



STRENGTHENING OUR NATIONAL SYSTEM FOR MEDICAL DEVICE POSTMARKET SURVEILLANCE

UPDATE AND NEXT STEPS

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
U.S. FOOD AND DRUG ADMINISTRATION**

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BACKGROUND

In September 2012, the Food and Drug Administration's (FDA), Center for Devices and Radiological Health (CDRH) issued a report entitled "Strengthening Our National System for Medical Device Postmarket Surveillance."¹ FDA's vision for medical device postmarket surveillance is the creation of a national system that serves four primary functions:

- Communicates timely, accurate, systematic, and prioritized assessments of the benefits and risks of medical devices throughout their marketed life using high quality, standardized, structured, electronic health-related data;
- Identifies potential safety signals in near real-time from a variety of privacy-protected data sources;
- Reduces the burdens and costs of medical device postmarket surveillance; and
- Facilitates the clearance and approval of new devices, or new uses of existing devices.

The report contained four key proposed actions to help fulfill the vision for the National System:

1. Establish a unique device identification (UDI) system and promote its incorporation into electronic health information;
2. Promote the development of national and international device registries for selected products;
3. Modernize adverse event reporting and analysis; and
4. Develop and use new methods for evidence generation, synthesis, and appraisal.

The FDA recognizes that input and active participation from many key national and international stakeholders is necessary to strengthen medical device postmarket surveillance and that a national system cannot be implemented or achieved by the FDA alone. Therefore, following release of the report, FDA held a series of public meetings in September 2012 and accepted comments via our website to garner stakeholder feedback.²

This update incorporates the public input we received and describes the next steps FDA intends to take to establish a National Medical Device Postmarket Surveillance System.

¹ Report available at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301912>

² <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm111051.htm>

LAYING THE FOUNDATION FOR AN INTEGRATED SYSTEM

Medical device postmarket surveillance presents unique challenges compared to drugs and biologics due to the greater diversity and complexity of medical devices, the iterative nature of medical product development, the learning curve associated with technology adoption, and the relatively short product life cycle.

The FDA believes that privacy-protected, routinely collected electronic health information containing UDI and device-specific registries³ in selected product areas complemented by additional data sources (e.g. adverse event reports, administrative and claims data) should serve as the foundation for such a national medical device postmarket surveillance system (Figure).

Such a system would have broad patient capture, real-world generalizability, scalable and reusable infrastructure, continuous accrual of information for near real-time analysis, and use structured data with standardized nomenclature and definitions. It would be capable of providing near real-time assessments of the benefits and risks of medical devices throughout their marketed life, identifying potential safety signals, reducing the burdens and costs of medical device postmarket surveillance, and facilitating the clearance and approval of new devices, or new uses of existing devices.

In 2012, the FDA issued the proposed rule for a UDI system for all medical devices⁴, proposing a five year, phased-in, risk-based approach to UDI implementation, focusing first on the highest-risk medical devices and exempting lower risk devices from some or all of the requirements. UDI will significantly enhance postmarket surveillance activities by providing a standard and unambiguous way to document device use in electronic health records, clinical information systems, claims data sources, and registries, potentially making vast amounts of previously untapped clinical information available for assessing the benefits and risks of medical devices and more meaningfully and efficiently linking data sources (like registries and claims data).

Registries play a unique and prominent role in medical device surveillance because they can provide additional detailed information about patients, procedures, and devices not routinely collected by electronic health records, administrative or claims data. For this reason, registries will continue to serve a critical, complementary role in medical device postmarket surveillance, even as UDI becomes more routinely incorporated into electronic health information. The creation of individual registries to meet the needs of a specific manufacturer or a specific product historically has been neither efficient nor economical, and

³ A registry is a system that collects and maintains structured records on a specific disease, condition, procedure, or medical product for a specified time period and population.

