



GIVING CURES A CHANCE



SUPPORT for **WOMEN** with
OVARIAN CANCER:

No cost tumor profiling

*Financial support for
genotype-matched treatment*

www.clarityfoundation.org

a 501(c)(3) not-for-profit

A Message from the Founder:



A handwritten signature in black ink that reads "Laura K. Shawver".

Laura K. Shawver, PhD
Ovarian Cancer Survivor

As a scientist and ovarian cancer survivor, I wanted to help change the frightening statistics for women with ovarian cancer. The Clarity Foundation is a not-for-profit organization that has been providing molecular profiling for women with ovarian cancer at no cost to patients or physicians since 2008.

Molecular profiling is changing the way physicians make choices among treatment options for a number of cancers such as leukemias, breast, lung and colon cancer. It has not been common practice in ovarian cancer, but in late 2014, olaparib became the first molecular profile-targeted treatment – specifically for women with germline BRCA1/2 mutations. We hope that this advance signals that molecular profiling will become a standard of care. The Clarity Foundation is helping expedite that process.

We bring molecular profiling to women who recur following first line platinum/taxane treatment. We have conducted the profiling on hundreds of cases and Clarity sponsors the tests if not covered by insurance or if your patient needs help with the co-pay. We provide an interpretation of the results using evidence from clinical research studies and our ovarian cancer-specific database.

In addition, Clarity has launched **our Match Pilot Program** to subsidize the cost of molecularly targeted agents for women with recurrent platinum-resistant or refractory ovarian cancer, whose tumor molecular profile matches certain FDA-approved drugs that are not yet approved for ovarian cancer. Such targeted drugs may provide more clinical benefit than another line of chemotherapy, especially for women with cancers of uncommon histology. Please contact us so that we can assist with tumor profiling for your recurrent ovarian cancer patients. We will subsidize the cost of some molecular targeted agents that match the tumor profile if you prescribe it but insurance is not willing to reimburse. Please visit www.clarityfoundation.org/claritymatch to learn more about our **Clarity Match Pilot Program**.



*Igniting research on novel
treatments for ovarian cancer*

"Prior to beginning Mekinist and Gemcitabine, my CA125 was on an aggressive climb upwards and had reached 205 and I was experiencing painful knife-like pain in my abdominal area. After 30 days on Mekinist, my CA125 is down to 53 and I am pain free. Please accept my sincere gratitude for your assistance in getting me back on this drug."

– Cathey N.
Clarity Match Patient

HOW THE CLARITY FOUNDATION HELPS PHYSICIANS & PATIENTS

- Provides comprehensive, ovarian cancer-specific, tumor profiling analysis: The Clarity Foundation partners with CLIA-certified labs to perform the testing. Our test panel evolves as new tests are developed, new scientific data emerge in the literature, and new technologies are advanced.
- Focuses on molecularly-based rationale for available drug options and is independent from companies and laboratories: Our panel includes protein markers as well as next-gen sequencing to determine genomic alterations that support the use of FDA-approved drugs or investigational agents in clinical trials.
- Helps prioritize among NCCN-recommended treatments for recurrent ovarian cancer (e.g. gemcitabine, topotecan, pegylated liposomal doxorubicin) and agents that are being evaluated in clinical trials.
- Fosters home-city treatment with approved therapies or clinical trial agents. If home-city treatment is not possible, The Clarity Foundation will help you identify the most relevant clinical trial as close to home as possible.
- Access to key opinion leaders who are available for consultation.

The Clarity Foundation is the *only* foundation in the United States dedicated to informing the choice of therapeutic options *now* for women with recurrent & refractory ovarian cancer.



THE
CLARITY
FOUNDATION

FACTS ABOUT MOLECULAR PROFILING



Molecular profiling has been used for decades to help choose the appropriate treatment for certain cancers and is now the standard of care for many tumors.

In ovarian cancer, germline BRCA status is an approved companion diagnostic for olaparib.

Other examples include:

- ER protein for breast cancer: anti-estrogens and aromatase inhibitors
- Her2 protein and copy number for breast cancer: trastuzumab
- Bcr/abl for CML: imatinib
- cKit status for GIST; imatinib and sunitinib
- EGFR mutation for lung cancer coupled with Kras status: erlotinib
- Kras status for colon cancer: cetuximab
- Alk translocations for lung cancer: crizotinib

Molecular profiles may also be utilized to help understand sensitivity and resistance to chemotherapy:

- Topoisomerase I level: topotecan, irinotecan
- Topoisomerase II level: anthracyclines such as pegylated liposomal doxorubicin
- Thymidylate synthase level: anti-folates such as pemetrexed
- Ribonucleotide reductase M1 level: gemcitabine

However, the results from molecular profiling are complex as there are often multiple markers for each drug. **The Clarity Foundation will provide an easy-to-read report which will increase your knowledge about this important field.**

Online informational tools are available at www.clarityfoundation.org.

We can help you
HELP WOMEN
battling this terrible disease.

