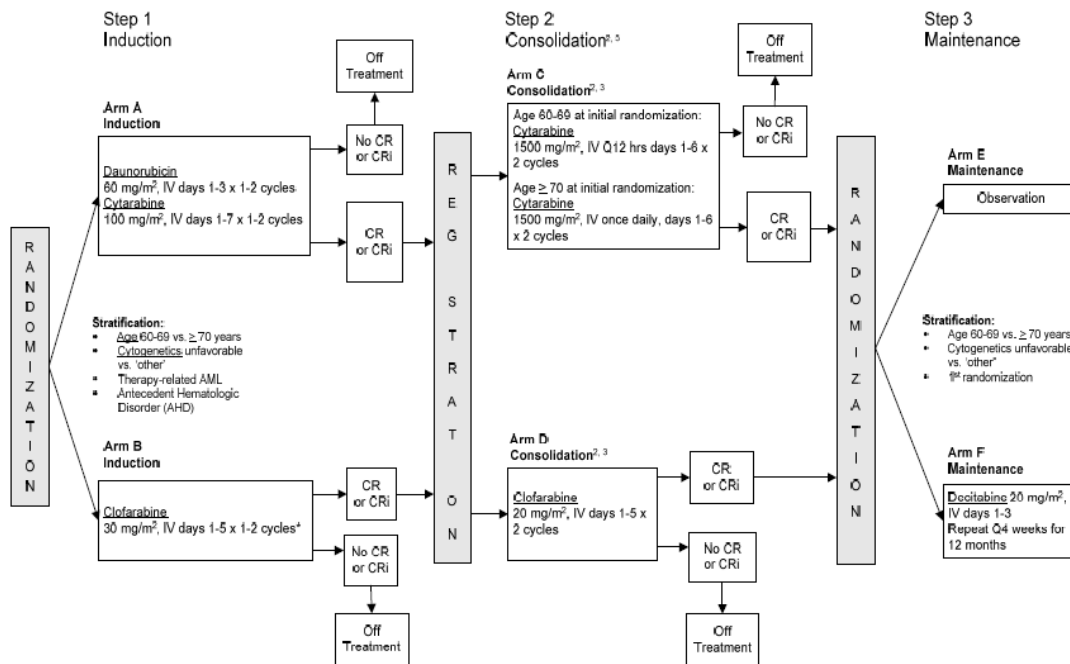


E2906: Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age ≥ 60 Years)

Schema



* Re-induction: Clofarabine 20 mg/m² days 1-5

1. See Section 3.8.5

2. For patients with an HLA matched donor who will proceed to transplant- see instructions for consolidation treatment in schema ii

3. Consolidation treatment is determined by induction.

Accrual: 747

*See protocol for schema for patients proceeding to transplant. **All patients should enroll on E3903

Key Eligibility:

- Age ≥ 60 years
- Newly diagnosed acute myeloid leukemia who are considered candidates for intensive chemotherapy based on peripheral blood or bone marrow aspirate specimens
- No prior therapy except hydroxyurea allowed
- Secondary AML without prior treatment of MDS with decitabine, low-dose cytarabine or azacitidine
- ECOG performance status 0-3 (restricted to 0-2 if ≥70 years)
- No APL or blastic transformation of CML
- Adequate organ function as defined by
 - Cardiac ejection function ≥ 45%
 - ALT, AST, total bili ≤ G1
- No active, uncontrolled infection, concurrent active malignancy, or HIV+ status