

PAHO



Pan American
Health
Organization



World Health
Organization
REGIONAL OFFICE FOR THE
Americas

PAHO Update

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IMDRF Meeting

23 September 2020

Regional Working Group on Medical Device Regulation

24 countries are currently members

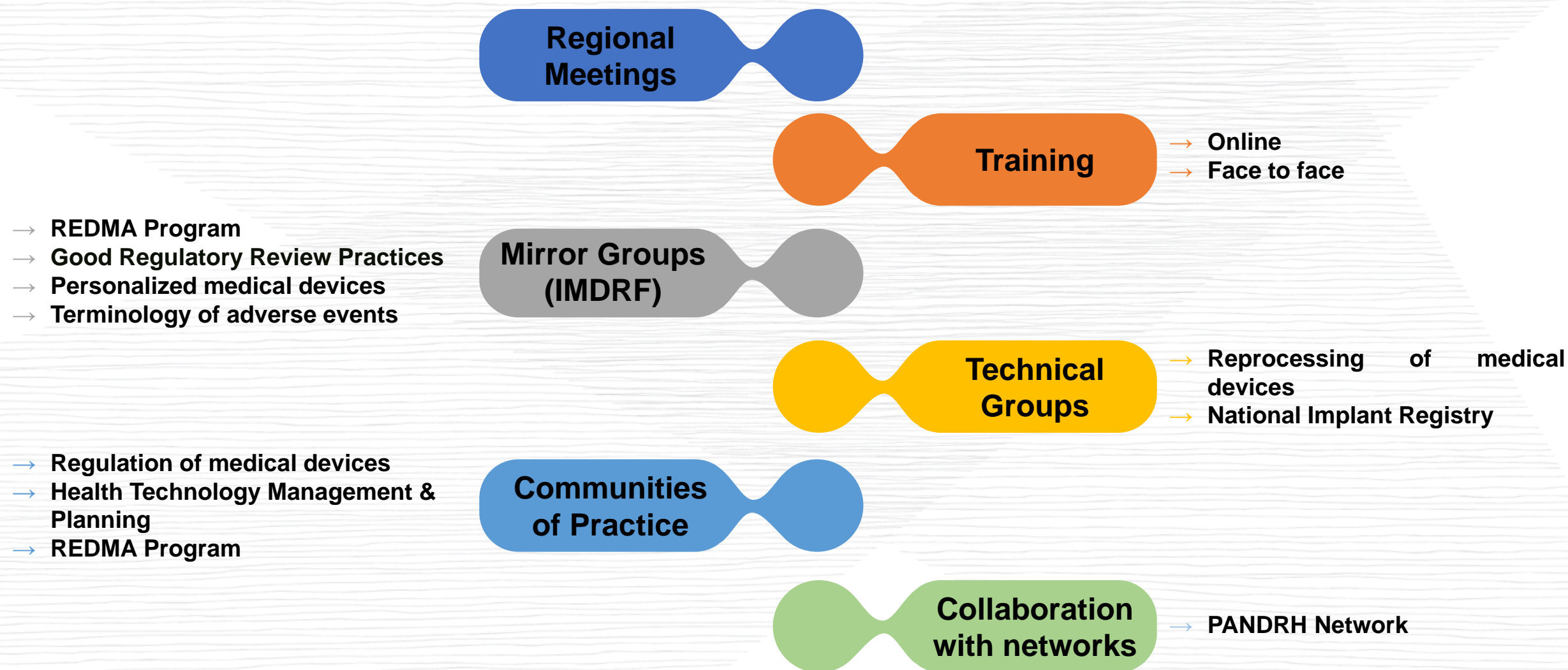
Argentina	Belize	Bolivia	Brazil	Canada
Chile	Colombia	Costa Rica	Cuba	Dominican Republic
Ecuador	El Salvador	Guatemala	Guyana*	Honduras
Jamaica	Mexico	Nicaragua	Panama	Paraguay
Peru	Trinidad & Tobago	Uruguay	Venezuela	



*Joined the Regional Working Group in December 2019.

