Standards Alliance: Phase 2

Quarterly Report

3rd Quarter July 1 to September 30, 2021

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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, 2024
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
Agreement Number:	#7200AA19CA00012
Name of Subcontractors/Subawardees:	Ethical Apparel Africa, AdvaMed, ASTM International, NSF, AWWA, ACI, CWSC, IAPMO
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	3Q 2021 – July 1 to September 30, 2021

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 third quarter of 2021 entailed the continued implementation of activities under approved subawards and the further development and finalization of additional subaward agreements. This has been a highly productive quarter as all subawards are now in the implementation phase. The MDRC program, in particular, made significant progress this quarter continuing outreach with key stakeholders, holding critical meetings, developing stakeholder mappings and gap analyses, and working towards other milestones as detailed in section 2.2. ANSI also continued to monitor the COVID-19 pandemic throughout Q3 and will continue to adjust activity implementation accordingly.

2.2 Activity Implementation Status

AFRICA

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

Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops

ANSI's partner Pivot Clean Energy (Pivot) continued planning events for West African member states to pave the way for regional adoption of clean cooking and transportation fuels during the ECOWAS Centre for Renewable Energy and Energy Efficiency (ECREEE) General Assembly in Q4 2021. Initially, Pivot

planned to host preliminary trainings on clean fuel standards in Ghana and Senegal during Q2; however, the ongoing pandemic has delayed the roll out of these events in-person.

Following consultation between Pivot, ANSI, and USAID; and due to a history of successes stemming from face-to-face interactions on past clean fuels programming, these activities will be tentatively postponed until Q4. If international travel remains restricted during Q4, Pivot will develop an online option to effectively deliver both planned trainings leading up to the 2021 ECREEE General Assembly in December.

This event series will both lay a foundation for local collaboration and will invite participation for the gathering of baseline information and establishment of pilot programs. Supplementing the workshops with these key findings demonstrates the importance of establishing policy and standards to support the practical applications in clean cooking and transportation fuel development.

Activity #2 – Support for African Organization for Standardization (ARSO)

In Q3, ANSI, ARSO and the Personal Care Product Council (PCPC) hosted one webinar as part of the cosmetics training series developed to support the harmonization of African personal care and cosmetics standards. These online trainings included events on cosmetics frameworks and enforcement strategies, the importance of international standards, and case studies from South Africa and Saudi Arabia on cosmetics enforcement and implementation.

This activity continued to target participants in ARSO Technical Committee 40 (TC40) on cosmetics. The training supported sharing of best practices in implementing and establishing regional cosmetics frameworks based on experiences from the Gulf States region aimed to assist ARSO in the development of an African standards framework for cosmetics that will support consumer and industry interests.

The forth webinar was held July 7 and included 56 participants. The webinar provided a thorough overview of the suggested framework for cosmetics standards and enforcement using a case study from Saudi Arabia and the GCC Standards Organization (GSO). Speakers included Ali Alghamdi, GCC Standards Organization; Dr. Mohammed Aljallal, Saudi Arabian Standards Organization, and Ali Wanas, P&G. The fifth webinar is also expected to take place on November 23, 2021.

In Q4, ANSI, ARSO and PCPC will continue to organize and host the cosmetics standardization web-series with the goal of assisting the African continent in adopting a cosmetics standards framework that will support two-way trade, safeguard African consumers, and decrease enforcement burdens and liability on African governments.

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

The Center for Water Security Cooperation (CWSC) has continued with conducting deskwork in Uganda. An introductory call with USAID Mission in Zambia occurred in 3Q 2021 and the Zambia Mission requested a concurrence memo be submitted. CWSC is awaiting notification of approval. An introductory call with Mission in the final project country, Ghana, will occur in Q4.

Activity #8 – Utility Management Standards Training for water sector utilities (Also appears in Indo-Pacific section)

The American Water Works Association (AWWA) subaward agreement is active in India, but to date the project is only planning for introductory calls with USAID Missions in Zambia, Malawi, and Lesotho to occur in 4Q 2021 per AWWA's interest to learn from the India coordination efforts before engaging in Africa. AWWA signed a sub-agreement with ROCKBlue including a scope of work and budget in preparation for work to begin in Africa.

Development Objective #2: Private sector actively participates in countries' national quality infrastructure

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

Work continues using virtual technology to create information sharing sessions with US government staff and stakeholders from the region. In addition, an extensive search for a technical consultant to assist with the technical aspects of the program has been conducted.

On July 28th, a meeting with USG Interagency staff working on standards or TBT issues was held to inform them about the work the Standards Alliance is doing so that they could get more involved if relevant to their work. About 40 people attended the meeting from a number of U.S. government organizations.

A country call with stakeholders in Nigeria was held on July 8th and the Standards Organization of Nigeria (SON) reported that many of their standards are up for 5-year review and SON would like to adopt international standards as a replacement for many of them. Thanks to an introduction by our contacts in Senegal, we also arranged a meeting with the African Refiners & Distributors Association (ARDA). ARDA identified the goal of reaching the specifications identified in African Fuels Roadmap Initiative (AFRI) 6 by 2030 and is drafting an implementation report for AFRI 5 as well as a roadmap to AFRI 6 that is scheduled to be released by the end of the summer 2021. ARDA staff recommended that the Working Group on Refining & Specifications would be the best place to focus our efforts. A country call with Cote d'Ivoire resulted in learning that although there is a national committee on petroleum products, Cote d'Ivoire is not currently aware of, or participating in, the ECOWAS harmonization efforts. In our follow up to Cote d'Ivoire, we encouraged involvement of Cote d'Ivoire in the ECOWAS harmonization work and shared the Feb 2020 ECOWAS Harmonization report. Lastly, we held a meeting with stakeholders in Ghana on 31 August. We learned that the harmonized ECOWAS specifications for gasoline and diesel were sent out for public comment and the responses are due in October. The Ghana Standards Authority (GSA) wants to determine where they can compromise as their national standards were working well. GSA also expressed interest in a more formal relationship with API.

In August, ASTM solicited members from our Petroleum Committee to submit proposals for suitable and qualified professional consultants who could provide their services by using their technical expertise in petroleum standards within the individual West African countries and Technical Harmonization Committees of Economic Community of West African States (ECOWAS) to identify, review and modify existing standards, which can be adopted and applied in the region. Nine candidates were ultimately interviewed, and a consultant based in Ghana with a good understanding of the regional fuel dynamics was selected at the end of September.

Implementation Status

- July 8, 2021 - Virtual meeting held to introduce the project to Nigerian stakeholders.
- July 12, 2021 – Virtual meeting held to introduce the project to the African Refiners and Distributors Association (ARDA).
- July 13, 2021 - Virtual meeting held to introduce the project to Ivorian stakeholders.

- July 28, 2021 – Virtual meeting with U.S. Interagency staff working on standards or TBT issues
- August 20, 2021 - ASTM's University Student Intern completes her preliminary research on important contacts, petroleum laboratories, and training programs in the region.
- August 31, 2021 – Virtual meeting held to introduce the project to Ghanaian stakeholders.
- September 30, 2021 – After extensive search, ASTM contracted with a technical consultant for the period Oct-Dec 2021 (with a possibility for an extension).
- October 2021 – Begin onboarding of new ASTM technical consultant
- Nov - Dec 2021 – Consultant to hold virtual meetings with technical persons in each of the four target countries to identify what methods they are using, how are they applying them, and to find out about any challenges they may have.
- March 2022 – Two-day technical workshop to be held in Ghana
- Ongoing – API has retained C&M International to research the global use and deployment of API standards by regulators and related authorities in West Africa.

Activity #6 Africa Concrete and Building Code Adoption Initiative

In Q2, USAID approved ACI's project for implementation under Standards Alliance, Phase 2 in Uganda, Tanzania and Kenya. ANSI and ACI signed a subaward at the end of June and began outreach to the USAID Missions in Uganda and Tanzania. ACI developed project factsheets and marketing materials to share with the various stakeholders it will be meeting with in preparation for implementation in the three countries.

In Q3 ANSI and ACI met with the USAID mission in Kenya and identified a list of stakeholders to begin building awareness on the project activity and securing buy-in for the adoption of ACI standards to support the construction sector. ANSI and ACI conducted introductory calls with the U.S. Commercial Service and La Femme Engineering Services, a key private sector company in Kenya. These two stakeholders provided market insights and recommendations for reaching out to other stakeholders including the Kenya Bureau of Standards, which is currently in the process of implementing the Euro standards in its new building code. ANSI will continue to support outreach efforts to 5 – 6 key stakeholder groups and hopes to complete this initial outreach to get buy-in for the project in Q4 2021.

INDO-PACIFIC

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

Activity #7 – Increase the Flow of WASH Services (Also appears in Middle East North Africa section)

The International Association of Plumbing & Mechanical Officials (IAPMO) participated in coordination calls with the Indonesia Mission. The Indonesia Mission requested concurrence and this is currently under review. IAPMO is preparing to begin work in Q4 and will work with BSN (Indonesia's National Standard Body) to revise an out-of-date SNI (Indonesian National Standard) related to water faucet products. The standard set for revision is SNI 03-0122-1998, namely household water faucets with door valves. As part of the update, the title and scope of the standard will be expanded. The formulation of this standard will be carried out by the Technical Committee 77-02 (downstream metal products).

