

Supplemental online content for:

NCCN Oncology Research Program’s Investigator Steering Committee and NCCN Best Practices Committee Molecular Profiling Surveys

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eAppendix 1: Investigator Steering Committee Survey

ISC Molecular Profiling Survey II

You will be asked some general questions about the performance of molecular profiling/diagnostics at your institution and then you will complete a questionnaire about your experiences with molecular profiling. The questionnaire should take no longer than 15-20 minutes to complete. Data will be transferred through secure socket layer (SSL) with encryption to be used. The data will then be stored in a server maintained at the National Comprehensive Cancer Network. This procedure helps protect your information from being viewed by anyone outside of the study.

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Welcome to the Survey!

FOR THE PURPOSES OF THIS SURVEY, "MOLECULAR PROFILING/DIAGNOSTICS" REFERS TO A PANEL OF AT LEAST 10 GENES EXAMINED AS TEST IN A CLIA LABORATORY.

1. Name of person completing this questionnaire**2. Administrative Title(s)*****3. Role(s) in institution*****4. Email addresss*****5. Telephone Number:*****6. May we contact you with questions or for further clarification?**

Yes

No

(continued on next page)

eAppendix 1: Investigator Steering Committee Survey (continued)

ISC Molecular Profiling Survey II

***7. Name of NCCN Member Institution**

- Fred & Pamela Buffett Cancer Center at The Nebraska Medical Center
- City of Hope Comprehensive Cancer Center
- Dana-Farber/Brigham and Women's Cancer Center | Massachusetts General Hospital Cancer Center
- Duke Cancer Institute
- Fox Chase Cancer Center
- Huntsman Cancer Institute at the University of Utah
- Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance
- The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
- Robert H. Lurie Comprehensive Cancer Center of Northwestern University
- Memorial Sloan-Kettering Cancer Center
- Moffitt Cancer Center
- The Ohio State University Comprehensive Cancer Center - James Cancer Hospital and Solove Research Institute
- Roswell Park Cancer Institute
- Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine
- St. Jude Children's Research Hospital / The University of Tennessee Health Science Center
- Stanford Cancer Institute
- University of Alabama at Birmingham Comprehensive Cancer Center
- UC San Diego Moores Cancer Center
- UCSF Helen Diller Family Comprehensive Cancer Center
- University of Colorado Cancer Center
- University of Michigan Comprehensive Cancer Center
- The University of Texas MD Anderson Cancer Center
- Vanderbilt-Ingram Cancer Center
- Other (please specify)

***8. Are molecular profiling/diagnostics (performed in a CLIA laboratory) used to make patient care decisions for cancer patients at your institution?**

- Yes
- No

(continued on next page)

eAppendix 1: Investigator Steering Committee Survey (continued)

ISC Molecular Profiling Survey II

***9. If molecular profiling/diagnostics are not used in the patient care setting at your institution, please explain why. (Please check all that apply)**

- Not enough evidence for its utility
- Molecular profiling/diagnostics not available at my institution
- Reimbursement concerns
- Uncertainty regarding interpretation of results
- Uncertainty regarding proper consent procedures
- Other (please specify)

***10. If molecular profiling/diagnostics are not used in the patient care setting at your institution, are single gene diagnostics used?**

- Yes
- No
- Not sure

***11. If yes, which single genes tests are commonly used in the patient care setting at your institution? (Please check all that apply)**

- EGFR
- KRAS
- ALK
- HER2
- BRAF
- Other (please specify)

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eAppendix 1: Investigator Steering Committee Survey (continued)

ISC Molecular Profiling Survey II

***12. In what settings are molecular profiling/diagnostics used to make patient care decisions at your institution? (Please check all that apply)**

- Patients with advanced refractory disease
- Patients on specific clinical trials that have a companion molecular test
- Patients with rare cancers
- Patients with cancer of unknown origin
- Patients for whom there is an FDA-approved therapy relevant to a molecular diagnostic, eg, KRAS for colorectal cancer, ALK or EGFR for lung cancer, and/or BRAF for melanoma
- Potentially any cancer patients
- Other Settings (please comment on the other types of situations in which you might utilize molecular profiling/diagnostics in the patient care setting)

