

Guidelines for Commercial Engagement Glut1 Deficiency Foundation

Solving the challenges posed by rare diseases requires the collaboration of multiple stakeholders - patients, patient advocacy organizations, academic researchers, clinicians, commercial companies, and regulators. Yet collaboration, while essential, is often challenging. The highest personal, professional, and business stakes are at play and the potential for considerable ethical and legal issues exist.

Successful collaborations between patient advocacy organizations and commercial companies are achieved when they have reciprocal relationships in which both parties recognize the value of the other. Mutual respect is essential, which requires honesty and authenticity. Transparency and commitment from both parties should begin on day one.

To help address some of these challenges and to clarify the views of the Glut1 Deficiency Foundation on commercial engagement, we have developed the following guidelines. These recommendations are adapted from the work of an expert panel and the [report](#) created from their efforts.

1. Identification and Engagement with Commercial Companies

1.1 The Glut1 Deficiency Foundation desires mutually beneficial dialogue with commercial companies developing potential therapies, products, or services for our patient community.

1.2 Dialogue between the Glut1 Deficiency Foundation and commercial companies may include information about the objectives and plans of the commercial company and the potential therapy being evaluated or product being developed. The Glut1 Deficiency Foundation may provide the commercial company with community-wide insight and perspective to inform the development efforts and strategic decisions of the company.

1.3 The Glut1 Deficiency Foundation may collaborate with biopharmaceutical companies that are conducting ethical, high-quality research in a responsible manner according to industry, national, and international regulatory [standards](#) and with other reputable and ethical commercial companies.

1.4 The Glut1 Deficiency Foundation aims to collaborate with multiple commercial companies to allow for a diversity of views and options. The purpose of the collaboration should be to advance understanding of the disease and/or to provide tools and resources to patients and families and should have a clearly stated purpose or set of objectives.

1.5 The Glut1 Deficiency Foundation reserves the right to disengage with a commercial company if the goals of the two organizations are not aligned.

1.6 In order to avoid conflicts of interest, the Glut1 Deficiency Foundation will not allow representatives of commercial companies actively developing or selling therapies or products for the disease to sit on its governing board – the Board of Directors.

2. Patient Engagement and Patient Privacy

2.1 The Glut1 Deficiency Foundation takes proper steps to protect all personal and confidential patient information both within the organization and when engaged with outside companies, and those companies must have proper guidelines in place for ensuring patient privacy.

2.2 The Glut1 Deficiency Foundation advises patients and industry that personal health information of patients must not be recorded by the commercial company or shared in any manner without proper and prior informed consent from the patient.

2.3 The Glut1 Deficiency Foundation encourages direct dialogue and information exchange between patients and commercial companies developing potential therapies and products for our rare disease so that patient/caregiver perspectives can be voiced.

2.4 Direct interactions between specific patients and commercial companies are best arranged with the involvement or general awareness of The Glut1 Deficiency Foundation Board of Directors, which accomplishes the following:

- ensures fairness and transparency within the patient community
- ensures that the patient community is adequately and well represented
- ensures 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 access to expert advice that may help individual patients avoid medical, financial and legal risks
- helps to avoid misunderstandings in conversations
- allows the Glut1 Deficiency Foundation to advise patients on the protection of their health and personal privacy in any data collection activities
- allows the Glut1 Deficiency Foundation to better understand the needs and intentions of both the patient and the commercial company in order to best move the field forward for the patient community as a whole

2.5 The Glut1 Deficiency Foundation encourages commercial companies to obtain disease insights from group discussion or advisory panels rather than from one-on-one conversations with single individuals and may help provide guidelines for best practice in this type of engagement.

2.6 The Glut1 Deficiency Foundation expects that learnings and outcomes from all interactions will be shared openly between both parties for mutual benefit.

2.7 Leaders of The Glut1 Deficiency Foundation (i.e., staff, board members, and committee members) or individuals representing the G1DF may be invited by commercial companies to speak at internal company meetings, public events hosted by the company, or meetings with regulatory agencies. The G1DF evaluates each invitation and accepts invitations that promote disease education or awareness and elevates the voice of the patient in a manner that is consistent with the points outlined in these Guidelines. Representatives of the G1DF will not accept personal honoraria for these invitations but may have reasonable travel expenses provided.

