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AN ELABORATE REVIEW OF CURRENT POST-MARKETING SURVEILLANCE TRENDS FOR MEDICAL DEVICES IN THE USA

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ABSTRACT

The current healthcare infrastructure is built upon medical devices. All aspects of their manufacture, advertisement, and utilization need to be controlled considering their importance in the daily practice of medicine. Higher dependability performance of the medical device can lead to higher reliability of diagnosis treatments and diagnosis when evidence-based conformance assessment of medical device during PMS is standardized and relies on traceability of medical device measurements. The Food and Drug Administration (FDA) is in charge of regulating PMS-related activities, which include mandated reporting platforms like Medical Device Monitoring (MDR) and as cutting-edge instruments that improve PMS performance by gathering and analyzing actual data. The contribution of post-approval studies (PAS) and post-market clinical follow-up (PMCF) studies to the generation of extra safety and performance data is also examined in this article. Important issues are covered, such as data quality, reporting compliance, and integrating emerging technologies like machine learning and artificial intelligence into PMS. The purpose of this review is to give readers a thorough overview of the PMS framework that is currently in place in the United States, emphasizing its advantages, disadvantages, and potential improvements for medical device safety and monitoring.

Keywords: **Medical Devices, Post-Market Surveillance (PMS), Food and Drug Administration (FDA), Medical Device Reporting (MDR), Data Quality, Reporting Compliance, Regulatory Compliance, post-approval studies (PAS), post-market clinical follow-up (PMCF)**

INTRODUCTION:

Medical devices, or MDs for short, are essential components of today's healthcare system. Their production, sale, and use are strictly regulated on a national and worldwide scale because to their vital role in safeguarding human health. MD-related activities are divided into two categories by regulations and guidelines: pre-market procedures and post-market surveillance (PMS), each of which is governed by different international laws and standards.

"Post-market surveillance" refers to the set of activities that manufacturers perform to collect and evaluate data from medical equipment they have released onto the market, determine whether any modifications are required, and keep an eye on the situation. Post-market surveillance is an essential tool for ensuring that medical devices continue to be safe and effective and that the right steps are taken in the event that the potential risks of using the device outweigh the benefits. Examining post-market surveillance data might also point out areas where the medical device can be improved **[1]**. The importance of medical devices in the delivery of healthcare is growing on a global scale. These technologies are medications that have been identified from other comparable or related articles that are intended for use in the diagnosis of illnesses or other conditions as well as in the "cure, mitigation, treatment, or prevention of diseases" and do not primarily accomplish their goals through chemical action. The World Health Organization (WHO) created a Medical Device Unit in recognition of the significance of medical devices. In order to facilitate device use globally, this section aims to concentrate research and policy on improving access to medical devices in low-resource areas, exchanging innovations, and training biomedical professionals **[2]**. Medical devices can improve disease identification and treatment, but there are significant hazards associated with them as well. The growth of therapeutic options and the preservation of public health are balanced by governmental regulatory bodies that oversee the approval of new medical devices. Regardless of the criterion for market authorization that is set, concerns regarding the safety and efficacy of a technology will always exist once it is incorporated into clinical practice. Medical devices do, however, provide a variety of unique challenges, including the operator variability, persistent implantation, procedural learning curves, and some devices' high level of technology.. Medical device safety and efficacy are governed by the "Food

and Drug Administration (FDA)," an organization under the "Department of Health and Human Services (HHS)." In terms of medical device regulation, 1982 saw the establishment of the FDA's "Center for Devices and Radiological Health (CDRH)". Under this framework, manufacturers of medical devices—as well as occasionally user facilities, device labellers, and importers—must adhere by a number of rules to ensure the safety and effectiveness of the devices and prevent them from being compromised or mislabeled. These specifications call for things like tracking devices and reporting removals and corrections **[3]**. The FDA notifies patients and doctors through safety messages when PS identifies possible device issues. Safety notifications from the FDA, manufacturers, or distributors are triggered by actual patient injuries **[4]**. For example, a 2012 safety alert described a faulty component in a "automated external defibrillator" that caused the device's ability to deliver high-voltage therapy to unexpectedly break down **[5]**. Recalls are an indication of larger problems with a device. The plan for managing the recall process must be developed by the manufacturer, who may choose to execute the recall on their own initiative or in response to the FDA application. More severe FDA recalls, including those involving "metal-on-metal designs" for hip prostheses, necessitate stricter oversight and auditing of provider or end-user communications. Safety warning and recall data is tracked by publicly searchable databases **[6]**.

CLASSIFICATION OF MEDICAL DEVICE

The Food and Drug Administration (FDA) in the United States divides medical devices into three groups according to the degree of control required to ensure the device's efficacy and safety. The regulatory standards that the gadget must adhere to are also determined by its categorization **[7]**.

