Standards Alliance: Phase 2

Quarterly Report

4th Quarter October 1 to December 31, 2021

Submission Date: January 31, 2022
Version 2: February 28, 2022

Agreement Number: 7200AA19CA00012
Activity Start Date and End Date: July 12, 2019 to July 11, 2024
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1. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2
Activity Start Date And End Date:	July 12, 2019 – July 11, 2024
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
Agreement Number:	#7200AA19CA00012
Name of Subcontractors/Subawardees:	Ethical Apparel Africa, AdvaMed, ASTM International, NSF, AWWA, ACI, CWSC, IAPMO
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	4Q 2021 – October 1 to December 31, 2021

1.1 Program Description/Introduction

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

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

The implementing partner for this cooperative agreement is the American National Standards Institute (ANSI). ANSI is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. ANSI's mission is to enhance U.S. global competitiveness and the American quality of life by promoting, facilitating, and safeguarding the integrity of the voluntary standardization and conformity assessment system. Because of ANSI's unique role as a coordinating body and a bridge between the private and public sectors, the Institute can build partnerships and foster

collaborative solutions for national and global priorities. And ANSI is a membership organization, providing members with the broadest access to up-to-date standards policy information and opportunities for participation, leadership, and influence. Finally, ANSI also promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community.

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

SA2 Focus on Medical Devices to Support COVID-19 Response

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

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The fourth quarter of 2021 entailed the continued implementation of activities under all approved subawards and the introduction of some projects to relevant USAID Missions. The MDRC program in particular made significant progress this quarter continuing outreach with key stakeholders, holding critical meetings, developing stakeholder mappings and gap analyses, and working towards other milestones as detailed in section 2.2. ANSI also continued to monitor the COVID-19 pandemic throughout 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

In Q4, ANSI's partner Pivot Clean Energy (Pivot) continued planning events for West African member states to pave the way for regional adoption of clean cooking and transportation fuels in Togo and the Gambia.

An invitation was extended to every member state in ECOWAS to attend the virtual introductory workshop in December of 2020, which was held with every member state in attendance. Two in-person follow-up workshops were planned for 2020, but have been on hold by the ECOWAS members' request until travel and group events were again possible; these workshops are now happening in March 2022.

Workshop planning for the two physical workshops was initiated with a Call for Interest that was sent to each ECOWAS member state to determine which two countries presented the greatest potential for a successful event. Previously the proposal had been submitted for Ghana and Senegal; ECREEE recommended that the Call for Interest determine which two countries would ultimately host. Togo and The Gambia responded as the two candidates interested to pursue and host physical workshops in 2022. An agenda was developed and speaker invitations were sent out at the end of December 2021.

The upcoming 2-day workshop is scheduled to be an in-person workshop in each country, will lay a foundation for local collaboration, and invite participants to gather baseline information for the establishment of pilot programs. Plans are underway currently to identify a suitable date for the workshop and to develop the agenda in collaboration with ECREE.

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

In Q4, ANSI, ARSO, and the Personal Care Product Council (PCPC) hosted one webinar as part of the cosmetics training series developed to support the harmonization of African personal care and cosmetics standards. This activity continued to target participants in ARSO Technical Committee 40 (TC40) on cosmetics, however broader stakeholder engagement was encouraged. The webinar was intended to provide a summary and review of the information provided in previous webinars. In addition, the webinar provided an opportunity for experts to respond to unanswered questions from the previous webinars.

The webinar was held on November 23rd and included 65 participants. All previous webinar speakers participated in the panel discussions including the following speakers: Ali Alghamdi, GCC Standards Organization; Dr. Mohammed Aljallal, Saudi Arabian Standards Organization, and Ali Wanas, P&G; Richard Sadiki, International Relations and Strategic Partnership Specialist for the South African Bureau of Standards (SABS), Dershana Jackison, Head of Policy and Regulatory Affairs for the Cosmetic, Toiletry & Fragrance Association (CFTA), Dr. Jay Ansell, Vice President of the Cosmetics Program of PCPC, with Dr. Gerald Renner, Director of Technical Regulatory and International Affairs, and Maxime Jacques, International Relations Manager, Mojdeh Rowsan Tabari, committee manager for ISO TC217 on cosmetics research; and Uli Osterwalder, chairman of ISO TC217. The panel was moderated by George Bouboulis Director, International Trade & Regulatory Affairs (PCPC).

The review of different global frameworks for cosmetics led the discussion to expand upon the importance of a standard that is well-tailored to the cosmetics industry. Such a standard applies to all products within the scope of cosmetics and is based on safety, not compositional requirements. Among other questions,

panelists elaborated on the GSO 1943/2021 Standard on Cosmetic Safety which is an innovative standard that functions well at different levels of capacity and is both business-enabling and ensures a high level of consumer safety. GSO 1943/2021 is applied both in countries where NSBs are responsible for cosmetics and in countries where the purview falls under Health Authorities. Panelists expressed that this eliminates most trade barriers within the GCC region as well as between the GCC region and major markets. Culminating this portion of the discussion the GSO speaker offered to collaborate more closely with ARSO based on an existing MoU to facilitate the drafting of an appropriate standard for cosmetics.

The next webinar date on labeling is TBD, however, the webinar is intended to expand upon an important aspect of ensuring consistent high quality: standardization of good manufacturing practices for cosmetics. This webinar is intended not only for TC 40 but also for industry stakeholders in the space. In Q1 2022, ANSI, PCPC, and ARSO will work to coordinate plans for this workshop.

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

The Center for Water Security Cooperation (CWSC) has continued with conducting deskwork in Uganda. The Zambia Mission granted concurrence to the project in Q4 and preliminary research has begun in Zambia. An introductory call with Ghana occurred in Q4 and no concurrence was necessary for CWSC to begin work. As a result, research in Ghana has begun.

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

The American Water Works Association (AWWA) sub-award agreement is active. Coordination for introductory calls with USAID Missions in Zambia, Malawi, and Lesotho occurred in Q4 2021 and calls will take place in Q1 2022. Considering there is no USAID Mission active in Lesotho, USAID will engage through USAID Lesotho staff at the South Africa Mission to provide guidance on next steps for AWWA in Lesotho.

AWWA also released a Request for Proposals in Q4 to solicit a subject matter expert (SME) to review the standards and to develop content for the workshops that will be held for African utilities. The deadline for the RFP proposals was Dec 22nd, 2021, and in Q1 2022 AWWA will be scoring, selecting, and completing a contract for the SME.

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

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

Work continues using virtual technology to inform stakeholders from the region about the project and introduce the new ASTM technical consultant working on the project. Planning has now begun for the first face-to-face engagement planned for Q1 of 2022. Further updates on the implementation are summarized below.

Implementation Status

- On October 14th, a Terms of Reference document was prepared and presented to Mrs. Joyce Okoree at the Ghana Standards Authority (GSA) in preparation for a meeting with the new ASTM technical consultant, Augustus Wiredu.
- On October 22nd, Mr. Wiredu met with the Petroleum Laboratory Manager, Mr. Darlington, to review existing testing capabilities.
- On October 25th, Mr. Wiredu met with the Director of Standards, Mrs. Joyce Okoree, to discuss a practical approach to support GSA's efforts at the ECOWAS level. Also discussed was the possibility of GSA's co-hosting an event in Q1 of 2022.
- On November 4th, a country call was held with stakeholders in Senegal to introduce the new technical consultant and discuss a practical approach to the harmonization of test methods in the region.
- On November 18th, a country call was held with stakeholders in Nigeria to introduce the new technical consultant and discuss a practical approach to the harmonization of test methods in the region.
- On November 19th, a follow-up call with key stakeholders in Senegal during which the names of focal point persons were identified to represent their country in the program.
- On December 8th, Jim Olshefsky made a presentation about the project to the members of the ASTM Committee on Petroleum Products, Liquid Fuels, and Lubricants at their meetings in Anaheim, CA and asked for their support.
- On December 21st, Jim Olshefsky participated in a call with private sector stakeholder Afton Chemical to garner support for the program.
- A draft agenda was prepared for a 3-day Workshop in Ghana tentatively planned for March 1-3, 2022 and a formal letter requesting support was sent to GSA's Director General on December 22.

Activity #6 Africa Concrete and Building Code Adoption Initiative

Despite constraints on travel and in-person meetings the pandemic has created, ANSI and ACI continued to identify contacts in Kenya and Uganda to explain the details of the program and seek/obtain assistance from local members of the USAID Missions in each country. In Q4 development activity began in Kenya with the assistance of Mary Wanjeri Mbugua, USAID who eagerly scheduled in-person visits to secure virtual meetings with stakeholders in Kenya. ANSI and ACI also met with Henry Mateega, USAID's Mission Engineer in Uganda to discuss a strategy for engaging stakeholders in the construction sector as well as academia. A list of contacts was provided by the mission to begin scheduling meetings. ANSI and ACI also scheduled a meeting with Boniphace Marwa from the USAID Tanzania Mission to discuss plans for engaging stakeholders in the construction sector but had to postpone the call to Q1 2022 due to a schedule conflict.

The next steps in Kenya include a few additional introductory meetings with American companies and academia and to schedule several longer, in-depth meetings with key stakeholders (either in-person or

virtually) to strengthen relationships, give stakeholders a clear understanding of ACI and the benefits of working with/joining the ACI team, and to identify a path/strategy leading to use and adoption of ACI codes and standards (which has become more difficult since Kenya has announced they will be adopting Eurocodes and have already started implementation).

In Q1 2022 ACI plans to re-engaged the Tanzania Mission and to meet stakeholders in Uganda to introduce the project. ACI also plans to host its first training workshop in Kenya with constituents of organizations they met in Q4.

Implementation Status

- Sept. 27-ACI Project Awareness - Enhancing Quality Infrastructure in East Africa – Meeting with USAID Kenya Mission
- Sept. 28-ACI Project Discussion with La Femme Engineering Services
- Oct. 1-ACI Project Introduction - Kenya Bureau of Standards
- Oct. 4-ACI Project Introduction - National Construction Authority
- Oct. 5-ACI Project Introduction - Architectural Association of Kenya
- Oct. 6-ACI Project Introduction - Institute of Quantity Surveyors of Kenya
- Oct. 12-ACI Project Introduction - Institution of Engineers of Kenya
- Oct. 13-ACI Project Coordination Meeting – Next steps in Kenya & planning for Tanzania and Uganda
- Nov. 23-Technical University of Kenya
- Nov. 30-ACI Project Introduction - Henry Mateega, USAID Uganda Mission Engineer
- Dec. 2 – Attempted Meeting with Tanzania USAID Mission Engineer, but he did not join us for the meeting.

INDO-PACIFIC

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

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

The International Association of Plumbing & Mechanical Officials (IAPMO) was granted concurrence to begin work in Indonesia in Q4. IAPMO has continued to work with BSN (Indonesia's National Standard Body) to update SNI 03-0122-1998, namely household water faucets with door valves. The formulation of this standard is being carried out by the Technical Committee 77-02 (downstream metal products).

IAPMO convened several meetings to discuss the formulation of the new faucet standard. These meetings were held on: 5 October, 19 October, 3 November, 10 November, 19 November, and 29 November. The meetings were held online via zoom with hybrid options as well as one full-day, in-person meeting. These meetings were attended by members of Technical Committee 77-02 and other stakeholders.

As of 31 December 2021, the status of standard formulation was on the stage of pre-consensus meeting (RSNI 2). Ongoing discussions are taking place with stakeholders who were involved with the implementation of SNI faucet for domestic purposes (SNI 03-0122-1998) and Small and Medium Enterprises which are members of Valve Industry Association. Additionally, a draft the standard has been developed by the committee.

IAPMO's work in the Philippines continues to be stalled in Q4. IAPMO is awaiting congressional notification approval before outreach with the Philippines Mission can occur. USAID is managing the congressional notification approval process and outreach.

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

The American Water Works Association (AWWA) continues to make progress in India. Mr. Srinivasan from the USAID India Mission is engaged in supporting and facilitating outreach between AWWA and relevant Indian stakeholders.

In Q4, AWWA reviewed and analyzed the survey data received in order to identify specific utility management standards and to begin developing tailored workshops to fit the needs of Indian utilities. The primary stakeholders contacted for this survey in Q3 were Utilities, Ministry of Urban and Housing Development - GOI, and private sector service providers.

AWWA received 93 responses to the needs assessment survey (83 from utilities, 10 from other water sector professionals). The utilities responding were 2/3 from Drinking Water utilities and 1/3 Wastewater utilities. The population covered by the utilities ranged from 5,000 people to over 20,000,000 people, with 100,000 as the median population served. Most respondents reported job function as Engineering Manager/Engineering or General Manager/Executive. Stakeholders reported that they are primarily interested in the AWWA training because utilities currently lack technical assistance to develop optimization strategies.

The needs assessment identified that 42 stakeholders currently use standards as part of their work, and 39 are aware of the AWWA Utility Management Standards. Among the 14 AWWA Utility Management Standards, the interest from utilities centered on 4 primary standards (core standards for treatment and distribution/collection):

- ANSI/AWWA G100 Water Treatment Plant Operation and Management
- ANSI/AWWA G200 Distribution System Operation and Management
- ANSI/AWWA G510 Wastewater Treatment Plant Operations and Management
- ANSI/AWWA G520 Wastewater Collection Systems Operations and Management

AWWA also released a Request for Proposals in Q4 to solicit a subject matter expert (SME) to review the standards and to develop content for the workshops that will be held for Indian utilities. The deadline for the RFP proposals was Dec 22nd, 2021, and in Q1 2022 AWWA will be scoring, selecting, and completing a contract for the SME.

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 Q4, NSF continued to conduct administrative project management and planning tasks and, stakeholder engagement/outreach in Brazil. The outreach survey developed in Q3 to assess the perception of stakeholders regarding country standards development or adoption of existing standards for water safety was sent to stakeholders in Brazil in Q4.

NSF analyzed survey data for the overview of the perception, interest, and acceptance of ANSI/NSF 60 and 61 standards in the country.

NSF identified four general themes from the stakeholder responses to include in the trainings: (1) general understanding of standards, (2) community health impact, (3) NSF Standards, and (4) business drivers. NSF has initiated the development of training materials to address these interest areas, recognizing that the content may be different for different audiences (such as manufacturers versus regulators). NSF will tailor the material accordingly.

Additionally, NSF survey responses recorded that stakeholders considered the following as the biggest barriers to trade: economic/high tariffs/taxes, lack of uniform practices/transparency and lack of capacity to meet demands. In regards to public health concerns, water treatment deficiency and source water quality were the most reported, alongside concerns about inadequate infrastructure and water scarcity. Participants cited the need for more investment in infrastructure, capacity building, regulation and knowledge and expertise.

With this information from stakeholders, the Needs Assessment phase was completed. The insights have been used to inform the training materials for Brazilian stakeholders. As such, part of the quarter's activities included to the development and preparation of the materials to be used during the trainings that are targeted to take place in early 2022.

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 Q3, the Jordan Mission requested IAPMO hold engagement in Jordan until 2022 due to a blanket exclusion for Washington based activities. As such, IAPMO did not undergo any activities in Q4.

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

NSF started the Needs Assessment phase in Morocco in Q4. The NSF team in Morocco has completed a preliminary assessment of potential stakeholders in the country and initiated contact and engagement efforts with those identified stakeholders. The outreach survey developed in Q3 to assess the perception of stakeholders regarding country standards development or adoption of existing standards for water safety has initially been sent to a small group of stakeholders. In Q4, an evaluation of the regulatory framework began as a result of the initial survey responses to better understand Morocco's regulatory landscape for WASH standards. The survey will also be sent to all remaining stakeholders in Q1 2022.

2.3 COVID-19 Related Activities Implementation Status

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)

Global

On 27 October, MDRC met with Melissa Torres from the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). MDRC discussed organizing "action-ready" clusters of relevant medtech National Regulatory Agencies (NRAs) and trade authorities in each project country to rapidly review and respond to medtech regulatory non-alignments, including those that trade ministries could deem constitute specific trade concerns (STCs). FDA/CDRH has standing meetings with the U.S. Trade Representative (USTR) to address such potential STCs and the next step would be for MDRC to support the establishment of similar frameworks in Colombia, Mexico, Peru, and Brazil. This aims to reduce the time it takes to convene appropriate parties in the context of addressing COVID-19 subjects. 'Country clusters' serve to facilitate inter-ministerial coordination, implement international treaty obligations and domestic legal obligations, and remedy bottlenecks at both Tier One and Tier Two. This whole-of-government approach is central to operationalizing GRPs, including the appropriate use of relevant international standards. FDA/CDRH supports MDRC's approach that NRAs – as a part of such country clusters – could eventually meet as part of a potential multilateral collaboration.

Latin America

Regional

In Q3 2021, the Coalition's website visits were 3,653. This is an increase of 9% over Q2 2021. In Q4 2021, the Coalition's website traffic continued to increase, with a total of 4,400 between October and December. This is 20.4% increase from Q3.

On 12 October, the Coalition met with the Pan American Health Organization (PAHO), which informed the Coalition that the 10th Meeting of Red PARF was scheduled for 1 December, for which the Coalition offered support in developing an agenda. The Coalition shared information on its series of webinars on GRP and related upcoming events. PAHO committed to drafting a formal proposal of cooperation with the Coalition.

On 28 October, the Asian Harmonization Working Party / Global Harmonization Working Party (AHWP/GHWP) leadership confirmed their support for the Coalition's application to become a liaison to the organization (see below on the application's endorsement on 30 November).

On 24 November, MDRC met with the Spanish National Standards Body (UNE), securing their commitment to support the Coalition and MDRC in increasing the availability of Spanish-language versions of ISO and IEC standards for LatAm country National Standards Bodies (NSBs).

On 30 November, MDRC and the Coalition met with World Bank, Brazil's ANVISA, and Colombia's Ministry of Commerce, Industry and Tourism (MinCIT), National Planning Department (DNP), Ministry of Health (MinSalud), and National Food and Drug Surveillance Institute (INVIMA). The parties discussed GRP, their impacts on the health sector, and Brazil's and Colombia's approaches to implementing them. Colombia, for example, is actively utilizing an inter-agency approach while updating their regulatory framework for Medical Devices and IVDs (Decrees 4725 and 3770, respectively). A total of 216 participants from 8 countries attended the meeting, including 12 trade associations, 5 NRAs, the World Trade Organization (WTO), and PAHO.

At the 25th Annual Meeting of the AHWP/GHWP which took place virtually 30 November and 1 December, the AHWP/GHWP formally rebranded itself as the Global Harmonization Working Party (GHWP) and also unanimously approved the Liaison Member status of the Coalition.

On 7 December, MDRC met with PAHO to discuss priorities for partnership. Those priorities include executing capacity-building trainings on international standards, GRP, and EUAs. PAHO proposed for the Coalition to become an Observer Member to the Pan American Network for Drug Regulatory Harmonization (PANDRH), an initiative of the national regulatory authorities within the region and PAHO. The Coalition prepared an application to do so in accordance with PAHO's guidance. PAHO also proposed to collaboratively develop the agenda for the upcoming PAHO Medical Device Stakeholders Session in April, as well as the possibility of developing a mechanism for joint PAHO-Coalition publications. The latter proposal is designed to expedite the availability of important documents to an array of stakeholders.

On 7 December, the Coalition partnered with the U.S. FDA to organize a webinar series on Utilization of International Standards and Conformity Assessment. During this session, FDA representatives shared their experience on the utilization of Standards and Conformity Assessment through their SCAP Program. In attendance were participants from 17 countries, 13 NRAs and 45 companies. Materials and recording of the session is available at the Coalition's website: Webinar Series on Utilization of Voluntary Consensus Standards and Conformity Assessment.

On 17 December, MDRC met with PAHO and reviewed MDRC's work plan proposal to become an Observer Member of PANDRH. MDRC will continue working with PAHO to become a member in January 2022.

Colombia

On 12 October, MDRC introduced the new Liaison, Susan Suárez, to MinSalud and INVIMA. MDRC then shared its proposal and next steps for future partnership with MinSalud and INVIMA. INVIMA and MinSalud confirmed that their priority topics for partnership include the assessment of Decrees 4725 and 3770, GMPs, Emergency Use Authorization (EUA), and Clinical Research. Participants agreed to set up a meeting with the planning and legal areas of INVIMA and MinSalud. Participants decided that their technical teams would meet for two hours every week to facilitate further collaboration.

On 14 October, MDRC updated the members of the National Association of Entrepreneurs of Colombia (ANDI), a Coalition member, and the DNP on the current status of proposed projects and timelines. DNP stressed that the proposal must align with the renewed regulatory improvement policy and agreed to a regular schedule of meetings to advance MDRC work. The parties agreed to set up a subsequent meeting to work on overarching procedures and processes for institutional strengthening.

On 19 October, MDRC shared a proposal with DNP to begin crafting an ex-post evaluation instrument with a methodology that defines necessary activities, information, responsibilities, and timelines. DNP agreed with the proposal and suggested including a step to identify stakeholders.

