



Global Clinical Trials for Alzheimer's Disease:

Chapter 11. Alzheimer's Disease Mortality and Patient Retention in Clinical Trials: The Impact of Alzheimer's Disease on Morality

H. Michael Arrighi

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Alzheimer's disease (AD) confers an additional risk of death. The magnitude of this impact is related to the person's underlying mortality and current AD stage. When planning clinical trials, estimating the number of deaths prior to study initiation, and periodically during the study as participants are enrolled, assists in providing an informative context, particularly if there are few life events. Additionally, deaths have the potential to introduce a bias, thus, equal follow-up needs to ensure for participants assigned to either active or placebo, particularly if the period of observation for safety events extends beyond the end of the study. During AD clinical trials, patients discontinue for reasons other than death and at substantially high rates, which has the potential to introduce significant bias. Planning and incorporating strategies to improve retention and identify successful techniques should be an integral part of the study process.



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