

Puerto Rico Consortium for Clinical Investigation



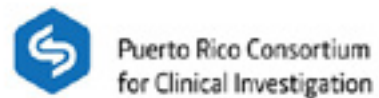
NEWSLETTER
March 2019

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

Puerto Rico Clinical Research Summit 2019



May 9 & 10, 2019
Sheraton Puerto Rico
Hotel Convention Center

SAVE
THE
DATE



Tickets for the Puerto Rico Clinical Research Summit on May 9th and 10th 2019 are now available. For more information on acquiring tickets and details of the agenda go to <https://bit.ly/2JlgPp2>

This event has been submitted for continuing education for the following professionals:

- | | |
|----------------------------------|---------------------------------|
| ✓ Physicians | ✓ Pharmacists |
| ✓ Nurses | ✓ Medical Technologists |
| ✓ Dentists | ✓ Social Workers |
| ✓ Nutritionists | ✓ Respiratory Care Technologist |
| ✓ Psychologist | ✓ Naturopathic Doctors |
| ✓ Pharmacy Techonologist | ✓ Health Educators |
| ✓ Health Services Administrators | |

The 2019 PRCCI Summit will be held during the Puerto Rico Clinical Research Week from May 6th to 10th. There will be several activities about clinical and translational research, as a joint effort among various institutions. If interested in sponsoring this outstanding educational and networking opportunity, please contact:

Menchu Agueros - The Big Think Group
Phone: 787-478-5282
Email: info@bigthinkgroup.com

The Clinical Research Summit will be held on May 9th & 10th, 2019 at the Sheraton Hotel Convention Center.

PUERTO RICO CLINICAL AND TRANSLATIONAL RESEARCH WEEK 2019: CONNECTING KNOWLEDGE PATHWAYS

We are excited to announce the celebration of The Puerto Rico Clinical and Translational Research Week which will take place during the week of May 6th, 2019. This is the result of a great collaboration among various organizations and institutions. On Monday May 6th, Governor Ricardo Rosselló Nevares will sign the official proclamation of this special week. It will be followed by a speech by Mrs. Sharon Terry, CEO and President of Genetic Alliances, an organization whose mission is to engage individuals, families and communities to transform health. The scientific and educational activities of the week include the 8th Annual Title V Symposium of the Univ of PR MSC and the Univ Central del Caribe, and the 8th Scientific Day of the Puerto Rico Clinical and Translational Research Consortium, (May 7th-8th). PRCCI will lead a workshop on May 8th entitled “Critical Factors for a Successful Clinical and Translational Research Career”. On May 9th - 10th, PRCCI will hold the Puerto Rico Clinical Research Summit 2019 entitled “Connecting the World.” This Summit will include keynote presentations, panel discussions, special presentations and poster sessions, with participation of key stakeholders from Government, Academia, Research Centers, NIH, FDA, the Clinical Research Industry and Patient Organizations.

For additional information and registration, please visit
<http://www.prcci.org/clinical-research-summit-2019>.



Transcelerate-certified Investigator Training Program

On Thursday, March 21, PRCCI offered a **Transcelerate-certified Investigator Training Program with GCP Certification** at the Innovation Center. The audience was composed of people from different backgrounds in clinical research, including investigators, regulatory officers, and students among others. Offering key training courses like this is a key step towards achieving PRCCI's goal to improve the impact, quality and speed of clinical research in Puerto Rico. Thank you to everyone who participated and helped make this event a success.

