
MAPS eCademy
Webinar Series
Medical Affairs Excellence and Ethics & Compliance in the Evolving Healthcare Landscape – Collaborating and Leading by Example

Disclaimer

The views expressed in this Webinar are those of the presenters, and are not an official position statement by MAPS, nor do they necessarily represent the views of the MAPS organization or its members.

Introductions

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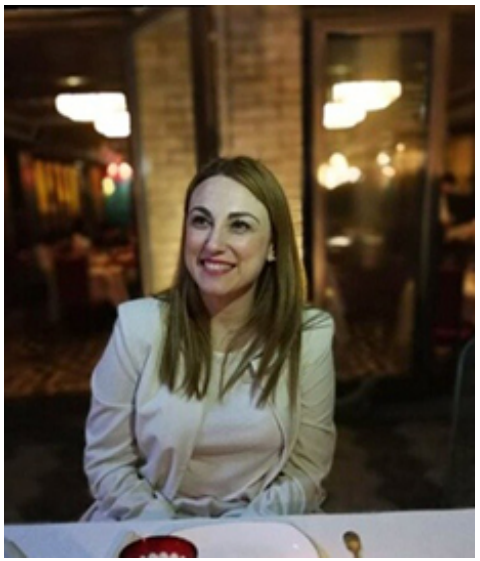

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Background

- Life science companies are facing unprecedented change requiring a rapid evolution of the Medical Affairs function.

- Patients are at the centre of Medical Affairs mission, which is the basis for ethical decision making and conduct of activities. Medical Affairs excellence is also achieved by following robust Ethics and Compliance principles and therefore leading by example within the organisation.

- Without doubt, a close collaboration between Medical Affairs and Ethics and Compliance functions for achieving excellence in Medical Affairs and beyond is needed.

Today's session

- Evolving role of Medical Affairs
- Environment, Major relevant Laws and Regulations
- Need for close collaboration between E&C and Medical Affairs
- Example:
  - Medical Affairs plans and Ethics and Compliance aspects

Industry trends lead to a growing demand on Medical Affairs

Medical Affairs Professional Society
FOR Medical Affairs Professionals
BY Medical Affairs Professionals

E M E R G I N G T R E N D S

1. Patient centricity

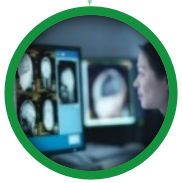
2. Increasing use of Real World Evidence

3. Role of Health Economics and Outcomes Research (HEOR)

4. **Importance of global compliance standards**

5. Digitalization

6. Growing role for customer facing Medical teams



7. Growing demands on Medical Affairs talent

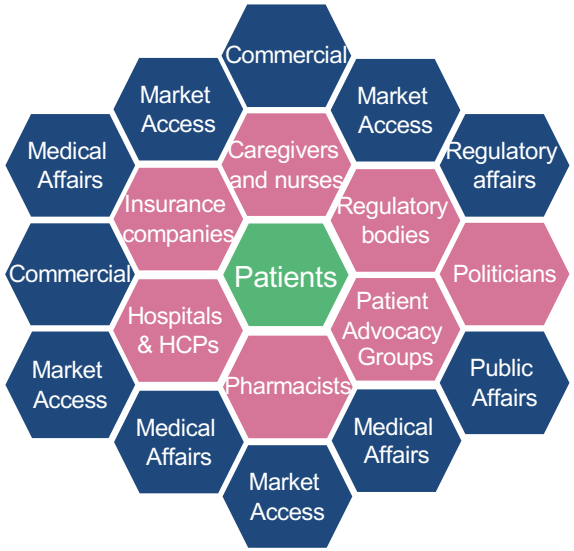
8. Strengthening of medical organizations

SOURCE: McKinsey Medical Affairs Leader Forum

As patients' influence is growing, Medical Affairs actions need to evolve

Medical Affairs Professional Society
FOR Medical Affairs Professionals
BY Medical Affairs Professionals

Patients emerge as key decision makers in healthcare



In 2016, US consumers went online for medical information:

57%
Accessed a website

21%
Used social media

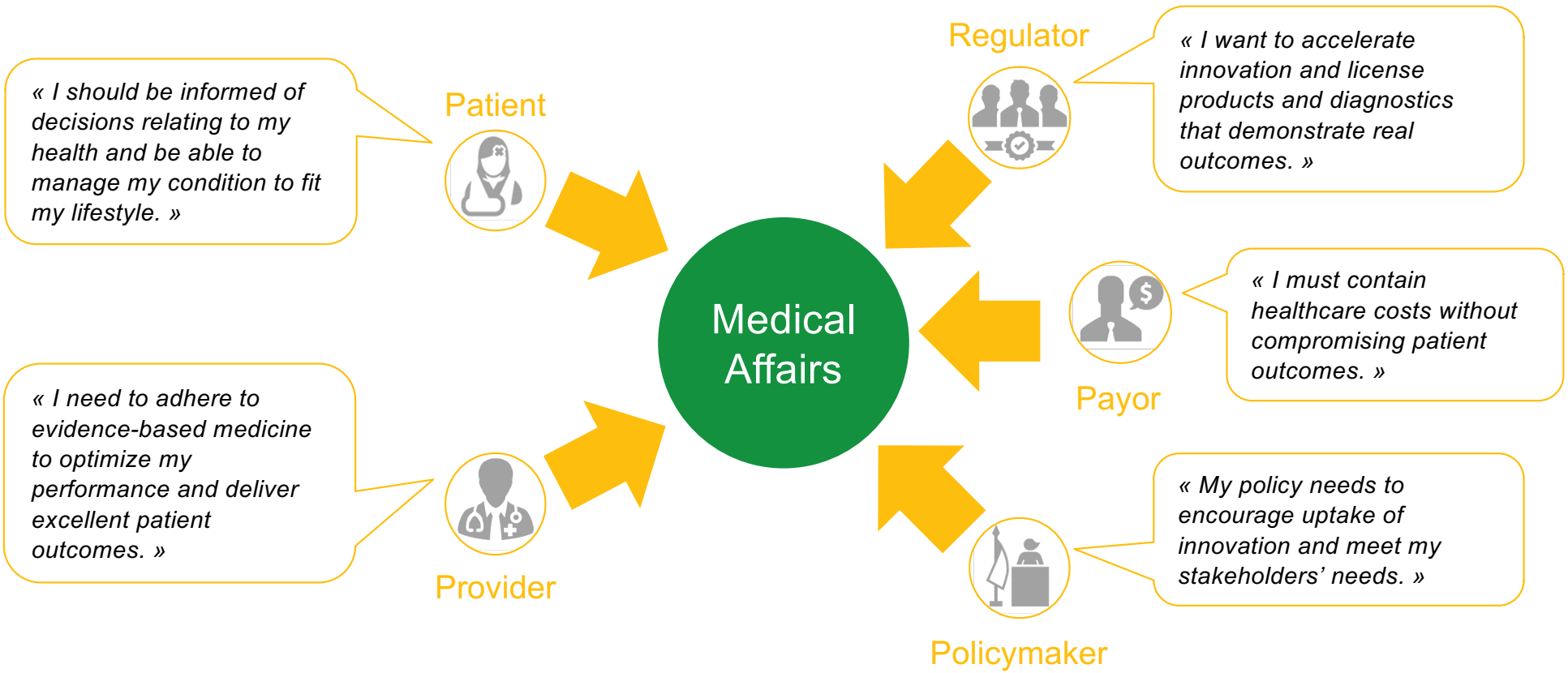
12%
Used online communities

SOURCE: Accenture Consumer Survey on Patient Engagement, 2016.

Medical Affairs responsibilities:

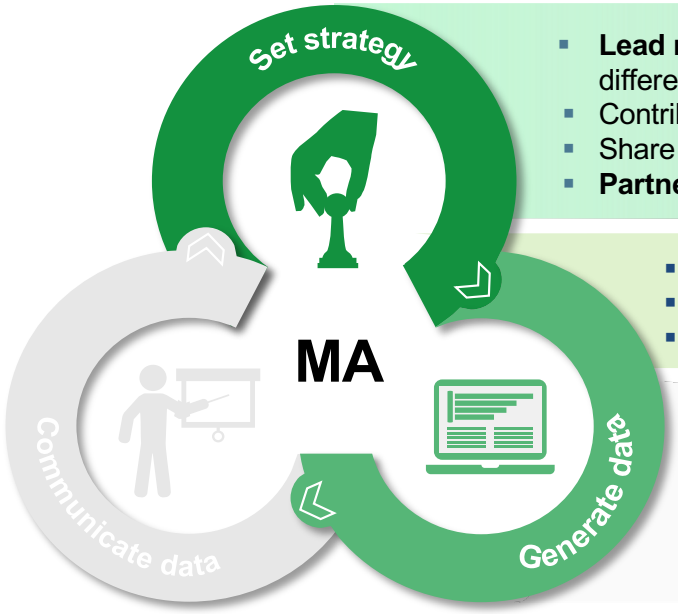
- **Actionable insights**: leverage the new sources of data to get better insights on patients needs and feedbacks, and translate them into action
- **Patient-centric projects**: orient the medical strategy around the patients' needs
- **Accessible information**: produce accessible and communicate valuable medical information that patients can understand

