

## 2020 First GMP Virtual Symposium



### When DMPK is out of sight but not out of mind

From 18<sup>th</sup> of September to 23<sup>rd</sup> of October 2020

#### DAY 1: 18<sup>th</sup> September 2020

##### 11:00-12:00 OPENING SPEAKER

**Impact of antibiotic therapy on the bacterial diversity of the intestinal microbiota**  
Charles Burdet, IAME Inserm, Paris, France

Chairs: N Gregoire (Poitiers Univ.), J Henri (Anses)

#### DAY 2: 25<sup>th</sup> September 2020

##### 10:30-12:00 SESSION 1

##### 10:30-11:15 1.1 *IN VITRO* TESTING

**An *in vivo* like 3D hepatic liver spheroid system for studies of aetiology and treatment of chronic drug hepatotoxicity and hepatic fibrosis**  
Magnus Ingelman-Sundberg, Karolinska Institute, Stockholm, Sweden

Chairs: M Rachid (Genoscience Pharma), Y Courbebaisse (Adocia)

##### 11:15-12:00 1.2 ARTIFICIAL INTELLIGENCE

**Machine Learning Approach to Forecast Chemotherapy-Induced Haematological Toxicities in Patients with Rhabdomyosarcoma**  
Vesna Cuplov, SmartC, Marseille, France

Chairs: C Serdjebi (Biocellvia), Y Parmentier (Servier), Q Nguyen (Ipsen)

#### DAY 3: 2<sup>nd</sup> October 2020

##### 10:30-12:00 SESSION 2

##### 10:30-11:15 2.1 *IN VITRO* TESTING

**A fluid-dynamic Multi-In Vitro Organ-MIVO device as alternative approach for in vitro drug testing**

Silvia Scaglione, React4life, Genoa, Italy

Chairs: M Rachid (Genoscience Pharma), M Fonsi (Charles River)

##### 11:15-12:00 2.2 INNOVATIVE THERAPIES

**Car-T cell development and registration – Opportunities for the application of Pharmacometrics**

Rik De Greef, Certara, Oss, The Netherlands

Chairs: V Duval (Certara), F Gattacceca (Aix-Marseille Univ.)

#### DAY 4: 9<sup>th</sup> October 2020

##### 10:30-12:00 SESSION 3

**PK challenges in pediatric drug development**

Chairs: R Barcham (Oroxcell), L Del Frari (Pierre Fabre), F Hurbin (Sanofi), A Coquerel (Caen Univ.)

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**10:30-11:00 3.1 Prediction of midazolam pediatric plasma profiles for multiple routes of administration using physiologically based pharmacokinetic model**

Maxime Le Merdy, SimulationsPlus, Basel, Switzerland

**11:00-11:30 3.2 PopPK/PD scaling from adults to children using priors: A case example with Alirocumab**

Elisa Calvier, Sanofi, Montpellier, France

**11:30-12:00 3.3 Use of model informed extrapolation in regulatory submissions - Examples**

Flora Musuamba Tshinanu, EMA, Brussels, Belgium

#### DAY 5: 16<sup>th</sup> October 2020

##### 15:00-16:30 SESSION 4

**DDI risk assessment and evaluation in pharmaceutical development**

Chairs: O Barberan (Elsevier), O Nicolas (Sanofi), Y Parmentier (Servier), A Sharma (Senzagen)

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**15:00-15:30 4.1 PBBM application to support formulation changes, prediction of pH related DDI and impact of beverages on exposure to acalabrutinib**

Xavier Pepin, AstraZeneca, Macclesfield, UK

**15:30-16:00 4.2 Drug-drug interactions of therapeutic proteins**

Antoine Deslandes, Sanofi, Alfortville, France

**16:00-16:30 4.3 Ivabradine metabolite PBPK modelling: CYP3A4 mediated DDI risk evaluation in adults and children**

Jennifer Lang, Manchester Univ., Manchester, UK

#### DAY 6: 23<sup>rd</sup> October 2020

**10:30 – 11:00  
Student presentation  
blitz AWARDS**



**11:00 – 12:00  
Assemblée générale  
du GMP**

Je vote!