Standards Alliance: Phase 2

Quarterly Report

Q4 October 1st- December 31st 2023

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1. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2
Activity Start Date and End Date:	July 12, 2019 – July 11, 2026
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
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Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, West Africa (regional), Ghana, Kenya, Mozambique, South Africa, Indo-Pacific (regional)
Reporting Period:	Q4 October 1st- January 31st 2023

1.1 Program Description/Introduction

Standards form the foundation of world trade and the efforts of the Standards Alliance help to create fertile ground for reciprocal trade with the U.S. Through increased adherence and understanding of standards and conformity assessment principles, participating nations will become more competitive in the global market, be more prepared for bilateral trade agreements, and be more capable of protecting their citizens from hazardous goods.

The Standards Alliance Phase 2 (SA2) will engage target populations including, but not limited to, foreign government officials and ministries responsible for standards, trade, and consumer protection; foreign private sector; industry groups; civil society; consumer interest groups; business professionals; trade policy experts; and academia. The objective of this initiative is to build on the past successes, lessons learned and impact measured to-date of the first iteration of the Standards Alliance to support the capacity of developing countries in the areas of legal and regulatory framework, standards development, conformity assessment procedures, and private sector engagement. Achieving these goals also helps companies succeed globally by increasing market access for U.S. companies through more predictable and transparent avenues for trade and investment in partner markets/regions.

The implementing partner for this cooperative agreement is the American National Standards Institute (ANSI). ANSI is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. ANSI's mission is to enhance U.S. global competitiveness and the American quality of life by promoting, facilitating, and safeguarding the integrity of the voluntary standardization and conformity assessment system. Because of ANSI's unique role as a coordinating body and a bridge between the private and public sectors, the Institute can build partnerships and foster collaborative solutions for national and global priorities. And ANSI is a membership organization, providing

members with the broadest access to up-to-date standards policy information and opportunities for participation, leadership, and influence. Finally, ANSI also promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community.

The Standards Alliance Phase 2 will include activities in markets representing a variety of geographical regions and levels of economic development, subject to the agreement of USAID. In consultation with USAID Missions, U.S. government, and private sector experts, ANSI will select the countries/regions based on demonstrated commitment and readiness for assistance, as well as U.S. private sector interest and development impact. ANSI expects to engage on both a national and regional level when appropriate, and to engage partners in the Latin America, Africa, Middle East/North Africa, and Indo-Pacific regions.

SA2 Focus on Medical Devices to Support COVID-19 Response

In June 2020 USAID further recognized the critical role of standards and conformity assessment in supporting public health and safety through an obligation of $3.5 million to the SA2, which is part of the more than $1 billion the agency has committed to aid the global COVID-19 pandemic response. This SA2 project will promote regulatory convergence in the context of COVID-19, good regulatory practice (GRP), and the adherence and adoption of medical device international standards. These objectives will also establish an efficient medical device regulatory environment and framework that will facilitate the COVID-19 response and diminish technical barriers to trade—thus promoting the exportation of quality U.S. medical devices. AdvaMed—a U.S. based trade association and ANSI member—will be the primary private sector partner of the project, and there will be select partner countries in Latin America, Africa, and Southeast Asia, with overflowing impacts within those regions.

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The fourth quarter of 2023 continued with the implementation of activities under the approved subawards, and carried out more progress in the development of new activities that will begin implementation in early 2024. In particular, three activities that were initiated during this quarter included: work on critical minerals and support for the creation of a US Technical Advisory Group (TAG) to ISO TC 345 on Specialty minerals; support for greater U.S. participation in ISO PC 343 (Management Systems for UN Sustainable development goals); and training on sustainable cities in Cote D'Ivoire (CDI). Related to this activity, a training on the ISO 37101 standard which establishes requirements for a management system for sustainable development in communities took place in November 2023. In Q4 good progress has also been made to prepare future work in the automotive sector in Brazil, and digital infrastructure in Tanzania, and Senegal.

Finally, during this reporting period the MDRC achieved significant milestones, including:
(1) through collaborations with regional and local partners. At the regional level, in conjunction with the Pan American Health Organization (PAHO) XI Regional Meeting on the Regulation of Medical Devices, MDRC and the Inter-American Coalition for Regulatory Convergence (IACRC) organized sideline meetings facilitating discussions on emergency use authorization (EUA) and regulatory reliance. MDRC

also facilitated government-to-government engagements, co-organizing a GRP Workshop with the U.S. Food and Drug Administration (USFDA), U.S. National Institute of Standards and Technology (NIST), the Brazilian Health Regulatory Agency (ANVISA), and the National Institute of Metrology, Standardization, and Industrial Quality (INMETRO).
(2) In Africa, focusing on coordination and capacity building through collaboration with stakeholders, including but not limited to, the African Union Development Agency's New Partnership for Africa's Development (AUDA-NEPAD), the Africa Medical Devices Forum (AMDF), and Africa Centres for Disease Control and Prevention (CDC). As a capstone regional engagement, MDRC held the MDRC-FDA-AMDF capacity-building workshop in Nairobi, Kenya, marking the largest ever USFDA delegation for an in-person capacity building event, which convened National Regulatory Authorities (NRAs) from African project countries and at the global level. Following these training sessions, MDRC held a subsequent training in Pretoria, South Africa to support capacity building with the South African Health Products Regulatory Authority (SAHPRA). During these sessions, MDRC enabled engagement between SAHPRA and the South African Bureau of Standards (SABS) for compliance with GRP – TBT as well as with the standards technical committee for medical devices.
(3) In Southeast Asia, MDRC submitted the Bahasa translations of the three MDRC deliverables to the Indonesian Ministry of Health (MoH): GRP recommendations for the MoH's SOP on medical device regulation; Guidance on implementation of GRP and the TBT/CA checklists; and GRP recommendations for implementation of the medtech-relevant articles of the Omnibus Health Law. To conclude the work, MDRC developed a final presentation for the Director General for Pharmaceutical and Medical Devices and held a briefing with the Director of Medical Device Production and Distribution. Following the presentation, the MoH shared action items that have been implemented as a result of the capacity building activities and GRP recommendations for the implementation of the medtech-relevant articles of the Omnibus Health Law.

2.2 Non-COVID-19 Related Activities Activity Implementation Progress

GLOBAL

Development Objective #1: Countries have developed their national quality infrastructure

Activity #13 – Support for critical minerals standardization coordination

In March 2023, ISO/TMB and ISO Council approved and accepted the report of the Strategic Advisory Group (SAG) on Critical Minerals. The group's mandate was agreed as follows:

Undertake an analysis of existing and potential standardization work in the area of critical minerals from the point of initial extraction (mining and production of raw materials), and processing steps through to pre-cursor materials; and make recommendations to the TMB in this regard.

ANSI, as the U.S. representative to ISO and an active member of ISO/TMB and ISO Council, participated in the SAG. The SAG on Critical Minerals recently provided a report of its recommendations to the ISO/TMB, and in parallel, a new technical committee was established, ISO TC 345 on Specialty Metals and Minerals. In Year 5, the SA2 will support the work of the SAG on Critical Minerals and TC 345 through

activities such as:

- Conducting awareness building to explore forming a U.S. mirror committee (TAG) to further bolster U.S. input and/or leadership in TC 345, thereby influencing outputs at the international level.
- With the input of the VTAG, support activities recommended by the SAG as next steps including dialogue with other ISO members in support of any new standards proposed or developed; training or awareness-building activities that would enable developing countries to participate in standards development for critical minerals.
- Coordinate within the U.S. stakeholder group including U.S. government agencies to align future work within ISO with U.S. strategy on critical minerals.

Implementation continued during Q4, 2023 where ANSI continued the setup of a U.S. TAG to participate in the activities of ISO/TC 345 by:

- Confirming that John Bonevich from NIST will be US TAG chair;
- Maintaining and updating the TAG website housing all the information related to the work of TC 345 for all US TAG members;
- Hosting biweekly meetings with the US TAG chair to continue coordination and planning;
- Holding biweekly meetings with USAID to move the project forward, starting in Q1 2024 those meeting will happen once a month;
- Proceeded to reach out to potential TAG members and informing them of the formation of the TAG. Including experts from the related TAGs for ISO committees on Lithium and Rare Earth;
- Using the IWA on Sustainable Critical Minerals Supply Chains as a tool for furthering the outreach efforts toward relevant stakeholders for the TC 345.

AFRICA

Development Objective #1: Countries have developed their national quality infrastructure

Activity #3 – Research on WASH-related product standards and their reference in law, regulation, and policy

Partner countries: Ghana, Uganda, and Zambia

Activity #3.3 – Incorporate findings from deskwork and interviews into comprehensive country-level reports

The comprehensive country-level report has been drafted and revised several times by ANSI, CWSC, and IAPMO staff. A final draft report was sent out to CWSC's stakeholders to collect their feedback, and CWSC has received comments from two contacts. The CWSC will be working to review the comments and revise the draft in Q1 2024. The CWSC will then provide a final copy to ANSI for publication by early February.

The webinar for the launch of the Report has been scheduled for Wednesday, February 21st. The CWSC anticipates using this webinar as an opportunity both to present the findings and seek feedback, including

questions and comments.

Activity #14 – Standards for Bioethanol Household Energy in Africa (STAND4BE) ***(new addition to work plan in Q3)***

Partner country: Mozambique

Over the last reporting quarter, the team organized a two-day capacity-building training in Maputo, which was hosted in collaboration with the National Institute for Normalization and Standards (INNOQ) and provided an opportunity for bioethanol energy and standards experts from Mozambique and the United States to share international best practices and policies for bioethanol standards development, both in the clean cooking and transportation sector.

The workshop was designed to support the development of Mozambique's bioethanol economy through blending mandates and other related goals stated by the government and specific to the August 2022, Economic Acceleration Stimulus Package (PAE). It was very timely as it allowed the program to pursue ways of implementing the biofuels strategy in synergy with other efforts undertaken by the U.S. Government. Pivot had been leading policy discussions with a group of stakeholders over the last year prior to this work, which allowed the Standards Alliance to structure the event with a greater awareness of dynamics in the country, and make connections that were beneficial to workshop implementation.

This activity aimed at creating a clear pathway for the adoption of ASTM E3050 following an in-depth technical working session in which INNOQ participated. The process of adoption was undertaken by INNOQ, and they successfully adopted the standard in December 2023.

During the post implementation of the project the team is also working to achieve other milestones that were discussed during the training such as the adoption of 3-4 additional relevant biofuel standards through ASTM. INNOQ is already in the process of vetting existing standards that they could adopt for Mozambique and anticipates these will be adopted early in 2024.

Finally, Pivot is also following up with the Ministry of Energy regarding agreements that would allow for capacity building, technical assistance, and knowledge transfer over the next three years in Mozambique. An MoU between USGC, Pivot, and the Ministry of Energy has been created, and approved by Pivot, USGC, and the Mozambican Ministry of Foreign Affairs. This document has been translated, and the next step is to host an official signing of the MoU in Mozambique. A tentative date of March 2, 2024 has been set, as this coincides with a USDA Deputy Secretary's visit to the region.

Activity #15 – Supporting localization through the implementation of ISO 37101: Sustainable Development in Communities — Management System for Sustainable Development (MSSD) ***(new addition to work plan in Q4)***

Partner country: Côte d'Ivoire

During this first reporting quarter for this activity the team was able to review existing national policies on decentralization and how the regulatory process works in Côte d'Ivoire, in consultations with the " Direction Générale de la Décentralisation et du Developpment Local" or the General Directorate of Decentralization and Local Development (DGDDL) and the National Standards Body CODINORM.

Based on this review the team organized a kick off meeting with ANSI and USAID HQ Program Manager on November 2, 2023 to coordinate future discussions with DGDDL and the USAID Mission in Côte d'Ivoire.

Starting in the next reporting quarter the team intends to organize a roundtable with key public stakeholders in the country to share best practices policies on decentralization, and also start training with two pilot communities on the ISO 37101 building on the lessons learned during trainings for ISO 37120 during the Phase 1 of the Standards Alliance.

INDO-PACIFIC

Development Objective #1: Countries have developed their national quality infrastructure

Activity #7 – Increase the Flow of WASH Services

Partner country: Indonesia

Activity #7.1 – Initiate development of new Indonesian national standard related to water faucets, based on existing international standards.

