



Agenda

Workshop 24-November-2023

Early phase clinical development – Estimands, biomarkers and decision making

Registration for the workshop and pre-event get-together is required!

<https://forms.office.com/r/r6M1wZJVwz>

Registration Deadline 09-Nov-2023

23-November-2023

Informal get-together from 6:30 pm

Venue: Grohe Brauhaus, Nieder-Ramstädter Strasse 3, 64283 Darmstadt

24-November-2023

from 09:00	Registration, Coffee, Get Together	
09:30 – 09:45	Welcome	
09:45 – 12:30	MORNING SESSION	
09:45 – 10:30	Enablers of precision medicine - the evolution of high-dimensional wet & digital biomarkers in clinical development	Karl Köchert, Bayer Innocent Agueusop, Sanofi
10:30 – 11:00	Innovative Proof-of-Mechanism (PoM) Decision-Making based on Biomarkers	René Kubiak, Sanofi
11:00 – 11:30	Coffee Break	
11:30 – 12:00	Simulating Biomarker Data – niche or important tool for study planning and decision making?	Hannes Buchner, Staburo
12:00 – 12:30	Panel discussion	
12:30 – 13:30	Lunch Break	



Sprecher:

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Registration Deadline 01-Nov-2023

24-November-2023

13:30 – 15:45	AFTERNOON SESSION	
13:30 – 13:45	APF Working Group Updates	
13:45 – 14:30	Will you learn more from your oncology dose escalation by using the estimands framework?	Anja Victor, Merck KGaA
14:30 – 15:15	Estimand Framework: A New Lens for Single-Arm Early Clinical Trials in Oncology	Stefan Englert, Janssen
15:15- 15:45	Discussion on the value and challenges of using estimands in early phase clinical development	
15:45	End of the meeting and Final Coffee	

Meeting Venue:

Merck KGaA
Auditorium - Innovation Center
Frankfurter Strasse 250
64293 Darmstadt



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