An introductory call with USAID Mission in the Philippines will occur in Q4.

Activity #8 – Utility Management Standards Training for water sector utilities (Also appears in Africa section)

The American Water Works Association (AWWA) has made significant progress in India. Mr. Srinivasan from the USAID India Mission continues to be engaged in supporting and facilitating outreach between AWWA and relevant Indian stakeholders, including utilities and ministries. Given the continuation of the effects of COVID-19 in India, AWWA has decided to shift all three of the in-person workshops to a virtual format.

AWWA exceeded its goal of 15-20 completions of the needs assessment survey by receiving approximately 70 responses. This will allow AWWA to identify specific utility management standards and develop tailored workshops to fit the needs of the utilities in India. The primary stakeholders contacted were Utilities, Ministry of Urban and Housing Development - GOI, and private sector service providers.

LATIN AMERICA

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

Activity #9 – Community Water Systems – Standards for safety and risk management (Also appears in Middle East North Africa section)

NSF International's efforts in Brazil continued with Needs Assessment activities. Stakeholders were contacted and an evaluation of the regulatory framework is under development. As concurrence in Colombia was denied in Q2, NSF subsequently decided to redistribute funds to Morocco and Brazil (remaining project countries).

Development Objective #3: Countries have fewer TBT's

MIDDLE EAST NORTH AFRICA

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

Activity #7 – Increase the Flow of WASH Services (Also appears in Indo-Pacific section)

The International Association of Plumbing & Mechanical Officials (IAPMO) is coordinating activates for Jordan. The Jordan Mission requested IAPMO hold engagement in Jordan until 2022. ANSI and IAPMO are exploring options for engagement in Jordan under these circumstances.

Activity #9 – Community Water Systems – Standards for safety and risk management (Also appears in Latin America section)

The NSF International concurrence request to the Morocco Mission submitted in Q2 was approved in

Q3. NSF will begin work on the needs assessment in Q4 and begin outreach to stakeholders. As concurrence in Colombia was denied in Q2, NSF subsequently decided to redistribute funds to Morocco and Brazil (remaining project countries).

COVID-19 Related Activities Implementation Status

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

GLOBAL

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

Global

On 28 July, MDRC presented to several U.S. government stakeholders as part of a regular series of interagency updates by the Standards Alliance projects. Those U.S. agencies included the U.S. Trade Representative, International Trade Administration, National Institute of Standards and Technology, U.S. Department of State, U.S. Department of Agriculture, U.S. Food and Drug Administration (FDA), and U.S. Environmental Protection Agency. These meetings help increase collaboration with U.S. government stakeholders, who are important partners in the execution of MDRC trainings (see Section 3 Stakeholder Participation and Involvement).

On 12 August, the Global Medical Technology Alliance's (GMTA) Regulatory Committee met and agreed to bring a proposal to the International Medical Device Regulators Forum (IMDRF) to develop formal guidelines for Emergency Use Authorizations (EUAs) at their upcoming meeting in September. This is a critical first step to the establishment of international benchmarks for EUAs and related emergency regulatory frameworks and approval processes at the global level – a core MDRC objective.

On 23 August, MDRC attended the quarterly PQM+/MTaPS /SA2-MDRC COVID-19 Project coordination meeting. MDRC provided participants with an overview of the project's current activities and updated the group on important developments. This meeting facilitated the advanced partnership between PQM+ and MDRC on global and African regional objectives (see section on Africa below).

On 26 August, MDRC met with the U.S. FDA Center for Devices and Radiological Health (CDRH) to coordinate MDRC global objectives. This includes the exploration of dates for a session with USAID, PQM+ and MTaPS during which CDRH would relay its positioning regarding WHO guidance and the WHO Global Benchmarking Tool as applicable to medical technology regulatory capacity building and convergence. On 27 August, AdvaMed connected with the CDRH team and confirmed USAID will take the lead on coordinating these efforts to host the above session.

On 20 and 31 August, AdvaMed coordinated with MedTech Europe on GMTA messaging for the 14 September IMDRF Stakeholder Virtual Forum. This includes MDRC messaging and recommendations regarding lessons learned from COVID-19 and best practices for addressing public health emergencies.

On 8 September, the GMTA Regulatory Committee agreed to (1) establish a GMTA-GDA COVID-19 Workstream, thereby constituting the International Center for Emergency Regulatory Response, (2) develop COVID-19 recommendations to IMDRF, WHO, G/AHWP regarding appropriate international benchmarks, (3) support the organization of a COVID-19 Regulatory Workshop with NRAs to address pandemic/emergency elements, (4) participate in MDRC direction and implementation, (5) accept support

for MDRC-Related Training, and (6) include links to the MDRC project website and any related resources on the GMTA website (when ready). To coordinate these elements, the GMTA agreed to form an MDRC advisory group with members from the Coalition, AdvaMed, MedTech Europe, Mecomed, private companies, and a standard developing organization (SDO).

On 22 September, MDRC launched a project URL www.standardsalliance-mdrc.org that links to the expanded and detailed MDRC web page currently housed on the Coalition website. The MDRC webpage serves as a repository for the project's resources. Over Project Year 2, MDRC will transition toward an independent website for MDRC content, given available resources. This URL also serves as the basis for project-specific email addresses. These email addresses, @standardsalliance-mdrc.org, standardize and streamline communication and project outreach across all geographies.

Latin America

REGIONAL: On 30 September, MDRC met with the Pan American Standards Commission (COPANT) to gain a deeper understanding of whether COPANT has any measures or policies that promote gender equality in the organization, gender representation in standards development, or any other initiatives or polices on gender. COPANT indicated it does not. However, the organization recently engaged in an August workshop on Best Practices on Gender Inclusion and Standardization. At AdvaMed's suggestion, COPANT will work to include one session on gender and one on GRP implementation in its next general assembly meetings (April 2022). MDRC and COPANT discussed how COPANT could issue recommended guidelines / best practices on gender inclusion for its members and co-hosting a potential workshop with the Coalition.

COLOMBIA: On 12 July, MDRC met with several government stakeholders, including the National Planning Department (DNP), Ministry of Health, Ministry of Commerce, Industry and Tourism (MinCIT), Colombia National Food and Drug Surveillance Institute (INVIMA), and the National Business Association of Colombia (ANDI). MDRC scheduled two trainings with government stakeholders, one on GRPs (Tier One) and the other on Ex-Post Analyses (Tier Two). MDRC scheduled a kick-off session with relevant stakeholder working groups to discuss Ex-Post Analyses and regulations pertinent to medical devices and in vitro diagnostic (IVD) products. MDRC and Colombian government stakeholders established a core, cross-departmental team for coordinating MDRC work. Attendees discussed the importance of establishing a dedicated MDRC Liaison to Colombia to help direct this work.

On 23 July, MDRC conducted a training on GRPs (Tier One) for Colombian government stakeholders and members of the private sector. The training helps develop a basic set of capacities among these stakeholders to advance GRPs in Colombia.

On 27 July, MDRC conducted a training on Ex-Post Evaluation (Tier Two) for Colombian government and private sector stakeholders. This training will enable its participants to pursue updates to Colombian regulation affecting medical devices and IVDs.

On 30 July, MDRC continued its training of Colombian regulators and private sector stakeholders on items related to Ex-Post Analysis. The U.S. FDA provided an overview of medical device and IVD regulations. Recordings of all the trainings in Colombia can be found in both English and Spanish here.

On 6 August, MDRC met with Colombia's DNP. DNP confirmed it is behind on its international commitments to implement GRPs and attributed the Department's inability to effectively regulate or initiate additional projects to inadequate resources. Following a discussion of MDRC's potential role supporting DNP overcome its resource challenges and promote GRPs, DNP voiced its support of the project. MDRC and DNP scheduled a meeting with DNP's Deputy Director, Daniel Gómez Gaviria, to

discuss DNP's challenges and MDRC's ability to provide technical assistance to the Department.

On 12 August, MDRC met with the DNP, INVIMA, ANDI, and the Ministry of Health to discuss the need to implement GRPs as part of a broader approach to effectively utilizing resources in the regulatory process. MDRC continued working with the stakeholders to map out all the project envisioned trainings in the project countries to ensure proper engagement.

On 23 August, MDRC met with U.S. National Institute of Standards and Technology (NIST), MinCIT, ProColombia and Colombian Trade Representatives. The attendees discussed the collaborative efforts of MDRC and NIST to construct a guide pertaining to PPE for the Colombian Government. NIST is hiring the individual that will be in charge of the project. The participants discussed the process by which the guide would be developed and what Colombian government stakeholders would provide feedback.

On 26 August, MDRC partnered with the DNP to convene a Tier One workshop on the construction of "Problem Trees," a GRP tool that is utilized among MDRC project groups both for Regulatory Impact Assessment (RIA) and ex-post evaluation. Recordings and training materials are available on the Coalition's website. See Section 3.

