IMDRF International Medical Device Regulators Forum

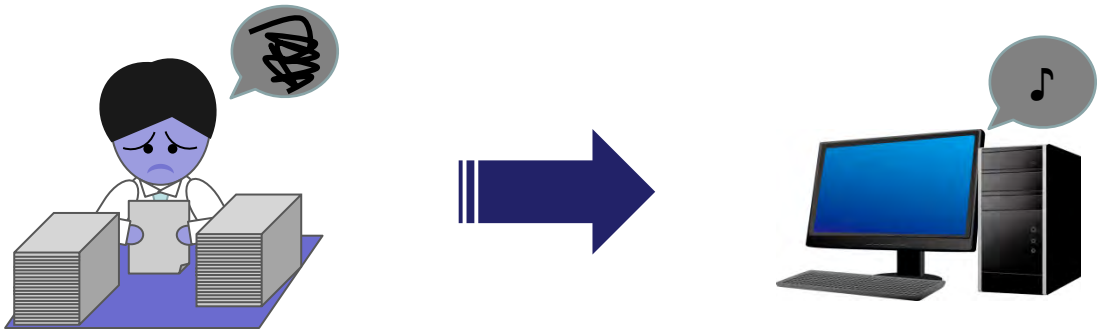
Development of common terminology and code related to adverse event of medical device

- NWIP –

September, 2014

Purpose and goal

- Common terminology and code related to adverse event of medical device will developed.



Expectation

- Common terminology and code will result in improvement of patient safety, including improvement of medical device due to the following for manufacturers/regulatory authorities;
  - Collecting safety information more precisely;
  - Analyzing safety information with higher reliability;
  - Developing a better system to collect safety information;
  - Sharing safety information among stakeholders more easily; and
  - Reducing burden for post marketing activities.

Terminology and code

- Will be composed of three parts;
  - terms and codes for malfunction of MD
  - terms and codes for adverse event (health damage)
  - terms and codes for part/component of MD

- May be prepared based on current relevant documents.

Draft timeline

- *Sep. 2014:* NWIP in IMDRF MC
- *Oct. 2014:* Establishment of WG with approximately 15 members from regulatory authorities and industries
- *Jul. 2015:* Preparation of draft terminology and code
- *Sep. 2015:* Proposal of the draft in IMDRF MC
- *Oct. 2015 to Dec. 2016:* Public consultations
- *Feb. 2016:* Preparation of final draft
- *2016:* Proposal of the final draft in IMDRF MC