

AdvaMed Device and Diagnostics Compliance Group Benchmarking

May 2023

Educational Grants

BACKGROUND

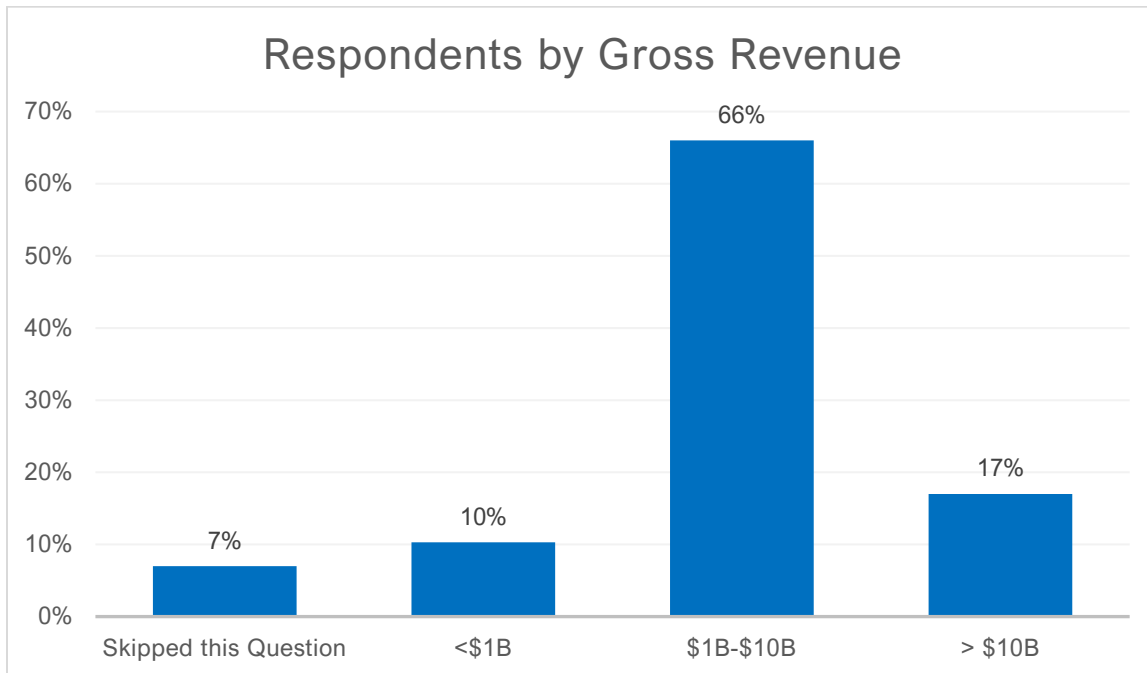
AdvaMed surveyed its members regarding their policies on educational grants. Twenty-nine companies completed the survey in April 2023. This document summarizes the survey responses, including additional commentary submitted by some (but not all) companies. The responses reflect a broad cross-section of company policies and is not intended to reflect all medical technology company policies on educational grants.

AdvaMed strongly encourages companies to adopt policies on educational grants, including addressing many of the aspects summarized in this benchmarking data.

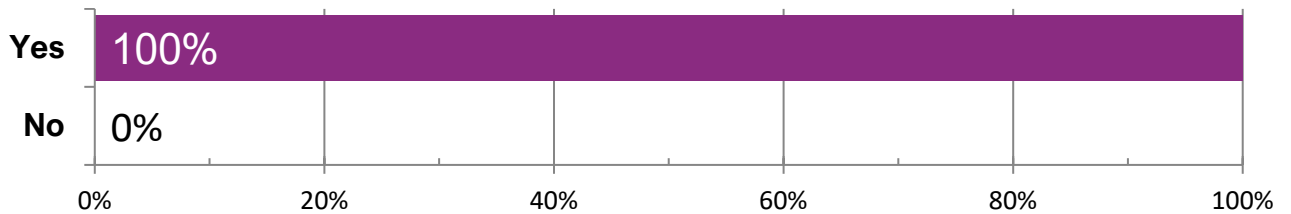
Note: AdvaMed periodically gathers and shares information from Member companies in order to assist companies in understanding industry trends and practices when the information is not competitively sensitive. In all cases, it is understood by AdvaMed and its Members that any company policy or practice that is adopted as a result of this sharing of information is done voluntarily and is a decision by the individual member. The information contained in this report is intended to provide benchmarking data on companies' existing policies only. It is not intended to endorse or mandate any one particular approach for medical technology companies' policies on educational grants.

DEMOGRAPHIC INFORMATION

Respondents reflected a broad cross-section of company sizes (by annual gross U.S. revenue from device and diagnostics technologies) and sector:



1. Does your company review the Third-Party Educational Conference venue, agenda, and other attributes as a condition precedent to funding an educational grant?



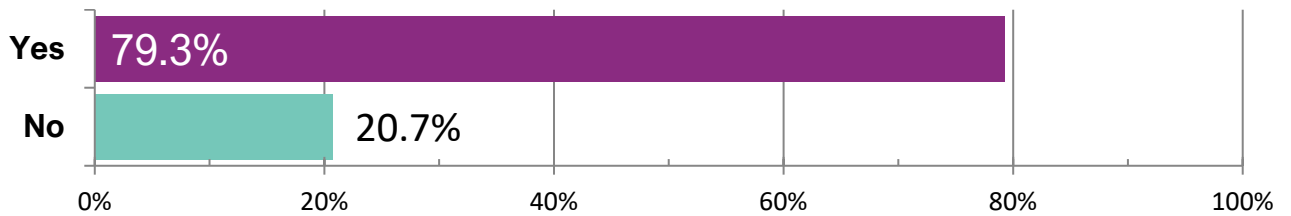
2. If you answered YES to question above, what measures does your company undertake to help ensure compliance with accepted ethical standards (select all that apply)?

- 93%** Undergo Communication and Training detailing appropriate role of company employees in HCP selection.
- 93%** Use a centralized grant committee to make all funding decisions and handle all communications about a grant.
- 83%** Have limits on the types of employees (sales, marketing, etc.) who can participate in grant funding decisions.
- 71%** Conduct auditing/monitoring of email and other back-up documentation underlying grant funding decisions.
- 0** Do not take any measures in this regard.

Comments:

- Compliance is represented on the centralized grant committee. Requests are submitted directly to the committee through a public website portal. Committee has its own funding and budget for all grants.
- In addition to the selected measure above, our company also has significant compliance oversight over the grant process and our Grants Committee. The Grants Committee is chaired by our Chief Compliance Officer and is coordinated by another representative in our compliance department.
- Each division within the company has its own grant committee.
- Variable by geography.
- All requests for educational grants are vetted through the compliance committee for approval.
- Coaching third parties on AdvaMed/ethical standards.
- Complete due diligence process is completed for each request.
- Using the checklist in the AdvaMed Code FAQ as criteria.
- We require application in a grants portal, detailed budgets, and soon will require evidence of completion, i.e., proof of performance
- Contracts are required; grants over a certain level are reviewed by senior manager; compliance sign-off on grants.