On September 1, USAID approved the Government of Colombia and MDRC's request to establish a dedicated project Liaison to Colombia to coordinate project implementation among local stakeholders. This development is outlined further in Section 2.2 Implementation Status.

On 6 September, MDRC organized a workshop in coordination with Ministry of Health for government and private sector stakeholders in Colombia. Stakeholders shared their experience developing a "Problem Tree," a critical component under the RIA process for Good Manufacturing Practices for Medical Devices. Recordings and training materials are available on the Coalition's website. See Section 3.

MEXICO: On 16 July, MDRC met with Mexico's Federal Commission for Protection against Sanitary Risks (COFEPRIS). MDRC and COFEPRIS discussed the status of the LOI signature process and agreed to host a training on GRPs in the coming months. COFEPRIS expressed interest in engaging with other project countries on relevant MDRC activities, including crafting/updating EUA frameworks.

On 23 July, MDRC continued coordination with COFEPRIS to schedule the formal signing of the LOI between COFEPRIS, USAID, and the Coalition. MDRC continued ongoing communications with USAID and COFEPRIS to finalize details related to the signing ceremony and any related meetings.

On 9 August, MDRC met with COFEPRIS to continue discussions on establishing a dedicated training plan for MDRC initiatives. The details of this program were still under consideration, with COFEPRIS considering the scope and nature of the program. On 13 August, COFEPRIS confirmed it was still reviewing the training plan, its technical areas, and potential participants. MDRC and COFEPRIS continued discussions on the status of the LOI, which was under review by COFEPRIS's legal department. In light of the upcoming U.S.-Mexico High Level Economic Dialogue (HLED) in September, USAID, MDRC and COFEPRIS worked to expedite the LOI's signing.

On 31 August, Alejandro Svarch Pérez, Federal Commissioner of COFEPRIS, Bruce Adams, Mission Director of USAID Mexico, Joseph Tretler, Vice President International Policy at ANSI, and Sandra Ligia González, Executive Secretary of the Coalition signed the Letter of Intent for MDRC. Mileydi Guilarte, Deputy Assistant Administrator at USAID participated as a witness of honor. This event represents a key milestone for the MDRC project in Mexico with Dr. Svarch Pérez acknowledging that the MDRC and LOI establish a route to work towards regulatory convergence for medical devices by promoting good

regulatory practices and reference to international standards. The official press release and additional information can be found here.

PERU: On 21 July, MDRC met with Peru's Directorate General of Medicines, Supplies and Drugs (DIGEMID). Dra. Ponce, DIGEMID's Director General, and members of the DIGEMID team communicated their focus on addressing challenges related to COVID-19 and need to access international standards. MDRC and DIGEMID discussed the possibility of developing a dedicated workstream on EUAs and agreed to meet again in August and work towards deeper collaboration.

On August 5, MDRC met with INACAL, which detailed its challenges in the regulatory process. INACAL attributed those challenges in part to its inadequate resources to participate in Technical Committees and access international standards. Moving forward, INACAL will provide MDRC with a list of priority standards on medical devices they are interested in adopting. MDRC will work with INACAL to overcome its resource challenges and difficulty utilizing international standards.

On 7-8 September, MDRC organized a two-day workshop in Peru to provide training for private sector and government stakeholders on the local and global obligations and benefits of implementing GRPs (tier One). This workshop convened 330 participants on the day one and 210 on day two. Those government attendees included representatives from the Ministry of Foreign Trade and Tourism (MinCETUR), the Presidency of the Council of Ministers (PCM), DIGEMID, Ministry of Health, DIGEMID, and USFDA. From academia, attendees included the Universidad Peruana Cayetano Heredia, Universidad Nacional de San Marcos, and the Universidad Pontificia Católica del Perú. In addition, this workshop advances MDRC regional objectives. Over 250 companies from 8 different countries (Argentina, Brazil, Colombia, Spain, Mexico, Panama, Peru, United States) participated in the training. Recordings and training materials are available here.

On 21 September, MDRC met with MinCETUR to discuss the project's next steps and approach in Peru. MDRC and MinCETUR discussed how the project could integrate its envisioned capacity building into both MinCETUR's and DIGEMID's schedule of trainings given overall resources in the project country. MDRC will draft a proposal for MinCETUR to address technical issues, present STCs, and develop specific SOPs for GRPs implementation. MDRC and MinCETUR agreed to reconvene to continue aligning on the project's implementation in Peru.

On 30 September, MDRC met with the Office of Regulatory Quality Analysis ("Análisis de Calidad Regulatoria," ACR) in the PCM, the government body which coordinates multisectoral policies and regulations. ACR confirmed that technical regulations are currently exempt from undergoing RIAs. However, beginning in 2022 the agency will be required to evaluate the quality of all regulations. In order define an action plan for MDRC partnership, ACR will organize a meeting with MDRC, the Ministry of Health, PCM, and ACR.

BRAZIL: On September 14, MDRC met with the Brazilian Chamber of Laboratory Diagnostics (CBDL) and the Brazilian Association of Technical Standards ("Associação Brasileira de Normas Técnicas," ABNT) CB-36 Brazilian Committee on Clinical Analyses and In Vitro Diagnosis. CB-36 is managed by the Brazilian Society of Clinical Analyses and functions as a mirror group of ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems. ISO/TC 212 has 44 published standards related to clinical laboratories and IVDs, 9 of which are directly linked to IVD products. Increasing the availability of ABNT /ISO standards in Portuguese is vital element of MDRC in the project country.

In that meeting, the parties discussed partnership opportunities to advance the work of Study Committee CE 036:000.003, which aims to standardize IVD products. The meeting served to introduce the project

and discuss the challenges faced by the IVD and clinical analysis sectors. The parties also discussed the need to expand the availability of ABNT NBR ISO technical standards, especially those related to IVD products. MDRC scheduled a follow-up meeting for early next quarter.

In Q3, MDRC continued to coordinate with the Ministry of Economy's Secretariat of Foreign Trade (SECEX) and Secretary for Competition Advocacy and Competitiveness (SEAE). However, maintaining continuity in the conversations has been difficult due to various organizational changes in the Ministry.

Africa

In Q3, MDRC secured Mission concurrence and undertook initial government outreach in all project countries in Africa. MDRC began collaborating with local and regional stakeholders in public and private sectors to advance project implementation.

REGIONAL: On 31 August, MDRC met with PQM+ so the two projects could share information on their ongoing activities and align on future initiatives in Africa. PQM+ provided MDRC with an in-depth review of its objectives, structure, and partners. In Africa, PQM+ shared that while it only has funding for COVID-related initiatives in Ethiopia, Burkina Faso, and Ghana, it does work regionally and in other African countries like Kenya. PQM+ has a field office in Nairobi that coordinates regional activities and works with the Kenyan Pharmacy and Poisons Board. The two projects discussed PQM+'s scope on Quality Assurance (QA) and whether it addresses international regulatory convergence for medical technologies, as well as the role of USAID Missions in advancing MDRC national and regional capacity building. Moving forward, MDRC and PQM+ considered strategies to formalize their collaboration to ensure each project's capacity building activities, curricula, design, and delivery are in alignment with one another. MDRC and PQM+ scheduled regular coordination calls at the local and higher project levels to ensure this alignment.

GHANA: On 1 July, the Mission to Ghana approved MDRC outreach letters to Ghanaian governmental stakeholders. On 9 July, MDRC conducted formal outreach to the Ghana Standards Authority (GSA), Ministry of Trade and Industry, Ministry of Health, Ghana Health Service, Ghana Food and Drug Authority, and Health Facilities Regulatory Authority.

On 24 August, MDRC conducted follow-up outreach with Ghanaian government stakeholders. On 26 August, MDRC leveraged contact information provided by the Mission to reach out to Ghana's Ministries of Trade and Health. MDRC did not receive a response from government stakeholders and sought approval from the Mission to reach out to these ministries/agencies via alternative channels at the technical level.

Following unsuccessful attempts to connect with those stakeholders by phone on 26 August, MDRC leveraged contact information provided by the Mission to reach out to the Ministries of Trade and Health again on 31 August. This attempt was also unsuccessful. Thereafter, on September 8, the Mission in Ghana reached out directly to the Personal Assistant to the Minister of Health on behalf of MDRC. Neither MDRC nor the Mission have received a response from government stakeholders to date.

KENYA: On 28 July, the Mission to Kenya granted concurrence to MDRC. This enables MDRC to begin outreach and coordination with Kenyan government stakeholders to advance in-country project objectives. Moving forward, the Mission has asked to be included in initial meetings with the Kenyan Ministry of Health and Pharmacy and Poisons Board (PPB) and be provided with the option to join any other important meetings thereafter.

On 23 August, MDRC met with Kenya's PPB to review the project's high-level objectives and envisioned

events. PPB reaffirmed the agency's desire to partner and collaborate with MDRC. The PPB team preliminarily identified priorities for collaboration with MDRC. Those priorities include enhancing regulatory capacity and institutional knowledge related to medical devices, assessments, registration, surveillance, site audits, verification, quality and self-sustaining initiatives, medtech tariff classification, quality control testing, laboratory capability, trade facilitation, and risk-based approaches to regulation. MDRC and PPB aim to schedule a series of technical meetings to formally review, begin collaborating, and establish triaged workstreams on these priorities and schedule trainings where appropriate.

