ACCREDITATION COUNCIL FOR MEDICAL AFFAIRS

THE ACCREDITATION STANDARDS AND KEY ELEMENTS FOR PROFESSIONAL DEVELOPMENT IN MEDICAL AFFAIRS FOR MEDICAL AFFAIRS PROFESSIONALS

STANDARDS 2018

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Standards 2018

Introduction

This Standards 2018 document was created to: (1) to provide a set of consistent standards which all pharmaceutical, biotechnology, medical devices, and diagnostic companies should adhere to when structuring their respective medical affairs organizations. (2) offer strategies to enhance the quality of medical affairs programs globally. (3) assist companies and organizations to improve compliance thereby mitigating risk and liability by maintaining certain standards of excellence in medical affairs practice. The Accreditation Council for Medical Affairs has created this document and anticipates that it will be updated periodically as healthcare evolves and the need, function, and regulations related to medical affairs change.

These standards are framed as s*uggested strategies* for quality improvement. These strategies are based on evidence gleaned from the literature, responses provided by multiple stakeholders, and insights gained during ACMA interviews and surveys. Experience has shown that when these strategies are implemented, quality improves.

Definitions:

Medical Affairs Professionals-include all employees, interns, and fellows working in the medical affairs functions. The functions within medical affairs include the following:

-Medical Science Liaison (Field based medical affairs)
-Health Economics Outcomes Research (HEOR) also known as Pharmacoeconomics
-Scientific Communications (also known as Publications Strategy or Publications Planning)
-Medical Information (Drug Information)
-Medical Strategy
-Medical Writing
-Pharmacovigilance (Drug Safety)
-Medical Affairs Operations
-Medical Affairs Excellence

The specific positions within medical affairs include:

- Medical science liaisons (or field based medical affairs)
- Directors, Medical Affairs

- Medical Directors
- Health economic outcomes research specialists (HEOR) and HEOR liaisons,
- Vice Presidents of Medical Affairs
- Chief Medical Officers (CMO)
- Medical information specialists
- Medical information managers
- Medical information directors
- Scientific communications director/manager
- Publications managers
- Publications Directors
- Pharmacovigilance Specialist
- Drug safety officer
- Medical affairs operations
- Medical affairs excellence (related functions),
- Medical affairs IT
- Medical sciences
- Laboratory directors
- Medical strategy and any other employee working in a medical affairs function in a similar position (titles will vary among companies).

ACMA Standards 2018

Goals & Outcomes: Standards 1-4

1. Scientific Platform – Each medical affairs organization should have a scientific platform developed for each therapeutic area of focus and/or product, device, or diagnostic. The scientific platform should provide the underlying basis from peer reviewed literature for the following:

- Disease State (Physiology & Pathophysiology)
- Epidemiology & Prevalence of the disease
- Clinical Practice Guidelines for diagnosing & treating the disease
- Clinical studies outlining the use of all treatment options
- Pivotal clinical trials for the company's product(s), device, or diagnostic test
- A thorough review and understanding of safety data

2. Therapeutic Area/Product-specific outcomes – In addition to a scientific platform, each medical affairs group should develop strategic goals for each therapeutic area with clear outcomes of success for all of medical affairs (including the field based medical affairs team (MSL team).

3. Overarching Outcome – Medical affairs organization should articulate the value of their function to others with a focus on education and data generation. There should be no mention or linkage of medical affairs activities to sales, marketing, or prescription level data. The primary outcome of medical affairs should be to provide unbiased, objective education to healthcare providers as well as assist the company in generating important data to help further inform the medical community as to the appropriate use of their product(s).

Key Thought Leader (KTL) and Academic Collaborations – Competencies for collaboration with KTLs and academic institutions should include the following:

Personal and Professional Development: Standard 4 4a. Defining and identifying KTLs – KTLs (also knowns as KOLs) are influential stakeholders. These are not limited to physicians only but also other ancillary health care providers, patient advocacy groups/organizations, regulatory affairs KOLs, and academic KOLs.

