About Summa Health System

Summa is an Integrated Healthcare Delivery System that provides coordinated, value-based care across the continuum for the people and populations we serve. We hold ourselves clinically and financially accountable for health outcomes in our communities. Summa Health System integrates the resources of seven owned, affiliated and joint venture hospitals, a regional network of ambulatory centers, a network of more than 1,000 physicians that includes a 240+ employed multi-specialty group, a 150,000+ member health plan, a System level foundation and 10,000+ employees, nurses and healthcare professionals. At Summa Health System today, you see the healthcare system of tomorrow.

For more information, visit summahealth.org.

Oncology Insights is an exclusive publication for oncology physicians and their staffs and is published by Summa Health System. If you have comments, questions or suggestions regarding this publication, please call (330) 375-6571.

Clinical Trials at Summa Health System

This Issue
1. Clinical Trials at Summa Health System
2. Summa in the Community
3. Q&A with Jennifer Payne, M.D., Medical Director of Cancer Research
4. Summa Barberton Hospital Wins Full NAPBC Accreditation
5. Summa Health Center at Lake Medina...
This issue of Oncology Insights focuses on one of the most important aspects of Summa’s cancer care program: clinical trials. The following pages include an overview of active studies, a Q&A with the medical director of research and an overview of a new Summa facility in Medina, Ohio.

ECOG 2607
A Phase II Trial of Dasatinib in Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Solar Melanomas
Site: Skin
Principal Investigator at Summa Health System: Jennifer Payne, M.D.
Eligibility Criteria: Metastatic or unresectable melanoma; measurable disease; prior treatment permitted except targeted therapies; more than 4 weeks since prior treatment; brain metastases allowed if treated and stable; performance status 0 to 1.

GOG 0249
A Phase III Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed by Paclitaxel and Carboplatin Chemotherapy in Patients with High-Risk, Early Stage Endometrial Carcinoma
Site: Uterus
Principal Investigator at Summa Health System: Vivian von Gruenigen, M.D.
Eligibility Criteria: Stage I high to intermediate risk (grade 2 or 3, lymphovascular space invasion and/or myometrial invasion); Stage II with or without risk factors; Stage I-B disease with serous or clear cell carcinoma with or without risk factors provided disease is confined to the uterus; no metastases; enrolled in study between 4 weeks and 12 weeks since total hysterectomy.

GOG 0252
Bevacizumab and Intravenous or Intraperitoneal Chemotherapy in Treating Patients with Stage II or Stage III Ovarian Epithelial Cancer, Fallopian Tube Cancer or Primary Peritoneal Cancer
Site: Ovary/Peritoneum/Fallopian Tube
Principal Investigator at Summa Health System: Vivian von Gruenigen, M.D.
Eligibility Criteria: Stage II or Stage III cancer with less than 1 centimeter of residual disease after surgery; no radiographically measurable disease; less than 12 weeks since surgery; no brain metastases; no prior treatment; performance status 0, 1, or 2.

For a full list of open studies and available locations, please visit summahealth.org/cancer.
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With a greater number of access points than any other health system in Summit, Portage and Medina counties, Summa Health System is among national leaders in accrual rates for oncology clinical trials. Summa regularly participates in a number of National Cancer Institute studies as well as those sponsored by the pharmaceutical industry. The following are open studies available across the health system.

**Radiation Therapy Oncology Group (RTOG)**

**RTOG 0539**
Phase II Trial of Observation for Low-Risk Meningiomas and of Radiotherapy for Intermediate- and High-Risk Meningiomas

- **Site:** Brain
- **Principal Investigator at Summa Health System:** William Demas, M.D.
- **Eligibility Criteria:**
  - Grade II totally resected OR recurrent Grade I irrespective of resection extent; OR newly diagnosed or recurrent Grade III OR recurrent Grade II disease of any resection extent; OR newly diagnosed Grade II that was sub-totally resected; no prior radiation therapy, performance status 0 or 1.

**RTOG 0413**
A Randomized, Phase III Study of Conventional Whole Breast Radiation vs. Partial Breast Irradiation for Women with Stage 0, I or II Breast Cancer

- **Site:** Breast
- **Principal Investigator at Summa Health System:** William Demas, M.D.
- **Eligibility Criteria:**
  - Stage 0, I or II breast cancer, lumpectomy, tumor size < 3.0 centimeters, < 3 positive lymph nodes.
  - (Ineligible: women > 50 years old with ductal carcinoma in situ or node negative and hormone receptor positive.)

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**Clinical Trials at Summa Health System**

Summa Health Center at Lake Medina opened its doors to patients in November 2010. Among a number of services, this is the only facility in Medina that offers radiation oncology.

The full list of available services and practices includes:

- SPI – Family Medicine Associates of Medina
- SPI – Gynecologic Oncology
- SPI – Medical Oncology
- SPI – Radiation Oncology
- SPI – Surgical Associates of Medina
- SPI – Women’s Health Center Lake Medina
- Summa Rehab Services
- Imaging Services
- Neuroscience Sleep Medicine
- Outpatient Infusion
- Comprehensive Pain Management
- Ferrell-Whited Physical Therapy Services
- LabCare Plus
- The Medina Surgery Center
- Patrick Naples, M.D. – OB/GYN
- Ohio Anesthesia Associates
- Radiation oncology unit

Additional elements will continue to be added over the coming months and years, most notably a fully staffed emergency department.

