

Puerto Rico Consortium for Clinical Investigation



2nd

2019

CLINICAL RESEARCH SUMMIT

NEWSLETTER
April 2019

041

SPECIAL EDITION



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

A program of:



Puerto Rico
Science, Technology
& Research Trust



Puerto Rico Consortium
for Clinical Investigation

2nd



CLINICAL

RESEARCH

SUMMIT

Connecting the World

The 2019 Puerto Rico Clinical Research Summit: Connecting the World

We are thrilled to announce The 2019 Puerto Rico Clinical Research Summit- Connecting the World, which will take place on May 9th and 10th in San Juan, Puerto Rico at the Sheraton Puerto Rico Hotel & Casino by the Convention Center. This is our second year and this time we will have a two day event that will bring together highly qualified local and global leaders from groups involved in clinical research, including but not limited to: patients, patient advocacy groups, the FDA, investigators, sponsors, clinical sites and clinical research organizations. This time the educational program will be attended by over 400 attendees during the two day event.

The 2019 Puerto Rico Clinical Research Summit: Connecting the World

The summit will provide a great opportunity to connect and network with key players and special guests in the clinical research area. We are organizing this event with great collaborators to bring an exciting forum: the US FDA Office of Minority Health, the Yale Center for Clinical Investigation (YCCI), University of Puerto Rico- Medical Sciences Campus, Universidad Central del Caribe, Ponce Health Sciences University and the Puerto Rico Science, Technology and Research Trust.

Together, we have prepared an agenda, which we are sure will be encouraging and suitable for the audiences. The two day event will commence with two keynote presentations followed by diverse discussion panels. Speakers/experts from the US FDA, academia, the pharmaceutical industry and the community of patients, patient advocacy and researchers will carry out unique sessions in the afternoons with sessions on Quality/Compliance, Precision Medicine, Best practices in Clinical Trials presentations, and the role of Manufacturing in clinical investigation among other relevant topics. The program will provide opportunities for attendees to visit the Exhibitors Hall to find out about our sponsors, research sites, patients/community groups and others. The educational activity has been requested for continuing education credits for physicians and other healthcare professionals subject to approval.

Keynote Speakers:



**Ms. Lisa
Bjornestad**
BA, CCRC



**Dr. Larissa
Aviles-Santa**
MD, MPH, FACP, FACE



**Dr. V.A. Shiva
Ayyadurai**
Ph.D.

Invited Speakers:



Ms. Lucy Crespo



**Dr. Amarilys
Silva-Boschetti**
Pharm.D



**Dr. Rafael
Rodriguez**
Ph.D.



**Ms. Stephanie
Berger**



Mr. Rick Rohrbach
MBA



Eng. Ivan Lugo



Dr. Lester Martinez



**Ms. Sandra
Rodriguez**

Invited Speakers:



**Dr. Humberto
Reynales**
Ph.D., MD



**Dr. Federico
Goodsaid**
Ph.D.



**Dr. L. Michelle
Bennett**
Ph.D.



**Dr. Jose Rodriguez
Orengo**
Ph.D.



Eng. Manuel Laboy



**Dr. Fabian
Sandoval**
MD



**Dr. Maria
Figliomeni**
Ph.D.



**Dr. Barbara
Segarra**
Ph.D.

Invited Speakers:



Dr. Yi Zeng
Ph.D., MD



Dr. Andres Emnuelli
MD



Dr. Jose Vidal
Ph.D.



Ms. Linda M. Coleman
JD, CIP, CHC, CHRC, CCEP-I



Dr. Carlos Baez
Ph.D.



Mr. Al O. Pacino II
B.S.



Ms. Alyssa Gateman
MPH, CCRP



Dr. Joel Vega-Rodriguez
Ph.D.

Invited Speakers:



**Dr. Ganesh
Vedantham**
Ph.D.



**Dr. Josimer
Mattei**
Ph.D.



**Dr. Cynthia
Kleppinger**
Ph.D.



**Dr. Jose R.
Moscoso Alvarez**
T.R., Ed.D., FAEIRS



Dr. Enid Garcia
MD, MPH



**Dr. Carlos
Luciano**
MD



Dr. Walter Frontera
MD, Ph.D.



