German Center for Infection Research
Product Development

CARB-X
Combating Antibiotic-Resistant Bacteria

INCATE

Agenda

PDU Training Program on Product Development

PDU-Workshop: Path(s) to transform your research into a product candidate

Day 1 | Thursday, 13th of November 2025:

Introduction, regulatory requirements and non-clinical development

Arrival & Coffee	**10:00 – 10:30**	
Chair: Nils Lilienthal		
Welcome and introduction What is translation?	**10:30 – 10:45**	**Nils Lilienthal** OSRA-BfArM
Introduction to DZIF and PDU	**10:45 – 11:05**	**Klaus Schwamborn** TPMO-VAC, Chair of DZIF-PDU
Introduction of participants	**11:05 – 11:30**	All participants
Case study of a successful product development: Hepcludex	**11:30 – 12:15**	**Stephan Urban** University Hospital Heidelberg
Lunch break	**12:15 – 13:15**	
Chair: Klaus Schwamborn		
Regulatory authorities, their roles, competencies and advice possibilities • Overview of the regulatory landscape in Germany and Europe • General overview of the legal framework (AMG, MPG, relevant EU regulations, etc.) • Regulatory pathways and licensing procedures in Germany and Europe	**13:15 – 14:00**	**Nadine Kirsch-Stefan** OSRA-PEI **Nils Lilienthal** OSRA-BfArM
Discovery process – What is a candidate?	**14:00 – 14:15**	**Thomas Hesterkamp** TPMO-DRUG
Product development towards a GMP process • Definition of GLP, GMP, GCP • Application of risk-based approach in development	**14:15 – 14:45**	**Timur Güvercinci** Consultant
Lab scale process development / technology transfer	**14:45 – 15:05**	**Wolfgang Hammerschmidt** Helmholtz Center Munich
Case study: EB-VLP	**15:05 – 15:35**	**Sebastian Goy** TPMO-VAC
Coffee break	**15:35 – 16:00**	
Non-clinical development, general considerations • Costs & timings of preclinical studies • Intersection of animal welfare and GLP, relevance of non-clinical studies in drug development	**16:00 – 16:30**	**Pia Empting** SciVii Labs
Breakout Sessions (A) or (B)		
Chair: Michael Schramm		
(A) Small molecules-specific non-clinical development • Non-clinical safety evaluation of small molecules • GLP toxicity testing and safety pharmacology • Short case study – CorA (30 min) • Q&A session (30 min)	**16:40 – 18:10**	**Andrea Teune** BfArM **Andrea Schiefer** University Hospital Bonn
Chair: Nadine Kirsch-Stefan		
(B) Biologicals-specific quality and non-clinical development • Quality and non-clinical safety evaluation of biologicals • Non-clinical GLP toxicology, efficacy and safety pharmacology studies • Short case study – DZIF-10c (30 min) • Q&A session (30 min)	**16:40 – 18:10**	**Nils Jost** PEI **Henning Grüll** University Hospital Cologne
Dinner at BfArM	**18:15**	

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Day 2 | Friday, 14th of November 2025:
Clinical development and funding sources

Start	**8:30**	
Chair: Thomas Hesterkamp		
Clinical trial design • Phases of clinical development • Design of clinical studies (in early development of drugs) • Complex study designs (e.g. adaptive, umbrella and basket studies) • Regulatory requirements and early steps	**8:30 – 9:15**	**Thomas Sudhop** BfArM
First-in-human clinical trials • Planning and implementation • Budgeting and timelines • Statistical considerations	**9:15 – 10:00**	**Ullrich Bethe** CTO
Coffee break	**10:00 – 10:30**	
Clinical trial application (CTA) • Process and timelines • Frequent questions on CTAs	**10:30 – 11:00**	**Saskia Borregaard** Consultant
Case study: TherVacB • Lessons learned on conducting clinical trials	**11:00 – 11:45**	**Marian Wiegand** Helmholtz Center Munich
Coffee break	**11:45 – 12:15**	
Chair: Nils Lilienthal		
FlexFunds process • Application process and parties involved • Important considerations and documents • Recommendations for the application / Things to consider • Involvement of TIs • Q&A session	**12:15 – 12:45**	**Klaus Cichutek** PEI, DZIF-IAB
Introduction to TI BBD	**12:45 – 13:00**	**Anna Wronska** TI BBD
Other sources for support and funding • INCATE • CARB-X • Others	**13:00 – 13:20**	**Silke Alt** TPMO-DRUG
Wrap-up and feedback	**13:20 – 13:30**	**Nils Lilienthal** OSRA-BfArM
End	**13:30**	

Venue
Federal Institute for Drugs and Medical Devices (BfArM)
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Organizers
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German Center for Infection Research (DZIF)
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