

**Individual and Joint Sessions of the  
Inter-American Coalitions for Business Ethics and Regulatory Convergence in the Medical  
Technology Sector & MDRC Project  
National Regulatory Authorities**

23 - 26 October 2022 | Boston, Massachusetts, United States

**Boston Convention Center**

*Draft Scenario – Updated 13 October 2022*

<b>Saturday, 22 October 2022 – Joint Coalition Event (In-Person)</b>	
<b>6:00 – 8:30</b>	<b>Joint Coalition Welcome Reception</b> <i>Location: Envoy Hotel, Overlook Terrace, 70 Sleeper St. Boston, MA 02210</i>
<b>Sunday, 23 October 2022 – Joint Coalition Event (In-Person &amp; Virtual) Boston Convention Center</b>	
<b>8:00 – 10:00</b>	<b>Ethics Coalition Meeting – Boston Convention Center</b> <i>Location: Room 258C</i>
<b>10:00 – 10:30</b>	<b>Break</b>
<b>Sunday, 23 October 2022 – Inter-American Coalition for Regulatory Convergence (In-person &amp; Virtual) Boston Convention Center – Room 258C</b>	
<b>10:30 – 10:40</b>	<b>Welcome Message &amp; Coalition + MDRC + Program Overview</b> Sandra Ligia González, IACRC - MDRC
<b>10:40 – 10:45</b>	<b><u>Workshop on Self-testing</u></b> <b>Opening Comments</b> Leticia Fonseca, IACRC - MDRC
<b>10:45 – 10:55</b>	<b>The Latin American Alliance for the Development of In Vitro Diagnostics – Its Role in Promoting Regulatory Convergence</b> Carlos Gouvea, ALADDIV
<b>10:55 – 11:25</b>	<b>The Use of Self-testing as a Public Health Tool</b> Rosanna Peeling, London School of Hygiene and Tropical Medicine (In-person) (25 min) Q&A 5 min
<b>11:25 – 11:55</b>	<b>The Use of Self-testing in addressing public health emergencies – Lessons Learned from COVID-19</b> Ute Ströher, Coordination of Emergency Use and Listing for In Vitro Diagnostics & Development of Specifications for In Vitro Diagnostics, WHO (Virtual) TBC (25 min) Q&A 5 min
<b>11:55 – 12:25</b>	<b>Self-testing, an experience: HIV Self-test distribution by the Ministry of Health in Brazil</b>

	TBD, Ministry of Health Brazil (Virtual) (25 min) Q&A 5 min
<b>12:25 – 12:30</b>	<b>Closing Remarks</b> Leticia Fonseca, IACRC - MDRC
<b>12:30 – 13:00</b>	<b>Light lunch</b>
<b>13:00 – 15:00</b>	<b>Meeting of the Global Medical Technology Alliance (GMTA)</b>
<b>5:00 – 7:00</b>	<b>International Reception - Registration to The MedTech Conference required</b>

**Monday, 24 October 2022 – Inter-American Coalition for Regulatory Convergence (In-Person & Virtual)  
- Boston Convention Center**

<b>08:00 - 08:45</b>	<b>MDRC Breakfast</b> <i>Location: Room 161</i>
<b>09:00 - 10:15</b>	<b>Global Regulatory Convergence Panel (MDRC relevant MedTech Conference content) - Registration to The MedTech Conference required</b> <i>Location: Room 160 ABC</i>
<b>10:15 - 11:30</b>	<b>LatAm Health Care Compliance and Integrity Outlook – (MDRC relevant MedTech Conference content) - Registration to The MedTech Conference required</b> <i>Location: Room 157 AB</i>
<b>12:00 - 13:30</b>	<b>Opening Plenary Lunch - Registration to The MedTech Conference required</b> <i>Location: Hall B2</i>
<b>2:00 - 3:30</b>	<b>Inter-American Regulatory Convergence Panel - Registration to The MedTech Conference required</b> <i>Location: Hall B2</i>  <b><u>The role of MedTech National Regulatory Authorities in the COVID-19 response and recovery and the paradigm moving forward</u></b> Moderator: Sandra Ligia González – IACRC – MDRC  Welcome Message - S. Bipes (3 min) Opening Remarks - Daniel Vázquez (3 min) Augusto Geyer, ANVISA, Brazil (In-person) (20 min) Mabel Barbosa, INVIMA (Pre-recorded message) TBC (10 min) Óscar Marín, MoH, Colombia – (Pre-recorded message) (10 min) Melissa Torres, USFDA, United States (In-person) (20 min)  Q&A – 20 min  Closing Remarks – Sandra Ligia González, IACRC – MDRC (4 min)  <i>Location: Room 157 AB</i>