Activities of the Regional Working Group

MOST OF THEM ARE ON HOLD DUE TO COVID-19



Collaboration with IMDRF

Translation of documents



Spanish

1. IMDRF/PMD WG/N49 FINAL:2018 | ***Definitions for Personalized Medical Devices***
2. IMDRF/Standards WG/N51 FINAL:2018 | ***Optimizing Standards for Regulatory Use***
3. IMDRF MDCE WG/N55 FINAL:2019 | ***Clinical Evidence - Key definitions and concepts***

Spanish & Portuguese

4. IMDRF/GRRP WG/N40 FINAL:2017 | ***Competence, Training, and Conduct Requirements for Regulatory Reviewers***
5. IMDRF/GRRP WG/N47 FINAL:2018 | ***Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices***
6. IMDRF/GRRP WG/N52 FINAL:2019 | ***Principles of Labelling for Medical Devices and IVD Medical Devices***



IMDRF Mirror Working Groups



Due to COVID-19, activities have remained on hold for most of the Mirror Working Groups

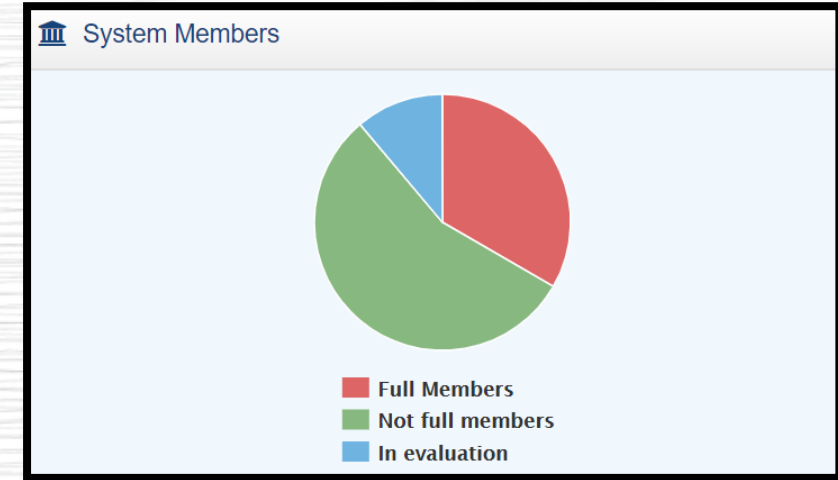
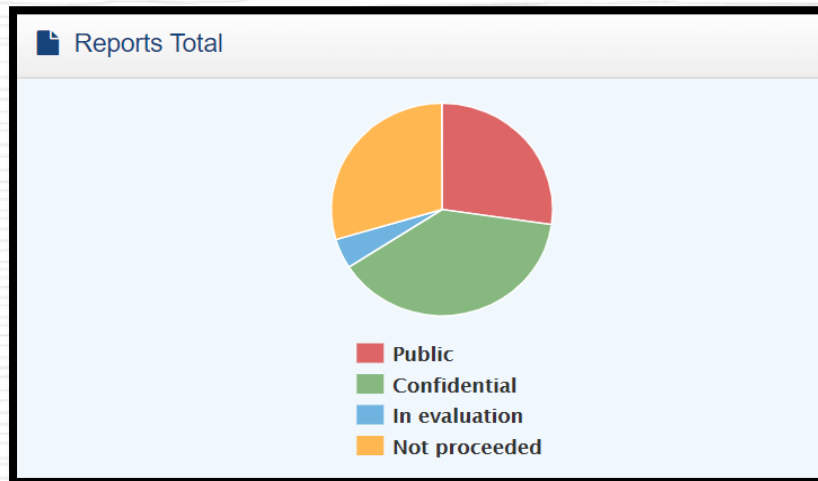
Program on exchange of reports on adverse events of Medical Devices - REDMA Program (1)

- **10 Associate Members**

- Bolivia, Ecuador (Ministry of Health), Honduras, Nicaragua, Paraguay, El Salvador, Uruguay, Panama, Dominican Republic, Venezuela

- **6 Full Members**

- Argentina, Brazil, Colombia, Cuba, Chile, Mexico



- Total number of **reports**: **29**
 - **17** confidential
 - **12** non-confidential

REDMA Program (2)

- **Training**

- Regional Virtual Course on the REDMA Program.
- Duration: from 20 January 2020 to 6 February 2020.
- 29 students from 15 countries completed the course.
- In collaboration with CECMED, PAHO/WHO Collaborating Centre.

- **Meetings**

- The Virtual Meeting of the REDMA Program was held on 11 August 2020.
- Participation of 55 representatives of 17 Regulatory Authorities from: ARG, BOL, BRA, CHL, COL, CRI, CUB, DOR, ECU, GTM, MEX, NIC, PRY, SLV, URY, USA, VEN.
- Discussion of COVID-19 related adverse events.

