



GDHN August 2023 Webinar

Flexible Digitalization of Regulatory Authorities



2023 Global Digital Health Forum: LAST CALL FOR ABSTRACTS



Abstract submission deadline:
Friday, 25 August 2023

Forum Theme: Driving Effective and Equitable Digital Health Innovation

Visit <https://www.gdhf.digital/> for more information and to submit your abstract

Questions:
forum@globaldigitalhealthnetwork.org

The 2023 Global Digital Health Forum will be held from 4–6 December as a hybrid event—in-person in Washington DC and virtually (Asia and East Africa time zones).



Webinar

Title: Flexible Digitalization of Regulatory Authorities

When: Thursday August 24, 2023, 8:00 AM–9:00 AM EDT (Washington D.C.)



USAID
FROM THE AMERICAN PEOPLE

Agenda

- Introduction
- Regulatory System Strengthening (RSS) – What is a Regulatory System?
- Describing the Challenge for National Regulatory Authorities (NRA)
- Bangladesh Success 1: **Product Registration and Pharmacovigilance**
- Philippines Success 2: **Pharmacovigilance**
- Progress in Other Countries:
- The Vision of a Harmonized RIMS
- Questions & Answers

Introduction

Our Mission as Management Sciences for Health (MSH)

We work shoulder-to-shoulder with countries and communities to save lives and improve the health of the world's poorest and most vulnerable people by building strong, resilient, sustainable health systems.

Medicines, Technologies and Pharmaceutical Services (MTaPS) Program

- Ensuring access to safe and quality-assured medicines at affordable prices while guarding their appropriate use demands a systems approach for sustainable results
- MTaPS builds on the successes of the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program (2011-2018), which globally cemented the pharmaceutical systems strengthening (PSS) approach and its pivotal role in health systems strengthening.
- MTaPS is implemented by a consortium, blending experience from prior USAID-funded PSS initiatives with updated and local expertise to effectively and sustainably help countries develop stronger pharmaceutical systems.

Overview of the Global Regulatory Challenge



Kim Øgendahl Hoppenworth

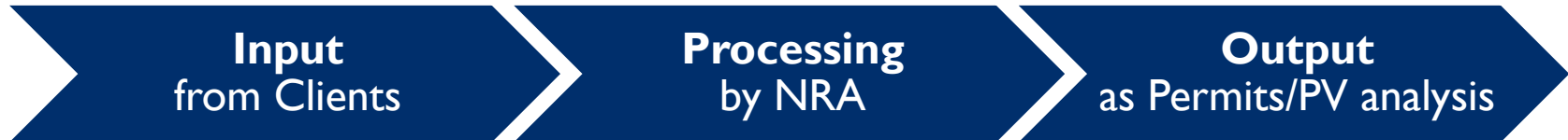
Principal Technical Advisor, RIMS
USAID MTaPS



USAID
FROM THE AMERICAN PEOPLE

Regulatory System Strengthening – What is a Regulatory System?

- National Regulatory Authorities is part of a government system and focus of three elements of the health sector:
 - **People:** Owners and staff of Wholesaler establishments, Pharmacies, Importers, Exporters
 - **Premises:** Wholesalers and Pharmacies
 - **Products:** Medicines, Medical Devices, Health Supplies incl laboratory
- WHO website: “Market Authorization and post-marketing surveillance and adverse events following immunization (AEFI) monitoring are functions that all NRAs have to establish”¹
- The NRAs also approves clinical trials in a country
- NRAs collaborate at regional, continental and global level



1) Source: <https://www.who.int/southeastasia/activities/national-regulatory-agencies#:~:text=%C2%A9-,Overview,quality%20and%20safety%20and%20efficacy.>

Describing the Challenge for National Regulatory Authorities (NRA)

1. The WHO GBT accelerates the **transformation** of National Regulatory Authorities into functional authorities with effective regulatory systems and control of the medical products market. WHO use the GBT to measure the MATURITY LEVEL of a given NRA and creates an improvement plan.
2. Part of the transformation require NRAs to establish **clear regulations, guidelines, procedures** for guiding and implementing regulatory functions according to the GBT requirements.
3. Our Challenge is to establish a solid **Regulatory Information Management System (RIMS)** which can automate and support these procedures e.g. Marketing Authorizations, Import Licensing or Clinical Trial approvals.



