GDHN August 2023 Webinar

Flexible Digitalization of Regulatory Authorities

2023 Global Digital Health Forum: LAST CALL FOR ABSTRACTS

Global Digital Health Forum

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).

Global Digital Health Network

Webinar

Title: Flexible Digitalization of Regulatory Authorities

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

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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

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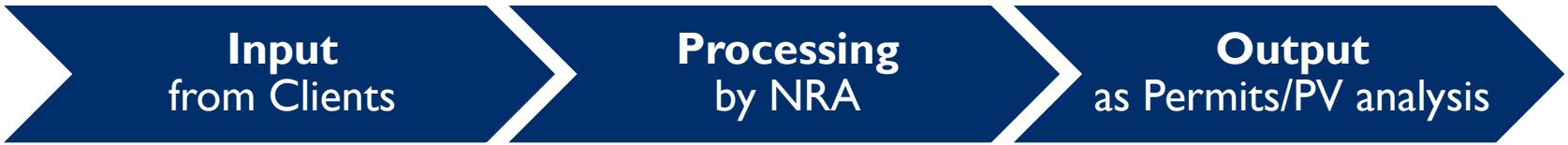
Regulatory System Strengthening – What is a Regulatory System?

- 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

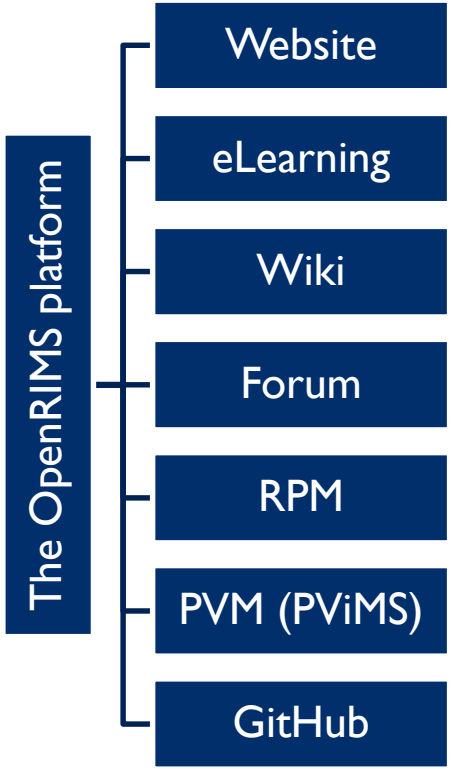
People, Premises & Products

- 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

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Formerly the mHealth Working Group

