

ADVANCING
PERSONALIZED
M E D I C I N E



2014-15 Biennial Report

MISSION

*Expand treatment options
for all cancer patients
through investigational vaccine,
gene and cellular therapies*

ADVANCING
PERSONALIZED
MEDICINE

HISTORY
OUR PATIENTS
PERSONALIZED MEDICINE
LOOKING FORWARD
OUR SUPPORTERS
HOPE



Mary C. Crowley (standing) conducting a Home Interiors & Gifts Home Show, c. 1957. Mary created a culture of excellence and integrity by training her employees in professional and interpersonal skills. Through her resilience and faith, Mary built a legacy of HOPE.

A LETTER FROM SHANNON CAGNINA, *Chief Operating Officer*



Mary C. Crowley impacted thousands of lives with her life's purpose to *honor God and bless and serve others*. Her heartfelt passion for the beauty of human life and the value of each individual continue today in ways she never could have dreamed.

At Mary Crowley Cancer Research, we are unlocking mysteries in the human genome that may allow the eradication of cancer. Our vision will persist until we harness scientific innovation toward a personalized treatment for each cancer patient.

For 20 years, Mary Crowley has been testing innovative molecular therapeutics in clinical trials for cancer patients, applying pioneering science in immunology and gene therapy. What was outside the box in 1997 has become routine, as we shoot for the moon to capture and understand genomic information for each individual patient. It's thrilling to see the *alignment* of a patient's individual molecular profile, from their own tumor tissue, to a therapy exquisitely designed to block the abnormalities in their cancer cells.

As we do this anecdotally and learn from each patient in each trial, we are working to build a molecular registry of patients that will allow us to assimilate the information and apply what we learn to every patient in the future. As our Trustee Merrick Reese, M.D., said recently, "it's exciting for physicians to come to work and see patients for whom we had no treatment at all a few years ago, but whose tumors are melting away with the new molecular therapies."

At Mary Crowley, we will pursue the understanding and application of molecular information until every patient has a beneficial treatment option. We believe that Hope is not weakness, nor based in wishful thinking, but represents a powerful discipline of heart and mind. Because we value every life, *HOPE lives here*.

