Promoting the Quality of Medicines Plus (PQM+)

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

Improved Access. Improved Services. Better Health Outcomes.

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

Report on the Consultative Process

September 2022

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About the USAID MTaPS Program

Funded by the US Agency for International Development (USAID) and implemented by a team led by Management Sciences for Health (MSH), the purpose of the five-year Medicines Technologies and Pharmaceutical Services (MTaPS) program (2018–2023) is to provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats, as well as expanding essential health coverage. The goal of the MTaPS Program is to help low- and middle-income countries (LMICs) strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality assured, and affordable essential medicines, vaccines, and other health technologies and pharmaceutical services.

About the USAID PQM+ Program

The Promoting the Quality of Medicines Plus (PQM+) program is a USAID funded cooperative agreement with the U.S. Pharmacopeial Convention (USP) with a goal to sustainably strengthen medical product quality assurance (QA) systems by providing technical assistance to manufacturers of priority health products and build in-country capacity of Medicines Regulatory Authorities to improve product registration, inspection, and post-marketing surveillance for product quality. PQM+ support also includes accreditation of national drug quality control laboratories per ISO/IEC 17025 and/or WHO pre-qualification standards in LMICs. PQM+ uses a system strengthening approach to program implementation to enhance sustainability.[1] The program considers the entire system when designing and delivering technical assistance, focusing on the interaction among all health systems functions[2] as they relate to medical product quality assurance.

To implement PQM+, USP joined forces with a diversified consortium of four core partners, six field-led extension partners, and eight technical resource partners[3] whose extensive technical expertise can be drawn on to achieve desired results.

[1] Chee G, Pielemeier N, Lion A, Connor C. Why differentiating between health system support and health system strengthening is needed. Int J Health Plann Mgmt. 2013; 28: 85-94. DOI: 10.1002/hpm.2122.
[2] governance, human resources, service delivery, information systems, financing https://www.usaid.gov/global-health/health-systems-innovation/health-systems/strengthening-pharmaceutical-systems
[3] https://www.usp.org/sites/default/files/usp/document/our-impact/pqm/pqm-plus-overview-brochure.pdf

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Participants represented over 17 organizations, including:

- African Union Development Agency (AUDA)–New Partnership for Africa's Development (NEPAD)
- Association of Southeast Asian Nations (ASEAN) Secretariat
- Asia Development Bank
- Bill & Melinda Gates Foundation
- Centre for Innovation in Regulatory Science
- Mahidol University
- Management Sciences for Health
- Medicines and Healthcare products Regulatory Agency (United Kingdom)
- School of Pharmacy Muhimbili University, Muhimbili University of Health and Allied Sciences
- Global Fund to Fight AIDS, Tuberculosis and Malaria
- U3 SystemsWork International
- United States Pharmacopeia
- Université Félix Houphouët-Boigny
- US Agency for International Development (USAID)
- USAID Global Health Supply Chain Program-Procurement and Supply Management project
- World Bank
- World Health Organization

Participants included representatives from 14 national medicine regulatory authorities:

- Bangladesh
- Benin
- Ghana
- Guinea
- Indonesia
- Kenya
- Liberia
- Mali
- Nepal
- Nigeria
- Pakistan
- Rwanda
- Senegal
- Uganda

Full participant lists for each consultative meeting are included in each meeting report, annexes 1–4.

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CONTENTS

Acronyms and Abbreviations

To facilitate readability and usability, the individual abbreviation lists in the annexes have been deleted and combined into this one list.

AMRH	African Medicine Regulatory Harmonization
ASEAN	Association of Southeast Asian Nations
ATC	Anatomical Therapeutic Chemical
AUDA-NEPAD	African Union Development Agency–New Partnership for Africa's Development
COMESA	Common Market for Eastern and Southern Africa
CTD	common technical document
DRAP	Drug Regulatory Authority of Pakistan
EAC	East African Community
ECOWAS	Economic Community of West African States
eCTD	electronic common technical document
FHIR®	Fast Health Interoperability Resources
GBT	Global Benchmarking Tool
GGP	Good Governance Practices
GMP	Good Manufacturing Practices
GRelP	Good Reliance Practices
GRP	Good Regulatory Practices
ICT	information and communications technology
IDMP	identification of medicinal product
IGAD	Intergovernmental Authority on Development
IMS	information management system
INN	international nonproprietary name
ISO	International Organization for Standardization standards
LMIC	low- and middle-income country
MCS	minimum common standard
MIS	management information system
MSH	Management Sciences for Health
MTaPS	Medicines Technologies and Pharmaceutical Services
NMRA	national medicine regulatory authority
PLM	product life cycle management
PQM+	Promoting the Quality of Medicines Plus
QA	quality assurance
RSS	regulatory system strengthening
SADC	Southern African Development Community
SEARN	South-East Asia Regulatory Network
SNOMED	Systematized Nomenclature of Medicine Clinical Terms
SPL	structured product labelling
USAID	US Agency for International Development
USP	US Pharmacopeial Convention
WHO	World Health Organization
XML	extensible markup language

EXECUTIVE SUMMARY

The USAID-funded Medicines, Technologies, and Pharmaceutical Services (MTaPS) and USAID-funded Promoting the Quality of Medicines Plus (PQM+) programs engaged global stakeholders and subject matter experts to identify and recommend a set of minimum common standards (MCSs) for regulatory information management systems (IMSs). Adoption of these common standards will streamline regulatory processes and help ensure that national medicine regulatory authorities (NMRAs) make technical decisions with a degree of consistency and uniformity. MCSs would also enhance the ability of NMRAs to collaborate and share information with one another, including use of reliance and recognition mechanisms.

The MCSs will enable uniform data capture and standardize the data, design, and workflow of digitalized regulatory functions. Specifically, MTaPS and PQM+ convened a group of international stakeholders and subject matter experts to:

- Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS for the eight regulatory functions outlined in the World Health Organization (WHO) Global Benchmarking Tool (GBT) for evaluation of national regulatory systems[4]
- Use existing relevant IMS and regulatory standards to derive a recommended set of MCSs for regulatory IMS to address identified gaps and challenges; this includes developing the selection criteria for prioritizing which standards to include in the set of recommended standards
- Develop the use case for the MCSs and promote their adoption and use

The consultations spanned a 10-month period and consisted of 4 virtual meetings, supplemented by written feedback and one-on-one and small group sessions to achieve the stated process objectives. Through this process, a minimum common set of standards for digitalization of regulatory IMSs was identified (figure 2), as well as an advocacy brief and pathway to digitalize regulatory IMSs (see Outputs of the Consultative Process).

[4] World Health Organization (2021). WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. https://www.who.int/tools/global-benchmarking-tools/VI; GBT Revision VI version 1 comprises registration and marketing authorization, vigilance, market surveillance and control, licensing establishments, regulatory inspection, laboratory testing, clinical trials oversight, and NRA lot release

BACKGROUND

NMRAs in low- and middle-income countries (LMICs) often lack fully operational IMSs to perform regulatory functions. These systems are often disparate and lack interoperability or are nonexistent, partially implemented, or nonfunctional. Many regulatory functions use paper-based systems, which results in inefficient workflows, backlogs and delays, lack of transparency, mismanagement, and vulnerability to corruption. Digitalization efforts aim to improve consistency, efficiency, and accountability in pharmaceutical regulatory service delivery. However, digitalization approaches vary across NMRAs, which often struggle with fully operationalizing their regulatory IMSs, either desk-based or web-based systems, which limit the availability of real-time data and collaboration between NMRAs.[5]

Ongoing regional regulatory harmonization efforts in both Africa and Asia will rely not only on common documents and processes, but also shared regulatory IMS that are fully interoperable. This work increases the need for a set of MCSs for regulatory IMS to help clarify how regulatory IMS should capture and report information to promote system interoperability within national regulatory systems and support regulatory harmonization efforts.

It is not feasible for countries to apply all the relevant standards to each regulatory IMS, so it is necessary to identify a set of MCSs for regulatory IMS that NMRAs should prioritize to streamline their workflows and documentation of regulatory processes, ensure uniform data capture, and enable data exchange within and between NMRAs and other stakeholders. The USAID-funded Medicines Technologies and Pharmaceutical Services (MTaPS) and USAID-funded PQM+ programs engaged global stakeholders and subject matter experts to help identify and recommend a set of MCSs for regulatory IMS. The adoption of these common standards will streamline regulatory processes and help ensure that NMRAs make technical decisions with a degree of consistency and uniformity. MCSs would also enhance the ability of NMRAs to collaborate and share information with one another, including use of reliance and recognition mechanisms.

OBJECTIVES OF THE CONSULTATIVE PROCESS

The primary objective of the consultative process was to derive and recommend a set of MCSs for regulatory IMSs that will enable uniform data capture and standardize the data, design, and workflow of digitalized regulatory functions. Specifically, MTaPS and PQM+ convened a group of international stakeholders and subject matter experts to:

- Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS for the eight regulatory functions outlined in the WHO GBT for evaluation of national regulatory systems[4]
- Use existing relevant IMS and regulatory standards to derive a recommended set of MCSs for regulatory IMSs to address identified gaps and challenges; this includes developing the selection criteria for prioritizing which standards to include in the set of recommended standards

[5] BEWSYS. (2020). Final Report. Consultancy for Scoping of a Continental Regulatory Information Management System Solution and Information Sharing Platform for the Member States in the African Union. Submitted to the World Bank Group. Washington DC.

- Develop the use case for MCSs and promote their adoption and use

Expected Results of the Consultative Process

The consultation was expected to:

- Produce a set of MCSs for the eight GBT regulatory functions identified to support digitalization of regulatory IMS
- Sensitize global stakeholders in regulatory system strengthening (RSS) to the importance of adoption and institutionalization of MCSs for regulatory IMSs

Process Overview

MTaPS and PQM+ facilitated a 10-month consultative process with adopters and end users, global and regional regulatory experts, and funders to develop the set of MCSs for regulatory IMS (table 1).

Table 1. Consultative Process Overview

Time (approx)	Activity	Task/objective	Expected results
Sept 15, 2021	Consultative meeting I	Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMSs	- Critical gaps and challenges with regulatory IMSs identified - The scope of the standards for addressing the gaps and challenges defined
		Discuss the scope of MCSs for regulatory IMS	
		Discuss how a set of MCSs for regulatory IMSs can best address or mitigate these challenges and start building the use case	
Oct 27	Consultative meeting II	Develop selection criteria for MCSs	- Preliminary core set of minimum common standards for regulatory IMSs identified - Advocacy brief developed
		Review collated existing standards	
		Finalize the use case	
Oct 27–Dec 1	External review I	Review of collated existing standards and identify which standards should be included in the MCS set	
Jan 26, 2022	NMRA meeting (Consultative meeting III)	Engage select NMRA representatives to gather additional input	
		Draft advocacy brief	
Jan 21–Feb 28	Internal analysis and synthesis of standards	Consolidate and synthesize the inputs from the experts	
		Draft MCSs for regulatory IMS	
March 1–31	External review II	Final expert review of the proposed MCSs	- Finalized set of MCSs for regulatory IMS - Inputs gathered for guidance on digitalization pathway
April 1–31	Internal revisions and finalization	Finalize MCSs based on feedback	
		Internal reviews and copyediting	
June 2	Consultative meeting IV	Present MCSs	
		Discuss guidance on pathway for countries to adopt MCSs to support the digitalization of regulatory functions	

There were three primary groups of stakeholders involved in the consultative process:

- **Adopters and end users:** NMRAs are the primary stakeholder group as they are the users of the systems. Software developers and programmers and managers/administrators of regulatory IMSs develop and manage the systems for NMRAs.
- **Global and regional regulatory experts:** This group includes the regional regulatory harmonization initiatives; other global and regional experts and normative bodies working in RSS; and subject matter experts who can provide technical inputs on the recommended MCSs and promote the adoption and use of standards. Examples of stakeholders in this group include WHO, the Bill & Melinda Gates Foundation, South-East Asia Regulatory Network (SEARN), African Union Development Agency–New Partnership for Africa's Development (AUDA-NEPAD), Association of Southeast Asian Nations (ASEAN) and other regional economic communities, and pharmaceutical industry associations.
- **Funders:** This group supports RSS development and implementation and may overlap with the global regulatory experts' group. Examples include the World Bank and the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

This report documents the outcomes of the consultative process.

CONSULTATIVE MEETING I

The USAID-funded MTaPS and PQM+ programs convened a virtual consultative meeting on September 15, 2021. The meeting is the first in a series of consultations aimed at identifying and recommending a set of MCSs for regulatory IMSs that will enable uniform data capture and standardize the data, design, and workflow of digitalized regulatory functions. The complete report of the first consultative meeting can be found in Annex 1.

MEETING I OBJECTIVES

The meeting brought together experts in RSS and IMSs from a variety of global, regional, and national organizations (See Annex 1B for a complete list of meeting participants), and objectives were to:

- Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing in regard to regulatory IMSs
- Discuss how a set of MCSs for regulatory IMSs can best address or mitigate these challenges
- Start building the use case for a set of MCSs for regulatory IMS

MEETING I OUTCOMES

The discussions were structured around introductory presentations given at the beginning of each session (see Annex 1A: Meeting Agenda for details) and a set of session-specific prompts/questions.

During the meeting, more than 50 participants representing over 20 organizations working to strengthen regulatory systems identified the following challenges to successful implementation of regulatory IMSs:

- Lack of interoperability
- Lack of integration
- Varying requirements/standards for regulatory processes
- High cost
- Unsustainable political will and commitment

The complete list of the challenges identified is included in Annex 1D. There was general agreement that the challenges to regulatory IMS implementation are consistent across regions. There are variations between the regions in terms of system maturity (both in terms of GBT levels and information system infrastructure) and the varying degrees of reliance/convergence that the regions have identified as the target/endpoint for their harmonization initiatives. These should be carefully considered throughout the process of identifying a minimum set of standards for regulatory IMSs and, particularly, when elaborating the use case for adoption of the standards and creating a plan for institutionalizing the standards when developing, improving, or implementing regulatory IMSs.

Meeting participants proposed that a minimum common set of standards to guide the development and implementation of regulatory IMSs could address these challenges and lead to improved:

- Effectiveness, efficiency, and performance
  - Regulatory activities can be performed faster, better, and with less cost
- Transparency and timely access to information and regulatory decisions
  - Possibility for faster and wider sharing of information
- Consistency in regulatory activities/functions
- Good Governance Practices (GGPs), reduced risk of corruption
- Collaboration, trust, and reliance among NMRAs

Finally, participants agreed on the following working definition of the term "standards" and the scope as it applies to this activity:

> *Standards refer to the basis of measure, norms, and guidelines for regulatory IMS that would enable uniform data capture, a standardized data exchange platform and workflow of digitalized regulatory functions, leading to efficiencies and enhanced governance.*

MTaPS and PQM+ proposed three categories of regulatory IMS standards:

- **Process or workflow standards**, which define standards for pharmaceutical procedures, processes, or workflows. Examples include Good Manufacturing Practices (GMP) and International Organization for Standardization (ISO) standards.
- **Pharmaceutical standard dictionaries and knowledge trees**, which are master or reference lists for terminology, nomenclature, and hierarchies. Examples include Systematized Nomenclature of Medicine Clinical Terms (SNOMED), Anatomical Therapeutic Chemical (ATC) classification, and International Nonproprietary Name (INN).
- **Data exchange standards** pertain to information and communications technology (ICT) and management information system (MIS) functions and determine how data should be structured, defined, and formatted to facilitate sharing across computer systems. Examples include structured product labelling (SPL), portable document format, and extensible markup language (XML), and platforms, such as Fast Health Interoperability Resources (FHIR®), which define a common standard for health system data exchange.

CONSULTATIVE MEETING II

The second consultative meeting focused on the development of the standards themselves. The report for the second meeting is included as Annex 2.

MEETING II OBJECTIVES

- Develop the use case for the set of MCSs
- Identify the selection criteria for the MCSs

MEETING II OUTCOMES

Regarding the development of the use case for the standards, MTaPS and PQM+ noted that the potential benefits of adopting MCSs for the different stakeholder groups must be identified. Potential benefits of adoption include creation of a common reference among stakeholders for developing and using regulatory IMSs; streamlining NMRAs' internal operations; and facilitating convergence and harmonization of regulatory services, both within and across NMRAs. Meeting participants acknowledged these benefits and discussed the need to learn from previous efforts of other organizations that have developed and promulgated standards. This could help identify a suitable process for identifying stakeholders and developing and promoting the standards.

Participants debated whether the GBT modules/regulatory functions or the pharmaceutical product life cycle should be used to structure further work on the standards and the use case. Participants agreed that the product should be the center of their thinking and that the regulatory functions at each stage in the product life cycle should be examined individually to identify stakeholders and build the use cases. Using this suggestion, meeting participants did some preliminary work identifying potential stakeholders for the different regulatory functions aligned with the various stages of the product life cycle. However, no final determination was made regarding the key stakeholders for developing use cases during the time allotted for the session.

The key selection criteria that MTaPS and PQM+ proposed for selecting the MCSs were:

- Relevance: The standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBT
- Feasibility of application: The extent to which NMRAs' capacity and resources feasibly allow adoption and what are the anticipated efficiency gains
- Priority: How would countries benefit or lose by not applying a given standard?
- Universality: Whether a given standard is recommended by WHO and the extent to which it is widely used

However, participants raised concerns about how best to apply these criteria and noted that, in some cases, determinations would have to be country specific. Much of the deliberation centered on the inclusion or exclusion of *process standards*—several participants proposed that we differentiate between *standards* and *guidelines* and asserted that including both was outside the proposed scope of the activity and confounded the activity objectives. Further, some meeting participants were concerned about the extent to which the applying the criteria aligned with the scope of the activity and the extent to which the objective was focused on system design versus system contents. Meeting participants further urged the team to revisit the definitions and the proposed scoring (1 being low priority, 3 being high priority) of the criteria.

Given the depth of the meeting discussions, MTaPS and PQM+ noted the need revisit the consultative process and the proposed approach for the use case development and standards selection. The next steps include a rethinking of the process and a potential revision of the background document for recirculation to participants for reactions and feedback.

Recommendations and next steps for MTaPS and PQM+ that emerged from the meeting include:

- Draft the use case and share with meeting participants for feedback.
- Map the regulatory functions to the product life cycle and use the resulting matrix to identify stakeholders.
- Use the feedback from the meeting to rethink the selection criteria and share with meeting participants for feedback.
- Share the full list of standards identified from the desk review with participants for review against the revised selection criteria.

CONSULTATIVE MEETING III – NMRAS

The third consultative meeting, held virtually on January 26, 2022, focused on inputs and perspectives from NMRAs. Many of the authorities were participating in the process for the first time, so the agenda (Annex 4A) set time aside to introduce the overall activity. Participants received the concept note as well as the compiled standards from the literature review and the selection criteria from the second consultative meeting in advance.

The meeting brought together NMRA experts in pharmaceutical regulatory systems and IMSs from 11 countries in Africa and Asia (Annex 4B).

MEETING III OBJECTIVES

The main purpose of the meeting was to provide an overview of the process for identifying a set of MCSs for regulatory IMS, including defining the scope, objectives, benefits, and the standards selection process.

MEETING III OUTCOMES

During this meeting, the importance and benefits of a minimum set of standards for regulatory IMSs and the challenges with its adoption were discussed. The PQM+ and MTaPS programs proposed that the adoption of a minimum set of common standards for regulatory IMSs will:

- Create a single language or common reference for use among regulators, software developers, and policymakers
- Guide the development of standards as developers incorporate them into software requirement specifications to design regulatory IMS software
- Streamline NMRAs' internal operations, such as workflow management throughout the life cycle of medical products, performance metric tracking, and reporting
- Facilitate convergence and harmonization of regulatory services, both within and outside a defined national regulatory authority

Meeting participants acknowledged these benefits; during the first session, NMRA participants identified the following challenges regarding regulatory IMSs in their settings:

- Lack of information technology (IT) materials, software, infrastructure, servers, and professionals to develop these systems
- Improper integration or non-existent IMSs for regulatory processes
- Minimal internet connectivity, data storage, and backup systems for regulatory information
- Minimal financial resources and time constraints to develop or improve regulatory IMSs
- Creation of systems (by outsourced and expensive software developers) that are not iterative, resulting in manual interventions and a fragmented approach to automating regulatory business processes.

Participants discussed how to address these challenges with the adoption of MCSs for regulatory IMSs. Attendees noted that MCSs can mitigate these challenges by:

- Providing appropriate technical support and capacity building for related IMS platforms to minimize errors and increase the accuracy of data capture
- Supporting reliance, harmonization, and information exchange to optimize regulatory resources
- Guaranteeing transparency and uniformity of activities, providing a structured framework for communication between the regulatory functions
- Improving and facilitating the product registration process in a timely manner
- Pressuring each regulatory authority to procure minimum equipment
- Encouraging NMRAs to adopt best practices from countries with stronger or more mature regulatory systems to improve technical capabilities
- Helping NMRAs better manage their policies and processes to achieve specific objectives and outcomes
- Supporting good documentation practices within NMRA functions

Session II of the meeting introduced the methodology for the desk review exercise conducted by PQM+ and MTaPS, which identified 56 regulatory standards organized into 3 categories:

- Process or workflow standards
- Data dictionary and knowledge tree standards
- Data exchange standards

The session also presented the 4 selection criteria and process that NMRA participants and other stakeholders will use to identify a minimum set of common standards from the list of 56 to prioritize for adoption. The selection criteria are:

- Relevance: Applicable to at least one of the eight core regulatory functions as defined in the WHO GBT
- Feasibility of application: Extent to which NMRAs' capacity and resources feasibly allow adoption
- Criticality: Whether the standard is critical (or required) to gain efficiencies in workflow and processes for at least one regulatory function
- Universality: How widely a standard is used (e.g., recommended by large normative bodies, industrywide standards, etc.)

Meeting attendees were also prompted to respond to following questions:

- What regulatory data standards have been adopted in your country?
- What is your feedback on the selection criteria used by PQM+/MTaPS to determine MCSs for regulatory IMSs?
- Do you have any suggestions on how these MCSs should be selected?

Based on the ensuing discussion, many countries are applying some of the standards identified in the original desk review. Participants recommended that PQM+ and MTaPS consider including flexibility, universality, and/or harmonization as part of the selection criteria for MCSs.

They also discussed next steps in the engagement process to set the expectations and outline the steps and timeline for completion of the selection process for a minimum set of standards for regulatory IMSs. The meeting closed with thanks to all attendees for their active engagement and reiterated a request that attendees work with their colleagues to complete the standard selection activity presented during the meeting.

CONSULTATIVE MEETING IV

The fourth and final consultative meeting brought together 49 experts in RSS and IMSs, representing 9 countries and 4 regional and global organizations, combining participants from the first 3 meetings.

MEETING IV OBJECTIVES

- Share the results of feedback from stakeholders on selecting MCSs for regulatory IMSs
- Agree on the MCSs for regulatory IMSs
- Propose next steps involving advocacy for adopting MCSs by NMRAs

MEETING IV OUTCOMES

During this meeting, MTaPS and PQM+ representatives provided an overview of the consultative process that led to the identification of 56 standards and culminated in the selection of MCSs for regulatory IMSs.

Session 1 discussed the consultative process and methodology for selecting MCSs based on the following criteria:

- Relevance: The standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBT v2.0
- Feasibility: The extent to which NMRAs' capacity and resources feasibly allow adoption and what are the anticipated efficiency gains
- Criticality: How would countries benefit or lose by not applying a given standard?
- Universality: Whether a given standard is recommended by WHO and the extent to which it is widely used

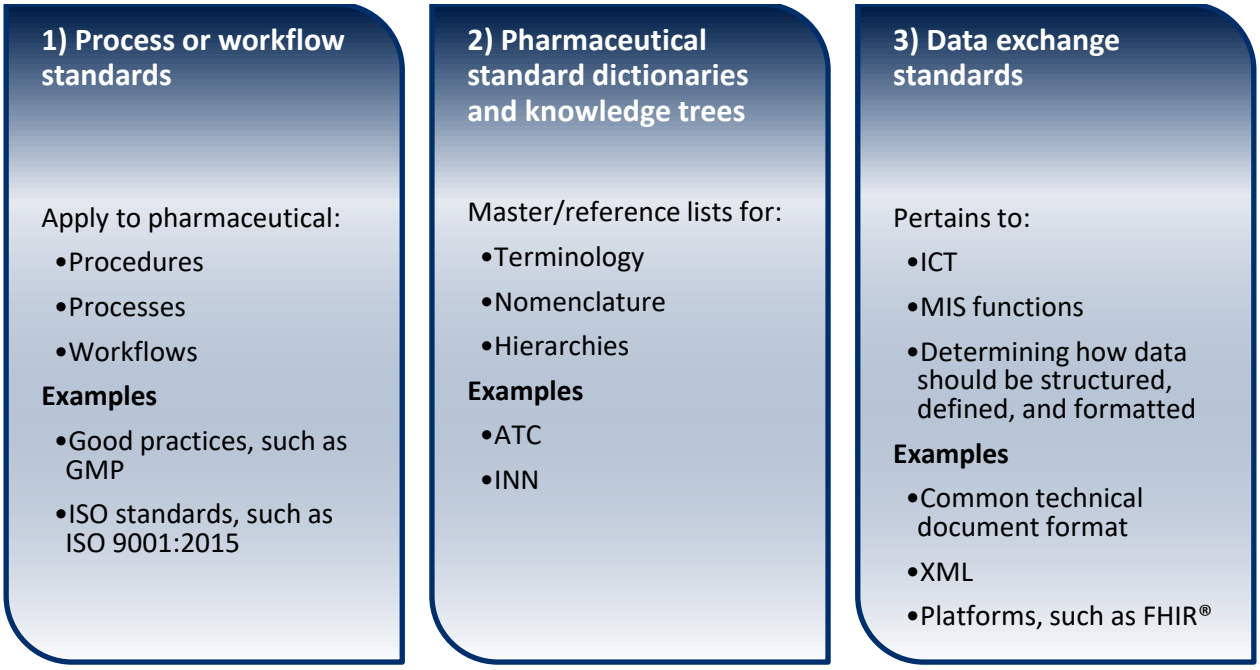
The list of 56 identified standards was circulated to all participants in the preceding 3 consultative meetings. Participants were asked to evaluate each criterion on a scale of 1 to 3 for each of the 56 standards. Definitions for each rating are included in table 2. During this selection exercise, relevance was excluded from participant consideration—the 56 identified standards were deemed relevant for inclusion by the MTaPS and PQM+ teams during the literature review process.

Table 2. Rating definitions by selection criteria

Rating scale	Feasibility	Criticality	Universality
1	Adopted with greater difficulty, significant technical assistance required	Regulatory performance/processes not impacted without the standard	Not widely used in LMICs
2	Adopted with medium difficulty, marginal technical assistance required	Regulatory performance/processes may be impacted without the standard	The standard is moderately widespread
3	Adopted with minimal, if any, technical assistance	Regulatory performance/processes impacted without the standard	Widely used or recommended by industry or normative bodies

These 56 standards were further divided into 3 categories (figure 1).

Figure 1. Categories of standards



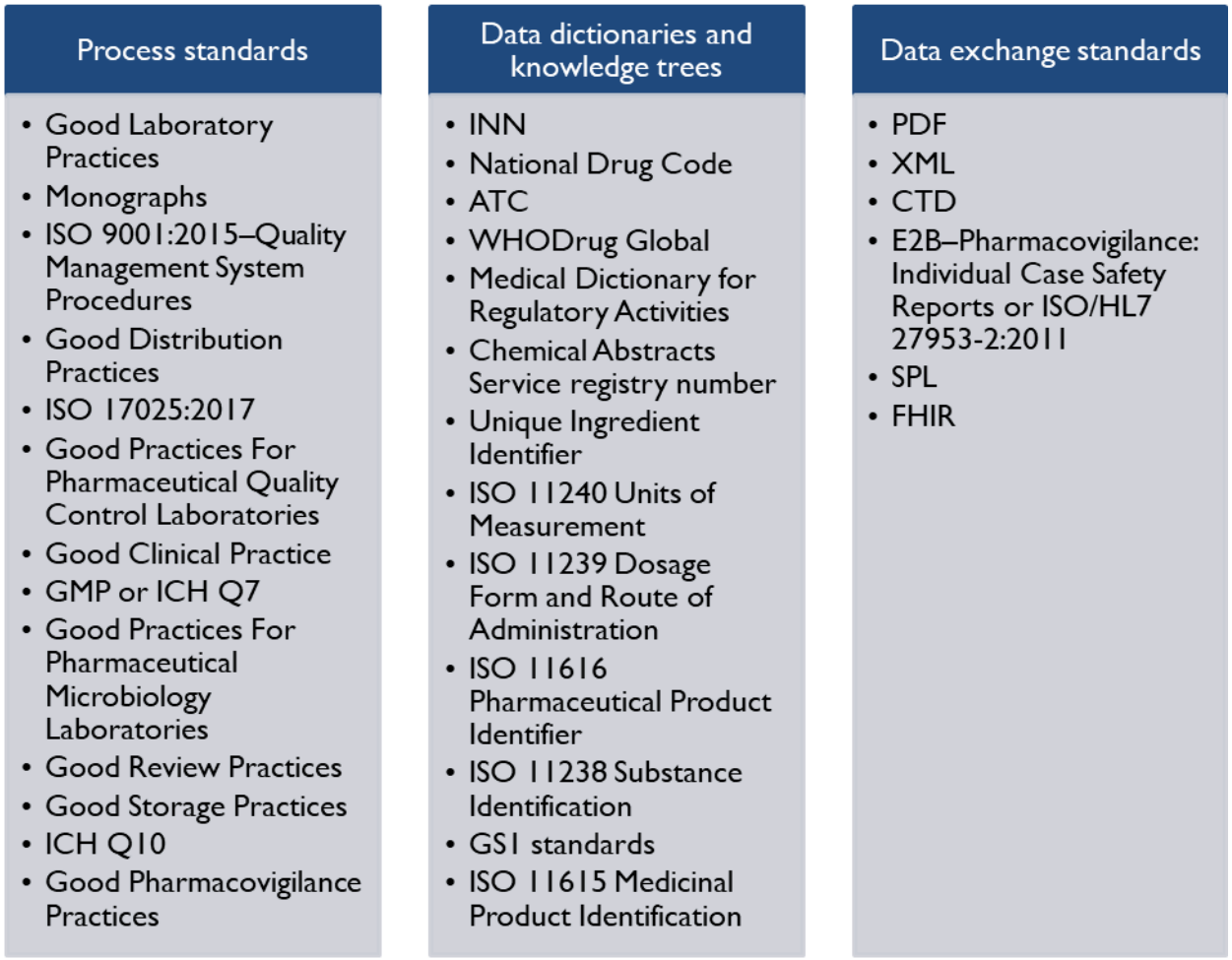
The final list of MCSs was developed based on analysis of the feedback received from 11 respondents and informed by the MTaPS and PQM+ teams' expertise across regulatory functions.

The first step in the data analysis was the computation of unweighted mean scores received from participants. As the analysis proceeded, MTaPS and PQM+ experts examined the results based on category of standard, respondent type (global, regional, or national), regulatory function according to the WHO

GBT v2.0, and pharmaceutical product life cycle alignment. The MTaPS and PQM+ teams determined that the criterion for feasibility should be excluded from the selection process—this criterion should determine the order in which NMRAs should adopt each standard in the list of MCSs. Universality and criticality were combined to select the standards, which were then sorted by their assigned feasibility scores to recommend how countries should incorporate the selected standards in their regulatory IMSs.

All the identified process standards, except for those pertaining specifically to medical devices, were selected for inclusion in the MCSs. The standards pertaining to medical devices were excluded to align with the WHO GBT v2.0 (medicines and vaccines). Participants expressed the expectation that standards for medical devices would be included the future set of MCSs. The remaining process standards are considered prerequisite to digitalizing regulatory IMSs or adopting the other standards (data dictionaries and knowledge trees, data exchange). The list of standards recommended for adoption (figure 2) are listed in order from the most to least feasible to adopt.

Figure 2. Selected MCSs for regulatory IMSs



The meeting was informed that MTaPS and PQM+ were developing a guidance document and advocacy brief for the adoption of regulatory IMSs.

Discussion included a detailed review of the data analysis process for the selection of the MCSs.

Session II consisted of discussions with participants about agreement on MCSs for each of the three categories (process, data dictionaries/knowledge trees, and data exchange). Participants strongly suggested including identification of medicinal product (IDMP) standards, such as ISO 11615, ISO 11616, ISO 11239, and ISO 11240, as part of the list of MCSs because they are key data entry elements required to create product information and are essential for identifying medicinal products regionally and internationally, particularly for pharmacovigilance activities.

Meeting attendees were prompted to share any challenges or lessons learned implementing regulatory IMSs in their context and provide general feedback on the presentations. Selected responses are below.

- The choice of data exchange standards was a prudent one as they are widely used.
- Include a comprehensive mapping of the selected standards and their respective WHO GBT function in the meeting report.
- Focus on incorporating IDMP standards.
- A feasibility analysis should be conducted before implementing regulatory IMSs.
- Selected standards should be aligned with international data interchange standards.

During the discussion, it was strongly recommended to adopt IDMP standards for sharing information internationally and regionally and to think about adding implementation tools to supplement the standards. It was also suggested that the regulatory IMS implementation guidelines be developed in close partnership with WHO.

Outputs of the Consultative Process

Set of MCSs

Based on the literature review, selection criteria, and extensive review and feedback over the course of the consultative process, the MTaPS and PQM+ teams selected the MCSs required for digitalization of regulatory IMSs (figure 2).

Advocacy Brief

A document that highlights the benefits of adopting the MCSs for digitalization of regulatory IMSs in LMICs was also developed through the consultative process. The document emphasizes feedback from the consultation participants regarding the challenges to digitalize regulatory IMSs and how the standards can be used to mitigate these challenges. The advocacy brief citation is below.

USAID PQM+ and USAID MTaPS. Adopting Minimum Common Standards for Regulatory Information Management Systems—A Call to Action. Submitted to the US Agency for International Development by the USAID PQM+ Program.

Pathway to Digitalize Regulatory IMS

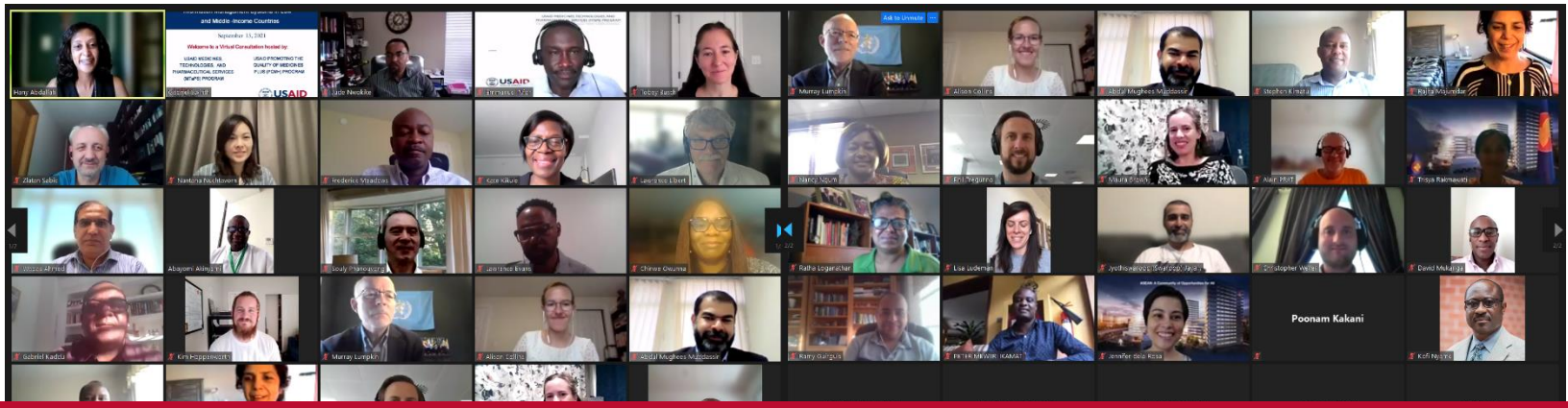
This document illustrates the steps and considerations that NMRAs should take when digitalizing regulatory IMS. The citation is below:

USAID MTaPS and USAID PQM+. A Pathway to Digitalize Regulatory Information Management Systems. Submitted to the US Agency for International Development by the USAID MTaPS Program.

Promoting the Quality of Medicines Plus (PQM+)

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

Improved Access. Improved Services. Better Health Outcomes.



Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

Report of the 1st Consultative Meeting

Held 15 September 2021

USAID FROM THE AMERICAN PEOPLE

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About the USAID MTaPS Program

Funded by the US Agency for International Development (USAID) and implemented by a team led by Management Sciences for Health (MSH), the purpose of the five-year Medicines Technologies and Pharmaceutical Services (MTaPS) program (2018–2023) is to provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats, as well as expanding essential health coverage. The goal of the MTaPS Program is to help low- and middle-income countries (LMICs) strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality assured, and affordable essential medicines, vaccines, and other health technologies and pharmaceutical services.

About the USAID PQM+ Program

The Promoting the Quality of Medicines Plus (PQM+) program is a USAID funded cooperative agreement with the U.S. Pharmacopeial Convention (USP) with a goal to sustainably strengthen medical product quality assurance (QA) systems by providing technical assistance to manufacturers of priority health products and build in-country capacity of Medicines Regulatory Authorities to improve product registration, inspection, and post-marketing surveillance for product quality. PQM+ support also includes accreditation of national drug quality control laboratories per ISO/IEC 17025 and/or WHO pre-qualification standards in low-and middle-income countries. PQM+ uses a system strengthening approach to program implementation to enhance sustainability.[6] The program considers the entire system when designing and delivering technical assistance, focusing on the interaction among all health systems functions[7] as they relate to medical product quality assurance.

To implement PQM+, USP joined forces with a diversified consortium of four core partners, six field-led extension partners, and eight technical resource partners[8] whose extensive technical expertise can be drawn on to achieve desired results.

[6] Chee G, Pielemeier N, Lion A, Connor C. Why differentiating between health system support and health system strengthening is needed. Int J Health Plann Mgmt. 2013; 28: 85-94. DOI: 10.1002/hpm.2122.
[7] governance, human resources, service delivery, information systems, financing https://www.usaid.gov/global-health/health-systems-innovation/health-systems/strengthening-pharmaceutical-systems
[8] https://www.usp.org/sites/default/files/usp/document/our-impact/pqm/pqm-plus-overview-brochure.pdf

ACKNOWLEDGEMENTS

The report authors would like to thank the meeting participants and presenters for their involvement in this activity. Their contributions are critical to identify and institutionalize a set of minimum common standards for regulatory information management systems to support efficient, transparent, and effective regulation of pharmaceutical products and services. Presentations were given by:

- Mr. Abayomi Akinyemi, chair of the IMS technical committee for AUDA-NEPAD
- Mr. Abdul Mughees Muddassir, Assistant Director, Quality Management System, Drug Regulatory Authority of Pakistan (DRAP
- Mr. Alireza Khadem, Scientist for Regulatory Systems Strengthening at WHO
- Dr. Murray Lumpkin M.D., M.Sc., Deputy Director – Integrated Development, Lead for Global Regulatory Systems Initiatives, at The Bill and Melinda Gates Foundation

Participants represented over 20 organizations, including:

- African Union Development Agency- New Partnership for Africa's Development
- ASEAN Secretariat
- Asia Development Bank
- Bill and Melinda Gates Foundation
- Centre for Innovation in Regulatory Science
- Drug Regulatory Authority of Pakistan
- Global Fund
- Independent Consultant
- Liberia Medicines & Health Products Regulatory Authority
- Mahidol University, Faculty of Pharmacy
- Medicines and Healthcare products Regulatory Agency
- National Agency for Food and Drug Administration and Control (Nigeria)
- Pharmacy and Poisons Board (Kenya)
- U3 SystemsWork International
- Université Félix Houphouët-Boigny
- USAID Global Health Supply Chain Program-Procurement and Supply Management project
- World Bank
- World Health Organization

A full list of participants is included in Annex 1B.

