STANDARD ALLIANCE: PHASE 2

FY 2021 Annual Report

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Acronyms

ACI	American Concrete Institute
ANSI	American National Standards Institute
APACMed	Asia Pacific Medical Technology Association
ARSO	African Organization of Standardization
ARSOGA	ARSO General Assembly
AWWA	American Water Works Association
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios
CWSC	Center for Water Security Cooperation
EAA	Ethical Apparel Africa
ECOWAS	Economic Community of West African States
ECREEE	ECOWAS Center for Renewable Energy and Energy Efficiency
ESEF	ECOWAS Sustainable Energy Forum
GDA	Global Diagnostics Alliance
GMTA	Global Medical Technology Alliance
GRP	good regulatory practice
IAPMO	International Association of Plumbing and Mechanical Officials
IMDRF	International Medical Device Regulators Forum
INVIMA	Instituto Nacional de Vigilancia de Medicamentos y Alimentos
LOI	Letter of Intent
MDRC	Medical Device and Regulatory Convergence
MEL	Monitoring, Evaluation and Learning
OIRA	US Office of Information and Regulatory Affairs
PAHO	Pan American Health Organization
PCPC	Personal Care Product Council
RTG	Royal Thai Government
SA2	Standards Alliance Phase 2
SABS	South African Bureau of Standards
SDO	Standards Developing Organization
STAMEQ	Directorate for Standards, Metrology and Quality of Vietnam
TC40	ARSO Technical Committee 40
WHO	World Health Organization

1. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2 (SA2)
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/Sub-awardees:	AdvaMed, American Concrete Institute (ACI), American Water Works Association (AWWA), ASTM International, Center for Water Security Cooperation (CWSC), Ethical Apparel Africa (EAA), International Association of Plumbing and Mechanical Officials (IAPMO), NSF International
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	July 12, 2020 – July 11, 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 from the first iteration of the Standards Alliance and 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 help countries remove non-tariff barriers, and stimulate economic growth, while also preserving and expanding markets 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. ANSI's role as a coordinating body and the bridge between the private and public sectors uniquely

positions the Institute to build partnerships and foster collaborative solutions that address both national and global priorities. ANSI is also 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 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.

SA2 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 at both the national and regional level where appropriate and to involve partners in the Latin America, Africa, Middle East/North Africa, and Indo-Pacific regions.

1.2 SA2 Focus on Medical Devices to Support COVID-19 Response

In June 2020, USAID recognized the critical role standards and conformity assessment play in advancing public health and safety during global health emergencies and obligated $3.5 million to SA2, as 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 international medical device 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 trade quality medical devices. AdvaMed – a U.S. based trade association and ANSI member – is the primary private sector partner for this project, which includes select partner countries in Latin America, Africa, and the Indo-Pacific, and overflowing impacts within those regions.

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative – Year Two

Year 2 of SA2 entailed significant progress in the implementation of the COVID-19 Medical Device and Regulatory Convergence (MDRC) program and the finalization of all sub-award agreements. MDRC achieved the most substantive progress by launching the Inter-American Coalition for Regulatory Convergence, solidifying international partnerships with relevant government and private sectors organizations, and executing medical device and good regulatory practice trainings and high-level meetings. SA2 also began early implementation and contract approval of

other sub-awards in the Water, Sanitation, and Hygiene (WASH) and energy sectors, and support for the African Organization of Standardization (ARSO).

Finally, ANSI has also launched SA2 content on the website (http://standardsalliance.ansi.org/SA2), which will continue to be updated throughout the rest of the program.

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

Due to the impacts of COVID-19, the original activities under this program were postponed as pandemic-related challenges led to the virtual delivery of the ECOWAS Center for Renewable Energy and Energy Efficiency (ECREEE) general assembly and ECOWAS Sustainable Energy Forum (ESEF) in 2020. Garner Advisors intended to implement two national trainings in the ECOWAS region in September 2020, targeting Senegal and Ghana, in anticipation of the larger regional ESEF 2020 slated to occur in November. With the closing of borders and limitations on international travel, the ESEF 2020 was executed virtually, and the two national workshops have been moved to 2021 in the hope of holding in-person activities.

In consultation with ANSI staff, in Q4 2020 Garner transferred the organization of these workshops to Pivot, a newly formed non-profit working to increase access to clean, household energy. As part of its mission in transitioning homes to bio-ethanol, Pivot will work with interested stakeholders to develop policy and standards in this arena across multiple geographies. In order to further progress in biofuel education and standards development, Pivot proposed that an adjusted format for introducing liquid fuels take place in the meantime to engage key stakeholders and government entities.

In Q1 2021, Pivot continued planning events for West African member states to pave the way for regional adoption of clean cooking and transportation fuels during the 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 in-person events.

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

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

In Q3 2020, ANSI coordinated with ARSO to identify areas for collaboration related to the annual ARSO General Assembly (ARSO GA). Unfortunately, due to travel complications related to the ongoing global health crisis, ARSO has postponed the 2020 ARSO GA.

In Q4 2020, ANSI continued to coordinate with ARSO to identify areas for collaboration related to the annual ARSO GA. Emphasizing sustainable programming, ANSI and ARSO additionally agreed to a cosmetics training series to support the harmonization of African personal care and cosmetics standards. This training series was under development with guidance from the PCPC and ARSO Technical Committee 40 (TC40) on cosmetics. The series was structured to include eight to ten 90-minute virtual trainings on international best practices for cosmetics standards culminating in a thematic session for TC40 members during the ARSO GA.

At the end of Q4, ARSO reviewed a webinar concept note before confirming the training schedule and specific training topics.

In Q1 2021, ANSI, ARSO and the PCPC hosted the first webinar of the ten-part cosmetics training series. This 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 the Personal Care Product Council (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.

In Q2 2021, ANSI, ARSO and PCPC continued to organize and host the cosmetics standardization web-series. Three webinars in the ongoing cosmetics training series occurred in Q2 2021. These online trainings included events on cosmetics frameworks and enforcement strategies, the importance of international standards, and case studies from South Africa and Saudi Arabia on cosmetics enforcement and implementation.

As with the first event, these activities target participants in TC40 on cosmetics. The trainings continue to support knowledge sharing on best practices for the development of an African standards framework for cosmetics that will support consumer and industry interests.

The second webinar in the series was held April 16 and focused on international best practices for cosmetics standardization, including ARSO technical committee members, as well as global private sector stakeholders. The event detailed existing cosmetics frameworks and enforcement strategies implemented by governments, regulatory entities, and standardization bodies. This included a case study describing South Africa's approach to cosmetics standards frameworks. The training drew over 67 participants. Cosmetics Europe opened the webinar with Dr. Gerald Renner, Director of Technical Regulatory and International Affairs, and Maxime Jacques,

International Relations Manager, delivering an overview of international cosmetics frameworks and the most efficient methods to ensure safety, quality, and efficacy in cosmetics products.

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

The third webinar was held on May 20 and attracted 45 participants. This event laid an important foundation discussing international best practices for standards development and the importance of using harmonized, international standards related to the cosmetics sector. Speakers included Mojdeh Rowsan Tabari, committee manager for ISO TC217 on cosmetics research; Uli Osterwalder, chairman of ISO TC217; and David Jankowski, ANSI.

The fourth webinar in the series was held July 7 and focused on a thorough overview of the Saudi Arabia and the Gulf Cooperation Council (GCC) Standards Organization's experience implementing the suggested cosmetics framework. The fifth webinar is also expected to take place in Q3/Q4 2021 and will host a panel of previous experts to discuss outstanding questions on the cosmetics framework by ARSO technical committee members.

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

In Q4 2020, the sub-award agreement was submitted to ANSI by the Center for Water Security Cooperation (CWSC) and entered review by USAID Agreement Officer. Research on WASH-related product standards is planned for Ghana, Zambia and Uganda.

In Q2 2021, the CWSC sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with CWSC on May 4, 2021. Coordination for introductory calls with USAID Missions in Ghana, Uganda, and Zambia occurred in Q2 2021. Country-level supporting documents for USAID Missions in these countries were developed. CWSC was approved to begin work in Uganda and has begun deskwork.

Activity #4 Training in Good Regulatory Practices for Regulatory Impact Analysis (RIA) Teams in Government Ministries

This activity was completed in Q3 2020. In Q2 2021, ANSI remained in contact with the Business

Regulatory Review Agency (BRRA) seeking updates on the development of the proposed RIA Quality Assessment Tool. BRRA leadership requested more time to consider the suggested Tool and to examine how this tool could be used in conjunction with Zambia's current RIA framework and reporting checklists that are currently in use. BRRA will submit its first monitoring and evaluation report at the end of Sept, following the implementation of trainings that were conducted in mid-2020.

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

In Q4 2020, the final sub-award agreement was submitted to ANSI by the American Water Works Association (AWWA) and entered review under the USAID Agreement Officer.

In Q1 2021, the 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 began development in Q2 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 Q3 and Q4 2020, ANSI worked with ASTM International and the American Petroleum Institute (API) to refine their project proposal and develop a final draft for USAID's review.

In Q1 2021, ANSI, ASTM International and API formally kicked-off their Harmonization of Petroleum in West Africa project. 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.

In Q2 2021, ANSI, API, and ASTM coordinated to begin the introductory phases of the ECOWAS Harmonization of Petroleum Standards project. In light of the COVID-19 pandemic and related travel uncertainty, ASTM and API consulted with USAID and ANSI and decided that the preferred option in moving forward with the program would be to pursue virtual events in 2021, followed by in-person meetings for the remainder of the program. Work began using virtual technology to create information sharing sessions with USAID staff and stakeholders from the region. In addition, desk research on the current use and implementation of standards in the four target countries (Cote d'Ivoire, Ghana, Nigeria, and Senegal) is underway.

The Standards Alliance also hosted an introductory meeting with USAID country missions from

the four target countries as well as regional missions including the West Africa Trade and Investment Hub, the USAID West Africa Mission, and ASSESS. This meeting enhanced local USAID staff understanding and created buy-in for the program.

On June 4, ANSI, ASTM, and API held a fact-finding call with stakeholders from Senegal. In addition to learning about the Senegal National Plan for standardization in the petroleum sector, the team received confirmation from the Director General at the national standards body that Senegal will look at aligning their goals with the goals of the Standards Alliance project. Senegal also noted that it holds the Secretariat of the Harmonization Committee at the ECOWAS level. Further, during this call, the implementation team was introduced to a key contact at the African Refiners & Distributors Association (ARDA) who will help ANSI to promote the SA2 work within that organization.

A list of outputs achieved in Q2:

- April 7, 2021 – Virtual meeting held to introduce the project to the USAID missions in West Africa. Participants included key mission participants from Cote d'Ivoire and Senegal, as well as ASSESS and the main USAID West Africa mission.

- April 15, 2021 – Planning for initial outreach to stakeholders in West Africa begins.

- April 28, 2021 – ANSI begins outreach to former participants from the four target countries of the November 2019 Workshop to inform them about the new SA II project.

- May 13, 2021 – Press release issued to ASTM petroleum media list as well as a regional list for West Africa that consists of 175+ outlets in the region.

- June 4, 2021 – Virtual meeting held to introduce the project to Senegalese stakeholders held.

- June 7, 2021 – Virtual meeting held to introduce ASTM stakeholders who are members of the ASTM Petroleum Subcommittee D02.93 Coordinating Subcommittee on International Standards and Related Activities to the project.

- July 8, 2021 - Virtual meeting held to introduce the project to Nigerian stakeholders.

Activity #6 Africa Concrete and Building Code Adoption Initiative

In Q4 2020, ANSI worked with the American Concrete Institute (ACI) to finalize a proposal which aims to promote ACI's premier standard, ACI 318 Building Code Requirements for Structural Concrete and Commentary, which references 83 standards developed by US Standards Developing Organizations (SDOs) in select African countries.

In Q1 2021, ANSI submitted ACI's sub-award for review by the USAID Agreement Officer. USAID

indicated that assistance has been paused in Ethiopia, and as a result ACI decided to substitute the partner country Ethiopia for partner country Tanzania.

In Q2 2021, USAID approved ACI's project for implementation under Standards Alliance, Phase 2 in Uganda, Tanzania and Kenya. ANSI and ACI signed a sub-award at the end of June and began outreach to the USAID Mission in Uganda and Tanzania. ACI developed project factsheets and marketing materials to share with the various stakeholders it will be meeting with in preparation for implementation in the three countries.

In Q3, a concurrence memo was submitted for the project to move forward in Tanzania and a strategic meeting was held to initiate outreach with a list of suggested contacts in Kenya's concrete sector.

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)

In Q2 2021, the IAPMO sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with IAPMO on June 17, 2021. Coordination for introductory calls with the USAID Missions in Indonesia and the Philippines and country-level supporting documents for USAID Missions in these countries will be developed in Q3 2021.

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

In Q4 2020, the final sub-award agreement was submitted to ANSI by AWWA and entered review under the USAID Agreement Officer.

In Q1 2021, the AWWA sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with AWWA on February 8, 2021.

In Q2 2021, coordination for introductory calls with the USAID India Mission began. USAID India Mission calls were fruitful and the Mission granted concurrence to the AWWA project. The India Mission assigned Mr. R.K. Srinivasan as the project's Activity Manager. Mr. Srinivasan is engaged in supporting and facilitating outreach between AWWA and relevant Indian stakeholders, including utilities and ministries.

Country-level supporting documents for the USAID Mission were additionally discussed and developed. The needs assessment survey and a project summary has been sent to nine utilities

in India. Outreach to a further 15 utilities will occur in Q3 2021. With the support of the India Mission, a letter was e-mailed to the Ministry of Housing and Urban Development requesting that the Department send a letter to Urban Utilities to consider participating in this program. Some delays in responsiveness from partners and utilities has been observed due to the outbreak of COVID-19 Delta variant in India.

LATIN AMERICA

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

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

In Q1 2021 the NSF International sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with NSF on February 17, 2021. Additionally, coordination for introductory calls with USAID Missions in Brazil and Colombia began. Country-level supporting documents for USAID Missions in these countries were discussed for further development in Q2 2021.

In Q2 2021, calls with USAID Mission staff in Brazil and Colombia continued. Country-level supporting documents for USAID Missions in these countries were further developed as well. The USAID Mission in Brazil approved the NSF project and requested quarterly updates from NSF/ANSI on activity progress. To better serve stakeholders, NSF has successfully translated the relevant standards (NSF 60 and 61) into Spanish and Portuguese.

Unfortunately, the Colombia Mission did not grant concurrence to NSF as the project did not align with the Mission's development objectives. NSF is considering next steps, including allocating funds to the Morocco (the target country for Activity #9 in the Middle East North Africa region) and Brazil projects.

Development Objective #3: Countries have fewer TBT's

Activity #10 – Energy Efficiency Standards in Mexico

In SA2 Year 2, ANSI continued its attempts to solidify topic and scope, but U.S. private industry is not equipped to support the proposed project area. The Mexican National Standards in question is unique to Mexico, and does not refer to the ICC code. After consulting with USAID contracting officers, both parties came to agreement that it will no longer pursue this activity. The allotted budget amount will be re-allocated to an existing project.

MIDDLE EAST NORTH AFRICA

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

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

In Q2 2021, the IAPMO sub-award agreement was approved by the USAID Agreement Officer. ANSI signed the sub-award with IAPMO on June 17, 2021. Coordination for introductory calls with the USAID Mission in Jordan will begin and country-level supporting documents will be developed in Q3 2021.

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

In Q1 2021, 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 and country-level supporting documents for the USAID Morocco Mission were discussed.

In Q2 2021, calls with USAID Mission staff in Morocco continued and country-level supporting documents for the Morocco Mission were developed. USAID submitted a concurrence request to the Morocco Mission in June 2021. Further discussions and approval process conversations are expected with the Mission and US Embassy in Morocco in Q3 2021.

2.3 COVID-19 Related Activities Implementation Status

AFRICA

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

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

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

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

Concurrence and Formal Outreach: Kenya, Ghana, South Africa

MDRC secured Mission concurrence from Ghana and South Africa in MDRC Project Year 1. The Mission to Ghana granted concurrence to MDRC on 30 December 2020. On April 20, MDRC met the Mission in South Africa to provide additional information on the project and the expected timeline for its objectives in-country and the greater region. Following this discussion, the Mission informed MDRC it would not require a concurrence memo and would collaborate on future efforts with MDRC.

MDRC formally introduced the project to the Mission in Kenya in March 2021 and to the Government of Kenya's Pharmacy and Poisons Board (PPB), Kenya's NRA for medical devices. While the PPB confirmed both MDRC's potential value to Kenya and a desire to collaborate, the Mission to Kenya has not yet granted concurrence to the project. MDRC expects concurrence in early Q3 2021.

