

Key Principle: Clinical Trials

Clinical Trial Definition for purposes of funding model work:

A clinical trial is an intervention to evaluate a systemic anti-cancer drug or biologic which has undergone institutional (peer) review and has obtained ethics approval at the institutional or provincial level.

Key Principle:

The CCO Systemic Treatment – Quality-Based Program will fund the standard of care, but will not fund the cost of the clinical trial drug(s) (anything incremental to the standard of care)

Trial Phase	Funding Approach
Phase 3 or Randomized Phase 2	For trials with an evidence-informed standard of care arm, funding for all patients entered onto the trial will be provided at the level (band) of the standard of care
Phase 1 or 2	For trials with a single arm study that adds or modifies a recognized evidence-informed standard of care, funding for all patients entered onto the trial will be provided at the level (band) of the standard of care
	Funding for all patients entered onto a trial where there is no existing standard of care option will be provided at the level (band) of supportive care, off active treatment

The NCT number needs to be reported as the regimen (or other unique identifier)

- Funding cannot be triggered without the unique identifier (linked to the standard of care)

