Author’s response to reviews

Title: Heterogeneity prevails: the state of clinical trial data management in Europe - results of a survey of ECRIN centres

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Version: 4 Date: 10 May 2010

Author’s response to reviews: see over
Dear Editors, Dear Reviewer.

Thank you for your comments. We have addressed all comments and here I explain how we have implemented the corrections.

Kind regards.

Wolfgang Kuchinke

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List of corrections

Version: 3 Date: 31 March 2010

Reviewer: Tania Shelby-James

Major compulsory revisions requested:
1. “No mention of ethical approval – It may be that it is not required but I would still have like to have seen a statement stating that”.

Correction: a chapter about the ethical aspects of data management was added (page 20). It describes how ethical concerns are considered in clinical data management by requiring compliance with GCP and EU Directive 2001/20/EC. Compliance is ensured by a process called “system validation”.

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Additional comments:
1. “The manuscript would still benefit from careful checking of the grammar. There are instances where the tense changes from past to present within the same sentence.”

Correction: the whole manuscript has been checked for grammar mistakes and especially the tense of sentences was harmonized. The tense was changed from past tense into present tense (pages 4, 7, 9, 15, 16, 18, 19, ...). In some cases, the tense was changed from present to past tense (pages 8, 10,...).

2. “English: Needs some language corrections before being published”

Correction: the entire manuscript was checked for mistakes and readability, numerous corrections were made (see text in correction mode).

In addition, the list of abbreviation was completed ("ePRO"), two new references were added (References 20 and 21), and all mentioned web links were checked for being up-to-date.

Version: 3 Date: 27 March 2010

Reviewer: Rebecca Kush

Major compulsory revisions requested:
“none”
Correction: no correction necessary

Minor Essential Revisions requested:
“the prior revisions suggested have been satisfactorily addressed”
Correction: no correction necessary