Contributors and Reviewers

Maura Soucy Brown, MTaPS Senior Technical Advisor and Tamara Hafner, MTaPS Principal Technical Advisor prepared this meeting report. The concept note for the meeting and the agenda were developed by Tamara Hafner, MTaPS Principal Technical Advisor. The meeting report and concept note were reviewed by members of the MTaPS and PQM+ teams as listed below.

USAID MTaPS program

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Timothy Nwogu, Technical Advisor

Hany Abdallah (MTaPS partner, U³ SystemsWork) facilitated this meeting and reviewed the draft of the meeting report. Gabriel Swinth provided planning and logistical support to the meeting and this activity, and Chris Weller, MTaPS Senior Project Associate, served as a rapporteur.

CONTENTS

EXECUTIVE SUMMARY

The US Agency for International Development (USAID) funded Medicines Technologies and Pharmaceutical Services (MTaPS) and USAID funded Promoting Quality of Medicines Plus (PQM+) programs convened a virtual consultative meeting on September 15, 2021. The meeting is the first in a series of consultations aimed at identifying and recommending a set of minimum common standards for regulatory information management systems (IMS) that will enable uniform data capture and standardize the data, design, and workflow of digitalized regulatory functions. The meeting brought together experts in regulatory system strengthening and information management systems from a variety of global, regional, and national organizations (Annex 1B) and the objectives were to:

- Clearly identify the critical gaps and challenges National Medicines Regulatory Authorities (NMRAs) and other stakeholders are facing with regards to regulatory IMS
- Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges
- Start building the use case for a set of minimum common standards for regulatory IMS

The discussions were structured around introductory presentations given at the beginning of each session (see Annex 1A: Meeting Agenda for details), and a set of session-specific prompts/questions.

During the meeting, more than 50 participants, representing over 20 organizations working to strengthen regulatory systems identified the following challenges to successful implementation of regulatory IMS:

- Lack of interoperability
- Lack of integration
- Varying requirements/standards for regulatory processes
- High cost
- Unsustained political will and commitment

The complete list of the challenges identified is included on page 96 in Annex 1D. There was general agreement that the challenges to regulatory IMS implementation are consistent across regions. There are variations between the regions in terms of system maturity (both in terms of Global Benchmarking Tool levels and information system infrastructure) and the varying degrees of reliance/convergence that the regions have identified as the target/endpoint for their harmonization initiatives. These should be carefully considered throughout the process of identifying a minimum set of standards for regulatory IMS, and particularly when elaborating the use case for adoption of the standards and creating a plan for institutionalization of the standards when developing, improving, or implementing regulatory IMS.

Meeting participants proposed that a minimum common set of standards to guide the development and implementation of regulatory IMS could address these challenges, and lead to improved:

- Effectiveness, efficiency, and performance
    - Regulatory activities can be performed faster, better and with less cost
- Transparency and timely access to information and regulatory decisions
    - Possibility for faster and wider sharing of information
- Consistency in regulatory activities/functions
- Good Governance Practices (GGP), reduced risk of corruption
- Collaboration, trust, and reliance among NMRAs

Finally, participants agreed on the following working definition of the term "standards" and the scope as applies to this activity:

Standards refer to the basis of measure, norms, and guidelines for regulatory IMS that would enable uniform data capture, a standardized data exchange platform and workflow of digitalized regulatory functions, leading to efficiencies and enhanced governance.

MTaPS and PQM+ proposed three categories of regulatory IMS standards:

- **Process or workflow standards**, which define standards for pharmaceutical procedures, processes, or workflows. Examples include Good Manufacturing Practices (GMP) and International Organization for Standardization standards (ISOs).
- **Pharmaceutical standard dictionaries and knowledge trees**, which are master or reference lists for terminology, nomenclature, and hierarchies. Examples include Systematized Nomenclature of Medicine Clinical Terms (SNOMED), Anatomical Therapeutic Chemical (ATC) classification, and International Nonproprietary Name (INN).
- **Data Exchange Standards**, pertain to information and communications technology (ICT) and management information system (MIS) functions and determine how data should be structured, defined, and formatted to facilitate sharing across computer systems. Examples include Structured Product Labelling (SPL), Portable Document Format (PDF) and Extensible Markup Language (XML) and platforms such as Fast Health Interoperability Resources (FHIR®) which define a common standard for health systems data exchange.

Next steps include agreeing on the proposed categories for the standards, developing selection criteria for a minimum set of common standards for regulatory IMS, reviewing existing standards to derive a set of minimum common standards, and finalizing the use case for the standards. These activities will be completed over the course of a six-month consultative process (Table 1).

BACKGROUND

National medicines regulatory authorities (NMRAs) in low- and middle-income countries (LMICs) often lack fully operational information management systems (IMS) to perform regulatory functions. These systems are often disparate and lack interoperability or are nonexistent, partially implemented, or nonfunctional. Many regulatory functions use paper-based systems, which results in inefficient workflows, backlogs and delays, lack of transparency, mismanagement, and vulnerability to corruption. Digitalization efforts aim to improve consistency, efficiency, and accountability in pharmaceutical regulatory service delivery. However, digitalization approaches vary across NMRAs, which often struggle with fully operationalizing their regulatory IMS, either desk-based or web-based systems, which limits the availability of real-time data and collaboration between NMRAs.[9]

Ongoing regional regulatory harmonization efforts in both Africa and Asia will rely not only on common documents and processes, but also shared regulatory IMS that are fully interoperable. This work increases the need for a set of minimum common standards for regulatory IMS to help clarify how regulatory IMS should capture and report information to promote system interoperability within national regulatory systems and support regulatory harmonization efforts.

It is not feasible for countries to apply all the relevant standards to each regulatory IMS, so it is necessary to identify a set of minimum common standards for regulatory IMS that NMRAs should prioritize to streamline their workflows and documentation of regulatory processes, ensure uniform data capture, and enable data exchange within and between NMRAs and other stakeholders. The USAID funded Medicines Technologies and Pharmaceutical Services (MTaPS) program and USAID funded Promoting Quality of Medicines Plus (PQM+) program will be engaging global stakeholders and subject matter experts to help identify and recommend a set of minimum common standards for regulatory IMS. The adoption of these common standards will streamline regulatory processes and help ensure that NMRAs make technical decisions with a degree of consistency and uniformity. Minimum common standards would also enhance the ability of NMRAs to collaborate and share information with one another, including use of reliance and recognition mechanisms.

OBJECTIVES OF THE CONSULTATIVE PROCESS

The primary objective of the consultative process is to derive and recommend a set of minimum common standards for regulatory IMS that will enable uniform data capture and standardize the data,

[9] BEWSYS. (2020). Final Report. Consultancy for Scoping of a Continental Regulatory Information Management System Solution and Information Sharing Platform for the Member States in the African Union. Submitted to the World Bank Group. Washington DC.

design, and workflow of digitalized regulatory functions. Specifically, MTaPS and PQM+ are convening a group of international stakeholders and subject matter experts to:

- Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS for the eight regulatory functions outlined in the WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems.[10]
- Use existing relevant IMS and regulatory standards to derive a recommended set of minimum common standards for regulatory IMS to address identified gaps and challenges. This includes developing the selection criteria for prioritizing which standards to include in the set of recommended standards.
- Develop the use case for the minimum common standards and help promote their adoption and use.

Expected results of the Consultative process

The consultation is expected to:

- Produce a set of minimum common standards for the eight GBT regulatory functions identified to support digitalization of regulatory IMS
- Sensitize global stakeholders in regulatory systems strengthening to the importance of adoption and institutionalization of minimum common standards for regulatory IMS

Process

MTaPS and PQM+ will facilitate a 6-month consultative process with adopters and end users, global and regional regulatory experts, and funders to develop the set of minimum common standards for regulatory IMS (Table 1).

There are three primary groups of stakeholders involved in the consultative process:

- **Adopters and end users.** NMRAs are the primary stakeholder group as they are the users of the systems. Software developers and programmers, and managers/ administrators of regulatory IMS develop and manage the systems for NMRAs.
- **Global and regional regulatory experts.** This group includes the regional regulatory harmonization initiatives, other global and regional experts and normative bodies working in regulatory systems strengthening (RSS), and subject matter experts who can provide technical inputs on the recommended minimum common standards and promote the adoption and use of the standards. Examples of stakeholders in this group include WHO, the Bill & Melinda Gates Foundation, South-East Asia Regulatory Network (SEARN), African Union Development Agency- New Partnership for Africa's Development (AUDA-NEPAD), Association of Southeast

[10] World Health Organization (2021). WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems.
The GBT Revision VI version 1 "comprises eight regulatory functions (Registration and Marketing Authorization, Vigilance, Market Surveillance and Control, Licensing Establishments, Regulatory Inspection, Laboratory Testing, Clinical Trials Oversight, and NRA Lot Release) under the overarching framework of the national regulatory system." https://www.who.int/tools/global-benchmarking-tools/VI

Asian Nations (ASEAN) and other regional economic communities, and pharmaceutical industry associations.

- **Funders.** This group supports RSS development and implementation and may overlap with the global regulatory experts' group. Examples include the World Bank and the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

This report documents the proceedings of the first consultative meeting, held virtually on 15 September 2021. Also included in this report are the next steps with timeline and intermediate results in the consultative process (Table 1).

Meeting Objectives

The objectives of the first consultative meeting were to:

- Clearly identify the gaps and challenges NMRAs and other stakeholders are facing with regards to regulatory IMS
- Discuss the scope of minimum common standards for regulatory IMS
- Discuss how a set of minimum common standards for regulatory IMS can address or mitigate the identified gaps and challenges and start building a use case for the standards

This meeting was structured around two sessions. The first session focused on clarifying the need for a minimum set of common standards for regulatory IMS. The presenters in this session provided context for regulatory information system implementation in Africa and Asia and identified the primary benefits of digitalization of regulatory functions globally. In the second session, meeting participants discussed the role of regulatory IMS standards, and provided feedback on the proposed definition of these standards for the purpose of this activity, as well as strategies for organizing these standards and opportunities to implement regulatory IMS standards to address identified challenges. The meeting agenda can be found in Annex 1A.

Each session began with a review of the session's objectives, outputs, and discussion questions, followed by structured presentations. Presentations were followed by facilitated discussions in plenary. The online collaboration tool PollEv was used throughout the meeting to collect and display responses from participants in real time. A list of participants can be found in Annex 1B. Hany Abdallah of MTaPS partner U^3 SystemsWork facilitated the meeting.

SUMMARY OF PROCEEDINGS

The following sections summarize the opening remarks, presentations, and ensuing discussions. All presentation slides are included in Annex 1C.

Welcome and Introductory Remarks

The meeting facilitator, Hany Abdallah introduced herself and formally welcomed all participants to the meeting. She gave a brief overview of the agenda and introduced the introductory speakers.

Kofi Aboagye-Nyame, Program Director, USAID MTaPS Program, MSH

Mr. Aboagye-Nyame welcomed attendees and expressed thanks on behalf of the MTaPS and PQM+ programs to all the contributors and participants. He highlighted the importance of the meeting objectives to the MTaPS program's work across Africa and Asia in regulatory systems strengthening. He stressed the need to clarify how regulatory IMS should capture and report information to support system interoperability within national regulatory systems and support regulatory harmonization efforts at regional, sub-regional, continental, and global levels.

Jude Nwokike, Vice President & Director, USAID PQM+ Program, USP

Mr. Nwokike again thanked the participants and stressed the importance of this consultative process in achieving the joint activity objectives to identify and support the adoption of a minimum set of standards for regulatory information systems. He stated that the pharmaceutical sector is quite data-driven, from monographs to dossiers to labels and formularies, and data systems are not currently advanced enough to adequately carry out and monitor these processes. He emphasized that there is tremendous value in leveraging regulatory information management systems to enable regulatory agencies to transform, unify, and drive exchange of standardized data to ensure safety. We all need to contribute towards ensuring that new information systems are deployed that are integrated and facilitate efficiency and transparency of regulatory operations.

An ideal regulatory information management system should be:

- Integrated
- Cover all regulatory functions
- Reflect Good Regulatory Practices (GRP)
- Based on data standards
- Connect to computerized instruments and a network of database systems

These systems should facilitate electronic transmission of regulatory data and enable the utilization of big data for regulatory decision making. This is a goal for the global community, particularly in low- and middle-income countries. Foundational to this goal is establishing standardized vocabularies and terminologies. These are key enablers for meaningful discussion and form the bedrock of managing pharmaceutical products throughout the life cycle.

Mr. Nwokike stressed the importance of the identification and adoption of a minimum set of relevant standards to guide the development of regulatory information systems, with tremendous potential benefits to regulatory agencies, manufacturers, and consumers of pharmaceutical products and services.

Tobey Busch, Senior Pharmaceutical Management Advisor, USAID Office of Health Systems

In her introductory remarks, Ms. Busch welcomed attendees on behalf of the USAID Office of Health Systems and stressed the importance of this first meeting in identifying a minimum set of regulatory information management system standards and developing a use case for the standards. She emphasized the importance of this work in support of USAID's Vision for Health System Strengthening 2030.[11] The Agency's pharmaceutical system strengthening approach laid out in this Vision focuses on advancing

[11] USAID Vision for Health System Strengthening 2030, Washington DC, 2021. https://www.usaid.gov/sites/default/files/documents/USAID_OHS_VISION_Report_FINAL_single_5082.pdf

country ownership and sustainability of health systems that are transparent and accountable, and use resources optimally to allow for effective, evidence-based decision making.

A critical piece of this work includes helping NMRAs establish stable and functional regulatory systems. Furthermore, ongoing work in regional regulatory harmonization efforts in both Africa and Asia will rely not only on common documents and processes, but also shared regulatory information management systems that are fully interoperable. Ms. Busch reminded participants that their work throughout the consultative process will assist in this effort by creating a global good to help guide NMRAs in the development and strengthening of their regulatory information management systems.

She concluded her remarks by emphasizing that the adoption of these common standards will help streamline regulatory processes and enhance the ability of NMRAs to collaborate and share information with one another, including use of reliance and recognition mechanisms.

Emmanuel Nfor, Technical Director, USAID MTaPS Program, MSH

Mr. Nfor set the stage for the first session by providing some additional context for digitalization of regulatory processes. He stated that low- and middle-income countries in Africa, Asia, and Latin America bear a significant proportion of the global burden of disease. NMRAs promote access to quality-assured, safe, and efficacious pharmaceutical products and combat substandard/falsified medical products to improve health outcomes. Inefficient regulatory workflows, lack of transparency, mismanagement, and vulnerability to corruption undermine the ability of NMRAs in LMICs to effectively perform their designated regulatory functions. Digitalization of regulatory processes is intended to improve consistency, efficiency, and accountability in regulatory services.

He concluded by presenting the activity objectives and the meeting objectives for the first consultative meeting and thanking participants for their inputs.

Session 1: Clarifying the need

Objective:

Identify the critical gaps and challenges NMRAs and other stakeholders are facing regarding implementation of regulatory IMS

Output:

Critical gaps and challenges regarding regulatory IMS clearly identified

Discussion Questions:

- What is the current landscape of regulatory IMS? What are the most critical challenges?
- How do these challenges vary across regions?
- How do these challenges vary, if at all, across regulatory functions?

Presentation 1: African Region—current landscape of regulatory IMS and critical challenges faced by NMRAs

The session began with a presentation by Mr. Abayomi Akinyemi, chair of the IMS technical committee for AUDA-NEPAD, reviewing the current progress of digitalization of regulatory functions and challenges faced in the African continent.

The African Medicine Regulatory Harmonization (AMRH) initiative provides a framework for regional economic bodies to implement regulatory harmonization and unify their regulatory information management systems. Disparate and partially implemented regulatory IMS poses a threat to the AMRH initiative, as NMRAs are unable to produce the right information for sharing and exchange at the correct time. The various regional bodies each have their own guidelines for harmonization and are in varying stages of implementation. The current situation by region is summarized in Figure 1.

A recent scoping study conducted on behalf of AUDA-NEPAD and the World Bank found that only 26 NMRAs (47%) of the 55 AU member states have regulatory IMS and only 24 NMRAs (44%) use them in their daily operations.[4] Further detail from the scoping study is available in the presentation slides, beginning on page 56 of this report in Annex 1C.

Economic Community of West African States (ECOWAS)	East African Community (EAC)	Intergovernmental Authority on Development (IGAD)	Southern African Development Community (SADC)
Regional Information sharing Portal and Medicines Regulatory Harmonization (MRH) Website to be launched by October 2021 Harmonised Guidelines for Marketing Authourization Harmonized Guidelines for Good Manufacturing Practices (GMP) Common Technical Document (CTD) guidelines adopted by 15 countries Carried out Joint Review and Inspection Product Lifecycle Management (PLM) project just commenced (eSubmission of regulatory data and document in CTD format) GBT Assessment of all Regulatory Functions No documented Common standard for regulatory processes	Regional Information sharing Portal and MRH Website fully functional Harmonised Guidelines for Marketing Authourization Harmonized Guidelines for GMP CTD guidelines adopted by 15 countries Carried out Joint Review and Inspection PLM partially implemented (Submission of regulatory data and document in CTD format) are semi-automated No documented Common standard for regulatory processes	Regional MRH Website fully functional Harmonised Guidelines for Marketing Authorization Harmonized Guidelines for GMP CTD guidelines adopted by 15 countries Carried out Joint Review and Inspection PLM partially implemented (Submission of regulatory data and document in CTD format) are semi-automated No documented Common standard for regulatory processes	Regional MRH Website to be functional Harmonised Guidelines for Marketing Authourization Harmonized Guidelines for GMP CTD guidelines adopted by15 countries Carried out Joint Review and Inspection PLM project just commenced (eSubmission of regulatory data and document in CTD format) No documented Common standard for regulatory processes

Figure 3. Current Regulatory IMS Situation in the Regional Economic Communities

Mr. Akinyemi listed the following challenges in the harmonization of regulatory IMS, with particular emphasis placed on the bolded items:

- Varying requirements for regulatory processes
- Increasing complexity of regulations and product portfolio
- Lack of IT experts to drive and sustain regulatory IMS
- Financial barrier/lack of support from Government and other stakeholders
- Practical and technological barrier
- Improper alignment of regulatory IMS with Product Lifecycle Management (PLM)
- Siloed mentality
- Legal and institutional barriers
- Political and cultural barriers
- **Lack of leadership commitment/support**
- **Unfriendly governance structure**
- **Lack of transparency across systems and departments**
- **Ineffective and weak coordination system**
- **Resistance to change**

He further identified support that would be needed from development partners to facilitate regulatory harmonization in Africa. This includes:

- Capacity building for NMRAs on GRP
- Support NMRAs, Regional and Continental IMS in developing Policy, Process and Data Harmonization Standards and Quality for Regulatory Convergence
- Support in the process of implementing the common standards for regulatory IMS across the NMRAs, Regions and Continent
- Support in implementing Product Lifecycle Management (PLM) in alignment with regulatory IMS
- Support the NMRAs, Regions and Continent to implement e-Submission of regulatory documents using common standard in a predefined format (eCTD)
- Support AUDA-NEPAD IMS technical committee to implement Zanzibar model of Integrated Information Sharing Platform

He concluded his remarks by affirming that with common standards, policies and processes in place, a good regulatory information management system could be developed to support and provide an effective and efficient regulatory system across the regulatory functions as objectively defined in the WHO GBT requirements for countries with no IMS in place and, for regional and continental regulatory IMS. This will support seamless information sharing and information exchange among the NMRAs, regional bodies and continental body. With adequate support from the management of the continental body (AUDA-NEPAD), regional bodies (Economic Community of West African States (ECOWAS), East African Community (EAC), Intergovernmental Authority on Development (IGAD), Southern African Development Community (SADC), Common Market for Eastern and Southern Africa (COMESA)), NMRAs (55 Member States), and development partners, common set of standards could be developed with an articulated clear use case for the regulatory IMS in Africa.

Presentation II: Asia Region—current landscape of regulatory IMS and critical challenges faced by NMRAs

The second presentation was given by Mr. Abdul Mughees Muddassir, Assistant Director, Quality Management System, Drug Regulatory Authority of Pakistan (DRAP) and articulated the implementation of regulatory IMS in Pakistan as a case study from Asia. He identified regulatory IMS as a proposed solution to a multitude of challenges facing NMRAs in the region (Figure 2).

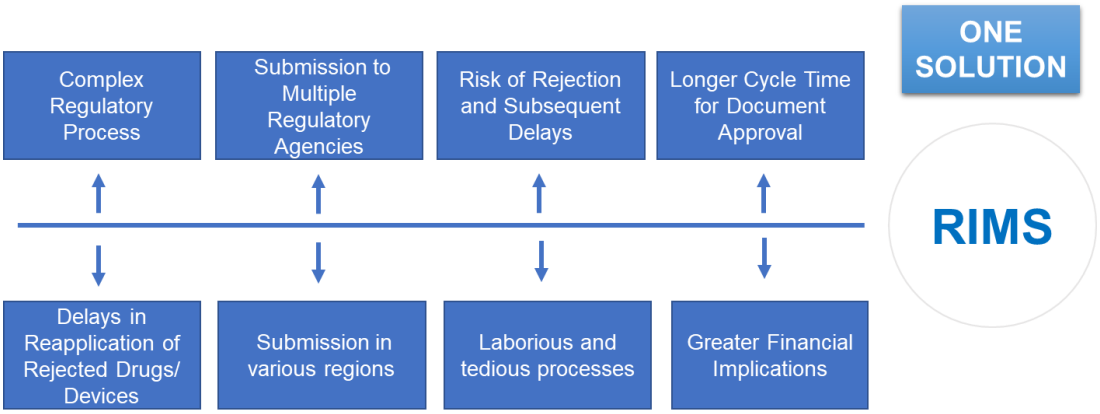

Figure 4. Challenges Addressed by Regulatory IMS

Mr. Muddassir presented several outcomes of successful regulatory IMS implementation that can serve to address many of the identified challenges (Figure 3).

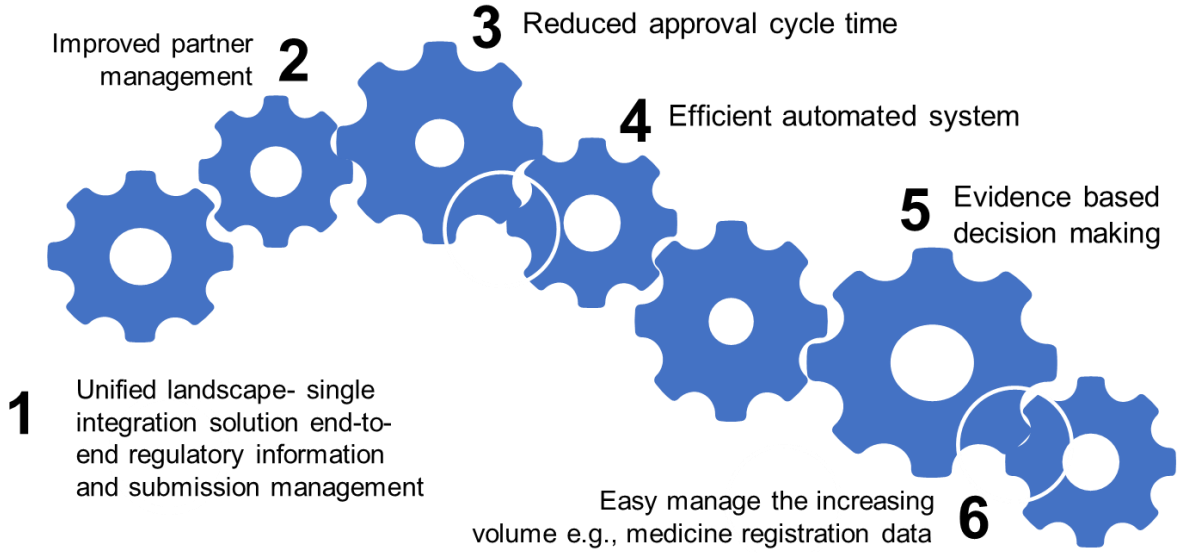

Figure 5. IMS Outcomes

Additional information about regulatory processes supported by regulatory IMS and the implementation process in Pakistan is available in his presentation, beginning on page 65 in Annex 1C. He articulated several challenges to implement regulatory IMS in Pakistan, including developing standard determination, trainings, and relevant technical human resource capacity; digitization of records, integration, and

infrastructure; change management and resistance; and variations in regulations and regulated products. He concluded his remarks by emphasizing the positive outcomes from regulatory IMS implementation in Pakistan, namely improved operations, evidence-based decision making, openness and ease of access, and harmonization, leading to ensured quality, safety, and efficacy of medical products.

Facilitated Discussion I

The first discussion was structured around three questions:

- What is the current landscape of regulatory IMS? What are the most critical challenges?
- How do these challenges vary across regions?
- How do these challenges vary, if at all, across regulatory functions?

Participants identified the most critical challenges using PollEv, including lack of interoperability, lack of integration, varying requirements/standards for regulatory processes, cost, and political will. The complete list of challenges is included in Annex 1D. There was general agreement that the challenges to regulatory IMS implementation are consistent across regions. There are variations between the regions in terms of system maturity (both in terms of GBT levels and information system infrastructure) and the varying degrees of reliance/convergence that the regions have identified as the endpoint for their harmonization initiatives. These should be carefully considered over the course of this activity, and particularly when developing the institutionalization plan. A broader perspective from the Asia region would be helpful to articulate their regional harmonization strategy more fully, particularly where regulatory IMS are concerned.

Participants noted that divergence across regulatory functions will increase with the complexity of the regulatory process concerned. Data-intensive processes and complex, multi-step and multi-stakeholder processes result in increased customization to national IMS and will make standardization more difficult without increased harmonization of regulatory processes. Participants stated that it would be helpful to use a regulatory process, e.g., drug recall to assess existing systems and standards and to identify challenges and gaps and what is needed to improve systems to support successful implementation in the selected use case.

Presentation III: The primary benefits of digitalization of regulatory functions

Mr. Alireza Khadem, Scientist for Regulatory Systems Strengthening at WHO gave the final presentation of the session, which articulated the primary benefits of digitalization of regulatory functions. Mr. Khadem opened his presentation noting that there is a large gap in terms of the assessment of digitalization of regulatory functions in the Global Benchmarking tool. Out of a total of 268 sub-indicators in the GBT, he identified eight that are relevant to digitalization. The complete list of relevant sub-indicators and their implementation status is included in the presentation slides included in Annex 1C.

Benchmarking and self-benchmarking in 84 countries from 2016-2020 found that 64% of countries have publicly available and updated information on laws, regulations, guidelines, and procedures (Figure 4) and 33% use computerized systems to process information, manage records, and analyze data (Figure 5).

Mr. Khadem noted that the most important benefits of digitalization include:

- Improved effectiveness, **efficiency**, and performance
    - Regulatory activities can be performed faster, better and with less cost
- Improved **transparency** and timely access to information and regulatory decisions
    - Possibility for faster and wider sharing of information
- Improved **consistency** in regulatory activities/functions
- Improved Good Governance Practices (GGP), reduced risk of corruption
- Improved collaboration, trust, and reliance among NMRAs

RS09.02: The information on laws, regulations guidelines and procedures is publicly available and is kept duly updated.

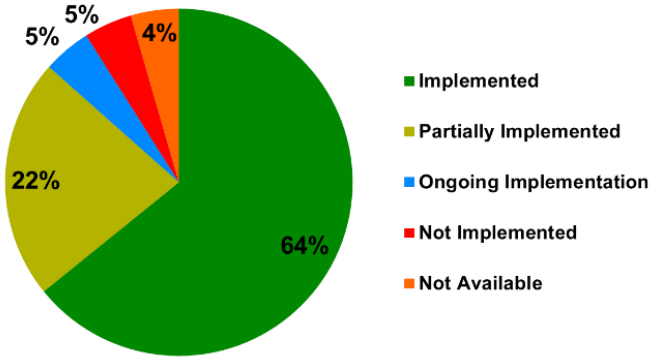

Figure 6. GBT Indicator RS09.02

RS09.08: The NRA uses computerized systems to process information, manage records, and analyze data.

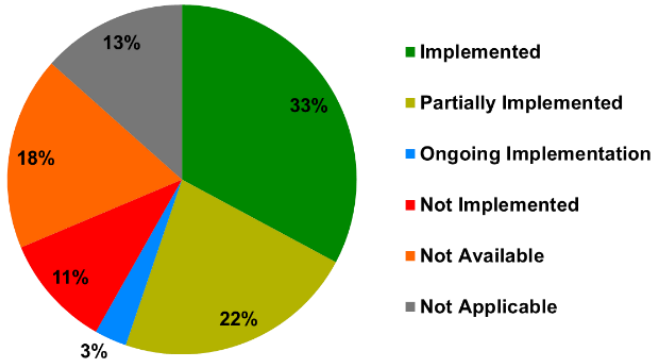

Figure 7. GBT Indicator RS09.08

He concluded his remarks by emphasizing that digitalization is a valuable tool to improve performance of a regulatory system and will result in improved implementation of Good Regulatory Practices (GRP) and Good Reliance Practices (GRelP) and facilitate convergence, harmonization, work-sharing, and reliance among NMRAs. However, NMRAs should have clear policy in this regard and include digitalization of their regulatory functions in their strategic plans. In addition, digitalization needs proper planning, resources, and training as well as strong management commitment.

Session II: The role of regulatory IMS standards

Objective:

Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges

Output:

The scope of the standards identified for addressing the most critical gaps and challenges associated with regulatory IMS

Discussion Questions:

- Which of the identified challenges should we try to solve given the diversity of identified needs with respect to regulatory IMS?
- What should be the scope/definition of "minimum common standards" for regulatory IMS? How will these standards address or mitigate the identified challenges?

Presentation I: "Minimum Common Standards"—Proposed Definition and Scope

The first presentation in Session II was given by Kate Kikule Principal Technical Advisor, Regulatory Systems Strengthening, USAID MTaPS. She opened by presenting the definition of the term "standards" that MTaPS and PQM+ propose for this activity (Figure 6).

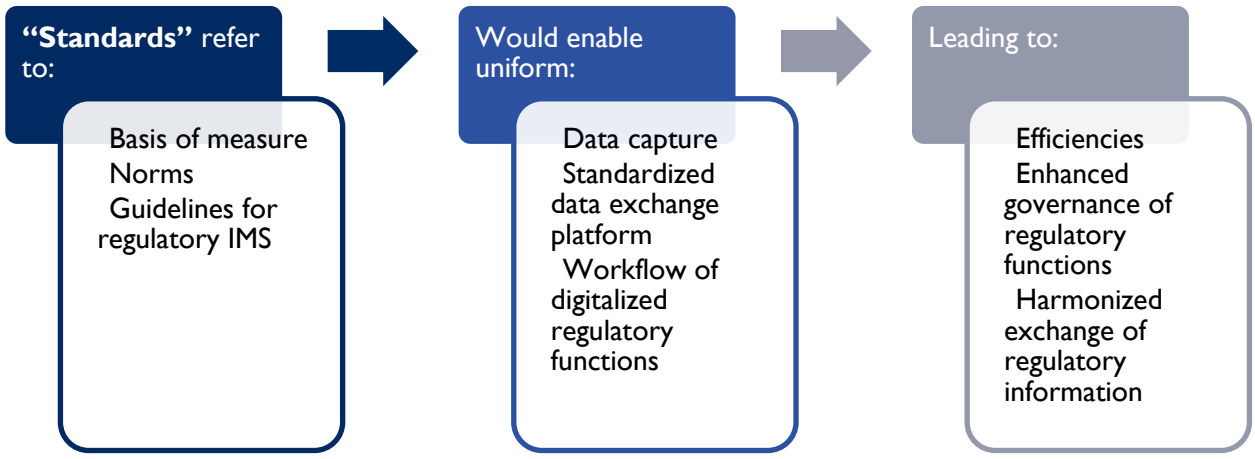

Figure 8. Definition of "Standards"

MTaPS and PQM+ have identified three primary categories of relevant standards:

- **Process or workflow standards**, which define standards for pharmaceutical procedures, processes, or workflows. Examples include Good Manufacturing Practices (GMP) and International Organization for Standardization standards (ISOs).
- **Pharmaceutical standard dictionaries and knowledge trees**, which are master or reference lists for terminology, nomenclature, and hierarchies. Examples include Systematized Nomenclature of Medicine Clinical Terms (SNOMED), Anatomical Therapeutic Chemical (ATC), and International Nonproprietary Name (INN).

- **Data Exchange Standards**,[12,13] pertain to information and communications technology (ICT) and management information system (MIS) functions and determine how data should be structured, defined, and formatted to facilitate sharing across computer systems. Examples include Structured Product Labelling (SPL), Portable Document Format (PDF) and Extensible Markup Language (XML) and platforms such as Fast Health Interoperability

Given this definition and these proposed categories, MTaPS and PQM+ proposed that standards as applicable to the eight regulatory functions as defined in the WHO GBT[5] be considered for inclusion in the minimum set of standards for regulatory IMS. Low-level data elements such as date, location, time, and support functions to the regulatory system, such as finance and human resources should be excluded from consideration.

Presentation II: Opportunities to leverage existing global RSS initiatives to address challenges and need to standardize regulatory IMS

The final presentation of the day was given by Dr. Murray Lumpkin M.D., M.Sc., Deputy Director – Integrated Development, Lead for Global Regulatory Systems Initiatives, at The Bill and Melinda Gates Foundation. Dr. Lumpkin began by sharing the Gates Foundation's experiences with IMS initiatives for NMRAs. He reflected that regulatory IMS efforts tend to be time and financially resource intensive, result in little progress or impact, and are frustrating. Coming up with a set of minimum standards aligned with the WHO Global Benchmarking Tool modules would be very helpful in focusing people and defining individual efforts to develop IT systems.

Dr. Lumpkin emphasized that IMS is a tool to support regulatory functions and is not the driver of those functions. As such, the business case and end users, rather than the information system technical experts, should drive system design and development. Regulatory IMS need to address internal operational functionalities, including workflow management (over the life cycle of the product, including digitalization of submissions and reports), performance metric tracking and reporting, financial management, and legacy data accessibility. Systems should also address external connectivity including maintaining confidentiality with other NMRAs and transparency with outside stakeholders. The use-case for systems should be clearly defined to support regulatory functions and processes.

Later in the presentation, Dr. Lumpkin noted that regulators in LMICs aspire to have functional IMS that facilitate their regulatory work and facilitate collaboration with peer regulators and communication with the regulated community. Design and implementation challenges, including potentially prohibitive initial and ongoing costs, as well as the need for alignment with Ministry and other systems pose major obstacles to the development and execution of custom or commercially available regulatory IMS.

Without a common set of minimum core requirements and standards for regulatory IMS, countries, regions, and their platform developers risk creating platforms that do not meet core and minimal expectations of regulators and the regulated community. Multiple iterations of a platform may be

[12] Defined by the US Environmental Protection Agency (n.d.) as guiding the "representation, format, definition, structuring, tagging, transmission, manipulation, use, and management of data." https://www.epa.gov/data-standards/learn-about-data-standards

[13] According to the US Federal Drug Authority, a data standard is a "set of rules on how a particular type of data should be structured, defined, formatted, or exchanged between computer systems." https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/cder-data-standards-program

required to arrive at a meaningful product, at high cost in terms of both time and financial resources. Making available open-source platforms that meet the to-be-agreed-upon IMS standards will be key to enabling these resource-limited agencies to enhance their operational capabilities.

Dr. Lumpkin concluded his remarks by noting that we do not need to start from scratch – many IMS solutions exist, and many agencies and regions have made efforts to develop their own bespoke systems. Hopefully, a set of minimum standards will allow development of commercial, off the shelf solutions and provide a framework for updating existing solutions to meet these requirements as needed.

Facilitated Discussion II

Participants began the discussion by reviewing the proposed definition of "standards" – they were in agreement with the definition proposed: "Standards, as used in this activity, refer to the basis of measure, norms, and guidelines for regulatory IMS that would enable uniform data capture, a standardized data exchange platform and workflow of digitalized regulatory functions, leading to efficiencies and enhanced governance."

Regarding the proposed categories for structuring the set of minimum common standards (Process or workflow standards, Pharmaceutical standard dictionaries and knowledge trees, and Data Exchange Standards) and the inclusion and exclusion criteria, participants suggested the following modifications:

- Data exchange standards should be broadened to include data standards, e.g., GS1 prescribed master data standards for pharmaceutical products
- Information security, cybersecurity, and business continuity standards should be considered for inclusion (alongside ISO 9001)
- Product and location identification standards should be considered for inclusion
- Traceability standards should be considered for inclusion

Participants also proposed that the activity should consider developing a common core business use case for the regulatory processes being digitalized as a starting point for the selection of a minimum common set of standards.

Finally, the participants used PollEv to identify how a minimum set of common standards can address or mitigate the challenges identified in Session I (Annex 1D). The most mentioned themes included:

1. Set common "language"/system designs/system architecture
2. Reduced cost of regulatory IMS system implementation
3. Improved regulatory IMS design capabilities
4. Increased transparency/enhanced information sharing
5. Improved efficiency

CLOSE OUT & NEXT STEPS

To conclude the meeting, an overview of the consultative process and next steps for the activity was provided on behalf of the MTaPS and PQM+ programs by Dr. Souly Phanouvong. These are summarized in Table 1, below. Lawrence Evans, the Technical Director of the PQM+ program provided closing remarks.

Table 1. Outline of the Consultative Process

Time (Approx.)	Activity	Task/Objective	Expected results
Sept 15	Consultative meeting I	Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS Discuss the scope of minimum common standards for regulatory IMS Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges and start building the use case	Critical gaps and challenges with regulatory IMS identified The scope of the standards for addressing the gaps and challenges defined
Oct 27	Consultative meeting II	Develop selection criteria for minimum common standards Review collated existing standards Finalize the use case	Preliminary core set of minimum common standards for regulatory IMS identified Advocacy brief developed
Oct 27 - Dec 1	External review I	Review of collated existing standards and identify which standards should be included in the minimum common standard set Engage select NMRA representatives to gather additional input	
Nov 1 - Jan 3	Internal analysis and synthesis of standards	Draft advocacy brief Consolidate and synthesize the inputs from the experts Draft minimum common standards for regulatory IMS	
Jan 3 - 27	External review II	Final expert review of the proposed minimum common standards	Finalized set of minimum common standards for regulatory IMS Inputs gathered for guidance on digitalization pathway
Jan 27 - Feb 24	Internal revisions and finalization	Finalize minimum common standards based on feedback Internal reviews and copyediting	
Mar 3	Consultative meeting III	Present minimum common standards Discuss guidance on pathway for countries to adopt minimum common standards to support the digitalization of regulatory functions	

Closing Remarks: Lawrence Evans – Technical Director, PQM+

Dr. Evans began by thanking the presenters, participants, USAID representatives, and facilitator. He proceeded to affirm that the ideal situation for regulatory systems would include a seamless, uninhibited, constant flow of information between and within NMRAs, but it will take some time to get there. This group has the opportunity to establish the pathway to that goal, through the development of these minimum standards that are appropriately tailored to NMRAs for the development of their regulatory IMS and their capacity to implement them.

