

PSDM

Pharmaceutische Statistiek & Data Management

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Agenda of the Annual PSDM Meeting 2017 Huizen, March 20, 2018

1. Opening
2. Annual Meeting 2017
 1. "From the Board"
 2. Finance
3. Board Members
4. Budget 2018
5. AOB
6. Closing

1. Opening

2. Annual Meeting 2017

2.1 From the Board

Although it is already March 2018, we didn't have an event in the last quarter of 2017 and as such this is the first opportunity to have our formal annual meeting of 2017.

The last event organised by the PSDM was the joined scientific event with EFSPi on '*Analysis of Safety Data in Clinical Trials*' on June 23, 2017 in Leiden, hosted by Astellas. With more than 60 participants and well-known speakers this was a successful event.

More details as well as all presentations of this event can be found here

https://www.efspi.org/EFSPi/Events/Archive_Items/European_Statistical_Meeting_on_Analysis_of_Safety_Data.aspx

In 2016, we organised our first joint event together with EFSPi (Biomarkers and subgroups), in 2017, our 2nd joint event mentioned above, and this year on March 23, 2018 we will have our 3rd joint event on Recent Advances in Clinical Trial Design. All three events are hosted by Astellas in Leiden.

Due to the recent announcement of Astellas to close its R&D business in Leiden, this will unfortunately be 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.

The intention to organise a PSDM event more focused towards the data managers within our community started in 2017. Therefore we are happy with today's event on '*Overview of CDASH and introduction to the new CDASHIG 2.0*' hosted by SAS in Huizen.

As we strive for two events per year, we are perfectly on track. Nevertheless, we may want to organise another event in the second half of 2018.

We will keep you informed via e-mails and through our website, which functions very well since the major update it received in 2016.

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

2.2 Financial overview PSDM 2017 31DEC17

(not enclosed – will be discussed at the meeting)

3. Board Members

Beginning of 2017 the board consisted of the following members.

Board members 2016 and early 2017:

- Chairman (and EFSPI): Egbert Biesheuvel
(Director Data Sciences AMN, Nutricia, Utrecht)
 - Secretary (Statistics and Registration Biostats): Corine Baljé-Volkers
(Consultant Biostatistics, Author!, Hilversum)
 - Treasurer (and Statistics): Frans Sollie
(Statistician, PRA International, Zuidlaren)
 - Data Mng (and website): Maritza Witteveen
(Data Management Coach, Pro-CDM, Huis ter Heide (UT))
 - Programming (and PhUSE): Yasemin Atil
(Business Unit Manager – Biometric Support Services, OCS Consulting, 's Hertogenbosch)
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In May 2017 we have welcomed Alexander Adema (QPS) to strengthen our team. Alexander is Data manager at QPS, Groningen. Alexander started informally but in the meantime, his membership has been formally approved by the VVS (the PSDM is a working group of the VVS). Alexander will also represent us at the INCDMA.

After her pregnancy leave Yasemin has decided to stop her PSDM activities. We would like to thank Yasemin for her contributions to the PSDM: thank you!

Maritza together with Alexander have organized today's meeting on CDASH. After this event, Maritza will also stop her activities for PSDM. Maritza, thank you for co-organizing today's meeting and your contributions to the PSDM.

As a result, the board in 2018 will consist of:

Board members 2018:

- Chairman (and EFSPI): Egbert Biesheuvel
(Director Data Sciences AMN, Nutricia, Utrecht)
 - Secretary (Statistics and Registration Biostats): Corine Baljé-Volkers
(Consultant Biostatistics, Author!, Hilversum)
 - Treasurer (and Statistics): Frans Sollie
(Statistician, PRA International, Zuidlaren)
 - Data Mng (and ICDMA): Alexander Adema
(Senior Clinical Data Manager, QPS, Groningen)
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At the moment, 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 2018

(not enclosed – will be discussed at the meeting)

5. Any Other Business

6. Closing