IMDRF-MC VIII
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 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
Thank you for your attention!