



CRED: Understanding Clinical Development Programme
13-14 October 2025

Day one

Chairperson: Steve Pinder, Envestia Ltd

Time	Activity	Speaker
09:20	Registration and Coffee	
09:30	Introduction to TOPRA	
09:35	Welcome and Introduction Clinical Development in Context <ul style="list-style-type: none"> • Target product profile • Use 10-year development diagram, say where everything fits in • Why are clinical data needed? • Relevance of preclinical data • Definitions of Phases I, II, III and IV. • Clinical development strategy and the Clinical Development Plan • Sources of advice and timing • Need for a PIP 	Steve Pinder Envestia Ltd
09:50	Clinical Pharmacokinetics <ul style="list-style-type: none"> • To see how the drug is handled in man • To understand the basic parameters used to describe the PK of a drug • To understand the importance of PK in drug development <ul style="list-style-type: none"> ○ Describe the different processes involved in Pharmacokinetics: absorption, distribution, metabolism and excretion ○ Define the PK parameters which describe each process, e.g. Cmax, t_{1/2}, AUC, Volume of distribution, Clearance, Bioavailability etc, and their relevance ○ Discuss multiple dosing and non-linear kinetics ○ Understand the importance of metabolism including, <ul style="list-style-type: none"> ▪ Drug metabolising enzymes, ▪ Importance of ensuring main metabolites in man are similar to those produced by preclinical toxicology species ○ Discuss generation of PK data throughout the different phases of Drug development including <ul style="list-style-type: none"> ▪ Overview of studies performed in phase I, II and III ▪ Standard PK sampling employed in Phase I and II. ▪ Use of sparse sampling and population PK approaches in Phase III. ○ Discuss importance of validation of analytical methods – as a regulatory requirement. 	TBC

Time	Activity	Speaker
10:30	Tea/ coffee break	
10:50	Clinical Pharmacodynamics <ul style="list-style-type: none"> • First in human trials • Guideline • Objectives of clinical pharmacodynamic studies • Mechanism/onset/duration of action • Examples of pharmacodynamic models • Different study designs • Identification of sub-group differences e.g. disease-related, gender, age, race, geography (racial sub-populations) • Biomarkers • Practicalities of clinical pharmacodynamic studies 	TBC
11:30	Panel Discussion	
12:00	Lunch	
13:00	Optimal Study Design – Objectives and Issues Relating to Phase II studies <ul style="list-style-type: none"> • Objectives of Phase II studies • “Proof of concept” • Design of Phase II studies • Definition of target patient population • Choice of end point(s) • Dose response • Initial identification of possible safety issues • Importance of keeping the target product profile in mind throughout • Adaptive design and accelerated development • Conditional approval 	TBC
14:00	Paediatric Investigation Plans <ul style="list-style-type: none"> • Legal framework • Why children are different • Preferred approaches to clinical development in children • Devising PIP strategy • Content and format of a PIP • PIP review process • Compliance Check 	Steve Pinder Envestia Ltd



Time	Activity	Speaker
14:35	Case study and feedback session	Katherine Bowen Boyd Consultants
	<i>Tea to be taken in case study groups</i>	
17:00	Close	



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Day two

Chairperson: Beatrix Friedeberg,

Time	Activity	Speaker
08:55	Introductory comments	Chair
09:00	Design of Clinical Trials to Support Proof of Efficacy (Phase III) <ul style="list-style-type: none"> • Confirmation of efficacy in the target patient population • Considerations for trial design e.g. control groups, duration of treatment • Long term safety data (circumstances when needed) • Choice of comparator (placebo vs active comparator) • Statistical issues – stats plan, primary and secondary endpoints, exploratory endpoints • Enlargement of the safety data-base to support the safety sections of the SmPC • Inclusion of quality of life (QoL) and other pharmaco-economic endpoints to support pricing/reimbursement • Master protocols 	Beatrix Friedeberg Eli Lilly
10:00	Tea/ coffee break	
10:30	Safety <ul style="list-style-type: none"> • Pharmacovigilance - aims and objectives • Definitions • Clinical Trial Regulation – Reporting • Causality attribution • Risk management plans • PASS Studies • The SPC • Current EU Pharmacovigilance Legislation – mention Reference Safety Information (RSI) and new guidance 	TBC
11:30	Panel discussion	
12:00	Lunch	
13:00	Case study and feedback session <i>Tea to be taken in case study groups</i>	Katherine Bowen Boyd Consultants



Time	Activity	Speaker
15:15	The Perspective of a Regulatory Authority Reviewer <ul style="list-style-type: none">• Specific examples of what regulatory agencies look for• Common problems with the clinical data in MAAs• Reasons for different views and decisions between regulatory authority reviewers• Obtaining regulatory agency input and appropriate timelines<ul style="list-style-type: none">○ CHMP scientific advice versus national agency advice○ Implementation of advice received	Pavína Chladová State Institute for Drug Control (SUKL)
16:00	Summary	Chair
16:30	Close	

Delegates will be encouraged to ask questions throughout the day so as to ensure the meeting is as interactive as possible.