DruQuaR

UNIVERSITEIT GENT

FACULTY OF **PHARMACEUTICAL SCIENCES**

DEVELOPMENT OF GERIATRIC MEDICINES:
TO GIP OR NOT TO GIP?

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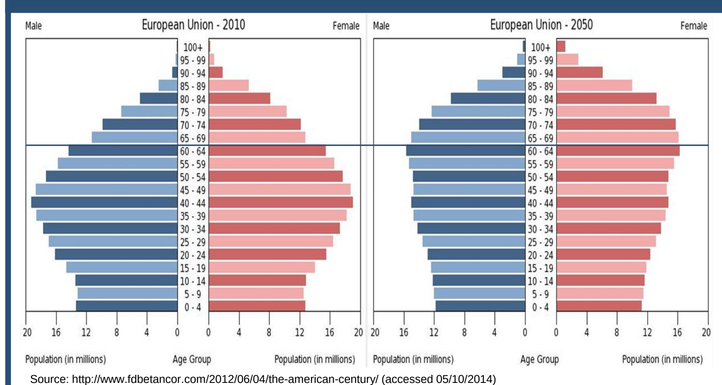
INTRODUCTION



Source: http://www.fdbetancor.com/2012/06/04/the-american-century/ (accessed 05/10/2014)

- Demographic trend: increase in age group > 65 y ↔ decrease in birth rate.
- Geriatric patients = heterogeneous group:
  - Inter-individually varying effects of aging (*i.a.* PK/PD changes due to altered organ functions)
  - Co-morbidity
  - Polypharmacy
- Elderly patients are main users of drugs: use 30-50% of prescription drugs.
- Old adults are underrepresented in clinical trials → lack of evidence-based medicine in this population.

OBJECTIVE

1. What is the current **regulatory status** of geriatric medicines?
2. What are the current views of different **stakeholders** on the development and regulation on geriatric medicines.
3. What are the current **challenges** in the regulatory development of geriatric medicines.

RESULTS and DISCUSSION

REGULATORY STATUS ⟷ Paediatric medicines (PIP)

Studies in support of special populations: geriatrics

ICH E7 guideline
+ Questions and Answers document

- Focus on clinical trials
- Geriatric patients = aged >65
  - older old >75 y
  - "frail" patients

subgroups

adopted by

European Medicines Agency (EMA)
- Geriatric medicines strategy.
- Geriatric expert group.

Food and Drug Administration (FDA)
- FDA guidance and regulations related to data on elderly persons in clinical drug trials (GAO-07-47R).

Pharmaceutical and Medical Device Agency (PMDA)
- No additional strategy for geriatric medicines.

VIEWS OF DIFFERENT STAKEHOLDERS

INDUSTRY

- Specific regulatory guidance needed.
- Engagement to address special needs of geriatric patients ↔ delay development of new drugs.

HEALTHCARE PROVIDERS

- Lack of relevant information to appropriately prescribe to the elderly in the clinical practice.

REGULATORS

- No formal requirements.
- No need for specific regulations.

CURRENT CHALLENGES

- Altered blood-brain barrier permeability
- Altered skin barrier permeability
- Changes in gut microbiota

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Age-related functional changes

To GIP or not to GIP?

Ethics
- Competence
- Informed consent
- Benefit/risk
- No evidence-based medicine for elderly

Cognitive impairment ?

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Age-appropriate drug formulations
- Swallowability of drug
- Manageability of packaging
- Complexity of drug therapy (polypharmacy)
- Appropriate dose strength

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Clinical trials
- Ethics
- Recruitment of patients
- Study design

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Heterogeneity
- Stratification during clinical trials

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Pharmaco-economics
- Development cost
- Social security
- Cost savings for medicines

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Personalized medicine
- Individualization
- Biomarkers

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CONCLUSION

The current regulatory guideline focusses on the inclusion of geriatric patients in clinical trials. However, the geriatric population represents a heterogeneous group of patients requiring a more individual therapy, administered in an appropriate, high quality formulation, enabling optimal healthcare.

REFERENCES

Extensive reference list see Stalmans *et al.* (2014) Regulatory development of geriatric medicines: to GIP or not to GIP? (*Manuscript in preparation).*