

# What is PViMS?

The Pharmacovigilance Monitoring System (PViMS) is a web-based application used by clinicians, regulatory bodies, and implementing partners to monitor the safety and effectiveness of medicines.

PViMS makes implementation of active surveillance activities feasible in low- and middle-income countries (LMICs) by addressing the entire data collection and data analysis process to identify signals for improving safety of patients on treatment. The enhanced PViMS was developed through the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program implemented by Management Sciences for Health (MSH).

## PLATFORM TECHNOLOGY



- Web-based interface
- Centralized deployment for Intranet/Extranet/Internet environment
- Microsoft .NET 4.0 Entity Framework
- Service-oriented architecture (SOA)
- HL7 compatibility
- E2B compatibility
- Smart-device compatibility
- Customized reporting component
- Reporting portal for result analysis, analysis-based publications, solicited reporting



Active surveillance for monitoring the safety and effectiveness of medical products is increasingly recognized as an approach that complements passive reporting, which is the most common method used by countries' pharmacovigilance systems. Active surveillance is particularly important to support the introduction of new essential medicines in LMICs whose regulatory systems are developing and need support. In resource-limited settings, active surveillance can help determine the real-life frequency, risk factors, and impact of clinically significant adverse drug events on treatment outcomes in the population. However, many of these countries lack the resources and capacity to implement active surveillance activities. One of the major resource constraints is the lack of a data collection and analysis tool to support active safety surveillance.

## Minimum Requirements

Windows XP, 7 32/64 bit  
Windows 2003/2008 R2 Server  
MS SQL Express/Standard 2008 R1/R2



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## WHY THE NEED FOR A TOOL?

# Pharmacovigilance Monitoring System



**USAID**  
FROM THE AMERICAN PEOPLE

**SIAPS**  
Systems for Improved Access  
to Pharmaceuticals and Services

# FEATURES AND BENEFITS

## Improves overall clinical documentation

Completion of required fields, including clinical stage, concomitant medications, test results, co-morbid conditions, and treatment regimen, initiation date, and adherence to improve clinical documentation at participating sentinel sites

## Provides for the use of common terms, checklists, and adoption of standard terminologies

Users enter the common terms or choose from pre-coded causality assessment lists and scales such as MedDRA, the National Cancer Institute Common Terminology Criteria for Adverse Events, WHO, and Naranjo; eventually users can develop a local dictionary using standard terms

## Provides for detailed description of adverse event (AE) outcome and generating signals

Description of AEs, severity and seriousness, laboratory values, AE outcome, and AE management; can be used to generate signals of increased incidence to inform action or be further evaluated

## Interoperable with third-party clinical systems and statistical tools

Can import and export data from third-party electronic medical record or dispensing tools in XML, CSV, and Excel; analyses can be cross-checked by analyzing data in previously validated statistical tools. PVIMS has the ability to export case safety data in E2B interface, and is health level -7 (HL7) compliant.

## Computes basic active surveillance metrics

Generates key metrics for cohort event monitoring, including incidence rates for exposed and non-exposed patient groups and adjusted/unadjusted risk ratios per AE/medication

## Reports and frequency tables

Generates customized reports and frequency tables

## Customizable data fields and auditability

Can assign and restrict user access; ability to track who and when changes are made

# HOW CAN THE TOOL BE USED?

Prior to data collection, site personnel are provided with detailed information on the active surveillance activity to enhance the accuracy of information entered into the tool and facilitate easy operation.

PVIMS will be implemented as an enterprise-level, web-based application that will require Internet connectivity for efficient use. A centrally deployed and managed web-based application allows for real-time data collection and processing and supports effective and timely decision making. It also enables consistent and quality data propagation of changes downstream to all facilities and entities involved. This is extremely important because the enhanced application will allow customization of datasets used in the active pharmacovigilance data gathering process.

Because PVIMS will need to work in LMICs where Internet connectivity may be limited, the application provides functionality in an offline mode.

## PViMS Safety Surveillance System

### Unified Data Repository

Custom Entity/Extensible Dataset Structures	Task Management	Meta Report Repository	CMS Repository
<b>Clinical Portal</b> <ul style="list-style-type: none"><li>• Patient Demographics</li><li>• Appointment Management</li><li>• Encounter History</li><li>• Cohort Management</li></ul>	<b>Analysis Portal</b> <ul style="list-style-type: none"><li>• Causative Drug Assessment</li><li>• Standardised Terminology</li><li>• Signal Detection (risk ratios)</li></ul>	<b>Reporting Portal</b> <ul style="list-style-type: none"><li>• Custom Report Designer</li><li>• Report Filter</li><li>• Export to XLS, CSV, PDF</li><li>• Stratification</li></ul>	<b>Publication Portal</b> <ul style="list-style-type: none"><li>• Report distribution</li><li>• Report scheduling</li><li>• Report publication</li><li>• Case studies</li></ul>

### APPN Interface and Business Logic Tier