MAPS Medical® Affairs Professional Society
FOR Medical Affairs Professionals BY Medical Affairs Professionals

Standards and Guidance

EXTERNAL EDUCATION

Standards & Guidance for External Education:
Best Practices for Medical Affairs

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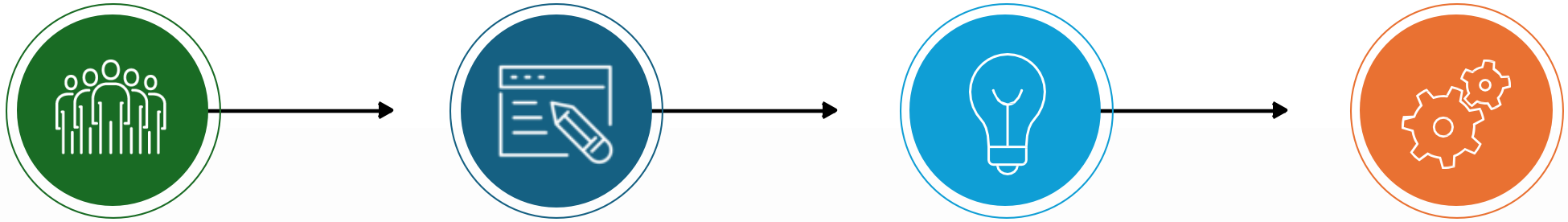
Purpose of the Standards & Guidance (S&G)



This S&G is intended to provide a common understanding of the framework in which external education, led by Medical Affairs, ultimately benefits patients

The information provided is not a “one size fits all” application, and should be tailored and applied to an individual organization based on its respective requirements and/or policies

The skills, knowledge, and attitudes of all learners, including healthcare professionals (HCPs), as well as the regulations and governance in each geography and specialty/therapeutic area of focus should be considered

The intent is to provide guidance and recommendations to Medical Affairs professionals and offer practical tools for planning, executing, and evaluating external education activities and funding determinations

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INTRODUCTION TO EXTERNAL EDUCATION

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Section 1

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1A

Definition of External Education

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What is external education?

External education is the provision of diverse learning opportunities to facilitate knowledge exchange, learning, and skills acquisition through funding of **independent** medical education (accredited or non-accredited), **industry-led medical education**, or collaborations addressing knowledge, competence, and performance gaps for HCPs, payers, and patients/caregivers

These initiatives led by Medical Affairs can be a proactive or reactive exchange of information and delivered through various programs, activities, or research-designed education and are critical to enhance medical practice and improve patient outcomes

1A

Terms associated with External Education

Collaborative Education
Activities stem from organizations working as partners to engage in design, development, and implementation. These mutually agreed upon scientific or educational activities have shared objectives, with each organization providing funds, resources, or expertise. May involve industry, professional societies, patient organizations, and/or academic and healthcare systems

Continuing Professional Development (CPD)
Generally, learner driven. Activities that physicians undertake, formally and informally. Includes CME and a broader range of relevant areas such as practice management, interprofessional patient-centered care, teaching, and leadership

Continuing Medical Education (CME)
Activities that maintain, develop, or increase the knowledge, skills, professional performance, and relationships of physicians in medical practice.

https://www.ama-assn.org/education/ama-pra-credit-system/performance-improvement-continuing-medical-education-pi-cme
Filipe HP, et al. *Middle East Afr J Ophthalmol.* 2014
WFME Office, University of Copenhagen, Denmark. 2018. https://wfme.org/standards/cpd/
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/industry-supported-scientific-and-educational-activities

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1A

Terms associated with External Education

Independent Medical Education
Activities supported by industry and independent from promotional influence as defined by the FDA in the 1997 Guidance for Industry, by the EFPIA Code of Practice in the 2019 *Annex 3 EFPIA Guideline on a Quality Framework – Principles in Lifelong Learning in Healthcare,* and by IFPMA in the 2018 *Note for Guidance on Continuing Medical Education*

Performance Improvement (PI)
Evidence-based performance measures are used to help physicians identify areas of improvement in patient care areas and change in performance. Applies to competencies of physicians and healthcare provider (HCP) teams. Outcomes can be compared to national benchmarks

Quality Improvement Education (QIE)
Integration of tools, techniques, and resources into the healthcare system and community QI initiatives. Response to quality to improve patient experiences, enhance population health, and reduce costs

Quality Improvement (QI) Quality improvement is the framework used to systematically improve care. Quality improvement seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations.

https://www.ama-assn.org/education/ama-pra-credit-system/performance-improvement-continuing-medical-education-pi-cme
Filipe HP, et al. *Middle East Afr J Ophthalmol.* 2014
WFME Office, University of Copenhagen, Denmark. 2018. https://wfme.org/standards/cpd/
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/industry-supported-scientific-and-educational-activities

Focus Area Working Group (FAWG) Position Statement

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1B

FAWG position on external medical education

- **Regulatory agencies** have diverse views on the classification of medical education developed by the pharmaceutical/biotech/device industry. Medical education and educational **materials are rarely defined by their intent, but by the originator or the supporter**. In this regard, industry-led education/educational **materials are considered promotional in many markets regardless of their nature**, and the internal function that develops them
- Medical education may play a role in influencing the market growth of therapeutics/devices by increasing the awareness of disease states, treatments, and changing guidelines. However, **the overall intent of medical education must not be to promote** company products, devices, or solutions, **but to improve HCPs' knowledge of relevant data and safe and effective use of technology, and integrate this into clinical competencies and skills to optimize patient outcomes**
- It is important to note that various functions within the industry develop educational materials and scientific programs. While the medical education developed by the **Medical Affairs function does so in a scientific and evidenced-based manner, either branded or non/unbranded**, there are components of education regularly developed or used by industry's commercial function to complement their solutions, with a primary intent to increase market share and sales of a product

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1B

Diversity, equity, and inclusion in external education

Medical Affairs Professionals should advance equity in healthcare through the following actions:

Directly address disparities in healthcare delivery for underserved populations and ensure collective accountability in creating culturally sensitive communications

Implement systems to positively influence the way in which medical education is delivered to ensure diversity and inclusion with respect to:

Faculty Selection

- Industry–Led Education: Select faculty that represent a diverse population
- Independent Medical Education: Encourage continuing medical education (CME) providers to ensure diversity in faculty selection

Intended Learners or Target Audience

- Industry–Led Education: Ensure education is equally available to all learners regardless of race, language, ethnicity, region, or gender
- Independent Medical Education: Consider the plan for diversity of the intended audience and content

Education Plan

- Is the plan inclusive and culturally sensitive?
- Are data for all diverse groups included?

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External Education Overview

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External education overview

1C

Non-independent/high level of influence → **Independent/No Influence**

	Industry-Led		Collaborations/Support for Societies		Independent Medical Education	
	Commercially-led	Medically-led	Collaborations or Partnerships	Medical Sponsorships	Continuing Medical Education	Fellowships or Young Investigator Award
Intent	Promotional	Non-promotional (disease state awareness or on-label) / Science driven promotion (brand aligned)	Non-promotional	Non-promotional	Non-promotional	Non-promotional
Content Focus	Disease state, On-label treatment	Relevant, scientifically balanced, non-promotional education aligned to company strategic goals and healthcare/patients' needs	Research-based or scientific	Research-based or scientific	Maintains, develops, and/or increases HCP knowledge, skills, and performance to improve patient outcomes	Building healthcare capacity/ specialist training
Industry Proactively Identifies the Provider	Yes	Yes/No	Not applicable	Not applicable	No; however, a call for grants or a request for proposal may also be utilized	No
Accreditation	Non-accredited	Non-accredited (pharma) / sometimes CE-accredited (device outside the US)	Mostly non-accredited	Mostly non-accredited	Accredited/non-accredited	Not applicable
Program Approval Process	As directed by internal company policy. Usually includes compliance/governance, medical, legal; may be at local, regional and global levels. Requires content approval.	As directed by internal company policy. Usually includes compliance/ governance, medical, legal; may be at local, regional, and global levels. Requires content approval	Appropriate governance and transparency requirements as directed by company policy and partner company/society policy. May require content approval	As directed by internal company policy and/or appropriate governance requirements, which may vary (e.g., review committee, non-promotional review)	Grant review committee Many organizations allow delegation of authority to grant managers to approve grants under a specified amount	Grant review committee
Faculty Selection	Company with/without external provider	Company with/without external provider (medical communications agency) Company-selected external steering committees	Scientific steering committee of partner/society with/without company input	Determined by external organization/society	Grant requestor/ Educational provider/Medical Education and Communication Company	Universities/Societies
Some Examples	Product presentations for meetings and events, speaker trainings, promotional speaker meetings, product/innovation theaters at congresses, ad campaigns, journal advertorials, unmet needs disease state campaign (unique to asset to be promoted)	Satellite symposia at congresses, webinars, scientific stand-alone meetings, review publication on disease burden, mechanism of disease video, disease website for HCPs providing overview of patient unmet needs, educational video series or infographics	Collaboration/Partnership with a professional society on an educational event or asset. May involve more than one industry partner Preceptorships with an academic Medical Center of Excellence	Disease-state think tank associated with a professional society Sponsorship of medical society or international congress (e.g., gold, silver or bronze with accompanying benefits)	Live/Virtual or enduring activities, quality improvement initiatives	Graduate Medical Education (GME) approved Fellowships Young Investigator Scholarships

Click to view chart columns

Healthcare charitable donations are handled separately from external medical education initiatives.

1C

Value of external education

The pharmaceutical industry, with its scientific expertise, geographic footprint, and access to multidisciplinary networks and resources, is an integral stakeholder in external education for HCPs in clinical practice, supporting them to make evidence-based decisions for their patients:

- **Elevate** the quality-of-care delivery to improve patient outcomes by enhancing knowledge and procedural skills in the HCP community
- **Provide** relevant unbiased information that improves and addresses evidence-based practice and performance gaps
- **Accelerate** the adoption of new knowledge into clinical practice
- **Optimize** patient care through better patient and HCP education

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Stakeholders and audiences in external education

Audience may vary depending on country certification and licensing practices.
Patient engagement is based on local & company policies/code of conduct

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Fundamental Elements in Planning External Education

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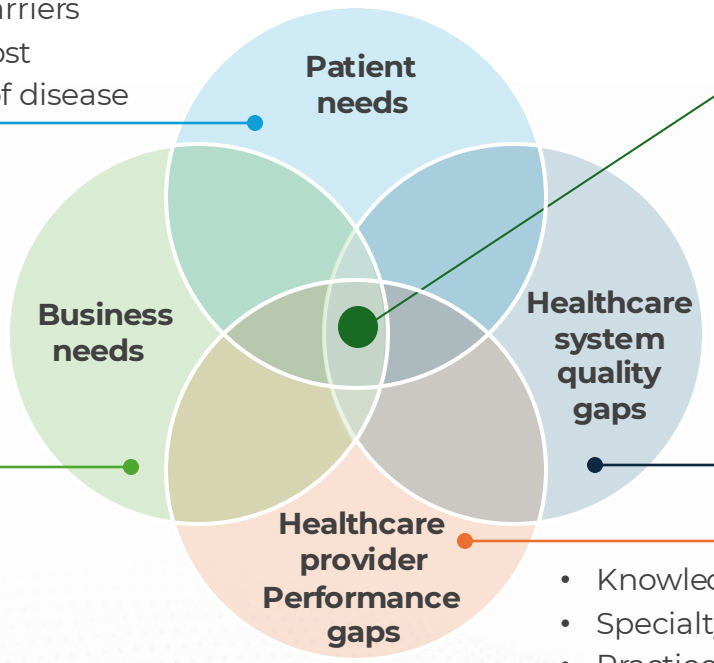
Industry support for external education starts with the convergence of interest for all stakeholders

- Adherence to treatment plans
- Social/cultural barriers
- Access to care/cost
- Understanding of disease

- Disease areas
  - Under-diagnosis
  - Appropriate and safe product use
- Mechanism(s) of action
- New or emerging data
- Product life cycle variables
- Insights gathering, data gaps



Overlapping area of mutual value

- Quality measures
- Prevalence
- Incidence
- Guidelines
- Cost/reimbursement/value
- Systems variables
- Social determinants of health

- Knowledge, skills and attitudes
- Specialty
- Practice setting
- Standards of care

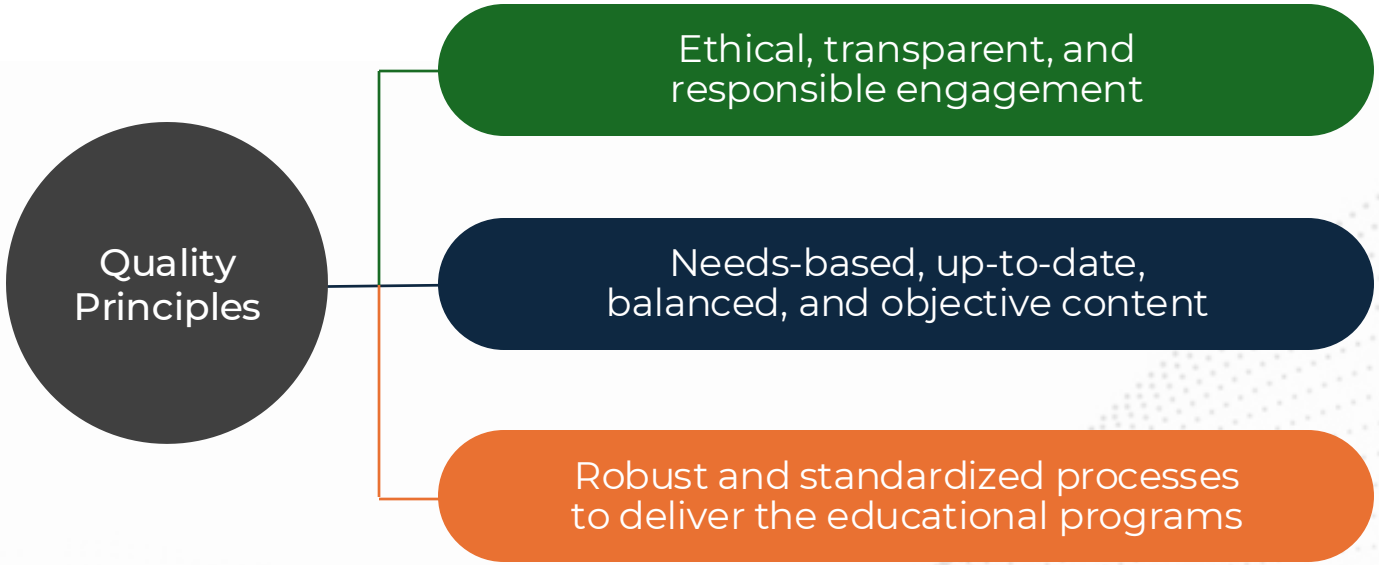
Based on Saxton M. *JCEHP*. 2009
IOM (Institute of Medicine). 2010. *Redesigning Continuing Education In the Health Professions*. Washington, DC: National Academy Press.

1D

Principles of quality external education

"Quality" is defined as the effectiveness of an educational activity or program in achieving the pre-defined educational objectives

- The quality principles proposed by industry closely align with regulators and accreditors
- Criteria emphasizes learning design, transparency, and maximizing educational impact



Elements required to deliver high-quality medical education

Allen T, et al. *JECME*. 2017

1D

Competencies for providers and supporters of continuing education (CE)

Medical Affairs professionals should have the ability to recognize and understand competencies required for CE

Develop a Rigorous Needs Assessment: Establish a multifaceted Needs Assessment that clearly identifies specific unmet educational needs amongst healthcare professionals, validated by literature

Use Adult Learning Principles: Use scientific and evidenced-based adult and organizational learning principles to improve the performance of healthcare professionals

Develop a Robust Learning Design: Implement and improve independent, fair, balanced, and evidence-based learning design that produce expected results for learners

Measure the Performance of the Program: Use data to evaluate the effectiveness of activities and the impact of the overall CE Program, including participant satisfaction surveys

Collaborate and Partnering with Stakeholders: Collaborate and partner with stakeholders to help meet the targets of the CE Program

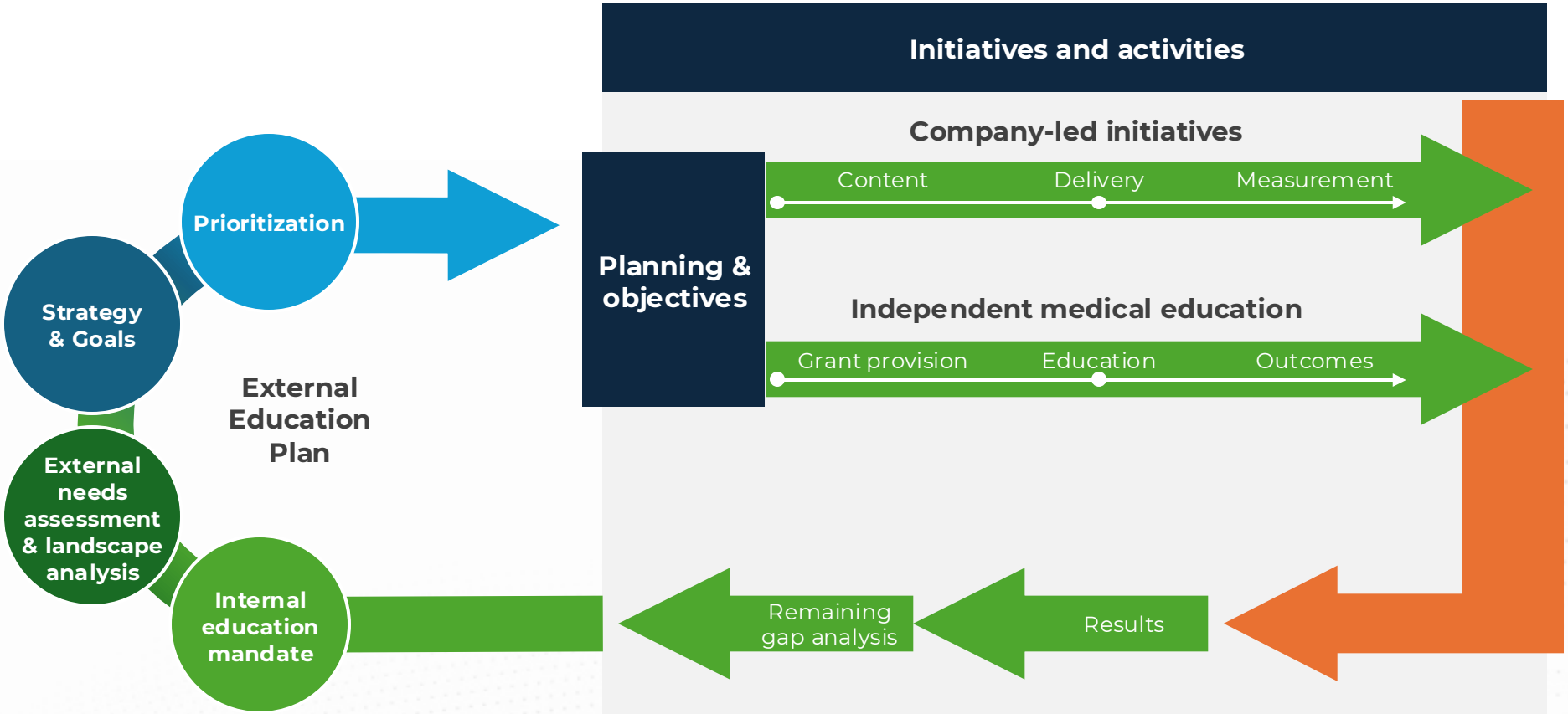
Manage and Oversee the CE Program: Manage and oversee the CE Program while maintaining its independence, in accordance with local Applicable Laws and Industry Codes

Engage in Self-Assessment and Lifelong Learning: Continually assess individual performance and CE Program effectiveness

Complete the Circle: Feedback lessons learned into the CE Program knowledge base through rigorous Program assessment

The key competencies are adapted from the Alliance for Continuing Education in the Health Professions (ACEHP) National Learning Competencies.

A framework for cohesive strategic planning of external education



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Aligning external education to medical advances and lifecycle management

Establishing needs
Identify learner audience
Identify educational and learner needs
Conduct a performance gap analysis
Consider educational formats and channels

Knowledge & attitude change Awareness/knowledge acquisition Confidence improvement Intention to adopt	**Skills & practice change** Competence improvement subjective/observed practice change individual/community adoption	**System-wide adoption** Quality improvement Adherence Reinforce best practice
Knowledge	**Competence**	**Performance**
• **Expert-driven methods** • Lectures (conferences, symposia) • Traditional web • Print materials	• **Learner-driven methods** • Case-based learning • Workshops • Interactive-web • Coaching or mentoring	• **System-driven methods** • Quality improvement methods • Customized tools • Barrier-mitigation • Teams-based learning • Patient strategies

These principles applies to both IME and CLE

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1D

Leveraging a backward planning strategy successfully drives external education

Patient Health Status

Clinical Performance

Competencies

Planning starts with the known patient healthcare gaps and ends with closing the HCP performance and competency gaps needed to improve care

Educational Activities

Patient Outcomes

Clinical Performance

Competencies

Learning outcomes

Adapted from Moore DE, Green JS, Gallis HA. *J Contin Educ Health Prof.* 2009, Dave Davis

1D

External education process components

See next slides for further details on the external education process components

Modified from ADDIE Model: https://www.instructionaldesign.org/models/addie/

Performance and competency gaps are identified through ongoing Needs Assessment

- Continuing education focused on specific performance needs and gaps results in improved physician learning and impact patient outcomes
- Gap identification (the difference between actual and ideal performance) should be done in the context of the expected outcomes or desired results
- Gaps are due to lack in:
  - Performance (actual behavior)
  - Competence (ability/skill)
  - Knowledge (facts and information)
- Ongoing practice-based Needs Assessments of various, relevant interactive learning methods support changes in outcomes

Cervero RM and Gaines JK. JCEHP. 2015. Dorman T, Miller BM. Academic Medicine. 2011. Davis D, Galbraith R. Chest. 2009

Types of Needs Assessment

Inferred

- New methods of diagnosis or treatment
- Availability of new medication(s) or indication(s)
- Development of new technology
- Input from experts regarding advances in medical knowledge
- Acquisition of new facilities or equipment
- Legislative, regulatory, or organizational changes affecting patient care

Verbalized

- Requests submitted on participants' activity evaluation forms
- Formal surveys of potential participants (mail and Internet- based)
- Informal comments
- Patient problem inventories compiled by potential participants
- Consensus of faculty members within a department or service area

Proven

- Epidemiological data
- Quality assurance/audit data
- Re-credential review
- Morbidity/Mortality
- Statistics Infection control data
- Surgical procedures statistics
- Professional society requirements
- Journal articles/literature citations
- News media

https://medicine.wright.edu/continuing-medical-education/needs-assessment-guidelines

Methodology for Needs Assessment

- **A Needs Assessment provides a systematic process for understanding a level of knowledge, ability, interest, or attitude** of an audience or individual, and establishes a foundation for education planning to support ideal standards of practice
  - A wider process demonstrating relevance to practice, and confirmation of learning may support individual and unpredictable practice needs
  - Individual and group learning needs can be different, and a balance may be beneficial
  - Multiple methodologies targeting different behavior may provide optimal change in desired behavior
- **Formal Needs Assessments can include:**
  - Critical incident review and significant event auditing techniques
  - Gap or discrepancy analysis
  - Objective knowledge and skills tests
  - Observation
  - Literature review
  - Revalidation
  - Self assessment
  - Video assessment
  - Peer review

Grant J. BMJ. 2002. Shannon S. *The Lancet*. 2003. Grant J. The good CPD guide. CRC Press; 2nd Edition; 2011.