***13. Have you used molecular profiling/diagnostics for the following purposes: (Please check all that apply)**

- To guide the use of FDA approved drugs
- To help decide off-label use of drugs
- To provide prognostic information
- To guide the choice of clinical trials for patients
- As part of a clinical trial to determine patient eligibility for a specific investigational agent
- Other (please comment)

***14. Who provides the molecular profiling/diagnostics used to make patient care decisions at your institution? (Please check all that apply)**

- In-house
- Outsourced
- Not sure
- Not applicable
- Other (please specify)

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eAppendix 1: Investigator Steering Committee Survey (continued)

ISC Molecular Profiling Survey II

***15. If molecular profiling/diagnostics are outsourced, please tell us which organizations/diagnostics are used. (Please check all that apply)**

- Not sure
- Not applicable
- Caris Molecular Intelligence
- Foundation One
- Knight Diagnostics
- Oncotype Dx, Genomic Health
- Mammaprint
- Response Genetics
- Other

***16. If molecular profiling/diagnostics are not performed in-house in the CLIA labs in your institution, are there plans for these tests to be performed in-house within the next year?**

- Yes
- No
- Not sure
- Not applicable

***17. What technology is used most frequently for molecular profiling/diagnostics in-house at your institution? (Please check all that apply)**

- Next generation sequencing
- Not applicable
- Other (please specify)

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eAppendix 1: Investigator Steering Committee Survey (continued)

ISC Molecular Profiling Survey II

***18. How many genes are analyzed by the most frequently used methodology for molecular profiling/diagnostics performed in-house at your institution?**

***19. Estimate what percent of the time the results of molecular profiling/diagnostics helps inform decisions regarding choice of patient therapy. (Therapy decisions informed by molecular profiling/diagnostics may include a choice of specific clinical trials or a choice of approved drugs used on or off-label).**

- 0-10%
- 10-20%
- 20-30%
- 30-40%
- 40-50%
- >50%

***20. At your institution, are molecular profiling/diagnostics most frequently done on:**

- New Biopsies
- Archived tissue
- Could be either new biopsy or archived tissue
- Not sure

***21. What is the most frequent source of tissue specimens for molecular profiling/diagnostics at your institution?**

- Primary tumor
- Metastatic site
- Could be either primary tumor or metastatic site
- Not sure

***22. Do you perform molecular profiling/diagnostics in the patient care setting on liquid biopsies (that is DNA derived from the blood) in solid tumor patients?**

- Yes
- No
- Not sure

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eAppendix 1: Investigator Steering Committee Survey (continued)

ISC Molecular Profiling Survey II

***23. Which of the following challenges have you faced in the ordering of molecular profiling/diagnostics? (Please check all that apply)**

- Inadequate reimbursement for the test
- Uncertainty as to when the test is indicated
- Difficulty obtaining tissue for molecular diagnostics
- Length of time from ordering to test result availability
- Concern that genetic abnormalities that could be hereditary might be found
- Concerns regarding proper patient consent
- Other (please comment)

***24. If inadequate reimbursement by insurance for tests are a challenge, what are the most common reasons? (Please check all that apply)**

- High copay for patients
- Denial of any coverage
- Refusal to cover specific test(s)
- Other

***25. What are the challenges to utilizing the results of molecular profiling/diagnostics to make patient care decisions? (You may check multiple challenges.)**

- No actionable aberrations
- Drugs not covered by insurance
- No appropriate clinical trial
- Difficulty with interpretation
- Inadequate scientific evidence
- Other (please specify)

(continued on next page)

eAppendix 1: Investigator Steering Committee Survey (continued)

ISC Molecular Profiling Survey II

***26. In your opinion, are more clinical trials needed to better refine the appropriate use of molecular profiling/diagnostics?**

- Yes
- No
- Not sure

***27. Do you use molecular profiling/diagnostics for decision making in the clinical trials setting?**

- Yes
- No

***28. What are the challenges to utilizing the results of molecular profiling/diagnostics in the clinical trials setting? (Please check all that apply)**

