



## Copenhagen ICC Newsletter No. 3 (January 2008)

### DSMB REVIEW

STALWART was evaluated by the Data and Safety Monitoring Board (DSMB) on 27 November 2007. The DSMB concluded that there are no concerns arising from either efficacy or safety data that warrant a change in the conduct of the study. The DSMB agreed with the following proposals from the STALWART protocol team:

- 1) **STALWART enrolment** will finish in conjunction with the planned closure of the ESPRIT and SILCAAT trials end of 2008. The main focus will be on increased enrolment and opening of sites during the first quarter of 2008
- 2) **A letter of amendment (LoA)** will be developed to allow genotyping beyond cycle 3 in participants randomised to IL-2 + pericycle Antiretroviral Therapy (ART) and the LoA will be distributed when available
- 3) **DSMB reviews** of STALWART safety data will occur every 6 months from now on

The DSMB summary has been circulated previously and is available at the INSIGHT website (<http://insight.cabr.umn.edu/>), together with the open report (click on 'study', 'STALWART' and 'safety').

### STATUS WORLDWIDE

While the ESPRIT and the SILCAAT study will close by the end of 2008, STALWART will close only for patient enrolment but patients will continue to be followed until a common closing date according to the protocol (i.e. 12 months after the last participant is randomised).

The INSIGHT Executive Committee has asked the STALWART team for an enrolment plan for 2008. Worldwide, there are currently 40 STALWART sites open, of which 28 have randomised a total of 203 patients. Fifteen of those 28 sites have enrolled less than 6 patients. There are also 16 sites not yet registered. Please find below the strategy of the INSIGHT Executive Committee on how to proceed in 2008:

### PLANS FOR 2008

- 1) **Productive Sites:** Sites that are enrolling and performing well will be queried to see if they can exceed their enrolment goal. This has already been done at some sites.
- 2) **Sites not yet registered:** Sites that cannot be registered by the end of March 2008 will not be pursued. Other considerations may need to be taken into account on a site by site basis.
- 3) **Sites that are open but have not yet enrolled:** Sites will be queried again to see if they can meet their enrolment goal by the end of 2008. If they cannot, the site would be deregistered.

4) **Sites that have few patients (<5):** The ICCs will continue to work with these sites to increase recruitment. This is already being done at many sites.

In accordance with this plan the sites in our region have already been contacted by their monitor or by their SCC end of 2007. We will continue to discuss the next steps of this plan with sites individually to ensure the successful conduct of STALWART in our region.

### STATUS IN OUR REGION

To date, 8 sites out of 15 are currently open for patient enrolment and overall 11 patients are enrolled in our region. Congratulations to Hospital de Santa Maria in Lisbon for enrolling their first 2 STALWART participants in December 2007. In Spain, 2 patients have been enrolled in total. The site in Warsaw, Poland, has taken the lead with 7 patients.

We urge all of you to identify additional study participants and kindly ask you to involve your colleagues in this process. We have to increase the enrolment numbers significantly for our region in order to fulfil our enrolment goal in this first INSIGHT study.

### SAMPLE SHIPMENT

The DSMB encouraged very current resistance data to ensure patient's safety. Participants in group C will have blood drawn on cycle 3, day 5 (or on the last day of IL-2 administration, +/- 1 day respectively) for HIV resistance genotyping. For those samples that demonstrate antiretroviral resistance mutations, plasma from cycle 1, day 5 (or from week 4 respectively) will be analysed as well. Hence, to ensure current resistance data all sites are asked to send genotyping samples no later than every 3 months throughout the whole study period. STALWART samples may be sent together with ESPRIT samples.

### GENOTYPING

The European Guidelines (European AIDS Clinical Society, EACS) as well as the U.S. Guidelines (U.S. Department of Health and Human Services, DHHS) are now recommending baseline genotyping before commencing ART. The STALWART Protocol Team therefore strongly encourages to perform genotyping locally prior to commencing pericycle ART in group C – particularly if this is standard-of-care in your clinic.

### NEXT MEETING

The next INSIGHT/SILCAAT joint scientific meeting for investigators is scheduled for Sunday, 3 February 2008, in Boston, USA, immediately preceding the start of the CROI conference. Lunch will be served and there will also be a short celebration of the completion of the SMART Study. An invitation and an agenda have been sent out recently. To register, please go to the following website: <http://insight.cabr.umn.edu/joint/>