Educational Needs Assessment

In order to support the highest quality educational activities that aim to address identified educational needs and gaps among HCPs, the Medical Education department will perform, with assistance from third party organizations, if necessary, an educational Needs Assessment for each therapeutic area when budget is available to support educational grants.
The Needs Assessment will be reviewed on an annual basis and the team should evaluate the need for an updated Needs Assessment based on new and emerging scientific information and/or data

The Needs Assessment may highlight the educational areas, content, and audiences for which medical or scientific education is most needed, as well as most effective educational formats. This information will form the basis for the annual education strategy plan

Needs Assessments can be based on (but not limited to) the following sources:

- Educational gap analysis for each therapeutic area
- Insights from company Medical personnel
- Data from existing and previous educational programs and grant submissions
- Independent third-party data
- Medical literature assessment or survey data

The Needs Assessment may include:

- Unmet medical needs /learning gaps/practice gaps
- Educational objectives
- Educational program formats (e.g., virtual, live, web) and/or Reach (i.e., national, local, regional)
- Potential learner audiences

Commercial or marketing resources where the primary objective is to promote, analyze, or research product or product messaging are **NOT** acceptable resources to inform the medical education Needs Assessment

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Questions to consider when identifying needs and objectives

Questions to identify needs and support the development of educational objectives

- How prevalent is the need among the target audience?
- How many different assessment sources indicated this need?
- How significantly will the unfulfilled need hinder healthcare delivery?
- How directly is the need related to actual physician performance?
- How likely will education meet the expected outcomes to sufficiently close existing gap(s) in knowledge, competence, and/or practice performance?
- Are sufficient resources available to effectively address this topic?
- How receptive will the target audience be to a session on this topic?

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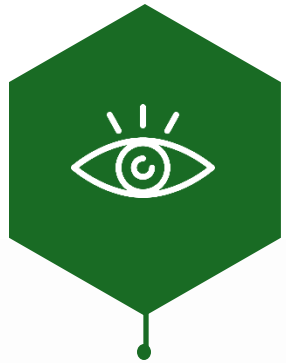
Adult learning theory plays a role in designing effective external education

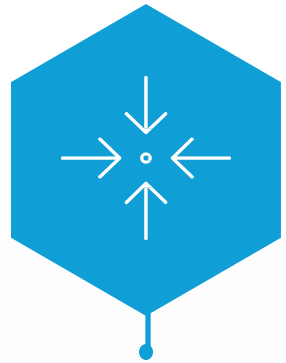
Categories for adult learning theories include instrumental, humanistic, transformative, social, motivational, reflective, and constructivist theories

The most influential theories of adult learning are the behaviorist, cognitivist, and constructivist theories

These theories suggest adults learn most effectively when they perceive the relevance of educational material, are actively engaged, have input into choosing experiences and directing their own learning, and can reflect on their learning



Primary learning styles to consider include visual, auditory, and kinesthetic



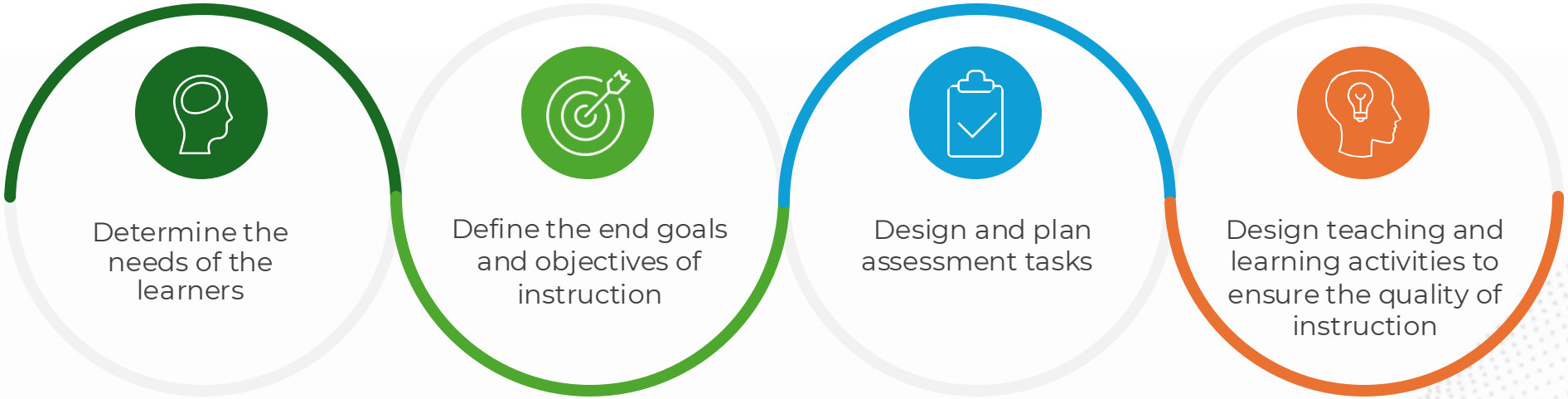
Essential elements of learning include motivation, reinforcement, retention, and transference

Note: Additional research may need to be performed on the theories mentioned above
Mukhalalati BA, Taylor A. *J Med Educ Curric Dev*. 2019

Instructional design includes learning formats, program design, and curriculum

Instructional design is the practice of systematically creating instructional products and experiences for learners to acquire knowledge in a manner that is efficient, effective, appealing, engaging, and inspiring

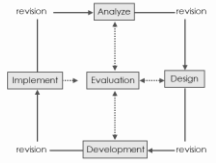
The process consists of:

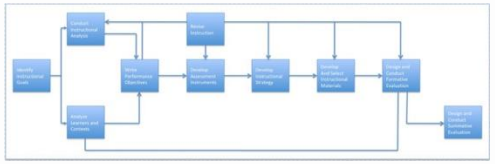


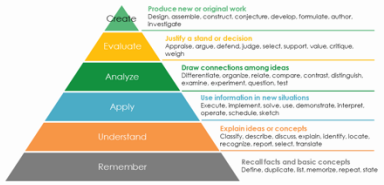
Battles JB. *Qual Saf Health Care*. 2006.
https://educationaltechnology.net/instructional-design/
Bloom's Taxonomy https://fctl.ucf.edu/teaching-resources/course-design/blooms-taxonomy/

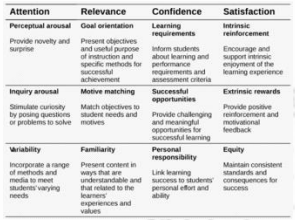
Instructional design models

- ADDIE Model (https://www.instructionaldesign.org/models/addie/)
- Dick and Carey Systems Approach Model (https://www.instructionaldesign.org/models/dick_carey_model/)
- Merrill's Principles of Instruction (https://mdavidmerrill.files.wordpress.com/2019/04/firstprinciplesbymerrill.pdf)
- Bloom's Taxonomy (https://fctl.ucf.edu/teaching-resources/course-design/blooms-taxonomy/)
- ARCS Model of Motivational Design (https://www.arcsmodel.com/motivational-design-cyrv)
- ISD & THE ADDIE Model (https://www.lib.purdue.edu/sites/default/files/directory/butler38/ADDIE.pdf)
- Gagne's Nine Events (https://www.mindtools.com/pages/article/gagne.htm)
- Kirkpatrick's Levels of Evaluation (https://www.kirkpatrickpartners.com/Our-Philosophy/The-Kirkpatrick-Model)









Attention	Relevance	Confidence	Satisfaction
Perceptual arousal Provide novelty and surprise	**Goal orientation** Present objectives and useful purpose of instruction and specific methods for successful achievement	**Learning requirements** Inform students about learning and performance requirements and assessment criteria	**Intrinsic reinforcement** Encourage and support intrinsic enjoyment of the learning experience
Inquiry arousal Stimulate curiosity by posing questions or problems to solve	**Motive matching** Match objectives to student needs and motives	**Successful opportunities** Provide challenging and meaningful opportunities for successful learning	**Extrinsic rewards** Provide positive reinforcement and motivational feedback
Variability Incorporate a range of methods and media to meet students' varying needs	**Familiarity** Present content in ways that are understandable and that related to the learners' experiences and values	**Personal responsibility** Link learning success to students' personal effort and ability	**Equity** Maintain consistent standards and consequences for success

The design selected must align with the needs of your learners and your objectives.

External education is delivered through various learning formats

Formats for external education activities typically include live, digital/online, and blended approaches

Learning format should be adjusted to address the identified gaps

While industry has traditionally provided external education in a didactic lecture format, use of interactive and social learning formats continue to increase; globalization of content, digitalization of tools, and availability of technology increase the need for digital elements to be integrated into in-person events

Trends influencing e-learning (web, intranet, and multimedia-based computer applications) include:

- Adoption of emerging communication, simulation, and information technology
- A call for competency-based, patient outcome-oriented training across the continuum of education
- Rapidly changing healthcare landscape
- Steady increase in HCP workload and staffing shortages and overexertion of expected responsibilities have led to disengagement risk
- Impact of a tech enabled world thus Increasing conversations on use of virtual reality, generative AI, and augmented reality creating a more immersive learning environment
- Addressing diversity, equity & inclusion in the educational gaps, educational design and faculty selection, global audiences, and educational outcomes & insights

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4A

HCP live educational activity examples

Face-to-face (F2F) or Virtual

PRECEPTORSHIPS
- HCPs only
- Forum hosted by Center of Excellence for sharing and discussing cases and best practice

MEDICAL BOOTH
- Specialists, HCPs, and nurses
- Possibly patients
- Associated with professional congress

MSL EDUCATIONAL PROGRAMS
- HCPs, nurses, and other care team members
- Focus on latest research and clinical data led by MSLs

SCIENTIFIC STANDALONE MEETINGS
- HCPs, specialists, or patients
- Half-day to multi-day meetings/presentations; may include workshops

SATELLITE SYMPOSIA
- HCPs or specialists
- Associated with professional congress

VISITING PROFESSORSHIPS/ PROCTORSHIPS/MENTORSHIPS
- Faculty traveling to institution to work with staff
- Brings expertise to institution
- Practice based education for teams
- Identifying gaps
- Builds collaborations between sites

Virtual

COMMUNITIES OF PRACTICE – VIRTUAL LEARNING
- Specialists, HCPs, or patients
- Virtual hub for learning and engagement of interdisciplinary audience

CHATROOMS/X (FORMERLY TWITTER) CHATS
- Specialists, HCPs, or specialists
- Social media hub for learning and engagement

REMOTE BROADCASTING PROCEDURE
- Host and broadcast surgery
- Remote training for physicians and procedure teams
- Secure platform used to observe proctors performing a case in real time
- Accessible through computers and mobile devices without geographic restrictions

4A

Digital self-learning educational program examples

FACEBOOK/INSTAGRAM/META CLOSED GROUP

- HCPs only
- Forum to share and discuss cases

E-MAGAZINE/NEWSLETTER FOR HCPs

- HCPs or specialists
- Distributed via email, X (formerly Twitter), or other social media

EDUCATIONAL APPS

- HCPs, specialists, or patients
- Engaging way to learn and be updated on latest advancements

SOCIAL MEDIA UPDATES: YOUTUBE, LINKEDIN, and X (formerly Twitter)

- HCPs and patients
- Updates to social media feeds (events/photos/videos)
- Videos of HCPs and patients focused on disease state

EDUCATIONAL WEBSITES

- HCPs, nurses, and possibly patients
- Focus on disease state, knowledge assessments

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4A

Patient educational programs

HEALTH PROMOTION AND COMMUNITY DISEASE EDUCATION

- Encourage health and wellness through education on topics such as chronic and infectious disease

DISEASE-SPECIFIC EDUCATION FOR PATIENTS

- Materials created based on specific educational needs of patients
- Disease awareness websites, fact sheets, dosing/administration guides, toolkits, FAQs

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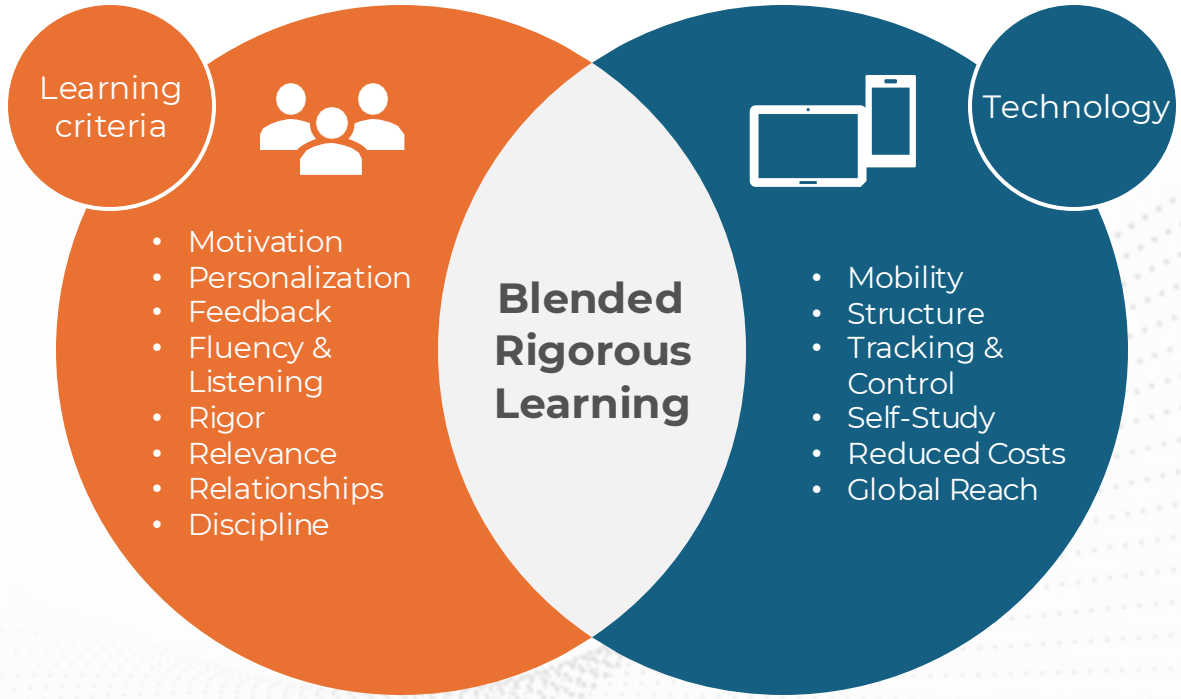
Blended learning formats in external education

- Optimal HCP learning often requires both digital and traditional formats to support optimal knowledge and clinical competency gains as recognized in 2017 by the American Medical Association (AMA) and the US Accreditation Council for Continuing Medical Education (ACCME)
- Blended learning is an educational format that features the benefits of both digital and traditional teaching methods
  - Supports learner's control over time, place, and path of some elements
  - Utilizes online learning, simulation, team training, and one-on-one coaching
  - Learners can review materials repeatedly and at their own pace for a customized learning experience



https://www.accme.org/highlights/amaaccme-alignment-providers-can-now-enter-activities-other-pars
https://www.ama-assn.org/press-center/press-releases/ama-accme-seek-comments-proposal-align-cme-requirements

Multiple channels are used by HCPs to access and share educational content

Social Media

Exchanging educational content by way of social media channels such as Linkedin, Sermo, X (formerly Twitter), Slack, YouTube, TikTok, and Facebook; the use of these platforms is expected to grow

Smartphone Applications

Smartphone apps, such as the Human Diagnosis Project (Human Dx), support easy access cases for rapid peer-review and dissemination

Open Access Conference

Open access conferences, such as Virtual Morning Report, welcomes live chat

Communities of Practice

Advancement of knowledge and skills, social networking, and sharing of experiences. Information exchange includes:

- Case-based learning
- Research sharing
- Topics relevant to a specific field
- Controversies
- Professional development
- Technical skills training
- Gamification and quizzes

Virtual Learning Communities

Online education and knowledge-sharing platforms to disseminate medical and public health knowledge, e.g., Project ECHO (Extension for Community Healthcare Outcomes):

- Real-time, multidirectional learning
- Collaborative learning, long-distance training, asynchronous or synchronous approach, and social networking on a global level
- Live discussion and problem solving
- Connects local, regional, and international specialists with academic medical centers, centers of excellence, and healthcare teams

Daniel J Minter, MD, Anand Patel, MD, Smitha Ganeshan, MD, MBA, Saman Nematollahi, MD. Medical Communities Go Virtual *J Hosp Med.* Published Online First October 8, 2020. DOI: 10.12788/jhm.3532.

External education must follow transparent, standardized processes to deliver objective content

Ethical, transparent, and responsible engagement

- **Transparency** with funding, roles and responsibilities, disclosure of interests, and potential conflicts
- **Non-promotional**
- **Compliance** with local laws, regulations, and local codes of practice, research ethics requirements, data protection legislation and copyright, and anti-bribery and corruption policies

Needs-based, up-to-date, balanced, and objective, quality content

- **Validated** by literature, scientific committee or an educational Needs Assessment
- **Scientifically fair and balanced**, current and evidence-based content
- **Adult learning principles** utilized
- **Relevant** to learners
- **Applicable** to clinical practice

Robust process to deliver educational programs

- **Structured policies and procedures** enforced by dedicated teams focusing on specialized functions to ensure best practices for implementation and quality control
  - Program and learning objectives
  - Effective format
  - Learning style
  - Experts to plan, develop, and review content
  - Conflict resolution
  - Outcomes measurement

Allen T, et al. *JECME*. 2017

1D

Execution

External education must continue to be agile to meet the needs of the evolving landscape

Unprecedented challenges impacted industry's ability to provide external education.
The current focus is on adapting to learners and their needs & environment

During the pandemic, rapid decisions were made for programs to be canceled, postponed, or go virtual. Afterward, the environment is still dynamic and adapting to a new reality (“new normal”)

Education providers are developing new innovative formats and platforms (e.g. AI, hybrid and virtual formats, mobile, on-demand)

Industry supporters are reevaluating strategy & impact of education aligned to learners needs

- When needed, Change of Scope process, addressing pandemics, and contingency plans are part of routine SOPs

Outcomes measures are used to assess impact of educational activities

- The World Health Organization (WHO) defines an outcome measure as a “change in the health of an individual, group of people,
- or population that is attributable to an intervention or series of interventions”
- Outcomes measures quantify changes in knowledge, competence or performance of learners and/or healthcare systems
- Education is planned with the intended outcome in mind
- Outcome measures provide information on whether educational activities had a quantifiable impact on clinical practice

Tinker, A. (2022) Top Seven Healthcare Outcome Measures and Three Measurement Essentials. https://www.healthcatalyst.com/insights/top-7-healthcare-outcome-measures

Considerations for outcomes measurement

- Quantitative or qualitative calculations are established with intent to evaluate level of change by educational intervention on degree of progress toward desired level of quality in knowledge, competence, and performance
- Comparing aggregate outcomes across different formats and therapeutic areas remains a challenge due to:
  - Data collection that varies across objectives, audiences, and activities, and may inherently be different by therapeutic area or program
  - The lack of consistency for standardized metrics beyond learner satisfaction
- A consistent approach provides standard evaluation for comparison of the value and impact of external education across therapeutic areas, types of activities, regions, and countries

http://almanac.acehp.org/p/bl/et/blogid=2&blogaid=681
Moore DE, Green JS, Gallis HA. *J Contin Educ Health Prof.* 2009:29(1):1–15

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Quantitative versus qualitative outcomes measures

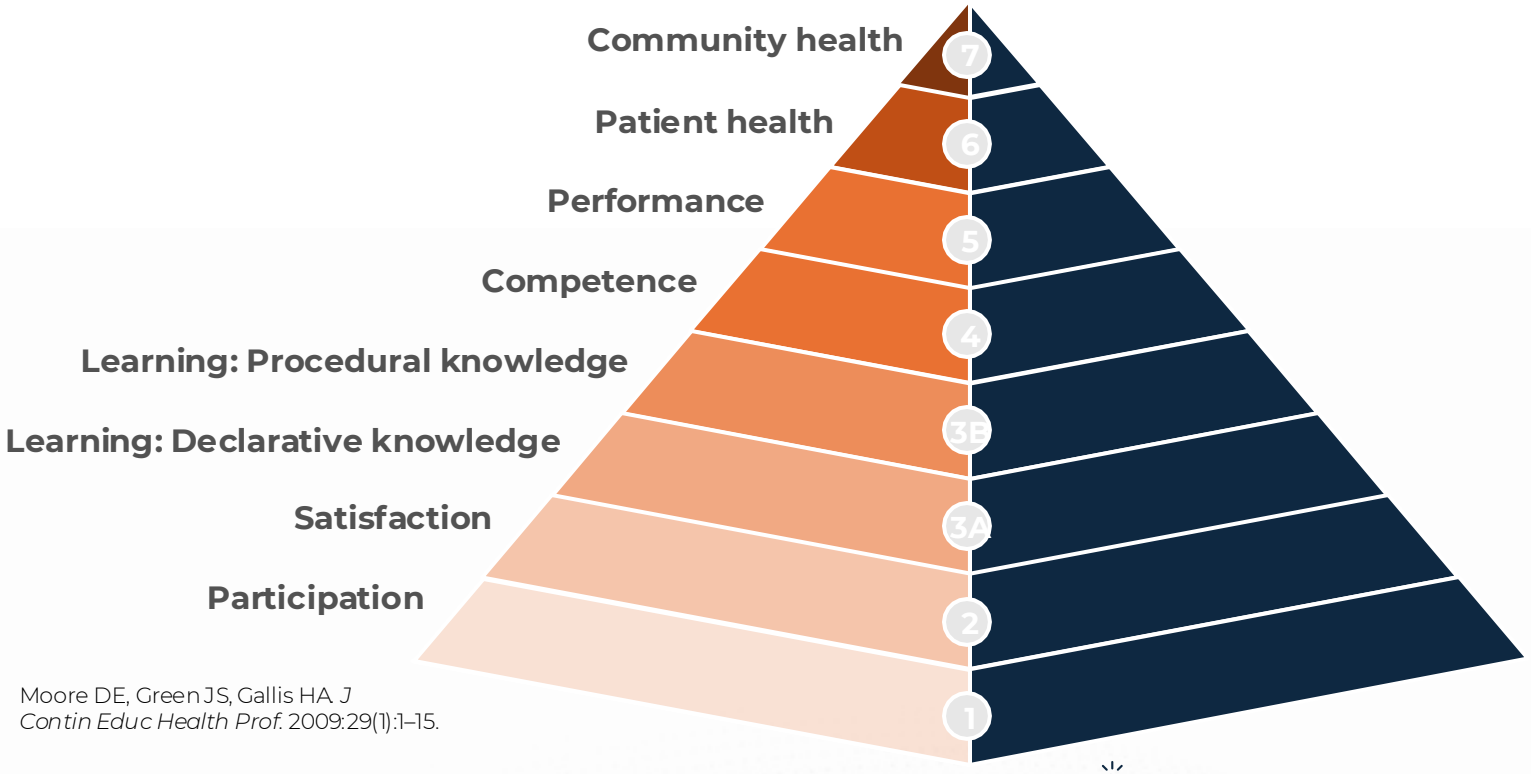
Quantitative Methods of Evaluation (measurable)

- Collection of data that can be analyzed using quantitative methods such as numbers, analysis based on facts and associated data, structured and statistical
- Examples include Electronic Medical Records (EMR) data, chart audits, quiz questions, pre- and post-test results

Qualitative Methods of Evaluation (descriptive)

- Qualitative measurement focuses on collecting information that is not numerical and provides a way of gaining a deeper understanding of a topic
- Examples include unstructured interviews, essays, focus groups, scenario discussions, self-reported personal experiences or introspection

Moore's Model: framework to assess outcomes of educational programs



Moore DE, Green JS, Gallis HA. *J Contin Educ Health Prof.* 2009:29(1):1–15.

