



# Copenhagen RCC Regional Newsletter

No. 7

10 March 2004

Dear ESPRIT investigator,

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

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## Data Safety & Monitoring Board (DSMB) meeting

The ESPRIT DSMB, which is also functioning as the DSMB for the SILCAAT study, met on the 9<sup>th</sup> of February 2004. After reviewing comparative safety and efficacy data from all participating sites, the DSMB concluded that there are no concerns arising from either efficacy or safety data at the present time warranting a change in the conduct of the ESPRIT. You are able to read and print the open DSMB report from the ESPRIT website ([www.esprit-il2.org](http://www.esprit-il2.org); click on "DSMB").

The next full DSMB review is expected to take place in February 2005.

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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 continue 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 ESPRIT 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 CD4 goal and the reasons why patients not at their CD4 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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## Lost-to-follow-up rate

An essential component to a successfully conducted trial is to keep the lost-to-follow-up rate low, and preferably absent. Currently, 3.2% of all patients in ESPRIT are considered lost to follow-up (2.6 % in our region). Overall, 4.5% of study visits have been missed. Although these percentages may seem low continuous focus is needed to keep them low over the coming years following patients in the trial for both primary and secondary outcome measures (CD4 count, HIV-1 RNA etc.). And please remember to forward the visit and cycling CRFs real time once all relevant data has become available. This should be a maximum of 2 weeks after the visit and/or cycle has been completed.

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## Progression of disease (POD)

This is the primary endpoint of the trial and it is hence pivotal to ensure that all events that fulfil the definition of POD are captured, documented and reported. In some cases, the documentation is less than optimal. Especially for patients suspected for pneumonia, a chest X-ray is sometime missing. Also, for patients clinically suspected of oesophageal candidiasis, description of the presence of oral and/or pharyngeal candidiasis is not outlined in the patient record. Please remind the staff at your clinic to carefully work up patients in ESPRIT suspected for a POD event.