PSDM

Pharmaceutische Statistiek & Data Management

- **Dutch network of statisticians, clinical programmers and data managers working in/for “pharmaceutical industry” (Life Sciences outside academic environment)**

- **Independent, non-profit organisation**

- **Facilitate professional conduct & development of its members**
- **Platform for exchange of expertise by meetings and workshops**
- **Excellent environment for networking and meeting colleagues**

History

- Beginning nineties acknowledge the need to create national network for our type of professionals
- Founded in 1993 as working group of the BMS of the VVS
- From the start an active member of the EFSPI
- Since 2003 PSDM joined the INCDMA
- PhUSE closely linked since 2016

VVS = Vereniging voor Statistiek en Operationele Research

EFSPI = European Federation of Statisticians in Pharmaceutical Industry

INCDMA =International Network of Clinical Data Management Associations

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Who are we?

vacancy
(Programming/SAS)

Corine Baljé-Volkers
(Author!)

Alexander Adema
(QPS)

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Frans Sollie
(PRA international)

Egbert Biesheuvel
(Nutricia Research)

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Recent activities

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, recent 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.

Agenda

8:00 – 9:00	**Registration and Coffee**
9:00 – 9:15	**Welcome**
9:15 – 10:00	**Gerd Rosenkranz (University of Vienna)** Can we identify patients at high risk of harm under a generally safe intervention?
10:00 – 10:30	**Axel Krebs-Brown (Astellas)** A Brief Overvie… …the EMA Guidance on FIH Studies
10:30 – 10:45	**Coffee**
10:45 – 11:30	**Kit Roes (U…**

EFSPI

PSD Pharmaceutische Statistiek

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For a…

8:00 – 9:00	
9:00 – 9:15	
9:15 – 10:00	
10:00 – 10:45	

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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

	Registration, Refreshments
	Welcome
	Variances as ends not means: designing to understand variation *Stephen Senn, LIH (Luxembourg)*
	Gaining Acceptance for Innovative Designs/Analyses in Pharmaceutical R&D *Andrew Grieve, UCB (UK)*

EFSPI

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Venue

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

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PSDM reminder:

Overview of CDASH and introduction to the new CDASHIG 2.0, 20th March 2018

CDASH 2.0

2.0 Release Date: 25 Sep 2017

CDASH 2.0 comprises the CDASHIG v2.0, the CDASH Model v1.0, and CDASHIG metadata tables to define basic standards for the collection of clinical trial data and how to implement the standard for specific case report forms.

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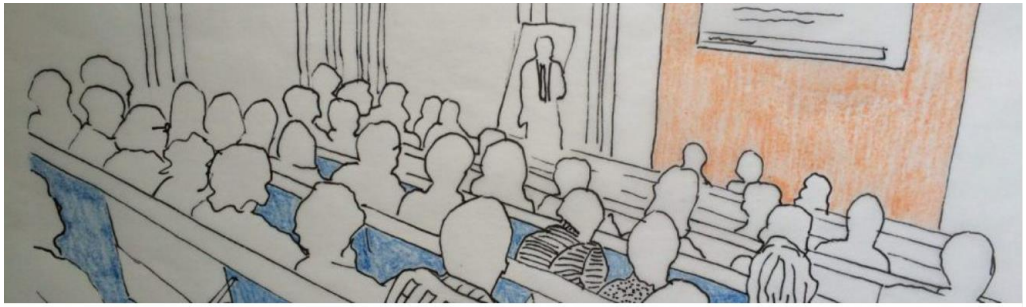

- If you have ideas for topics…
- please contact us www.psdm.nl
- Membership is free

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PHARMACEUTICAL STATISTICS AND DATA MANAGEMENT

Thanks for your attention

Enjoy this afternoon!

BIOSTATISTICAL CHALLENGES IN R&D: JOINT BMS-ANED AND PSDM MEETING