

Invitation MEB Regulatory Science Day

Is drug treatment gender neutral?
Gender during the drug life-cycle

8 FEBRUARY 2018 / 12:00-18:00 (INCLUDING LIGHT LUNCH)

DE MUNT, LEIDSEWEG 90, 3531 BG UTRECHT





Program

Chair dr. Peter van Meer

- 12.00 - 13.00 **Registration and lunch**
- 13.00 - 13.10 **Opening and introduction**
Dr. Peter van Meer, assessor (MEB/UU)
- 13.10 - 13.30 **Migraine in women**
Dr. Antoinette Maasen, pharmacologist and associate professor EUR
- 13.30 - 13.50 **Differences between women and men in Adverse Drug Reactions**
Dr. Sieta de Vries, post-doc RUG
- 13.50 - 14.10 **Inclusion of women in clinical trials, a regulator's perspective**
Dr. Christine Gispen, researcher MEB
- 14.10 - 15.00 **Break and regulatory science pitch podia**
PhD Candidates and students
- 15.00 - 15.20 **Methodological implication of gender (differences) for clinical trials and postmarketing research**
Prof. dr. ir. Eric Boersma, Professor of Clinical Epidemiology of Cardiovascular Diseases EUR MC, board member MEB
- 15.20 - 15.40 **Gender differences in effectiveness of rheumatic disease treatment**
Dr. Irene van der Horst, rheumatologist VUMC
- 15.40 - 16.00 **Reflection on the day**
Jannet Vaessen, director Women Inc
Prof. dr. Ton de Boer, chair MEB Board / UU
- 16.00 - 16.30 **Panel discussion**
Panel: Dr. Antoinette Maasen, Dr. Sieta de Vries, Prof. dr. ir. Eric Boersma, Dr. Irene van der Horst
- 16.30 - 18.00 **Drinks and networking**



About

Gender is increasingly becoming an important issue in drug development, treatment and monitoring. Initially the discussion focussed whether women are underrepresented in clinical trials, but report more adverse reactions compared to men after marketing authorization has been granted. Currently the focus of the discussion is moving towards recognising gender differences in pathophysiology of diseases and nonspecific complaints probably are not (always) that nonspecific as has generally been assumed. Better understanding of gender differences is paramount to offer improved diagnosing and treatment options to both men and women. Consequently, this might have a positive effect on drug development in the future.

It should be no surprise that the previous minister of Health has rightly called for attention to gender differences. The task of the regulator is to ensure that efficacious and safe medicines are available for all patients, men and women alike, and the evidence from studies with an experimental drug should be assessed with this in mind. Meanwhile, in the process of establishing benefit/risk it remains a challenge to determine which data are important for healthcare practitioners and how to best present these in the label, taking into account legislative consequences. It is essential that this discussion takes place with all stakeholders and is based on scientific evidence.

This is the main goal of this MEB Science Day: promote and share our endeavours in regulatory science with our collaborating (academic) partners and to enhance knowledge and network building: 'The knowledge of the world is only to be acquired in the world and not in the library' (after Lord Chesterfield 1694-1773).

Registration

Deadline for registration is February 1st 2018. Please use the link below to register:
<http://www.formdesk.com/collegeterbeoordelingvangenees/wetenschapsdag2018>

After registering, you will receive a mail confirmation in your inbox.

For more information:

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