

## SATELLITE SYMPOSIUM: FORENSIC PSYCHIATRY

### INFORM CONSENT FOR CLINICAL TRIAL OBTAINED FROM PERSON WITH ALZHEIMER'S DISEASE – FORENSIC ASPECTS

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**Introduction/Objectives:** In 2001, Croatia had 4,437,460 inhabitants and 15.7% were older than 65 years. The same source of information registered 1,455 persons between 95 and 108 years of age. In the database of the Croatian Institute for Health Insurance, 806,070 persons older than 65 years were registered in December 2006. The newest estimate for the Croatian population, from July 2009, is 4,489,409. Life expectancy at birth is estimated to be 79 years for the female population and 72 years for the male population. Demographic trends observed over the past 5-6 decades show depopulation, and the overall population getting older. An extrapolation of these data to the year 2050 predicts 26.2% of people older than 65 years. The above data place Croatia among the oldest populations among European countries.

**Participants, Materials/Methods:** Croatia has no register of persons with dementia (PWD). If 10% of people above 65 years of age are affected by dementia, the number of PWD would be about 80,000, the majority being patients with Alzheimer's disease (AD). It is assessed that up to 15,000 PWD live in Zagreb, the capital of Croatia.

Five drugs are currently approved by the United States Food and Drug Administration (FDA) for the treatment of PWD. All five drugs are recommended

for use in Croatia, but only three are registered in Croatia. However, none of the three is on the reimbursement list of the Croatian Institute for Health Insurance. Due to the high cost of these drugs, the majority of PWD cannot afford to buy these drugs.

**Results:** In connection with above mentioned some of the patients undergo clinical trials and are treated with investigational agents which, if they are lucky, may be adequate treatment for them, but usually with short or limited duration.

Clinical studies of new antidementia drugs have been conducted in Croatia since 1989, and some PWD participating in these studies benefit directly from them. The trials began with pentoxifylline and continued with propentofylline, donepezil, phenserine-tartrate and EVP-6124. Clinical trials will include some novel potential antidementia agents in the near future.

**Conclusions:** Inform consent for clinical trial obtained from person with Alzheimer's disease is a valid and useful piece of evidence in evaluation of post-mortem competency. Namely, this document is signed by patient personally and represents ability of person to understand the scope and procedure of protocol and actively participate in one complex process.