Standards Alliance: Phase 2

Quarterly Report

1st Quarter January 1 to March 31, 2021

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1. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2
Activity Start Date And End Date:	July 12, 2019 – July 11, 2024
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
Agreement Number:	#7200AA19CA00012
Name of Subcontractors/Subawardees:	Ethical Apparel Africa, AdvaMed, ASTM International, NSF, AWWA
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	1Q 2021 – January 1 to March 31, 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 first quarter of 2021 entailed the continued implementation of activities under approved subawards and the further development and finalization of additional subaward agreements. 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 Q1 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 and ANSI 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 Q3. If international travel remains restricted during Q3, Pivot will develop an online option to effectively deliver both planned trainings leading up to the 2021 ECREEE General Assembly.

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 Q1, ANSI, ARSO and the Personal Care Product Council (PCPC) hosted the first webinar of a ten-part cosmetics training series developed to support the harmonization of African personal care and cosmetics standards. This webinar series is the result of a close collaboration between ANSI and ARSO related to the annual ARSO General Assembly (GA), which has been moved to June 2021 in Nigeria. With guidance from PCPC and ARSO Technical Committee 40 (TC40) on cosmetics, ANSI and ARSO have set into motion a virtual series including ten 90-minute webinars on international best practice for cosmetics standards as well as a thematic session for TC40 members during the ARSO GA.

The first webinar was held February 26 and focused on international best practices for cosmetics standardization, introducing important concepts and setting the foundation for future activities in the series. The inaugural training drew over 65 participants. Dr. Jay Ansell, Vice President of the Cosmetics Program of PCPC, provided an overview of the importance of standardization in the cosmetics industry and outlined pragmatic approaches to implement best practices. Dr. Ansell further emphasized the pivotal role ARSO plays in providing a forum for collaboration among members seeking to develop a harmonized trade-promotion framework while simultaneously leaving room for safety-oriented innovation in the personal care products industry.

The second webinar in the series will be hosted on April 16, focusing on the implementation of cosmetics frameworks with a focus on compatibility through the lens of a case study on South Africa. The third webinar has also been scheduled for May 11.

In Q2, 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 sub-award agreement was submitted to ANSI by the Center for Water Security Cooperation (CWSC) and is under review by USAID Agreement Officer. Research on WASH-related product standards is planned for Ghana, Zambia and Uganda beginning immediately following USAID approval (hopefully 2Q21).

Activity #4 Training in Good Regulatory Practices for Regulatory Impact Analysis

(RIA) Teams in Government Ministries

In order to build upon the momentum following completion of this activity in Q3 2020, ANSI remained in close contact with RIA consultant Nathan Frey, RSS Strategies, and BRRA to discuss next steps for RIA Teams implementation in Zambian government ministries. Mr. Frey proposed the development of a *RIA Quality Assessment Tool* that will enhance reporting on RIA implementation in Zambia. Developing a system to evaluate the quality RIA reports will be key in helping improve the consistency of RIA implementation, and the quality of regulation.

BRRA was receptive to this proposal, and showed interest in discussing this idea further to better understand the role this tool will play in complementing existing tools, such as the RIA handbook, and the implementation process. Mr. Frey provided multiple examples of existing RIA quality assessment tools and methods, while emphasizing that the Zambian approach would need to be tailored to the country's specific needs as there is no one-size-fits-all solution. He further noted the need to collect data tracking RIA completeness and for the integration of RIA within policy-making and regulatory decisions.

While BRRA remains receptive to Mr. Frey's feedback and proposal, the development of this *RIA Quality Assessment Tool* will ultimately depend on BRRA's ability to fully fund these elements independently of Standards Alliance Phase 2 assistance. In Q2, ANSI will maintain open lines of communication with Mr. Frey and BRRA to facilitate further discussions and provide support where possible.

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 was approved by the USAID Agreement Officer. ANSI signed the sub-award with AWWA on February 8, 2021. Work is planned in Zambia, Malawi, and Lesotho, but will not begin until 3Q 2021. Country-level supporting documents for USAID Missions in these countries were discussed and will be developed in 2Q 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 Q1, ANSI, ASTM International and the American Petroleum Institute (API) formally kicked-off their Harmonization of Petroleum in West Africa project. This collaboration aims to identify, review and modify existing standards that can be adopted and applied in West Africa, focusing primarily on Economic Community of West African States (ECOWAS) with programming intending to be held at the national or regional level, as appropriate. The current focus countries include Côte d'Ivoire, Ghana, Nigeria, and Senegal.

This collaboration will have a dual trade and development impact on the region. Harmonization of standards is known to reduce Technical Barriers to Trade (TBT), and the project will ultimately bolster two-way trade and investment between the U.S. and West Africa. Many of the largest international oil companies operating in West Africa are members of both ASTM and API, and have identified petroleum standards harmonization as a top priority. Ultimately, this collaboration will serve to improve access to global markets for ECOWAS countries, through promoting a level playing field that benefits end consumers, advancing operating efficiency, and increasing the value of product yield. Higher efficiency, increased safety, decreased environmental impact, and more effective delivery of public goods and services will ultimately come from this harmonization of

standards effort.

In identifying, reviewing, and modifying existing standards that can be adopted and applied in West Africa, the Standards Alliance will contribute to developing market-relevant and science-based guides that support consistent requirements and evaluation of products; provide reference documents for citation in regulation; and facilitate market access.

The project will be carried out in seven phases: fact-finding, introductory workshops, working groups, study tours, training, establishing mechanisms to maintain quality, and assessing sustainability of outcomes. The Standards Alliance will engage with National Standards Bodies, Petroleum Regulatory Authorities, Ministries of Trade and Ministries of Foreign Affairs, Customs and Border Authorities and Private sector companies. The project will rely on four main performance measures: capacity building (standards development and technical training); decrease in technical barriers to trade (using WTO/TBT Principles for NSBs, Good Regulatory Practices); quality infrastructure (inspection protocols, laboratory accreditation); private sector engagement (protocols for manufacturers, personnel certification).

Throughout Q1, the Standards Alliance focused on fact-finding and gathering stakeholder input. An initial meeting was held with relevant USAID missions to kick-off the project. Throughout Q2, 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.

Activity #6 Africa Concrete and Building Code Adoption Initiative

In Q1, ANSI submitted ACI's subaward for review by the USAID Agreement Officer. USAID indicated that assistance has been paused in Ethiopia, and as a result ACI decided to swap Ethiopia for Tanzania and is currently updating their proposal to share with USAID.

ANSI will continue to support these efforts and hopes to start sharing introducing ACI to USAID missions in Uganda, Kenya and Tanzania in in Q2 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)

Updated sub-award agreement is pending submission to ANSI by the International Association of Plumbing & Mechanical Officials (IAPMO). Activities are planned for Indonesia and the Philippines.

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

The American Water Works Association (AWWA) sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with AWWA on February 8, 2021. Coordination for introductory calls with the USAID India Mission began in 2Q 2021. Country-level supporting documents for the USAID Mission were discussed and will be developed in 2Q 2021.

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 was approved by the USAID Agreement Officer. ANSI signed the sub-award with NSF on February 17, 2021. Coordination for introductory calls with USAID Missions in Brazil and Colombia began in 1Q 2021. Country-level supporting documents for USAID Missions in these countries were discussed and will be developed in 2Q 2021.

Development Objective #3: Countries have fewer TBT's

Activity #10 – Energy Efficiency Standards in Mexico

ANSI and the Lawrence Berkeley National Laboratory (LBNL) and the International Code Council (ICC) continue to brainstorm the types of trainings that would be tailored to the needs of the Mexican partners. LBNL conducted outreach to the Mexico Mission regarding next steps and ICC met with Calidad y Sustentabilidad en la Edificación, A.C. (CASEDI), the Chapter of The International Code Council (ICC) in Mexico. ICC and CASEDI shared the following points:

- The National Commission for the Efficient Use of Energy (CONUEE), an administrative agency of the Ministry of Energy, is not currently in the position to promote the IECC-Mexico 2016 Code.

- The International Energy Agency (IEA) working very closely with the past administration helped ICC promote the Code through Mexico's Energy Secretary and CONUEE.

- A law was enacted on July 1, 2020, "Ley de la Infraestructura de la Calidad" (Quality of the Infrastructure Law) which replaces la "Ley de Metrología y Normalización" (Metrology and Normalization Law). Currently there are many changes and unknown areas on application and enforcement.

CASEDI continues to be interested to support training seminars on the International Energy Conservation Code (IECC-Mexico), but ANSI and LBNL will need to further deliberate the appropriateness of SA2 support.

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)

Updated sub-award agreement is pending submission to ANSI by the International Association of Plumbing & Mechanical Officials (IAPMO). Activities are planned for Jordan.

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

The NSF International sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with NSF on February 17, 2021. Coordination for introductory calls with the USAID Morocco Mission began in 1Q 2021. Country-level supporting documents for the USAID Morocco Mission were discussed and will be developed in 2Q 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)

While MDRC rapidly expanded outreach and collaboration with private and public sector actors across the three project regions throughout Q1 2021, the prior delay during Q4 2020 in outreach set back the scheduled completion of Phase One regional outputs. Phase One outputs are scheduled for completion in the early weeks of Q2 2021. The MDRC team does not expect this delay to interfere with the wider implementation timeline of the project beyond Q1 2021. MDRC continues to assess whether capacity-building activities with each project countries in 2021 will need to remain virtual as a result of COVID-19 travel and local gathering restrictions.

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 Q1 2021. MDRC has conducted formal outreach to government agencies in all Latin American project countries and secured USAID Mission concurrence from Colombia and Mexico.

Regional: The Coalition and broader MDRC team met with the Pan American Health Organization (PAHO) on 29 January. The Coalition and PAHO discussed how to work towards increased cooperation in a manner that supports both parties' efforts while not duplicating or obstructing existing initiatives. Following the meeting, the Coalition submitted its formal application to be recognized as a Non-State Actor under PAHO's FENSA process. This process remains underway. Once approved, the Coalition can deepen collaboration with PAHO.

Between 22 and 24 February, the Drug Information Association (DIA) held their Annual Latin America Regulatory Conference. There, global regulators, industry, and academia engaged in a series of discussions on the current regulatory landscape, globalization, and harmonization initiatives in Latin America. The Coalition participated in two sessions addressing regulatory convergence, GRPs, and emergency responses to COVID-19. During the first session, titled "Reliance and Regulatory System

Strengthening," the Latin American Federation of the Pharmaceutical Industry (FIFARMA) and the Coalition issued a joint message on the relevance of reliance and recognition in the pharmaceutical and medical technology sectors. Both organizations emphasized that proper differentiation between the two sectors is required for their proper regulation. During the second session, titled "Regulatory Convergence in Pandemic Situations," the Coalition spoke to the need for a holistic approach to regulatory convergence. Such an approach maximizes the inclusion of all relevant stakeholders and the implementation of GRPs. Thereafter, the Brazilian National Health Surveillance Agency (ANVISA) shared lessons learned on the challenges posed by the COVID-19 pandemic from the perspective of a regulator.

