PAHO Update

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IMDRF Meeting
Moscow, March 2019

Pan American Health Organization
World Health Organization
Regional Office for the Americas

PAHO

REGIONAL WORKING GROUP ON MEDICAL DEVICE REGULATION

ESTABLISHED: July, 2012 with 12 countries; currently with 23.

OBJECTIVE: Strengthen regulatory capacity and promote regulatory convergence for medical devices in the Region of the Americas.

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

Pan American Health Organization
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REGIONAL MEETINGS

VIII REGIONAL MEETING
22 – 23 OCTOBER 2018 - EL SALVADOR

- Hosted by DNM (NRA of El Salvador)
- Regulators session: 32 participants representing 24 countries
- Stakeholders forum: 90 participants
- 2nd Regional Meeting in conjunction with the PANDRH meeting

22 October
Regulators session

- Advances and challenges, at national level, on Medical Device Regulation
- Collaboration with IMDRF
- International experiences (Spain and Portugal)
- Capacity building activities
- Update on the Mirror Groups & Technical Groups
- Definition of the 2019 Work Plan

23 October
Stakeholders forum

- Medical Device Cyber security
- Standards
- Postmarketing Surveillance for Medical Devices in the US
- Regulatory framework for medical devices in Europe

COLLABORATION WITH IMDRF

- REDMA Program on the exchange of post market safety information on medical devices was launched following a mirror group of the IMDRF working group on NCAR system
- Creation of two new mirror working groups
- Participation in the IMDRF Working Groups of Medical Device Clinical Evaluation and Personalized Medical Devices (Regional Working Group represented by ANMAT, Argentina)
- Stakeholder forum in the Regional meetings

MIRROR WORKING GROUPS

- Two new Mirror Working Groups were created in the last Regional Meeting (October 2018)

	NCAR Exchange Program: REDMA Program	Software as a Medical Device	Personalized Medical Devices	Adverse Event terminology
COORDINATOR	CECMED, CUBA	COFEPRIS, MÉXICO	ANMAT, ARGENTINA	MINISTRY OF HEALTH, URUGUAY

REDMA PROGRAM

PILOT

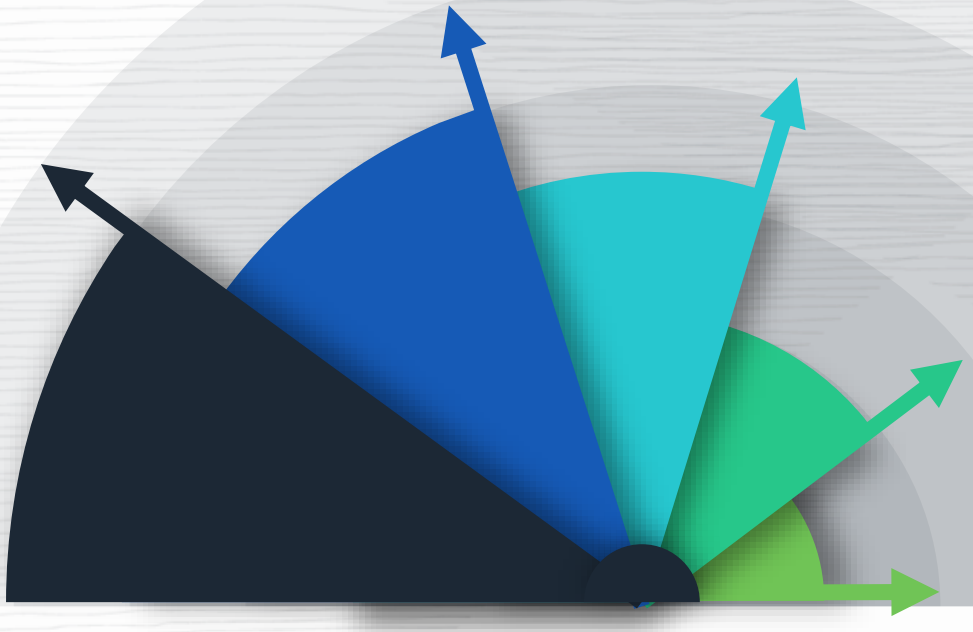
10 PARTICIPANT COUNTRIES (ARG, BRA, CHI, COL, CUB, MEX, ELS, PAN, DOR, URU); 12 REPORTS WERE EXCHANGED THROUGH A SECURE SYSTEM DEVELOPED BY CECMED

DOCUMENTS

UPDATE OF THE PROGRAM'S OPERATIONAL AND PROCEDURAL DOCUMENTS BASED ON IMDRF DOCUMENTS.

