McLaren

RESEARCH

Matters

WINTER 2017

Wishing you a happy holiday season!

Self-Auditing for Quality

SEE PAGE 4

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Added Resources in the Works for Resident Research

SEE PAGE 9

McLaren RESEARCH Matters

Connecting the McLaren Research Community

Enjoying the Best of Both Worlds

Thomas Boike, MD, is enjoying the best of both worlds as the new Medical Director of the Karmanos Cancer Network and as a practicing radiation oncologist at McLaren Northern Michigan.

In balancing both roles, he values the care connection he maintains with his own patients at McLaren Northern Michigan, but also respects his extended role in impacting patients' lives by influencing the quality of care across the cancer continuum.

In his position with the Karmanos Cancer Network, Dr. Boike provides physician leadership as part of the executive team at Karmanos Cancer Institute. His particular focus is on standardizing and enhancing quality and patient safety initiatives across the cancer network.

As someone who enjoys working in a team environment, Dr. Boike welcomes the collaboration that comes with his role at Karmanos. He chairs the Network Oncology Quality Committee, a 30-person multidisciplinary team that focuses on quality metrics across the cancer service line. This committee is charged with standardizing quality reporting across the network through the development of a patient safety dashboard specific to oncology.

"It is rewarding to see where there are opportunities to share best practices to raise the bar across the network," he said.

He also is responsible for arranging quarterly Network Oncology Forums. Open to anyone in the oncology network, these educational forums focus on various topics in cancer care. Participants can attend in person or via Web Ex sessions. The most recent forum examined the financial burden facing many cancer patients and introduced the development of a new clinical trial that will be exploring this issue.

Dr. Boike further heads the Clinical Leadership Council, which includes representatives

CONTINUED ON PAGE 10

In this issue...

Why Research Matters

CONNECT-HF Trial Seeks to Improve Quality of Life for Heart Failure Patients

Why does research matter? Ibrahim Shah, M.D., a fellowship-trained interventional cardiologist at McLaren Greater Lansing, has a ready answer to this question.

"Without research, we would not know if the interventions we do are working for patients or not," he said. "Research benefits patients in the most advanced way by allowing us to effectively measure interventions and improve care accordingly."

A longtime proponent of research, Dr. Shah is McLaren Greater Lansing's principal investigator for the CONNECT-HF Trial, which stands for Care Optimization Through Patient and Hospital Engagement Clinical Trial for Heart Failure.

Sponsored by Duke Clinical Research Institute (DCRI), the trial began in April of 2017 and is a large-scale, pragmatic clinical trial involving 160 sites across the United States. Eight thousand patients across the country will be enrolled in the trial and will be monitored on a quarterly basis for one year post hospital discharge. The objective of the trial is to evaluate the usual care protocols for heart failure patients against two quality improvement initiatives to determine how increased education and involvement of patients, combined with more streamlined processes in the hospital setting, impacts heart failure outcomes and quality metrics one year after discharge.

"The goal is to improve quality of life for heart failure patients and to give them a better chance of staying out of the hospital," Dr. Shah emphasized.

McLaren Greater Lansing was randomized to participate in the direct engagement arm of the study. At the hospital level, teams of healthcare professionals from DCRI with specialized training and field experience conduct site visits and work with local cardiologists to design and revise quality improvement plans. An initial meeting with DCRI and the McLaren Greater Lansing Heart Failure Team occurred on November 6th, 2017. DCRI will provide the team with suggestions on making our Heart Failure program more robust and work with us to implement any new programs or quality initiatives.

CONTINUED ON PAGE 12

Research Leads to Improved Outcomes and Processes

By Brian Wicker, RRT, Director of Respiratory Services – Wound & Hyperbaric, McLaren-Lapeer Region

Personally, I feel our people take pride in making healthcare better. If we can identify and overcome barriers, change happens. Of course, this benefits patients in every way - better outcomes, less time in a facility, better quality of life, and more. When we strive for a better patient outcome everyone wins. Improved results (decreased length of stay, less time of mechanical ventilation, less time in recovery of the event, less time in ICU) makes Respiratory Services a valuable asset. Patients are safer, mortality rate decreases and there is a cost avoidance/ decreased costs to the facility in the care of the patient.