On 25 August, MDRC met with the Mission to Kenya to introduce the project to the Mission's new point of contact, Charles Lwanga. MDRC and the Mission discussed the project's objectives in the country and greater region, and aligned on approach to in-country project activities. MDRC will provide the Mission with quarterly updates on project implementation progress and challenges.

On 30 August, MDRC met with Mecomed, the medical devices, imaging and diagnostics trade association for medtech manufacturers across the Middle East & Africa. As a key MDRC partner in the region, Mecomed and MDRC aligned on the project's approach to Tier Two work in Kenya. MDRC and Mecomed began to formally identify industry priorities for developing a workstream with PPB in the coming weeks.

On 2 September, MDRC and Mecomed met to follow-up on the 23 August PPB meeting and align on next steps for Kenya. Mecomed shared an overview of the industry's perspective on the priorities for MDRC workstreams in the project country. The team collaboratively organized the perceived technical and procedural challenges into a dedicated matrix for sharing with PPB. MDRC intends to share this overview with PPB ahead of the next meeting so that the two parties may develop a formal workstream.

On 15 September, MDRC met with PQM+'s team in Kenya to align on approach in the project country. PQM+ confirmed that one of its major activities in Kenya is to promote the domestication of regional and international agreements/guidance pertaining to recognition and reliance. Because PQM+'s focus in Kenya is on medicines, MDRC's activities on medical devices can complement PQM+'s work without overlapping. PQM+ and MDRC noted the importance of regulating medical devices and pharmaceuticals differently. PQM+ acknowledged PPB's desire to update their laws and regulations as an opportunity to solidify this distinction and integrate GRPs into standard procedures. As PPB works to update its rulemaking process, MDRC and PQM+ will coordinate to provide the agency with information.

In that meeting, PQM+ identified a challenge to the efficient regulation of medical devices in Kenya as an interagency turf dispute over mandate. PPB, KEBS, and the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) all have some claim to regulatory aspects of medical devices. PQM+ is helping craft an online platform for self-assisted learning that provides information to Kenyan government actors. This platform needs additional information on medical devices, which MDRC will work with PQM+ to provide.

On 29 September, MDRC met with PQM+ to touch base and continue aligning on the projects' work in Kenya. MRC overviewed envisioned next steps with PPB, including the development of a dedicated workstream and related trainings. MDRC is in the process of packaging important information related to GRPs, international commitments, and regulatory convergence for PPB's reference as it works to update its regulations. For now, that information will take the form of one-pager list of key WHO IMDRF WTO guidance and related international agreements. MDRC will provide more detailed information as the process continues.

PQM+ confirmed it is working to incorporate international commitments and related guidance on GRPs and reliance into PPB's work as it relates to pharmaceuticals. However, PQM+ is not currently working

to address PPB's recognition processes.

PQM+ confirmed the ongoing turf dispute over regulatory mandate between PPB and KMLTTB. This dispute remains an issue despite some recent direction by the Ministry of Health. PQM+ advised that MDRC should turn to the Ministry's Division of Health Products and Technology for guidance on those mandates. PPB can provide MDRC with a point of contact in that Division.

On 30 September, MDRC met with representatives of the U.S. International Trade Administration (ITA) based in DC and Kenya. The parties discussed MDRC's regional approach in Africa and local activities in Kenya, as well as global elements. The parties discussed leveraging the Global Harmonization Working Party (GHWP) in the project's work and the Coalition's GHWP membership status. ITA indicated that there was not significant overlap between GHWP activities and relevant African regional body initiatives - such as those of AMDF, AUDA-NEPAD, ARSO, and AfCFTA. In Kenya, ITA recommended reaching out to the local American Chamber of Commerce and the Kenya Healthcare Federation to assist with government stakeholder outreach. Once the USAID Mission in Kenya approves MDRC outreach, the project will share those endorsed letters with ITA.

SOUTH AFRICA: On 4 August, MDRC conducted official outreach with government stakeholders in South Africa. MDRC sent letters to the Parliamentary Portfolio Committee on Health, National Regulator for Compulsory Specification (NRCS), Department of Trade, Industry and Competition (DTIC), Department of Planning, Policy, Monitoring and Evaluation (DPME), Department of Health, Department of Health - Port Health Authority, and the South African Health Products Regulatory Authority (SAHPRA).

On 24 August, MDRC received a response from the South African Health Products Regulatory Authority (SAHPRA) indicating interest to partner with the project and designate a point of contact.

On 13 September, MDRC and the South African Medical Technology Industry Association (SAMED) met to internally align on approach and next steps for collaboration with SAHPRA. As MDRC primary industry partner in the project country, SAMED reviewed and shared a formal list of its Tier Two priorities in South Africa. This list will be used in the development of a formal MDRC workstream with SAHPRA in the coming weeks.

On 22 September, MDRC provided an overview of the project, its scope, and methodologies to members of SAHPRA's leadership – including the Chief Operations and Regulatory Officers and Senior Manager for Medical Devices. MDRC outlined the project's role providing capacity building trainings and resources to government and medtech industry stakeholders. MDRC emphasized that an ultimate goal of the project is enabling medical device regulatory authorities, such as SAHPRA, to have the tools to most effectively utilize limited resources during COVID-19 while building long-term resilience and regulatory capacity. MDRC described its public and private sector partners across the three geographies and how MDRC works with them to harmonize best practices not just locally but also at the regional and global levels.

When asked about SAHPRA's recommended level of commitment, MDRC indicated that the project would be flexible and open to collaborating with SAHPRA in the manner it deems most effective. In the immediate future, this may take the form of routine meetings to establish a dedicated workstream to address SAHPRA and the industry's immediate regulatory priorities as they relate to COVID-19. SAHPRA vocalized interest in the project and will discuss internally before formally agreeing to partner with MDRC.

<u>Southeast Asia</u>

REGIONAL: At the project's outset, MDRC planned to host an event on the *sidelines* of the 20th IMDRF Stakeholder Virtual Forum in September 2021. This event had two parts: (A) a COVID-19 Medical Device

regulatory review conference, and (B) a targeted session for Southeast Asian project countries to apply the lessons from Part A. However, over Q3 MDRC continued experiencing engagement challenges with government stakeholders in Vietnam and Indonesia (see Section 2.3). In order to advance project outputs, MDRC worked with the GMTA to integrate Part A *directly into* the September 2021 IMDRF event and postpone Part B until the next Forum, currently scheduled for March 2022 in Singapore. In that postponed session, MDRC intends to host a targeted training for Indonesian and Vietnamese NRAs, and is considering inviting other MDRC country authorities, GMTA members, and IMDRF members.

On 14 September, the GMTA presented MDRC's recommendations related to COVID-19 and beyond in a special session of the IMDRF. Those recommendations include: (1) ensure that current IMDRF documents acknowledge the need to ensure rapid review and approval, (2) utilize reliance mechanisms to promote rapid reviews and approval, (3) consider the development of specific IMDRF guidance to promote the use of rapid review and approval mechanisms during a global pandemic, (4) ensure adequate training and communication for regulators, and (5) regulatory agility should be leveraged beyond the pandemic.

On 21 September, GMTA presented on those same MDRC recommendations to the WHO's International Conference of Drug Regulatory Authorities (ICDRAs).

Between 17-20 August, AdvaMed attended the Asia Pacific Economic Cooperation Subcommittee on Standards and Conformance (APEC SOM3 SCSC) meetings as an accredited U.S. delegate to ensure MDRC implementation alignment with related regional activity. Those meetings include the 17 August SCSC Workshop on GRPs as well as the 19-20 August SCSC Plenary. AdvaMed noted the participation of the MDRC project country authorities in the meetings and has used this information to reinforce MDRC engagement and outreach with local stakeholders.

VIETNAM: On 7 July, MDRC presented on the MDRC to the European Chamber of Commerce (EuroCham) in Vietnam Medical Device & Diagnostic Sector Committee's Regulatory Affairs Working Group. The Working Group's members were supportive of MDRC's objectives and communicated a number of priority concerns for MDRC's work in the country. Those concerns included government authorities' lack of resources and delays in registration for medical devices. Members recommended trainings for government officials on issues related to medical device regulatory convergence, GRPs, and reliance principles. EuroCham offered to support MDRC with establishing contact with relevant government stakeholders.

On 15 July MDRC met with the Government of Vietnam's Department of Medical Equipment and Construction (DMEC), the country's medical device regulatory authority. The DMEC officer was supportive of MDRC's objectives in Vietnam and identified a series of priority areas for MDRC-DMEC collaboration. Chief among them was helping address DMEC's limited capacity and remedying delays in re-registration approvals. DMEC expressed desire to undergo trainings related to GRPs, regulatory reliance models, implementation of unique device identification (UDI), and EUA frameworks. MDRC will work to secure deeper buy-in from DMEC leadership for collaboration with the project.

