

## Pediatric Adverse Events in MedDRA

### 1. Uses of the Pediatric Adverse Events List

One of the key drivers for development of the Pediatric Adverse Event Terms List is to support pharmacovigilance activities in surveillance of adverse events in the pediatric population. Medicinal products may affect physical and cognitive growth and development, and adverse event profiles may differ in pediatric patients. Because developing systems may respond differently than mature adult organs, some adverse events and drug interactions that occur in pediatric patients may not be identified in adult studies and therefore need specific monitoring. In addition, dynamic processes of growth and development may not manifest adverse events acutely, but at a later stage of growth and maturation.

For aggregate data analysis of adverse drug events observed in the pediatric population, it is recommended that the relevant age groups provided in the Individual Case Safety Reports (ICSRs) be taken into account. When no age information is available, the Pediatric Adverse Event Terms List can facilitate overall monitoring of adverse events in this population.

The Pediatric Adverse Event Terms List is intended as recommendation only, providing a basis for a common understanding of pediatric 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 Pediatric Adverse Event Terms List

The preparation of the Pediatric Adverse Event Terms List consisted of identifying the MedDRA Preferred Terms (PTs) that are specific to the pediatric population.

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

Pediatric Roots/Words		
Accel	Gestat	Paedia
Adolescen	Grow	Perinat
Behavi	Inborn	Pubert
Child	Infant	Retard
Develop	Juvenile	Toddl
Embry	Matur	Young
Foet	Neona	Youth
	Newborn	

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 EMEA Paediatric Committee).

The inclusion criteria are:

- Terms that relate exclusively to the pediatric population.  
e.g., PT *Neurotic disorder of childhood*
- Terms for conditions that could occur in the non-pediatric population but are characteristic or more common in the pediatric age group.  
e.g., PT *Varicella*
- Terms for maternal disorder(s) that directly impact the fetus or newborn.  
e.g., PT *Maternal hypertension affecting foetus*

The exclusion criteria are:

- Terms for conditions that occur exclusively (or nearly exclusively) in the adult population e.g., PT *Parkinson's disease*
- Pregnancy-related terms (including placental and amniotic conditions) that do not necessarily result in a harm to the fetus or newborn e.g., PT *Retained placenta or membranes*
- Pediatric terms that are not typically adverse events/adverse drug reactions. Such terms are found primarily in SOC *Social circumstances*, e.g., PT *Childhood*