Review of the NCAR Exchange Program

- PROGRESS REPORT -

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The NCAR Exchange Program


- 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 identifying weaknesses
→ rev. & change to N79 (rev. reporting form: readability, completeness, separate enquiry and final report)
Expected delivery

> Review guidance on AE reporting & FSCA

end 2013
Thank you for your attention!