

WHITE PAPER

MEDICAL AFFAIRS IN TRANSITION

**TOWARDS A FULLY
INTEGRATED MODEL**

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EXECUTIVE SUMMARY

"THE ONLY CONSTANT IN LIFE IS CHANGE." THIS IS NOT DIFFERENT FOR MEDICAL AFFAIRS, BUT THE PACE OF CHANGE IN THAT SPACE IS ACCELERATING. WE ARE AT A CLEAR TURNING POINT AND THE FUTURE MEDICAL AFFAIRS FUNCTION WILL LOOK SIGNIFICANTLY DIFFERENT FROM WHAT WE SEE TODAY IN MOST PHARMA COMPANIES. EVERYONE IS TALKING ABOUT IT, BUT IN PRACTICE, WE SEE LITTLE CHANGE. FOR MANY COMPANIES, WHAT THE FUTURE LOOKS LIKE IS VAGUE AND THE ROAD TOWARDS IT EVEN VAGUER.

WITH THIS WHITE PAPER, WE AIM TO SUPPORT MEDICAL AFFAIRS IN ITS JOURNEY TO A NEW FUTURE. WE DEFINE A CLEAR VISION AND AMBITION FOR THE FUTURE OF MEDICAL AFFAIRS. AND, MORE IMPORTANTLY, WE ARTICULATE A PRAGMATIC STEPWISE APPROACH TO HELP MEDICAL AFFAIRS LEADERS DRIVE AND GUIDE THEIR ORGANISATION IN AN IMPORTANT TRANSFORMATION.

WE ENCOURAGE YOU TO START DEFINING YOUR OWN AMBITION FOR MEDICAL AFFAIRS AND INITIATE THE JOURNEY TOWARDS IT NOW!

Pim Kooreman, Medical Affairs CoE Lead
Casper Paardekooper, Partner

We are reaching a turning point in healthcare; aging populations and rise in chronic diseases are amplifying medical needs, whilst unprecedented number of innovations and breakthrough treatments is exerting greater pressure on healthcare budgets. Instead of working together to solve these challenges, we see there is a growing disconnect between healthcare stakeholders. We believe that Medical Affairs is uniquely positioned to bridge this gap and to facilitate co-creation of better outcomes for patients. We believe that these trends provide a tremendous opportunity for Medical Affairs to respond and evolve the scope and delivery of internal and external propositions.

However, to become a real partner in co-improving healthcare, Medical Affairs should evolve to a fully integrated organisational model transforming their four main propositions: stakeholder' education & engagement; partnership & solutions; insights collection and sharing; and evidence generation and analysis. This fully integrated model is characterised by crucial elements across four dimensions: propositions, people, organisational design and systems.

The leap towards the fully integrated model is substantial. Therefore, it requires a pragmatic step by step approach. In order to make this journey tangible, Vintura developed a maturity model detailing three steps that take Medical Affairs from their traditional organisation, to focused, coordinated and, ultimately, to an integrated model.

Defining this journey means Medical Affairs leaders need to define their current reality, set future ambition, identify the gaps and priorities, develop a plan for success and drive the change. It is well known that transformation means change and change always impacts people. Our experience shows, that it is important to focus on both the rational and the emotional elements of change.

This is our call to action to Medical Affairs leaders. To remain relevant, the industry needs transform towards a fully integrated healthcare model and partner to improve care. Medical Affairs will be a crucial player in this change. By being the objective and unbiased face of the industry, Medical Affairs can bring stakeholders together driving real healthcare improvements! In order to do this, your function needs to evolve. When do you start your journey?

CHAPTER 1

THE WORLD IS CHANGING AND SO SHOULD MEDICAL AFFAIRS

1.1.

KEY TRENDS SHAPING THE FUTURE OF MEDICAL AFFAIRS

The only constant in life is change, Medical Affairs is not excluded from this truth. We see several trends that are directly impacting Medical Affairs and provide a huge incentive to change.



Value-Based healthcare (VBHC)¹ is gaining momentum and is driving healthcare systems in a 180-degree shift focussing on a broader definition of value of care rather than price or volume of care delivered;



The role of medical data, both clinical trial data and RWE, in market access and pricing decisions is increasing;²



Healthcare decision makers are becoming more medically sophisticated; whilst their available time is decreasing. There is an increased need for objective discussions with Medical Affairs focussing on value of care underpinned by objective science;³



Complex innovative therapies are transforming treatment paradigms, complex knowledge transfer is a “must”. The traditional sales rep model is not the answer;



Digital developments are driving new ways of analysing data and connecting stakeholders. The quantity of data and the need for medical information is steeply increasing, also in complexity. Healthcare professionals expect a personalised approach to access simplified and prioritized relevant data;^{4,5}



