COG-ALTE22C1: Chronic Health Conditions in Down Syndrome-Associated Acute Leukemia: The Down Syndrome Phenotyping Acute Leukemia Study in Survivors (DS-PALS Survivors)

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. Age
Patients age ≥ 6 and < 40 years at the time of enrollment.

___2. Diagnosis

- A diagnosis of Down syndrome is required and may include any of the three recognized types: trisomy 21 resulting from chromosomal nondisjunction (most common), translocation (the patient has 46 chromosomes, but all or part of an additional copy of chromosome 21 is attached to another chromosome), or mosaicism (trisomy 21 that is present in only a fraction of cells).

- All patients must be DS-AL survivors (ALL or AML)

  Note 1: Myeloid leukemia of Down syndrome (ML-DS) is included in the AML category above. Per the World Health Organization (WHO) definition of ML-DS, this diagnosis encompasses both myelodysplastic syndrome (MDS) and overt AML. Also, note that Survivors of relapsed disease are eligible, so long as the patient otherwise meets eligibility criteria, i.e., treatment for relapse was completed at least 36 calendar months prior to enrollment (see Section 3.2.4) and did not include stem cell transplant (see Section 3.2.7).

  Note 2: A diagnosis of transient abnormal myelopoiesis (TAM), also known as transient myeloproliferative disease (TMD), is not alone sufficient for inclusion in this study.

___3. Prior Therapy
Patients must have been treated for ALL or AML.

Note: History of COG therapeutic trial participation is not required. As a reminder ML-DS would be included under the AML category here above.

____4. Timing
All cancer treatment (oral or intravenous) must have been completed at least 36 calendar months prior to enrollment.

_____5. Life Expectancy
Patients must have a life expectancy of > 1 year.

_____6. Language

For Part 1 participation, parent of subject must be English or Spanish speaking. At least one parent or guardian must be able to read and write in English or Spanish. For Parts 2 and 3 participation, the subject must be able to understand either English or Spanish.

Note: *Parents or guardians are responsible for completing all questionnaires, even in the case of subjects that are ≥ 18 years old.*

Exclusion Criteria

Patients with history of Hematopoietic Stem Cell Transplant (HSCT) are excluded.

Note: Patients with previous chimeric antigen receptor T-cell (CAR T-cell) therapy, and other cellular cancer therapies can participate, as long as all other eligibility criteria are satisfied.

Patients with a history of cancer prior to their ALL or AML diagnosis are excluded. Patients that developed a subsequent malignant neoplasm following their ALL or AML diagnosis are also excluded.

Note: Prior history of transient abnormal myelopoiesis is allowed but is not sufficient for eligibility.

Patients whose parents or guardians are unable to complete the required forms are excluded.

REQUIRED OBSERVATIONS:

1. Part 1 Activities
   The ALTE22C1 Coordinating Centers will conduct all Part 1 activities. The DCC will collect the Medical Outcomes Survey, Medical Record Release forms, and saliva kit. The NPCC will administer the Parent Proxy Neurocognitive Assessment and provide brief feedback reports to families.

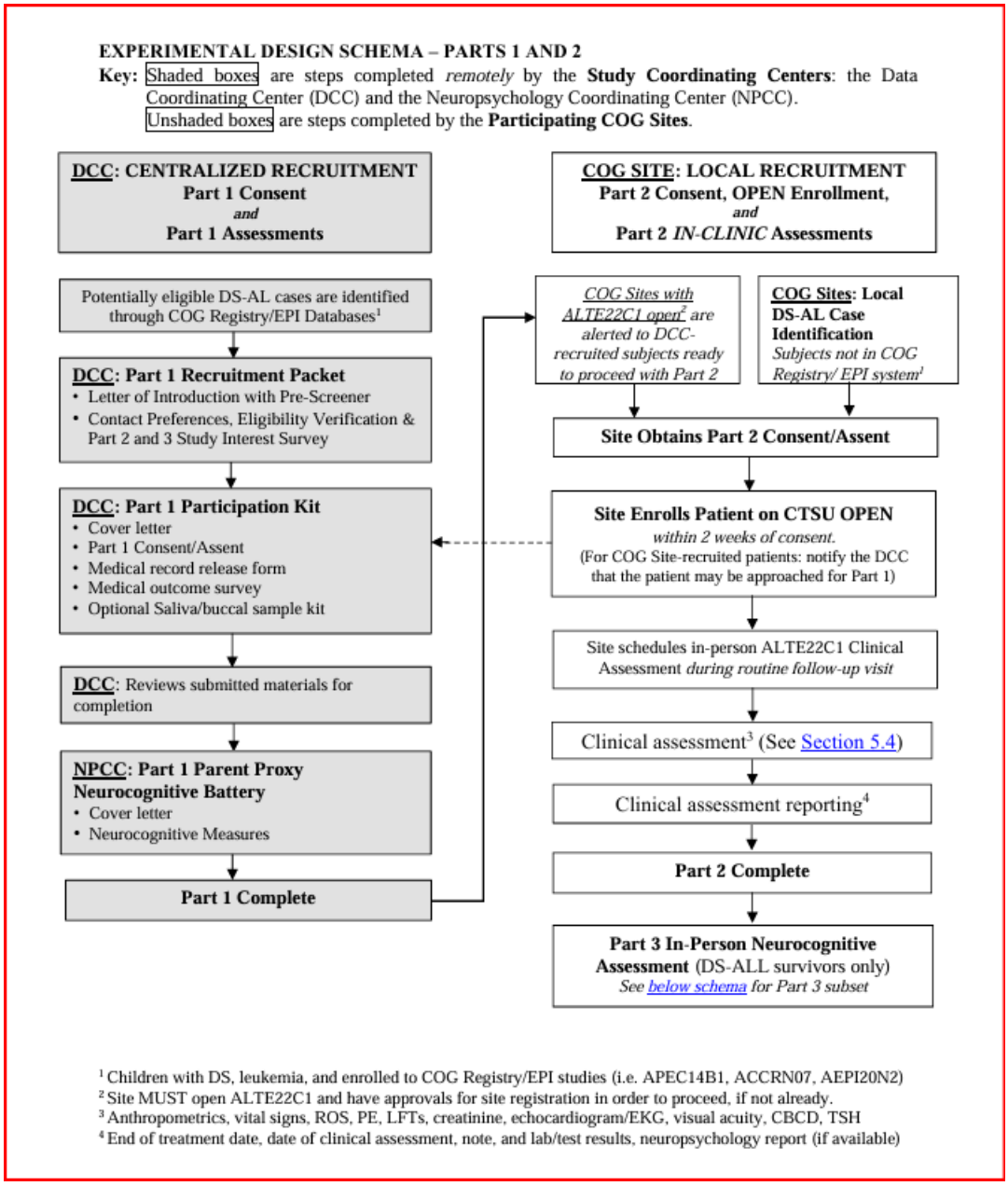
2. Part 2 Activities
   Participating Sites will conduct all Part 2 activities, which include the in-person Clinical Assessment, Clinical Assessment Reporting.