Shannon Cagnina
Chief Operating Officer

MARY CROWLEY CANCER RESEARCH RIBBON CUTTING CEREMONY, 1997



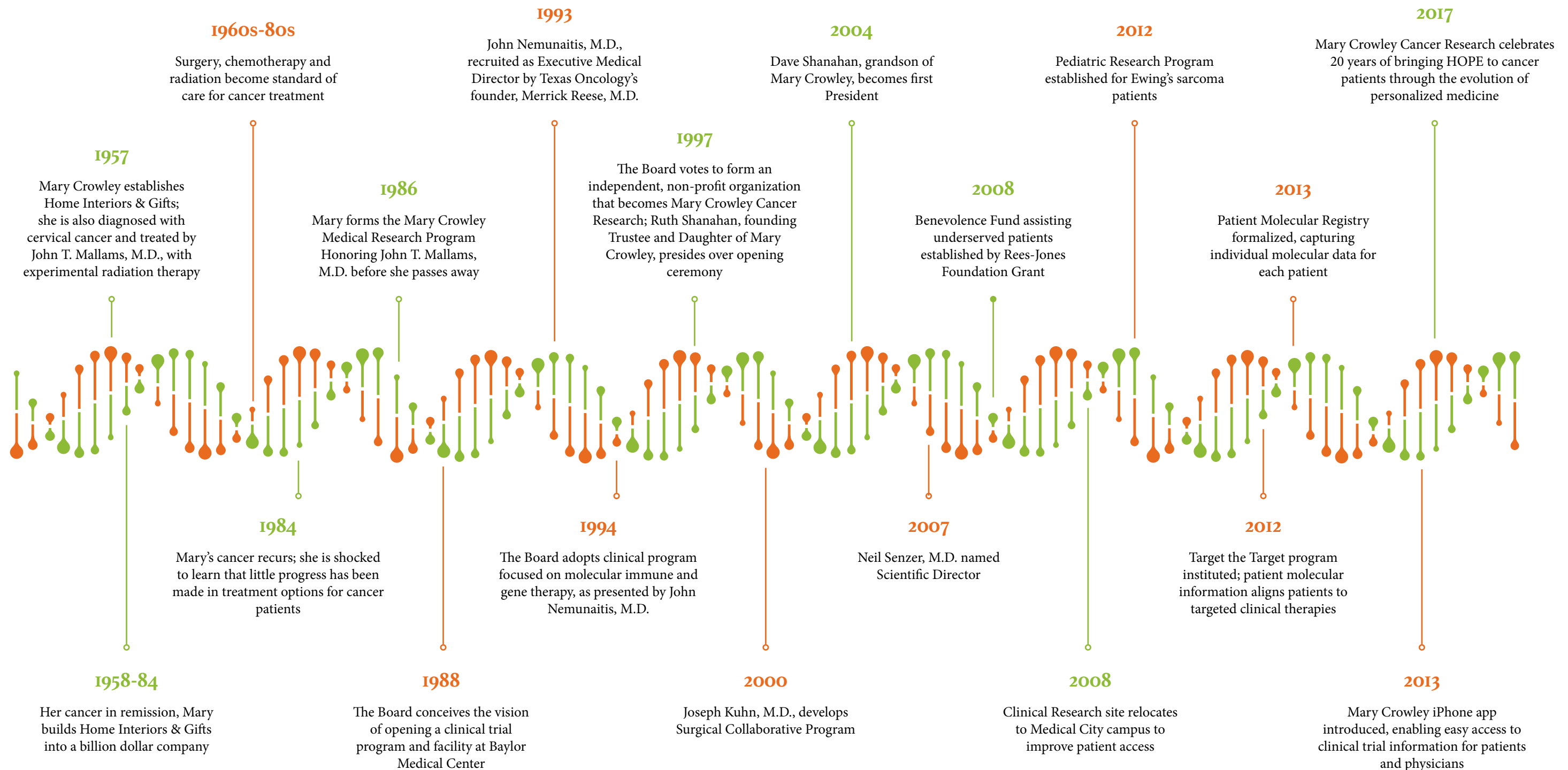
(Front) Lane Newsome; Patient Grover Cummings; **MARY'S DAUGHTER, RUTH SHANAHAN**; John T. Mallams, M.D.
(Back) Joel Allison; Harold "Hal" Urschel, Jr., M.D.; M. Douglas Adkins, J.D.; John Nemunaitis, M.D.; Gary Brock



Mentors of John Nemunaitis, M.D.: Merrick Reese, M.D., Founder of Texas Oncology, and E. Donnell Thomas, M.D., Director Emeritus of Clinical Research at Fred Hutchinson Cancer Research Center in Seattle, WA, and 1990 Nobel Laureate for Medicine

ADVANCING PERSONALIZED MEDICINE: A Timeline for *HOPE*

Mary Crowley dreamed of helping future generations of cancer patients gain access to the latest scientific advancements. Mary Crowley Cancer Research fulfills this legacy of *HOPE* by advancing personalized medicine.



GROVER'S CANCER STORY: *Against All Odds, A 20-Year Survivor*

Grover L. Cummings is a legend at Mary Crowley as one of the first patients enrolled on a clinical trial at the center. But that is not the only reason we remember him. We pay tribute to Grover because of his determination to survive cancer just long enough to walk his daughter, January, down the aisle on her wedding day. His physicians had only given him six months to live, and January's wedding date was fast approaching.

In 1994 at the age of 55, Grover discovered a lesion on his back. His physician said it was nothing to worry about, but after it bled a few times, Grover insisted his physician remove it. His physician then discovered that the lesion was, in fact, melanoma. From 1994 to 1996, Grover underwent four more major surgeries. The melanoma first metastasized to his lung, where the tumor was surgically removed along with some of his ribs. Then Grover began chemotherapy. Not long after the lung surgery, the melanoma appeared in his intestines, and a portion was removed surgically. The third time his cancer appeared, the Chief of Surgery said there was no point in operating because the cancer would just keep returning. However, Grover was able to find one surgeon who was willing to remove an encapsulated tumor between his kidney and liver.

