Puerto Rico Consortium for Clinical Investigation

NEWSLETTER

May 2019

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

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

The 2019 Clinical Research Summit: Connecting the World Highlights the Value of Patients in Clinical Research

The event was organized by **the Puerto Rico Consortium for Clinical Investigation** (PRCCI) and **the Puerto Rico Science, Technology and Research Trust** (PRSTRT). It took place at the Sheraton Hotel Convention Center on May 9th and 10th with over 40 speakers and panelists.

The **Second Clinical Research Summit** began with the powerful affirmation "Clinical trials work!", a testimonial given by **Sheila McGlown**. A patient diagnosed with Breast Cancer HER-II + phase IV with metastasis in the liver and ribs at the age of 43 years in 2009.

Sheila spoke about the importance of clinical trials being accessible to patients, so that more people like her, who have been in 6 different treatment plans, may have new opportunities regardless of race, ethnic group, level of income or place of residence.

Dr. Amarilys Silva, Executive Director of PRCCI, said: "We all agree that Puerto Rico has unique advantages as a destination for clinical research. Resources, infrastructure, strategic location and excellent universities, producing qualified health professionals, place the island in a privileged position to lead the role of the clinical research around the world. Our goal at PRCCI and this Summit is supporting this ecosystem to make Puerto Rico a center of innovation in research".

Among the main speakers, **Lisa Bjornestad**, Director of Site Alliance for the Americas at Parexel, shared the trends in the industry in preparation for future studies by putting the patient as the center and final objective of all clinical research. In this sense, “Strategies for Defense and Patient Centricity” moderated by **Cariny Nuñez**, Senior Public Health Advisor to the Office of Minority Health and Health Equity at the FDA, stressed the importance of building alliances and public-private partnerships to establish platforms for communication between communities.

Continuation...

Dr. Bárbara Segarra, Dean of the School of Health Professionals; and one of the main researchers of the Hispanic Education in Clinical Research and Translational Research and Career Development, talked about **Team Science** highlighting it as a collaborative effort to address challenges of health taking advantage of the strengths and experience of scientists and researchers trained in different fields. The main objective of the clinical research institutions is to increase the recruitment and involvement of patients in clinical trials while learning about available options and thus eliminating the disparities in health.

Dr. VA Shiva Ayyadurai, President of CytoSolve, company that supports the development of multiple evidence combination drugs in animals, presented the keynote "**Discovering Cures for Major Diseases**". With his charismatic gift of motivation, Dr. Shiva, who also credited the invention of email, raised the role of clinical trials aimed at discovering the cure of chronic diseases such as Cancer, Diabetes, Alzheimer's disease, among others.

The Second Clinical Research Summit presented a series of lectures devoted to the regulations of the Food and Drug Administration (FDA) in research and trials, and the participation of representatives of the National Institute of Health (NIH) and Yale Center for Clinical Investigation (YCCI). Also discussed were topics related to precision medicine, transfer of technology, and diversity in clinical trials. Testimonials of best practices for research in the Dominican Republic and Colombia were shared.

Also, this year, The Clinical Research Summit displayed over 60 posters by students and faculty, presenting their investigations. The top three posters were granted awards.

The great closing of the Summit was the Panel "**Creating a Portfolio for Clinical and Translational Research in Puerto Rico**" with the participation of members of the Academy, as well as experts in research.


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PRCCI's New Employee

We are pleased to introduce our newest PRCCI employee

Ricardo Garcia Toledo, CPA

Finance Manager

Ricardo's career began in public accounting transitioning then to the manufacturing industry (medical devices, pharmaceutical and contract manufacturing) acquiring extensive experience supporting multiple sites and organizations including supporting the VP of Operations as well as Corporate Headquarters. Ricardo brings extensive experience from having leadership positions working for KPMG, Wyeth and Merck as; Auditor, Controller and Associate Director of Finance. In addition he worked in consulting for a privately owned business and construction firm. Ricardo's accomplishments include implementation of SAP, lean manufacturing processes, legal entity integrations, contract re-negotiation, worldwide product cost standardization project, time and attendance systems and foreign trade zone implementation among others. Ricardo's experience includes: financial planning (budgeting and forecasting), financial reporting, incremental cost analysis, financial analysis, inventory, compliance, taxes, payroll, collections, accounts payables and general accounting. Ricardo completed a Bachelor's Degree in Business Administration-Accounting from the University of PR-Bayamon and is also a Certified Public Accountant.

