



European Charter for Older People in Clinical Trials



1 OLDER PEOPLE HAVE THE RIGHT TO ACCESS EVIDENCE-BASED TREATMENTS

- 1.1 Older people have the right to be offered evidence-based treatments..
- 1.1.1 Older people should expect to be offered drugs and other treatments that have been properly evaluated in clinical trials and demonstrated to be effective in people of their age.



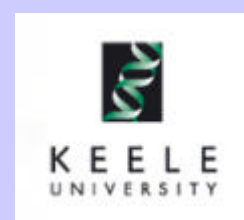
2 PROMOTING THE INCLUSION OF OLDER PEOPLE IN CLINICAL TRIALS AND PREVENTING DISCRIMINATION.

- 2.1 Older people should not be discriminated against in the recruitment for clinical trials
- 2.1.1 Older people should be informed about and invited to participate in clinical trials of treatments that are intended for use in older people.
- 2.1.2 National and International Regulators should ensure that older people are included in clinical trials without discrimination on grounds of age, gender, ethnicity or social class.
- 2.1.3 Research Ethics Committees, Sponsors, Medical Journal Editors and Regulators should review all studies critically for unjustified exclusions based on age, other illnesses, disability and existing drug treatment. All such exclusions must be justified.
- 2.2 The participation in clinical trials of people with multiple morbidities should be encouraged
- 2.2.1 National and International Regulators should require that trials with drugs or other treatments intended for use in older people include those with multiple morbidities that are common in later life.
- 2.2.2 National and International Regulators should require that trials with drugs or other treatments intended for use in later life include older people who are taking commonly prescribed medications.



3 CLINICAL TRIALS SHOULD BE MADE AS PRACTICABLE AS POSSIBLE FOR OLDER PEOPLE

- 3.1 Clinical trials should be designed so that older people can participate easily
- 3.1.1 Older people should receive information about clinical trials that helps them make an informed decision about participation.
- Informed consent procedure should be adapted to the specific needs of older people, taking into account their level of literacy, any sensory deficits, and involving their family or caregiver if needed.
- 3.1.2 Specific training is needed in order to perform clinical trials in older people.
- Researchers should be trained to conduct clinical trials in people with communication, sensory, mobility or cognitive problems.
- 3.1.3 Researchers should be prepared to spend additional time with older people participating in a clinical trial in order to support their participation and adherence.
- 3.1.4 Trial Sponsors should recognise that older people may need extra support to take part in trials.
- Trial sponsors should provide support to enhance the inclusion and adherence of older people, especially those with mobility and communication problems and those who also have responsibilities caring for others.
- 3.1.5 National and international regulators should encourage clinical trials that are designed to make the participation of older people easier.



4 THE SAFETY OF CLINICAL TRIALS IN OLDER PEOPLE

- 4.1 Clinical trials in older people should be as safe as possible.
- 4.1.1 Researchers should assess the benefits and risks of older people's participation in clinical trials.



5 OUTCOME MEASURES SHOULD BE RELEVANT FOR OLDER PEOPLE

- 5.1 Clinical trials for common conditions in older people should employ outcome measures that are relevant for older people.
- 5.1.1 Researchers, trial sponsors and regulators should ensure that clinical trials for common conditions in older people use outcome measures that are relevant for older people, including quality of life measurements.
- 5.1.2 Clinical trial sponsors should involve older people and carers in the design of clinical trials and in the choice of outcome measures for clinical trials of diseases of later life.



6 THE VALUES OF OLDER PEOPLE PARTICIPATING IN CLINICAL TRIALS SHOULD BE RESPECTED.

- 6.1 The individual values of each older person participating in clinical trials should be respected.
- 6.1.1 Researchers should respect the values of each older person as an individual.
- 6.1.2 Older people should be able to withdraw from clinical trials without detriment to other treatments and their overall care.

