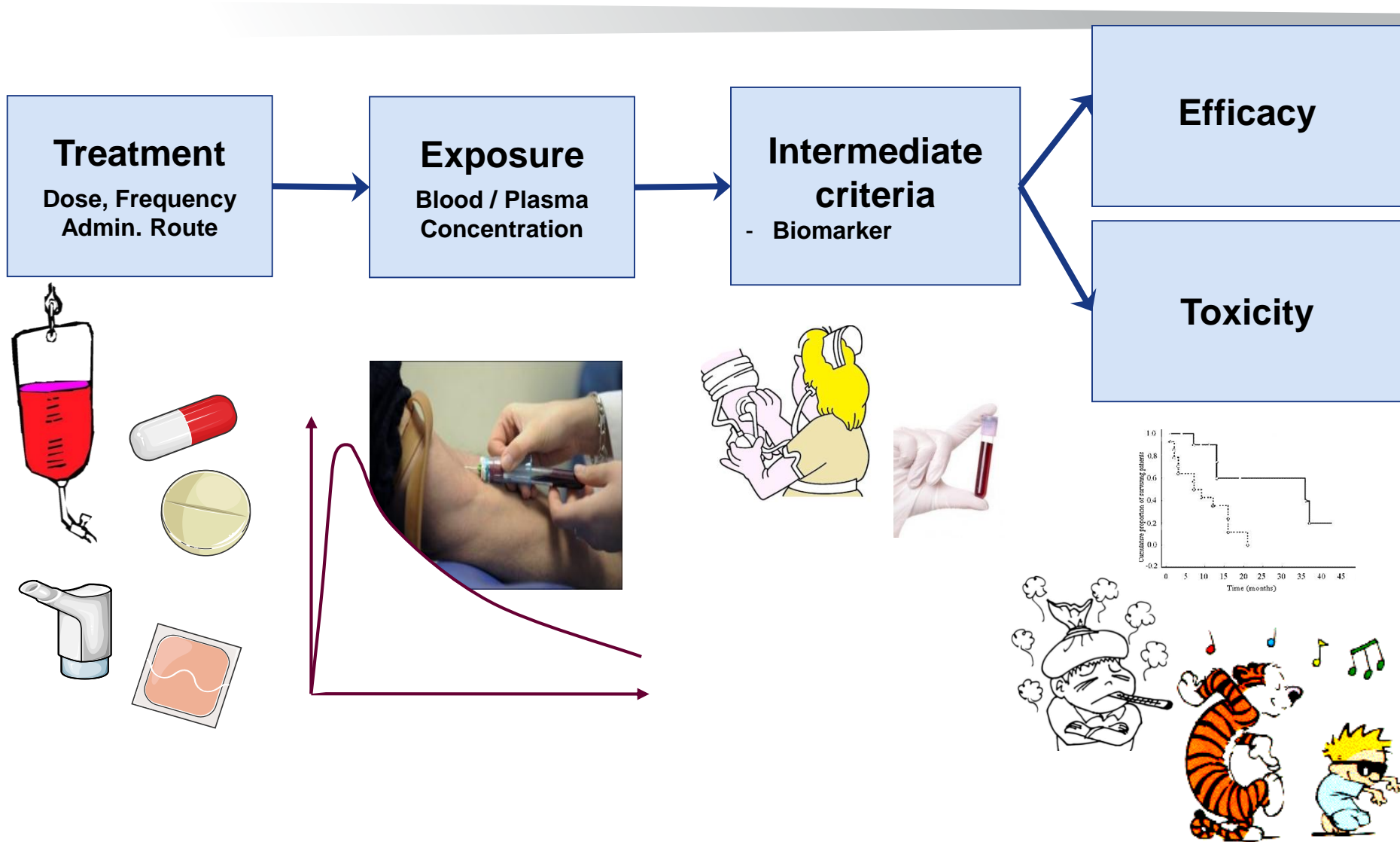


PHARMACOKINETICS (PK)

What the body does to the drug...

PHARMACODYNAMICS (PD)

What the drug does to the body...