**Dr. Raul
Mayo-Santana**
Ph.D., MA, MS

Invited Speakers:



Ms. Anne Johnson



Dr. Angel A. Roman
Ph.D., MD



Ms. Bhanu Kannan
MS



Dr. Karen G. Martinez
MD, MSc



Ms. Sheila Mcglown



Ms. Cariny Nuñez
MPH, CHRM



Mr. Eugene Patin



Ms. Andrea Furia-Helms
MPH

Invited Speakers:



**Dr. Maria
Figliomeni**
Ph.D.



**Dr. Milena
Lolic**
MD, MS



**Ms. Marisel
Brignoni**



Ms. Nilda Villegas

MAY 9 / AM

Agenda	San Juan 6-8	Miramar 1-3	Miramar 4
7:30am	Registration / Continental Breakfast		
8:30am	Welcome & Summit Intoduction		All Day Poster Sessions & One on One Meetings
8:40am	Opening Remarks Ms. Lucy Crespo, CEO, PR Science Trust, Dr. Rafael Rodriguez, PR Secretary of Health, Dr. Lester Martinez, PRCCI Board Member, and Dr. Amarilys Silva, Pharm.D., Executive Director, PRCCI		
9:00am	Puerto Rico Knowledge Economy Eng. Manuel Laboy, Secretary of Economic Development and Commerce		
9:20am	Patient Testimonial Ms. Sheila Mcglown		
9:40am	* Keynote *		
	Preparing for the Studies of the Future: Industry Trends, Pipeline, Review and Patient/Site Centricity, A new Model Ms. Lisa Bjornestad, Director of Site Alliances for the Americas, Parexel		
10:30am	Coffee & Networking Break - Foyer		
11:00am	Connecting and Educating the Community on the Value and Potential Benefits of Clinical Research Moderator: Ms. Cariny Nuñez, MPH, CHRM, Senior Public Health Advisor, Office of Minority Health and Health Equity, U.S Food and Drug Administration Speaker: Dr. Fabian Sandoval, CEO and Research Director, Emerson Clinical Research Institute		All Day Poster Sessions & One on One Meetings
11:45am	Novel Technologies and Initiatives to Increase Patients Access and Recruitment to Clinical Trials Dr. Maria Figliomeni, Head, Early Development, Novartis; Mr. Eugene Patin, Head US Clinical Operations Excellence, Novartis		
12:30pm	Lunch		

MAY 9 / PM

Agenda	San Juan 6-8	Miramar 1-3	Miramar 4
1:30pm	Strategies on Patient Advocacy and Centricity Moderator: Ms. Cariny Nuñez, MPH, CHRM, Senior Public Health Advisor, Office of Minority Health and Health Equity, U.S Food and Drug Administration Panelists: Dr. Barbara Segarra, Dean School of Health Professions, Medical Sciences Campus, University of Puerto Rico; Ms. Andrea Furia Helms, MPH, Director, Patient Affairs Staff, Office of the Commissioner U.S. Food and Drug Administration; Ms. Marisel Brignoni, President & Patient, Comprehensive Cancer Center Coalition	Quality Update Levering Strategic Partnership in Quality Ms. Stephanie Berger, Director, Quality and Training Puerto Rico Consortium for Clinical Investigation (PRCCI); Ms. Alyssa Gateman, Associate Director, Quality Assurance, Yale Center for Clinical Investigation (YCCI).	All Day Poster Sessions & One on One Meetings
2:20pm	Historical Roots of Clinical Research in Puerto Rico Moderator: Dr. Jose Rodriguez Orengo, Professor School of Medicine and Senior Consultant PRSTRT Panelists: Dr. Angel A. Roman Franco, Professor of Pathology and Immunopathology & Distinguished Professor, University of Puerto Rico; and Dr. Raul Mayo Santana	Impact of Clinical Investigations on the Healthcare System Dr. Andres Emanuelli, President and Research Director at Emanuelli Research and Development Center, President of Retina Care, PSC, Assistant Professor at the Ophthalmology Department at the Medical Science Campus of the University of Puerto Rico	
3:20pm	Coffee & Networking Break - Foyer		
3:30pm	CASE STUDIES: Experiences in Latin America starting and Developing a Clinical Research Center Dr. Humberto Reynales, CAIMED Executive Director; Dr. Ellen Koenig, Medical Director Instituto Dominicano de Estudios Viroológicos (IDEV) (Creating a Clinical Care Site in the Dominican Republic)	EXPANDING THE BUSINESS: Importance of Strategic and Financial Planning Mr. Rick Rohrbach, Managing Director HURON Consulting	
4:10pm	<div><div></div><div>* Keynote *</div><div>Discovering Cures for Major Diseases Dr. V.A. Shiva Ayyadurai, President CytoSolve</div></div>		All Day Poster Sessions & One on One Meetings
4:40pm	The Role of Manufacturing in Clinical Investigation Moderator: Eng. Ivan Lugo, Executive Director INDUNIV Panelists: Ms. Sandra Rodriguez, Executive Director, Drug Product, AMGEN Manufacturing; Dr. Ganesh Vedantham, Executive Director AMGEN; Dr. V.A. Shiva Ayyadurai, President CytoSolve; Dr. Jose Vidal, Sr. VP Drug Development and Member of the Leadership Team of AtaraBio		
5:40pm	Closing Remarks, Housekeeping Announcements		
5:45pm	Networking Cocktail clinical Research Summit Poster Session- Foyer		

