

## Gender Specific Adverse Events in MedDRA

### 1. Uses of the Gender Specific Adverse Events List

One of the key drivers for the development of the Gender Specific Adverse Event Terms List is to improve data quality.

The list could be helpful to users at Regulatory Authorities and pharmaceutical companies as well as sponsors of clinical trials. For example, the list could be used in pharmacovigilance databases as a standard query to check coding quality at the data entry level by highlighting possible gender inconsistencies in Individual Case Safety Reports (for example, a female patient with prostate cancer). Based on the specific inclusion/exclusion criteria for the gender terms list (see below), this check of coding quality would occur by comparing terms in the adverse event/adverse drug reaction (AE/ADR) field with the patient's gender as recorded elsewhere in the report.

The Gender Specific Adverse Event Terms List is intended as recommendation only, providing a basis for a common understanding of gender specific adverse event terms, and leaving organizations the option to modify the list – either adding terms or deleting terms – according to their own organization specific needs.

### 2. Development of the Gender Specific Adverse Event Terms List

The preparation of the Gender Specific Adverse Event Terms List consisted of identifying the MedDRA Preferred Terms (PTs) that are gender specific (male/female).

Initially, all terms in MedDRA with the following roots/words were identified:

Female Roots/Words			
Abort	Endomet	Menar	Pareun
Adnex	Fallopian	Menop	Partum
Amnio	Female	Menor	Pelv
Bartho	Femin	Menstr	Placent
Birth	Gestat	Metr	Pregna
Broad ligament	Gravid	Myomet	Puerp
Cervical	Gynae	Obstet	Salpin
Cervix	Hydatid	Oestrogr	Tropho
Chorio	Hymen	Oocyt	Turner
Clito	Hyster	Ooph	Uteri
Colpo	Labia	Ovar	Utero
Concept	Labium	Ovi	Vagin
Deliver	Labour	Ovula	Vulv
Diethylstil	Lactat	Ovum	XX
Eclamp	Matern	Paramet	

Male Roots/Words			
Andro	Fragile X	Prepuc	Testes
Balan	Klinefelter	Priap	Testi
Chordee	Male	Prostat	Testo

Ejacul	Orchi	Scrot	Vas deferen
Epidid	Patern	Semen	Vasec
Erect	Peni	Semin	Viril
Father	Phimo	Spadi	YY
Foreskin	Posth	Sperm	

The retrieved PT terms were then reviewed by an MSSO physician and the list completed by drilling up and down into the MedDRA hierarchy. The list was additionally reviewed by external pharmacovigilance experts (the EudraVigilance Expert Working Group and the Pharmacovigilance Working Party of the EMEA Committee for Medicinal Products for Human Use).

The inclusion criteria for each gender are:

- Terms that relate exclusively only to one gender.  
e.g., PT *Testicular injury* (male), PT *Ovarian cyst* (female)
- Terms that are – or could possibly represent – AEs/ADRs.  
e.g., PT *Scrotal erythema* (male), PT *Cervix carcinoma stage II* (female)
- Terms for surgical and medical procedures and for social circumstances that might represent AEs/ADRs.  
e.g., PT *Spermatocele excision* (male), PT *Endocervical curettage* (female)
- Terms for investigations used to follow-up on a clinical or suspected observational of disease.  
e.g., PT *Sperm count* (male), PT *Biopsy ovary* (female)
- Terms for abnormal results of investigations.

The exclusion criteria for each gender are:

- Terms which are not typically AEs/ADRs.  
e.g., PT *Nocturnal emission* (male), PT *Menopause* (female)
- Terms that could be applied to each gender, even if they are more common in one than the other  
e.g., PT *Varicocele*, PT *Breast engorgement*
- Terms for investigations that are typical screening tests that may not be performed in the setting of suspicion of disease.  
e.g., PT *Prostate examination* (male), PT *Smear cervix* (female)
- Terms for normal results of investigations.