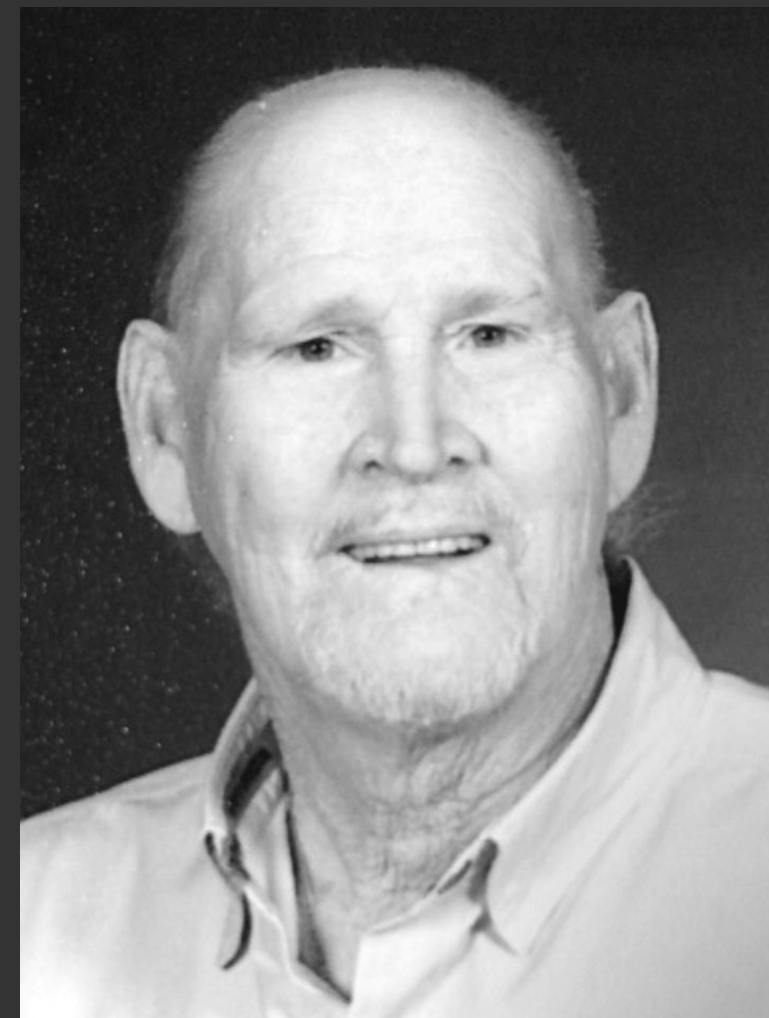
Grover, the 6'4" gentle giant, was not ready to give up, though he had not yet discovered that his melanoma had progressed to his brain stem. A physician told Grover he might be a candidate for a new clinical trial. Acting on his advice, Grover found his way to an office filled with unopened boxes and Dr. John Nemunaitis. It was there that he asked the young oncologist, brought to Dallas to conduct cancer research, to keep him alive so that he could walk his daughter down the aisle. Dr. Nemunaitis accepted the challenge.

However, scans revealed that the cancer had progressed to his brain which had to be removed before the clinical trial could commence. Dr. Nemunaitis called several neurosurgeons before finding one who would remove a brain tumor from a terminal cancer patient. This was Grover's fourth surgery, which was followed by full brain radiation. The radiation was extensive, but patients like Grover were not supposed to live long enough to experience its long term effects.

Dr. Nemunaitis subsequently enrolled Grover onto the clinical trial that he hoped would keep him alive through the wedding. The clinical trial seemed to work, and Grover and Dr. Nemunaitis were elated. **HE WALKED HIS DAUGHTER DOWN THE AISLE.** Grover continued to improve year after year with no evidence of cancer. The rest is a 20 year history. Grover lived to enjoy the birth of January's daughter, who turned eighteen in 2015, and he continued to spend time with his wife Joyce, the love of his life; his three children, Norma, Jimme and January; seven grandchildren and one great-grandson.

Grover's second wish was **not** to die of cancer. He received that wish as well. In his last years, Grover began to have periodic brain seizures, due to the radiation dose he previously received. Grover died on December 7, 2015, of pneumonia and not cancer. He was 75.

