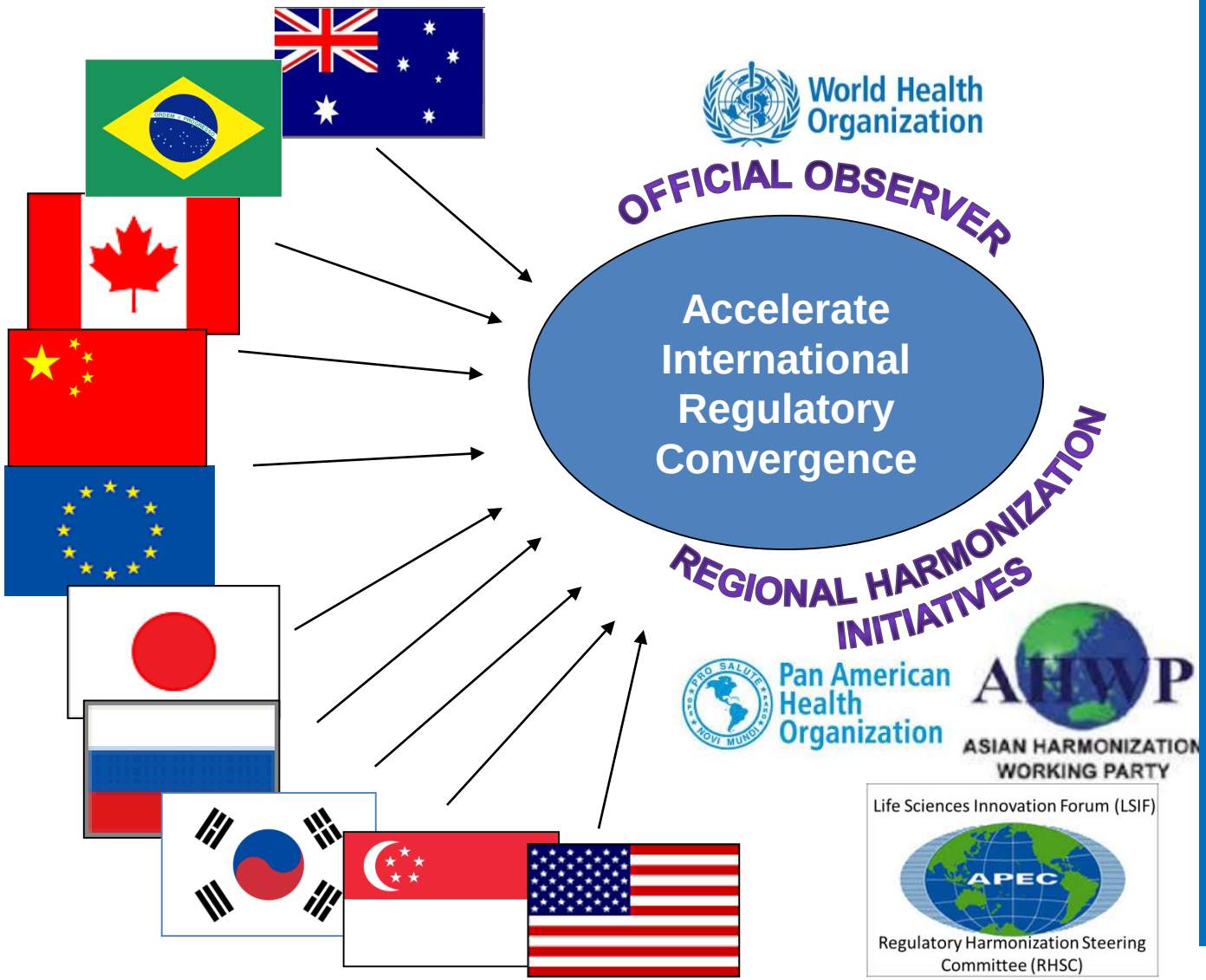
Overview of the International Medical Device Regulators Forum

Melissa Torres
Associate Director for International Affairs
Office of the Center Director
Center for Devices and Radiological Health
melissa.torres@fda.hhs.gov

Overview

- Provide updates and overview of International Medical Device Regulators Forum (IMDRF) activities
  - Active working groups
  - Closed working groups
- Current programs developed under IMDRF
  - National Competent Authority Reports (NCAR) program
  - Medical Device Single Audit Program (MDSAP)

