

Improving data collection in pregnancy safety studies: Towards standardisation of data elements in pregnancy reports from public and private partners, a contribution from the ConcePTION project.

Drug Safety

Favre Guillaume^{1&2}, Richardson Jonathan L.^{3&4}, Moore Alan⁵, Geissbühler Yvonne⁵, Jehl Valentine⁵, Oliver Alison³, Shechtman Svetlana⁶, Diav-Citrin Orna⁶, Berlin Maya⁷, De Haan Tal⁷, Baud David², Panchaud Alice^{8&9}, Mor Anil¹⁰, Sabidó Meritxell¹¹, de Souza Sabrina¹¹, Chambers Christina¹², van Rijt-Weetink, Yrea R.J.¹³, van Puijenbroek Eugène P.¹³, Yates Laura M.^{14&15}, Girardin François¹, Stellfeld Michael^{16*}, Winterfeld Ursula^{1*}

1. Swiss Teratology Information Service and Clinical Pharmacology Service, Lausanne University Hospital and University of Lausanne, Lausanne, Switzerland
2. Materno-fetal and Obstetrics Research Unit, Department "Femme-Mère-Enfant", Lausanne University Hospital and University of Lausanne, Lausanne, Switzerland
3. UK Teratology Information Service, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, United Kingdom.
4. Institute of Health and Society, Newcastle upon Tyne, United Kingdom.
5. Novartis Pharma AG, Basel, Switzerland.
6. The Israeli Teratology Information Service, Ministry of Health, Jerusalem, Israel.
7. Clinical Pharmacology and Toxicology Unit, Drug Consultation Center, Shamir Medical Center (Assaf Harofeh), Zerifin TIS, affiliated with the Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel.
8. Institute of Primary Health Care (BIHAM), University of Bern, Switzerland
9. Service of Pharmacy, Lausanne University Hospital and University of Lausanne, Lausanne, Switzerland
10. Epidemiology and Benefit Risk, Sanofi, North York, Ontario, Canada.
11. Merck Healthcare KGaA, Darmstadt, Germany.
12. University of California San Diego, and Organization of Teratology Information Specialists (OTIS), United States.
13. Pharmacovigilance Centre Lareb, 's-Hertogenbosch, the Netherlands.
14. Northern Genetics Service, Newcastle upon Tyne Hospitals NHS Foundation Trust, UK
15. KRISP, University of KwaZulu-Natal, South Africa
16. Novo Nordisk A/S, Søborg, Denmark.

* contributed equally

E-mail corresponding author: ursula.winterfeld@chuv.ch

Table S1: Questionnaire for data access providers (DAPs) - Example of the *Maternal details* items

Data variable	Definition	Notes: Refer also to the full version of the CDE for details of data format and suggested values of each CDE item	Question 1: Can this item be taken directly from an existing field in the DAP database (Y/N - please select)?	Question 2: Can this item be derived by combining data from fields in the DAP database (Y/N - please select)?	Question 3: Does the DAP collect data which is similar to this item, but the CDE definition is too different from that used in the DAP database (Y/N - please select)?	Question 4: If this item is missing from DAP database, please summarise the reasons
Mother's date of birth	Mother's date of birth	Availability depends on local law/data collection and storage permissions				
Mother's age at last menstrual period (LMP)	Mother's age (in years) on the first day of the last menstrual period prior to the pregnancy	Availability depends on local law/data collection and storage permissions				
Maternal BMI pre-pregnancy	Maternal BMI at the time of conception (kg/m ²)	Local dataset may code this categorically (e.g. underweight, normal weight, overweight or obese)				

BMI: body mass index

Y/N: Yes or No

DAPs: data access providers