Project Details

DAR-901 whole cell booster vaccine to prevent TB infection in adolescents (“DAR-PIA”)

Awarded Year	2015
Awarded Amount	$1,423,590
Disease	Tuberculosis
Intervention	Vaccines
Development Stage	Drug Clinical Phase2
Collaboration Partners	Tokyo Medical and Dental University, Muhimbili University of Health and Allied Sciences (MUHAS), Geisel School of Medicine at Dartmouth

Introduction and Background of the Project

The goal of global tuberculosis (TB) elimination by 2035 cannot be achieved without the development of a new vaccine against tuberculosis. The only new TB vaccine in development to have shown efficacy in humans is an inactivated whole cell booster vaccine derived from a bacterium known as *Mycobacterium obuense* (a bacterium closely related to TB). The vaccine is now produced by a new manufacturing method and is known as DAR-901. A Phase I study in the United States is confirming that 3 doses of the DAR-901 booster to adults who received BCG at birth (the current TB vaccine) is safe and produces an immune response. The DAR-PIA trial will be a Phase II study of the DAR-901 booster conducted among 13-15 year old adolescents in Tanzania. Unlike most TB vaccine trials that test whether a vaccine prevents full blown TB disease, the DAR-PIA trial will test whether DAR-901 works even earlier and prevents the initial TB infection. We will screen 1,000 adolescents for the trial and anticipate identifying 350 who already have TB infection and 650 who do not yet have TB infection. Both groups will be interviewed to identify risk factors for TB infection, information that could prove valuable in preventing TB infection. The 650 subjects without baseline TB infection will be entered in the trial and randomized 1:1 to receive 3 doses of DAR-901 or 3 doses of saline placebo. All participants will be followed for 2 years and retested to determine if those in the vaccine group had a reduced risk of new TB infection. A successful outcome of the trial will position DAR-901 for a final confirmatory trial and possible subsequent licensure as the first new vaccine against TB in over 100 years.

Role and Responsibility of Each Partner

TOKYO MEDICAL AND DENTAL UNIVERSITY (TMDU)
TMDU is responsible for study design, site development, subject recruitment, study initiation, data collection and analysis. TMDU develops protocol for screening and enrolling adolescents into the clinical trial, baseline and follow-up questionnaire for clinical trial, consent and assent forms, coordinates ethical clearance processes, trains site personnel, coordinates secondary schools for study participants’ recruitment, identifies and recruits Community Advisory Board members, assists study staff to recruit study participants, analyses baseline and follow-up data collected from clinical trial, analyses data collected of case report forms (CRF) to determine safety and efficacy of DAR-901 vaccine, analyses data from CRF and baseline data to identify characteristics associated with vaccine induced protection against infection with tuberculosis. These contributions are made in Dar es Salaam as well as from Tokyo.

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)

As the partner stationed in the clinical trial study site, MUHAS is responsible for study protocol and the conduction of the clinical trial. MUHAS develops study protocol, coordinates ethical clearance processes, develops a plan of recruitment of adolescents, coordinates Community Advisory Board, screens and recruits participants, administer vaccine and placebo, and monitor conditions of participants after administration of vaccine or placebo. MUHAS ensures participants' consent and assent process, compliance with Good Clinical Practices, quality control of the T-spot assays, reporting of adverse events as required by the protocol. MUHAS is also responsible for liaison with secondary schools where study participants are studying and with study monitors regarding filing of reports and reporting of participants' data and reports.

GIESEL SCHOOL OF MEDICINE AT DARTMOUTH (DMS)

DMS is responsible for overall study design, study protocol, laboratory protocol, conduction of the clinical trial and data analysis. DMS develops case report forms (CRF) and severe adverse events forms (SAE), liaises with ethical clearance bodies, data safety monitoring board, study monitors, receives reports on adverse events, and receives and analyses reports of CRF and SAE. DMS further analyses safety, efficacy, and effectiveness of DAR-901 vaccine. These contributions are made in Dar es Salaam as well as from Hanover.

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