4b. Standards for collaboration with academic institutions – The following standards should be adhered to when academic institutions collaborate with industry:

Clear and unbiased transparency is a critical aspect of industry-academia relationship. There should be a detailed research agreement establishing clear roles, responsibilities and rules of engagement.

Industry will typically engage academia for a company sponsored trial or an investigator-initiated study. The agreement should specify the following:

- the study/research question and scope of research and activities, including aspects related

to protocol development and data management/programming
- study conduct in compliance with the protocol, governmental laws, rules and regulations, including ethical considerations and human subjects
- Protections if applicable. All applicable medical privacy (HIPAA), personal data laws, regulations and public disclosure policies should be adhered to.

- Good Medical Affairs Practices should include the following:
    - periodic updates on study progress
    - interim results/reports
    - final study reports provided in a timely fashion to the appropriate parties. This information should not be provided to a commercial (sales/marketing) function.
    - reporting to regulatory agencies or other agencies such as payer organizations if applicable
    - Data ownership, access to data and record keeping should be available in accordance with agreements between the two parties and in compliance with Good Publication Practice Guidelines (GPP3).
    - Payments should be made in a timely fashion in accordance with milestone events for the study.
    - All confidentiality agreements should be adhered to as applicable.
    - Publication guidelines, including
        - applicable disclosure of protocols, results and manuscripts on publicly available registries
        - jointly determined publication plan including authorship and agreed review process for intended manuscripts and presentations should comply with (GPP3).

Conflicts of interest (COI)

- Transparency. Minimizing COIs through complete disclosure
- Addressing nonfinancial COIs
- Adherence to local laws/regulations

Study Conduct

The latest version of the full study protocol or the study proposal should be an attachment to the study agreement as well as a description of the system in place for documentation of changes to the original version of the protocol. An analytic plan should be described and included as an attachment to the study protocol. The protocol should include a description of plans for protecting human subjects and assuring privacy that satisfy governmental regulations. This would also include the process for ethical committee review (e.g. IRB approval). A steering committee and/or an independent advisory committee may provide value to ensure the integrity and independence of the study and should be considered. A description of the purpose and function of each of these committees should be provided as well as a description of the membership composition, the process for selection of committee members, as well as their responsibilities.

The agreement should include a description of the institutions involved as well as a description of the key personnel who will be conducting the project, services (e.g. database access and license agreement) and equipment which will be required to conduct the study. This includes a brief description of the roles of the personnel assigned to the project. Resumes of the principal investigators and other key personnel with major responsibilities are useful as attachments to the agreement.

The agreement or protocol should also include a description of the timelines for the study (anticipated initiation and completion dates, length of time anticipated for various aspects of the

study including data collection and analysis) and the deliverables from the study.
It is recognized that, at times, a study may have to be terminated earlier than planned, or, conversely, extended beyond its original term. The processes for addressing such changes should be described, as well as the steps to be followed if these situations occur.
ACMA endorses the opportunity to register and publicly disclose research protocols in a suitable public site, such as ClinicalTrials.gov. The agreement should state whether and how the protocol should be registered and who will be responsible to do so.

Publication Process

One of the core missions of public and private academic institutions is to advance knowledge for the benefit of the population at large. There is a common interest between academia and industry in assuring the validity of any research and a general obligation to disseminate and publish research findings of potential scientific or public health importance irrespective of results. To avoid delay in publication, several institutions have put policies in place to ensure timely publication of study results. An example of an international guideline comes from the
Guideline on Good Pharmacovigilance Practices for Post Authorization Safety Studies (PASS) published by the European Medicines Agency and the Heads of Medicines Agencies.

Academic institutions across the world need to maintain the right to publish research results.
Any research agreement between academia and industry should have language addressing a) who is responsible for dissemination of results; b) the right of academia to publish the research findings with or without concordance of industry investigators; and c) the right of the sponsor to review manuscripts prior to their submission for publication within a specified time. Authorship decisions, including the inclusion of coauthors employed by the sponsor, should follow guidelines established by the International Committee of Medical Journal Editors, recommending that authorship be based on the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Organization and Governance Requirements: Standard 5

5a. Autonomy – Medical Affairs Organization should not report to any sales and/or marketing leadership team members. This creates an inherent conflict of interest. The CMO should report either directly to the CEO of the company or the head or R&D ideally. The reporting structure should be to a non-commercial function.

