Update on the Regional Working Group

Pan American Health Organization

World Health Organization

REGIONAL OFFICE FOR THE Americas

Murilo Contó

IMDRF Meeting

Florianopolis, Brazil

13 – 14 September 2016

Regional Working Group on Medical Devices – PAHO/WHO

Argentina	Brazil	Canada	Chile
Costa Rica	Cuba	Colombia	Dominican Republic
Ecuador	El Salvador	Honduras	Mexico
Panama	Paraguay	Peru	Uruguay

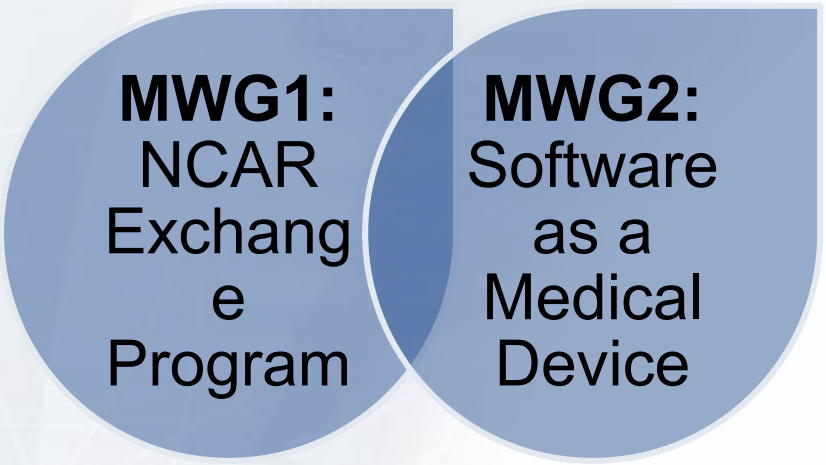
- **Established:** July, 2012 with 12 countries; currently with 16 countries
- **Objective:** strengthen the regulatory capacity for medical devices in the Region of the Americas

Regional WG Activities

- ✓ **5 Regional Annual meetings: Cuba (2012), Argentina (2013), USA (2014), Colombia (2015) and Brazil (2016)**
- ✓ **3 Additional on-site training activities: Workshop on HTA & Regulation in Brasilia (2013), Technical Meeting in La Havana (2015), Technical Meeting for the implementation of the Report Exchange Program in La Havana (2016)**
- ✓ **Last Regional Meeting: March, 2016, in Brasilia** (2-day meeting; 35 participants from 12 countries; hosted by ANVISA)
  - Analysis of the advanced indicators and the Global NRA Assessment Tool (PAHO, WHO)
  - Participation of the Asian Harmonization Working Party (AHWP)
  - Update on the Report Exchange Program on Medical Devices between NRAs in the Americas Region – REDMA Program (CECMED)
  - Update on the Mirror Group: “Software as a Medical Device” (ANMAT)
  - Update on the Technical Group: “Reprocessing of Medical Devices” (INVIMA)
  - Experience on Nomenclature Harmonization for medical devices (ANVISA)

Collaboration with IMDRF

- PAHO was recognized as an Affiliate Organization in September 2014
- Participation in the meetings in Tokyo and Kyoto (2015); & Brasilia (2016)
- 2 Regional Working Group meetings in conjunction with IMDRF meetings (Washington DC, September 2014 and Brasilia, March 2016)
- The first concrete activity as part of this new interaction was the creation of 2 WGs which mirror the IMDRF WGs on the selected topics:



Mirror Working Group on the NCAR Exchange Program: REDMA Program

- The Secretariat is composed of regulatory officials from: Cuba (CECMED), Brazil (ANVISA) and Colombia (INVIMA)
- The final documents “Secretariat functions of the REDMA Program”, Criteria and Form to exchange reports about adverse events was compiled by CECMED, shared and analyzed with the Regional WG
- Technical Meeting for the REDMA Program implementation was held in La Havana (2-day meeting; 26 participants; 8 countries; hosted by CECMED)
- Virtual Training Course (50-hour course; 15 participants from 6 countries) hosted by INVIMA and the National University of Colombia
- A Pilot Activity is being scheduled in order to streamlining of the REDMA Program and the exchange process of information

Mirror Working Group on "Software as a Medical Device"

- Topic identified as a priority for the Regional WG during the 4th Regional Meeting in Bogota, Colombia (2015)
- The Secretariat was established and is composed of: ANMAT (Argentina), CECMED (Cuba) and MoH Uruguay
- The general guidelines draft document was developed by ANMAT and shared with the Regional WG for their input
- A questionnaire (14 questions) for the analysis of the current regulatory situation in the Americas Region was developed by ANMAT and shared with the WG
  - At the moment, we received feedback from seven countries

Technical Group on "Reprocessing of Medical Devices"

- The Secretariat was established and is composed of: INVIMA (Colombia), ANVISA (Brazil) and DIGEMID (Peru).

