White Paper

Their Finest Hour: Medical Affairs in a Disrupted World

When patient centricity meets healthcare system impact.

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Introduction

The ascent of Medical Affairs

Medical affairs has been on a transformative journey. It was originally set up as a supporting function separate from commercial to provide scientific information about pharmaceutical products in response to enquiries from healthcare professionals and to address unsolicited off-label questions in a compliant manner.

Driven by recent macro-trends, spanning the shift to specialty care and increasingly complex therapies, a changing stakeholder landscape with a broader set of relevant stakeholders beyond prescribers, a higher evidence burden and more stringent compliance requirements, the role of medical affairs has dramatically evolved.

Medical affairs has now moved centre-stage to increasingly play a strategic and pro-active role,[1-3] by

- Leading the value and evidence agenda, including integrated, lifecycle evidence planning and innovation in evidence generation.[4]
- Being the home of deep insight on therapy areas, clinical practice, patient journeys and key stakeholders, such as KOLs, HCPs and patients.[5]
- Engaging with a wide range of external stakeholders, including KOLs, HCPs, payers and HTA bodies to disseminate evidence and educate on the clinical and economic value of innovative products.
- Playing a pivotal role during the pre-launch phase[6,7] and even further upstream in the lifecycle to shape development programmes early on with insights on patients and the market for an optimal target product profile (TPP) and real-world relevant end points.
- Being the voice of the patient in the company, with ultimate focus on achieving optimal patient outcomes.

Medical affairs has come a long way to emerge as a success critical capability and strategic differentiator for biopharmaceutical companies today.

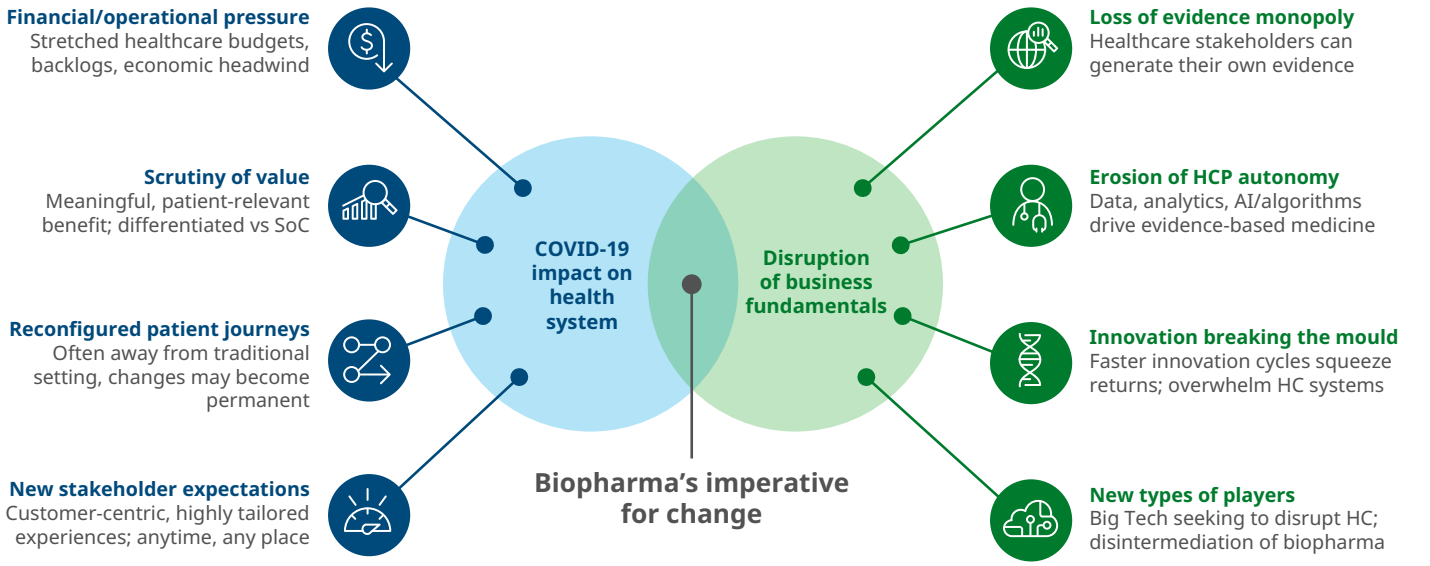
Medical affairs has moved centre-stage to increasingly play a strategic and pro-active role. Post-pandemic realities are now taking hold which further elevate the role of medical affairs and accelerate the need to expand its remit.

