

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 S4: Details and comments on not available (A) and divergent (B) core data elements (CDE) items for E2B(R3) standard

A. Not available CDE items details

CDE items	Comments
Database Administrative Details	
Prospective status	Information not collected
Pregnancy Details	
Source of directly-reported EDD	Information not collected
Plurality	Information not collected
Pregnancy Outcome Details	
Pregnancy outcome collection status	Information not collected
Date of end of pregnancy	Information not collected
Gestational age at end of pregnancy	Information not collected
Malformation Details	
Details of all congenital anomaly(ies)	Information not collected
Infant malformation case classification	Information not collected

EDD: expected date of delivery

B. Divergent CDE items details

CDE items	Comments
Maternal Details	
Maternal BMI pre-pregnancy	No information about the timing of data collection (pre-pregnancy/during pregnancy/after pregnancy)
Live Stillborn Outcome Details	
Infant birth length	No information about the timing of data collection (at birth or later after birth)
Infant birth weight	No information about the timing of data collection (at birth or later after birth)

BMI: Body Mass Index