Standards Alliance: Phase 2

Quarterly Report

3rd Quarter June 1 to September 30, 2020

Submission Date: October 30, 2020

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:	
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	3 Q 2020 – July 1 to September 30, 2020

1.1 Program Description/Introduction

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

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

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

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

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

SA2 Focus on Medical Devices to Support COVID-19 Response

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

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The third quarter of 2020 entailed the selection of partners and initiation of activities from the Year 2 work plan. The SA2 team worked with USAID and the U.S. private sector to finalize the SA2 Year 2 work plan, which details each activity for Year 2—including the largest activity, the SA2 COVID-19 Medical Device Regulatory Convergence Project (MDRC).

Many partners continued finalizing their proposals while others started working with stakeholders to establish relationships and further develop their implementation plans. Two projects—the Zambia RIA Training and the MDRC—reached milestones this quarter. SA2 began holding virtual trainings with Zambian regulators on regulatory impact assessment (RIA) and good regulatory practices. The MDRC project launched the Inter-American Coalition of Regulatory Convergence for the Medical Technology Sector in Q2 and continued its development throughout Q3.

ANSI continued to monitor the COVID-19 pandemic throughout Q3, and the work plan was drafted taking into account implementation that will either begin virtually or once travel and meeting restrictions are lifted. This report details the implementation status of each activity in section 2.2.

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

Coronavirus has necessitated the need to adjust many activities throughout 2020, and conferences globally have not been unaffected. Garner Advisors had intended to implement two national conferences in the ECOWAS region in September, targeting Senegal and Ghana, in anticipation of the larger regional ECOWAS Sustainable Energy Forum (ESEF) 2020 slated to occur in November. With the closing of borders and limitations on international travel, the ESEF 2020 will now be executed virtually, and the two national workshops will be shifted to 2021.

Garner will seeks to transfer the organization of these workshops to Pivot Clean Energy (Pivot), a newly formed non-profit working to increase access to clean, household energy. As part of its mission in transitioning homes to bioethanol, Pivot would work with interested stakeholders to develop policy and standards in this arena across multiple geographies. In order to further progress in biofuel education and standards development, Pivot is proposing that an adjusted format for introducing liquid fuels take place in the meantime to engage key stakeholders and government entities. The ability to present in conjunction with the ESEF 2020 as part of their agenda would help prepare these entities in advance of the 2021 physical workshops. This not only lays the foundation for local collaboration, but also invites participation for the gathering of baseline information and establishment of pilot programs. Supplementing the workshops with these key findings demonstrates the importance of establishing policy and standards to support the practical applications in clean cooking and transportation fuel development.

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

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

In Q3, ANSI coordinated with ARSO to identify areas for collaboration related to the annual ARSO General Assembly (GA). Unfortunately, due to travel complications related to the ongoing global health crisis, ARSO has postponed this year's GA until June 2021 and will host this event in Nigeria. ANSI and ARSO continue to coordinate on activities to best compliment the upcoming GA and to highlight some of the existing work under the Standards Alliance Phase 2.

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

Final proposal is pending submission to ANSI. Research on WASH-related product standards is planned for Ghana, Zambia and Uganda beginning 1Q21.

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

In Q3, ANSI in coordination with the Zambian Business Regulatory Review Agency (BRRA) organized a four week training series on **"Good Regulatory Practices for Regulatory Impact Assessment (RIA) Teams in Government Ministries."** The 4-day workshop series targeting 92 government officials from 23 Zambian ministries, took place virtually with the first and second cohort of officials attending trainings on September 21 – October 2, 2020 and the third and fourth group of officials attending on October 13 – 23, 2020. The trainings were designed to promote best practices in the development of RIA reports, a decision-making tool that's used to appraise the potential impacts of new and existing regulations or policy options on the business environment and foreign investments. The workshops also provided systematic training on the key steps for performing RIA and highlighted training strategies for participants to use as they lead their individual ministries and colleagues in performing RIAs.

The training featured both live presentations via WebEx and pre-recorded videos and reading materials, which were provided by RIA experts Nathan Frey of RSS Group, Jason Ighani of Kite Global, and Brandon de Bruhl of the University of Southern California. Targeted group exercises provided hands on guidance and opportunities to critically analyze existing RIA reports in Zambia. These sessions emphasized practical steps on how to write and structure a RIA report, gather qualitative and quantitative data from all relevant stakeholders, conduct consultations, and effectively utilize cost-benefit and cost-effective analysis.