On 20 October, the MDRC Colombia working group began to craft the ex-post evaluation instrument with the methodology proposed by MDRC. The group developed the structure of the first chapter of the design evaluation document, which includes an analysis of Colombia's international agreements and their impacts to date. The group acknowledged the need to interview the regulators who drafted and defined decrees 4725 and 3770. MDRC committed to developing a tool to do so. In that process, MDRC will informally ask the Presidency for context on the justification for those decrees.

On 21 October, MDRC met with DNP and outlined its proposal for the instrument's overarching procedures, processes and institutional architecture. DNP agreed with the proposal, which MDRC and DNP agreed to present to the planning and legal areas of INVIMA and MinSalud in late November.

On 27 October, MDRC continued development of the ex-post evaluation instrument and defined which persons would be interviewed as part of that process. MinSalud and INVIMA established a team responsible for designing a glossary which will allow the interviewer to apply the qualitative assessment instrument. MinSalud and INVIMA requested that the MDRC liaison advance the interviews, process them, and propose a problem tree.

On 3 November, MDRC finalized development of the tool to interview the aforementioned regulators. MinSalud and INVIMA's teams continued to develop the glossary. MDRC requested background information from the Presidency for incorporation into the glossary.

On 10 November, MDRC met with INVIMA, DNP and MinSalud. MDRC shared the recent advances by the working group with regards to ex-post evaluation. Those include: (1) the development of the design evaluation document's first chapter, which includes an analysis of Colombia's international agreements and their impacts, (2) the finalization of the tool to interview the regulators who defined decrees 4725 and 3770, (3) the informal request of the justifications for those decrees, and (4) the finalization of the methodology that defines activities, necessary information, responsibilities, and schedule for structuring ex-post evaluation document of decrees 4725 and 3770.

On 11 November, MDRC met with DNP to discuss the proposal for the ex-post evaluation instrument's overarching procedures, processes and institutional architecture. DNP and MDRC continued preparing to present the project to DNP's sectoral head and to INVIMA and MinSalud.

On 11 November, MDRC met with ANDI to discuss the status of MDRC's proposed projects, timelines, and recent developments. Those were previously outlined in this report.

On 11 November, MDRC met with the head of the MinSalud's legal office to introduce the project. MDRC invited the office to participate in the ongoing efforts with DNP to update the Ministry's processes and procedures. MDRC and the legal office scheduled a follow-up call to continue the conversation.

On November 16, MDRC met with MinSalud to review the Ministry's document on international references. MinSalud explained it does not require the adherence to specific international standards and that the use of Colombia Technical Norms (NTCs) is voluntary. Further, the document requires quality standards but does not indicate which standards must be met. MDRC invited MinSalud to review its international commitments and offered support to help align its commitments with international standards and references. MinSalud agreed to solicit relevant international commitments from INVIMA to begin this process.

On November 17, MDRC, INVIMA, DNP, and MinSalud met to continue revising the design assessment document's chapters related to ex-post evaluation.

On November 19, MDRC met with INVIMA to explain and suggest wording for the design assessment document's element on "institutionality." Prior to issuing decrees, INVIMA committed to reviewing the proposed institutional architecture and analyzing how the Government has designed its institutional capacity to respond to stakeholder demand.

On November 24, MDRC met with DNP to review the schedule for ex-post evaluation. DNP recommended incorporating six more months into the schedule. In response, MDRC and DNP explored the possibility of initiating ex-ante evaluation in parallel with the ex-post evaluations. DNP committed to continue working on the new schedule.

On November 24, MDRC met with DNP and the head of the MinSalud's legal office, where DNP and MDRC overviewed the regulatory improvement policy and the proposal to ensure the Ministry's processes and procedures are aligned with this policy. MinSalud was supportive and vocalized interest in MDRC's assistance for reviewing similar internal procedures.

On November 24, MDRC met with INVIMA, DNP and MinSalud to present on MDRC's progress and align on next steps. INVIMA was supportive of moving forward on topics related to MDSAP, EUA, and clinical research. MinSalud asserted that its priority for the next six months is working on EUA. The attendees committed to working on a new schedule that will prioritize EUA.

On November 25, MDRC met with DNP, which presented its new proposed timeline for ex-post and ex-ante evaluation. This proposal is to begin ex-ante evaluation in April and end in June, simultaneously with the ex-post evaluation.

On November 29, MDRC introduced the project to an economic analyst at MinSalud and discussed how

the analyst could support MDRC's execution. The analyst agreed to undertake a review of relevant MinSalud documents for MDRC.

On December 1, MDRC, INVIMA, DNP, and Ministry of Health met to continue reviewing the chapters related to ex-post evaluation. DNP presented a new schedule on ex-post evaluation and recommended adding three more months to the original schedule including ex-ante evaluations alongside with the ex-post evaluations. Both would finalize in June 2022.

On December 3, MDRC interviewed Claudia Guevara as part of the ex-post evaluation process for decrees 4725 and 3770. Claudia was the person responsible for regulating medical devices for INVIMA at the time decrees 4725 and 3770 were issued.

On December 3, MDRC met ANDI, which proposed partnering with MDRC to address INVIMA's problems related to medical devices. MDRC welcomed this proposal and explored how to take this partnership forward.

On December 3, MDRC connected with the Ministry of Health to discuss EUA in depth. The Ministry indicated its desire to regulate both medicines and medical devices before next June. However, MDRC contended that since the Ministry of Health has already regulated medicines and *not* medical devices, the developed Impact Analysis should be different. The Ministry agreed to meet with MDRC alongside the Ministry's medical devices and medicines groups to analyze whether it is possible to advance on both projects at the same time and with the same timeline.

On December 6, MDRC met with DNP and the head of the Ministry of Health's legal office to learn about the Ministry's processes and procedures so MDRC could continue the standardization of regulatory policy. They agreed to a subsequent meeting to learn more about MDRC and begin advancing changes to internal processes and procedures.

On December 6, MDRC met with the Ministry of Health's medical devices group to prepare for the upcoming meeting with medicines group about EUA. MDRC and the medical devices group agreed to stress the necessity of delineating issues between medicines and devices as well as the importance of reviewing relevant updated impact analyses.

On December 7, MDRC met with the Ministry of Health's medical devices and medicines groups. The medicines group shared that the impact analysis on EUA has not begun. The medicines group contended that since the forthcoming regulation will be the same as before, it justifies conducting a simple impact analysis rather than a complete one. MDRC recommended conferring with DNP to discuss whether a complete analysis should be conducted given medical device implications. Accordingly, MDRC met with DNP on December 9 to begin preparing a presentation to make the case regarding medical devices and the EUA impact analysis.

On December 10, MDRC met with Ministry of Health to answer a questionnaire through the Unique Public Consultation System (SUCOP) to determine whether the impact analysis on EAU related to medical devices should be complete or simple.

On December 10, MDRC interviewed Rocio Losada as part of the ex-post evaluation process for decrees 4725 and 3770. Rocio is a former team member of INVIMA, responsible for regulating medical devices at

the time decrees 4725 and 3770 were issued.

On December 10, MDRC met with Ministry of Health and INVIMA to discuss the timeline on GMP and clinical research based on steps added by MDRC on DNP's tool. The schedule aims to complete the process by January 2023.

On December 15, MDRC met with DNP to present the MDRC project to Daniel Gómez, Sectorial Subdirector of DNP. MDRC and DNP agreed that there is a lack of qualified personal and the absence of institutional architecture to appropriately advance regulatory policy. MDRC will propose content for a new health policy and action plan to ensure the government has the tools to address this problem.

On December 16, MDRC met with INVIMA, DNP, and the Ministry of Health to continue the ex-post evaluation process. The attendees discussed whether they should interview additional persons as part of the problem tree development process. Thereafter, MDRC interviewed Napoleón Ortiz as part of the process. Ortiz was a member of the Ministry of Health responsible for regulating medical devices at the time decrees 4725 and 3770 were issued.

On December 16, MDRC met with MinCIT, DNP, INVIMA, and the Ministry of health to review the draft schedule for GMP, EUA, and Clinical Research evaluations. The parties agreed that these evaluations should start simultaneously, despite their scheduled completion in January 2023, after the government change. The Ministry of Health agreed to send a request to the Ministry of Commerce to determine whether the impact analysis on EAU should a simple analysis rather than a complete analysis.

On 22 December, MDRC, INVIMA, DNP, and the Ministry of Health continued to identify stakeholders for interviewing as part of the ex-post evaluation.

On 22 December, MDRC formally introduced the project to DNP's regulatory improvement group and health group. MDRC and those groups discussed the introduction of new health policy to strengthen institutional architecture of the Ministry of Health and the advance GRPs.

On 27 and 28 December, MDRC interviewed María Cristina Latorre and Sofía Rivera Castro as part of the ex-post evaluation process. These individuals were members of the Ministry of Health responsible for regulating medical devices at the time decrees 4725 and 3770 were issued.

Mexico

On 11 October, MDRC met with the Federal Commission for Protection against Health Risks (COFEPRIS). COFEPRIS shared information on the status of NOM241 and NOM137. NOM241's implementation is pending confirmation following COFEPRIS's submission of feedback to CONAMER. For NOM137, a technical group has been established and will be restructured to ensure the proper development of a draft. MDRC offered to support this process. COFEPRIS described two events in November with the FDA related to GMPs and requested MDRC support sponsoring simultaneous translation.

On 14 October, MDRC met with COFEPRIS and shared a draft agenda for future trainings. COFEPRIS preliminarily agreed with the proposal but wished to review before finalizing. For relevant trainings, COFEPRIS intends to invite all government authorities and the WHO, as well as private sector

representatives. MDRC and COFEPRIS considered simultaneous translation services and agreed to start building an action plan.

On 27 October, MDRC and COFEPRIS co-hosted the first webinar of a series of four on GRP and their implementation in the Medical Device Sector. Advancing MDRC LatAm Tier Two Phase 3 and 4 work, this workshop convened a total of 267 participants, including 53 attendees from COFEPRIS and 1 from the Secretariat of Economy in Mexico. Government agencies from Brazil, Bolivia, Colombia, El Salvador, Honduras, Peru and the United States also participated. A total of 192 representatives from the private sector attended, including 5 trade associations from Brazil, Peru and the United States. Materials and recordings will be made available on the Coalition's website.

On 5 November, MDRC met with Mexican Pharmacopeia (FEUM, "Farmacopea de los Estados Unidos Mexicanos") to discuss GRP elements, their applicability, and the responsibility to comply with international agreements and treaties. Even though FEUM's current processes include public consultations, MDRC identified some missing elements, including notification of draft and final technical regulations. MDRC was invited to discuss GRP at the First International Meeting of Pharmaceutical Sciences Professionals, organized by the National College of Pharmaceutical Sciences on 10 November.

On 10 November, MDRC contributed to the discussion on GRPs the First International Meeting of Pharmaceutical Sciences Professionals, highlighting GRP implementation and international trade obligations. A recording of the session can be found here.

On 10 November, MDRC and COFEPRIS co-hosted the second webinar of the series of four on GRP and their implementation in the Medical Technology Sector. This workshop convened a total of 183 participants. Of those, government agencies from Bolivia, Colombia, El Salvador, Honduras and Peru were represented, in addition to 52 attendees from COFEPRIS, 1 from de Secretariat of Economy, 1 from CONAMER and 1 from the Mexican Pharmacopeia from Mexico; 3 Trades Associations from Ecuador, Mexico and the United States and a total of 131 representatives from the private sector. Materials and recordings will be made available at the Coalition's website.

On 17 November, MDRC co-hosted with COFEPRIS the third webinar of a series of four on GRP and their implementation in the medical device sector. This workshop convened a total of 165 participants. Of those, government agencies from Bolivia, Colombia, El Salvador and Honduras were represented, in addition to 52 attendees from COFEPRIS, 1 from DGN - Secretariat of Economy, and 1 from the Mexican Pharmacopeia from Mexico; 6 Trades Associations from Brazil, Colombia, Chile, Ecuador, Mexico and the United States and a total of 113 representatives from the private sector. Materials and recordings will be made available at the Coalition's website.

A significant output of this session was COFEPRIS's acknowledgement of the need to implement internal processes to ensure compliance with international obligations on GRP. Mexican Pharmacopeia also acknowledged the need to align their processes to comply with international obligations on GRPs, highlighting the need to implement a process for TBT notifications.

On 24 November, MDRC co-hosted with COFEPRIS the fourth webinar of a series of four on GRP and their implementation in the medical device sector. This workshop convened a total of 153 participants. Of those, government agencies from Colombia, Honduras and Spain were represented, in addition to 52 attendees from COFEPRIS, 3 from de Secretariat of Economy and 2 from the Mexican Pharmacopeia from

Mexico; PAHO and five Trades Associations from Ecuador, Mexico and the United States and a total of 131 representatives from the private sector. Materials and recordings will be made available at the Coalition's website.

On 29 November MDRC met COFEPRIS to discuss next steps for the project, including MDRC's proposed training plan and specific actions to advance their priorities. COFEPRIS discussed its internal conversations to address its acknowledgements from the training sessions regarding GRP implementation. COFEPRIS proposed for MDRC to connect with CONAMER to secure its engagement in the project.

On 17 December, MDRC met with the Secretariat of Economy to discuss potential avenues to engage the National Commissioner and CONAMER, a critical stakeholder in the implementation of GRP.

On 17 December, COFEPRIS informed MDRC that the Office of the Federal Commissioner had not responded regarding MDRC's recent proposal. COFEPRIS agreed to share the draft report on the High-Level Economic Dialogue (HLED) in the coming weeks.

Peru

On 4 October, MDRC met with the Office of Regulatory Quality Analysis ("Análisis de Calidad Regulatoria," ACR). Ana Sofía del Carpio of ACR informed MDRC that she met with the Ministry of Health to discuss their ability to support efforts in aligning Peruvian Regulations with International Standards. MDRC overviewed the project and Coalition, including some of the priority industry challenges for Peru. Those challenges include labeling and manufacture registration. MDRC will develop a PowerPoint on MDRC, the Coalition, and those challenges for the ACR.

On 21 October, MDRC met with the Ministry of Foreign Trade and Tourism (MinCETUR) to discuss the Ministry's initiatives on gender and inclusion, which are structured under Peru's national gender policy. This policy took effect in 2019 and sets goals that must be met and monitored by every ministry. To meet the policy's requirements, MinCETUR has a commission which tracks and annually reports on its progress.

On 12 November, MDRC shared an overview of its project priorities with ACR-PCM for their reference in coordinating a meeting with the Ministry of Health. This meeting is still being scheduled.

On 17 November, upon receipt of MDRC's priorities, MinCETUR proposed a follow up meeting with DIGEMID in early December to align on next steps.

On 15 December, MDRC met with MinCETUR to align on a revised proposal for collaboration with the Ministry of Health and DIGEMID. MinCETUR indicated its desire to participate in an upcoming meeting with ACR to offer support on GRP trainings.

Brazil

On 8 October, MDRC met with representatives from the Latin American Alliance for the Development of In Vitro Diagnostics (ALADDiV) and the Brazilian Chamber of Laboratory Diagnostics (CBDL). CBDL and ALADDiV overviewed their priority standards for nationalization. Participants proposed creating a working group to coordinate future activities related to the ISO 18113 series of standards and ISO Standard 15197:2013.

On 25 October, representatives from MDRC, CBDL, ALADDiV and the Brazilian Society of Clinical Analysis ("Sociedade Brasileira de Analses Clinicas," SBAC) – the ABNT-designated administrator of Brazilian Standardization Technical Committee CB-36 for In-Vitro Diagnostics – met to discuss a workplan for CB-36. Dr. Humberto Tibúrcio of CB-36 shared that TC 212 will have its first standard published in Spanish through the work of IRAM-Argentina. The attendees defined two standards: ISO 15197:2013 (in vitro diagnostic test systems and ISO 19001:2013 (in vitro diagnostic medical devices). The group also discussed developing an event to train industry representative on the importance of the use of international standards and participation in the activities of CB-36. The tentative date for the event is 2 December and the proposed topics include medical device regulation and international trade, international standards, ISO and ISO TC 212 structure and operation, CB-36 working process, and the IMDRF Document on Optimizing Standards for Regulatory Use.

Significantly, SBAC agreed to work in partnership with CBDL, ALADDIV and the Coalition in the context of advancing the MDRC.

On 22-23 November, the Coalition member ABIIS held a two-day workshop with ANVISA on GRP and medical device regulatory convergence. The event was executed with the Coalition's support and convened more than 400 attendees, including from Colombia, Mexico and Peru. Participants included the ABNT-designated entities for Brazilian medical device technical committees CB-26 (ABIMO) and CB-26 (SBAC).

On 6-7 December, the Coalition supported ALADDiV and CBDL to hold their XI International Workshop – "Quality Assured and Accessible Diagnostic Tests for Public Health Programs." Support was also provided by the London School of Hygiene and Tropical Medicine (LSHTM), the Welcome Trust, The International Diagnostics Centre, and Aldimed. The topics addressed include:

- Lessons from COVID-19 for the future;
- Access to new healthcare technologies; and
- The use of self-testing for COVID-19 as a complimentary tool to contain the pandemic.

The hybrid event convened nearly 300 participants, including regulatory authorities – such as ANVISA (Brazil), INVIMA (Colombia), Dinavisa (Paraguay), and AGEMED (Bolivia) – Ministries of Health, Institutions dedicated to scientific research, Universities, Hospitals, Pharmacies, and Industry.

On 15 December, MDRC met with the National Institute of Metrology, Standardization and Industrial Quality (INMETRO) to discuss details of the Project and opportunities for collaboration. MDRC will provide a formal presentation and introduction of the project to INMETRO again in January for those who were previously unable to attend.

Africa

Regional

On 16 November, MDRC met with the U.S. Department of Commerce International Trade Administration (ITA) to overview the project's current implementation status in Africa and discuss how ITA can partner with MDRC to advance its objectives. MDRC and ITA agreed that this collaboration

would broadly take three forms: (1) facilitating country-specific outreach and initial engagement with relevant government stakeholders, (2) subsequent country-specific coordination to implement MDRC on a local level, and (3) regional-level cooperation and engagement. MDRC requested that ITA reference the project in their ongoing engagements with relevant stakeholders in Africa, especially as those engagements relate to implementation of the TBT agreement, medical device regulatory functions, or COVID-19 response.

The discussion with ITA branched out in to project country-specific conversations. For South Africa, ITA asked MDRC to attend the next meeting of their recently-established local health working group, which includes representatives from USAID, Commerce, Department of State, and others. In that meeting, MDRC would briefly overview the project and its proposed work in South Africa. ITA offered to assist MDRC in outreach to Tier One stakeholders. For Kenya, ITA suggested that MDRC also meet with their local health working group. ITA informed MDRC that it followed up with USAID regarding the project's formal outreach letters and will update the project on any developments. Regionally, ITA advised MDRC that collaboration with the AfCFTA Secretariat could be difficult due to several factors. MDRC has since followed up with each country-specific ITA team to arrange targeted coordination calls in early December.

On 24 November, per invitation of the African Medical Devices Forum (AMDF), the MDRC team attended the virtual meeting of the 7th African Medicines Regulatory Conference (AMRC VII) including the AMDF meeting. The MDRC team will leverage the information shared during this meeting to propose MDRC-specific workstreams to the AMDF.

On 1 December, MDRC met with the U.S. Trade Representative (USTR), which explained its interest in promoting projects that strengthen supply chains in critical industrial sectors such as those related to pandemic and emergency preparedness. Due to the negative impacts of regulatory non-alignments on access to medical devices in Africa, MDRC's scope positions it to support this objective. USTR and MDRC discussed the project's role advancing the implementation of GRP and eliminating trade bottlenecks at both the regional and country levels in Africa. USTR vocalized interest in referencing MDRC in pertinent meetings and helping facilitate local engagements. MDRC has since connected with Africa project country-specific USTR points of contact to provide them with supplementary information. MDRC is scheduling introductory meetings with those contacts for early Q1 2022.

On 6 December, MDRC attended the monthly Standards Alliance 2.0 project coordination meeting with PQM+, MTaPS, and relevant USG officials. The initiatives shared updates on their recent progress. PQM+ shared with MDRC that it was working to secure Kenya's Pharmacy and Poisons Board (PPB) approval to share the draft document to revise PPB's regulatory processes. While this document primarily pertains to medicines and quality assurance mechanisms, it has broader implications on medical devices and the whole of the agency's regulatory process.

On 15 December, MDRC provided FDA CDRH with an overview of MDRC's current state of play in Africa and context for their upcoming meeting with Kenya's PPB. MDRC and CDRH aligned on priorities for the region and next steps for engaging with relevant stakeholders on the continent.

On 16 December, MDRC and the ADMF discussed the project's ability to review and comment on AMDF's Five-Year Plan and relevant documents that are crafted in AMDF sub-working groups. AMDF informed MDRC that it would have an opportunity to provide input on the Five-Year Plan following a January AMDF meeting, to which MDRC has been invited. Moving forward, once relevant sub-working

groups' documents are considered by the AMDF Secretariat, MDRC will strive to provide input where appropriate. AMDF informed MDRC that the AMDF no longer has an active COVID-19 Taskforce.