ANNEX 1A: MEETING AGENDA

8:00 - 8:20	**Introductions**
8:00 – 8:05	***Meeting logistics*** Hany Abdallah
8:05 – 8:15	***Welcome remarks*** Kofi Aboagye-Nyame, Program Director, USAID MTaPS Program Jude Nwokike, Vice President & Director, Promoting the Quality of Medicines Plus (PQM+) Program, USP Tobey Busch, Senior Pharmaceutical Management Advisor, USAID Office of Health Systems
8:15 – 8:20	***Overview of activity and meeting objectives*** Emmanuel Nfor, Technical Director, USAID MTaPS
8:20 - 9:25	**Session I: Clarifying the need** *Objective:* Identify the critical gaps and challenges NMRAs and other stakeholders are facing regarding implementation of regulatory IMS
	Output: Critical gaps and challenges regarding regulatory IMS clearly identified
	Discussion Questions: What is the current landscape of regulatory IMS? What are the most critical challenges? How do these challenges vary across regions? How do these challenges vary, if at all, across regulatory functions?
8:20 - 8:30	Presentation I: African Region—current landscape of regulatory IMS and critical challenges faced by NMRAs Abayomi Akinyemi, AUDA-NEPAD Information Management Systems Technical Working Group
8:30 - 8:40	Presentation II: Asia Region—current landscape of regulatory IMS and critical challenges faced by NMRAs Abdul Mughees Muddassir, Assistant Director, Quality Management System, Drug Regulatory Authority of Pakistan (DRAP)
8:40 - 9:10	Facilitated discussion
9:10 - 9:20	Presentation III: The primary benefits of digitalization of regulatory functions Alireza Khadem, Scientist, Regulatory Systems Strengthening, WHO
9:20 - 9:25	Session I recap Stephen Kimatu – Consultant, MTaPS
9:25 - 9:40	**Break**

9:40 - 10:40	**Session II: The role of regulatory IMS standards** *Objective:* Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges
	Output: The scope of the standards identified for addressing the most critical gaps and challenges associated with regulatory IMS
	Discussion Questions: Which of the identified challenges should we try to solve given the diversity of identified needs with respect to regulatory IMS? What should be the scope/definition of *"minimum common standards"* for regulatory IMS? How will these standards address or mitigate the identified challenges?
9:40 - 9:50	Presentation I: "Minimum Common Standards"—Proposed Definition and Scope Kate Kikule, Principal Technical Advisor, RSS, USAID MTaPS
9:50 - 10:00	Presentation II: Opportunities to leverage existing global RSS initiatives to address challenges and need to standardize regulatory IMS Murray Lumpkin, Deputy Director – Integrated Development, Lead for Global Regulatory Systems Initiatives, The Bill and Melinda Gates Foundation
10:00 - 10:35	Facilitated discussion
10:35 - 10:40	Session II recap Chinwe U. Owunna – Senior Manager, PQM+
10:40 - 11:00	**Close out** Next steps Souly Phanouvong – Senior Technical Advisor, RSS, PQM+
	Closing remarks Lawrence Evans – Technical Director, PQM+

ANNEX 1B: LIST OF MEETING PARTICIPANTS

Name	Affiliation
Ben Coghlan	ADB
Jennifer Dela Rosa	ASEAN Secretariat
Mia Ulfa	ASEAN Secretariat
Trisya Rakmawati	ASEAN Secretariat
Nancy Ngum	AUDA-NEPAD
Abayomi Akinyemi	AUDA-NEPAD and NAFDAC
David Mukanga	Bill and Melinda Gates Foundation
Murray Lumpkin	Bill and Melinda Gates Foundation
Anna Somuyiwa	CIRS
Lawrence Liberti	CIRS
Abdul Mughees Muddassir	Drug Regulatory Authority of Pakistan
Alain Prat	Global Fund
Michael Ward	Independent Consultant
Juwe D. Kercula	Liberia Medicines & Health Products Regulatory Authority
Nantana Nuchtavorn	Mahidol University, Faculty of Pharmacy
Abu Zahid	Management Sciences for Health
Christopher Weller	Management Sciences for Health
Comfort Ogar	Management Sciences for Health
Deane Putzier	Management Sciences for Health
Emmanuel Nfor	Management Sciences for Health
Gabriel Swinth	Management Sciences for Health
Kate Kikule	Management Sciences for Health
Kim Hoppenworth	Management Sciences for Health
Kofi Nyame	Management Sciences for Health
Maura Soucy Brown	Management Sciences for Health
Mwesigye John Patrick	Management Sciences for Health
Nicole Barcikowski	Management Sciences for Health
Rajita Majumdar	Management Sciences for Health
Ratha Loganathan	Management Sciences for Health
Refiloe Mabejane	Management Sciences for Health
Rodel Sibulo	Management Sciences for Health
Stephen Kimatu	Management Sciences for Health
Phil Tregunno	Medicines and Healthcare products Regulatory Agency
Olufemi Balogun	National Agency for Food and Drug Administration and Control (Nigeria)
Dr. Peter Mbwiiri Ikamati	Pharmacy and Poisons Board (Kenya) and AUDA-NEPAD
Hany Abdallah	SystemsWork International
Zlatan Sabic	The World Bank

Name	Affiliation
Agbaya Oga	Université Félix Houphouët-Boigny
Alexis Leonard	USAID
Alison Collins	USAID
Daniella Mensah Abrampah	USAID
Lisa Ludeman	USAID
Poorna Ramasubramanian	USAID
Ramy Guirguis	USAID
Tobey Busch	USAID
Jyothiswaroop (Swaroop) Jayaprakash	USAID GHSC-PSM (IBM)
Frederick Meadows	USP
Poonam Kakani	USP
Chinwe Owunna	USP, PQM+
Gabriel Kaddu	USP, PQM+
Jude Nwokike	USP, PQM+
Lawrence Evans	USP, PQM+
Souly Phanouvong	USP, PQM+
Steven Emrick	USP, PQM+
Waqas Ahmed	USP, PQM+
Alireza Khadem Broojerdi	WHO

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

Online Collaboration - Please log on to:

www.pollev.com/RIMS

- ✓ Use phone or computer browser
- ✓ Enter a screen name
- ✓ Respond to poll

Please Note: This meeting is being recorded.

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

USAID PROMOTING THE QUALITY OF MEDICINES PLUS (PQM+) PROGRAM

USAID MTaPS and PQM+ Programs

September 15, 2021

USAID FROM THE AMERICAN PEOPLE

Minimum Common Standards for Regulatory Information Management Systems (IMS) in Low- and Middle-Income Countries

September 15, 2021

Welcome to a Virtual Consultation hosted by:

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

USAID PROMOTING THE QUALITY OF MEDICINES PLUS (PQM+) PROGRAM

Facilitator

Hany Abdallah
U³ SystemsWork (MTaPS Partner)

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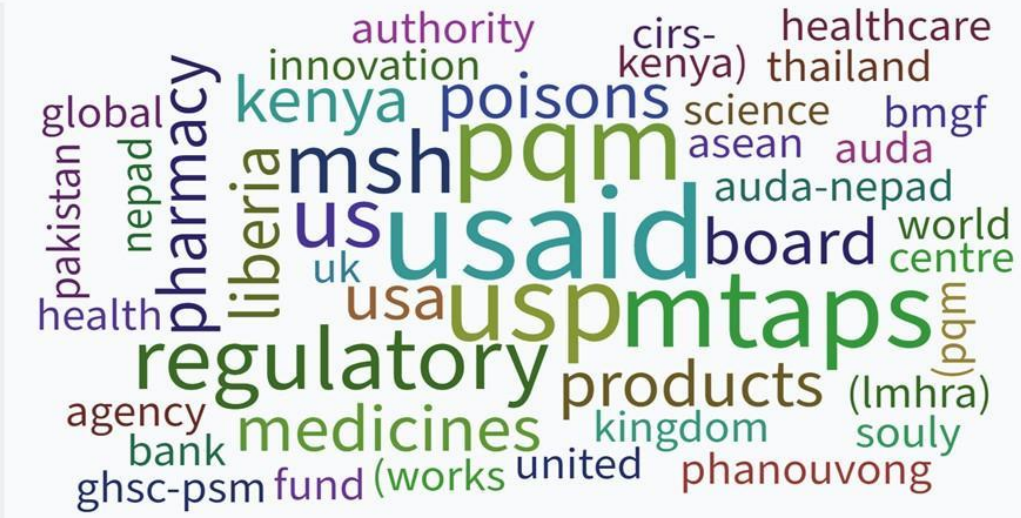
In 1 Word - State the Country or Organization You Represent:



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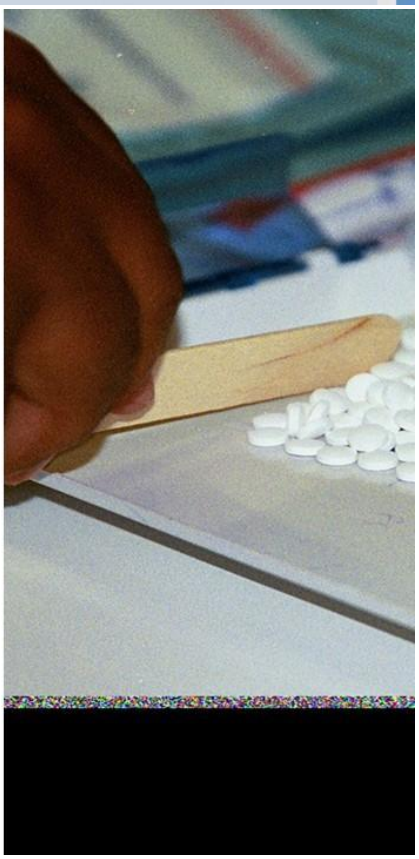
Agenda Overview

8:00 – 8:20	Introductions
8:20 – 9:25	Session I: Clarifying the need
9:25 – 9:40	Break
9:40 – 10:40	Session II: The role of regulatory IMS standards
10:40 – 11:00	Close out



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Minimum Common Standards for Regulatory Information Management Systems (IMS) in Low- and Middle-Income Countries

8:00 – 8:20 Introductions

8:00 – 8:05	**Meeting Logistics**	**Hany Abdallah** U³ SystemsWork (MTaPS Partner)
8:05 – 8:15	**Welcome Remarks**	**Kofi Aboagye-Nyame** Program Director, USAID MTaPS Program
		Jude Nwokike Vice President & Director, Promoting the Quality of Medicines Plus (PQM+) Program, USP
		Tobey Busch Senior Pharmaceutical Management Advisor, USAID Office of Health Systems
8:15 – 8:20	**Overview of activity and meeting objectives**	**Emmanuel Nfor** Technical Director, USAID MTaPS

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Welcome Remarks

Kofi Aboagye-Nyame
Program Director, USAID MTaPS Program

Jude Nwokike
Vice President & Director,
Promoting the Quality of Medicines Plus (PQM+) Program, USP

Tobey Busch
Senior Pharmaceutical Management Advisor, USAID Office of Health Systems

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Remarks from Kofi Aboagye-Nyame
Program Director, USAID MTaPS Program

Overview

of Activity and Meeting Objectives

Emmanuel Nfor
Technical Director, USAID MTaPS

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Context

- LMICs of Africa, Asia, and Latin America bear a significant proportion of the global burden of disease
- NMRAs promote access to quality-assured, safe, and efficacious medicines and combat substandard/falsified medical products but capacity in LMICs is insufficient
- Inefficient regulatory workflows, lack of transparency, mismanagement, and vulnerability to corruption
- NMRAs have initiated digitalization to improve consistency, efficiency, and accountability in regulatory services

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Activity Objectives Today

Main Objective:

- Develop and recommend a set of minimum common standards for regulatory IMS

Sub Objectives:

- Identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS
- Derive a recommended set of minimum common standards for regulatory IMS
- Develop the use case for the minimum common standards
- Promote their adoption and use in digitalization of regulatory IMS

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Meeting Objectives

Identify critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS

Discuss the scope of minimum common standards for RIMS

Discuss how a set of minimum common standards for RIMS can best address critical challenges

Build the use case for a set of minimum common standards

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Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

8:20 – 9:25 Session 1: Clarifying the need

Objective:

Identify the critical gaps and challenges NMRAs and other stakeholders are facing regarding implementation of regulatory IMS

Output:

Critical gaps and challenges regarding regulatory IMS clearly identified

Discussion Questions:

- What is the current landscape of regulatory IMS? What are the most critical challenges?
- How do these challenges vary across regions?
- How do these challenges vary, if at all, across regulatory functions?

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8:20 – 9:25 Session 1: Clarifying the Need

Session 1: Clarifying the need

8:20 – 8:30	**Presentation I: African Region—**current landscape of regulatory IMS and critical challenges faced by NMRAs	**Abayomi Akinyemi** AUDA-NEPAD Chairperson, Information Management Systems Technical Working Group
8:30 – 8:40	**Presentation II: Asia Region—**current landscape of regulatory IMS and critical challenges faced by NMRAs	**Abdul Mughees Muddassir** Assistant Director, Quality Management System, Drug Regulatory Authority of Pakistan (DRAP)
8:40 – 9:10	**Facilitated Discussion**	
9:10 – 9:20	**Presentation III: The primary benefits of digitalization of regulatory functions**	**Alireza Khadem** Scientist, Regulatory Systems Strengthening, WHO
9:20 – 9:25	**Session Recap**	**Stephen Kimatu** Consultant, MTaPS
9:25 – 9:40	**Break**	

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Presentation I:

African Region—current landscape of regulatory IMS and critical challenges faced by NMRAs

Abayomi Akinyemi
AUDA-NEPAD Chairperson, Information Management Systems Technical Working Group

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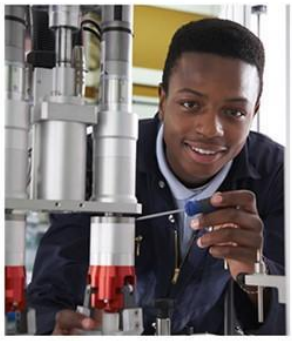
AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AMRH INFORMATION MANAGEMENT SYSTEM TECHNICAL COMMITTEE



Current Landscape of RIMS and Critical Challenges Faced by NMRAs in Africa

Presented by Akinyemi Abayomi Tosin, Chair, IMS TC

INTRODUCTION

- National Medicines Regulatory Authorities (NMRAs) are responsible for the management of therapeutic products regulatory data.
- Their regulatory scope encompasses developing the data standards to be used and management of such data.

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BACKGROUND

- These standards are supposed to form the basis for sharing information across these NMRAs in Africa, but this is not the case as the regulatory activities are carried out in silos.
- While some NMRAs implemented Regulatory Information Management System (RIMS), some could not and among those that implemented, the RIMS are disparate and not interoperable or in some countries, are partially implemented or non-functional.

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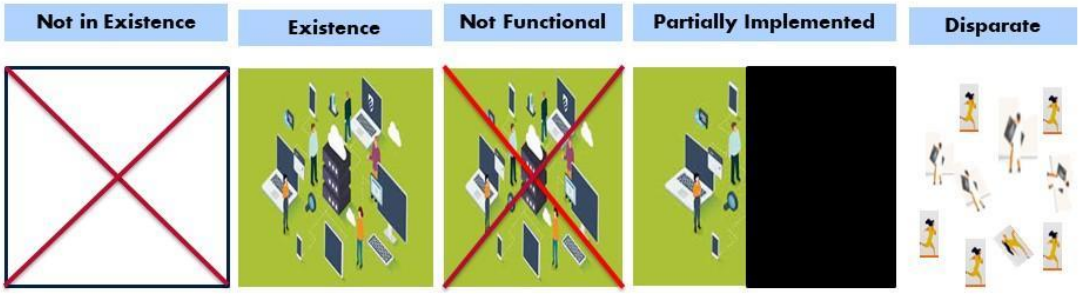
BACKGROUND



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CURRENT SITUATION

- **Disparate/silos mentality and partially implemented regulatory IMS have posed a lot of threats to the African Medicine Regulation Harmonization (AMRH) initiative due to the fact that NMRAs would not be able to produce the right information for information sharing and exchange at the right time.**
- The AMRH initiative was instituted to ensure different NMRAs can work together and form a forum through which data can be managed and exchanged through Regional, economic bodies (ECOWAS, IGAD, EAC, SADC and COMESA).
- Each of these regional bodies have developed harmonization guidelines that would encourage harmonization of regulatory processes; all regional bodies are in different stages of the Harmonization project and implementation of RIMS.

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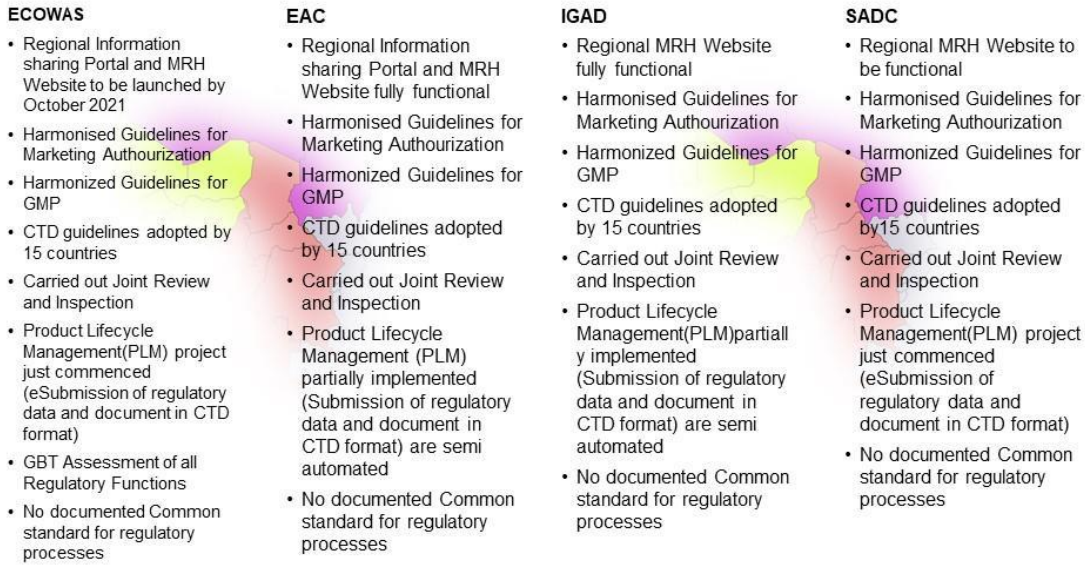
CURRENT RIMS SITUATION IN THE RECS



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CURRENT SITUATION

- AUDA-NEPAD is pioneering Africa Medicines Regulation Harmonization (AMRH)
- In collaboration with AUDA-NEPAD, the World Bank contracted a consultant who conducted a scoping exercise on Regulatory IMS in AU member states
- 32 out of 55 countries responded
- 13 Countries had virtual interviews and desk review

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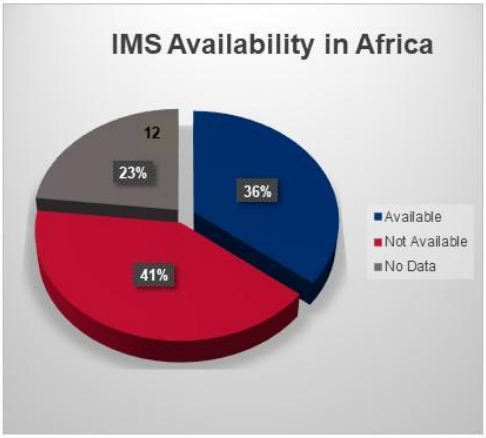
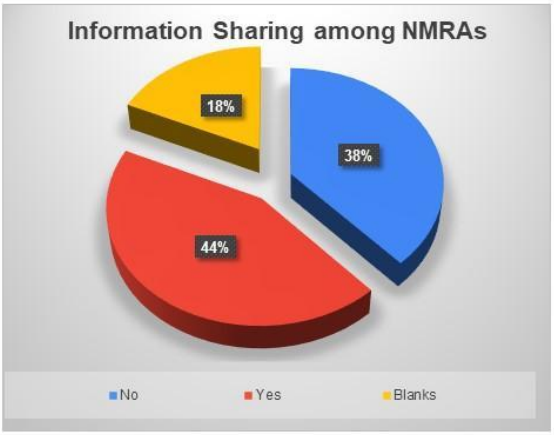
RESULTS





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Countries Medicine Regulatory Functions

Region[1]	Total Number of Countries	Number of Countries with Medicines Regulatory Functions on:							
		MA	RI	LT	VL	MC	LI	IE	CT
Central Africa[2]	8	6	5	2	3	3	6	6	6
East Africa[3]	14	8	8	10	9	9	8	9	9
North Africa[4]	6	4	2	3	3	3	3	3	3
South Africa[5]	11	6	8	3	7	5	7	6	6
West Africa[6]	16	10	11	9	11	11	11	11	8
Total	55	34	34	27	33	31	35	35	32

Table 1 Coverage of national medicines regulatory functions in Africa Union Member States

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Countries Without Medicine Regulatory Functions

Region	Total Number of Countries	Number of Countries Without[7] Medicines Regulatory Functions on:							
		MA	RI	LT	VL	MC	LI	IE	CT
Central Africa	8	0	1	3	2	2	0	0	3
East Africa	14	3	1	0	3	1	2	1	3
North Africa	6	0	2	1	1	1	1	1	1
South Africa	11	1	0	2	1	1	0	1	1
West Africa	16	2	1	3	1	1	1	1	4
Total	55	6	5	9	8	6	4	4	12

Table 2 Non-coverage of national medicines regulatory functions in Africa Union Members States

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Countries with RIMS Function

Region	Total Number of Countries in Region	Number of Countries with R-IMS Functionality			
		Availability of R-IMS	Availability of NMRA/MoH Website	Information sharing with REC	Collaboration with other Countries
Central Africa	8	1	3	6	5
East Africa	14	7	8	5	4
North Africa	6	1	1	1	1
South Africa	11	6	11	10	7
West Africa	16	5	14	4	5
Total (Africa)	55	20	37	25	22

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CHALLENGES

- Varying requirements for regulatory processes
- Increasing complexity of regulations and product portfolio
- Lack of IT experts to drive and sustain Regulatory RIMS
- Financial barrier/lack of support from Government and other stakeholders
- Practical and technological barrier
- Improper alignment of RIMS with Product Lifecycle Management (PLM)
- Silos mentality

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CHALLENGES

- Legal and institutional barriers
- Political and cultural barriers
- **Lack of leadership commitment/support**
- **Unfriendly governance structure**
- **Lack of transparency across systems and departments**
- **Ineffective and weak coordination system**
- **Resistance to change**

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SUPPORT NEEDED FROM DEVELOPMENT PARTNERS

- Capacity building for NMRAs on Good Regulatory Practices
- Support NMRAs, Regional and Continental IMS in developing Policy, Process and Data Harmonization Standards and Quality for Regulatory Convergence
- Support in the process of implementing the common standards for regulatory IMS across the NMRAs, Regions and Continent.
- Support in implementing Product Lifecycle Management (PLM) in alignment with RIMS
- Support the NMRAs, Regions and Continent to implement e-Submission of regulatory documents using common standard in a predefined format eCTD.
- Support AUDA-NEPAD IMS TC to implement Zanzibar model of Integrated Information Sharing Platform

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CONCLUSION

- **With common standards, policies and processes in place, a good regulatory information management system could be developed to support and provide effective and efficient regulatory sytem across the regulatory functions as objectively defined in the WHO GBT requirements for Countries with no IMS in place and, for regional and Continental regulatory IMS**

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CONCLUSION

- This will give room for seamless information sharing and Information exchange among the NMRAs, Regional bodies and Continental body.
- With adequate support from the management of the Continental body (AUDA NEPAD), Regional bodies (ECOWAS, EAC, SADC, IGAD, COMESA), NMRAs (55 Member States), and development partners, common set of standards could be developed with an articulated clear use case for Regulatory Information Management System in Africa.

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One Africa

Thank you!

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Presentation II:

Asia Region—current landscape of regulatory IMS and critical challenges faced by NMRAs

Abdul Mughees Muddassir
Assistant Director, Quality Management System,
Drug Regulatory Authority of Pakistan (DRAP)

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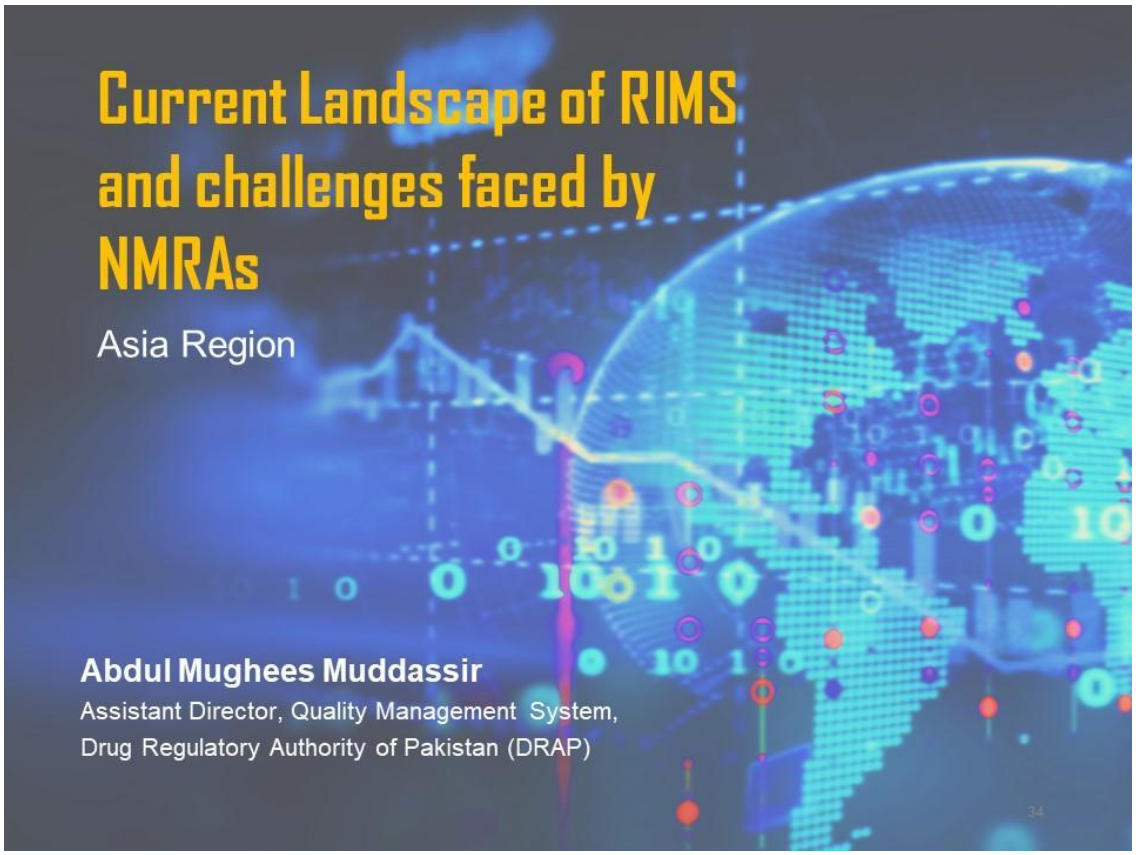
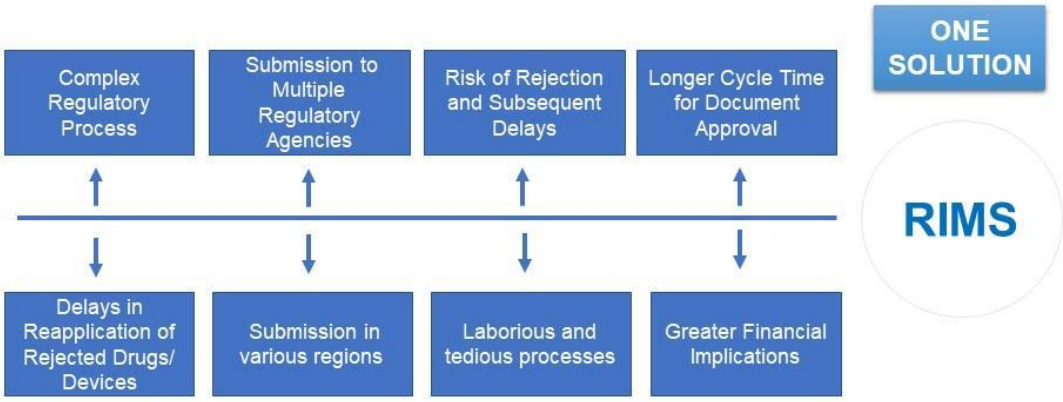


Regional Perspective: IMS is Need of the Day



03

35

Pakistan

Drug Regulatory Authority of Pakistan (DRAP) regulates licensing, manufacturing, sale, distribution, import and export of therapeutic goods.

DRAP has also been mandated to implement internationally recognized standards and IMS.

DRAP has digitized 4.2 million records in last 2 years, developed and implemented IMS and is developing track and trace system for medicinal products up to the point of retail.

DRAP's steps in deploying IMS

04

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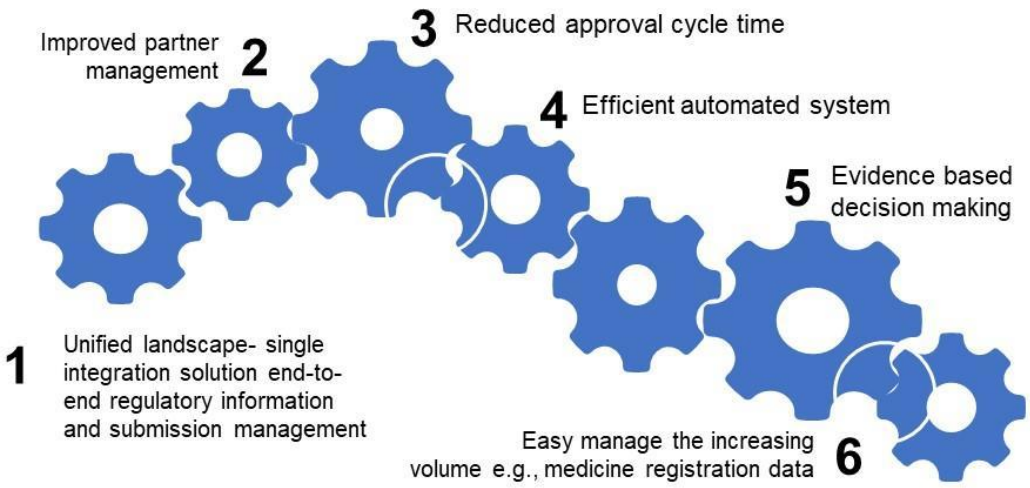
IMS Outcomes



05

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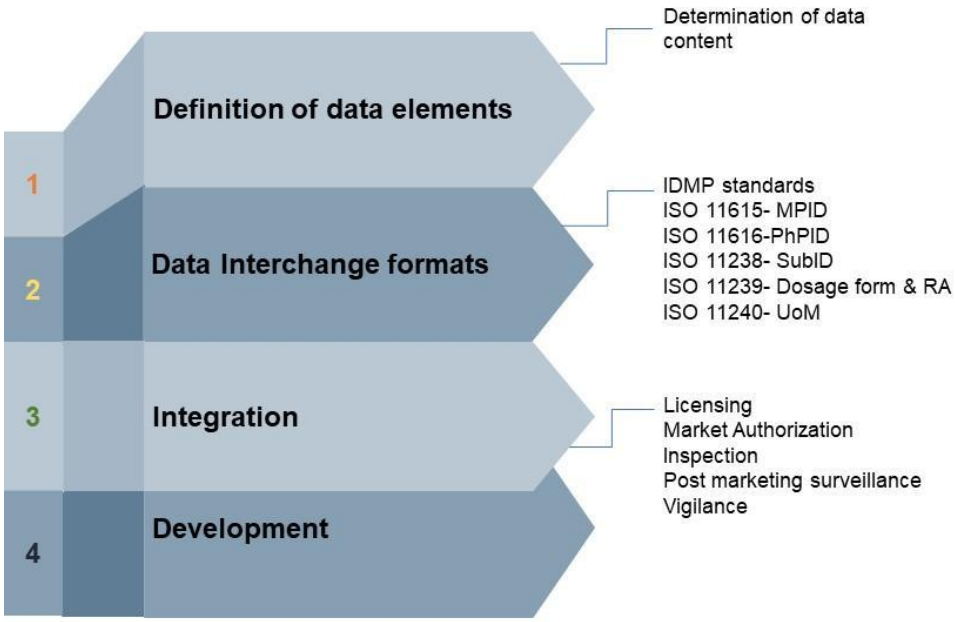
Preliminary considerations for RIMS, example



04

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Application of data standards

Basic dose form	*Tablet*
Pharmaceutical dose form	Extended release
Release characteristics	Extended
Transformation	None
Administration Method	Swallowing
Intended site	Oral
Packaging Category	
Container	Immediate container: blister
	Outer packaging: box
Administration device	None
Combined pharmaceutical dose form	None

05

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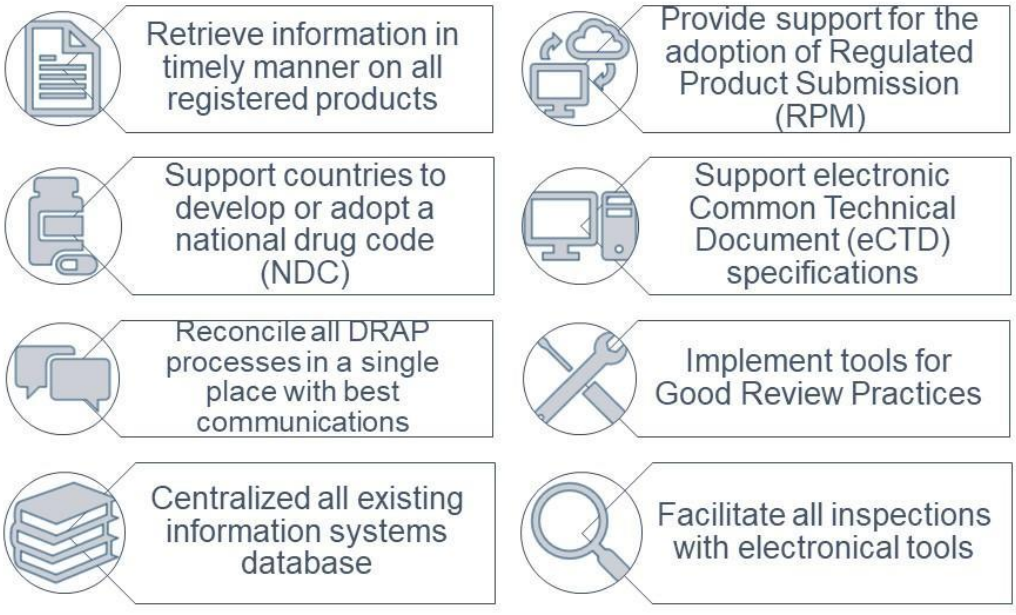
Pakistan – RIMS Key Features



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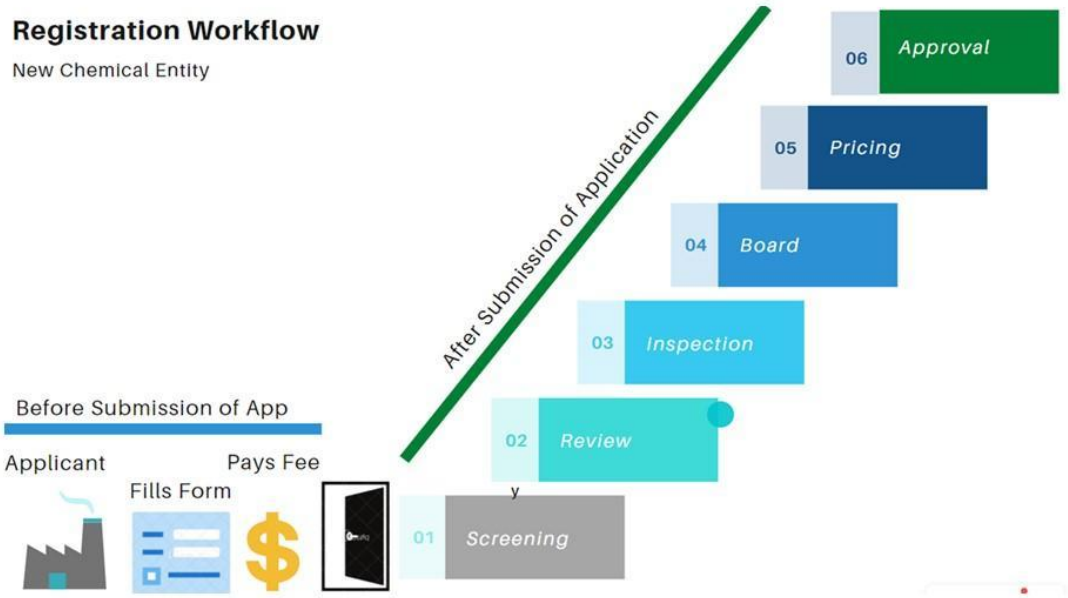

07

41

RIMS Challenges

- Standard determination, trainings and relevant technical HR
- Digitization of Record, integration, space & Infrastructure
- Change Management & Resistance
- Variations in regulations and regulated products

08

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RIMS Lessons Learned

09

Facilitated Discussion

8:40 – 9:10
Hany Abdallah

USAID MTaPS and PQM+ Programs

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Critical gaps/ challenges with regards to RIMS - submit each gap separately

Top

Upvote RIMS challenges you consider most critical

Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

1. **How do these challenges vary from issues raised by regional presentations?**

   → Do challenges vary across regions?

