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From: Matt Todd <ToddM@api.org>
Cc:
Bcc:
Received Date: 2005-10-14 20:46:51 GMT
Subject: SHS Summary

BHRC Committee Member:

Attached is the draft final of the SHS Summary document for the upcoming Symposium. Some slight changes have been made based on final review and comments provided by Lynn Russo. Please inform me if you feel any additional changes need to be made.

Regards,

Matt

Matthew Todd

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Washington DC 2005

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Attachments:

SHS_summary_10-14-2005.doc

DRAFT

Shanghai Health Study

Descriptive Overview

In December 2003, a gathering in Shanghai, China marked the opening of the Joint Sino-U.S. Clinical and Molecular Laboratory. The Laboratory is key to the Shanghai Health Study, a cooperative research project involving leading researchers from the U.S. and China, facilities at Fudan University, and a network of Shanghai hospitals. This project, to further the understanding of the human health effects of benzene, is funded by a number of oil and chemical companies. Data collection is scheduled for completion late next year (2006).

Purpose: The project studies were designed to advance the medical and scientific understanding of the relationship between benzene exposure and the risk of certain hematopoietic diseases (certain blood and lymph related disorders). The sponsor companies view the project as important to their product stewardship programs.

A unique set of circumstances in Shanghai enabled investigators to launch this meaningful benzene research. These include a long history of working with occupational exposures and qualified, experienced investigators familiar with the local scientific, medical and regulatory establishments. The studies should contribute to the scientific literature regarding a number of issues that have long complicated benzene health risk assessment.

The Studies: The program involves three inter-related studies:

- Case-Control Study - A hospital-based case control study investigating the potential relationship between exposures to benzene, other diverse variables and both Non-Hodgkins Lymphoma (NHL) and Acute Myelogenous Leukemia (AML).
- Disease Progression Study - A hospital and clinic-based investigation of the potential relationship between non-cancer diseases of the bone marrow and AML to determine if effects on bone marrow progress through non-cancer stages to an ultimate leukemia. This study is also attempting to define the shape of the dose response for possible "precursor" diseases. It could result in characterization of unique identifiers of benzene-induced AML.
- Molecular Epidemiology Study – An investigation of whether there is a quantitative relationship between benzene exposure and potential early biological indicators of both exposure and effect in a focused population of workers.

The combined studies apply advanced technologies to advance the medical and scientific knowledge of benzene-induced disease. The investigators are leading experts in their fields. The three Principal Investigators are Dr. Fu Hua of Fudan University, Dr. Richard Irons of the University of Colorado Health Sciences Center, and Dr. Otto Wong of Applied Health Sciences (an independent U.S. research firm).

Benefits: Beyond advancing knowledge of benzene toxicology, these studies will further assist the contributing companies in their continuing efforts to provide high quality product stewardship and continuous improvement of their risk management programs. In addition, the studies may contribute to analyses conducted when governments debate future regulatory standards.

Challenges: The studies have met several technical and ethical challenges, which were addressed with the assistance of a Scientific Review Panel and an Ethics Review Panel.

- Scientific Review Panel. In order to stand up to rigorous scientific standards, studies must pass scientific scrutiny, be well-managed, and incorporate the best technology. State-of-the-art research is absolutely necessary to make real progress in developing a sound risk assessment. To that end, a Scientific Review Panel was assembled, made up of independent leading experts from a number of fields relevant to these studies. They reviewed, commented on, and, after revisions, endorsed the research protocols. In addition, the protocols met the rigorous requirements of three separate Use of Human Subjects Committees (Institutional Review Boards or IRB's), two in the US and one in China. The Scientific Review Panel also meets with the Principal Investigators to hear about progress and provide their perspectives on issues that may arise. They will remain available to the investigators throughout the research program.

- Ethics Review Panel. To address ethical issues posed by the project, the protocols have undergone a thorough analysis to ensure that they meet international standards for research involving humans (guidelines established by the Council for International Organizations of Medical Sciences or CIOMS). An Ethics Review Panel is part of the oversight for the project. It consists of independent bioethicists from the U.S., China and Europe. This panel also consults with the Principal Investigators during the course of the research.

Collaboration: A key to the program's success is local partnerships. Collaborators on these studies include researchers from the Medical School at Fudan University, the Institute for Public Health Supervision, and the Shanghai Municipal Centers for Disease Control and Prevention (the latter two are responsible for occupational exposure monitoring and enforcement in Shanghai).

Equally critical is the Joint Sino-U.S. Clinical and Molecular Laboratory which was developed for this research project. This state-of-the-art clinical and molecular laboratory operates on the Fudan Medical University campus. It supports the research studies as well as providing diagnostic services for over 30 major hospitals in the Shanghai region. The facility will remain at Fudan once the project is completed. This sustainable technology transfer is an important aspect of the project design.

Conclusion: The project sponsors (listed below) are committed to seeing that the Shanghai Health Study is conducted openly and in a manner that assures the investigators' research independence in conducting the studies, analyzing the data, and publishing their conclusions. The sponsors' goal is for the results of the studies to become an important part of the body of scientific research on benzene.

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