# Unexplored fields in DMPK: terra incognita?

## *Day 1 : 25th October2017*

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| **13.00 – 14:00** | **Arrival and Registration** |
| **14:00 - 15.30** | **Session 1 : From monomeric to polymeric and combined analyte- Bioanalysis Challenges**<br><br>*Bioanalysis is always the starting point and a corner stone of DMPK studies. Based on concrete cases, this session will address : some "Evidences" in Bioanalysis to acquire robust metabolic and pharmacokinetic profiles in early drug development of small or large molecules, and also their evolutions, to seek pragmatic and conclusive solutions for new DMPK challenges related to biologics with complex endogenic and exogenic structures such as antibody-drug conjugates (ADCs).*<br><br>Chairs : Yann Courbebaisse (Berthin Pharma), Jerome Henri (ANSES) & Marc Trellu (Sanofi) |
| | S1. 1 Microsampling & High Resolution Mass Spectrometry as Bioanalytical Tools Used Daily in Drug Discovery (Antonio Grondin, Pierre Fabre, Toulouse, France) |
| | S1. 2 Bioanalytical assay strategies to support nonclinical and clinical PK of antibody-drug conjugates (Antoine Deslandes, Sanofi, Alfortville, France) |
| | S1. 3 Contribution of physicochemistry and affinity assays to the understanding of Antibody Drug Conjugates pharmacokinetics (Guillaume Brachet., Medical & Pharmacy School, Tours University, France) |
| **15:30 – 16:00** | **Break** |
| **16 :00 – 17 :00** | **Students Poster Blitz**<br><br>Chairs: Marion Millet (Pierre Fabre)- Marion Dehez (Ipsen) |
| **17 :00 – 19 :00** | **Poster Session & Cocktail** |

## *Day 2 : 26th October 2017*

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| **8:30 – 9:00** | **Welcome Coffee/Tea** |
| **09:00 – 10:00** | **Key note Speaker : Neil Parrott (Roche Pharma, Basel, Switzerland)**<br>**A Pharmaceutical Industry Perspective on the value of Physiologically Based Pharmacokinetic Modelling in Drug Discovery and Development** |
| **10:00 – 10:30** | **Break** |
| **10 :30 – 12 :00** | **Session 2 : New challenges in drug metabolism investigation**<br>*This session will be focused on drug metabolism investigation, covering both NCEs and NBEs. One of the discussed themes will be the role of metabolism investigation in the mechanistic studies and in vitro models of DILI. Another topic of the session will focus on the approach in the study of ADCs metabolism (payload and antibody moieties) which is recognized as a key challenge in preclinical development due to the multiple entities to identify and monitor.*<br>Chairs: Massimiliano Fonsi (Citoxlab) & Marion Millet (Pierre Fabre) |
| | S2.1 HepatoPearl, a novel 3D liver spheroid model for high throughput drug screening (Noushin Dianat, Cyprio, Paris, France) |
| | S2. 2 Integration of biokinetic, metabolism-related and omics data in (repeat-dosing) hepatocyte toxicity studies: a novel approach for improved risk assessment from in vitro data (Lysiane Richert, KaLy-Cell, Plobsheim, France) |
| | S2. 3 Trends & challenges in the metabolism & disposition assessment of Antibody Drug Conjugates (Alain Krick, Sanofi, Chilly-Mazarin, France) |
| **12:30 – 13:30** | **Lunch** |
| **13:30 – 14:30** | GMP Assemblée Générale |
| **14:30 – 16:00** | **Session 3 : Exploring alternative routes of administration for systemic drug delivery**<br>*Alternative solutions to oral or parenteral routes of administration have gained significant attention, to complement approved drug products, or enable development of new molecular entities that have deficiencies or suboptimal pharmacokinetic profiles. Some drug delivery challenges or promising non-invasive routes of administration (Intranasal, transdermal) will be illustrated in this session.*<br>Chairs : Rola Barcham (Oroxcell) & Sylvaine Cartot-Cotton (Sanofi) |
| | S3. 1 Development of high dose subcutaneous monoclonal antibody therapeutics – challenges and successes (Wolfgang Richter, Roche Pharma, Basel, Switzerland) |
| | S3.2 Highway to brain: the intranasal route for peptide brain delivery (Jerome Leprince, Inserm, Normandie Université, Mont-Saint-Aignan, France) |
| | S3. 3 Delivering drugs transdermally: What is new? What is the promise? What are the challenges? (Begoña Delgado-Charro, University of Bath, Bath, UK) |

