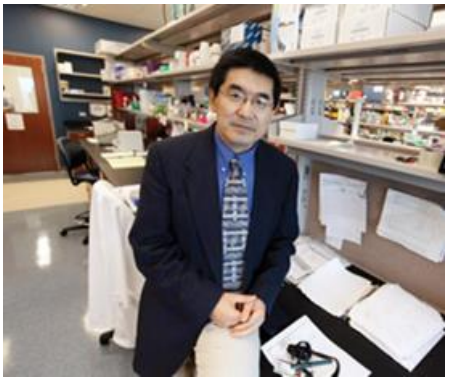
Director's Update

November 22, 2016

The Time is Now

Message from Ming You, MD, PhD, Director of the MCW Cancer Center



I want to thank you all for a successful External Scientific Advisory Board (ESAB) review and visit in September. The work we've done to refine our Cancer Center Support Grant (CCSG) draft and prepare for the NCI site visit is evident in the feedback we received and, ultimately, the decision to move forward with a January 2018 CCSG submission.

We've made a tremendous amount of progress over the past five years and in particular within the past 24 months. There is every reason for us to succeed. We have the outstanding basic, translational and outcomes research needed to compete nationally.

Undoubtedly, we have substantial institutional resources and strong leadership support. Our clinical trials portfolio, accruals and infrastructure rival those of designated centers. Our administration core, strategic planning and leadership infrastructure are already operating at the level of NCI designated cancer centers around the country.

It is on me, our associate directors, research program leaders, shared resource directors, members and staff to leverage these accomplishments and the tremendous support and resources that are available to help us finish this job.

Yes, we have some gaps. We also have an amazing team of members, leaders and staff who are committed to filling these gaps -- by increasing peer-reviewed funding, publishing in high-

impact journals and developing collaborative, multi-investigator projects. Our associate directors and administration team are currently writing and supporting multiple P01 and T32 applications for January 2017 submissions. We have department and division leaders who share our urgency to recruit game-changing faculty members who can complement and transform existing research at MCW.

I'd like to share the specific feedback and recommendations from our ESAB. Attached to this newsletter is the full review provided by our ESAB members and board chair Dr. Skip Trump. I ask you to review this information carefully, as this document will drive our areas of focus and many decisions in the near future.

Over the next 18 months, you'll be hearing from me often as we track our progress, recognize accomplishments and milestones and provide updates on the submission. I've also asked the most successful cancer center leaders from around the country to help guide us. You'll be hearing from them about the game-changers, challenges and triumphs that led other centers to NCI Designation. If you go to page 12 of this newsletter, you will see an interview with Nathan Vanderford, PhD from the Markey Cancer Center at the University of Kentucky. Dr. Vanderford is the assistant director of research at Markey and provided valuable insight about their membership and program process and the keys to a successful designation submission.

As I send these updates, I encourage you to respond – to provide feedback, ideas and updates and to ask questions. NCI Designation is about telling the story of the MCW Cancer Center, and we can't tell this story without you. Please feel free to contact me directly at any time, and if you have information about a new grant, collaboration, publication or other milestone, please let Anne Mathias know.

On the following two pages we've provided a high-level overview and infographic about NCI Designation created by Anne Mathias. If you have questions about the CCSG or details about the designation process, I encourage you to speak with our resident expert, Associate Director of Administration Marilyn Larson.

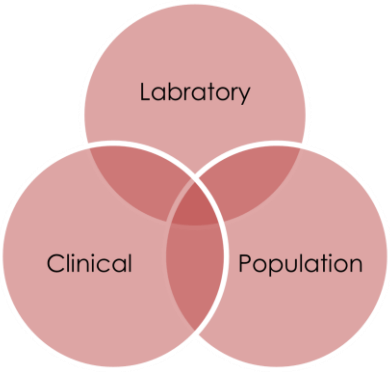
NIH NATIONAL CANCER INSTITUTE

NCI Cancer Center Program in Brief

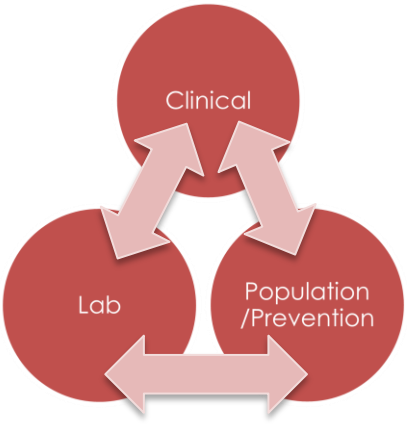
- Established in 1971 with passage of National Cancer Act
- Currently 69 NCI cancer centers throughout the country
- Research-oriented designation, funds are distributed to relevant freestanding, academic and consortia institutions
- Types of cancer centers supported by the program include comprehensive and clinical centers and centers that conduct only basic science research

