Cognitive and functional outcomes are generally the co-primary endpoints in most symptomatic and disease-modifying clinical trials for Alzheimer’s disease (AD). But Quality of Life (QOL) is also an important component in understanding the devastating disease and evaluating its effects.

There are several measures currently used in clinical trials to determine QOL levels of AD patients. However, like other clinical outcomes in Alzheimer’s disease, there are unique challenges in determining QOL and its fluctuations in patients over time.
One important factor to consider when evaluating Quality of Life is that as the dementia in patients progresses, insight into their condition worsens. Therefore, it can prove challenging to determine when a reported change in quality is valid and when a change is colored by diminished insight. Oftentimes caregivers will be asked to serve as proxies for their patients in order to better collect this information. But this raises the question of at what point throughout the course of the illness the patient’s insight is impacted and the caregiver’s insight is more reliable.

A recent study explored some of the issues related to these challenges by examining a cohort of patients and caregivers, analyzing both patient and caregivers’ reports of QOL to attempt to better understand reported differences. Among the study’s many significant results, it was discovered that older patient age was associated with the overestimation of Quality of Life by caregivers. Neuropsychiatric inventory score and caregiver burden were associated with underestimation.

Bracket’s initiatives in this area of study have focused on ensuring that Quality of Life outcome measures are implemented in a valid and consistent way. This includes the coordination of clear, concise training for both investigators and raters; how QOL information is collected is essential to improving the integrity and usefulness of this data. Distinguishing between patient and proxy versions is critical, as well as effectively outlining how the sponsor company wants caregivers to provide collected information. An example of this distinction might be a caregiver’s own estimate of a patient’s health and a caregiver’s estimate of how he or she believes a patient would answer on their own. Generally, the particular way QOL information is handled, whether it’s by the subject or the proxy, will be specified in the protocol. It is not left up to the rater to decide which way to administer Quality of Life measures.
The intricacies of Quality of Life research are important and should always be incorporated into available customized training programs. Through effective training and remediation efforts, researchers will stand better prepared for resolving patient issues when they arise during a clinical trial. With the continued use of these methods, QOL assessments can become a valuable quantitative asset rather than an obstacle in AD clinical trial evaluations.

**Takeaways**

» Quality of Life is an essential tool in Alzheimer’s disease clinical trials assessments that can bring another dimension to insights from clinical trial outcomes

» Administers and raters of Quality of Life measures should follow detailed protocol to obtain accurate and consistent results that carry the potential to influence the success of clinical trials
ABOUT BRACKET

Bracket, with nine offices and more than 700 employees worldwide, is a clinical trial technology and specialty services provider dedicated to helping biopharmaceutical sponsors and contract research organizations increase the power of their clinical research data by leveraging core competencies in Science, Technology, and Service. Bracket eCOA™ is a flexible platform for electronic clinical outcomes assessments. Bracket RTSM™ is a best-in-breed, scalable and configurable clinical IRT solution for the life sciences industry. Bracket SmartSupplies™ is a proven platform for improving a clinical supply chain. Bracket Rater Training and Quality Assurance improve outcomes through customized training and quality assurance programs.

For help with your next Alzheimer’s disease clinical trial, contact Bracket: (610) 225.5900 | Bracketglobal.com

David S. Miller, MD, MA, Clinical Vice President at Bracket

Dr. Miller has over 20 years of clinical, clinical research and teaching experience, primarily in the field of geriatric psychiatry. After completing his 2-year fellowship in geriatric psychiatry at the University of Pennsylvania, he joined the faculty and served as an Assistant Professor of Psychiatry. Dr. Miller then went on to the University of Medicine and Dentistry of New Jersey, where he served as an Associate Professor of Psychiatry.

Dr. Miller serves as the Co-Chair of the ISTAART funded Neuropsychiatric Syndromes in Dementia – Professional Interest Area (NPS-PIA), and as the Co-Chair of the ISCTM Working Group focusing on the same area. Additionally, Dr. Miller is a co-author on the updated ADCS ADAS-Cog administration and scoring manual.

Since joining Bracket, Dr. Miller has consulted on multiple dementia protocols and has served as the Expert Presenter at dozens of investigators’ meetings across the globe, including those addressing behavioral abnormalities and agitation in the context of dementia.

References: