

Shanghai Health Study

Sponsor: Benzene Health Research
Consortium

November 2003

Shanghai Health Study

- Program
- Program Management
- Accomplishments
- Events and Path Forward
- Shell Activities

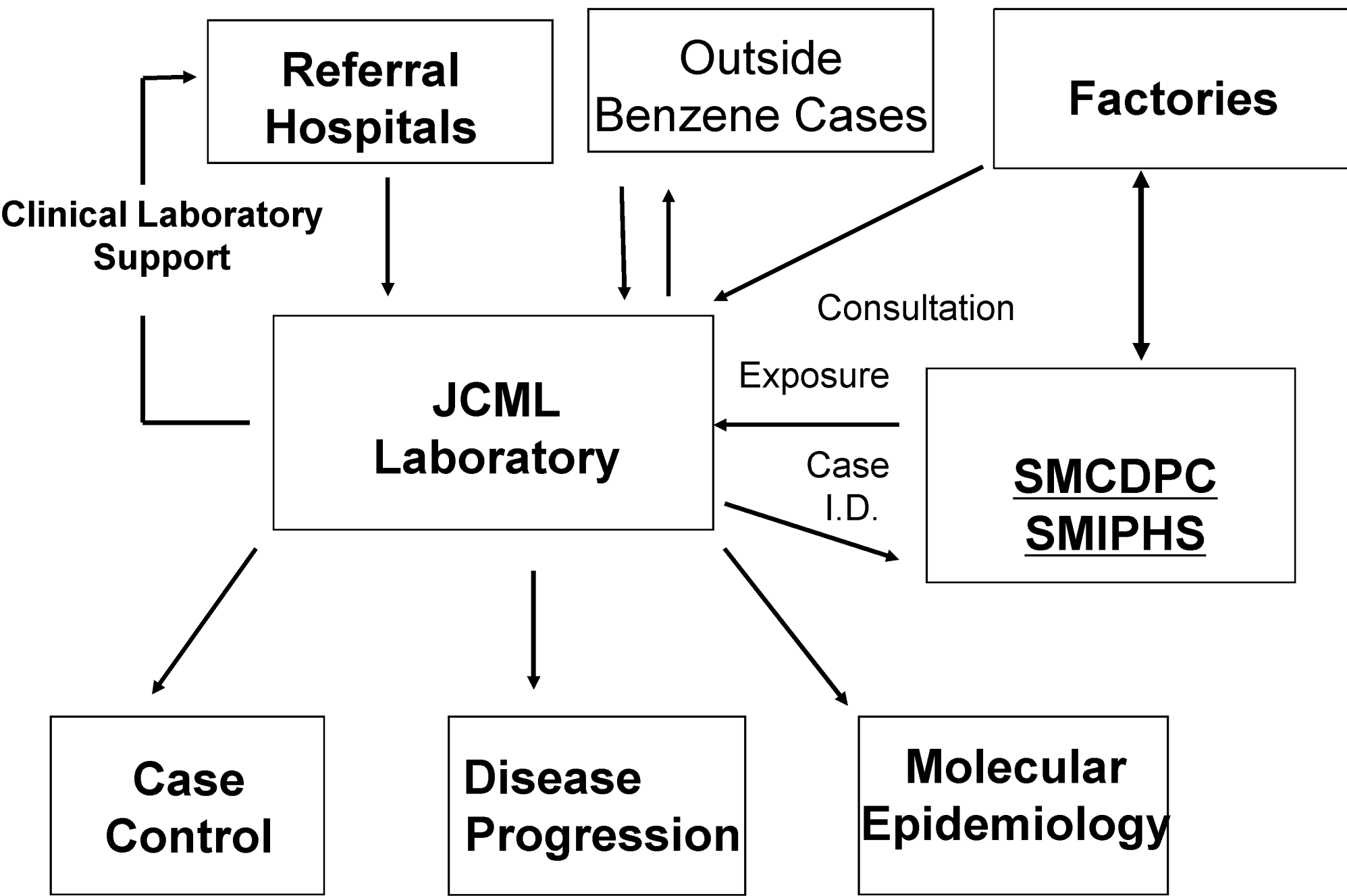
Health Effect Study of Benzene in Shanghai