Work related to Medical Devices in response to COVID-19

Develop guidance and recommendations on **regulation** and **management** of medical devices

Develop **technical specifications** for priority medical devices

Organize **Webinars** and **Virtual Meetings** to share guidance and experiences between countries

Technical support to Member States through consultations related to medical devices

Conduct the **QA** of Medical Devices procured by PAHO for Member States

Identification and exchange of information on **innovative** ventilator **projects** in development

Webinars & Virtual Meetings related to medical devices in the context of COVID-19

Date	Topics
1 April 2020	Meeting of the <i>Regional Working Group on ventilators in the context of COVID-19</i>
8 April 2020	Meeting of the Regional Working Group on ventilators in the context of COVID-19 Line of work: <i>Technology Management</i>
9 April 2020	Meeting of the Regional Working Group on ventilators in the context of COVID-19 Line of work: <i>Innovation and Production</i>
10 April 2020	Meeting on the <i>Regulation of Ventilators in the Context of COVID-19</i>
21 May 2020	<i>Discussion on the challenges for the Regulation of Ventilators in the context of COVID-19</i>
2 June 2020	Webinar “ <i>Technical and regulatory aspects of prolonged use, reuse and reprocessing of respirators in periods of shortage</i> ”
5 June 2020	Webinar “ <i>National Coordination Strategies for the Development and Production of Ventilators in the Context of COVID-19</i> ”
23 July 2020	Webinar “ <i>Experiences in pharmacovigilance, technovigilance and hemovigilance in the Americas Region in the context of the pandemic</i> ”

Publications on Medical Devices in the context of COVID-19

List of Priority Medical Devices in the context of COVID-19

13 August 2020

<https://iris.paho.org/handle/10665.2/52580>

Technical and Regulatory Aspects of the Use of Pulse Oximeters in Monitoring COVID-19 Patients

7 August 2020

<https://iris.paho.org/handle/10665.2/52589>

Post-authorization Surveillance of Medical Products during a Pandemic Emergency

21 July 2020

<https://iris.paho.org/handle/10665.2/52578>

Technical and Regulatory Aspects of the Extended Use, Reuse, and Reprocessing of Respirators during Shortages

10 June 2020

<https://iris.paho.org/handle/10665.2/52431>

Regulation of Medical Devices in the Context of COVID-19

14 May 2020

<https://iris.paho.org/handle/10665.2/52489>

Document *List of Priority Medical Devices in the context of COVID-19*

- 5th Version | Updated on 13 August 2020 - Available in English and Spanish
- Technical description and specifications for priority medical devices.

Category	Medical device	Triage and initial care	Sampling diagnosis	Early supportive therapy and monitoring	Treatment of AHRF, ARDS and septic shock	1 st level	2 nd level	3 rd level
Medical equipment	Oxygen concentrator			x	x	•	•	•
	Portable aspirator/ Suction system				x	•	•	•
	Portable ultrasound			x	x	•	•	•
	Portable X-ray equipment			x	x	•	•	•
	Pulse oximeter, fingertip	x		x	x	•	•	•
	Pulse oximeter, handheld			x	x	•	•	•
	Pulse oximeter, tabletop			x	x		•	•
	Sphygmomanometer, with cuffs (adult / children)	x		x	x	•	•	•
	Stethoscope	x		x	x	•	•	•
	Ventilator for Intensive Care Unit				x		•	•
	Ventilators for Sub-Acute Care				x		•	•
	Ventilators for Transport				x		•	•
	Patient monitor multiparametric, basic			x		•	•	•
	Patient monitor multiparametric, intermediate			x	x	•	•	•
	Patient monitor multiparametric, advanced				x		•	•

Table 1. List of medical devices, organized by COVID-19 attention stages and levels of care

Regional Working Group on Ventilators in the context of COVID-19

20

Projects in total
from **9** countries

First virtual meeting

Thursday, 9 April 2020

Possibilities for
Technology transfer (9)

Communication flow

Through emails and videoconferences

Developers

Universities | Hospitals | Industries
Collaboration between academia and the industry

**Types of
ventilator**

Invasive

8

Non-invasive

4

Invasive / Non-invasive

8

**Ventilation
principle**

Mechanized Ambu

9

Mechanical ventilator

9

Adaptation*

2

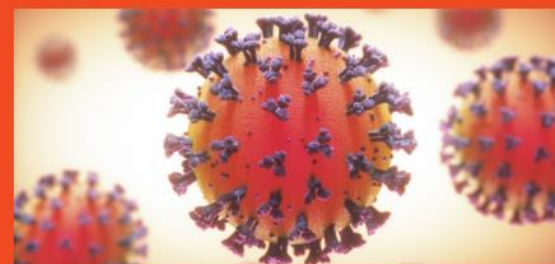
* Veterinary ventilator and anesthesia machines

COVID-19 resources

All technical documents related to COVID-19 developed by PAHO are available at:

<https://www.paho.org/en/technical-documents-coronavirus-disease-covid-19>

COVID-19 Resources



Technical Guidelines



The background consists of several overlapping geometric shapes in two colors: a vibrant blue and a burnt orange. The shapes are angular and layered, creating a sense of depth and movement. The blue shapes are more prominent, while the orange shapes are layered behind or to the side of them.

Thank you!