U.S. FOOD & DRUG ADMINISTRATION

Postmarket Surveillance: A Regulator's Perspective

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Overview

- Postmarket surveillance is a set of activities to collect and evaluate experience gained from medical devices that have been placed on the market, and to identify the need to take any action.

- Ensuring the safety of medical devices on an ongoing basis is far more complex than having a vigilant postmarket surveillance system for quick identification of new or increased safety concerns, timely public communication about them, and effective interventions.

- It is also important to foster innovation that spurs the development of safer, more effective technologies and assures timely patient access and ultimately improves patient safety.

- Postmarket surveillance and fostering innovation are key objectives and priority areas of the IMDRF Strategic Plan

- Postmarket surveillance and medical device safety have been long standing priorities at US FDA

Key Aspects of a Postmarket Surveillance System

- Communicates timely, accurate, systematic, and prioritized assessments of the benefits and risks of medical devices throughout their marketed life using high quality, standardized, structured, electronic health-related data

- Ensures that medical devices continue to be safe and well performing, and ensures that actions are undertaken if the risk of the use of a particular medical device outweighs the benefit

- Identifies potential safety signals in near real-time from a variety of data sources

- Can facilitate the approval of new devices, or new uses of existing devices

Challenges

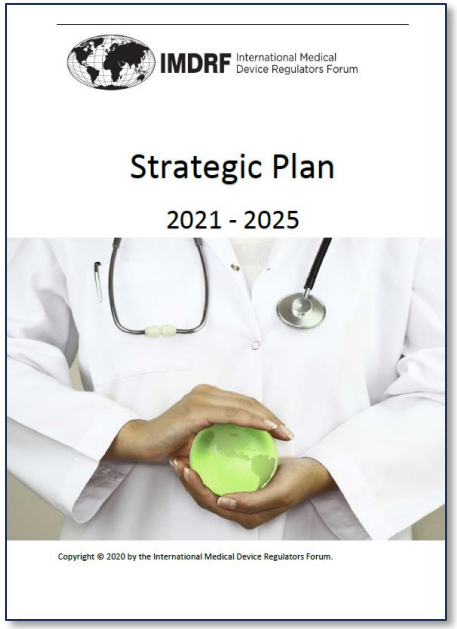
- Medical device postmarket surveillance presents unique challenges compared to drugs and biologics due to the
  - greater diversity and complexity of medical devices,
  - iterative nature of medical product development,
  - learning curve associated with technology adoption, and
  - relatively short product life cycle.
- Lack of alignment in terminology globally
  - Adverse Event Reporting
  - Safety Notices/Recalls
- Multiple/complex data sources
  - Global
  - Reactive and proactive
- Reliance on traditional surveillance studies can take a long time before you can characterize any risks and determine whether a signal represents a true safety concern

Postmarket Surveillance:
An International Perspective

IMDRF Strategic Plan

Key Objectives

1. Strengthen postmarket surveillance for medical devices and implement regulatory life cycle processes.
2. Manage regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance.



Priority Areas

- Premarket: Develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices.
- Postmarket: Leverage post-market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients.

IMDRF Adverse Event Terminology Working Group

The purpose of the IMDRF AE WG is to provide a comprehensive, improved terminology and coding system for adverse events. This

- Helps regulatory agencies by
  - enabling them to analyze safety information about medical devices with higher accuracy and reliability;
  - facilitating communication about medical device adverse events between regulatory agencies.
- Helps regulated industry by
  - reducing the burden of managing safety information on medical device products
  - reducing the burden of preparing multiple adverse event reports to regulatory agencies.
- Widespread use of an improved coding system will improve signal detection by adverse event management systems enabling a faster response by both manufacturers and regulatory authorities.

IMDRF/AE WG/N43FINAL:2020 (Edition 4)

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

Authoring Group: IMDRF Adverse Event Terminology Working Group

Date: 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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IMDRF Annexes and Alignment with FDA Coding

The FDA is fully harmonized with IMDRF AE Codes, so each FDA code is mapped to a single corresponding IMDRF code.

