Standards Alliance: Phase 2

Quarterly Report

4th Quarter October 1 to December 31, 2020

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Table of Contents

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
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	4 Q 2020 – October 1 to December 31, 2020

1.1 Program Description/Introduction

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

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

The implementing partner for this cooperative agreement is the American National Standards Institute (ANSI). ANSI is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. ANSI's mission is to enhance U.S. global competitiveness and the American quality of life by promoting, facilitating, and safeguarding the integrity of the voluntary standardization and conformity assessment system. Because of ANSI's unique role as a coordinating body and a bridge between the private and public sectors, the Institute can build partnerships and foster collaborative solutions for national and global priorities. And ANSI is a membership organization, providing members with the broadest access to up-to-date standards policy information and opportunities for participation, leadership, and influence. Finally, ANSI also promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards

organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community.

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

SA2 Focus on Medical Devices to Support COVID-19 Response

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

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The fourth quarter of 2020 entailed the initiation and continued implementation of activities under approved subawards and further development of some subcontract agreements. Many partners continued developing their proposals to near completion while others started working with stakeholders to establish relationships and further develop their implementation plans. The MDRC program, in particular, made significant progress this quarter continuing outreach with key stakeholders and working towards other milestones as detailed in section 2.2.

ANSI has begun conducting desk research and worked with USAID to continue brainstorming and developing tools for the country needs assessments, which will be completed virtually. ANSI also continued to monitor the COVID-19 pandemic throughout Q4, 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

Garner Advisors had intended to implement two national conferences in the ECOWAS region in September, targeting Senegal and Ghana, in anticipation of the larger regional ECOWAS Sustainable Energy Forum (ESEF) 2020 slated to occur in November. With the closing of borders and limitations on international travel, the ESEF 2020 will now be executed virtually, and the two national workshops will be shifted to 2021.

Garner Advisors seeks to transfer the organization of these workshops to Pivot Clean Energy (Pivot), a newly formed non-profit working to increase access to clean, household energy. As part of its mission in transitioning homes to bioethanol, Pivot would 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 is proposing that an adjusted format for introducing liquid fuels take place in the meantime to engage key stakeholders and government entities. The ability to present in conjunction with the ESEF 2020 as part of their agenda would help prepare these entities in advance of the 2021 physical workshops. This not only lays the foundation for local collaboration, but also invites 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.

This adjustment to the structure of Activity #1 is being reviewed by ANSI staff before finalization to verify the value of shifting the lead organization from Garner Advisors to Pivot.

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

In Q4, ANSI coordinated with ARSO to identify areas for collaboration related to the annual ARSO General Assembly (GA), which had been moved to June 2021 in Nigeria. Emphasizing sustainable programming, ANSI and ARSO have agreed to a cosmetics training series to support the harmonization of African personal care and cosmetics standards. This training series is under development with guidance from the Personal Care Product Council (PCPC) and ARSO Technical Committee 40 (TC40) on cosmetics. The series aims to create eight to ten 90-minute virtual trainings on international best practice for cosmetics standards culminating in a thematic session for TC40 members during the ARSO GA.

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

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 (1Q21).

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

Building upon the success of the workshop held during Q3, BRRA has continued to work with the 23 ministries in Q4 to develop close working relationships with the designated RIA Team officials and working with ministries to assign RIA team leads, who will handle day-to-day coordination and information sharing with BRRA staff. In Q4, ANSI shared with BRRA a comprehensive report detailing the successes and key takeaways of the workshop. With this activity shifting from Standards Alliance Phase 1 to Phase 2, ANSI is able to enhance monitoring and evaluation to track the progress of activities carried out between now and 2024, when Standards Alliance Phase 2 expires.

In order to meet these new monitoring objectives, ANSI has asked that BRRA track the number of RIAs submitted in 2021, and share a list of ministries beginning to produce RIAs following the training hosted in October 2020. Lastly, ANSI noted that there were more women than men represented in the RIA teams. In line with Standards Alliance Phase 2 objectives, ANSI has asked that BRRA begin to monitor gender representation in RIA teams and RIA-producing ministries.

At the end of Q4, ANSI touched-based with RIA expert Nathan Frey, from RSS group, to discuss potential next steps and reporting deadlines for BRRA to meet through Phase 2.

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

The sub-award agreement was submitted to ANSI by the American Water Works Association (AWWA) and is under review by USAID Agreement Officer. Activities are planned for Zambia, Malawi, and Lesotho beginning Q4 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 Q4, ANSI worked with ASTM International and the American Petroleum Institute (API) to refine their project proposal and budget and to develop a final draft proposal for USAID's review. This proposal is in strong working shape and, pending USAID approval, positions this project to begin as soon as Q1 of 2021.

Activity #6 Africa Concrete and Building Code Adoption Initiative

In Q4, 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 SDOs in select African countries. The establishment of a functioning reinforced concrete building code based on ACI 318, will benefit economic development in host countries by providing up to date technical expertise and information and enabling construction and design firms to build safe, strong, long lasting, and cost-efficient structures. The US economy will also benefit as US companies (construction, engineering, materials suppliers, etc.) will find it easier to do business in a country with a reinforced

concrete building code similar to that used in the US and most of the western hemisphere.

