

**Global Vaccine Safety Initiative**  
**Activities Portfolio**  
**2012-2020**

**World Health Organization**  
**Switzerland**  
**April 2013**

# **Activities Description**

## Global Vaccine Safety initiative activities portfolio

### Introduction

The Global Vaccine Safety Initiative (GVSU) is the implementation mechanism for [the global vaccine safety Blueprint](#) (the Blueprint). The GVSU is a forum administered by WHO which provides its secretariat. In this regard, GVSU is not a separate legal entity.

The Blueprint is the strategic framework reference document endorsed by WHO's Strategic Advisory Group of Experts (SAGE) on immunization and is regarded as the vaccine safety strategy of the [Global Vaccine Action Plan](#). The purpose of the Blueprint is to optimize the safety of vaccines through effective use of vaccine pharmacovigilance principles and methods.

[The GVSU Planning Group \(PG\)](#) provides overall direction for the Initiative. It is composed of the designated representatives of the GVSU and WHO is an ex-officio member. At present, GVSU Participants come from Brighton Collaboration Foundation, Switzerland; University of Ghana; Ministry of Health Sri Lanka; International Vaccine Institute, Korea; Ministry of Health, Brazil; Uppsala Monitoring Centre, Sweden

One of the tasks of the GVSU PG is to maintain a portfolio of activities to enhance vaccine pharmacovigilance capabilities in low- and middle-income countries. The GVSU portfolio is a dynamic listing of activities identified as priorities for implementing the Blueprint. Each activities in the portfolio the PG has prioritized based on the following:

1. **Expected impact.**
2. **Level of impact (global or national).**
3. **Change of current practice.**
4. **Anticipated exploitation.**
5. **Valuable stand alone or enabling.**

Based on the above, the PG recommends funding for portfolio activities as follows:

**Priority 1-** Key activity for which funding is immediately needed.

**Priority 2:** Important activity for which funding is recommended..

**Priority 3:** Desirable activity that should be part of a full GSVI work plan.

Activities proposed in the portfolio reflect the work of their initiators, managers and donors regardless of the source of funding. They do not reflect WHO activities but have been identified by WHO as valuable contributions towards the shared goal of implementing the Blueprint. In this regard, WHO is not responsible nor accountable for activities implemented by individual GVSU Participants.

## **Overview of the GVSI Portfolio activities**

The current GVSI portfolio includes activities reviewed by the GVSI PG in November 2012, some of which are expected to extend up to 2020, that is the duration of the [Decade of Vaccine endorsed by the World Health Assembly](#).

All GVSI projects are listed and monitored through the portfolio. Portfolio activities benefit from the visibility provided by the GVSI through its broad base of stakeholders. GVSI participants and stakeholders may refer to the portfolio to assist in making funding decisions. Interested parties can request further details on the nature of the activities, outputs, outcomes and expected impact by contacting the responsible contact person or on request to [GVSI@who.int](mailto:GVSI@who.int)

## Objective 1: To strengthen vaccine safety monitoring in all countries.

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<b>PIN</b>	147908
<b>Short Title</b>	<b>Cohort Event Monitoring in vaccine pharmacovigilance: Using Measles, Mumps, and Rubella (MMR) vaccine and Japanese Encephalitis (JE) vaccine as models in one country.</b>
<b>End Product</b>	1. Safety data from spontaneous reports related to MMR and Live JE Vaccine. 2. Broader understanding of CEM as a pharmacovigilance tool to assess safety profile in an immunization programme in a developing country setting.
<b>Status</b>	Partially Funded <b>Ongoing</b>
<b>Priority*</b>	2
<b>Completion date</b>	2013 <b>Activity contact person:</b> ana_amarasinghe@yahoo.co.uk

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<b>PIN</b>	148046
<b>Short Title</b>	<b>Development of IT bridges among existing softwares to ensure regional data safety collection and analysis.</b>
<b>End Product</b>	Development of IT bridges to extract safety data, the solution utilizes ESAVI core variables developed by WHO and GAVCS.
<b>Status</b>	Partially Funded <b>Ongoing</b>
<b>Priority*</b>	1
<b>Completion date</b>	2014 <b>Activity contact person:</b> pamelab@who.int

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<b>PIN</b>	150550
<b>Short Title</b>	<b>Study on Factors affecting AEFI detection in one SEARO country.</b>
<b>End Product</b>	Analysis of the factor that prevent AEFI reporting at each level of the immunization delivery system.
<b>Status</b>	Partially Funded <b>Ongoing</b>
<b>Priority*</b>	1
<b>Completion date</b>	2013 <b>Activity contact person:</b> guichards@who.int

