

Recent Advances In Clinical Trial Design

Friday March 23, 2018, Leiden (NL)

This meeting will offer participants the opportunity to interact with speakers from academia, regulatory agencies and industry on recent developments in designing clinical trials. Apart from presentations on a diverse range of topics including the use of modeling and simulation in designing a study, there will be a formal debate. The motion of the debate is "This house believes the arrival of Big Data makes controlled clinical trials obsolete". Members of the audience are invited to submit short contributions to the debate in writing to the organisers.

Draft Agenda

8:00 – 9:00	Registration, Refreshments
9:00 – 9:15	Welcome
9:15 – 10:00	Variances as ends not means: designing to understand variation <i>Stephen Senn, LIH (Luxembourg)</i>
10:00 – 10:45	Gaining Acceptance for Innovative Designs/Analyses in Pharmaceutical R&D <i>Andrew Grieve, UCB (UK)</i>
10:45 – 11:00	Tea & Coffee
11:00 – 11:45	Small populations and "big" – observational data? <i>Kit Roes, University of Utrecht (Netherlands)</i>
11:45 – 12:30	Accelerating clinical trials through the use of historical subject level data <i>Josephine Wolfram, Astellas (Netherlands)</i>
12:30 – 13:30	Lunch
13:30 – 15:00	Debate: "This house believes the arrival of Big Data makes controlled clinical trials obsolete." <i>Proponents: Billy Franks, Andy Grieve</i> <i>Opponents: David Brown, Stephen Senn</i>
15:00 – 15:15	Tea & Coffee
15:15 – 15:45	Model-informed study design <i>Martin Fink, Novartis (Switzerland)</i>
15:45 – 16:15	A robust Bayesian approach for borrowing information from animal data in first-in-man clinical trials <i>Lisa Hampson, Novartis (Switzerland)</i>
16:15 – 17:00	Current Statistical Considerations and Regulatory Perspectives on the Planning of Confirmatory Basket, Umbrella and Platform Trials <i>David Brown, MHRA (UK)</i>



Venue

Astellas Pharma Europe B.V.,
Sylviusweg 62,
2333BE Leiden,
Netherlands

Registration Costs

Fee includes lunch & refreshments

Industry	€190
Academic	€120
Students	<i>a limited number of places is available free of charge, please contact the organizers</i>

TO REGISTER PLEASE GO TO:

www.efspi.org

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Note that there is limited parking space. Public transport is recommended