

---

# YELLOW CARD-COMPATIBLE GUIDELINES FOR ANNOTATING ADVERSE DRUG REACTIONS AND THEIR IMPACT ON THE QUALITY OF LIFE IN PATIENT REPORTS FROM SOCIAL MEDIA

Version: 0.4  
Created: 9 January 2018  
Last revision: 8 May 2018

## Aim

The aim of this task is to annotate individual patient reports in social media about beneficial and harmful effects of drugs, their severity and impact on the health-related quality of life. The annotation scheme described in this document will be used for extracting and transferring information from unstructured patient reports in social media into YellowCard reports.

## Scope

- Judge the experience and medical concepts from the **perspective of the content of the text**
  - Do not try to guess what likely could happen
- Focus only on **individual patient posts** (i.e. where the author describes either his **own or someone else's experience**)
- Focus only on events that occurred in the **present or past** (i.e. ignore hypothetical or 'future' events)
- **Ignore** generic statements, comments and feedback on someone else's reported experience
- Annotate **everything** not just those items related to the context of the post. This may include other drugs or health states mentioned
- You can annotate words or statements **multiple times**, this may be relevant where a post mentions quality of life and side effects from drugs.
- The posts most likely will not be related to each other, therefore do not **assume** that a post is a reference to another post.
- If you cannot find an appropriate annotation for a section of a post, ignore this section and move onto the next section of the post. However, try to annotate **as much as possible**

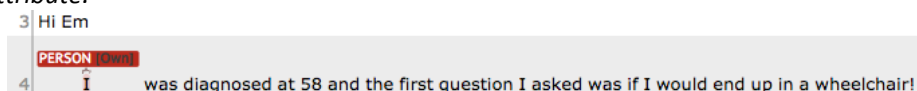
## Annotation process

### Information about the affected person

1. Identify the **person** whose experience is described in a post, annotate the corresponding word/phrase as **PERSON** and choose an appropriate **PersonType** value from:
  - Self
  - Child
  - Someone else

Must be **only one person**, so only one annotation per post. It could be name of the person, pronoun or any other word that makes you think that experience of this person is described.

*BRAT: Select (highlight) the text you want, choose PERSON entity type and define PersonType entity attribute.*



### Information about medications

2. Indicate any **drug exposures** and their **suppliers** (i.e. where it comes from). Annotate corresponding drug name(-s) as **DRUG** and set the **Supplier** attribute value from:
  - No information (default)
  - Prescription
  - Bought in pharmacy
  - Bought on the internet
  - Bought elsewhere

If information not available, leave as default

*BRAT: Select (highlight) the text you want, choose DRUG entity type and define Supplier entity attribute.*

3. Locate and annotate any **time expressions** that define **drug exposure start date** and/or **end date**, annotate them as **DATE** and link an associated **DRUG** entity with them using **Starts** and **Ends** relations.

*BRAT: Select (highlight) the text you want and choose DATE entity type. Then draw a link from DRUG to DATE and choose Starts/Ends relation type.*

4. Locate and annotate any **time expressions** that define the **drug exposure duration**, annotate them as **DURATION** and link an associated **DRUG** entity with them using **LastsFor** relation.

*BRAT: Select (highlight) the text you want and choose DURATION entity type. Then draw a link from DRUG to DURATION and choose Starts/Ends relation type.*

5. Indicate any **drug dosages** mentioned in a text, annotate corresponding phrases as **DOSAGE** and link an associated **DRUG** entity with them using **HasDosage**.

*BRAT: Select (highlight) the text you want and choose DOSAGE entity type. Then draw a link from DRUG to DOSAGE and choose HasDosage relation type.*

## Information about health conditions

6. Indicate any descriptions of **health conditions**. For each mention, annotate the minimum number of words that describe it as **CONDITION** entity, then map to the closest single concept in MEDDRA (preferably PT level). If there is a **change** mentioned (e.g. “increased weight”), then map to a concept that describes the change, otherwise (if there is no such concept, like “Pain reduced”), map to a closest concept without a change (i.e. Pain) and specify that change (i.e. “reduced”) explicitly (see the next step)

*BRAT: Select (highlight) the text you want and choose CONDITION entity type. Then select MedDRA and normalize to the closest single concept using the search.*

7. Indicate any **changes** in a health condition and annotate word/phrase as **CHANGE** and choose an appropriate **Change** value from:

- No change (still has symptoms; default)
- Resolved (better)
- Improving (getting better)
- Deteriorating (more seriously ill)
- Other (please provide any details in a comment box)

**Then link an associated **CONDITION** with a change using **HasChange** relation.**

*BRAT: Select (highlight) the text you want and choose CHANGE entity type and define Change attribute. Then draw a link from CONDITION to CHANGE and choose HasChange relation type.*

8. Locate any **indications** (i.e. reasons to take a drug) among the annotated *experienced* health conditions (or changes to condition) and link them to a corresponding **DRUG** entity with an **IsIndicationFor** relation. If no indication is identified, assign as the condition the generic grouping of conditions of the communities the post has been extracted on. For example, if post from BLF, assign as Respiratory etc.

*BRAT: For each indication, draw a link from CONDITION/CHANGE to DRUG and choose IsIndicationFor relation type.*

9. Indicate any **drug responses** (i.e. potentially causal relationships between drug and health condition or change) and link them as either **HasBeneficialEffect** or **HasADR** relations if the effect (beneficial for the indication or suspected ADR) is clearly stated, otherwise use generic **HasUnknownResponse** relation.

