The Role of Cognitive Testing in Nutraceuticals Trials

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In 2023 the global nutraceuticals market value was $87.02 billion, and by 2032 it is projected to grow to $161.82 billion (1). The word “nutraceutical” combines “nutrient” (derived from food) and “pharmaceutical” (medical drug). Nutraceuticals are becoming increasingly popular as preventative healthcare and wellbeing measures, as consumers seek natural alternatives to drugs. With the worldwide growth in aged population, the surge in demand will only continue to grow as consumers seek to understand how they can improve age-related health issues [2]. Over the past decade there has been a substantial interest in nutraceuticals for their ability to enhance cognitive function. The main groups of consumers are those seeking to treat or delay neurodegeneration, modification of the normal ageing process [3], and enhancement beyond therapy [4].

Regulatory requirements for nutraceuticals labeling

Given this growing popularity, in recent years we have seen regulations toward health benefits claims put in place in addition to safety and labeling requirements. Many food products regulatory bodies across the globe (e.g., USA, Canada, E.U, Japan) have released regulations and recommendations specific to health claims for these products [5,6,7,8]. They are unanimously requiring scientific evidence determined by independent assessment(s) using the highest possible standard. Therefore, assessing nutraceuticals health benefits in the same manner as drugs in regulated clinical trials is required, if claims are to be scientifically validated.

The value of computerized cognitive testing to support health claims

As with drug development, supporting product claims with scientific evidence is vital. This includes understanding the impact on cognitive function, both positive and negative. In this way, tools or systems for assessing cognition within nutraceutical trials should be scientifically relevant, specific as well as sensitive, easy to administer, and of little burden for the participants. Many paper and pencil cognitive scales lack the

sensitivity to detect relevant changes in these populations and require highly trained clinicians to be correctly administered.

Selecting an effective computerized cognitive test solution for nutraceutical trials

Effective computerized cognitive assessment solutions should provide specific capabilities to fulfil these requirements. They should:

- Assess distinct cognitive domains to provide specific profiling of the product
- Allow for testing at multiple time without inducing practice/ learning effects
- Be brief and simple to administer, yet highly sensitive
- Demonstrate good test-retest reliability
- Not need of specialized units or staff to administer the assessment
- Be available in multiple language versions
- Not be cost-prohibitive

Signant Health's CDR System®: A computerized cognitive assessment solution

The Signant SmartSignals® CDR System®, backed by 40 years of validation data, is a comprehensive and proven solution for cognitive assessment in clinical trials as well as for nutraceuticals clinical assessments. Well-received by volunteers, patients, sites and clinicians, the CDR System has extensive nutraceuticals experience [9] and its data have been used for health benefit claims.

The CDR system has been shown to be sensitive to positive effects of a variety of foodstuffs and naturally occurring products. These improvements have been seen primarily in volunteers, but also in patients with neurasthenia [10], mild cognitive impairments [11,12], and Alzheimer's disease [13]. Improvements have also been observed in children given breakfast compared to no breakfast [14], or in children given low GI breakfast versus high GI breakfast [15]. Performance of healthy young and/or elderly volunteers can be improved by caffeine [16], guarana [17,18], melissa [19], huperzine [20], an energy drink [21], sage [22,23], aroma of rosemary [24], ginkgo biloba [11,25], Panax ginseng [26,27], Actimind® (a combination of ginkgo and ginseng) [10,28,29,30] and Pharmaton Capsules® [31].

Moreover, the CDR System demonstrated nutraceuticals cognitive benefits in young healthy volunteers subjected to sleep deprivation [31], elderly impaired volunteers [11], healthy volunteers with neurasthenic complaints [10] and fatigue related to working

night shifts [32].

Finally, as a result of several studies, data from the CDR System were used to support marketing and labeling claims for Actimind®, Gincosan®, Ginsana®, Pharmaton capsules® and Tanakan®.

Summary

Computerized cognitive batteries are fit to purpose tool to provide unbiased, sensitive, and cognitive-domains-specific assessments for nutraceuticals, providing the required evidence to be used for the specific health claim mandated by the regulatory bodies.

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REFERENCES

About the Authors

Helen Brooker is a specialist in cognitive test development and aging, with over 18 years of experience in academic and clinical research. She leverages her expertise in neuropsychological assessment, clinical trial delivery, and digital health solutions as a Senior Product Manager at Signant, where she oversees the company's proprietary computerized cognitive test solution. reliability of clinical data, ultimately contributing to more effective and patient-centric healthcare solutions.

Pascal Goetghebeur is an experienced CNS pharmacologist and behavioral scientist specializing in psychiatry and neurodegeneration. At Signant Health, he serves as Clinical Principal for Cognition, Science & Medicine in the Digital Health Sciences division, focusing on the role of cognition in drug development and managing the clinical aspect of Signant's proprietary cognitive assessment battery.