Standards Alliance: Phase 2

Quarterly Report

2nd Quarter April 1 to June 30, 2021

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AOR Name: Eleanor Thornton

Submitted by: Leslie McDermott
American National Standards Institute
1899 L Street NW, 11th Floor, Washington, DC 20036
Tel: 202-331-3626
Email: lmcdermott@ansi.org

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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:	2Q 2021 – April 1 to June 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 second 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 one of the most productive quarters as all subawards have been finalized and approved by USAID. 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 Q2 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 Q2, ANSI, ARSO and the Personal Care Product Council (PCPC) hosted three webinars in the ongoing 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.

As with the first event, these activities target participants in ARSO Technical Committee 40 (TC40) on cosmetics. The trainings continue to support knowledge sharing on best practices for the development of an African standards framework for cosmetics that will support consumer and industry interests.
The second webinar was held April 16 and focused on international best practices for cosmetics standardization, including ARSO technical committee members, as well as global private sector stakeholders. The event detailed existing cosmetics frameworks and enforcement strategies implemented by governments, regulatory entities, and standardization bodies. This included a case study describing South Africa's approach to cosmetics standards frameworks. The training drew over 67 participants.

Cosmetics Europe opened the webinar with Dr. Gerald Renner, Director of Technical Regulatory and International Affairs, and Maxime Jacques, International Relations Manager, delivering an overview of international cosmetics frameworks and the most efficient methods to ensure safety, quality, and efficacy in cosmetics products.

This introductory presentation was followed by a two-part case study on South Africa's experience. Richard Sadiki, International Relations and Strategic Partnership Specialist for the South African Bureau of Standards (SABS), outlined the mandate and priorities of SABS and how these apply to cosmetics. Next, Dershana Jackison, Head of Policy and Regulatory Affairs for the Cosmetic, Toiletry & Fragrance Association (CFTA), delved deeper into the trade and regulatory challenges faced by the South African cosmetics industry. Together these presentations clearly described the standardization landscape in South Africa, how it affects the cosmetics industry, and the benefits of implementing South African National Standards to promote compliance and safety.

The third webinar was held on May 20 and attracted 45 participants. This event laid an important foundation discussing international best practices for standards development and the importance of using harmonized, international standards related to the cosmetics sector. Speakers included Mojdeh Rowsan

Tabari, committee manager for ISO TC217 on cosmetics research; Uli Osterwalder, chairman of ISO TC217; and David Jankowski, ANSI.

The fourth webinar in the series will be hosted on July 7 and will provide 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). The fifth webinar is also expected to take place in Q3 2021.
In Q3, 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) sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with CWSC on May 4, 2021. Coordination for introductory calls with USAID Missions in Ghana, Uganda, and Zambia occurred in 2Q 2021. Country-level supporting documents for USAID Missions in these countries were developed. CWSC was approved to begin work in Uganda and has begun deskwork.

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

The American Water Works Association (AWWA) sub-award agreement is active. Coordination for introductory calls with USAID Missions in Zambia, Malawi, and Lesotho will occur in 3Q 2021 per AWWA's interest to learn from the India coordination efforts before engaging in Africa. Country-level supporting documents for USAID Missions in these countries will continue to be developed in 3Q 2021.

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

In Q2, ANSI, API, and ASTM coordinated to begin the introductory phases of the ECOWAS Harmonization of Petroleum Standards project. In light of the COVID-19 pandemic and related travel uncertainty, ASTM and API consulted with USAID and ANSI and decided that the preferred option in moving forward with the program would be to pursue virtual events in 2021, followed by in-person meetings for the remainder of the program.

In Q2, work began using virtual technology to create information sharing sessions with USAID staff and stakeholders from the region. In addition, desk research on the current use and implementation of standards in the four target countries (Cote d'Ivoire, Ghana, Nigeria, and Senegal) is underway.
In Q2, the Standards Alliance hosted an introductory meeting with USAID country missions from the four target countries as well as regional missions including the West Africa Trade and Investment Hub, the USAID West Africa Mission, and ASSESS. This meeting enhanced local USAID staff understanding and created buy-in for the program.

On June 4, ANSI, ASTM, and API held a fact-finding call with stakeholders from Senegal. In addition to learning about the Senegal National Plan for standardization in the petroleum sector, the team received confirmation from the Director General at the national standards body (ASN) that Senegal will look at aligning their goals with the goals of the Standards Alliance project. Senegal also noted that it holds the Secretariat of the Harmonization Committee at the ECOWAS level. Further, during this call, the implementation team was introduced to a key contact at the African Refiners & Distributors Association (ARDA) who will help us to promote our work within that organization. A meeting with ARDA is set for 12 July.

Throughout Q2, the Standards Alliance focused on fact-finding meetings and gathering stakeholder input. An initial meeting was held with relevant USAID missions to kick-off the project. Throughout Q3, ANSI, ASTM and API will continue to gather stakeholder input, and through those meetings identify and narrow project scope as necessary. This will lead to a virtual introductory workshop and planning for future activities. A list of outputs achieved in Q2 as well as planned activities for Q3 are listed below:

Implementation Status

- April 7, 2021 – Virtual meeting held to introduce the project to the US AID missions in West Africa. Participants included key mission participants from Cote d'Ivoire and Senegal, as well as ASSESS and the main USAID West Africa mission.
- April 15, 2021 – Planning for initial outreach to stakeholders in West Africa begins.
- April 28, 2021 – ANSI begins outreach to former participants from the four target countries of the November 2019 Workshop to inform them about the new SA II project.
- May 13, 2021 – Press release issued to ASTM petroleum media list as well as a regional list for West Africa that consists of 175+ outlets in the region.
- June 4, 2021 – Virtual meeting held to introduce the project to Senegalese stakeholders held
- June 7, 2021 – Virtual meeting held to introduce ASTM stakeholders who are members of the ASTM Petroleum Subcommittee D02.93 Coordinating Subcommittee on International Standards and Related Activities to the project.

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 sub-award at the end of June and began outreach to the USAID Mission 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.

ANSI will continue to support these efforts and hopes to complete the final introduction to the USAID missions in Kenya in Q3 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) sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with IAPMO on June 17, 2021. Coordination for introductory calls with USAID Missions in Indonesia and the Philippines will occur in 2021. Country-level supporting documents for USAID Missions in these countries will be developed in Q3 2021.

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

The American Water Works Association (AWWA) sub-award agreement in India is active. USAID India Mission calls were fruitful and the Mission granted concurrence to the AWWA project. The India Mission assigned Mr. R.K. Srinivasan as the project's Activity Manager. Mr. Srinivasan is engaged in supporting and facilitating outreach between AWWA and relevant Indian stakeholders, including utilities and ministries.

The needs assessment survey and a project summary has been sent to nine utilities in India. Outreach to a further 15 utilities will occur in Q3. With the support of the India Mission, a letter has been emailed to the Ministry of Housing and Urban Development requesting that the Department send a letter to Urban Utilities to consider participate in this program. Some delays in responsiveness from partners and utilities is being observed due to the outbreak of COVID-19 Delta variant in India.

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)

The NSF International sub-award agreement is active. Calls with USAID Mission staff in Brazil and Colombia continued in 2Q 2021.

Country-level supporting documents for USAID Missions in these countries were developed in 2Q 2021. The USAID Mission in Brazil approved the NSF project and requested quarterly updates from NSF/ANSI on activity progress. To better serve stakeholders, NSF has successfully translated the relevant standards (NSF 60 and 61) into Spanish and Portuguese.

Unfortunately, the Colombia Mission did not grant concurrence to NSF as the project did not align with the Mission's development objectives. NSF is considering next steps, including allocating funds to the Morocco and Brazil projects.

Development Objective #3: Countries have fewer TBT's

Activity #10 – Energy Efficiency Standards in Mexico

ANSI continued its attempts to solidify topic and scope, but U.S. private industry is not equipped to support. The Mexican National Standards (NOM) is domestic, and does not refer to the ICC code. After consulting with USAID contracting officers, both parties came to agreement that it will no longer pursue this activity. The allotted budget amount will be re-allocated to an existing project.

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) sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with IAPMO on June 17, 2021. Coordination for introductory calls with the USAID Mission in Jordan will occur in 2021. Country-level supporting documents will be developed in Q3 2021.

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

The NSF International sub-award agreement is active. Calls with USAID Mission staff in Morocco continued and country-level supporting documents for the Morocco Mission were developed in 2Q 2021. USAID submitted a concurrence request to the Morocco Mission in June 2021. Further discussions and approval process conversations are expected with the Mission and US Embassy in Morocco in 3Q 2021.

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)

Latin America

MDRC, in tandem with the Inter-American Coalition for Regulatory Convergence (IACRC, "the Coalition"), made large strides in advancing project outputs in Latin America during Q2 2021. MDRC has secured USAID Mission concurrence and conducted formal outreach to government stakeholders in all Latin American project countries.

Regional: On 20 April, ANSI connected with several Latin American standards bodies during the Pan

American Standards Commission (COPANT) General Assembly networking meetings. Those bodies included the Colombian Institute of Technical Standards and Certification (Instituto Colombiano de Normas Técnicas y Certificación, ICONTEC), Mexican Dirección General de Normas (DGN), and the Peruvian National Institute of Quality (Instituto Nacional de Calidad, INACAL). DGN confirmed receipt of ANSI outreach sent on 17 March. INACAL indicated informal interest in MDRC but required further internal coordination with Peru's Ministry of Foreign Trade and Tourism (MINCETUR) and Directorate General of Drug Supplies and Drugs (DIGEMID) before proceeding. See *Peru* for more information.

On 18 May, the Coalition met with the Pan American Health Organization (PAHO) to discuss avenues for collaboration on MDRC. First, attendees discussed the formal status of the Coalition as a partner of PAHO. As the Coalition advances its application to qualify as a Non-State Actor with PAHO, it will continue to work with PAHO to formalize their relationship in the appropriate manner to advance MDRC objectives. Second, the attendees discussed engaging PAHO member country medical device regulators in the Pan American Network for Drug Regulatory Harmonization (PANDRH, or la Red Panamericana para la Armonización de la Reglamentación Farmacéutica, Red PARF). Third, PAHO offered to organize a virtual meeting of regional external stakeholders. The Coalition began the process of planning this meeting in June. The Coalition will propose topics and share materials and unofficial translations of documents produced by WHO and other relevant entities with PAHO in their next meeting.

On 2 June, the Coalition presented at the *WTO Webinar on Regulatory Cooperation During the COVID-19 Pandemic* to advance MDRC objectives. The Coalition, along with a Global Medical Technology Alliance (GMTA) representative and a group of experts, presented on the challenges the pandemic posed for the medical technology sector while outlining opportunities for leveraging lessons learned to advance regulatory convergence.

On 8 June, MDRC met representatives from the World Health Organization (WHO) to explore opportunities for further collaboration. Those representatives were Marie Valentin, Technical Officer for Regulatory Convergence and Networks Team, Anita Sands, Technical Officer for Incidents and Substandard/Falsified Medical Products, and Leticia Megias Lastra, Technical Officer for Incidents and Substandard/Falsified Medical Products. WHO shared their work on the development of a Global Benchmarking Tool for medical device companies for which a pilot implementation plan is being designed. In line with MDRC objectives, the WHO confirmed it was hosting a webinar on 29 June on GRPs, Good Reliance Practices (GRelPs), and resources to enhance their global implementation. MDRC is awaiting WHO's feedback to schedule a follow-up meeting, where WHO officials and MDRC will discuss potential avenues for collaboration.

MDRC collaborated with the United States Food and Drug Administration (USFDA) to organize a webinar series for stakeholders across Latin America. This series took place over three sessions between 2 and 17 June. These sessions focused on ISO 13485 and Medical Device Single Audit Program (MDSAP) outcomes utilization for regulatory purposes. During the first session on 2 June, representatives from the USFDA and ANVISA provided an overview of MDSAP and their experiences to implement ISO 13485. In the second session on 10 June, DEKRA – an MDSAP Auditing Organization – and the USFDA presented on MDSAP audits and discussed a case study where regulators from MDRC project countries Colombia and Mexico shared criteria to manage certain non-conformities. During the third session on 17 June, ANVISA, ANMAT and the USFDA shared their experiences on the use of MDSAP documents. ANMAT presented on its experience becoming an MDSAP Affiliate Member while USFDA offered visibility on the process and MDSAP's training resources. The three sessions engaged 15 National Regulatory Authorities (NRAs) and convened an average of about 400

attendees, totaling 17 countries. Of the total attendees, 300 were from MDRC partner countries, including Brazil, Colombia, and Mexico.

The Coalition, the Latin American Alliance for the Development of In Vitro Diagnostics (ALADDIV), the London School of Hygiene and Tropical Medicine, the International Diagnostics Center, and CBDL launched the Laboratory Diagnostics White Book for 2021-2022 on 16 June. These organizations convened around 300 health professionals from 17 countries (Brazil, Canada, Chile, Colombia, France, Germany, Italy, Kenya, Republic of Korea, Mexico, Paraguay, Peru, Spain, Trinidad and Tobago, United Kingdom, United States and Vietnam) to share the unveiling of this tool and convene a round table on "The Future of Diagnostics in a Post Pandemic World." This tool may serve as a resource for MDRC project countries in advancing policy that reinforces early and effective diagnostic tools in a post-pandemic world.

Colombia: MDRC met with the Colombian National Food and Drug Surveillance Institute (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA) and the National Business Association of Colombia (ANDI) on 22 April to advance discussions on priorities for project activities and trainings in Colombia. Attendees included Dra. Lucia Ayala, Dir. Medical Devices and Other Technologies at INVIMA, and Marisol Sánchez, Director of the Chamber of Medical Devices and Health Supplies at ANDI. INVIMA and ANDI identified (1) clinical research, (2) Good Manufacturing Practices (GMPs), and (3) Decree 4725 as its top priorities for collaboration with MDRC on GRPs. Dra. Ayala proposed that MDRC designate a dedicated MDRC Liaison to Colombia to coordinate and facilitate all activities related to the project in-country. INVIMA advised that the deployment of project resources for an MDRC Liaison would enable Colombian government partners to fully dedicate themselves to MDRC implementation without disrupting essential COVID-19 functions and response. The MDRC team views this recommendation as a unique opportunity to advance Colombia's outputs under the MEL Plan objectives. As such, the MDRC is working to secure approval from USAID to deploy this Liaison. Please see Section 2.2 for additional information.

On 10 June, MDRC met with the National Planning Department (Departamento Nacional de Planeación, DNP), the Ministry of Health, INVIMA and ANDI to coordinate strategy for a series of MDRC relevant projects in Colombia. Those projects include the implementation of Medical Device Single Audit Program (MDSAP), the ex-post evaluation of Decrees 4725 and 3770, and developing regulation related to Emergency Use Authorizations.

On June 24, MDRC met again with the DNP, the Ministry of Health, the Ministry of Commerce, Industry and Tourism (MINCIT), INVIMA and ANDI. Participants agreed on initial steps to advance: (1) the ex-post analysis of Decrees 4725 and 3779, (2) Regulatory Impact Assessments (RIAs) for GMPs, (3) regulation related to clinical research and Emergency Use Authorizations, and (4) GRPs under a collaborative approach between government and private sector.