Although concurrence was granted in Ghana and South Africa, MDRC aims to conduct formal outreach to government stakeholders across all three project countries in close sequence. This enables MDRC to advance regional objectives while coordinating project progress across the continent. Draft outreach letters for all stakeholders are being drafted with input from MDRC's industry partners in the region and are undergoing review by each Mission. MDRC expects to extend outreach in early July 2021.

On 22 April, ANSI conducted outreach to SABS.

Stakeholder Engagement:

MDRC cultivated partnerships with key medical device industry bodies to accelerate project implementation in Africa. In Q1 2021, MDRC began its partnership with Mecomed, the leading medical device, imaging and diagnostics trade association for Middle East and Africa. Mecomed and MDRC have collaborated to identify industry priority areas, developing capacity building workshops, train local industry members on both Tier One and Two elements, and craft MDRC's Phase One outputs. Mecomed continues to provide MDRC with local expertise on Tier Two issues in Ghana, Kenya, and the greater region.

In South Africa, MDRC began working with the South African Medical Device Industry Association (SAMED) to extend outreach to South African government stakeholders. SAMED has provided critical local expertise on the content and acculturation of outreach letters to maximize their effectiveness. MDRC will continue to partner with SAMED in its engagement and training of local stakeholders.

In Q1 2021, MDRC met with MEDAK, the Medical Technology Association of Kenya. MDRC and MEDAK discussed the regional scope of the project as well as how MDRC may align its efforts with ongoing initiatives and the U.S. trade negotiations with Kenya.

Trainings and Events

In June 2021, MDRC and Mecomed held a two-part webinar training covering GRPs, technical barriers to trade, and their impacts on the medical technology sector during COVID-19. In the first session, MDRC presented on the differences between technical regulations and standards, harmonizing cross-border requirements through the adoption and use of international standards, and major challenges for the region's medical device sector. On 24 June, MDRC and Mecomed held the second part of this webinar series, dedicated to Tier Two elements for project countries in Africa. This session addressed regulatory convergence in the medical technology sector and Tier Two international benchmarks from the WHO, IMDRF, and GHWP. These sessions convened approximately 30 participants from the private sector.

GLOBAL

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

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

Over MDRC Project Year 1, MDRC advanced efforts to establish a dedicated work stream at the global level on behalf of the Global Medical Technology Alliance (GMTA) and Global Diagnostics Alliance (GDA) working in conjunction with the International Medical Device Regulators Forum (IMDRF). In Q3 2020, the Coalition submitted its application for membership to the GDA and was accepted in Q4 2020. This development will help strengthen MDRC's ability to pursue global COVID-19 related objectives.

MDRC has crafted an easily-navigable resource center, embedded as a core feature within the Coalition website and with its own unique URL, for information related to combating the COVID-19 pandemic. The COVID-19 Toolkit is one-stop-shop for available information from the U.S. FDA and other relevant guidance released by industry to fight the pandemic. This information serves as an archive for parties, including regulatory and customs authorities, to validate non-proprietary information from industry related to foreign approvals, licenses, regulations, and applicable standards. These international benchmarks may serve as additional reference for MDRC capacity building and training exercises across Latin America, Africa and the Indo-Pacific.

MDRC and the Coalition continuously ensured, measured, and reported the engagement of women throughout the implementation of the project in all geographies. See Section 4 Success Stories.

Stakeholder Engagement

Throughout MDRC Project Year 1, MDRC expanded collaboration with stakeholders at the global level.

Notably, the Coalition, alongside the GMTA, presented at the *World Trade Organization (WTO) Webinar on Regulatory Cooperation During the COVID-19 Pandemic* in Q2 2021. The Coalition presented on the challenges the pandemic posed for the medical technology sector while outlining opportunities for leveraging lessons learned to advance regulatory convergence.

In the United States, MDRC collaborated with a series of stakeholders, including USAID, ANSI, AdvaMed and its project experts as well as regulatory experts from AdvaMed's membership. Further, MDRC engaged with the U.S. Department of Health and Human Services, U.S. Food and Drug Administration Global Office, the Office of the United States Trade Representative, the U.S. Department of Commerce, and U.S. State Department.

Latin America

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

In MDRC Project Year 1, MDRC progressed the development and implementation of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (the Coalition). Launched in Q2 2020, the Coalition has 20 members and has hosted 10 virtual meetings and capacity-building workshops, convening over 2,000 participants. The Coalition has partnered with global, regional, and local project country stakeholders to advance local GRP implementation and medical device regulatory convergence.

On behalf of MDRC, the Coalition led project outreach in the region and hosted a number of trainings at the Tier One (horizontal, cross-cutting good regulatory practices) and Tier Two (vertical, medical device specific regulatory convergence) levels. As part of those efforts, the Coalition has engaged with important regional and global stakeholders, such as the World Health Organization (WHO), Pan American Health Organization (PAHO), Inter-American Development Bank, and WTO.

The Coalition developed and released an online resource library through an easily-navigable website, which can be accessed here: https://interamericancoalition-medtech.org/regulatory-convergence/. This website is a tool to convene stakeholders for events, share translated recordings of trainings and capacity building exercises, and publish and disseminate resources pertaining to GRPs and medical device regulatory convergence. The website is accessed by 1,268 visits in Q3 2020, 1,238 visits in Q4 2020, 1,637 visits in Q1 2021, and 3,357 visits in Q2 2021.

Concurrence and Formal Outreach: Brazil, Colombia, Mexico, Peru

As a prerequisite to activities in each project country, MDRC must secure concurrence from the local USAID Mission. MDRC secured Mission concurrence from all project countries in Latin America. Concurrence was granted in Brazil, Colombia, and Peru in Q3 and Q4 2020, and Mexico in Q1 2021. Thereafter, MDRC conducted formal outreach to local stakeholders:

BRAZIL: On 7-8 January, the Coalition conducted initial outreach on behalf of MDRC to the Brazilian Ministries of Foreign Affairs, Health, and Trade. Outreach was also 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.

