Reliance in a Post Market Setting

IMDRF Adverse Event Terminology. What else? A successful case study. What's next?

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GMTA Global Medical Technology Alliance
Innovating for a Healthier World

IMDRF International Medical Device Regulators Forum

IMDRF codes- successes

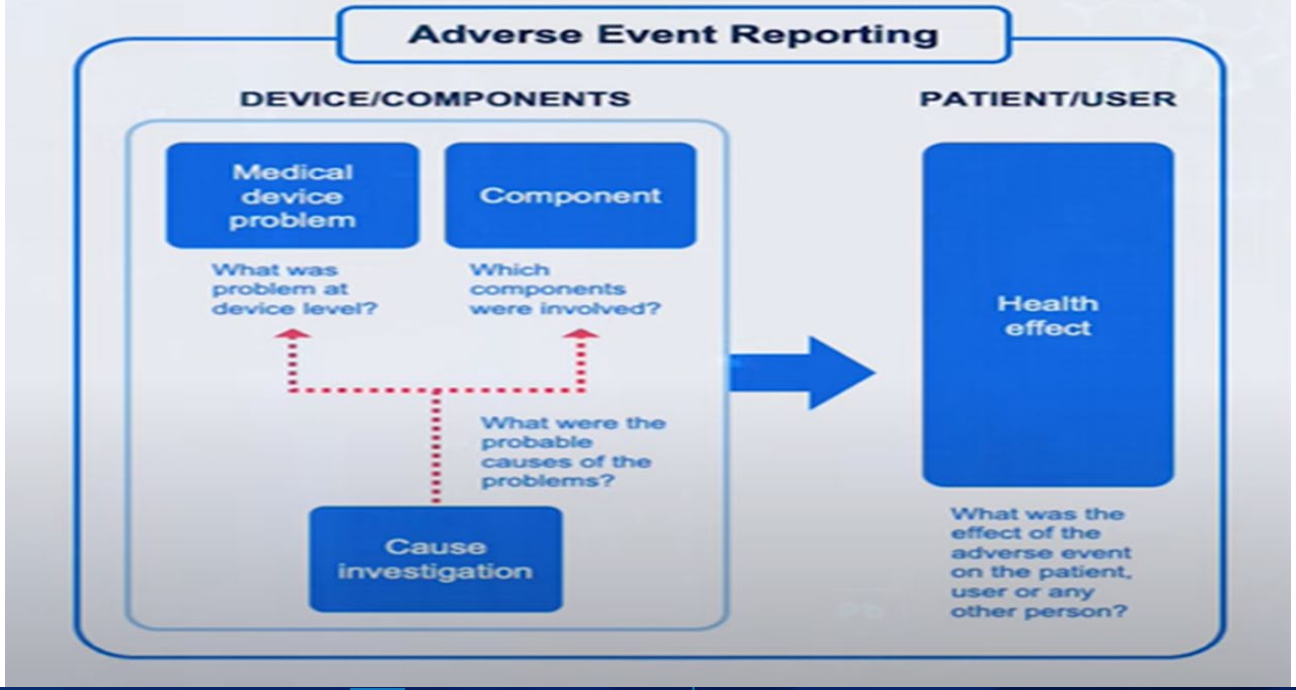
Global Medical Technology Alliance
Innovating for a Healthier World

- **IMDRF AE coding established on Global alignment, driving consistency**
- **The web browser for IMDRF AE terms ensures user-friendly searching and hence better and more adequate use of terms by reporters/regulators.**

- Annex A: Medical Device Problem
- Annex B: Cause Investigation - Type of Investigation
- Annex C: Cause Investigation - Investigation Findings
- Annex D: Cause Investigation – Investigation Conclusion
- Annex E: Health Effects - Clinical Signs and Symptoms or Conditions
- Annex F: Health Effects - Health Impact
- Annex G: Medical Device Component

IMDRF codes- successes

- IMDRF Guidance Document: IMDRF terminologies for categorized Adverse Event Reporting(AER): terms, terminology structure and codes IMDRF/AE WG/N43FINAL:2020
- Video training available – https://www.imdrf.org/imdrf-trainings



IMDRF codes- successes

Wide adoption – non limitative

- US FDA / EU 27 member states / Iceland. Liechtenstein. Norway. Switzerland/ United Kingdom…..

Benefits

- More efficient use of regulator and industry resources
- More efficient use of taxpayer funds
- Spread compliance costs over more markets
- Develop and promulgate regulatory best practices
- Pooling of expertise
- Regulatory capacity-building

What is next?

- In the end an “event” with device is globally the same, so why is reporting and relevant information are so different around the world?

Some potential improvements:

- Report – What – how?
- serious incident reporting- greater harmonization between forms/required formats (XML scheme?)
- Provide information globally -Establish a database to pool and analyze trends
- Limit country specific requirements and rely on available data across countries

Country requirements

Limits specific country requirement to enable a better and quicker identification of issue – improve safety

- **Enable pooling results- and avoid language translation**
- **Give a larger view instead of a macro country limited data**
- **Can establish an early warning system based on large data pool**
- **Use of Real World Data**
- **Enable for early detection signals**

Examples-

- Rely on cross country data as more efficient than national practices – e.g routine sample testing in lieu of comprehensive vigilance reporting
- Use of existing documents. EU PSUR adoption (Health Canada guidance), Serbia, Tanzania…


"Logic will get us from A to B.
Imagination and Vision will take us everywhere "
A. Einstein

GMTA's message

"The future of medical products regulation is in convergence/harmonization, collaboration, and networking based on reliance and trust."

IMDRF
International Medical Device Regulators Forum

United States of America

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