

From: Cagen, Stuart Z SCC <szcagen@Shell.Com>
Sent: Wednesday, July 25, 2001 2:47 PM (GMT)
To: 'George Woodall' <Woodallg@api.org>; Cagen, Stuart Z SCC <szcagen@Shell.Com>; Carol Fairbrother (E-mail) <carol.a.fairbrother@exxonmobil.com>; Patrick Beatty (E-mail) <pwbe@chevron.com>; Donald Burnett (E-mail) <burnetdm@bp.com>; Chris Roythorne (E-mail) <roythorc@bp.com>; Shan Tsai (E-mail) <sptsai@shellus.com>; William Broddle (E-mail) <bill.d.broddle@usa.conoco.com>
Cc: Lorraine Twerdok <twerdokl@api.org>; Clegg, Patsy M SCC-CHSE-PC <pmclegg@Shell.Com>
Subject: RE: Technical Review Committee Conference Call Summary

All:

George: Thanks for providing a quick summary of our call. You correctly captured what was discussed. I would add my request that the technical committee act as a whole for all questions - big or small, and not the alternative model where day to day questions would be only brought to Pat (the Chair). The main reason for this is for educational purposes; that is, for me to be well informed to explain progress and problems of the program to the folks back here. I think this will work as we only have 5 sponsors.

Some comments:

Regarding the relationship of the technical committee to the oversight committee as well as the relationship of the technical committee to the investigators: I would favor an active role, where the technical committee should have an obligation to seek and recommend program issues on behalf of the oversight committee. Although scientific issues will be the purview of the investigators and the scientific peer reviewers, study monitoring might be expected to raise programmatic implementation issues (timing, protocol, other modifications) needing sponsor input. These issues should be directed to the oversight committee via the technical committee.

Regarding reports or manuscripts: The investigators should have full authority over publications with their option to consider sponsor comments. Via the technical committee, the sponsors should participate in discussions between the scientific review panel and the investigators, and their role in meetings should be passive.

Additional issues: the technical committee should also have some sort of relationship with the communications committee to help with the translation of study intent and findings.

Regarding the scientific review panel: timing: do we think the official scientific review panel will (functionally) be arriving a bit late in the game if the current cadre of 4 or 5 reviewers (with some overlap) will be the only ones technically commenting on the protocols before IRB review. Can the university review wait until the full panel is engaged or are there timing issues. Anticipating a yes to the timing issues question: What are these timing issues.

The scientific review panel: I would recommend Julian Preston as he would bring experience and knowledge in the area of genetic toxicology and the relationship of biological markers of exposure to markers of potential biologic activity. Would work well together with Albertini.

Other comments on the scientific review committee:

I do not agree with the comment about Elizabeth Delzell and would still keep her on the list of possibles. She is a fair and thoughtful scientist.

I am still working on possibles from Europe.

I hope this helps.

Thanks

Stuart

.
> -----Original Message-----

> From: George Woodall [SMTP:Woodallg@api.org]

> Sent: Tuesday, July 24, 2001 10:28 AM

> To: Stuart Cagen (E-mail); Carol Fairbrother (E-mail); Patrick Beatty

> (E-mail); Donald Burnett (E-mail); Chris Roythorne (E-mail); Shan Tsai

> (E-mail); William Broddle (E-mail)

> Cc: Lorraine Twerdok

> Subject: Technical Review Committee Conference Call Summary

> Importance: High

>

> To all,

>

> Attached is the draft summary from yesterday's conference call. Since

> then I have also done a little digging to come up with some names for a

> Genetic Toxicologist and this is what I found.

>

> Julian Preston (EPA) He is the head of the Environmental Carcinogenesis

> Division at EPA (Part of the National Health Effects and Environmental

> Research Laboratory which is under ORD), and was formerly head of a

> department at CIIT and previous to that, at Oak Ridge. He is a

> world-class cytogeneticist.

>

> Ray Tice (Integrated Laboratory Systems) Also a world-class

> cytogeneticist, he was formerly at Brookhaven. ILS is a contract lab

> located in RTP, NC doing a lot of work for NIEHS.

>

> Regards,

>

> George

> << File: TechCommCallSummary23July2001.doc >>