

Annotation Guidelines

Adverse Events of COVID-19 Vaccine

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Background

The fast spread of the emerging infectious coronavirus disease-2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), led to a worldwide pandemic ¹. COVID-19 vaccination will help protect people from getting COVID-19, but there are some adverse events. This guideline describes the specific types of information that should be annotated for detecting some adverse events of COVID-19 vaccine from texts.

The annotation corpus are reports from the Vaccine Adverse Event Reporting System (VAERS), which accepts reports from anyone including patients, parents, caregivers and healthcare providers (HCP). They are encouraged to report adverse events after vaccination to VAERS even if it is not clear that the vaccine caused the adverse event. Patient identity is kept confidential. VAERS complies with all U.S. Government security standards and protections concerning health information.

Annotation Tool

The annotation tool for this project is the MedTator, a serverless web tool for corpus annotation. All annotation tasks will be defined in a document type definition (DTD) file. Due to its lightweight feature, the software can be easily shared and updated across multiple sites without configuration and testing.

Instructions

Please use this document for annotation to make sure we are consistently collecting the same information in the same way. Annotators will be given access to a sample of VAERS reports with .txt file format. After opening a .txt file in the MedTator tool and allowing MedTator to convert the file to an .xml format, annotators will identify and highlight keywords or phrases pertaining to two major concepts: fever and pain. For “pain”, it’s also required to label associated “severity” information and link back to “pain”.

No Extrapolation of evidence: Annotation should only be based on the textual information of the given context. Annotators should not make inference, assumptions or use any prior knowledge to make annotation decisions.

Mark semantically sufficient minimum span: Annotators should treat each unique concept independently. Choose the smallest possible span that semantically enclose the problem, condition, or diagnosis, but do not choose a span that indicates something too generic or non-specific.

Adverse Events

1) FEVER

Definition: Elevated body temperature due to failed thermoregulation. Hyperthermia is defined as a temperature greater than 37.5-38.3 degree celsius (100-101 degree Fahrenheit).

Definition reference: Human phenotype ontology (HPO)

HPO code: HP:0001945

Cross

References: *UMLS:C0015967, SNOMEDCT_US:50177009, SNOMEDCT_US:386661006, MSH:D005334*

Mentions of the following:

- fever
- high temperature
- high body temperature
- hyperthermia
- elevated temperature
- elevated body temperature
- febrile
- febris
- pyrexia
- pyrexial
- temperature greater than 37.5-38.3 degree celsius (100-101 degree Fahrenheit).

Or any other mention of fever.

Example: **Temperature 38.5°** temporal, recheck

2) PAIN

Definition: An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

Definition reference: Human phenotype ontology (HPO)

HPO code: HP: 0012531

Cross References: *UMLS:C0030193, MSH:D010146, SNOMEDCT_US:22253000*

Mentions of the following:

- pain

Or any other mention of pain.

Example: She felt severe **pain** after vaccination.

Severity of pain: in the above example, we will further annotate severity of pain (severe) in the above example, and then link the severity back to pain.

Definition: strength or intensity of the pain sensation

Definition reference:

[file:///Users/m095909/Downloads/medinform_v8i11e18659_app1%20\(1\).pdf](file:///Users/m095909/Downloads/medinform_v8i11e18659_app1%20(1).pdf)

Severity level:

Not Bothersome (0) (SCTID: 81765008)

Mild (1-3) (SCTID: 40196000)

Moderate (4-6) (SCTID: 50415004)

Severe (7-10) (SCTID: 76948002)

Attributes:

1) CERTAINTY

Negated: the problem does not exist in the patient

- Patient does not have fever.

Possible: patient may have a problem, but there is uncertainty expressed in the note. Possible takes precedence over negated, so terms like “probably not” or “unlikely” categorize problems as being possible just as “probably” and “likely” do

- Fever is possible / probable.

Hypothetical: medical problems that the note asserts the patient may develop

- If you had pain.

Positive

- Patient experienced pain.

*yellow highlight is a default value