



**IMDRF** International Medical  
Device Regulators Forum

## **FINAL DOCUMENT**

### **International Medical Device Regulators Forum**

**Title:** Medical Devices: Post-Market Surveillance -IMDRF National Competent Authority Report (NCAR) Pilot Plan

**Authoring Group:** National Competent Authority Report Working Group

**Date:** 2 October 2015

A handwritten signature in black ink, appearing to read 'T. Tominaga', with a stylized flourish at the end.

Toshiyoshi Tominaga, IMDRF Chair

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## 1.0 Executive Summary

The National Competent Authorities Report (NCAR) Exchange Program document IMDRF/NCAR WG N14 FINAL: 2015 was adopted by IMDRF Management Committee (MC) at IMDRF-7 session in March 2015.

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

The NCAR Working Group<sup>1</sup> to this point has accomplished the following:

1. Established the NCAR Exchange Guidelines, including the Exchange Criteria, adopted by the Management Committee in March 2015<sup>2</sup>;
2. Established the NCAR Report Form adopted by the Management Committee (MC) in March 2015<sup>3</sup>.

Further IMDRF piloting is to be conducted with the following general objective:

- To develop implementing materials for support of the proper functioning of the new NCAR Exchange Program.
- To test in real conditions the use of the new exchange criteria and the new NCAR form from a regulatory perspective when applying to multiple participating jurisdictions using real NCAR submissions based on historical cases.

The proposed timeline for this pilot is described below.

Development of implementing materials	June to September 2015
Initiation of pilot	beginning-October 2015
Close of pilot	end-March 2016

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<sup>1</sup> The IMDRF NCAR Working Group is composed of the regulatory authorities from the jurisdictions represented by the IMDRF Management Committee.

<sup>2</sup> See IMDRF/NCAR WG/N14 FINAL:2015

<sup>3</sup> See IMDRF/NCAR WG/N14 FINAL:2015

## 2.0 Background

Launched in 2012, the IMDRF is a multi-lateral voluntary group of global medical device regulators from around the world whose main aim is to achieve convergence among the regulatory environments on participating members in the field of medical devices. Built in the wake of the Global Harmonization Task Force (GHTF), IMDRF was conceived, unlike its predecessor, as a regulators-led forum.

The National Competent Authorities Report (NCAR) Exchange Program document was adopted by IMDRF Management Committee (MC) at IMDRF-7 session in March 2015. The NCAR Working Group to this point has accomplished the following:

1. Established the NCAR Exchange Guidelines, including the Exchange Criteria, adopted by the Management Committee in March 2015;
2. Established the NCAR Report Form adopted by the Management Committee in March 2015.

IMDRF piloting is considered necessary to test the new exchange criteria and the new NCAR form. Participating jurisdictions to the IMDRF NCAR Pilot will perform this test by using real electronic NCAR notifications based on historical cases<sup>4</sup>.

## 3.0 NCAR Pilot Implementation Design

The design for the IMDRF NCAR Pilot Implementation includes both administrative and technical components. The sections below provide an overview of the pilot and a description of the pilot study phases.

The NCAR Pilot Implementation seeks to work across regulatory jurisdictions:

- To develop common practices for NCAR notifications in accordance with the N14 document and;
- To start receiving notifications from the medical device National Competent Authorities (NCAs) using the IMDRF NCAR form.

### 3.1 Pilot Objectives

The IMDRF NCAR Pilot Plan implementation will be driven by the following objectives:

- To provide participating jurisdictions with implementation materials to support the use of new exchange criteria and the new NCAR form and to support the exchanges with the NCAR Secretariat.
- To identify potential challenges in the implementation process of:
  - The use of the new exchange criteria and the new NCAR form and the management of confidential information;
  - Developing a common approach and best practices on how these can be addressed.

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<sup>4</sup> These historical cases might have been identified as confidential or non-confidential by individual authors of the NCARs at their time of issuing but measures have since been taken and made public.

- To facilitate the transfer from the current GHTF NCAR Exchange Program to the IMDRF Exchange Program.

