Solve M.E.

Guidelines for Interactions Between Solve M.E. and Biopharmaceutical Companies

Background

The interactions between patient advocacy organizations and biopharmaceutical companies are important and may be complex. Collaborations between these two stakeholders have become more common in recent years as patient advocacy organizations have evolved. Given the important and dynamic nature of their work and the complexity of drug development, many patient advocacy organizations desire clarity and guidance on effective approaches to engaging with the biopharmaceutical industry to realize their vision of meaningful therapeutics. The principles outlined in the following Guidelines are intended to help Solve M.E. navigate critically important interactions with biopharmaceutical companies, seeking the optimal way to serve patient needs while recognizing the complexity of drug development for serious health conditions.

Introduction

Solve M.E. seeks the highest level of ethical conduct in engagement with biopharmaceutical companies. The goal of engaging with biopharmaceutical companies is to help enable the development of therapies while maintaining autonomy as a patient advocacy and research organization. All interactions between Solve M.E., industry, and the disease community should be transparent; should enable trust, accountability, and shared learning; and ultimately should work most efficiently and effectively toward advancing meaningful health outcomes for patients.

There are four main areas of engagement between Solve M.E. and biopharmaceutical companies described in the following Guidelines:

1. **Identification and Engagement with Companies**
2. **Patient Engagement and Patient Privacy**
3. **Financial Contributions**
4. **Clinical Trial Communication and Support**

1. Identification and Engagement with Companies

Solve M.E. desires mutually beneficial dialogue and information exchange with biopharmaceutical companies developing potential diagnostics, therapies and preventive approaches for ME/CFS and other infection-associated diseases such as Long Covid. Dialogue

is mutually beneficial when it is aligned with and advances the missions of Solve M.E. and the biopharmaceutical company.

1.1. Solve M.E. proactively seeks contact with biopharmaceutical companies that show interest or activity in drug discovery, preclinical research, or clinical research in ME/CFS and other infection-associated diseases. Solve M.E may also contact companies that are not yet working in this area, but have a relevant technology.

1.2. Solve M.E. seeks insights into the objectives and plans of the biopharmaceutical company and the potential therapy being evaluated, as appropriate. In exchange, Solve M.E. provides the biopharmaceutical company with community-wide insight and perspective as needed and appropriate, to inform the development efforts and strategic decisions of the company to best meet the needs of patients.

1.3. Solve M.E. collaborates with biopharmaceutical companies that are conducting ethical, high-quality research in a responsible manner according to industry, national, and international regulatory standards. Collaboration can include a wide range of activities such as information exchange, access to disease experts, access to tools and infrastructure (e.g., natural history data and biologic samples through the You+ME Registry and Biobank), and exchange of resources.

1.4. Solve M.E. 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.

1.5. Solve M.E. discusses goals and expectations of the collaboration at the outset to ensure they are mutual. Solve M.E. reserves the right to disengage with a biopharmaceutical company if the goals of the two organizations are not aligned.

1.6. To avoid conflicts of interest, Solve M.E. does not allow employees of biopharmaceutical companies actively developing or selling therapies for the disease to sit on its board of directors.

2. Patient Engagement and Patient Privacy

Solve M.E. encourages and enables direct dialogue and information exchange between patients and biopharmaceutical companies developing potential therapies ME/CFS and other infection-associated diseases, such as Long Covid. The voice of the patient is crucial throughout drug development.

Solve M.E. ensures the privacy of data provided to the organization by its membership and constituents.

2.1. Any engagement between a biopharmaceutical company and Solve M.E. should be done to advance understanding of the disease or research efforts and should have a clearly stated purpose or set of objectives.

