Session 1.4

Medicines Regulation and Medical Education

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Objectives of Session 1.4

- This session will concentrate on current medicines regulations, clinical trials, legislation, good clinical practice guidelines and research policies and how these support implementation of sex and gender aspects.
- It will also discuss the integration of sex and gender in medical training

1. Medical Regulation

Defining the context

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2. How are Sex & Gender issues included in the regulatory assessment?

- Do we currently have data from clinical trials for a robust analysis of S&G?
- How will inclusion of women in Clinical Trials allow for a more robust analysis?
- Present situation, new Clinical Trials Regulation?
- How do Ethics Committees consider the S&G perspective?
- Are women included as members of Ethics Committees?
- Do we need Guidelines for Ethics Committees to address these aspects?
- How do GCP Guidelines include S&G considerations?

3. How can we fulfill unmet medical needs?

- What can we do about the unmet medical need of pregnant women who have to take medicines for their chronic condition?
- Include them in Clinical Trials under strict conditions?
- Pregnancy registers, post-marketing surveillance?
- How can IMI 2 include S&G in their research projects?

4. Medical Education

- What is the current CPME position regarding S&G in medical training?
- How can medical associations promote the integration of S&G in general practice and specialty training?
- How to integrate S&G in continuous medical education (CME) across Europe?
- What tools are available to help integrate S&G into medical education?

4. Medical Education

- How do we campaign for S&G guidelines for medical education at EU and national level? At bachelor/master level?
- What are the education/training requirements of clinical trial experts and regulators to include S&G considerations?
- How can we involve medical students in the process?

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