To solidify the gains made throughout Q1 2021, the Coalition further strengthened its online module development and virtual resource library, which can be accessed here: https://interamericancoalition-medtech.org/regulatory-convergence/. Throughout Q1, the Coalition website saw a steady increase in website traffic with a total of 1,637 visits between January and March. This represents a 32% increase from Q4 2020. These advances position the Coalition as a leader in building the capacity of project countries for standards and conformity assessment procedures and in fostering private sector engagement in the medical technology regulatory convergence.

Peru: On 13-14 January, the Coalition conducted outreach with government ministries and agencies in Peru. Since initial outreach, MDRC has continued to coordinate with the USAID Mission to Peru and private sector stakeholders, setting the stage for MDRC to advance relevant objectives in the project country.

Brazil: On 7-8 January, the Coalition conducted outreach on behalf of MDRC to the Brazilian Ministries of Foreign Affairs, Health, and Trade. Further, outreach was sent to INMETRO, the Advocacy and Competition Law Secretariat of the Ministry of Economy (SEAE), the Special Secretary of Debureaucratization, Management and Digital Government of the Ministry of Economy, and ANVISA.

The MDRC project team met with ABNT, the Brazilian National Standards Organization on 3 and 10 February. During these meetings, ABNT presented on its initiatives related to medical device standardization, ABNT's relationships with SDOs and NSBs, and the recent developments in INMETRO/ANVISA medical technologies and technical regulations. ABNT agreed to help conduct a joint introductory session with MDRC on the project to INMETRO. In early Q2, ABNT and MDRC intend to reconvene with the objective of working toward a convergence of scope and efforts, including the possibility of formalizing ABNT membership in the Coalition.

On 16-17 March, the Coalition hosted a workshop on GRPs and International Trade for a series of Brazilian stakeholders across the public, private, and academic sectors. The workshop was co-hosted and supported by local associations representing the medical technology sector, including ABIMED, ABIIS, ABRAIDI and CBDL. The workshop was also joined by several Brazilian authorities, including The National Institute of Metrology, Standardization and Industrial Quality (INMETRO), the Ministry of Economy, and the Ministry of Health. The event had 184 registrants. The first day of the workshop was dedicated to providing a general overview on the GRP process and its connection with international trade, while the second day used a set of round tables and panels to cover topics more in depth. Those discussion sessions were titled "Outlook of the Regulatory Process in Brazil," "Changes in the Brazilian Regulatory Process," and "The Future and the Inclusion of New Technologies in the GRP Process." See Section 3, *Stakeholder Participation and Involvement*, for further breakdown of the workshop and its attendees.

Colombia: Throughout Q1, MDRC coordination with the USAID Mission to Colombia led to rapid expansion of outreach in the project country. The Mission agreed to champion outreach with MDRC to government stakeholders, facilitating conversations between the Government of Colombia (GoC) and MDRC.

On 22 January 2021, MDRC and the Mission jointly met with the National Food and Drug Surveillance Institute (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA). MDRC introduced INVIMA to the second phase of the Standards Alliance and discussed the role MDRC could play in advancing the 2021 regulatory agenda of the Ministry of Health (MOH). On 26 March, INVIMA and MDRC met again to align topics of interest ahead of a scheduled meeting with MOH in April. The MDRC team stressed the importance properly implementing GRPs as essential to the success of all projects and the effective utilization of resources – in addition to ensuring compliance with country specific and WTO/TBT & OECD obligations. INVIMA proposed the following topics as priorities for subsequent meetings: Clinical Investigations, GMPs pursuing full recognition of ISO13485 and MDSAP rather than producing a local regulation, and the need to develop competencies on GRPs. MDRC and INVIMA agreed to work towards developing a specific training for INVIMA incumbents, and for INVIMA to generate a status report regarding the challenges addressed by SA Phase 1 in Colombia.

Following an introductory meeting with the Ministry of Finance on 28 January, MDRC and the Mission met with Colombian Ministries of Finance and Foreign Affairs on 23 and 26 of February, respectively. After being introduced to MDRC and its potential operations in Colombia, members of the Ministry of Finance agreed to align approaches, share project progress, and periodically connect with MDRC. Following MDRC's meeting with the Ministry of Foreign Affairs, the Ministry decided to continue discussions internally before assigning a point contact for MDRC project coordination.

Thereafter, MDRC continued to develop relationships with stakeholders in Colombia, meeting with the National Planning Department (Departamento Nacional de Planeación, DNP) on 1 March. Representatives from the DNP were extremely interested in the project, committing to align approaches with the MOH and INVIMA.

Following the meeting with the DNP, MDRC met with the Colombian Institute of Technical Standards and Certification (Instituto Colombiano de Normas Técnicas y Certificación, ICONTEC) on 3 March. ICONTEC welcomed the project and discussed how the organization could help advance MDRC objectives. MDRC and ICONTEC conducted a follow-up meeting on 19 March. There, all parties worked to identify specific items and areas of interest where MDRC can prioritize engagement and optimize the advancement of project outcomes in the country. That discussion included how best to align approaches between ICONTEC, INVIMA, and MOH, a potential future workshop on developing specific policies related to adopting international standards, and increasing industry participation in technical committees. ICONTEC and MDRC will continue to work jointly to advance GRPs and medical device standardization in Colombia.

Mexico: On 11 March, the USAID Mission to Mexico provided concurrence for MDRC, enabling the project to proceed with pursuing all outputs associated with Mexico and permitting formal outreach to relevant government agencies.

ANSI conducted formal outreach to Dirección General de Normas (DGN) of the Ministry of Economy, the standards body for Mexico, on 17 March. Thereafter, on 25-26 March, MDRC sent outreach letters to a series of Mexican Government ministries and agencies, including the Ministries of Finance, Economy, and Health.

While outreach and coordination with Mexican government extended to a number of ministries and agencies, MDRC has prioritized project collaboration with the Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS). On 26 March, MDRC formally met with COFEPRIS. 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. In order to maximize the level of collaboration between MDRC and the Government of Mexico, MDRC and COFEPRIS are in the process of developing a memorandum of understanding (MOU). This MOU lays the groundwork for continual engagement with COFEPRIS that will enable the advancement of GRPs and medical device regulatory capacity building in the project country. The MOU is a significant step forward in advancing project objectives in Mexico.

Southeast Asia

While MDRC has successfully secured USAID Mission concurrence and conducted formal outreach to government agencies in Vietnam, efforts remain underway to gain concurrence from the Mission to Indonesia. Following consultations with the USAID Mission to Thailand, MDRC will focus project resources toward Vietnam and Indonesia for the remainder of the project. Please see the below sub-section on Thailand and section 2.3 *Implementation Challenges* for more information on this development and its impacts for the MDRC project design.

Regional: On 19 and 22 February, AdvaMed participated as an observing member of the U.S. delegation to the meetings of the APEC Subcommittee on Standards and Conformance (SCSC). The delegations from Mexico and Peru also participated in the SCSC meetings. Participants discussed topics related to the scope of the MDRC, including GRP and TBT compliance. MDRC aims to dovetail its work with Mexico and Peru regarding SCSC activities in a complementary, non-duplicative and synergistic fashion.

Vietnam: The USAID Mission to Vietnam provided concurrence to the MDRC project on 13 January. Thereafter, MDRC opted to delay outreach to Vietnamese government agencies to account for changes in government appointments following the 13th National Congress of the Communist Party of Vietnam and the Tet holidays in the second week of February. MDRC conducted comprehensive outreach to relevant ministries and standards bodies in Vietnam on 16 March.

On 15 January, ANSI conducted outreach to STAMEQ's Directorate for Standards, Metrology and Quality of Vietnam. MDRC met with STAMEQ on 8 February, where the MDRC introduced the project to the standards body. On 17 March, STAMEQ confirmed its willingness to collaborate with MDRC in advancing project outputs, such as promoting the use of international standards, in Vietnam and the greater region.

On 6 March, MDRC introduced the project to representatives of the US Foreign Commercial Service (FCS) in Vietnam. MDRC sought feedback from the FCS on future stakeholder engagement and secured a commitment from FCS to review and provide comments on Phase One MDRC Vietnam outputs. For additional information on these outputs, please see the sub-section below titled *Other Notable Progress*.

MDRC has been submitted for inclusion under the US-ASEAN Business Council's (USABC) ongoing Memorandum of Understanding (MOU) with the Vietnam Ministry of Health (MOH) on 6 March. This submission aims to raise the profile of MDRC and increase engagement with MOH on project outputs in the near and long-term.

Indonesia: On 23 February, MDRC met with the USAID Mission to Indonesia. MDRC and the Mission discussed projected MDRC outputs/outcomes in the project country, including potential avenues for collaboration. The Mission suggested MDRC secure an Indonesian "host" representative within the government to act as an anchor for the project and emphasized the importance of having a local contact on the ground. On 22 March, MDRC conducted a follow-up call with the Mission, where the parties discussed recent developments and challenges to potential MDRC work in the country. MDRC's partnership with a "host" agency remained of primary importance to the Mission.

On 17 March, MDRC introduced the project to the FCS Standards Attaché for ASEAN in Indonesia and the Commercial Specialist at the US Embassy in Indonesia. The FCS voiced support for the project. MDRC sought guidance on remedying the Mission's aforementioned concerns. The Commercial Specialist at the Embassy offered to act as a local liaison for the project. Further, the Standards Attaché suggested leveraging future local USTDA presence as additional support.

The Mission and MDRC continue to work towards a resolution where local stakeholders maintain a key role in advancing MDRC objectives. MDRC is preparing a concurrence memo for the Mission's review which will outline ongoing work in the project country as well as how MDRC may align with and reinforce those activities.

On March 30, ANSI held a preliminary meeting with The National Standardization Body of Indonesia (Indonesian: Badan Nasional Standardisasi, BSN). BSN was interested in learning more about potential collaboration with MDRC to advance GRPs, both in Indonesia and APEC. MDRC will await Mission concurrence prior to conducting follow-up meetings with BSN.

