Improving outcomes with personalized treatments

Cancer Program Annual Report
SUMMA AKRON CITY AND
ST. THOMAS HOSPITALS

2011 PROGRAM YEAR

Summa Health System
Contents

3 Summa Health System

4 Medical Director’s Report

6 Melanoma Report 2011

8 Melanoma – Volumes, Demographics, Survival Rates

11 Cancer Registry Summary 2011

12 Statistics 2011 Primary Sites

15 Reports

16 Colon Cancer: Reducing Time to Initiation of Colon Cancer Adjuvant Chemotherapy Following Surgery

18 Accomplishments

20 Clinical Trials Review

22 Clarence’s Story: Ipilimumab Clinical Trial ECOG1608

26 Russell’s Story: Ipilimumab Clinical Trial ECOG1608

29 Cancer Committee Members 2011

30 Definition of Terms

31 Locations – Cancer Care Centers

www.summahealth.org/cancer
Summa Health System

Summa Health System – headquartered in Akron, Ohio – is one of the largest integrated healthcare delivery systems in the state. Formed in 1989 with the merger of Akron City and St. Thomas Hospitals, this nonprofit system now encompasses a network of:

- Hospitals
- Community-based health centers
- A health plan
- A multi-specialty group practice
- An entrepreneurial entity
- Research and medical education
- Multiple foundations

Summa serves more than one million patients each year in comprehensive, acute, critical, emergency, outpatient and long-term/home-care settings and represents more than 2,000 licensed inpatient beds in the following clinical settings:

- Summa Akron City Hospital
- Summa Barberton Hospital
- Summa St. Thomas Hospital
- Summa Wadsworth-Rittman Hospital
- Summa Western Reserve Hospital
- Summa Rehab Hospital
- Robinson Memorial Hospital, an affiliate of Summa Health System
- Crystal Clinic Orthopaedic Center

Outpatient care is extended throughout Summit, Portage and Medina counties in multiple community health centers. Providing superior, multi-specialty patient care, medical research and continuing medical education, Summa is consistently ranked one of the best healthcare providers in the country.

Various Summa Health System hospitals, service lines, joint ventures and affiliates are recognized by the following organizations:

- American College of Surgeons Commission on Cancer (CoC)
- American Nurses Credentialing Center
- American Osteopathic Association’s Healthcare Facilities Accreditation Program (HFAP)
- Centers for Medicare and Medicaid Services
- Magnet Recognition by American Nurses Credentialing Center
- National Accreditation Program for Breast Centers (NAPBC)
- Premier Healthcare Alliance
- The American Heart Association
- The Joint Commission on the Accreditation of Healthcare Organizations
- Thomson Healthcare (formerly Solucient)
- U.S. News & World Report

Our Mission
The mission of Summa Health System is to provide the highest quality, compassionate care to our patients and members and to contribute to a healthier community.

Our Vision
Summa Health System will be recognized as one of the finest healthcare organizations in the United States and will be the preferred provider of healthcare services in our service area.

Our Values
- Personal and organizational integrity
- Quality, caring organizational environment
- Excellence in leadership
- Valuing one another
- Individuality
- Respect and fair treatment
- Open communications
- Teamwork
- Community service
As we look back over 2011, we see continued development and progress in the cancer program at Summa Health System. **Summa provides the majority of cancer care in the Akron region** with 1,303 analytic cases accessioned at Summa Akron City and St. Thomas Hospitals.

These newly-diagnosed cases represent a broad spectrum of malignant diseases. The data reflects the national experience with cancer as reported in the literature, with about two-thirds of patients being age sixty or older.

Three-fourths of Summa’s oncology patients are residents of Summit County, with the remaining 25 percent drawn from communities in Portage, Stark, Medina and Wayne counties.

Breast cancer remains the most commonly diagnosed malignancy, while lung cancer continues to be the second most frequently diagnosed malignancy. Other frequently noted malignant diagnoses include: colorectal, prostate, lymphoma, uterine cancer and bladder.

Patients are given the opportunity to participate in investigational clinical trials utilizing the latest available drugs and treatment techniques.

Eight percent of Summa’s patients chose this option for their care, which is well above the national average of less than one percent. This level of participation in clinical trials qualifies a program for recognition at the “commendation” level by the American College of Surgeons Commission on Cancer, an honor which few programs earn.

Highlights from 2011 include:

- Accredited by the American College of Surgeons Commission on Cancer, with commendation (CoC)
- U.S. News & World Report named Summa Akron City and St. Thomas Hospitals as #1 for cancer care in Akron
• **Oncology nursing staff participated in the Magnet Survey**, which validated the high quality of nursing care patients receive at Summa Akron City and St. Thomas Hospitals

• A **process improvement intervention** led by Fred Sle Zak, M.D., and Sameer Mahesh, M.D., shortened the time between patients’ colorectal cancer surgery and when adjuvant chemotherapy could begin, which improves patient outcomes

• Continued participation in several **community outreach programs**, including:
  - An evidence-based survivorship program known as “A Time to Heal”
  - The successful “I Can Cope” program was again offered in 2011
  - The “Breast Education and Screening Together” (BEST) program provides free screening and diagnostic mammograms to women.
  - “Summa Screens” project created to encourage age-appropriate cancer screening for women
  - Added **new staff member**, hematologist and medical oncologist, John Jakob, M.D., to the medical staff of Summa Health Center at Lake Medina and Parkview Cancer Center

• **Promotion** of Kim Moeller, MSN, RN, ACNS-BC, OCN to manager for outpatient infusion at the Cooper Cancer Center

• **Promotion** of John Shanahan, MS, DABR to chief medical physicist of Radiation Oncology

In this report, Dr. John A. Jakob provides an overview of new treatment options for patients with advanced melanoma. Also included are two articles which share the unique perspectives of two patients with melanoma who are participating in the clinical trials of these new drugs.
Breakthroughs in the treatment of advanced melanoma

Advanced melanoma, a skin cancer, is an often lethal condition which claims 8,000 to 10,000 lives annually in the United States.