MDRC met with the U.S. Foreign Commercial Service (FCS) in Vietnam on 4 August to discuss the project's objectives and timelines in the project country. The FCS Commercial Specialist offered to support MDRC's outreach efforts by facilitating meetings with their contacts in various Vietnamese government agencies. However, the Specialist emphasized that language and cultural barriers might continue to hinder project development. The Specialist also voiced concerns over MDRC's ability to host a training workshop with Vietnamese regulators in September, reporting that the U.S. Trade and Development Agency (USTDA) has tried for months to arrange an event with the Vietnamese Ministry of Health.

Following the advice of the Commercial Specialist at the U.S. Embassy in Hanoi, on 23 September, MDRC emailed Director General Ta Hoang Linh, European-American Market Department, Ministry of Industry & Trade seeking a call to introduce the project and solicit his advice on implementing it in Vietnam.

INDONESIA: On 9 July, the U.S. ASEAN Business Council (USABC) Indonesia reached out to MDRC discuss the project's priorities in Indonesia for the remainder of the year. USABC offered support to MDRC to help raise awareness among government stakeholders and put MDRC in touch with officials directly, if necessary.

On 11 August, MDRC met with the National Standardization Agency of Indonesia ("Badan Standardisasi Nasional", or BSN). Following the government body's prior meeting with ANSI, BSN had written officially to the Ministry of Health, the National Food and Drug Control Agency (BPOM), and the Ministry of Finance to seek their views on MDRC. While there was no official response, the Ministry of Health unofficially raised bandwidth concerns over engaging in a new project. Since the BSN may only facilitate the interest of other ministries, it cannot commit to partnering with MDRC until they receive an official positive response from the Ministry of Health and BPOM. However, BSN voiced support of MDRC, saying they would partner with MDRC once the other government bodies approved.

MDRC continues to leverage meetings with private sector actors and partners, including in the U.S. FCS and local Missions, to establish contact with local government stakeholders.

Other Implementation Progress

MDRC shared its Tier One and Two Stakeholder mapping reports for Africa and Southeast Asia with U.S. government stakeholders for their review and feedback on 10 August. Those stakeholders include the International Trade Administration (ITA), National Institute of Standards and Technology (NIST), and the U.S. Trade Representative (USTR).

MDRC has packaged the findings of its Phase One, Tier One gap analyses and literature reviews from all project countries in a unified Tier One report. This report includes assessments of GRP implementation by country as well as an overarching chart to allow for comparison across project countries. The Tier One report is in the process of final graphic design and alignment with USAID branding requirements. As more input and feedback from governments and relevant stakeholders are received, this report may be updated again in late 2021 or early 2022.

On 24 September, MDRC submitted the final MDRC Tier One Report for USAID's review and approval of the report's branding.

MDRC sought input on Phase One outputs from a variety of stakeholders, including industry associations, USAID Missions, and U.S. government agencies. In Q1 2021, MDRC shared its Tier One country reports with local and industry stakeholders in Africa for their review and input, including the USAID Missions to Ghana and Kenya, Mecomed, MEDAK, SAMED, and SALDA. In Q2 2021, MDRC shared updated drafts of MDRC's Phase One, Tier One gap analyses and stakeholder maps with ANSI, the U.S. International Trade Administration (ITA), the U.S. National Institute of Standards and Technology (NIST), the Office of the U.S. Trade Representative (USTR), and the U.S. Office of Information and Regulatory Affairs (OIRA).

While this is the final draft, it remains a *live document*. As more input and feedback from governments and relevant stakeholders are received, this report may be updated throughout the project.

AFRICA

Activity #11 - COVID-19: Surgical Mask Production Project

COVID-19 has emerged as a global health crisis. As countries are faced with a surge in cases, access to personal protective equipment for healthcare providers have also become a challenge with shortages reported globally. In Ghana, the Government aims at making the country self-sufficient in manufacturing the materials required to combat the pandemic. However, local capacity to produce such equipment is lacking.

Though the country already has the capability to produce high volumes of cotton fabric masks, these cotton masks are not suitable for use by healthcare providers as they do not provide proper protection against virus transmission per the Center for Disease Control (CDC) and World Health Organization (WHO) guidelines. There is therefore the need to pivot current production capacity, through capacity development of local industries, to produce surgical masks at the required international standards. There are significant benefits to developing local capacity, including accessing research findings for wider transmissions in the apparel sector, improved capacity of local workers, job creation, and increased exports.

However, pivoting to this highly technical product requires significant investment both in machinery but also in skill development and know how.

Ethical Apparel Africa (EAA) has worked in partnership with Maagrace Garment Industries Limited to establish a plan, first for surgical grade Level 2 masks and then potentially into other areas of PPE such as disposable gowns.

The Program aims to achieve the following

1. **Job Creation:** EAA will track new jobs created as a result of the mask making production. Directly, it is expected that this machinery will require between 30 and 40 individuals to manage it.
2. **Increased trade**: Development of strengthened and/or new relationships with clients both in Ghana, ECOWAS and eventually export to the USA

EAA believes the proposed ISO Level 7 accredited cleanroom for the production of surgical face masks is the first of its kind in Ghana.

2.3 Implementation Challenges

Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops

The ECOWAS Clean Renewable Fuels workshops continue to meet challenges to implementation presented by the ongoing global pandemic. Initially, Pivot planned to host preliminary trainings on clean fuel standards in Ghana and Senegal during Q2 2021; however, the ongoing pandemic has delayed the roll out of these events in-person. Following consultation between Pivot, ANSI, and USAID; and due to a history of successes stemming from face-to-face interactions on past clean fuels programming, these activities will be tentatively postponed until Q4. If international travel remains restricted during Q4, Pivot

will develop an online option to effectively deliver both planned trainings leading up to the 2021 ECREEE General Assembly in December.

Activity #2 – Support for African Organization for Standardization (ARSO)

In Q2, the Standards Alliance faced few challenges related to the implementation of the cosmetics webinar series. However, the main challenge during this quarter was communication with ARSO due to the establishment of the African Continental Free Trade Area (AfCFTA) Secretariat in Accra, Ghana. The establishment of the AfCFTA Secretariat created a great deal of additional work for the ARSO team and created gaps in communication, which delayed the third webinar in the series. These delays have been mitigated for the fourth event by adjusting contact methods and coordinating with ARSO to create a specific ARSO point of contact to roll out training activities.

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

During Q3, Researching the current use of standards by regulators and related authorities is time consuming and some stakeholders are new since the original 2019 Standards Alliance Phase 1 Workshop. Collecting up-to-date information via virtual calls has been key and this work will continue until meetings can be held on the ground in 2022.

Activity #11 - COVID-19: Surgical Mask Production Project

In Q3, EAA faced continued challenges with international shipment and retrieving equipment from the port in Accra among other issues. A list of the challenges and mitigating actions taken during Q3 is included below:

- Masks cannot be tested in composite form, only in finished goods form so testing cannot start until the mask machine is ready
- COVID delayed the launch of the mask machine and for the technicians to visit. Eventually we commission the machine ourselves with online support from China
- The Cleanroom electricity costs are a significant part of the mask costing. As the price for general use masks has dropped we have decided to wait to commission the Cleanroom element until we are ready to begin production of the surgical grade masks (i.e. post testing approval)

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

Overcoming project implementation delays related to USAID Mission concurrence remained a significant project challenge in Q3 2021. After meeting the Mission in Kenya in Q1 2021, the Mission did not grant project concurrence until the end of July 2021. The Mission has yet to approve MDRC project outreach in Kenya. These delays prevent timely MDRC engagement with project countries to advance project outputs.

Internal USAID Mission miscommunications can also contribute to delays in MDRC implementation. Following formal outreach in South Africa on 4 August, the Mission called MDRC asking to halt correspondence with government stakeholders. A Health Officer at the Mission communicated to MDRC that his office was not aware that the MDRC outreach letters had been approved. However, the Mission confirmed in April and June that MDRC could proceed without formal concurrence, the outreach letters were confirmed, and their recipients were approved. This internal miscommunication led to a delay in follow-up outreach and collaboration with South African government agencies.

Another challenge to project implementation remains limited engagement by some project country governments. The project team cannot commence its work in project countries without engagement by Tier One and/or Tier Two government agency partner(s). In Ghana, the USAID Mission granted concurrence to MDRC in December 2020. In order to synchronize messaging with South Africa and Kenya, MDRC opted to delay outreach until July when those project countries secured Mission concurrence. MDRC has received no responses from any government agency despite follow-up attempts by MDRC and the Mission. MDRC is attempting to leverage the Ghanaian Embassy in DC to contact government agencies. The Embassy has yet to respond to MDRC outreach.

In Vietnam and Indonesia, MDRC maintains high levels of engagement with the private sector. However, government stakeholders have been less responsive despite several outreach attempts. In discussions with MDRC, private sector stakeholders attribute the agencies' unresponsiveness to government stakeholders' lack of bandwidth as a result of addressing COVID-19-related challenges. One private sector stakeholder indicated that that officers at the working-level might not know or be confident conversing in English, while more senior officials can be selective in engaging foreigners. MDRC has sought input from the U.S. FCS and Vietnamese branches of the European and American Chambers of Commerce on relevant contacts in the government.

