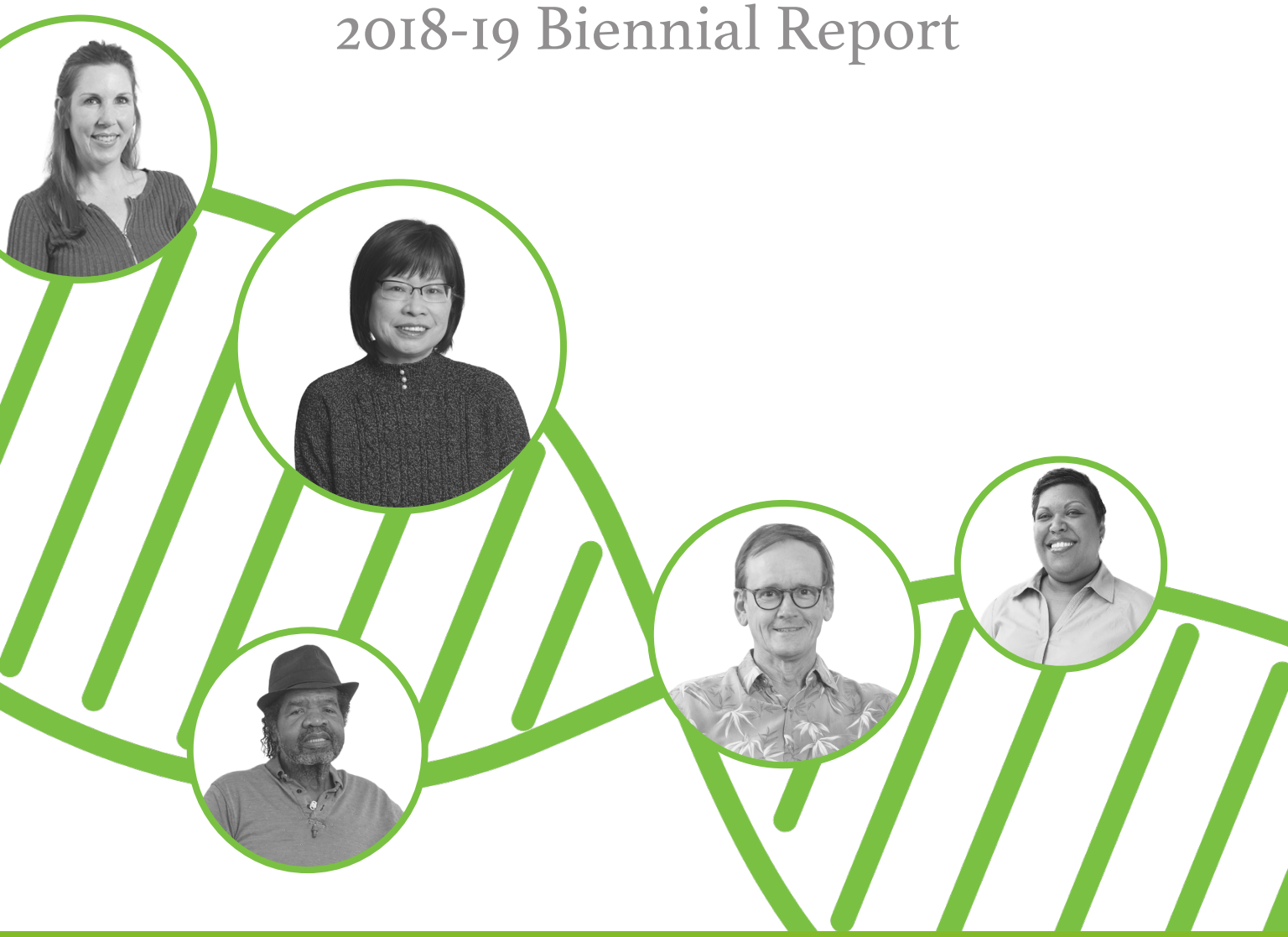
CONNECTION

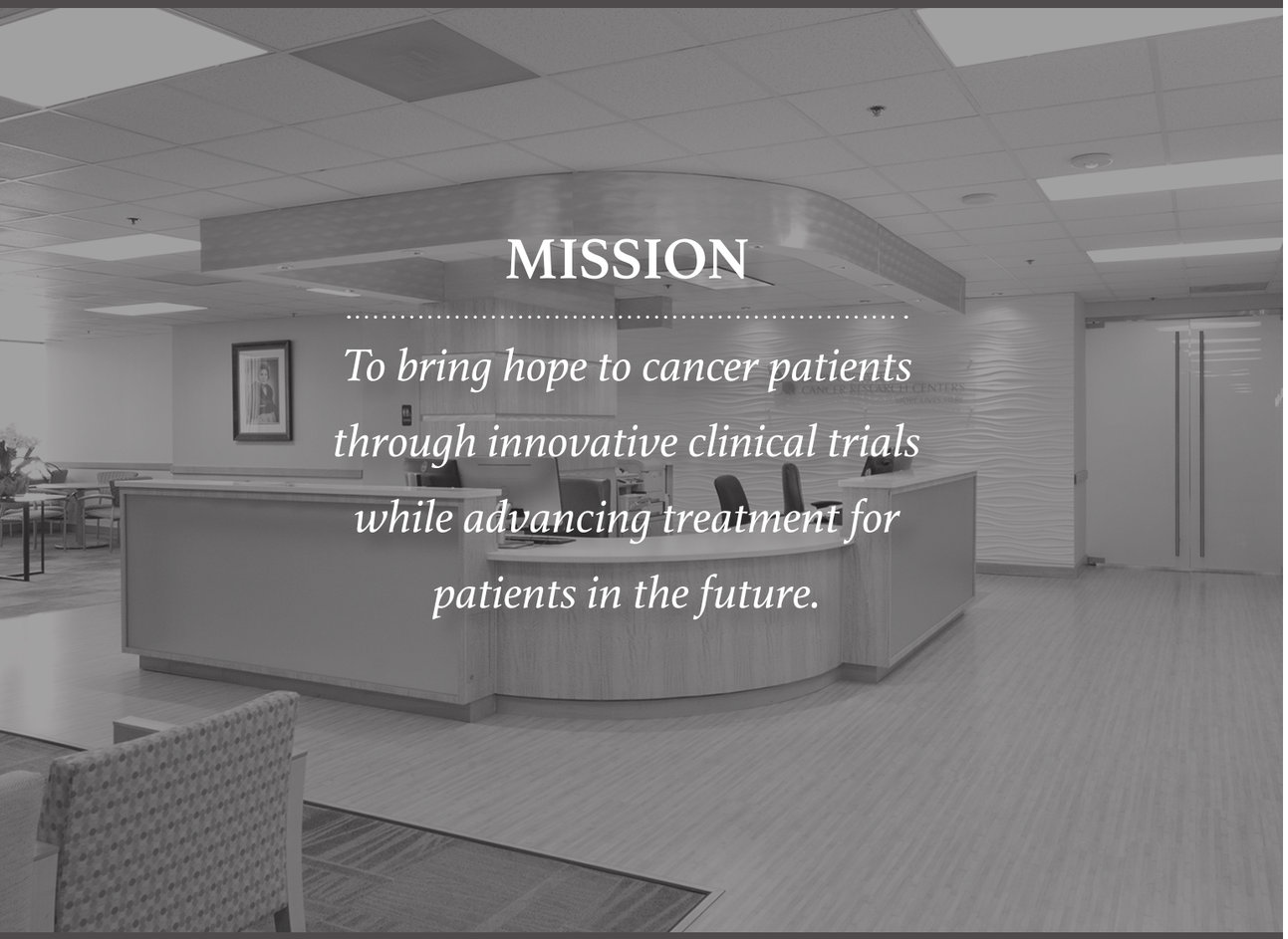
IN ACTION

2018-19 Biennial Report



MARY CROWLEY CANCER RESEARCH

HOPE LIVES HERE™



MISSION

To bring hope to cancer patients through innovative clinical trials while advancing treatment for patients in the future.

MARY CROWLEY CANCER RESEARCH
HOPE LIVES HERE™

CONNECTION
IN ACTION

A MESSAGE FROM THE CEO

BY THE NUMBERS

THE ROAD TO FDA APPROVAL

LOOKING FORWARD

- *A Note from the Chairman of the Board*
- *Up Next from our Executive Medical Director*
- *Trials with Promise*

PATIENT STORY

DONOR IMPACT

A MESSAGE FROM MERRICK REESE, MD
Chief Executive Officer

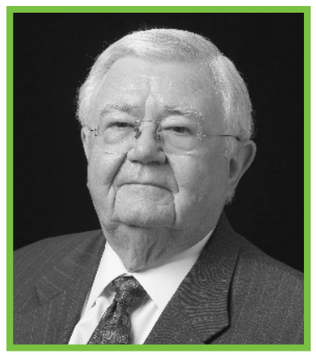
Mary Crowley Cancer Research has been fighting cancer for over 20 years, and we don't plan on stopping anytime soon. During that time, we have served over 7,000 patients, conducted 685 trials, and have been the starting place for at least 17 FDA cancer approved drugs through phase I and phase II clinical trials.

With access to these therapies, many of our patients have experienced a better quality of life as well as an extended lifetime and precious time with their families and loved ones. Our mission "to bring hope to cancer patients through innovative clinical trials while advancing treatment for patients in the future" is stronger than ever.

Earlier this year, we announced Dr. Minal Barve as our new Executive Medical Director. Dr. Barve has been with Mary Crowley for more than 14 years. In that time, she has helped hundreds of patients by guiding our clinical trial selection process as well as working directly with patients enrolled on our trials. Working closely with the staff at Mary Crowley, she has extended the lives of many, and we look forward to her leadership for years to come. She replaces Dr. Ashley Ross, who has been named the Associate Professor of Urology; Director of Urologic Oncology Center at Northwestern's Feinberg School of Medicine. This is an excellent opportunity for Dr. Ross, and we wish him the best of luck in his new endeavor. We are honored for Dr. Ross to continue his relationship with Mary Crowley as a board member, so that our patients may continue to benefit from his expertise.

We stand at an exciting time in Mary Crowley's history, as we find new ways to expand our reach in the community. We are broadening our trial offerings beyond solid tumors to include options for hematology patients. We are also opening more trials than ever in order to serve more cancer patients who so desperately need us. To reach these patients, we have focused our efforts on outreach to community oncologists, which increases our visibility and access to more patients than ever. This outreach is vital to our ability to fulfill our charitable mandate to serve the cancer community by helping to shepherd cancer research to FDA approval. To further achieve this goal, we have continuously found ways to streamline our processes and improve efficiency, ultimately allowing us to open trials in a matter of weeks, far speedier than the industry average of 6 months or more. Mary Crowley was founded to make a difference in cancer patients' lives, and we work every day with that mission in mind.

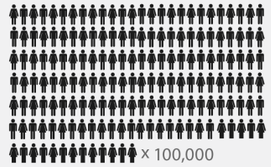
At Mary Crowley Cancer Research, we are proud to be able to serve cancer patients by offering them access to innovative clinical trials and cutting edge therapies. With the help of our patients, staff, and donors, we are able to provide tomorrow's treatment to those who need it today.



Merrick Reese, MD

CONNECTION
IN ACTION

BY THE NUMBERS



× 100,000

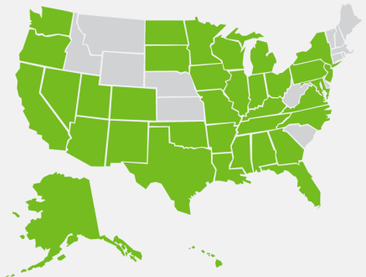
16,900,000+

US ADULTS AND CHILDREN ARE CANCER SURVIVORS[1]

OVERALL CANCER DEATH RATES DECLINE

FROM 1991- 2017
CANCER DEATH RATES DROPPED BY

29%[1]



PARTICIPANT ORIGIN
shown in green

COUNTRIES:
Argentina, Australia, Brazil, Canada, England, Germany, India, Mexico, Turkey

110
FIRST IN HUMAN TRIALS CONDUCTED AT MARY CROWLEY

698
OF CLINICAL TRIALS CONDUCTED, 1997-2020

7120
OF PARTICIPANTS ENROLLED, 1997-2019

141
PEER-REVIEWED PUBLICATIONS 2009-2020

TOP TEN TUMOR TYPES TESTED AT MARY CROWLEY

1. COLON & RECTAL
2. PROSTATE
3. PANCREATIC
4. BREAST
5. OVARIAN
6. NON-SMALL CELL LUNG
7. SARCOMA
8. SMALL CELL LUNG
9. UTERINE/ENDOMETRIAL
10. ESOPHAGEAL