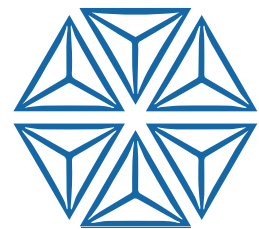
MAY 10 / AM

Agenda	San Juan 6-8	Miramar 1-3	Miramar 4
7:00am	Registration / Continental Breakfast		
8:30am	Welcome		All Day Poster Sessions & One on One Meetings
8:35am	<div>————— * Keynote * —————</div> <div>Health Disparities Research: In The Quest for Better Health Outcomes for All</div> <div>Dr. Larissa Aviles-Santa, Director of Clinical and Health Services Research for the National Institute of Minority Health Disparities, National Institute of Health, PRCCI Board Member</div>		
9:00am	<div>Welcome and Introduction of FDA Team</div> <div>Nilda Villegas, Health Communications Specialist, Office of Regulatory Affairs, Office of Public Affairs and Editorial Branch Services, FDA</div>		
9:10am	<div>Strategies/ Considerations for Managing Federally Funded and FDA Regulated Research</div> <div>Ms. Linda M. Coleman, JD, CIP, CHC, CHRC, CCEP-I, Director Human Research Protection Program, Office of Research Protection Program, Yale University</div>	<div>Technology Transfer</div> <div>Dr. Carlos Baez, Technology Manager, Technology Transfer Office, PR Science Technology and Research Trust</div>	
9:50am	Coffee & Networking Break - Foyer		
10:20am	<div>From Bench to Bedside: How to Develop a Pharmaceutical Company</div> <div>Dr. Federico Goodsaid, CEO, MBQ Pharma</div>	<div>Why Diversity in Clinical Trials Matters?</div> <div>Dr. Milena Lolic, M.D., M.S., Lead Medical Officer, Office of Center Director, Professional Affairs and Stakeholder Engagement, Center for Drugs and Evaluation Research, US Food and Drug Administration</div>	All Day Poster Sessions & One on One Meetings
11:10am	<div>Precision Medicine in Pediatric Cancer Care</div> <div>Dr. Yi Zeng, Assistant Professor of Pediatrics, University of Arizona Cancer Center</div>	<div>The Future of Compliance, Investigator Site and Industry Sustainability - Here Today!</div> <div>Mr. Al O. Pacino II, President HealthCarePoint.com</div>	
12:00pm	Lunch Posters Award Ceremony		

