EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ICH E21: inclusion of pregnant & breastfeeding individuals in clinical trials

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An agency of the European Union

Presentation outline

- EMA strategic approach to reducing the information gap of medicine B/R in pregnancy & breastfeeding
- Addressing the information gap: what's in scope for ICH E21

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Pregnancy & breastfeeding considerations in EU marketing authorisations: reality of medicine use in pregnancy

130 million births globally per annum, 5 million in Europe

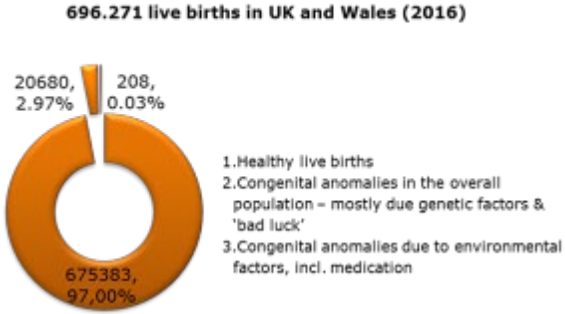
In high resource countries:

90% of pregnant women take medications in pregnancy

- 25% chronic diseases
- Infections
- Complications of pregnancy
- Unplanned pregnancies

Similar disorders, plus 10% postnatal depression, in breastfeeding

Labelling information on pregnancy & breastfeeding generally uninformative



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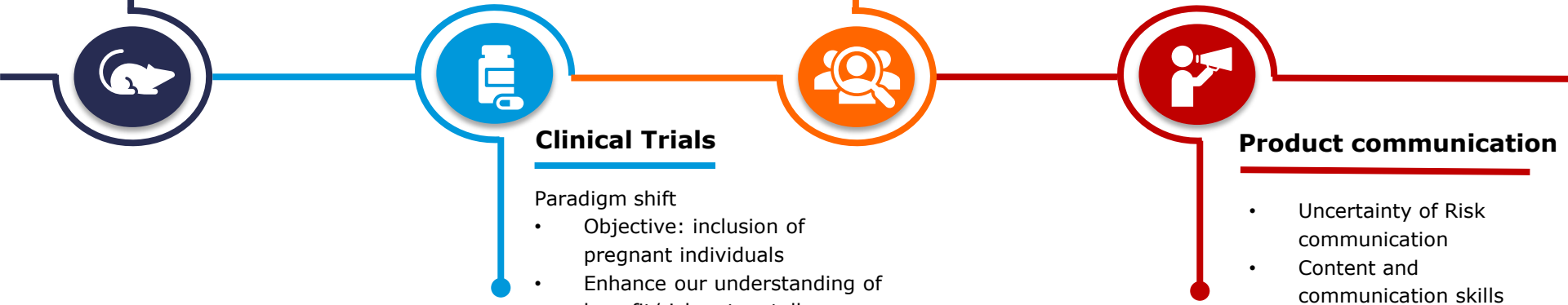
Pregnancy strategy: opportunities throughout product life cycle



Preclinical

- Better use of PK
- Development of novel methodologies

Clinical Trials

Paradigm shift

- Objective: inclusion of pregnant individuals
- Enhance our understanding of benefit/risk antenatally
- Obtaining the benefits while protecting the women

Post-authorisation

- Better use of existing & development of novel methods & infrastructure

Product communication

- Uncertainty of Risk communication
- Content and communication skills

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Addressing the information gap

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ICH E21: including pregnant & breastfeeding individuals in clinical trials

- Scientific & regulatory principles to ensure appropriate inclusion
- Considerations regarding data collection on dosing, clinical efficacy & safety
  - Trial design
  - Timing of inclusion
  - Strategies for generating data
  - Impact of the treatment modality
- Bridging principles to other ICH guidelines e.g. S5, M3, E11
- Strategies for timing of preclinical testing
- Considerations for the use of prior knowledge to inform assumptions for foetal exposure and metabolism

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Consensus Building – Technical Document content

- Clinical Development Plan
  - From ‘exclude unless’ to ‘include unless’; opportunities for lactation / breastfeeding studies; does this fit with timing of reprotox studies
- Study Design & Outcomes
  - RCT vs open label, design implications when retaining vs recruiting, what exposure measures & outcome measures, implications of the fact pregnancy lasts 9 months
- Recruitment and Retention Strategies
  - If & when to change to open label arm, unblinding or not
- Ethical, Regulatory and Legal considerations (high level)

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Work plan: Key Milestones

Expected Completion date	Deliverable
Jul 2023	Submited updated Work Plan
Jun – Dec 2023	Continue drafting Technical Document (Step 1)
Oct/Nov 2023	Face-to-Face meeting to work on the Technical Document
Q1/Q2 2024	*Consultation with other WGs*
Jun 2024	*Face-to-Face meeting to discuss and implement input from the WGs and advance drafting of Technical Document*
Q4 2024	*PWP review and incorporate feedback*
Q1 2025	Step 1 Sign off

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Thank you

Further information

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