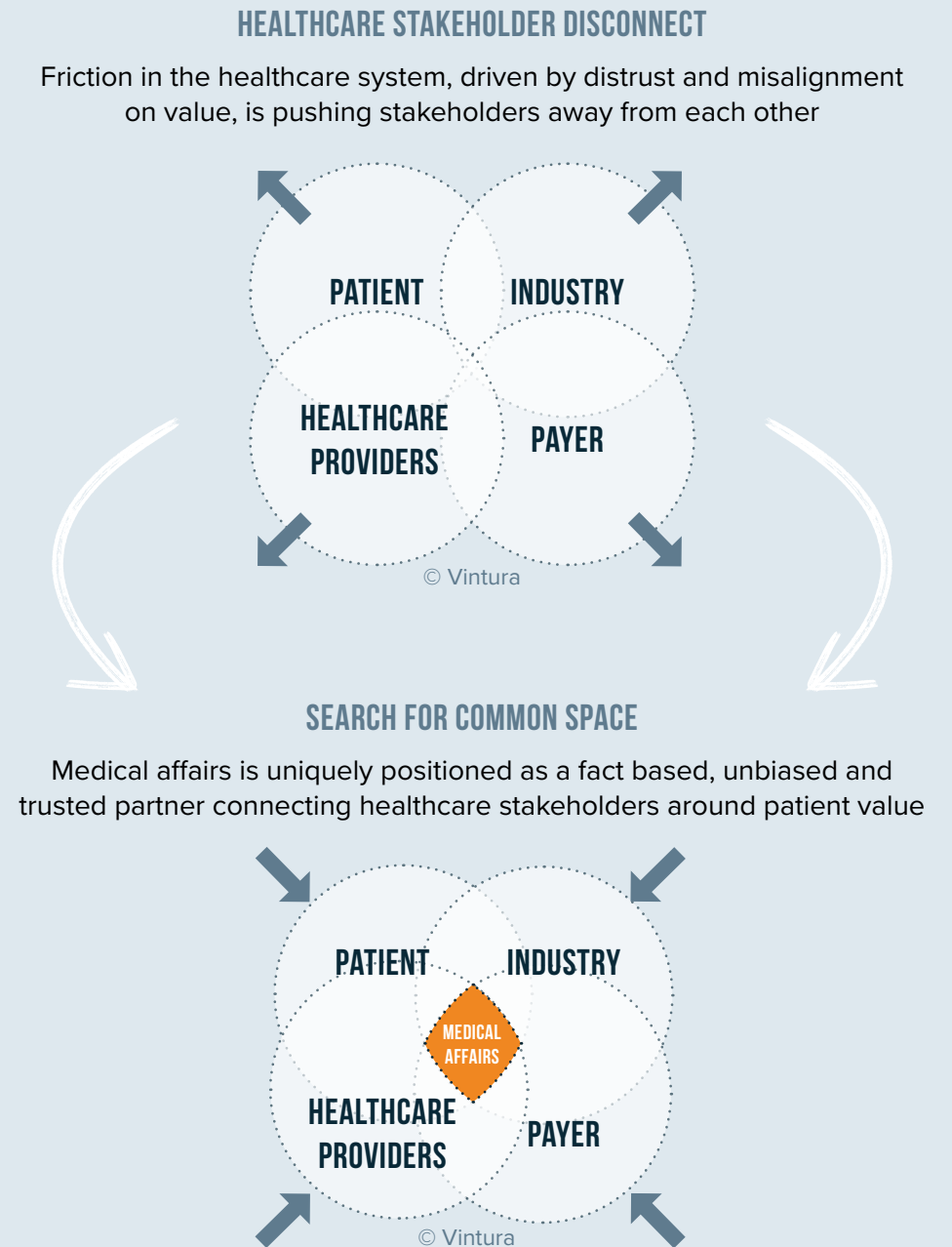
Early engagement (Phase II) is becoming critical to ensure future successful treatment of patients, this is only possible via the Medical Affairs function. Early engagement allows market feedback to be integrated in clinical programs to ensure patients’, payers’ and HCPs’ needs are addressed.⁶

MEDICAL AFFAIRS HAS A CRITICAL ROLE IN BRINGING HEALTHCARE STAKEHOLDERS TOGETHER

Additionally, it is no secret; healthcare systems are under pressure. Aging populations and chronic diseases are increasing the demand for care, while the introduction of innovation is increasing care costs. At the same time, instead of working together to face these challenges, the industry, payers, healthcare providers (HCPs) and patients are becoming increasingly disconnected. This disconnect is driven by distrust and misalignment on value, causing unnecessary friction. To make our healthcare systems sustainable, we need to find common ground now. We will not be able to solve these challenges on our individual islands; we need a collaborative approach.

The Medical Affairs function is uniquely positioned to bridge the gap between healthcare stakeholders and facilitate the search for common space (Figure 1). Medical Affairs is the fact-based, unbiased and trusted face of the industry. It is driven by improving patient outcomes on a foundation of objective scientific information. However, to take this new role and drive the move towards an integrated model, Medical Affairs needs to transform first.

Figure 1
THE DISCONNECT BETWEEN HEALTHCARE STAKEHOLDERS IS GROWING, MEDICAL AFFAIRS IS UNIQUELY POSITIONED TO BRIDGE THE GAP IN THE SEARCH FOR COMMON SPACE.



MEDICAL AFFAIRS IS EXTENDING ITS ROLE

To further improve their role as healthcare partner, Medical Affairs will need to work together with a broader internal and external stakeholder group beyond the status quo. As healthcare decision makers are demanding more sophisticated medical and value-based data, it is key that Medical Affairs engages into value discussions with payers and other healthcare authorities supported by objective science. We recommend Medical Affairs leaders to embrace and evolve four main medical roles:

1. **Stakeholder education & engagement:** The current and future key role of Medical Affairs is to ensure proper stakeholder' education & engagement; this will not change. Medical Affairs will continue to play a crucial role in ensuring HCPs are capable to optimally treat patients in line with the latest science. This will only become more important in the future considering the advances in science and complex technologies, e.g. CAR-T and CRISPR-CAS. However, Medical Affairs should think broader, beyond a specific indication and beyond pure science. They need to shift the conversation to value underpinned by science across the full care pathway. Additionally, how Medical Affairs will engage is evolving. Declining access to HCP drives engagement through a more personalised omni-channel approach.
2. **Partnership and solutions:** Keeping our healthcare system sustainable is not the responsibility of one stakeholder, it is our collective responsibility. This means, the industry will have to shift into a partner role to the healthcare ecosystem, instead of the traditional supplier role. Developing and co-creating innovative solutions with other healthcare players will deliver superior health outcomes ultimately benefitting patients and the society. As the trusted, unbiased and objective face of the industry, Medical Affairs' role will become increasingly important to realise this.
3. **Insights collection and sharing:** To successfully introduce innovation and solutions, that truly benefit patients, the industry needs to fully understand healthcare needs. Medical Affairs plays a key role as the antenna picking up signals that other functions will not receive. These signals provide crucial insights on HCP and patient needs. Medical Affairs needs to share these insights internally to make sure the industry can act upon this and create real value. It is, therefore, crucial to shift the insight collection from an individual point of view to collaborative, cross-functional and integrated collecting, reporting and acting.
4. **Evidence generation and analysis:** The digital revolution is influencing how data is being shared and analysed. Future Medical Affairs will be able to generate, combine and analyse a higher quantity of more complex data. Taking ownership of evidence planning and generation, in the digital age, requires new capabilities and systems from Medical Affairs.

CHAPTER 2

MEDICAL AFFAIRS NEEDS TO INTEGRATE TO CO-IMPROVE PATIENT OUTCOMES

2.1.

MEDICAL AFFAIRS' RESPONSE CANNOT BE SUSTAINED BY THE TRADITIONAL MODEL

The Medical Affairs' response to the previously mentioned trends can no longer be sustained by a traditional model. Rapid evolution to an integrated model focused on improving patient outcomes is required.

Traditionally, Medical Affairs teams act as a supporting function operating in a silo. They tend to be focused on disseminating medical and scientific data and engaging based on science. Traditional Medical Affairs teams are reactive and do not drive strategy.

The transition from the traditional modal towards the integrated model will take Medical Affairs through three maturity stages (Figure 2).