PT IAPMO Group hit an important milestone in Q2 2023. Its faucet testing laboratory has full capabilities to test to SNI 122:2022. The lab's accreditation by KAN is still pending. Final paperwork was submitted to KAN in Q4 2023. IAPMO's lab is now waiting for its scope expansion assessment by KAN; based on conversations with KAN, IAPMO anticipates that the audit will take place by Q2 with official accreditation and recognition following shortly thereafter by Q3 2024.

IAPMO continues to collaborate the Indonesian Plumbing Association (APIN) on the implementation of SNI 122:2022. This quarter, IAPMO joined PERPAMSI (Association of Indonesian Drinking Water Companies) in November 2023 to broaden the coalition of support for this effort. In January 2024 an article is scheduled to be published in PERPAMSI's magazine to raise public awareness of this effort. Recipients of this magazine include water companies, city managers, and other government and industry stakeholders.

2.3 COVID-19 Related Activities Implementation Progress

GLOBAL

Development Objective #4: Countries have COVID-19 plans that leverage their NQI in a trade-facilitating manner

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Global

Partner countries: Brazil, Colombia, Ghana, Indonesia, Kenya, Mexico, Peru, South Africa

In Q4 2023, MDRC advanced GRP in medical technology regulatory frameworks through engagements at local, regional, and global levels. During meetings with stakeholders, including ministries of health, regulatory coordinating bodies, national standards bodies, standards organizations, and regional trade associations, MDRC observed that the absence or lack of proper implementation of legal foundations, the lack of sufficient and skilled resources at the NRAs and inappropriate application of pharmaceutical regulatory criteria to medical devices and in vitro diagnostics (IVDs) constitute a barrier to advancing regulatory convergence. MDRC also highlighted that many regulatory bodies have limited dedicated staff for medical devices, emphasizing the importance of prioritizing training on reliance and regulatory convergence over resource-intensive processes such as dossier reviews, which can create medtech trade and health barriers.

During Q4, MDRC supported project countries' efforts to conduct appropriate regulatory oversight while minimizing regulatory burden on industry through meetings held on the sidelines of the Medical Device Single Audit Program (MDSAP) 2023 Forum, which ANVISA hosted in Brasília, Brazil. MDRC meetings with USFDA, ANVISA, and COFEPRIS provided an opportunity to strengthen COFEPRIS's understanding of ANVISA's implementation of medical device regulatory best practices including standards and conformity assessment – with a focus on reduction of dossier review backlogs. The complementary participation of MDRC and COFEPRIS in the MDSAP Forum together with other global NRAs allowed COFEPRIS to hear from other reference authorities presenting overviews of regulatory updates specific to their countries and discuss utilization of the MDSAP program, which also contributed to their acceptance as a MDSAP Affiliate Member.

Finally, MDRC through the Inter-American Coalition for Regulatory Convergence continued its engagement with the World Health Organization (WHO) to address future collaboration to advance MDRC recommendations and efforts to address WHO internal processes that are not aligned with WHO guidance for NRAs on GRP (See Section 2.4: Implementation Challenges). In December, MDRC attended the 11th Annual Collaborative Review Program WHO hosted in Doha, Qatar. These panels brought the Medical Device and IVDs sector to the conversation, by highlighting the critically necessary differentiation between pharmaceuticals and devices, as well as on GRP and the relevance of capacity building for their implementation. During this event, WHO acknowledged the need to revise its own internal implementation of GRP, including public consultation its own process to develop guidelines.

Africa

Activity #12.6 – Tier One and Two Regional Meetings/Trainings

Regional

In Q4, following extensive coordination with AMDF members and partner NRAs – principally USFDA – MDRC held the MDRC-FDA-AMDF capacity building workshop on 6-10 November. Sessions incorporated the training curriculum co-developed by MDRC and USFDA – with critical input from stakeholders such as PPB and SAHPRA – and the workshop marked a capstone regional engagement for the project.

In preparation for the MDRC-FDA-AMDF workshop, MDRC conducted key meetings with session speakers and partners, including USFDA, the Medical Technology Industry Association of Kenya (MEDAK), global SMEs, the Association for the Advancement of Medical Instrumentation (AAMI), and AMDF to

finalize the MDRC agenda, align messages, and secure participation from NRAs of Australia (TGA), Brazil (ANVISA), and Singapore (HSA) to share experiences on reliance.

Key takeaways and highlights from the session may be found below, with additional information in the November monthly report and the MDRC website.

Over the four-day continental workshop, the sessions were structured to cover a diverse range of topics, fostering knowledge exchange and collaboration among participants. The opening day commenced with welcoming remarks from distinguished figures from PPB, AUDA-NEPAD, and Africa CDC. MDRC set the goals for the week, emphasizing information exchange and capacity building among AMDF members, partner NRAs, Africa CDC, and industry. The subsequent sessions delved into crucial subjects pertaining to regulation of medical devices and international standards, including ISO 13485 and ISO 14971 conformity assessment. The day concluded with a recap by the AMDF Vice Chair, who stressed the importance of reliance and stakeholder engagement.

Day 2 focused on standards, featuring discussions on voluntary consensus standards, their regulatory use, conformity assessment, and optimization for regulatory purposes. The agenda included open discussion and panel insights with representatives from USFDA and Standards Developing Organizations including ISO and AAMI and in which the relevance of multiple medical device SDOs and standards were highlighted including IEC, CLSI, IEEE, ASTM International, et al.

Day 3 centered on the Medical Devices Single Audit Program (MDSAP), including aspects such as audit report and certificate, audit approach, assessment program, and the current state of the program. An interactive session on post-market activities, addressing reporting and actions from both a regulator's and industry's perspective, concluded the day.

Day 4 commenced with an in-depth exploration of GRP, featuring case studies from regulatory bodies, including the Australian Therapeutic Goods Administration (TGA) and Singapore Health Sciences Authority - Medical Devices Branch (HSA) to facilitate global dialogue. The discussions extended to the regional landscape of In Vitro Diagnostics (IVDs), with insights from Africa CDC and Roche Diagnostics. USFDA presented on GRP with regard to the WTO Agreement on Technical Barriers to Trade, which concluded the continental scope of the engagements.

