



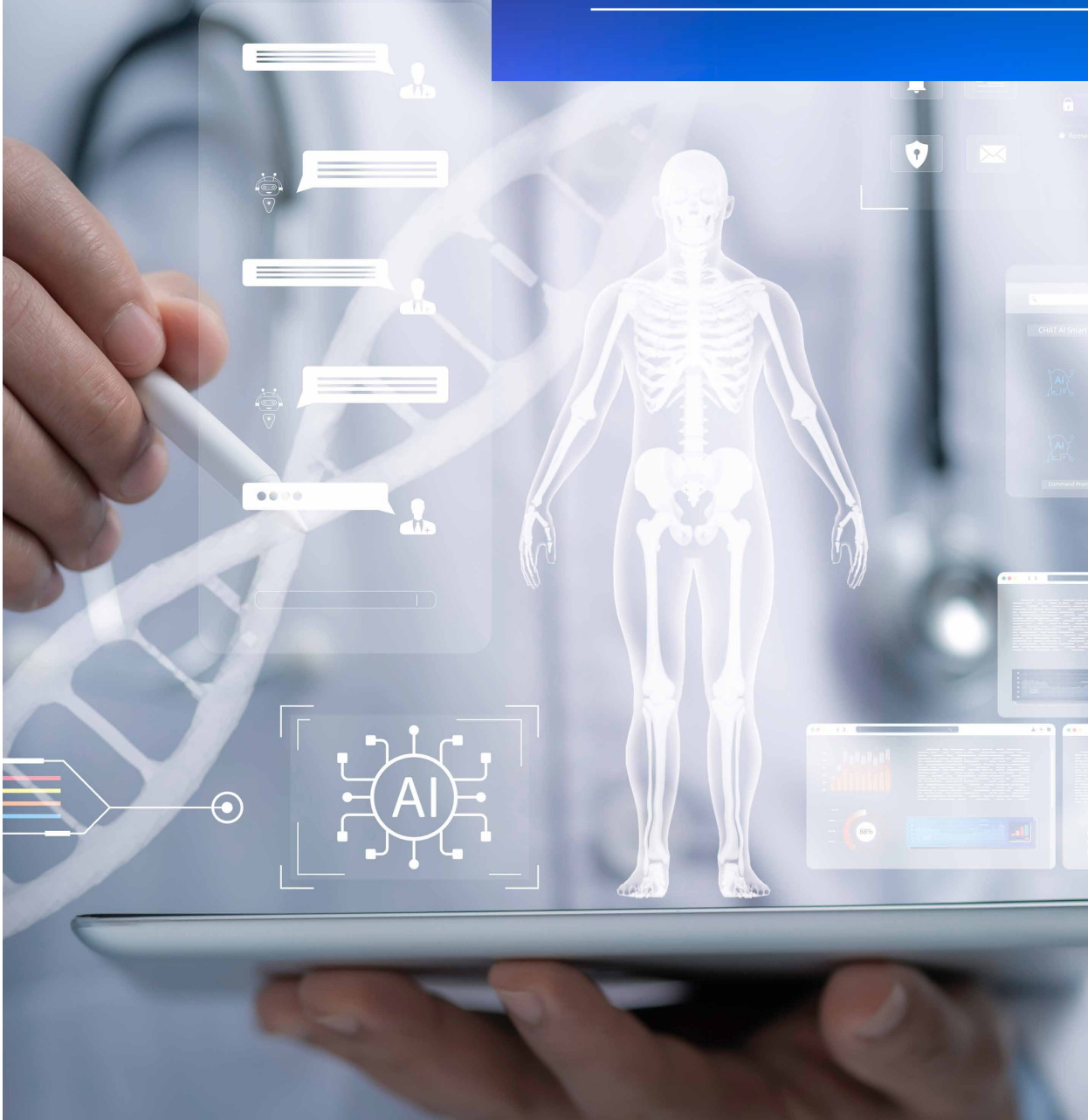
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Digitisation and AI in Medical Affairs

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DIGITISATION AND AI IN MEDICAL AFFAIRS

Artificial Intelligence (AI) and broader digitisation are now key areas of focus and investment for many biopharma companies. While use cases have been proven and are relatively mature in areas such as candidate selection and commercial engagement models, the progress in Medical Affairs has been slower. Many Medical Affairs organisations are exploring AI and focusing on digitisation of certain processes steps, but progress beyond pilot initiatives appears to be slow. It is essential to work from a digital strategy that is grounded in end-to-end process improvement with a focus on scalability to enable genuine gains in productivity and/or quality. Robust governance and change management are vital to clarify and achieve these goals.