⁴ <http://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/default.htm>

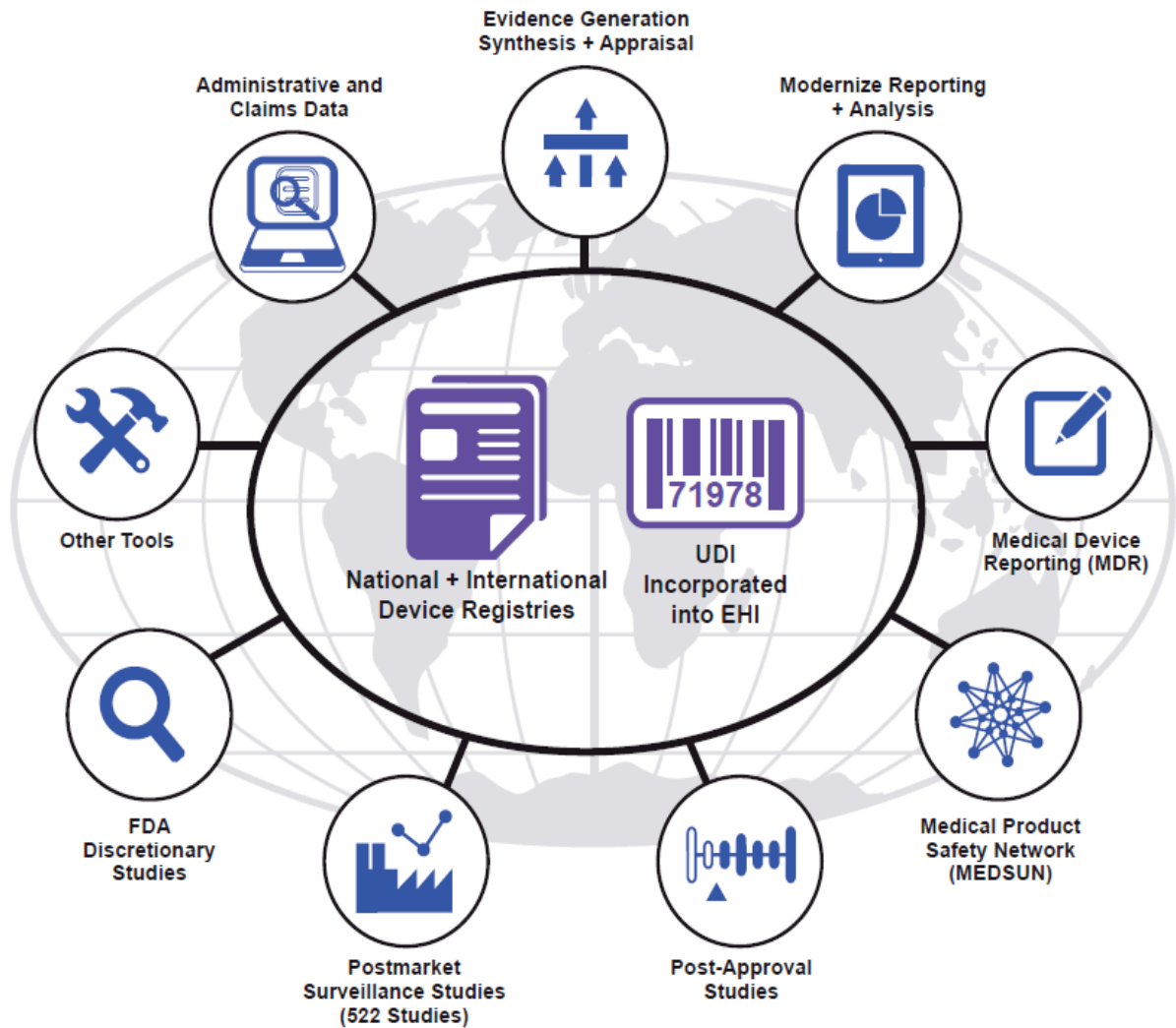


Figure. FDA believes that national and international device registries in selected product areas and electronic health information containing unique device identifiers (UDI) should serve as the foundation of our National Medical Device Postmarket Surveillance System. The system could be linked to longitudinal data, such as administrative and claims data, and would employ novel methods for evidence generation, synthesis and appraisal, modernized adverse event reporting and analysis, and would complement existing tools such as Medical Device Reporting (MDR), an enhanced surveillance network of approximately 280 hospitals (Medical Product Safety Network – MedSun), studies ordered by the FDA for selected devices (Post-Approval Studies and Postmarket Surveillance Studies), FDA research using other data sources (FDA Discretionary Studies), and other tools such as device tracking.

it is impractical and unnecessary to have registries for every medical device type. Instead, targeted registry efforts should be based on wide stakeholder input and support and should focus on selected areas of high importance as reflected by a large public health need, patient exposure, uncertain long-term or real-world device performance, or societal cost.