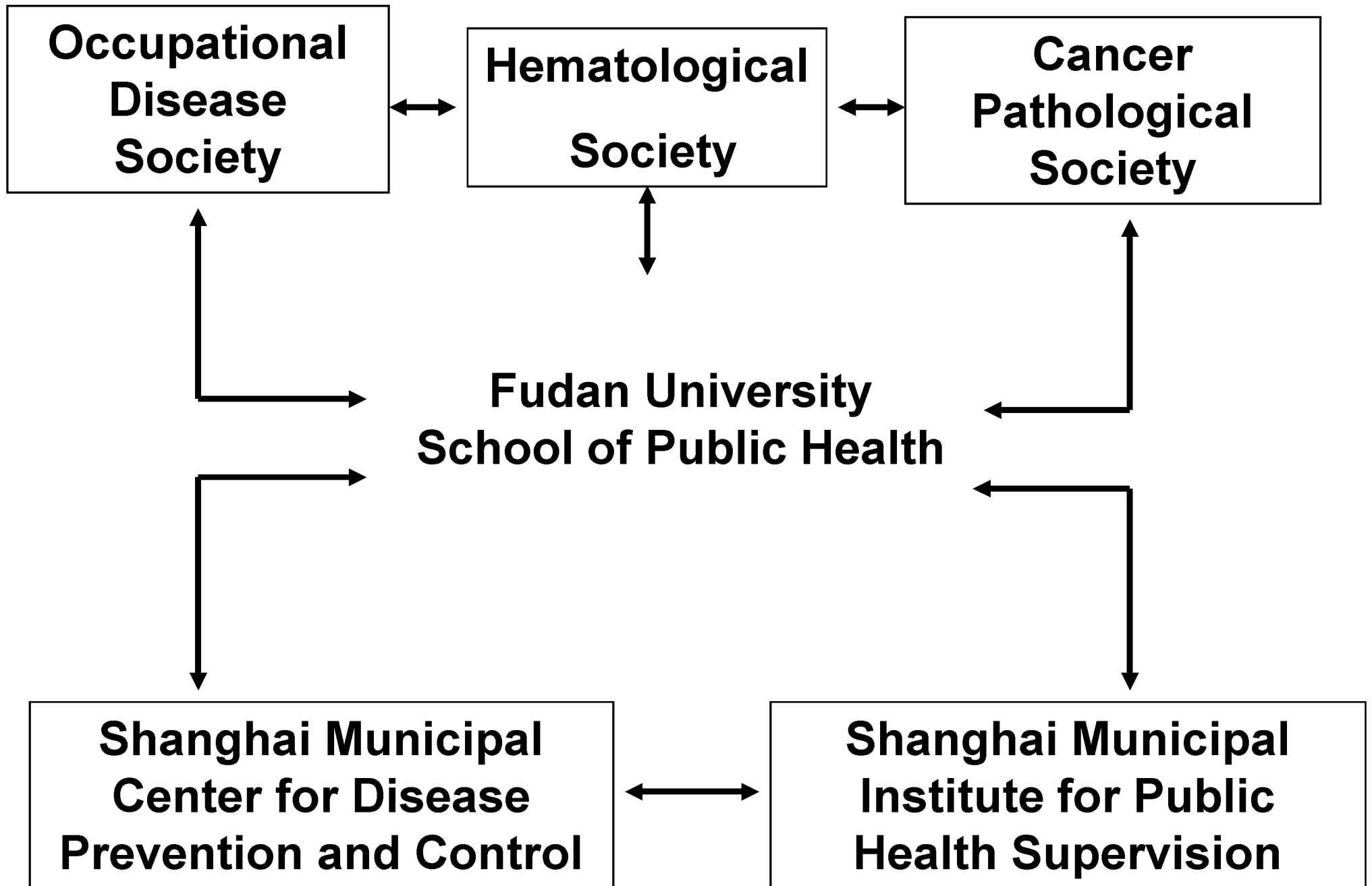
**AML/NHL
Case Control
Study**

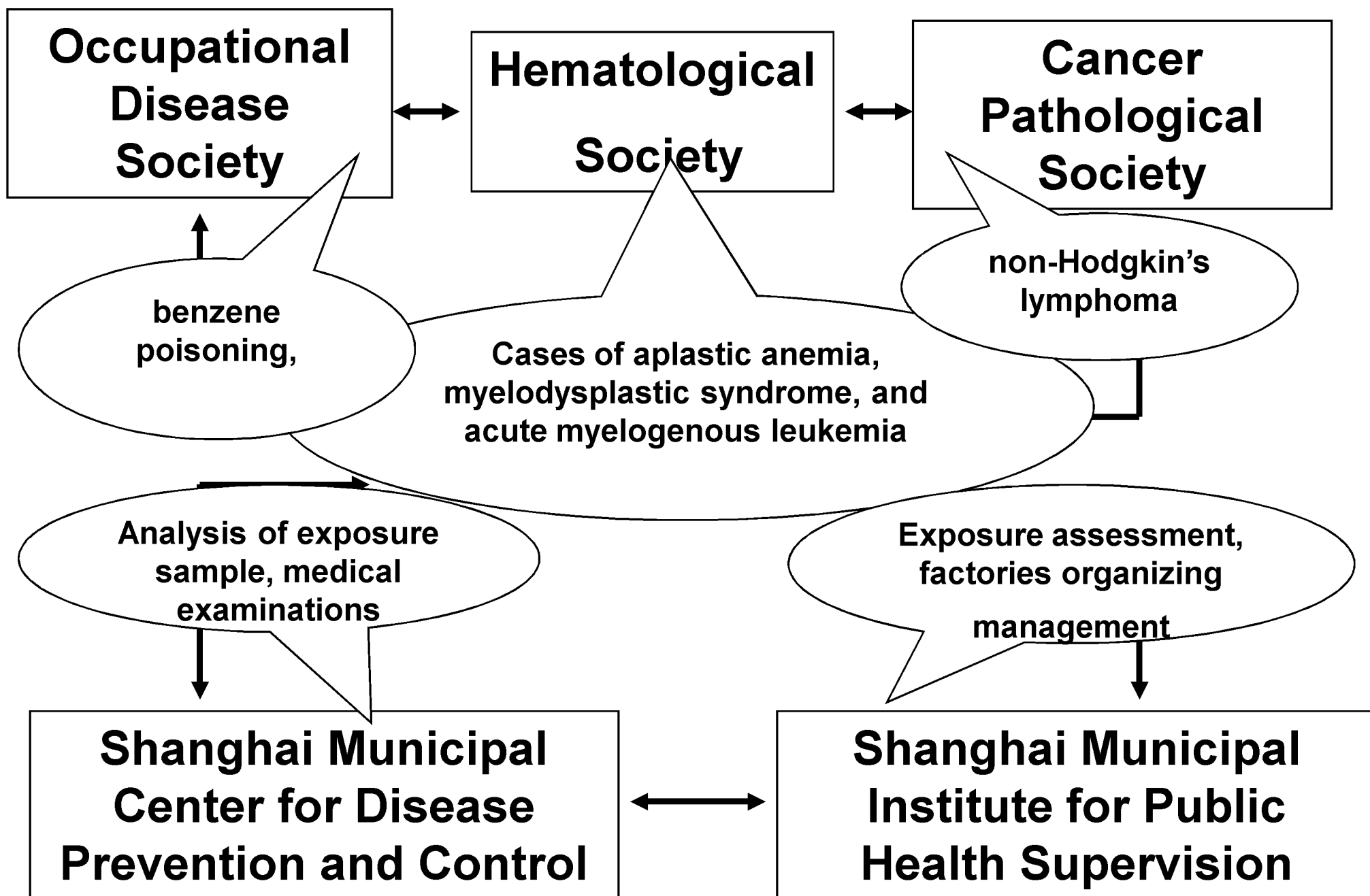
**AA/MDS/AML/BP
Disease