Post-pandemic realities: New rules of engagement for Medical Affairs

Post-pandemic realities are taking hold which further elevate the role of medical affairs and accelerate the need to expand its remit:[8,9]

- Healthcare systems are reeling from severe financial pressures. Already before the pandemic key spend areas, such as oncology or immunology, were growing faster than healthcare budgets while the need to spend on covid vaccines and therapeutics translates into an estimated cumulative budget impact of $300 billion globally for the period of 2020-2026.[10] Furthermore, healthcare systems continue to struggle under operational strains as they are working to clear massive patient backlogs. For example, in May 2022, 6.6 million patients were on waiting lists for consultant-led elective care in England.[11]
- Tighter scrutiny of value by healthcare systems demands true differentiation of novel therapies over the standard of care, with increasing emphasis on meaningful, patient-relevant benefits by regulators, payers and providers, to secure approval, reimbursement and access. For example, in the past 5 years, the number of drug exclusions among key US payers has increased fourfold, and 6 in 10 new prescriptions were rejected in 2021 via patient utilisation management by commercial plans. Even in oncology, once a sheltered class, over 60 products were excluded from formularies in 2021.[12]
- Expectations of healthcare professionals have been reset. They are looking for customer-centric approaches and highly tailored experiences reflecting their preferences and needs.[13] This has elevated the role of medical and of remote channels, especially digital, over traditional salesforce engagement, as healthcare professionals seek greater value through deeper medical insight at the time of their choosing.[14,15]

Figure 1: Post-pandemic realities are taking hold



Source: IQVIA EMEA Thought Leadership
Note: HC = Healthcare

At the same time, the pharma business model is being disrupted:

- Proliferation and democratisation of healthcare data erodes biopharma's role in the value chain. Biopharma is losing control of its value narrative and no longer has an evidence monopoly as other stakeholders such as payers, providers, IDNs or clinics can utilise real world data sets to generate their own evidence to inform decisions, e.g. around practice guidelines or treatment choices.[16]
- Patient-generated and/or reported data, e.g. via digital devices or wearables, fuel the rise of the patient as a key stakeholder, while technologies such as blockchain and web3 have the potential to empower patients to become the owners of their data.[17]
- The pace and nature of innovation is changing dramatically,[18] which upends the traditional biopharma model:
  - Faster innovation cycles shorten de facto exclusivity periods and thus erode lifetime sales of products, thereby further increasing the pressure on already squeezed P&Ls: Between 2016-2021, R&D cost and COGS were rising faster than sales, at 5-year CAGR of 8.1% and 8.9% vs. 6.9%, respectively, for the top 15 big pharma companies.[19]
  - Innovation is also becoming more complex, more personalised and more precise, with numbers to treat (NTT) approaching 1 in many cases. Healthcare systems are often overwhelmed as legacy care pathways are not equipped to adopt such innovations which 'break the mould', for example cell and gene therapies[20] or tumour-agnostic therapies.
- New types of players are seeking to disrupt healthcare, such as technology companies, with advanced data and analytics capabilities and deep expertise in consumer engagement via technology or logistics platforms to create unique patient experiences and outcomes, thus posing the risk of disintermediation to biopharma.

This has profound implications for biopharmaceutical companies, and especially for the future of medical affairs. Healthcare system partnering around a broader, common agenda to enable the adoption of innovation becomes a key prerequisite for achieving commercial success, alongside the continued focus on patient outcomes.

Given the mounting pressures healthcare systems are facing, we are observing their growing willingness to explore novel collaboration[21,22] and market access models[23,24] with the biopharmaceutical industry.

Healthcare system partnering around a broader, common agenda to enable the adoption of innovation becomes a key prerequisite for achieving commercial success, alongside the continued focus on patient outcomes.

Medical affairs will be instrumental in facilitating such collaborations.