Despite intense research conducted during the past 40 years, very few advances were made in extending the survival of these patients.

This changed in 2009, when vemurafenib, a new oral medication, was found to produce dramatic responses in some patients with advanced disease. Subsequently, vemurafenib was also shown to increase survival in patients with susceptible tumors.

In 2010, ipilimumab, an antibody given as an intravenous (IV) therapy, was shown to improve the survival of advanced melanoma patients. Both vemurafenib and ipilimumab, two very different therapies, were approved by the FDA for use in patients with advanced melanoma.

Vemurafenib, the oral agent, is also known as Zelboraf, its commercial name. It inhibits the B-RAF protein, whose activation by genetic mutation is found in roughly half of advanced melanoma tumors; the B-RAF protein is involved in regulation of cell growth.
Not surprisingly, a patient’s tumor (but not the patient!) must be tested for a mutation in the *BRAF* gene to determine eligibility for vemurafenib treatment. The test can take ten days to complete, but if the mutation is found, then the patient is an appropriate candidate for vemurafenib therapy.

Vemurafenib is administered as four 240-mg tablets taken twice daily. This therapy is strictly outpatient, with only periodic visits to a medical oncologist required. Generally, it is well tolerated; however, some patients experience fatigue, rashes, and skin photosensitivity.

There is also a risk of secondary skin cancers, consisting of unrelated, distinct tumors called squamous cell carcinomas which can be treated with the assistance of a dermatologist and/or surgeon.

The new IV therapy, ipilimumab, has several differences when compared with vemurafenib, the oral therapy. Ipilimumab effectively reprograms the body’s immune system to aggressively fight the melanoma cancer cells. Importantly, all patients with advanced melanoma are eligible for this treatment, regardless of the status of their tumor’s *BRAF* gene.

In addition, this therapy must be given in a traditional chemotherapy unit. Ipilimumab also has a unique side effect profile; because the body’s immune system has been “activated,” inflammation of the gastrointestinal tract, liver and skin can present unique challenges for the patient and his/her oncologist.

The term “melanoma” denotes several subtypes of cancer, including: “mucosal” (arising from the mucous membranes) and “acral-lentiginous” (arising on the hands and feet). These types of melanoma sometimes harbor mutations in the *c-KIT* gene and are a very active area of investigation. Lastly, “uveal” melanoma, a tumor that arises in pigment cells of the eye, is a rare condition whose genetic profile has been clarified in the past two years.

In summary, the care of patients with advanced melanoma has changed greatly during the past two years, with FDA approval of two medications, ipilimumab and vemurafenib. Although these medications differ in mechanism and means of administration, they both extend survival in metastatic disease. Our oncologists work with our patients with this diagnosis to formulate a care plan to utilize these new therapies in an effective fashion in order to maximize patient outcomes and quality of life during treatment for advanced melanoma.
Graph 1

2011 Melanoma Cases – Histologies
Summa Akron City and St. Thomas Hospitals – 28 cases

- Acral Lentiginous Malignant Melanoma: 1 case
- Melanoma in situ: 1 case
- Superficial Spreading Melanoma: 2 cases
- Malignant Melanoma: 24 cases

Graph 2

2011 Melanoma Cases – Age at Diagnosis
Summa Akron City and St. Thomas Hospitals – 28 cases

- 20-29: 1%
- 30-39: 3%
- 40-49: 9%
- 50-59: 22%
- 60-69: 26%
- 70-79: 22%
- 80-89: 15%
- 90-99: 2%

Graph 3

2011 Melanoma Cases – Race Distribution
Summa Akron City and St. Thomas Hospitals – 28 cases

- Caucasian: 97%
- African American: 3%
Graph 4

Melanoma Five-Year Survival by AJCC Stage
Summa Akron City and St. Thomas Hospitals (Cases DXD 2003-2005)

Graph 5

Melanoma Five-Year Survival by Year – All Stages
Summa Akron City and St. Thomas Hospitals (Cases DXD 2003-2005)

Graph 6

Melanoma Five-Year Observed Survival – By Stage
Summa Akron City and St. Thomas Hospitals (Cases DXD 2003-2005)
**Graph 7**

**Melanoma Five-Year Observed Survival**
National Cancer Database (Cases DXD 2003-2005)

![Graph showing melanoma survival rates over five years by stage.]

