



Personalized Medicine

hypothesizes that:

- Targeting mechanisms that are necessary to cancer growth, proliferation and metastasis formation can improve a patient's outcome;
- These mechanisms are individual;
- It is possible to identify these mechanisms at the individual level; and
- Knowing these mechanisms allows us to specifically target them.¹

Mary Crowley has pioneered the field with clinical application of personalized cancer medicine for twenty years, since autologous cancer vaccines entered clinical trials in Dallas in 1997. One of our first late-stage cancer patients had a complete remission and lived for twenty years without recurrence. Those results were rare two decades ago. However, the relentless pursuit of targeted therapies and an understanding of how to select them for individual patients continue to take ground.

Mary Crowley staff and patients are seeing more glimmers of hope. New targeted drugs have been approved in some cancers and are still experimental in others. Some of our patients receiving targeted therapies in clinical trials, selected on the basis of

their molecular profiles, are seeing tumor shrinkage. These are cases in which all standard treatments have failed and the attempt to manage the cancer with an experimental regimen is a last option. For Mary Crowley staff, positive scan results have always been cause for celebration: 65% tumor decrease, 28% tumor decrease, and complete response. These were patients who had been given no hope of ever pushing back the cancer from unlimited growth. Many, however do not see positive results at this point, but we are seeing the positives more frequently than before.

And we are learning how to administer the novel therapies. Some may cause adverse side effects, similar to chemotherapy drugs. But our physicians are seeing anecdotal evidence of the body re-setting after a side effect is properly managed, allowing a targeted therapy to impact the cancer cell growth. One patient, for example, experienced significant organ dysfunction, possibly related to the experimental treatment. Diligent research physicians addressed the organ function with early intervention, and the patient was able to resume the experimental therapy to see scans reveal tumor shrinkage.

In 2016, neurosurgeon and lung cancer patient Paul Kalanithi wrote,

I got a phone call saying that I did, in fact, have a treatable mutation. Chemo was off, thankfully, and... a little white pill became my treatment. I soon began to feel stronger. And even though I no longer really knew what it was, I felt it: a drop of hope. The fog surrounding my life rolled back another inch, and a sliver of blue sky peeked through. II 2

Hope. This is the essence of personalized medicine. In 2017, we are seeing promising results. The results are still anecdotal, but observing the growing influx of patient responses, one senses an impending wave. It's a positive wave developing. Bringing forth hope.

By Shannon Cagnina, COO, MCCR

- 1. Neil Senzer, M.D. (2016)
- 2. Kalanithi, When Breath Becomes Air, (2016)

There's More to Personalized Medicine than Meets the "I"

By Neil Senzer, M.D., Mary Crowley Scentific Director

The bipartisan Precision Medicine Initiative introduced in 2015 allocated \$215 million dollars for advancing research in personalized treatment and genomic testing with the ultimate goal of enhancing patient engagement and participation so as to generate better data and more effective care. This Initiative is in large part due to the data obtained from retrospective reviews and clinical research trials as well as to the benefits of increasingly widespread use of genetic and protein molecular testing by community clinical oncologists.

Oncologists at the University of California at San Diego published meta-analyses (a combined review from several studies using methods to reach a conclusion with greater statistical power) of 346 Phase I and 570 Phase II cancer studies comprising 13,203 and 32,149 patients, respectively. Both showed significant relapsefree survival. The Phase II meta-analysis revealed a significant overall survival advantage with molecularly targeted therapy matched to the patient compared to chemotherapy and to the use of unmatched targeted therapy. Furthermore, a prospective study of 500 patients performed at three leading cancer institutes confirmed the benefits of patient-specific molecular target based therapy. Clearly, data reflects improved patient benefit in clinical research centers, such as Mary Crowley, with access to both FDA approved and investigational targeted agents.

At Mary Crowley, research physicians interpret patientspecific molecular information and align relevant targeted therapies for individual patients. With the use of our Patient Molecular Registry, initiated in 2013, we match patients to specific targeted therapies and anticipate new therapies currently in development.



To find more information about Mary Crowley's personalized medicine, visit www.marycrowley.org

Mary Crowleys Research Operations Experience to be Recognized at ACRP

The Association of Clinical Research Professionals (ACRP) has accepted two abstracts submitted by Nadine Nemunaitis, Mary Crowley's V.P. of Research Operations, for oral presentation. These two abstracts will be presented at ACRP's annual international meeting in May of 2017. The ACRP is highly regarded by the research community, including the NIH and FDA, and is recognized as the annual meeting of influencers, innovators and regulators driving change in clinical trial operations. Mary Crowley is one those influencers, as Nadine has previously been invited to present to this prestigious gathering. The titles of her oral presentations at this year's meeting are:

 Trends, Strategies and Tools for Achieving Informed Consent and
 Key Considerations in Building Your Site's Quality Improvement Program



Founded in 1976, ACRP is a Washington,

D.C.-based nonprofit with more than 13,000 members who work in clinical research in more than 70 countries. ACRP is setting standards for clinical research competence and workforce development. They support professionals and organizations across the clinical research enterprise with the Membership, Training, and Certification programs necessary for clinical trial quality and efficiency improvements.