Medical Affairs' finest hour: When patient centricity meets healthcare system impact

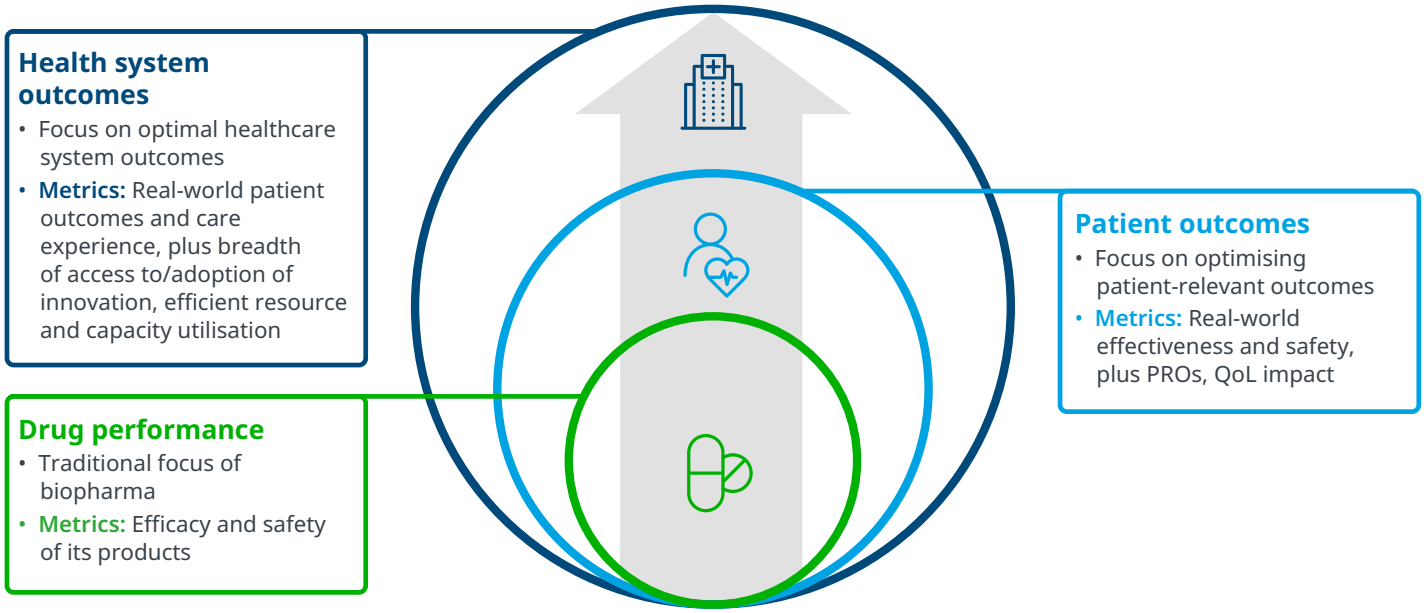
The post-pandemic world requires biopharmaceutical companies to broaden the basis of engagement with healthcare, looking beyond drug development and commercialising therapies to focus on system impact. It completes the journey from the industry's traditional focus on drug efficacy and safety to optimising patient-relevant outcomes and finally facilitating optimal healthcare system outcomes.

Medical affairs, as a non-promotional function, the home of deep scientific and clinical insight and with its pivotal role in driving the evidence agenda, is best placed for leading broader healthcare system engagement to establish trusted, mutually beneficial partnerships to achieve three objectives:

- Enable care pathways to adopt novel, innovative therapies.
- Ensure patient journeys and care pathway configuration are aligned with delivering optimal patient outcomes and superior patient experience.
- Facilitate healthcare system efficiency in optimal capacity and resource utilisation to ease its operational burden, ensure the sustainable delivery of high-quality care and unlock funds for broadening patient access to cutting edge innovation in a budget- and resource-constrained world.

Evidence, especially real world evidence (RWE), is the critical enabler of such healthcare system engagement by providing objectivity and transparency as the foundation for trusted, mutually beneficial partnerships, which puts medical affairs in prime position to lead as orchestrator of evidence generation and its communication. While data generated during clinical development forms the foundation of a product's value proposition, during the peri-launch and on-market stages in the lifecycle it is RWE which captures the reality of routine practice and thus is most suitable for engaging healthcare systems to address joint challenges.