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<b>PIN</b>	150561
<b>Short Title</b>	<b>Enhance capacity of National Pharmacovigilance programs for active/targeted Pharmacovigilance, including the design of pilot projects.</b>
<b>End Product</b>	Two protocols developed and piloted in two countries.
<b>Status</b>	Not Funded <b>Planned</b>
<b>Priority*</b>	1
<b>Completion date</b>	2015 <b>Activity contact person:</b> pombomar@who.int

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### Priority \*

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

## Objective 1: To strengthen vaccine safety monitoring in all countries.

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<b>PIN</b>	<b>150580</b>	
<b>Short Title</b>	<b>Pilot project in one SEARO country to field test new notification forms including serious and mild AEFI and to update AEFI investigation template which meet requirement for new vaccine introduction.</b>	
<b>End Product</b>	Notification forms, updated AEFI investigation forms are finalized.	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> guichards@who.int

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<b>PIN</b>	<b>150779</b>	
<b>Short Title</b>	<b>Develop IT tool for AEFI collection and analysis for selected countries.</b>	
<b>End Product</b>	Development of effective networks and implementation sustainable pharmacovigilance (IT) systems in participating countries for analysis of data and response on vaccine safety issues of regional importance.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> AjitPalSingh@ivi.int

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<b>PIN</b>	<b>150905</b>	
<b>Short Title</b>	<b>Build regulatory capacity of countries for evaluation of safety data from novel vaccines.</b>	
<b>End Product</b>	Trained NRAs staff from AVAREF countries on reviewing safety data from novel vaccines.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> akanmorib@who.int

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<b>PIN</b>	<b>150907</b>	
<b>Short Title</b>	<b>Promote harmonization through adoption of common post-marketing surveillance strategy in the 22 AVAREF countries.</b>	
<b>End Product</b>	Trained NRAs and improved PMS.	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> akanmorib@who.int

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### Priority \*

*Priority 1: Key activity for which funding is immediately needed.*

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## Objective 2: To strengthen the ability of countries to evaluate vaccine safety signals.

<b>PIN</b>	147966	
<b>Short Title</b>	<b>Review of AEFI surveillance system in one EMRO country and implementation of intussusception surveillance with the introduction of rotavirus vaccine in EPI.</b>	
<b>End Product</b>	1-Evaluation of the pharmacovigilance system in one EMRO country and produce institutional development plan (IDP) to strengthen the AEFI surveillance. 2-Protocol to implement intussusception surveillance developed.	
<b>Status</b>	Partially Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2015	<b>Activity contact person:</b> langarh@who.int
<b>PIN</b>	147967	
<b>Short Title</b>	<b>Implementation of intussusception surveillance activities in one EMRO country introducing rotavirus vaccine.</b>	
<b>End Product</b>	Development of intussusception surveillance protocol and implementation of intussusception surveillance activities in one EMRO country introducing rotavirus.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> langarh@who.int
<b>PIN</b>	148525	
<b>Short Title</b>	<b>Adverse events and immunogenicity following the yellow fever vaccine in patients in usage of immunomodulator therapies.</b>	
<b>End Product</b>	Early identification of risk and the development of an AEFI and the establishment of control measures and timely intervention.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>2</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> sandra.deotti@saude.gov.br
<b>PIN</b>	150587	
<b>Short Title</b>	<b>To conduct postmarketing vaccine safety study in one SEARO country.</b>	
<b>End Product</b>	Background rates of AEFI for all vaccines including for the new vaccines in one selected SEARO country introducing pentavalent vaccines in 2013.	
<b>Status</b>	Partially Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>2</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> guichards@who.int

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## Objective 2: To strengthen the ability of countries to evaluate vaccine safety signals.