Brazil: On 12 April, MDRC introduced the project to the Brazilian Ministry of Economy's Foreign Trade and International Affairs Secretariat. The Secretariat and MDRC discussed future project activities in the country and will work to jointly develop an agenda for MDRC work in Brazil.

MDRC introduced the project to ANVISA on 15 April. ANVISA and MDRC discussed how the project and the Coalition can support ANVISA's activities during the pandemic while advancing efforts related to regulatory convergence in Brazil.

On 30 April, MDRC met with the Government of Brazil's Secretariat for Economic Monitoring of the Ministry of Economy (SEAE). MDRC emphasized Brazil's differentiated role in the project, serving as a

partner to support the development of capacities among other regulators in the region. SEAE expressed the Brazilian government's desire to implement GRPs consistent with a 'whole of government' approach, including those authorities that issue technical regulations that pertain to medical technologies, such as the National Institute of Metrology, Standardization and Industrial Quality (INMETRO). To ensure a coordinated strategy between INMETRO, the Brazilian Association of Technical Standards (ABNT), and ANVISA, SEAE recommended that ANVISA should play the leading organizational role.

Mexico: On 25-26 March, shortly after receiving local USAID Mission project concurrence, MDRC sent outreach letters to Government of Mexico stakeholders, including the Ministries of Finance, Economy, and Health. On 26 March, MDRC met with COFEPRIS, the Federal Commission for Protection against Sanitary Risk in Mexico. In this meeting, the parties discussed the timeliness and importance of MDRC as well as challenges unique to Mexico as they relate to the medical technology sector, compliance with treaty obligations, and underutilization of Equivalence Agreements. MDRC and COFEPRIS began working towards the conclusion of a Letter of Intent (LOI) so that they may optimize and deepen their collaborative efforts moving forward.

On 26 April, MDRC met with COFEPRIS in Mexico to overview the project's objectives, approach, and potential for collaboration with the Government of Mexico's agencies and initiatives. MDRC explained that it would work with COFEPRIS and relevant stakeholders to draft a tailored work plan to meet Mexico's unique circumstances and needs. Thereafter, MDRC discussed the importance of GRPs on the regulatory process and the importance of utilizing international standards. To serve as a reference, MDRC shared priority issue-areas identified by the Mexican Association of Innovative Medical Device Industries (AMID), the Medical Device Division of the National Chamber of the Pharmaceutical Industry (CANIFARMA), and the Confederation of Industrial Chambers of the United Mexican States (CONCAMIN) with COFEPRIS.

On 26 April, MDRC introduced the project to CONAMER, Mexico's National Commission for Regulatory Improvement. MDRC and CONAMER prioritized discussion on how MDRC could facilitate alignment between CONAMER, COFEPRIS, and DGN to advance project objectives. MDRC and CONAMER discussed three MDRC project areas of particular interest to COFEPRIS: regulatory convergence, regulatory simplification, and digitization. COFEPRIS informed MDRC that the Government of Mexico lacks written procedures to ensure proper alignment with GRPs. MDRC will work to advance the development of written procedures that ensure GRPs are embedded in COFEPRIS' Quality Management System.

On 24 May, ANSI and MDRC met with the DGN. MDRC and DGN reviewed and agreed to jointly advance a number of the project's objectives. Those include: developing a standing policy/statement of support for GRP implementation within the country as conducive to international standardization and trade; establishing a standing work stream to implement GRPs with the Government of Mexico; and increasing international regulatory, standards and conformity assessment convergence for the medical technology sector within Mexico. DGN and MDRC will coordinate with regional and multilateral organizations to move these outputs forward.

MDRC met with the COFEPRIS on 11 June to discuss formal collaboration with the project and ongoing negotiations to conclude a joint Letter of Intent as an alternative to an MoU.

MDRC met the Secretariat of Economy on 14 June to share additional information on the project and discuss areas of primary importance to the Secretariat for MDRC. The Secretariat informed MDRC the implementation process has begun on the U.S. Mexico Canada Agreement (USMCA) Annexes

related to medical devices and GRPs. Effective implementation of these Annexes will help facilitate trade while improving access to medical technologies during COVID-19, key objectives of MDRC.

On 28 June, MDRC met with COFEPRIS and continued to align on both joint priority issue areas and the final language for a Letter of Intent. COFEPRIS proposed a hybrid event as a forum to sign the Letter of Intent, where the Federal Commissioner, USAID and MDRC representatives in Mexico may attend in person. This proposal remains under consideration.

Peru: On 1 April, the Coalition and ALADDIV met with Patricia García, former Minister of Health of Peru, to discuss challenges to communication with DIGEMID as well as alternate avenues for collaboration. See Section 2.3 for further information on challenges engaging with the Government of Peru.

Throughout Q2, MDRC communicated with MINCETUR to assess potential opportunities for collaboration. MINCETUR confirmed its interest to participate in MDRC, but required further internal consultations before proceeding. Since, MINCETUR has agreed to participate in an MDRC Peru-specific GRP workshop. This workshop is still being organized and has secured interest from DIGEMID.

On 17 June, MDRC met with Oscar Caipo, the President of National Confederation of Private Business Institutions (CONFIEP) and one of the co-chairs of the Americas Business Dialogue's Transparency and Regulatory Working Group. Following an introduction to the project, MDRC and CONFIEP discussed potential avenues of collaboration with the project, including through the Coalition.

Southeast Asia

MDRC has successfully secured USAID Mission concurrence and conducted formal outreach to government agencies in Vietnam and Indonesia.

Regional: On 27 May, MDRC met with the Asia Pacific Medical Technology Association (APACMed), which represents manufacturers and suppliers of medical equipment, devices and in-vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific. MDRC and APACMed Regulatory Affairs lead Nishith Desai discussed medical device regulatory challenges in the region. MDRC will coordinate with APACMed's Southeast Asia Center of Excellence (COE), which has identified a series of medical device regulatory convergence needs in Indonesia and Vietnam.

On 25 June, the U.S. ASEAN Business Council (USABC) hosted a call to update members on the ASEAN Medical Device Directive. MDRC used this call as an opportunity to introduce attending members to the project and emphasize collaboration with the USABC to advance project objectives. MDRC noted Tier Two concerns by members relevant to the project countries. For Indonesia, those concerns centered on potential new Local Content Requirements and Import Substitution Policies. Members voiced support for improving the transparency of regulatory processes in the project country. In Vietnam, companies highlighted concerns over the delayed approval of dossiers for registration.

Vietnam: On 10 May, the General Department of Vietnam Customs responded to MDRC's outreach letter to confirm their participation in the project. The letter states that the Ministry of Finance has designated Customs Department as the focal point for future partnership with MDRC. In the letter, the Department recognized MDRC's potential to "reinforce the Government's efforts to support businesses in importing and exporting COVID-19 medical device in compliance with Vietnam's legal

regulations and international commitments."

On 20 May, MDRC met with Abbott Vietnam to seek feedback on medical device regulatory convergence opportunities and challenges. Issues discussed, include: (i) medical device re-registration; (ii) requirements for independent quality testing on medical equipment at healthcare facilities; (iii) the implementation of unique identification number for medical devices; (iv) labelling procedures for medical device packaging; and (v) the price-sensitive nature of the medical device tendering process.

On 27 May, MDRC met with the Chair of the Healthcare Committee of the American Chamber of Commerce in Vietnam to discuss Tier Two priorities in the country. The Chair identified the sector's priority as addressing the requirement for companies to re-register medical devices by January 2022 as a prerequisite to their importation. Vietnamese authorities remain unable to process all the applications due to capacity issues. MDRC will coordinate with the Chair to present at the next monthly Healthcare Committee meeting to member country leads and government affairs teams. The Chair and MDRC will work to facilitate subsequent meetings with interested regulatory teams to dig deeper into key issues.

On 9 June, MDRC met with the European Chamber of Commerce in Vietnam to discuss working with the Chamber's Medical Devices and Diagnostics Sector Committee to identify regulatory hurdles as well as training and capacity-building opportunities for Vietnamese authorities. The Committee echoed the American Chamber of Commerce in Vietnam's concern on the requirement to re-register medical devices and the authorities' lack of capacity. MDRC and the Committee will continue conversations to discuss these priorities on a technical level.

Indonesia: On 29 April, MDRC had a series of communications with the DOC/ITA/FCS Standards Attaché at the U.S. Embassy in Indonesia on MDRC-related issues. The Attaché connected the project with relevant officials in the U.S. Commerce Department who in turn have expressed willingness to assist and participate in relevant MDRC activities. The Attaché reiterated the support of the U.S. Commercial Office in Jakarta and his colleagues as a resource for the MDRC.

On 17 May, the USAID Mission to Indonesia issued project concurrence to MDRC. The Mission recommended that MDRC closely coordinate with the U.S. Foreign Commercial Service (FCS) and participate in the US Embassy Medical Device Roundtable meeting every two months. The Mission provided MDRC with additional requirements for engaging with the Government of Indonesia and reporting project progress.

On 19 May, MDRC presented an overview of the MDRC and its relevance to medical device manufacturing companies operating in Indonesia at the US Embassy to Indonesia Medical Device Roundtable. Following the presentation, the roundtable raised specific areas of importance to the industry in Indonesia. This includes, pre- and post-market processes such as prior approval, E-Katalog listing delays, and post-market surveillance.

On 1 June, MDRC met with Stryker, a leading medical device company, to discuss medical device regulatory convergence priorities, opportunities, and challenges in Vietnam and Indonesia. Items discussed for Indonesia included the country's E-Katalog, advancing transparent regulatory processes, and local content requirements.

On 22 June, MDRC sent electronic outreach letters to government stakeholders in Indonesia after aligning with the Mission's requirements. MDRC will send hard copies of the letters in early Q3 2021.

Africa

MDRC continues to work with local and regional stakeholders, including industry associations and USAID Missions, to ready government outreach in alignment with local requirements and Mission specifications. MDRC has met with all three project country USAID Missions, securing project concurrence in Ghana and South Africa. Concurrence in Kenya remains under Mission consideration.

Regional: On 21 May, MDRC advanced discussions with Mecomed, the leading medical device industry association for the region, on partnership to advance MDRC objectives in Kenya, Ghana, and broader region (they do not cover South Africa). Mecomed and MDRC discussed ways in which the project could execute the Tier One regional forum and Tier One/Two local trainings in Ghana/Kenya in the most effectual and efficient manner. This discussion resulted in the parties agreeing to shift those events by one quarter (see Section 6). Mecomed noted that it developed a preliminary list of industry priority areas for MDRC support in the project countries and expressed willingness to work with the Medical Device Association of Kenya (MEDAK) in hosting the local Kenyan government and stakeholder consultations once Mission concurrence was received.

On 17 June, MDRC and Mecomed held the first of a two-part webinar training series on Tier One and Two issues with the region's medical device industry, including numerous participants from project countries. The first session was Tier One-focused, covering GRPs, technical barriers to trade (TBT), and their impacts on the medical technology sector during COVID-19. MDRC presented on the differences between technical regulations and standards, and harmonizing cross-border requirements through the adoption and use of international standards. MDRC also covered major challenges for the region's medical device sector related to trade/WTO rules. Those challenges include the lack of or improper implementation of the TBT agreement by most medical device regulators and the inappropriate regulation of medical devices as pharmaceuticals.

On 24 June, MDRC and Mecomed held the second part of this webinar series, dedicated to Tier Two elements for project countries in Africa. This session addressed regulatory convergence in the medical technology sector and Tier Two international benchmarks from the World Health Organization (WHO), International Medical Device Regulators Forum (IMDRF) (IMDRF), and Global Harmonization Working Party (GHWP). MDRC and Mecomed facilitated discussion on Medical Device Single Audit Program (MDSAP) as well as challenges to regulatory and industry capacity building in the Tier Two, Africa-specific context.

Kenya: On 6 May 2021, MDRC and the Mission to Kenya introduced the project to the Kenyan Pharmacy and Poisons Board (PPB). PPB affirmed its desire to collaborate with MDRC, including the appointment of a project focal point within the agency, and will identify key priorities for advancement with the project. PPB noted that it has a similar program underway in the pharmaceutical sector that is achieving good results and MDRC's work in the medical device sector would be valuable for Kenya as a new focus area. MDRC spoke to the project's envisioned process in the country and region, and agreed to co-create an action plan with PPB, the Mission, and other stakeholders to ensure alignment with local needs.

This meeting follows the project's formal introduction to the meeting on 24 March. Since then, MDRC has corresponded regularly with the Mission to secure full concurrence. While the PPB confirmed both MDRC's potential value to Kenya and a desire to collaborate, the Mission to Kenya has not granted concurrence to the project. Concurrence is still under review.

Ghana: On 9 June, MDRC and Mecomed met with the USAID Mission to Ghana to introduce the

project to the Economic Growth Team. MDRC discussed its Tier One and Two objectives in Ghana and expanded upon the intersection between the project's health and trade elements. MDRC provided the Mission with a preliminary draft action plan which outlines MDRC projected outcomes, milestones, and timelines in Ghana. MDRC also shared a draft template outreach letter for government stakeholders in Ghana. The draft template outreach letter is undergoing final review by all parties and will extended to government stakeholders in early July 2021.

South Africa: On April 20, MDRC met the Mission in South Africa to provide additional information on the project and the expected timeline for its objectives in-country and greater region. MDRC and the Mission discussed expectations for Mission engagement with the project in achieving those objectives. MDRC also elaborated on the various approaches the project had taken in other countries. The project noted that it is possible to address Tier One and Tier Two individually or in parallel, and in whichever order is appropriate for in-country circumstances. Following this discussion, the Mission informed MDRC it would not require a concurrence memo and would collaborate on future efforts with MDRC.

On 22 April, ANSI conducted outreach to the South African Bureau of Standards (SABS), the national standards body for South Africa.

On 7 May, MDRC met with the South African Medical Device Industry Association (SAMED) to discuss the association's partnership with MDRC to advance project outputs in South Africa. MDRC and SAMED have since collaborated to extend outreach to South African government stakeholders. SAMED has provided critical local expertise on the content and acculturation of outreach letters to maximize their effectiveness. The Mission to South Africa reviewed and approved the MDRC's template outreach letter on 11 June. SAMED and MDRC are in the final process of customizing letters and identifying proper contact information for each government stakeholder. MDRC will extend outreach in early July 2021.

Other Notable Progress

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. This report will serve as a resource for closing key gaps and communicating MDRC objectives to both private and public stakeholders at local and regional levels.

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.

MDRC has sought input on Phase One outputs from a variety of stakeholders, including industry associations, USAID Missions, and US government agencies. On 23-24 March, 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.

On 5 May, MDRC shared updated drafts of MDRC's Phase One, Tier One gap analyses and Phase One, Tier Two stakeholder maps with ANSI, the US International Trade Administration (ITA), the US National Institute of Standards and Technology (NIST), the Office of the US Trade Representative (USTR), and the US Office of Information and Regulatory Affairs (OIRA).

MDRC experienced a temporary delay to the planned implementation schedule in Q4 2020. At the request of USAID, MDRC activity and outreach to partner country governments was placed on hold at the outset of the quarter until the USAID Office of Acquisition and Assistance could issue a letter providing consent for the subaward to AdvaMed under the SA2-MDRC project. USAID formalized consent of the subaward on 1 December 2020, which impacted the implementation timeline of the MDRC project in Q1 2021 by delaying USAID Mission concurrences.