Figure 2: Broadening the basis of biopharma–healthcare engagement



Source: IQVIA EMEA Thought Leadership

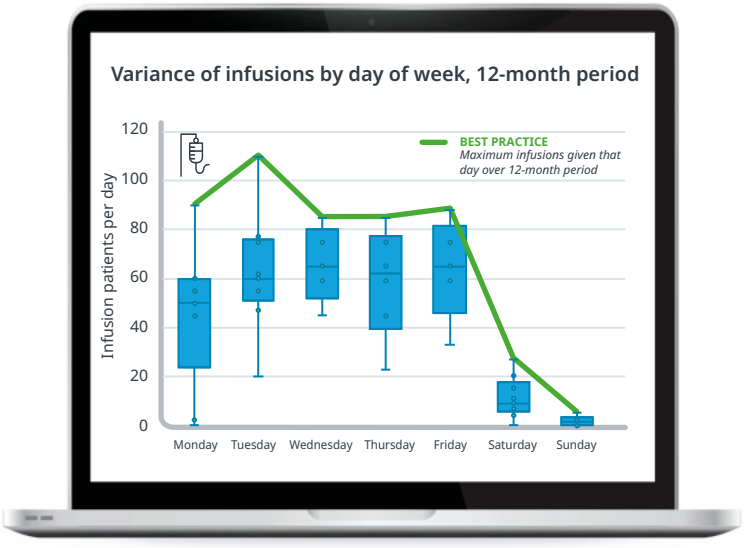
Furthermore, evidence is essential for creating opportunities to co-develop local solutions to deliver on a joint agenda of optimal patient and healthcare system outcomes. For example:

- Care pathway analytics, e.g. for the objective measurement of healthcare system performance via metrics for quality of care, resource utilisation, uptake of innovation and patient outcomes. This allows benchmarking within and across systems and helps uncover root causes of sub-optimal performance, such as unwarranted variations in care pathways,[25,26] inconsistent adherence to guidelines across geographies or institutions or a disconnect between outdated clinical practice and state-of-the-art medical innovation.
- Data-driven, highly tailored patient programmes offering continuous support, for example with closed-loop, (near) real-time digital biomarkers informing dynamic care adjustment to create unique patient experiences.
- Early access programmes to broaden access to patients with high unmet need, for example in rare diseases without treatment options, while collecting required data.
- New access models that align incentives around shared objectives, such as value-based contracts, e.g. the agreement between Novartis and Colorado Medicaid for Entresto tied to a reduction in hospitalisations[27], novel subscription models, e.g. fixed payments for access to antibiotics, independent of prescription volume, to address antimicrobial resistance from overuse while incentivising investment in innovation,[28] or population health deals, e.g. Novartis-NHS England agreement for Leqvio anchored on cardiovascular outcomes,[29] the latter still being experimental with numerous practical implementation challenges yet to be overcome.

Medical affairs will be instrumental in facilitating such collaborations between biopharma and healthcare systems, both through external stakeholder engagement and internally by orchestrating cross-functional alignment around an agenda of delivering optimal patient and healthcare system outcomes. This will create mutual benefits by reconciling fair commercial returns on biopharma innovation with sustainable healthcare system impact.

Figure 3: Optimising capacity and demand management

Case study: Analytics partnership to uncover root causes of unwarranted variation of infusion performance



Data-driven approach to optimise capacity and demand management for checkpoint inhibitor infusions

- Retrospective Patient Level Information & Costing (PLICS) data combined with on-the-ground audit to build capacity and infusion performance dashboard
- Longitudinal view highlights best practice and quantifies unwarranted variation in capacity utilisation and associated resource costs
- Overlaying infusion performance with profile of treated patients, treating consultant and infrastructure data (eg specific chairs used) helps understand underlying drivers of variance
- Comparing profiles of treated patients vs waiting list enables proactive planning to optimise infusion capacity utilisation and demand management

Source: IQVIA Healthcare Consulting UK & Ireland

Implications and considerations for the future of Medical Affairs

To fulfil its promise, medical affairs has to expand its remit and operate differently in the future. Specifically, three key priorities must be addressed:

1. **Driving internal alignment around the new agenda:** Transform medical affairs from being a third pillar alongside R&D and commercial to becoming the bridge between key functions, including R&D, commercial, market access and HEOR, to drive alignment around an agenda of optimal patient and healthcare system outcomes. This will require medical affairs to

   a. Capture and relay insight about healthcare system needs to other functions to inform joined-up strategic decision making. Mastering the abundance and richness of information medical affairs collates and can access will be critical, especially using powerful, advanced analytics to turn information into actionable insight.

