pharmaphorum deepdive

SCALING THE DTx SUMMIT

Plus, key insights and innovations from Frontiers Health 2023

November 2023: Digital Health

Unlocking key opinion leaders in the digital landscape

How new technologies help keep brand planning simple

Precision in practice: GenAI in clinical trials

Deep Dive: Digital Health 2023

Dear reader,

As we reflect on the year gone by, it's hard to overlook the remarkable strides and paradigm shifts seen in the dynamic field of digital health. The rapid influx and evolution of tools, systems, and services have certainly kept us all on our toes as we seek to separate the benefits from the buzzwords, and focus on the innovations that will bring meaningful value to patients.

It's safe to say that AI has dominated headlines over the past 12 months. So, it is only fitting that, for our final issue of the year, Deep Dive has called upon experts from across the industry to discuss how the technology is helping to shape the future of pharma.

We begin with the 2023 edition of the Frontiers Health conference in Rome, Italy, where the Deep Dive team caught up with industry experts and healthcare stakeholders to learn more about the trends and challenges being seen in the space, plus our own Nicole Raleigh runs us through the key talking points from the inaugural Digital Medicine & DTx Global Policy Summit.

Meanwhile, AXON's Silvia De Carvalho details how generative AI is ushering in a new era of expedited, data-driven clinical research, experts from Research Partnership discuss how artificial intelligence could impact future decision-making, and guest contributor Fairtility explores the transformative potential of AI in the fertility space.

Of course, AI is not the only hot topic in digital health at the moment. Elsewhere in this issue, Lumanity experts discuss how to unlock key opinion leaders in the digital landscape, M3's Maxim Polyakov talks us through the need to evolve HCP communications, Viseven explores how to use content experience platforms in 2024, and managing director of PurpleLeaf Strategy, Daniel Kohlstaedt, details the value of simplicity in brand planning.

Finally, I extend my heartfelt gratitude for your continued readership. Your engagement fuels our commitment to delivering thought-provoking content that mirrors the pulse of healthcare evolution.

Until next year,

Eloise

Eloise McLennan – editor, Deep Dive

Next issue:
R&D 2024
Plus:

- How drugmakers are tackling climate challenges

Catch up on recent issues:

Patients & Partnerships – October 2023

Communications & Commercialisation – September 2023

Oncology – June 2023

Market Access – April 2023

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TOP 5 TAKEAWAYS FROM FRONTIERS HEALTH 2023

On 8th November, Healthware Group and EVERSANA invited some of the biggest names in health innovation to the heart of Rome, Italy, for Frontiers Health 2023.

The event was an opportunity for experts, investors, patients, and other stakeholders from across the industry to come together and explore ongoing challenges, strategic trends, and scalable solutions likely to impact healthcare.

In an upcoming booklet, pharmaphorum and Healthware explore 20 of the biggest trends and learnings from this year's event. Below is a sneak peek at five of these key takeaways.

Self-care is healthcare

Patients are increasingly looking to manage their own healthcare using evidence-based interventions and tools. Lucas Scherdel, global vice president of external innovation and partnering for Bayer Consumer Health, illustrated this growing appetite for healthcare information and highlighted that Google receives approximately 200 billion health-related searches each year.

"Self-care is not just about bubble baths and looking after yourself. It is one of the biggest socio-economic opportunities that we have in this century and one of the greatest opportunities to impact patients in their care continuum and change the way that we approach healthcare innovation in the 21st century," he said.

Self-care offers a significant opportunity for digital health, as it is an affordable way to improve people's lives. Integrating digital therapeutics with wearables and artificial intelligence will help people manage their health more easily. Moreover, partnerships between companies and governments will encourage people to adopt healthier lifestyles by addressing cultural barriers that keep people from making positive changes.

The rise and fall of AI in drug development

AI has long been a key talking point in healthcare, but in 2023, generative AI (GenAI) is taking over the spotlight, becoming an integral part of healthcare. With GenAI, clinicians can streamline arduous tasks and improve patient care with data-driven insights into dose optimisation and treatment selections.

"AI is changing in a very big way," explained Alex Zhavoronkov, Insilico Medicine. "But, while there is much hype surrounding GenAI and AI in consumer applications in AI-powered drug discovery, we are currently living through a winter of doom and gloom."

According to Zhavoronkov, the decline in AI drug discovery is partly due to the fact that no AI-discovered and AI-designed drug has completed phase II for a broad disease since ImageNet 2014.

Many big pharmaceutical companies still do not believe in AI software's power to create new therapeutics. With GenAI, however, drug developers can identify patterns in data in a matter of moments to accelerate the application of precision healthcare. But GenAI's success in drug development and patient care won't come from technology alone. We need quality data, effective change management within organisations, educated and upskilled workforces, and powerful tech to realise its true potential in healthcare.

Precision medicine + AI = personalised healthcare

During his keynote address on the topic of AI Enhanced Care Pathways, EVERSANA CMO Dr Pierantonio Russo illustrated how the way we evaluate risk has come a long way since the days of Babylon.

"Today, the large volume of data, powerful computers, and mathematical models converge to support the production of predictions through various forms of AI," he said. "Indeed, most of the applications in medicine use machine learning in various forms to support personalised medicine. The right treatment, for the right patient, at the right time, by the right doctor."

He explained that achieving the ambitious goal of delivering precision medicine through traditional care delivery systems had been difficult, but there was increasing evidence that machine learning techniques and artificial intelligence-assisted pathways would get us to the point of value care.

Elevating the patient experience

While it may seem like an obvious statement, improving the healthcare journey for patients is a fundamental task. Closed Loop Medicine's CEO and co-founder, Hakim Yadi, clearly demonstrated how digital tools can help address patient challenges head-on during his presentation on how a data-driven approach to dose optimisation can improve the effectiveness of treatments.

Historically, we have prescribed medications for their average effects in a population, rather than how they perform for each individual in daily life, he explained. Evaluating the accurate dose using this non-existent average individual (largely based on research in white males) means that women are often overdosed, and people over a certain weight are receiving an insufficient dose for their individual needs.

Consequently, there is a huge opportunity to use digital tools to fine-tune and understand the balance between efficacy and side effects for therapeutics and patients.

"Treatments should be data-driven," says Yadi. "We live in a world where we can collect high fidelity information from biomarkers, wearables, and patient-reported outcome measures that matter to patients, rather than ones we define ourselves. So why can't we bring these two ideas together?"

Investing in this area can improve adherence and engagement, but it takes effort. Ultimately, though, solutions that don't bring with them a strong patient experience are doomed to fail in execution, no matter how well they might work on paper.

A grand new world tour of healthcare

The days when healthcare only took place in traditional medical locations are long gone, said Jessica DeMassa of WTF Health during a talk on The Hot New Spaces of Health in the US: Big Retail, Virtual Pharmacies, & The American Stomach.

"These new spaces of healthcare in the US are really coming from the confluence of three trends [consumerisation, digitisation, and economisation] that started before the pandemic and really found a tailwind during the pandemic. Now, especially in the US, we are enabled by technology and consumer choice, and that environment is creating new spaces of health."

With the entry of big names in the consumer pharmacy world, such as Walgreens and CVS, into primary care and the agile subscription model and virtual pharmacies offered by Amazon transforming patient experiences, DaMassa said there is a clear shift in how and where healthcare is delivered. Importantly, she explained that consumers now expect healthcare to be easily accessible wherever they are in the country – both in and out of the home.

For more insights and trends from the floor of Frontiers Health 2023, keep your eyes peeled for the upcoming booklet, 'Frontiers Health 2023: key takeaways for health innovation'.

About the author

Eloise McLennan is the editor for pharmaphorum's Deep Dive magazine. She has been a journalist and editor in the healthcare field for more than five years and has worked at several leading publications in the UK.

FH23: Inside the first Digital Medicine & DTx Global Policy Summit

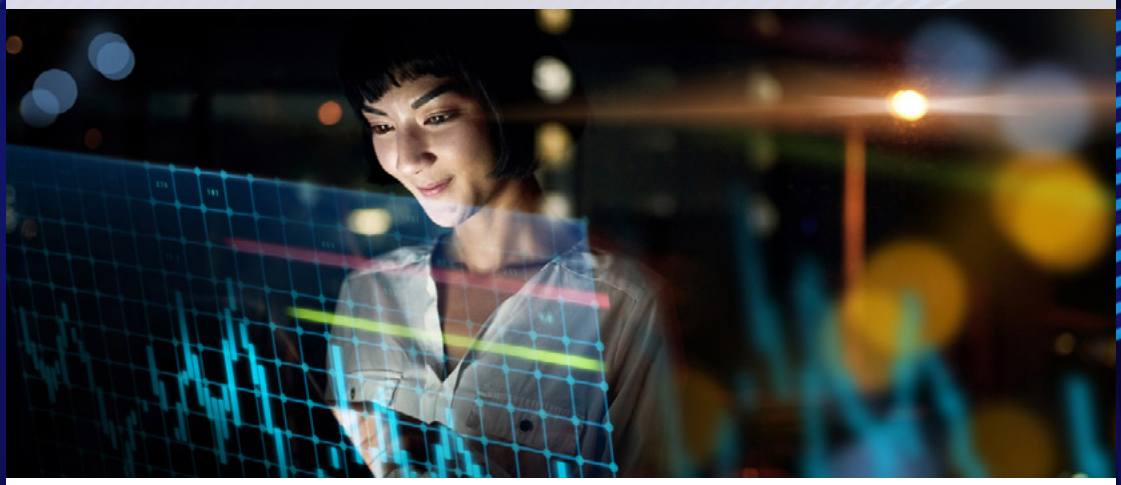
In early November, the inaugural Digital Medicine & DTx Global Policy Summit, part of Frontiers Health 2023, brought together experts, policymakers, and industry leaders from Europe, the US, and APAC to discuss best practices in cross-country scaling, harmonisation, and mutual recognition in appraisal criteria, access, and reimbursement processes, as well as strategies for systemic integration, adoption, and value generation.

In his opening address, Roberto Ascione, Healthware Group CEO, highlighted the importance of policy innovation to support developments in the DTx space. From technology and process he held high hopes for productive outcomes from the discussions of the Summit – a collaborative effort by Healthware Group, Digital Therapeutics Alliance (DTA), and other organisations – which he dubbed an "ecosystem and community effort".

Global challenges: Seeking harmonisation

Alberta Spreafico – global head of digital health & innovation strategy, senior director of the global management team, and managing director of digital health & innovation at Healthware Group – welcomed to the stage Professor Dr Jochen Klucken, FNR PEARL chair of digital medicine at the University of Luxembourg, and Rosanna Tarricone, chair of the advisory group for the European Taskforce for Harmonised Evaluation of Digital Medical Devices in the EU, and associate SDA dean for the government and health division at SDA Bocconi. Klucken and Tarricone have been working together on analysing the ecosystem and the different policy frameworks across Europe, looking at supporting harmonisation. They are the chairs of the taskforce.

The Summit spanned three macro-sessions: the first focused on Europe, sharing the evolving scenario and trends possible for harmonisation; the second, was focused on APAC; and third, focus shifted to the US. By sharing the different evolving scenarios, best practices, and opportunities it was hoped that attendees and speakers would be able to connect the dots needed to achieve harmonisation across countries.



The issue of reimbursement

Looking at the EU frameworks, then: they ensure the device is safe, is protective, and they enable the technologies, but none are linking to reimbursement, noted Prof Klucken. Germany's DiGA makes the accelerator, the incubator, and the investor all worth it, due to evidence proving the benefit for the patient, which is an interesting aspect introduced to the German model. But what must be remembered, he said, is that these are low-risk devices: they are the game-changers in the healthcare system. Countries are setting out their own frameworks, and they use different functional components and not each country is supporting each of those. Therefore, the European Taskforce for Harmonised Evaluation of Digital Medical Devices (DMDs) was set up in 2022 and inclusion and exclusion criteria are assessed under this.

"We're not talking about one single mechanism of action, swallowing a pill and letting it work," Prof Klucken clarified, "but a lot of different levels of user interaction are needed, and different levels of research and evaluation. Perhaps it will be done next year?"

Overcoming disparities between geographies

In Europe, particularly, a framework is emerging (e.g., Germany, France, England, and Belgium, with Italy close behind). Discussing the evolution of access and reimbursement models currently being undertaken in these countries, Spreafico noted, has led to an assessment framework adapting to fit for purpose criteria; there has been a convergence on building fast tracks and managed access agreements – the condition of generating evidence.

Indeed, "tunnelling down" into fit-for-purpose evaluation and early access pre-requisites, adapting the HTA core model, Spreafico and a colleague examined the different dimensions, the series of standards, and found that countries are asking similar things: a great starting point to avoid fragmented dossiers across geographies.

However, the issue with clinical proof of value is that evidence has to be generated locally. But, as things scale, enhancing the transferability of clinical evidence across Europe can be made possible, Spreafico explained, resulting in usability and access for all.

Currently, there is inequity across countries. In Italy, for example, it's an out-of-pocket scenario: there's no reimbursement framework in place, and digital health technologies are only available for those who can afford it. The risk of adopting the medical device pathway that breaks up across the municipalities is also a real risk in Italy, Spreafico noted. So, how can these issues be overcome? Spreafico suggested a 10-step pathway of scaling:

A 10-STEP pathway

- Scale recognition and common nomenclatures
- Scale fit-for-purpose common HTA criteria
- Scale access and reimbursement with CED-managed entry agreements
- Scale joint clinical evaluations and voluntary cooperation
- Scale mutual recognition agreements, evidence transferability, and RWE
- Scale clinical guidelines and digitally enhanced protocols
- Scale systemic integration and a seamless UX
- Scale multi-stakeholder engagement
- Scale innovation-driven ecosystems
- Scale future-proof system readiness

Germany, France, and Belgium: Three jurisdictions

Germany was the first to link assessment process with reimbursement, declaring that Risk Class 1 and 2a were the major object of the assessment, although incorporation of other types of DMDs are being considered. Other countries, such as Belgium and France, are more interested in the nature of the DMD – so, whether there is a positive effect on patients and/or a positive effect on the delivery of health services.

In the case of Belgium, they recommend a prospective study design, while France's transitory PECAN system doesn't recommend a specific study design, Tarricone noted, but in a perhaps more illuminated way a manufacturer can put forth the most suitable study design for the DMD wanting to submit. The same type of attitude can be seen in the comparator, also. Germany's approach was prescriptive in the beginning, while more recently the later countries to the scene were more open, not prescribing anything specific, but dependent on the manufacturer.

Finally, in terms of financing schemes, another convergence and learning effect is the type of reimbursement system and pricing negotiations. Germany tends to assess, prescribe, and price technology, while other countries are more prone to considering the possibility of incorporating more innovative pricing schemes. Incorporation of the DMD might change the whole patient's clinical pathway, after all, instead of demonstrating an isolated 'plus' in terms of a positive health outcome for the patient, Tarricone advised.

Overall, innovation is welcome, but it must be regulated. There is a longitudinal revolutionary aspect representing a learning effect, in her opinion. From an academic perspective, this can be seen in terms of scope, benefits, and remuneration. Additionally, the measurement of the benefits, what makes the difference between a DMD and a medical device, is the possibility to trigger patient outcomes not seen in the past with conventional medical devices. Talk of patient engagement, autonomy, and self-confidence – these benefits make these devices work more effectively than the comparator, Tarricone said.

But how can the triggers be measured? If these are missed, the whole story is missed. So, a dual approach is necessary. In some jurisdictions, there's the approach of a multidimensional, deliverative approach.

In short, Tarricone believes the route to harmonisation is already here. There is certainly the momentum to do so. Those countries who have already begun can help other countries to catch up and not make the same mistakes. Yet, there is a strong momentum to include also other stakeholder perspectives, and this is what the Taskforce does with its external advisory board for DMDs. The Summit was a sign of positive momentum for one of Tarricone's dreams: the dream for these types of technologies, and medical devices, to no longer have a division between pre- and post-market.

The European situation

A panel and presentations with Alberta Spreafico, Marco Marchetti, Dr Wolfgang Lauer, Lily Tang, and Vincent Vercamer followed.

Dr Wolfgang Lauer commented that in past years there had been tremendous increase in approaches to DMDs and into national healthcare systems and reimbursement and business models. The main point, he said, is sitting together, talking challenges and experiences and standardisation where possible, but importantly exchanging ideas for a European initiative.

Vercamer thinks harmonisation requires broad movement and lots of differences done separately, but that they can move forwards together step by step, collaboratively, creating a common market for the solution and resulting in the best outcomes for patients. Spreafico responded that clinical evidence transferability is what will make a difference, here.

Tang, meanwhile, mentioned reimbursement, commissioning, and funding – but that what is missing is greater health economic assessment that keeps pace with the evolution of the digital health technology market. There has to be value-adding for investment there for parity: when a patient swallows a pill or uses an Apple watch, there isn't yet enough work done on health economics to help purchasers. So, digital health technology must be supported to be more agnostic of the means to the end for the same outcomes. Secondly, upstreaming and articulating the demand on the ground, a supplier and developer push onto markets, rather than pull, must be undertaken. This will result in adoption and access. Behavioural economics is important in this to support the awareness and empowerment of patients, too.

Marchetti noted the common interest in building something that could be very fast and effective. If it's based on the availability of the clinical evidence, it is something that will be useful to transfer between different countries. "We are in a very enthusiastic season of the process, but there is much to be done in the next year," he said.

Tarricone and Klucken also added final thoughts on the European situation, Tarricone commenting that harmonisation is dependent on jurisdictions and other stakeholders to work closely with the European Commission, with the EU, to make the harmonisation process within the MDR and NDHR. Otherwise, she said, there is risk of harmonising a third pole – which is not needed. It took 15 years with EUNECTA to get NDHR, she noted – a true harmonisation of assessment process – and what is not needed is another 15-year wait.

The APAC perspective

Anh Bourcet – founder of Health Access Solutions (HAS4P), strategic advisor at the Asia Pacific Medical Technology Association (APACMed), and VP of healthcare & Middle East Africa at Stratence Partners – and Roberta Sarno – director of APAC Liver Disease Alliance, advisor to APACMed, and founder of and global health advisor for D-Health Consulting – were joined virtually by Dr Chaemin Shin and Dr Izzuna Mudla Mohamed Ghazali to discuss the current landscape in the APAC region.

In APAC, there is a lack of a specific fit-for-purpose framework to assess value, and coverage is fragmented across countries and solutions. Evidence generation requirements are also unclear. In fact, in most APAC countries, reimbursement is very new, and the patient voice needs to be better incorporated into the policy development framework. Such countries as Japan, Australia, and Singapore lack this framework, so, technologies are funded through a mix of private, public, and out of pocket mechanisms. This is the environment in which APACMed is trying to create a new space.

Dr Shin presented the innovative health technology policy in Korea. In March 2023, the Korean Government officially announced private investment and tax support to foster biohealth and increased government R&D in this area. HTA assessment (nHTA) has been continuously improved as well, Dr Shin said, deciding upon reimbursement and non-reimbursement items. Looking for simultaneous decision through improvements of processes, value-based assessment for innovative technologies, is a new pathway for these to enter the clinical field. This will take 120 days, and after approval, side effects must be reported and evidence accumulated for a period of three years. In 2023, integrated assessment for AI and DTx began.

In comparison with DiGA, Korea's framework allows three years of use, after which there is reassessment of safety and effectiveness. Patient consent will be mandatory.

APAC in comparison with the US

Dr Ghazali provided the Malaysian perspective. With a multimedia 'super corridor' introduced in 1996, there was a digitalisation national policy of science, technology, and innovation, and a national integrated offsetting roadmap – yet, there were hiccups along the way, she said. The first paperless hospital was introduced in 2000, and a Malaysian health data warehouse in 2017. It is a matter of health and digital literacy though. Therefore, in 2021, the government introduced a national digital economy and 4IR policy/council.

Internet within even rural areas is, of course, crucial. The prioritisation of this has been clear: empower, integrate, and include sustainable and secure digital services. Again, as in other countries, evidence gathering and demonstration have been a challenge – and evidence is important for commercialisation and adoption.

Compared with the US, Bourcet stated that Asia Pacific is still behind because it consists of 60+ countries with very diverse health systems and reimbursement and funding pathways. The Philippines, for example, only started talking about universal healthcare in 2010. In terms of prioritisation and budget allocation, it is quite disparate. In terms of reimbursement, it can be categorised in three ways: fully reimbursed (Japan, Taiwan, Korea, and Australia); then, high out-of-pocket like the Philippines, with limited coverage, and restricted coverage as seen in Singapore; in the middle is the mixed market – China, with a culture of high out-of-pocket, yet, there is reimbursement. In terms of infrastructure and value recognition of digital technologies, APAC is still in its infancy.

Nonetheless, Bourcet said, there are opportunities, despite challenges. It is an attractive region to consider, due in part to the unmet need, ameliorating standard of and access to care. Encouraging policies and building ecosystems to accelerate the implementation is crucial, though. Up to 2019, telemedicine was a taboo topic in Korea, however – there is, in other words, hope enough yet.

The test case of the United States

Andy Molnar, CEO of the DTA, and Marty Culjat, SVP global head of digital medicine & regulatory innovation at EVERSANA, provided the US example. To begin with, there was a recorded interview between Molnar and Aubrey Shick, senior digital advisor for the FDA at CDRH's Digital Health Center of Excellence.

Centring the conversation around regulatory challenges, Shick said one such issue is terminology – many want to know if their software product is a medical device, but the terminology doesn't necessarily align. This impacts guidance and supporting materials for submission, she said. A great first step, therefore, is the Digital Health Policy Navigator, which helps with the understanding of a device. There's also a digital health FAQs page, to know the unknowns; then, there's the Q-submission and pre-submissions, she said.

The FDA takes a risk-based approach in general. Hip implants and pacemakers go through pre-market approval, and there is comprehensive review of safety and effectiveness. Two main ways to do this include, firstly, the first-of-its-kind product de novo pathway, or with a predicate the 5-10K pathway, talked about the most with traditional non-specifically digital health devices, for which there are the same mechanisms. Since 2017, on digital health and DTx products, Shick said the FDA has recognised at least six new categories of device software functions.

An international conference, Molnar asked about cooperations with other countries regarding assessment and Shick replied that collaborations with other countries are a priority and commitment, aligning to the questions asked and information sought, with many ongoing work groups operating in these topics. Additionally, Shick noted that understanding of the use of AI and ML is increasing within the remit of lifecycle considerations and pre-market condition recommendations.

Meanwhile, Culjat said that the FDA has been innovating in digital health for the past decade, adapting to rapidly changing times, and with new guidance documents in 2023 on handling change control and much activity around pharma's working with digital tools. The number one challenge is trying to understand the kind of clinical evidence needed to go to the FDA, he said, and it is the same for DTx, the same for digital diagnostics – it's not more, but what kind.

It is hard to have one guidance document to provide all the answers, and then there remain many questions about prognostics and diagnostics, what kind of pathway to choose, etc. There are challenges with change control plans that are more AI-focused, too. DTx are relatively simple from a tech standpoint, but Culjat's take on all this is the defining of evidence requirements, and the importance of real-world data for supporting submissions. There are some suggestions for expanding label from real-world evidence, but not for approval.

There's been a lot of interest from pharma for the companion app framework, he continued, essentially creating an option for including software on the drug label, instead of it being considered a combination product and Culjat mentioned that the DTA does an amazing job, the

outlines of which are on their website, and for different markets at that. Indeed, he was buoyed by the efforts for harmonisation across Europe. On data portability, in general, the FDA likes to see data with demographics that match the US population, but more clarity is needed there, he said.

Molnar added that regulatory is step one, whereas reimbursement is fragmented in the US. Trying to change policy on a state level is a challenge because – for myriad reasons – it just isn't streamlined.

In conclusion

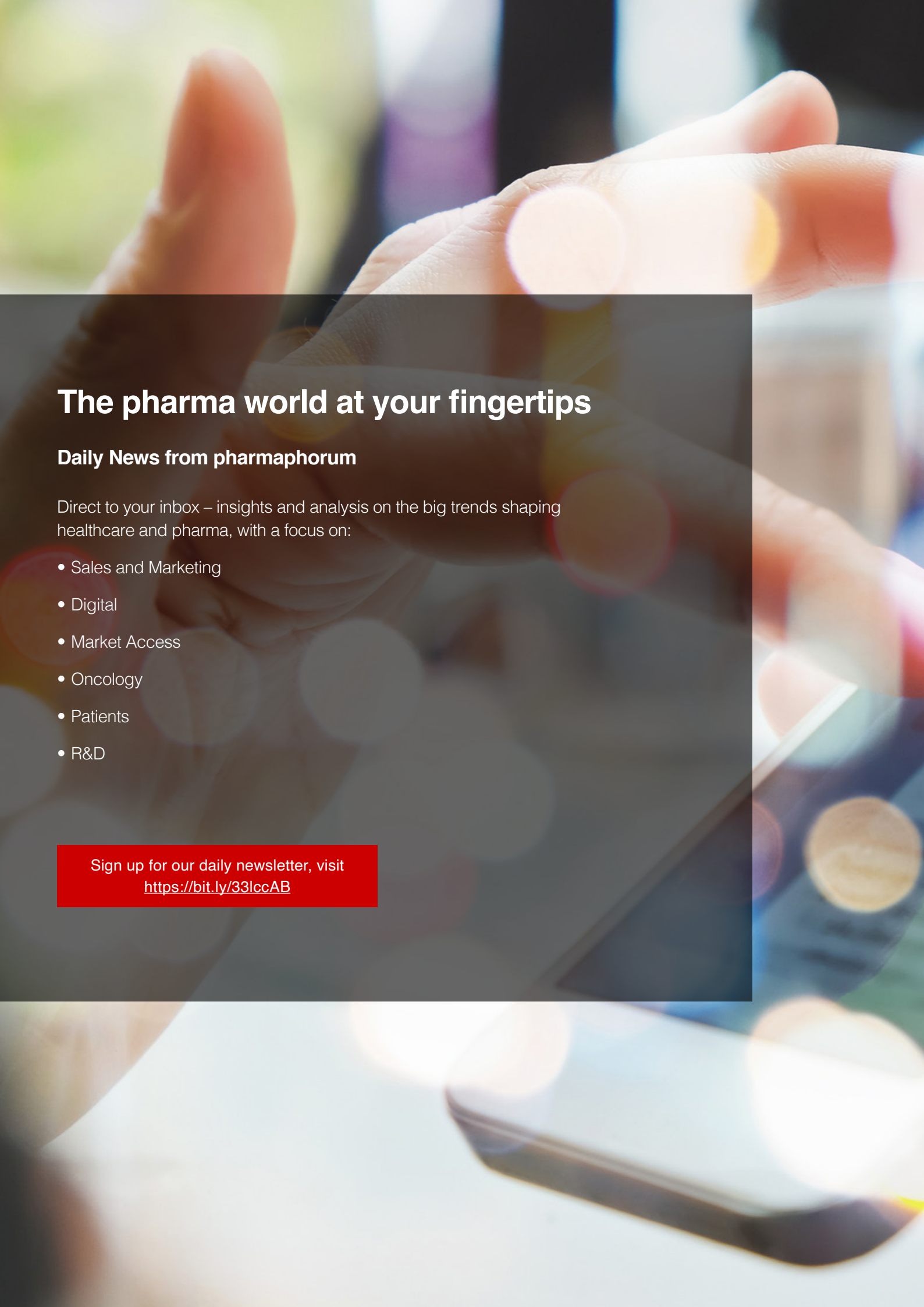
Spreafico closed the Summit, saying that it had been the first time all these high-level institutions had come together to share country-level insights on how the scenario is unfolding and evolving, but doing so collaboratively. This is just the start of the journey, though, and one that must continue to be built together.

