



VIENNA VACCINE SAFETY INITIATIVE

## **ViVI**

### **Promoting the Global Implementation of Vaccine Safety Standards**

#### **- The ViVI Implementation Working Group -**

#### **I. Background and Rationale**

Any medical intervention should be safe and effective. However, immunization safety concerns have become increasingly prominent with the near elimination of many vaccine preventable diseases worldwide. In some immunization programs, reports of Adverse Events Following Immunization (AEFI) – with real or perceived causal relation to immunization – outnumber reports of the vaccine-preventable diseases. With most vaccines being administered to healthy individuals, safety assessments are crucial to maintaining public trust in immunization programs. The effort undertaken, to process of case verification and the results of safety evaluation should be transparent and communicated clearly to the public.

#### **II. The ViVI Implementation Working Group**

With more vaccines available and accessible around the world, globalization of vaccine safety efforts has come increasingly important. While generation of case definitions is a remarkable step in the creation of an international vaccine safety terminology, this common language will need to be used and “spoken” in order to be effective in improving vaccine safety around the world. The concept of the ViVI Implementation Working Group is fairly simple: There are approved and evidence-based standards available; there are people willing to use them, and others who can help and counsel in the process. Bringing these people to one table will be the next logical step to the implementation of vaccine safety standards in different parts of the world.

#### **III. Objectives for the Working Group**

##### **Goal**

To facilitate the implementation of international vaccine safety standards in different parts of the world.

##### **Objectives**

- To identify challenges in the international implementation of vaccine safety standards.
- To generate “user-feedback” and new ideas for the improvement of vaccine safety standards.
- To identify opportunities to facilitate usage of vaccine safety standards in resource-poor settings.
- To generate well-defined implementation proposals and partnerships.

#### **IV. Rationale**

The ViVI Implementation Working Group provides a forum of clinical researchers and members of regulatory and donor agencies to discuss how to facilitate the implementation of vaccine safety standards in different parts of the world. The Implementation Working Group will act as a “Think Tank” generating new concepts for harmonization of evidence-based in industrialized countries and non-industrialized countries. Interested personnel in industrialized and non-industrialized countries will be encouraged to share their experience in the design and conduct of vaccine safety studies, promoting comparability and high quality evidence-based research.

#### **V. Working group composition**

The ViVI Implementation Working Group includes well-published experts in international vaccine trials and organization leaders in their respective countries. The Implementation Working Group aims for a minimum of 50% active participation from non-industrialized countries. The Implementation Working Group explicitly advocates for the use of established, international vaccine safety standards and recommendations by the Brighton Collaboration, WHO, GACVS, CIOMS and others. The group remains open to organizations conducting centralized harmonization efforts with state health institutions and regulatory as well as donor agencies and/or NGOs involved in immunization programs and vaccine trials/ surveillances in developing countries.

#### **VI. Process**

Think Tank. Limited time commitment with regulatory conferences calls and/ or emails.

#### **VII. Expected Outcomes**

- Regulatory publications on vaccine safety topics, according to the contributions of individual working group members and guest authors.
- Increased awareness of international vaccine safety standards among opinion leaders in international vaccine research, development and surveillance.
- Improved collaboration and communication among partner networks and organizations involved in international vaccine safety initiatives.

#### **VIII. Chair of the ViVI Implementation Working Group**

##### **Barbara Rath, MD**

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#### **IX. Project Website: <http://www.vi-vi.org>**