Mission Statement

To provide patients with the opportunity to participate in clinical research and have access to cutting edge therapies. We provide education to staff and the public about our clinical research program. Recruit primary investigators with a passion for research.

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Kim Williams, CAO

The Providence in Northwest Washington has a long history of serving the community beginning when the Sisters of Providence established a hospital in Everett in 1905. Today, Providence cares for the community through a comprehensive network of facilities and services including Providence Regional Medical Center, one of the busiest hospitals in the state; and Providence Medical Group, a network of primary care, urgent care and specialty physicians.

As the Chief Administrative Officer for Northwest Washington, I am honored to be sharing the Center for Clinical Research’s annual report with you. The caregivers and physicians work hard to make the Clinical Research program one of the best in the Northwest. The team runs a wide gamut of pharmacological, medical device, and quality of life trials. You will read about many of those trials in this annual report.

One of our organizational goals is to adopt greater accountability for the overall health of the community, joining with our clinicians, care teams and other partners to develop innovative care delivery models that focus on population health and pioneering technology that results in improved health care value. The work of the Center for Clinical Research is a great example of furthering this goal.

The NCI Oncology Research Program clinical trials, sponsored by the National Cancer Institute, is one of the many innovative programs that you will read about in this report. These trials are available to cancer patients at the Providence Regional Cancer Partnership. This work gives PRMCE an opportunity to compare standards of care with new and innovative cancer therapies. It is important that we participate in this research so that we can provide the most effective care for our patients.

Being part of Providence St. Joseph Health allows us to share best practices and learn from our colleagues across the system. The Clinical Research caregivers have worked collaboratively with Swedish, Providence Spokane and Providence Portland to implement one Institutional Review Board hub. Additionally, PRMCE will be one of the first ministries within Providence St. Joseph Health to implement Velos. This clinical trials management system gives us greater opportunities to communicate our trials more broadly, and provides a tracking mechanism that will assure our patients are meeting the milestones for the studies they are participating in.

If you would like to learn more about our clinical research programs or support the growth of our efforts, please don’t hesitate to contact our research office at clinicalresearch@providence.org.

Thank you.
Best Wishes,
Kim
Clinical Research Oversight Committee

Research is to see what everybody else has seen, and to think what nobody else has thought.”

Albert Szent-Gyorgyi, Nobel Prize winning physiologist

Providence Regional Cancer Partnership has long been dedicated to providing pertinent clinical research trials to our patients. In participating in clinical research we aim to advance the practice of medicine and create opportunities for our patients to undergo cutting edge treatment. To ensure safe, ethical and financially responsible care, the Clinical Research Oversight Committee meets bimonthly to review each newly proposed clinical trial in detail and hear updates regarding ongoing trials.

The Clinical Research Oversight Committee is a multidisciplinary panel of unique individuals invested in clinical research and includes physicians, nurses, pharmacists, research coordinators, ethicists, administrators and financial analysts. The research coordinators and principle investigators prepare a presentation regarding the clinical background for the trial, relevant data regarding the drug, device or treatment to date, and a risk benefit discussion for the group. The ethics of the trial, the drug/device, the treatment schedule, the plan for close monitoring, the patient information and the informed consent are closely reviewed by our team to ensure complete transparency and equipoise. At the conclusion of the review, the group votes on proceeding with the trial should all appropriate criteria be met. In the event there is a concern, more data is requested and the proposed trial is presented again for review at a subsequent meeting. The decision to approve a new clinical trial must be unanimous.

The Clinical Research Oversight Committee is dedicated to close monitoring of existing clinical trials as well. Once a trial is underway, the committee is updated by the principle investigator on a regularly scheduled basis. The number of patients screened, enrolled and actively participating in the trial is reviewed. Potential adverse outcomes reported by the sponsor and the health of our patients are analyzed in detail. Additionally, the sub-investigators are updated quarterly at the disease specific Multidisciplinary Tumor Boards held at Providence Regional Cancer Partnership.

We are proud to report that we are currently conducting 39 clinical trials which span several service lines including surgery, infectious disease, cardiovascular disease, dermatology, breast, lung, renal, prostate, skin, head and neck and hematologic malignancies. Every patient presented at the Providence Regional Cancer Partnership Multidisciplinary Tumor Board is evaluated for eligibility in a clinical trial. The American College of Surgeons Committee on Cancer requires 6% of all cancer patients to be enrolled in a clinical trial for accreditation of the institution. We have exceeded that goal with 8.5% of Providence Regional Cancer Partnership patients currently enrolled in a clinical trial, and we have seen great benefit. As an example, we participated in the Monaleesa trial, a drug investigation trial which evaluated a unique medication developed to treat advanced breast cancer. This treatment was found to be so effective the trial was stopped early and the drug was fast tracked for evaluation by the FDA with final approval arriving March 13, 2017. Because we participated in this trial, our patients had access to cutting edge medication well in advance to the general public.

It has been a pleasure to serve as the Chair of the Clinical Research Oversight Committee and work with such wonderful individuals. I look forward to the coming year and what there is to be found on the horizon.

“Somewhere, something incredible is waiting to be known.”

Dr. Carl Sagan

~Kimberly Costas, MD

Kimberly Costas, MD
Chair, Clinical Research Oversight Council

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~Kimberly Costas, MD
One of my strongest memories of childhood is that of the endlessly exciting nature of discovery – of watching ants march, wolf spiders jump, watching a sleepy cat purr in the sun and seeing the light catch on the fur. Today, it’s watching my two year old discover new things – the amazing color purple, blowing the seeds of the dandelion, biting into a freshly picked apple and many others. In oncology, that same kind of excitement can be seen in the efforts to jumpstart the immune system with the PD1 and PDL1 inhibitors, aka checkpoint agents, pembrolizumab and nivolumab, among others. We have a number of trials using these agents and we have seen some excellent and durable long term responses in diseases that these kind of responses were unheard of. It is an astounding and gratifying time to be in hematology/oncology, and I tell my patients, often, that “if you had to have cancer, now is the time to have it.”

As exciting as this branch of clinical research is, it’s crucial to remember that it could slowed down or stopped by the administration’s plan to cut the budget of NIH by 20%. Basic science is the trunk of the tree of knowledge and the branches of clinical trials support its fruits. These fruits represent pioneering and truly revolutionary efforts, so effective and often without major side effects such as we have never seen in melanoma or lung cancer, and extending now into lymphoma and bladder cancer. I am so very proud to be associated with Clinical Research team and the Providence Regional Cancer Partnership as we work very well together and the Research team does such a fantastic job landing great trials for our patients, they make us all look good!

~Jason Lukas, MD, PhD
We are excited to share our 2016 Annual Report for Research this year with our patients, providers and staff. We are very proud of the studies we have been selected to participate in. These studies are important in understanding disease processes and contributing to the future for better treatments and improved quality of life for individuals.

We could not have provided such amazing care without our research staff. We have well trained research coordinators and assistants who work directly with the physicians and study sponsors to assure that the patient has all the information they need as well as assures that all study related events take place and are documented appropriately. We also have essential staff that assure our operations run smoothly and that we are compliant with all regulatory requirements.

We have met some incredible study participants. Many individuals are interested in contributing to the science and want to help others who may be in similar situations with their health. Patients often participate in studies because they want to improve their own health and the idea of being able to receive the latest treatments before they are widely available is exciting for them. All the advances we have experienced in treatments start with patient participants who engage in clinical research.

Patients tell us they appreciate our research team because of the additional set of eyes added to their healthcare team. Patients are glad their providers are involved in studies and it gives them confidence that they are staying informed about the latest treatments and technologies currently being studied.

We have an amazing group of physicians to work with in clinical research. These providers appreciate the ability to provide additional options for their patient’s treatment. It is an honor to work with such committed research physicians who are so passionate about finding the very best treatments for their patients.

The research department also supports research activities that benefits our patients through nursing, pharmacy and behavioral health services. We have several individual researchers who are advancing their education and conducting studies using our research services. This body of work is important as we strive to be the best we can be as healthcare providers.

We are fortunate to have Providence Regional Medical Center Everett’s commitment to research here in our community. We appreciate the hospital’s support for allowing us to provide research services to our patients, staff and providers.

~Marilyn Birchman, RN, MSN, AOCNS
Regional Director, Cancer Services & Research

Many individuals are interested in contributing to the science and want to help others who may be in similar situations with their health
Clinical Research Services

Regulatory Analyst

- Prepares documents for submission to the institutional review board (IRB).
- Works with the sponsor and/or IRB on informed consent wording.
- Maintains regulatory study documents, from site selection to study closure.
- Coordinates sponsor and/or regulatory audits.

Business Analyst

- Works with department staff in order to assess the financial feasibility of performing a new study
- Responsible for the optimal negotiation of clinical research contracts and budgets with multiple sponsors
- Manages Clinical Trial Budgets to ensure optimal and accurate reimbursement
- Manages Departmental Revenue Cycle
- Ensures integrity and compliance with regards to research billings and continually evolving contractual terms
- Ensures federal grant compliance for all federally funded trials.

Clinical Research Coordinator

- Assists in evaluating new studies for feasibility of patient eligibility, resources, timelines, etc.
- Collaborate and send out information about the study to other departments as necessary.
- Screen and contact potential patients for the study.
- Present potential patients with the informed consent, discussing the study requirements and answering questions about the study, procedures, and risks associated with participating.
- Coordinate and prepare for patient study visits to ensure that all tests are completed.
- Ensure all necessary data is gathered and recorded in the appropriate documents.
- Work with the pharmacy to make sure all study drugs are dispensed correctly to patients.
- Act as the liaison between the study sponsor and the patients; working with physicians and other health care providers to ensure the safety of patients.
- Work in an ethical manner within HIPPA guidelines and other federal rules to ensure the confidentiality and safety of patients.

Clinical Research Team

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Working with the Research Staff

A Physician’s Perspective

Working with the research team at PRMCE has been a real treat. When I arrived at PRMCE I had a strong interest in research but did not know how I could fit research into a busy clinical practice. The research staff at PRMCE has vastly surpassed my expectations and made participation in research a very smooth process.

The clinical research staff here is a pleasure to work with for so many reasons.

1) They are very accessible.
2) They are very motivated to bring new research projects to PRMCE, despite having a very busy workload.
3) They are extremely thorough with all components of the study process.
4) They handle almost all of the red tape and paperwork involved in a study.
5) They do their best to work with a PI’s clinical schedule and do not expect a PI to make large concessions to participate in research. A simple but powerful example: the staff has never asked me to come to their office to sign any paperwork. Instead, on countless occasions members of the clinical research staff have brought research documents to the hospital for me to sign between procedures or to the clinic for me to sign between patients.

Working with the PRMCE clinical research staff has been so positive that I have now been emboldened to start pursuing investigator initiated projects. Not surprisingly, the research staff has been incredibly helpful in this area as well, from helping determine study costs to helping draft an IRB.

Providence also has excellent statisticians who can help with calculations and scientific writers who can help with document drafting once a study is complete.

All in all I have enjoyed my experience as a PI at PRMCE. I look forward to continued work with the research staff at PRMCE and encourage anyone interested in research to contact this great team.

~Maheer Gandhavadi, MD

Katie Lyon, Rachel Macomber, Lynda Oehlsen, Courtney Nichols, Terry Stoeckilhuber, Kim Nordstrom McCaw, Marilyn Birchman, Dean Rocco, Tija Schmiesing
Novartis LEE011 (ribociclib) Granted FDA Priority Review for First-Line Treatment of HR+/HER2– Advanced Breast Cancer

On November 1, 2016 Novartis reported that the US Food and Drug Administration (FDA) accepted the company’s New Drug Application (NDA) for filing and granted Priority Review for LEE011 (ribociclib) as first-line treatment of postmenopausal women with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer in combination with letrozole (Press release, Novartis, NOV 1, 2016, View Source [SID1234516136]). The NDA is based on a comprehensive clinical package, including results of the Phase III MONALEESA-2 trial. The trial, which was presented at the European Society for Medical Oncology (ESMO) 2016 Congress and published simultaneously in the New England Journal of Medicine, showed LEE011 plus letrozole reduced the risk of progression or death by 44% (HR = 0.556, 95% CI: 0.429-0.720; P = 0.00000329) over letrozole alone, significantly extending progression-free survival (PFS) across all patient subgroups[1]. The company also announced that the EMA has accepted for review the marketing authorization application for LEE011 plus letrozole in the same patient population.