The Summit will return for Frontiers Health 2024.

About the author

Nicole Raleigh, Web Editor

Nicole Raleigh is pharmaphorum's web editor. Transitioning to the healthcare sector in the last few years, she is an experienced media and communications professional who has worked in print and digital for over 18 years.



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AXON CLINICAL STUDIES

Precision in practice: GenAI in clinical trials

In the dynamic world of the healthcare industry, clinical research stands at the forefront of innovation, using emerging techniques and technologies to bring generation after generation of new therapies to patients around the world.

With the buzz around generative AI (GenAI) growing at a rate of knots, it is no surprise that one of the most promising areas for the technology is in clinical trials. GenAI's prowess in data analysis, its ability to transform arduous tasks into actionable assets in a matter of mere seconds, has the potential to empower navigating information with unprecedented speed, ushering in a new era of expedited, data-driven clinical research.

"The clinical trial space is, as we all know, an area where we have a lot of repetitive and very time-consuming tasks," explains Silvia De Carvalho, clinical studies lead at AXON. "GenAI is really a tool that enables an acceleration in some of these tasks, where before it would be a very manual prolonged process for both sponsors and sites."

With nearly 20 years of experience in digital communication and engagement, De Carvalho understands the multifaceted influence generative AI presents, as well as the challenges that remain with fully realising this potential. Here, she discusses the use of GenAI in clinical trials, from data analysis to patient engagement.

Navigating the uncharted waters of GenAI in clinical research

While the concept has been in development for more than a decade, the potency of GenAI has surged in recent years, with ChatGPT being perhaps the most prominent example in the public space.

In the realm of clinical development, De Carvalho explains that a primary and most immediate advantage of GenAI lies in its ability to swiftly process and summarise extensive structured and unstructured datasets, offering insights and learnings from various data sources, such as protocols within a therapeutic area. This, she says, has enormous potential in reducing the time and resources required to complete certain tasks.

"The power of GenAI has really exploded, and that's why we now have the challenge of fully grasping its potential. One of the most immediate benefits is its ability to extract from content and summarise information, based on simple queries," says De Carvalho. "Now, we have the capability not just to look at and understand text, but also imagery. It's getting more sophisticated in its capacity to learn and create from that knowledge. Certainly, in the clinical development space, there are a lot of areas where that can be a beneficial tool in conjunction with specialists and analysts who can look at the data."

To illustrate how GenAI can support decision-making, De Carvalho describes the process of protocol design. Rather than dedicate hours of precious time to scrutinising each protocol that touches the same therapeutic area, she explains that GenAI can perform the same task, quickly extracting and summarising the relevant information.

"The clinical operation lead can then look at this information and say, 'Okay, these are the learnings', whereas it would take hours for someone to go through all that data," she says. "In terms of summarising existing data sets, it's extremely powerful. The main concern that is still present is potential hallucinations (responses generated that contain false or misleading information presented as fact), which is why the process still requires human analysis and supervision to avoid creating insights from incorrect data."

De Carvalho continues: "Another good example of its potential is its capacity to fill in for missing data, allowing researchers to work with more complete and reliable information for downstream analysis and modelling. Knowing how challenging it is for programs to gain complete data, this has the potential to really impact approval processes."

Improving recruitment and retention

Successful recruitment and retention of trial participants are the two most challenging aspects of clinical research today. Whereas traditional – manual – approaches to identifying and enrolling candidates prove lengthy and inefficient, with the aid of GenAI, healthcare professionals can analyse large volumes of patient data to rapidly pinpoint eligible patients.

"Recruitment is so difficult and competitive," says De Carvalho. "It's not just finding the right patient, it's finding the right patient ahead of the next trial, or another trial trying to recruit the same population. Being able to do that very quickly and efficiently is going to be critical in driving the speed that everyone is trying to achieve, while ensuring the right patient population is included. The other challenge is retention, because you might have initially recruited patients, but then you lose that population through the funnel."

Many sponsors have been looking at new ways to communicate with potential patients, and help sites recruit. De Carvalho highlights two pioneers in the space: Pfizer and Novartis. Pfizer is using generative AI to personalise recruitment messages to potential patients and has created a chatbot that generates personalised messages that are tailored to the specific needs of that patient and can answer questions about the clinical trial.

Novartis is also creating personalised recruitment materials for a clinical trial for a new drug for psoriasis. The results of the campaign showed a 20% increase in the number of patients who responded to the recruitment campaign.

However, she notes, it is important that healthcare professionals remain closely involved with the identification process to prevent unintended biases from excluding demographics. Biases can be reinforced when the model learns from data sources that do not fully represent all communities. This is especially true for communities that rely on oral traditions or non-digital means of communication.

"It's not perfect, she says. "GenAI should, by its nature, enable us to identify patients that we might not have recognised or identified at site level because now we're looking at billions of parameters at the same time versus a couple. But, at the same time, you need that human check to make sure that we're purposeful in the populations we're including."

Beyond initial recruitment, De Carvalho explains that GenAI can play an important role in improving retention rates.

Proactive communication, a hallmark of GenAI, will be instrumental in mitigating challenges and expediting the trials' progression. As the industry transitions towards decentralised and hybrid trials, GenAI allows for increased touch points with participants who may not physically visit the trial sites, bolstering engagement and providing an opportunity to acquire data that can be used to accelerate the road to approvals, for example, through synthetic control arms.

"As patients are increasingly monitored at home, for instance with wearables, data points are being measured outside of sites and that data can be quickly seen and processed through the AI, enabling faster insights and optimisation," she says.

Clinical trials can span months, and keeping individuals engaged requires time and resources to deliver effectively. However, today's GenAI is sophisticated enough to help streamline and personalise communications efforts.

"Now, we're able to produce initial communication that is personalised and engaging people early on," explains De Carvalho. "That should also accelerate our ability to recruit certain populations that might not have been accessible based on just looking at all the electronic health record (EHR) data at the sites, identifying the patients, and then pushing communication to those patients."

She continues: "If I can tell you every week or every month how you are doing, and guide you through the process, chances of accelerating the outcomes of the trial and chances of getting all the patients to stay from a retention point of view are also increased. Most sites are understaffed and struggling to effectively coordinate all that information at speed. GenAI can substantially decrease site burden as it takes over simple things, such as appointment scheduling, reminders, or even integrated notes across stakeholders to provide only relevant information to the patients."

Addressing limitations and misconceptions

Integrating GenAI into clinical trials presents a promising frontier, yet, as De Carvalho is clear to note, it is not without its share of challenges and barriers. Of paramount concern is the need to address compliance and privacy issues associated with the integration of these tools into healthcare practices.

"That is probably still the number one challenge," she says. "As we are identifying use cases for the technology, everybody's trying to think, 'What are the boundaries?'. If we're asking the tool to look at EHR data and patient personal data, and we're training the tool based on that information, is that compliant? Where is the line? Where is the data privacy bridge?"

The level of disclosure and consent required for patients participating in clinical trials, who may be unaware of AI leveraging their personal data and communicating with them, poses a significant ethical dilemma that demands careful consideration.

"AI is not a substitute for those relationships and those communications, and the transparency of knowing who's communicated to you," she says. "We don't want to create a false sense of it's all automated and de-humanised by leveraging too much AI. You still need to have a limit that requires people to be that check and balance of biases to make sure that you didn't avoid an entire population because of an X-factor, for example."

Of course, any tool – no matter how sophisticated – only performs as well as the person using it. This is particularly true in the instance of GenAI, where the comprehensive prompts and queries are essential to ensuring that the tool provides the intended responses. As such, a fundamental challenge lies in the upskilling and training of staff members to optimise the utilisation of GenAI. As the technology advances, the workforce must evolve alongside it to effectively harness its capabilities.

"For people to feel comfortable with the technology, you need to know how to use the tool. It's going to take time to get to that level of comfort and knowledge for it to be widely used in the same way we're seeing the barriers with digital health solutions. It's not going to be a simple switch for sites and sponsors to leverage the technology for sure."

Clinicians and GenAI: A dynamic duo in clinical research

Currently, the integration of generative AI into clinical trials is creating incredible opportunities that will undoubtedly transform the R&D framework in pharma. Beyond its major impact on new targets and new drug identification, it offers efficient solutions for data management, streamlined patient engagement, and reduced site burden, and has the potential to improve overall trial outcomes. However, it is imperative that we approach this technology with a focus on data privacy, compliance, and inclusive practices to avoid further dividing communities.

"There's a lot of scepticism around AI and GenAI," says De Carvalho. "With all the buzz around it, I think it's good to remind ourselves that it is a very new technology that most people haven't embraced yet, and that it's still representing a huge transformation for the industry. I think we're going to see the cases, and the pros and cons, as people continue to leverage the technology. The FDA, EMA, and China's government have already introduced draft recommendations and we will continue to see the regulators intervene, as we are in a much more regulated, low-risk industry."

As with any new technology, the key to unlocking the potential of GenAI in clinical research is embracing the transformation responsibly. But, while there are, indeed, still a variety of unknowns when it comes to the future of AI in pharma research, for Carvalho, it's an exciting time to be working in the sector.

"It's a fascinating era for us," she concludes. "The speed at which GenAI integration is taking place is incredible. But we are still in the early days of the technology enhancement curve. I certainly expect that, within the next five to ten years, our traditional RCT model will be completely disrupted, and new data-driven models will have taken over in how we get drugs to the road of approval."

About the interviewee

Silvia De Carvalho, a seasoned professional with nearly two decades of experience in healthcare marketing, currently serves as the driving force behind AXON's Clinical Studies Practice. Formerly the senior vice president of activation strategy at Klick Health, she brings a wealth of expertise in digital communication and engagement to her role at AXON.

De Carvalho's career path began at Sanofi, where she collaborated with clinical development teams to optimise protocols and assess product viability in the diabetes landscape. This early experience instilled in her a profound understanding of aligning clinical development with the genuine needs of patients. Now, as a key leader at AXON, De Carvalho is passionately navigating the Clinical Studies Practice through a dynamic phase of accelerated growth and innovation.

About AXON

AXON

AXON is a global healthcare communications agency that ignites change in healthcare. Through the power of life-changing communications, we contribute to medical advances that improve lives. At the core of every scientific innovation and advancement, there is a simple and compelling story to be told. We know how to tell that story, how to use the right tools to reach the right audiences at the right time, to provoke meaningful change.

We specialise in advising clients on medical affairs, clinical studies, real-world evidence, marketing, advocacy, and communications, all underpinned by insights and creative strategy. AXON has an international reach, with offices in Copenhagen, London, New York, and Toronto, and a worldwide affiliate network. Established in 2002, we have a deep heritage and expertise in healthcare strategy and communication, and we continue to learn and grow in the fast-changing healthcare sphere. AXON is proudly an AVENIR GLOBAL company.

Lumanity

Cracking the code: Unlocking key opinion leaders in the digital landscape

With new guidance, treatment pathways, and medical advances emerging on a regular basis, the pursuit of knowledge and innovation is a never-ending process for healthcare providers. For many years, influential figures known as Key Opinion Leaders (KOLs) stood at the forefront of this endeavour, establishing themselves as thought leaders in their field by publishing research findings and articles in peer-reviewed journals, presenting their research at annual medical society conferences, and helping to shape industry perspectives. However, as the digital age continues to redefine how we connect and share information, a new breed of influencers has emerged – Digital Opinion Leaders (DOLs).

