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ENHANCING MEDICAL DEVICE SAFETY: A REVIEW OF NCAR AND REDMA INITIATIVES

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Abstract

Post Market Surveillance (PMS) plays a vital role in ensuring the continued safety performance and effectiveness of medical devices throughout their life. This studyhighlights the importance of the National Competent Authority Report (NCAR) program and its regional counterpart, the REDMA (Red de Evaluación de Dispositivos Médicos de las Américas) initiative by the Pan American Health Organization (PAHO). A structured literature review was conducted using official regulatory documents and published reports from IMDRF, PAHO, and the World Health Organization. This program strengthens the early detection of device-related safety issues, ultimately improving the patient safety on a global scale. In addition to the structured format to facilitate the exchange of information,Similarly, the REDMA program supports regional collaboration by standardizing adverse event reporting and enabling communication among national regulatory authorities in the Latin America and Caribbean. Finally, the article concludes that with these initiatives, there is a high chance of attaining global regulatory alignment and enhancement of the safety of public health.

INTRODUCTION

According to world health organization (WHO) Post Marketing Surveillance is a set of activities conducted by manufacturers, to collect and test and experience gained from medical devices that have been placed on the market, and to identify the need to take the action. A vital method is to ensuring that medical devices remain safe and effective is post-market surveillance, which also makes sure that if the risk of continuing to use the device surpasses the benefit, appropriate action is done [1].

The Global Harmonization Task Force (GHTF) SG2 was the original developer of the National Competent Authority Report (NCAR) program in 1995 and was later adopted by the International Medical Device Regulators Forum (IMDRF**)**. This program aims to enhance the safety and effectiveness of medical devices through improved post-market surveillance.

A regulatory guidance document, referred to as WG N14, was introduced by the Global Harmonization Task Force (GHTF) Study Group 2 (SG2) for the monitoring of adverse events of medical devices. It includes information about the national competence reporting program and instructions on how to report an event in NCAR [2].

IMDRF will be centred on enhancing robust premarket review and Post Market Surveillance. As a component of their mandate, IMDRF has also established on-going communication and cooperation with other regulatory bodies. Harmonization is a long-term endeavour and an on-going process. To overcome those challenges as well as several others, all-encompassing approaches and in advance of implementing the policy, plans must be established.

OBJECTIVE

The objective of this review is tosummarize the present state of research on IMDRF NCAR by reviewing recent studies. This review aims to highlight NCAR Program in order toachieve better understanding ofPost Marketing Surveillance

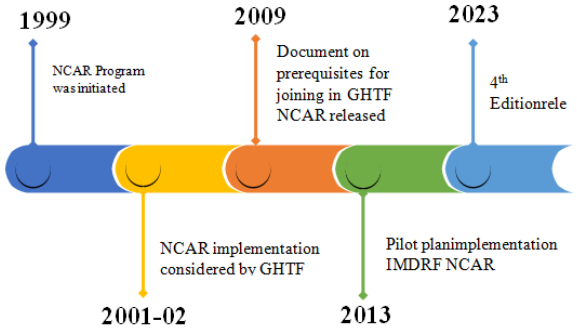

Figure 01: History of NCAR

Participants in IMDRF NCAR

The participation in this program confined to management committee regulators, the current participants in this program are The United States of America, Canada, Brazil, Europe, Russia, South Korea, China, Japan, Singapore, Australia. To Participate in this program, they must be IMDRF Managerial Committee (MC) regulator and they are required to review key

aspects of exchange of information and confidentiality before joining. Application will be scrutinised by study group 2 of GHTF and steering committee. The official observers of this programme are world health organization (WHO). NCAR program offers two degrees of participation they are full participant and associate participant.

Associate participant: An organization can be part of this "program" but only receive public information. A National Competent Authority (NCA) is not a requirement for associate participation.

Full Participant: An NCAR program participant that obtains information from other NCAR participants, both publicly and privately. Only NCAs are eligible for full participant [3, 4].

Pre requisites for joining into NCAR PROGRAM as full participant

1. **Existence of national adverse event program**: An active national program is essential prerequisite to participate in the program. NCA receive reports from manufacturers of medical devices or from user reports of medical devices. This information will be utilised by NCA to prepare NCAR NCAs must receive reports from inside their own jurisdiction in order to fully engage in the NCAR exchange program.
2. **Training:**All GHTF SG2 publications and principles, as well as risk assessment or health hazard analysis principles, must be incorporated into training for NCAs that are interested in participating completely in the NCAR program. It might be required by trainers to recoup the expenses related to giving guidance and training.
3. **Mandatory NCA establishment:** The only people eligible for full participation are NCAs because Full Participants may receive extremely sensitive or commercially sensitive information in confidence [4].

