I. Background

Astellas (the "Company") is committed to supporting high quality, evidence-based independent medical education (IME) that seeks to improve the overall safety and quality of patient care and treatment. Independent Medical Education must be designed to close knowledge and practice gaps identified in the public healthcare landscape, drive measurable improvements in knowledge, competence and performance of healthcare professionals, and advance patient health outcomes. "Independent" means that the projects funded by the company are the full responsibility of the recipient organization. Astellas does not have influence over any aspect of the supported projects and only asks for interim and final outcomes reports including a description of the impact of the projects.

These guidelines provide transparency and clarity on how proposals are evaluated for support. They outline the criteria Astellas uses to assess quality, independence, compliance, and expected impact of proposed activities. Proposals that align with these guidelines will be considered stronger candidates for support, as they demonstrate thoughtful planning, measurable outcomes, reference-backed methodology, and a clear commitment to independent, evidence-based education.

For all grant proposals, please adhere to the following guidelines in addition to the established requirements for the Astellas IME grant application process. All applications must be submitted online through the Astellas Grant Management System, accessible at https://www.astellas.com/en/science/research-and-development/external-funding/medical-education Where applicable, information included in your proposal should align with the data entered within the online application.

II. Eligibility

Geographic Scope:	United States (Primary percentage of target audience from US for global activities)
Applicant Eligibility Criteria:	Eligible applicants (the "Organization") include hospitals, academic medical centers and medical schools (Note: the CME Office must submit the request for accredited activities); professional medical associations/societies; medical education companies; and publishers of medical and scientific publications. ***Grants may not be provided to individuals, sole proprietorships, private medical practices, medical group practices, or other for-profit healthcare provider organizations.*** Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/ organizations/ associations are strongly encouraged. Please note all partners must have a relevant role and the requesting Organization must have a key role in the project. For programs offering continuing education credit, **the requesting Organization must be the accredited grantee. Non-accredited medical education may be submitted by the lead organization.**

III. Guidelines

Section	Guideline Summary
Gap Analysis / Needs Assessment	Proposals must include a comprehensive gap analysis and needs assessment, referenced and demonstrating clear understanding of specific practice gaps, underlying educational needs, root causes, and barriers to change specific to each target audience(s) included in the activity. Practice gaps and needs must be distinguished from each other. Each practice gap should have a documented root cause . If more than one audience is targeted, the gaps and needs for each audience must be clearly described. Multiple data sources should be used to support the assessment. In addition to describing each identified gap, providers must assign a prioritization rating (High, Medium, Low) to indicate its relative significance. This prioritization should reflect the anticipated impact on patient outcomes and the degree to which the gap is under-addressed in current education. Prioritization will guide the depth of coverage for each gap in the proposed activity
Target Audience	Clearly define the intended learner population, including specialties, roles, and care team members. The proposal should explain why these audiences are critical to addressing identified gaps and needs. For multi-disciplinary audiences, describe how each audience's unique educational needs will be addressed.

	In addition to describing the intended target audience (e.g., specialists, primary care, allied health), providers must estimate expected audience size and impact, broken out by live learners versus enduring learners. Providers should also explain how they will verify actual audience composition post-activity (e.g., registration data, specialty breakdown, practice setting). This distinction will allow flexibility in determining support for the live and/or enduring components separately.
Learning Objectives	Provide specific, measurable, achievable, relevant, and time-bound (SMART) objectives that align with the needs assessment. Objectives should focus on measurable changes in knowledge, competence, or performance, rather than vague intentions.
Educational Design	The proposed educational design should be innovative, interactive, and evidence-based, reflecting adult learning principles. Proposals must cite authoritative sources (e.g., NBME, AMWA, ACCME, peer-reviewed literature) when referencing 'standard practice.' Designs should demonstrate how they will address the identified needs, engage learners, and lead to measurable change relative to the identified learning objective. Multi-format approaches are encouraged to reach diverse audiences. Providers should move beyond simply naming adult learning principles and instead clearly describe how each principle will be implemented in the educational activity. Explanations should include the planned methods, formats, or instructional techniques that will bring these principles into practice. This level of detail will allow reviewers to assess whether the design meaningfully incorporates adult learning theory into the learner experience, ensures active engagement.
Outcomes Measurement	Proposals must include an outcomes plan aligned with established frameworks (e.g., Moore's Levels of Outcomes). Outcomes should demonstrate meaningful learner impact—knowledge, competence, performance, or patient outcomes, based on the goals of the program—not just participation counts. Methods for data collection, analysis, and reporting should be described clearly. Any claims of 'best practice' must be supported with references. Moore's Level 3 (knowledge) or higher is required for all IME activities. If multiple-choice questions are proposed as part of the outcomes strategy, applicants must describe how they will capture baseline (pre-activity) data to enable valid pre/post comparison. This ensures that improvements can be attributed to the activity rather than assumptions about learner knowledge ****Impact reports from previous activities must be fully reconciled in order to be eligible.***
Independence and Accreditation	All applicants must ensure that proposed educational activities adhere to all applicable legal, regulatory and (when relevant) accreditation requirements.

