



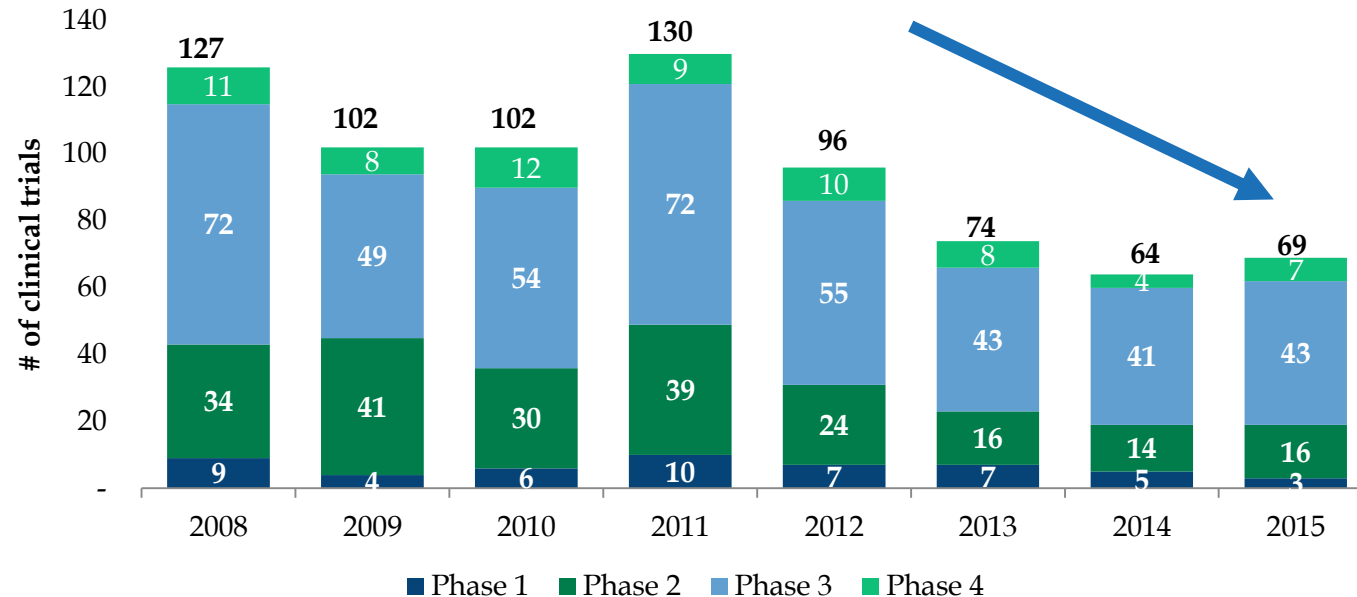
Puerto Rico Consortium for Clinical Investigation

THE PUERTO RICO EXPERIENCE

MAY 2017

IRENE WALLSTABE

THE SITUATION: CLINICAL TRIAL ACTIVITY HAD BEEN DECLINING IN PUERTO RICO ACROSS ALL PHASES, BOTH IN TERMS OF PATIENT ENROLMENT AND CLINICAL TRIAL NUMBERS



Source: clinicaltrials.gov (accessed Oct 2016), PwC Analysis

Note: Clinical trial numbers by year first received on clinicaltrials.gov. Not all clinical trials are captured on clinicaltrials.gov but this is a good source to identify trends and make comparisons

THE APPROACH: PRCCI WAS BORN FOLLOWING AN INNOVATIVE AND COMPREHENSIVE ASSESSMENT OF PUERTO RICO'S COMPETITIVENESS FOR CLINICAL TRIALS

1

Market Assessment

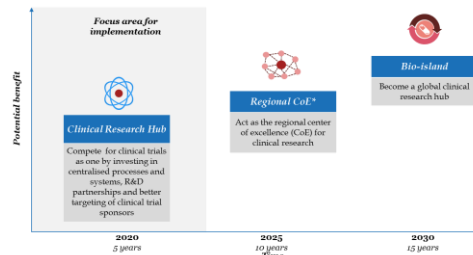
Puerto Rico was assessed against PwC's 6 levers that drive clinical trials competitiveness framework



2

Strategy and Business Case Development

A strategy was developed to establish an entity with a compelling value proposition for Sponsors / CROs, Research sites and Patients



3

Execution

PRCCI was established by forming strategic partnerships and establishing world-class capabilities



Puerto Rico Consortium
for Clinical Investigation

February 2015

April 2015

Launch: April 2016

Evolution of PRCCI

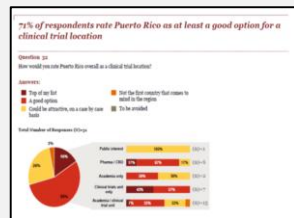


ONE OF THE KEY FACTORS THAT SET UP PRCCI FOR SUCCESS FROM THE START, WAS A PR-TAILORED MARKET ASSESSMENT BY AN INDEPENDENT THIRD PARTY

