

COG-ALTE07C1: Neuropsychological, Social, Emotional and Behavioral Outcomes in Children with Cancer

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. Concomitant Treatment - The patient must currently be enrolled or plan to be enrolled on a COG therapeutic study that aims to examine neuropsychological, social, emotional, and/or behavioral functioning.
- ___2. Language - The patient must have receptive and expressive language skills in English, French, or Spanish. If a patient meets these criteria but the parent/guardian speaks a language other than English, French, or Spanish, the patient may still be enrolled and tested, and the parent-report measures should be omitted.

EXCLUSION CRITERIA:

- ___1. Patients with a history of moderate to profound intellectual disability (i.e. IQ < 55) are not eligible for enrollment. PLEASE NOTE: Children with a prior history of attention deficit hyperactivity disorder (ADHD) or a specific learning disability (e.g., dyslexia) **are** eligible for this study.

TREATMENT PLAN:

The ALTE07C1 standard neuropsychological and behavioral battery is a focused assessment of critical functional domains that have been empirically shown to be most affected by childhood cancer, its treatment, or other disease-related factors. This battery was designed to provide a brief measure of neuropsychological and behavioral function in order to strike a balance between research goals, the clinical needs of the patient, and time constraints on the institutional neuropsychologist / psychologist. The battery of tests will take only about 1 hour to administer and all patients will be tested at 3 standardized timepoints. Parent-completed or self-report questionnaires will also be utilized to gather information about the patient's function, specifically in terms of attention, memory, executive abilities, and behavioral/social/emotional adaptation.

Standardized Time Points

- | | |
|----|---------------------------------------|
| T1 | 9 +/- 3 months post diagnosis |
| T2 | 30 months +/- 6 months post diagnosis |
| T3 | 60 +/- 12 months post diagnosis |

EXPERIMENTAL DESIGN SCHEMA

