



The International FOP Association's Guidelines for Engagement with Pharmaceutical Companies

Version 1.0, September 13, 2016

Introduction

The International FOP Association (IFOPA) is a 501(c)(3) non-profit organization supporting medical research, education and communication for those afflicted by the rare genetic condition Fibrodysplasia Ossificans Progressiva (FOP). Our mission is to fund research to find a cure for FOP while supporting individuals and their families through education, public awareness and advocacy. Our vision is a cure for FOP.

In support of our mission, the IFOPA engages in dialogue and collaboration with pharmaceutical companies. The IFOPA seeks the highest level of ethical conduct in our partnerships with pharmaceutical companies. The IFOPA's goal in engaging pharmaceutical companies is to enable development of therapies to meet patient needs while maintaining our independence as a patient organization.

Our approach to interacting with pharmaceutical companies is informed by the European Federation of Pharmaceutical Industries and Associations (EFPIA) "Code on Interactions between Pharmaceutical Companies and Patient Organizations" and the Pharmaceutical Manufacturers of America (PhRMA) "Principles on Interactions with Patient Organizations."

The principles outlined in this document are intended to guide the IFOPA, including board members, staff, committees, International President's Council (IPC) representatives, and interested FOP national organizations, in engagement with the pharmaceutical industry.

1.0 Identifying and Engaging Companies

The IFOPA desires mutually beneficial dialogue and information exchange with pharmaceutical companies developing potential therapies for FOP.

- 1.1. The IFOPA will actively seek contact with companies that show interest or activity in drug discovery, preclinical research, or clinical research in FOP.
- 1.2. The IFOPA will collaborate with companies, at the IFOPA's discretion, which are conducting ethical, high-quality research in a responsible manner, according to industry and international regulatory standards.

- 1.3. The IFOPA will seek insight into the company's objectives, plans, and the potential drug being evaluated and will provide companies with community-wide insight and perspective as needed and appropriate.

2.0 Patient Engagement

We encourage and enable direct dialogue between patients and pharmaceutical company representatives for the purposes of promoting disease awareness and sharing patient perspective, according to the following principles:

- 2.1. We believe direct interactions between patients and pharmaceutical companies are best arranged with the involvement of the IFOPA, IPC representative, and/ or the relevant national FOP organization. Including a patient organization in these interactions can:
 - ensure fairness and transparency within the patient community;
 - ensure that the patient community is well and adequately represented to the pharmaceutical company;
 - allow for access to experts and professional advisers who can inform the dialogue;
 - help avoid misunderstanding in the conversation;
 - ensure the protection of patient privacy in any data collection activities; and
 - allow the patient organization to better understand the needs of both the patient and the pharmaceutical company.
- 2.2. We believe that disease insight can best be provided by an advisory group rather than via individual input. An advisory board format helps ensure that the community is adequately represented and that work is not unduly requested of one individual.
- 2.3. We recommend that learnings and outcomes from any interaction be shared in an open manner.
- 2.4. We recommend that personal health data are not recorded by the company without proper informed consent, and that patient identifiers are not recorded at all.
- 2.5. Leaders of the IFOPA (e.g., board members, International President's Council members) or individuals representing the FOP community may be invited by pharmaceutical companies to speak about FOP at internal company meetings, public events hosted by the company, or in meetings with regulatory agencies. This should be done for the purposes of disease education or awareness in a manner consistent with the points outlined in this document.

3.0 Financial Contributions

Strong and healthy patient organizations are vital partners to pharmaceutical companies developing drugs for FOP. Financial resources are a key need for the growth and maintenance of a patient organization. Demands on the organization are increased by drug development activities in the clinical and commercial stages. We receive pharmaceutical company donations according to the following principles:

- 3.1. Financial contributions from a pharmaceutical company should be initiated by a written request from the patient organization, on the organization's letterhead, stating the organization's mission, activities, and reason for the request.
- 3.2. It is ideal to receive a single, unrestricted donation from any given pharmaceutical company in a year, rather than multiple smaller donations, however it is recognized that this is not always practical or possible.
- 3.3. Donations from pharmaceutical companies must be given in a named manner; i.e., we do not accept anonymous donations from pharmaceutical companies.
- 3.4. It is ideal that any financial contribution be made either as (1) an unrestricted grant or (2) sponsorship of a specific activity initiated by the patient organization to support its stated mission.
- 3.5. Patient organizations and their leadership should not operate as paid service providers to a pharmaceutical company.
- 3.6. Leaders of a patient organization (e.g., board members, presidents) should not receive honoraria to speak on behalf of their organization.
- 3.7. Travel expenses incurred to participate in advisory board meetings or disease-awareness activities may be reimbursed directly to the individual or the organization.

4.0 Clinical Trial Communication

The IFOPA, through various means and committees, including the International President's Council, serves as a conduit for information about clinical trials, according to the following principles:

- 4.1. The IFOPA shares information about clinical trials with the community to ensure that patients and families are aware of clinical trials and have the opportunity to make informed decisions about participating. The choice to participate in any given trial is an individual one; the IFOPA does not seek to influence that choice, but rather to ensure informed decisions can be made.

- 4.2. The IFOPA disseminates accurate and fair-balanced clinical trial information that it receives from a pharmaceutical company. The IFOPA shall not provide additional commentary or opinion that may influence an individual's decision to participate in a clinical trial or that may change the meaning of the information.
- 4.3. In order to support optimal trial design and communications, the IFOPA provides pharmaceutical companies with community-wide observations, needs and barriers to participation.
- 4.4. The IFOPA does not encourage the sharing of individual clinical trial experiences in social media, for reasons of individual privacy and maintaining the integrity of the clinical trial. However, the choice to share information is personal and the IFOPA shall not dictate what clinical trial participants do or do not share in public forums.
- 4.5. The IFOPA board and committee members have a responsibility to represent the IFOPA in their conduct. Information about clinical trials that is accessible to the community via social media, including in personal blogs or other forms of communication, should adhere to the principles outlined in this document.

5.0 Patient Privacy

- 5.1. In order to ensure patient privacy, the IFOPA does not disclose the town or state in which a patient lives as this can uniquely identify a patient with a disease as rare as FOP.
- 5.2. The collection of personal health information by a pharmaceutical company for research purposes shall be guided by a protocol and reviewed by an ethics committee.
- 5.3. A pharmaceutical company should not collect and store patient identifiers.

References

EFPIA Code http://transparency.efpia.eu/uploads/Modules/Documents/code_po2011.pdf

PhRMA Principles:

http://www.phrma.org/sites/default/files/pdf/phrma_principles_paper_20120919_final.pdf