International Medical Device Regulators Forum (IMDRF)



- Forum established in 2011 to accelerate international medical device regulatory harmonization and convergence building on the work of the Global Harmonization Task Force (GHTF)
- Address common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies
- Accelerate innovation by clear and practical regulatory expectations

IMDRF Mission and Strategic Plan

Mission

To strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

Strategic Plan

- Enhance Post-Market Surveillance
- Improve the Effectiveness and Efficiency of Pre-Market Review

IMDRF Working Groups

- Active Working Groups – Comprised of regulators only or regulators and stakeholders depending on the topic.
  - Adverse Event Terminology
  - Good Regulatory Review Practices
  - Patient Registries
  - Regulated Product Submission (RPS)
  - Standards
  - Unique Device Identification (UDI)*
  - Patient Specific Devices*
- Closed Working Groups
  - National Competent Authority Report (NCAR)
  - Software as a Medical Device (SaMD)
  - Medical Device Single Audit Program (MDSAP)

* New Working Groups

IMDRF Active Working Group: Adverse Event Terminology

FDA

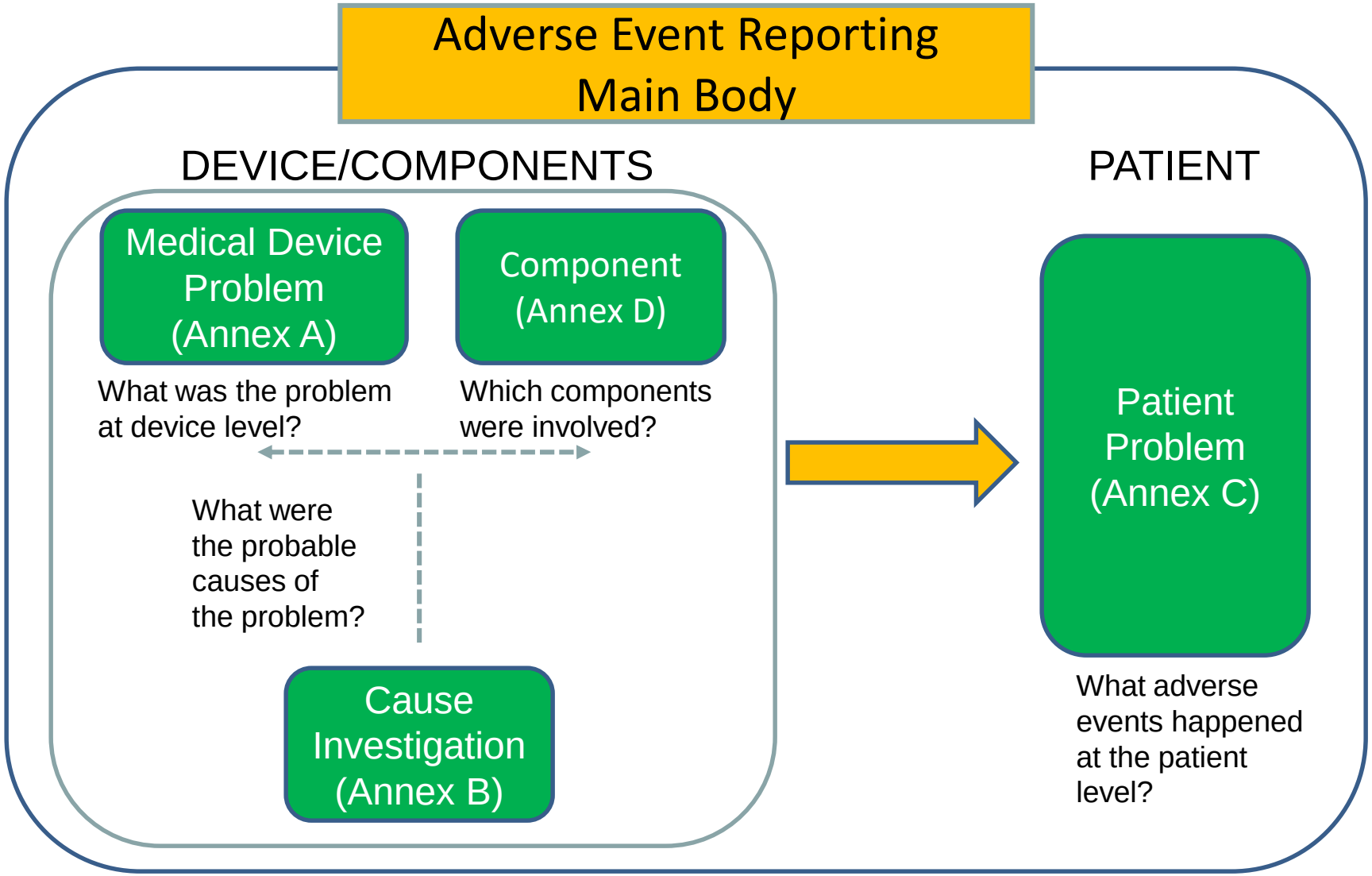
Goal

To develop harmonized terminology and systems being used to code information relating to medical device adverse events in order to improve the efficiency of adverse event management systems for faster response by both industry and regulatory agencies, with the use of a single harmonized adverse event terminology and coding system.

Benefits

- Improved accuracy of capturing and reporting of medical device related adverse events
- Reduced ambiguity
- Better usability
- More sophisticated signal detection

IMDRF Terminologies for Categorized Adverse Event Reporting (AER): Terms, Terminology Structure and Codes



IMDRF Active Working Group: Good Regulatory Review Practices

Goal

To develop harmonized requirements for assessing conformity to safety and performance regulatory requirements for new medical devices.

Benefits

- Promotes consistency, predictability, transparency, and quality of regulatory programs and criteria for assessing premarket technical documentation for medical devices
- Provides greater global convergence and harmonization of premarket requirements
- Reduces regulatory redundancies
- Can ultimately lead to the development of a single globally harmonized premarket review program

Good Regulatory Review Practices Documents

- IMDRF/GRRP WG/N40FINAL:2017 *Competence, Training, and Conduct Requirements for Regulatory Reviewers*
