

Medical Device Epidemiology Network Initiative (MDEpiNet)

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Research Areas



Tool Development

Data Sharing



Basic Research



Data-Sharing Enabler



Product Development

At a Glance

- Status: **Active Consortium**
- Year Launched: **2012**
- Initiating Organization: **Center for Medical Technology Policy**
- Initiator Type: **Government**
- Location: **North America**

Abstract

The Medical Device Epidemiology Network Initiative (MDEpiNet) is part of the Epidemiology Research Program (ERP) at the U.S. Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH). The initiative is a collaborative program through which CDRH and external partners share information and resources to enhance understanding of the safety and effectiveness of medical devices after they are marketed.

Mission

By bridging gaps in evidence, developing datasets, and creating new methods of conducting robust analytic studies, MDEpiNet aims to develop new ways to study medical devices that improve the understanding of their safety and effectiveness throughout their life cycle.

CDRH is developing MDEpiNet in stages, with the expectation that it will ultimately become a self-

sustaining, independent public-private partnership between FDA and participating partners. By providing more complete and accurate information on device use and performance, MDEpiNet will help FDA, the medical device industry, medical professionals, and the American public make better, more informed healthcare decisions.

The MDEpiNet mission is to bridge evidentiary gaps and to develop datasets and innovative methodological approaches for conducting robust analytic studies to improve medical device safety and effectiveness understanding throughout the device life cycle.

Its objectives are as follows:

Impact/Accomplishment

MDEpiNet has advanced from concept to operational public-private partnership over the period of this project. Significant investment has been made to fund scientific projects to develop new methodology and infrastructure for medical device epidemiology and surveillance. For example, in the field of orthopedic devices, the MDEpiNet partnership resulted in the development of the International Consortium of Orthopedic Registries (ICOR), a pioneering worldwide effort to share data and perform distributed analyses on the safety and effectiveness of medical devices used in orthopedic procedures with data collected from more than 20 countries.

Links/Social Media Feed

Homepage <http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm>

Points of Contact

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Sponsors & Partners

Food and Drug Administration

Updated: **04/08/2016**