Pre requisites for joining as associate participant

Training: since associate participants restricted to exchange public information. The training they receive to them will be based on document exchange procedures (GHTFSG2 79).

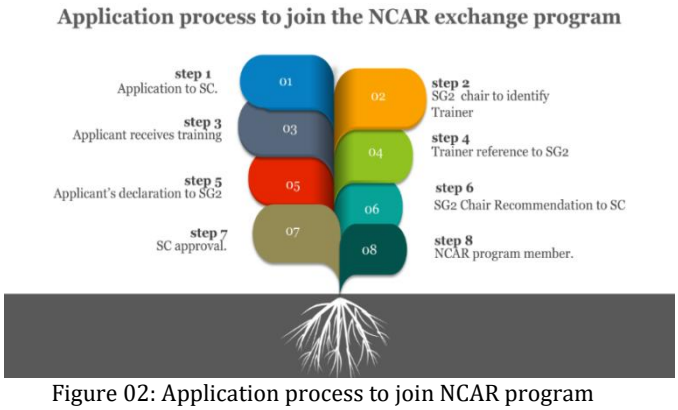

Figure 02: Application process to join NCAR program

NCAR REPORTING GUIDELINES

Exchange criteria

The exchange criteria of adverse event of medical device can be of these categories

1. Unforeseen public health crisis
2. Insights from national trend studies
3. Information request and sharing

Incident resulting in an unexpected public health risk

Medical device-related incidents that have resulted in or are very likely to result in an unexpected, significant public health risk and meet the following requirements are reportable:

1. An applicant, patient, or other person passes away
2. Serious harm to a user, patient, or other individual
3. There were no fatalities or severe injuries, but if the incident happens again, it could cause fatality of a user, patient, or other individual or suffer severe injuries. These occurrences are referred to as close incidents in some jurisdictions **[**5].

Insights from a national trend analysis

A Pattern identified by one NCA is shared with more NCAs when:

1. The device's incident rate is significantly higher than what is recorded in the manufacturer's data or significantly higher than that of devices of a similar nature, and
2. There has been or is anticipated to be a significant public health risk as a result of the occurrence.

Request and Disseminating Information:

An NCA can inquire for or disclose details on an identifiable device or group of devices pertaining to:

1. Specific events,
2. A rise in the seriousness or frequency of previously reported issues,
3. Significant weaknesses or deviations in A Project Management System (PMS) or Quality Management System (QMS) of a manufacturer,
4. Changes in the regulatory situation of the devices.

The implications of these issues may include:

1. A serious public health threat that has occurred or is highly likely to occur,
2. Potential impacts on other domains.
3. The appropriate NCA may find out whether other NCAs implementing the NCAR Exchange Program have encountered equivalent situations and what steps- such as recalls or Field Safety Corrective Actions (FSCA), have been taken or considered to resolve the issue.

Exchange format: The exchange format is NCAR form is used for exchange of reports.

However, whether it's confidential or not, if the receiving NCA requires further details about a certain NCAR, they might need to get in touch with the authorizing NCA. Only then can the receiving NCA get in touch with the device's manufacturer.

If a receiving NCA believes that national action is required, it should contact the authorized NCA to make sure that the onset of any action doesn't compromise the continuing risk evaluation, and no important data is unnecessarily disclosed. Neither confidential nor non-confidential NCAs may exchange any information that could be used to identify a specific patient.

Table 01: Differentiating confidential and non-confidential reporting mechanisms

Confidential	Non confidential
1.Authoring NCA sends report as confidential ↓ 2. A copy sent to NCAR secretariat ↓ 3.Reference confirmation by NCAR secretariat ↓ 4.Circulation of report to other NCAR members who have confidentiality agreement. ↓ 5.Summaries of feedback report should be provided in the sec 28 of NCAR form ↓ 6. If NCA and the NCAR secretariat do not have a confidentiality agreement and anonymise meta data should be sent to NCAR secretariat.	1. Authoring NCA sends report as confidential ↓ 2. A copy sent to NCAR secretariat ↓ 3. Reference confirmation by NCAR secretariat ↓ 4. Circulation of report to other NCAR members ↓ 5. Summaries of feedback should be provided as per request for information template.