- The Implementation Plan draft was developed by INVIMA and shared with the Regional WG for feedback.

- The draft document "Mapping of reprocessing and reuse of MD" was developed by INVIMA and later edited and approved by the Regional WG.

- A Mapping activity on the Regulation of the Reprocessing of Medical Devices in the Americas Region was held and results are being analyzed by the Secretariat
  - ➢ It consists of 16 questions divided into 3 main categories:
    1. Structure of the local Sanitary Regulation
    2. Regulation of Reuse and Reprocessed Medical Devices
    3. Regulation of companies/establishments of Medical Devices

    At the moment, we received feedback from 12 countries

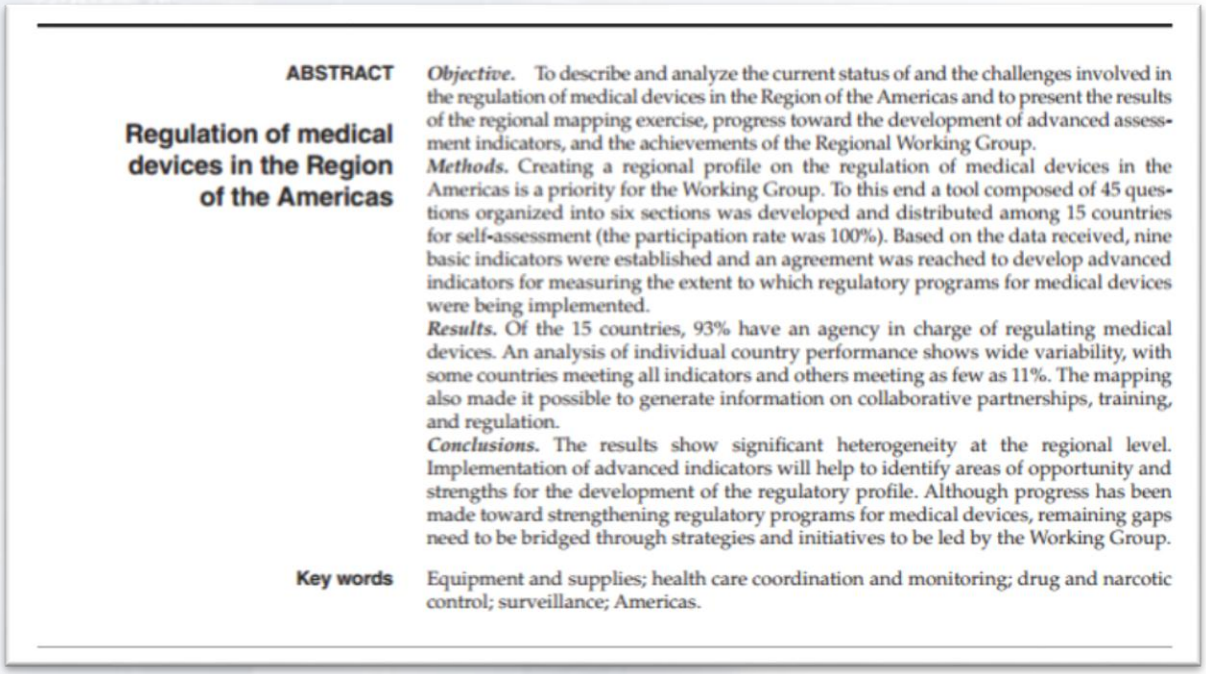
Virtual Training

- Virtual Course on Technical Suveillance and Adverse Events
  - Hosted by INVIMA and the National University of Colombia within the Platform INVIMA Learning.
  - 50-hour course
  - Successfully completed by 15 participants from 6 countries (Brazil, Cuba, Costa Rica, Ecuador, Panama, Paraguay)
  - To be included in the PAHO Virtual Campus for Public Health

- Virtual course on Regulation of Medical Devices
  - Hosted in CECMED Virtual Classroom
  - Starting September 19th, 2016
  - Registration includes 38 participants from 9 countries (Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Mexico, Panama and Paraguay)

Original Research Article

- Published on June, 2016
- Pan American Journal of Public Health Special Issue: Strengthening of Regulatory Systems in the Americas



