



Medical[™]
Affairs
Professional
Society

Elements of a Successful Medical Affairs Digital Strategy Framework

Ka-Wing Chong, Medical External Engagement Director, Amgen

Richard Kemper, Medical Omnichannel Head, General Medicines Global Business Unit, Sanofi

Rishi Ohri, Sr. Director, Medical Affairs, Astellas

Rahela Penovski, Founder, Cogned

This publication represents the consensus opinions of the authors and various members of MAPS but does not represent formal endorsement of conclusions by their organizations.

Background: A Vision-First Approach to Digital Transformation

This white paper is inspired by an inquiry to the Medical Affairs Professional Society (MAPS) Digital Focus Area Working Group (FAWG) requesting guidance on best practices to establish a digital framework within Medical Affairs at a small pharmaceutical company. While this paper seeks to provide this specific guidance, the digital framework described herein is not only applicable to small organizations but can be seen as a basic digital framework for Medical Affairs teams in biopharmaceutical and MedTech organizations of any size.

Digital tools power the ability of Medical Affairs teams to generate, analyze and disseminate data to external stakeholders across the product lifecycle, while at the same time bringing essential learnings from these stakeholders back to the organization in the form of insights. That said, no single digital structure or set of digital tools will be appropriate for all organizations. Thus, rather than considering the recommendations of this paper a one-size-fits-all system, it is important to evaluate how digital transformation may empower and support a company's core beliefs and key messages.

Importantly, no matter the specifics of implementation, we recommend a vision-first approach to digital – only once an organization's vision has been established is it appropriate or even possible to successfully define the digital pillars needed to implement and execute this vision.

Once a company's vision is clear, Medical Affairs teams may consider the core components of developing a Medical Affairs digital strategy and plan shown in Figure 1, each of which will be discussed in turn.

MAPS Digital Strategic Framework		
Category	Category	Examples
Omnichannel Scientific Strategy & Engagement	Evaluation of stakeholder, product and content needs to enhance scientific exchange and support continuous medical education to deliver meaningful value supported by cross-functional collaboration	KEE identification, Digital Med. Ed. Content needs, planning tools, etc.
	Build digital capabilities and channels to enhance seamless omnichannel experiences using the right content at the right time for the right stakeholder	Omnichannel - New channels, optimizations, MA Websites, MI Inquires, Chatbot, scientific exchange, etc
Advanced Data Generation	Drive digital health solutions and Real-world evidence generation supported by disruptive innovation and trends.	Integrated Data Platforms for Publications, CRMs, Grants, Advisory Boards, etc.
Foundational Systems/ Capabilities	All necessary capabilities/systems to enable collaboration internally and externally, processing and analysis of data, tools to support productivity and efficiency	System/Platforms for Publications, Medical Information, CRMs, Grants, Advisory Boards, etc.
People and Culture	Understanding and accommodating the necessary core competencies, Talent, skillsets, training, resource models, etc.	Key training programs, Digital advocacy for Sr. Leadership, presentation skills, etc.

Figure 1. Components of a Medical Affairs Digital Strategic Framework

Omnichannel Scientific Strategy & Engagement

Digital omnichannel engagement describes the many forms of information and messages produced by Medical Affairs, along with the outlets/channels used to reach diverse groups of external stakeholders. Done well, omnichannel engagement allows Medical Affairs teams to efficiently reach individual stakeholders through preferred channels and formats. For example, healthcare professionals (HCPs) are coming to increasingly expect scientific exchange personalized to their information needs and delivered through a preferred platform (face-to-face, hybrid, or virtual). At the same time, Medical Affairs is learning to use digital tools to engage new categories of external stakeholders including patient advocacy organizations, payers/policy makers and even Digital Opinion Leaders (DOLs). Again, in a vision-first approach, the digital tools used to engage each of the stakeholder groups is driven by scientific strategy and a clear understanding of stakeholder needs/preferences. Without strategy driving digital tactics, Medical Affairs organizations risk generating and communicating data that is irrelevant or even counter to strategic goals. Thus, it is important to consider omnichannel engagement according to the following four elements of strategy, content, channels/analytics and stakeholder insights.

