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Received Date: 2001-12-31 20:42:48 GMT
Subject: RE: Benzene budget issues

Stu/Patsy,

Additional options we may have are:

- 1) Oversight committee approves additions and continues to acknowledge shortfall as Stu suggested in his #1. However, we should consider to reduce the scope of the project, particularly some components of the biomarkers (molecular epidemiology) study.
- 2) Shorten the project by one year if an "adequate" sample size can be reached by year 4.

It is my understanding from the 12/19 conference call that the project will not get officially started until the 3rd quarter of 2002.

Happy New Year!!!

Shan

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

From: Cagen, Stuart Z SCC
Sent: Thursday, December 27, 2001 11:58 AM
To: Clegg, Patsy M SCC-CHSE-PC; Tsai, Shan SP SHLOIL-SPS
Subject: Benzene budget issues

Shanghai benzene study budget issues:

Budget issues for the Shanghai study have been a previously recognized concern. Throughout the development of this program, budget estimates have been revised (significantly) upwards more than once. The current estimated budget of almost \$ 23 million is at least \$ 3 million above the estimate developed at the beginning of 2001, when potential consortium members were recruited. A large amount of the recent increase is a result of protocol additions following advice from the Scientific Review Panel (SRP), although SRP concurrence of investigator developed protocol changes are pending.

On the basis of the lower budget figure, sponsors were identified, and by third quarter of 2001 there was agreement among five (5) sponsors, which led to the signing of a contract agreement. With respect to budgetary considerations, the contract agreement acknowledged, either directly or indirectly, a commitment inconsistency such that the budget needs have always been at least \$ 2 million above maximum sponsor commitments. It has been expected – either directly or indirectly – that over the course of the multiyear study, additional funding partners would be identified to cover expected budget shortfalls. With the new additions, the budget shortfall has at least doubled.

On December 19, 2001, the technical committee agreed that the SRP initiated (and investigator developed) protocol additions should be considered, and final approval for the new protocols by the sponsors is sought from the oversight committee.

The issue of the budget shortfall – now the greater shortfall – might need further consideration very soon as the next step is the University of Colorado IRB review. It was learned on December 19, 2001 that the IRB would expect sponsor support for the entire protocol. The oversight committee protocol and budget approval would therefore carry a financial obligation beyond what the sponsors are currently expecting.

I recommend that we discuss the situation among ourselves as soon as feasible (2 January ?) and then offer advice to (and then seek approval from) the Aromatics PBU.

Additional funding partners within Shell might still be possible (the Group or US Oil Products, etc), and I have volunteered to help the outreach effort (now a project of Patrick Beatty of Chevron and Myron Harrison of ExxonMobil).

Options with or without the recruitment of additional sponsors:

- 1) Oversight committee approves additions and continues to acknowledge shortfall.
- 2) Oversight committee approves additions and acknowledges shortfall with a revised greater commitment as a backup to less than needed (failed ?) outreach effort.
- 3) Oversight committee reports back to investigators that it is more prudent to only plan on a protocol with a budget that is fully funded. This means significant time loss due to protocol re-writes and required SRP re-review. Possible China political ramifications. Additions can be made later as funds from other sources are received. The University of Colorado IRB would agree to additions but not subtractions, especially for financial reasons.

Shell possibilities: recommend options to oversight committee with recommendations to other sponsors. For example, Shell still agrees to the \$ 3 million but this is the maximum. If other sponsors agree with protocols additions with the funding enigma, Shell expects the program to be fully funded by the other sponsors. This condition would imply # 3 above but would allow 1 and 2 if other sponsors are more ambitious (or less cautious).

Shan: anything to add ?

Patsy: Oversight committee votes are due early-mid January (I do not recall the date, perhaps 15 January)

Thanks

Stuart