<b>PIN</b>	<b>151048</b>	
<b>Short Title</b>	<b>Study testing feasibility of different designs for active surveillance in LMIC.</b>	
<b>End Product</b>	Proof of principle studies in LMIC demonstrating the feasibility of collaborative incidence rate, coverage rate, signal verification and hypothesis testing studies in LMIC.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	3	
<b>Completion date</b>	2015	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>151053</b>	
<b>Short Title</b>	<b>Global map of databases for signal verification and hypothesis testing.</b>	
<b>End Product</b>	Global searchable map of healthcare databases for rapid identification of appropriate data sources for collaborative studies.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	2	
<b>Completion date</b>	2015	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>151745</b>	
<b>Short Title</b>	<b>Active monitoring for intussusception following deployment of rotavirus vaccine in one AFRO country.</b>	
<b>End Product</b>	Research report on an estimated 500 cases of intussusception collected from 6 health facilities in one AFRO country.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	1	
<b>Completion date</b>	2015	<b>Activity contact person:</b> alexooo@yahoo.com
<b>PIN</b>	<b>154822</b>	
<b>Short Title</b>	<b>Multi-country collaboration project.</b>	
<b>End Product</b>	Report defining necessary infrastructure for vaccine safety sentinel sites.	
<b>Status</b>	Funded	Ongoing
<b>Priority*</b>	1	
<b>Completion date</b>	2013	<b>Activity contact person:</b> lambachp@who.int

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## Objective 2: To strengthen the ability of countries to evaluate vaccine safety signals.

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<b>PIN</b>	<b>159691</b>	
<b>Short Title</b>	<b>Inter-country workshop on causality assessment of adverse events following immunization.</b>	
<b>End Product</b>	Increased capacity to investigate Adverse Events Following Immunization (AEFI) and causality assessment in SEARO region.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> guichards@who.int

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### **Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

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**Objective 3: To develop vaccine safety communication plans at country level to ensure awareness of vaccine risks and benefits, understand perceptions of risk, and prepare for managing any adverse events and crises promptly.**

<b>PIN</b>	<b>147714</b>	
<b>Short Title</b>	<b>Vaccine Safety Net.</b>	
<b>End Product</b>	A web based list of vaccine safety web sites providing reliable information on Vaccine Safety. <i>(<a href="http://www.who.int/vaccine_safety/initiative/communication/network/approved_vaccine_safety_website/en/index.html">http://www.who.int/vaccine_safety/initiative/communication/network/approved_vaccine_safety_website/en/index.html</a>)</i>	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> bellaham@who.int
<b>PIN</b>	<b>150911</b>	
<b>Short Title</b>	<b>Convene a Regional Advisory Group on Vaccine Safety.</b>	
<b>End Product</b>	Scientific advice on vaccine safety.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> akanmorib@who.int
<b>PIN</b>	<b>151040</b>	
<b>Short Title</b>	<b>Impact of public concerns on coverage; seasonal influenza and batch quality an example of a one-time concern leading to withdrawal.</b>	
<b>End Product</b>	Cost-benefit analysis of the a one-time public concern leading to withdrawal of Influenza vaccine batch(es).	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	3	
<b>Completion date</b>	2015	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>151041</b>	
<b>Short Title</b>	<b>Understanding geographic and cultural differences of public concerns to guide program implementation.</b>	
<b>End Product</b>	Geographic and cultural information of public concerns to guide program implementation.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	3	
<b>Completion date</b>	2014	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com

**Priority \***

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**Objective 3: To develop vaccine safety communication plans at country level to ensure awareness of vaccine risks and benefits, understand perceptions of risk, and prepare for managing any adverse events and crises promptly.**

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<b>PIN</b>	<b>151042</b>	
<b>Short Title</b>	<b>Methods for rumor detection in public media.</b>	
<b>End Product</b>	Method for signal detection of vaccine safety concerns in public media.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com

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<b>PIN</b>	<b>151043</b>	
<b>Short Title</b>	<b>Quantifying bias in epidemiologic studies introduced by public concern.</b>	
<b>End Product</b>	Method to quantify unmeasured bias in observational vaccine safety studies e.g., (media attention, diagnostic awareness).	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	3	
<b>Completion date</b>	2015	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com

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## Objective 4: To develop internationally harmonized tools and methods for vaccine pharmacovigilance.

<b>PIN</b>	<b>147926</b>	
<b>Short Title</b>	<b>Development and evaluation of narcolepsy case definition and investigation of reporting patterns of Narcolepsy over time.</b>	
<b>End Product</b>	Publication of narcolepsy case definition and report on changes of reporting patterns in international databases.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>147929</b>	
<b>Short Title</b>	<b>Algorithms for case validation of AEFI following influenza vaccines.</b>	
<b>End Product</b>	Algorithms for all AEFI developed.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	3	
<b>Completion date</b>	2013	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>147930</b>	
<b>Short Title</b>	<b>Standardized disease concepts for international collaborative studies.</b>	
<b>End Product</b>	Library of mapped and standardized disease concepts across different coding terminologies for international collaborative studies.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	3	
<b>Completion date</b>	2013	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>147933</b>	
<b>Short Title</b>	<b>Translation of Standardized Brighton Case Definitions.</b>	
<b>End Product</b>	Translation of Brighton Collaboration Case definitions in all WHO official languages.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>2</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com