Strategy

Traditionally, Medical Affairs teams presented data primarily through in-person MSL interactions, Medical Education, Medical Information, publications and conferences/congresses, with the format of information presented through each of these channels primarily driven by the requirements of the channel and/or the organization. Digital omnichannel engagement allows teams to instead take a stakeholder-centric approach to data dissemination, scientific exchange and even evidence generation. Of course, this strategic approach requires a robust understanding of stakeholder needs across dimensions including who are external audiences and where are their gaps in understanding. To define the composition of external audiences, organizations traditionally used (and still make some use of) market research to create stakeholder personas, allowing teams to build digital engagement plans based on these personas. Increasingly, Medical Affairs teams are using digital tools such as artificial intelligence to constantly analyze the data of a worldwide connected digital channel ecosystem including not only PubMed but also social media and other emerging sources to identify opinion leaders within many categories of external stakeholders. Emerging digital tools are also helping Medical Affairs teams create meaning from the unstructured data of these stakeholders' digital interactions, for example using natural language processing to identify stakeholder gaps, which may take the form of knowledge gaps (does not know a fact/data/skill), attitude gaps (does not believe or is not confident of the fact/data/skill), practice & skill gaps (does not perform or know how to perform actions based on knowledge). Clearly conceptualizing external stakeholders and their needs allows Medical Affairs teams to start defining their vision that in turn becomes strategy, only after which can teams make specific choices used to decide omnichannel engagement tactics.

“

Digital omnichannel engagement allows teams to instead take a stakeholder-centric approach to data dissemination, scientific exchange and even evidence generation.

”

Content

As Medical Affairs expands the external stakeholders with whom we engage and also the channels used for engagement, the function requires more content in different formats. This is especially true as content is localized from the global level to reach individual stakeholders in regional/local markets. However, while the increased volume of content generation presents a challenge, for many organizations, the true challenge lies in the bottleneck of medical/legal/regulatory review or other approval processes. Several solutions can be put in place to manage this. For example, global production of “atomized” content can be used to allow local combinations to meet stakeholder needs – meaning that localization of content may be accomplished through appropriate combinations of modular content contained in a central digital asset management platform. In this model, local adaptations of content (translations, regulatory requirements, etc.) can vice versa be made available centrally, thereby amplifying content production and availability across the organization. In addition, involving MLR or other review teams very early in the content production process may speed review. In fact, when a Medical Affairs teams implements a vision-first approach, MLR review may start as early as review of the editorial plan for the production of digital content rather than waiting for the full production of content itself.

Channels & Analytics

Organizations used to consider these two activities separately: Channels would be chosen and then organizations would pick metrics or KPIs to measure the effectiveness of these channels. However, starting with vision and strategy allows Medical Affairs teams to define how to measure the impact of a digital tool or system concurrently with choosing digital tools, themselves. This integrated channel/analytics approach becomes especially essential in light of omnichannel engagement where many channels interface to offer many paths through the customer journey, individualized by stakeholder persona. For example, imagine an MSL email sent from the organization’s CRM system inviting a KOL for an educational session hosted on the company website, which in turn is also connected to the CRM. One could analyze many different aspects of these engagement touchpoints, from quantitative analytics like open rate, click through rate, and conversion rate of the email, to qualitative satisfaction analytics following the educational session. Defining metrics/KPIs within this interconnected digital system based on the company’s vision and key

messages ensures these metrics speak to meaningful, strategic outcomes, rather than risking becoming trivia points with no strategic purpose. Ideally, data/analytics captured across channels is combined with AI or human oversight to drive strategic actions, such as initiation of the next, most appropriate step in the customer journey.

Stakeholder Insights

Though digital insights will be discussed in more depth later in this paper, it is important to touch on the importance of insights when designing a system (or systems) of omnichannel engagement. Specifically, Medical Affairs has traditionally considered “channels” as the outlets that allow data dissemination; but rather than this one-way street of information dissemination, a more modern approach considers channels as a forum for scientific exchange in which information flows not only away from but also into the organization. This means the choice of channels and analytics for omnichannel engagement must also include mechanisms that allow external stakeholders to contribute their opinions, attitudes, questions, observations and knowledge back to the organization. Figure 2 summarizes this section by visualizing how clear understanding of external stakeholders and their education gaps can form the basis of strategy that allows teams to define learning formats and the technologies needed to deliver on these actions.

