USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Approaches and Tools for Strengthening Pharmaceutical Systems

Strengthening Regulatory Information Management Systems

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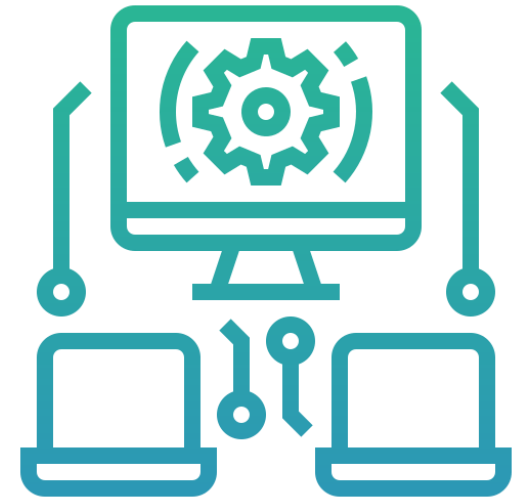Information Systems
USAID MTaPS Program

Why are regulatory information systems important?

Well-functioning **regulatory information management systems (RIMS)**

- Enable national regulatory authorities (NRAs) to perform key regulatory functions:

  - Product registration or marketing authorization
  - Vigilance
  - Market surveillance and control
  - Licensing

  - Inspection
  - Testing
  - Clinical trial oversight
  - Lot release

- Enhance NRAs' ability to collaborate and share information with one another

- Improve the consistency, efficiency, and accountability in regulatory services provision

Why are regulatory information systems important?

Key challenges with RIMS:

- Disparate and lack interoperability

- Nonexistent, partially implemented, or nonfunctional

- Many regulatory processes are still paper-based, resulting in inefficient workflows, lack of transparency, mismanagement, and vulnerability to corruption

- Lack of clarity of manual processes and information flow hinder digitalization—a key feature of well-functioning RIMS

Well-functioning RIMS help NRAs perform their regulatory functions with consistency, efficiency, and accountability, ultimately helping ensure access to safe, effective, quality-assured, and affordable medical products and related services.
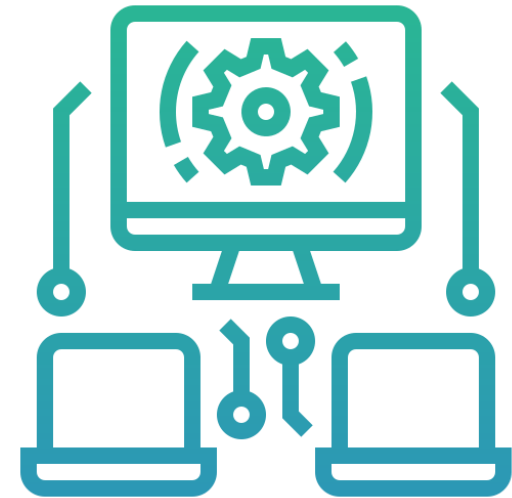
MTaPS' approaches and tools for strengthening RIMS

MTaPS' approach to strengthening RIMS entails improving local capacity for the generation, governance, analysis, interoperability, and integration of pharmaceutical data in NRA workflows. Specific tools and approaches include:

- Designing and improving NRA data generating processes, which may then be suitable for digitalization
- Developing and implementing digital RIMS solutions
  - OpenRIMS
  - PharmacoVigilance Monitoring System (PViMS)
- Developing minimum common standards for RIMS and promoting their adoption
- Providing training and mentorship to strengthen capacity to use RIMS to generate and use data in improving regulatory processes

MTaPS' approaches and tools for strengthening RIMS

OpenRIMS

- Free and open-source software
- Digitalizes and automates NRA's work processes without the routine need of a software developer

PViMS

- Web-based application
- Supports both passive surveillance and spontaneous reporting

Together, OpenRIMS and PViMS will ultimately support the work processes aligned with the eight regulatory functions.