Terry CockerhamOfficial Mary Crowley Photographer

A quick glance at Mary Crowley's website reveals images of smiling patients and staff. Many of those photos have been taken by one photographer –

Terry Cockerham. Since 2012, Terry has graciously volunteered his photography skills to capture portraits of Mary Crowley patients, physicians and staff. He frequently makes himself available at a moment's notice in order to accommodate busy schedules, and then he makes a gift of the photos he takes.

Photography allows Terry to combine his interest in science and math with his eye for art. He launched his career as a self-taught commercial photographer and has worked as a photojournalist, photography teacher and freelance photographer. For many years he worked as the staff photographer at Medical City Dallas Hospital, which is how he became acquainted with Mary Crowley. Pro bono photographs are Terry's way of giving back and helping us give HOPE to cancer patients. Mary Crowley Cancer Research salutes Terry Cockerham for his generous donation of time and talent.

Did you know... the "Like" button on Facebook was originally going to be called "Awesome"? Stay awesome Facebook friends.





Join us! In celebration of our 20th Anniversary, Mary Crowley is launching a \$2 million campaign so that we may open MORE clinical trials for waiting patients. **100%** of donations to Mary Crowley go directly to patients in need of clinical trials.

Funds will be used to:

Recruit & Open 30 new innovative Clinical Trials.

Grow Patient Services Programs such as Patient Navigation and Benevolence Program which assist eligible patients with hardship expenses.

Sustain strong Physician/Scientific Leadership - Our Physician Investigators. determine best Clinical Trials for patients by evaluating data and contextualizing and translating molecular information.

Invest in Capital Needs - Ensuring patients and staff have access to the most up-to-date facility and equipment.

Help give HOPE to cancer patients. Donate Today!

Planned Giving

Planned giving is one way our donors impact our mission of giving HOPE to cancer patients. Sometimes a patient becomes a donor, and we are excited to share one patient's beautiful legacy of hope.

Having enjoyed a 34-year business career, devoted to her family and friends, our friend was diagnosed with cancer. After several rounds of chemotherapy that became ineffective, she was referred to Mary Crowley, where Physician Investigators worked to find several trials that aligned with her cancer. She was enrolled on several successive clinical trials, and her survival extended beyond what she had expected with standard therapies. She was beloved by the Mary Crowley staff, always brightening the Infusion Room with her joyful presence. Likewise, she appreciated the warm and compassionate environment at Mary Crowley.

This patient never considered herself "well to do," but she was delighted to learn that her wise estate planning over the years allowed her to make a significant gift to charity. She named Mary Crowley as a beneficiary through a planned gift.

After she passed away in August 2016, Mary Crowley was honored to receive more than \$50,000 from her estate. These funds will help enroll more patients on innovative Clinical Trials, just like the trials that extended her life. In addition, the gift will allow her legacy to continue into the future.



Please contact Ellen Dearman, edearman@ marycrowley.org, for more information about Planned Giving donations.

Be the Difference Foundation Grant to Mary Crowley

Be the Difference recently honored Mary Crowley Cancer Research with a generous grant of \$88,750 to further our Ovarian



Lee Knox & Meghan Manley

Clinical Trial Program. Currently Mary Crowley has 12 clinical trials open for ovarian cancer patients.

Julie Shrell, Co-Founder and President of Be the Difference, said "We are excited about the research and discovery that your team is working on and hope that our support will be a great catalyst" in advancing better options for ovarian cancer.

Be the Difference Foundation was founded by four ovarian cancer survivors who challenge the community to "Be the Difference" in the fight against ovarian cancer. They raise awareness about ovarian cancer, support women who are currently facing the disease and raise funds for research they hope will one day lead to a cure.

When detected early, ovarian cancer is typically manageable. Unfortunately, symptoms are usually masked as other conditions, so women tend to be diagnosed at later stages. Ovarian cancer can respond to standard chemotherapy and radiation; however, when it recurs, 50% of patients do not survive more than five years. This is why Mary Crowley's personalized gene, immune and targeted clinical trials are so important.

On Sunday, February 26, Be the Difference hosted their 5th annual Wheel to Survive Dallas, an indoor cycling fundraiser. For the second year in a row, Mary Crowley's employee team – the "Wheelers for HOPE" -- raised funds and rode in the event. For more information, visit www.bethedifferencefoundation.org



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COVER: Ovarian Tumor Microenvironment, NCI Cancer Close Up 2016. Created by Chris Booth, Kyle Cowdrick & Frank C. Marini, July 2013













Six years ago during a Texas snow Storm I started treatment at Mary Crowley. At the time my doctors had given up hope and called this my last chance - my tumor was large and the aggressive treatment had little effect. As I walked in the doors I aldn't know what to

expect ... but 6 years later, here I am! None of this would be possible without yall—the hugs, the laughter, the treatment, the downs, the ups have gotten me here & I'm forever

THANKFUL!

Forever grateful,

Another patient "graduates" from Mary Crowley!

Thanks to her successful clinical trial at Mary Crowley, former patient Elisa Martin (pictured above, far right) is cancer-free and no longer requires regular visits. Recently she dropped by to bring cookies and express her gratitude to Mary Crowley staff for giving her HOPE.

Oncologists use the term "complete response" to indicate a patient is cancer-free, meaning the disappearance of all signs of cancer. Mary Crowley Graduates are patients who have a complete response to our personalized/targeted therapies – remarkable, considering most are at late stages and have exhausted all other options. Mary Crowley Graduates like Elisa give us HOPE in the fight against cancer! Read her story at www.marycrowley.org. #HopeLivesHere