Working with ANSI, and keeping in mind population size, GDP, language, travel safety and ACI market knowledge/contacts, ACI created a list of priority countries and will propose to start its pilot in 3 East African countries (Kenya, Ethiopia and Uganda).

Once USAID reviews and approves ACI's proposal, the organization aims to move into the introductory phase of the project in Q2 2021. The key steps involved in this phase are meetings with policy personnel of appropriate ministries and invited participants, and establishing the feasibility of proceeding to Phase 2. ANSI will continue to support these efforts in Q1 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)

Final sub-award agreement was submitted to ANSI by the American Water Works Association (AWWA) and is under review by USAID Agreement Officer. Activities are planned for Zambia, Malawi, and Lesotho beginning 4Q21.

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)

Sub-award agreement is pending submission to ANSI by NSF International. Activities are planned for Brazil and Colombia.

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 new 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 is interested in supporting ICC and SA2 to develop and deliver training seminars on the International Energy Conservation Code (IECC-Mexico).

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 Indonesia and the Philippines.

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

Sub-award agreement is pending submission to ANSI by NSF International. Activities are planned for Brazil and Colombia.

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)

Building on the advancements made in Q3 2020, Q4 featured several activities including official government outreach and obtaining USAID Mission concurrence for MDRC operations in partner countries. Notably, at the request of USAID, MDRC activity and outreach to partner country governments were placed on hold at the outset of Q4 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, reinitiating the process to seek stakeholder input for, and secure USAID approval of formal MDRC outreach letters. That iterative process, which operated between 1 December 2020 and 21 December 2020, incorporated feedback from local USAID Missions and private sector actors including AMID in Mexico, COMSALUD in Peru, ANDI in Colombia, and ABIIS/ABIMED/ABRAIDI/CBDL in Brazil. USAID approved outreach to government agencies in Peru and Brazil for distribution in Q1 2021, with letters to Colombia and Mexico to be transmitted in Q1 following additional consultations with local Missions.

In Southeast Asia, the project team met with the USAID Mission to Vietnam on 4 November 2020. Subsequently and at the Mission's request, the project team transmitted an overview of the MDRC's proposed work in Vietnam and region as a whole. MDRC's proposal to USAID Vietnam for Mission concurrence remains under final review and is expected to proceed in Q1 2021.

During the week of 14 December 2020, USAID, ANSI, and the AdvaMed team met with the USAID Missions to Colombia, Mexico, and Brazil as well as representatives for the Peruvian medical device regulatory authority DIGEMID. These meetings affirmed the value of MDRC to each organization and secured support for future coordination to achieve project objectives.

The USAID Mission offered to send the initial project outreach to the Government of Colombia. MDRC has since maintained routine communication with and worked alongside the Mission to formulate and transmit MDRC outreach to relevant agency and ministry leads.

On 16 December 2020, the MDRC team held a US government interagency coordinating teleconference to introduce the project and align efforts with its objectives. The session was attended by members of the US State Department, HHS, and US Department of Commerce.

On 17 December 2020, the USAID, ANSI, and AdvaMed teams met with the USAID Mission to Mexico alongside representatives stationed with the US Embassy to Mexico, including State, Health and Human Services (HHS), and International Trade Administration to discuss the benefits of MDRC and next steps in formal outreach to the Government of Mexico (GOM).

On 17 December, the MDRC team help preliminary meetings with the ANVISA medical device (GGTPS) and regulatory process (GGREG) teams, gauging their initial interest in the MDRC and providing them notification that the formal letters would soon be issued.

The USAID Missions to Colombia and Ghana provided concurrence to MDRC on 16 December 2020, and 30 December 2020. Concurrence enables MDRC to move forward with all project outputs associated with these countries, permitting USAID and the Coalition to conduct formal outreach to relevant ministries and agencies in Colombia and Ghana in Q1 2021.

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

The Inter-American Coalition for Regulatory Convergence (IACRC) continues to scale up its activities across project countries in Latin America, hosting two meetings on 1-2 December 2020 as well as a virtual training on GRP with attendees from Mexico on 12 November 2020. 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.

As a member of the Americas Business Dialogue (ABD), the Coalition began working with the Inter-American Development Bank in November 2020 to mutually undertake a survey of GRP in Latin

American project countries. As part of the Coalition's Phase 2 work under MDRC, this survey will serve to update and expand the existing assessment of GRP policies in Latin American project countries, thus improving project countries' knowledge about the value of using national quality infrastructure, and increasing private sector participation in regulatory development.

On 30 November 2020, the IACRC met with the Pan-American Health Organization (PAHO), highlighting COVID-19, GRPs and transparency, and trade as the three primary areas of potential future engagement with MDRC. During the meeting, the Coalition also discussed the possibility of the Coalition applying for non-state member status to facilitate deeper collaboration with PAHO on MDRC objectives.

