Practical proposals on recruitment improvement:

R&D approach and focus on possible bottleneck issues

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- Survey conducted to assess the general approach but also the critical issues when trying to obtain meaningful data for new drugs specifically also in a geriatric population
- Fifteen pharmaceutical companies participated in the survey

Question: mostly data from clinical randomized trials?

(yes/no, in which patients)

- 7 out of 10 said YES (No 1; Depends: 2)
- in most of the cases, it will make sense to have the older patients as a subgroup of patients in phase 3 trials in other cases, it will make more sense to have a completely separate trial for the geriatric population
- depends on product, indication

Question: would you suggest a specific innovative design for CTs?

- NO: no known innovative strategy unique for use in older patients
- Depends: often older patients who are fitter and thus maybe not representative of the general geriatric population are participating in trial then only age effects but not effects of co-morbidities are evaluated – this can be rectified by over-sampling of these patients and a separate analysis plan
- Yes: consider enriching designs and meta-analyses

Question: please give practical proposals how to improve recruitment of older patients?

- Communication & Logistics !!
- Careful choice of wording in patient information and use of appropiate media
- Try to accomodate patients and their caregivers as much as possible maybe even arrange for home visits where feasible

Question: would you systematically introduce adapted endpoints, to complement standard endpoints?

- Choice of endpoints should be driven by science not age
- Depends on product and indication, in some cases adapted endpoints could be helpful
- Maybe more focus on quality of life measures / PRO

Question: are standard endpoints always relevant in older patients?

- Choice of endpoints should be driven by science not age
- Criteria for a clinically relevant change could be different in young vs old patients
- Use quality of life measures / PRO /ADL
- Use holistic approach across multiple EP since it will be high risk to run a single (or dual) traditional EP in a quite variable population

Question: are clinical trials in frail older patients realistic? how can we generate data from this group?

- Definition of frailty?
- Needed and appropriate if “frail older patients” is the patient population for the study drug
- Ethical challenges? consider open label design or observational studies and close monitoring
- Consider that the underlying disease to be treated with the study drug can be the reason for frailty and can be improved
- Additional resources and specific expertise

Main outcome:

data from clinical randomized trials remain the preferred option!

- Data from ad-hoc registries were seen as less desirable and rather as supportive evidence
- How the older patients would be represented in clinical trials seems still to be topic for debate, testing of frail older patients was seen as an additional challenge
- Limitations and practicality were queried including possible ways to improve recruitment, choice of endpoints as well as enrollment and data generation in a geriatric population
- More collaboration between academia/industry/regulators needed to find more scientifically grounded solutions for these challenges

Thank you!