Progress
Study**

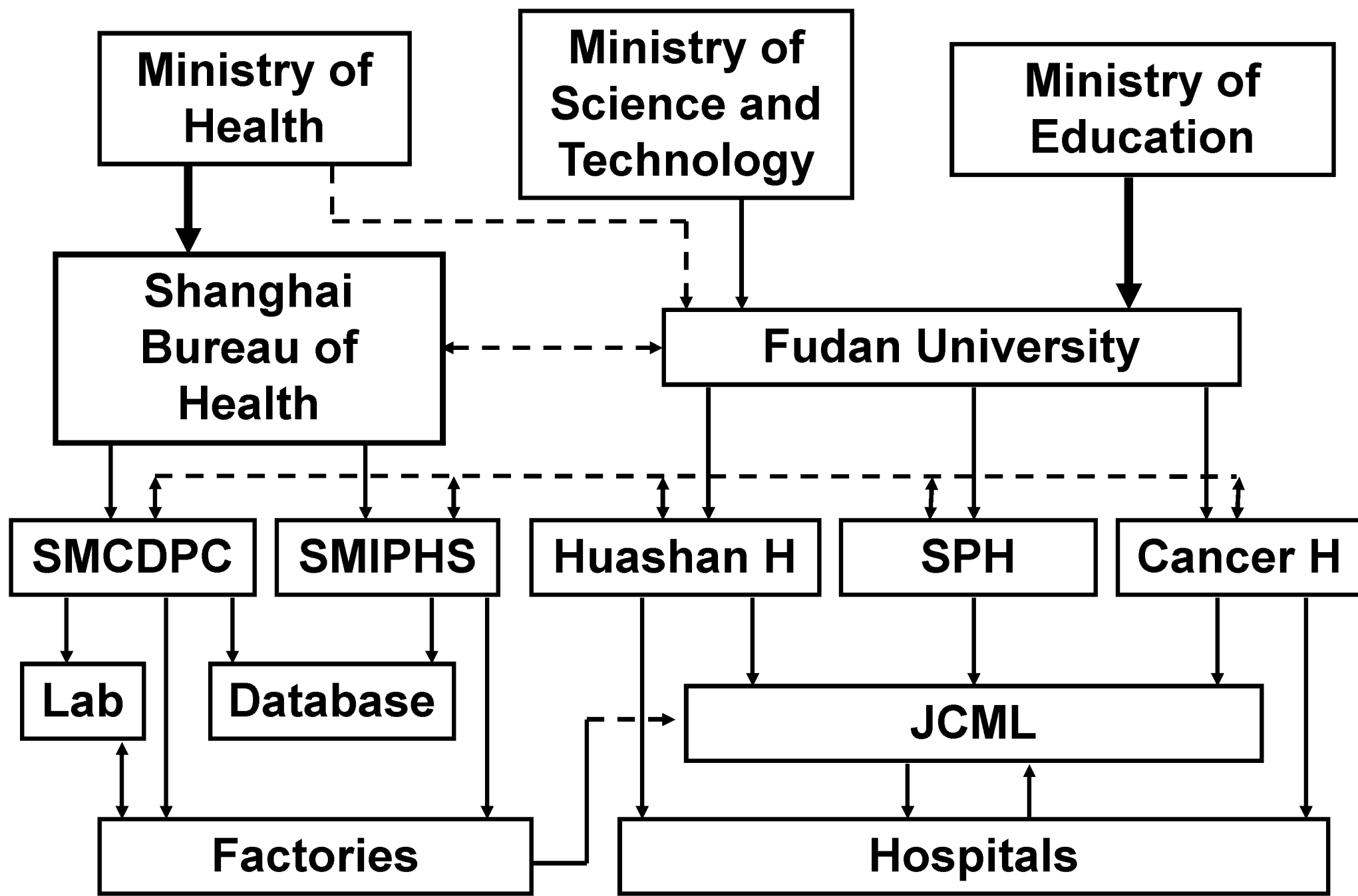
**Molecular
Epidemiological
Study
of Benzene
Exposure**