Classification	Description	Examples	Post-Marketing Surveillance Requirements	Relevant CFR Sections
Class I	**Devices that pose the least danger. Usually governed by general regulations**	**Elastic bandages, Examination gloves**	**Manufacturers are required to adhere to general controls, which include PMS, (GMP), and labeling.**	**21CFR Part 803 (MDR) 21 CFR Part 820 (QSR)**
Class II	**Device danger than Class1.Necessitate specific controls in addition to broad ones**	**X-ray machines, Infusion pumps**	**Special controls, like performance benchmarks, post-market surveillance, patient registries, and FDA guidelines, must be adhered to in addition to general controls.**	**21 CFR Part 803 (MDR) 21 CFR Part 820 (QSR) 21 CFR Part 822 PMS**
Class III	**Devices that pose the most risk. (PMA) is necessary**	**Pacemakers, Heart valves**	**Subject to the strictest regulations. requires comprehensive post-market supervision, including periodic reporting of adverse events and clinical trials, as well as PMA.**	**21 CFR Part 803 (MDR) 21 CFR Part 820 (QSR) 21 CFR Part 822 (PMS)**

Procedure of post marketing surveillance:

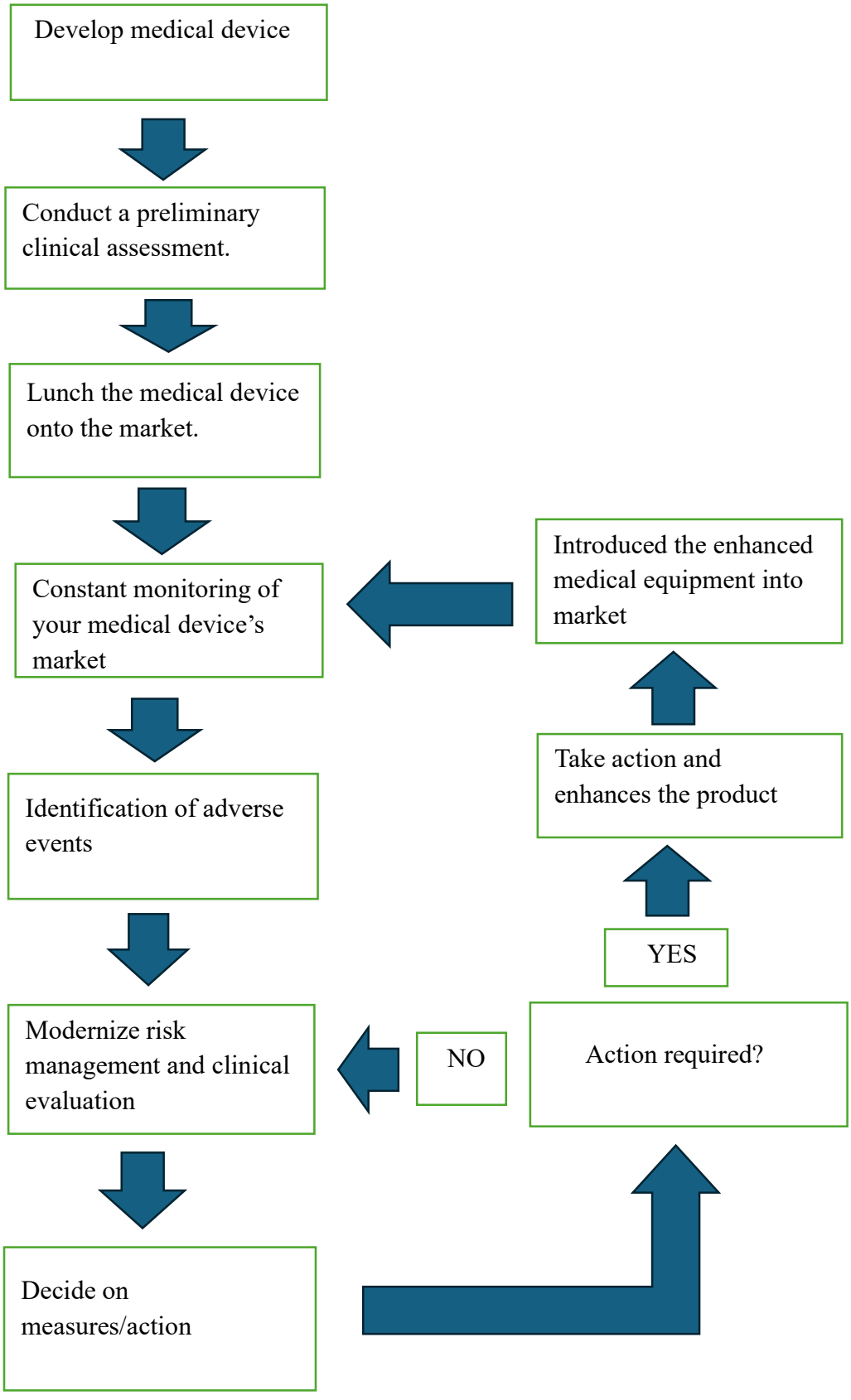

Table 1: Time lines for submission of PMS

Activity	Description	Timeline	CFR Section / Guideline
Device Registration and Listing	List the Device in the FDA database and register with the FDA	Before marketing the device in the USA	21 CFR 807
Initial Post- Market Surveillance plan	Create and record a PMS plan.	Before device marketing	21CFR 820.100(a)
Adverse Event Reporting (MDR)	Report significant adverse events to FDA	Within 30 days of becoming aware of the event	21 CFR 803.50(a)
Serious injury Reporting	Report events that resulted in serious injury or death	Within 10 days of becoming aware of the event	21 CFR 803.50(b)
Device Malfunction Reporting	Report device malfunctions that could lead to death or serious injury.	Within 30 days of becoming aware of the event	21CFR 803.50(a)
Periodic Safety Update Reports (PSUR)	Submit summary of PMS data and analysis	Annually, biannually, or as specified by the FDA	Guideline-based on device classification and risk
Corrective and Preventive Actions (CAPA)	Implement and document CAPA for identified issues.	Ongoing, as issues are identified	21 CFR 820.100(b)
Corrections and Removals Reporting	Report any changes made in an effort to reduce health hazards	Within 10 working days of initiating the action	21 CFR 806
Design Changes and Reassessments	Reassess and document changes to the PMS plan based on findings.	Periodically, at least annually	21 CFR 820.30(g)
Annual Establishment Registration Renewal	Renew the registration of the manufacturing establishment with the FDA.	Annually between October 1 and December 31	21 CFR 807.21
Annual Report for Approved PMA Devices	Submit an annual report summarizing the PMS activities and findings.	Annually, on the anniversary date of PMA approval	21 CFR 814.84

ADVANTAGES OF POST MARKETING SURVEILLANCE OF MEDICAL DEVICE'S