The December virtual meetings convened public and private stakeholders from across the Americas to exchange best practices and lessons learned from COVID-19, the role of the WTO TBT Agreement & GRPs in support of medical device regulatory convergence in Latin America, recommendations for the implementation of international standards, and the key achievements of members. These meetings included representatives from the World Health Organization, PAHO, US Trade Representative, Brazilian Ministry of Economy, and the London School of Hygiene and Tropical Medicine. These meetings advance the Coalition's capacity to convene government and industry representatives and engage with them on aligning medical device regulatory frameworks and standards as well as improving patient access through increased regulatory efficiency.

The proceedings of these external stakeholder meetings are available at:
https://interamericancoalition-medtech.org/regulatory-convergence/training-and-capacity-building-resources/grp-and-tbt-training-webinars-2020/

In order to solidify the gains made by the Coalition throughout Q4 2020, the IACRC further strengthened its online module development and virtual resource library, which can be accessed here: https://interamericancoalition-medtech.org/regulatory-convergence/. These advances position the Coalition as a leader in building the capacity of partner countries for standards and conformity assessment procedures and in fostering private sector engagement in the medical technology regulatory convergence.

Other Notable Progress
The US WTO TBT Enquiry Point of the National Institute of Standards and Technology (NIST) submitted comments on behalf of AdvaMed on Chile's WTO Notification G/TBT/N/CHL/536. In alignment with MDRC objectives, the comments assert not only that the Chilean definition of medical devices should be internationally aligned, but also the restrictions by medical technology sector representatives are inappropriate to the sector. To those ends, the comments recommend that: (1) the regulatory authority (ISP) and the private sector be provided sufficient transition time to implement the provisions of the draft law and its regulations, and (2) the regulatory authority (ISP) be provided sufficient resources to conduct the increased scope of its mandate under this bill, following international benchmarks. Chile acknowledged the receipt of those comments. In addition, for the first time, the Coalition Technical Secretariat achieved the following:

1. Identified the TBT through the review of notifications to the WTO;

2. Translated the relevant technical regulation and positioning;

3. Achieved alignment of the AdvaMed positioning with the two Coalition members from Chile (ADIMECH/APIS);

4. Achieved alignment of the AdvaMed-ADIMECH/APIS positioning with all of the Coalitions members, establishing a harmonized hemispheric industry position;

5. Succeed in having the Coalition members from the major medtech manufacturing countries also submit comment to the Chilean government through their respective WTO TBT Enquiry Points (Argentina, Brazil, Colombia, Mexico);

As a result, this constituted the first successful execution of the Coalition Technical Secretariat aligning industry positioning on a draft medical device regulatory framework in alignment with international reference documents and standards.

Beyond the Coalition's work in Latin America, MDRC continued to advance Phase One and Two project outputs in the other project regions. In Southeast Asia, MDRC sustained development of the Tier 1 and 2 literature review and stakeholder mapping reports for this region. In Africa, the AdvaMed team began working with Africa Practice, an advisory firm with operations in all MDRC project countries on the continent, to assist with the implementation of project objectives 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. All aforementioned outputs are planned for completion in Q1 2020.

SA2-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, unfreezing efforts to coordinate with local USAID Missions and begin government outreach. The MDRC team expects this minor delay to not interfere with the implementation timeline of the MDRC project beyond Q1 2021, with government outreach and Phase One regional outputs scheduled for completion by the end of the next quarter.

AFRICA

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

In Q4 of the Standards Alliance Phase 2, ANSI and Ethical Apparel Africa (EAA) conducted four interviews to hire a technical advisor for 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.

EAA has worked in partnership with Maagrace Garment Industries Limited to establish a plan, first for surgical grade Level 2 masks and then potentially into other areas of PPE such as disposable gowns. USAID are already supporting this project with a capex grant, but the SA2 will support the technical expertise needed to ensure the production processes and PPE is fully accredited, tested and certified to ASTM standards for sale to the USA and West Africa.

In addition, properly developing Ghana as a hub for PPE production requires knowledge transfer and increased understanding both at government level and in other agencies such as the Ghana FDA and the Ghana Standards Authority.

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

ANSI faced no major challenges in Q4 2020 apart from the on-going COVID-19 pandemic. ANSI continues to closely monitor travel and meeting capabilities and will adjust activity schedules accordingly.

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. Many activities still have pending proposals, and ANSI is working with relevant stakeholders to finalize them. Activities with finalized proposals have begun stakeholder outreach to promote the program, establish the scope and further plan implementation. The major of stakeholder engagement has been with the MDRC project detailed below.

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

MDRC saw numerous stakeholders deepen their engagement with project activities in Q4 2020 and push to advance critical outputs. In the United States, MDRC expanded collaboration with the 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 US State Department as supportive government entities, with substantial collaboration anticipated in 2021. Email exchanges and virtual

webinars have facilitated these engagements and no challenges have been identified to-date.

The IACRC continued to play a critical part in developing further MDRC stakeholder engagement, both in Latin America and globally. In November, as discussed in Section 2, the IACRC began collaborating with the IDB to mutually undertake a survey of GRP in Latin American project countries. This undertaking will encourage greater participation in MDRC-related activities by both public and private sector entities.

