

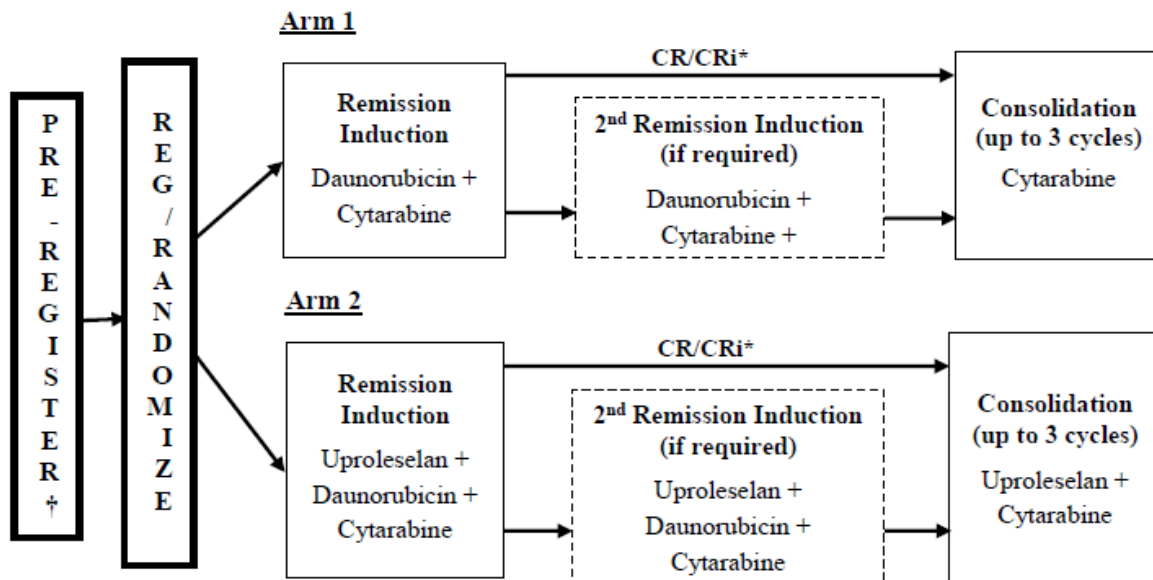
FAST FACTS

ALLIANCE A041701
A RANDOMIZED PHASE II/III STUDY OF CONVENTIONAL CHEMOTHERAPY +/-
UPROLESELAN (GMI- 1271) IN OLDER ADULTS WITH ACUTE MYELOID
LEUKEMIA RECEIVING INTENSIVE INDUCTION CHEMOTHERAPY

Registration Eligibility Criteria (Step 1)

1. Documentation of Disease
 - Diagnosis of AML based on 2017 WHO criteria [22] excluding acute promyelocytic leukemia with PML-RARA. Note: Patients with myeloid sarcoma without bone marrow involvement, acute leukemia of ambiguous lineage or blast transformation of CML are not eligible.
 - No activating mutation in the Fms-like tyrosine kinase-3 (FLT3) defined as a ratio of mutant to wild-type allele ≥ 0.05 by capillary electrophoresis or a variant allele fraction of $\geq 5\%$ by next generation sequencing from either bone marrow or peripheral blood.
 - No evidence of CNS involvement of AML
2. Prior Treatment
 - No prior chemotherapy for MDS, MPN, or AML including hypomethylating agents (e.g. azacitidine and decitabine), ruxolitinib or lenalidomide with the following exceptions:
 - Emergency leukapheresis
 - Hydroxyurea
 - Growth factor/cytokine support
 - All-trans retinoic acid (ATRA)
 - Single dose of intrathecal cytarabine and/or methotrexate for patients undergoing lumbar puncture to evaluate for CNS involvement
3. Age ≥ 60 years
4. Required Initial Laboratory Values
 - Total Bilirubin ≤ 3 x upper limit of normal (ULN)
 - Creatinine ≤ 3 x upper limit of normal (ULN)
OR
 - Creatinine Clearance ≥ 30 mL/min/1.73m²

Schema



† All patients must be pre-registered in order to submit the required bone marrow and peripheral blood specimens to the Alliance HEME Biorepository (see [Sections 4.3](#) and [6.2](#)).

* During Remission Induction, a bone marrow examination (aspirate and biopsy) on Day 14 (+3 days) is required in all patients. Patients with evidence of persistent leukemia on day 14 or a subsequent bone marrow biopsy will receive a second induction course (See [Section 7.0](#)). Patients who achieve either a CR or CRi are eligible to proceed to consolidation therapy.