This 100,000-square-foot outpatient medical center represents a significant partnership between Summa, local physicians and – most importantly – members of the Medina community.

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NSABP P-5
Statin Polyp Prevention Trial in Patients with Resected Colon Cancer
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Eligibility Criteria: Stage I or II adenocarcinoma of the colon or rectum with curative intent within the past year; complete resection; pre-op and post-op colonoscopy within 180 days; more than 30 days since prior statins and prior investigational agents; no chronic use of NSAIDS (low dose aspirin is allowed); performance status 0 to 1.

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Eligibility Criteria: No T4 tumors including inflammatory breast cancer; no definite clinical or radiologic evidence of metastatic disease; no synchronous or metachronous contralateral invasive breast cancer; no history of ipsilateral invasive breast cancer or ipsilateral ductal carcinoma in situ; performance status 0 to 1.

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**Q&A continued**

Are patients generally apprehensive when it comes to enrollment? If yes, how do Summa physicians help them overcome or alleviate it?

“‘Yes, absolutely. You have to educate patients when it comes to clinical research. They immediately think treatment becomes a science experiment. It’s important to lay out all available options. There is first-line therapy – standard of care – and experimental treatment, which can be more aggressive and involve differences in dosage, medication, etc. I only suggest a clinical trial to a patient who meets the eligibility requirements and can handle it. The idea can be overwhelming.”

What are Summa’s accrual rates?

“We currently have 100 to 130 patients enrolled and are monitoring more than 700. Our accrual rates have earned us a number of designations and awards as well as benefited a significant number of patients.”

Where do you see oncology clinical trials going in the future?

“As cancer care continues to improve, more of an emphasis will be placed on survivorship, which explains our commitment to developing a survivorship program here at Summa. This is extremely important because, thankfully, more people are surviving and living longer following diagnosis and treatment.

“Also, there have been talks of smaller, regional clinical research cooperatives being rolled into one large national network headed by NC. The goal is increased efficiency, better accrual rates, faster data collection and analysis, the list goes on. I really hope this happens. There will be fewer overlapping studies, increased standardization and, most importantly, increased access for patients.”

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**Coping Well During Cancer Treatment and Beyond**

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Jennifer Payne, M.D., medical director of cancer research, is the physician leader of Summa Health System’s oncology clinical trials initiative. She is a practicing medical oncologist based at the Jean and Milton Cooper Cancer Center on the Summa Akron City Hospital campus and the Summa Health Center at Lake Medina.

What led you to a career in medicine and your specialization in oncology?
“[My decision on a career in medicine had more to do with really wanting to help people. I wanted something difficult and challenging but I wanted to help people. I always loved science and oncology treatment is constantly evolving, innovating and improving. And, based on my training and experience, oncology patients were always the best. What more could you want to do than help these people?”

How did your role as a physician evolve to include such an emphasis on research?
“The field lends itself well to clinical research because of varying treatment options. I’ve always enjoyed and been interested in clinical research because it requires you to work directly with patients. It’s that research that has a direct and noticeable impact on people in multiple ways. Research at the bench is extremely important but just because something works in a Petri dish doesn’t mean it will help cancer patients.”

What level of importance does Summa place on oncology clinical trials?
“It’s very extensive. Summa is extremely committed to clinical research. Making such treatment options available to patients is what we want and try to do. Many resources and a lot of talented people are dedicated to oncology research. It’s a real commitment.”

How does a hospital or health system begin or grow participation in clinical trials?
“In most cases, you have to be affiliated with a cooperative group or a large national organization — NCI, RTOG, ECOG, GOG, etc. — to become a designated site for clinical research. Also, members of the medical staff could have contacts in the pharmaceutical industry to participate in specific drug trials.”

What factors determine an institution’s participation in specific clinical trials? Is it a result of the patient population or physician areas of interest and specialities?
“Participation is primarily based on three things: appropriate staffing, physician interest and the needs of the patient population. As mentioned before, you have to have a dedicated research staff. The same goes for physician specialization and patient demand for that type of care. For example, we didn’t participate in many gynecologic oncology trials until we recruited two new specialists.

Who, at Summa, is involved in the decision-making process for participation?
“It’s really driven by the research department – they know our patients. The research team identifies patient need and, along with our oncologists, looks for opportunities to provide as many treatment options as possible. Once we decide to participate, all administrative details are taken care of, such as approval from the Institutional Review Board.”

In what types of trials does Summa frequently participate? (Treatment, prevention, diagnostic, screening, quality of life, etc.)
“Roughly 80 percent of our research is in treatment trials. The reason being, once patients are here, they already know they have cancer. They’re here for treatment. Diagnostic and screening trials are more appropriate in a primary care setting. The focus at Summa is cancer care.”

What types are rarer in terms of participation?
“Quality of life trials are difficult to enroll. They’re usually too hard on the patients. Surveys, questionnaires, interviews, journaling – it’s just too much for someone during treatment. However, there is an increasing emphasis on survivorship, which will likely result in additional research attention. We’re in the process of developing our own survivorship program.”

Does Summa generally focus on trials in a certain phase?
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Does the sponsor have any influence on the trial once opened and patients are enrolled?
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**Q&A**

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