Use Raise Hand (click Reactions button)

Or

Use Chat (click Chat button)

2. **How do these challenges vary, if at all, across regulatory functions?**

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Presentation III:

The primary benefits of digitalization of regulatory functions

Alireza Khadem
Scientist, Regulatory Systems Strengthening, WHO

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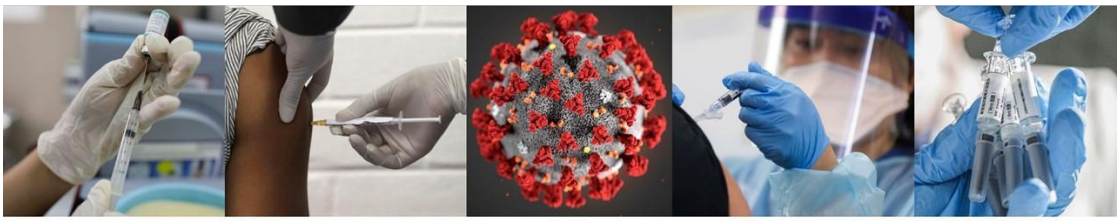
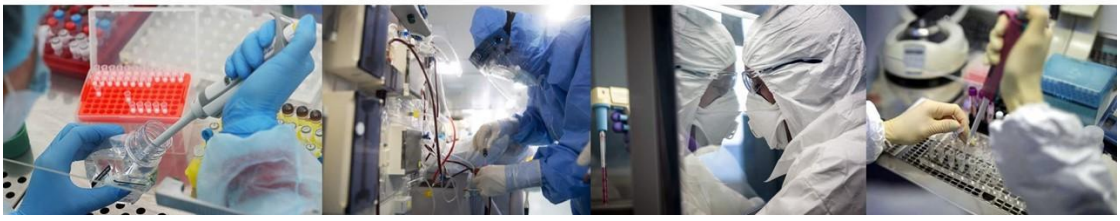


The Primary Benefits of Digitalization of Regulatory Functions

World Health Organization

Alireza Khadem WHO/RPQ/REG/RSS

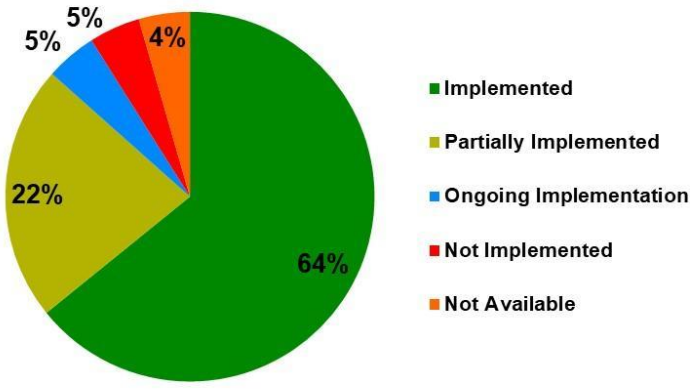


WHO GBT selected sub-indicators list related to digitalization

Sub indicators
RS09.02: The information on laws, regulations guidelines and procedures is publicly available and is kept duly updated.
RS09.08: The NRA uses computerized systems to process information, manage records, and analyze data.
RS09.09: The NRA has its own web page with timely information that gives public access to related legal provisions, guidelines and decisions.
MA05.01: Web site or other official publication with SPC-like information is available and regularly updated
MA06.01: There is a database of all product applications received, approved, rejected, suspended or withdrawn along with their supporting documentation.
MC05.02: Database for product batches that have undergone surveillance along with their relevant testing results and regulatory actions is established and periodically reviewed.
RI06.02: The updated list or database of all inspected facilities along their regulatory decisions, actions and enforcement activities, is regularly published and publicly available.
LT08.01: There is an updated database of all medical products batches that have undergone quality testing.

2

RS09.02: The information on laws, regulations guidelines and procedures is publicly available and is kept duly updated.



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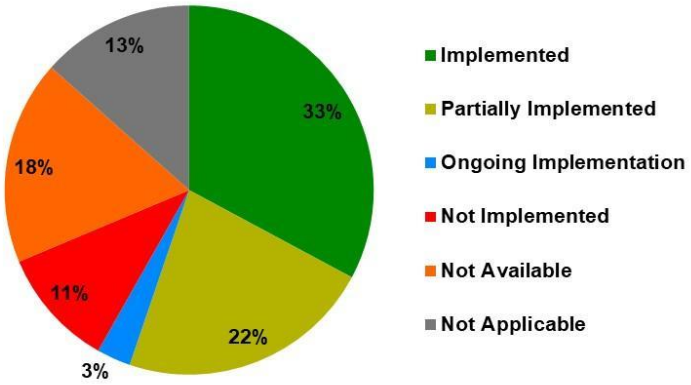
RS09.08: The NRA uses computerized systems to process information, manage records, and analyze data.



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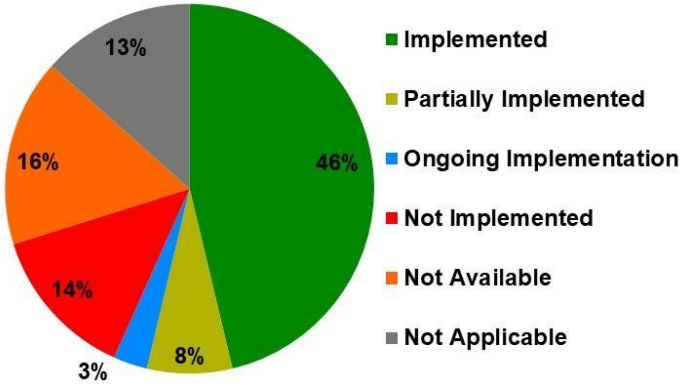
RS09.09: The NRA has its own web page with timely information that gives public access to related legal provisions, guidelines and decisions.



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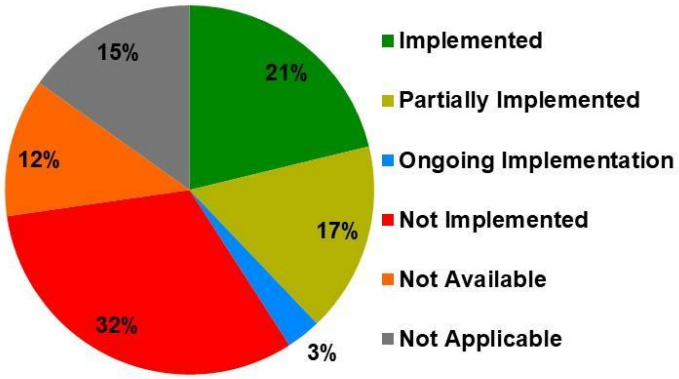
World Health Organization

MA05.01: Web site or other official publication with SPC-like information is available and regularly updated



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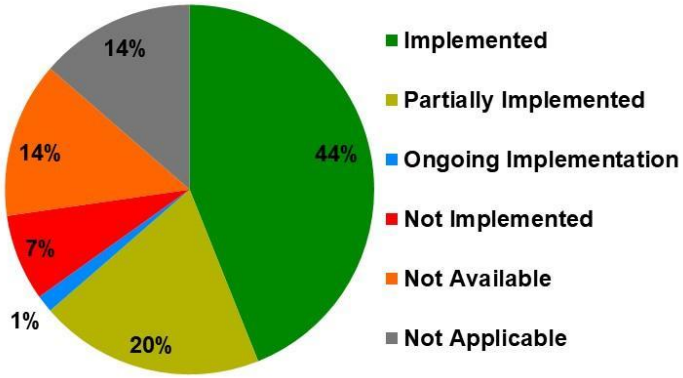
World Health Organization

MA06.01: There is a database of all product applications received, approved, rejected, suspended or withdrawn along with their supporting documentation.



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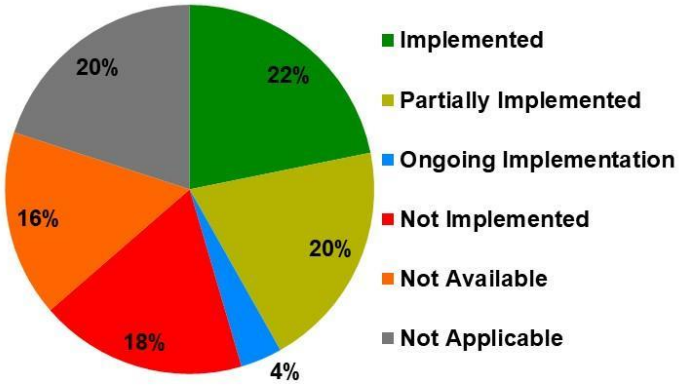
MC05.02: Database for product batches that have undergone surveillance along with their relevant testing results and regulatory actions is established and periodically reviewed.



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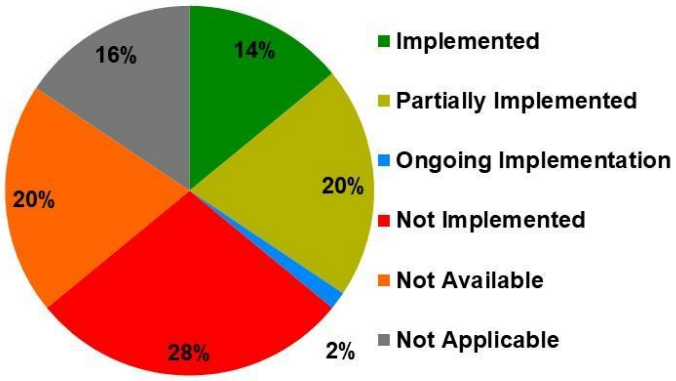
RI06.02: The updated list or database of all inspected facilities along their regulatory decisions, actions and enforcement activities, is regularly published and publicly available.



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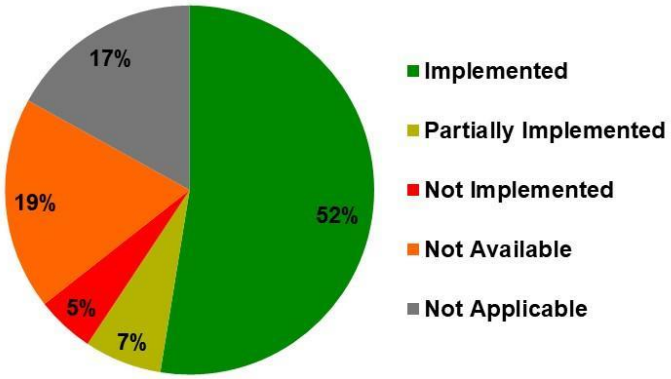
World Health Organization

LT08.01: There is an updated database of all medical products batches that have undergone quality testing.



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World Health Organization

Most important benefits of digitalization

- Improved effectiveness, **efficiency** and performance
  - Regulatory activities can be performed faster, better and with less cost
- Improved **transparency** and timely access to information and regulatory decisions
  - Possibility for faster and wider sharing of information
- Improved **consistency** in regulatory activities/functions
- Improved Good Governance (GGP), reduced risk of corruption
- Improved collaboration, trust and reliance among NRAs

WHO GRP Principles

World Health Organization

Digitalization is a valuable tool to improve performance of a regulatory system and will result to have improved implementation of GRP and GRelP and facilitate convergence, harmonization, work-sharing and reliance among NRAs.

However, NRAs should have clear policy in this regard and include digitalization of their regulatory functions in their strategic plans. In addition, digitalization needs proper planning, resources and training as well as strong management commitment.

Challenges

Dr Alireza Khadem
Scientist
Email: khadembroojerdia@who.int
Regulatory Systems Strengthening [RSS] Team
Regulation and Safety [REG] Unit
Regulation and Prequalification [RPQ] Department
Access to Medicines and Health Products [MHP] Division
World Health Organization (Geneva, Switzerland)

Thank you

Session I Recap

9:20 – 9:25
Stephen Kimatu
Consultant, MTaPS

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Break

9:25 – 9:40

USAID FROM THE AMERICAN PEOPLE

Welcome Back

Session II: The role of regulatory IMS standards

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Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

9:40 – 10:40 Session II: The role of regulatory IMS standards

Objective:

Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges

Output:

The scope of the standards identified for addressing the most critical gaps and challenges associated with regulatory IMS

Discussion Questions:

- Which of the identified challenges should we try to solve given the diversity of identified needs with respect to regulatory IMS?
- What should be the scope/definition of *"minimum common standards"* for regulatory IMS? How will these standards address or mitigate the identified challenges?

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9:40 – 10:40 Session II: The role of regulatory IMS standards

Session II: The role of regulatory IMS standards

9:40 – 9:50	**Presentation 1: "Minimum Common Standards"—Proposed Definition and Scope**	**Kate Kikule** Principal Technical Advisor, RSS, USAID MTaPS
9:50 – 10:00	**Presentation II: Opportunities to leverage existing global RSS initiatives to address challenges and need to standardize regulatory IMS**	**Murray Lumpkin M.D., M.Sc.** Deputy Director – Integrated Development, Lead for Global Regulatory Systems Initiatives, The Bill and Melinda Gates Foundation
10:00 – 10:35	**Facilitated Discussion**	
10:35 – 10:40	**Session Recap**	**Chinwe Owunna** Senior Manager, PQM+

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Presentation 1: "Minimum Common Standards"—Proposed Definition and Scope

Kate Kikule
Principal Technical Advisor, RSS, USAID MTaPS

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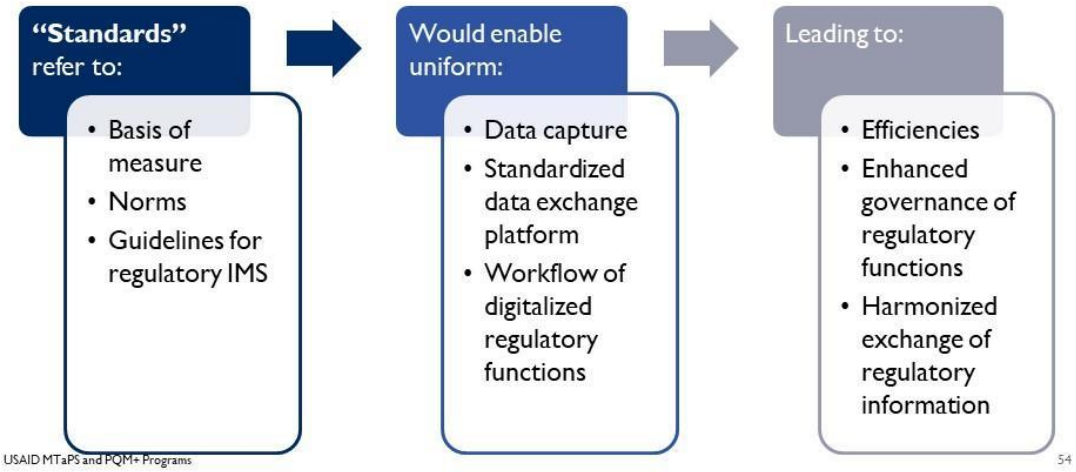
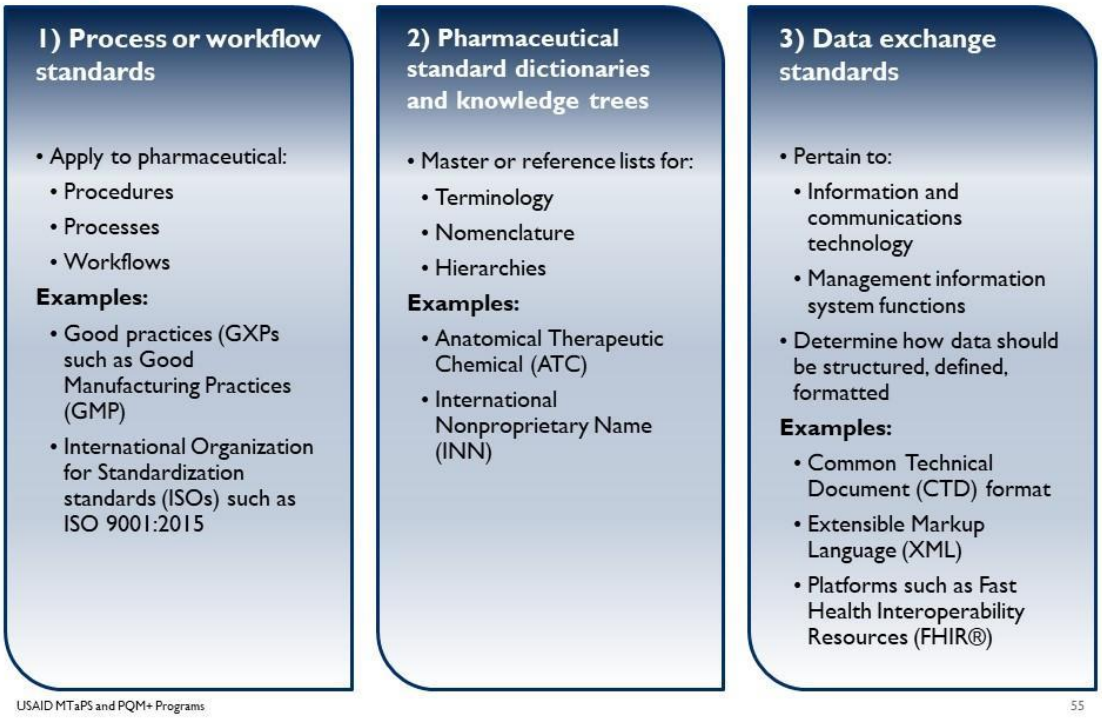
What do we mean by "Standards"?



Categories of Standards



Scope

Inclusion

- Standards as applicable to the 8 regulatory functions as defined in WHO GBT (ref)

Exclusion

- Low-level data elements such as date, location, time
- Support functions to the regulatory system, such as finance and human resources

https://www.who.int/tools/global-benchmarking-tools/VI

Presentation II:

Opportunities to leverage existing global RSS initiatives to address challenges and need to standardize regulatory IMS

Murray Lumpkin M.D., M.Sc.
Deputy Director – Integrated Development
Lead for Global Regulatory Systems Initiatives,
The Bill and Melinda Gates Foundation

USAID FROM THE AMERICAN PEOPLE

BILL & MELINDA GATES foundation

WORKSHOP ON MINIMUM COMMON STANDARDS FOR REGULATORY INFORMATION MANAGEMENT SYSTEMS IN LOW- AND MIDDLE-INCOME COUNTRIES

Murray M. Lumpkin, M.D., M.Sc.
Deputy Director – Integrated Development
Lead for Global Regulatory Systems Initiatives
The Bill and Melinda Gates Foundation

15 September 2021
Virtual

EXPERIENCES WITH NRA IMS INITIATIVES

- Resources intensive – time and financial
- Often little progress or ultimate impact
- Frustrating – a set of minimum standards would be very helpful in focusing and defining the effort
- IMS is a tool to help with regulatory agency functions, not the driver of those functions – the business case should drive the system, not the other way around

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STANDARDS – FOR WHAT?

- Glad to see this workshop focusing on mapping the standards to the modules in the GBT

- Defining what functionalities the system is to address:
  - Internal Operational
    - Work-flow management – life cycle of the product (clinical trials through post-authorisation variations)
      - Digitalisation of submissions and reports
    - Performance metric tracking and reporting
    - Financial management (both internal and with external stakeholders – user fees)
    - Legacy data accessibility
  - External Connectivity
    - Confidentially with other NRAs
    - Transparently with outside stakeholders

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OUR EXPERIENCE TO DATE

- Regulators in Africa and other LMICs aspire to have information management systems (IMS) that can facilitate their regulatory work, as well as facilitate collaboration with peer regulators and communication with the regulated community.

  - Not a problem of desire
  - Challenge of design and implementation, including
    - initial and ongoing costs, which are often prohibitive
    - need to be in alignment with Ministry or other entity systems

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OUR EXPERIENCE TO DATE

- Many agencies and regions have made efforts to develop their own bespoke systems.
  - Hopefully, a set of minimum standards will allow development of commercial, off the shelf solutions
- Without a common set of minimum core requirements and standards for Regulatory IMS, countries and regions, as well as their platform developers, risk creating platforms that do not meet core and minimal expectations of regulators and the regulated community.
- Without these standards, countries, regions and their developers go through multiple iterations at high cost in terms of time and financial resources before arriving at a meaningful platform. (ex. WHO PQ, EAC)
- It is important that people clearly define the use-case; e.g., platform to receive applications and communicate with applicants? Platform to manage reviews (assign applications, follow up reviews, collate questions, share reports)? Platform to manage receipt of fees, and link with application review and management? All of these, a combination, or other?

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OUR EXPERIENCE TO DATE

- Many LMIC agencies do not have the resources to develop their own IMS or purchase commercial solutions.
- Making available opensource platforms that meet the IMS standards that will be agreed will be key to enabling these resource-limited agencies enhance their operational capabilities.
- As we have seen working with national agencies and regional initiatives, the technical capabilities are often not the key constrain to performance, but the operational side of things.

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OUR EXPERIENCE TO DATE

- Many IMS solutions exist
  - WHO SharePoint used to download dossiers, inspection reports, and assessment reports during COVID vaccine review sessions in Africa
  - PAHO – PRAIS system
  - ASEAN – IMS system developed with WHO
  - ICH – Data exchange standards for the eCTD and MedDRA Terminology
  - Don't need to re-invent the wheel

- I hope these can be tweaked to meet minimum standards (if they don't already meet these) and shared.

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THANK YOU

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Facilitated Discussion

10:00 – 10:35
Hany Abdallah

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Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

1. **Feedback & Consensus on Standards:**
   1. Do you agree with definitions? Would you add or change anything?
   2. Is anything missing from proposed categories of "Standards"? What would you change?
   3. Is anything being excluded that should be included? What would you change if anything?

2. **How can standards address/ mitigate the critical RIMS challenges ?**

Use Raise Hand (click Reactions button)

Or

Use Chat (click Chat button)

pollev.com/RIMS

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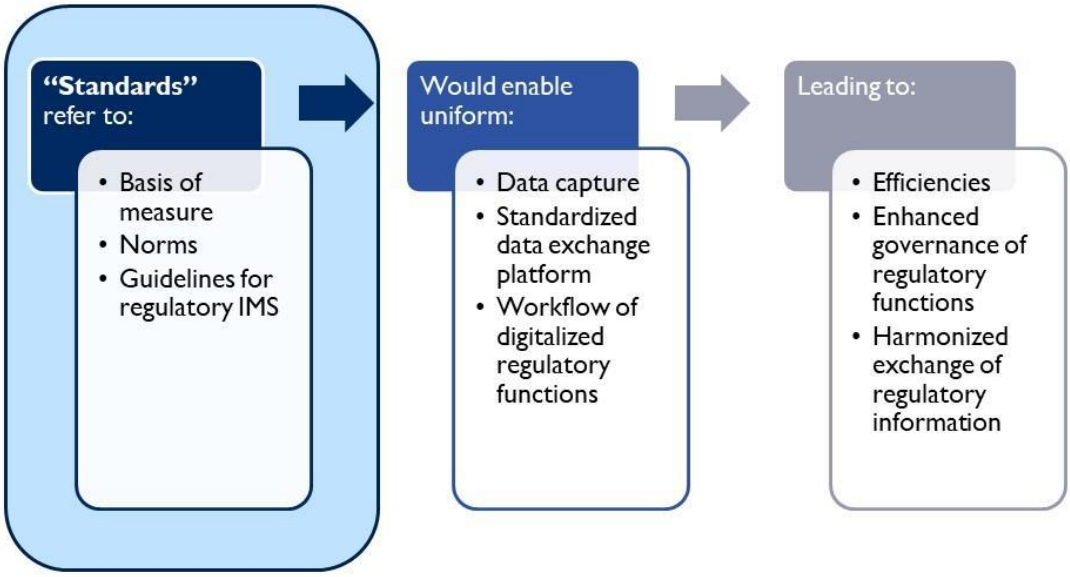
1. Do you agree with definitions? Would you add or change anything?



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2. Is anything missing from proposed categories of "Standards"? What would you change?

1) Process or workflow standards

- Apply to pharmaceutical:
  - Procedures
  - Processes
  - Workflows

Examples:

- Good practices (GXPs such as Good Manufacturing Practices (GMP)
- International Organization for Standardization standards (ISOs) such as ISO 9001:2015

2) Pharmaceutical standard dictionaries and knowledge trees

- Master or reference lists for:
  - Terminology
  - Nomenclature
  - Hierarchies

Examples:

- Anatomical Therapeutic Chemical (ATC)
- International Nonproprietary Name (INN)

3) Data exchange standards

- Pertain to:
  - Information and communications technology
  - Management information system functions
- Determine how data should be structured, defined, formatted

Examples:

- Common Technical Document (CTD) format
- Extensible Markup Language (XML)
- Platforms such as Fast Health Interoperability Resources (FHIR®)

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3. Is anything being excluded that should be included? What would you change if anything?

Inclusion	Exclusion
• Standards as applicable to the 8 regulatory functions as defined in WHO GBT (ref)	• Low level data elements such as date, location, time • Support functions to the regulatory system such as finance, human resources

https://www.who.int/tools/global-benchmarking-tools/VI

Recalling Most Critical Issues –

How can standards address/ mitigate the critical RIMS challenges ?

Session II Recap

10:35 – 10:40
Chinwe Owunna
Senior Manager, PQM+

USAID MTaPS and PQM+ Programs

Next Steps

10:40 – 11:00	**Next Steps**	**Souly Phanouvong** Senior Technical Advisor, RSS, PQM+
	Closing Remarks	**Lawrence Evans** Technical Director, PQM+

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Next Steps

Souly Phanouvong
Senior Technical Advisor, RSS, PQM+

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Outline of the Consultative Process

Time (Approx)	Activity	Task/Objective	Expected results
Sept 15	**Consultative meeting I**	Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS Discuss the scope of minimum common standards for RIMS Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges and start building the use case	Critical gaps and challenges with regulatory IMS identified The scope of the standards for addressing the gaps and challenges defined
Oct 27	**Consultative meeting II**	Develop selection criteria for minimum common standards Review collated existing standards Finalize the use case	Preliminary core set of minimum common standards for regulatory IMS identified Advocacy brief developed
Oct 27 - Dec 1	**External review I**	Review of collated existing standards and identify which standards should be included in the minimum common standard set Engage select NMRA representatives to gather additional input	
Nov 1 - Jan 3	**Internal analysis and synthesis of standards**	Draft advocacy brief Consolidate and synthesize the inputs from the experts Draft minimum common standards for regulatory IMS	
Jan 3 - 27	**External review II**	Final expert review of the proposed minimum common standards	Finalized set of minimum common standards for regulatory IMS Inputs gathered for guidance on digitalization pathway
Jan 27 - Feb 24	**Internal revisions and finalization**	Finalize minimum common standards based on feedback Internal reviews and copyediting	
Mar 3	**Consultative meeting III**	Present minimum common standards Discuss guidance on pathway for countries to adopt minimum common standards to support the digitalization of regulatory functions	

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Closing Remarks

Lawrence Evans
Technical Director, PQM+

USAID MTaPS and PQM+ Programs

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USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

Prime: Management Sciences for Health (MSH)

COR: Alexis Leonard, aleonard@usaid.gov

Learn more: www.mtapsprogram.org

USAID Promoting the Quality of Medicines (PQM+) Program

Prime: U.S. Pharmacopeia (USP)

AOR: Alison Collins, alcollins@usaid.gov

Learn more: www.usp.org/global-public-health/promoting-quality-of-medicines

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1. **Responses to Country/ Organization Represented.**

2. Response to Critical gaps/ challenges with regards to regulatory IMS

Participant count	17
Total responses	33

Responses	Upvotes	Downvotes
3. Lack of interoperability	11	0
4. Lack of integration with other HIS	10	0
5. Political will and commitment	9	0
6. Various requirements/standards for regulatory process	8	0
7. Cost	8	0
8. Decision-making authority to determine scope of regulatory IMS	6	1
9. The design of some regulatory IMS is fit-for-purpose for today but not for the possibility of adapting to changes in regulatory systems in the future.	6	1
10. What information should and shouldn't be included in a regulatory IMS	6	0
11. Lack of knowledge and importance of data standards	5	0
12. Lack of adoption of Global Product Identification Standard	5	0
13. Lack of data standards for the regulatory IMS	5	0
14. Non interoperable regulatory IMS	4	0
15. Non interoperable regulatory IMS	4	1
16. Standards	4	0
17. Complexity	4	0
18. noninterpretable regulatory IMS	4	0
19. lack of financial support on regulatory IMS development	3	0
20. Lack of integration with other HIS	3	0
21. Alignment of policy with regulatory IMS	3	0
22. Cost	3	1
23. insufficient infrastructure	3	0
24. Human resource and technologies	3	0
25. Lack of clear policy and strategic directions	3	0
26. Necessary steps alongside implementing regulatory IMS, e.g., streamlining workflows	3	0
27. lack of infrastructure	3	0
28. Manually driven processes	2	1
29. Interoperability	2	0
30. Lack of appreciation for ensuring that IT, Pharmaceutical and ISO standards are considered in developing regulatory IMS	1	0
31. regulatory IMS is a relatively long journey to see results	1	1
32. national IT system and IT equipment of different maturity	1	1
33. too many options	1	1
34. Access to relevant data standard such as ISO	1	0
35. Lack of standards	1	1

3. Response to "How can Standards Address/ Mitigate Challenges"

Total responses	18
Unique participants	11

Responses

i. Simplify the regulatory process
ii. Improved efficiency
iii. Will enhance information sharing
iv. Enable streamlined and consistent regulatory processes
v. Increased transparency
vi. quickly identify drugs on the market that are impacted by a recall
vii. Improved regulatory IMS design capabilities
viii. Reduced cost of regulatory IMS system implementation
ix. Advocacy and clear, practical path forward to assist NMRAs to adopt and institutionalize
x. Reduce cost
xi. Help design interoperable regulatory IMS
xii. Promote trust
xiii. Facilitate efficiencies within and between NMRAs
xiv. Improve ability for regulators to quickly identify risks associated w/drug filings
xv. standards can establish de minimus elements on which regulatory IMS can be built by any agency
xvi. Set common "language"
xvii. Common standards lead to standard designs and standard systems architecture.
xviii. increase transparency

Promoting the Quality of Medicines Plus (PQM+)

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

Improved Access. Improved Services. Better Health Outcomes.

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

Report of the 2nd Consultative Meeting

Held October 27, 2021

November 16, 2021

USAID FROM THE AMERICAN PEOPLE

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About the USAID MTaPS Program

Funded by the US Agency for International Development (USAID) and implemented by a team led by Management Sciences for Health (MSH), the purpose of the five-year Medicines Technologies and Pharmaceutical Services (MTaPS) program (2018–2023) is to provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats, as well as expanding essential health coverage. The goal of the MTaPS Program is to help low- and middle-income countries (LMICs) strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality assured, and affordable essential medicines, vaccines, and other health technologies and pharmaceutical services.

About the USAID PQM+ Program

The Promoting the Quality of Medicines Plus (PQM+) program is a USAID funded cooperative agreement with the U.S. Pharmacopeial Convention (USP) with a goal to sustainably strengthen medical product quality assurance (QA) systems by providing technical assistance to manufacturers of priority health products and build in-country capacity of Medicines Regulatory Authorities to improve product registration, inspection, and post-marketing surveillance for product quality. PQM+ support also includes accreditation of national drug quality control laboratories per ISO/IEC 17025 and/or WHO pre-qualification standards in low-and middle-income countries. PQM+ uses a system strengthening approach to program implementation to enhance sustainability.[14] The program considers the entire system when designing and delivering technical assistance, focusing on the interaction among all health systems functions[15] as they relate to medical product quality assurance.

To implement PQM+, USP joined forces with a diversified consortium of four core partners, six field-led extension partners, and eight technical resource partners[16] whose extensive technical expertise can be drawn on to achieve desired results.

Recommended Citation

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[14] Chee G, Pielemeier N, Lion A, Connor C. Why differentiating between health system support and health system strengthening is needed. Int J Health Plann Mgmt. 2013; 28: 85-94. DOI: 10.1002/hpm.2122.
[15] governance, human resources, service delivery, information systems, financing https://www.usaid.gov/global-health/health-systems-innovation/health-systems/strengthening-pharmaceutical-systems
[16] https://www.usp.org/sites/default/files/usp/document/our-impact/pqm/pqm-plus-overview-brochure.pdf

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Participants represented 17 organizations, including:

- African Union Development Agency - New Partnership for Africa's Development
- Bill & Melinda Gates Foundation
- Centre for Innovation in Regulatory Science
- Drug Regulatory Authority of Pakistan
- Liberia Medicines & Health Products Regulatory Authority
- Mahidol University
- Management Sciences for Health
- Medicines and Healthcare products Regulatory Agency (United Kingdom)
- Pharmacy and Poisons Board (Kenya)
- School of Pharmacy Muhimbili University, Muhimbili University of Health and Allied Sciences
- The Global Fund to Fight AIDS, Tuberculosis and Malaria
- The National Agency for Food and Drug Administration and Control (Nigeria)
- United States Pharmacopeia
- Université Félix Houphouët-Boigny
- US Agency for International Development
- World Bank
- World Health Organization

A full list of participants is included in Annex 2B.

Contributors and Reviewers

The MTaPS and PQM+ teams listed below developed the technical content for the meeting. Afeke Kambui, Technical Advisor and Maura Soucy Brown, Senior Technical Advisor prepared this meeting report. Tamara Hafner developed the concept note and agenda for the meeting and facilitated the meeting. Gabriel Swinth provided planning and logistical support to the meeting and this activity.

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CONTENTS

EXECUTIVE SUMMARY

The US Agency for International Development (USAID) funded Medicines Technologies and Pharmaceutical Services (MTaPS) and USAID funded Promoting Quality of Medicines Plus (PQM+) programs convened a virtual meeting on October 22, 2021. The meeting is the second in a series of consultations aimed at identifying and recommending a set of minimum common standards for regulatory information management systems (IMS) that will enable uniform data capture and standardize the data, design, and workflow of digitalized regulatory functions. The meeting brought together experts in regulatory system strengthening and information management systems from 17 global, regional, and national organizations and the objectives were to:

- Develop the use case for the set of minimum common standards
- Identify the selection criteria for the minimum common standards

Regarding the development of the use case for the standards, MTaPS and PQM+ noted that this needs to involve identifying the potential benefits of adopting minimum common standards for the different stakeholder groups. Potential benefits of adoption include creation of a common reference among stakeholders for the development and use of regulatory IMS; streamlining of NMRAs' internal operations; and facilitating convergence and harmonization of regulatory services both within and across NMRAs. Meeting participants acknowledged these benefits and discussed the need to learn from previous efforts of other organizations that have developed and promulgated standards. This could help identify a suitable process for identifying relevant stakeholders, and for developing and promoting the standards.

Participants debated whether the GBT modules/regulatory functions or the pharmaceutical product life cycle should be used to structure further work on the standards and the use case. Participants agreed that the product should be in the center of their thinking, and that the regulatory functions at each stage in the product life cycle should be examined individually to identify relevant stakeholders and build the use cases. Using this suggestion, meeting participants did some preliminary work identifying potential stakeholders for the different regulatory functions aligned with the various stages of the product life cycle. However, no final determination was made regarding the key stakeholders for developing use cases during the time allotted for the session.

The key selection criteria that MTaPS and PQM+ proposed for selecting the minimum common standards were:

- Relevance—the standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBT
- Feasibility of application—the extent to which NMRAs' capacity and resources feasibly allow adoption and what are the anticipated efficiency gains
- Priority—what would countries benefit or lose by not applying a given standard
- Universality—whether a given standard is recommended by WHO and extent to which it is widely used

However, participants raised concerns about how best to apply these criteria and noted that in some cases the determinations would have to be country specific. Much of the deliberation centered on the

inclusion or exclusion of *process standards* – several participants proposed that we differentiate between *standards* and *guidelines* and asserted that including both was outside the proposed scope of the activity and confounded the activity objectives. Further, some meeting participants were concerned about the extent to which the applying the criteria aligned with the scope of the activity, and the extent to which the objective was focused on system design versus the system contents. The meeting participants further urged the team to revisit the definitions and the proposed scoring (1 being low priority, 3 being high priority) of the criteria.

Given the depth of the meeting discussions, MTaPS and PQM+ noted the need revisit the consultative process and the proposed approach for the use case development and standards selection. The next steps include a rethinking of the process and a potential revision of the background document for recirculation to the participants for reactions and feedback.

Recommendations and next steps for MTaPS and PQM+ that emerged from the meeting include:

- Draft the use case and share with meeting participants for feedback
- Map the regulatory functions to the product life cycle and use the resulting matrix to identify relevant stakeholders.
- Use the feedback from the meeting to rethink the selection criteria and share with the meeting participants for feedback.
- Share the full list of standards identified from the desk review with participants for review against the revised selection criteria

MTaPS and PQM+ committed to follow up on the next steps.

Background

National medicines regulatory authorities (NMRAs) in low- and middle-income countries (LMICs) often lack fully operational information management systems (IMS) to perform regulatory functions. These systems are often disparate and lack interoperability or are nonexistent, partially implemented, or nonfunctional. Many regulatory functions use paper-based systems, which results in inefficient workflows, backlogs and delays, lack of transparency, mismanagement, and vulnerability to corruption. Digitalization efforts aim to improve consistency, efficiency, and accountability in pharmaceutical regulatory service delivery. However, digitalization approaches vary across NMRAs, which often struggle with fully operationalizing their regulatory IMS, either desk-based or web-based systems, which limits the availability of real-time data and collaboration between NMRAs.[17]

Ongoing regional regulatory harmonization efforts in both Africa and Asia will rely not only on common documents and processes, but also shared regulatory IMS that are fully interoperable. This work increases the need for a set of minimum common standards for regulatory IMS to help clarify how regulatory IMS should capture and report information to promote system interoperability within national regulatory systems and support regulatory harmonization efforts.

It is not feasible for countries to apply all the relevant standards to each regulatory IMS, so it is necessary to identify a set of minimum common standards for regulatory IMS that NMRAs should prioritize to streamline their workflows and documentation of regulatory processes, ensure uniform data capture, and enable data exchange within and between NMRAs and other stakeholders. The USAID funded Medicines Technologies and Pharmaceutical Services (MTaPS) program and USAID funded Promoting Quality of Medicines Plus (PQM+) program will be engaging global stakeholders and subject matter experts to help identify and recommend a set of minimum common standards for regulatory IMS. The adoption of these common standards will streamline regulatory processes and help ensure that NMRAs make technical decisions with a degree of consistency and uniformity. Minimum common standards would also enhance the ability of NMRAs to collaborate and share information with one another, including use of reliance and recognition mechanisms.

Objectives of The Consultative Process

MTaPS and PQM+ will facilitate a consultative process with adopters and end users, global and regional regulatory experts, and funders to develop the set of minimum common standards for regulatory IMS (Annex 2A).

The primary objective of the consultative process is to derive and recommend a set of minimum common standards for regulatory IMS that will enable uniform data capture and standardize the data,

[17] BEWSYS. (2020). Final Report. Consultancy for Scoping of a Continental Regulatory Information Management System Solution and Information Sharing Platform for the Member States in the African Union. Submitted to the World Bank Group. Washington DC.

design, and workflow of digitalized regulatory functions. Specifically, MTaPS and PQM+ are convening a group of international stakeholders and subject matter experts to:

- Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS for the eight regulatory functions outlined in the WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. [18]
- Use existing relevant IMS and regulatory standards to derive a recommended set of minimum common standards for regulatory IMS to address identified gaps and challenges. This includes developing the selection criteria for prioritizing which standards to include in the set of recommended standards.
- Develop the use case for the minimum common standards and help promote their adoption and use.

There are three primary groups of stakeholders involved in the consultative process:

- **Adopters and end users.** NMRAs are the primary stakeholder group as they are the users of the systems. Software developers and programmers, and managers/ administrators of regulatory IMS develop and manage the systems for NMRAs.
- **Global and regional regulatory experts.** This group includes the regional regulatory harmonization initiatives, other global and regional experts and normative bodies working in regulatory systems strengthening (RSS), and subject matter experts who can provide technical inputs on the recommended minimum common standards and promote the adoption and use of the standards. Examples of stakeholders in this group include WHO, the Bill & Melinda Gates Foundation, South-East Asia Regulatory Network (SEARN), African Union Development Agency- New Partnership for Africa's Development (AUDA-NEPAD), Association of Southeast Asian Nations (ASEAN) and other regional economic communities, and pharmaceutical industry associations.
- **Funders.** This group supports RSS development and implementation and may overlap with the global regulatory experts' group. Examples include the World Bank and the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

Expected results of the Consultative process

The consultation is expected to:

- Produce a set of minimum common standards for the eight GBT regulatory functions identified to support digitalization of regulatory IMS
- Sensitize global stakeholders in regulatory systems strengthening to the importance of adoption and institutionalization of minimum common standards for regulatory IMS

[18] World Health Organization (2021). WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems.
The GBT Revision VI version 1 "comprises eight regulatory functions (Registration and Marketing Authorization, Vigilance, Market Surveillance and Control, Licensing Establishments, Regulatory Inspection, Laboratory Testing, Clinical Trials Oversight, and NRA Lot Release) under the overarching framework of the national regulatory system." https://www.who.int/tools/global-benchmarking-tools/VI

This report documents the proceedings of the second consultative meeting, held virtually on 27 October 2021.