The IACRC also serves an important role in convening and engaging crucial stakeholders in project countries throughout the Americas. The Coalition's December virtual meetings (discussed in Section 2) assembled a number of leading industry and non-industry stakeholders in Latin America. This includes nine private sector companies, three SDOs, and thirteen Coalition members, representing ten countries. Many stakeholders – including the World Health Organization, Pan American Health Organization, the US Trade Representative, Brazilian Ministry of Economy, and the London School of Hygiene and Tropical Medicine – engaged with the Coalition at these meetings for the first time since the Coalition's inception.

On 3 December 2020, the Coalition Technical Secretariat was introduced to the Executive Secretary of the Pan American Standards Commission (COPANT) as a future essential institution and partner in the advancement of MDRC regional outputs and outcomes. The Coalition introduced MDRC objectives and operations and intends to collaborate with COPANT on project implementation in the region.

On the global level, the IACRC received confirmation on 14 December 2020 that it was formally accepted as a member to the Global Diagnostics Alliance (GDA). This development will help strengthen MDRC's ability to pursue global COVID-19 related objectives.

In Africa and Southeast Asia, MDRC is awaiting USAID Mission concurrence in five of the six regional partner countries to begin communication with local public and private sector stakeholders. While awaiting Mission concurrence, the MDRC team has identified a number of key stakeholders in Vietnam, Thailand, Indonesia, Ghana, Kenya, and South Africa for engagement in Q1 2021.

4. RESULTS ACHIEVED

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

USAID Mission Concurrence and Project Country Government Outreach

- The USAID Missions to Colombia and Ghana provided concurrence to the MDRC project on 16 December and 30 December 2020, respectively. 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).
- The Coalition prepared outreach letters to government agencies in Brazil, Colombia, Peru, and Mexico in Q4 2020 for submission in 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).
- In meeting with representatives for the Peruvian medical device regulatory authority DIGEMID (Activity 1.1,4.2), the project team raised government awareness of the MDRC project outputs, relevant international standards (Output 1.1.2), and GRPs (Output 1.1.4). The DIGEMID team voiced their interest and support for MDRC as well as designated a point contact to facilitate collaboration with MDRC on advancing GRP in the medical device sector.

- The Coalition Technical Secretariat and AdvaMed held informal conversations with key agencies in the Brazilian government (Activity 2.1.1.2). Those agencies include the Brazilian Ministry of Economy on 11 December 2020 and ANVISA on 17 December 2020. These meetings introduced MDRC ahead of formal government outreach and secured informal interest in future collaboration with the project.
- ANSI finalized its outreach to NSBs for Brazil and Peru, which served the dual purpose of introducing the NSBs to MDRC (Output 1.1.1, Output 1.1.2, Output 1.1.3) and enabling the MDRC team to proceed with government outreach in these project countries.
- The IACRC has frequently engaged leading industry and non-industry stakeholders in Latin America, including every principal member of the Coalition (Activity 2.1.1.2), increasing private sector participation in regulatory development (IR 2.1). These members provided input during the government outreach process (Output 2.1.1).
- On 16 December 2020, the MDRC team held a US government interagency coordinating teleconference to introduce MDRC to US government agencies so that they may align their efforts with MDRC objectives and activities. The session was attended by members of the, US State Department, HHS, and US Department of Commerce (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).

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

- The IACRC began working with the IDB in November 2020 to mutually undertake a survey of GRP in Latin American project countries (Activity 1.1.6.1), assisting with the completion of the Tier 1 and 2 gap analysis. This partnership 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).
- The IACRC held a virtual training on GRP in Mexico on 12 November 2020 (Activity 2.1.1.1, Activity 2.1.4.1) leading to training curricula (Output 2.1.4), increasing private sector knowledge on avenues for participation in the development of countries' national quality infrastructure (Output 2.1.1) and participation in regulatory development (IR 2.1).
- Under IR 2.1, the Coalition hosted virtual Coalition meetings on 1-2 December 2020 (Activity 2.1.1.2) which convened principal members and industry stakeholders to improve medical device regulatory convergence in the region (IR 1.1, IR 1.2, IR 2.1, 3.1) by advancing: the number of international GRPs, regulations, and standards aligned in project countries (Output 1.2.1); the number of regulatory agency and private sector experts engaged in international standardization (IR 1.1, IR 1.2, IR 2.1, IR 3.1, CC IR 2.1); number of project countries agreeing to implement GRP policies (IR 1.1, IR 1.2) and the number of project countries agreeing to implement WTO TBT consistent standards and conformity policies (IR 3.1). These meetings also facilitated the engagement of stakeholders key to those project objectives, including World Health Organization (Output 1.2.1), Pan American Health Organization (Output 1.2.1), the US Trade Representative, Brazilian Ministry of Economy (IR 1.1, IR 1.2, IR 3.1), and the London School of Hygiene and Tropical Medicine (DO 4).
- On 30 November 2020, the IACRC met with the PAHO, highlighting health and COVID-19 (DO 4), GRPs and transparency (IR 1.1, IR 1.2), and trade (IR 3.1, IR 4.1, IR 4.1) as three primary areas of future engagement with MDRC. The Coalition also discussed the possibility of applying for non-state member status in PAHO, which could facilitate deeper collaboration between PAHO and MDRC.
- On 3 December 2020, the Coalition met with the Pan American Standards Commission (COPANT) as a future essential institution and partner in the advancement of MDRC regional outputs and outcomes related to standards development (Output 1.1.1, Output 1.1.2, Output 1.1.3). The Coalition introduced MDRC objectives and operations and intends to collaborate with COPANT

on project implementation in the region (Activity 1.1.3.1).

