



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Measuring the Effectiveness of Risk Minimisation Measures

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The Risk Minimisation Plan

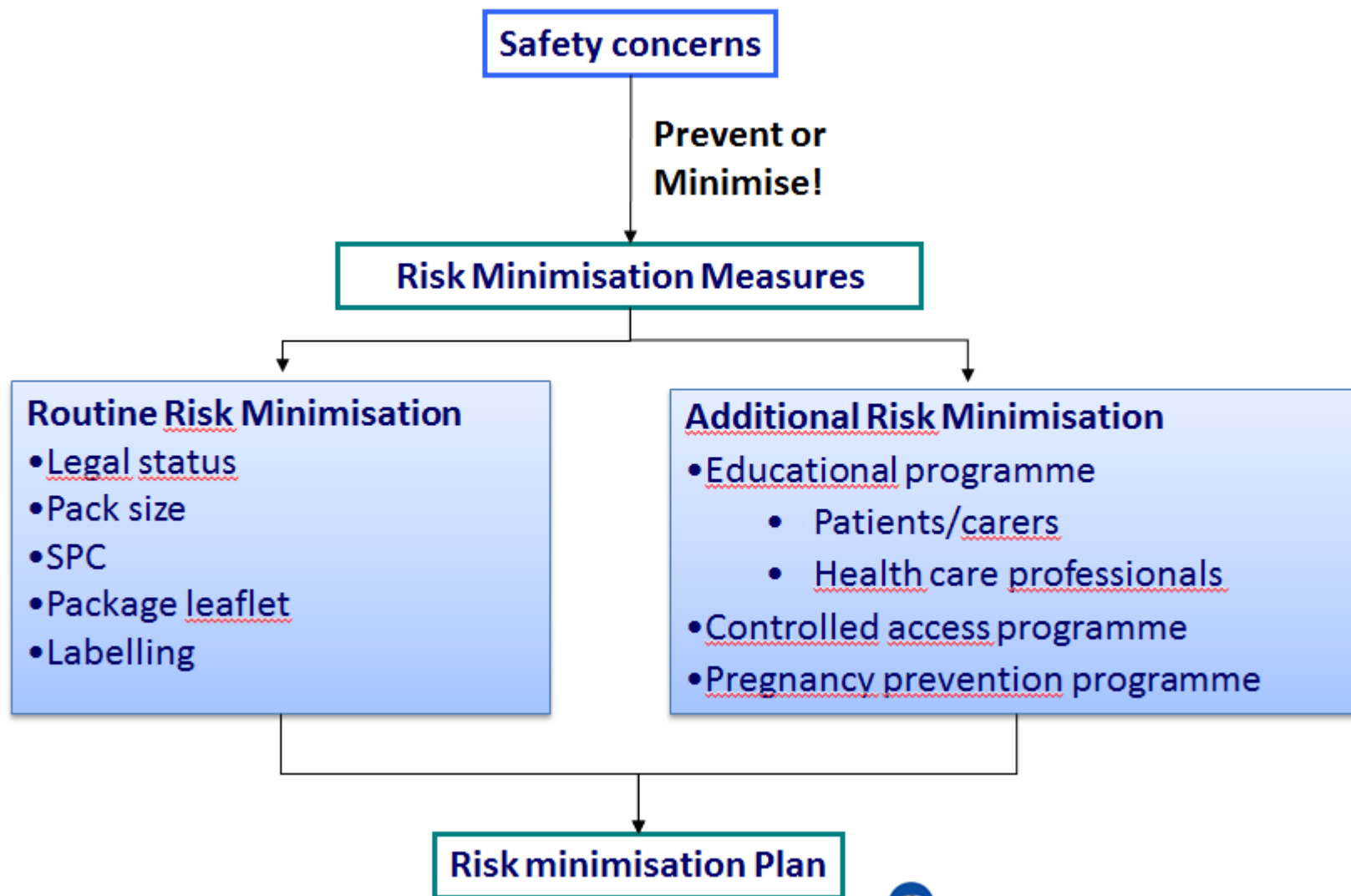
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An agency of the European Union