Artificial Intelligence (AI) and digitisation are now key areas of investment for biopharma companies.

This is a broad and technically complex area with wide-ranging application. Clear and broadly communicated definitions are required to enable effective discussion and alignment to corporate

and functional strategies. Those strategies must underpin any investment decisions, such as which capabilities are to be built in-house and which are to be procured externally.

Category	Modality description	Category	Use cases
Natural language processing	Analyses human language with machine learning and deep learning models which enable computers to 'understand' meaning	Classical AI	Classify, Optimise, Predict
Predictive AI	Uses statistical algorithms to analyse data and make predictions about future events	Generative AI	Summarise, Assist, Create
Generative AI	Generates a range of medica using probabilistic algorithms on large language models		

Figure 1:

Left: Definitions from 'Harnessing AI to create economic and patient value' (McLoughlin, Croft, Black, Lucid Consulting 2023)

Right: Summary of use cases presented at MAPS (Medical Affairs Professional Society, Madrid, May 2024)

Continuing the theme of aligning to corporate strategy, there are often benefits for Medical Affairs to partner early with functions that have made most progress, and build from their experiences in areas such as customer engagement and data analytics.

However, investments in AI and digital are driven by an expectation of driving business improvement. It is therefore important for

Medical Affairs organisations to articulate a holistic vision of digitisation where processes and sourcing models are also reconsidered to ensure that resources are allocated as effectively as possible. It is equally important that these improvements demonstrably enhance the core company processes of drug development and commercialisation. All assessments of value must ultimately connect to the company's mission to get the right medicine to the right patients faster.



Many Medical Affairs organisations are exploring AI and focusing on digitisation of certain process steps, but progress beyond pilot initiatives appears to be slow.

Many Medical Affairs organisations have started to apply technology to areas such as content creation, chatbots, MLR, insight management, and external engagement analytics. However, in many organisations initiatives largely remain in pilot stages and have not yet been fully integrated into processes or scaled effectively. 2024 seems to be a key test period for many pilots in several organisations.

A compounding issue is that pilot initiatives often tend to focus on areas that have arisen opportunistically, often prompted by technology vendors.

This can create a fragmented environment where budgets are allocated ineffectively and with limited oversight. It also often means that there may not be the necessary capability within the organisation to expand a pilot or to evolve the digitisation of the end-to-end process. Benefits can therefore often be hard to demonstrate, leading to frustration with a perceived lack of progress. 'Omnichannel engagement' is an example where investments

were made but the majority of Medical Affairs organisations are still focusing on realising synergies between field medical engagement and website portals, for example. Similarly, many have invested in AI to 'improve insights' but the overarching insights process (including multiple sources and channels) and link to strategy is not always obvious. This results in challenges in demonstrating better quality insights, or whether investments have led to new insights that truly inform strategic decision making.

Barriers to progress that are often cited include compliance and data governance concerns, whether generative AI outputs will become sufficiently accurate to be helpful in drafting detailed documents on novel scientific and technical topics with limited training data, and how much the "human in the loop" can be removed from review and output development. However, we also see different types of challenges in how these technologies are scaled seamlessly and effectively, and how process improvement and use of vendors evolves accordingly, what capabilities will be required internally, and how associated quality management systems (QMS) and governance frameworks must evolve with the emerging ways of working.

It is essential to work from a digital strategy that is grounded in process improvement with a focus on scalability to improve productivity and/or quality.