Medical device post-market monitoring, or PMS, has several benefits that improve device performance, patient safety, and regulatory compliance.

Improved safety for patients

Pre-market testing may not have shown adverse events or device faults, but PMS aids in their identification. Constant observation makes it possible to identify hazards early on and take action to reduce them, eventually protecting patient health **[8]**.

Enhanced functionality of the device

Manufacturers may improve the functionality and design of their devices by using PMS data, which gives them insights into how their products operate in real-world situations. Innovation and iterative improvements depend on this feedback cycle.

Regulatory compliance

To guarantee that manufacturers continue to adhere to safety and efficacy requirements, organizations like the FDA have mandated PMS compliance. By doing this, recalls and fines from the authorities are avoided.

Cost-effectiveness

Preventing expensive recalls and lawsuits can be achieved by using PMS to identify possible problems early. Manufacturers can protect their finances and brand from the harm caused by gadget malfunctions by solving issues as soon as they arise **[9]**.

ENHANCED PUBLIC TRUST

Patients, the public, and healthcare professionals all benefit from transparent PMS actions. Strong PMS demonstrates a dedication to quality and safety, which builds brand loyalty and a favorable reputation.

TYPES OF POST MARKETING SURVEILLANCE:

Mandatory Reporting Systems

Medical Device Reporting (MDR): The FDA is authorized to regulate "medical devices under Section 517 of the Federal Food, Drug and Cosmetic Act". The Safe Medical Device Act of 1990 and the Medical Device Amendments of 1992 made changes to this section 3.

In accordance with 21 CFR 803, the Food and Drug Administration has required producers, importers, and user facilities to comply with the MDR standards. One of these responsibilities is to notify the FDA of any significant adverse events related to medical devices so that the issues can be quickly identified, minimized, and fixed. In the past, the MDR requirements were exclusive to importers and manufacturers.

Post-Approval Studies (PAS)

The post-market requirements for devices include PS studies under "Section 522 of the FD&C Act" as well as post-approval studies necessary at the time of approval of a device, in addition to tracking systems like MDR and establishment registration. Applications for "humanitarian device exemption (HDE)", premarket approval (PMA), or "product development plan (PDP)" may be submitted **[10]**.

Device Tracking

Device tracking is intended to guarantee that producers of specific devices set up tracking mechanisms that allow them to quickly identify devices that are being distributed commercially. Through the facilitation of device recalls and patient notifications, device monitoring systems can lower significant hazards **[11]**.

On August 29, 1993, regulations implementing the SMDA's tracking obligations went into force.

