



Global Clinical Trials for Alzheimer's Disease: Chapter 7. Why the Negative Studies in Alzheimer's Disease?

Hans J. Möbius

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Regulatory approval of the first rational AD therapeutic tacrine occurred in 1993, followed by the approval of three other, AChEIs, and the NMDA antagonist memantine in 2002 (EMA) and 2003 (FDA) respectively. Since then, despite an enormous research and development effort, the past 10 years have seen a series of failures to translate pathophysiological understanding of dementia into new medicines. This includes a move away from neurotransmission to a focus on underlying pathological processes. The major reason for these failures was probably the continued absence of a unified disease theory of AD and too narrow a focus on the potential aetiologies of this complex disorder. To foster progress and not repeat mistakes of the past it is time to critically analyze the past approach. This chapter serves as a reminder of potential shortcomings in the field across the complete spectrum flow from animal testing through regulatory approval to daily practice.

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