ABSTRACT

Regulation of medical devices in the Region of the Americas

Objective. To describe and analyze the current status of and the challenges involved in the regulation of medical devices in the Region of the Americas and to present the results of the regional mapping exercise, progress toward the development of advanced assessment indicators, and the achievements of the Regional Working Group.
Methods. Creating a regional profile on the regulation of medical devices in the Americas is a priority for the Working Group. To this end a tool composed of 45 questions organized into six sections was developed and distributed among 15 countries for self-assessment (the participation rate was 100%). Based on the data received, nine basic indicators were established and an agreement was reached to develop advanced indicators for measuring the extent to which regulatory programs for medical devices were being implemented.
Results. Of the 15 countries, 93% have an agency in charge of regulating medical devices. An analysis of individual country performance shows wide variability, with some countries meeting all indicators and others meeting as few as 11%. The mapping also made it possible to generate information on collaborative partnerships, training, and regulation.
Conclusions. The results show significant heterogeneity at the regional level. Implementation of advanced indicators will help to identify areas of opportunity and strengths for the development of the regulatory profile. Although progress has been made toward strengthening regulatory programs for medical devices, remaining gaps need to be bridged through strategies and initiatives to be led by the Working Group.

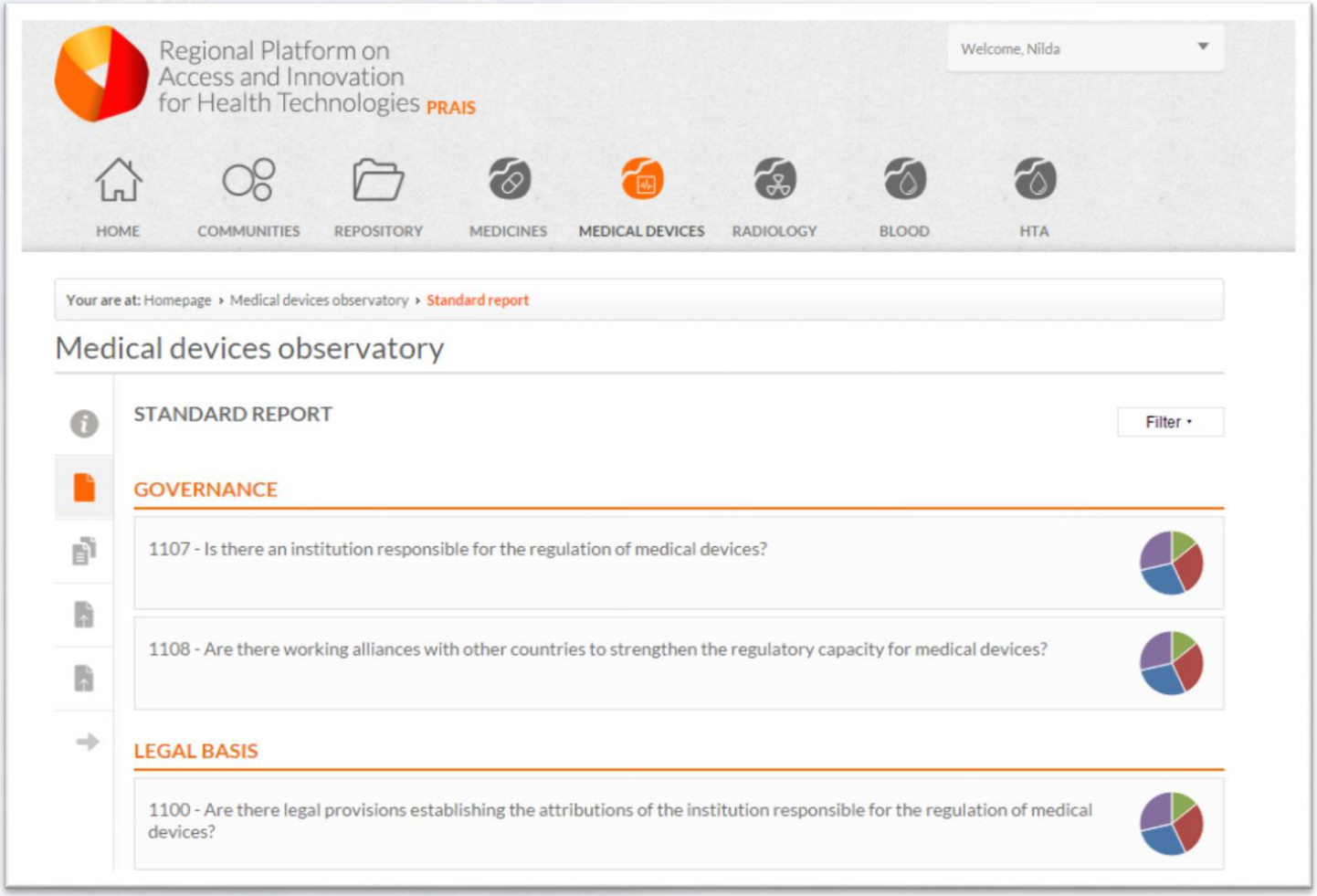
Key words Equipment and supplies; health care coordination and monitoring; drug and narcotic control; surveillance; Americas.