"These regulatory milestones, along with the FDA Breakthrough Therapy designation granted in August, underscore the need for new treatment options for women living with HR+/HER2- advanced breast cancer," said Bruno Strigini, CEO, Novartis Oncology. "Priority Review allows a shorter review period compared with FDA standard review in the US, helping us to potentially bring LEE011 plus letrozole to patients more quickly. We also are working diligently with the EMA and other Health Authorities to bring this treatment to patients around the world as fast as possible."

FDA Priority Review designation requires the agency to take action on an application within six months of its filing date compared to ten months under standard review[2]. FDA grants Priority Review to applications for new drug candidates that treat serious conditions, such as advanced breast cancer for which there is currently no cure, and if approved, would provide a significant improvement in treatment safety or efficacy [2].

About LEE011 (ribociclib) LEE011 (ribociclib) is a selective cyclin dependent kinase inhibitor, a class of drugs that help slow the progression of cancer by inhibiting two proteins called cyclin dependent kinase 4 and 6 (CDK4/6). These proteins, when over-activated in a cell, can enable cancer cells to grow and divide too quickly. Targeting CDK4/6 with enhanced precision may play a role in ensuring cancer cells do not grow uncontrollably.

LEE011 is not approved for any indication in any market at this time. LEE011 was developed by the Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals.

About the MONALEESA...
Novartis LEE011 (ribociclib) Granted FDA Priority Review for First-Line Treatment of HR+/HER2– Advanced Breast Cancer

Clinical Trial Program
Novartis is continuing to assess LEE011 through the robust MONALEESA (Mammary ONcology Assessment of LEE011’s Efficacy and SAfety) clinical trial program, which includes MONALEESA-2, MONALEESA-3, and MONALEESA-7. These trials are evaluating LEE011 in multiple endocrine therapy combinations across a broad range of patients, including men and premenopausal women.

MONALEESA-2 is a Phase III randomized, double blind, placebo controlled, multicenter global registration trial to evaluate the safety and efficacy of LEE011 in combination with letrozole compared to letrozole alone in postmenopausal women with HR+/HER2- advanced breast cancer who have received no or a maximum of one prior endocrine therapy.

The MONALEESA-3 trial is investigating LEE011 in combination with endocrine therapy and goserelin compared to endocrine therapy and goserelin alone in pre-menopausal women with HR+/HER2- advanced breast cancer who have not previously received endocrine therapy. Both MONALEESA-3 and MONALEESA-7 are fully enrolled.

About Advanced Breast Cancer
Up to one-third of patients with early-stage breast cancer will subsequently develop metastatic disease[3]. Survival rates for women living with advanced breast cancer are lower than those for women with earlier stage disease. The 5-year relative survival rate for stage 3 breast cancer is approximately 72%, while metastatic (stage 4) breast cancer has a 5-year relative survival rate of approximately 22%[5].
On September 12th, 2016, after over a year of diligent planning and preparation, The Center for Clinical Research opened to enrollment for The Comparison of Outcomes of Antibiotic Drugs and Appendectomy (CODA) Trial. PRMCE is a sub recipient of the UW for this Patient Centered Outcomes Research Institute (PCORI) funded study, and is one of 9 CODA sites in Washington and California. The input and expertise of local Principal Investigators Dr. Careen Foster (Surgical) and Dr. Brandon Tudor (ED), as well that of Dr. Bill Finley, has been critical to logistical planning efforts.

**From the Protocol:**
“The Comparison of Outcomes of Antibiotic Drugs and Appendectomy (CODA) trial aims to test, if from a patient’s perspective, the antibiotics strategy is "just as good as" appendectomy for acute uncomplicated appendicitis. We believe that patients, clinicians, and the people who pay for healthcare (both patients and insurers) will find the antibiotics approach acceptable if 1) it results in high rates of treatment success, 2) does not increase complications, and 3) provides an equivalent or better patient experience…If non-inferiority is demonstrated (or superiority of the antibiotics approach identified), that finding will improve patient choice and should support a shift to the less invasive approach. If non-inferiority is not established, results may help to delineate the trade-offs between the two treatment approaches and inform decision-making.”

The CODA study is a Randomized controlled 50/50 trial, with an overall enrollment goal of 1,552 subjects. The CODA budget allowed for the hiring of three temporary Research Assistants at PRMCE, who are now screening and enrolling patients every day. Screening of potential subjects will take place 17 hours per day, seven days per week, primarily in the Emergency Department. To date, PRMCE has consented 121 patients. Of these, 50 are in the randomized cohort, 22 in the observational cohort and 49 in the medical record cohort.

A multi-disciplinary approach has been essential in preparing for this important study at PRMCE. Communications with Surgery, Imaging, Emergency, and Clinical Data Analytics, to name a few, have been essential to successful preparation for and execution of this study.

~Tija Schmiesing, CODA Project Manager
Women’s Cardiology

Pregnancy and the Heart

Women who are pregnant have increased risk for abnormal rhythms (arrhythmias). They are at risk for coronary artery dissection during delivery.

During the delivery of the baby there are rapid changes in the mother’s circulatory system. The heart rate and blood pressure increase. Each contraction brings about rapid changes in the circulatory system.

Delivery pain can also increase blood pressure and heart rate.