The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) requires expansion of FDA's Sentinel System⁵ to include medical devices. The current Sentinel data model focuses on querying privacy-protected administrative and claims data complemented, in part, by information in electronic health records (such as lab results) and maintained by partner organizations. Unfortunately, most records accessible to Sentinel lack manufacturer or brand-specific device identifiers and therefore cannot currently be leveraged to perform meaningful medical device postmarket surveillance. However, as UDIs are implemented and adopted throughout the healthcare system, current efforts can be expanded to include this essential information for the purpose of medical device postmarket surveillance. Ultimately, we envision a medical device postmarket surveillance system using distributed data sources, focusing on electronic health information containing UDI and registries linked to, or integrated with, other longitudinal data sources. FDA is not seeking to develop a centralized

repository of medical device-related electronic health information. Rather each data owner should retain physical and operational control over their data, provide input into valid use and data interpretation, and maintain patient privacy.

⁵ <http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm>

IMPLEMENTATION

In 2013, the FDA intends to pursue the following critical efforts towards creating a national medical device postmarket surveillance system (see Appendix):

1. Establish a multi-stakeholder Medical Device Postmarket Surveillance System Planning Board⁶ to identify the governance structure, practices, policies, procedures, methods and business model(s) necessary to facilitate the creation of a sustainable, integrated medical device postmarket surveillance system that leverages and complements existing and on-going efforts.
2. Establish a unique device identification (UDI) system and promote its incorporation into electronic health information.
 - Finalize the UDI rule.
 - Develop and implement a fully functional and publically accessible global UDI database (GUDID) to provide detailed, non-confidential device information to stakeholders and the general public.
3. Promote the development of national and international device registries for selected products.
 - Take steps to facilitate the incorporation of UDI into electronic health records as part of EHR certification.
 - Complete a pilot demonstrating the ability to incorporate UDI into a multi-hospital information system.
 - Complete an initial think tank report to inform the development of a roadmap for successful UDI implementation.⁷
 - Establish a Medical Device Registry Task Force consisting of key registry stakeholders under CDRH's Medical Device Epidemiology Network (MDEpiNet)⁸ Program.

⁶ FDA intends to issue a public call for nominations to establish a multi-stakeholder Planning Board that includes the medical device industry, health care provider community, medical professional societies, patient and consumer groups, third-party payers, hospitals and other health care facilities, health care data centers, government agencies, and other relevant stakeholders. The public will have an opportunity to comment on recommendations from the Planning Board before a decision is made to implement them.

⁷ This effort is conducted in collaboration with the Engelberg Center for Health Care Reform at Brookings and Chickasaw Nation Industries, Inc. See www.brookings.edu/about/centers/health/projects/development-and-use-of-medical-devices.

⁸ <http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm>

4. Modernize adverse event reporting and analysis.
 - Issue final report on the ASTER-D[†] pilots to detect and automatically report to FDA select device-related adverse events through hospital electronic health records and incident reporting systems.
 - Implement a mobile application for voluntary adverse event reporting.
 - Pilot an initial functional release of the FDA Adverse Event Reporting System (FAERS), a modernized database for adverse event reports.
 - Implement prospective “data mining” tools in at least three major device areas to enhance the identification of high quality adverse event reports and report trends and clusters.
5. Develop and use new methods for evidence generation, synthesis, and appraisal.
 - Identify gaps in current methodological efforts to promote data standardization, interoperability, and linkage between registries and disparate data sources.
 - Advance the development of interoperability between registries and electronic health records.
 - Collaborate with stakeholders and leverage on-going efforts to develop an approach for evidence synthesis to integrate registry-based information with other data sources to provide more timely and comprehensive assessments of device benefit-risk profiles.

[†] ADE Spontaneous Triggered Electronic Reporting for Devices

CONCLUSION

Postmarket surveillance of medical devices presents unique challenges. Although the United States has a robust medical device postmarket surveillance system, we believe it can be strengthened by developing a more integrated national system. Our planned strategic actions will complement our existing programs and other ongoing efforts and can be accomplished under our existing authorities within our current budget. These efforts, and the envisioned medical device postmarket surveillance system as a whole, are intended to be collaborative and transparent because we recognize that our postmarket vision cannot be implemented or achieved by the FDA alone.

We will continue to provide updates on our postmarket activities on our website.

APPENDIX

STRENGTHENING OUR NATIONAL SYSTEM FOR MEDICAL DEVICE POSTMARKET SURVEILLANCE

Update and Next Steps

SUMMARY OF 2013 PLANNED FDA ACTION

ITEM	ACTION	Deliverable Date
Medical Device Postmarket Surveillance System Governance	Establish a multi-stakeholder medical device postmarket surveillance system planning board to identify the governance structure, practices, policies, procedures, methods and business model(s) necessary to facilitate the creation of a sustainable, integrated medical device postmarket surveillance system that leverages and complements existing and on-going efforts.	9/30/2013
Establish a unique device identification (UDI) system and promote its incorporation into electronic health information	Finalize the Unique Device Identification (UDI) rule.	6/30/2013
	Develop and implement a fully functional and publically accessible global UDI database (GUDID) to provide detailed, non-confidential device information to stakeholders and the general public.	6/30/2013
	Provide UDI technical requirements and UDI electronic health record (EHR) use cases to Office of the National Coordinator for Health Information Technology (ONC) standards workgroups to facilitate UDI adoption as part of EHR certification.	9/30/2013
	Complete technical and final reports on a pilot, demonstrating issues and challenges involved in incorporating UDI into a multi-hospital information system.	12/31/2013
	Complete an initial thinktank report to inform the development of a roadmap for successful UDI implementation addressing critical issues including: 1) opportunities and challenges associated with capturing UDIs in claims; 2) steps necessary for implementation and integration of UDI within electronic data infrastructure of care delivery sites; and 3) patient and provider access to and linking of device information across data sources.	6/30/2013
Promote the development of national and international device registries for selected products	Establish a Medical Device Registry Task Force consisting of key stakeholders under CDRH's Medical Device Epidemiology Network (MDEpiNet) Program to: 1) identify existing registries that may contribute to the system; 2) leverage on-going registry efforts focused on quality improvement, reimbursement, patient-centered outcomes and other activities to best meet the needs of multiple stakeholders; 3) identify priority medical device types for which the establishment of a longitudinal registry is of significant public health importance; 4) define registry governance and data quality practices that promote rigorous design, conduct, analysis, and transparency to meet stakeholder needs; and 5) develop strategies for the use of registries to support premarket approval and clearance.	6/30/2013

STRENGTHENING OUR NATIONAL SYSTEM FOR MEDICAL DEVICE POSTMARKET SURVEILLANCE

Update and Next Steps

SUMMARY OF 2013 PLANNED FDA ACTION, Continued

ITEM	ACTION	Deliverable Date
<p>Modernize adverse event reporting and analysis</p>	<p>Issue final reports on two pilots demonstrating use of ASTER-D for the detection and automated reporting of select device-related adverse events through hospital electronic health records.</p>	<p>12/31/2013</p>
	<p>Implement a mobile application for voluntary adverse event reporting.</p>	<p>6/30/2013</p>
	<p>Pilot an initial functional release of the FDA Adverse Event Reporting System (FAERS), a modernized database for adverse event reports.</p>	<p>12/31/2013</p>
	<p>Implement prospective “data mining” tools in at least three major device areas to enhance the identification of high quality adverse event reports and report trends and clusters.</p>	<p>9/30/2013</p>
<p>Develop and use new methods for evidence generation, synthesis and appraisal</p>	<p>Identify gaps in current methodological efforts to promote data standardization, interoperability, and linkage between registries and disparate data sources.</p>	<p>9/30/2013</p>
	<p>Advance the development of interoperability between registries and electronic health records by: 1) beginning collaboration with stakeholders on the use of structured data capture capabilities within electronic health information sources; 2) facilitating a demonstration pilot focusing on registry-EHR integration; and 3) assessing methodologies to optimize linkage of registries with other longitudinal data sources such as administrative and claims data.</p>	<p>9/30/2013</p>
	<p>Collaborate with stakeholders and leverage on-going efforts to develop methodology for evidence synthesis for two classes of implantable devices to combine diverse data sources and/or combine data from multiple registries to provide more timely and comprehensive assessments of device benefit-risk profiles.</p>	<p>9/30/2013</p>



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