TRAINING

ONLINE &
FACE-TO-FACE



IMPLEMENTATION

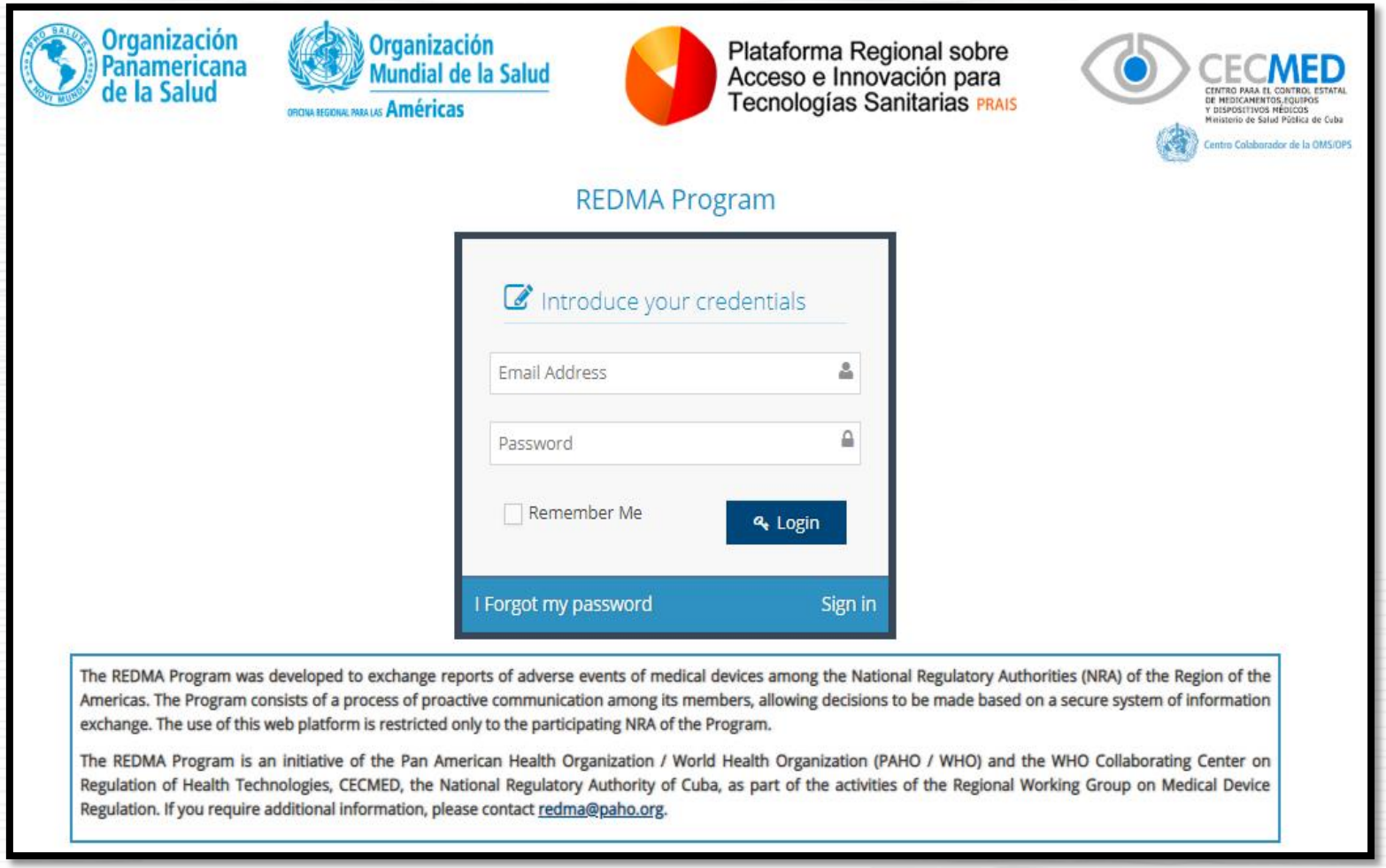
LAUNCHED ON 14 MARCH 2019

SECRETARIAT

CECMED (Cuba), INVIMA (Colombia) and ANVISA (Brazil)

REDMA PROGRAM

- Secure exchange of reports on medical devices' adverse events.
- Fully integrated within the Regional Platform on Access and Innovation for Health Technologies (PRAIS).
- Access only allowed to the NRA members of the REDMA Program.
- Access to the web platform is done through a single contact designated by each NRA.