# Risk Minimisation Measures





# Additional RMMs

## 1. Educational Programme

- *For HCP: e.g. Prescribing Guide/checklist; Safety Guide*
- *For Patients/Carers: e.g. Alert Card; Reminder Card*

## 2. Controlled Access Programme

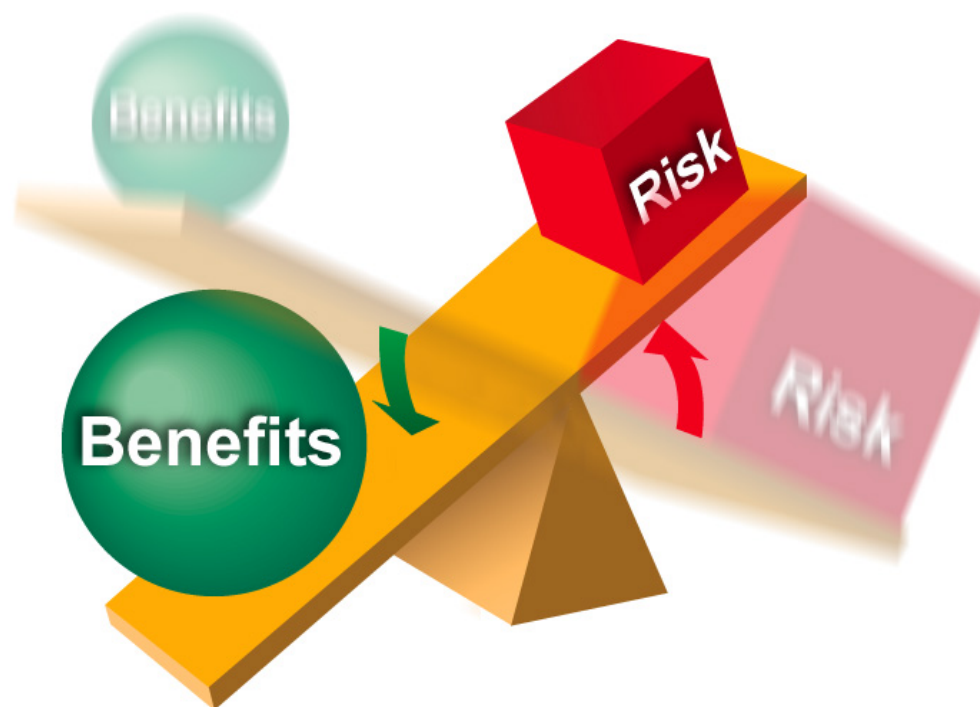
- Access subject to compliance with specific RMMs applied at the level of prescribing, dispensing, or use of a medicinal product. E.g:
  - Specific testing and/or examination of the patient to ensure compliance with strictly defined clinical criteria
  - Patient enrolment in a registry

## 3. Pregnancy prevention programme:

- A set of interventions to prevent pregnancy during treatment with a product with potential/known teratogenicity
- Male fertility: Interventions may involve the father

