



# External Stakeholder Engagement Guidelines 2020

## STAKEHOLDERS

### Internal

Internal stakeholders include all board members and staff of Progressive Familial Intrahepatic Cholestasis Advocacy & Resource Network, Inc. (PFIC Network). Additional internal stakeholders include any individuals introduced to external stakeholders by PFIC Network board member and/or staff.

### External

External stakeholders include any commercial industry entity including pharmaceutical companies, biotech companies, and contract research organizations. Additional external stakeholders could include any for-profit program partner.

## OVERVIEW

Patient-focused drug development practices are dynamic and evolving rapidly. Regulators in the United States and globally are recognizing the benefits of patient representation throughout the entire drug development process from research conception to post market access and communications. Continued communications and collaboration between patient organizations and industry are resulting in improved disease understanding, research targets, endpoint identification, clinical trial development, regulatory understanding, post-commercial resources, patient education and so much more. In order to maximize these benefits and continue progressing these relationships it is important to ensure that the exchange of ideas is conducted within an ethical framework and without compromising independence of both parties.

## PURPOSE

The purpose of these guidelines is to set clear expectations between PFIC Network and industry partners. The guidelines were developed to build a strong foundation for positive collaboration between PFIC Network and external stakeholders.

## PFIC Network PRINCIPLES OF ENGAGEMENT

**CLARITY OF PURPOSE** Collaboration between PFIC Network and external stakeholders should be clear about the purpose of the engagement and the desired outcomes.

**TRANSPARENCY** All financial relationships between PFIC Network and external stakeholders should be proportional and commensurate with experience, expertise and the time invested. PFIC Network will comply with all 501(c)3 reporting requirements.

**INDEPENDENCE** PFIC Network will remain independent in all aspects of decision-making, development of policies and external communications to ensure credibility and patient confidence. Funding from a wide range of sources is preferable and will support organizational capacity building and/or patient programs that support the PFIC Network mission.

**RESPECT** In any collaboration, stakeholders bring their own perspectives, skills and experience. Collaboration should be based on mutual respect, prioritizing long-term commitment over short-term needs and valuing each other's contribution.

## PRINCIPLES IN ACTION

- PFIC Network strives to collaborate with multiple biopharmaceutical companies to ensure the sustainability of its initiatives and to allow for a diversity of views and therapeutic approaches. Each collaboration will be conducted with the same principles.
- PFIC Network Reserves the right to disengage with an external stakeholder if the goals of the two organizations are not aligned and/or if the Principles of Engagement are not respected.
- PFIC Network will avoid any and all conflicts of interest. Representatives of external stakeholders actively developing or selling therapies for the disease will not sit on the board of directors for PFIC. Further, PFIC Network board and staff

members will not seek employment at respective companies while serving on the PFIC Network board.

- PFIC Network requires advance understanding of the disease or research efforts and should have a clearly stated purpose or set of objectives before projects and/or programs are pursued.
- PFIC Network will pursue multiple sources of funding for capacity building and patient programs. All funding requests will be documented on the letterhead of the organization and clearly state the mission and activities of PFIC Network and reasons for the request. Any financial contribution to PFIC Network will be made either as (1) unrestricted funding or (2) sponsorship of a specific activity initiated by the patient advocacy organization to support its stated mission. PFIC Network will maintain proper documentation of all requests for financial support from external stakeholders.
- PFIC Network will not pursue any funding that does not align with the foundation mission statement and/or provide need resources identified by the patient community.
- PFIC Network values the privacy of the patient community. External stakeholders, including all employees and contractors, are not allowed to join any closed or private patient community online group. PFIC Network reserves the right to *immediately* disengage with any stakeholder that is found to violate this policy.
- PFIC Network requests that patients providing information to external stakeholders be valued for their time and expertise at a fair market value. Travel expenses incurred to participate in advisory board meetings or disease awareness activities may be reimbursed directly to the individual patient or to PFIC Network as predetermined by the project plan.
- PFIC Network acts as a conduit for information about research opportunities such as advisory boards or clinical trial opportunities by providing education and resources to the patient community without bias. PFIC Network does not seek to influence that choice, but rather, assists patients and families in making informed decisions through education and awareness. Further, PFIC Network will share public information about programs such as clinical trials but will not serve as the liaison between the community and external stakeholders regarding specific questions or needs regarding the program.
- PFIC Network serves as a trusted resource for the patient community and therefore requests prior communication about any patient community program or

activity that is conducted by partnering external stakeholders even if the foundation is not participating in the program.

- PFIC Network requests board and/or staff representation during program activities that involve the patient community such as patient advisory boards.
- PFIC Network requests advance review of patient participation agendas and any contracts patients are required to sign in any program that PFIC Network assisted in.
- PFIC Network requires that patient information remain confidential and program specific. If a patient participates in a program in which PFIC Network was involved such as an advisory board, the patients contact information will not be used in future program recruitment. Any future communication must be conducted through the patient foundation (PFIC) in order to protect patient privacy.
- PFIC Network requests regularly scheduled meetings with external stakeholders to ensure open and consistent communication.
- PFIC Network is currently run by a group of volunteers and will respond to external stakeholder requests via email within 72 business hours.
- PFIC Network will uphold non-disclosure agreements and will be compliant when providing information about research and/or program activities.

## REFERENCES

21st Century Cures Act, 42 USC 201 (2016). Available at: <https://www.congress.gov/bill/114th-congress/house-bill/34/text>. Accessed 5 Dec 2017.

CDER Patient Focused Drug Development (2019). Available at: <https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development>

European Guideline between Pharma and Patient Organisations: Working Together With Patient Groups (2017). Available at: <https://www.efpia.eu/media/288492/working-together-with-patient-groups-23102017.pdf>

Principles for interactions with biopharmaceutical companies: the development of guidelines for patient advocacy organizations in the field of rare diseases (2018). Available at: <https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0761-2>

