EUGenMed Workshop
Medicines Regulation

Hildrun Sundseth
President
European Institute of Women’s Health
Expert Workshop Participants

Co-chair: Ingrid Klingmann, EFGCP
Hildrun Sundseth: EIWH

Christiane Druml, Vice Rector, Medical University of Vienna
Marco Stramba-Badiale, Dept of Geriatrics & CVD Medicine, IRCCS Milan
Fabio D’Atri, Sante, European Commission
Katrin Fjeldsted, CPME,
Kevin Blake, European Medicines Agency
Lode Dewulf, UCB
Laurene Souchet, European Patients Forum
Sophie Peresson, IDF
Ute Seeland, Charite
Ineke Klinge, Maastricht
Medicines Regulation
Why consider S&G

- Medicines are safer and more effective for all when clinical research includes diverse population groups of all ages
- Women are under-represented in many clinical trials and if included, robust analysis is often lacking
- Sex differences of tissues and cells, every cell has a sex
- Women metabolise medicines differently
  \textit{example: Ambien} - FDA halved dose for women
“The general assumption prevailed that women did not differ from men except where their reproductive organs were concerned and data obtained from clinical research involving men could simply be extrapolated to women.”

Considerations for Inclusion of Women in Clinical Trials and Analysis of Data by Sex – 2013 Guidance Document
Sex and Gender in Medicines Regulation

- Translating the evidence from S&G research into regulatory practice will lead to more targeted, effective opportunities for prevention, diagnosis, treatment and care.
Major Step forward – New Clinical Trials Regulation EU 536/2014

• Unless otherwise justified in the protocol, the subjects participating in a clinical trial should represent the population groups, for example gender and age groups, that are likely to use the medicinal product investigated in the clinical trial.

• A justification for the gender and age allocation of subjects and, if a specific gender or age group is excluded from or underrepresented in the clinical trials, an explanation of the reasons and justification for these exclusion criteria.
Specific considerations for vulnerable populations

Article 10.3

Where the subjects are pregnant or breastfeeding women, specific considerations shall be given to the assessment of the application for authorisation of a clinical trial on the basis of expertise in the relevant condition and the population represented by the subject concerned.
WS Medicines Regulation
Recommendations

- Ethics Committees to develop guidelines that address inclusion of women in CTs, following good practice example from Medical University of Vienna

- Stakeholders to propose IMI project to develop robust methodology for subgroup analysis, address existing barriers for the recruitment and retention of women and older people in CTs
WS Medicines Regulation
Recommendations

• In preparation of implementing new Clinical Trials Regulation, EMA together with key stakeholders draft Guidelines on S&G analysis in CTs (example: Health Canada, FDASIA)

• Improve rigorous sex and age-specific pharmacovigilance reporting for existing products

• Address knowledge gap: develop regulatory framework for safe use of medicines during pregnancy: post-marketing data collection, common rules for pregnancy exposure registries, etc.
• EMA to follow the FDA Snapshot example and make sex- and age-specific data more readily available and transparent

• http://www.fda.gov/Drugs/InformationOnDrugs/ucm446899.htm

Source: FDA, 2015
Example: FDA Snapshot
Atrial Fibrillation: Savaysa

SAVAYSA Baseline Demographics
21,026 patients

Female 8006
38%

Male 13,020
62%

Source: FDA, 2015