AMYLYX
Rooted in Connection

Grants and Sponsorships

Request Submission and Process

- Support may only be provided to eligible organizations or entities, rather than individual recipients
- Requests for support should be in English; supporting materials for country/region specific requests may be submitted in local language
- Requestors may be asked for additional information from Amylyx; to ensure timely review, responses should be prompt
- Unless initiated by request for proposal (RFP) or otherwise clarified, all types of support are reviewed on a rolling basis
- Once all materials have been received, the Grants and Sponsorships Review Committee will begin the review process, which can take up to 45 business days
    - For Externally Sponsored Research (ESR) grants, the review process can take up to 60 business days
- Requestors will receive email notifications of approval or denial directly from Amylyx Grants and Sponsorships
- Approved requests are subject to electronic execution of an agreement before any support is provided

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Sponsorships

Amylyx will consider support in the form of financial contributions to eligible organizations for initiatives and events, programs, and projects where Amylyx is involved or receives tangible benefit.

These events may be medical/scientific or patient-focused. Examples include but are not limited to event sponsorships, corporate memberships, advertising opportunities, exhibit booths, awards, congress support, health awareness campaigns, roundtables, forums, and satellite symposiums.

As part of the submission process, Amylyx will require specific details about the event or activity and how the funds will be used, along with the following (if available):

- Tax ID
- Letter of request
- Agenda (or brochure)
- Agreement (if provided by organization)
- Detailed program budget
- W9 (US Requests Only; W8 may be required for certain requests from foreign organizations)

Submission of a request for support does not imply or guarantee approval. Requestors will be notified by Amylyx of the decision to either decline or grant support, along with next steps.

Advocacy and Independent Community Education (ICE) Grants

In alignment with Amylyx's community education interests, Amylyx will consider programs provided by advocacy and non-profit organizations that support the communities we serve. This includes Independent Community Education (ICE) provided by patient or professional advocacy organizations to improve public health and patient experiences and outcomes, and to expand the scientific knowledge of persons impacted by neurodegenerative diseases.

Amylyx will consider Advocacy and ICE applications that align with the following:

Scope:

- Amyotrophic Lateral Sclerosis (ALS) disease area
- Global

Limitation:

- The Advocacy Grant Program does not provide financial assistance to individual patients nor support for the operation or staffing of clinics (or offices) providing patient care services.

Areas of Interest:

Amylyx is committed to building and maintaining trust and partnerships to drive change for the communities we serve, so we welcome grant requests from advocacy and non-profit organizations that are directed to:

- Support and benefit the ALS Community
- Educate or advocate for the ALS Community stakeholders, including people living with ALS, caregivers, and families
- Support for healthcare quality improvement initiatives
- Initiatives that address health inequities

Independent Medical Education (IME)

In alignment with corporate areas of interest, Amylyx will consider IME programs for healthcare professionals (HCPs) that are designed and implemented independent of any Amylyx influence or input (as defined by standards such as the Accreditation Council for Continuing Medical Education (ACCME) guidelines, the FDA's Guidance on Industry Supported Scientific and Educational Activities), and country/region specific standards and guidelines (as applicable).

Amylyx is currently accepting applications from educational providers that are accredited to provide continuing education (i.e., CME or CE) by a national accrediting body, such as ACCME, Committee on Accreditation of Continuing Medical Education (CACME), European Accreditation Council for Continuing Medical Education (EACCME), American Nurses Credentialing Center (ANCC), Accreditation Council for Pharmacy Education (ACPE), or other such accreditors, including country/region specific accreditors (as applicable).

Amylyx will consider IME applications that align with the following:

Scope:

- Neurologists specializing in the management of ALS
- Physicians providing care for PLWALS outside of an ALS specialty clinic setting
- Referring Physicians (Primary Care and General Neurologists) who would be referring patients to neurodegenerative disease experts for diagnosis and/or treatment
- Other healthcare professionals who are members of the ALS Patient Care Team, including Allied Health professionals, such as NPs/PAs, nurses, other members of the multidisciplinary care team, and pharmacists
- Population Health Decision Makers (aka Healthcare Decision Makers), individuals who have responsibility for formulary (healthcare access) decisions on behalf of healthcare organizations, or plans (payers: private or public)

Areas of Interest:

- Transforming the care landscape for ALS
    - Pathogenesis and pathophysiology of ALS
    - Timely recognition and diagnosis of ALS
        - Enhancing symptom recognition and suspicion for ALS
        - Recognizing the potential for disparities in the diagnosis of ALS
        - Overcoming barriers to diagnosis
    - Optimizing outcomes for persons living with ALS
        - Recognizing the value of multidisciplinary care
        - Understanding barriers to accessing multidisciplinary care
        - Ensuring health literacy and partnering with the person living with ALS in care decision making
        - Managing symptoms of disease and potential adverse reactions from treatment
        - Reviewing the therapeutic landscape: current and emerging therapies

Amylyx support for IME programs is restricted to organizations that meet the Eligibility Criteria and is compliant with federal and state laws, as well as guidelines that govern such activities.

Amylyx requires all IME grant requests be multi-sourced, and Amylyx will not provide IME funding for any of the following:

- Reimbursement or payment to an individual
- Capital expenses, building expenses, or general operating expenses
- Entertainment or recreational expenses
- Costs of travel, lodging, or personal expenses of non-faculty attending IME (either directly to the individuals participating in the event or indirectly to the event provider; US Requests Only)
- Meals (Amylyx does not prohibit organizers from serving meals at IME events; however, Amylyx IME funds shall not be used to provide meals at IME events)
- Fellowships or internships (US Requests Only)

If approved, Amylyx requires that a fully executed Letter of Agreement, signed by the requesting IME provider and Amylyx, be completed prior to the commencement of the educational program.

IME providers are required to confirm initiation and completion of the activity.

Documentation of how funds were used must be submitted to Amylyx within 90 days of completion of the IME program for reconciliation and any funds not utilized for the program returned to Amylyx; failure to return any reconciliation and/or any unused funds may result in rejection of future requests.

Submission of a request for support does not imply or guarantee approval. Requestors will be notified by Amylyx of the decision to either decline support of the grant or be invited to complete and sign a Letter of Agreement.

Requirements for IME Applications:

All IME applications should be submitted to Amylyx as directed.

The following documents should be included with the application:

- Letter of Request* and/or proposal (or brochure)
- Full itemized program budget
- W9 (US Requests Only; W8 may be required for certain requests from foreign organizations)

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*Letters of Request must include the following:

- Program title, date(s), and location(s)
- Description of the proposed activity
- Identification of the target audience and projected number of attendees
- Name of accrediting body and accredited provider, including type and number of medical education credits offered for the proposed activity (program MUST be accredited)
- If applicable, identification of co-requesting organization(s) or medical education partner(s), including contact information for these organizations.
- Needs assessment
- Educational objectives

Externally Sponsored Research (ESR) Grants

In alignment with our clinical and non-clinical areas of interest, Amylyx will consider externally-sponsored research grant requests that advance scientific knowledge of amyotrophic lateral sclerosis, including work to define and validate targets of interest, better understand patient populations and subgroups, and to understand mechanisms and effects of Relyvrio better. This includes the following types of research grant requests:

- **Investigator Initiated Study (IIS):** Unsolicited research with scientific and medical merit that is fully initiated, designed, developed, and conducted by a qualified, independent investigator or academic sponsor
- **Collaborative Research Study (CRS):** Research that may be solicited by Amylyx or proposed by an investigator or institution, conducted in collaboration with joint decision-making on the design, interpretation, and publication and/or presentation of the results

Amylyx will consider research grant requests that align with the following focuses and corresponding areas of interest:

For ALS Real World Evidence/Clinical Studies[1]

Scope:

- PB & TURSO only (for therapy related studies)[2,3]

Limitations:

- Amylyx will not reprise any clinical trials

Areas of Interest:

- Transforming the care landscape for ALS
- Understand and advance outcome measures in ALS
    - Identification/validation of new outcome measures
    - Endpoints for evaluation of time to clinical worsening/time to deterioration
- Approaches to support patient usage, experience, and long-term adherence
- Data mining to:
    - Promote understanding of the Real World Experience with PB & TURSO
    - Promote understanding of the impact of PB & TURSO on health economics of ALS management
- Contribute to understanding of PB & TURSO therapy outcomes
    - Benefits of early treatment when combined with other approved therapies

[1] Clinical studies include any trial proposal that involves either an intervention in humans or utilizing RWE derived from human subjects

[2] Any PB & TURSO studies must be collaborative research study grants only

[3] PB & TURSO refers to the Amylyx-developed fixed-dose combination of sodium phenylbutyrate and taurursodiol/ursodoxicoltaurine. This is also known as AMX0035, RELYVRIO, and ALBRIOZA.

