



IMDRF

International Medical
Device Regulators Forum

IMDRF-MC IX
National Competent Authority Report
Exchange Programme

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WG composition

□ Australia:

Pamela Carter (Director, Device Vigilance and Monitoring Section, Office of Product Review, TGA)

□ Brazil:

▫ Stela Candioto Melchior (Gerência de Análise e Avaliação de Risco, ANVISA)

▫ Maria Gloria Vicente & Guillerme Buss (Health Surveillance Specialists, ANVISA)

□ Canada:

▫ Barbara Harrison (Senior Corporate Regulatory Compliance Advisor , Health Canada)

□ European Union:

▫ Jean-François Roche [Chair] (Policy Officer, GROW D4, EU Commission)

▫ Andrea Hanson (Product Manager, Health Products Regulatory Authority, Ireland)

▫ Carmen Ruiz-Villar (Head of Service , Vigilance Unit , Medical Devices Department, AEMPS)

▫ Ekkehard Stoesslein (Deputy Head of Division, BfArM)

□ Japan:

▫ Koichi Fujiwara & Miho Sato (Office of Safety, PMDA)

▫ Masahiro Takahata (MHLW)

□ USA:

▫ Nancy Pressly (Associate Division Director, FDA)

▫ Millin Courtney (MDR Analyst, FDA)



State of play

- At IMDRF-8 management committee meeting in Kyoto, the **implementing materials for N14** document on NCAR Exchange Program were endorsed.
- The MC also endorsed a **Pilot Plan** for the phasing in of the NCAR Exchange from October 2015 to March 2016
- Participation to the Pilot Plan was limited to IMDRF members which were part of former GHTF exchange



Main aspects of Pilot Plan

- The Pilot Plan defines the framework and timelines for the support of participating jurisdictions and for the transfer from the GHTF to the IMDRF NCAR Exchange Program
- It includes the setting up of training sessions within the various jurisdictions and between them
- Implementing materials consisting in a detailed PPT presentation were used for training purposes



Timeframe

1. 1st October 2015

- Initiation of the pilot phase with current participants of GHTF NCAR Exchange who are IMRDF MC members
- Transfer from GHTF NCAR Exchange to IMDRF NCAR Exchange

2. October 2015 – March 2016 (Functioning Pilot phase)

- National and regional implementing teleconferences based on implementation materials

3. From April 2016 (full implementation)

- Possible participation of other interested IMDRF MC members provided relevant confidentiality arrangements are in place

4. March 2017

- Evaluation of functioning and report to the MC with possible proposals for follow-up



Feed-Back from Pilot Plan

- 16 NCARs were exchanged between IMDRF Members in a 4-month period and from most participants
- Some NCARs did not comply with N14 requirements
- The Exchange Program is perceived as useful by all participants but the need for bilateral confidentiality arrangements (CAs) to exchange confidential information restricts the exchange of NCARs due to the limited number of CAs which has been concluded up to now



Next Steps (1/2)

- To keep on with organizing training sessions
- To address some interpretation issues related to the N14 document by further developing the implementing materials
- The need for an update of N14 to be assessed for the March 2017 MC



Next Steps (2/2)

- To facilitate the involvement of IMDRF members which are not yet part of the NCAR Exchange (though application remains voluntary)
- To keep on with the development of new confidential arrangements to allow the increase of exchanged NCARS and a wider participation to the program