Ghana

On 2 December, MDRC met with ITA and USTR points of contact in Ghana. MDRC provided a summary of its objectives in Ghana and broader region, overview of stakeholders with which the project has conducted outreach, and timeline of engagement in the country. MDRC clarified its role in COVID-19 response and recovery as providing technical expertise to remedy regulatory non-alignments and bottlenecks while helping relevant government ministries meet their legal obligations rooted in international treaties and guidance documents. The U.S. Embassy officials offered their support in connecting with the proper points of contact in government ministries to advance project objectives.

Following attempts by MDRC in October, November, and December to schedule a meeting with the Ministry of Health's designated focal point, MDRC received a response from the focal point on 14 December. MDRC is requesting an introductory meeting with the focal point for January 2022.

Kenya

On 6 October, MDRC met with PPB to agree on next steps and develop a dedicated workstream. PPB and MDRC agreed that developing a formal situational analysis of areas for improvement among relevant Tier Two Kenyan stakeholders was an appropriate next step. MDRC committed to drafting a one-pager of the project's envisioned outputs and outcomes in Kenya and share this with PPB. PPB confirmed that it is currently formulating a document to assist in reforming its SOPs and regulator procedures. PPB is open to working with MDRC to ensure the document includes medical device-specific elements and differentiates between MedTech and pharmaceutical needs. The two agreed to establish a regular meeting schedule for collaboration.

On 26 October, MDRC shared with PPB an overview of the project's implementation objectives in Kenya, including an initial list of industry-identified priorities for collaboration, proposed schedule of meetings and workplan, and annex of proposed GRP implementation policies with PPB (Tier Two). PPB indicated its excitement to implement GRP alongside MDRC, but required additional time to review the document and confer internally. MDRC and PPB discussed the need for a formal situational analysis of PPB's Tier Two gaps. Due to staffing constraints, PPB asserted that a dedicated liaison would be helpful in generating a baseline for meaningful partnership in the country. PPB agreed to confer internally and provide MDRC with a recommendation on whether to formally request the liaison from USAID. While PPB discusses internally and during any subsequent approval process for the Liaison with USAID, PPB and MDRC agreed that the project should focus its attention on advancing regional objectives – such as those with AUDA-NEPAD. Following the meeting, Mecomed shared with PPB additional information on industry's identified priorities for collaboration. PPB indicated it would try to obtain and share with MDRC the document being constructed with PQM+ to update PPB's regulatory processes so that MDRC can provide input.

On 27 October, MCRC updated PQM+ on PPB's request to undertake a formal Tier Two situational analysis in the project country. MDRC discussed PQM+'s efforts to craft a document with PPB to update the authority's regulatory functions. PQM+ indicated this document only pertained to pharmaceuticals and would discuss internally on their ability to share it with MDRC. MDRC and PQM+ briefly discussed the project's regional-level objectives.

On 17 November, MDRC met with PQM+ and discussed the regulatory framework in Kenya, including the regulatory impact assessment (RIA) requirements. PQM+ would try to share with MDRC the Ministry of Health's policy document on supply chain strategy for health products. This document will provide MDRC with crucial background to ensure future project capacity building resources in Kenya are anchored in appropriate government policy. While this meeting was originally slated to be for PPB-MDRC discussions, Dr. Paulyne Wairimu, head of medical devices for PPB, was unable to attend the meeting.

On 16 December, MDRC and PPB aligned on the next steps and processes to formalize an MDRC workstream with PPB. MDRC and PPB will proceed to formulate an MOU which will provide the legal basis for future collaboration on Tier Two-specific capacity building. Concurrently, PPB will send MDRC a formal letter requesting a dedicated project liaison to coordinate work in the project country. Once the MOU is concluded, MDRC and PPB will develop a consensus-based prioritized workstream to address identified issue areas through capacity building consultations and trainings.

On 16 and 17 December, MDRC extended outreach to the Kenyan Bureau of Standards (KEBS) and the Kenyan Customs and Border Control Department. While MDRC has begun partnering with PPB at Tier Two, this outreach formalizes MDRC's efforts to begin Tier One work in Kenya.

On 19 December, KEBS indicated it would partner with MDRC.

On 22 December, Customs responded and designated a focal point for coordinating MDRC-Customs work. MDRC will set up introductory meetings with these stakeholders in the new year.

South Africa

On 2 December, MDRC met with the USAID Mission in South Africa to provide the point of contact with an update on the project's current status and ongoing engagements with project partners.

On 7 December, MDRC provided SAHPRA with an overview of the MDRC's proposed scope for partnership, including a notional schedule of meetings and role of MDRC resources. Following a discussion on the methodology and goals of MDRC, SAHPRA agreed to proceed with MDRC and develop a dedicated MDRC workstream. Given SAMED's recent workshops to address specific technical elements with SAHPRA, the groups agreed that the MDRC workstream should emphasize the procedural elements of GRP as they pertain to COVID-19 response and recovery. SAHPRA indicated it has identified priority procedural issue areas, which will be used in the development of the MDRC workstream. This workstream will align with and operationalize the recommendations of regional bodies, such as the AMDF. SAHPRA noted that MDRC work can complement their recent engagement with the WHO on regulatory practices pertaining to medicines, emphasizing the importance of leveraging international guidance in the local context. MDRC is scheduling a kickoff meeting with SAHPRA for late January in which the two will align on:

- The schedule of subsequent workshops/trainings and their content;
- The responsibilities of each team; and
- The content of the SAHPRA-MDRC workstream.

Once the initial series of workshops/trainings are complete, MDRC will partner with SAHPRA's relevant

teams (and other South African government agency representatives, where applicable) to implement the series' learnings.

Southeast Asia

Vietnam

On 5 October, MDRC introduced the project to the Embassy of Vietnam in Washington, D.C. and solicited the Embassy's guidance on how to best engage relevant government agencies. Hanh Duong, Head of Economic Section, suggested MDRC identify a focal point for future coordination. The Embassy committed to sharing MDRC's outreach letters with the Ministry of Health to help establish a focal point.

On 6 October, MDRC introduced the project to the Embassy of Vietnam in Singapore. MDRC asked the Embassy for guidance on how to best engage relevant government agencies. Le Cong Dung, Minister Counsellor and Deputy Chief of Mission, offered to follow up with the Ministry of Health on MDRC's behalf.

On 15 October, MDRC met with USABC's Senior Vice President and Regional Managing Director, Michael Michalak. MDRC sought Amb. Michalak's assistance to share a letter drafted by MDRC and signed by Amb. Michalak to the Minister of Health. The letter introduces MDRC and requests that the Minister assign focal points from the Ministry of Health and DMEC to set up a meeting to discuss the project. USABC agreed to assist MDRC in connecting with the Ministry of Health and DMEC. Since the project addresses regulatory issues that USABC companies face, the organization will also consider directly partnering with MDRC.

On 1 November, MDRC hosted a joint call with AdvaMed, interested AdvaMed members, APACMed, and EuroCham Vietnam to discuss the projects current status in the Vietnam. Those stakeholders suggested that engaging DMEC might be a challenge because of limited manpower and other COVID-19 related issues. Attendees also suggested that because DMEC DG Tuan is retiring soon, MDRC should postpone engagement to when there is new leadership. Private sector companies vocalized similar experience with DMEC and suggested engaging the Vice Minister of Health, Ministry of Health Director, and Deputy Director. Attendees discussed the Ministry of Health's approach to medical devices during the pandemic, including how medical devices qualify for fast-track approval if there is a pre-sale certificate from the U.S., EU, Canada, Australia, or Japan. Private sector members suggested that MDRC focus on post-market issues, like reimbursement and health insurance. Attendees discussed developing and sending a joint letter to the Prime Minister. MDRC has since drafted that letter. APACMed and EuroCham Vietnam confirmed their willingness to sign onto the letter with AdvaMed. As of 31 December, the MDRC project team is awaiting the Mission's approval to transmit.

On 3 November, the USABC shared with MDRC that it contacted DMEC DG Tuan on MDRC's behalf. DG Tuan expressed "shared interest in organizing an in-depth discussion" on MDRC and said DMEC will "look into" assigning a focal point once it received "guidance" from superiors. However, on 4 November, it was reported that a number of political office holders and officials within DMEC, including Vice Minister Cuong and DG Tuan, have been censured and/or removed from their positions. MDRC sought views on these developments from local stakeholders in order to ascertain next steps.

Indonesia

On 6 October, MDRC held a meeting with the Indonesian Embassy in Singapore and sought guidance on engagement with Indonesian agencies. The Embassy representatives were receptive to MDRC, indicating they will update their Ambassador and follow up with government agencies once they receive approval. MDRC forwarded materials and letters with the Embassy for sharing with relevant agencies.

On 19 October, MDRC connected with the European Chamber of Commerce (EuroCham) Indonesia's Health Committee after being introduced by USAID. MDRC and EuroCham discussed hosting a formal introductory call with relevant members and the possibility of participating in the Health Business Gathering in Bali from 2-3 December.

On 21 October, MDRC sent an email to the Indonesian Minister of Health Budi Sadikin following an in-person conversation in Washington, DC. The email sought his support to assign relevant senior officials for MDRC to coordinate with and advance the project in Indonesia. MDRC also forwarded this email to Professor Laksono Trisnantoro, Minister Budi's Special Assistant, offering to schedule a discussion with him to further explain the project.

On 25 October, MDRC met with USAID Indonesia and EuroCham Indonesia's Pharmaceutical and Medtech Working Group. After a briefing on MDRC, the working group provided multiple comments. They recommended MDRC's outreach focus on a specific agency rather than all relevant ones. They also suggested that two to three issues relevant to the agency should be identified. The working group also recommended having an individual on the ground to follow up with relevant agencies. Finally, they suggested approaching political office holders, senior officials or the foreign cooperation bureau at the Ministry of Health, which MDRC has already explored. MDRC agreed to send the Working Group project informational material and contact points, and the Working Group agreed to forward MDRC's outreach letter to their contact in the MOH's Pharmaceutical and Medical Devices Directorate General for insight.

On 25 October, MDRC met with Anastasia Susanto, the USAID Mission's Health System Strengthening Lead. Anastasia reiterated the need for a local contact or a focal point on the ground to coordinate the MDRC. She advised USAID Indonesia would consider forwarding a letter on MDRC to the Ministry of Health. Anastasia committed to checking with USAID's Alliance and Partnership Specialist to confirm the feasibility of sending the letter.

On 2 November, Indonesia's National Public Procurement Agency (LKPP), sent a letter conveying its "in-principle" agreement to collaborate with MDRC and providing a focal point for follow-up. The LKPP is responsible for the national procurement of government goods and services, including medical devices, and maintenance of the national e-catalog. MDRC has followed-up, proposing a meeting with the focal point and representatives from the Ministry of Health, but has not received a response as of 31 December. MDRC will follow up in January 2022.

On 5 November, MDRC introduced the project to representatives of the Indonesian Embassy in DC. The embassy agreed to assist MDRC in following up with the Ministry of Health. MDRC provided the embassy with materials and project outreach letters.

On 16 November, Prof. Laksono Trisnantoro, the special assistant to the Indonesian Minster of Health, contacted the USAID Indonesia Mission to inquire about MDRC. Following an overview of the project, Prof. Trisnantoro put the Mission in touch with the Ministry of Health's Medical Device Assessment department.

On 29 November, MDRC met with the Mission to discuss the above conversation and strategize future engagement with the Ministry of Health. The Mission outlined some of the Ministry's preliminary priorities and indicated the Ministry welcomes MDRC's ideas on providing training, technical expertise, and general capacity building.

On 4 December, MDRC presented on the project at the Indonesia Health Business Gathering, emphasizing the project's alignment with the Indonesia Healthcare Transformation Plan. This Gathering convened policymakers and industry representatives.

On 17 December, MDRC introduced the project to the Ministry of Heath, which indicated initial support for collaborating on the project. The Ministry mentioned some preliminary priorities for collaboration, including pre-market assessment & post-market quality surveillance of medical devices, capacity building on regulatory standards, ensuring safety and efficacy of medical devices, and local production of medical devices. MDRC committed to developing and sharing a workplan for collaboration with the Ministry ahead of a January 2022 meeting. In that meeting, MDRC and the Ministry will discuss specific issue areas for partnership. The USAID Mission in Indonesia proposed that once the Ministry is comfortable and a workplan is developed, the Ministry could issue a letter of endorsement of the project which MDRC could use in outreach to other Indonesian agencies.

Other Implementation Progress

MDRC has packaged the findings of its Phase One, Tier One gap analyses and literature reviews from all project countries in a unified Tier One report. This report includes assessments of GRP implementation by country as well as an overarching chart to allow for comparison across project countries. The Tier One report has been reviewed by USAID and is undergoing final edits to align with USAID branding requirements.

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

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

MDRC also continued development of its Stakeholder Mapping Reports. These reports outline Tier One, Two, and regional (where appropriate) stakeholders in Indonesia, Vietnam, SE Asia, Ghana, South Africa, and Kenya. They have been reviewed by the same industry associations, US Missions, and US agencies, such as the International Trade Administration (ITA). These reports, which were designed to align with USAID branding requirements, have been reviewed by ANSI and are undergoing edits before they are sent to USAID for final approval. Like the Tier One Report, these may be updated as necessary through the remainder of the project.

2.4 Implementation Challenges

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

COVID-19 has brought with it many complications, including the ability to plan for and host physical workshops. These, in particular, have been delayed over a year, and could still face challenges if a new strain of COVID becomes prevalent or individual countries create new policies regarding their management of the virus. It has also caused hesitation with a number of panelists who would like to participate, but are currently uncertain of traveling abroad. The virtual forums are much easier to implement currently as they are simply a matter of scheduling. Virtual workshops will mean physical one on one meetings with standards experts will be limited, however, Pivot will follow-up with stakeholders to see if follow-up meetings can be scheduled for specific questions that are not addressed during the training.

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

Researching the current use of standards by regulators and related authorities is time-consuming and some stakeholders are new since the original 2019 Standards Alliance Phase 1 Workshop. Collecting up-to-date information via virtual calls has been key. To date, ASTM's technical consultant on the ground in Ghana has been able to collect information virtually via email or via phone. Cote d'Ivoire remains as the only country not yet engaged in identifying focal point persons for the meetings to be held on the ground in 2022.

Activity #6 Africa Concrete and Building Code Adoption Initiative

The biggest challenges are:

- The constraints on travel and in-person meetings caused by the pandemic. ACI is waiting for the COVID Omicron wave to settle down and will plan in-person meetings with countries that show interest to proceed to Phase 2 and 3 following its awareness building trainings.
- Trying to overcome historical, colonial bias to the use of European-based codes and standards. ACI has decided to host a general training for all 3 countries to build awareness of ACI and the benefits of having the standard recognized as deemed to comply if adoption is too big of a commitment for countries to make at this stage.

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

Overcoming project implementation delays related to USAID Mission concurrence remained a project challenge in Q4 2021. Following the Mission in Kenya's concurrence at the end of July 2021, the Mission did not explicitly approve MDRC project outreach in Kenya despite multiple requests by the project. However, in coordination with USAID in DC, MDRC inferred the 'OK' to proceed with outreach in December after providing the Mission with appropriate time to review and comment. Outreach was sent in December.

Another challenge to project implementation remains limited engagement by some project country governments. The project team cannot commence work in countries without engagement by Tier One and/or Tier Two government agency partner(s). In Ghana, MDRC outreached in July when Kenya and South Africa had secured Mission concurrence. Following extensive follow-up by MDRC and the Mission, the Ghanaian Ministry of Health responded in October to designate a point of contact. Thereafter, the point of contact did not respond to outreach until late December. MDRC is requesting an introductory call with the contact for January 2022.

In Vietnam and Indonesia, MDRC maintains high levels of engagement with the private sector but are pending heightened engagement by government stakeholders. In Vietnam this November, it was reported that a number of political office holders and officials within DMEC, including Vice Minister Cuong and DG Tuan, were censured and/or removed from their positions.

In order to overcome this challenge, MDRC convened relevant associations and industry stakeholders to seek their support raising MDRC with relevant government contacts. Further, MDRC connected with Vietnamese and Indonesian embassies in Singapore and Washington, D.C. to seek their advice on implementing MDRC. MDRC efforts have been successful in Indonesia, securing a meeting with the Ministry of Health in December. MDRC continues to drive follow-up engagement in Vietnam despite the change in leadership.

While COVID-19 has, as expected, made in-person capacity building impossible to date, the project is actively addressing this challenge through the execution of high-quality virtual engagements. These engagements continue to improve both in their ability to disseminate quality resources and convene relevant stakeholders from the public and private sectors. Please see Section 3 – Stakeholder Participation and Involvement for further information.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

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

Q4 2021 MDRC Capacity-Building Trainings and Workshops:

MDRC hosted or helped execute 7 trainings and events, convening 1,638 participants from academia, the private sector, Standards Developing Organizations (SDOs), national regulatory authorities (NRAs), international organizations, and numerous other vital stakeholders. Of those, over 838 were female (51%) and 1,173 were from the private sector. An overview of those trainings is provided below:

Date	Meeting/Event	Location	Participants	Region
27 Oct 21	GRPs in Health Regulations – COFEPRIS, One of Four	Virtual	267 attendees 194 female, 70 male, 3 undeclared	Mexico

Date	Meeting/Event	Location	Participants	Region
			(192 private sector)	
10 Nov 21	GRPs in Health Regulations – COFEPRIS, Two of Four	Virtual	183 attendees 130 female, 53 male (131 industry)	Mexico
17 Nov 21	GRPs in Health Regulations – COFEPRIS, Three of Four	Virtual	165 attendees 118 female, 46 male, 1 undeclared (113 private sector)	Mexico
22-23 Nov 21	ABIIS Medical Devices Webinar – Regulation, Advances, and Perspectives	Virtual	22 Nov: 247 attendees (226 private sector) 23 Nov: 198 attendees (182 private sector) Gender data not reported	MDRC Countries + LatAm
24 Nov 21	GRPs in Health Regulations – COFEPRIS, Four of Four	Virtual	153 attendees 104 female, 48 male, 1 undeclared (131 private sector)	Mexico
6-7 Dec 21	ALADDIV and CBDL's XI International Workshop – "Quality Assured and Accessible Diagnostic Tests for Public Health Programs"	Hybrid	Dec 6: 176 attendees 108 female, 67 male, 1 undeclared (79 private sector) Dec 7: 119 attendees 87 female, 32 male (57 private sector)	MDRC Countries + LatAm
7 Dec 21	Joint MDRC-FDA Webinar on Utilization of International Standards and Conformity Assessment	Virtual	130 attendees 97 female, 33 male (62 private sector)	MDRC Countries + LatAm

Stakeholder Engagement

- 27 October 2021: MDRC and COFEPRIS co-hosted the first webinar of a series of four on GRP and their implementation in the Medical Device Sector. This workshop convened a total of 267 participants, including 53 attendees from COFEPRIS and 1 from the Secretariat of Economy in Mexico. Government agencies from Brazil, Bolivia, Colombia, El Salvador, Honduras, Peru and the United States also participated. A total of 192 representatives from the private sector attended, including 5 trade associations from Brazil, Peru and the United States.
- 10 November 2021: MDRC and COFEPRIS co-hosted the second webinar of the series of four on GRP and their implementation in the Medical Technology Sector. This workshop convened a total of 183 participants. Of those, government agencies from Bolivia, Colombia, El Salvador, Honduras and Peru were represented, in addition to 52 attendees from COFEPRIS, 1 from de Secretariat of Economy, 1 from CONAMER and 1 from the Mexican Pharmacopeia from Mexico; 3 Trades Associations from Ecuador, Mexico and the United States and a total of 131 representatives from the private sector. Materials and recordings will be made available at the Coalition's website.
- 17 November 2021: MDRC co-hosted with COFEPRIS the third webinar of a series of four on GRP and their implementation in the medical device sector. This workshop convened a total of 165 participants. Of those, government agencies from Bolivia, Colombia, El Salvador and Honduras were represented, in addition to 52 attendees from COFEPRIS, 1 from DGN - Secretariat of Economy, and 1 from the Mexican Pharmacopeia from Mexico; 6 Trades Associations from Brazil, Colombia, Chile, Ecuador, Mexico and the United States and a total of 113 representatives from the private sector.
- 22-23 November 2021: The Coalition member ABIIS held a two-day workshop with ANVISA on GRP and medical device regulatory convergence. The event was executed with the support of the Coalition and convened more than 400 attendees, including from Colombia, Mexico and Peru. Participants included the ABNT-designated entities for Brazilian medical device technical committees CB-26 (ABIMO) and CB-26 (SBAC).
- 24 November 2021: MDRC co-hosted with COFEPRIS the fourth webinar of a series of four on GRP and their implementation in the medical device sector. This workshop convened a total of 153 participants. Of those, government agencies from Colombia, Honduras and Spain were represented, in addition to 52 attendees from COFEPRIS, 3 from de Secretariat of Economy and 2 from the Mexican Pharmacopeia from Mexico; PAHO and five Trades Associations from Ecuador, Mexico and the United States and a total of 131 representatives from the private sector.
- 6-7 December 2021: The Coalition supported ALADDiV and CBDL to hold their XI International Workshop – "Quality Assured and Accessible Diagnostic Tests for Public Health Programs." Support was also provided by the London School of Hygiene and Tropical Medicine (LSHTM), the Welcome Trust, The International Diagnostics Centre, and Aldimed. The hybrid event convened nearly 300 participants, including regulatory authorities – such as ANVISA (Brazil), INVIMA (Colombia), Dinavisa (Paraguay), and AGEMED (Bolivia) – Ministries of Health, Institutions dedicated to scientific research, Universities, Hospitals, Pharmacies, and Industry.
- 7 December 2021: The Coalition partnered with the U.S. FDA to organize a webinar series on Utilization of International Standards and Conformity Assessment. During this session, FDA representatives shared their experience on the utilization of Standards and Conformity Assessment through their SCAP Program. In attendance were participants from 17 countries, 13 NRAs and 45 companies.