Thailand: MDRC met the USAID Mission to Thailand on 4 February to introduce the MDRC and how it may align with ongoing local initiatives. The Mission informed MDRC on 10 February that Thailand will not partner with MDRC. The Royal Thai Government (RTG) believes it is currently implementing stringent regulatory oversight in line with international standards and does not have the necessary bandwidth to partner with MDRC. Following this announcement, MDRC decided to focus efforts and resources on Vietnam and Indonesia for the remainder of the project timeline. Please see section 2.3 *Implementation Challenges* for more information on this development and its impact on MDRC project design moving forward.

Africa

MDRC continues to work with local and regional stakeholders, including industry associations and USAID Missions, to ready government outreach. MDRC has met with all three project country USAID Missions, securing concurrence from Ghana.

Regional: AdvaMed continued working with Africa Practice to assist with the implementation of Phase One project outputs in the region. In particular, Africa Practice is supporting MDRC's production of an assessment of existing GRP policies in the region's project countries as well as maps of their relevant stakeholders responsible for or involved in (1) the implementation of GRP, and (2) the implementation of medical device regulations, standards, and requirements. These outputs are nearly complete and will be finalized in early Q2 2021. Please see *Other Notable Progress* below for additional information on MDRC Gap Analysis and Stakeholder Mapping reports.

On 8 February, MDRC met with Mecomed, the medical devices, imaging and diagnostics trade association for Middle East and Africa. Mecomed committed to future engagement with MDRC, including providing input on Phase One outputs, circulating information on Tier Two gaps/priorities in

the African project countries, and collaborating on curriculum development for MDRC planned trainings in the region. MDRC and Mecomed met again on 24 March, where they continued to align on both the process and scope of partnership on this project. The two groups discussed the extent to which the industry in Africa is engaged in international standards activities and regulatory processes of the project countries. MDRC and Mecomed agreed to work together towards developing capacity building workshops geared at increasing those levels of participation and growing industry engagement related to GRPs.

Ghana: The USAID Mission to Ghana granted concurrence to MDRC on 30 December 2020. Thereafter, MDRC met with the USAID Mission to Ghana on 11 January. This meeting detailed anticipated MDRC work in the project country and established expectations for future collaboration between the Mission and project team. As MDRC works to finalize development of Phase One outputs, it will work with the Mission in Ghana to develop a special project plan for the country – a prerequisite for local government outreach.

South Africa: MDRC met with the South African Medical Device Industry Association (SAMED) and South African Laboratory Diagnostics Association (SALDA) on 21 January. The parties discussed the regulatory atmosphere in South Africa in addition to avenues of collaboration. On 28 January, SALDA expressed its desire to assist the MDRC. On 29 January, SAMED's board of directors convened and agreed to support MDRC.

On 2 February, MDRC introduced the project to the USAID Mission to South Africa. While it voiced some initial support for MDRC, the Mission is internally assessing how it can best assist the project. MDRC is working with the Mission to outline next steps for advancing project objectives. Those steps include securing concurrence and designing initial government outreach.

Kenya: On 16 February, MDRC met with and provided MEDAK, the Medical Technology Association of Kenya, with an overview of the project. MDRC and MEDAK discussed the regional scope of the project as well as how MDRC may align its efforts with ongoing initiatives and the US trade negotiations with Kenya. As MDRC works to complete its Phase One outputs, MDRC and MEDAK intend to connect again to discuss MEDAK's future relationship with MDRC.

On 24 March, MDRC met with the USAID Mission to Kenya, where the parties discussed MDRC objectives in the project countries and broader region. The Mission representatives agreed with the importance of the initiative and are seeking internal confirmation whether concurrence is required to partner with MDRC. MDRC anticipates government outreach to commence in Q2.

Other Notable Progress

MDRC continued to advance Phase One and Two project outputs in all project regions. In Southeast Asia, MDRC has continued to develop the Tier One and Two literature review and stakeholder mapping reports. MDRC has sought input from FCS representatives in Indonesia and Vietnam on the respective Tier One outputs. On 23-24 March, MDRC shared its draft African Phase One Tier One country reports and Tier Two stakeholder maps 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. These organizations are expected to provide feedback in the first weeks of Q2.

MDRC is packaging and will soon present the findings of its Tier One gap analyses and literature reviews from all project countries in a unified Tier One report. This report will include 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. Moreover, the Tier One report will be supplemented by stakeholder maps for each project country in Southeast Asia and Africa. These maps outline all relevant stakeholders in the project countries responsible for or involved in the implementation of medical device regulations, standards, and requirements at the Tier Two level, both nationally and regionally.

In the development of these resources, MDRC is incorporating input from stakeholders across each region, including from industry associations, USAID Missions, and US government agencies like the FCS in Indonesia and Vietnam. As stakeholders continue to review these resources, MDRC expects to integrate input and complete the reports in early Q2 2021.

AFRICA

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

In Q1 of the Standards Alliance Phase 2, ANSI and Ethical Apparel Africa (EAA) hired Jeffery Stulls of International Personal Protection, Inc. as a technical consultant to lead the project to establish production of surgical grade Personal Protective Equipment (PPE) within Ghana to supply the West African region and to develop a sales pipeline of export to the USA.

During Q1, Mr. Stulls worked with EAA to develop an action plan for a series of train-the-trainer activities for EAA staff. These trainings will occur in Q2 and support managerial-level understanding of the best practices for PPE production. Following the first round of trainings, EAA management staff, under Mr. Stull's remote supervision, will provide technical trainings for all EAA staff and relevant Ghanaian government agencies including the Ghana FDA and Ghana Standards Authority (GSA).

Achievements to Date

- 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.
- Widely sourced for machinery and material to enable production of surgical masks meeting the above specs, in the face of global shortages
- Procured with USAID support a reliable and available machinery source for a machinery system of surgical mask production. This machinery has been specifically chosen to ensure quality construction (ultrasonic welding).
- 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
- Researched options to secure welding machines for the production of disposable gowns and scrubs.
- Tendered and signed contract for the production of an ISO Level 7 Cleanroom

Challenges and Mitigating Actions

- EAA received equipment funding from a partner source significantly later than planned. This delayed the production and shipment of the cleanroom, which will now leave Ghana end of

October and construction of the Cleanroom has been delayed and therefore production of the surgical mask sampling will also be delayed until post-Christmas.

2.3 Implementation Challenges

Overall, ANSI the main challenge in Q1 2021 is the on-going COVID-19 pandemic. However, ANSI has been implementing work virtually and adjusts activity schedules accordingly. ANSI continues to closely monitor travel and meeting capabilities.

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

A major challenge to MDRC implementation has been overcoming delays related to securing USAID Mission concurrence across a number of project countries. For example, the USAID Mission to Thailand informed MDRC on 10 February that the RTG believes it is currently implementing stringent regulatory oversight in line with international standards and that it does not have the necessary bandwidth to partner with MDRC. This follows internal discussions and consultations between the Mission and key interlocutors in the RTG, such as the Thai FDA.

In AdvaMed communication with the FDA on Jan 21, the FDA concurred with the MDRC assessment that Thailand is not currently implementing stringent regulatory oversight in line with international standards.

Since this development, MDRC has undertaken consultations internally and with local stakeholders to develop a course of action that simultaneously produces the most effective outcomes regionally and strengthens the project's work in Indonesia and Vietnam. MDRC has determined that it will focus attention and resources towards Vietnam and Indonesia for the remainder of the project timeline. MDRC expects this decision to optimize the project team's ability to deliver on regional and project country-specific outcomes, including hosting regional and local Tier Two trainings scheduled throughout the remainder of this project.

AdvaMed will also closely monitor the impact of COVID-19 on travel capabilities in 2021 to ensure the achievement of capacity-building objectives. Preparations are already underway to establish virtual capacity-building resources and tools to mitigate potential challenges in this area, should they arise.

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. ANSI is working with relevant stakeholders to finalize a few final subcontracts. Activities with finalized proposals have begun stakeholder outreach to promote the program, establish the scope and further plan implementation.

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

The Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector

In Latin America, the Coalition continued to play a critical part in expanding stakeholder engagement with MDRC. As discussed briefly in Section 2, on 16-17 March, the Coalition hosted a "Workshop on GRPs and International Trade" for Brazilian stakeholders across the public, private, and academic sectors. The workshop was co-hosted and supported by local associations representing the medical technology sector and joined by several Brazilian government authorities. The event had 184 registrants.

A significant number of these stakeholders played an active role in the hosting of the workshop and development of its curriculum. On 16 March, the workshop featured a panel titled "Commitments of Brazil before the WTO and GRPs." This panel was moderated by José Márcio Cerqueira Gomes, Executive Director of ABIIS, who conducted the discussion with Léa Contier, from Brazil's focal point INMETRO, and Juliana Ghizi Pires, who coordinates the work of the Brazilian government on GRP and international trade at the Ministry of Economy. On 17 March, the workshop featured a set of round tables titled "Outlook of the Regulatory Process in Brazil," "Changes in the Brazilian Regulatory Process," and "The Future and the Inclusion of New Technologies in the GRP Process." These round tables included panelists from ABIIS, ABIMED, ABRAIDI, CBDL, the Brazilian Ministry of Economy, INMETRO, Ministry of Health, Boston Scientific, the State University of Paraíba, and the University of Brasilia.

The Coalition continued to support 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 will reinforce Phase One and Two regional outputs and may encourage greater participation in MDRC-related activities by both public and private sector entities.

United States

Throughout Q1 2021, MDRC continued to expand collaboration with US Government stakeholders.

MDRC and the Coalition frequently engaged with the US FDA to share MDRC project developments and advance the project in Latin America. On 29 January, the Coalition and AdvaMed shared with the FDA the outcomes of Coalition's meeting PAHO earlier that day and coordinated on the content of their respective presentations to the DIA's annual event in late February (outlined in Section 2). On 19 February, MDRC discussed opportunities for collaboration with the FDA in 2021, including a shared interest in hosting a joint training program on ISO 13485 for Latin America in Q2. MDRC continued brainstorming on a training workshop with the FDA on 23 February, discussing the utilization of ISO 13485 by regulators, leveraging updated electronic reporting systems to assist the transition from CFR-820 to ISO 13485. Following that conversation, on 5 March, MDRC shared the first draft of this workshop, which is tentatively scheduled for June 2021 and lists FDA and ANVISA as co-hosts with ANMAT as an invitee, to be open for INVIMA, DIGEMID, COFEPRIS and ISP, along with the private sector in those countries. In that meeting, MDRC also shared (1) an overview of the challenges companies are facing regarding consularization of legal documents due to personnel resourcing difficulties, and (2) a proposal by ANDI for the FDA to participate in a Q&A session. MDRC and FDA resumed discussions on the workshop on 8 March. On 23 March, MDRC continued the practice of sharing project updates with the FDA, discussing recently-held or scheduled introductory meetings with stakeholders in Latin America, such as the aforementioned meeting with COFEPRIS on 26 March.