  - Defines basic competence, training, and conduct requirements that shall be demonstrated and maintained by Regulatory Authorities and/or their designated Conformity Assessment Body for personnel involved in performing regulatory reviews.
- Current work item:
  - Revision of GHTF Essential Principles of Safety and Performance of Medical Devices (GHTF/SG1/N68:2012)
    - Based on EU MDR
    - ISO 16142: 2016
  - Draft document for public comment should be published by soon on IMDRF website

IMDRF Active Working Group: Patient Registries

Goal

To develop shared essential principles of informatics infrastructure and best epidemiologic and statistical analytic methodologies to enhance the quality, speed and cost-efficiencies of regulatory science for medical devices.

Benefits

- Linking relevant data sources and tools to an international system of registries would add value to multiple stakeholders by assuring analysis validity
- Provides definitions and qualifiers that define the impact, value, and sustainability of registries
- Builds upon the successes in building national registries and international collaborations
- Not all countries may be able to contribute registry data to every device evaluation; however, all countries will benefit

Patient Registries Documents

IMDRF/REGISTRY WG/N33FINAL:2016 *Principles of International System of Registries Linked to Other Data Sources and Tools*

- Defines essential principles for linking electronic patient, device and outcome registries and/or related data repositories or identifiers such as unique device identifiers, including the principles behind data access, security, informatics formats, governance and other key areas related to global regulatory applications for medical device evaluation.

IMDRF/Registry WG/N42FINAL:2017 *Methodological Principles in the Use of International Medical Device Registry Data*

- Defines essential principles related to methodologies for the analysis of data sources applied to medical device safety signal detection, performance, and reliability.

<u>Current Work Item:</u>

- Development of a qualification tool for international registries taking into consideration a variety of regulatory decisions.

IMDRF Active Working Group: Regulated Product Submission

Goals

- Establish a standard system for the electronic exchange of information related to premarket medical device applications.
- Establish Common Data Elements – mapping data types and common vocabularies.
- Define a common 'Table of Contents' for medical device regulatory submissions as a first step in defining a common data set for regulatory submissions.

