

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 S3: Alignment of the E2B(R3) standard variables with the core data elements (CDE) items

CDE items	E2B(R3)			
	Directly taken	Derived	Similar	Not available
Database Administrative Details				
Mother case identifier	X			
Baby case identifier	X			
Mother-Baby case identifier/link		X		
Primary reporter type	X			
Primary reporter contact details	X			
Initial report date	X			
Prospective status				X
Maternal Details				
Mother's date of birth		X		
Mother's age at last menstrual period (LMP)		X		
Maternal BMI pre-pregnancy			X	
Pregnancy Details				
Date of LMP		X		
Expected date of delivery (EDD)		X		
Source of directly-reported EDD				X
Plurality				X
Prenatal test(s)		X		
Maternal Medical History				
Maternal pre-pregnancy medical conditions (history)		X		
Medication Exposure Details				
Drug name(s)	X			
Drug start date	X			
Drug stop date	X			
Drug indication(s)	X			
Peri-LMP exposure		X		
Trimester 1 exposure		X		
Trimester 2 exposure		X		
Trimester 3 exposure		X		
Route of exposure	X			
Dose per use	X			
Frequency of use	X			
Maternal Outcome Details				
Maternal medical conditions arising in pregnancy		X		
Maternal death		X		
Pregnancy Outcome Details				
Pregnancy outcome collection status				X
Date of end of pregnancy				X
Gestational age at end of pregnancy				X
Induced termination		X		
Ectopic pregnancy		X		
Stillbirth		X		
Spontaneous abortion		X		
Molar pregnancy		X		
Blighted ovum		X		
Live birth		X		
Live Stillborn Outcome Details				
Gestational timing of live/stillborn offspring		X		
Infant birth weight			X	
Infant sex		X		
Infant head circumference		X		
Infant birth length			X	
Small for Gestational Age at delivery		X		
Large for Gestational Age at Delivery		X		
Neonatal Infant Outcome Details				
Complications in the first year of life		X		
Postnatal death of live born infant		X		
Malformation Details				
Congenital anomaly		X		
Details of all congenital anomaly(ies)				X

Infant malformation case classification	X
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