NCAR Secretariat and its role

The entity that, in accordance with this advice, supports and oversees the sharingof NCARs between other NCAR participants and reporting National Competent Authorities (NCAs). All NCARs are stored and managed by the NCAR Secretariat.

Role:

1. To maintain a repository of all NCARs communicated through the NCAR Exchange Program.
2. Validate that the exchange criteria are appropriately applied in order to track the NCAR Exchange Program's consistency and quality. Proper terminology and documentation are used.
3. To periodically compile data analysis and reports regarding NCAR Exchange Program participation
4. To facilitate instruction regarding the NCAR Exchange Program.
5. Effectively maintaining the NCAR Exchange Program participant list [5, 6].

CASE STUDIES

1. **Hemodialyzer**

   An examination of the deaths of numerous patients with multiple hemodialyzer units found that the dialyser these patients were using was not produced in compliance with the right guidelines.

   • The manufacturing records stated that the dialysers were sold to a single hospital; however, the deaths occurred from multiple hospitals that were not connected to the hospital listed in the manufacturer's records. Furthermore, the filaments used in the dialyzers were constructed from a material that had not been certified for such use, resulting in toxic leachate when exposed to blood. In response, the National Competent Authority (NCA) swiftly shut down the manufacturing facility and informed all member nations about the issue through a NCAR.

2. **Breast implant**

   Reports of fatalities and severe injuries that occurred six months after a breast implant. The symptoms of patient suggestthat a chemical used in the production of silicone as the source of their poisoning. During this inspection, the NCA found that a potentially hazardous gel had been used in the production of implants. According to both the manufacturer's records and the NCA's investigation, this gel was utilized in only five production batches. To alert the countries that received these five batches, the NCA issued a notification regarding the issue. (5)

3. **Zirconia femoral heads**

   This case was reported in the year 8th October 2001. The manufacturer provided 80% of the global market for zirconia femoral heads. Nearly all implant suppliers obtained their zirconia femoral heads from this single manufacturer. The problem was reported as disintegration at first. investigation reveals that the problem lies in Combination of Processing change and marginal implant geometries which can severe the damage, employed for healing in the first place. Outcome of the reported event is maximum recalls are reported from Australia and rest of world recall restricted to 8 batches. The regulatory body of Australia was criticised by MC for media release of confidential information **[7]**.

Statistical Analysis

The assessment of NCAR program relies mainly on regular reports released by Global Harmonization task force GHTF and subsequently by the international medical device regulatory forum (IMDRF). These documents offer details on the count of valid NCARs exchanged their categorization across various medical device industries and the conditions under which these reports are disseminated among involved regulatory bodies [8,9].

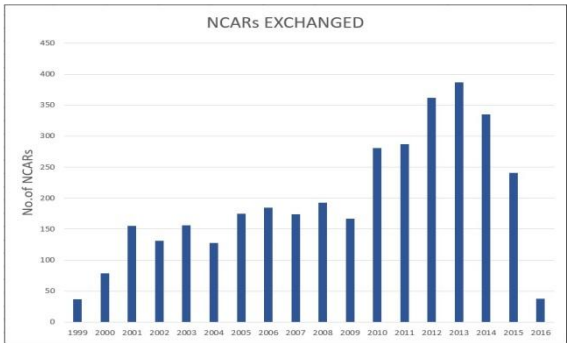

Figure 03: Valid NCAR's exchanged

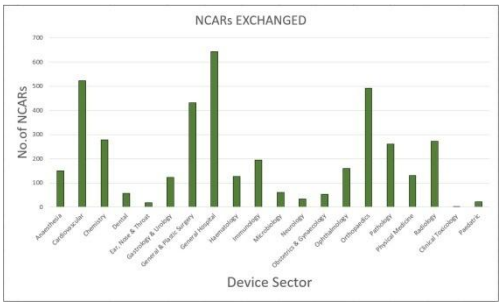

Figure 04: NCAR classification as per device sector

Data from the NCAR working group indicates that, following the program's relaunch in 2015, a total of 38 reports were generated between October 2015 and September 2016, out of which 29 were considered valid, with only one report being categorized as invalid during the functional phase. Among the valid reports originating from non-European Union countries, approximately 56% were publicly accessible, highlighting efforts toward transparency in regulatory communication.

Of the valid reports from non-EU countries, 56% were made public, while 8 out of 26 NCAR reports did not comply with IMDRF/NCAR WG/N14 standards. According to these outcomes, it's critical to develop new protection measures. agreements between the Management Committee's regulators for improved NCAR communication and increased program participation [10].