One of the problems that some women experience after delivery is finding out that they have heart failure from a postpartum cardiomyopathy. This is a heart muscle problem which is affected by the process of gestation. The heart muscle can weaken and place the mother at risk for congestive heart failure and death. The patient will then need to be treated for heart failure over time. Sometimes the heart muscle never returns to normal function.

Another problem during delivery is a risk for a heart attack secondary to dissection of one of the coronary arteries that feed the heart muscle. This is a rare event, but women need to know about it. The estimated incidence of a heart attack during pregnancy is 3 to 10 cases per 100,000 deliveries. Women are particularly at risk for a coronary artery dissection. Approximately 80% of acute coronary artery dissections occur in women vs. men. This is a process where a coronary artery develops a tear, causing blood flow between the layers of the artery which force the layers apart. This can be corrected using coronary stents.

Risk of Ischemic Heart Disease in Women after Radiotherapy for Breast Cancer

Exposure of the heart to ionizing radiation during radiation therapy for breast cancer increases the subsequent rate of ischemic heart disease. The increase is proportional to the mean dose to the heart, begins within a few years after exposure, and continues for at least 20 years. Women with preexisting cardiac risk factors have greater absolute increases in risk from radiotherapy than other women without preexisting risk factors.

Reviewing the research regarding women and heart disease is enlightening and concerning. When compared to studies of heart disease in men, there have been historically less studies on women and overall less women enrolled in trials. Current research guidelines attempt to decrease the disparity between studying women’s and men’s cardiovascular conditions.

~Gerrie Gardner, DO, FACC, FACP

Risk of Major Coronary Events after Radiation Therapy for Breast Cancer

![Graph showing the increase in risk of major coronary events with increased dose of radiation to the heart. The graph demonstrates a linear relationship between mean dose of radiation to the heart and the percentage increase in the rate of major coronary events.](image-url)
Increased stress has been associated with preterm birth, a complication affecting almost 12% of pregnancies in the United States. Helping reduce stress during pregnancy could potentially benefit pregnant women and their infants. A proven technique for stress reduction is mindfulness, a type of meditation that helps people focus their attention on the present and accept their feelings, thoughts, and sensations without judgment. Typical mindfulness training happens in classroom settings over many weeks. Pregnant women who are hospitalized or confined to bed because of the likelihood of giving birth too early are unlikely to be able to attend classes. In 2013 I received funding from the University of Washington’s Center for Child and Family Well-Being to conduct a research study at the Pavilion for Women and Children to see if a mindfulness training program could be delivered over the Internet to pregnant women on the antepartum unit.

There were many steps to get this project ready: build the mindfulness training website with audio, video, and written materials; hire a study coordinator to help with recruitment, enrollment, and participant contact; obtain approval for the research from the Human Subjects Division at University of Washington, the Providence Nursing Research Council, and nursing leaders at the Pavilion; and print flyers, posters, and consent forms. When recruitment began in 2014, we distributed flyers to the nurses on antepartum and examined patient census reports for eligible participants. The nurse for eligible patients would hand out the flyers and facilitate contact with the study coordinator for enrollment. Patients who were interested met with the study coordinator to learn about the study and complete enrollment forms. They were encouraged to practice the mindfulness meditation exercises on a daily basis. They were asked to complete questionnaires upon enrollment, after four weeks, and at six weeks postpartum.

We had hoped to enroll up to 30 participants in the program but recruitment was very difficult. We tried to increase enrollment by advocating for the research directly to the nursing staff and by adding an additional site at Swedish First Hill. By the end of the study only 10 women agreed to participate, all from the Pavilion. Of those, only 6 completed the training and the postpartum questionnaire. Although it is difficult to know why recruitment and retention were so challenging, one possible explanation is that the high level of stress and disruption for these patients made participation in this type of project too difficult. It may have also been difficult for nurses to encourage patients to participate in an unfamiliar behavioral intervention.

Despite the frustrations, we learned important lessons from this research. Because engaging high-risk pregnant women was so difficult in the hospital, we have changed direction to engage women and their partners during pregnancy as outpatients. We are currently testing mindfulness-based childbirth classes modified for women with a history of sexual trauma. By offering the intervention in small groups using in-person classes we hope to increase engagement and social support within the group. The goal is to help women decrease stress during pregnancy and birth; but ultimately to provide skills that they find useful for years to come as parents.

~Ira Kantrowitz-Gordon, CNM,
Diabetes Prevention requires lifestyle modification plus identifying patients who are at risk for diabetes. The PMG Monroe Clinic participated with Omada Health and the California Foundation to research if the online group-based, lifestyle intervention called Prevent would be an effective intervention for underserved populations, including those whose primary language is Spanish.

The effort was led by Monroe provider Wendy Imberg, RN, ARNP, PhD as the PI, with study coordination provided by Stacy Hernandez and Cathy Hagglund, MA-C (certified medical assistants). Working closely with the Omada implementation team and three other study sites in California, the study coordinators identified patients who were uninsured or insured by a Medicaid product, had a borderline A1c or slightly elevated fasting blood glucose and invited them to participation with the Prevent program.

The Prevent program was adapted for Spanish translation, the curriculum set at a 5th grade reading level, and patients needed a cell phone and access to a computer for participation. The study coordinators followed participating patients throughout the study to identify barriers and facilitate program engagement. Study coordinators heard from patients regularly how pleased they were to be losing weight and feeling better.

Over the 12 month study period the participants used a Prevent wireless scale, completed three mail-in HbA1c, and used logins, posts, health coach interactions to change lifestyle. The evaluation data was weight (BMI), A1c, engagement as measured by lesson completion, and lastly their total health service utilization. Monroe is now identifying patients with pre-diabetes who did not participate providing a match control group in order to compare the outcomes and utilization data to the intervention group.

The Monroe Clinic was enthusiastic to participate in the Prevent Program for underserved populations. Daily they see the effects of diabetes and believe early and innovative interventions are key to turning the tide in the diabetes epidemic.

~Wendy Imberg, ARNP, PhD
Cerebral oxygen desaturation is a common event during cardiac surgery. This event has been associated with significant postoperative complications.