5b. Field Medical Affairs –
Field medical affairs teams should include a diverse group of individuals from different academic backgrounds. There should be alignment of field medical affairs teams with therapeutic area heads (medical directors) to ensure that communication is as streamlined as possible.

Interactions with sales teams-The ACMA encourages collaboration between medical affairs and sales /marketing within the appropriate boundaries and with the spirit of collaboration as outlined in the PhRMA guidelines as well as taking into consideration the specific circumstances.

Training: Standard 6

6a. Therapeutic Area Expertise – All medical affairs members that are responsible for the education, dissemination, or generation of scientific data or materials should undergo a thorough disease state and product training. This training should ensure that all medical affairs professionals understand and demonstrate a minimal level of competency of all functions within medical affairs. Additionally, for those individuals with highly scientific roles, they should successfully complete a competency based on-boarding training and assessment which ensures a minimal level of knowledge in that particular disease state(s) in which they will be focused on prior to educating or interacting with health care providers (HCPs). Failure to do so puts patients at risk indirectly.

6b. Compliance – All medical affairs members should be adequately trained on company policies and procedures, including compliance and legal issues related to interactions with health care providers.

6c. Board Certification in Medical Affairs – All medical affairs members that are responsible for the education, dissemination, or generation of scientific data or materials should be trained in all aspects of medical affairs and be board certified in medical affairs via the Board certified medical affairs specialist program (BCMAS).

The following areas should be adequately assessed:

The Pharmaceutical Industry
Introduction to the Pharmaceutical Industry, History and Development, Publicly Traded vs. Private Companies, Global Needs Driving the Growth of the Pharma Industry, The Different Functions Within the Pharmaceutical Industry (Drug Manufacturing, Supply Chain, Regulatory Agencies, International Regulatory Bodies), Pharmaceutical Industry Organizational Structure and Organization Function, Drug Discovery: Research and Development (R&D), The Drug Development Process – Path to Drug Approval, Drug Advertising, Generic Drugs, Problem Reporting, Active Surveillance, Staying Competitive

Medical Device Industry
Introduction to the Medical Device Industry, Market Segmentation Categories, The Device Business Market, Exportation of Medical Devices, Global Market Growth Drivers, US Medical Device Industry Constraints, Medical Device Regulatory High Points, Medical Device Pathway

Diagnostics Industry
The Diagnostics Industry, Segments of In Vitro Diagnostics (IVDs), Molecular Diagnostics, Point-of-Care (POC) Diagnostics, Regulation of IVDs, Classification of IVDs

Rules Governing Interactions with Healthcare Professionals
The Importance of Interactions of Pharma Companies with Healthcare Professionals (HCPs), Rules Governing the Interactions with HCPs, Independence and Decision Making, Training and Conduct of Company Representatives, Physician Payments Sunshine Act, Impacts of Medical Affairs on the Interactions of Companies with HCPs

Health Economics Outcome Research
Introduction to Health Economics Outcome Research (HEOR), Models of Pharmacoeconomics,

Assessment of Costs and Outcomes, Conducting a Pharmacoeconomic Analysis, Health Outcome Research, Quality-of-Life Measures

Evidence-Based Medicine

What is Evidence-Based Medicine (EBM), Five Steps to Practice EBM, Study Designs, Evidence Hierarchy, Classification of Literature Resources

Clinical Trial Designs

Introduction to Clinical Trials, Importance of Clinical Trials, Clinical Trial Structural Designs, Clinical Trial Hypothetical Designs, Clinical Trial Parameters, Statistical Analysis, Diagnostics Tests, Bias and Confounding in Research

Presentation and Communication Skills

Importance of Presentation Skills, The People: Who is Your Audience, Presentation Preparation, Communication Skills, Emotional Intelligence (EI) vs Intelligence Quotient (IQ)