PAN AMERICAN HEALTH ORGANIZATION -PAHO

The Pan American Health Organization (PAHO) is one of the major international health agencies for the Americas. It works with countries throughout the region to improve and protect people's health.

To combat infectious and non-communicable illnesses and their root causes, this organization had a technical collaboration with its member countries in order to foster medical and health care facilities and also help for disaster preparedness through various initiatives. PAHO is committed to providing everyone with access to high-quality healthcare when they need it, without fear of sliding into poverty. PAHO strives to promote every individual's right to good health.

PAHO is affiliated member of the IMDRF, introduced a mirror programme in collaboration with IMDRF [11,12].

Table 02: Relationship between IMDRF original programs and corresponding PAHO mirror initiatives

Original program	Mirror program	Coordinator
NCAR Exchange Program	REDMA	Cecmed, cuba
Good Regulatory Review Practices	Good Regulatory Review Practices	Invima, colombia
Personalized medical devices	Personalized medical devices	Anmat, argentina
Adverse Event Terminology	Adverse Event Terminology	Ministry of health, uruguay

REDMA

The REDMA (Red de Evaluación de Dispositivos Médicos de las Américas) program, developed by the Pan American Health Organization (PAHO), serves as a regional counterpart to the NCAR exchange system. Conceptualized in 2014 and initiated through a pilot phase in 2017, REDMA was designed to facilitate structured communication and information exchange related to adverse events associated with medical devices among national regulatory authorities (NRAs) within the PAHO network.

The initiative seeks to normalise the reporting process and to improve regional co-operation in materiovigilance through the systematic exchange of safety related information. The complete implementation of REDMA was accomplished in march 2019 with its incorporation into regional platform on innovation access and health technologies (PRAIS), enhancing its operational structure. At present the program consists of six full participants and eleven associate participants. Recent reports indicated that around 39 adverse events reports have been shared with in the network, with 26 designated as confidential and 13 available to public. Regarding risk classification, documented medical devices fall into various categories such as low, low – moderate, moderate- high, highrisk devices illustrating the varied nature of reported occurrences, Cardiovascular devices are the most common reported category, making upto21% cases, underscoring their vital importance and related safety issues in the health care system. In summary REDMA is essential for enhancing regional regulatory capabilities, advancing adverse event reporting frameworks and fostering the standardization of medical device safety protocols throughout Latin America and the Caribbean [13,14].

Table 03: Comparison between IMDRF, NCAR and REDMA

Feature	IMDRF NCAR	PAHO REDMA
Organization	International Medical Device Regulators Forum (IMDRF)	Pan American Health Organization (PAHO)
Scope	Global – harmonized framework for confidential exchange of post-market safety reports among regulators.	Regional – Latin America & Caribbean, focusing on adverse event reporting and surveillance
Purpose	Ensure consistent, harmonized reporting of significant public health concerns related to medical devices.	Build regional regulatory capacity, harmonize reporting, and reduce disparities in device safety
Target Audience	National regulatory authorities worldwide	Ministries of Health, regulators, and healthcare institutions in the Americas
Strengths	Mature global platform; strong emphasis on harmonization; updated guidance (2025) incorporates latest adverse event terminology.	Tailored to resource-limited settings in Latin America/Caribbean; promotes capacity-building and regional cooperation.
Challenges	Restricted to IMDRF MC members; requires robust national systems and confidentiality agreements.	Gaps in techno vigilance persist (only 13/22 countries had legal measures as of 2024); underreporting and resource constraints in many member states.

REGULATORY INSIGHTS

The National Competent Authority Report (NCAR) System developed under International medical device regulatory forum (IMDRF) marks an important advancement in worldwide cooperation in medical device monitoring; nonetheless, variety regulatory constraints remain. A major concern is the significant dependence on the exchange of confidential data among regulators which although essential for protecting commercially sensitive information. Additionally, involvement in the NCAR program is restricted to regulators that fulfil certain infrastructural and regulatory criteria, consequently leaving out large number of low and emerging economic countries leading to insufficient universal safety coverage. Simultaneously the REDMA initiative by PAHO showcases regional advancements but underscores differences in regulatory capabilities among member countries potentially impacting the consistency and quality of adverse event reporting and risk evaluation.

