

Amendment 16

Date of amendment: 1 February, 2023

Protocol change: In the protocol and in Amendment 10 upper age limits for further invitations to the study is regulated for various PSA cut offs. As there has been some uncertainties what is meant with ≥ 62 years, ≥ 65 years, ≥ 70 years and ≥ 75 years the following definition should be applied and has been in use in the database since start:

- ≥ 62 years includes all men from the date they become 62 years of age
- ≥ 65 years includes all men from the date they become 65 years of age
- ≥ 70 years includes all men from the date they become 70 years of age
- ≥ 75 years includes all men from the date they become 75 years of age