Dear EU Staff,

I apologize up front – I haven't caught up with all the different Directives that differentiate between Paediatrics and other trials, which may explain some of my questions. Many individuals in industry have said that their interpretation of the data set is that it is intended to address the WHO twenty, or minimal registration data set. Some of my questions concern the WHO twenty, while others are seeming contradictions between either the two data sets in review, or the data sets and the posted data set in Annex 1 for Q1 2009, available about the same time as the two data sets under discussion. If you have time to answer my questions that are included here, I will appreciate it greatly. I know I have much to learn.

1) Why are results postings for paediatric trials within 6 months of end of trial, but all other trials for EudraPharm are 1 year?
2) Why is it important to include the sponsor status (B.3.1/B.3.2) for Paediatrics, but not for everyone else?
3) If the system will be set up to make all the identified Paediatrics fields available to the public, why not use the same set for EudraPharm?
4) The fields and trial types that are missing from the EudraPharm data sets (but included in Paediatrics) are important –
    a. Sponsor name (WHO Primary Sponsor),
    b. all Phase I trial information (required by updated WHO definition of clinical trial, and thus ICMJE requirement), and
    c. the Trial / Site Investigator contact information (WHO Contact for Scientific Queries and Countries of Recruitment, effectively)
5) And if the settings and locations where the data were collected are important enough to include in results, shouldn't they be in the registry at EudraPharm for transparency during the trial?
6) Section N, Review by the Competent Authority… differs between the two data sets, including the content of the fields and the status values. It seems like they should be identical, other than the time frame, perhaps
7) Field A.5 is reserved for ISRCTN in EudraCT, so if it's filled in, why would it show up as if in Field A.6 for Paediatric and EudraPharm?
8) Field B.1.1 is the Name of the sponsor organization, not the name and country of the sponsor, at least by Annex 1: Clinical trial Application Form Version 26 June 2008 for Q1 2009 and Annex 1 of the Detailed Guidance … Revision 2.
9) Again with regard to Annex 1 vs the public data fields, Field B.4 Sources of Monetary or Material Support include Name of Organization (B.4.1) and Country (B.4.2), not Commercial and Non-commercial. Was this confused with B.3? To fulfill the WHO field, the name must be provided (see WHO field value)
10) Field D.1 is IMP Identification, not Status of the IMP?
11) Shouldn't field D.1.1 (IMP number) be included? Isn't it effectively like an arm number or label?
12) Dosing and duration of dosing appear to be excluded from Paediatric and EudraPharm, both of which are included as part of the WHO definition for Intervention(s).
13) Field D.3.11.12. should probably be D.3.11.12.1, although this is D.3.11.13 and 13.1 in the 26 June 2008 Annex 1
14) Field D.6.4.1 should not have Nucleic acid (e.g. plasmid) after "Type of gene transfer product:", but rather that should be the first part of D.6.4.1.1, at least to agree with Annex 1. I see what you've done, but it's a little confusing, at least to me.
15) Since it appears that D.6.4.1 was done that way to eliminate the confusion as to whether a question is being asked by it (as in fill in the blank) or if it's a title, and obviously this issue arises elsewhere, perhaps a means of differentiating between

titles/headings and actual questions needs to be addressed overall in the Annex (but later, obviously)

16) Field D.6.5.3.1 should reference species
17) Field E.8.10, .1 and .2, Proposed date of start of recruitment (WHO Date of First Enrollment) have not been included in Paediatric or EudraPharm. Shouldn't they be?
18) Field F.1.2 should probably read Adult (18-64 years) and F.1.3 as Elderly (>=65 years)
19) Why exclude Subjects incapable of giving consent personally and Others (F.3.3.6-F.3.3.7.1) when you give all the other groups?
20) Field G1.1-G1.5, based on the Annex 1, will not include email and telephone fields, as they are Fields G.1.6 and G.1.7. Update to G1.1-G1.7?
21) If G1.1-G1.7 are intended as the WHO Contact for Scientific Queries, then the Affiliation of the individual should be included as a field
22) Will the date of registration in EudraCT (WHO field) be made publicly available? It's not listed as a public field.
23) Secondary sponsors do not appear to be addressed in the EudraCT data set. Will they be added in the future to fulfill the WHO field requirement?
24) Is A.3 a field unto itself, for WHO Scientific Title, or is it a header for A.3.1 and A.3.2?

Thank you for reviewing my questions. If you have any questions or I can better clarify my comments, please let me know. I look forward to seeing EudraPharm and the Paediatric Trials.

Sincerely,

Lori

Lori J. McKenney
SEC Associates, Inc.
www.secassociates.com

8601 Six Forks Road, Suite 400
Raleigh, NC 27615
Ph: 919-845-9614
Fax: 919-845-9941