During Q2, MDRC secured concurrence from the USAID Missions in Mexico and Indonesia, and permission to proceed without a formal concurrence memo in South Africa.

While the prior delay set back scheduled outreach, MDRC rapidly expanded collaboration with private and public sector actors across the three project regions throughout Q1 and Q2 2021. This includes coordination with relevant stakeholders on feedback for Phase One outputs. The Tier One, Phase One report is complete and is in the process of final graphic design and alignment with USAID branding requirements. Phase One, Tier Two stakeholder maps are under final review by various local and regional stakeholders and are scheduled for completion in early Q3.

MDRC continues to assess whether capacity-building activities with each project countries in 2021 will remain virtual as a result of COVID-19 travel and local gathering restrictions.

Following the decision by the USAID Mission in Thailand to decline project concurrence in Q1, MDRC initially decided to focus those resources earmarked for Thailand towards Vietnam and Indonesia for the remainder of the project timeline. However, following the Government of Colombia's request for a MDRC Liaison to coordinate project implementation among government and local stakeholders, MDRC is working to secure approval from USAID to deploy this Liaison. The Government of Colombia has indicated that the deployment of such a Liaison would enable Colombian government partners to fully dedicate themselves to MDRC implementation without disrupting essential COVID-19 functions and response (see Section 2, Colombia).

While final USAID approval of the new Liaison is still under consideration, MDRC believes this development is a potential avenue to overcome prior implementation challenges and accelerate MEL Plan achievement in Colombia. The focused scope, full-time, and short-term nature of the Liaison's work lends itself to the rapid deployment of MDRC capacity building central to the MEL plan. The Liaison's singular focus coordinating and working with relevant Colombian government stakeholders, even in a virtual setting, is expected to promote rapid project goal realization. Coupled with the strong demonstrated desire of the Government of Colombia to implement regulatory convergence and GRPs, the Liaison is well-positioned to fast-track MEL plan fulfillment.

Mission Correspondence

Each USAID Mission requested specific correspondence and items when implementing project work. The table below displays the Missions' requests, with which the MDRC team complies:

Country	USAID Mission Date of	Concurrence memo requested?	Received Concurrence memo?	Date of Approval	Items requested by Mission

	First Meeting				
Colombia	10/23/2020	Yes	Yes, approved	16-Dec-20	With Concurrence the Mission noted: The Mission's 1-POC for the activity is Nora Maresh. 2-Please inform the Mission Health Officer (Nora Maresh) prior to any meetings with Government officials or direct communications with Government of Colombia officials. 3-Provide final technical deliverables to the Mission. Nora Maresh wants the Mission to be very involved, and wanted to make the introduction to the MOH.
Ghana	10/23/2020	Yes	Yes, approved	30-Dec-21	The POC must review and concur on Ghana-specific work plans and reports and receive regular implementation and progress updates. While no travel is envisioned for this request should it arise it must fall in line with all COVID-19 related travel restrictions including a two week quarantine upon arrival in Ghana. The POC must be notified of any TDY at least six weeks in advance (an eCC is required) and ensure that the required in/out brief with the Mission is planned. All team members must provide a travel itinerary for security purposes. Prior to scheduling any meetings in Ghana, the POC must be notified to brief on Mission equities and will participate in meetings if available. Meetings and communication with the Government of Ghana MUST be approved by the Mission Director. All public events, including training, conducted in Ghana must have Mission representation and the POC must be notified at least one month in advance to assist with coordination. All forms of media engagement, including press releases, must be cleared by the Mission at least 5 business days prior to release date.
Indonesia	02/24/2021	Yes	No	17-May-21	"The Mission recommends that the MDRC team to closely coordinate with the FCS and participate in the US Embassy Medical Device Round-table meeting every two months with

					12 companies that manufacture in the USA. Members of the Round-table have a regulatory and government affairs background and would be in a good position to provide ongoing advice to the activity. In addition, the activity should: 1) Coordinate, inform and engage the Mission should there is a plan to engage with the Government of Indonesia, particularly with Ministry of Health and other relevant health stakeholders including the Indonesia National Agency of Drug and Food Control (BPOM); 2) Provide monthly progress update; 3) Share any report or progress to the google link that the Mission will provide; 4) Inform FCS team in advance on the request for support; and 5) Mission POC is: Ignatius Indriartoto (iindriartoto@usaid.gov)."
Kenya	03/24/2021	Yes	Yes, approved	28-Jul-21	Prior to concurrence, sent tier 1 reports and stakeholder mapping for their review. With The Mission's concurrence, the mission asked for regular sharing of quarterly progress reports and any other important reports on MDRC. The mission would also like to "participate in initial implementation planning meeting with MOH and in other critical meetings that MDRC team would determine that USAID team would need to attend."
Mexico	12/17/2020	Yes	Yes, approved	11-Mar-21	The Mission is fine with MDRC reaching out to other Agencies of the GoM, including DGN, Economia, or CONAMER. However, they have asked that the project prioritizes building the relationship with COFEPRIS. Mission, COFEPRIS, and Coalition are working to conclude a LOI.
Thailand	02/04/2021	No	N/A		Mission and Royal Thai Government decided to not participate in or partner with the MDRC project.
Vietnam	11/04/2020	Yes	Yes, approved	13-Jan-21	1. Share the USAID Flyer (when available) 2. Share a breakdown of the specific scope and estimated funding related to Vietnam of the SA2 – MDRC project Following the review of those items, the mission requested concurrence memo. That concurrence was granted on 13 Jan 2021.

South Africa	2/2/2021	No	N/A	20-Apr-21	Following several consultations, on 20 April, the Mission informed MDRC it would not require a concurrence memo and would be happy to collaborate on future efforts.
Peru	week of 14 December 2020	No	N/A	Q3 2020	Peru did not require a concurrence memo for outreach.
Brazil	week of 14 December 2020	No	N/A	Q3 2020	Brazil did not require a concurrence memo for outreach.

AFRICA

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

In Q2, ANSI and Ethical Apparel Africa (EAA) worked to understand material and performance requirements of surgical masks that can be used in healthcare settings. This has included already connecting with ANSI for guidance to ensure the surgical masks meet international standards. Specifically, the production set up is designed to an ISO 7 clean room standard with the product meeting at least Level 1 ASTM surgical mask standard for bacterial filtration efficiency, particulate filtration efficiency, fluid resistance to synthetic blood, and flame spread. EAA has also engaged in detail with the Ghana FDA to ensure that all local requirements will be met. The current project status is further summarized below:

- Widely sourced for machinery and material to enable production of surgical masks meeting the above specs, in the face of global shortages. Procured a reliable and available machinery source for a machinery system of surgical mask production.
- Sourced filtration fabric to begin production of general use medical masks whilst the certification process is in process for the surgical grade ones.
- Secured sampling of fabrics needed for surgical grade masks.
- Tendered and purchased an ISO Level 7 Cleanroom. Cleanroom components including the delayed Chiller finally arrived in Ghana at the beginning of April 2021. The American National Standards Institute is supporting the program through the provision of a certification and accreditation consultant to enable the Surgical masks to be approved to the right standard. The consultant, Jeffrey Stull, has extensive experience working with the US government and FDA on establishing face mask standards. In collaboration with EAA he will also train the Ghana Standards Authority and FDA on standards expectations for PPE.
- Positive meeting was held in Accra in early July with the Ghana Standards Authority. This established that the surgical face mask standard in Ghana is already aligned to the ASTM standard. We also identified that there is not an accreditation and quality management system standard yet and the GSA are open to working with EAA to establish this.
- Additional Technical Assistance has been sourced on a cost share basis with the FCDO (UK) to certify the cleanroom management team with international standards certification on running and managing a cleanroom.

- Cleanroom Supervisor has been recruited and undergoing training at Maagrace on general production and quality processes.

Next Steps

- Cleanroom Construction will begin in August and expected to be completed in October 2021.
- Mask production will commence with general use masks that can be sold locally whilst the Surgical masks go through certification and accreditation

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 Q2, the Standards Alliance experienced delayed communication in email correspondence with West African stakeholders. Additionally, the translation of French/English messages and meetings created an additional hurdle for communications. Email correspondence is easily translated with online translation tools and interpreters have been retained to assist with simultaneous interpretation of online meetings. Researching the current use of standards by regulators and related authorities is time consuming and some information found via desk research is out of date. Collecting up-to-date information via virtual calls has been key.

In Q3, the project team plans to engage interpretation experts to support more streamlined communications and clarity of information between the project team and partners in francophone nations.

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

In Q2, 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 Q2 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 has had a significant impact on deliveries of all the composite parts of the cleanroom, meaning the final elements did not arrive in Ghana until April 2021 against an original plan of September 2020. This has also meant the technicians that need to commission the machinery have been delayed. Ethical Apparel Africa are not planning to commission the machinery in August.
- The start of 2021has been an intense period of production for Maagrace's US Uniform Client as their Chef business has come back on line. This has meant the space for the cleanroom has had to be dedicated to garment production until the end of July. Further delays are not anticipated at this time.

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

Overcoming project implementation delays related to local USAID Mission concurrence across a number of project countries remained the largest project challenge in Q2 2021. In some cases, the time between initial consultation with a USAID Mission and formal concurrence was several months. MDRC is still awaiting final concurrence from the USAID Mission in Kenya after seven months (*note: after drafting this report, Kenya Mission concurrence was granted in July*). These delays prevent MDRC from engaging with project countries to advance project outputs.

Another challenge to project implementation is limited engagement by some project country government stakeholders. In Peru, MDRC is experiencing communication delays and unresponsiveness from DIGEMID, a key stakeholder for advancing medical device regulatory convergence and related GRP implementation. MDRC believes that Peru's current political climate, in conjunction with the challenges precipitated by COVID-19, have stymied government capacity to collaborate with the project in the short-term. Following the 1 April meeting with Patricia García (See Section 2, Peru), MDRC has worked to identify a number of potential avenues for advancing MDRC objectives in country. Patricia and MDRC discussed DIGEMID's organizational structure and explored the idea of approaching the agency through MINCETUR, who has the leading role implementing GRPs.

In Vietnam, while MDRC maintains high levels of engagement with the private sector, government stakeholders have been less responsive. MDRC conducted outreach on 16 March to six government agencies. Two agencies, STAMEQ and the Ministry of Finance, have formally responded and assigned Vietnam Customs as their MDRC focal point (See Section 2, Vietnam). Since this development, MDRC has experienced additional delays engaging with Vietnam Customs. At the working-level, Vietnam's Ministry of Health conveyed that it would defer to the Department of Medical Equipment and Construction (DMEC), whose purview includes MDRC objectives. DMEC, the Ministry of Industry and Trade, and the Ministry of Foreign Affairs have been unresponsive to date.

MDRC is exploring all available avenues to engage Vietnamese authorities. 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 US

FCS and Vietnamese branches of the European and American Chambers of Commerce on relevant contacts in the government. These parties are awaiting go-ahead from the relevant ministries before providing MDRC with that contact information. The MDRC team continues to follow-up directly via email and phone calls with the agencies to encourage them to participate in the project.

While COVID-19 has, as expected, made in-person capacity building impossible to date, the project is actively addressing this challenge through the execution of high-quality virtual engagements. These engagements continue to improve both in their ability to disseminate quality resources and convene relevant stakeholders from the public and private sectors.

The Standards Alliance/MDRC would also suggest that increased coordination of scope management of other USAID projects running parallel to the MDRC could facilitate MDRC implementation and MEL plan realization and increase coherence and effectiveness with select project governments. On the Global Health side, this should include a clear designation of scope clarification between the MDRC, MTaPS and PQM+ regarding implementation of Medical Device Regulatory Convergence with National Regulatory Authorities in common project countries. Most helpful would be a clear project scope delineation and formalized invitations for engagement of the MDRC team in project initiatives with overlapping scopes. On the trade side, coordination and information sharing by USAID of the projects of the USAID funded US Support for Economic Growth in Asia (US-SEGA) work in Asia-Pacific Economic Cooperation (APEC) on Good Regulatory Practices would be beneficial to MDRC implementation – in particular the GRP assessments for Peru and Indonesia. The MDRC also stands ready to share its GRP assessment with those implementing teams and to otherwise coordinate interactions with the common project country governments.

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

In Q2, ASTM and API began the information-gathering phase of their workplan with various stakeholders. Outreach included introductory emails with the National Standards Bodies in Côte d'Ivoire, Ghana, Nigeria and Senegal, as well as with the African Refiners and Distributors Association. Despite slow response times from many counterparts, we pressed for meetings and finalized virtual meeting dates with three of the four target countries.

On June 4th, ANSI, ASTM, and API arranged a fact-finding meeting with Senegalese stakeholders. This session was productive in learning about the priorities of current harmonization efforts. We were introduced to the Senegal National Plan (2021 – 2024) and informed that the Senegalese specifications are within the parameters set out by the ECOWAS harmonization decisions reached at a Feb 2020 meeting of ECOWAS ministers. The Director General of the National Standards Body (ASN) said that they will look at aligning the Senegalese national goals with the goals of the Standards Alliance project. In addition to the Director General, four other key government representatives from Senegal attended. Similar

sessions are to be held with each of the other three target countries to collect current information. Key contacts have been responsive in each of the four target countries.

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

Global: The Coalition, along with the GMTA, presented at the *WTO Webinar on Regulatory Cooperation During the COVID-19 Pandemic* on 2 June. The Coalition presented on the challenges the pandemic posed for the medical technology sector while outlining opportunities for leveraging lessons learned to advance regulatory convergence.

MDRC is working to expand its collaboration with the WHO, meeting with WHO representatives on 8 June. The WHO has since hosted a webinar on GRPs, Good Reliance Practices (GRelPs), and resources to enhance their global implementation. MDRC will discuss potential avenues for partnership with the WHO in future meetings.

Latin America: The Coalition continued to advance regional and local MDRC objectives through coordination with key stakeholders. Through PAHO, the Coalition is working to engage project country medical device regulators in PANDRH and organize events to align external stakeholders on the importance of regulatory convergence, GRPs, and GRelPs.

The Coalition continues to collaborate with the Inter-American Development Bank's (IDB) efforts to undertake a GRP survey and report on Latin American project countries. The data and insights gained from this survey, once complete, will reinforce Phase One and Two regional outputs and may encourage greater participation in MDRC-related activities by both public and private sector entities.

MDRC collaborated with the USFDA to organize a three-part webinar series for stakeholders across Latin America between 2 and 17 June. This series was co-led by USAID, ANSI, and AdvaMed through the Coalition. The three sessions engaged 6 National Regulatory Authorities (NRAs) and convened 300 attendees from Brazil, Colombia, and Mexico amongst other participating countries. Please see Section 2, Latin America for additional information on this webinar series.

Southeast Asia: MDRC collaborated with industry bodies to advance private sector participation in advancing regulatory convergence across Southeast Asia. MDRC received input from industry members on the opportunities and challenges for the medical technology sector in the region and sought buy-in from those members to partner on MDRC objectives.

