The Society for Immunotherapy of Cancer (SITC) appreciates the opportunity to comment on the Food and Drug Administration’s (FDA) recent draft guidance: *Decentralized Clinical Trials for Drugs, Biological Products, and Devices.*

SITC is the world’s leading member-driven organization specifically dedicated to improving cancer patient outcomes by advancing the science, development and application of cancer immunology and immunotherapy. For decades, SITC members have been at the forefront of cancer immunotherapy research working to develop and advance novel therapeutics into the clinic for the treatment of various cancers, including modalities such as established immune checkpoint inhibitors and emerging cellular therapies.

SITC leadership and members are very engaged on the topic of decentralized clinical trials. Multiple SITC initiatives over the past year have discussed the opportunity for increased use of decentralized clinical trials to increase patient access and decrease staffing burden at respective sites. Most recently, SITC has hosted several roundtables on diversity in clinical trials as well as the overall crisis in clinical research concerning staffing and inefficiencies. Throughout discussions across both fronts, decentralization of clinical trials was cited as an effective model to advance clinical care. More detail on SITC’s Diversity, Equity, and Inclusion Strategic Plan can be found at sitcancer.org/aboutsitc/diversity-strategy/dei. More detail on SITC’s efforts to address the crisis in clinical research can be found at sitcancer.org/crisis.

Based on the importance of this topic to our mission, SITC collected member feedback on the provided draft FDA guidance. Overall, SITC applauds the FDA for providing this draft guidance and hopes that this serves as the start of a continued effort by FDA for years to come. SITC identified specific areas where further clarity and discussion may be warranted, detailed below:

1. **As noted in the draft guidance,** adaptation of centralized IRB’s, implementation of digital health technologies, and use of electronic informed consent are all tools that could help reduce the administrative burden and patient burden participating in trials and require multistakeholder collaboration to implement. SITC members emphasized that manual data entry serves as a large burden and often limits sites from participating in trials. SITC encourages FDA to provide further detail within the guidance concerning adaptation of electronic systems for accurate, automated data submission.

2. **Many sponsors and sites who participated in SITC’s various roundtables have expressed the desire to optimize the amount of data collected for clinical trials,** which currently is posing a significant burden on trial sites and increasing the complexity of decentralized trials. The FDA’s efforts in the PRAGMATICA trial were cited often as an example of how data collection could be optimized as an important step for increasing the adoption of decentralized trials. Towards reducing site and patient burden, SITC recommends further guidance and collaboration concerning essential data required for FDA submission in order to provide boundaries to the amount and type of data collected by sponsors and sites.

3. **Lines 15-44; It is unclear whether the scope of the guidance is limited to exploratory studies only, or whether it also applies to decentralized clinical trials intended to support market approval.** Providing clarity on the scope of the guidance would greatly assist involved stakeholders.

4. **Lines 103-110; Discussion within this section appears to focus on randomized trials.** However, many oncology trials are single-arm trials and in some situations, they are still designed to support an approval. Hence,
expanded discussion and guidance on the impact of the single-arm decentralized clinical trials intended to support a market approval could provide value for the community

(5) Lines 323-325; Many immunotherapy trials require collection of blood samples from enrolled patients at multiple timepoints for immune monitoring purposes. This often presents challenges for patients that must travel to clinical trial sites. Patient burden would be lessened if local HCPs are able to collect blood samples and send them to a centralized lab. However, per the guidance this proposed mechanism may become burdensome for HCPs if they must be listed on Form 1572 as sub-investigators. This section could be enhanced if it clarifies specific situations where local HCPs can perform phlebotomy for experimental tests and not be listed on Form 1572.

SITC members understand that implementation of a decentralized model across the entire clinical trial ecosystem will take collaboration across many stakeholder groups. We hope the FDA’s draft guidance will prove an effective tool to encourage additional stakeholders to take steps to decentralize their trials. Please consider SITC and our volunteers as a resource as this work continues.

Again, SITC values our relationship with the FDA and appreciates the opportunity for providing comments on this important effort. If there are any questions or concerns regarding the comments or the guidance at large, please contact Mary Dean, SITC’s Executive Director, at mdean@sitcancer.org.

We look forward to future iterations of this effort and appreciate any feedback.

Best,

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