Click each number starting at the top in the pyramid for further details

Description

Number of people who participated in the activity

Potential Data Sources

Attendance records

ACCME educational outcomes criteria

PERFORMANCE	HEALTHCARE QUALITY IMPROVEMENT	PATIENT or COMMUNITY IMPACT
Criterion 36: Measures performance changes of learners AND demonstrates improvements • The Standard: Attest to meeting this criterion in at least 10% of activities (but no less than two) during the accreditation term	Criterion 37: Demonstrate improvements in processes and quality of care, or system performance • The Standard: Demonstrate healthcare quality improvement related to the CME program twice during the accreditation term	Criterion 38: Demonstrate improvements in health-related outcomes for patients or their communities • The Standard: Demonstrate improvement in patient or community health in areas related to the CME program twice during the accreditation term

ACCME. The ACCME Accreditation Requirements. https://accme.org/wp-content/uploads/2024/05/626_20211221_Accreditation_Requirements.pdf. Accessed September 6, 2024.

1D

Concise overview of the educational process

Needs Assessment
- Identify and critically analyze the knowledge, attitude, and performance deficits to be addressed by the program

Goals & Objectives
- Develop overall goals for the program
- Define specific measurable knowledge, skill/performance, attitude, and process objectives

Implementation
- Create implementation plan (curriculum) including timelines and resources required
- Develop plan for faculty development

Targeted Needs Assessment
- Apply general Needs Assessment to targeted learners

Educational Strategies
- Prepare a plan to maximize the impact of the program, including content and educational methods congruent with the objectives

Evaluation & Feedback
- Develop learner and program evaluation plans
- Define plan to disseminate

Thomas PA, Kern DE. *J Gen Intern Med*. 2004. Schneiderhan J, et al. *Fam Med Com Health*. 2019.

Section Navigation

Click to navigate to the section you would like to visit

SECTION 2

RISK AND REGULATORY LANDSCAPE FOR EXTERNAL EDUCATION

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Section 2

Chapters

2A
Oversight & Scrutiny of Industry Support of Medical Education

2B
Actions to Mitigate Risk and Ensure Compliance

2C
Stakeholder Organizations that Impact Medical Education

Click a circle to navigate to the section you would like to visit

2A

Oversight & Scrutiny of Industry Support of Medical Education

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Oversight of external education

- Public scrutiny has led to new expectations and external oversight of Industry's interactions with HCPs, demanding an increase in transparency, credibility, value, accountability, and quality for the benefit of patients
- To ensure industry supported activities provide credible, accurate, and evidence-based communications to all stakeholders and audiences, oversight has been established and continues to evolve with Industry codes of practice, laws, regulations and internal company policies, procedures, and protocols
- Laws and regulations between Industry and their stakeholders are governed by global, regional, and local regulatory organizations
- Local laws and regulations are upheld by the regulatory bodies of individual countries, and enforcement varies from country to country

Francer J, et al. *Philos Ethics Humanit Med.* 2014.

2A

Background on the public scrutiny of Industry support of Medical Education

- Since the 1950s some industry advertisers, believing physicians needed to keep pace with new information, moved to educate physicians on the risks and benefits of their products
- Sales representative and marketing influence is believed to have resulted in over-prescribing
- Concern regarding Industry's role in inappropriately influencing and creating bias in physicians' knowledge
- In the late 1990s in the United States, Industry found opportunity in providing educational solutions, giving rise to numerous for-profit Medical Education/Communications organizations and providers
- Anti-bribery and anti-corruption legislation brought attention to transfers of value between Industry and healthcare professionals in exchange for benefits

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Global CME/CPD guidelines landscape

- Globally, there is minimal standardization of CME/CPD regarding:
  - A regulating body
  - Implementation guidelines
  - Quantifying and monitoring
  - Quality review and approval
  - Dependency on re-licensure
  - Voluntary or mandatory requirements
  - Consequences for non-compliance

- While there is currently a lack of harmonization across controls from country to country and among regulators and associations, organizations like ACCME, IFPMA, International Academy of CPD (IACPD), and the European Federation of Pharmaceutical Industries and Associations (EFPIA) are actively working to harmonize standards worldwide in the interest of optimizing patient health

Medical Affairs professionals must assess the risks associated with determining the global, regional, local, and corporate guidelines to be followed for all external medical education initiatives

Allen T, et al. *JECME*. 2017.

2A

Industry engagement in global external education continues to be scrutinized

Industry involvement in external education continues to be defined, regulated and watched closely to ensure appropriate use and to safeguard its non-promotional Needs Assessment, due to Industry involvement in:

Content development

Faculty selection

Collaborating with Medical Communications agencies and faculty

Overseeing the planning and conduct of events

Providing support/transfers of value

The industry's global insights and collective experience will continue to benefit healthcare professionals, patients, and communities in a transparent fashion

As the need for continuing professional development grows, the industry will be required to take a more structured and transparent stance to comply with regulatory demands

Allen T, et al. *JECME*. 2017.

2A

Industry and society collaboration for quality education

- Despite a long history of Industry and medical society collaboration in the interest of training and education to improve patient care, the relationship has been complex due to a lack of structure around roles, responsibilities, and appropriate content
- Industry is positioned to provide HCPs with accurate, fair, and objective product information use for appropriate clinical use, based on in-depth disease area knowledge and expertise in clinical development
- As new global codes of conduct, monitoring, and transparency requirements continue to evolve, Industry and not-for-profit medical societies can develop honor standards for transferring information for the goal of HCP education and patient health

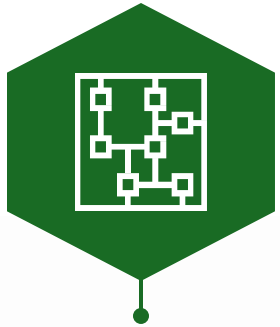
Allen T, et al. *J Eur CME*. 2017. Fabbri A, et al. *BMJ Open*. 2016.

2B

Actions to Mitigate Risk and Ensure Compliance

2B

Industry actions to mitigate risk and ensure compliance*



Governance

Provide appropriate oversight, accountability, and decision-making for external education activities to ensure effective risk management, strategic planning, and operational excellence

Policies

Implement robust policies and procedures and align to requirements defined in laws, regulations, accreditation standards, and industry codes

Monitoring

Perform ongoing monitoring to gain insights into whether external education activities are being conducted in compliance with company policies and procedures, laws, regulations, industry codes, etc.

*Note: Recommendations may not cover all circumstances; Medical Affairs teams should follow local policies, guidelines, processes, etc.

2B

Governance

Appropriate oversight and management of external education is needed

- Governance structures will vary across Industry (pharma & device) companies and there isn't a "one size fits all" approach; consideration should be given to company size, structure, and risk tolerance
- A set of overarching principles per policy & internal practice should be in place to set up global minimal standards within the company
- Review generally includes non-commercial functions (e.g., Medical, Compliance, Legal, Medical Education)
- Minimum standards for review and approval should be established for evaluating all requests to support independent Medical Education, external educational programs, and to develop Industry-led education
- Ensure objective criteria are defined and applied consistently to assess the merit of external educational activities, depending on activity type, may include:
  - Addressing appropriate gaps and needs
  - Providing high quality educational information
  - Ensuring appropriate faculty conduct and support
  - Tangible benefits for sponsorships

Minimum policy requirement examples for independent medical education

Industry support of Independent Medical Education

- Budget for grants must be owned by non-commercial function
- Grant decisions must not be made by commercial functions
- Education provider must independently control selection of program content, faculty, educational methods, and materials
- Company must not influence program content, faculty, educational methods, and materials
- Objective review criteria should be used to review requests for support
- Primary bona fide purpose is objective scientific and educational activities and discourse
- Applicable accreditation standards must be adhered to, if accredited educational activity
- Written letter of agreement
- Due diligence/screening of requestors
- Requested amount should be reasonable, as determined by local standards
- No tangible benefit
- Appropriate venue
- Reconciliation of funds
- Outcomes reporting
- Transparency/transfer of value disclosure

Minimum policy requirement examples for industry-led external education

Industry-led External Education

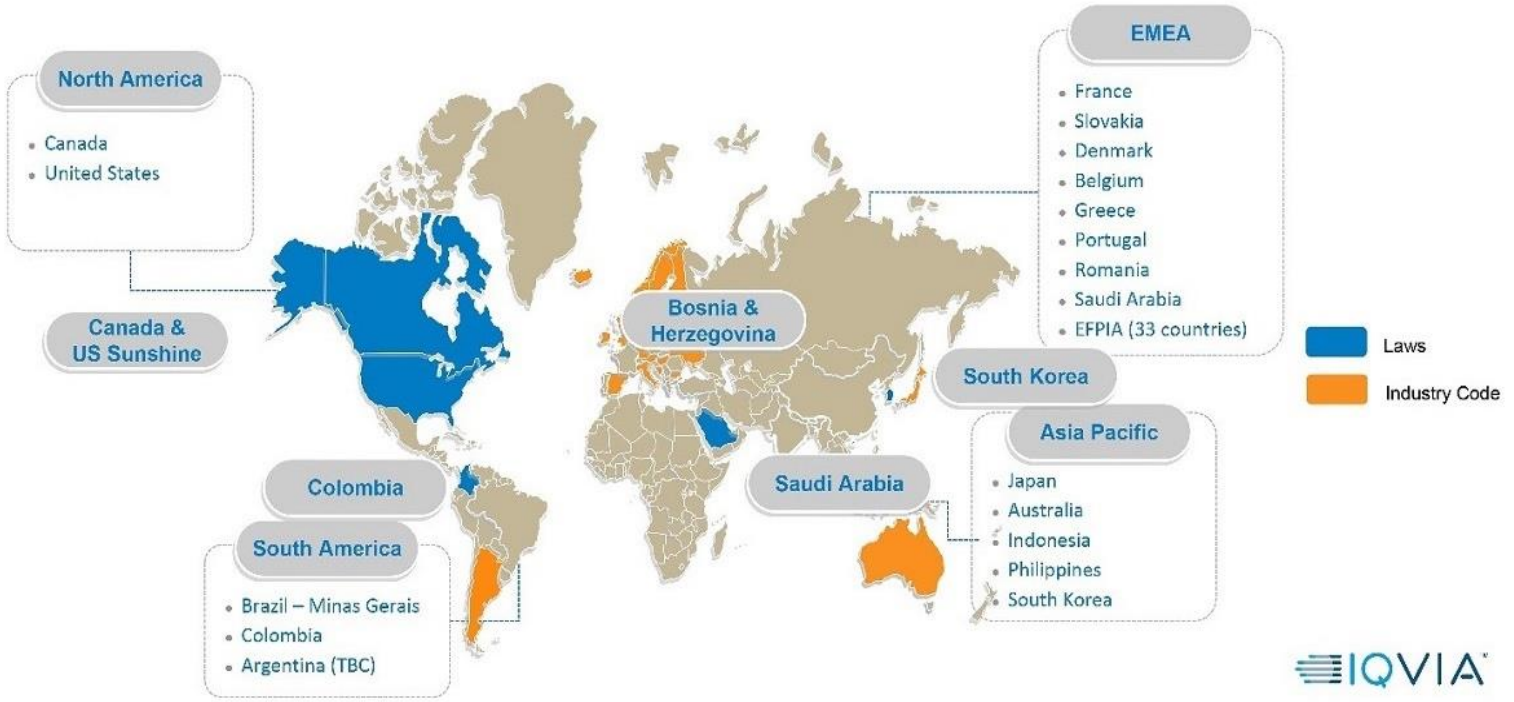
- Written agreement
- Due diligence on faculty
- Faculty selection criteria
- Fair market value compensation for faculty
- Employer notification requirements for faculty, according to local requirements
- Appropriate venue
- Logistical requirements (e.g., food and setting)
- Material review requirements
- Content must be aligned to local approved product label
- Transparency/transfer of value disclosure, according to regional/local requirements

Impact of Transparency Reporting Requirements

- Over the past several years, pharmaceutical and medical device companies have been faced with an increasing number of laws, regulations and industry codes of practice, worldwide, that require them to disclose their financial relationships with healthcare professionals and healthcare organizations
- Transparency began in the United States with state-level reporting and the passage of the federal Sunshine Act ("US Sunshine Act") in 2010
- The US Sunshine Act has had a significant impact on companies operating in the United States that have been designing and implementing spend-tracking systems to capture and report the required data
- Although the rest of the world has been influenced by the US Sunshine Act, governments outside the United States have chosen to pass their own transparency laws and various industry groups have adopted their own requirements on information to be disclosed including grants, honoraria for speaking engagements or consultancies, and other transfers of value
- Companies may consider implementing flexible transparency and spend-tracking systems on a global scale that simultaneously ensure compliance with US law while taking into account similar policies and legislation in other countries

https://www.lexology.com/library/detail.aspx?g=62469f5e-6cf4-48d2-99b7-6f47e4eda4a0

Global transparency reporting requirements



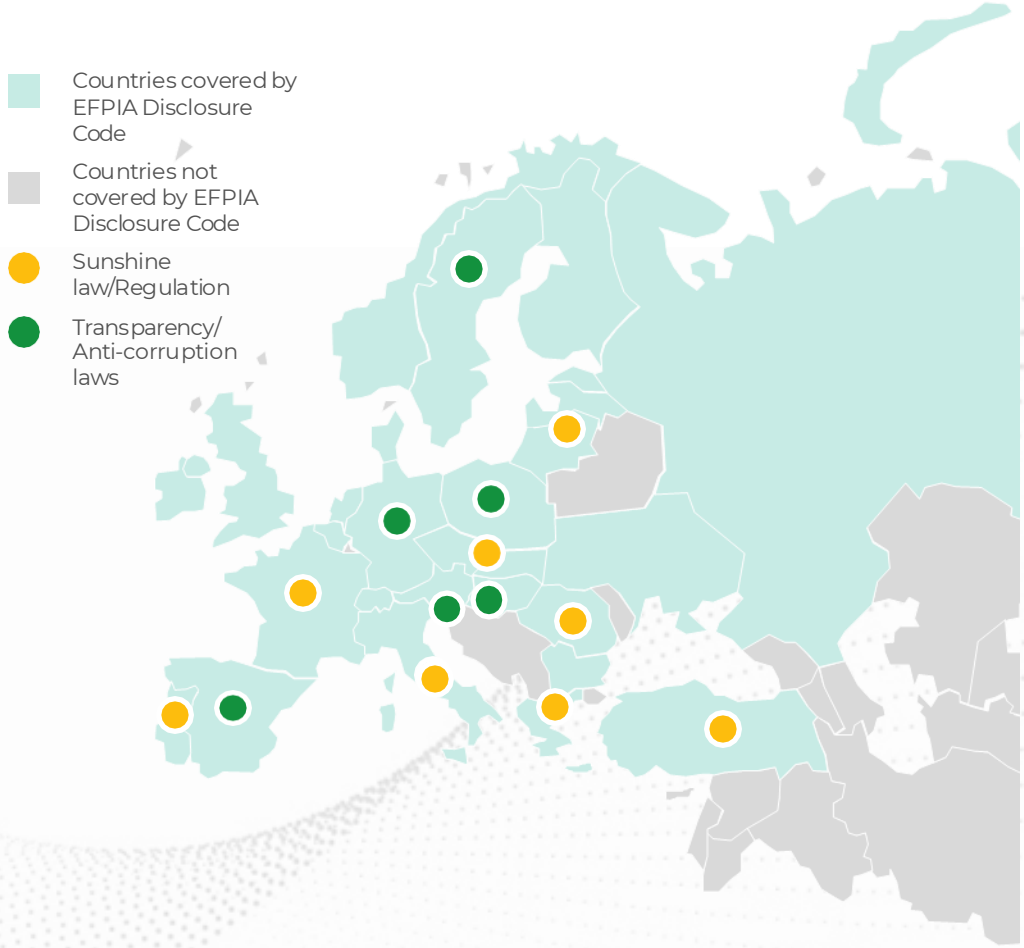
Countries continue to mandate specific regulations requiring transparency of transfers of value between HCPs, organizations, and industry.

The map to the left shows updates from 2019.
For further updates, see here

https://www.iqvia.com/blogs/2018/11/the-compliance-roadmap

Sunshine and transparency laws, regulations, and codes across Europe

- Transparency provisions vary across countries in the EU
- Most countries have adopted a self-regulatory relationship
- In 2013, The European Disclosure Code was implemented by the EFPIA requiring member companies to report transfer of value to HCPs
- Legally binding regulations have been introduced in Italy, France, Belgium, Greece, Portugal, Denmark, Romania, and Slovakia requiring HCPs to disclose transfer of value
- When HCPs can "opt-out" from disclosing individual data under the UK Data Protection Act 1998, reporting of payments are published in aggregate
- Differences exist in the types of payments included and excluded from reporting
- Location and searchability of the data varies and is often not user-friendly
- Monitoring is often passive and in reaction to a complaint



Fabbri A, et al. *Int J Health Policy Manag*. 2018. https://mhe-sme.org/wp-content/uploads/2017/09/Mapping-of-Sunshine-Laws-in-Europe.pdf
https://www.medispend.com/italy-transparency-reporting/

2B

Monitoring

Monitoring external education activities enables an ongoing assessment of potential compliance risks

Collaborate with internal compliance functions to establish monitoring approach, which will involve the ongoing review and analysis of data and documentation, and assess adherence to policies and procedures

Select samples of activities (e.g., grants, non-promotional speaking engagements, etc.) for review, utilizing a risk-based sampling approach (e.g., higher dollar requests, requests from specific countries (event locations), etc.)

Review supporting documentation (e.g., approval documents, contracts, payment documentation, materials/work product, etc., related to the activity to assess whether the activities were conducted in accordance with company policies and procedures

Leverage data analytics to provide insights into potential issues, for example:

- Grant amount as a percentage of the requesting organization's operating expenses
- Year-over-year trends

Results from monitoring may include the identification of potential violations of policies and may also highlight opportunities to enhance policies/procedures/guidelines and/or reinforce training/communications

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Complaint procedures

- Well established complaint procedures encourage organizations and the public to report concerns or questionable activities
- Industry typically first looks to resolve complaints through local affiliate or international headquarters in confidence, via its website for timely resolution
- While most national codes provide provisions for complaint reporting and resolution process, this process may vary from country to country, depending on local legal and regulatory restrictions. For example:
  - The ACCME has a multitiered accreditation process for evaluating CME providers' compliance with the ACCME's requirements. As an additional safeguard, the ACCME Policy Regarding Inquiries and Allegations of Noncompliance is used for responding to complaints from the public and the CME community, regarding ACCME-accredited providers' compliance with accreditation requirements
  - The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) has a well-established process and member companies are open to receive complaints from any source and take accountability for addressing and correcting infringements

IFPMA Complaint Procedure

Complaint to IFPMA Secretariat	
Complaint Validation by IFPMA Secretariat	
Possible Second Review by Appeal Group	
Inform Respondent Company	• Preferably within 5 working days from its receipt by IFPMA • 30 working days for company to respond
IFPMA Adjudication Group	• 20 working days from receipt of company response
Complaint Advised of Ruling	• Accepted • Appealed
Respondent Advised of Ruling	• Appealed • Accepted
IFPMA Appeal Group	• Appeal request within 20 working days of original ruling
Final Decision	
Breach	• With all details of the complaint
No Breach	• With details of the complaint without respondent company, product, and complainant
Summary of Case on IFPMA Website	

For more details visit https://www.ifpma.org

Francer J, et al. *Philosophy, Ethics, and Humanities in Medicine*. 2014.

Stakeholder Organizations that Impact Medical Education

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Stakeholder organizations impacting external education

*Note: Lists are not exhaustive

To view more information on each subsection, please click the arrow links

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Back to stakeholder overview

Regulatory Authorities

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2C

External regulatory agencies and laws

- Regulatory agencies play a vital role in interpreting laws, implementing, monitoring, and reinforcing the legalities related to drug development, which ensure the safety and efficacy of medicines and devices
- Regulatory agencies have continued to expand their authority largely due to tragic drug-related events that resulted in the demand for stronger laws and greater restrictions to protect the public
- Regulations may include guidelines, recommendations, procedures, or policies
- Regulations can be altered more easily and faster than laws
- Once approved, regulations may have power similar to the law
- Regulatory agencies can impose penalties, sanctions, or corrective actions as needed

https://www.pharmatutor.org/articles/pharmaceutical-regulatory-agencies-and-organizations-around-world-scope-challenges-in-drug-development
Pierre-Louis Lezotre MS, PhD, in International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations, 2014

Laws and regulations*

THE UNITED STATES DEPARTMENT of JUSTICE

US Foreign Corrupt Practices Act, 1977

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Advertising Guidance for Providers of Disease Education Activities, 2020
Therapeutic Good Act of 1989

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Compliance Program Guidance for Pharmaceutical Manufacturers, 2003 Special Fraud Alert: Speaker Programs, 2020

1970s | **1990s** | **2000s**

US False Claims Act, 1863
US Anti Kickback Statute, 1972
US Physician Payments Sunshine Act, 2010

Guidance for Industry: Industry-Supported Scientific and Educational Activities, 1997

FDA U.S. FOOD & DRUG ADMINISTRATION

UK Bribery Act, 2010

*Note: List is not exhaustive

2C

FDA guidance on industry-supported scientific and CME activities 1997

- FDA asserts regulatory authority over any scientific or educational activities supported by industry when content pertains to industry products with intent to influence
- FDA does not assert any regulatory authority over programs that are both independent and nonpromotional
- Factors used to determine independence:
  - Provider has full control of content and speaker selection
  - Disclosure provided regarding funding, significant relationships, discussion of unapproved product use
  - Focus of the activity and content is free from commercial influence or bias, and supports alternative treatments
  - Relationships that may influence content
  - Provider is also involved with product promotion
  - Provider demonstrates ability to meet standards of independence
  - Multiple presentations of the same activity
  - Audience selection with intent to influence
  - Opportunity for discussion
  - Additional dissemination of product information
  - Ancillary promotional activities nearby
  - Complaints made regarding efforts to influence content
- Written agreement of roles and responsibilities will support evidence of independence
- This guidance resulted in increased industry spending on independent CME, and paved the way for the growth of many medical education companies

Federal Register Vol. 62, No. 232 Wednesday, December 3, 1997
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/industry-supported-scientific-and-educational-activities

2C

US Office of Inspector General: 2003 Compliance Guidance

U.S. Department of Health and Human Services
Office of Inspector General

Considerations for Grant Making

- The focus of the OIG is to fight waste, fraud and abuse in Medicare, Medicaid and over 100 other programs under the Health and Human Services (HHS) institutions, including the Centers for Disease Control and Prevention, National Institutes of Health, and the Food and Drug Administration
- 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers describes three areas of risk:
  1. Payments
  2. Kick-backs
  3. Samples
- OIG recommendation related to medical education grants:
  - The grant making function is separate from sales/marketing
  - Grants must not be treated as incentives/kick-backs
  - Initiatives must be in place to ensure that they are independent of company control/influence
  - Grants must be in compliance with the PhRMA code

Federal Register Vol. 68, No. 86 Monday, May 5, 2003 [https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf]

2C

US Office of Inspector General: special fraud alert: speaker programs

Considerations for Faculty Programs

- The US Office of Inspector General (OIG) defines speaker programs to include company sponsored events at which a physician or other healthcare professional makes a speech or presentation to other HCPs about a drug, device product, or disease state on behalf of the company
- Speaker programs have historically:
  - Helped HCPs stay current on the benefits, risks, and appropriate use of the latest approved products, clinical data, and new indications
  - Provided a format for valuable exchange of information to improve patient care
- November 16, 2020, the OIG issued a Special Fraud Alert regarding industry-led speaker programs due to concerns regarding inherent risks for fraud and abuse OIG recommends:
  - Companies evaluate the need for paid speaker programs (in-person or virtual)
  - Speakers consider the associated risks of solicitation with these activities
- As in the past, associated risk is dependent on the facts, circumstances, and intent