3. Does your company specifically review gaps within the agenda when assessing events?



4. If you responded YES to question above, how does your company determine if an agenda gap is too large?

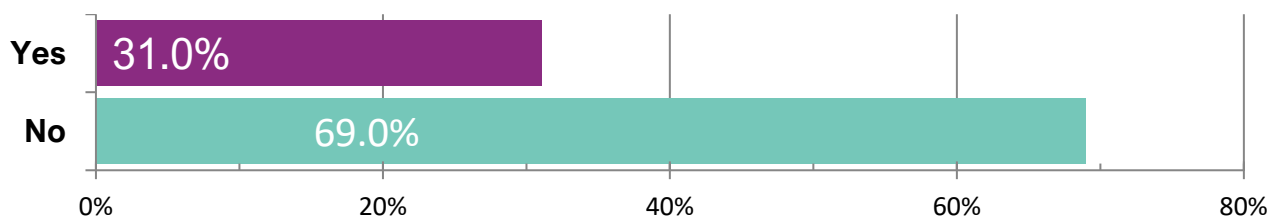
Comments:

- Looking for mid-day gaps, no specific time period; gaps that cause the overall educational duration to be less than one “full day” (approx. 6 hours active educational instruction).
- Entire program is evaluated. Agenda gaps as a standalone issue are not an automatic ground for a decline. Generally, we look for 4+ hours of scientific/clinical/educational content for half-days of programming and 7+ hours for full-days of programming. Problematic destinations/venues or the provision of entertainment and recreation would be aggravating factors in combination with gaps in agenda.
- We typically do not approve any grants that have a gap of more than 2 hours, particularly if the venue or the brochure are highlighting a venue that involves any recreation, site seeing, entertainment or family time.
- We have a rule that there should be at least 6 hours of educational content on the agenda (applicable to our strategic objectives/business) per day (3 hours if half day) - If we see reference to recreational activity (e.g., ski break, afternoon social, free time), that invites a higher level of scrutiny with regards to overall educational robustness of the program.
- A gap more than 3 hours is not acceptable. We also look at other factors such as venue and AdvaMed guidelines for these events.
- Gaps of 2 hours or more, gaps in the afternoon or during times where participants can participate in extracurricular activities.
- We look at it as a whole; e.g., if the event is in winter, near a ski destination, and the agenda is all morning and late afternoon, leaving mid-day free for skiing, we will reject. We scrutinize agendas, but don't have a hard and fast rule about 2-hour gaps vs 3-hour gaps.
- Look at gaps over 3 hours and if there is a side activity for that time, like sporting activity or entertainment.
- Percentage of time on agenda, significance of the activity and its risk.
- Follow up requests are made asking for information about gaps in the agenda. If there is an intentional gap in the agenda, we would evaluate whether the gap in time could be used for entertainment or recreational activities considering the setting, location and venue for the meeting. Total amount of time per day allocated to educational/scientific programming, compared to free time, networking time, and/or gaps in time are also considered. We do not have a mandatory number of hours of educational content per day requirement at this time.
- Additional scrutiny will be given to an Educational Program with an agenda during which HCP attendees

are provided with significant amounts of “free time”.

- Expertise of committee members, incorporating experience from past events. May seek clarification from event organizers on apparent gaps as part of the evaluation process.
- Document legitimate funding rationale through independent review process (U.S.).
- We determine whether the overall content is consistent with our therapeutic areas and strategic goals. We also check to see whether there is sufficient substance on the agenda that warrants providing financial support.
- We review the agenda in its entirety for overall robust educational sessions and discussions in alignment to the educational strategy. If the agenda allows for significant gaps in the day for attendee recreational activities, this is taken into consideration on approval decisions and type of support. Additional consideration is given to third-party meetings that take place in resort locations during in-season recreational activities. We review global industry codes as well.
- We consider the purpose of the gap and make a holistic decision based on the overall agenda.
- Review and discussion by grants committee on what is permissible. Dependent on the location and what type of recreational activity could take place.
- Totality of the circumstances -- location, prior experience, info from employees, what is advertised.
- Assess quality of education and attendance requirements. We may also reach out to medical education for additional insight.
- Evaluate size of gap, time of day that gap occurs, potential reasons for gap (i.e., leisure).
- We review agenda gaps and consider the amount of time and side activities that may be offered. We make an assessment based on factual information and the overall event organization (location, organizer reputation etc.).
- Case-by-case analysis. We focus on how robust the agenda is and if the focus of the TPEC is education.

5. Does your company require post-event feedback for evaluation (i.e. was the event an effective educational program)?



Comments:

- The process to reconcile Grants includes actual attendance, final agenda, course evaluation (if available), etc. The staff attends in-kind grants to ensure products are properly utilized. They also provide feedback.
- We do an informal post assessment for the events to make sure the event makes sense both from a business perspective but also compliance perspective.
- We ask the company attendees to provide feedback, particularly when there are other factors or potential risks identified.
- When we consider the same event for a following year, we consider the effectiveness of prior years.
- If there was a particular concern about the event or funding was more general (e.g., not a specific event

but education like multiple webinars provided by a society).

- Some events selected for audit.
- Required and the organization cannot apply for a new grant until this is provided.

6. Who from your company can receive educational grant requests from a Third-Party Educational Conference? [multiple selection]

- **76%** Online Submission process.
- **69%** Grant Committee.
- **17%** Working through employees that most frequently come into contact with the hospital/training institution.
- **.07%** My company does not fund educational grants to hospital/training institutions.

Comments:

- Communication between third-party requestors and the company is done via a grant coordinator, a company employee who serves as a liaison.
- As an initial point of contact, an employee that frequently comes into contact with the hospital/training institution may receive an inquiry about a grant request, but that employee would then direct the requesting organization to the appropriate process or point of contact in the Company, and does not handle the processing, evaluation, or decision making regarding the request.
- U.S. uses online submission process. In some other countries, we currently rely on employees who come into contact with the requesting institution.
- Requests often are emailed to someone in the commercial business. Those are forwarded to the Chief Compliance Officer and the compliance committee reviews and approves/denies the request.
- Our U.S. process runs through a U.S. grant committee.
- All grants are routed to the grants specialist who screens them to confirm they meet our grant criteria. Once screened, they are either rejected or presented to the Grants Committee for review.
- Historically, we have allowed orgs to work through employees that most frequently come into contact with the hospital/training institution, but a new Grants policy will train employees to direct third parties to Compliance.
- If an event is a pure tradeshow sponsorship without an educational grant aspect, it goes through a separate process, which we monitor.

7. With respect to Third-Party Educational Conference requests for educational grants, who at your company decides whether to fund an educational grant in response to such a request?