## *Day 2 : 26th October 2017 (Cont'd)*

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| **16:00 - 16:30** | **Break** |
| **16:30 - 18:00** | **Session 4 : Dosing optimization, from 0 to 99 years** |
| | *During drug development, clinical trials usually do not include patients at the two extremes of age. Consequently, pharmacokinetic and pharmacodynamic knowledge is missing in younger or elderly patients. The aim of this session is to describe the progresses that have been made toward the optimal care of pediatric and geriatric patients, through the evolution of the "way of thinking" and the modelling and adaptation tools.*<br><br>Chairs: Vincent Duval (Novartis), Antoine Coquerel (CHU Caen) & Florence Gattacceca (Marseille University) |
| | S4. 1 Pharmacometric approaches to support dosing in neonates and infants with focus on antibiotics (Marc Pfister, University of Basel Children's Hospital (UKBB), Basel, Switzerland) |
| | S4. 2 From adult to child: can we predict the pharmacology of drugs in children from adult data? (Jean-Marc Treluyer, Université Paris Descartes, Hôpital Cochin, Paris, France) |
| | S4. 3 Individualizing drug therapy in the elderly (Pascal Maire, Université de Lyon, Geriatric Hospital Antoine Charial, Lyon, France) |
| **19:30** | **Gala Diner** |

## *Day 3 : 27th October 2017*

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| **8 :30 - 9 :00** | **Welcome coffee/Tea** |
| **9 :00 - 10 :30** | **Session 5 : Design and analysis of clinical trials for small rare disease populations: how to manage scarcity?**<br><br>*The objective of this session will be to focus on the challenges of developing drugs in rare or small population diseases :*<br>*-translation from animal to human*<br>*-how to perform efficient clinical trials with small sample size*<br>*-potential modelling techniques that can be applied to inform such development*<br><br>Chairs : Virginie Gualano (Phinc), Marion Dehez (Ipsen) |
| | S5. 1 Models and mechanism preclinical (Speaker TBC) |
| | S5. 2 Application of Physiologically-Based Pharmacokinetic Modelling to Drug Development in Rare Diseases: A Literature Review and Novel Application (Pau Aceves, Certara) |
| | S5. 3 Big data : application on rare disease (Sebastien Tourlet, Ipsen, France) |
| **10:30 - 11:00** | **Break** |
| **11:00 - 12.30** | **Session 6 : Terra Incognita : how to regulate, validate and monitor**<br><br>*There are situations in clinical research where applying existing guidelines/guidances can be very challenging. Either the domain is not sufficiently covered or the field is continuously evolving. This session will focus on how conducting clinical trials in very small children or in urgency indications, how to prepare registration for rare or ultra-rare diseases and regulatory requirements for therapeutic proteins immunogenicity characterization (based on the revised EMA Note for Guidance).*<br><br>Chairs: Antoine Coquerel (CHU Caen) & Olivier Petricoul (Novartis) |
| | S6.1 Pediatry : Difficulty for conducting clinical trials in very small children or in urgency indication (Hélène Chappuy, Hopital Trousseau, APHP, Paris) |
| | S6.2 Rare disease : How to prepare registration for rare or ultra-rare disease (Jean-Luc Barnoux, PharmaDev, Geneve) |
| | S6.3: Regulatory requirements for therapeutic proteins immunogenicity characterization : What interpretation of the revised EMA NfG (Ridha Belaiba, ANSM, Paris, France) |
| **12.30 - 12.45** | **Closing Remarks** |

23rd August 2017