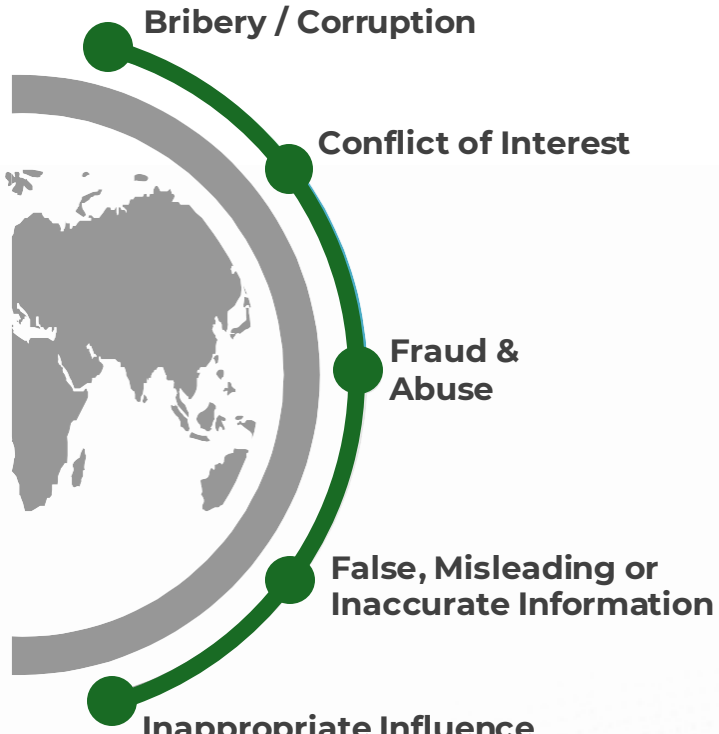
https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf

2C

Our Regulatory Environment

- Food, Drug and Cosmetic Act (FDCA):
  - Presentations promoting prescription products are regulated by the FDA
  - Content must be consistent with approved labeling, fair and balanced
- False Claims Act:
  - Intended to prevent, detect, and punish health care fraud and abuse
  - Liable provides for double the government's damages plus a penalty of $2,000 for each false claim
  - Violators are liable for damages plus a penalty that is linked to inflation
  - Presentations (including Disease State Programs) can be cited in a False Claims Act allegation if presenter engages in off-label promotion
- Federal Anti-Kickback Statute:
  - Prohibits "kickback" or the provision of anything of value to an HCP to induce continued or increased prescribing of a product

Possible consequences of non-compliance with regulations



Civil settlement with Purdue provides the United States with claim for recovery of $2.8 billion – October 2020

"…Purdue paid certain doctors ostensibly to provide educational talks to other healthcare professionals and serve as consultants, but in reality to induce them to prescribe more OxyContin…"

Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians – July 2020

"…the United States alleged that Novartis hosted tens of thousands of speaker programs and related events under the guise of providing educational content, when in fact the events served as nothing more than a means to provide bribes to doctors…"

Novartis, Alcon Pay $347 Million to Settle Bribery Probes in Greece, Vietnam and South Korea – June 2020

"…agreements announced Thursday detailed a scheme by the Novartis subsidiary, based in Greece, to bribe employees of Greek state-owned and state-controlled hospitals and clinics by sponsoring their travel to international medical conferences, including events held in the U.S.…."

Jazz Pharmaceuticals' subsidiary, Orphan Medical Inc., to pay $20 million to settle charges – July 2009

"…U.S. government alleged Jazz Pharmaceuticals' subsidiary, Orphan Medical Inc., paid a psychiatrist tens of thousands of dollars for speaking engagements that promoted a wide range of off-label indications. Some of these speaking engagements were characterized as independent CME programs, when in fact they were promotional events approved by Orphan's marketing department. …"

Back to stakeholder overview

Back to stakeholder overview

Industry/Trade Associations

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Organizations behind industry codes of practice*

Association of the British Pharmaceutical Industry (ABPI)
Established 1891
ABPI Code of Practice, 1958, regularly updated, most recent 2021

Korea Pharmaceutical Manufacturers Association (KPBMA)
Founded 1945
Code of Practices 2014

World Health Organization (WHO)
Established 1948
Ethical Criterial for Medicinal Drug Promotion 1988

Organization of Pharmaceutical Producers of India (OPPI)
Established 1965
OPPI Code of Practice, 2019

Established 1968
Latest Code of Practice, 2019

Japan Pharmaceutical Manufacturers Association (JPMA) Founded 1968
JPMA Latest Code of Practice, 2019

European Federation of Pharmaceutical Industries and Associations (EFPIA) Established 1978
Latest Code of Practice update in 2023

Advanced Medical Technology Association(AdvaMed) Established 1974
AdvaMed Code of Ethics, 2023

Founded 1914
Renamed Canadian Pharmaceutical Manufacturers Association, 1915
Renamed Medicines Canada, 2016, Code of Ethics Practices 2020

Pharmaceutical Research and Manufacturers of America (PhRMA)
Founded 1958
Code on Interactions With Healthcare Professionals 2009, Latest update 2022

Medicines Australia
Code of Conduct, 1960, revised on a regular basis, Edition 19 as of 2020

Singapore Association of Pharmaceutical Industries (SAPI)
Founded 1968
SAPI Code of Conduct 2012, 2016, 2019, 2020, 2021, 2022, 2023
Transparency Guidelines, 2015, 2018

Research and Development-based Pharmaceutical Association in China (RDPAC)
Established 1999
RDPAC Code of Practice, 1999, latest update in 2022

MedTech Europe
Established 2012
Code of Ethical Business Practice, 2017, latest update in 2022

*Note: List is not exhaustive

IFPMA Note for Guidance on CME

- CME activities, terminology, extent of industry involvement, accreditation status, infrastructure, and quality of activities vary greatly across regions and countries
- This Guidance supports cooperation amongst HCPs, industries, and other stakeholders and should be followed in accordance with laws, regulations, and other applicable industry codes
- The intent of CME is to provide HCPs with interventions that impact performance, improve patient outcomes, and do not aim to increase sales
- CME may be referred to as life-long learning, CDP, QI initiatives, or IME typically accredited
- Frameworks for industry engagement varies
  - Independent ME (IME/CME) can be funded by industry but the program, speakers, and content must be independent from industry involvement
  - Collaborative ME (partnership) may be provided by multiple industries or other stakeholders by written agreement indicating:
    - Clear intent and objectives
    - Defined roles and responsibilities
    - Transparency and disclosure of financial support
  - Industry-led ME may cover disease state or product specific topics

IFPMA International Federation of Pharmaceutical Manufacturers & Associations

IFPMA Note for Guidance on Continuing Medical Education. October 25, 2018

Council of Medical Specialty Societies – Code of Conduct

- The Council of Medical Specialty Societies (CMSS) is committed to education, professionalism, and quality of care, and has developed a voluntary code of conduct for Medical Specialty Societies to “enhance professionalism and to disclose, manage, and resolve relationships with the industry”
- **The Code for Interactions with Companies (2015) provides guidance to societies for the development of policies and procedures to maintain program, policy, and advocacy position independence**
- Societies can agree to the CODE and adopt the policies and procedures that meet their organizational needs, as well as incorporate additional and more stringent policies
- The Code is divided into Principles and Annotations
  - The Principles state what is expected of Societies that sign on to the Code
  - The Annotations provide current interpretation of a given Principle by explanation or example, based on a changing landscape

For more information visit https://cmss.org/wp-content/uploads/2016/02/CMSS-Code-for-Interactions-with-Companies-Approved-Revised-Version-4.13.15-with-Annotations-1.pdf

Back to stakeholder overview

Medical Education Societies

Medical Affairs Professional Society (MAPS)® 2024

Medical education societies*

amee
AN INTERNATIONAL ASSOCIATION FOR MEDICAL EDUCATION

1972

1970s

1990s

1976

The Alliance for Continuing Education in the Health Professions

Society for ACADEMIC Continuing Medical Education
LEADERSHIP • SCHOLARSHIP • COLLABORATION

1995

GAME
Global Alliance for Medical Education

*Note: List is not exhaustive

Association for Medical Education in Europe

- The Association for Medical Education in Europe (AMEE) has grown into a worldwide organization that promotes educational excellence for HCPs across the continuum of undergraduate, postgraduate, and continuing education
- Working with other organizations, AMEE develops new approaches to educational management, including learning methods and assessment techniques to ensure HCPs can keep up-to-date with rapidly evolving advances in medicine, and changes in healthcare delivery

For more information visit https://amee.org/links-and-resources

2C

Society for Academic Continuing Medical Education

- The Society for Academic Continuing Medical Education (SACME) is dedicated to advancing patient care through continuing medical and interprofessional education
- Society membership includes medical schools, academic medical centers, teaching hospitals, and medical specialty societies throughout the US and Canada
- SACME focuses on advancing CME through study of educational theory, striving to solve challenges, and providing an infrastructure to address competencies required for excellence in clinical practice

For more information visit https://sacme.org/

2C

Alliance for Continuing Education in the Health Professions

The Alliance for Continuing Education in the Health Professions

- The Alliance membership consists of over 1,400 continuing professional healthcare educators who share, promote, and implement best practices across healthcare settings and professions, validating the value and impact of continuous learning and improving patient outcomes
- The Alliance provides healthcare educators with an array of learning opportunities that meet different learning styles for professional development as well as a code of conduct for defined minimal competencies for various levels of certification to navigate challenges of educational delivery and support career advancement

For more information visit http://www.acehp.org/p/cm/ld/fid=1

Global Alliance for Medical Education

- The Global Alliance for Medical Education (GAME) has been promoting lifelong learning of HCPs and providing resources and supporting best practices and collaboration to improve healthcare worldwide
- GAME is obtaining worldwide membership through activities that include:
  - Engaging stakeholders that benefit from lifelong learning in healthcare
  - Providing opportunities and resources for evidence-based best practices
  - Addressing barriers and developing solutions to learning
  - Committing to inclusivity, credibility, integrity, and transparency

For more information visit https://www.gamecme.org/

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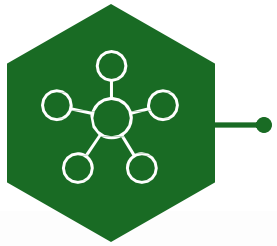
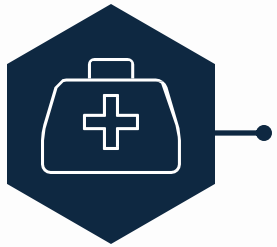
Accreditation Bodies

Medical Affairs Professional Society (MAPS)® 2024

Accreditation bodies for CME/CPD



Accreditation providers play a pivotal role in recognizing appropriate and unbiased CME programs, based on established criteria

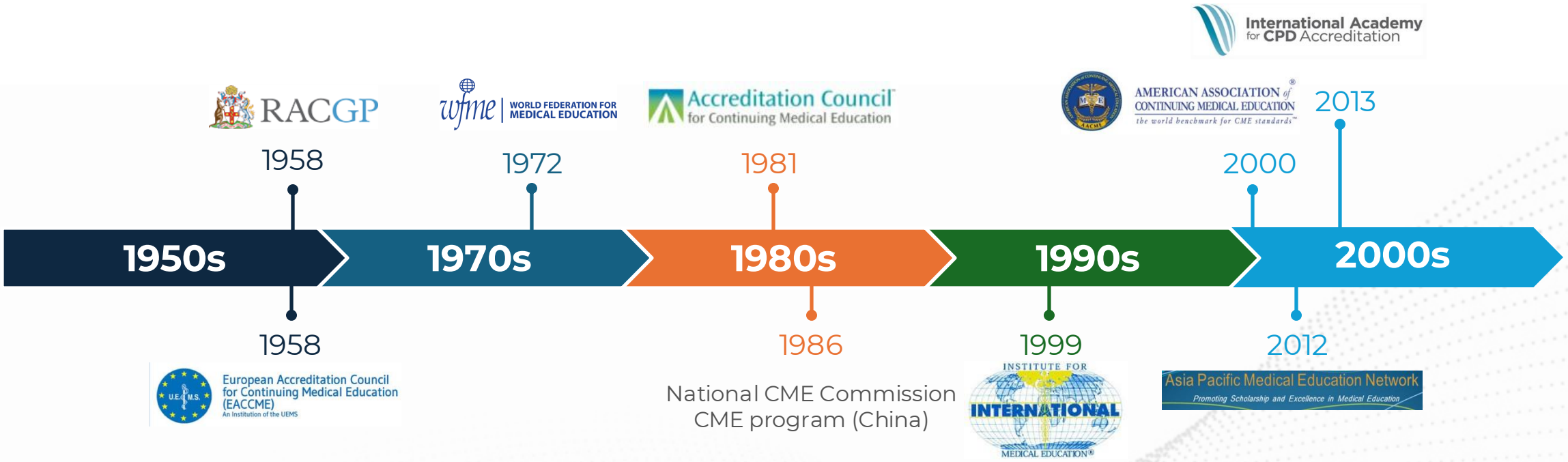


While CME accreditation systems vary regarding differences between countries and regions, socioeconomic conditions, cultures, resources, and healthcare delivery systems, CME credits are becoming increasingly necessary for physicians to fulfill statutory obligations to maintain competency, and stay current in an ever-changing healthcare landscape

The credibility of CME programs depends on delivery of unbiased education, requiring a continuous review and independent governance of activities

https://wfme.org/accreditation/
https://www.jointaccreditation.org//
https://www.leveragerx.com/blog/cme-for-physicians/
Allen T, et al. *J Eur CME*. 2017

Medical education accreditation bodies*



*Note: List is not exhaustive

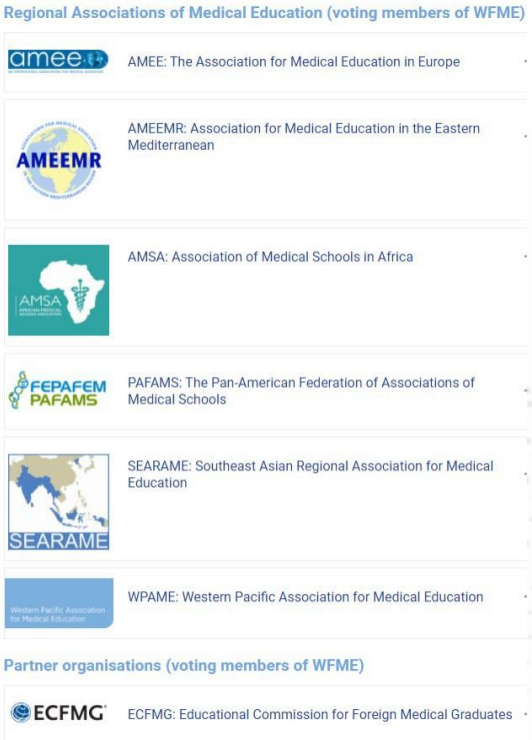
World Federation for Medical Education

wfme | WORLD FEDERATION FOR MEDICAL EDUCATION

- The World Federation for Medical Education (WFME) is focused on enhancing the quality of medical education worldwide by working with HCPs, educators, and universities through its 6 member associations to ensure the provision of medical education at its highest standards
- WFME promotes accreditation and raising the standards for postgraduate medical education and CPD through expert consensus of minimum and quality standards
- WFME maintains a searchable World Directory of Medical Schools [https://search.wdoms.org/]

For more details visit https://wfme.org/

Member Associations



2C

European Accreditation Council for Continuing Medical Education

European Accreditation Council for Continuing Medical Education (EACCME)
An Institution of the UEMS

- Initially named the Union Eurpoéenne des Médecins Spécialistes (UEMS) and later evolving into the European Accreditation Council for Continuing Medical Education (EACCME) in 2000, with the aim of encouraging the highest standards in the development, delivery, and harmonization of CME and CPD
- The EACCME provides accreditation of international CME in Europe and facilitates recognition of credits between the various European countries
- EACCME accredited events are recognized by most European countries, as well as the US and Canada
- The EACCME does not permit industry involvement due to concerns of conflicts of interest, and potential bias concerns

For more information visit https://eaccme.uems.eu/home.aspx

2C

Accreditation Council for Continuing Medical Education

- The ACCME is a nonprofit organization responsible for accrediting institutions and establishing the standards for CME accreditation providing HCPs with learning, teaching, and engagement opportunities independent from commercial bias to serve the healthcare needs of patients
- The ACCME was founded in 1981, to oversee the accreditation of institutions providing CME, and to promote improvement in physician performance and patient care
- The Standards for Commercial Support: Standards to Ensure Independence in CME Activities℠ were established in 1992, and updated in 2004 to:
  - Accredit institutions and organizations offering CME
  - Define criteria for evaluation of educational programs and ensure compliance with these standards
  - Develop methods for measuring the effectiveness

ACCME's seven founding member organizations include the:

- American Board of Medical Specialties (ABMS) [https://www.abms.org/]
- American Hospital Association (AHA) [https://www.aha.org/]
- American Medical Association (AMA) [https://www.ama-assn.org/]
- Association of American Medical Colleges (AAMC) [https://www.aamc.org/]
- Association for Hospital Medical Education (AHME) [https://www.ahme.org/]
- Council of Medical Specialty Societies (CMSS) [https://cmss.org/]
- Federation of State Medical Boards (FSMB) [https://www.fsmb.org/]

For more information visit https://www.accme.org/

Royal College of Physicians

- The Royal College of Physicians (RCP) core mission is to drive improvements in health and healthcare through advocacy, education and research
- The RCP has a truly global network, with nearly one-fifth of our members based in over 80 countries worldwide. Its work spans high-, middle- and low-income countries, ranging from accreditation work and guideline development in the Middle East to clinical skills workshops in rural Nigeria
- The Accreditation Unit at the RCP manages a range of accreditation programs, with the aim of improving the quality, safety and experience of patients and improving service delivery
- Standards are developed with a multi-professional group of clinicians, managers and patients and working to an accreditation pathway which involves self-assessment and quality improvement against the standards. *The Accreditation Unit also supports the quality assurance process and certification of endoscopy trainee practitioners*

Links to other Royal Colleges (not exhaustive):

- Royal Australian College of General Practitioners
- Royal College of Anesthetists
- Royal College of Dental Surgeons of Ontario
- Royal College of Dentists of Canada
- Royal College of Emergency Medicine
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologist

For more information visit RCP London/

2C

International Academy for CPD Accreditation

- The International Academy for CPD Accreditation (IACPD) promotes and enhances global CPD accreditation systems
- Serves as a platform to facilitate peer-to-peer support for leaders of CPD/CME accreditation systems and encourage networking, mentoring and interactions
- The IACPDA established the first standards for international guidelines for accreditation of CPD and CME for both physicians and healthcare teams
- The standards support substantive equivalency between accrediting bodies ensuring that accredited education meets the standards set for evidence-based content, educational design, outcomes measure, and independence from commercial influence

For more information visit https://academy4cpd-accreditation.org/standards-for- substantive-equivalency-between-cpd-cme-accreditation-systems/

2C

National CME Commission—China

- The CME program that began in China is controlled by CME commissions with oversight at national, provincial, and city levels
- Although no centralized platform containing all CME activities exists, CME is mandatory for all physicians
- The quantity and quality of CME programs vary by geographical areas, medical disciplines, and medical facilities due to the inequality of healthcare resource distribution
- The current system does not differentiate CME requirements or accreditation between physician generalists or specialists, nor between physicians, nurses, and pharmacists
- CME providers can be public institutions, universities, hospitals, accredited medical societies, and medical education companies
- Industry cannot develop or provide accreditation of its own programs; however, they can provide support through grants made directly to a provider
- Currently there is no regulation that describes what industry or medical device companies can or cannot do beyond sponsorship not biasing the educational activity

For more information visit https://www.gamecme.org/post/china-mekipedia-2017

Institute for International Medical Education

- The Institute for International Medical Education (IIME) was established to address unification and quality standards, as well as develop "global minimum essential (core) requirements" for physicians throughout the world
- The main goal of IIME is to assure that there is a baseline of acceptable training globally to remedy variable competency levels, based on worldwide differences in medical curricula
- The Global Minimum Essential Requirements specify the professional attitudes, knowledge, skills, and behavior of the universal value to the practice of medicine, and sets post-graduation expectations for students

For more information visit https://www.who.int/workforcealliance/members_partners/member_list/iime/en/

2C

The American Association of Continuing Medical Education

- The AACME was founded to uphold the highest standards in medical education, practice, and research, meeting or exceeding international standards through a voluntary, self-regulated system
- It is the world's largest accreditation organization, serving over 71 countries and supporting physicians (CME), dentists (CDE), pharmacists (CPE), nurses (CNE), and all other allied health professionals (CPD)
- Responsibilities include setting CME standards, validating organization competency, providing ongoing support, and promoting and improving methods for CME deliver
- Note that this is a different organization than the ACCME and does not offer AMA PRA Category 1 credit

For more information visit https://aacmet.org/

Asia Pacific Medical Education Network

- The Asia Pacific Medical Education Network (APMENet) was established to provide an Asia Pacific regional perspective on medical education, innovation, and scholarship in professional education
- The APMENet provides a platform for medical/health professional educators in the Asia Pacific region to initiate, facilitate, collaborative, and establish guidelines for fair and equitable compensation policies for activities
- The APMENet initiates and support projects and encourages experience exchange of member countries, and the sharing of resources
- Activities include undergraduate, postgraduate, or continuing education in medicine and allied health sciences throughout Asian (including Middle Eastern countries) and Australian continents

For more information visit https://sites.google.com/site/apmenet/home

Medical Affairs Professional Society (MAPS)® 2024

Section Navigation

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SECTION 3

INDEPENDENT MEDICAL EDUCATION

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Section 3

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Grant-Submission

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Click a circle to navigate to the section you would like to visit

Medical Affairs Professional Society (MAPS)® 2024

History of IME & Institutional Regulation in the US & Europe

3A

Introduction to accreditation bodies globally

- Currently, there is no global, centralized accreditation approach/process. There is significant variation from region- to-region and country-to-country, and CME requirements still do not exist in some countries. For example, in Europe, each country has its own CME/CPD system, (e.g., Royal College of Physicians – UK) and Health Authorities can also provide accreditation
- Governing bodies may either accredit organizations that provide continuing medical education for physicians (e.g., ACCME, ANCC) or accredit individual educational programs/activities/e-learning materials (e.g., ACPE, AAFP, EACCME)
- Several organizations are working toward unifying international standards in IME: The International Academy for CPD Accreditation (IACPDA) serves as a platform that facilitates peer-to-peer support for leaders of CPD/CME accreditation systems and encourages networking, mentoring and interactions about common issues. AMEE is currently assessing CPD systems in 4 continents
- *Note: List is not exhaustive.