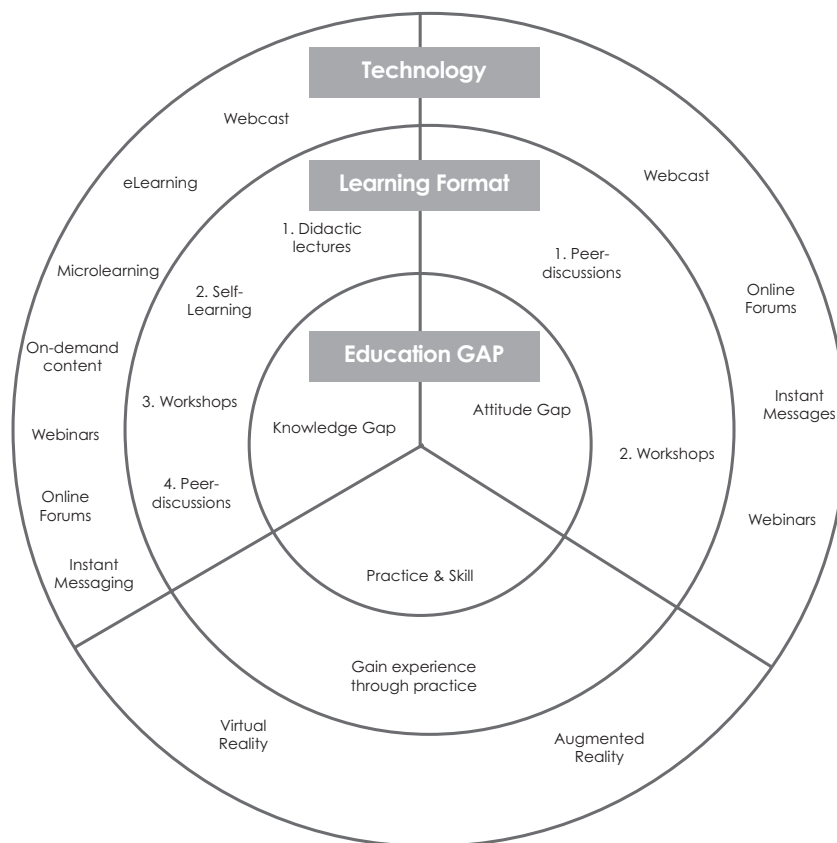


Figure 2. A Sampling of Educational Gaps, Learning Formats and Technologies

Advanced Data Generation

Disruptive innovation and digital technologies allow Medical Affairs teams to generate and evaluate data in new ways. One important opportunity is the ability to generate Real-World Evidence (RWE). This RWE is somewhat parallel to the traditional data generated by randomized-controlled trials (RCTs) in that RCTs may show a drug's effectiveness and safety, whereas RWE is increasingly used to enrich understanding of a drug's effects in real-world populations or in emerging uses or to clarify prescribing and regulatory decisions. Common sources of RWE include patient databases such as Medicare's SEER database or other collections of electronic medical records. However, new sources of RWE are emerging at a pace so fast it can be challenging to integrate these sources into an organization's digital strategic framework. Technologies such as wearable devices and increased granularity of data generated during healthcare interactions allows Medical Affairs teams to incorporate ever-increasing volume of digital endpoints into RWE study design and implementation. Again, a vision-first approach allows teams to drive evidence generation based on the strategic identification of clinically important endpoints/outcomes. Figure 3 describes three distinct categories of digital tools and the RWE they may generate.

“

“Digital health technologies (DHTs) have potential to generate rich and comprehensive information on how patients are functioning and feeling and help to minimize barriers to obtaining patient experience data during clinical investigations. DHTs can be operated and accessed remotely, can streamline study and data monitoring procedures, and can help maximize recruitment efforts among hard-to-reach patient populations. In addition, they can allow patients access to data about their health. Ultimately, DHTs may be used to assess study endpoint concepts that are meaningful to patients and can be used to evaluate clinical benefit.”

Dr. Andrew Potter, Mathematical Statistician, Office of Biostatistics, Division of Biometrics, US FDA Center for Drug Evaluation and Research

Products in three categories serve different purposes. They cannot be interchanged and are subject to different degrees of rigor, security, privacy, clinical evaluation, and regulatory oversight.