COLOMBIA: In Q1 2021, MDRC coordination with the USAID Mission to Colombia led to rapid expansion of outreach. The Mission agreed to champion outreach on MDRC's behalf to Government of Colombia stakeholders, facilitating conversations between the government and MDRC.

MEXICO: On 25-26 March, MDRC sent initial outreach letters to a series of Mexican Government ministries and agencies, including the Ministries of Finance, Economy, and Health.

PERU: On 13-14 January, the Coalition conducted outreach with government ministries and agencies. 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 country.

Trainings and Events

Following concurrence and outreach, MDRC has continued to engage with government and private sector stakeholders in all Latin America project countries to advance MDRC objectives. While MDRC did not originally budget or plan to host dedicated trainings or capacity building exercises, MDRC expedited its work by hosting five virtual such events in Latin America at the project country and regional levels. These trainings convened a total of 1,360 diverse participants, advanced both Tier One and Tier Two objectives, and were frequently hosted in partnership with local and regional stakeholders.

Other Major Developments:

MEXICO: MDRC advanced formal collaboration with several Mexican government stakeholders. In alignment with Mission's guidance, MDRC prioritized partnership with the Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS). In order to maximize the effectiveness of the relationship between MDRC and the Government of Mexico, MDRC and COFEPRIS are in the process of developing and signing a Letter of Intent (LOI). Once signed, the LOI will establish the groundwork for continual engagement with COFEPRIS and enable the advancement of GRPs and medical device regulatory capacity building in the project country. The LOI is a significant step forward in advancing project objectives in Mexico.

While MDRC and COFEPRIS continue to align on the LOI's final language, they will sign the LOI in a hybrid virtual/in-person event at the end of August. This event, in Mexico, will include COFEPRIS's Federal Commissioner and other agency representatives, USAID representatives, ANSI leadership, and the Coalition Secretariat.

COLOMBIA: MDRC met with the Colombian National Food and Drug Surveillance Institute (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA) and the National Business Association of Colombia (ANDI) on 22 April. In that meeting, INVIMA proposed that MDRC designate a Liaison to coordinate and facilitate project activities in-country.

INVIMA advised that the deployment of project resources for an MDRC Liaison would enable Colombian government partners to dedicate themselves to MDRC implementation without disrupting essential COVID-19 functions and response. Coupled with the strong demonstrated desire of the Government of Colombia to implement regulatory convergence and GRPs, the Liaison is well-positioned to enable the rapid deployment of MDRC capacity building under the MEL plan. MDRC expects to secure approval from USAID to deploy this Liaison in Q3 2021.

Stakeholder Engagement

The Coalition serves an important role in convening and engaging crucial stakeholders throughout the Americas. The Coalition's virtual meetings assemble leading industry and non-industry stakeholders in Latin America, including private sector companies, SDOs, national regulatory authorities, and international organizations (e.g., WHO, PAHO, and the Pan American Standards Commission).

As a member of the Americas Business Dialogue, the Coalition began collaborating with the Inter-American Development Bank in November 2020 to mutually undertake a survey of GRP in Latin American project countries. The survey will update and expand existing assessments of GRP policies in Latin American project countries. This supports MDRC work by helping improve project countries' knowledge about the value of using national quality infrastructure and increasing private sector participation in regulatory development.

On behalf of MDRC, the Coalition began working with the WHO and PAHO to coordinate training and capacity building activities in alignment with MDRC objectives. Notably, the WHO hosted a webinar in Q2 2021 on GRPs, Good Reliance Practices, and resources to enhance their global implementation. The Coalition is advancing its application to qualify as a Non-State Actor with PAHO and is undergoing discussions with PAHO to host a virtual meeting of its regional external stakeholders. MDRC and PAHO have also discussed engaging PAHO member country medical device regulators in the Pan American Network for Drug Regulatory.

MDRC also engages with U.S. government stakeholders in the advancement of its objectives in Latin America. In Q1 2021, MDRC met with the U.S. Department of Commerce to secure its support for the project from Washington, DC and its posts across the region. Commerce and MDRC are working to elevate the importance of GRPs and regulatory convergence in the medical technology sector with other U.S. government stakeholders as they identify priorities and outcomes for the upcoming U.S.-hosted Summit of the Americas.

MDRC collaborated with the U.S. Food and Drug Administration to organize a three-part webinar series for stakeholders across Latin America in Q2 2021. This series was co-led by USAID, ANSI, and AdvaMed through the Coalition. The three sessions engaged 15 NRAs and convened an

average of about 400 attendees each session from 17 countries. Of the total attendees, 300 were from MDRC partner countries, including Brazil, Colombia, and Mexico.

Indo-Pacific

Concurrence and Formal Outreach: Indonesia, Thailand, Vietnam

MDRC has successfully secured USAID Mission concurrence and conducted formal outreach to government agencies in Vietnam and Indonesia. Following consultations with the USAID Mission to Thailand, where Mission concurrence was not received, MDRC will focus project resources toward Vietnam and Indonesia for the remainder of the project. Please see the below paragraph on Thailand and Section 2.2 Implementation Challenges for more information on this development and its impacts for the MDRC project design.

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 in late Q1 2021. ANSI conducted outreach to STAMEQ, the Directorate for Standards, Metrology and Quality of Vietnam, in Q1 2021. 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.

INDONESIA: Following several conversations with the USAID Mission to Indonesia in Q1 and Q2 2021, the Mission to issued project concurrence on 17 May. As part of concurrence, the Mission recommended MDRC secure an Indonesian "host" representative to act as an anchor for the project in-country and emphasized the importance of having a local contact on the ground. On 22 June, MDRC sent electronic outreach letters to government stakeholders in Indonesia after aligning with the Mission's requirements. MDRC will send hard copies of the letters in early Q3 2021.