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Level of Scale Up

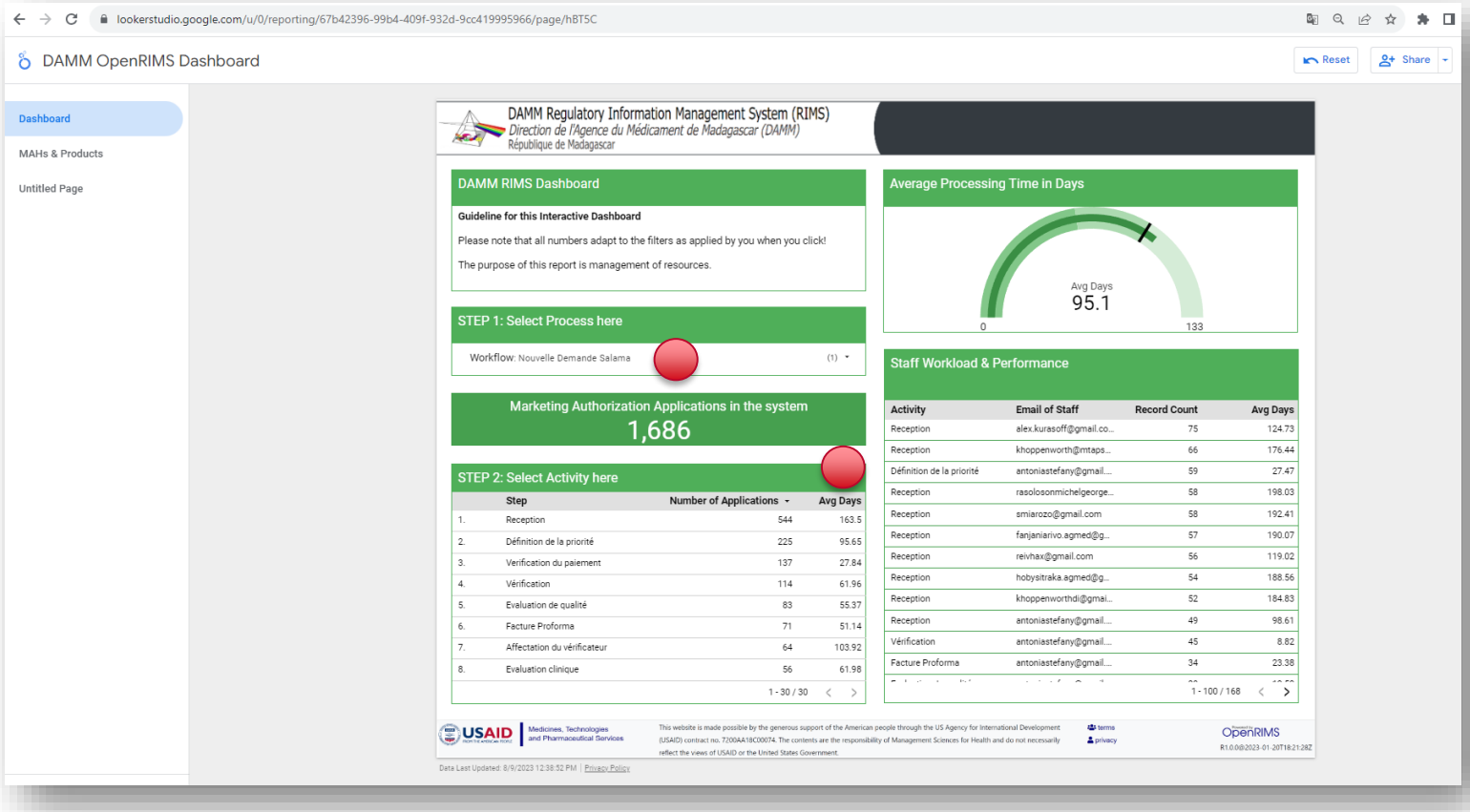
Active Surveillance for the PV module

- 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)

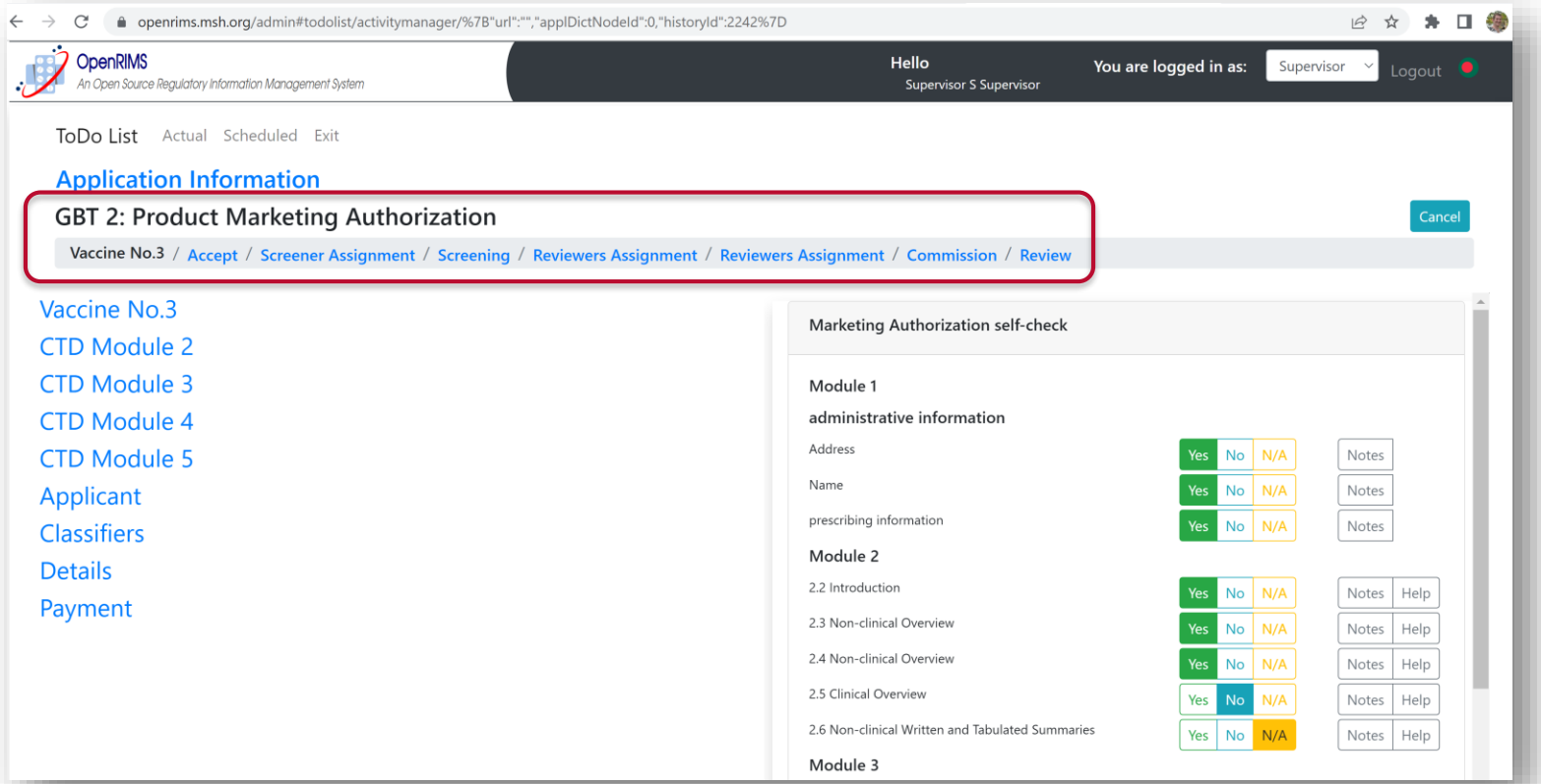
- Bangladesh for Vaccines/Biosimilars and Yellow Card (RPM+PVM) – *Presenting today!*
- Nepal for Pharmacy/Product/Manufacturer registration set to go Live proximo September (RPM)
- Madagascar for Marketing Authorization for a group of products SALAMA (RPM)

