



Life Sciences Consulting and Outsourcing

Kinapse White Paper

Medical Affairs at the centre of life sciences innovation

Expertise ► Collaboration ► Innovation ► Results

Medical Affairs at the centre of life sciences innovation

Kinapse Consulting, 2010

In today's challenging business environment, many innovative life sciences companies are raising questions about the return on investment of internal resources and external expenditures. These questions are now being asked of Medical Affairs Leaders. It is very challenging to measure Medical Affairs 'value' in this way, and we see many instances of Medical Affairs investments being constrained in light of general budgetary pressures. We argue that this is a short-sighted and potentially hazardous trend as we believe that Medical Affairs capabilities must evolve to be at the centre of life sciences companies' therapeutic innovation, product development and stakeholder interactions.

Today's complex environment requires more than Research & Development and Commercial operations *Medical Affairs has a key role in bringing about a strategic shift to real world development*

Today's healthcare environment calls for transparency from life sciences innovators – transparency of data of a product's performance in the real world and open, constructive dialogue with all stakeholders. It calls for information sharing based on scientific and medical knowledge, understanding of benefit-risk and therapeutic value and will rapidly evolve away from the claims-based promotional model of old. When the increasingly complex range of healthcare stakeholders with differing needs for evidence of comparative effectiveness is added to this mix, effective engagement and communication requires specialist medical leaders, working as trusted partners across the entire stakeholder community.

Health Authorities are demanding more rigorous risk management plans and resource-intensive post marketing commitments before they will grant approvals. In tandem, many payers wish to see evidence of 'value' of a product before they will grant reimbursement. In both instances, these stakeholders are asking to see performance of the product in the real world. This is a challenge which industry-leading Medical Affairs groups are already tackling head on, working closely with several specialist functions such as Pharmacovigilance, Epidemiology, Health Economics and Outcomes Research.

We believe that the early assessment of these real world data will benefit product innovators, the broad

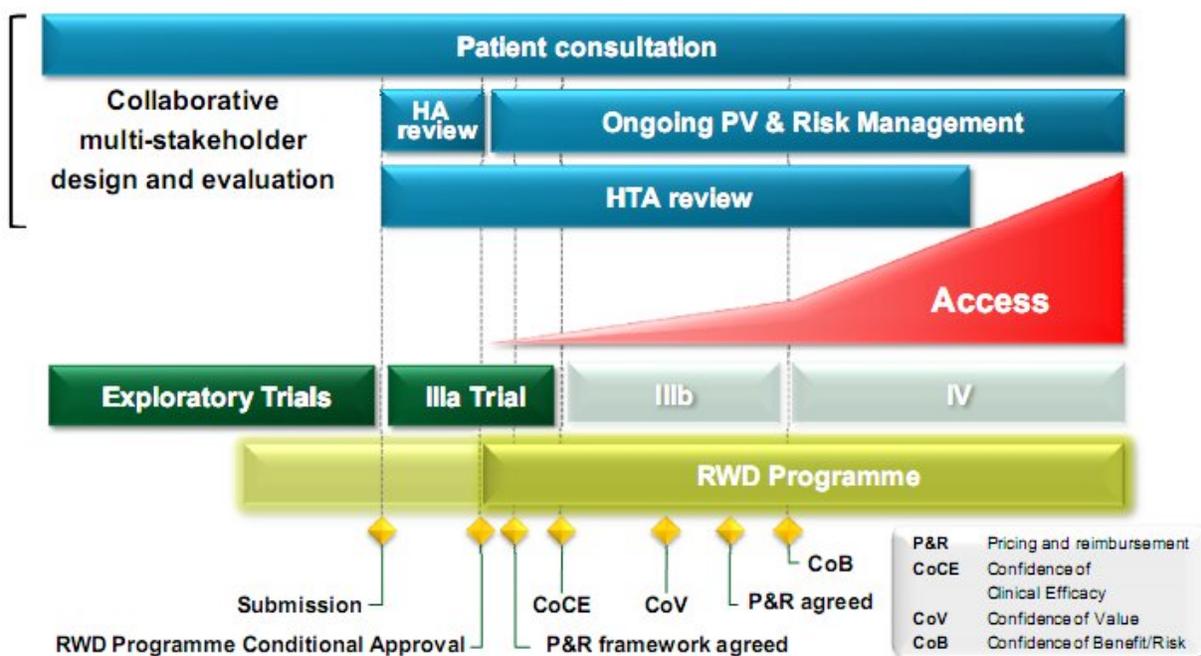


Figure 1: Real World Development model

array of institutional stakeholders and most importantly patients. When undertaken with the appropriate controls and standards in place, it will enable earlier access to innovative medicines and improve value for money. We continue to advocate 'Real World Development', an approach which continuously assesses a product in as close to post-marketing use as possible (see Figure 1). We expect Medical Affairs leaders to play a major role in conceiving and designing such a development approach, working closely with R&D and Commercial colleagues in the selection of suitable pilots and their implementation, and ultimately leading the way in establishing these methodologies as accepted best practices.

