STALWART

Copenhagen ICC Newsletter No. 2 (September 2007)

Dear STALWART investigators,

This is the second STALWART Newsletter issued by the Copenhagen International Coordinating Centre (ICC), Copenhagen HIV Programme, Denmark.

DSMB REVIEW

STALWART was reviewed by the Data and Safety Monitoring Board (DSMB) in November 2006 and the DSMB announced that there are no safety concerns. The Board was concerned about the rate of enrolment and encouraged the investigators to make every effort to increase enrolment without compromising adherence or retention. The DSMB open report and summary are available at the INSIGHT website (http://insight.ccbr.umn.edu/), click on study, STALWART and safety. Passwords for the INSIGHT website have been sent to you previously but please let us know, if you cannot get access to the website.

STALWART STATUS

STALWART enrolment reached 167 on 24 September 2007. STALWART opened in December 2005 with an enrolment goal of 480, but initial delay of insurance coverage, new requirements for local laboratories as well as delays in obtaining regulatory approvals significantly delayed site registration. Most of these issues have been successfully resolved by now and to date 36 out of 56 sites in 9 countries are open for enrolment and the remaining sites are expected to follow shortly. Participants enrolled in STALWART will be followed to a common closing date 12 months after the last participant is randomised.

STALWART IN OUR REGION

Congratulations to Wojewodzki Szpital Zakazny in Warsaw for enrolling the first two STALWART participants in our region on 19 September 2007 as well as to Hospital Clinic in Barcelona for enrolling their first patient on 25 September. To date, five sites out of 15 are currently open for patient enrolment and they soon expect to randomise their pre-screened patients into the study. The remaining sites are expected to open shortly.

In addition to the reasons mentioned above, the implementation of STALWART in our region has been prolonged due to extensive regulatory requirements related to the new EU Directive. These new regulations are demanding a lot of time and effort from all parties to get the trial implemented in a timely manner. We at CHIP will continue to do our outmost to assist you in this process.

PRE-SCREENING

Prolongation of study implementation in our region provides sufficient time to pre-screen patients for enrolment into the study. It is essential that each site has pre-screened patients lined up to be able to randomise them immediately after receiving final Division of AIDS (DAIDS) approval to begin enrolment. We hope very much that you still share our enthusiasm and motivation to reach our projected enrolment number as quickly as possible in this first INSIGHT trial.

RE-TRAINING & ASSISTING TOOLS

As a short but intense phase II study, STALWART relies on committed investigators and study participants. All sites have had protocol training initially at initiation visits. But due to the delay of opening sites some will need re-training before enrolling patients. This will take place via teleconferences and will be arranged with sites individually.

The following tools have been developed to assist in the everyday study conduct:

1) Scheduling table specified by group assignment (A, B or C) which clearly lists all measures and actions required at each visit. This table nicely complements the individual 'data collection schedule' that will be forwarded at time of randomisation.

2) Pro and Con list meant for investigators as a helpful tool when screening and selecting potential study participants and listing key points to assist when discussing STALWART with them.

PROFICIENCY TESTING

The primary endpoint in STALWART is the change in CD4 cell count during the course of the trial. The results of this trial may have significant impact for HIV infected individuals and may result in many individuals being treated with a new drug (IL-2). Therefore, it is a responsibility of the sponsor (DAIDS, National Institute of Allergy and Infectious Diseases, NIAID) to ensure the quality of the clinical trial data, including laboratory data. This is why all laboratories must be enrolled in a DAIDS approved proficiency testing (PT) program.

We foresee that an approved PT program as external quality assurance for local laboratories will be a requirement also for future HIV trials within INSIGHT, especially for CD4 cell counts.

NEXT MEETING

The next INSIGHT/SILCAAT joint scientific meeting for investigators is scheduled for Thursday, 25 October 2007, in Madrid, Spain, in conjunction with the 11th European AIDS conference (EACS). An invitation and an agenda have been sent out recently. Please confirm your attendance by mailing/faxing back to us.

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