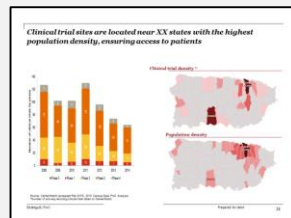
Sample outputs of a market assessment

Success factors:

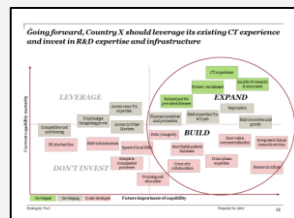
- An *independent, neutral* and *unbiased* third party conducted the market analysis
- Solutions were developed in *co-creation* with local stakeholders
- The strategy and business case were developed by *experienced professionals*



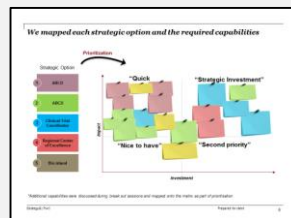
Survey output



Local R&D landscape analysis



Capability assessment



Strategic options prioritization

Result:

A Puerto Rico-tailored solution that had buy-in from local stakeholders from the start.

SOME FINDINGS: PERCEPTIONS ABOUT PUERTO RICO OFTEN DO NOT MATCH REALITY BUT NEVERTHELESS, THERE ARE CERTAIN CHALLENGES TO OVERCOME

Findings from the market assessment showed that...

PR has obvious **STRENGTHS** as a
clinical research location...



Strong doctor-patient relationships



FDA regulated



World-renown researchers

...but there are also significant
CHALLENGES to overcome



Prevailing misconceptions about PR



De-flux of research professionals



High levels of bureaucracy



INTRODUCING PUERTO RICO AND PRCCI

PUERTO RICO IS AN EPICENTER OF CLINICAL TRIAL ACTIVITY ACROSS THE AMERICAS AND BENEFITS FROM US FDA REGULATION AND EXPERTISE

Puerto Rico is an epicenter in the Americas



Benefits of conducting clinical research in Puerto Rico

1. Strategically located midway between North and South America
2. Favorable regulatory environment
3. World class business environment
4. Outstanding human capital
5. Unrivalled financial incentives*

*Eligibility for tax incentives is subject to assessment by PRIDCO / The Puerto Rico Government

INTRODUCING THE PUERTO RICO SCIENCE, TECHNOLOGY AND RESEARCH TRUST (PRSTRT)



Puerto Rico
Science, Technology
& Research Trust

Who we are

We are a private non-profit organization created in 2004 to encourage and promote innovation, transfer and commercialization of technology and creation of jobs in the technology sector. We are responsible for Puerto Rico's public policy for science, technology, research and development.

Our mission

We invest, facilitate and build capacity to continually advance Puerto Rico's economy and its citizens' well-being through innovation-driven enterprises, science and technology and its industrial base.

Our vision

By 2022, the Trust's vision is to transform Puerto Rico into a globally recognized innovation hub that develops, attracts, and retains scientists, technology entrepreneurs, and enterprises to unlock world class creativity and competitiveness.

Our initiatives



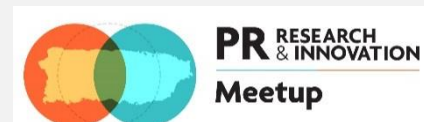
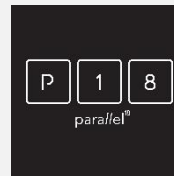
Colmena 66
Tu Conexión Empresarial.



Puerto Rico Brain Trust
for Tropical Diseases
Research & Prevention



Puerto Rico Consortium
for Clinical Investigation



INTRODUCING PRCCI - OUR VISION AND MISSION



PRCCI Vision

To promote and enhance clinical research & development for the benefit of patients, the Puerto Rican economy and global scientific innovation



PRCCI Mission

*To improve the impact, quality, and speed of clinical research in Puerto Rico through: **Building a Collaborative Network** of investigators, **Establishing Best Practices** for the conduct of clinical trials, and **Educating Patients, Sponsors and Researchers***



