Impact of COVID-19 Pandemic Mitigation Strategies on Industry and NCI Cancer Treatment Trials

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Background:

- The COVID-19 pandemic disrupted enrollment and conduct of cancer treatment trials
- Regulators allowed flexibilities to trial processes to enable clinical research and care to continue
- ASCO and Friends of Cancer Research (*Friends*) established a task force to evaluate how sponsors perceived the impact of these mitigation strategies on data quality and overall trial conduct

Methods:

- The task force surveyed and interviewed eligible industry and National Cancer Institute (NCI) Network Group sponsors with cancer treatment trials active in the United States from January 2015-May 2022
- We assessed sponsors' perceived impacts of the pandemic on protocol deviations (PDs), types of mitigation strategies employed, trial closures, dropouts, adverse events (AEs), and data integrity

Most sponsors perceived that the COVID-19 pandemic had little or no impact on trial data integrity

Future Directions for Research:

- An ASCO-*Friends* meta-analysis will further quantify the impact of mitigation strategies on data quality and representativeness of trial participants and will inform recommendations for future clinical trials

Results:

- 20 sponsors (49%; 15 industry and 5 NCI) completed the survey and 11 (55%; 7 industry and 4 NCI) were interviewed (**Figure 1**)
- 83% reported that the pandemic had "minimal" (14) or "no" impact (1) on data integrity
- The most widely adopted mitigation strategies were:
  - Remote distribution of oral anticancer therapies (**70%**)
  - Remote consenting (**65%**)
  - Remote symptom monitoring for AEs (**65%**)
- Sponsors primarily reported "no change" in trial drop-out rates (77%), the number of trials closed due to low accrual (90%), or rates of AEs (81%) during the pandemic (**Figure 2**)
- The proportion of sponsors reporting a "substantial" increase in PDs compared to pre-pandemic dropped from 42% in the Initial Wave (March-April 2020) to 16% thereafter (**Figure 3**)

Figure 1: Study CONSORT Diagram

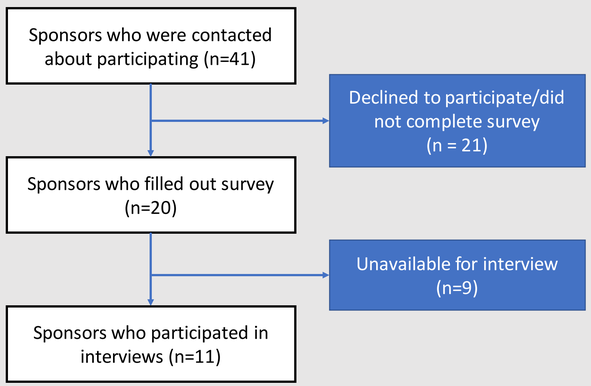

Figure 2: COVID-19 impact on dropouts, closures, and AEs

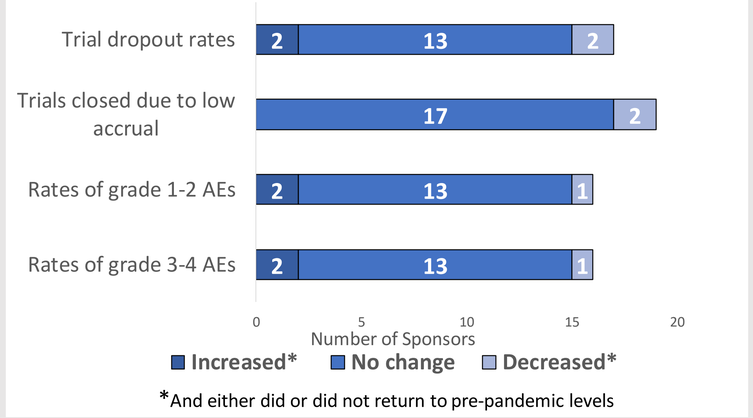

Figure 3: Comparison of average volume of PDs collected