What are the benefits of Regulatory Systems Strengthening?

- A High level of automation of an NRA results in several regulatory benefits:
 - Sufficient data with **high quality**
 - Increased **traceability, accountability, transparency** and good governance
 - Adequate **access** to statistical evaluation
 - Decreased **processing times** thereby increasing access to safe and high-quality medicines to the patients.
- We want to enable and empower NRAs to adapt and use modern technologies with **No or Low** code to address these challenges.
- We want to use the power of **Business Intelligence** for decision making and pave the way for AI/ML in regulatory affairs.



Figure credit: Ball, D., Roth, S., & Parry, J. (2016). Better Regulation of Medicines Means Stronger Regional Health Security.

People & Technologies

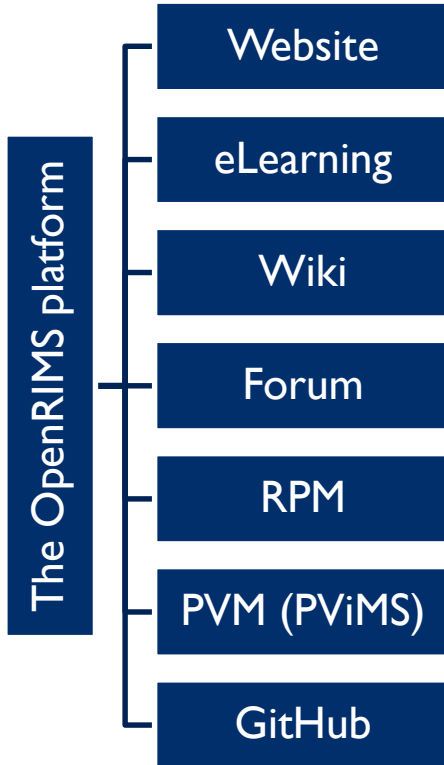
People, Premises & Products

- The Challenge ahead involves a number of actors in addition to the NRA:
 - **People:**
Owners and staff of Wholesaler establishments, Pharmacies, Importers, Exporters
 - **Premises:**
Wholesalers, Warehouses, Manufacturers and Pharmacies
 - **Products:**
Medicines, Medical Devices, Health Supplies incl laboratory

Technologies

- Main Technologies:
 - **Java** for the OpenRIMS-RPM
 - **Angular** and **C#** for the OpenRIMS-PVM
 - **AWS & Oracle** Cloud Services for Servers
 - **Google** Looker Studio for Data Use
 - **GraphQL** for interoperability
- Other Technologies applied:
 - **MediaWiki**
 - **Discourse**
 - **Moodle**
 - **WordPress**

The OpenRIMS platform



- A **Global Platform** and **Community** to support development, deployment and sustainability of OpenRIMS.
- The software can contribute to increasing the **GBT Maturity Level** of an NRA (RSS and IT).
- OpenRIMS is **FOSS** (Free and Open-Source Software).
- Minimal system requirements means **rapid deployment (2-3 days for cloud)** for then initiating configuration while decision and procurement of production servers are going on.
(1Gb RAM, 30Gb SSD, 1 CPU; AWS T2.micro)
- Designed for Scale to additional processes.

Global Overview & Illustrative Screenshots



Level of Scale Up

Active Surveillance for the PV module

- Philippines for TB (Bedaquiline) and interoperability (PVM) – *Presenting today!*
- Mozambique for HIV (TLD) and TB (TPT) regimens (PVM)
- Rwanda for HIV (DTG) regimen and Ebola vaccine (PVM)

Registration Workflows (Registration, Inspection/import)

- Bangladesh for Vaccines/Biosimilars and Yellow Card (RPM+PVM) – *Presenting today!*
- Nepal for Pharmacy/Product/Manufacturer registration set to go Live proximo September (RPM)
- Madagascar for Marketing Authorization for a group of products SALAMA (RPM)

