WHITE PAPER

Medical affairs at a crossroads in Japan

Patient-centric, AI-powered and outcome-driven

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This white paper includes contributions from guest author Masahisa Jinushi, head of medical affairs, Gilead Sciences.

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Japan's healthcare landscape faces significant challenges stemming from fragmentation among patients, healthcare providers and biopharma functions, which frequently results in suboptimal patient care. Continued pressure from regulators to control rising healthcare costs has created both an urgent need and a unique opportunity to enhance the efficiency of existing care models. The pharmaceutical industry now stands at a crossroads. To ensure Japan's healthcare sector becomes a critical driver of future economic growth, pharma must proactively champion improvements in efficiency and quality of care to help the sector become a key player influencing both government policy and society at large.

Medical affairs teams can lead this charge by establishing a rigorous framework for evaluating the real-world impact and tangible outcomes of teams' current activities. By centering assessments on outcomes, medical affairs can ensure resources and efforts are aligned with the most critical needs, laying a solid foundation for any future initiatives.

To discuss this opportunity and more, ZS facilitated a roundtable discussion in Tokyo with nine heads of medical affairs from leading pharmaceutical companies in Japan.

Throughout the discussion, panelists highlighted five key steps medical affairs organizations can take to elevate their role in the healthcare ecosystem. These steps include:

1. **Adopting outcome-oriented metrics to measure tangible medical affairs impact.** Teams should transition away from tracking volume of activities to establishing robust feedback systems that assess patient activation, shifts in key opinion leader (KOL) perception and behavior, registry enrollments and reductions in hospital readmissions. These outcome-focused KPIs help clearly demonstrate medical affairs' strategic value to leadership.

2. **Elevating the patient and public voice to contribute to the healthcare ecosystem and shape clinical care pathways.** Medical affairs should be more proactive with patient and public engagement initiatives, ensuring their voices are amplified as actionable insights to support important internal decisions throughout the product life cycle. The team should inform the creation of external-facing narratives and should act as a systematic input for physicians to facilitate shared decision-making with a goal of shaping the clinical care pathway.