MDRC met with Asia Pacific Medical Technology Association (APACMed) on 27 May to discuss some of those challenges and opportunities in the region. Following this meeting, MDRC and APACMed agreed to continue coordination through the Association's Southeast Center of Excellence, an important source of information on medical device regulatory convergence needs in Indonesia and Vietnam. MDRC leveraged a USABC meeting to introduce attending members to the project and emphasize collaboration with the USABC to advance project objectives. MDRC gained insight into the Tier Two priorities for those members in Indonesia and Vietnam.

In Vietnam, MDRC met with the American and European Chambers of Commerce to note the industry perspective of Tier Two priorities in the project country. In Indonesia, MDRC leveraged U.S. Embassy's Medical Device Roundtable as a platform to introduce the project and the importance of regulatory convergence to local medical device manufacturers.

Africa: MDRC cultivated partnerships with key medical device industry bodies to accelerate project

implementation in the region. Mecomed, the leading medical device industry association for the region, has helped MDRC identify industry priority areas and train local industry members on both Tier One and Two elements. On 17 June, MDRC and Mecomed held the first of a two-part webinar training covering GRPs, technical barriers to trade, and their impacts on the medical technology sector during COVID-19. MDRC presented on the differences between technical regulations and standards, harmonizing cross-border requirements through the adoption and use of international standards, and major challenges for the region's medical device sector. On 24 June, MDRC and Mecomed held the second part of this webinar series, dedicated to Tier Two elements for project countries in Africa. This session addressed regulatory convergence in the medical technology sector and Tier Two international benchmarks from the WHO, IMDRF. and GHWP. See Section 2, Africa for more information.

MDRC has also collaborated with SAMED to advance project outreach in South Africa. SAMED and MDRC are finalizing government outreach letters and identifying proper contact information for each stakeholder. MDRC expects to extend outreach in South Africa in early July 2021.

4. RESULTS ACHIEVED

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

As of July 2021, the Standards Alliance has completed four cosmetics workshops in the complete series included a combined 210 participants. Overall, participant feedback and event reviews have been positive with positive feedback on all collected measures including event organization, quality of material shared, event duration, and ease of registration.

Additional positive outcomes include follow up from various National Standards Bodies with ANSI and PCPC with interest in more detail on standards implementation as well as awareness building. Due to these messages, ANSI and PCPC are considering creating an open forum event within the series to allow ARSO members to interact an expert panel without a constraint on topics. This should allow ARSO members to gain specific details that will support further committee discussions on these standards. A brief review of each event as well as survey responses are included below:

Workshop 1: **Introduction to Best Practices**

Date: February 26, 2021

Speaker: Jay Ansell, Vice President, PCPC

Participants: 42 participants

Review: As the first event in this series, this activity was both well received and well attended. Participants were able to a gain a brief introduction to the cosmetics sector and an overview of the web series. While survey responses indicated that registration was clear and easy (100%), there were some miscommunications between ANSI and ARSO as to which organization would circulate invitations and when. It does not appear this confusion affected attendance or the experience of participants, but in future events invitation circulation has been better clarified to avoid confusion.

Following the event, a post activity survey was circulated to registrants with a PDF copy of all presentations. Survey respondents provided strongly positive event reviews. All respondents

found the webinar to be as good as they would have anticipated or better, with 31% ranking the event "much better than expected." Further, all survey respondents ranked the event speaker as somewhat (38%), very (46%), or extremely engaging (18%).

In considering event duration, 31% of respondents felt the 90-minute training could have been longer with remaining respondents believing the duration was adequate. Additionally, 64% of respondents said the event was very well organized and the remaining 36% of respondents believed the event was somewhat well organized.

Workshop 2: Implementation of cosmetics frameworks: A Case Study from South Africa

Date: April 16, 2021

Speakers:

- Gerald Renner, Director Technical Regulatory & International Affairs, Cosmetics Europe
- Maxime Jacques, International Relations Manager Cosmetic Europe
- Richard Sadiki, Specialist of International Relations & Strategic Partnership Department, South African Bureau of Standards (SABS)
- Dershana Jackison, Head: Policy and Regulatory Affairs, Cosmetic, Toiletry & Fragrance Association

Participants: 67 participants

Review: The second event in this series was the best-attended activity to date attracting 67 participants. Clarity in in the invitation process and more organized coordination between ANSI and ARSO helped to support the increased participation. Following the event, a post activity survey was circulated will all participants along with PDF copies of all presentations.

Again, survey responses were strongly positive. All respondents found the webinar to be as good as they would have anticipated or better, with 89% ranking the event "better than expected." Further, survey respondents ranked has positive reviews of the event speakers ranking them as somewhat (22%), very (44%), or extremely engaging (22%). The remaining 12% of respondents felt the speakers were not very engaging.

Considering event duration, 11% of respondents believed the 90-minute training could have been longer with remaining (89%) respondents believing the duration was adequate. Additionally, 89% of respondents said the event was very well organized and the remaining 11% of respondents believed the event was somewhat well organized.

Workshop 3: International Standards in the Cosmetics Sector

Date: May 20, 2021

Speakers:

- Mojdeh Rowshan Tabari, Committee Manager ISO TC 217- Cosmetics; Research Microbiologist, Iran National Standard Organization (INSO)
- Uli Osterwalder, Chairperson of the ISO TC 217- Cosmetics; Principal and Owner Sun Protection Facilitator GmbH Basel, Switzerland
- David Jankowski, American National Standards Institute (ANSI)

Participants: 45

Review: Webinar 3 was attended by 45 participants. While this is strong attendance, it would have

been good to see higher turnout. This can be attributed to the more basic information shared during this activity, which focused on the important on international standards. While this is a critical foundational event, most ARSO members likely found this activity too elementary. In future web series, a brief version of this webinar could be incorporated into the introductory webinar to retain the foundational information but avoid taking a full 90 minutes to discuss topics that are very familiar to participants.

Following the event, a post activity survey was circulated will all participants along with PDF copies of all presentations. Despite lower attendance, survey responses were very positive for this activity. All respondents found the webinar to be as good as they would have anticipated or better, with 43% ranking the event "much better than expected." Further, survey respondents ranked has positive reviews of the event speakers ranking them as somewhat (33%) or very engaging (67%).

Considering event duration, 71% of respondents believed the 90-minute training duration was adequate and the remaining 29% or respondents believing the event should have been longer. Additionally, 100% of respondents said the event was "very well organized."

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

In Q2, the ECOWAS Harmonization of Petroleum Standards team achieved the following results:

- SA II project has been launched and promoted globally. Press release can be found here
- In coordination with USAID and ANSI, ASTM and API hosted a virtual project launch for U.S. government staff in West African to introduce the Standards Alliance program and West Africa Petroleum Harmonization Project.
- First country call held with Senegal.
- Connection made to the African Refiners & Distributors Association (ARDA)
- Information gathering from individual stakeholders is underway
    - The subaward team has made contact with the National Standards Bodies in each of the four target countries to begin the landscaping phase of the project.
    - Drafted terms for a technical consultant to be hired by ASTM

Significant progress has been made with desk research by the ASTM Intern. Seven reports included and attached to this report include: General Report on Petroleum West Africa, ASTM Standard Use in West Africa, Key Training Programs West Africa, Petroleum Labs Report, Key Contacts West Africa, UNEP in West Africa, and ARDA Research. These reports help to set a benchmark from which to measure future work and identify key stakeholders in each of the target countries.

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

Global

- On 5 May, the implementation team shared updated drafts of MDRC's Tier One gap analyses and Tier Two stakeholder maps with ANSI, ITA, NIST, USTR, and OIRA. (Activity 1.1.6.1, Output 1.1.6, IR 1.1, Activity 2.1.2.1, Output 2.1.2, IR 2.1).
- MDRC's Tier One Report is complete and undergoing final graphic design and alignment with USAID branding requirements (Activity 1.1.6.1, Output 1.1.6, IR 1.1, Activity 2.1.2.1, Output 2.1.2, IR 2.1).

Latin America

- REGIONAL: The IACRC continued to advance joint efforts with the IDB to mutually undertake a survey of GRP in Latin American project countries (Activity 1.1.6.1), assisting with the completion of the Tier One and Two gap analysis. This collaboration will improve project countries' knowledge about the value of using national quality infrastructure (IR 1.1) and increase private sector participation in regulatory development (IR 2.1).
- BRAZIL: On 12 April, MDRC introduced the project to the Brazilian MoE's Foreign Trade and International Affairs Secretariat. MDRC was well received by the Secretariat (IR 1.1, IR 3.1, IR 4.1, IR 4.2)
- BRAZIL: MDRC introduced the project to ANVISA on 15 April. ANVISA and MDRC discussed potential future collaboration with ANVISA during the pandemic and on efforts related to regulatory convergence (IR 1.1, DO 4).
- COLOMBIA: MDRC met with INVIMA on 22 April. INVIMA identified its top priorities for project outputs and activities in the country, including trainings to develop capacities on GRPs (IR 1.1, Output 1.1.1, Output 1.1.13, Output 1.1.4 Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1).
- PERU: On 1 April, the Coalition and ALADDIV met with Patricia García, former Minister of Health of Peru, to discuss collaborative opportunities and challenges in Peru. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- MEXICO: On 26 April, MDRC met with COFEPRIS. MDRC discussed the importance of GRPs and utilizing international standards (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.4, IR 3.1, Output 3.1.1). MDRC mentioned the training program being jointly developed with the USFDA LATAM office on ISO13485 and MDSAP (Activity 1.1.3.1, Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1, IR 3.1, Output 3.1.2).
- MEXICO: On 26 April, MDRC introduced the project to CONAMER. MDRC and CONAMER discussed three areas of MDRC project implementation which harmonize with COFEPRIS's interests: regulatory convergence, regulatory simplification, and digitization (IR 1.1, IR 1.2, IR 3.1).
- BRAZIL: On 30 April, MDRC met with the SEAE and discussed approaches to developing a harmonized strategy across all interested government entities to address (1) INMETRO's challenges regarding medical devices, and (2) the development of new regulations under a proper regulatory process (IR 1.1, IR 1.2, IR 3.1).
- REGIONAL: On 18 May, the Coalition met with PAHO. The attendees discussed the formal status of the Coalition as a partner of PAHO and potential avenues for future collaboration. PAHO offered to work with the Coalition to organize a meeting with external regional stakeholders and foster regulatory alignment among medical device regulators in the region (IR 1.1, IR 1.2, DO 4).
- MEXICO: On 24 May, MDRC met with DGN. MDRC and DGN agreed to jointly develop a standing NSB policy/statement of support for GRP implementation within Mexico. DGN and MDRC will establish a work stream to implement GRPs with the Government of Mexico and work to increase international regulatory, standards and conformity assessment convergence for the medical technology sector. DGN and MDRC will coordinate with regional and multilateral organizations to advance these objectives. (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3, Output 1.1.4)
- REGIONAL: On 2 June, the Coalition presented at the WTO Webinar on Regulatory Cooperation during the COVID-19 Pandemic. The Coalition presented on the challenges the pandemic posed for the medical technology sector and discussed ways to leverage lessons learned from the pandemic to advance regulatory convergence. (IR 1.2, IR 3.1).
- REGIONAL: On June 8, MDRC met with the WHO to explore opportunities for further collaboration, including the development of a Global Benchmarking Tool for medical device companies (IR 2.1).
- COLOMBIA: On 10 June, MDRC met with the DNP, the Ministry of Health and Social Protection and INVIMA. MDRC and those stakeholders coordinated strategy for a series of projects including

the implementation of MDSAP, the ex-post evaluation of Decrees 4725 and 3770, and developing regulation related to Emergency Use Authorizations (IR 1.1, Output 1.1.1, Output 1.1.4, Output 1.1.5, Output 1.17, IR 1.2, Output 1.2.1, DO 4).

- REGIONAL: MDRC collaborated with the USFDA to organize a webinar series for stakeholders across Latin America. Co-lead by USAID, ANSI, and AdvaMed through the Coalition, this series took place over three sessions between 2 and 17 June. These sessions focused on ISO 13485 and Medical Device Single Audit Program (MDSAP) outcomes utilization for regulatory purposes (IR 1.1, IR 1.2, IR 2.1).
- MEXICO: On 11 June, MDRC met with the COFEPRIS to discuss formal collaboration with the project and ongoing negotiations to conclude a joint Letter of Intent as an alternative to an MoU. (IR 1.1, IR 1.2, IR 3.1, DO 4, Crosscutting IR 2.1).
- MEXICO: On 14 June MDRC met the Secretariat of Economy and discussed areas of primary importance to the Secretariat for MDRC. The Secretariat informed MDRC the implementation process has begun on the USMCA Annexes related to medical devices and GRPs (IR 1.1, IR 1.2, IR 3.1, DO 4).
- REGIONAL: One 16 June, the Coalition partnered with ALADDIV, The London School of Hygiene and Tropical Medicine, The International Diagnostics Center, and CBDL to launch Laboratory Diagnostics White Book for 2021-2022. The event convened a round table on "The Future of Diagnostics in a Post Pandemic World," which was attended by around 300 health professionals from 17 countries (IR 2.1).
- PERU: On 17 June, MDRC introduced the project to CONFIEP and discussed potential avenues of collaboration with the project through the Coalition (IR 2.1).
- COLOMBIA: On June 24, MDRC met with the DNP, the Ministry of Health, the Ministry of Commerce, INVIMA and ANDI. Participants agreed on initial steps to advance: (1) the ex-post analysis of Decrees 4725 and 3779, (2) RIAs for GMPs, (3) Clinical Research and Emergency Use Authorizations, and (4) GRPs under a collaborative approach between government and private sector. (IR 1.1, IR 1.2, IR 2.1, IR, 3.1, DO 4)
- MEXICO: On 28 June, MDRC met with COFEPRIS and continued to align on both joint priority issue areas and the final language for a Letter of Intent. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- PERU: Throughout Q2, MDRC communicated with MINCETUR which confirmed its interest to participate in MDRC pending further internal consultations. (IR 3.1, DO 4, IR 4.1, IR 4.2)

Southeast Asia

- INDONESIA: On 1 April, MDRC introduced the project to USABC-Indonesia and discussed common interests and issues related to medical devices in Indonesia (IR 2.1). USABC's Chief Country Representative for Indonesia offered the organization's capacities to serve as a local interlocutor on behalf of MDRC where necessary. (IR 2.1, IR 2.1.2).
- INDONESIA: On 29 April, MDRC had a series of communications with Standards Attaché at the U.S. Embassy in Indonesia, Bruce Elsworth, who reiterated the support of the U.S. Commercial Office in Jakarta (IR 1.1, IR 1.2, IR 2.1). Bruce connected the project with other relevant officials in the U.S. Commerce Department, who in turn have expressed their willingness to assist and participate in relevant MDRC activities.
- VIETNAM: On 10 May, the General Department of Vietnam Customs responded to MDRC's outreach letter to confirm their participation in the project. (IR 3.1)
- INDONESIA: On 17 May, the USAID Mission to Indonesia issued concurrence to MDRC. This enables MDRC to proceed with all project outputs and government outreach (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- INDONESIA: MDRC presented at the US Embassy to Indonesia Medical Device Roundtable. MDRC provided an overview of the MDRC, explained its relevance to medical device

manufacturing companies operating in Indonesia, and discussed specific areas of importance to the industry in Indonesia (IR 2.1, Output 2.1.1, Output 2.1.3)

- VIETNAM: On 20 May, MDRC met with Abbott Vietnam to seek feedback on Tier Two-related regulatory challenges the company faces in-country (IR 2.1, Output 2.1.2, IR 3.1).
- REGIONAL: On 27 May, MDRC met with APACMed to discuss medical device regulatory challenges in the region. MDRC will coordinate with APACMed's Southeast Asia COE, which has identified a series of regulatory challenges and needs in Indonesia and Vietnam. (IR 2.1, Output 2.1.1, Output 2.1.5)
- VIETNAM: On 27 May, MDRC met with the Chair of the Healthcare Committee of the American Chamber of Commerce in Vietnam to discuss Tier Two priorities in the country, including the requirement for companies to re-register medical devices by January 2022. MDRC will continue to work with the Healthcare Committee and its members to identify Tier Two priorities. (IR 2.1, Output 2.1.1)
- REGIONAL: On June 1, MDRC met with Stryker to discuss its priorities and challenges in Vietnam and Indonesia (IR 2.1, Output 2.1.1)
- VIETNAM: On 9 June, MDRC met with the European Chamber of Commerce in Vietnam to discuss working with the Chamber's Medical Devices and Diagnostics Sector Committee to identify regulatory hurdles as well as training and capacity-building opportunities for Vietnamese authorities. The Committee identified the requirement to re-register medical devices and the authorities' lack of capacity as a priority. MDRC and the Committee will continue conversations to discuss these concerns on a technical level. (IR 2.1, Output 2.1.1)
- INDONESIA: On 22 June, MDRC sent electronic outreach letters to government stakeholders in Indonesia, enabling MDRC to begin coordination with the Government of Indonesia. MDRC will send hard copies of the letters in the coming weeks. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC 2.1)
- REGIONAL: On 25 June, MDRC joined a meeting with the U.S. ASEAN Business Council (USABC) where MDRC introduced attending members and noted Tier Two concerns by members relevant to the project countries.