Compliance

Tiers of Compliance Regulations, First Tier Compliance Regulations and Subparts (FDA 21 CFR Parts 210 Current Good Manufacturing Practices for Manufacturing, FDA 21 CFR Parts 211 Current Good Manufacturing Practices for Finished Products, FDA 21 CFR Parts 280 Quality System Regulation for Good Manufacturing Practices), Second Tier Compliance Regulations and Subparts (FDA 21 CFR Part 50 Protection of Human Subjects, FDA 21 CFR Part 56 Institution Review Board, FDA 21 CFR Part 58 Good Laboratory Practice for Non-Clinical Laboratory Studies (GLPs)), Third Tier Compliance Regulations and Subparts (FDA 21 CFR Part 7 Enforcement Policy)

Abstract and Medical Writing

Introduction to Abstracts, Purpose of Writing an Abstract, Types of Abstracts, Effective Abstract Writing for Scientific/Research Papers, Components of the Abstract, Medical Writing in the HealthCare Industry, Types of Medical Writing, General Steps in Writing Scientific Documents

Publication Practices

Introduction to Publications in Medical Affairs, Landmarks in Publications, Publications Workflow, The Scientific Platform, Working with Authors

Drug Development Process

Phases of Drug Development Process (Discovery, Pre-Clinical, Clinical), Regulatory Submission and Approval, Post-Market Research, Drug Approval Applications, Drug Life Cycle Management

Medical Information

Medical Information: Here and Now, Structure, Roles Within Medical Information, Medical Information Stakeholders, Medical Information Core Responsibilities, Scientific Review Committee, MI Key Challenges and Opportunities

Medical Science Liaisons and Field Based Medical Teams

Medical Science Liaisons: Here and Now, Introduction to Field Based Medical Teams and the Role of the MSL, Key Opinion Leaders, Geographic Coverage by MSL Teams, Roles Within an MSL Organization, Communication and Meeting Preparation, Networking and KOL

Identification, Clinical Research Support, Maintaining Scientific Accuracy and Product Initiative Support, MSL Key Challenges and Opportunities

Grant and Investigator-Initiated Study Funding and Process

Grants Process, Investigator Initiated Studies (IIS), Funding Opportunities and Sources

Advisory Boards

Role of Advisory Boards, Challenges and Key Elements to the Success of Advisory Boards, Members of Advisory Boards, Value of Advisory Boards in Changing the Landscape of Medical Affairs

Phase IV/Post-Marketing Studies

Purpose of Post-Marketing Research, Advantages and Disadvantages of Post-Market Research, Types of Post-Marketing Studies, FDA-Mandated vs Non-FDA-Mandated, Roles of Medical Affairs in Post-Marketing Activities of Drugs

Regulatory Affairs

Introduction to Regulatory Affairs, Regulatory Affairs in the Medical Device Industry, Medical Device Classification, Performance Standards, Medical Device Filing Types, Regulatory Affairs in the US Pharmaceutical Industry, Regulatory Affairs in the EU and Canadian Pharmaceutical Industries

Risk Evaluation and Mitigation Strategies (REMS)

Introduction to REMS, Examples of the Types of Risk REMS Requirements Aim to Mitigate, Determining When a REMS is Needed, What the FDA Takes into Consideration When Identifying the Need for REMS, REMS Elements, Elements to Assure Safe Use (ETASU)

Medication Safety and Pharmacovigilance

Safety Signals, Adverse Events, Adverse Drug Reactions, FDA Pre-Market and Post-Market Safety

6d. Continuing Professional Development – All medical affairs members are strongly encouraged to pursue continuing professional development and education. This can be in either the disease state or continuing education and a greater understanding of medical affairs and/or related healthcare areas. Maintenance of certification as a Board Certified Medical Affairs Specialist (BCMAS) is strongly recommended to maintain the most up to date knowledge on important changes in medical affairs.

The ACMA also believes that ensuring training on “soft- skills” such as presentation skills, communication, cultural sensitivity, and other related topics are important and critical for medical affairs professionals who may interact with patient advocates or patient advocacy groups and even patients.