**Graph 8**

**2011 Analytic Melanoma Cases by AJCC Stage**
Summa Akron City and St. Thomas Hospitals – 28 cases   NCDB – 40,926 cases

![Graph showing melanoma cases by AJCC stage for 2011.]  
- Summa Akron City and St. Thomas Hospitals:  
  - Stage 0: 21%  
  - Stage I: 62%  
  - Stage II: 31%  
  - Stage III: 7%  
  - Stage IV: 0%  
- NCDB:  
  - Stage 0: 0%  
  - Stage I: 50%  
  - Stage II: 15%  
  - Stage III: 10%  
  - Stage IV: 5%

**Graph 9**

**2011 Melanoma Cases – Gender Distribution**
Summa Akron City and St. Thomas Hospitals

![Pie chart showing gender distribution of melanoma cases in 2011.]  
- Male: 46%  
- Female: 54%
The cancer registry is an essential component of the Commission on Cancer accredited cancer program. The Cancer Program at Summa Akron City and St. Thomas Hospitals achieve their goals by collecting and reporting quality cancer data in support of their business planning and outreach initiatives.

Data collected by the cancer registry is an invaluable tool in the fight against cancer. As an accredited CoC facility the registry collects demographic and disease specific data elements on each cancer patient presenting for diagnosis or treatment. The information collected is utilized by physicians, administration and other healthcare professionals. Among the many uses are:

- Measuring quality outcomes
- Tracking community outreach initiatives
- Supporting clinical, diagnostic, and treatment research
- Evaluating the effectiveness of current treatment modalities
- Presenting data for individualized patient treatment planning
- Submitting to local and national databases for incidence and outcome comparison
### Statistics

#### 2011 Primary Sites

Summa Akron City & St. Thomas Hospitals

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<th>Total</th>
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<th>Class of Case</th>
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<th>Non-Analytic</th>
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<td>566</td>
<td>737</td>
<td>1262</td>
<td>40</td>
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of all new cancer cases diagnosed in 2011 at Summa Akron City and St. Thomas Hospitals were breast, lung or colorectal cancers.

2011 Data Summary
Summa Akron City Hospital’s cancer registry accessioned 1,303 new cancer cases for 2011. The following graph illustrates the most frequent primary sites seen at this facility.

The top five sites for all patients are breast, lung, colorectal, prostate and non-Hodgkin’s lymphoma. The gender distribution for these top sites is represented in the graph below.
Demographics
The majority (74 percent) of the patients presenting to Summa Akron City and St. Thomas Hospitals reside in Summit County. This is represented by the following chart.

County of Residence
Summa Akron City and St. Thomas Hospitals

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<thead>
<tr>
<th>County</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Summit</td>
<td>74%</td>
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<tr>
<td>Portage</td>
<td>11%</td>
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<tr>
<td>Medina</td>
<td>5%</td>
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<tr>
<td>Stark</td>
<td>4%</td>
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<tr>
<td>Wayne</td>
<td>2%</td>
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<tr>
<td>Other</td>
<td>4%</td>
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</table>

Primary Payor at Diagnosis

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<tr>
<th>Payor</th>
<th>Percentage</th>
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<tr>
<td>HMO</td>
<td>51%</td>
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<td>Medicare</td>
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<td>Medicaid</td>
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<td>Insurance NOS</td>
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<td>Not Insured</td>
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<td>Other</td>
<td>1%</td>
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</table>

Follow-Up
Meaningful survival and outcome measures require reliable tracking of disease, recurrence and vital status for the lifetime of each patient record. Accurate follow-up data enables Summa to compare outcomes with regional, state or national statistics. The successful follow-up rate at Summa Akron City and St. Thomas Hospitals for the last five years is 92% and the rate since the established registry reference year (2000) is 87%. Both rates are above the CoC requirement of 90 percent and 80 percent respectively.

Continuing Education
In 2011 registry staff attended the Ohio Association of Cancer Registrars 41st Annual Education Conference, the NAPBC Pursuing Excellence Through Accreditation Workshop and the Fourth Annual Vincent and Nancy DiGirolamo Oncology Symposium in addition to other local and regional events.
### 2011 Reports

#### Professional Education

Eight cancer-related educational activities were held in 2011.

<table>
<thead>
<tr>
<th>Date</th>
<th>Programs</th>
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<tr>
<td>01/2011</td>
<td>NCDB Edits – Find-Correct – Submit Error Free</td>
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<td>02/2011</td>
<td>Understanding the NAPBC Components and Standards</td>
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<td>06/2011</td>
<td>Oncology Nursing Society Chemotherapy/Biotherapy Course</td>
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<td>07/2011</td>
<td>Entering the Era of Personalized Medicine in Non-Small Cell Lung Cancer</td>
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<tr>
<td>08/2011</td>
<td>Summa Thinks Pink 2011 Starting the Conversation</td>
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<tr>
<td>10/2011</td>
<td>The Fourth Annual Vincent and Nancy DiGirolamo Oncology Symposium</td>
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<td>12/2011</td>
<td>How to Find What the Edits Miss</td>
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#### Cancer Conferences 2011

During 2011, there were 52 Cancer Conferences conducted. Case specific presentations included 401 cases. Of these case presentations, 401 were prospective and none were retrospective.

