

## Standardization of ADR Terms

If the pre-formatted ADR record can be mapped to MedDRA:

**Case 1. The ADR record is mapped to SOCs, HLGs, HLTs or PTs of MedDRA:** The ADR record is referred to its hit term in MedDRA as the standard ADR term.

Example

ADR record	Standard ADR term	Comment
Rash	Rash	Rash is a PT of MedDRA

**Case 2. The ADR record is mapped to LLTs of MedDRA:** LLT level in MedDRA is discarded in ADRReCS. Hence, the hit LLT term is taken as synonym of its corresponding PT term.

Example

ADR record	Standard ADR term	Comment
Cramp muscle	Muscle spasms	LLT <i>Cramp muscle</i> is a synonym of PT <i>Muscle spasms</i>

**Otherwise, the ADR record is manually amended. This is followed by second or multiple round of MedDRA mapping.**

The ADR record is amended by selecting the most appropriate medical term (or terms) in the hit list from manual keyword search of Unified Medical Language System (UMLS). The selected medical term is passed for next round of MedDRA mapping. If the ADR record is ambiguous, additional information (e.g., lesions) is needed (e.g., from the drug label of DailyMed) to help amendment.

**Case 3. ADR record contains multiple symptoms:** The ADR record is split into multiple new ADR terms for further standardization without enlarge or shrink the original medical concepts.

Example

ADR record	Standard ADR term
diarrhea and vomiting	Diarrhoea Vomiting
fatal bleeding	Haemorrhage Death

**Case 4. The ADR record is an abbreviated term:** The ADR record is replaced by its full name for standardization. Additional information (e.g., lesions) may be needed (e.g., from the

drug label of DailyMed) to help amendment.

Example

ADR record	Standard ADR term	Comment
OA	Osteoarthritis	Replace abbreviated term by its full name
GU pain	Pain	'GU' could be either 'genitourinary' or 'gastric ulcer'. If additional information is not available, then an unambiguous and broader term is selected without changing the medical concept, i.e., Pain
Digestive System: GU pain	Gastric ulcer pain	The abbreviated ADR term can be correctly interpreted with the help of additional information (i.e., Digestive System)

**Case 5. The ADR record contains body-site specific events:** The ADR record is preferred to reword to a concise term without changing its exact medical concept (e.g., searching UMLS). If multiple lesions are included and the record cannot be properly reworded, the record is split into multiple ADR terms without enlarge or shrink the original medical concepts.

Example

ADR record	Standard ADR term
Skin rash on face	Rash on face
Edema of hands and feet	Oedema of extremities
Respiratory chlamydial infection	Chlamydial infection Respiratory infection

**Case 6. The ADR record contains age-specific events:** The ADR record is preferred to reword to a concise term without changing its exact medical concept. If multiple concepts are included and the record cannot be properly reworded, the record is split into multiple ADR terms without enlarge or shrink the original medical concepts.

Example

ADR record	Standard ADR term
Jaundice in a newborn	Neonatal jaundice
Oral candidiasis in a neonate	Oral candidiasis Neonatal candida infection

**Case 7. The ADR record is a congenital event:** The ADR record is preferred to reword to a

concise term without changing its exact medical concept. Normally, the ADR record contains words like 'congenital' or indicates the ADR presenting at the time of birth. Such record is usually assigned into SOC: *Congenital, familial and genetic disorders*.

Example

ADR record	Standard ADR term
Congenital heart disease	Heart disease congenital
Child born with heart disease	

**Case 8. The ADR record is related to neoplasm:** The ADR record is preferred to reword to a concise term without changing its exact medical concept. Normally, terms like *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* are preferred when the record contains the word 'tumor', 'cancer', or 'neoplastic'. Term like '*malignancy*' is preferred when 'malignant', 'cancer', 'carcinoma' or other malignant term is used in the record.

Example

ADR record	Standard ADR term
Benign liver tumors	Benign hepatic neoplasm
Cancer growing on tongue	Malignant tongue cancer

**Case 9. The ADR record contains investigation results in laboratory:** Qualitative results are seldom used in describing ADR; hence, the qualitative descriptions like '*increased*', '*decreased*', '*abnormal*', '*positive*', '*negative*', '*change*' and so on are used to reword the ADR record. Additional information is often needed to help rewording ADR record. If multiple concepts are included and cannot be properly reworded, the record is split into multiple ADR terms without enlarge or shrink the original medical concepts.

Example

ADR record	Standard ADR term	Comment
Glucose 40 mg/dL	Blood glucose decreased	Glucose is clearly below the reference range
Glucose 40	Blood glucose abnormal	Ambiguous investigation result without unit is normally reworded as "abnormal".
SGPT and SGOT Increased	Alanine aminotransferase increased Aspartate aminotransferase increased	The record contains multiple results so that it is split into two independent ADR terms and reworded.

**Case 10. The ADR record contains new medical concept:** Some ADR records can be properly mapped to MedDRA even after several rounds of rewording and MedDRA mapping. In these cases, new standard ADR PT terms are assigned, and at the same time, the new PTs are linked to the most related upper level HLT, HLG or SOC term. The descriptions of the standard ADR PT term will normally learn from similar word in MedDRA, WHO-ART and UMLS.

Example

ADR record	Standard ADR term	Comment
Cerebellar dysfunction	Cerebellar dysfunction	'Cerebellar dysfunction' cannot be mapped to MedDRA, hence new standard PT term is decided by learning from the standard term 'Cerebral dysfunction' in MedDRA.
Reflux in stomach	Gastric reflux	'Reflux in stomach' cannot be mapped to MedDRA, hence new standard PT term " Gastric reflux " is decided by learning from the standard term 'Duodenogastric reflux' in MedDRA.