Regional oximetry (rSO₂) monitoring has the potential to reduce these risks, improve outcomes and improve cardiac surgery financial performance. Yet currently, 30% of adult cardiac surgical procedures are monitored using cerebral oximetry monitoring. This is a noninvasive technology that monitors cerebral oxygen status or saturation and provides an early warning of hemodynamic changes to help alert clinicians and mitigate complications.

Cerebral/somatic monitoring with the INVOS™ system has been clinically proven to help clinicians decrease complications and improve outcomes associated with cerebral desaturation during cardiac surgery.

The objective of this analysis was to measure the impact of INVOS™ monitoring on cardiac surgical complications. Medtronic partnered with PotentiaMed, a third-party healthcare analytics firm to assure an objective analysis of clinical and cost end points/outcomes.

The favorable association that INVOS™ monitoring had on the incidence and cost of postoperative surgical complications was impressive.

More specifically, results showed a favorable economic association and total cost benefit for three primary complications of permanent stroke, prolonged mechanical ventilation and renal failure amounting to $7,858,334 for the analysis population.

PotentiaMED analysts noted: “applying median costs to observed incidence, the opportunity to save costs associated with complications is staggering,” with an estimated annual opportunity cost nationally of $273 million.

Overview of the INVOS™ system Comparative Effectiveness Analysis

The analysis is a multi-center retrospective analysis of patients monitored with the INVOS™ system during cardiac surgery and patients who were not monitored using cerebral oximetry. We compared the occurrence of postoperative complications and the related financial burden of specific complications within each group.

We collected five years of detailed case data as submitted to and approved by the national registry from seven cardiac hospitals in various U.S. geographic regions, including Providence Regional Medical Center Everett.

The analysis collected 10,778 cardiac surgery cases with a distribution of 49% monitored cases and 51% not monitored. The case mix included all cardiac surgery procedures for participating hospitals.

The favorable association that INVOS™ monitoring had on the incidence and cost of postoperative surgical complications was impressive.
Total Knee and Hip Replacement

In 1743, Dr. William Hunter eloquently observed that “…ulcerated cartilage is universally allowed to be a very troublesome disease…when it is destroyed, it is never recovered…” For the past nearly 300 years, mankind had attempted to address the disease of an “injured cartilage”, also known more commonly as arthritis, with various methods. Until a solution is found that helps the cartilage heal from injury and regenerate from damage, replacing a damaged joint appears to be our best endeavor.

Today, total knee and hip replacements are among the most successful interventions in modern medicine and are also among the most commonly performed surgeries world-wide. It is projected that in the US alone, nearly 4 million hip and knee replacements will be performed annually by 2030. With this substantial increase in the need for hip and knee replacement, continuing research into better prosthetic design to improve the junction and longevity of these implants is crucial to provide a long-lasting, durable solution for patients suffering from arthritic pain.

Current research has been focused on finding implant materials with the most favorable durable characteristics. A traditional joint replacement bearing utilizes polyethylene and tends to fail over time due to wear of the plastics, necessitating additional, more complicated revision surgeries in the future.

Providence Regional Medical Center Everett (PRMCE) Center for Clinical Research and Dr. Bill Huang, Proliance Surgeons Everett Bone and Joint (EBJ), collaborated to become involved in a nationwide, multi-site clinical trial studying the effectiveness of using a ceramic bearing for total hip replacement. This FDA approved clinical trial began patient enrollment in 2013 and completed 2 years patient follow up in 2016. This study compared the outcomes of patients receiving a ceramic bearing total hip replacement to patients getting a traditional polyethylene bearing total hip replacement. The study focused on patient performance and adverse outcomes. The early data demonstrated satisfactory results in both cohorts without adverse reactions. The enrolled patients will be followed over the next 10 years.

The success of the clinical research team in executing this clinical trial has led to additional valuable studies to be planned at PRMCE. Again, Dr. Huang and the clinical research team will be a major participant in an upcoming FDA approved, nationwide, multi-center clinical research trial involving a new total knee replacement system likely to be initiating enrollment in 2017. This knee system is designed to mimic the natural mechanics of the normal knees by preserving all the ligaments during the replacement operation. This is potentially important because, despite the current wide utilization of current modern total knee replacement for curing arthritic pain, there remains a fairly high patient complaint regarding limited functions after a replacement surgery.

Many patients with a traditional knee replacement find it difficult to participate in sports that require agility. Unlike a traditional knee replacements that require removal of several knee ligaments, mainly the ACL and PCL, this system will allow for preservation all of the knee ligaments. The patients will be evaluated for their functions through both objective measures and self-reporting outcomes. The hope of this new type of prosthesis is to provide the patients with a more “normal” feeling knee replacement and allow the patient to participate in more active life style such as involvement in certain sporting actives.

These types of involvement in research and clinical trials will keep PRMCE at the forefront of orthopedic care. This is the testament to the quality of medical work at PRMCE and the dedication of its staff. The outcome of these studies will not only benefit the patients in the immediate surrounding community, it will also contribute to advancement of orthopedic knowledge that may potentially affect many patients world-wide.

~Bill Huang, M.D.
Aphinity Positive Outcome of Primary Analysis

Phase III APHINITY study shows Roche’s Perjeta® regimen helped people with an aggressive type of early breast cancer live longer without their disease returning compared to Herceptin® and chemotherapy.

- Perjeta plus Herceptin and chemotherapy showed a statistically significant improvement in invasive disease-free survival (iDFS) for people with HER2-positive early breast cancer (eBC) compared to Herceptin and chemotherapy alone.
- Data will be discussed with health authorities, including the US Food and Drug Administration (FDA) and European Medicines Agency (EMA).

Roche (SIX: RO, ROG; OTCQX: RHHBY), the Breast International Group (BIG), Breast European Adjuvant Study Team (BrEAST) and Frontier Science Foundation (FS) today announced positive results from the phase III APHINITY study. The study met its primary endpoint and showed that adjuvant (after surgery) treatment with the combination of Perjeta® (pertuzumab), Herceptin® (trastuzumab) and chemotherapy (the Perjeta-based regimen) achieved a statistically significant reduction in the risk of recurrence of invasive disease or death (invasive disease-free survival; iDFS) in people with HER2-positive early breast cancer (eBC) compared to Herceptin and chemotherapy alone. The safety profile of the Perjeta-based regimen was consistent with that seen in previous studies, and no new safety signals were identified. Full results from the APHINITY trial will be presented at an upcoming medical meeting in 2017.

“These results from the positive APHINITY study represent an important addition to the body of data for Perjeta in the treatment of people with HER2-positive early breast cancer,” said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development at Roche. “We look forward to discussing these adjuvant results with global regulatory authorities.”

Gunter von Minckwitz, MD, study coordinator from the Breast International Group and academic study partners, added, “APHINITY provides yet another example of the importance of industry-academic collaborations and their value in advancing cancer care for people affected by this challenging disease.”

HER2-positive breast cancer is an aggressive form of the disease, which affects approximately one in five people with breast cancer and is associated with a poor prognosis if left untreated.

Despite advancements in the treatment of HER2-positive eBC, up to one in three people treated with Herceptin and chemotherapy may eventually see their cancer return. Treatment options are needed to improve the outcomes of people with this aggressive disease. Treating breast cancer early, before it has spread, may improve the chance of preventing the disease from returning and potentially reaching an incurable stage. Adjuvant therapy is given after surgery and is aimed at killing any remaining cancer cells to reduce the risk of the cancer returning.

The combination of Perjeta, Herceptin and chemotherapy is licenced as a neoadjuvant (before surgery) treatment for people with HER2-positive eBC in more than 75 countries worldwide following approvals by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). In the US, the regimen is currently available under the FDA accelerated approval programme. The APHINITY trial reflects the commitment to evaluate the Perjeta-based regimen as part of a complete treatment approach for eBC. These data will be discussed with health authorities across the world, including the US FDA with the hope to convert the current US accelerated approval to a full approval.

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Velos Clinical Trials Management System

After nearly three years of diligent planning and preparation, the PRMCE Center for Clinical Research is proud to be the system wide flagship and the first of 13 sites to go live with the Velos Clinical Trials Management System (CTMS). Our site implemented Velos in October of 2016 and immediately began to reap the benefits of this major initiative.

The benefits of this implementation are many and include:

- Dramatically improved efficiency of all aspects of financial management
- Velos will allow for the capture of revenue that was previously “left on the table” due to the complexities involved with reconciliation
- Ensured billing and regulatory compliance
- Nimble reporting provides real time data for staffing models and performance metrics
- Streamlined start up, enrollment and close out processes
- Consistency of data input processes = improved data quality
- Calendaring with dependencies for complicated study schedules

In short, the Velos CTMS provides a robust framework for the enhanced and continued growth and success of the PRMCE Center for Clinical Research.

~Tija Schmiesing, Supervisor Research Business Analyst

Studies by Service Line

<table>
<thead>
<tr>
<th>SERVICE LINE</th>
<th>INVESTIGATOR INITIATED STUDIES</th>
<th>SPONSORED STUDIES</th>
<th>SUBJECTS IN ACTIVE TREATMENT</th>
<th>SUBJECTS IN ACTIVE FOLLOW-UP</th>
<th>SUBJECTS IN ANNUAL FOLLOW-UP</th>
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**Clinical Trials by Service Line**

**Cancer**

**Breast**

**Active Enrolling**

**HER2 3+**  Phase II Trial of Combination Immunotherapy With Nelipepimut-S + GM-CSF (NeuVax™) and Trastuzumab in High-risk HER2+ Breast Cancer Patients  
Jason Lukas, M.D., Ph.D.

**NEUVAX**  Combination Immunotherapy With Herceptin and the HER2 Vaccine E75 in Low and Intermediate HER2-expressing Breast Cancer Patients to Prevent Recurrence  
Jason Lukas, M.D., Ph.D.

**MASTECTOMY SURVEILLANCE**  Post-Mastectomy Surveillance to Detect Locally Recurrent Breast Cancer  
Steve Martinez, M.D.

**COMPLEEMENT**  An Open-label, Multicenter, Phase IIIb Study to Assess the Safety and Efficacy of Ribociclib (LEE011) in Combination With Letrozole for the Treatment of Men and Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2-) Advanced Breast Cancer (aBC) With no Prior Hormonal Therapy for Advanced Disease  
Peter Jiang, M.D., Ph.D.

First Site to enroll a patient Globally with over 40 countries participating

**ADVANCE**  RAnDomized Trial of SPI-2012 Versus Pegfilgrastim in the Management of Chemotherapy Induced Neutropenia in Breast CANCER Patients Receiving Docetaxel and Cyclophosphamide (TC)  
Renee Curtis, Pharm.D., BCOP

**PROMPT**  Prospective Registry of Multiplex Testing  
Joy Varady, ARNP

**Active Follow-up**

**MONALEESA -2**  A Randomized Pre-surgical Pharmacodynamics Study to Assess the Biological Activity of LEE011 Plus Letrozole Versus Single Agent Letrozole in Primary Breast Cancer  
Peter Jiang, M.D., Ph.D.

**MONALEESA-3**  A Randomized Double-blind, Placebo-controlled Study of Ribociclib in Combination With Fulvestrant for the Treatment of Postmenopausal Women With Hormone Receptor Positive, HER2-negative, Advanced Breast Cancer Who Have Received no or Only One Line of Prior Endocrine Treatment  
Peter Jiang, M.D., Ph.D.

**MONALEESA-7**  A Phase III Randomized, Double-blind, Placebo-controlled Study of LEE011 or Placebo in Combination With Tamoxifen and Goserelin or a Non-steroidal Aromatase Inhibitor (NSAI) and Goserelin for the Treatment of Premenopausal Women With Hormone Receptor Positive, HER2-negative, Advanced Breast Cancer  
Peter Jiang, M.D., Ph.D.
Completed

**BRAVO** A Phase III, Randomized, Open Label, Multicenter, Controlled Trial of Niraparib Versus Physician’s Choice in Previously-treated, HER2 Negative, Germline BRCA Mutation-positive Breast Cancer Patients  
Elie Saikaly, M.D.

