COG-ALTE05N1: Umbrella Long-term Follow-up Protocol

FAST FACTS
Eligibility Reviewed and Verified By
_____ MD/DO/RN/LPN/CRA Date _____
_____ MD/DO/RN/LPN/CRA Date _____
Consent Version Dated_____

PATIENT ELIGIBILITY:
<u>Important note</u>: 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)*; **<u>or</u>**

___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).

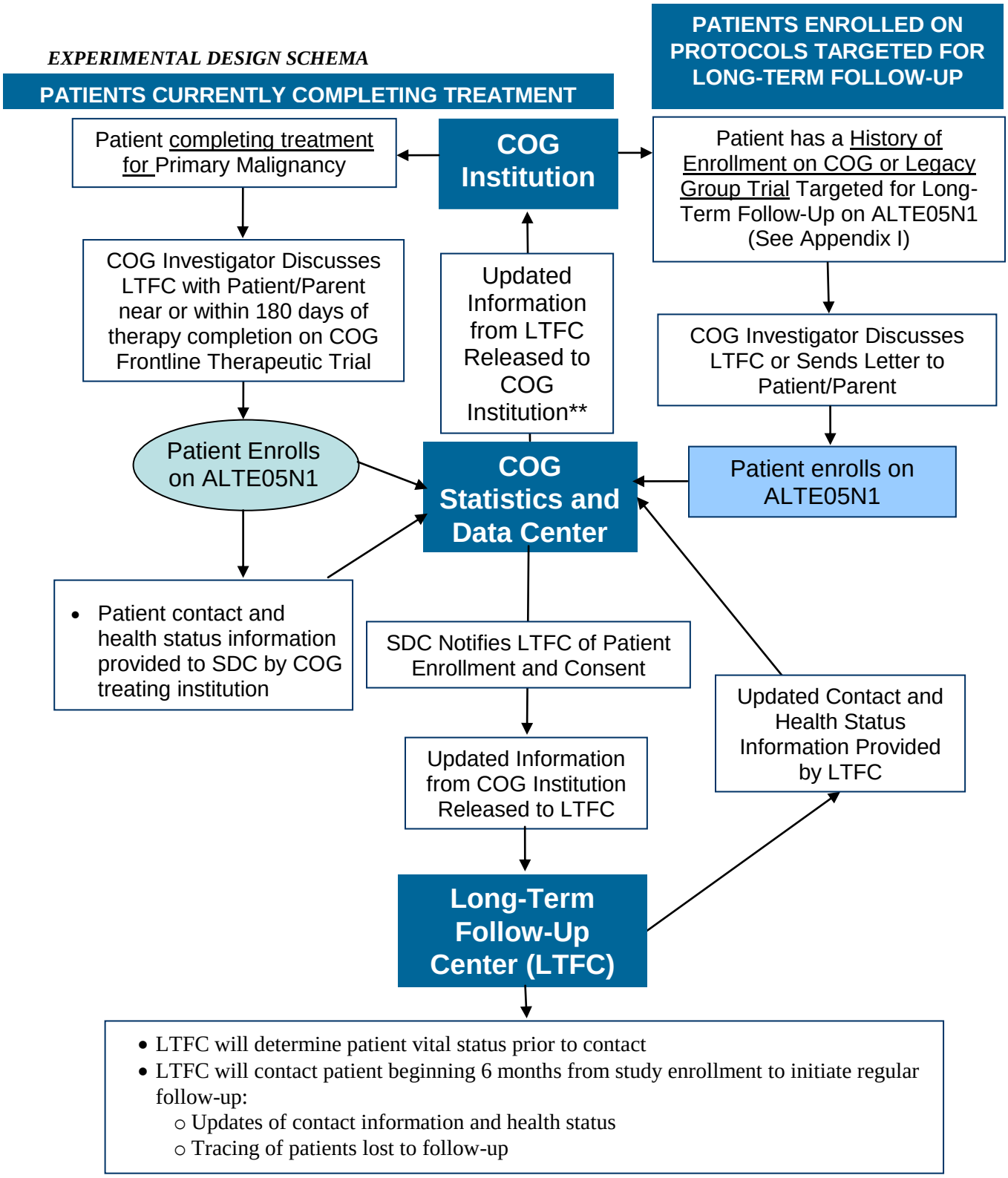
___3. The patient must reside in the U.S. on the date of enrollment to ALTE05N1.

*Note: For purposes of enrollment onto this study, completion of treatment is defined as **the <u>date protocol therapy was terminated</u>** 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.

Note: For purposes of eligibility for ALTE05N1, "early termination of protocol therapy" means that the patient has finished protocol therapy and will not receive further treatment. Patients whose therapy is terminated early due to toxicity or who opt out of an end-of-therapy randomization (e.g., randomization to continue with an experimental agent vs. no further treatment) are eligible because they will not be receiving further therapy. However, a patient who is removed from protocol therapy or opts to discontinue protocol participation early in the course of treatment (e.g., following Induction) is not eligible - because those patients will receive additional therapy and therefore will not have completed (or be nearing completion of) therapy for their primary malignancy.

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



**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.