THAILAND: MDRC met the USAID Mission to Thailand on 4 February, 2021 to introduce MDRC and how it may align with ongoing local initiatives. The Mission informed MDRC on 10 February, 2021 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.

While MDRC has received some limited governmental response to outreach in Vietnam and Indonesia, overall government engagement with MDRC was limited.

Other Major Developments:

In Indonesia, MDRC attended and leveraged the U.S. Embassy's Medical Device Roundtable as a platform to introduce the project and the importance of regulatory convergence to local medical device manufacturers. On 19 May, 2021, MDRC presented to the Roundtable an overview of the MDRC and its relevance to medical device manufacturing companies operating in Indonesia. Following the presentation, the Roundtable communicated specific areas of importance to the industry in Indonesia.

In Vietnam, MDRC submitted the project for inclusion under the US-ASEAN Business Council's ongoing Memorandum of Understanding with the Vietnam Ministry of Health on 6 March, 2021. This submission aims to raise the profile of MDRC and increase engagement with the Ministry of Health on project outputs in the near and long-term.

Stakeholder Engagement:

MDRC collaborated with industry bodies to strengthen private sector participation in advancing regulatory convergence across the Indo-Pacific over MDRC Project Year 1. MDRC received input from industry members on the opportunities and challenges for the medical technology sector in the region and sought buy-in from those members to partner on MDRC objectives.

MDRC met with the Asia Pacific Medical Technology Association (APACMed) in Q2 2021 to discuss project collaboration. Following this meeting, MDRC and APACMed agreed to coordinate through the Association's Southeast Center of Excellence, an important source of information on medical device regulatory convergence needs in Indonesia and Vietnam.

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

Trainings and Events

While MDRC did not originally budget or plan to host dedicated trainings or capacity building exercises in MDRC Project Year 1, MDRC expedited its work by hosting 12 virtual events/trainings that convened over 2,000 participants. These events convened stakeholders at the local, regional, and global levels. An overview of those events is included below, followed by brief descriptions of those events:

MDRC Trainings and Events, Q4 2020 – Q2 2021

Date	Meeting/Event	Location	Participants	Region
12 Nov 20	GRPs Training – Mexico	Virtual	115 Coalition members 80 female, 35 male (115 Private Sector)	Mexico
1 Dec 20	Coalition Meeting – Engagement with	Virtual	52 participants	Americas

	External Stakeholders		34 female, 18 male (35 private sector)	
2 Dec 20	Coalition Member Virtual Meeting	Virtual	44 participants 27 female, 17 male (44 private)	Americas
16 Mar 21 / 17 Mar 21	Workshop on GRP and International Trade – Brazil	Virtual	184 registrants (166 Private sector)	Brazil
18 May 21	Coalition Meeting - Engagement with External Stakeholders	Virtual	173 Participants 133 female, 40 male (142 private sector)	Americas
19 May 21	Coalition Member Virtual Meeting	Virtual	121 participants 84 female, 37 male (121 private sector)	Americas
02 June 21	Medical Device Webinar Series with USFDA – Part 1 of 3 – ISO 13485 and MDSAP Audit Model	Virtual	489 participants 356 female, 133 male (268 private sector)	Americas
10 June 21	Medical Device Webinar Series with USFDA – Part 2 of 3 – MDSAP Audits	Virtual	319 participants 221 female, 98 male (275 private sector)	Americas
16 June 21	Release of the Laboratory Diagnostics White Book	Virtual	298 participants 164 female, 134 male	Global
17 June 21	Medical Device Webinar Series with USFDA – Part 3 of 3 – Leveraging MDSAP resources	Virtual	254 participants 174 female, 80 male (125 private sector)	Americas
17 June 21	MDRC & Mecomed Medical Device Industry Training – Part 1 of 2 – GRPs, TBTs, and the Impact for MedTech and COVID-19	Virtual	Approximately 15 participants 10 female, 5 male (all private)	Africa
24 June 21	MDRC & Mecomed Medical Device Industry Training – Part 1 of 2 – Tier Two in Africa: Regulatory convergence in MedTech and international benchmarks from the WHO, IMDRF and GHWP.	Virtual	16 participants 11 female, 5 male (all private)	Africa

- GRPs Training – Mexico: A Coalition-hosted virtual training on GRP for attendees in Mexico. The training aimed to increase private sector knowledge on participation in the development of national quality infrastructure as well as private sector participation in regulatory development. 115 members of the Coalition from 10 countries participated in the training session.

- Workshop on GRP and International Trade – Brazil: A 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, the Ministry of Economy, and the Ministry of Health.

- Coalition Meetings (December 2020 and May 2021): In both December 2020 and May 2021, the Coalition hosted a set of two meetings. The first focused on coordinating engagement with external stakeholders. The second updated Coalition members on the Coalition's activities (such as MDRC) and aligned priorities for future initiatives. These meetings convened both regional and local stakeholders across the Americas and supported MDRC advancement in the region.

- Medical Device Webinar Series with USFDA: MDRC collaborated with the USFDA to organize a three-part webinar series for stakeholders across Latin America in Q2 2021. This series was co-led by USAID, ANSI, and AdvaMed through the Coalition. The three sessions engaged 15 NRAs and convened an average of about 400 attendees each session from 17 countries. Of the total attendees, 300 were from MDRC partner countries, including Brazil, Colombia, and Mexico.

