

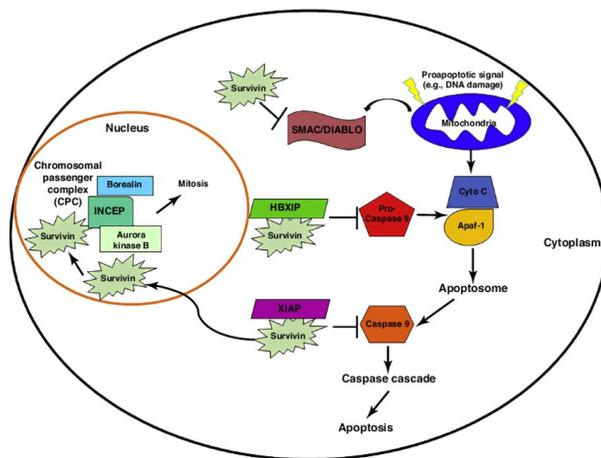
NEW STUDY AIMS ATTACK ON SURVIVIN

Study 18-23 has just opened at the Clinic. This study is an important step forward in the development of this investigational immunotherapy called DPX-Survivac. Study 18-23 is the third study at the Clinic using this study drug.

DPX-Survivac is directed against a protein called survivin. All cells have a self-destruct system called apoptosis. Certain kinds of injury to a cell trigger this pathway resulting in degradation of the cell so that it can be replaced. Survivin is a protein that blocks activation of apoptosis. Many kinds of cancer cells have more survivin protein than normal cells leading to the idea that therapy directed against survivin might be able to start an attack on tumor cells by the immune system.

The first study using DPX-Survivac at Mary Crowley was in 2011. An innovation in the design for this study drug was making use of information about the way immune cells recognize their targets. Fragments called peptides of an abnormal protein in a cell bind to HLA proteins on the surface of the cell. DPX-Survivac combines several peptides from the survivin protein, which are chosen so that at least one will bind to one in the HLA

proteins in about 85% of the population. The first study in our clinic with DPX-Survivac showed that its use was well-tolerated in patients and that an immune response could be detected in participants with ovarian cancer.



Peery, Liu, and Zhang. Drug Discovery Today, 2017; 22:1466

The second study here started in 2016 and combined DPX-Survivac with two drugs that might increase the strength of the immune response. This study enrolled patients with advanced ovarian cancer. There were significant responses with measurable tumor decrease for some

patients. These responses were in the patients with smaller tumors, as in other studies of immune therapy.

This new study builds on these results. In this study, DPX-Survivac is combined with one of the drugs used in the last study (cyclophosphamide) and also with one of the recently FDA-approved checkpoint inhibitor antibodies (pembrolizumab). This study will be open to patients with ovarian cancer, lung cancer, bladder cancer, hepatocellular (liver) cancer and other solid tumors that express a certain type of biomarker called Microsatellite Instability High (MSI-H) For ovarian cancer patients, the study is also restricted to patients with tumor lesions smaller than 5 cm. Restrictions on enrollment are always difficult decisions. We want the study available to as many patients as possible, but we also want patients who participate in the study to have the best chance to benefit.

The development of this study drug shows that careful conduct and analysis of new treatments can take time but may lead to very promising results.

By James Strauss, MD, Clinical Scientific Director

TEMPUS AND MARY CROWLEY JOIN FORCES TO TAKE ON LUNG CANCER

Tempus is a Chicago-based leading technology company that is ushering precision medicine as a means to advance cancer care. It collects and analyzes molecular and clinical data. It aims to build the world's largest library of cancer care information and place that database at the fingertips of physicians.

Tempus is constantly expanding its repertoire of tools by which it adds to the ongoing battle against cancer. The company is well positioned to tackle one of the biggest problems that is plaguing the health care industry today, namely a plethora of disorganized and siloed patient information that could provide insight into future patient care.

Tempus is rich with collaborations, as well. It is currently working with nearly all of the nation's National Cancer Institute-designated Comprehensive Cancer Centers as well as several prestigious academic and health care institutions whose oncologists send their patients to Tempus for sequencing.