Day 5 featured parallel sessions with USFDA government-to-government (G2G) meetings with participating NRAs and a workshop convening PPB, the Kenyan Bureau of Standards (KEBS) and MEDAK to analyze Kenya's MD conformity assessment regime for medical devices, utilization of international standards and post-market vigilance and surveillance, including the scope of responsibilities at PPB and KEBS. Speakers from MDRC, USAID, ANSI, USFDA, PPB, and MEDAK set the stage for sessions "Conformity Assessment Process for Medical Devices in Kenya", the "Role of PPB concerning the Pre-Export Verification of Conformity to Standard (PVoC)", and the "Role of National and regional Standards Development Organizations". The workshop concluded with the commitment of all institutions to continue discussions on several areas of concern shared by MEDAK and the international experts, as well as to provide the necessary trainings to develop the necessary framework to streamline PVoC and restructure scope of responsibilities and work among KEBS and PPB.

Ghana:

MDRC sponsored five Ghana FDA officials to attend the MDRC-FDA-AMDF capacity building workshop

on 6-9 November and facilitated in-person interactions that lead to a follow up session mainly focused on implementation of GRPs where the GRP and CA checklists were shared to facilitate the process.

In December, MDRC held a formal meeting with Ghana FDA whose representatives highlighted ISO 13485 as a top priority and requested additional training. MDRC also identified reliance – specifically the need to develop specific guidance for implementation – as a priority area. MDRC mentioned raised the importance of GRP implementation and offered to analyze Ghana FDA's current policy for comparison with GRP alignment and proposed several dates in January to regroup.

Kenya:

During Q4, MDRC continued the momentum from capacity building activities with PPB in August 2023 and led PPB through a review of their regulatory instrument development processes. MDRC provided three critical documents to assist the review:

1. Report containing recommendations and a gap analysis on the current guidelines for regulatory process and the Standard Operating Procedure (SOP) on public consultation
2. MDRC-annotated guideline for regulatory process, and a compliance checklist that considers the TBT agreement
3. African Continental Free Trade Area (AfCFTA) requirements

MDRC committed to remain available, offering further discussion or clarification.

On 10 November, MDRC, KEBS, PPB and MEDAK conducted the Workshop on "Conformity Assessment, Product Imports & International Standards for discussions on Conformity Assessment Process for Medical Devices in Kenya", the "Role of PPB concerning PVoC", and the "Role of National and regional Standards Development Organizations and the IECEE CB Scheme". The workshop concluded with closing remarks from MDRC, USAID, KEBS, MEDAK, and PPB, solidifying the collaborative commitment to advancing medical device standards and conformity assessment.

MDRC also continued its engagement with MEDAK, specifically regarding the Pre-Export Verification of Conformity to Standard (PVoC) in advance of the workshop. MDRC regularly emphasized the importance of case studies to support the elimination of duplicative, redundant and overly restrictive requirements established through PVoC for medical devices.

South Africa:

Following extensive planning, MDRC held a capacity building workshop with SAHPRA on 14-16 November.

In advance of the training sessions, MDRC met with the South African Health Products Regulatory Authority (SAHPRA) to discuss the agenda, speaker series, and logistics for the capacity building session. MDRC sent invitations to U.S. FDA, Australia TGA, Singapore HSA, Brazil ANVISA, and WHO. To ensure coordination, MDRC also met with the South African Medical Technology Industry Association (SAMED), the Southern African Laboratory Diagnostics Association (SALDA), and Medical Device Manufacturers of South Africa (MDMSA) prior the MDRC-FDA-AMDF and SAHPRA events.

Additionally, MDRC provided guidance regarding proper responses to open public consultations on medical device technical regulations. It was shared that MDRC is helping SAHPRA navigate the local process to ensure notification of the new proposed regulations to the TBT for international commenting. As a result of this collaboration, MDRC succeeded in organizing the first-ever meeting between SAHPRA and the SABS Standards Division and WTO/TBT Enquiry Point, where the need to establish an inter-institutional MoU was identified. SABS and SAHPRA leaders committed to establishing this MoU.

On 14-16 November 2023, MDRC along with SAHPRA delivered the workshop tailored to the needs of south Africa, all under the Training Curriculum. WH and NRAs from Australia, Brazil and Singapore contributed to the development of competencies by sharing their experiences on implementation of reliance and utilization of international standards, whereas experts from USFDA supported both in technical topics, as well as on GRP and Conformity Assessment, the later along with SABS and the South African National Accreditation System (SANAS). In-person and virtual participants totaled 317, featuring representation of 17 African NRAs.

As a result of the training, SAHPRA has had multiple new engagements at an accelerated pace with both the regulated sector and well as with several government institutions to address the lack of the compliance with GRP and TBT legal obligations. For example, SAHPRA plans to hold a meeting with the National Department of Health to be held early in 2024 to understand how the current inter-agency system should operate with regard to WTO notifications.

SAHPRA has also met with the following institutions:

- SANAS and SABS on standards and conformity assessment, where the institutions agreed to continue to work in improving the understanding and work on the medical device standards

- The Department of Trade and Industry for SAHPRA to present on their current status regarding medical devices.

- The National Department of Health and Africa-CDC to identify priority diseases and apply them to decisions on related IVDs

- The Council for Scientific and Industrial Research (CSIR) to discuss and align on the scope of responsibilities of the two institutions, in particularly how CSIR may assist medical device manufactures comply with regulatory, standards and conformity assessment requirements
- South African WTO TBT Enquiry Point at SABS to re-establish the required processes to operationalize notifications to TBT

MDRC and SAHPRA also explored the possibility of developing an SOP on GRP implementation; an area that will need to be followed up on during the post implementation phase of the project.

Indo-Pacific

Activity #12.10 – Tier Two Regional Meetings/Trainings

Indonesia:

During Q4, MDRC submitted the Bahasa translations of the three MDRC deliverables to the Indonesian Ministry of Health (MoH): GRP recommendations for the MoH's SOP on medical device regulation; Guidance on implementation of GRP and the TBT/CA checklists; and GRP recommendations for implementation of the medtech-relevant articles of the Omnibus Health Law.

