**Medical Affairs Collection**

**Description:**

Dossier Report Collections

The authors are pleased to showcase Report Collections, focused on areas of critical importance to Pharma's success, present and future. These Collections deliver expert views, exclusive analysis and insights to help you, your colleagues, and company gain a knowledge edge in each of the topics. Specially priced, these Report Collections provide significant value.

Report Collections include:

- Biosimilars
- Emerging Markets
- Market Access
- Medical Affairs
- Pharma Marketing

The 'Medical Affairs Collection' comprises the following titles:

- MSL-KOL Engagement: Delivering Value Under New Rules
- Ensuring Optimal Medical Affairs Performance: Delivering Measurable Value
- The Path to Product Inclusion in Clinical Guidelines: Strategies for Success
- Pharma and the mHealth Revolution - Engaging with Mobile-enabled Physicians and HCPs
- Publication Practices for Compliance and Credibility

Please see the Table of Contents for a detailed breakdown of each report.

*PLEASE NOTE: This is a bundle package containing multiple titles*

**Contents:**

***MSL-KOL Engagement: Delivering Value Under New Rules***

The role of MSLs is changing. Once a position that straddled the area between scientific insight and sales, global demands for transparency and disclosure in MSL-KOL relationships have caused a seismic shift.

For the pharmaceutical industry, the fallout is clear: companies are now examining how MSLs are engaging with KOLs and creating distance between their unbiased, informational role and explicit, promotional behaviours. Even where there is no clear, official guidance overseeing MSL-KOL relations, many companies are implementing their own rigorous measures for handling training, standard operating procedures and monitoring.

Like its best-selling predecessor, MSL-KOL Engagement: Ensuring Compliance (2nd Edition) tackles the evolving MSL-KOL relationship head on. Cast against tougher regulations being implemented worldwide such as Sunshine Act in the US, the report not only addresses the heightened need for measurable, demonstrable MSL compliance, but how companies can better grasp the legislative landscape and develop on-going strategies to support long term MSL-KOL interactions. In an era of increased scrutiny, penalties and skepticism, MSL-KOL Engagement: Ensuring Compliance (2nd Edition) is an invaluable and timely roadmap for any company.

This report provides:

- Access to the most current and up-to-date strategies developed by companies ensuring MSL-KOL relationships remain without censure
- Insight into the very latest US and European regulations and legislation governing MSL-KOL interactions
- Discussion of proactivity versus reactivity, off-label information, standard operating procedures, training/tracking, and how to incentivise MSLs
- Measures that demonstrate MSL value without crossing the line into promotion
- Insight into how MSL-KOL relationships can be maintained over the long term

Key benefits

Under the scrutiny of the Sunshine Act and similar legislation, the time has come for companies to address MSL training, metrics and activities from a far different viewpoint than in the past. MSL-KOL Engagement: Ensuring Compliance (2nd Edition) offers clear and concise guidelines for doing so. Amongst the benefits, this report will help you to:

- Understand the regulatory environment in order to protect and support MSLs
- Grasp the key issues that may arise and develop preventative strategies
- Negotiate 'grey-area' compliance issues in MSL-KOL interactions, such as off-label information and proactive versus reactive MSL activities
- Better know the value of MSL operations and the metrics that can be used to measure and demonstrate compliance
- Expert views from Bayer, Bausch & Lomb, Philips Healthcare, Quintiles, Sequenom, PDI Healthcare, Scientific Advantage and LNR Enterprises

Key Quotes

“The peer to peer relationship an MSL achieves creates greater access. With the traditional sales model, access became more limited, so for a few years we were seeing companies utilising MSLs to drive sales. We learned, however, that in a regulated environment we need to take a role that has greater access and use it appropriately.” – Stewart Rosen, Vice President Medical Affairs, Quintiles

“If we come up with a specific activity for an MSL, the first people we talk to are legal and compliance. We run the idea past them, we get their blessing before we move any further. And before we implement, we are again assured that we've been approved to do so by legal and compliance.” – Mitch Trujillo, Vice President of Medical Affairs and Head of Global MSL Excellence at Bayer HealthCare.

