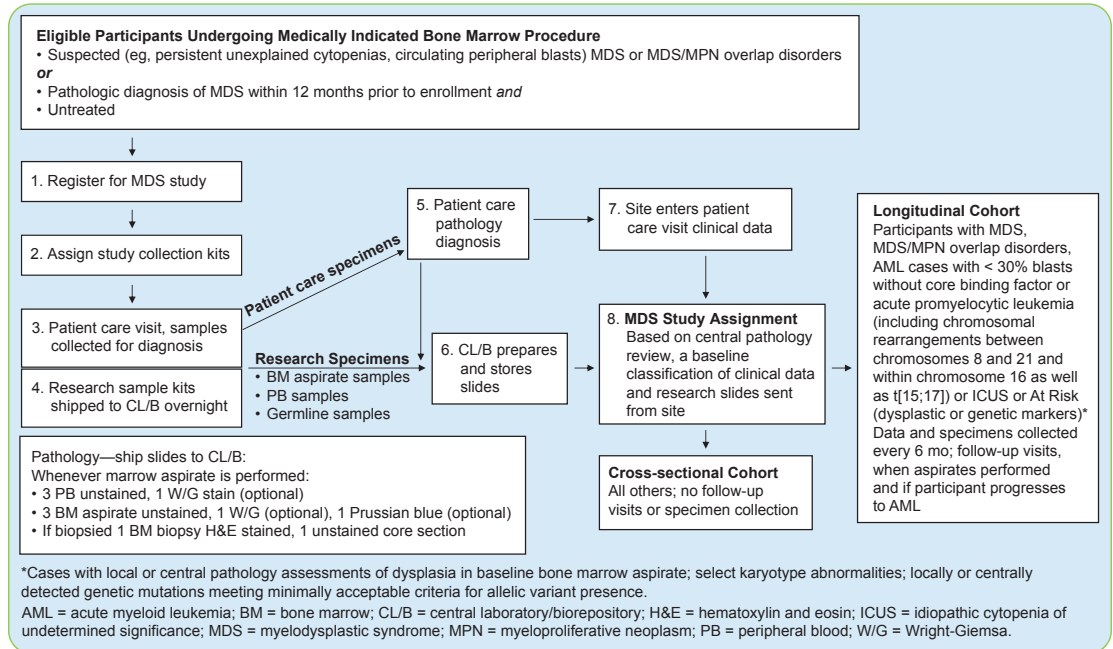


Overall Study Goal

To establish a publicly available resource to facilitate the study of MDS natural history by creating a multi-institutional, longitudinal biorepository of consistently processed and clinically well-annotated blood and tissue specimens, collected prospectively from cases of suspected MDS and cases of idiopathic cytopenia of undetermined significance (ICUS) up to 2000 overall accrual, and to support investigator-initiated studies with high impact for MDS patients

Study Schema



Objectives

- Develop a high-quality clinical database containing clinical history, including environmental exposure history presenting signs and symptoms, diagnostic testing results, coexisting diseases, therapies and response to therapies, disease progression, quality of life, and survival
- Develop a high-quality biorepository linked to clinical data that will facilitate diverse studies, including genetic, epigenetic, immunologic, proteomic, and cell-functional and -phenotypic studies
- Facilitate broad use of these linked data and specimens to support studies focused on
 - Improving diagnostic accuracy, risk stratification and prognostication, and medical decision-making in MDS
 - Understanding quality of life and its relationship to changing disease and treatment status
 - Understanding the pathogenesis of MDS and diverse MDS subtypes, including genetic, epigenetic, and immunologic mechanisms
 - Optimizing treatment strategies for specific MDS subtypes
 - Identifying novel biomarkers for MDS outcomes
 - Identifying novel targets for therapeutic interventions in MDS

How Your Site Can Participate

- **Before recruitment**, investigators must be registered members of an NCTN network group
- All individuals contributing to NCI-sponsored trials must register and renew annually
- Registrants must obtain a Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) account (<https://ctepcore.nci.nih.gov/iam>)
- Investigator (IVR), Non-physician Investigator (NPiVR), or Associate Plus (AP) must complete annual registration using CTEP's Web-based Registration and Credential Repository (RCR) (<https://ctepcore.nci.nih.gov/rcr>)
- Required documentation for IVR, NPiVR, and AP includes FDA Form 1572 (IVR and NPiVR only), Financial Disclosure Form, NCI Biosketch, HSP/GCP training, Agent Shipment Form (IVR only), and CV (optional)
- IVRs and NPiVRs must list clinical practice sites and IRBs covering their practice sites on FDA Form 1572 in RCR to allow the following: added to site roster; assigned treating, credit, consenting, or drug shipment (IVR only) tasks in OPEN; acting as site-protocol Principal Investigator (PI) on IRB approval
- For questions, please contact RCR Help Desk via e-mail: RCRHelpDesk@nih.gov
- Sites participating on the NCI CIRB initiative that are approved by the CIRB need not submit IRB approval documentation to the CTSU. For these sites, IRB data automatically load to RSS. However, sites must submit a Study Specific Worksheet for Local Context (SSW) to the CIRB (via IRB Manager) to indicate their intention to open the study locally. The CIRB's approval of the SSW is then communicated to the CTSU Regulatory Office