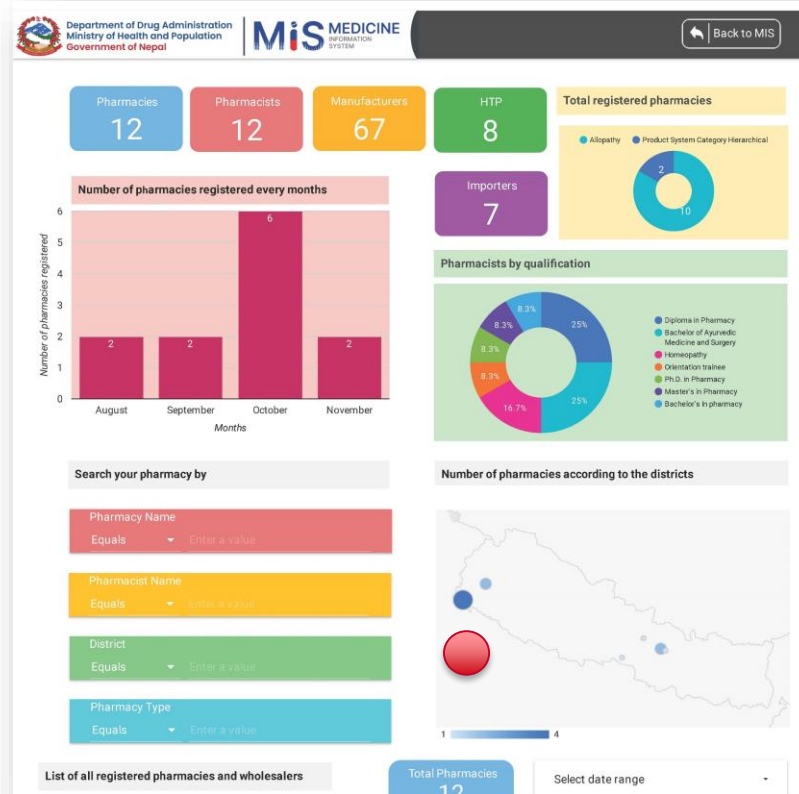
Using the data to identify process bottlenecks

The screenshot displays the DAMM OpenRIMS Dashboard. The header includes the USAID logo and the text 'Medicines, Technologies and Pharmaceutical Services'. The dashboard is divided into several sections:

- DAMM RIMS Dashboard:** A green header with a sub-header 'DAMM Regulatory Information Management System (RIMS) Direction de l'Agence du Médicament de Madagascar (DAMM) République de Madagascar'. Below it, a 'Guideline for this Interactive Dashboard' states: 'Please note that all numbers adapt to the filters as applied by you when you click! The purpose of this report is management of resources.'
- STEP 1: Select Process here:** A green header with a dropdown menu showing 'Workflow: Nouvelle Demande Salama (1)'.
- Marketing Authorization Applications in the system:** A green header with a large number '1,686'.
- STEP 2: Select Activity here:** A green header with a table showing the process steps and their average processing times.
- Average Processing Time in Days:** A gauge chart showing 'Avg Days 95.1' on a scale from 0 to 133.
- Staff Workload & Performance:** A table listing staff members, their activities, record counts, and average days.

At the bottom, there is a footer with the USAID logo, contact information, and a disclaimer: 'This website is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.'

Interactive Dashboards



Common Technical Document Format (CTD)

The screenshot displays the OpenRIMS web application interface. The browser address bar shows the URL: `openrimms.msh.org/admin#todolist/activitymanager/%7B"url":"","applDictNodeld":0,"historyId":2242%7D`. The application header includes the OpenRIMS logo and the text "An Open Source Regulatory Information Management System". The user is logged in as "Supervisor" with the role "Supervisor S Supervisor".

The main content area is titled "Application Information" and features a red-bordered box containing the text "GBT 2: Product Marketing Authorization". Below this box is a breadcrumb trail: "Vaccine No.3 / Accept / Screener Assignment / Screening / Reviewers Assignment / Reviewers Assignment / Commission / Review". A "Cancel" button is located to the right of the breadcrumb trail.

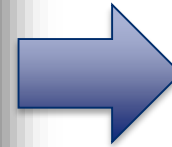
On the left side, there is a navigation menu with the following items: "ToDo List", "Actual", "Scheduled", "Exit", "Application Information", "Vaccine No.3", "CTD Module 2", "CTD Module 3", "CTD Module 4", "CTD Module 5", "Applicant", "Classifiers", "Details", and "Payment".