“We definitely in the past have been a much more reactive organisation from a clinical standpoint. We have definitely moved into a more proactive stance. And we're not being advocates: it's addressing the different challenges and complex problems and dealing with those upfront rather that reacting to them.” – Dr. Hudson Garrett, Senior Director of Clinical Affairs. PDI Healthcare.

“The MSL function in the US is really strictly focused on traditional KOL development and things like that, whereas I'm finding in the more global areas, it has to be more than just a medical affairs function. The rules surrounding MSL-KOL interactions in emerging markets are as a whole, a little bit less regulated right now. But I will say with those areas it's really important to have your local team and compliance take the lead on what is appropriate in a given region.” – Doral Fredericks, Vice President, US medical affairs and global communications, Bausch & Lomb

MSL-KOL Engagement: Ensuring Compliance (2nd Edition) answers key questions:

- What is the current state of affairs for legislation and regulation governing MSL-KOL relationships?
- What guidance is currently available?
- How can a company develop self-governing strategies where no official guidelines exist?
- How can MSLs maintain integrity and credibility while demonstrating their value?
- What future is there for compliant MSL-KOL interactions?

Expert Views Include:

- Doral Fredericks, Vice President, US medical affairs and global communications, at Bausch & Lomb
- Elizabeth Kupferer, Sr. Director, Medical Affairs at Sequenom
- Dr. Hudson Garrett, Senior Director of Clinical Affairs at PDI
- Kevin Appareti, Senior Director, Global Medical Science Liaison at Philips Healthcare
- Michelle Stith, Founder of SpendTrenz
- Mitch Trujillo, Vice President of Medical Affairs and Head of Global MSL Excellence at Bayer HealthCare
- Robin Winter-Sperry, MD, President and Chief Executive Officer of Scientific Advantage
The stakes are high in maintaining compliance in MSL-KOL relations. In this report, you will discover:

- How MSLs can stay within compliance boundaries without impeding scientific exchange
- How can MSLs and their managers negotiate grey-area compliance issues such as off-label information or proactive versus reactive MSL activities
- A country-by-country breakdown of new and established MSL compliance regulations, as well as insight into regional challenges
- Understand ways in which MSL value to your organisation can be measured and demonstrated compliantly
- How other emerging medical affairs roles are creating challenges in reporting

***Ensuring Optimal Medical Affairs Performance: Delivering Measurable Value***

In this era of transparency, Medical Affairs is rapidly becoming the new voice of Pharma.

Positioned at the interface between Commercial and R&D, and as the hub of communications with key stakeholders, Medical Affairs is in a prime position to lead Pharma's transition from merely selling drugs, to playing an integral role in the entire healthcare ecosystem.

The perceived importance of this function is reflected in the growth of its budget and responsibilities. However, the value that Medical Affairs brings to an organisation is notoriously hard to measure. Yet effective measurement can lead to greater efficiency and expertise in bringing stakeholder insights into the company.

Ensuring Optimal Medical Affairs Performance: delivering measurable value is an invaluable resource for anyone interested in the evolution, measurement, and management of Medical Affairs – including Medical Affairs directors; Brand, MSL, and IIT managers; and Global Communications executives.

This up-to-the-minute report draws on the expert opinions and experiences of Medical Affairs leaders at top Pharma companies including Astellas, Bayer, Boehringer Ingelheim, and Ferring.

Key Benefits:

Medical Affairs plays a vital role in meeting rising demands from increasingly varied stakeholders. However, while nobody disputes the essential nature of their work, there is still a significant benefit in understanding which Medical Affairs activities are the most effective in gathering insights of strategic value. Companies looking for ideas on how to assess the impact of their Medical Affairs programmes and conversations, and how to manage change within the organisation, will find effective answers in this extensive report. Ensuring Optimal Medical Affairs Performance: delivering measurable value will help you to:

- Understand the growing importance of Medical Affairs as the voice of the company
- Gain practical know-how on ways to measure the 'unmeasurable'
- Receive guidance on effective implementation of measurement throughout the organisation (including how to ensure that Medical Affairs staff don't feel alienated)
- Be aware of the benefits of cloud computing and tablet technology

Executive summary

Introduction

- Engine of change

What is Medical Affairs?
- A rapidly changing field
- Diverse skill-set
- Regulatory pressures
- Compliance
- Physician Payment Sunshine provisions
- Data integration
- New ways of working with physicians

