FAST FACTS
Eligibility Reviewed and Verified By
______________________ MD/DO/RN/LPN/CRA Date ________
______________________ MD/DO/RN/LPN/CRA Date ________
Consent Version Dated__________

PATIENT ELIGIBILITY:
Important note: The eligibility criteria listed below are interpreted literally and cannot be waived (per COG policy posted 5/11/01). All clinical and laboratory data required for determining eligibility of a patient enrolled on this trial must be available in the patient’s medical research record which will serve as the source document for verification at the time of audit.

___1. The patient must be enrolled on a frontline COG therapeutic trial for treatment of a primary malignancy and is nearing completion of or has recently completed protocol treatment (within the past 180 days)*; or

___2. The patient must have been enrolled on a COG (or Legacy Group) therapeutic or non-therapeutic trial targeted for long-term follow-up by ALTE05N1 (see Section 4.1.2 for more details and Appendix I for list of targeted protocols).

___3. The patient must reside in the U.S. on the date of enrollment to ALTE05N1.

*Note: For purposes of enrollment onto this study, completion of treatment is defined as the date protocol therapy was terminated as reported (or will be reported) on this patient’s last “Reporting Period Worksheet/CRF” for their frontline therapeutic protocol. Patients become eligible as they approach this date, and remain eligible for 180 days following the date that protocol therapy was terminated. Early termination of protocol therapy per the decision of the patient, family and/or investigator does NOT preclude enrollment on this study.

TREATMENT PLAN:
MATERIALS AND METHODS
The regular data updates from the LTFC will assist COG institutions in maintaining ongoing follow-up with patients, conducting follow-up examinations and protocol-specified investigations if indicated, and offering the patient opportunities to participate in further long-term follow-up research, if applicable.
**EXPERIMENTAL DESIGN SCHEMA**

### PATIENTS CURRENTLY COMPLETING TREATMENT

- Patient completing treatment for Primary Malignancy

  - COG Investigator Discusses LTFC with Patient/Parent near or within 180 days of therapy completion on COG Frontline Therapeutic Trial

  - Patient Enrolls on ALTE05N1

  - Patient contact and health status information provided to SDC by COG treating institution

### PATIENTS ENROLLED ON PROTOCOLS TARGETED FOR LONG-TERM FOLLOW-UP

- Patient has a History of Enrollment on COG or Legacy Group Trial Targeted for Long-Term Follow-Up on ALTE05N1 (See Appendix I)

  - COG Investigator Discusses LTFC or Sends Letter to Patient/Parent

  - Patient enrolls on ALTE05N1

  - Updated Contact and Health Status Information Provided by LTFC

  - Updated Information from LTFC Released to COG Institution**

  - SDC Notifies LTFC of Patient Enrollment and Consent

  - Updated Information from COG Institution Released to LTFC

  - Long-Term Follow-Up Center (LTFC)

    - LTFC will determine patient vital status prior to contact
    - LTFC will contact patient beginning 6 months from study enrollment to initiate regular follow-up:
      - Updates of contact information and health status
      - Tracing of patients lost to follow-up

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**Note:** Patients will be given the choice to ‘opt out’ from having their information forwarded by the SDC to the COG institutions. Patients will be able to indicate this ‘opt out’ request in the consent form.