52 Cancer Conferences conducted in 2011
Colon Cancer

REDUCING TIME TO INITIATION OF COLON CANCER ADJUVANT CHEMOTHERAPY FOLLOWING SURGERY

A presentation at an American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium inspired Summa oncologist Sameer A. Mahesh, M.D. to think about ways to improve outcomes for colorectal cancer patients.1

Colorectal cancer is the third leading cause of cancer mortality in the Western world.2 Surgery, followed by adjuvant chemotherapy (AC), has been proven to improve overall survival in certain patients with colon cancer after surgery.

However, a recent data analysis suggests that a longer time to AC is associated with worse survival among patients with resected colorectal cancer. In fact, the results indicated relative overall survival decreases by 14 percent for every four-week delay in initiation of AC.

Study findings suggest that timing of AC plays a critical role in the management and outcomes of patients with colorectal cancer and clinicians should take steps to avoid delays in access to chemotherapy.

Dr. Mahesh also is the process improvement director for Summa’s oncology services department.

The results of the meta-analysis intrigued him. He decided to take a second look at the elapsed time between surgery and the initiation of chemotherapy at Summa’s Cooper Cancer Center.

The analysis showed 24 percent of patients undergoing colon cancer surgery in 2010 subsequently received chemotherapy following surgery. The process took a median of 41 days from date of discharge to the patient’s first chemotherapy session (a range of 12 to 166 days).

Dr. Mahesh knew this was an opportunity to improve patient outcomes, but he also knew he needed help.

A multidisciplinary team comprised of an oncologist, surgeon, administrator, cancer care nurse navigator and Six Sigma process improvement experts was formed with the goal of reducing the time it took for a patient to begin adjuvant chemotherapy following surgery.

The first step was analyzing how patients flowed through the colorectal cancer treatment process. Previously, starting AC was a serial process, beginning with:

1. Patient’s post-operative visit to surgeon
2. Patient’s initial visit to medical oncologist
3. Surgical placement of port in patient
4. Initiation of adjuvant chemotherapy in patient

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3 Biagi JJ, Raphael M, King WD, Kong W, Mackillop WJ, Booth C. Association between time to initiation of adjuvant chemotherapy (AC) and survival in colorectal cancer (CRC): A systematic review and meta-analysis. JAMA, 2011; 305(22):2335-2342. Published online June 4, 2011.
“All of the steps in the process were scheduled and completed serially,” said Dr. Mahesh. “This was inefficient, for both patients and clinicians. And, more importantly, it delayed the start of a patient’s chemotherapy.”

“We knew we could do better,” he said. “Instead of a sequential, serial process, what was needed was for these steps to be scheduled concurrently.”

The team’s goal was to reduce the time from a median of 41 days to a median of 28 days as well narrow down the standard deviation.

In order to accomplish their goal, the team began to look at their clinical processes from a different perspective.

“We initiated a program of concurrent scheduling of appointments by the colorectal cancer nurse navigator (CRCN) which began as soon as the pathology report became available,” Dr. Mahesh said.

Utilizing the CRCN to coordinate appointments for patients who required adjuvant chemotherapy significantly reduced the time to start of chemotherapy from date of discharge, moving from a median of 41 days to 27 days.

Dr. Mahesh and his team expect this success to eventually translate into better colon cancer outcomes for patients as well as increase patient satisfaction since moving through the system would be a quick and effortless process.

Another plus – the change required no additional funding.

Reasons for a delay in time to AC may be due to patient factors such as postoperative complications, comorbid conditions or health system logistic factors such as delays in referral or wait times.

With healthcare reform efforts and increasing demands for transparency from healthcare consumer advocates, timely access to adjuvant chemotherapy will be cited and tracked as a quality indicator.

Clinicians should reexamine their clinical processes and take steps to eliminate bottlenecks and inefficiencies.

Dr. Mahesh has some advice for other healthcare providers looking to improve their own clinical processes and patient outcomes.

“Analyze the process and eliminate or modify roadblocks to improve patient care,” he said. “Sometimes, the solutions are quite simple.”

### Results

<table>
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<th>Status prior to program</th>
<th>TTCD-days (median)</th>
<th>Range (days)</th>
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<table>
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<th>Status after program</th>
<th>TTCD-days (median)</th>
<th>Range (days)</th>
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<td>27 (p=0.01)*</td>
<td>12-69</td>
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</table>

* Modified Mood Median Test

### AUTHORS:
Karen Bochert, Brian Rentschler, Chris Powers, Frederick Slezak, M.D., Sameer A. Mahesh, M.D., MBBS; Summa Health System, Akron, OH

Contact Dr. Sameer A. Mahesh at (330) 376-1043 or maheshs@summahealth.org for more information about this project.
Cancer Care Program
ACCOMPLISHMENTS 2011

Programmatic

- American College of Surgeons Commission on Cancer – Received three year accreditation with commendation.
- Applied for American College of Radiology Radiation Oncology Accreditation
- Established data benchmarks; working toward NQMBC accreditation for the Breast Center
- Continued to increase patient and family attendance to/participation in supportive care programs

Clinical

- Developed System-wide order sets for chemo/infusions treatments
- Cross-trained radiation and medical oncology staff throughout the System
- Implemented Dietitian Services at the Cooper Cancer Center eight hours a week offering individual counseling and group programs for patients
- Implemented a post acute treatment psychosocial follow-up pilot for patients; began recruiting patients in the first quarter of 2011
- Magnet status was achieved at Akron City and St. Thomas Hospitals. Oncology nursing staff participated in the Magnet Survey which validated the high quality of nursing care patients receive at Summa.

