FDA PUBLIC MEETING
MEDICAL DEVICE USER FEE AMENDMENTS
2023-2027
OCTOBER 27, 2020

USA PATIENT NETWORK
MDUFA V
AND
THE CONSUMER
PENNY BURAU & LINDA J L RADACH
HOW’S IT WORKING?

MISSION & METRICS

Industry/FDA

MISSION: Resources & Process

METRICS:
- Speed to Market
- Quality Review Processes
- Response Times

Patients

MISSION: Improved Outcomes

METRICS:
- Safety & Effectiveness
- Patient Outcomes
- Quality & Reliability
HOW’S IT WORKING?

FDA and INDUSTRY GRADE

A (ACCESS)

PATIENT GRADE

F (AILING)
HOW TO IMPROVE?

PRIORITIZE SAFETY & EFFECTIVENESS

510(k) Predicates
NESTcc Clinical Data
Balanced Resources for Pre and Postmarket Adverse Event Reporting Education
How to Improve?

What Types of Events Should I Report?

You should report any adverse event that happens after getting a vaccine, even if you are not sure that the vaccine caused the adverse event. It is especially important to report any adverse event that resulted in hospitalization, disability, or death. If you are not sure that a certain type of adverse event should be reported to VAERS, talk with your healthcare provider.

Healthcare providers are required by law to report certain adverse events. To get a list of these, please call 1-800-822-7967 or go to https://vaers.hhs.gov/report-event.html

How Do I Report?

Go to vaers.hhs.gov then choose one of two ways to report to VAERS:
1) Report online (preferred method)
2) Report using a Writable PDF Form. Download the Writable PDF Form to your computer, complete it and then return to the VAERS website to upload the completed form. Important: Use a desktop or laptop computer on which you can securely save a document that contains protected health information, personal identifiers or other sensitive personal or patient information.

If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967. Operates on duty from 9:00 a.m. to 5:00 p.m., Eastern Time, Monday through Friday. After you submit a report, VAERS staff may contact you for additional information.

CDC and FDA use VAERS data to monitor vaccine safety. VAERS data are also available to the public after all identifying information, such as names and addresses are removed to protect the privacy of the patient.

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a separate federal program that provides compensation to individuals whose injuries may have been caused by certain vaccines. Please be aware that reporting an event to VAERS does not constitute filing a claim with the VICP. Information on the VICP can be obtained by calling 1-800-338-2382 or visiting their website at https://www.hrsa.gov/vaccinecompensation/

For More Information

• Centers for Disease Control and Prevention For general information on vaccines and immunization schedules you can call 1-800-232-2322 or visit www.cdc.gov/vaccines.
• FDA For safety and effectiveness information on FDA-licensed vaccines you can call 1-888-354-6696 and visit www.fda.gov/ohrms/dockets/dockets/vib.htm.

VAERS

vaers.hhs.gov
Tel: 1-800-822-7967
Fax: 1-877-722-0566
info@vaers.org

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
Food and Drug Administration
THE ECOSYSTEM AND MDUFA

PRIORITIZE PATIENT OUTCOMES

Business Focus on Quality
Increased Presence of Patient Voice
THE ECOSYSTEM AND MDUFA

BUSINESS CASE FOR QUALITY

- Provides transparent, objective information
- Protects Patient Outcomes
- Reduces costs of recall events by half
  ON AVERAGE - $2.5-$5 billion per year & 10-13% Stock Price Jump
- Increases revenues $3.5 Billion

https://www.mckinsey.com/~/media/McKinsey/dotcom/client_service/Public%20Sector/Regulatory%20excellence/The_business_case_for_medical_device_quality.ashx
THE ECOSYSTEM AND MDUFA

BUILDING AN ENVIRONMENT OF QUALITY

- Adopt quality practices used by other industries such as life testing and failure analysis
- Cross research biocompatibility of materials
- Use quality materials to lengthen product lifecycle and reduce revisions.
- Develop integrated, cross team development processes

https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/public%20sector/regulatory%20excellence/the_business_case_for_medical_device_quality.ashx
THE ECOSYSTEM AND MDUFA

INCREASED RESPONSIVENESS TO PATIENT VOICE

Pervasive Patient Representation
Balanced Patient Voice (Rare Disease, Harmed, Public)
THE ECOSYSTEM AND MDUFA

ALIGNED MISSION AND METRICS

Prioritizes safety and effectiveness
Postmarket equally balanced with premarket
Pursues quality and reliability
Serves the mission of protecting public health