IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

11:35 – 11:50

Argentina – Official observer

Mariela Aranda

Head of the Service of In Vitro Diagnostic Products, National Institute of Medical Devices

Carolina Magnatti

Office of Monitoring and Risk Management of Medical Devices Establishments, National Institute of Medical Devices

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Regulatory Update - ANMAT- Argentina

Bioq. Mariela Aranda
Bioing. Carolina Magnatti
National Intitute of Medical Devices

March 28, 2023

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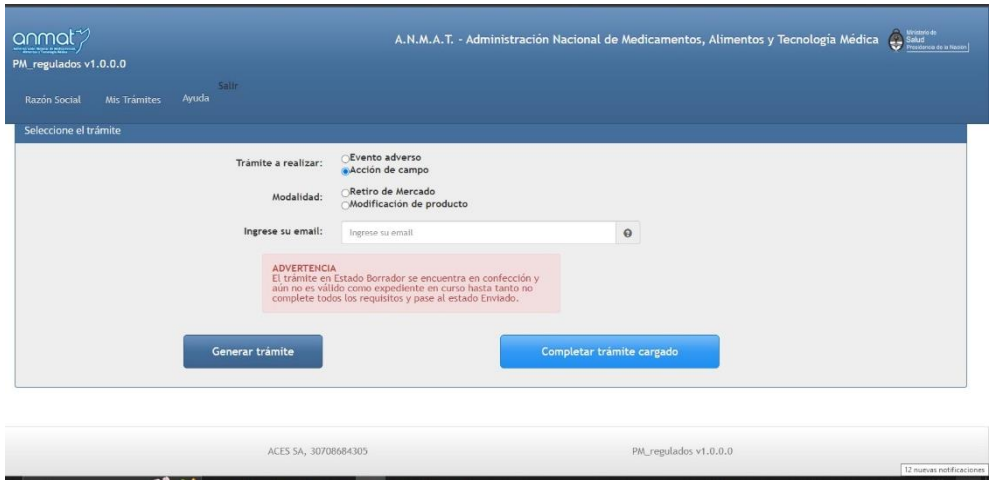
Postmarket Surveillance

Main objectives:

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

Stakerholder

ARGOS (software)



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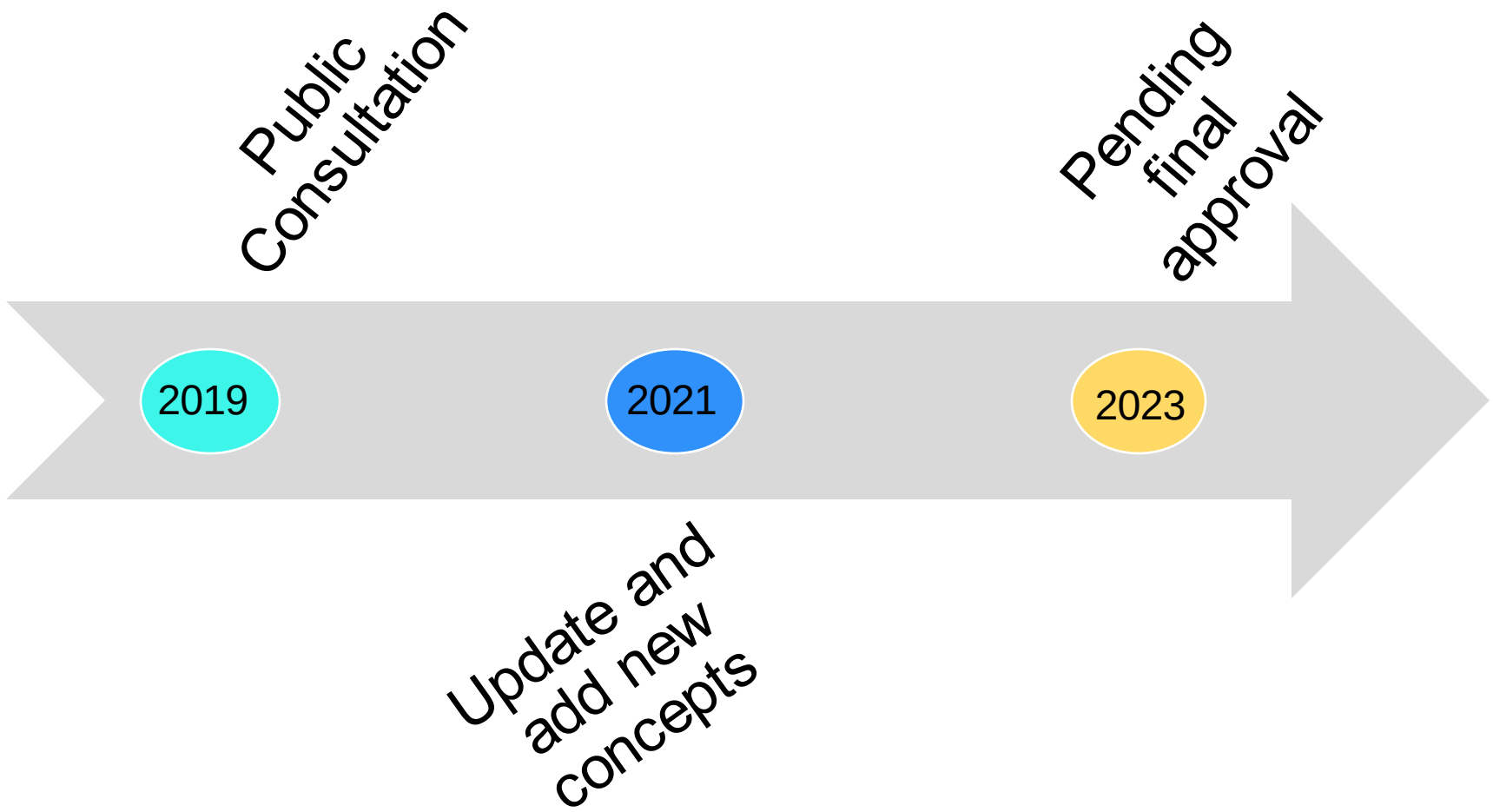
Postmarket Surveillance



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IMDRF MDCE WG/N65FINAL:2021 Post-Market Clinical Follow-Up Studies.

(extensión del grupo de trabajo MDCE)

•**Post-Market Clinical Follow-Up Studies:** El documento proporciona la orientación en relación con las circunstancias en la que está indicado los estudios clínicos post comercialización, la determinación de los objetivos, diseño, la realización del estudio y el uso de la información generada.

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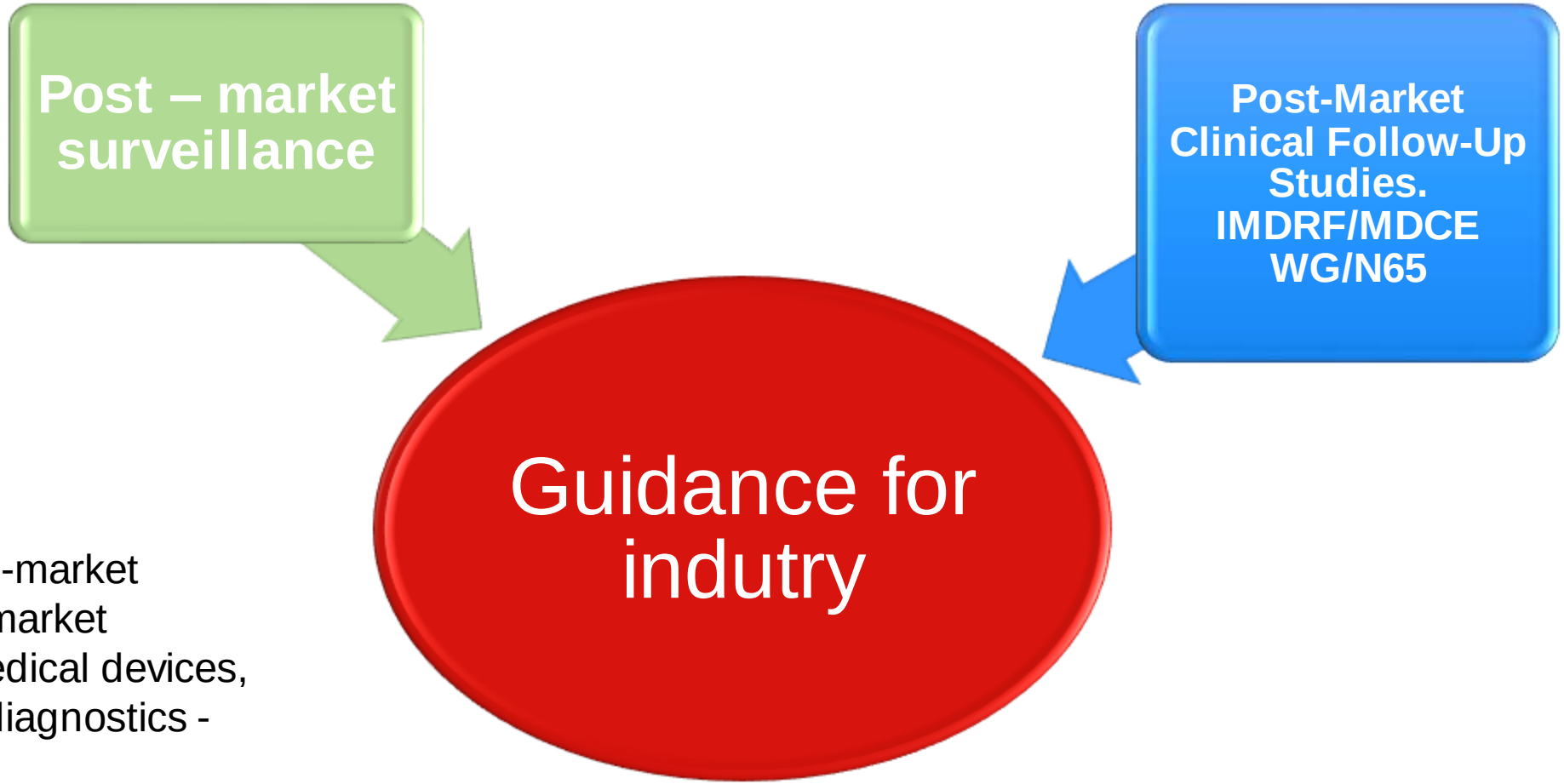

Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics - WHO2021

MERCOSUR

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

Public Consultation was close in December 2022
Evaluation of comments: in process
Expected approval of the final document: 2023

Based on:
Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018) (IMDRF, 2018)

- Update safety and performance requirements of MD and IVDMD and to restructure the previous regulation
- Alignment of requirements for Mercosur jurisdictions

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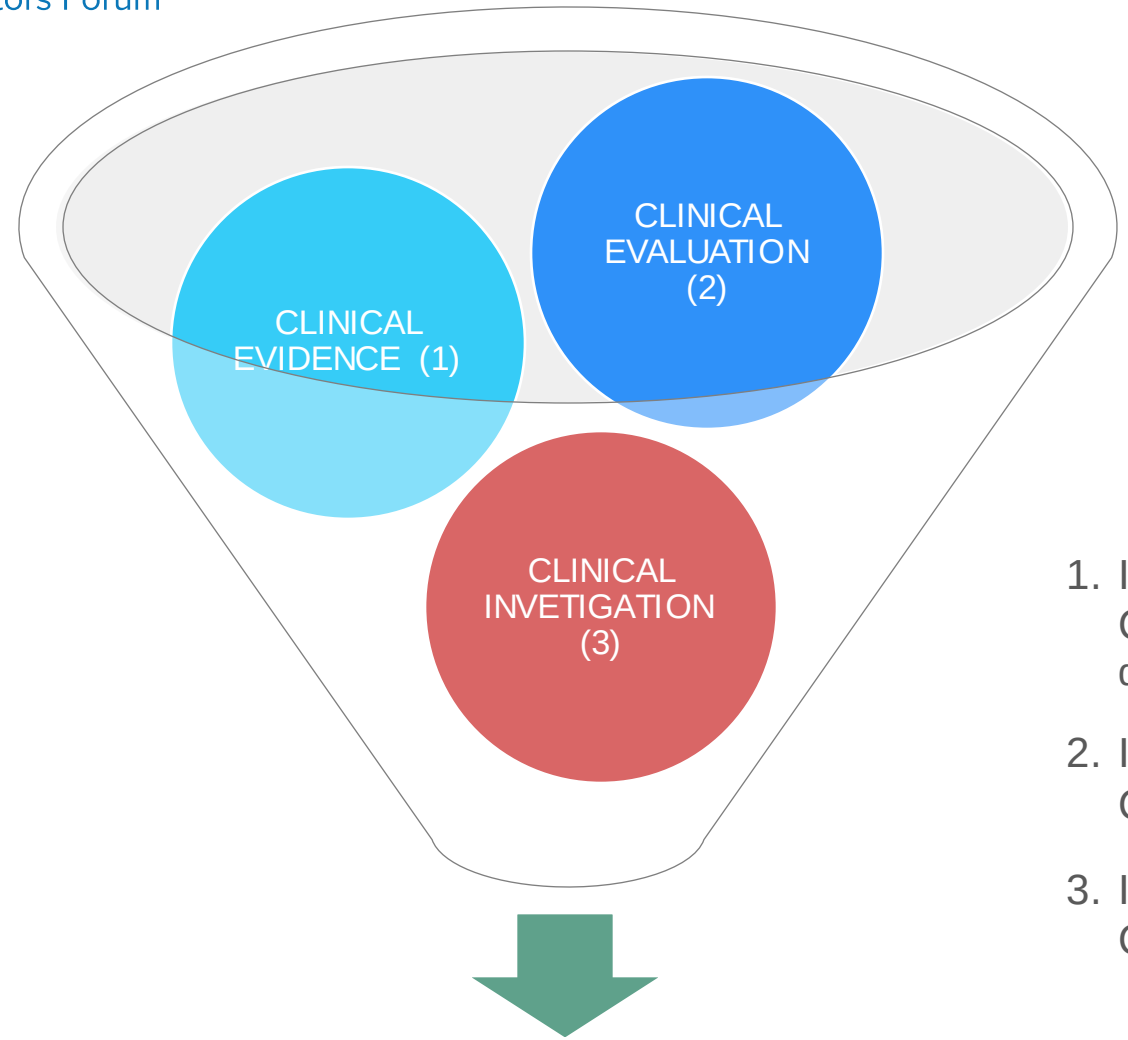
Medical Device Clinical Evaluation



1. IMDRF MDCE WG/N55:19 CLINICAL EVIDENCE - Keys 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

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ANMAT participation in working groups:

- ✓ Artificial Intelligence Medical Devices (AIMD)
- ✓ Medical Device Cybersecurity Guide
- ✓ Personalized Medical Devices
- ✓ Software as Medical Devices
- ✓ Clinical Evidence of Medical Products for IVD (Close)