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Patient Testimonial

FAST-FORWARD FROM 2010 TO JANUARY 2016 TO CHECK ON THE PROGRESS OF ELISA MARTIN

We shared Elisa's story a few years ago, that she was diagnosed with cancer in April 2009, just after her 34th birthday. Elisa took a turn for the worse in November 2010, and doctors told Elisa's family to start planning her funeral. Thanksgiving 2010 left little HOPE for Elisa— until she was referred to Mary Crowley. It is now January 2016, and Elisa feels good and is without cancer! However, Elisa has not been without some struggles. First, Mary Crowley was recently informed that her investigational therapy, keeping her cancer at bay, was no longer available because the clinical trial was closed. The therapy proved effective and the pharmaceutical company was advancing the therapy to full FDA approval; further testing was no longer required. Nevertheless, there would be a gap of time between the trial closure and when it would be available to community oncologists. Mary Crowley contacted the pharmaceutical company and discussed the critical need for Elisa to continue this therapy during the time gap. In compliance with FDA protocol, they



agreed to continue providing it to Mary Crowley for Elisa -- another WIN for Elisa! Secondly, her monthly secondary insurance increased over \$700 per month, and she could no longer afford to maintain it. But with the grace of Mary Crowley's Benevolence Fund, she has been able to keep afloat.

Looking at Elisa, who just turned 40, no one would ever suspect she has so valiantly fought cancer for the past six years. Says Elisa, "I never imagined this milestone. I have HOPE and am determined that cancer will not kill me. Mary Crowley has given me not just great treatment but also remarkable results!"

While Elisa has seemingly had doors closed at multiple junctures during her cancer journey, others have opened. Mary Crowley is privileged to provide HOPE and support for Elisa and all cancer patients who are in need of an open door.



JANUARY 2016
VOLUME 6, ISSUE 1

MARY CROWLEY QUARTERLY



PREDICTING NEXT PIVOTAL CANCER ADVANCES - 2016

One of the few silver linings in the past decade has been the advances in understanding the mechanics of cancer and the consequent changes in therapy. Naming but a few: *timely, low-cost gene sequencing; the introduction of patient-centric trials; a more rapid and efficient FDA approval process; front-line immunotherapy; and the approval of the first immune-enhanced, oncolytic virus.* All of these and more will continue to develop. So from where do I think the next generation of life-promoting changes will come for patients with cancer diagnoses?

Firstly, from a change in our conceptual approach. Despite progress made, basic research and clinical applications continue to be based on reductionist thinking. This involves breaking down "cancer" into its component parts and then studying the behavior of these parts. However, "cancer" is not a thing, it is a process, a complex adaptive system, and therefore would best be approached by systemic thinking. In other words, evaluating the connections and flows between its functional components both temporally (the evolution of mutations) and spatially (between cancer and both local surrounding tissues and distant metastatic sites).

Secondly, from the development of computational multiscale algorithms. Gene sequencing suggests what changes in control and information pathways have been involved in the development of the cancer: but only by understanding the interactions between the gene changes, the coded template mRNA and the proteins produced along with their effects on

each other, can we even begin to understand cancer's complexity and the multiple targets needed to destroy it.

Thirdly, from the introduction of liquid biopsies. To allow for maximum benefit from computational multiscale algorithms, we need to sample cancers not only at diagnosis but serially in order to initially choose the best therapy, to rapidly assess its effectiveness, and to understand mechanisms of resistance so that we can rationally defend against them. Serial blood sampling is easy and safe, whereas multiple surgical biopsies are difficult, potentially painful, and could produce complications.

Fourthly, from the clinical application of gene editing technologies. Although existing technologies, for example, Zinc Finger Nucleases (ZFN) and Transcription Activator Like Effector Nucleases (TALEN) have shown some promise, they are cumbersome and can evoke off-target side effects leading to adverse side effects for patients. A new and exciting technology, Clustered Regionally Interspaced Short Palindromic Repeats (CRISPR), appears to be easy to construct, efficient, capable of deleting cancer-associated mutated genes, and adding cancer suppressing genes, and more and more allowing for prevention of unwanted off-target side effects.

