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Puerto Rico Consortium for Clinical Investigation

NEWSLETTER

Any questions? Please contact us via contact@prcci.org

A program of: Puerto Rico Science, Technology & Research Trust

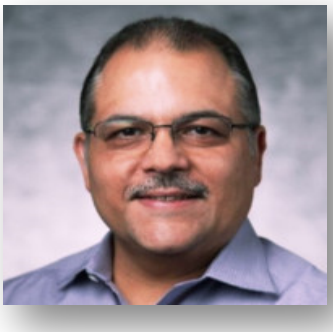
Gathering Momentum

Spotlight on Our Consortium

Puerto Rico Consortium for Clinical Investigation

Spotlight on PRCCI's Most Recent Employee:

New Director of Business Development & Operations
Miguel Vázquez Padua , PH.D.



PRCCI is happy to introduce Dr. Miguel Vázquez Padua, the new Director of Business Development and Operations.
Dr. Miguel A. Vázquez Padua is an experienced executive leader in the healthcare industry in Puerto Rico with significant breadth of experiences in various roles and organizations.
His experiences include leadership roles in Academia, Pharmaceutical and the Healthcare System in Puerto Rico. Before joining the Puerto Rico Consortium for Clinical Research, he served as Assistant Vice President for Medical Affairs at First Medical Health Plan, Inc. (FMHP).
Dr. Vázquez Padua has over 18 years in the Pharmaceutical Industry successfully serving in different roles: Commercial Business Unit Head (Sales and Marketing), Country Lead, Clinical Director for Medical and Regulatory Affairs, Medical Research Manager, and Medical Science Liaison. These various roles provided him with diverse experiences to further strengthen his skills and capabilities. Specifically in the medical research area, he and his team were involved in clinical trials (identification of sites, investigator development/training) as well as supervising a team of local monitors and CRAs from the USA.
Other roles included health outcomes, public health initiatives, individual research grants, educational grants and training of local speakers.
Prior to his roles in the Pharmaceutical Industry, Dr. Vázquez Padua was involved in the academic community. He served as Chairman and Associate Professor of Anatomy and Cell Biology with appointments in the Departments of Pharmacology, Biochemistry and Nutrition at the Universidad Central del Caribe School of Medicine (UCC).
His educational background includes a Bachelor of Science from the University Of of Puerto Rico (UPR) - Río Piedras (Magna Cum Laude) with a major in Biology and minors in Chemistry and Mathematics. He also completed all requirements of the MARC (Minority Access to Research Careers) and the Honors Studies Program at the UPR. He then completed a PhD in Human Cancer Biology at the University of Wisconsin-Madison School of Medicine (Comprehensive Cancer Center) with a minor in Biochemistry. His postdoctoral work in Pharmacology (Cancer, HIV and HSV) was done at both the University of North Carolina-Chapel Hill and Yale University School of Medicine, where he was awarded the Leslie H. Warner Foundation grant for his research project.
Dr. Vázquez Padua has published 13 articles in peer-reviewed journals, two chapters in specialized book series, 18 presentations at specialized meetings in the USA and also 9 publications in local media.

"I am very excited about joining PRCCI. This is a unique opportunity to learn and contribute in the continuous evolution of Clinical Investigation in Puerto Rico. It's a great way to contribute back to our island, the scientific community, the development of new therapeutic alternatives for many important diseases and being able to help patients have a better access to new alternatives at the forefront of Medicine."

PRCCI's Newest Site Member:

Oncology Health Group by Dr. Rafael Betancourt and Dr. Luis Flores

PRCCI is pleased to announce **Oncology Health Group** as our newest site member.
Dr. Rafael Betancourt-Garcia specializes in Hematology and Oncology and has been a principal investigator on studies about Myelodysplastic Syndrome or Acute Myeloid Leukemia. Dr. Rafael Betancourt collaborated as a sub investigator in 2009 with pharmaceuticals studies involving Hepatitis C Patients. During that time he had the experience of being the first Oncologist in Puerto Rico to treat subjects with the first drug that improved the survival rate in stage III (unresectable) melanoma and stage IV, "ipilimumab" ("yervoy"). Dr. Betancourt was also the first principal investigator in treating patients of advanced cancer and pain, with "cannabis", by means of an "oromucosal" aerosol. Further to these experiences in clinical studies, he is the CEO of "Living Learnings", a company that is creating an interactive platform to teach medicine and other disciplines of biology by incorporating 3D anatomy images, animations and physiological interactions, in addition to developing a technology to locate intraoperative tumors.
Dr. Luis Flores-Caban is an Hematology and Oncology with over 23 years of experience. He has previous experience in Clinical Research as well.

continued...