- Many patients need to be tested to find a small subset who may be eligible for the trial
- Paying for the molecular profiling/diagnostic
- Developing the molecular profiling/diagnostic in the CLIA setting
- Obtaining an IDE for the molecular profiling/diagnostic
- Obtaining tissue biopsies
- Other (please comment)

***29. Overall, what are the two biggest challenges you face when considering the use of molecular profiling/diagnostics in the patient care (including clinical research) setting?**

#1 Challenge

#2 Challenge

(continued on next page)

eAppendix 1: Investigator Steering Committee Survey (continued)

ISC Molecular Profiling Survey II

*** 30. Are there specific elements in molecular profiling/diagnostic reports that help you in your practice? (Please check all that apply)**

- Listing of agents associated with potential clinical benefit
- Listing of agents associated with lack of potential clinical benefit
- Patient-specific information such as biomarker expression levels and pathologic diagnosis
- Relevant clinical trials based on the patient's tumor type and biomarker expression
- Analysis of scientific literature to provide a level of evidence supporting recommended agents associated with potential clinical benefit
- Analysis of scientific literature to provide a level of evidence associated with agents associated with lack of clinical benefit
- Breakdown of specific results for all biomarkers analyzed by IHC, FISH and CISH, PCR, DNA sequence analysis and Next-Generation sequencing
- Description of each of the relevant biomarkers, as well as a summary of these biomarkers' roles in cancer biology and treatment
- Other

*** 31. How could NCCN best assist with enhancing the use or utility of molecular profiling/diagnostics?**

32. Additional Comments

(continued on next page)

eAppendix 1: Investigator Steering Committee Survey (continued)

ISC Molecular Profiling Survey II

Thank you for taking the time to to participate in this important survey. If you have any questions, please contact Diane Paul, MS, RN at 215-690-0232 or paul@nccn.org. Please go to the next page and click on DONE to exit the survey.

Please click on Done to exit this survey.

eAppendix 2: Best Practices Committee Survey

Molecular Profiling/Diagnostics

As you may recall, molecular diagnostic testing was highly rated on the September 2014 Best Practices Committee meeting topics survey. Following the distribution of the survey results, several committee members posed questions regarding molecular testing. We have designed this survey to help answer those questions.

You will be asked about the general management of testing and testing results, as well as funding and reimbursement for testing services. It is anticipated that you may need to consult with multiple individuals at your institution in order to obtain accurate responses.

Please note that some of the questions raised by Best Practices Committee members regarding molecular diagnostic testing services provided (types of tests utilized and which patients are tested, for example) are excluded from this survey because they were asked in a recent survey conducted by another NCCN committee. Responses to applicable questions from the other survey will be provided to the NCCN Best Practices Committee members in order to provide a complete picture of molecular diagnostic testing issues at the NCCN Member Institutions.

Please consult with the appropriate staff members to assist with your survey responses. We anticipate the survey to take approximately 10 minutes to complete.

1. Please provide the following background information:

Name:	<input type="text"/>
Title:	<input type="text"/>
Institution:	<input type="text"/>
Email:	<input type="text"/>
Phone Number:	<input type="text"/>

Management of Testing and Testing Results

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eAppendix 2: Best Practices Committee Survey (continued)

Molecular Profiling/Diagnostics

2. Which test results from molecular diagnostic testing are placed in the patients' medical record? Please check all that apply.

- CLIA labs
- FDA approved tests
- Testing done for research purposes only
- All tests considered actionable
- All tests (even those not currently clinically actionable)
- Other

Comments:

3. Does your institution have policies (formal or informal) regarding the management of clinical lab results in repositories, databases, registries, etc.?

4. Does your institution have a research and development infrastructure to promote the creation and development of new molecular diagnostic tests?

- Yes
- No

Please explain:

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eAppendix 2: Best Practices Committee Survey (continued)

Molecular Profiling/Diagnostics

5. In general, what is the current governance within your institution to oversee the quickly evolving field of molecular testing? If the governance is anticipated to change significantly in the near future, please indicate the expected change(s). Check all that apply.