Authors: Nilda Enríquez (PAHO), Yadira Álvarez (CECMED), Dulce María Martínez (CECMED), Ana Pérez (Ministerio de Salud Pública de Uruguay) and Alexandre Lemgruber (PAHO)

http://iris.paho.org/xmlui/handle/123456789/28529

Medical Devices Observatory on PRAIS

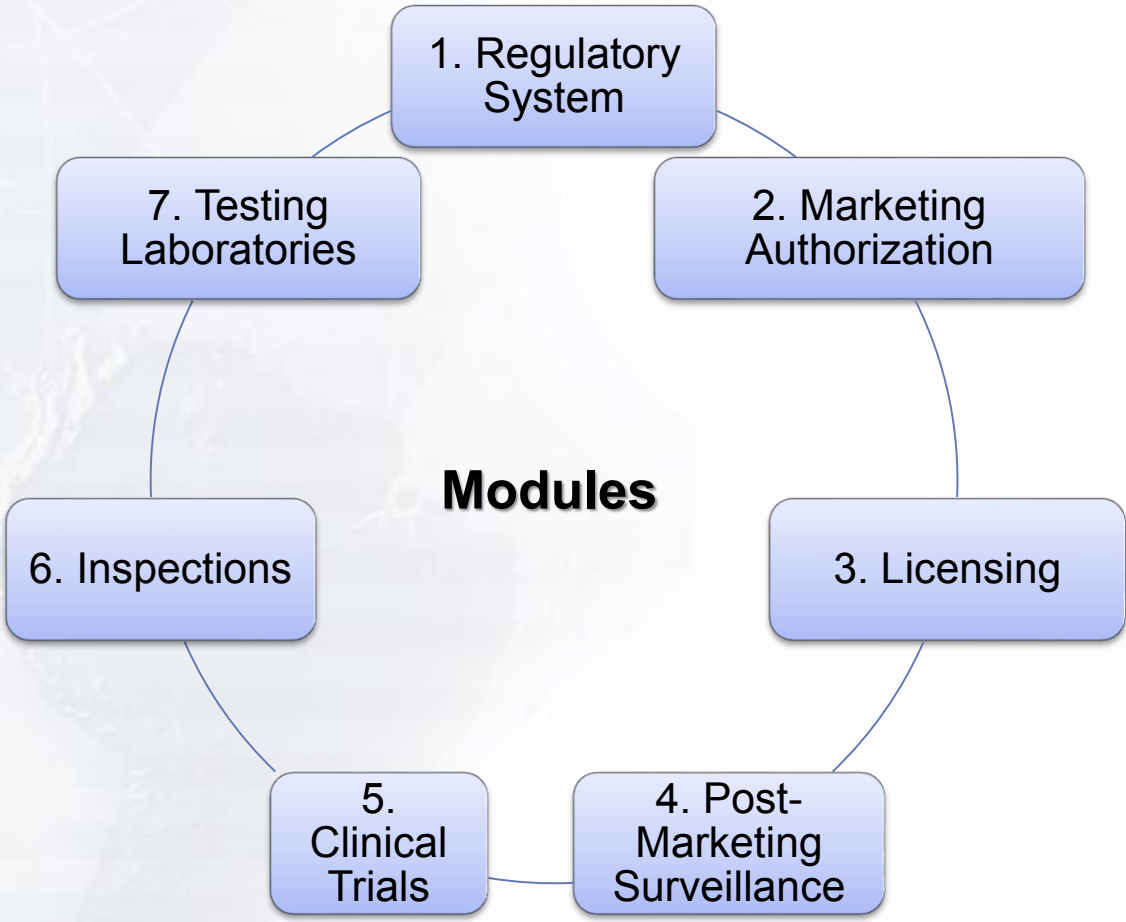
- Information of basic indicators from 15 countries of the Americas Region. (http://prais.paho.org)



Advanced Indicators

- **OBJECTIVE:** To develop and validate advanced indicators in order to assess the level of implementation of the Medical Devices Regulation in the Region

- **TOOL:** Adapted from PAHO/WHO National Regulatory Authority assessment tool for medicines, in collaboration with CECMED as WHO/PAHO Collaborating Centre for the Regulation of Health Technologies and the constant feedback of the Regional Working Group.