4. RESULTS ACHIEVED

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

- The onboarding of a new technical consultant based in Ghana, Mr. Augustus Wiredu, was completed.
- Focal point persons were identified in 3 of the 4 target countries.
- An agenda for a March 2022 workshop in Ghana was prepared and a letter requesting support was sent to GSA.

Activity #9 – Community Water Systems – Standards for safety and risk management

Indicators	Results Achieved - Brazil
DO1, Indicator 9: Number of workshop/reserve trade mission participants.	Twenty (20) stakeholders are interested in becoming training participants from the public and private sector who attend project activities (trainings, etc.) related to awareness and reducing TBT. Among these stakeholders, there are manufacturer and consumer associations that have interest in promoting the trainings for their members and associates

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

Global

- On 27 October, MDRC met with the U.S. FDA CDRH, which noted that the U.S. Department of State intends to bring an AMA delegation to DC in the second half of 2022. CDRH confirmed that if there is a medical device component, MDRC can try to participate. CDRH supported MDRC's idea of developing "action-ready" clusters of relevant medtech NRA and trade authorities in each project country to rapidly review and respond to medtech STCs and regulatory non-alignments. (DO 3, IR 3.1)

Latin America

- REGIONAL: In Q3 2021, the Coalition's website visits were 3,653. This is an increase of 9% over Q2 2021. In Q4 2021, the Coalition's website visits were 4,400. This is 20.4% increase from Q3 2021. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)

- PERU: On 4 October, MDRC met with the ACR and overviewed the project, the Coalition, and some of the priority industry challenges for Peru. Those challenges include labeling and manufacture registration. (IR 1.1, IR 1.2, IR 3.1)
- BRAZIL: On 8 October, MDRC met with ALADDiV and CBDL, who outlined their priority standards for nationalization. Participants proposed creating a working group coordinate future activities. (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3, Output 1.1.4, Output 1.1.6)
- MEXICO: On 11 October, MDRC met with COFEPRIS, which shared information on NOM241 and NOM137. MDRC and COFEPRIS began coordinating the development of two events in November with the US FDA related to GMPs, for which MDRC would provide support on simultaneous translation. (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3, Output 1.1.4, Output 1.1.6)
- COLOMBIA: On 12 October, MDRC introduced the new Liaison and shared its proposal and next steps for future partnership with MinSalud and INVIMA. INVIMA and MinSalud confirmed their priority for collaboration and agreed to host regular coordination meetings. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 12 October, the Coalition met with PAHO. The Coalition offered support developing an agenda for the X Meeting of Red PARF in December. The Coalition shared information on its GRP webinars on and upcoming events. PAHO committed to drafting a formal proposal of cooperation with the Coalition. (IR 1.1, Output 1.1.4, Output 1.1.7, IR 1.2, Output 1.2.1, IR 2.1, Output 2.1.1)
- COLOMBIA: On 14 October, MDRC updated ANDI and the DNP on the current status of proposed projects and timelines. The parties agreed to a regular schedule of meetings to advance MDRC work. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- MEXICO: On 14 October, MDRC met with COFEPRIS and shared a draft agenda for future trainings. COFEPRIS preliminarily agreed with the proposal but wished to review before finalizing. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- COLOMBIA: On 19 October, DNP approved MDRC's proposal to craft an ex-post evaluation instrument with a methodology that defines necessary activities, information, responsibilities, and timelines. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- COLOMBIA: On 20 October, the working group began crafting the ex-post evaluation instrument and developed the structure of the first chapter of the design evaluation document. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- COLOMBIA: On 21 October, DNP approved MDRC's proposal for the ex-post evaluation instrument's overarching procedures, processes, and institutional architecture. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- PERU: On 21 October, MDRC met with MinCETUR to discuss the Ministry's initiatives on gender and inclusion. (CC IR 2.1)
- BRAZIL: On 25 October, representatives from MDRC, CBDL, CB-36, and ALADDiV met to discuss a workplan for CB-36 and an event to train industry representative on the importance of the use of international standards. Such an event would include topics such as medical device regulation and international trade, international standards, the CB-36 working process, and the IMDRF Document on Optimizing Standards for Regulatory Use. (IR 1.1, Output 1.1.1, Output

1.1.2, Output 1.1.3, Output 1.1.4, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.2, IR 2.1, Output 2.1.1, IR 3.1, Output 3.1.1, IR 4.1)

- MEXICO: On 27 October, MDRC and COFEPRIS co-hosted the first webinar of a series of four on GRP and their implementation in the Medical Device Sector. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- COLOMBIA: On 27 October, MDRC continued development of the ex-post evaluation instrument and defined which persons would be interviewed as part of that process. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- REGIONAL: On 28 October, AHWP/GHWP leadership confirmed support for the Coalition's application to become a liaison to the organization. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4)
- COLOMBIA: On 3 November, MDRC finalized development of the tool to interview the regulators who defined decrees 4725 and 3770. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- MEXICO: On 5 November, MDRC met with FEUM to discuss GRPs elements, their applicability, and the responsibility to comply with international agreements and treaties. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4)
- MEXICO: On 10 November, MDRC contributed to the discussion on GRPs the First International Meeting of Pharmaceutical Sciences Professionals, highlighting GRP implementation and international trade obligations. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4)
- MEXICO: On 10 November, MDRC and COFEPRIS co-hosted the second webinar of the series of four on GRP and their implementation in the Medical Technology Sector. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- COLOMBIA: On 10 November, MDRC UPDATED INVIMA, DNP and MinSalud on the above recent advances by the working group with regards to ex-post evaluation. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On 11 November, MDRC met with DNP to discuss the proposal for the ex-post evaluation instrument's overarching procedures, processes and institutional architecture. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On 11 November, MDRC met with ANDI to discuss the current status of MDRC's proposed projects, timelines, and recent developments. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On 11 November, MDRC met with the head of the MinSalud's legal office to introduce the project and invite the office to participate in the ongoing efforts with DNP to update the Ministry's processes and procedures. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- PERU: On 12 November, MDRC shared an overview of its priorities with ACR-PCM for their reference in coordinating a meeting with the Ministry of Health. (IR 1.1, IR 1.2, IR 3.1, IR 4.1, IR 4.2)
- COLOMBIA: On November 16, MDRC met with MinSalud to review the Ministry's document on international references. MDRC invited MinSalud to review its international commitments and offered support to help align its commitments with international standards and references. (IR 1.1,

Output 1.1.2, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)

- MEXICO: On 17 November, MDRC co-hosted with COFEPRIS the third webinar of a series of four on GRP and their implementation in the Medical Device Sector. A significant output of this session was COFEPRIS and Mexican Pharmacopeia's acknowledgement of the need to implement internal processes to ensure compliance with international obligations on GRPs. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.3, Output 2.1.4, Output 2.1.5, IR 3.1, Output 3.1.1)
- PERU: On 17 November, upon receipt of MDRC's priorities, MinCETUR proposed a follow up meeting with DIGEMID in early December to align on next steps to address those priorities. (IR 1.1, IR 1.2, IR 3.1, IR 4.1, IR 4.2)
- COLOMBIA: On November 17, MDRC, INVIMA, DNP, and MinSalud met to continue revising the design assessment document's chapters related to ex-post evaluation. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On November 19, MDRC met with INVIMA to explain and suggest wording for the design assessment document. INVIMA committed to reviewing a proposed decree's institutional architecture and the Government's institutional capacity to respond to stakeholder demand prior to issuing the decree. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- REGIONAL: On 24 November, MDRC met with UNE, securing their commitment to support the Coalition and MDRC in increasing the availability of Spanish-language versions of ISO and IEC standards for LatAm country NSBs. (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3)
- BRAZIL: On 22-23 November, ABIIS held a two-day workshop with ANVISA on GRP and medical device regulatory convergence with the support of the Coalition. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1, IR 1.2, Output 1.2.1, IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.2, Output 2.1.3, Output 2.1.4, Output 2.1.5, IR 3.1, Output 3.1.1)
- COLOMBIA: On November 24, MDRC met with DNP to review the schedule for ex-post evaluation and agreed to incorporate six more months into the schedule. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- MEXICO: On 24 November, MDRC co-hosted with COFEPRIS the fourth webinar of a series of four on GRP and their implementation in the Medical Device Sector. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.3, Output 2.1.4, Output 2.1.5, IR 3.1, Output 3.1.1)
- COLOMBIA: On November 24, the head of the MinSalud's legal office vocalized interest in MDRC's proposal to overviewed to ensure the Ministry's processes and procedures are aligned with DNP's regulatory improvement policy. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On November 24, MDRC met with INVIMA, DNP and MinSalud to agree on a new schedule for advancing topics related to MDSAP, EUA, and clinical research. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1, DO 4, IR 4.1, IR 4.2)

- COLOMBIA: On November 25, MDRC met with DNP, which presented its new proposed timeline for ex-post and ex-ant evaluation. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1)
- COLOMBIA: On November 29, MDRC introduced the project to an economic analyst at MinSalud and discussed how the analyst could support MDRC's execution. The analyst agreed to undertake a review of relevant MinSalud documents. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1)
- MEXICO: On 29 November MDRC met COFEPRIS to discuss next steps for the project, including MDRC's proposed training plan, as well as specific actions to advance the priorities identified by the two entities. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1)
- REGIONAL: On 30 November, MDRC and the Coalition met with World Bank, Brazil's ANVISA, and Colombia's DNP, MinCIT, MinSalud, and INVIMA. The parties discussed GRP, their impacts on the Health sector, and Brazil's and Colombia's approaches to implementing them. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1)
- REGIONAL: On 30 November and 1 December, the GHWP unanimously approved the Liaison Member status of the Coalition. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- COLOMBIA: On December 3, MDRC and ANDI began exploring opportunities for partnership to address medical device-related issues in INVIMA. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1, DO 4, IR 4.1, IR 4.2)
- COLOMBIA: On December 6, MDRC continued partnering with DNP and the head of the Ministry of Health's legal office to advance the standardization of regulatory policy and changes to internal processes and procedures. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- BRAZIL: On 6-7 December, the Coalition supported ALADDiV and CBDL to hold their XI International Workshop – "Quality Assured and Accessible Diagnostic Tests for Public Health Programs" which addressed opportunities to respond to COVID-19. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 7 December, MDRC met with PAHO to discuss priorities for partnership, including executing capacity-building trainings on international standards, GRP, and EUAs. Following PAHO's suggestion, the Coalition is preparing an application to become an Observer Member to PANDRH. PAHO and the Coalition will begin developing a mechanism for joint PAHO-Coalition publications. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 7 December, the Coalition partnered with the U.S. FDA to organize a webinar series on Utilization of International Standards and Conformity Assessment. (IR 1.1, IR 1.2, IR 2.1, IR 3.1)
- COLOMBIA: On December 15, MDRC and DNP greed that MDRC will propose content for a new health policy and action plan to address the lack of qualified personal and absence of institutional architecture to appropriately advance regulatory policy. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)

- BRAZIL: On 15 December, MDRC met with INMETRO to discuss details of the Project and opportunities for collaboration. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- PERU: On 15 December, MDRC met with MinCETUR to advance collaboration with the Ministry of Health and DIGEMID, including through future GRP trainings. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- REGIONAL: On 17 December, MDRC met with PAHO to review and update MDRC application to join the PANDRH. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- MEXICO: On 17 December, MDRC met with Secretariat of Economy to discuss potential avenues to engage the National Commissioner and CONAMER, a critical stakeholder in the implementation of GRP. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On 22 December, MDRC formally introduced the project to DNP's regulatory improvement group and health group. MDRC proposed new health policy to strengthen institutional architecture of the Ministry of Health and the advance GRPs. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: In December, MDRC interviewed previous members of INVIMA and the Ministry of Health as part of the ex-post evaluation process for decrees 4725 and 3770. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: In December, MDRC continuously worked MinCIT, DNP, INVIMA and the Ministry of Health to determine whether the impact analysis on EUAs should be simple or complete. This includes answering answer a questionnaire through SUCOP as well as meeting with the Ministry of Health's medicines and medical devices groups. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1, DO 4, IR 4.1, IR 4.2)

Africa

- KENYA: On 6 October, MDRC met with the PPB to agree on next steps and develop a dedicated workstream. PPB confirmed it is open to working with MDRC to ensure its new document reforming regulatory procedures includes medical device-specific elements and properly differentiates between MedTech and pharmaceutical needs. (IR 1.1, IR 1.2, IR 3.1, IR 4.1)
- KENYA: On 26 October, MDRC shared with PPB an overview of the project's implementation objectives in Kenya, including an initial list of industry-identified priorities for collaboration, proposed schedule of meetings and workplan, and annex of proposed GRP implementation policies with PPB (Tier Two). Mecomed shared with PPB additional information on industry's identified priorities for collaboration. (IR 1.1, IR 1.2, IR 3.1, IR 4.1)
- REGIONAL/KENYA: On 27 October, MCRC updated PQM+ on PPB's request to undertake a formal Tier Two situational analysis as well as on Ghanaian government stakeholders' low levels of engagement. MDRC discussed PQM+'s efforts to craft a document with PPB to update the authority's regulatory functions. MDRC and PQM+ briefly discussed the project's regional-level objectives. (IR 1.1, IR 1.2, IR 3.1, IR 4.1)
- REGIONAL: On 16 November, MDRC met with ITA to align on next steps for collaboration in Africa. MDRC and ITA agreed that this collaboration would begin with facilitating country-specific

outreach and extend to subsequent country-specific/regional coordination on project engagements. ITA agreed to reference MDRC in its ongoing engagements with relevant stakeholders in Africa. MDRC and ITA also discussed the project's implementation status in the three African project countries. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)

- KENYA: On 17 November, MDRC met with PQM+ and discussed the regulatory framework in Kenya, including the RIA requirements. PQM+ will share with MDRC the Ministry of Health's policy document on supply chain strategy for health products. (IR. 1.1, Output 1.1.5)
- REGIONAL: On 24 Nov, per invitation of the AMDF, the MDRC team attended the virtual meeting of the 7th African Medicines Regulatory Conference. The MDRC team will leverage the information shared during this meeting to propose MDRC-specific workstreams to the AMDF. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 1 December, MDRC met with the USTR and discussed the project's role advancing the implementation of GRP and eliminating trade bottlenecks at both the regional and country levels in Africa. USTR vocalized interest in referencing MDRC in pertinent meetings and helping facilitate local engagements where applicable. MDRC has since connected with Africa project country-specific USTR points of contact to provide them with supplementary informational materials and talking points. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- SOUTH AFRICA: On 2 December, MDRC met with the USAID Mission in South Africa to provide the primary point of contact with a refresher on the project's current status in the country and ongoing engagements with project partners. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- GHANA: On 2 December, MDRC met with ITA and USTR in Ghana and provided a summary of objectives in Ghana and broader region, overview of local stakeholders with which the project has conducted outreach, and timeline of engagement in the country. The U.S. Embassy officials offered their support in connecting with the proper points of contact in government ministries to advance project objectives. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 6 December, MDRC attended the monthly Standards Alliance 2.0 project coordination meeting with PQM+, MTaPS, and relevant USG officials. The initiatives shared updates on their recent progress. PQM+ shared with MDRC that it was working to secure PPB approval to share the draft document to revise PPB's regulatory processes. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- SOUTH AFRICA: On 7 December, SAHPRA agreed to proceed with MDRC and develop a dedicated MDRC workstream. MDRC and SAHPRA agreed that the MDRC workstream should emphasize the procedural elements of GRP as they pertain to COVID-19 response and recovery. The MDRC workstream will align with and operationalize the recommendations of regional bodies, such as the AMDF. MDRC work will complement SAHPRA's recent engagement with the WHO on regulatory practices pertaining to medicines, emphasizing the importance of leveraging international guidance (i.e. from the WHO) in the local context. MDRC is scheduling a kickoff meeting with SAHPRA for late January. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- GHANA: On 14 December, following attempts by MDRC in October, November, and December to schedule a meeting with the Ministry of Health's designated focal point, MDRC received a response from the focal point. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 15 December, MDRC provided FDA CDRH with an overview of MDRC's current state of play in Africa and context for their upcoming meeting with Kenya's PPB. MDRC

and CDRH aligned on priorities for the region and next steps for engaging with relevant stakeholders on the continent. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)

- REGIONAL: On 16 December, MDRC and the ADMF discussed the project's ability to review and comment on relevant documents that are crafted in AMDF sub-working groups. MDRC was invited to the January AMDF meeting. AMDF informed MDRC that the AMDF no longer has an active COVID-19 Taskforce. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- KENYA: On 16 December, MDRC and PPB aligned on the next steps and processes to formalize an MDRC workstream with PPB. MDRC and PPB will proceed to formulate an MOU which will provide the legal basis for future collaboration on Tier Two-specific capacity building. Concurrently, PPB will send MDRC a formal letter requesting a dedicated project liaison to coordinate work in the project country. Once the MOU is concluded, MDRC and PPB will develop a consensus-based prioritized workstream to address identified issue areas through capacity building consultations and trainings. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- KENYA: On 16 and 17 December, MDRC extended outreach to KEBS and the Kenyan Customs and Border Control Department. On 19 December, KEBS responded positively, indicating it would be happy to partner with MDRC. On 22 December, Customs responded and designated a focal point for coordinating MDRC-Customs work. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)

Southeast Asia

- VIETNAM: On 5 October, MDRC introduced the project to the Vietnamese Embassy in Washington, D.C. and solicited the Embassy's guidance on how to best engage Vietnamese agencies. The Embassy committed to sharing MDRC's outreach letters with government stakeholders to help establish the focal point. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- INDONESIA: On 6 October, MDRC met with the Indonesian Embassy in Singapore to seek guidance on engagement with Indonesian agencies. The Embassy agreed to update their Ambassador and follow up with government agencies once they receive approval. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- VIETNAM: On 6 October, MDRC introduced the project to the Vietnamese Embassy in Singapore and sought guidance on how to best engage with local agencies. The Embassy agreed to forward MDRC materials and outreach letter to the Ministry of Health on MDRC's behalf. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- VIETNAM: On 15 October, MDRC sought USABC's assistance to share a prepared drafted letter to the Vietnamese Minister of Health that introduces MDRC and requests that the Minister assign focal points to discuss the project. USABC agreed to assist and said it would consider directly partnering with MDRC. (IR 1.1, IR 1.2, IR 2.1, IR 3.1)
- INDONESIA: On 19 October, MDRC connected with EuroCham Indonesia's Health Committee. Participants discussed hosting a formal introductory call and the possibility of participating in the Health Business Gathering in Bali from 2-3 December. (IR 2.1)
- INDONESIA: On 21 October, MDRC conducted outreach to the Indonesian Minister of Health seeking support to advance the project in Indonesia. (IR 1.1, IR 1.2, IR 3.1)

- INDONESIA: On 25 October, MDRC met with USAID Indonesia and EuroCham Indonesia's Pharmaceutical and Medtech Working Group, who provided guidance on MDRC outreach. The Working Group agreed to forward MDRC's outreach letter to their contact in the MOH's Pharmaceutical and Medical Devices Directorate General. (IR 1.1, IR 1.2, IR 2.1, IR 3.1)
- INDONESIA: On 25 October, MDRC met with the USAID Mission's Health System Strengthening Lead, which reiterated the need for a local focal point on the ground to coordinate MDRC implementation. Th Mission agreed to consider forwarding a letter on behalf of MDRC to the Ministry of Health. (IR 1.1, IR 1.2, IR 3.1)
- VIETNAM: On 1 November, MDRC hosted a joint call with AdvaMed, AdvaMed members, APACMed, EuroCham Vietnam, and APCO to discuss the projects current status in the Vietnam. Those stakeholders provided input on MDRC engagement and the Ministry of Health's approach to medical devices during the pandemic. Attendees discussed developing and sending a joint letter to the Vietnamese Prime Minister to bring the project to his attention. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- VIETNAM: On 3 November, the USABC informed MDRC it connected with DMEC on MDRC's behalf. DMEC expressed interest in MDRC and advised it was awaiting guidance from superiors. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- VIETNAM: Following reports on 4 November, that a number of political office holders and officials within DMEC have been censured and/or expelled from their positions, MDRC sought views on these developments from local stakeholders. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- INDONESIA: On 2 November, the LKPP sent a letter to MDRC conveying its "in-principle" agreement to collaborate with the project. MDRC is working to schedule a follow-up meeting. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- INDONESIA: On 5 November, MDRC introduced the project to representatives of the Indonesian Embassy in DC. The Embassy agreed to assist MDRC in following up with the Ministry of Health. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- INDONESIA: On 16 November, the special assistant to the Indonesian Minster of Health, contacted the USAID Indonesia Mission to inquire about MDRC and subsequently put the Mission in touch with the Ministry of Health's Medical Device Assessment department.
- VIETNAM: APACMed and EuroCham Vietnam have confirmed that they are agreeable to signing on to the joint letter with AdvaMed to the Vietnamese Prime Minister seeking his support for MDRC implementation. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- INDONESIA: On 29 November, MDRC met with the Mission to strategize future engagement with the Ministry of Health. The Mission outlined some of the Ministry's preliminary priorities. MDRC is finalizing the details for a meeting with the Medical Device Assessment department in early December. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- INDONESIA: On 4 December, MDRC presented on the project at the Indonesia Health Business Gathering, emphasizing the project's alignment with the Indonesia Healthcare Transformation Plan. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- INDONESIA: On 17 December, MDRC introduced the project to the Ministry of Heath, which indicated initial support for collaborating on the project. The Ministry mentioned some preliminary priorities for collaboration, including pre-market assessment & post-market quality

surveillance of medical devices, capacity building on regulatory standards, and ensuring safety and efficacy of medical devices. MDRC committed to developing and sharing a workplan for collaboration with the Ministry ahead of a January 2022 meeting. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)

5. LESSONS LEARNED

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

We need to be clear to stakeholders that the "harmonization" intended for the region is related to the testing capabilities of the participant countries. The project does not intend to reinvent or replace the decisions already reached on fuel specifications at the ECOWAS level. We will also need to be clear that the project does not intend to fund capital improvements for laboratories. Focal point persons should be decision-makers with a firm understanding of petroleum testing in order to make the program successful. Lastly, we'll need to make sure that the standards bodies are positioned to keep their standards up-to-date. Through the workshop planned for March 1-3, these issues will be highlighted and addressed through further collaboration between the technical consultant on the ground in Ghana and the selected focal points who will be champions for their countries.