Using the data to identify process bottlenecks

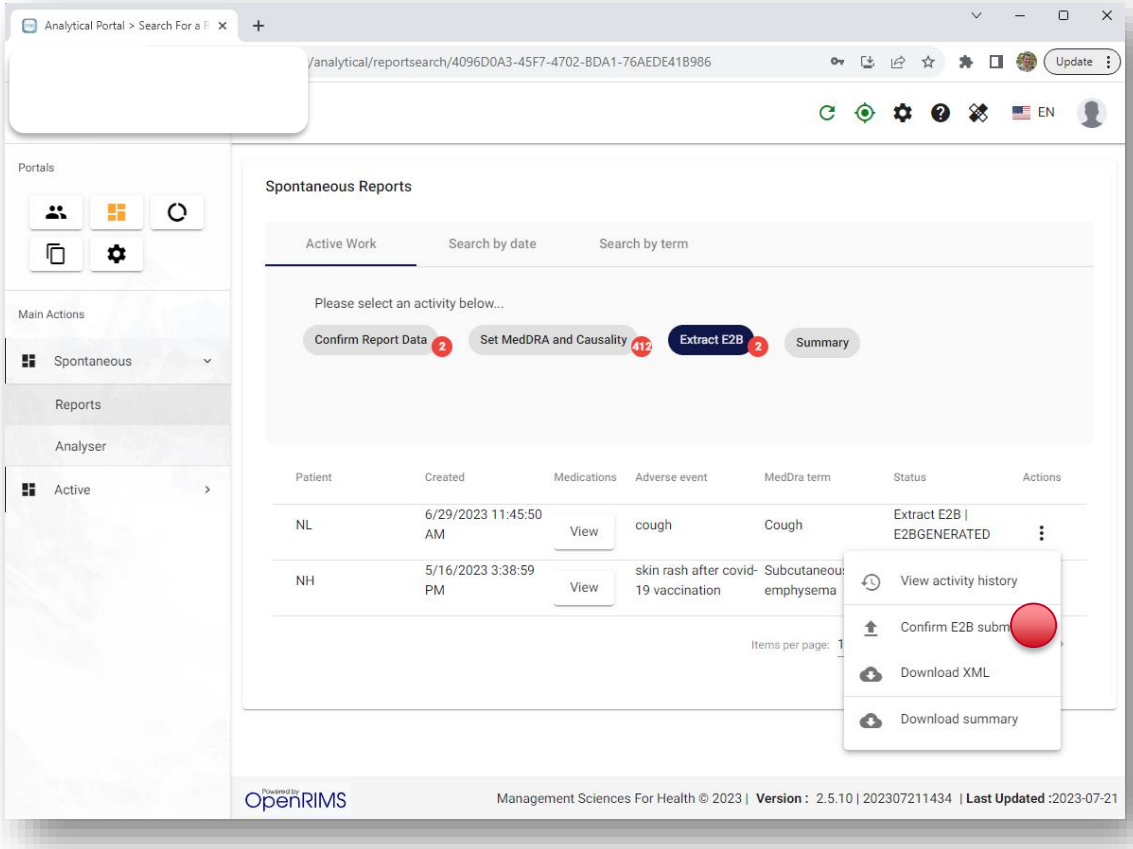


Interactive Dashboards

Common Technical Document Format (CTD)



Interoperability with VigiFlow (WHO UMC)



