

Sullivan Jonathan Dale CHBS

From: Wilks Martin CHBS
Sent: Dienstag, 30. Juni 2009 11:02
To: Sullivan Jonathan Dale CHBS
Subject: RE: Comments on latest Tomenson draft protocol

CONFIDENTIAL AND PRIVILEGED COMMUNICATION

Jonathan,

I have spoken to John - he will send a revised protocol.

Best wishes

Martin

-----Original Message-----

From: Sullivan Jonathan Dale CHBS
Sent: Freitag, 26. Juni 2009 20:19
To: Wilks Martin CHBS
Subject: Comments on latest Tomenson draft protocol

CONFIDENTIAL AND PRIVILEGED COMMUNICATION

Martin,

Please can you discuss the attached orally with John Tomenson (do not forward this message to him) .

Thanks,

Jonathan .

----- Original Message -----

From: Wolff, Jeffrey <jwolff@fulbright.com>
To: Sullivan Jonathan Dale CHBS; Nadel Alan USGR
Sent: Fri Jun 26 20:11:39 2009
Subject: Comments on latest Tomenson draft protocol

Jonathan:

Alan and I have discussed the revised Tomenson protocol you forwarded today.

Attached is a document highlighting the changes to the Tomenson protocol since the last version we saw at the end of May. The substantive changes are as follows:

The start and completion dates of the study have been slightly modified.

A portion of the introduction summarizing PQ / PD studies by Li, Brown, Liou, and Kamel has been eliminated. This summary was probably unnecessary in the context of a study protocol.

A problematic parenthetical has been removed that suggested the possibility of obtaining work history from "other ICI sites and for other employers."

The language that remains in that paragraph now reads as follows:

"If there is a significant excess of mortality from PD, an attempt will be made to obtain a more complete work history and information about potential risk factors, for each subject with a mention of PD in their death certificate."

The modified paragraph (and the highlighted language) raises the question of whether the written commitment to obtain a "more complete work history," if there is a significant excess of mortality from PD, effectively would require obtaining information from other ICI sites. In other words, is there any source from which to obtain a more complete work history about such persons other than from other ICI sites?

A suggested modification of this language is: 1

"If there is a significant excess of mortality from PD, an attempt will be made to obtain additional information for each subject with a mention of PD in their death certificate."

We have no further comments to the draft protocol.

Regards.

Jeff

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