MDRC also engaged the US Department of Commerce, meeting with Ian Saunders, Deputy Assistant Secretary of Commerce for the Western Hemisphere along with seven senior members of his team, on 18 March. After hearing an introductory presentation on the project, Commerce agreed to support MDRC both from Washington, DC as well as from posts across Latin America. Ian Saunders also committed to elevating the importance of GRPs and Regulatory Convergence in the medical technology sector as part of his discussions with the U.S. Department of State in identifying priorities and outcomes

for the US-hosted Summit of the Americas.

4. RESULTS ACHIEVED

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

Global

- On 12 January, the MDRC Tier Two team held a call with the MTaPS team to explore synergies and ensure that any and all medical technology related bottlenecks they have identified will be addressed by MDRC efforts (IR 2.1, IR 3.1). During this meeting, it was confirmed that the project countries are virtually distinct and where there is overlap, MTaPS does not address medical technologies. The two teams committed to sharing relevant technical findings with each other moving forward, with MTaPS pledging to flag any medical technology-related aspects they identify for the MDRC team.

Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector

- The Coalition continued to support efforts by the IDB to undertake a survey of GRP in Latin American project countries (Activity 1.1.6.1), reinforcing the objectives of the Tier One and Two gap analysis. This survey 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).
- Between 22 and 24 February, the Coalition participated in two sessions addressing regulatory convergence (IR 1.1), GRPs (IR 1.1, IR 1.2, IR 2.1, IR 3.1, Output 3.1.1), and emergency responses to COVID-19 (DO 4) during the Drug Information Association's Annual Latin America Regulatory Conference.
- On 16-17 March, the Coalition hosted a Workshop on GRPs and International Trade for a series of Brazilian stakeholders across the public, private, and academic sectors. The workshop was co-hosted and supported by local associations representing the medical technology sector (Output 2.1.1, Activity 2.1.1.1, Output 2.1.3, Output 2.1.4, Activity 2.1.4.1, Output 2.1.5), and was joined by several Brazilian government authorities (Activity 1.1.4.1, Output 1.1.4, Activity 1.1.7.1). The event had 184 registrants, most of them from medical devices companies (IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.3, Activity 2.1.3.1).

Latin America

- MDRC met with representatives from PAHO on 29 January to discuss how to work towards increased coordination between them (IR 1.1, IR 1.2, IR 3.1, CC IR 2.1). The Coalition's formal application to be recognized as a Non-State Actor under PAHO's FENSA process remains under review.
- Brazil
    - The Coalition sent formal outreach letters on behalf of MDRC to relevant government agencies and ministries in Brazil on 7-8 January (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - On 21 January, MDRC met with ABNT, which voiced support for MDRC. ABNT indicated desire to partner with regulatory stakeholders and assist with the creation of a gap analysis outlining GRPs and international standards in Brazil (Output 1.1.1, Output 1.1.2, Output 1.1.3, IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1).
    - MDRC conducted follow-up meetings with ABNT, on 3 and 10 February. The parties

continued discussions on working toward deeper collaboration with MDRC, including the possibility of formalizing ABNT membership in the Coalition (Output 2.1.1, Activity 2.1.1.2). ABNT and MDRC also discussed the recent developments in INMETRO/ANVISA medical technologies technical regulations, establishing ABNT in a regional coordination role as a part of MDRC, and ABNT's facilitation of a joint introductory session of MDRC to INMETRO (Output 1.1.1, Output 1.1.2, Output 1.1.3, IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1).

- Colombia
  - Throughout Q1 2021, the USAID Mission in Colombia has supported MDRC by sending outreach letters on behalf of the project to local government stakeholders and coordinating subsequent introductory meetings (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
  - On 22 January, MDRC and the USAID Mission to Colombia met with INVIMA, the Colombian medical device regulatory authority (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1). MDRC introduced INVIMA to the project, and discussed how MDRC could help advance the 2021 regulatory agenda of the Ministry of Health.
  - On the 23 and 26 of February, MDRC and the Mission held introductory meetings with with Colombian Ministries of Finance and Foreign Affairs, respectively. Members of the Ministry of Finance agreed to collaborate in the future, with MDRC consenting to share project process periodically (IR 1.1).
  - MDRC met with the DNP on 1 March. The DNP was receptive, committing to align approaches with the Colombian Ministry of Health and INVIMA (IR 1.1, IR 3.1, DO 4).
  - On 3 March, MDRC met with ICONTEC. ICONTEC welcomed the project and discussed how the organization could help advance MDRC objectives – including confirming a high-level partnership and jointly working to advance GRPs (IR 1.1, Output 1.1.4, IR 2.1, Output 2.1.1, Output 2.1.5, IR 3.1, Output 3.1.1) and medical device standardization in Colombia (DO 4).
  - On 19 March, MDRC conducted a follow-up meeting with ICONTEC. All parties worked to identify specific items and areas of interest where MDRC can prioritize engagement and optimize the advancement of project outcomes in the country (Output 1.1.1, Output 1.1.2, Output 1.1.3). They discussed how best to align approaches between ICONTEC, INVIMA, and MOH (Output 1.1.4, Output 1.1.6), a potential future workshop on developing specific policies related to adopting international standards (Activity 1.1.3.1, Activity 1.1.4.1, Activity 1.1.7.1), and increasing industry participation in technical committees (Activity 1.1.2.1, IR 2.1).
  - The Coalition met with MinCIT on March 25 to address the regulatory process regarding the UDI Semantic Standard, a concrete trial case for the proper implementation of GRP and use of international standards for medical device regulatory convergence (IR 1.1, IR 3.1).
  - MDRC met with INVIMA on 26 March, where the parties worked to align topics of interest ahead of their joint meeting with Ministry of Health in April. The MDRC team highlighted the importance properly implementing GRPs and ensuring compliance with country specific and WTO/TBT & OECD obligations (IR 1.1, Output 1.2.2).
- Mexico
  - On 11 March, the USAID Mission in Mexico provided concurrence to the project, enabling MDRC move forward with all outputs and permitting formal outreach to government ministries and agencies (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
  - On 17 March, ANSI conducted formal outreach to Dirección General de Normas (DGN) of the Ministry of Economy, the standards body for Mexico (Output 1.1.1,

Output 1.1.2, Output 1.1.3).
    - On 25-26 March, MDRC sent outreach letters to a broader series of government ministries and agencies, including Finance, Economy, and Health (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - On 26 March, MDRC met with COFEPRIS. In this meeting, the parties discussed the timeliness and importance of MDRC as well as challenges unique to Mexico in the medical technology sector (IR 1.1, IR 3.1), compliance with treaty obligations, and underutilization of Equivalence Agreements (IR 1.1, IR 2.1, IR 3.1, IR 4.1). COFEPRIS and MDRC are finalizing an MOU which will formalize partnership between the Government of Mexico and MDRC in advancing project objectives (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- Peru
    - The Coalition sent formal outreach letters on behalf of MDRC to relevant government agencies and ministries on 13-14 January (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - MDRC introduced the project to the Ministry of Foreign Trade and Tourism (MinCETUR) on 23 March, where the team emphasized the differences between the pharmaceutical and medical device industries as well as the use of international standards (IR 1.1, IR 3.1). The parties also discussed MinCETUR's potential role in MDRC implementation.

Southeast Asia

- The project team has continued to advance efforts to complete the Tier One and Two literature review and stakeholder report (IR 1.1, Activity 1.1.6.1, IR 2.1, Activity 2.1.2.1).
- On 19 and 22 February, AdvaMed participated as an observing member of the U.S. delegation to the meetings of the APEC Subcommittee on Standards and Conformance (SCSC). Participants, including delegations from Mexico and Peru, discussed topics related to the scope of the MDRC, including GRP and TBT compliance (IR 1.1, IR 3.1).

- Vietnam
    - The USAID Mission to Vietnam provided concurrence to the MDRC project on 13 January. Concurrence enables MDRC to move forward with all project outputs associated with these countries, permitting formal outreach to relevant government ministries and agencies (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - On 15 January, ANSI conducted outreach to STAMEQ. MDRC met with and introduced the project to STAMEQ on 8 February. STAMEQ agreed to collaborate with MDRC in advancing project outputs on 17 March. This coordination will include promoting the use of international standards in Vietnam and greater region. (Output 1.1.1, Output 1.1.2, Output 1.1.3).
    - On 6 March, MDRC introduced the project to representatives of the US Foreign Commercial Service in Vietnam. MDRC sought input from those representatives on future engagement and secured commitment from the officers to review Phase One outputs (IR 1.1, Output 1.1.6, Activity 1.1.6.1, IR 2.1, Output 2.1.2, Activity 2.1.2.1).
    - On 6 March, MDRC was submitted for inclusion under the US-ASEAN Business Council's (USABC) MoU with the Vietnam Ministry of Health (MOH). This aims to raise the profile of MDRC and increase opportunities for MDRC engagement with the MOH. USABC has acknowledged receipt of the submission. (IR 1.1, IR 2.1, Output 2.1.1, Output 2.1.2, Output 2.1.3, DO 4, IR 4.1).

- MDRC conducted outreach to relevant government ministries in Vietnam on 16 March (IR 1.1, IR 1.2, IR 3.1, DO 4, Crosscutting IR 2.1). This comes after the USAID Mission to Vietnam provided concurrence to the MDRC project on 13 January, and MDRC opted to delay formal outreach to Vietnamese agencies until after February to account for changes in government appointments as well as the Tet holidays.

- Indonesia
  - MDRC met with the USAID Mission to Indonesia on 23 February and 22 March, where the parties discussed projected MDRC outputs/outcomes and avenues for and challenges to progress (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
  - MDRC met with the US Foreign Commercial Service's (FCS) Standards Attaché for ASEAN in Indonesia and the Commercial Specialist for the US Embassy in Indonesia on 17 March. The discussion underscored the FCS, US Trade and Development Agency (USTDA), and US companies' strong interest in and support for MDRC's objectives in the region, particularly as they relate to GRPs (IR 2.1).
  - On March 30, ANSI held a preliminary meeting with BSN to discuss potential collaboration with MDRC to advance GRPs (IR 1.1). MDRC will await Mission concurrence prior to conducting follow-up meetings with BSN.
- Thailand
  - MDRC met with the USAID Mission to Thailand on 4 February, in which the team introduced the Mission to MDRC and aligning with ongoing initiatives. The Mission informed MDRC on 10 February that Thailand should not serve as a project country under MDRC at this time and concurrence would not be issued (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).

