Survey Gauges Early Impact of COVID-19 on Clinical Trial Sites

BY KURT SAMSON

In the first 3 months of the ongoing COVID-19 pandemic, breast cancer clinical trials became increasingly more difficult to manage and conduct, according to response analysis of questionnaires sent to researchers participating in a large clinical trial presented at the San Antonio Breast Cancer Symposium.

In a poster session, Debasish Tripathy, MD, Professor and Chairman of the Breast Medical Oncology Department at MD Anderson Cancer Center, presented an overview of how the pandemic affected researchers participating in the POLARIS trial (Abstract SS2-10). This research is an ongoing, prospective, real-world, noninterventional study of palbociclib plus endocrine therapy in patients with hormone receptor-positive/human epidermal growth factor receptor 2-negative advanced breast cancer.

“Although a number of COVID-19 guidelines have been published, including NCCN, ESMO, IQVIA, and Lancet Oncology, there remains no consensus on how to treat patients in the current environment,” Tripathy noted. “Understanding and quantifying the impact of the pandemic on clinical study sites will help inform the rational development of a consensus approach.”

Two rounds of questionnaires were sent to investigators at POLARIS study sites: one via email March 26-27, 2020, and one via telephone from April 30-May 20, 2020. Eighty of 122 POLARIS study sites contacted responded to the March questionnaire, and 86 responded to the April-May questionnaire. In March, 33 percent (26/80) of the surveyed population were working predominantly remotely, 26 percent (21/80) were working both onsite and remotely, and 31 percent (25/80) were working onsite.

Tripathy said that about 94 percent (81/86) of surveyed sites felt they were able to maintain clinical studies despite the challenges due to COVID-19, and 79 percent (68/86) of sites had the option for telemedicine and/or office visits. Approximately 24 percent of sites reported delayed data entry. The option of telemedicine or office visits was offered to subjects at approximately 73 percent (58/80) of sites, and 11 percent (9/80) of sites were restricted to telemedicine visits.

In April-May, 36 percent (31/86) of respondents reported an impact on study management while 64 percent (55/86) reported no impact. A total of 18 percent (16/86) had no telemedicine alternative. In April-May, 38 percent of sites reported an impact on patient visits.

“Although these findings must be interpreted with caution due to the limitations of survey studies, the results suggest that approximately one-third of the study sites will experience an impact on their responsiveness to correspondence, timely data entry, and subject management due to the COVID-19 pandemic,” according to Tripathy, “although telemedicine may be used to mitigate the effect of the pandemic on clinical trial execution.”

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