U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Medical Device Reporting (MDR)

MDR Overview

Each year, the FDA receives several hundred thousand medical device reports of suspected device-associated deaths, serious injuries and malfunctions. Medical Device Reporting (MDR) is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

Mandatory reporters (i.e., manufacturers, device user facilities, and importers) are required to submit certain types of reports for adverse events and product problems to the FDA about medical devices. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.

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Mandatory Medical Device Reporting Requirements:

The Medical Device Reporting (MDR) regulation (**21 CFR 803 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803)**) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA.

Manufacturers: Manufacturers are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. Manufacturers must also report to the FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Importers: Importers are required to report to the FDA and the manufacturer when they learn that one of their devices may have caused or contributed to a death or serious injury. The importer must report only to the manufacturer if their imported devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Device User Facilities: A "device user facility" is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office. User facilities must report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must report a medical device-related serious injury to the manufacturer, or to the FDA if the medical device manufacturer is unknown.

A user facility is not required to report a device malfunction, but can voluntarily advise the FDA of such product problems using the voluntary **MedWatch (https://www.accessdata.fda.gov/scripts/medwatch/)** Form FDA 3500 under FDA's Safety Information and Adverse Event Reporting Program. Healthcare professionals within a user facility should familiarize themselves with their institution's procedures for reporting adverse events to the FDA. See "**Medical Device Reporting for User Facilities (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095266.pdf)**", a guidance document issued by FDA.

Please visit **Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** for specifics on requirements and associated processes.

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Voluntary Medical Device Reporting:

The FDA encourages healthcare professionals, patients, caregivers and consumers to submit voluntary reports of significant adverse events or product problems with medical products to **MedWatch (https://www.accessdata.fda.gov/scripts/medwatch/)**, the FDA's Safety Information and Adverse Event Reporting Program or through the **MedWatcher mobile app (/MedicalDevices/Safety/ReportaProblem/ucm385880.htm)**.

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How to Report a Medical Device Problem:

Medical device reports are submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters (health care professionals, patients, caregivers and consumers).

Mandatory Reporting for Manufacturers, Importers and Device User Facilities (Form FDA 3500A):

Find information and instructions for mandatory device reporting at:

- **Reporting Medical Device Adverse Events for Manufacturers, Importers and Device User Facilities (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)**
- **Instructions for Completing Form FDA 3500A**

(/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM387002.pdf)

- **eMDR- Electronic Medical Device Reporting (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/ucm2019327.htm)**
- **Draft Guidance for Industry and Food and Drug Administration Staff: Medical Device Reporting for Manufacturers (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359130.htm)**
- **FDA Guidance: Medical Device Reporting for User Facilities (PDF Only) (PDF - 313KB) (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095266.pdf)**

For Questions about Medical Device Reporting, including interpretation of MDR policy:

- Call: (301) 796-6670
- Email: **MDRPolicy@fda.hhs.gov (mailto:MDRPolicy@fda.hhs.gov)**
- Or write to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR Policy Branch
10903 New Hampshire Avenue
WO Bldg. 66, Room 3217
Silver Spring, MD 20993-0002

Voluntary MedWatch Reporting for Patients, Health Professionals and Consumers (Form FDA 3500):

Patients, healthcare professionals and consumers who find a problem related to a medical device are encouraged to report medical device adverse events or product problems to FDA through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Submit reports to FDA through the MedWatch program in one of the following ways:

- Using the **MedWatcher mobile app (ssLINK/UCM348271)** that allows individuals to submit voluntary reports of serious medical device problems to the FDA using a smart phone or tablet.

Download the MedWatcher Mobile App

- **iTunes Store: MedWatcher App Download (https://itunes.apple.com/us/app/medwatcher-for-drugs-vaccines/id391767048?mt=8) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Google Play Store: MedWatcher App Download (https://play.google.com/store/apps/details?id=org.medwatcher&hl=en) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Complete the MedWatch Online Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/)**
- **Download form (/Safety/MedWatch/HowToReport/DownloadForms/ucm2007307.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

To Report an Emergency

If you have identified a public health emergency, you may use the following contact information to alert the FDA:
FDA Office of Crisis Management, Emergency Operations Center

- Voice (24hr/day) phone: 866-300-4374 or 301-796-8240
- FAX: 301-847-8543

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Searching Medical Device Reports

The **Manufacturer and User Facility Device Experience (MAUDE) database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM)** contains mandatory reports filed by manufacturers and importers from August 1996 to present, all mandatory user facility reports from 1991 to present, and voluntary reports filed after June 1993. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important postmarket surveillance data sources.

Individuals are also able to request information related to Medical Device Reports by submitting a **Freedom of Information Act (FOIA) request (/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/ucm2007229.htm)** either in writing or online.

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Contact

For general questions, please **contact the Division of Industry and Consumer Education (DICE) (/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/ucm20041265.htm)** by telephone at (301) 796-7100, or by email at **DICE@fda.hhs.gov (mailto:DICE@fda.hhs.gov)**.

Additional Resources

- **MedWatch: FDA's system for voluntary reporting (https://www.accessdata.fda.gov/scripts/medwatch/)**

- MDR Database Search: This database captures MDRs that were received prior to July 31, 1996. (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMDR/Search.cfm)
- Device Advice: Regulatory Assistance for Industry on Mandatory Reporting and Regulation History (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)
- Electronic Medical Device Reporting (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/default.htm)
- CDRH Learn with Medical Device Reporting (/Training/CDRHLearn/default.htm)

More in Medical Device Reporting (MDR) (/MedicalDevices/Safety/ReportaProblem/default.htm)

MedWatcher Mobile App (/MedicalDevices/Safety/ucm385880.htm)

All At HOME Health Care

MDR POST TEST

NAME: _____ **DATE:** _____

1. **MDR** stands for Medical Device Reporting.
   TRUE **FALSE**

2. Agency/Device user facility mandated report a suspected medical device – related to death to both the FDA and manufacturer.
   TRUE **FALSE**

3. Health care professionals who find a problem related to medical devices are encouraged to report problems to FDA through MedWatch.
   TRUE **FALSE**

Instructor: _____ Date: _____