

# 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.

## Platform Technology

PViMS makes it feasible to implement active surveillance activities in low- and middle-income countries (LMICs) by addressing the entire data collection and data analysis process to identify signals for improving the safety of patients undergoing treatment. When used for spontaneous reporting, PViMS provides a comprehensive pharmacovigilance solution for LMICs. It was developed by the US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services Program, implemented by Management Sciences for Health.

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



## Why is PViMS needed?

Active surveillance for monitoring the safety and effectiveness of medical products is increasingly recognized as a complement to spontaneous reporting commonly used by pharmacovigilance systems. Active surveillance is particularly important to support the introduction of new essential medicines in LMICs whose regulatory systems are being developed and are in need of support. In resource-limited settings, active surveillance can help determine the real-life frequency, risk factors, and impact of clinically significant adverse medicine events on treatment outcomes. However, many of these countries lack the resources and capacity to implement active surveillance. The lack of a data collection and analysis system to support active safety surveillance is a significant resource constraint.

### Minimum Requirements

Windows XP, 7 32/64 bit

Windows 2003/2008 R2 Server

MS SQL Express/Standard 2008 R1/R2



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# Pharmacovigilance Monitoring System



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to Pharmaceuticals and Services

# Features and Benefits

**Improves overall clinical documentation.** PViMS enables the 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.

**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, the World Health Organization, and Naranjo. Users can also develop a local dictionary using standard terms.

**Provides detailed descriptions of adverse event (AE) outcome and generates signals.** PViMS can be used to describe AEs, severity and seriousness, laboratory values, AE outcomes, and AE management and can generate signals of increased incidence to inform action or for further evaluation.

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**Interoperable with third-party clinical systems and statistical tools.** The system can import and export data from third-party electronic medical record or dispensing tools in XML, CSV, and Excel, and 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.** PViMS 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.** The system can generate customized reports and frequency tables

**Customizable data fields and auditability.** PViMS can be programmed to assign and restrict user access and has the ability to track who made changes and when.

# How can PViMS be used?

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

PViMS is implemented as an enterprise-level, web-based application and requires 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 application allows datasets used in the active pharmacovigilance data gathering process to be customized.

Because PViMS is used in LMICs where Internet connectivity may be limited, the application provides limited functionality in an offline mode.

## PViMS Safety Surveillance System

### Unified Data Repository

#### Custom Entity/ Extensible Dataset Structures

##### Clinical Portal

- Patient demographics
- Appointment management
- Encounter history
- Condition group management

#### Task Management

##### Analysis Portal

- Causative drug assessment
- Standardized terminology
- Signal detection (risk ratios)

#### Meta Report Repository

##### Reporting Portal

- Custom report designer
- Report filter
- Export to XLS, CSV, PDF
- Stratification

#### CMS Repository

##### Publication Portal

- Report distribution
- Report scheduling
- Report publication
- Case studies

### APPN Interface and Business Logic Tier