Baystate Health

# FDA Finalizes 3 Guidances on Cancer Clinical Trial Eligibility Criteria

The FDA has released 3 final guidance documents aimed at broadening and improving eligibility criteria in cancer clinical trials. Together, they address eligibility criteria that are more restrictive than necessary, which can limit patient access to clinical trials and result in study populations that do not fully represent the patients who will ultimately receive the treatment in clinical practice.

This guidance offers recommendations for investigators and sponsors developing clinical trials, and IRBs reviewing eligibility criteria. The goal is to broaden eligibility when appropriate while maintaining participant safety and scientific integrity of the trial.

The FDA recommendations do not automatically require changes to existing protocols. When developing, reviewing, or implementing a cancer clinical trial, consider whether eligibility criteria are necessary, scientifically justified, and appropriate for the population expected to receive the treatment.

**Laboratory Values**
Eligibility criteria should not use unnecessarily restrictive laboratory thresholds when they are not needed to address a specific safety concern. This guidance includes recommendations for selecting appropriate laboratory values as trial eligibility criteria and emphasizes that laboratory criteria should be tailored to the investigational drug, its mechanism of action, pharmacology, and anticipated toxicities. Appropriately broadening the eligibility criteria can improve the generalizability of trial results and provide a more detailed characterization of the drug's benefit-risk profile across the patient population likely to use the drug in clinical practice. *Learn More - FDA: Cancer Clinical Trial Eligibility Criteria: Laboratory Values*

**Washout Periods and Concomitant Medications**
Eligibility criteria should not use unnecessarily restrictive washout periods or medication exclusions when they are not needed to protect patients safety or ensure the integrity of the trial. The guidance recommends using relevant clinical or laboratory parameters, when appropriate, rather than automatically relying on time-based wash-out periods. When a time-based washout period is used, it should be scientifically justified and consider the pharmacokinetics and pharmacodynamics of the prior therapy. Patients taking concomitant medications should generally only be excluded when clinically relevant, known, or predicted drug-drug interactions or overlapping toxicities could affect participant safety. Sponsors should reconsider medication exclusions as additional information about the investigational drug becomes available. *Learn More - FDA: Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications*

**Performance Status**
FDA recommends broader consideration of patients with lower performance status in adult oncology trials. Patients with ECOG Performance Status 2 (or Karnofsky Performance Status 60-70) should be included unless there is a scientific or clinical rationale for exclusion based on established safety considerations. Performance-based criteria should reflect the population expected to receive the treatment in clinical practice and be reevaluated as safety and efficacy data accumulate. The guidance also recommends considering additional assessments of functional status, including patient-reported outcomes and other tools, to provide a more complete understanding of the patient's functional status. *Learn More - FDA: Cancer Clinical Trial Eligibility Criteria: Performance Status*

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