- The IACRC received confirmation on 14 December 2020 that it was formally accepted as a member to the Global Diagnostics Alliance (GDA). This development will help strengthen MDRC's ability to pursue global COVID-19 related objectives (DO 4).
- The Coalition has made substantial movements to improve and strengthen its online module development and virtual resource library (Activity 2.1.4.1).

Other Results

- In Southeast Asia, the project team has continued to advance efforts to complete the Tier 1 and 2 literature review and stakeholder report (IR 1.1, Activity 1.1.6.1, IR 2.1, Output 2.1.2, Activity 2.1.2.1).
- Following a meeting on 4 November 2020, MDRC crafted and submitted an overview of MDRC's proposed work in Vietnam and Southeast Asia to the USAID Mission to Vietnam. The Mission has subsequently begun reviewing the project's application for Mission concurrence (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- The MDRC team continued active recruitment and engagement of women and diverse representation in all MDRC activities (CC Activity 2.1.2.1) leading to gender and diversity inclusion into development of country national quality infrastructure (CC Output 2.1.2).
- 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 capacity-building and resource capabilities to advance project objectives. This will remain a priority for much of the life of the project, as the world and technology adapt to the current pandemic and post-pandemic environment.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

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

Q1 2021 will capitalize on the advances made in Q4 2020, particularly in outreach with government stakeholders across all ten project countries and their expanded engagement in project activities planned for 2021. Advancing awareness of MDRC project objectives and deepening coordination with project countries and international government organizations will be a major focus in Q1 2021.

Building on the productive cross-coordination and exchanges between USAID, ANSI, and AdvaMed and entities across the U.S. Government – including U.S. FDA, USTR, Commerce, and

others – MDRC will also synchronize U.S. Government coordination on project objectives.

While engaging government stakeholders across project countries remains central to achieving MDRC objectives, the project team will also conduct several private sector activities in Q1 2021. This includes building on the results of the December 2020 meeting with all IACRC industry association and standards development organization members. MDRC intends to strengthen member engagement with the project as it prepares for its next virtual meeting in Q2/Q3 2021. The emphasis on private sector advancement of MDRC objectives coincides with the ongoing collaboration with the IDB to complete the GRP Survey and Report for Latin America in Q1 2021. This partnership will serve as an opportunity to incorporate a major inter-governmental organization into project activities in an unprecedented manner.

MDRC anticipates similar private sector and standards development organization engagement in Africa and Southeast Asia. As USAID Mission concurrences are approved in the six project countries of Africa and Southeast Asia, MDRC will expand outreach and collaboration with governments as well as with local and regional stakeholders. This communication with public and private sector stakeholders will be a critical input to the proper development and execution of project activities in these regions, including the creation of stakeholder assessment, literature review, and gap analysis items for these regions – which MDRC anticipates will be published in Q1 2021. Further, MDRC will begin preparations in Q1 for a number of trainings and meetings in these regions in Q3 and Q4 2021. In Africa, this includes a Tier 1 regional forum as well as Tier 1& 2 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 2 regional meeting/training with medical device regulators in Vietnam, and an additional local session with medical device regulators on Tier 2 issues.

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, Thailand, Viet Nam)
Reporting Period:	1 October 2020 – 31 December 2020

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

USAID Mission Concurrence and Project Country Government Outreach

Building on the advancements made in Q3 2020, Q4 featured several activities including official government outreach and obtaining USAID Mission concurrence for MDRC operations in partner countries. Notably, at the request of USAID, MDRC activity and outreach to partner country governments were placed on hold at the outset of Q4 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, reinitiating the process to seek stakeholder input for, and secure USAID approval of formal MDRC outreach letters. That iterative process, which operated between 1 December 2020 and 21 December 2020, incorporated feedback from local USAID Missions and private sector actors including AMID in Mexico, COMSALUD in Peru, ANDI in Colombia, and ABIIS/ABIMED/ABRAIDI/CBDL in Brazil. USAID approved outreach to government agencies in Peru and Brazil for distribution in Q1 2021, with letters to Colombia and Mexico to be transmitted in Q1 following additional consultations with local Missions.

In Southeast Asia, the project team met with the USAID Mission to Vietnam on 4 November 2020. Subsequently and at the Mission's request, the project team transmitted an overview of the MDRC's proposed work in Vietnam and region as a whole. MDRC's proposal to USAID Vietnam for Mission concurrence remains under final review and is expected to proceed in Q1 2021.

During the week of 14 December 2020, USAID, ANSI, and the AdvaMed team met with the USAID Missions to Colombia, Mexico, and Brazil as well as representatives for the Peruvian medical device regulatory authority DIGEMID. These meetings affirmed the value of MDRC to each organization and secured support for future coordination to achieve project objectives.