Another significant drawback of these two programmes is the reliance on passive surveillance system. The world health organization states that spontaneous reporting system are naturally linked to underreporting, insufficient data, delays in identifying signals which restricts their capability to promptly recognise new risks [19]. Comparable issues have been well recorded in established databases like United States Food and Drug Administration MAUDE systems, where reports of concern regarding the reliability and completeness of data have emerged. Conversely, regulatory developments like centralised EUDAMED database launched under the regulation EU MDR2017/745 underscore the significance of transparency interoperability and immediate data access in enhancing Post Market Surveillance systems.

To overcome these limitations, upcoming regulatory approaches ought to emphasize moving from passive to active more active and cohesive surveillance frameworks. The implementation of active surveillance strategies such as device registries and post market clinical monitoring systems has been highly advised to improve early signal identification and risk management. Moreover, the development of interoperable global vigilance platforms integrating NCAR, REDMA, and national systems could significantly improve data sharing and regulatory coordination, drawing from the centralized approach demonstrated by EU MDR[15,16]. Emerging technologies such as artificial intelligence also hold promise in improving signal detection and predictive risk assessment, thereby addressing delays inherent in traditional reporting systems.[17]Strengthening regulatory capacity in resource-limited settings and adopting tiered data-sharing models that balance confidentiality with public health transparency will be essential to achieving a more robust and globally harmonized materiovigilance framework.

RECENT UPDATES

The National Competent Authority Report Exchange Criteria and Report Form for Medical Devices: Post-Market Surveillance, Edition 2 was approved by the MC. In addition, the MC decided to establish a webpage on the IMDRF website that would link to the recall notification sections of the websites of participating IMDRF members. The MC also agreed to close the NCAR Working Group.

NMPA (China) joined into IMDRF NCAR in the year 2019. During the 16th management committee meeting in Yekaterinburg Russia, Management Committee unanimously approved Chinese delegation application to join IMDRF NCAR.

Over 20 countries and regions have joined the NCAR Exchange Program cooperation mechanism as of September 2019.Singapore organized an online conference on March 18, 2020. During the meeting, the management committee decided to include Singapore in the NCAR program.

The latest edition of IMDRF NCAR was released in April 2024.26th management committee meeting was held on 16th-20th September 2024 in Seattle, Washington USA [18-21].

RECOMMENDATIONS

A transition from passive to active surveillance is crucial to enhance the effectiveness of NCAR and REDMA systems. The combination of device registries, sentinel systems, and post-market clinical follow-up (PMCF), as advised by the World Health Organization, can improve early signal identification and prompt risk management. The creation of a unified and interoperable global materiovigilance system is also essential. Although NCAR facilitates the exchange of regulatory information, it does not have a centralized public database. Emulating a structure akin to the European Commission EUDAMED framework within the EU MDR can enhance transparency, enable real-time data access, and boost cross-border regulatory collaboration. Moreover, implementing a layered data sharing strategy can reconcile privacy with public health clarity, facilitating prompt disclosure of safety hazards. The incorporation of cutting-edge technologies like artificial intelligence for signal detection along with the establishment of worldwide regulatory learning database can enhance surveillance systems by facilitating proactive risk identification and averting the reappearance of device-related malfunctions.

CONCLUSION

In summary, this program has a significant impact on adverse event reporting of medical devices, and it will help in global regulatory alignment. The goal of this program is the prevention of repetitive errors by improvising field safety corrective actions.The NCAR Exchange Program is an important component of the IMDRF's goal to harmonize medical device regulation worldwide. Moreover, the REDMA program introduced by PAHO plays a vital role in enhancing the safety of medical devices through systematic reporting of events with the collaboration of every regulatory authority in the Americas, which not only enhances public safety but also helps in regulatory harmonization across the region. The success of the pilot plan of these programs helps in detecting deficiencies and gaps in filling regulatory gaps, which are crucial for the protection of public health.

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AUTHORSHIP CONTRIBUTIONS STATEMENT

B. Sri Lakshmi: Conceptualization, literature review, data creation, and manuscript drafting.
P. Anjali: Methodology design, data analysis, and critical revision of the manuscript.
N.Nandhini: Literature search, data interpretation, and drafting of specific sections.
L. Sruthi: Data collection, formatting, and assistance in manuscript preparation.
Devi Priya Bonthu: Supervision, validation of content, and critical review for intellectual input.
Ramaiah Maddi: Final review, editing, and approval of the manuscript for submission.

CONFLICTS OF INTEREST

The author declares that there is no conflict of interest regarding the publication of this article.

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