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

Final proposal is pending submission to ANSI. Activities are planned for Zambia, Malawi, and Lesotho beginning 4Q21.

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

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

In Q3, ANSI worked with ASTM International and the American Petroleum Institute (API) to refine their project proposal and develop a final draft for USAID's review. This proposal is in strong working shape and, pending USAID approval, positions this project to begin as soon as Q4 of 2020.

Activity #6 Africa Concrete and Building Code Adoption Initiative

Updated proposal is pending submission to ANSI.

INDO-PACIFIC

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

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

Updated proposal is pending submission to ANSI. Activities are planned for Indonesia and the Philippines.

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

Final proposal is pending submission to ANSI. Activities in India are planned to begin 2Q21.

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)

Proposal is pending submission to ANSI. Activities are planned for Brazil and Colombia.

Development Objective #3: Countries have fewer TBT's

Activity #10 – Energy Efficiency Standards in Mexico

On September 9, 2020 the USAID Mexico Mission approved ANSI's Mexico Energy Efficiency proposal. The proposal includes coordination between the Lawrence Berkeley National Laboratory (LBNL) and the International Code Council (ICC) on the implementation of the Energy Efficiency Code of Mexico City. Before moving forward with an implementation plan, the two organizations noted the following necessary actions items and information to gather:

- Identify the kind of training that would be the most useful (municipal level, but the federal government should be made aware of the program).
- Identify responsible entity for the enforcement of the energy efficiency code in Mexico.
- Update the energy code (2012 version is currently being utilized).
- Identify which entities are conducting certification.

MIDDLE EAST NORTH AFRICA

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

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

Updated proposal is pending submission to ANSI. Activities are planned for Jordan.

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

Updated proposal is pending submission to ANSI. Activities are planned for Morocco.

COVID-19 Related Activities Implementation Status

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

GLOBAL

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

ANSI and AdvaMed have agreed on terms for a subaward agreement for the MDRC, which is pending USAID approval. Q3 2020 saw major advancement in SA2-MDRC internal and external project team setup and coordination, including the finalizing the project's Monitoring, Evaluation and Learning (MEL) Plan, submitted as an addendum to the SA2 MEL Plan. The quarter also focused on substantial scale-up in U.S. government and U.S./in-country private sector engagement to socialize and build support to achieve the project's multi-year objectives. These engagements are expected to intensify in Q4 2020 and begin to include in-country government engagement. A brief status report is included in this section, but a full progress report provided by AdvaMed is included as Annex 1.

Q3 2020 also saw substantial progress in the implementation of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector. Launched in Q2 2020, the Coalition participated in Global Medical Technology Alliance (GMTA) Regulatory Working Group sessions on July 9, August 27, and September 10 and is planning to participate in a session jointly with GMTA and GDA on 8 October. MDRC coordination with the GMTA, International Medical Device Regulators Forum (IMDRF), and Ad Hoc Working Group (AHWG) trainings efforts formally commenced on 2 September. The Coalition also submitted its application for membership to the Global Diagnostics Alliance on September 14, a key step towards collective efforts to implement the project's global objectives. Several AdvaMed committees were also activated in Q3 2020 to commence support for MDRC objectives, including the Global Harmonization Working Group on 27 August, Standards Working Group on July 23, August 27, and September 24, and numerous task forces focused on COVID-19 and project countries. The Coalition introduced the MDRC project objectives to the U.S. FDA Global and Latin America teams on September 8 and full support was extended. Additional sessions are planned with FDA and U.S. Government leaders in Q4 2020.

Lastly, work has commenced to identify strategic partners to help implement MDRC project objectives in Africa, including GRP and stakeholder assessments by the end of Q4 2020. A GRP Survey and Report for Latin America, and similar Tier 1/Tier 2 reports to help identify stakeholders and gaps for Southeast Asia, was also advanced and is planned for completion in Q4 2020.

AFRICA

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

In Q3 of the Standards Alliance Phase 2, ANSI and Ethical Apparel Africa (EAA) began laying the groundwork for the project to establish production of surgical grade Personal Protective Equipment (PPE) within Ghana to supply the West African region and to develop a sales pipeline of export to the USA.