How Your Site Can Participate (cont)

- **Requirements for NHLBI-MDS site registration:**
 - For sites not participating via the NCI CIRB: IRB approval/documentation, an IRB-signed CTSU IRB Certification Form, Protocol of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption Form, or combination
 - Protocol, biospecimen acquisition, biospecimen shipping, GlobalTrace, and Medidata Rave training
- **OPEN blocks enrollment until this training is completed:**
 - One investigator per site takes the NHLBI-MDS investigator training course on the protocol and biospecimen acquisition by accessing <https://coccg813.mindflash.com/PublicCoursePage.aspx?c=1483326417>
 - One coordinator per site takes the NHLBI-MDS coordinator training course on the protocol, CLB shipping, biospecimen acquisition, GlobalTrace, and Medidata Rave by accessing <https://coccg813.mindflash.com/PublicCoursePage.aspx?c=1483397179>
 - Submit copies of the investigator and coordinator training certificates via the CTSU Regulatory Submission Portal (details below). Direct questions to EAClinEd@ecog-acrin.org
- For all sites, Central Laboratory/Biorepository registration processes are required including the following:
 - Identification of at least one member of the study staff certified with IATA or equivalent training to ship biological substances
 - Completed CL/B Information Checklist
- **Submit all required regulatory documents to:**
 - CTSU Regulatory Office via the Regulatory Submission Portal (www.ctsu.org [members' area] → Regulatory Tab → Regulatory Submission)
 - Sites with patients waiting that are unable to use the Portal should contact the CTSU Regulatory Office at (866) 651-2878 or CTSURegHelp@coccg.org
- **Required regulatory documentation:**
 - Copy of IRB Informed Consent Document
 - CTSU IRB Certification Form **or** signed HHS OMB No. 0990-0263 (replaced Form 310) **or** IRB Approval Letter

Note: Submission must include all sites approved for the protocol under an assurance number; OHRP assurance number of reviewing IRB; full protocol title and number; version date; type of review (full board vs expedited); date of review; signature of IRB official.
- Verify registration status at <https://www.ctsu.org>
- **Once documentation has been submitted and approved:**
 - Study samples should not be collected prior to registration
 - Patient enrollment is via OPEN, accessed at <https://open.ctsu.org>. Data collection is exclusively through Medidata Rave. Address OPEN and Medidata Rave questions to the CTSU Help Desk at (888) 823-5923 or ctscontact@westat.com

NHLBI-MDS Funding and NCORP Credit Reimbursement

- All participating sites (non-NCORP and NCORP [Standard and High Performance]) will receive a base payment of \$1250.00 per enrollment
- For enrollment of patients with MDS and related conditions who proceed to the longitudinal study cohort, institutions will receive an additional payment of \$1250. For patients eligible to be rescreened and who proceed to the longitudinal study cohort, institutions will receive an additional \$625. Sites having patients who are entitled to receive the \$625 to participate in the longitudinal study cohort after rescreening are not entitled to receive the \$1250 to participate in the longitudinal study cohort
- Total potential federal funds are \$3125.00 for all participating sites
- Funds are provided per-case reimbursement through ECOG-ACRIN Cancer Research Group (EA)
- In addition to capitation payments for enrollments, these groups give credit toward membership requirements:
 - Alliance: 1.0 credit for initial protocol enrollment for base intervention
 - ECOG-ACRIN: 0.5 credit for initial protocol enrollment for base intervention; 0.5 credit for any patient assigned to longitudinal cohort
 - NRG: 1.0 credit for initial protocol enrollment for base intervention
 - SWOG: 0.5 credit for initial protocol enrollment for base intervention; 0.5 credit for any patient assigned to longitudinal cohort
- For more information or any questions, please contact ea.fundingsheet@jimmy.harvard.edu

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For Further Study Information

- For more information about the NHLBI-MDS study, please visit the following:
 - The National MDS Study Web site, <https://thenationalmdsstudy.net>
 - Cancer.gov; search **NHLBI-MDS**
 - Clinicaltrials.gov; search **NCT02775383**