

Benzene Health Research Consortium Program

The Benzene Health Research Consortium was formed October 1, 2001 based on a total program costing \$19,761,000, to be funded entirely from participating sponsor companies. The cost of the program was derived from detailed research cost estimates provided by the investigators and other costs associated with the project determined by the funding sponsor companies. Any changes to the program need the endorsement of the Consortium Oversight Committee. The founding members committed up to \$16,500,000 (11 shares at \$1,500,000/share; BP - 3 shares, ChevronTexaco – 2 shares, ConocoPhillips – 1 share, ExxonMobil – 3 shares, Shell – 2 shares) and agreed to find additional sponsors for the study.

In December 2001, the Consortium Oversight Committee endorsed a revised program of \$22,789,300 (11 shares at \$2,071,755/share or an increase of \$571,755 per share). This revised cost estimate increased the funding shortfall from \$3,261,000 to \$6,289,300. Increases in the research cost estimates were made to address protocol modifications recommended by the Scientific and Ethics Review Panels. The recommendations included substantial additional procedures for exposure assessments, increases in the number of study subjects, increases in subject compensation, net addition of 2 laboratory studies, and adding a Workgroup for consultation on difficult diagnoses. The consortium also modified other costs associated with the program by increasing estimates for the expert panels, and adding costs for outside legal council and study Quality Assurance/Quality Control (QA/QC). The original cost estimate included reimbursement to API for direct staff time, direct expenses related to the program, overhead to cover the fair share of API corporate services burden and the reimbursement of start-up costs of the program incurred by API prior to formation of the consortium. Since the program costs were increasing and the start up costs had already been budgeted by API, the revised cost estimate eliminated this \$500,000 reimbursement. The estimate for the other reimbursements to API for direct expenses and burden increased moderately with the increasing scope of the program. Reimbursements to API are based on actuals as incurred and not on the program estimate. The details of the API reimbursement is described further in Note 4 to the table below. API staff resources on the program have been ranging from .5FTE to 1.6FTEs being budgeted for 2004. These resources include .5FTE of a scientist, .5FTE program associate, and .5FTE administrative.

Modifications to the currently endorsed program (December 2001) have been proposed by the Technical Committee Budget Workgroup for Oversight Committee endorsement at the upcoming August 19, 2003 meeting. The proposal does not change the total program cost, but rather reallocates funds between existing budget line items. Proposed changes include increases in Field Expenses and Fudan University Costs, with corresponding decreases in Review Panels costs, outside legal council, public affairs, and QA/QC.

As with all API special solicitations, funds received from the participating companies are only spent on the approved Benzene Health Research program and remaining funds, if any, at the conclusion of the program would be returned to those members in the same proportion as the funds had been contributed.

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Item	Original Cost Estimate (Jan. 2001)	Program Cost Changes (Dec. 2001)	Revised Cost Estimate (Dec. 2001)	Modifications to Program under consideration
Case-Control Study ¹	\$1,761,000	\$522,095*	\$2,283,095	\$2,283,095
Disease Progression & Molecular Epidemiology Studies ¹	\$13,665,017	\$1,593,000*	\$15,258,017	\$15,258,017
Field Expenses ²	\$1,253,428		\$1,253,428	\$1,596,833
Fudan University	\$190,555		\$190,555	\$661,423
Total Research Costs	\$16,870,000	\$2,115,095	\$18,985,095	\$19,799,368
Scientific Review Panel (SRP)	\$350,000	\$298,000**	\$648,000	\$551,736
Ethics Review Panel (ERP)	\$100,000	\$116,000**	\$216,000	\$192,000
External Pathology & Cytogenetics Panel		\$130,000*	\$130,000	
Total Panel Costs	\$450,000	\$544,000	\$994,000	\$743,736
Outside Counsel		\$500,000**	\$500,000	\$100,576
Public Affairs ³	\$1,000,000		\$1,000,000	\$960,600
Research Quality Assurance/Quality Control Activities		\$225,000**	\$225,000	\$100,000
Other Costs	\$1,000,000	\$725,000	\$1,725,000	\$1,161,176
Start up Costs	\$500,000	(\$500,000)**		
Reimbursement of Direct Expenses	\$771,000	\$114,205**	\$885,205	\$885,020
Reimbursement of API corporate services burden	\$170,000	\$30,000**	\$200,000	\$200,000
Total Reimbursements to API⁴	\$1,441,000	(\$355,795)	\$1,085,205	\$1,085,020
GRAND TOTAL	\$19,761,000	\$3,028,300	\$22,789,300	\$22,789,300

* SRP and ERP recommended changes endorsed by Consortium Oversight Committee

** Consortium Oversight Committee recommended and endorsed changes

Notes

¹The consortium endorsed research costs increases in December 2001, to implement protocol modifications recommended by the SRP and ERP. Independent scientific and ethics protocol and study review is a continuing requirement of funding sponsor companies.

² US scientists' travel and living expenses in China.

³ Public Affairs contracts of \$485,000 have been executed and nearly 50% spent.

⁴ Estimate for reimbursement to API; actual charges are based on billable hours/costs incurred (the direct technical and legal time to develop and manage approximately 25 contracts/grants and provide administrative support for consortium committees); overhead calculated as 25% of salary to cover the fair share of API corporate services burden. The corporate services burden include staff time and overhead to invoice and collect consortium funds, administer the contracts; and provide budget, financial review and proper accounting of consortium finances. Also includes direct consortium committee meeting costs, web site development and hosting, and other miscellaneous costs (e.g. contract translations into Chinese) incurred while managing program.