

White Paper

Communicating the Value of Independent Medical Education to Key Stakeholders

Demonstrate the impact and value of your IME program with technology and data-driven insights

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Introduction

Anyone visiting a physician, no matter how small the complaint, wants to feel confident that their healthcare provider is up to date on the latest scientific and medical developments. That is the goal of licensing board and professional organization requirements for independent medical education (IME).

A highly organized system of approximately 1,680 accredited education providers, accreditation, standards, and regulatory organizations, government agencies, and watchdog groups work to govern, track, and deliver the education healthcare providers need to stay current. In 2020, educators delivered more than 1 million hours of instruction and over 45 million interactions with healthcare providers.¹

The dollars involved in supporting medical education programs are significant. Accredited providers reported approximately \$2.2 billion in investment in education in 2020. The majority of income (56%) came from participant registration fees, with 32%, or \$722.8 million, coming from commercial support. The remaining income is from advertising and exhibits (10%), government grants (2%) and private donations (<1%).¹

A key mission of this system is to ensure that the education provided is designed to create change in healthcare provider competence, provider performance, or patient outcomes. The system is also responsible for ensuring that the education is delivered independently

and without influence from any third party that may be providing funding — often pharmaceutical and medical device companies that provide grants to the education provider.

The professionals who manage company grants programs have both external- and internal-facing responsibilities. In our conversations with grants professionals from the industry, we often hear that the following topics pose professional challenges:

1. Communicating the value of supporting IME
2. Measuring outcomes
3. Adapting to globalization
4. Capturing and aggregating program data
5. Operational Program Management

In this paper, we will look at the role of grants professionals in pharmaceutical and medical device companies, the challenges they face working with internal stakeholders, and how technology and data-driven insights can help.

Figure 1: 1,680 IME accredited education providers, delivered in 2020



MANAGING COMPLIANCE WITHIN A SUPPORTER ORGANIZATION

The professionals who manage grants programs within a pharmaceutical or medical device organization are charged with evaluating applications and making sound scientific and business decisions about which programs to support this, while keeping in mind compliance and regulatory requirements.

As IME supporters, life sciences companies are required to keep grant programs separate from the commercial business to remain compliant. The PhRMA Code states that, "...financial support for Continuing Medical Education (CME) is intended to support education on a full range of treatment options and not to promote a particular medicine. Accordingly, a company should separate its CME grant-making functions from its sales and marketing departments." The Code continues, "...a company should develop objective criteria for making CME grant decisions to ensure that the program funded by the company is a bona fide educational program and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment."³ The AdvaMed Code of Ethics contains similar guidance: "Medical Technology Companies should establish processes and guidelines so that decisions to support Third-Party Programs are made objectively and not used as unlawful inducements to Health Care Professionals."⁴

In addition to adhering to strict industry codes, life sciences companies are required to do the necessary due diligence work with respect to grants recipients. To that end, firms must have confidence that grants recipients meet their companies' compliance requirements, including criteria such as accreditation, tax status, and debarment history.

DESIGNING OPERATIONS, PROCESSES, AND GRANTS STRATEGY

From an operational perspective, life science companies should design their infrastructure and work processes to ensure that grant-making activities are separated from the commercial business. This includes not only the decision-making processes (e.g., Grant Review Committee membership), but also the internal source of grant funding. It is highly recommended to separate grant budgets into either their own cost center or a specific line item in a non-promotional area such as Medical Affairs. Commercial teams should not have access to grant management systems and should receive only limited information about the grants supported by the company.

A key component of being able to speak to the value of IME is the overarching grants program strategy. Defining and documenting a strategic plan requires and medical areas of interest and unmet need, program types, audience, geographic regions, accredited or non-accredited status, and more. Legal and compliance teams should be involved with creating the company's overarching grants program strategy. They can help ensure that it is not driven by commercial goals.

Having an agreed-upon grant program strategy makes it easier to demonstrate the grants program's purpose and benefits to the various stakeholders. Its creation requires that companies consider the "why" behind the decisions to include or exclude certain criteria in the strategic plan. For example, why are we supporting more programs in a specific region of the country? Is there a higher prevalence of a disease state resulting in a need to support more educational programs for healthcare providers in the area?



