Proposal for guidance on medical research for and with older people in Europe

Dr Florian von Raison, Chairman

On behalf of

Geriatric Medicine Working Party (GMWP)
European Forum of Good Clinical Practice (EFGCP)

Outline

- Introduction
- All topics addressed in research guidance and details of the following :
  - Topic : Informed consent process
  - Topic : Age, Gender , frailty
  - Topic : Participant guide clinical trials
  - Topic : Geriatric compentencies on Ethics Commitees
  - Topic : Study design
  - Topic : Benefit/risk measure

Introduction EFGCP

- Is a non-profit organisation, based in Brussels
- Is established by and for those with a professional involvement in the conduct of biomedical research
- To promote good clinical practice
- To encourage the practice of common, high-quality standards in all stages of biomedical research throughout Europe

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Introduction Research Guidance Older People

- The membership of the GMWP recognised the lack of consistent ethical guidance in Europe
- Workshops with key stakeholders from academia, investigators, patient representatives and pharma were held to develop a consensus
- Initially the EMA peadiatric ethical guideline from 2007 was used as benchmark
- Document initiated by Francois Hirsch and Jean-Marie Vetel and than later co-ordinated by Laurence Hugonot-Diener

Topics Research Guidance Older People

- Ethical principals and fundamental rights (autonomy, dignity, respect and privacy), ethical violations and GCP non-compliance
- Legal context and relevant guidelines
- Process of informed consent and assent
- Geriatric population definition
- Vulnerable and frail population
- Legal representatives

Topics Research Guidance Older People

- Design of clinical trials
- Geriatric control groups
- Pain, distress and minimisation of fear
- Risk assessment and monitoring
- Trial with healthy older participants
- Individual data protection

Topics Research Guidance Older People

- Unnecessary replication of trials
- Publication of geriatric trials and results
- International database and public availability
- Adverse reactions and reporting
- Inducement versus compensation
- Insurance issues
- Trials in non-EU countries

Details : Informed Consent Process

- Information and consent should be adapted to cope with hearing or other sensory impairments
- Use of simple tools or questions to check participant understanding of given information should be recommended
(UBACC scale, Newcastle +85)
- Informed consent from the legal representative, surrogate caregiver, personal advocate as appropriate (eg “personne de confiance” in France, or “Consultee” in the UK etc).

Details : Age, Gender and Frailty

- Age cut off for geriatric population to be raised from 65 to 80
- In groups age 80 + more women than men should be recruited in clinical trials (except special diseases occuring in men only)
- Frail population should be included in clincial programs as well. Use of structured scales eg SOF index (2 of 3: weight loss, inability to raise from a chair, poor/low energy) to define frailty is recommended

Details : Participant Guide Clinical Trials

- Its advisable to produce a specific participant guide with simple instructions such as:
  - ✓Tests and procedures to be carried out
  - ✓The need to be fasting or not, medication taken the consultation day, return of bottles etc, etc
  - ✓Contact, End of the study or in case of premature stopping
  - ✓Adverse event , new safety details, publication of results etc.

Details : Geriatric Competence in EC

- Every ethics commitee should have access to geriatric expertise such as:
  - ✓physicians with geriatric qualifications
  - ✓geriatric ethicists
  - ✓geriatric pharmacologists
  - ✓qualified geriatric nurses or psychologists, etc

to facilitate evaluation of research projects and protocols in older participants

Details : Study Design

- Avoidance of unnessessary data collection in older people
- Study size as small as possible but large enough to demonstrate the appropriate efficacy with sufficient statistical power
- Uncontrolled trials should be avoided
- Use of placebo more restricted in comparison to studies in younger adults
- Assays and sampling should be adapted to physiological state of older people.

Details : Benefit/risk Measures

- Benefit could be individual either increased efficacy or safety
- Benefit defined as progress for a group of older patients affected by same disease (knowledge about condition)
- Benefit may include issues around patient care eg dosing, route of administration, improvement of compliance or less medication errors, etc.

Acknowledgment to Key Contributors

- L. Hugonot-Diener, *France* (coordination)
- Participants GMWP : S. Alvini : *Italie*,
  M. Bone, A. Tinker : *UK*, D. Chirita : *Germany,*
  M. Maman, F. von Raison : *Switzerland*
  JM Vetel, F. Hirsch, JM. Husson : *France*
- Reviewers : JP. Baeyens, *Belgium*
  A. Franco, T. Marquet, F. Piette, B. Vellas :
  France, F. Wells : *UK*

www.efgcp.eu - info@efgcp.eu

Next Steps for Validation

- Document available from today on EFGCP website (www.efgcp.eu) for public consultation
- Final public workshop prepared by EFGCP to hold on **Monday, June 11th in London at UCL**. Please register through the EFGCP website if interested.