

To: Sullivan, Nancy E SCC-CBAR <nesullivan@Shell.Com>;
Cagen, Stuart Z SCC <szcagen@Shell.Com>; Tsai, Shan SP
SHLOIL-SPS <sptsai@Shell.Com>; Colletti, Sarah SJ SCC
<sjcolletti@Shell.Com>; Draper, Joe J SC-CHSE-JFD
<Joe.J.Draper@OPC.shell.com>
From: Clegg, Patsy M SCC-CHSE-PC
</O=SHELL/OU=MSXSCC/CN=RECIPIENTS/CN=PH197432>
Cc:
Bcc:
Received Date: 2001-07-30 14:59:39 GMT
Subject: FW: Benzene Health Research Consortium

Attached is a note that I sent to Don Burnett, bp, chair of the Benzene Health Research Consortium. I wanted to communicate our support and desire to be actively involved.

Patsy

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

From: Clegg, Patsy M SCC-CHSE-PC
Sent: Monday, July 30, 2001 9:54 AM
To: 'burnetdm@bp.com'
Cc: 'Woodall, George'; 'Twerdok, Lorraine'; 'Beatty, Pat'
Subject: Benzene Health Research Consortium

Don,

Thank you to you and bp (how do you spell - lower case or upper case - your company name?) for volunteering to chair the Benzene Health Research Consortium. Shell is very interested in fully participating in this project. As vice-chair, I would appreciate being included in all correspondences and conversations. It is Shell's desire to be adequately briefed to keep Shell as well as the consortium well informed of the decisions and progress of the project. Please let me know if there are specific items that could be handed off to me to do. I look forward to working with you. You can "Count on Shell".

Patsy

Patsy M. Clegg
Product Steward, HSE
Shell Chemical Company, PO Box 4320, Houston, TX 77002
Phone: 713-241-2521 FAX: 713-241-3325
e-mail: pmclegg@shellus.com

To: Clegg, Patsy M SCC-CHSE-PC <pmclegg@Shell.Com>;
Cagen, Stuart Z SCC <szcagen@Shell.Com>
From: Tsai, Shan SP SHLOIL-SPS
</O=SHELL/OU=MSXSOC/CN=RECIPIENTS/CN=ST196949>
Cc:
Bcc:
Received Date: 2001-07-30 15:53:26 GMT
Subject: RE: Benzene Consortia Oversight Mtg - Action Items

Patsy/Stu,

I talked to one of the original China/NCI benzene study investigators, Dr. Guilan Li is willing to serve on the Scientific Review Panel. Dr. Li is a biochemist in training and is currently the director of Industrial Toxicology at the Institute of Occupational Medicine, Chinese Academy of Preventive Medicine. She is one of the two major collaborators from China for the China/NCI study (the other person - Dr. Yin who has officially retired a couple years ago). I have asked her to recommend an hematologist and should hear from her by Thursday.

Shan

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

From: Clegg, Patsy M SCC-CHSE-PC
Sent: Monday, July 30, 2001 8:49 AM
To: Cagen, Stuart Z SCC; Tsai, Shan SP SHLOIL-SPS
Subject: FW: Benzene Consortia Oversight Mtg - Action Items

Hi Stu and Shan,

Attended the 1st Benzene Health Research Program Oversight Committee meeting Thursday of last week. It was a very productive meeting. We agreed to rotate chair. BP will be chair now with Shell as co-chair. Shell will then become chair. Attached is the long list of action items from the meeting. You might want to review the items titled Technical Committee, Scientific and Ethics Review Panels and Protocol Issues .