*BRAT: For each drug response, draw a link from DRUG to CONDITION/CHANGE and choose an appropriate drug response relation type.*

10. Indicate any expressions of the **severity** of ADRs, annotate trigger word/phrase as **SEVERITY** entity and set an appropriate **Grade** value from:

- Not serious
- Mild or slightly uncomfortable
- Uncomfortable, a nuisance or irritation, but able to carry on with everyday activities
- Had short term effect that was bad enough to affect everyday activities
- Significant enough to lead you to seek advice from a doctor
- Admitted to hospital

- Caused an abnormality in an unborn child
- Caused very serious illness (life threatening)
- Caused death
- Other (provide details in a comment box)
- No information (default)

Then link an associated **CONDITION** or **CHANGE** entities with them with using **HasSeverity** relations.

*BRAT: Select (highlight) the text you want, choose SEVERITY entity type and define Grade attribute. Then draw a link from CONDITION/CHANGE to SEVERITY and choose HasSeverity relation type.*

11. Locate and annotate any **time expressions** that define **health condition start date** and/or **end date**, annotate them as **DATE** and link an associated **CONDITION** or **CHANGE** entity with them using **Starts** and **Ends** relations.

*BRAT: Select (highlight) the text you want and choose DATE entity type. Then draw a link from CONDITION/CHANGE to DATE and choose Starts/Ends relation type.*

12. Locate and annotate any **time expressions** that define the **health condition** and/or **change duration**, annotate them as **DURATION** and link an associated **CONDITION** or **CHANGE** entity with duration using **LastsFor** relation.

*BRAT: Select (highlight) the text you want and choose DURATION entity type. Then draw a link from CONDITION/CHANGE to DURATION and choose LastsFor relation type.*

13. Locate any **drug exposures**, **health conditions** or **changes** among the annotated entities that are **not related to an individual patient experience** and set **Unrelated** attribute for such entities (tick the box).

*BRAT: Double-click on the annotated entity and tick the box for Unrelated attribute.*

## Information about the affected health-related quality of life

14. Indicate any **health-related quality of life (HrQoL)** concepts and annotate such words/phrases as **HRQOL** entities, then map them to a corresponding domain or facet from the WHOQOL terminology. See Appendix for a list of available domains and facets.

*BRAT: Select (highlight) the text you want and choose HRQOL entity type. Then select WHOQOL and normalize to the closest domain/facet using the search (see Appendix for a list of available domains and facets).*

15. Indicate any subjects among the annotated entities (such as conditions, changes or drug exposures) that have an impact on the HrQoL either definitely or potentially and link them appropriately using **HasDefiniteImpact** or **HasPossibleImpact** relations.

*BRAT: For each impact, draw a link from CONDITION/CHANGE/DRUG to HRQOL and choose an appropriate relation type.*

## Summary of annotation items

Step	Item to identify	Annotate as...	Assign to value as...	Link to
Information about the affected person				
1	<b>Person</b>	<b>PERSON</b>	PersonType	
Information about medications				
2	<b>Drug exposures</b>	<b>DRUG</b>	Supplier	
3	<b>Temporal information</b>	<b>DATE</b>	Starts Ends	DRUG → DATE
4	<b>Duration</b>	<b>DURATION</b>	LastsFor	DRUG → DURATION
5	<b>Dosage</b>	<b>DOSAGE</b>	HasDosage	DRUG → DOSAGE
Information about health conditions				
6	<b>Health Condition</b>	<b>CONDITION</b>	MEDDRA CODE	
7	<b>Health Condition Change</b>	<b>CHANGE</b>	HasChange	CONDITION → CHANGE
8	<b>Indications</b>		IsIndicationFor	CONDITION/CHANGE → DRUG
9	<b>Drug Response</b>		HasBeneficialEffect, HasADR, HasUnknownResponse	DRUG → CONDITION/CHANGE
10	<b>Severity</b>	<b>SEVERITY</b>	Grade HasSeverity	CONDITION/CHANGE → SEVERITY
11	<b>Temporal information</b>	<b>DATE</b>	Starts Ends	CONDITION/CHANGE → DATE
12	<b>Duration</b>	<b>DURATION</b>	LastsFor	CONDITION/CHANGE → DURATION
13	<b>Unrelated entities</b>		<u>Unrelated</u>	
Information about health-related quality of life				
14 15	<b>Health-Related QoL</b>	<b>HRQOL</b>	HasDefiniteImpact OR HasPossibleImpact	DRUG/ CONDITION/CHANGE → HRQOL

## Appendix

### WHOQOL Domains and facets

#### *Overall Quality of Life and General Health*

- **Physical Health**
  - Energy and fatigue
  - Pain and discomfort
  - Sleep and rest
- **Psychological**
  - Bodily image and appearance
  - Negative feelings
  - Positive feelings
  - Self-esteem
  - Thinking, learning, memory and concentration
- **Level of Independence**
  - Mobility
  - Activities of daily living
  - Dependence on medicinal substances and medical aids
  - Work capacity
- **Social Relations**
  - Personal relationships
  - Social support
  - Sexual activity
- **Environment**
  - Financial resources
  - Freedom, physical safety and security
  - Health and social care: accessibility and quality
  - Home environment
  - Opportunities for acquiring new information and skills
  - Participation in and opportunities for recreation/leisure
  - Physical environment (pollution/noise/traffic/climate)
  - Transport
- **Spirituality/Religion/Personal beliefs**
  - Religion/Spirituality/Personal beliefs (Single facet)