



IMDRF International Medical
Device Regulators Forum

Final Document

Title: Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form.

Authoring Group: National Competent Authority Report Working Group

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A handwritten signature in black ink, appearing to read 'J. P. Stewart', written in a cursive style.

J. Patrick Stewart, IMDRF Chair

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world.

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Introduction

This document was developed by the IMDRF National Competent Authority report (NCAR) Exchange Program Working Group as an update to the original document (N79) authored by Study Group 2 of the Global Harmonization Task Force (GHTF) in relation to the GHTF Exchange Program.

This document concerns a two way communication system involving confidential information for serious public health issues.

This document will provide guidance, procedures and forms for exchange of reports between IMDRF members. Other forms of information exchange may be addressed in the future.

1. Scope

This document provides guidance on:

- the criteria to be used for deciding when to exchange information,
- the procedures to follow when exchanging information,
- the forms to use for exchanging information,
- the requirements for IMDRF members participation in the NCAR Exchange Program.

2. References

The latest revision of GHTF SG2 N57 Medical Devices Post Market Surveillance: Content of Field Safety Notices.

3. Definitions

NCAR Secretariat

The organization which facilitates and monitors the exchange of NCARs between reporting National Competent Authorities (NCAs) and other NCAR participants in accordance with this guidance. The NCAR Secretariat is the recipient and repository of all NCARs.

The NCAR Secretariat monitors the quality and consistency of the NCAR Exchange Program and circulates NCARs in line with the provisions of section 6.1 of this guidance. The NCAR Secretariat produces and publishes statistical analysis /reports regarding participation and report exchange on a periodic basis. The NCAR Secretariat also maintains an updated list of participants in the NCAR Exchange Program and keeps this list publicly available on the IMDRF website.

The NCAR Secretariat does not assess or propose action on the NCARs received; this is the responsibility of the originator and recipients of the NCAR.

Field Safety Corrective Action - FSCA

A Field Safety Corrective Action (FSCA) is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. Such actions should be notified via a field safety notice.

In assessing the need of the FSCA the manufacturer may use the methodology described in the international standard ISO 14971.

FSCAs may include:

- Return of a medical device to the manufacturer or its representative;
- Device modification
- Device exchange;
- Device destruction;
- Advice given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants).

Device modifications may include:

- Retrofit in accordance with the manufacturer's modification or design change;
- Permanent or temporary changes to the labelling or instructions for use;
- Software upgrades including those carried out by remote access;
- Modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device. For example: for implantable devices it is often clinically unjustifiable to explant the device.
 - Corrective action taking the form of special patient follow-up, irrespective of whether any affected un-implanted devices remain available for return.
 - For any diagnostic device (e.g. IVD, imaging equipment or devices) the retesting of affected patients, samples or the review of previous results.
- Advice on a change in the way the device is used (e.g. IVD manufacturer advises revised quality control procedure -use of third party controls or more frequent calibration).

Serious Public Health Threat

Any event type which results in imminent risk of death, serious injury or serious illness that requires prompt medical action.

A serious injury is either:

- A life threatening illness or injury,

- A permanent impairment of a body function or permanent damage to a body structure¹,
- A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

Unanticipated

A condition leading to an event that was not considered in a risk analysis performed during the design and development phase of the device.

Note:

The reportable event may be unanticipated because of:

- A lack of historical information (rare),
- A change in the situation in which it is occurring,
- A change in the patient, health-care professional or user outcome,
- Off-label use of the device.

4. Reporting guidelines

The NCAR Exchange Program will be used to exchange information relating to significant concerns or potential trends that individual authorities have observed in their jurisdictions, but have not yet resulted in recalls or Field Safety Corrective Actions (FSCAs).

4.1 Exchange criteria

4.1.1 EVENTS LEADING OR HIGHLY LIKELY TO LEAD TO UNANTICIPATED SERIOUS PUBLIC HEALTH THREAT.

Reportable events, associated with a medical device that have led or are highly likely to lead to unanticipated serious public health threat and fulfill the following criteria:

- Death of a patient, user or other person.
- Serious injury of a patient, user or other person.
- No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs. Some jurisdictions refer to these events as near incidents.