In terms of the review process and the timeline, I was not able to get agreement/commitment to slow the process, but I asked a lot of questions that seemed to me to have support from ExxonMobil and, maybe BP. It was kind of hard to gauge. I asked:

1. When in Oct is the U of C IRB? Big difference between the beginning and end of the month? Would there really be a big delay if we waited until the Jan meeting in order to accommodate a more broad-based SRP?
2. When is University of Shanghai IRB review? If it isn't until late 4Q, then what is the rush?
3. Can we not go ahead and be setting up the lab while we are waiting for the IRBs? Irons has said that it will take 6 months to get FDA certification of the lab, which is apparently required. I suggested that the lab get equipped, people trained and certification sought parallel to the IRBs. Patrick seemed to think that there might be a problem with going ahead without IRB approval. It might be perceived as not honoring the process.
4. I reminded them that 2+ years have been invested so far, so why the rush now?
5. I reminded them, with very helpful support from Lynn Russo, ExxonMobil, and chair of the PR committee, that we really needed the expanded review from the beginning. Lynn strongly supported that there were too many Harvard people; the lack of international expertise (except Rice), and the fact that there were no Chinese on the board. We expressed the concern that the whole study might be jeopardized from the beginning without this expanded review board. The suggestion to the Technical committee was made to have at least one expert in all

the named disciplines before doing the review.

Hence, we need your help. I know that you made suggestions during your technical call last week. But, now, with the push to internationalize the review board, we need some nominations. Shan, we thought you were in a particularly good position to provide some names from the Chinese scientific community.

Unfortunately, this all has a short time line - I need your decisions by COB Thursday so I can get them to API by Friday.

Thanks for your support on this project.

Patsy

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

From: Lorraine Twerdok [mailto:twerdokl@api.org]

Sent: Thursday, July 26, 2001 4:42 PM

To: 'pmclegg@shellus.com'; 'Beatty, Patrick'; 'Carol A Fairbrother'; 'BURNETT, Don'; 'lynn.b.russo@exxon.com'

Cc: George Woodall; John Wagner; Lorraine Twerdok; Paula Podhasky; Susan Hahn; Bill Frick; 'Broddle, William'

Subject: Benzene Consortia Oversight Mtg - Action Items

To Benzene Health Research Consortium Oversight Committee:

Thanks to you all for a very productive meeting today. While everything is fresh in our minds, I want to get out the action items we developed today.

ALL ACTION ITEMS ARE DUE FRIDAY, AUGUST 3, unless otherwise indicated.

Consortium Agreement Issues:

1. JOHN WAGNER will write & distribute a one-pager listing the pros and cons for an agreement between companies and API vs incorporation of the consortium to include a contractual agreement between companies.
2. JOHN WAGNER will edit the exiting contract agreement based on comments from today's meeting. John will also list sections to be reworked by the consortium agreement workgroup.
3. OVERSIGHT COMMITTEE (OC) MEMBERS will send Lorraine and Paula nominations (minimum = 1 per company) for a consortium agreement workgroup to be staffed by JOHN WAGNER.
4. PATRICK BEATTY and the Technical Committee will develop a 1-page scope of research work, referencing study protocols, to be added to consortium agreement.
5. LORRAINE TWERDOK will circulate relevant API Policies and Procedures to OC for review.

Technical Committee, Scientific and Ethics Review Panels and Protocol Issues:

1. LORRAINE TWERDOK will transcribe and circulate template for technical issue review and flow of information, e.g. protocol amendments.
2. TECHNICAL COMMITTEE will evaluate QA/QC measures for study conduct and report back to OC (due date to be determined).
3. TECHNICAL COMMITTEE will develop milestones for study progress assessment from study protocols (due date to be determined).
4. The following contacts will be made to seek recommendations for international participants on the Scientific Review Panel (SRP):
Myron Harrison - LYNN RUSSO

Chris Roythorne - DON BURNETT & PATRICK BEATTY
Shan Shai - PATSY CLEGG
Otto Wong - PATRICK BEATTY & GEORGE WOODALL
Chinese Investigators - PATRICK BEATTY & GEORGE WOODALL
Jerry Rice - PATRICK BEATTY & GEORGE WOODALL
concauwe - LORRAINE TWERDOK

5. The TECHNICAL COMMITTEE will contact existing list of proposed SRP nominations (due date to be determined).
6. PATRICK BEATTY will contact Rich Irons to find out dates for upcoming U. of CO and Chinese IRB reviews, and also seek advice from Rich on how much "up front" work (purchase lab equipment; train technicians, etc.) is appropriate & advisable before IRB approval is in place.