- Clinical laboratory service chiefs named on institutional CLIA licenses
- Clinical service chiefs in other relevant specialties (medical oncology, surgery, etc.)
- Clinical administrative leadership
- Academic leadership (clinical departments)
- Academic leadership (basic-science departments)
- Other

Other (please specify):

Funding and Reimbursement for Testing Services

6. How does your institution fund molecular testing conducted solely for research purposes?

7. Does your institution receive reimbursement for new or developing tests, and/or panels ("batched tests") from third party payers?

- Yes
- No

Please explain:

Funding and Reimbursement for Testing Services

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eAppendix 2: Best Practices Committee Survey (continued)

Molecular Profiling/Diagnostics

8. Please estimate the percentage of all molecular diagnostic testing cases in which your institution receives third party reimbursement.

- More than 90% of cases
- 75% to 90% of cases
- 50% to 74% of cases
- 25 to 49% of cases
- Less than 25% of cases

Other (please specify):

9. Does your institution bill patients if a molecular test is not covered by third party payers?

- Yes
- No
- Sometimes

Please explain:

10. Has your cancer center implemented any billing practices that have been successful in obtaining third-party reimbursement for non-standard (new/developing) molecular diagnostic testing? If so, please describe:

11. Please provide any additional information regarding molecular diagnostic testing at your institution you believe would be helpful for NCCN Best Practices Committee members to be aware of.

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eAppendix 2: Best Practices Committee Survey (continued)**Molecular Profiling/Diagnostics****Thank you**

Thank you for taking the time to complete this NCCN Best Practices Survey regarding molecular diagnostic testing. Results will be shared with the Committee once the responses have been collected and summarized.

eAppendix 3: Participating NCCN Member Institutions and Affiliates

City of Hope Comprehensive Cancer Center, Los Angeles, CA
 Dana-Farber/Brigham and Women's Cancer Center | Massachusetts General Hospital Cancer Center, Boston, MA
 Duke Cancer Institute, Durham, NC
 Fox Chase Cancer Center, Philadelphia, PA
 Fred & Pamela Buffett Cancer Center at The Nebraska Medical Center, Omaha, NE
 Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance, Seattle, WA
 Huntsman Cancer Institute at the University of Utah, Salt Lake City, UT
 Mayo Clinic Cancer Center, Phoenix/Scottsdale, AZ; Jacksonville, FL; and Rochester, MN
 Memorial Sloan Kettering Cancer Center, New York, NY
 Moffitt Cancer Center, Tampa, FL
 The Ohio State University Comprehensive Cancer Center - James Cancer Hospital and Solove Research Institute, Columbus, OH
 Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL
 Roswell Park Cancer Institute, Buffalo, NY
 The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD
 Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine, St. Louis, MO
 St. Jude Children's Research Hospital/The University of Tennessee Health Science Center, Memphis, TN
 Stanford Cancer Institute, Stanford, CA
 UC San Diego Moores Cancer Center, La Jolla, CA
 UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA
 University of Colorado Cancer Center, Aurora, CO
 University of Michigan Comprehensive Cancer Center, Ann Arbor, MI
 The University of Texas MD Anderson Cancer Center, Houston, TX
 Vanderbilt-Ingram Cancer Center, Nashville, TN
 Yale Cancer Center/Smilow Cancer Hospital, New Haven, CT

Affiliates:

Virtua (Fox Chase Cancer Center)
 AtlantiCare Cancer Care Institute (Fox Chase Cancer Center)
 Inspira Health Network (Fox Chase Cancer Center)
 Wenatchee Valley Medical Center (Fred Hutchinson Cancer Research Center)
 MultiCare Health System (Fred Hutchinson Cancer Research Center)
 Norton Cancer Institute (Moffitt Cancer Center)
 Lehigh Valley Health Network (Moffitt Cancer Center)
 Northside Hospital Cancer Institute (University of Alabama at Birmingham Comprehensive Cancer Center)

eAppendix 4: Investigator Steering Committee Survey Open-Ended Responses

In addition to the challenges tabulated in the preceding text, open-ended responses captured the following issues/challenges regarding the use of molecular profiling/diagnostics in the patient care (including clinical research) setting:

Cost/Reimbursement

- Cost coverage by insurance; adequate reimbursement; reimbursement for emerging molecular profiling tests (ie, not all patients can get molecular profiling due to lack of reimbursement for the test)
- Reimbursement for medications; coverage for off-label use of drugs
- Funding mechanisms to establish infrastructure to facilitate genomic tools and research biopsies for trials
- Justifying the cost, because actionable mutations are rare
- Informatics and billing

Lack of data regarding actionable targets and targeted therapies

- Lack of good evidence to support use of a targeted therapy in many settings
- Lack of data regarding correlative science/actionable mutations
- Lack of known and/or actionable targets and targeted therapies in many cancers (eg, liver cancer)
- Need for evidence
- Inability to identify an actionable mutation
- Need to establish meaning of results
- Need to expand the knowledge base for the use of molecular profiling/diagnostic tests in specific clinical settings
- Difficulty interpreting the results in order to determine which aberrations are actually actionable
- Applicability of treatment options
- Need for an evidence base showing that an intervention/treatment will work
- Limited utility
- Lack of conclusive clinical data to support action on information obtained from these tests
- Lack of scientific evidence for individual variants
- Too many tests without actionable treatment
- Lack of scientific evidence
- Limited bioinformatics expertise, which becomes a limiting reagent
- Need to develop the knowledge database
- Need to reach broad consensus regarding the appropriate use for molecular markers and to educate oncologists on the health care effectiveness of the use of molecular profiling/diagnostic tests
- Need to demonstrate that results make a difference
- Challenges matching molecular profile to available therapy or clinical trial
- Interpretation; lack of scientific evidence
- Inadequate number of targeted therapies (including too few clinical trials)

Obtaining tissue

- Obtaining the slides or block for testing; tissue not available
- Amount of tissue; sample size too small to run the test
- Tissue quality

Clinical trials

- Inability to find appropriate clinical trial eligibility
- Need for an Investigational Device Exemption for clinical trials

Testing timeline

- Timeliness/turnaround; time to generate results; long turnaround time in getting results
- When to order

Miscellaneous

- Access to FDA-approved drugs for the target
- Physicians do not want to order tests regularly (eg, *ALK* and *EGFR*: only in certain cases, not all lung cancers)
- Developing Clinical Laboratory Improvement Amendments (CLIA)-compliant testing, lack of reference standards, and FDA quality platforms and tests
- The complex level of standard operating procedures and validation required as a laboratory developed test
- Identifying the appropriate patients
- Creation of reporting that is useful to clinicians (annotation of variants)

eAppendix 5: Best Practices Survey Open-Ended Responses

Details on the research and development infrastructures within institutions to promote the creation and development of new molecular diagnostic tests were stated in individual responses as follows:

- *Kras* testing for colon cancer by pathology department. We also have a molecular pathology group that vets new tests.
- Institution recently created a Center for Molecular Oncology with a focus on precision oncology to support the development of new, individualized cancer therapies and diagnostic tools. The Diagnostic Molecular Pathology's Clinical Laboratory Improvement Amendments (CLIA) laboratory also performs test development and validations to increase test offerings.
- Research cores have collaborated with the clinical laboratories to develop new tests, although they transition to the clinical Research and Development (R&D) area relatively early. The strong research environment has contributed to development. Research grants have been applied for by/in conjunction with the clinical laboratory (eg, ET-CTN, NCI-MATCH).
- We lack overall infrastructure for the research and development of new test. We do use our Genomics Advisory Board (GAB) to provide direction towards improved application. Our GAB includes members of the relevant clinical departments (ie, Pathology and Medical Oncology), researchers from the basic science laboratories and biostatistics.
- The Diagnostic Molecular Biology Laboratory has an R&D budget, and there is an additional small endowment that funds some research and development as well.
- We do most of the clinical development and validation of new tests in the CLIA laboratory. We do not do a lot of transitioning of research tests into the clinical laboratory.
- The institution conducts research on molecular diagnostics assays that contributes overall to the development of molecular diagnostic tests.
- The laboratory has an internal procedure to validate laboratory-developed tests.
- Most of this infrastructure resides in the Department of Laboratory Medicine, but there are numerous collaborations between the department and other research laboratories throughout the organization that provide developmental support.
- There are no formal R&D resources for molecular test development in the clinical laboratory, but test development is actively ongoing in collaboration with research initiatives, trainees, etc.
- We have clinical test development department that consists of technologists and PhD-level scientists whose sole purpose is to validate new molecular tests and develop tests for novel biomarkers for research and potential future clinical use.
- The CLIA-certified molecular diagnostics laboratory has some budgetary ability to create and develop new molecular diagnostic tests. In addition, researchers at our institutions can develop tests and if they are promising, they can be moved into a CLIA environment using institutional resources.