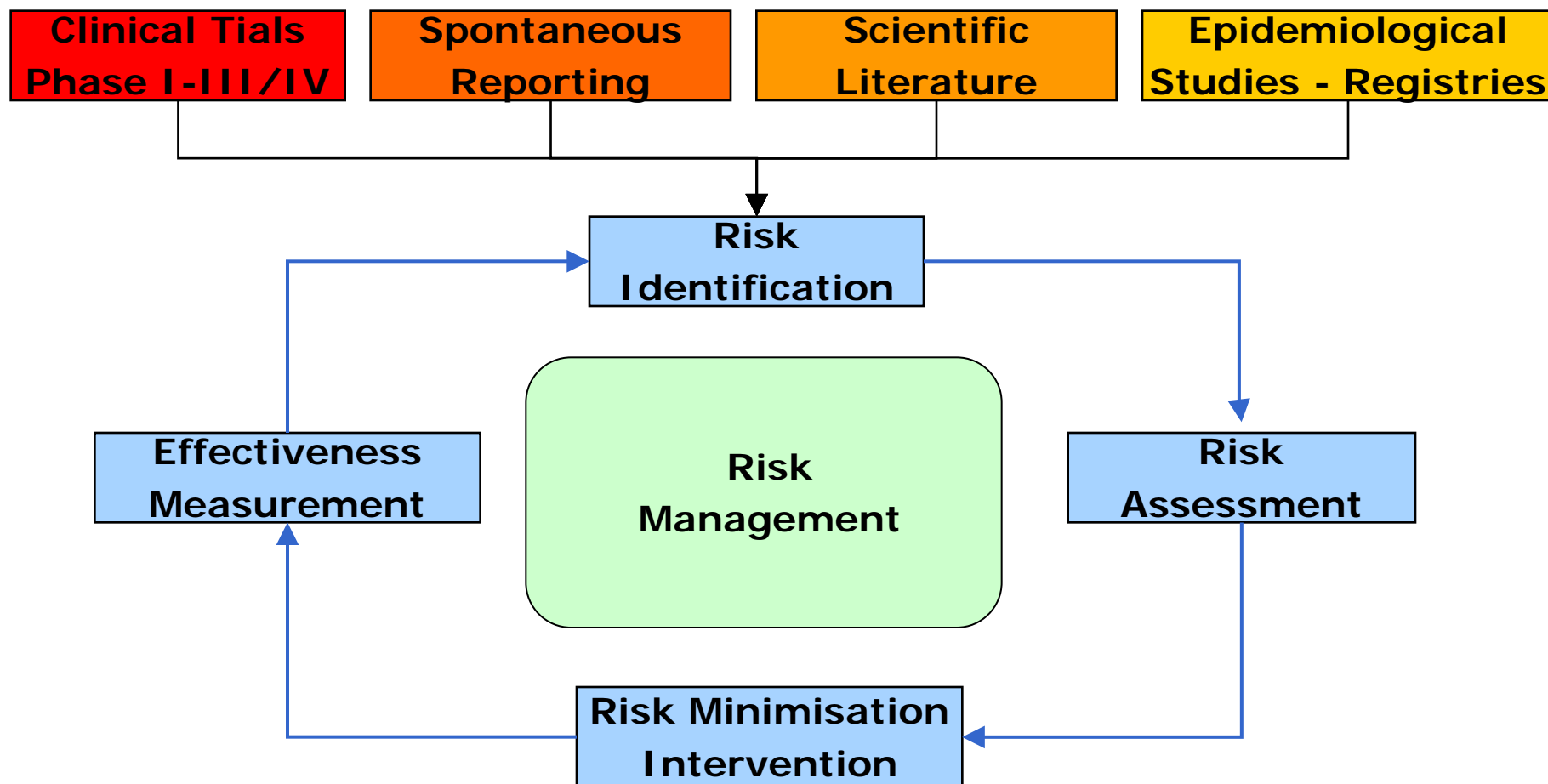
# RMMs: Why To Assess the Effectiveness

- Legislation requires **active monitoring of the outcome** of risk minimisation measures
- Crucial aspect of continuous pharmacovigilance



