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# Top four considerations for sites and sponsors designing immuno-oncology studies

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Immuno-oncology studies require some unique considerations. By addressing these issues early in study design, you can help avoid costly delays. Here are four you should prioritize.

- Selecting the right patients: The promise of targeted therapy requires precise identification of those patients likely to benefit from treatment, either by using commercially available assays or co-development of a companion diagnostic. A study design should ensure realistic accommodation for patient screening. Archival tissue may not be available, or even informative, in patients completing one or more cycles of chemotherapy. As the number of candidates grow, finding treatment-naïve patients in classes such as checkpoint inhibitors is a growing challenge.
- Assigning the right dose: Choosing a treatment dose may not be straightforward. Many immunologic candidates are well-tolerated and a maximum tolerated dose may not be a realistic dose selection strategy. Consider pharmacokinetic (PK) data to determine a clinically effective dose, a strategy that requires timing of assays and may often increase study costs, should samples require real-time versus batch processing.
- Choosing endpoints: While time-to-event endpoints are tracked, approvals are now often sought on surrogate endpoints, such as overall response rate and duration of response. Immuno-oncology studies introduce new challenges in establishing tumor response or disease progression.
- Managing safety: Infusion reactions, both in terms of patient safety and potential unblinding, must be considered. Sites and sponsors must be trained to recognize and characterize immune-related adverse events which can be life-threatening.

Study designs that address precise identification of patients, determine a clinically effective dose, establish specific endpoints and manage safety will help speed your trial to a successful conclusion.

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