

Event Description	Suggested AE Term
Pregnancy-related	
Anemia during pregnancy	Antepartum anemia
Nausea during pregnancy	Antepartum nausea
Vomiting during pregnancy	Antepartum vomiting
Diabetes during pregnancy	Gestational diabetes
Reflux during pregnancy	Antepartum reflux
Burping during pregnancy	Antepartum burping
Gastritis during pregnancy	Antepartum gastritis
Heart burn during pregnancy	Antepartum heart burn
Lower back pain during pregnancy	Antepartum lower back pain
Pubic symphysis pain during pregnancy	Antepartum pubic symphysis pain
Sciatica during pregnancy	Antepartum sciatica
Headache during pregnancy	Antepartum headache
Gas during pregnancy	Antepartum gas
Breast engorgement	Breast engorgement
Engorgement of breast associated with childbirth, antepartum	Engorgement of breast associated with childbirth, antepartum
Engorgement of breast associated with childbirth, postpartum	Engorgement of breast associated with childbirth, postpartum
Clogged breast duct	Galactostasis/mammary duct obstruction
Alcohol use during pregnancy	Antepartum alcohol consumption
Drug use during pregnancy	Antepartum recreational drug use
Gestational hypertension (meaning hypertension only identified during pregnancy)	gestational hypertension
pregnancy induced hypertension	gestational hypertension
Worsening chronic hypertension (patient with htn prior to pregnancy)	worsened gestational hypertension
Eclampsia (antepartum or postpartum)	Eclampsia
Chorioamnionitis	Chorioamnionitis
Puerperal sepsis	Puerperal sepsis
Endometritis	Endometritis postpartum
Preterm rupture of membranes (PROM)	Preterm Premature Rupture of Membranes
Painful cramping/uterine contractions (0 - 20 weeks gestation) - associated with pregnancy loss	Pelvic pain antepartum, associated with miscarriage
Painful cramping/uterine contractions (0 - 20 weeks gestation) <u>not</u> associated with pregnancy loss	Pelvic pain, antepartum
Painful cramping/uterine contractions (20 - 37 weeks gestation)	Preterm contractions
Preterm Delivery	Report etiology of preterm delivery (for example, abruption or chorioamnionitis). If etiology unknown, report "preterm contractions". Do not report separate AE for "preterm birth"--this will be captured on PO CRF.
Vaginal bleeding not associated with pregnancy loss or delivery (prior to delivery)	Bleeding Prior to Onset of Labor
Vaginal bleeding associated with pregnancy loss or delivery (0 - 20 weeks gestation)	Vaginal bleeding associated with miscarriage
Post partum haemorrhage (primary and/or secondary)	Post partum hemorrhage (only report it if it is out of normal range)
Third stage post partum haemorrhage	Third stage postpartum hemorrhage (only report it if it is out of normal range)
Bleeding that occurs during labor, but not at delivery or after delivery	Intrapartum hemorrhage
3rd degree perineal trauma/lacerations following delivery	third-degree perineal laceration

4th degree perineal trauma/lacerations following delivery	fourth-degree perineal laceration
Ring-related	
Pelvic pain due to act of ring removal	pelvic pain due to ring removal
Vulvar laceration due to act of ring insertion	vulvar laceration due to ring insertion
Other	
Two or more of the genital/vaginal signs or symptoms in the absence of laboratory-confirmed STI or RTI diagnosis: pain, itching, erythema, edema, rash, tenderness, discharge	Vulvovaginitis
Two or more of the genital/vaginal signs or symptoms in the absence of laboratory-confirmed STI or RTI diagnosis: dyspareunia, erythema, edema, tenderness, discharge	Cervicitis
Sexual assault (only report it when there is no physical/mental sequelae--otherwise, report the sequelae)	Survivor of sexual assault
Bacterial Vaginosis confirmed with saline wet mount testing and that fulfills Amsels criteria	Symptomatic bacterial vaginosis
Candidiasis, symptomatic infections that are confirmed with KOH wet prep and/or culture	Vulvovaginal candidiasis
Chlamydia	Genitourinary chlamydia infection
Gonorrhea	Genitourinary gonorrhea infection
Suspected genital herpes outbreaks	Report using the term marked on the Pelvic Exam CRF describing the lesion together with the anatomical location (e.g., vulvar ulceration, vaginal blister).
Genital herpes confirmed by laboratory testing	Genital herpes
Genital warts	Report the AE using the term "condyloma" and include the anatomical location of the warts (e.g., cervical, vaginal, vulvar, perianal).
Vulvar ulceration	Vulvar ulceration
Vaginal blister	Vaginal blister
Syphilis	Syphilis infection
Trichomoniasis with laboratory confirmation	Vaginal trichomoniasis
Urinary tract infection (diagnosed by symptoms and positive lab results)	Urinary tract infection
Abdominal pain: if participant not pregnant, abdominal pain that is assessed as gastrointestinal in nature and no other overarching or unifying diagnosis	abdominal pain
Abdominal pain: if participant not pregnant, abdominal pain that is assessed as genitourinary and a specific anatomic location is known	describe using anatomic location, e.g. "bladder pain"
Abdominal pain: if participant not pregnant, abdominal pain that is assessed as reproductive in nature and a specific anatomic location is known	describe using anatomic location, e.g. "adnexal uteri pain" or "uterine pain"
Abdominal pain: if participant not pregnant, abdominal pain associated with menstruation	dysmenorrhea
Abdominal pain: if participant not pregnant, abdominal pain that cannot be localized to a specific organ	describe using anatomical location, e.g., "pelvic pain" or "urinary tract pain"
Respiratory Tract Infection	"upper respiratory tract infection" or "lower respiratory tract infection"
COVID-19 (suspected or confirmed)	COVID-19
Seroconversion illness (report it for s/sx from HIV infection)	seroconversion illness
Viral illness (not related to HIV seroconversion)	Viral illness
Anemia, If treatment, including diet recommendations, are offered	Anemia

Anemia, if no instruction is provided to participant	Decreased hemoglobin
Diarrhea	Diarrhea
Gastroenteritis	Gastroenteritis
Fetal AEs (report on maternal AE Log using maternal PTID, except for congenital anomalies)	
Fetal distress	Fetal distress
Fetal growth abnormality	Fetal growth abnormality
Fetal growth restriction	Fetal growth restriction
Infant AEs	
Meconium aspiration syndrome	Meconium aspiration syndrome
Malpresentation	Malpresentation
Poor growth	Poor growth
Rash, seborrheic dermatitis	Seborrheic dermatitis
Rash, atopic dermatitis	Atopic dermatitis
Rash, diaper/nappy	Nappy rash
Candida diaper/nappy rash	Candida nappy rash
Thrush	Candida infection
Anal thrush	Anal thrush
Esophageal thrush	Esophageal thrush
Oral thrush	Oral thrush
Thrush of skin NOS	Skin thrush
Thrush vaginal	Vaginal thrush
Thrush, newborn (< 28 days)	Neonatal candida infection
Undernutrition, stunting and wasting (infants >=28 days)	Poor weight gain
Undernutrition, stunting and wasting, newborn (< 28 days)	small for gestational age
Diarrhea	Diarrhea or infectious diarrhea
Diarrhea, newborn (< 28 days)	Neonatal diarrhea or neonatal infectious diarrhea
Vomiting	Vomiting neonatal
Serious respiratory bacterial infection	Pneumonia
Serious respiratory bacterial infection, newborn (< 28 days)	Neonatal pneumonia
Lower respiratory tract infection	Lower respiratory tract infection