Respiratory Therapists focus on caring for patients with a wide variety of cardiopulmonary disorders ranging from asthma to emphysema, major trauma, cardiac arrest and other life-threatening conditions. RT's can do everything from maintaining and operating breathing machines, (ventilators in ER or ICU), to supporting someone trying to quit smoking, educating patients and being there at the newborns first breath, or someone's last breath. We are there every step of their stay – helping patients breathe easier. RT's are 'unsung heroes'. My role in leadership allows me to participate in many different aspects of the respiratory care. I am so glad to be part of the healthcare team, and I support all that they do.

CONTINUED ON PAGE 10

1. Research drives what we do. It impacts patient care every day.

2. Evidence based research helps guide us to learn and develop solutions to problems we face.

3. By engaging employees in research it leads to improved outcomes and improved processes.

EQuIP Corner
Self-Auditing for Quality Part 1

By Patricia Ivery, QI and Education Specialist, McLaren Health Care

No matter if you are involved in sponsoring, managing, or conducting a clinical trial there are three events that may cause worry or fear. The first is low subject enrollment, which may be manageable. The second is poor study results, which may be uncontrollable. The third is a notification from a sponsor or regulatory agency that you are going to be audited. Feelings of worry or fear about an impending audit are normal. The mere notion that someone charged with authority to determine the fate of your clinical trial is coming to inspect your work causes anxiety, even when you know you have been following the protocol and have nothing to hide. Let's face it, audit findings can have cascading consequences for researchers who are unprepared or have not been conducting a trial properly. These consequences can include invalidation of study data, loss of study subjects because they were not eligible, suspension of study activities, or worse yet, termination of the study at their site.

Self-auditing is more than just a check list. It is a method used to evaluate quality in a clinical trial and falls under the umbrella of quality assurance. The GCP definition of quality assurance is "all those planned and systematic actions that are established to ensure that the trial is performed and the data is generated, documented and reported in compliance with Good Clinical Practice and applicable requirements.

The question is not if you are going to get audited, but when you will be audited. Researchers can take measures to alleviate some of the anxiety associated with an upcoming audit by establishing a process of on-going self-assessment. Self-auditing allows you to:

- Be proactive rather than reactive by waiting for someone else to find your mistake or simply relying on monitor visits alone. Monitors will identify the problems, however, they will not conduct a root cause analysis of the issues. Root cause analysis is very important, as it can lead to the discovery of systemic problems. Identification of such problems will help you to develop quality improvement measures.
- Correct problems early in study before they get out of hand, that can raise a red flag to a sponsor and prompting a for-cause audit.
- Keep on top of the most common audit findings of regulatory agencies (Table 1).
- Evaluate principal investigator oversight.
- Demonstrate to the IRB, sponsor and regulatory agencies that you are committed to quality.

Brown Bag Series

What Would You Do
December 12, 2017 • 12:00 noon - 1:00 pm
LIVE WEBINAR
Registration is required. Contact Markeda Richards via email at markeda.richards@mclaren.org to be put on notification list.

SoCRA Detroit Chapter
Speaker: Dr. Susan Szpunar, Director of Research at Ascension
Date: TBD

Upcoming Education and Conferences

Clinical Trial Billing & Research Compliance
February 25 - 28, 2018 • Orlando, FL

AAHRPP Annual Conference
April 20 - 22, 2018 • Denver, CO

ACRP Annual Conference
April 27 - 30, 2018 • Washington, DC

MAGI Clinical Research Conference
May 20 - 23, 2018 • San Diego, CA

Table 1

Most Common Audit Findings

- Failure to follow protocol
- Inadequate record keeping
- Inadequate accountability for the investigational product
- Inadequate subject protection, including informed consent issues
- Inadequate adverse events recording and reporting
- Failure of PI to delegate appropriately

According to the ICH Good Clinical Practice document, sponsors and CROs alike are required to implement and maintain quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented and reported in compliance with the protocol, GCP guidelines and applicable regulatory requirements. A requirement for investigators to have the same quality systems in place is not specifically spelled out in the ICH GCP document. However, ICH principle 2.13 does state that systems with procedures that assure the quality of every aspect of the trial should be implemented.

What is quality in a research trial?

A simplistic definition of quality is the "absence of errors". However, we know that errors in the research context range in severity and their potential to introduce risk to subjects or impact data integrity. These errors range from not initialing a correction on a document to enrolling subjects in a trial without IRB approval to administering an investigational drug to an ineligible subject. The best explanation of quality in clinical research is a study that:

- Generates data that is accurate, verifiable, and credible.
- Protects the rights, welfare, and confidentiality of trial subjects.
- Proceeds smoothly with few interruptions from errors and omissions.
- Adheres to the protocol, GCP guidelines, federal regulations, laws and institutional policies.