Eligibility and Reporting Requirements: Standard 7

7a. Qualifications for employment within medical affairs – list out educational requirements. Include preferred vs. required. Medical affairs team members should typically hold earned

doctoral degrees appropriate to their responsibilities of their job function. Many disciplines use post-doctoral training as a component of professional preparation. They may also possess additional professional training (residency, fellowship, or equivalent experience). Working or having a board certification in medical affairs via BCMAS should be sought after to ensure the candidate has a broad skill set which will be applicable to several areas within medical affairs. The BCMAS credential will also ensure that a minimal level of competency has been verified and established.

7b Reporting Requirements

Medical affairs organizations are responsible for reporting certain data in accordance with applicable laws. This section outlines these reporting requirements.

7b1 External Reporting

The following reports should be produced by medical affairs:

- Pharmacovigilance
    - Annual safety reports (PADER, PSUR, etc.)
- Medical Information
    - Number of inquiries
    - Types of inquiries
- Physician Payment Sunshine Act Annual Reporting
    - Requires that manufacturers collect this information on a yearly basis and then report it to Centers for Medicare & Medicaid Services ("CMS") by the 90th day of each subsequent year. On June 30th of each year, CMS plans to post the reported payments and other transfers of value on its public website.

7b2 Internal Reporting

- Creation of policies/procedures to control provision of off-label information by Medical Affairs personnel.
- Creation of policies/procedures to require sales reps to refer requests for off-label information to Medical Affairs.
- Development and maintenance of inquiries databases to track and monitor HCP requests for off-label information and company responses.
- Policies/procedures related to the manner and circumstances under which Medical Affairs personnel participate in meetings or events with HCPs (either alone or with sales reps or account executives) and the role of the Medical Affairs personnel at such meetings or events.
- Develop annual publication plans and establish a publication monitoring program
- The process by which KTLs were identified.
- Documentation of all company participants in meetings/discussions where clinical trial concepts were discussed.
- Process by which authors are selected for publications.

Vision, Mission, and Goals: Standard 8

The vision, mission and goals of a medical affairs organization should not include any reference to commercial incentives. The focus should be on objectively providing and disseminating education to HCPs. Additionally, focused on generated data which would be deemed as filling a 'gap' in the medical literature for the betterment of patient welfare.

Organizational Culture: Standard 9

The culture of a company is different from organization to organization. And even within organizations, cultures can be different within teams. The intention of this section is to simply ensure that there is a culture which adheres to the highest standards of professional ethics. Additionally, that 'scientific excellence' is something that all individuals try to attain and are assessed routinely on in performance reviews. This is critical being that medical affairs is meant to be the objective, subject matter expert for the company.

Performance Metrics: Standard 10

The ACMA cannot prescribe specific performance metrics as each role and company have their specific goals and outcomes. However, it is important to note that no medical affairs professional should have any goals focused on commercial interest (i.e., number of prescriptions written by an HCP).

Special note about MSLs: MSL metrics should not be focused on the number of interactions an MSL has with an HCP. The value of the MSL should be assessed in keeping with the larger context that the MSL is providing a broad range of both supportive, operational and strategic services for the company and these cannot be valued based on the number of interactions. The ACMA strongly discourages the use of analytics to measure MSL value based on the number of interactions with a HCP.

10a. Evaluation of team members – Assessment should include the following:

- Scientific acumen, communication skills, and effectiveness related to learning
- Generation and dissemination of knowledge through research and other scholarly activities, including publications and presentations at local, regional, and national meetings of scientific, practice or academic peers
- Commitment to personal continuing professional development
- Understanding of scientific advances and their implications
- Collegiality and positive contributions to the organizational culture

10b. Components of assessment plans – In addition to the characteristics described within the standards, assessment plans contain:

- Desired outcomes of the company and medical affairs' functions mission, vision, and goals,
- Employee self-assessments,
- Formative and summative measures of goal achievement
- Input from cross functional team members, manager, other memberswithin medical affairs and KTLs (if doable).