1. **Focused:** Medical Affairs as a supporting function, delivering specific value messages through uncoordinated channels;
2. **Coordinated:** Medical Affairs as an internal partner, communicating a streamlined Medical value story through coordinated multichannel engagement;
3. **Integrated:** Medical Affairs as the strategic pillar, delivering value by orchestrating offerings around the HCP & patient journey delivered through omni-channel engagement.

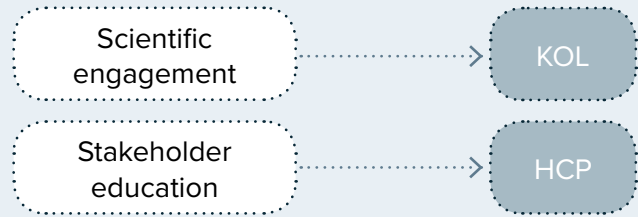
Figure 2

MEDICAL AFFAIRS' RESPONSE CAN NO LONGER BE SUSTAINED BY THE TRADITIONAL MODEL, RAPID EVOLUTION TOWARDS A FULLY INTEGRATED MODEL IS REQUIRED

TRADITIONAL

Medical Affairs in silo

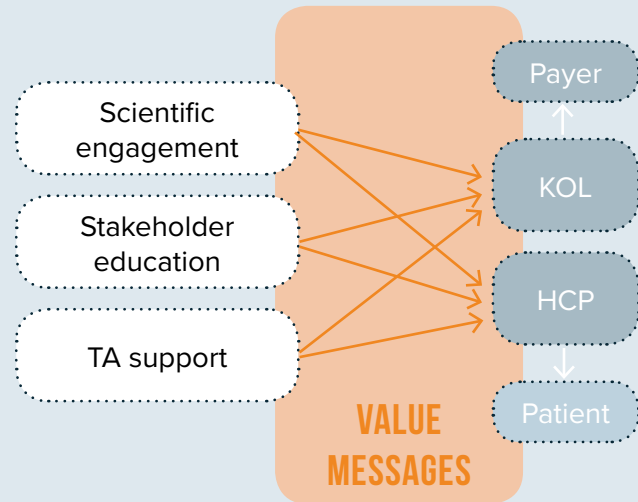
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FOCUSED

Medical Affairs supporting function

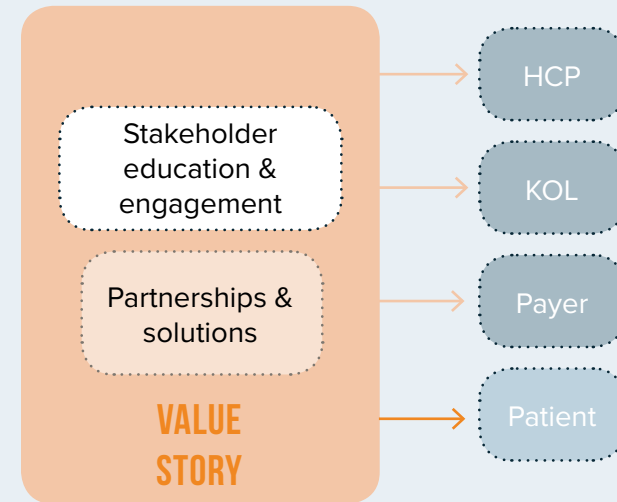
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COORDINATED

Medical Affairs as an internal partner

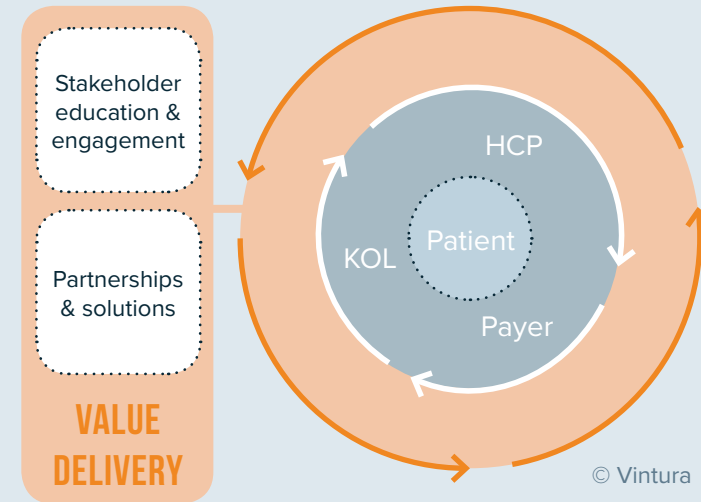
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INTEGRATED

Medical Affairs as strategic pillar

3



THE AMBITION: A FULLY INTEGRATED MODEL FOR MEDICAL AFFAIRS

In order to realise the Integrated model, Medical Affairs needs a fully mature organisation delivering the future medical propositions. This means Medical Affairs will embark on a growth journey across four dimensions: propositions, people, organisational design, and systems. The fully mature and integrated Medical Affairs function, looks as follows:

PROPOSITIONS

Medical propositions integrated in the care pathway and focused on partnerships

Integrated Medical Affairs is a partner in the improvement of healthcare. They deliver integrated offerings and an evolving value story around the care pathway which is focused on actual delivery of improved patient outcomes. Engagement is aligned with stakeholder preferences and their needs. Therefore, it needs to be driven by sharp behavioural segmentation and structured engagement planning. Integrated Medical Affairs engages through pro-active omni-channel engagement, always in line with local compliance regulations. It is of utmost importance that Medical Affairs protects its non-commercial role and remains the unbiased and objective function in the industry. Only this way they can be a trusted partner collaborating with healthcare stakeholders to improve patient outcomes.

PEOPLE

Medical employees with a broad skill set, proactive and externally focused

The fully integrated Medical Affairs organisation is led and executed by proactive and intrinsically motivated employees with a broad skillset. They are focused on external partnerships to shape healthcare system & improve patients' outcomes.

ORGANISATIONAL DESIGN

Medical organisation that is internally integrated, involved early and focused on people development

The integrated medical organisation is focused on people development & external impact. Medical Affairs needs to work and collaborate cross-functionally with Market Access and Commercial; be early involved in the R&D strategy; and, drive brand planning. Their performance management is fully integrated across offerings and across non-Medical functions.

