

## 4. AEFI CASE DEFINITION DOCUMENT

«Brighton» case definition documents are intended to standardize collection, analysis and presentation of vaccine safety data. The case definitions aim to define the levels of diagnostic certainty of reported events following immunisation. Their global use will enhance data comparability within and across clinical trials and surveillance systems. They are neither intended for causality assessment nor to establish criteria for management of patients.

### 4.1. Format

A Case Definition document is developed for each adverse event following immunization (AEFI). The format of each «Brighton» Case Definition document

includes the following four sections:

- > A preamble to highlight the rationale for essential decisions made and to briefly describe the methodology of how Working Groups arrived at a particular Case Definition document.
- > The Case Definition itself, which is structured in a three level format to accommodate the different levels of resources available in different research and geographic settings.
- > Guidelines for data collection, analysis, and presentation of a given AEFI.
- > References for selected points discussed in the preamble. A comprehensive list of references used as a basis for discussion is available on the «Brighton» website (<http://brightoncollaboration.org>).

### 4.2. Template Case definition document

#### [NAME] AS AN ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)

##### Preamble

##### *Methodology*

Describes the process to arrive at a Case Definition document including the literature review performed (e.g., type of literature search, number of articles reviewed), the group consensus and any other pertinent information regarding the process used for developing the respective Case Definition document.

##### *Rationale*

Describes essential factors that were considered in deciding the content of the defi-

inition, including reasons for the specific guidelines, as appropriate.

##### Case Definition

##### *Levels of diagnostic certainty*

Each case definition is categorized into three levels of diagnostic certainty. Each level is defined by a set of clinical and/or additional diagnostic criteria. All three levels should be applied to all Case Definitions. However, for some definitions (e.g., those based solely on clinical signs and symptoms) Level 2 and/or Level 3 may not be applicable.



**Level 1**

In the *presence* of:

criterion 1: \_\_\_\_\_ AND/OR  
 criterion 2: \_\_\_\_\_ AND/OR  
 criterion n: \_\_\_\_\_

In the *absence* of:

criterion a: \_\_\_\_\_ AND/OR  
 criterion b: \_\_\_\_\_ AND/OR  
 criterion n: \_\_\_\_\_

**Level 1**

- Highest level of specificity
- Sensitive for the respective AEFI
- Applicable primarily in clinical trials and settings of active follow-up & settings with more resources

**Level 2**

In the *presence* of:

criterion 1: \_\_\_\_\_ AND/OR  
 criterion 2: \_\_\_\_\_ AND/OR  
 criterion n: \_\_\_\_\_

In the *absence* of:

criterion a: \_\_\_\_\_ AND/OR  
 criterion b: \_\_\_\_\_ AND/OR  
 criterion n: \_\_\_\_\_

**Level 2**

- Intermediate level of specificity
- Sensitive for the respective AEFI
- Applicable in clinical trials, post-marketing surveillance

**Level 3**

In the *presence* of:

criterion 1: \_\_\_\_\_ AND/OR  
 criterion 2: \_\_\_\_\_ AND/OR  
 criterion n: \_\_\_\_\_

In the *absence* of:

criterion a: \_\_\_\_\_ AND/OR  
 criterion b: \_\_\_\_\_ AND/OR  
 criterion n: \_\_\_\_\_

**Level 3**

- Lower level of specificity
- Highly sensitive for the respective AEFI
- Applicable in clinical trials, post-marketing surveillance & primarily in settings with less resources



### Guidelines for data collection, analysis, and presentation

The Brighton Collaboration Working Groups recognized the essential need for guidelines to enable meaningful collection, analysis, and presentation of information about a given AEFI. It is understood that levels of reporting detail may vary depending upon available resources, geographical region, and whether the source of information is a prospectively designed clinical trial, a post-marketing surveillance study, or an individual report of an adverse event following immunization.

Guidelines include recommendations regarding:

- > Case classification
- > Case assessment, e.g. patient demographics, duration of follow-up, duration of AEFI, concurrent signs and symptoms and medication, increments of measured variables, outcomes, reporting source, vaccine details, numerator and denominator, reported cases which do not meet the Case Definition, etc.
- > Data presentation, e.g. mention of search strategy in surveillance databases, data distribution in predefined increments

#### 4.2.4. References

Include some essential references in support of decisions made discussed in the preamble.