

PAHO Update

Alexandre Lemgruber

IMDRF Meeting
Moscow, March 2019



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.



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

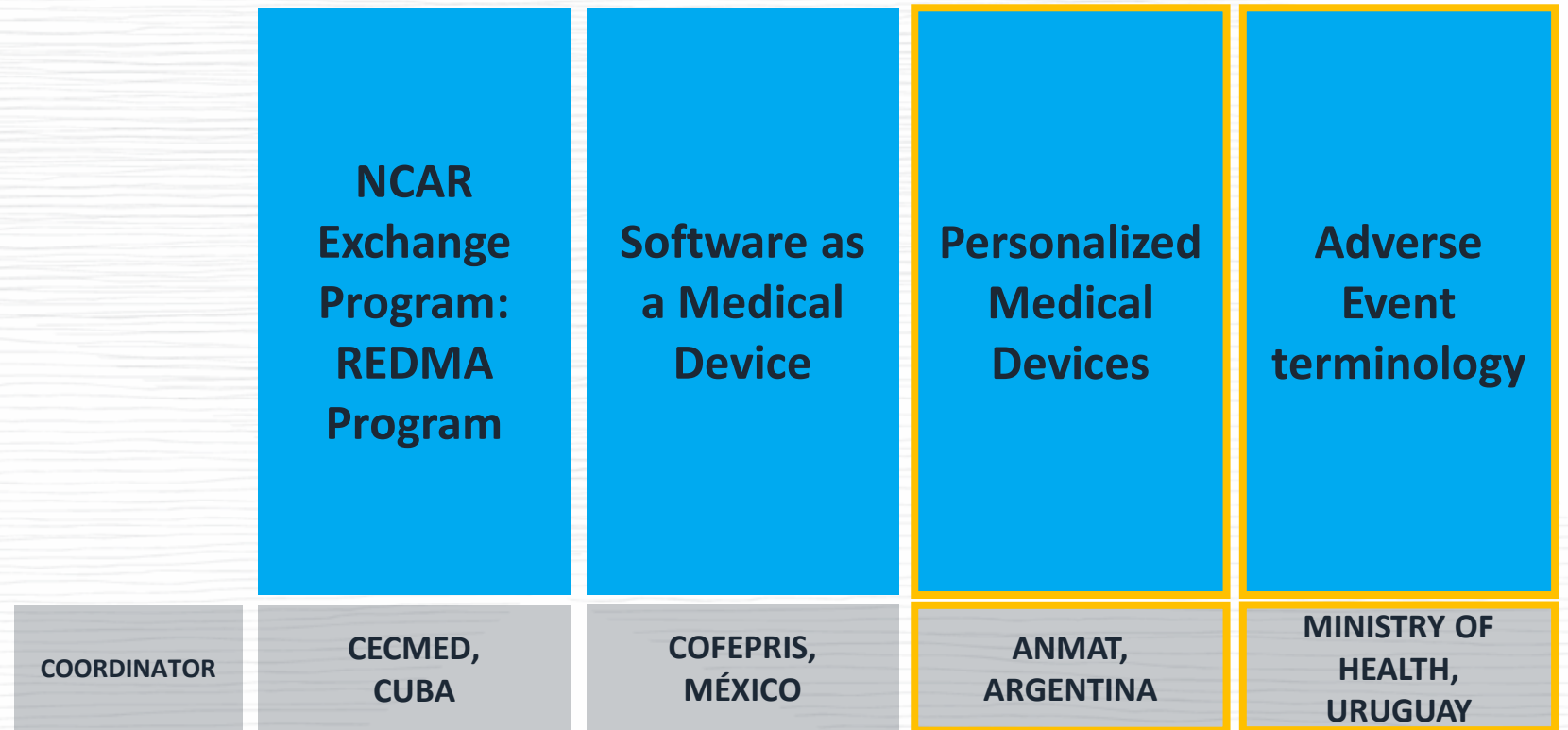


- REDMA Program on the exchange of post market safety information on medical devices was launched following a mirror group of the IMDRF working group on NCAR system
- Creation of two new mirror working groups
- Participation in the IMDRF Working Groups of Medical Device Clinical Evaluation and Personalized 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)