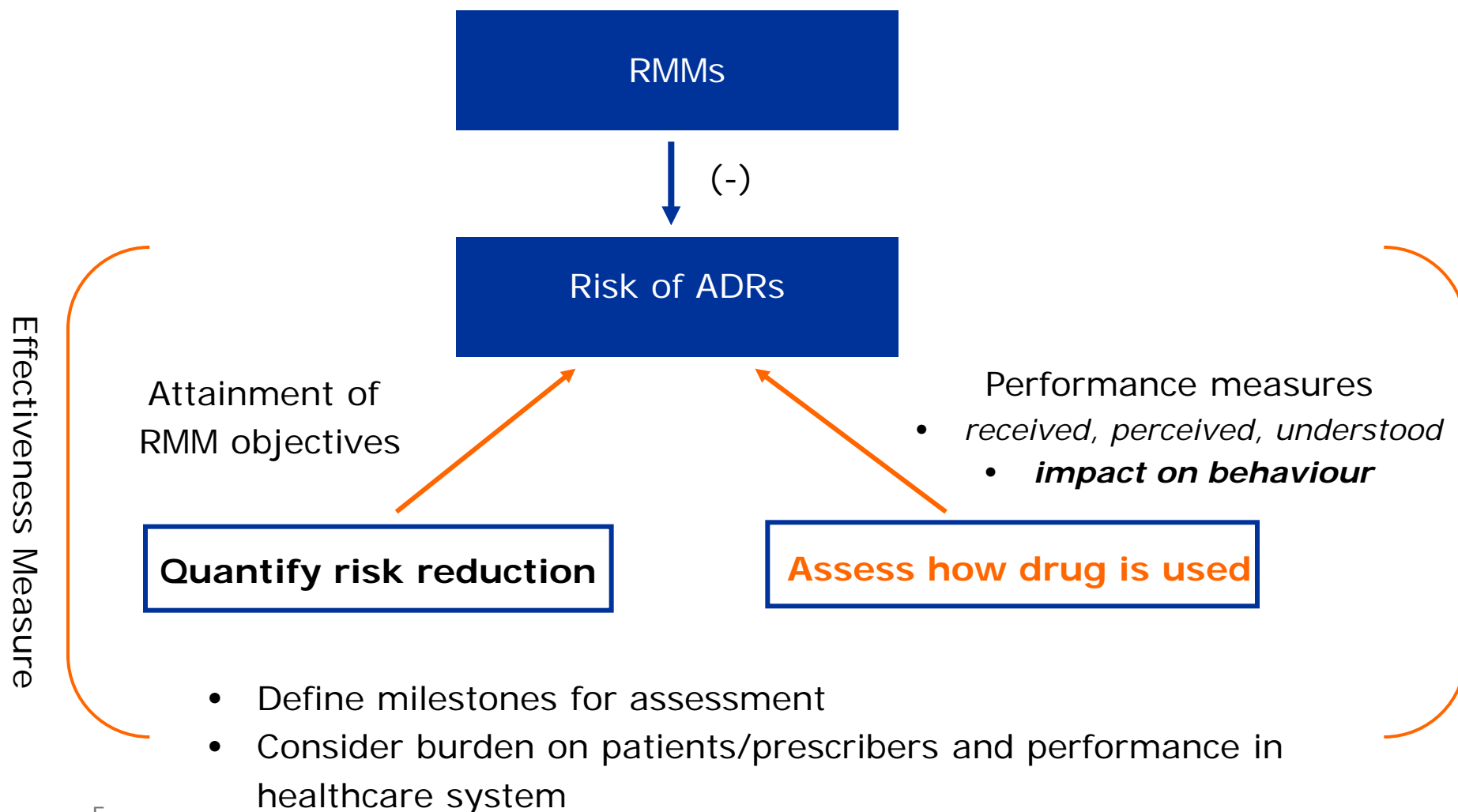


# Risk Management Cycle



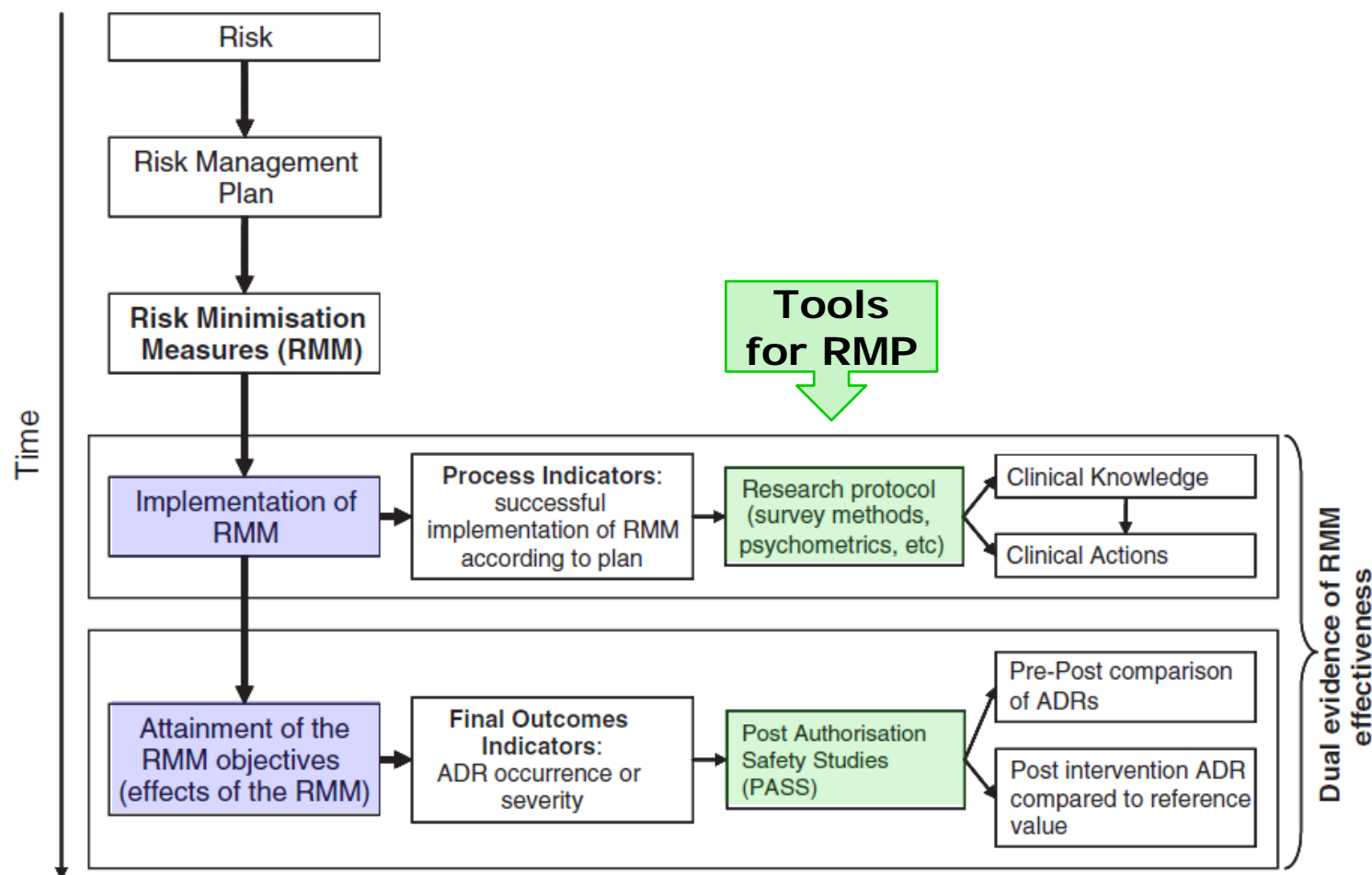


# RMMs: How To Assess The Effectiveness





# Dual Approach to assess effectiveness





# Patients Contribution

- Survey targeting patients and/or HCPs
  - To monitor understanding and knowledge by means of appropriate psychometric measures (e.g. was an educational intervention *received*, *perceived*, *understood*?)
  - To evaluate the impact of interventions on behavior
- Prospective observational studies
  - Pregnancy registry
  - Disease/product registry
- Spontaneous report of ADR
- Studies conducted by mean of secondary use of electronic records:
  - Anonymised electronic databases across EU





# Thank you!