Necessary Elements for Designation

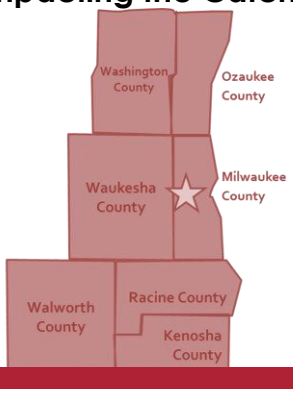
Research Mix



Translational Research



Research Impacting the Catchment Area



NIH NATIONAL CANCER INSTITUTE

Six Essential Characteristics of NCI Designated Cancer Centers

Cancer Focus

- Clearly defined institutional focus on cancer research
- Evident from the center's strategic objectives, peer-reviewed funding, high-impact publications, clinical trials enterprise, and faculty and staff

Institutional Commitment

- Parent institution provides the space, authority and resources to ensure stability and growth
- Status of cancer center comparable or greater than other areas of importance within institution

Organizational Capabilities

- Center's organization creates cross-disciplinary activity and research throughout parent institution
- Governing structure includes mechanisms for prioritizing and sustaining both joint and individual investigator initiatives such as pilot funding and shared resources

Facilities

- Ample and appropriate space devoted to cancer research, controlled by center director
- Facilities that encourage transdisciplinary activity and support growth

Center Director

- Highly qualified scientist and administrator
- At least 50% effort devoted to directing the center

Transdisciplinary Research

- High degree of coordinated collaboration between basic, clinical and population cancer researchers
- Evidenced by multi-PI grants, inter- and intra-programmatic publications

Congratulations MCW Cancer Center Members

Dr. Joan Neuner Receives $2.33M NIH Grant to Study Breast Cancer Disparities

By Rachel Italiano

Joan Neuner, MD, MPH, the co-leader of the MCW Cancer Center Cancer Control and Outcomes program, was recently awarded a new R01 from the National Institute on Minority Health and Health Disparities (NIMHD) to study "Socioeconomic Disparities in Adherence to Oral Hormonal Therapy for Breast Cancer." The research is based on her 2015 *Journal of the National Cancer Institute* (JNCI) paper which showed trends toward high rates of nonadherence in using Aromatase inhibitors were reversed with either copayment elimination or low-cost generics.

With further work showing that subsidized copayments eliminated racial disparities in drug adherence, this compelling pilot data led to her grant from the NIMHD to further investigate how policy could reduce disparities in breast cancer outcomes. The grant will further explore the cost of oral cancer drugs on treatment adherence and also use innovative investigations of prescription synchronization and the role of pharmacy deserts. This national study will include data about the local community, so that Dr. Neuner's team can compare Milwaukee neighborhoods to neighborhoods across the country.

Through its research into the experience of over 65,000 patients with breast cancer, this study will provide new information on how barriers to care create inequities. It will examine if, and by how much, patients' ability to pay, medication complexity, and distance to pharmacies affects patients' use of outpatient oral medications for cancer therapy. It will also estimate how different policy strategies to reduce or remove these barriers can decrease mortality disparities.

Dr. Neuner's work is among the first to show the impact of high cost brand-name drugs on patient discontinuation of medications and that cost reductions associated with generic approval reversed this. She also found that very poor patients with low-income subsidies (LIS) that protected them from high out-of-pocket costs had high adherence to both brand-name and generic medications.

"Joan's innovative ideas and research on breast cancer disparities is exactly the type of work we need as we prepare to submit for NCI Designation." Said Ming You, MD, PhD, Director of the MCW Cancer Center. "This work not only puts us on the map nationally; it will have a direct influence on underserved populations in Southeastern Wisconsin."