The right side of the interface displays a "Marketing Authorization self-check" form. The form is organized into three modules:

- Module 1: administrative information**
 - Address: Yes (green), No (blue), N/A (yellow), Notes
 - Name: Yes (green), No (blue), N/A (yellow), Notes
 - prescribing information: Yes (green), No (blue), N/A (yellow), Notes
- Module 2**
 - 2.2 Introduction: Yes (green), No (blue), N/A (yellow), Notes, Help
 - 2.3 Non-clinical Overview: Yes (green), No (blue), N/A (yellow), Notes, Help
 - 2.4 Non-clinical Overview: Yes (green), No (blue), N/A (yellow), Notes, Help
 - 2.5 Clinical Overview: Yes (green), No (blue), N/A (yellow), Notes, Help
 - 2.6 Non-clinical Written and Tabulated Summaries: Yes (green), No (blue), N/A (yellow), Notes, Help
- Module 3**

Interoperability with VigiFlow (WHO UMC)

The screenshot displays the 'Analytical Portal' interface. The main content area is titled 'Spontaneous Reports' and includes search filters for 'Active Work', 'Search by date', and 'Search by term'. Below these filters, there are buttons for 'Confirm Report Data' (with a red notification badge '2'), 'Set MedDRA and Causality' (with a red notification badge '112'), 'Extract E2B' (with a red notification badge '2'), and 'Summary'. A table lists report entries with columns for Patient, Created, Medications, Adverse event, MedDra term, Status, and Actions. Two entries are visible: one for patient 'NL' with a cough and another for patient 'NH' with a skin rash after COVID-19 vaccination. A context menu is open over the 'NH' entry, showing options: 'View activity history', 'Confirm E2B submit' (with a red notification badge), 'Download XML', and 'Download summary'. The footer of the interface includes the OpenRIMS logo and version information: 'Management Sciences For Health © 2023 | Version : 2.5.10 | 202307211434 | Last Updated :2023-07-21'.



Bangladesh



Md. Abul Kalam Azad

Senior Technical Advisor, RSS/PV
USAID MTaPS Bangladesh



USAID
FROM THE AMERICAN PEOPLE

Background

- DGDA is the National Regulatory Authority of Bangladesh, responsible for assuring QSE of medical products.
- Achieving ML3 for DGDA as per WHO GBT is a GoB priority.
- Challenges in GRP emerged due to lack of automation to comply with WHO GBT indicators.
- MTaPS was formally requested by DGDA to assist in addressing those challenges with a digital approach.
- MTaPS responded to the request by keeping it in the WP and got it approved by USAID.

Directorate General of Drug Administration (DGDA)
Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh

Home About DGDA Information Center Registered Products Pharmaceuticals Pharmacovigilance Export NCL Innovation বাংলা

Login Form

Username
Password

Remember Me

Log in

Forgot your username?
Forgot your password?

Search Price

Publications

Newsletters

Citizen Charter

Laws and Policies

Blocklist Submission

Blocklist Verification
Blocklist Clearance

DGDA Notice Board

New Notice

More News

Home

Latest News 1-15 vaccines DGDA-RIMS for Vaccine/Biosimilar product online registration. Plotting

Welcome

The Directorate General of Drug Administration (DGDA) under the Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh, is the Drug Regulatory Authority of the country. This DGDA supervises and implements all prevailing Drug Regulations in the country and regulates all activities related to import, procurement of raw and packing materials, production and import of finished drugs, export, sales, pricing, etc. of all kinds of medicines including those of Ayurvedic, Unani, Herbal and Homoeopathic systems, drugs and medicines. At present, there are 47 district offices under the DGDA in the country. All the officers of the DGDA function as "Drug Inspector" in pursuant to the Drug Laws and assist the Licensing Authority to discharging his responsibilities properly. Besides, a number of Committees, such as Drug Control Committee (DCC), Standing Committee for imports of raw materials and finished drugs, Pricing Committee and a number of other relevant Committees, which comprise of experts of different fields, are there to advise Licensing Authority and recommend him about the matters related to drugs and medicines.

