



Principles for Ethical Engagement:

BIO, Our Members, and Patient Advocacy Organizations

BIO's North Star

BIO's member companies save, extend, and enhance lives by preventing and alleviating disease. Our shared aim is to be good partners in patient advocacy and to change the course of each patient's life for the better.

We support the development and commercialization of innovative medicines and believe every patient should have access to the innovations prescribed to them.

Our Principles for Ethical Engagement serve as a framework for engaging the patient community, specifically Patient Advocacy Organizations (PAOs), responsibly, meaningfully and with integrity.

What is a Patient Advocacy Organization (PAO)?

Within the ecosystem of patients and biopharmaceutical stakeholders, various nonprofit organizations and groups exist. Patient advocacy organizations play a crucial role in representing and supporting patients and their families.

For the purposes of BIO's Principles for Ethical Engagement, we define PAOs as independently formed, non-profit entities that support, serve, and advocate for patients, caregivers, and their families. Typically, their membership includes individual patients, family members, and loved ones, although some organizations operate as coalitions of aligned stakeholder groups.

PAOs are uniquely positioned to reflect patients' perspectives, values, hopes, and expectations. They play an important role in educating patients, families, and the public, and can serve as key allies by providing patient and caregiver insights that may assist BIO members' clinical development efforts.

Beyond enhancing clinical development, insights from PAOs help inform decision-making processes for regulators, payers, and policymakers.

Many PAOs advocate at both the federal and state levels, giving voice to their grassroots networks so that policymakers hear directly from the patient community on a wide range of issues.



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These Principles for Ethical Engagement inform BIO and BIO members' engagement with Patient Advocacy Organizations and will help keep us focused on our North Star: the patients and families whose lives we touch through biotechnology.

BIO's Principles are a distillation of guidance from our members' and multiple PAO. We encourage members who have not yet created principles around PAO interaction to consider adopting BIO's Principles for Ethical Engagement, in whole or in part as their own.

It is important to note that our Principles for Ethical Engagement are not intended to establish or supplant any legal requirement or binding/official standard. Rather, we aim to provide an ethical framework for ourselves and our members as we interact with Patient Advocacy Organizations.

Principles

1 Respecting Independence

BIO and our members value and embrace patient advocacy organizations as independent entities whose purpose is to support patients and their families. PAOs are subject matter experts, fierce advocates, and often, they are a lifeline for patients. PAOs establish their own goals with complete independence from BIO and BIO's member companies.

Patient advocacy organizations are a trusted voice of patients, and we respect each PAO's responsibility to independently develop public policy positions and scientific agendas on behalf of their constituencies.

There may be situations in which BIO or our members' position on a given issue may differ from a PAO's. We will respect these differences and focus on the areas where there is common ground. We will seek to understand each other's perspectives and to pursue mutually beneficial solutions.

Neither BIO nor our members should attempt to compel a PAO to adopt a specific policy position.

Principles Continued

2 Providing Support

BIO and/or our members may choose to provide financial support to PAOs to advance our shared goal of improving patient outcomes. This support may include, but is not limited to, sponsorships, grants, donations, or charitable contributions.

BIO and our members will not require that a PAO receive funding solely from one entity. Although there may be times when a single entity is the sole source of support, PAOs are encouraged to seek multiple funders.

Any financial support from BIO or our members should strengthen the PAO's mission but should not compromise the independence of the PAO's public policy or scientific agendas.

3 Patient Engagement in Clinical Development

Patient advocacy organizations often possess a uniquely holistic understanding of patients' and family members' needs, concerns, and daily lives. As such, they are uniquely positioned to provide meaningful insights that can inform BIO members' clinical development efforts.

BIO's members work with PAOs thoughtfully, ethically and with mutual respect to advance clinical development. PAOs may inform improved trial designs, lead to more patient friendly language, and can advise on how best to communicate accurate and balanced information to patients.

BIO strongly recommends that companies engage with PAOs early and regularly throughout clinical development to incorporate patient perspectives and insights.

4 Transparency and Valuing Privacy

BIO and our members recognize the importance of transparency and its role in developing trust-based relationships with stakeholders, the public, and the patient advocacy community. As such, when we work with PAOs, we commit to do so with transparency and mutually respectful communications.

BIO and our members respect the privacy of data that may be received or collected from patient advocacy organizations, and there should not be any expectation that personal patient or family information be shared with BIO or our members.



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Principles Continued

5 Advocating for Policies to Improve Patient Outcomes

BIO and our members advocate for policies that ultimately recognize, reward and speed innovation and thus improve patient outcomes. At times, PAOs may also choose to work with BIO and/or our members to advance shared policy objectives.

Irrespective of the nature of these policy objectives, when we work with patient advocacy organizations in this way, we work with mutual respect as advocates of equal standing.