Medical Affairs will become central to the future life sciences value model

We believe the linear approach of research, development, product launch and lifecycle management is unsustainable. Increased cycle times and reduced success rates have led companies to pursue outsourcing, with a focus on concentrating on core competencies. With more and more drug developers in-licensing assets in development, it is possible to envisage some companies eliminating internal R&D altogether. However, we find it much harder to imagine established product companies outsourcing their relationships with key external stakeholders including health authorities, payers, providers, healthcare practitioners and patients. Building effective trust-based communications with these stakeholders, founded on transparent sharing of evidence of product value in the real world will remain a core competency for companies in the years to come.

How can we realise the potential of Medical Affairs?

1. Ensuring robust medical governance & communication policy

A critical success factor for Medical Affairs is that it operates at arms length from the Commercial organisation in the evaluation and decision-making of comparative benefit-risk. While a selling role in healthcare will certainly remain, the strength of the Medical Affairs function is that it is not there to sell – its key role is to communicate complex medical and scientific information peer-to-peer with stakeholders. As such, an effective structure for stakeholder communications (what, when, by whom and how) and medical decision-making that is separate from commercial must be maintained. Medical Affairs is in a unique position to help the industry enhance its reputation amongst its external stakeholders in this way.

2. Measuring 'true' Medical Affairs value

Returning to an observation made at the start of this article, many life sciences companies are asking how Medical Affairs activities add value to the organisation. Kinapse has worked with a range of such companies, specifically evaluating the productivity of clinical development, regulatory affairs, safety and medical affairs. Common to all of these projects is a definition of the major outputs of these groups, and the associated cost of generating them. In general, we believe that the return on Medical Affairs activities should not be evaluated in a financial sense but instead judged on their successes in surfacing and optimising patient benefit-risk and the value of products to patients.

3. Proactively engaging Medical Affairs' partner functions

The complexity of stakeholder needs requires life sciences companies to be better at 'joined up thinking'. Medical Affairs Leaders must work to partner with its interfacing functions in R&D and Commercial roles. A pre-requisite for this partnership is a commonly shared view of the R&D, Medical Affairs and Commercial roles in product development and launch preparation, with clear responsibilities and alignment of objectives between the various parts of the organisation. Transparency of activities, timelines and accountabilities will help the organisation leverage the best that Medical Affairs can offer.

4. Continuously evaluating & innovating the Medical Affairs role

To fully realise the potential value of Medical Affairs, life sciences companies will have to continuously shape, and react to, the changing healthcare environment. Within life sciences companies, practical steps to innovation include:

- Conduct lessons learned reviews for new product introductions, successful or otherwise
- Challenge executives at all levels to identify creative approaches to development and launch of specific assets building on existing precedents of real world approaches
- Increase proactive and sustained engagement with external stakeholders to strengthen collaboration and ensure transparent communication on plans and evolving findings
- Establish dedicated cross-functional teams to pilot selected innovative approaches.

Conclusion

Medical Affairs is a life sciences company's most credible link with external stakeholders. In the context of increased healthcare budgetary pressure some medical affairs investments are being detrimentally constrained. The increasing complexities in the external stakeholder environment, the growing importance of generating data from the 'real world' and the unsustainability of the current value model all increase the need for innovation. We believe that by ensuring robust medical governance; measuring 'value' in patient's terms; proactively engaging with partner functions and continuously evaluating and innovating its role, Medical Affairs will move to the centre of life sciences companies' therapeutic innovation, product development and customer interactions.

About the Authors

Mudit Mohan is a Consultant at Kinapse and has previously worked on a range of Healthcare and Life Sciences engagements.



James Man is a Manager at Kinapse and specialises in organisation and process improvement in Clinical Development and Medical Affairs.



Andy Black is a Co-founder of Kinapse and the Global Head of Client Services. In the last 20 years Andy has consulted to many of the world's leading Life Sciences Organisations.



About Kinapse

Kinapse provides consulting and outsourcing services to the life sciences industries, globally.

Our mission statement is: '*Collaborating with our clients to innovate for exceptional results*'. Kinapse clients include many of the world's leading pharmaceutical, biotechnology, medical device and specialty pharmaceutical companies, government organisations and life sciences service providers.

Our key advantages are:

- Focus on the life sciences industries
- Deep industry experience and technical acumen
- Proven blended onshore-offshore delivery model
- Track-record of innovative solutions and results

For more information please visit www.kinapse.com or email info@kinapse.com

Kinapse Ltd.,
Tuition House,
27-37 St George's Road,
Wimbledon,
London, SW19 4EU
UK

Phone: +44 20 8946 7600

