IMDRF International Medical Device Regulators Forum

IMDRF Stakeholder Open Forum

Regulatory Updates
ANMAT- Argentina

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About ANMAT

ANMAT's **objective** is to control and monitor the activities, processes and technologies related to drug products, **medical devices**, foods, household sanitizing products and cosmetics; as well as to surveil their efficacy and the detection of adverse events resulting from the consumption and use of said products.

Service attitude

Confidentiality and Integrity

Commitment and sense of belonging

Response capacity

Reliability and credibility

Transparency

About ANMAT

1

National Regulatory Authority with capacities and resources based on Regulatory Science.

2

Regulatory framework adapted to international regulatory convergence and coherence criteria.

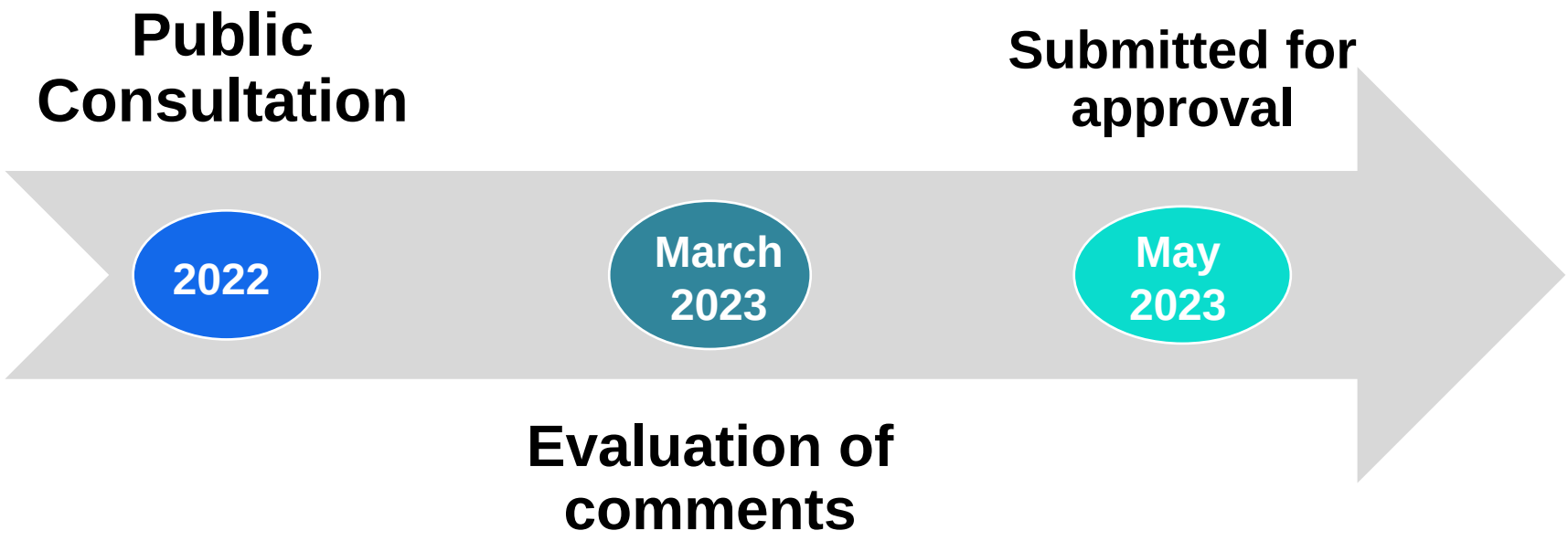
3

Active involvement in the international arena, with participation in several WGs from different fields.

4

Being a part of the convergence and harmonization processes within the IMDRF framework.

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.



Based on:

IMDRF/GRRP WG/N47FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

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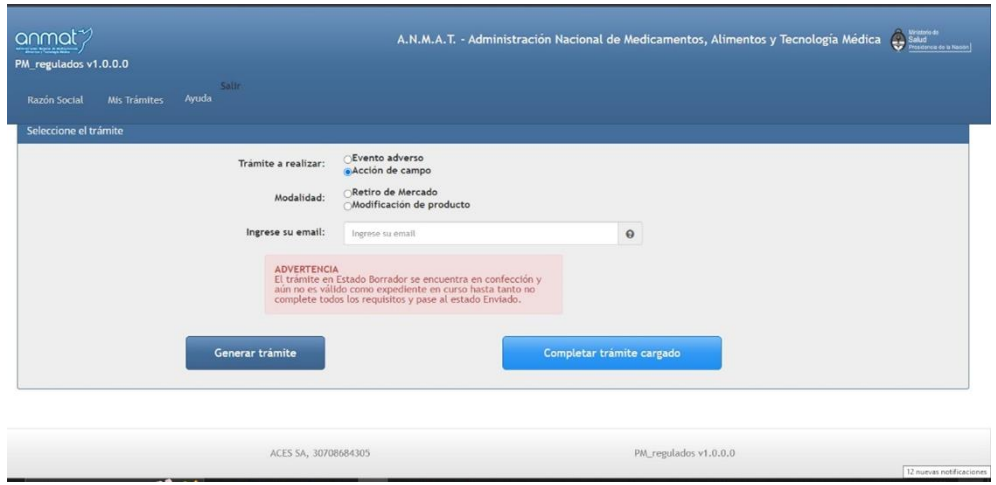
Postmarket Surveillance

Main objectives:

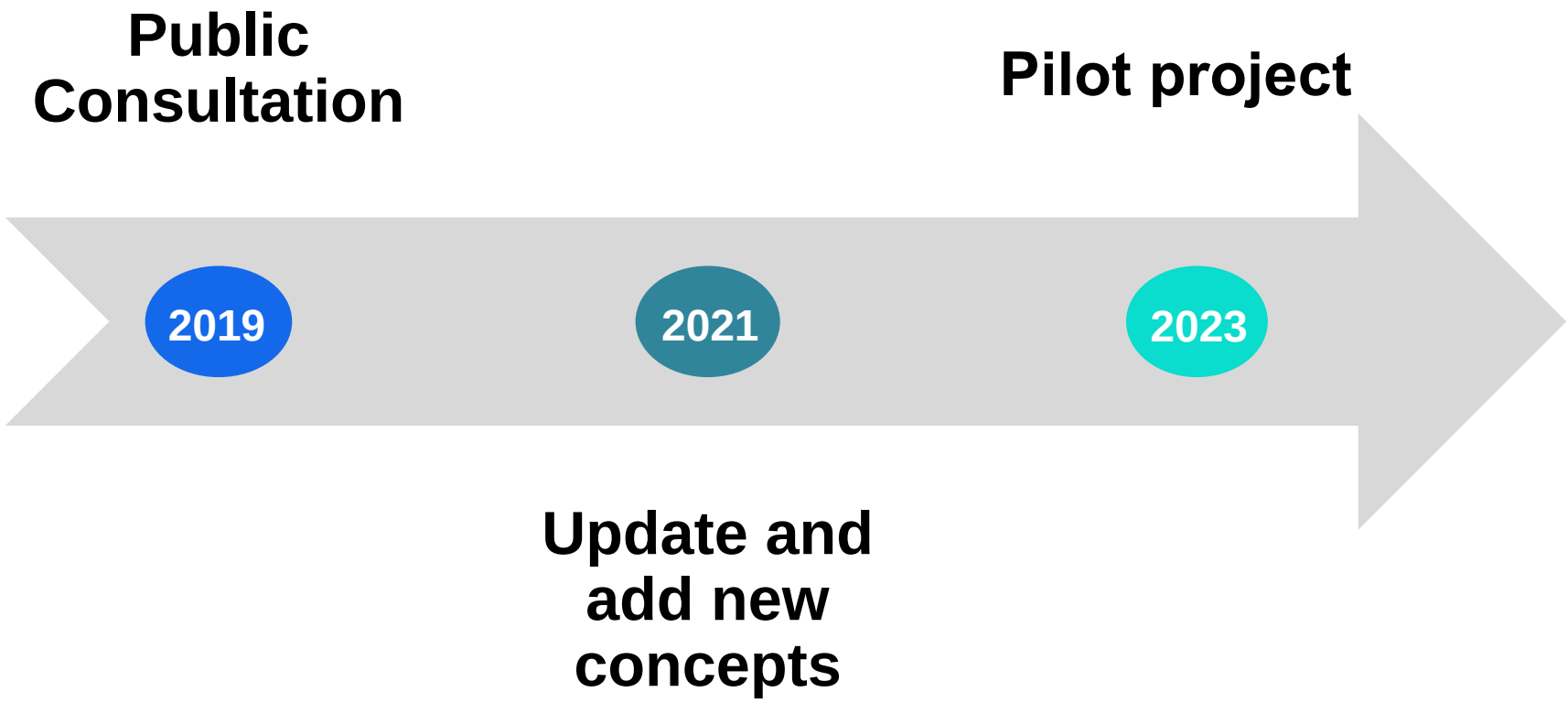
- Update the concepts of Post-Marketing Surveillance
- Establish new deadlines and notification criteria.
- Database available

