



CEPI | Brighton Collaboration

# APPENDIX 4: KEY ELEMENTS FOR DATA COLLECTION FOR PREGNANT WOMEN AND NEWBORNS

Work Package: [WP10]

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## DOCUMENT INFORMATION

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# DOCUMENT HISTORY

NAME OF DOCUMENT	DATE	VERSION	CONTRIBUTOR(S)	DESCRIPTION
Key elements for data collection for pregnant women and newborns	17-Sept-2024	V1.0	SPEAC Executive Board	Creation of the document

## APPENDIX 4: KEY ELEMENTS FOR DATA COLLECTION FOR PREGNANT WOMEN AND NEWBORNS

<b>A. GENERAL INFORMATION</b>			
<ul style="list-style-type: none"> <li>• Date of initial report</li> <li>• Source of information (e.g. pregnant woman, primary care physician, obstetrician, pediatrician, other)</li> </ul>			
<b>B. MATERNAL INFORMATION</b>			
• Identification of patient	Study ID	Site	
• Date of enrollment in trial	Vaccine administered: Name of vaccine administered (brand and lot number), dose(s) given, and the gestational timing of vaccine administration		Study group assignment (if pertinent)
• Demographics:	Date of birth (or age)	Occupation	Education level
<ul style="list-style-type: none"> <li>• Obstetrical history: Parity, number of previous pregnancies and outcome (live birth, miscarriage, elective termination, with specification of gestational length and context, late fetal death, ectopic pregnancy, molar pregnancy); Previous maternal pregnancy complications; Previous fetal/neonatal abnormalities and type</li> </ul>			
<ul style="list-style-type: none"> <li>• Maternal medical history: Risk factors for adverse pregnancy outcomes including environmental or occupational exposures e.g. hypertension, diabetes, seizure disorder, thyroid disorder, asthma, allergic disease, heart disease, depression or other psychiatric disorders, sexual transmitted disorders, hepatitis, AIDS (specify viral load, CD4 count), other.</li> </ul>			
<ul style="list-style-type: none"> <li>• Family history: History of congenital abnormality, psychomotor conditions in the family (specify paternal/maternal and relationship); Consanguinity between parents (specify degree)</li> </ul>			

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- Current pregnancy
  - Date of last menstrual period (LMP); Gestational age at the time of IP exposure, preferably given as gestational week+days, based on ultrasound (specify if based on ultrasound or LMP); Estimated date of delivery
  - Exposure to products subject to medical prescription, OTC products, pregnancy supplements such as folic acid, multivitamins (include name, Dosage & route, Date of first use, date of end of treatment, duration, Indication)
  - Recreational drug use, e.g. tobacco, alcohol, illicit drugs (specify amount and if stopped during pregnancy)
  - Antenatal check-up (specify dates and results), e.g. fetal ultrasound, serum markers (AFP, other), chorionic villi biopsy (CVS), amniocentesis, results of antenatal care tests including serology tests, e.g. rubella, toxoplasmosis etc.
  - Complications during pregnancy and date (including any adverse drug reactions)
  - Disease course(s) during pregnancy and any complications
- End of Pregnancy Event or Delivery
  - End of pregnancy event: Ectopic pregnancy, Molar pregnancy; Elective termination, SAB, Stillbirth, Delivery
  - Date of event
  - GA at event, interval from IP administration to event
  - Mode of delivery
- Labour / Delivery complications (fetal distress, amniotic fluid abnormal, abnormal placenta, etc)
- C. FETAL INFORMATION in case of elective termination, spontaneous abortion and late foetal death
  - Date of receipt of information and Source of information
  - End of pregnancy event: SAB, Stillbirth, other
  - Gestational age at end of event
  - Results of physical examination (gender, external anomalies)
  - Results of laboratory testing and pathology (if available)

<ul style="list-style-type: none"><li>Reason for or factors contributing to end of pregnancy event (if known)</li><li>Other specific testing relevant to IP</li></ul>
<b>D. NEONATAL INFORMATION</b>
<ul style="list-style-type: none"><li>Initial -<ul style="list-style-type: none"><li>Source of information -</li><li>Date of receipt of information -</li><li>Outcome of pregnancy and date (live birth, miscarriage, late foetal death, elective termination, ectopic pregnancy, molar pregnancy) -</li><li>Date of birth</li><li>Gestational age at birth -</li><li>Gender of neonate -</li><li>Results of neonatal physical examination including: ⇒</li><li>Weight at birth ⇒</li><li>Length, head circumference at birth -</li><li>Malformation/anomalies diagnosed at birth -</li><li>Conditions at birth (including Apgar scores at 1 and 5 minutes, need for resuscitation, admission to intensive care unit)</li><li>Dysmaturity</li></ul></li></ul>
<ul style="list-style-type: none"><li>Follow-up -<ul style="list-style-type: none"><li>Source and date of information -</li><li>Malformation/anomalies diagnosed since initial report -</li><li>Developmental assessment -</li><li>Infant illnesses, hospitalisations, drug therapies, breastfeeding</li></ul></li></ul>
<b>E. INFANT INFORMATION</b>

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- Follow up
  - Infant weight: baseline at 3, 6, 9, and 12 months
  - Infant developmental milestones: baseline at 6, 9, and 12 months
  - Infant height: baseline at 6, 9, and 12 months