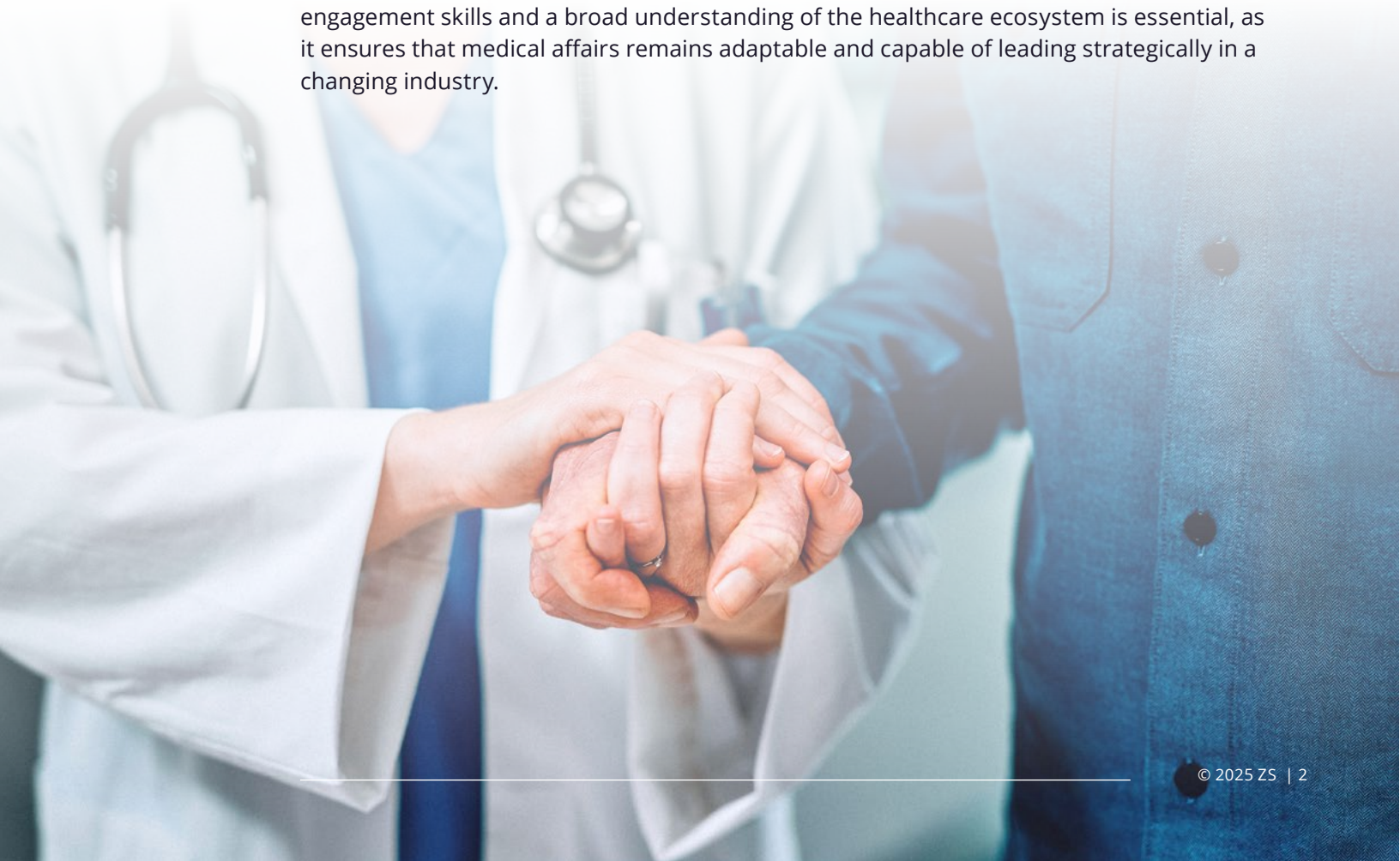
3. **Leveraging advanced real-world data (RWD) infrastructures to generate evidence and expand strategic use cases.** Leverage cross-functional collaborations to collect RWD, integrating sources such as electronic medical records (EMRs), registries and patient-reported outcomes. Seek improvements in existing study designs to accelerate safety-signal detection, streamline post-marketing surveillance and deliver real-world evidence (RWE) that informs policy, regulatory approvals and reimbursement strategies.

4. **Harnessing AI to optimize medical affairs efficiency and impact:** Deploy AI-driven tools to automate routine tasks such as literature summarization, slide quality control and insight extraction from medical science liaison (MSL) interactions. At the same time, explore applications of AI that can enhance healthcare professional (HCP) engagement, such as rapid insight analytics and predictive modeling in complex medical scenarios. By doing so, medical affairs can shift focus from repetitive tasks to building trust-based HCP relationships, while navigating an increasingly complex healthcare environment with improved efficiency.

5. **Cultivating talent and fostering a future-ready team culture:** Equip medical affairs professionals with digital fluency, business acumen, stakeholder-engagement skills and broad understanding of the healthcare ecosystem. Foster a forward-looking mindset within the medical affairs team to proactively identify emerging trends, leverage cross-functional insights and strategically shape healthcare innovation and policy development.

Medical affairs must also proactively amplify the voices of patients and the public. Integrating patient perspectives into clinical trial designs, healthcare provider communications and educational strategies will ease the burden on healthcare providers, foster greater patient engagement and significantly enhance overall care outcomes. Japan's rapidly expanding RWD infrastructure and AI-driven analytics offer unprecedented opportunities, which medical affairs should leverage to streamline operations, enhance data quality and accelerate evidence generation that drives better patient care.

