



TERMS OF REFERENCE

Vision

The Vision of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (“the Coalition”) is one standard, one test, accepted everywhere for any medical technology scope. This Vision implies that medical technology regulators across the Western Hemisphere base their national medical device regulations, standards and conformity assessment criteria on the relevant international standards for medical technology.

Mission

The Coalition’s Mission is to lead the coordination of all materially affected stakeholders to achieve this Vision. This includes promoting regulatory cooperation across the Western Hemisphere to achieve internationally aligned medical technology regulations, standards and conformity assessment requirements within a continual process of convergence to maximize patient access to innovative, effective, life-saving and life-improving medical technologies.¹

Terms of Governance

- The Coalition’s “Principal Members” include industry associations related to the medical technology sector based in the Western Hemisphere.
- The Coalition also welcomes standardization parties to serve as “Standardization Members” who are defined as: (1) any Standards Developing Organization (SDO), national member body to ISO, IEC or other SDO, or other organization, or technical committee thereof engaged in, or dedicated to, the international standardization of medical devices; (2) any organization engaged in activities pertaining to the conformity assessment of medical devices including the international standardization of medical device conformity assessment criteria. The conditions of Coalition membership for these entities are: (A) agreement with the Coalition Vision, Mission and Objectives; (B) approval by the Principal Members
- The Coalition welcomes as “Observers” all affected stakeholders, such as governmental and regulatory authorities, professionals and healthcare organizations, which can support the Coalition’s mission.

¹ “Medical Technologies” includes medical devices, diagnostic products, digital health technologies and is formally defined in GHTF/SG1/N071:2012 and referred to by the IMDRF in IMDRF/SAMD WG/N10final:2013.



- The Coalition will have: (a) an Executive Committee, comprised of seven representatives from “Principal Members” who will meet periodically to advance the Coalition’s Action Plan as well as prepare for Coalition meetings and external engagements, (b) an Executive Secretary and Technical Secretariat responsible for coordinating, assisting, and executing the Coalition’s work as advised by the Executive Committee. AdvaMed, ALDIMED, and ALADDIV will each have a permanent seat on the Executive Committee, with four seats open for election by Coalition members every two years. Each of these four seats should represent a different country. AdvaMed will fund the Technical Secretariat and manage the Executive Secretary, taking into consideration the orientation and guidance of the Executive Committee and Coalition members.
- The Executive Committee will analyze and approve by full vote by majority, the documents proposed by the Technical Secretariat to be then be circulated to the Principal Members, for voting according to the process established in this document.
- The Coalition’s Principal Members will convene at least twice per calendar year, with at least one meeting held in person. The meeting may be convened in any Coalition member country.
- The Coalition will establish an agreed process for allowing Principal Members and Standardization Members to join and to remain in good standing once they have joined.
- The Coalition will set a process to review, adopt, and/or amend new or existing Coalition documents, including the Action Plan, the Terms of Reference, and relevant resources, among others. The Executive Committee shall review and provide inputs on all documents before they are circulated to Principal Members. Once circulated, Coalition members will have a minimum of thirty days to comment. Coalition members may approve final documents by full vote by majority. The Coalition should strive to achieve consensus; members who do not agree with a vote result should undertake remediation with the Executive Committee. The Coalition’s Action Plan should undergo periodic review every two years.
- Every member of the Coalition will comply with the Bogota Principles.