INDUSTRY

ARGOS (software)



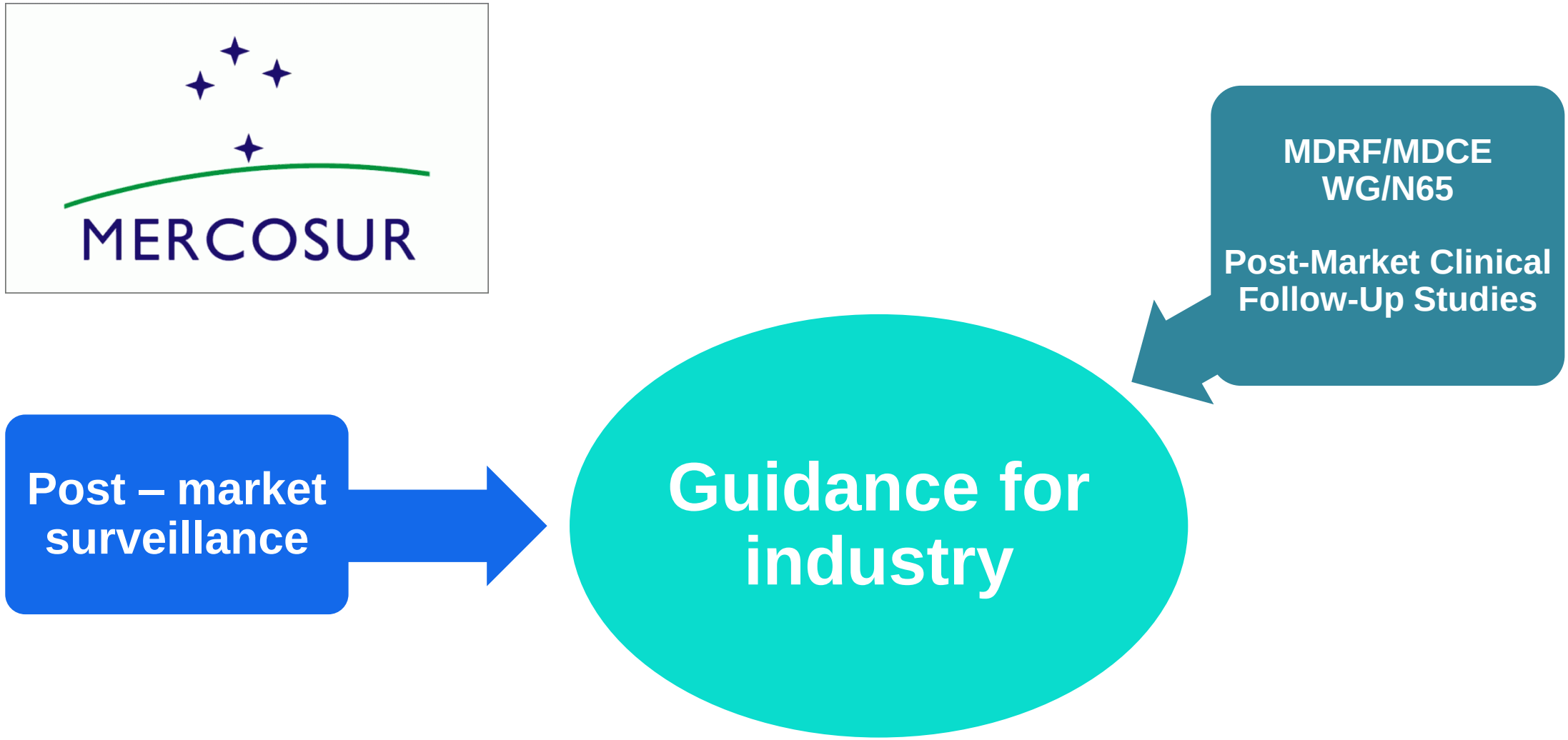
Good Technovigilance Practices



Based on:

IMDRF/AE WG/N43 – IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

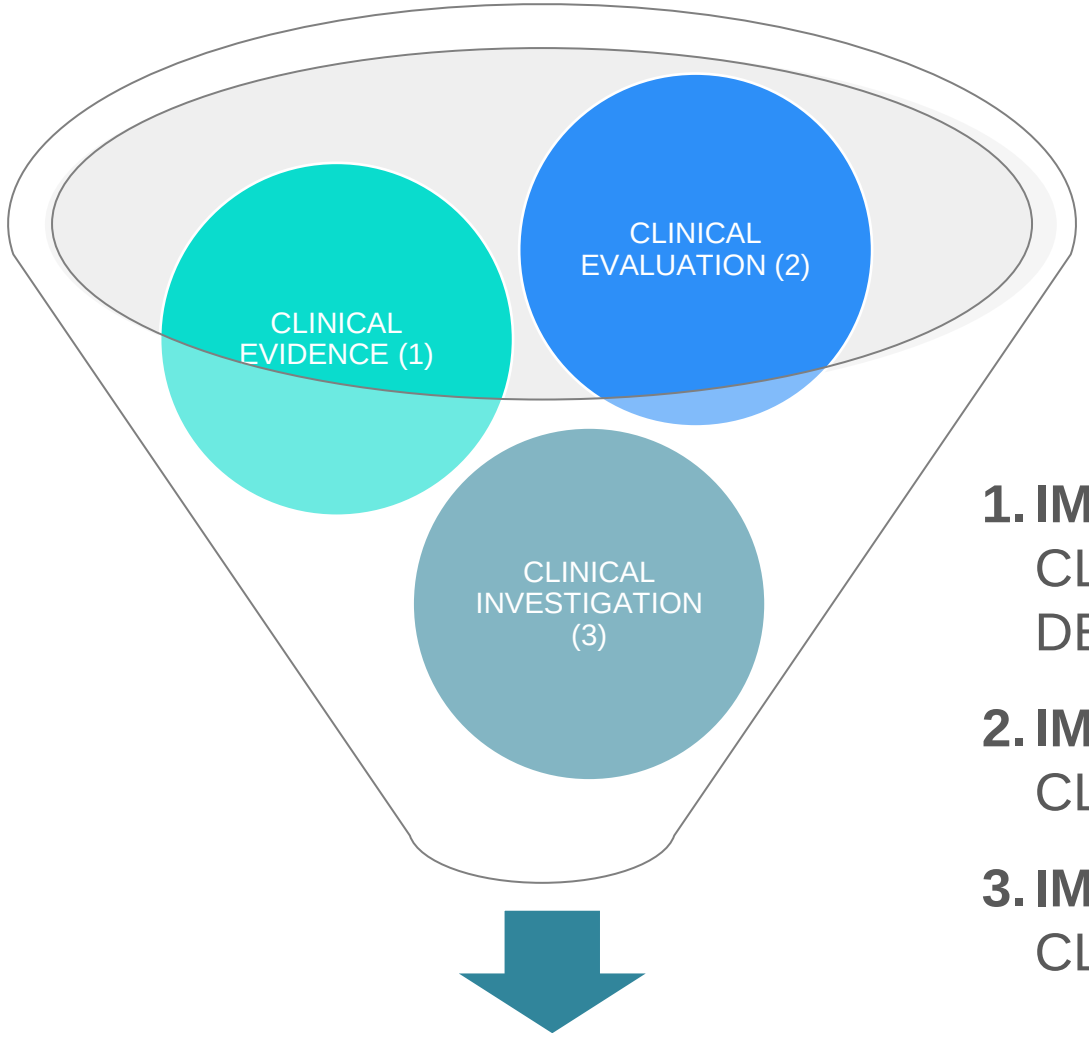
ISO/TR 20416:2020 – Post-market surveillance for manufacturers



Based on:

WHO 2021 – Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics

Medical Device Clinical Evaluation



1. **IMDRF MDCE WG/N55:19**
   CLINICAL EVIDENCE - KEY DEFINITIONS AND CONCEPTS
2. **IMDRF MDCE WG/N56:19**
   CLINICAL EVALUATION
3. **IMDRF MDCE WG/N57:19**
   CLINICAL INVESTIGATION

Internal working group for the implementation of these documents

CHALLENGES

ANMAT intends to continue joining regulatory convergence and harmonization processes that represent IMDRF foundational objectives

- ➢ Update medical device classification rules.
- ➢ New document about IVD clinical evidence
- ➢ Actively participate in new IMDRF WG.
- ➢ **Member of the Management Committee**

IMDRF International Medical Device Regulators Forum

Thank you

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