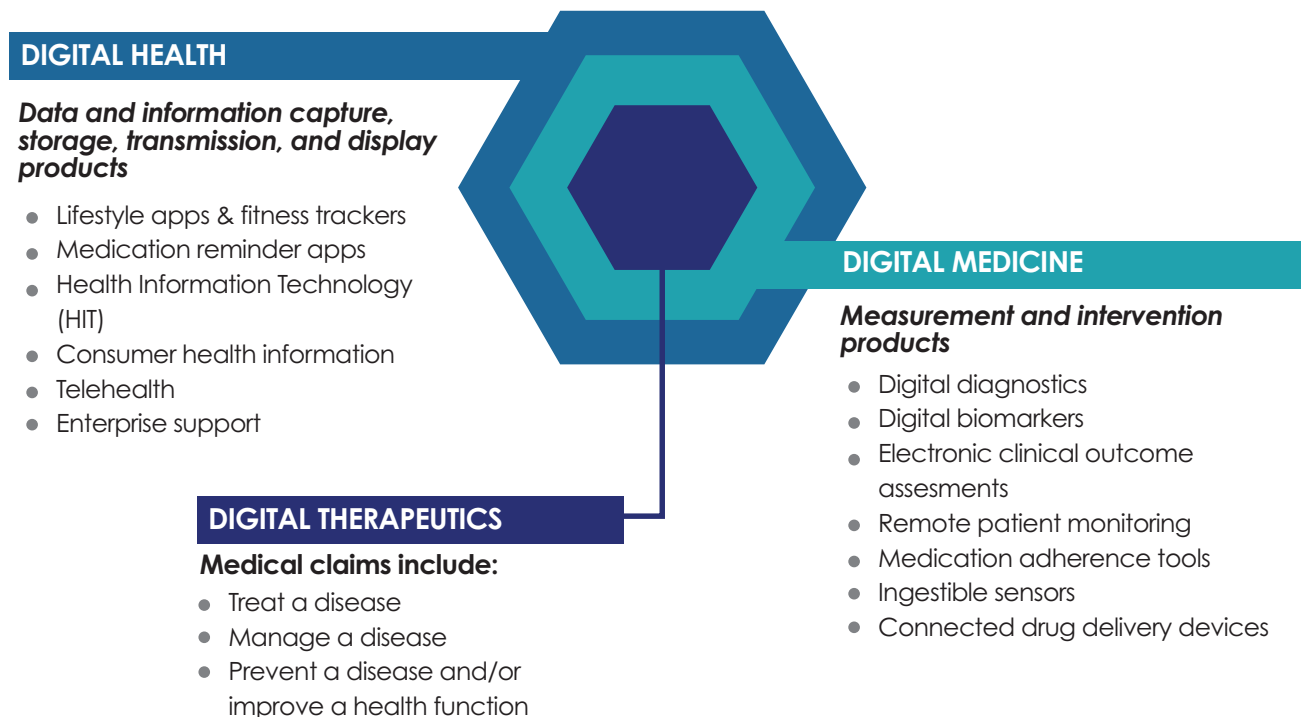


Figure 3. Three Categories of Digital Tools Generating RWE

Insights

In modern Medical Affairs teams, omnichannel also means omnidirectional, creating a rich space for the collaborative generation of knowledge that benefits both external stakeholders and the organization, and eventually patients. The term insights is shorthand for the contributions of external stakeholders to organizational understanding. Digital can facilitate insights gathering in multiple ways. For example, CRM systems may capture insights from Field Medical teams; artificial intelligence can be used to analyze those insights to monitor pharmacovigilance, ensure compliance and elevate the most actionable insights; and social media listening tools can be used to find relevant insights in public scientific data sources. Digital is even offering new formats for insights gathering through advisory boards, for example using asynchronous digital platforms that allow equal expert contributions, auto-translation and easy/compliant reporting. Based on the vision of how insights have the potential to influence organizational strategy, teams may then design or choose digital tools with the ability to generate, integrate and analyze insights from these various, pre-identified sources.

Foundational Components

Once vision and strategy are clear, the Medical Affairs function is finally ready to propose and implement a digital strategic framework. These frameworks are evolving at the pace of innovation. That said, most Medical Affairs teams will require foundational digital components that allow engagement, evidence generation and insights. Establishing such foundational components will take time, investment and often require collaboration across divisions to secure alignment, such as when collaborating with Commercial and Information Systems/Information Technology groups.

The following table is not a complete listing but should be considered a foundational list of components common in a MA digital technology stack.

