

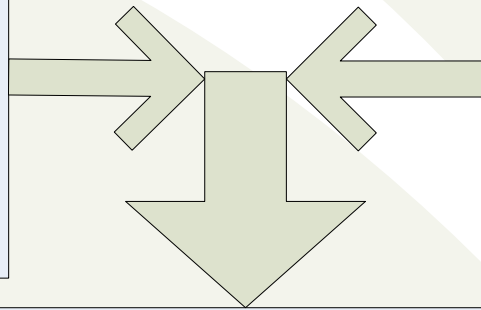
What Happens to an Adverse Event Report submitted to FDA

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)