



Agenda

<p>Workshop on 25. November 2022 Planning and Estimands for Safety/Benefit-risk External/Synthetic Control Arms</p>
<p>Registration for the workshop and pre-event get-together is required! https://forms.office.com/r/qENMjjhams Registration deadline 09-Nov-2022</p>

24 November 2022

Informal get-together (from 7 pm)

Wine and fingerfood at Cytel (details will be provided with the registration confirmation).

25 November 2022

from 09:00	Registration, Coffee	
09:30 – 09:45	Welcome	
09:45 – 12:45	MORNING SESSION	
9:45 – 10:10	Aggregated Safety Assessment Planning – Mission Impossible?	Jürgen Kübler, QSciCon
10:10 – 10:35	On the road to Benefit Risk Assessment Planning	Martin Gebel, Bayer
10:35 – 11:00	Safety Endpoints for HTA – what is needed in the future?	Katrin Kupas, BMS
11:00 – 11:30	Coffee Break	
11:30 – 11:55	Safety Estimands – One Size Fits All?	Anja Loos, Merck
11:55 – 12:45	Panel Discussion	Speakers, Armin Koch, Bill Wang
12:45 – 13:45	Lunch Break	



Sprecher:
 Dr. Frank Langer
 c/o Lilly Deutschland GmbH
 Werner-Reimers-Straße 2-4
 61352 Bad Homburg
 Tel.: +49 (163) 273 0235
 E-Mail: langer_frank@lilly.com

Stellvertreter:
 Prof. Dr. Christoph Gerlinger
 c/o Bayer AG
 13342 Berlin
 Tel: +49 (30) 2215 41328
 E-Mail: christoph.gerlinger@bayer.com

Dr. Frank Fleischer
 c/o Boehringer Ingelheim Pharma GmbH & Co KG
 88397 Biberach an der Riss
 Tel: +49 (7351) 54-2372
 E-Mail: frank.fleischer@boehringer-ingelheim.com

Dr. Thomas Bregenzer
 c/o Cytel
 Potsdamer Str. 58
 10785 Berlin
 Tel.: +49 (177) 7452315
 E-Mail: thomas.bregenzer@cytel.com

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Workshop on 25. November 2022

Planning and Estimands for Safety/Benefit-risk
External/Synthetic Control Arms

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25 November 2022

13:45 – 16:00	AFTERNOON SESSION	
13:45 – 14:00	APF business meeting	
14:00 – 14:30	External/Synthetic Control Arms in Early and Late Phase Clinical Development [overview/introduction]	Armin Schueler, Merck
14:30 – 15:00	Multistate Models for Early-phase Decision Making leveraging external/synthetic patient level control data	Ulrich Beyer, Roche
15:00 – 15:30	Synthetic Control Arms in Regulatory and HTA Assessments	Marco Ghiani, Cytel
15:30 – 16:00	AoB	
16:00	End of the working meeting and Final Coffee	

ATTENTION NEW VENUE:

Mövenpick Hotel Berlin
Saal Enzian
Schöneberger Str. 3
10963 Berlin

(S Anhalter Bahnhof, U Mendelssohn-Bartholdy Park)

Since networking is a key motivator for our workshops, this will be a face-to-face in-person meeting. No streaming, no video conferencing, etc.



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E-Mail: lang_frank@lilly.com

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c/o Bayer AG
13342 Berlin
Tel: +49 (30) 2215 41328
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Dr. Frank Fleischer
c/o Boehringer Ingelheim Pharma GmbH & Co KG
88397 Biberach an der Riss

Tel: +49 (7351) 54-2372
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