



Policy for Engaging with Industry

Article I - Purpose

Alport Syndrome Foundation (ASF) is a 501(c)(3) non-profit organization whose mission is to improve the lives of those affected by Alport syndrome through education, empowerment, advocacy, and research. The vision of ASF is to conquer this rare genetic disease by finding new treatments to slow or prevent disease progression for all patients.

To accomplish this mission, ASF has created, and seeks to enhance, a landscape that encourages investment in research into Alport syndrome by all stakeholders. This includes actively engaging and collaborating with pharmaceutical and biotech companies.

ASF has developed this policy to ensure the highest level of ethical conduct is followed in ASF's collaborations with pharmaceutical companies. ASF's goal in engaging pharmaceutical companies is to enable development of therapies to meet patient needs while maintaining independence and neutrality as a patient organization.

ASF's sole priority is the best interest of patients. No collaborations with industry will influence ASF's efforts to advocate for accessible, affordable treatments for patients or cause ASF to provide biased information to our membership and the patient community.

ASF's approach to interacting with industry was influenced by consultation with other similarly sized health organizations, including the International FOP Association, 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 ASF, including board members, staff, volunteers and advisors in engagement with companies working in both the pharmaceutical and biotech industry.

Article II - Engagement with Pharmaceutical and Biotech Companies

ASF seeks mutually beneficial dialogue and information exchange with pharmaceutical and biotech companies developing potential therapies for Alport syndrome, according to the following:

1. ASF will actively engage with companies that show interest or activity in drug discovery, preclinical research, or clinical research in Alport syndrome.
2. ASF will collaborate with companies, at ASF's discretion and in consultation with our Medical and Scientific advisors, which are conducting ethical, high-quality research in a responsible manner, according to industry and international regulatory standards.
3. ASF 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. ASF continues to update a presentation for this purpose to share with industry.
4. ASF will advocate on behalf of the patient community to make new therapies accessible. Medications can only change lives if patients have access to them.
5. ASF will actively seek the guidance and utilize the expertise of the organization's volunteer advisory groups including our Medical Advisory Committee and Scientific Advisory Research Network in the process of working with each company. It is recommended and anticipated that companies may have interest in retaining members of ASF's Medical Advisory Committee and/or Scientific Advisory Research Network for direct scientific and clinical research advisement. In this case, ASF encourages companies to enter into independent agreements (outside of ASF) with these advisors and/or their institutions.
6. ASF Board and Staff Members, and members of the Medical Advisory Committee, will disclose any and all relationships with companies with whom ASF engages including signing ASF's Conflict of Interest Policy. ASF expects individual members of our advisory groups, such as our Medical Advisory Committee and Scientific Advisory Research Network, to disclose any and all paid industry collaborations when presenting or authoring on any Alport syndrome research.
7. ASF will sign confidentiality/non-disclosure agreements with pharmaceutical companies on an as-needed basis, which cover the organization's staff and board members.
8. ASF does not accept sponsorship for any paid content or messaging from a pharmaceutical company.
9. Third-party contractors, such as Clinical Research Organizations (CROs), working on behalf of a company for Alport syndrome research are expected to adhere to the above sub-articles 1 through 8. While ASF will endeavor to help as much as possible to progress shared goals, our organization has limited staff resources and reserves the right to discontinue or limit requested activities with a third-party contractor. If ASF finds requests from third-party contractors to be overly burdensome and too dependent on staff time, ASF will make the company sponsor aware and work to find resolution. In fulfilling its mission, ASF's staff time is primarily dedicated to supporting education and support for individuals and families living with Alport syndrome.

Article III - Engagement with Genetic Testing Companies

ASF considers Genetic Testing Companies (GTCs) a special class of biotechnology company that offers a critical, well defined, and regulated diagnostic. Specifically, a GTC to be in scope of this policy must offer, at minimum, an FDA approved exome sequencing panel that includes the three defining genes of Alport syndrome: the COL4A3 and COL4A4 genes on the 2-chromosome and the COL4A5 gene on the X-chromosome.

1. ASF will actively engage with companies that provide genetic testing options for Alport syndrome patients. ASF will work with genetic testing companies to help provide patient-friendly information regarding how to properly order the correct test, how to properly take the test, how results are received by patients, estimated out-of-pocket costs for patients, customer service information, and options for meeting with associated genetic counselors to interpret test results.
2. ASF does not accept sponsorship or fees of any kind to promote biotech services or products to our membership or community.
3. Article II parts 2, 5, 6, 7, 8, and 9 are otherwise the same for Article III.
4. Article II parts 1, 3, and 4 do not apply for Article III.