Objectives of the Second Consultative Meeting

This meeting had two sessions, which were structured around the two meeting objectives:

- Develop the use case for the set of minimum common standards
- Identify the selection criteria for the minimum common standards

Each session began with a review of the session's objectives, expected outputs, and discussion questions. Annex 2B lists the meeting agenda and participants. Tamara Hafner of the USAID MTaPS program facilitated the meeting.

SUMMARY OF PROCEEDINGS

The following sections summarize the opening remarks, presentations, and ensuing discussions. Annex 2C includes all the presentation slides.

Welcome and Introductory Remarks

The meeting facilitator, Tamara Hafner, MTaPS Principal Technical Advisor, welcomed participants who joined virtually from 17 organizations (Annex 2B). The USAID MTaPS Program Director, Kofi Aboagye-Nyame, gave opening remarks and thanked everyone for their collaboration. He expressed the importance of improving regulatory standards and access to quality medicines for LMICs, citing the similarity in challenges across LMICs in Africa and Asia for establishing regulatory IMS interoperability, integration, and other requirements. He stated that this group of global experts, led by the USAID MTaPS and PQM+ programs, is working to address a gap that will meet a global need to assist countries adopt uniform standards for regulatory IMS and facilitate smooth exchange of information and data. He wished all fruitful deliberations in the exercise.

Activity Background and Recap of Previous Consultative Meeting

To set the stage for the meeting, Lawrence Evans, Technical Director, USAID PQM+ Program summarized the overarching consultative process and reviewed the outcomes of the previous consultative meeting (held September 15, 2021). The objectives of the previous (first) meeting were to:

- Clearly identify the gaps and challenges NMRAs and other stakeholders are facing with regards to regulatory IMS
- Discuss the scope of minimum common standards for regulatory IMS
- Discuss how a set of minimum common standards for regulatory IMS can address or mitigate the identified gaps and challenges and start building a use case for the standards

At the first meeting, meeting participants discussed the importance of establishing minimum standards, which was a preliminary step in developing the use case. Participants also identified several challenges that might impede the establishment of common minimum standards, such as:

- Interoperability with the international systems with which LMIC national systems must communicate
- Costs that may be prohibitive and impact sustainability of the systems
- Political will and commitment to fund and implement the systems

Participants in the first meeting also agreed on a starting definition for standards that would guide the process of establishing minimum common standards throughout the remainder of the consultative process. Standards were defined as ***the basis of measures, norms, and guidelines for regulatory IMS that would enable uniform data capture, a standardized data exchange platform and workflow of digitalized regulatory functions***, leading to efficiencies and enhanced governance for regulatory IMS.

MTaPS and PQM+ also proposed three categories for the minimum standards, as follows.:

- Process and workflow standards (e.g., good manufacturing practices)
- Standard dictionaries, knowledge trees standard, (e.g., international nonproprietary names)
- Data exchange standards (e.g., CTD and FHIR)

These outcomes lay the foundation for the second consultative meeting, which aims to develop a use case for the set of minimum common standards and the selection criteria for the standards.

Session I: Developing the Use Case for Regulatory IMS Standards

Objective: To clearly define the importance of adopting the minimum common standards and the challenges they will address for NMRAs and other relevant stakeholders.

Output: Draft of key points on the use case to be used in drafting the advocacy brief

Discussion Questions:

- Initial reactions and reflections on the presentation
- Other than NMRAs, who are the target actors/stakeholders for these standards?
- What are the critical needs that these standards should address for each stakeholder group?
- What is the ultimate value for each stakeholder group?

Presentation I

Kate Kikule, Principal Technical Advisor, Regulatory Systems Strengthening, USAID MTaPS, presented an overview of some of the existing standards and some potential benefits to start the discussion of the use case. She also reviewed the working definition of *standards* agreed upon in the previous meeting and the key challenges identified, which are also summarized in the Activity Background and Recap of Previous Consultative Meeting section above. Her overview also explained how the standards would address those challenges and serve as a reference for software development. The potential benefits for the standards include:

- Creation of a single language or common reference for use among regulators, software developers, and policy makers for regulatory IMS

- Guidance for the development of regulatory IMS as they are incorporated into software requirement specifications used by software developers to design regulatory IMS software
- Streamlining NMRAs' internal operations such as workflow management throughout the life cycle of medical products, performance metric tracking, and reporting
- Facilitation of the convergence and harmonization of regulatory services both within and outside of a defined national regulatory authority

The overview presented considerations for adoption of standards by countries and other stakeholders, such as advocacy needs, guidance (or a roadmap) for adoption and dissemination to development partners. Her presentation also included illustrative examples of each category of standards. The full presentation is included in Annex 2C.

Facilitated Discussion I

Initial reactions and reflections to the presentation centered around the proposed benefits to the implementation and adoption of the standards. Participants emphasized the importance of a common language for use by stakeholders in different countries, especially from the perspective of those working on the collection of safety data. The adoption of these standards will also allow for interoperability considerations to be included during system design, rather than retroactively updating systems after launch, which is a much more resource- and time-intensive process. Participants recognized that the potential benefits apply to both LMICs and countries that currently employ advanced regulatory IMS and underscored the need to develop multiple use cases for the standards. Several contributors suggested that the discussion of standards should be more inclusive of standards for medicines, medical devices, and combination products to ensure inclusion of devices for the systems we are discussing (e.g., close relationship between needles and vaccines/insulin as devices and medicines that are used in combination). The USAID MTaPS and PQM+ programs explained that as a result of the desk review exercise, 56 relevant standards were identified. This full list of examples will be shared for review against the selection criteria following the meeting, as part of the consultative process.

Participants were asked to identify the target actors and stakeholders for the regulatory IMS standards and were prompted to consider the use case for NMRAs as a starting point. One response suggested that the team examine the experiences of other standard setting organizations (e.g., Council for International Organizations of Medical Sciences) to identify stakeholders at each point in the regulatory process (e.g., development, clinical trials, registration, surveillance, pharmacovigilance, procurement, waste). This led to a comprehensive discussion of how the standards should be organized/framed and how the participants should think about stakeholder identification for the development of the use cases.

Participants debated whether the GBT modules/regulatory functions or the pharmaceutical product life cycle should be used to structure further work on the standards and the use case. One participant referred to a WHO graphic that overlays the GBT modules with the product life cycle and suggested this could be used as a starting point. The meeting organizers located and projected the graphic for participants to discuss (figure 1).

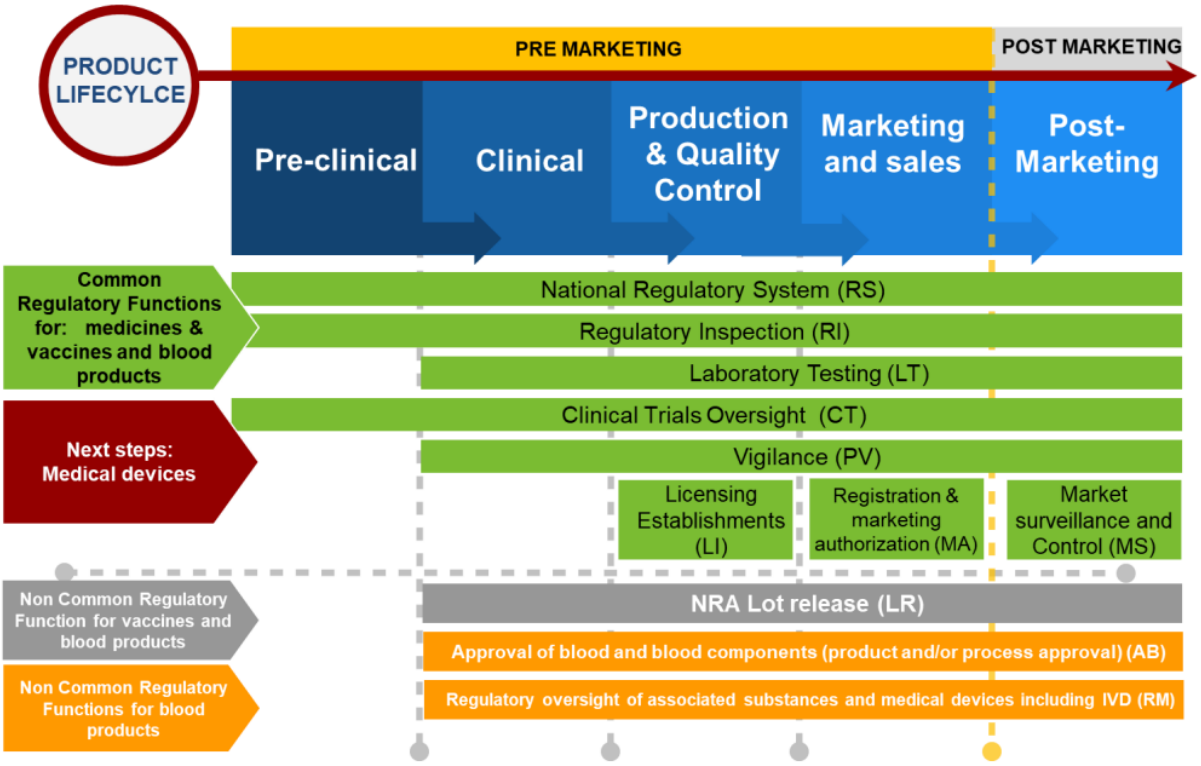

Figure 1. WHO Global Benchmarking Modules and Pharmaceutical Product Lifecycle[19]

Participants agreed that the product should be in the center of their thinking, and that the regulatory functions at each stage in the product life cycle should be examined individually to identify relevant stakeholders and build the use cases. It was suggested that just looking at regulatory functions may miss key points in the product lifecycle that should be considered for adoption of the standards, for example the clinical perspective. Several stakeholders or categories of stakeholders were then proposed by various participants. No final determination was made regarding the key stakeholders for developing use cases during the time allotted for the session. The initial stakeholders discussed during the session are:

- Borrowing from the pharmaceutical inspection cooperation scheme (PICS) process, which is revising the risk mitigation guidance document for PICS member states, some categories that we can build into the various stages of the product life cycle are:
    - Primary audience, such as NMRA, contract research organizations
    - Stakeholders expected to comply with the standards (e.g., manufacturers, distributors, procurement agencies)
    - Those who make the decisions to implement the standards (e.g., policy makers)
    - Those involved in the process of implementation of the standards (e.g., disease programs, development/implementing partners, donor, and funding organizations, etc.)

[19] World Health Organization. Manual for benchmarking of the national regulatory system of medical products and formulation of institutional development plans. Version 1. February 2021. Available: https://cdn.who.int/media/docs/default-source/medicines/regulation-systems/benchmarking_manual_v2_09mar2021_clean.pdf?sfvrsn=33b0038d_5&download=true

    - Beneficiaries of standards (e.g., end users/patients, healthcare providers/Patients (interaction between the regulatory system and care system is important))
    - Others who are affected by the standards (e.g., researchers, academics) and those that help to facilitate adoption
- Other stakeholders to include in the different stages of interest listed above would be:
    - software developers
    - public
    - industry
    - contract research organizations
- Stakeholders categorized by lifecycle stages:
    - Pre-clinical/clinical stage stakeholders (NMRAs, CROs, ethics committee, product sponsors, clinical labs)
    - Production/quality control (NMRAs, CDMOs, manufacturers, standalone quality control (QC) labs, supply chain groups)
    - Marketing/sales (procurement agencies and logistics service providers, suppliers, importers, wholesalers, marketing agencies, advertising agencies)
    - Post-marketing (importers, wholesalers, patients/consumers, drug promotional agency)

During the session, a few participants mentioned that confidentiality should be considered in data sharing arrangements and in the transparency aspects of the standards adoption process. This was noted for further discussion and for future development of guidance documents for adoption that will be developed following the selection of the standards.

Next steps:

- Internal exercise to share with group for reaction/review: Overlay appropriate international standards on the product lifecycles in the slide (e.g., those in the slide, IMDRF, ICH, ISO, etc.) and then as a matrix approach look at who are the stakeholders to which they are applicable.
- Questions to consider:
    - To whom would these standards add value and how do we rank them by priority here?
    - What are the critical needs that these standards should address for each stakeholder group?
    - What are potential consequences for each group if the standards are not adopted?
    - What are some necessary preconditions for adoption?

Session II: Identifying Selection Criteria for Minimum Common Standards

Objective: Identify the criteria the group will use to select the regulatory REGULATORY IMS standards
Output: List of selection criteria
Discussion Question: • In light of the challenges identified and our agreed-on use cases, what should be the selection criteria?

Presentation II

Chinwe U. Owunna, Senior Manager, Health Elements, USAID PQM+ Program provided an overview, which started with a recap of agreed upon approaches from the first consultative meeting. Participants of the first consultation had agreed:

- That the standards are applicable to 8 regulatory functions defined in WHO GBT
- That we would exclude low-level data elements (e.g., date, location, time) and support functions to the regulatory system (e.g., finance, human resources).

The overview summarized the desk review that was conducted internally since the 1st consultative mtg as having yielded 56 standards grouped as follows:

- Process or workflow standards
- Pharmaceutical standard dictionaries and knowledge trees standards
- Data exchange standards

Participants were invited to add to the list any standards that they feel that the desk review missed when it will be shared with them for review. Since we are aiming to trim down the list, the ensuing discussion would identify selection criteria for doing so. An example of how we might apply selection criteria was provided for discussion purposes (figure 2). The complete presentation is available in Annex 2C.

Selection Criteria Application Example

1 = Low priority, 2 = Medium priority, 3 = High priority

Standard	Category	Criteria				Total
		1. Relevance: Be applicable to any of the 8 core regulatory functions as defined in the WHO GBT	2. Feasibility of application: Country capacity, efficiency gains	3. Priority: What would countries lose by not applying a certain standard	4. Universality: Widely used, recommended by the WHO	
Good Clinical Practice (GCP)	Process Standards					
The Medical Dictionary for Regulatory Activities (MedDRA)	Dictionaries & Knowledge Trees					
Structured Product Labelling (SPL)	Data Exchange					

Figure 2. Selection Criteria Application Example

Facilitated Discussion II

Following the presentation and example exercise, participants extensively discussed the proposed scope of the activity, categories of the standards, and selection criteria. Much of the deliberation centered on the inclusion or exclusion of *process standards* – several participants proposed that we differentiate between *standards* and *guidelines* and asserted that including both was outside the proposed scope of the activity and confounded the activity objectives. Others saw the benefit of including these *process*

standards or *guidelines* as a way to identify and harmonize the regulatory processes that are being digitalized. In this framing, the *process standards* can be thought of as prerequisites to the application of the *data dictionaries and knowledge trees* and *data exchange standards*. The need to identify existing tools and standards for each regulatory process and identify gaps was also discussed. Participants proposed that non-existent standards to fill gaps and enable LMICs to collaborate in this space should be considered for inclusion in the scope of the activity. This portion of the discussion concluded with participants wondering whether the scope of the activity should be on system design or rather the content of the system – is there a need to harmonize NMRA regulatory processes from the pre-clinical to post marketing product life cycle stages according to WHO GBT regulatory process requirements, before the selection of standards can be considered?

In terms of the selection criteria, participants discussed the addition of whether NMRAs have a legal mandate to implement a given standard, which turned the discussion to whether the proposed selection criteria could be applied generically to each standard, or whether individual country context needed to be considered when applying the selection criteria. Some participants stated that the selection would need to be done on a country-by-country basis, while others expressed that the selection criteria should be refined to be applicable internationally. Participants also requested clarification on the definitions for the rankings of 1, 2, and 3 for the exercise, and expanded definitions of each of the selection criteria and their relationships and/or weights relative to one another.

In response to the feedback and discussions during this session, the USAID MTaPS and PQM+ programs referenced the agreed definition of *standards*, which includes three elements – measures, norms, and guidelines for regulatory IMS for this exercise. The activity is geared towards the end user and guiding software development, which is why guidelines are included in the definition. This exercise is geared toward putting forward standards that countries can adopt, whether their processes are digitalized or not. The underlying regulatory processes must be clear and strong for any digitalization to be successful. The emphasis is on strengthening the system and ideally but not necessarily digitalizing the system for improved efficiency. Participants will have opportunity to review and add to the standards produced by the desk review and provide feedback on the proposed definitions for the selection criteria and other aspect of the standards selection process. Given the depth of the discussion during the meeting, the USAID MTaPS and PQM+ programs stated that they need to take a step back to consider these points and the consultative process. The next steps include a rethinking of the process and a potential revision of the background document for recirculation to the participants for reactions and feedback.

Close Out & Next Steps

Comfort Ogar, Principal Technical Advisor, Pharmacovigilance USAID MTaPS Program, and Tamara Hafner delivered closing remarks, recapping the meeting's developments. The discussions highlighted the need to reconsider how the activity is defining the prioritization of selection criteria, the scope, and clarify the communication around it. Discussions were rich with feedback and ideas for how to reconsider these issues.

Souly Phanouvong, Senior Technical Advisor, RSS, USAID PQM+ Program summarized the next steps for the consultative process as outlined in the original background document for the consultation. Based on this meeting's discussions, this process will be revised and reshared with the group for feedback and

agreement. Annex 2A shows the revised consultative process, based on the outcomes of the second consultative meeting.

The following action items were identified during the meeting:

- Share the meeting report within the next three weeks with participants
- Revise consultative process and background document and share with participants for feedback
- Propose selection criteria with revised definitions for the group's input
- Share the full list of standards identified from the desk review with participants for review against the selection criteria
- Organizers will draft use case and share for review, additional input, and feedback

ANNEX 2A: OUTLINE OF THE CONSULTATIVE PROCESS

Time (Approx.)	**Activity**	**Task/Objective**	**Expected results**
Sept 15	Consultative meeting I	Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS Discuss the scope of minimum common standards for REGULATORY IMS Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges and start building the use case	Critical gaps and challenges with regulatory IMS identified The scope of the standards for addressing the gaps and challenges defined
Oct 27	Consultative meeting II	Develop selection criteria for minimum common standards Review collated existing standards Finalize the use case	
Nov 19 – Jan 11	External Review I	Review of collated existing standards and identify which standards should be included in the minimum common set	Feedback on standards and selection criteria received from stakeholders Selection criteria applied to standards by stakeholders
Nov 19 – Jan 11	NMRA engagement and review	Engage select NMRA representatives to gather additional input (based on standards selection package)	Feedback on standards and selection criteria received from NMRAs Selection criteria applied to standards by NMRAs Inputs incorporated into draft advocacy brief and adoption guidance document
Nov 30	Collaborative working session 1 (optional)	Optional working session for stakeholders to discuss and complete standards selection and review	
Nov 14	Collaborative working session 2 (optional)	Optional working session for stakeholders to discuss and complete standards selection and review	

Time (Approx.)	Activity	Task/Objective	Expected results
Jan 5	Collaborative working session 3 (optional)	Optional working session for stakeholders to discuss and complete standards selection and review	
Jan 11	Due date for standards selection		
Jan 7 – Feb 8	Internal analysis and synthesis of standards	Consolidate and synthesize the inputs from the experts Draft minimum common standards for regulatory IMS	Preliminary core set of minimum common standards for regulatory IMS identified
Feb 9	Disseminate 1st draft of standards report, advocacy brief, meeting agenda		
Feb 16	Consultative meeting III	Discuss first draft of standards and advocacy brief	Inputs gathered for advocacy brief and second draft of minimum standards
Mar 4	Disseminate 2nd draft of standards & meeting report		
Mar 7 – Mar 18	External review II	Review of proposed standards/report	
Apr 1	Disseminate meeting agenda & standards report		
Apr 13	Debrief	Present minimum common standards Discuss guidance on pathway for countries to adopt minimum common standards to support the digitalization of regulatory functions	Inputs gathered for guidance document

Meeting Agenda

8:00 - 8:20	**Introductions**
8:00 – 8:05	***Meeting logistics*** Tamara Hafner
8:05 – 8:15	***Welcome remarks*** Kofi Aboagye-Nyame, Program Director, USAID MTaPS Program
	Jude Nwokike, Vice President & Director, Promoting the Quality of Medicines Plus (PQM+) Program, USP
8:15 – 8:20	***Review of outcomes from 1st consultation*** Lawrence Evans – Technical Director, PQM+
8:20 - 9:25	**Session I: Developing the use case for the standards** *Objective:* Clearly define the importance of adopting the minimum common standards and the challenges they will address for NMRAs and other relevant stakeholders
	Output: Draft of key points on the use case to be used in drafting the advocacy brief
8:20 - 8:30	Presentation 1: Use case—a proposed starting point Kate Kikule, Principal Technical Advisor, RSS, USAID MTaPS
8:30 - 9:20	Facilitated discussion
9:20 - 9:25	Session I recap Frederick Meadows, Senior Technical Advisor, PSM & CMC, PQM+
9:25 - 9:40	**Break**
9:40 - 10:40	**Session II: Identifying selection criteria for minimum common standards** *Objective:* Identify the criteria the group will use to select the IMS standards
	Output: List of selection criteria
9:40 - 9:50	Presentation I: Overview of proposed process for standards selection Chinwe U. Owunna, Senior Manager, Health Elements, PQM+
9:50 - 10:35	Facilitated discussion
10:35 - 10:40	Session II recap Comfort Ogar, Principal Technical Advisor, Pharmacovigilance, MTaPS

10:40 - 11:00	**Close out** Next steps Souly Phanouvong – Senior Technical Advisor, RSS - PQM+
	Closing remarks Emmanuel Nfor, Technical Director, USAID MTaPS

Participants

First Name	Last Name	Organization
Nancy	Ngum	African Union Development Agency - New Partnership for Africa's Development
David	Mukanga	Bill & Melinda Gates Foundation
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Lawrence	Liberti	Centre for Innovation in Regulatory Science
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Juwe D.	Kercula	Liberia Medicines & Health Products Regulatory Authority
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Kate	Kikule	Management Sciences for Health
Kim	Hoppenworth	Management Sciences for Health
Afeke	Kambui	Management Sciences for Health
Abu	Zahid	Management Sciences for Health
Deane	Putzier	Management Sciences for Health
Kofi	Nyame	Management Sciences for Health
Comfort	Ogar	Management Sciences for Health
Nicole	Barcikowski	Management Sciences for Health
Emmanuel	Nfor	Management Sciences for Health
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Alison	Collins	US Agency for International Development

Alexis	Leonard	US Agency for International Development
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Zlatan	Sabic	World Bank
Michael	Ward	World Health Organization
Alireza	Khadem Broojerdi	World Health Organization

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

October 27, 2021

Welcome to a Virtual Consultation hosted by:

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

USAID PROMOTING THE QUALITY OF MEDICINES PLUS (PQM+) PROGRAM

Facilitator

Tamara Hafner, PhD
Principal Technical Advisor, USAID MTaPS Program

USAID MTaPS and PQM+ Programs

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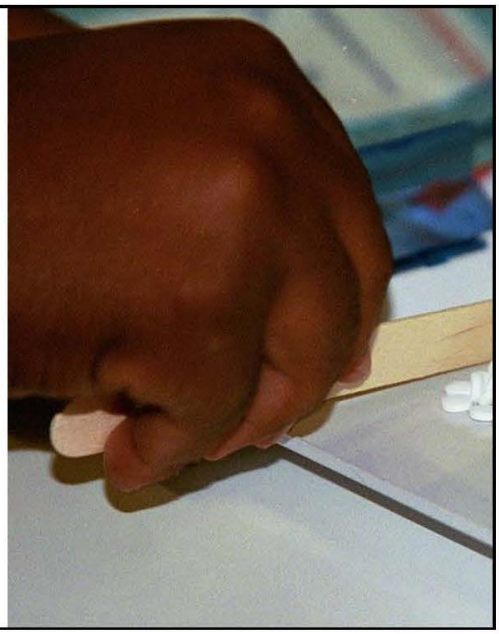
Agenda Overview

8:00 – 8:20	**Introductions**
8:20 – 9:25	**Session I: Developing the use case for the standards**
9:25 – 9:40	**Break**
9:40 – 10:40	**Session II: Identifying selection criteria for minimum common standards**
10:40 – 11:00	**Close out**



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Minimum Common Standards for Regulatory Information Management Systems (IMS) in Low- and Middle-Income Countries

8:00 – 8:20 Introductions

8:00 – 8:05	**Meeting Logistics**	**Tamara Hafner** USAID MTaPS Program
8:05 – 8:15	**Welcome Remarks**	**Kofi Aboagye-Nyame** Program Director, USAID MTaPS Program
8:15 – 8:20	**Review of Outcomes from 1st Consultation**	**Lawrence Evans** Technical Director, USAID PQM+ Program

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Welcome Remarks

Kofi Aboagye-Nyame
Program Director
USAID MTaPS Program

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Review of Outcomes from 1st Consultation

Lawrence Evans
Technical Director
USAID PQM+ Program

5

Activity Objectives

Main Objective:

- Develop and recommend a set of minimum common standards for regulatory IMS

Sub Objectives:

- Identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS
- Derive a recommended set of minimum common standards for regulatory IMS
- Develop the use case for the minimum common standards
- Promote their adoption and use in digitalization of Regulatory IMS

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Meeting Objectives

- Develop the use case for the set of minimum common standards
- Identify the selection criteria for the minimum common standards

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Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

8:20 – 9:25 Session 1: Developing the use case for the standards

Objective:

Clearly define the importance of adopting the minimum common standards and the challenges they will address for NMRAs and other relevant stakeholders

Output:

Draft of key points on the use case to be used in drafting the advocacy brief

Discussion Questions:

- Other than NMRAs, who are the target actors/stakeholders for these standards?
- What are the critical needs these standards should be addressing for each stakeholder group?
- What is the ultimate value for each stakeholder group?
- What are potential consequences for each group if the standards are not adopted?
- What are some necessary preconditions for adoption?

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Presentation 1:
Use case—a proposed starting point

Kate Kikule
Principal Technical Advisor, RSS
USAID MTaPS Program

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What do we mean by "Standards"?

"Standards" refer to:
- Basis of measure
- Norms
- Guidelines for regulatory IMS

Would enable uniform:
- Data capture
- Standardized data exchange platform
- Workflow of digitalized regulatory functions

Leading to:
- Efficiencies
- Enhanced governance of regulatory functions
- Harmonized exchange of regulatory information

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What are some common challenges with regulatory IMS?

- Lack of interoperability
- Lack of integration
- Varying requirements/standards for regulatory processes
- High cost
- Insufficient political will and commitment

How could common minimum standards address some of these challenges?

- Create a common "language"/system design/system architecture.
- Lower the cost of implementing a regulatory IMS system
- Enhance regulatory IMS design capabilities
- Improve collaboration, trust, information sharing and reliance among NRAs
- Enhance efficiency, effectiveness, and performance
- Improve good governance

Standards as a reference for software development

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Potential Benefits of the Standards

- Create a single language or common reference for use among regulators, software developers, and policy makers for regulatory IMS.
- Guide the development of regulatory IMS as they are incorporated into software requirement specifications (SRS) used by software developers to design regulatory IMS software.
- Streamline NMRAs' internal operations such as workflow management throughout the life cycle of medical products, performance metric tracking, and reporting.
- Facilitate convergence and harmonization of regulatory services both within and outside of a defined national regulatory authority.

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Considerations for Adoption

- Countries will need support to develop a roadmap for adoption and identify resources for adoption – human, financial, technical capacity (both IT and regulatory affairs) among others.
- Create awareness through advocacy events - Identify the benefits to countries for using common standards including benefits to patients, manufacturers, distributors, regulators and other stakeholders.
- Dissemination to target groups, Identify development partners and donors that will support countries on this journey –

Example Process & Workflow Standards

Standard	Description
Good Clinical Practices (GCP)	A process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human subjects.
Good Manufacturing Practices (GMP) or ICH Q7	A system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product
ICH Q10	A model for a pharmaceutical quality system that can be implemented throughout the different stages of a product lifecycle. Much of the content of ICH Q10 applicable to manufacturing sites is currently specified by regional GMP requirements.
ISO 13485	Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
Monographs	Pharmacopeial monographs provide an important tool for assurance of the quality of marketed pharmaceutical ingredients and products through testing of their quality. They generally cover chemical, biological and herbal finished pharmaceutical products and their ingredients, which have either been approved by national regulatory authorities or are otherwise legally marketed.

Example Data Dictionaries & Knowledge Trees

Standard	Description
International Nonproprietary Names (INN)	Facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.
Defined Daily Dose (DDD)	The assumed average maintenance dose per day for a drug used for its main indication in adults. Drug utilization data presented in DDDs give a rough estimate of consumption and not an exact picture of actual use.
The Medical Dictionary for Regulatory Activities (MedDRA)	An extensive medical terminology designed for use in the regulation of medical products with a unique architecture and features that support public health monitoring, data analysis, communication (both electronic and traditional) and data management. This terminology is hierarchical, multiaxial, multilingual, regularly-updated, and strictly maintained.
ISO 3166	Defines internationally recognized codes of letters and/or numbers that refer to countries and their subdivisions.
Logical observation identifiers names and codes (LOINC)	A common language (set of identifiers, names, and codes) for identifying health measurements, observations, and documents.

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Example Data Exchange Standards

Standard	Description
Analysis Dataset Model (AdaM)	ADaM defines dataset and metadata standards that support efficient generation, replication, and review of clinical trial statistical analyses, and traceability among analysis results, analysis data, and data represented in the Study Data Tabulation Model (SDTM).
Clinical Data Acquisition Standards Harmonization (CDASH)	Establishes a standard way to collect data consistently across studies and sponsors so that data collection formats and structures provide clear traceability of submission data into the Study Data Tabulation Model (SDTM), delivering more transparency to regulators and others who conduct data review.
Common Technical Document (CTD)	A common format for all quality, safety and efficacy information for application for marketing authorization.
Structured Product Labelling (SPL)	A document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information.
XML	A simple text-based format for representing structured information: documents, data, configuration, books, transactions, invoices, and much more. XML is one of the most widely-used formats for sharing structured information today: between programs, between people, between computers and people, both locally and across networks.

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Facilitated Discussion

8:30 – 9:20
Tamara Hafner

Discussion Questions

- Other than NMRAs, who are the target actors/stakeholders for these standards?
- What are the critical needs these standards should be addressing for each stakeholder group?
- What is the ultimate value for each stakeholder group?
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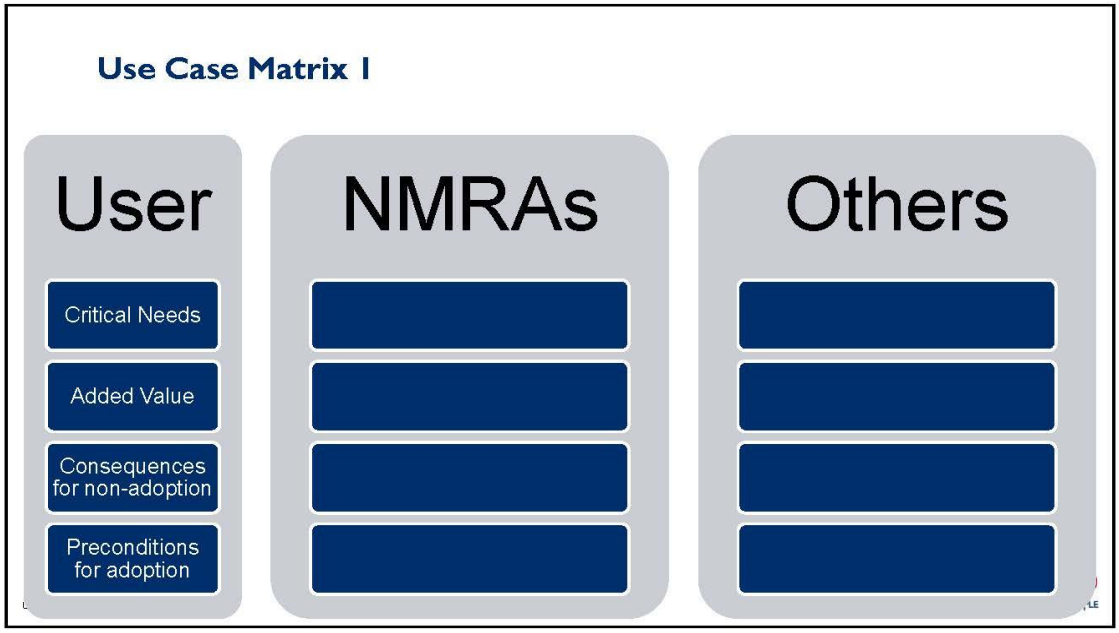
- What are some necessary preconditions for adoption?


Use Case Matrix I
User
Critical Needs
Added Value
Consequences for non-adoption
Preconditions for adoption
NMRAs
Others

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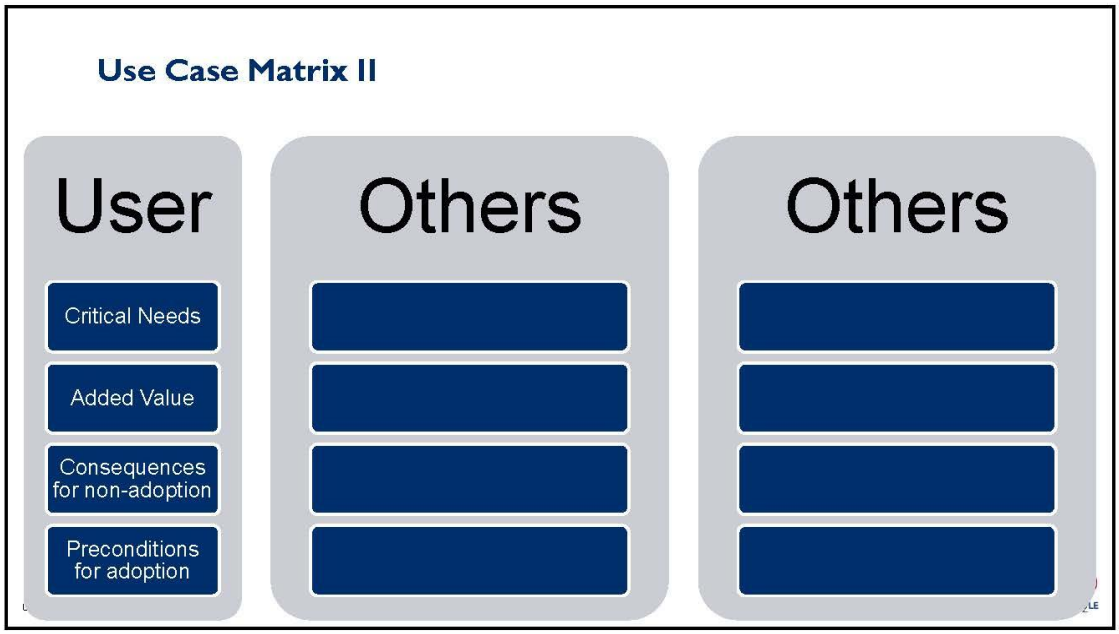
Use Case Matrix II
User
Critical Needs
Added Value
Consequences for non-adoption
Preconditions for adoption
Others
Others

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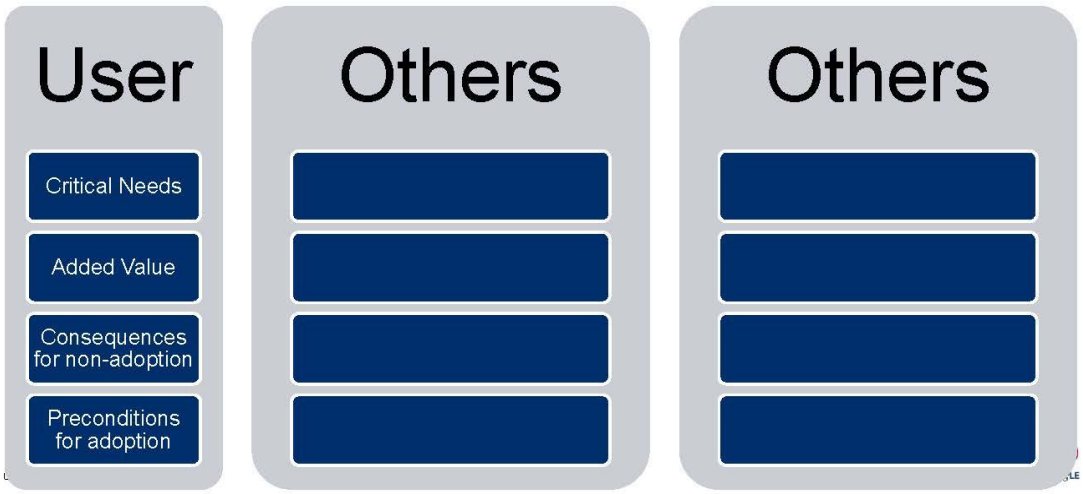
Use Case Matrix III



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Session 1 Recap

9:20 – 9:25
Frederick Meadows
Senior Technical Advisor, PSM & CMC
USAID PQM+ Program

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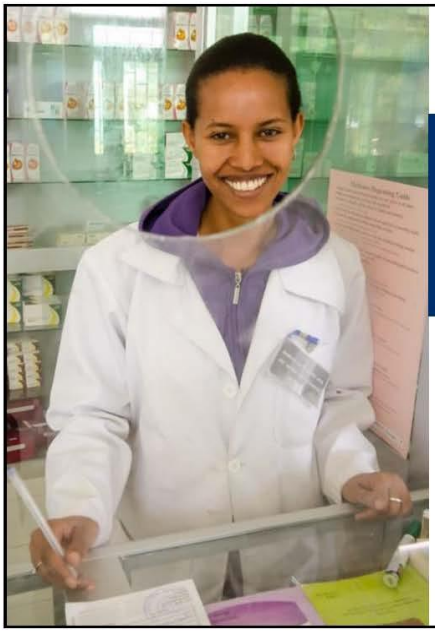

Break

9:25 – 9:40

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Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

9:40 – 10:40 Session II: Identifying selection criteria for minimum common standards

Objective:

Identify the criteria the group will use to select the IMS standards

Output:

List of selection criteria

Discussion Question:

- In light of the challenges identified and our agreed on use cases, what should be the selection criteria?

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Presentation 11:
Overview of proposed process for standards selection

Chinwe U. Owunna
Senior Manager, Health Elements
USAID PQM+ Program

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Review of Existing Standards

Inclusion

- Standards as applicable to the 8 regulatory functions as defined in WHO GBT (ref)

Exclusion

- Low level data elements such as date, location, time
- Support functions to the regulatory system such as finance, human resources

https://www.who.int/tools/global-benchmarking-tools/VI

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Categories of Standards

Desk review yielded 58 standards, grouped into 3 categories

1) Process or workflow standards

- Apply to pharmaceutical:
  - Procedures
  - Processes
  - Workflows

Examples:

- Good practices (GXPs such as Good Manufacturing Practices (GMP)
- International Organization for Standardization standards (ISOs) such as ISO 9001:2015

17 standards identified

2) Pharmaceutical standard dictionaries and knowledge trees

- Master or reference lists for:
  - Terminology
  - Nomenclature
  - Hierarchies

Examples:

- Anatomical Therapeutic Chemical (ATC)
- International Nonproprietary Name (INN)

21 standards identified

3) Data exchange standards

- Pertain to:
  - Information and communications technology
  - Management information system functions
- Determine how data should be structured, defined, formatted

Examples:

- Common Technical Document (CTD) format
- Extensible Markup Language (XML)
- Platforms such as Fast Health Interoperability Resources (FHIR®)

20 standards identified

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Standards Selection Process

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Proposed Selection Criteria

- Relevance—the standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBT
- Feasibility of application—the extent to which NMRAs' capacity and resources feasibly allow adoption and what are the anticipated efficiency gains
- Priority—what would countries benefit or lose by not applying a given standard
- Universality—whether a given standard is recommended by WHO and extent to which it is widely used.