Both KOL and DOL cohorts serve a unique role in healthcare communications, but, as we navigate this dynamic landscape, it becomes increasingly evident that a holistic approach – one that seamlessly integrates the expertise of "traditional" KOLs with the digital fluency of DOLs – holds the key to a more comprehensive and insightful understanding of the healthcare landscape.

Here, Lumanity's VP of analytics & business solutions, Craig Burgess, VP of consulting and medical director services, Julie Cahill, and group business director of insight and analytics, Damian Eade, delve into the dynamic interplay between the traditional and digital realms and why fully understanding the value of both options is fundamental to identifying the right mix of opinion leaders needed to maximise reach and communicate your message with credibility, authenticity, and authority.

Navigating the shifting paradigm of digital influence

It used to be that marketeers could look at a list of established expert opinion leaders in their industry and know exactly who they needed to reach out to in order to get the word out about their brand or product. However, the rapid rise of social media sparked a metamorphosis in the communications landscape. With platforms such as Twitter, YouTube, and more recently TikTok, offering users a free tool to disseminate information at the click of a mouse, anyone, anywhere can rapidly become an influencer with a potential audience of millions of followers worldwide.

As such, the process of identifying the right opinion leader and the right channel for specific communications efforts has become much more complicated.

"The nature of influence can mean that it is not something that can only be exclusively held by your traditional KOL, healthcare professional, or scientist," explains Eade. "The increasing democratisation of healthcare means that everyone can have a voice."

Spurred on in no small part by the COVID-19 pandemic, social media has given users an enhanced sense of ownership over the content they engage with as they cultivate their feeds to reflect their interests, both professional and private, by following and interacting with other users who regularly post about these subjects. These channels are often more informal than the more structured and episodic traditional options, such as medical journals or conference presentations, which have been the go-to environments for KOLs.

"Different people gather information from different sources," says Cahill. "Some people go to conferences and listen to who's on the podium or they read the latest publications coming out of the New England Journal of Medicine, where other people will turn to Twitter to get their information."

In response to the growing influence of social media and digital platforms, companies are beginning to adapt their strategies to broaden the reach of communications efforts. It is important to note that the rise of the DOL does not replace the role of the traditional KOL. Instead, Burgess explains, they "operate on parallel tracks", with some KOLs also crossing over into the DOL space, while others may be KOL only or DOL only.

"It's helpful to focus on the names that overlap. Those are experts who are active online and on social media, but they also score on traditional measures of expertise," explains Burgess. "This may be a small group, but it helps to demonstrate there are people who are very knowledgeable who are using social media."

"What's really interesting is that [companies] could be working with these individuals in a traditional domain, let's say, and they have no idea that they're the world's biggest DOL on the topic," adds Eade.

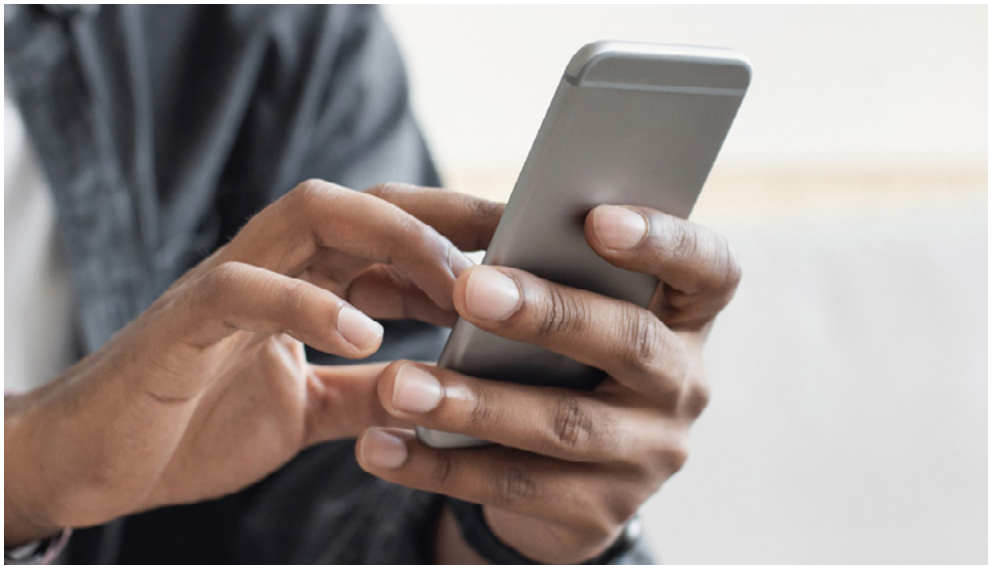
Activating a new generation of opinion leaders

Of course, in a world where anyone can have a platform, it's important to know how to identify who's worth listening to. Whereas traditional KOLs are typically clinicians or researchers with expertise in a given field, DOLs can include people who don't fit into traditional categories, such as patients or bloggers. So how can companies evaluate the right individuals to partner with for each project?

One easy starting point is to evaluate the number of followers and impressions a post receives, metrics that are a staple feature across multiple social media platforms. However, as Cahill notes, while a high number may appear encouraging on the surface, ensuring that the content reaches the right people is equally, if not more, important than numbers alone.

"You're not just looking at the numbers. You're not looking at how much content they're putting out or how many people are following them," she says. "You're looking at who their followers are, who their network is, and what that content looks like.

"If you're looking to target a certain group, you want to make sure that digital person, that thought leader, has that network that reaches that group that you're looking for. Maybe they have fewer followers, but they may be the key people that you want to reach."

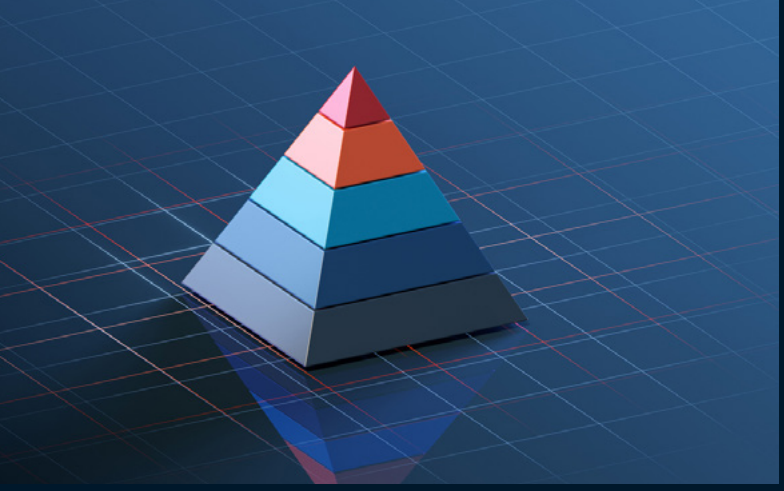


"It's also important to apply a qualitative review because someone who may be the loudest on social media may not be credible or truly influencing the right types of people," adds Burgess. "We saw with COVID, where you had people who tweet about all kinds of things, and they get lots of engagement, but it's not credible.

"On the flip side of the coin, you may have a traditional thought leader who is active on social media, but his activity might not be focused on the scientific area of interest. Someone might be posting about his cats or his football team. It does require a little bit of qualitative review. You'd be mistaken to rely solely on a quantitative approach."

As Eade explains, while there are numerous metrics that can be applied to selecting a DOL or KOL, ultimately, the most crucial piece of the puzzle is intent. Understanding what you are trying to achieve will determine the right metrics to identify the best opinion leader and the best platform for the job.

"This isn't about an off-the-shelf one-and-done metric, because the degree of influence that might be relevant is going to be wholly dependent on what you are trying to achieve."



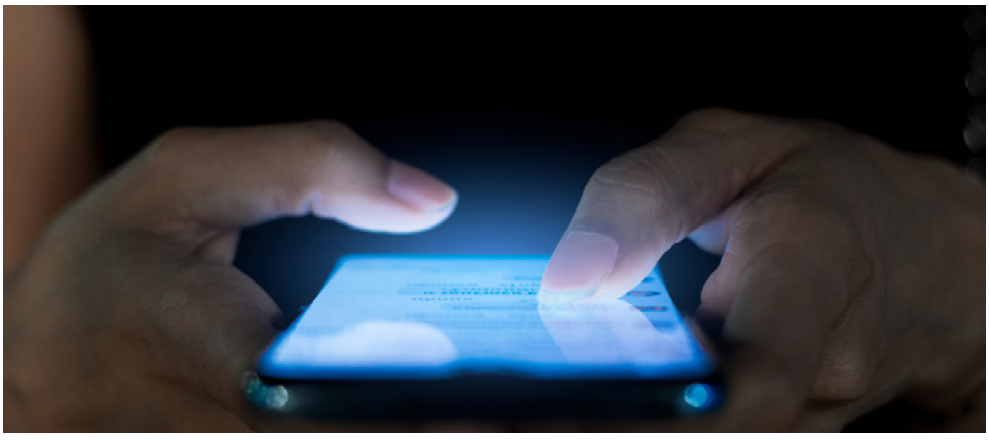
Rebuilding the pyramid of success

Realising the potential impact of activating both DOLs and traditional KOLs to broaden the reach and impact of your message requires a well-thought-out strategy.

As Cahill explains, establishing this is a team effort, with strategy, digital insights, and traditional KOL experience coming together to ensure that the message and delivery align with the intended audience and outcome. By adopting a holistic approach to identifying DOLs and KOLs, companies can expand their reach, not just among healthcare providers, but in the public domain.

Alongside professional DOLs, patients, family members, and disease advocates use social media platforms on a daily basis, meaning that companies have a unique opportunity to reach other relevant audiences, offering information and signposting them to additional content. Communicating with this group requires a different tone, format, and opinion leader than may be used to engage with established healthcare professionals. As such, Cahill notes, it is important to keep the end goal in mind when developing your strategy.

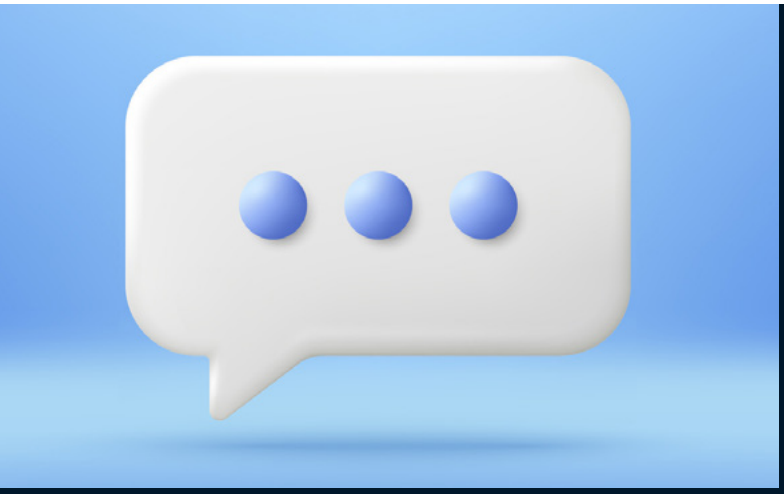
"We spend a lot of time in that beginning stage to make sure that we're approaching the problem correctly," she explains. "When you start looking at the list, we do a gut check and ask, 'Did we use the right search terms?', 'Are we missing people?', 'Are there other things we should be looking at?'. It's not just a one-time thing. It's an important piece to think about through the whole project."



Moreover, Eade adds that developing an initial list of potential DOLs and KOLs for each communication initiative can help ensure that each individual is incorporated appropriately. Here, he explains, is where an integrated approach is beneficial.

"If you've got more people and more tools at your disposal, it means that you can do more," he says. "Expanding into a digital domain where you are going to get that diversity of viewership, range, and wide reach, is something you wouldn't be able to achieve necessarily through traditional KOL channels.

"Then, equally, if you are trying to establish yourself with the greatest credibility in terms of very established processes, you may need to go through a more traditional route to identify those people who could be most relevant. It's not to say that digital or social online influencers are more or less important. It's just saying that, for certain jobs, that is going to really help you do things more effectively."



Final thoughts

From the conference room floor to online community forums, the collaborative efforts of KOLs and DOLs create a powerful narrative that not only influences medical decision-making, but also fosters a more inclusive and dynamic dialogue within the healthcare ecosystem.

Of course, as with any seismic mindset shift, not everyone is completely on board with the transition from traditional KOLs to an integrated hybrid approach to communications. Trust in something new takes time, particularly when it comes to healthcare, but DOLs are continuing to demonstrate the impact they can have in the space and, while there may be regulatory and compliance hurdles to address moving forwards, for Cahill, by resisting the change, companies miss out on an opportunity to be at the centre of important conversations that could shape the next era of healthcare.

"If you ignore the digital space, then people are going to be putting messages out related to your data or your drug that you don't have any potential to influence. So, they're shaping your story without you having any input," she explains.