External forces are pressuring Medical Affairs



SOURCE: Strategy& analysis - A critical makeover for pharmaceutical companies: Overcoming industry obstacles with a cross-functional strategy, Jan. 2017

As a result, Medical Affairs must evolve to cover a broader set of activities



- **Lead medical strategy** across portfolio (e.g., identify unmet need) to drive scientific differentiation
- Contribute to **brand strategy** (e.g., support positioning)
- Share **medical insights** to improve internal business decisions
- **Partner with HCPs** and other stakeholders

- Conduct **post-approval** clinical studies
- Manage **ISS review** and **approval processes**
- Lead other **data generation** activities<

- **Communicate value** through HEOR/dossiers
- **Engage** thought leaders and medical customers
- **Educate** physicians
- Develop **publications**
- **Coordinate** Medical Information responses

Standardize practices

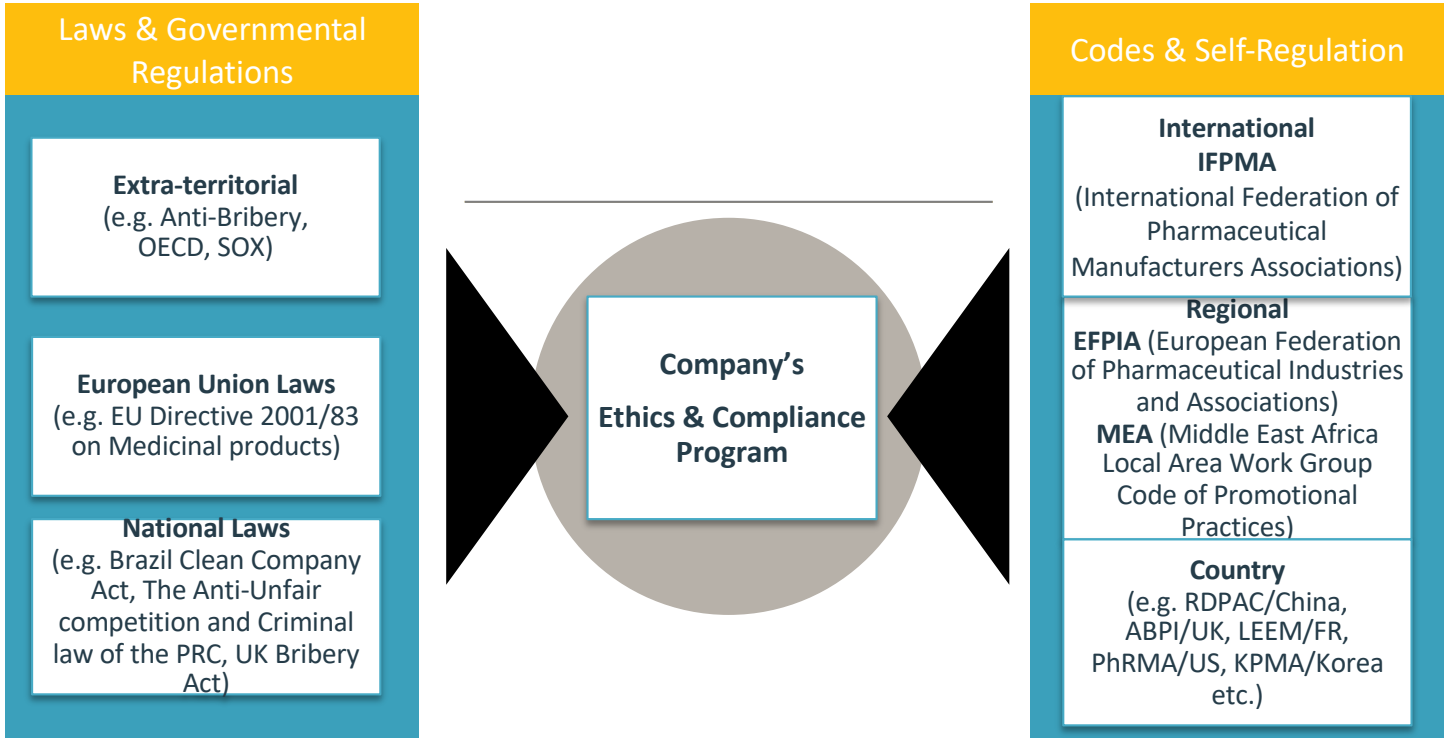
Build skills and capabilities

Set roles and organization

SOURCE: McKinsey Medical Affairs Leader Forum

Environment

A highly complex environment



SCIENTIFIC INFORMATION (1)