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

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

Achievements to Date

- Worked to understand material and performance requirements of surgical masks that can be used in healthcare settings. This has included already connecting with ANSI for guidance to ensure the surgical masks meet international standards. Specifically, the production set up is designed to an ISO 7 clean room standard with the product meeting at least Level 1 ASTM surgical mask standard for bacterial filtration efficiency, particulate filtration efficiency, fluid resistance to synthetic blood, and flame spread. EAA has also engaged in detail with the Ghana FDA to ensure that all local requirements will be met.
- Widely sourced for machinery and material to enable production of surgical masks meeting the above specs, in the face of global shortages
- Procured with USAID support a reliable and available machinery source for a machinery system of surgical mask production. This machinery has been specifically chosen to ensure quality construction (ultrasonic welding).
- Sourced filtration fabric to begin production of general use medical masks whilst the certification process is in process for the surgical grade ones.
- Secured sampling of fabrics needed for surgical grade masks
- Researched options to secure welding machines for the production of disposable gowns and scrubs.
- Tendered and signed contract for the production of an ISO Level 7 Cleanroom

Challenges and Mitigating Actions

- EAA received equipment funding from a partner source significantly later than planned. This delayed the production and shipment of the cleanroom, which will now leave Ghana end of October and construction of the Cleanroom has been delayed and therefore production of the surgical mask sampling will also be delayed until post-Christmas.

2.3 Implementation Challenges

The third quarter of 2020 dealt with the ongoing COVID-19 moratorium of international travel and meetings. The SA2 team and private sector partners continue to monitor the impact of COVID-19 and have remained flexible with planning by hosting events virtually and/or focusing on project development until safe travel recommences. Despite the COVID-19 challenges, the implementation plans of SA2 and its activities remain on track.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

To varying degrees across all activities, the SA2 team has been in constant contact with stakeholders from both international and domestic private and public sectors. Many activities still have pending proposals, and ANSI is working with relevant stakeholders to finalize them. Activities with finalized proposals have begun stakeholder outreach to promote the program, establish the scope and further plan implementation. The major of stakeholder engagement has been with the MDRC project detailed below.

Activity #12 - COVID-19 Medical Device Regulatory Convergence Project

While SA2-MDRC has only just recently commenced, a significant number of stakeholders are already involved in its rapid scale-up. In the United States, this includes USAID, ANSI, AdvaMed and its project experts as well as regulatory experts from AdvaMed's membership. ASTM International and the Association for the Advancement of Medical Instruments (AAMI) have also commenced participation with the project as standards development organizations and will serve a central role in successful project implementation. The U.S. Food and Drug Administration Global Office, the Office of the United States Trade Representative (USTR), and the U.S. Department of Commerce have also commenced engagement as supportive government entities in Q3 2020 with substantial collaboration anticipated in Q4 2020. Email exchanges and virtual webinars have facilitated all of these engagements and no challenges have been identified to-date.

Internationally, there was substantial early participation by leading industry and non-industry stakeholders in Latin America during Q3, with every principal member of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector. This includes six leading organizations from MDRC project countries: AMID in Mexico, COMSALUD in Peru, ANSI in Colombia, and ABIIS/ABIMED/ABRAIDI/CBDL in Brazil. Coalition members have held one-on-one consultations with MDRC project team member in Q3 2020 as well as held several multi-party virtual sessions. No challenges have been identified to-date and significant ramp-up in activity is expected in Q4 2020 through 2021. No challenges have surfaced to-date in these engagements.

In addition, the MDRC project team continues to hold routine exchanges with the Inter-American Development Bank's (IDB) Integration and Trade Team regarding an IDB partnership with the Coalition to conduct a GRP survey and report for the region. These exchanges continue to progress and further details will be reported in Q4 2020 when the survey is expected to be circulated across the region and a report is prepared demonstrating where gaps exist. One potential challenge in these efforts would be a delay or decline by the IDB in partnering with the Coalition to conduct the survey and report. Should that take place, a mitigating strategy would be to confirm a new survey partner.

Stakeholder participation was just getting underway in Africa and Southeast Asia at the conclusion of the Q3 2020 and thus further information on stakeholders in these regions will be outlined in the Q4 2020 Report. Consultations with Mecomed, the leading medical technology industry body for Africa (ex-South Africa) initiated consultations with the project team in Q3 2020 and provided several recommendations for strategic partnerships to advance local objectives.

Lastly, at the international level, early consultations are underway with the Global Medical Technology Alliance (GMTA) and Global Diagnostics Alliance (GDA) about the MDRC project, including global COVID-19 related objectives where these entities and others will serve an important role. Early progress

is already underway, with GMTA indicating their support for MDRC in Q3 2020 and granting formal membership to the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector within the quarter.

See ANNEX with MDRC Quarterly Report for full detail.

