Analysis of Safety Data

Friday June 23, 2017, Leiden (NL)

Safety data are the most common and one of the most important types of data collected in clinical trials. However, in general, the emphasis is on efficacy data. In this meeting, we will take a look at various aspects of safety data in clinical trials. Statisticians from different backgrounds will come together to discuss latest regulatory requirements, recent developments for the statistical analysis of adverse events, current practices in the conduct of data monitoring committees, and related topics on safety data in clinical trials. We will also hear thoughts on personalized safety analyses. During a podium discussion, delegates will have the opportunity to ask questions directly to the speakers.

Confirmed Speakers and Topics

Gerd Rosenkranz *(University of Vienna)*	**Can we identify patients at high risk of harm under a generally safe intervention?**
Axel Krebs-Brown *(Astellas)*	**A Brief Overview of the EMA Guidance on FiH Studies**
Kit Roes *(University of Utrecht)*	**An Insider's View of DMCs**
Adam Crisp *(GSK)*	**Decision Criteria for DMCs – The Sponsor's View**
Johannes Hengelbrock *(University of Hamburg)*	**Analysis of Recurring Adverse Events**
Maria Costa *(GSK)*	**Bayesian Benefit-Risk Analysis**
Bernd Heinen *(JMP)*	**Using Risk Indicators for Visualizing High-Dimensional Safety Data**
Robert Snijder *(Astellas)*	**How to Make Adverse Events Look Pretty**

Venue

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

For a route description, klick here.

Registration Costs

Fee includes lunch & refreshments

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

TO REGISTER PLEASE GO TO:
www.efspi.org

Or contact:

EFSPI Secretariat
Tel: +44 (0)1625 664549
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Note that there is limited parking space.
Public transport is recommended