"I am very excited about the opportunity of working alongside a group of professionals of the caliber that works at PRCCI and the Trust. I am looking forward to contribute with all my heart, mind and strength to the future of the organization and Puerto Rico."

Highlights from Operations and Business Development: May 2019

Tips About Feasibility Questionnaires (FQ)

The FQ is an opportunity for the sites to demonstrate or showcase how your clinical trial site fits the criteria that a sponsor is looking for to place a study. In our industry, this is a critical step in business development. Sponsors rely on the information we provide to be able to assess how suitable a site is for a trial. This is a highly competitive process…a big filter! Thus, it is important that we review key points to put together a strong FQ. The following tips were recently shared during a webinar by ClinEdge:

- Answer all the questions. Do not leave questions blank.
- Highlight your key strong or selling points.
- Provide enough detail…do not be shy on the information requested.
- Be realistic (not too conservative) with the key numbers.
- Showcase all the available patient sources that you have access to (databases, affiliations, etc.).
- Make sure that you have the data to support your estimates on enrollment potential.
- Use the comments section to further explain why your site should be selected for the study and reemphasize your interest.

In addition to the above tips, at PRCCI we strive for strong FQ's and good communication with our sponsors. The strengths of our Consortium, our value-added services and tools, make a unique ecosystem for a strong business case as a team. In fact, later this summer, we will launch another new tool that will help our efforts for exposure and marketing of our strengths and capabilities at a global level. Please, look out for this new tool in a later edition.

Opportunities in Fighting Rare Diseases

According to the NIH, about 10 percent of the American population have one of the nearly 7,000 known rare diseases. The classification as a rare disease is that it affects fewer than 200,000 people in the United States. Since the passage of the Orphan Drug Act in 1983, the FDA has approved over 770 orphan drugs but there is still significant unmet needs. Only 5% of all rare disease have an approved treatment. The organization PhRMA (www.phrma.org) quotes that there is a promising pipeline with more than 560 medicines in development for rare diseases. As clinical researchers, we need to continue reading about potential opportunities within our areas of expertise. We encourage you to visit www.phrma.org/rare-disease for further information. A recent publication by Wei Sun and collaborators is also a good source of information. Their article entitled “Drug discovery and development of rare genetic disorders” (Am J Med Genet A. 2017 Sep: 179(9): 2307-2322) is publicly available at www.ncbi.nlm.nih.ogv/pms/articles.

Monthly Quality Corner

2019: A Spirit of Excellence

As PRCCI acknowledges National Mental Health Awareness Month along with the National Alliance on Mental Illness (NAMI) (www.nami.org/), we dedicate our focus for the month of May to the supportive concept of providing templates to promote success.

Why Reinvent the Wheel?

There is a reason why people use templates. It is because they work! Templates serve as very powerful tools in conducting clinical trials. When utilized appropriately, templates can save time, streamline processes, and enhance quality data collection across clinical trial sites. Instead of continually reinventing the proverbial wheel, templates allow for the uniform application of regulations, guidelines, standard operating procedures, and best practices.

Guidance and Support

Organizations can enhance the provision of oversight by providing templates. As a tool, templates can provide succinct guidance and support for clinical trial site personnel as they perform tasks common to most clinical trial protocols. It is critical to validate templates to ensure that all aspects of compliance are protected. For example, source document collection templates can support flawless data collection, but only if they reflect all aspects of protocol and regulatory compliance. Reviews and revisions should follow triggering events such as protocol deviations and protocol amendments.