Africa

- AdvaMed continues to work with Africa Practice in the implementation of Phase One project outputs. Africa Practice is supporting MDRC's production of an assessment of existing GRP policies in the region's project countries as well as maps of their relevant stakeholders responsible for or involved in (1) the implementation of GRP, and (2) the implementation of medical device regulations, standards, and requirements (IR 1.1, Activity 1.1.6.1, IR 1.2, IR 2.1, Activity 2.1.2.1). These outputs are planned for completion in early Q2 2021.
- On 8 February, MDRC met with Mecomed, which committed to future engagement with MDRC. Mecomed agreed to circulate information on Tier Two gaps/priorities in the African project countries, and collaborate with MDRC on curriculum development for planned trainings in the region (Output 2.1.1, Output 2.1.2, Output 2.1.4, Output 2.1.5, Output 2.1.5.1).
- MDRC conducted a follow-up meeting with Mecomed on 24 March, where the two groups continued to align on both the process and scope of partnership on this project. MDRC and Mecomed agreed to work together towards developing capacity building workshops geared at increasing levels of industry participation in international standards activities and engagement with government related to GRPs (IR 1.1, IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.2, Output 2.1.5, Activity 2.1.5.1).
- On 23-24 March, MDRC shared Phase One draft country reports with local and industry stakeholders in Africa for their review and input, including the USAID Missions to Kenya and Ghana, Mecomed, MEDAK, SAMED, and SALDA. These organizations are expected to provide feedback by early Q2 2021 (IR 1.1, Activity 1.1.6.1, IR 2.1, Output 2.1.2, Activity 2.1.2.1).
- Ghana
  - The USAID Mission to Ghana provided concurrence to the MDRC project on 30 December. Concurrence enables MDRC to move forward with all project outputs associated with these countries, permitting formal outreach to relevant government ministries and agencies (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
  - MDRC met with the USAID Mission to Ghana on 11 January. This meeting detailed

anticipated MDRC work in the project country and established expectations for future collaboration with the Mission (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).

- South Africa
  - MDRC met with SAMED and SALDA on 21 January. The parties discussed the regulatory atmosphere in South Africa in addition to potential avenues of collaboration with MDRC (Output 2.1.1, Output 2.1.5, IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1). SALDA expressed its desire to assist the MDRC on 28 January and SAMED's board of directors agreed to support MDRC on 29 January.
  - On 2 February, MDRC introduced the project to the USAID Mission to South Africa. MDRC is working with the Mission assess next steps, including securing concurrence and designing initial 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).
- Kenya
  - On 16 February, MDRC introduced MEDAK to the project. MDRC and MEDAK discussed the regional scope of the project and how MDRC may align its efforts with ongoing initiatives and US trade negotiations with Kenya (Output 2.1.1, Output 2.1.2, Output 2.1.3, Output 2.1.5, Output 2.1.5.1).
  - On 24 March, MDRC met with the USAID Mission to Kenya. MDRC and the Mission discussed MDRC objectives in Kenya and broader region. The Mission committed to reviewing and providing feedback on MDRC's draft Phase One reports/resources (IR 1.1, Activity 1.1.6.1, IR 2.1, Activity 2.1.2.1).

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 #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 newly-acquired Zoom license to interact with actors across the public and private sectors. Moving forward, the Zoom platform will also facilitate more timely and streamlined connectivity and communication across the languages of English, Portuguese and Spanish. In preparation for and execution of a virtual training workshop (*See Section 2 Brazil, Section 3*), MDRC has broadened its institutional knowledge for online capacity building and using digital tools to advance MDRC objectives.

Over the regular course of Coalition website maintenance, MDRC is working to optimize the level of resources devoted to running the Coalition's online presence. While it requires higher levels of time investment than previously anticipated, the Coalition's online modules and virtual resource library have proven to be an invaluable tool for housing and disseminating information vital to the project.

In order to avoid any unnecessary delays, MDRC will work to ensure stakeholders are provided

with all relevant information on the project prior to any introductory meetings. By providing full context in advance of such meetings, MDRC prevents any avoidable confusion among attendees

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Q2 2021 Planned Activities

Activity #	Activity Name	Meeting/Event	Date	Location	USAID participation?
2	Support for ARSO	Webinar #2 on April 16th with PCPC focusing on the implementation of cosmetic frameworks with a focus on South African case study	April 16, 2021	Virtual	Optional
2	Support for ARSO	Webinar #3/10 on May 11: details pending	May 11, 2021	Virtual	Optional
12	MDRC	Virtual Meeting - Engagement with External Stakeholders	May 18, 2021	Virtual	No
12	MDRC	Medical Device Webinar Series • 02 June 21 - Part I - ISO 13485 and MDSAP Audit Model • 10 June 21 - Part II - MDSAP Inspections • 17 June 21 - Part III - Leveraging MDSAP audits outcomes • 24 June 21 - Part IV - Regulators Only - Recap and Feedback Session - Facilitated by FDA and Anvisa: ○ ANMAT ○ ISP ○ INVIMA ○ COFEPRIS ○ DIGEMID	June 2, 10, 17, and 24, 2021	Virtual	No
12	MDRC	Webinar GRPs - Peru - June	June (final date pending)	Virtual	No

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

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

Building on the productive cross-coordination and exchanges between USAID, ANSI, and AdvaMed and entities across the U.S. Government – including FDA, USTR, Commerce, TDA, and others – MDRC will also work to broaden support for project objectives.

MDRC intends to build on recent and frequent meetings with governments, NSBs, and industry associations in Africa, Latin America, and Southeast Asia to encourage collaboration on specific, actionable trainings and capacity-building exercises. Moreover, MDRC will continue preparations in Q2 for trainings and forums in Southeast Asia and Africa. In Africa, this includes a Tier One regional forum as well as Tier One & Two local meetings/trainings for Kenya and Ghana. In Southeast Asia, MDRC will advance the groundwork for a COVID-19 medical device regulatory review conference with the IMDRF with targeted sessions for project countries in the region, a Tier Two regional meeting/training with medical device regulators in Vietnam, and an additional local session with Vietnam medical device regulators on Tier Two.

7. ANNEX

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

8. 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 January – 31 March 2021

8.1 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.

9. ACTIVITY IMPLEMENTATION PROGRESS

9.1 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 Q1 2021. MDRC has conducted formal outreach to government agencies in all Latin American project countries and secured USAID Mission concurrence from Colombia and Mexico.

Regional: The Coalition and broader MDRC team met with the Pan American Health Organization (PAHO) on 29 January. The Coalition and PAHO discussed how to work towards increased cooperation in a manner that supports both parties' efforts while not duplicating or obstructing existing initiatives. Following the meeting, the Coalition submitted its formal application to be recognized as a Non-State Actor under PAHO's FENSA process. This process remains underway. Once approved, the Coalition can deepen collaboration with PAHO.

Between 22 and 24 February, the Drug Information Association (DIA) held their Annual Latin America Regulatory Conference. There, global regulators, industry, and academia engaged in a series of discussions on the current regulatory landscape, globalization, and harmonization initiatives in Latin America. The Coalition participated in two sessions addressing regulatory convergence, GRPs, and emergency responses to COVID-19. During the first session, titled "Reliance and Regulatory System Strengthening," the Latin American Federation of the Pharmaceutical Industry (FIFARMA) and the Coalition issued a joint message on the relevance of reliance and recognition in the pharmaceutical and medical technology sectors. Both organizations emphasized that proper differentiation between the two sectors is required for their proper regulation. During the second session, titled "Regulatory Convergence in Pandemic Situations," the Coalition spoke to the need for a holistic approach to regulatory convergence. Such an approach maximizes the inclusion of all relevant stakeholders and the implementation of GRPs. Thereafter, the Brazilian National Health Surveillance Agency (ANVISA) shared lessons learned on the challenges posed by the COVID-19 pandemic from the perspective of a regulator.

To solidify the gains made throughout Q1 2021, the Coalition further strengthened its online module development and virtual resource library, which can be accessed here: https://interamericancoalition-medtech.org/regulatory-convergence/. Throughout Q1, the Coalition website saw a steady increase in website traffic with a total of 1,637 visits between January and March. This represents a 32% increase from Q4 2020. These advances position the Coalition as a leader in building the capacity of project countries for standards and conformity assessment procedures and in fostering private sector engagement in the medical technology regulatory convergence.

Peru: On 13-14 January, the Coalition conducted outreach with government ministries and agencies in Peru. Since initial outreach, MDRC has continued to coordinate with the USAID Mission to Peru and private sector stakeholders, setting the stage for MDRC to advance relevant objectives in the project country.

Brazil: On 7-8 January, the Coalition conducted outreach on behalf of MDRC to the Brazilian Ministries of Foreign Affairs, Health, and Trade. Further, outreach was sent to INMETRO, the

Advocacy and Competition Law Secretariat of the Ministry of Economy (SEAE), the Special Secretary of Debureaucratization, Management and Digital Government of the Ministry of Economy, and ANVISA.

The MDRC project team met with ABNT, the Brazilian National Standards Organization on 3 and 10 February. During these meetings, ABNT presented on its initiatives related to medical device standardization, ABNT's relationships with SDOs and NSBs, and the recent developments in INMETRO/ANVISA medical technologies and technical regulations. ABNT agreed to help conduct a joint introductory session with MDRC on the project to INMETRO. In early Q2, ABNT and MDRC intend to reconvene with the objective of working toward a convergence of scope and efforts, including the possibility of formalizing ABNT membership in the Coalition.

On 16-17 March, the Coalition hosted a workshop on GRPs and International Trade for a series of Brazilian stakeholders across the public, private, and academic sectors. The workshop was co-hosted and supported by local associations representing the medical technology sector, including ABIMED, ABIIS, ABRAIDI and CBDL. The workshop was also joined by several Brazilian authorities, including The National Institute of Metrology, Standardization and Industrial Quality (INMETRO), the Ministry of Economy, and the Ministry of Health. The event had 184 registrants. The first day of the workshop was dedicated to providing a general overview on the GRP process and its connection with international trade, while the second day used a set of round tables and panels to cover topics more in depth. Those discussion sessions were titled "Outlook of the Regulatory Process in Brazil," "Changes in the Brazilian Regulatory Process," and "The Future and the Inclusion of New Technologies in the GRP Process." See Section 3, *Stakeholder Participation and Involvement*, for further breakdown of the workshop and its attendees.

Colombia: Throughout Q1, MDRC coordination with the USAID Mission to Colombia led to rapid expansion of outreach in the project country. The Mission agreed to champion outreach with MDRC to government stakeholders, facilitating conversations between the Government of Colombia (GoC) and MDRC.