Annex A – Device Problem	= FDA Device Problem Codes
Annex B – Type of Investigation	= FDA Evaluation Method Code
Annex C – Investigation Findings	= FDA Evaluation Results Code
Annex D – Investigation Conclusion Code	= FDA Evaluation Conclusions
Annex E – Health Effects Clinical Signs, Symptoms & Conditions	= FDA Patient Problem Code
Annex F- Health Effects Health Impact	= FDA Patient Problem Code
Annex G – Components	= FDA Component Code

IMDRF Adverse Event Terminology Working Group

Current Work Item

– Expanding the harmonization of adverse event terminology, and standardising data fields across jurisdictions in view of fully exploiting adverse event reporting for signal detection.

– This will allow standardization of the data fields and requirements used in forms and templates of the different jurisdictions (e.g., adverse event / incident reporting, FSCA, trend reporting, NCAR exchange).

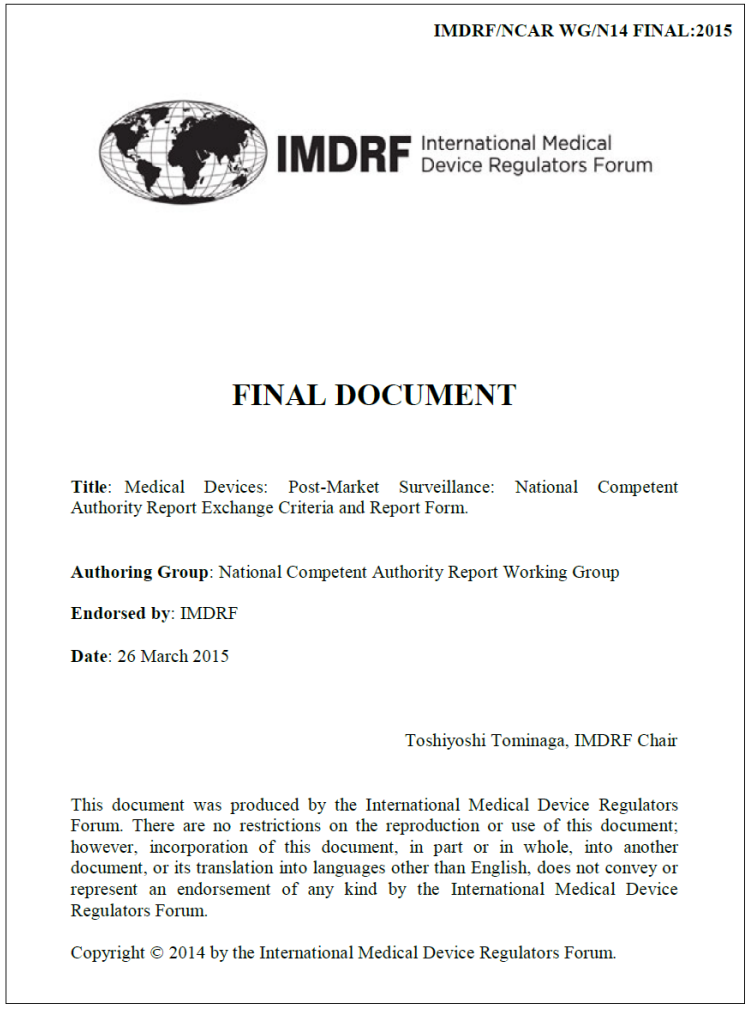
– This work item will enable improved information sharing across jurisdictions to facilitate subsequent collaborative analysis of trending and signal detection

National Competent Authority Report (NCAR)

Program established in IMDRF to facilitate the exchange of relevant post market safety information on medical devices with global distribution in order to trigger rapid adoption of field safety corrective actions in all concerned geographies to avoid death or serious deterioration of health, when relevant.

IMDRF/NCAR WG/N14 FINAL:2015 ***Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form***

- Full Implementation: April 2016 – Present
- NCAR is used to send information that another regulator may not already be aware of and is used to gather information from multiple regulators



IMDRF/NCAR WG/N14 FINAL:2015

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form.

