Revision of the NCAR Exchange Program

Dr. Isabelle Demade
NWI Chair

IMDRF Sydney
23-26/09/2012
Background

- **Current scope:** 
  exchange of (confidential) info on serious Adverse Event (AE) concerning MD with global distribution

- **Participants**
  - GHTF Reg. Authorities
  - Reg. Authorities fulfilling the criteria of N38 & successfully trained on N54 & N79
Background

State of Play

- Total: 29 participants (out of which 9 are non-GHTF members)
  - Interest of AHWP members & more recently South America
- Number of NCARs exchanged: approx. 250 per year.
Underlying requirements

- one focal point for supervision & distribution: NCAR Exchange Program Secretariat (currently TGA)

- Expanding membership
  † training (and re-training)

  requires training materials, trainers,
  = N 120: training on PMS
Critical Review-Step 1

2 regulators-only sessions prior to SG2 meetings

- NCAR Exchange provides **useful information**.
- Downside: **uneven participation**
  - limited contribution from **key GHTF jurisdictions**
  - poor participation from **new members** ram.
Critical Review-Step 1

The benefits:

- **early access** to relevant safety-related information;
- knowledge about action taken (FSCA, recall,..)

The frustration:

- why are so **few (GHTF) jurisdictions** using the NCAR Exchange Program?
Critical Review-Step 1

- Trend: besides AE & FSCA/recalls reporting
  - sharing information on action taken by Manufacturer (Field Safety Notice),
  - on newly identified issues (and request for feedback)
  - requesting information on post-market issue.
Critical Review-Step 2

conducting a survey on participants' views:
- on contribution level,
- recommendations for improvement
- training needs,
- scope

Critical Review

- **Step 2 (cont.)**
  Reviewing survey data & setting priorities
  Through 2012-early 2013

- **Step 3**
  Developing proposals
  Through 2013
Critical Review

WG composition

- **Experience:**
  SG2 regulators & fresh view

- **Geographic representation:**
  GHTF jurisdictions, IMDRF new member(s), +inviting AHWP representative;

- **Must have:** operational responsibilities in post market safety.
Thank you for your attention!

K