**Joint Sino-US Clinical and Molecular Laboratory
(JCML)**









Shanghai Health Study

Program Management

- Budget planning
 - Budget revised to meet new funding level, \$21.08M
 - Working with investigators for protocol revisions, with scientific review, to meet new budget.
 - Quarterly financial report format finalized.
- Contract reviews
 - Process in place
- External Stakeholders Engagement
 - Process beginning

Budget Revision

Item	Original Cost Estimate (Jan. 2001)	Approved Revised Cost Estimate (Dec. 2001)	Unapproved Changes API not approved (June 2003)	Approved 11 NOV 03 OC mtg
AHSciences Case-Control Study	\$1,595,000	\$2,283,095	\$2,283,095	\$2,283,095
DP & ME Studies (UCHSC)	\$13,665,017	\$15,258,017	\$15,258,000	\$14,508,000
Irons(T & E)	\$1,253,428	\$1,253,428	\$1,597,273	\$1,413,428
Fudan University	\$165,700	\$190,555	\$661,000	\$230,000
Total Research Costs	\$16,679,145	\$18,985,095	\$19,799,368	\$18,434,523
Scientific Review Panel		\$648,000	\$551,736	\$300,000
Ethics Review Panel		\$216,000	\$192,000	\$64,000
External Pathology & Cytogenetics Workgroups(Co		\$130,000	\$0	\$0
Total Panel Costs	\$450,000	\$994,000	\$743,736	\$364,000
API Seed Monies	\$500,000	\$0	\$0	\$0
Outside Counsel		\$500,000	\$100,576	\$100,000
Public Affairs	\$1,000,000	\$1,000,000	\$960,600	\$550,000
QA/QC Activities		\$225,000	\$100,000	\$100,000
UCHSC Interest				(\$100,000)
contingency	\$190,855	\$0	\$0	\$390,272
Miscellaneous Costs	\$1,690,855	\$1,725,000	\$1,161,176	\$1,040,272
Subtotal	\$18,820,000	\$21,704,095	\$21,704,280	\$19,838,795
API Admin.	\$941,000	\$1,085,205	\$1,085,019	\$1,245,205
GRAND TOTAL	\$19,761,000	\$22,789,300	\$22,789,299	\$21,084,000

Shanghai Health Study

Accomplishments

Participating Organizations

University of Colorado Health Sciences Center

Fudan University

University of Cincinnati

Shanghai Hematology Society

Shanghai Pathology Society

Shanghai Occupational Medicine Society

Shanghai Municipal Center for Disease Prevention

Institute for Public Health Supervision

Shanghai Public Health Bureau

ExxonMobil Biomedical Sciences, Inc.