Authoring Group: National Competent Authority Report Working Group

Endorsed by: IMDRF

Date: 26 March 2015

Toshiyoshi Tominaga, IMDRF Chair

International Medical Device Safety Meetings

Goal

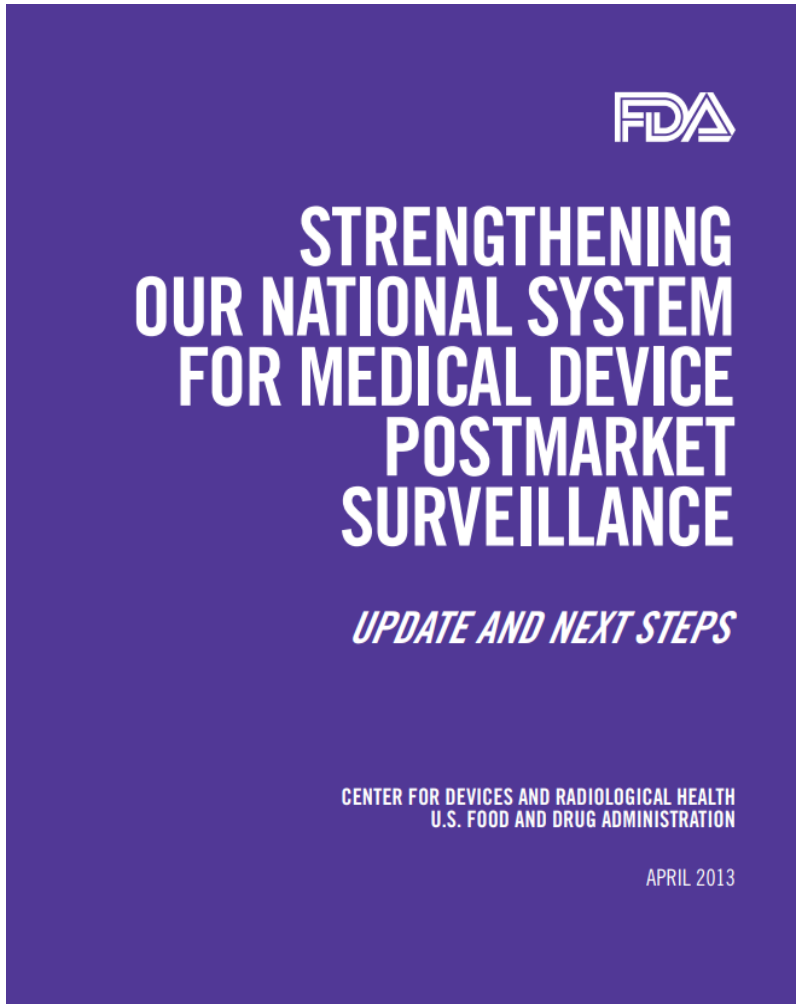
To combine and improve upon regulatory intelligence from multiple regulatory authorities (who have confidentiality commitments with each other) in order to identify and act as quickly as possible on proactive risk reduction and post market medical device safety issues.

Objectives

- share up to date information related to post market safety performance of medical devices;
- notify of pending or complete regulatory/compliance actions, including communications;
- share approaches to collection, analysis, and benefit-risk decision-making regarding post market medical device performance;
- share and collaborate on pro-active risk reduction activities;
- share / develop strategic approaches to the post market regulation of medical devices and
- identify potential actions and projects for future collaboration.

Postmarket Surveillance:
A US FDA Perspective

US FDA
Postmarket Surveillance and Medical Device Safety



Key Accomplishments

- Established a Unique Device Identification System
- Improved regulatory clarity regarding use of real world evidence
- Developed the National Evaluation System for health Technology (NEST) - an active surveillance and evaluation system
- Established a signal management program
- Recalibrated the benefit-risk framework for device oversight in the pre- and post-market settings
  - Issued several benefit-risk guidance documents
- Established the Case for Quality Program
- Continued to fostered innovation towards safer medical devices
- Continued to modernize our adverse event reporting system

Summary

- Opportunities for greater global alignment
  - Build upon the IMDRF Adverse Event work
  - Greater global adoption of the IMDRF Adverse Event codes
  - Harmonization/convergence of terminology and requirements for safety notices/recalls
  - Update existing GHTF Study Group 2 documents on Postmarket Surveillance/Vigilance

- Optimize postmarket data collection, quality, completeness, and analysis

Thank you/Questions?