Field Operations Dashboard

Quality Reporting	Quality Inspections
100%	100%
100%	100%

Quality Reporting	17,531
Quality Inspections	3,766
100%	100%
100%	100%

Registration Dashboard

DGDA Office Locations

You need to upgrade your Flash Player

Related Links Gallery Search FAQ Online Application Pharmaceuticals Reporting System - PVRMS
ফর্মসহ বিক্রয় - বিক্রয় প্রতিবেদন আবেদনাদাও Procurement Plan Complaints DGDA-RIMS for Vaccine/Biosimilar Registration

Key Interventions: Bangladesh DGDA Digitalization

- **Introduction of Digital Tools:**

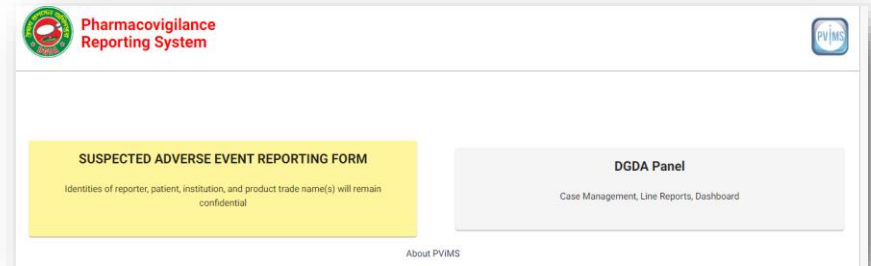
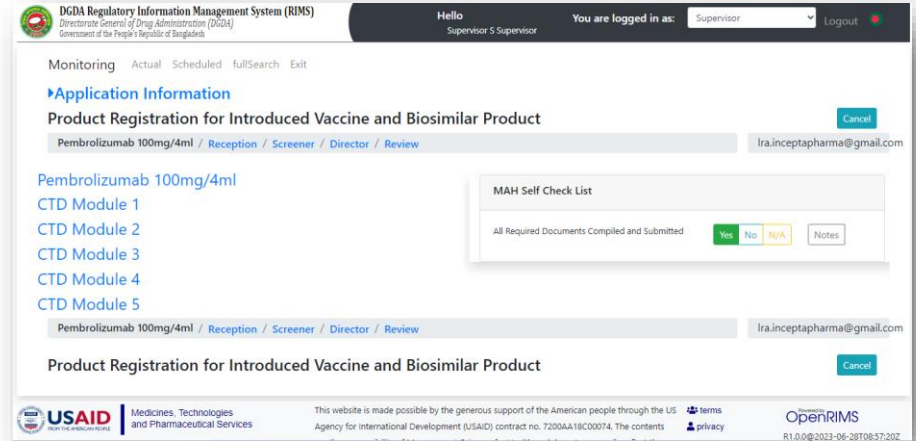
- Piloting PViMS:AE reporting and monitoring tool (107 reports received till 23 Aug 2023)
- Implementation of DGDA RIMS: Registration of vaccine/biosimilar (4 applications received till 23 Aug 2023)

- **Next Step:**

- Scale Up
- PViMS Integration with UMC VigiFlow
- Transition

- **Benefits:**

- Ease of Tracking applications/reports
- Promote transparency and accountability



Lessons Learnt

- DGDA RIMS to use for other regulatory functions
- Lack of dedicated IT cell hinders implementation
- Frequent changes in the regulatory processes and Workflows
- Impact on WHO GBT requirements



Philippines



Patrice Cabasis

PV Technical Advisor,
USAID MTaPS Philippines



USAID
FROM THE AMERICAN PEOPLE

Background

- With the assistance of USAID (SIAPS), an open-source tool was created.
- Initially implemented in the Philippines to support active surveillance of the 9MTR and BDQ OR (12,000+ AEs captured for 404 patients (329 9MTR + 75 BDQ))



Where We Are Now?

- New TB drugs and novel TB treatment regimens
- aDSM: A form of active pharmacovigilance
 - Actively monitoring, management and reporting
 - Implementation can be tailored based on resources available in the country (PH: SAE and AESI)
- One of the overall objectives is to generate standardized aDSM data to inform future policy updates on the use of such medicines
- DOH – Pharmaceutical Division – system owner



-
- <https://pvims.doh.gov.ph/security/login>

- This is the landing page of PVIMS.