4. RESULTS ACHIEVED

Activity #12 - COVID-19 Medical Device Regulatory Convergence Project

As this is the first quarterly report for MDRC, initial results are limited as the project team focuses on setup and scale-up. However, several project outputs have already been realized in alignment with the project's results framework and sought intermediate results. These include:

- GRP Training (Activity 1.1.4.1.) leading to countries having knowledge about GRPs (Output 1.1.4)
- Virtual resources and online training modules (Activity 1.2.2.2) leading to Countries having increased awareness of trade implications (Output 1.2.2)
- GRP Training (Activity 2.1.1.1) and the Inter-American Coalition (Activity 2.1.1.2) leading to private sector having knowledge on avenues for participation (Output 2.1.1) that is already demonstrating enhanced private sector participation in regulatory development (IR 2.1)
- Online module development/delivery and virtual training platforms (Activity 2.1.4.1) leading to training curricula (Output 2.1.4) that is already demonstrating enhanced private sector participation in regulatory development (IR 2.1)
- Support for local industry associations (Activity 2.1.5.1) and twinning for industry associations (Activity 2.1.5.2) leading to local industry association mentorship (Output 2.1.5) that is already demonstrating enhanced private sector participation in regulatory development (IR 2.1)
- Progress toward the launch of a COVID-19 medical device portal (Activity 4.0.0.3) under Development Objective 4.
- Active recruitment and engagement of women and diverse representation in all MDRC activities (CC Activity 2.1.2.1) leading to gender and diversity inclusion into development of country national quality infrastructure (CC Output 2.1.2)

5. LESSONS LEARNED

Given the tremendous need, rapid scale-up, and ambition for MDRC, enhanced coordination mechanisms between a large number of stakeholders worldwide will require sophisticated tracking tools instead of traditional coordination practices by the project team. This lesson was quickly realized upon launch of the project and will be successfully adapted into Q4 2020 throughout the life course of the project. The project team is also continuing to incorporate lessons learned on virtual capacity-building and resource capabilities to advance project objectives. This will remain a priority for much of the life of the project, as the world and technology adapt to the current pandemic and post-pandemic environment.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

The SA2 team will begin in depth planning of country needs assessments in Q4. These assessments will likely be held virtually and start in late Q4 2020 or early 2021. Definitive activities for next quarter are detailed below by activity.

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

In Q4, ANSI and the Zambian Business Regulatory Review Agency (BRRA) will finish its "**Good Regulatory Practices for Regulatory Impact Assessment (RIA) Teams in Government Ministries.**" 4-day workshop training series on October 1 –2, 2020 and October 13 – 23, 2020. ANSI will hold these trainings virtually as they did in Q3.

Activity #12 - COVID-19 Medical Device Regulatory Convergence Project

- Q4 2020 will serve as an intensive period for planned activities amidst the project's rapid scale-up. These planned activities include formal outreach to diverse government stakeholders across all ten project countries and follow-up sessions to commence engagement in project activities. Similar outreach and follow-up sessions are anticipated with international government organizations, such as the Pan American Health Organization (PAHO).

- Q4 2020 will see significant cross-coordination and exchanges between USAID, ANSI, and AdvaMed and entities across the U.S. Government, including U.S. FDA, USTR, Commerce, and others to build in project objectives into their engagements with counterparts spanning all 10 project countries and international government organizations. MDRC aims to achieve complete synchronization of U.S. Government coordination on project objectives by the end of Q4 2020.

- In addition to government stakeholders, MDRC will see intensive private sector activities in Q4 2020, including a formal meeting in December 2020 of all Coalition principal and standards development organization members. This meeting will serve as a crucial opportunity to align all medical device entities across the Americas to advance project objectives in 2021 and beyond. In Latin America, the completion of the GRP Survey and Report is also anticipated in Q4 2020.

- Similar scale-up of private sector and standards development organization engagement is anticipated in Africa and Southeast Asia in tandem with substantial stakeholder assessment, literature review, and gap analysis items for these regions, which are essential to ensuring proper development and execution of project activities for 2021.