### Priority \*

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*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

## Objective 4: To develop internationally harmonized tools and methods for vaccine pharmacovigilance.

<b>PIN</b>	<b>147934</b>	
<b>Short Title</b>	<b>Ad hoc case definition development.</b>	
<b>End Product</b>	Ad hoc case definition as prioritized by WHO.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>147935</b>	
<b>Short Title</b>	<b>Automatic case classification of spontaneous reports.</b>	
<b>End Product</b>	An application programming interface (API) is produced and integrated in a target spontaneous reporting system allowing the reporter and/or the receiver to automatically classify submitted cases. The tool also informs the classifier about missing information to improve diagnostic certainty of reported event.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>2</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>147951</b>	
<b>Short Title</b>	<b>Developing Regional AEFI guidelines.</b>	
<b>End Product</b>	Publication: Immunization Safety Surveillance. <a href="http://www.wpro.who.int/topics/immunization_safety/ImmunizationSafetySurveillance.pdf">http://www.wpro.who.int/topics/immunization_safety/ImmunizationSafetySurveillance.pdf</a>	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> hossains@who.int
<b>PIN</b>	<b>147954</b>	
<b>Short Title</b>	<b>Training to strengthen AEFI monitoring and causality assessment in one EMRO country.</b>	
<b>End Product</b>	Training of NRA and EPI staff on AEFI monitoring, causality assessment and strengthening of the national Pharmacovigilance system.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> langarh@who.int

### Priority \*

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

## Objective 4: To develop internationally harmonized tools and methods for vaccine pharmacovigilance.

<b>PIN</b>	<b>148000</b>	
<b>Short Title</b>	<b>Develop international SOPs for spontaneous AEFI reporting.</b>	
<b>End Product</b>	International Standard Operating Procedures for spontaneous AEFI reporting.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> lambachp@who.int
<b>PIN</b>	<b>148002</b>	
<b>Short Title</b>	<b>Provide a repository for the storage of national AEFI reports.</b>	
<b>End Product</b>	A national electronic repository linked to the UMC database.	
<b>Status</b>	Partially Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> balakrishnanm@who.int
<b>PIN</b>	<b>148004</b>	
<b>Short Title</b>	<b>Defining essential information for AEFI reporting.</b>	
<b>End Product</b>	AEFI Core Variables identified and available online. <a href="http://www.who.int/vaccine_safety/news/AEFI_Core_Variables_2013.pdf">http://www.who.int/vaccine_safety/news/AEFI_Core_Variables_2013.pdf</a>	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> balakrishnanm@who.int
<b>PIN</b>	<b>148009</b>	
<b>Short Title</b>	<b>Development of standard AEFI reporting form.</b>	
<b>End Product</b>	Model AEFI reporting form available online. <a href="http://www.who.int/vaccine_safety/REPORTING_FORM_FOR_ADVERSE_EVENTS_FOLLOWING_IMMUNIZATION.pdf">http://www.who.int/vaccine_safety/REPORTING_FORM_FOR_ADVERSE_EVENTS_FOLLOWING_IMMUNIZATION.pdf</a>	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> balakrishnanm@who.int

### Priority \*

*Priority 1: Key activity for which funding is immediately needed.*

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## Objective 4: To develop internationally harmonized tools and methods for vaccine pharmacovigilance.

<b>PIN</b>	<b>148011</b>	
<b>Short Title</b>	<b>AEFI Causality Assessment classification.</b>	
<b>End Product</b>	A tool for assessing causality at individual level including a manual and aide-memoire.	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> balakrishnanm@who.int
<b>PIN</b>	<b>148018</b>	
<b>Short Title</b>	<b>Development of a Vaccine Pharmacovigilance Toolkit.</b>	
<b>End Product</b>	A WHO Vaccine Pharmacovigilance Toolkit.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> alexooo@yahoo.com
<b>PIN</b>	<b>148030</b>	
<b>Short Title</b>	<b>Information sheets on vaccine reaction rates.</b>	
<b>End Product</b>	Information sheets on vaccine reaction rates <a href="http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/index.html">http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/index.html</a>	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> lambachp@who.int
<b>PIN</b>	<b>148047</b>	
<b>Short Title</b>	<b>Update regional ESAVI guidelines and standard operational procedures (SOP), including causality assessment algorithm.</b>	
<b>End Product</b>	Updated safety package of training, which includes ESAVI monitoring, causality assessment and risk communication.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> pamelab@who.int

### Priority \*

*Priority 1: Key activity for which funding is immediately needed.*

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## Objective 4: To develop internationally harmonized tools and methods for vaccine pharmacovigilance.