Comments:

- **3** responses provided the applicable Compliance Committee/Compliance function decides whether to fund educational grants.
- **18** responses provided that the Grants Committee decides whether to fund an educational grant when requested.
 - Some responses provided specifics about their Grants Committee:
 - Grants Committee chaired and managed by Medical Affairs, with Compliance and Legal

- on the Committee. Marketing (if any) is non-voting and sales may not sit on Grants Committee.
- Grants Committee - no sales employees are part of the committee.
- Charitable Donations & Grants Review Board (made up of non-sales personnel).
- Dedicated Grants Committee w/ no decision-making authority granted to employees in commercial roles.
- Grants Committee or collection of non-commercial functions.
- Grants Committee includes input from Medical Affairs.
- Each division has its own Grants Committee; each Grants Committee is comprised of cross-functional employees at mid- to senior-level experiences.
- Grants Committee has cross-functional representation.
- U.S. Grants Committee.
- Global Grants Committee.
- If the grant is >\$50K, Grants and Donations Committee reviews and approves - if the grant is <\$50K, Compliance has authority to review/approve (if respective business unit has budget).
- 5 responses provided that a multi-department review process decides on educational grants - specifics include:
 - Independent review process at the per-business level. Typical roles include Medical Affairs, Education, etc.; sales may not be involved.
 - There is a multi-department review process made up of compliance, legal, medical education, finance, commercial promotional, and global marketing. A majority of the committee members must approve before confirmation of support. Compliance approval is always required.
 - Educational grants are run through the medical affairs organization and decisions to fund are made at the VP level. For grants coming in from other organizations within the company, the employee and their manager that comes into contact with the institution will decide whether to fund the grant, in consultation with the compliance department.
 - A Committee where Legal, Finance, Compliance, Medical Affairs have representations and voting rights.
 - Business and Compliance with advice from Legal.
- An Executive Committee who reviews and decides which grants to fund.

8. With respect to Third-Party Educational Conference requests for educational grants, what documentation do you require to support the educational grant?

Comments:

- Name and contact information of Requester; Type of request (Independent Medical Education Program, Exhibit, Fellowship); Type of support requested (monetary, product); Description of how funds will be used; Budget; Agenda and Venue Information regarding the target audience such as: Anticipated number of attendees - Make-up of the target audience by job, title, role, or patient status.
- Overview of course, basic needs assessment, brief educational objectives, agenda, budget, proposed use of company funds, supporting collateral such as a letter of request, marketing collateral, IRS Determination Letter (or similar for non-US), IRS Form W-9, product list when seeking in-kind support.

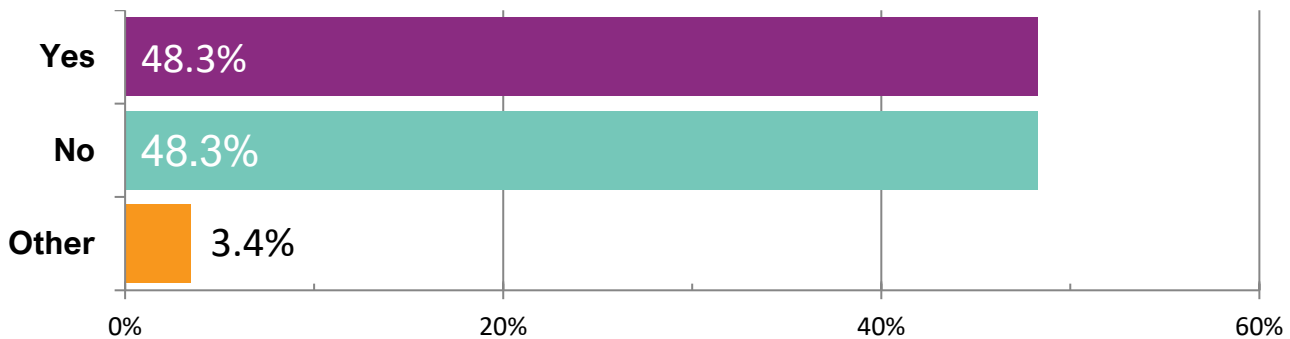
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- Completed application which outlines benefitting organization, details about the educational program, program objectives, number of industry sources of support, historical support, description of how funds should be used. Agenda, tax ID and tax status if applicable and a detailed budget.
- Full meeting agenda, brochure advertising the meeting, a letter of request from the sponsoring organization/hospital, budget for the program, and W-9 to understand if the organization's tax status.
- Letter of Request (on organization's letterhead); Detailed Program Brochure, Explanation of Objectives/Goals and Selection Criteria (as applicable); Detailed Budget (lump sum amounts will not be considered to satisfy this requirement); Evidence of Accreditation (if applicable); Tax-Exempt Status Determination Letter (if applicable); Completed W-9 (US only).
- Program Type/Area of Focus and Need for Program Requested Amount vs. overall budget review; Delivery Format and to whom/attendees Location/Venue appropriateness Program/Content/Agenda - Robust vs. Non-robust Non-profit vs. for profit review; all Tax documentation review Accreditation vs. non-accredited Use of funds.
- Agenda of conference or program, where the program will take place and who will be in attendance, outline of how the grant funds will be used, signed agreement outlining commitment to independent control of content and proper use of funds etc.
- Accreditation (if applicable); Program Agenda and Description [it usually includes gap analysis on educational needs]; Documentation relevant to third-party conference organizer (AoA, W9 etc.); Application Form which includes questions on past funding, potential conflict of interests, use of in-kind products.
- How the grant request came to the company (email, etc.); agenda; contract with the third party; names of individuals involved (initiator and approver(s)); proof/documentation that the educational session occurred as set out in the contract.
- Budget materials, proof of accreditation, substantive agenda and rationale for funding requests.
- Agenda, proof of accreditation, tax related forms, intended audience.
- Agenda/content, audience, location, budget.
- Budget, agenda, learning objectives, needs assessment, W9, outcomes measurement plan.
- Request letter, agenda, list of members of the organization's board, fully executed written agreement,
- Agenda/brochure, budget, tax forms (990 and/or W-9).
- Robust agenda with topics and presenters, letter of request/application, W9 form, budget for the funding requests and list of products required for in-kind support.
- Agenda/Program, Location/Hotel Information, and Written Request.
- Agendas, tax forms and other financial documentation.
- Internal form, agenda, any letters or advertising.
- Application, agenda, budget, background for event, whether event provides CME.
- Agenda, topic, and amount requested.
- Request letter, agenda, budget.
- All information from the event - agenda, training program, details, etc.
- Letter of request, list of board of directors/faculty, W-9, conflict of interest disclosure, proposal summary or full proposal, certification of nonprofit status, budget.
- Letter of request, detailed agenda, detailed budget; in general, we only support programs that are CME-

accredited.

- Letter of request from the organization, detailed program/agenda, and summary of the program and participants.
- Letter of Request; Agenda; Budget.
- Agenda; Formal Grant Request (not from a practicing physician).
- Completed application on our online submission website, a detailed agenda, and a detailed budget.

9. With respect to Third-Party Educational Conference requests for educational grants, do you require a budget reconciliation or accounting from the entity after the event?

