April 16, 2018

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted electronically

Re: FDA Docket Number: FDA-2017-N-6607
Oncology Center of Excellence Listening Session; Public Meeting; Request for Comments

Dear Sir or Madam:

On behalf of the Cancer Support Community (CSC) and the patients we represent, we thank you for the opportunity to provide comments on the United States Food and Drug Administration’s (FDA or Agency) March 15, 2018 Oncology Center of Excellence (OCE) Listening Session to share our thoughts on how we believe the OCE should be structured to approve cancer therapies that best support the needs of people living with cancer.

CSC has a unique understanding of the patient experience as we serve patients and caregivers through a network of 175 locations, including CSC and Gilda’s Club centers, health-care partnerships, and a dynamic online community. Overall, we deliver more than $50 million in free, personalized services each year to individuals and families affected by cancer nationwide and internationally. The following comments reflect what we have learned from that frontline experience, captured scientifically through our Cancer Experience Registry which serves as the cornerstone of our research efforts. Our Registry of over 13,000 individuals allows us to measure what matters most to patients and caregivers so that we can translate these findings into policy recommendations.

We are heartened by the leadership within the FDA and the OCE to work towards a more patient-centered regulatory approach to cancer treatment. At CSC, we have worked closely with the OCE on how to integrate and measure the full patient experience into clinical trial protocols. It is deeply encouraging to us that the FDA recognizes that what matters to patients is more than the physical and biological impacts of treatments but also the equally and often more complicated social, emotional, and logistical implications of a given treatment. We have also worked closely with Congress to educate them on these issues and they have fully recognized the importance of them which resulted in passing the Food and Drug Reauthorization Act of 2017 (FDARA) with an expanded definition of patient experience data that explicitly includes psycho-social measures along with physical measures.
**Background**

The social and emotional impact of cancer is undeniable. What is perhaps more compelling to the FDA is that distress related to cancer also can negatively impact a patient’s adherence to a clinical trial, to their medications, and ultimately their path towards health. Nearly half of all cancer patients experience moderate levels of distress (Institute of Medicine, 2008) which has been defined as emotional, social, spiritual, or physical pain or suffering (National Cancer Institute, n.d.). “Cancer patients may have trouble coping with their diagnosis, physical symptoms, or treatment” (National Cancer Institute, n.d.) ultimately leading to such distress.

CSC has found that when patients experience distress that interrupts their work, family, or school life, they have an 86% probability of developing a clinical diagnosis of depression (Miller et al., 2016). Patients with depression can have lower rates of treatment adherence (Buzaglo et al., 2014), higher health care utilization rates, and higher annual health care costs (Jeffrey et al., 2011).

Patients who have the full range of their needs assessed and met are more likely to maintain enrollment in a study, adhere to treatment, and ultimately experience improved outcomes—as they define them. For example, studies have shown that breast cancer patients who were engaged in social and emotional interventions had significant psychological and physiological benefits over those who do not, including survival advantages (1.5 years), reduced risk of recurrence (45%), as well as decreases in anxiety, and fewer symptoms and toxicities from cancer treatment (Andersen et al., 2010, 2008, 2004).

As we consider more integrated, comprehensive approaches to cancer treatment, we must account not only for biological endpoints and outcomes in trials, but for the full range of patient experiences and values. Cancer research, treatment, and care should attend to the aspects of life that patients define as the most important—family and friends, career, psychological wellbeing, exercise and nutrition, etc. Information about levels of experiential distress should be collected, reported on, and used as part of shared decision-making process both for the benefit of the patient and their family but also for future trial design and intervention.

Simply put, incorporating patient experience metrics into trial design and developing treatments that truly meet patient needs is not just the right thing to do but also will dramatically improve the quality and relevance of the data that is collected. The intent of measuring patient experience as part of a clinical trial is to better understand the patient response to each arm of a trial, similar to documenting physical response to the interventions in each arm of a trial.

As noted above, Congress recognized this by expanding the definition of “patient experience data” in FDARA to include both physical and psychosocial impacts of a condition, therapy, or clinical investigation. Therefore, it is incumbent upon the FDA to implement this expanded definition and the CSC stands ready to assist the agency.

**Looking Forward**
The OCE mission is “to achieve patient-centered regulatory decision-making through innovation and collaboration.” In order to achieve this mission, the full patient experience, including physical and psychosocial impacts of a therapy, must be taken into account. Just as a patient’s blood is measured in a clinical trial, so should their level of distress.

As such, we respectfully make the following recommendations to actualize the expanded definition of patient experience data:

1. It is vital that professionals with expertise of the full patient experience—including the social and emotional aspects of cancer research and treatment—be integrated into the Center. Ideally, the OCE would create a dedicated position responsible for overseeing this aspect of all packages, and at a minimum, the OCE will ensure that reviewers have competency in this area to ensure that data sources under consideration are actually capturing values that matter to patients and accurately reflect the true and comprehensive impact of an investigational drug product under review.

2. Every investigational new drug (IND), protocol review, and approval should include consideration of the psychosocial aspects of the study, and ways to mitigate patient challenges, as part of the overall consideration of the patient experience. One simple way to start this process is to include a section for psychosocial impacts of an investigational agent on the checklist that is used during product review.

We appreciate the opportunity to provide these comments and look forward to working with the OCE to develop the capacity to ensure that the full patient experience is integrated into the regulatory process.

Sincerely,

Kristen Cox Santiago
Senior Director, Policy and Advocacy
Cancer Support Community Headquarters

References


*Journal of Clinical Oncology, 22 (17), 3570-3580.*

