



# Neuroscience Working Table

Working Together to Achieve a Neuroscience Center of Excellence

## Understanding the Need for a Neuroscience Center of Excellence at the FDA

### Central Nervous System (CNS) Diseases Afflict Millions and Cost Billions Each Year

As of 2020, nearly 100 million Americans suffered from psychiatric and neurological diseases, costing \$760 billion annually. The Centers for Disease Control and Prevention (CDC) forecasts that the number of Americans with some form of dementia will double by 2060 to 13.9 million people (3.3 percent of the estimated 2060 U.S. population), which Milliman [estimated](#) could cost \$243 billion annually. CNS not only increases costs for private sector payers and government programs, but also places a heavy financial and social toll on many individuals, families, and caregivers.

### COVID-19 Worsened Human, Social, and Financial Impacts of CNS Diseases

A large [study](#) published in *the Lancet Psychiatry* produced the staggering finding that one in five patients who contracted COVID-19 were diagnosed with a psychiatric disorder within 90 days. The study showed that anxiety, depression, and insomnia were the most common mental health problems that developed among recovered COVID-19 patients. Researchers also found significantly higher risks for developing dementia. More must be done to support the now-magnified need for research into treatments for CNS diseases and disorders.

### The Need for Treatments and Cures for CNS Diseases Has Outpaced Development

Despite the tremendous human and financial costs CNS diseases place on Americans, CNS treatments face greater development challenges and approval [hurdles](#) compared to other therapeutic areas even with bipartisan agreement that more needs to be done. Challenges include the complex pathologies of the diseases, heterogeneity, difficulties in identifying and developing biomarkers and clinical endpoints, and length of clinical trials and regulatory processes that have lagged behind other therapeutic areas. CNS drugs take 20 percent longer to [develop](#) and approve than other drugs. The Government Accountability Office [reported](#) that in recent years, FDA reviewers of CNS new drug applications denied more requests for breakthrough therapy designation (and granted fewer), compared to other disease areas.

## Neuroscience Center of Excellence (NCoE) Builds Upon Successes of Existing Center of Excellence

As part of the 21<sup>st</sup> Century Cures Act, Congress authorized the Food and Drug Administration (FDA) to establish Intercenter Institutes at the Agency for major diseases or other areas. One of the major stakeholders advocating for creating this authority was the cancer community, leading to the first Intercenter Institute – the Oncology Center of Excellence (OCE). FDA’s OCE has been a robust success in coordinating the activities of the FDA’s product centers related to oncology even during the COVID-19 pandemic. Just last year, the FDA (with OCE staff) issued multiple guidance documents related to conducting clinical trials during the COVID-19 pandemic; held more than 10 listening sessions with patient advocacy groups with the Office of Oncologic Diseases; and, [according to](#) FDA, between January 1 and November 1, 2020, the oncology review teams “approved 15 new molecular entities and more than 80 efficacy supplements for the treatment of patients with cancer.”

## Congress Should Establish an NCoE at FDA to Aid Development of CNS Therapies

Given these successes, Congress should continue this model created by 21<sup>st</sup> Century Cures and establish an NCOE at FDA to tackle CNS diseases and disorders. Such an effort brings together several different disease areas and their respective stakeholders, and accelerates development in the space through:

- Placing a stronger emphasis on drug development tools for CNS treatment and cures;
- Increasing utilization of patient-focused drug development for patients with CNS diseases and disorders; and,
- Improving engagement between FDA and stakeholders and strengthening internal coordination within FDA.

The NCoE would include programs that would:

- Address concerns over equity challenges in neuroscience research and development;
- Improve the understanding of the neuroscience-related impacts of COVID-19;
- Better integrate digital health technology into the neuroscience product review process; and,
- Inform the design and implementation of natural history studies to aid development for neuroscience therapies.

### For additional information please contact:

Clay Alspach at [clay.alspach@leavittpartners.com](mailto:clay.alspach@leavittpartners.com)

Josh Trent at [josh.trent@leavittpartners.com](mailto:josh.trent@leavittpartners.com)

Mark Roberts at [mark.roberts@leavittpartners.com](mailto:mark.roberts@leavittpartners.com)

Convened & Managed By

**LEAVITT**  
PARTNERS