

From: Cagen, Stuart Z SCC
Sent: Wednesday, September 12, 2001 3:50 PM (GMT)
To: Tsai, Shan SP SHLOIL-SPS <sptsai@Shell.Com>; Clegg, Patsy M SCC-CHSE-PC <pmclegg@Shell.Com>
Subject: RE: Issues regarding 2nd epi position and the hematopathologist posit ion on the SRP.

Patsy/Shan:

I would recommend trying to convince Elizabeth Delzell to join the SRP. I think this is option 3. Shan and I have worked with her on her extensive well conducted butadiene study and find her to be most capable. This is particularly important for our benzene study in that she has a good sense of the diseases the benzene study will be following (that is, how epidemiology studies should handle lymphomas and leukemias). I would request that we should not limit her involvement with the benzene study and we should ask her to join the SRP now and stay on as a full member. I tried to make this point earlier but to no avail.

Since Shan and I know her I think we would be in as good a position as anyone to try to convince her to change her mind. If this is done I would like to present to her option 3. If she chooses to limit her participation to just the current protocol (option 2) then let that be her decision.

In other news: regarding Dr. van Belle: he looks OK as a statistician but does not seem to have much experience in epidemiology. He should definitely be someone we should discuss but I am not sure yet whether I would recommend him. It looks like his note to George was also a bit out of sequence as he accepted the SRP position with our even asking.

In addition, I am still concerned about the quorum of SRP members who will review the protocols on or before Sept 27. For reference see my prior notes about the difficulty in getting adequate review in time for the IRB submission.

I am available this week to discuss this further if you think it is necessary (Shan: thanks again for the help earlier this week. My stress test yesterday was OK , so I might be available for the next 70 years to discuss this.).

Thanks

Stuart

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

From: Tsai, Shan SP SHLOIL-SPS
Sent: Wednesday, September 12, 2001 7:51 AM
To: Clegg, Patsy M SCC-CHSE-PC; Cagen, Stuart Z SCC
Subject: RE: Issues regarding 2nd epi position and the hematopathologist posit ion on the SRP.

Patsy/Stu,

Dr. Delzell is my choice. I would like to know who sent, although inadvertently, the e_mail to her.

Shan

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

From: Clegg, Patsy M SCC-CHSE-PC
Sent: Tuesday, September 11, 2001 6:29 AM
To: Tsai, Shan SP SHLOIL-SPS; Cagen, Stuart Z SCC
Subject: FW: Issues regarding 2nd epi position and the hematopathologist posit ion on the SRP.
Importance: High
Gentlemen,

If possible, please give me your preference by the end of the day. If the 2 of you could talk and agree a response, I will respond to Pat.

Thanks,
Patsy

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

From: Beatty, Patrick (PWBE) [mailto:PWBE@chevron.com]

Sent: Monday, September 10, 2001 5:39 PM

To: 'BenzConsort-OC@listserve.api.org';

'BenzConsort-TC@listserve.api.org'

Cc: 'twerdokl@api.org'; 'woodallg@api.org'

Subject: Issues regarding 2nd epi position and the hematopathologist position on the SRP.

Importance: High

Oversight Committee,

Epidemiology review of protocol and 2nd Epidemiologist

Dr. Linet (NCI) has declined our invitation to serve on the SRP. She indicated that her workload is such that she cannot take on any additional responsibilities. This leaves us with only one epidemiologist at this time, Dr. Mueller from Harvard.

The situation is complicated by the fact that Dr. Elizabeth Delzell has informed us that she no longer plans to review and comment on the protocol. She was inadvertently sent an e-mail implying that Dr. Linet had been picked for the SRP and that she, Dr. Delzell, for a variety of reasons would not be asked to serve on the SRP. Shortly thereafter, Dr. Delzell responded that she would no longer participate in the protocol review. I infer from the wording of her e-mail, that she was upset by the note indicating that she would not be asked to be on the SRP. Since Dr. Mueller will be out of the country on 9/27, as it stands now there will be no epidemiologist participating in the protocol review meeting.

This leaves us with a number of options.

1.) Try to find another epidemiologist who can serve on the SRP and hope that person can prepare comments on the protocols within two weeks. If not, (and I suspect this will be the case) comments at a later date if not too extensive could be incorporated into the protocols without necessitating resubmittal to the IRB process.

2.) Contact Dr. Delzell and attempt to change her mind about the protocol review. This will still involve explaining why we would use her for this but not as a full SRP member. Unfortunately, the e-mail to her did not spell out the concerns about perceptions of conflict of interest due to her funding history by the petrochemical industry. This would still require eventually finding a second epidemiologist for the SRP. If anyone knows Dr. Delzell personally or has an epidemiologist in their company who does it might help to have them help with this effort.

3.) Revisit Dr. Delzell's history and reconsider her as a full SRP member in the hopes that she would consent and finish the protocol review. If she were to still decline, we are back to No. 1.

My preference is to do 2. Even if she is adamant about no further participation, I think that we should fully explain why she was not invited to join the SRP.

I am asking the Oversight Committee to respond ASAP, because we need a ruling on this before we can take option number 2..

I also want the Technical Committee to schedule a Conference call to discuss and propose candidates for the 2nd epidemiologist. I have been given a number of possibilities.

Hematopathologist

Four of the five companies have agreed with holding off on a search for a hematopathologist for the SRP. ExxonMobil was the one company that did not respond. Instead it will be left to the SRP to decide if they need that expertise. If so it would be one of the two additional positions that the Oversight Committee has agreed to fund at the discretion of the SRP.

Thanks

Patrick Beatty

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