



Pharmaceutische Statistiek & Data Management

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## **Agenda of the Annual PSDM Meeting Weesp, December 1, 2016**

1. Opening and announcements
2. Feedback since last Annual meeting 2013 (September 1, 2013, Leiden)
3. Annual Meeting 2016
  1. "From the Board"
  2. Scientific Activities
  3. Finance
4. Board Election
5. Budget 2017
6. AOB
7. Closing

## 1. Opening and Announcements

## 2. Feedback since last Annual meeting 2013

## 3. Annual Meeting 2016

### 3.1 From the Board

So far 2016 has been a good year when looking at our aim to have two (scientific) local events a year, and to have a good representation of our disciplines of data managers, (SAS) programmers and statisticians in the pharmaceutical industry or related businesses.

Our last annual meeting has been in 2013.... Let's explain a little bit.

In 2011 we already discussed the difficult landscape of the pharmaceutical industry in the Netherlands during the PSDM meeting hosted here in Weesp, June 2011 "*The future of PSDM disciplines*". The reason of this topic was the recent reorganization examples of Astellas (most SAS programmers external), closing of Genzyme (upcoming) and the implemented reductions at MSD. Sadly, it didn't end in 2011, because since then, this situation continued with the closure of MSD (2014), and the recent reorganization of Abbott (2016) as examples.

In 2013 we had our last Annual Meeting together with a successful event "*Risk-based monitoring: opportunities and challenges in clinical development*" hosted by Astellas in Leiden.

In 2014 we did not have any scientific event and as a consequence also no Annual Meeting. Part of the explanation was that the chair of PSDM (Egbert) temporarily lost his position.

Luckily, in 2015 we had a successful event on the "*Implementation of CDISC standardization: Pragmatic Approaches*" hosted by SAS in Huizen, in September. Mainly due to the timing of this event, we did not have an Annual Meeting.

This year, in 2016 PSDM was co-organiser of the joined EFSPI/PSDM meeting on "*Biomarkers and Subgroups*" hosted by Astellas in June. See section 3.2 for more details.

In summary, we are happy to be back on track with having a second event this year and an Annual Meeting 2016.

As you may have noticed we also have a new website! The main reason was that our old website was built in older software and did not allow us to change contents on the website easily by ourselves. The new website is based on modern software and provides us with much more and easier access rights. Maritza (our new board member) has done an excellent job in taking the lead on this.

In addition, she was not the only change in the PSDM board since 2013. Please see section 4 for more details.

### **3.2 Scientific Activities**

The last event organised by the PSDM was the joined scientific event with EFSPI on Biomarkers and Subgroups on June 24 2016 in Leiden. With 7 speakers and more than 50 participants, this was a successful event on this interesting topic on biomarkers & subgroups. Due to the organisational structure, PSDM joined at a later state, and as such we did not had a financial share in this meeting.

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

[http://www.efspi.org/EFSPi/Events/Archive\\_Items/Biomarkers\\_and\\_Subgroups.aspx](http://www.efspi.org/EFSPi/Events/Archive_Items/Biomarkers_and_Subgroups.aspx)

Today's event on DATA SHARING is hosted by Abbot, Weesp. Since the introduction of the EMA policy on publication of clinical data in October 2014, data sharing is an on-going hot topic in clinical development. Next to sharing of clinical reports it also concerns the publication of Individual Patient Data (IPD) in the future. Obviously this will help physicians and patients making better decisions and is in the advantage of researchers too. Today's meeting has various speakers who will highlight important aspects of the dynamic topic and present two case studies of DATA SHARING.

With a forward looking view to 2017, PSDM is planning to organise two events in 2017. Although the preparations are very preliminary at this moment, we are in discussion to have a joined meeting of PSDM/EFSPi on Safety Data before the summer break hosted by Astellas.

Preparations of the second event have not been started, so please feel free to forward ideas for topics to us.

### **3.3 Financial overview PSDM 20162 per 31DEC16**

(not enclosed – will be discussed at the meeting)

As a recap:

In 2013/2014 we have clarified the legal responsibilities of the PSDM workgroup of the BMS/ANed (which is a section of the VVS). It was concluded that the best and most practical option was to strengthen the relationship with the BMS/ANed. ANed is a formal association and is registered at the Chamber of Commerce. ANed has opened a new bank account dedicated to the PSDM to ensure that the finances of ANed and PSDM will remain separate. The only noticeable difference for the PSDM will be that the treasurer of the ANed will receive our yearly financial overview and budget, which will be presented in the yearly BMS/ANed member meeting.

## 4. Board Election

As mentioned in Section 3, we have had some board changes since 2013.  
Please find here the board members in 2013.

In 2013, the board consisted of:

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• Chairman (and EFSPI):	Egbert Biesheuvel (Director Late Dev Statistics, MSD, Oss)
• Secretary:	<i>to be decided</i>
• Treasurer (and BMS):	Sophie Swinkels (Team Leader Statistics, Danone Research, Wageningen)
• Statistics:	Frans Sollie (Statistician, PRA International, Zuidlaren) Wouter Wijker (Head Statistics, Auxiliis Pharma, Budapest, Hungary)
(and Registration Biostats)	<i>Corine Baljé-Volkers (New), Manager Biostatistics and Medical Writing at QPS Netherlands BV, Groningen)</i>
• Data Mng (and INCDMA):	Martijn Oostendorp (Senior Data Manager, Julius Clinical, Zeist)
• Programming (and PhUSE):	Yasemin Atil (Business Development, OCS Consulting, 's Hertogenbosch)
• Assistance	Frank Kok (previously Senior Statistician, CROMSOURCE, Vianen)

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We would like to thank once more the board members, who have left us (being Frank Kok, Wouter Wijker, Martijn Oostendorp and Sophie Swinkels).

And we would like to propose Maritza Witteveen, from Pro-CDM, as new member.  
(If agreed, the Biometrische Section of the VVS has to approve formally as required by our regulations as well.)

In 2016, the board consists of:

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• Chairman (and EFSPI):	Egbert Biesheuvel (Sr. Teamleader Data Sciences AMN, Nutricia, Utrecht)
• Secretary (Statistics and Registration Biostats):	Corine Baljé-Volkers (Consultant Biostatistics, Author!, 's Graveland)
• Treasurer (and Statistics):	Frans Sollie (Statistician, PRA International, Zuidlaren)
• Data Mng (and website):	<i>Maritza Witteveen (Data Management Coach, Pro-CDM, Huis ter Heide (UT)) - NEW</i>
• Programming (and PhUSE):	Yasemin Atil (Business Unit Manager – Biometric Support Services, OCS Consulting, 's Hertogenbosch)

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## **5. Budget 2017**

(not enclosed – will be discussed at the meeting)