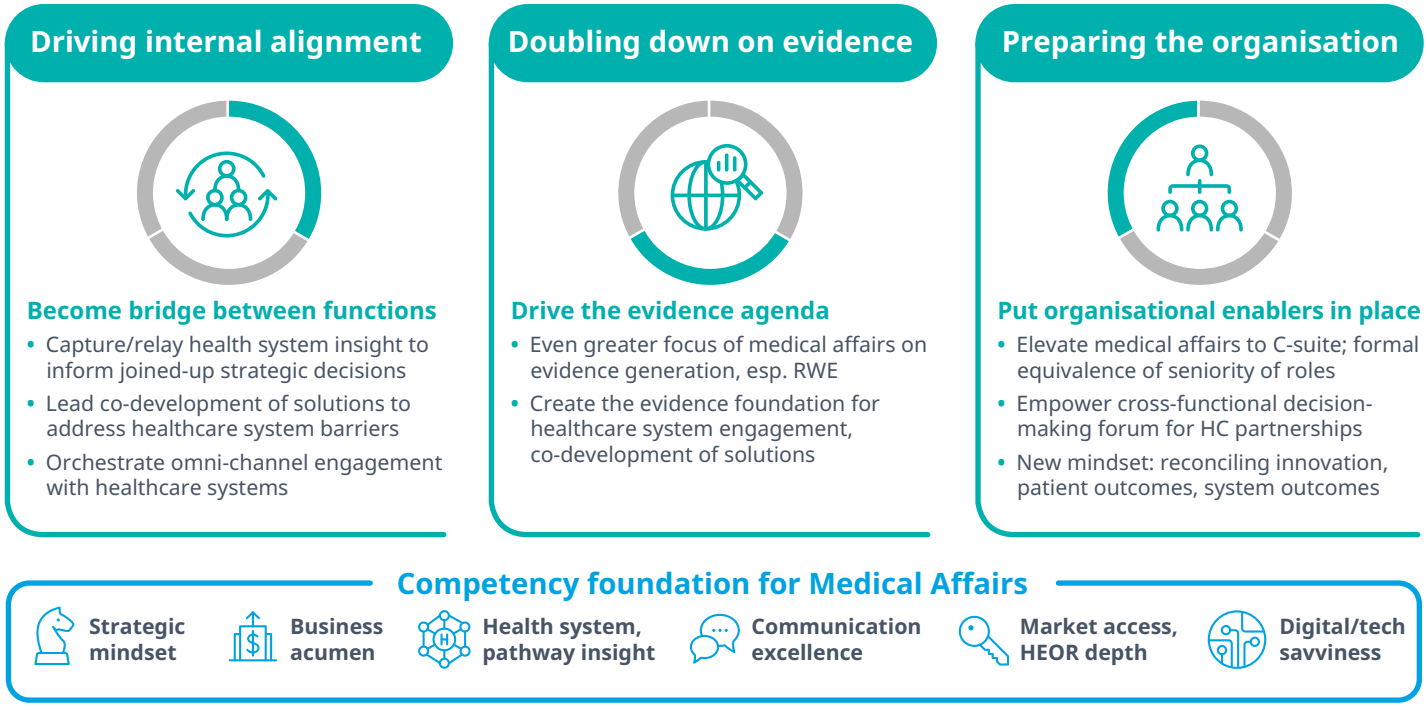
   b. Lead the co-development of solutions to address (local) healthcare system bottlenecks in the adoption of innovation and barriers to achieving optimal patient outcomes and the efficient utilisation of related healthcare resources.

   c. Orchestrate omni-channel engagement with healthcare systems, internally across functions, and externally across an expanded stakeholder remit, including payers, providers, integrated networks and individual institutions.

2. **Doubling down on evidence:** Medical affairs to place even greater emphasis on driving the evidence agenda, especially RWE, as the strategic enabler of healthcare system engagement and the foundation for the co-development of solutions.