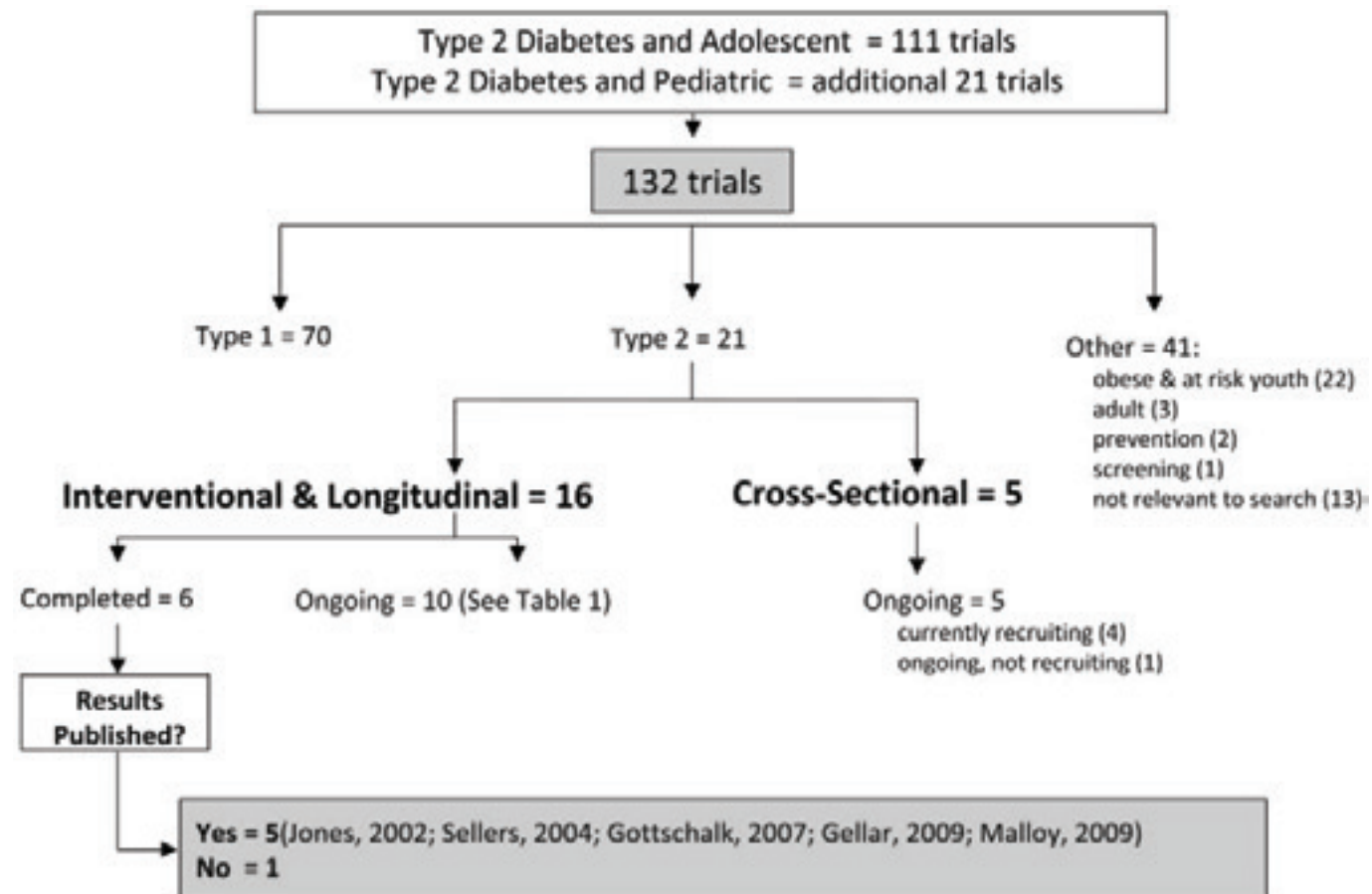


Highlights from Operations and Business Development: February 2019

Our team continues to search for study opportunities for our Consortium members. We will use this section in this and upcoming Newsletters to provide information about current trends in several therapeutic areas. In this month's section, we focus on the Endocrinology landscape.

Gemmill JA, Brown RJ, Nandagopal R, Rodriguez LM, Rother KI, wrote an article titled "Clinical trials in youth with type 2 diabetes", a review of published and ongoing clinical trials of type 2 diabetes in children and adolescents exhibit that few randomized clinical trials have been completed and published in children with type 2 diabetes.

In regards to Type 2 youth diabetes, it was pretty much unheard of just two decades ago. The tracking of the recent dramatic rise in childhood obesity, type 2 diabetes has become increasingly prevalent, proving that there is an urgent need for high-quality clinical trials to increase in-depth knowledge about pathophysiology, optimal treatment, and prevention. Clinical trials in type 1 diabetes outnumber trials in type 2 diabetes. Recruitment and enrollment for type 2 diabetes is challenging, however once achieved, drop-out rates are not too high (Gemmill JA, Brown RJ, Nandagopal R, Rodriguez LM, Rother KI, 2012).



The frequency of type 2 diabetes in adolescents and young adults continues to increase and much remains to be learned about etiology and pathophysiology in order to develop effective prevention and treatment approaches. In contrast individuals with type 1 diabetes, patients with type 2 diabetes frequently have a strong family history of the disease and share many high-risk features.