On 22 January 2021, MDRC and the Mission jointly met with the National Food and Drug Surveillance Institute (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA). MDRC introduced INVIMA to the second phase of the Standards Alliance and discussed the role MDRC could play in advancing the 2021 regulatory agenda of the Ministry of Health (MOH). On 26 March, INVIMA and MDRC met again to align topics of interest ahead of a scheduled meeting with MOH in April. The MDRC team stressed the importance properly implementing GRPs as essential to the success of all projects and the effective utilization of resources – in addition to ensuring compliance with country specific and WTO/TBT & OECD obligations. INVIMA proposed the following topics as priorities for subsequent meetings: Clinical Investigations, GMPs pursuing full recognition of ISO13485 and MDSAP rather than producing a local regulation, and the need to develop competencies on GRPs. MDRC and INVIMA agreed to work towards developing a specific training for INVIMA incumbents, and for INVIMA to generate a status report regarding the challenges addressed by SA Phase 1 in Colombia.

Following an introductory meeting with the Ministry of Finance on 28 January, MDRC and the Mission met with Colombian Ministries of Finance and Foreign Affairs on 23 and 26 of February, respectively. After being introduced to MDRC and its potential operations in Colombia, members of the Ministry of Finance agreed to align approaches, share project progress, and periodically connect with MDRC. Following MDRC's meeting with the Ministry of Foreign Affairs, the Ministry decided to continue discussions internally before assigning a point contact for MDRC project coordination.

Thereafter, MDRC continued to develop relationships with stakeholders in Colombia, meeting with the National Planning Department (Departamento Nacional de Planeación, DNP) on 1 March. Representatives from the DNP were extremely interested in the project, committing to align approaches with the MOH and INVIMA.

Following the meeting with the DNP, MDRC met with the Colombian Institute of Technical Standards and Certification (Instituto Colombiano de Normas Técnicas y Certificación, ICONTEC) on 3 March. ICONTEC welcomed the project and discussed how the organization could help advance MDRC objectives. MDRC and ICONTEC conducted a follow-up meeting on 19 March. There, all parties worked to identify specific items and areas of interest where MDRC can prioritize engagement and optimize the advancement of project outcomes in the country. That discussion included how best to align approaches between ICONTEC, INVIMA, and MOH, a potential future workshop on developing specific policies related to adopting international standards, and increasing industry participation in technical committees. ICONTEC and MDRC will continue to work jointly to advance GRPs and medical device standardization in Colombia.

Mexico: On 11 March, the USAID Mission to Mexico provided concurrence for MDRC, enabling the project to proceed with pursuing all outputs associated with Mexico and permitting formal outreach to relevant government agencies.

ANSI conducted formal outreach to Dirección General de Normas (DGN) of the Ministry of Economy, the standards body for Mexico, on 17 March. Thereafter, on 25-26 March, MDRC sent outreach letters to a series of Mexican Government ministries and agencies, including the Ministries of Finance, Economy, and Health.

While outreach and coordination with Mexican government extended to a number of ministries and agencies, MDRC has prioritized project collaboration with the Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS). On 26 March, MDRC formally met with COFEPRIS. 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. In order to maximize the level of collaboration between MDRC and the Government of Mexico, MDRC and COFEPRIS are in the process of developing a memorandum of understanding (MOU). This MOU lays the groundwork for continual engagement with COFEPRIS that will enable the advancement of GRPs and medical device regulatory capacity building in the project country. The MOU is a significant step forward in advancing project objectives in Mexico.

Southeast Asia

While MDRC has successfully secured USAID Mission concurrence and conducted formal outreach to government agencies in Vietnam, efforts remain underway to gain concurrence from the Mission to Indonesia. Following consultations with the USAID Mission to Thailand, MDRC will focus project resources toward Vietnam and Indonesia for the remainder of the project. Please see the below sub-section on Thailand and section 2.3 *Implementation Challenges* for more information on this development and its impacts for the MDRC project design.

Regional: On 19 and 22 February, AdvaMed participated as an observing member of the U.S. delegation to the meetings of the APEC Subcommittee on Standards and Conformance (SCSC). The delegations from Mexico and Peru also participated in the SCSC meetings. Participants discussed topics related to the scope of the MDRC, including GRP and TBT compliance. MDRC aims to

dovetail its work with Mexico and Peru regarding SCSC activities in a complementary, non-duplicative and synergistic fashion.

Vietnam: The USAID Mission to Vietnam provided concurrence to the MDRC project on 13 January. Thereafter, MDRC opted to delay outreach to Vietnamese government agencies to account for changes in government appointments following the 13th National Congress of the Communist Party of Vietnam and the Tet holidays in the second week of February. MDRC conducted comprehensive outreach to relevant ministries and standards bodies in Vietnam on 16 March.

On 15 January, ANSI conducted outreach to STAMEQ's Directorate for Standards, Metrology and Quality of Vietnam. MDRC met with STAMEQ on 8 February, where the MDRC introduced the project to the standards body. On 17 March, STAMEQ confirmed its willingness to collaborate with MDRC in advancing project outputs, such as promoting the use of international standards, in Vietnam and the greater region.

On 6 March, MDRC introduced the project to representatives of the US Foreign Commercial Service (FCS) in Vietnam. MDRC sought feedback from the FCS on future stakeholder engagement and secured a commitment from FCS to review and provide comments on Phase One MDRC Vietnam outputs. For additional information on these outputs, please see the sub-section below titled *Other Notable Progress*.

MDRC has been submitted for inclusion under the US-ASEAN Business Council's (USABC) ongoing Memorandum of Understanding (MOU) with the Vietnam Ministry of Health (MOH) on 6 March. This submission aims to raise the profile of MDRC and increase engagement with MOH on project outputs in the near and long-term.

Indonesia: On 23 February, MDRC met with the USAID Mission to Indonesia. MDRC and the Mission discussed projected MDRC outputs/outcomes in the project country, including potential avenues for collaboration. The Mission suggested MDRC secure an Indonesian "host" representative within the government to act as an anchor for the project and emphasized the importance of having a local contact on the ground. On 22 March, MDRC conducted a follow-up call with the Mission, where the parties discussed recent developments and challenges to potential MDRC work in the country. MDRC's partnership with a "host" agency remained of primary importance to the Mission.

On 17 March, MDRC introduced the project to the FCS Standards Attaché for ASEAN in Indonesia and the Commercial Specialist at the US Embassy in Indonesia. The FCS voiced support for the project. MDRC sought guidance on remedying the Mission's aforementioned concerns. The Commercial Specialist at the Embassy offered to act as a local liaison for the project. Further, the Standards Attaché suggested leveraging future local USTDA presence as additional support.

The Mission and MDRC continue to work towards a resolution where local stakeholders maintain a key role in advancing MDRC objectives. MDRC is preparing a concurrence memo for the Mission's review which will outline ongoing work in the project country as well as how MDRC may align with and reinforce those activities.

On March 30, ANSI held a preliminary meeting with The National Standardization Body of Indonesia (Indonesian: Badan Nasional Standardisasi, BSN). BSN was interested in learning more about potential collaboration with MDRC to advance GRPs, both in Indonesia and APEC. MDRC will await Mission concurrence prior to conducting follow-up meetings with BSN.

Thailand: MDRC met the USAID Mission to Thailand on 4 February to introduce the MDRC and

how it may align with ongoing local initiatives. The Mission informed MDRC on 10 February that Thailand will not partner with MDRC. The Royal Thai Government (RTG) believes it is currently implementing stringent regulatory oversight in line with international standards and does not have the necessary bandwidth to partner with MDRC. Following this announcement, MDRC decided to focus efforts and resources on Vietnam and Indonesia for the remainder of the project timeline. Please see section 2.3 *Implementation Challenges* for more information on this development and its impact on MDRC project design moving forward.

Africa

MDRC continues to work with local and regional stakeholders, including industry associations and USAID Missions, to ready government outreach. MDRC has met with all three project country USAID Missions, securing concurrence from Ghana.

Regional: AdvaMed continued working with Africa Practice to assist with the implementation of Phase One project outputs in the region. In particular, Africa Practice is supporting MDRC's production of an assessment of existing GRP policies in the region's project countries as well as maps of their relevant stakeholders responsible for or involved in (1) the implementation of GRP, and (2) the implementation of medical device regulations, standards, and requirements. These outputs are nearly complete and will be finalized in early Q2 2021. Please see *Other Notable Progress* below for additional information on MDRC Gap Analysis and Stakeholder Mapping reports.

On 8 February, MDRC met with Mecomed, the medical devices, imaging and diagnostics trade association for Middle East and Africa. Mecomed committed to future engagement with MDRC, including providing input on Phase One outputs, circulating information on Tier Two gaps/priorities in the African project countries, and collaborating on curriculum development for MDRC planned trainings in the region. MDRC and Mecomed met again on 24 March, where they continued to align on both the process and scope of partnership on this project. The two groups discussed the extent to which the industry in Africa is engaged in international standards activities and regulatory processes of the project countries. MDRC and Mecomed agreed to work together towards developing capacity building workshops geared at increasing those levels of participation and growing industry engagement related to GRPs.

Ghana: The USAID Mission to Ghana granted concurrence to MDRC on 30 December 2020. Thereafter, MDRC met with the USAID Mission to Ghana on 11 January. This meeting detailed anticipated MDRC work in the project country and established expectations for future collaboration between the Mission and project team. As MDRC works to finalize development of Phase One outputs, it will work with the Mission in Ghana to develop a special project plan for the country – a prerequisite for local government outreach.

South Africa: MDRC met with the South African Medical Device Industry Association (SAMED) and South African Laboratory Diagnostics Association (SALDA) on 21 January. The parties discussed the regulatory atmosphere in South Africa in addition to avenues of collaboration. On 28 January, SALDA expressed its desire to assist the MDRC. On 29 January, SAMED's board of directors convened and agreed to support MDRC.

On 2 February, MDRC introduced the project to the USAID Mission to South Africa. While it voiced some initial support for MDRC, the Mission is internally assessing how it can best assist the project. MDRC is working with the Mission to outline next steps for advancing project objectives. Those steps include securing concurrence and designing initial government outreach.

Kenya: On 16 February, MDRC met with and provided MEDAK, the Medical Technology Association of Kenya, with an overview of the project. MDRC and MEDAK discussed the regional scope of the project as well as how MDRC may align its efforts with ongoing initiatives and the US trade negotiations with Kenya. As MDRC works to complete its Phase One outputs, MDRC and MEDAK intend to connect again to discuss MEDAK's future relationship with MDRC.

On 24 March, MDRC met with the USAID Mission to Kenya, where the parties discussed MDRC objectives in the project countries and broader region. The Mission representatives agreed with the importance of the initiative and are seeking internal confirmation whether concurrence is required to partner with MDRC. MDRC anticipates government outreach to commence in Q2.