To conclude the work, MDRC developed a final presentation for the Director General for Pharmaceutical and Medical Devices and held a briefing with the Director of Medical Device Production and Distribution. The MoH expressed its gratitude for the capacity building exercises, as well as the analyses done as part of the three deliverables; they have started implementing some of the recommendations, which are outlined below.

Item	Capacity building thematic area	Action
1	SaMD and AI Regulatory Opportunities and Solutions	The Directorate of Medical Device Production and Distribution is using the training materials as a guide and reference as it drafts a set of regulations on SaMD.
2	Personalized Medical Devices – International References and Regulators' Experience	There is currently no guidance on PMDs in Indonesia. The Directorate is reviewing the training materials and plans to draft a set of regulations in the future.
3	Good Regulatory Practices	MoH Indonesia is currently drafting an agreement to enter into an MoU with MoH Malaysia on Good Reliance Practices, amongst other collaborations with the country.

Item	SOP recommendation	Action
1	Check competence and legal feasibility of the alternatives	Article 23: In preparing the draft Minister of Health Regulation, a feasibility test must be carried out. A team at MoH has been formed, and the test has been carried out in accordance with the guidelines as stated in the Feasibility Test Implementation Mechanism and Checklist Table.
2	Conduct a public consultation	Article 24: In preparing the previous Ministry of Health Regulation, discussions were held with technical units within the Ministry of Health, other related agencies/institutions, professional organizations, universities, legal experts, and other related experts.
3	Ex Ante Regulatory Impact Analysis (RIA)	Article 24: The preparation of the analysis document for the formation of the Minister of Health Regulation is carried out by referring to the guidelines as stated in the Guidelines for Preparing Analysis Documents for the Formation Regulations.

		In conducting the analysis, the team has used the RIA method to systematically assess the positive and negative impacts of a draft health ministerial regulation.

Latin America

Activity #12.11 – The Coalition will lead regional MDRC project efforts, convene stakeholders for meetings/trainings, and provide capacity-building resources.

The Coalition led regional and local project efforts throughout Q4 2023. An overview meetings and trainings may be found in the MDRC quarterly report and Section 3 Stakeholder Participation and Involvement. An overview of the major developments is listed below:

- Held a regional convening and the on the sidelines of the XI Regional Meeting on the Regulation of Medical Devices.
- MDRC provided capacity building resources through the Coalition website https://www.interamericancoalition-medtech.org/regulatory-convergence/.
- Mexico: 13 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development. MDRC continued efforts to develop and approve checklists for implementing GRP in key governmental bodies. MDRC advanced several workstreams.
- Peru: 0 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development.
- Colombia: 32 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development. See Activity 12.24 for more info.
- Brazil: 1 formal meeting with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development.

Activity #12.16 – Tier One and Two Implementation Meetings and Workshops with Project Countries and regional stakeholders

During Q4, MDRC worked in close coordination with the U.S. FDA Latin America office to plan a workshop deepening understanding and implementation of GRPs, with a focus on public consultations and regulatory impact effectiveness. The program also included the participation of MDRC and the Latin American Federation of the Pharmaceutical Industry (FIFARMA), which presented an opportunity for both entities to outline their activities and intended impacts to avoid duplicative work.

Additionally, following extensive planning in Q2 and Q3 2023, MDRC, in partnership with the IACRC and PAHO, organized a gathering of more than 230 stakeholders including 10 NRAs from Latin America, both in person and virtually, at a side event of the XI Regional Meeting on the Regulation of Medical Devices in San Salvador, El Salvador. This meeting provided a platform for discussion and engagement among NRAs, industry representatives, and other relevant stakeholders on topics including EUA and the implementation of regulatory reliance.

The program of the XI Regional Meeting, prepared by the MDRC in collaboration with PAHO, enabled the exchange of experiences regarding reliance among NRAs and stakeholders in Latin America. The participating countries included Brazil, Colombia, and Mexico. The program was hosted by the Dirección General de Medicamentos (DNM) in San Salvador, El Salvador, with over 100 attendees participating in person, and PAHO acknowledged the relevance of the joint collaboration with the IACRC/MDRC.

On the sidelines of the PAHO regional meeting, which provided a timely opportunity for MDRC to advance MEL plan metrics with national and regional partners, the IACRC convened its semi-annual meeting of Coalition medtech association members to advance collaborative efforts in the areas of reliance, GRP, public consultations, increased participation in Standard Development Organization (SDO) Committees, MDSAP, and the utilization of electronic tools.

As a regional complement – and as a result of the halo effect of the MDRC work in the region – the IACRC met with the Salvadorian Central Regulatory Coordination Body (OMR) to present on IACRC/MDRC objectives, workstreams, and results. IACRC extended an invitation to OMR to participate in the upcoming open webinars on Good Regulatory Practices (GRPs). Finally, IACRC offered to explore the possibility of providing OMR with online training in 2024. OMR expressed its appreciation for the presentation and agreed to explore potential collaboration on topics of mutual interest.

This series of engagements allowed MDRC to advance objectives in the region and deepen relations with project partners. Notably, for the first time under SA2, COFEPRIS participated in person, presenting on EUA during the External Stakeholders Session.

Brazil

During Q4, MDRC concluded workstreams with key stakeholders including ANVISA, MDIC, and INMETRO focused on regulatory cooperation and international agreements.

In Q3 2023, Brazil's engagement in the August PPB trainings highlighted the project country's active involvement in international agreements, collaborative regulatory efforts, and capacity building initiatives pertaining to medical devices. ANVISA's engagement with international partners in Q4 further emphasized Brazil's role in advancing regulatory practices at the regional and global level.

For example, on 24 October, MDRC, INMETRO, ANVISA, NIST, and USFDA engaged in a workshop to exchange knowledge on GRPs in the medical devices sector and specifically on the conformity assessment procedures (CAP). The four authorities present shared their experiences and procedural rules in CAP. Each authority delivered a presentation outlining its roles and responsibilities, followed by a question-and-answer session among the participants. The authorities agreed to continue their dialogue and considered arranging a dedicated meeting between INMETRO and MDRC to further examine the topic of regulatory impact analysis within CAP.