What better way to commemorate the 20th anniversary of Mary Crowley than to reflect on Grover's 20-year survival and the **HOPE** he gave to all of us.



(Left to right) Grover and January at the wedding; Grover welcomes January's daughter, Angelica; January, Grover, wife Joyce and Angelica, who was 18 years of age in 2015

GROVER L. CUMMINGS

Grover was the fourth Mary Crowley patient to be enrolled on a clinical trial and a participant in the official opening of Mary Crowley Cancer Research in 1997 (see page 7 of this report).

PATRICIA'S CANCER JOURNEY: *Beating the Statistics through Immunotherapy*

In 2004 Patricia noticed a small mole on the heel of her foot that over the next three years grew to a 4" x 3" tumor. Patricia was a busy lady. She was living in San Antonio, working full time, and going to school part time. One day the tumor burst, requiring her to seek medical attention. On January 14, 2008, Patricia learned from her physician that she had Stage III-B melanoma and to expect a 6 -12-month survival. Over the course of that year, Patricia underwent five surgeries to remove numerous tumors throughout her leg. She started chemotherapy treatment in November 2008 for three months which caused her to have severe depression.

By July 2009, more tumors had appeared, and her physician recommended a nine hour surgery followed by a clinical trial with an oral chemotherapy. Soon after the surgery, it was discovered that the cancer had spread to her abdomen and right arm. She had two more surgeries including reconstruction surgery and another melanoma treatment regimen.

The tumors kept returning, so her physicians suggested a clinical trial. She enrolled in several immunotherapy trials in San Antonio. The first trials were unsuccessful; however, a subsequent trial proved to be effective. In August 2014, her husband was transferred to Dallas, and fortunately Patricia was able to enroll in the same immunotherapy trial at Mary Crowley in Dallas.

