Review of the NCAR Exchange Program

- PROGRESS REPORT -

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The NCAR Exchange Program

- N79:2009
National Competent Authority Report
Exchange Criteria and Report Form

- N38:2009
Application Requirements for participation to the Exchange Program

The NCAR Exchange Program

- **Current scope**:

exchange of (confidential) info on serious Adverse Event (AE) information on MD with global distribution

- **Participants**

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

The NCAR Exchange Program

State of Play

- 29 participants (5 of which are AHWP members)

- approx. 280 NCARs distributed each year

NCAR Review

Core tasks:

> review current arrangements

> advise on:

- opportunities for improvements
- possible expansion to include certain pre-market decisions & post-market actions.

→ On-line survey on the NCAR Exchange Program

> **18 questions** covering:

degree of (un-)satisfaction, NCAR Form, scope, type of NCAs

> **Participation**:

ALL completed the survey (36 responses, 29 participants)

Survey main messages

> Keep the Program

> Improve the Program

> Review scope

Survey highlights

- **Program is useful**
  - more visibility on international issues & concerns
  - info. about actions with MD supplied in the country
  - exchange of info on devices under investigation

Survey highlights

➢ The concerns

- criteria for sending NCAR
- timing (too late)
- type of information exchanged

(primarily Field Corrective Action)

- NCAR Form

Survey highlights

- **Consider scope extension**
  - premarket assessment when unfavourable
  - license/certificate withdrawal
  - inspection results (cancellation/withdrawal of MFRing licenses)
  - safety-related compliance activity
  - signals & trends/ early warning

Survey highlights

Other suggestions:

- Improve quality of the NCARs (e.g. root cause, "event type code", "evaluation code",...)
- More interpersonal collaboration
- More specific guidance with examples
- Re-training

Tasks to be considered

(1) **Scope:**

- clarify existing scope & consider expansion to other action potentially impacting health

<->other IMDRF WGs (e.g. SAP)

Tasks to be considered

(2) **Develop guidance on each individual component**

with specific focus on identif. weaknesses

→ rev. & change to N79 (rev. reporting form: readibility, completeness, separate enquiry and final report)

Expected delivery

>Review guidance on AE reporting & FSCA

end 2013

Thank you

for

your attention !