European Directive on Medicinal Products Directive 2001/83/EC, articles 86 & 88

- Definition and requirements for Advertising
- Limited information on scientific information

IFPMA Code of Practice, article 3, *Pre-Approval Communications and Off-Label Use*

- No pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country.
- Right of the scientific community and the public to be fully informed concerning scientific and medical progress.
- Proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences.
- Public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

SCIENTIFIC INFORMATION (2)

EFPIA HCP Code, *Scope*

- It does not regulate the provision of non promotional medical, scientific and factual information.
- EFPIA acknowledges that some member associations address these activities in their respective national codes, and encourages other member associations to do so, where appropriate.

Trends on Anti-corruption: Legislations & Enforcement

- **Consistent trend towards stricter compliance requirements in Europe and beyond**
  - France: New law Sapin II imposing the setting up of an anti-corruption program
  - Germany: stricter court decisions on personal liability of board members and group compliance organization
  - Italy: Legislative Decree no. 231 of 8 June 2011 dealing with group/corporate liability
  - Spain: Spanish Criminal Code, Spanish Companies Act and sector-specific legal provisions
  - UK: UK Bribery Act requires preventive compliance organizational measures and adequate procedures, in addition: extraterritorial reach
  - United States: Foreign Corrupt Practices Act (FCPA)

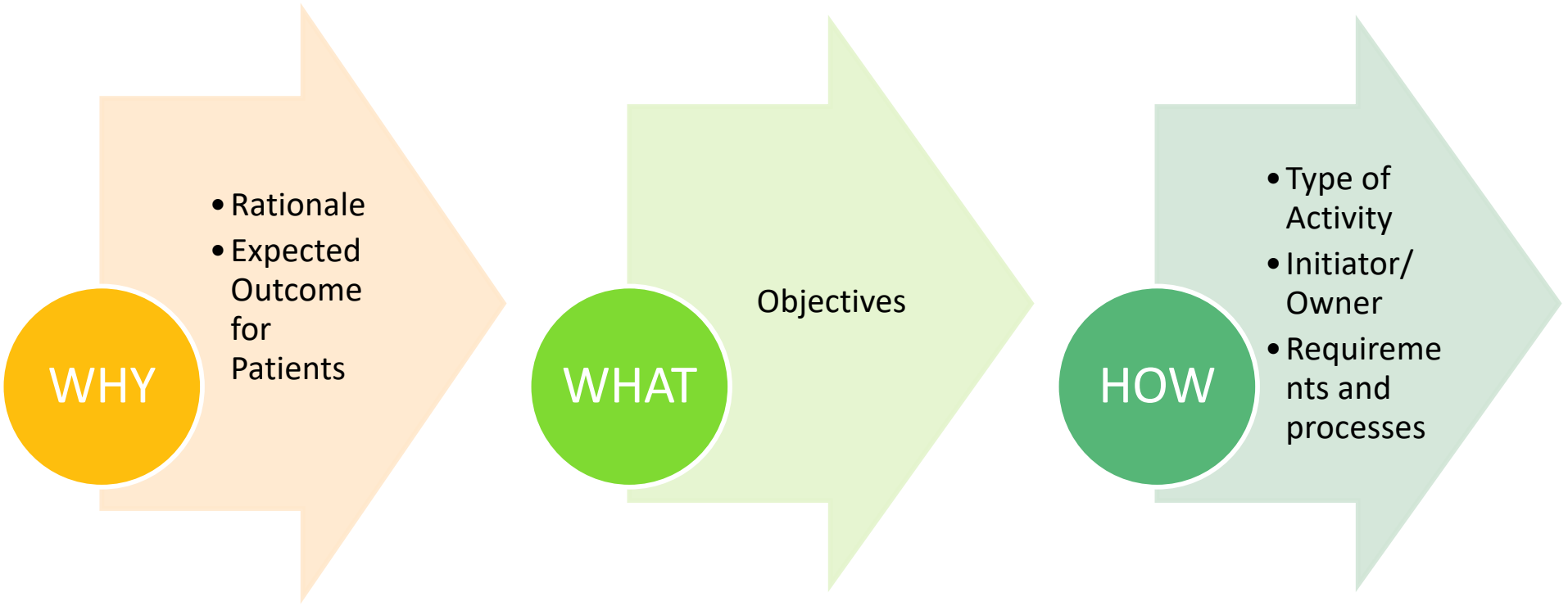
- **Increased enforcement in relation to personal responsibility of management**
  - France: creation of a prosecutor office, increased penalties against corporations and individuals
  - Germany: public prosecutors as well as competition and tax authorities are becoming more active