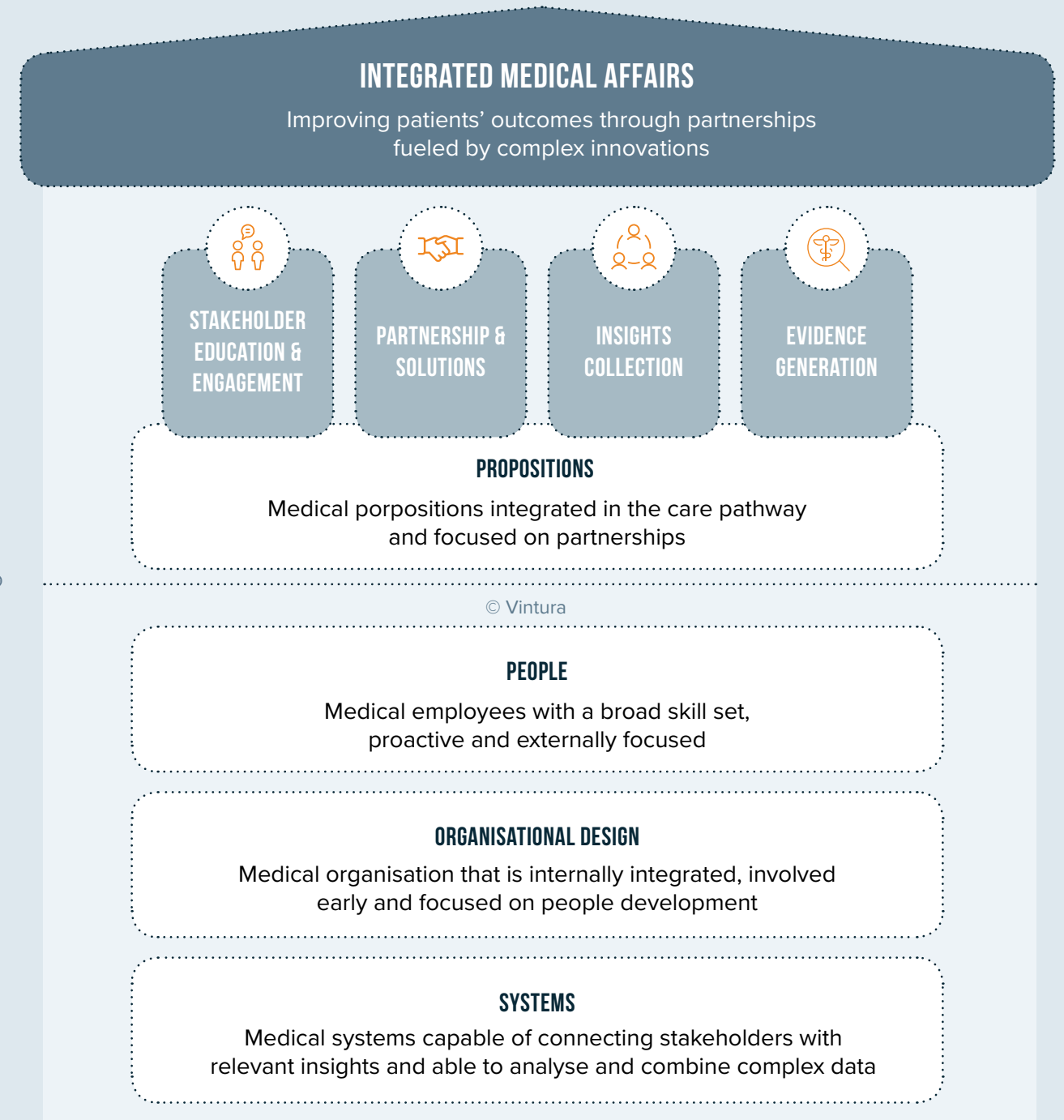
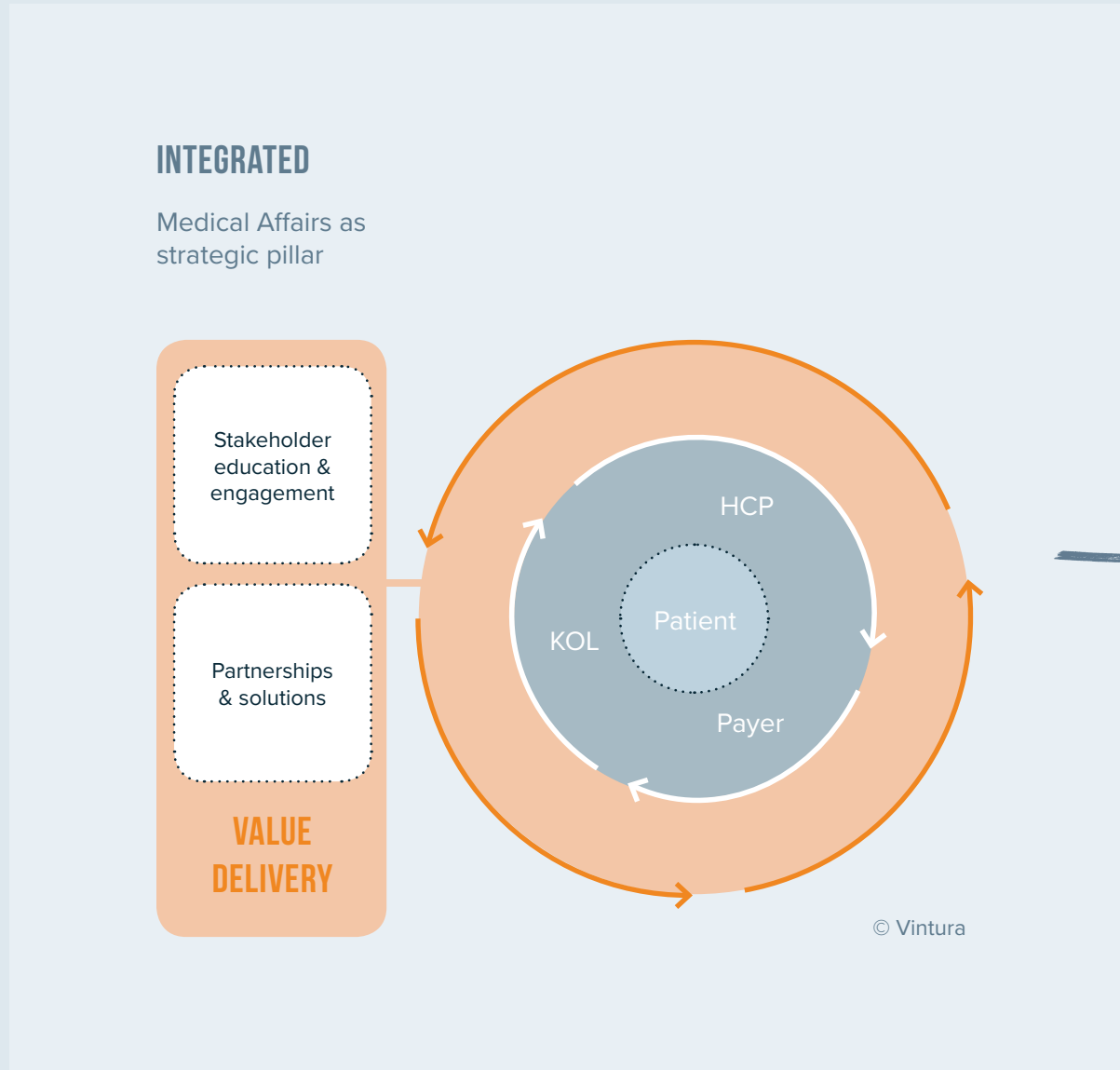
SYSTEMS

