

PSDM

Pharmaceutische Statistiek & Data Management

- Dutch network of statisticians, clinical programmers and data managers working in/for “pharmaceutical industry” (Life Sciences)
- 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 ≥ 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?

Yasemin Atil
(OCS Consulting)



Corine Baljé-Volkers
(Author!)



Maritza Witteveen
(Procdm)



Egbert Biesheuvel
(Nutricia Research)



Frans Sollie
(PRA international)

Activities

Risk-based Monitoring: opportunities and challenges in clinical development

Biomarkers and Subgroups

Friday June 24, 2016, Leiden (NL)

Biomarkers are increasingly present in modern drug development. They can be used as predictive or prognostic markers, and ideally will help scientists understand why a patient responds in a particular way to treatment. When biomarkers are used to identify sub-groups of patients who are likely to benefit from new therapies, a whole host of challenges arises, and many of them are of a statistical nature:

- *How should biomarker development be included in clinical development planning?*
- *What do regulators expect to see to support a biomarker-based indication?*
- *How should we design a study that aims to identify a sub-group of patients with enhanced treatment effect, and what needs to be done to confirm this effect?*
- *What statistical methods are there to deal with these situations?*

In this meeting, experts from industry, academia and regulatory agencies will come together to discuss these challenges, with a focus on practical applications



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Venue

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

integration:
lessons learned

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- If you have ideas for topics...
please contact us www.psdm.eu

- Membership is free

Thanks for your attention

Enjoy lunch & the afternoon!