Influence, Eade clarifies, does not mean control of the narrative, but a chance to pull up a seat at the table and tell your side of the story.

"It's about giving ourselves the maximal opportunity to have an impact and to be able to work with a wider scope of audiences and message," he says. "Why would we not want to have a broad suite of opportunities available in front of us?"

About the authors

Craig Burgess, vice president, analytics, and business solutions, Lumanity

Craig Burgess has over 20 years of agency experience in medical communications and publications. He is currently responsible for implementation of analytic services and business solutions to support medical communication strategy and scientific publication planning. Burgess oversees development and execution of initiatives to integrate analytics as a key component of agency services and client solutions. He partners with colleagues and clients to support better decision making through analytics.

Burgess has developed an industry-leading approach to KOL mapping, including identification, ranking, segmentation, profiling, and engagement planning. Other areas of focus include social media listening, competitive intelligence, publication impact assessments, text analytics, interactive dashboards, and data visualisation. Each analytics service line is designed to transform data to meaningful insights for pharmaceutical clients.

He joined Lumanity in October 2020 and received a BA in psychology from Tufts University.

Julie Cahill MD, vice president, consulting and medical director services

As vice president of consulting and medical director services, Dr Cahill has been an integral part of the Medical Affairs Consulting team since 2016. With a deep medical knowledge and analytical mindset, she regularly leads the creation of cross-functional medical strategies and has helped with numerous drug launches. Her clinical experience also provides the background needed to identify medical needs and direct the development of medical data generation programs. In addition, it lends her the insight necessary to work with thought leaders and execute engaging advisory boards that result in impactful recommendations. Overall, her leadership, strategic thinking, and medical education help her clients demonstrate their value both within their organisation and to external stakeholders.

Dr Cahill is a graduate of the University of Virginia with a BA in biology and distinction in mathematics. She received her MD, cum laude, at Georgetown University and went on to general surgery residency at the University of Alabama at Birmingham. She also completed specialised training in breast surgery at Northwestern University, including both benign breast disease and breast cancer, and she is a board-certified general surgeon.

Damian Eade, managing director, social analytics, insight

Damian Eade currently leads Lumanity's dedicated social media insights and analytics business, with methodological expertise in social media landscaping, influencer mapping, congress tracking, trend monitoring, and competitive assessment, across healthcare audiences including HCPs, payers, patients, carers, and advocacy groups.

With over 20 years of experience in healthcare market research, specialising in digital research methods for the past 10+ years, Eade previously served as global head of digital at Cello Health Insight (acquired by Lumanity in 2020). Past roles also include managing director and head of healthcare positions at a technology-driven insight and content generation agency, where he focused on utilising mobile technology to bring to life the experiences of patients, carers, healthcare professionals, and consumers.

More recently he has lead the development of Lumanity's syndicated research services focused on omnichannel tracking and social media reporting.

About Lumanity

Lumanity applies incisive thinking and decisive action to cut through complex situations and deliver transformative outcomes to accelerate and optimise access to medical advances. With deep experience in medical, commercial, and regulatory affairs, Lumanity transforms data and information into real world insights and evidence that powers successful commercialisation and empowers patients, providers, payers, and regulators to take timely and decisive actionv.

To learn more, contact contact@lumanity.com or visit https://lumanity.com/.

Cultivating data-driven decisions: How to use content experience platforms in 2024

Data-driven decisions matter, and it is hardly surprising when looking at statistics. McKinsey suggests that effective data strategies in the US healthcare alone can bring up to $100 billion annually. Ironically, the major challenge for pharmaceutical companies today is abundance of data, yet, a lack of data-driven decisions. How is that even possible?

"This data is often non-standardised, unstructured, and just too complex to process and extract valuable insights from," explains Viseven CEO Nataliya Andreychuk. "When creating marketing campaigns, teams may struggle to find information in siloed content libraries, so they end up either creating duplicate content for diverse channels or investing a fair bit of time to write from scratch. And, when it is time to track campaign effectiveness, the lack of end-to-end visibility becomes evident. If marketers analyse the performance of eDetailers, emails, and social media posts patched together, it becomes difficult to discern what makes a campaign successful or a failure."

With an advanced content experience platform, a pharmaceutical brand can make use of their data to craft engaging content that resonates with the audience on their preferred channels, all while trimming time and costs.

Create once, publish everywhere with a content experience platform

Pharmaceutical companies are increasingly leveraging content strategy platforms to generate compelling, tailored content with minimal effort and cost. These solutions usually cover the entire content creation lifecycle, from initial planning and briefing to approval and distribution.

As Andreychuk explains, the beauty of content experience software is that it allows automating tasks, like writing fresh content from scratch, translating into a preferred language, and accelerating the previously time-consuming and costly medical legal regulatory (MLR) processes. Digital content platforms make approved high-quality content versatile, allowing swift adaptation for diverse channels and audiences.

Producing compelling content with ease in 2024

Modern content experience solutions make a wealth of hidden data speak, driving resonating marketing campaigns. Here's how:

Auto-tagging for the modular approach

Pharma companies often find themselves swamped with gigabytes and terabytes of data. An advanced artificial intelligence (AI)-powered content marketing platform allows users to automatically tag text, video, and audio content, structuring and organising all data into semantically categorised bite-sized chunks. This makes it easier for brands to find necessary assets and assemble them together to cater to a specific format, platform, channel, or audience.

The underlying principle, says Andreychuk, is based on the concept of maximising the use of each content piece. The modular approach boosts the team's efficiency and uplifts campaign effectiveness, without requiring substantial resources.

Recycling approved assets

Given the nature of the pharmaceutical industry, every content asset must comply with the rigorous MLR requirements for healthcare communications. While these procedures do minimise the risk of spreading misinformation and potentially harmful content, they tend to impede agile and dynamic interactions with patients, as each fresh content piece must be examined and approved separately.

In content experience platforms, metadata assigned to each content asset allows pharma marketers to track its approval status. Once the module is approved, pharma brands can safely repurpose and reuse it without resubmitting it for MLR review.

"Modular content has to be created and approved only once, which not only cuts spending by removing extra work for MLR teams and marketers, but also helps to get to the market faster. In this way, pharma can quickly deliver crucial information to healthcare providers (HCPs) and patients, contributing to the ultimate goal of saving lives," highlights Andreychuk.

Making data-driven tweaks

"Making decisions without data means leaning on intuition or subjective opinions. It is prone to biases, is risky, and is potentially costly. By contrast, when pharma companies use analytics, they can trace the performance of a reusable asset across diverse channels and make comprehensive revision based on evidence," adds Andreychuk.

Additionally, marketers no longer need to spend considerable amounts of time updating modular content. When new data or regulations arise, users can simply change an asset without overhauling the whole document. For example, if there are changes in the contraindication guidelines, it is necessary to update only the relevant module.

Generating fresh personalised content at scale

While AI chatbots allow production of new content in practically no time, they often miss the mark when it comes to personalisation. This cannot but leave some in the C-Suite feeling sceptical about its consistent use. "Pharma and life sciences companies have their specialised jargon that is not always baked into the chatbot, leading to inaccuracies and lack of precision," as Andreychuk points out.

"To address this challenge, certain content experience platforms, like our eWizard, have the integrated ChatGPT model directly linked to the clients' databases. Since the solution relies on the company's internal data, rather than only on the world wide web, the output results are relevant, accurate, and personalised".

If a pharma company targets international markets, this tailored content can then be translated into a preferred language. AI algorithms store information from past translation results in a client's separate memory server. For a pharma company, having its own memory server substantially improves the translation quality.

Pre-approving your content before MLR

The MLR review can eat into the company's budget and take a long time. According to Andreychuk, the downsides extend beyond the financial impact. Prolonged procedures may result in some chronically ill patients not accessing information about their treatment options in a timely manner, or individuals at risk of developing life-threatening diseases remaining uninformed and neglecting much-needed preventative care. The lack of evidence-based data could also mean that some patients endure a reduced quality of life for a longer period, as they are unaware of up-to-date strategies to manage their drug side effects or conditions.

Effective content experience platforms are designed to speed MLR, making sure that content summited for the initial review is of high quality. "Instead of waiting for content to shuttle back and forth between MLR teams and content creators, advanced solutions, such as eWizard, enable users to see the likelihood of content approval before undergoing the formal process. These tools show context mismatches and missed references as well as make suggestions for improvements," Andreychuk says.

Taking advantage of content experience solutions in 2024

The outlook for pharma marketing appears to be bright with ongoing advancements in technologies, notably the rise of AI-based content experience platforms. With abundant and fragmented data, technologies are set to play a paramount role in helping life sciences brands implement two fundamental marketing principles: getting the right data and getting the data right.

Tech solutions, like advanced content experience software, emerge as the key tools for gathering quality information and establishing a cohesive data layer across entire organisations. This capability is essential for staying agile and competitive in the face of challenges impeding communications with patients and HCPs.

About the interviewee

Nataliya Andreychuk is the CEO and co-founder of Viseven, a global MarTech services provider for life sciences and pharma industries. She is one of the top experts in digital pharma marketing and digital content implementation and has more than 14 years of solid leadership behind her belt. Andreychuk is among the strongest female leaders in the marketing technology world. She has been contributing her vast expertise to developing smart digital solutions and software, which are now serving clients in over 70 global markets, delivering intelligent, personalised content across channels, platforms, and countries.

About Viseven

Viseven is a future-inspired global MarTech Services Provider for Pharma and Life Sciences industries with more than a decade of experience. Viseven's digital transformation centre offers innovative solutions for companies of different sizes and digital maturity levels by merging marketing and digital technology expertise with innovation and strategic capabilities. The company's solutions, products, and services are actively used by the TOP 100 Pharma and Life Sciences companies in more than 50 countries around the globe.

Follow Viseven on social media: LinkedIn, Twitter, YouTube, Facebook

Follow Nataliya Andreychuk on LinkedIn

Research Partnership
Inizio Advisory

Healthcare in the age of AI: How will artificial intelligence impact future decision-making?

Artificial intelligence (AI) has recently surged in popularity, thanks in part to innovations like ChatGPT, which represents a significant step towards generating human-like text from simple prompts. In the healthcare sector, AI's advancement has begun to impact prescribing, particularly in addressing the growing challenge of antimicrobial resistance. A pivotal study in 2023 has revealed that an AI model produced better therapeutic outcomes than prescriptions written by doctors.

However, AI models such as ChatGPT have their limitations, including deficiencies in mathematical capabilities and a restricted knowledge scope, limited to data available up to 2021. Furthermore, they carry a substantial risk of generating false information. This raises a fundamental question: where does AI acquire its learning? A 2023 Pew Research study has highlighted the concerns of many US patients regarding AI-driven robots in surgical procedures and the security of AI in managing health records. Given these current apprehensions surrounding AI, researchers have emphasised the critical need to combine AI with human expertise.

To navigate through these complexities, we have been investigating how AI is transforming the prescribing process and its impact on patient outcomes and healthcare costs. To achieve this, we recently collaborated with Medefield to conduct a survey involving 177 general practitioners (GPs) across the United States, France, Germany, Spain, and the United Kingdom. Additionally, we surveyed 14 payers from Research Partnership's global payer network in France, Germany, Italy, Spain, and the UK.

Current AI usage, perceptions, and prospects of AI adoption

Our findings reveal that, in Europe, 40% of GPs have never utilised AI tools to assist in their prescribing practices. In the US, the adoption of AI is even lower, with 60% of GPs not using AI at all. Moreover, their perceptions of AI's role in supporting prescription practices vary significantly, with European GPs generally holding a more favourable view compared to their US counterparts. Conversely, European payers hold even more positive perceptions than both European and US GPs (see Figure 1).

Current perceptions of AI as an aid for prescribing

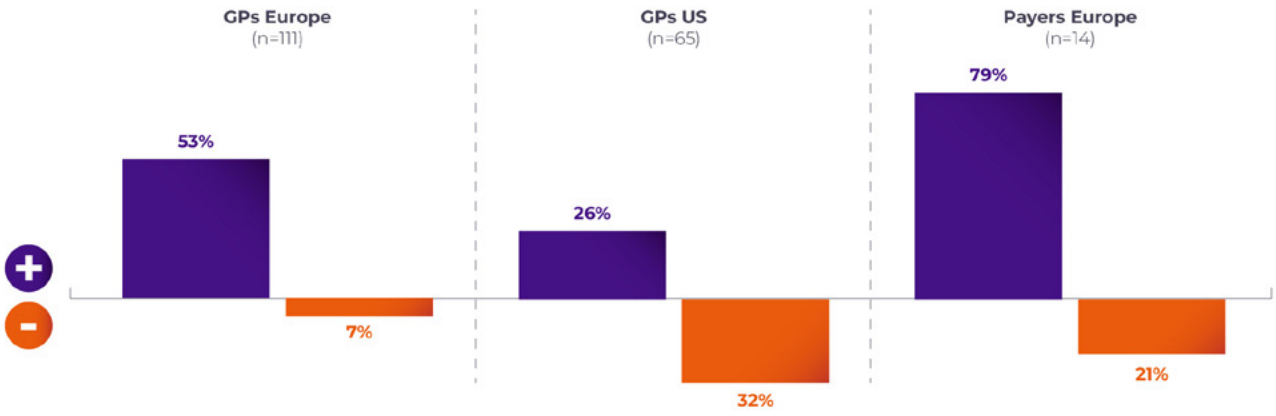


Figure 1. What is your current general perception of AI technologies as an aid for prescription in healthcare? Please select one (1. Very negative, 2. Negative, 3. Neutral, 4. Positive & 5. Very positive) – % of respondents who selected option 1 & 2 as **negative**, and 4 & 5 as **positive**

To understand the underlying reasons for these perceptions, we delved into the primary challenges that GPs believe hinder the increased use of AI. In Europe, half of the GPs mentioned "standards or regulations in the use of AI" as their main challenge, while GPs in the US identified a different obstacle, with over half of them indicating a lack of "awareness or knowledge of AI tools" as a major factor (see Figure 2).

