

From: Cagen, Stuart Z SCC <stuart.cagen@shell.com>
Sent: Tuesday, April 15, 2003 12:07 AM (GMT)
To: Tholstrup, Susan C SCC <susan.tholstrup@shell.com>
Cc: Tsai, Shan SP SHLOIL-SHLOIL-HE <Shan.Tsai@shell.com>; Clegg, Patsy M SCC-CHSE-PC <patsy.clegg@shell.com>; Owen, David DE SC-CHSE-DO <david.owen@shell.com>
Subject: RE: Benzene Shanghai

Susan:

There is an action for API staff to send me yearly budget spreadsheets from the University of Colorado and from Applied Health Sciences. I can forward these to a Shell finance person.

Requested is help in:

1) tracking study costs, including costs peripheral to the study such as investigator expenses and travel, as well as costs peripheral to the investigators, communications budgets (contractors), and main study administration via API. All of this is captured in a total study budget of almost \$ 23 million..

2) this tracking should be in association with study performance milestones, including projected costs and milestones until work is in public literature

3) early warning in possible overspending.

While these tasks are a bit nebulous, the idea is to give confidence to the sponsors that costs are managed within contractual commitments. I would envision an iterative process which will include the finance person discussing details with the finance office of the University of Colorado and, if necessary, the investigators. We, of course, have to be sensitive to even the appearance of interference. I think this can be managed but my sensitivity to the appearance of study control is my justification to learn as we go (iterative).

I am concerned that Patsy, Shan and myself are not in the inner loop with respect to study tracking but perhaps our leadership in financial responsibility will help correct this. Finally, I am again concerned the technical committee (expect me) is quite comfortable waiting until around the August meeting to challenge our financial situation instead of prior to the 19 June API executive committee meeting.

Shan and Patsy: please weigh in on these matters.

Thanks

Stuart

Stuart Cagen

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

From: Tholstrup, Susan C SCC

Sent: Monday, April 14, 2003 8:18 AM

To: Cagen, Stuart Z SCC

Subject: RE: Benzene Shanghai

Stuart,

I am having Shirley find a meeting for all of us so we'll move this forward shortly. Can you give me a few bullets around what you would like the Shell finance person to do?

thanks,

Susan

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

From: Cagen, Stuart Z SCC

Sent: Saturday, April 12, 2003 10:36 PM

To: Clegg, Patsy M SCC-CHSE-PC; Tholstrup, Susan C SCC; Tsai, Shan SP SHLOIL-SHLOIL-HE;
Iannarone, Lauren B SCC-CSEA; Owen, David DE SC-CHSE-DO

Subject: RE: Benzene Shanghai

All:

Shan: Please embellish or correct as necessary, but here are some observations from Thursday and Friday's Shanghai technical committee meeting:

- 1) The Shanghai is projected to be about 9 months behind the original schedule, as Sept 1 2002 was estimated as the date for the first case and it is now projected to be somewhere between 15 April and 31 May 2003.
- 2) The technical committee agreed to draft a letter to the investigators (Rich Irons and Otto Wong) that will request an update in the study plan including cost parameters. The current committee recommendation is that a response will be requested in time for the August 2003 annual meeting and not in preparation for the 19 June API executive committee meeting. The expectation is that a) the API executive committee will only consider helping a study at its current cost (\$ 22.7 million) and that b) there are contractual expectations with the University of Colorado that the study will be completed with previously defined costs.
- 3) API staff will develop written procedure listing tracking mechanisms that this Committee is using to track / chart / steward the financial performance of the investigators, staff costs and other costs associated with the Shanghai study.
- 4) API staff will contact UC financial department (Mary McConnell) to assist with tracking of Irons' expenditures, with level of detail that we need and in a useful format.
- 5) A possibility of help from a Shell finance expert was suggested and, if this happens, a set of financial information from the investigators will be delivered via API staff.
- 6) Some personal notes: a) Regarding # 2, above: While I was more in favor of getting a more accurate picture of expected costs before the 19 June API executive session, the group voted me down. Their reasoning was that it would not help to know the study costs would increase beyond \$ 22.7 million earlier because even if the consortium is successful in getting API as a safety net, they will not pay more than the current shortfall. My argument in favor of finding out sooner rather than later was in response to an earlier question of budget creep from the API executive committee (and Nancy, as you might recall) and I would anticipate the same question on 19 June. b) It still seems that Patrick Beatty is in contact with the investigators (with or without API staff) on some regular basis without including the rest of the technical committee, and although I asked about this, there was no time or inclination by others for clarification or correction of this. c) Finally, the next benzene symposium was discussed. Patrick is working with a steering committee for a 2 day meeting in Lyon (IARC HQ) in Oct or Nov of 2004. The vision is for a limited session with only about 80 participants, by invitation only. Discussed will be new data since the 1995 benzene symposium, such as the NCI China study, the Australian study and an introduction to the Shanghai study that will be well underway but not nearly completed (expected completion in 2007). Shan asked about presenting some of his work.

Next steps: I recommend we collect our Shell thoughts regarding the above, with some possible actions, such as identify a Shell finance person to help the consortium understand the budget, accounting and payment program, and agree on Shell positions on some of my gripes, with possible resolution via future technical or oversight

committee discussions.

Stuart

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

From: Cagen, Stuart Z SCC

Sent: Thursday, April 10, 2003 4:19 PM

To: Clegg, Patsy M SCC-CHSE-PC; Tholstrup, Susan C SCC; Tsai, Shan SP SHLOIL-SHLOIL-HE;
Iannarone, Lauren B SCC-CSEA; Owen, David DE SC-CHSE-DO

Subject: RE: Benzene Shanghai

All:

In preparation for the Benzene Shanghai Technical committee meeting tomorrow, I met (via telephone) with Pat Beatty, Shan Tsai, and API Staff this afternoon to review financials from the University of Colorado and Applied Health Sciences (Otto Wong). We seem to be making progress in understanding how close budgets are matching costs and how costs match study milestones. In this regard, I offered a suggestion that there might be a Shell financial person resource available to help us through the paperwork and perhaps work with the University of Colorado financial office, as we discussed. Notice I offered the suggestion but I did not officially offer someone to help us.

I think it is still a good idea to get expert advice and a Shell person helping the consortium seems to me to be an effective strategy.

Thoughts ?

Stuart

Stuart Cagen

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

From: Cagen, Stuart Z SCC

Sent: Friday, April 04, 2003 2:45 PM

To: Clegg, Patsy M SCC-CHSE-PC; Tholstrup, Susan C SCC; Tsai, Shan SP SHLOIL-SHLOIL-HE;
Iannarone, Lauren B SCC-CSEA; Owen, David DE SC-CHSE-DO

Subject: Benzene Shanghai

All:

For your information.

The long overdue technical committee meeting of the Shanghai consortium will take place next Friday at API. Shan and I will attend. I have not seen an agenda yet but it is encouraging that Patrick Beatty (Chevron) has called the meeting and that he invited Shan and myself to help him review some of the financial books the day before.

Stuart Cagen

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