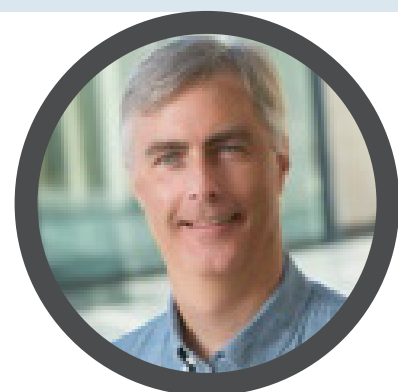


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ON THE HORIZON: THE VALUE AND PROMISE OF THE GLOBAL LATE STAGE PIPELINE OF ALZHEIMER'S DISEASE THERAPEUTICS

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A string of recent phase 3 Alzheimer's disease (AD) trial failures targeting primarily amyloid beta (A- β) have challenged hopes for finding an effective disease-modifying therapeutic. Despite some recent advances, this has resulted in some skepticism regarding the current value of the AD pipeline and its potentially over-weighted focus on therapeutics targeting A- β . To investigate these concerns, we have compiled a database of all current phase 2 and 3 AD therapeutics that has disease-modifying targets through a query of the National Institutes of Health's ClinicalTrials.gov. We then assessed the potential therapeutic success as well as financial value of the current AD pipeline. Financial modeling utilized risk-adjusted net present value (rNPV) measurements. Results indicate that the preponderance of current phase 3 trials is indeed targeting A- β with only 15% of the therapeutics addressing other targets. However, the current pipeline of phase 2 trials consists of a rich diversity of targets, with A- β based therapeutics representing <30% of those in development. Modeling data with commercial assumptions built on the experiences of adjacent fields such as cardiovascular disease, the estimated total risk adjusted net present value of current phase 2 and 3 therapeutics combined is \$182 billion over 10 years. This figure increases to a theoretical cumulative value of \$422 billion when also treating asymptomatic individuals at high risk for developing AD. This value requires the global availability of rapid and easy to use diagnostic biomarker(s) of AD risk. Results from sensitivity analyses of financial model assumptions and different drug development strategic approaches will be reported. The promise of the current AD therapeutic pipeline will be discussed in addition to the complex financial ecosystem necessary to maintain a healthy AD pipeline. Diagnostic biomarkers of AD risk will be critical to reach the full global potential of treating individuals in need.

Biography

Michael A Cole received his MA in Behavioural Neuroscience from University of Colorado, MBA from UC Berkeley; PhD in Neuropsychology from the University of Florida and completed his Internship and Residency in Clinical Neuropsychology at the UCLA School of Medicine. He is an Assistant Clinical Professor in the UC Berkeley Clinical Science Program and Founding Partner for Global Neurohealth Ventures. He has published 20+ peer-reviewed journal articles and continues active practice as a Clinical Neuropsychologist.

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