ANCC
AMERICAN NURSES CREDENTIALING CENTER

Society for ACADEMIC Continuing Medical Education
LEADERSHIP • SCHOLARSHIP • COLLABORATION

Accreditation Council for Continuing Medical Education

European Accreditation Council for Continuing Medical Education (EACCME)
An Institution of the UEMS

fsmb FEDERATION OF STATE MEDICAL BOARDS

International Academy for CPD Accreditation

AMA

AAFP

ACPE ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

3A

The Flexner Report – The birth of modern medical education in the US

- In 1910, Abraham Flexner, an educator and expert in educational practices and member of the research staff of the Carnegie Foundation, conducted a survey to investigate the state of medical education in the United States and Canada
- The Flexner Report provided a critical review of over 150 medical schools and identified substandard and best characteristics for medical education, bringing about widespread reform

Along with philanthropic support to eliminate for-profit and proprietary institutions, the Flexner Report contributed to putting the US in a position of international dominance in medical education and scientific research

- The number of medical schools were reduced
- Prerequisites to enter medical school were increased
- Training focused on practicing in a scientific manner and was firmly based in human physiology and biochemistry, and ensured research protocols were established and followed
- Curricula was standardized with a formal instructional plan in a formal setting
- Physician quality has increased significantly, and the profession is well respected
- Medical schools are subject to state regulation with state oversight from the American Medical Association (AMA)

https://www.scielosp.org/article/ssm/content/raw/?resource_ssm_path=/media/assets/bwho/v80n7/a12v80n7.pdf
Stahnisch FW, Verhoef M. Evidence-Based Complementary and Alternative Medicine. 2012. Schindler S. The Transformation of American Medical Education: the Flexner Report. Case 3. Carnegie Foundation for the Advancement of Teaching. 1906.

American Medical Association CME

- Concerns regarding physician training in US medical schools in late twenties resulting in the first mandatory CME program in urology in 1934
- By 1957, the AMA established the initial guidelines for good medical practice, which were implemented over the next decade with state variations
- As other professional hospital and school associations questioned and debated the political influence of the AMA, the Accreditation Council for Continuing Medical Education (ACCME) was founded in 1981 as a nonprofit corporation

For detailed guidance on AMA CME procedures visit [https://www.ama-assn.org/education/ama-pra-credit-system/guidance-new-procedure-cme]

https://www.scielosp.org/article/ssm/content/raw/?resource_ssm_path=/media/assets/bwho/v80n7/a12v80n7.pdf
Stahnisch FW, Verhoef M. Evidence-Based Complementary and Alternative Medicine. 2012. Schindler S. The Transformation of American Medical Education: the Flexner Report. Case 3. Carnegie Foundation for the Advancement of Teaching. 1906.

3A

Less traditional CME programs: Performance Improvement CME

- In 2004, The AMA Council on Medical Education approved Performance Improvement (PI) CME activities based on evidence-based performance measures and QI interventions
- The PI CME activity is structured as a 3-stage process:
  - Learn the performance measures
  - Assess practice using the performance measures
  - Implement interventions to improve performance and utilize the same measures to evaluate change
- The activity or intervention focuses on clinical practice and may address structure, process, or outcome with direct implication for patient care

For more details on PI CME, visit [https://www.ama-assn.org/education/ama-pra-credit-system/performance-improvement-continuing-medical-education-pi-cme]

3A

Federation of State Medical Boards

- Founded in 1912, the Federation of State Medical Boards (FSMB) represents 71 state medical and osteopathic regulatory boards in the US with the focus of improving the long-term effectiveness and viability of the nation's state medical board system to achieve safe and high-quality healthcare
- The FSMB engages in educational and scientific research projects to expand public and medical professional knowledge and increase awareness of challenges impacting healthcare and its regulation
- FSMB Education Services provides educational tools and resources that enhance the quality of medical regulation and raise public awareness of the vital role of state medical boards
- The FSMB works to identify, develop, and implement CME activities that address content areas that include medical regulation, licensure, discipline, and advocacy and policy to promote public health, safety and welfare

For more information on FSMB CME accreditation services visit [https://www.fsmb.org/education/apply-for-cme/]

Maintenance of Certification in the US

- Maintenance of certification (MOC) is a continuous learning and testing process that aims to ensure that physicians keep abreast of the latest medical knowledge, develop improved practice systems, and show a commitment to lifelong learning through a series of varied educational opportunities
- In 2002, the American Board of Specialties (ABMS) mandated that physicians must complete MOC to maintain board certification through one of 24 approved medical specialty boards of the ABMS, and the 18 approved medical specialty boards of the AOA
- The MOC, also known as Continuing Certification or Continuous Certification, continues to evolve and each certifying board chooses the name of its own program
- The MOC program requirements address six core competencies:
  - Practice-based learning and improvement
  - Patient care and procedural skills
  - Systems-based practice
  - Medical knowledge
  - Interpersonal and communication skills
  - Professionalism
- The MOC process is controversial with proponents believing it improves physician knowledge and demonstrates lifelong commitment to learning; critics claim it is a burdensome and irrelevant process created for financial interest to benefit the ABMS and AOA
- MOC critics also argue that CME can provide the same degree of education and ensure that physicians are up-to-date and participating in lifelong knowledge acquisition, without the burden of MOC and with greater flexibility

American Board of Medical Specialties
Higher standards. Better care.®

https://www.abms.org/media/1109/standards-for-the-abms-program-for-moc-final.pdf Kempen PM. JCHIMP. 2013

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5753319/

3A

Medicare Access and CHIP Reauthorization Act (MACRA): Learning impact and behavior change at the team, organization, and system level, not just individual level

- The **Medicare Access and CHIP Reauthorization Act** of 2015 (**MACRA**) established the **Quality Payment Program** for eligible clinicians
- Under the Quality Payment Program, eligible clinicians can participate via one of two tracks:
- Advanced Alternative Payment Models (APMs)
- Merit-based Incentive Payment System (MIPS)
- CMS released proposed the 2018 MACRA Rule on June 20, 2017 to now include QI CME as **an acceptable Continuous Performance Improvement Activity (CPIA)** as part of the Quality Payment Program requirement under alternative payment modules
- **QI proposals must meet all of the following criteria:**
  - ✓ Address specific Quality Priorities
  - ✓ Improve systems of care
  - ✓ Improve the quality of patient care by integrating system level, actionable outcomes
  - ✓ Incorporates educational intervention(s)
  - ✓ Results in real-world data reporting
  - ✓ Share results via publication or dissemination of findings
- Supports **HHS Agency for Healthcare Research and Quality (AHRQ) Needs Assessment Quality Strategy** AND the **Institute for Healthcare Improvement's (IHI) Triple Aim** to improve health system performance measures or quality indicators **aligned to National Quality Priorities** (Table 1)
- Incorporates elements of IITs (research methodology/design, real world evidence, publications,) plus Medical Education (educational intervention, adult learning principles)
- Annual Med Ed Industry Benchmarking Survey across 23 Med Ed Depts (pharma, device and biotech) in 2017 revealed that 67% of the respondents support Quality Improvement Education (QIE) to close quality gaps within health system, IDNs, ACOs

Table 1. National Quality Strategies Priorities

Making care safer by reducing harm caused in the delivery of care	Ensuring that each person and family is engaged as partners in their care
Promoting effective communication and coordination of care	Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease
Working with communities to promote wide use of best practices to enable healthy living	Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models

Annual Med Ed Industry Benchmarking Survey across 23 Med Ed Depts (pharma, device and biotech) in 2017 revealed that 67% of the respondents support Quality Improvement Education (QIE) to close quality gaps within health system, IDNs, ACOs

The Society for Academic Continuing Medical Education

- CME was increasingly funded by industry raising concerns for biased information, which led to the creation of the Society for Academic Continuing Medical Education (SACME) to represent medical associations and academic institutions in the US, Canada, Great Britain, and Europe
- The SACME was founded in 1976 to improve patient care through CME
- Current membership includes over 300 members from medical schools, academic medical centers, teaching hospitals, and medical specialty societies in the US and Canada
- SACME activities evolve around delivering excellence in continuing education to better serve patient care by:
  - Advancing the theory and evidence to improve continuing education
  - Studying, planning, implementing, and evaluating programs and activities
  - Collaborating to solve challenges in continuing education
  - Supporting scholarship and dissemination of continuing education
  - Addressing professional competencies

For more details about SACME policies and bylaws visit [https://www.sacme.org/About]

3A

Accreditation Council for Continuing Medical Education

- Today, CME for physicians in the US is regulated by the Accreditation Council for Continuing Medical Education (ACCME) and the American Osteopathic Association (AOA); the accredited CME addresses every medical specialty
- As of December 2020, the Standards for Integrity and Independence in Accredited Continuing Education have been newly designed to:
  - Ensure that accredited CME serves the needs of patients and the public
  - Provide only accurate, balanced, scientifically justified recommendations
  - Assure HCPs receive trustworthy education to support delivery of safe, effective, cost-effective, and compassionate care based on best practices and evidence
  - Create a clear separation between accredited CME and marketing and sales
- In addition to the ACCME, the following accreditation bodies have adopted the new Standards including:
- American Nurses Credentialing Center (ANCC) [https://www.nursingworld.org/ancc/]
  - Accreditation Council for Pharmacy Education (ACEP) [https://www.acpe-accredit.org/]
  - Association of Regulatory Boards of Optometry's Council on Optometric Practitioner Education (ARBO/COPE) [https://www.arbo.org/]
  - American Academy of Family Physicians (AAFP) [https://www.aafp.org/home.html]
  - Joint Accreditation for Interprofessional Continuing Education (IPCE) [https://www.jointaccreditation.org/]
- The ACCME supports over 1,700 CME providers of accrediting organizations in the US and around the world
- The ACCME accredits organizations from Canada, Korea, Pakistan, Qatar, Saudi Arabia, and the United Kingdom

For more information visit [https://www.accme.org/]

Eligibility for accreditation

- The ACCME accredits organizations to provide CME for physicians based on clear criteria, but does not provide accreditation of individual educational activities
- For an organization to be eligible for accreditation, they must:
  - Provide clinical services directly to patients
  - Function to educate healthcare professionals
  - Serve as fiduciary to patients, the public, or population health; and other organizations that are not otherwise ineligible
- Eligible organizations include:
  - Ambulatory procedure centers
  - Blood banks
  - Diagnostic labs that do not sell proprietary products
  - Electronic health records companies
  - Government or military agencies
  - Group medical practices
  - Health law firms
  - Health profession membership organizations
  - Hospitals or healthcare delivery systems
  - Infusion centers
  - Insurance or managed care companies
  - Nursing homes
  - Pharmacies that do not manufacture proprietary compounds
  - Publishing or education companies
  - Rehabilitation centers
  - Schools of medicine or health science universities
  - Software or game developers

For more information visit [https://www.accme.org/]

3A

ACCME standards for integrity & independence in accredited continuing education

- The new ACCME standards (effective January 2022) address new and existing challenges based on the complexities around disclosure, and the separation of education and marketing
- A toolkit of resources for transitioning to the new standards can be found here
- The ACCME's Substantial Equivalency program recognizes a CME/CPD accreditation system as being substantially equivalent, based on significant commonality with some differences expected and accepted

STANDARD 1:	STANDARD 2:	STANDARD 3:	STANDARD 4:	STANDARD 5:
Ensure content is valid	Prevent commercial bias and marketing in accredited continuing education	Identify, mitigate, and disclose relevant financial relationships	Manage commercial support appropriately	Manage ancillary activities offered in conjunction with accredited continuing education

For details regarding Substantive Equivalency visit [https://accme.org/about-accreditation/colleague-accreditors/international-accreditors/]

3A

ACCME Standard 4: Managing commercial support appropriately

- Standard 4 applies to accredited continuing education that receives financial or in-kind support from industry
- Accredited providers that choose to accept ***commercial support**** are responsible for ensuring that the education remains independent of the supporting company
  - Support must <u>not</u> result in commercial bias or commercial influence, or establish a financial relationship between the company and planners, faculty, and others in control of content
  - The accredited provider must make all decisions regarding the receipt and disbursement of the commercial support
    - Supporting companies must not pay directly for any of the expenses related to the education or the learners
    - The accredited provider may use commercial support to fund honoraria or travel expenses of planners, faculty, and others in control of content, but may <u>not</u> use commercial support to pay for travel, lodging, honoraria, or personal expenses for individual or group of learners
    - Commercial support may be used to reduce or eliminate the cost of the education for all learners
- The terms, conditions, and purposes of the commercial support must be documented in an agreement between the supporting company and the accredited provider prior to the activity
- The accredited provider must keep a record of the details of commercial support received and its use, and disclose the names of the commercial supporter(s) and the kind of support provided without use of product logos, trade names, or product group messages

Accreditation Council for Continuing Medical Education

*Financial or in-kind support from ineligible companies https://www.accme.org/accreditation-rules/standards-for-commercial-support.

3A

The Accreditation Council for Pharmacy Education

- The ACPE was originally founded as the American Council on Pharmaceutical Education (ACPE) in 1932, before changing its name in 2003
- The ACPE established the standards for pharmacist education and is recognized by the US Department on Education as the national agency for the accreditation of professional degree programs in pharmacy
- ACPE's Continuing Education Provider Accreditation Program is designed to assure pharmacists, boards of pharmacy, and other members of pharmacy's community of interests, of the quality of continuing pharmacy education programs
- Along with the American Society of Health-System Pharmacists, the ACPE accredits pharmacy technician education and training programs
- In 2011, the ACPE's International Services Program (ISP) secured the ACPE's ability to assist international stakeholders seeking guidance related to quality assurance and advancement of pharmacy education

For more details about the ACPE accreditation program visit [https://www.acpe-accredit.org/continuing-education-provider-accreditation/]

3A

Accreditor: American Academy of Family Physicians

- Through the American Academy of Family Physicians (AAFP) Credit System, CME providers may apply for AAFP credit for CME activities
- The Commission on Continuing Professional Development (COCPD) reviews eligibility requirements to ensure that AAFP credit is awarded to activities that are appropriate for AAFP members
- CME providers must comply with the ACCME Standards for Integrity & Independence in Accredited Continuing Education and state the activity meets all requirements, whether the activity is being supported with commercial funding or not
- In addition to live activities, the AAFP offers a variety of CME activity formats including knowledge self-assessment, enduring materials, medical journals, PI, point-of-care, and bended learning
- The AAFP offers CME providers templates and check lists to navigate through the process

For more details about the AAFP Credit System visit [https://www.aafp.org/cme/credit-system.html]

AMA & UEMS-EACCME collaboration

- The European Union of Medical Specialists (UEMS)- EACCME reached an agreement in 2000 concerning mutual recognition of credits with the AMA for live educational events and e-learning materials, which was renewed in 2018 for an additional 4 years
- Both organizations are fully responsible for the activities taking place or organized. The UEMS- EACCME is the central body for accrediting events in Europe, and the AMA is the central body for recognition of CME credits in the US
- E-learning activities need to be certified for credit by the process in place where the CME provider is based, i.e., AMA PRA Category 1 Credit for US CME providers and European CME Credits (ECMEC®)credit for organizations in countries that are represented by the UEMS

3A

Accreditation Bodies support Lifelong Learning: A UK Example: The General Pharmaceutical Council

General Pharmaceutical Council

- The General Pharmaceutical Council (GPhC) regulates pharmacists, pharmacy technicians and registered pharmacies in Great Britain. The GPHC established a set of standards that every pharmacy professional is accountable for meeting.
- Of the nine standards, Standard#4 requires Pharmacy professionals to maintain, develop and use their professional knowledge and skills. More specifically:
  - A pharmacy professional's knowledge and skills must develop over the course of their career to reflect the changing nature of healthcare, the population they provide care to and the roles they carry out. Examples of number of ways to meet this standard include carrying out a range of CPD activities relevant to their practice and recording development activities to demonstrate that their knowledge and skills are up-to-date

https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf

3A

Geographic application and global transfer considerations for IME

Increasing digitization in external education is allowing greater geographic mix of far larger audiences

- Consideration needed of IME Programs with globally transferable content, which is applicable across multiple countries and regions
- Such content needs to be carefully balanced with varying national and legal frameworks for the regulation of medical education
- Similarly, the global transfer of IME accreditation and CME credits remains a challenging frontier. Strategies for multi- accreditation may need support to encompass greater geographical reach of IME Programs

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Grant Operations

Overview of grant-making function

Location of grant-making function varies across organizations and typically resides within the Medical division. This function must never report into Commercial team/function per OIG 2003 Guidance to Manufacturers. Depending on several factors, such as company size, risk tolerance, etc., portions of grant-making function may reside in Finance, Legal Affairs or Compliance.

The Medical Affairs organization structure is evolving. New functions/models are being created within Medical Affairs where grant-making team/personnel may interact reside, such as: Medical Excellence, Medical Customer Engagement, Digital Medical Capabilities, External Partnerships and Strategic Alliances

There are different models/structures for Grant's team/function including but not limited to: centralized grants function versus decentralized versus hybrid model. The current trend is companies are looking to centralize or utilize common systems and processes to gain broader oversight and understanding into how funds are used to support enterprise-wide education

IME budgets are typically set annually and based on strategy/educational objectives. Size of budget should be proportional to achieve the defined educational objectives. An IME grants budget should not be owned or managed by Commercial (sales and marketing). Transfers of funding in or out of the IME budget may require significant, documented justification and appropriate approvals

3B

Centralized versus decentralized structures for grant-making function

Centralized

- Global Grants office defines annual strategy and budget and controls a single, global grants system/portal and facilitates grant reviews/meetings
- Grant requests (regardless of requestor location) are submitted to central grants system/portal and triaged by Global Grants Coordinator(s)/Manager(s)
- Regardless of the format for the educational activity (e.g., symposia, live events, virtual programs, etc.), grants are managed by the Global Grants office
- Global Grant Coordinator(s)/Manager(s) organizes and facilitates relevant Medical, Legal, and/or Compliance reviews to make funding decisions

Decentralized

- Grants are managed by local operating company/unit via a local grants personnel that defines strategy and budget and facilitates grant reviews meetings
- Grant requests are submitted via a local grants portal/system or via email to the local grants personnel in the country of the requestor's location
- For educational activities which impact multiple countries, local grants personnel liaise with counterparts in the other countries

Hybrid

- Global Grants office controls a single, global grants system/portal. Either the global group or the affiliate countries define annual strategy and budget
- All grants go through central grants system/ portal and are triaged. If the education is purely local the grant is managed by the country. If more than one country, should have process for coordination with all regions involved
- Affiliate countries must first seek local approval (e.g., Medical, Legal and/or Compliance) for grants and then regional approval (to avoid duplication and ensure alignment with strategy)
- Education accredited by or taking place on the soil of a specific region is managed by that region

3B

Key advantages for centralized/hybrid grants administration

- Ensure consistent management, review/approval and funding of grant requests while allowing for local input into strategy and decision-making
- Confirm request/grant type, ensure the completeness of the supporting documentation and where appropriate, triage the request for management review
- Support coordination and monitoring the completion and retention of control documentation related to grants and sponsorships
- Efficiently track incoming requests and mitigate risk of duplicate requests submitted to multiple entities and functional areas
- Enhance transparency across the company and functional areas involved in grants and sponsorships

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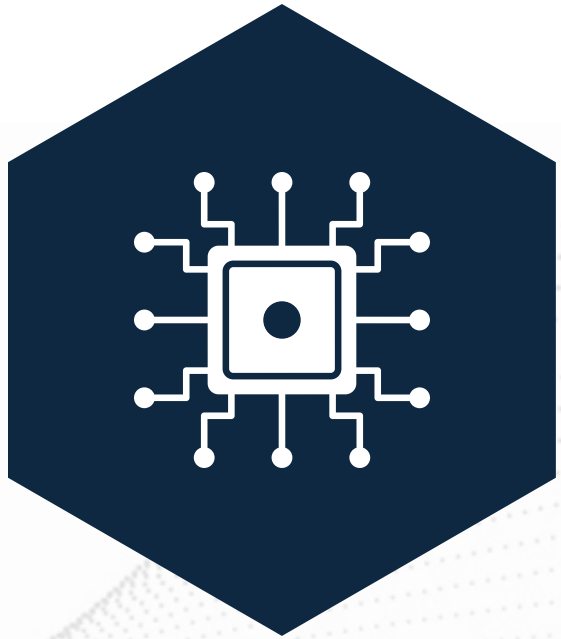
3B

Overview of grant management platforms

- Grant-making operations have become more complex to manage, as educational activities are reaching audiences across borders, in an evolving regulatory landscape
- Many mid-size and large global companies are leveraging technology solutions to automate the end-to-end grant management process from intake to review, approval, payment, and reconciliation
- Smaller companies who manage grants via email still need to have standardized process and submission component to ensure transparency and compliance
- Emerging trend for companies to leverage a single global technology solution/platform to manage all types of industry support, e.g., IME grants, sponsorships, corporate memberships, investigator- initiated studies, individual patient expanded access requests, charitable donations/contributions



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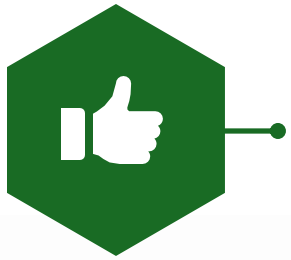
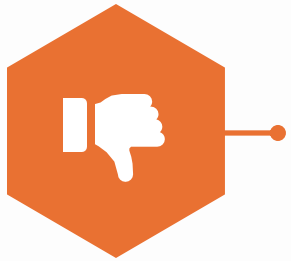
Comparison of grants platform solutions



Pros



Cons

Homegrown (Custom) Solutions

Pros

- Specifically tailored to meet specific business needs

Cons

- Starting from scratch
- Lengthy implementations/limited process coverage
- Significant resource commitment from business functions/subject matter experts
- Expensive support and maintenance
- Significant investments to address changes
- Risk of having an “outdated” system quickly
- Any subsequent systems-upgrade can negatively impact functionality

Commercial Off-the-shelf Solutions

Pros

- Reduced cost
- Shorter timelines for implementation
- Leverages best practices

Cons

- Need to customize/tailor the solution to your business needs
- Expensive maintenance when customized
- Changes subject to vendors’ release cycle

Advantages of grants platform solutions

Key Functionalities/ Capabilities	• Global solution that manages all types of industry support beyond IME grants (e.g., investigator-initiated studies, charitable contributions, sponsorships, etc.) • Mobile-enabled • Multi-language/translation capabilities • Centralized document repository • Seamless integration with corporate website to facilitate user-friendly/easy online registration • Capture review decisions • Flexibility to facilitate electronic reviews or live reviews expedited approvals	• Clear approval parameters • Role-based access rights • Automated workflows • Configurable dashboards • Global oversight and consistency across all locations • Reporting functionalities • Integration with other existing solutions e.g., transparency reporting tool, contract management system, etc. • Automated compliance controls • Enable enterprise-wide visibility into activities/support globally
Key Benefits from a Requestor's Perspective	• Save time with request submissions • User-friendly and easy to use • Visibility into request status • Accessible with a single login	• Automated communications • Online support • Mobile-enabled • Faster review and approval

3B

Examples of grants platform solution providers

pwc

IQVIA

CyberGrants

benevity

ENVISION PHARMA GROUP

SteepRock

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Grant-Submission

3C

IME pre-grant submission guidelines

Independent medical education supported through grant funding is planned and implemented without the influence or control of the industry supporter

Industry funding should support diversified activities across multiple education providers

To help mitigate any perception of influence or bias industry, when possible, should support activities with multiple funding sources

Activities supported should incorporate key principles of independent medical education including an ethical, transparent, and responsible approach, aimed at providing fair, balanced, and objective content

Requests for funding are channeled through a review and approval process that is compliant with industry codes and established laws and regulations

IME grant submission overview

- Grants requests can be submitted by external education providers, or submitted in response to a formalized Call for Grants (CFG)/Request for Proposals (RFP)/Call for Grant Applications (CGA)
- The intent of the CGA/RFP is to provide public notice to potential grant applicants of the availability of funds in a strategic area of interest for the company while preserving the independence of the requestor to independently develop the content of the program
- Industry using different tactics allowing some flexibility which preserves independence of the educational provider such as RFPs/CGAs, letters of intent, general concepts, information on websites, capabilities related to new technology in order to save time and search for alignment
- Funding Independent Needs Assessments and extensive information-gathering may be used to inform an independent medical education strategy. Companies receive grant requests aligned with the strategy, either spontaneously or in response to a CGA/RFP

