

PDU Online Workshop: Early-phase clinical trials

Thursday, 7th of May 2026:

Start	15:00	
Chair: Nils Lilienthal and Nadine Kirsch-Stefan		
Welcome and introduction	15:00 – 15:10	Nadine Kirsch-Stefan OSRA-PEI, DZIF PDU
Fast Track to Europe: Navigating the new CTR process <ul style="list-style-type: none"> Regulatory aspects on clinical trials EU-Pilot project FAST EU 	15:10 – 15:35	Andreas Bonertz Section Clinical Trials, PEI
First-in-human clinical trials <ul style="list-style-type: none"> Design and statistical considerations Planning and implementation Budgeting 	15:35 – 16:30	Ullrich Bethe CTO, DZIF PDU
<i>Short break</i>	<i>10 min</i>	
Case study on clinical trial application via CTIS: Managing the process from submission to approval	16:40 – 17:10	Marian Wiegand Helmholtz Center Munich
How to fine-tune your clinical trial application - Frequently requested information by regulatory authorities	17:10 – 17:35	Claudia Riedel Department Clinical Trials, BfArM
Wrap-up and conclusion of the workshop	17:35 – 17:45	Nils Lilienthal OSRA-BfArM, DZIF PDU
End	17:45	

Videoconference

Webex

Link will be provided after registration before the workshop.

Organizers

Product Development Unit (PDU)
German Center for Infection Research (DZIF)

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