

FY24 SITC NCI Appropriations Language

Topic: Clinical Research Workforce Training

The Committee is concerned that a shortage of staff who are qualified to support and administer cancer clinical trials has reached a crisis point and is slowing our nation's progress in developing new treatments. In some cases, trials have been delayed or even abandoned because the sponsor or cancer center conducting the trial could not hire enough staff to run them. The shortage is especially acute in trials involving cellular therapies, such as CAR-T, which are customized for each individual patient. Specialized skills are required to run trials that involve extracting a patient's cells, re-engineering them in the lab, and infusing them back into the patient. Training staff who are responsible for the safe conduct of such studies takes time and resources, and a focused effort is needed. Therefore, the Committee urges the NCI to address this problem by working with the academic community to support the training of highly specialized clinical research staff, particularly in the area of cellular therapy.

FY24 SITC FDA Appropriations Language

Topic: Clinical Trial Operations

The Committee recognizes that the COVID-19 pandemic further increased the staffing shortages already present at clinical research sites, exacerbating longstanding challenges to the timely collection and efficient reporting of clinical trial data in cancer research. The burden of data collection, entry, and verification is high and rests primarily with site staff, who most often input data manually. Meanwhile, the data fields requested for developing a given drug class have become increasingly numerous and may be complex. The Committee urges the FDA to provide guidance to cancer trial sites, sponsors, and contractors that both defines necessary data elements and streamlines data entry and verification processes. Such guidance will be foundational in maximizing clinical trial efficiency through a targeted reduction of the administrative burden currently placed upon research staff.