Africa

- SOUTH AFRICA: On April 20, MDRC reviewed regional and in-country objectives and timelines for project activity with the Mission to South Africa. MDRC discussed various approaches to stakeholder outreach. The Mission informed MDRC it would not require a concurrence memo and would be happy to collaborate on future efforts (IR 1.1, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- On 22 April, ANSI conducted outreach to SABS (IR 2.1, IR 3.1).
- KENYA: On 6 May 2021, MDRC and the Mission to Kenya provided an overview of the project to the Kenyan PPB. PPB affirmed its desire to collaborate with MDRC and will identify key priorities for advancement with MDRC. MDRC will co-create an action plan with PPB, the Mission, and other stakeholders to ensure alignment with local needs (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, CC IR 2.1).
- SOUTH AFRICA: On 7 May, MDRC met with SAMED to discuss the association's partnership with MDRC to advance project outputs in South Africa. MDRC and SAMED have since collaborated to extend outreach to South African government stakeholders (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, CC IR 2.1).
- SOUTH AFRICA: The Mission to South Africa reviewed and approved the MDRC's template outreach letter on 11 June (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, CC IR 2.1).
- REGIONAL: On 21 May, MDRC discussed the possibility of a partnership with Mecomed to implement Phase Two objectives in Africa, and brainstormed ways in which the project could

execute the Tier One regional forum and Tier One/Two local trainings in Ghana/Kenya in the most effectual and efficient manner. In the advancement of Tier Two specific objectives, Mecomed noted that it has developed a preliminary list of industry priority areas for MDRC support in the project countries and expressed willingness to work with MEDAK in hosting the local Kenyan consultations (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.2, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).

- GHANA: On 9 June, MDRC and Mecomed met with the Mission to Ghana to introduce the project to the Mission's Economic Growth Team. MDRC expanded upon the intersection between the project's health and trade elements. MDRC provided the Mission with a preliminary draft action plan and shared a draft template outreach letter for government stakeholders for the Mission's review and approval. (IR 1.1 IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 17 and 24 June, MDRC and Mecomed held a two-part webinar series for members of the African medical device industry. MDRC introduced the MDRC project, and presented on a series of topics related to Tier One and Two and their impacts on the medical technology sector during COVID-19. This includes elaborating on the differences between technical regulations and standards, and harmonizing cross-border requirements through the adoption and use of international standards. MDRC also covered major challenges for the medical device sector related to trade/WTO rules, regulatory convergence in the medical technology sector, and Tier Two international benchmarks. (IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.2, Output 2.1.3, Output 2.1.5)

Other Results

- MDRC maintained progress toward the launch of a COVID-19 medical device portal (Activity 4.0.0.3) under Development Objective 4.

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

Although initial rollout of the project has been slowed because of the pandemic and exclusive use of electronic correspondence and virtual meetings, one important stakeholder meeting was held which proved to be very beneficial in understanding the current landscape. Each of the remaining target countries has been contacted and several additional meetings set for next quarter. Future follow-up with an important trade association (ARDA) has been identified as a key next step in collecting regional data. ARDA plays a leading role in the development and promotion of the AFRI fuels roadmap which sets the standards for cleaner and higher quality fuels for the region and continent. Need to continue to monitor the recovery from the pandemic in Africa as it may further delay some of the project objectives planned for 2022. Many of the African nations are suffering from the Delta variant. At API there was a short gap due to the unanticipated departure of a staff person involved in the project.

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

The project team is continuing to incorporate lessons learned on virtual engagements with stakeholders, online capacity-building, and digital resource capabilities. MDRC is leveraging virtual platforms and a Zoom license to interact with actors across the public and private sectors. These digital software licenses have streamlined connectivity and communication across the languages of English, Portuguese and Spanish. However, MDRC had to upgrade its Zoom license configuration to accommodate higher-than-expected volumes of participants in Coalition webinars. While the previous participant limit was 500, MDRC now has the capacity to accommodate up to 1000 attendees.

MDRC is working to optimize the level of resources devoted to running the Coalition's online presence. MDRC is heightening the Coalition's capacity to provide online modules and virtual resource library through a more efficient, lower cost web development vendor. Virtual Coalition resources have proven to be an invaluable tool for hosting and disseminating information vital to the project.

MDRC is working to craft a series of USAID-approved and branded templates for project use in external engagements. These templates will ensure consistent alignment with USAID branding guidelines across all project activities and streamline future USAID approval processes for such products.

With the concurrence of most countries' USAID Missions, MDRC will work to keep those Missions regularly informed and engaged in ongoing outreach and the subsequent capacity-building process. This will serve to simplify communications between the project team and USAID, preventing any unnecessary delays.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Q2 2021 Planned Activities

Activity #	Activity Name	Meeting/Event	Date	Location	USAID participation?
1	ECOWAS Clean Renewable Fuels Workshops	Clean Fuels Workshops	TBD, Q4 2021	TBD, West Africa	Optional
2	Support for ARSO	Webinar #4 on July 7th with PCPC focusing on the implementation of cosmetic frameworks with a focus on GSO and Saudi Arabian case studies	July 7, 2021	Virtual	Optional
2	Support for ARSO	Webinar #5 August/September: details pending	Aug/Sept, 2021	Virtual	Optional

5	ECOWAS Harmonization of Petroleum Standards	Meeting scheduled with stakeholders in Nigeria	July 8, 2021	Virtual	No
5	ECOWAS Harmonization of Petroleum Standards	Meeting scheduled with The African Refiners & Distributors Association (ARDA)	July 12, 2021	Virtual	No
5	ECOWAS Harmonization of Petroleum Standards	Meeting scheduled with stakeholders in Cote d'Ivoire	July 13, 2021	Virtual	No
5	ECOWAS Harmonization of Petroleum Standards	Meeting with stakeholders in Ghana	TBD	Virtual	No
5	ECOWAS Harmonization of Petroleum Standards	Conduct a teleconference among Department of Commerce staff (in country and D.C.) to communicate information about the project and gather information about existing cooperation in the region	July 28, 2021	Virtual	Yes
5	ECOWAS Harmonization of Petroleum Standards	Hold a virtual Validation Workshop with the African stakeholders from all four countries concurrently to present information gathered to-date and to further prioritize and collect data to develop a strategy for the further development of harmonized standards in the region	TBD	Virtual	Optional
11	Surgical Mask Production	Cleanroom Construction	August – October, 2021	Accra, Ghana	No
11	Surgical Mask Production	Training for EAA and Maagrace staff on surgical mask standards and production standards	TBD Q3, 2021	Accra, Ghana	No
11	Surgical Mask Production	Training for Ghanaian government representatives on surgical mask standards and production standards	TBD Q3, 2021	Accra, Ghana	No
11	Surgical Mask Production	Production will commence with general use masks that can be sold locally whilst the Surgical masks go through	Q3, 2021	Accra, Ghana	No

		certification and accreditation			
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 Q4 of 2021 due to a history of successes stemming from face-to-face interactions on past clean fuels programming. If international travel remains restricted during Q4 of 2021, Pivot will 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 fourth webinar in the series will be hosted on July 7 and will provide 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). The fifth webinar is also expected to take place in Q3 2021.

In Q3, 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 #11 - COVID-19: Surgical Mask Production Project

In Q2, EAA plans the following actions:

- Cleanroom Construction will begin in August and expected to last until October.
- Production will commence with general use masks that can be sold locally whilst the Surgical masks go through certification and accreditation. Training for Ghanaian government representatives will begin in Q3.
- EAA and Maagrace production staff will attend in-person training sessions on best practices and international management system standards for surgical mask production.

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

In Q3, MDRC will continue to focus on outreach and capacity-building with private and public sector stakeholders across all project countries. MDRC will advance awareness of MDRC objectives and leveraging the relationships built in Q1 and Q2 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.

MDRC and Mecomed agreed to host the 2021 events in Africa virtually and shift them back by one quarter into Q4 2021 and Q1 2022. Those events include: (1) Tier One Regional Forum in Nairobi, Kenya, (2) Tier One Local Meeting/Training in Nairobi, Kenya, and (3) Tier Two Local Meeting/Training with MD Regulators. MDRC and Mecomed believe this schedule shift is critical to enabling proper preparation for those events and providing appropriate time for government stakeholders to digest/enact learnings in-between trainings. This decision was driven in part due to the delays MDRC has experienced in the USAID Mission concurrence process. MDRC expects the expanded time frames

to result in improved project outcomes through the added benefits it provides to local government and industry stakeholders.

Please find below a chart outlining planned MDRC activities for the next quarter:

Meeting/Event	Location	USAID participation?	Region
MDRC - FDA Webinar on UDI	Virtual	Yes	Americas
MDRC - FDA Webinar on Use of International Standards by Regulators	Virtual	Yes	Americas
GRPs Workshop - Peru	Virtual	Yes	Peru
PAHO - Regulators - Private Sector	Virtual	Yes	Americas
GRPs Training DNP, INVIMA, MinSalud - Colombia	Virtual	Yes	Colombia
GRPs Training COFEPRIS - Mexico	Virtual	Yes	Mexico
MDRC Review Conference - IMDRF	Virtual	Yes	Southeast Asia

7. ANNEX

AdvaMed MDRC Quarterly Report
STANDARDS ALLIANCE:
PHASE 2 QUARTERLY REPORT TO ANSI

PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2 (SA2) COVID-19 Medical Device Regulatory Convergence Project (MDRC)
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 Subcontractor/Subawardee:	The Advanced Medical Technology Association (AdvaMed)
Geographic Coverage (cities and or countries)	Latin America (Brazil, Colombia, Mexico, Peru), Africa (Ghana, Kenya, South Africa), Southeast Asia (Indonesia, Viet Nam)
Reporting Period:	1 April – 30 June 2021

7.1 Program Description/Introduction

Amidst the COVID-19 pandemic, nations have scrambled to increase the production of and access to medical devices to prevent and treat the virus, such as rapid diagnostic test kits, ventilators, and personal protective equipment (PPE). However, countries cannot safely deploy these products without a strong medical device regulatory framework and knowledge of emergency use authorization (EUA) procedures and rules. The Standards Alliance Phase 2 COVID-19 Medical Device Regulatory Convergence Project (MDRC) increases the transparency and predictability of partner governments regulatory ecosystems for medical devices, aligning them with international standards and overall improving the National Quality Infrastructure. The MDRC aims at: (1) building capacity of partner countries for standards and conformity assessment procedures related to medical device; (2) removing countries' technical barriers to trade for medical devices; (3) increasing patient's access to needed high-quality PPE and other medical technologies to respond to and recover from COVID-19 and future global health crises; and, (4) fostering private sector engagement in the medical technology regulatory space. Spearheaded by the Advanced Medical Technology Association (AdvaMed) and supported by a diverse team of experts, the project:

- Delivers tailored training to central regulatory coordination bodies, on cross-sectoral good regulatory practices (GRPs) and international standardization that is required for regulatory convergence in the medical device sector.

- Delivers tailored technical training on medical device-specific GRPs and international standardization and conformity assessment, to health regulatory bodies, that directly facilitates regulatory convergence in the medical device sector.

- Advises agencies of partner governments on the adoption of international benchmarks for EUAs and related emergency regulatory frameworks and approval processes, providing a transparent, convergent, predictable, and agile international reference so medical devices are received across and within borders at points of care in times of health crisis.

- Assists customs authorities in understanding and following the import criteria and policies set by the health ministries and centers of disease control for addressing COVID-19.

- Establishes an international reference center for Emergency Regulatory Response, in collaboration with the Global Medical Technology Alliance, including an easy to use digital library that complies information from the FDA or other relevant agencies of the newest medical devices released by the industry to fight the COVID-19 pandemic.

ACTIVITY IMPLEMENTATION PROGRESS

7.2 Progress Narrative

Latin America

MDRC, in tandem with the Inter-American Coalition for Regulatory Convergence (IACRC, "the Coalition"), made large strides in advancing project outputs in Latin America during Q2 2021. MDRC has secured USAID Mission concurrence and conducted formal outreach to government stakeholders in all Latin American project countries.

Regional: On 20 April, ANSI connected with several Latin American standards bodies during the Pan American Standards Commission (COPANT) General Assembly networking meetings. Those bodies included the Colombian Institute of Technical Standards and Certification (Instituto Colombiano de Normas Técnicas y Certificación, ICONTEC), Mexican Dirección General de Normas (DGN), and the Peruvian National Institute of Quality (Instituto Nacional de Calidad, INACAL). DGN confirmed receipt of ANSI outreach sent on 17 March. INACAL indicated informal interest in MDRC but required further internal coordination with Peru's Ministry of Foreign Trade and Tourism (MINCETUR) and Directorate General of Drug Supplies and Drugs (DIGEMID) before proceeding. See *Peru* for more information.

On 18 May, the Coalition met with the Pan American Health Organization (PAHO) to discuss avenues for collaboration on MDRC. First, attendees discussed the formal status of the Coalition as a partner of PAHO. As the Coalition advances its application to qualify as a Non-State Actor with PAHO, it will continue to work with PAHO to formalize their relationship in the appropriate manner to advance MDRC objectives. Second, the attendees discussed engaging PAHO member country medical device regulators in the Pan American Network for Drug Regulatory Harmonization (PANDRH, or la Red Panamericana para la Armonización de la Reglamentación Farmacéutica, Red PARF). Third, PAHO offered to organize a virtual meeting of regional external stakeholders. The Coalition began the process of planning this meeting in June. The Coalition will propose topics and share materials and unofficial translations of documents produced by WHO and other relevant entities with PAHO in their next meeting.