A simple model for quality assurance used by industry sponsors, is the **PDCA** cycle, which stands for **plan, do, check and act**. This simple four step process has no end point, allowing for continuous quality improvement. The PDCA cycle is very similar to the FDA mantra for a quality system: Say what you are going to do, do what you say, prove it, and improve it.

In the next issue of the "Research Matters" I will discuss each step of the PDCA cycle, when and how to self-audit, and how to handle your findings.

McLaren Represented at SOCRA's 2017 Annual Conference

Patricia Ivery, BSN, MSN, RN, QI and Education Specialist, McLaren Health Care, recently presented at SOCRA's 2017 Annual Conference.

The Society of Clinical Research Associates (SOCRA) is a non-profit, charitable and educational membership organization committed to providing education, certification, and networking opportunities to all persons involved in clinical research activities.

Her presentation was titled: *Quality Assessment of Research Conduct: Auditing Yourself Before They Do.* Why wait for the sponsors or regulatory agencies to audit you? She discussed auditing your own study conduct as a way to determine if you are conducting your study accordingly, identifying areas of weakness or gaps, and instituting quality improvement measures to address those gaps. The premise of her presentation was to educate the attendees that by establishing a system of self-auditing on an on-going basis, they can reduce some anxiety when they receive an audit invitation.

"The premise of my presentation was to educate the attendees that by establishing a system of self-auditing on an on-going basis, they can reduce some anxiety when they receive an audit invitation."

– Patricia Ivery

Feedback from conference attendees:

"I wanted to send a quick note of thanks for your wonderful presentation at SOCRA. It was my first time attending and I took away an entire EXCEL spreadsheet of new ideas to implement. I'm excited to see how we can improve our processes."

"Thank you for your informative talk during the SoCRA annual conference! I enjoyed your presentation and look forward to reviewing my notes with my supervisor as we look to hire a quality assurance team member and establish a QA program."

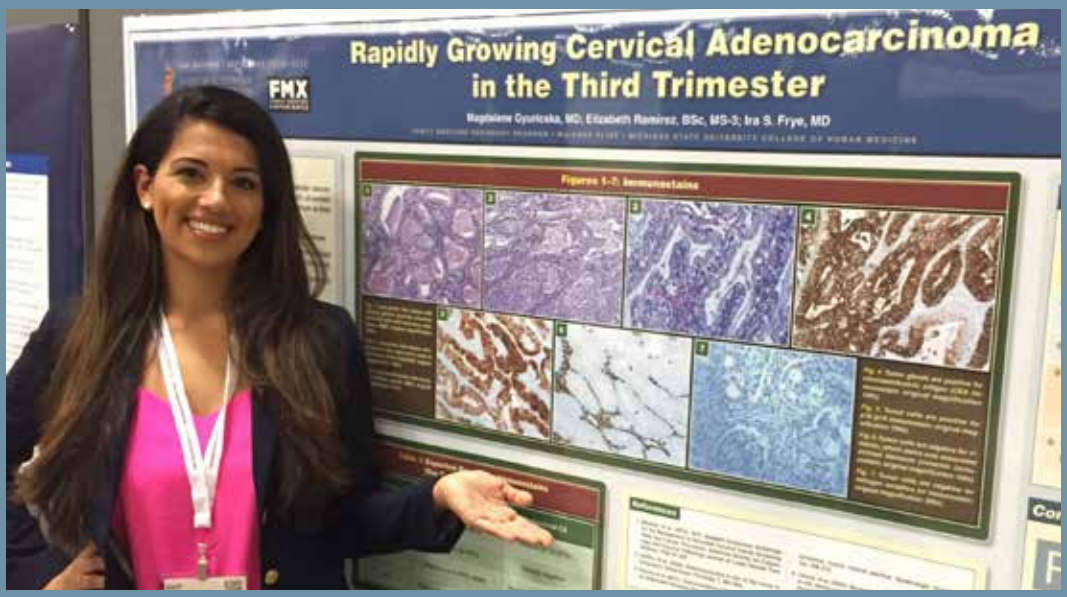
"Your presentation at SOCRA was great. I would love a copy of your quality assurance audit checklist. We are working on SOPs for our program and this would be a great starting point."