Welcome to PVIMS, your tool for strengthening pharmacovigilance services

Pharmacovigilance Monitoring System

Username

Password

Portals

PVIMS

version 2.3.2202281554



Portals



Main Actions

- Patients
- Forms
- Encounters
- Cohorts
- PV Feedback
- Appointments

Patient Search

Facility

All facilities Unique ID First name Last name
Maximum length 30 Maximum length 30

Date of birth Condition case number
Maximum length 50

Id	First name	Last name	Facility name	Case number	Date of birth	Last encounter	Actions
1420	N	Y	ABRA PROVINCIAL HOSPITAL	082522-014	1971-10-19 51	2022-08-25	
1419	Z	Q	ABRA PROVINCIAL HOSPITAL	082522015	1976-05-16 47	2021-08-12	
1418	L	K	ABRA PROVINCIAL HOSPITAL	082522-016	1971-10-12 51	2022-08-25	

Clinical Portal

PViMS

version 2.3.2202281554

Portals



Main Actions

- Patients
- Forms
- Encounters
- Cohorts
- PV Feedback
- Appointments



Patient Search

Facility

All facilities Unique ID First name Last name
Maximum length 30 Maximum length 30

Date of birth Condition case number
Maximum length 50

Id	First name	Last name	Facility name	Case number	Date of birth	Last encounter	Actions
1420	N	Y	ABRA PROVINCIAL HOSPITAL	082522-014	1971-10-19 51	2022-08-25	
1419	Z	Q	ABRA PROVINCIAL HOSPITAL	082522015	1976-05-16 47	2021-08-12	
1418	L	K	ABRA PROVINCIAL HOSPITAL	082522-016	1971-10-12 51	2022-08-25	

Analytical Portal

PViMS

version 2.3.2202281554



Portals



Main Actions

Active Work

Search by date

Search by term

Please select an activity below...

Confirm Report Data 23

Set MedDRA and Causality 52

Extract E2B 456

Summary

Reports Portal

PViMS

version 2.3.2202281554



Portals



Main Actions

- Standard Reports
 - Patients on Treatment
 - Adverse Events
 - Adverse Events Frequency
 - Causality
 - Outstanding Visits
 - Custom Reports
- USAID MTaPS Program

Causality Report | (Meta data last refreshed :)

Facility * All facilities Criteria * Causality set Search from * 1/1/2023 Search To * 8/24/2023

First name	Last name	Facility	Adverse event	Serious	Onset date	Medication	WHO causality	Naranjo causality
M	M	PANGIL RURAL HEALTH UNIT - PMDT STC		No	2023-01-03	Linezolid (Unknown); 600 mg	Possible	
E	J	SCHISTOSOMIA CONTROL AND RESEARCH HOSPITAL - PMI STC		Yes	2023-02-07	Prothionamide (); 750 mg	Possible	
		EVERSLEY						

Administration Portal

PViMS

version 2.3.2202281554



Portals



Main Actions

- Audit Trail
- Reference Data >
- Medicines >
- System Configuration >
- User Configuration >
- Work Configuration >

General

- Audit Trail

Reference Data

- Condition Groups
- Scale Gradings
- Test Results
- Tests and Procedures
- MedDRA Terms

Medicines

- Active Ingredients
- Products

System Configuration

- Configuration
- Contact Details

User Configuration

- Users
- Roles

Work Configuration

- Attributes
- Care Events

Lessons Learned

- There are memoranda that have been issued to report to PViMS.
- Ease of reporting.
- Continuous training of newly hired staff on the use of PViMS.
- Continuous mentoring and supervision are necessary.
- Continuous training of iDOTS facilities by Public Health Pharmacists and PMDT facilities.

The Vision of a Harmonized RIMS



Deane Putzier

Senior Principal Technical Advisor, RIMS,
USAID MTaPS



USAID
FROM THE AMERICAN PEOPLE

How do we achieve the Vision?