World Health Organization

Uppsala Monitoring Centre

Bangladesh

Md. Abul Kalam Azad

Senior Technical Advisor, RSS/PV
USAID MTaPS Bangladesh

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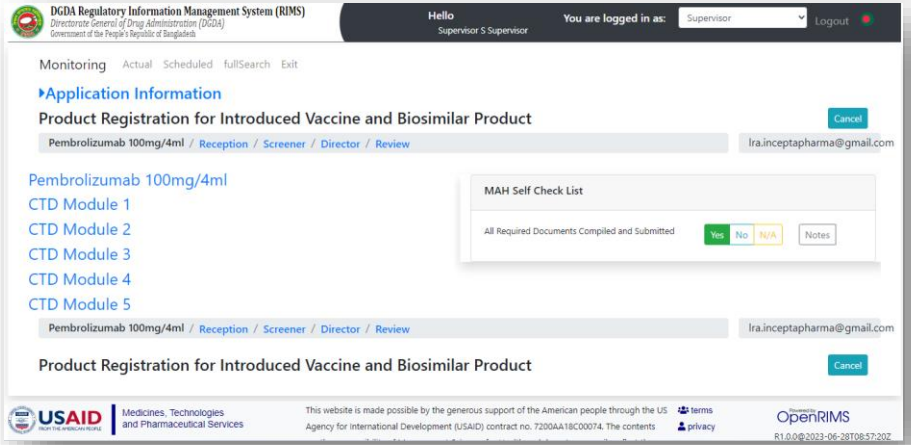
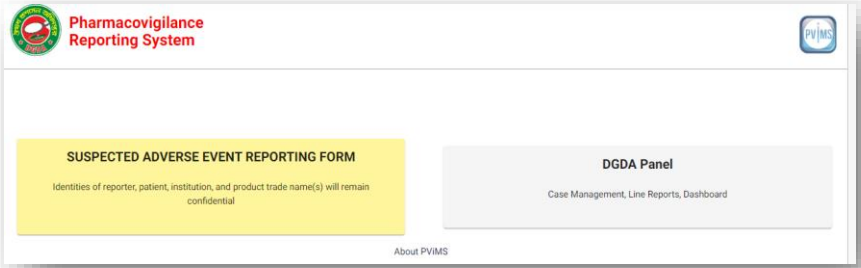
Background

- 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.

Key Interventions: Bangladesh DGDA Digitalization

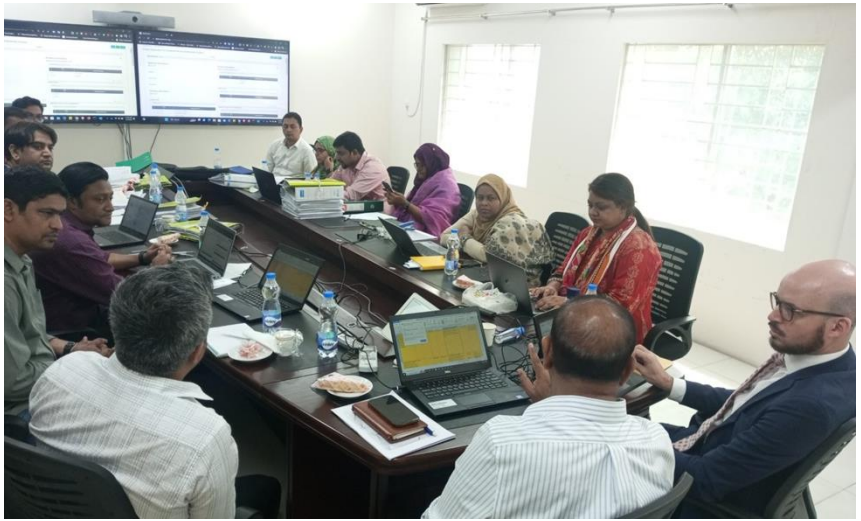
- **Introduction of Digital Tools:**
  - Piloting PViMS: AE reporting and monitoring tool (107 reports received till 23 Aug 2023)
  - Implementation of DGDA RIMS: Registration of vaccine/biosimilar (4 applications received till 23 Aug 2023)
- **Next Step:**
  - Scale Up
  - PViMS Integration with UMC 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

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Background

- With the assistance of USAID (SIAPS), an open-source tool was created.

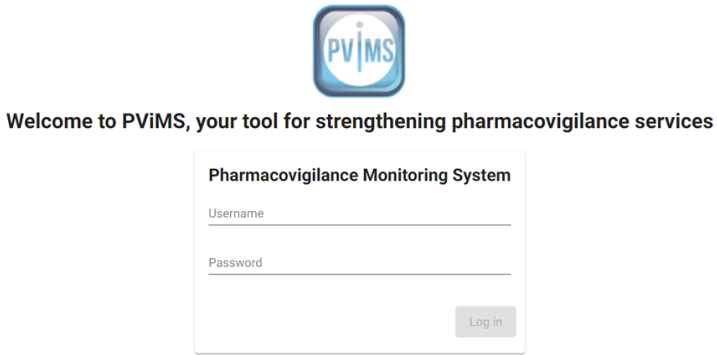
- Initially implemented in the Philippines to support active surveillance of the 9MTR and BDQ OR (12,000+ AEs captured for 404 patients (329 9MTR + 75 BDQ)

Where We Are Now?