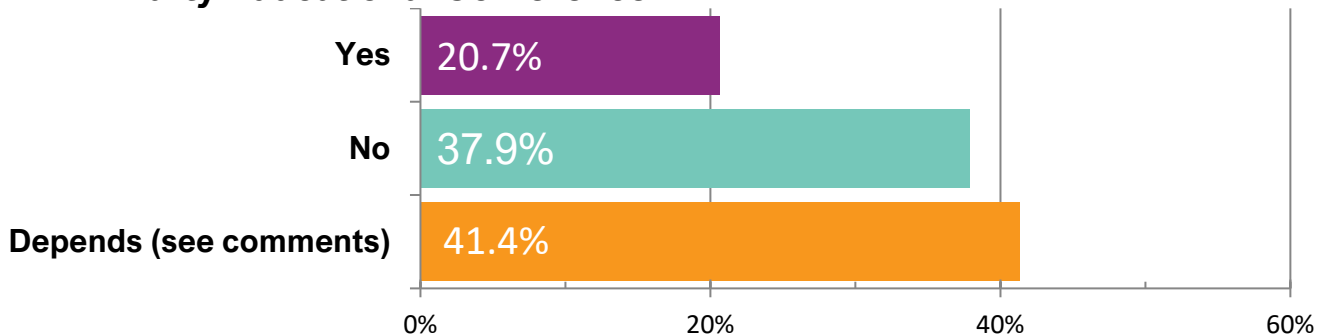


Comments:

- Unused funds are expected to be returned but no formal process for auditing budgets post-event.
- Require that any unused funds be returned.
- The recipient organization is required to complete online reconciliation comparing the proposed budget (revenue and expenses) and proposed use of company funds to the actual budget and use of company funds.
- Our letter agreements document the required use of the educational grant funds received from the company.
- Both - we ask for a budget in advance and we request unused funds to be returned after the meeting.
- New requirement for grants over US\$50,000.
- Request for reconciliation is based on preliminary assessment of potential reporting obligation under Sunshine (e.g., awareness of indirect payments to faculty or attendees).
- Varies by business.
- We ask for this, but it is not a requirement.
- Reserve the right to make this request.
- Agreements state that we could request this.
- Only if the funds are for more general education (not one event).
- It is not part of our regular practice to collect this information after the event, however, it is in our grant agreement that we have the right to do so.
- Sometimes.
- Internal Audit will verify after the fact.

- We require proof that the activities were performed - the educational sessions took place.

10. Does your company provide educational grants to hospitals or other training institutions to support their physicians’ attendance at a Third-Party Educational Conference?



Comments:

- We permit grants to be used to defray the costs for medical students and teaching faculty only. Funds cannot be used to defray the costs of attendees at third-party educational conferences.
- In some cases, we may provide funding to conference organizers or professional societies that can be used to support the attendance of doctors and training, such as, residents or medical students.
- Some limited support for residents and fellows, but transitioning to third-party support only.
- Only permitted for HCPs-in-training.
- We provide educational grants for HCPs-in-Training to attend third-party education.
- We usually consider these to be sponsorships.
- This does happen outside of the U.S. on occasion.
- We have allowed this for international HCPs where it is permissible (e.g., Australia).
- Possibly in countries outside the U.S.
- Not in U.S., but oUS this is permitted in some locations. In U.S., we would potentially defray costs of an HCP-in-training such as a resident.
- We will occasionally support fellows’ events in the U.S. and will occasionally support EU-based physicians to attend conferences.
- Only in Europe and subject to Medtech code guidelines.

11. If you responded YES to the previous question, do you:

100% of Yes Responses: Provide advance payment to the hospital or training institution to use the educational grant funds towards their intended purpose under the hospital’s/training institution’s direction.

Comments

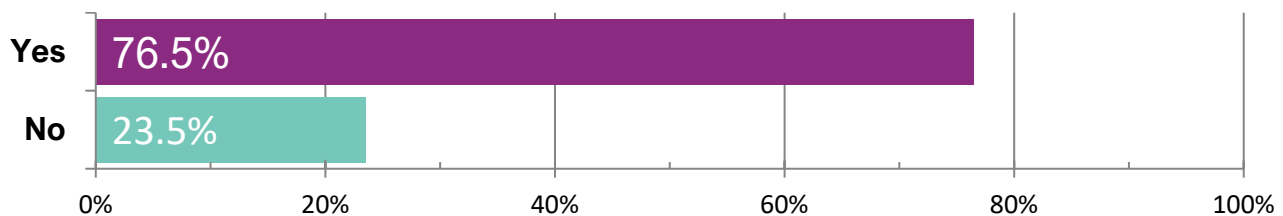
Companies that responded “Depends” above:

- Payment is usually made prior to the event, although in some cases payment may not be made until after the event. All payments are made to the hospital or training institution organizing the program, never to individual physicians or other HCPs.



- We provide both advance and post-event payments. For advance payments, we request receipts and require a refund if the award exceeds actual costs. For post-event payments, we award a set scholarship amount per HCP in advance but do not issue payment until afterward. Payment is provided only for actual expenses and payable to the HCP's institution.
- There is always an Educational Grant agreement that outlines funds must go to intended purpose.
- We will execute a grant agreement/contract with the hospital or training institution and then will provide them the requested funding to be used for the intended purpose.

12. If you indicated in your response to the previous question that you provide advance payment, do you base the amount of the advance grant funding on the estimated fair market value of the costs that the grant will cover?



Comments:

- Our decision to fund and at what level is based on our assessment of the educational value of the program as compared to other funded programs and in accordance with overall budgeted amounts. Normally funding amount is below the amount requested.
- We also require that the specific requested amount be provided in a written request.

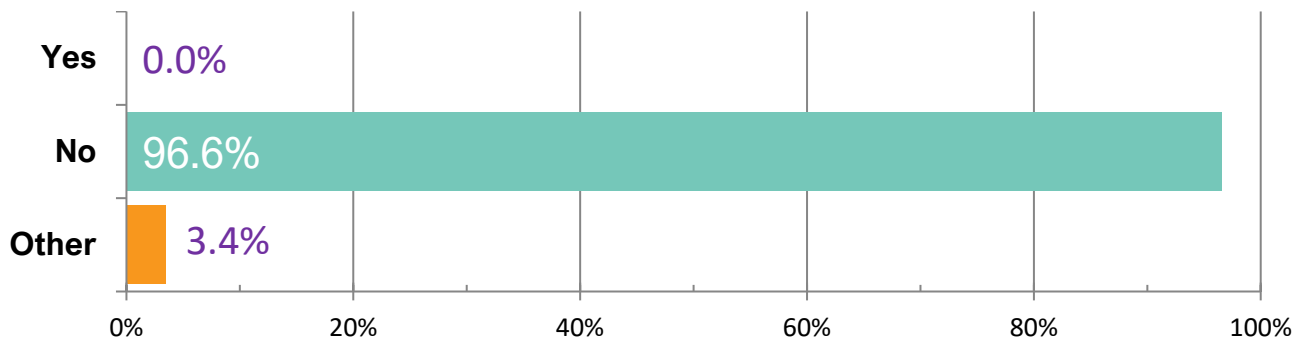
13. If you answered yes to the previous question, what is the general methodology you use for determining fair market value (e.g., data sources, type of event, etc.)?