In order to overcome this challenge, MDRC is exploring a range of options. Those options include,

- Convening relevant associations and industry stakeholders to seek their support raising MDRC with relevant government contacts,
- Connect with Vietnamese and Indonesian embassies in both Washington, D.C. and Singapore to seek their advocacy on behalf of the MDRC with relevant agency officials and/or advice on implementing the MDRC
- Explore whether Singapore might be open to act as an "implementing partner" with the MDRC project team to convene relevant agencies from Vietnam and Indonesia, and
- Look for an opening to engage ASEAN on the MDRC.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

To varying degrees across all activities, the SA2 team has been in constant contact with stakeholders from both international and domestic private and public sectors. Activities with finalized subawards have begun stakeholder outreach to promote the program, establish the scope and further plan implementation.

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

MDRC Workshops and the Engagement of Women in Project implementation:
In Project Year 1 (PY1), MDRC hosted nine trainings and workshops to advance objectives for global, regional, and local stakeholders in the governmental and private sectors. These workshops convened an estimated 2,080 participants between November 2020 and June 2021, of which almost 1,300 were women (62.5%). This group of women are experts and professionals from academia, the private sector, Standards Developing Organizations (SDOs), national regulatory authorities (NRAs), international organizations, and numerous other vital stakeholders. A full breakdown of this engagement is outlined in the PY1 Annual Report narrative.

In Q3, MDRC hosted six trainings and events, convening 929 participants. Of those, 741 were female (79.7%) and 710 were from the private sector. An overview of those trainings is provided below:

Date	Meeting/Event	Location	Participants	Region
23 Jul 21	GRPs Training	Virtual	124 Colombia 100 female, 24 male (59 Private Sector)	Colombia
27 Jul 21	Training on Ex-Post Analysis	Virtual	81 participants 66 female, 15 male (56 private sector)	Colombia
30 Jul 21	Overview of U.S. FDA Regulations for MDs	Virtual	64 participants 53 female, 11 male (43 private sector)	Colombia
26 Aug 21	Joint MDRC – DNP Workshop on GRP: Problem Tree Methodology	Virtual	64 participants 56 female, 9 male (43 Private sector)	Colombia
6 Sep 21	Joint MoH – MDRC Workshop on RIA Problem Trees	Virtual	56 Participants 46 female, 10 male (41 private sector)	Colombia
7-8 Sep 21	Workshop on GRPs	Virtual	540 participants 7Sep: 260 female, 68 male, 2 N/A (264 private sector) 8Sep: 160 female, 44 male (204 private sector)	Peru

Stakeholder Engagement

- COFEPRIS–Coalition LOI – On 31 August, Alejandro Svarch Pérez, Federal Commissioner of COFEPRIS, Bruce Adams, Mission Director of USAID Mexico, Joseph Tretler, Vice President International Policy at ANSI, and Sandra Ligia González, Executive Secretary of the Coalition signed the Letter of Intent for MDRC. Mileydi Guilarte, Deputy Assistant Administrator at USAID participated as a witness of honor.
- 23 July GRPs Training: MDRC conducted a training on GRPs for Colombian government stakeholders and members of the private sector. The training helps develop a basic set of capacities among these stakeholders to advance GRPs in Colombia. Attending government stakeholders

included MinCIT, Ministry of Health, DNP, and INVIMA. In addition to ANDI, the National Business Association of Colombia, participants from 34 companies attended.

- 27 July Training on Ex-Post Analysis: MDRC conducted a training on Ex-Post Evaluation for Colombian government and private sector stakeholders. This training will enable its participants to pursue updates to Colombian regulation affecting medical devices and IVDs. Government stakeholders included MinCIT, Ministry of Health, DNP, and INVIMA. In addition to ANDI, participants from 34 companies attended.
- 30 July Overview of U.S. FDA Regulations for MDs – Colombia: MDRC conducted a training for Colombian regulators and private sector stakeholders on items related to Ex-Post Analysis. The U.S. FDA provided an overview of medical device and IVD regulations. Attending government stakeholders include the Ministry of Health, DNP, and INVIMA.
- 26 August Joint MDRC – DNP Workshop on GRP: Problem Tree Methodology: MDRC partnered with Colombia's DNP to organize a workshop on the construction of "Problem Trees," a GRP tool that is utilized among MDRC project groups both for Regulatory Impact Assessment (RIA) and ex-post evaluation. The workshop convened participants from the Ministry of Health, INVIMA, DNP, and the private sector.
- 6 September Joint Ministry of Health – MDRC Workshop on RIA Problem Trees: MDRC organized a workshop in coordination with Ministry of Health for government and private sector stakeholders in Colombia. Stakeholders shared their experience developing a "Problem Tree," a critical component under the RIA process for GMPs for Medical Devices. This workshop convened participants from the Ministry of Health, INVIMA, the DNP, and the private sector
- 7-8 September Workshop on GRPs: On, MDRC organized a workshop in Peru to provide training for private sector and government stakeholders on the local and global obligations and benefits of implementing GRPs. Those government attendees included representatives from MinCETUR, PMC, DIGEMID, Ministry of Health, DIGEMID, and U.S. FDA. From academia, attendees included the Universidad Peruana Cayetano Heredia, Universidad Nacional de San Marcos, and the Universidad Pontificia Católica del Perú. In addition, over 250 companies from 8 different countries (Argentina, Brazil, Colombia, Spain, Mexico, Panama, Peru, United States) participated in this workshop.

4. RESULTS ACHIEVED

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

Global

- On 28 July, as part of a regular series of interagency updates by the Standards Alliance projects, MDRC presented to a number of U.S. government stakeholders.
- On 12 August, at MDRC's request, GMTA's Regulatory Committee agreed to propose to the IMDRF that it develop guidelines for EUAs at their upcoming meeting in September. (DO 4, Activity 4.0.0.1)
- On 26 August, MDRC met with the U.S. FDA CDRH to coordinate MDRC global elements. MDRC and CDRH discussed hosting a session for CDRH to convey its positioning on WHO guidance and the WHO Global Benchmarking Tool to the other Standards Alliance 2.0 initiatives. USAID will take the lead on this session. (DO 4)
- On 20 and 31 August, AdvaMed and MedTech Europe aligned on GMTA messaging for the 14 September IMDRF Stakeholder Virtual Forum regarding lessons learned from COVID-19 and best practices for addressing public health emergencies. (DO 4)
- On 8 September, the GMTA Regulatory Committee agreed to:
    - establish an MDRC / GMTA-GDA COVID-19 Workstream, thereby constituting

the International Center for Emergency Regulatory Response,
    - develop COVID-19 recommendations to IMDRF, WHO, GHWP regarding appropriate international benchmarks,
    - support the organization of a COVID-19 Regulatory Workshop with NRAs to address pandemic/emergency elements,
    - participate in MDRC direction and implementation,
    - accept support for MDRC-Related Training, and
    - include links to the MDRC project website and any related resources on the GMTA website (when ready). (IR 1.1, IR 1.2, DO 4, IR 4.1, IR 4.2, CCIR 2.1)
- On 14 September, the GMTA presented MDRC's recommendations related to COVID-19 and beyond to the 20th IMDRF Stakeholder Virtual Forum. Those recommendations include:
    - ensure that current IMDRF documents acknowledge the need to ensure rapid review and approval,
    - utilize reliance mechanisms to promote rapid reviews and approval,
    - consider the development of specific IMDRF guidance to promote the use of rapid review and approval mechanisms during a global pandemic,
    - ensure adequate training and communication for regulators, and
    - regulatory agility should be leveraged beyond the pandemic. (DO 4)
- On 21 September, GMTA presented on the above MDRC recommendations to the WHO's ICDRAs. (DO 4)
- On 24 September, MDRC submitted the final MDRC Tier One Report for USAID's review and approval of the report's branding. (Output 1.1.6, Activity 1.1.6.1, Output 2.1.2, Activity 2.1.2.1)
- MDRC launched a project-specific URL and email service. The project webpage is a repository for the MDRC resources, and the email streamlines communication and outreach across geographies. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1)
- As part of the annual reporting process, MDRC produced its yearly assessment of the engagement of women in project implementation (CC IR 2.1)

Latin America

- COLOMBIA: On 12 July, MDRC met with the DNP, Ministry of Health, MinCIT, INVIMA, and ANDI. MDRC scheduled two trainings on GRPs and Ex-Post Analyses with MinCIT and DNP. The attendees established a core, cross-departmental team for coordinating work related to the project. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1)
- MEXICO: On 16 July, MDRC met with COFEPRIS, where COFEPRIS asked to engage with other project countries on relevant MDRC activities, such as those related EUA frameworks. MDRC and COFEPRIS discussed the status of the LOI signature process and agreed to host a training on GRPs in the coming months.
- PERU: On 21 July, MDRC met with DIGEMID, where they discussed DIGEMID's need to access the international standards while addressing challenges related to COVID-19. MDRC and DIGEMID discussed developing a dedicated workstream on EUAs. (IR 1.1, Output 1.1.1, Activity 1.1.3.1, DO 4)
- COLOMBIA: On 23 July, MDRC conducted a training on GRPs for Colombian government stakeholders and members of the private sector. The training helps develop a basic set of capacities among these stakeholders to advance GRPs in Colombia and broader region. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1, IR 1.2, IR 2.1, Output 2.1.1, Activity 2.1.1.1, IR 3.1, Output 3.1.1)
- MEXICO: On 23 July, MDRC continued coordination with COFEPRIS to schedule the formal signing of an LOI between COFEPRIS, USAID, and the Coalition. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- COLOMBIA: On 27 July, MDRC conducted training for Colombian government and private sector

stakeholders on Ex-Post Evaluation and regulation affecting medical devices and IVDs. (IR 1.1, IR 2.1, DO 4)

