

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:

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. Diagnosis

The patient must have been enrolled on a frontline COG therapeutic trial for treatment of a primary malignancy;

or

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 II](#) for guidance regarding the targeted protocols);

___ 2. Timing

Enrollment on ALTE05N1 must occur within 24 calendar months of the date the patient was enrolled on a frontline COG therapeutic trial.

or

Patients previously enrolled on a COG (or Legacy Group) trial targeted for long-term follow-up by ALTE05N1 may enroll on ALTE05N1 at any time. See [Appendix II](#) for guidance regarding the targeted protocols.

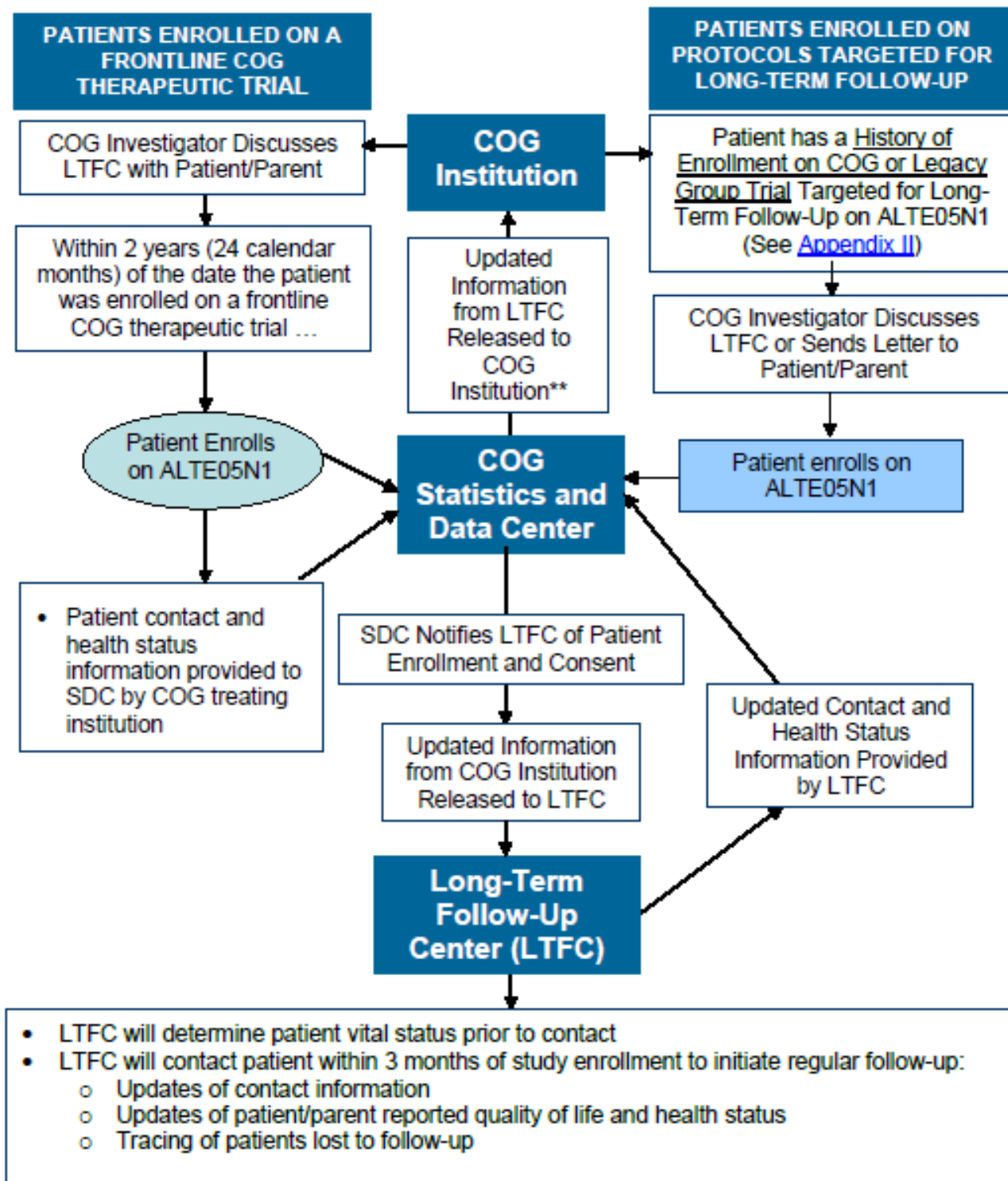
___ 3. The patient must reside in the U.S. on the date of enrollment to ALTE05N1.

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.