The USAID Mission offered to send the initial project outreach to the Government of Colombia. MDRC has since maintained routine communication with and worked alongside the Mission to formulate and transmit MDRC outreach to relevant agency and ministry leads.

On 16 December 2020, the MDRC team held a US government interagency coordinating teleconference to introduce the project and align efforts with its objectives. The session was attended by members of the US State Department, HHS, and US Department of Commerce.

On 17 December 2020, the USAID, ANSI, and AdvaMed teams met with the USAID Mission to Mexico alongside representatives stationed with the US Embassy to Mexico, including State, Health and Human Services (HHS), and International Trade Administration to discuss the benefits of MDRC and next steps in formal outreach to the Government of Mexico (GOM).

On 17 December, the MDRC team help preliminary meetings with the ANVISA medical device (GGTPS) and regulatory process (GGREG) teams, gauging their initial interest in the MDRC and providing them notification that the formal letters would soon be issued.

The USAID Missions to Colombia and Ghana provided concurrence to MDRC on 16 December 2020, and 30 December 2020. Concurrence enables MDRC to move forward with all project outputs associated with these countries, permitting USAID and the Coalition to conduct formal outreach to relevant ministries and agencies in Colombia and Ghana in Q1 2021.

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

The Inter-American Coalition for Regulatory Convergence (IACRC) continues to scale up its activities across project countries in Latin America, hosting two meetings on 1-2 December 2020 as well as a virtual training on GRP with attendees from Mexico on 12 November 2020. 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.

As a member of the Americas Business Dialogue (ABD), the Coalition began working with the Inter-American Development Bank in November 2020 to mutually undertake a survey of GRP in Latin American project countries. As part of the Coalition's Phase 2 work under MDRC, this survey will serve to update and expand the existing assessment of GRP policies in Latin American project countries, thus improving project countries' knowledge about the value of using national quality infrastructure, and increasing private sector participation in regulatory development.

On 30 November 2020, the IACRC met with the Pan-American Health Organization (PAHO), highlighting COVID-19, GRPs and transparency, and trade as the three primary areas of potential future engagement with MDRC. During the meeting, the Coalition also discussed the possibility of the Coalition applying for non-state member status to facilitate deeper collaboration with PAHO on MDRC objectives.

The December virtual meetings convened public and private stakeholders from across the Americas to exchange best practices and lessons learned from COVID-19, the role of the WTO TBT Agreement & GRPs in support of medical device regulatory convergence in Latin America, recommendations for the implementation of international standards, and the key achievements of members. These meetings included representatives from the World Health Organization, PAHO, US Trade Representative, Brazilian Ministry of Economy, and the London School of Hygiene and Tropical Medicine. These meetings advance the Coalition's capacity to convene government and industry representatives and

engage with them on aligning medical device regulatory frameworks and standards as well as improving patient access through increased regulatory efficiency.

The proceedings of these external stakeholder meetings are available at: https://interamericancoalition-medtech.org/regulatory-convergence/training-and-capacity-building-resources/grp-and-tbt-training-webinars-2020/

In order to solidify the gains made by the Coalition throughout Q4 2020, the IACRC further strengthened its online module development and virtual resource library, which can be accessed here: https://interamericancoalition-medtech.org/regulatory-convergence/. These advances position the Coalition as a leader in building the capacity of partner countries for standards and conformity assessment procedures and in fostering private sector engagement in the medical technology regulatory convergence.

Other Notable Progress

The US WTO TBT Enquiry Point of the National Institute of Standards and Technology (NIST) submitted comments on behalf of AdvaMed on Chile's WTO Notification G/TBT/N/CHL/536. In alignment with MDRC objectives, the comments assert not only that the Chilean definition of medical devices should be internationally aligned, but also the restrictions by medical technology sector representatives are inappropriate to the sector. To those ends, the comments recommend that: (1) the regulatory authority (ISP) and the private sector be provided sufficient transition time to implement the provisions of the draft law and its regulations, and (2) the regulatory authority (ISP) be provided sufficient resources to conduct the increased scope of its mandate under this bill, following international benchmarks. Chile acknowledged the receipt of those comments. In addition, for the first time, the Coalition Technical Secretariat achieved the following:

6. Identified the TBT through the review of notifications to the WTO;

7. Translated the relevant technical regulation and positioning;

8. Achieved alignment of the AdvaMed positioning with the two Coalition members from Chile (ADIMECH/APIS);

9. Achieved alignment of the AdvaMed-ADIMECH/APIS positioning with all of the Coalitions members, establishing a harmonized hemispheric industry position;

10. Succeed in having the Coalition members from the major medtech manufacturing countries also submit comment to the Chilean government through their respective WTO TBT Enquiry Points (Argentina, Brazil, Colombia, Mexico);

As a result, this constituted the first successful execution of the Coalition Technical Secretariat aligning industry positioning on a draft medical device regulatory framework in alignment with international reference documents and standards.

