



IMDRF

International Medical
Device Regulators Forum

IMDRF-MC VIII
National Competent Authority Report
Exchange Programme

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DG GROWTH - Health Technology and Cosmetics Unit,
European Commission



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 & Guilherme Buss (Health Surveillance Specialists, ANVISA)
- Canada:
Barbara Harrison (Senior Corporate Regulatory Compliance Advisor , Health Canada)
- European Union:
Jean-François Roche [Chair] (Policy Officer, GROW I4, 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)
- Invited expert: AHWP/ Saudi Arabia:
Essam M. Al Mohandis (Executive Director of Surveillance and Biometrics, SFDA)



State of play

- At IMDRF-7 management committee meeting in Tokyo, the N14 document on NCAR Exchange Program was adopted as a final document.
- The MC also adopted an implementation work plan which foresees submission of implementing materials and of a pilot plan for adoption at IMDRF-8.
- The pilot plan is intended to be in place from October 2015 to March 2016.



Main points of Pilot Plan

- 7 teleconferences held with the NCAR Working Group to prepare the Pilot Plan and implementing materials as a PPT Presentation
- 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
- Implementing materials consists in a detailed PPT presentation of how to implement the new Exchange Program
- It is also intended to develop a webinar from this presentation for online use



Work Plan Pilot Phase

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)

- Regional implementing teleconferences based on implementation materials
- Possible multilateral teleconference with all participating members

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



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Thank you
for your attention!