



Our Workflow of Developing Case Definitions and Complementary Guidelines

International consensus is achieved through a global network of individuals and organisations concerned with immunisation safety or with associated medical and methodological aspects. The resulting accrual of expertise and the sharing of knowledge within and outside the Collaboration along with the availability of case definitions and guidelines will lead to data comparability. This will benefit vaccine recipients, scientists, health officials and healthcare providers, who need to obtain, interpret, provide, and report information on immunisation safety and make scientifically sound decisions.

Format

For each defined adverse event following immunisation (AEFI) a document is developed including 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 Brighton document.
- The **case definition** itself, which is structured in a three-level format taking into account current scientific evidence and 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.

Step-By-Step: Developing Case Definitions and Complementary Guidelines

Selection of Topic	AEFI Prioritization	Based on severity, frequency of reporting, enhanced public interest and emerging scientific needs.
Working Groups	Call for Volunteers	Announcement on our website, contacting of pertinent scientific authors and request for referrals.
	Composition of Groups	Based on the balanced composition of professional expertise and geographical location.
Exploratory Review	Inventory	Systematic search and compilation of relevant published and unpublished evidence.
	Assessment	Evaluation of inventory through discussions by the Working Group.
Draft Definition	Consensus	A draft document is developed based on the exploratory review and group consensus.
Reference Group	Call for Reviewers	Announcement on our website, contacting of pertinent scientific authors and request for referrals.
Peer Review	Survey	An online survey guides structured review of the draft document to stimulate critical review.
	Assessment	Survey data are compiled and discussed by the Working Group.
Finalization	Modification	The draft is revised based on Reference Group comments.
	Harmonization	The final document is harmonised with other case definition documents.
Maintenance	Cyclical Revision	Case definition documents are revised in 3-5 year intervals or upon the availability of new scientific information or critical feedback from evaluation and implementation of documents.