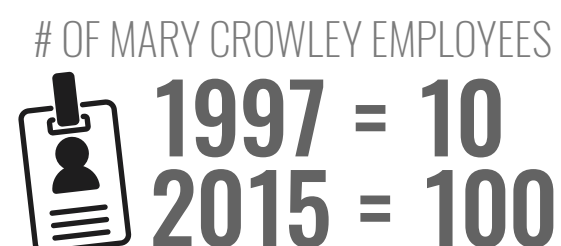
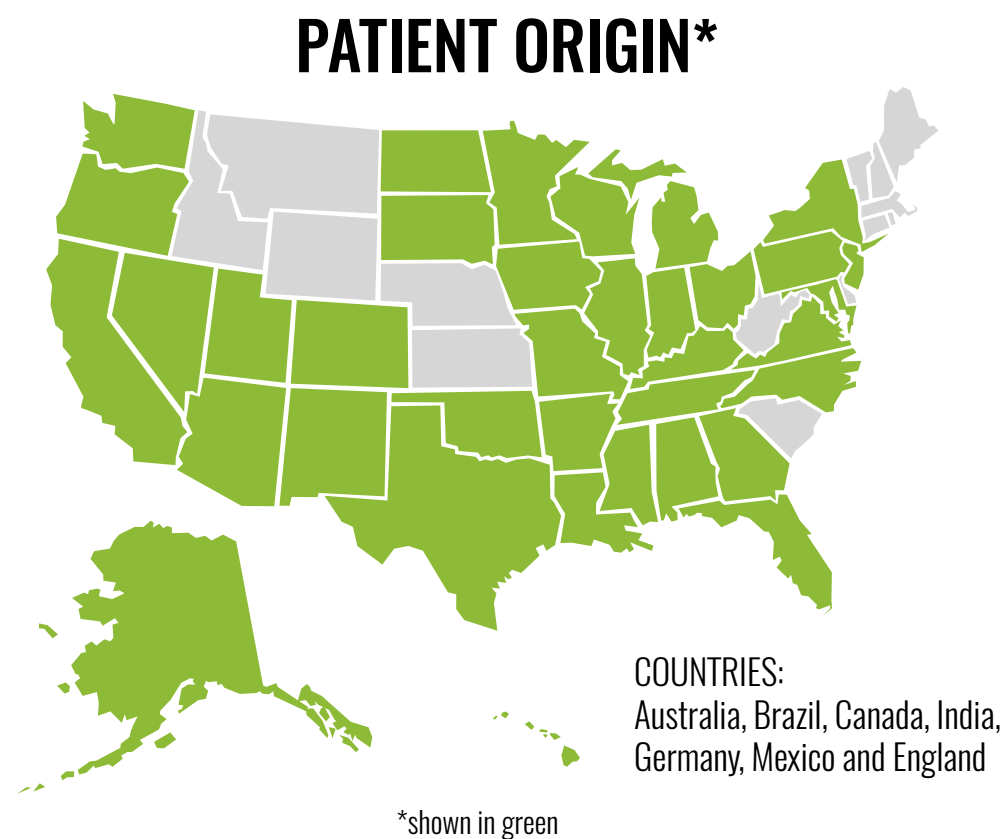
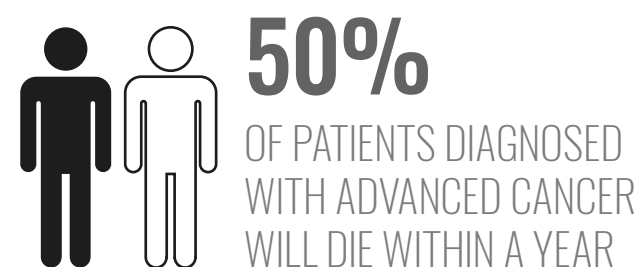
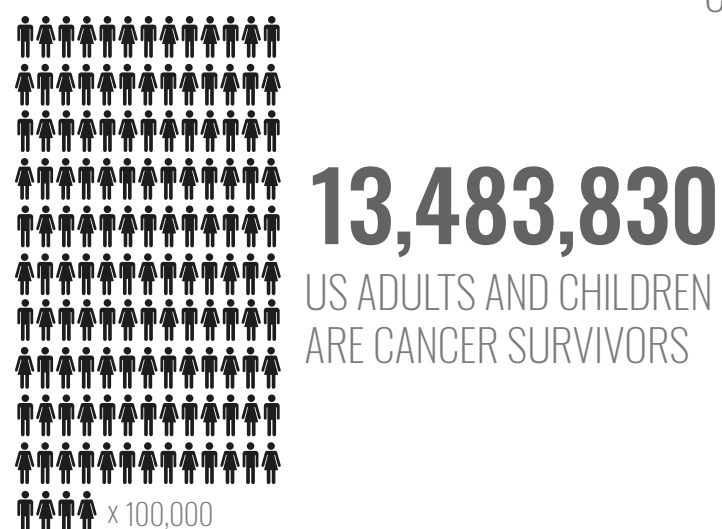
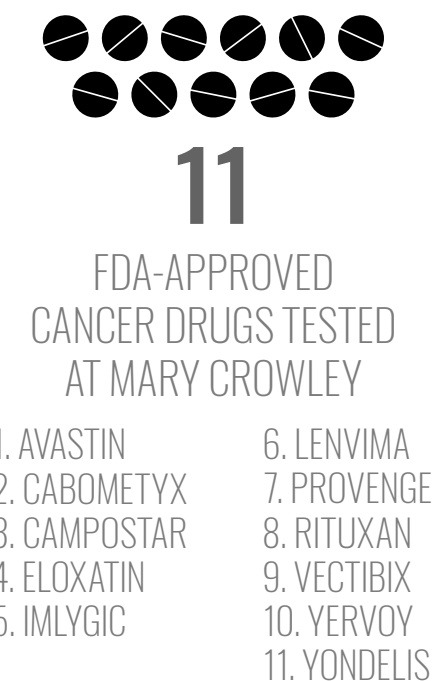
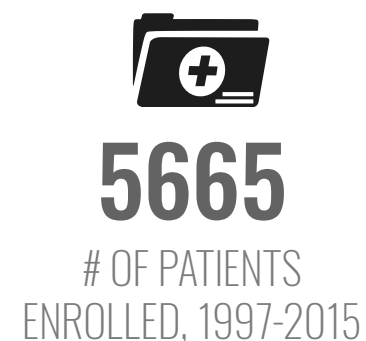
Patricia had only two tumors remaining, and immunotherapy appeared to be shrinking them. In November 2015, she was doing so well she was able to stop her clinical trial while still under the observation of Mary Crowley physicians. To offset some of her transportation and medication costs, Patricia received support from Mary Crowley's Benevolence Program.