**AMGEN CABS** Prospective Observational Study of Febrile Neutropenia (FN) and Pegfilgrastim Primary Prophylaxis in Breast Cancer and Non-Hodgkin’s Lymphoma Patients Receiving High (>20%) FN-risk Chemotherapy  
Xiaowen Wang, M.D.

**MARIANNE** A Study of Trastuzumab-DM1 Plus Pertuzumab Versus Trastuzumab [Herceptin] Plus a Taxane in Patients With Metastatic Breast Cancer  
Xiaowen Wang, M.D.

**Colorectal**

Completed

**XCITE** Phase III Double-blinded, Placebo Controlled Study of Xilonix™ for Improving Survival in Metastatic Colorectal Cancer  
Yoshio Inoue, M.D.

**Gastrointestinal**

Completed

**XCITE** Phase III Double-blinded, Placebo Controlled Study of Xilonix™ for Improving Survival in Metastatic Colorectal Cancer  
Yoshio Inoue, M.D.

**Genitourinary**

Active Enrolling

**TRUMPET** A Prospective Observational Cohort Study of Patients With Castration-Resistant Prostate Cancer (CRPC) in the United States  
Peter Jiang, M.D., Ph.D.

**KEYNOTE 361** A Phase III Randomized, Controlled Clinical Trial of Pembrolizumab with or without Platinum-Based Combination Chemotherapy versus Chemotherapy in Subjects with Advanced or Metastatic Urothelial Carcinoma  
Peter Jiang, M.D., Ph.D.

**ARASENS** A randomized, double-blind, placebo-controlled Phase III study of ODM-201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer  
Yoshio Inoue, M.D.
Active Follow-up

**AXITINIB**  Randomized, Double-blind Phase 2 Study Of Axitinib (Ag-013736) With Or Without Dose Titration In Patients With Metastatic Renal Cell Carcinoma  
Elie Saikaly, M.D.

**Hematologic**

Active Enrolling

**Connect® MDS/AML**  The Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry  
James Congdon, D.O.

**Connect® MM**  The Multiple Myeloma Disease Registry  
James Congdon, D.O.

**ACE-CL-006**  A Randomized, Multicenter, Open-Label, Non-Inferiority, Phase 3 Study of ACP-196 Versus Ibrutinib in Previously Treated Subjects With High Risk Chronic Lymphocytic Leukemia  
Elie Saikaly, M.D.

**informCLL™**  A Disease Registry for Patients with Chronic Lymphocytic Leukemia  
Peter Jiang, M.D., Ph.D.

**PANORAMA 3**  A Multicenter, Randomized, Open-label Phase 2 Study Evaluating the Safety and Efficacy of Three Different Regimens of Oral Panobinostat in Combination With Subcutaneous Bortezomib and Oral Dexamethasone in Patients With Relapsed or Relapsed/Refractory Multiple Myeloma Who Have Been Previously Exposed to Immunomodulatory Agents  
Jason Lukas, M.D., Ph.D.

**CHL REGISTRY**  Hodgkin Lymphoma Molecular Profiling and Clinical Outcomes in U.S. Community Oncology Practices  
Jason Lukas, M.D., Ph.D.

Active Follow-up

**REVEAL**  Prospective, Non-Interventional Study of Disease Progression and Treatment of Patients With Polycythemia Vera in United States Academic or Community Clinical Practices  
Peter Jiang, M.D., Ph.D.

Completed

**Connect™ CLL**  The Chronic Lymphocytic Leukemia Disease Registry  
James Congdon, D.O.

**ACE-CL-007**  A Randomized, Multicenter, Open-Label, 3 Arm Phase 3 Study of Obinutuzumab in Combination With Chlorambucil, ACP-196 in Combination With Obinutuzumab, and ACP-196 Monotherapy in Subjects With Previously Untreated CLL  
Elie Saikaly, M.D.

**PERCIST**  A Randomized Controlled Phase 3 Study of Oral Pacritinib Versus Best Available Therapy in Patients With Thrombocytopenia and Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, or Post-Essential Thrombocytemia Myelofibrosis  
Peter Jiang, M.D., Ph.D.
Lung

Active Enrolling

**IMPOWER010** A Phase III, Open-Label, Randomized Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) Compared With Best Supportive Care Following Adjuvant Cisplatin-Based Chemotherapy in PD-L1-Selected Patients With Completely Resected Stage IB-IIIA Non-Small Cell Lung Cancer

**INIVATA** Prospective observational multicenter study to evaluate the performance of Inivata liquid biopsy analysis compared with standard tissue biopsy analysis for detection of genomic alterations in patients with advanced non-small cell lung cancer.

**NILE** Noninvasive vs. Invasive Lung genotyping Evaluation

**CheckMate 370** A Master Protocol of Phase 1/2 Studies of Nivolumab in Advanced NSCLC Using Nivolumab as Maintenance After Induction Chemotherapy or as First-line Treatment Alone or in Combination With Standard of Care Therapies (CHECKpoint Pathway and nivoluMAb Clinical Trial Evaluation 370)

Active Follow-up

**IMPOWER150** A Phase III, Open-Label, Randomized Study of MPDL3280 (anti-PD-L1 Antibody) in Combination With Carboplatin + Paclitaxel With or Without Bevacizumab Compared with Carboplatin + Paclitaxel + Bevacizumab in Chemotherapy Naive Patients With Stage IV Non-Squamous Non-Small Cell Lung Cancer

**IMPOWER131** A Phase III Study of MPDL3280A (Anti-PD-L1) in Combination With Carboplatin + Paclitaxel or Carboplatin + Nab-paclitaxel Compared With Carboplatin + Nab-paclitaxel in Patients With Stage IV Squamous Non-Small Cell Lung Cancer (NSCLC)

Outside Studies

F/U of Patients Surgically Treated for NSCLC: patterns of Recurrence and Secondary Primary Lung Cancer
Melanoma

Active Enrolling

ELIOS 1  A Prospective, Randomized, Blinded, Placebo-controlled, Phase IIb Trial of an Autologous Tumor Lysate (TL) + Yeast Cell Wall Particles (YCWP) + Dendritic Cells (DC) Vaccine vs Unloaded YCW + DC in Stage III and Stage IV (Resected) Melanoma to Prevent Recurrence.  

