



Revision of the NCAR Exchange Program

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Background

Ø Current scope:

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

Ø Participants

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



Background

Ø State of Play

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



Underlying requirements

- Ø one focal point for supervision & distribution:
NCAR Exchange Program Secretariat
(currently TGA)
- Ø Expanding membership
à **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

è NCAR Exchange provides **useful information**.

è Downside: **uneven participation**

- limited contribution from key GHTF jurisdictions

- poor participation from new members ram.



Critical Review-Step 1

è The benefits:

early access to relevant safety-related information;

knowledge about action taken (FSCA, recall,..)

è The frustration:

why are so **few (GHTF) jurisdictions** using the NCAR Exchange Program?



Critical Review-Step 1

è 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

Oct. 2012



Critical Review

-Step 2 (cont.)

Reviewing survey data & setting priorities

Through 2012-early 2013

- Step 3

Developing proposals

Through 2013



Critical Review

WG composition

Ø Experience:

SG2 regulators & fresh view

Ø Geographic representation:

GHTF jurisdictions, IMDRF new member(s),
+inviting AHWP representative;

Ø Must have: operational responsibilities in post market safety.



*Thank you
for
your attention!*

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