Benefits

- Multiple regions using a harmonized, consistent format thus reducing the IT burden on industry and saving time and resources by mitigating the risk of significantly different methods being developed amongst regulators
- Minimal revisions needed to address regional differences and/or requirements in content
- Harmonized regulatory submission requirements

Regulated Product Submission Documents

- Table of Contents Pilot Program: September 2015 – Present
  - IMDRF/RPS WG/N9FINAL:2014 *Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)*
  - IMDRF/RPS WG/N13FINAL:2014 *In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)*
- Common Data Elements
  - IMDRF/RPS WG/N19 FINAL:2016 *Common Data Elements for Medical Device Identification*
    - Outlines harmonized definitions used for the submission of medical device information to regulatory authorities
  - IMDRF RPS WG/N45FINAL:2017 *Data Exchange Guidelines - Common Data Elements for Medical Device Identification*
    - Outlines the data exchange guidelines for the common data elements identified in N19

IMDRF Active Working Group: Standards

<u>Goals</u>

Improve the quality of international medical device standards for regulatory use and increase confidence in standards and how they can be better used for regulatory purposes by:

- Increasing Regulators' engagement with IEC/ISO and National Committees
- Developing resources, knowledge and expertise to improve standards
- Create guidance on how to ensure standards are created to meet Regulator's needs

IMDRF Active Working Group: Unique Device Identification (UDI)

FDA

Goals

Establish a system for the positive identification of medical devices.

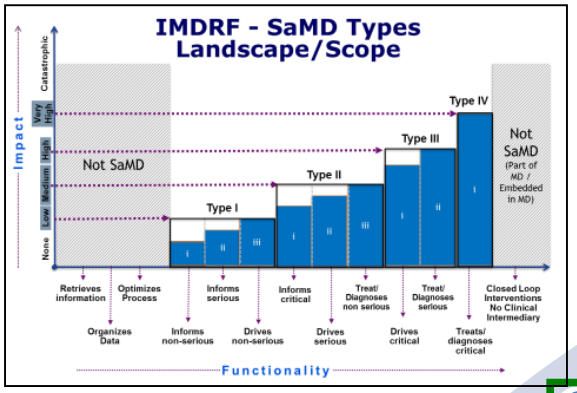
Final Document

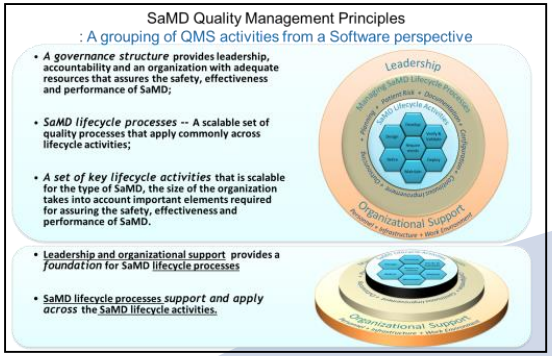
- IMDRF/UDI WG/N7FINAL:2013 *UDI Guidance Unique Device Identification (UDI) of Medical Devices*
  - Provided a framework for regulatory authorities that intend to develop UDI systems that achieves a globally harmonized approach to UDI implementation.

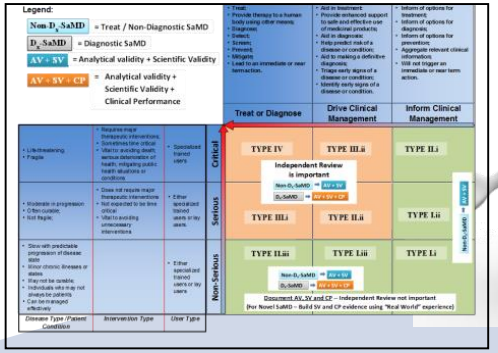
Current Work Item

To develop a harmonized UDI implementation guide that aims to eliminate the risk that a product may be referenced differently in different countries.

Software as a Medical Device (SaMD) IMDRF Documents – On a Path Towards Global Convergence







2017 SaMD – Application of clinical Evaluation

2015 – QMS control
➔Translating Software development practices to regulatory QMS

2014 – Risk framework based on impact to patients

2013 Foundational vocabulary

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
  - Pilot: Oct 2015-March 2016
  - Full Implementation: April 2016 – Present

*Limited to IMDRF Management Committee Members with confidentiality agreements.

Conclusion

How can you get involved in IMDRF?

- Work through regional harmonization initiatives
- Review and provide feedback on draft documents
- Attend IMDRF stakeholder sessions
  - Meetings in March and September
  - China is the Chair in 2018
    - Meeting in Shanghai – March 20 – 22, 2018
    - Meeting in Beijing – September 2018

Questions?