STAKEHOLDERS, THEIR INTERESTS, AND THE GRANTS PROFESSIONAL'S RESPONSIBILITY

When developing education, IME providers often reach out for help creating education to the same healthcare professionals that a company's commercial and medical teams are trying to reach. This can put the grants professional "in the middle" between the responsibilities associated with maintaining an impactful, compliant grant program and the need to have compliant conversations with internal stakeholders who may view the grants process through a different lens.

Therapeutic area commercial leadership. When meeting with these stakeholders, consider that they are very interested to learn what IME is being supported and may want to know more information regarding who the IME program will be reaching, learning objectives, programming type and how this relates to the healthcare providers with whom they interact. Because grants should never be used as an inducement to prescribe or recommend a company's products, involving commercial teams in the grants review and decision-making process, or even having the perception of involvement, can result in the appearance of grant activities serving as inducements to recommend or prescribe the company's products. Grants professionals should work with their legal and compliance teams to determine the types of information that would be appropriate to share with the commercial teams.

Medical Affairs. Medical Affairs teams are usually part of the grants review committee and they are tasked with reviewing grant requests from scientific and medical perspectives. These stakeholders want to ensure that the learning and educational objectives of grants programs supported by the company are in alignment with the overall grants program strategy with respect to educating healthcare providers and improving patient care. However, caution is warranted because Medical Affairs teams are also focused on managing

relationships with healthcare providers, especially key opinion leaders (KOLs). Viewing grant activities through the lens of KOL relationship management can lead to compliance issues. For example, viewing grant activities as an opportunity to persuade healthcare providers to adopt the company's point of view on a therapeutic approach would be problematic.

Organizational leadership. When presenting to organizational leadership, come prepared to provide a broad perspective on the types of funding and high-level impact of your grants program. Company executives have a broader view of the organization's grants programs and typically understand that compliance and transparency are important investments in the company's reputation as well as the advancement of science and patient care. At the same time, they may want to be assured that grant funding is aligned with the company's scientific mission; for example, improving patient outcomes in certain diseases, and stated social goals, such as meeting the needs of underserved populations.

OVERCOMING COMMUNICATIONS CHALLENGES

Due to their "in the middle" position, grants professionals can sometimes find themselves in challenging situations when communicating the value of IME to key stakeholders. Follow these key strategies to overcome these key pitfalls.

Stakeholder management. Plan regularly scheduled meetings with stakeholders to walk them through the grants program at a high level. Select a few requests that show an improvement in healthcare provider behavior resulting from the education that was supported. The objective is to demonstrate to leadership that supporting independent educational programs that focus on independent science can be impactful in changing healthcare provider behavior in a way that is beneficial to patient outcomes.

The sharing of information with commercial stakeholders is often scrutinized closely by the company's legal and compliance team.

Compliance. Make sure that before discussing any IME related activities with stakeholders, you partner with your legal and compliance teams to create processes for sharing appropriate information with other parts of the organization. Consult with legal and compliance on how best to provide guidance to field representatives on referring questions from healthcare providers about the company's grants program to the grants office.

Grants impact. Determining and measuring the success of grants is often complex. The more meaningful the desired outcome, the more challenging it is to measure the actual results. For example, measuring the actual change in community or patient health outcomes that are associated with an educational intervention requires longitudinal analysis of claims data, chart data, or similar data sources. Measuring change in participants' knowledge, on the other hand, may be accomplished with pre- and post-testing.

The solution? Make sure IME grants include clearly stated outcome objectives and appropriate, data-based measurement strategies. A robust grants management technology system that enables quick insight into historical data, past performance, and outcomes can help focus conversations on data-driven outcomes reporting.

“To justify future funding, grants professionals need to be able to extract and report meaningful data.”

CHOOSING A GRANTS MANAGEMENT SYSTEM THAT CAN SHOWCASE IMPACT

When selecting a grant management platform, it is wise to keep in mind the ongoing industry conversations about standardizing the grant process globally and the changes that may be impending. The approach to independent education varies globally. U.S. organizations prefer to support programs across multiple scientific and therapeutic areas to demonstrate lack of influence. Outside the U.S., companies are more likely to support one program area for ease of execution and confidence in content.

