



## 8<sup>th</sup> CONFERENCE Clinical Trials on Alzheimer's Disease

and reducing waste in biomedical research regulation and

November 5-7, 2015 - BARCELONE



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### INCREASING VALUE AND REDUCING WASTE IN ALZHEIMER'S DISEASE CLINICAL RESEARCH

Barcelona, Spain, November 6, 2015. The large number of failed clinical trials of Alzheimer's disease treatments has led many investigators to rethink the way clinical trials are conducted. At a symposium to be held at the 8<sup>th</sup> International Conference on Clinical Trials for Alzheimer's Disease (CTAD), an international group of clinicians, researchers from academia, industry, and editors from *The Lancet* journals, will address one of the central problems in clinical research: wastefulness.

Moderator Lon S. Schneider, M.D., professor of psychiatry, neurology, and gerontology at the University of Southern California, said the symposium was organized in response to observations of substantial waste in clinical development, specifically with respect to Alzheimer's disease drug development. "There has been considerable concern about the lack of success in clinical trials in Alzheimer's disease and the performing of very, very large trials in an effort to detect small signals; or moving from phase 2 to phase 3 trials absent a proof of concept," he said.

Wastefulness and inefficiency come in at multiple levels of the drug development process: when designing and conducting the trial and analyzing the results, as well as in the regulation and management of clinical studies. As stated by Rustam Al-Shahi Salman, Professor of Clinical Neurology at the University of Edinburgh, in a recent paper in *The Lancet*, "Waste arises from questions being overlooked or unnecessarily addressed, research being underpowered or done too slowly, and research being too costly." He went on to say that "Ultimately, these problems are a threat to public health – they cost people their lives through a failure to identify and introduce effective treatments and prevent harmful treatments from continuing."

Panelists at the symposium included Professor Salman along with Professor Malcolm Macleod, also from the University of Edinburgh; Elisabetta Vaudano, from the Innovative Medicines Initiative (IMI); Rachel J. Schindler, M.D., from Pfizer; José Luis Molinuevo, M.D., from Hospital Clinic in Barcelona, Spain; and two editors from *The Lancet* journals: Sabine Kleinert and Elena Becker-Barroso. They discussed problems and possible solutions for clinical trials from multiple aspects. For example, Vaudano described IMI's European Prevention of Alzheimer's Disease (EPAD) initiative, which created a pan-European platform for a standing, adaptive, multi-arm phase 2 clinical trial and patient registry for a trial-ready cohort to maximize recruitment efficiency; and the editors discussed *The Lancet* REWARD campaign to "REduce research Waste And Reward Diligence"<sup>ii</sup>

Inefficiency and waste are concerns not only for those conducting and funding clinical trials but for patients as well, said Schneider. "Both patients and physicians need to be able to assess whether a trial in which they might participate is efficient and necessary," he said. Moreover, improving the efficiency and value of trials should lead to more transparent and optimal outcomes, which would help ensure that participants benefit from the trials for which they volunteer.



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