



Workshop report "Preparatory work on how to report, use and interpret historical control data in (eco)toxicity studies"

Annex C Feedback to the workshop

Following the workshop, all participants (182 in total) were kindly asked to respond (anonymously) in the following questions:

Question A

Based on the discussions held during the workshop, please specify three topics of high priority for further considerations. (Please include just 3 keywords, if possible)

1.
2.
3.

Question B

Do you think that the workshop program and the discussions held captured all relevant issues? (YES/NO)

If 'NO' what do you think that was missing?

For this purpose, the questionnaire was developed as an online form in a WordPress site. Forty-four (44) responses have been provided in total.

Analysis of responses

1.1 Question A

In order to analyse the participants' feedback regarding the topics considered of high priority for further considerations on HCD, the keywords provided were clustered/grouped in 10 categories, i.e.:

- Harmonisation/guidance on use and interpretation of HCD
- Route of exposure
- Relevance/suitability - Reliability/Acceptability criteria
- Understanding - experience
- Concurrent control
- Databases/sources
- Time period
- Statistics
- Specific toxicity area
- More general issues raised - Others



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The majority of the responders (more than 66 %) highlighted the need for harmonisation and the development of specific data requirements and guidance on the use and interpretation of HCD, including data requirements and reporting (format).

While the statistics and the relevant time period to be considered have been pointed out by more than 30 % of the responders regarding the prioritization of more specific issues to be dealt with, 27 % of the responders made a specific reference to relevance/suitability or/and reliability/acceptability criteria (Table 1).

Table 1. General topics for prioritisation

General topics prioritised	% of responders
Harmonisation/guidance on use and interpretation including data requirements and reporting (format)	66
Statistics	36
Time period	32
More general issues raised - Others	32
Relevance/suitability - Reliability/Acceptability criteria	27
Specific toxicity area	27
Databases/sources	14
Understanding - experience	7
Concurrent control	7
Route of exposure	5

Only few responders mentioned specific area where they believe prioritisation for use, reporting and interpretation of HCD is necessary. This suggests that there is more need for general issues to be clarified and agreed upon than to focus on specific toxicity areas (Table 2).

Table 2. Toxicity areas for prioritisation

Toxicity area	# of responders
Acute toxicity	1
Carcinogenicity	2
Reproductive Toxicity	1
Genotoxicity	3
Neurotoxicity	1
Hematology	1
Histopathology	1
Ecotoxicology	2

Additional keywords provided concerned the HCD databases/sources, the limitations due to no experience and different understanding (again indirectly related to the absence of a harmonised guidance), the use of the concurrent control and the route of exposure.



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1.2 Question B

Forty (40) participants (91% of the responders) answered that the workshop program and the discussions held captured all relevant issues. Those stating that there were topics missing referred more to concerns regarding the use of HCD and not to a particular issue that was not discussed within the workshop.