Activity #6 Africa Concrete and Building Code Adoption Initiative

Because of the pandemic, we learned that we could make progress using virtual meetings which, while not as effective as in-person meetings, are the best we can do for now. We also learned that the colonial history of African countries and the Codes used while a colony, may make it more difficult for ACI codes to be adopted. ACI is pushing for deemed to comply support in countries where adoption would be a tougher commitment for NSBs and plans to discuss this option during its planned awareness building workshop with stakeholders it has already met with. ACI is also considering the option of putting more emphasis on influencing university curriculums as a means of continuing relationship building and culture change. Feedback/ reception from the workshop will help ACI determine whether ACI needs to move to other countries on interest/ difficulty of overcoming the colonial history.

Activity #9 – Community Water Systems – Standards for safety and risk management

NSF has learned that in Morocco cultural and social factors have a big impact on how to create engagement and trusting relationships with stakeholders. Face to face communication is preferred and NSF has faced difficulties in fostering connections with WASH stakeholders virtually. As such, NSF has verbally discussed with ANSI that it will amend its budget to include travel costs for two staff member to travel to Morocco in Q1/Q2 2022 for in-person stakeholder meetings. NSF staff will be traveling from Abu Dhabi and Brussels for this task. Further details are to be expected in Q1 2022 reporting, including the budget request.

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

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

MDRC continues to optimize the level of resources devoted to running MDRC and the Coalition's online presence. The execution of effective virtual project country capacity building does not require the allocation of extensive travel resources. With the reallocation of resources otherwise earmarked for travel to the Colombia Liaison, MDRC facilitated rapid progress in the project country. MDRC will continue to look for ways to maximize the effectiveness of resources to achieve MEL Plan objectives in the current non-travel environment.

In Q4, the Coalition continued to leverage a more experienced, lower cost web development vendor. This has heightened the Coalition's capacity to provide online modules and virtual resource library. Virtual Coalition resources have proven to be an invaluable tool for hosting and disseminating information vital to the project.

MDRC has continued to leverage the recently-launched project URL www.standardsalliance-mdrc.org and related email @standardsalliance-mdrc.org. These project elements streamline and standardize project communication across geographies.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Q4 2021 Planned Activities

Activity #	Activity Name	Meeting/Event	Date	Location	USAID participation?
#7	Increase the Flow of WASH Services	Indonesia: Pre-consensus meeting with the implementers of previous existing standard (SNI 03-0122-1998) and members of Association of Valve Industry to solicit their input and assess their capabilities for the implementation of new standard in the future. Consensus meeting for RSNI 3 as the final stage of SNI	Q1 2022	TBD	No

		formulation Preparation for the public comment period of the new standard to gain input from society			
9	Community Water Systems – Standards for safety and risk management	Workshop Training Activity #1, Brazil	March 2022	Virtual	Optional
12	MDRC	See table below			

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

ECOWAS Bioethanol Workshops

Logistics will be finalized with stakeholders in January and February 2022, speakers finalized with travel logistics in place, and two physical workshops held in Togo and the Gambia March 17-22, 2022.

ARSO Standards Support

A webinar training has been approved through ARSO and scheduled for Q2/Q3 of 2022; actual dates still to be determined. Actively coordinating with ARSO leadership.

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

Upcoming events depend on the work of TC40 restarting:

- Good Manufacturing Practices, **Q1, late March, or maybe April**
- Best Practices for Labelling, **TBD, 2022**
- Implementation Considerations; guidelines and voluntary standards, **TBD, 2022**

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

- Jan/Feb 2022 – Continue planning for a three-day technical workshop to be held in Ghana

- March 2022 – Hold a three-day technical workshop in Ghana and follow up on the resulting outcomes. It is expected that the training will facilitate the development of a baseline report and testing facilities report on the use of ASTM/API standards in the 4 primary ECOWAS countries and the development of a working group.

  It is also anticipated that as quality infrastructure is further developed in West Africa, the stakeholders will participate in ASTM's Proficiency Testing Programs (PTP) and that their products would become certified under API's Engine Oil Licensing and Certification System (EOLCS). ASTM's PTP's are statistical quality assurance programs that enable laboratories to evaluate and improve performance and maintain and fulfill mandatory accreditation requirements. API's EOLCS is a voluntary licensing and certification program that authorizes engine oil marketers that meet specified requirements to use the API Engine Oil Quality Marks. Both programs aim to ensure the sustainability of the outcomes achieved via the proposal.

Activity #6 Africa Concrete and Building Code Adoption Initiative

In the next quarter, ACI will be conducting introductory meetings in Tanzania and meeting with stakeholders in Uganda. In all three countries, we will also be working to organize longer, more detailed meetings with key stakeholders to give them a clearer understanding of ACI. At this point, all meetings will be virtual, until the pandemic eases and international travel is deemed safe for business travelers.

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

In Q1 2022, MDRC will continue to focus on outreach and development of capacity-building workstreams with private and public sector stakeholders, particularly in Southeast Asia and Africa. MDRC will advance awareness of MDRC objectives and dive deeper into specific Tier One and Tier Two areas with those stakeholders, identifying where MDRC can remedy regulatory non-alignments and promote the use of GRPs.

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

Date	Meeting/Event	Location	USAID participation?	Region
January 20 & 27	Joint MDRC - FDA webinar series on UDI	Virtual	Yes	LATAM
March 10, 17, 24 & 31 (TBC)	Joint MDRC – FDA webinar series continuation on International Standards and Conformity Assessment	Virtual	Yes	LATAM
TBD	Emergency Use Authorization – International References	Virtual	Yes	COL/MX - LATAM

Date	Meeting/Event	Location	USAID participation?	Region
TBD	IMDRF – Essential Principles & Table of Content	Virtual	Yes	COL - LATAM
TBD	Clinical Research for MDs	Virtual	Yes	COL - LATAM
TBD	Software as Medical Device – International References	Virtual	Yes	MX - LATAM
TBD	Tier One Regional Forum: relevant stakeholders from Ghana, Kenya, and South Africa (and broader region, as appropriate)	Virtual	Yes	Africa
TBD	Tier Two Regional Forum: relevant stakeholders from Indonesia and Vietnam (and broader region, as appropriate)	Virtual	Yes	Southeast Asia
TBD	Tier Two local Forum - Vietnam	Virtual	Yes	Vietnam

7. ANNEX

STANDARDS ALLIANCE: PHASE 2 QUARTERLY REPORT TO ANSI

7.1 PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2 (SA2) COVID-19 Medical Device Regulatory Convergence Project (MDRC)
Activity Start Date and End Date:	July 12, 2019 – July 11, 2024
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
Agreement Number:	#7200AA19CA00012
Name of Subcontractor/Subawardee:	The Advanced Medical Technology Association (AdvaMed)
Geographic Coverage (cities and or countries)	Latin America (Brazil, Colombia, Mexico, Peru), Africa (Ghana, Kenya, South Africa), Southeast Asia (Indonesia, Viet Nam)
Reporting Period:	1 October – 31 December 2021

- ### 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.

7.2 ACTIVITY IMPLEMENTATION PROGRESS

7.3 Progress Narrative

Global

On 27 October, MDRC met with Melissa Torres from the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). MDRC discussed organizing "action-ready" clusters of relevant medtech National Regulatory Agencies (NRAs) and trade authorities in each project country to rapidly review and respond to medtech specific trade concerns (STCs) and regulatory non-alignments. FDA/CDRH has standing meetings with the U.S. Trade Representative (USTR) to address STCs and the next step would be to arrange similar frameworks in Colombia, Mexico, Peru, and Brazil. FDA/CDRH supports MDRC's approach that country clusters would meet as part of an eventual World MedTech Trade Group.

Latin America

REGIONAL: In Q3 2021, the Coalition's website visits were 3,653. This is an increase of 9% over Q2 2021. In Q4 2021, the Coalition's website traffic continued to increase, with a total of 4,400 between October and December. This is 20.4% increase from Q3.

On 12 October, the Coalition met with the Pan American Health Organization (PAHO), which informed the Coalition that the 10th Meeting of Red PARF was scheduled for 1 December, for which the Coalition offered support in developing an agenda. The Coalition shared information on its series of webinars on GRP and related upcoming events. PAHO committed to drafting a formal proposal of cooperation with the Coalition.

On 28 October, the Asian Harmonization Working Party / Global Harmonization Working Party

(AHWP/GHWP) leadership confirmed their support for the Coalition's application to become a liaison to the organization (see below on the application's endorsement on 30 November).

On 24 November, MDRC met with the Spanish National Standards Body (UNE), securing their commitment to support the Coalition and MDRC in increasing the availability of Spanish-language versions of ISO and IEC standards for LatAm country National Standards Bodies (NSBs).

On 30 November, MDRC and the Coalition met with World Bank, Brazil's ANVISA, and Colombia's Ministry of Commerce, Industry and Tourism (MinCIT), National Planning Department (DNP), Ministry of Health (MinSalud), and National Food and Drug Surveillance Institute (INVIMA). The parties discussed GRP, their impacts on the health sector, and Brazil's and Colombia's approaches to implementing them. Colombia, for example, is actively utilizing an inter-agency approach while updating their regulatory framework for Medical Devices and IVDs (Decrees 4725 and 3770, respectively). A total of 216 participants from 8 countries attended the meeting, including 12 trade associations, 5 NRAs, the World Trade Organization (WTO), and PAHO.

At the 25th Annual Meeting of the AHWP/GHWP which took place virtually 30 November and 1 December, the AHWP/GHWP formally rebranded itself as the Global Harmonization Working Party (GHWP) and also unanimously approved the Liaison Member status of the Coalition.

On 7 December, MDRC met with PAHO to discuss priorities for partnership. Those priorities include executing capacity-building trainings on international standards, GRP, and EUAs. PAHO proposed for the Coalition to become an Observer Member to the Pan American Network for Drug Regulatory Harmonization (PANDRH), an initiative of the national regulatory authorities within the region and PAHO. The Coalition prepared an application to do so in accordance with PAHO's guidance. PAHO also proposed to collaboratively develop the agenda for the upcoming PAHO Medical Device Stakeholders Session in April, as well as the possibility of developing a mechanism for joint PAHO-Coalition publications. The latter proposal is designed to expedite the availability of important documents to an array of stakeholders.

On 7 December, the Coalition partnered with the U.S. FDA to organize a webinar series on Utilization of International Standards and Conformity Assessment. During this session, FDA representatives shared their experience on the utilization of Standards and Conformity Assessment through their SCAP Program. In attendance were participants from 17 countries, 13 NRAs and 45 companies. Materials and recording of the session is available at the Coalition's website: Webinar Series on Utilization of Voluntary Consensus Standards and Conformity Assessment.

On 17 December, MDRC met with PAHO and reviewed MDRC's work plan proposal to become an Observer Member of PANDRH. MDRC will continue working with PAHO to become a member in January 2022.

COLOMBIA: On 12 October, MDRC introduced the new Liaison, Susan Suárez, to MinSalud and INVIMA. MDRC then shared its proposal and next steps for future partnership with MinSalud and INVIMA. INVIMA and MinSalud confirmed that their priority topics for partnership include the assessment of Decrees 4725 and 3770, GMPs, Emergency Use Authorization (EUA), and Clinical Research. Participants agreed to set up a meeting with the planning and legal areas of INVIMA and MinSalud. Participants decided that their technical teams would meet for two hours every week to facilitate further collaboration.

On 14 October, MDRC updated the members of the National Association of Entrepreneurs of Colombia (ANDI), a Coalition member, and the DNP on the current status of proposed projects and timelines. DNP stressed that the proposal must align with the renewed regulatory improvement policy and agreed to a regular schedule of meetings to advance MDRC work. The parties agreed to set up a subsequent meeting to work on overarching procedures and processes for institutional strengthening.

On 19 October, MDRC shared a proposal with DNP to begin crafting an ex-post evaluation instrument with a methodology that defines necessary activities, information, responsibilities, and timelines. DNP agreed with the proposal and suggested including a step to identify stakeholders.

On 20 October, the MDRC Colombia working group began to craft the ex-post evaluation instrument with the methodology proposed by MDRC. The group developed the structure of the first chapter of the design evaluation document, which includes an analysis of Colombia's international agreements and their impacts to date. The group acknowledged the need to interview the regulators who drafted and defined decrees 4725 and 3770. MDRC committed to developing a tool to do so. In that process, MDRC will informally ask the Presidency for context on the justification for those decrees.

On 21 October, MDRC met with DNP and outlined its proposal for the instrument's overarching procedures, processes and institutional architecture. DNP agreed with the proposal, which MDRC and DNP agreed to present to the planning and legal areas of INVIMA and MinSalud in late November.

On 27 October, MDRC continued development of the ex-post evaluation instrument and defined which persons would be interviewed as part of that process. MinSalud and INVIMA established a team responsible for designing a glossary which will allow the interviewer to apply the qualitative assessment instrument. MinSalud and INVIMA requested that the MDRC liaison advance the interviews, process them, and propose a problem tree.

On 3 November, MDRC finalized development of the tool to interview the aforementioned regulators. MinSalud and INVIMA's teams continued to develop the glossary. MDRC requested background information from the Presidency for incorporation into the glossary.

On 10 November, MDRC met with INVIMA, DNP and MinSalud. MDRC shared the recent advances by the working group with regards to ex-post evaluation. Those include: (1) the development of the design evaluation document's first chapter, which includes an analysis of Colombia's international agreements and their impacts, (2) the finalization of the tool to interview the regulators who defined decrees 4725 and 3770, (3) the informal request of the justifications for those decrees, and (4) the finalization of the methodology that defines activities, necessary information, responsibilities, and schedule for structuring ex-post evaluation document of decrees 4725 and 3770.

On 11 November, MDRC met with DNP to discuss the proposal for the ex-post evaluation instrument's overarching procedures, processes and institutional architecture. DNP and MDRC continued preparing to present the project to DNP's sectoral head and to INVIMA and MinSalud.

On 11 November, MDRC met with ANDI to discuss the status of MDRC's proposed projects, timelines, and recent developments. Those were previously outlined in this report.

On 11 November, MDRC met with the head of the MinSalud's legal office to introduce the project. MDRC invited the office to participate in the ongoing efforts with DNP to update the Ministry's processes and

procedures. MDRC and the legal office scheduled a follow-up call to continue the conversation.

On November 16, MDRC met with MinSalud to review the Ministry's document on international references. MinSalud explained it does not require the adherence to specific international standards and that the use of Colombia Technical Norms (NTCs) is voluntary. Further, the document requires quality standards but does not indicate which standards must be met. MDRC invited MinSalud to review its international commitments and offered support to help align its commitments with international standards and references. MinSalud agreed to solicit relevant international commitments from INVIMA to begin this process.

On November 17, MDRC, INVIMA, DNP, and MinSalud met to continue revising the design assessment document's chapters related to ex-post evaluation.

On November 19, MDRC met with INVIMA to explain and suggest wording for the design assessment document's element on "institutionality." Prior to issuing decrees, INVIMA committed to reviewing the proposed institutional architecture and analyzing how the Government has designed its institutional capacity to respond to stakeholder demand.

On November 24, MDRC met with DNP to review the schedule for ex-post evaluation. DNP recommended incorporating six more months into the schedule. In response, MDRC and DNP explored the possibility of initiating ex-ante evaluation in parallel with the ex-post evaluations. DNP committed to continue working on the new schedule.

On November 24, MDRC met with DNP and the head of the MinSalud's legal office, where DNP and MDRC overviewed the regulatory improvement policy and the proposal to ensure the Ministry's processes and procedures are aligned with this policy. MinSalud was supportive and vocalized interest in MDRC's assistance for reviewing similar internal procedures.

On November 24, MDRC met with INVIMA, DNP and MinSalud to present on MDRC's progress and align on next steps. INVIMA was supportive of moving forward on topics related to MDSAP, EUA, and clinical research. MinSalud asserted that its priority for the next six months is working on EUA. The attendees committed to working on a new schedule that will prioritize EUA.

On November 25, MDRC met with DNP, which presented its new proposed timeline for ex-post and ex-ante evaluation. This proposal is to begin ex-ante evaluation in April and end in June, simultaneously with the ex-post evaluation.

On November 29, MDRC introduced the project to an economic analyst at MinSalud and discussed how the analyst could support MDRC's execution. The analyst agreed to undertake a review of relevant MinSalud documents for MDRC.

On December 1, MDRC, INVIMA, DNP, and Ministry of Health met to continue reviewing the chapters related to ex-post evaluation. DNP presented a new schedule on ex-post evaluation and recommended adding three more months to the original schedule including ex-ante evaluations alongside with the ex-post evaluations. Both would finalize in June 2022.

On December 3, MDRC interviewed Claudia Guevara as part of the ex-post evaluation process for decrees 4725 and 3770. Claudia was the person responsible for regulating medical devices for INVIMA at

the time decrees 4725 and 3770 were issued.

On December 3, MDRC met ANDI, which proposed partnering with MDRC to address INVIMA's problems related to medical devices. MDRC welcomed this proposal and explored how to take this partnership forward.

On December 3, MDRC connected with the Ministry of Health to discuss EUA in depth. The Ministry indicated its desire to regulate both medicines and medical devices before next June. However, MDRC contended that since the Ministry of Health has already regulated medicines and *not* medical devices, the developed Impact Analysis should be different. The Ministry agreed to meet with MDRC alongside the Ministry's medical devices and medicines groups to analyze whether it is possible to advance on both projects at the same time and with the same timeline.

On December 6, MDRC met with DNP and the head of the Ministry of Health's legal office to learn about the Ministry's processes and procedures so MDRC could continue the standardization of regulatory policy. They agreed to a subsequent meeting to learn more about MDRC and begin advancing changes to internal processes and procedures.

On December 6, MDRC met with the Ministry of Health's medical devices group to prepare for the upcoming meeting with medicines group about EUA. MDRC and the medical devices group agreed to stress the necessity of delineating issues between medicines and devices as well as the importance of reviewing relevant updated impact analyses.

On December 7, MDRC met with the Ministry of Health's medical devices and medicines groups. The medicines group shared that the impact analysis on EUA has not begun. The medicines group contended that since the forthcoming regulation will be the same as before, it justifies conducting a simple impact analysis rather than a complete one. MDRC recommended conferring with DNP to discuss whether a complete analysis should be conducted given medical device implications. Accordingly, MDRC met with DNP on December 9 to begin preparing a presentation to make the case regarding medical devices and the EUA impact analysis.