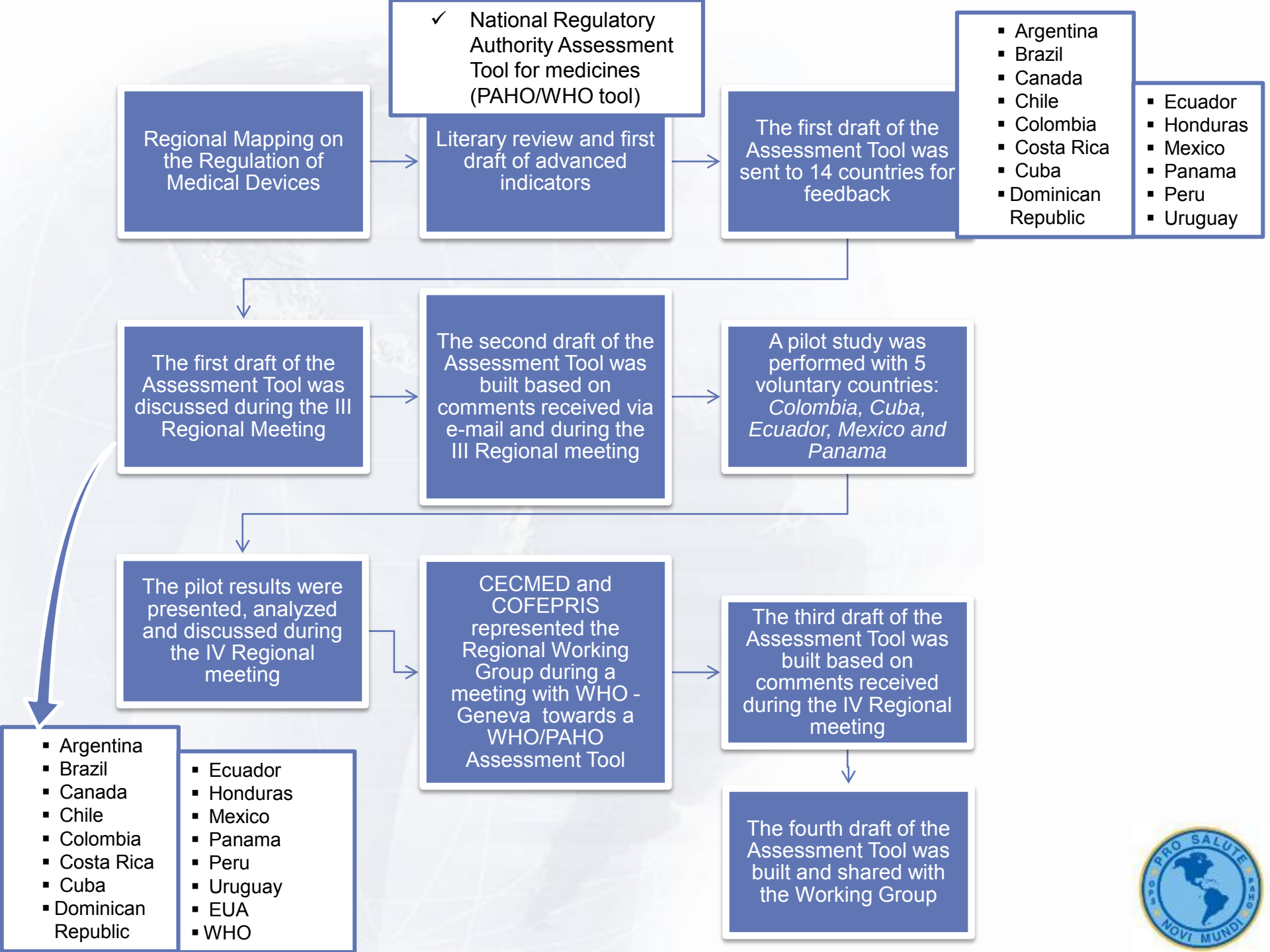
Advanced indicators – assessment tool

- 5 voluntary countries (Colombia-INVIMA, Cuba-CECMED, Ecuador-ARCSA, México-COFEPRIS and Panama-Ministry of Health) self-assessed with the 2nd version of the Assessment Tool.

