Fifth Anniversary Meeting

Internal Session

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR

5 ANNIVERSARY

10 December 2025

IACRC Metrics for Authorization Timelines

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

“If you can’t measure it, you can’t manage it” – Peter Drucker

- Performance measurement and communication are of essence for: public administration, transparency, predictability, planning, legal compliance
- Most National Regulatory Authorities (NRAs) in the Western Hemisphere either do not measure or publish NRA metrics for medical devices
- NRAs that measure and publish use different methodologies and formats
- Not all medtech trade associations consistently capture metrics from their members
- Medtech trade associations do not currently have a standard methodology throughout the region
- Companies do generally measure approval times for their applications

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

IACRC Metrics Proposal

- IACRC to map available metrics published by NRAs
- IACRC members agreement on a methodology to track performance of critical processes by NRAs:
  - NRA public performance data
  - NRA type of public data
  - Medtech association data
  - Company data
- IACRC to compile, analyze and publish the report on a quarterly basis
- Report to be used as a tool to:
  - Have a common IACRC, association, company metric and data
  - Provide visibility to Top Management on outcomes of the RA Teams + IACRC
  - Promote transparency and performance improvements with NRAs
  - Have a common metric with which to capture and report regulatory improvements to medtech management and governments

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Progress report

Data collection

- High complexity: great diversity (quali-auentitative) of data
- Public databases – raw data
- Analytical tools: Excel
- Delivery of data by Trade Associations or companies

Identification of stakeholders needs: NRAs, RA teams, CEOs

Data reporting

- Second mockup of aggregated data

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

IACRC – Consolidated timeliness

IACRC Aggregated Assessment of Timelines			
Country	New Product		Comments
	Higher-Risk (Days)	Lower-Risk (Days)	
Brazil	246	27	Higher risk - Class III and IV - Average IVD & MD , Lower Risk - Class I and II - Public ANVISA Database
Canada	220	40	HC Public Data
Mexico	121	65	Information provided by AMID October 2025 Class III and Class I
U.S.A.	436	152	Higher Risk - Class III - Lower Risk - Class I and II - Public FDA Database

What has changed from May to December 2025 - NRAs

- **Mexico**
  - COFEPRIS pulished reduced legal approval times as follows:

Mexico (COFEPRIS) Official Approval Times			
Process	Approval Times (Working days)		
	Regular Submissions (prior to August 2025)	Agreement for Simplification of Processes Regular Submissions August 2025	Agreement for Abridged Pathways July 2025
Sanitary Registration for Low Risk	30	15	30
Sanitary Registration Class I	30	20	30
Sanitary Registration Class II	35	25	30
Sanitary Registration Class III	60	35	30
Changes - Technical	22	11	N/A
Renewals	120	45	N/A

Next Steps

1. Standardize data gathering process from Primary Members and companies – identify best possible tool: quarterly bases
    1. Identify volunteer leaders by country to collect and share data
2. Data processing and publication of targeted reports to CEOs and for NRAs and RA communities
3. Update report on Databases published by NRAs

THANK YOU

SANDRA LIGIA GONZÁLEZ

Executive Secretary

Sandra@interamericancoalition-medtech.org

LETICIA FONSECA

Deputy Executive Secretary
Executive Secretary Brazil

leticia@interamericancoalition-medtech.org

MARINA CARVALHO

GRP and Trade Lead
marina@interamericancoalition-medtech.org

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR