17th Symposium on Pharmacokinetics and Drug Metabolism, 12-13 november 2024

Agenda at glance – sessions and scope

Tuesday 12th November	
11.30 – 13.00	Registration and Lunch
13.00 – 13.15	Opening and introduction of meeting
13.15 – 14.45	**Session 1: Biotransformation and impact of drug metabolites**
14.45 – 15.30	Break with posters & coffee
15.30 – 17.00	**Session 2: Drug Transporter considerations across drug modalities**
17.00 – 17.15	Break
17.15 – 18.00	**Candlelight speaker**
18.00 – 18.45	Break & refreshments and poster session
19.00 – 23.00	Dinner

Wednesday 13th November	
08.45 – 10.15	**Session 3: Pharmacokinetic and pharmacodynamic considerations in rare disease and special populations**
10.15 – 10.45	Break with posters & coffee
10.45 – 12.15	**Session 4: Bridging strategies for drug-device products**
12.15 – 13.15	Lunch
13.15 – 13.45	**Rosenön Award**
13.45 – 14.45	**Session 5: Pharmacokinetics-Pharmaco-dynamics of drug combination therapies**
14.45 – 15.00	Closure of meeting

If you would like to propose a topic for presentation, please contact the session chairs below (abstract deadline 20th of May).

Sessions and Scope:

Session 1: Biotransformation and impact of drug metabolites
Chairs: Johanna Haglund, MetaSafe, Johan Bylund, CTC, Clinical Trial Consultants
Scope: The purpose of the conference session on biotransformation and the impact of metabolites is to explore and discuss the crucial role of biotransformation processes and metabolic fate in the field of pharmaceutical research. Biotransformation refers to the chemical modifications that drugs undergo within the body, primarily through enzymatic reactions, leading to the formation of metabolites. Researchers will share science that emphasises the significance of understanding biotransformation pathways and the subsequent impact of metabolites on drug efficacy, safety, and pharmacokinetics. The session aims to shed light on how metabolites, through their formation, character, distribution, and elimination, affects therapeutic outcomes and potential adverse effects.

Please contact Johanna.Haglund@metasafe.se and Johan.Bylund@ctc-ab.se for further info or submit an abstract for consideration of an oral presentation.

Session 2: Drug transporter considerations across drug modalities
Chairs: Anna Nordmark, Nordmark ClinPharm consulting, Rasmus Jansson-Löfmark, AstraZeneca
Scope: Drug transporters play a critical role in drug disposition by affecting absorption, distribution, and excretion. They translocate drugs, as well as endogenous molecules and toxins, across membranes using ATP hydrolysis, or ion/concentration gradients. Drug transporters have a key relevance not only for small molecule drugs but also for all other drug modalities (e.g. biologics, oligonucleotides, CarTs, Tregs). Purpose of this session is fairly broad but with the red thread of drug transporters, e.g. DDI studies, Biomarkers for DDIs, Predicting DDIs, Considerations of Transporters for PK scaling, Drug transporters for delivering drugs to a certain tissue, Drug transporters for non-small molecules.

Please contact Anna Nordmark, anna@nordmarkclinpharm.se and Rasmus Jansson-Löfmark, Rasmus.Jansson.Lofmark@astrazeneca.com for further info or submit an abstract for consideration of an oral presentation.

Session 3: Pharmacokinetic and pharmacodynamic considerations in rare disease and special populations
Chairs: Anna Nordmark, Nordmark ClinPharm Consulting , Mia Lundblad, Novo Nordisk, Pawel Baranczewski SciLifeLab, Uppsala University
Scope: With the new initiative from the FDA there is now an increasing demand to obtain data from pregnant and lactating women as well as breastfed infants during drug development in order to predict and study drug concentrations in these special populations. The purpose is to address the challenges which are related to obtaining sufficient physiological as well as concentration data and how to develop robust (PBPK)models.

Another focus will be on the development of therapies within rare diseases and diseases affecting primarily paediatric populations. Here, the importance of designing optimal clinical PKPD studies including modelling approaches to obtain sufficient dose-response data and obtain a relevant clinical pharmacology label will be discussed.

Please contact Mia Lundblad, mslu@novonordisk.com and Anna Nordmark, anna@nordmarkclinpharm.se for further info or submit an abstract for consideration of an oral presentation.

Session 4: Bridging strategies for drug-device products
Chairs: Markus Fridén, AstraZeneca, Mia Lundblad, Novo Nordisk
Scope: With growing clinical use and R&D of new modalities and non-small molecules comes an increasing demand for reliable delivery of the drug using various delivery systems such as syringes, autoinjectors, implants or (for that part) inhalers. The development of drug-device products is associated with their own challenges when transitioning between clinical phases/studies since frequently either the drug formulation or the drug formulation as well as the device is being changed towards their intended commercial form. This sometimes causes difficult-to-explain changes in drug exposure which makes bridging challenging. Bridging can be said to represent the processes of managing a transition between drug products (i.e. a new formulation and/or a new device) such that previously generated clinical safety and PK/PD data can be leveraged into the design of the next-coming study. Even moderate-to-small changes in exposure, if not foreseen, can lead to results not supporting the planned bridging strategy during development. Moreover, for marketed drugs, environmental aspects and manufacturing costs for drug or device can be expected to drive future requirements for pharmaceutical post-approval changes where it is needed to establish bioequivalence – and area which can be notoriously challenging.

In this session we aim to address the underlying pharmacokinetic processes and pharmaceutical properties governing common changes in exposure when altering drug formulation or delivery device, and how quantitative in silico tools can be used to execute effective bridging and bioequivalence strategies.

Please contact Markus Fridén, Markus.Friden@astrazeneca.com and Mia Lundblad, mslu@novonordisk.com for further info or submit an abstract for consideration of an oral presentation.

Session 5: Pharmacokinetics-Pharmacodynamics of drug combination therapies
Chairs: Markus Fridén, AstraZeneca, Rasmus Jansson-Löfmark, AstraZeneca
Scope: Combination therapies, involve the simultaneous administration of multiple drugs to achieve a desired effect(s) that either alone of the drugs cannot achieve. Combination therapies can either be done by combining several novel chemical entities or adding on novel drug treatment on a standard of care treatment, e.g. as fixed dose combinations. Additionally, a variant of "combination therapies" are also drugs designed to target more than one receptor (e.g. bispecific antibodies) to achieve their desired pharmacology.

Purpose of this session is to highlight challenges (e.g. regulatory aspects), advantages (e.g. synergies, overcoming resistance), and Pharmacokinetic-Pharmacodynamic approaches that needs to be considered for combination therapies. The session is open to both discovery, development, and clinical aspects.

Please contact markus.friden@astrazeneca.com and rasmus.jansson.lofmark@astrazeneca.com for further info or submit an abstract for consideration of an oral presentation.