- **Complex group structures / matrix organizations increase legal liability**

Ethics & Compliance Approach for Interactions/Activities

- All interactions and activities must be conducted on the basis of a set of ethical principles defined and applied
- The underlying rationale for every interaction must be the contribution to the care and well-being of patients
- Ethical principles must be accompanied by clearly defined requirements and clear roles and responsibilities within an organization
- Prior to deciding how to do, reply to why and what

Projects/Activities: Key Questions to ask



Need for collaboration

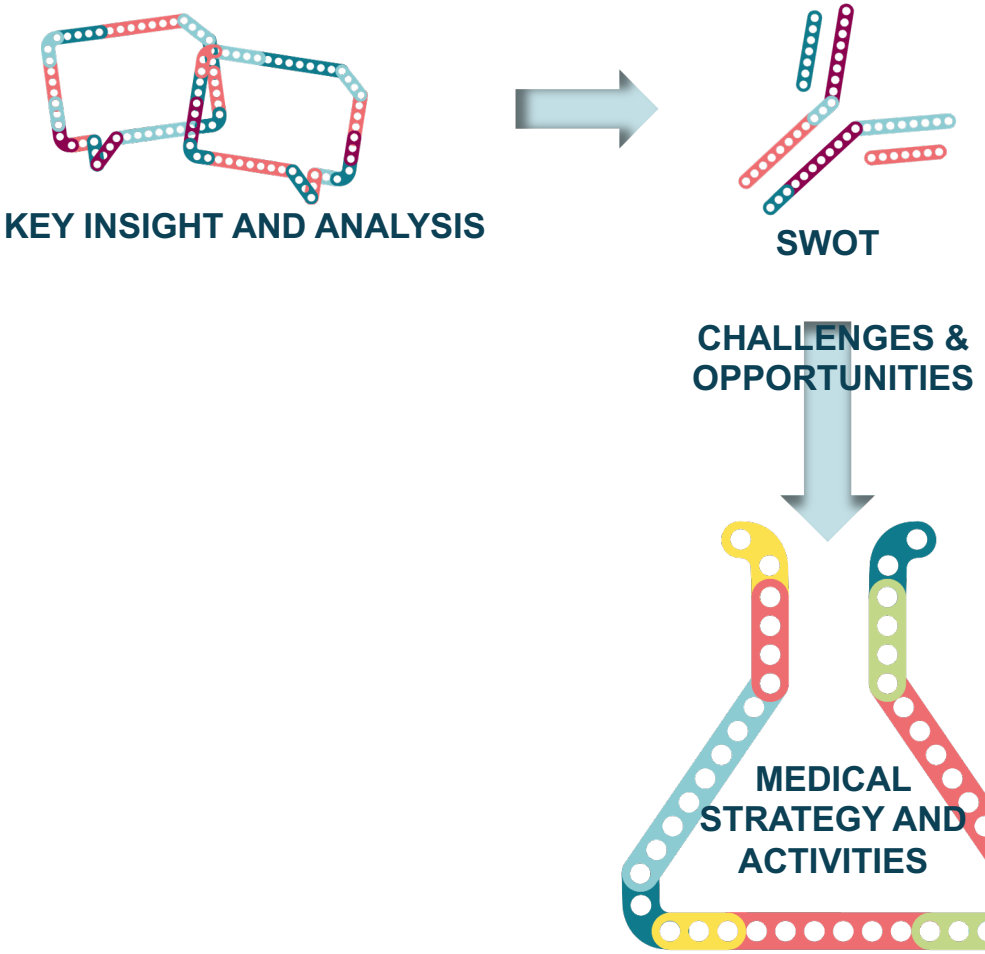
- Evolving Medical Affairs function
- Complex environment
- Integration of ethics can compliance approach in Medical Affairs
- Lead by example for the entire organization

MANY TOPICS FOR COLLABORATION!

