DZIF German Center for Infection Research

Federal Institute for Drugs and Medical Devices

Paul-Ehrlich-Institut

CARB-X Global Accelerator Network

DZIF/ BfArM / PEI Webinar Series

Clinical Workshop on Small Molecules and Biologicals - Part 2 -

Webinar
January - February 2023

Thursday, 19.01.2023

Session 1: Introduction on clinical development

Time	Topic	Speaker
3:00 pm – 3:05 pm	Welcome & introduction	**DZIF-PDU**
3:05 pm – 3:40 pm	The new clinical trial regulation – Regulation (EU) 536/2014	**Claudia Riedel** (BfArM)
3:40 pm – 4:30 pm	Introduction on clinical trials - Phases and designs of clinical studies (in early development of drugs) - Complex study designs (e.g. Umbrella and Basket studies) - Challenges for regulatory authorities in the approval, monitoring and licensing	**Thomas Sudhop** (BfArM)
4:30 pm – 5:00 pm	Documents for Clinical Trial Application (CTA)	**Saskia Borregaard** (Consultant)
5:00 pm – 5:15 pm	Closing remarks	
5:15 pm	End of first session	

Abbreviations: BfArM: Federal Institute for Drugs and Medical Devices, CARB-X: Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator, OSRA: Office for Scientific and Regulatory Advice, PEI: Paul-Ehrlich Institute, TPMO: Translational Project Management Office, KKS: Koordinierungszentrum für Klinische Studien

Thursday, 26.01.2023

Session 2: Role of ethics committee and supporting infrastructures

Time	Topic	Speaker
3:00 pm -3:30 pm	The role of ethics committees in biomedical research projects and clinical trials	**Sebastian Harder** (Ethics Committee, University Hospital Frankfurt)
3:30 pm – 4:00 pm	Presentation of the KKS-network in Germany	**Sebastian Klammt** (KKS Network)
4:00 pm – 4:30 pm	Presentation of the DZIF Clinical Trial Unit (DZIF-CTU)	**Sarah Heringer & Lea Tischmann** (University Hospital Cologne)
4:30 pm – 5:00 pm	Case study: BTZ-043 – a promising antibiotic for tuberculosis	**Julia Dreisbach & Florian Kloss** (LMU University Hospital Munich)
5:00 pm – 5:15 pm	Closing remarks	
5:15 pm	End of second session	

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Thursday, 02.02.2023

Session 3: Regulatory background of clinical studies

Time	Topic	Speaker
3:00 pm – 3:40 pm	First in human clinical trials – biologicals - Regulatory considerations - Common "mistakes"	**Karen Götz** (PEI)
3:40 pm – 4:15 pm	First in human clinical trials – small molecules - Regulatory considerations - Common "mistakes"	**Andrea Marzol** (BfArM)
4:15 pm – 4:45 pm	Case study: Discovery and development of bulevirtid (Hepcludex) the first approved medication to treat chronic hepatitis D infections	**Stephan Urban** (Ruprechts-Karls-University Heidelberg)
4:45 pm – 5:15 pm	Case study: Malaria vaccine PfSPZ	**Benjamin Mordmüller** (Eberhard-Karls-Universität Tübingen)
5:15 – 5:30 pm	Closing remarks	
5:30 pm	End of workshop	

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