

DRAFT

SHS Proposed Budget Revision
Oversight Committee

December 14, 2006
San Francisco

Conditions for Additional Funding

- Additional QA/QC process implemented
 - SRP Chair leads
 - Team of Otto Wong, QA/QC Specialist (Judy Baldwin), other SRP members
 - Total process review and documentation
 - Checks and metrics put in place
 - Metrics on “reportable” cases provided monthly to SRP Chair and OC
 - QA/QC team will identify

Conditions for Additional Funding (Continued)

- Payments geared to study progress milestones
- Ensure database backup in the U.S. and availability for use by QA/QC team
- Total additional funds for SHS will not exceed \$9.1M (\$827K/share)

Proposed Timeline

- 1/5/07 -- SHS members make funding decision
- 1/8/07 -- Funding & conditions relayed to PI
- 1/31/07 -- QA/QC team identifies metrics
- 1/31/07 -- Amendment to research agreement drafted and signed by SHS companies
- 3/15/07 -- First metrics report to SRP Chair and OC for Feb. '07... additional monthly metrics generated thereafter on same schedule
- 3/31/07 -- U of Co Grant contract revised by API
- Case accrual to YE 2007
- Data analysis completed by YE 2008
- Payment Schedule (U of Co funded through June '07)
 - First payment 15 Days after receipt of 3/15/07 metrics report
 - Additional payments to follow upon completion of 300, 400, and 500 NHL cases
- Closing ceremony 4Q'08
- Consortium terminated 12/31/08

Background -- Case Definitions

- Accrued Case is “reportable” when:
 - Finalized diagnosis completed
 - Consent form completed
 - Interviews of cases and matched controls completed
 - All 3 above stored in the database
- Additional steps to “finalize” data for use:
 - Stored data is QA’d within the database by QA/QC function
 - All data for Bz cases translated into English

3/18/07

Proposed Extention of Studies on Benzene Toxicity in Shanghai, China

RESEARCH PROTOCOL AND CRITERIA DOCUMENT

I. ANALYSIS OF DISEASE PROGRESSION FOR APLASTIC ANEMIA, MYELO-DYSPLASTIC SYNDROME, ACUTE MYELOGENOUS LEUKEMIA AND BENZENE POISONING IN SHANGHAI, CHINA

II. MOLECULAR EPIDEMIOLOGY OF BENZENE-EXPOSED WORKERS IN SHANGHAI, CHINA

III. DIAGNOSIS AML AND LYMHOD NEOPLASMS IN SHANGHAI, CHINA

A MULTICENTER INTERNATIONAL STUDY

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SHANGHAI HEMATOLOGY SOCIETY

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