Karmanos Cancer Institute's Representation at SOCRA

Representatives of the Karmanos Cancer Institute Clinical Trials Office presented an abstract and poster for the national SoCRA meeting that took place October 6-8 in Orlando Florida. Cathy Galasso proudly carried the poster and represented Karmanos on the development of "Using a Team Strategy to Coordinate Institutional Biosafety Practices".

Special Congratulations to:

Sarah Bigelow- CTO Project Manager of Research Integration
Cathy Galasso- CTO Research Nurse Supervisor and Phase I Lead
Kasha Krul- CTO Regulatory Manager
Barb Manica- Manager, Investigational Drug Services
Morris Magnan- Clinical Nurse Specialist



Resident's Corner

Recognizing McLaren Residents

McLaren Flint residents presented case studies at the 2017 FMX conference. This is the biggest national conference of the American Academy of Family Physicians.

Magdalene Gyuricska, MD, along with her co-authors (Ira Frye and Elizabeth Ramirez) won first place for their case presentation: "HPV to Adenocarcinoma during Pregnancy."

Three additional residents, Dr. Ahmed Aldabdob, Dr. Sara Elsayed and Dr. Siddharth Vannemreddy, also presented their case reports in the same conference.

At a different conference, the Director's Meeting and Fall Retreat held in Shanty Creek, MI (state level), Dr. Adebayo Akindele and Dr. Raza Cheema presented their scholarly activity.

Congratulations to all!

Carol Myzuk

Congratulations

Congratulations goes to Carol Myzuk from Karmanos Cancer Institute on her recent SOCRA certification.

What's New?

Corporate Research Administration

McLaren Health Care has had remarkable growth in our research program and has made great strides in establishing a centralized research infrastructure. With this growth it has become important to be efficient, drive quality research opportunities and meet the growing needs of our physician investigators as well as meet the needs of the changing research industry. Refinement in the structure becomes imperative as we have more system based Investigators and system level clinical trials.

McLaren Health Care would like to announce the newly developed Corporate Research Administration Office, a division of the Office of Clinical Excellence, and welcome Lana Gevorkyan as its newly appointed Corporate Director. In this new role, Ms. Gevorkyan will oversee the Research Integrity department (formerly known as Human Research Protections Program) and McLaren Center for Research and Innovation's Clinical Trials Office. This newly centralized Clinical Trials Office includes all non-oncology research sites across the system. Bringing research together under this centralized structure will support more fully functioning and high performing research operations for all of McLaren.

The Research Integrity department will continue to ensure compliance with federal regulations, state laws and institutional policies.

The Research Integrity Department includes:

- Institutional Review Board
- Office of Research Compliance and Quality Improvement
- Office of Research Education, Training and Resources

The HRPP will continue to be an integral part of the McLaren research structure. As such, accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP) will be maintained.

Welcome Omar Gayar, MD

A warm welcome is extended to Dr. Omar Gayar as the newest member of the MHC IRB. Dr. Gayar is a board certified Radiation Oncologist at Karmanos Cancer Institute (Flint) and has joined McLaren's IRB effective October 1, 2017. Dr. Gayar attended medical school at University of Missouri – Kansas City and completed his residency at Henry Ford Hospital. His involvement in research and expertise in the field of radiation oncology is an invaluable resource to the board. Welcome, Dr. Gayar!

Enrollment Announcements

Congratulations to Dr. Robert Molnar of Michigan Vascular Center for making McLaren Flint the top enrolling site in the country in the Phase II study for Evaluation of Safety and Efficacy of Hymacyte's Human Acellular Vessel for Use as a Vascular Prosthesis for Femoro-Popliteal Bypass in Patients with Peripheral Arterial Disease.

Carlos Rios-Bedoya discusses research with Emaad Basith, MD, Family Medicine resident at McLaren Flint.

Added Resources in the Works for Resident Research

In his new role as Corporate Director of Scholarly Inquiry with the McLaren Health Care Department of Academic Affairs, Carlos F. Rios-Bedoya, MPH, ScD, works collaboratively with McLaren's Research Integrity department. Since starting his role in October 2017, he has identified three short-term goals. They include:

1. Implementing "Protocol Builder", a secure web-based application that provides a step-by-step process to make clinical trial protocol development faster and less demanding;
2. Developing a dedicated webpage featuring online resources and links for residents and physicians to utilize in developing research projects; and,
3. Hiring additional doctorate-level faculty with expertise in research who can provide one-on-one guidance to residents.

Since joining McLaren earlier this year, Dr. Ríos-Bedoya has been working closely with Robert Flora, MD, MBA, MPH, Chief Academic Officer/ VP of Academic Affairs at McLaren Health Care, to assess the structure, resources and personnel required to support and advance resident research among McLaren subsidiaries. The goal is to standardize this approach systemwide.