So, to paraphrase the author Chuck Palahniuk, when will the future switch from being a promise to being a reality? We at Mary Crowley Cancer Research are trying to make it so!

- Neil Senzer MD, Mary Crowley Scientific Director

UPDATES



MOLECULAR PATIENT REGISTRY: MARY CROWLEY TOOL BOX

Currently the Food and Drug Administration (FDA) has approved over 30 targeted therapies for cancer. However, with increasing knowledge of complex genetic changes in cancer, more targeted investigational agents are still needed to support new findings. Since 2012, Mary Crowley has conducted molecular testing on the majority of its patients and has preserved their data in a Molecular Patient Registry to support the Target the Target Program* which will bring new cancer options to patients. This molecular data base serves several purposes for Mary Crowley Investigators:

- Correlating and aligning existing patients with the most appropriate available targeted clinical trials.
- Providing a prospective view of new cancer signals and for dialogue with potential new drug developers.

HOW IT WORKS:

- Patients in the database (without a prior matching targeted trial available) may be contacted when a new clinical trial is opened that matches their molecular defects.
- If a new investigational targeted agent has less effectiveness for a patient, the expert investigators at Mary Crowley are trained to analyze alternative molecular mechanisms to approach the cancer target.
- The use of the data contained in the Molecular Patient Registry and corollary response data enable the Mary Crowley team to coordinate focused development with FDA and the sponsor to a specific target population for product approval opportunity.

This tool box of molecular patient data also demonstrates how many patients have similar mutations. The top 10 seen among Mary Crowley patients are: TP53, KRAS, APC, PIK3CA, CDKN2A, CDKN2B, PTEN, MYC, CCND1, and BRAF.

*A form of molecular medicine that utilizes therapies to target or block the growth of cancer cells by interfering with specific molecules needed for carcinogenesis and tumor growth.

MARY CROWLEY RESEARCH VP TO ADDRESS ACRP

Nadine Nemunaitis, Vice President of Research Operations at Mary Crowley, has been invited to speak at the Association of Clinical Research Professionals (ACRP) 2016 Meeting & Expo in Atlanta on Tuesday, April 19. She will present "Standardizing Principle Investigator Delegation Records: An Alternative Approach for Sites;" with co-presenter Certified Principal Investigator and Medical Director, Dorian Williams of West Virginia University School of Medicine. Of the 232 abstracts she has presented to ACRP, this is the 89th to be accepted for presentation. Nemunaitis directs the development, implementation and oversight of Research Operations, and she provides regulatory expertise to Mary Crowley's Research Operations and Central Institutional Review Board (IRB). ACRP's Meeting & Expo supports the professional growth and development of individuals conducting clinical trials through education, exchange, and peer-to-peer engagement.

DALLAS COWBOYS BIRTHDAY SURPRISE FOR MICHELE

Some Mary Crowley patients travel great distances to access one-of-a-kind clinical trials. When Dallas Cowboys Executive VP, Charlotte Jones Anderson heard about Michele Baron being in Dallas to receive a cancer vaccine on his 14th birthday, she and her dad Jerry Jones decided to make it special. The Baron family traveled from Germany to Dallas in December because they found the best option for Michele's cancer in a clinical trial at Mary Crowley, which is not available anywhere else in the world. Michele received an autographed Tony Romo jersey and a Jerry Jones-signed Cowboys hat from the famous father-daughter Cowboys' owners, who wanted to give Michele a Texas-sized Happy Birthday. Pictured: Ellen Dearman, VP Philanthropic Development with Andrea, Michele, Ada and Luna Baron



NIH NATIONAL CANCER INSTITUTE

NCI-MATCH TRIAL NCI-Molecular Analysis for Therapy Choice (NCI-MATCH) is a clinical trial that analyzes patients' tumors to determine whether they contain genetic abnormalities for which a targeted drug exists (that is, "actionable mutations") and assigns treatment based on the abnormality. NCI-MATCH seeks to determine whether treating cancers according to their molecular abnormalities will show evidence of effectiveness.

