

## Service Successes: Reports from the Front Lines of WISHH

WISHH's First Clinical Trial of Soy Protein in HIV/AIDS Finishes Baseline Enrolment/Data Collection Activities

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In collaboration with The Solae Company, TetraPak, Dewfresh Company, and the University of Stellenbosch in Tygerberg, South Africa the first formal clinical trial of soy protein in HIV/AIDS was approved and began baseline data collection early in 2007. The trial is a well-designed placebo-controlled, double-blinded study of a daily dose of 25 grams of soy-based protein contained in a 250 ml TetraPak of flavored beverage compared with a protein-free placebo. Both products were produced at Dew Fresh in Johannesburg and contain the same micronutrient premix that provides 100% of the RDA for micronutrients.



Kobus deKlerk from The Solae Company enjoys sampling the flavored product in the storage facility outside of Cape Town

Adults with HIV infection attending clinics selected by the Provincial Health Department in the Western Cape were invited to participate. The entry criteria was a body mass index (BMI or the amount of weight for height) of less than 20 or recent unintentional weight losses greater than 5% of body weight.

Many challenges were faced during the planning and implementation phases of this project. The project had to be approved by the university's Ethics Committee and registered as a clinical trial to the satisfaction of the government of South Africa. Delays in approvals and changes in participation by the local clinics also presented challenges as the study sponsors had to make quick decisions about adjusting both personnel support and the expectations for a speedy baseline recruitment.

Because there is a porridge-based

supplementation program sponsored by the government in place for people who are moderately malnourished, the primary target for the study was concentrated on adults with BMIs of between 18.5 and 20.

Nutrition supplementation studies, especially when they target people living with HIV and AIDS (PLHA) are often fraught with difficulties. Stigma associated with HIV-specific interventions were also faced. A small number of enrollees either returned their product to the clinic or even left it outside the clinic fence for fear that it might identify them as HIV-infected to be using the study product. Even without the stigma issue, it is often difficult to maintain study participation and adherence because of the effort required by participants to consume the right amount of product daily and keep the required records for the study, the potential for taste fatigue over several months, and the additional effort to both travel to clinic and transport products home on a monthly basis.



Xhosa translator, Sizwe, demonstrates a "chicken dance rap" he uses with the product to enhance understanding and study adherence



A day-labor crew works on the labeling of study products according to Ethics Committee requirements

Each step of the way has involved labor-intensive efforts to shore up many unanticipated issues. Local personnel had to be hired and trained to continue baseline recruitment. The intrepid team in South Africa persisted and baseline enrolment was closed at the end of September 2007, having completed baseline recruitment and measures on more than 400 study participants. As expected, there is a high drop-out rate of more than 25% within the initial three-month period of the study. However, the first full six-month study completers are starting to come in and there are more than 50 participants who have gone beyond the three-month point.

The study is expected to continue through the end of February 2008 for final measurement at the six-month mark. March 2008 will see the evaluation of the results and the preparation of a publishable report. While results on the value of the protein supplementation will not be available until the study is unblinded, consumer acceptability appears to be quite high for the flavored beverages. With good results, the products may be further refined for inclusion in both commercial and government program markets.