The implementation of Protocol Builder is a first step toward that standardization.

"We recognize that sometimes it is challenging to move from a clinical mindset to a research mindset," Dr. Ríos-Bedoya noted, adding that carrying out a research project can be a formidable task for a resident with little experience in this arena.

Protocol builder provides a step-by-step process that can set the roadmap for a successful research project. It provides user-friendly framework to navigate the complex regulatory infrastructure that surrounds clinical research in the U.S. Protocol Builder ensures efficiency and accuracy in developing a complete study protocol that is ready to submit to

CONTINUED ON PAGE 11

"We want to develop a very interactive and streamlined system."

– Carlos Ríos-Bedoya, MPH, ScD

Enjoying the Best of Both Worlds

CONTINUED FROM PAGE 2

from throughout the cancer network. The objective of this group is to help define and align goals between physicians and administrators at Karmanos. Dr. Boike noted this council gives physicians a critical voice in the development and direction of the oncology service line.

He also holds a seat on the Network Operations Steering Committee involving representatives from the Karmanos Cancer Hospital in Detroit, as well as the network of community cancer centers.

Between all of these responsibilities, Dr. Boike is making time in his first few months on the job to visit all oncology clinics throughout the Karmanos network to talk about ways to further collaborate and to identify common threads across the system.

Dr. Boike finds his role both challenging and engaging, and he is well prepared for all aspects.

After earning his medical degree at Wayne State University, he completed a residency at the University of Texas Southwestern, in Dallas and earned a master's degree in medical management with Carnegie Mellon University. Dr. Boike joined McLaren Northern Michigan in 2011 in the department of radiation oncology. At the state and national level, he has been a member of the Michigan Radiation Oncology Quality Consortium Executive Committee and serves as a quality site reviewer for ASTRO's Accreditation Program for Excellence.

"It is rewarding to see where there are opportunities to share best practices to raise the bar across the network."

– Thomas Boike, MD

Research Leads to Improved Outcomes and Processes

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A common question is "Where would we like to do research in the future?" One answer is to focus more on chronic disease management and maintenance. When we focus on programs in these arenas we can improve quality and health outcomes. All respiratory department managers and directors are involved with quality improvement activities, and such activities can be of valuable context for research if this is done appropriately. Research leads to process care changes, and the key is getting staff buy-in and involvement in change. The saying "we have always done it that way" is gone. When you engage staff, they take pride in ownership and their work. We must foster change and cultivate people to continue to be passionate for leading change.

Added Resources in the Works for Resident Research

CONTINUED FROM PAGE 9

an IRB. Dr. Rios-Bedoya noted it is an excellent tool for both novice and experienced researchers.

The second initiative currently underway is developing a dedicated website that features content and functionality specifically dedicated to research. Feedback is currently being sought from potential users, with the next step involving testing the website to insure it is "user-friendly".

"We want to develop a very interactive and streamlined system," Dr. Ríos-Bedoya emphasized. He also noted for those physicians who prefer hard copies of training materials and research guides, print materials will be available as well.

Dr. Ríos-Bedoya is projecting the third initiative on his list of goals to be accomplished in early 2018. The Division of Scholarly Inquiry is seeking to augment its faculty capacity by adding at least two doctorate level research experts.

"The idea is to have one of these doctoral level research experts conducting brainstorming sessions in which residents and faculty advisors can talk through research ideas, analyze logistics of the project, evaluate timeframes and then determine the feasibility to move forward into Protocol Builder and thereafter approval by the IRB."

He noted research projects and residents' schedules are very time-intensive, so a one-year timetable is optimal. The first quarter involves the brainstorming phase and IRB submission, the second quarter the implementation phase, the third quarter data analysis and abstract submissions, and the fourth quarter the presentation and publication phase. He noted the vision is to turn the research projects into high quality poster presentations that are presented at regional, state and national meetings. Thereafter, into a publication manuscript in a peer-reviewed journal.

By the year 2020, Dr. Ríos-Bedoya expects every resident in the McLaren system to be participating in a research project.

Some of this relates to new ACGME guidelines requiring resident research, but it also is reflective of McLaren's philosophy about the benefits of research for both residents and the program as a whole.

"Involvement in research is critical in promoting the practice of evidence-based medicine," Dr. Ríos-Bedoya said. "It also helps set residents apart from their peers in terms of competing for fellowships and other positions."

