



July 25, 2019

TO: U.S. Food and Drug Administration

RE: **Docket ID: FDA-2019-D-1264-0001**
Draft Guidance for Industry Entitled “Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment Practices and Trial Designs”

The Chris Elliott Fund DBA the EndBrainCancer Initiative (EBCI) fully supports FDA’s efforts to create guidelines and recommendations for increasing inclusive research practices for clinical trial sponsors/drug companies/industry in order to broaden eligibility criteria and increase enrollment of underrepresented populations, all of which will increase IMMEDIATE ACCESS to clinical trials, an item that is core to EBCI’s mission, vision, services & programs.

As a brain tumor patient services and advocacy organization who works directly and daily with patients, we can tell you that from the “patient perspective and voice” the goal of the brain cancer patient as it relates to clinical trials is IMMEDIATE ACCESS to ALL treatment options, including clinical trials, as for this disease and patient population, there currently is no effective Standard of Care (SOC) under the NCCN Guidelines. Additionally, current SOC for this population, often disqualifies these patients from clinical trial enrollment due to restrictive enrollment eligibility requirements.

We applaud FDA’s efforts to utilize Advocacy organizations to assist with the FDA’s goal to increase inclusive research practices and to increase enrollment of underrepresented populations into clinical trials. Having said that, we urge the FDA to understand that very few Advocacy organizations actually have direct services & programs that assist in enrollment of clinical trials. It is for this reason that the EBCI wishes to introduce the concept of utilizing outside “patient partner navigation services” companies as well as Advocacy organizations providing direct patient navigation services, pre-qualification of clinical trials services and “Directly Connecting” the patient/caregiver to the principal investigator for the trial the patient qualifies for per EBCI’s “Direct Connect” Services & Program model. EBCI’s model of pre-qualifying these patients via our one-on-one consulting services with our Clinical Research Nurses/Patient Navigators is highly successful getting patients to specialists and into clinical trials and this model would be an asset if added to the proposed guidelines and the impact would be increased inclusive research practices and increased clinical trial recruitment/participation.

Utilization of patient partner navigation services for rare diseases such as brain cancer is necessary as a special effort to ensure representation of a broad spectrum of the patient population.

In the recently published article “Overcoming Barriers to Clinical Trial Enrollment” Dr. Ryan Nipp et al review barriers to clinical trial enrollment that contribute to low participation in cancer clinical trials. (May 17, 2019)¹. 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

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few studies more recently were cited that looked at the use of patient navigators to improve the clinical trial accrual process. The authors included a reference to written communication in the Education Network to Advance Cancer Clinical Trials program by Margo Michaels in January 2019 recommending that clinical trial navigators should be mandated (page 111).

This recommendation by Dr. Michaels along with the comprehensive recommendations for the role of patient navigation described by Dr. Nipp et al provide strong support for EndBrainCancer Initiative's comments and content changes to the draft guidance in this letter.

EBCI specifically suggests the following updates indicated in red to these guidelines:

On page 8:

232 B. Adopt Enrollment and Retention Practices That Enhance Inclusiveness

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- 234 • Work directly with communities to address participant needs and to involve
- 235 patients, **patient partners navigation services**, patient advocates, and caregivers in the design of clinical
- 236 trial protocols.
- 237 Patients may provide valuable insight into challenges and burdens and may be
- 238 more willing to accept risk for a potential benefit as long as the risks are clearly
- 239 communicated in the informed consent and the research team explains the risks.
- 240 Community-based participatory research promotes the design of clinical research
- 241 with the assistance of community members and leaders to more effectively meet
- 242 the needs of potential participants.22 Understanding how participants choose
- 243 whether to participate in a clinical trial allows sponsors to more effectively recruit
- participants who may be reluctant to enroll.

On page 9 insert the additional content in red below as 2nd and 3rd bullets beginning on line 310 as follow:

304 • Engage early in the drug development process with **patient partners navigation services and** patient

305 advocacy groups that are strongly committed to finding new therapies, to elicit their suggestions for the

306 design of trials, including trial protocols, that participants will be willing to enroll in and

307 support. For a number of rare diseases, there are active patient advocacy groups that

308 are strongly committed to finding new therapies and supporting clinical trials.

309

310 *** Make available patient partner navigation services, such as the services provided under EBCI's**

311 **“Direct Connect” services & programs, for the individual patient to optimize timely**

312 **delivery of education needed for clinical care and clinical trial eligibility decisions prior to proceeding to**

313 **surgery and standard of care treatments.**

314 *** Make available patient partner navigation services to facilitate a patient-friendly design of patient**

315 **reported outcomes (PRO) and ensure participant compliance with PRO documentation that reports those**

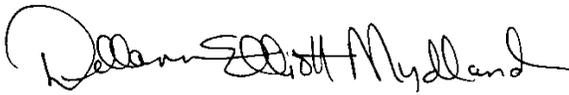
316 **secondary outcomes that impact quality of life separate from overall survival.**

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- 318 • Plan to re-enroll participants from early-phase trials into later-phase trials when
- 319 studying the effectiveness of treatments for rare diseases — in limited circumstances,
- 320 if medically appropriate, and if there is no unreasonable anticipated safety issue.

321 Traditionally, participants are often ineligible for a phase 3 trial if they had been
322 previously exposed to the drug in an earlier-phase trial; however, with so few
323 participants in rare disease trials, re-enrolling participants may facilitate the analysis
324 of safety and efficacy in the broadest possible population. Caution should be
325 exercised to avoid selection bias, as the participants who better tolerated the drug and
326 experienced more effectiveness in early phases may be disproportionately selected for
327 a phase 3 trial, which may contribute to efficacy findings that are not representative
328 of the larger population that will use the drug if the drug is approved.
329
330 • Make available an open-label extension study after early-phase studies to encourage
331 participation by ensuring that all study participants, including those who received
332 placebo, will ultimately have access to the investigational treatment.

Blessings,



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1. Ryan D. Nipp, MD; Kessely Hong, PhD, MPA; and Electra D. Paskett, PhD, Overcoming Barriers to Clinical Trial Enrollment, DOI: 10.1200/EDBK_243729 American Society of Clinical Oncology Educational Book 39 (May 17, 2019) 105-114., PMID: 31099636