Device manufacturers must create, record, and maintain a tracking system that enables them to promptly alert distributors, medical professionals, and patients to a recall or a major health concern. FDAMA modifies the range of devices that may be required to track,

and also mandates that the agency send out a "order" telling manufacturers to implement a tracking mechanism. By making revisions to the 1993 regulation, this final rule gives FDA more authority to issue and revoke tracking orders in response to shifting risk levels, therefore codifying the FDAMA changes.

Post-market Surveillance Studies (Section 522 Studies)

In the USA, the term "post-market surveillance" (PMS) refers to the procedures and mechanisms put in place by producers, authorities, and other interested parties to keep an eye on the functionality and safety of medical devices after they have been put on the market. Ensuring continued safety, efficacy, and regulatory compliance is the main objective. Understanding long-term device performance, spotting unanticipated bad occurrences, and initiating appropriate corrections or recalls when problems occur are all made possible using PMS.

Post-Market Clinical Follow-up (PMCF) Studies

One kind of clinical investigation that is carried out on medical devices after they have been put on the market is called a “Post-Market Clinical Follow-up (PMCF)” study. The purpose of PMCF studies is to gather more information on the functionality and safety of medical devices as well as to find any potential problems that might not have come to light during pre-market testing **[12]**.

Quality System Regulations (QSR)

On February 02, 2024, the "U.S. Food and Drug Administration (FDA)" released a final rule1 that modified the Quality System Regulation (QSR)2's requirements for "Good manufacturing practice (GMP)" for devices and brought them into compliance with globally recognized standards outlined in "ISO 13485:2016In early 2018, the FDA initially declared its intention to better "align U.S. regulatory requirements with ISO 13485." The FDA acknowledged the need to update the QSR in the preamble of both the proposed and final rules. The QSR had not undergone significant revisions since 1996. ISO 13485 has been instrumental in the development and maintenance of medical device quality management standards since its launch in 1996. Each revision of the standard has aimed to align more closely with the Quality System Regulation (QSR) and other related standards, enhancing consistency and integration in the field.

RECENT POST MARKETING SURVEILLANCE OF MEDICAL DEVICE'S

522 Order Number	Manufacturer	Device Name	Medical Specialty	Study Name	Study Status	Date Original Plan Accepted	Date Current Plan Accepted
PS210001 / PSS001	Abbott Diabetes Care Inc.	Freestyle libre 2 flash glucose monitoring system	Clinical Chemistry	Post market Surveillance	Delayed	5/25/2021	1/20/2023
PS160001 / PSS001	Bayer Healthcare LLC	Essure system for permanent birth control	Obstetrics /Gynecology	post market Surveillance Study	Ongoing	9/2/2016	7/1/2022
PS240001 / PSS001	Beta Bionics Inc.	Ilet dosing Decision software	Clinical Chemistry	Ilet Post market Surveillance Study	Study Pending	5/1/2024	NA
PS200005 / PSS001	Caldera Medical Inc.	Desara One Single Incision Sling System	Gastroenterology /Urology	Post market Surveillance Study	Delayed	6/05/2020	7/19/2023
PS230003 / PSS001	Empower Medical Devices	Breast Implant Removal Device (BIRD) previously the Bateman Bottle	General & Plastic Surgery	Bateman Bottle Post Market Surveillance Study	Study Pending	6/5/2024	NA
PS230004 / PSS001	Laminate Medical Technologies Ltd.	Vasq	Cardiovascular	VasQ Post market Surveillance Study	Delayed	2/22/2021	6/21/2023
PS110004 / PSS001	Merit Medical Systems Inc.	Surfacer inside-out access catheter system	Cardiovascular	Surfacer Post market Surveillance Study	Ongoing	7/28/2023	3/12/2024
PS210002 / PSS001	Nexus CMF	Surfacer inside-out access catheter system	Dental	Prospective Post market Surveillance Study Plan	Progressive inadequate	2/4/2011	11/14/2016
PS210002 / PSS001	Pentax	Tmj fossa-eminence/condylar prosthesis system	Gastroenterology/ Urology	Post market Surveillance (PS) Study	Delayed	6/17/2021	9/15/2021
PS230005 / PSS001	Tandem Diabetes Co.	Control-iq technology	Clinical Chemistry	Post market Surveillance (PS) Study	Ongoing	6/17/2021	5/3/2024

CONCLUSION:

In conclusion, the FDA's strict supervision of post-market surveillance (PMS) for medical devices is essential to guaranteeing the security and effectiveness of these devices used in healthcare. By leveraging mandated reporting platforms such as Medical Device Reporting (MDR) and innovative tools for real-world data collection and analysis, the FDA enhances the reliability of medical device performance. The integration of post-approval studies (PAS) and post-market clinical trials.

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