#1 in Akron

U.S. News & World Report named Summa Akron City and St. Thomas Hospitals as #1 for cancer care in Akron.
Quality

- Conducted revision meetings in regards to the My Journey Treatment Planner for system-wide utilization and implement changes.
- Utilized LEAN to improve patient care processes

Quality Improvement Projects

- Palliative Care – Sooner Than Later
  - Patients to be served include those diagnosed with Stage III & IV cancers: metastatic melanoma or renal cell carcinoma, advanced lymphoreticular malignancy and any other patients who physicians and staff feel increased support for symptom control or psychosocial support and spiritual support might be necessary
  - Palliative Care consult can take place in the Palliative Care Clinic, Center for Senior Health, Radiation Oncology Center or the Infusion Center in the Cooper Cancer Center

Community Outreach

- Expanded programming into Medina County
- Applied for additional funding sources to continue “Summa Screens,” Summa’s mammography program for the uninsured and underinsured.
- Increased patient, provider and staff awareness and knowledge of common physical and psychosocial needs of survivors as well as ways to access multi-disciplinary treatment resources at Summa Health System through in-service trainings and community presentations
Clinical Trials

**REVIEW**

Melanoma Clinical Trials at Summa Health System

**Protocol: ECOG 1609**
A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CGTLA4 Therapy versus High-Dose Interferon alpha-2b for Resected High-Risk Melanoma

**Eligibility Criteria:** Stage IIIB or IIIC or IV, no ocular or mucosal melanoma, completely resected with negative margins within 12 weeks of study enrollment, no prior adjuvant treatment after resection, recurrent melanoma included, more than 30 days since radiation therapy and more than 4 weeks since IL-2 or other chemotherapy

**Protocol: ECOG 2607**
A Phase II Trial of Dasatinib in KIT-Positive Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Vulvovaginal Melanomas

**Eligibility Criteria:** metastatic or unresectable melanoma (acral, vagina and/or vulva or other mucosal surface); measurable disease, must be KIT positive, prior treatment allowed but no targeted therapy permitted, prior treatment more than 4 weeks before study entry, mandatory central tissue review
There’s only one way to end cancer: research

“You have cancer.”

It’s only three words, but receiving a cancer diagnosis changes everything. Not just for patients, but for everyone who loves and cares for them.

Fifty years ago, many cancer treatments we take for granted today did not exist.

But by investing in clinical research, the National Cancer Institute, along with pharmaceutical and biotechnology companies, have made significant progress in developing effective treatments for many forms of cancer.

These advances would not have been possible without patients who chose to enroll in studies to evaluate the safety and efficacy of new treatments.

Summa Health System supports one of the most active clinical research programs in the region, participating in multiple national research organizations which are funded by the National Cancer Institute and the pharmaceutical industry.

Summa researchers also have established collaborative relationships with local universities and medical programs to expand opportunities for patients to participate in clinical research studies.

Currently, researchers are conducting more than 100 clinical studies to evaluate a wide range of new treatment options, including surgical and radiation therapy techniques, various chemotherapy combinations and improvements in supportive care for patients who are undergoing treatment for cancer.

Improving outcomes for cancer patients is a team effort. Clinicians rely on patients’ participation in research studies to continue to improve care and outcomes across the nation for all cancer patients – now and in the future.

For more information regarding cancer clinical trials at Summa or for a complete list of open protocols and corresponding sites, please contact Joyce Neading, program director, cancer research and cancer registry, (330) 375-4221 or neadinja@summahealth.org.

About eight percent of our patients (as opposed to the national average of less than one percent) participated in investigational clinical trials offered at Summa.
It all began in 2006 when Clarence Rohr noticed a small dark spot on his face.

“I had just a little speck on my left cheek,” he said.

Rohr, a soft-spoken, 84-year-old semi-retired farmer from Doylestown, Ohio, didn’t think it was anything serious.

“I went in and they took it out,” he said. “Then they told me I had the melanoma.”

Clarence hoped the surgery to remove the lesion would be the end of it. He was eager to get back to doing the things he loves - working with his two sons on their 135-acre family farm and helping them manage Bass Lake, their fishing business.

Bass Lake encompasses a series of 30 ponds and lakes which are stocked with various types of game fish, including: bass, bluegill, striped bass, walleye and crappie. It is open to weekend anglers and Clarence also sells fish to people who wish to stock their own ponds. The Rohrs’ acreage also produces more than 20,000 bales of hay each year to sell.

Following the removal of the lesion on his cheek, Clarence returned to farming, tending the family garden and helping anglers enjoy a day of fishing.

Four years later, however, the melanoma returned. Clarence noticed new lesions on his ear and neck.

In August 2010, Clarence made an appointment with Sameer A. Mahesh, M.D., an oncologist at the Jean and Milton Cooper Cancer Center at Summa Akron City Hospital. Dr. Mahesh told Clarence his cancer had metastasized to his parotid gland, one of the large salivary glands located just in front of his ear.

Dr. Mahesh recommended Clarence undergo treatment with Interferon and also have radiation therapy.

Clarence declined treatment with Interferon, but he did receive radiation treatments at Summa Barberton Hospital, where he was under the care of Summa radiation oncologist William F. Demas, M.D.