Medical systems capable of connecting stakeholders with relevant insights and able to analyse and combine complex data

Integrated Medical Affairs needs to leverage innovative CRM & analytics systems to monitor activities and impact and analyse complex and connected data sources.

Only when equipped with the right propositions, people, organisational design and systems, Medical Affairs can become the connecting strategic pillar and the unbiased face of the industry partnering with external stakeholders (Figure 3).

Figure 3
VINTURA'S VISION OF A FULLY INTEGRATED MODEL FOR MEDICAL AFFAIRS TO BECOME THE STRATEGIC PILLAR



CHAPTER 3

STEP BY STEP TRANSFORMATION TOWARDS INTEGRATED MODEL

3.1.

MEDICAL AFFAIRS' TRANSFORMATION WILL INCREASE VALUE

Rome was not built in a day, neither will the fully integrated Medical Affairs function. Getting to the integrated end state means Medical Affairs will embark on a growth journey moving away from the traditional model towards the integrated model through three distinct phases. This may seem like a daunting task. However, Medical Affairs leaders should realise, that taking even small steps will add a lot of value for society and the industry (Figure 4).

1. Moving to FOCUSED is a must!

Moving to focused, Medical Affairs will align key value messages to drive proper education of physicians to ensure proper treatment of patients. Structuring MSL and medical education engagement planning will reduce inefficiencies introducing cost-efficiencies.

2. COORDINATING Medical Affairs will optimise patient access to medicines

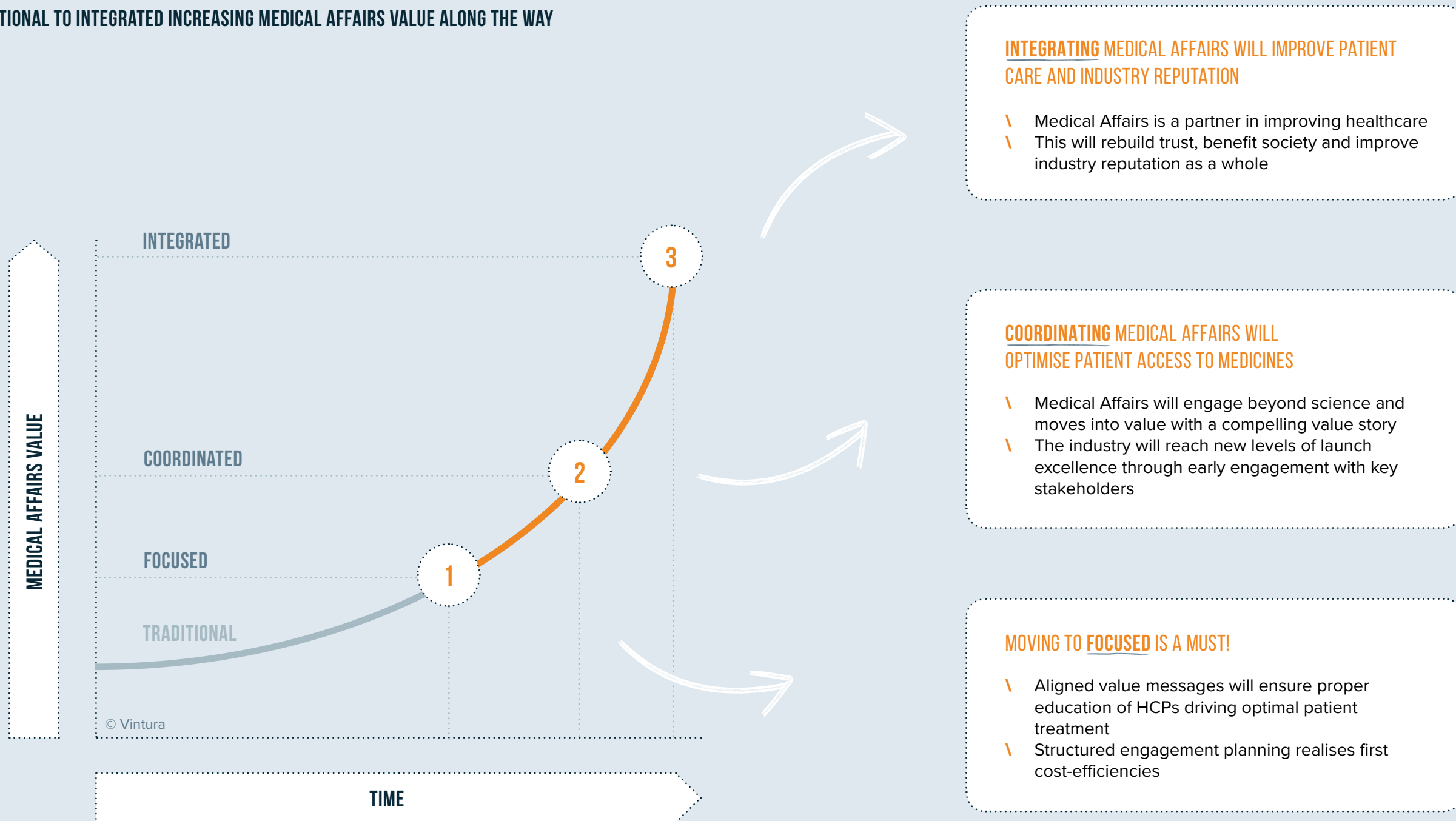
Becoming coordinated will optimise future patient access to innovation. In its coordinated role, Medical Affairs will engage beyond science and moves into value with a compelling value story. The industry will reach new levels of launch excellence through early engagement with key stakeholders ultimately benefitting patients.