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Selection Criteria Application Example

1 = Low priority, 2 = Medium priority, 3 = High priority

Standard	Category	Criteria				Total
		1. Relevance: Be applicable to any of the 8 core regulatory functions as defined in the WHO GBT	2. Feasibility of application: Country capacity, efficiency gains	3. Priority: What would countries lose by not applying a certain standard	4. Universality: Widely used, recommended by the WHO	
Good Clinical Practice (GCP)	Process Standards					
The Medical Dictionary for Regulatory Activities (MedDRA)	Dictionaries & Knowledge Trees					
Structured Product Labelling (SPL)	Data Exchange					

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Facilitated Discussion

9:50 – 10:35
Tamara Hafner

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Discussion Question

- In light of the challenges identified and our agreed on use cases, what should be the selection criteria?

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Proposed Selection Criteria

- Relevance—the standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBT
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- Priority—what would countries benefit or lose by not applying a given standard
- Universality—whether a given standard is recommended by WHO and extent to which it is widely used.

Session II Recap

10:35 – 10:40
Comfort Ogar
Principal Technical Advisor, Pharmacovigilance
USAID MTaPS Program

Next Steps

Souly Phanouvong
Senior Technical Advisor, RSS
USAID PQM+ Program

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Outline of the Consultative Process

Time (Approx)	Activity	Task/Objective	Expected results
Sept 15	Consultative meeting I	Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS Discuss the scope of minimum common standards for RIMS Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges and start building the use case	Critical gaps and challenges with regulatory IMS identified The scope of the standards for addressing the gaps and challenges defined
Oct 27	Consultative meeting II	Develop selection criteria for minimum common standards Review collated existing standards Finalize the use case	Preliminary core set of minimum common standards for regulatory IMS identified Advocacy brief developed
Oct 27 - Dec 1	External review I	Review of collated existing standards and identify which standards should be included in the minimum common standard set Engage select NMRA representatives to gather additional input	
Nov 1 - Jan 3	Internal analysis and synthesis of standards	Draft advocacy brief Consolidate and synthesize the inputs from the experts Draft minimum common standards for regulatory IMS	
Jan 3 - 27	External review II	Final expert review of the proposed minimum common standards	Finalized set of minimum common standards for regulatory IMS Inputs gathered for guidance on digitalization pathway
Jan 27 - Feb 24	Internal revisions and finalization	Finalize minimum common standards based on feedback Internal reviews and copyediting	
Mar 3	Consultative meeting III	Present minimum common standards Discuss guidance on pathway for countries to adopt minimum common standards to support the digitalization of regulatory functions	

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Poll

Feedback Process on Standards

1. What is your prefered process for providing feedback on the standards? (Single Choice) *

- ○ A two-hour working meeting
- ○ Independent extended review

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Closing Remarks

Emmanuel Nfor
Technical Director
USAID MTaPS Program

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USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

Prime: Management Sciences for Health (MSH)

COR: Alexis Leonard, aleonard@usaid.gov

Learn more: www.mtapsprogram.org

USAID Promoting the Quality of Medicines (PQM+) Program

Prime: U.S. Pharmacopeia (USP)

AOR: Alison Collins, alcollins@usaid.gov

Learn more: www.usp.org/global-public-health/promoting-quality-of-medicines

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Promoting the Quality of Medicines Plus (PQM+)

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

Improved Access. Improved Services. Better Health Outcomes.

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

Report on the 3rd Consultative Meeting with NMRAs Representatives

Held 26 January 2022

1 February 2022

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This document is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074 and Cooperative Agreement No. AID-7200AA19CA00025. The contents are the responsibility of Management Sciences for Health and U.S. Pharmacopeial Convention (USP) and do not necessarily reflect the views of USAID or the United States Government.

About the USAID MTaPS Program

Funded by the U.S. Agency for International Development (USAID) and implemented by a team led by Management Sciences for Health (MSH), the purpose of the five-year Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) is to provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats, as well as expanding essential health coverage. The goal of MTaPS is to help low- and middle-income countries strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines, vaccines, and other health technologies and pharmaceutical services.

About the USAID PQM+ Program

Promoting the Quality of Medicines Plus (PQM+) is a program operating under a USAID-funded cooperative agreement with the U.S. Pharmacopeial Convention (USP) with a goal to sustainably strengthen medical product quality assurance (QA) systems by providing technical assistance to manufacturers of priority health products and build in-country capacity of medicines regulatory authorities to improve product registration, inspection, and post-marketing surveillance for product quality. PQM+ support also includes accreditation of national drug quality control laboratories per ISO/IEC 17025 and/or World Health Organization (WHO) prequalification standards in low- and middle-income countries. PQM+ uses a systems strengthening approach to program implementation to enhance sustainability.[20] The program considers the entire system when designing and delivering technical assistance, focusing on the interaction among all health systems functions[21] as they relate to medical product quality assurance.

To implement PQM+, USP joined forces with a diversified consortium of four core partners, six field-led extension partners, and eight technical resource partners[22] whose extensive technical expertise can be drawn on to achieve desired results.

Recommended Citation

This document may be reproduced if credit is given to USAID PQM+. Please use the following citation:

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[20] Chee G, Pielemeier N, Lion A, Connor C. Why differentiating between health system support and health system strengthening is needed. Int J Health Plann Mgmt. 2013; 28: 85-94. DOI: 10.1002/hpm.2122.
[21] Governance, human resources, service delivery, information systems, financing: https://www.usaid.gov/global-health/health-systems-innovation/health-systems/strengthening-pharmaceutical-systems
[22] https://www.usp.org/sites/default/files/usp/document/our-impact/pqm/pqm-plus-overview-brochure.pdf

ACKNOWLEDGMENTS

The authors would like to thank the participants representing national medical regulatory authorities (NMRAs) for their involvement in this activity. Their contributions are critical to identify and institutionalize a set of minimum common standards for regulatory information management systems that support efficient, transparent, and effective regulation of pharmaceutical products and services.

Fifty-seven participants representing NMRAs from 11 countries contributed, including:

- African Union Development Agency (AUDA) - New Partnership for Africa's Development (NEPAD)
- Bangladesh
- Benin
- Ghana
- Guinea
- Indonesia
- Kenya
- Mali
- Nepal
- Nigeria
- Rwanda
- Uganda

Annex 3B contains a full list of participants.

CONTRIBUTORS AND REVIEWERS

The PQM+ and MTaPS teams listed below developed the technical content for the meeting. Technical Associate Diana Diaz and Project Associate Tarek Abdelhalim prepared this meeting report. Technical Advisor Gabriel K. Kaddu and Principal Technical Advisor Kate Kikule developed the agenda for the meeting. PQM+ Monitoring, Evaluation, and Learning (MEL) Director Leslie Rider-Araki, facilitated the meeting. Senior Technical Advisor for Chemistry Manufacturing Control (CMC) Frederick Meadows and Senior Manager for Health Elements Chinwe U. Owunna developed the workshop materials. Members of the PQM+ and MTaPS teams listed below reviewed the report.

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CONTENTS

EXECUTIVE SUMMARY

Two programs funded by the United States Agency for International Development (USAID) — Promoting the Quality of Medicines Plus (PQM+) and Medicines, Technologies, and Pharmaceutical Services (MTaPS) — convened a virtual consultative meeting on January 26, 2022. It was the third in a series of consultations aimed at identifying and recommending a set of minimum common standards for regulatory information management systems (REGULATORY IMS) that national medicines regulatory authorities (NMRAs) should prioritize to streamline their workflows and documentation of regulatory processes, ensure uniform data capture, and enable data exchange within and between NMRAs and other stakeholders.

The meeting brought together NMRA experts in pharmaceutical regulatory systems and information management systems from 11 countries in Africa and Asia. The main purpose of the meeting was to:

- Provide an overview of the process for identifying a set of minimum common standards for REGULATORY IMS, including defining the scope, objectives, benefits, and the standards selection process.

During this meeting, the importance and benefits of a minimum set of standards for REGULATORY IMS and the challenges with its adoption was discussed. The discussions were structured around the two presentations given at the beginning of each session, and a set of session-specific questions.

As discussed during the meeting, the PQM+ and MTaPS programs proposed that the adoption of a minimum set of common standards for regulatory IMS will:

- Create a single language or common reference for use among regulators, software developers, and policymakers for REGULATORY IMS;
- Guide the development of standards for REGULATORY IMS as developers incorporate them into software requirement specifications (SRS) to design REGULATORY IMS software;
- Streamline NMRAs' internal operations such as workflow management throughout the life cycle of medical products, performance metric tracking, and reporting; and
- Facilitate convergence and harmonization of regulatory services both within and outside a defined national regulatory authority.

Meeting participants acknowledged these benefits; during the first session, NMRA participants identified the following challenges regarding REGULATORY IMS in their settings:

- Lack of information technology (IT) materials, software, infrastructure, servers, and professionals to develop these systems;
- Improper integration or non-existent IMS for regulatory processes;
- Low internet connectivity, data storage, and backup systems for regulatory information;
- Low financial resources and time constraints to develop or improve REGULATORY IMS; and
- Outsourced and expensive software developers sometimes create systems that are not iterative, resulting in manual interventions and a fragmented approach to the automation of regulatory business processes.

Participants discussed how to address these challenges with the adoption of minimum common standards for REGULATORY IMS. Attendees noted that minimum common standards can mitigate these challenges by:

- Providing appropriate technical support and capacity building for related IMS platforms to help minimize errors and increase the accuracy of data capture;
- Supporting reliance, harmonization, and information exchange to optimize regulatory resources;
- Guaranteeing transparency and uniformity of activities, providing a structured framework for communication between the regulatory functions;
- Improving and facilitating the product registration process in a timely manner;
- Pressuring each regulatory authority to procure minimum equipment;
- Encouraging NMRAs to adopt best practices from countries with stronger or more mature regulatory systems to improve technical capabilities;
- Helping NMRAs better manage their policies and processes to achieve specific objectives and outcomes; and
- Supporting good documentation practices within NMRA functions.

The complete list of responses by meeting attendees to the four formulated questions is in the Facilitated Discussion I section.

Session II of the meeting introduced the methodology for the desk review exercise conducted by PQM+ and MTaPS, which identified 56 regulatory standards organized into three categories:

1. Process or workflow standards
2. Data dictionary and knowledge tree standards
3. Data exchange standards

The session also presented the four selection criteria and process that NMRA participants and other stakeholders will use to identify a minimum set of common standards from the list of 56 to prioritize for adoption. The selection criteria are:

1. Relevance: applicable to at least one of the eight core regulatory functions as defined in the World Health Organization (WHO) Global Benchmarking Tool (GBT).
2. Feasibility of application: the extent to which NMRAs' capacity and resources feasibly allow adoption.
3. Criticality: whether the standard is critical (or required) to gain efficiencies in workflow and processes for at least one regulatory function.
4. Universality: how widely a standard is used (e.g., recommended by large normative bodies, industry-wide standards, etc.).

Meeting attendees were also prompted to respond to following questions:

1. What regulatory data standards have you adopted in your country?
2. What is your feedback on the selection criteria used by PQM+/MTaPS to determine minimum common standards for REGULATORY IMS?
3. Do you have any suggestions on how these minimum common standards should be selected?

Based on the ensuing discussion, many countries are applying some of the standards identified in the original desk review. Participants recommended that PQM+ and MTaPS consider including flexibility, universality, and/or harmonization as part of the selection criteria for minimum common standards.

They also discussed next steps in the engagement process to set the expectations and outline the steps and timeline for completion of the selection process for a minimum set of standards for REGULATORY IMS. The meeting closed with thanks to all attendees for their active engagement throughout the meeting and a reiterated request for attendees to work with their colleagues to complete the standard selection activity as presented during the meeting.

BACKGROUND

National medicines regulatory authorities (NMRAs) in low- and middle-income countries (LMICs) often lack fully operational information management systems (IMS) to perform regulatory functions. These systems are often disparate and lack interoperability or are nonexistent, partially implemented, or nonfunctional. Many regulatory functions use paper-based systems, which results in inefficient workflows, backlogs and delays, lack of transparency, mismanagement, and vulnerability to corruption. Digitalization efforts aim to improve consistency, efficiency, and accountability in pharmaceutical regulatory service delivery. However, digitalization approaches vary across NMRAs, which often struggle with fully operationalizing their regulatory IMS (REGULATORY IMS), either desk-based or web-based systems. This limits the availability of real-time data and collaboration between NMRAs.

Ongoing regional regulatory harmonization efforts in Africa and Asia will rely not only on common documents and processes, but also shared REGULATORY IMS that are fully interoperable. This work increases the need for a set of minimum common standards for REGULATORY IMS to help clarify how these systems should capture and report information to promote interoperability within national regulatory systems and support regulatory harmonization efforts.

It is not feasible for countries to apply all the relevant standards to each REGULATORY IMS, so it is necessary to identify a set of minimum common standards for REGULATORY IMS that NMRAs should prioritize to streamline their workflows and documentation of regulatory processes, ensure uniform data capture, and enable data exchange within and between NMRAs and other stakeholders. Two USAID-funded programs — Medicines, Technologies, and Pharmaceutical Services (MTaPS) and Promoting the Quality of Medicines Plus (PQM+) — will engage global stakeholders and subject matter experts to help identify and recommend a set of minimum common standards for REGULATORY IMS. The adoption of these common standards will streamline regulatory processes and help ensure that NMRAs make technical decisions with a degree of consistency and uniformity. Minimum common standards would also enhance the ability of NMRAs to collaborate and share information, including use of reliance and recognition mechanisms.

OBJECTIVES OF THE CONSULTATIVE PROCESS

The primary objective of the consultative process is to derive and recommend a set of minimum common standards for REGULATORY IMS that will enable uniform data capture and standardize the data, design, and workflow of digitalized regulatory functions. Specifically, PQM+ and MTaPS are convening national medicine regulatory authorities' representatives in Africa and Asia to:

- Clearly identify the critical gaps and challenges NMRAs face regarding REGULATORY IMS for the eight regulatory functions outlined in the WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems.
- Use existing relevant IMS and regulatory standards to derive a recommended set of minimum common standards for REGULATORY IMS to address identified gaps and challenges. This includes using defined selection criteria for prioritizing the standards to include in the set of recommended minimum standards.
- Develop the use case for the minimum common standards and help promote their adoption and use.

Welcome and Introductory Remarks

Kofi Aboagye-Nyame, Program Director, USAID MTaPS Program, MSH

Mr. Aboagye-Nyame welcomed attendees and highlighted the importance of the meeting objectives and the benefits to NMRAs. He briefly described how the MTaPS Program's activities support regulatory systems strengthening in Africa and Asia. He stressed the need for support and collaboration at the national level, to build institutional capacity, and to strengthen regional convergence and harmonization. He emphasized that establishing regulatory standards in addition to other regulatory system strengthening efforts will help advance NMRA goals to achieve higher maturity levels (according to the WHO GBT) to provide effective regulatory services to their populations. In closing, he highlighted that this important work aims to address a gap that will support better data and information exchange within and between regulatory authorities and to promote regulatory harmonization and convergence within regions.

Jude Nwokike, Vice President and Director, USAID Promoting the Quality of Medicines Plus (PQM+) Program, USP

Mr. Nwokike welcomed attendees and reiterated the importance of this effort led by USAID's PQM+ and MTaPS programs. He emphasized that every regulatory agency PQM+ assists has at some point explored ways to use information management tools to improve the processes and documentation of one or more aspects of their regulatory function. He stated that REGULATORY IMS in many LMICs currently are fragmented and do not serve the needs of the agencies, partly due to insufficient use of defined common standards. He stressed that efforts to retool and develop new information management systems for regulatory and quality assurance activities need to consider a REGULATORY IMS that is integrated, facilitates efficiency, and ensures transparency in regulatory operations. Mr. Nwokike closed by thanking participants for being part of this important work.

SUMMARY OF PRESENTATIONS AND DISCUSSIONS

Session I: An Introduction to the REGULATORY IMS Activity

Objective:

- Provide an overview of the scope and objectives of the activity and update on current status.

Discussion Questions:

- What are other common challenges with REGULATORY IMS in your setting?
- How could minimum common standards address some of these challenges?
- What are the key considerations for adoption of data standards in your country?
- What regulatory data standards have you adopted in your country?

Presentation I: Activity Objectives, Process Overview, and Key Outcomes

Kate Kikule, Principal Technical Advisor for Pharmaceutical Regulatory Systems

Kate Kikule, principal technical advisor for regulatory systems strengthening at USAID MTaPS, welcomed attendees and presented a summary of the activity, highlighting the problem statement, specific activity objectives, and the consultative process both MTaPS and PQM+ use to engage global, regional, and national regulatory experts to derive a set of minimum common standards for REGULATORY IMS.

She elaborated on the stakeholder engagement process that defines the scope of this activity and identifies potential challenges that can impact the adoption of the common regulatory standards. Prior to this consultative meeting with NMRAs, MTaPS and PQM+ convened two stakeholder consultations. Attendees included global, regional, and national stakeholders, such as WHO, the Bill and Melinda Gates Foundation, the World Bank, the Global Fund, the Center for Innovation in Regulatory Sciences, the New Partnership for Africa's Development (NEPAD), academic institutions, and select NMRAs in Africa and Asia.

The earlier consultative process also identified the following considerations for adoption:

- Countries will need support to develop a roadmap and identify resources for adoption – human, financial, technical capacity (both IT and regulatory affairs), among others.
- Create awareness through advocacy events – identify the benefits to countries for using common standards including benefits to patients, manufacturers, distributors, regulators, and other stakeholders.
- Dissemination to target groups – identify development partners and donors that will support countries on this journey.

Facilitated Discussion I

Following the presentation, participants answered the discussion questions below using the chat function on the WebEx platform.

<u>What are other common challenges with regulatory IMS in your setting?</u>

Challenges identified included:

- Lack of IT professionals and capacity to develop regulatory information management systems;

- Improper integration of systems;
- Nonexistent IMS for regulatory processes;
- IT/information system policy adoption;
- Low internet connectivity;
- Data storage and backup systems for regulatory information;
- Level of effort associated with building a user-friendly system;
- Lack of IT materials/servers and low financial resources; and
- Outsourced and expensive software developers sometimes create systems that are not iterative, resulting in manual interventions and a fragmented approach to automating regulatory business processes.

How could minimum common standards address some of these challenges?

Participants note that minimum common standards can help by:

- Providing appropriate technical support, training, and a universal link for related IMS platforms.
- Minimizing errors (accuracy of captured data and information).
- Supporting reliance and harmonization, information sharing becomes easier and regulatory resources are optimized;
- Standards would be a resource during the design and development of the systems that are expensive to change.
- Minimum common standards may help overcome these challenges through transparency and uniformity in activities.
- Providing a structured framework for communication between the regulatory functions.
- Regulators could adopt IMS from other regulators with minimal changes.
- Improve and facilitate product registration process in a timely manner.
- Providing timely regulatory decision and action.
- Helping NMRAs manage their policies and processes to achieve specific objectives.
- Eliminating user confusion that may arise due to varying system designs.
- Supporting good documentation practices helps accelerate integration efforts in information systems design across all NMRAs and improves regulatory information processing time.

What are the key considerations for adoption of data standards in your country?

Feedback from attendees included:

- Data integrity and security;
- User friendliness and transparency;
- Procurement of IT infrastructure, availability of equipment;
- Implementation of effective change management;
- Need for IT expertise and integrated data management systems;
- Good and unified regulatory decisions, capacity building, and enabling legislation where required;
- Competent personnel through capacity building;
- Budget allocation to purchase and implement the system;
- Support from stakeholders, management, ministries, etc., to ensure a seamless transition from paper-based to digitalized systems while ensuring preservation of existing data;

- Need to implement regulatory data protection and privacy compliance while deploying information systems;
- A robust disaster management plan;
- Strong willingness of the NMRA and government, strong legislation, and the ability to increase support among other stakeholders;
- Rigid political climates, stakeholder engagement and buy-in;
- Periodic training sessions concerning all the weaknesses specified; and
- Business continuity standards, strategies, and legislation adopted.

What regulatory data standards have you adopted in your country?

Attendees noted the following:

- International Council for Harmonization multidisciplinary guideline 4 Common Technical Document (ICH M4 CTD) format is adopted by DGDA for biological products;
- United States of America Title 21Code of Federal Regulations part 11 (21 CFR part 11), National Agency for Food and Drug Administration and Control (NAFDAC) also adopted International Council for Harmonization multidisciplinary guideline 4 Common (ICH M4 CTD);
- World Health Organization Technical Report Series 996 Annex 5 (WHO TRS 996 Annex 5) on data management is considered for other regulatory aspects
- United States of America Title 21Code of Federal Regulations (CFR) part 11 compliant[23]

**Question was posed again following the second presentation to provide more information and clarity on identification and selection of standards for REGULATORY IMS.*

Session II: Selection of Minimum Common Standards for Regulatory IMS/Benefits

Objective:

- Explain the standards selection process.
- Discuss the benefits of having common standards for REGULATORY IMS.

Discussion Questions:

- Which regulatory data standards have you adopted in your country (Common Technical Document (CTD), etc.)?
- What is your feedback on the selection criteria used by PQM+/MTaPS to determine minimum common standards for REGULATORY IMS?
- Do you have suggestions on how the minimum common standards should be selected?

Presentation II: Overview of Collated Standards and Selection Process

Chinwe Owunna, Senior Manager, Health Elements, USAID PQM+ Program

[23] Helpful links for additional context to this bulleted list can be found here: Welcome to the ICH Official Website, Multidisciplinary Guidelines, Code of Federal Regulations - Title 21 - Food and Drugs, National Agency for Food and Drug Administration and Control, Annex 5 Guidance on good data and record management practices

Categories of Standards

Ms. Owunna welcomed attendees and presented a summary of the results of the desk review conducted jointly by PQM+ and MTaPS to compile a shortlist of common regulatory standards that mature regulatory authorities use, along with recommended standards from global bodies (e.g., WHO, International Conference on Harmonization [ICH], International Organization for Standardization [ISO])..

She described the three categories of standards identified through this exercise (see Figure 1).

Seventeen (17) process or workflow standards were identified. She noted that the standards in this category are precursors to the adoption of the other standards, as they are required to establish the process flow of activities for each regulatory function. Twenty-one (21) data dictionaries and knowledge trees were identified to standardize data across various systems. Twenty (20) data exchange standards that facilitate data and information exchange from one electronic system to the next were identified in the third category.

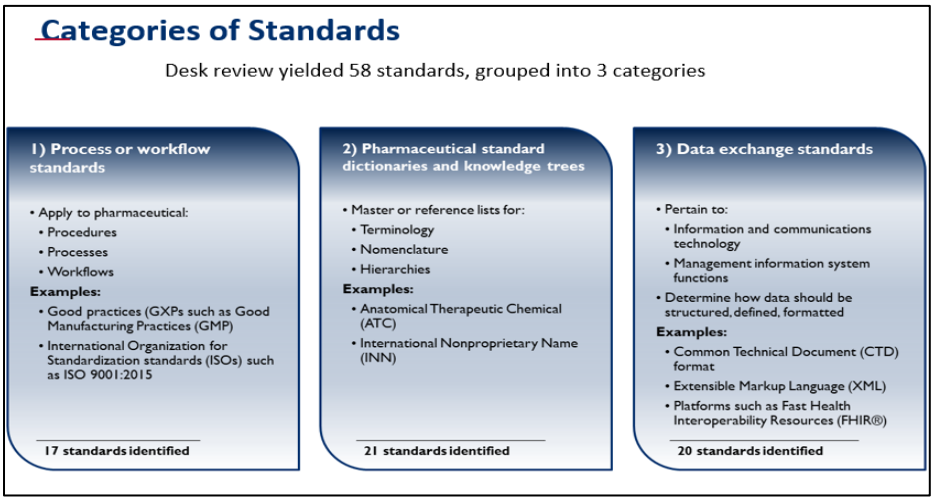

Figure 1. Categories of standards.

Detailed examples were provided. Refer to the meeting slides in Annex 3C for more information.

Ms. Owunna continued the presentation by presenting the steps of the standards selection process.

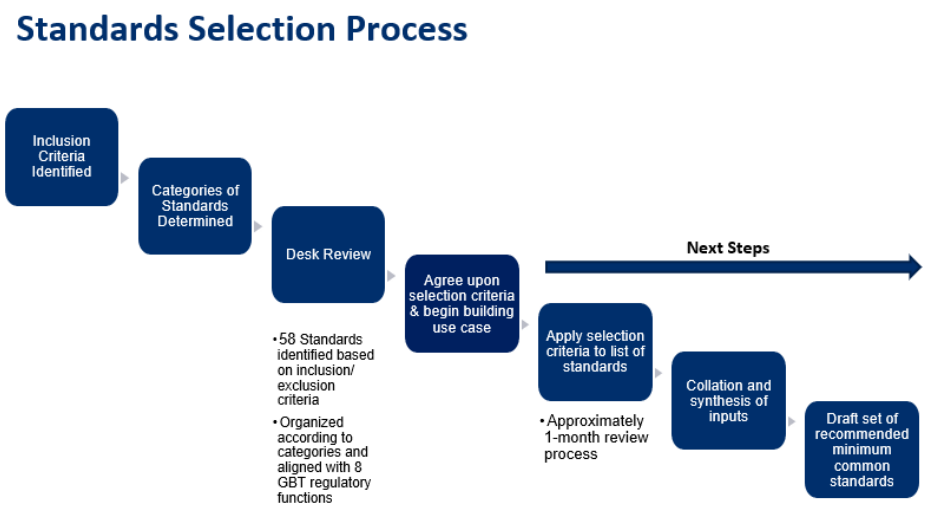

Figure 2. Steps of the standards selection process.

Finally, she introduced the four criteria for selecting the set of minimum common standards that countries should adopt for their REGULATORY IMS.

She identified four main selection criteria and explained the rationale for their selection:

1. Relevance: applicable to at least one of eight core regulatory functions in the WHO GBT;
2. Feasibility of application: the extent to which NMRAs' capacity and resources feasibly allow adoption.
3. Criticality: whether the standard is critical (or required) to gain efficiencies in workflow and processes for at least one regulatory function; and
4. Universality: hw widely a standard is used - recommended by large normative bodies, industry-wide standards, etc.

Ms. Owunna provided a demonstration of the tool developed jointly by PQM+ and MTaPS for applying the selection criteria to each standard identified through the desk review. It was determined that the first criterion cut across all the regulatory functions and therefore did not need to be included in the tool. Ms. Owunna later informed attendees that the tool, with detailed instructions for completion, will be emailed to participating NMRAs within a few days of the meeting.

Facilitated Discussion II

Ms. Rider-Araki facilitated the discussion for the second session of the meeting. Attendees used the WebEx platform chat to respond or raise a hand to speak. Questions and responses received are outlined below.

Which regulatory data standards have you adopted in your country (Common Technical Document [CTD], etc.)?

Meeting participants provided a list of standards their NMRAs has adopted: Good Manufacturing Practices (GMP); Good Distribution Practices (GDP); Good Clinical Practices (GCP); Quality Control Laboratory (QCL); International Organization for Standardization (ISO) 9001; ISO 17025; CTD for registration submissions, etc.; pharmacopoeia; CTD; Harmonized UEMOA CTD; ISO 9001-2015; ISO

13485; International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH); MedDRA; Anatomical Therapeutic Chemical (ATC).

What is your feedback on the selection criteria used by PQM+/MTaPS to determine minimum common standards for REGULATORY IMS?

Participants noted other selection criteria to consider, including flexibility, universality, and harmonization. Attendees were informed they could email the team with any follow-up feedback after the meeting.

Do you have suggestions on how the minimum common standards should be selected?

Participants noted they would like minimum common standards to be selected by the following criteria.

- By the scope of operations of the NMRA, since not all the NMRAs have the same maturity level in all nine functions defined by the Global Benchmarking Tool (GBT).
- REGULATORY IMS that NMRAs have already used with a high level of performance.
- Minimum common standards should meet a minimum of requirements to perform robust, and consistently.
- Harmonization must be part of the selection criteria.

Attendees were also asked about their preference for providing feedback on the minimum standards.

The participants chose between selecting the standards during a two-hour working meeting or through independent extended review. It was agreed that countries should meet on their own to discuss and complete the Excel tool, but if another demonstration on the spreadsheet is necessary, a two-hour meeting will be conducted to help complete the Excel sheet.

Next Steps and Closeout

Gabriel K. Kaddu, technical advisor for regulatory systems strengthening at PQM+, wrapped up the meeting and summarized the next steps. See Figure 3 for details. He highlighted that the aim of the consultative process is to consolidate and synthesize the input from the experts to finalize a draft of the minimum common standards for REGULATORY IMS. After completion of this phase, the team will have a draft document to share for further discussion in March. He noted that in March, the MTaPS and PQM+ programs hope to have another external feedback meeting on the minimum common standards. In May the team hopes to have a consultative meeting to present the minimum common standards compiled for final feedback. Mr. Kaddu concluded by noting that the final output will be the agreed-upon minimum common standards and the implementation pathway document that PQM+ and MTaPS will develop.

Outline of the Consultative Process (Tentative Timelines)

Time (Approx)	Activity	Task/Objective	Expected results
Sept 15	Consultative meeting I	Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS Discuss the scope of minimum common standards for RIMS Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges and start building the use case	Critical gaps and challenges with regulatory IMS identified The scope of the standards for addressing the gaps and challenges defined
Oct 27	Consultative meeting II	Develop selection criteria for minimum common standards Review collated existing standards Finalize the use case	Preliminary core set of minimum common standards for regulatory IMS identified Advocacy brief developed
Oct 27 - Dec 1	External review I	Review of collated existing standards and identify which standards should be included in the minimum common standard set	
Jan 3- 30	NMRA Consultative meeting I	Engage select NMRA representatives to gather additional input Draft advocacy brief	
Jan 21 – Feb 28	Internal analysis and synthesis of standards	Consolidate and synthesize the inputs from the experts Draft minimum common standards for regulatory IMS	
Mar 1 - 31	External review II	Final expert review of the proposed minimum common standards	Finalized set of minimum common standards for regulatory IMS
April 1 - 31	Internal revisions and finalization	Finalize minimum common standards based on feedback Internal reviews and copyediting	Inputs gathered for guidance on digitalization pathway
May 1 - 30	Consultative meeting III	Present minimum common standards Discuss guidance on pathway for countries to adopt minimum common standards to support the digitalization of regulatory functions	

Figure 3. Outline of the consultative process.

Emmanuel Nfor, technical director at MTaPS, delivered the closing remarks. He thanked participants, facilitators, and technical teams at PQM+ and MTaPS for their efforts, highlighting the call for participants to provide feedback on the criteria for selecting of a set of minimum common standards. This includes rating of the selected standards with some justification comments for the rating. Mr. Nfor encouraged attendees to advocate for REGULATORY IMS common standards within their regulatory agencies and among colleagues so they are ready to adopt the common standards once this activity is finalized.

ANNEX 3A: MEETING AGENDA

8:00 - 8:20	Introductions
8:00 – 8:10	Meeting logistics Leslie RiderAraki Evaluation Monitoring and Learning (MEL) Director PQM+
8:10 – 8:20	Welcome remarks Kofi Aboagye-Nyame, Program Director, USAID MTaPS Program Jude Nwokike, Vice President & Director, Promoting the Quality of Medicines Plus (PQM+) Program, USP
8:20 - 9:25	Session I: An introduction to the REGULATORY IMS Activity Objective: Provide an overview of the scope and objectives of the activity and update on current status.
8:20 - 8:45	Presentation 1: Activity objectives, process overview and key outcomes Kate Kikule, Principal Technical Advisor, RSS, USAID MTaPS
8:45 - 9:20	Q&A
9:20 - 9:25	Session I recap Frederick Meadows, Senior Technical Advisor, PSM & CMC, PQM+
9:25 - 9:40	Break
9:40 - 10:40	Session II: Selection of minimum common standards Objective: Explain the standards selection process Discuss the benefits of having common standards for REGULATORY IMS
9:40 - 10:00	Presentation II: Overview of collated standards and selection process Chinwe U. Owunna, Senior Manager, Health Elements, PQM+
10:00 - 10:35	Q&A
10:35 - 10:40	Session II recap Maura Soucy Brown, Senior Technical Advisor, USAID MTaPS
10:40 - 11:00	Closeout Next steps Souly Phanouvong – Senior Technical Advisor, RSS - PQM+
	Closing remarks Emmanuel Nfor – Technical Director, USAID MTaPS

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Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

January 26, 2021

Welcome to a Virtual Consultation hosted by:

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

USAID PROMOTING THE QUALITY OF MEDICINES PLUS (PQM+) PROGRAM

Facilitator

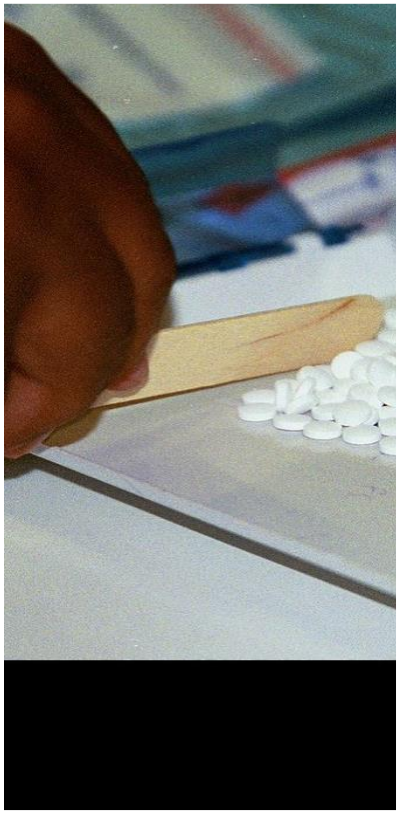
Leslie RiderAraki
USAID PQM+ Program

USAID FROM THE AMERICAN PEOPLE

USAID MTaPS and PQM+ Programs

Agenda Overview

8:00 – 8:20	**Welcome**
8:20 – 9:25	**Session I: An introduction to the RIMS Activity**
9:25 – 9:40	**Break**
9:40 – 10:40	**Session II: Selection of minimum common standards/ benefits of common standards**
10:40 – 11:00	**Next steps & closing remarks**



USAID MTaPS and PQM+ Programs

Meeting Logistics

Leslie RiderAraki
MEL Director
USAID PQM+ Program

Welcome Remarks

Kofi Aboagye-Nyame
Program Director
USAID MTaPS Program

Jude Nwokike
Vice President & Director,
USAID PQM+ Program

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

January 26, 2022

8:20 – 9:25 Session I: An introduction to the RIMS Activity

8:20 – 8:45	**Presentation I**	**Kate Kikule** Principal Technical Advisor for Pharmaceutical Regulatory Systems USAID MTaPS Program
8:45 – 9:20	**Q&A**	**Leslie RiderAraki** MEL Director USAID PQM+ Program
9:20-9:25	**Session I recap**	**Fred Meadows** Senior Technical Advisor USAID PQM+ Program
9:25-9:40	**Break**	

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Presentation 1:
Activity objectives, process overview and key outcomes

Kate Kikule
Principal Technical Advisor, RSS
USAID MTaPS Program

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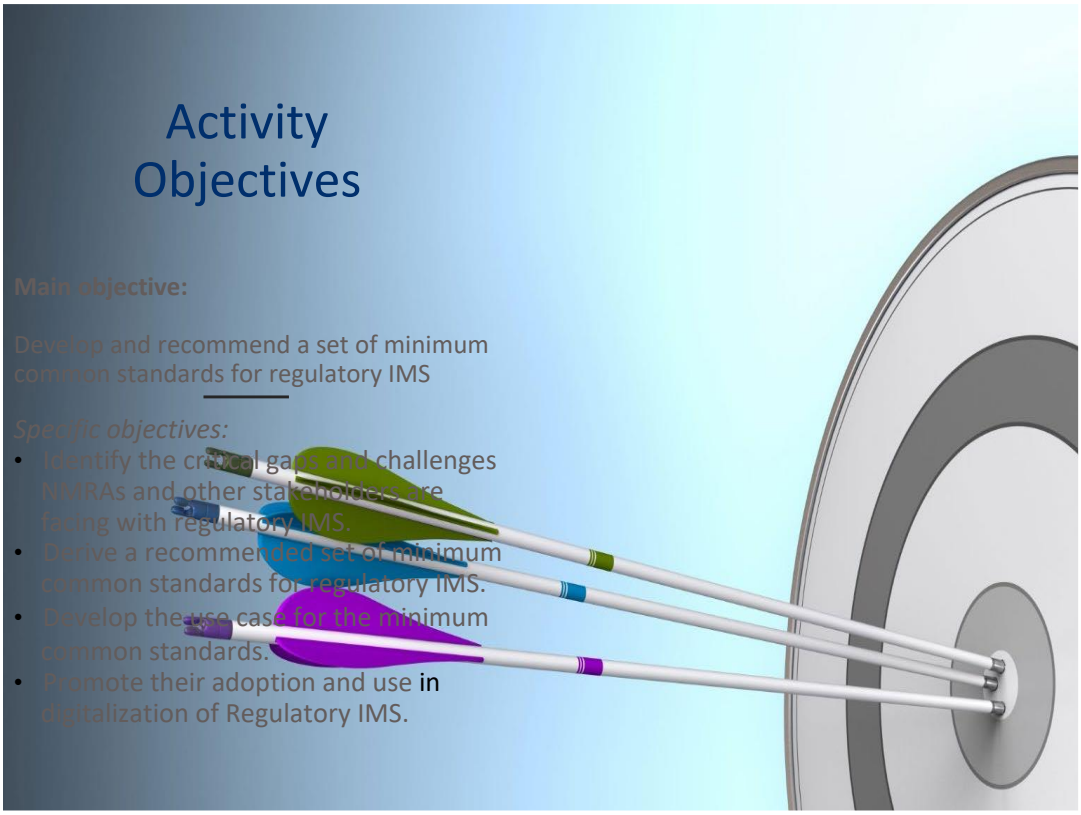
Context

- LMICs of Africa, Asia and Latin America bear a significant proportion of the global burden of disease.
- NMRAs promote access to quality-assured, safe and efficacious medicines and combat SF medical products but capacity in LMICs is insufficient.
- Inefficient regulatory workflows, lack of transparency, mismanagement, and vulnerability to corruption.
- NMRAs have initiated digitalization to improve consistency, efficiency, and accountability in regulatory services.