A follow-up study, recently accepted for publication in the *Journal of Clinical Oncology*, showed that, since subsidies are received by nearly 70% of black and Hispanic women, previously reported racial and ethnic disparities in medication discontinuation were eliminated by Medicare D's LIS policy.

Dr. Neuner is a physician-scientist focusing on outcomes of breast cancer therapies. She completed her residency and fellowship at Harvard Medical School. Through funding from her NIA K-award (K08 AG021631) and national ACS research scholar grant (RSG-11-098-01-CPHPS), Dr. Neuner made significant contributions to understanding comparative effectiveness and risks of adjuvant therapies for breast cancer. Her studies have been published in JAMA, JNCI and Cancer. She has also served as an NCI and ACS reviewer. She also serves as the national chair of the Society of General Internal Medicine Research Committee, was selected to participate in the American Society of Clinical Oncology's Cancer Disparities Committee and is a recent recipient of the MCW Department of Medicine Dunn Research Award. Dr. Neuner has also served on mentorship teams for cancer-related investigators for the last eight years.

Dr. Roy Silverstein Elected to Major Leadership Position for the American Society of Hematology

Adapted from MCW News

Congratulations to Dr. Roy Silverstein, MCW Cancer Center Associate Director of Clinical Research, who will serve a one-year term as vice president, followed by successive terms as president-elect and president of the American Society of Hematology (ASH). This is the world's largest professional society focused on the causes and treatment of blood disorders.

ASH is the world's largest professional society concerned with the causes and treatment of blood disorders. Recently, ASH leadership announced the election of four new members to its Executive Committee for terms beginning after the 2016 ASH Annual Meeting December 3-6 in San Diego.

Roy L. Silverstein, MD, will serve a one-year term as vice president followed by successive terms as president-elect and president. Robert A. Brodsky, MD, will serve a four-year term as secretary, and John C. Byrd, MD, and Cynthia E. Dunbar, MD, will each serve four-year terms as councilors.

"Hematologists are at the forefront of cutting-edge advancements in science and patient care, and as the premier professional society for the field, ASH plays an important role in providing high-quality training, education, and research. All of these attributes require support and strong leadership to develop and grow," said 2016 ASH President Charles S. Abrams, MD, of the University of Pennsylvania. "Drs. Silverstein, Brodsky, Byrd, and Dunbar have demonstrated impressive commitment to hematology and to the Society through their years of service as editors, program leaders, and mentors. These experiences, coupled with their breadth of knowledge in hematology, will shape the future of the field."

Dr. Silverstein is the John and Linda Mellowes Professor and Chair, Department of Medicine at the Medical College of Wisconsin (MCW) in Milwaukee, where he also serves as the associate director of clinical research for the MCW Cancer Center. Dr. Silverstein is also senior investigator for the Blood Research Institute at BloodCenter of Wisconsin. His research interests include clinical non-malignant hematology translational research on the molecular, cellular, and genetic causes of thrombosis; angiogenesis; and atherosclerosis.

Dr. Silverstein has been an ASH member for more than 30 years, and during that time he has served in various leadership roles in virtually all aspects of the Society. Recently, he chaired the search committees for founding editor-in-chiefs of ASH Clinical News and the Society's new journal, Blood Advances. He has served as the editor-in-chief of The Hematologist, chaired the Society's Committee on Government Affairs, and co-chaired the 2012 ASH Annual Meeting Scientific Program. Dr. Silverstein is also a past member of the Society's Committees on Educational Affairs and Training.

As vice president of ASH, Dr. Silverstein will aim to engage the Society's members to examine hematology training and develop innovative pathways for clinicians and researchers to successfully enter the field. He plans to lead ASH as a forceful advocate for continuing to invest in hematology research and in support of training and practice.

The American Society of Hematology (ASH) is the world's largest professional society of hematologists dedicated to furthering the understanding, diagnosis, treatment, and prevention of disorders affecting the blood. For more than 50 years, the Society has led the development of hematology as a discipline by promoting research, patient care, education, training, and advocacy in hematology. The official journal of ASH is Blood, the most cited peer-reviewed publication in the field, which is available weekly in print and online.