On December 10, MDRC met with Ministry of Health to answer a questionnaire through the Unique Public Consultation System (SUCOP) to determine whether the impact analysis on EAU related to medical devices should be complete or simple.

On December 10, MDRC interviewed Rocio Losada as part of the ex-post evaluation process for decrees 4725 and 3770. Rocio is a former team member of INVIMA, responsible for regulating medical devices at the time decrees 4725 and 3770 were issued.

On December 10, MDRC met with Ministry of Health and INVIMA to discuss the timeline on GMP and clinical research based on steps added by MDRC on DNP's tool. The schedule aims to complete the process by January 2023.

On December 15, MDRC met with DNP to present the MDRC project to Daniel Gómez, Sectorial Subdirector of DNP. MDRC and DNP greed that there is a lack of qualified personal and the absence of institutional architecture to appropriately advance regulatory policy. MDRC will propose content for a new health policy and action plan to ensure the government has the tools to address this problem.

On December 16, MDRC met with INVIMA, DNP, and the Ministry of Health to continue the ex-post evaluation process. The attendees discussed whether they should interview additional persons as part of the problem tree development process. Thereafter, MDRC interviewed Napoleón Ortiz as part of the process. Ortiz was a member of the Ministry of Health responsible for regulating medical devices at the time decrees 4725 and 3770 were issued.

On December 16, MDRC met with MinCIT, DNP, INVIMA, and the Ministry of health to review the draft schedule for GMP, EUA, and Clinical Research evaluations. The parties agreed that these evaluations should start simultaneously, despite their scheduled completion in January 2023, after the government change. The Ministry of Health agreed to send a request to the Ministry of Commerce to determine whether the impact analysis on EAU should a simple analysis rather than a complete analysis.

On 22 December, MDRC, INVIMA, DNP, and the Ministry of Health continued to identify stakeholders for interviewing as part of the ex-post evaluation.

On 22 December, MDRC formally introduced the project to DNP's regulatory improvement group and health group. MDRC and those groups discussed the introduction of new health policy to strengthen institutional architecture of the Ministry of Health and the advance GRPs.

On 27 and 28 December, MDRC interviewed María Cristina Latorre and Sofía Rivera Castro as part of the ex-post evaluation process. These individuals were members of the Ministry of Health responsible for regulating medical devices at the time decrees 4725 and 3770 were issued.

MEXICO: On 11 October, MDRC met with the Federal Commission for Protection against Health Risks (COFEPRIS). COFEPRIS shared information on the status of NOM241 and NOM137. NOM241's implementation is pending confirmation following COFEPRIS's submission of feedback to CONAMER. For NOM137, a technical group has been established and will be restructured to ensure the proper development of a draft. MDRC offered to support this process. COFEPRIS described two events in November with the FDA related to GMPs and requested MDRC support sponsoring simultaneous translation.

On 14 October, MDRC met with COFEPRIS and shared a draft agenda for future trainings. COFEPRIS preliminarily agreed with the proposal but wished to review before finalizing. For relevant trainings, COFEPRIS intends to invite all government authorities and the WHO, as well as private sector representatives. MDRC and COFEPRIS considered simultaneous translation services and agreed to start building an action plan.

On 27 October, MDRC and COFEPRIS co-hosted the first webinar of a series of four on GRP and their implementation in the Medical Device Sector. Advancing MDRC LatAm Tier Two Phase 3 and 4 work, this workshop convened a total of 267 participants, including 53 attendees from COFEPRIS and 1 from the Secretariat of Economy in Mexico. Government agencies from Brazil, Bolivia, Colombia, El Salvador, Honduras, Peru and the United States also participated. A total of 192 representatives from the private sector attended, including 5 trade associations from Brazil, Peru and the United States. Materials and recordings will be made available on the Coalition's website.

On 5 November, MDRC met with Mexican Pharmacopeia (FEUM, "Farmacopea de los Estados Unidos Mexicanos") to discuss GRP elements, their applicability, and the responsibility to comply with international agreements and treaties. Even though FEUM's current processes include public consultations,

MDRC identified some missing elements, including notification of draft and final technical regulations. MDRC was invited to discuss GRP at the First International Meeting of Pharmaceutical Sciences Professionals, organized by the National College of Pharmaceutical Sciences on 10 November.

On 10 November, MDRC contributed to the discussion on GRPs the First International Meeting of Pharmaceutical Sciences Professionals, highlighting GRP implementation and international trade obligations. A recording of the session can be found here.

On 10 November, MDRC and COFEPRIS co-hosted the second webinar of the series of four on GRP and their implementation in the Medical Technology Sector. This workshop convened a total of 183 participants. Of those, government agencies from Bolivia, Colombia, El Salvador, Honduras and Peru were represented, in addition to 52 attendees from COFEPRIS, 1 from de Secretariat of Economy, 1 from CONAMER and 1 from the Mexican Pharmacopeia from Mexico; 3 Trades Associations from Ecuador, Mexico and the United States and a total of 131 representatives from the private sector. Materials and recordings will be made available at the Coalition's website.

On 17 November, MDRC co-hosted with COFEPRIS the third webinar of a series of four on GRP and their implementation in the medical device sector. This workshop convened a total of 165 participants. Of those, government agencies from Bolivia, Colombia, El Salvador and Honduras were represented, in addition to 52 attendees from COFEPRIS, 1 from DGN - Secretariat of Economy, and 1 from the Mexican Pharmacopeia from Mexico; 6 Trades Associations from Brazil, Colombia, Chile, Ecuador, Mexico and the United States and a total of 113 representatives from the private sector. Materials and recordings will be made available at the Coalition's website.

A significant output of this session was COFEPRIS's acknowledgement of the need to implement internal processes to ensure compliance with international obligations on GRP. Mexican Pharmacopeia also acknowledged the need to align their processes to comply with international obligations on GRPs, highlighting the need to implement a process for TBT notifications.

On 24 November, MDRC co-hosted with COFEPRIS the fourth webinar of a series of four on GRP and their implementation in the medical device sector. This workshop convened a total of 153 participants. Of those, government agencies from Colombia, Honduras and Spain were represented, in addition to 52 attendees from COFEPRIS, 3 from de Secretariat of Economy and 2 from the Mexican Pharmacopeia from Mexico; PAHO and five Trades Associations from Ecuador, Mexico and the United States and a total of 131 representatives from the private sector. Materials and recordings will be made available at the Coalition's website.

On 29 November MDRC met COFEPRIS to discuss next steps for the project, including MDRC's proposed training plan and specific actions to advance their priorities. COFEPRIS discussed its internal conversations to address its acknowledgements from the training sessions regarding GRP implementation. COFEPRIS proposed for MDRC to connect with CONAMER to secure its engagement in the project.

On 17 December, MDRC met with the Secretariat of Economy to discuss potential avenues to engage the National Commissioner and CONAMER, a critical stakeholder in the implementation of GRP.

On 17 December, COFEPRIS informed MDRC that the Office of the Federal Commissioner had not responded regarding MDRC's recent proposal. COFEPRIS agreed to share the draft report on the High-Level Economic Dialogue (HLED) in the coming weeks.

PERU: On 4 October, MDRC met with the Office of Regulatory Quality Analysis ("Análisis de Calidad Regulatoria," ACR). Ana Sofía del Carpio of ACR informed MDRC that she met with the Ministry of Health to discuss their ability to support efforts in aligning Peruvian Regulations with International Standards. MDRC overviewed the project and Coalition, including some of the priority industry challenges for Peru. Those challenges include labeling and manufacture registration. MDRC will develop a PowerPoint on MDRC, the Coalition, and those challenges for the ACR.

On 21 October, MDRC met with the Ministry of Foreign Trade and Tourism (MinCETUR) to discuss the Ministry's initiatives on gender and inclusion, which are structured under Peru's national gender policy. This policy took effect in 2019 and sets goals that must be met and monitored by every ministry. To meet the policy's requirements, MinCETUR has a commission which tracks and annually reports on its progress.

On 12 November, MDRC shared an overview of its project priorities with ACR-PCM for their reference in coordinating a meeting with the Ministry of Health. This meeting is still being scheduled.

On 17 November, upon receipt of MDRC's priorities, MinCETUR proposed a follow up meeting with DIGEMID in early December to align on next steps.

On 15 December, MDRC met with MinCETUR to align on a revised proposal for collaboration with the Ministry of Health and DIGEMID. MinCETUR indicated its desire to participate in an upcoming meeting with ACR to offer support on GRP trainings.

BRAZIL: On 8 October, MDRC met with representatives from the Latin American Alliance for the Development of In Vitro Diagnostics (ALADDiV) and the Brazilian Chamber of Laboratory Diagnostics (CBDL). CBDL and ALADDiV overviewed their priority standards for nationalization. Participants proposed creating a working group to coordinate future activities related to the ISO 18113 series of standards and ISO Standard 15197:2013.

On 25 October, representatives from MDRC, CBDL, ALADDiV and the Brazilian Society of Clinical Analysis ("Sociedade Brasileira de Analses Clinicas," SBAC) – the ABNT-designated administrator of Brazilian Standardization Technical Committee CB-36 for In-Vitro Diagnostics – met to discuss a workplan for CB-36. Dr. Humberto Tibúrcio of CB-36 shared that TC 212 will have its first standard published in Spanish through the work of IRAM-Argentina. The attendees defined two standards: ISO 15197:2013 (in vitro diagnostic test systems and ISO 19001:2013 (in vitro diagnostic medical devices). The group also discussed developing an event to train industry representative on the importance of the use of international standards and participation in the activities of CB-36. The tentative date for the event is 2 December and the proposed topics include medical device regulation and international trade, international standards, ISO and ISO TC 212 structure and operation, CB-36 working process, and the IMDRF Document on Optimizing Standards for Regulatory Use.

Significantly, SBAC agreed to work in partnership with CBDL, ALADDIV and the Coalition in the context of advancing the MDRC.

On 22-23 November, the Coalition member ABIIS held a two-day workshop with ANVISA on GRP and medical device regulatory convergence. The event was executed with the Coalition's support and convened more than 400 attendees, including from Colombia, Mexico and Peru. Participants included the ABNT-designated entities for Brazilian medical device technical committees CB-26 (ABIMO) and CB-26

(SBAC).

On 6-7 December, the Coalition supported ALADDiV and CBDL to hold their XI International Workshop – "Quality Assured and Accessible Diagnostic Tests for Public Health Programs." Support was also provided by the London School of Hygiene and Tropical Medicine (LSHTM), the Welcome Trust, The International Diagnostics Centre, and Aldimed. The topics addressed include:

- Lessons from COVID-19 for the future;
- Access to new healthcare technologies; and
- The use of self-testing for COVID-19 as a complimentary tool to contain the pandemic.

The hybrid event convened nearly 300 participants, including regulatory authorities – such as ANVISA (Brazil), INVIMA (Colombia), Dinavisa (Paraguay), and AGEMED (Bolivia) – Ministries of Health, Institutions dedicated to scientific research, Universities, Hospitals, Pharmacies, and Industry.

On 15 December, MDRC met with the National Institute of Metrology, Standardization and Industrial Quality (INMETRO) to discuss details of the Project and opportunities for collaboration. MDRC will provide a formal presentation and introduction of the project to INMETRO again in January for those who were previously unable to attend.

Africa

REGIONAL: On 16 November, MDRC met with the U.S. Department of Commerce International Trade Administration (ITA) to overview the project's current implementation status in Africa and discuss how ITA can partner with MDRC to advance its objectives. MDRC and ITA agreed that this collaboration would broadly take three forms: (1) facilitating country-specific outreach and initial engagement with relevant government stakeholders, (2) subsequent country-specific coordination to implement MDRC on a local level, and (3) regional-level cooperation and engagement. MDRC requested that ITA reference the project in their ongoing engagements with relevant stakeholders in Africa, especially as those engagements relate to implementation of the TBT agreement, medical device regulatory functions, or COVID-19 response.

The discussion with ITA branched out in to project country-specific conversations. For South Africa, ITA asked MDRC to attend the next meeting of their recently-established local health working group, which includes representatives from USAID, Commerce, Department of State, and others. In that meeting, MDRC would briefly overview the project and its proposed work in South Africa. ITA offered to assist MDRC in outreach to Tier One stakeholders. For Kenya, ITA suggested that MDRC also meet with their local health working group. ITA informed MDRC that it followed up with USAID regarding the project's formal outreach letters and will update the project on any developments. Regionally, ITA advised MDRC that collaboration with the AfCFTA Secretariat could be difficult due to several factors. MDRC has since followed up with each country-specific ITA team to arrange targeted coordination calls in early December.

On 24 November, per invitation of the African Medical Devices Forum (AMDF), the MDRC team attended the virtual meeting of the 7th African Medicines Regulatory Conference (AMRC VII) including the AMDF meeting. The MDRC team will leverage the information shared during this meeting to propose MDRC-specific workstreams to the AMDF.

On 1 December, MDRC met with the U.S. Trade Representative (USTR), which explained its interest in

promoting projects that strengthen supply chains in critical industrial sectors such as those related to pandemic and emergency preparedness. Due to the negative impacts of regulatory non-alignments on access to medical devices in Africa, MDRC's scope positions it to support this objective. USTR and MDRC discussed the project's role advancing the implementation of GRP and eliminating trade bottlenecks at both the regional and country levels in Africa. USTR vocalized interest in referencing MDRC in pertinent meetings and helping facilitate local engagements. MDRC has since connected with Africa project country-specific USTR points of contact to provide them with supplementary information. MDRC is scheduling introductory meetings with those contacts for early Q1 2022.

On 6 December, MDRC attended the monthly Standards Alliance 2.0 project coordination meeting with PQM+, MTaPS, and relevant USG officials. The initiatives shared updates on their recent progress. PQM+ shared with MDRC that it was working to secure Kenya's Pharmacy and Poisons Board (PPB) approval to share the draft document to revise PPB's regulatory processes. While this document primarily pertains to medicines and quality assurance mechanisms, it has broader implications on medical devices and the whole of the agency's regulatory process.

On 15 December, MDRC provided FDA CDRH with an overview of MDRC's current state of play in Africa and context for their upcoming meeting with Kenya's PPB. MDRC and CDRH aligned on priorities for the region and next steps for engaging with relevant stakeholders on the continent.

On 16 December, MDRC and the ADMF discussed the project's ability to review and comment on AMDF's Five-Year Plan and relevant documents that are crafted in AMDF sub-working groups. AMDF informed MDRC that it would have an opportunity to provide input on the Five-Year Plan following a January AMDF meeting, to which MDRC has been invited. Moving forward, once relevant sub-working groups' documents are considered by the AMDF Secretariat, MDRC will strive to provide input where appropriate. AMDF informed MDRC that the AMDF no longer has an active COVID-19 Taskforce.

GHANA: On 2 December, MDRC met with ITA and USTR points of contact in Ghana. MDRC provided a summary of its objectives in Ghana and broader region, overview of stakeholders with which the project has conducted outreach, and timeline of engagement in the country. MDRC clarified its role in COVID-19 response and recovery as providing technical expertise to remedy regulatory non-alignments and bottlenecks while helping relevant government ministries meet their legal obligations rooted in international treaties and guidance documents. The U.S. Embassy officials offered their support in connecting with the proper points of contact in government ministries to advance project objectives.

Following attempts by MDRC in October, November, and December to schedule a meeting with the Ministry of Health's designated focal point, MDRC received a response from the focal point on 14 December. MDRC is requesting an introductory meeting with the focal point for January 2022.

KENYA: On 6 October, MDRC met with PPB to agree on next steps and develop a dedicated workstream. PPB and MDRC agreed that developing a formal situational analysis of areas for improvement among relevant Tier Two Kenyan stakeholders was an appropriate next step. MDRC committed to drafting a one-pager of the project's envisioned outputs and outcomes in Kenya and share this with PPB. PPB confirmed that it is currently formulating a document to assist in reforming its SOPs and regulator procedures. PPB is open to working with MDRC to ensure the document includes medical device-specific elements and differentiates between MedTech and pharmaceutical needs. The two agreed to establish a regular meeting schedule for collaboration.

On 26 October, MDRC shared with PPB an overview of the project's implementation objectives in Kenya, including an initial list of industry-identified priorities for collaboration, proposed schedule of meetings and workplan, and annex of proposed GRP implementation policies with PPB (Tier Two). PPB indicated its excitement to implement GRP alongside MDRC, but required additional time to review the document and confer internally. MDRC and PPB discussed the need for a formal situational analysis of PPB's Tier Two gaps. Due to staffing constraints, PPB asserted that a dedicated liaison would be helpful in generating a baseline for meaningful partnership in the country. PPB agreed to confer internally and provide MDRC with a recommendation on whether to formally request the liaison from USAID. While PPB discusses internally and during any subsequent approval process for the Liaison with USAID, PPB and MDRC agreed that the project should focus its attention on advancing regional objectives – such as those with AUDA-NEPAD. Following the meeting, Mecomed shared with PPB additional information on industry's identified priorities for collaboration. PPB indicated it would try to obtain and share with MDRC the document being constructed with PQM+ to update PPB's regulatory processes so that MDRC can provide input.

On 27 October, MCRC updated PQM+ on PPB's request to undertake a formal Tier Two situational analysis in the project country. MDRC discussed PQM+'s efforts to craft a document with PPB to update the authority's regulatory functions. PQM+ indicated this document only pertained to pharmaceuticals and would discuss internally on their ability to share it with MDRC. MDRC and PQM+ briefly discussed the project's regional-level objectives.

On 17 November, MDRC met with PQM+ and discussed the regulatory framework in Kenya, including the regulatory impact assessment (RIA) requirements. PQM+ would try to share with MDRC the Ministry of Health's policy document on supply chain strategy for health products. This document will provide MDRC with crucial background to ensure future project capacity building resources in Kenya are anchored in appropriate government policy. While this meeting was originally slated to be for PPB-MDRC discussions, Dr. Paulyne Wairimu, head of medical devices for PPB, was unable to attend the meeting.

On 16 December, MDRC and PPB aligned on the next steps and processes to formalize an MDRC workstream with PPB. MDRC and PPB will proceed to formulate an MOU which will provide the legal basis for future collaboration on Tier Two-specific capacity building. Concurrently, PPB will send MDRC a formal letter requesting a dedicated project liaison to coordinate work in the project country. Once the MOU is concluded, MDRC and PPB will develop a consensus-based prioritized workstream to address identified issue areas through capacity building consultations and trainings.

On 16 and 17 December, MDRC extended outreach to the Kenyan Bureau of Standards (KEBS) and the Kenyan Customs and Border Control Department. While MDRC has begun partnering with PPB at Tier Two, this outreach formalizes MDRC's efforts to begin Tier One work in Kenya.

On 19 December, KEBS indicated it would partner with MDRC.

On 22 December, Customs responded and designated a focal point for coordinating MDRC-Customs work. MDRC will set up introductory meetings with these stakeholders in the new year.

SOUTH AFRICA: On 2 December, MDRC met with the USAID Mission in South Africa to provide the point of contact with an update on the project's current status and ongoing engagements with project partners.

On 7 December, MDRC provided SAHPRA with an overview of the MDRC's proposed scope for partnership, including a notional schedule of meetings and role of MDRC resources. Following a discussion on the methodology and goals of MDRC, SAHPRA agreed to proceed with MDRC and develop a dedicated MDRC workstream. Given SAMED's recent workshops to address specific technical elements with SAHPRA, the groups agreed that the MDRC workstream should emphasize the procedural elements of GRP as they pertain to COVID-19 response and recovery. SAHPRA indicated it has identified priority procedural issue areas, which will be used in the development of the MDRC workstream. This workstream will align with and operationalize the recommendations of regional bodies, such as the AMDF. SAHPRA noted that MDRC work can complement their recent engagement with the WHO on regulatory practices pertaining to medicines, emphasizing the importance of leveraging international guidance in the local context. MDRC is scheduling a kickoff meeting with SAHPRA for late January in which the two will align on:

- the schedule of subsequent workshops/trainings and their content;
- the responsibilities of each team; and
- the content of the SAHPRA-MDRC workstream.

Once the initial series of workshops/trainings are complete, MDRC will partner with SAHPRA's relevant teams (and other South African government agency representatives, where applicable) to implement the series' learnings.

Southeast Asia

VIETNAM: On 5 October, MDRC introduced the project to the Embassy of Vietnam in Washington, D.C. and solicited the Embassy's guidance on how to best engage relevant government agencies. Hanh Duong, Head of Economic Section, suggested MDRC identify a focal point for future coordination. The Embassy committed to sharing MDRC's outreach letters with the Ministry of Health to help establish a focal point.

On 6 October, MDRC introduced the project to the Embassy of Vietnam in Singapore. MDRC asked the Embassy for guidance on how to best engage relevant government agencies. Le Cong Dung, Minister Counsellor and Deputy Chief of Mission, offered to follow up with the Ministry of Health on MDRC's behalf.

