



DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TX 78234-6000

REPLY TO
ATTENTION OF

MCCS

30 OCT 2003

MEMORANDUM FOR Commanders, MEDCOM Regional Medical Commands

SUBJECT: MEDCOM Participation in ACAM2000 Smallpox Vaccine Post-Licensure Safety Surveillance and Research Requirements

1. The Regional Medical Commands (RMCs) will support efforts between the vaccine manufacturer Acambis and the MEDCOM for participation in the ACAM2000 smallpox vaccine post-licensure safety surveillance and research requirements.
2. RMC and military treatment facilities leadership will provide logistical support for study organizers for approximately 1-2 years. Logistical support may include space near the Soldier Readiness Processing (SRP) immunization station and an area to store study equipment when not in use. The Military Vaccine (MILVAX) Agency is coordinating study activities, and the Naval Health Research Center (NHRC) will implement. Study organizers will provide all study personnel and equipment.
 - a. Support and participation in these safety studies have national importance. ACAM2000 is the only Food and Drug Administration (FDA) licensed smallpox vaccine in the United States, and represents a significant piece of our national bio-preparedness strategy.
 - b. The Department of Defense (DoD) has a vested interest in the viability and safety of ACAM2000. The DoD Smallpox Vaccination Program (SVP) was initiated in 2002 and supports DoD's policy of vaccinating service members who are deployed for more than 15 days to higher threat areas such as the Korean Peninsula or the CENTCOM AOR. A continuous supply of licensed vaccine that is safe and effective is vital to this program.
 - c. The FDA has mandated a phase IV prospective cohort safety study in the military population receiving the vaccine. Study groups will include approximately 15,000 ACAM2000 vaccinees and an appropriately sized control group. The conduct of this study is required for Acambis to ensure the continued licensure of ACAM2000.
 - d. SRP sites at Ft Bliss, Ft Bragg, Ft Campbell, Ft Carson, and Ft Hood were selected for the conduct of the phase IV prospective study based on smallpox vaccine usage rates and study logistical requirements.

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e. The MILVAX Agency will coordinate DoD efforts in meeting these requirements with the manufacturer and the FDA. The NHRC will take the lead in managing the phase IV prospective cohort safety study. The United States Army Medical Research and Materiel Command Human Research Protection Office will provide input into study protocols.

f. Three conditions exist for MEDCOM's collaboration and participation in this safety study. The study will be conducted in full compliance with all human research subject protection rules and FDA regulations. Acambis will be responsible for funding the study activities that are beyond the current mission requirements of participating MEDCOM organizations, and participation will not adversely affect the primary mission of the volunteers.

g. The well-being of our service members is our top priority. Through participation with the manufacturer in this post-licensure requirement, the MEDCOM can better understand the safety profile of ACAM2000. This will in turn enhance the effectiveness of the DoD's SVP and the national preparedness posture.

3. My point of contact for this issue is LTC Patrick Garman, MILVAX, (703) 681-5101, DSN 761-5101.

FOR THE COMMANDER:


WILLIAM H. THRESHER
Chief of Staff