Cancer Clinical Trial Accrual Update

By Jennifer Bolmer, PhD

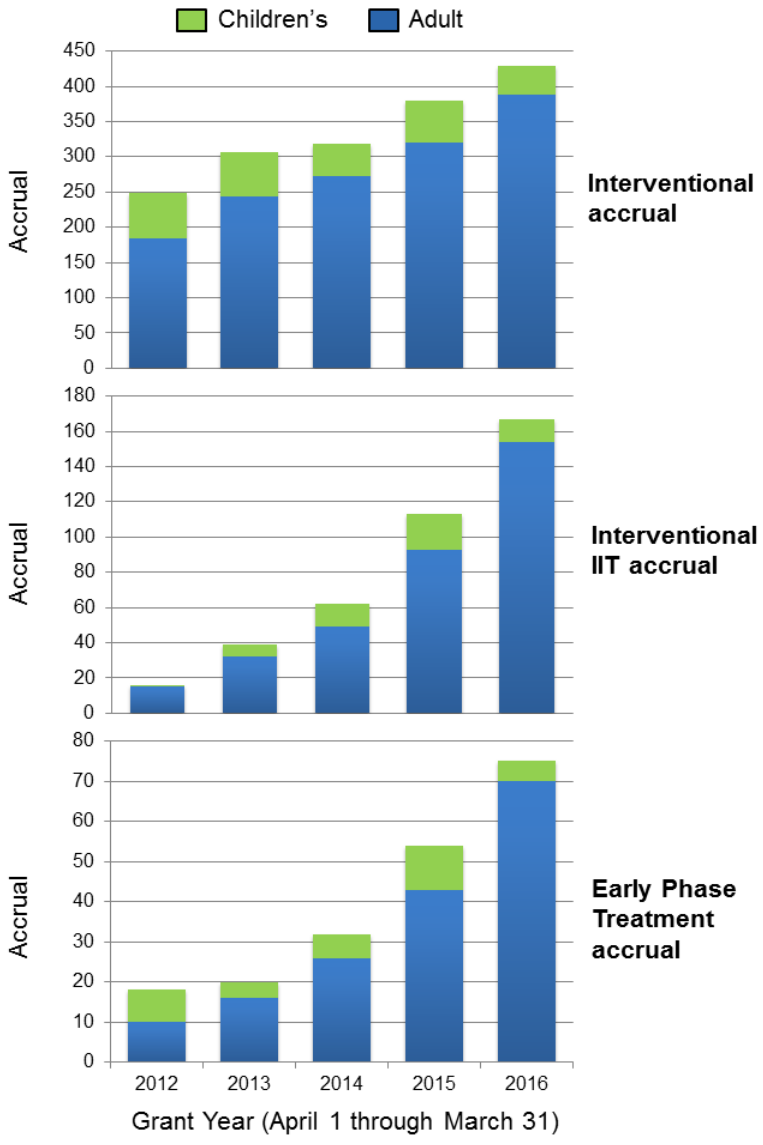
As part of our journey toward NCI Designation, our External Scientific Advisory Board (ESAB) reviewed MCW Cancer Center progress on September 26th. We presented a lot of data, including a clinical trial accrual update. The reviewers were very impressed with the graphs on this page, which show our continued improvement in interventional trial enrollment during the past five years. Your hard work is evident!

The accrual increase has been especially dramatic for interventional investigator-initiated trials (IITs) and early phase trials. The number of interventional IITs open to accrual has risen from eight to 28 during the past five years, with a corresponding increase in accrual. The number of adult phase I and phase I/II trials has also increased since the formation in 2014 of the Early Phase Team, led by Katy Schroeder. The team had a very busy year, accruing more than 75 subjects since January 2016.

In the past seven months (April through October), we have had 236 treatment interventional accruals. Dr. Riese's Incyte trial led with 16. This multidisease, phase I/II study tests the safety and efficacy of combining INCB24360 (an IDO1 inhibitor) and nivolumab (an anti-PD-1), both of which inhibit tumor tolerance. The molecular profiling pancreatic IIT (PI: Dr. Susan Tsai, primary coordinator: Haley Heaviland) enrolled nine more subjects, and now has a total of 118 subjects accrued. A phase III COG trial co-chaired nationally by Dr. Mike Burke led the way in pediatric treatment accruals with eight.

This study evaluates regimens for acute lymphoblastic leukemia patients at high risk for relapse and has accrued 39 patients locally to date (local PI: Dr. Richard Tower, primary coordinator: Danielle Starke).

