



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

NHLBI-MDS Site Registration Process

1. Sites access NHLBI-MDS study information on the Cancer Trials Support Unit (CTSU) website.
2. The NCI's National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) adult sites can participate in the study. Site investigators and staff must be registered with Cancer Therapy Evaluation Program (CTEP) to access the study documents on the CTSU members' website. The CTEP Identity Access and Management (CTEP-IAM) application will be used for initial and annual registration with CTEP and to obtain a user account (See section 4.3 Site Registration and Activation in the MOP for details).
3. Site staff view the NHLBI-MDS Site registration requirements on the CTSU members' website.
 - a. Go to <https://www.ctsuo.org> and log in to the members' area using your CTEP-IAM username and password
 - b. Click on the Protocols tab in the upper left of your screen
 - c. Click on the Lead Group = ECOG-ACRIN to expand, then select trial protocol NHLBI-MDS
 - d. Click on the Site Registration Documents link
4. Sites should complete the following requirements for NHLBI-MDS site registration first and submit them to the CTSU Regulatory Office via mail, fax, or email*:
 - a. Protocol, Biospecimen Acquisition, Biospecimen Shipping, GlobalTrace, and Medidata Rave training. Site personnel must complete the 5 training modules as noted below:
 - i. At least one investigator from the enrolling site must complete the Protocol and Biospecimen Acquisition training modules.
URL: <https://coccg813.mindflash.com/PublicCoursePage.aspx?c=1483326417>
 - ii. In addition, at least one coordinator from the enrolling site must complete all five training modules: Protocol, Biospecimen Acquisition, Biospecimen Shipping, GlobalTrace, and Medidata Rave.
URL: <https://coccg813.mindflash.com/PublicCoursePage.aspx?c=1483397179>
 - b. Complete and submit the "The National MDS Study: Site Information Checklist" (Appendix III) to the CTSU Regulatory Office.
 - i. On the Site Information Checklist, the site must identify at least one International Air Transport Association (IATA) certified staff member and also submit their IATA certificate with Site Information Checklist to the CTSU Regulatory Office.
 - ii. The CL/B reviewer may contact the site directly (with a copy to the CTSU and the DCC) to resolve questions or comments.

- iii. Final approval for the enrolling site will be submitted directly from the CL/B to the CTSU Regulatory Office and is required prior to first patient enrollment.

5. Sites should then submit the required documentation to the CTSU Regulatory Office. Regulatory documents may be submitted via mail, fax, or email. Sites utilizing local IRBs are responsible for submitting their IRB approval documentation to CTSU.

Additional Requirements for NHLBI-MDS Site Registration:

- a. CTSU IRB Certification (for sites not participating via the NCI CIRB) **or** Signed HHS OMB No. 0990-0263 (replaces Form 310) **or** IRB Approval Letter
- b. CTSU IRB/Regulatory Approval Transmittal Sheet (for sites not participating via the NCI CIRB)
- c. Copy of the IRB approved Informed Consent Document

Note: Regulatory documentation must be received and approved prior to shipment of sample collection kits from the CL/B to the sites.

6. Sites check their registration status by logging in to the members' section of the CTSU website and querying the Regulatory Support System (RSS). Sites will not receive formal notification of regulatory approval from CTSU.
7. The Data Coordinating Center (DCC) and CL/B receive notification when site regulatory requirements are met.
8. The CL/B will send the specimen collection kits and barcode scanner (if needed) to the site once all site regulatory requirements are met.
9. Site confirms receipt of the specimen collection kits.
10. Site enrolls study participants through Oncology Patient Enrollment Network (OPEN). OPEN initializes the participant in the Medidata Rave database. **Note:** There is usually a 5-10 minute lag between enrollment in OPEN and the participant appearing in Medidata Rave.
11. The DCC receives notification of enrollment and initializes the participant in GlobalTrace.

*CTSU Regulatory Office contact information for submission of regulatory documents:

CTSU Regulatory Office
1818 Market Street, Suite 1100
Philadelphia, PA 19103
Phone: 1-866-651-2878
FAX: (215) 569-0206
E-mail: CTSUSRegulatory@ctsu.cocccg.org (for regulatory document submission only)