Notes:

¹ The term "permanent" means irreversible impairment or damage to a body structure or function excluding minor impairment or damage.

- The interpretation of "serious" in the context of serious public health threat may be difficult to assess and should be determined in consultation with a medical practitioner when appropriate.
- NCARs should not be used for advising of single incidents, unless those incidents have a clear implication for public health.

Examples:

(a) A contaminated eye rinsing solution is used during eye surgery. The possible outcome is serious vision impairment or blindness. The issue was not identified until testing was conducted following several reports of patients having infection and visual problems. The size of the concerned batch is such that the contaminated solution is likely to be distributed in different geographical areas/regions.

(b) A spinal disc prosthesis is inserted between two cervical vertebrae to treat the pain and numbness associated with the collapse of the disc space. Cases of implanted patients suffering from paralysis several months following surgery have been reported. The investigation concluded that the root cause of the paralysis is mechanical failure of the disc, resulting in the disc moving out from between the vertebrae. Subsequent investigation shows that there is no warning for when the disc might break. Advice provided is that all implanted patients should have the disc replaced.

(c) An IVD manufacturer had identified a problem with his HIV test which can result in the generation of false negative results. The problem is not detected by the device control and therefore the incorrect false negative result could be given to medical staff and the patient. The device is widely used across the world and in some jurisdictions it is used for testing prior to blood / organ donation.

4.1.2 OBSERVATIONS FROM NATIONAL TREND ANALYSIS

A trend noticed by a NCA is circulated to the other NCAs when:

- The frequency of the event associated with the device is significantly higher than the frequency recorded in the manufacturer's file or significantly higher than the frequency observed with similar devices and,
- The event has led or is highly likely to lead to a serious public health threat.

Examples:

(a) The review of data from a national registry, complemented by adverse event data indicates a potential concern regarding high revision rates for hip prosthesis that have Metal on Metal (MoM) articulations. The consequence for implanted patients can be permanent impaired mobility and/or the need for surgical re-intervention to avoid further impairment.

(b) Review of adverse event data and literature for a specific atrial septal occluder device indicated an increase in tissue erosion compared with other devices in this category. This type of device failure has not been seen in similar devices to treat this condition. This

erosion can require immediate interventional surgery to remove the device and repair the erosion.

4.1.3 REQUEST AND/OR SHARE OF INFORMATION

An NCA may request and/or share information about a specific device or class/group of devices concerning:

- An event or events,
- An increased seriousness or frequency to what was previously reported to the NCA,
- Major weaknesses and/or major deviations regarding a manufacturer's Project Management System (PMS) / Quality Management System (QMS),
- Regulatory status changes of a device(s).

The consequences of which:

- Have led or are highly likely to lead to serious public health threat and,
- May affect other jurisdictions.

The concerned NCA can ask whether other NCAs participating to the NCAR Exchange Program have similar experience and what actions were initiated or are being discussed to address the issue, e.g. recalls or Field Safety Corrective Actions (FSCA).

Examples:

(a) An NCA has received an increasing number of reports for thrombosis in association with a particular Left Ventricular Assist Device (LVAD). These devices are used in very ill patients who depend on these devices for survival. If the LVAD is stopped or slowed because of thrombosis the patient requires immediate treatment such as thrombolytics or surgical intervention to avoid patient death. The root cause is not identified.

The NCA requests information and assistance if other jurisdictions have encountered this issue and have any additional information that might be useful in determining a root cause.

(b) Several reports have been received of embolus, which has led to or could lead to the death of the patient during an operation, for devices delivering fibrin to seal the gut during surgery. It is unclear whether the device or the drug is responsible for the observed event. The competent authority circulates the NCAR and requests information from other competent authorities regarding any reported adverse events associated with fibrin and embolus.

(c) An NCA notes a series of field actions that have been conducted by a manufacturer. The field actions all relate to one specific device that is used both in the High Dependency Unit setting and palliative care settings. The large number of field actions and the manner in which the manufacturer has managed the identified issues raise questions about the manufacturer's quality management system. The competent authority seeks information from other authorities relating to their experience with the manufacturer and the product.