Tempus most recently established a collaboration with Mary Crowley Cancer Research with the objective of expanding research options for lung cancer patients. As part of the collaboration, Tempus will be a preferred provider for Mary Crowley Cancer Research to perform molecular sequencing, analysis and provide clinical support for patients diagnosed with lung cancer.

Lung cancer is one of the most common cancers in the United States, affecting both men and women. When detected in time and when it is still localized within the lungs (either Stage I or Stage II), the five-year survival rate is 56 percent. However, less than half of lung cancer cases (~43 percent) are actually diagnosed at these favorable disease stages as signs and symptoms only become apparent after the disease has advanced beyond them.

According to the Director of Clinical Trial Development at Mary Crowley, "Unfortunately, a match is not always found, which leads providers to test for gene alterations specific to clinical trials. This process, although key in personalizing and expanding cancer treatment options, is often lengthy and requires extra tissue."

James Strauss, MD, the Clinical Scientific Director at Mary Crowley, is optimistic about the collaboration, stating that his team views it as a means to be more efficient about incorporating their available studies and finding the best therapeutic solution for lung cancer patients.

Eric Lefkowsky founded Tempus in 2015. The company uses an interactive and analytical machine learning platform that leverages data from biological models, proteomics and single cell genomics. The company organizes unstructured data, particularly focusing on combining clinical and molecular cancer data and makes it available to physicians so that they can make more informed and more personalized cancer care decisions. Lefkowsky's ultimate goal with Tempus is to enable each patient to benefit from the treatment of those who came before. In other words, his goal is a personalized cancer care approach.



The Role of Data Coordination in Clinical Research Trials

by Caitlin Cowart, Data Coordinator II

As a data coordinator, what I do may seem far removed from direct patient care. The essential function of my role is to navigate and analyze the medical records of patients on trial at Mary Crowley. I transcribe the information into a database so the sponsor is able to track the efficacy of their investigational agent and review things such as blood tests, CT scans, and adverse events. The ultimate goal, of course, is to find a safe, viable, and measurably effective treatment for cancer.

It is true that I may never meet the patient in person; that we may never have the opportunity to shake hands, or greet each other by name while exchanging warm smiles. Regardless of this, I am an active participant in their care and experience at Mary Crowley. My role provides me with not only access to a patient's clinical treatment, but also insight to their personal journey.

Data coordinators are tasked with interpreting clinical data and transforming it into a compelling and cohesive narrative for the sponsor. This narrative must detail the patient's complete experience

while on trial. We read through progress notes that tell us when a patient has experienced increased swelling in their legs, or that they have much more energy than they did during their last visit and were able to play a few rounds of golf that weekend. We delight in the triumphs of our patients and share in their sadness.

My heart swells when I see there is a decrease in disease on a CT scan report. I feel a grip of worry when reviewing hospital records. I am filled with hope when I see patients return for treatment – in these moments, I feel their determination, too.

The role of a data coordinator continues long after our patients come off trial. We may continue for years, combing through medical records for whatever information may be needed to get the drug approved. When the work becomes taxing, it takes only a moment of reflection to remember that the role I provide extends beyond myself and even beyond the realm of Mary Crowley. I am only a small part of a much larger movement, the foundation of which is laid by the patients we serve today. We are a part of the movement that is Hope.



Million Dollar Round Table

Thank you to longtime supporter Allan Newbury for endorsing Mary Crowley for a grant from the Million Dollar Round Table Foundation! Million Dollar Round Table Foundation is the charitable arm of the Million Dollar Round Table, The Premier Association of Financial Professionals. Mary Crowley received \$20,000 from MDRT and will use the funds to expand access to our clinical trials.



Wheel to Survive

Mary Crowley participated in Be the Difference Foundation's annual cycling fundraiser Wheel to Survive on February 24. This marks the fourth year the Mary Crowley Wheelers for Hope have ridden in this indoor cycling relay-style event. Taking turns on the bike, the Wheelers for Hope rode for 6 consecutive hours and raised money to fight ovarian cancer. The generous funds received from Be the Difference Foundation each year allows Mary Crowley to provide more research options to ovarian cancer patients than ever before. We are grateful for our continued partnership with Be the Difference to bring hope to ovarian patients!



