## S14-4 Evaluating Drug Safety in Patients with Alzheimer's Disease

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The evaluation of drug safety in elderly patients who have a neurodegenerative condition such as Alzheimer's disease is complicated because of the complex and evolving symptoms of their progressive disease, use of multiple concomitant medications and the background of other medical conditions in an elderly population. Drugs used for neurodegenerative diseases and in the elderly are said to have relatively high reporting rates of adverse events during postmarketing. This presentation will examine the issues arising in drug safety evaluation in Alzheimer's populations by examining results for clinical trials using Aricept, an approved drug for this condition, and also reviewing results for atypical antipsychotic drugs used in the CATIE-AD study. Adverse events observed during clinical studies may be divided heuristically between those related to primary pharmacology of the drug, those related to off-target pharmacology or toxicity, and those more likely due to the background of the patient population and their underlying disease but there is always some uncertainty in the degree to which causality can be attributed to the investigational treatment. Handling of safety issues arising in these populations in light of recent international trends in data mining for safety signal detection, pharmacoepidemiologic research and risk management planning will also be discussed.