PAHO/WHO

CAPACITY BUILDING

POST-MARKETING SURVEILLANCE (e-learning)

- Collaboration INVIMA-PAHO
- The Spanish version of the course had two editions, with 90 participants
- First edition in English for the Caribbean countries
- 7 Modules were translated into English: *Technovigilance; London Protocol; Failure Mode and Effects Analysis; patient safety and clinical risk management; Reuse and reprocessing of medical devices; Signal generation; Intense surveillance and sentinel network*.
- Starting date: 13 May 2019

HEALTHCARE TECHNOLOGY MANAGEMENT WORKSHOP

- In collaboration with the University of Vermont
- 27-29 March 2019
- 20 participants from the Caribbean countries

MEDICAL DEVICE REGULATION (e-learning)

- Developed by CECMED
- Course had two editions, for a total of 159 participants
- English version will be offered in 2020

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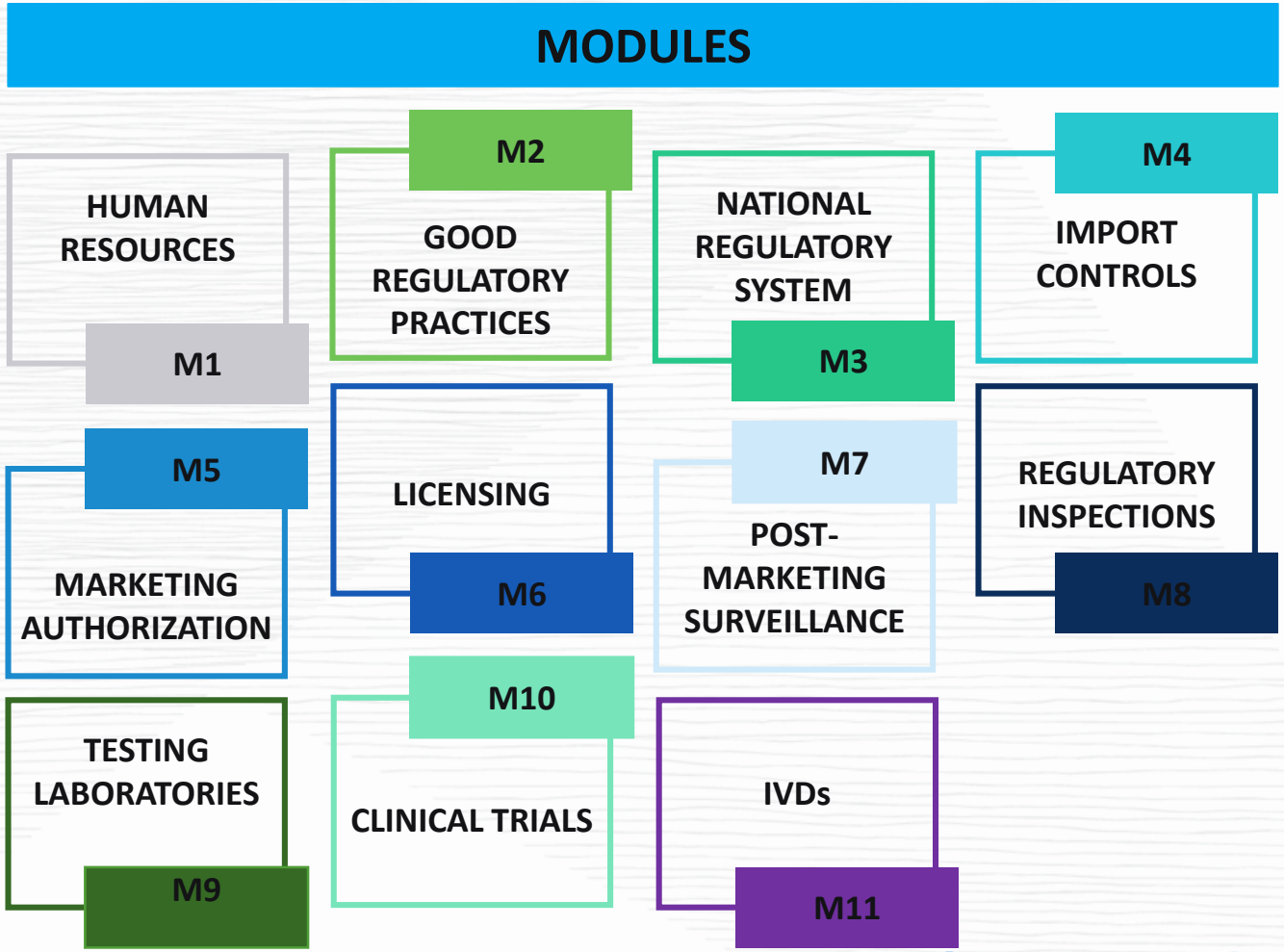
REGIONAL REGULATORY PROFILE

- Part of the first project on Medical Device Regulation at PANDRH; coordinated by INVIMA and CECMED with PAHO as the Secretariat.
- Basic indicators tool
  - ✓ Sent to the NRA members of the PANDRH Network.
  - ✓ Structured in *11 main categories*.
  - ✓ Includes 47 questions.
  - ✓ **Self-assessment from 22 countries.**



THANK YOU!