The strong hereditary component of type 2 diabetes may present a significant barrier to participation in clinical research, particularly if relatives with the disease are not sufficiently concerned about their own disease management and are not supportive in the management of the affected adolescent. Children with type 1 diabetes benefit from support by organizations such as the Juvenile Diabetes Research Foundation, which is the largest charitable funder and advocate of type 1 diabetes research in the world. Finally, several studies in adolescent type 2 diabetes report that a large percentage of screened patients do not meet eligibility criteria. Ongoing clinical studies, such as the TODAY trial, are expected to shed light on important questions, such as whether the natural history and treatment response of youths with type 2 diabetes is different compared to the well characterized condition of type 2 diabetes in older adults (Gemmill JA, Brown RJ, Nandagopal R, Rodriguez LM, Rother KI, 2012).

Reference: (Gemmill, J. A., Brown, R. J., Nandagopal, R., Rodriguez, L. M., & Rother, K. I. (2011). Clinical trials in youth with type 2 diabetes. *Pediatric diabetes*, 12(1), 50-7.)

PRCCI: Celebrating 3 Years of Excellence

The Puerto Rico Consortium for Clinical Investigation (PRCCI) will be celebrating our 3rd Anniversary on April 11, 2019. As we pause for a moment to look back on how far we've come together, we invite you to join us in celebrating three years of humble service. Our diverse team at PRCCI strives to exceed expectations in fulfilling our mission to improve the clinical trial landscape in Puerto Rico for the benefit of patients, researchers, and the Puerto Rican economy. Every day, we move forward with purpose, speed, and agility. Thank you to all of our stakeholders and supporters for three amazing years of innovation with many, many more ahead!

PRCCI Growth Continues

From our launch in 2016, PRCCI has grown from 5 founding member sites to a strong consortium of 30 clinical trial sites across 25 member organizations. Our members include private practice physicians, ambulatory care centers, stand-alone research sites, hospitals, and academic organizations. We want to take this opportunity to thank each of our members for their commitment to our mission and their unique contributions to accelerating the clinical development process.

Together, we are stronger!

PRCCI Evolving: New Approaches

Moving into our 4th year of operations, PRCCI continues to evolve with great agility to meet the needs of our unique stakeholders. We listen, learn, and implement initiatives based on our continual assessment of the clinical trial landscape in Puerto Rico and globally. Our business processes position PRCCI member sites on the leading edge of our industry. PRCCI specializes in creating synergy between our sites in Puerto Rico and sponsors and CROs throughout the world. We look forward to another wonderful year of providing the right services to the right stakeholders at just the right time.

Celebrate with Us!

Stay tuned for details about PRCCI's 3rd anniversary celebration. We will combine our celebration with an informative presentation for PRCCI investigators regarding vital tax incentives. We look forward to continuing to grow stronger together in the coming year and for many years to come. For more information on our consortium, please contact PRCCI's Executive Director, Dr. Amarilys Silva-Boschetti (amarilys.silva@prcci.org) or our Director of Business Development and Operations, Dr. Miguel Vazquez-Padua (miguel.vazquez@prcci.org). To learn more about building quality into your clinical trial site operations, please contact our Director of Quality and Training, Ms. Stephanie Berger (stephanie.berger@prcci.org). We look forward to serving you!