Twenty One Shanghai Referral Hospitals

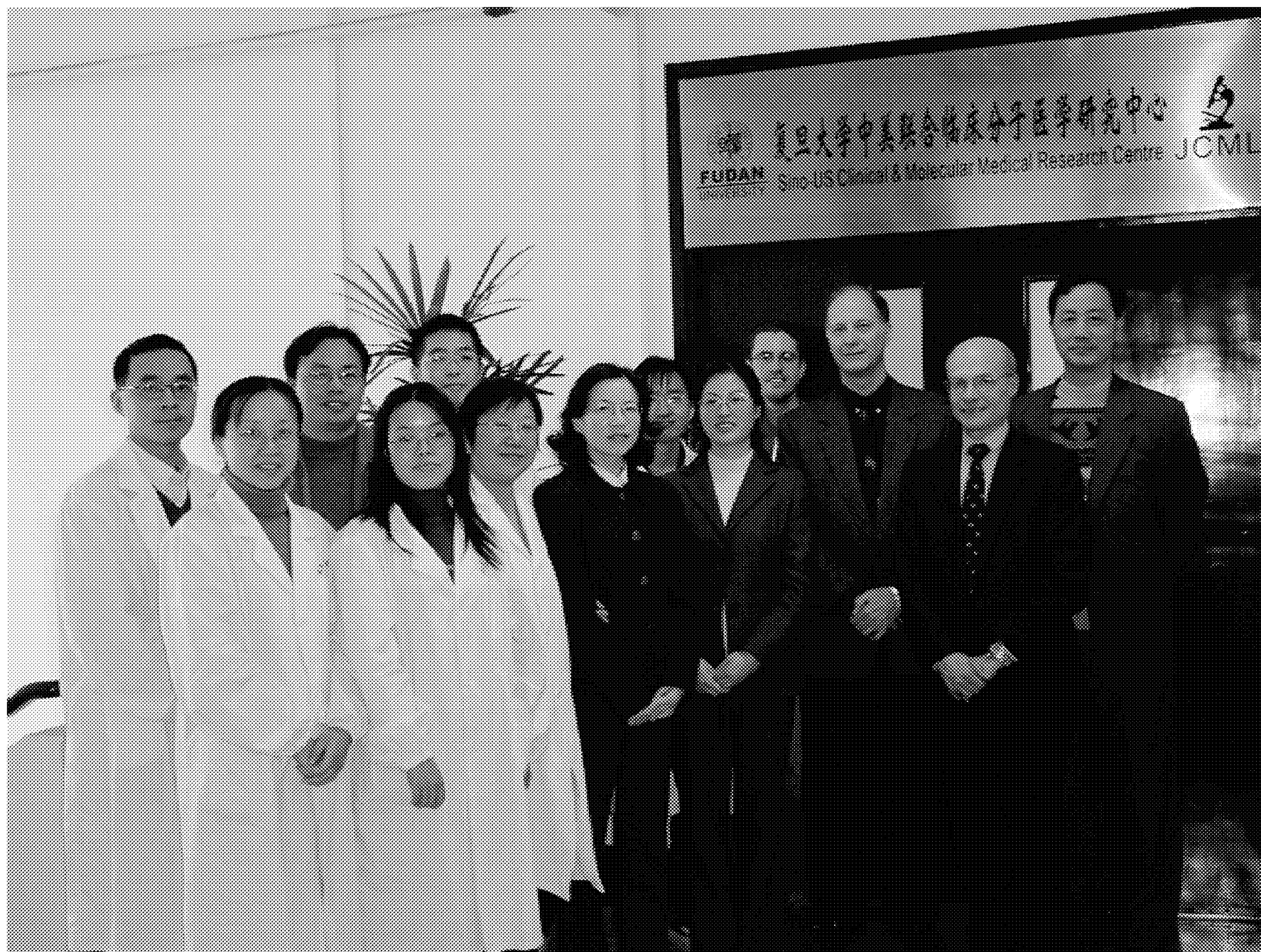
Chinese National Committee on Occupational Standards

Milestones

Feasibility Analysis Shanghai	Aug, 1999
DP/ME Proposals (Prospective)	Nov, 1999
Final SAP Approval	Jan, 2001
Training of clinical and laboratory personnel	Feb, 2001
Laboratory construction begins in Shanghai	Feb, 2001
Intl. Ethics Committee Approves Protocols	Mar, 2001
Contractual Arrangements Completed	Aug, 2001
Laboratory construction completed	Aug, 2002

Milestones

Equipment installation and training	Jan 2002- Mar, 2003
COMIRB Approval of Protocols (Provisional)	May, 2002
Fudan IRB Approval of Protocols	Aug, 2002
COMIRB Approval of Protocols (Final)	Nov, 2002
Bilingual database system, installed	Jan, 2003
Chinese licensing and approval	Feb, 2003
US training of Chinese personnel completed	Mar, 2003
Clinical Laboratory Start-up	Jun, 2003
Case Accrual CC, DP	Jul, 2003



Shanghai Health Study

Events and Path Forward

- First Annual Meeting was a success
- Launch event celebrating completion and start up of the laboratory – December 2003
- Stakeholder Engagement discussions to begin– December 2003
- Next annual meeting – August 2004

Shanghai Health Study

Shell Activities

- Shell Communication
- Quarterly updates
- Other?