To advance medical affairs capabilities requires investing in future-ready talent. Developing professionals who blend deep scientific knowledge with digital fluency, strong stakeholder engagement skills and a broad understanding of the healthcare ecosystem is essential, as it ensures that medical affairs remains adaptable and capable of leading strategically in a changing industry.



Step
one

Adopt outcome-oriented metrics to measure tangible medical affairs impact

"We should stop counting slides or HCPs visited but instead begin counting HCPs for whom we have evidence of behavioral change."

A 2016 study of almost 500 KOLs in Japan showed that the quality of medical affairs activities matters much more to satisfaction and impact than how many activities are completed. Zooming out, this means medical affairs must move beyond activity tracking and focus on measuring tangible outcomes. It's essential to assess the impact of each initiative carefully and report results clearly to leadership teams.

For example, data generation activities require careful planning to produce high-quality data and strong narratives that influence behaviors. Such activities should be assessed at different milestones, such as during study design, congress presentation, publication and tracking of behavioral change. Distilling insights about long-term influence into concise impact narratives for local general managers and global leadership is key to reinforcing medical affairs' strategic value.

Strategic actions for medical affairs

- Integrate and analyze multiple data sources, such as MSL and commercial rep interaction logs, claims data and patient-reported engagement metrics, to assess changes in behavior resulting from medical affairs activities. This integrated approach enables a comprehensive evaluation of impact, demonstrating tangible value to leadership teams.
- Outcome-oriented KPIs across key medical affairs focus areas may include:
  - Measurable shifts in KOL perception, knowledge and advocacy level
  - The percentage of HCPs surveyed who correctly apply insights from the newly communicated clinical data into clinical practices
  - Patient activation scores (e.g., patients' ability to articulate symptoms), growth in registry enrollments and reductions in hospital readmissions

- Deploy AI-driven speech analytics and insight extraction tools to track HCPs' engagement level and behavior change. Use comprehensive behavioral mapping across the customer journey to optimize resource allocation based on impact metrics.
- Craft concise impact narratives to illustrate medical affairs' strategic contributions. Use concrete examples such as increased KOL advocacy or reduced emergency department visits following educational programs to contextualize data and effectively communicate medical affairs' tangible value to the leadership team.

Step two

Elevate patient and public voice to contribute to the healthcare ecosystem and shape clinical care pathways

"By building frameworks that give patients access to information, the dialogue between doctor and patient becomes easier."

Medical affairs' involvement in patient and public engagement today varies widely. Some teams lead advocacy and education initiatives while others defer these responsibilities to corporate affairs. Medical affairs has a unique role in understanding true patient and public needs by creating an ecosystem involving academic societies and community-based organizations. That's why medical affairs should leverage the power of digital platforms to derive insights that inform internal evidence generation strategies and education narratives. These insights can also be systematically shared with HCPs to facilitate the shared decision-making process in clinical settings.

Throughout the product life cycle, medical affairs should assess whether diverse perspectives are incorporated to accurately inform study protocols and educational materials. That can include implementing symptom-tracking applications and patient portals, which facilitate more effective communication of patient concerns and support timely responses from HCPs. In conjunction with remote monitoring programs developed alongside local health systems, these initiatives contribute to ongoing patient engagement, adherence to treatment and decreased rates of readmission.

Strategic actions for medical affairs:

- Elevate medical affairs' role as the bridge between patient and public voices and corporate strategy by integrating insights into medical strategy and health literacy campaigns. Medical affairs can help shape cross-functional initiatives and strategies that drive better outcomes across the healthcare ecosystem.
- Establish formal partnerships with established advocacy networks and integrate patient representatives into clinical study advisory boards or use patient and public feedback data for informed decision-making. This ensures that clinical development programs, materials and engagement strategies are directly informed by real-world needs and lived experiences.
- Classify patients by disease stage, digital literacy and engagement readiness to deliver the right resources, such as peer-support webinars for highly engaged groups and self-guided portals for others. Train medical affairs staff in patient communication techniques to facilitate effective dialogue with patients and patient groups.
- Deploy digital symptom-tracking applications and patient portals that capture critical information before and between consultations. During postlaunch, extend engagement through remote monitoring programs in partnership with local health systems to sustain adherence and reduce readmissions.