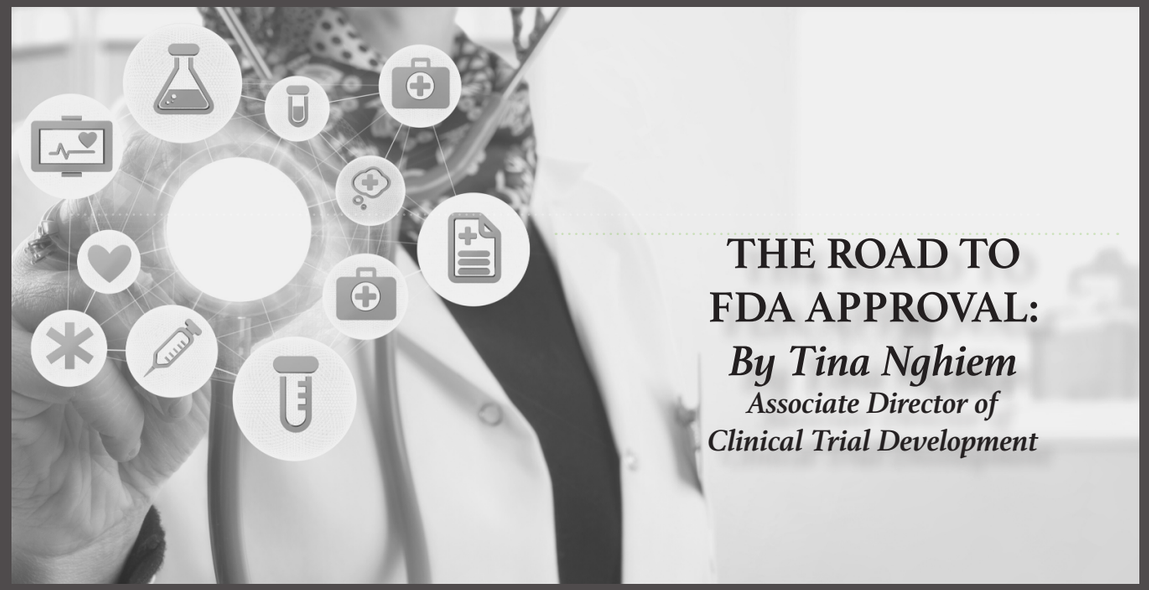
PARTNERED WITH **282** LEADING GLOBAL PHARMACEUTICAL COMPANIES

17
FDA-APPROVED CANCER DRUGS TESTED AT MARY CROWLEY

1. BAVENCIO
2. ROZLYTREK
3. LIBTAYO
4. CABOMETYX
5. LYNPARZA
6. NINLARO
7. PROVENGE
8. YERVOY
9. IMLYGIC
10. CAMPOSTAR
11. IMFINZI
12. PEMAZYRE
13. NIRAPARIB
14. TAZEMETOSTAT
15. ABEMACICLIB
16. LENVIMA
17. YONDELIS

1. Cancer Statistics 2019, National Cancer Institute

MARY CROWLEY CANCER RESEARCH



THE ROAD TO FDA APPROVAL:

By Tina Nghiem
Associate Director of Clinical Trial Development

As part of the U.S. Food and Drug Administration (FDA), the Center for Drug Evaluation and Research oversees the drug development process to ensure that brand-name and generic drugs are efficacious and that their health benefits outweigh their known risks.

To initiate the regulatory review process, pharmaceutical companies must have conducted preclinical research. This involves the testing of laboratory and animal models to determine whether the drug affects the intended target and to understand the basic toxicity profile. With satisfactory findings and intended study plans, the pharmaceutical company will file an investigational new drug application with the FDA. If the trial meets Federal standards, the FDA will approve the application, and the pharmaceutical company may proceed with conducting clinical research.

Clinical research refers to clinical trials that involve human volunteers. During phase I cancer trials, the drug is tested in a small group of patients, usually agnostic of tumor type, to evaluate safety and determine a safe dosage range. Then during Phase II cancer studies, the drug is administered at a dose determined from the previous phase I trial to a larger group of patients with the tumor type for which the drug is being developed.

Phase II studies provide additional safety data and initial efficacy data. Phase III cancer trials further expand the number of patients and continue to assess the safety and efficacy of the drug against either a placebo or the existing standard of care.

Following results from the phase III trial, the pharmaceutical company will file a new drug application with the FDA. The pharmaceutical company will also submit labeling information: safety data, efficacy data, dosage, and the indication for intended approval. If everything is acceptable, the FDA will approve the marketing of the new drug for the specified indication. Now, the oncologist can prescribe the drug to patients.

Mary Crowley Cancer Research has been active in the drug development process for over 20 years and specializes in performing phase I and II cancer trials. Before visiting Mary Crowley, cancer patients have received standard of care/approved therapies with their primary oncologist. Upon disease progression, phase I or II trials will be the best option because the patient can access an investigational drug years prior to approval. Mary Crowley will continue to bring hope to cancer patients by offering innovative phase I and II trials for patients in need of additional treatment options.

MARY CROWLEY'S CAPABILITIES AND THE FUTURE OF CLINICAL CANCER TRIALS:

A note from Roy Lamkin, Chairman of the Board

I believe that Mary Crowley is one of the premier 501(c)(3) cancer charities in not just Dallas-Fort Worth, but the entire Southwest. Let me explain why I am so enthusiastic about what Mary Crowley is doing for cancer patients.

These are exciting times at Mary Crowley! In 2019 we saw a growth of 30% in new trials, an expansion of our Board capabilities, including broadening Board involvement in awareness, oversight, and active participation, and an updating of our Mission Statement to align with the rapid evolution of technologies. Our team is strong and dedicated, and the Board is both actively involved in offering their guidance and expertise as well as supporting the Mission financially; EVERY Board member is an active donor.

We have reexamined and reevaluated all aspects of what Mary Crowley does to aid cancer patients. A thorough review of our capabilities has highlighted four distinct areas that differentiate Mary Crowley from other cancer research clinics:

1. We are NOT a classic "research" organization. We implement new, leading-edge phase I and II clinical trials under the guidance of experienced professionals in close coordination with the patient's personal oncologist.

2. As an independent organization, we process new trials more than twice as fast as the industry average, providing life-altering trials to needy patients more rapidly than our peers.

3. We are not restricted to a limited type of cancer trials. We treat a vast array of cancer patients, and we do so in a personalized and service-oriented manner.

4. Located within a hospital system complex, we provide seamless support for overnight stays and any additional analysis that goes beyond the normal trial requirements.

As cancer treatments and trials evolve, we are now seeing a movement towards trials more frequently being offered in lieu of standard-of-care treatments for patients not in the latter stages of cancer, making the importance of having phase I and II trials available even more significant. So, as we move forward, the abilities of Mary Crowley that differentiate us from our peers take on even more significance.

An important footnote to this is the impact that the COVID-19 pandemic has had on the availability and well-being of cancer patients participating in our trials. Many university and independent cancer research centers had to curtail or even stop offering phase I or II trials because of safety and availability concerns. Mary Crowley's team of dedicated professionals took extraordinary steps to ensure safe and reliable trials not only continued for existing patients, but that new trials were added for new cancer patients. In this manner, hope remained alive for both current and prospective cancer patients.

I encourage you to learn more about the efficacy of phase I and II clinical trials and to explore what Mary Crowley is doing to "bring hope to cancer patients through innovative clinical trials while advancing treatment for patients in the future."

Roy Lamkin

UP NEXT:
A Scientific Outlook from Executive Medical Director Minal Barve, M.D.

Coming to Mary Crowley Cancer Research 15 years ago has been one of the most rewarding things I have done in my career. My true love is research and science, and Mary Crowley has given me the ability to help patients in real-time. With the help of compassionate and competent staff at Mary Crowley, we have been able to extend the lives of many.

At Mary Crowley, we are proud to offer patients access to some of the most innovative trials in the country. Over the last two years, our primary focus has been in developing targeted trials, combination immunotherapy trials as well as antibody drug conjugates. We have also expanded into the hematology space from our previous focus on solely solid tumors.

Additionally, as of the end of 2019, Mary Crowley is participating in Just-In-Time (JIT) programs. The requirement for opening a JIT trial at our site is that we must have an eligible patient pre-identified for that trial. This is in contrast to a traditional trial where patients are not screened until after the site is activated for opening. Initiating the JIT method gives Mary Crowley two major advantages. First, we have access to a larger number of potential trials which offers more options for our patients. Secondly, once an eligible patient is identified, the JIT trial will be opened at our site in a matter of only two weeks. We recently placed our first patient on a JIT trial and look forward to growing this exciting new program.

