DZIF/ BfArM / PEI Webinar Series

Clinical Workshop on Small Molecules and Biologicals
- Part 1 -

26.09. & 27.09.2022

Monday, 26.09.2022, Start at 1.30 pm (CET)
Session 1: Introduction & Regulatory Background

Time	Topic	Speaker
1:00 pm – 1:30 pm	Welcome Coffee	
1:30 pm – 1:45 pm	Welcome & Introduction	DZIF-PDU
1:45 pm – 3:00 pm	First-in-human - Regulatory Requirements - Phase 1a vs. 1b - Early steps	Maximilian Posch, PhD (Chief Medical Officer, Scirent GmbH, Berlin)
3:00 pm – 3:30 pm	Break	
3:30 pm – 4:30 pm	General study design	Martin Coenen, PhD (Medical Head of Phase I-Unit, Study Center Bonn)
4:30 pm – 5:00 pm	Mono- vs. multicentric studies	
5:00 pm – 5:45 pm	Hands-on experiences	Saskia Borregaard, PhD (Director Scientific Affairs, CTC-North, Hamburg)
5:45 pm – 6:00 pm	Discussion and further information	DZIF-PDU
From 7:00 pm	Get together	

Abbreviations: PDU: Product Development Unit, BfArM: Federal Institute for Drugs and Medical Devices, PEI: Paul-Ehrlich-Institut, CARB-X: Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (Subject to change without notice.)

Tuesday, 27.09.2022, Start at 9 am (CET)

Session 2: Application process and documents

Time	Topic	Speaker
9:00 am – 9:05 am	Opening remarks	DZIF-PDU
9:05 am – 10:20 am	Clinical Trial Application (CTA) - Investigator Medicinal Product Dossier (IMPD) - Investigator's Brochure (IB) - Study protocol	Hansjoerg Rittler, (Associate Director, Global Regulatory Oncology, Merck Healthcare KGaA, Darmstadt)
10:20 am – 11:05 am	Submission in several countries	Maximilian Posch, PhD (Chief Medical Officer, Scirent GmbH, Berlin)
11:05 am – 11:35 am	Labelling and release of IMPs	Hansjoerg Rittler, (Associate Director, Global Regulatory Oncology, Merck Healthcare KGaA, Darmstadt)
11:35 am – 12:15 am	Break	
12:15 am – 1:00 pm	Pitfalls (Response Letters)	Hansjoerg Rittler, (Associate Director, Global Regulatory Oncology, Merck Healthcare KGaA, Darmstadt)
1:00 pm – 1:45 pm	Vaccine specific aspects of early clinical trials	Gerald P. Parzmair, PhD (Chief Scientific Officer, Vakzine Projektmanagement GmbH, Hannover)
1:45 pm – 2:00 pm	Closing remarks	DZIF-PDU

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