Regulatory Update for ANMAT

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IMDRF International Medical Device Regulators Forum

Good Post-market Surveillance Practices

DI-2023-8194-APN-ANMAT#MS: This document provides guidance on the post-market surveillance process to be conducted by medical devices manufacturers and importers. It updates some concepts and establishes new deadlines and notification criteria.

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Good Post-market Surveillance 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

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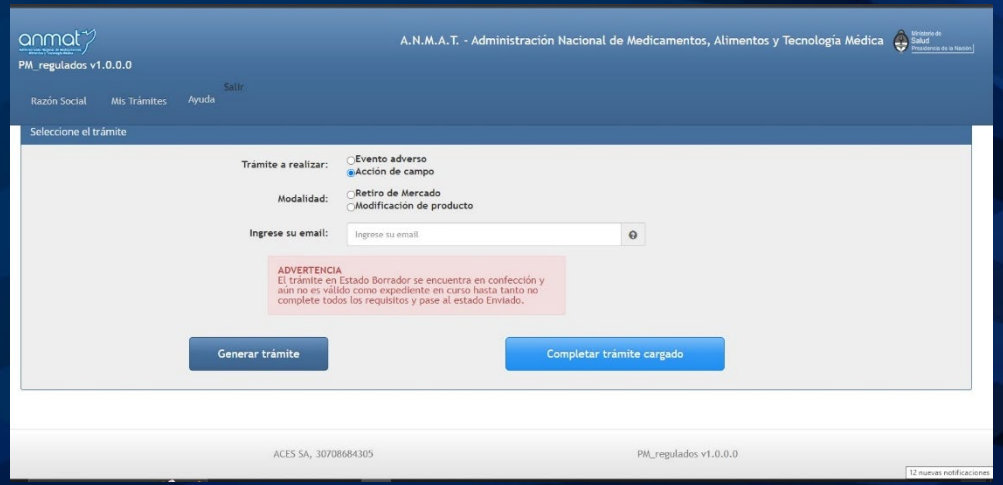
ARGOS: Post-market Surveillance System

Stakeholders



Pilot project: Initial testing of Argos System

Stakeholders chambers	Participants
CADIEM- Argentine Chamber of Distributors and Importers of Medical Equipment	5
CADIT - Chamber of Traumatology Industry	2
CAPRODI – Argentine Chamber of Diagnostic Reagents	5
CAFIME – Argentine Chamber of Medical Implant Manufacturers	3
CADIME - Chamber of Medical Diagnostic Institutions	1
CADIPO – Argentine Chamber of Distributors and Importers of Medical Devices and Orthopedic Products	1
UAPE – Argentine Union of State Suppliers	3
CAEHFA – Chamber of Hospital Equipment Manufactured in Argentina	1
Total:	20

Training to Stakeholders

→**Face-to-face training**

→**Online course** (ANMAT Virtual Campus)

→**External events** (Congress, Conference, Exhibition)

- ANMAT Federal meetings
- ExpoMedical 2023
- CACI: College of Interventional Cardioangiologists
- CACID - Chamber of Commerce and Dental Industry

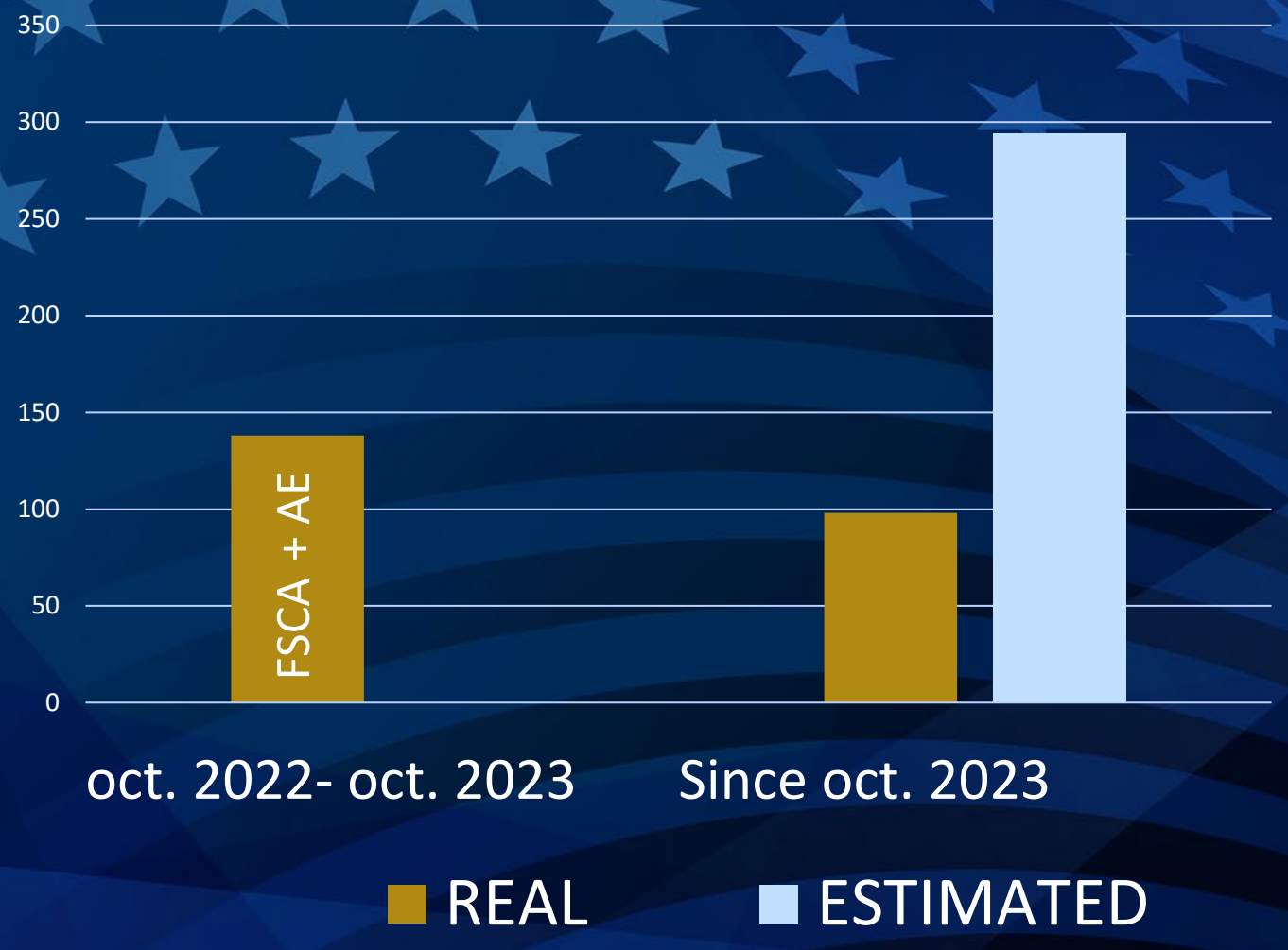
MAIN OBJECTIVES:

- New deadlines and notification criteria.
- Implementation of a new IT system.
- Database available

ACHIEVEMENTS:

- Optimize communication channels.
- Reduce evaluation times.
- Data Analysis: analytics tools to classify reports into categories

Number of reports



Total = FSCA + AE

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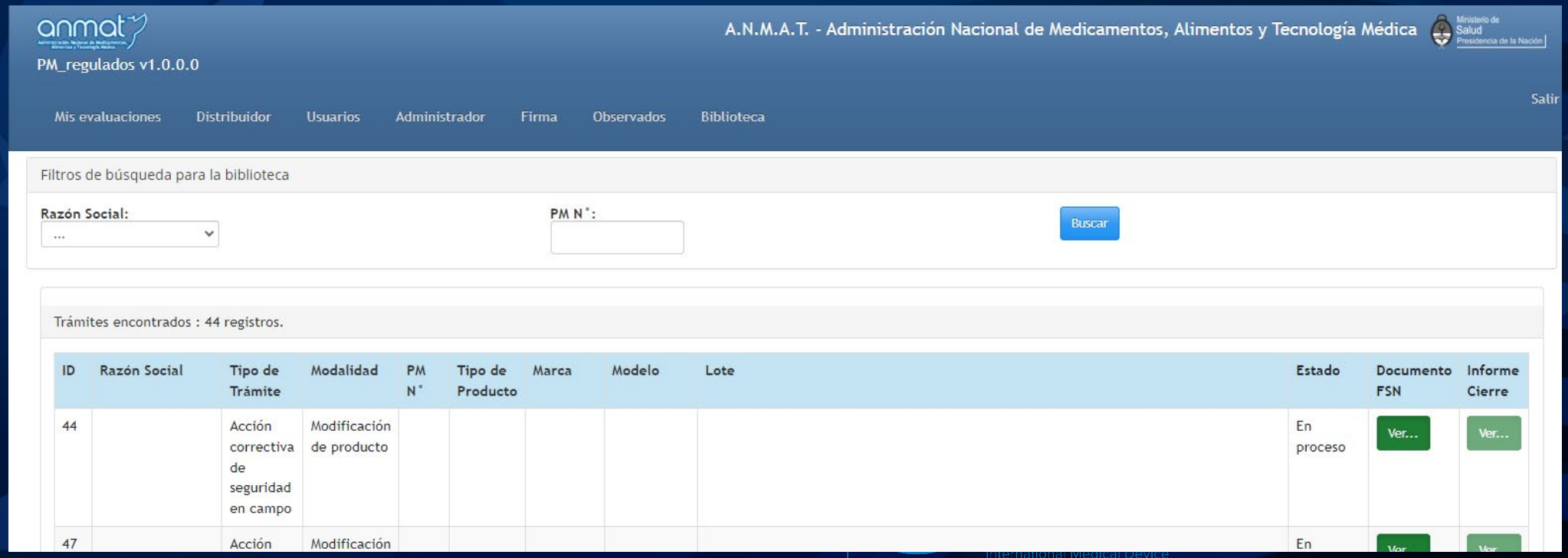
ARGOS: “Public Library”

- Public access to view the reports (only FSCA) with the corresponding FSN and its status (In Process or Closed)
- In “Closed” notification shows the Final Report.



Post-Marketing Monitoring Plan

Product: ELISA test for determination of IgG/IgM antibodies to anti *Trypanosoma cruzi* in human serum/plasma.

Objective: Comparative evaluation of ELISA test for the detection of specific antibodies against *Trypanosoma cruzi* in serum/plasma, to verify specificity and sensitivity of the IVD available in the national market.

Post-Marketing Monitoring Plan

We requested 3 kits (x192 tests) from 10 companies with marketed products.

The study is carried out by the Reference Center for Research and Diagnosis of Chagas Disease INP “Dr. “Fatala Chaben”.

Current status: two brands were evaluated (6 kits) and 5 remain (15 kits). The trials are expected to be completed in March.

Guideline for SaMD and AIMD

The guideline focuses on the requirements for pre-market approval and application of Quality Management System

- Public Consultation: November-December 2023.
- Current Status: Analysis of comments

Based on:

IMDRF/SaMD WG/N23 Software as a Medical Device (SaMD): Application of Quality Management System

IMDRF/AIMD WG/N67 Machine Learning-enabled Medical Devices: Key Terms and Definitions

IMDRF/SaMD WG/N10 Software as a Medical Device (SaMD): Key Definitions

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