Looking forward, we will continue to bring new and scientifically sound clinical trials for our patients. We will continue to expand our offerings for solid tumors, while also adding a new focus on trials for lymphoma and myeloma. I am honored to have the opportunity to serve as the Executive Medical Director for Mary Crowley Cancer Research. In my time here, the work that each and every staff member does to help improve patient's lives has continued to amaze me on a daily basis. Everyone, whether they work directly with the patient or serve on the regulatory and administrative side, truly strives to provide hope to cancer patients. It is my hope that we can continue to grow by opening more innovative clinical trials and helping more and more patients until the day that a cure for cancer is found and we are not needed anymore.

Minal Barve, M.D.

TRIALS WITH PROMISE:
Working on Tomorrow's Treatments Today

Our physician investigators and trial development team work hard to identify and recruit the most promising trials to bring to our patients, some of which are highlighted below.

Study #18-26

A phase I/II trial targeting the KRAS G12C mutation, which causes uncontrolled cellular growth and malignant transformation. This therapy has demonstrated inhibition of tumor cell growth and viability in cells harboring KRAS G12C mutations and broad spectrum antitumor activity across a panel of KRAS G12C-positive tumor models.

Study #19-09

A phase I study of CTX-471 in patients with inadequate responses to PD-1/PD-L1 checkpoint inhibitors. Immuno-oncology therapies that activate costimulatory receptors may help patients who failed PD-1/PD-L1 therapy. CTX-471 targets CD137, a costimulatory receptor that enhances the cytotoxic effector function of T cells and has long been considered a promising target for cancer immunotherapy.

Study #19-05

A phase Ib, first-in-human study of XMT-1536 in patients with solid tumors likely to express the NaPi2b protein, often found in ovarian epithelial cancer, nonsquamous NSCLC, and papillary thyroid cancer. Upon binding of XMT-1536 to NaPi2b, XMT-1536 releases a cytotoxin that is highly toxic to dividing cells, while also killing neighboring cancer cells via "bystander-effect" killing.

Study #19-12

A phase I/II study of LOXO-305 in patients with previously treated chronic lymphocytic leukemia/small lymphocytic lymphoma or Non-Hodgkin lymphoma. BTK is overexpressed or mutated in B-cell malignancies. Unlike current approved BTK inhibitors, LOXO-305 is a reversible, non-covalent BTK inhibitor that preserves activity in the presence of the C481-acquired resistance mutations and avoids off-target kinases.

"Everybody, from the receptionist to the people that work with you, is just so kind and caring."

Sandra Peeples, Patient

SANDRA'S CANCER JOURNEY:
Five-Year Survivor Beating the Odds with a Combination Clinical Trial

Sandra Peeples was 10 years into enjoying her retirement from teaching when a visit with her family in East Texas took a distressing turn. She awoke with a strange pain in her lower abdomen that wouldn't go away. "Meme is always very active, and my grandkids realized she was not herself," she remembers.

She made an appointment with her gastrologist when she returned to Dallas the next week. They promptly scheduled a CT scan suspecting colitis, "and there it was. A big mass on my ovaries." It was June of 2015, and Sandra was diagnosed with stage 3C aggressive ovarian cancer.

She was referred to oncologist Bruce Fine, M.D., at Medical City, and just one week after her diagnosis, she was in surgery. She spent 12 days in the hospital and started chemo three weeks later. Around nine months after her initial treatment, her CA 125 began to rise, and they found the cancer had spread to her abdomen. She started a different chemotherapy regimen, which again worked well for around nine months when her doctor expressed that it might be time to try something new.

She decided to try a therapy regimen that was proving successful from a center based in Houston. Before she could even begin, they called to let her know that her CA 125 levels were rising rapidly and had shot up to over 1000. Once on the plan, that level dropped dramatically, leaving both her and Dr. Fine elated.

Unfortunately, the excitement was short-lived. In the Fall of 2019, her levels began to rise again. Having explored so many options, Dr. Fine was hesitant to return to the same treatments. She recalls him saying, "Sandy, you've had so much chemo that I'm afraid if I give it to you next time, you might die." Sandra asked, "If I don't do anything, how many months do I have?" to which Dr. Fine responded, "Two."

He suggested a new route, a clinical trial at Mary Crowley Cancer Research. She was interested but wanted to hear some success stories first, and Dr. Fine instantly recalled a patient whose life was extended for five years after a trial at Mary Crowley. With that, she was ready.

After a swift referral and screening process, Sandra began Trial #18-23, a combination immunotherapy trial targeting advanced and recurrent solid tumors. Her CA 125 levels steadily dropped and have remained more stable than in the past. She has also been enjoying a higher quality of life with few side effects, "I feel great!" Before the pandemic, her sister Joyce accompanied her to appointments, and now her husband Joe joins her for each one. Joe and Sandra have been impressed with the additional safety measures put in place in response to COVID-19. "Everybody has a mask on. Everybody is 6 feet away. You feel very safe."