Comments:

- Quotes are submitted and assessed, e.g., hotel spend is compared to corporate hotel limits; airfare requires quotes from airlines.
- Experience through supporting the event in prior years and comparisons against transparent sources of information (travel agency, hotel websites, internal travel guidance, etc.). The requestor will also provide a breakdown of the funding required for the particular activity.
- We consider other programs of similar design, the location, and other sources of comparison.
- Review of prior funding requests from the organization and other organizations.
- Review submitted budget travel related information, event location, registration costs to determine alignment with our HCP travel and expense policies.
- Duration of the event, cost to run the event, agenda and topics being covered, etc.
- Look at event location and compare with FMV of this location based on company experience/similar events at same location and past internal spend.
- Rely on historical data/requests.
- Agenda, type of event, experience.

- Grant system asks requesting institutions for the estimated cost and FMV (if not provided, we ask for this information).
- Certification from requester that value is consistent with FMV.

14. With respect to hospital/training institution requests for educational grants, does your company actively solicit requests for educational grants from these entities?



Comments:

- Other: All grants are non-solicited.

15. With respect to hospital/training institution requests for educational grants, what documentation do you require to support the educational grant?

Comments:

- 4 responses require the same documentation as required with respect to Third-Party Educational Conference requests.
- Treated as educational grants but may do additional diligence given the nature of the relationship.
- Same documentation required for all grants except accreditation for CME is not required for events for Fellows.
- Do not provide grants to individual HCOs unless they are offering attendance to multiple HCOs. If that requirement is met, we require an overview of the course, basic needs assessment, brief educational objectives, agenda, budget, the proposed use of company funds, supporting collateral such as a letter of request, marketing collateral, IRS Determination Letter (or similar for non-US), IRS Form W-9, product list when seeking in-kind support.
- Completed application which outlines benefitting organization, details about the educational program, program objectives, number of industry sources of support, historical support, description of how funds should be used, agenda, tax ID and tax status (if applicable), and a detailed budget.
- Letter of Request (on hospital/institution letterhead); Detailed Program Brochure, Explanation of Objectives/Goals and Selection Criteria (as applicable); Detailed Budget (lump sum amounts will not be considered to satisfy this requirement); Evidence of Accreditation (if applicable); Tax-Exempt Status Determination Letter (if applicable); and Completed W-9 (U.S. only).
- A formal letter of request, the purpose/use of funds of the educational grant, a budget, W-9 to understand the tax status of the sponsor.

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- Robust agenda with topics and presenters, letter of request/application, W9 form, budget for the funding requests and list of products required for in-kind support.
- Letter of request from the organization, detailed budget, detailed program/agenda, and summary of the program and participants.
- Request letter, agenda, list of members of the organization's board, fully executed written agreement.
- Completed application on our online submission website, a detailed agenda, and a detailed budget.
- Application, agenda, budget, background for event, whether event provides CME.
- Purpose of the educational session, agenda, who is participating, contract for the grant.
- Agenda/brochure, budget, tax forms (990 and/or W-9).
- Agenda/Program, Location/Hotel Information, and Written Request.
- Agenda/content, audience, location, budget.
- Budget, agenda, learning objectives, needs assessment, W9, outcomes measurement plan.
- Detailed request, agenda.
- Agenda, Budget per number of physicians by country.
- Event information, agenda, levels of support, etc.

16. If a budget is provided that includes entertainment, how do you address?

Comments:

- Letter agreement restricts use of the funds to educational costs. Grants cannot be used for entertainment or other non-educational related activities.
- Entertainment included in the agenda or budget would be examined carefully by the committee in the context of the overall robustness of the educational component of the submission. Heavy focus on entertainment would lead to denial. Also, our agreements provide that our funding should not be used for any entertainment portion of the program.
- Reject the grant as we only provide grants that focus on education and cover the costs to put on the event, which do not include entertainment.
- Decline the request if entertainment is a focus. Otherwise, funds must support non-entertainment aspects of the conference.
- If grant is approved, agreement states that funds cannot be used toward entertainment, recreation etc. Compliance may decline the request based on concerns/issues.
- Either deny the funding, or specifically include in the grant agreement language that the funding being provided shall only be used against certain costs and never entertainment.
- Do not fund entertainment activity and exclude entertainment expenses from our evaluation of “financial need”.
- We specifically inform the requestor that we will not support entertainment of any kind and strike those items from the budget request. If we provide a grant, we provide in writing a document with information to the requestor that company funds may not be used to support entertainment, food, etc.
- Funding is restricted to educational activities and we would make clear in the LOA that no funding will be used for entertainment and recreation.
- In our letter of acceptance, we state that none of the funds provided by our company may be used to fund the entertainment, gifts, etc. We call out the AdvaMed Code of Ethics as well as our own Code of

Ethics as the reason.

- We carve entertainment out of any funding approved.
- Clarify with the meeting organizer and ensure that our company funding is not being used for entertainment via written documentation. Also have language in our grant agreement if necessary.
- We do not fund entertainment. The presence of entertainment at the program or associated with the program may result in us refusing to fund any portion of the requested grant.
- Inform the applicant that our policies do not allow funding for entertainment and we request an updated budget.
- Limit participation or restrict funding for the activities.
- Funds cannot be used for entertainment.
- Do not provide entertainment funding for any events/requests.
- No payment for entertainment is made - refuse request.
- State that the company money cannot be used for entertainment items per Compliance rules.
- We do not provide grants that include entertainment expenses.
- We are very clear that our funding cannot be used for catering or entertainment.
- We would ask the requester to resubmit without the entertainment portion.
- Grants Committee would discuss and would consider restricting in the grant agreement that funds are limited to scientific or educational use.
- Funding limited only to appropriate agenda topics. Documented rationale through independent review process should reflect holistic view of the program's legitimate educational value.
- If it's a large conference, combining scientific sessions we want to support, as well as an annual society meeting that might have a gala, we are explicit in the contract which budget categories may be used with our company's funds.

17. With respect to hospital/training institution requests for educational grants, do you require a budget reconciliation or accounting from the entity after the event?



Comments:

- 3 responses provided that their agreements reserve the right to request this.
- Unused funds are expected to be returned but no formal process for auditing budgets post-event.
- Recipient organization is required to complete online reconciliation comparing the proposed budget (revenue and expenses) and proposed use of company funds to the actual budget and use of company funds.
- Request for reconciliation is based on preliminary assessment of potential reporting obligation under

Sunshine (e.g., awareness of indirect payments to faculty or attendees).

