

# 14<sup>th</sup> International Congress of TDM & Clinical Toxicology

Rotterdam, The Netherlands

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## Immunosuppressive Drugs Scientific Committee Meeting

Monday 12<sup>th</sup>, October 2015, 12:15-13:15

### Minutes

#### Attending members:

Maria Shipkova, Dennis A. Hesselink, Ofelia Noceti, Olga Millian, Mercè Brunet, Pawel Kunicki, Tomasz Pawinski, Michael Oellerich, Klemens Budde, Eberhard Wieland, Michael Milone, Loralie Langman, Pierre Wallemacq, Pierre Marquet, Uwe Christians, Stein Bergan, Christoph Seeger, Satoshi Masuda, Carol Thompson, Alexander Vinks, Laure Elens, David Holt, Markus Barten Teun van Gelder (partly).

#### Guests:

Dario Cattaneo, Don S. Mason, Anders Åsberg, Iain McPhee

1. Maria Shipkova opens the meeting and welcomes all attending members of the Committee and guests. As a new member Michael Milone was welcomed. All attendees briefly presented themselves.
2. Maria Shipkova gave a short summary of the activities 2014-2015. The full report was distributed electronically to the members in advance and will be posted on the website.
3. Suggested projects 2016-2017
  - 3.1. Thomas Pawinski and Pawel Kunicki reported on difficulties in obtaining bioequivalence data for generic immunosuppressive drugs which delayed the scheduled review. They would like to stay with project and are going to prepare the

review article on generic immunosuppressive drugs and TDM next year. They will approach with help of committee members pharmaceutical companies to get more PK information of the generic drugs. Klemens Budde suggested that also authorities such as FDA should be approached.

3.2. Pierre Marquet suggested focusing more on TDM of biodrugs (antibodies and recombinant proteins). He proposed to develop standardized LC-MS methods using pure and labeled peptides. Once these methods have been established prospective clinical trials investigating the potential benefit of a TDM guided therapy and models may be approached and developed.

3.3. Michael Oellerich claimed that better standardization of methods for immunosuppressive drug monitoring is needed. It was agreed that a project group lead by Christoph Seeger or Uwe Christians will try to persuade the Industry to prepare standard reference material and to set up a reference method. David Holt suggested to approach Michael Mussel at LCG for this purpose. It was also decided to ask IATDMCT for financial support.

3.4. Thomas Pawinski announced a symposium organized by the ISD committee under the auspices of IATDMCT 4th EFLM-UEMS congress, Poland, Warsaw, September 2016. Speakers will be Pierre Marquet, Dennis Hesselink and Pawel Kunicki. Eberhard Wieland is the scientific chair of this congress.

3.5. Maria Shipkova offered to design a template with the categories of educational material for the resources area of the website according to the results of the survey which was done by the directors of education. This list will be distributed to all committee members and everybody is asked to fill in the material she/he can provide or think that we should make available for the website.

In addition, Maria Shipkova proposed to produce 1 podcast/year. She talked to Pierre Marquet about posting his lecture on TDM of once daily formulations of tacrolimus and to Christoph Seeger about a presentation summarizing the recommendations of the opinion paper on analytical methods to assure proper measurement of ISDs, which has been recently submitted to *Therapeutic Drug Monitoring*. Maria Shipkova will also collect information about the technical requirements to produce podcasts and will deliver this information to the committee members.

- 3.7. Satoshi Masuda will represent the ISD committee in the organizing committee of the Kyoto 2017 meeting. The new Chair of our Committee D. Hesselink will submit on behalf of the ISD committee proposals for the program.
- 3.7. Dennis Hesselink suggested an update of the Tacrolimus Consensus Document from 2011. This proposal was highly appreciated.
3. Mercè Brunet gave an update of the work of the BWG. Two symposia were organized in Barcelona one in 2014 and one in 2015. A Consensus Document on biomarker monitoring will be published alongside with single papers on specific topics in a special issue of *Therapeutic Drug Monitoring*. Her report is part of the committee report mentioned above, which has been already forwarded to the members.
4. Elections: The Vice Chair Dennis Hesselink will become the Chair of the Committee for the period 2016-2017. As a new Vice Chair Mercè Brunet was elected (10 votes for Stein Bergan, 11 votes for Mercè Brunet). Uwe Christians will step in and become the Leader of the BWG.
5. Any other business: None

Maria Shipkova, October, 14. 2015

Modifications by D.A. Hesselink, November, 11. 2015

Addendum (November 2015):

Under point 1.

After the meeting, Donald S. Mason from Waters Company, Dirk-Jan Moes, PharmD, PhD (Hospital Pharmacist / Clinical Researcher / Pharmacometrician) from Leiden University Medical Center, the Netherlands, Nils Tore Vetthe, PharmD, PhD (Clinical Pharmacologist / Researcher) from Oslo University, Norway, and Iain MacPhee, MD, PhD, expressed their interest in our committee and decided to join.

Under point 3.3

After the meeting it was decided, that this project would be led by the co-chairs Christoph Seeger, Uwe Christians, Maria Shipkova and Loralie Langman in partnership with the IFCC.