April 24, 2023

U.S. Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. #1061
Rockville, MD 20852

RE: Docket ID: FDA-2022-D-2983

Draft Guidance for Industry: Considerations for the Design and Conduct of Eternally Controlled Trials for Drug and Biological Products

The Chris Elliott Fund DBA the EndBrainCancer Initiative (EBCI) recognizes the benefits of novel trial designs to accelerate advances and fully supports FDA's efforts to update industry guidelines for clinical trials and FDA approvals that take into consideration the use of external Real-World Data/Real-World Evidence (RWD/RWE) from patient data that has been collected from past clinical trials/historical data as well as from electronic records (EHRs) and medical claims, thus allowing researchers to accelerate evidence generation and achieve a range of clinical development objectives*. It is particularly important that this external information be allowed to serve as the basis for efficacy determination for product approval. For these reasons, EBCI strongly recommends the following updates, **indicated in RED**, to these draft guidelines:

Line 487 in Section C: Analysis Considerations

Word "estimation" should be updated to "estimated"

Line 507 in IV: CONSIDERATIONS TO SUPPORT REGLATORY REVIEW at Section B: Access to Data and Documents:

The word "must" should be replaced with the words "should include, when available", so the line reads "Sponsors should include, when available, in their marketing applications relevant patient-level data (i.e., data on…….)

We also appreciate the FDA hearing EBCI's patient advocacy voice in addition to the voices of the patient/caregiver/family member impacted by this disease on this subject. As a 501(c)3 non-profit brain tumor advocacy, patient services & support organization who speaks to multiple patients, caregivers and family members, including specialists and researchers, on a daily basis for this disease state/community, **we can tell you that patients with brain cancer DO NOT want a placebo as part of the clinical trial experience and often, it is the placebo protocol/control arm in the clinical trial protocol that causes them to not enroll in the trail at all.**

For patients diagnosed with Glioblastoma Multiforme (GBM) and Recurrent Disease (rGBM), they will quickly die, therefore, EBCI does not support providing this patient population a placebo but rather in

providing them upfront, the drug/device/treatment option offered in a clinical trial while utilizing data for this patient population from external RWD/RWE, EHR's, etc. to act as the "controlled arm" in clinical trials. To sacrifice and condemn another group of GBM/rGBM patients to a placebo arm is cruel when the outcome for this patient population is well documented nor does this same approach lead to novel trial designs leading to accelerated and approved treatment options for this patient population.

Again, the EndBrainCancer Initiative team and I appreciate this opportunity to comment on these very important draft guidelines in an effort to move HOPE, science and increased survivorship forward.

Sincerely,

Dellann Elliott Mydland
President & Board Chair

The EndBrainCancer Initiative | Chris Elliott Fund
Dellann@EndBrainCancer.org

www.EndBrainCancer.org

*External Controls in Research: The "What, Why and How". Ubc.com/external-controls-in-research