<b>3:45 - 5:00</b>	<b>EU MDR/IVDR – (MDRC relevant MedTech Conference content) - Registration to The MedTech Conference required</b> <i>Location: Room 160 ABC</i>
<b>5:30 - 6:30</b>	<b>Boston Reception - Registration to The MedTech Conference required</b> <i>Hall C</i>

<b>Tuesday, 25 October 2022 – Inter-American Coalition for Regulatory Convergence (In-Person &amp; Virtual) Boston Convention Center</b>	
<b>8:00 - 8:45</b>	<b>MDRC breakfast at Boston Convention Center</b> <i>Location: Room 258 AB</i>
<b>9:00 - 11:00</b>	<b>Inter-American Regulatory Convergence Panel (Overtime session)</b>  <b>MDRC Project Countries NRAs representatives</b>  Augusto Geyer, ANVISA, Brazil (In-person) Mábel Barbosa, INVIMA (Virtual) Óscar Marín, MoH, Colombia (Virtual) Melissa Torres, USFDA, United States (In-person) Steven Bipes – AdvaMed, MDRC (In-person)  <i>Location: Room 258 AB</i>
<b>12:30 - 2:00</b>	<b>Plenary Lunch - Registration to The MedTech Conference required</b> <i>Location: Hall B2</i>
<b>2:30 - 5:00</b>	<b>MedTech Conference Session on MDRC Project - Open Session</b> Moderator: Sandra Ligia González, IACRC - MDRC  <b>Opening Remarks</b> <b>Daniel Vázquez, USAID</b>  <b>Brazil</b> <b>Augusto Geyer, ANVISA (In-person) (20 min)</b> <ul style="list-style-type: none"> <li>Cooperation in Capacity Building in the region</li> </ul> <b>S. Bipes, AdvaMed – MDRC (20 min)</b> <ul style="list-style-type: none"> <li>INMETRO – Conformity Assessment</li> </ul> <b>Colombia</b> <b>Susan Suárez – MDRC Liaison Colombia</b> <ul style="list-style-type: none"> <li>MDRC Achievements (20 min)</li> </ul> <b>Mábel Barbosa, INVIMA (Virtual) 20 minutes</b> <b>Óscar Marín, MoH, Colombia (Virtual) 20 minutes</b> <ul style="list-style-type: none"> <li>Decrees 4725 and 4770</li> <li>Good Manufacturing Practices</li> <li>Clinical Evaluation</li> </ul>

	<ul style="list-style-type: none"> <li>Emergency Use Authorization</li> </ul> <p><b>Gabriel Bustamante</b> – MoH TBC (10 min)</p> <ul style="list-style-type: none"> <li>GRP Implementation</li> </ul> <p><b>Mexico</b></p> <p><b>Sandra Ligia González</b>, IACRC – MDRC (10 min)</p> <ul style="list-style-type: none"> <li>Capacity Building</li> <li>GRPs Legal Obligations – Checklist</li> <li>Quality Infrastructure Law – Implementing Regulation</li> </ul> <p><b>Peru</b></p> <p><b>Sandra Ligia González</b>, IACRC – MDRC (5 min)</p> <ul style="list-style-type: none"> <li>DIGEMID / ACR - Procedures Updates</li> </ul> <p><i>Location: Room 257 AB</i></p>
<b>5:15 - 6:15</b>	<p><b>Reception - Registration to The MedTech Conference required</b></p> <p><i>Location: Hall C</i></p>

**Wednesday, 26 October 2022 – Inter-American Coalition for Regulatory Convergence (In-Person & Virtual) Boston Convention Center**

<b>08:00 - 08:45</b>	<p><b>MDRC breakfast at Boston Convention Center</b></p> <p><i>Location: Room 258C</i></p>
<b>09:00 - 11:00</b>	<p><b>MDRC – Internal Session</b></p> <p><b>Opportunities to strengthen cooperation and further leverage the MDRC project</b></p> <p>Moderator: Sandra Ligia González, IACRC – MDRC</p> <p><b>Opening Remarks</b></p> <p><b>Daniel Vázquez</b>, USAID</p> <p><b>Brazil</b></p> <p><b>Augusto Geyer</b>, ANVISA (In-person)</p> <p><b>Colombia</b></p> <p><b>Mábel Barbosa</b>, INVIMA (Virtual)</p> <p><b>Óscar Marín</b>, MoH, Colombia (Virtual)</p> <p><i>Location: Room 258 C</i></p>
<b>12:30 - 2:00</b>	<p><b>Plenary lunch - Registration to The MedTech Conference required</b></p> <p><i>Location: Hall B2</i></p>
<b>2:00 - 4:00</b>	<p><b>FDA/CDRH Town Hall (MDRC relevant MedTech Conference) - Registration to The MedTech Conference required</b></p> <p><i>Location: Room 160 ABC</i></p>