During the past seven months, nontreatment interventional accruals (55 in all) were led by two supportive care trials: 11 accruals by Dr. Mehdi Hamadani's phase I IIT (primary coordinator: Bob Thompson) investigating the tolerability and efficacy of using ixazomib for the prophylaxis of chronic graft-versus-host-disease in patients undergoing allogeneic stem cell transplants, and 10 accruals by Dr. Baumann Kreuziger's study evaluating edoxaban for the prevention of recurrent



venous thromboembolism, which was mentioned in the previous newsletter.

We had 195 accruals to ancillary, correlative and observational trials in the past seven months. On the pediatric side, Dr. Craig Erker's and Dr. Julie Panepinto's IIT studying the impact of treatment-associated stress continued to accrue well, adding 54 more subjects for a total of 146 to date. Adult accruals were led by 43 to Dr. Eric Paulson's IIT, which is developing improved methods for acquiring high resolution MR images of body organs (e.g., in chest, pelvis) that are especially challenging to image due to patient respiration, peristalsis, etc.

New Trial Highlights

We opened 45 new adult cancer trials in the past seven months. The breast team is now accruing to Dr. Adam Currey's phase II treatment trial (primary coordinator: Maria Pigsley). This study takes advantage of MRI technology advances to utilize accelerated partial breast irradiation in a preoperative setting, as opposed to the standard postoperative. The hope is that this will improve the toxicity profile of breast conservation therapy. This study opened in July 2016 and has accrued five subjects to date.

The adult BMT team is working on a cellular therapy study sponsored by Celgene (local PI: Dr. Parameswaran Hari, primary coordinators: Bob Thompson, Kirsten Jacobson). This is a phase I study testing the safety and efficacy of PNK-007 (natural killer cells derived from human cord blood hematopoietic stem cells) in combination with interleukin-2 in patients with relapsed and/or refractory acute myeloid leukemia. The trial opened at MCWCC in July 2016 and has accrued two subjects. This is a first in human study, and one of our patients was the very first person to receive this drug!

Gynecology Oncology opened several new trials recently, including a study for patients with advanced recurrent ovarian cancer, a patient population with few good options. Sponsored by Merck, this phase II study investigates the efficacy and safety of pembrolizumab, a PD-1 inhibitor that has shown success in treating other cancer types. The local PI for this trial is Dr. Denise Uyar (primary coordinator: Qiana Christian), and the study has accrued three subjects since it opened in June, 2016.

At Children's Hospital of Wisconsin, Dr. Mike Kelly has accrued two subjects to his COG study that opened in May 2016 (primary coordinator: Chris Henchen). This phase II, multidisease study assesses the efficacy and tolerability of IMGN901, a humanized monoclonal antibody, against tumors that express the CD56 antigen. This drug has only been previously tested in adults. The hope is that, due to its targeted nature, IMGN901 will demonstrate better efficacy than vincristine against these tumor types.

"The Clinical Trials Office has supported my research endeavors in more ways than I could ever imagine. From protocol design, to acquisition of funds, to study maintenance...they have been supporting and guiding me through every step of the way. Without the integral members of the CTO, our research efforts and ideas would not come to fruition."

--Meena Bedi, MD

MCW Cancer Center and Dr. Stuart Wong Launch New Course on Cancer Clinical Trial Development

By Anne Mathias

Friday, November 18 marked the first in a new series of lectures and workshops aimed at helping MCW clinical faculty and fellows become more comfortable and effective in cancer clinical trial development. This new career development course, *Clinical Trials: From Concept to Publication* will run through June 2017.

"It is critically important that we develop this new generation of cancer physicians into great clinical researchers," said James Thomas, MD, PhD, Director of the MCW Cancer Center Clinical Trials Office. "We know clinical trials are the best option available for patients with almost any type of cancer, and we are committed to offering our patients as many clinical trial choices as possible – now and in the future."

The course opened on Friday with a talk by Dr. Jim Dignam titled "*Trial Design Basics: Biostatistics Principles for Feasible, Scientifically Sound, and Informative Studies.*" James J. Dignam, PhD, is an Associate Professor of Biostatistics in the Department of Public Health Sciences at the University of Chicago and the Deputy Group Statistician of NRG Oncology.