Shanghai Health Study

Sponsor: Benzene Health Research
Consortium

Shell Steering Team Update
September 2004

Shanghai Health Study

Agenda

- Study Briefing
 - Program
 - Program Management
 - Accomplishments
 - Shell Activities
- Shell Business Sponsor Transfer
- Issues

Health Effect Study of Benzene in Shanghai

**AML/NHL
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Study**

**AA/MDS/AML/BP
Disease
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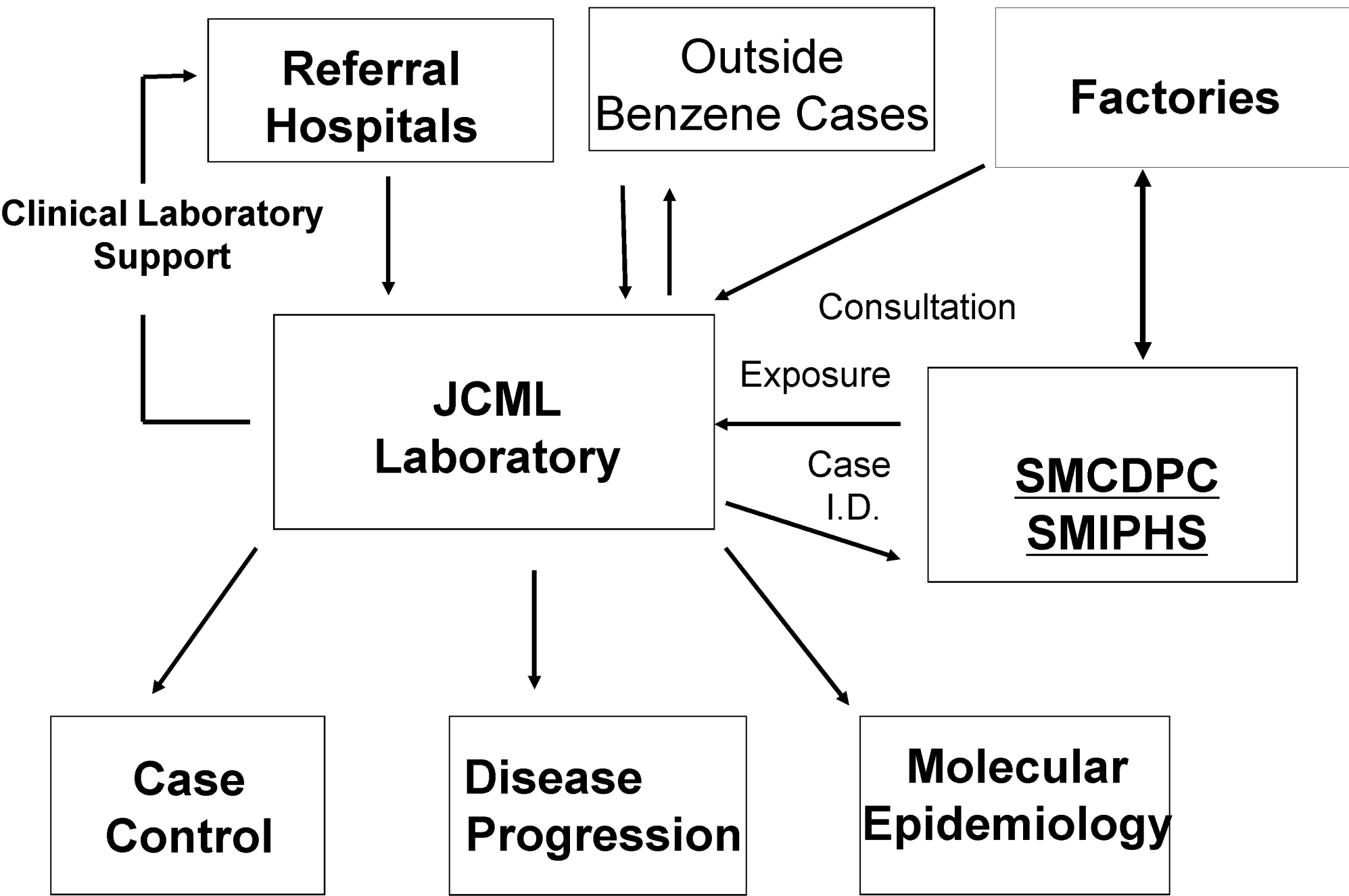
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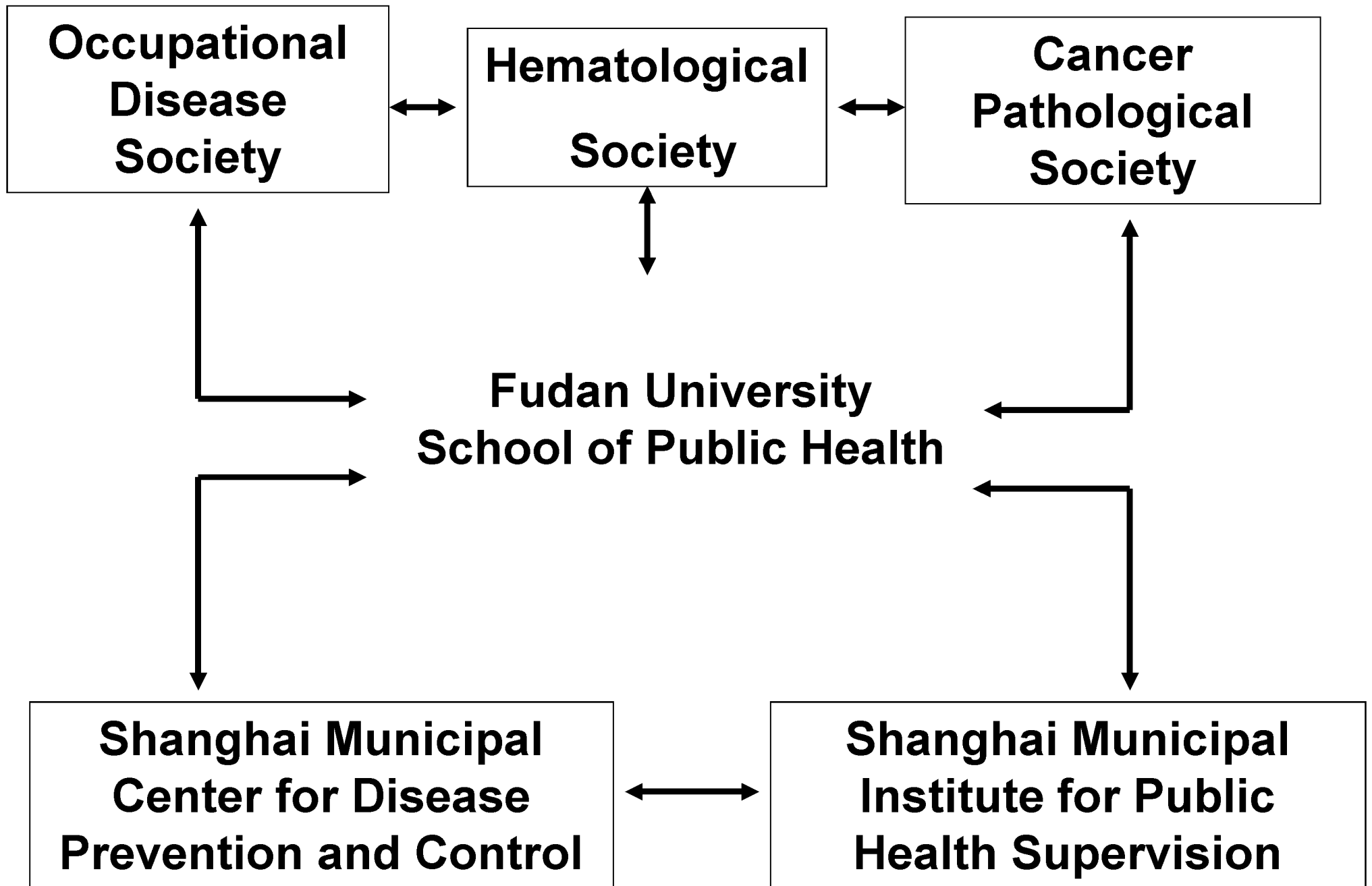
**Joint Sino-US Clinical and Molecular Laboratory
(JCML)**