Article IV - Patient Engagement

ASF encourages and enables direct dialogue between patients and industry representatives for the purposes of promoting disease awareness and sharing patient perspective, according to the following principles:

1. Direct interactions between patients and industry are best arranged with the involvement of ASF. Including our patient organization in these interactions can:
 - a. ensure fairness and transparency within the patient community;
 - b. ensure that the patient community is well and adequately represented to industry;
 - c. allow for access to experts and professional advisors who can inform the dialogue;
 - d. help avoid misunderstanding in the conversation;
 - e. ensure the protection of patient privacy in any data collection activities;
 - f. allow for the formation of advisory or focus groups if appropriate;
 - g. ensure better communication with ASF understanding the needs of both the patients and the company.
2. Any information learned from these interactions should be shared in an open manner.
3. Personal health data are not recorded by the company without proper informed consent, nor are patient identifiers recorded.

4. For the purpose of raising awareness and providing education about Alport syndrome, ASF Board Members, staff, or individuals representing the Alport syndrome community may be invited by industry to speak about Alport syndrome at internal company meetings, public events hosted by the company, or in meetings with regulatory agencies. Board and staff members will not accept personal remuneration for speaking engagements or presentations, however, honorariums can instead be contributed to Alport Syndrome Foundation in their honor.
5. For pharmaceutical and/or biotech companies exploring our disease or providing services of benefit to patients, ASF provides opportunities to share relevant information directly with Alport patients and families. This includes invitations to our annual in-person Alport Connect event. Alport Connect is the single largest education and awareness event of the year, attended by hundreds of patients and often by clinicians and researchers.
6. As a patient-led and focused organization, ASF's mission includes efforts (at no charge) to assist companies understand the patient journey in Alport syndrome. The sharing of numerous, wide-ranging Alport patient journeys can better inform a company's understanding of our disease and potentially improve services or study designs to be more patient-friendly and accessible. Without associated fees or payment, ASF can partner with companies to bring together patients for surveys, interviews, and other ways of sharing their perspectives and experiences.

Article V - Financial Contributions

All collaboration and communication efforts outlined in this document will be conducted with industry regardless of their financial support of ASF, or lack thereof. ASF will not operate in any manner as a paid service provider to a pharmaceutical or biotech company. However, financial resources are critical for ASF to achieve its mission and vision to improve the lives of all patients affected by Alport syndrome, and therefore, ASF will gratefully accept donations from industry according to the following principles:

1. Financial contributions from a pharmaceutical company should be initiated by a written request from ASF stating the organization's mission, activities, programs, and reason for the request.
2. A single, unrestricted donation from any given company in a year is preferable, rather than multiple smaller donations, whenever possible.
3. Donations from companies must be given in a named manner; ASF does not accept anonymous donations from industry.
4. Financial contributions should be made either as (1) an unrestricted grant or (2) sponsorship of a specific activity or program initiated by ASF to support its stated mission.
5. ASF Board Members and staff may not receive honoraria to speak on behalf of ASF. Travel expenses incurred to participate in disease-awareness activities may be reimbursed directly to the individual or the organization.

Article VI - Clinical Trial and Approved Therapy Communication

ASF will provide information about clinical trials, according to the following principles:

1. ASF 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; ASF does not seek to influence that choice, but rather to ensure informed decisions can be made. Patients and families with questions about various trials will be provided with factual information regarding all options and directed to their healthcare provider.
2. ASF disseminates accurate, fair, and balanced information about clinical trials provided by the pharmaceutical company without 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.
3. ASF recognizes that the choice to share information regarding participation in a clinical trial is personal and does not seek or encourage the sharing of individual clinical trial experiences via social media, email, or other means. However, when unsolicited information is shared on ASF's social media platforms, ASF provides pharmaceutical companies with community-wide observations and insight regarding the needs and barriers to participation to encourage optimal design and implementation of the trial.
4. ASF board, consultants, volunteers, and staff have a responsibility to represent ASF 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, must adhere to the principles outlined in this document.
5. ASF only provides information about clinical trials that have been approved by appropriate regulatory bodies.
6. In order to provide equal opportunities for study sponsors to share patient-friendly information regarding clinical studies, ASF has developed templates for use by study sponsors to produce informative content for the ASF website and YouTube channel. ASF reserves the right to modify templates and/or suggest revisions to provide educational content in patient-friendly terms before publicly sharing with the Alport community.
7. ASF reserves the right to share study sponsor–approved information regarding new active clinical trial sites with the larger patient community via email, the ASF website, and social media. ASF will do so as appropriate and in the context of other ongoing non-industry communications planning. Due to the scope of work, ASF cannot directly call attention to the activation of each new study site for various trials but will continuously update our website, alportsyndrome.org, as these details are provided to ASF from study sponsors.
8. ASF does not communicate information in a manner that could be interpreted as advertising or promoting a drug or treatment that has not been approved.
9. When a therapy receives appropriate regulatory approval, ASF will disseminate information for educational purposes only and does not promote or encourage the use of any treatment over another. Patients and families with questions about various treatments will be provided with factual information regarding all options and directed to their healthcare provider.

Article VII - Patient Privacy

ASF places high value on the privacy of patients. Thus, ASF does not disclose any personal information or information that can identify a patient.

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