3. INTEGRATING Medical Affairs will improve patient care and industry reputation

In its integrated role, Medical Affairs will be a true partner instead of a supplier to the healthcare ecosystem with an orchestrated offering, engaging stakeholders around the patient journey in an omni-channel approach. This will drive disease area leadership and create opportunities for the industry to partner in improving patient care and outcomes. Working together with other stakeholders to improve patient care will rebuild trust, significantly benefit society and improve the industry's reputation.

Figure 4

MEDICAL AFFAIRS NEEDS TO GO THROUGH A STEP BY STEP MATURITY PROCESS FROM TRADITIONAL TO INTEGRATED INCREASING MEDICAL AFFAIRS VALUE ALONG THE WAY



THE ELEVEN ELEMENTS DESCRIBING THE MEDICAL AFFAIRS EVOLUTION

The Medical Affairs transformation is a journey across 11 elements in four dimensions (Figure 5). The evolution from traditional to integrated is achieved by growth across all elements.

1. Integrate medical propositions

In the focused model, Medical Affairs has many offerings focussing on delivering a medical-scientific story based on structured engagement planning. Stakeholders' channel preferences are not driving the engagement strategy resulting in an uncoordinated multi-channel approach.

Evolving to the coordinated model, propositions are coordinated with a cross-offering alignment within Medical Affairs. Medical Affairs teams communicate an aligned value story pertinent to stakeholders' needs and priorities. Stakeholder archotyping and segmentation allows a structured engagement planning through multi-channel engagement.

In the integrated model, propositions are fully patient- and customer-centric. The offerings and value story are integrated around the patient pathway and clearly defined outcomes. Also, Medical Affairs will be able to partner in healthcare, co-creating solutions to improve care.

2. Empower people

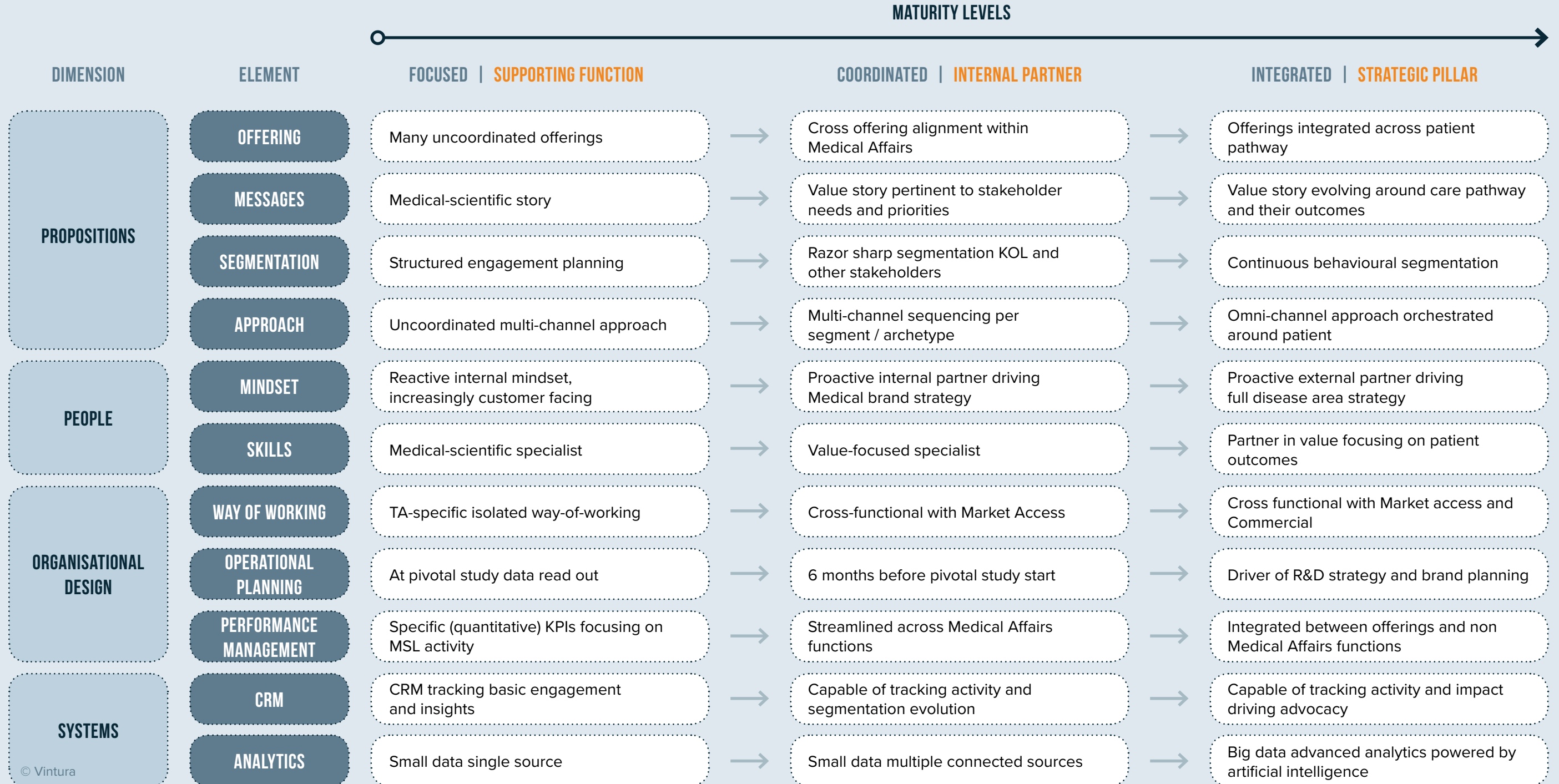
A key enabler for successful delivery of the Medical Affairs propositions are people. The two most important elements in the people dimension are **mindset** and **skills**.

In the focused model, Medical Affairs employees are generally focused on actively supporting other industry functions. They are seen as scientific specialists increasingly customer facing upon own initiative.

With the evolution to the coordinated model, delivering new proposition in a different way, the external and internal environment expect different behaviour from the n Medical Affairs function. They need to be a proactive partner taking ownership of the medical strategy and the medical value story. This requires a different skillset and mindset focussing more on value rather than science. The difference might appear trivial, but is in fact an enormous change.