Current challenges of AI technology

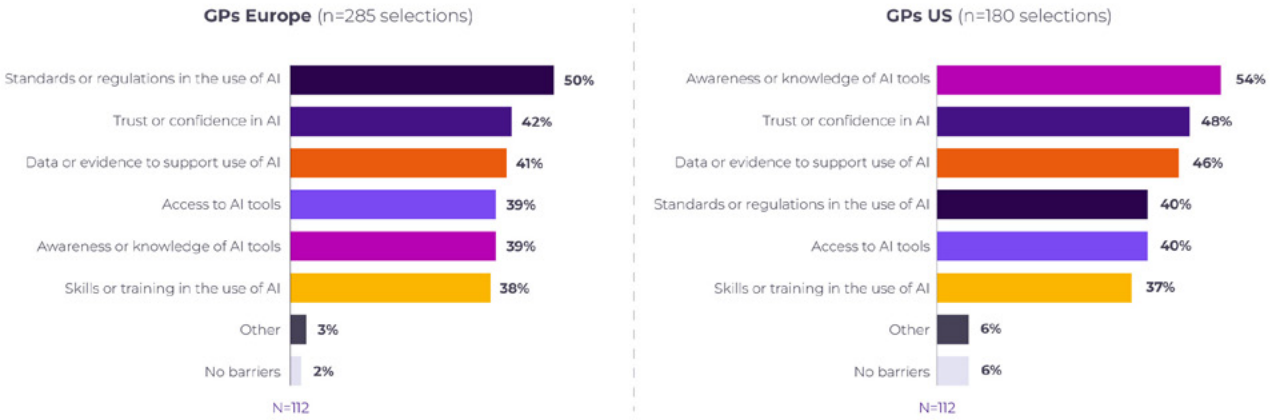
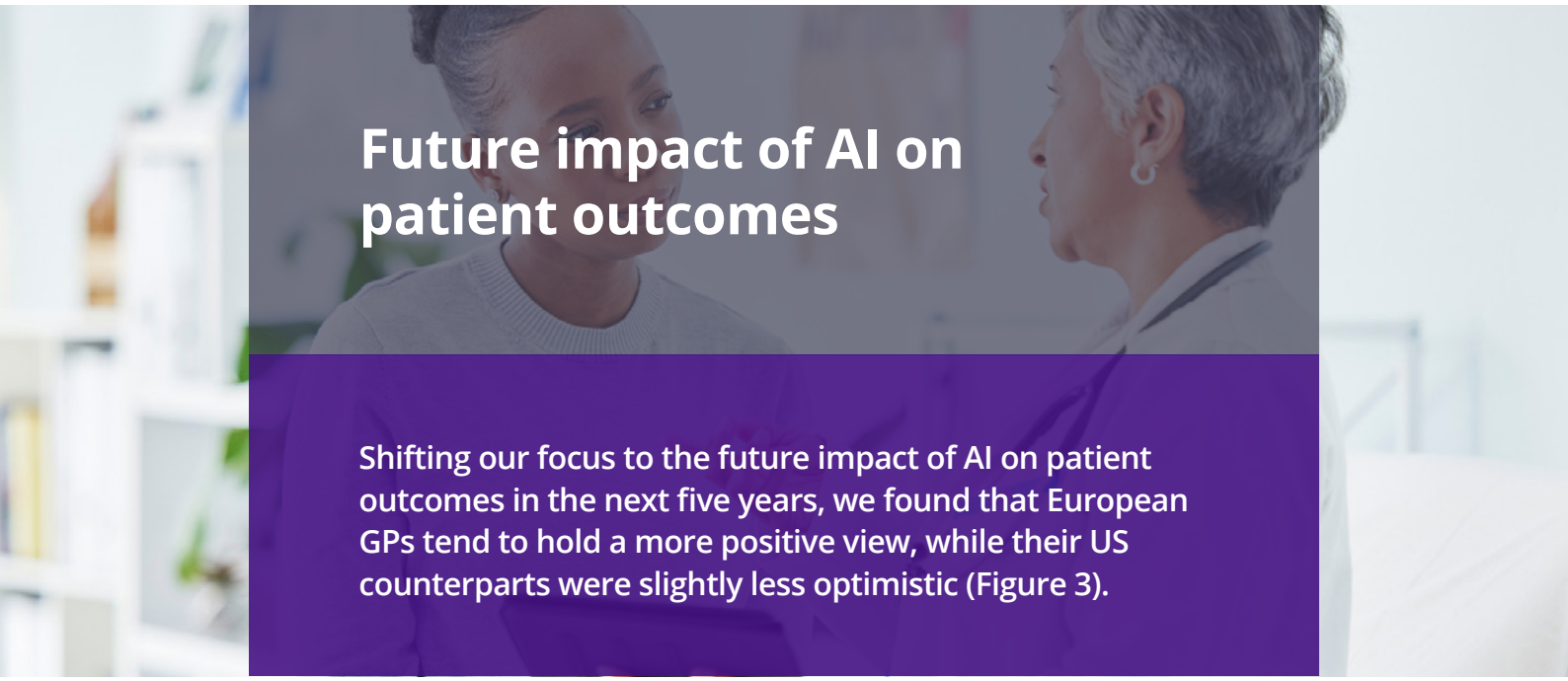


Figure 2. What are the main barriers or challenges that currently prevent you from using AI tools more frequently to support prescription decisions? Please select all that apply - % of selections per option.

Having examined the current usage, perceptions, and obstacles surrounding the utilisation of AI in prescription practices, we questioned our respondents about the future prospects of AI adoption in their field over the next five years. Remarkably, 62% of European GPs expressed their willingness to increase their use of AI in the prescription process, while in the US only 49% of GPs shared a similar inclination.



Future impact of AI on patient outcomes

Shifting our focus to the future impact of AI on patient outcomes in the next five years, we found that European GPs tend to hold a more positive view, while their US counterparts were slightly less optimistic (Figure 3).

Perceptions of how the use of AI to support prescribing decisions will impact patient outcomes & satisfaction

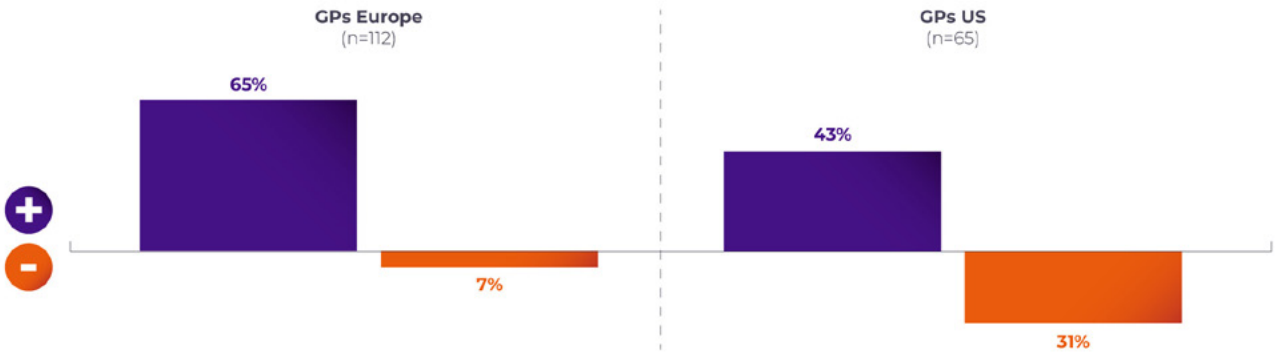


Figure 3. Overall, how do you think the use of AI to support prescribing decisions will impact patient outcomes and satisfaction in the next 5 years? Please select one (1. Very negatively, 2. Negatively, 3. No change, 4. Positively, 5. Very positively) – % of respondents who selected option 1 & 2 as **negative**, and 4 & 5 as **positive.**

In alignment with current AI perceptions, European payers tend to be the most optimistic about AI's impact on patient outcomes over the next five years. Over 70% of payers expressed a positive perception of how the use of AI to support prescription decisions will enhance the quality of care and patient outcomes. An analysis of the rationale provided by payers is presented below (see Figure 4).

Rationale - Perceptions of how the use of AI to support prescribing decisions will impact quality of care & patient outcomes

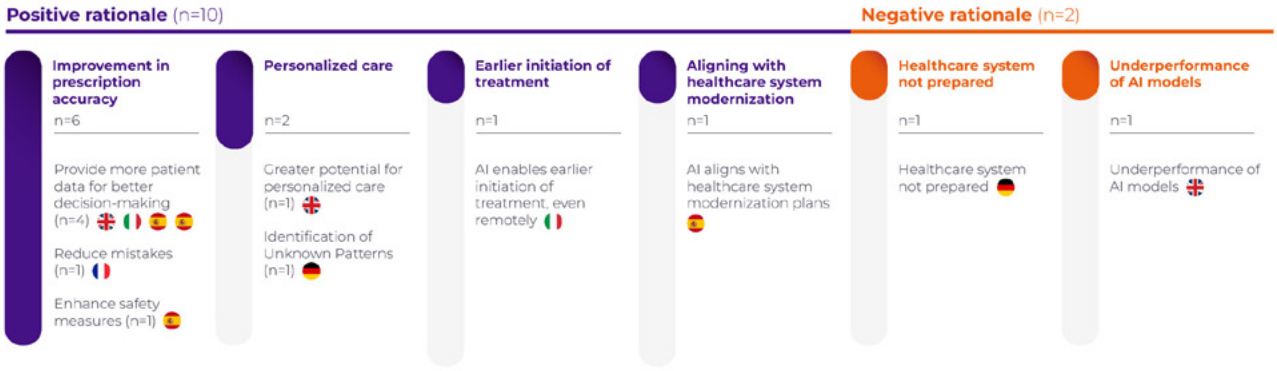


Figure 4. Analysis of **positive** and **negative** rationale based on answers from Figure 4, using n= number of payers and each payer is symbolized by a countryball.

Future impact of AI on healthcare costs and market access

Regarding the impact of AI on healthcare costs, 43% of European payers anticipate that AI technologies will decrease healthcare costs within the next five years. Italy exhibits notably positive expectations, followed by France, while other countries hold more mixed views. Those who believe that AI will reduce healthcare costs anticipate savings through improved efficiency, including the reduction of unnecessary steps, better patient data management, and avoidance of expenditures related to inappropriate treatment. One payer, based in the UK, noted that they are "less likely to provide treatments with little or no efficacy using historical data [with the use of AI], thus avoiding expenditures related to inappropriate treatment."

Overall, payers tend to agree that AI has the potential to support health technology assessment (HTA) evaluations in the next five years (see Figure 5). Some of the reasons given for this positive perspective include faster clinical trial and real-world data analyses or providing further evidence for HTA decisions and support with routine tasks. Nevertheless, certain payers, particularly those in Germany, maintain a more negative view, primarily due to the need for human oversight, lack of current use or evidence, and concerns about bias in the AI models. A German payer commented, "The issue lies in AI models that have potentially been trained with biases."