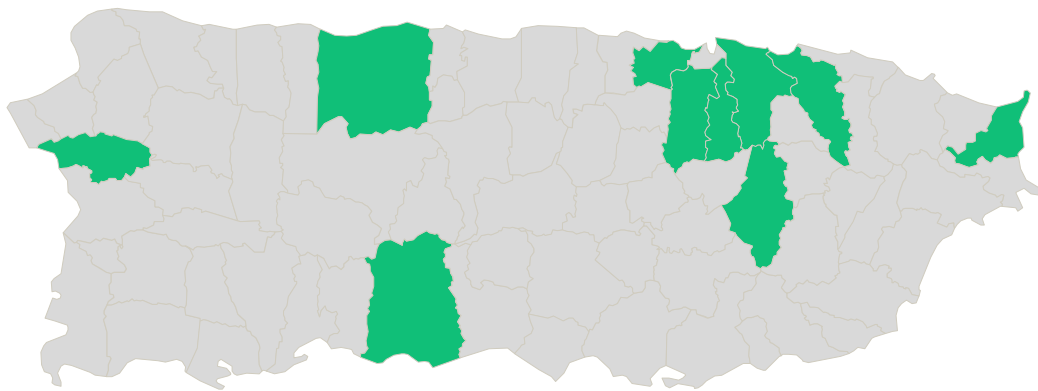


OUR ACHIEVEMENTS TO DATE

WE HAVE BROUGHT TOGETHER 22 RESEARCH SITES ACROSS A WIDE RANGE OF THERAPEUTIC AREAS

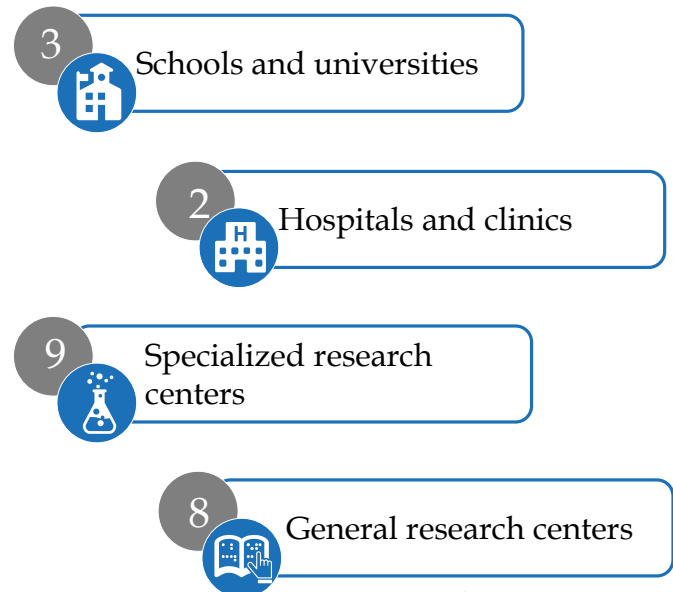
- Established in April 2016, PRCCI is a not-for-profit collaborative of 22 (and counting...) top academic and private research sites.
- We focus on clinical research quality and speed of execution, driving performance and efficiencies across our sites, and establishing world-class capabilities to compete as one.

Map of Puerto Rico



 Research site locations in PR

22 PRCCI Research Sites



60 INVESTIGATORS ARE PART OF PRCCI, WITH EXPERIENCE IN A WIDE RANGE OF THERAPEUTIC AREAS

Number of PRCCI
Principal Investigators
across various
therapeutic areas



PRCCI HAS PUT TOGETHER A WORLD-CLASS TEAM OF INTERNATIONAL EMPLOYEES AND BOARD MEMBERS

The PRCCI team...



Dr. Kosmas Kretsos
Executive Director
PRCCI



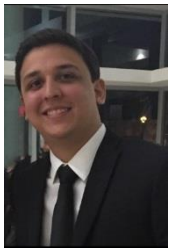
Astrid Navarro, CPA
Director of Finance



Dr. Roberto Torres,
Director of Business
Development



Stephanie Berger
Director of Quality



Jorge Martínez
Business Support
Specialist



Salima Dhanji
Director of
Operations



Irene Wallstabe
Director of
Performance
Management



Michelle Martínez
Operations Support
Specialist

The PRCCI board...



General (retired)
Lester Martínez



Gil Medina



Dr. Ken Ramos



Dr. Larissa Avilés-
Santos



Dr. Donald
Sebastian

TOGETHER WITH ITS STRATEGIC PARTNERS AND THROUGH CUSTOM-MADE PROCESSES, PRCCI REALISES CLEAR BENEFITS FOR MANY STAKEHOLDERS

Yale University

PharmaSeek



Established strategic partnerships

PAREXEL®
THE CLINICAL RESEARCH
GROUP, INC.



Custom-made processes

Developed custom-made processes and key performance indicators



PRCCI KPIs

205 Clinical trial opportunities brought to PR

Developed a strong study pipeline

9 Clinical trial agreements signed

2 TransCelerate training courses delivered

Trained 240 people across Puerto Rico

3 Yale training courses

Yale



PLEASE CONTACT US IF YOU HAVE ANY QUESTIONS
AND FOLLOW US ON SOCIAL MEDIA



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Management and
Strategic Projects*



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