- The role of Medical Affairs in strategic brand planning
- Ethics and compliance considerations in Medical Affairs Plans
- Early access to treatments
- Pro-active and reactive scientific exchange
- Interactions between medical and commercial functions
- Medical Education
- Advisory boards
- Clinical studies
- Scientific publications

Typical structure of Medical Plans

Medical strategy should be insight driven



What is the difference between information and insight?

Versus

Provides the WHAT

Provides the WHY

Making medical objectives SMART

- **S**pecific
- **M**easurable
- **A**chievable
- **R**elevant
- **T**imed

Crafting medical activities to address evidence gaps

Do they support new data related to the brand or the disease?

Do they help to counter or put into perspective recent competitor study findings

Do they help to generate new data, e.g. real world evidence, Investigator sponsored study (ISS)

Ensuring the right balance in medical activities

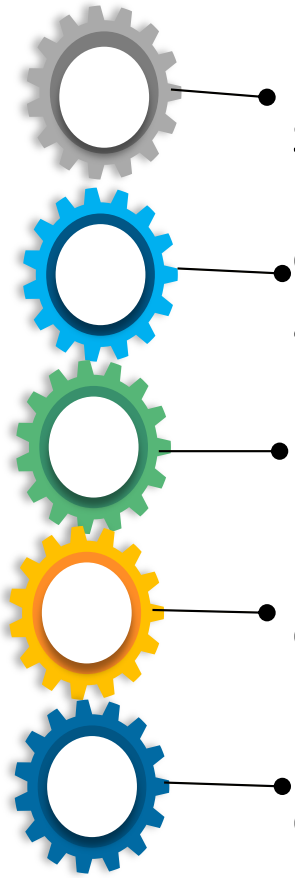
Does the investment in each activity reflect the order of prioritisation of objectives within your plan?

Is the activity meeting the medical objective and does it have a scientific rationale?

Have you considered how you can best use investment, and increase the reach and impact of each activity?

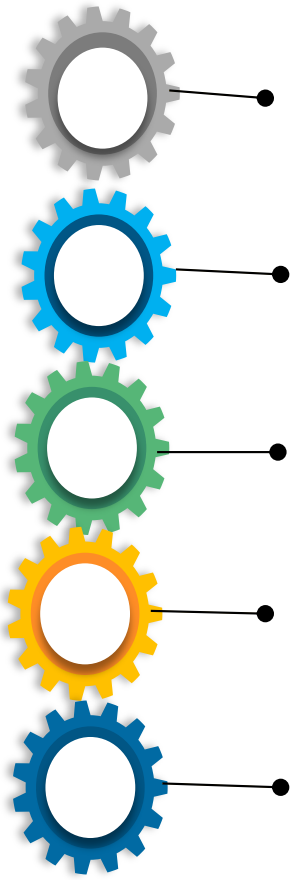
Have you considered whether an alternative format or channel can achieve more for less?

Ethics and Compliance Considerations in Medical Affairs Plans (1)



- Legitimate Intent/Rationale: Activities are linked to specific Objectives and Strategic Priorities (why, what, how)
- Clarity: There is a proper distinction between strategic priorities, objectives and activities; avoid repetition
- Nature: Objectives and activities are indeed non promotional and not based on commercial considerations
- Context: sufficient contextual background and specificity for a reader, fully referenced
- Open for interpretation: written in an accurate, objective and respectful manner, all acronyms explained

Ethics and Compliance Considerations in Medical Affairs Plans (2)



- Tactics versus activities for collection of insights or information
- Activities for insights/information accompanied by clear rationale and objectives; pull vs. push; e.g., a simple number of advisory boards in a plan could be potentially concerning
- Specific ISS, Research or Educational Grants not to be included unless the requests have been received, reviewed and approved, or in the process thereof
- Measurement and assessment of objectives' achievement must not be based on commercial criteria such as Return on Investment
- Additional considerations for plans at sub-national level may exist; key centers etc.

Medical Affairs Plans & Brand Plans

- Need for Medical Affairs plans to be aligned with the global strategy for a therapeutic area or product
- Medical Affairs plans should be distinct from Marketing Plans but can be incorporated in a brand related or operational plan for a therapeutic area or brand
- Medical activities must not be linked to commercial objectives
- Medical Affairs Plans can be shared on a need to know basis