Active and Healthy Aging in Clinical Trials

Presented by Sergio Bonini

Professor of Medicine, Second University of Naples
Expert-on-Secondment, European Medicine Agency

Montpellier - October 20, 2014
Disclaimer

The views expressed in this presentation are the personal views of the speaker and may not be understood or quoted as being made on behalf of or reflecting the position of the EMA or one of its committees or working parties.

© European Medicines Agency, 2013. Reproduction is authorised provided the source is acknowledged.
Legislative acts

REGULATIONS

Low intervention Clinical Trials

• the investigational drug is authorized

• according to the protocol
  - the drug is used in accordance with the terms of the marketing authorization
  - the efficacy and safety is supported by published evidence in any Member State

• the additional diagnostic and monitoring procedures do not pose more than minimal additional risk to the safety of subjects compared to normal clinical practice
Types of Approval

100% Adequate Data

Time to Approval

- Normal: no specific obligations
- Conditional: specific obligations (conditional MA)
- Exceptional: specific obligations (supervised use)
Current scenario:
Post-licensing, treatment population grows rapidly; treatment experience does not contribute to evidence generation.

Courtesy of H-G Eichler
Adaptive licensing

“AL is a prospectively planned, flexible approach to regulation of drugs and biologics”

Adaptive licensing:
after initial earlier license, number of treated patients grows more slowly, due to restrictions; patient experience is captured to contribute to real-world information

Courtesy of H-G Eichler
The future of real-life clinical research

- Post-authorization efficacy studies (PAES)
- Post-authorization safety studies (PASS)
- Pharmacovigilance
- Registries
The importance of an AHA definition for future Clinical Research

• An outcome measure of health, rather than disease
  - definition of a significantly relevant change produced by interventions
• A dynamic end-point for the evaluation of any intervention
• A surrogate outcome measure of morbidity and mortality... or better of a healthy and active survival