WHO-ART
(WHO-Adverse Reaction Terminology)
The need for a medical terminology

dyspnoea  ?  tinnitus  ARDS

fever  feeling high

mood swings  breath shortness

?  unconsciousness

heart disorder  headache

SOB  somnolence  rash

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# General requirements

**Data entry:**
- comprehensive
- specific
- consistent
- user friendly

**Data retrieval:**
- flexible
- accurate
- consistent
- user friendly

**Other:**
- multilingual
- definitions
- computer adaptation
- continuous updating
WHO-ART

Developed for the WHO Drug Monitoring Programme

• in use for 40 years
• for adverse reaction monitoring
  – NOT for indications, tests, background diseases etc.
• used by both regulatory agencies and pharmaceutical manufacturers
• maintained by the UMC
WHO-ART cont.

- 4 level hierarchical structure
- New terms added when necessary
- Created in English
- Translations in French, German, Italian, Spanish, Portuguese (Chinese, Japanese, Korean, Russia)
- Paper print, CD and electronical version
- Latest version available in VigiSearch (and VigiFlow)
WHO-ART hierarchy

- **System Organ Class (SOC)**
  - group of preferred terms pertaining to the same body organ (32*)

- **High level term (HLT)**
  - group of similar preferred terms (184*)

- **Preferred Term (PT)**
  - principal terms for coding and presentation (2158*)

- **Included Term (IT)**
  - terms similar to preferred terms (3607*)

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WHO-ART hierarchy - an example

- SOC Musculo-skeletal system disorders
- HLT Arthropathy
- PT Arthritis
  - IT Joint inflammation
  - IT Osteoarthritis
- PT Arthropathy
  - IT Osteoarthritis
  - IT Polyarthropathy
  - IT Joint dysfunction

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WHO-ART hierarchy

- example I I

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Complete list of System Organ Classes

<table>
<thead>
<tr>
<th>Category</th>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>Skin and appendages disorders</td>
<td>0100</td>
</tr>
<tr>
<td>Musculo-skeletal system disorders</td>
<td>0200</td>
</tr>
<tr>
<td>Collagen disorders</td>
<td>0300</td>
</tr>
<tr>
<td>Central &amp; peripheral nervous system disorders</td>
<td>0410</td>
</tr>
<tr>
<td>Autonomic nervous system disorders</td>
<td>0420</td>
</tr>
<tr>
<td>Vision disorders</td>
<td>0431</td>
</tr>
<tr>
<td>Hearing and vestibular disorders</td>
<td>0432</td>
</tr>
<tr>
<td>Special senses other, disorders</td>
<td>0433</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>0500</td>
</tr>
<tr>
<td>Gastro-intestinal system disorders</td>
<td>0600</td>
</tr>
<tr>
<td>Liver and biliary system disorders</td>
<td>0700</td>
</tr>
<tr>
<td>Metabolic and nutritional disorders</td>
<td>0800</td>
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<tr>
<td>Endocrine disorders</td>
<td>0900</td>
</tr>
<tr>
<td>Cardiovascular disorders, general</td>
<td>1010</td>
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<tr>
<td>Myo-, endo-, pericardial &amp; valve disorders</td>
<td>1020</td>
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<tr>
<td>Heart rate and rhythm disorders</td>
<td>1030</td>
</tr>
<tr>
<td>Vascular (extracardiac) disorders</td>
<td>1040</td>
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<tr>
<td>Respiratory system disorders</td>
<td>1100</td>
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<tr>
<td>Red blood cell disorders</td>
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<tr>
<td>White cell and RES* disorders</td>
<td>1220</td>
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<tr>
<td>Platelet, bleeding &amp; clotting disorders</td>
<td>1230</td>
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<tr>
<td>Urinary system disorders</td>
<td>1300</td>
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<tr>
<td>Reproductive disorders, male</td>
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<tr>
<td>Reproductive disorders, female</td>
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<tr>
<td>Foetal disorders</td>
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<td>Neonatal and infancy disorders</td>
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<td>Neoplasms</td>
<td>1700</td>
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<tr>
<td>Body as a whole - general disorders</td>
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<tr>
<td>Application site disorders</td>
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<tr>
<td>Resistance mechanism disorders</td>
<td>1830</td>
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<tr>
<td>Secondary terms - events</td>
<td>2000</td>
</tr>
<tr>
<td>Poison specific terms</td>
<td>2100</td>
</tr>
</tbody>
</table>

* RES - Reticuloendothelial system

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WHO-ART
System Organ Classes

Skin and appendages disorders  0100
Musculo-skeletal system disorders  0200
Collagen disorders  0300
   etc...

Secondary terms  2000
   events not likely to be a direct effect of a drug,
      e.g. medication error, wound infection, burn, fall

Poison terms  2100
   e.g. foetal alcohol syndrome, silicosis, chemical burn
WHO-ART - Critical terms

Definition;
A subset of adverse reaction terms referring to, or possibly being indicative of, serious disease states, which have been regarded as particularly important to monitor

e.g.
Death, anaphylactic shock, convulsions, erythema multiforme
WHO-ART summary

- WHO-ART makes it easy to sort and search information on ADRs
- 4 level hierarchial structure
  - Preferred terms are the principle terms for coding and output
- Multilingual
- Critical terms list for focus on more serious outcomes

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But... what about MedDRA
Features of MedDRA in comparison to WHO-ART

- More terms in MedDRA
  - More fine granular
  - Easier to give correct description of a reaction
- More levels in MedDRA
  - Other interesting levels for statistical analysis
- SMQs (Standardized MedDRA Queries)
  - To simplify analysis when using MedDRA
- ICH MedDRA Points-to-Consider Documents
  - Developed to facilitate consistent input and output
Structure comparison
Content and mapping comparison
MedDRA/ WHO-ART grouping

- Given the differences, how can MedDRA and WHO-ART be used in parallel
  - Reports are always coded on PT/LLT level, same as for WHO-ART where PT/IT is used
  - Multiple MedDRA terms can correspond to the same WHO-ART term (and in rare cases vice versa)
  - Some MedDRA terms representing indications, non ADR events and laboratory tests must be mapped to a generic WHO-ART term

The above considerations result in what we call a “Grouping Structure”!
MedDRA grouping structure

WHO-ART view
- 2 reports
- 1 term

MedDRA view
- 2 reports
- 2 terms