On 2 June, the Coalition presented at the *WTO Webinar on Regulatory Cooperation During the COVID-19 Pandemic* to advance MDRC objectives. The Coalition, along with a Global Medical Technology Alliance (GMTA) representative and a group of experts, presented on the challenges the pandemic posed for the medical technology sector while outlining opportunities for leveraging lessons learned to advance regulatory convergence.

On 8 June, MDRC met representatives from the World Health Organization (WHO) to explore opportunities for further collaboration. Those representatives were Marie Valentin, Technical Officer for Regulatory Convergence and Networks Team, Anita Sands, Technical Officer for Incidents and Substandard/Falsified Medical Products, and Leticia Megias Lastra, Technical Officer for Incidents and Substandard/Falsified Medical Products. WHO shared their work on the development of a Global Benchmarking Tool for medical device companies for which a pilot implementation plan is being designed. In line with MDRC objectives, the WHO confirmed it was hosting a webinar on 29 June on GRPs, Good Reliance Practices (GRelPs), and resources to enhance their global implementation. MDRC is awaiting WHO's feedback to schedule a follow-up meeting, where WHO officials and MDRC will discuss potential avenues for collaboration.

MDRC collaborated with the United States Food and Drug Administration (USFDA) to organize a webinar series for stakeholders across Latin America. This series took place over three sessions between 2 and 17 June. These sessions focused on ISO 13485 and Medical Device Single Audit Program (MDSAP) outcomes utilization for regulatory purposes. During the first session on 2 June, representatives from the USFDA and ANVISA provided an overview of MDSAP and their experiences to implement ISO 13485. In the second session on 10 June, DEKRA – an MDSAP Auditing Organization – and the USFDA presented on MDSAP audits and discussed a case study where regulators from MDRC project countries Colombia and Mexico shared criteria to manage certain non-conformities. During the third session on 17 June, ANVISA, ANMAT and the USFDA shared their experiences on the use of MDSAP documents. ANMAT presented on its experience becoming an MDSAP Affiliate Member while USFDA offered visibility on the process and MDSAP's training resources. The three sessions engaged 6 National Regulatory Authorities (NRAs) and convened 300 attendees from Brazil, Colombia, and Mexico amongst other participating countries.

The Coalition, the Latin American Alliance for the Development of In Vitro Diagnostics (ALADDIV), the London School of Hygiene and Tropical Medicine, the International Diagnostics Center, and CBDL launched the Laboratory Diagnostics White Book for 2021-2022 on 16 June. These organizations convened around 300 health professionals from 17 countries (Brazil, Canada, Chile, Colombia, France, Germany, Italy, Kenya, Republic of Korea, Mexico, Paraguay, Peru, Spain, Trinidad and Tobago, United Kingdom, United States and Vietnam) to share the unveiling of this tool and convene a round table on "The Future of Diagnostics in a Post Pandemic World." This tool may serve as a resource for MDRC project countries in advancing policy that reinforces early and effective diagnostic tools in a post-pandemic world.

Colombia: MDRC met with the Colombian National Food and Drug Surveillance Institute (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA) and the National Business Association of Colombia (ANDI) on 22 April to advance discussions on priorities for project activities and trainings in Colombia. Attendees included Dra. Lucia Ayala, Dir. Medical Devices and Other Technologies at INVIMA, and Marisol Sánchez, Director of the Chamber of Medical Devices and Health Supplies at ANDI. INVIMA and ANDI identified (1) clinical research, (2) Good Manufacturing Practices (GMPs), and (3) Decree 4725 as its top priorities for collaboration with MDRC on GRPs. Dra. Ayala proposed that MDRC designate a dedicated MDRC Liaison to Colombia to coordinate and facilitate all activities related to the project in-country. INVIMA advised that the deployment of project resources for an MDRC Liaison would enable Colombian government partners to fully dedicate themselves to MDRC implementation without disrupting essential COVID-19 functions and response. The MDRC team views this recommendation as a unique opportunity to advance Colombia's outputs under the MEL Plan objectives. As such, the MDRC is working to secure approval from USAID to deploy this Liaison. Please see Section 2.2 for additional information.

On 10 June, MDRC met with the National Planning Department (Departamento Nacional de Planeación, DNP), the Ministry of Health, INVIMA and ANDI to coordinate strategy for a series of MDRC relevant projects in Colombia. Those projects include the implementation of Medical Device Single Audit Program (MDSAP), the ex-post evaluation of Decrees 4725 and 3770, and developing regulation related to Emergency Use Authorizations.

On June 24, MDRC met again with the DNP, the Ministry of Health, the Ministry of Commerce, Industry and Tourism (MINCIT), INVIMA and ANDI. Participants agreed on initial steps to advance: (1) the ex-post analysis of Decrees 4725 and 3779, (2) Regulatory Impact Assessments (RIAs) for GMPs, (3) regulation related to clinical research and Emergency Use Authorizations, and (4) GRPs under a collaborative approach between government and private sector.

Brazil: On 12 April, MDRC introduced the project to the Brazilian Ministry of Economy's Foreign Trade and International Affairs Secretariat. The Secretariat and MDRC discussed future project activities in the country and will work to jointly develop an agenda for MDRC work in Brazil.

MDRC introduced the project to ANVISA on 15 April. ANVISA and MDRC discussed how the project and the Coalition can support ANVISA's activities during the pandemic while advancing efforts related to regulatory convergence in Brazil.

On 30 April, MDRC met with the Government of Brazil's Secretariat for Economic Monitoring of the Ministry of Economy (SEAE). MDRC emphasized Brazil's differentiated role in the project, serving as a partner to support the development of capacities among other regulators in the region. SEAE expressed the Brazilian government's desire to implement GRPs consistent with a 'whole of government' approach, including those authorities that issue technical regulations that pertain to medical technologies, such as the National Institute of Metrology, Standardization and Industrial Quality (INMETRO). To ensure a coordinated strategy between INMETRO, the Brazilian Association of Technical Standards (ABNT), and ANVISA, SEAE recommended that ANVISA should play the leading organizational role.

Mexico: On 25-26 March, shortly after receiving local USAID Mission project concurrence, MDRC sent outreach letters to Government of Mexico stakeholders, including the Ministries of Finance, Economy, and Health. On 26 March, MDRC met with COFEPRIS, the Federal Commission for Protection against Sanitary Risk in Mexico. In this meeting, the parties discussed the timeliness and importance of MDRC as well as challenges unique to Mexico as they relate to the medical technology sector, compliance with treaty obligations, and underutilization of Equivalence Agreements. MDRC and COFEPRIS began working towards the conclusion of a Memorandum of Understanding (MoU) or Letter of Intent (LOI) so that they may optimize and deepen their collaborative efforts moving forward.

On 26 April, MDRC met with COFEPRIS in Mexico to overview the project's objectives, approach, and potential for collaboration with the Government of Mexico's agencies and initiatives. MDRC explained that it would work with COFEPRIS and relevant stakeholders to draft a tailored work plan to meet Mexico's unique circumstances and needs. Thereafter, MDRC discussed the importance of GRPs on the regulatory process and the importance of utilizing international standards. To serve as a reference, MDRC shared priority issue-areas identified by the Mexican Association of Innovative Medical Device Industries (AMID), the Medical Device Division of the National Chamber of the Pharmaceutical Industry (CANIFARMA), and the Confederation of Industrial Chambers of the United Mexican States (CONCAMIN) with COFEPRIS.

On 26 April, MDRC introduced the project to CONAMER, Mexico's National Commission for Regulatory Improvement. MDRC and CONAMER prioritized discussion on how MDRC could facilitate alignment between CONAMER, COFEPRIS, and DGN to advance project objectives. MDRC and CONAMER discussed three MDRC project areas of particular interest to COFEPRIS: regulatory convergence, regulatory simplification, and digitization. COFEPRIS informed MDRC that the Government of Mexico lacks written procedures to ensure proper alignment with GRPs. MDRC will work to advance the development of written procedures that ensure GRPs are embedded in COFEPRIS' Quality Management System.

On 24 May, ANSI and MDRC met with the DGN. MDRC and DGN reviewed and agreed to jointly advance a number of the project's objectives. Those include: developing a standing policy/statement of support for GRP implementation within the country as conducive to international standardization and trade; establishing a standing work stream to implement GRPs with the Government of Mexico; and

increasing international regulatory, standards and conformity assessment convergence for the medical technology sector within Mexico. DGN and MDRC will coordinate with regional and multilateral organizations to move these outputs forward.

MDRC met with the COFEPRIS on 11 June to discuss formal collaboration with the project and ongoing negotiations to conclude a joint Letter of Intent as an alternative to an MoU.

MDRC met the Secretariat of Economy on 14 June to share additional information on the project and discuss areas of primary importance to the Secretariat for MDRC. The Secretariat informed MDRC the implementation process has begun on the U.S. Mexico Canada Agreement (USMCA) Annexes related to medical devices and GRPs. Effective implementation of these Annexes will help facilitate trade while improving access to medical technologies during COVID-19, key objectives of MDRC.

On 28 June, MDRC met with COFEPRIS and continued to align on both joint priority issue areas and the final language for a Letter of Intent. COFEPRIS proposed a hybrid event as a forum to sign the Letter of Intent, where the Federal Commissioner, USAID and MDRC representatives in Mexico may attend in person. This proposal remains under consideration.

Peru: On April 1, the Coalition and ALADDIV met with Patricia García, former Minister of Health of Peru, to discuss challenges to communication with DIGEMID as well as alternate avenues for collaboration. See Section 2.3 for further information on challenges engaging with the Government of Peru.

Throughout Q2, MDRC communicated with MINCETUR to assess potential opportunities for collaboration. MINCETUR confirmed its interest to participate in MDRC, but required further internal consultations before proceeding. Since, MINCETUR has agreed to participate in an MDRC Peru-specific GRP workshop. This workshop is still being organized and has secured interest from DIGEMID.

On 17 June, MDRC met with Oscar Caipo, the President of National Confederation of Private Business Institutions (CONFIEP) and one of the co-chairs of the Americas Business Dialogue's Transparency and Regulatory Working Group. Following an introduction to the project, MDRC and CONFIEP discussed potential avenues of collaboration with the project, including through the Coalition.

Southeast Asia

MDRC has successfully secured USAID Mission concurrence and conducted formal outreach to government agencies in Vietnam and Indonesia.

Regional: On 27 May, MDRC met with the Asia Pacific Medical Technology Association (APACMed), which represents manufacturers and suppliers of medical equipment, devices and in-vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific. MDRC and APACMed Regulatory Affairs lead Nishith Desai discussed medical device regulatory challenges in the region. MDRC will coordinate with APACMed's Southeast Asia Center of Excellence (COE), which has identified a series of medical device regulatory convergence needs in Indonesia and Vietnam.

On 25 June, the U.S. ASEAN Business Council (USABC) hosted a call to update members on the ASEAN Medical Device Directive. MDRC used this call as an opportunity to introduce attending members to the project and emphasize collaboration with the USABC to advance project objectives. MDRC noted Tier Two concerns by members relevant to the project countries. For Indonesia, those

concerns centered on potential new Local Content Requirements and Import Substitution Policies. Members voiced support for improving the transparency of regulatory processes in the project country. In Vietnam, companies highlighted concerns over the delayed approval of dossiers for registration.

Vietnam: On 10 May, the General Department of Vietnam Customs responded to MDRC's outreach letter to confirm their participation in the project. The letter states that the Ministry of Finance has designated Customs Department as the focal point for future partnership with MDRC. In the letter, the Department recognized MDRC's potential to "reinforce the Government's efforts to support businesses in importing and exporting COVID-19 medical device in compliance with Vietnam's legal regulations and international commitments."

On 20 May, MDRC met with Abbott Vietnam to seek feedback on medical device regulatory convergence opportunities and challenges. Issues discussed, include: (i) medical device re-registration; (ii) requirements for independent quality testing on medical equipment at healthcare facilities; (iii) the implementation of unique identification number for medical devices; (iv) labelling procedures for medical device packaging; and (v) the price-sensitive nature of the medical device tendering process.

On 27 May, MDRC met with the Chair of the Healthcare Committee of the American Chamber of Commerce in Vietnam to discuss Tier Two priorities in the country. The Chair identified the sector's priority as addressing the requirement for companies to re-register medical devices by January 2022 as a prerequisite to their importation. Vietnamese authorities remain unable to process all the applications due to capacity issues. MDRC will coordinate with the Chair to present at the next monthly Healthcare Committee meeting to member country leads and government affairs teams. The Chair and MDRC will work to facilitate subsequent meetings with interested regulatory teams to dig deeper into key issues.

On 9 June, MDRC met with the European Chamber of Commerce in Vietnam to discuss working with the Chamber's Medical Devices and Diagnostics Sector Committee to identify regulatory hurdles as well as training and capacity-building opportunities for Vietnamese authorities. The Committee echoed the American Chamber of Commerce in Vietnam's concern on the requirement to re-register medical devices and the authorities' lack of capacity. MDRC and the Committee will continue conversations to discuss these priorities on a technical level.

Indonesia: On 29 April, MDRC had a series of communications with the DOC/ITA/FCS Standards Attaché at the U.S. Embassy in Indonesia on MDRC-related issues. The Attaché connected the project with relevant officials in the U.S. Commerce Department who in turn have expressed willingness to assist and participate in relevant MDRC activities. The Attaché reiterated the support of the U.S. Commercial Office in Jakarta and his colleagues as a resource for the MDRC.

On 17 May, the USAID Mission to Indonesia issued project concurrence to MDRC. The Mission recommended that MDRC closely coordinate with the U.S. Foreign Commercial Service (FCS) and participate in the US Embassy Medical Device Roundtable meeting every two months. The Mission provided MDRC with additional requirements for engaging with the Government of Indonesia and reporting project progress.

On 19 May, MDRC presented an overview of the MDRC and its relevance to medical device manufacturing companies operating in Indonesia at the US Embassy to Indonesia Medical Device Roundtable. Following the presentation, the roundtable raised specific areas of importance to the industry in Indonesia. This includes, pre- and post-market processes such as prior approval, E-Katalog

listing delays, and post-market surveillance.

On 1 June, MDRC met with Stryker, a leading medical device company, to discuss medical device regulatory convergence priorities, opportunities, and challenges in Vietnam and Indonesia. Items discussed for Indonesia included the country's E-Katalog, advancing transparent regulatory processes, and local content requirements.

On 22 June, MDRC sent electronic outreach letters to government stakeholders in Indonesia after aligning with the Mission's requirements. MDRC will send hard copies of the letters in early Q3 2021.

Africa

MDRC continues to work with local and regional stakeholders, including industry associations and USAID Missions, to ready government outreach in alignment with local requirements and Mission specifications. MDRC has met with all three project country USAID Missions, securing project concurrence in Ghana and South Africa. Concurrence in Kenya remains under Mission consideration.

