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-Viller (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

- IMDRF N14 REV 4 DOCUMENT WAS ENDORSED FOR PUBLIC CONSULTATION BY IMDRF MC IN WASHINGTON.

- PUBLIC CONSULTATION TOOK PLACE UNTIL END DECEMBER.

- COMMENTS RECEIVED FROM 1 JURIDICTION, 4 PROFESSIONAL ORGANISATIONS AND 1 COMPANY

- 2 TELECONFERENCES HOLD WITH THE NCAR WORKING GROUP ON 14 AND 21 JANUARY

- SOME LIMITED CHANGES INTRODUCED IN FINAL DOCUMENT
Main changes in N14 Final

• More accurate definition of the role of NCAR Secretariat
• Clarification of wording of chapter 6.1 on report exchange for confidential and non confidential NCARs
• No changes on substance
• Editorial changes throughout the document
Work Plan

1. March–mid April 2015
   • Drafting of implementation materials on reporting criteria, participation, confidentiality and reporting forms

2. Mid April – October 2015 (Pilot phase)
   • Participation limited to IMDRF MC members who already participated to the GHTF exchange program
   • Use of implementation materials for new members
   • Twinnings between a new and a former participant

3. November 2015- April 2016 (full implementation)
   • Progress report to the MC (IMDRF IX)
   • Possible proposal for an extension (2nd phase)
Thank you for your attention!