(d) An NCA restricts the importation of a medical device(s) due to concerns about device safety that could result in a serious public health threat.

4.2 Participation

Participation in the NCAR Exchange Program will be limited to the IMDRF Management Committee (MC) Regulators from Australia, Brazil, Canada, China, Europe, Japan, Russia and the United States of America.

IMDRF MC Regulators who to date have not been involved in the GHFT NCAR Exchange Program shall inform the Management Committee of their wish to join the IMDRF NCAR Exchange. Applicants will be required to review implementation materials on the key elements of the exchange, the definitions and confidentiality before joining the NCAR Exchange Program.

IMDRF MC Regulators who intend to participate in the NCAR Exchange Program must ensure that they have confidentiality arrangements in place with other participating NCAs and the NCAR Secretariat.

Note:

- Non-IMDRF MC Regulators that are currently involved in the existing GHFT Exchange will not be eligible for participation in the IMDRF NCAR Exchange.

4.3 Confidentiality

National Competent Authority Reports (NCARs) identified as "Confidential" by the author of the NCAR may only be shared with NCAR Exchange Program members with whom the NCA who authors the NCAR has confidentiality arrangements. NCARs identified as "Non Confidential" by the author of the NCAR may be shared with all NCAR Exchange Program members.

The recipients of NCARs may use the information in the report to assist in their assessment of the risk issue. The form is not a releasable document. None of the information in the NCAR may be released without the explicit authorization of the authoring NCA. However specific information in the form may be deemed appropriate for release by the authoring NCA, in which case it would be clearly noted by the latter.

Notes:

- The NCAR Secretariat having a pivotal role in ensuring/maintaining the quality and consistency of the circulated NCARs will need to have confidentiality arrangements with all participants to the Exchange Program.

- No data which can identify individual patient(s) can be shared among NCAs in either confidential or non-confidential NCARs.

4.4 Implementation Materials

It is necessary to ensure that all participants have a full understanding of the key features of the Exchange. Implementation materials to support the NCAR Exchange Program will be developed and posted on the IMDRF website.

5. National Competent Authority Report (NCAR) Form

5.1 Exchange format

The NCAR form in Annex 1 should be used for the exchange reports.

Note: other regional exchange networks may exist in addition to the IMDRF NCAR Exchange Program. These forms should not be used for the NCAR Exchange Program.

5.2 Instructions for completing the NCAR Form

The form should be completed in English.

The point of contact identified in Field 4 of the NCAR form, acting for the NCA identified in Field 3, is considered to be the author of the report. The author is responsible for:

- ensuring that the NCAR is issued in accordance with the criteria described in Section 4;
- the accuracy, completeness and relevance of the content; and
- the scope of its distribution.

NCARs should not to be used for advising of single incidents, unless those incidents have a clear implication for public health. In such cases, the implied recommendation is for other NCAs to be aware and take such local actions they find appropriate.

If the NCAR involves a specific manufacturer's device, then the manufacturer or authorized representative may be consulted regarding the NCARs content and distribution of the device prior to it being sent – preferably by providing a copy for the manufacturer or authorized representative to comment on. This will help to ensure the accuracy, particularly the technical content, of the NCAR. An appropriate timeframe for receiving manufacturer's comments should be communicated.

Field:

- 1 Use the rules for numbering NCARs (use the ISO 3166 for country codes) which incorporates a two-letter code of the issuing country to fill in this item. For example: CA-2004-10-19-004 is a report from Canada sent 19 October 2004 and is the 4th report for 2004. Each new NCAR should be given a unique NCAR number. If an NCAR relates to a previously exchanged NCAR ensure that the "Amended" box has been checked.