Explanations of institutional reimbursement structures were as follows:

- Single analyte tests.
- However, payment is not consistent and we are performing an ongoing analysis to monitor.
- We bill for only medically relevant genes for specific diagnosis as they relate to appropriate information in medical literature, payer policies, etc. The medically relevant genes may be tested in the context of a larger gene panel, inclusive of genes considered “new or developing” tests however those nonstandard genes are not billed. We are typically being reimbursed for Tier I and Tier II that meet payer specific guidelines but very limited success with unlisted codes.
- Not currently, but we do expect to receive reimbursement for gene panels to be launched within the coming year.
- All nongovernment payers are precertified.
- It has recently become increasingly difficult to obtain reimbursement for new molecular tests, particularly those that involve next-generation sequencing or panels. Payers are beginning to require an unrealistic level of evidence for medical necessity and so are instituting broad policies that exclude reimbursement for all panel-based testing by next-generation sequencing, in particular. The Current Procedural Terminology (CPT) coding structure requires modification to appropriately code testing of this type and this contributes to the problem.
- There may be limited reimbursement from a few payers, but overall, we are finding that most third party payers will not pay for molecular testing that does not have a defined CPT code. They will pay for the routine molecular markers that have a unique CPT code assigned, but not the remaining “undefined” codes.
- We have received reimbursement for some of the developing clinical tests we perform: EGFR analysis in lung cancer, BRAF analysis in melanoma. If panels contain these tests, and they are performed in the appropriate clinical context, then we are reimbursed.

Respondents' institutions fund molecular testing conducted solely for research purposes through the following mechanisms:

- Institute and donor funds.
- Ad hoc based on investigators resources. Major resources held by one investigator. Others access funds from CTSA or CC's Clinical and Translational Resource Allocation Committee

- Molecular testing solely for research must be performed in the institution's core labs. Such requests are usually retrospective and are not reported in the patient's medical records. Testing for clinical trial enrollment or actionable patient care is performed in the CLIA laboratory.
- Through research funds. There are discounts from the laboratory for local investigators using the CLIA tests.
- Grants, Cancer Center discretionary funds, institutional funds.
- We have internal grant funding sources from the university to cover some of our research projects. We also look to incorporate research costs into industry clinical trial agreements and applicable NCI/NIH funded projects.
- Small grants through various Centers and Institutes and a small R&D fund for the molecular laboratory.
- Grants and some departmental funds.
- Grants and institutional gifts and endowments.
- Research testing is fully funded by the researcher's financial resources.
- Most research testing is funded through investigator obtained funding sources, most commonly external grants, although collaborative research projects or developmental work for clinical tests is often heavily subsidized by the Department of Laboratory Medicine.
- Research funding.
- Research grants.
- Core molecular laboratory facilities for research testing are grant funded. Individual investigators are charged back for services performed if clinical laboratory testing is required for research purposes only. However, if a patient is enrolled in a clinical trial and the testing is performed as a requirement of the trial, the test will be billed to the patient if it is considered "standard of care" per the protocol.
- Grants and philanthropy, with ad hoc departmental subsidies for very small projects.