



Philanthropy at Mayo Clinic

Expanding Multicancer Early Detection Testing to Tapestry Patients
Impact Report | Prepared for Desert Mountain CARE



Philanthropy Fuels the Future

Thank you for your support of the Mayo Clinic Center for Individualized Medicine Tapestry DNA Sequencing Research Study and our work on early cancer detection in patients genetically predisposed to cancer. We hope you enjoy reading the following update on the Tapestry study and next steps for our research of multicancer early detection (MCED) using noninvasive blood samples. Your philanthropic investment in Tapestry is critical to demonstrate the power of preemptive screening for disease and proof of concept to expand our efforts in the next phase that will offer earlier diagnosis to patients with cancer — revolutionizing patient care for years to come.

We have achieved a milestone, finishing study recruitment after exceeding our enrollment goal a year and a half ahead of schedule. The Tapestry study, a massive, decentralized clinical research study, aimed to complete exome sequencing of 100,000 Mayo Clinic patients and return the results to their electronic health records for three hereditary conditions: familial hypercholesterolemia — a form of high cholesterol; hereditary breast and ovarian cancer (HBOC) syndrome; and Lynch syndrome — a form of colorectal cancer.



114,000+

consented patients enrolled in Tapestry



95,000+

exomes sequenced



130+

research teams using data

More than 1.3 million patients from diverse backgrounds were invited to participate in the Tapestry study, which investigated large-scale patterns of distinctive mutations that fuel disease. Of those invited, 8.8% consented to participate. Of those who participated, 1.8% received a positive result for genetic mutations, such as those related to breast and ovarian cancers and other diseases.

Participants' results are returned to them and their Mayo Clinic provider, becoming a part of their electronic health record. Access to these results allows Mayo researchers to evaluate the benefits of sequencing and the short- and long-term effect on health-related outcomes, utilization and physician acceptance.

Your funding is an important part of our ability to accelerate our collection and analysis of patient samples for Tapestry — helping us speed impact for patients and overcome challenges to scale this approach to more patients and more specific disease profiles.

Multicancer Early Detection

We are now preparing to study MCED, which will leverage the teams and architecture of Tapestry. MCED tests have the potential to find more than one type of cancer from a single sample of blood. The blood sample is tested for certain pieces of DNA or proteins from cancer cells. If these are found, it might mean that the person has cancer, and it might also show which organ the cancer started in. We plan to collect noninvasive blood samples in patients who are genetically predisposed to and/or

have a high risk for cancer. This clinical trial will use a blood test to detect multiple cancers and follow the results and the patients' cancer screening over the next five years. With the funding now secured to launch this trial, we have designed the trial and infrastructure, such as the build out for the blood collection process for the study.

The aims of the MCED study are to:

- Evaluate the performance of a multicancer elevated risk test in a subset of high-risk Tapestry patients.
- Leverage the e-COST study (economic and clinical outcomes of sequencing in Tapestry) to identify the cost-effectiveness of an elevated risk test compared to standard screening for participants at elevated risk of cancer.
- Build a repository of biospecimens and information that can be utilized for future discovery research by the Center for Individualized Medicine and other researchers.

The success of the MCED study will result in enhanced cancer detection in high-risk populations such as those who are carriers of HBOC and Lynch syndrome. The long-term aim is to better align routine testing guidelines with risk based on a patient's predisposition to cancer using a noninvasive blood test.

Recent Milestones

- Protocol developed
- Statistical design completed
- MCED testing partner discussions taking place
- Infrastructure set up for collection of blood in home and at local lab
- Infrastructure built to identify patient population

On the Horizon

Once regulatory approvals are obtained, we will launch the study and begin blood collection and data collection to meet study objectives.

Impact of Philanthropy

This type of work can only happen at a place like Mayo Clinic, where a continuous line of discovery science leads straight to the bedside through a robust translational science approach. The complementary expertise of the members of our team and our extensive collaborations are key factors in the success of our research. Our team is poised to make discoveries that will transform patient care. Thank you for helping make this possible.