Case Study: Implementing OpenRIMS and PViMS in Mozambique

Supporting Autoridade Nacional Reguladora de Medicamentos to increase its GBT score with an effective RIMS that will facilitate control of the medical products market:

- ✓ Updated the regulatory framework
- ✓ Supported OpenRIMS and PViMS implementation for efficient delivery of integrated regulatory services
    - Configuring OpenRIMS to meet context-specific needs
- ✓ Engaged in capacity building activities for regulators

Use of OpenRIMS expected to improve customer service and reduce registration processing timelines

Case Study: *Digitalizing the RIMS in Nepal*

Supporting the Department of Drug Administration to digitalize its RIMS and increase its GBT maturity level

- ✓ Updated the legal and regulatory framework
- ✓ Proposed reorganization of the DDA
- ✓ Built capacity and competency of DDA staff
- ✓ Revised workflows and practices in line with WHO best practices
- ✓ Established a quality management system in support of ISO certification
- ✓ Deployed OpenRIMS for registration, inspection, and import/export control

MTaPS is helping to customize OpenRIMS to the context of Nepal and increase the DDA's efficiency through better use of management information and reporting capacity.

Digitalization will improve the registration and regulation of medical products, health technology products, manufacturers, pharmacies, and wholesalers and importers.

How can you apply these approaches and tools?

- **Adopting Minimum Common Standards for Regulatory Information Management Systems**: This document summarizes the consultative process by which a set of minimum common standards for RIMS in LMICs was developed and provides advocacy tools and guidance for NMRAs' adoption of the standards for an RIMS.

- **WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products – Revision VI**: This tool assesses regulatory systems for the regulation of medical products. It provides WHO and regulatory authorities with information on areas of strength as well as areas for improvement to facilitate the development of institutional development plans and help monitor countries' progress.

- **OpenRIMS:** OpenRIMS is a free and open-source software (FOSS) that enables NMRAs to digitalize and automate their work processes, such as medicines registration and licensing, without the routine need of a software developer.

WHO Global Benchmarking Tool (GBT)

for Evaluation of National Regulatory System of Medical Products

Revision VI

World Health Organization

OpenRIMS
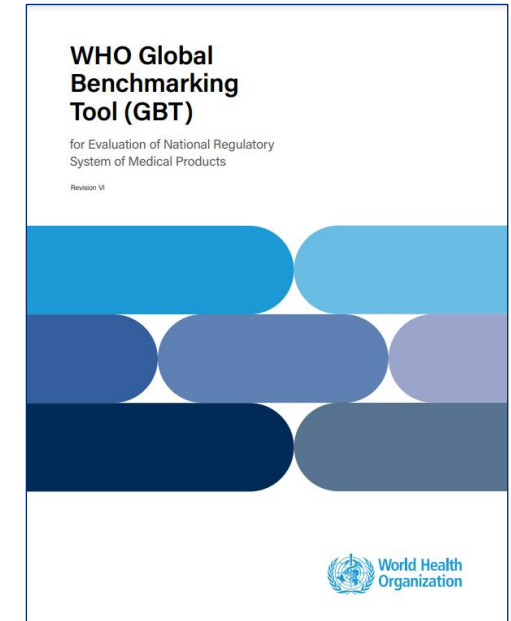
Additional resources: readings

- **Making the Investment Case for National Regulatory Authorities**

- **Advancing Regulatory Systems for Improved Access to Safe, Effective, Affordable, and Quality-Assured Medical Products**

Additional resources: e-learning and videos

- **Open RIMS** https://OpenRIMS.org : This suite of courses educates developers, regulatory authorities, and business clients to regulatory authorities on the use of OpenRIMS for regulatory work processes. For instance, business clients can receive training here on how to submit applications for marketing authorization, export license, pharmacy registration, and other regulatory processes.

- **Pharmaceutical Systems Strengthening (PSS) 101 in English and French:** This course, developed by MTaPS, teaches participants the basic principles of PSS, including how addressing pharmaceutical system problems advances universal health coverage; combats antimicrobial resistance, HIV and AIDS, malaria, TB and other public health threats; and promotes maternal and child health.

Who to contact

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