Monthly Quality Corner



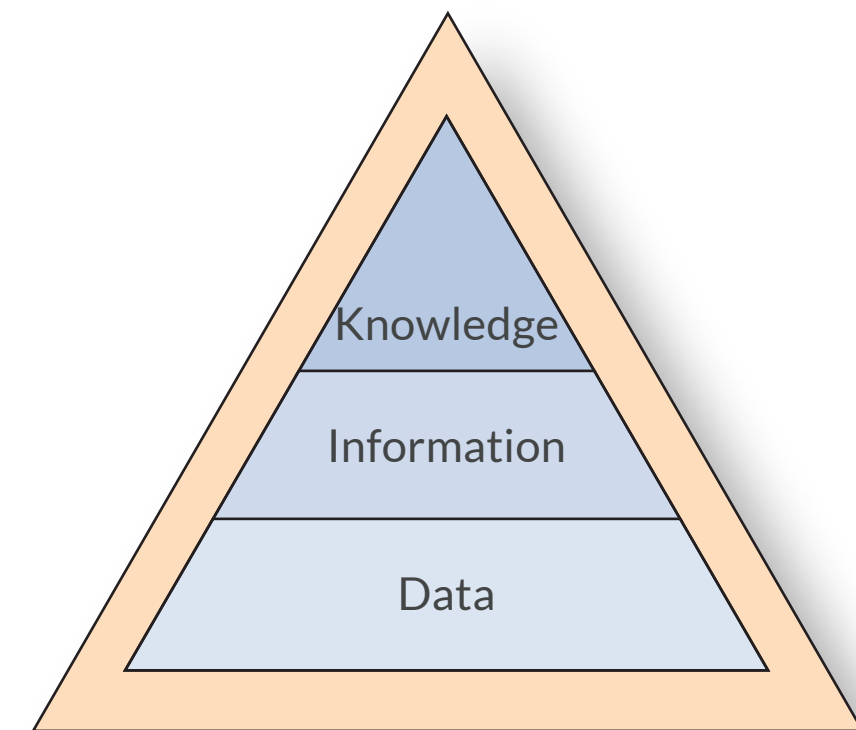
2019: A Spirit of Excellence

Each month in 2019, this space will be dedicated to exploring how clinical trial sites can optimize to conduct clinical trials with a spirit of excellence. As PRCCI acknowledges National Kidney Month along with the National Kidney Foundation (www.kidney.org), we dedicate our focus in March to a concept as central to maintaining quality as the kidneys are to our bodies: knowledge management

What is Knowledge?

Professional experience, judgement, and wisdom are essential attributes to managing knowledge. But what is knowledge? The Oxford English Dictionary defines knowledge as “acts, information, and skills acquired through experience or education; the theoretical or practical understanding of a subject.” Synonyms for knowledge are understanding, comprehension, expertise, know-how, and proficiency.

These attributes make it impossible to store knowledge in a computer because computers cannot apply wisdom and professional judgement to information. Organizations that best organize, analyze and manage the information and data that support knowledge enjoy a natural competitive advantage. Knowledge is power!



Types of Knowledge: Explicit vs. Tacit

Knowledge can also be categorized by its source. The two main sources of knowledge are tacit and explicit. Both categories of knowledge are vital to organizational success. Tacit knowledge can be described as difficult to write down, visualize, or transfer from one person to another. It is also what makes clinical research sites special. Spoken language, leadership, emotional intelligence, and knowledge gained over years of experience are examples of tacit knowledge. Conversely, explicit knowledge can be shared in written form. Organizations share explicit knowledge in working instructions and standard operating procedures (SOPs). Tools, checklists, guidance documents, and best practices can be a bridge between tacit and explicit knowledge. These resources are created, managed, and updated by individuals with robust tacit knowledge. The first steps in building a strong knowledge management program are understanding your explicit knowledge catalog and identifying tacit knowledge resources within your organization.

Right Knowledge, Right Person, Right Time

Knowledge management is fundamentally about getting the right knowledge to the right person at the right time. This requires a healthy understanding of where and in what form organizational knowledge exists. The overall goal is to create quality by leveraging and refining your group's knowledge assets to meet and exceed organizational goals. PRCCI seeks to assist member sites in understanding their knowledge needs, identifying gaps in knowledge availability, and building, maintaining and improving knowledge management methods. This in-depth approach to knowledge management maximizes resources and capitalizes on site knowledge assets. Ensuring the right person has the right knowledge at the right time ensures the collection of quality data, the ultimate output of a quality research site.

Let's Talk!

We look forward to assisting PRCCI member sites in achieving a spirit of excellence in 2019. For quality support, please reach out to our Director of Quality and Training, Stephanie Berger, stephanie.berger@prcci.org



SPECIAL ANNOUNCEMENTS

- For Patient Advocacy Groups and Organizations: We are updating our list of Patient Advocacy Groups and Organizations that work with patients and their relatives. PRCCI actively collaborates with various Patient Advocacy Groups and Organizations with a focus on health education, promotion and to facilitate access to clinical investigations, as appropriate. Please, send us your information (Name of the Organization, Name of the Leader, website address, email and telephone) to contact@prcci.org. Thank you!
- For Organizations that are members of PRCCI: We are planning a special presentation about the various incentives and grants that are available to develop clinical research in Puerto Rico. This will be done in collaboration with leaders of the Puerto Rico Department of Economic Development and Commerce. Stay tuned for dates and time.