After his talk, investigators joined Dr. Dignam for a workshop where attendees were able to present their draft protocols and trial design ideas to review and discuss together. Dr. Dignam also met with Radiation Oncology faculty to discuss biostatistics methodology specific to RadOnc clinical trials. Dr. Dignam is a nationally recognized expert in this area.

"Today's visit from Dr. Dignam was a great way to begin this exciting new series," said Dr. Stuart Wong, who created the course. "I'm so pleased at the response and interest from our faculty and the support we've received from leadership at MCW. I'm proud to be a part of something that will have a real and tangible impact on the quality and breadth of cancer clinical trials at MCW."

As the MCW Cancer Center prepares for Designation from the National Cancer Institute, a broad and effective clinical research portfolio is critical to that process, as are unique education and training programs that target upcoming generations of cancer researchers.

In the next few months, the course will address broad topics regarding clinical cancer trial design and development and is intended to increase the number of investigator-initiated trials at MCW and to improve the quality of proposed studies. The sessions are designed for clinicians who are new to cancer clinical research, junior faculty, and new faculty who wish to orient to MCW's clinical research systems. It is also highly recommended for those applying for MCW Cancer Center pilot funds for clinical or translational research.

Response has been high, and there are currently 70 faculty and fellows registered for the six remaining classes. If you are interested in attending, please register here:

http://www.mcw.edu/cancercenter/Clinical-Trials/Registration-IIT-Seminars

As a junior investigator, it is incredibly helpful to have a dedicated staff in the clinical trials office to help me navigate the logistics of getting a clinical trial started. I have been the beneficiary of an incredible amount of patience, and hard work. The staff members working on my trials have gone above and beyond on multiple occasions to help me. Their insight and experience has been invaluable! I have received great support from the CTO leadership. I can't thank you all enough - you have been so kind to me, but more importantly, you've helped OUR patients. At the end of the day, that is the reason we all do what we do. What a team!

--Adam Currey, MD

Dr. Nevalainen's Goal: Solidify Cancer-Focused Graduate Education

By Rachel Italiano

Dr. Marja Nevalainen, Associate Director of Education and Training, has three goals for the coming year as the Cancer Center prepares for CCSG submission: establish a cancer-focused graduate course, submit a cancer-focused T32 grant, and expand the marketing of cancer education at MCW to improve recruitment of new graduate students interested in cancer research to the institution.

"We need to solidify cancer-focused graduate education within the institution and the Cancer Center," she said. Numerous advances have been made within a short period of time, such as renewal of the ACS-IRG grant, improvement of centralization of the CME events, establishment of the MCW CC Education and Training Committee and a cancer-focused graduate course, which will be launched in the fall pending final approval, many more are still to come.

Dr. Nevalainen noted that the discussion format at the ESAB meeting this year allowed for more specific and tangential feedback in all target areas. The highlight of the visit for her was the extremely positive feedback for the CCO program, which is under the guidance of Drs. Melinda Stolley, Joan Neuner and Ann Nattinger.

She believes the most significant game-changers for the Cancer Center are the focused strategic planning and guidance by the Cancer Center's Director's Council on time-sensitive areas as well as the tremendous support for the Cancer Center from the Dean and President, which was also noted by ESAB as a strength of MCW.

There are three support areas Nevalainen lists as essential to overcoming challenges. First, she stressed the building of a large enough base of NCI grant support through successful and thoughtful recruitments. Second is providing further institutional support for specific focus areas, like key PPG submissions. Finally, institutional support to bring middle-tier manuscript submissions to top-tier submissions is a necessity.

As submission time approaches, Dr. Nevalainen wants to assist Cancer Center members with improving and building projects between themselves and increase the number of collaborative publications.

I would like to thank the Cancer Center administration for the terrific help with the Education and Training activities and events!

--Marja Nevalainen, MD, PhD

Above: Dr. Marja Nevalainen, Associate Director of Education and Training for the MCW Cancer Center at the Cancer Moonshot Summit in June 2016.

Markey Cancer Center's Keys for a Successful Designation Bid: Catchment Area, Administration Support and Membership

By Anne Mathias

An interview with Nathan Vanderford, PhD, MBA, Assistant Professor, Department of Toxicology and Cancer Biology and Assistant Director for Research, Markey Cancer Center. Dr. Vanderford was the leader of the CCSG submission and site visit process.

