# MSP AG pre-read

MSP AG

17.09.2026

# MSP AG pre-read

- ACT EU Focus groups:
  - Risk-based approaches
  - Training for academia and SME
  - Sponsors serious breaches notifications
- ACT EU activities on contractual agreements
- Reminder on public consultation on cross border clinical trials in paediatric
- MedEthicsEU status update
- Women’s health workshop

# Focus groups update

- **Focus group on risk-based approaches**
  - Valuable contribution of the focus group providing use cases on risk appropriate safety management
  - A revised draft of the document on risk proportionate approaches in clinical trials has been prepared during summer and is currently in consultation within the drafting group
  - Next steps:
    - Review of drafting group consultation
    - Preparation of a mature draft to share with reference groups in fall

# Focus groups update

- **Focus group on training for academia and SME**
  - Monthly focus group meetings with EU regulators, academia and SME stakeholders' members
  - List of criteria for appraising existing trainings finalised
  - Draft list of existing training modules created
  - First mock webpages for ACT EU website being developed
  - Draft change management strategy created
  - Collaboration with WHO training group

# Focus groups update

## Focus group on Serious breaches reporting

- **19 March 2026** - Kick-off meeting of the focus group, discussing proposed updates to the serious breaches sponsor guideline available in EudraLex, Volume 10.
- Over summer consultation with the focus group, also to include additional examples of serious breaches to be reported
- **20 July 2026** - Consolidated review of the focus group comments (>160) discussed with the European Medicines Regulatory Network (EMRN).
- Relevant Focus Group feedback integrated into the revised draft.
- Next steps – presenting the revised text within the relevant EMRN working groups

# Contractual agreement

Follow up actions after 1st webinar held in April 2026:

**Centralisation of existing contractual templates**

- Collection of existing models in consultation with the EU Member States
- Signposting of existing models on the ACT EU website
- Website go-live expected by the end of the year displaying contractual models organised by Member States for easy access

**Second webinar by end of 2026**

- Bring together National and EU-level experiences on clinical site agreements between sponsors and trial sites.

**Checklist of key considerations (long term deliverable)**

- Develop a practical checklist of key considerations for drafting and negotiating multinational clinical trial contracts which might focus on specific aspects, like data protection
- Further discussions needed

# Public consultation on cross-border access to paediatric clinical trials

- E-mail regarding public consultation circulated to the MSP AG on 17 July.
- The deadline for comments, originally 31 August, has been extended to **30 September**.
- For convenience:
  - draft recommendations - **Cross-border access to paediatric clinical trials in Europe: preventing language exclusion**
  - **Consultation template**
  - Completed templates should be sent to **enprema@ema.europa.eu**
- Following the consultation, EnprEMA will review all comments received and publish a revised version of the recommendations.

# MedEthicsEU

- The MedEthicsEU updates presented at the previous MSP AG meeting (18 June 2026) remain relevant.
- Please refer to the presentation for details.

EMA
EUROPEAN MEDICINES AGENCY

# Multistakeholder workshop on women's health

## 28-29 September 2026


MSP AG – 17 September 2026

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# Background and objectives

## Background

- Why now?
- Women's health activities
  - DARWIN EU studies
  - Framework contract studies
  - Pregnancy community
  - ICH E21
  - Webpage / corporate website
  - Afternoon talks
  - Video on women's health
  - **Multistakeholder event**

## Objectives

- highlight the contribution of the EMRN partners to women's health, including the impact of regulatory frameworks, scientific committee activities, and epidemiological evidence;
- take stock of current gaps and challenges, drawing on epidemiological data, clinical research, and patients' and healthcare professionals' experience;
- explore opportunities to strengthen the evidence base and support more inclusive and representative clinical research;
- bring together perspectives from stakeholders and global partners to identify priority areas for action;
- contribute to the identification of actionable steps and potential indicators to measure meaningful progress.

# Women’s Health Workshop: key information

- Co-chaired by EMA Executive Director and the Head of the AEMPS
- Two-day hybrid workshop hosted at EMA in Amsterdam
  - 28 September 2026: 09:30–17:10 CEST
  - 29 September 2026: 09:00–18:00 CEST
- In-person and online participation, with broadcast access
- Online registration open until **15 September 2026**
- Registration link: Multistakeholder workshop on women’s health

- Latest information and updates: Multistakeholder workshop on women’s health | European Medicines Agency (EMA)
- Learn more about EMA’s work on women’s health: Women's health | European Medicines Agency (EMA)

# Day 1: Setting the scene

**09:50 Session 1: Setting the scene**

*Moderators: Pilar Aquar (EC) and Steffen Thirstrup (EMA)*

**Session introduction** **5'**
*Moderators*

**The Patient perspective** **15'**
*Sandrine Dumont (Fertility Europe)*

**The European Institute of Women's Health perspective** **15'**
*Peggy Maguire (EIWH)*

**Healthcare professional perspective** **15'**
*Elena Petelos (European Public Health Association and European Forum for Primary Care)*

**The EU perspective** **15'**
*Orsolya Symmons (European Innovation Council)*

**Women's health in medicines regulation & guidelines in the EU** **15'**
*Patrick Vrijlandt (MEB)*

# Day 1: Uncovering gaps in data

**11:15 Session 2: Uncovering gaps in data**

*Moderators: Peter Arlett (EMA) and Outi Mäki-Ikola (FIMEA, CHMP vice-chair)*

**Session introduction** **5'**
*Moderators*

**Learning from epidemiological studies** **30'**
*Patrice Verpillat (EMA), Andrej Segec (EMA) and María Clara Restrepo-Méndez (EMA)*