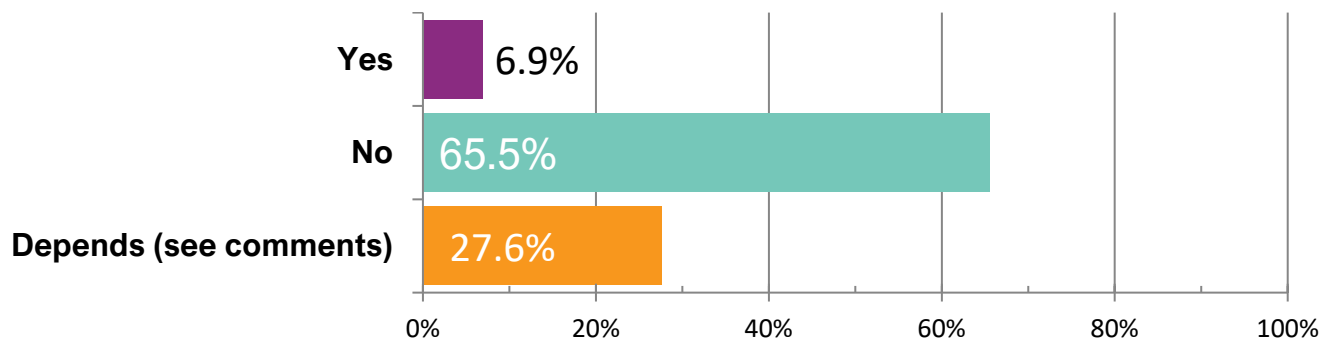
- Letter w/the grant amount states that we expect unused funds to be returned and request that we are provided with “actual” vs. “planned” budget.
- New requirement for all educational grants over US\$50,000.
- Internal Audit will verify after the fact.
- Sometimes.

18. If you responded Yes to the previous question, does your company collect unused funds?

Comments:

- 17 responses stated that “Yes” they collect unused funds – some specifics provided:
 - Request post-meeting accounting.
 - If over a certain threshold.
 - We require a refund in the event of an advance payment that exceeded the costs (demonstrated by receipts).
 - LOA with Grantee requires the return of unused funds. Unused funds identified from reconciliation.
 - We specifically inform the requestor that we will not support entertainment of any kind and strike those items from the budget request. If we provide a grant, we provide in writing a document with information to the requestor that company funds may not be used to support entertainment, food, etc.
 - Reserve the right to collect unused funds.

19. If the HCPs who benefit from your educational grant are unknown at the time of funding, does your company expect to learn these HCPs’ identities?



Comments

- If we knew that our funding was going to be used for honorariums, for example, we would capture the identities for the purposes of sunshine act reporting.
- For fellowship grants, we request this information for transparency reporting purposes.
- The only circumstance under which we may expect to know the HCP names is to comply with national transparency laws.
- Require requesters to provide this information if we have awareness that funding will be used to benefit HCPs (versus general programmatic overhead expenses).



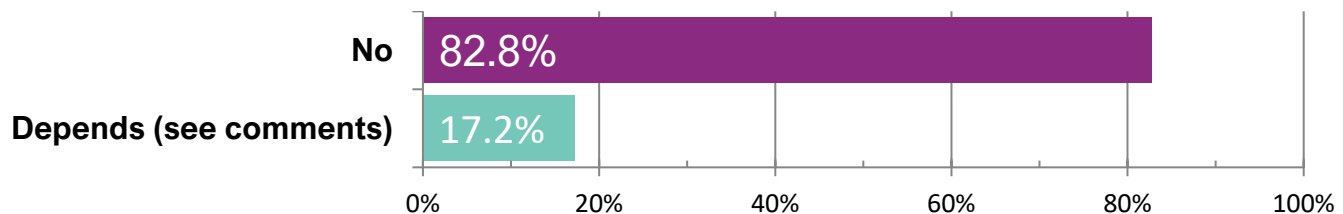
- If expense documentation is audited, we may become aware of HCP identities.
- We typically structure our grants so that we do not control or influence faculty selection and we also do not have control or influence over attendees.
- We don't usually provide grants that benefit individual HCPs.

20. If you responded yes to the previous question, at what point and by what means does your company become aware of the HCPs' identities that benefitted from your company's grant (if at all)?

Comments

- During the reconciliation process per the letter of agreement, grant recipients are required to submit indirect payments made on behalf of covered recipients to facilitate Open Payments reporting.
- For HCPs-in-training, we require HCP names in advance to confirm they meet scholarship requirements. In all other cases, we require HCP names 30 – 60 days post-event. Follow-up is assigned to requesting organization through our internal grant system.
- By the requestor/teaching institution.
- Some organizations are proactive in providing this information and, if not, we request annually.
- The information may be required as part of the post-event documentation, or recipients may inform the company that they have received funding.
- Following the approval of the event.
- After the fact.

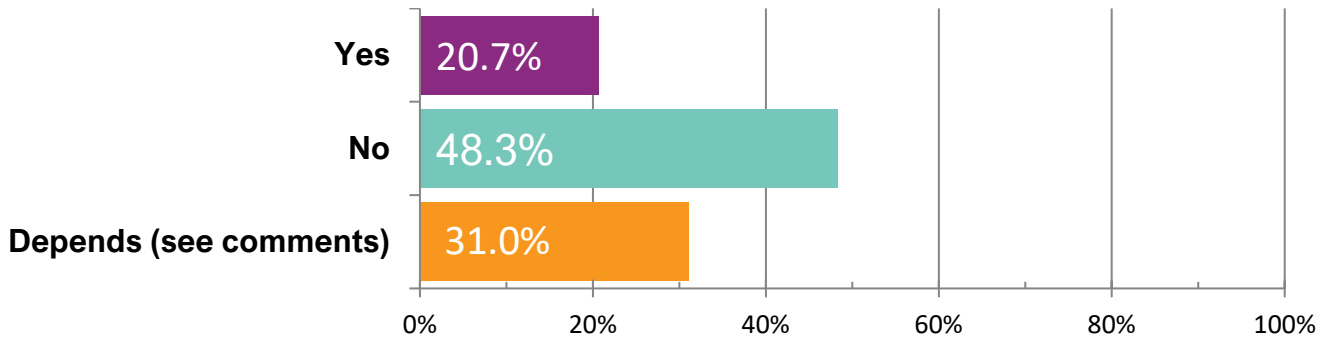
21. Do you provide a list of suggested HCPs who could potentially benefit from your company's educational grant?



Comments

- Only when the organization asks us because they are looking for physician presenters for a particular topic.
- Only if requested, and then it would come from Medical Affairs (not Sales) and we would have to provide a robust list of names, not just one or two names.
- In some cases, we may provide educational conference organizers suggested faculty names.
- Grants provided are independent of HCPs; these are strictly for educational purposes that meet our criteria.