In the next step towards the fully integrated model, we expect even more from Medical Affairs employees. To become an external partner, co-creating better healthcare, Medical Affairs needs to be fully proactive and entrepreneurial. This can only be achieved, when Medical Affairs becomes the primary owner of the therapeutic area strategy, and when they have the skills to be a partner in delivering value for the healthcare system.

Figure 5
THERE ARE 3 LEVELS OF MATURITY ACROSS ALL 11 ELEMENTS



3. Optimise organisational design

The organisational design dimension is characterized by different elements. The three most relevant elements for Medical Affairs transformation are **integration, operational planning, and performance management**.

In the focused model, Medical Affairs works isolated in a specific disease area with limited involvement in brand planning. Resources are deployed around pivotal study data read out. Performance is measured via simple key performance indicators (KPIs) isolated in each Medical Affairs function.

Evolving to coordinated means more cross-functional alignment with Market Access to engage with a more streamlined value story. Medical resources are deployed six months before pivotal study start to allow earlier engagement and initiate dialogue with multiple relevant stakeholders. Finally, Medical Affairs performance and development is holistically organised within the function, in which each department (i.e. field force, medical education, RWE generation, etc.) are managed towards one overall Medical Affairs ambition.

The fully integrated organisation is embedded across all functions including Market Access and Commercial. This allows a comprehensive integration of offerings and partnerships around the patient. Medical Affairs is the driver of brand planning and external partnerships. Finally, performance is also measured holistically across functions and fully focused on improving patient outcomes.

4. Embed key systems

The systems dimension is defined by two key elements: **CRM** and **analytics**. Advanced CRM and analytics systems are crucial prerequisites that support Medical Affairs to be able to fully integrate and operate around the patient.

Focused Medical Affairs leverage simple CRM tracking engagement touchpoints and insights within Medical Affairs. Small data analytics is used to analyse singular data sources.

Coordinated Medical Affairs uses a more sophisticated CRM capable of tracking engagement touchpoints across KOL segments as well as evolution across segments. Insights are collected and communicated across functions. Analytics become more advanced, focussing on small data but connecting different data sources.

The fully integrated Medical Affairs function needs a sophisticated CRM, capable of tracking engagements' impact and leveraging big data analytics powered by Artificial Intelligence to provide fully patient centred solutions.

In summary, all four dimensions are crucial in the Medical transformation towards the fully integrated model. Getting to this fully integrated model seems daunting, however our step-by-step maturity model makes the transition from traditional to the integrated model pragmatic and clear. But how can Medical Affairs leaders practically manage a transformation this size?

CHAPTER 4

DEFINING THE TRANSFORMATION ROADMAP

Every journey starts with a first step. The time is now for Medical Affairs leaders to initiate the journey and guide their organisation towards the integrated model. Only with a compelling vision for the future, a clear plan and strong change management skills Medical Affairs leaders will be able to manage this transformation. There are 5 key steps to define the Medical Affairs transformation for a given organisation (Figure 6):



Define current reality

Where does our Medical Affairs department currently fit on the maturity model across each element?



Set future ambition

What is our ambition for the future?



Identify the gap and prioritise

What is the gap and what are the priority steps we need to address first?



Plan for success

For the priority steps, what are the concrete actions we should undertake to move our organisation forward?



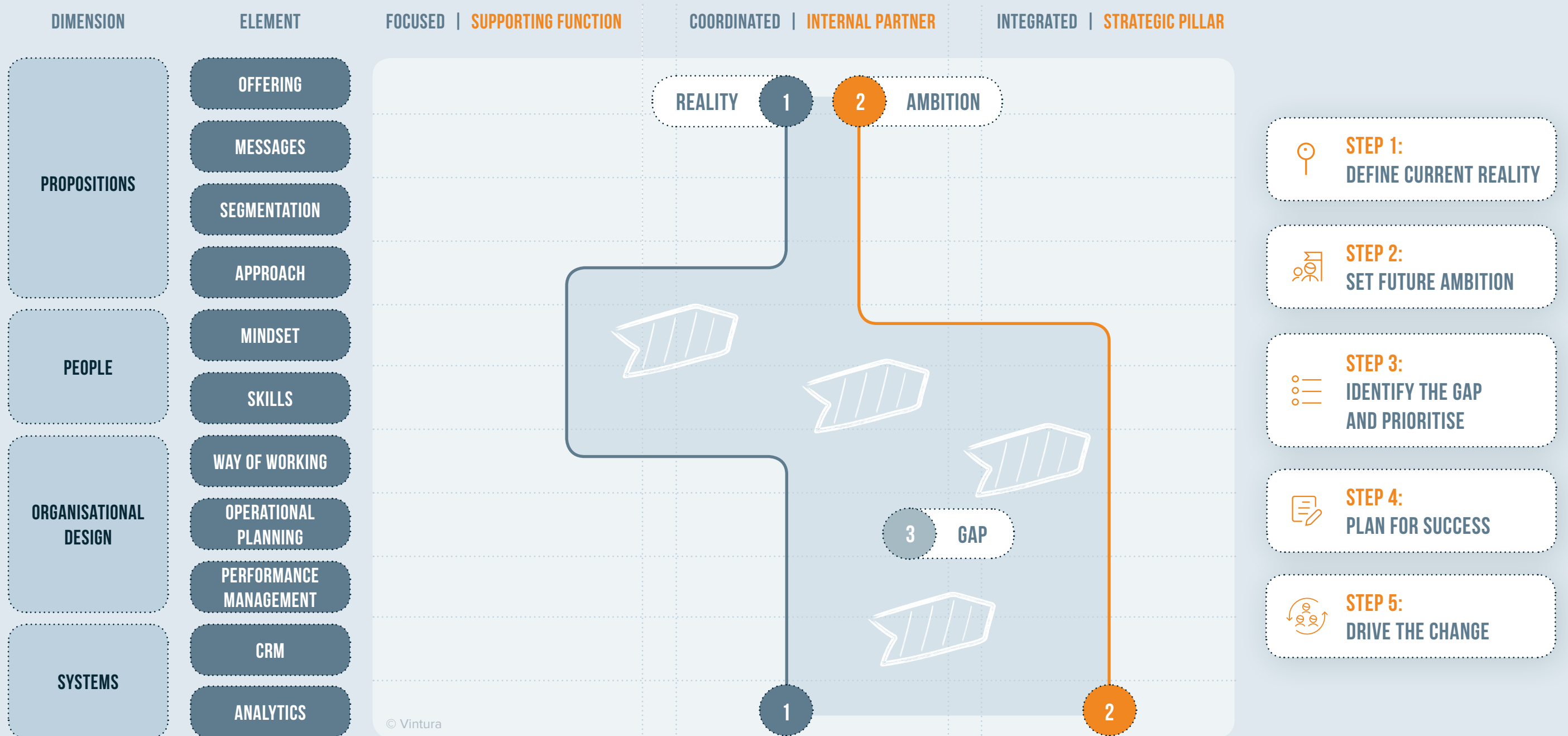
Drive the change

How do we successfully drive the change towards our ambition?

