SCIENTIFIC LEADER SPOTLIGHT



The People of George Clinical: Profiles in Passion

Nothing defines the unique character of George Clinical more than the people who do the important work of researching treatments and clinical practices that will shape medical policies and practices in every corner of the world. While our Scientific Leadership Team members are a diverse group from many countries and therapeutic areas, one thing they all share is a passion for making an impact on the treatment, and thus the lives, of the patients they serve. These are their stories.



Roberto Pecoits-Filho, MD, PhD, FACP, FASN

Dr. Roberto Pecoits-Filho is a key member of the George Clinical Scientific Leadership Team. He is a Senior Research Scientist at Arbor Research Collaborative for Health, Ann Arbor, Michigan, and a full professor of Medicine at the Pontifical Catholic University of Paraná (PUCPR) in Brazil, where he is a practicing Nephrologist and Clinical Researcher. He is currently the Principal Investigator for CKDopps, a multinational observational study of practice patterns and outcomes. He is also the chair of the Education Working Group of the International Society.

Your journey to becoming a Scientific Leader at George Clinical began at The George Institute for Global Health in Sydney. Could you tell us a little about how you got there and your experience?

I first heard about the George Institute from Vlado Perkovic when we met in international nephrology meetings. I was very interested in what this research organization was doing that was really impactful in the area of nephrology and in medicine in general. At the time I was working in the south of Brazil in a large academic institution and I felt that at that phase of my career, going to the George would help me to better think about what I wanted to do on my own.

First of all, you know Sydney is a great place—Australia is a great country. My family loved it. The experience was really great for us—we just fit in so easily. My son went to public high school in North Sydney and got with a group of guys who organized a football team. My wife had a great experience working in North Sydney with refugees. It was something completely new for both of them.

For me, the experience was a very rich and interesting one at that time of my career. In a way the George is a think tank. It's really about the people working there, not only at the Sydney offices but also in other countries where the George is present and active. The connections are incredible. And they are truly global. If you want to know

who is the right person anywhere to talk to about a certain thing, they know who that person is.

The George is also very nicely organized. It has a great structure and is very professional and very efficient. Being there helps to really develop great skills in this area—learning how to set up observational studies and trials—because they understand how to design and implement these studies in any setting or region in the world. And the application of this skill can really change the reality of how research can impact practice and public health in different areas—not only in developed countries but also in very poor resource areas.

Another thing I took from the George that has become a part of my life is planning. It's all about understanding, from the beginning, why it's important to ask those particular questions and answers through a study or a trial—about how the information is going to be disseminated and implemented in practice so that you have in mind what you want at the end—something that could change the reality of a particular setting. The George is very good at choosing the best place to do the study and also structuring it right from beginning to end. And they are not afraid of challenges—of challenging the status quo and more traditional approaches to studies. Innovation in trials is taken very seriously by the George—introducing innovative

ways from trial design to implementation and dissemination in post trial application. That's a valuable quality that I now strive to carry with me in my own work

What has your life and career looked like since you've left the George?

What I learned in the year at the George allowed me to go back to Brazil and introduce some of the George model to our own university clinical trial center, which is now thriving very nicely including in cooperation with the projects the George is doing in Latin America.

I have three main roles—at home in the US, I am a senior research scientist at the Arbor Research Collaborative for Health, a non-profit research organization working mainly on observational studies in nephrology. Then I spend about 20% of my time with my academic and clinical activities in the south of Brazil in Curitiba, and even during the pandemic I spent a significant amount of time in Brazil. Finally, with the experience and contacts I made at the George, I began my work with George Clinical acting as a Scientific Leader for clinical trials in the US, Canada and Latin America. Being involved in the George Clinical's Scientific Leadership model is so important because it increases trial efficiency and quality and ensures that we reach the right sites, motivate investigators and bring the study to completion more efficiently.

Many things have happened in my life after my George experience to change the way I participate in clinical trials. I've gone from a position of site investigator and recruiting patients to a more proactive lead investigator in terms of proposing new studies and helping in study design, implementation and also searching for funding.