ELIOS 2  Multi-center Phase I/IIa Trial of an Autologous Tumor Lysate (TL) + Yeast Cell Wall Particles (YCWP) + Dendritic Cells (DC) Vaccine in Addition to Standard of Care Checkpoint Inhibitor of Choice in Metastatic Melanoma Patients With Stable or Slowly Progressing Disease.  

OPTIMiZe  A US Multi-Site Observational Study in Patients With Unresectable And Metastatic Melanoma  

Non-Specific Disease Site

Active Enrolling

NOPR  The National Oncologic PET Registry  

Completed

ZOSTER  A Phase III Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of V212 in Adult Patients With Solid Tumor or Hematologic Malignancy  

Oral, Head and Neck

Active Enrolling

GT-201  A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Trial of the Effects of GC4419 on Severe Oral Mucositis in Patients Receiving Cisplatin + IMRT for Locally Advanced Non-Metastatic SCC of the Oral Cavity/Oropharynx  

Digestive Health

Active Enrolling

CODA  The Comparison of Outcomes of Antibiotic Drugs and Appendectomy  

Outside Studies

Retrospective Clinicopathologic and Genetic Evaluation of Diseases Involving the Gastrointestinal System Using Archived Pathology Material
Heart & Vascular

**Angiogenesis**

**Completed**

RE-DUAL  A Prospective Randomised, Open Label, Blinded Endpoint (PROBE) Study to Evaluate DUAL Antithrombotic Therapy With Dabigatran Etxilate (110mg and 150mg b.i.d.) Plus Clopidogrel or Ticagrelor vs. Triple Therapy Strategy With Warfarin (INR 2.0 - 3.0) Plus Clopidogrel or Ticagrelor and Aspirin in Patients With Non Valvular Atrial Fibrillation (NVAF) That Have Undergone a Percutaneous Coronary Intervention (PCI) With Stenting

**Coronary Artery Disease**

**Active Enrolling**

**CHIP Cohort 1** Comparison of Employees Enrolled in CHIP vs Employees Not Enrolled in CHIP  
Kevin Clay, M.D.

**CHIP Cohort 2** Comparison Study of Office Based Patients Enrolled in CHIP vs Patients Not Enrolled in CHIP  
Kevin Clay, M.D.

**CHIP Cohort 3** Comparison Study Cardiac Rehabilitation Patients Enrolled in CHIP vs Patient Not Enrolled in CHIP  
Kevin Clay, M.D.

**Active Follow-up**

ODYSSEY  A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome  
Geraldine Gardner, D.O.

**Interventional Cardiology**

**Active Follow-up**

**ABSORB III** A Clinical Evaluation of Absorb™ BVS, the Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Subjects With de Novo Native Coronary Artery Lesions  
Mahesh Mulumudi, M.D.

**ABSORB IV** A Clinical Evaluation of Absorb™ BVS, the Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Subjects With de Novo Native Coronary Artery Lesions  
Mahesh Mulumudi, M.D.

**Completed**

TRYTON  PIVOTAL IDE Coronary Bifurcation Extended Access Study  
Mahesh Mulumudi, M.D.
Electrophysiology
Active Enrolling

**ENABLE MRI** ImageReady MR Conditional Defibrillation System Study
Maheer Gandhavadi, M.D.

Active Follow-up

**NAVIGATE X4** Evaluation of ACUITY™ X4 Quadripolar Coronary Venous Leads and RELIANCE™ 4-FRONT Defibrillation Leads
Maheer Gandhavadi, M.D.

Completed

**RE-CIRCUIT** Randomized Evaluation of Dabigatran Etxilate Compared to warfarIn in pulmonary Vein Ablation: Assessment of an Uninterrupted periprocedural anticoagulation strategy
Maheer Gandhavadi, M.D.

Genetics
Outside Studies

**Clinicopathologic Assessment** of IgG4-related Disease Using Archived Pathology Tissue
Jey-Hsin Chen, M.D.

Internal Medicine Sub Specialties

Diabetes
Outside Studies

**Evaluation of an Online Diabetes** Prevention Program Adapted for Safety Net Users
Wendy Imberg, ARNP

Pulmonary
Active Follow-up

**MERCURY** MultiEnter Trial of Rivaroxaban for Early disCharge of Pulmonary Embolism From the Emergency Department
Ryan Keay, M.D.

Highest enrolling site
**Miscellaneous**

**Dermatology**

**Active Enrolling**

**CORRONA**  Corrona Psoriasis Registry  
David Smith, M.D.

**CLARITY**  A 52-week, multicenter, randomized, double-blind study of secukinumab (300 mg) to demonstrate efficacy as assessed by Psoriasis Area and Severity Index and Investigator’s Global Assessment after 12 weeks of treatment, compared to ustekinumab, and to assess longterm safety, tolerability, and efficacy in subjects with moderate to severe plaque psoriasis  
David Smith, M.D.

**Musculoskeletal**

**Active Enrolling**

**OXINIUM◊ DH**  A Multi-Center, Randomized Controlled Study of Efficacy and Safety of the OXINIUM◊ DH Total Hip Replacement System in Subjects With Non-Inflammatory Arthritis  
Bill Huang, M.D.

**Completed**

**CONTINUUM HIP**  Prospective Post Market Clinical Follow-Up Study of the Continuum Metal on Polyethylene Acetabular System  
Bill Huang, M.D.
Visit our website

http://washington.providence.org/hospitals/regional-medical-center/services/clinical-research