Consortium Highlights:
2018 Global Site Solutions Summit

PRCCI's Executive Director, ***Dr. Amarilys Silva Pharm. D.*** will be attending the ***Global Site Solutions Summit*** in Boca Raton, Florida from October 11th to the 14th. At this event she will have the opportunity to connect with professionals of the industry while promoting Clinical Research in Puerto Rico. She will lbe introduced to the newest updates in technology that are being incorporated in Clinical Research, the best practices regarding diversity recruitment and retention in clincal trials and the challenging topics the industry faces.
We are all very excited about her participation and knowledge obtained for the benefit of Clinical Research in Puerto Rico.

Great Progress at the Manati Medical Center:

On September 26, 2018, Manatí Medical Center had the Site Initiation Visit for their first clinical research study. PRCCI's Director of Quality and Training, Stephanie Berger, Director of Operations and Business Development, Dr. Miguel Vazquez, and Quality Assurance Specialist, Michelle Martinez attended the presentation as well as the clinical research team at the Hospital.
We are proud that Manatí Medical Center has this oppotunity to conduct this study, expanding clinical research in Puerto Rico.

Upcoming Events:
Investigator Training Program

Puerto Rico Consortium for Clinical Investigation

Investigator Training Program
-offering GCP Training

On October 3rd, 2018, Dr. Luis Samuel Abreu, Pharm D. from Pfizer will be offering an Investigator Training Program Event at the Puerto Rico Science, Technology and Research Trust (PRSTRT).
The Investigator Training Program, which has been approved by ***TransCelerate***, will offer Good Clinical Prractice (GCP) training for Clinical Research Investigators (CRIs) and Clinical Research Coordinators (CRCs). The training is aimed at staff with between 0 - 7 years of clinical research experience, however, we also welcome more experienced staff, so that they can share their knowledge and experience amongst the training cohort.
The training will cover the following modules:
- Drug development process,
- Planning and preparation,
- Recruitment and enrollment,
- In-trial procedures,
- Safety in clinical trials,
-Monitoring, audits, inspections, and publications, and
- Additional regulations (self-study module)
For tickets see link below:
https://bit.ly/2KRaZXW

Monthly Quality Corner

2018 The Year of Best Practices

For the month of September, we will take a moment to focus on best practices during an **FDA Audit**.

Surprise!

You receive a notice of an FDA audit. PRCCI's Quality program ensures that sites are audit ready. Here's how:
• During member site onboarding, PRCCI evaluates the 12 core quality indicators that support our value proposition to clinical trial sponsors.
• PRCCI's quality partner, Yale Center for Clinical Investigation (YCCI), conducts quality assessments to your site in order to validate that sites are conducting clinical research according to all applicable guidelines, regulations, standard operating procedures (SOPs), and protocols, to identify any areas that might need improvement or benefit from optimization, and equip you with solutions for any site-level operational concerns

Cause and Effect

FDA conducts clinical investigator inspections to determine if the clinical investigators are conducting clinical studies in compliance with applicable statutory and regulatory requirements.
There are two types of audits:
1. **Routine:** conducted to assess the validity of the study data, normally determined by subject accrual rate or amount of data obtained from a given site
2. **For Cause:** conducted potentially based upon a complaint of non-compliance or FDA concern over data submitted by a given site.

Preparation and Teamwork

Successfully managing an FDA inspection begins with the development of a clear policy at your site which defines the role and responsibility of all team members. The team shall cooperate in accommodating the investigator's lawful requests while assuring that conditions necessary for the continuing conduct of business are not jeopardized.

Let's Talk!

If you would like to learn more about how your site can maintain an audit-ready clinical trial site, please feel free to reach out to our Director of Quality and Training, Stephanie Berger, stephanie.berger@prcci.org