Dear sanco-pharmaceuticals,

I am Gary Mills, deputy Coordinator of the FP7 PREDICT project, which has been looking at increasing the participation of the elderly in clinical trials. As such I represent a 9 nation group that with EU funding has been studying this area for close to 3 years and has produced a European Charter for the inclusion of older people in clinical trials.

Based on the findings of PREDICT research – (please see presentations from our charter launch http://www.predicteu.org/Charter_Launch/charter_launch.html )- we would like to suggest that:

- in addition to the >65 age category suggested there should also be an >80 category

- the number of subjects excluded from trials should be reported, including the 2 groups >65 or >80 and the reasons for exclusion should also categorized by age

- adverse effects should be reported according to age groups, to see whether there is a safety issue in older subjects

I hope this is helpful. If you have any questions or would like any clarification or further input please contact me.

Yours sincerely,

Gary H Mills

(On behalf of the FP7 PREDICT consortium)