Clinical research interest, experience, strengths, and difficulties of physicians in Puerto Rico survey

For INDUNIV’s Puerto Rico Health Care Council and Colegio de Médicos Cirujanos de Puerto Rico
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Colegio de Médicos Cirujanos de Puerto Rico

- Clinical Research and Technological Development Institute
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- Dr. Wilfredo E. De Jesú-Monge – San Juan Medical District Representative and Advisor
Introduction
Clinical Research in Puerto Rico

- Clinical research quality in PR is at the level of key US states and has clinical research expertise in global research focused disease areas (pwc, 2015)

- However, clinical trial activity is declining in PR, both in terms of patient enrollment and clinical trial numbers; PR is not perceived as having superior clinical research and expertise; and lacks a strong research culture (pwc, 2015)

- Therefore, there are few reasons for physicians to become principal investigators and to train staff (pwc, 2015)

- A qualified physician, who is an investigator or a sub-investigator, for the trial, should be responsible for all trial-related medical decisions (ICH-GCP, 1996)
INDUNIV

- Industry University Research Center
- Nonprofit organization representing industry, government and the academic sector
- **Puerto Rico Health Care Council**
  - Focused on promoting initiatives that will improve the life of our people and promote the development of new business in the field
Colegio de Médicos Cirujanos de Puerto Rico

- Organization that groups all licensed physicians in Puerto Rico

- Clinical Research and Technological Development Institute
  - Promotes, foster, and facilitates clinical studies and scientific research that contribute to the advancement of medicine and the public health of Puerto Rico
The survey

- The purpose of this survey is to know the profile of clinical investigators, where are they located, their strengths and the difficulties they face.
- In addition, a registry of clinical investigators in PR will be made, to which respondents can voluntarily sign up.
- The registry may be used to directly provide clinical studies opportunities in PR to the registrants.
- The participation is voluntary and the information will be kept confidential.
- There are approximately 10,000 licensed physicians in PR, all members of the Colegio de Médicos Cirujanos de Puerto Rico.
Methods

- The survey was designed, reviewed, and tested as a group with members and guests of INDUNIV’s Puerto Rico Health Care Council monthly meetings.
- The survey was placed in the SurveyMonkey platform and sent to the members of the Colegio de Médicos Cirujanos de Puerto Rico via e-mail blast for a few months.
- The survey was closed and results were collected and analyzed.
Results
Do you currently conduct clinical research in your medical practice? (all that apply)

- Clinical research
  - Research with human subjects that is:
    - Patient-oriented research (or on material of human origin such as tissues, specimens, and cognitive phenomena) that can be linked to a living individual
    - Epidemiological and behavioral studies
    - Outcomes research and health services research

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>I did in the past and I am interested now</th>
<th>I did in the past and I am not interested now</th>
<th>I have never done it, but I am interested now</th>
<th>I have never done it and I am not interested now</th>
</tr>
</thead>
<tbody>
<tr>
<td>all respondents</td>
<td>28.7%</td>
<td>20.9%</td>
<td>8.4%</td>
<td>27.4%</td>
<td>15.5%</td>
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</tbody>
</table>
Physicians who currently conduct clinical research in PR

**Gender**
- Male: 48%
- Female: 49%
- Prefers not to answer: 3%

**Age (years)**
- 20-30: 17%
- 31-40: 21%
- 41-50: 5%
- 51-60: 5%
- 61-70: 5%
- 71+: 1%
- Prefers not to answer: 8%
Physicians who currently conduct clinical research in PR

In which medical specialty would your clinical research be classified? (all that apply)

- Top 5
  - Subspecialties: 47%
  - Internal Medicine: 19%
  - Pediatrics: 16%
  - Psychiatry/Neurology: 13%
  - General Medicine and Obstetrics/Gynecology: 10%

Which type of clinical practice you currently conduct? (all that apply)

- Individual: 45%
- Group: 24%
- Academic: 54%
- Exclusively associated with clinics and/or hospitals: 24%
- Do not practice: 6%
Physicians who currently conduct clinical research in PR

If you are a specialist: are you board certified?
- Yes: 63%
- No: 28%
- Not specialist: 9%

For how many years have you conducted clinical research?
- 1-5 years: 19%
- 6-10 years: 28%
- 11-15 years: 16%
- 16-20 years: 9%
- 21 or more years: 28%
Physicians who currently conduct clinical research in PR

Clinical research coordination staff, facilities, and setting (all that apply)

<table>
<thead>
<tr>
<th>Have staff</th>
<th>No staff</th>
<th>Have facilities</th>
<th>No facilities</th>
<th>Independent</th>
<th>Collaborates with other professionals</th>
</tr>
</thead>
<tbody>
<tr>
<td>57%</td>
<td>28%</td>
<td>40%</td>
<td>20%</td>
<td>33%</td>
<td>81%</td>
</tr>
</tbody>
</table>

Sponsors (all that apply)

<table>
<thead>
<tr>
<th>Companies (industry) in USA</th>
<th>54%</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH and other federal agencies</td>
<td>13%</td>
</tr>
<tr>
<td>Contract Research Organizations</td>
<td>35%</td>
</tr>
<tr>
<td>Academia</td>
<td>55%</td>
</tr>
<tr>
<td>Foundations</td>
<td>13%</td>
</tr>
<tr>
<td>Cooperative groups</td>
<td>5%</td>
</tr>
<tr>
<td>Other</td>
<td>7%</td>
</tr>
</tbody>
</table>
Physicians who currently conduct clinical research in PR