In addition, Sandra has grown close to the staff and medical team at Mary Crowley. She's been thrilled with her treatment and cannot stop singing their praises, "Everybody, from the receptionist to the people that work with you, is just so kind and caring. It's a very loving place."

When Trial #18-23 closed, the doctors at Mary Crowley had another option lined up for her in 19-07, a combination trial targeting advanced solid tumors that she has begun.

While the pandemic has meant a quieter lifestyle, she's still able to enjoy distanced visits and regular FaceTime calls with family, friends, and her treasured grandchildren and great-grandchild. Even in a tough year, she finds reasons to celebrate saying, "I have a wonderful support group. You have to. And I have God!"

Sandra Peeples has shown immense strength throughout her cancer journey and is looking to her future with HOPE!

MARY CROWLEY MEDICAL RESEARCH CENTER AND AFFILIATES
CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As of December 31, 2018 and 2019

Assets

CURRENT ASSETS	2019	2018
Cash and cash equivalents	$ 2,944,760	$3,648,777
Investments in securities	1,375,415	1,132,152
Accounts receivable	4,293,161	3,121,894
Contributions receivable	74,675	86,772
Prepaid expenses & other current assets	55,693	51,964
Total current assets	8,743,704	8,041,559
PROPERTY AND EQUIPMENT (NET)	**249,164**	**307,682**
OTHER ASSETS		
Deposits	30,432	30,432
Total other assets	30,432	30,432
TOTAL ASSETS	**9,023,300**	**8,379,673**

Liabilities and Net Assets

CURRENT LIABILITIES		
Accounts payable	799,235	655,519
Accrued expenses	336,390	449,826
Deferred revenue	276,706	
Total current liabilities	1,412,331	1,105,345
NET ASSETS		
Without Donor Restrictions	5,777,969	5,405,746
With Donor Restrictions	1,833,000	1,868,582
Total net assets	7,610,969	7,274,328
TOTAL LIABILITIES AND NET ASSETS	**9,023,300**	**8,379,673**

MARY CROWLEY MEDICAL RESEARCH CENTER AND AFFILIATES
CONSOLIDATED STATEMENT OF ACTIVITIES

For the Year Ended December 31, 2019
With summarized financial information for the year ended December 31, 2018

	Without Donor Restriction	With Donor Restriction	Total All Funds 2019	Total All Funds 2018
SUPPORT AND REVENUE:				
Research revenue	$7,353,904	$831,744	$8,185,648	$7,973,777
Contributions and grant revenue	604,901	567,104	1,172,005	1,170,610
Interest income	51,719	-	51,719	59,906
Realized gain on investments	16,941	-	16,941	5,158
Unrealized gain (loss) on investments	213,386	-	213,386	(159,336)
Net assets released from restrictions	1,434,430	(1,434,430)	-	-
Total support and revenue	9,675,281	(35,582)	9,639,699	9,050,115
OPERATING EXPENSES:				
Program				
Medical & research	7,181,812	-	7,181,812	7,589,992
General & administrative	1,755,162	-	1,755,162	2,076,511
Fundraising	371,787	-	371,787	291,453
Total operating expenses	9,308,761	-	9,308,761	9,957,956
Changes in net assets from operations	366,520	(35,582)	330,938	(907,841)
Other income (expense)	5,703	-	5,703	6,682
INCREASE (DECREASE) IN NET ASSETS	372,223	(35,582)	336,641	(901,159)
NET ASSETS, beginning of period	5,405,746	1,868,582	7,274,328	8,175,487
NET ASSETS, end of period	**5,777,969**	**1,833,000**	**7,610,969**	**7,274,328**

Donor Spotlight: Be the Difference Foundation
Supporting a future for all ovarian cancer patients!

In 2015, Be the Difference Foundation and Mary Crowley Cancer Research came together as partners and have remained so to this day. Both agencies are committed to providing hope to ovarian cancer patients and improving treatment options for the patients that so desperately need them.