3C

IME pre-grant submission: communicating areas of interest and funding availability

- Companies communicate interest in financially supporting IME in a specific field through posting of therapeutic areas of interest or educational gaps
- CGAs/RFPs are based on an assessment of gaps identified by relevant literature and/or in consultation with an appropriate scientific committee
- A dedicated online portal is often the most appropriate way to raise awareness of CGA/RFP without the misconception of solicitating participation
- One approach is to co-create and execute an RFP in collaboration with an external partner that shares similar goals in improving specific aspects of patient care
- Portals present a range of calls for grant submissions, open calls or focused funding rounds

An effective on-line platform should:

- Offer a clear distinction of CGA/RFP by disease area
- Provide sufficient information made readily available to prospective applicants
- Provide a standardized format for transparency and clarity
- Present clear and transparent company funding information

Examples of industry grant information websites

Grant submission timelines

Grant applications and supporting documentation should be received by the company in enough time to review prior to the start date of the IME program to ensure timely evaluation (e.g., at least 45 to 60 days)

Grant submissions may be rolling throughout the calendar year, or focused within specific application windows

- ”Rolling Submission” grant applications are accepted throughout the year with no deadline
- Specific time-sensitive application windows support a selection process that offers companies greater strategic focus and alignment
- A mix of both approaches can maximize strategic focus and allow greater reach throughout the year
- The best approach will depend on the specific strategic priorities, internal practices, and therapeutic areas of interest

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3C

Appropriate communication principles to ensure independence

- Transparent, fair, and equal communication with providers throughout the application process is essential to ensure efficient and compliant practices
- Email communication from prospective grant applicants seeking to bypass the formal grant application process must be redirected to follow the standard process
    - Inform grant applicants of the formal process and provide relevant information for the preparation and submission of application
    - Responses should be a standardized format within the company to mitigate any perception of inappropriate solicitation of an application
- Only IME Associates should communicate information to a requesting organization as this may be perceived as undue influence on the proposed activity. It is appropriate to obtain missing or incomplete information but for informational purposes only

3C

Key guidelines for company employees

Medical personnel may engage in unsolicited discussions with an external organization to understand the nature of the funding request to determine the appropriate review and approval process or company contact

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Any company employee who is approached with a request for an educational grant should instruct the external organization to visit the grants management system application website/IME department

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Company employees must not assist external organization/medical education provider with the IME funding request process (e.g., by advising on completion of the request, completing and submitting a request on behalf of a requestor, or attempting to advocate funding for a request)

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3C

General guidelines for distributing invitations to accredited IME programs

- While there aren't global standards for how industry supporters of IME programs may distribute invitations for/communicate about IME programs, we can consider the US ACCME standards for general guidelines including:
  - The Education Provider must develop the invitation or brochure
  - The information must clearly identify the IME provider and include a statement that the activity is supported by an IME grant from the company
  - Educational providers are responsible for ensuring that education is separate from marketing by supporters
  - Pharmaceutical company employees may distribute invitations to an IME activity with provider's approval
  - Commercial supporter must not be the sole source of distribution
  - Pharmaceutical companies may not provide access or distribute content directly to learners; however, educational providers may allow the pharmaceutical company to link to its homepage/ landing page from which a learner may then choose to engage in an educational activity
- Even though the ACCME provides the guidance above, many companies have internal policies that either allow or prohibit invitation distribution. One consideration is to avoid possible perception of influence or control

Common components of a grant application

Grant Application and Supporting Documentation

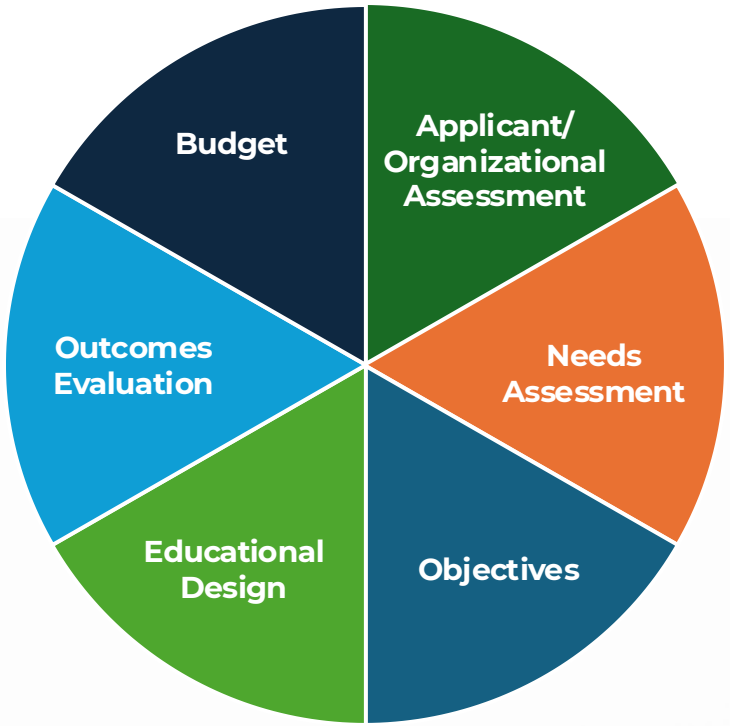
- Organization information
- Program title & description
- Learning objectives
- Needs assessment
- Education methods & design
- Recruitment plan
- Therapeutic area
- Start date and end date of the program
- Accrediting organizations (if applicable)
- Outcome measures/plans
- Audience description
- Geographic reach
- Associated congress (if applicable)
- Amount of funding requested
- Proposed itemized budget for the entire program
- Content overview/agenda for program or preliminary program/topics for discussion (may include date, times, topics, faculty)
- Grant request on letterhead
- Accreditation status of the education provider
- Proof of tax status, if appropriate

*Note: List is not exhaustive and may vary according to local laws, policies, regulations, etc.

Review and Decision Making

3D

Elements of grant review



Grant due diligence typically includes the following:

- Number, format of programs
- Audience
- Outreach
- Appropriate firewalls within requestor organization
- Conflict of interest policy and disclosure
- Organization expertise
- Medical relevancy
- Scientific balance
- Strategic alignment
- Assessment of educational need & learning objectives
- Appropriateness of budget/cost per learner
- Educational impact/outcome measurement

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3D

Examples of elements to assess in a typical grant scoring framework

Description:

Applicant/Organizational Assessment

- The requesting organization and its educational partners should have the competence and demonstrated history of implementing high quality educational initiatives

Needs Assessment

- The grant application should incorporate educational needs (knowledge, competence or performance) that underlie the professional practice gaps of the target audience
- It should include current references (1-3 years) and be based upon a sufficient level of evidence
- Needs assessments should include multiple sources (quantitative/qualitative methods)
- Needs assessments should include methods for continuous assessment
- Ideal needs assessments have specific localized quantitative data sources to document practice gaps and linkage to show how the educational intervention proposed is likely to close the gaps

Objectives

- The educational objectives or stated purpose of the activity or intervention should be clearly measurable and appropriate
- Objectives should be designed to change competence, performance, or patient outcomes
- Objectives should match the target audience's current or potential scope of professional activities
- The best objectives are performance based, focusing on specific process or outcomes measures that are linked to the identified performance gap or need

3D

Examples of elements to assess in a typical grant review framework (continued)

Description:

Educational Design

- The activity or intervention should incorporate multiple methods and be based upon adult learning principles
- The design should be appropriate for the target audience, objectives, and desired results
- The activity or educational intervention should include educational strategies to remove, overcome or address barriers to healthcare provider change
- CME/CE should be integrated into a process for improving professional practice. It should utilize non-education strategies to enhance change as an adjunct to its activities/interventions (e.g., reminders, patient feedback)
- Ideally, projects should incorporate collaboration with others, quality improvement system methodology, or use of non-educational interventions alongside educational interventions

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3D

Examples of elements to assess in a typical grant review framework (continued)

Description:

Outcomes Evaluation

- The grant application should include a plan to gather data or information in order to analyze changes in the knowledge, competence, or performance of the target audience
- The plan should aim for higher levels of outcomes measurement beyond just the acquisition of knowledge and skills. The plan should demonstrate clarity and innovation

Budget

- Is the budget reasonable based on the expected reach and impact of the project?
- Is the organization contributing any in-kind resources?
- Are there multiple sources of funding or is the grant request for the full amount?

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3D

Grant review committee composition & function

Membership	• Review committee may have representation from Medical Affairs and Medical Education • May be organized by therapeutic area or franchise level at a larger organization or in a smaller organization; there may be one GRC for all IME grants and a separate one for Patient advocacy grants • Additional members may include Compliance, Legal, R&D, Health Economics & Outcomes, Corporate Affairs, Patient Advocacy, Strategic Alliances, or External Affairs
Remit	• Review grant requests after the initial eligibility and reputation evaluations are conducted • Review grant requests to ensure support of independent and high-quality educational programs based on scientific merit, unmet need, and available funding to enhance patient care in areas that complement the organization's research or commercial interests • Extent of GRC review and ability to approve can vary based on organizational policy
Meeting Cadence	• Meet on a weekly or monthly basis depending on grant request volume

Additional considerations for Medical Sponsorships & Corporate Memberships

- Organizations that receive Medical Sponsorships and Corporate Memberships on the same portal and have a similar workflow/review process may still maintain a separate review committee than those for IME grants
- Stakeholders who may have a relationship with the organizations that submitted the Medical Sponsorship or Corporate Membership may provide additional information or insight into the organization

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3D

Common grant review committee members

*Only for organizations that also use GRC for sponsorships. If an organization uses a GRC for sponsorships it should be a separate meeting

GRC requires a consensus decision

Example of GRC roles & responsibilities

IME Lead / Grant Manager

IME Lead / Grant Manager is responsible for the review of grants to:

- Develop the IME strategy and annual plan in collaboration with Medical Affairs Therapeutic Area Lead and managing the initial reviews
- Determine alignment with organization's established medical education objectives, process and policy
- Ensure due diligence assessment of the reputation, quality, and capabilities of the Grant Requestor is completed
- Assess the medical, scientific, and clinical validity and quality, as applicable, of the requested activity and the grant application
- Ensure risk assessment has been completed
- Lead the GRC and record decisions and follow-up actions
- Ensure that all aspects of the IME Grants procedure are followed
- Manage program status and outcomes measurement reports from Grantees

Grant Coordinator

Grant Coordinator is the IME operations lead responsible for:

- Grant support with concentration on post-approval operations including Letter of Agreement (LOA) processing, payment processing, reporting, management, and retention of such documentation

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3D

Example GRC roles & responsibilities (continued)

Medical Affairs Therapeutic Area Lead / Medical Sponsorship

GRC member acting as Medical Representative responsible for the review of IME Grants to:

- Determine if in scope, scientifically balanced and aligned with established Medical Education strategy and objectives
- Assess the medical, scientific and clinical validity and quality, as applicable, of the requested activity and the grant application
- Ensure alignment of submitted Medical Sponsorships with agreed level of funding to be allocated before the grant is processed for GRC review
- Clarify when the purpose of the funding is unclear (i.e., items in the budget appear to include a mix of education related fees and typical sponsorship costs) based on their communication with the requesting organization

Patient Advocacy Lead / Corporate Affairs

GRC member acting as the Patient Advocacy Representative responsible for reviewing patient education grants

Legal

GRC member responsible for the review of IME Grants to:

- Ensure compliance with applicable laws, regulations and codes, including, but not limited to intent of the Grant; assessment of disguised promotion; or potential perception of inappropriate inducement
- Ensure clarity of content of the Grant activities to ensure they are articulated appropriately in the corresponding contracts/paperwork/agreements for approved Medical Education Grants

Compliance

GRC member responsible for the review of IME Grants to:

- Ensure compliance with company policies and procedures regarding approval of Grant requests
- Ensure compliance with transparency/disclosure requirements
- Assess appropriateness of the budget based on fair market value knowledge

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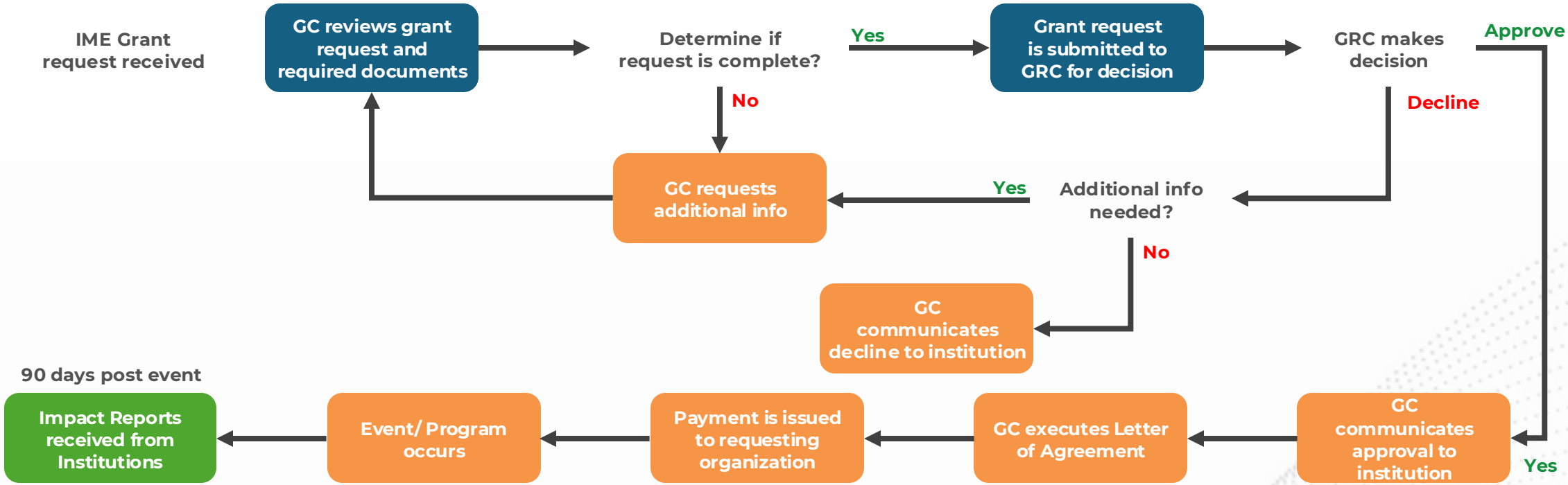
3D

Example of an IME grant review process



GC: Grant Coordinator; IME: Independent Medical Education; GRC: Grant Review Committee; LOA: Letter of Agreement

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3D

Considerations during grant quality assessment in terms of potential effectiveness of proposed activities

- Multiple interventions are better than single interventions
- Interactive programs that engage the audience and peers
- Educational programs that offer enduring activities
- Leverage technology and simulation engagement
- Related to life experience
- Includes support for self-directed methods
- Reflection and feedback
- Role modeling by faculty

Marinopoulos SS, et al. Effectiveness of Continuing Medical Education. Evidence Report/Technology Assessment No. 149 (Prepared by the Johns Hopkins Evidence- based Practice Center, under Contract No. 290-02-0018.) AHRQ Publication No. 07-E006. Rockville, MD: Agency for Healthcare Research and Quality. January 2007

3D

Geographic considerations in terms of potential effectiveness of proposed activities

- In an increasingly digitized world, the need for local providers with links to the specific territories where activities will take place continues to be an important factor
- Local education providers may offer expertise and knowledge that can serve as a competitive advantage in an application
- Education Providers with local, real-world expertise may include disease area specialization, knowledge of legal and regulatory frameworks and local HCP networks to support promotion of the activity
- Online digital activities fall within specific legal and regulatory jurisdictions requiring appropriate oversight
  - Determining jurisdiction can be complex and must be considered carefully within the context of each activity
  - Consideration of applicable laws regarding digitalized activities will determine HCP invitation and participation restrictions

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Post-grant Approval

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Managing post-approval monitoring

Failure to provide the required reconciliation and outcomes impact report after the conclusion of an event could impact future grant submissions and reviews

All materials provided at program completion, including financial reconciliation and outcomes report, when required, should be reviewed/analyzed

Many organizations maintain grades or ratings for requesting organizations based on several evaluation criteria, as it gives them a general idea of quality of the education provider; examples of criteria include:

Quality of grant submission and all the required mandatory documents

Timeliness of outcomes report submission

Accuracy of budget reconciliation and if return of funds required

Number of change of scope requested

Accuracy of outreach estimation (planned versus actual)

Quality of the overall program, faculty selection, content, and enduring materials

Quality of outcomes report (quantitative and qualitative)*

*If Sunshine Report/Transparency was required: Did they submit all the necessary information proactively?

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Change of scope

For any approved grant where the program will deviate significantly from the original application, the Requestor must submit a Change of Scope request

- The grant requestor must document all changes to the approved program in detail and submit the Change of Scope (COS) Request
- Examples of Changes in Scope:
  - Timeline Delay
  - Increase in request amount from previously approved amount
  - Educational objectives
  - Number of supporters
  - Significant change in educational format
  - Audience type

Depending on the extent of changes to these elements of the program, then the Grant Manager may decide to approve or decline the COS. Once a decision is rendered, the Grantee is notified.

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3E

Key considerations for ongoing IME program reconciliation & tracking

- Regularly evaluate IME funding recipients and IME programs to assess the quality of the program and the compliance of the IME funding recipient with the requirements set forth in the LOA
- Review information about past IME funding requests involving current IME requestors and review evaluations of past performance of any IME requestors who were previously IME funding recipients
- Implement a tracking and reporting system to provide readily available information relating to issues such as: (1) pending, denied, and approved funding; (2) comparison and evaluation of funding (a) contract amounts, (b) the IME provider's budget and actual costs incurred by the provider in conducting the event; or (3) other information relating to IME, such as reconciliation of IME funding to general ledger and payment information

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3E

Company employee attendance at IME activities

- Company employees may attend an IME activity as a silent observer, when permitted by company policy and guidelines. Company employees cannot participate in audience discussions or ask the presenter questions
- If permitted under the IME Provider's guidelines, the company may exhibit in an area designated by the IME Provider, provided that adequate separation between educational and branded activities is ensured
- If any company employee identifies/learns of product or safety related inaccuracies or misrepresentations of approved labeling within the IME activity, employee should report the misinformation to the IME Department and/or Compliance
- Medical personnel can attend and monitor programs live to ensure quality and document poor performing programs. They can also complete the IME activity evaluation form as a part of this process

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Quality Improvement

3F

Quality improvement & continuing medical education

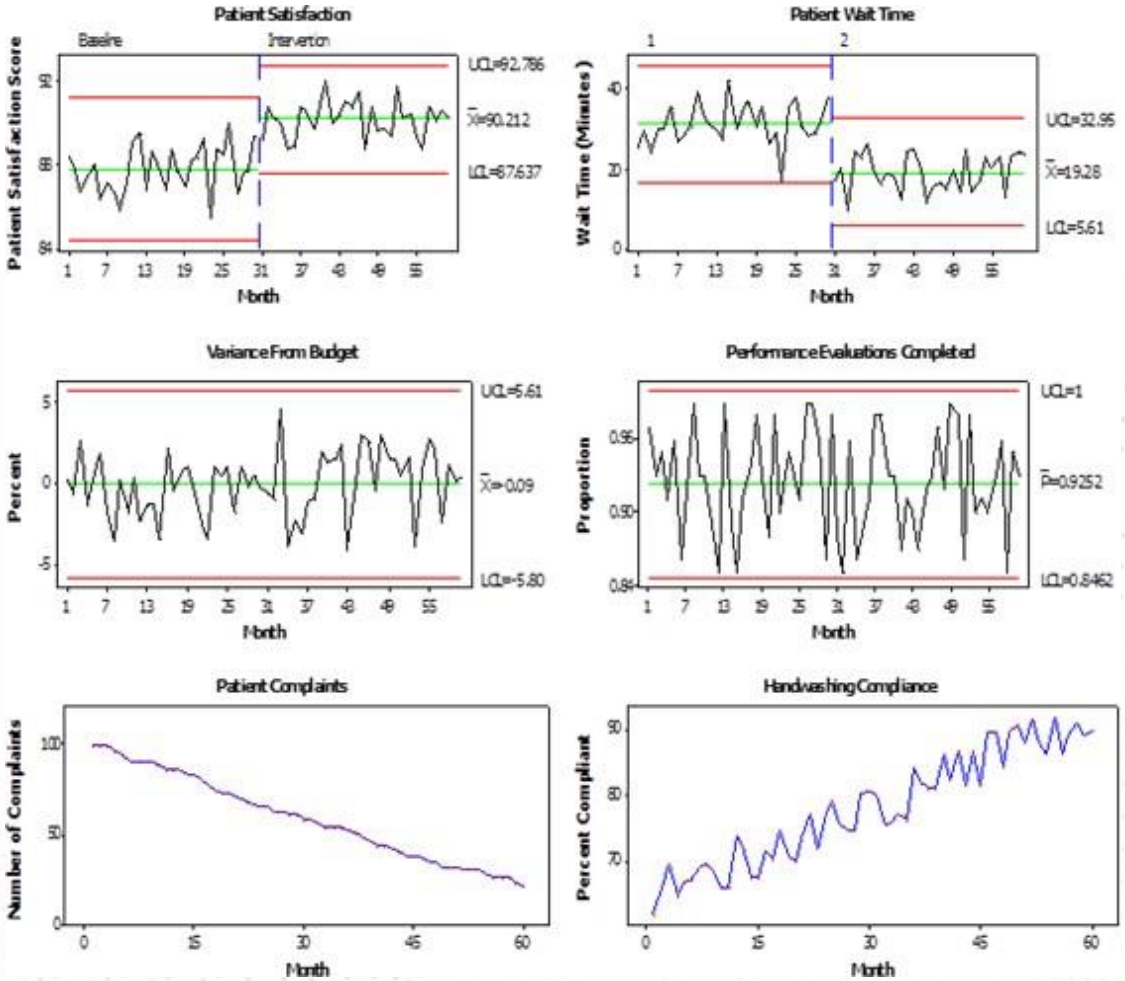
- QI is a type of project designed to systematically address and improve the ways care is delivered to patients
- QI projects can include a training or education component for healthcare professionals. The training is sometimes, but not often, certified for CME credit
- CME shares some of the same basic goals as QI (e.g., behavior change, systems redesign)[1]
- PI CME is a process by which evidence-based performance measures and QI interventions are used to help physicians identify patient care areas for improvement and to enhance performance[2]
- The ACEHP has created terminology to capture the overlap between CME and QI, namely Quality Improvement Education (QIE)[3]
- The integration of CME and QI offers the opportunity to improve health care quality[1] and achieve Moore's level 6 and 7 outcomes

1. Shojania, KG, Silver, I, Levinson, W., Continuing Medical Education and Quality Improvement: A Match Made in Heaven? *Ann Intern Med.* 2012;156:305-308
2. https://www.ama-assn.org/education/ama-pra-credit-system/performance-improvement-continuing-medical-education-pi-cme
3. http://www.acehp.org/page/qie-initiative
4. 1. Agency for Healthcare Research and Quality. (2013). Module 4. Approaches to Quality Improvement. https://www.ahrq.gov/ncepcr/tools/pf-handbook/mod4.html

3F

What is quality improvement?