Pictured: Team Mary Crowley Wheelers Rider Alli DeLuca

Dallas Stars Night

The Dallas Stars featured Mary Crowley Cancer Research at its game against the Nashville Predators on February 19 at the American Airlines Center. As the featured non-profit, Mary Crowley received half of the proceeds from its nightly 50/50 raffle sales, and the Stars showed a video about Mary Crowley on the big screen. Mary Crowley staff had a great time helping to sell raffle tickets and cheering for the Stars during the game and raised over \$5,000 for cancer patients!



Hello Shoppers!

Give the gift of HOPE each time you shop at your local Tom Thumb or Kroger. Link your Tom Thumb Reward card or your Kroger Plus Card to Mary Crowley and help fund cancer research.

To link your Kroger Plus Card visit:
<https://www.kroger.com/account/enrollCommunityRewardsNow>

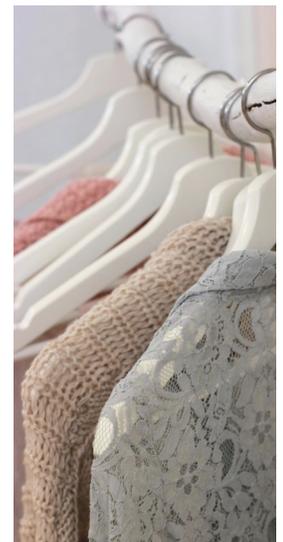
To link your Tom Thumb Reward Card, visit the Customer Service Counter at your local Tom Thumb to complete a program form and fill in Mary Crowley's charity number of 13757.

Use your card each time you shop. The more people who link their card to Mary Crowley's account number, the more money we will raise, and the more HOPE we will be able to provide.



Save the Date - Fashion Show

Keep an eye out for more information about Be the Difference Foundation's first annual fashion show benefitting Mary Crowley on September 26, 2019! It will feature the latest looks from Nordstrom's of the Galleria and Kendra Scott, as well as a piece specially designed by Kendra Scott just for this event!



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of innovative clinical trials.

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Cover Image: IHC of Survivin on an FFPE Colon Tissue provided with
permission from Bio SB, Inc.



Patient Story: Bob Umphred

If 58-year-old Bob Umphred is anything, he is a fighter with a great outlook on life. In May of 2009, Bob was diagnosed with **small intestinal mucinous adenocarcinoma**. A portion of his small intestine was removed, and Bob needed no additional treatment at that time. He had regular follow-up appointments with his oncologist, Dr. Stone, for the next three years. Unfortunately, at the end of the three years, the cancer had come back.

Bob then went through two rounds of chemotherapy. Two small tumors were found during this time, which were surgically removed. The cancer, however, had metastasized to his lungs. Dr. Stone suggested Bob contact Mary Crowley Cancer Research to see if there were any good trial options for him. Bob met with Mary Crowley physician investigator Dr. Minal Barve in July 2014, who consulted with him about the clinical trials for which he would be eligible.

Bob's cancer was unresponsive to the first trial he enrolled on, but he was not ready to give up yet. Bob enrolled onto a second trial, MC#13-04, which he has been on for three years now, and involves a daily dosing with an oral PI3K inhibitor (GDC-0032, aka Taselisib). He comes in to Mary Crowley every 28 days. He is considered to have **stable disease** per CT scans, and at this time he has not progressed on this study drug. Because he has minimal side effects, Bob continues to work full time and travels for business and for pleasure. When asked his impression of the staff at Mary Crowley, he said he felt welcomed and truly had a feeling of "caring." Bob has 100% trust in his doctors at Texas Oncology and Mary Crowley.

Bob and his wife Sharon just celebrated their thirty-first anniversary. Sharon is a quilter and has even won ribbons at quilt shows. Bob works at Depository Trust and Clearing as an IT Manager. He is from Long Island, New York, and lived there for 49 years, when he transferred to Dallas for work. He and Sharon have been in The Colony for the past nine years and said they should have moved here a lot sooner! Bob and Sharon, together, have a 29-year-old son, and Sharon has a 45-year-old daughter from a previous marriage.

Bob prides himself for having taken only a couple of days of sick time since his first chemotherapy treatment in 2012. Bob is truly a FIGHTER!

