

# FIP STATEMENT OF PRINCIPLE

## PHARMACEUTICAL RESEARCH IN GERIATRIC SUBJECTS

**O**lder patients have the right to benefit from new medicinal therapies. Therefore, they should be represented in clinical trials of medicinal therapy. Their exclusion from these trials results in a lack of evidence to support rational medicinal therapy in older people. Exclusion particularly limits the availability of evidence to demonstrate the benefits of newer products for this sector of the population. Furthermore, with prevention, or effective treatment, there will be a saving in the health and/or social care expenditure, that would otherwise inevitably have to be faced.

The study of medicines in older people is necessary because the efficacy and safety of medicinal therapies in this subpopulation may differ significantly from younger patients, due to ageing-related body changes, coexisting diseases and the simultaneous use of other medicines.

Conclusions reached in studies of young people cannot properly be extrapolated to older people. Therapeutic decisions for older people should be based on results of clinical trials specifically designed for, and conducted with, this patient population. The need to provide adequate conditions for prevention and effective treatment of chronic diseases affecting this rapidly growing segment of the population means that the number of clinical trials targeting older subjects should be increased. Risks associated with studying older subjects in clinical trials may be minimised, by careful selection of younger patients for Phase I and II studies and through the building of confidence and understanding about the pharmacokinetics and possible adverse effects of new medicines, prior to enrolling older people in large, Phase III trials.

For these reasons, FIP **recommends**

1. In the light of available pharmacokinetic data, older people, in various age groups, should be included in clinical trials, in a proportion related to their representation in the overall population for which the medicine under investigation is intended, the number of older people included always to be sufficient to provide statistically sound information.
2. All precautions regarding performance status of an older person, clinical and laboratory data, coexisting diseases, multiple medication use, the risk-benefit ratio of the treatment, and quality of life should be taken into account in the consideration for admission to the study.

3. Studies should be well designed since it is not acceptable to involve any person in poorly designed studies unlikely to result in measurable benefit to patients, or to scientific advancement.

4. Because the conduct of clinical trials involving older people requires specialised skills and experience, pharmacists and other professionals involved in the conduct of these trials should be qualified to conduct them. The research group should include specialists in the treatment of geriatric patients. As with all clinical trials, the studies should be carefully supervised to ensure the accuracy of the resultant data.

5. To ensure compliance with clinical trial protocols, pharmacists and other healthcare professionals should provide counselling specially addressing the needs of the participants, concerned family members, and those caring for the participants, about possible treatment outcomes. Family members and carers should also be informed about their rights to intervene on behalf of the patient if problems arise during the trial.

6. Economic barriers (e.g., expenses for travelling, experimental treatment not covered by insurance, additional costs for investigators) should not be permitted to preclude older people from participating in clinical trials.

7. Mechanisms should be put in place to improve recruitment of older people to clinical trials. Recruitment strategies should be transparent, efficient, cost effective and address possible barriers, beliefs, and concerns involving older patients.

8. Although additional factors are likely to be encountered in obtaining consent with this group of patients, older people like all other patients involved in clinical trials, should give, in advance, their express informed consent for inclusion.
9. National and state authorities, professional bodies and patient support groups should encourage the recruitment into clinical trials of older people, including those from ethnic minority groups.
10. Development of a mechanism to facilitate the worldwide dissemination of information on clinical trial design, conduct, and results in older populations should be considered because this would provide valuable information on the safety and efficacy of medicinal therapy in older people. It could also serve as the basis for the evaluation and improvement of the design of future studies and the revision of inclusion/exclusion criteria for participation in trials.
11. The pharmaceutical industry and regulatory agencies should take steps to ensure that people generally are fully informed about the development process for new medicinal products, the important role of clinical trials within this process and the reasons for the need to include older people in these trials.
12. The requirements of regulatory agencies relating to clinical trials involving older participants, should be harmonised internationally, to ensure maximum benefit and protection from risk for older people from the studies.