

FOR IMMEDIATE RELEASE  
August 1, 2019

Media Contact: Dellann Elliott Mydland  
425.785.8489 | [Dellann@EndBrainCancer.org](mailto:Dellann@EndBrainCancer.org)

## The EndBrainCancer Initiative Urges Support for New FDA Clinical Trial Diversity Guidelines and Proposes Key Amendments

Proposed Changes Offer Patients with Brain Cancer and Other Rare Diseases  
Access to Advocacy Oriented “Patient Partner Navigation Services”

Seattle, WA - July 31, 2019 - Seattle, Washington - The EndBrainCancer Initiative (EBCI) urges support for the new guidelines proposed by the FDA entitled “[Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry.](#)” With the [public comment period](#) ending on August 6th, the EBCI also proposes changes to the guidelines that would ensure that brain cancer patients and other rare disease patients are offered the opportunity to interact with advocacy oriented outside “Patient Partners Navigation Services” at the time of diagnosis prior to surgery and as a regular part of clinical trial participation to increase inclusion, diversity, and enrollment in support of the growth goals of the guidelines ([EBCI Letter](#) and [Public Comment](#)).



Overall, this FDA draft guidance document provides recommendations for inclusive research practices for industry/drug companies clinical trial sponsors to broaden eligibility criteria and increase enrollment of underrepresented populations, including patients with other diseases (known as “medically complex patients”), vulnerable patient populations (e.g, pediatric or elderly patients), and racial and ethnic minorities.

“The [EndBrainCancer Initiative](#) (EBCI) fully supports FDA’s efforts to broaden eligibility criteria for enrollment into clinical trials and increase enrollment of underrepresented populations,” commented Dellann Elliott Mydland, President and CEO of EBCI. “Currently an estimated only 3% of brain cancer patients enroll in trials. As an organization, our aim is to increase that significantly through immediate access and decreased barriers.”

As a brain tumor patient navigation services and advocacy organization that works directly and daily with patients, EBCI advocates for IMMEDIATE ACCESS to ALL treatment options, including clinical trials, as for this disease and patient population, there currently is no effective FDA-approved Standard of Care (SOC). Additionally, current SOC for this population often disqualifies these patients from clinical trial enrollment due to restrictive enrollment eligibility requirements.

FDA’s draft document strongly encourages the role of advocacy organizations in clinical trial design, recruitment, and participation. Many advocacy organizations do not offer direct patient navigation services focused on getting patients into clinical trials and some do. In EBCI’s [“Direct Connect” Services & Program model](#), a clinical nurse/patient navigator pre-qualifies patients via one-on-one consulting and “directly connects” the patient to the principal investigator for the trial the patient qualifies for. Delores Kannas (RN MSN MHA),

EBCI's Industry Liaison & Patient Navigator, noted, "Since 2002, EBCI's "Direct Connect" program has been very successful in placing patients into clinical trials and connecting them with advanced treatments and specialists. We think this model would be an asset if added to the proposed FDA guidelines and the impact would be increased inclusive research practices and increased clinical trial recruitment/participation."

In its public comment on the guidelines, EBCI proposes utilizing outside "patient partner navigation services" which could be provided by advocacy organizations or patient navigation services companies. This navigation service would be offered to patients near the time of diagnosis before surgery as part of clinical trial pre-qualification and also during the design, accrual, and participation phases. The organizations/companies and their navigators will help where specifically needed, especially in adding Patient Reported Outcomes (PRO) in the trial design and supporting patients in reporting those outcomes.

The [EBCI letter](#) also references the recently published article "[Overcoming Barriers to Clinical Trial Enrollment](#)" where Dr. Ryan Nipp et al review barriers to enrollment that contribute to low participation in cancer clinical trials (American Society of Clinical Oncology Educational Book 39, May 17, 2019). They conclude, "A promising solution involves the use of patient navigators to help enhance clinical trial recruitment, enrollment, and retention" (page 105). Multiple studies were cited using patient navigators that demonstrated effectiveness during the patient's treatment process and a few more recent studies were cited that looked at the use of patient navigators to improve the clinical trial accrual process. These comprehensive recommendations were cited as support for the EndBrainCancer Initiative's comments and suggested specific additions to the FDA draft guidance document.

Dellann Elliott Mydland concluded, "Brain cancer and rare disease patients want immediate access to the most advanced knowledge, specialists, devices, diagnostics, treatments, and the best potential clinical trials possible. We believe offering patients access to outside Patient Partner Navigation Services will help ensure the best opportunity for greater diversity and greater numbers of patients participating in clinical trials and ultimately, increased survivorship."

**CONTACT:**

Dellann Elliott Mydland  
President & CEO  
EndBrainCancer Initiative  
425-785-8489  
[dellann@endbraincancer.org](mailto:dellann@endbraincancer.org)