What Happens to an Adverse Event Report submitted to FDA

**Mandatory Report**
is sent to FDA by:

- manufacturer
- importer
- hospital or other healthcare facility

**Voluntary Report**
is sent to FDA by:

- healthcare provider
- patient
- consumer/product user

**FDA processes the report:**

- quality checks of certain report fields
- enters the complete report in FDA's proprietary database (MAUDE)
- prepares a non-confidential version of report

**FDA publishes non-confidential version of report (www.fda.gov)**

**FDA reviews and analyzes the adverse event report, which may lead to one or more of these actions:**

- focused monitoring of adverse events by FDA for trends
- request from FDA to submitter of report for additional details about the adverse event
- device recall by device manufacturer
- change in device design by device manufacturer
- change in device labeling (e.g., changes in instructions) by device manufacturer
- decision by device manufacturer to stop selling device
- issuance of Public Health Notification (PHN) by FDA to healthcare providers; PHNs usually describe a risk associated with device use and provide recommendations on reducing risk
- issuance of safety-related communication by FDA intended for patients or consumers
- FDA inspection of device manufacturer
- testing of device by FDA scientists
- change in FDA's future regulatory decisions (test methods/requirements, design, labeling)