

euromedicat

# EUROmedICAT

Safety of Medication Use in Pregnancy



## Background

- Drug use during pregnancy is common - 40-90% women use at least 1 drug in pregnancy.
- Safety in pregnancy for many drugs has not been established at the time of licensing because 1) animal studies are seriously limited in their ability to predict human teratogenesis\* and 2) pregnant women are excluded from pre-marketing clinical trials in humans.
- Teratogenic effects in humans cannot be predicted reliably from the class of a drug or from what is known about its pharmacology and toxicology.
- Therefore, we learn about teratogenic effects in humans only after marketing, when the drugs have been used by pregnant women.
- Many drugs are subject to contraindications or special warnings because investigations in pregnancy are insufficient for possible harms to be identified.

## Aims and objectives

In EUROmediCAT we aim to build a European system for reproductive safety evaluation:

- to identify systematically and comprehensively the possible adverse effects in pregnancy of drugs at the earliest possible stage post marketing
- to monitor and evaluate European safety measures.

The specific objectives of EUROmediCAT are:

- To develop and test an efficient system for safety evaluation of drugs during pregnancy. This is based on an existing network of congenital anomaly (CA) registers in Europe (EUROCAT, [www.eurocat-network.eu](http://www.eurocat-network.eu)) combined with existing healthcare databases.
- To quantify the risk of CA\*\* related to four drug classes:
  - new antiepileptics,
  - insulin analogues,
  - anti-asthmatics,
  - antidepressants, in particular the selective serotonin re-uptake inhibitors
- To develop a framework for evaluation of the efficacy of pregnancy-related drug safety measures including:
  - drug utilisation studies
  - monitoring the effectiveness of pregnancy prevention programmes
  - a scoping study of the role of internet access to drugs and related safety information by pregnant women

EUROmediCAT builds on:

- the EUROCAT database, enriched with detailed data on prescribing and dispensing drugs in pregnancy,
- the EUROCAT network, enriched with a broader network of expertise on drug safety.

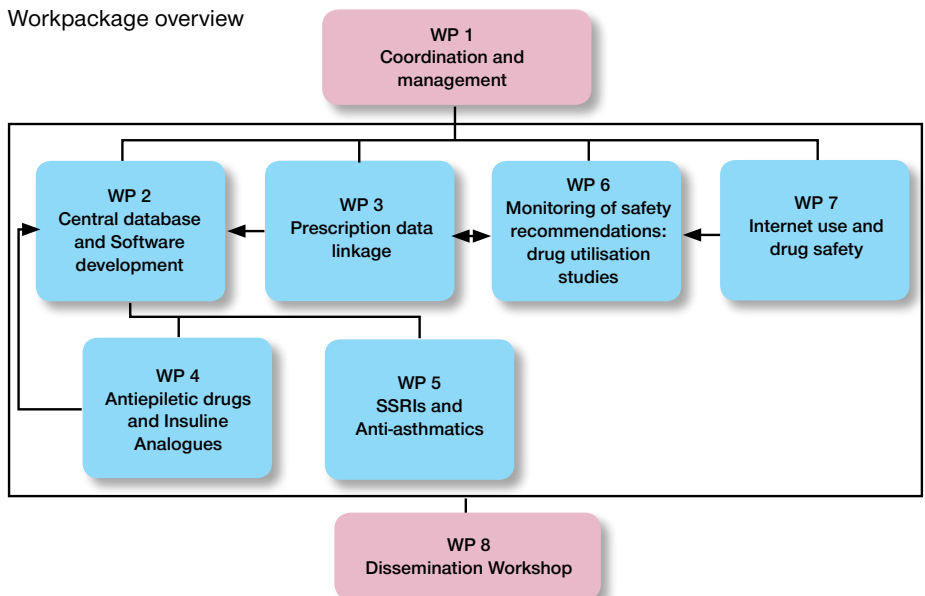
\* Teratogenesis is the impaired development of fetal organs, leading to structural or functional abnormalities

\*\* CA (congenital abnormality, congenital malformation, birth defect) is a condition which is present at or before birth which varies from the standard presentation. The definition may be restricted to structural abnormalities and those resulting from imperfect development of the embryo.

## Advantages of EUROMediCAT for postmarketing surveillance of medicines

- Many countries participate in EUROMediCAT. The resulting diversity in prescribing practice allows us to:
  - dissociate drug-related effects from disease
  - generalise and disseminate our findings across the European Union, impacting on practice
- EUROMediCAT will cover at least 3.7 million births from 1995 to 2010. This is essential for the study of rare outcomes (CA) and rare drug exposures.
- The data reflect the whole population. Information comes from all women and all pregnancies, including all types of CA and irrespective of medication use in pregnancy.
- The size of the database on babies/fetuses with anomalies and the detail and standardisation of the description and coding of anomalies allows associations between specific types of anomalies and specific drugs to be studied
- EUROMediCAT also includes data on terminations of pregnancy for fetal anomaly (TOPFA) following prenatal diagnosis. TOPFA inclusion is essential as the proportion of TOPFA is 14% (average for EUROMediCAT registries 2000-2007), rising to 40-80% for some specific anomalies such as anencephaly, spina bifida, hydrocephaly, hypoplastic left heart, omphalocele and bilateral renal agenesis. Demographic and other factors affect the proportion of pregnancies ending in TOPFA. Studies not accounting for these variables are likely to be biased.

### Workpackage overview



## **EUROmediCAT Details**

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Further information can be found at [www.euromedicat.eu](http://www.euromedicat.eu)

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Mainz, Germany

Malta

Norway

Paris, France

Vaud, Switzerland

Zagreb, Croatia

The logo for euromedicat features the word "euromedicat" in a lowercase, sans-serif font. The "e" is blue, the "o" is pink, and the "i" is blue. The remaining letters are in a dark blue color.