Communications Committee Issues:

1. SUSAN HAHN of API will contract PR firm with CC guidance (mid-late September timeline).
2. JOHN WAGNER will contract outside council for consortium needs (due date to be determined).

Ad Hoc Consortium Membership Committee - BILL FRICK will spearhead:

1. OVERSIGHT COMMITTEE MEMBERS will submit committee nominations (1/company) to Lorraine Twerdok.
2. GEORGE WOODALL will circulate to OC a list of NGOs & foundations for potential consortium membership.
3. MEMBERSHIP COMMITTEE will develop a list of companies (refining, chemical, other business sectors), associations, NGOs, Foundations, Agencies, etc, to target for membership "drive." Strategies for contacting the various organizations will be developed. (will be a continuing effort over at least the next few months).

Did I forget anything??

Regards,
Lorraine

Lorraine E. Twerdok, Ph.D., DABT
Manager, Health Sciences
American Petroleum Institute
1220 L Street, N.W.
Washington, DC 20005

tel: 202-682-8344
fax: 202-682-8270
email: twerdokl@api.org <<mailto:twerdokl@api.org>>

To: Cagen, Stuart Z SCC <szcagen@Shell.Com>
From: Clegg, Patsy M SCC-CHSE-PC
</O=SHELL/OU=MSXSCC/CN=RECIPIENTS/CN=PH197432>
Cc: Tsai, Shan SP SHLOIL-SPS <sptsai@Shell.Com>
Bcc:
Received Date: 2001-07-30 17:18:45 GMT
Subject: RE: Benzene Health Research Consortium

Stu,

I think it would be great if you were vice chair of the technical committee. I made a point at the meeting that I thought the decision making process should be done by committee and not just by the committee chair. That I saw the chair as a facilitator. Pat seemed to squiggle a little; most everyone concurred with me (or, at least, did not object or take issue). I think I made the point, but it is yet to be determined whether things are actually handled that way. I think we will have to be very proactive at being included.

As far as review meetings, etc, I came away with the feeling that the oversight committee thought that they should be open. We absolutely support the independence of the PI and SRP, but, at the same time recognize our obligation to our companies and to the study as a whole to monitor progress. We suggested, or maybe it was support of an idea that came from the Technical team, to have an annual meeting. 2 purposes. One to hear the progress, findings, etc from the PIs, with an opportunity for the ethics and SRP to comment. Second, to monitor progress of the project against budget. 2 separate activities, but both essential.

Everyone seemed to support the idea of a rotating chair. I felt like the chair position had been pre-determined, but, at least, we got the vice-chair position. It will be important to build a good image and respect during the coming year, so when it is time for the transition, there will not be dragging of the feet.

Patsy

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

From: Cagen, Stuart Z SCC
Sent: Monday, July 30, 2001 10:16 AM
To: Clegg, Patsy M SCC-CHSE-PC; Sullivan, Nancy E SCC-CBAR; Tsai, Shan SP SHLOIL-SPS; Colletti, Sarah SJ SCC; Draper, Joe J SC-CHSE-JFD
Subject: RE: Benzene Health Research Consortium

Patsy:

I just spoke with Pat Beatty and I asked him about the idea of my becoming the vice-chair of the technical committee. This might serve as a vehicle for me (Shell) to become educated during the course of the study, along with the chair of the technical committee, but would not include the 3 or 4 or so other members of the technical committee, so that meetings between the investigators and the science review committee would be limited as discussed by the steering committee. In the end it was only Shell interested in the this level on involvement anyway. Pat thought the vice-chair idea was OK but asked that I work the request through you (Patsy). This would be consistent with the idea of rotation as decided for the steering committee.

Thanks

Stuart

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

From: Clegg, Patsy M SCC-CHSE-PC
Sent: Monday, July 30, 2001 10:00 AM

To: Sullivan, Nancy E SCC-CBAR; Cagen, Stuart Z SCC; Tsai, Shan SP SHLOIL-SPS; Colletti, Sarah SJ
SCC; Draper, Joe J SC-CHSE-JFD
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Cc: 'Woodall, George'; 'Twerdok, Lorraine'; 'Beatty, Pat'
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