
EFEMERIS

*Evaluation chez la Femme Enceinte des **MED**icaments et de leurs **RIS**ques*

The first French database evaluating drug risks during pregnancy

French women are heavy drug users, even through pregnancy. Nevertheless, drug intake during pregnancy can lead to congenital malformations or neonatal pathologies. Thalidomide or diethylstilboestrol (Distilbène®) are some of memorable cases. Data about teratogenic risks are limited; physicians are often deprived of relevant and sufficient information regarding medicinal prescriptions during pregnancy.

In 2005, in Haute-Garonne (a department in south-west France), we set up a database, EFEMERIS, evaluating the risk of medicine intake during pregnancy. EFEMERIS merges four databases (Figure 1): 1- the French health insurance database (drugs prescribed before and during pregnancy), 2- the mother and child protection centre database (newborn health) 3- the multidisciplinary prenatal diagnostic centre database (medical pregnancy interruptions) and 4- medical data from the hospital (pregnancy interruptions and hospitalization of mothers). Currently, EFEMERIS records anonymous data concerning more than 137,600 pregnancy outcomes, who delivered in Haute-Garonne between July, 1 2004 and December, 31 2017.

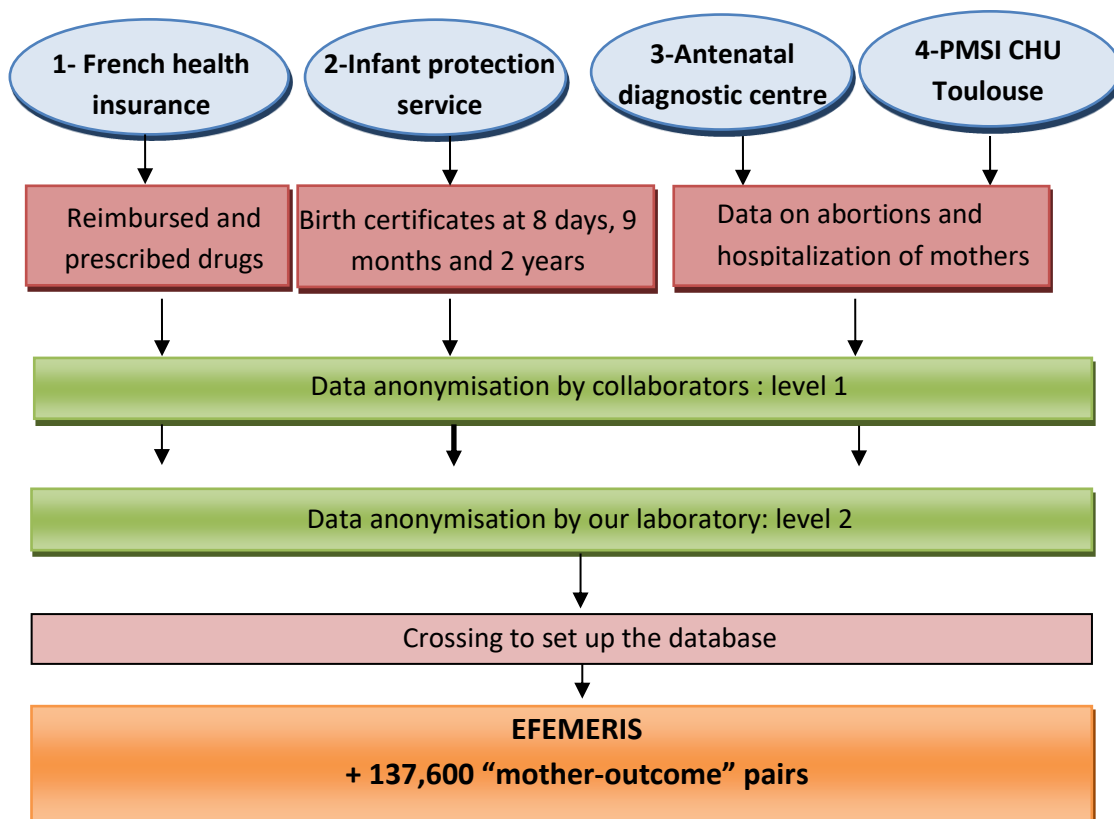


Figure 1. EFEMERIS DESIGN

EFEMERIS is the first French database on prescriptions during pregnancy in general population which enables the study of prescribed and reimbursed medicines during pregnancy and pregnancy outcomes. Prescribing practices over the time can be studied through EFEMERIS. The database allows the evaluation of drug risks for the foetus, plays a role in safety alerts on malformations or on the contrary highlights potential innocuousness of misjudged medicines.

Consequences in terms of prevention of malformations, neonatal pathologies, children's handicap, and costs reduction linked to these pathologies are significant.

Several studies have been conducted in EFEMERIS database to evaluate drug risks during pregnancy, especially risks for phloroglucinol (Spasfon°), benfluorex (Mediator°), or influenza H1N1 vaccination.