Patricia says, "Mary Crowley has been wonderful to me. Their caring and loving support has been a blessing. When the physicians said NO in 2008, God said YES." She gives God the credit for these last eight years. Only 0.01% of African Americans are diagnosed with melanoma, and the statistical survival rate is five years. After 23 surgeries and many treatment options, Patricia has beaten these statistics!

"Mary Crowley has been wonderful to me. Their caring and loving support have been a blessing."

Patricia Wilcox, Patient

1 OUT OF 2 MEN
1 OUT OF 3 WOMEN
WILL BE DIAGNOSED WITH CANCER



JESSICA'S CANCER JOURNEY: *Thriving After Stage IV Ewing's Sarcoma*

It all started when Jessica began experiencing pain in her lower back. Her physician initially diagnosed her with bronchitis and possible growing pains for a 13 year old. When the pain became severe, her family rushed her to the emergency room thinking her bronchitis had progressed to pneumonia. It was there on December 24, 2013, they learned that Jessica had Stage IV Ewing's sarcoma with a tumor the size of a basketball wrapped across her chest, blocking 80% of her airway. The physician told the family that if they did not start chemo right away, she would probably not make it through the week, and with treatment, she only had two to six months to live.

After receiving emergency chemotherapy, Jessica began the standard frontline regimen of chemotherapy for four months to shrink her tumor. It was during this time that her family began doing their own research on the internet and found Mary Crowley Cancer Research's Phase I immunotherapy vaccine trial for Ewing's sarcoma. Once Jessica completed her frontline treatment in the summer of 2014, the family drove from Georgia to Dallas for a consultation with Mary Crowley, and Jessica enrolled in the trial. She had surgery to remove her tumor, and a portion of the tissue was used to manufacture a personalized vaccine. The vaccine was then stored for later use, as Jessica needed to have additional chemotherapy and radiation to rid her body of as many cancer cells as possible.

Her stepmother was to begin military training in Texas, and the family also wanted Jessica to move to Texas to receive proton therapy which was unavailable in Georgia. However, due to the short assignment, the military would not pay for the family to move to Texas. Jessica's father spent his retirement savings so Jessica could receive treatment and the family could be together. Unfortunately, Jessica was diagnosed with pneumonia while receiving this treatment. She recovered, and the family moved to Seattle, Washington, for the next military assignment. One month later Jessica was diagnosed again with pneumonia and was in a coma for three months. Thanks to the excellent care she received on the military base Jessica miraculously pulled through, and after only a week of rehabilitation she was feeling well.

In February 2015, Jessica returned to Mary Crowley to receive her first of six monthly vaccines. The immunotherapy educates and boosts her immune system to fight the cancer. On April 8, 2015, Jessica's scans showed that she was CANCER FREE!

After overcoming all of these challenges, the family considers Jessica their miracle. Jessica finished her seventh grade year with stellar grades at the top of her class. She is also secretary of her class and enjoys playing the violin. Her goal is to attend Southern Methodist University and become a lawyer. Everyone is cheering her on!

"The family considers Jessica their miracle."

Jessica Courtright, Patient

MOLECULAR TESTING: *Roadmap to Cancer*

Travelers frequently use an app or navigation device to reach their destination accurately and more quickly. Next Generation Genomic Sequencing (NGS) represents the current, state-of-the-art molecular test that works like a roadmap for physicians and their cancer patients.

Molecular testing through NGS is routinely ordered for each Mary Crowley patient using a tissue sample of their tumor from an earlier surgery. The results identify the gene alterations and biomarkers that contribute to the patient's cancer growth and act as a roadblock to traditional cancer treatments. Identification of gene mutations is valuable for the physician, but only with accurate interpretation and correlated therapies

that address the molecular signature of the patient. With this information, a patient can be appropriately aligned to a matching therapy designed to impact a specific mutation or cancer signal (see below for an example of how this works in a Foundation One™ partial report).

All patient sequencing results are maintained in a dynamic Patient Molecular Registry at Mary Crowley and regularly assessed for a potential clinical trial match. Additionally, any patient may ask Mary Crowley to conduct NGS of a portion of their surgical tumor in the event they may need a research option after their initial cancer surgery and standard treatment.

