

Fifth Anniversary Meeting

Internal Session

08 May 2025



INTER-AMERICAN COALITION FOR

REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR



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

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

Initial Proposal - Data

Information gathering: MS Excel

Information compilation and analysis – MS Access

Country	Period	New registration									
		Class I		Class II		Class III		Class IV		Total	
		Quantity	Avg. approval time (days)	Quantity	Avg. approval time (days)	Quantity	Avg. approval time (days)	Quantity	Avg. approval time (days)	Quantity	Avg. approval time (days)

Good Manufacturing Practices Certification			
Issuance timeframes			
Avg. Issuance time (days)	Issuance Pathway		
	NRA inspection	MDSAP	ISO 13485

Progress report

Data collection

- High complexity: great diversity (quali-aumentative) 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

- First mockup of aggregated data

Anvisa - Life cycle of petition analysis

🏠 CICLO DE VIDA DA ANÁLISE DE PETIÇÕES FINALIZADAS

Deixe sua opinião

A representação a seguir expressa as etapas do ciclo de vida. Os filtros podem ser selecionados para uma análise detalhada da quantidade de petições que passaram por cada etapa e o tempo médio dessas etapas. **Foram consideradas para os cálculos deste painel, apenas petições finalizadas.**

Período de Finalização

1/1/2025 4/30/2025

Área de Interesse

Produtos para diagnóstico de u... ▼

Fila de Análise

All ▲
☐ Alterações
☐ Notificações
☐ Registros
☐ Retificações
☐ Revalidações
☐ Transferências de Titularidade

SubFila

All ▼

FILA DE ANÁLISE
PETIÇÕES
2.055
TEMPO MÉDIO
49 dias

ANÁLISE
PETIÇÕES
1.065
TEMPO MÉDIO
24 dias

...
TEMPO MÉDIO
81 dias

SOBRESTADO ANVISA
PETIÇÕES
11
TEMPO MÉDIO
137 dias



Ciclo de Vida da Análise de Petições de Produtos Para Diagnóstico de Uso In Vitro

Dados sobre o ciclo de vida da análise de petições de Produtos Para Uso em Diagnóstico In Vitro, informando as principais etapas relacionadas ao processo de análise, desde o recebimento do documento pela Anvisa até a etapa atual do processo de análise.

IMPORTANTE: Apenas petições com análise finalizada.

Anvisa

diagnostico

Sanitária

vitro

Vigilância

FEDERAL
CSV
PDF



2 Recursos
0 Reusos
34 Downloads
0 Seguidores

US FDA Database

510(k) Premarket Notification

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A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act) that is not subject to premarket approval.

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510K Number	<input type="text"/>	Type	<input type="text"/>	Product Code	<input type="text"/>
Center	<input type="text"/>	Combination Products	<input type="checkbox"/>	Cleared/Approved In Vitro Products	<input type="checkbox"/>
Applicant Name	<input type="text"/>	Redacted FOIA 510(k)	<input type="checkbox"/>	Third Party Reviewed	<input type="checkbox"/>
Device Name	<input type="text"/>	Decision	<input type="text"/>	Decision Date	<input type="text"/> to <input type="text"/>
Panel	<input type="text"/>	Sort by	<input type="text"/>	Clinical Trials	<input type="checkbox"/>
Decision	<input type="text"/>	Quick Search Clear Form Search			

Premarket Approval (PMA)

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Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

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Applicant	<input type="text"/>	Product Code	<input type="text"/>	PMA Number	<input type="text"/>
Device	<input type="text"/>	Expedited Review	<input type="text"/>	Docket Number	<input type="text"/>
Decision Date	<input type="text"/> to <input type="text"/>	Advisory Committee	<input type="text"/>	Cleared/Approved IVD Products	<input type="checkbox"/>
Supplement Type	<input type="text"/>	Combination Products	<input type="checkbox"/>	Center	<input type="text"/>
Sort by	<input type="text"/>	Quick Search Clear Form Search			

IACRC – Consolidated timeliness

IACRC Aggregated Assessment of Timelines (Days) Consolidated A

Country	New Product		Changes		Comments
	Higher-Risk	Lower-Risk	Higher-Risk	Lower-Risk	
	(Days)	(Days)	(Days)	(Days)	
Argentina	143	49	77	34	Information provided by two companies: 1 Agile + non-agile pathway for changes
Brazil	370	69	135	38	Higher risk - Class III and IV - Average IVD & MD , Lower Risk - Class I and II - Public ANVISA Database
Canada					
Colombia	241	45	45	45	Information provided by two companies
Costa Rica	332	332	185	185	Information provided by two companies
Ecuador	128	120	105	105	Information provided by two companies
Mexico	103	68	92	66	Information provided by AMID 2024 - 2025
Peru	195	165	150	91	Information provided by two companies
U.S.	404	159	250	47	Higher Risk - Class III - Lower Risk - Class I and II - Public FDA Database
Region	239	126	130	76	

*Risk that the change poses to health

IACRC – Consolidated timeliness

IACRC Aggregated Assessment of Timelines (Days) Consolidated B

Country	New Product		Changes		Comments
	Higher-Risk	Lower-Risk	Higher-Risk	Lower-Risk	
	(Days)	(Days)	(Days)	(Days)	
Argentina	143	49	77	34	Information provided by two companies: 1 Agile + non-agile pathway for changes
Brazil	370	69	135	38	Higher risk - Class III and IV - Average IVD & MD , Lower Risk - Class I and II - Public ANVISA Database
Canada					
Colombia	241	45	45	45	Information provided by two companies
Costa Rica	332	332	185	185	Information provided by two companies
Ecuador	128	120	105	105	Information provided by two companies
Mexico	461	413	388	324	Information provided by AMID 2023 - 2024
Peru	195	165	150	91	Information provided by two companies
U.S.	404	159	250	47	Higher Risk - Class III - Lower Risk - Class I and II - Public FDA Database
Region	284	169	167	109	

*Risk that the change poses to health

Next Steps

1. IACRC Principal Member confirmation on data availability and accuracy of public sources of information identified by IACRC Secretariat
2. Identify member companies to provide information for countries where not available through Primary Members
3. Data gathering from Primary Members and companies – identify best possible tool
4. Data processing and publication of targeted reports to CEOs and for NRAs and RA communities



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