This "International Experience Exchange Workshop" was the first of four items in the project action plan developed with the Ministry of Industry and Development – Division of Competitiveness and Regulatory Practices (MDIC/SCPR) in Q3 2023. Through its Q4 engagement, MDRC successfully concluded work on the remaining items in the action plan, which included:

- **Internal Regulatory Alignment**: INMETRO enhanced internal regulatory alignment by analyzing the checklist – developed with guidance from MDRC – to understand how to improve its internal guidance on GRP regarding technical and conformity assessment regulations. As a result, INMETRO provided a document to MDRC which contains the INMETRO assessment on compliance with the checklist and identifies areas for improvement. This document is an important output for further engaging INMETRO on a more effective implementation of foundational GRP.
- **Subsidy Taking**: With contributions from IACRC and MDRC, INMETRO evaluated the public consultation rationale within the existing plan and explored how to improve rules applicable to CAP of medical devices by INMETRO.
- **INMETRO Good Regulatory Practices Manual**: INMETRO began revising its Regulatory Practices Manual in alignment with the Ministry's strategic development.

Finally, following Q3 2023 meetings with ANVISA to review the WHO/TBT Agreement and the U.S.-Brazil ATEC Protocol which addressed the potential negotiation of a sectorial annex on medical devices between Brazil and the United States, AdvaMed suggested to the USFDA and ANVISA that they consider the establishment of an enhanced USFDA-ANVISA medical device regulatory cooperation agreement, incorporating the recommendations of the MDRC, that could later be formalized by the respective trade authorities into a U.S.-Brazil ATEC medical device annex, building and expanding upon the USMCA.

Colombia

In Q4 2023, under the direction of workplans developed during Q3, MDRC made substantial advancements in its collaborative efforts with local Colombian stakeholders to enhance regulatory practices, promote international alignment, and foster collaboration with government entities to streamline processes and achieve a stronger regulatory environment. Key stakeholders and work advanced include:

- **Ministry of Commerce, Industry and Tourism (MinCIT)**: MDRC collaborated with MinCIT on final project initiatives, including designing guidelines for the identification of technical regulations based on the application of the term "administrative requests" included in the definition of technical regulation that is part of the TBT Agreement. Simultaneously, MDRC supported the development of a comprehensive checklist for the TBT/CA. Both are cross-cutting tools available to all entities developing technical regulations at the national level.

  MDRC presented the checklist and a guideline to align interpretation criteria of technical regulations under their current regulatory framework. The checklist and guideline were approved as foundational resources in November and December.

  Additionally, efforts were made in conjunction with the National Planning Department (DNP) to incorporate the guide and checklist into the procedure developed by the DNP for the implementation of public regulatory policy, which is part of the Integrated Planning and Management Model (MIPG) applicable to national and municipal government entities. By December, both were officially included on the MIPG.

- **Ministry of Health (MoH)**: MDRC collaborated with the Ministry of Health (MoH) to successfully include an enhanced version of the checklist in the approved procedure. Enhancements are related to additional activity details to specifying stages such as regulatory

agenda setting, ex-ante analysis, ex-post analysis, and public participation processes. At the end of December 2023, the Ministry approved and incorporated the checklist into the regulatory procedure, which includes technical regulations on medical devices and is applicable to the entire Ministry.
Additionally, MDRC participated in a problem tree presentation by MoH on the ex-ante analysis of decrees 4527 and 3770. This problem tree, developed collaboratively with MDRC in the Q1 2023, was reaffirmed as relevant, emphasizing the ongoing importance of implementing reliance and aligning with international standards.

- **National Planning Department (DNP)**: Utilizing the GRP procedure adopted by the Ministry of Health, MDRC collaborated with the National Planning Department (DNP) to further refine a proposed procedure aimed at implementing the Regulatory Improvement Policy across all national government entities. In December 2023, DNP incorporated this procedure into the Integrated Planning and Management Model (MIPG) for adoption by national and local entities, starting in the Q1 2024, which will be supported by the procedural toolkit developed by MDRC. Finally, interactions with Colombia's single public consultation system (SUCOP) led to the development of a format accepted by the DNP to promote and analyze stakeholder participation, which will be made available to all national and municipal government entities.

Finally, MDRC engaged with the National Business Association of Colombia (ANDI), Medical Devices Chamber to provide a project update and overview workstreams with MinCIT, MoH, and DNP in regards to GRP implementation and interpretation criteria linking international and domestic obligations.

Mexico

In Q4, MDRC made significant progress in its engagement with COFEPRIS. Most noteworthy should be the achievement, on 31 October, 2023 when COFEPRIS submitted NOM-241 to the Ministry of Economy for inclusion for revision within the 2024 National Quality Infrastructure Plan.

In discussions with COFEPRIS, plans were confirmed for representatives' participation in the MDRC External Stakeholders' session, where expectations for MDSAP application approval were shared. During these discussions, COFEPRIS mentioned challenges in ISO 13485 recognition, prompting MDRC to offer technical support, while the status of an equivalence agreement consultation awaits legal department advice. COFEPRIS also shared the plans for multi-stakeholder working groups to draft updates on NOM-137 (labeling) and NOM-240 (Post-market Surveillance). These workstreams have advanced quickly, and the first drafts were completed in November. The updates will be published for open public consultation in 2023-2024, and the working groups expected that TBT will be notified of these drafts for international consultation. It was agreed that the additional training session on stability studies would be held in 2024.

In October, in collaboration with Dorantes Advisors, MDRC conducted a training session on the application of Good Regulatory Practices (GRPs) in Mexico. This session, held in anticipation of upcoming regulatory revisions, primarily focused on preparing for regulatory reviews, especially in the context of good manufacturing practices (GMPs).

On 17 October, COFEPRIS published a document "Regulatory Certainty Strategy for the Medical Device Sector", highlighting longstanding collaborative efforts with MDRC, particularly in the development of the GRP Checklist. The document reflects the regulatory intent to promoting compliance with domestic and

international obligations, including GRP and the recognition of MDSAP reports. On 7 December, an English language version was also published by COFEPRIS.

During Q4, frequent meetings with industry members complemented engagement with COFEPRIS. In meetings with medical device manufacturers, MDRC discussed NOM-241, outlining plans to connect with industry associations including but not limited to the Mexican Association of Innovative Industries of Medical Devices (AMID) and the National Chamber of the Pharmaceutical Industry (CANIFARMA). Participants used these meetings to align on their approach for requesting NOM-241 inclusion in the 2024 National Quality Infrastructure Program. This request is supported by analyses identifying areas not aligned with international standards or applicable to medical devices.

In November, 2023, MDRC delivered an analysis developed along with Dorantes Advisors regarding the Mexican Pharmacopeia and its Supplements, including medical devices, which concludes its categorization as a technical regulation. Therefore, in addition to requiring the implementation of the GRP and CA Checklists developed by MDRC upon the request by COFEPRIS, the "Mexican Official Norm NOM-001-SSA1-2020" must also be updated to ensure compliance with all Mexico's GRP international obligations.

In December, COFEPRIS published the Guideline for Registration of Medical Devices, which includes a definition of medical devices aligned with the definition agreed upon by the Pacific Alliance Members. The definition varies slightly from the current definition accepted by the IMDRF members, but the variations are unlikely to create any impact for registration/trade purposes.

Peru:

Active engagement of the newly appointed director of DIGEMID and the private sector represented by CCL COMSALUD and the Medical Device Committee of AMCHAM-ALAFARPE (CDMMAA) during the Engagement with External Stakeholders Session and PAHO's Open stakeholders' session, provided visibility of an intention to revamp the Peruvian regulatory framework for medical devices.

2.4 Implementation Challenges

Activity #3 – Research on WASH-related product standards and their reference in law, regulation, and policy

The CWSC has received very little engagement from stakeholders via email in Q4 2023. The CWSC is hoping that the workshop event will spark further interest in engagement and are committed to hosting a successful workshop.

Activity #7 – Increase the Flow of WASH Services

Work on the RIA, scheduled for Year 5 has been delayed. The Ministry of Industry has let IAPMO know that they would like time for the SNI 122:2022 to be normalized with Indonesian manufacturers prior to taking steps to make it mandatory (including the RIA). While no set timeline has been given by the Ministry, IAPMO is working to build local and international support for the new standard to be made mandatory. This includes encouraging Indonesian manufacturers to certify their relevant products to the new standard who are reluctant to do so without the standard being made mandatory.

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

WHO MedTech Guidance

MDRC continues to include the WHO and its international benchmark guidance for Medical Device National Regulatory Authorities (MD NRAs) in programming with project country NRAs. However, MDRC is of the assessment that a number of WHO recommendations and practices work at cross-purposes to MDRC efforts to build NRA capacities as well as guidance developed by the WHO itself as well as the IMDRF, FDA/CDRH, WTO and the WHO.

In Q3 2023, project partners, such as the FDA/CDRH, agreed with these concerns directly to the WHO. During coordination calls with USAID and project teams, MDRC discussed NRAs' reliance on WHO, especially in LMICs, and how inappropriate provisions of the Global Benchmarking Tool Plus (GBT+) and lack of GRP references in WHO guidance documents can hinder MDRC's ability to realize its full project objectives. USAID and FDA shared that they will seek additional opportunities to engage with WHO on pilot tools and to provide feedback on GBT+, noting that support from MDRC and other project teams will be beneficial.

As MDRC outlined in-depth three examples of inappropriate WHO practices in the Q2 2022 Report, they are briefly enumerated and expanded upon below:

1) WHO inappropriate inclusion of medicines regulatory provisions in the WHO Global Benchmarking Tool Plus (GBT+) as applicable to medical device NRA function and assessment
2) WHO non-compliance with its own guidance on Good Regulatory Practices in the development and publishing of WHO guidance documents for MD NRAs. Example: The WHO does not systematically provide sufficient time for public comment on draft documents particularly for LMICs (for example 60 days per the WTO TBT agreement);
3) WHO lack of adherence to the WHO Global Model Regulatory Framework (GMRF) stepwise approach in its recommendations to MD NRAs. Example: The WHO continues to emphasize capacity building for LMIC MD NRAs on complex regulatory functions such as dossier review and facility inspection vs emphasizing reliance models such as use of international standards and conformity assessment like MDSAP which can free up MD NRA resources for attention with local medtech industries.

MDRC has recommended that its U.S. Government partners (such as the HHS, FDA, and USAID) consider establishing a dialogue with the WHO to address these points in bilateral or multilateral fora. The MDRC has also recommended the GMTA consider a parallel dialogue with the WHO with a view to aligning international aid and capacity building approaches with NRAs.

Activity #13 – Support for critical minerals standardization coordination

The challenge of recruiting members for the TAG continues to an extent since this is still in its very early phases and therefore there is no fully detailed work or specific proposal yet. The first ISO/TC 345 meeting has been announced, however, and will be held in Paris in May 2024 which will help the outreach effort toward new members for the TC.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Activity #	Sub activity #	Country	Meeting/ Event	Date	Participants
12	12.16	Mexico	Hybrid GRP Training for MedTech Associations	5 October	121 attendees 84 female, 37 male 0 public sector, 121 private sector
12	12.16	Latin America - Regional	External Stakeholders Meeting on the Sidelines of the XI PAHO Regional Meeting on the Regulation of Medical Devices	10 October	233 attendees 161 female, 71 male, 1 did not disclose gender 68 public sector, 165 private sector
12	12.11	Latin America - Regional	MDRC-Inter-American Coalition for Regulatory Convergence in the Medical Technology	12 October	68 attendees 54 female, 14 male 0 public sector, 68 private sector
12	12.16	Brazil	MDRC Workshop with INMETRO, ANVISA, NIST, and USFDA	24 October	17 attendees 8 female, 9 male 14 public sector, 3 private sector
12	12.6	Africa - Regional	MDRC-FDA-AMDF Capacity-building Workshop	6-9 November	**Day 1**: 175 attendees 87 female, 88 male 74 public sector, 101 private sector **Day 2**: 147 attendees 75 female, 70 male, 2 did not disclose gender 61 public sector, 84 private

					sector **Day 3**: 141 attendees 75 female, 63 male, 3 did not disclose gender 55 public sector, 86 private sector **Day 4**: 123 attendees 73 female, 48 male, 2 did not disclose gender 43 public sector, 80 private sector
12	12.5	Kenya	MDRC, KEBS, PPB, and MEDAK – Workshop on Conformity Assessment, Product Imports, and International Standards	10 November	50 attendees 25 female, 21 male, 4 did not disclose gender 18 public sector, 32 private sector
12	12.5	South Africa	Good Regulatory Practices & Technical Competencies – South African Health Products Regulatory Authority (SAHPRA) & Regulated Sector Workshop	14-16 November	**Day 1**: 234 attendees 180 female, 44 male, 10 did not disclose gender 19 public sector, 215 private sector **Day 2**: 208 attendees 158 female, 40 male, 10 did not disclose gender 21 public sector, 187 private sector **Day 3**: 176 attendees 135 female, 30 male, 11 did not disclose gender 20 public sector, 156 private sector