On 15 October, MDRC met with USABC's Senior Vice President and Regional Managing Director, Michael Michalak. MDRC sought Amb. Michalak's assistance to share a letter drafted by MDRC and signed by Amb. Michalak to the Minister of Health. The letter introduces MDRC and requests that the Minister assign focal points from the Ministry of Health and DMEC to set up a meeting to discuss the project. USABC agreed to assist MDRC in connecting with the Ministry of Health and DMEC. Since the project addresses regulatory issues that USABC companies face, the organization will also consider directly partnering with MDRC.

On 1 November, MDRC hosted a joint call with AdvaMed, interested AdvaMed members, APACMed, and EuroCham Vietnam to discuss the projects current status in the Vietnam. Those stakeholders suggested that engaging DMEC might be a challenge because of limited manpower and other COVID-19 related issues. Attendees also suggested that because DMEC DG Tuan is retiring soon, MDRC should postpone engagement to when there is new leadership. Private sector companies vocalized similar experience with DMEC and suggested engaging the Vice Minister of Health, Ministry of Health Director,

and Deputy Director. Attendees discussed the Ministry of Health's approach to medical devices during the pandemic, including how medical devices qualify for fast-track approval if there is a pre-sale certificate from the U.S., EU, Canada, Australia, or Japan. Private sector members suggested that MDRC focus on post-market issues, like reimbursement and health insurance. Attendees discussed developing and sending a joint letter to the Prime Minister. MDRC has since drafted that letter. APACMed and EuroCham Vietnam confirmed their willingness to sign onto the letter with AdvaMed. As of 31 December, the MDRC project team is awaiting the Mission's approval to transmit.

On 3 November, the USABC shared with MDRC that it contacted DMEC DG Tuan on MDRC's behalf. DG Tuan expressed "shared interest in organizing an in-depth discussion" on MDRC and said DMEC will "look into" assigning a focal point once it received "guidance" from superiors. However, on 4 November, it was reported that a number of political office holders and officials within DMEC, including Vice Minister Cuong and DG Tuan, have been censured and/or removed from their positions. MDRC sought views on these developments from local stakeholders in order to ascertain next steps.

INDONESIA: On 6 October, MDRC held a meeting with the Indonesian Embassy in Singapore and sought guidance on engagement with Indonesian agencies. The Embassy representatives were receptive to MDRC, indicating they will update their Ambassador and follow up with government agencies once they receive approval. MDRC forwarded materials and letters with the Embassy for sharing with relevant agencies.

On 19 October, MDRC connected with the European Chamber of Commerce (EuroCham) Indonesia's Health Committee after being introduced by USAID. MDRC and EuroCham discussed hosting a formal introductory call with relevant members and the possibility of participating in the Health Business Gathering in Bali from 2-3 December.

On 21 October, MDRC sent an email to the Indonesian Minister of Health Budi Sadikin following an in-person conversation in Washington, DC. The email sought his support to assign relevant senior officials for MDRC to coordinate with and advance the project in Indonesia. MDRC also forwarded this email to Professor Laksono Trisnantoro, Minister Budi's Special Assistant, offering to schedule a discussion with him to further explain the project.

On 25 October, MDRC met with USAID Indonesia and EuroCham Indonesia's Pharmaceutical and Medtech Working Group. After a briefing on MDRC, the working group provided multiple comments. They recommended MDRC's outreach focus on a specific agency rather than all relevant ones. They also suggested that two to three issues relevant to the agency should be identified. The working group also recommended having an individual on the ground to follow up with relevant agencies. Finally, they suggested approaching political office holders, senior officials or the foreign cooperation bureau at the Ministry of Health, which MDRC has already explored. MDRC agreed to send the Working Group project informational material and contact points, and the Working Group agreed to forward MDRC's outreach letter to their contact in the MOH's Pharmaceutical and Medical Devices Directorate General for insight.

On 25 October, MDRC met with Anastasia Susanto, the USAID Mission's Health System Strengthening Lead. Anastasia reiterated the need for a local contact or a focal point on the ground to coordinate the MDRC. She advised USAID Indonesia would consider forwarding a letter on MDRC to the Ministry of Health. Anastasia committed to checking with USAID's Alliance and Partnership Specialist to confirm the feasibility of sending the letter.

On 2 November, Indonesia's National Public Procurement Agency (LKPP), sent a letter conveying its "in-principle" agreement to collaborate with MDRC and providing a focal point for follow-up. The LKPP is responsible for the national procurement of government goods and services, including medical devices, and maintenance of the national e-catalog. MDRC has followed-up, proposing a meeting with the focal point and representatives from the Ministry of Health, but has not received a response as of 31 December. MDRC will follow up in January 2022.

On 5 November, MDRC introduced the project to representatives of the Indonesian Embassy in DC. The embassy agreed to assist MDRC in following up with the Ministry of Health. MDRC provided the embassy with materials and project outreach letters.

On 16 November, Prof. Laksono Trisnantoro, the special assistant to the Indonesian Minster of Health, contacted the USAID Indonesia Mission to inquire about MDRC. Following an overview of the project, Prof. Trisnantoro put the Mission in touch with the Ministry of Health's Medical Device Assessment department.

On 29 November, MDRC met with the Mission to discuss the above conversation and strategize future engagement with the Ministry of Health. The Mission outlined some of the Ministry's preliminary priorities and indicated the Ministry welcomes MDRC's ideas on providing training, technical expertise, and general capacity building.

On 4 December, MDRC presented on the project at the Indonesia Health Business Gathering, emphasizing the project's alignment with the Indonesia Healthcare Transformation Plan. This Gathering convened policymakers and industry representatives.

On 17 December, MDRC introduced the project to the Ministry of Heath, which indicated initial support for collaborating on the project. The Ministry mentioned some preliminary priorities for collaboration, including pre-market assessment & post-market quality surveillance of medical devices, capacity building on regulatory standards, ensuring safety and efficacy of medical devices, and local production of medical devices. MDRC committed to developing and sharing a workplan for collaboration with the Ministry ahead of a January 2022 meeting. In that meeting, MDRC and the Ministry will discuss specific issue areas for partnership. The USAID Mission in Indonesia proposed that once the Ministry is comfortable and a workplan is developed, the Ministry could issue a letter of endorsement of the project which MDRC could use in outreach to other Indonesian agencies.

Other Implementation Progress

MDRC has packaged the findings of its Phase One, Tier One gap analyses and literature reviews from all project countries in a unified Tier One report. This report includes assessments of GRP implementation by country as well as an overarching chart to allow for comparison across project countries. The Tier One report has been reviewed by USAID and is undergoing final edits to align with USAID branding requirements.

MDRC sought input on Phase One outputs from a variety of stakeholders, including industry associations, USAID Missions, and U.S. government agencies. In Q1 2021, MDRC shared its Tier One country reports with local and industry stakeholders in Africa for their review and input, including the USAID Missions to Ghana and Kenya, Mecomed, MEDAK, SAMED, and SALDA. In Q2 2021, MDRC shared updated drafts of MDRC's Phase One, Tier One gap analyses and stakeholder maps with ANSI, the U.S. International

Trade Administration (ITA), the U.S. National Institute of Standards and Technology (NIST), the Office of the U.S. Trade Representative (USTR), and the U.S. Office of Information and Regulatory Affairs (OIRA).

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

MDRC also continued development of its Stakeholder Mapping Reports. These reports outline Tier One, Two, and regional (where appropriate) stakeholders in Indonesia, Vietnam, SE Asia, Ghana, South Africa, and Kenya. They have been reviewed by the same industry associations, US Missions, and US agencies, such as the International Trade Administration (ITA). These reports, which were designed to align with USAID branding requirements, have been reviewed by ANSI and are undergoing edits before they are sent to USAID for final approval. Like the Tier One Report, these may be updated as necessary through the remainder of the project.

7.4 Implementation Status

MDRC expanded collaboration with public and private sector stakeholders across the three project regions. The project rolled out the Colombia Liaison to coordinate project implementation among government and local stakeholders in the country. As demonstrated in Section 2.1 – Latin America, the Liaison is rapidly developing and leading capacity building efforts. Coupled with the strong demonstrated desire of the Government of Colombia to implement regulatory convergence and GRPs, the Liaison has fast-tracked MEL plan fulfillment and catapulted Colombia to the forefront of MDRC goal realization. Beyond Colombia, MDRC has continued to deepen partnership with and execute capacity building for stakeholders in Mexico, Peru, and Brazil.

In Africa, Tier Two work in Kenya and South Africa rapidly expanded in Q4. Following a number of preliminary coordination meetings, PPB and SAHPRA agreed to partner with MDRC to develop and implement MDRC workstreams. In Kenya, PPB and MDRC will execute an MOU in Q1 to provide the legal basis for future collaboration. In South Africa, MDRC is scheduling formal "kick-off" meetings in January 2022 to jumpstart workstream development.

Although MDRC secured Mission concurrence and conducted formal outreach in Ghana, there remains a delay in the planned implementation schedule. Please see above Section 2.1 – Africa, and Section 2.3 Implementation Challenges for more information on the implementation status in Ghana.

In Southeast Asia, following extensive outreach, MDRC formally met and introduced the project to the Indonesian Ministry of Health. The Ministry indicated initial support for collaborating on the project and identified some priorities for collaboration. MDRC has now formally introduced the project to Tier Two government stakeholders in both Southeast Asian project countries.

In the first half of Project Year 2 (PY2), MDRC capacity building activities have remained largely virtual as a result of COVID-19 travel and local gathering restrictions. As part of the approval for the Colombia Liaison, MDRC has redeployed resources otherwise earmarked for travel and in-person workshops through the end of 2021. In 2022, MDRC continues to assess whether capacity building will remain virtual in response to COVID-19.

7.5 Implementation Challenges

Overcoming project implementation delays related to USAID Mission concurrence remained a project challenge in Q4 2021. Following the Mission in Kenya's concurrence at the end of July 2021, the Mission did not approve MDRC project outreach letters in Kenya, despite multiple requests by the project. In coordination with USAID in DC, MDRC inferred the 'OK' to proceed with outreach in December after providing the Mission with appropriate time to review and comment. Outreach was sent in December.

Another challenge to project implementation remains limited engagement by some project country governments. The project team cannot commence work in countries without engagement by Tier One and/or Tier Two government agency partner(s). In Ghana, MDRC outreached in July when Kenya and South Africa had secured Mission concurrence. Following extensive follow-up by MDRC and the Mission, the Ghanaian Ministry of Health responded in October to designate a point of contact. Thereafter, the point of contact did not respond to outreach until late December. MDRC is requesting an introductory call with the contact for January 2022.

In Vietnam and Indonesia, MDRC maintains high levels of engagement with the private sector but are pending heightened engagement by government stakeholders. In Vietnam this November, it was reported that a number of political office holders and officials within DMEC, including Vice Minister Cuong and DG Tuan, were censured and/or removed from their positions.

In order to overcome this challenge, MDRC convened relevant associations and industry stakeholders to seek their support raising MDRC with relevant government contacts. Further, MDRC connected with Vietnamese and Indonesian embassies in Singapore and Washington, D.C. to seek their advice on implementing MDRC. MDRC efforts have been successful in Indonesia, securing a meeting with the Ministry of Health in December. MDRC continues to drive follow-up engagement in Vietnam despite the change in leadership.

While COVID-19 has, as expected, made in-person capacity building impossible to date, the project is actively addressing this challenge through the execution of high-quality virtual engagements. These engagements continue to improve both in their ability to disseminate quality resources and convene relevant stakeholders from the public and private sectors. Please see Section 3 – Stakeholder Participation and Involvement for further information.

7.6 STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Q4 2021 MDRC Capacity-Building Trainings and Workshops:

MDRC hosted or helped execute 7 trainings and events, convening 1,638 participants from academia, the private sector, Standards Developing Organizations (SDOs), national regulatory authorities (NRAs), international organizations, and numerous other vital stakeholders. Of those, over 838 were female (51%) and 1,173 were from the private sector. An overview of those trainings is provided below:

Date	Meeting/Event	Location	Participants	Region
27 Oct 21	GRPs in Health Regulations – COFEPRIS, One of Four	Virtual	267 attendees 194 female, 70 male, 3 undeclared (192 private sector)	Mexico
10 Nov 21	GRPs in Health Regulations – COFEPRIS, Two of Four	Virtual	183 attendees 130 female, 53 male (131 industry)	Mexico
17 Nov 21	GRPs in Health Regulations – COFEPRIS, Three of Four	Virtual	165 attendees 118 female, 46 male, 1 undeclared (113 private sector)	Mexico
22-23 Nov 21	ABIIS Medical Devices Webinar – Regulation, Advances, and Perspectives	Virtual	22 Nov: 247 attendees (226 private sector) 23 Nov: 198 attendees (182 private sector) *Gender data not reported*	MDRC Countries + LatAm
24 Nov 21	GRPs in Health Regulations – COFEPRIS, Four of Four	Virtual	153 attendees 104 female, 48 male, 1 undeclared	Mexico

			(131 private sector)	
6-7 Dec 21	ALADDIV and CBDL's XI International Workshop – "Quality Assured and Accessible Diagnostic Tests for Public Health Programs"	Hybrid	Dec 6: 176 attendees 108 female, 67 male, 1 undeclared (79 private sector) Dec 7: 119 attendees 87 female, 32 male (57 private sector)	MDRC Countries + LatAm
7 Dec 21	Joint MDRC-FDA Webinar on Utilization of International Standards and Conformity Assessment	Virtual	130 attendees 97 female, 33 male (62 private sector)	MDRC Countries + LatAm

Stakeholder Engagement

- 27 October 2021: MDRC and COFEPRIS co-hosted the first webinar of a series of four on GRP and their implementation in the Medical Device Sector. This workshop convened a total of 267 participants, including 53 attendees from COFEPRIS and 1 from the Secretariat of Economy in Mexico. Government agencies from Brazil, Bolivia, Colombia, El Salvador, Honduras, Peru and the United States also participated. A total of 192 representatives from the private sector attended, including 5 trade associations from Brazil, Peru and the United States.
- 10 November 2021: MDRC and COFEPRIS co-hosted the second webinar of the series of four on GRP and their implementation in the Medical Technology Sector. This workshop convened a total of 183 participants. Of those, government agencies from Bolivia, Colombia, El Salvador, Honduras and Peru were represented, in addition to 52 attendees from COFEPRIS, 1 from de Secretariat of Economy, 1 from CONAMER and 1 from the Mexican Pharmacopeia from Mexico; 3 Trades Associations from Ecuador, Mexico and the United States and a total of 131 representatives from the private sector. Materials and recordings will be made available at the Coalition's website.
- 17 November 2021: MDRC co-hosted with COFEPRIS the third webinar of a series of four on GRP and their implementation in the medical device sector. This workshop convened a total of 165 participants. Of those, government agencies from Bolivia, Colombia, El Salvador and Honduras were represented, in addition to 52 attendees from COFEPRIS, 1 from DGN - Secretariat of Economy, and 1 from the Mexican Pharmacopeia from Mexico; 6 Trades Associations from Brazil, Colombia, Chile, Ecuador, Mexico and the United States and a total of 113 representatives from the private sector.
- 22-23 November 2021: The Coalition member ABIIS held a two-day workshop with ANVISA on GRP and medical device regulatory convergence. The event was executed with the support of the Coalition and convened more than 400 attendees, including from Colombia, Mexico and Peru. Participants included the ABNT-designated entities for Brazilian medical device technical committees CB-26 (ABIMO) and CB-26 (SBAC).

- 24 November 2021: MDRC co-hosted with COFEPRIS the fourth webinar of a series of four on GRP and their implementation in the medical device sector. This workshop convened a total of 153 participants. Of those, government agencies from Colombia, Honduras and Spain were represented, in addition to 52 attendees from COFEPRIS, 3 from de Secretariat of Economy and 2 from the Mexican Pharmacopeia from Mexico; PAHO and five Trades Associations from Ecuador, Mexico and the United States and a total of 131 representatives from the private sector.
- 6-7 December 2021: The Coalition supported ALADDiV and CBDL to hold their XI International Workshop – "Quality Assured and Accessible Diagnostic Tests for Public Health Programs." Support was also provided by the London School of Hygiene and Tropical Medicine (LSHTM), the Welcome Trust, The International Diagnostics Centre, and Aldimed. The hybrid event convened nearly 300 participants, including regulatory authorities – such as ANVISA (Brazil), INVIMA (Colombia), Dinavisa (Paraguay), and AGEMED (Bolivia) – Ministries of Health, Institutions dedicated to scientific research, Universities, Hospitals, Pharmacies, and Industry.
- 7 December 2021: The Coalition partnered with the U.S. FDA to organize a webinar series on Utilization of International Standards and Conformity Assessment. During this session, FDA representatives shared their experience on the utilization of Standards and Conformity Assessment through their SCAP Program. In attendance were participants from 17 countries, 13 NRAs and 45 companies.

7.7 RESULTS ACHIEVED

Global

- On 27 October, MDRC met with the U.S. FDA CDRH, which noted that the U.S. Department of State intends to bring an AMA delegation to DC in the second half of 2022. CDRH confirmed that if there is a medical device component, MDRC can try to participate. CDRH supported MDRC's idea of developing "action-ready" clusters of relevant medtech NRA and trade authorities in each project country to rapidly review and respond to medtech STCs and regulatory non-alignments. (DO 3, IR 3.1)

Latin America

- REGIONAL: In Q3 2021, the Coalition's website visits were 3,653. This is an increase of 9% over Q2 2021. In Q4 2021, the Coalition's website visits were 4,400. This is 20.4% increase from Q3 2021. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- PERU: On 4 October, MDRC met with the ACR and overviewed the project, the Coalition, and some of the priority industry challenges for Peru. Those challenges include labeling and manufacture registration. (IR 1.1, IR 1.2, IR 3.1)
- BRAZIL: On 8 October, MDRC met with ALADDiV and CBDL, who outlined their priority standards for nationalization. Participants proposed creating a working group coordinate future activities. (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3, Output 1.1.4, Output 1.1.6)
- MEXICO: On 11 October, MDRC met with COFEPRIS, which shared information on NOM241 and NOM137. MDRC and COFEPRIS began coordinating the development of two events in November with the US FDA related to GMPs, for which MDRC would provide support on simultaneous translation. (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3, Output 1.1.4, Output 1.1.6)

- COLOMBIA: On 12 October, MDRC introduced the new Liaison and shared its proposal and next steps for future partnership with MinSalud and INVIMA. INVIMA and MinSalud confirmed their priority for collaboration and agreed to host regular coordination meetings. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 12 October, the Coalition met with PAHO. The Coalition offered support developing an agenda for the X Meeting of Red PARF in December. The Coalition shared information on its GRP webinars on and upcoming events. PAHO committed to drafting a formal proposal of cooperation with the Coalition. (IR 1.1, Output 1.1.4, Output 1.1.7, IR 1.2, Output 1.2.1, IR 2.1, Output 2.1.1)
- COLOMBIA: On 14 October, MDRC updated ANDI and the DNP on the current status of proposed projects and timelines. The parties agreed to a regular schedule of meetings to advance MDRC work. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- MEXICO: On 14 October, MDRC met with COFEPRIS and shared a draft agenda for future trainings. COFEPRIS preliminarily agreed with the proposal but wished to review before finalizing. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- COLOMBIA: On 19 October, DNP approved MDRC's proposal to craft an ex-post evaluation instrument with a methodology that defines necessary activities, information, responsibilities, and timelines. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- COLOMBIA: On 20 October, the working group began crafting the ex-post evaluation instrument and developed the structure of the first chapter of the design evaluation document. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- COLOMBIA: On 21 October, DNP approved MDRC's proposal for the ex-post evaluation instrument's overarching procedures, processes, and institutional architecture. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- Peru: On 21 October, MDRC met with MinCETUR to discuss the Ministry's initiatives on gender and inclusion. (CC IR 2.1)
- BRAZIL: On 25 October, representatives from MDRC, CBDL, CB-36, and ALADDiV met to discuss a workplan for CB-36 and an event to train industry representative on the importance of the use of international standards. Such an event would include topics such as medical device regulation and international trade, international standards, the CB-36 working process, and the IMDRF Document on Optimizing Standards for Regulatory Use. (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3, Output 1.1.4, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.2, IR 2.1, Output 2.1.1, IR 3.1, Output 3.1.1, IR 4.1)
- MEXICO: On 27 October, MDRC and COFEPRIS co-hosted the first webinar of a series of four on GRP and their implementation in the Medical Device Sector. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- COLOMBIA: On 27 October, MDRC continued development of the ex-post evaluation instrument and defined which persons would be interviewed as part of that process. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- REGIONAL: On 28 October, AHWP/GHWP leadership confirmed support for the Coalition's application to become a liaison to the organization. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4)
- COLOMBIA: On 3 November, MDRC finalized development of the tool to interview the regulators who defined decrees 4725 and 3770. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)

