



The **Br**i**ghton**TM
Collaboration



European Vaccine Initiative

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Mission and Goal

- Founded in 1999
- Mission
 - The Brighton Collaboration is an international voluntary collaboration to facilitate the development, evaluation, and dissemination of high-quality information about the safety of human vaccines
- Goal
 - To enable comparability of vaccine safety data across clinical trials, surveillance systems, epidemiologic studies across different geographic regions



Background

- The Need:
 - Safety can not be measured directly, only inferred from the relative absence of vaccine adverse events
 - Assessing safety requires standardized terminology of adverse events across studies
 - Lack of a standard “vocabulary” (i.e., case definitions & guidelines) for vaccine adverse events have hindered comparability of vaccine safety data



Background

- The Solution:
 - A global collaboration to address this “missed opportunity”
 - Development of standardized case definitions and guidelines
 - Case definitions categorized by levels of evidence
 - Clinical trials vs. post marketing surveillance
 - Developed vs. developing countries



Objectives

- **A. Global Collaboration**
 - *To establish a global collaboration of professionals and organizations concerned with immunization safety.*
- **B. Development**
 - *To develop a single standardized case definition per AEFI and guidelines for data collection, analysis, and presentation for global use.*



Objectives

- C. Evaluation

- *To develop and implement study protocols for evaluation of case definitions and guidelines in clinical trials and surveillance systems.*

- D. Implementation

- *To raise global awareness of the availability, educate about the benefit of use, facilitate access to and monitor worldwide use of standardized case definitions and guidelines for data collection, analysis, and presentation.*



Brighton Process

- Select a topic, i.e.,
 - prioritization of adverse event to be defined by science board
- Brighton Process
 - Use a 6-step process
 - Search for available evidence
 - Form working groups
 - Develop draft definitions and guidelines
 - Review and evaluate draft
 - Review and endorsement by the CIOMS/WHO working group on vaccine Pharmacovigilance
 - Finalize and disseminate documents



Products

- 27 Case Definitions & Guidelines
- 3 General Guidelines
- 5 Editorials
- 5 Reviews
- 5 Evaluation studies
- Automatic Classification Tool