Markey Cancer Center at the University of Kentucky was designated by the NCI in 2012. As one of the newest designated cancer centers and a center of similar size to MCWCC, we asked Dr. Vanderford to share some of his experiences.

MCWCC: From a research program standpoint (membership, program organization, aims) what were the most critical actions you took to support a successful designation submission?

Dr. Vanderford: Membership is a huge challenge. You want to be inclusive and you need to be inclusive to drive engagement, but for CCSG purposes, membership MUST be very tight. However, there is your "grant membership" that's behind the scenes and only for the purposes of the CCSG, and then there's your true membership, where you can be completely inclusive.

We have three levels of members: full research members, associate members and affiliate members. Only full research and associate members are included the CCSG. We culled membership down to about 115 full and associate members, we then have tons of affiliate members. This allows us to be more inclusive, and we don't differentiate between the membership levels except for CCSG purposes. All three levels get the same support and benefits from the cancer center.

I would say that well-defined and very tightly controlled membership is the starting point and one of the keys to a successful CCSG application. We spent hours and hours working on criteria and discussing each member. We have a membership committee that meets quarterly to review new members, with an extended summer meeting when we review all membership. That is when faculty can move up or down within the three categories.

Even within these criteria, it's still very hard and there are lots of grey areas. Another membership decision we made was to not have non-aligned or "ZY" members. This made it much more difficult for some of those "grey area" members who had to be assigned to a program but didn't really fit into any programs' goals. It was difficult trying to retro-fit these members into one of our existing programs. This becomes an even bigger problem if you don't have a programmatic home for your clinical research members

Once you cull your members, you see who you have –who fits together in a group or program in a cohesive, goal-oriented way, and that's where your strengths are. You have to be a little inventive. It does make it so much easier if you first take a really hard look at membership and then use your members' strengths to re-define your programs and aims. It's a bit like a piecing together a puzzle. Something I repeated over and over to leadership and staff, "Our membership drives our research program organization and program aims, and not the other way around."

Another key issue is setting your reporting period and data cutoffs. As a new center, I would encourage you to use the same reporting period. You are going to be under the microscope, so I would encourage you to do everything possible to make this as easy as you can for your reviewers. If your reviewers get confused about your data reporting periods, that's time and effort they are spending that could be focused elsewhere. Also remember that not every reviewer will review every section of the grant, so using consistent reporting periods will help your reviewers stay on the same page.

We use a FY reporting period for the grant. This aligns well with the timing of our annual membership review, and like I said before, membership is the key to your CCSG.

We lean toward having the same reporting period for everything except for clinical research. We used a different reporting period for Data Table 3 because as you know, the state registry data runs about six months behind. One very critical thing we did was paid for additional temporary staff at the state registry to help ensure that we got the data we needed, when we needed it. We knew that we were increasing our clinical trials and that our trajectory was good, so we wanted to show the most recent data that we could.

"We made sure that we really told the story of how our cancer center provides value to our research programs and shared resources. After all, this is what cancer centers are supposed to do – it's why the (cancer center) program and CCSG exists."

Well defined and well demonstrated cancer center support is another key. We made sure that we really told the story of how our cancer center provides value to our research programs and shared resources. After all, this is what cancer centers are supposed to do – it's why the (cancer center) program and CCSG exists.

One way to show the value provided by your cancer center is to organize this support around the goals and themes of each research program. You can take each program theme or aim and tie things like recruitment, pilot funding initiatives and shared resource development to the themes. This is a good way to directly tie value added by the cancer center to the science in each program.

MCWCC: As a smaller cancer center pursuing designation (and from what you know about MCWCC) what are two or three critical priorities we should invest in, no matter the time and resources needed?

Dr. Vanderford: The first thing that came to mind is really strong administration support so your members become more effective with grants and pubs. This might be additional staff positions, training opportunities, tools, whatever you feel would best fill gaps. When Dr. Evers came here, he had the idea of creating a grants and manuscripts office. This resource really helped faculty submit the best possible grants and papers possible. We provide writing, editing, graphic design and scientific figures. We started this in 2009 with one editor and one graphic designer and it grew to 9 FTE by the time we submitted in 2012. This office was also absolutely critical in putting the (CCSG) grant together. That team ended up providing project management support, coordination of activities, meetings and timelines and drafting and editing sections

of the (CCSG) grant. It took a little time to get it off of the ground, but really started growing after the first year. As you know, part of it is a trust issue, and it takes a little while until faculty members are willing to see you mess with their stuff. Now it's developed into a full service research communications office – grants, manuscripts, oral and slide presentations, and poster presentations.