2.2. Direct interactions between individual patients and biopharmaceutical companies are best arranged with the involvement or general awareness of Solve M.E. There can be a range of approaches regarding these interactions, from actively facilitating such dialogues to passively providing training and education for patient community members on best practices for effective interactions with biopharmaceutical companies. Including Solve M.E. in these dialogues accomplishes the following:

- Ensures fairness and transparency in interactions with patients. Information provided by the biopharmaceutical company to one patient is shared with all patients who have a right to that information, and patients outside of the conversation have an equal opportunity to express their opinions to the biopharmaceutical company. This information is provided in an accessible format and easily understood.
- Ensures that the patient community is adequately and well represented to the biopharmaceutical company. The voices of individual patients must be considered in the context of the community as a whole; one patient's experience may not reflect the experiences of other patients.
- Allows for access to professional advisers, such as financial experts and attorneys, who may advise Solve M.E., inform the dialogue, and help individual patients avoid financial and legal risks.
- Helps to avoid misunderstandings in conversations between individual patients and biopharmaceutical companies.
- Allows Solve M.E. to better understand the needs and intentions of both the patient and the biopharmaceutical company in order to best move the field forward for the patient community as a whole.

2.3. Solve M.E. encourages biopharmaceutical companies to obtain disease insights from group discussion rather than from one-on-one conversation with single individuals. One best practice is the formation of advisory boards composed of at least seven patients. An advisory board format helps to ensure that community views are adequately represented and that work is not unduly requested of any one individual. Solve M.E. may offer guidelines and training to patients

and caregivers on best practices for effective interactions with biopharmaceutical companies as part of an advisory board.

2.4. Solve M.E. expects that learnings and outcomes from all interactions will be shared openly between both parties for mutual benefit. At the outset of these collaborations, Solve M.E. may offer the companies guidelines or expectations for how learnings and outcomes can best be shared with their particular community.

2.5. Leaders of Solve M.E. (i.e., staff and board members) or individuals representing the community may be invited by biopharmaceutical companies to speak at internal company meetings, public events hosted by the company, or meetings with regulatory agencies. Solve M.E. evaluates each invitation and accepts invitations that promote disease education or awareness and elevate the voice of the patient in a manner that is consistent with the points outlined in these Guidelines.

2.6. Solve M.E. takes proper steps to protect all personal and confidential patient information both within the organization and when shared with outside entities, in accordance with applicable laws and regulations. Solve M.E. ensures that biopharmaceutical companies, and other organizations, have in place at minimum basic guidelines or policies for ensuring patient privacy prior to any data collection, including surveys, photographs, video and audio recordings, slide decks, and consent forms.

2.7. Solve M.E. advises patients and industry that personal health information of patients must not be recorded by the biopharmaceutical company without proper and prior informed consent from the patient and encourages use of consent documents that allow for secondary research on data as permitted by patients.

2.8. Solve M.E. advises patients and industry on the value of sharing data with the research community for future research needs. Solve M.E. may encourage, and in some cases mandate sharing of data upon completion of studies.

3. Financial Contributions

A robust patient advocacy organization is a vital partner to biopharmaceutical companies in the development of potential diagnostics, therapies or vaccines. Financial resources are key for the growth and maintenance of Solve M.E. Demands on the organization are increased by drug development activities, particularly during the clinical and commercial stages. The following principles guide Solve M.E. in the receipt of biopharmaceutical company donations:

3.1. Solve M.E. requires and maintains proper documentation of all requests for financial support from a biopharmaceutical company. All requests are documented on the letterhead of the organization signed by the CEO and clearly state the mission and activities of Solve M.E. and reasons for the request.

3.2. Solve M.E. accepts financial contributions that support its stated mission and allow the organization to maintain its autonomy. Solve M.E. assesses the alignment of mission between the two organizations as part of the funding discussion. Financial contributions should comply with Solve M.E.'s Policy on Corporate Relationships.

3.3. Solve M.E. does not accept financial support from biopharmaceutical companies for product promotional activities. Solve M.E. avoids taking payment from a biopharmaceutical company that could be perceived as buying special privileges, such as the opportunity to promote a product to a patient audience, to solely direct a meeting agenda, to dictate content of educational materials, to promote participation in a specific clinical trial, to influence the outcome of a specific research program, or to provide exclusive support of a particular research program.

