Establishing a new clinical site

The UNC MDS program currently uses the following clinical sites for clinical rotations:

- UNC Hospitals, Chapel Hill, NC
- Duke University Medical Center, Durham, NC
- Laboratory Corporation of America, Research Triangle Park and Burlington, NC
- Quest Diagnostics Nichols Institute, Chantilly, VA
- North Carolina State Laboratory of Public Health, Raleigh, NC

In these institutions, MDS students have the educational opportunities needed to master the goals and objectives of CLSC 740L (Molecular Diagnostic Science Clinical Rotation, 7 credits, Fall semester). Students will also work on an applied research project that will be the focus of CLSC 780 (Capstone Seminar, 3 credits, Spring semester).

Additional clinical sites may be added to the list of clinical sites for the MDS program if the following criteria are met:

1. **Clinical Contract.**
   The laboratory director at the site signs an affiliation agreement with the Division of Clinical Laboratory Science at UNC-CH. This document describes the responsibilities of the MDS program and the clinical site. It ensures that all parties have agreed to teach the students in this clinical setting.

2. **Clinical Coordinator.**
   The clinical site must assign a clinical coordinator who will oversee the student’s clinical rotation and ensure that the student has the opportunity to meet the MDS course goals and objectives.

3. **Full service molecular Laboratory.**
   The clinical site must perform a full range of molecular tests so that the student can practice and gain competence.

   A. The student must be able to perform testing in all of the following laboratory areas of the institution:
      - Molecular Genetics/Inherited Disease
      - Molecular Oncology
      - Molecular Microbiology/Infectious Disease

   B. The student must be able to achieve competency by performing a variety of tests using different test methodologies (see section C. below) in each of the three laboratory areas. Examples of appropriate molecular test menu assays for competency include, but are not limited to:
      - Genetics/Inherited Disease
        - Fragile X Syndrome
- Cystic Fibrosis
- Hemochromatosis
- Factor II and/or Factor V
- Prader-Willi / Angelman Syndrome
- NKX2.5 mutation analysis
- Connexin 26 and connexin 30 for hearing loss
- Medium-chain acyl-CoA dehydrogenase deficiency (MCADD)
- Galactosemia (GALT)
- Primary Ciliary Dyskinesia/Kartagener Syndrome (DNAI1 and DNAH5)
- Clopidogrel or warfarin resistance testing

Oncology
- B-cell/T-cell gene rearrangement
- JAK2, EGFR, KRAS, NRAS, KIT, MLH1, BRAF, … mutation detection
- BRCA1 and BRCA2 mutations
- BCR-ABL1 translocation
- FLT3 and NPM1 defects
- DNA fingerprinting for bone marrow transplant
- Microsatellite instability

Microbiology/Infectious Disease
- Microorganism Detection
- Viral Loads
- Viral Genotyping
- Antimicrobial Resistance Testing

C. The clinical site must enable the student to become competent in all of the following phases of testing:

1. Pre-Analytical
   - Receive and evaluate specimens for acceptability and proper test orders.
   - Prepare samples for molecular analysis, storage, or send-out.
   - Perform all methods of nucleic acid extraction, isolation, and purification used by the laboratory to include all manual and automated methods.
   - Evaluate nucleic acids for concentration and purity.

2. Analytical
   - The site must provide opportunities for the student to become competent in performing testing using the following methods if used by the institution:
     - Polymerase Chain Reaction
       - Endpoint PCR
       - Real-time PCR
       - Reverse transcription PCR
       - Other variations of PCR
     - Non-PCR Amplification
       - Transcription Mediated Amplification (TMA)
       - Strand Displacement Amplification (SDA)
       - Nucleic Acid Sequence Based Amplification (NASBA)
     - Electrophoresis
       - Capillary
       - Gel
- Melt Curve Analysis
- Microarrays
- Matrix Assisted Laser Desorption Ionization Time-of-Flight (MALDI-TOF)
- Sequencing
  - Sanger
  - Pyrosequencing
  - Next-Generation
- Nucleic Acid Hybridization Techniques
  - Invader™
  - Hybrid Capture
  - Southern Blot
  - Sequence Specific Primer (SSP)
  - Sequence Specific Oligonucleotide Probe (SSOP)
  - Fluorescent In situ Hybridization (FISH)- desirable, but not required
- Other molecular-based methods or test platforms used by the institution
  - The site must enable to the student to demonstrate competence in organizing workflow, instrument operation and maintenance, and trouble-shooting.

3. Post-Analytical
  - Review and verify patient results.
  - Evaluate assay controls for acceptability.
  - Report results using the laboratory information system.

A prospective student who is interested in establishing a new clinical site should:

1. Ensure that the institution performs a full range of molecular tests and will enable the student to demonstrate the competencies described in 3 A – C. Most institutions post their test menus on their web pages.

2. Contact the site and determine whether or not they are willing to teach a student for the duration of the clinical rotation.

3. Provide the name of the contact person at the site to the UNC-CH MDS program.

The UNC MDS program will contact the site and determine whether or not the site is appropriate for the program. If the site is acceptable, the UNC MDS program will begin the process of establishing a clinical contract with the site. Please note that this process can take 6 months. Whenever possible, a UNC faculty member will visit the new clinical site prior to a students’ clinical rotation. If an on-site visitation is not possible, the UNC faculty member will work closely with the clinical coordinator at the new site to ensure that the setting supports the goals and objectives of the MDS program. If a student accepted into the MDS program needs to complete the clinical rotation before the site is established, the student will be offered an existing clinical site.