

PSDM

Pharmaceutische Statistiek & Data Management

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Agenda of the Annual PSDM Meeting 2018 Wageningen, November 23, 2018 (12.00 hrs)

1. Opening
2. Annual Meeting 2018
 1. "From the Board"
 2. Finance
3. Board Members
4. Budget 2019
5. AOB
6. Closing

1. Opening

2. Annual Meeting 2018

2.1 From the Board

Welcome to our meeting.

As usual the PSDM has organized meetings for its members in 2018. This year we've had three events, including the one of today.

The first event took place on March 20th in Huizen. With the title '*Overview of CDASH and introduction to the new CDASHIG 2.0*', it was a meeting focused towards the data managers within our community.

This CDASH event was hosted by the SAS institute and attracted close to 50 attendees. The event consisted of an interactive session and several presentations by professionals from the field, about the recent updates to the CDASH standard as well as two case studies detailing the implementation of CDASH in specific scenarios. This event was very interesting for anyone working with data collection. The event's program, as well as several presentations from the event can be found on our website at the following url: <https://psdm.nl/psdm-cdash-event/>

In the same week, on March 23rd, we had a joined scientific meeting with EFSPi on '*Recent Advances in Clinical Trial Design*'. With almost 70 attendees and high-quality presentations it has been a very successful event. In particular, the pilot of the first formal debate was a successful exercise on the motion: "***This house believes the arrival of Big Data makes controlled clinical trials obsolete***" More details as well as all presentations of this event can be found here [https://www.efspi.org/EFSPi/Events/Archive_Items/Recent advances in Clinical Trials.aspx](https://www.efspi.org/EFSPi/Events/Archive_Items/Recent_advances_in_Clinical_Trials.aspx)

This last meeting has been the third joint scientific meeting together with EFSPi in a row hosted by Astellas:

In 2016, we organised our first joint event (Biomarkers and subgroups), in 2017, our 2nd joint event on '*Analysis of Safety Data in Clinical Trials*' on June 23, and this year our 3rd joint event on the '*Recent Advances in Clinical Trial Design*'.

Unfortunately, due to the closure of Astellas R&D business in Leiden, this has been the last event hosted by Astellas. Again, a large pharmaceutical company with a long presence in the Netherlands and with a department of data managers, programmers and statisticians has decided to stop our type of activities. We feel sorry for the Astellas people.

Today's meeting is a joint meeting with the BMS-ANed on '*Biostatistical Challenges in R&D*' with speakers from both industry and academia. Please realise that formally the PSDM is a working group of the BMS-ANed (<https://www.vvsor.nl/biometrics/pages/organization/>). We hope today's

symposium is a nice way to allow attendees to interact with members from both organisations and enhance interaction between statisticians from the industry and the academia.

New this year is the General Data Protection Regulation. As a working group of the BMS, we will follow the VVS and BMS-ANed wrt GDPR to comply with the new rules on personal data.

We are in the planning phase for 2019 and would like to organize at least 1, but preferably 2-3 events for our members, being data managers, clinical programmers and statisticians working in or for the pharmaceutical industry or similar.

Suggestions for relevant topics as well as other ideas for future events are welcome.

We will keep you informed via e-mails and through our website.

2.2 Financial overview PSDM 2018 31DEC17

(not enclosed – will be discussed at the meeting)

3. Board Members

In 2018 the board consisted of the following members.

Board members 2018:

• Chairman (and EFSPI):	Egbert Biesheuvel (Director Data Sciences AMN, Nutricia, Utrecht)
• Secretary (Statistics and Registration Biostats):	Corine Baljé-Volkers (Head Biostatistics and Programming, Author!, Hilversum)
• Treasurer (and Statistics):	Frans Sollie (Statistician, PRA International, Zuidlaren)
• Data Mng (and INCDMA):	Alexander Adema (Senior Clinical Data Manager, QPS, Groningen)

Egbert represents PSDM in the EFSPI (European Federation of Statisticians in the Pharmaceutical Industry)

Corine is also active in the registry committee and

Alexander is active in the INCDMA (International Network of Clinical Data Management Associations)

As already mentioned earlier, Maritza Witteveen (Data Management Coach, Pro-CDM, Huis ter Heide (UT)) stopped her activities after the CDASH event in March,

As a result, we don't have a direct representative for the statistical programmers, and therefore we encourage you to contact us if you want to strengthen our board, in particular to represent the programmers among us.

4. Budget 2019

(not enclosed – will be discussed at the meeting)

5. Any Other Business

6. Closing