3.4. It is ideal that any financial contribution to Solve M.E. be made either as (1) unrestricted funding or (2) sponsorship of a specific activity initiated by Solve M.E. to support its stated mission.

3.5. All donations must be given in a named manner (i.e., not given anonymously). Solve M.E. is transparent and open about its funding sources. Any funding provided by a biopharmaceutical company is disclosed by the patient organization (e.g., "project supported by…").

3.6. Solve M.E. seeks donations in a fair and transparent manner among multiple partners to avoid real or perceived exclusive relationships and to maintain autonomy. Relying on a single partner can compromise sustainability and autonomy; therefore, the organization attempts to receive donations from more than one partner whenever possible.

3.7. Solve M.E. establishes metrics to evaluate the effectiveness of an activity or initiative in which it has collaborated with a biopharmaceutical company and regularly communicates back to the company results of the specific project or use of funds.

3.8. Solve M.E. may provide consultation to a biopharmaceutical company if the consultation is consistent with the mission of the organization and allows it to maintain autonomy. Terms of these services will be documented by mutual agreement between the patient organization and the biopharmaceutical company. The leaders (i.e., staff, board members, advisory committee

members) of Solve M.E. will not operate as independent consultants to a biopharmaceutical company outside of their roles within Solve M.E.

3.9. The leaders of the Solve M.E. will not accept personal honoraria to speak on behalf of the organization but, alternatively, may have the honoraria given to the organization.

3.10. Travel expenses incurred to participate in advisory board meetings or disease awareness activities may be reimbursed directly to the individual patient or to Solve M.E.

3.11. Any transfers of value or benefits provided to Solve M.E. by a biopharmaceutical company should be documented by a signed agreement between the two organizations.

4. Clinical Trial Communication and Support

As a representative of the patient community, Solve M.E. is committed to providing education and resources about clinical trials to its members. The organization informs the patient community about open and upcoming clinical trials. Solve M.E. also educates patients about their vital role during the clinical trial process, from design to conclusion. Overall community participation in clinical trials is essential to advance the science and understanding of the disease.

4.1. Solve M.E. acts as a conduit for information about clinical trials by providing education and resources to the patient community.

4.2. The choice to participate in any particular trial is an individual one; Solve M.E. does not seek to influence that choice, but rather, assists patients and families in making informed decisions through education and awareness.

4.3. Solve M.E. disseminates accurate and fair-balanced information about clinical trials without adding commentary or opinion that may influence an individual's decision in any way.

4.4. To support optimal clinical trial design and communication, Solve M.E. may provide the biopharmaceutical company with communitywide observations, needs, and barriers to participation.

4.5. Solve M.E. shall develop and communicate a position on our role in the sharing of individual clinical trial experiences in social media. Disclosing clinical trial experiences in social media can compromise the validity and conduct of a clinical trial and has implications for individual health privacy. However, ultimately, the choice to share information is personal; thus, Solve M.E.

cannot dictate what information clinical trial participants do or do not share in public forums. Solve M.E. may provide the community with educational materials on the potential implications, both positive and negative, of disclosing clinical trial experiences publicly.

4.6. Board and staff members of Solve M.E. have a responsibility to represent the organization in their conduct. Information about clinical trials that is accessible to the community through social media, including in personal blogs or other forms of communication, should adhere to the principles outlined in these Guidelines.

4.7. At the end of a clinical trial, Solve M.E. asks the biopharmaceutical company to provide a summary of available trial results for trial participants and the patient community in a timely fashion. Solve M.E. requests that the company inform patients, in a way that is easily understandable and offers the option to seek clarification, about the ways in which the patients' participation has resulted in a valuable contribution to the knowledge base or to the development of a therapy.

Adapted from Stein et al. Orphanet Journal of Rare Diseases, 2018