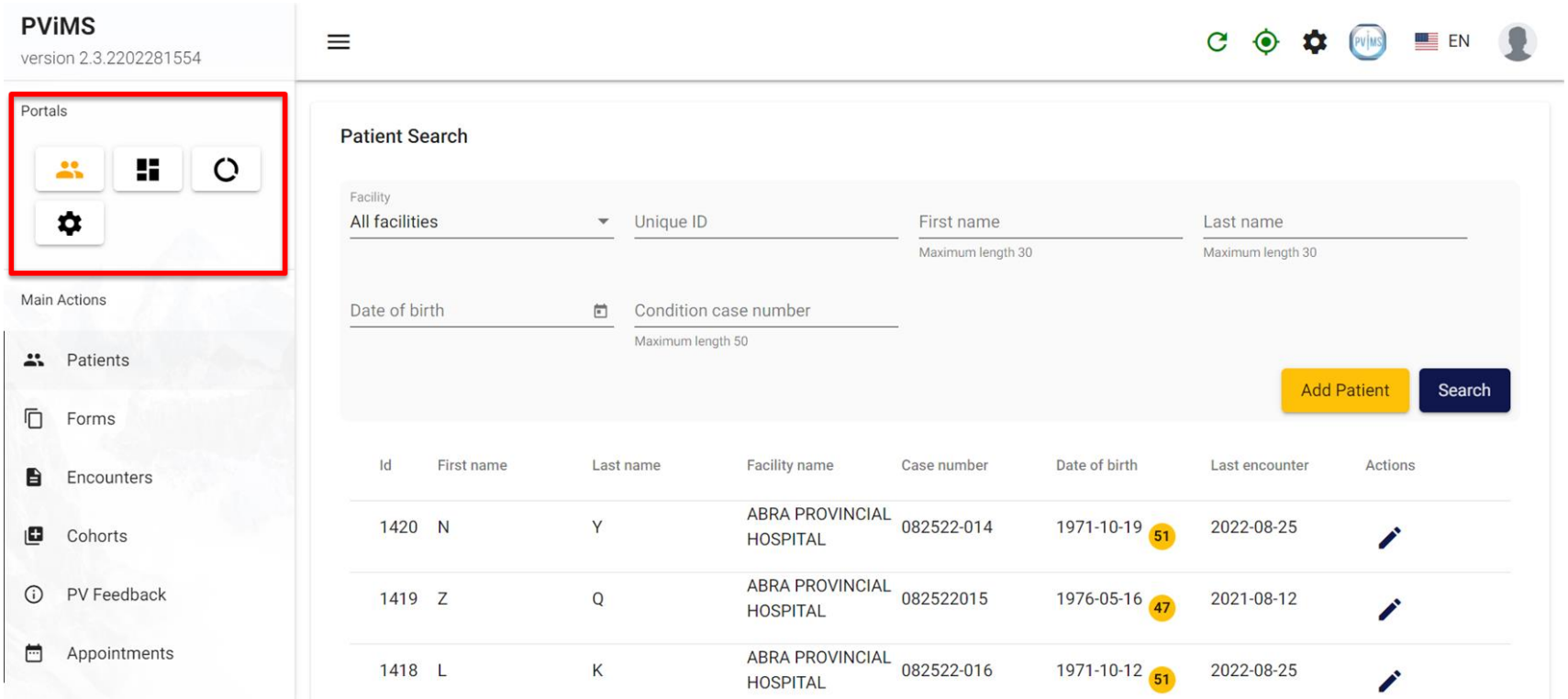
- New TB drugs and novel TB treatment regimens
- aDSM: A form of active pharmacovigilance
  - Actively monitoring, management and reporting
  - Implementation can be tailored based on resources available in the country (PH: SAE and AESI)
- One of the overall objectives is to generate standardized aDSM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