Which type of clinical research do you currently conduct? (all that apply)

- Mechanism of disease: 57%
- Clinical trials: 31%
- Phase 1: 42%
- Phase 2: 25%
- Phase 3: 19%
- Phase 4: 18%
- Medical devices: 7%
- Epidemiology: 11%
- Behavioral: 29%
- Health Services: 81%
- Other: 8%

To which health and disease application may your clinical research be classified? (all that apply)

- Prevention (including vaccines): 25%
- Early detection: 27%
- Diagnostics: 42%
- Treatment: 29%
- Quality of life: 8%
- Other: 8%
Physicians who currently conduct clinical research in PR

In which therapeutic area may your clinical research be classified? (all that apply)

- Infectious: 37%
- Cardiovascular: 23%
- Cancer: 18%
- Substance addiction: 17%
- Pulmonary: 16%
- Digestive: 13%
- Hematology: 11%
- Endocrine: 8%
- Renal: 8%
- Pain management: 4%
- Reumathology: 1%
- Trauma: 1%
- Other: 1%

In which professional stage have you conducted clinical research? (all that apply)

- High school: 16%
- Undergraduate: 25%
- Post-bach (no degree): 16%
- Graduate: 47%
- Medical school: 46%
- Residency: 25%
- Research resident or fellow: 7%
- Fellowship: 46%
- Practice: 80%
- Other: 5%
Physicians who currently conduct clinical research in PR

Which represents your clinical research education and training? (all that apply)

- National Institutes of Health: 81%
- Mentorship: 59%
- IRB-required: 48%
- Training program: 46%
- Sponsor training: 49%
- Self taught: 41%
- Continued medical education: 29%
- Other: 5%

What motivates you to conduct clinical research? (all that apply)

- Variety in daily medical practice: 89%
- Personal, family, or emotional experience with disease: 52%
- Producing or contributing to new knowledge: 49%
- Professional recognition: 27%
- CME credits: 20%
- Financial income: 5%
Physicians who currently conduct clinical research in PR

Which statement best describes your circumstance for each of the following items related with the conduct of clinical research: "I have it and it strengthens me" or "I do not have it and, therefore, gives me difficulty"?

- Knowledge about the process and topics of clinical research: 87% have it and it strengthens me, 8% do not have it and it gives me difficulty.
- Experience: 89% have it and it strengthens me, 6% do not have it and it gives me difficulty.
- Good English language communication skills: 95% have it and it strengthens me, 1% do not have it and it gives me difficulty.
- Available time or its effective organization: 73% have it and it strengthens me, 20% do not have it and it gives me difficulty.
- Effective communication with sponsors: 73% have it and it strengthens me, 19% do not have it and it gives me difficulty.
- Available resources in my office or institution: 64% have it and it strengthens me, 31% do not have it and it gives me difficulty.
- Institutional support: 70% have it and it strengthens me, 19% do not have it and it gives me difficulty.
- Federal government funding: 51% have it and it strengthens me, 28% do not have it and it gives me difficulty.
- PR government funding: 63% have it and it strengthens me, 7% do not have it and it gives me difficulty.
- Other: 63% have it and it strengthens me, 4% do not have it and it gives me difficulty.
Municipalities where clinical research is conducted
Do you want to learn about initiatives, events, courses, and/or lectures related with clinical studies topics?

98% 2%

Physicians who currently conduct clinical research in PR

Si 84.5 %
No 15.5 %

all respondents = n = 296
Summary of results and discussion

- The response rate was very low, approximately 3%.
- Among the respondents, approximately, 3 out of 10 physicians currently conduct clinical research in his/her medical practice.
- Physicians who currently conduct clinical research in PR:
  - Genders are evenly distributed and the largest age groups are 51-60 and 31-40 years old.
  - Most of them practice in an academic setting.
  - The top medical specialties in which clinical research may be classified are Internal Medicine and Pediatrics.
  - The majority are board certified specialists.
Summary of results and discussion

- Physicians who currently conduct clinical research in PR:
  - The largest groups conduct clinical research for 6-10 and more than 21 years
  - The majority collaborates with other professionals and have clinical research coordination staff; are sponsored by industry in the USA and academia; conduct clinical trials, mainly Phase 3, treatment trials; and are educated / trained through IRB certifications and mentorship
  - The largest group conduct Infectious diseases research
  - A trend of clinical research experience through professional stages can be seen since undergraduate
Summary of results and discussion

- Physicians who currently conduct clinical research in PR:
  - The majority are motivated by the production or contribution to new knowledge and variety in medical practice
  - Good English language communication skills is the most common attribute that strengthens and lack of PR government funding is the most common attribute that causes difficulty
- Almost all of physicians who currently conduct clinical research in PR and most of the respondents overall want to learn about initiatives, events, courses, and/or lectures related with clinical studies topics
Limitations

- Low response rate, with known physician researchers not being voluntarily registered
- Recall bias
- Some of the questions may have been confusing
Future work

- Fix the questions as needed and repeat trying to gather a larger sample
- Design a more specific survey, based on focus groups, for Internal Medicine and Pediatrics physician researchers
Conclusion

- This survey is a good starting point to know the profile of clinical investigators, where are they located, their strengths and the difficulties they face.
- In addition, the produced registry of clinical investigators in PR is the beginning to which more physician researchers can be added.
- Physicians in PR want to learn about initiatives, events, courses, and/or lectures related with clinical studies topics.
Acknowledgments

Members and guests who provided feedback and valuable discussion during the INDUNIV’s Puerto Rico Health Care Council monthly meetings