	Activities must be independent, evidence-based, present a balanced view of therapeutic options, and remain free from commercial bias at every stage of planning, implementation, and evaluation. For accredited CME/CE activities, the accredited provider holds full responsibility for ensuring compliance with all relevant accreditation standards, including ACCME requirements related to independence, content integrity, and the eligibility of any non-accredited collaborating organization. Proposals must describe how independence criteria, and (if applicable) accreditation requirements will be met.
Budget	Budgets must be transparent, reasonable, and detailed, with costs aligned to fair market value. Astellas reserves the right to request clarification or justification of budget items. *If funds are being provided to patient advocacy organizations, each collaborative partner and amount provided must be listed.* Multi-supported initiatives are highly preferred. If multi-support isn't possible, the following must be included: • Indicate how many companies were sought for monetary funding support for the specific grant, and their responses. • A detailed rationale for sole support
Proposal Content	Proposals should include only information directly relevant to the proposed educational activity. Marketing materials, awards, organizational history, or unrelated achievements are not relevant and will not be considered.
Patient Centricity	Preference will be given to proposals that meaningfully incorporate the patient perspective through deliberate and well-considered strategies. Proposals should clearly demonstrate how patient input influences the design, delivery, and relevance of the education in ways that improve communication, decision-making, and individualized care.
Independence and Compliance	Proposals must demonstrate that educational content and design will remain independent from industry influence. All activities must comply with relevant Accreditation Criteria, PhRMA Code, OIG guidance, federal Anti-Kickback Statute, and other applicable U.S. regulations and standards.
Collaborations	Roles and responsibilities of all collaborative partners must be clearly described. Applicants must define the role of any collaborating organizations or partners, including their specific responsibilities in planning, delivery, or evaluation of the activity. A 'relevant role' is one in which the partner provides substantive contributions (e.g., content expertise, learner access, or outcomes analysis) that materially impact the program's quality and reach.
Contingency Plans	Proposals must include a contingency plan should full funding not be achieved.

IV. Review Criteria

The grant review committee evaluates proposals according to their scientific merit, alignment with Astellas' areas of interest, compliance with these guidelines, and available funding, along with the following criteria:

- Ability to adhere to all requirements in submission.
- Requestor's knowledge of and experience within the relevant therapeutic area or disease state.
- Quality of researched gap analysis/needs assessment specifying the current practice gap of identified learners.
- Education focused on supporting excellence in patient care.
- Linkage of educational needs to practical and measurable learning objectives.
- Incorporation of adult learning principles, instructional design methods, interaction, and innovation in the educational format reflecting the preferred learning styles of the target audience.
- Outcomes measures aligned with learning objectives and educational format, using best practices in assessment methods and supported by references.
- Audience generation methods specific to the activity and target audience.
- Rigor of mechanisms to validate content and mitigate financial relationships, including review and revision of content to ensure a balanced view of therapeutic options and elimination of bias.
- Compliance with guidelines, regulations, and local governance related to medical education, such as accreditation, as applicable.
- Fiscal responsibility and fair market value.
- Clarity and relevance of submission: proposals must include only activity-specific content; extraneous material such as awards, marketing claims, or organizational promotion will not be considered.
- Validity of rationale for sole support or equity of support of other organizations.
- Alignment of timing of proposed activity with other supported activities

Submission Checklist

✅ Eligibility

☐ Organization is U.S.-based (hospital, academic medical center, medical school, national society/association, medical education company, or scientific publisher).
☐ If CE credit is offered, the accredited provider submits the request.
☐ All collaborating partners have a defined, relevant role; the requesting organization holds primary responsibility.
☐ Impact reports from any previously funded Astellas-supported activities are complete and up to date.

✅ Required Proposal Components

Gap Analysis / Needs Assessment

☐ Clearly distinguishes *gaps*, *needs*, and *root causes*.
☐ References multiple data sources (e.g., literature, learner data, practice metrics).
☐ Identifies gaps for each target audience.
☐ Includes prioritization of gaps (High / Medium / Low) based on significance and impact on patient outcomes.

Target Audience

☐ Defines intended learners (specialties, roles, care team members).
☐ Explains why each audience is essential to addressing the identified gaps.
☐ Estimates expected reach (live and enduring) and describes how actual audience composition will be verified post-activity.

Learning Objectives

☐ Objectives are SMART—specific, measurable, achievable, relevant, and time-bound.
☐ Each objective directly aligns with identified gaps and needs.

Educational Design

☐ Evidence-based, interactive design incorporating adult learning principles.
☐ Clearly describes *how* each principle will be applied (methods, formats, instructional techniques).
☐ Educational formats are appropriate for the audience; multi-format approaches encouraged.
☐ References credible sources when citing “standard practice.”