- The project team anticipates several activities to advance global objectives related to countries having COVID-19 plans or actions that incorporate good regulatory practices

7. ANNEX

AdvaMed MDRC Quarterly Report

STANDARDS ALLIANCE:
PHASE 2 QUARTERLY REPORT TO ANSI

8. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2 (SA2) COVID-19 Medical Device Regulatory Convergence Project (MDRC)
Activity Start Date and End Date:	July 12, 2019 – July 11, 2024
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
Agreement Number:	#7200AA19CA00012
Name of Subcontractor/Subawardee:	The Advanced Medical Technology Association (AdvaMed)
Geographic Coverage (cities and or countries)	Latin America (Brazil, Colombia, Mexico, Peru), Africa (Ghana, Kenya, South Africa), Southeast Asia (Indonesia, Thailand, Viet Nam)
Reporting Period:	July 1, 2020 to September 30, 2020 *Note: For Items 1 through 6 in this Quarterly Report, the project is focused on activities from July 1, 2020 to September 30, 2020. However, for Item 8 (Quarterly Financial Report), this submission covers Federal Share from August 27, 2020 to September 30, 2020 and Non-Federal Share from May 18, 2020 to September 30, 2020.*

8.1 Program Description/Introduction

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

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

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

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

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

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

9. ACTIVITY IMPLEMENTATION PROGRESS

9.1 Progress Narrative

Q3 2020 saw major advancement in SA2-MDRC internal and external project team setup and coordination, including the finalizing the project's MEL Plan Addendum. The quarter also focused on substantial scale-up in U.S. Government and U.S./In-Country private sector engagement to socialize and build support to achieve the project's multi-year objectives. These engagements are expected to intensify in Q4 2020 and begin to include In-Country Government engagement.

Q3 2020 also saw substantial progress in the implementation of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector. Launched in Q2 2020, the Coalition participated in GMTA Regulatory Working Group sessions on July 9, August 27, and September 10

and is planning to participate in a session jointly with GMTA and GDA on 8 October. MDRC coordination with the GMTA, IMDRF, and AHWG trainings efforts formally commenced on 2 September. The Coalition also submitted its application for membership to the Global Diagnostics Alliance on September 14, a key step towards collective efforts to implement the project's global objectives. Several AdvaMed committees were also activated in Q3 2020 to commence support for MDRC objectives, including the Global Harmonization Working Group on 27 August, Standards Working Group on July 23, August 27, and September 24, and numerous task forces focused on COVID-19 and project countries. The Coalition introduced the MDRC project objectives to the U.S. FDA Global and Latin America teams on September 8 and full support was extended. Additional sessions are planned with FDA and U.S. Government leaders in Q4 2020.

Lastly, work has commenced to identify strategic partners to help implement MDRC project objectives in Africa, including GRP and stakeholder assessments by the end of Q4 2020. A GRP Survey and Report for Latin America, and similar Tier 1/Tier 2 reports to help identify stakeholders and gaps for Southeast Asia, was also advanced and is planned for completion in Q4 2020.

9.2 Implementation Status

SA2-MDRC remains on track with the planned implementation schedule. There have not been any delays or changes to the plan since its launch within the quarter.

9.3 Implementation Challenges

There have been no challenges to-date in the implementation of project tasks. AdvaMed and the project team are closely monitoring the impact of COVID-19 on travel capabilities in 2021 that could impact capacity-building objectives. Preparations are already underway to establish virtual capacity-building resources and tools to mitigate potential challenges in this area, should they arise.

10. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

While SA2-MDRC has only just recently commenced, a significant number of stakeholders are already involved in its rapid scale-up. In the United States, this includes USAID, ANSI, AdvaMed and its project experts as well as regulatory experts from AdvaMed's membership. ASTM International and the Association for the Advancement of Medical Instruments (AAMI) have also commenced participation with the project as standards development organizations and will serve a central role in successful project implementation. The U.S. Food and Drug Administration Global Office, the Office of the United States Trade Representative, and the U.S. Department of Commerce have also commenced engagement as supportive government entities in Q3 2020 with substantial collaboration anticipated in Q4 2020. Email exchanges and virtual webinars have facilitated all of these engagements and no challenges have been identified to-date.

Outside the United States, we have seen substantial early participation by leading industry and non-industry stakeholders in Latin America, with every principal member of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector. This includes six leading organizations from MDRC project countries: AMID in Mexico, COMSALUD in Peru, ANSI in Colombia, and ABIIS/ABIMED/ABRAIDI/CBDL in Brazil. Coalition members have held one-on-one consultations with MDRC project team member in Q3 2020 as well as held several multi-party virtual sessions. No

challenges have been identified to-date and significant ramp-up in activity is expected in Q4 2020 through 2021. No challenges have surfaced to-date in these engagements.