- MEXICO: On 5 November, MDRC met with FEUM to discuss GRPs elements, their applicability, and the responsibility to comply with international agreements and treaties. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4)
- MEXICO: On 10 November, MDRC contributed to the discussion on GRPs the First International Meeting of Pharmaceutical Sciences Professionals, highlighting GRP implementation and international trade obligations. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4)
- MEXICO: On 10 November, MDRC and COFEPRIS co-hosted the second webinar of the series of four on GRP and their implementation in the Medical Technology Sector. (IR 1.1, Output 1.1.4, Activity 1.1.4.2, Output 1.1.7, IR 1.2, IR 3.1, Output 3.1.1, DO 4)
- COLOMBIA: On 10 November, MDRC UPDATED INVIMA, DNP and MinSalud on the above recent advances by the working group with regards to ex-post evaluation. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On 11 November, MDRC met with DNP to discuss the proposal for the ex-post evaluation instrument's overarching procedures, processes and institutional architecture. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On 11 November, MDRC met with ANDI to discuss the current status of MDRC's proposed projects, timelines, and recent developments. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On 11 November, MDRC met with the head of the MinSalud's legal office to introduce the project and invite the office to participate in the ongoing efforts with DNP to update the Ministry's processes and procedures. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- PERU: On 12 November, MDRC shared an overview of its priorities with ACR-PCM for their reference in coordinating a meeting with the Ministry of Health. (IR 1.1, IR 1.2, IR 3.1, IR 4.1, IR 4.2)
- COLOMBIA: On November 16, MDRC met with MinSalud to review the Ministry's document on international references. MDRC invited MinSalud to review its international commitments and offered support to help align its commitments with international standards and references. (IR 1.1, Output 1.1.2, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- MEXICO: On 17 November, MDRC co-hosted with COFEPRIS the third webinar of a series of four on GRP and their implementation in the Medical Device Sector. A significant output of this session was COFEPRIS and Mexican Pharmacopeia's acknowledgement of the need to implement internal processes to ensure compliance with international obligations on GRPs. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.3, Output 2.1.4, Output 2.1.5, IR 3.1, Output 3.1.1)
- PERU: On 17 November, upon receipt of MDRC's priorities, MinCETUR proposed a follow up meeting with DIGEMID in early December to align on next steps to address those priorities. (IR 1.1, IR 1.2, IR 3.1, IR 4.1, IR 4.2)
- COLOMBIA: On November 17, MDRC, INVIMA, DNP, and MinSalud met to continue revising the design assessment document's chapters related to ex-post evaluation. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On November 19, MDRC met with INVIMA to explain and suggest wording for the design assessment document. INVIMA committed to reviewing a proposed decree's institutional architecture and the Government's institutional capacity to respond to stakeholder

demand prior to issuing the decree. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)

- REGIONAL: On 24 November, MDRC met with UNE, securing their commitment to support the Coalition and MDRC in increasing the availability of Spanish-language versions of ISO and IEC standards for LatAm country NSBs. (IR 1.1, Output 1.1.1, Output 1.1.2, Output 1.1.3)
- BRAZIL: On 22-23 November, ABIIS held a two-day workshop with ANVISA on GRP and medical device regulatory convergence with the support of the Coalition. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.7, Activity 1.1.7.1, IR 1.2, Output 1.2.1, IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.2, Output 2.1.3, Output 2.1.4, Output 2.1.5, IR 3.1, Output 3.1.1)
- COLOMBIA: On November 24, MDRC met with DNP to review the schedule for ex-post evaluation and agreed to incorporate six more months into the schedule. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- MEXICO: On 24 November, MDRC co-hosted with COFEPRIS the fourth webinar of a series of four on GRP and their implementation in the Medical Device Sector. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 2.1, Output 2.1.1, Activity 2.1.1.1, Output 2.1.3, Output 2.1.4, Output 2.1.5, IR 3.1, Output 3.1.1)
- COLOMBIA: On November 24, the head of the MinSalud's legal office vocalized interest in MDRC's proposal to overviewed to ensure the Ministry's processes and procedures are aligned with DNP's regulatory improvement policy. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On November 24, MDRC met with INVIMA, DNP and MinSalud to agree on a new schedule for advancing topics related to MDSAP, EUA, and clinical research. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1, DO 4, IR 4.1, IR 4.2)
- COLOMBIA: On November 25, MDRC met with DNP, which presented its new proposed timeline for ex-post and ex-ant evaluation. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1)
- COLOMBIA: On November 29, MDRC introduced the project to an economic analyst at MinSalud and discussed how the analyst could support MDRC's execution. The analyst agreed to undertake a review of relevant MinSalud documents. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1)
- MEXICO: On 29 November MDRC met COFEPRIS to discuss next steps for the project, including MDRC's proposed training plan, as well as specific actions to advance the priorities identified by the two entities. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1)
- REGIONAL: On 30 November, MDRC and the Coalition met with World Bank, Brazil's ANVISA, and Colombia's DNP, MinCIT, MinSalud, and INVIMA. The parties discussed GRP, their impacts on the Health sector, and Brazil's and Colombia's approaches to implementing them. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1)
- REGIONAL: On 30 November and 1 December, the GHWP unanimously approved the Liaison Member status of the Coalition. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- COLOMBIA: On December 3, MDRC and ANDI began exploring opportunities for partnership to address medical device-related issues in INVIMA. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1, DO 4, IR 4.1, IR 4.2)

- COLOMBIA: On December 6, MDRC continued partnering with DNP and the head of the Ministry of Health's legal office to advance the standardization of regulatory policy and changes to internal processes and procedures. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- BRAZIL: On 6-7 December, the Coalition supported ALADDiV and CBDL to hold their XI International Workshop – "Quality Assured and Accessible Diagnostic Tests for Public Health Programs" which addressed opportunities to respond to COVID-19. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 7 December, MDRC met with PAHO to discuss priorities for partnership, including executing capacity-building trainings on international standards, GRP, and EUAs. Following PAHO's suggestion, the Coalition is preparing an application to become an Observer Member to PANDRH. PAHO and the Coalition will begin developing a mechanism for joint PAHO-Coalition publications. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 7 December, the Coalition partnered with the U.S. FDA to organize a webinar series on Utilization of International Standards and Conformity Assessment. (IR 1.1, IR 1.2, IR 2.1, IR 3.1)
- COLOMBIA: On December 15, MDRC and DNP greed that MDRC will propose content for a new health policy and action plan to address the lack of qualified personal and absence of institutional architecture to appropriately advance regulatory policy. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- BRAZIL: On 15 December, MDRC met with INMETRO to discuss details of the Project and opportunities for collaboration. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- PERU: On 15 December, MDRC met with MinCETUR to advance collaboration with the Ministry of Health and DIGEMID, including through future GRP trainings. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- REGIONAL: On 17 December, MDRC met with PAHO to review and update MDRC application to join the PANDRH. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- MEXICO: On 17 December, MDRC met with Secretariat of Economy to discuss potential avenues to engage the National Commissioner and CONAMER, a critical stakeholder in the implementation of GRP. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: On 22 December, MDRC formally introduced the project to DNP's regulatory improvement group and health group. MDRC proposed new health policy to strengthen institutional architecture of the Ministry of Health and the advance GRPs. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: In December, MDRC interviewed previous members of INVIMA and the Ministry of Health as part of the ex-post evaluation process for decrees 4725 and 3770. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3)
- COLOMBIA: In December, MDRC continuously worked MinCIT, DNP, INVIMA and the Ministry of Health to determine whether the impact analysis on EUAs should be simple or complete. This includes answering answer a questionnaire through SUCOP as well as meeting with the Ministry of Health's medicines and medical devices groups. (IR 1.1, Output 1.1.4, Activity 1.1.4.1, Output 1.1.6, Output 1.1.7, IR 1.2, Output 1.2.1, Output 1.2.3, IR 3.1, Output 3.1.1, DO 4, IR 4.1, IR 4.2)

<u>Africa</u>

- KENYA: On 6 October, MDRC met with the PPB to agree on next steps and develop a dedicated workstream. PPB confirmed it is open to working with MDRC to ensure its new document reforming regulatory procedures includes medical device-specific elements and properly differentiates between MedTech and pharmaceutical needs. (IR 1.1, IR 1.2, IR 3.1, IR 4.1)
- KENYA: On 26 October, MDRC shared with PPB an overview of the project's implementation objectives in Kenya, including an initial list of industry-identified priorities for collaboration, proposed schedule of meetings and workplan, and annex of proposed GRP implementation policies with PPB (Tier Two). Mecomed shared with PPB additional information on industry's identified priorities for collaboration. (IR 1.1, IR 1.2, IR 3.1, IR 4.1)
- REGIONAL/KENYA: On 27 October, MCRC updated PQM+ on PPB's request to undertake a formal Tier Two situational analysis as well as on Ghanaian government stakeholders' low levels of engagement. MDRC discussed PQM+'s efforts to craft a document with PPB to update the authority's regulatory functions. MDRC and PQM+ briefly discussed the project's regional-level objectives. (IR 1.1, IR 1.2, IR 3.1, IR 4.1)
- REGIONAL: On 16 November, MDRC met with ITA to align on next steps for collaboration in Africa. MDRC and ITA agreed that this collaboration would begin with facilitating country-specific outreach and extend to subsequent country-specific/regional coordination on project engagements. ITA agreed to reference MDRC in its ongoing engagements with relevant stakeholders in Africa. MDRC and ITA also discussed the project's implementation status in the three African project countries. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- KENYA: On 17 November, MDRC met with PQM+ and discussed the regulatory framework in Kenya, including the RIA requirements. PQM+ will share with MDRC the Ministry of Health's policy document on supply chain strategy for health products. (IR. 1.1, Output 1.1.5)
- REGIONAL: On 24 Nov, per invitation of the AMDF, the MDRC team attended the virtual meeting of the 7th African Medicines Regulatory Conference. The MDRC team will leverage the information shared during this meeting to propose MDRC-specific workstreams to the AMDF. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 1 December, MDRC met with the USTR and discussed the project's role advancing the implementation of GRP and eliminating trade bottlenecks at both the regional and country levels in Africa. USTR vocalized interest in referencing MDRC in pertinent meetings and helping facilitate local engagements where applicable. MDRC has since connected with Africa project country-specific USTR points of contact to provide them with supplementary informational materials and talking points. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- SOUTH AFRICA: On 2 December, MDRC met with the USAID Mission in South Africa to provide the primary point of contact with a refresher on the project's current status in the country and ongoing engagements with project partners. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- GHANA: On 2 December, MDRC met with ITA and USTR in Ghana and provided a summary of objectives in Ghana and broader region, overview of local stakeholders with which the project has conducted outreach, and timeline of engagement in the country. The U.S. Embassy officials offered their support in connecting with the proper points of contact in government ministries to advance project objectives. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 6 December, MDRC attended the monthly Standards Alliance 2.0 project coordination meeting with PQM+, MTaPS, and relevant USG officials. The initiatives shared updates on their recent progress. PQM+ shared with MDRC that it was working to secure PPB approval to share the draft document to revise PPB's regulatory processes. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)

- SOUTH AFRICA: On 7 December, SAHPRA agreed to proceed with MDRC and develop a dedicated MDRC workstream. MDRC and SAHPRA agreed that the MDRC workstream should emphasize the procedural elements of GRP as they pertain to COVID-19 response and recovery. The MDRC workstream will align with and operationalize the recommendations of regional bodies, such as the AMDF. MDRC work will complement SAHPRA's recent engagement with the WHO on regulatory practices pertaining to medicines, emphasizing the importance of leveraging international guidance (i.e. from the WHO) in the local context. MDRC is scheduling a kickoff meeting with SAHPRA for late January. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- GHANA: On 14 December, following attempts by MDRC in October, November, and December to schedule a meeting with the Ministry of Health's designated focal point, MDRC received a response from the focal point. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 15 December, MDRC provided FDA CDRH with an overview of MDRC's current state of play in Africa and context for their upcoming meeting with Kenya's PPB. MDRC and CDRH aligned on priorities for the region and next steps for engaging with relevant stakeholders on the continent. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- REGIONAL: On 16 December, MDRC and the ADMF discussed the project's ability to review and comment on relevant documents that are crafted in AMDF sub-working groups. MDRC was invited to the January AMDF meeting. AMDF informed MDRC that the AMDF no longer has an active COVID-19 Taskforce. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- KENYA: On 16 December, MDRC and PPB aligned on the next steps and processes to formalize an MDRC workstream with PPB. MDRC and PPB will proceed to formulate an MOU which will provide the legal basis for future collaboration on Tier Two-specific capacity building. Concurrently, PPB will send MDRC a formal letter requesting a dedicated project liaison to coordinate work in the project country. Once the MOU is concluded, MDRC and PPB will develop a consensus-based prioritized workstream to address identified issue areas through capacity building consultations and trainings. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- KENYA: On 16 and 17 December, MDRC extended outreach to KEBS and the Kenyan Customs and Border Control Department. On 19 December, KEBS responded positively, indicating it would be happy to partner with MDRC. On 22 December, Customs responded and designated a focal point for coordinating MDRC-Customs work. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)

Southeast Asia

- VIETNAM: On 5 October, MDRC introduced the project to the Vietnamese Embassy in Washington, D.C. and solicited the Embassy's guidance on how to best engage Vietnamese agencies. The Embassy committed to sharing MDRC's outreach letters with government stakeholders to help establish the focal point. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- INDONESIA: On 6 October, MDRC met with the Indonesian Embassy in Singapore to seek guidance on engagement with Indonesian agencies. The Embassy agreed to update their Ambassador and follow up with government agencies once they receive approval. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- VIETNAM: On 6 October, MDRC introduced the project to the Vietnamese Embassy in Singapore and sought guidance on how to best engage with local agencies. The Embassy agreed to forward MDRC materials and outreach letter to the Ministry of Health on MDRC's behalf. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- VIETNAM: On 15 October, MDRC sought USABC's assistance to share a prepared drafted letter to the Vietnamese Minister of Health that introduces MDRC and requests that the

Minister assign focal points to discuss the project. USABC agreed to assist and said it would consider directly partnering with MDRC. (IR 1.1, IR 1.2, IR 2.1, IR 3.1)

- INDONESIA: On 19 October, MDRC connected with EuroCham Indonesia's Health Committee. Participants discussed hosting a formal introductory call and the possibility of participating in the Health Business Gathering in Bali from 2-3 December. (IR 2.1)
- INDONESIA: On 21 October, MDRC conducted outreach to the Indonesian Minister of Health seeking support to advance the project in Indonesia. (IR 1.1, IR 1.2, IR 3.1)
- INDONESIA: On 25 October, MDRC met with USAID Indonesia and EuroCham Indonesia's Pharmaceutical and Medtech Working Group, who provided guidance on MDRC outreach. The Working Group agreed to forward MDRC's outreach letter to their contact in the MOH's Pharmaceutical and Medical Devices Directorate General. (IR 1.1, IR 1.2, IR 2.1, IR 3.1)
- INDONESIA: On 25 October, MDRC met with the USAID Mission's Health System Strengthening Lead, which reiterated the need for a local focal point on the ground to coordinate MDRC implementation. Th Mission agreed to consider forwarding a letter on behalf of MDRC to the Ministry of Health. (IR 1.1, IR 1.2, IR 3.1)
- VIETNAM: On 1 November, MDRC hosted a joint call with AdvaMed, AdvaMed members, APACMed, EuroCham Vietnam, and APCO to discuss the projects current status in the Vietnam. Those stakeholders provided input on MDRC engagement and the Ministry of Health's approach to medical devices during the pandemic. Attendees discussed developing and sending a joint letter to the Vietnamese Prime Minister to bring the project to his attention. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- VIETNAM: On 3 November, the USABC informed MDRC it connected with DMEC on MDRC's behalf. DMEC expressed interest in MDRC and advised it was awaiting guidance from superiors. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- VIETNAM: Following reports on 4 November, that a number of political office holders and officials within DMEC have been censured and/or expelled from their positions, MDRC sought views on these developments from local stakeholders. (IR 1.1, IR 1.2, IR 3.1, DO 4)
- INDONESIA: On 2 November, the LKPP sent a letter to MDRC conveying its "in-principle" agreement to collaborate with the project. MDRC is working to schedule a follow-up meeting. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- INDONESIA: On 5 November, MDRC introduced the project to representatives of the Indonesian Embassy in DC. The Embassy agreed to assist MDRC in following up with the Ministry of Health. (IR 1.1, IR 1.2, IR 2.1, IR 3.1, IR 4.1)
- INDONESIA: On 16 November, the special assistant to the Indonesian Minster of Health, contacted the USAID Indonesia Mission to inquire about MDRC and subsequently put the Mission in touch with the Ministry of Health's Medical Device Assessment department.
- VIETNAM: APACMed and EuroCham Vietnam have confirmed that they are agreeable to signing on to the joint letter with AdvaMed to the Vietnamese Prime Minister seeking his support for MDRC implementation. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- INDONESIA: On 29 November, MDRC met with the Mission to strategize future engagement with the Ministry of Health. The Mission outlined some of the Ministry's preliminary priorities. MDRC is finalizing the details for a meeting with the Medical Device Assessment department in early December. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)
- INDONESIA: On 4 December, MDRC presented on the project at the Indonesia Health Business Gathering, emphasizing the project's alignment with the Indonesia Healthcare Transformation Plan. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)

- INDONESIA: On 17 December, MDRC introduced the project to the Ministry of Heath, which indicated initial support for collaborating on the project. The Ministry mentioned some preliminary priorities for collaboration, including pre-market assessment & post-market quality surveillance of medical devices, capacity building on regulatory standards, and ensuring safety and efficacy of medical devices. MDRC committed to developing and sharing a workplan for collaboration with the Ministry ahead of a January 2022 meeting. (IR 1.1, IR 1.2, IR 3.1, DO 4, IR 4.1, IR 4.2)

4.1 AdvaMed Staff Activities

The team of AdvaMed staff contributing to the MDRC are continuously engaged in ongoing activities that advance the project objectives. A non-exhaustive list of some of the more pertinent activities that occurred over the past two-week period are included here:

- Global staff engagement with USTR and ITA on GRP, TBT and regional activities (IR 1.1, IR 1.2, IR 3.1, IR 4.1)
- Staffing of the Global Harmonization Working Group (DO 4, IR 4.1, IR 4.2).
- Staffing of the AdvaMed COVID-19 Supply Chain Task Force (DO 4, IR 4.1, IR 4.2).
- Staffing of the AdvaMed MDRC Steering Group (SG) (IR 1.1, IR 1.2, IR 2.1, IR 3.1, DO 4, IR 4.1, IR 4.2)
- Staffing of the AdvaMed Standards Working Group (IR 1.1, IR 2.1, I 3.1, IR 4.1)
- Staffing of the GMTA Regulatory Working Group (IR 2.1).
- Meeting with the U.S. Food and Drug Administration – Center for Devices and Radiological Health (FDA/CDRH) – Global and LatAm teams (IR 1.1)
- Coordination with AdvaMed partner medical technology associations (IR 2.1).

7.8 LESSONS LEARNED

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

MDRC continues to optimize the level of resources devoted to running MDRC and the Coalition's online presence. The execution of effective virtual project country capacity building does not require the allocation of extensive travel resources. With the reallocation of resources otherwise earmarked for travel to the Colombia Liaison, MDRC facilitated rapid progress in the project country. MDRC will continue to look for ways to maximize the effectiveness of resources to achieve MEL Plan objectives in the current non-travel environment.

In Q4, the Coalition continued to leverage a more experienced, lower cost web development vendor. This has heightened the Coalition's capacity to provide online modules and virtual resource library. Virtual Coalition resources have proven to be an invaluable tool for hosting and disseminating information vital to the project.

MDRC has continued to leverage the recently-launched project URL www.standardsalliance-mdrc.org and related email @standardsalliance-mdrc.org. These project elements streamline and standardize project communication across geographies.

7.9 PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

In Q1 2022, MDRC will continue to focus on outreach and development of capacity-building workstreams with private and public sector stakeholders, particularly in Southeast Asia and Africa. MDRC will advance awareness of MDRC objectives and dive deeper into specific Tier One and Tier Two areas with those stakeholders, identifying where MDRC can remedy regulatory non-alignments and promote the use of GRPs.

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

Planned Events for Q1 2022:

Date	Meeting/Event	Location	USAID participation?	Region
January 20 & 27	Joint MDRC - FDA webinar series on UDI	Virtual	Yes	LATAM
March 10, 17, 24 & 31 (TBC)	Joint MDRC – FDA webinar series continuation on International Standards and Conformity Assessment	Virtual	Yes	LATAM
TBD	Emergency Use Authorization – International References	Virtual	Yes	COL/MX - LATAM
TBD	IMDRF – Essential Principles & Table of Content	Virtual	Yes	COL - LATAM
TBD	Clinical Research for MDs	Virtual	Yes	COL - LATAM
TBD	Software as Medical Device – International References	Virtual	Yes	MX - LATAM
TBD	Tier One Regional Forum: relevant stakeholders from Ghana, Kenya, and South Africa (and broader region, as appropriate)	Virtual	Yes	Africa

TBD	Tier Two Regional Forum: relevant stakeholders from Indonesia and Vietnam (and broader region, as appropriate)	Virtual	Yes	Southeast Asia
TBD	Tier Two local Forum - Vietnam	Virtual	Yes	Vietnam