-Medical Affairs in perspective
- Growth of Medical Affairs
- Budget allocation to Medical Affairs
- Relative importance of Medical Affairs
- Spending breakdown in Medical Affairs
- Key findings for best practices

-Organisation of Medical Affairs
- Maturation along similar lines
- Interacting with brand teams
- Matrix structure at Ferring
- Strategic thinking at Astellas
- Doctor's Guide Publishing Limited. All Rights Reserved
- Delivering Measurable Value
- Working with the affiliates
- Training

-Measurement of Medical Affairs
- Assessing relationship quality
- Demonstrating a good job
- Short-term measures of long-term value
- Operational metrics
- Assessing output
- Workflow
- Investigator-initiated research
- Managing stakeholders
- Collaboration plans
Clinical guidelines are taking hold in the practice of medicine. Though not always voluntarily followed in real-world patient care, they increasingly form the basis of formulary and reimbursement decisions, as well as the continuing medical education (CME) materials used by physicians.

In this guidelines-centric culture, it is more imperative than ever for drugs to be on the guidelines, and also harder than ever to influence the data that determines them.

Best practices around clinical guideline development call for independent analysis of raw data – untainted by financial gain or academic prestige.

In this tightly controlled and highly sensitive environment, what can Pharma do to maximise the credibility and visibility of its products?

Overview:

- The Path to Product Inclusion in Clinical Guidelines: Strategies for Success

If you've looked for information about clinical guidelines written with Pharma in mind, you've probably ended your search empty-handed.

The sensitive nature of the Pharma-clinical guideline relationship has made it difficult for Pharma to talk about this important topic.

This report addresses this critical knowledge gap, and has been designed to get Pharma up to speed with the complexities of clinical guideline development and adherence, and to be prepared for future trends. The report also provides practical insights on how to increase visibility of medicines, even in an area that is beyond commercial influence.

In spite of most companies' reluctance to speak on this subject, FirstWord has sourced illuminating commentary from Big Pharma representatives and prominent clinical guidelines experts.

Don't miss this ground-breaking report – available now.

Learn about

- Exclusive insights from industry experts
Clear documentation of how Pharma's footprint is being eliminated from the appraisal of evidence
Explanation of the critical importance of clinical guidelines in rationalising the use of medicine
Cautionary tales of challenges to the guidelines
Detailed description of the latest standardised methods and best practices for research and guideline development worldwide (e.g., CONSORT, PRISMA, AGREE)
Up-to-date findings on adherence to guidelines
Handy global list of websites for referencing clinical guidelines

Key benefits:
- Understand and effectively respond to the profound cultural shift towards evidence-based healthcare
- Know how to gain a tactical advantage by considering a product's place in clinical guidelines before development starts
- Receive expert advice on how to position data and products for better visibility
- Get up to speed with the new concept of “activation of evidence”
- Hear how the full and open disclosure of clinical trial results is likely to become the norm rather than the exception
- Learn how clinical guidelines are moving from demonstrating best practice to best value

Key questions answered:
- What can Pharma do to make best use of the evidence they have?
- What do opinion leaders want from Pharma?
- What are the major trends in guideline development, and how can we ensure that our scientific messaging is in line with that thinking?
- Why don't doctors always follow the guidelines?
- How holy is the holy grail of evidence-based medicine?

Key quotes:
“The perspective of people who know how to manage data and the pitfalls would be valuable on [guideline] committees and I think they would also mitigate the influences where there are conflicts of interest,” Dr. Philip Mackowiak, chief of the Medical Care Clinical Centre, VA Maryland Health Care System

“[The PPSA's policy on KOL payments] suggests that anybody who works with a pharmaceutical company is somehow doing something wrong. We are not going to move forward. We are not going to advance medical science.” Dr. Maurie Markman, senior vice president of clinical affairs, Cancer Treatment Centres of America

“The only way forward is to look at the very early phase development work, which is about defining the clinical need around which you need to design your future products.” Charlie Buckwell, chief executive, McCann Complete Medical.