Other Notable Progress

MDRC continued to advance Phase One and Two project outputs in all project regions. In Southeast Asia, MDRC has continued to develop the Tier One and Two literature review and stakeholder mapping reports. MDRC has sought input from FCS representatives in Indonesia and Vietnam on the respective Tier One outputs. On 23-24 March, MDRC shared its draft African Phase One Tier One country reports and Tier Two stakeholder maps 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. These organizations are expected to provide feedback in the first weeks of Q2.

MDRC is packaging and will soon present the findings of its Tier One gap analyses and literature reviews from all project countries in a unified Tier One report. This report will include 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. Moreover, the Tier One report will be supplemented by stakeholder maps for each project country in Southeast Asia and Africa. These maps outline all relevant stakeholders in the project countries responsible for or involved in the implementation of medical device regulations, standards, and requirements at the Tier Two level, both nationally and regionally.

In the development of these resources, MDRC is incorporating input from stakeholders across each region, including from industry associations, USAID Missions, and US government agencies like the FCS in Indonesia and Vietnam. As stakeholders continue to review these resources, MDRC expects to integrate input and complete the reports in early Q2 2021.

9.2 Implementation Status

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.

While MDRC rapidly expanded outreach and collaboration with private and public sector actors across the three project regions throughout Q1 2021, the prior delay in outreach set back the scheduled completion of Phase One regional outputs. Phase One outputs are scheduled for completion in the early weeks of Q2 2021. The MDRC team does not expect this delay to interfere with the wider

implementation timeline of the project beyond Q1 2021. MDRC continues to assess whether capacity-building activities with each project countries in 2021 will need to remain virtual as a result of COVID-19 travel and local gathering restrictions.

9.3 Implementation Challenges

A major challenge to MDRC implementation has been overcoming delays related to securing USAID Mission concurrence across a number of project countries. For example, the USAID Mission to Thailand informed MDRC on 10 February that the RTG believes it is currently implementing stringent regulatory oversight in line with international standards and that it does not have the necessary bandwidth to partner with MDRC. This follows internal discussions and consultations between the Mission and key interlocutors in the RTG, such as the Thai FDA.

In AdvaMed communication with the FDA on Jan 21, the FDA concurred with the MDRC assessment that Thailand is not currently implementing stringent regulatory oversight in line with international standards.

Since this development, MDRC has undertaken consultations internally and with local stakeholders to develop a course of action that simultaneously produces the most effective outcomes regionally and strengthens the project's work in Indonesia and Vietnam. MDRC has determined that it will focus attention and resources towards Vietnam and Indonesia for the remainder of the project timeline. MDRC expects this decision to optimize the project team's ability to deliver on regional and project country-specific outcomes, including hosting regional and local Tier Two trainings scheduled throughout the remainder of this project.

AdvaMed will also closely monitor the impact of COVID-19 on travel capabilities in 2021 to ensure the achievement of capacity-building objectives. Preparations are already underway to establish virtual capacity-building resources and tools to mitigate potential challenges in this area, should they arise.

10. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

The Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector

In Latin America, the Coalition continued to play a critical part in expanding stakeholder engagement with MDRC. As discussed briefly in Section 2, on 16-17 March, the Coalition hosted a "Workshop on GRPs and International Trade" for Brazilian stakeholders across the public, private, and academic sectors. The workshop was co-hosted and supported by local associations representing the medical technology sector and joined by several Brazilian government authorities. The event had 184 registrants.

A significant number of these stakeholders played an active role in the hosting of the workshop and development of its curriculum. On 16 March, the workshop featured a panel titled "Commitments of Brazil before the WTO and GRPs." This panel was moderated by José Márcio Cerqueira Gomes, Executive Director of ABIIS, who conducted the discussion with Léa Contier, from Brazil's focal point INMETRO, and Juliana Ghizi Pires, who coordinates the work of the Brazilian government on GRP and international trade at the Ministry of Economy. On 17 March, the workshop featured a set of round tables titled "Outlook of the Regulatory Process in Brazil," "Changes in the Brazilian Regulatory Process," and "The Future and the Inclusion of New Technologies in the GRP Process." These round tables

included panelists from ABIIS, ABIMED, ABRAIDI, CBDL, the Brazilian Ministry of Economy, INMETRO, Ministry of Health, Boston Scientific, the State University of Paraíba, and the University of Brasilia.

The Coalition continued to support 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 will reinforce Phase One and Two regional outputs and may encourage greater participation in MDRC-related activities by both public and private sector entities.

United States

Throughout Q1 2021, MDRC continued to expand collaboration with US Government stakeholders.

MDRC and the Coalition frequently engaged with the US FDA to share MDRC project developments and advance the project in Latin America. On 29 January, the Coalition and AdvaMed shared with the FDA the outcomes of Coalition's meeting PAHO earlier that day and coordinated on the content of their respective presentations to the DIA's annual event in late February (outlined in Section 2). On 19 February, MDRC discussed opportunities for collaboration with the FDA in 2021, including a shared interest in hosting a joint training program on ISO 13485 for Latin America in Q2. MDRC continued brainstorming on a training workshop with the FDA on 23 February, discussing the utilization of ISO 13485 by regulators, leveraging updated electronic reporting systems to assist the transition from CFR-820 to ISO 13485. Following that conversation, on 5 March, MDRC shared the first draft of this workshop, which is tentatively scheduled for June 2021 and lists FDA and ANVISA as co-hosts with ANMAT as an invitee, to be open for INVIMA, DIGEMID, COFEPRIS and ISP, along with the private sector in those countries. In that meeting, MDRC also shared (1) an overview of the challenges companies are facing regarding consularization of legal documents due to personnel resourcing difficulties, and (2) a proposal by ANDI for the FDA to participate in a Q&A session. MDRC and FDA resumed discussions on the workshop on 8 March. On 23 March, MDRC continued the practice of sharing project updates with the FDA, discussing recently-held or scheduled introductory meetings with stakeholders in Latin America, such as the aforementioned meeting with COFEPRIS on 26 March.

MDRC also engaged the US Department of Commerce, meeting with Ian Saunders, Deputy Assistant Secretary of Commerce for the Western Hemisphere along with seven senior members of his team, on 18 March. After hearing an introductory presentation on the project, Commerce agreed to support MDRC both from Washington, DC as well as from posts across Latin America. Ian Saunders also committed to elevating the importance of GRPs and Regulatory Convergence in the medical technology sector as part of his discussions with the U.S. Department of State in identifying priorities and outcomes for the US-hosted Summit of the Americas.

11. RESULTS ACHIEVED

Global

- On 12 January, the MDRC Tier Two team held a call with the MTaPS team to explore synergies and ensure that any and all medical technology related bottlenecks they have identified will be addressed by MDRC efforts (IR 2.1, IR 3.1). During this meeting, it was confirmed that the project countries are virtually distinct and where there is overlap, MTaPS does not address medical technologies. The two teams committed to sharing relevant technical findings with each other moving forward, with MTaPS pledging to flag any medical technology-related aspects they identify for the MDRC team.

Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector

- The Coalition continued to support efforts by the IDB to undertake a survey of GRP in Latin American project countries (Activity 1.1.6.1), reinforcing the objectives of the Tier One and Two gap analysis. This survey 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).
- Between 22 and 24 February, the Coalition participated in two sessions addressing regulatory convergence (IR 1.1), GRPs (IR 1.1, IR 1.2, IR 2.1, IR 3.1, Output 3.1.1), and emergency responses to COVID-19 (DO 4) during the Drug Information Association's Annual Latin America Regulatory Conference.
- On 16-17 March, the Coalition hosted a Workshop on GRPs and International Trade for a series of Brazilian stakeholders across the public, private, and academic sectors. The workshop was co-hosted and supported by local associations representing the medical technology sector (Output 2.1.1, Activity 2.1.1.1, Output 2.1.3, Output 2.1.4, Activity 2.1.4.1, Output 2.1.5), and was joined by several Brazilian government authorities (Activity 1.1.4.1, Output 1.1.4, Activity 1.1.7.1). The event had 184 registrants, most of them from medical devices companies (IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.3, Activity 2.1.3.1).

Latin America

- MDRC met with representatives from PAHO on 29 January to discuss how to work towards increased coordination between them (IR 1.1, IR 1.2, IR 3.1, CC IR 2.1). The Coalition's formal application to be recognized as a Non-State Actor under PAHO's FENSA process remains under review.
- Brazil
    - The Coalition sent formal outreach letters on behalf of MDRC to relevant government agencies and ministries in Brazil on 7-8 January (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - On 21 January, MDRC met with ABNT, which voiced support for MDRC. ABNT indicated desire to partner with regulatory stakeholders and assist with the creation of a gap analysis outlining GRPs and international standards in Brazil (Output 1.1.1, Output 1.1.2, Output 1.1.3, IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1).
    - MDRC conducted follow-up meetings with ABNT, on 3 and 10 February. The parties continued discussions on working toward deeper collaboration with MDRC, including the possibility of formalizing ABNT membership in the Coalition (Output 2.1.1, Activity 2.1.1.2). ABNT and MDRC also discussed the recent developments in INMETRO/ANVISA medical technologies technical regulations, establishing ABNT in a regional coordination role as a part of MDRC, and ABNT's facilitation of a joint introductory session of MDRC to INMETRO (Output 1.1.1, Output 1.1.2, Output 1.1.3, IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1).
- Colombia
    - Throughout Q1 2021, the USAID Mission in Colombia has supported MDRC by sending outreach letters on behalf of the project to local government stakeholders and coordinating subsequent introductory meetings (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - On 22 January, MDRC and the USAID Mission to Colombia met with INVIMA, the Colombian medical device regulatory authority (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1). MDRC introduced INVIMA to the project, and discussed how MDRC could help advance the 2021 regulatory agenda of the Ministry of Health.
    - On the 23 and 26 of February, MDRC and the Mission held introductory meetings with with Colombian Ministries of Finance and Foreign Affairs, respectively. Members of the