MAY 10 / PM

Agenda	San Juan 6-8	Miramar 1-3	Miramar 4
1:00pm	Developing a Framework for Cardiovascular Health Research and Promotion in Puerto Rico: The Prospect Study Dr. Josimer Mattei, Assistant Professor of Nutrition, Department of Nutrition, Harvard T.H. Chan School of Public Health	Compliance in Clinical Research: Doing it Right Dr. Cynthia Kleppinger, Senior Medical Officer, Division of Clinical Compliance Evaluation, Center for Drug Evaluation and Research, US Food and Drug Administration	All Day Poster Sessions & One on One Meetings
1:500pm	Transmission-Blocking Vaccines: Challenges of a Promising Strategy to Control Vector-Borne Diseases Dr. Joel Vega-Rodriguez, Earl Stadtman Investigator and NIH Distinguished Scholar, Chief, Molecular Parasitology and Entomology Unit Laboratory of Malaria and Vector Research National Institutes of Health	Office of Bioresearch Monitoring Operations (OBIMO) Regulatory Update Ms. Anne Johnson, Program Division Director, BIMO East; District Director, Philadelphia, Office of Regulatory Affairs, US Food and Drug Administration	
2:40pm	Coffee & Networking Break - Foyer		
3:15pm	Team Science and Collaboration: From Theory to Practice Dr. Michelle Bennet, Director, Center for Research Strategy at the National Cancer Institute	FDA Perspective on Investigator Sponsored Clinical Trials Ms. Bhanu Kannan, MS, Consumer Safety Officer, Bio-Research Monitoring Branch, Division of Inspections and Surveillance, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, FDA	All Day Poster Sessions & One on One Meetings
4:05pm	Creating a Pipeline for Clinical and Translational Research in Puerto Rico Undergraduate Moderator: Dr. Karen G. Martinez, MD, MSc, Associate Professor, Director, Center for the Study and Treatment of Fear and Anxiety, Department of Psychiatry, Principal Investigator, Hispanic Clinical and Translational Research Education and Career Development program, University of Puerto Rico, Medical Sciences Campus Panelists: Dr. Jose R. Moscoso Alvarez, T.R., Ed.D., FAEIRS, Director Programa de Tecnología en Imágenes Médicas, UCC; Dr. Enid Garcia, MD, MPH, Director, Endowed Health Services Research Center, University of Puerto Rico School of Medicine; Dr. Barbara Segarra, Dean School of Health Professions, Principal Investigator, Hispanic Clinical and Translational Research Education and Career Development program, Chair- Internal Advisory Committee PRCTRC, Director Clinical Laboratory Sciences Program, University of Puerto Rico (Post-Graduate); Dr. Carlos Luciano, M.D., Professor of Neurology, University of Puerto Rico Medical Sciences Campus; Dr. Amarilys Silva, Ph.D, Executive Director PRCCI (Clinical Research); Dr. Walter Frontera, MD, Ph.D., Co-Principal Investigator, Hispanics in Research Capability (HiREC).	Clinical Research Regulatory Panel Discussion Moderator: Ms. Cariny Nuñez, MPH, CHRM, Senior Public Health Advisor, Office of Minority Health and Health Equity, U.S Food and Drug Administration Panelists: Andrea Furia-Helms, M.P.H, Director, Dr. Milena Lolic, M.D., M.S., Lead Medical Officer, Dr. Cynthia Kleppinger, M.D., Senior Medical Officer, Ms. Anne Johnson, Division 1, District Program Director, Ms. Bhanu Kannan, MS, Consumer Safety Officer	
5:15pm	Closing Remarks		

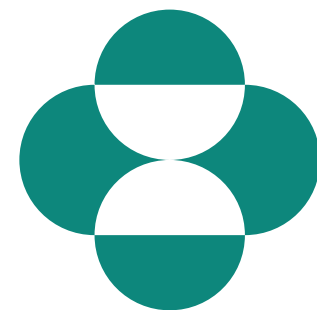
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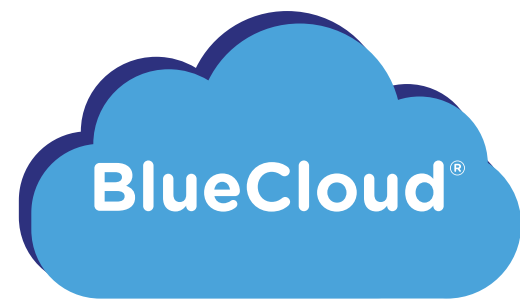


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