I'd also suggest bringing in some outside help, which I know you've already done. We didn't get a lot of outside help for the grant, but we absolutely did for the site visit. We used Bob Powell, who I know is also currently supporting you, and Bev Ginsburg, who I also believe worked with you guys, is still helping us, particularly with our PRMS. We were only conditionally approved for PRMS and she's helping us with the critiques.

I can't recommend enough having some external help at the faculty level – and especially people who have reviewed the PRMS systems before. Every cancer center's PRMS is being reviewed VERY CLOSELY and almost all are getting conditional approval – that's the default right now. I would absolutely recommend outside expertise, particularly if none of your staff are familiar with recent CCSG PRMS systems.

Another suggestion is a strong focus on your shared resource support, and in particular the equipment, expertise and activities that really support the science of your programs. There is more and more emphasis on how each shared resource provides added value and truly drives the science of your research programs. It's not good enough anymore to have a basic "xyz" resource that's used by most of your members. Much more important is how usage is aligned with program themes and goals and how the resource adds value.

One (extreme) example is what we did with our free radical shared resource facility. In our initial application, it didn't score very well because there were very few users, and we didn't really have a program for this resource to support. Instead of simply making equipment investments, we recruited a large group of systems biology cancer researchers, focused on metabolism. Once we created this cancer metabolism team, we then made multi-million dollar investments in the equipment -- based on the exact needs of the new faculty. So our new Redox Biology shared resource was created by our new faculty members' research focus, instead of force feeding an existing resource upon the research of our members.

> "…it is critically important that you show the NCI that no other cancer center is addressing your population. This is your key to designation – there is a high, ***high*** need in your area and there must be a designated cancer center there to do this work.

MCWCC: What were the game-changers that got you to designation?

Dr. Vanderford: When we were designated, Dr. Henry Ciolino, the director of the NCI Cancer Center program, told us over and over that it was all about our catchment area. The state had cancer rates that were the highest in the nation, and rates were even 30% higher in our eastern Kentucky catchment area. There were decades of research going on throughout Kentucky to address these disparities, including targeted developmental therapeutics. We didn't

do it all, but we found ways to support the research and tie it to the work we've done.

Even if you're in the early stages of disparities research, it is critically important that you show the NCI that no other designated cancer center is addressing your population. This is your key to designation –there is a high, ***high*** need in your area and there must be a designated cancer center there to do this work.

We also adjusted our research program goals to address the catchment area. Think really critically about how the goals align with the problems in our catchment area. Once we developed these goals, we used pilot mechanisms to drive research in this area. We also recruited a faculty member or two -- key recruits that filled holes in the programs in both disparities and clinical research areas. Because you need to make sure that your clinical trial portfolio includes studies that address your area's cancer disparities.

One way we're working to increase our minority accrual is to diversify our faculty and staff. We're recruiting hard to find African American medical oncologists, nurses and other medical staff for each major disease area.

Of course, clinical research is always a struggle when docs are required and rewarded for clinical billing. We developed a credit system where we paid the hospital a significant amount of money to buy out clinical faculty time to do clinical research. This made a big difference in our trial rates.

At your site visit, make sure your friends and supporters show up. Our governor made a video for our site visit – he was treated for prostate cancer at Markey, so that was very powerful. Our senate majority leader came to speak at the site visit, he had family treated here.

Don't forget about sending letters after you're scored. After we got our score, Mitch McConnell wrote a letter to the NCI on our behalf. As chair of the Senate Appropriations Committee, and an eastern Kentucky native, he wrote a powerful letter about the need for a cancer center in our state. We got a letter from him for the application as well, but wanted him to make an even bigger impact after we got the score.

I think you are very well on your way and right about where we were when we submitted. Remember, you don't have to be everything to everybody. Show that you're taking care of your own and you'll do well.

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--Nathan Vanderford