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

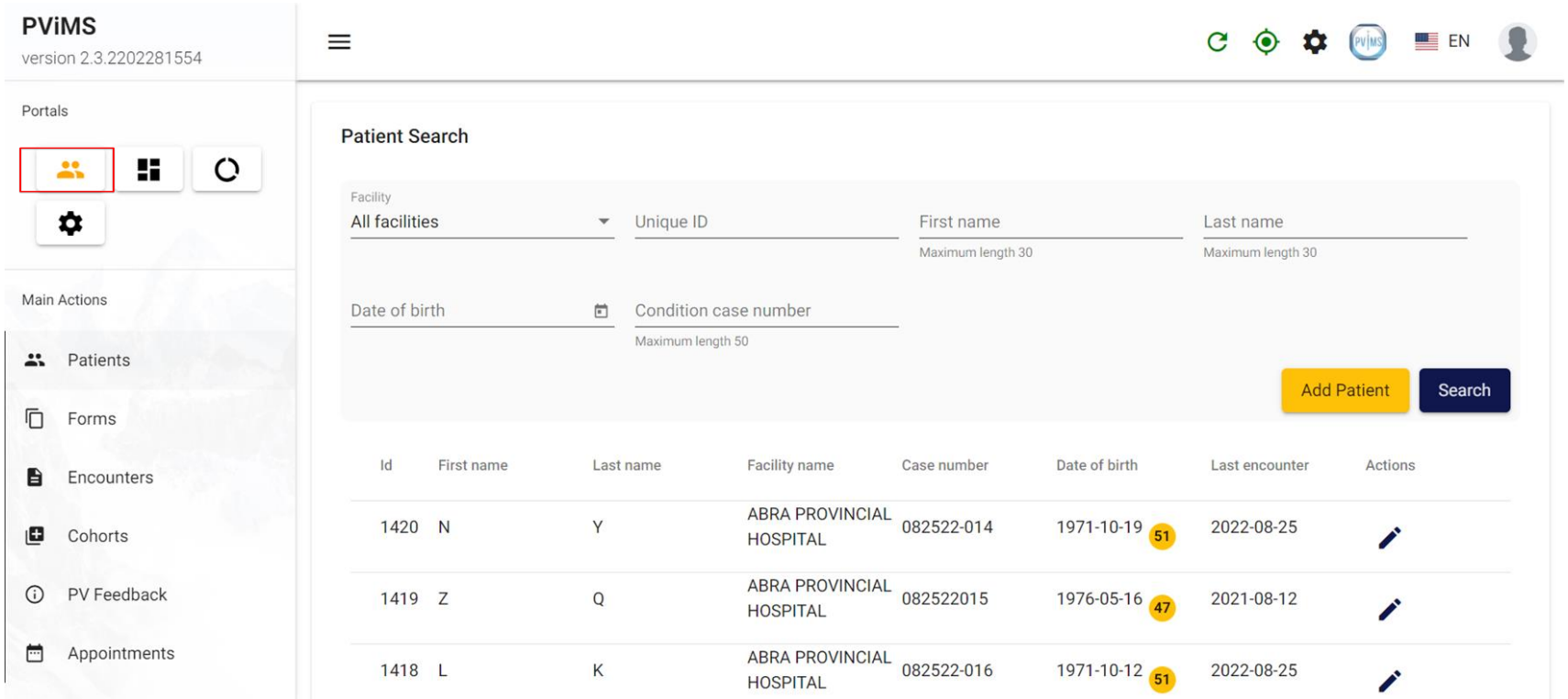
- This is the landing page of PViMS.



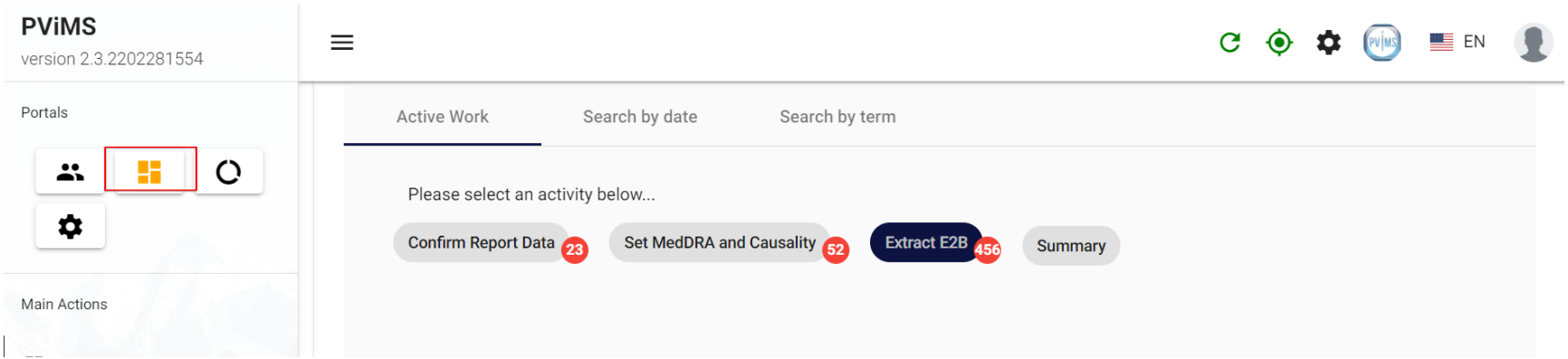
Portals


PViMS
version 2.3.2202281554
Portals
Main Actions
Patients
Forms
Encounters
Cohorts
PV Feedback
Appointments
EN
Patient Search
Facility
All facilities
Unique ID
First name
Maximum length 30
Last name
Maximum length 30
Date of birth
Condition case number
Maximum length 50
Add Patient
Search
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

