

PSDM

Pharmaceutische Statistiek & Data Management

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Agenda of the Annual PSDM Meeting Oss, November 8, 2012

1. Opening and announcements
2. Feedback Annual Meeting 2011 (November 18, 2011)
3. Annual Meeting 2012
 1. "From the Board"
 2. Scientific Activities
 3. EFSPi
 4. INCDMA
 5. Finance
4. Board Election
5. Budget 2013
6. AOB
7. Closing

3. ANNUAL MEETING 2012

3.1 From the Board

So far year 2012 resembles the previous year 2011. The pharmaceutical landscape in the Netherlands is more stable than the years before, although even in 2012 there are companies in restructuring with major consequences for our disciplines (e.g. Genzyme). And similar to 2011, PSDM has been able to organize two events in 2012: a successful event in June on the topic of Open Source Software in Clinical Research (see also 3.2) and today's workshop on Adaptive Designs.

Due to the restructuring of programming activities at Astellas in 2011, Edwin van Stein decided to stop his board membership. Therefore we have been looking for a replacement of Edwin to represent the discipline of programmers within our board. See Section 4 for more details.

This year PSDM didn't organize a joined event with EFSPI like last year, however, newsletters of EFSPI have been forwarded to you by PSDM on a regular basis. The relationship with INCDMA which started a few years ago is in good shape and exchanging information is working well, see also Section 3.4.

Last years annual meeting took place in Brussels at the combined EFSPI meeting on Missing Data. Due to the location we had a limited agenda with a limited number of participants. As a result we don't have formal minutes, but we will give feedback on the annual meeting of 2011 at this meeting.

On request we have decided to change the language of the annual meeting as well as the minutes into English to allow that non-Dutch speaking members can participate.

3.2 Scientific Activities

Two events were scheduled for 2012. On the 19th of June a workshop on “Open Source Software in Clinical Research: cost-saving opportunity or high-risk solution?” was held. This event was hosted by Julius Clinical Research BV in Zeist. Four speakers were planned to participate in this event, unfortunately one speaker declined his participation at the day of the meeting, and as such no replacement could be found anymore.

Nevertheless the meeting went in a good spirit and there were a lot of animated discussions during the whole afternoon. The day started with the presentation of Philippe Lamote who discussed the potential the Innovative Medicines Initiative Projects could have for open source projects in Europe. A vast amount of European funding is waiting to be spent on projects in this area and the audience was stimulated to come forward with project.

The second speaker of the day was Dimitris Rizopoulos who gave an introduction to the use of R for clinical research. R is open source software, and Dimitris showed the audience the capabilities of R. His talk was followed by a vivid discussion of the use of SAS, as the default program in our industry, versus the use of R, especially as used in registration trials.

The last speaker, Kevin Kane, gave an overview of the latest developments in the FDA/PHUSE initiative to create the reporting facilities based on the CDISC standards. The day ended with a plenary discussion about the use of open source software in clinical trials, after which discussions could be continued during the social part of the meeting. More than 40 people participated in this event, which by all was considered a successful meeting.

The second activity of this year is a course on adaptive designs by Professor Andy Grieve to be held at November 8th. The course will be hosted by MSD in Oss. More details can be found on the PSDM website (PSDM.nl)

For 2013 the PSDM is minimally planning to have two events. The first will probably be an event dedicated to risk based monitoring, the second event, during the autumn, will be most likely centered on 'The International Year of Statistics' (See also www.statistics2013.org)

3.3 EFSPI

European Federation of Statisticians in the Pharmaceutical Industry

EFSPI celebrates its 20 years anniversary! EFSPI was founded on August 3, 1992 by 7 countries and currently has 10 national organisations that are members: Belgium (SBS/BVS), Denmark (DSBS), Finland (SSL), France (SFdS B&S), Germany (APF), Italy (BIAS), Netherlands (PSDM), Sweden (FMS), Switzerland (BBS) and UK (PSI). Collectively the national organisations within EFSPI serve approximately 2800 statisticians and statistical programmers.