Regional: On 21 May, MDRC advanced discussions with Mecomed, the leading medical device industry association for the region, on partnership to advance MDRC objectives in Kenya, Ghana, and broader region (they do not cover South Africa). Mecomed and MDRC discussed ways in which the project could execute the Tier One regional forum and Tier One/Two local trainings in Ghana/Kenya in the most effectual and efficient manner. This discussion resulted in the parties agreeing to shift those events by one quarter (see Section 6). Mecomed noted that it developed a preliminary list of industry priority areas for MDRC support in the project countries and expressed willingness to work with the Medical Device Association of Kenya (MEDAK) in hosting the local Kenyan government and stakeholder consultations once Mission concurrence was received.

On 17 June, MDRC and Mecomed held the first of a two-part webinar training series on Tier One and Two issues with the region's medical device industry, including numerous participants from project countries. The first session was Tier One-focused, covering GRPs, technical barriers to trade (TBT), and their impacts on the medical technology sector during COVID-19. MDRC presented on the differences between technical regulations and standards, and harmonizing cross-border requirements through the adoption and use of international standards. MDRC also covered major challenges for the region's medical device sector related to trade/WTO rules. Those challenges include the lack of or improper implementation of the TBT agreement by most medical device regulators and the inappropriate regulation of medical devices as pharmaceuticals.

On 24 June, MDRC and Mecomed held the second part of this webinar series, dedicated to Tier Two elements for project countries in Africa. This session addressed regulatory convergence in the medical technology sector and Tier Two international benchmarks from the World Health Organization (WHO), International Medical Device Regulators Forum (IMDRF) (IMDRF), and Global Harmonization Working Party (GHWP). MDRC and Mecomed facilitated discussion on Medical Device Single Audit Program (MDSAP) as well as challenges to regulatory and industry capacity building in the Tier Two, Africa-specific context.

Kenya: On 6 May 2021, MDRC and the Mission to Kenya introduced the project to the Kenyan Pharmacy and Poisons Board (PPB). PPB affirmed its desire to collaborate with MDRC, including the appointment of a project focal point within the agency, and will identify key priorities for advancement with the project. PPB noted that it has a similar program underway in the pharmaceutical sector that is achieving good results and MDRC's work in the medical device sector would be valuable for Kenya

as a new focus area. MDRC spoke to the project's envisioned process in the country and region, and agreed to co-create an action plan with PPB, the Mission, and other stakeholders to ensure alignment with local needs.

This meeting follows the project's formal introduction to the meeting on 24 March. Since then, MDRC has corresponded regularly with the Mission to secure full concurrence. While the PPB confirmed both MDRC's potential value to Kenya and a desire to collaborate, the Mission to Kenya has not granted concurrence to the project. Concurrence is still under review.

Ghana: On 9 June, MDRC and Mecomed met with the USAID Mission to Ghana to introduce the project to the Economic Growth Team. MDRC discussed its Tier One and Two objectives in Ghana and expanded upon the intersection between the project's health and trade elements. MDRC provided the Mission with a preliminary draft action plan which outlines MDRC projected outcomes, milestones, and timelines in Ghana. MDRC also shared a draft template outreach letter for government stakeholders in Ghana. The draft template outreach letter is undergoing final review by all parties and will extended to government stakeholders in early July 2021.

South Africa: On April 20, MDRC met the Mission in South Africa to provide additional information on the project and the expected timeline for its objectives in-country and greater region. MDRC and the Mission discussed expectations for Mission engagement with the project in achieving those objectives. MDRC also elaborated on the various approaches the project had taken in other countries. The project noted that it is possible to address Tier One and Tier Two individually or in parallel, and in whichever order is appropriate for in-country circumstances. Following this discussion, the Mission informed MDRC it would not require a concurrence memo and would collaborate on future efforts with MDRC.

On 22 April, ANSI conducted outreach to the South African Bureau of Standards (SABS), the national standards body for South Africa.

On 7 May, MDRC met with the South African Medical Device Industry Association (SAMED) to discuss the association's partnership with MDRC to advance project outputs in South Africa. MDRC and SAMED have since collaborated to extend outreach to South African government stakeholders. SAMED has provided critical local expertise on the content and acculturation of outreach letters to maximize their effectiveness. The Mission to South Africa reviewed and approved the MDRC's template outreach letter on 11 June. SAMED and MDRC are in the final process of customizing letters and identifying proper contact information for each government stakeholder. MDRC will extend outreach in early July 2021.

Other Notable Progress

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. This report will serve as a resource for closing key gaps and communicating MDRC objectives to both private and public stakeholders at local and regional levels.

The Tier One report is in the process of final graphic design and alignment with USAID branding requirements. As more input and feedback from USAID, governments, and relevant stakeholders are

received, this report may be updated again in late 2021 or early 2022.

MDRC has sought input on Phase One outputs from a variety of stakeholders, including industry associations, USAID Missions, and US government agencies. On 23-24 March, 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.

On 5 May, MDRC shared updated drafts of MDRC's Phase One, Tier One gap analyses and Phase One, Tier Two stakeholder maps with ANSI, the US International Trade Administration (ITA), the US National Institute of Standards and Technology (NIST), the Office of the US Trade Representative (USTR), and the US Office of Information and Regulatory Affairs (OIRA).

7.3 Implementation Status

During Q2, MDRC secured concurrence from the USAID Missions in Mexico and Indonesia, and permission to proceed without a formal concurrence memo in South Africa.

While the prior delay set back scheduled outreach, MDRC rapidly expanded collaboration with private and public sector actors across the three project regions throughout Q1 and Q2 2021. This includes coordination with relevant stakeholders on feedback for Phase One outputs. The Tier One, Phase One report is complete and is in the process of final graphic design and alignment with USAID branding requirements. Phase One, Tier Two stakeholder maps are under final review by various local and regional stakeholders and are scheduled for completion in early Q3.

MDRC continues to assess whether capacity-building activities with each project countries in 2021 will remain virtual as a result of COVID-19 travel and local gathering restrictions.

Following the decision by the USAID Mission in Thailand to decline project concurrence in Q1, MDRC initially decided to focus those resources earmarked for Thailand towards Vietnam and Indonesia for the remainder of the project timeline. However, following the Government of Colombia's request for a MDRC Liaison to coordinate project implementation among government and local stakeholders, MDRC is working to secure approval from USAID to deploy this Liaison. The Government of Colombia has indicated that the deployment of such a Liaison would enable Colombian government partners to fully dedicate themselves to MDRC implementation without disrupting essential COVID-19 functions and response (see Section 2, Colombia).

While final USAID approval of the new Liaison is still under consideration, MDRC believes this development is a potential avenue to overcome prior implementation challenges and accelerate MEL Plan achievement in Colombia. The focused scope, full-time, and short-term nature of the Liaison's work lends itself to the rapid deployment of MDRC capacity building central to the MEL plan. The Liaison's singular focus coordinating and working with relevant Colombian government stakeholders, even in a virtual setting, is expected to promote rapid project goal realization. Coupled with the strong demonstrated desire of the Government of Colombia to implement regulatory convergence and GRPs, the Liaison is well-positioned to fast-track MEL plan fulfillment.

7.4 Implementation Challenges

Overcoming project implementation delays related to local USAID Mission concurrence across a number of project countries remained the largest project challenge in Q2 2021. In some cases, the time between initial consultation with a USAID Mission and formal concurrence was several months. MDRC is still awaiting final concurrence from the USAID Mission in Kenya after seven months. These delays prevent MDRC from engaging with project countries to advance project outputs.

Another challenge to project implementation is limited engagement by some project country government stakeholders. In Peru, MDRC is experiencing communication delays and unresponsiveness from DIGEMID, a key stakeholder for advancing medical device regulatory convergence and related GRP implementation. MDRC believes that Peru's current political climate, in conjunction with the challenges precipitated by COVID-19, have stymied government capacity to collaborate with the project in the short-term. Following the April 1 meeting with Patricia García (See Section 2, Peru), MDRC has worked to identify a number of potential avenues for advancing MDRC objectives in country. Patricia and MDRC discussed DIGEMID's organizational structure and explored the idea of approaching the agency through MINCETUR, who has the leading role implementing GRPs.

In Vietnam, while MDRC maintains high levels of engagement with the private sector, government stakeholders have been less responsive. MDRC conducted outreach on 16 March to six government agencies. Two agencies, STAMEQ and the Ministry of Finance, have formally responded and assigned Vietnam Customs as their MDRC focal point (See Section 2, Vietnam). Since this development, MDRC has experienced additional delays engaging with Vietnam Customs. At the working-level, Vietnam's Ministry of Health conveyed that it would defer to the Department of Medical Equipment and Construction (DMEC), whose purview includes MDRC objectives. DMEC, the Ministry of Industry and Trade, and the Ministry of Foreign Affairs have been unresponsive to date.

MDRC is exploring all available avenues to engage Vietnamese authorities. 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 US FCS and Vietnamese branches of the European and American Chambers of Commerce on relevant contacts in the government. These parties are awaiting go-ahead from the relevant ministries before providing MDRC with that contact information. The MDRC team continues to follow-up directly via email and phone calls with the agencies to encourage them to participate in the project.

While COVID-19 has, as expected, made in-person capacity building impossible to date, the project is actively addressing this challenge through the execution of high-quality virtual engagements. These engagements continue to improve both in their ability to disseminate quality resources and convene relevant stakeholders from the public and private sectors.

Greater USAID coordination of scope management of other USAID projects running parallel to the MDRC could facilitate MDRC implementation and MEL plan realization and increase coherence and effectiveness with select project governments. On the Global Health side, this should include a clear designation of scope clarification between the MDRC, MTaPS and PQM+ regarding implementation of Medical Device Regulatory Convergence with National Regulatory Authorities in common project countries. Most helpful would be a clear project scope delineation and formalized invitations for engagement of the MDRC team in project initiatives with overlapping scopes. On the trade side, coordination and information sharing by USAID of the projects of the USAID funded US Support for Economic Growth in Asia (US-SEGA) work in Asia-Pacific Economic Cooperation (APEC) on Good Regulatory Practices would be beneficial to MDRC implementation – in particular the GRP assessments for Peru and Indonesia. The MDRC also stands ready to share its GRP assessment with those

implementing teams and to otherwise coordinate interactions with the common project country governments.

STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Global: The Coalition, along with the GMTA, presented at the *WTO Webinar on Regulatory Cooperation During the COVID-19 Pandemic* on 2 June. The Coalition presented on the challenges the pandemic posed for the medical technology sector while outlining opportunities for leveraging lessons learned to advance regulatory convergence.

MDRC is working to expand its collaboration with the WHO, meeting with WHO representatives on 8 June. The WHO has since hosted a webinar on GRPs, Good Reliance Practices (GRelPs), and resources to enhance their global implementation. MDRC will discuss potential avenues for partnership with the WHO in future meetings.

Latin America: The Coalition continued to advance regional and local MDRC objectives through coordination with key stakeholders. Through PAHO, the Coalition is working to engage project country medical device regulators in PANDRH and organize events to align external stakeholders on the importance of regulatory convergence, GRPs, and GRelPs.

The Coalition continues to collaborate with the Inter-American Development Bank's (IDB) efforts to undertake a GRP survey and report on Latin American project countries. The data and insights gained from this survey, once complete, will reinforce Phase One and Two regional outputs and may encourage greater participation in MDRC-related activities by both public and private sector entities.

MDRC collaborated with the USFDA to organize a three-part webinar series for stakeholders across Latin America between 2 and 17 June. This series was co-led by USAID, ANSI, and AdvaMed through the Coalition. The three sessions engaged 6 National Regulatory Authorities (NRAs) and convened 300 attendees from Brazil, Colombia, and Mexico amongst other participating countries. Please see Section 2, Latin America for additional information on this webinar series.

Southeast Asia: MDRC collaborated with industry bodies to advance private sector participation in advancing regulatory convergence across Southeast Asia. MDRC received input from industry members on the opportunities and challenges for the medical technology sector in the region and sought buy-in from those members to partner on MDRC objectives.

MDRC met with Asia Pacific Medical Technology Association (APACMed) on 27 May to discuss some of those challenges and opportunities in the region. Following this meeting, MDRC and APACMed agreed to continue coordination through the Association's Southeast Center of Excellence, an important source of information on medical device regulatory convergence needs in Indonesia and Vietnam. MDRC leveraged a USABC meeting to introduce attending members to the project and emphasize collaboration with the USABC to advance project objectives. MDRC gained insight into the Tier Two priorities for those members in Indonesia and Vietnam.

In Vietnam, MDRC met with the American and European Chambers of Commerce to note the industry perspective of Tier Two priorities in the project country. In Indonesia, MDRC leveraged U.S. Embassy's

Medical Device Roundtable as a platform to introduce the project and the importance of regulatory convergence to local medical device manufacturers.

Africa: MDRC cultivated partnerships with key medical device industry bodies to accelerate project implementation in the region. Mecomed, the leading medical device industry association for the region, has helped MDRC identify industry priority areas and train local industry members on both Tier One and Two elements. On 17 June, MDRC and Mecomed held the first of a two-part webinar training covering GRPs, technical barriers to trade, and their impacts on the medical technology sector during COVID-19. MDRC presented on the differences between technical regulations and standards, harmonizing cross-border requirements through the adoption and use of international standards, and major challenges for the region's medical device sector. On 24 June, MDRC and Mecomed held the second part of this webinar series, dedicated to Tier Two elements for project countries in Africa. This session addressed regulatory convergence in the medical technology sector and Tier Two international benchmarks from the WHO, IMDRF. and GHWP. See Section 2, Africa for more information.

MDRC has also collaborated with SAMED to advance project outreach in South Africa. SAMED and MDRC are finalizing government outreach letters and identifying proper contact information for each stakeholder. MDRC expects to extend outreach in South Africa in early July 2021.

RESULTS ACHIEVED

Global

- On 5 May, the implementation team shared updated drafts of MDRC's Tier One gap analyses and Tier Two stakeholder maps with ANSI, ITA, NIST, USTR, and OIRA. (Activity 1.1.6.1, Output 1.1.6, IR 1.1, Activity 2.1.2.1, Output 2.1.2, IR 2.1).
- MDRC's Tier One Report is complete and undergoing final graphic design and alignment with USAID branding requirements (Activity 1.1.6.1, Output 1.1.6, IR 1.1, Activity 2.1.2.1, Output 2.1.2, IR 2.1).

Latin America

- REGIONAL: The IACRC continued to advance joint efforts with the IDB to mutually undertake a survey of GRP in Latin American project countries (Activity 1.1.6.1), assisting with the completion of the Tier One and Two gap analysis. This collaboration will improve project countries' knowledge about the value of using national quality infrastructure (IR 1.1) and increase private sector participation in regulatory development (IR 2.1).
- BRAZIL: On 12 April, MDRC introduced the project to the Brazilian MoE's Foreign Trade and International Affairs Secretariat. MDRC was well received by the Secretariat (IR 1.1, IR 3.1, IR 4.1, IR 4.2)
- BRAZIL: MDRC introduced the project to ANVISA on 15 April. ANVISA and MDRC discussed potential future collaboration with ANVISA during the pandemic and on efforts related to regulatory convergence (IR 1.1, DO 4).
- COLOMBIA: MDRC met with INVIMA on 22 April. INVIMA identified its top priorities for project outputs and activities in the country, including trainings to develop capacities on GRPs (IR 1.1, Output 1.1.1, Output 1.1.13, Output 1.1.4 Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1).
- PERU: On 1 April, the Coalition and ALADDIV met with Patricia García, former Minister of Health of Peru, to discuss collaborative opportunities and challenges in Peru. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- MEXICO: On 26 April, MDRC met with COFEPRIS. MDRC discussed the importance of GRPs

and utilizing international standards (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.4, IR 3.1, Output 3.1.1). MDRC mentioned the training program being jointly developed with the USFDA LATAM office on ISO13485 and MDSAP (Activity 1.1.3.1, Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1, IR 3.1, Output 3.1.2).

