Regional Working Group on Medical Device Regulation

- **Established:** July, 2012 with 12 member countries; currently with 20
- **Objective:** To Strengthen the Regulatory capacity for Medical Devices in the Region of the Americas.
Regional Meetings


- VII Regional Meeting: 21-22 September 2017 - Ottawa (hosted by Health Canada)
  - 3rd Regional meeting in conjunction with the IMDRF meeting (other ones in US and Brazil)
  - 21 September: open session
  - 22 September: regulators only
  - 26 representatives from 18 countries participated in the IMDRF Stakeholder Forum and in the Regional Meeting
  - Representatives from 4 regulatory authorities (ANMAT-Argentina, CECMED-Cuba, COFEPRIS-Mexico and INVIMA-Colombia) participated as observers in the Management Committee Meeting

- VIII Regional Meeting will be on 22-23 October, in El Salvador, in conjunction with the PANDRH (Pan American Network for Drug Regulatory Harmonization) Conference
Mirror Working Group for the NCAR Exchange Program: REDMA

- Operation and procedures documents of the REDMA Program, based on IMDRF
- On-line and f2f training
- Secretariat: CECMED (Cuba), INVIMA (Colombia) and ANVISA (Brazil)
- Software developed by CECMED (WHO Collaborating Center) for the secure exchange of adverse events reports (REDMA Web System)
- Pilot exercise performed with the participation of 10 countries (Argentina, Brazil, Chile, Colombia, Cuba, Mexico, El Salvador, Panama, Dominican Republic and Uruguay); completed in October 2017, with the exchange of 12 reports (9 confidential)
- Full implementation in 2018: next meeting in Havana, Cuba, 26 April
REDMA Web System

✓ Allows the secure exchange of the adverse events reports

✓ Only accessible to the members of the REDMA Program

✓ Access to the system is done through a single contact designated by each Regulatory Authority

✓ Integration with PRAIS (Regional Platform on Access and Innovation for Health Technologies) under development
Capacity Building

- **E-learning programs:**
  - Medical device regulation: developed by CECMED (Cuba)
    - 1st edition: 38 participants from 9 countries
    - 2nd edition: 121 participants from 16 countries
      (7 January – 3 March)
  - Post-marketing Surveillance: developed by INVIMA (Colombia)
    - 1st edition: 15 participants from 6 countries
    - 2nd edition: 75 participants from 15 countries
      (9 August – 31 October)
    - All modules translated into English; launch of the English version planned for late this year

- Training hosted by INVIMA in December 2017 with representatives from 10 NRA
Update of the Regional Mapping

- Original mapping was performed in 2014-2015; the results were published in the PAHO Journal in 2016.
- First version had results from 15 NRA.
- The new mapping exercise is part of the first project on medical device regulation at PANDRH, proposed and coordinated by INVIMA and CECMED, with PAHO as the Secretariat.
- The final results will be available at the Regional Platform on Access and Innovation for Health Technologies (PRAIS).
Update of the Regional Mapping (2)

- Mapping of the Regulation of Medical Devices in the Americas Region
  - Mapping tool
    - Sent to the NRA members of the PANDRH Network
    - Structured in 11 main categories.
    - Includes 47 questions.
    - Feedback received from 20 countries in the first phase
Medical Devices Observatory

- Basic Indicators will be available in the Medical Devices Observatory within PRAIS.