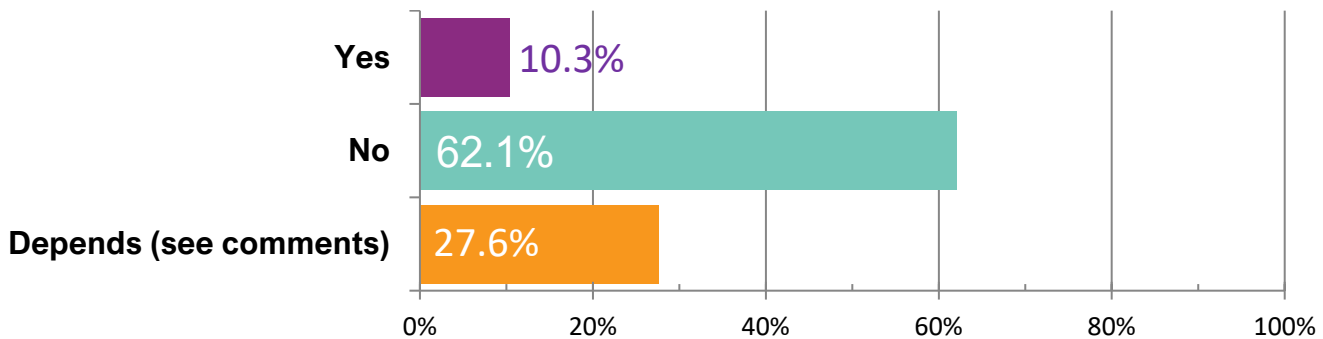
22. Does your company permit the same HCP to benefit multiple times from your company’s educational grants to attend different Third-Party Educational Conferences?



Comments

- Identities are unknown at time of funding.
- Don't know the identities of attendees.
- We don't know which HCPs are benefitting.
- We are not typically aware of the names of the physicians that may attend the events.
- Don't provide educational grants that are related to a specific HCP.
- We are not directing funds to individuals and make efforts not to be sole support so we would not be made aware.
- We do not fund attendance at third-party meetings.

23. If the Third-Party Conference Organizer selects its own HCP faculty but asks industry to arrange and pay for the HCP faculty travel, do you view this as permissible?



Comments

- We have not encountered requests for educational grants that indicate funds will be used to pay for faculty travel. A program that only contains faculty working for the conference organizer is not likely to be approved for funding under our grant review process.
- We would consult the AdvaMed code for the particular situation, but, generally, we only provide funding to the organizer (unless an exception applies).
- We will consider a grant directly to the organizer.
- We have not been asked to arrange travel, but funds may go towards faculty expenses as determined

by the third-party organization.

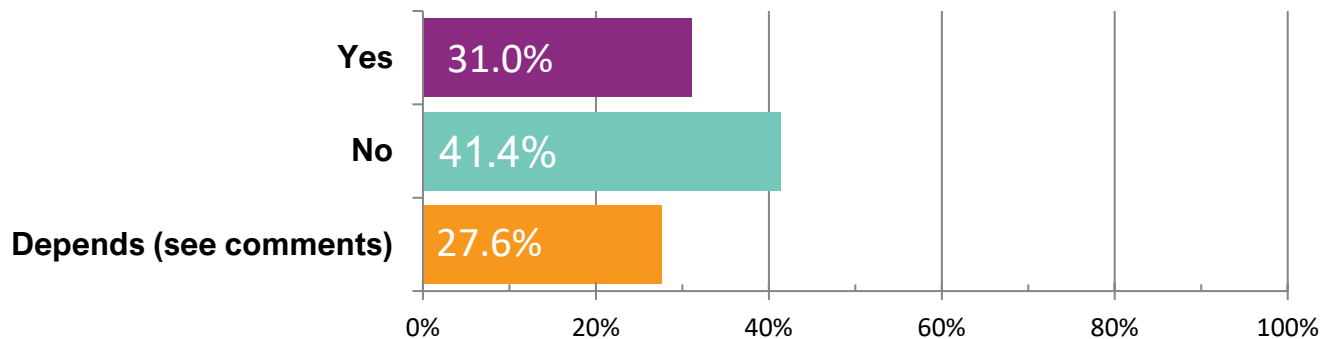
- If this is related to a workshop, this might be something we would cover.
- If the purpose of the grant is to fund the expenses associated with have a HCP faculty present, then we assume this covers faculty travel.
- Permissible only in countries that permit direct sponsorship.

24. If you responded yes to the previous question, how does your company handle the situation in which a Third-Party Educational Conference sends an invoice after the fact to industry to pay for HCP faculty travel and lodging?

Comments

- Approved expenses would be determined prior to the event and captured in the relevant documentation, so no after-the-fact expenses would be covered.
- We generally provide payment in advance when permissible.
- We will not cover additional cost above the grant request - we simply provide a set amount in advance.
- The grant would note that it can be used to cover the costs of event including HCP speaking and travel fees.
- Don't pay as it was not approved.

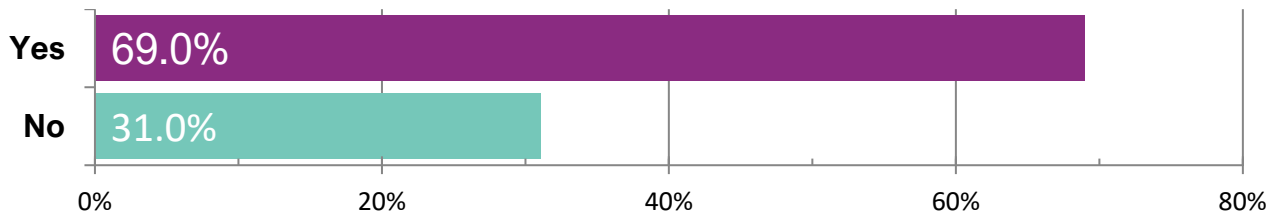
25. Do you provide a list of suggested faculty if the Third-Party Conference Organizer asks for such a list?



Comments

- 5 responses provided they have not received requests for suggested faculty or it's a rare request – some specifics noted:
 - Would evaluate the request.
 - Medical Affairs department would be the only department that might suggest faculty.
- All grants are unrestricted grants, meaning that the requestor has full discretion over how to use the funds and how to run their program. If we are asked for suggested faculty for certain topics, we will provide a list, but only after a grant has been reviewed and approved.
- If expressly requested by the conference organizer, we may recommend faculty consistent with product labeling. No additional control over faculty permitted.
- In some regions (APAC and LatAm), we may provide input if asked.

26. Does your company pay for exhibit space or commercial sponsorships, even if your company determines not to fund an educational grant due to inappropriate venue or conference agenda (for example, due to the MedTech Europe Conference Vetting System)?



Comments

- 4 responses noted that the criteria/process to evaluate educational grants is different/separate from the criteria for evaluating sponsorships.
 - We require that educational grants and commercial sponsorships be reviewed, approved, and contracted separately, since there are different criteria for both.
- If the conference involves both an educational grant and a sponsorship opportunity, both are set out in the agreement with the conference organizer. If the venue or conference does not meet our trade association partners requirements, we do not participate in the conference.
- Yes, except in EMEA.
- Robust agenda with topics and presenters, letter of request/application, W9 form, with the exception of a prospectus but need documentation of sponsorship levels in lieu of a budget.
- If it is booth space, the company can decide to participate and only attend with company employees.
- If the MedTech Europe Conference Vetting System rejected a program, we would likely not participate in any capacity.

