AGENDA
May 9 and 10, 2019
Sheraton Puerto Rico Hotel & Casino
In collaboration with:

Puerto Rico Science, Technology & Research Trust

GOBIERNO DE PUERTO RICO
Departamento de Desarrollo Económico y Comercio

DEPARTAMENTO DE SALUD
GOBIERNO DE PUERTO RICO

FDA
U.S. FOOD & DRUG ADMINISTRATION

INDUNIV
Industry University Research Center, Inc.

UPR - Medical Sciences Campus
School of Health Professions

ERD

Colmena66
Tu Célula Empresarial

MBQ PHARMA

PRINBRE
The Network of Molecular Research Excellence

GCM
Medical Group

IDEV
Instituto Universitario de Estudios Veterinarios


Yale Center for Clinical Investigation

PAREXEL

Novartis

Emerson Clinical Research Institute

HARVARD TH. CHAN
SCHOOL OF PUBLIC HEALTH

THE UNIVERSITY OF ARIZONA
Cancer Center

HurOn

Emerson Clinical Research Institute

Atara Bio®

Yale

AMGEN

NIH
National Institutes of Health
Tumor Discovery into Health
Our deepest appreciation to the professionals who worked in the planning and organization of this event since last year. Their dedication and commitment have been essential to the success of this program.
**Agenda**

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

**San Juan 6-8**

**1:30pm**
- **Strategies on Patient Advocacy and Centricity**
  - **Moderator:** Ms. Cariny Nuñez, MPH, CPHRM, Senior Public Health Advisor, Office of Minority Health and Health Equity, U.S. Food and Drug Administration
  - **Panelist:** Dr. Barbara Segarra, Dean School of Health Professions, Medical Sciences Campus, University of Puerto Rico; Ms. Andrea Faria Heils, MPH, Director, Patient Affairs Staff, Office of the Commissioner U.S. Food and Drug Administration; Ms. Mariel Brignoni, President & Patient, Comprehensive Cancer Center Coalition

**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

**3:20pm**
- **Coffee Break and Networking - 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 Virológicos (IDEV)
  - (Creating a Clinical Care Site in the Dominican Republic)

**4:10pm**
- **Discovering Cures for Major Diseases**
  - Dr. V.A. Shiva Ayyadurai, President CytoSolve

**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**

**Miramar 1-3**

**1:30pm**
- **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)

**2:20pm**
- **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

**3:30pm**
- **CASE STUDIES: Experiences in Latin America Starting and Developing a Clinical Research Center**
  - Mr. Rick Rohrbach, MBA, Managing Director HURON Consulting

**4:10pm**
- **EXPANDING THE BUSINESS: Importance of Strategic and Financial Planning**
  - Mr. Rick Rohrbach, MBA, Managing Director HURON Consulting

**5:40pm**
- **Closing Remarks, Housekeeping Announcements**

**Miramar 4**

**All Day Poster Sessions & One on One Meetings**
## Agenda

### 7:00am
Registration / Continental Breakfast

### 8:30am
Welcome

### 8:35am
**Keynote**
Health Disparities Research: In The Quest for Better Health Outcomes for All
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

### 9:00am
Welcome and Introduction of FDA Team
Ms. Nilda Villegas, Health Communications Specialist, Office of Regulatory Affairs, Office of Public Affairs and Editorial Branch Services, FDA

### 9:10am
Strategies/ Considerations for Managing Federally Funded and FDA Regulated Research
Ms. Linda M. Coleman, JD, CIP, CHC, CHRC, CCEP-I, Director Human Research Protection Program, Office of Research Protection Program, Yale University

### 9:50am
Coffee Break and Networking - Foyer

### 10:20am
From Bench to Bedside: How to Develop a Pharmaceutical Company
Dr. Federico Goodsaid, CEO, MBQ Pharma

### 11:10am
Precision Medicine in Pediatric Cancer Care
Dr. Yi Zeng, Assistant Professor of Pediatrics, University of Arizona Cancer Center

### 12:00pm
Lunch Posters Award Ceremony

### All Day
Poster Sessions & One on One Meetings

### All Day
Poster Sessions & One on One Meetings

### 10:20am
Why Diversity in Clinical Trials Matters?
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

### 11:10am
The Future of Compliance, Investigator Site and Industry Sustainability - Here Today!
Mr. Al O. Pacino II, President HealthCarePoint.com
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| 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 | **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 | **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** |
| 1:50pm | **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 | **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 | **All Day Poster Sessions & One on One Meetings** |
| 2:40pm | **Coffee Break and Networking - 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** | **All Day Poster Sessions & One on One Meetings** |
MAY 10 / PM

Agenda

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 PRCTR, 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).

5:15pm
Closing Remarks

SanJuan 6-8

4:05pm
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

Miramar 1-3

All Day Poster Sessions & One on One Meetings

Miramar 4