WHAT IS THE PROCESS?

The Clarity Foundation coordinates the entire process from requisition to block shipment tracking to results reporting.

- We provide all the necessary documents (i.e. patient consent for us to help with the profiling, medical information authorization/release forms and laboratory test requisitions, as well as a simple grant application form when help with payment is needed).
- Our patient coordinator will fill out most of the forms in collaboration with your oncology nurse. You will need to sign the laboratory requisitions.
- We arrange for the testing of the tumor block at each of the CLIA- certified laboratories.
- In addition to tumor specimens, some of the profiling can be performed on a cell pellet from peritoneal ascites fluid or pleural effusions. Tumor samples from core biopsies (3 cores/block) can also be used for this profiling.
- It has been demonstrated that the results from a recent specimen *may be different* from results obtained from the primary tumor or older specimens. (e.g., Zajchowski et al, Mol Cancer Ther 2012; 11:492-502). Therefore, we require a sample from a surgery or biopsy collected within the last year.
- We utilize CLIA-certified laboratories that use the latest technologies for molecular profiling. Our testing panel evolves as new evidence becomes available. Please consult our website for our current tests and laboratories or email us at patientsupport@clarityfoundation.org.
- Upon completion of the testing, an easy-to-read summary report will be sent to you. The Clarity Foundation offers assistance or consultation to interpret the information on the reports. We also offer consults with physicians familiar with our test panel.
- The Clarity Foundation has an IRB-approved protocol to incorporate the clinical histories and profiling results of consenting patients into a de-identified Data Repository that can be used for research purposes. Clinical follow up data is essential to enable studies that can lead to future advances. We will contact your office to obtain the relevant follow up data.

The tests utilized by The Clarity Foundation have been developed and their performance characteristics determined by the CLIA certified labs, Caris Life Sciences, Clariant, Inc and Foundation Medicine. The tests have not been cleared or approved by the Food and Drug Administration. Decisions on care and treatment should not be based on a single test but on the independent medical judgment of the treating physician and all available information concerning the patient's condition should be taken into consideration. The Clarity Foundation provides these services for clinical consideration but recognizes that the results are entirely experimental and they are for informational purposes only. The test results do not necessarily indicate pharmacological effectiveness of the associated agents.

WHAT IS **UNIQUE** ABOUT CLEARITY MOLECULAR PROFILES:

JUST FOR OVARIAN CANCER. Clarity profiling data are specific to ovarian cancer. While the markers themselves are not exclusive to ovarian cancer, we emphasize key markers based on what we know about ovarian cancer, and what we can translate to ovarian cancer from knowledge of other cancers.

ACCESSIBLE TO ALL. Clarity Profiles are available to all women in the U.S. regardless of where they are treated, their willingness or ability to pay and whether their insurance covers all or part of Clarity Profiles.

DYNAMIC. Cancer biology is a fast-moving field that is exploding with new information about molecular pathways and new targeted drugs in development. Clarity is flexible and seeks to respond quickly to new technologies and new biomarkers, as well as new drugs as they are approved or become available in clinical trials or practice.

IMPARTIAL. The biomarkers are measured using a combination of well-established scientific methods (e.g., IHC, FISH, DNA sequencing). Clarity has no financial or other interest in any particular technology or company.

COMPREHENSIVE. Clarity Profiles measure markers for responses to chemotherapy and to a long and growing list of targeted therapies. The list of potential drugs is drawn from the NCCN guidelines for ovarian cancer, approved agents for other cancers available in a clinical trial setting and investigational agents through clinical trials.

INDEPENDENT. Clarity Profiles are carried out by independent CLIA-certified laboratories that have been selected for technical capability, reputation for scientific integrity and ability to adapt new science.



Dr. Beth Karlan
Clarity SAB Chair

SCIENTIFIC ADVISORY BOARD:

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Deb Zajchowski, PhD, Scientific Director, The Clarity Foundation

We seek to improve treatment outcomes in patients with recurrent and progressive disease by providing diagnostic services that determine the molecular profile of the individual patient's tumor, allowing you to prioritize treatment options or choose a clinical trial. We sponsor the tests if they are not covered by insurance or if help is needed with co-pays. You will be provided with results of the profiling and an opportunity for consultation. We can also help you determine which clinical trial may be right for your patient.

We are committed to assuring that ovarian cancer patients can benefit from cutting edge discoveries and treatments that are being advanced for more common malignancies. Many molecular drivers of cancer biology are universal, and Clarity aims to highlight the importance of incorporating these findings into treatments for women with ovarian cancer. With informed patient consent, we maintain a Data Repository and collaborate on research that will identify patterns, which over time, may help with new treatments.

The Clarity Foundation would like to give special thanks to **Royal Neighbors of America**, a not-for-profit life insurer with a difference, for its continued support.



www.royalneighbors.org
(800) 627-4762

HOW TO CONTACT CLARITY FOUNDATION

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IMPROVING TREATMENT OPTIONS FOR OVARIAN CANCER PATIENTS