A partial example of a Next Generation Sequencing Report by Foundation One Medicine showing genetic alterations with therapeutic implications.

Genomic Alterations Detected	FDA Approved Therapies IN PATIENT'S TUMOR TYPE	FDA Approved Therapies IN ANOTHER TUMOR TYPE	Potential Clinical Trials
ALK EML 4-ALK fusion	Crizotinib	None	Yes, See Clinical Trials Section
TSC2 Splice Site 3285-1 G>A	None	None	Yes, See Clinical Trials Section
CDKN2A/B Loss	None	None	Yes, See Clinical Trials Section
TP53 L194R	None	None	None

LOOKING FORWARD: *Clinical Innovation for Cancer*



*John Nemunaitis, M.D.,
Executive Medical Director*



*Neil Senzer, M.D.,
Scientific Director*

Our Physician Investigators Predict Advances

- **Combination Targeted Immunotherapies** will become routine in frontline management of advanced cancer
- **Liquid Biopsy** will use circulating cell-free DNA/miRNA and circulating tumor cells for early diagnosis and screening in high-risk populations, prognosis, response prediction and real time monitoring of responsiveness to therapy
- **Single Cancer Cell Genomic Sequencing** will provide a higher resolution understanding of cancer initiation, maintenance and evolution
- **Computerized Multi-“omic” Systems Analysis** will provide the ability to integrate information at the DNA (gene) level, RNA (messenger) level, protein (product) level and metabolome (catabolic) level to allow a better understanding of functional dynamics within the cancer cell
- **CRISPR** (Clustered Regularly Interspaced Short Palindromic Repeats) will provide the ability to selectively remove or add a gene (gene editing), modify non-structural genetic changes (epigenomic changes) and label genes to facilitate detection
- **Oncolytic Viruses** will use cancer-specific cell-killing viruses to selectively kill cancer cells and, by immune enhancement, to concurrently vaccinate against the cancer, allowing for a double-pronged attack
- **Stereoscopic Integrated Imaging for Multimodal Intraoperative Image Guidance** labeling cancer cells in the patient with detectable probes will allow intraoperative detection of otherwise non-visualizable local spread to improve the results of surgery
- **Expanded array of molecular targeting therapies** will become available for cancer patients

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

As of December 31, 2015 and 2014

	<i>Assets</i>	
	2015	2014
CURRENT ASSETS		
Cash and cash equivalents	\$3,939,932	\$3,819,187
Investments in securities	1,619,552	1,660,018
Accounts receivable	3,149,941	2,166,864
Accounts receivable - related parties	327,128	387,852
Contributions receivable	50,000	-
Notes receivable	208,731	100,521
Prepaid expenses	29,287	94,892
Total current assets	9,324,571	8,229,334
PROPERTY AND EQUIPMENT (NET)	510,015	529,696
OTHER ASSETS		
Notes receivable, net of current portion	-	156,019
Deposits	30,432	62,843
Total other assets	30,432	218,862
TOTAL ASSETS	\$9,865,018	\$8,977,892
	<i>Liabilities and Net Assets</i>	
CURRENT LIABILITIES		
Accounts payable	\$951,298	\$1,201,680
Accounts payable - related party	23,000	20,000
Accrued expenses	352,068	251,352
Deferred revenue	296,363	176,199
Other current liabilities - related party	90,750	-
Total current liabilities	1,713,479	1,649,231
NET ASSETS		
Unrestricted	6,080,154	5,159,780
Temporarily restricted	2,071,385	2,168,881
Permanently restricted	-	-
Total net assets	8,151,539	7,328,661
TOTAL LIABILITIES AND NET ASSETS	\$9,865,018	\$8,977,892

MARY CROWLEY MEDICAL RESEARCH CENTER AND AFFILIATES
SUMMARY STATEMENT OF ACTIVITIES

For the Year Ended December 31, 2015
 With summarized financial information for the year ended December 31, 2014