Be the Difference Foundation was formed in 2012 by four ovarian cancer survivors, Helen Gardner, Jill Bach, Julie Shrell, and Lynn Lentscher, who share the same passion to Be the Difference in the fight against ovarian cancer. These women experienced first-hand the little hope given for survival when they were diagnosed. Several organizations focus on early detection efforts, but very few organizations provide hope to women in the fight. Be The Difference Foundation was started to give survivors hope: Hope for better treatment options; hope for longer remissions, and ultimately hope for a cure. Just five years after diagnosis, Co-founder Helen Gardner lost her battle in August 2014. Be The Difference Foundation is working tirelessly to realize Helen's dream to make a difference in the fight against ovarian cancer. Their mission is "to create awareness and improve the lives of all people affected by ovarian cancer through education, support, and research".

Since 2015, Be the Difference Foundation has given Mary Crowley close to half a million dollars in financial support to conduct Phase I and Phase II trials for ovarian cancer. In 2019, the chairman of the Be The Difference Foundation board, Lynn Lentscher, came to Deborah Montonen, Vice President and Chief Development Officer at Mary Crowley, and said she had an idea. That idea was a fashion show and luncheon to support ovarian cancer awareness. These two ladies, sitting at lunch, planned the entire event on the back of a napkin. The result was the inaugural Runway For Hope.

Runway For Hope is a celebration of those bravely battling ovarian cancer and a rallying cry to support the future of cancer care. The September 2019 event quickly sold out and helped bring awareness to the cause as well as a significant gift to help Mary Crowley Cancer Research open more ovarian cancer clinical trials. "As our inaugural event, there was no question who we wanted as the beneficiary from Runway For Hope," said Lentscher. "Mary Crowley Cancer Research matches our mission of raising hope and creating awareness for ovarian cancer with a quick and personal response to women facing this insidious disease." The event was such a success that it will be repeated annually for years to come.

Mary Crowley Cancer Research is grateful for a supporter, partner, and fellow fighter in the battle against ovarian cancer. Vice President and Chief Development Officer Deborah Montonen, CFRE, affirms, "because of the great partnership with Be the Difference Foundation, Mary Crowley Cancer Research has been able to serve more ovarian cancer patients by opening more ovarian clinical trials. We are extremely grateful for their support and look forward to this partnership for many years to come."

From the staff, board, and patients of Mary Crowley Cancer Research, thank you to Be the Difference Foundation for your unwavering support. You are truly making an impact on the lives of cancer patients today and helping to bring new treatment options to ovarian cancer patients in the future!

be the difference foundation.
Raising Hope. Targeting Ovarian Cancer.

CONNECTION
IN ACTION

DONOR SUPPORT:
The Impact You Make

Deborah Montonen, CFRE
Vice President and Chief Development Officer

Since I started to work at Mary Crowley Cancer Research more than two years ago, I have seen how vital this agency is in the world of cancer clinical trials. Mary Crowley Cancer Research is a specialized clinical research center that offers access to new investigational therapies through the administration of phase I and II clinical trials. Our approach is to rapidly advance the discovery of potential new therapies and positively impact the care of cancer patients in their lifetime.

For those of you who don't know, there are four phases of cancer clinical trials. Without the work that we do at Mary Crowley, potential cancer drugs would not happen. There are more than 17 cancer drugs that have started in phase I clinical trials at MCCR and gone on through the next three phases to become FDA approved cancer drugs. How amazing is that!

Our donors have made all of this work possible, and for that, we thank you! YOU are the reason Mary Crowley Cancer Research continues to conduct clinical trials.

OUR LEADERSHIP

Merrick Reese, M.D., Chief Executive Officer

Minal Barve, M.D., Executive Medical Director

James Strauss, M.D., Clinical Scientific Director

Deborah Montonen, CFRE, Vice President and Chief Development Officer

Jeanne Jones, RN, MSN, Vice President of Clinical Operations

Angela Ebel, Vice President of Research Operations

Jennifer Sala, MBA, Vice President of Compliance

Amber Craft, MBA, Controller

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Merrick Reese, M.D.

Mary Elizabeth Warner, J.D.

MEDICAL STAFF

Minal Barve, M.D., Executive Medical Director

James Strauss, M.D., Clinical Scientific Director

Reva Schneider, M.D., Physician Investigator

Jairo Olivares, M.D., Physician Investigator

Douglas Orr, M.D., Physician Investigator

Maurizio Ghisoli, M.D., Physician Investigator

Leah Plato, P.A., Associate Director of Clinical and Scientific Operations

MARY CROWLEY CANCER RESEARCH
HOPE LIVES HERE

www.marycrowley.org

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