

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

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Table S2: Data access providers (DAPs) alignment with core data elements (CDE) items by DAPs

	GPR				TPR				TOPR				Lareb				Gilenya PRIM				MAPLE-MS				ENTIS consortium			
CDE items	Directly taken	Derived	Divergent	Not available	Directly taken	Derived	Divergent	Not available	Directly taken	Derived	Divergent	Not available	Directly taken	Derived	Divergent	Not available	Directly taken	Derived	Divergent	Not available	Directly taken	Derived	Divergent	Not available	Directly taken	Derived	Divergent	Not available
Database Administrative Details																												
Mother case identifier	X				X				X				X				X				X				X			
Baby case identifier	X				X				X				X				X				X				X			
Mother-Baby case identifier/link	X				X				X				X		X		X				X				X			
Primary reporter type	X				X				X				X				X				X				X			
Primary reporter contact details	X				X				X				X				X				X				X			
Initial report date	X				X				X				X				X				X				X			
Prospective status	X				X				X				X				X				X				X			
Maternal Details																												
Mother's date of birth	X						X		X				X				X				X				X			
Mother's age at last menstrual period (LMP)	X				X				X		X		X				X		X		X			X				
Maternal BMI pre-pregnancy	X							X	X				X				X				X						X	
Pregnancy Details																												
Date of LMP	X				X				X				X				X				X				X			
Expected date of delivery (EDD)	X				X				X				X		X		X				X				X			
Source of directly-reported EDD	X					X			X				X				X				X					X		
Plurality	X				X				X				X				X				X					X		
Prenatal test(s)	X				X				X				X				X				X				X			
Maternal Medical History																												
Maternal pre-pregnancy medical conditions (history)	X				X				X				X				X				X				X			
Medication Exposure Details																												
Drug name(s)	X				X				X				X				X				X				X			
Drug start date	X				X				X		X		X				X				X					X		
Drug stop date	X				X				X				X		X		X				X					X		
Drug indication(s)	X				X				X				X				X				X					X		
Peri-LMP exposure	X				X				X				X		X		X		X					X		X		
Trimester 1 exposure	X				X					X			X				X				X				X			
Trimester 2 exposure	X				X					X			X				X				X				X			
Trimester 3 exposure	X				X					X			X				X				X				X			
Route of exposure	X			X	X				X				X				X				X				X			
Dose per use	X			X	X				X				X				X				X				X			
Frequency of use	X						X		X				X				X					X			X			
Pregnancy Outcome Details																												
Maternal medical conditions arising in pregnancy	X				X				X				X				X				X				X			
Maternal death	X				X				X						X		X				X				X			
Pregnancy Outcome Details																												
Pregnancy outcome collection status	X				X				X				X				X					X			X			
Date of end of pregnancy	X			X					X				X				X		X		X				X			
Gestational age at end of pregnancy	X				X				X				X				X				X					X		
Induced termination	X				X				X				X				X				X				X			
Ectopic pregnancy	X				X				X				X				X				X				X			
Stillbirth	X				X				X				X				X				X				X			
Spontaneous abortion	X				X				X				X				X				X				X			
Molar pregnancy				X	X				X				X				X				X				X			
Blighted ovum				X	X				X				X				X				X				X			
Live birth	X				X				X				X				X				X				X			
Live Stillborn Outcome Details																												
Gestational timing of live/stillborn offspring	X				X				X				X		X		X				X				X			
Infant birth weight	X				X				X				X				X				X				X			
Infant sex	X				X				X				X				X				X				X			
Infant head circumference	X				X				X				X			X	X				X				X			
Infant birth length	X				X				X				X				X				X				X			
Small for Gestational Age at delivery	X				X				X				X				X		X		X				X		X	
Large for Gestational Age at Delivery	X				X				X				X		X		X				X				X		X	
Neonatal Infant Outcome Details																												
Complications in the first year of life	X				X				X				X				X				X				X			
Postnatal death of live born infant	X				X				X				X				X				X				X			
Malformation Details																												
Congenital anomaly	X				X				X				X				X				X				X			
Details of all congenital anomaly(ies)	X				X				X				X				X					X			X			
Infant malformation case classification	X				X				X				X		X				X			X				X		

GPR: Novartis Gilenya Pregnancy Registry

TPR: Teriflunomide Pregnancy Registry

TOPR: Teriflunomide OTIS pregnancy registry

Lareb: The Dutch Pregnancy Drug Register

Gilenya PRIM: Novartis Gilenya Pregnancy outcomes Intensive Monitoring

MAPLE-MS: Worldwide pregnancy surveillance program of oral cladribine

ENTIS consortium: European Network of Teratology Information Service consortium

Note: There are some differences in CDE alignment between Gylenia PRIM and MAPLE-MS that are explained by the approach taken to obtain it. While Gylenia PRIM reflects presence of the CDE in the MAH safety database, MAPLE-MS takes into account derivation rules applied at analysis level to obtain the CDE.