- The results were presented during the 4th Regional Meeting in Bogota-Colombia (2015); the countries concluded that the Assessment Tool contributes to the development of the NR Systems in the Americas Region. It allows to identify gaps which favor actions to improve NR Systems.

- Based on the feedback received, the 3rd draft of the Assessment Tool was built and shared with the WG for feedback.

- After the 5th Regional Meeting, the structure of the Assessment Tool was changed into Modules with indicators and sub-indicators and the 4th draft was built and shared with the WG for feedback.
- Currently, we are receiving feedback from the countries


✓ National Regulatory Authority Assessment Tool for medicines (PAHO/WHO tool)
Regional Mapping on the Regulation of Medical Devices
Literary review and first draft of advanced indicators
The first draft of the Assessment Tool was sent to 14 countries for feedback
Argentina
Brazil
Canada
Chile
Colombia
Costa Rica
Cuba
Dominican Republic
Ecuador
Honduras
Mexico
Panama
Peru
Uruguay
The first draft of the Assessment Tool was discussed during the III Regional Meeting
The second draft of the Assessment Tool was built based on comments received via e-mail and during the III Regional meeting
A pilot study was performed with 5 voluntary countries: Colombia, Cuba, Ecuador, Mexico and Panama
The pilot results were presented, analyzed and discussed during the IV Regional meeting
CECMED and COFEPRIS represented the Regional Working Group during a meeting with WHO - Geneva towards a WHO/PAHO Assessment Tool
The third draft of the Assessment Tool was built based on comments received during the IV Regional meeting
The fourth draft of the Assessment Tool was built and shared with the Working Group
Argentina
Brazil
Canada
Chile
Colombia
Costa Rica
Cuba
Dominican Republic
Ecuador
Honduras
Mexico
Panama
Peru
Uruguay
EUA
WHO

Comparison between the 3rd and the 4th DRAFT (assessment tool)

4TH DRAFT								
Modules	**RS**	**HR**	**LI**	**PS**	**CT**	**RI**	**TL**	**Total**
N° of indicators	5	4	3	4	3	4	4	27
N° of sub-indicators	27	15	8	15	7	18	14	104
N° of sub-indicators Critical	13	14	8	11	5	13	11	75
N° of sub-indicators Necessary	11	1	0	4	2	5	2	25
N° of sub-indicators Informative	3	0	0	0	0	0	1	4
3RD DRAFT								
Modules	**RS**	**HR**	**LI**	**PS**	**CT**	**RI**	**TL**	**Total**
N° of indicators	27	15	8	15	7	18	14	104
N° of sub-indicators	0	0	0	0	0	0	0	0
N° of indicators Critical	13	14	8	11	5	13	11	75
N° of indicators Necessary	11	1	0	4	2	5	2	25
N° of indicators Informative	3	0	0	0	0	0	1	4

RS - Regulatory system
HR - Health registration (marketing authorization)
LI - Licensing/authorization of manufacturers, importers, distributers, and providers
PS - Post-marketing surveillance
CT - Clinical Trials
RI - Regulatory inspections
TL - Testing laboratories

Next steps…

- **6th Regional Meeting of the Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas Region –** Hosted by COFEPRIS, Mexico City (October 19th and 21st)
  - In conjunction with the 7th PANDRH Conference.
  - The agenda includes the following topics:
    1. Priorities of PANDRH and synergies with the Regional Working Group
    2. Update on the Mirror Working Groups: REDMA Program and Software as a Medical Device (present of the current regulatory situation in the Americas Region)
    3. Update on the Technical Group: Reprocessing and Reuse of Medical Devices (present results of the mapping activity in the Americas Region)
    4. IMDRF Working Group on Table of Contents and the potential for the creation of a Regional Mirror Working Group
    5. For the very first time, there will be an Open Session with the industry on the following: Technovigilance, Software as MD and Reprocessing & Reuse of MD

- Launch the Pilot Activity (REDMA Program) and continue with the training activities
- Expand the information on the MD Observatory within PRAIS (include a larger number of countries).
- To seek convergence between the PAHO and the WHO assessment tools

Thank you

Pan American Health Organization

World Health Organization

REGIONAL OFFICE FOR THE Americas

Murilo Contó

IMDRF Meeting

Florianopolis, Brazil

13 – 14 September 2016