What challenges were there in moving from Brazil to the US?

Mostly it was understanding the complex healthcare system in the US. Brazil is a middle income country with low resources but universal healthcare through a public system. The US is very different and it is so important to understand how care is delivered in order to know the best way you can benefit from your clinical research. One reason I moved to the US is to have better conditions for research—an infrastructure that more adequately supports clinical research. It's about organization, and some of the organizational skills I've learned both at the George and in the US I can use in my projects in low resource settings, so that is a positive outcome.



What is your role in global clinical trials now?

Coming from my experience at the George is learning how to take advantage of all aspects of clinical research, study design and study models to navigate the discovery that needs to happen to change practice. I try to take full advantage of my opportunities in observational clinical research and how this can optimize intervention clinical trials—I am very interested in connecting these two with benefits going in both directions. Observational studies are a great source of inspiration that define targets for intervention, and clinical trials need validation of their findings in clinical practice settings. Also, understanding practice patterns usually helps in study design and study performance. It's part of my world now to make the connections between different models of clinical research with a clear objective of really making a difference in bringing clinical science to become the real driver of changes in clinical practice.

The more you understand about a disease or a common practice in a different setting or region, the more you can actually design and perform a trial that would bring more pragmatic results—not only that the trial needs to be pragmatic but the design should include a good understanding of the real world through observational research to actually make the information that you generate from a clinical trial something that is more applicable to the real world.

I'm also interested in ensuring that the right sites are chosen for clinical trials. The typical way of approaching sites is very inefficient and based on information that is not very robust about performance—about real information about patient populations that would fit into a trial. Therefore, often you end up with a gap between what is promised or planned in the beginning and what is actually delivered. It's about networking—about knowing the right people in different regions, collecting data



about performance in previous trials and information on patient populations through observational research and through platforms that capture patient data. The trial community in general is making efforts to make these site choice improvements, but initiatives from the George are really going in that direction of understanding where the patients are, which sites are best qualified and connecting the right people that can work together to deliver studies very efficiently.

What is exciting to you about the current state of clinical research in nephrology?

We are in a great moment in many different areas of nephrology with a variety of initiatives from observational studies to new approaches to intervention trials. It's really a privilege to live as a clinician scientist in an era like this—it was not this way ten years ago. Nephrology has been blessed in recent years with an active community of clinical trialists that have been advocating for more patient participation—for understanding the importance of patient voices and communicating with patients. Then there's the movement of how clinical guidelines are actually aligning to the concept that the best clinical action in

particular situations is to refer a patient to a clinical trial. KDIGO has actually included that recommendation in their recent guidelines for particular situations in glomerular disease. That's an important development—where their recommendation is not drug X or drug Y but instead referring a patient to a clinical trial. As treatment continues to evolve, this option will hopefully become more embedded into clinical care.

We are seeing a very diverse scenario of breakthroughs and advances. There are advances in very simple things like an expansion of observational study initiatives like registries across the globe, for example some in Africa where no information was available before. There are global observational studies like the one that I lead from Arbor Research called CKDopps which is a multi-national perspective observational study collecting data about real practices in CKD and comparing practices in different countries and how they may be associated with different outcomes and generating some hypothesis for important interventions. There are new therapies like biologic drugs or cell therapy using modern technology that can dramatically change treatment for diabetic kidney disease and glomerular diseases.

We're also seeing innovation that perhaps will provide solutions in areas that were difficult to tackle in the past—like a project at the George Institute to develop a device that can be used to provide dialysis at point of care in a very simple and cheap way that might improve the access to kidney replacement therapy in very low resource areas. It's a great example of how global and collaborative initiatives can make a difference in problems that before were impossible to solve.

It's exciting to be working in this time because my ultimate goal is to change clinical practice—to be a part of connecting research and science to really evolve the way patients are treated in day-to-day practice. In the end, this is why we do what we do.

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