### **3.2 Pilot Scope**

The scope of the IMDRF NCAR pilot for implementation purposes should be:

- To provide support to participating jurisdictions using real electronic NCAR notifications based on historical cases,
- To start with the IMDRF NCAR Exchange Program using the new National Competent Authority Report (NCAR) form. See Annex I of the document IMDRF/NCAR WG/N14 FINAL: 2015.  
<http://www.imdrf.org/documents/documents.asp>

### **3.3 Timelines and Targets**

To ensure that members of the current NCAR Exchange Program which are also eligible to the IMDRF NCAR Exchange Program are adequately prepared and supported to exchange information satisfactorily, regional teleconferences and possibly one multilateral teleconference are recommended according to the following modalities:

- Organisation of regional teleconferences is the responsibility of each jurisdiction which is involved:
  - The number of regional teleconferences will be set by each region when considering the pilot success criteria.
  - Participation into the teleconferences will be defined by each jurisdiction.
- Organisation of a possible multilateral teleconference meeting is the responsibility of the NCAR Working Group.

Note: Participation to the Pilot Plan is limited to IMDRF MC members which have already participated in the GHTF NCAR Exchange Program. Other IMDRF MC members can join the IMDRF NCAR Exchange Program after the completion of the pilot phase provided they officially apply and fulfill the criteria.

The pilot phase is expected to take place from the beginning of October 2015 to the end of March 2016. The completion date and target number of teleconferences may be modified based on experience/feedback.

Milestone	Timeline
Development of implementing materials intended for participating jurisdictions and of a pilot plan for the NCAR Exchange Program by the NCAR Working Group	June- mid August 2015
Adoption of the pilot plan by the Management Committee at IMDRF-8 session	September 2015
Teleconference of NCAR WG to prepare the start of the pilot phase including recording of supporting webinar	September 2015
<b>Initiation of the pilot phase</b>	<b>October 2015</b>
Transfer from GHTF to IMDRF NCAR Exchange Program with prior notification to be sent to GHTF participants that GHTF NCAR Exchange Program ceases from end September 2015	October 2015
Beginning of exchange of NCAR reports between eligible IMDRF MC members in accordance with IMDRF/NCAR WG/N14 FINAL: 2015	October 2015
Regional implementation teleconferences between participating IMDRF MC Members followed by a multilateral implementation teleconference	October 2015 – February 2016
Update of implementing materials if necessary	February 2016
<b>End of Pilot phase</b> and full implementation of the IMDRF NCAR Exchange Program  Report of Pilot outcomes to the Management Committee	<b>March 2016</b>
Evaluation of the functioning of the IMDRF NCAR Exchange Program by the NCAR WG and reporting to the IMDRF-MC with possible proposals for follow-up	March 2017

### **3.4 Success Criteria**

The success of the NCAR pilot will be measured by the following criteria:

- Eligible IMDRF MC members have been trained in accordance with the new procedures for the exchange of NCARs.
- Exchange of NCAR notifications under the new system during the pilot phase occurs.
- Compliance of NCAR notifications with the exchange criteria and with the confidentiality rules.

### **3.5 Confidentiality**

Participation to the Pilot Plan is limited to IMDRF MC members which participated to the former GHTF Exchange Program and which have implemented appropriate confidentiality arrangements with other participants.

### **3.6 Publication of Pilot Documents**

Final versions of the NCAR Pilot documentation and any future revisions of the NCAR forms will be posted to [imdrf.org](http://imdrf.org) at the conclusion of the pilot, when the success criteria are met.

## **4.0 Management of the IMDRF NCAR Exchange Program**

### **4.1 Role of NCAR Secretariat**

- NCAR Secretariat is the participating National Competent Authority (NCA) which facilitates and monitors the exchange of NCARs between reporting NCAs and other NCAR participants in accordance the guidance provided in IMDRF/NCAR WG/N14 FINAL: 2015. The NCAR Secretariat is the recipient and repository of all NCARs.
- It ensures the daily management of the functioning of the NCAR Exchange Program and monitors the quality and consistency of the NCAR Exchange Program and circulates NCARs in line with the provisions of section 6 of IMDRF/NCAR WG/N14 FINAL: 2015.
- It manages the bi-annual teleconferences between participating jurisdictions.
- It produces and publishes statistical analysis/reports regarding participation and report exchange on a periodic basis.
- It supports training in relation to the NCAR Exchange Program. It maintains a repository of the implementation materials and of the information exchanged through the NCAR Exchange Program.
- It also maintains an updated list of participants in the NCAR Exchange Program and keeps this list publicly available on the IMDRF website.

### **4.2 Role of the Management Committee**

- The Management Committee will decide on whether an application to join the NCAR Exchange Program is accepted.
- The Management Committee will appoint and decide on the transfer of the NCAR Secretariat.
- The Management Committee will review and decide on a possible extension of the scope of the NCAR Exchange Program.