<b>PIN</b>	<b>148762</b>	
<b>Short Title</b>	<b>Scoping exercise on innovative clinical trial design &amp; optimal allocation of safety data collection at each phase of the product development cycle</b>	
<b>End Product</b>	Plan of work developed and implemented during the subsequent years of the US FDA grant. The work will operationalize aspects of the global regulatory science agenda as developed in context of the Global Vaccine Action Plan of the Decade of Vaccine	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> <a href="mailto:hombachj@who.int">hombachj@who.int</a>
<b>PIN</b>	<b>150557</b>	
<b>Short Title</b>	<b>Develop norms and reference documents on risk-benefit reports and risk management.</b>	
<b>End Product</b>	New documents on risk management and periodic safety update reports. Good Pharmacovigilance practices updated.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>2</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> <a href="mailto:pombomar@who.int">pombomar@who.int</a>
<b>PIN</b>	<b>150560</b>	
<b>Short Title</b>	<b>Support harmonization of databases including ESAVIs fields in national Pharmacovigilance systems.</b>	
<b>End Product</b>	1-Document on basic criteria for database management developed. 2-Two countries with updated pilot databases fields/systems developed. 3-Work group for supporting and monitoring performance established.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2015	<b>Activity contact person:</b> <a href="mailto:pombomar@who.int">pombomar@who.int</a>

### Priority \*

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

## Objective 4: To develop internationally harmonized tools and methods for vaccine pharmacovigilance.

<b>PIN</b>	<b>150689</b>	
<b>Short Title</b>	<b>Optimizing signal analysis in VigiBase for vaccine related individual case safety reports (ICSRs)</b>	
<b>End Product</b>	Improved statistical algorithms for routine use by UMC signal review team. Statistical associations are provided to the clinical review team for assessment of validity and public health interest. New signals considered interesting by the clinical reviewers are shared with WHO and national pharmacovigilance centres.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> Sten.Olsson@who-umc.org
<b>PIN</b>	<b>150889</b>	
<b>Short Title</b>	<b>Web Based Causality Assessment Tool.</b>	
<b>End Product</b>	A web based version of the WHO causality assessment algorithm.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>2</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>150894</b>	
<b>Short Title</b>	<b>Standard AEFI case set for global evaluation and training related to new causality assessment paradigms.</b>	
<b>End Product</b>	Standard multilingual set of AEFI cases for use in evaluation and training related to the WHO and CISA causality assessment algorithms.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>150902</b>	
<b>Short Title</b>	<b>Develop Regional AEFI guidelines</b>	
<b>End Product</b>	1-Training and capacity building of MOH and NRA staff. 2-Vaccine safety surveillance system Strengthened.	
<b>Status</b>	Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> akanmorib@who.int

### Priority \*

*Priority 1: Key activity for which funding is immediately needed.*

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## Objective 4: To develop internationally harmonized tools and methods for vaccine pharmacovigilance.

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<b>PIN</b>	<b>150908</b>	
<b>Short Title</b>	<b>Regional consultation for harmonization of guidelines for on surveillance for intussusception surveillance.</b>	
<b>End Product</b>	Common guidelines for intussusception surveillance developed.	
<b>Status</b>	Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> akanmorib@who.int

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<b>PIN</b>	<b>151051</b>	
<b>Short Title</b>	<b>New designs for integrated benefit risk assessment.</b>	
<b>End Product</b>	Methods for integrated benefit/risk assessment of vaccines.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2015	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com

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### **Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 5: To establish a legal, regulatory and administrative framework to ensure compliance with vaccine pharmacovigilance requirements at national, regional and international levels.**

