



BRAIN DISEASES IN THE ELDERLY

**JOINT WORKSHOP
EUROPEAN SCHOOL FOR SCIENTIFIC AND REGULATORY ASSESSMENT OF NEW MEDICINES
AND EUROPEAN MEDICINES AGENCY (EMA)**

ROME MAY 16-17, 2008

**LOCATION: AULA MAGNA PIETRO GISMONDI
UNIVERSITY OF ROME TOR VERGATA
ITALY**

PRESIDENT

Prof. Alessandro Finazzi-Agrò, *Rector of University of Rome Tor Vergata*

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CHAIRPERSONS

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Tomas Salmonson *EMEA, Vice-Chairman of Committee for Human Medicines (CHMP)*

Giuseppe Nisticò *EMEA, Member of CHMP and Director of Pharmaceutical Biothechnologies Center University of Rome Tor Vergata*

ORGANIZING COMMITTEE

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Maria Lo Ponte, *University of Rome Tor Vergata*

Filippo Gesualdi, *Accademia Romana di Scienze Mediche e Biologiche*

Friday May 16

19:00-20:00 **Registration for foreign invited speakers, Hotel Flora, Frascati**

Saturday May 17

08:45 Welcome and Introduction:

Prof. A. Finazzi-Agrò, Prof. G. Nisticò, Prof. G. Sirchia

SESSION 1 CLINICAL TRIALS IN NEURODEGENERATIVE DISEASES

Chairmen: **Prof. G. Bernardi, Dr. K. Broich, Prof. S. Bakchine**

09:15 **C. Caltagirone**, *Clinical Trials in Alzheimer's Diseases*

09:45 **P. Stanzione**, *Clinical Trials in Parkinson's disease*

10:15 **S. Bakchine**, *Vascular Dementia: the state-of-the-art*

10:45 **K. Broich**, *Dementia from a Regulatory perspective*

11:15 Coffee Break

SESSION 2 THERAPEUTIC APPROACH TO THE BEHAVIOURAL AND PSYCHIATRIC DISORDERS OF THE ELDERLY

Chairpersons: **Dr. B. Van Zwieten-Boot, Prof. A. Cherubini, Prof. A. Siracusano**

11:30 **A. Rossi**, *Anxiety and Depression*

12:00 **R. Silvestri**, *Sleep Disorders*

12:30 **L. Annunziato**, *Nicotinic receptors and psychotic disorders*

13:00 Lunch

SESSION 3 AN INTEGRATED VIEW ON DEVELOPMENT OF NEW MEDICINES FOR THE ELDERLY

Chairmen: **Dr. T. Salmonson, Prof. R. Bernabei**

14:00 **S. Del Signore**, *The participation of elderly patients in regulatory aimed Clinical Trials*

14:20 **P. Folino**, *The objectives of the AIFA Geriatric Working Group*

14:30 **R. Bernabei**, *High quality databases as alternatives to clinical trials in the elderly*

15:00 **M. Fini**, *The Italian Scientific network of Excellence Centers*

15:10 **M. Trabucchi**, *Drug interactions in the treatment of patients with neurodegenerative diseases*

GENERAL DISCUSSION

15:30 *Coffee Break*

SESSION 4 A STEP FORWARD: APPLICATION OF EMERGING TECHNOLOGIES

Chairpersons: **Dr. C. Deguines, Prof. R. Floris**

16:00 **G. Sancesario**, *Cerebrospinal fluid and blood biomarkers in Alzheimer's disease and mixed dementia*

16:30 **H. Hampel**, *Update on the use of neuroimaging and biomarkers in the characterisation and neuropharmacology of Alzheimer's disease*

17:00 **P.M. Rossini**, *The use of Transcranial Magnetic Stimulation to assess memory disorders in man*

17:30 **CONCLUDING REMARKS AND FUTURE ACTIONS: T. Salmonson**

Objective of the Meeting

A number of clinical development programmes is presently undertaken by the Industry aimed at making available new medicines for the Brain Diseases of the Elderly. These conditions, like the behavioural syndromes often concomitant or concurrent to neurodegenerative disorders, may deserve specific therapeutic approaches, and some of these may be already dealt with during development clinical trials.

The regulatory frame to develop and to approve new medicines is set at EU Community level.

Recently some learned societies, EUGMS and the Italian Geriatrics Working Group (GWG) raised the question on the adequacy of guidance on the elderly regarding medicinal products for human use, and the EMEA clarified the needs for the extent and modalities of the involvement of Elderly patients in investigational clinical trials aiming to the optimal assessment of use of the candidate medicine in this special population.

The present workshop intends to further enlarge the debate between Academia, Regulators, Patients' representatives and Industry from the methodology of clinical programmes to the specific therapeutic approaches suitable for CNS (both in neurodegenerative and psychiatric) frequently observed conditions in the elderly patients. Adequateness of clinical end-points as well as the integrated therapeutic approach beyond pharmacotherapy could be part of the discussion.

The Workshop should allow the participants to convey their respective views and identify a common ground of enrichment. The elements originating during the discussion will not constitute a formal specific advice on a particular product or class of products. The positions expressed by the Experts or the EMEA during that Meeting will not be regarded as binding in relationship to any aspect of subsequent institutional work.

LIST OF PARTICIPANTS

Patrizia Aducci, *Director of Biology Department, University of Rome Tor Vergata*

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Industry Representatives