- Release of the Laboratory Diagnostics White Book: The Coalition, the Latin American Alliance for the Development of In Vitro Diagnostics, the London School of Hygiene and Tropical Medicine, the International Diagnostics Center, and CBDL launched the Laboratory Diagnostics White Book for 2021-2022 in Q2 2021. These organizations convened around 300 health professionals from 17 countries (Brazil, Canada, Chile, Colombia, France, Germany, Italy, Kenya, Republic of Korea, Mexico, Paraguay, Peru, Spain, Trinidad and Tobago, United Kingdom, United States and Vietnam) to share the unveiling of this tool and convene a round table on "The Future of Diagnostics in a Post Pandemic World." This tool may serve as a resource for MDRC project countries in advancing policy that reinforces early and effective diagnostic tools in a post-pandemic world.

- MDRC & Mecomed Medical Device Industry Trainings: MDRC and Mecomed held a two-part webinar training series on Tier One and Two issues with the region's medical device industry, Mecomed, for industry participants from African project countries. The first session was Tier One-focused, covering GRPs, TBT, and their impacts on the medical technology sector during COVID-19. MDRC presented on the differences between technical regulations and standards, and harmonizing cross-border requirements through the adoption and use of international standards. MDRC also covered major challenges for the region's medical device sector related to trade/WTO rules.

  The second part of this webinar series was dedicated to Tier Two elements, covering regulatory convergence in the medical technology sector and Tier Two international benchmarks from the WHO, IMDRF, and GHWP. MDRC and Mecomed facilitated discussion on MDSAP as well as challenges to regulatory and industry capacity building in the Tier Two, Africa-specific context.

Other Major Developments:

MDRC packaged the findings of its Phase One, Tier One gap analyses and literature reviews from all project countries in a unified Tier One report. This report includes assessments of GRP implementation by country as well as an overarching chart to allow for comparison across project countries. This report will serve as a resource for closing key gaps and communicating MDRC objectives to both private and public stakeholders at local and regional levels.

The Tier One report is in the process of final graphic design and alignment with USAID branding requirements. As more input and feedback from governments and relevant stakeholders are received, this report may be updated in 2022.

MDRC has sought input on Phase One outputs from a variety of stakeholders, including industry associations, USAID Missions, and US government agencies. In Q1 2021, MDRC shared its Tier One country reports with local and industry stakeholders in Africa for their review and input, including the USAID Missions to Ghana and Kenya, Mecomed, MEDAK, SAMED, and SALDA.

In Q2 2021, MDRC shared updated drafts of MDRC's Phase One, Tier One gap analyses and Phase One, Tier Two stakeholder maps with ANSI, the US International Trade Administration, the US National Institute of Standards and Technology, the Office of the US Trade Representative, and the US Office of Information and Regulatory Affairs (OIRA).

Lessons Learned:

AdvaMed created a project dashboard to improve coordination and organization of MDRC project efforts across project countries and regions. The dashboard has supported regular reporting requirements, improved accountability to project administrators, and increased the efficiency of program execution.

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

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

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.

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

2.4 Implementation Challenges

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

Concurrence and Outreach

Overcoming project implementation delays related to local USAID Mission concurrence across a number of project countries was the largest implementation challenge in MDRC Project Year 1. In some cases, the time between initial consultation with a USAID Mission and formal concurrence was several months. MDRC was still awaiting final concurrence at the end of this reporting period from the USAID Mission in Kenya since outreach commenced in December 2020 / January 2021. The SA2 fully supports and understands the need for USAID Mission concurrence in project activities, however sometimes these delays result in delays with MDRC project outputs.

Another implementation challenge to project is limited engagement by some project country governments. In Peru, MDRC is experiencing communication delays and unresponsiveness from the General Directorate of Medicines, Supplies and Drugs ("La Dirección General de Medicamentos Insumos y Drogas,"), a key stakeholder for advancing medical device regulatory convergence and related GRP implementation. MDRC believes that Peru's current political climate, in conjunction with the challenges precipitated by COVID-19, have stymied government capacity to collaborate with the project in the short-term. In Q2 2021, MDRC met with Patricia García, former Minister of Health of Peru, to discuss these challenges to identify a number of potential avenues for advancing MDRC objectives in Peru. Patricia and MDRC discussed DIGEMID's organizational structure and explored the idea of approaching the agency through MINCETUR, who has the leading role implementing GRPs.

In Vietnam, while MDRC maintains high levels of engagement with the private sector, government stakeholders have been less responsive. MDRC conducted outreach on 16 March, 2021 to six government agencies. Two agencies, STAMEQ and the Ministry of Finance, have formally responded and assigned Vietnam Customs as their MDRC focal point. Since this development, MDRC has experienced additional delays engaging with Vietnam Customs. At the working-level, Vietnam's Ministry of Health conveyed that it would defer to the Department of Medical Equipment and Construction (DMEC), whose purview includes MDRC objectives. DMEC,

the Ministry of Industry and Trade, and the Ministry of Foreign Affairs have been unresponsive to date.

MDRC is exploring multiple avenues to engage relevant Vietnamese government stakeholders. In discussions with MDRC, private sector stakeholders attribute the agencies' unresponsiveness to limited capacity as a result of addressing COVID-19-related challenges. One private sector stakeholder indicated that that officers at the working-level might not know or be confident conversing in English, while more senior officials can be selective in engaging foreigners. MDRC has sought input and support from the U.S. Foreign Commercial Service and Vietnamese branches of the European and American Chambers of Commerce on relevant contacts in the government. These parties are awaiting go-ahead from the relevant ministries before providing MDRC with that contact information. The MDRC team continues to follow-up directly via email and phone calls with the agencies to encourage them to participate in the project.

Thailand

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. See Section 2.1 Indo-Pacific.

In AdvaMed communication with the U.S. FDA on 21 January the agency agreed 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 regional attention towards Vietnam and Indonesia for the remainder of the project timeline. However, resources previously earmarked for Thailand will be redirected towards to implementation of a dedicated Liaison to the Government of Colombia, pending USAID approval. 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.