<b>PIN</b>	<b>147965</b>	
<b>Short Title</b>	<b>Review of AEFI surveillance system in one EMRO country.</b>	
<b>End Product</b>	Review of NRA system in one EMRO country and establishment of institutional development plan.	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> langarh@who.int
<b>PIN</b>	<b>148008</b>	
<b>Short Title</b>	<b>Updated benchmarks for vaccine pharmacovilance function of the NRA assessments.</b>	
<b>End Product</b>	Revised list of indicators and sub-indicators of the vaccine pharmacovigilance function of the WHO NRA assessment tool.	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> maurec@who.int
<b>PIN</b>	<b>148010</b>	
<b>Short Title</b>	<b>Perform national vaccine PV system evaluation against agreed benchmarks (NRA assessment tool).</b>	
<b>End Product</b>	Perform national vaccine PV system assessment in at least 5 countries per year.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2020	<b>Activity contact person:</b> maurec@who.int
<b>PIN</b>	<b>150552</b>	
<b>Short Title</b>	<b>Support NRA exchange and analysis of information for decision making on vaccine safety issues.</b>	
<b>End Product</b>	Establishment of Network for monitoring and analyzing reports in pharmacovigilance centers in two PAHO countries.	
<b>Status</b>	Partially Funded	Planned
<b>Priority*</b>	<b>2</b>	
<b>Completion date</b>	2015	<b>Activity contact person:</b> pombomar@who.int

**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 5: To establish a legal, regulatory and administrative framework to ensure compliance with vaccine pharmacovigilance requirements at national, regional and international levels.**

<b>PIN</b>	150555	
<b>Short Title</b>	<b>Staff in information centres trained on critical information appraisal and communication and supporting the pharmacovigilance network. Bulletin of medicines information centers designed and disseminated.</b>	
<b>End Product</b>	Staff in information centres trained on critical information appraisal and communication and supporting the pharmacovigilance network.	
<b>Status</b>	Partially Funded	<b>Ongoing</b>
<b>Priority*</b>	2	
<b>Completion date</b>	2015	<b>Activity contact person:</b> pombomar@who.int
<b>PIN</b>	150559	
<b>Short Title</b>	<b>Improve National PV centres performance through a quality evaluation program.</b>	
<b>End Product</b>	Develop indicators to assess the performance of PV centers and pilot in two PAHO countries.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	2	
<b>Completion date</b>	2015	<b>Activity contact person:</b> pombomar@who.int

**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 6: To strengthen regional and global technical support platforms for a vaccine pharmacovigilance system that meets countries' expressed needs.**

<b>PIN</b>	147898	
<b>Short Title</b>	Training course on vaccines safety provided by US FDA (CBER) to participants of UMC annual pharmacovigilance training course and others	
<b>End Product</b>	A training for healthcare professionals with a special interest in vaccine safety assessment, specifically as applied by US FDA.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> Sten.Olsson@who-umc.org
<b>PIN</b>	147937	
<b>Short Title</b>	Training modules for pharmacoepidemiologic vaccine safety studies.	
<b>End Product</b>	Development of 4 advanced modules for vaccine safety assessment with specific focus on standard methodology, signal verification and hypothesis testing.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	147953	
<b>Short Title</b>	AEFI training workshop for 8 countries in WPRO region.	
<b>End Product</b>	Capacity building for EPI and NRA staff on vaccine safety in WPRO region.	
<b>Status</b>	Partially Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> hossains@who.int
<b>PIN</b>	147955	
<b>Short Title</b>	AEFI training workshop for seven countries in Western Pacific Region in 2014.	
<b>End Product</b>	Training and capacity building for EPI and NRA staff on vaccine safety in WPRO countries.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>2</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> hossains@who.int

**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 6: To strengthen regional and global technical support platforms for a vaccine pharmacovigilance system that meets countries' expressed needs.**

<b>PIN</b>	<b>147961</b>	
<b>Short Title</b>	<b>Second regional meeting on pharmacovigilance of vaccines.</b>	
<b>End Product</b>	Training and capacity building on vaccine safety communication.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> langarh@who.int
<b>PIN</b>	<b>147962</b>	
<b>Short Title</b>	<b>Training on AEFI and causality assessment in one EMRO country.</b>	
<b>End Product</b>	Training of NRA and EPI staff on AEFI monitoring, causality assessment and strengthening of the national Pharmacovigilance system.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> langarh@who.int
<b>PIN</b>	<b>147963</b>	
<b>Short Title</b>	<b>First regional meeting on pharmacovigilance of vaccines.</b>	
<b>End Product</b>	1-Training and capacity building of NRA, pharmacovigilance and EPI staff on AEFI surveillance system. 2-Updated information on AEFI with use of rotavirus vaccine and BCG vaccine.	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> langarh@who.int
<b>PIN</b>	<b>147985</b>	
<b>Short Title</b>	<b>Regional Vaccine Safety Workshop in Asia.</b>	
<b>End Product</b>	Enhanced capacity for vaccine safety assessment by NRAs, AEFI and vaccination advisory committees in countries that introduce newly developed vaccines in settings with novel characteristics and use prequalified vaccines either directly or through UN supply.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> AjitPalSingh@ivi.int

