FUEHRING Stefan (SANCO)

From: Dr. Susanne Jena [susanne.jena@imbi.uni-freiburg.de]
Sent: vendredi 1 octobre 2010 13:40
To: SANCO PHARMACEUTICALS
Subject: Comments on LIST OF FIELDS FOR RESULT-RELATED INFORMATION TO BE SUBMITTED TO THE 'EUDRACT' CLINICAL TRIALS DATABASE

Dear Sir or Madam,

in addition to my comments made on the technical meeting on September 13th in Brussels, we want to comment the following points:

1. In our opinion as much fields as possible should be collected in a coded manner, using controlled vocabularies. For example R53, R 58 and some other fields should be collected in this way.
2. It should be possible to change some parameters, if necessary (due to international developmentds, for example, if ClinicalTrials.gov will add or change some parameters, and EMA wants to follow these modifications), without the necessity of asking the comission. Experience shows that databases like EudraCT are subject to continuous improvement and therefore uncomplicated and straightforward changes should be facilitated. I am not shure if this is just the case, but it would be an important facilitation of working with this database.

Kind regards
Dr. Susanne Jena on behalf of the German Clinical Trials Register

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