- COLOMBIA: On 30 July, MDRC collaborated with the USFDA to host a training for Colombian regulators and private sector stakeholders on items related to Ex-Post Analysis as well as medical device and IVD regulations. (IR 1.1, IR 2.1, DO 4)
- PERU: On August 5, MDRC met with INACAL, which detailed its challenges in the regulatory process. MDRC will work to assist INACAL with the adoption of priority standards on medical devices and help it overcome resource challenges related to the regulatory process and utilizing international standards. (IR 1.1, Output 1.1.2, Output 1.1.3)
- COLOMBIA: On 6 August, MDRC met with the DNP, which confirmed its delays implementing international commitments related to GRPs. The DNP attributed many of its challenges to inadequate resources and voiced its support for the project. MDRC and the DNP will continue to discuss how MDRC may provide technical assistance to the DNP. (IR 1.1, Output 1.1.4, IR 1.2)
- MEXICO: MDRC met with COFEPRIS on 9 August to continue discussions on establishing a dedicated training plan for MDRC initiatives. (IR 1.1, IR 1.2, DO 4)
- MEXICO: On 13 August, COFEPRIS confirmed it is still reviewing MDRC's training plan. MDRC and COFEPRIS discussed the status of the LOI and how to expedite its signing ahead of the upcoming U.S.-Mexico HLED. (IR 1.1, IR 1.2, DO 4)
- COLOMBIA: On 12 August, MDRC met with the DNP, INVIMA, ANDI, and MinSalud to discuss the need to implement GRPs. MDRC continued to map out its envisioned trainings in the project countries. (IR 1.1, Output 1.1.4, IR 1.2)
- COLOMBIA: On 23 August, MDRC met with NIST, MinCIT, ProColombia and Colombian Trade Representatives to the construction of a guide pertaining to PPE for the Colombian Government. (DO4, IR 4.1, IR 4.2)
- COLOMBIA: On 26 August, MDRC partnered with DNP to organize a workshop that introduced an analysis tool for GRP implementation to the project country's government and private sector stakeholders. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.5, Activity 1.1.5.1, Output 1.1.6, Output 1.1.7, Activity 1.1.7.1, IR 1.2, Output 1.2.1, Output 1.2.2, Activity 1.2.2.2)
- MEXICO: On 31 August, COFEPRIS, the USAID Mission in Mexico, ANSI, the Coalition signed the Letter of Intent for MDRC. The LOI launches a formal collaboration towards regulatory convergence for medical devices by promoting good regulatory practices with reference to international standards. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- COLOMBIA: On 6 September, MDRC organized a workshop in coordination with Ministry of Health for government and private sector stakeholders on the development of "Problem Trees," a critical component under the RIA process for Good Manufacturing Practices for Medical Devices. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.5, Activity 1.1.5.1, Output 1.1.7, Activity 1.1.7.1, IR 2.1, Output 2.1.1, Activity 2.1.1.1)
- PERU: On 7-8 September, MDRC organized a workshop to provide training for private sector and government stakeholders on the local and global obligations and benefits of implementing GRPs. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1, IR 2.1, Output 2.1.1, Activity 2.1.1.1)
- BRAZIL: On September 14, MDRC met with CBDL and the ABNT CB-36 Committee to discuss partnership opportunities to advance the work of Study Committee CE 036:000.003. The parties discussed the challenges faced by the IVD and clinical analysis sectors and the need to expand the availability of ABNT NBR ISO technical standards.
- PERU: On 21 September, MDRC met with MinCETUR to discuss the project's next steps and approach in Peru. MDRC and MinCETUR will continue discussions to address technical issues and develop specific SOPs for GRPs implementation. (IR 1.1, Output 1.1.4, Output 1.1.6, Output 1.1.7)
- REGIONAL: On 30 September, MDRC met with COPANT to determine whether the organization

has any measures or policies that promote gender equality in the organization or in standards development. While it does not, COPANT and MDRC discussed how COPANT could use its general assembly meetings and the issuance of recommended guidelines for its members to advance those initiatives. (CC IR 2.1)

- PERU: On 30 September, MDRC met with the ACR and PCM to discuss partnership with the project and Peru's regulatory practices. (IR 1.1, Output 1.1.4, Output 1.1.5, Output 1.1.7, IR 1.2, Output 1.2.1, IR 3.1)

Africa

- GHANA: On 1 July, the Mission to Ghana approved MDRC outreach letters to government stakeholders. On 9 July, MDRC conducted formal outreach to the Ghana Standards Authority (GSA), Ministry of Trade and Industry, Ministry of Health, Ghana Health Service, Ghana Food and Drug Authority, and Health Facilities Regulatory Authority. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC 2.1)
- KENYA: On 28 July, the USAID Mission to Kenya granted concurrence to MDRC, enabling MDRC to begin outreach and coordination with Kenyan government stakeholders to advance in-country project objectives. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1)
- SOUTH AFRICA: On 4 August, MDRC conducted official outreach with government stakeholders in South Africa. This enables the project to begin building relationships with those stakeholders and advance project objectives. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2).
- KENYA: On 23 August, MDRC met with Kenya's PPB to review the project's high-level objectives envisioned events in 2021-2022. PPB reaffirmed the agency's desire to partner with MDRC and preliminarily identified priorities issues for collaboration with MDRC. MDRC and PPB are scheduling technical meetings to formally review and establish workstreams on these priorities and schedule trainings where appropriate. (IR 1.1, IR 1.2, IR 3.1)
- GHANA: On 24 August, MDRC conducted follow-up outreach with Ghanaian government stakeholders. On 26 August, MDRC leveraged phone contact information provided by the Mission to reach out to Ghana's Ministries of Trade and Health. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.1)
- SOUTH AFRICA: On 24 August, MDRC received a positive response from SAHPRA, indicating it is interested in partnering with the project and designating a point of contact. MDRC is working to schedule an introductory meeting with SAHPRA. (IR 1.1, IR 1.2, IR 3.1)
- KENYA: On 25 August, MDRC met with the Mission to Kenya to introduce the project to the Mission's new point of contact and align on approach to in-country project activities. The Mission and MDRC will work to develop an action plan for MDRC activities in Kenya. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.1)
- KENYA: On 30 August, MDRC met with Mecomed to align on the approach to Tier Two work in Kenya. MDRC and Mecomed began to formally identify industry priorities for developing a workstream with PPB in the coming weeks. (IR 2.1, Output 2.1.1, Activity 2.1.4.1)
- REGIONAL: On 31 August, MDRC and PQM+ met to share information on their ongoing activities and align on future initiatives in Africa. MDRC and PQM+ discussed strategies to formalize collaboration between the two to ensure each project's capacity building activities, curricula, design, and delivery are in alignment with one another. (IR 1.1, IR 1.2, DO 4, IR 4.1, IR 4.2, CCIR 2.1)
- GHANA: MDRC advanced outreach to government stakeholders. Following unsuccessful attempts to connect with those stakeholders by phone on 26 and 31 August, the Mission in Ghana reached out directly to the Personal Assistant to the Minister of Health on behalf of MDRC on September 8. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2, CCIR 2.1)
- KENYA: On 2 September, MDRC and Mecomed met to follow-up on the 23 August PPB meeting. MDRC and Mecomed aligned on next steps and continued development of a formal list of the industry's perceived technical and procedural challenges in Kenya. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR

4.1, IR 4.2)

- SOUTH AFRICA: On 13 September, MDRC and SAMED met to internally align on approach and next steps for collaboration with SAHPRA. SAMED reviewed and shared a formal list of its Tier Two priorities in South Africa WHICH will be used in the development of a formal MDRC workstream with SAHPRA. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- KENYA: On 15 September, MDRC and PQM+ Kenya aligned on approach in Kenya. As PPB works to update its rulemaking process, MDRC and PQM+ will coordinate to provide the agency with relevant information, underscore the importance of regulating medical devices and pharmaceuticals differently, and integrate GRPs into standard procedures. MDRC will help PQM+ build out an online platform for self-assisted learning that provides information to Kenyan government actors by providing relevant information on medical devices. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- SOUTH AFRICA: On 22 September, MDRC introduced the project to SAHPRA. MDRC emphasized its role enabling medical device regulatory authorities, such as SAHPRA, to effectively utilize limited resources during COVID-19 and build long-term resilience and regulatory capacity. MDRC and SAHPRA discussed next steps for project implementation in South Africa, including scheduling regular meetings and creating a dedicated MDRC workstream. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- KENYA: On 29 September, MDRC and PQM+ Kenya continued to align on approach in Kenya. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- On 30 September, MDRC met with representatives of the U.S. ITA in DC and Kenya. The parties discussed MDRC's regional approach in Africa, local activities in Kenya, and leveraging the GHWP. ITA recommended reaching out to the American Chamber of Commerce in Kenya and the Kenya Healthcare Federation to assist with government stakeholder outreach. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)