**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 6: To strengthen regional and global technical support platforms for a vaccine pharmacovigilance system that meets countries' expressed needs.**

<b>PIN</b>	<b>148007</b>	
<b>Short Title</b>	<b>Strengthening network countries capacity for data analysis and signal detection.</b>	
<b>End Product</b>	1-Standard training package on AEFI data analysis and signal detection. 2-Workshop conducted in the 12 network countries.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2014	<b>Activity contact person:</b> maurec@who.int
<b>PIN</b>	<b>148013</b>	
<b>Short Title</b>	<b>Establish global pool of qualified trainers for WHO trainings in countries</b>	
<b>End Product</b>	Development of a Web based database of experts.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> bellaham@who.int
<b>PIN</b>	<b>148031</b>	
<b>Short Title</b>	<b>Global learning resource centre.</b>	
<b>End Product</b>	Web-platform linking to E-learning tools, trainer databases, PPT toolkits and a contact to organize WHO trainings in countries. <a href="http://www.who.int/vaccine_safety/initiative/tech_support/en/">(http://www.who.int/vaccine_safety/initiative/tech_support/en/)</a>	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> lambachp@who.int
<b>PIN</b>	<b>148035</b>	
<b>Short Title</b>	<b>E-learning training material on Vaccine Safety.</b>	
<b>End Product</b>	E-learning course on Vaccine Safety. <a href="http://www.who.int/vaccine_safety/initiative/tech_support/ebasic/en/index.html">http://www.who.int/vaccine_safety/initiative/tech_support/ebasic/en/index.html</a>	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> lambachp@who.int

**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 6: To strengthen regional and global technical support platforms for a vaccine pharmacovigilance system that meets countries' expressed needs.**

<b>PIN</b>	148039	
<b>Short Title</b>	Basic training toolkit for trainers in countries.	
<b>End Product</b>		
<b>Status</b>	Funded	Completed
<b>Priority*</b>	1	
<b>Completion date</b>	2012	Activity contact person: lambachp@who.int
<b>PIN</b>	148042	
<b>Short Title</b>	Strengthening of ESAVI Committees and members.	
<b>End Product</b>	Regional Standard Operational Procedures Guidelines, to support the constitution of ESAVI Committees at the national level.	
<b>Status</b>	Funded	Ongoing
<b>Priority*</b>	1	
<b>Completion date</b>	2013	Activity contact person: pamelab@who.int
<b>PIN</b>	148045	
<b>Short Title</b>	Enhance the causality assessment capacity of vaccine pharmacovigilance officers.	
<b>End Product</b>	Report and insights to continuously improve the methodology.	
<b>Status</b>	Partially Funded	Ongoing
<b>Priority*</b>	1	
<b>Completion date</b>	2013	Activity contact person: pamelab@who.int
<b>PIN</b>	148048	
<b>Short Title</b>	Identify and establish accredited training institutions at global, regional, and sub-regional levels.	
<b>End Product</b>	Availability of a training network with harmonized curricula, translation of training materials, adaptation of training modules based on the evolution of science.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	2	
<b>Completion date</b>	2015	Activity contact person: zuberp@who.int

**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 6: To strengthen regional and global technical support platforms for a vaccine pharmacovigilance system that meets countries' expressed needs.**

<b>PIN</b>	150554	
<b>Short Title</b>	<b>Support NRA capacity building.</b>	
<b>End Product</b>	Online and face to face training and capacity building for NRA staff on causality assessment, performance evaluation, ESAVIs and risk management in 7 PAHO countries.	
<b>Status</b>	Partially Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2015	<b>Activity contact person:</b> pombomar@who.int
<b>PIN</b>	150579	
<b>Short Title</b>	<b>Support to the establishment of the national AEFI secretariat in one SEARO country</b>	
<b>End Product</b>	Operational national AEFI committee to collect, analyze and report AEFI cases.	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> guichards@who.int
<b>PIN</b>	150586	
<b>Short Title</b>	<b>To conduct refresher training on AEFI detection and reporting in one SEARO country.</b>	
<b>End Product</b>	Trained 79 trainers who in turn trained 523 EPI and AEFI focal persons on AEFI detection analysis and reporting at the district level.	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> guichards@who.int
<b>PIN</b>	150588	
<b>Short Title</b>	<b>Conduct AEFI training workshop in two SEARO countries.</b>	
<b>End Product</b>	60 EPI and AEFI focal persons trained on AEFI detection and reporting.	
<b>Status</b>	Funded	<b>Completed</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2012	<b>Activity contact person:</b> guichards@who.int