Step three

Leverage advanced RWD infrastructures to generate evidence and expand strategic use cases

"RWD can demonstrate how new therapies change patient outcomes at a systems level, beyond the clinical trial environment."

Japan is at a strategic juncture. The Next-Generation Medical Infrastructure Law and widespread My Number Card adoption, which now covers 80%-90% of medical records, unlock unprecedented access to RWD. This enables medical affairs to map complete patient journeys by integrating patient-level claims data, disease registries and patient-reported outcomes to drive earlier diagnosis and optimize referral pathways. It also positions medical affairs to influence policy development by providing cost-effectiveness insights, leveraging granular data on generic and biosimilar utilization to inform payers and government discussions traditionally led by market access, health economics and outcomes research (HEOR) and regulatory teams. Finally, by consolidating post-marketing surveillance and phase 4 studies under a unified protocol, medical affairs can generate higher-quality evidence for regulators and clinicians, complementing broader access and reimbursement strategies.

Strategic actions for medical affairs:

- Form cross-functional teams to integrate data sources (e.g., from clinical EMRs and patient registries to e-diaries and mobile apps), especially in rare diseases. This integration enables medical affairs to pinpoint gaps in screening, referral and adherence, and then tailor interventions at the point of care.
- Combine post-marketing surveillance and phase 4 under a single medical-affairs-led protocol to avoid duplication, reducing costs and improving data integrity. Early pilots should proceed with regard for the Good Post-Marketing Study Practice (GPSP) safety-surveillance framework to establish necessary precedents. Once in place, a unified design can capture both safety and efficacy signals, delivering continuous RWE to inform clinical and commercial strategies.

- Distill outcomes, such as reduction in emergency department visits following shared decision-making programs and improvements in patient quality-of-life scores, into concise regulatory briefs that highlight the endpoints most relevant for approval and policy discussions.
- Anchor these briefs with linked claims and EMR data to support conditional-approval pathways and reinforce reimbursement dossiers and health policy dialogues with concrete RWE of improved healthcare delivery.

Step four

Harness AI to optimize medical affairs efficiency and impact

> **"We may be able to discard entire workflows that we currently take for granted."**

Since its public launch in late 2022, generative AI has been automating routine medical affairs tasks, such as medical insight extraction, literature summary, slide quality checks and document management, all of which free up personnel for more critical tasks. Next-generation AI platforms can quickly analyze MSL insights by reviewing call transcripts to identify unmet medical needs, new safety signals and changing practice trends. These rapid advancements allow medical affairs talent to shift from low-value workflows while helping medical affairs deliver an outsized impact on the business and evidence generation strategies.

Strategic actions for medical affairs:

- Deploy AI-driven tools for literature summarization, slide quality checks and insight extraction to cut MSL prep time. This efficiency gain shifts MSL effort away from manual data mining toward in-depth scientific exchanges and proactive problem-solving with key HCPs.

- Leverage real-time AI analysis of MSL insights to parse call transcripts and field notes to flag unmet medical needs, emerging safety signals and evolving practice patterns.
- Deploy AI-enabled engagement platforms to capture and act on patient and HCP insights, leverage predictive modeling and RWE integration. Use these platforms to accelerate evidence generation and apply those insights to inform evidence-led policy making and reimbursement strategy.
- Appoint dedicated AI governance roles to set data privacy guardrails, vet vendors and codify compliant use cases; develop structured training programs on secure AI usage (covering model validation and regulatory considerations) to ensure consistent, risk-aware adoption.