Who Should Read This Report?
Professionals with responsibilities for:
- Brand Management
- Marketing
- Medical Education
- Pharma Publications
- Medical Affairs
- Clinical Trials

***Pharma and the mHealth Revolution - Engaging with Mobile-enabled Physicians and HCPs***

The media's dubbed them ‘a doctor in your pocket' and ‘health care helpers'. Yet despite the explosion of mobile apps in other industries, pharma has generally been slow to exploit the possibilities they represent. What are the hurdles facing the industry and who are the leaders overcoming them? How can companies develop a mHealth approach that both addresses end-user needs and key messaging? What does pharma need to know about regulatory and legal hurdles?

Concisely written and expertly researched, this FirstWord Dossier report succinctly addresses the issues surrounding the emerging mHealth industry—and finds the answers.
Report Overview:

Offering a compelling case for pharma to firmly establish its voice in mHealth, the report contains detailed insight into the opportunities app development represents. Encompassing the full range of questions demanded by the industry, the report includes expert insight from both those in pharma currently working ahead of the curve and mHealth developers themselves.

Whether your company is looking to expand into mHealth apps or seeking sound advice on a way forward, Pharma and the mHealth Revolution - engaging with mobile-enabled physicians and HCPs has the answers.

Key Report Features:

- Convincing arguments for further involvement from pharma in developing mHealth apps for healthcare providers
- Detailed insight into five major pharma mHealth projects
- Methodologies for determining the platforms on which mHealth apps should be launched
- Advice on how to maximise end-user needs to make mHealth products popular with health care professionals
- Insight into navigating legal, regulatory and intellectual property issues
- Solid predictions of future mHealth growth
- Case study of how one major pharma company has evolved its mHealth strategy

Key Benefits

- Discover how to develop an mHealth approach that aligns with company goals
- Learn the key lessons of optimising apps and websites for healthcare providers
- Learn how to navigate the main road bumps, including legal, regulatory and intellectual property issues
- Gain insight into what the leaders in the field know and how they're making mHealth apps work for them
- Get access to detailed case studies from companies such as Eli Lilly, AstraZeneca, Johnson & Johnson, AliveCor and GSK

Key Questions Answered

- When should a pharma company enter the mHealth market?
- What approach should be taken in answering both company strategy and end-user needs?
- What are the main hurdles facing the industry and how can they be overcome?
- What realities do app designers for international markets face?
- How can apps be developed for maximum usage across HCPs?
- What are the guidelines for designing apps for tablet or smartphones?

Key Quotes:

“The business case for pharma to engage in mHealth makes a lot of sense. But pharma has been quite slow to really embrace things in mobile health in a strategic or systematic way.” Dr. Patricia Meachael, executive director, mHealth Alliance

“There is substantial opportunity for pharmaceutical companies to be involved; it's just that they have to walk that fine line between providing a service to the patient population and having what they're doing viewed as just a kind of marketing. As soon as it gets perceived as the latter, all the alarm bells will go off.” Dr. Satish Misra, managing editor, iMedicalApps

Who Should Read This Report?

- Pharma medical affairs directors
- Marketing executives
- Compliance directors and legal teams
- IT managers
- PR firms with interests in the pharmaceutical industry
- Digital marketing agencies
- App and web designers

Expert Views
- Introductory summary
- Introduction
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    - On the go
  - Device ownership
  - Medical practice has changed
    - Using mHealth devices
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  - Global diversity

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  - The pioneers
  - Rules of engagement
  - Phone or web?

- Pharma's role in mHealth - Five detailed examples
  - Eli Lilly: Glucagon mobile app
  - AstraZeneca: EGFR mutation test
  - Johnson & Johnson: BlackBag
  - AliveCor: Heart monitor
  - GlaxoSmithKline: Mozambique vaccines programme

- Case Study
  - Sanofi's mHealth strategy
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  - The bottom line

- Uncertainties
  - Regulators weighing options
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  - User hesitancy

- What's ahead?
  - Predicted growth
  - Emerging technology
  - Listening to the users
  - Ensuring efficacy
  - The final requirement: Patience

- Acknowledgements

***Publication Practices for Compliance and Credibility***

Pharma's efforts to disseminate the results of its clinical research have never been under such intense...
Such high levels of suspicion make publication compliance and credibility two top priorities for pharma companies. GlaxoSmithKline's recent well-received decision to open up its raw clinical trial data to independent researchers will only accelerate the rush towards transparency. The question for publication managers and planners is not whether to follow GSK's example, but how. What is their response to an increasingly transparent environment? What must go into a publications strategy in order to comply with gold standards, meet stakeholder needs, and ultimately, gain credible exposure?

