

Glossary of Terms
CTEP Operational Efficiency Working Group (OEWG)
Version date: September 1, 2019

Absolute Deadline – Time, in calendar days, by which a trial must be open to patient enrollment. Trials that are not open to patient enrollment by the Absolute Deadline will be automatically terminated.

Approval on Hold – The document has received CTEP scientific approval and is “approved on hold.” To achieve protocol approval status, the following checklist items must be completed: receipt of local IRB or CIRB approval, protocol sent to FDA (when applicable), all investigator registration issues resolved, all agent availability/supply issues have been resolved, and all other trial- and agent-specific issues are resolved.

Open to enrollment/ “Patient ready” – Trial is ready to enroll a patient and at least one site has IRB approval or CIRB approval has been granted for the study (if applicable).

Protocol activation: Trial opens to enrollment – i.e., it is “patient ready” (please see the definition, above, of “Open to enrollment/ ‘Patient ready’”).

Protocol approval – Protocol document is acceptable to the NCI and all NCI regulatory/logistical issues have been resolved, including IRB approval for Non CIRB reviewed trials. Studies that are reviewed by the CIRB do NOT require local IRB approval.