- "Systematic, data-guided activities designed to bring about **immediate improvement** in healthcare delivery in **particular settings**."[1] Based upon evidence-based practice (well- accepted research results or established guidelines)
- Utilizes metrics and measures (process, performance, outcomes)
- Usually, the goal is an increase/decrease in key metrics seen following team intervention
- The goal can also be to maintain consistency/reduce variations in care
- Healthcare organizations use a number of established methods to do quality improvement work, including Six Sigma, Lean, etc. One of the most widely used the Plan Do Study Act (PDSA)



1. Lynn, et al. ANCC Magnet Application Manual, 2008. p. 667

3F

Quality improvement methods

Kaizen or "continuous improvement" from Japanese

- The Kaizen event is a micro process improvement project happening typically within seconds, minutes or hours
- A team comes together at the place where the work is done and makes a small change and immediately validates if the change improves the process

Lean, or the Toyota Production System

- A tool used to streamline manufacturing and production processes
- Lean uses a technique called Value Stream Mapping (VSM)
- In VSM, a QI team creates a visual map of each step in the flow of the current process

Lean Six Sigma: DMAIC

Define	Measure	Analyze	Improve	Control
Define the problem	Quantify the problem	Identify the cause of the problem	Implement and verify the solution	Maintain the solution

Six Sigma is to eliminate defects and waste, thereby increasing quality and efficiency by streamlining and improving all business processes

www.AHRQ.gov

3F

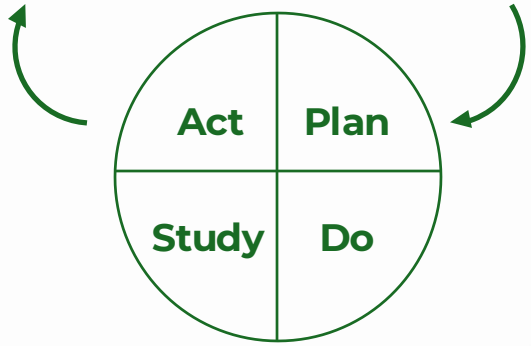
Plan Do Study Act (PDSA): Institute for Healthcare Improvement (IHI) method

Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement

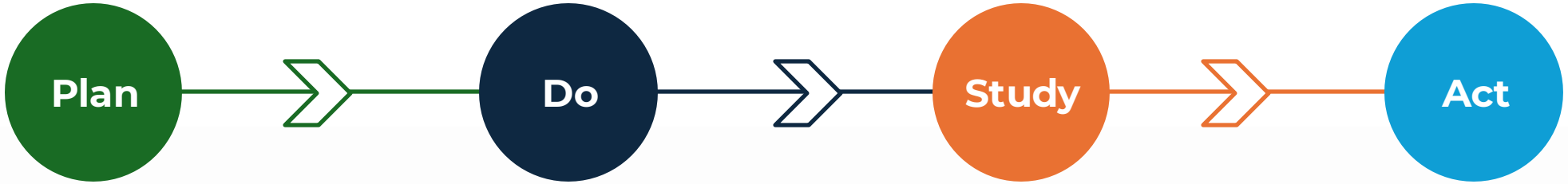


- One of the most widely used methods
- W. Edwards Deming (1900-1993) taught that by adhering to certain principles of management, organizations can increase quality and simultaneously reduce costs
- Based on his work, the IHI Model for Improvement was created by Associates for Process Improvement (API) as a simple, effective tool for bringing about positive change. The IHI QI model involves:
  - A clear, measurable aim
  - A measurement framework in support of reaching the aim
  - A clear description of the ideas (content) and how these ideas are expected to impact the results (the causal pathway from changes to desired outcomes)
  - A clear description of the execution strategy (what will be done to ensure reliable adoption of the content?)
  - Dedication to rapid testing (PDSA cycles), prediction, and learning from tests
  - Understanding, describing, and visualizing systems (e.g., using a process map or value stream map)
  - Learning from variation and heterogeneity:
  - Use of time-ordered data to detect special cause and improvement
  - Understanding why results differ by location (ward, organization, etc.)
  - Application of behavioral and social sciences

www.IHI.org (Oct 16, 2020)

Quality improvement–PDSA cycle

Project Roadmap



Set aim, measure, analyze problem, and select changes

- Create an aim statement
- Measure baseline performance
- Map the process
- Identify and evaluate causes of the problem
- Select the changes to be made
- Develop plan to test the change

Test the change

- Acquire staff, resources, changes for test
- Prepare management, staff, and environment for the change
- Use feedback to make adjustments
- Measure progress and capture lessons learned

Analyze test results and determine actions

- Measure and analyze post performance
- Incorporate test results and lessons into final implementation

Act on the test results

- Decide, finalize and spread the change. Return to plan or abandon project
- Monitor results and sustain the gain
- Conduct a cost-benefit analysis

www.IHI.org (Oct 16, 2020)

Differentiating quality improvement from research

Quality Improvement

1. Implements new knowledge
2. Improves care-delivery processes
3. Often generalizable
4. Knowledge implementation without controlled environment
5. Multiple variables within a heterogeneous population
6. Outliers not excluded
7. Variation measured over time using both statistical process control and appropriate statistical analysis
8. 20-30 representative data points to sufficiently analyze data; small test of change (pilot) before full implementation, or multiple small cycles of change
9. Typical duration of project is 4-6 months
10. Investigators monitor data real time as they are collected, and intervene as indicated

Research

1. Discovers new knowledge
2. Provides an alternative to standard of care
3. Generalizable
4. Specific, tightly-controlled tests
5. One-variable within a homogenous population
6. Outliers excluded
7. Statistically compares means/medians within large sets of aggregate data
8. Power calculations required to generate population size and significance
9. Study occurs over a long period of time
10. Investigators blinded to details and results until end of study

www.IHI.org (Oct 16, 2020)

Section Navigation

Click to navigate to the section you would like to visit

SECTION 4

INDUSTRY-LED EXTERNAL EDUCATION

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Section 4

Chapters

4A
Introduction to Industry-led External Education

4B
Governance

4C
Program Development

Click a circle to navigate to the section you would like to visit

Introduction to Industry-led External Education

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Value of Industry-led external education

Leverage Company MA Expertise

Breakthrough scientific innovations and new clinical evidence generated by companies can be disseminated to accelerate the transition from bench to bedside

Industry-led external education

Targeted Engagement

Organizations can cover multiple geographies and range of target audiences, providing broad access to medical education

Company-aligned Messaging

Partnerships with renowned faculty led by Medical Affairs can generate focused and strategically-aligned content that is scientifically rigorous and balanced based on a transparent and mutual company-faculty collaboration

EFPIA 2019 Securing the future of collaboration between industry and healthcare professionals. www.efpia.eu/disclosure

4A

An introduction to industry-led external education by Medical Affairs

- The pharmaceutical industry, with its scientific expertise, extensive geographic footprint, and access to multidisciplinary networks and resources, can be an integral part of innovative external educational solutions to accelerate transition of research into clinical practice
- In accordance with local laws, regulations, and industry codes, there is a rationale for both independent medical education and industry-led education to bring added value to lifelong learning in the healthcare ecosystem for the benefit of HCPs and patients
- Medical Affairs professionals are trained to serve as trusted partners and scientific experts for industry-led external education, thereby raising the standard of care and improving patient outcomes
    - Providing relevant, scientifically balanced and nonpromotional education to the clinical and research community
    - Aligning company strategic goals with healthcare stakeholders' and patients' needs
    - Contributing relevant scientific information and data
- These activities are organized by individual pharmaceutical companies and may involve collaboration with scientific and professional organizations. Examples include scientific symposia, patient educational programs, scientific standalone meetings, and educational websites
- Industry-led education is bound to the highest standards for quality, transparency, and ethics in medical learning. Content must be relevant, credible, and timely, addressing educational gaps through a sound instructional design and outcome measure plan

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4A

Benefits of industry-led external education by Medical Affairs

Industry-led external education presents several benefits

- Allows the creation of educational content addressing the clinical gaps that is directly aligned to the strategic goals and vision of the company
- Provides education and dissemination for the immediate impact of emerging clinical data
- Education can be targeted and personalized based on learner knowledge and preferences
- Medical Affairs colleagues or external faculty can directly deliver education to learners through their skillset and scientific knowledge
- Content can be re-used by Medical and potentially cross-functionally during interactions with external stakeholders across various channels and formats

- Current EACCME and ACCME guidelines do not allow industry-led education programs to be accredited/certified. In certain regions or countries, local societies and institutions may provide local credit
- Developing industry-led programs includes taking direct control over the production of learning design, selection of faculty, educational content, and enduring materials, and assuming responsibility for program roll-out, content review, monitoring, and reporting
- Industry-led external education programs must be developed with the same rigor and scrutiny as those developed by an external education provider to ensure credibility and lack of bias
- While the content is driven by the company, it must remain educational and scientific in focus, with clear separation of intent from promotional and commercial interests
  - Firewalls between Medical and Commercial functions ensure independence of decision making

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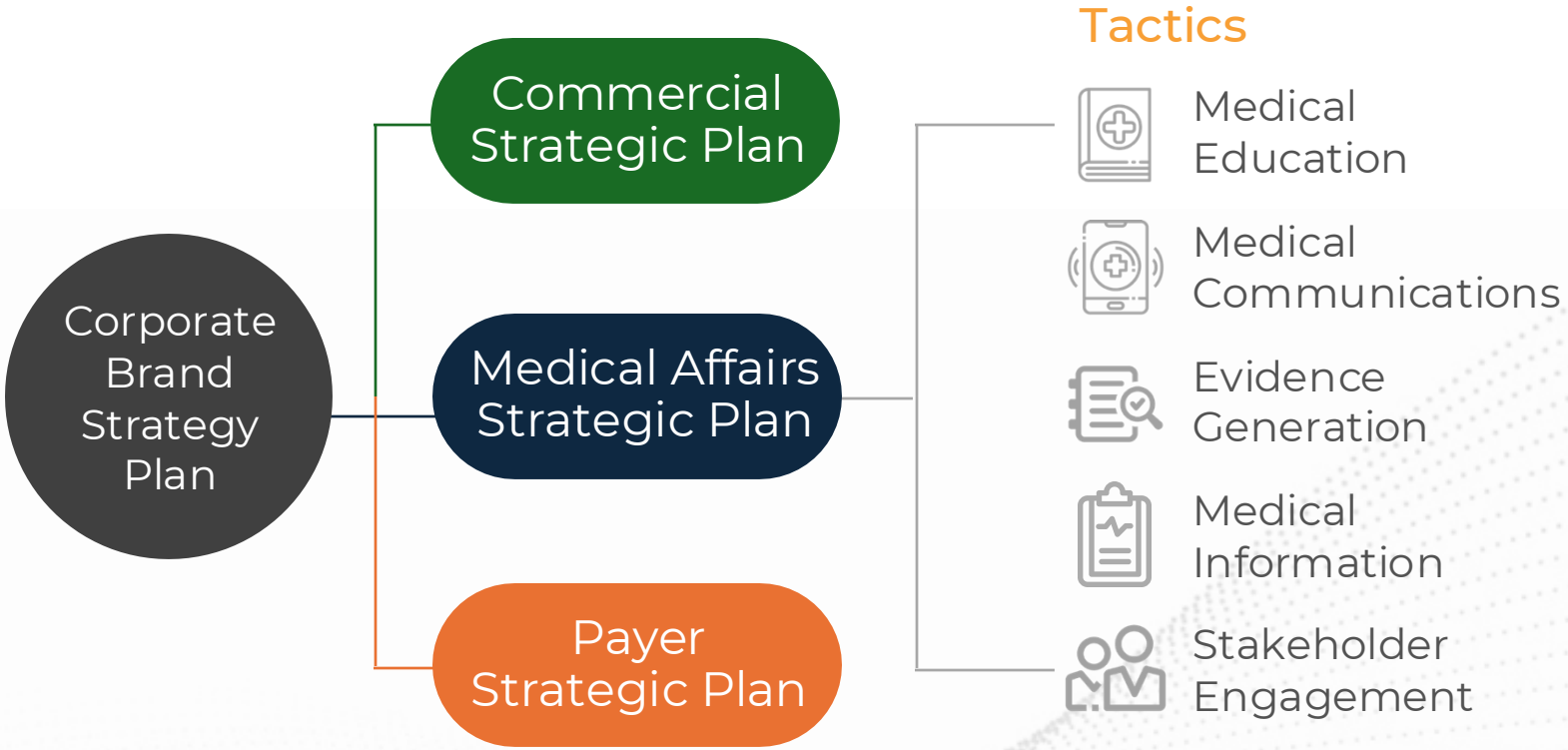
Industry-led external education

- External education initiatives are one part of a wider medical affairs lead engagement plan, usually referred to as the Medical Affairs Strategic Plan. They should be based on already identified relevant educational gaps aligned with company priorities
- Medical education activities will follow an instructional design and outcomes measure plan



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Orchestrating OCE

Aligning company strategic priorities with the gaps, tactics, and accountability across Medical Affairs teams

		Knowledge Build Awareness	**Behavior and Confidence** Build a Position	**Skills** Learn How and Practice	**HCP/Care Team Performance** Enhance and Advocate
Strategic company policies	**Evidence dissemination**	**Publications, Medical Information** Congress/Manuscripts, Orals, Posters, Scientific Response Documents, Social Media, Websites*			
	Field Medical/ Scientific Exchange	**Field Medical, Content Development, and Training** Proactive/Reactive Decks, Scientific Discussion, MSL Triggered Emails, Apps, and Pipeline Information*			
	External Education	**External Education: IME and Company Led** CLE or IME – standalones, Symposia, Websites, Applications, Apps, and Podcasts*			

* This is not an exhaustive list of tactics

4A

External education strategic & tactical approach

Key features

NEEDS ASSESSMENT

Identification of gaps is performed following the convergence of interest between

- Patients
- HCPs
- Pharma
- Payers

INSTRUCTIONAL DESIGN

Content could be:

- Fully developed by industry
- Co-developed with contracted faculty
- Fully developed by contracted faculty

All content must be reviewed following local rules and regulations

EXECUTION

Interventions usually are usually deployed as part of a multichannel education plan including:

Company-owned channels

- Field Based Medical activities
- Emails
- Meetings
- Industry led websites
- Apps

Third-party channels

- Third-party websites
- Congress sponsorship of symposia or booths
- Social Media
- Preceptorships

OUTCOMES MEASUREMENT

Medical education must not be linked to sales or (ROI) calculations.

Appropriate education impact measures should be part of the programs following Moore's level, usually to level 1-4

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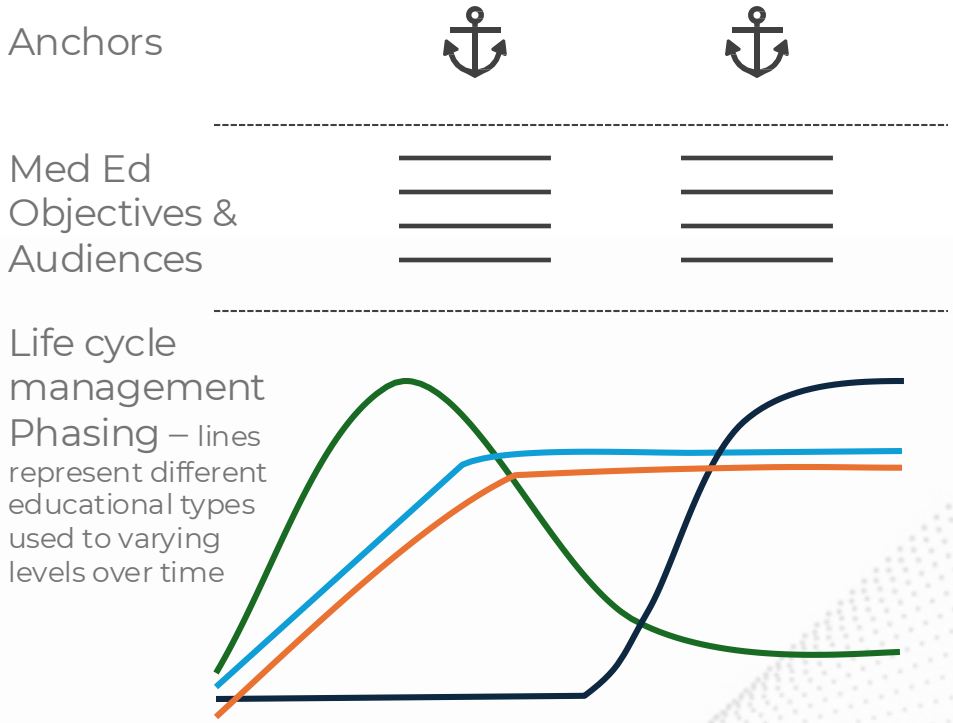
4A

Industry-led educational strategic plan

A Medical Affairs industry-led educational strategic plan includes the key elements of the educational strategy over time: audience, gaps, education objectives, key events, and data releases

Plan Tips

- Consider limited pre-approval disease awareness education per local regulatory environment
- Consider launch & post-approval educational roadmaps
- Serves as the base for curriculum planning
- These strategic documents may or may not include tactical programs



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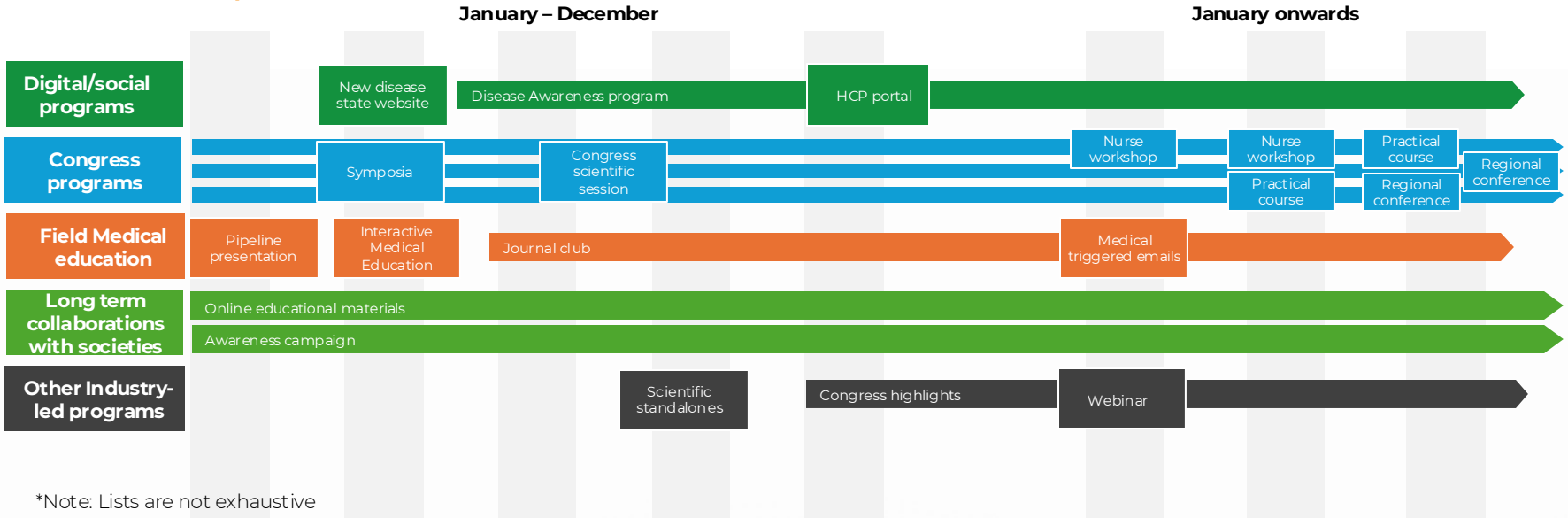
4A

Industry-led educational tactical plan

A Medical Affairs industry-led educational tactical plan includes a summary of activities aligned with strategy over a defined period. The plan can also include information about content and with linkages and sequencing of the multiple tactics



*Note: Lists are not exhaustive

Tips

- Do not skip the medical education strategy
- Ensure the sequence is created following instructional design principles
- Leverage multichannel approach (see next slide)

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Industry-led medical education tactical plan

Multichannel

The education engagements in the medical education tactical plan need to adjust to the most effective learning format and the preferred channel of the audience. In today's world, audiences access the content through multiple channels. Medical Affairs professionals need to understand the appropriate channel to use and how to orchestrate multiple channels to amplify education

Multichannel

- Engages use of multi-sensory channels to teach concepts and enable practice and application
- Ensures that HCP engagement is possible regardless of where, when, and how they choose to access information
- Enables flexibility in delivering content in the channel that the learner prefers, and can customize to individual learning style

Omnichannel

Omnichannel Learning

- Puts learner at center of its strategy
- Focuses on delivering consistent, personalized experience across all channels and devices, regardless of where interaction is occurring
- Focused on learner's needs, rather than individual goal of each channel

4A

Utilizing multi-channel engagement strategies in industry-led medical education

Multichannel educational plans incorporate different channels in sequence to reach a wider user base of preferences

Kooi R, Schenck F, Smet B. Evidence-based multichannel. Across Health. 2019.

A well-structured medical multichannel engagement strategy is built around the learner:

1. **Right communication** derived from insights obtained from understanding your audience/learners' journey and segmentation. The goal is to use Multichannel methodology to deliver a seamless communication experience for audience/learners
2. **Right channel** using the optimal mix of digital and non-digital, as well as message amplification and deep engagement channels. Setting up channels requires time and resources. Make sure that effective and impactful messages can be communicated through the channels your audience/learners prefer
3. **Right timing** of communication. Build an ecosystem to understand the context of audience/learner engagement and response. Combine Customer Relationship Management (CRM) infrastructure together with (predictive) analytics, enabling timely and organized delivery of impactful educational content

Importance of content

- A common pitfall for industry communications is that there is too much focus on channels and too little focus on content
- Content must be the cornerstone of every strategy with channels being the enabling tool
- Content should be high quality, unbiased, and differentiated from generic vendor content because these characteristics drive trust and adoption
- Different HCP segments require tailored types of content, levels of detail, and sophistication to find the output appealing
- To maximize spend, repurpose internal content or be creative about content sourcing (for instance, crowdsourcing of content through online medical community platforms)
- Only then can the right content be strategically placed throughout the year using the right channels, including medical conferences and journals
- Overall, tailoring content and channels to different HCP segments is the key to effective engagement

Governance

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4B

Role of Medical Affairs in industry-led external education

For industry-led external education, Medical Affairs:

- For industry-led external education, Medical Affairs:
  - is the initiator, project owner and overall responsible function, as outlined in the respective Medical Affairs strategic plan
  - ensures-that the initiative/project serves to facilitate legitimate scientific exchange and education
  - owns the budget
  - may consult with other functions in planning, and depending on company specific guidance and principles,
  - may also utilize commercial channels (e.g., field sales force) to distribute invitations to medical education events if allowed by applicable laws and codes
- Medical Affairs may also utilize a medical communications agency to support with the planning, execution, and post-project follow-up activities

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4B

Involvement of external experts in industry-led education

In external education programs where professional competency gaps have been identified, or scientific developments warrant further discussion and understanding, the scientific program and faculty selection can be developed under the guidance of an external steering committee, comprised of relevant external scientific experts

In external education programs where professional competency gaps have been identified, or scientific developments warrant further discussion and understanding, the scientific program and faculty selection can be developed under the guidance of an external steering committee, comprised of relevant external scientific experts

This brings:

- Medical credibility
- External expertise in agreeing to the program objectives and key learning points
- Guidance in developing the overall program theme and agenda
- A broader base of faculty through utilizing steering committee personal networks for identifying and nominating faculty
- Outside the US in pharma or in the device industry, accreditation may be sought based on the educational nature of the content (e.g., CPD, allied health professionals), in accordance with applicable laws and regulations. The project team should decide at the start of the project whether or not to apply for accreditation or endorsement from a scientific society.

