

## Valley Fever Vaccine Project

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**Project Description:** The goal of this laboratory-based collaboration is to produce a candidate vaccine for coccidioidomycosis (valley fever) that would lead to initiation of human clinical trials in early 2005. The approach taken by investigators (based at five different academic institutions) has been (1) antigen discovery through recombinant and genomic approaches, (2) antigen evaluation in mice, and (3) secondary evaluation in large animal model(s). To date, four antigens have been designated as possible vaccine candidates, of which two have been used to create a single chimeric fusion protein that is being developed as the vaccine for clinical trials. Efforts to manufacture and formulate the vaccine are now underway.

Under the sponsorship of the project, a Phase 1 trial was recently completed that assessed the safety and activity of the skin-test antigen coccidioidin. The study was conducted at two study sites with Drs. Rutherford, Lindan and Hector monitoring the study. It is hoped that with validation of the skin test reagent, large prospective incidence and prevalence studies for coccidioidomycosis will be conducted in military personnel at Twenty-nine Palms, Ft. Irwin, Luke AFB and Edwards AFB. This information will be utilized in the design of efficacy trials for the vaccine in this targeted population.

**Significance:** Presently available therapeutics for coccidioidomycosis are unsatisfactory and the relapse rate is high. There is significant morbidity and public health care costs associated with this disease. An effective vaccine may therefore have a significant impact.

**Interesting Findings:** Protection against lethal challenge in mouse models has been demonstrated for candidate vaccines. However, experiments are underway to confirm the efficacy and safety of the clinical candidate in a primate model before human trials will be initiated. Earlier this year, the entire genome of the causative fungus was sequenced, with annotation slated to begin early in 2004.

**Project Web Site:** <http://www.valleyfever.com/>