But in March 2011, doctors learned Clarence’s melanoma had metastasized again.

“They took an X-ray and found I had a couple of spots on my liver and on my spleen. They went in and took a biopsy to make sure it was the same cancer – and it was,” Clarence said.

Metastatic melanoma is one of the most challenging malignancies to treat, with a five-year survival rate of nine to 15 percent and a median survival rate of seven to nine months, according to most studies.

Until recently, dacarbazine and high-dose interleukin-2 were the only agents approved by the FDA for treatment of metastatic melanoma.

But in 2011, the FDA approved the drug ipilimumab for the treatment of metastatic melanoma based on positive results obtained from randomized trials.

In a large phase III trial of 676 advanced, inoperable melanoma patients published in 2010 in the New England Journal of Medicine, subjects previously treated unsuccessfully with other agents who received ipilimumab a melanoma vaccine (gp100) lived on average 32 percent longer and had a 20 percent greater chance (45 percent vs. 25 percent) of surviving.
one year than those who received gp100 alone. And 24 percent were alive after two years, compared with just 14 percent of those treated with the other therapy. The impact of this trial cannot be overemphasized, as ipilimumab was shown to be the first treatment ever to improve overall survival in advanced melanoma patients.1

Since 2011, a number of clinical trials of ipilimumab have been underway.

Ipilimumab is an anti-CTLA-4 monoclonal antibody designed to restore and strengthen the patient’s immune system by supporting the activation and proliferation of T-cells, a key component of the immune system. Ipilimumab “removes the brakes” from the immune system by blocking the activity of a protein (CTLA-4) that normally keeps the T-cells in check. Blocking the action of CTLA-4 allows T-cells to activate and proliferate so they can attack the melanoma cells.

Clarence was offered the opportunity to participate in one of the ipilimumab clinical trials. He didn’t hesitate for a second to enroll.

“There are 25 of us in the study – and I’m the oldest one!” Clarence said.

Lynn Kaplan, RN, BSN, OCN a clinical research nurse at Summa, was Clarence’s nurse during the trial.

“We offered him the clinical trial ECOG 1608. He was randomized to Arm A of the trial, in which he was given GM-CSF in daily self-injections for 14 days and ipilimumab infusions every three weeks for eight cycles – and then every 12 weeks for maintenance,” she explained.

“He had a lot of symptoms when he was first diagnosed, but those symptoms have gone,” Kaplan said.

For Clarence, the new regimen meant an end to abdominal pain as a result of the lesions in his spleen and liver.

“I had a bad bellyache before they started me on these treatments,” he said. “Then that left.”

When asked whether he had experienced any side effects with the medications, Clarence mentioned just one.

“I had a bad itch from it,” he said.

Side effects of ipilimumab are related to the over-activation of the patient’s immune system by the drug, which can result in itching, skin rash, colitis and diarrhea, as well as more serious effects.

Ipilimumab makes patients’ T-cells more responsive to many agents, not just cancer cells. This can cause powerful autoimmune reactions in which the patient’s immune system attacks normal cells within their body. For this reason, oncologists monitor patients’ liver and endocrine function carefully, as hepatitis and dysfunction of the pituitary, adrenal or thyroid glands have been reported.

But despite the annoying itch, the new drug regimen has allowed Clarence to maintain his active lifestyle.

He says he can’t walk as far and as fast as he used to, but he can still lend a hand with farm chores.

“This year I helped the boys bale hay – I drove the baler,” he said.

Even the summer’s 90-degree-plus temperatures didn’t stop this octogenarian.

The only concession Clarence makes to melanoma is to wear a layer of sunscreen and a straw hat when he works outdoors. He continues to make trips to the store to pick up supplies for the farm and still tends the family garden.

Clarence readily admits he isn’t much of a tourist, but he was able to fly to Florida for a mini family reunion not long ago.

Clarence and his family had a great time in Florida.

Today, Clarence continues his maintenance regimen, while oncologist, Dr. Mahesh, and nurse, Lynn Kaplan, still monitor him carefully.

“They say they’ve got the cancer stopped,” he said.

Clarence and Dolores, his wife of 58 years, are very satisfied with the care Clarence has received from the oncology team at the Cooper Cancer Center.

“We’re so glad we came here,” said Dolores. “They’ve all been so nice to us.”

Clarence also appreciates Summa’s convenient locations across Summit and Medina counties.

“They’re close to home – they have Summa in Akron, Wadsworth, Medina and Barberton,” said Clarence. “I’ve been to all of ‘em for different things.”

When asked what advice he would give to other patients facing a melanoma diagnosis and who may be considering enrolling in a clinical trial, Clarence said simply:

“Get the treatments,” he said. “They’re helping me.”
Dr. Russell Bowermaster is a bit of a Renaissance man – athlete, surgeon, inventor, businessman, bank director, avid outdoorsman and bio-tech entrepreneur.

Russell is a 76-year-old retired oral and maxillofacial surgeon from Hamilton, Ohio, a suburb near Columbus. A large, broad-shouldered man, he was a stand-out athlete in high school and college.

He played football at The Ohio State University in the mid-1950’s for legendary coach, Woody Hayes. Russell played in the Rose Bowl and was a member of a national championship team.