- 2 Check the box associated with the purpose of the exchange.
- 3 Indicate if the NCAR will be circulated exclusively to the NCAs with whom the authoring NCA has confidentiality arrangements or to all NCAR Exchange Program members.
- 4-5 Identify person and organization sending the NCAR. This should be the single point of contact, previously identified to the NCAR Secretariat.
- 6-8 Telephone, Fax and e-mail of person in (4) above.
- 9 Add the date this NCAR has been circulated
- 10 Kind of device or generic descriptor
- 11 Identify the nomenclature system used (e.g. Global Medical Device Nomenclature [GMDN] etc.).
- 12 Number or code to identify the device based on the nomenclature system identified in (11).
- 13 IMDRF Medical speciality Area, are listed in the Annex 2.
- 14 Trade name / Brand name AND Model number
- 15 List the marketed trade name(s) in other countries, if different.
- 16 Enter information related to the UDI.
- 17-19 If there are many lot/batch numbers or serial numbers (i.e., more than 3 or 4), a detailed list should be appended to the bottom of the report.
- 20 Manufacturer of device - full address, including country, fax, phone numbers and e-mail.
- 21 Identify the natural or legal entity in reporting country who is responsible for placing the subject device on the market where the incidents occurred, full address, including country, fax, phone numbers and e-mail.
- 22 Indicate name or code number of Conformity Assessment Body / Notified Body involved, if applicable.
- 23 Provide a description of what has happened, including consequences to patients or users. With reference to the criteria for reporting (SECTION 4-1 ABOVE), describe the reason for the report and why you want to inform other NCAs about these events. Such information will lead to a better understanding by the recipient on what is considered to be appropriate follow-up.

Identify any investigation taken by the manufacturer and also whether there has been any regulatory, legal or company-initiated action taken in advance of sending out the report.

Indicate if the investigation of the report is complete or not.

Check either the 'Yes' or 'No' boxes to indicate whether there are any attachments associated with this report.
- 24 Indicate a date for which the sending NCA would like to receive responses from recipients of the NCAR.

- 25 List questions under the heading 'Questions'. Number the questions for ease in replying.
- 26 Add any information that is relevant and will assist the receiver of the information to undertake action or to be able to answer the questions appropriately.
- 27 Provide the name of the NCA, the name of the person that the sending NCA can contact if they need to clarify any responses, a telephone and/or fax number and an email address for the contact person.
- 28 This section is used by the sending NCA to inform other NCAR members of the outcome of enquires related to a 'Request for Information' under the heading Purpose of the Exchange' (Section 2 above). For Confidential NCARs, this section should provide a general summary of the responses received and should not include specific feedback from any individual NCAR Exchange participants.

Sending NCAs should provide feedback on their non-confidential requests for information using the summary template provided in Annex 3.

6. Report Exchange Method

6.1 Exchange mechanism and process

The NCARs Exchange Program is supported by the existing email exchange system. At a later stage, the feasibility of a more secure cost effective exchange system may be explored.

The NCAR– the Exchange Form (annex 1) should be used.

NCARs identified as "Confidential" by the authoring NCA are circulated by the authoring NCA to participants of the NCAR Exchange Program in accordance with the confidentiality rules referred under section 4.3. A copy is sent to the NCAR secretariat for recording purposes. The correct sequential references are confirmed by the NCAR Secretariat after circulation has taken place.

NCARs identified as "Non-Confidential" by the authoring NCA are circulated by the NCAR Secretariat to all participants of the NCARs Exchange Program. The NCAR Secretariat confirms the correct sequential references and attachments have been provided prior to circulating the NCAR. Content is not edited.

When an NCAR, either identified as "Confidential" or "Non-Confidential", by the authoring NCA concerns a critical issue of significant public health threat and one NCA enforces measures on the affected manufacturer, the measure(s) should be communicated via the Secretariat to all participants of the Exchange Program.

When the NCAR concerns a request for information, responses to queries are communicated directly to the contact name detailed on the requesting NCAR. Summaries of the feedback received are collated by the original requester. For confidential NCARS a general summary of the responses received should be provided in section 28 of the form. The summary should not

include specific feedback from any individual NCAR Exchange participants. The form should be sent back to all countries that received the original NCAR. For non-confidential NCARs, the responses should be distributed to the recipients of the original NCAR using the form detailed in annex 3. In both cases a copy is sent to the NCAR Secretariat.