The trial opened for enrollment in August 2015 with ten arms. Each arm will enroll adults 18 years of age and older with advanced solid tumors and lymphomas that are no longer responding (or never responded) to standard therapy and have begun to grow. Source: www.cancer.gov

NEW MOLECULAR THERAPY COORDINATOR

Rachel received B.A. in Health Science from the University of South Florida and minored in Public Health before moving to Dallas in 2013.

Rachel worked at Mary Crowley as Data Coordinator for one year before taking on her new role as Molecular Therapy Coordinator for the Molecular Patient Registry, which tracks the molecular profiles of Mary Crowley patients. Rachel works with patients to secure their consent, transcribes pathology reports into the database, and runs reports for Mary Crowley researchers.

In her spare time, Rachel leads a small group of 6th grade girls from her church. She enjoys travel and outdoor activities. Rachel says, "I love helping people. I also love Mary Crowley's message of HOPE. The Molecular Patient Registry is providing more options for cancer patients."



PHILANTHROPY

Bringing Hope

ALLISON'S HOPE: 1 MILLION AND COUNTING

Founder Linda Cassens (second from right) traveled to Dallas to present a \$75,000 check to Shannon Cagnina, COO; Jeanne Jones, VP of Clinical Operations and Pat Brown, VP of Strategic Development. This is one of many donations from Allison's HOPE, based in Edwardsville, Illinois. They have raised



over \$1M for Mary Crowley since 2004 through their annual Golf Outing, the Hauling Hope transport fleet, HOPE Gala and other community events. Allison's HOPE was established to honor Allison Cassens' dying wish to raise money for cancer research. Years later her father Allen Cassens was also diagnosed with cancer and was a patient at Mary Crowley. Thanks to the generosity of family and friends, Allison's HOPE is on their way toward raising another \$1M to advance new treatments for cancer patients. Thank you, Allison's HOPE!



SPEEDING UP CANCER RESEARCH Pat Brown, VP of Strategic Development, and Ellen Dearman, VP Philanthropic Development, joined Santa Claus and his elves at the 2015 Texas Motor Speedway Tree Lighting Ceremony to receive \$46,438 from Speedway Children's Charities-Texas Chapter (SCC-TX) on behalf of Mary Crowley's Ewing's Sarcoma Program. The gift was made possible by SCC-TX's annual "Silver Dollar at the Ranch" fundraising event. Sherri Hale, 2015 "Silver Dollar at the Ranch" Event Chair, and Scott Murray, SCC-TX President, presented the check at the annual tree lighting and grant ceremony. SCC-TX was created to assist non-profit organizations in improving the lives of children in North Texas; they have awarded \$10M in grants since 1997. "Silver Dollar at the Ranch" has raised \$571,438 for Mary Crowley since 2012.

YTAC PUTS THE FUN IN FUNDING CANCER RESEARCH

Young Texans Against Cancer (YTAC)-Dallas was founded in 2008 by young people who have personally battled cancer or witnessed loved ones struggling with the disease. YTAC-Dallas members, ages 22-45, raise funds and awareness among their peer-group through a multitude of events. YTAC-Dallas selected Mary Crowley to receive \$70,000 for their targeted therapy clinical trial for children with Ewing's Sarcoma. Pictured: YTAC-Dallas Co-Presidents Allison Eidson (left) and Ashley O'Malley (right), Ellen Dearman (center), VP of Philanthropic Development at Mary Crowley



BE THE DIFFERENCE MAKING A DIFFERENCE

Be the Difference Foundation selected Mary Crowley as a 2015 beneficiary of a \$150,000 grant. The foundation was formed by four ovarian cancer survivors who share the same passion: to Be the Difference and end the fight against ovarian cancer. Says Julie Shrell, Co-Founder, President and Survivor, "We are excited about the research and discoveries occurring at Mary Crowley and have great hope that our support, along with the other funding for this study, will be a catalyst in finding better treatments or a cure for ovarian cancer." Mary Crowley has conducted nine clinical trials for ovarian cancer since 2012, with an additional trial in development that targets MIF macrophage-migration inhibitory factor. "With this grant, Mary Crowley will expedite the targeted molecular therapy program specifically designed for ovarian cancer. By opening new and more clinical trial options for patients in 2016, Be the Difference Foundation has brought our vision one BIG step forward in ovarian cancer management," said Dr. John Nemunaitis, Mary Crowley Executive Medical Director.