Overall “ownership” and accountability for these programs remains with the Medical Affairs lead/owner

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4B

Ensuring credible and unbiased industry-led external educational initiatives

- Industry codes, as detailed in the PhRMA, IFPMA, AdvaMed, and EFPIA Codes of Conduct, for example, apply to all initiatives to ensure activities remain unbiased and credible
- The credibility of the industry-led external education program can be established based on the foundation of a robust Needs Assessment and learning design and evidence based, non promotional content

Use of established compliance tools and/or related processes for overseeing budgets and contractual agreements:

Ensures compliance in contractual agreements with external providers or suppliers, and budgetary oversight

Supports resolution of Conflicts of Interest (COI) that may emerge during the planning and execution

Provides transparent budgetary management that helps to trace and manage transfers of value, as well as track reporting on all financial exchanges, and ensure financial transparency

4B

Industry expectations for ensuring non-promotional intent

Industry involvement in running external education programs need to follow clear rules to guarantee credibility of the programs

Non-promotional intent is achieved through:

- Use of faculty selection criteria
- Transfer of value standard policies
- Review appropriateness of event venues and timings
- Content requirements (e.g., fair balance, accurate, non-misleading, non-promotional etc.)
- Appropriate internal review of content (e.g., Medical, Legal, Compliance, Regulatory)
- Outcomes reporting
- Transparency (company disclaimer and disclosure of interest)
- Monitoring by internal processes

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Program Development

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4C

General budget considerations

Medical Affairs should be the preferred owner of medical education budgets

Budget categories often include:

Program management

Scientific service provider support

Faculty

Appropriate out-of-pocket, honoraria, travel, lodging expenses limited to faculty

Fair market value for the proposed activity and/or length of activity

Pass-through costs/live or digital events

Enduring material costs

Budgets can vary based on where the product/compound is in the lifecycle, breadth and depth of activities, target audiences, and available spend

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4C

Transfers of value standard policies

Allowable transfers of value may include:

- Third-party support services, such as medical writing (in alignment with fair market value)
- Travel support for faculty related to presentation (e.g., oral poster presentation at a congress); faculty registration should only be covered if faculty was not already attending the congress

- Transfers of value should be disclosed/reported in accordance with local laws, regulations, and/or industry codes
- Restrictions on reasonable meal limits, lodging, and travel expenses limited to faculty members, teachers, and learners are common but not defined clearly and vary widely in interpretation
- Companies interpret industry codes and often impose more stringent compliance guidance to mitigate bribery/corruption risks

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4C

Event/program timeline considerations

- In some jurisdictions, the external authority (e.g., industry body, Ministry of Health, etc.) may be required to approve medical education events, as with other industry-led meetings
- In the case of external approval requirements, the timelines of the authority must be strictly adhered to, which also means timelines of internal processes must be aligned accordingly
  - External governance bodies may require companies to maintain periodic plans of faculty that are engaged
- If external approval is not required, the company formulates internal approval timelines. To avoid rushed reviews prone to mistakes and risks, good practice dictates starting the review process as early as possible, ideally at least 10–12 weeks before the activity

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4C

Overview of event/ program development

4C

Industry-led: Event/program review & approval

The review process must ensure that the medical education activity, as a whole, (and not its individual segments) is acceptable, based upon a holistic assessment of many factors, including:

- The intended audience
- Faculty selection
- The purpose and objectives of the meeting
- Content should be scientifically relevant, approved and referenced
- The content of the meeting materials, including
- whether the materials will be distributed (or only displayed) to the audience
- The proposed or likely discussion topics, including medications
- The business unit responsible for organizing or supporting the meeting

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4C

Industry-led: Faculty selection

- Companies may engage faculty to provide and deliver educational content for an activity
- Selection of faculty must be based on professional and scientific merit, and calibrated to the broader scope of the program
  - Formalized selection criteria should be established
  - Contracting of faculty is managed in accordance with relevant legal and/or compliance processes
  - Conflict of interest resolution must be managed promptly in accordance with legal and/or compliance processes
  - Faculty must disclose all potential conflicts of interest and other relationships that may infringe on contractual or compliance obligations
  - Disclaimers must be evident in all engagements by the faculty during the program, clearly stating the nature of the industry sponsorship

4C

Industry-led: Faculty briefing considerations

In-person meeting

- Faculty must acknowledge that the question is off-label and beyond the scope of the approved content for the presentation, and suggest one of the following options:
- Invite the attendee to discuss the question privately after the conclusion of the program, being sure to answer the specific off-label questions with a narrowly tailored response
- Company associates may not participate in the speaker's one-on-one discussion with the attendee
- Invite the attendee to contact the Medical Affairs department of the organizing company for a response, providing the contact email or phone number

Web-based program

- Faculty must state that because they are not able to answer the off-label question in private, a Medical Inquiry Form will be provided by the organizing company, so the question can be properly addressed

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4C

Industry-led: Faculty briefing considerations

(continued)

- Avoid discussion of or an attempt to answer questions regarding:
  - Reimbursement
  - Insurance coverage
  - Price-related information
- Only provide company-approved statements or company supplied data
- Refrain from engaging in any patient or practice discussion or questions that might appear to be providing consulting services
- If asked to compare product attributes, faculty must inform the audience that the request is beyond the scope of the presentation and product label, and that it cannot be addressed during the presentation
- Faculty may offer to have a one-on-one discussion to address the question in private, following the conclusion of the presentation
- No company associate can participate in the one-on-one discussion

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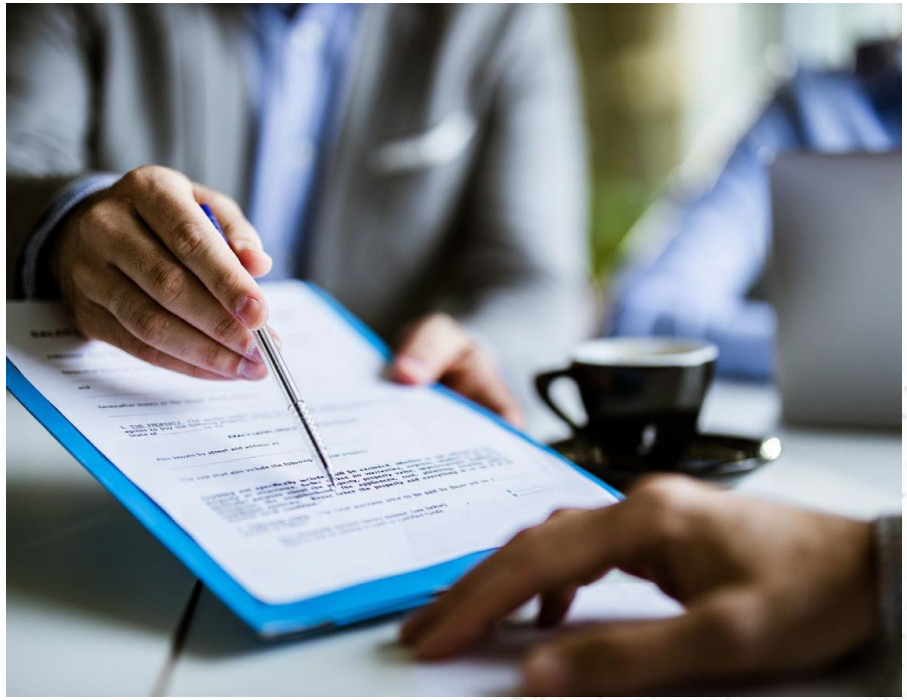
4C

Industry-led: Faculty contracting and engagement

Any transfers of value provided to faculty must be compliant with applicable local laws, regulations, and industry codes

- Contracts must only offer compensation for direct costs incurred through attendance; no payment can be made for time away from work while attending an activity
- Compensation must be at fair market value, and within the allotted annual limit “cap” (applicable according to local laws and codes)
- Any transfer of value not included in the faculty agreement is not permitted
- No gifts or cash are allowed



4C

Industry-led: Content development overview

- Like IME, industry-led education is bound to the highest standards for quality, transparency, and ethics in medical learning
- Content must be relevant, credible, and timely, addressing educational gaps through a sound instructional design and outcome measure plan
- Regulatory agencies have diverse views on the classification of medical education developed by the pharmaceutical/biotech/device industry. Medical education and educational materials are rarely defined by intent, but by originator or supporter. Industry-developed education/educational materials are considered promotional in many markets regardless of their nature and the internal developing function
- Once all appropriate event/program* approvals are in place (e.g., governance board, contracting, etc.), work with faculty can begin to actualize content
- A faculty briefing document can be prepared to guide the faculty member through program objectives
- A medical communications professional (scientific writer) can be engaged to work on the content format with the faculty member

* Note: For purposes of this Standards & Guidance document, there are times when a single event versus a program may be discussed, which may cover multiple events and/or other types of education

4C

Instructional design is important

Optimizing content requires making it relevant for the channel and audience segment being targeted, in order to engage, inform, and educate

When developing content, consider communicating key data as scientific stories, or using practical case studies to illustrate complex approaches and bring clinical data to life

For example, using an outline can be a useful way to plan:

- Learning objectives
- Learning approach (didactic, demonstration, case based)
- The content – scientific communication
- The best visual to use depending on the channel (e.g., PowerPoint, video, PDF)
- The required interaction of the audience
- The timing – e.g., a webinar/ webcast optimum length is 15–30 minutes
- Check the structure, flow, and clarity, and rearrange as necessary

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4C

Competency gaps in instructional design

Align the educational formats with the types of competency gaps

KNOWLEDGE GAP

Didactic

SKILLS

Simulation, demonstration

ATTITUDE/CONFIDENCE

Problem based, case based, F2F

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4C

Examples of instructional design and formats

Data visualizations in scientific communications can simplify and focus information, minimize time to interpret key data, and organically increase audience engagement. Common formats include:

Videos

Podcasts

Infographics

Advanced analytics

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4C

Factors to consider that increase audience engagement

Accessible
Make it easy for learners to find what they want, when they need it

Actionable
Help learners to answer questions with easy-to-use Q&A features

Interactive
Learners want interactive content that allows them to dive deeper into topics

On-demand
Learners want video-on-demand formats that meet their learning styles

Current
Help learners stay up-to-speed in a world of constant alerts

Network
More HCPs expect content delivery based on personal needs

Bite-sized
Learners want short content 15–30 minutes in duration

Reflection and reinforcement
Have learners repeat back what they've understood and keep them engaged throughout to ensure knowledge retention

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4C

Industry-led: Content review and approval considerations

For industry-led medical education activities, all presentation materials developed by the company must be approved through applicable internal review procedures to evaluate the following, and any other relevant risks

- Acknowledgement of industry involvement in development of content
- Faculty conflict of interest disclosure
- Alignment with the identified educational needs, educational methods, and objectives
- Compliance with disclosure of information policy on any pipeline compounds, in the context of a balanced and accurate review of emerging treatment landscapes
- Compliance with industry policies, and all applicable laws and codes
- Ensure that no aspect of the meeting is or would be considered promotion of unapproved products or uses
- Ensure that the scientific data being presented are accurate, substantiated, fair and balanced, and not misleading
- Company proprietary or confidential information may be shared in accordance with rules and regulations

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4C

Post-event/activity evaluation

Post-event activity evaluation allows program organizers to:

- Review the strengths and weaknesses of their learning design in practice
- Judge whether the program was able to successfully accomplish its learning objectives
- Demonstrate the learning impact on clinical practice and patient care

For more information on outcomes reporting (see Section 1 for additional details on outcomes reporting)

4C

Industry-led: Monitoring

Industry-led educational programs are also monitored to ensure Compliance, which may include confirmation of:

- A fair and balanced activity and delivery of information
- No inclusion or distribution of non-approved materials
- Content and discussion consistent with local rules and regulations
- No guests or unapproved attendees

Be sure the roles and responsibilities of faculty are clear:

- Ensure the correct presentation is used
- Provide full disclosure of any affiliation or financial interest with the company, including grants, research support, consultancy services, shareholder interests, and honoraria
- Follow policy for addressing unsolicited off-label questions
- Understand topics to avoid
- Appropriately encourage audience participation
- No discussion of competitor products or product comparisons
- No discussion of politics

Monitor the activity for compliance

4C

Program reconciliation

Reconciliation of completed programs and initiatives helps quality improvement and risk management

Logistics

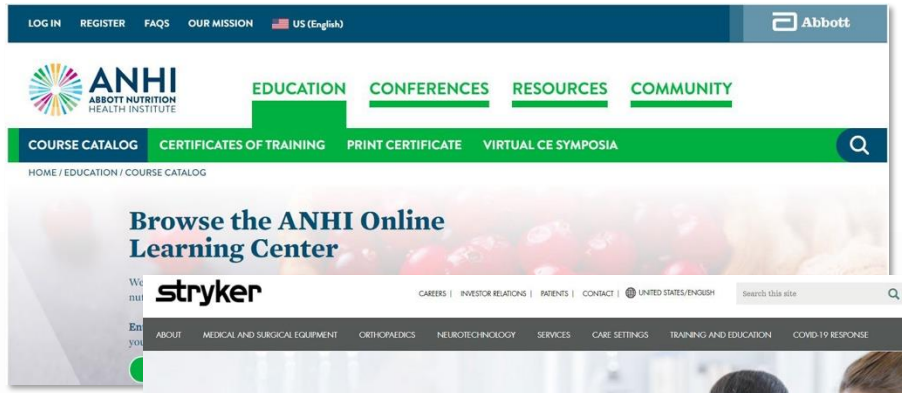
- Validate that appropriate venues were selected with limited overflow and delay cost
- Travel accommodations and audience onsite stays were adjusted to local rules and regulations
- Audience registration, sponsoring documentation, and transparency, were accurately processed and country food and beverage limits were maintained
- Faculty honoraria were processed on time and according to agreement

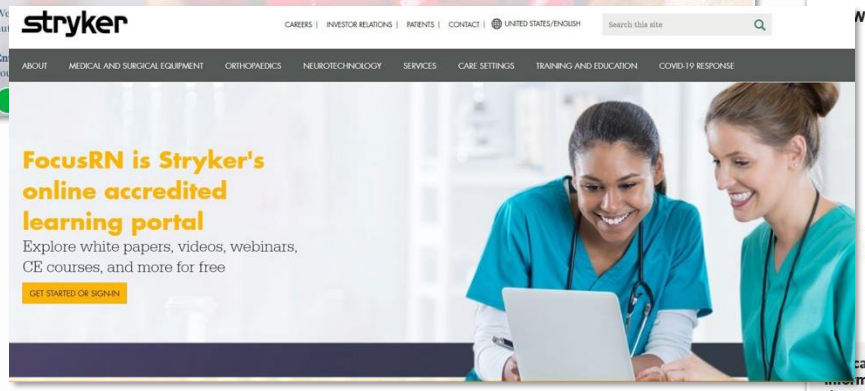
Agencies

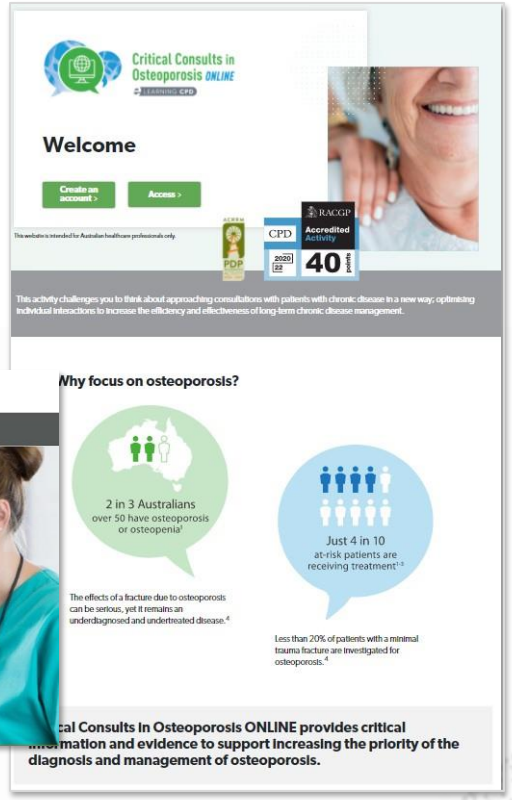
- Adequate services were reimbursed
- Quality of content and faculty engagement standards were met

4C

Examples of industry-led external education websites







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Section Navigation

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SECTION 5

OTHER EXTERNAL MEDICAL EDUCATION ENGAGEMENTS

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Section 5

Chapters

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Medical Sponsorships

5B
Fellowships

5C
Preceptorships

5D
Educational Collaborations

5E
Other Medical Affairs External Funding Requests

Click a circle to navigate to the section you would like to visit

Medical Affairs Professional Society (MAPS)® 2024

5A

Medical Sponsorships

Sponsorships by medical affairs

Definition

- Medical Affairs provides funding of sponsorships (may be solicited or unsolicited) for a wide range of local, national, and international events or programs
- Sponsorships to non-profit (most of the time) and for-profit organizations are the provision of funds to support events, most often meetings, congresses, or medical or patient education programs, in which a tangible benefit is received in return for the sponsorship funding
- Sponsorships may support healthcare initiatives, programs addressing care gaps, improving system processes, or coordination of care

Tangible benefits

- A tangible benefit is quantifiable and measurable and is an opportunity for visibility or promotion. It may include:
  - Opportunities for collaborative input with other industry sponsors
  - Exhibit space or a booth at a trade show
  - Advertising space
  - Participation as a speaker or in a panel discussion, or providing/ selecting a speaker
  - Registrations or tickets to events

Review/reporting

- Recognition alone is not considered a tangible benefit
- Requests for sponsorships may be reviewed by a group similar to the grant review committee (see Section 3), or a separate group
- Budget reconciliation, transparency reporting, and outcomes reporting may not be required for sponsorships to organizations
- Internal policies may dictate scope and level of sponsorships and acceptable tangible benefits

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Sponsorship recipient considerations

Recipients of sponsorships to organizations may include:

- Medical centers and other academic health professional schools (public health, nursing, or graduate schools) or centers focused on patient care and residency training
- Professional medical associations for physicians and other healthcare providers, such as nurses, nurse practitioners, physician assistants, and pharmacists
- Patient organizations
- Scientific associations that conduct meetings or conferences for the presentation and discussion of new research results, and publishing or sponsoring academic journals
- Civic organizations that promote social welfare

In general, sponsorships to organizations do not support:

- Research studies, including clinical trials and investigator-initiated trials (IITs)
- Political or religious activities
- Infrastructure, capital expenditures, or building support

5B

Fellowships

Fellowships

Industry supports the awarding of specialized training experiences to graduate students, junior faculty, or researchers through professional organizations or institutions, such as medical schools or teaching hospitals, to contribute to the development of science and knowledge in line with a therapeutic area of interest

- The recipient is selected for a fellowship by the organization or academic institution and is independent of the company's direct or indirect influence and support
- Fellowship grants are paid to the healthcare-related organization only, and not to any individual recipient
- Industry funding is based on objective research accomplishments and credibility of the organization, and is not related to any product
- Some companies within the industry may restrict the use of funds so that fellowship grants may not be used for any portion of the salary of the fellowship recipient
- A company may be designated as a site for specific fellowships in which the company may be involved in the recipient selection process and the fellow works onsite in R&D, Medical Affairs, Medical Information, Regulatory and other areas

5C

Preceptorships

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Preceptorships & Proctorships

A preceptorship is a non-promotional, educational program, offered to HCPs by a leading medical institution. A proctorship or professorship brings the expert to the institution and the HCPs

Funding is provided to an organization for content development and to host trainees with the express purpose of engaging in an intensive, immersion-type program based on a curriculum in a clinical area of interest

The host medical institution owns the content

HCPs can benefit from the knowledge acquisition and onsite, hands-on experience received by participating in a preceptorship program conducted at the host institution, by medical experts who might otherwise be inaccessible

Considerations

- Can be industry-led or through independent grants; typically, programs are accredited
- Can be a one-time standalone program, or repeated in a series
- May be international, national, regional, or local
- Usually held face-to-face; reach can be extended through virtual participation
- Logistics: onsite execution, managing registrations, etc.
- Local regulations for compliance (e.g., transparency reporting)
- No honorarium required for participants

Educational Collaborations

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5D

Educational collaborations

- Collaborations stem from one or more organizations working as partners to engage in design, development, and implementation of mutually agreed- upon scientific or educational activities that advance specific and shared objectives with each organization bringing funds, resources, or expertise to the table.
- Industry-led education may be perceived to lack credibility, and independent education may lack resources. Collaborative education provides education by leveraging the strengths of both approaches.
- Collaborating on educational programs often presents significant challenges, particularly in navigating the complex landscape of Ethics & Compliance (E&C) and Legal considerations.
- Collaborating organizations may involve industry, professional societies, patient associations, and/or academic and health institutions.
- A collaborative partnership **framework** may address an educational gap through a joint effort that clearly defines the roles and responsibilities of each partner.
- A collaboration agreement or charter can help to establish a guide for the nature of the collaboration documenting and disclosing roles and responsibilities.

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Educational collaborations framework

Flexibility and Adaptability:

collaborative education allows for the adaptation of programs to the needs of different audiences, increasing relevance and effectiveness.

Involving Multiple Entities:

partnerships may involve not only industry and medical organizations but also professional societies, patient associations, academic, and health institutions.

Addressing Educational Gaps:

a collaborative partnership framework helps address specific educational gaps, co-creating relevant educational content that aligns with the pharmaceutical company's education strategy and addresses gaps in care.

Establishing Guidelines:

a collaboration agreement or charter should be used to document and disclose the roles and responsibilities of each partner, guiding the nature of the collaboration.

5E

Other Medical Affairs External Funding Requests

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5E

Other external funding requests: memberships, donations, and fundraisers

These requests are mentioned for completeness;
however, how each type of request should be managed is out of scope for this guidance

Corporate memberships	• Funding payable to a group or organization at a regular interval in return for certain privileges and prerogatives • As a corporate member, the company generally receives a “seat at the table” and participates in leadership meetings • Memberships to professional societies may include benefits such as several individual memberships, complimentary meeting registration, discounts on exhibits, and access to mailing lists
Charitable donations*	• Financial or in-kind support provided to non-profit organizations, including patient advocacy groups, professional medical associations, and other charitable organizations with 501(c)(3), (c)(4), (c)(6) tax status • Applications may be evaluated with priority given to innovative programs that meaningfully address therapeutic areas of interest, disparities, and/or unmet needs
Fundraisers*	• General fundraising activities by non-profit organizations to raise money for programs that would ultimately benefit patients, families, and caregivers • Examples include a gala dinner, recreational outing, walks/runs, etc.

*Requests may come initially to Medical Affairs, and depending on company policies, will be reviewed and processed by different functions

Other external funding requests: research and training

These requests sometimes fall under Medical and based on company structure are handled by broader groups. They are mentioned for completeness but are out of scope for External Education Standards and Guidance

Research

- Investigator-sponsored research (ISR)/investigator-sponsored trial (IST)/ investigator-initiated study (IIS)
- Non-interventional studies
- Research collaborations
- Health economics and outcomes research (HEOR)/real-world evidence (RWE)/ real-world data (RWD) studies
- Registries
- Young investigator awards – typically open to graduate students, postdoctoral fellows, or early career investigators to support ongoing or future research projects

5E

Other external funding requests: scholarships and individual travel sponsorships

These requests are mentioned for completeness;
however, how each type of request should be managed is out of scope for this guidance

Scholarships

- Support for an individual HCP's training or continuing education

Sponsorship for an individual's travel

- May rarely occur outside of the United States
- May be subject to frequency limitations (e.g., an HCP may benefit only a certain number of times per calendar year)
- Must not be offered to compensate merely for the time spent by an HCP to attend events
  - Sponsorship benefits may include consultancy/speaking services by an HCP

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Thank you

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For more information please visit the External Education page on the MAPS website:
https://medicalaffairs.org/external-education/

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