Overview of Activity

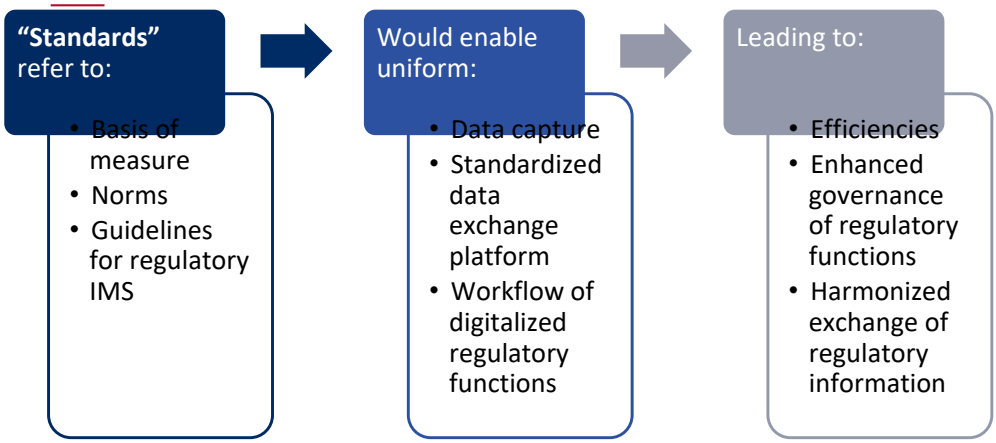
- First consultative meeting held September 15, 2021
  - Identify critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS
  - Discuss the scope of minimum common standards for RIMS
  - Discuss how a set of minimum common standards for RIMS can best address critical challenges
  - Build the use case for a set of minimum common standards
- Second consultative meeting held October 27, 2021
  - Develop the use case for the set of minimum common standards
  - Identify the selection criteria for the minimum common standards

Meeting Objectives

Orient NMRAs on the RIMS activity and consultative process

Explain the standards selection process

What do we mean by “Standards”?



Scope

Inclusion

- Standards as applicable to the 8 regulatory functions as defined in WHO GBT

Exclusion

- Low-level data elements such as date, location, time
- Support functions to the regulatory system, such as finance and human resources

https://www.who.int/tools/global-benchmarking-tools/VI

Some common challenges with regulatory IMS

- Lack of interoperability
- Lack of integration
- Varying requirements/standards for regulatory processes
- High cost
- Insufficient political will and commitment

Potential benefits of the standards

- Create a single language or common reference for use among regulators, software developers, and policy makers for regulatory IMS.
- Guide the development of regulatory IMS as they are incorporated into software requirement specifications (SRS) used by software developers to design regulatory IMS software.
- Streamline NMRAs' internal operations such as workflow management throughout the life cycle of medical products, performance metric tracking, and reporting.
- Facilitate convergence and harmonization of regulatory services both within and outside of a defined national regulatory authority.

Considerations for adoption

- Countries will need support to develop a roadmap for adoption and identify resources for adoption – human, financial, technical capacity (both IT and regulatory affairs) among others.
- Create awareness through advocacy events – identify the benefits to countries for using common standards including benefits to patients, manufacturers, distributors, regulators and other stakeholders.
- Dissemination to target groups – identify development partners and donors that will support countries on this journey

Questions and Answers

Leslie RiderAraki
MEL Director
USAID PQM+ Program

USAID MTaPS and PQM+ Programs

Q&A Session I

- What are other common challenges with regulatory IMS in your setting?
- How could minimum common standards address some of these challenges?
- What are the key considerations for adoption of data standards in your country?

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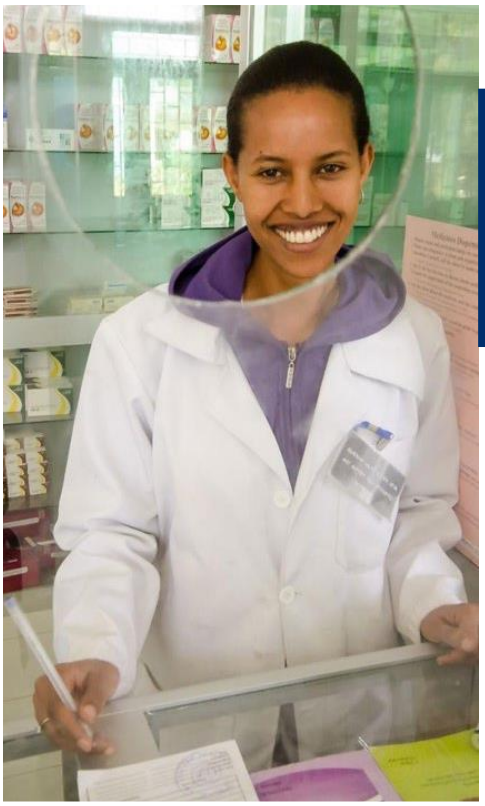
Session I recap

Fred Meadows
Senior Technical Advisor, PSM & CMC
USAID PQM+ Program

USAID MTaPS and PQM+ Programs



Break

Session I – 9:25 – 9:40

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

January 26, 2022

9:40 – 10:40 Session II: Selection of minimum common standards for RIMS/Benefits

9:40 – 10:00	**Presentation II**	**Chinwe U. Owunna** **Senior Manager** USAID PQM+ Program
10:00 – 10:35	**Q&A**	**Leslie RiderAraki** **Mel Director** USAID PQM+ Program
10:35 - 10:40	**Session II recap**	**Maura Soucy Brown** **Senior Technical Advisor** USAID MTaPS Program

Presentation I1:
overview of collated standards and selection process

Chinwe U. Owunna
Senior Manager, Health Elements
USAID PQM+ Program

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Categories of Standards

Desk review yielded 58 standards, grouped into 3 categories

1) Process or workflow standards

- Apply to pharmaceutical:
  - Procedures
  - Processes
  - Workflows

Examples:

- Good practices (GXPs such as Good Manufacturing Practices (GMP)
- International Organization for Standardization standards (ISOs) such as ISO 9001:2015

17 standards identified

2) Pharmaceutical standard dictionaries and knowledge trees

- Master or reference lists for:
  - Terminology
  - Nomenclature
  - Hierarchies

Examples:

- Anatomical Therapeutic Chemical (ATC)
- International Nonproprietary Name (INN)

21 standards identified

3) Data exchange standards

- Pertain to:
  - Information and communications technology
  - Management information system functions
- Determine how data should be structured, defined, formatted

Examples:

- Common Technical Document (CTD) format
- Extensible Markup Language (XML)
- Platforms such as Fast Health Interoperability Resources (FHIR®)

20 standards identified

Example Process & Workflow Standards

Standard	Description
Good Clinical Practices (GCP)	A process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human subjects.
Good Manufacturing Practices (GMP) or ICH Q7	A system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.
ICH Q10	A model for a pharmaceutical quality system that can be implemented throughout the different stages of a product lifecycle. Much of the content of ICH Q10 applicable to manufacturing sites is currently specified by regional GMP requirements.
ISO 13485	Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
Monographs	Pharmacopeial monographs provide an important tool for assurance of the quality of marketed pharmaceutical ingredients and products through testing of their quality. They generally cover chemical, biological and herbal finished pharmaceutical products and their ingredients, which have either been approved by national regulatory authorities or are otherwise legally marketed.

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Example Data Dictionaries & Knowledge Trees

Standard	Description
International Nonproprietary Names (INN)	Facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.
Defined Daily Dose (DDD)	The assumed average maintenance dose per day for a drug used for its main indication in adults. Drug utilization data presented in DDDs give a rough estimate of consumption and not an exact picture of actual use.
The Medical Dictionary for Regulatory Activities (MedDRA)	An extensive medical terminology designed for use in the regulation of medical products with a unique architecture and features that support public health monitoring, data analysis, communication (both electronic and traditional) and data management. This terminology is hierarchical, multiaxial, multilingual, regularly-updated, and strictly maintained.
ISO 3166	Defines internationally recognized codes of letters and/or numbers that refer to countries and their subdivisions.
Logical observation identifiers names and codes (LOINC)	A common language (set of identifiers, names, and codes) for identifying health measurements, observations, and documents.

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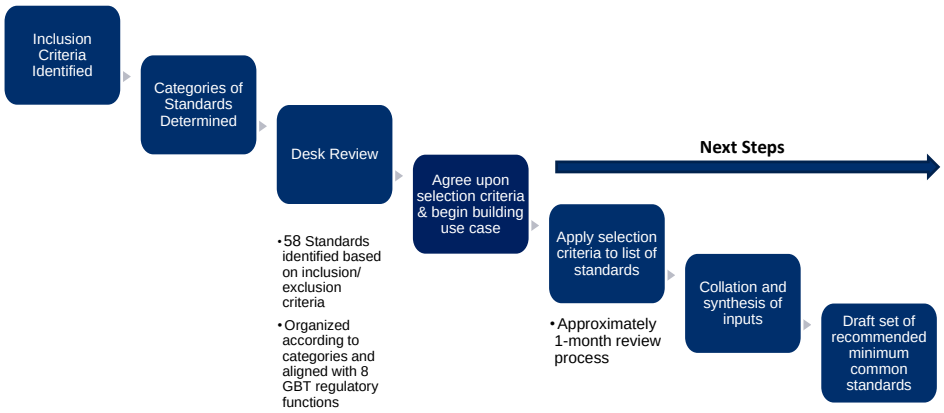
Example Data Exchange Standards

Standard	Description
Analysis Dataset Model (AdaM)	ADaM defines dataset and metadata standards that support efficient generation, replication, and review of clinical trial statistical analyses, and traceability among analysis results, analysis data, and data represented in the Study Data Tabulation Model (SDTM).
Clinical Data Acquisition Standards Harmonization (CDASH)	Establishes a standard way to collect data consistently across studies and sponsors so that data collection formats and structures provide clear traceability of submission data into the Study Data Tabulation Model (SDTM), delivering more transparency to regulators and others who conduct data review.
Common Technical Document (CTD)	A common format for all quality, safety and efficacy information for application for marketing authorization.
Structured Product Labelling (SPL)	A document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information.
XML	A simple text-based format for representing structured information: documents, data, configuration, books, transactions, invoices, and much more. XML is one of the most widely-used formats for sharing structured information today: between programs, between people, between computers and people, both locally and across networks.

Standards Selection Process



Selection Criteria

- Relevance— Applicable to at least one of the eight core regulatory functions as defined in the WHO GBT.
- Feasibility of application—The extent to which NMRAs' capacity and resources feasibly allow adoption.
- Criticality—Whether the standard is critical (or required) to gain efficiencies in workflow and processes for at least one regulatory function.
- Universality—How widely a standard is used - recommended by large normative bodies, industry-wide standards, etc.

Display Excel File

Session II: Questions and Answers

Leslie RiderAraki
MEL Director
USAID PQM+ Program

Q&A Session 2

- What regulatory data standards have you adopted in your country (CTD, ICR, etc.)?
- What is your feedback on the selection criteria used by PQM+/MTaPS to determine minimum common standards for RIMS?
- Do you have an suggestions on how the minimum common standards should be selected?

Poll

Feedback Process on Standards

1. What is your prefered process for providing feedback on the standards? (Single Choice) *

- ◯ A two-hour working meeting
- ◯ Independent extended review

Session II: recap

Maura Soucy Brown
Senior Technical Advisor
USAID MTaPS Program

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Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

January 26, 2022

10:40 – 11:00 Closeout

Next steps	**Gabriel Kaddu** **Technical Advisor, RSS** USAID PQM+ Program
Closing remarks	**Emmanuel Nfor** **Technical Director** USAID MTaPS Program

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Next Steps

Gabriel Kaddu
Technical Advisor, RSS
USAID PQM+ Program

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Outline of the Consultative Process (Tentative Timelines)

Time (Approx)	Activity	Task/Objective	Expected results
Sept 15	**Consultative meeting I**	Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS Discuss the scope of minimum common standards for RIMS Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges and start building the use case	Critical gaps and challenges with regulatory IMS identified The scope of the standards for addressing the gaps and challenges defined
Oct 27	**Consultative meeting II**	Develop selection criteria for minimum common standards Review collated existing standards Finalize the use case	Preliminary core set of minimum common standards for regulatory IMS identified Advocacy brief developed
Oct 27 - Dec 1	**External review I**	Review of collated existing standards and identify which standards should be included in the minimum common standard set	
Jan 3- 30	**NMRA Consultative meeting I**	Engage select NMRA representatives to gather additional input Draft advocacy brief	
Jan 21 – Feb 28	**Internal analysis and synthesis of standards**	Consolidate and synthesize the inputs from the experts Draft minimum common standards for regulatory IMS	
Mar 1 - 31	**External review II**	Final expert review of the proposed minimum common standards	Finalized set of minimum common standards for regulatory IMS Inputs gathered for guidance on digitalization pathway
April 1 - 31	**Internal revisions and finalization**	Finalize minimum common standards based on feedback Internal reviews and copyediting	
May 1 - 30	**Consultative meeting III**	Present minimum common standards Discuss guidance on pathway for countries to adopt minimum common standards to support the digitalization of regulatory functions	

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Closing remarks

Emmanuel Nfor
Technical Director
USAID MTaPS Program

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USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

Prime: Management Sciences for Health (MSH)

COR: Alexis Leonard, aleonard@usaid.gov

Learn more: www.mtapsprogram.org

USAID Promoting the Quality of Medicines (PQM+) Program

Prime*:* U.S. Pharmacopeia (USP)

AOR: Alison Collins, alcollins@usaid.gov

Learn more: www.usp.org/global-public-health/promoting-quality-of-medicines

ANNEX 3D: OUTLINE OF THE CONSULTATIVE PROCESS

Time (Approx)	Activity	Task/Objective	Expected results
Sept. 15	Consultative meeting I	Clearly identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS	Critical gaps and challenges with regulatory IMS identified The scope of the standards for addressing the gaps and challenges defined
		Discuss the scope of minimum common standards for regulatory IMS	
		Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges and start building the use case	
Oct. 27	Consultative meeting II	Develop selection criteria for minimum common standards	Preliminary core set of minimum common standards for regulatory IMS identified Advocacy brief developed
		Review collated existing standards	
		Finalize the use case	
Oct. 27 – Dec. 1	External review I	Review of collated existing standards and identify which standards should be included in the minimum common standard set	
Jan. 3 – 30	NMRA Meeting (Consultative meeting III)	Engage select NMRA representatives to gather additional input	
		Draft advocacy brief	
Jan. 21 – Feb. 28	Internal analysis and synthesis of standards	Consolidate and synthesize the inputs from the experts	
		Draft minimum common standards for regulatory IMS	
March 1 – 31	External review II	Final expert review of the proposed minimum common standards	Finalized set of minimum common standards for regulatory IMS Inputs gathered for guidance on digitalization pathway
April 1 – 31	Internal revisions and finalization	Finalize minimum common standards based on feedback	
		Internal reviews and copyediting	
May 1 – 30	Consultative meeting III	Present minimum common standards	
		Discuss guidance on pathway for countries to adopt minimum common standards to support the digitalization of regulatory functions	

Promoting the Quality of Medicines Plus (PQM+)

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

Improved Access. Improved Services. Better Health Outcomes.

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

Report on the 4TH Consultative Meeting

Held 02 June 2022

USAID FROM THE AMERICAN PEOPLE

This document is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074 and Cooperative Agreement No. AID-7200AA19CA00025. The contents are the responsibility of Management Sciences for Health and U.S. Pharmacopeial Convention (USP) and do not necessarily reflect the views of USAID or the United States Government.

About the USAID MTaPS Program

Funded by the U.S. Agency for International Development (USAID) and implemented by a team led by Management Sciences for Health (MSH), the purpose of the five-year Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) is to provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats, as well as expanding essential health coverage. The goal of MTaPS is to help low- and middle-income countries strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines, vaccines, and other health technologies and pharmaceutical services.

About the USAID PQM+ Program

Promoting the Quality of Medicines Plus (PQM+) is a program operating under a USAID-funded cooperative agreement with the U.S. Pharmacopeial Convention (USP) with a goal to sustainably strengthen medical product quality assurance (QA) systems by providing technical assistance to manufacturers of priority health products and build in-country capacity of medicines regulatory authorities to improve product registration, inspection, and post-marketing surveillance for product quality. PQM+ support also includes accreditation of national drug quality control laboratories per ISO/IEC 17025 and/or World Health Organization (WHO) prequalification standards in low- and middle-income countries. PQM+ uses a system strengthening approach to program implementation to enhance sustainability.[24] The program considers the entire system when designing and delivering technical assistance, focusing on the interaction among all health systems functions[25] as they relate to medical product quality assurance.

To implement PQM+, USP joined forces with a diversified consortium of four core partners, six field-led extension partners, and eight technical resource partners[26] whose extensive technical expertise can be drawn on to achieve desired results.

Recommended Citation

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[24] Chee G, Pielemeier N, Lion A, Connor C. Why differentiating between health system support and health system strengthening is needed. Int J Health Plann Mgmt. 2013; 28: 85-94. DOI: 10.1002/hpm.2122.
[25] Governance, human resources, service delivery, information systems, financing: https://www.usaid.gov/global-health/health-systems-innovation/health-systems/strengthening-pharmaceutical-systems
[26] https://www.usp.org/sites/default/files/usp/document/our-impact/pqm/pqm-plus-overview-brochure.pdf

ACKNOWLEDGMENTS

The authors would like to thank the participants representing national medicines regulatory authorities (NMRAs), continental, and international organizations for their involvement in this activity. Their contributions are critical to identify and institutionalize a set of minimum common standards for regulatory information management systems that support efficient, transparent, and effective regulation of pharmaceutical products and services.

Forty-nine participants representing nine countries and four regional and global organizations contributed, including:

- African Union Development Agency (AUDA) - New Partnership for Africa's Development (NEPAD)
- Benin
- Ghana
- Kenya
- Mali
- Nigeria
- Pakistan
- Rwanda
- Senegal
- Uganda
- The Global Fund
- The World Health Organization (WHO)
- United States Agency for International Development (USAID)

CONTRIBUTORS AND REVIEWERS

The PQM+ and MTaPS teams listed below developed the technical content for the meeting. Technical Coordinator Diana Diaz and Senior Technical Advisor Nereah Kisera prepared this meeting report. Senior Technical Advisor Souly Phanouvong developed the agenda for the meeting. PQM+ Monitoring, Evaluation, and Learning (MEL) Director Leslie Rider-Araki facilitated the meeting. Senior Technical Advisor Frederick Meadows, Senior Technical Advisor Maura Soucy Brown, Principal Technical Advisor Kate Kikule and Senior Principal Technical Advisor Deane Putzier developed the workshop materials. Members of the PQM+ and MTaPS teams listed below reviewed the report.

USAID PQM+ Program

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Gabriel Kaddu, Technical Advisor, Regulatory Systems Strengthening
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Maura Soucy Brown, Senior Technical Advisor
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CONTENTS

EXECUTIVE SUMMARY

The United States Agency for International Development (USAID) funded Medicines Technologies and Pharmaceutical Services (MTaPS) and USAID funded Promoting Quality of Medicines Plus (PQM+) programs convened a virtual meeting on June 2, 2022. The meeting was the fourth in a series of consultations aimed at identifying and recommending a set of minimum common standards for regulatory information management systems (IMS) that will enable uniform data capture and standardize the data, design, and workflow of digitalized regulatory functions. The meeting brought together forty-nine experts in regulatory system strengthening and information management systems representing nine countries and four regional and global organizations, and the objectives were to:

- Share the results of feedback from stakeholders on selection of the minimum common standards for regulatory IMS
- Agree on the minimum common standards for regulatory IMS and
- Propose next steps involving advocacy for adoption of the minimum common standards by NMRAs

During this meeting, the MTaPS and PQM+ representatives provided an overview of the consultative process that led to the identification of 56 standards and culminated in the selection of minimum common standards (MCS) for regulatory IMS.

Session 1 discussed the consultative process and methodology for selecting the minimum common standards based on the following criteria:

- Relevance—the standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBT v2.0
- Feasibility—the extent to which NMRAs' capacity and resources feasibly allow adoption and what are the anticipated efficiency gains
- Criticality—what would countries benefit or lose by not applying a given standard
- Universality—whether a given standard is recommended by WHO and extent to which it is widely used

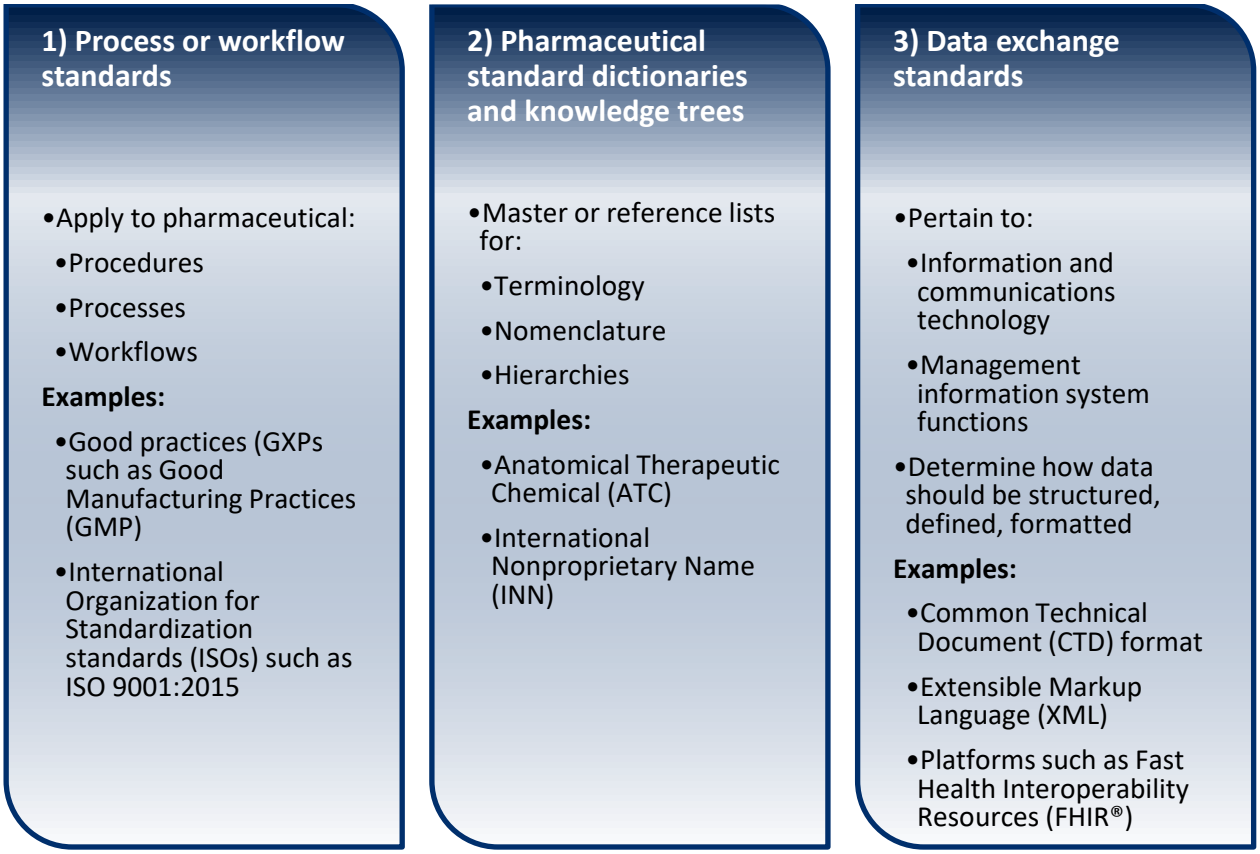
The list of 56 identified standards was circulated to all participants in the preceding three consultative meetings. Participants were asked to evaluate each criterion on a scale of 1 to 3 for each of the 56 standards. Definitions for each rating are included in Table 1. During this selection exercise, relevance was excluded from participant consideration – the 56 identified standards were deemed relevant for inclusion by the MTaPS and PQM+ teams during the literature review process.

Table 1 – Rating definitions by selection criteria

Rating Scale	Feasibility	Criticality	Universality
1	Adopted with greater difficulty, significant technical assistance required	Regulatory performance/ processes not impacted without the standard	Not widely used in LMICs
2	Adopted with medium difficulty, marginal technical assistance required	Regulatory performance/ processes may be impacted without the standard	The standard is moderately widespread
3	Adopted with minimal, if any, technical assistance	Regulatory performance/ processes impacted without the standard	Widely used or recommended by industry or normative bodies

These 56 standards were further divided into three categories:

Figure 9 - Categories of Standards



The final list of MCS was developed based on analysis of the feedback received from eleven respondents and informed by the MTaPS and PQM+ teams' expertise across regulatory functions.

The first step in the data analysis was the computation of unweighted mean scores received from participants. As the analysis proceeded, MTaPS and PQM+ experts examined the results based on category of standard, respondent type (global, regional, or national), regulatory function according to the WHO GBT v2.0, and pharmaceutical product lifecycle alignment. The MTaPS and PQM+ teams determined that

the criterion for feasibility should be excluded from the selection process – this criterion should determine the order in which NMRAs should adopt each standard in the list of MCS. Universality and criticality were combined to select the standards, which were then sorted by their assigned feasibility scores to recommend how countries should incorporate the selected standards in their regulatory IMS.

All the identified process standards, except for those pertaining specifically to medical devices, were selected for inclusion in the MCS. The standards pertaining to medical devices were excluded to align with The World Health Organization Global Benchmarking Tool Version 2.0 (medicines & vaccines). Participants expressed the expectation that standards for medical devices would be included the future set of MCS. The remaining process standards are considered prerequisite to digitalizing regulatory IMS or adopting the other standards (data dictionaries & knowledge trees, data exchange). The list of standards recommended for adoption are below, listed in order from the most to least feasible to adopt.

Figure 10 - Selected minimum common standards for regulatory IMS

Process Standards	Data Dictionaries & Knowledge Trees	Data Exchange Standards
•Good Laboratory Practices (GLP) •Monographs •ISO 9001:2015 - Quality Management System Procedures •Good Distribution Practices (GDP) •ISO 17025:2017 •Good Practices For Pharmaceutical Quality Control Laboratories •Good Clinical Practice (GCP) •Good Manufacturing Practices (GMP) or ICH Q7 •Good Practices For Pharmaceutical Microbiology Laboratories •Good Review Practices (GRevP) •Good Storage Practices (GSP) •ICH Q10 •Good Pharmacovigilance Practices	•International Nonproprietary Names (INN) •National Drug Code (NDC) •Anatomical Therapeutic Chemical Index (ATC) •WHODrug Global •The Medical Dictionary for Regulatory Activities (MedDRA) •Chemical Abstracts Service (CAS) registry number •Unique Ingredient Identifier (UNII) •ISO 11240 Units of Measurement (UoM) •ISO 11239 Dosage Form and Route of Administration •ISO 11616 Pharmaceutical Product Identifier (PhPID) •ISO 11238 Substance Identification (SubID) •GS1 Standards •ISO 11615 Medicinal Product Identification (MPID)	•Portable Document Format (PDF) •XML •Common Technical Document (CTD) •E2B - Pharmacovigilance: Individual Case Safety Reports (ICSR) or ISO/HL7 27953-2:2011 •Structured Product Labelling (SPL) •Fast Healthcare Interoperability Standards (FHIR)

The meeting was informed that MTaPS and PQM+ were developing a guidance document and advocacy brief for the adoption of regulatory IMS.

Discussion included a detailed review of the data analysis process for the selection of the MCS.

Session II consisted of discussions with the participants about agreement on MCS for each of the three categories. (Process, Data dictionaries/knowledge trees, and Data exchange). Participants strongly suggested including Identification of Medicinal Products (IDMP) standards such as ISO 11615, ISO 11616, ISO 11239, and ISO 11240 as part of the list of MCS as they are key data entry elements required to create product information and are essential for medicinal product identification regionally and internationally, particularly for pharmacovigilance activities.

Meeting attendees were prompted to share any challenges or lessons learnt implementing regulatory IMS in their context and provide general feedback on the presentations

- The choice of data exchange standards was a prudent one as they are widely used
- Include a comprehensive mapping of the selected standards and their respective WHO GBT function in the meeting report
- Focus on incorporating IDMP standards
- A feasibility analysis should be conducted before implementing regulatory IMS
- Selected standards should be aligned with international data interchange standards

During the discussion, there was a strong recommendation to adopt IDMP standards for sharing information internationally and regionally and to think about adding implementation tools to supplement the standards. It was also suggested that the regulatory IMS implementation guidelines be developed in close partnership with the WHO.

The next steps include distribution of the meeting report, the minimum set of recommended common standards for regulatory information management systems, and the advocacy brief. The regulatory IMS implementation guidelines will also be developed in collaboration with the WHO and disseminated for review.

BACKGROUND

National medicines regulatory authorities (NMRAs) are increasingly implementing information management systems (IMS) to streamline their regulatory functions to improve efficiency and transparency and ensure access to access to high-quality, safe, and effective medical products. Despite the benefits, adoption of IMS in low- and middle-income countries (LMICs) remains disproportionately low in comparison to high-income countries. Many LMICs rely on paper-based processes, IMS systems are underutilized, fragmented, non-interoperable or mismanaged. The delayed implementation of digital IMS has been attributed to a lack of adequate financial and human resources, as well as a lack of political will, among other factors. Consequently, there is an absence of effective communication between regulatory agencies, a lack of transparency in the regulatory process, information loss, backlogs, and delays in the regulatory approval process.

The lack of interoperable IMS in LMICs, as well as the absence of standardized common technical documents (CTDs), documentation, work processes, and timelines limit the use of harmonization actions such as joint assessments and Good Manufacturing Practices (GMP) site inspections. Implementation of regulatory procedures such as reliance and recognition for the registration of medical products, which require the deployment of systems of dependable regulatory IMS for efficient information management.

To further harmonization efforts, a set of minimum common standards for regulatory IMS is required to promote interoperability and communication between international and regional NMRAs. The United States Agency for International Development (USAID) funded Medicines, Technologies, and Pharmaceutical Services (MTaPS) and Promoting the Quality of Medicines Plus (PQM+) programs initiated a series of consultative meetings with regulatory experts to define a minimum set of applicable common standards for regulatory IMS. The purpose of the fourth consultative meeting is to submit for discussion and validation the selected minimum common standards which were based on feedback received from the individual NMRAs and partners from the broader list of standards identified earlier in the process.

MEETING OBJECTIVES

The primary purpose of the meeting was to present and discuss the findings and proposed minimum common standards to be implemented by NMRAs. The minimum set of standards was determined through a desk review that identified 56 relevant standards for regulatory IMS. The desk review process and the rationale for the list of minimum common standards, as well as their anticipated use case were presented and discussed with global, regional, and national level regulatory and IMS experts and stakeholders through a consultative process beginning in September 2021. Prior to this fourth meeting, stakeholders were asked to rank the identified standards according to three criteria: criticality, universality, and feasibility. This meeting was jointly coordinated by PQM+, MTaPS, and their collaborating partners to:

- Share the results of feedback from stakeholders on selection of the minimum common standards for regulatory IMS
- Agree on the minimum common standards for regulatory IMS and
- Propose next steps involving advocacy for adoption

Welcome and Introductory Remarks

Kofi Aboagye-Nyame, Program Director, USAID MTaPS Program, MSH

Mr. Aboagye-Nyame welcomed the participants to the meeting. He noted that National Regulatory Authorities in low- and middle-income countries face some challenges in carrying out their functions, especially in the licensing of medical products. Even though well-functioning regulatory IMS would enhance consistency, efficiency, and accountability in pharmaceutical regulatory service delivery, he noted that many LMICs have been slow to achieve this, and where IMS currently exist, they are often inefficient and fragmented. He stressed the significance of harmonizing regulatory IMS across different regions and expressed his appreciation to the MTaPS and PQM+ teams and collaborators participating in the formulation of the minimum common standards for regulatory IMS. He encouraged attendees to actively participate in the consultative process and to validate and incorporate the selected standards into their regulatory frameworks.

Summary of Presentations and Discussions

The slides for all presentations are included in Annex 4C.

Session I: Proposed Minimum Common Standards for Regulatory Information Management Systems

Presentation I: Overview of responses from the NMRAs and other stakeholders on selection of MCS

Kate Kikule, Principal Technical Advisor for Pharmaceutical Regulatory Systems, MTaPS Program

Kate Kikule presented an overview of the consultative process and methodology used to select the MCS. She provided a summary of the actions, objectives, and conclusions of the prior sessions that culminated in the fourth consultative meeting. This included a description of the standard identification process, which consisted of a literature review to identify suitable standards based on their relevance to the activity objectives and scope of regulatory information management systems. Based on the previous three consultations, the selection criteria for narrowing the list of 56 identified standards from regulatory IMS to a set of minimum common standards are:

- Relevance—the standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBT v2.0
- Feasibility—the extent to which NMRAs' capacity and resources feasibly allow adoption and what are the anticipated efficiency gains
- Criticality—what would countries benefit or lose by not applying a given standard
- Universality—whether a given standard is recommended by WHO and extent to which it is widely used

The 56 standards were circulated to stakeholders for feedback and assessment. Stakeholders assigned scores of 1, 2, or 3 to each of the standards according to the proposed criteria (Table 1). Relevance was excluded from stakeholder consideration because all the included standards were considered relevant to the scope based on the desk review. As a result of the experts' evaluation, and based on the feedback received from countries, regional, and global entities, a total of 27 Minimum Common Standards were

selected: thirteen (13) Process Standards, eight (8) Data Dictionaries and Knowledge Trees, and six (6) Data Exchange Standards.

Table 1 – Rating definitions by selection criteria

Rating Scale	Feasibility	Criticality	Universality
1	Adopted with greater difficulty, significant technical assistance required	Regulatory performance/ processes not impacted without the standard	Not widely used in LMICs
2	Adopted with medium difficulty, marginal technical assistance required	Regulatory performance/ processes may be impacted without the standard	The standard is moderately widespread
3	Adopted with minimal, if any, technical assistance	Regulatory performance/ processes impacted without the standard	Widely used or recommended by industry or normative bodies

She presented a summary of the stakeholder responses received. Respondents were classified according to their level of operation: countries (NMRAs), regional, and global. Eleven (11) responses were received in total. She informed the meeting that the selected minimum common standards for regulatory IMS will be included in a guidance document to enable countries implement the standards and support digitalization of regulatory IMS. In addition, MTaPS and PQM+ are developing an advocacy brief which will be disseminated to stakeholders.

Questions and Clarifications

Following the presentation, participants were invited to ask questions regarding the proposed MCS. Leslie Rider Araki, Monitoring, Evaluation and Learning Director for PQM+ led the question-and-answer session.

Will there be a consideration to include medical devices standards in future?

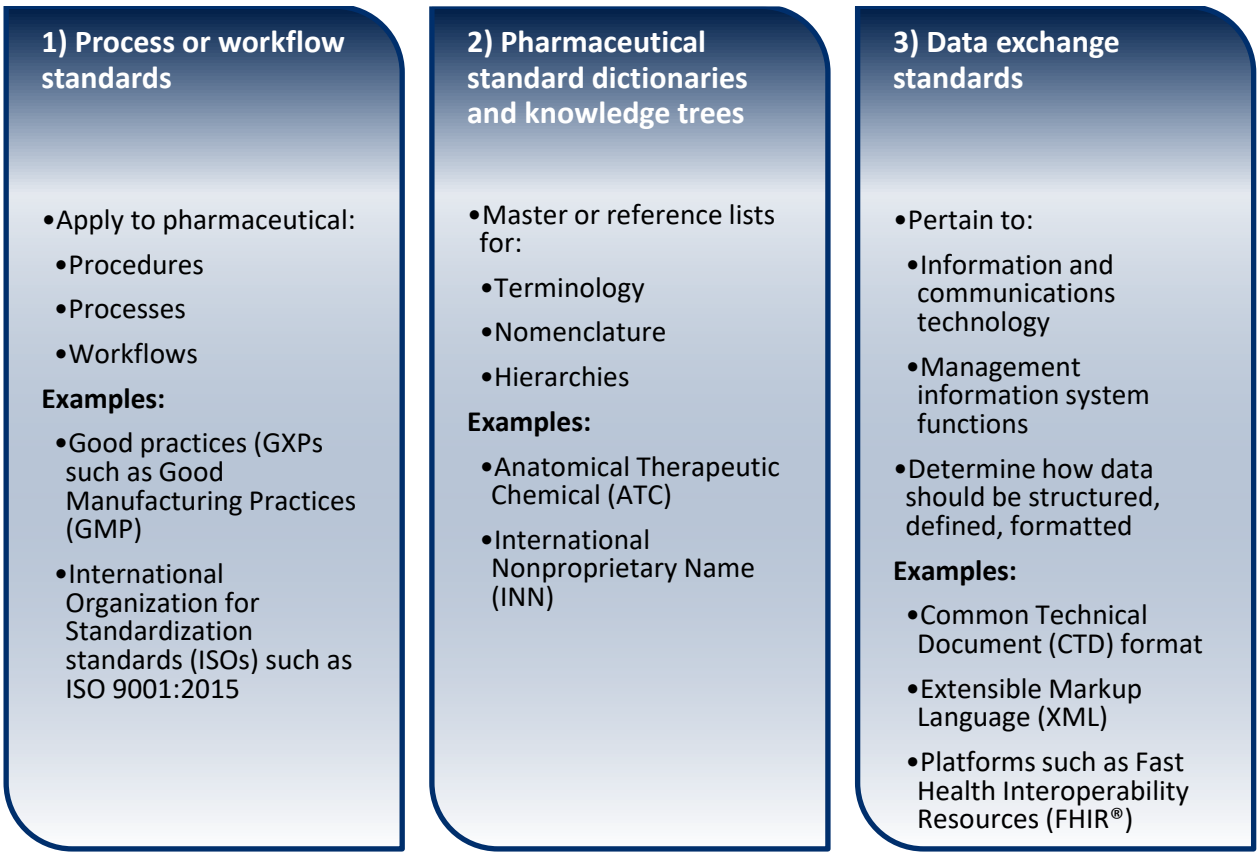
The teams decided to align with the WHO GBT Version 2.0 (medicines & vaccines), which is restricted to medicines, vaccines, and blood products. The WHO GBT guidance for medical devices was not available for consideration during the implementation of the consultative process, thus minimum standards for medical devices may be considered in the future.

Presentation II: Overview of the analysis of the responses and proposed MCS

Maura Soucy Brown, Senior Technical Advisor, MTaPS Program

Maura Soucy Brown presented an overview of the standards that were identified and shortlisted during the earlier standard selection process because of the desk review completed by PQM+ and MTaPS. She described the three categories of standards identified in this exercise (Figure 1) These consisted of fifteen (15) process or workflow standards, twenty-one (21) data dictionaries and knowledge trees, and twenty (20) data exchange standards.

Figure 11 - Categories of Standards



She then presented the data analysis process as outlined below:

- Each category of standards was analyzed separately (Process, Data dictionaries/knowledge trees, Data exchange)
- Each criterion was analyzed separately (Feasibility, Criticality, Universality) and compiled together (Overall Score)
- Disaggregated results based on respondent type, standard category

The MTaPS and PQM+ teams decided to compile country, regional and global responses together based on the response rates and consistency of responses received. They decided to use feasibility to determine the adoption order for the proposed set of minimum common standards. Those with the greatest feasibility scores were proposed to be adopted first, proceeding to those that would be most challenging to implement (lowest feasibility scores). This eliminated the need to benchmark NMRAs to guide the adoption of the standards and allows the proposed list of minimum common standards to operate as a top-to-bottom checklist when sorted according to feasibility.

Ms. Brown provided a detailed overview of the data analysis procedure. The criticality and universality scores were combined to inform the selection of the standards for inclusion in the minimum common set. Feasibility was omitted from the total score and used independently to determine the order of adoption for the selected standards. Medical device standards were removed to conform to WHO GBT version 2, which pertains to only medicines and vaccines.

Process Standards

The adoption of process standards is considered prerequisite to digitalization/adoption of recommended minimum common standards for regulatory IMS.