Ovarian cancer is the most lethal gynecological cancer affecting 1 in 70 women. Today more than 70% of ovarian cancer patients will die of their disease. When ovarian cancer is detected and treated early, the five year survival rate is greater than 92%.

Pictured Above From BTDF: Gary Gardner - Board Member; Jill Bach - Co-Founder and Survivor; Lynn Lentscher - Co-Founder and Survivor; Julie Shrell; Dr. John Nemunaitis, Sheryl Yonack - BTDF Board Member; Ellen Dearman - VP of Philanthropic Development at Mary Crowley, and Jon Mize - Director of Wheel to Survive



SEE INSERT FOR DETAILS ON UPCOMING EVENTS

2016 Upcoming Events

WHEEL TO SURVIVE DALLAS



Be the Difference Foundation (BTDF) and Mary Crowley are pedaling toward HOPE in the fight against ovarian cancer. BTDF's annual cycling event "Wheel to Survive Dallas" is an inspirational fundraiser that promotes awareness of ovarian cancer symptoms, funds programs for women battling the disease, and provides research funds for a cure. Cyclists of all levels participate as teams or individuals. The event will feature uplifting stories from survivors and their families. Proceeds will benefit Mary Crowley's targeted molecular therapy program specifically designed for ovarian cancer. Join us!



Raising Hope. Targeting Ovarian Cancer.



WHEEL TO SURVIVE DALLAS DETAILS:

WHEN: Saturday, February 28th
9 AM - 3 PM

WHERE: Jewish Community Center of Dallas
7900 Northaven Road

HOW: Register as a team or individual at
www.wheeltosurvive.org

Wheel to Survive events are also taking place in Austin, Lubbock, El Paso, Houston, and San Francisco, CA.

STRUT: FASHION SHOW

The Dallas Chapter of Young Texans Against Cancer (YTAC) has raised funds for beneficiaries through a variety of creative platforms, and the March 3rd event will certainly be a "show stopper." The first annual YTAC fashion show - STRUT (Striving to Resolve, Unite, and Triumph) - will highlight cancer survivors and champions as models, including a Mary Crowley patient! These women will "strut" down the runway and take a stand against cancer. Participants will be pampered, styled, and accessorized by Front Door Fashion. The evening will include a VIP reception, silent auction, and refreshments. Don't miss this fun event!



WHEN: Thursday, March 3, 2016 | VIP 6-7 PM
General Admission 7-10 PM

WHERE: Front Door Fashion
2251 Vantage St. #400, Dallas

WHY: Supporting cancer survivors and organizations

HOW: Purchase tickets at dallas.ytac.org

ADDITIONAL UPCOMING YTAC EVENTS INCLUDE:

YTAC Chili Cookoff | Saturday, April 2nd
1-4 PM at the Foundry Bar

Young Texans RACE Against Cancer | Saturday, May 14th
8 AM at Trinity Groves

BubblyQ | Thursday, October 13th
7-10 PM at Fearing's at The Ritz - Carlton, Dallas

Drive Cancer Away: Golf Tournament | TBD November

For additional information, please visit dallas.ytac.org



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MARY CROWLEY IS BENEFICIARY OF 2016 SILVER DOLLAR AT THE RANCH EVENT



Saturday, May 14th

6:30 PM TO MIDNIGHT

XO RANCH
AUBREY, TX

TICKET PRICES START AT \$150
INCLUDES: DINNER, OPEN BAR, DANCING & CONCERT

Event Details

ENTERTAINMENT BY FAN FAVORITE NEAL MCCOY

APPEARANCES BY LOCAL AND NATIONAL CELEBRITIES INCLUDING
PAM MINICH, HONORARY CHAIRPERSON

LIVE AND SILENT AUCTIONS

MIDWAY GAMES THAT GIVE THE STATE FAIR OF TEXAS A RUN FOR THEIR MONEY

ROUNDING UP A CURE FOR PEDIATRIC CANCER RESEARCH

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