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 be 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