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

Beyond the Coalition's work in Latin America, MDRC continued to advance Phase One and Two project outputs in the other project regions. In Southeast Asia, MDRC sustained development of the Tier 1 and 2 literature review and stakeholder mapping reports for this region. In Africa, the AdvaMed team began working with Africa Practice, an advisory firm with operations in all MDRC project countries on the continent, to assist with the implementation of project objectives 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. All aforementioned outputs are planned for completion in Q1 2020.

9.2 Implementation Status

SA2-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, unfreezing efforts to coordinate with local USAID Missions and begin government outreach. The MDRC team expects this minor delay to not interfere with the implementation timeline of the MDRC project beyond Q1 2021, with government outreach and Phase One regional outputs scheduled for completion by the end of the next quarter.

9.3 Implementation Challenges

While MDRC has not encountered any major challenges to the implementation of project tasks, newly added process requirements have slowed initial rate of output completion. Barring additional process requirements, this implementation challenge is not expected to continue in 2021.

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

MDRC saw numerous stakeholders deepen their engagement with project activities in Q4 2020 and push to advance critical outputs. In the United States, MDRC expanded collaboration with the 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 US State Department as supportive government entities, with substantial collaboration anticipated in 2021. Email exchanges and virtual webinars have facilitated these engagements and no challenges have been identified to-date.

The IACRC continued to play a critical part in developing further MDRC stakeholder engagement, both in Latin America and globally. In November, as discussed in Section 2, the IACRC began collaborating with the IDB to mutually undertake a survey of GRP in Latin American project countries. This undertaking will encourage greater participation in MDRC-related activities by both public and private sector entities.

The IACRC also serves an important role in convening and engaging crucial stakeholders in project countries throughout the Americas. The Coalition's December virtual meetings (discussed in Section 2) assembled a number of leading industry and non-industry stakeholders in Latin America. This includes nine private sector companies, three SDOs, and thirteen Coalition members, representing ten countries. Many stakeholders – including the World Health Organization, Pan American Health Organization, the US Trade Representative, Brazilian Ministry of Economy, and the London School of Hygiene and Tropical Medicine – engaged with the Coalition at these meetings for the first time since the Coalition's inception.

On 3 December 2020, the Coalition Technical Secretariat was introduced to the Executive Secretary of the Pan American Standards Commission (COPANT) as a future essential institution and partner in the advancement of MDRC regional outputs and outcomes. The Coalition introduced MDRC objectives and operations and intends to collaborate with COPANT on project implementation in the region.

On the global level, the IACRC received confirmation on 14 December 2020 that it was formally accepted as a member to the Global Diagnostics Alliance (GDA). This development will help strengthen MDRC's ability to pursue global COVID-19 related objectives.

In Africa and Southeast Asia, MDRC is awaiting USAID Mission concurrence in five of the six regional partner countries to begin communication with local public and private sector stakeholders. While awaiting Mission concurrence, the MDRC team has identified a number of key stakeholders in Vietnam, Thailand, Indonesia, Ghana, Kenya, and South Africa for engagement in Q1 2021.

11. RESULTS ACHIEVED

USAID Mission Concurrence and Project Country Government Outreach

- The USAID Missions to Colombia and Ghana provided concurrence to the MDRC project on 16 December and 30 December 2020, respectively. 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).
- The Coalition prepared outreach letters to government agencies in Brazil, Colombia, Peru, and Mexico in Q4 2020 for submission in 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).
- In meeting with representatives for the Peruvian medical device regulatory authority DIGEMID (Activity 1.1,4.2), the project team raised government awareness of the MDRC project outputs, relevant international standards (Output 1.1.2), and GRPs (Output 1.1.4). The DIGEMID team voiced their interest and support for MDRC as well as designated a point contact to facilitate collaboration with MDRC on advancing GRP in the medical device sector.
- The Coalition Technical Secretariat and AdvaMed held informal conversations with key agencies in the Brazilian government (Activity 2.1.1.2). Those agencies include the Brazilian Ministry of Economy on 11 December 2020 and ANVISA on 17 December 2020. These meetings introduced MDRC ahead of formal government outreach and secured informal interest in future collaboration with the project.
- ANSI finalized its outreach to NSBs for Brazil and Peru, which served the dual purpose of

introducing the NSBs to MDRC (Output 1.1.1, Output 1.1.2, Output 1.1.3) and enabling the MDRC team to proceed with government outreach in these project countries.

- The IACRC has frequently engaged leading industry and non-industry stakeholders in Latin America, including every principal member of the Coalition (Activity 2.1.1.2), increasing private sector participation in regulatory development (IR 2.1). These members provided input during the government outreach process (Output 2.1.1).
- On 16 December 2020, the MDRC team held a US government interagency coordinating teleconference to introduce MDRC to US government agencies so that they may align their efforts with MDRC objectives and activities. The session was attended by members of the, US State Department, HHS, and US Department of Commerce (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).