Step

five

Cultivate talent and foster a future-ready team culture

> **"In the next era of medical affairs we need to imagine multiple possible futures and plan accordingly."**

Over the last five years, medical affairs has been expected to evolve into the third strategic pillar of the global operation of pharma companies, together with R&D and commercial. In this "next era," medical affairs will grow beyond its supportive function to become a strategic partner with other departments. Realizing this vision requires medical affairs to cultivate T-shaped expertise, blending deep scientific and clinical knowledge with a broad range of skills such as digital fluency, trust-building techniques, business acumen, the ability to foresee landscape shifts and knowledge about the extended health ecosystem, including insurance and e-health commerce.

Such expertise ensures medical affairs personnel can dedicate talent and time to strategic dialogues with external stakeholders, ecosystem-building activities and internal coordination.

Medical affairs should focus on translating complex evidence into powerful narratives for HCPs and regulatory agencies. This approach can help change clinical practice. Additionally, medical affairs should share actionable insights with internal cross-functional stakeholders to drive strategic decision-making.

Strategic actions for medical affairs:

- Develop medical affairs professionals who combine therapeutic depth with competencies in data science, digital strategy and patient engagement, supported by dedicated AI champions to govern vendor selection and data privacy.
- Empower the medical affairs team to build trusted relationships with key external stakeholders by honing engagement skills that focus on value exchange instead of unilateral information collection and deploying digital tools to level up external-facing narratives about clinical care pathway shaping based on scientific evidence.

- Help the medical affairs teams strengthen their business understanding so they can better identify useful medical insights, learn about the wider healthcare ecosystem and see how these insights support decision-making across different teams.
- Foster a proactive mindset to anticipate trends based on scientific expertise and stakeholder insights to coordinate cross-functional collaborations and drive strategic priority identification to improve a company's overall level of readiness in the competitive market environment.

How Japan medical affairs organizations can emerge as pharma's 'third pillar'

In an era defined by rapid technological change and growing demand for patient-centered care, medical affairs organizations in Japan are prepared to become the driving force that shape tomorrow's healthcare ecosystem. By embedding medical affairs initiatives early in product life cycles, harnessing AI to streamline operations and amplifying patient voices through engagement efforts, medical affairs can serve as the linchpin between commercial, regulatory, R&D, government affairs and public affairs.

Central to the evolving value of medical affairs are three strategic directions that can guide medical initiatives in shaping the healthcare ecosystem. They are:

1. **Elevating the patient voice across clinical development and the postlaunch phase** should ensure that future therapies address patients' unmet needs while reducing the burden of participation in trials.
2. **Facilitating the appropriate and timely use of medicines** through targeted HCP education and digital tools for patients, such as symptom-tracking applications, can help medical affairs ensure treatment outcomes and reinforce the therapy's clinical value.
3. **Accelerating the generation and dissemination of RWE** through unified clinical study protocols, innovative digital platforms and integrated data initiatives should enable medical affairs to drive measurable improvements in care delivery through higher-quality data and insights that resonate with both HCPs and regulators.

To realize this vision, medical affairs must cultivate T-shaped talent: Professionals who combine deep scientific expertise with digital fluency, trust-building engagement skills, business acumen, broad knowledge of the extended healthcare ecosystem and an ability to stay ahead of medical trends. At the same time, medical affairs should adopt outcome-based metrics to adapt to an ever-shifting landscape while providing the feedback needed to expand into new strategic roles beyond traditional medical activities. By taking these steps, medical affairs organizations in Japan will affirm their emergence as the pharma companies' "third pillar." They will drive innovation, foster trust and, above all, improve patient outcomes across the healthcare ecosystem.

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Masahisa Jinushi serves as head of medical affairs at Gilead Japan, where he leads the growth of medical affairs through organizational excellence, cross-functional partnership and digital innovation. Before joining Gilead, he worked in the pharmaceutical industry for over 10 years in oncology, clinical development and medical affairs. Prior to this, he worked in academia for 15 years in translational and clinical sciences to explore new cancer treatments.

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