"The idea is to have one of these doctoral level research experts conducting brainstorming sessions in which residents and faculty advisors can talk through research ideas."

– Carlos Ríos-Bedoya, MPH, ScD

Ventilator Utilization Topic of IRB Study 2017-00039

Five year retrospective study of comparing ventilator utilization before and after implementation of the endOclear restore device.

The results of cleaning the ETT before weaning trials are supported by this five year, retrospective, observational study of 1,320 subjects on mechanical ventilation greater than twenty-four hours. Data was collected on 426 subjects prior to using the daily ETT cleaning protocol and 894 subjects after implementing the protocol. This resulted in a decrease in average time on the ventilator from 4.2 to 3.5 days (0.7±0.8, $p<0.01$), a decrease in length of stay in the hospital from 9.9 to 8.3 days (1.6±1.9, $p<0.01$) and a decrease in direct cost per case from $13,101 to $12,024 ($1,077±2,784, $p<0.15$), a total of $926,838 net benefit. I was so proud to share our successes at McLaren Lapeer at the AARC – American Association for Respiratory Care Conference Poster presentation in Indianapolis, IN.

Introducing Protocol Builder

McLaren realizes that many of our new and seasoned investigators find the regulatory and compliance hurdles difficult and time-consuming when writing research protocols. Often investigators struggle with writing protocols and are in need of assistance to ensure that protocols are complete and ready for submission to the IRB. In an effort to assist with this issue, we are excited to introduce Protocol Builder to our research community.

Protocol Builder is a web-based application, accessible from any desktop or mobile device with any operating system, which will assist researchers in the development of investigator initiated research protocols that meet regulatory standards. This will not replace the IRB eProtocol application, but will rather serve as a great resource for investigators to use while developing research protocols.

Currently we are in the training phase of the implementation process and will provide more information as it becomes available.

CONNECT-HF Trial Seeks to Improve Quality of Life for Heart Failure Patients

CONTINUED FROM PAGE 3

At the participant level, patients enrolled in the study are provided with learning materials and other patient resources unique to the CONNECT-HF trial. These resources give patients useful ideas and suggestions regarding how to manage their heart failure once they have left the hospital. CONNECT-HF participants continue to receive their regular medical care from their personal physician. However, the research team contacts the research patients by phone four times a year to monitor their medication use, quality of life status and track any hospital readmissions.

"The information gained from this trial will help hospitals and doctors determine how to better support patients with heart failure in the future," Dr. Shah said, adding that this could be just as important as research looking at new medicines or treatments for heart failure.

McLaren Corporate Research
2701 Cambridge Court, Ste. 110
Auburn Hills, MI 48326

Office of Clinical Excellence

VICE PRESIDENT
Chandan Gupte
chandan.gupte@mclaren.org

Corporate Research Administration

CORPORATE DIRECTOR
Lana Gevorkyan
lana.gevorkyan@mclaren.org

ADMINISTRATIVE ASSISTANT
René Bruns
rene.bruns@mclaren.org

Research Integrity (formerly HRPP)
hrpp@mclaren.org
(248) 484-4950

IRB ANALYSTS
Jodi Reetz
jodi.reetz@mclaren.org

Katherine Pittel
katherine.pittel@mclaren.org

RESEARCH INTEGRITY COORDINATOR
Markeda Richards
markeda.richards@mclaren.org

QI & EDUCATION SPECIALIST
Patricia Ivery
patricia.ivery@mclaren.org

McLaren Center for Research and Innovation
mclaren.org/Main/Research.aspx
(248) 484-4960

CORPORATE RESEARCH MANAGER
Jill George
jill.george@mclaren.org

REGULATORY SPECIALIST
Tanya Gardner-Mosley
tanya.gardner-mosley@mclaren.org

CONTRACT AND BUDGET SPECIALISTS
Rachel Dick
rachel.dick@mclaren.org

Jennifer Dunaj
jennifer.dunaj@mclaren.org

Corporate Clinical Research Associates

Karmanos Cancer Institute Clinical Trials Office

VICE PRESIDENT
Lisa Lange
langel@karmanos.org

DIRECTOR
Maureen Kelley
kelleym@karmanos.org

MANAGER
Elizabeth Bowie
bowiee@karmanos.org

CRC-REGULATORY
Raven Miller
millerr@karmanos.org

CRC-REGULATORY
Vidya Yarlagadda
yarlagas@karmanos.org