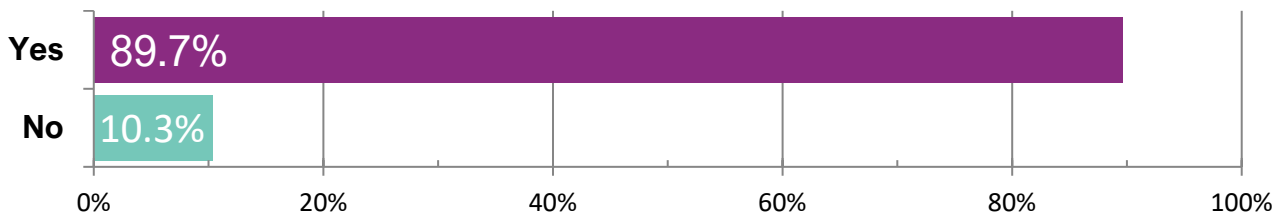
27. How is your company handling the situation in which a Third-Party Conference Organizer submits a request as a package seeking a combination of both educational grant support and commercial/advertising sponsorship? For example, a Third-Party Conference Organizer submits a request for \$100,000, which ensures that the company receives a certain level of advertising opportunities but also incorporates an educational grant.

- 34.5% My company requires Third-Party Conference Organizers to resubmit as a separate request for marketing/commercial/exhibit support and for an educational grant.
- 24% My company reviews all such combination requests together and does review them separately or require the requestor to resubmit.
- 34.5% My company reviews the marketing/commercial/exhibit support and the educational grant support requests separately, but we do not require the requestor to resubmit.
- 7% Other.

Comments

- 3 responses provided that combined requests are reviewed as an educational grant- some specifics provided:
 - We will review them together but review them within the same framework as educational grants: review the agenda in its entirety for overall robust educational sessions and discussions in alignment to the educational strategy. If the agenda allows for significant gaps in the day for attendee recreational activities, this is taken into consideration on approval decisions and type of support. Additional consideration is given to third-party meetings that take place in resort locations during in-season recreational activities. We review global industry codes as well.
- We do not require re-submission. The grant board reviews the grant application and we forward the commercial sponsorship request to the business.
- These need to be separated as they are handled through separate processes and have different reviews, approvals and details that need to be provided. If a grant is submitted that states we will receive an advertising benefit, we will reject the grant and have the organization submit the request through our sponsorship process.
- If a single submission effectively delineated the two separate requests so that it is functionally two requests in one submission, we would likely process the requests without requesting a new submission.
- In some regions, we may ask the requestor to resubmit separate requests.

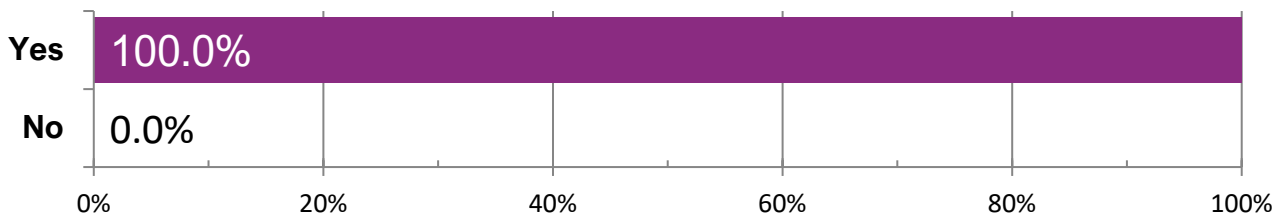
28. Will your company continue to sponsor virtual conferences as people start to travel more “post-covid?”



Comments

- If the educational content is appropriate, we would sponsor, but with very limited funds and only to offset the costs related to program platform, advertising the program, and other overhead.

29. Do you have the same sponsorship process for virtual conferences as in-person conferences? If different, what are the differences?

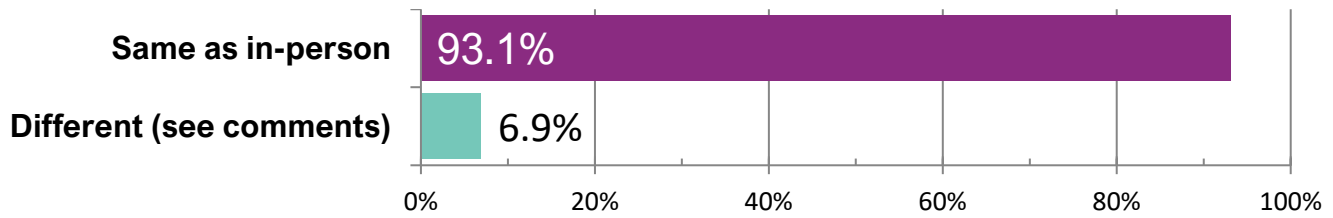


30. How do you determine FMV for virtual sponsorships?

Comments

- 7 responses provided that the methodology for evaluating FMV of virtual sponsorships is the same/similar to in-person events – some specifics provided:
 - Similar to in-person conferences - require a budget with itemization of overhead expenses or faculty compensation (reasonably based on hourly presentation time).
 - Same as in person - based on the value of the tangible benefits of the sponsorship opportunities and expected attendance.
 - FMV for all promotional opportunities (in-person or virtual sponsorships) is assessed on a commercially reasonable standard.
- 5 responses provided that lower costs for virtual events are expected and funding is reduced – some specifics provided:
 - We reduce the funding substantially but view it similar as other FMV analysis.
 - Funding virtual sponsorships is permitted only to help offset the organization overhead for the virtual program and has a very low threshold; look at their budget and determine the amount we are willing to pay.
 - Usually the value is at least 1/4 of the in-person, if the same size event.
 - Utilize a calculation based on an objective rubric and will determine the FMV as a percentage of an in-person course.
 - We generally expect lower costs and look at itemized budget lines to ensure it is reasonable considering technology facilitation.
- This is a multi-factorial evaluation taking into account size of the event, nature of sponsorship benefits, time period receiving the sponsorship benefits, etc.
- Generally, there would be an assessment of the audience size and the exact mechanism on the virtual platform or the company to get marketing/advertising exposure to the audience.
- We review the detailed agenda, educational topics, duration, and the number of attendees expected.
- Compare the event to other events of similar scope.
- There are typically still costs for a/v consultants and speakers.
- We have a FMV process with medical education.
- Agenda, budget, experience.
- Analysis based on the event, the costs, etc.
- Benchmarking of other events.

31. What type of post-event documentation does your company require for virtual events?



Comments

- We have a “menu” of acceptable proof of performance documentation from which an organizer can pick, e.g., photographic evidence, meeting participant survey results, a receipt for audio visual expenses, etc.
- We do not require post-event documentation at this time.