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## Regional Newsletter for Belgium, Germany, and Spain

### No. 3

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Dear colleagues and collaborators in SILCAAT,

This newsletter describes issues that we all should focus on over the next months in order for the SILCAAT trial to maintain its scientific integrity.

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#### Data Safety & Monitoring Board (DSMB) meeting

The SILCAAT Scientific Committee has accepted a proposal from the DSMB for ESPRIT to also act as DSMB for SILCAAT. This new SILCAAT DSMB met on the 9<sup>th</sup> of February 2004. After carefully reviewing comparative safety and efficacy data from all participating sites, the DSMB concluded that there are currently no efficacy or safety concerns, which would warrant a change in the conduct of SILCAAT. At the same time, the DSMB was very concerned about the current high lost-to-follow-up rate, an intrinsic result of the transition of management of the trial.

You are able to read and print the open DSMB report from the SILCAAT website (click on "Safety Information" and then "DSMB").

The next full DSMB review will take place in October 2004. It is essential that we - as a study group - are able to show progress especially in the proportion of patients that have provided re-consent to protocol version 4 before this time. The aim is to have 70 % re-consent by May 1 and 100 % by July 1. You are encouraged to seek re-consent from all randomised patients irrespective of their current status in the trial. A high proportion of patients not re-consenting may leave the trial inconclusive or bias the results.

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#### IL-2 cycling initiative

For the trial to provide conclusive evidence of the role of IL-2 in HIV management, it is essential that study participants allocated to receive IL-2 remains taking the drug throughout the course of the trial. The IL-2 cycling initiative aims at ensuring that this actually occurs. The initiative was presented at the recent International Steering Committee meeting in San Francisco, and can be accessed at the SILCAAT website (click on "Publications and Presentations").

The first element of the IL-2 Cycling Initiative is to collect detailed information about the patterns of

provision of IL-2 for patients in the IL-2 arm not currently at their CD<sub>4</sub> goal and the reasons for why patients not at their CD<sub>4</sub> goal are not (re)-cycling. A special CRF has been developed to capture this information. All sites are encouraged to complete this form as soon as possible and hopefully within the next 3 months.

The first results of this data and elements of an action plan will be discussed in connection with the 15<sup>th</sup> World AIDS Conference in Bangkok, at the joint ESPRIT-SILCAAT investigator meeting on Sunday the 11<sup>th</sup> of July 2004 in the afternoon. If you are going to Bangkok, please reserve the time for participation in this meeting.

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#### Progression of disease (POD)

The primary objective of SILCAAT is to compare the rate of disease progression including death between the IL-2 and the No IL-2 arm. Three hundred (previously 210) confirmed primary events are needed to address the primary efficacy outcome of the trial. The same Endpoint Review Committee (ERC) that is reviewing PODs in ESPRIT reviews all POD events and death in SILCAAT too.

Since last summer a huge effort has been made to identify PODs not previously included in the Chiron endpoint database. One result of this major undertaking has been the detection of previously unrecognised PODs and deaths. Thanks to all that have contributed to this process.

To ensure adequate documentation of two frequent PODs, please make sure that a chest radiogram is performed for all participating subjects clinically suspected of pneumonia and that observed candidiasis of the oral cavity and pharynx is described for patients suspected of oesophageal candidiasis.

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#### Websites

If you are not routinely accessing the SILCAAT website ([www.silcaat.org](http://www.silcaat.org)) we encourage you to do so. The website is an important resource for trial management. To enter this website you need a log-on and password. Should you not have this available please contact CHIP.

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