Shanghai Health Study

- Program

- 6 Sponsors (Shell, ChevronTexaco, ExxonMobil, ConocoPhillips, BP, Marathon)
- Three studies
- Benzene and leukemia/lymphoma epidemiology
 - Benzene exposure estimation in Shanghai community – a challenge.
 - Leukemia/lymphoma epidemiology - a science based approach to understanding disease progression of a complex family of diseases:
 - **The older concept that leukemias are fundamentally different from solid tumors of the same cell type, is replaced in the new WHO classification in which lymphoid tumors of a given cell type are a single entity that may present either as leukemia or lymphoma.**





Shanghai Health Study

Program Management

- Budget planning
 - Funding level: \$21.08M
 - Shell's contribution:\$ 4.12M
- External Stakeholders Engagement
 - Process beginning

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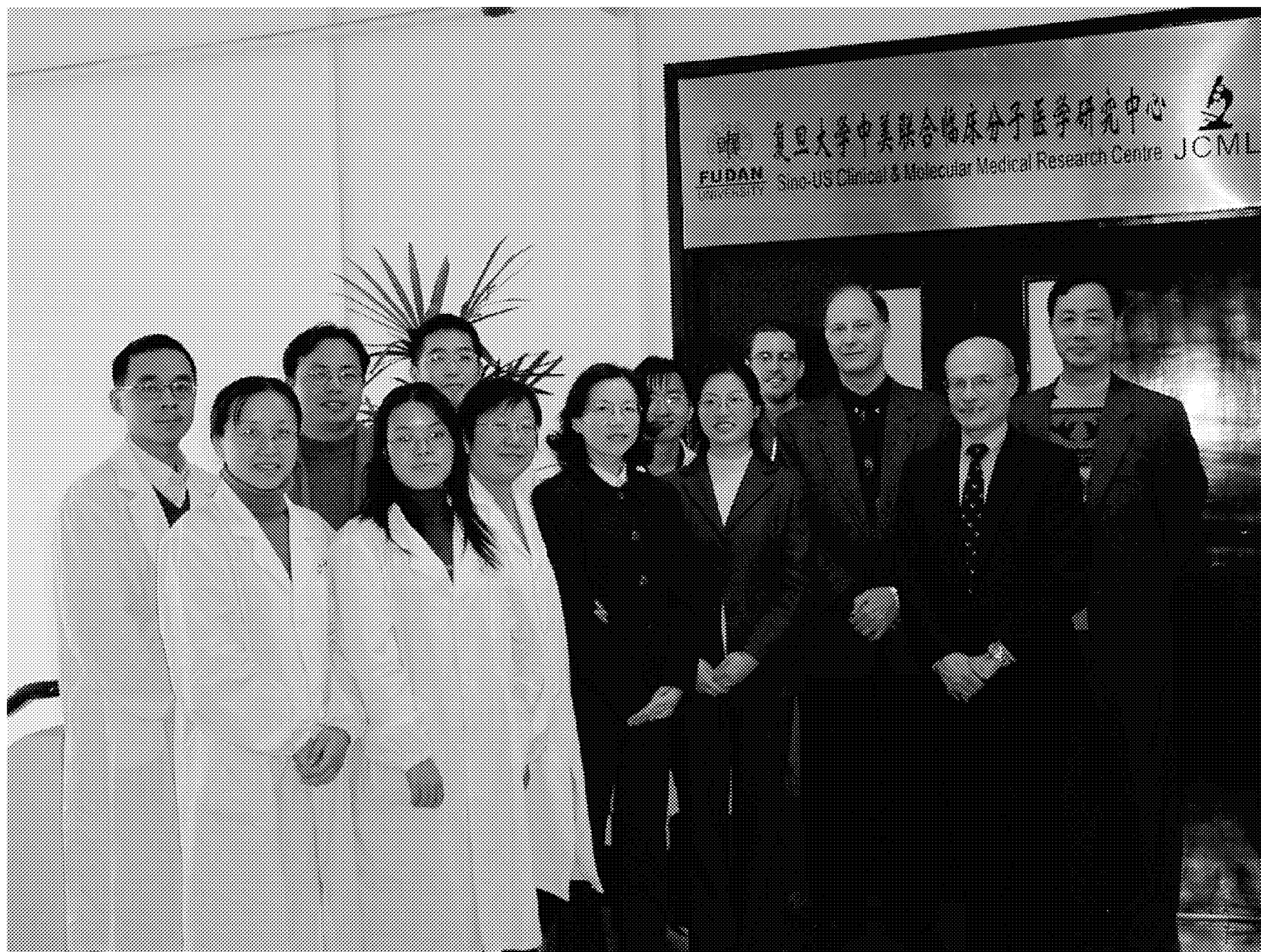
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Shanghai Health Study

Events and Path Forward

- First and Second Annual Meetings successfully provided engagement environment for investigators and sponsors to discuss progress and challenges.
- Launch event celebrating completion and start up of the laboratory – December 2003
 - Shell participation
- Stakeholder Engagement discussions underway
- Next annual meeting – November 2005 in Shanghai

Shanghai Health Study (SHS)

Shell Activities

- SHS sponsors are leading petrochemical industry in science based approach to leukemia/lymphoma and relationships to benzene exposure, and Shell is leading the consortium.
- Global Shell communication continuing
- Chemicals & RDS Issue
- Sustainable Development Opportunities being discussed.

Shanghai Health Study

Shell Steering Team

- Team:
 - Nancy Sullivan, Business sponsor
 - Susan Tholstrup, HSE sponsor
 - Patsy Clegg, Oversight Committee
 - Stuart Cagen, Technical & Budget Committees
 - Shan Tsai, Technical Committee
 - Sarah Colletti, External Affairs
 - Lauren Iannarone, Issues Management
 - John Schmid, Legal
 - Tarita Samuel, Finance
- Business Sponsor Transition:
 - Contract & Financial Support -
 - Business Sponsor -

Shanghai Health Study

Issues

- Laboratory sustainability after conclusion of study
 - Sustainable Development Opportunity
- Chinese support for exposure assessment
 - Malcolm Brinded letter to/meeting with Shanghai mayor
- Budget
 - Need for prioritization of work
 - Additional funding being sought from industry & associations