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

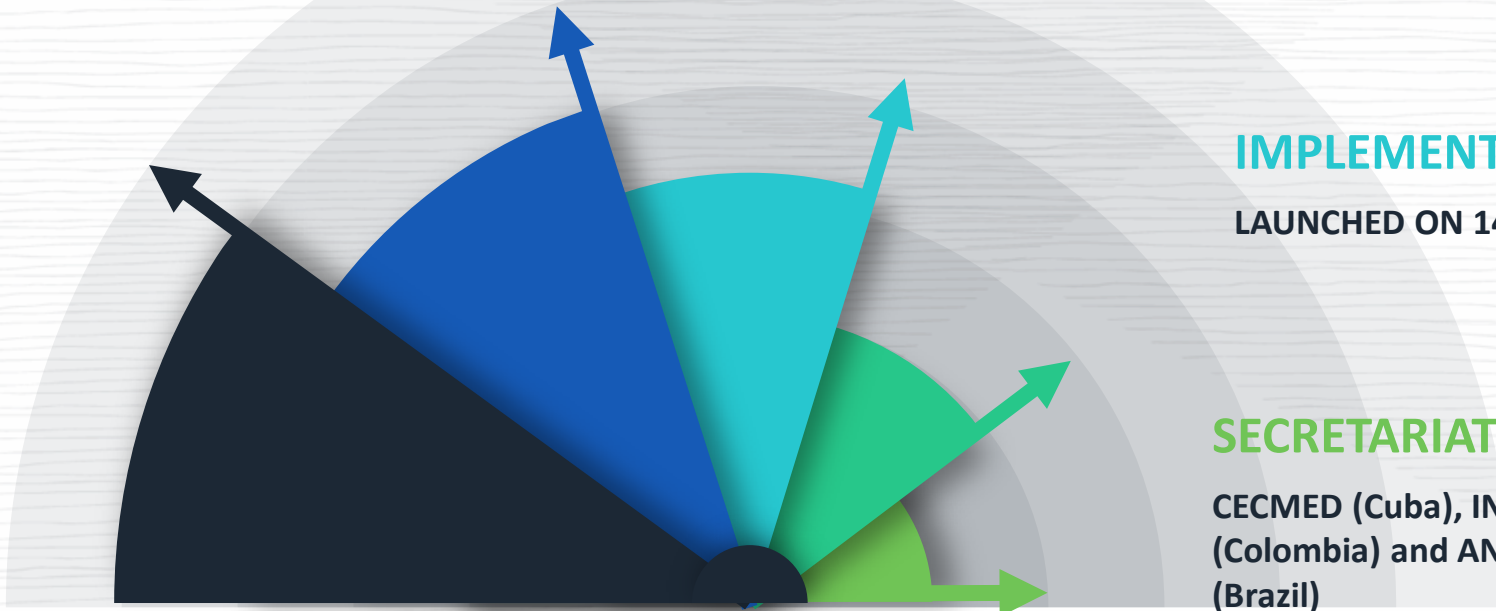
ONLINE &
FACE-TO-FACE

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.



Organización Panamericana de la Salud



Organización Mundial de la Salud
 ORGANIZACIÓN REGIONAL PARA LAS Américas



Plataforma Regional sobre Acceso e Innovación para Tecnologías Sanitarias PRAIS

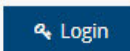

CECMED
 CENTRO PARA EL CONTROL ESTATAL DE MEDICAMENTOS, EQUIPOS Y DISPOSITIVOS MÉDICOS
 Ministerio de Salud Pública de Cuba
 Centro Colaborador de la OMS/OPS

REDMA Program

 Introduce your credentials

Email Address 

Password 

Remember Me 

[I forgot my password](#) [Sign in](#)

The REDMA Program was developed to exchange reports of adverse events of medical devices among the National Regulatory Authorities (NRA) of the Region of the Americas. The Program consists of a process of proactive communication among its members, allowing decisions to be made based on a secure system of information exchange. The use of this web platform is restricted only to the participating NRA of the Program.

The REDMA Program is an initiative of the Pan American Health Organization / World Health Organization (PAHO / WHO) and the WHO Collaborating Center on Regulation of Health Technologies, CECMED, the National Regulatory Authority of Cuba, as part of the activities of the Regional Working Group on Medical Device Regulation. If you require additional information, please contact redma@paho.org.