- 15 identified through the desk review
- Two (2) pertaining specifically to medical devices were removed (greyed out) in alignment with The WHO GBT v2.0 (medicines & vaccines)
- The remaining thirteen (13) are recommended and sorted according to feasibility scores

The list of process standards recommended for adoption, sorted according to feasibility is included in Table 2.

Table 2 – Process Standards

Standard	Feasibility	
	Score	Response Rate
Good Laboratory Practices (GLP)	2.4444	82%
Monographs	2.3333	82%
ISO 9001:2015 - Quality Management System Procedures	2.3333	82%
Good Distribution Practices (GDP)	2.2222	82%
ISO 17025:2017	2.1111	82%
Good Practices for Pharmaceutical Quality Control Laboratories	2	91%
Good Clinical Practice (GCP)	2	91%
Good Manufacturing Practices (GMP) or ICH Q7	1.9	91%
Good Practices for Pharmaceutical Microbiology Laboratories	1.8889	82%
Good Review Practices (GRevP)	1.8889	82%
Good Storage Practices (GSP)	1.8889	82%
ICH Q10	1.8	91%
Good Pharmacovigilance Practices	1.7778	82%
ISO 14971	1.5714	64%
ISO 13485	1.5	73%

Data Dictionaries and Knowledge Trees

Criticality and universality were combined and sorted from highest to the lowest score. The team selected standards that had a score of two and above which was later expanded to include a score of 1.9. GSI standards were included based on expert feedback.

The list of data dictionaries and knowledge trees recommended for adoption, sorted according to their criticality/universality scores is included in Table 3.

Standards highlighted in green are selected for inclusion in the minimum common set, all others are omitted from the final selection.

Table 3 – Data Dictionaries and Knowledge Trees

Standard	Criticality/ Universality	
	Score	Response Rate
International Nonproprietary Names (INN)	2.60805	91%
The Medical Dictionary for Regulatory Activities (MedDRA)	2.18637	91%
Anatomical Therapeutic Chemical Index (ATC)	2.07011	82%
Unique Ingredient Identifier (UNII)	2.00566	73%
WHODrug Global	1.98737	73%
Chemical Abstracts Service (CAS) registry number	1.95508	82%
National Drug Code (NDC)	1.90974	73%
Adverse Drug Reaction Probability Scale (Naranjo scale)	1.84151	73%
International Statistical Classification of Diseases and Related Health Problems (ICD)	1.78474	73%
ISO 3166	1.77269	73%
GS1 Standards	1.73678	82%
Common Terminology Criteria for Adverse Events (CTCAE)	1.66385	82%
ISO 11239 Dosage Form and Route of Administration[27]	1.62184	73%
SNOMED CT	1.59232	64%
Defined Daily Dose (DDD)	1.57006	73%
ISO 11240 Units of Measurement (UoM)[27]	1.52689	82%
ISO/IEC 11179-5:2015 - Metadata Registries (MDR)	1.51828	73%
ISO 11616 Pharmaceutical Product Identifier (PhPID)[27]	1.46334	73%
ISO 11238 Substance Identification (SubID)[27]	1.46334	73%
ISO 11615 Medicinal Product Identification (MPID)[27]	1.37184	73%
Logical observation identifiers names and codes (LOINC)	1.37184	73%

Data Exchange Standards

Data exchange standards were selected using the same criteria as data dictionaries and knowledge trees. E2B, Fast Health Interoperability Standards (FHIR), and Structured Product Labelling (SPL) were incorporated as a result of expert input. Selected data exchange standards are highlighted in green in Table 4, sorted according to their criticality/universality scores.

[27] Included based on participant feedback during consultative meeting 4 – request to include ISO standards pertaining to Identification of Medical Products (IDMP)

Table 4 – Data Exchange Standards

Standard	Criticality/ Universality	
	Score	Response Rate
Portable Document Format (PDF)	2.47704	100%
Common Technical Document (CTD)	2.29799	100%
XML	2.27217	82%
American Standard Code For Information Interchange (ASCII)	1.88308	64%
E2B - Pharmacovigilance: Individual Case Safety Reports (ICSR) or ISO/HL7 27953-2:2011	1.87374	82%
Therapeutic Area User Guides (TAUGs)	1.76828	73%
Dataset - XML	1.68292	82%
Resource Description Framework (RDF)	1.68119	73%
Define - XML	1.64328	73%
Operational Data Model ODM - XML	1.64328	73%
Fast Healthcare Interoperability Standards (FHIR)	1.46651	73%
Structured Product Labelling (SPL)	1.44506	73%
Analysis Dataset Model (AdaM)	1.39561	82%
Controlled Terminology	1.38046	82%
SAS XPORT	1.37184	73%
Standard for Exchange of Nonclinical Data (SEND)	1.35355	73%
Study Data Tabulation Model (SDTM)	1.32006	73%
Clinical Data Acquisition Standards Harmonization (CDASH)	1.32006	73%
The Biomedical Research Integrated Domain Group (BRIDG)	1.24684	73%
Protocol Representation Model (PRM)	1.17339	82%

Complete Set of Recommended Standards (Sorted by Feasibility)

Table 5 – Selected Process Standards sorted by feasibility

Standard	Compiled Feasibility
Good Laboratory Practices (GLP)	2.4444
Monographs	2.3333
ISO 9001:2015 - Quality Management System Procedures	2.3333
Good Distribution Practices (GDP)	2.2222
ISO 17025:2017	2.1111
Good Practices For Pharmaceutical Quality Control Laboratories	2
Good Clinical Practice (GCP)	2
Good Manufacturing Practices (GMP) or ICH Q7	1.9
Good Practices For Pharmaceutical Microbiology Laboratories	1.8889
Good Review Practices (GRevP)	1.8889
Good Storage Practices (GSP)	1.8889
ICH Q10	1.8
Good Pharmacovigilance Practices	1.7778

Table 6 – Selected Data Dictionaries and Knowledge Trees sorted by feasibility

Standard	Compiled Feasibility
International Nonproprietary Names (INN)	2.4
National Drug Code (NDC)	2
Anatomical Therapeutic Chemical Index (ATC)	2
WHODrug Global	2
The Medical Dictionary for Regulatory Activities (MedDRA)	1.9
Chemical Abstracts Service (CAS) registry number	1.88889
Unique Ingredient Identifier (UNII)	1.75
ISO 11240 Units of Measurement (UoM)	1.44444
ISO 11239 Dosage Form and Route of Administration	1.375
ISO 11616 Pharmaceutical Product Identifier (PhPID)	1.25
ISO 11238 Substance Identification (SubID)	1.25
GS1 Standards	1.22222
ISO 11615 Medicinal Product Identification (MPID)	1.125

Table 7 – Selected Data Exchange Standards sorted by feasibility

Standard	Compiled Feasibility
Portable Document Format (PDF)	2.5455
XML	2.1111
Common Technical Document (CTD)	2
E2B - Pharmacovigilance: Individual Case Safety Reports (ICSR) or ISO/HL7 27953-2:2011	1.5556
Structured Product Labelling (SPL)	1.125
Fast Healthcare Interoperability Standards (FHIR)	1

Session II: Discussion & Agreement on Minimum Common Standards

Facilitated Discussion I: Process Standards, Data Dictionaries & Knowledge Trees

Fredrick Meadows, Senior Technical Advisor, PQM+ Program

Mr. Meadows hosted a discussion on the process standards & standard dictionaries and knowledge trees that were presented in the previous session. Attendees used the Zoom platform chat to respond or raise a hand to comment. Questions and responses received are described below.

Are there standards that were left out of the final list that you think should have been included and vice versa?

Comments for attendees

- ISO 11240 and ISO 11239 are key data entry elements required to create product information. (These two are part of the five IDMP standards)
- IDMP standards are essential for medicinal product identification regionally and internationally notably for pharmacovigilance activities. In addition, they are a worldwide priority being considered by the WHO, EMA, and FDA

After reviewing and evaluating the stakeholders' suggestion to include the suite of five IDMP standards, the PQM+ and MTaPS teams agreed to include them as part of the MCS (Table 6), since these standards provide an international framework to uniquely identify and describe medicinal products with consistent documentation and terminologies, as well to ensure the exchange of product information between global regulators, manufacturers, suppliers, and distributors. They also facilitate the unique identification of medicinal products in the context of pharmacovigilance and the safety of medications.[28]

Facilitated Discussion II: Data Exchange Standards

Deane Putzier, Senior Principal Technical Advisor, MTaPS Program

Next, the participants were asked to provide feedback on the selected data exchange standards. Attendees used the Zoom platform chat to respond or raise a hand to comment. Questions and responses received are described below.

Deane began the discussion by describing the proposed data exchange standards:

PDF Standard

- Developed by Adobe for use without requiring software, hardware, or any operating system
- Permits the incorporation of multimedia Includes fonts, victor graphics and rich media i.e., video content
- Versatile open format
- Enables information storage and intersystem communication
- Encrypts username and owner
- Not so much a standard as a system common tool

The Common Technical Document (CTD)

- Standard for the registration of medicines is an internationally accepted format for new drugs applications to be submitted to the NMRA
- Administrative, prescribing information quality, pharmaceutical documentation, preclinical, which includes pharmacology and toxicology, and clinical trials data components are included
- Non-information system standard originally created as a paper document; it is now available in electronic format as the eCTD

XML

- Ubiquitous across several of these diverse standards
- Is a markup language, which means it is meant to store and transfer information in a human-readable way
- The purpose of XML was to stress usability and simplicity across diverse information systems
- Not bound to a specific hardware platform
- WC3 recommendation
- Permits users to describe data, as necessary. It is versatile. Plane XML can be used to describe virtually anything in this XML based on the two systems that are communicating with one another.

[28] FDA Data Standards Advisory Board. Identification of Medicinal Products (IDMP). May 2022.

E2B

- XML standard
- International standard for reporting adverse events. It is necessary that adverse event reports be communicated in XML format, and it is also widely used for reporting adverse events to WHO-hosted databases Vigibase and Vigiflow.
- Received a very low score in terms of the first healthcare interoperability standards, but it is a very essential forthcoming standard in healthcare and regulatory systems that defines a common language between systems. It is the format of information systems that enables users to speak with a common understanding across countries and systems

FHIR Standard

- HL 7 is a comprehensive standard in XML as well
- HL 7 is quite broad, so Fast Healthcare Interoperability Resource narrows the scope and outlines the procedure between systems. There is a major emphasis on implementation, and numerous implementation materials are available.
- Built on a solid foundation of web standards.
- While it employs XML, Additionally, it uses JSON hdp http etc. JSON is a common, more understandable format than XML, and it is also used to transport data between computers. It is also a standard utilized by all web and RESTful systems.

SPL Standard

- Is an XML format and is mostly used by manufacturers and distributors to send product documentation
- Includes a summary of the space-critical, specific information required for the successful and safe use of the medicine. It is essentially divided into several components: adverse reactions, indications, prescriptions, drugs, etc., for over-the-counter medications. This is the default definition of the structured product labelling, and it is also the reason why our standards employ this definition.

He explained why ASCII was excluded despite being highly rated by experts. Essentially, it is a notepad document. Users could easily enter their text into a notepad and share it across several platforms. It was also eliminated due to its broadness. It is not a true standard, but rather a way for systems to share data.

Please share any challenges or lessons learnt implementing IMS in your context

Feedback from participants

- Including CTD, XML, E2B and PDF was an excellent move as they are widely used across different regions. They can be easily advocated for and adopted

Please provide any general feedback from the presentation

Comments from participants

- The meeting report should include a comprehensive mapping of the selected standards and their respective WHO GBT function. Kate indicated that the mapping was completed during the beginning phases of the project and would be included in the final report.
- CTD and E2B are highly ranked, indicating respondents' top priorities.
- It appeared that there was a combination of tools, underlying software, and practical standards. It was suggested that they be delineated.
- Focus on incorporating IDMP standards. Deane indicated that XML and FHIR may fulfil the purpose, but the suggestion would be carefully considered.
- Need to identify regulatory IMS implementation tool
- Prior to the introduction of regulatory IMS, feasibility, compatibility of standards, functional systems, and system maintenance should be examined.
- Requirement that selected standards be aligned with international data interchange standards to allow global, regional, and institutional communication
- Recommendation for additional collaboration between the USAID MTaPS PQM+ team and the WHO to implement regulatory IMS. The USAID MTaPS PQM+ team is developing a guidance document for the implementation of regulatory IMS; The WHO may play a complementary role by developing recommendations for the adoption of regulatory IMS by NMRAs.

Next Steps and Closeout

Gabriel K. Kaddu, Technical Advisor for Regulatory Systems Strengthening at PQM+, wrapped up the meeting and summarized the next steps. He described the final documents that would be distributed to the stakeholders, including the meeting report, the minimum common set of standards for regulatory IMS, and the advocacy brief. He highlighted that the USAID MTaPS PQM+ team will collaborate with WHO to develop a guideline for regulatory IMS standards adoption.

Allison Collins (PQM+) made the closing remarks on behalf of Alexis Leonard, Senior Health Systems Technical Advisor USAID Bureau for Global Health. She begun by acknowledging the presence of the participants and commending them for the robust discussion regarding the proposed regulatory IMS standards. She also appreciated the efforts of the MTaPS and PQM+ teams and all collaborating partners for their contribution towards selecting the MCS. She spoke about the significance of highly functional regulatory systems and the necessity of streamlining regulatory systems in LMICs, which are frequently paper-based leading to sub-optimal results. She stressed the need for purpose-built IMS to solve the issues faced by LMICs and enhance harmonization. She emphasized USAID's support for bolstering regulatory mechanisms in accordance with its 2030 Vision for Health Systems Strengthening.

Jude Nwokike, Vice President, USAID PQM+ Program, gave the final closing remarks. He thanked all participants for a productive engagement during the meeting. He thanked all collaborating partners including the WHO, Global Fund, ASEAN secretariat, and the World Bank. He also lauded the support provided by the MTaPS and PQM+ programs. He remarked on the increased participation of NMRAs in the consultative process. He was especially pleased that CTD, E2B, and SPL were included in the MCS, and he expressed optimism that NMRA's incorporating regulatory IMS to streamline regulatory operations would enhance regulatory transparency and consistency, as well as improve reliance, recognition, and information sharing.

ANNEX 4A: MEETING AGENDA

Introductions & Welcome	
8:00 – 8:10	**Introductions, meeting logistics and objectives** Leslie RiderAraki, Monitoring, Evaluation and Learning Director. USAID PQM+ Program.
8:10 – 8:15	**Welcome remarks** Kofi Aboagye-Nyame, Program Director. USAID MTaPS Program
Session 1: Proposed Minimum Common Standards for Regulatory Information Systems	
8:15 - 8:25	**Presentation 1: Overview of responses from the NMRAs and other stakeholders on selection of MCS** ***Objective:*** *Provide an overview of the process for gathering the feedback from the NMRAs and stakeholders, and their responses received* Kate Kikule Principal Technical Advisor. MTaPS
8:25 – 9:00	**Presentation 2: Overview of the analysis of the responses and proposed MCS** Maura Soucy Brown, Senior Technical Advisor. MTaPS
9:00 - 9:10	**Questions for Clarification** Leslie RiderAraki, Monitoring, Evaluation and Learning Director. PQM+
Session II: Discussion & Agreement on Minimum Common Standards	
9:10 – 9:35	**Facilitated Discussion 1: Process standards & Standard dictionaries and knowledge trees** Fredrick Meadows, Senior Technical Advisor, PQM+
9:35- 9:55	**Facilitated Discussion 2: Data exchange standards** Deane Putzier, Senior Principal Technical Advisor, MTaPS
Next Steps & Closing	
9:55 – 10:00	**Next Steps:** Gabriel K. Kaddu, Technical Advisor, USAID PQM+ Program **Closing:** Alexis Leonard, Senior Health Systems Technical Advisor, USAID Bureau for Global Health Jude Nwokike, Vice President, USAID PQM+ Program

ANNEX 4B: LIST OF MEETING PARTICIPANTS

Name	Country/ Organization
Abayomi Akinyemi	Nigeria
Alexis Leonard	USAID
Alison Collins	USAID
Andrew Rutebuka	Uganda
Asad Ullah	Pakistan
Assma Gafur	
Brenda Kitimbo	Uganda
Colette Ifudu	
Daniel Teye-Narh	Ghana
Deane Putzier	MTaPS
Diana Diaz	USP
Djibril Fall	Senegal
Eliangiringa Kaale	
Ellie Bahirai	PQM+
Francis Aboagye-Nyame	MTaPS
Frederick Meadows	PQM+
Gabriel Kaddu	PQM+
Gabriel Swinth	MTaPS
Galaxy A21s	
Gedion Murimi	Kenya
Henry Nsereko	Uganda
Ifunanya Ezekiel	Nigeria
Isaac Dapaah	Ghana
Joyce Batera	Uganda
Jude Nwokike	PQM+
Kalat Musa	Nigeria
Kate Kikule	MTaPS
Khadijah Ade-Abolade	Nigeria
Kofi Nyame (Francis Aboagye-Nyame)	MTaPS
Leslie Rider-Araki	PQM+
Lisa Ludeman	USAID
Marvin Buleera	Uganda
Maura Brown	MTaPS
Michael Ward	WHO
Mochtar SALAMI	
Nabila Gani	
Nancy Ngum	NEPAD
Nereah Kisera	MTaPS
Ousmane Dembélé	Mali
Patrick Opati	Uganda

Peter Ikamati	Kenya
Rhanda ADECHINA	Benin
Richard Habimana	Rwanda
Salim Kazibwe	Uganda
Samuel Asante-Boateng	Ghana
Sarah Khattab	USAID
Serge Shyirambere	Rwanda
Stephen Kimatu	The global Fund
Tobey Busch	USAID

Minimum Common Standards for Regulatory Information Management Systems in Low- and Middle-Income Countries

June 2, 2022

Welcome to a Virtual Consultation hosted by:

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

USAID PROMOTING THE QUALITY OF MEDICINES PLUS (PQM+) PROGRAM

Facilitator

Leslie Rider Araki
Monitoring, Evaluation and Learning Director, USAID PQM+ Program

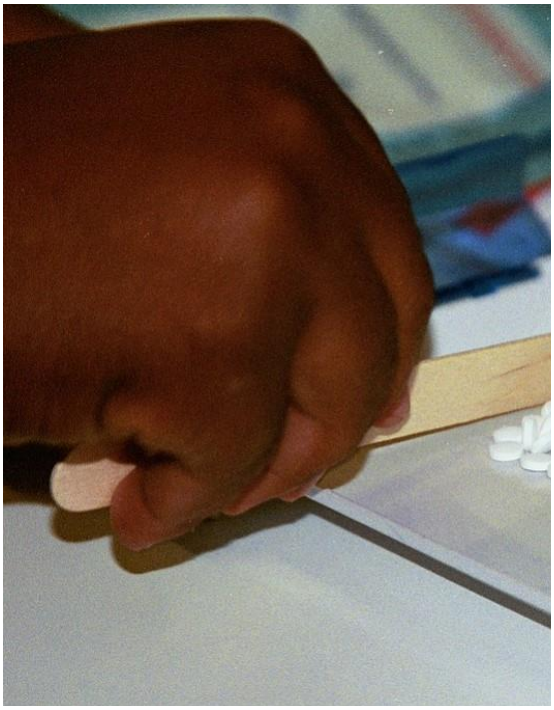
USAID MTaPS and PQM+ Programs

USAID FROM THE AMERICAN PEOPLE

Agenda Overview

8:00 – 8:15	Introductions, Welcome & Meeting Objectives
8:15 – 9:10	Session I: Proposed Minimum Common Standards for Regulatory Information Management Systems
9:10 – 9:55	Session II: Discussion & Agreement on Minimum Common Standards
9:55 – 10:00	Next Steps & Closing

USAID MTaPS and PQM+ Programs



8:00 – 8:15 Introductions & Welcome

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Introductions, Meeting Logistics and Objectives

Leslie RiderAraki
Monitoring, Evaluation and Learning Directo
USAID PQM+ Program

USAID MTaPS and PQM+ Programs

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Activity Objectives

Main Objective:

- Develop and recommend a set of minimum common standards (MCS) for regulatory IMS

Sub Objectives:

- Identify the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS
- Derive a recommended set of minimum common standards for regulatory IMS
- Develop the use case for the minimum common standards
- Promote their adoption and use in digitalization of Regulatory IMS

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Meeting Objectives

- Share the results of feedback from stakeholders on selection of the minimum common standards for Regulatory Information Management System (IMS)
- Agree and finalize the minimum common standards for Regulatory IMS
- Propose next steps involving advocacy for adoption and use of the standards

USAID MTaPS and PQM+ Programs

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Welcome Remarks

Kofi Aboagye-Nyame
Program Director
USAID MTaPS Program

8:15 – 9:10 Session 1: Proposed Minimum Common Standards for Regulatory Information Systems

USAID MTaPS and PQM+ Programs

Presentation 1:

Overview of responses from the NMRAs and other stakeholders on selection of MCS

Kate Kikule
Principal Technical Advisor, RSS
USAID MTaPS Program

USAID MTaPS and PQM+ Programs

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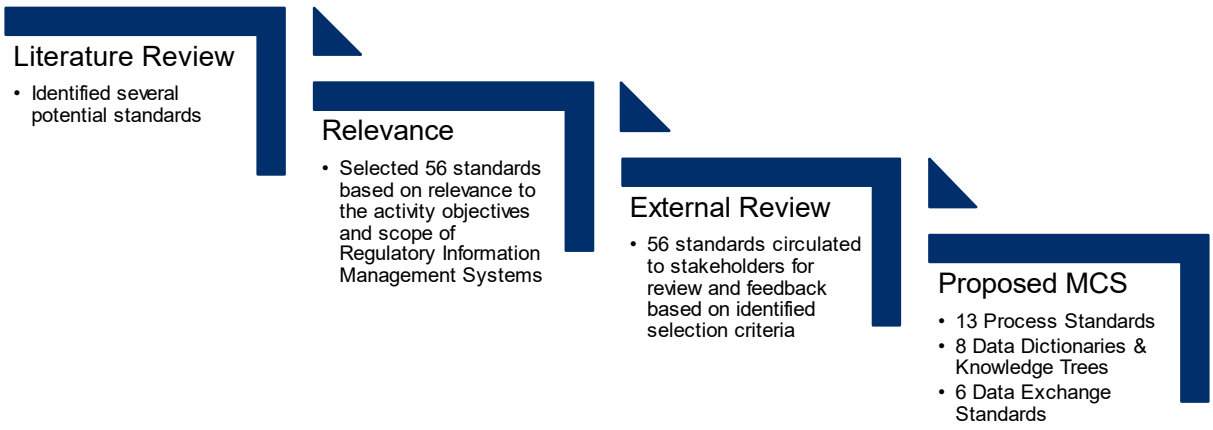
Consultative Process in Review

Activity	Task/Objective	Expected results
Consultative meeting I	Clearly identify the critical gaps and challenges NMRAs and other stakeholders facing with regulatory IMS Discuss the scope of minimum common standards for RIMS Discuss how a set of minimum common standards for regulatory IMS can best address or mitigate these challenges and start building the use case	Critical gaps and challenges with regulatory IMS identified The scope of the standards for addressing the gaps and challenges defined
Consultative meeting II	Develop selection criteria for minimum common standards Review collated existing standards Finalize the use case	Preliminary core set of minimum common standards for regulatory IMS identified
External review I	Review of collated existing standards and identify which standards should be included in the minimum common standard set	Advocacy brief developed
NMRA Consultative meeting (Meeting III)	Engage select NMRA representatives to gather additional input	
Internal analysis and synthesis of standards	Consolidate and synthesize the inputs from the experts	
External review II	Final expert review of the proposed minimum common standards	Finalized set of minimum common standards for regulatory IMS
Internal revisions and finalization	Finalize minimum common standards based on feedback Internal reviews and copyediting	
Consultative meeting IV	Present minimum common standards Discuss guidance on pathway for countries to adopt minimum common standa to support the digitalization of regulatory functions	Inputs gathered for guidance on digitalization pathway

Standards Selection Process



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Selection Criteria

- Relevance—the standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBTv2.0
- Feasibility—the extent to which NMRAs' capacity and resources feasibly allow adoption and what are the anticipated efficiency gains
- Criticality—what would countries benefit or lose by not applying a given standard
- Universality—whether a given standard is recommended by WHO and extent to which it is widely used

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Standards Selection Workbook

- Stakeholders assigned scores of 1, 2, or 3 to each of the 56 standards according to the proposed criteria
  - Relevance was previously applied by MTaPS and PQM+ team, excluded from stakeholder consideration

	A	C	D	E	F	G	H
1	**Standard**	**Rating Scale**	**Feasibility**	**Criticality**	**Universality**	**Justification**	
2		1	Adopted with greater difficulty, significant technical assistance required	Regulatory performance/ processes not impacted without the standard	Not widely used in LMICs		
3		2	Adopted with medium difficulty, marginal technical assistance required	Regulatory performance/ processes may be impacted without the standard	The standard is moderately widespread		
4		3	Adopted with minimal, if any, technical assistance	Regulatory performance/ processes impacted without the standard	Widely used or recommended by industry or normative bodies		
5	**Good Clinical Practice (GCP)**		**3**	**2**	**3**	Feasibility	Standard being implemented for the past 15yrs
6						Criticality	Local guidelines exist to supplement the standard
7						Universality	Every NMRA with clinical trial oversight needs this standard

Responses Received

- Solicited feedback from all participants in consultative process
- Categorized respondents:
  - Countries (NMRAs)
  - Regional
  - Global
- 11 total responses received
- Feedback compiled and analyzed to select the proposed set of minimum common standards

7 Countries
- Bangladesh
- Benin
- Ghana
- Guinea
- Kenya
- Mali
- Uganda

2 Regional
- AUDA - Nepad
- Mahidol University

2 Global
- CIRS
- Global Fund

11 Total Responses

Presentation II:
Overview of the analysis of the responses and proposed MCS

Maura Soucy Brown
Senior Technical Advisor
USAID MTaPS Program

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Categories of Standards

Desk review and relevance selection yielded56 standards, grouped into 3 categories

1) Process or workflow standards

- Apply to pharmaceutical:
  - Procedures
  - Processes
  - Workflows

Examples:

- Good practices (GXPs such as Good Manufacturing Practices (GMP)
- International Organization for Standardization standards (ISOs) such as ISO 9001:2015

15 standards identified

2) Pharmaceutical standard dictionaries and knowledge trees

- Master or reference lists for:
  - Terminology
  - Nomenclature
  - Hierarchies

Examples:

- Anatomical Therapeutic Chemical (ATC)
- International Nonproprietary Name (INN)

21 standards identified

3) Data exchange standards

- Pertain to:
  - Information and communications technology
  - Management information system functions
- Determine how data should be structured, defined, formatted

Examples:

- Common Technical Document (CTD) format
- Extensible Markup Language (XML)
- Platforms such as Fast Health Interoperability Resources (FHIR®)

20 standards identified

Selection Criteria

- Relevance—the standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBT
- Feasibility—the extent to which NMRAs' capacity and resources feasibly allow adoption and what are the anticipated efficiency gains
- Criticality—what would countries benefit or lose by not applying a given standard
- Universality—whether a given standard is recommended by WHO and extent to which it is widely used

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Data Analysis Process

- Analyzed each category of standards separately (Process, Data dictionaries/knowledge trees, Data exchange)
- Analyzed each criterion separately (Feasibility, Criticality, Universality) and compiled together (Overall Score)
- Disaggregated results based on respondent type, standard category

Standard	Feasibility					Criticality					Universality					Overall Score					
	Countries	Global	Regional	Compiled	# Responses	Countries	Global	Regional	Compiled	# Responses	Countries	Global	Regional	Compiled	# Responses	Countries	Global	Regional	Compiled	# Responses	Response Rate
Good Clinical Practice (GCP)	2	1	2	2	10	2.14	1	2.5	2.2	10	2.43	1	2.5	2.4	10	2.1905	1	2.33	2.17	10	91%
Good Distribution Practices (GDP)	2.428571	0	1.5	2.2222	9	2.57	0	2.5	2.56	9	2.71	0	2	2.56	9	2.5714	0	2	2.42	9	82%

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Data Analysis Process

- Based on response rates and consistency of responses, determined that compiled scores (Country, Regional, and Global respondents together) were most appropriate for selection
- Feasibility should be used to determine the order of adoption for the proposed set of MCS
  - Those with highest feasibility scores should be implemented first
  - Continuum to most difficult to implement (lowest feasibility scores)
  - Removes consideration for benchmarking NMRAs for adoption
    - Functions as checklist starting from top to bottom

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Data Analysis Process

Not Considered for Selection; Used to determine order of adoption

Combined these categories

Used Compiled Criticality/Universality Score for Selection

Removed from Consideration

Standard	Feasibility					Criticality					Universality					Criticality/Universality					Overall Score					
	Countries	Global	Regional	Compiled	# Responses	Countries	Global	Regional	Compiled	# Responses	Countries	Global	Regional	Compiled	# Responses	Countries	Global	Regional	Compiled	# Responses	Countries	Global	Regional	Compiled	# Responses	Response Rate
Good Clinical Practice (GCP)	2	1	2	2	10	2.14	1	2.5	2.2	10	2.43	1	2.5	2.4	10	2.28571	1	2.5	2.28637	10	2.19 05	1	2.33	2.17	10	91%
Good Distribution Practices (GDP)	2.428571	0	1.5	2.2222	9	2.57	0	2.5	2.56	9	2.71	0	2	2.56	9	2.64286	0	2.25	2.54433	9	2.57 14	0	2	2.42	9	82%

Process Standards

- Treated as prerequisites to digitalization/adoption of recommended minimum common standards for Regulatory Information Systems
- 15 identified
- Removed 2 pertaining specifically to medical devices
  - Alignment with WHO GBT v2.0 (medicines & vaccines)
- Remaining 13 are recommended, sorted according to feasibility scores

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Process Standards

Standard	Description	Feasibility	
		Compiled	Response Rate
• **Good Laboratory P**Treated as prerequisites to digitalization/adoption of recommended minimum common standards for Regulatory Information Systems • 15 identified • Removed 2 pertaining specifically to medical devices • Alignment with WHO GBT v2.0 (medicines & vaccines) • Remaining 13 are recommended, sorted according to feasibility score**sractices (GLP)**	A set of principles intended to assure the quality and integrity of non-clinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies.	2.4444	82%
Monographs	Pharmacopoeial monographs provide an important tool for assurance of the quality of marketed pharmaceutical ingredients and products through testing of their quality.	2.3333	82%
ISO 9001:2015 - Quality Management System Procedures	Specifies requirements for a quality management system	2.3333	82%
Good Distribution Practices (GDP)	Ensures products are consistently stored, transported, and handled under suitable conditions as required by the marketing authorization (MA) or product specification.	2.2222	82%
ISO 17025:2017	Specifies the general requirements for the competence, impartiality and consistent operation of laboratories.	2.1111	82%
Good Practices For Pharmaceutical Quality Control Laboratories	Provide advice on the quality management system within which the analysis of active pharmaceutical ingredients (APIs), excipients and pharmaceutical products should be performed to demonstrate that reliable results are obtained.	2	91%
Good Clinical Practice (GCP)	A process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human subjects.	2	91%
Good Manufacturing Practices (GMP) or ICH Q7	A system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product	1.9	91%
Good Practices For Pharmaceutical Microbiology Laboratories	Provide guidance on the quality management systems relating to microbiology laboratories	1.8889	82%

Data Dictionaries & Knowledge Trees

Standard	Criticality/ Universality	
	Compiled	Response Rate
International Nonproprietary Names (INN)	2.60805	91%
The Medical Dictionary for Regulatory Activities (MedDRA)	2.18637	91%
Anatomical Therapeutic Chemical Index (ATC)	2.07011	82%
Unique Ingredient Identifier (UNII)	2.00566	73%
WHODrug Global	1.98737	73%
Chemical Abstracts Service (CAS) registry number	1.95508	82%
National Drug Code (NDC)	1.90974	73%
Adverse Drug Reaction Probability Scale (Naranjo scale)	1.84151	73%
International Statistical Classification of Diseases and Related Health Problems (ICD)	1.78474	73%
ISO 3166	1.77269	73%
GS1 Standards	1.73678	82%
Common Terminology Criteria for Adverse Events (CTCAE)	1.66385	82%

Standard	Criticality/ Universality	
	Compiled	Response Rate
ISO 11239 Dosage Form and Route of Administration	1.62184	73%
SNOMED CT	1.59232	64%
Defined Daily Dose (DDD)	1.57006	73%
ISO 11240 Units of Measurement (UoM)	1.52689	82%
ISO/IEC 11179-5:2015 - Metadata Registries (MDR)	1.51828	73%
ISO 11616 Pharmaceutical Product Identifier (PhPID)	1.46334	73%
ISO 11238 Substance Identification (SubID)	1.46334	73%
ISO 11615 Medicinal Product Identification (MPID)	1.37184	73%
Logical observation identifiers names and codes (LOINC)	1.37184	73%

Data Exchange Standards

Standard	Criticality/ Universality	
	Compiled	Response Rate
Portable Document Format (PDF)	2.47704	100%
Common Technical Document (CTD)	2.29799	100%
XML	2.27217	82%
American Standard Code For Information Interchange (ASCII)	1.88308	64%
E2B - Pharmacovigilance: Individual Case Safety Reports (ICSR) or ISO/HL7 27953-2:2011	1.87374	82%
Therapeutic Area User Guides (TAUGs)	1.76828	73%
Dataset - XML	1.68292	82%
Resource Description Framework (RDF)	1.68119	73%
Define - XML	1.64328	73%
Operational Data Model ODM - XML	1.64328	73%
Fast Healthcare Interoperability Standards (FHIR)	1.46651	73%

Standard	Criticality/ Universality	
	Compiled	Response Rate
Structured Product Labelling (SPL)	1.44506	73%
Analysis Dataset Model (AdaM)	1.39561	82%
Controlled Terminology	1.38046	82%
SAS XPORT	1.37184	73%
Standard for Exchange of Nonclinical Data (SEND)	1.35355	73%
Study Data Tabulation Model (SDTM)	1.32006	73%
Clinical Data Acquisition Standards Harmonization (CDASH)	1.32006	73%
The Biomedical Research Integrated Domain Group (BRIDG)	1.24684	73%
Protocol Representation Model (PRM)	1.17339	82%

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Complete Set of Recommended Standards (Sorted by Feasibility)

Process Standards

Standard	Compiled Feasibility
Good Laboratory Practices (GLP)	2.4444
Monographs	2.3333
ISO 9001:2015 - Quality Management System Procedures	2.3333
Good Distribution Practices (GDP)	2.2222
ISO 17025:2017	2.1111
Good Practices For Pharmaceutical Quality Control Laboratories	2
Good Clinical Practice (GCP)	2
Good Manufacturing Practices (GMP) or ICH Q7	1.9
Good Practices For Pharmaceutical Microbiology Laboratories	1.8889
Good Review Practices (GRevP)	1.8889
Good Storage Practices (GSP)	1.8889
ICH Q10	1.8
Good Pharmacovigilance Practices	1.7778

Dictionaries & Knowledge Trees

Standard	Compiled Feasibility
International Nonproprietary Names (INN)	2.4
Anatomical Therapeutic Chemical Index (ATC)	2
WHODrug Global	2
National Drug Code (NDC)	2
The Medical Dictionary for Regulatory Activities (MedDRA)	1.9
Chemical Abstracts Service (CAS) registry number	1.8889
Unique Ingredient Identifier (UNII)	1.75
ISO 11238 Substance Identification (SubID)	1.25
GS1 Standards	1.2222
ISO 11615 Medicinal Product Identification (MPID)	1.125

Data Exchange Standards

Standard	Compiled Feasibility
Portable Document Format (PDF)	2.5455
XML	2.1111
Common Technical Document (CTD)	2
E2B - Pharmacovigilance: Individual Case Safety Reports (ICSR) or ISO/HL7 27953-2:2011	1.5556
Structured Product Labelling (SPL)	1.125
Fast Healthcare Interoperability Standards (FHIR)	1

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Questions for Clarification

Leslie RiderAraki
Monitoring, Evaluation and Learning Directo
USAID PQM+ Program

9:10 – 9:55 Session 1I: Discussion & Agreement on Minimum Common Standards

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Facilitated Discussion I: Process standards & Standard dictionaries and knowledge trees

Frederick Meadows
Senior Technical Advisor
USAID PQM+ Program

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Process Standards

Standard	Description	Feasibility	
		Compiled	Response Rate
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Good Practices For Pharmaceutical Microbiology Laboratories	Provide guidance on the quality management systems relating to microbiology laboratories	1.8889	82%
Good Review Practices (GRevP)	Documented best practices for any aspect related to the process, format, content and management of a medical product review. The objective of GRevPs is to help achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality in both the content and management of reviews.	1.8889	82%
Good Storage Practices (GSP)	Guidelines that describe the special measures considered appropriate for the storage and transportation of pharmaceuticals. The guidelines are applicable not only to manufacturers of medicinal products but also to pharmaceutical importers, contractors and wholesalers, and community and hospital pharmacies	1.8889	82%
ICH Q10	A model for a pharmaceutical quality system that can be implemented throughout the different stages of a product lifecycle. Much of the content of ICH Q10 applicable to manufacturing sites is currently specified by regional GMP requirements.	1.8	91%
Good Pharmacovigilance Practices	A set of guidelines for the conduct of pharmacovigilance, applying to marketing authorization holders and regulatory agencies. The definition and principles vary across regulatory bodies.	1.7778	82%
ISO 14971	Specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical devices.	1.5714	64%
ISO 13485	Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.	1.5	73%

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Logical observation identifiers names and codes (LOINC)	1.37184	73%

Facilitated Discussion II: Data exchange standards

Deane Putzier
Senior Principal Technical Advisor
USAID MTaPS Program

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Data Exchange Standards

Standard	Criticality/ Universality	
	Compiled	Response Rate
Portable Document Format (PDF)	2.47704	100%
Common Technical Document (CTD)	2.29799	100%
XML	2.27217	82%
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9:55 – 10:00 Next Steps & Closing

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Next Steps

Gabriel Kaddu
Technical Advisor
USAID PQM+ Program

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Next Steps

- Develop and distribute Meeting Report
- Finalize and document the minimum recommended set of common standards for Regulatory Information Management Systems
  - Circulate to stakeholders and make publicly available online (USAID, program websites)
- Finalize Advocacy Brief
  - Circulate to stakeholders and make publicly available online (USAID, program websites)
- Work with World Health Organization (WHO) to develop a global guidance on digitalization of regulatory information management system incorporating the identified set of minimum common standards of regulatory IMS

Additional Feedback

Further feedback and comments regarding the standards or consultative process may be directed to:

USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

Kate Kikule
Principal Technical Advisor, RSS
kkikule@mtapsprogram.org

USAID Promoting the Quality of Medicines (PQM+) Program

Souly Phanouvong
Senior Technical Advisor
SXP@usp.org

USAID MTaPS and PQM+ Programs

Closing Remarks

Alexis Leonard
Senior Health Systems Technical Advisor
USAID Bureau for Global Health

Closing Remarks

- **JudeNwokike**
- Vice President
- USAID PQM+ Program

USAID MTaPS and PQM+ Programs

USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

Prime: Management Sciences for Health (MSH)

COR: Alexis Leonard, aleonard@usaid.gov

Learn more: www.mtapsprogram.org

USAID Promoting the Quality of Medicines (PQM+) Program

Prime : U.S. Pharmacopeia (USP)

AOR: Alison Collins, alcollins@usaid.gov

Learn more : www.usp.org/global-public-health/promoting-quality-of-medicines

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