Ministry of Finance agreed to collaborate in the future, with MDRC consenting to share project process periodically (IR 1.1).
    - MDRC met with the DNP on 1 March. The DNP was receptive, committing to align approaches with the Colombian Ministry of Health and INVIMA (IR 1.1, IR 3.1, DO 4).
    - On 3 March, MDRC met with ICONTEC. ICONTEC welcomed the project and discussed how the organization could help advance MDRC objectives – including confirming a high-level partnership and jointly working to advance GRPs (IR 1.1, Output 1.1.4, IR 2.1, Output 2.1.1, Output 2.1.5, IR 3.1, Output 3.1.1) and medical device standardization in Colombia (DO 4).
    - On 19 March, MDRC conducted a follow-up meeting with ICONTEC. All parties worked to identify specific items and areas of interest where MDRC can prioritize engagement and optimize the advancement of project outcomes in the country (Output 1.1.1, Output 1.1.2, Output 1.1.3). They discussed how best to align approaches between ICONTEC, INVIMA, and MOH (Output 1.1.4, Output 1.1.6), a potential future workshop on developing specific policies related to adopting international standards (Activity 1.1.3.1, Activity 1.1.4.1, Activity 1.1.7.1), and increasing industry participation in technical committees (Activity 1.1.2.1, IR 2.1).
    - The Coalition met with MinCIT on March 25 to address the regulatory process regarding the UDI Semantic Standard, a concrete trial case for the proper implementation of GRP and use of international standards for medical device regulatory convergence (IR 1.1, IR 3.1).
    - MDRC met with INVIMA on 26 March, where the parties worked to align topics of interest ahead of their joint meeting with Ministry of Health in April. The MDRC team highlighted the importance properly implementing GRPs and ensuring compliance with country specific and WTO/TBT & OECD obligations (IR 1.1, Output 1.2.2).
- Mexico
    - On 11 March, the USAID Mission in Mexico provided concurrence to the project, enabling MDRC move forward with all outputs and permitting formal outreach to government ministries and agencies (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - On 17 March, ANSI conducted formal outreach to Dirección General de Normas (DGN) of the Ministry of Economy, the standards body for Mexico (Output 1.1.1, Output 1.1.2, Output 1.1.3).
    - On 25-26 March, MDRC sent outreach letters to a broader series of government ministries and agencies, including Finance, Economy, and Health (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - On 26 March, MDRC met with COFEPRIS. In this meeting, the parties discussed the timeliness and importance of MDRC as well as challenges unique to Mexico in the medical technology sector (IR 1.1, IR 3.1), compliance with treaty obligations, and underutilization of Equivalence Agreements (IR 1.1, IR 2.1, IR 3.1, IR 4.1). COFEPRIS and MDRC are finalizing an MOU which will formalize partnership between the Government of Mexico and MDRC in advancing project objectives (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- Peru
    - The Coalition sent formal outreach letters on behalf of MDRC to relevant government agencies and ministries on 13-14 January (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - MDRC introduced the project to the Ministry of Foreign Trade and Tourism (MinCETUR) on 23 March, where the team emphasized the differences between the pharmaceutical and medical device industries as well as the use of international

standards (IR 1.1, IR 3.1). The parties also discussed MinCETUR's potential role in MDRC implementation.

Southeast Asia

- The project team has continued to advance efforts to complete the Tier One and Two literature review and stakeholder report (IR 1.1, Activity 1.1.6.1, IR 2.1, Activity 2.1.2.1).
- On 19 and 22 February, AdvaMed participated as an observing member of the U.S. delegation to the meetings of the APEC Subcommittee on Standards and Conformance (SCSC). Participants, including delegations from Mexico and Peru, discussed topics related to the scope of the MDRC, including GRP and TBT compliance (IR 1.1, IR 3.1).

- Vietnam
    - The USAID Mission to Vietnam provided concurrence to the MDRC project on 13 January. Concurrence enables MDRC to move forward with all project outputs associated with these countries, permitting formal outreach to relevant government ministries and agencies (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - On 15 January, ANSI conducted outreach to STAMEQ. MDRC met with and introduced the project to STAMEQ on 8 February. STAMEQ agreed to collaborate with MDRC in advancing project outputs on 17 March. This coordination will include promoting the use of international standards in Vietnam and greater region. (Output 1.1.1, Output 1.1.2, Output 1.1.3).
    - On 6 March, MDRC introduced the project to representatives of the US Foreign Commercial Service in Vietnam. MDRC sought input from those representatives on future engagement and secured commitment from the officers to review Phase One outputs (IR 1.1, Output 1.1.6, Activity 1.1.6.1, IR 2.1, Output 2.1.2, Activity 2.1.2.1).
    - On 6 March, MDRC was submitted for inclusion under the US-ASEAN Business Council's (USABC) MoU with the Vietnam Ministry of Health (MOH). This aims to raise the profile of MDRC and increase opportunities for MDRC engagement with the MOH. USABC has acknowledged receipt of the submission. (IR 1.1, IR 2.1, Output 2.1.1, Output 2.1.2, Output 2.1.3, DO 4, IR 4.1).
    - MDRC conducted outreach to relevant government ministries in Vietnam on 16 March (IR 1.1, IR 1.2, IR 3.1, DO 4, Crosscutting IR 2.1). This comes after the USAID Mission to Vietnam provided concurrence to the MDRC project on 13 January, and MDRC opted to delay formal outreach to Vietnamese agencies until after February to account for changes in government appointments as well as the Tet holidays.
- Indonesia
    - MDRC met with the USAID Mission to Indonesia on 23 February and 22 March, where the parties discussed projected MDRC outputs/outcomes and avenues for and challenges to progress (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
    - MDRC met with the US Foreign Commercial Service's (FCS) Standards Attaché for ASEAN in Indonesia and the Commercial Specialist for the US Embassy in Indonesia on 17 March. The discussion underscored the FCS, US Trade and Development Agency (USTDA), and US companies' strong interest in and support for MDRC's objectives in the region, particularly as they relate to GRPs (IR 2.1).
    - On March 30, ANSI held a preliminary meeting with BSN to discuss potential collaboration with MDRC to advance GRPs (IR 1.1). MDRC will await Mission concurrence prior to conducting follow-up meetings with BSN.
- Thailand

- MDRC met with the USAID Mission to Thailand on 4 February, in which the team introduced the Mission to MDRC and aligning with ongoing initiatives. The Mission informed MDRC on 10 February that Thailand should not serve as a project country under MDRC at this time and concurrence would not be issued (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).

Africa

- AdvaMed continues to work with Africa Practice in the implementation of Phase One project outputs. Africa Practice is supporting MDRC's production of an assessment of existing GRP policies in the region's project countries as well as maps of their relevant stakeholders responsible for or involved in (1) the implementation of GRP, and (2) the implementation of medical device regulations, standards, and requirements (IR 1.1, Activity 1.1.6.1, IR 1.2, IR 2.1, Activity 2.1.2.1). These outputs are planned for completion in early Q2 2021.
- On 8 February, MDRC met with Mecomed, which committed to future engagement with MDRC. Mecomed agreed to circulate information on Tier Two gaps/priorities in the African project countries, and collaborate with MDRC on curriculum development for planned trainings in the region (Output 2.1.1, Output 2.1.2, Output 2.1.4, Output 2.1.5, Output 2.1.5.1).
- MDRC conducted a follow-up meeting with Mecomed on 24 March, where the two groups continued to align on both the process and scope of partnership on this project. MDRC and Mecomed agreed to work together towards developing capacity building workshops geared at increasing levels of industry participation in international standards activities and engagement with government related to GRPs (IR 1.1, IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.2, Output 2.1.5, Activity 2.1.5.1).
- On 23-24 March, MDRC shared Phase One draft country reports with local and industry stakeholders in Africa for their review and input, including the USAID Missions to Kenya and Ghana, Mecomed, MEDAK, SAMED, and SALDA. These organizations are expected to provide feedback by early Q2 2021 (IR 1.1, Activity 1.1.6.1, IR 2.1, Output 2.1.2, Activity 2.1.2.1).
- Ghana
  - The USAID Mission to Ghana provided concurrence to the MDRC project on 30 December. Concurrence enables MDRC to move forward with all project outputs associated with these countries, permitting formal outreach to relevant government ministries and agencies (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
  - MDRC met with the USAID Mission to Ghana on 11 January. This meeting detailed anticipated MDRC work in the project country and established expectations for future collaboration with the Mission (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- South Africa
  - MDRC met with SAMED and SALDA on 21 January. The parties discussed the regulatory atmosphere in South Africa in addition to potential avenues of collaboration with MDRC (Output 2.1.1, Output 2.1.5, IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1). SALDA expressed its desire to assist the MDRC on 28 January and SAMED's board of directors agreed to support MDRC on 29 January.
  - On 2 February, MDRC introduced the project to the USAID Mission to South Africa. MDRC is working with the Mission assess next steps, including securing concurrence and designing initial 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).
- Kenya
  - On 16 February, MDRC introduced MEDAK to the project. MDRC and MEDAK discussed the regional scope of the project and how MDRC may align its efforts with ongoing initiatives and US trade negotiations with Kenya (Output 2.1.1, Output 2.1.2, Output 2.1.3, Output 2.1.5, Output 2.1.5.1).

- On 24 March, MDRC met with the USAID Mission to Kenya. MDRC and the Mission discussed MDRC objectives in Kenya and broader region. The Mission committed to reviewing and providing feedback on MDRC's draft Phase One reports/resources (IR 1.1, Activity 1.1.6.1, IR 2.1, Activity 2.1.2.1).

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 Q1 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).

12. 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 newly-acquired Zoom license to interact with actors across the public and private sectors. Moving forward, the Zoom platform will also facilitate more timely and streamlined connectivity and communication across the languages of English, Portuguese and Spanish. In preparation for and execution of a virtual training workshop (*See Section 2 Brazil, Section 3*), MDRC has broadened its institutional knowledge for online capacity building and using digital tools to advance MDRC objectives.

Over the regular course of Coalition website maintenance, MDRC is working to optimize the level of resources devoted to running the Coalition's online presence. While it requires higher levels of

time investment than previously anticipated, the Coalition's online modules and virtual resource library have proven to be an invaluable tool for housing and disseminating information vital to the project.

In order to avoid any unnecessary delays, MDRC will work to ensure stakeholders are provided with all relevant information on the project prior to any introductory meetings. By providing full context in advance of such meetings, MDRC prevents any avoidable confusion among attendees.

13. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

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

Building on the productive cross-coordination and exchanges between USAID, ANSI, and AdvaMed and entities across the U.S. Government – including FDA, USTR, Commerce, TDA, and others – MDRC will also work to broaden support for project objectives.

MDRC intends to build on recent and frequent meetings with governments, NSBs, and industry associations in Africa, Latin America, and Southeast Asia to encourage collaboration on specific, actionable trainings and capacity-building exercises. Moreover, MDRC will continue preparations in Q2 for trainings and forums in Southeast Asia and Africa. In Africa, this includes a Tier One regional forum as well as Tier One & Two local meetings/trainings for Kenya and Ghana. In Southeast Asia, MDRC will advance the groundwork for a COVID-19 medical device regulatory review conference with the IMDRF with targeted sessions for project countries in the region, a Tier Two regional meeting/training with medical device regulators in Vietnam, and an additional local session with Vietnam medical device regulators on Tier Two.