- Vision is Two-fold: **Technical and Operational**
- **Technical Vision**
 - Build technical **community of practice** on the technical side
 - **Grow** the teams we currently have working with us
 - **Continuous alignment** with Public Digital Good Alliance and the Principles for Digital Development
 - OpenRIMS is one of the FOSS applications available from MSH and we also have a selection of other tools available for Pharmaceutical Systems Strengthening:
 - <https://mtapsprogram.org/tools/>



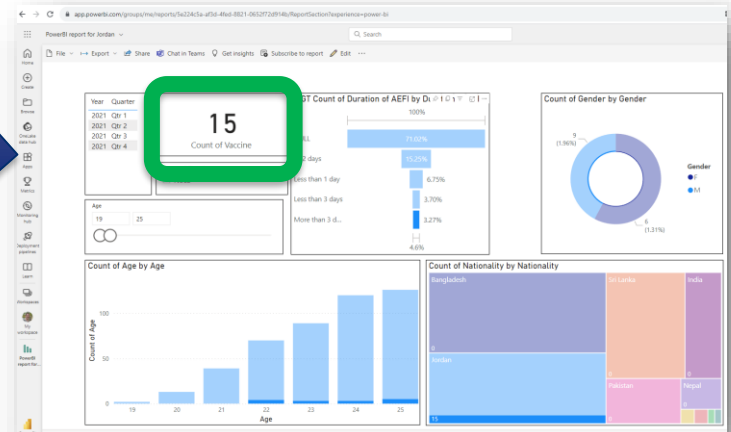
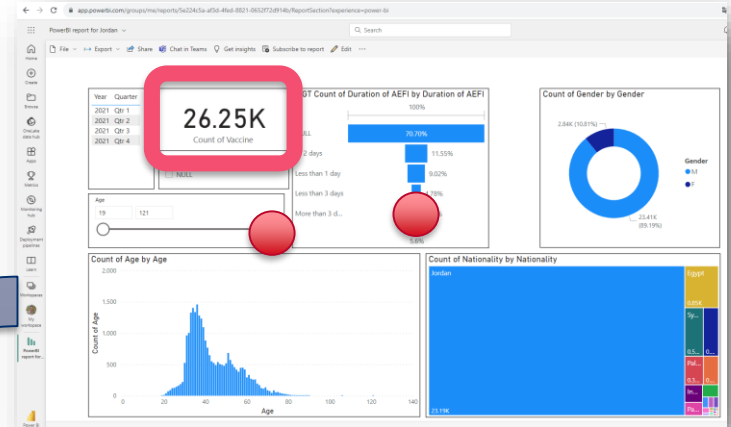
Digital
Public
Goods
Alliance



Principles *for*
Digital Development

How do we achieve the Vision?

- **Systems Strengthening (harmonization) Vision**
 - Not a software company but we are the system architects
 - Our role is to encourage **best practice** in both the technical and systems strengthening processes
 - Use **software companies** and **locally** (country) based organizations for development
 - Build **community of practice** out to localized organizations
 - **Collaboration** – NEPAD, AMA, ASEAN
 - Standards – minimum **common standards** collaboration between MSH, WHO, PQM+ and more
 - Expose data for decision making the power of data:
 - Actionable Reports
 - **Machine Learning/AI** for PV adverse events



Current Resources

- OpenRIMS Brochure/Flyer:
<https://www.openrims.org/wp-content/uploads/2022/12/OpenRIMS-Brochure.pdf>
- The full OpenRIMS platform:
<https://OpenRIMS.org>
 - Direct Links to sub-sites:
 - Wiki: wiki.openrims.org
 - Forum: talk.openrims.org
 - eLearning: learn.openrims.org
 - Demo Instance: openrims.msh.org
- The Global Benchmarking Tool: Lessons Learned Strengthening National Medicines Regulatory Systems:
<https://www.mtapsprogram.org/our-resources/the-global-benchmarking-tool-lessons-learned-strengthening-national-medicines-regulatory-systems/> (2020)
- <https://msh.org/>
- <https://mtapsprogram.org/tools>

Q&A

You have

Questions

We have

Answers

Join the next GDHN webinar

TECH-ENABLED PHC: REIMAGINING A CLIENT JOURNEY

When: September 28 @ 9:00–10:00 EDT (New York/UTC-4)

Hosted by:



More details and registration link coming soon!

Join the GDHN!



<https://bit.ly/GDHNSignUp>