In addition, the MDRC project team continues to hold routine exchanges with the Inter-American Development Bank's (IDB) Integration and Trade Team regarding an IDB partnership with the Coalition to conduct a GRP survey and report for the region. These exchanges continue to progress and further details will be reported in Q4 2020 when the survey is expected to be circulated across the region and a report is prepared demonstrating where gaps exist. One potential challenge in these efforts would be a delay or decline by the IDB in partnering with the Coalition to conduct the survey and report. Should that take place, a mitigating strategy would be to confirm a new survey partner.

Stakeholder participation was just getting underway in Africa and Southeast Asia at the conclusion of the Q3 2020 and thus further information on stakeholders in these regions will be outlined in the Q4 2020 Report. Consultations with Mecomed, the leading medical technology industry body for Africa (ex-South Africa) initiated consultations with the project team in Q3 2020 and provided several recommendations for strategic partnerships to advance local objectives.

Lastly, at the international level, early consultations are underway with the Global Medical Technology Alliance (GMTA) and Global Diagnostics Alliance (GDA) about the MDRC project, including global COVID-19 related objectives where these entities and others will serve an important role. Early progress is already underway, with GMTA indicating their support for MDRC in Q3 2020 and granting formal membership to the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector within the quarter.

11. RESULTS ACHIEVED

As this is the first quarterly report for MDRC, initial results are limited as the project team focuses on setup and scale-up. However, several project outputs have already been realized in alignment with the project's results framework and sought intermediate results. These include:

- GRP Training (Activity 1.1.4.1.) leading to countries having knowledge about GRPs (Output 1.1.4)
- Virtual resources and online training modules (Activity 1.2.2.2) leading to Countries having increased awareness of trade implications (Output 1.2.2)
- GRP Training (Activity 2.1.1.1) and the Inter-American Coalition (Activity 2.1.1.2) leading to private sector having knowledge on avenues for participation (Output 2.1.1) that is already demonstrating enhanced private sector participation in regulatory development (IR 2.1)
- Online module development/delivery and virtual training platforms (Activity 2.1.4.1) leading to training curricula (Output 2.1.4) that is already demonstrating enhanced private sector participation in regulatory development (IR 2.1)
- Support for local industry associations (Activity 2.1.5.1) and twinning for industry associations (Activity 2.1.5.2) leading to local industry association mentorship (Output 2.1.5) that is already demonstrating enhanced private sector participation in regulatory development (IR 2.1)
- Progress toward the launch of a COVID-19 medical device portal (Activity 4.0.0.3) under Development Objective 4.
- Active recruitment and engagement of women and diverse representation in all MDRC activities (CC Activity 2.1.2.1) leading to gender and diversity inclusion into development of country national quality infrastructure (CC Output 2.1.2)

12. LESSONS LEARNED

Given the tremendous need, rapid scale-up, and ambition for MDRC, enhanced coordination mechanisms between a large number of stakeholders worldwide will require sophisticated tracking tools instead of traditional coordination practices by the project team. This lesson was quickly realized upon launch of the project and will be successfully adapted into Q4 2020 throughout the life course of the project.

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

13. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Q4 2020 will serve as an intensive period for planned activities amidst the project's rapid scale-up. These planned activities include formal outreach to diverse government stakeholders across all ten project countries and follow-up sessions to commence engagement in project activities. Similar outreach and follow-up sessions are anticipated with international government organizations, such as the Pan American Health Organization (PAHO).

Q4 2020 will see significant cross-coordination and exchanges between USAID, ANSI, and AdvaMed and entities across the U.S. Government, including U.S. FDA, USTR, Commerce, and others to build in project objectives into their engagements with counterparts spanning all 10 project countries and international government organizations. MDRC aims to achieve complete synchronization of U.S. Government coordination on project objectives by the end of Q4 2020.

In addition to government stakeholders, MDRC will see intensive private sector activities in Q4 2020, including a formal meeting in December 2020 of all Coalition principal and standards development organization members. This meeting will serve as a crucial opportunity to align all medical device entities across the Americas to advance project objectives in 2021 and beyond. In Latin America, the completion of the GRP Survey and Report is also anticipated in Q4 2020.

Similar scale-up of private sector and standards development organization engagement is anticipated in Africa and Southeast Asia, in tandem with substantial stakeholder assessment, literature review, and gap analysis items for these regions which are essential to ensuring proper development and execution of project activities in these regions for 2021.

Lastly, the project team anticipates several activities to advance global objectives related to countries having COVID-19 plans or actions that incorporate good regulatory practices