**Representation of women in clinical trials** **15'**
*Marianne Lunzer (AGES)*

**Developing an infrastructure for data generation on medicine safety in pregnancy and breastfeeding** **15'**
*Hedvig Nordeng (University of Oslo)*

**Panel discussion and audience interaction** **60'**
*Peggy Maguire (EIWH)*
*Elena Petelos (European Public Health Association)*
*Orsolya Symmons (EIC)*
*Meritxell Sabidó Espin (EFPIA)*
*Miriam Sturkenboom (ConcePTION, UMCU)*

# Day 1: Progress and challenges in medicines development

**14:20 Session 3: Progress and challenges in medicines development**

*Moderators: Marianne Lunzer (AGES) and Michael Berntgen (EMA)*

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| **Session introduction**<br>*Moderators* | **5′** |
| **The EU perspective – EP**<br>*Billy Kelleher (EP)* | **15′** |
| **DG Research and Innovation perspective**<br>*Pilar Aguar (EC)* | **15′** |
| **Healthcare professional perspective**<br>*Piotr Szymanski (Co-chair of the HCPWP)* | **15′** |
| **Industry perspective**<br>*Rita Lobo (EUCOPE)* | **15′** |
| **Academic perspective** | **15′** |
| **Panel discussion**<br>*Pilar Aguar (EC)*<br>*Piotr Szymanski (Co-chair of the HCPWP)*<br>*Rita Lobo (EUCOPE)*<br>*Sandrine Dumont (Fertility Europe)*<br>*Academic speaker (TBD)* | **60′** |

# Day 2: Making it happen: defining actions

**09:15 Session 4: Making it happen: defining actions**

*Moderators: Bruno Sepodes (INFARMED, CHMP chair) and Francesca Day (EMA)*

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| **Session introduction**<br>*Moderators* | **5'** |
| **Patient perspective**<br>*Janis Morrissey (European Heart Network)* | **15'** |
| **Healthcare professional perspective**<br>*Marta Mosca (European Alliance of Associations for Rheumatology)* | **15'** |
| **Industry perspective**<br>*Jonathan Douxfils (Medicines for Europe)* | **15'** |
| **Gates Foundation perspective** | **15'** |
| **Panel discussion**<br>*WHO Speaker*<br>*Janis Morissey (European Heart Network)*<br>*Marta Mosca (European Alliance of Associations for Rheumatology)*<br>*Jonathan Douxfils (Medicines for Europe)*<br>*Gates Foundation Speaker*<br>*Gisela Abbam (Dove Foundation for Global Change)* | **60'** |

# Day 2: Reproductive health – Medicines in pregnancy & breastfeeding

**11:40 Session 5: Reproductive health – Medicines in pregnancy & breastfeeding**

*Moderators: Corinne de Vries (EMA) and Catherine Paugam-Burtz (ANSM)*

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| **Session introduction**<br>*Moderators* | **5'** |
| **Good pharmacovigilance practices (GVP) guidelines**<br>*Ulla Wändel Liminga (Swedish Medical Products Agency)* | **15'** |
| **Post-authorisation studies of medicines in pregnancy**<br>*Kelly Plueschke (EMA)* | **30'** |
| **Patient and HCP perspectives on including pregnant and breastfeeding women in clinical trials**<br>*Patient speaker (TBD)*<br>*Fionnuala McAuliffe (EBCOG)* | **30'** |

# Day 2: Reproductive health – Inclusion of pregnant & breastfeeding individuals in development programs

**14:00** **Session 6: Reproductive health - Inclusion of pregnant & breastfeeding individuals in development programs**

*Moderators: Giorgia Beardi (AIFA) and Sam Schoenmakers (EMA)*

**Session introduction** **5'**
*Moderators*

**Clinical trials in pregnancy & breastfeeding** **15'**
*Corinne de Vries (EMA)*

**How can this work in practice?- insights from Principal Investigators** **30'**
*Jane Salmon (Lupus and APS Center of Excellence)*
*Wessel Ganzevoort (Amsterdam UMC)*

**Industry perspective** **15'**
*Marie Teil (EFPIA)*

**Assessor experience** **15'**
*Carlijn Litjens (MEB)*

**Panel discussion with audience interaction** **60'**
*Corinne de Vries (EMA)*
*Jane Salmon (Lupus and APS Center of Excellence)*
*Ana Olearova (Ethics representative, Slovakia)*
*Kaveeta Vasisht (FDA)*
*Patient representative (TBD)*
*Marie Teil (EFPIA)*
*Carlijn Litjens (MEB)*

# Day 2: Shaping the way forward

**16:40 Session 7: Shaping the way forward**

*Moderator: Melanie Carr (EMA)*

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| **Session introduction**<br>*Moderator* | **5'** |
| **Panel discussion with audience interaction**<br>*Emer Cooke (EMA)*<br>*Maria Lamas (AEMPS)*<br>*Pilar Aguar -online (EC)*<br>*Agnes Mathieu-Mendes (DG SANTE)*<br>*FDA Representative (FDA)*<br>*Delese Mimi Darko (African Medicines Agency)*<br>*Peggy Maguire (EIWH)*<br>*Global perspective (Gates foundation + WHO - TBD)*<br>*Industry rep (TBD)* | **60'** |

# What next?

# Thank you