Interactions with Sales & Marketing: Standard 11

The FDA has no official definition for what is considered scientific dissemination. Scientific dissemination is very different from a promotional activity. Medical Affairs professionals (and in particular, MSLs) should not engage in or use promotional materials when engaging HCPs, allied health professionals, pharmacy students/fellows, medical students/fellows or patient advocacy groups.
Below are illustrations of practices commonly understood to be scientific exchange:

- Responding to unsolicited requests for off-label information in accordance with FDA draft guidance.
- Distributing scientific and medical publications on off-label uses in accordance with FDA draft guidance
- Providing financial support for independent medical education programs
- Appropriate scientific discussions at legitimate scientific or medical conferences
- Scientific advisory meetings/focus groups, in appropriate circumstances and with limitations
- Appropriate communications intended for recruitment of clinical investigators and study subjects

Therefore, interactions with sales professionals is not completely discouraged, however, the company needs to be cognizant of perception within the medical community. It is generally acceptable practice that MSLs may visit an HCP when it is their first time with a sales representative to have the representative make an introduction (otherwise known as an "introductory call"). However, once the introduction is made, the sales representative should leave the vicinity so the MSL/medical affairs professional can have a private interaction with the HCP.

Medical affairs professionals should also be cautious about sharing subject specific content related to disease state, research, clinical trials with sales representatives as it relates to the interactions they have had with physicians. It is permissible for the MSL to share high level logistics information such as office hours, confirming attendance at an event, etc. It is generally advisable to not provide detailed level information (in particular off-label information) with a sales representative.

Appendices to the Standards

A series of appendices are included within the Standards which provide additional guidance:

Appendix A

Communication Skills Presentation Skills: Being that medical affairs professionals are presenting information to a variety of stakeholders, it is recommended that medical affairs/MSL professionals continuously seek opportunities to improve their presentation and communication skills.

In particular, related to health professional communications. When a medical affairs professional is:

Given a scientific question, they should be able to access and utilize appropriate drug information resources and provide an accurate and credible solution in both written and oral forms

- Develop a variety of drug-related reports, monographs, reviews, and policies using drug literature evaluation skills.
- Evaluate appropriateness of clinical trials and other study designs, including validation of methodology and assessment of data credibility
- Access appropriate drug information resources required for patient and HCP education

Appendix B
Competencies Needed for
Those working with Managed Care/HEOR

Performance competencies include:

Cognitive domain

- Explain the general concept of managed care
- Describe the differences between healthcare delivery models, including preferred provider organizations (PPOs), accountable care organizations (ACOs), integrated systems, and patient-centered medical homes
- Define Pharmacoeconomics and explain practical applications
- Outline the general provisions of Medicare Parts A, B, C, and D, and Medicaid, including coverage of medications
- Define formulary systems and explain the rationale for and practical applications of a formulary system
- Describe the steps involved in developing a formulary system
- Discuss the concept of utilization management and provide functional definitions of key elements associated with drug-related utilization management (such as prior authorization, step therapy, and quantity limits)
- Discuss general concepts associated with the benefit structure of a health plan, including co-pay vs. co-insurance, premium vs. deductible, and maximum out-of-pocket costs
- Identify the major factors influencing drug costs for a managed care organization (e.g., pharmacy costs, drug-pricing methodologies, contracts/rebates, discounts)
- Identify and explain the steps involved in the drug-approval process in the U.S.
- Explain the purpose and function of pharmacy benefit management programs
- Discuss the principles of patient-centered care management programs
- Discuss the principles of quality management
- Explain the role of quality organizations in ensuring quality in the managed care setting
- Identify and explain the major roles of the pharmacist in population-based provision of care (as distinguished from direct patient care)
- Explain the term “specialty pharmaceuticals,” give examples of such products, and describe generally how they are procured, stored, and dispensed to patients
- Identify several major factors that contribute to drug-related fraud and abuse
- Identify several major factors that contribute to drug waste
- Discuss the requirements for patient confidentiality as provided for under the 1996 Health Insurance Portability and Accountability Act (HIPAA) and professional practice guidelines