	Unrestricted	Temporarily Restricted	Permanently Restricted	Total All Funds	
				2015	2014
SUPPORT AND REVENUE:					
Research revenue	\$7,875,103	\$912,000	\$ -	\$8,787,103	\$8,568,044
Contributions and grant revenue	830,986	1,404,690	-	2,235,676	2,063,721
Interest income	66,424	-	-	66,424	90,485
Realized gain (loss) on investments	89,183	-	-	89,183	(60)
Unrealized gain (loss) on investments	(192,276)	-	-	(192,276)	(21,032)
Net assets released from restrictions	2,414,186	(2,414,186)	-	-	-
Total support and revenue	11,083,606	(97,496)	-	10,986,110	10,701,158
OPERATING EXPENSES:					
Program					
Medical & research	7,592,971	-	-	7,592,971	6,776,248
General & administrative	2,364,204	-	-	2,364,204	2,298,203
Fundraising	206,945	-	-	206,945	218,330
Total operating expenses	10,164,120	-	-	10,164,120	9,292,781
Changes in net assets from operations	919,486	(97,496)	-	821,990	1,408,377
Other income (expense)	888	-	-	888	2,145
INCREASE (DECREASE) IN NET ASSETS	920,374	(97,496)	-	822,878	1,410,522
NET ASSETS, beginning of period	5,159,780	2,168,881	-	7,328,661	5,981,139
NET ASSETS, end of period	6,080,154	2,071,385	-	8,151,539	7,328,661

Rx FOR CANCER: *Our Research Pharmacy*

A key element in conducting clinical cancer research at Mary Crowley is the ability to provide novel testing agents for patients in a carefully controlled environment known as an Investigational Drug Repository (IDR)

Ground-breaking:

With our focus on targeted and immunotherapies, the staff of Mary Crowley's research pharmacy are often the first to prepare novel agents. This leads to collaboration with the pharmaceutical industry for the preparation of these agents beyond the research setting.

Exclusive:

Our research pharmacy (IDR) provides services exclusively for clinical trials at Mary Crowley and is equipped to handle oral and IV research agents, including human, bacterial, or viral DNA-based therapies.

Proximity to Patients:

Located within our research center, the research pharmacy is capable of providing immediate delivery of agents to patients. This design drastically shortens wait times for patients, as agents are prepared onsite.

Record Keeping:

Each study has its own drug accountability logs, drug packing lists, correspondence, and protocol. Our research staff tracks investigational agents from the time of receipt to preparation and administration, destruction, or return to the manufacturer.

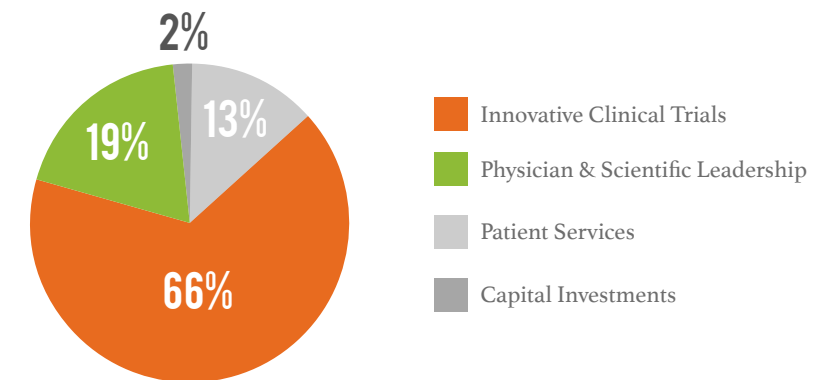
Storage, Safety, and Monitoring:

The research pharmacy staff have extensive experience in clean room processes and operates multiple separate Biosafety Cabinets for the preparation of novel molecular therapies. Additionally, they have the expertise, equipment, and information systems to track and monitor extremely low temperatures for the storage of novel DNA-based therapies.



*Board-certified Oncology Pharmacist
Robert Nunan, PharmD*

DONOR SUPPORT *Over \$4 Million Given in 2014-15*



“Private donations make up 40% of Mary Crowley’s budget. Without these contributions, our mission of advancing personalized medicine would not be possible. 100% of all donations go directly to patient-centered programs that advance clinical trials, which in turn expands new options for cancer patients.”

–ELLEN DEARMAN, VP OF DEVELOPMENT

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