Another trend is the increasing desire to standardize the approach to outcomes. It continues to be challenging to capture outcomes in a format that allows for easy aggregation and reporting. The Outcomes Standardization Project (OSP) is beginning the approach by simply gaining agreement on definitions of the most commonly used words/phrases in the outcomes field. A grant management program should provide the flexibility to accommodate new data structures as well as unstructured text for search and analysis.

A third trend to consider while selecting a platform is the increasing complexity of grants. While the need still exists to deliver educational programs through traditional formats, such as symposia and online education, the desire for innovative educational programs that can be validated and published is increasing. This type of education increases both time and cost. It often requires more in-depth participation by learners, such as chart pulls and mentoring, or the increased cost of using outside data such as claims data. The payoff is in measurable outcomes that document changed provider behavior and impact on patients.

Conclusion

Using technology and data-driven insights can help with demonstrating the impact of your grants program. This is essential to gaining continued support from key stakeholders. A technology platform purpose-built for life sciences, with embedded compliance and streamlined workflows, can help accelerate funding, improve efficiency, and provide visibility across the full suite of funding programs.

Seamless access to consistent and reliable data is crucial, along with tools that provide quick insight into historical data, past performance, and outcomes. Key data points include activity year-over-year, attendance, participation, type of programming, length of programming, learning objectives, and therapeutic area-specific information.

Analytics tools should aggregate data for reporting across multiple grant requests and extract insights from key data points to determine trends, effectiveness, and potential compliance risks. For example, data might reveal that a company is focusing too much funding on one therapeutic area or on one learning objective.

These are the key points that should be shared when communicating with stakeholders to demonstrate the quality of programming that is being supported. This information may also be used to make sure that the education provided is achieving its learning objectives and reaching the right audience in the most effective formats.

In sum, the independent medical education ecosystem is undergoing changes that will impact data collection and outcome analysis. Pharma companies should look for a technology solution that is open and flexible and can provide more complex outcomes reporting and analytics dashboards for easy consumption of insights. At the same time, technology needs to support standardization and increased collaboration across regions and countries. Keep these factors in mind while choosing a solution that simplifies compliance, improves efficiency and program effectiveness, and helps grants professionals communicate with stakeholders today.

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Meet the authors



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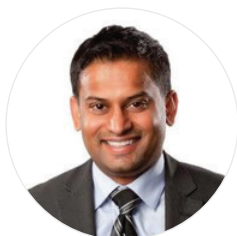
Regina leads the US Commercial Compliance Consulting team at IQVIA and has 20+ years of combined life sciences industry and consulting experience providing advisory and project leadership for compliance-driven initiatives and programs, especially those focused on process design and optimization. She has strong domain expertise in medical affairs, grants & IIT/IIS management, materials review processes, and transparency reporting. Regina is a certified Project Management Professional (PMP) and received an MBA with a specialization in project management from Jones International University. She also holds a Graduate Certificate in pharmaceutical and medical device law and compliance from Seton Hall University School of Law.



MARY FAULKNER

Program Manager

Mary Faulkner joins IQVIA with over 18 years of experience in the pharmaceutical industry. She began her career just as the newly created Pharma Code was issued. In her role at the Ethics & Compliance (OEC) organization, she collaborated with the legal team to interpret the new Code, rewrite the company guidance, and educate thousands of internal personnel on the company's accepted policies and procedures. While a member of the OEC team, Mary became the recognized subject matter expert for the process and execution of grants and donations activities across the organization. As a seasoned industry expert, Mary brings years of experience, knowledge, and insights to the evolution of IQVIA Grants & Funding Management.



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Rajesh Patel is a Senior Director within IQVIA's Commercial Compliance Technology Division and has overall responsibility of the HCP/O Engagement and Grants & Funding Management technology products. Rajesh defines strategic product direction and manages the product strategy execution to ensure the product meets the current and future needs of our clients and the broader industry. Rajesh has 10+ years of experience in life sciences technology and has held various client supporting roles across the technology lifecycle. In addition to product management, Rajesh's past experience also includes overseeing client consulting and process definition, system implementations, support, and account management.



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