

### 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.