When a receiving NCA needs more information on a particular NCAR, the NCA may contact the authoring NCA for more information. The receiving NCA may only contact the concerned manufacturer or its representative if the authoring NCA has agreed to it.

If a receiving NCA considers that it is important that it takes national action, the NCA should contact the authoring NCA to seek permission to contact the manufacturer and to ensure no confidential data is unduly released and the timing of such action would not compromise the ongoing risk assessment.

6.2 Timelines for submitting reports

Submission of reports will be dependent on the issue identified. Where assistance is requested NCAR Exchange Program participants are expected to respond by the identified deadline.

**ANNEX 1: NATIONAL COMPETENT AUTHORITY REPORT EXCHANGE FORM
(NCAR)**

This form should be used for the exchange of medical device information between NCAR participants only. Completed forms should not be released to the public. All information contained in this form is considered confidential unless specifically indicated otherwise in section 3 or in the background section of the annex.

<p>1. CA Report Number: <CA reference number></p> <p style="text-align: center;"> <input type="checkbox"/> New <input type="checkbox"/> Amended </p>
<p>2. PURPOSE of the EXCHANGE:</p> <p><input type="checkbox"/> Share Information</p> <p style="margin-left: 20px;"> <input type="checkbox"/> Events leading or highly likely to lead to unanticipated serious public health threat. <input type="checkbox"/> Observations from national trend analysis <input type="checkbox"/> Share Information as outlined in Section 4.1.3 </p> <p><input type="checkbox"/> Request Information</p> <p><input type="checkbox"/> Summary of query findings</p>
<p>3. Confidentiality/DISTRIBUTION CHANNEL</p> <p><input type="checkbox"/> Yes/Restricted. (The authoring NCA may share <u>only with NCAR exchange program members with whom the NCA has confidentiality arrangements</u>).</p> <p><input type="checkbox"/> No/ All NCAR Exchange Program members.</p>

DETAILS OF INITIATING NCA	
4. Authoring NCA: <name of CA>	
5. Contact Person: <name of contact person>	6. Telephone: <telephone number>
7. E-mail: <email address>	8. Fax: <fax number>
9. Circulated: <date circulated - dd/mm/yyyy>	
DEVICE DETAILS	
10. Generic name / kind of device:	
11. Nomenclature Type:	12. No / Code:
13. IMDRF Medical Speciality Area: (list detailed in Annex 2)	

QUESTIONS AND RESPONSES (If Applicable)

24. **Deadline For Response:** <date of deadline for response - dd/mm/yyyy>

Question	Answer	Rationale / Remarks
25.		

ADDITIONAL RATIONALE AND REMARKS

26.

DETAILS OF RESPONDING NCA

27. **Responding NCA:** <name of CA>

Contact Person: <name of contact person> **Telephone:** <telephone number>

E-mail: <email address> **Fax:** <fax number>

FINAL SUMMARY / COMMENTS

28.

ANNEX 2: IMDRF MEDICAL SPECIALITY AREAS

in relation to field 12 of the NCAR Form of Annex 1.

- 1- Anaesthesia
- 2- Cardiovascular
- 3- Chemistry
- 4- Dental
- 5- Ear, nose and throat
- 6- Gastroenterology/urology
- 7- General and plastic surgery
- 8- General hospital
- 9- Haematology
- 10- Immunology
- 11- Microbiology
- 12- Neurology
- 13- Obstetrics and gynaecology
- 14- Ophthalmology
- 15- Orthopaedics
- 16- Pathology
- 17- Physical medicine
- 18- Radiology
- 19- Clinical toxicology
- 20- Paediatrics

ANNEX 3: REQUEST FOR INFORMATION. SUMMARY TEMPLATE

in relation to field 28 of the NCAR Form of Annex 1.

FOR NON-CONFIDENTIAL EXCHANGE ONLY

SUMMARY FORM			
COUNTRIES	QUESTIONS	ANSWERS	ADDITIONAL COMMENTS