This timely new report will help anyone in the publications field discover ways to tackle new challenges and maximise new opportunities as open access transforms publishing.

Report Overview:

This comprehensive report explains what is driving change in publication practices, and provides insights into how three major pharma companies are adapting.

Many experts have shared their experiences, including Gary Evoniuk, director of publication practices at GlaxoSmithKline, who talks candidly about GSK's recent announcement to open the doors on its data.

Anyone with an interest in publication development will benefit from an overview of the latest association-led publication guidelines, a discussion of global compliance, guidance on coordinating publication development to meet new standards, pros and cons of traditional journals vs. open access publishing, and the latest techniques for measuring impact.

Key Report Features:

- Examination of changing attitudes from GPP to GPP2 and beyond
- Compelling arguments for unlocking the doors to your data
- Case studies from GlaxoSmithKline, Lundbeck, and Janssen
- Up-to-date roundup of guidelines on publishing
- Overview of the ISMPP-sponsored Global Publication Survey (GPS)
- Principal factors driving rapid adoption of open access (OA) publishing
- Implications of the increased acceptance of the OA publication model
- Newest ways of measuring an article's influence

Key Benefits:

- Understand why evidence has to be free of either academic or industry bias
- Be better prepared to stand up to authors who insist on trying journals where there is no chance of acceptance
- Grasp the pace and direction of open access publishing, what it offers, and how it challenges the most prestigious titles
- Know the most basic compliance guidelines. Get practical guidance on conducting training programmes
- Be aware of the challenges of expanding best practices globally

Key Questions Answered:

- Should companies subject all their affiliates to the high standards of the FDAAA in the US?
- How can I measure the impact of a publication in the context of OA, social media, and other new channels? And do impact factors always matter?
- How do companies organise their publications efforts?
- Who should sit on a steering committee?
- What is the difference between a publications planner and manager?

Key Quotes

“If you want your publication plan to be strategic and co-ordinated you have got to really look at the global picture.” Elizabeth Wager, Co-author of the original Good Publication Practice (GPP) guidelines

“I think a CIA ensures that a company puts the infrastructure in place to support good publication practice and this can help the publications department do its job properly.” Anna-Lisa Fisher, publications consultant

“In my dream world, the academic institutions would start making judgements based on the quality of what's published no matter what journal it's in.” Gary Evoniuk, director of publication practices, GlaxoSmithKline
Who Should Read This Report?
- Publication managers
- Publication planners
- Brand managers
- Medical writers
- Librarians
- Publishers

Expert Views:
- Gary Evoniuk, director of publication practices, GlaxoSmithKline
- Tom Grant, publications director, AstraZeneca
- Wendy Battisti, director of scientific and medical publications, Janssen Research & Development, Janssen Pharmaceutical Companies of J&J
- Jayme Trott, director, global medical affairs strategic operations, Janssen Global Services, Janssen Pharmaceutical Companies of J&J
- Anna-Greta Nylander, publications manager at Lundbeck
- Elizabeth Wager, co-author of the original Good Publication Practice (GPP) guidelines
- John Fallows, marketing director, BioMed Central (a pioneer open access publisher)

Executive summary
Publication planning in a suspicious world
- Total transparency
- Industry resistance
- FDA Amendments Act
- More clarity needed on trial registration

Closing the credibility gap
- Roche v the BMJ
- Guidelines galore
- Where is the industry at?
- The GPP2 guidelines

The ethical dimension
- Authorship criteria
- Authorship contracts
- Relationship management
- Timing is critical

Rise in Open Access publishing
- The Open Access movement
- Transforming the publishing landscape
- Journals or databases
- Measuring impact
- OA measures
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- Peer review

What makes a great publication planner?
- Organisation of the publication effort
- Johnson & Johnson
- Steering committees
- Early start at Lundbeck
- Following the data at GlaxoSmithKline

The global dimension
- Centralising operations
- Cultural differences
- Journal selection
- A changing environment
Are teams measuring up?
- Monitoring every step
- Training
- Project management

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