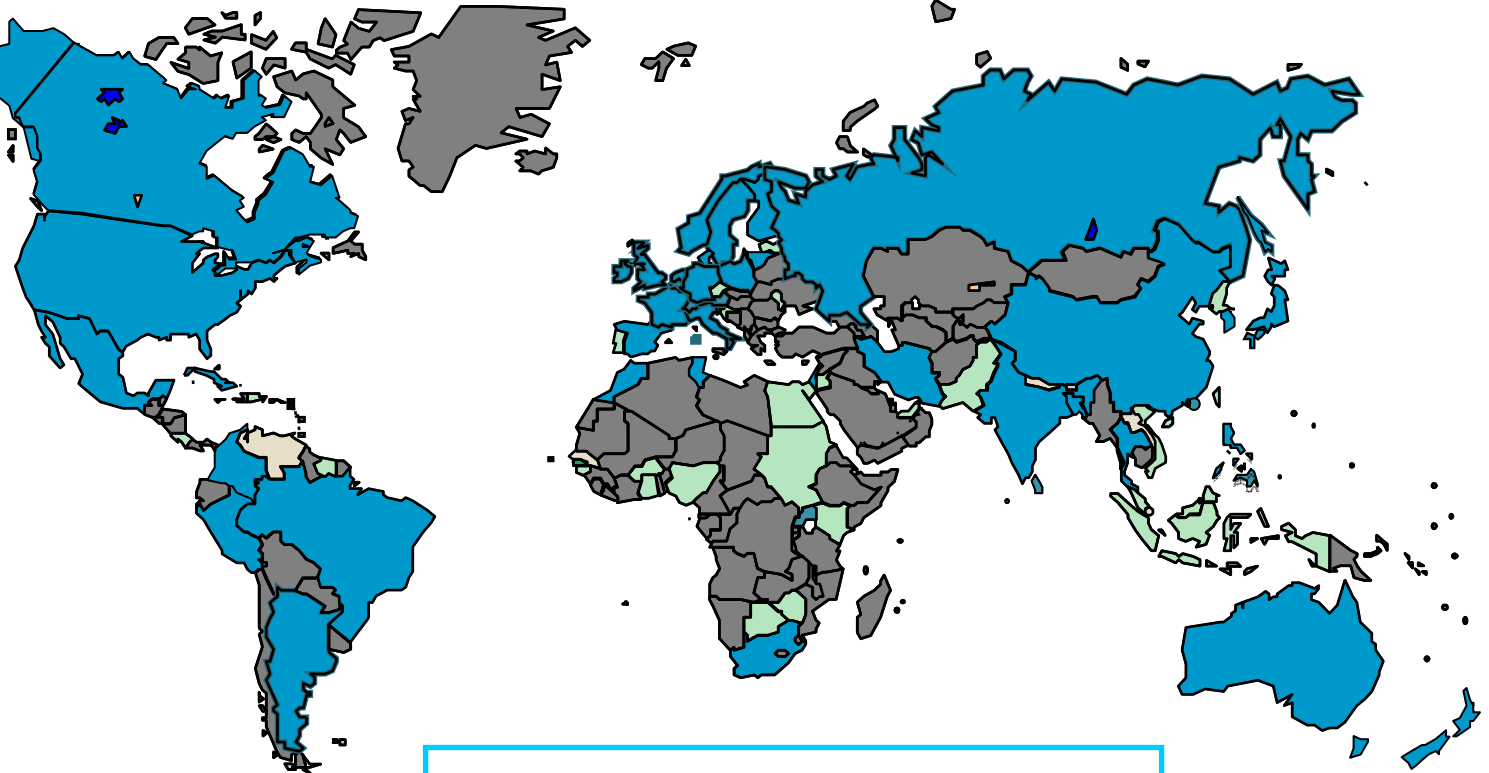


Growth, Global Recognition, & Endorsement

- Network of ~1500 volunteers from 91 countries, including 320 active working group members from 60 countries
- > 250 scientists have downloaded and used the Brighton case definitions



Network of Participants (N=1547) August 2007



68 countries

with ≥ 2 participants

23 countries

with 1 participant

www.brightoncollaboration.org - secretariat@brightoncollaboration.org



More Developing Countries

Proportion of Current Active Participants

	Multiple Roles		Singular Role*	
	N	%	N	%
Developing Countries	93	20,6	69	19,8
Developed Countries	358	79,4	279	80,2

Classification of Developed/Developing Countries from the World, Economic and Social Survey 2008

*Participants are counted only once, regardless of multiple roles



Currently Active - by Region

Region	N (%)
Africa	12 (2,7)
Asia	52 (11,5)
Australia	10 (2,2)
Europe	110 (24,4)
North America	250 (55,4)
South America	17 (3,8)

Classification of Region derived
from the World Economic and Social Survey 2008



Key Orgs recommend Brighton





Brighton Standards Widely Used

- >100 Citations in Scientific Literature
- > 10000 Downloads from our Website
- Ongoing User Survey: Very Positive Feedback
- Evaluation: Ease of Use and Usefulness



Financial Support





INYVAX (implementation)

- Optimisation of the development of poverty related disease vaccines by a transversal approach, addressing common gaps and challenges
- Eight partners across six countries
- Address difficulties in:
 - accessing some technology platforms e.g. synthetic peptides
 - accessing certain know-how e.g. Lyophilisation
 - accessing some delivery platforms e.g. Adjuvants
 - **harmonising safety data collection in clinical trials**
 - the insufficient number of trained scientists to lead vaccine development (focus on African Scientists)



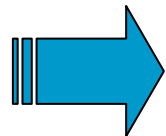
INYVAX

- To identify challenges in the implementation of vaccine safety standards internationally in clinical trials of PRD vaccines, in Europe and in developing countries.
- To generate immediate “user-feedback” for the improvement of BC safety standards in clinical trials.
- To identify opportunities to facilitate usage of BC safety standards in resource-poor settings.
- To generate well-defined BC implementation proposals and partnerships.
- To develop standard section for safety assessment in clinical trial protocols



Global Vaccine Safety Blueprint

- WHO coordinated project
- Gates Foundation funded
- Aim: Global plan to enhance vaccine safety monitoring, investigation and response
- Brighton: assess needs and identify possible minimum capacity requirements for a global vaccine safety system.



Call for widest participation shortly



Brighton Collaboration Science Board

- Michael Blum, Industry-USA
- Paul T. Heath, Academia, Great Britain
- Hector Izurieta, Regulatory, USA
- Brigitte Keller-Stanislawski, Regulatory, Germany
- Dr. Najwa Khuri-Bulos, Academia, Jordan
- Katrin Kohl, Public Health, USA
- Odile Leroy, Public Health, Germany



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 - Jan Bonhoeffer, Basel, Switzerland
 - Sabine Faisst, Basel, Switzerland



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