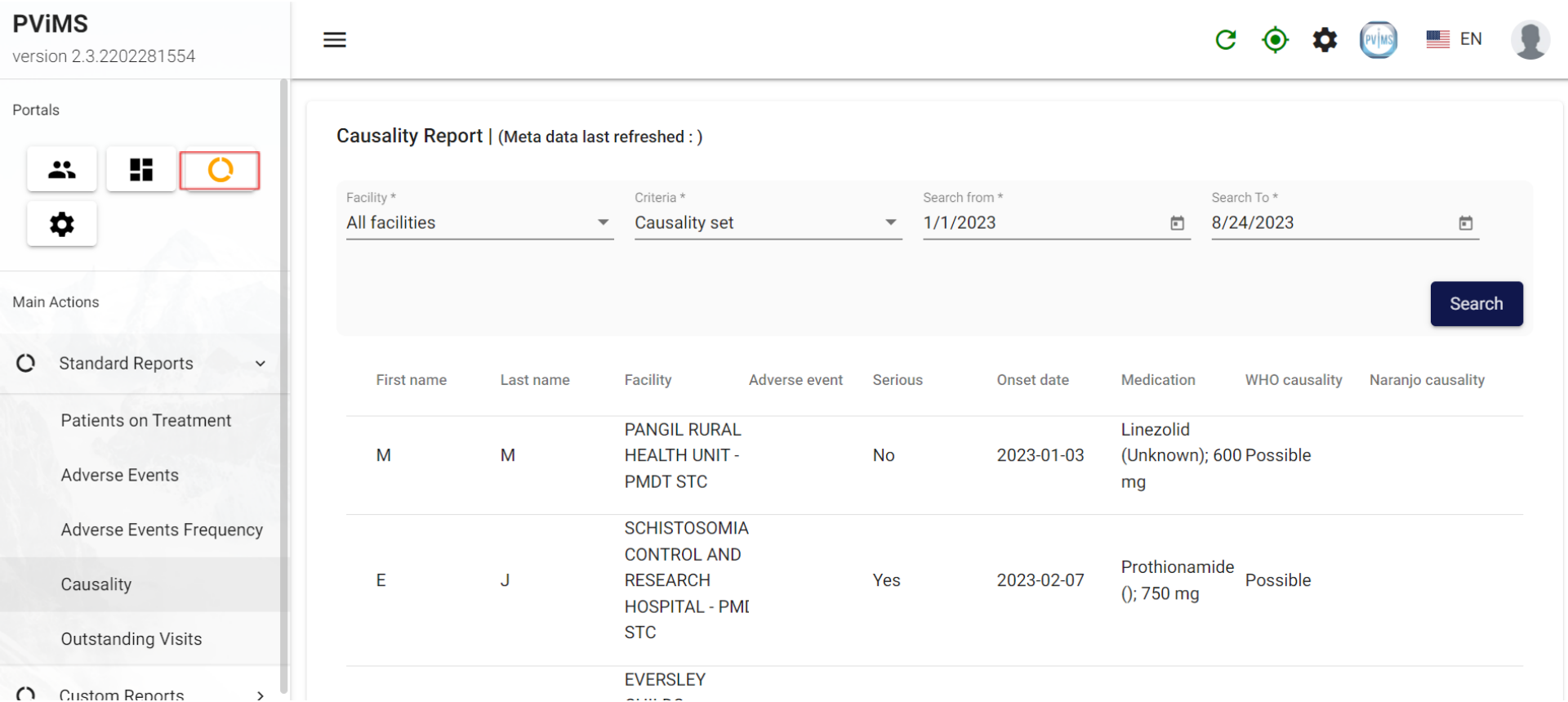
Clinical Portal



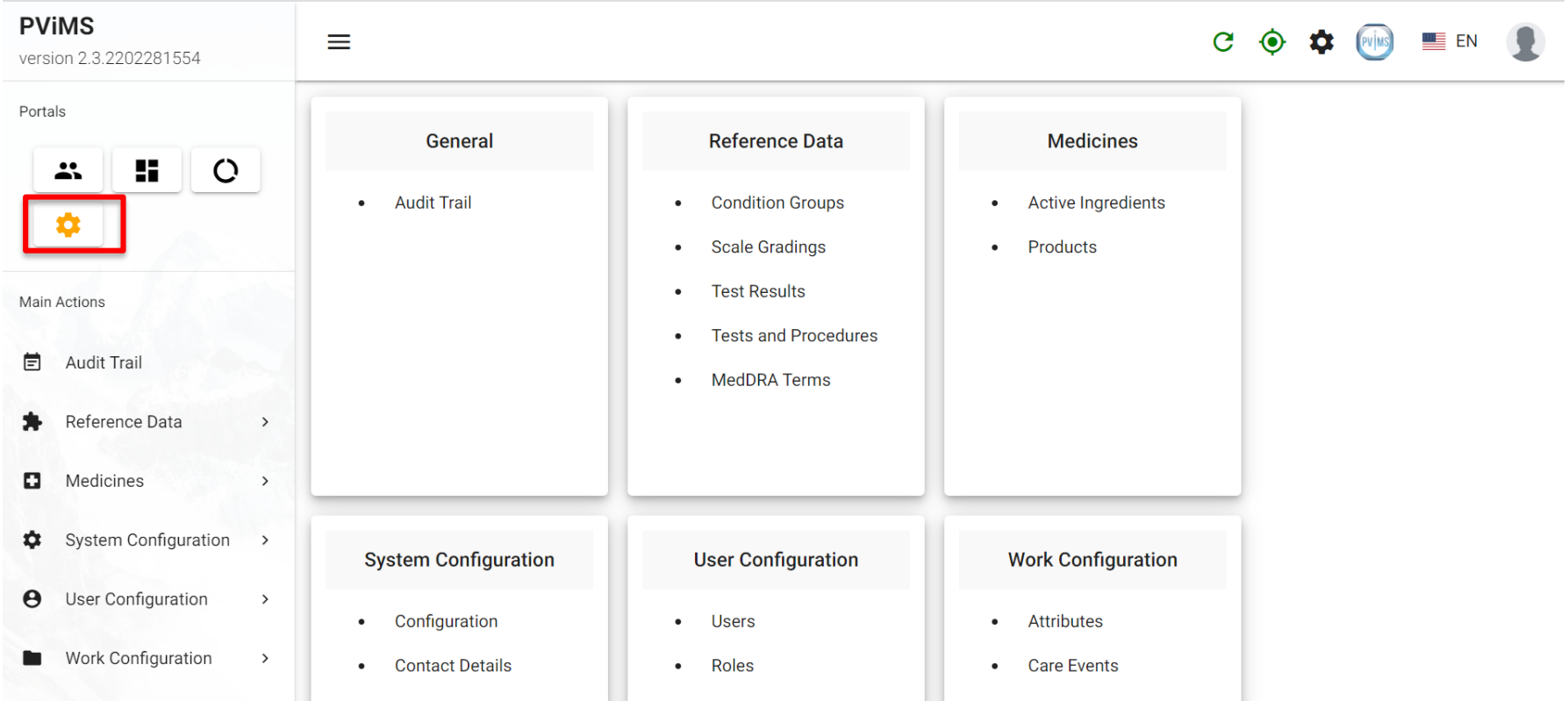
Analytical Portal



Reports Portal



Administration Portal



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

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How do we achieve the Vision?

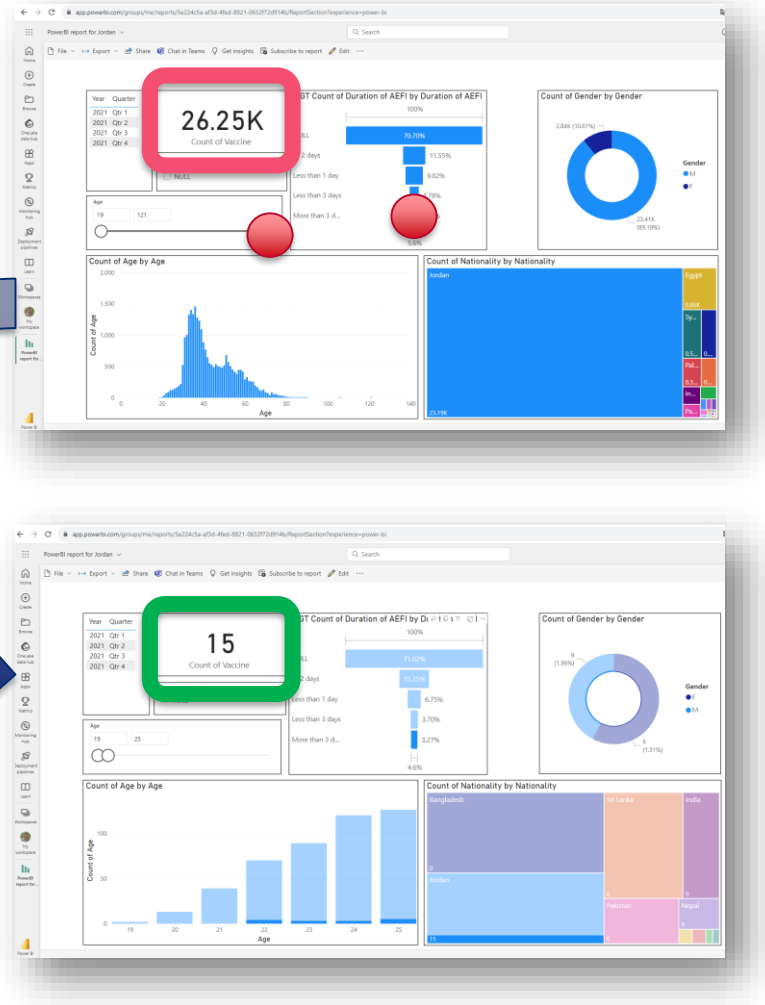
- Vision is Two-fold: **Technical and Operational**
- **Technical Vision**
  - Build technical **community of practice** on the technical side
  - **Grow** the teams we currently have working with us
  - **Continuous alignment** with Public Digital Good Alliance and the Principles for Digital Development
  - 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:

jhpiego

More details and registration link coming soon!

Global Digital Health Network

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