



## INTRODUCTION

Advising pregnant women on the risks and benefits of medication is difficult due to insufficient fetal safety information. Testing safety of new medication on pregnant women is often unethical, and thus 10 years after drugs are introduced to the market more than 97% still have uncertain fetal safety profiles. This results in a huge knowledge gap. The consequence is a choice between accepting a beneficial medication with an unknown risk to the unborn child or forgoing treatment to prioritize the child's safety.

## METHODS

**FREIA** combines data on all singleton pregnancies in the Central Denmark Region (covering 1/5 of Denmark's population), identified from electronic charts and linked on an individual level. Information on medication exposure and outcomes (pregnancy, birth, and neonatal) are provided by the electronic patient records of the women and children.

An interface provides access to this information with filters that allow for queries customized to specific clinical questions.

## INTERFACE

### 1 Select filters

**Pregnancy end year**  
January 2013 January 2025

**Gender**  
☒ Unknown  
☒ Boy  
☒ Girl

**Include genetic anomaly**  
☒ Pregnancies without genetic anomalies  
☒ Pregnancies with genetic anomalies

**Liveborn**  
☒ Liveborn  
☒ Not liveborn

**Gestational week at the end of pregnancy**  
Stratifies the entire dataset  
13 45

### 2 Select ATC exposure (400 ATC codes)

L04AB04 Adalimumab (Administration)

- ☐ Exposed in 1<sup>st</sup> trimester
- ☐ Exposed in 2<sup>nd</sup> trimester
- ☐ Exposed in 3<sup>rd</sup> trimester
- ☐ Exposed any time in the pregnancy

### 4 Select outcomes

Malformations, EUROCAT (20 categories)

Birth outcomes (30 categories)

Neonatal outcomes (50 categories)

Daily updated singleton's pregnancies from Central Denmark Region

# FREIA

Fetal Risk & Embryotoxicity Information service Aarhus

1. Use filters to select the population that is appropriate for the clinical question. E.g. only pregnancies that continue beyond week 37.
2. Select the ATC code (drug).
3. Select time of exposure. E.g. 1st trimester regarding malformations, 3rd trimester regarding neonatal abstinence.
4. Select the outcome of interest. E.g. Major malformation, growth (SGA-22%, LGA+22%), Apgar score, hypoglycaemia, C-PAP, duration of neonatal admission.
5. View the result, the outcome registered among exposed compared to unexposed.

Contingent upon either administration or prescription in the electronic patient journal

- [n=] Exposed in 1<sup>st</sup> trimester
- [n=] Exposed in 2<sup>nd</sup> trimester
- [n=] Exposed in 3<sup>rd</sup> trimester
- [n=] Exposed any time in the pregnancy

### 5 Result

**[Outcome]** was registered in [n=...] out of [n=...] pregnancies exposed to **[ATC]**, prevalence of [ % ]

Among unexposed **[outcome]** was registered in [n=...] out of [n=...] pregnancies, prevalence of [ % ]

## RESULTS

**FREIA** holds information on 175.000 singleton pregnancies from 2013 onwards and is updated daily.

The interface provides access to over 400 different medications and the outcomes of 100 pregnancy-, birth-, and neonatal variables. The system has been integrated into the existing medication advisory service at the Department of Clinical Pharmacology and is used at highly specialized multidisciplinary conferences.

## CONCLUSIONS

**FREIA** provides daily updated clinical information on drug safety in pregnancy. The underlying data can form the backbone of future automated surveillance systems.

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