3. Part 3 Activities (DS-ALL only)
   Participating Sites will conduct all Part 3 activities, which include the Direct Neurocognitive Assessment and Study Blood Draw.

   Eligibility for Part 3 will be limited to a subset of 55 DS-ALL participants.
   Part 3 will be closed to further entry once the accrual goal is met.

   Prior to initiating recruitment for Part 3, sites must complete training to administer the NIH Toolbox Neurocognitive Battery. Sites personnel must complete online training prior to receipt of the study tablet, and 'hands-on' training once the study tablet has been delivered. The training and provision of study materials are coordinated through the NPCC. See the Experimental Design Schema – Part 3 Subset for a summary of the stepwise process, and Section 5.3.2 for details.

TREATMENT PLAN:

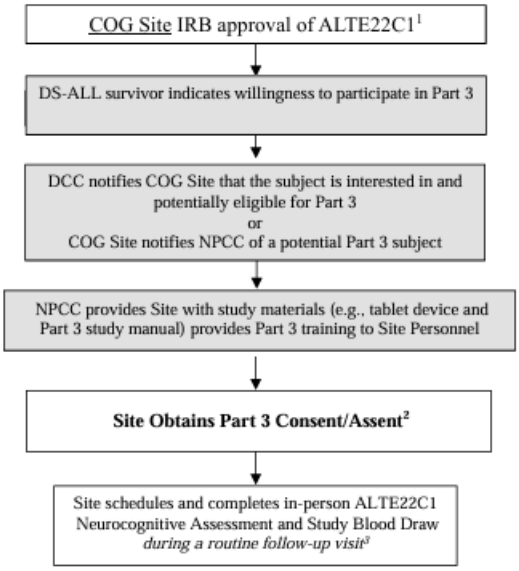


EXPERIMENTAL DESIGN SCHEMA – PART 3 SUBSET

Key: Shaded boxes are steps completed *remotely* by the **Study Coordinating Centers**: the Data Coordinating Center (DCC) and the Neuropsychology Coordinating Center (NPCC).
Unshaded boxes are steps completed by the **Participating COG Sites**.

Part 3 participation includes an in-person neurocognitive assessment and blood draw in a subset of 55 DS-ALL survivors. DS-ALL survivors may indicate interest in Part 3 participation on the Contact Preferences, Eligibility Verification, & Part 2 and 3 Study Interest Survey or may be identified at site approach. Due to the additional training and preparation required, Part 3 participation is limited to subjects and Sites that meet the following criteria.

(1) Sites affiliated with a DS-ALL survivor that has indicated an interest in Part 3 participation must confirm to the NPCC receipt of Part 3 study materials (materials will be sent by the NPCC).
(2) Sites affiliated with a DS-ALL survivor that has indicated an interest in Part 3 participation must undergo Part 3 training prior to approaching the patient for Part 3 consent (training is provided by the NPCC).



[1] Site MUST open ALTE22C1 in order to proceed, if not open already.
[2] Subjects may be approached for Part 3 Consent once Part 3 site training is completed and study materials are received. Part 3 Consent may be obtained together with Part 2 Consent.
[3] In-person neurocognitive assessment and study blood draw may be obtained during the same visit as the Part 2 Clinical Assessment. If > 30 days elapse between Part 3 Site Personnel Training and the scheduled Neurocognitive Assessment, the NPCC will verify site preparedness prior to the visit, and may provide a refresher of the training.