AI integration in HTA decisions

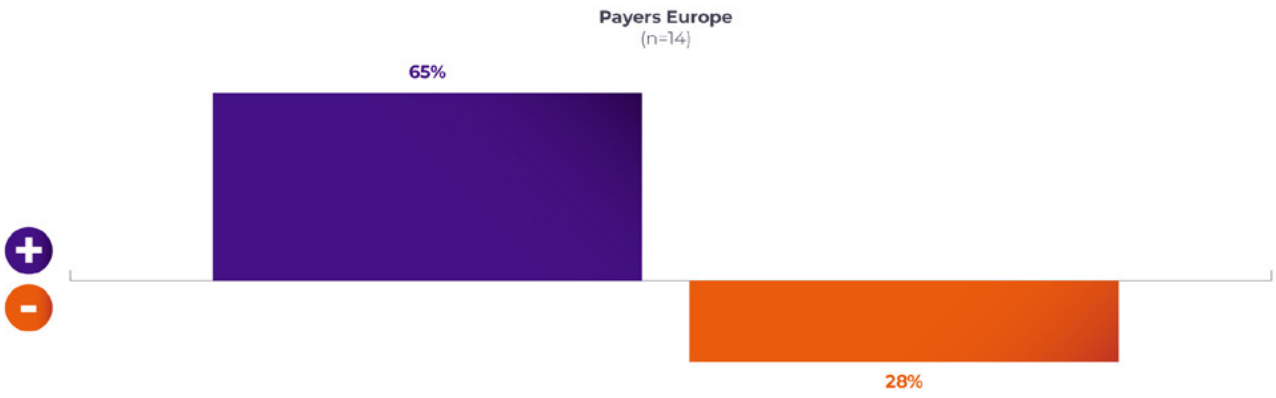


Figure 5. To what extent do you agree that Health Technology Assessment bodies should use AI-based tools to support with Health Technology Assessments (HTAs) in the next 5 years? Please select one (1. Strongly disagree, 2. Disagree, 3. Neutral, 4. Agree & 5. Strongly agree) - % of respondents who selected option 1 & 2 as **disagree**, and 4 & 5 as **agree**.

We gathered concluding thoughts from our surveyed payers. Some believe that collaborating on AI algorithms is more reliable than human analysis. For example, an Italian payer noted that "[AI] might be helpful, but the final decision should always be made by humans. It is important to establish laws and specific legislation regarding the proper use of AI to protect data and privacy." Others contend that humans will always have the final say, emphasising the necessity of data protection legislation for AI use. A Spanish payer expressed the belief that "AI has great potential, offering benefits such as increased accuracy and speed, reduced costs and human errors, and improved access to healthcare in remote areas."

Work to be done

Our research revealed that US GPs are currently less open to AI-aided prescribing than their European counterparts. This reflects a lower experience level with these tools to date and aligns with US patient concerns outlined in other literature. European payers showed more optimism about the use of AI for this purpose.

There is recognition among both GPs and payers that adopting AI in prescribing can improve patient outcomes, increase patient satisfaction and, from the payer perspective, ultimately translate to cost savings. However, some point out that, for these benefits to be realised, there is work to be done in preparing healthcare systems to effectively adopt these tools. In particular, concerns relating to awareness, regulations, data protection, and bias need to be addressed to fully embrace AI. Ultimately, even if AI can realise its immense potential within healthcare, there is a consensus that human checking will still be required.

In conclusion, the rapid advancement of AI, exemplified by innovations like ChatGPT, is reshaping the landscape of healthcare and prescription practices. While AI holds great promise in improving therapeutic outcomes and potentially reducing healthcare costs, our research underscores the need for a thoughtful and measured approach.

As we navigate through the evolving relationship between AI and healthcare, it is essential to address the challenges that currently hinder its widespread adoption. These include the need for standardised regulations, increased awareness and knowledge among healthcare practitioners, and vigilant efforts to mitigate biases in AI models. Moreover, the human element remains indispensable in healthcare decision-making, with AI serving as a valuable tool, rather than a replacement.

The divergent perceptions of AI's role and impact among healthcare professionals across different regions underline the importance of a nuanced and region-specific strategy for AI integration. European and US healthcare stakeholders have their unique perspectives and concerns, necessitating tailored approaches to maximise AI's benefits while minimising its risks.

In this dynamic landscape, it is crucial to strike a balance between AI's capabilities and human expertise. The collaboration between technology and healthcare professionals, along with the development of robust regulatory frameworks, will be pivotal in harnessing AI's full potential for the betterment of patient outcomes, cost-effective healthcare, and the advancement of the healthcare industry as a whole.

In the coming years, as AI continues to evolve and healthcare systems adapt, our collective efforts to bridge the gap between AI's promise and practical implementation will play a decisive role in shaping the future of healthcare. The path forwards may be challenging, but it is one that holds the promise of more efficient, effective, and accessible healthcare for all.

About the authors

Tom Donnelly, PhD, Director
Tom Donnelly, PhD, is a director in Research Partnership's MedTech division. Based in the US, Donnelly has over 18 years of experience in healthcare insights with a particular focus in medical technology. In addition to Chairing Intellus Worldwide's Clear Health Communications Committee, he is a frequent industry author and presenter, and active in numerous industry groups, including the Advanced Medical Technology Association, the Human Factors and Ergonomics Society, and the Digital Healthcare Collaborative. After receiving his PhD in Cognitive Psychology from New York University, Donnelly remained in education as a visiting professor at Rutgers University where he taught a variety of psychology courses for several years, before moving into the health and life sciences industry.

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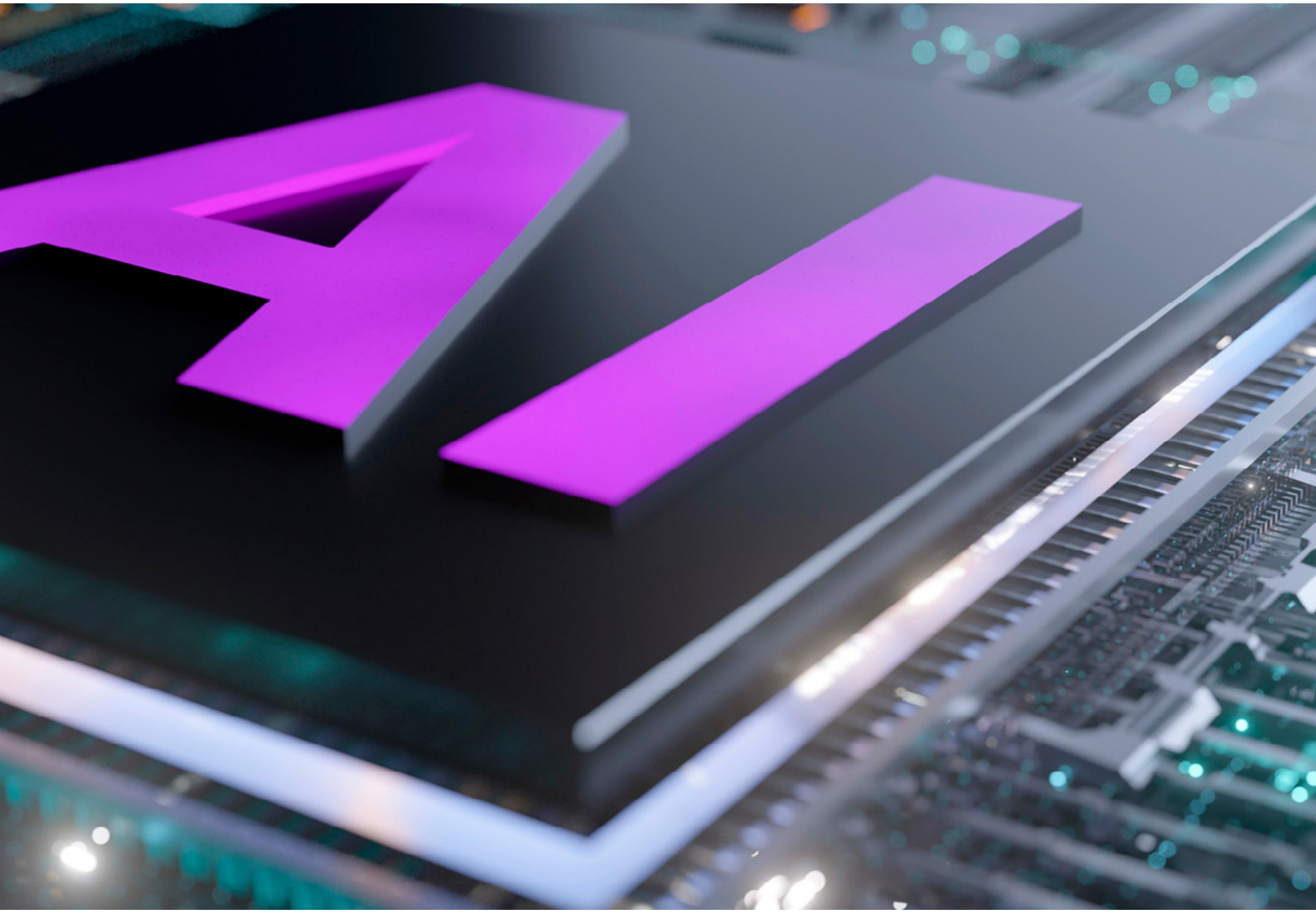
About Research Partnership

Research Partnership
Inizio Advisory

Research Partnership, an Inizio Advisory company, is a world-leading provider of market research and insights for global life science companies. We provide custom and syndicated research that delivers fresh insights and perspectives from stakeholders across the healthcare value chain. Our passionate team holds centers of expertise, with a depth and breadth of knowledge and experience across therapeutic areas and geographies. Through custom design, robust data analysis, and consulting, we help our clients make strategic decisions across the product lifecycle, driving commercial success and positive patient outcomes.



How new technologies help keep brand planning simple

Daniel Kohlstaedt, managing director of PurpleLeaf Strategy, says that a brand plan should tell a story. "It justifies your budget requests and communicates to your field force what they need to do to follow a given strategy," he continues. Too often, however, the ways teams build their brand plans get in the way of efficient and effective strategy development.

For many brand leaders – whose functions can sit within commercial excellence, global or regional brand leadership, or go-to-market teams – brand planning happens in slide decks or spreadsheets. Teams collaborate in PowerPoint templates, entering tonnes of data on their brand's market performance, the environmental factors that impact their strategy, and competitive landscape into static documents. This can feel more like a menial task than a true strategic project.

"Every brand manager knows that brand planning is an important process, but often they feel they're filling in meaningless slides that are randomly sequenced," Kohlstaedt says. "This leads them to focus on the wrong questions: the 'how' of filling in brand plans, rather than the 'what' of their strategy."

Kohlstaedt, who has served as a global brand director himself, knows these pain points all too well: “Brand leaders are very busy and carry a lot of responsibility. There is no room for redundant or useless exercises done for the sake of making a slide deck.”

Pharma has transformed much of its business to fit today’s digital demands. Kohlstaedt argues that brand planning should do the same. With the right technology – built specifically for the needs of brand teams as they develop impactful strategies – brand leaders can use the most complete, up-to-date data to hone their brand storytelling and position their products for success.

“The brand plan should tell a concise story, with one element building on the next to better understand business challenges and help inform the right decisions,” Kohlstaedt says. “This is where technology comes into the game.”

Why the brand planning status quo isn’t serving pharma

Brand planning, though it involves cross-functional teams and requires several different types of data, is a straightforward process – or at least it should be. Teams analyse information to guide strategic decisions that impact allocation and tactics for the year ahead. But today’s standard procedure for developing a plan adds unnecessary roadblocks.

“It’s actually quite simple to come up with a good brand plan,” Kohlstaedt says, “but the complexity in slide templates makes things difficult.”

There are three key challenges that slide-based brand planning introduce. One is the version control issues that inevitably arise when working in static documents. A marketing team may update information in their slides one day, but their medical colleagues won’t get to theirs until next week. How can local and global leaders know which is the latest version of the file from which to evaluate tactics and inform their decisions?

Secondly, teams face challenges when manoeuvring the complex taxonomy of brand planning terms and criteria often included in slide templates. These require users to input information that meets a variety of different fields – with little context on the value of the exercise. Kohlstaedt recalls a brand plan template he reviewed for a large pharma company which contained 'Strategic Imperatives', 'Strategic Options', 'Business Issues', 'Moments-that-Matter', 'Growth Opportunities', 'Strategic Drivers/Barriers', and 'SWOT' as necessary items.

"It's difficult to cater to all these elements; they make the exercise complex without adding value," Kohlstaedt says.

Instead, teams can narrow their brand planning focus to two make-or-break elements: their brand's leverage points and the drivers of or barriers to success. Leverage points are the moments in a customer journey that prevent patients from getting the right treatment, which, once addressed, can eventually be harnessed as competitive differentiators. The drivers of/barriers to success are the environmental or competitive elements that either hinder or promote your brand's success.

"Once you have this information, you're in a position to make some solid decisions," Kohlstaedt says.

The third key challenge to slide-based brand planning lies in using PowerPoint decks as a "brand knowledge base", as Kohlstaedt describes it. Currently, teams store all of their brand data, calculations, and knowledge in slide decks, as they don't have a convenient alternative. But brand plans should be simple when presented to leadership – they don't need to house all of this information.

Kohlstaedt offers a helpful analogy: "Imagine you wanted to write a menu for a restaurant, but, instead of naming the dishes on the menu, you write out the recipe for each dish. The guest only needs to know what they can order." He argues that brand planning follows the same model.

"When a brand team presents their plan, it doesn't need to show all the work that went into its development," Kohlstaedt says. "The stakeholder should see that the brand team did the work to come to a good decision, but no senior manager will ever check all the details."

Instead, if brand data are stored in a database, brand teams can host all data in the cloud, then run analyses to gather the insights they need. When it comes time to present findings to leadership, they can generate reports and even slides that share the key decisions that are relevant to their stakeholders, without extraneous information.

Brand planning technology moves teams from confusion to concrete tactics

Today's platform technologies outstrip PowerPoint as a brand planning tool.