Southeast Asia

- VIETNAM: On 7 July, MDRC presented on MDRC to members of EuroCham Vietnam's Medical Device & Diagnostic Sector Committee Regulatory Affairs Working Group. The members vocalized approval for MDRC and shared a number of priority areas for MDRC's work in the country, including supporting government authorities' lack of capacity and conducting trainings on issues related to medical device regulatory convergence, GRPs, and reliance principles. (IR 1.1, Output 1.1.4, Ativity 1.1.4.1, IR 1.2, IR 2.1, IR 3.1)
- INDONESIA: On 9 July, USABC Indonesia and MDRC discussed the project's priorities. USABC offered support to help raise awareness among government stakeholders and connect MDRC with officials directly. (IR 2.1)
- VIETNAM: On 15 July, MDRC met with DMEC, which was supportive of MDRC's objectives. DMEC identified a series of priority areas for collaboration, including helping address DMEC's limited capacity, and hosting trainings related to GRPs, regulatory reliance models, and Emergency Use Authorization frameworks. (IR 1.1, Output 1.1.4, Ativity 1.1.4.1, IR 1.2, IR 2.1, IR 3.1, DO 4)
- VIETNAM: On 4 August, MDRC met with the FCS in Vietnam to discuss the project's objectives and timelines in the project country. The FCS offered to support MDRC's outreach efforts, but voiced concerns over MDRC's ability to host a training workshop with Vietnamese regulators in September. (IR 1.1, IR 1.2, IR 2.1, IR 3.1)
- INDONESIA: On 11 August, MDRC met with the BSN. The BSN is awaiting formal approval from the Ministry of Health and BPOM before committing to partnering with MDRC. (IR 1.1, IR 1.2, IR 3.1)
- REGIONAL: Between 17-20 August, AdvaMed attended the APEC SOM3 SCSC meetings as an accredited U.S. delegate to ensure MDRC implementational alignment with related regional activity. MDRC is leveraging the attendance of MDRC project country authorities to these meetings to reinforce project engagement and outreach with local stakeholders. (IR 1.1, IR 1.2, IR 2.1, DO 4, IR

4.1, IR 4.2)

- On 23 September, MDRC emailed Director General Ta Hoang Linh, European-American Market Department, Ministry of Industry & Trade to schedule a call to introduce the project. This action follows the advice of the Commercial Specialist at the U.S. Embassy in Hanoi. (IR 3.1, IR 4.1, IR 4.2)

5. LESSONS LEARNED

Activity #2 – Support for African Organization for Standardization (ARSO)

The project team continues to build on past successes and incorporate lessons learned from the first three virtual sessions with stakeholders. The project team also continues to work with ARSO to identify areas for more thorough engagement. Through continued communications with the ARSO team and TC40 members, the project team continues to strengthen connections and the quality of material shared during online sessions.

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

Standards are technical documents. Although it is clear that each country desires to adopt international standards, it is somewhat challenging to explain technical things in simple terms to non-technical executives. Country meetings held to-date have included stakeholders with a mix of backgrounds and experience in the petroleum industry. It's possible that some of the training from the initial Phase 1 workshop held in 2019 may need to be repeated. We will also need to be clear that the project does not intend to fund capital improvements for laboratories. However, even though some labs are not properly equipped, there are others in the region that are capable of performing more advanced testing. Lastly, we'll need to make sure that the standards bodies are positioned to keep their standards up-to-date.

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

The project team continues to incorporate lessons learned on virtual engagements with stakeholders, online capacity-building, and digital resource capabilities. MDRC is expanding its virtual platform and Zoom licenses to enable simultaneous stakeholder meetings and engagement across geographies. MDRC has learned to more effectively coordinate with local stakeholders in determining their virtual capabilities and filling the gap with MDRC technologies.

The execution of effective virtual project country capacity building does not require the allocation of extensive travel resources. As such, MDRC's partner governments are asking for those funds to be used in different ways – like with the creation of the Colombia Liaison. MDRC believes that going forward the project should be more flexible in the deployment of resources to maximize its ability to execute MEL Plan objectives in the current non-travel environment.

MDRC continues to optimize the level of resources devoted to running MDRC and the Coalition's online presence. Using a more experienced, lower cost vendor has heightened the Coalition's capacity to provide online modules and virtual resource library. Virtual Coalition resources have proven to be an invaluable tool for hosting and disseminating information vital to the project.

MDRC has streamlined and standardized project communication across geographies by launching a project

URL www.standardsalliance-mdrc.org and related email @standardsalliance-mdrc.org. This URL links to the expanded and detailed MDRC web page housed on the Coalition website. Over the course of the project, MDRC will partner with its new vendor towards establishing a separate website for MDRC content, given available resources.

MDRC has crafted a series of USAID-branded templates for project use in external engagements. These templates will be shared with USAID for approval in Q4 2021 and ensure consistent alignment with USAID branding guidelines across all project activities.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Q4 2021 Planned Activities

Activity #	Activity Name	Meeting/Event	Date	Location	USAID participation?
1	ECOWAS Clean Renewable Fuels Workshops	Clean Fuels Workshops	December, 2021	Virtual	Optional
2	Support for ARSO	Webinar #5: Cosmetics Panel	November 2021	Virtual	Optional
5	ECOWAS Harmonization of Petroleum Standards	Consultant to hold virtual meetings with technical persons in each of the four target countries to identify what methods they are using, how are they applying them, and to find out about any challenges they may have.	November-December, 2021	Virtual	No
5	ECOWAS Harmonization of Petroleum Standards	Begin planning for a two-day technical workshop to be held in Ghana	December, 2021	Virtual	No
11	Surgical Mask Production	Training for Ghanaian government representatives on surgical mask standards and production standards	TBD Q4, 2021	Accra, Ghana	No
12	MDRC	See table below			

Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops

The ECOWAS Clean Renewable Fuels workshops have been scheduled for Q1 of 2022 following requests from ECREEE and due to an ECREEE preference for face-to-face interactions on clean fuels standards with the two key countries. Pivot will also develop online options to deliver both planned trainings leading up to the 2021 ECREEE General Assembly in December, 2021.

Activity #2 – Support for African Organization for Standardization (ARSO)

The fifth webinar in the series will be hosted on November 23 and will showcase a panel of past speakers from the first four webinars to provide an open forum for ARSO members to ask questions and discuss various cosmetics frameworks and solutions for the African continent.

In Q4, ANSI, ARSO and PCPC will continue to organize and host the cosmetics standardization web-series with the goal of assisting the African continent in adopting a cosmetics standards framework that will support two-way trade, safeguard African consumers, and decrease enforcement burdens and liability on African governments.

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

In Q4, ASTM and API plan the following actions:

- Nov - Dec 2021 – Consultant to hold virtual meetings with technical persons in each of the four target countries to identify what methods they are using, how are they applying them, and to find out about any challenges they may have.

- Dec 2021 – Begin planning for a two-day technical workshop to be held in Ghana

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

In Q4, MDRC will continue to focus on outreach and capacity-building with private and public sector stakeholders, particularly in Southeast Asia and Africa. MDRC will advance awareness of MDRC objectives and leveraging the relationships built between Q1 and Q3 to dive deeper into specific Tier One and Tier Two areas with those stakeholders, identifying where MDRC can remedy regulatory non-alignments and promote the use of GRPs.

Please find below a chart outlining planned MDRC activities for the next quarter, understanding that current conditions might require delays for certain events:

Date	Meeting/Event	Location	USAID participation?	Region
18 Nov 21	Joint FDA – MDRC Webinar Series on UDI – Session 1	Virtual	Yes	MDRC Countries + LatAm
30 Nov 21	GRPs: A Key to improve access to medical technology & a practical implementation experience	Virtual	Yes	MDRC Countries + LatAm
TBD	GRPs in Health Regulations - COFEPRIS	Virtual	Yes	Mexico
TBD	Regulatory Systems for MDs and IVDs – INVIMA & MoH	Virtual	Yes	Colombia

07 Dec 21	Joint FDA – MDRC Webinar Series on Recognition of International Standards – Session I	Virtual	Yes	MDRC Countries + LatAm
TBD	Tier One Regional Forum: relevant stakeholders from Ghana, Kenya, and South Africa (and broader region, as appropriate)	Virtual	Yes	Africa
TBD	Tier Two Regional Forum: relevant stakeholders from Indonesia and Vietnam (and broader region, as appropriate)	Virtual	Yes	Southeast Asia
TBD	Tier Two local Forum - Vietnam	Virtual	Yes	Vietnam