FOCUS AREA	SYSTEM	DESCRIPTION
Scientific Exchange	Content Management System (NPMM)	Manage content and approval workflows for non-promotional materials (NPMM)
	Medical CRM	System used by, Medical Science Liaison (MSLs) to manage and document interactions, scientific discussions and activities.
	eMSL Capabilities	Enables eMSL interactions and content analytics for field personnel
	Virtual Engagement	System leveraged to enable virtual engagement, i.e. support Virtual Advisory Board meetings
Medical Information	Medical Information System	Call center, case/ inquiry management, processing and link to Medical Information content
Sponsorship and Grants for Research & Education	Investigator Sponsored Studies	System used globally by Medical Affairs to manage Investigator Sponsored Research (ISR) approvals and monitoring throughout all regions and including external investigators.
	Grants Management	The system records Medical Affairs educational and general research grant requests, correspondence between Astellas and requestors, approval documentation, post-activity documentation, and related reports.
Cross-Functional Alignment	Library	Various platforms/subscriptions/libraries
Data Generation	Clinical Trial Management System	Documenting progress of MA Studies, i.e., Non-Interventional, Retrospective, etc.
Internal Collaboration	MA Community Collaboration	Internal collaboration tools to share information, resources and knowledge
Planning	Core Medical Planning	Core Medical tactic ideation, adjudication and tracking
	Publication	Publication planning, authoring, workflow and tracking
Data / Analytics	Data Lake	System enabling the linkage between data/systems to support reporting and analysis
	Visualization Tools	Tools used for measuring performance, tracking milestones, dashboards, etc. This also may include Natural Language Processing (NLP) toolsets to detect and manage insights from internal/external data sources.

People and Culture

The successful implementation of a digital strategy requires not only tools, but the skill set for Medical Affairs team members to optimize the use of these tools. This can be especially challenging due to the fact that many Medical Affairs professionals who trained in MD, PhD or PharmD programs are not necessarily digital natives who are inherently facile with emerging digital systems. Organizational leadership may also lack understanding of the opportunities presented by digital transformation. The implications are twofold: First, to create organizational alignment, digital leaders may need to message the opportunities of digital in the language of the organization's strategic priorities; and second, the organization or a digital team within the organization may need to provide significant training to Medical Affairs teams and individuals on any new digital systems. Keep in mind the following when helping people and culture adapt to an evolving digital landscape:

Digital Missions & Goals

Work with leadership to define the mission of digital and what areas of Medical Affairs the company should digitalize. This may include sharing current and future trends and benchmarking across the industry to demonstrate the competitive need for digital transformation. Consider a phased approach to proposed digital transformation that is matched to the pace of organizational evolution.

Driving a Culture of Change

Not all digital skills depend on the ability to manipulate any single digital platform or tool. People naturally fear change and newness. Therefore, it is important to create an overall culture that allows creativity and room for error while rewarding digital behavior. Consider training that seeks to augment overall creativity, offers basic knowledge about the uses and purpose of any technology, and trains for compliance and internal processes to help the various Medical Affairs functions and team members integrate their use of digital technologies with other areas of the organization. Conducting a needs assessment may help define which areas to focus training to. When training a new digital skill, start by addressing barriers and challenges; use workshops to demonstrate the technology and encourage ideation; and for more complex or new projects, put together a core team to drive initial implementation and document learnings in a playbook.

Collaboration with Internal Stakeholders

Digital leaders within Medical Affairs do not have to be the only agents driving digital transformation. Work with IT, IS, Legal, Compliance, Regulatory, Safety, Quality and Commercial to increase awareness of digital strategy and inform how they can support the transformation. When formulating project teams, include members of the above functions where appropriate to help drive your projects and standardize guidance for future digital projects.

Conclusion

Pre-pandemic, digital transformation was a “like to have” for many organizations; now digital strategy and tools are a “must have” for any Medical Affairs team working in biopharmaceutical or MedTech companies of any size. We use digital to generate data, analyze data in ways that create knowledge, communicate this understanding, and to evaluate the effectiveness of this communication toward the goal of improving patient outcomes from emerging and existing treatments. Many organizations attempt digital transformation from a tools-first perspective, adopting technologies that seem to offer individual capabilities to individual teams within the function. However, driving digital from the perspective of organizational strategic priorities not only helps to ensure integration of digital systems, but also ensures digital technologies serve a purpose. Digital should not be for digital’s sake; it should be for the sake of Medical Affairs’ ability to benefit patients within the larger healthcare ecosystem.

