Reliance in a Post Market Setting

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

Philippe Auclair, Senior Director - Abbott GSR
Chair of the Medtech Europe PMS group, FRAPS
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


- Video training available - https://www.imdrf.org/imdrf-trainings
IMDRF codes - successes

Wide adoption - non limitative

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.”