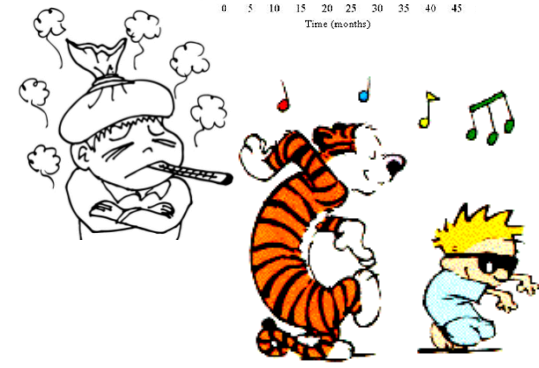
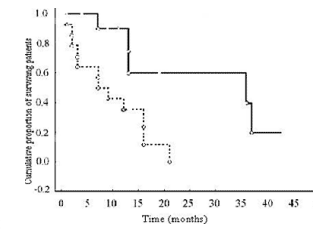
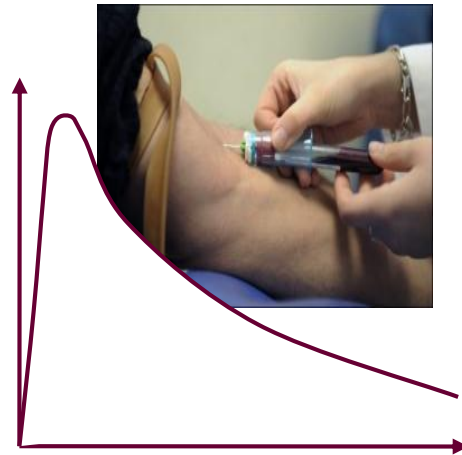
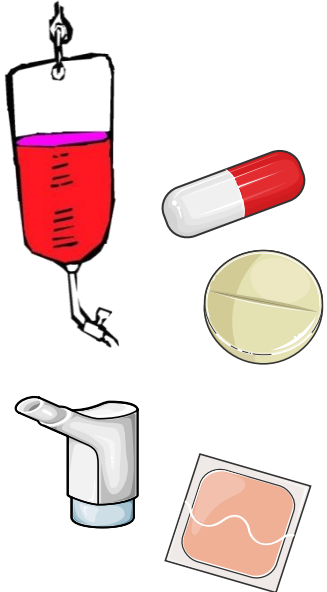
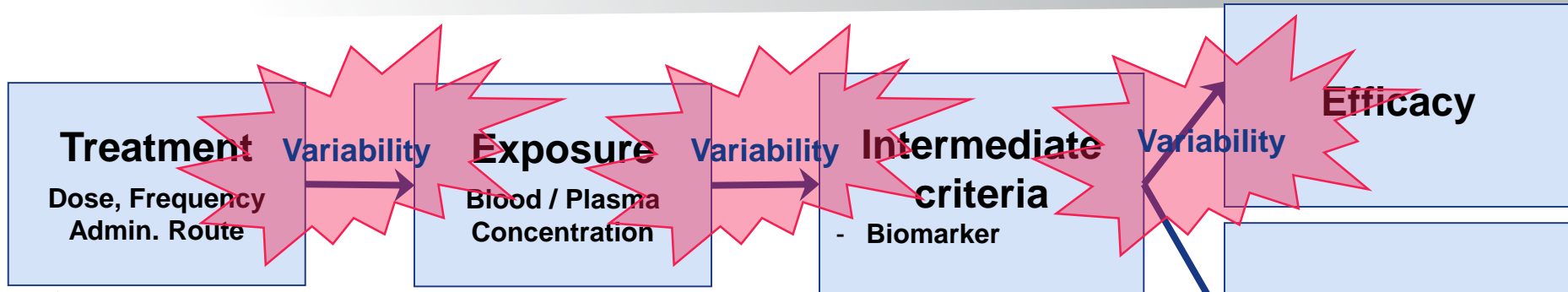


PHARMACOKINETICS (PK)

What the body does to the drug...

PHARMACODYNAMICS (PD)

What the drug does to the body...





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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