Later, he was drafted by the Cleveland Browns, but chose to pursue a career in dentistry instead.

He earned a Doctor of Dental Surgery and a Master of Science in Physiology from OSU.

During graduate school, he still managed to stay close to the gridiron, however.

“I coached for Woody Hayes,” said Russell. “I was a graduate assistant for him for three years.”

He became an oral and maxillofacial surgeon, a dental specialty which focuses on the mouth, jaw and neck.

Along the way, Russell met and married Sally, his wife of 55 years. Together, the couple raised two daughters.

An avid sportsman, Russell was on a hunting trip in Saskatchewan, Canada, in late 2010 when he noticed soreness in his armpit.

“I had shot a shotgun numerous times. I started getting a swelling here (pointing to his armpit). I thought I had a hematoma in the axilla.”

He didn’t think it was anything serious, attributing it to a broken blood vessel caused by the recoil from the shotgun.

But the soreness persisted – even after he returned to Ohio.

“I finally went to a surgeon I knew,” Russell said.

The surgeon examined him and found a suspicious-looking lesion on the back of his shoulder.

“It had been a mole – but it never bothered me,” he said.”And it wasn’t in a place where I could easily see it.

Lesions also had appeared on his scalp.

“This stuff on my head occurred so quickly – boom!” he said. “Within a matter of two or three weeks. It started showing itself pretty quickly.”

A biopsy of the primary lesion was performed.

“It came back melanoma,” Russell said.

In March 2011, Russell was diagnosed with Stage IV metastatic malignant melanoma. He had metastatic lesions on his scalp, neck, shoulder, axilla (armpit) and the left side of his torso.

“I went to an oncology group out of OSU,” he said. “I had a young oncologist who looked at me – and he didn’t give me much of a chance.”

“They did PET scans and I didn’t have any lesions in my vital organs, brain or lungs – which was good,” he said.
When Russell returned for a follow-up visit to the young oncologist, his doctor said, “I know who you are.”

“My father-in-law was a fraternity brother of yours and he told me all about you,” his physician explained.

As it turned out, the oncologist had a connection at the University of Pittsburgh Medical Center who specialized in melanoma research and treatment.

“He told me they have some new things out, like vaccines to ramp up your immune system,” said Russell.

Being a medical professional himself, Russell understood better than most patients what he was up against with advanced melanoma.

Life expectancy in patients with advanced metastatic melanoma is typically measured in months, not years. Until recently, there were few treatment options available to patients with advanced disease.

Russell realized a clinical trial was his best hope of holding the cancer at bay.

Russell made the trip to Pittsburgh.

“They gave me the option of either getting into the program here at Summa or I could have gone to the University of Cincinnati for treatment,” he said.

Initially, Russell chose Summa for his treatment because his daughter lives in nearby Cuyahoga Falls.

But, once enrolled in the melanoma clinical trial ipilimumab ECOG 1608, the quality of the care he received at Summa impressed him.

“This is a wonderful place,” he said. “The people here are top-notch and very patient-oriented.”

“It’s been over a year now, and all of these superficial lesions are going away,” he said. “It’s just amazing the way this stuff works.

“It’s cutting edge. It’s probably the way most cancers will be cured, because we’re all different genetically. If you can get your own immune system to go after what you’ve got, then you’re way ahead of the game,” said Russell.

Like any other treatment or procedure, however, there are some risks.

“You have to be careful that you don’t have a severe autoimmune reaction where your body starts attacking the ‘good stuff,’” he said.

Fortunately, Russell has not experienced any severe side effects as a result of treatment, other than fatigue and weakness.

For Russell, the opportunity to participate in a clinical trial also was a way to help others who are battling melanoma.

“The FDA fast-tracked this drug,” he said. “Now they’re trying to figure out the side effects and the right dosages.

“I’m a very, very lucky person who was in the right place at the right time.

“I am fortunate to get into a program that’s working for me,” he said. “It’s keeping me alive.”
## 2011 Cancer Committee Members

### Physician Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Department</th>
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<tbody>
<tr>
<td>Stephen Andrews, M.D.</td>
<td>Attending, Gynecology/Oncology</td>
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<tr>
<td>Raymond Clarke, M.D.</td>
<td>Division Chief, Pathology</td>
</tr>
<tr>
<td>Joseph Dankoff, M.D.</td>
<td>Attending, Urology</td>
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<tr>
<td>William Demas, M.D.</td>
<td>Chief, Radiation Oncology</td>
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<tr>
<td>Desiree Doncals, M.D.</td>
<td>Attending, Radiation Oncology</td>
</tr>
<tr>
<td>Daniel Finelli, M.D.</td>
<td>Chair, Department of Radiology</td>
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<tr>
<td>Lauren Kinsell, M.D.</td>
<td>Medical Director of the Breast Center</td>
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<tr>
<td>Joseph Koenig, M.D.</td>
<td>Attending, Hematology/Oncology</td>
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<tr>
<td>Erik Lichtenberger, M.D.</td>
<td>Cancer Liaison Physician</td>
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<tr>
<td>Joseph Myers, M.D.</td>
<td>Department Chair, Medicine</td>
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<tr>
<td>Steven Radwany, M.D.</td>
<td>Medical Director, Palliative Care and Hospice Services</td>
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<tr>
<td>Pars Ravichandran, M.D.</td>
<td>Attending, Pathology</td>
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<tr>
<td>Frederick Slezak, M.D.</td>
<td>Chief, Division of Colorectal Surgery Services</td>
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<tr>
<td>Douglas Trochelman, M.D.</td>
<td>Medical Director, Oncology Service Line</td>
</tr>
<tr>
<td>Scott Weiner, M.D.</td>
<td>Chair, Department of Orthopaedics</td>
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<td>Gary Williams, M.D.</td>
<td>Attending, Surgery</td>
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### Non-Physician Members