3. Financial Contributions

3.1 The Glut1 Deficiency Foundation requires and maintains proper documentation of all requests for financial support from a commercial company. All requests are documented on the letterhead of the G1DF and clearly state the mission and activities of the G1DF and reasons for the request.

3.2 The Glut1 Deficiency Foundation may accept financial contributions that support its stated mission and allow the G1DF to maintain its autonomy. The G1DF assesses the alignment of mission between the two organizations as part of the funding discussion.

3.3 The Glut1 Deficiency Foundation does not accept financial support from commercial companies for product promotional activities. The G1DF avoids taking payment from a commercial company that could be perceived as buying special privileges, such as the opportunity to promote a therapy or product to a patient audience, to direct a meeting agenda, to guide 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 or product.

3.4 Any financial contribution to the Glut1 Deficiency Foundation will ideally be made either as (1) unrestricted funding or (2) sponsorship of a specific activity initiated by the G1DF to support its stated mission.

3.5 All donations must be given in a named manner (i.e., not given anonymously). The Glut1 Deficiency Foundation is transparent and open about its funding sources. Any funding provided by a commercial company is disclosed by the G1DF (i.e. “program supported by” acknowledgement).

3.6 The Glut1 Deficiency Foundation accepts donations in a fair and transparent manner among multiple partners to avoid real or perceived exclusive relationships and to maintain autonomy.

3.7 The Glut1 Deficiency Foundation establishes metrics to evaluate the effectiveness of an activity or initiative in which it has collaborated with a commercial company and regularly communicates back to the company results of the specific project or use of funds.

3.8 The Glut1 Deficiency Foundation may provide consultation to a commercial company if the consultation is consistent with the mission of the G1DF and allows it to maintain autonomy. Terms of these services will be documented by mutual agreement between the G1DF and the commercial company. The leaders (i.e., staff, board members, committee members) of the Glut1 Deficiency Foundation will not operate as independent consultants to a commercial company outside of their roles within the organization.

3.9 The leaders of the Glut1 Deficiency Foundation will not accept personal honoraria to speak or advise on behalf of the organization.

3.10 Reasonable travel expenses incurred to participate in advisory board meetings or disease awareness activities may be reimbursed directly to the individual patient or to the Glut1 Deficiency Foundation.

3.11 Any transfers of value or benefits provided to the Glut1 Deficiency Foundation by a commercial company should be documented by a signed agreement between the two organizations.

4. Clinical Trial, Products and Services Communication and Support

4.1 The Glut1 Deficiency Foundation strives to act as a conduit by providing education and resources to the patient community for products and services and for clinical trials and research that are being conducted in an ethical, high-quality and responsible manner according to industry, national, and international regulatory standards.

4.2 The choice to use a product or service or to participate in any particular trial is an individual one; The Glut1 Deficiency Foundation does not seek to influence that choice, but rather, assists patients and families in making informed decisions through education and awareness.

4.3 The Glut1 Deficiency Foundation disseminates accurate and fair-balanced information about products, services, and clinical trials without adding commentary or opinion that may influence an individual's decision in any way.

4.4 To support optimal products, services, and clinical trial design and communication, The Glut1 Deficiency Foundation may provide the commercial company with community-wide observations, and input about needs and barriers to patient participation.

4.5 The Glut1 Deficiency Foundation may provide the community with educational materials on the potential implications, both positive and negative, of disclosing clinical trial experiences publicly, such as on social media.

4.6 Board and committee members of The Glut1 Deficiency Foundation have a responsibility to represent the patient organization in their conduct. Information about products, services, and 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, The Glut1 Deficiency Foundation asks the biopharmaceutical company to provide a summary of available trial results for trial participants and the patient community in a timely fashion. The G1DF 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.

Secretary's Initials: _____

Date: _____