



Inter-American Coalition for Regulatory Convergence
Welcome Call
January 29, 2020

Agenda and Meeting Minutes

Attendees:

Technical Secretariat:

Andrew Blasi – Institutional, administrative and strategic support

Sandra Ligia González – Executive Secretary

Leticia Seixas Fonseca – Deputy Executive Secretary

Renata Amaral – Good Regulatory Practices

Adriana Belza – AdvaMed (J&J)

Steven Bipes – AdvaMed

Jamie Wolszon – AdvaMed

José Márcio Cerqueira Gomes – ABIIS

Fernando Silveira – ABIMED/ABIIS

Carlos Goulart – ABIMED/ABIIS

Angélica Marques – ABIMED/ABIIS

Carlos Gouvêa – CBDL/ABIIS (and representing the Brazilian Health Ethics Institute)

Sérgio Madeira – CBDL/ABIIS

Sérgio Rocha – ABRAIDI/ABIIS

Bruno Boldrin – ABRAIDI/ABIIS

Ana Riquelme – AMID

Verónica García – AMID (B Braun)

Sergio Ramos – AMID (Zimmer-Biomet)

Marisol Sánchez – ANDI/CDMIS

Gabriela Garnham – ADIMECH / Victoria Del Castillo, CADIEM

Sebastian Parigi, CADIEM (J&J)

Brian Lewis, MedTech Canada

Diana Johnson, MedTech Canada

Omar Neyra, COMSALUD/CCL

Amanda Martinez, COMSALUD/CCL

Lucia Azalgara, COMSALUD/CCL

Agenda

- Introductions and Roll Call
- Brief Remarks from Steven Bipes, AdvaMed



- Brief Overview by Executive Secretary (Sandra Ligia González) and Deputy Executive Secretary (Leticia Fonseca) on preparing the Coalition's Terms of Reference, Action Plan, and Members' Priorities Form.
- Brief Overview by Coalition Technical Secretariat (Andrew Blasi) on Mexico City Preparations: Agenda, Logistics
- Questions / Comments / Next Steps

Meeting Minutes

1. A. Blasi welcomed the participants, shared the agenda and dynamics of the meeting and introduced the members of the Technical Secretariat and their respective roles:
 - a. Sandra Ligia González – Executive Secretary
 - b. Leticia Seixas – Deputy Executive Secretary
 - c. Renata Amaral – Good Regulatory Practices
 - d. Andrew Blasi and Patty Wu – Institutional, administrative and strategic support
2. S. Bipes welcomed the attendees and provided a high-level overview of the scope of the Inter-American Coalition for Regulatory Convergence, highlighting the importance of the alignment in efforts to reach regulatory convergence both transversal and vertically through a broader implementation of Good Regulatory Practices (GRPs).
3. S.L. González, representing the Executive Secretariat, shared the Vision and Mission of the Coalition and a brief summary of the contents of the Coalition's Terms of Reference and Action Plan, which drafts would be forwarded to the Principal Members to gather their input by February 28th. 2020, for the Technical Secretariat to compile and prepare the versions to be discussed during the first in-person meeting to be held in March, 2020. The above-mentioned documents, along with a List of current IMDRF Technical Documents and International Benchmarks – Regulator Use of Standards, are included as Annex to this meeting minutes.
4. S.L. González proposed to create a WhatsApp Group including one representative of each Principal Member and the Technical Secretariat to facilitate communication, for which the name and mobile number of the appointed individuals was kindly requested to be forwarded via e-mail.
5. A. Blasi presented an overview of the Agenda for the in-person meeting to be held in Mexico City on March 24-25 at the Four Seasons hotel in Mexico City. Meeting agenda, link to the hotel site to access preferential room rates and nearby lodging options will be forwarded to the Coalition Members, whom were also invited to confirm their attendance to the meeting:
 - a. ADVAMED representatives attending the meeting:



- i. Janet Trunzo, Senior Advisor to the President and Senior Executive Vice President, Technology and Regulatory Affairs
 - ii. Steven Bipes, Vice President Global Strategy & Advocacy
 - iii. Adriana Belza, Acting Chair AdvaMed LatAm Working Group (J&J)
 - b. Principal Members already confirmed to attend the meeting:
 - i. AdvaMed, AMID, ABIIS, ABIMED, ABRAIDI, and CBDL (Others Pending)
6. Call was closed offering all attendees the support of the Coalition Technical Secretariat and the Executive Committee and inviting all the Members for a continued close collaboration.