One of its main activities is to organize scientific events on relevant topics. In 2012 EFSPI has been organizing three events:

- Benefit-Risk Assessment Methodology Workshop in Malmö Sweden on June 7, a joined event with the FMS and DSBS. A successful meeting with almost 50 participants
- Modelling and Simulation and applications with longitudinal data in Basel, Switzerland on September 13, a joined meeting with the BBS and MSB. Also a successful meeting with approximately 85 participants
- European Statistical meeting on Sub-group Analyses in Brussels, Belgium on November 30.

Slide decks and additional information of the first two events can be found on EFSPI website www.efspi.org (tab 'EFSPI activities')

In June 2012, the 3rd Statistical Leaders meeting took place and was hosted by Abbott, Weesp, the Netherlands. Representatives of most major pharmaceutical companies within Europe were attending. Topics in this 3rd successful meeting were: Risk Benefit, Adaptive Statisticians & the Challenges beyond Clinical Trials, update of the Special Interest Groups (SIGs), Career Path and a brain steering session on 'Strategic Do's and Don'ts for the statistical community in EU pharma'. Most SIGs have been initiated by the PSI but are now also EFSPI groups to encourage non-UK based statisticians to join. The Career Path initiative has submitted a paper to an international journal.

The afternoon session was focused on the changes in the pharmaceutical landscape, in particular within Europe, the impact on statisticians and the way to move forward.

Information of all three EFSPI Statistical Leaders meeting can be found on the EFSPI website www.efspi.org. (tab 'EFSPI activities')

On the 19th of November EFSPI will organize its first webinar on the exciting topic "Are we finding the right dose(s) in Phase II?"

EFSPI is sending regular Newsletters to all of their national organizations, with updates on regulatory affairs, scientific meetings and other council news.

The next EFSPI council will take place in December.

3.4 INCDMA

International Network of Clinical Data Management Associations

INCDMA (International Network of Clinical Data Management Associations) has organized a Hot Topic Discussion Webinar in collaboration with, and hosted by, ACDM (Association for Clinical Data Management): eSource data transcription and EDC Integration: thumbs up - or "off with their heads". It proved to be a very successful event, chaired by two experienced speakers David Quarm and Michel Arnoult. Around 30 persons joined the Webinar, originating from multiple local Data Management organizations (including PSDM), 8 countries and different companies (pharma, food, CRO, EDC vendors, academics, etc). This resulted in a very interactive session with a very international feel to it. Due to the positive response INCDMA aims to organize similar Hot Topic Webinars on a regular basis. Next one is targeted for Q1 2013. Possible topics include "changes in Data Management oversight", "risk-based monitoring" and "eSource data transcription" (which proved such a hot topic that it deserves a second session). INCDMA was also able to promote itself on the DIA Clinical Forum (October 2012, The Hague, Netherlands). However, due to travel restrictions of its members, no presentation was provided by INCDMA this year.

3.5 Financial overview PSDM 2011 per 31DEC11

(not enclosed – will be discussed at the meeting)

4. Board Election

Edwin van Stein has decided to stop as board member due to his change in work environment. We would like to thank Edwin for his contributions to the board and helping in the organization of our events.

Edwin was representing the discipline of programming within our board. We have noticed that it is important to have board members to represent each of our disciplines: data management, programming and statistics. Therefore we have been looking for a replacement of Edwin and we are glad to announce that we have been successful.

We are proposing Yasemin Atil, Business Development, OCS Consulting to replace Edwin in the board of PSDM as a representative for programming. (She has already been formally approved by the Biometric Section of the VVS, as required by our regulations.)

The board will then consist of:

- Chairman and EFSPI: Egbert Biesheuvel (Director Late Dev Statistics, MSD, Oss)
- Secretary: Frank Kok (Senior Statistician, CROMSOURCE, Vianen)
- Treasurer: Frans Sollie (Statistician, PRA International, Zuidlaren)
- Statistics: Sophie Swinkels (Team Leader Statistics, Danone Research, Wageningen)
Wouter Wijker (Head Statistics, Auxiliis Pharma, Budapest, Hungary)
- Data Management and INCDMA: Martijn Oostendorp (Senior Data Manager, Julius Clinical, Zeist)
- Programming: Yasemin Atil (Business Development, OCS Consulting, 's Hertogenbosch)

5. Budget (Begroting) PSDM 2012/2013

(not enclosed – will be discussed at the meeting)