NCI Community Oncology Research Program

NHLBI-MDS

NHLBI-MDS Available Through ECOG-ACRIN Cancer Research Group

The National Myelodysplastic Syndromes (MDS) Study

Patient Population

See Section 3.0 for Complete Eligibility Details

- Suspected (e.g., persistent unexplained cytopenia, circulating peripheral blasts etc.) MDS or MDS/MPN overlap disorders and undergoing diagnostic work-up with planned bone marrow assessments **OR** diagnosed with de novo or therapy-related MDS within 6 months of enrollment per WHO criteria and undergoing clinical evaluation and planned bone marrow assessments to confirm MDS or to evaluate disease status
- Bone marrow aspirate expected to be performed within 1 week of registration, and in all cases must be performed no later than 4 weeks after enrollment
- Age ≥ 18 years
- No prior treatment for MDS at entry and through the time of the entry bone marrow aspirate
- No treatment with hematopoietic grown factors in prior 6 months
- If anemic without prior MDS: B12, serum folate, MCV, RDW, ferritin, and iron studies tests performed within the prior 6 months
- No diagnosis of a solid tumor or hematologic malignancy within 2 years prior to enrollment except for in situ cancer of the skin (basal or squamous cell), cervix, bladder, breast, or prostate
- No treatment with radiation therapy in the 2 years prior to registration
- No non-hormonal treatment for malignancy within 2 years prior to registration
- No established hereditary bone marrow failure syndrome
- No known primary diagnosis of aplastic anemia, classical paroxysmal nocturnal hemoglobinuria, amegakaryocytic thrombocytopenic purpura, or large granular lymphocyte leukemia
- Not enrolled in the Connect MDS/AML Disease Registry
- *Note: Alternative causes for cytopenias should be considered (see protocol for recommended tests)*

Treatment Plan

See Section 5.0 for Study Design Details

An Observational Study with Specimen Acquisition

- Patient histories will be obtained and medical records will be reviewed to obtain past medical history, baseline laboratory tests, and diagnostic information (including pathology reports and treatment history)
- Bone marrow and peripheral blood slides will be centrally reviewed (patient is required to contribute for storage and provide eyebrow hairs and buccal swab)
- Based on central pathology review, a baseline classification into Cases (MDS, MDS/MPN overlap disorders, AML with < 30% blasts without core binding factor or acute promyelocytic leukemia, or ICUS); or the cross-sectional cohort (all others) will be made
  - ◊ Follow-up will occur based on these classifications and will not be altered by subsequent clinical events
  - ◊ No post baseline biological samples/data will be captured for those classified into the cross-sectional cohort
- Sites will be notified via email when longitudinal follow-up is required
- Capture of biologic samples will be discontinued if the participant receives an HCT
- Biologic samples are submitted for cases in the longitudinal cohort at the time of AML diagnosis. Subsequent samples will not be collected for AML cases with > 30% marrow blasts, core binding factor, or acute promyelocytic leukemia
- Individuals may participate in other studies but will continue to submit data and specimens for this protocol

Refer to the Manual of Procedures (MOP) for additional details regarding the procedures that are used for this study

Study Chair:
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Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, http://ecog-acrin.org (Member Login)

Please Enroll Your Eligible Patients!

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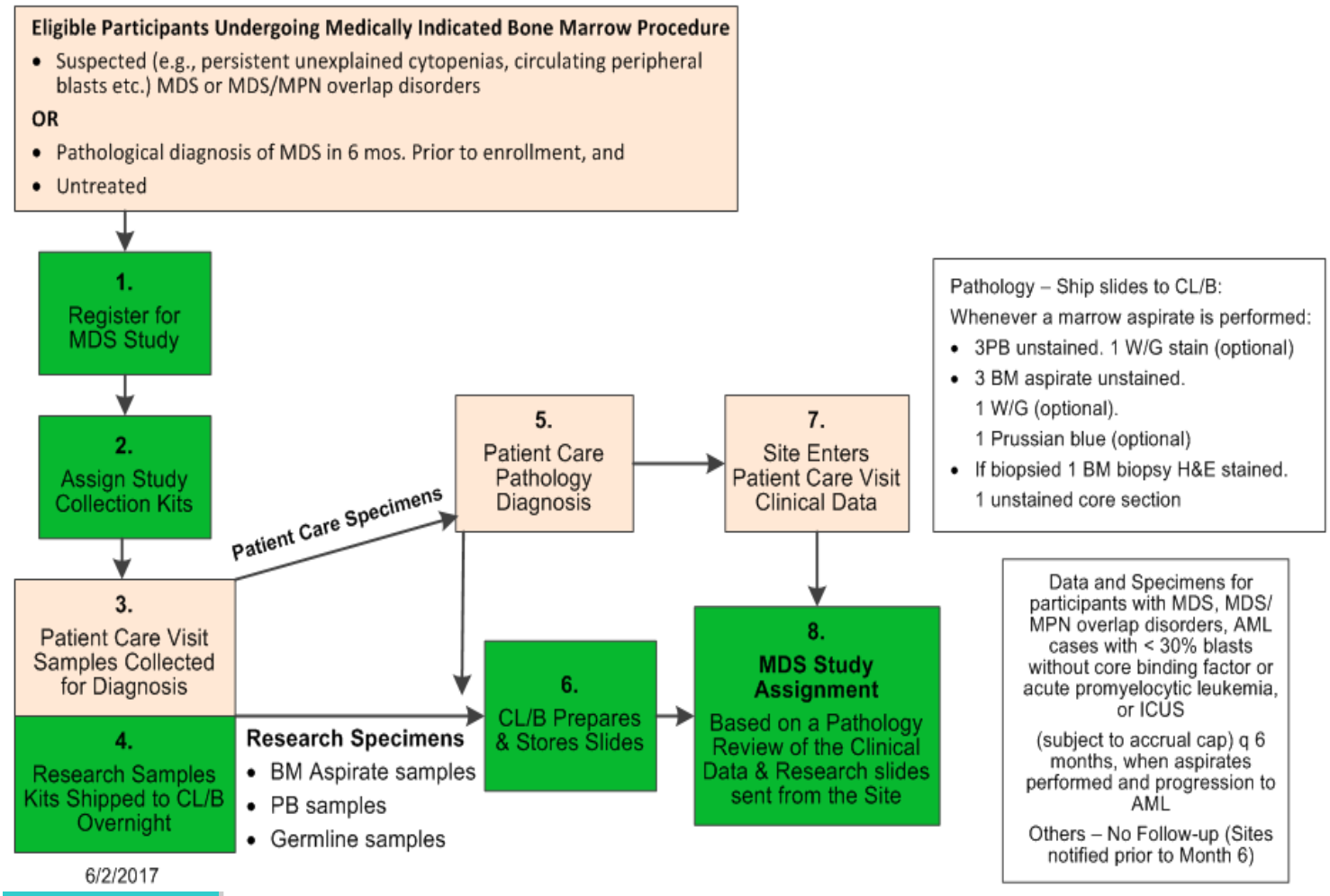
Schema



The National Myelodysplastic Syndromes Natural History Study

Sponsored by the National Heart, Lung, and Blood Institute in collaboration with the National Cancer Institute

ECOG-ACRIN cancer research group

Reshaping the future of patient care