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

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INTRODUCTION

- Demographic trend: increase in age group > 65 y ↔ decrease in birth rate.
- Geriatric patients = heterogeneous group:
  - Inter-individually varying effects of aging (i.e. 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)
  - Geriatric medicines strategy.
  - Geriatric expert group.
  - FDA guidance and regulations related to data on elderly persons in clinical drug trials (GAO-07-47R).
  - 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

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

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

- Cognitive impairment

- Age-related functional changes

- Ethics
- Age-appropriate drug formulations
- Clinical trials
- Heterogeneity

- Pharmaco-economics
- Personalized medicine

To GIP or not to GIP?

CONCLUSION

The current regulatory guideline focuses 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).