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<tr>
<td>Catherine Bentley</td>
<td>Clinical Dietitian</td>
</tr>
<tr>
<td>Scott Berry</td>
<td>System Director, Radiation Oncology</td>
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<tr>
<td>Karen Bochert</td>
<td>Colorectal Care Coordinator</td>
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<tr>
<td>Becki Brown</td>
<td>Coordinator, Guest Services, Cancer Library</td>
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<tr>
<td>Dawn Canda</td>
<td>Program Manager, Breast Imaging Services</td>
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<tr>
<td>Deborah Damore</td>
<td>Director, Pastoral Care Services/Education</td>
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<td>Jeannette Doria</td>
<td>System Director, Imaging Services</td>
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<tr>
<td>Heidi Eve-Cahoon</td>
<td>Breast Care Coordinator</td>
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<tr>
<td>R. Stephen Folk</td>
<td>Pharmacist</td>
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<td>Erin Lohr</td>
<td>American Cancer Society Representative</td>
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<tr>
<td>Lynn Kaplan</td>
<td>Clinical Research Nurse</td>
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<tr>
<td>Melinda Koch</td>
<td>Physical Therapist</td>
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<tr>
<td>Kim Kousaie</td>
<td>Director, Palliative Care and Hospice</td>
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<tr>
<td>Paula Lett</td>
<td>Unit Manager, Inpatient Oncology</td>
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<td>Kim Moeller</td>
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<tr>
<td>Joyce Neading</td>
<td>Program Director, Cancer Research and Registry</td>
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<td>Susan Newbrough</td>
<td>Clinical Manager, Radiation Oncology</td>
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<tr>
<td>Sally Olszewski</td>
<td>Lung Care Coordinator</td>
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<td>Susan Popovici</td>
<td>Social Worker</td>
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<tr>
<td>Sarah Reimer, PhD</td>
<td>Clinical Psychologist</td>
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<tr>
<td>Brian Rentschler</td>
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<tr>
<td>Melissa Sauer</td>
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<td>Susan Savage</td>
<td>Technical Manager, Radiation Oncology</td>
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<tr>
<td>Barb Saylor</td>
<td>Director, Medical Oncology</td>
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<tr>
<td>Peggy Schlosser</td>
<td>Certified Tumor Registrar</td>
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<tr>
<td>Mario Schmidt</td>
<td>Coordinator, Cancer Outreach/Education</td>
</tr>
<tr>
<td>Rose Skinner</td>
<td>Special Registry Clerk</td>
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<tr>
<td>Diane Strachan</td>
<td>Consultant, Foundation</td>
</tr>
<tr>
<td>Jeannie Terry</td>
<td>Certified Tumor Registrar</td>
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**Program Year:** 2011  
**Volume:** XVII  
**Date Of Publication:** October 2012
Definition of TERMS

American College of Surgeons (ACoS)
The ACoS Commission on Cancer surveys and approves cancer programs.

Analytic
Pertains to those cases initially diagnosed and/or receiving their first course of treatment at Summa Akron City/St. Thomas Hospitals.

National Accreditation Program for Breast Centers (NAPBC)
The NAPBC represents a consortium of national, professional organizations dedicated to the quality of care and monitoring of outcomes of patients with diseases of the breast, through standard-setting, scientific validation and patient and professional education. The NAPBC has instituted nationally recognized breast cancer quality performance measures that serve as an initial program for measuring quality improvement in breast disease treatment.

Nonanalytic (N/A)
A case diagnosed and treated elsewhere prior to being seen at a hospital or cases that were treated greater than four months after initial diagnosis. Cases that were initially diagnosed at autopsy are considered nonanalytic as well.

Stage
The registry records stage using the AJCC (American Joint Committee on Cancer Manual) for staging guide. Stages include Stage O, I, II, III, IV or Unknown.

Survival
The actuarial method of calculating survival provides a means for using all follow-up information accumulated up to the closing date of study.
At Summa Health System, high-quality, compassionate cancer care is available at five convenient Ohio locations spanning Portage, Summit and Medina Counties.

The Jean and Milton Cooper Cancer Center
Summa Akron City Hospital Campus
161 North Forge Street
Akron, Ohio 44304
(330) 375-7280

Parkview Center
Summa Barberton Hospital Campus
155 Fifth Street NE
Barberton, OH 44203
(330) 615-4126

Summa Western Reserve Hospital
1900 23rd Street
Cuyahoga Falls, OH 44223
Phone (330) 971-7246

Robinson Memorial Hospital
– An affiliate of Summa Health System
6847 North Chestnut Street
Ravenna, OH 44266
(330) 297-0811

Summa Health Center at Lake Medina
3780 Medina Road
Medina, Ohio 44256
(877) 504-7849