COVID-19

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

As MDRC moves into MDRC Project Year 2, it will continue to analyze the most efficient use of

funds previously earmarked for travel in MDRC Project Year 1 and the first half of MDRC Project Year 2.

3. RESULTS ACHIEVED

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

Global

MDRC, through the Coalition, advanced efforts to establishing a dedicated work-stream at the global level on behalf of the Global Medical Technology Alliance and GDA working in conjunction with the IMDRF. In Q3 2020, the Coalition submitted its application for membership to the GDA and was accepted in Q4 2020.

MDRC crafted a COVID-19 resource center to share available information from the U.S. FDA and other relevant guidance released by industry to fight the pandemic. The COVID-19 Toolkit serves as an archive for parties, including regulatory and customs authorities, to validate non-proprietary information from industry related to foreign approvals, licenses, regulations, and applicable standards.

MDRC and the Coalition sought to promote, ensure, measure, and report the engagement of women throughout the implementation of the project in all geographies. See Section 4 Success Stories.

Latin America

MDRC established and oversaw the rapid expansion and deployment of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector. This includes the creation of a Technical Secretariat, Terms of Reference, Action Plan, website and resource library, and training curricula.

The Coalition's convening power has garnered stakeholder support and aligning global, regional, and local initiatives at the global, regional, and local levels.

MDRC oversaw the updating of Tier One and Two Implementation Guides and Gap Analysis Reports for all project countries in Latin America. MDRC packaged the findings of its Phase One, Tier One gap analyses and literature reviews from all project countries in a unified Tier One report. This report will serve as a resource for closing key gaps and communicating MDRC objectives to both private and public stakeholders at local and regional levels. The Tier One report

is in the process of final graphic design and alignment with USAID branding requirements. As more input and feedback from governments and relevant stakeholders are received, this report may be updated again in late 2021 or 2022.

MDRC engaged a large quantity of regulatory agency and private sector technical experts engaged in international standardization across the project countries. In doing so, MDRC and the Coalition hosted a number of Tier One and Two Trainings and workshops at the local and regional levels, although none were budgeted or planned for in MDRC Project Year 1. These workshops convened private sector representatives, key local agencies and authorities responsible for Tier One and Two implementation, and regional stakeholders.

Africa

MDRC began partnering with a number of key local and regional stakeholders in the advancement of project outputs. These industry stakeholders have proven instrumental in the development of MDRC's Tier One and Two Gap Analyses and Stakeholder mapping reports and local government outreach letters for project countries in the region.

In partnership with Mecomed, MDRC held a two-part webinar training for industry members in Africa on Tier One and Two topics. The trainings addressed the implementation of GRPs, regulatory convergence, technical barriers to trade, international benchmarks, and their impacts on the medical technology sector during COVID-19.

MDRC continues to work towards building relationships with government stakeholders in Africa and expects to conduct outreach to African project countries in Q3 2021.

Indo-Pacific

MDRC expanded engagement with both project country government and private sector stakeholders throughout MDRC Project Year 1. Throughout this engagement, MDRC gained a deeper understanding of the medical device industry priorities for collaboration with the project in addressing key Tier Two bottlenecks.

In close coordination with those stakeholders, MDRC crafted Tier One and Two literature review and stakeholder mapping reports for Vietnam and Indonesia.

MDRC continues to work towards building relationships with government stakeholders in Indo-Pacific and overcoming challenges related to their limited engagement.

4. SUCCESS STORIES

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

Women's Essential Role in Combatting COVID-19 and Increasing Patient Access to Vital Medical Technologies

The SA2 COVID-19 MDRC increases the transparency and predictability of partner governments' regulatory ecosystems for medical devices, aligning them with international standards, and improving their overall National Quality Infrastructure. MDRC is a partnership funded through the ANSI-USAID cooperative agreement between USAID and the ANSI in collaboration with AdvaMed.

In partnership with national and regional health, trade, and regulatory authorities, MDRC works to reduce barriers to countries' importation of medical devices that aid in the fight against COVID-19. MDRC recognizes that medical device standards have a broad impact on society and tend to have a foundation in STEM fields, which often include an underrepresentation of women. As such, MDRC has worked to ensure gender representation in its events, training, capacity building exercises, and speaking roles as part of a larger effort to address gender-based issues such as representation in policy making and technical work.

One major component of this work lies in MDRC's rapid development and operation of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (the Coalition). The Coalition's Technical Secretariat is led by the medical device industry's leading and highly experienced professionals who are also women from a diversity of national and ethnic backgrounds. The Secretariat's team of women are experts in the fields of medical technology, global strategy, technology, and regulatory affairs, and more. This team is actively working with key government agencies and local private sector partners to identify how the industry can help ensure that providers and patients have access to the medical technologies they need to help diagnose and fight the COVID-19 pandemic.

Since the Coalition's creation in 2020, MDRC has hosted nine trainings and events to advance those objectives for global, regional, and local stakeholders in the governmental and private sectors. These workshops convened about 2,080 participants between November 2020 and June 2021, of which almost 1,300 were women. This group of women are experts and professionals from academia, the private sector, Standards Developing Organizations, national regulatory authorities, international organizations, and more.

Over twenty women lead MDRC's efforts as part of the AdvaMed MDRC Core Team, the AdvaMed – MDRC Support team, the AdvaMed MDRC Steering Group (Global) & AdvaMed Global Harmonization Working Group, the AdvaMed MDRC Steering Group (Regional), women in leadership within ANSI, and others involved in the effort against COVID-19.

MDRC recognizes the critical and central role women should play in the response and recovery to COVID-19. MDRC will continue to emphasize and track women's representation in its activities and general policy making and technical work across Latin America, the Indo-Pacific and Africa.