**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 6: To strengthen regional and global technical support platforms for a vaccine pharmacovigilance system that meets countries' expressed needs.**

<b>PIN</b>	<b>150780</b>	
<b>Short Title</b>	<b>Provide access to online training for vaccine safety to avaref countries.</b>	
<b>End Product</b>	NRA staff trained on vaccine safety.	
<b>Status</b>	Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> akanmorib@who.int
<b>PIN</b>	<b>150906</b>	
<b>Short Title</b>	<b>Training for AEFI for two countries each in ITST West and IST Central Africa</b>	
<b>End Product</b>	Training and capacity building for MOH and NRA staff on vaccine safety.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> akanmorib@who.int
<b>PIN</b>	<b>150910</b>	
<b>Short Title</b>	<b>Regional Vaccinology course.</b>	
<b>End Product</b>	Trained NRAs staff.	
<b>Status</b>	Partially Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> akanmorib@who.int
<b>PIN</b>	<b>151424</b>	
<b>Short Title</b>	<b>Vaccine safety fellowship.</b>	
<b>End Product</b>	A framework and curriculum for a Vaccine Safety Fellowship	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com
<b>PIN</b>	<b>151425</b>	
<b>Short Title</b>	<b>Develop a vaccine safety fellowship training programme.</b>	
<b>End Product</b>	Annual training of 2 to 4 vaccine safety specialists.	
<b>Status</b>	Not Funded	Planned
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> jan.bonhoeffer@gmail.com

**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

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**Objective 6: To strengthen regional and global technical support platforms for a vaccine pharmacovigilance system that meets countries' expressed needs.**

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<b>PIN</b>	152151
<b>Short Title</b>	<b>Annual global vaccine safety update.</b>
<b>End Product</b>	Annual one day scientific conference and publication.
<b>Status</b>	Partially Funded <b>Ongoing</b>
<b>Priority*</b>	<b>1</b>
<b>Completion date</b>	2020 <b>Activity contact person:</b> jan.bonhoeffer@gmail.com

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**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 7: To make international expert scientific advice on vaccine safety issues available to support vaccine safety systems at national, regional and international levels.**

<b>PIN</b>	<b>148044</b>	
<b>Short Title</b>	<b>Establishment of a Regional Advisory Group on Vaccine Safety.</b>	
<b>End Product</b>	Regional meeting to review selected safety cases and publication of a report and article for each meeting.	
<b>Status</b>	Partially Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2013	<b>Activity contact person:</b> pamelab@who.int
<b>PIN</b>	<b>148050</b>	
<b>Short Title</b>	<b>Rapidly and effectively deal with serious vaccine-related adverse events in order to maintain confidence in a vaccine.</b>	
<b>End Product</b>	Technical support for investigation, analysis and response with the possibility of prompt independent expert advice.	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2020	<b>Activity contact person:</b> zuberp@who.int
<b>PIN</b>	<b>148051</b>	
<b>Short Title</b>	<b>Publish GACVS assessments in WER within 6 weeks of the committee deliberations.</b>	
<b>End Product</b>	Up-to-date GACVS review of vaccine safety profiles published in WER since 1999. <a href="http://www.who.int/vaccine_safety/committee/reports/en/">http://www.who.int/vaccine_safety/committee/reports/en/</a>	
<b>Status</b>	Funded	<b>Ongoing</b>
<b>Priority*</b>	<b>1</b>	
<b>Completion date</b>	2020	<b>Activity contact person:</b> zuberp@who.int

**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*

**Objective 8: To put in place systems for appropriate interaction between national governments, multilateral agencies, and manufacturers at national, regional and international levels**

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<b>PIN</b>	148052
<b>Short Title</b>	Assess, evaluate and adapt the global AEFI information exchange mechanism.
<b>End Product</b>	Improved information exchange mechanisms between industry and public sector.
<b>Status</b>	Not Funded      Planned
<b>Priority*</b>	<b>1</b>
<b>Completion date</b>	2020 <b>Activity contact person:</b> zuberp@who.int

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**Priority \***

*Priority 1: Key activity for which funding is immediately needed.*

*Priority 2: Important activity for which funding is recommended.*

*Priority 3: Desirable activity that should be part of a full GSVI work plan.*