



Association Française
des Sociétés de Services et d'Innovation



Centre de recherche
FRANCAIS

afssi.fr

Les **membres AFSSI**
ont la **parole** ”

WEBINAIRE



Le partenaire incontournable de vos innovations

Proche de chez vous



Make your drug development a success!



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Les membres AFSSI ont la parole ”
WEBINAIRE

Qui suis-je ?
La réponse en 20 min

Sciences de la Vie
AFSSI
Association Française des Sociétés de Services et d'Innovation

NOTRE ACTIVITÉ

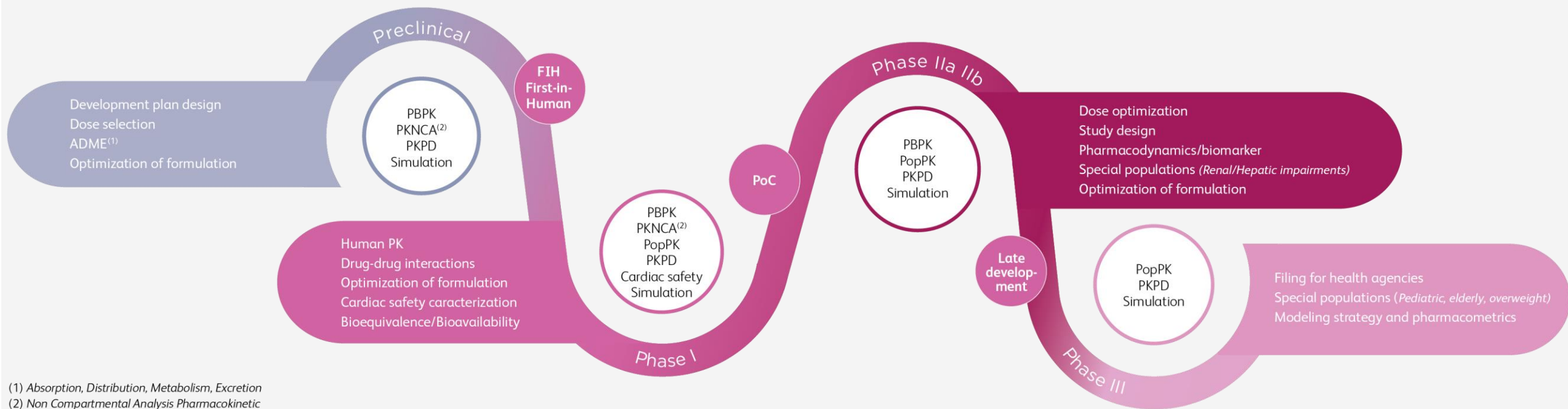
Aide à la prise de décisions concernant le développement de médicaments en utilisant l'ensemble des **outils existants de pharmacologie et de modélisation et de simulation pharmacométriques (M&S)**

WE GUIDE YOU THROUGH YOUR ENTIRE DRUG DEVELOPMENT PROCESS



From Drug candidate to Patient Proof of Concept (PoC)

MODEL BASED DRUG DEVELOPMENT



(1) Absorption, Distribution, Metabolism, Excretion
 (2) Non Compartmental Analysis Pharmacokinetic

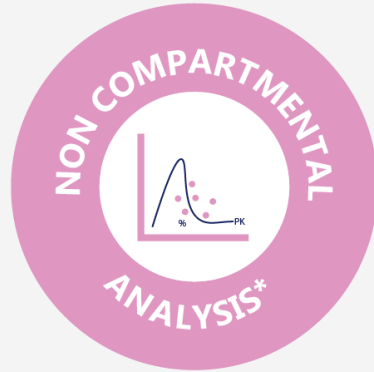
PHARMACOKINETICS, AN ESSENTIAL BRICK IN YOUR DRUG DEVELOPMENT



We bring our PK and EDD expertise to assess project potential and design development strategies



We set-up the PK clinical studies and **supervise** their good execution



We develop comprehensive analysis for a thorough understanding of the drug **PK properties**



We deliver *state-of-the-art* reporting and **CDISC compliant** PK data

Thanks to our clinical vision we guarantee a coherent PK & PD assessment throughout your development



PBPK | Physiologically Based Pharmacokinetics

With relevant *in vitro*, preclinical or clinical data at hand, a PBPK model is assembled to characterize and predict the drug's ADME. PBPK approaches allows you to consider all the drug's behavior in one model to determine the best dose and dose regimen.

PBPK enables predictions **based on actual physiological and physiochemical knowledge.**

First In Human dose prediction
Optimize drug formulation
IVIVC (In vivo in vitro correlation)

Simulation of PK profiles in special population
Likely magnitude of Drug-Drug interaction

Mechanistic ADME
Simulate the change in administration route
Assess modified release formulation

In partnership with

S+ *SimulationsPlus*



PopPK | Population Pharmacokinetic

This sophisticated analysis gathering all your clinical data and using statistical algorithms allows you to consider all subjects and all timing points.

PopPK allows accurate estimates in:

- Various subject groups, e.g. body, weight, gender, impaired organs, etc.
- Source variability, e.g. food, co-med, time of the day, etc.
- Special population analysis, e.g. elderly, obese, hepatic impairment, renal insufficiency, children, etc.

SUBSTITUTION METHOD TO

Subjective evaluation based on multiple trials and errors

USING THESE TOOLS IN
TARGETED EXPOSURE
WILL LEAD TO:

- Identifying relevant covariates in patients
- Simulating exposure, predicting therapeutic dose, anticipating activity for special populations
- Saving you dedicated studies in special populations
- Coverage of proper dose range
- Phases II and III dose selection rational strength for regulatory authorities



PK/PD | Pharmacokinetic/ Pharmacodynamic

Knowing the relation between exposure and response allows you to be more efficient by using optimized drug concentrations.



Clear targets will avoid **starting too low** (*efficacy*) or **escalating too high** (*safety*).

SUBSTITUTION METHOD TO

Subjective evaluation

Qualitative evaluation

USING PK/PD WILL
QUANTIFY TARGETED
EXPOSURE, WHICH **WILL**
LEAD TO:

- Phases I and II cohorts number reduction (money, time and patient exposure savings)
- Coverage of proper dose range
- Phases II and III dose selection rational strength for regulatory authorities.



Les points clés à retenir

- La Pharmacométrie est une discipline transverse, désormais reconnue et pleinement intégrée au développement de médicament
- Règle des 3 “i” : intégratif, itératif et interactif
- Nécessité d’être déployé en lien avec la stratégie globale du développement
- Penser le positionnement des Sociétés de Services Innovants :
 - Prestation de recherche ciblée
 - Connaissance mutuelle pour créer une synergie d’offre
 - Conseil auprès de Biotech à très haute valeur ajoutée