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

- The IACRC began working with the IDB in November 2020 to mutually undertake a survey of GRP in Latin American project countries (Activity 1.1.6.1), assisting with the completion of the Tier 1 and 2 gap analysis. This partnership 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).
- The IACRC held a virtual training on GRP in Mexico on 12 November 2020 (Activity 2.1.1.1, Activity 2.1.4.1) leading to training curricula (Output 2.1.4), increasing private sector knowledge on avenues for participation in the development of countries' national quality infrastructure (Output 2.1.1) and participation in regulatory development (IR 2.1).
- Under IR 2.1, the Coalition hosted virtual Coalition meetings on 1-2 December 2020 (Activity 2.1.1.2) which convened principal members and industry stakeholders to improve medical device regulatory convergence in the region (IR 1.1, IR 1.2, IR 2.1, 3.1) by advancing: the number of international GRPs, regulations, and standards aligned in project countries (Output 1.2.1); the number of regulatory agency and private sector experts engaged in international standardization (IR 1.1, IR 1.2, IR 2.1, IR 3.1, CC IR 2.1); number of project countries agreeing to implement GRP policies (IR 1.1, IR 1.2) and the number of project countries agreeing to implement WTO TBT consistent standards and conformity policies (IR 3.1). These meetings also facilitated the engagement of stakeholders key to those project objectives, including World Health Organization (Output 1.2.1), Pan American Health Organization (Output 1.2.1), the US Trade Representative, Brazilian Ministry of Economy (IR 1.1, IR 1.2, IR 3.1), and the London School of Hygiene and Tropical Medicine (DO 4).
- On 30 November 2020, the IACRC met with the PAHO, highlighting health and COVID-19 (DO 4), GRPs and transparency (IR 1.1, IR 1.2), and trade (IR 3.1, IR 4.1, IR 4.1) as three primary areas of future engagement with MDRC. The Coalition also discussed the possibility of applying for non-state member status in PAHO, which could facilitate deeper collaboration between PAHO and MDRC.
- On 3 December 2020, the Coalition met with the Pan American Standards Commission (COPANT) as a future essential institution and partner in the advancement of MDRC regional outputs and outcomes related to standards development (Output 1.1.1, Output 1.1.2, Output 1.1.3). The Coalition introduced MDRC objectives and operations and intends to collaborate with COPANT on project implementation in the region (Activity 1.1.3.1).
- The IACRC received confirmation on 14 December 2020 that it was formally accepted as a member to the Global Diagnostics Alliance (GDA). This development will help strengthen MDRC's ability to pursue global COVID-19 related objectives (DO 4).
- The Coalition has made substantial movements to improve and strengthen its online module development and virtual resource library (Activity 2.1.4.1).

Other Results

- In Southeast Asia, the project team has continued to advance efforts to complete the Tier 1 and 2 literature review and stakeholder report (IR 1.1, Activity 1.1.6.1, IR 2.1, Output 2.1.2, Activity 2.1.2.1).
- Following a meeting on 4 November 2020, MDRC crafted and submitted an overview of MDRC's proposed work in Vietnam and Southeast Asia to the USAID Mission to Vietnam. The Mission has subsequently begun reviewing the project's application for Mission concurrence (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2, CC IR 2.1).
- The MDRC team continued active recruitment and engagement of women and diverse representation in all MDRC activities (CC Activity 2.1.2.1) leading to gender and diversity inclusion into development of country national quality infrastructure (CC Output 2.1.2).
- MDRC maintained progress toward the launch of a COVID-19 medical device portal (Activity 4.0.0.3) under Development Objective 4.

12. LESSONS LEARNED

The project team is continuing to incorporate lessons learned on virtual capacity-building and resource capabilities to advance project objectives. This will remain a priority for much of the life of the project, as the world and technology adapt to the current pandemic and post-pandemic environment.

13. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Q1 2021 will capitalize on the advances made in Q4 2020, particularly in outreach with government stakeholders across all ten project countries and their expanded engagement in project activities planned for 2021. Advancing awareness of MDRC project objectives and deepening coordination with project countries and international government organizations will be a major focus in Q1 2021.

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While engaging government stakeholders across project countries remains central to achieving MDRC objectives, the project team will also conduct several private sector activities in Q1 2021. This includes building on the results of the December 2020 meeting with all IACRC industry association and standards development organization members. MDRC intends to strengthen member engagement with the project as it prepares for its next virtual meeting in Q2/Q3 2021. The emphasis on private sector advancement of MDRC objectives coincides with the ongoing collaboration with the IDB to complete the GRP Survey and Report for Latin America in Q1 2021. This partnership will serve as an opportunity to incorporate a major inter-governmental organization into project activities in an unprecedented manner.

MDRC anticipates similar private sector and standards development organization engagement in Africa and Southeast Asia. As USAID Mission concurrences are approved in the six project countries of Africa and Southeast Asia, MDRC will expand outreach and collaboration with governments as well as with local and regional stakeholders. This communication with public and private sector stakeholders will be a critical input to the proper development and execution of project activities in these regions, including the creation of stakeholder assessment, literature review, and gap analysis items for these regions – which MDRC anticipates will be published in Q1 2021. Further, MDRC will begin preparations in Q1 for a number of trainings and meetings in these regions in Q3 and Q4 2021. In Africa, this includes a Tier 1 regional forum as well as Tier 1& 2 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 2 regional meeting/training with medical device regulators in Vietnam, and an additional local session with medical device regulators on Tier 2 issues.