



Pachyonychia Congenita Project

Fighting for a cure. Connecting & helping patients. Empowering research.

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PC Project's Guidelines for Collaborating with Industry Partners

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Overview

PC Project is a 501(c)(3) non-profit organization that supports patients and families affected by PC, while simultaneously promoting PC research, educating the public about this rare health condition, and advocating on behalf of our community. PC Project's mission is fighting for a cure by connecting and helping patients and empowering research.

In support of our mission, PC Project maintains ongoing interactions and collaborations with industry partners who share our goals. PC Project believes that development of safe and effective PC treatments cannot be achieved without strategic partnerships with pharmaceutical companies. PC Project requires that these collaborations maintain the highest levels of transparency and ethical conduct. In collaborating with pharmaceutical companies, PC Project's dual objectives are to facilitate the development of safe and effective PC treatments while remaining an independent, patient-focused advocacy organization. To achieve these parallel objectives, PC Project follows guidelines set forth by the Pharmaceutical Manufacturers of America (PhRMA) "Principles on Interactions with Patient Organizations." These principles include:

- Patient organizations and pharmaceutical companies share many common interests, including a common commitment to patients and shared mission to discover cures and fight disease.
- All of PC Project's interactions with pharmaceutical companies must be consistent with PC Project's mission.
- No pharmaceutical company can require that it is the sole supporter of PC Project or any of PC Project's programs.
- Pharmaceutical companies that provide financial or in-kind support to PC Project must document the nature of the support, including the purpose of any activity and its funding.
- Pharmaceutical companies may provide financial support for PC Project meetings or other activities if the primary purpose of the activity is professional, educational, or scientific in nature, or if the activity otherwise supports PC Project's mission.

The principles outlined below guide PC Project, including board members, staff, committees, ambassadors, and representatives in engagement with the pharmaceutical industry.

General principles for engaging with pharmaceutical companies

PC Project is eager to develop mutually beneficial relationships, advocacy, and educational efforts with pharmaceutical companies that develop therapies for PC. PC Project will engage with companies that are interested in any aspect of drug discovery or clinical research that aims to develop treatments for PC. PC Project will only consider collaborations with companies that conduct ethical, high-quality research.

Patient Engagement

PC Project strongly encourages and facilitates dialogue between patients and pharmaceutical company representatives to promote PC awareness and share patient perspectives. PC Project feels that these interactions promote transparency to the patient community, ensure that patients are represented in pharmaceutical company initiatives that focus on PC, and allow PC Project to continually improve its understanding of the needs of both patients and pharmaceutical companies.

Examples of how PC Project can collaborate with pharmaceutical companies include:

- Conducting or facilitating patient/family focus groups
- Helping to develop and deploying patient/family surveys
- Facilitating access to de-identified PC registry data
- Providing genetic testing and genetic testing reports for patients in the International PC Research Registry who wish to participate in a clinical study
- With patient permission, facilitating mutation-based screening and enrollment through the International PC Research Registry (IPCRR)
- Providing feedback during clinical trials from the patient community to Facilitating introductions with leaders of the International PC Consortium (IPCC)

We strongly encourage interested pharmaceutical companies to sponsor and attend patient support meetings to gain an understanding of the challenges of PC patients.

Financial Support

Financially stable patient advocacy organizations are a critical element of pharmaceutical companies' ability to develop new treatments, and this is especially true for rare diseases like PC. PC Project needs financial resources to grow and continue to serve its stakeholders. To this end, we receive pharmaceutical company contributions under certain circumstances:

- PC Project provides a written request on organizational letterhead stating the reason and amount of the request.

- Donations from pharmaceutical companies are attributed to the company that made the contribution. PC Project does not accept anonymous donations from pharmaceutical companies.
- Financial contributions to PC Project should be made either as an unrestricted grant or sponsorship of a specific activity initiated by PC Project.
- PC Project staff and Board members will not act as paid service providers to a pharmaceutical company.
- PC Project staff and Board members should not receive honoraria to speak on behalf of PC Project.
 - PC Project staff and Board members can direct honoraria for speaking engagements to a fund that supports PC Project.

Clinical Trial Communication

PC Project has unique access to PC patients, families, and other stakeholders. It therefore acts as a bridge between pharmaceutical companies that seek to develop new products for PC and the PC patient community. PC Project follows certain principles in this role:

- PC Project shares information about clinical trials with the PC community to ensure that patients and families are aware of clinical trials and have an opportunity to make informed decisions about participating.
- The choice to participate in a clinical trial is made by individuals and families. PC Project's role is to provide patients with information about ongoing trials.
- PC Project supports clinical trials for PC treatments by providing pharmaceutical companies with information about PC patient needs, feedback from patients, as well as potential barriers to trial participation. Once again, the choice to participate in a trial is made by individuals and families.
- PC Project staff and Board members act as ambassadors of PC Project. In this role, they are expected to conduct themselves appropriately on social media, including communications concerning ongoing clinical trials for PC treatments.

Patient Privacy

- PC Project does not provide identifiable data or contact information for any PC patients or their families without permission.
- Collection of personal health information by a pharmaceutical company as part of a research protocol must be conducted under the auspices of an institutional review board (IRB).
- Pharmaceutical companies should not collect and store patient identifiers.