For Neurodegenerative Diseases/Non-Clinical

Scope:

- PB & TURSO only

Limitations:

- Provision of compound only (PB & TURSO)

Areas of Interest:

- Assessment of PB & TURSO effect with other agents in cellular models of neurodegenerative diseases outside of ALS
- Impact of PB & TURSO fixed-dose combination vs. PB and TURSO individually in cellular models of neurodegenerative diseases
- Investigation of neurodegenerative disease pathophysiology using various approaches, including: metabolomics, epigenomics, transcriptomics, and proteomics in in vitro models as well as in silico or molecular modeling
- Models to improve and accelerate translational research (e.g., stem cells, organoids, novel biomarkers)

ESR sponsors may request provision of funding and/or drug product (only drug product offered for neurodegenerative and non-clinical studies).

Financial support for ESR will be considered on a case-by-case basis. Priority will be given to studies that can be completed and published within a 2-year time period from the date of contract finalization.

Amylyx funds research at fair market value and all costs are subject to that evaluation. The Amylyx ESR program will not cover ordinary operating expenses, travel costs, or support capital equipment requests.

Requirements for Initial Submission:

Types of information and materials included in the initial submission step:

- Concept/research proposal, including:
    - Therapeutic area
    - Title
    - Study type
    - Short 2-5 page summary of concept/research proposal, including:
        - Study objectives and end points
        - Study design
        - Proposed study location(s)
        - Number of participants (or animals) to be studied
        - Inclusion and exclusion criteria
        - Study procedures and safety data collection plans
        - Data analysis plan
- Support requested (study budget and/or product supply)
- Confidentiality Agreement, if necessary, for consideration of the request

Requirements for ESR Applications:

The following supporting documents may also be required with the application, if applicable.

- Investigator curriculum vitae (signed and dated)
- Proof of current medical license
- Proof of Good Clinical Practice (GCP) training within the past 3 years
- Proposed budget
- Privacy notice
- Certifications

Preliminary Review:

Amylyx reviews each ESR proposal taking into account scientific merit, innovation, methodological and statistical practicability, and patient safety. Proposals must also align with Amylyx strategic areas of interest. If further information to support an ESR request is required during the preliminary review, a member of the Amylyx Medical Affairs team will reach out to the Investigator/Sponsor.

Submission of an ESR proposal does not imply or guarantee approval. Requestors will be notified by Amylyx of the decision to either decline the proposal or be invited to submit a full protocol for review.

Preliminary Decision and Post-Initial Approval Materials:

If a requestor is invited to submit a full protocol, Amylyx will require additional materials for the Investigator/Sponsor prior to Amylyx completing its review and providing a final decision.

Full protocols are submitted via correspondence. Protocol submissions must contain the following:

- Institutional Review Board (IRB)/Ethics Committee (EC) approval of protocol and consent form or documented exemption/ reasoning for exemption from IRB approval
- W9 (US Requests Only; W8 may be required for certain requests from foreign organizations)
- “Final” itemized study budget

The following must also be included, when applicable:

- Informed consent form
- Attestation of filing an application with the relevant regulatory authority and allowance to proceed with the study
- Investigator training documentation and/or any instructions that will be provided to sites
- HA approval (if applicable)
- Clinical supplies (drug product) request

Contracting:

Following protocol approval, an ESR agreement will be negotiated between Amylyx and the Investigator (and sponsoring institution as applicable), with terms regarding (but not limited to) intellectual property, indemnification, reporting requirements per list below, and publication rights.

Funding milestones will be agreed upon during contracting and will be based upon study type and length.

Investigator/Sponsor must register clinical trials in a public database such as www.clinicaltrials.gov.

Study Initiation and Conduct:

During conduct of the ESR, Investigators commit to the following reporting via correspondence:

- Amendments to the protocol
- Amendments to the informed consent form
- Quarterly progress
- Adverse Events
- Any additional reporting requirements as agreed upon

Study Completion and Close-Out:

Within 3-6 months of completion of ESR, a final study report along with support closeout reconciliation, including safety reports, drug supply, and milestone invoices, are to be submitted.

Publication:

Amylyx expects that results from all ESR studies be communicated in an appropriate scientific forum, such as a peer-reviewed journal or medical meetings.

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