A digital strategy for Medical Affairs will depend on the individual organisation, but a structured approach with go / no-go decisions is a must. Initial questions could include:

- What are the end-to-end core Medical Affairs processes, and where and how could digitisation improve these processes?
- What Medical Affairs digital initiatives are currently ongoing within countries, and could potentially be co-ordinated and leveraged at the global level?
- What technologies are proven within the company and could be extended or adapted to digitise selected Medical Affairs processes?
- What is the maturity and accessibility of external supplier capabilities in these areas?
- What technology and capability must be built in-house to be successful, and to be able to select and leverage the best of what is available externally?



On any strategic initiative, and particularly where significant investments are being made, progress must be assessed – not only on execution of the plan but also progress towards the desired state and vision. The measurement of impact of digitisation can be subjective and challenging. A maturity model which recognises the key dimensions of success and provides objective descriptors of levels of maturity on each

dimension allows alignment on a baseline and the ability to track progress. Organisations will determine the key areas of focus based on the baseline, the organisational objectives, portfolio, geographic focus and availability of proven use cases internally. Such a model is therefore useful not only as a measurement tool, but also as a communication and management tool.

	Basic	Intermediate	Leading
Insight management	<ul style="list-style-type: none"> • CRM in place to collect insights from HCP interactions. CRM not integrated with other tools, and there may be more than one CRM in use globally • Simple document-based process for analysis and reporting of insights – limited or no automation or AI involved • Excessive reliance on a single channel for insights – typically MSLs – with limited integration of insights from different sources 	<ul style="list-style-type: none"> • One CRM in use globally, linked to insights process and tool(s) • Actively piloting digital tool(s) to assist insights analysis and reporting • Some integration of insights from different sources, e.g. MSL notes and Medical Info inquiries into one data pool 	<ul style="list-style-type: none"> • Digitally-enabled integration of insights from multiple sources • AI-based insights analysis and report generation in support of company-wide insights process • AI-assisted tools for data input, curation and quality control in place or under exploration • Exploratory use of AI-assisted decision making, such as engagement topic and approach recommendations

Figure 2: Sample section from a maturity model on digital and AI in Medical Affairs

Medical Operations groups have a critical role to play in co-ordinating and driving change enabled by digitisation.

Central operational governance and management are vital to ensure any proposed pilots are aligned with strategy, scalable, co-ordinated across therapy areas and geographies, and not duplicative. Fit-for-purpose governance does not stifle innovation and experimentation but ensures that knowledge and capabilities are built in a cumulative manner across the organisation. It is also vital to ensure that the required specialist capabilities are in place, including the ability to evaluate the external landscape to maintain an optimal sourcing strategy. There is a huge array of AI-enabled vendors on the market promising

access to cutting edge innovation. However, unproven marketing promises alongside the need for client companies to provide access to large volumes of proprietary data and sign up to service subscription models have made this proposition unappealing to several companies who ultimately opted to build the capabilities internally. Medical Operations should also take ownership for ensuring a consistent approach to benefits realisation is in place for go / no-go decisions, and to enable Medical Affairs to credibly demonstrate value within the function and across the company.



A more holistic and effective digitisation strategy for a Medical Affairs organisation.

To successfully implement digital and AI-enabled change, we recommend that Medical Affairs organisations:

1. Understand the broader corporate context, including progress and sources of innovation in partner functions
2. Clarify and communicate digital objectives and priorities, with a focus on process improvements that can make the most global impact in delivering greater productivity and/or quality
3. Define what internal capabilities are required in terms of technology and in terms of ability to navigate the vendor landscape
4. Understand potential barriers and resistance to digital transformation

5. Ensure appropriate investment in managing operating enablers and barriers, in addition to technologies and associated vendors
6. Articulate what success looks like, and track progress from a baseline on a maturity model framework.

In order to achieve the full potential of digitisation and AI, companies must invest not only in digital technologies, but also in the governance and change management that will ensure effective uptake and new ways of working.

Lucid Consulting continues to work extensively with Medical Affairs organisations to assist them in developing their digital strategies.

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About Lucid Consulting

Lucid Consulting is the consulting division in Lucid Group focused solely on the life sciences industry. We bring a combination of deep health & life sciences expertise with the capabilities, discipline and resources of a leading management consulting firm. Our consulting teams have worked extensively in R&D and Medical Affairs. We continue to focus on emerging trends, needs and best practices across the industry.