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

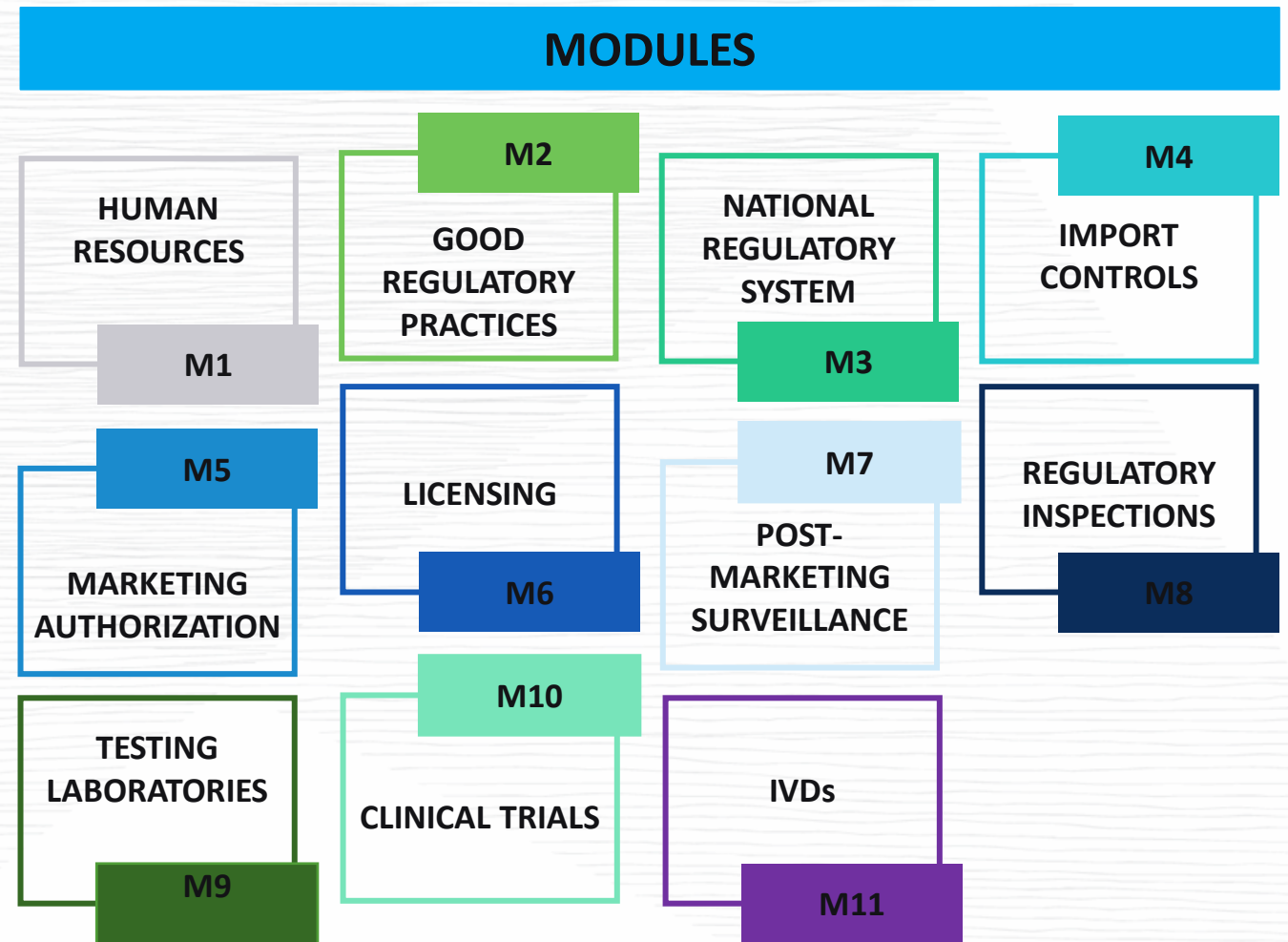
- In collaboration with the University of Vermont
- 27-29 March 2019
- 20 participants from the Caribbean countries

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

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.**



A light gray background with a large, blue, abstract shape on the right side. Inside the blue shape is a white circle containing the text "THANK YOU!" in white, uppercase, sans-serif font.

THANK
YOU!