3. **Preparing the organisation for the future:** Ambitiously expanding the remit of medical affairs has clear implications for a biopharmaceutical company's organisation. It is critical to put in place the following key organisational enablers for medical affairs to realise its bold vision:

Figure 4: Implications for the future of Medical Affairs – key priorities



Source: IQVIA EMEA Thought Leadership

a. Elevation of medical affairs to the C-suite, in recognition of its critical role in shaping and communicating a company's patient-relevant value narrative and as the facilitator and interface in healthcare system partnerships

b. Formal recognition of the equivalence in seniority of medical roles vs other functions, especially commercial, by aligning grading and titles to facilitate cross-functional collaboration as equals in a true partnership

c. Setup of a formal cross-functional decision body ('Partnership governance forum') which is empowered to jointly set the agenda, strategic priorities, investment and tactical plans for the company's healthcare system partnership initiatives

d. New organisational mindset that looks beyond traditional business objectives and performance metrics and also considers patient outcomes alongside healthcare system impact. Its emphasis mirrors the apex of the PRIME model for assessing the impact of continuing medical education (CME) for healthcare professionals.[30]

e. New medical affairs capabilities and competencies, including upskilling in HEOR and market access; deep understanding of healthcare systems and care pathways; ability to credibly communicate with non-clinical stakeholders, especially payers and HTA bodies; business acumen and mindset to play a strategic role in cross-functional brand teams; data fluency and technological/digital savviness. Some of these will require creating new, specialised roles, e.g. care pathway specialists or digital medical content specialists. The new competencies and mindset need to be consistently role modelled by medical leadership to reinforce change.

f. New medical career path framework spanning global, regional and local roles, focused on talent development, aligned to new capability and competency requirements, and on retention, as competition for experienced medical affairs top talent is heating up.

A key consideration in making strategic choices about expanding the remit of medical affairs is a company's attitude to the perceived exposure to potential compliance risk, for example, as a result of external collaborations involving direct engagement with patients, or internally due to closer interactions between medical and commercial.

While these are legitimate concerns, adopting a blanket approach based on undue conservatism is counterproductive. Instead, differentiated, case-based and objective risk assessment combined with robust processes and governance models will provide a framework in which medical affairs can fulfil its future promise in a compliant way.

To fulfil its promise, medical affairs must transform from being a third pillar alongside R&D and commercial to becoming the bridge between key functions, including R&D, commercial, market access and HEOR, to drive alignment around an agenda of optimal patient and healthcare system outcomes.

Closing thoughts

The biopharmaceutical industry has a rare opportunity to fundamentally re-define its relationship with healthcare systems, providers and patients, by reconciling innovation, patient outcomes and healthcare system outcomes. Building trust-based, mutually beneficial partnerships will enhance the industry's reputation with key healthcare stakeholders and strengthen its contract and reputation with society at large.

Medical affairs as critical facilitator is at the very heart of enabling this new collaborative model, by positioning the biopharmaceutical industry as a worthy partner.

Over the medium term, embedding broader partnerships between healthcare systems and biopharma as an integral part of the industry's future business model has the potential to turn a bold aspiration into reality: Expanding access to innovative therapies to all eligible patients and eliminating delays to receiving treatment, while balancing stakeholders' legitimate interests, including fair financial returns.

The inevitability of change facing healthcare systems means companies have a clear choice: being part of shaping the new model or being swallowed by it. The imperative to seize this opportunity is now.

The inevitability of change facing healthcare systems means companies have a clear choice: being part of shaping the new model or being swallowed by it. The imperative to seize this opportunity is now.

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Markus has over 20 years of experience in life sciences, advising clients in all major geographies on a broad range of topics, including real world evidence strategy, launch readiness, go-to-market models, brand and commercial strategies, and building enabling organisational capabilities.

Markus is a frequent speaker on the latest industry trends and regularly engages with senior leadership teams of pharmaceutical companies.

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Markus holds a PhD in Pharmaceutical Chemistry from the University of Hanover and has completed post-doctoral research at the University of California.

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Reinhard has more than 15 years of medical affairs experience in the pharmaceutical industry, holding country-level, regional and global roles. He has successfully covered all facets of medical affairs , including launch readiness, digital transformation, RWE generation, medical education, MSL excellence and medical strategy, and was responsible for leading medical affairs teams with direct accountability to senior management.

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Prior to his current role, and before moving into medical affairs, Reinhard gained experience in drug discovery and pre-clinical development in the pharmaceutical industry.

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