To make the change more manageable and less daunting, Medical Affairs leaders should focus on piloting the transformation in a single disease area. Then use the experience and learnings to scale tried and tested concepts across other disease areas and the full organisation.

Figure 6

TO APPLY THIS TO YOUR OWN SITUATION, MEDICAL AFFAIRS LEADERS GO THROUGH 5 KEY STEPS



CHAPTER 5

TRANSFORMATION MEANS CHANGE, CHANGE IMPACTS PEOPLE

Organisations often underestimate the impact of change processes on employees resulting in a value gap (Figure 7). Research shows that 70% of transformations fail in practice⁷, as a result of badly managed processes and an underestimation of the impact for people. This results in lack of employees' trust, commitment and engagement, loss of productivity and creativity, key staff leaving the organisation and losing business and long-term competitive edge.

Knowing that 70% of transformations fail in practice we have very specific and practical beliefs about change management, see Exhibit 1.

Exhibit 1

CHANGE IS ALL ABOUT PEOPLE

- \\ people change not just functions, departments or business units. Be conscious of the people involved in the project and change process
- \\ change addresses people in all impacted organisational layers – from board room to factory floor
- \\ change is not about creating slides but about impacting behaviour of individuals
- \\ change is not only about messages being sent, but how these messages are received and understood by people, and having a dialogue

CHANGE IS ALL ABOUT THE PROCESS

- \\ change begins right at the start and is not something you initiate along the way
- \\ organisational change does not need to take longer and be more costly than business leaders and managers anticipate when the right process is used from the start

CHANGE IS ALL ABOUT EXPERIENCE

- \\ experience with change helps to understand motivations and barriers to change

These beliefs are embedded in Vintura's change management process. Change programs are often driven by the brain, but the heart is as (or more) important. We believe successful change can only be realised when addressing both (Figure 7).



Brain

Whether you like it or not, change is about making and executing a plan with concrete deliverables, timelines and milestones. It is key to clearly establish and communicate this plan so employees know what they can expect and what is expected from them.



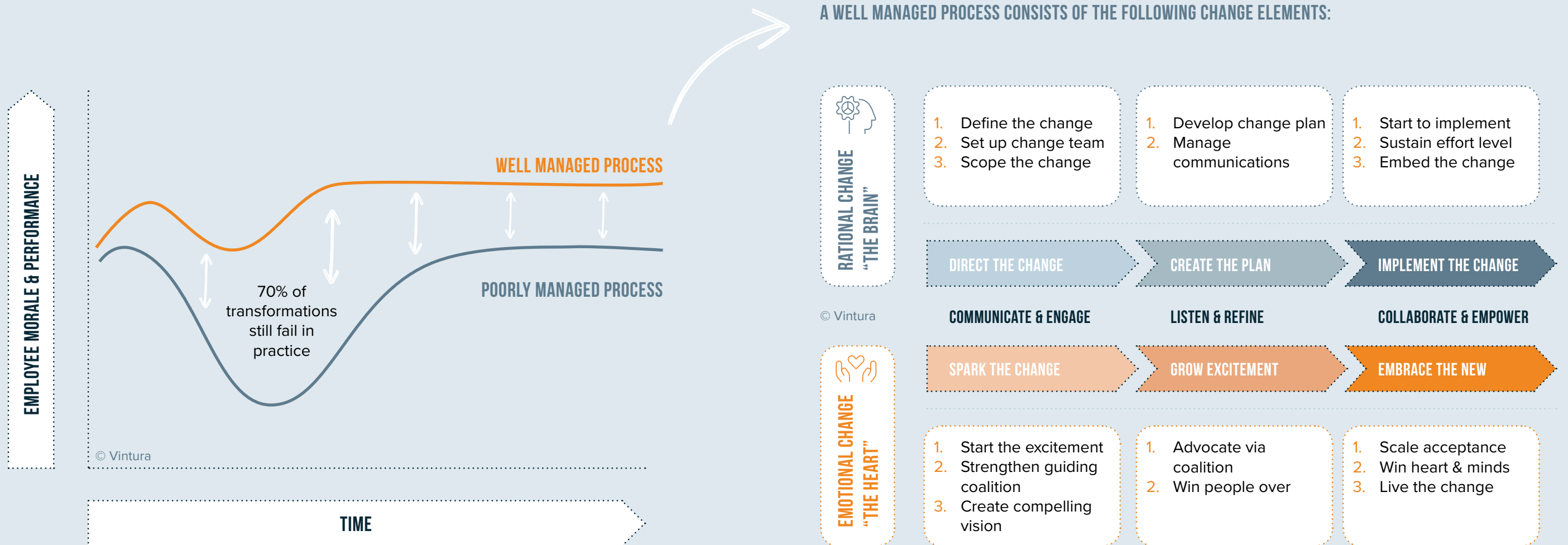
Heart

Real change is achieved through people. The objective of our change approach is to impact people by being clear on the overall ambition, addressing their (individual) needs and understanding the effect of change. The heart is all about listening to understand, not just reply through logic. Each of the steps in this approach addresses people's emotions and feelings to ensure they embrace the change.



Figure 7

NOT PROPERLY MANAGING CHANGE LEADS TO A VALUE GAP, WE DEVELOPED A CHANGE PROCESS FOCUSING ON THE HEART AND THE BRAIN TO MINIMISE THE VALUE GAP



CHAPTER 6

WHEN WILL YOU START YOUR JOURNEY?

This is our call to action to all Medical Affairs leaders. To remain relevant, the industry needs to partner to improve care and outcomes for patients. Medical Affairs will be a crucial player moving forward. By being the objective and unbiased face of the industry, Medical Affairs can bring stakeholders together driving real healthcare improvements! In order to do this, your function needs to evolve. When do you start your journey?

To find out more about our vision on Medical Affairs and to see what Vintura can do to support you, scan the QR code below or visit us on

[HTTPS://WWW.VINTURA.COM/EN/LIFE-SCIENCE-CONSULTING/MEDICAL-AFFAIRS/](https://www.vintura.com/en/life-science-consulting/medical-affairs/)



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