

FAST FACTS

EAA181 - Effective Quadruplet Utilization After Treatment Evaluation (EQUATE): A Randomized Phase 3 Trial for Newly Diagnosed Multiple Myeloma Not Intended For Early Autologous Transplantation

Eligibility Criteria- Step 0 Preregistration

1. Patient must be ≥ 18 years of age.
2. Patient must have the ability to understand and the willingness to sign an informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be eligible.
3. Patient must have an ECOG Performance Status (PS) of 0-2 (PS 3 allowed if secondary to pain).
4. Patient must have suspected or confirmed newly diagnosed multiple myeloma (MM) by International Myeloma Working Group (IMWG) criteria and must not have received more than one cycle of treatment.

NOTE: Patient does not need to have bone marrow evaluation prior to Step 0 pre-registration. Bone marrow evaluation may be deferred to after Step 0 pre-registration to confirm presence of $>10\%$ clonal bone marrow plasma cells per IMWG criteria.

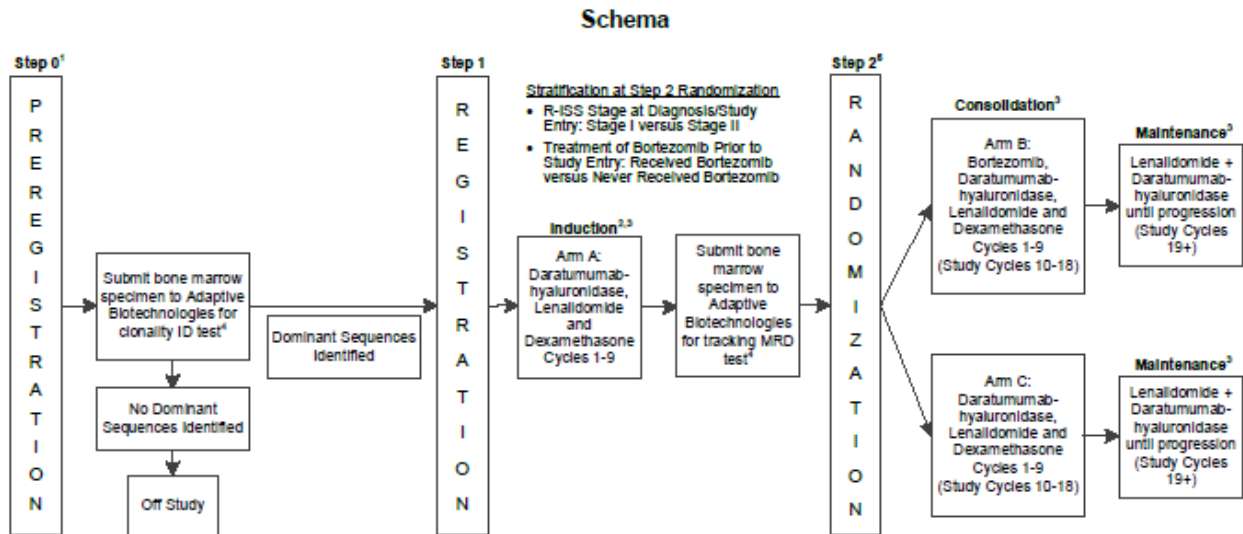
5. Patient must be considered ineligible for autologous stem cell transplantation by the treating physician, or willing to delay stem cell transplantation until first relapse or later.
NOTE: Stem cell collection is allowed on study.
6. Patient must agree to register to the mandatory Celgene Revlimid REMS program and be willing and able to comply with the requirements of the Revlimid REMS program. See Section [8.3.10](#) for details.
7. Patient must not have any known allergies, hypersensitivity, or intolerance to corticosteroids, monoclonal antibodies or human proteins, or their excipients (refer to respective package inserts or Investigator's Brochure), or known sensitivity to mammalian-derived products.

8. Patient must be able to undergo diagnostic bone marrow aspirate following preregistration if not performed previously. If the bone marrow aspirate was performed previously, archival bone marrow aspirate smears (3-5) or FFPE slides/scrolls from the clot section (5- 10) must be available for clonoSEQ[®] Assay.

NOTE: Bone marrow aspirate specimen, or an acceptable alternative [high disease specimen – at least 5% disease] (i.e.: FFPE slides/scrolls from the clot section, or bone marrow aspirate smears) must be submitted to Adaptive Biotechnologies for clonoSEQ[®] Assay. Decalcified specimens (core) or whole blocks are not acceptable.

NOTE: Adaptive Biotechnologies will release results to the diagnostic portal from the Clonality (ID) test within fourteen (14) days of receipt and reconciliation of fresh bone marrow specimen to the submitting institution.

NOTE: If clonoSEQ® Assay was performed previously as part of standard of care, results can be used for Step 1 registration.



Accrual Goal:
Step 1 - 542
Cycle Duration: 28 days (4 weeks)

- Please refer to Section 5.1 for an overview of the Step 0 process.
- Patients can mobilize stem cells any time after 4 cycles of induction therapy. If stem cells are harvested, patients can be off treatment for up to 42 days for completion of stem cell collection. While stem cell collection is strongly recommended for patients who are considered eligible for transplant, it is not mandated.
- Refer to Section 5.1 for detailed dosing instructions.
- Institutions will be notified of the results of the Clonality ID and tracking MRD tests. Patients for whom dominant sequences were identified must submit bone marrow specimen for MRD test.
- As of Addendum #4: Patients must be MRD positive after induction to be randomized to Step 2. Patients with post-induction MRD status of negative or indeterminate will not be randomized. Please refer to Section 3.3.2 for additional details.