- MEXICO: On 26 April, MDRC introduced the project to CONAMER. MDRC and CONAMER discussed three areas of MDRC project implementation which harmonize with COFEPRIS's interests: regulatory convergence, regulatory simplification, and digitization (IR 1.1, IR 1.2, IR 3.1).
- BRAZIL: On 30 April, MDRC met with the SEAE and discussed approaches to developing a harmonized strategy across all interested government entities to address (1) INMETRO's challenges regarding medical devices, and (2) the development of new regulations under a proper regulatory process (IR 1.1, IR 1.2, IR 3.1).
- REGIONAL: On 18 May, the Coalition met with PAHO. The attendees discussed the formal status of the Coalition as a partner of PAHO and potential avenues for future collaboration. PAHO offered to work with the Coalition to organize a meeting with external regional stakeholders and foster regulatory alignment among medical device regulators in the region (IR 1.1, IR 1.2, DO 4).
- MEXICO: On 24 May, MDRC met with DGN. MDRC and DGN agreed to jointly develop a standing NSB policy/statement of support for GRP implementation within Mexico. DGN and MDRC will establish a work stream to implement GRPs with the Government of Mexico and work to increase international regulatory, standards and conformity assessment convergence for the medical technology sector. DGN and MDRC will coordinate with regional and multilateral organizations to advance these objectives. (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3, Output 1.1.4)
- REGIONAL: On 2 June, the Coalition presented at the WTO Webinar on Regulatory Cooperation during the COVID-19 Pandemic. The Coalition presented on the challenges the pandemic posed for the medical technology sector and discussed ways to leverage lessons learned from the pandemic to advance regulatory convergence. (IR 1.2, IR 3.1).
- REGIONAL: On June 8, MDRC met with the WHO to explore opportunities for further collaboration, including the development of a Global Benchmarking Tool for medical device companies (IR 2.1).
- COLOMBIA: On 10 June, MDRC met with the DNP, the Ministry of Health and Social Protection and INVIMA. MDRC and those stakeholders coordinated strategy for a series of projects including the implementation of MDSAP, the ex-post evaluation of Decrees 4725 and 3770, and developing regulation related to Emergency Use Authorizations (IR 1.1, Output 1.1.1, Output 1.1.4, Output 1.1.5, Output 1.17, IR 1.2, Output 1.2.1, DO 4).
- REGIONAL: MDRC collaborated with the USFDA to organize a webinar series for stakeholders across Latin America. Co-lead by USAID, ANSI, and AdvaMed through the Coalition, this series took place over three sessions between 2 and 17 June. These sessions focused on ISO 13485 and Medical Device Single Audit Program (MDSAP) outcomes utilization for regulatory purposes (IR 1.1, IR 1.2, IR 2.1).
- MEXICO: On 11 June, MDRC met with the COFEPRIS to discuss formal collaboration with the project and ongoing negotiations to conclude a joint Letter of Intent as an alternative to an MoU. (IR 1.1, IR 1.2, IR 3.1, DO 4, Crosscutting IR 2.1).
- MEXICO: On 14 June MDRC met the Secretariat of Economy and discussed areas of primary importance to the Secretariat for MDRC. The Secretariat informed MDRC the implementation process has begun on the USMCA Annexes related to medical devices and GRPs (IR 1.1, IR 1.2, IR 3.1, DO 4).
- REGIONAL: One 16 June, the Coalition partnered with ALADDIV, The London School of Hygiene and Tropical Medicine, The International Diagnostics Center, and CBDL to launch Laboratory Diagnostics White Book for 2021-2022. The event convened a round table on "The Future of Diagnostics in a Post Pandemic World," which was attended by around 300 health professionals

from 17 countries (IR 2.1).

- PERU: On 17 June, MDRC introduced the project to CONFIEP and discussed potential avenues of collaboration with the project through the Coalition (IR 2.1).
- COLOMBIA: On June 24, MDRC met with the DNP, the Ministry of Health, the Ministry of Commerce, INVIMA and ANDI. Participants agreed on initial steps to advance: (1) the ex-post analysis of Decrees 4725 and 3779, (2) RIAs for GMPs, (3) Clinical Research and Emergency Use Authorizations, and (4) GRPs under a collaborative approach between government and private sector. (IR 1.1, IR 1.2, IR 2.1, IR, 3.1, DO 4)
- MEXICO: On 28 June, MDRC met with COFEPRIS and continued to align on both joint priority issue areas and the final language for a Letter of Intent. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- PERU: Throughout Q2, MDRC communicated with MINCETUR which confirmed its interest to participate in MDRC pending further internal consultations. (IR 3.1, DO 4, IR 4.1, IR 4.2)

Southeast Asia

- INDONESIA: On 1 April, MDRC introduced the project to USABC-Indonesia and discussed common interests and issues related to medical devices in Indonesia (IR 2.1). USABC's Chief Country Representative for Indonesia offered the organization's capacities to serve as a local interlocutor on behalf of MDRC where necessary. (IR 2.1, IR 2.1.2).
- INDONESIA: On 29 April, MDRC had a series of communications with Standards Attaché at the U.S. Embassy in Indonesia, Bruce Elsworth, who reiterated the support of the U.S. Commercial Office in Jakarta (IR 1.1, IR 1.2, IR 2.1). Bruce connected the project with other relevant officials in the U.S. Commerce Department, who in turn have expressed their willingness to assist and participate in relevant MDRC activities.
- VIETNAM: On 10 May, the General Department of Vietnam Customs responded to MDRC's outreach letter to confirm their participation in the project. (IR 3.1)
- INDONESIA: On 17 May, the USAID Mission to Indonesia issued concurrence to MDRC. This enables MDRC to proceed with all project outputs and government outreach (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- INDONESIA: MDRC presented at the US Embassy to Indonesia Medical Device Roundtable. MDRC provided an overview of the MDRC, explained its relevance to medical device manufacturing companies operating in Indonesia, and discussed specific areas of importance to the industry in Indonesia (IR 2.1, Output 2.1.1, Output 2.1.3)
- VIETNAM: On 20 May, MDRC met with Abbott Vietnam to seek feedback on Tier Two-related regulatory challenges the company faces in-country (IR 2.1, Output 2.1.2, IR 3.1).
- REGIONAL: On 27 May, MDRC met with APACMed to discuss medical device regulatory challenges in the region. MDRC will coordinate with APACMed's Southeast Asia COE, which has identified a series of regulatory challenges and needs in Indonesia and Vietnam. (IR 2.1, Output 2.1.1, Output 2.1.5)
- VIETNAM: On 27 May, MDRC met with the Chair of the Healthcare Committee of the American Chamber of Commerce in Vietnam to discuss Tier Two priorities in the country, including the requirement for companies to re-register medical devices by January 2022. MDRC will continue to work with the Healthcare Committee and its members to identify Tier Two priorities. (IR 2.1, Output 2.1.1)
- REGIONAL: On June 1, MDRC met with Stryker to discuss its priorities and challenges in Vietnam and Indonesia (IR 2.1, Output 2.1.1)
- VIETNAM: On 9 June, MDRC met with the European Chamber of Commerce in Vietnam to discuss working with the Chamber's Medical Devices and Diagnostics Sector Committee to identify regulatory hurdles as well as training and capacity-building opportunities for Vietnamese authorities. The Committee identified the requirement to re-register medical devices and the

authorities' lack of capacity as a priority. MDRC and the Committee will continue conversations to discuss these concerns on a technical level. (IR 2.1, Output 2.1.1)

- INDONESIA: On 22 June, MDRC sent electronic outreach letters to government stakeholders in Indonesia, enabling MDRC to begin coordination with the Government of Indonesia. MDRC will send hard copies of the letters in the coming weeks. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC 2.1)
- REGIONAL: On 25 June, MDRC joined a meeting with the U.S. ASEAN Business Council (USABC) where MDRC introduced attending members and noted Tier Two concerns by members relevant to the project countries.

Africa

- SOUTH AFRICA: On April 20, MDRC reviewed regional and in-country objectives and timelines for project activity with the Mission to South Africa. MDRC discussed various approaches to stakeholder outreach. The Mission informed MDRC it would not require a concurrence memo and would be happy to collaborate on future efforts (IR 1.1, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- On 22 April, ANSI conducted outreach to SABS (IR 2.1, IR 3.1).
- KENYA: On 6 May 2021, MDRC and the Mission to Kenya provided an overview of the project to the Kenyan PPB. PPB affirmed its desire to collaborate with MDRC and will identify key priorities for advancement with MDRC. MDRC will co-create an action plan with PPB, the Mission, and other stakeholders to ensure alignment with local needs (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, CC IR 2.1).
- SOUTH AFRICA: On 7 May, MDRC met with SAMED to discuss the association's partnership with MDRC to advance project outputs in South Africa. MDRC and SAMED have since collaborated to extend outreach to South African government stakeholders (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, CC IR 2.1).
- SOUTH AFRICA: The Mission to South Africa reviewed and approved the MDRC's template outreach letter on 11 June (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, CC IR 2.1).
- REGIONAL: On 21 May, MDRC discussed the possibility of a partnership with Mecomed to implement Phase Two objectives in Africa, and brainstormed ways in which the project could execute the Tier One regional forum and Tier One/Two local trainings in Ghana/Kenya in the most effectual and efficient manner. In the advancement of Tier Two specific objectives, Mecomed noted that it has developed a preliminary list of industry priority areas for MDRC support in the project countries and expressed willingness to work with MEDAK in hosting the local Kenyan consultations (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.2, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- GHANA: On 9 June, MDRC and Mecomed met with the Mission to Ghana to introduce the project to the Mission's Economic Growth Team. MDRC expanded upon the intersection between the project's health and trade elements. MDRC provided the Mission with a preliminary draft action plan and shared a draft template outreach letter for government stakeholders for the Mission's review and approval. (IR 1.1 IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 17 and 24 June, MDRC and Mecomed held a two-part webinar series for members of the African medical device industry. MDRC introduced the MDRC project, and presented on a series of topics related to Tier One and Two and their impacts on the medical technology sector during COVID-19. This includes elaborating on the differences between technical regulations and standards, and harmonizing cross-border requirements through the adoption and use of international standards. MDRC also covered major challenges for the medical device sector related to trade/WTO rules, regulatory convergence in the medical technology sector, and Tier Two international benchmarks. (IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output

2.1.2, Output 2.1.3, Output 2.1.5)

Other Results

- MDRC maintained progress toward the launch of a COVID-19 medical device portal (Activity 4.0.0.3) under Development Objective 4.

4.1 AdvaMed Staff Activities

The team of AdvaMed staff contributing to the MDRC are continuously engaged in ongoing activities that advance the project objectives. A list of some of the more pertinent activities that occurred over Q2 2021 are included here:

- Global staff engagement with USTR and ITA on GRP, TBT and regional activities (IR 1.1, IR 1.2, IR 3.1, IR 4.1)
- Participation on the U.S. delegation to the APEC Subcommittee on Standards and Conformance – of relevance for work with the U.S. Mexico and Peru (IR 1.1, IR 3.1, IR 4.1).
- Staffing and convening of the weekly AdvaMed All Member COVID-19 Task Force (DO 4, IR 4.1, IR 4.2).
- Staffing and convening of the weekly AdvaMed COVID-19 Supply Chain Task Force (DO 4, IR 4.1, IR 4.2).
- Establishment, staffing and convening of the AdvaMed MDRC Steering Group (SG) (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
    - Staffing and convening of the AdvaMed Global Harmonization Working Group (GHWG) addressing recommendations of the MDRC SG for the GMTA and IMDRF
- Staffing of the GMTA Regulatory Working Group (IR 2.1).
- Staffing of the AdvaMed Standards Working Group (IR 1.1, IR 2.1, I 3.1, IR 4.1)
- Meeting with the U.S. Food and Drug Administration – Center for Devices and Radiological Health (FDA/CDRH) – Global and LatAm teams (IR 1.1)
- Coordination with AdvaMed partner medtech associations (IR 2.1).

LESSONS LEARNED

The project team is continuing to incorporate lessons learned on virtual engagements with stakeholders, online capacity-building, and digital resource capabilities. MDRC is leveraging virtual platforms and a Zoom license to interact with actors across the public and private sectors. These digital software licenses have streamlined connectivity and communication across the languages of English, Portuguese and Spanish. However, MDRC had to upgrade its Zoom license configuration to accommodate higher-than-expected volumes of participants in Coalition webinars. While the previous participant limit was 500, MDRC now has the capacity to accommodate up to 1000 attendees.

MDRC is working to optimize the level of resources devoted to running the Coalition's online presence. MDRC is heightening the Coalition's capacity to provide online modules and virtual resource library through a more efficient, lower cost web development vendor. Virtual Coalition resources have proven to be an invaluable tool for hosting and disseminating information vital to the project.

MDRC is working to craft a series of USAID-approved and branded templates for project use in external engagements. These templates will ensure consistent alignment with USAID branding guidelines across all project activities and streamline future USAID approval processes for such products.

With the concurrence of most countries' USAID Missions, MDRC will work to keep those Missions regularly informed and engaged in ongoing outreach and the subsequent capacity-building process. This will serve to simplify communications between the project team and USAID, preventing any unnecessary delays.

PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

In Q3, MDRC will continue to focus on outreach and capacity-building with private and public sector stakeholders across all project countries. MDRC will advance awareness of MDRC objectives and leveraging the relationships built in Q1 and Q2 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.

MDRC and Mecomed agreed to host the 2021 events in Africa virtually and shift them back by one quarter into Q4 2021 and Q1 2022. Those events include: (1) Tier One Regional Forum in Nairobi, Kenya, (2) Tier One Local Meeting/Training in Nairobi, Kenya, and (3) Tier Two Local Meeting/Training with MD Regulators. MDRC and Mecomed believe this schedule shift is critical to enabling proper preparation for those events and providing appropriate time for government stakeholders to digest/enact learnings in-between trainings. This decision was driven in part due to the delays MDRC has experienced in the USAID Mission concurrence process. MDRC expects the expanded time frames to result in improved project outcomes through the added benefits it provides to local government and industry stakeholders.

Please find below a chart outlining planned MDRC activities for the next quarter:

Meeting/Event	**Location**	**USAID participation?**	**Region**
MDRC - FDA Webinar on UDI	Virtual	Yes	Americas
MDRC - FDA Webinar on Use of International Standards by Regulators	Virtual	Yes	Americas
GRPs Workshop - Peru	Virtual	Yes	Peru
PAHO - Regulators - Private Sector	Virtual	Yes	Americas
GRPs Training DNP, INVIMA, MinSalud - Colombia	Virtual	Yes	Colombia

GRPs Training COFEPRIS - Mexico	Virtual	Yes	Mexico
MDRC Review Conference - IMDRF	Virtual	Yes	Southeast Asia