15		Côte d'Ivoire	Kick off meeting with USAID Local Mission and DGDDL	2 November	

4. RESULTS ACHIEVED

Performance Indicator #2: Number of trainings conducted about the value of using their national quality infrastructure

Under this reporting period for this performance indicator there are a total of **3** training to report. A breakdown of the different workshops is presented below by activity.[1]

Activity #3 – Research on WASH-related product standards and their reference in law, regulation, and policy

The CWSC anticipated 1 workshop in Q4 2023. This target was not met as CWSC noted in early Q4 2023 that the December-January holiday/festive period in the target countries conflicted with their workshop dates. Therefore, the dates were moved to accommodate the local holiday schedules and to maximize participation. As such, **1** workshop is anticipated for Q1 2024.

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

For Q4 2023, MDRC set a target of **1** workshop. This was exceeded by hosting the following capacity-building workshops:

- MDRC-FDA-AMDF Capacity-building Workshop
- Good Regulatory Practices & Technical Competencies – South African Health Products Regulatory Authority (SAHPRA) & Regulated Sector Workshop

For Q1 of 2024 this activity sets a target of **0.**

Performance Indicator #9: Number of workshop/reserve trade mission participants (Related to Technical Barriers to Trade awareness)

Under this reporting period for this performance indicator there were a total of **1** workshop to report with an objective of **100** participants. A breakdown of the different participants in said workshops is presented below by activity.[2]

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

[1] Activities not mentioned under this section did not select it for their implementation or are no longer under implementation.
[2] *Idem*

For Q4 2023, MDRC had a target of **100** participants; which it exceeded counting with approximately **547** participants in the training. These trainings are essential to building good regulatory capacities and addressing barriers to trade by:

- Delivering high-level presentations on GRP policy implementation at both Tiers One and Two;
- Emphasizing the role of GRP in both recovery from COVID-19 and reducing barriers to trade;
- Participating in in-depth examinations of workstreams to implement GRPs, including timelines and plans for future implementation;
- Exploring efforts to document GRP implementation within pilot project regulatory agencies; and
- Facilitating long-term GRP collaboration among the project countries.

For Q1 of 2024 this activity sets a target of **0.**

5. LESSONS LEARNED

Activity #7 – Increase the Flow of WASH Services

Domestic manufacturers are hesitant about supporting a mandatory standard for faucets. IAPMO is working to educate these manufacturers about the role of this new standard in ensuring the safety and performance of their products as well in making their products more competitive in the global market. The new costs of testing and certification processes which have never been incurred before by these manufacturers continue to be a barrier.

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

The project team continued to incorporate lessons learned on hybrid in-person/virtual engagements with stakeholders. Learning from the execution of the events alongside the June 2022 Summit of the Americas, MDRC organized both virtual and in-person trainings in Q4 2023. Scheduling MDRC programming in conjunction with other major events and multilateral forums per requests from the FDA and MDRC NRAs has significantly facilitated MDRC advancement.

The project team continues to utilize its online capacity-building and digital resource capabilities to extend programming to a large virtual audience. While in-person training is extremely effective, most participants of MDRC trainings remain virtual. MDRC's virtual platform and Zoom licenses are critical to reaching those participants and offering simultaneous language interpretation for both in-person and virtual attendees. These learnings are increasingly critical in the effective execution of capacity building. Identifying the appropriate possible balance between theorical, hand-on trainings and open dialogue guided sessions is critical while planning future capacity building events, to maximize learning opportunities.

Throughout the course of the project, the MDRC has made the majority of its training sessions public, both real time as well as making the video and audio recordings publicly available (in various MDRC country languages) together with event agendas and presentations, as an enduring information resource. This has served three primary functions: (1) it has provided increased "shelf life" to MDRC trainings that include the limited time of global subject matter experts, accommodating audience schedules, particularly important for LMIC NRAs and industry; (2) it has provided transparency to MDRC-provided technical

assistance, allowing partner authorities such as the USFDA, USTR, WHO, WTO et al to be aware of the content that MDRC is advancing and providing them an opportunity to provide feedback; (3) it has provided transparency to MDRC-provided technical assistance, allowing other USAID and USTDA divisions and project teams, in many cases working with the same partner country authorities, to be aware of the content that MDRC is advancing with a view to maximizing coordination of USG-funded TA to partner countries. The MDRC recommends considerations of these lessons learned as a benchmark for similar capacity building projects with medical device NRAs and industry.

Activity #14 – Standards for Bioethanol Household Energy in Africa (STAND4BE)

The physical capacity-building training helped immensely in setting the stage for productive next steps. It allowed Pivot to engage directly with stakeholders and hear firsthand where the challenges and opportunities were, and brainstorm on best practices for addressing them. It also allowed the team to begin building rapport with those stakeholders so that it could effectively continue the conversation from abroad.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Activity[3] #	Sub activity #	Country	Publications/ Reports	Meeting/ Event	Date	Location	USAID participation
3	3.3	Ghana, Uganda, Zambia	Trend Reports	CWSC Workshop	February 2024	Virtual	TBD
15		Côte d'Ivoire		Roundtable on best practices for decentralization	January 2024	Hybrid	TBD
15		Côte d'Ivoire		Training on ISO 37101 w/ pilot communities	January 2024	Hybrid	TBD

[3] Activity #12 has concluded the activities it had under its work plan. As such it does not foresee the organization of new events until the end of its implementation phase at the end of Q2 2024. However, experts from this activity will remain in contact with partner countries and may, on an ad hoc basis, have meetings with relevant stakeholders so that defined outputs be reached in the project lifespan.