

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 of medicines.

PLATFORM TECHNOLOGY

PHARMACOVIGILANCE MONITORING SYSTEM (PViMS)

PViMS makes it feasible to implement active surveillance activities in low- and middle-income countries (LMICs). It addresses the entire data collection and analysis process to identify signals for improving the safety of patients undergoing treatment. When used for spontaneous reporting, PViMS provides a comprehensive pharmacovigilance (PV) solution for LMICs. The tool is developed under the SIAPS program and implemented by the Medicines, Technologies, and Pharmaceutical Services (MTaPS) program, both of which are funded by the U.S. Agency for International Development and led by Management Sciences for Health.

- Web-based interface with limited offline functions
- 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 results analysis, analysis-based publications, and solicited reporting
- User-defined data entry forms to match local paper forms

Minimum Requirements

Client: Windows 10
Server: Windows 2012 and MS SQL Express/Standard 2017

Why is PViMS needed?

Active surveillance for monitoring the safety and effectiveness of medical products is recognized as a complement to spontaneous reporting commonly used by pharmacovigilance systems. Active surveillance is particularly important to support the introduction of new medicines in LMICs whose regulatory systems are developing and in need of support. Active surveillance can help determine the real-life frequency, risk factors, impact of clinically significant adverse medicine events, and improve treatment outcomes. However, many LMICs 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 that PViMS addresses.



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FEATURES AND BENEFITS

Improves overall clinical documentation. PViMS enables the collection of data, including clinical stage; concomitant medications; test results; co-morbid conditions; and treatment regimens, initiation date, and adherence, to facilitate clinical assessment. It also provides feedback to clinicians on the adverse event (AE) reports they submitted.

Provides for the use of common terms, checklists, and adoption of standard terminologies. Users enter the common terms or choose from pre-coded standard terminologies and scales, such as MedDRA®, the National Cancer Institute Common Terminology Criteria for Adverse Events, the World Health Organization, and Naranjo causality assessment scales. Users can also develop a local dictionary using standard terms.

Provides detailed description of adverse event (AE) outcomes 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. Analyses can be cross-checked by analyzing data in previously validated statistical tools. PViMS can export case safety data in E2B format 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. It also enables sharing of feedback between clinicians and PV centers.

Customizable data fields and auditability. PViMS can be programmed to assign and restrict user access. It tracks changes to the system, including by whom and when such changes were made.

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 can also be used to collect spontaneous /passive reports.

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

Information Portal

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

APPN Interface and Business Logic Tier