Outcomes Measurement

☐ Outcomes plan aligns with Moore’s Levels of Outcomes (Level 3 or higher required).
☐ Includes baseline (pre-activity) and post-activity data collection for valid comparison.
☐ Focuses on learner knowledge, competence, or performance—not only participation.
☐ Methods for data collection, analysis, and reporting are clearly defined.

Independence and Accreditation (if applicable)

☐ Describes how accreditation criteria and independence standards will be met by all educational partners.

Budget

☐ Budget is transparent, detailed, and reflects fair market value.

☐ Lists all collaborative partners and funding allocations (especially for patient advocacy organizations).

☐ For sole support, includes:

– Number of other companies approached and their responses.

– Justification for single-support funding.

Patient Centricity

☐ Demonstrates meaningful incorporation of patient perspectives into the educational design.

☐ Explains how patient input enhances communication, decision-making, or individualized care.

Independence & Compliance

☐ Educational content and design are independent of industry influence.

☐ Complies with all relevant regulations and standards (PhRMA Code, OIG, Anti-Kickback Statute, ACCME Criteria, etc.).

Collaborations

☐ Clearly defines roles and responsibilities of each partner.

☐ Each partner provides a substantive contribution (e.g., content expertise, learner access, or outcomes analysis).

Contingency Plans

☐ Includes a clear plan for partial funding or unanticipated changes in support.

References

Learning Objective References

1. Chatterjee D, Corral J. How to Write Well-Defined Learning Objectives. J Educ Perioper Med. 2017 Oct 1;19(4):E610. PMID: 29766034; PMCID: PMC5944406.
2. 2. Liu, P.L. & Lohr, L. (2004). Do You Know How to Write Learning Objectives? -- An Action Research. In R. Ferdig, C. Crawford, R. Carlsen, N. Davis, J. Price, R. Weber & D. Willis (Eds.), Proceedings of SITE 2004--Society for Information Technology & Teacher Education International Conference (pp. 979-981). Atlanta, GA, USA: Association for the Advancement of Computing in Education (AACE). Retrieved September 30, 2025

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1. Moore D., Green J., & Gallis H. (2009). Achieving desired results and improved outcomes: Integrating planning and assessment throughout learning activities. JCEHP, 29(1), 1-15
2. McMahon G. (2015). Advancing continuing medical education. JAMA, 314(6), 561-562. doi:10.1001/jama.2015.7094
3. Mostofian F., Ruban C., Simunovic, N. & Bhandari, M. (2015). Changing physician behavior: What works? AJMC, 21(1),75-84.
4. Cervero RM, Gaines JK. Effectiveness of Continuing Medical Education: Updated Synthesis of Systematic Reviews. Accredit Counc Contin Med Educ. 2014;(July).
5. Marinopoulos, S.S.; Dorman T., Ratanawongsa, N., Wilson, L. M., Ashar, B., Magaziner, J.L., Miller, R. G., Thomas, P. A., Propowicz, G.P., Qayum, R., Bass EB. Effectiveness of continuing medical education. Evid Report/technology Assess Agency Healthc Res Qual Rockville, MD. 2007;149.
6. Nissen SE. Reforming the continuing medical education system. JAMA - J Am Med Assoc. 2015;313(18):1813-1814. doi:10.1001/jama.2015.4138
7. Mansouri M, Lockyer J. A meta-analysis of continuing medical education effectiveness. J Contin Educ Health Prof. Published online 2007. doi:10.1002/chp.88
8. Dirksen J. Design for How People Learn. New Riders, Berkeley, CA; 2012
9. Mayer RE. Applying the science of learning to medical education. Med Educ. 2010;44(6):543-549. doi:10.1111/j.1365-2923.2010.03624.
10. Ericsson KA. Deliberate practice and the acquisition and maintenance of expert performance in medicine and related domains. In: Academic Medicine. ; 2004. doi:10.1097/00001888-200410001- 00022
11. Branch WT, Paranjape A. Feedback and Reflection: Teaching Methods for Clinical Settings. Acad Med. 2002;77(12):1185-1188. doi:10.1097/00001888-200212000-00005
12. Ratelle JT, Wittich CM, Yu RC, Newman JS, Jenkins SM, Beckman TJ. Relationships between reflection and behavior change in CME. J Contin Educ Health Prof. Published online 2017. doi:10.1097/CEH.0000000000000162
13. Moore DE. How physicians learn and how to design learning experiences for them: an approach based on an interpretive review of the literature. In: Continuing Education in the Health Professions: Improving Healthcare Through Lifelong Learning. ; 2007. Accessible at www.josiahmacyfoundation.org
14. Handley MA, Gorukanti A, Cattamanchi A. Strategies for implementing implementation science: a methodological overview. Emerg Med J. 2016 Sep;33(9):660-4. doi: 10.1136/emermed-2015- 205461. Epub 2016 Feb 18. PMID: 26893401; PMCID: PMC8011054.