"Without being too self-confident, I think one of the biggest trends in brand planning in the next five years will be a move away from PowerPoint," Kohlstaedt predicts. "Imagine a pharma company using Excel as their Customer Relationship Management system today? It wouldn't happen."

Brand planning platforms like PurpleLeaf Strategy's Enavia automate and streamline the most complex parts of brand planning by putting all information, analytics, and collaboration into one cloud-based system.

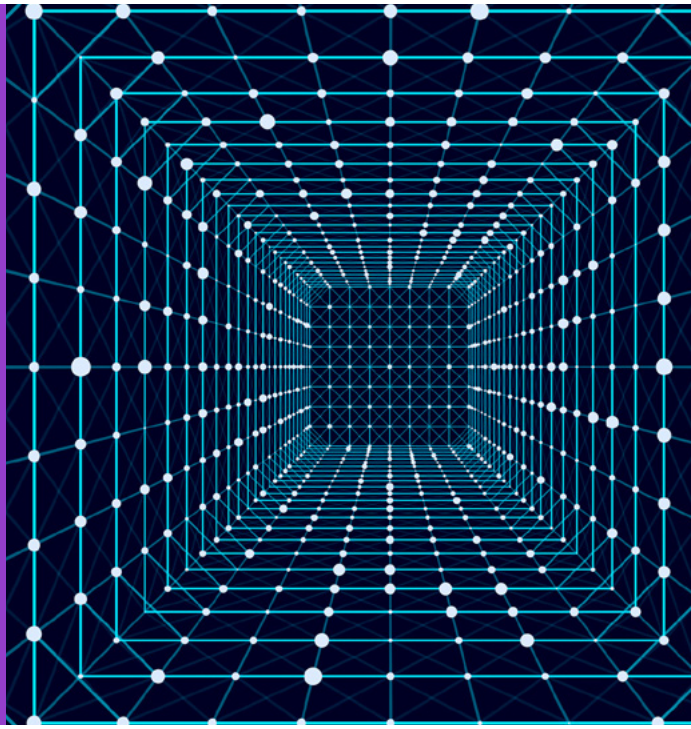
In establishing a database to store all brand information, these technologies eliminate the version control issues teams face with PowerPoint as their main tool. This means all colleagues work from a single source of truth with the latest, most complete brand data at their fingertips. Similarly, cloud-based technologies ensure global-to-local consistency of information. Local teams can share information in a consistent manner, and global teams can review progress in automatically generated dashboards.

Crucially, brand planning platforms also enable teams to collaborate in real time, working cross-functionally to input and assess brand data efficiently – and attach budget to each KPI in a brand plan.

Kohlstaedt sees the promise in brand planning technology to phase out legacy methods and improve strategic efforts. With wider adoption across the pharma industry, he predicts "PowerPoint will be reduced to its core strength: presentations."

Optimising brand planning with deeper market insights

Certainly, pharma – along with the rest of the world – has moved to base decisions on data. "As an industry, we do want to be more data-driven to eliminate failures that happen when we base decisions on gut feeling," Kohlstaedt says.



With more data stored in an accessible, complete database, he explains, comes deeper insights for brand teams. One key example is with PEST analyses. These have been used for decades to assess the Political, Economic, Social, and Technical factors – hence, PEST – that drive or hinder brand success. When all of this data is brought together in a timeline view, brand teams can more easily run analyses and identify the levers that impact their business.

A robust database will also hold information on a brand's strengths, weaknesses, opportunities, and threats to success – known as a SWOT analysis – relative to its competition. Finally, brand teams can visualise the ways patients interact with the healthcare system to learn about current trends in patient care, and why certain therapies or interventions are used over others.

With a strong foundation of data, accessible to relevant colleagues across the organisation – brand teams can unlock even more insights that shape the future of their brand.

Next steps towards a simpler future for brand planning

Despite advances in brand planning technologies, there is progress to be made in improving the quality of databases and tools used to store and analyse brand information. This data is the fuel for any insight generation tool, so, without good brand strategy data available to relevant teams, technology's ability to generate new knowledge is limited.

"We keep hearing requests to include artificial intelligence (AI) in brand planning, but as long as teams store their brand strategy data in slide decks, we won't be able to apply any AI algorithms to it," Kohlstaedt says.

The first step to brand planning's continued move into the modern era, Kohlstaedt continues, is for brand teams to move all brand planning data out of closed files and into a database structure. While this won't solve all of pharma's brand planning data challenges, it will help ensure brand strategy data is useful and impactful over time as teams continue to build and revise their market approaches.

"Any AI or machine learning dream for strategic decision-making only becomes true when we move from the closed container of PowerPoint to a database-driven system," Kohlstaedt says.

Think, for example, of a company with 100 country affiliates, all working on brand plans for 20 products over five years. If they use a database system to collect and analyse this data, they may have 10,000 data points that AI can crawl to draw out a brand's success drivers automatically – and at no extra cost or effort. "This might not sound like a lot, but how large is our database today when only using PowerPoint for brand planning? Zero."

This is something Kohlstaedt and PurpleLeaf Strategy are working to investigate; they have a research grant from the German government to assess how to utilise brand plan data over time and recognise patterns in strategic and tactical decision-making.

With pharma's next steps identified to help advance brand planning's digital transformation, Kohlstaedt offers words of advice for those embarking on a brand planning project: "Keep things simple, and don't create complexity artificially. This will help your brand teams make better decisions."

About the interviewee

Daniel Kohlstaedt is founder and managing director of PurpleLeaf Strategy and has over 19 years' extensive experience in commercial excellence and global marketing implementation. He is an expert in global roll-out.

About PurpleLeaf Strategy

PurpleLeaf
STRATEGY

At PurpleLeaf Strategy we strive to help Pharma and Biotech businesses achieve their commercial goals through our cloud-based platform, Enavia. Through structured cloud-based systems, Enavia guides teams through brand strategy development and execution on many fronts. Automated data collection and sharing, analytics through modular tools, and planning & execution through interrogative exercises help business in their go-to-market strategies and commercial excellence. Tools like Relative Competitive Analysis, Patient Flow and Journey, Timeline Dynamics, and many more help in pulling actionable levers for commercial success.

Get the benefit of our highly experienced professionals and tools, custom made for you. Visit www.enavia.io or write to us at sales@enavia.io for a demo.

The results are in: HCP communications need to evolve

Time is a precious commodity in healthcare. In an era characterised by rapid innovation, complex treatment options, and increasingly challenging workloads, it's easy for healthcare professionals (HCPs) to become overloaded with information. For pharma communications, the time constraints faced by HCPs present a unique challenge: in order to cut through the noise of today's engagement landscape, hitting the right note first time is no longer optional, it is a necessity.

But how can marketing teams ensure that their approach to engagement aligns with the needs of their intended audience? New research by M3, based on a survey conducted in September 2023 with 900 doctors from the EU5 (Spain, Italy, Germany, France, and the UK), elucidates the contours of the answer. Here, M3's SVP of business intelligence and research, Dr Maxim Polyakov, discusses its key findings.

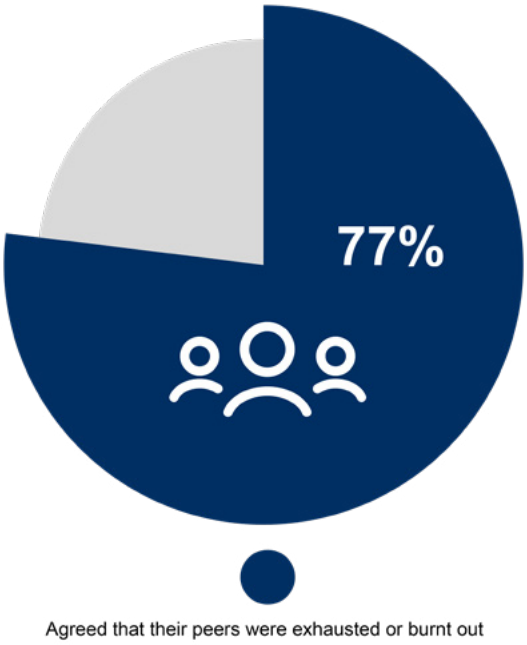
HCPs are under pressure

While the struggles facing healthcare systems have dominated headlines in recent years, M3's research spotlights that, over the past 12 months, swollen treatment backlogs, staffing issues, and time constraints have put immense strain on doctors at an individual level.

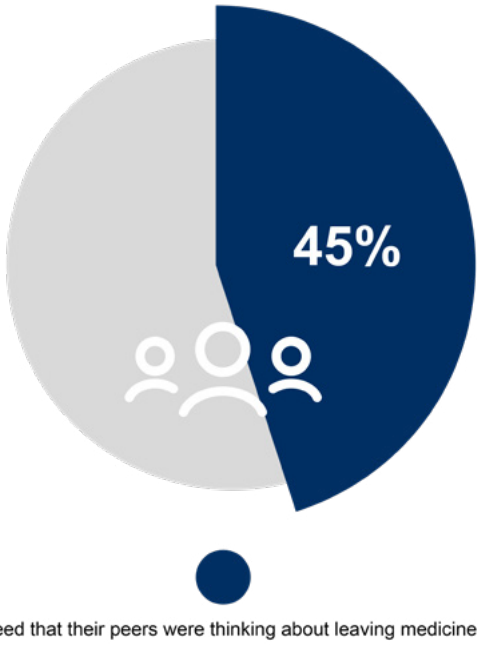
In a concerning, but sadly unsurprising, outcome from the survey, more than 75% of the surveyed EU5 doctors categorised their workload as unsustainable, with only about a quarter of respondents reporting a fully sustainable workload.

"That lack of sustainability has knock-on effects," explains Polyakov. "It means high levels of exhaustion and burnout. It means low morale. It means attrition."

Indeed, ~75% of surveyed doctors agreed that their peers were exhausted or burnt out, and a similar proportion reported their peers as having low morale. Moreover, ~45% of respondents agreed that their peers were thinking about leaving medicine.



Agreed that their peers were exhausted or burnt out



Agreed that their peers were thinking about leaving medicine

At the same time, doctors remain hungry for new and relevant information: when asked which are the most important pieces of information they would like to have about a new treatment before prescribing it for the first time, M3's respondents selected on average between five and six categories of information.

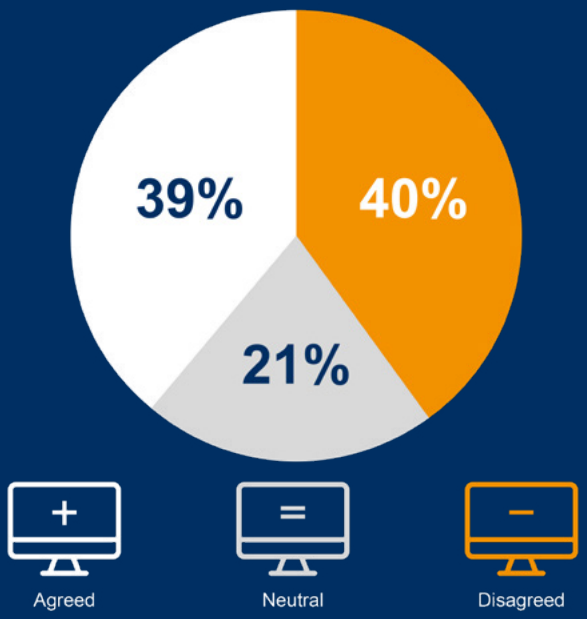
For pharma, the combination of time-starved HCPs and the need to communicate large amounts of complex information to them is a clear challenge. "This will put further pressure on marketing teams to optimise and evolve their approach to HCP comms," adds Polyakov. "Pharma increasingly needs to communicate with doctors in just the right way."

Different doctors have different needs

But what does 'just the right way' mean? "Ultimately, companies should be aiming to understand the varied needs and preferences of their audiences, and transform this insight into meaningfully different customer journeys," says Polyakov. "Ideally, the optimisation of each HCP's customer journey should happen at an individual level, which is achievable if you can use data to unlock an understanding of individual doctors' evolving preferences and behaviours."

For instance, while there is little doubt that external professional opinion is important for doctors, the M3 survey found an almost even split between doctors who preferred the 'opinion of experts in my local health system', as opposed to 'the opinion of national- or international-level experts' (~30% preferring the former, ~40% preferring the latter, and ~30% neutral).

Another example: ~40% of respondents agreed that they would 'prefer to read product information online, rather than have a meeting with a pharma rep', ~40% disagreed, and ~20% were neutral. This is important information, as, for example, in the context of a product launch, third-party websites were ranked to have the same reach as pharma reps for the doctors who agreed with the statement above.



Polyakov continues: "An HCP's customer journey should be shaped according to their market and specialty, of course, but also according to a plethora of insights, such as those gathered in M3's research, that would permit the identification of more nuanced audience segments or 'personas'. This could drive an increasingly tailored and highly effective comms approach; one that can be adapted and evolved, both as more data becomes available, but also because individuals' comms preferences can change over time."

Quality as a differentiator

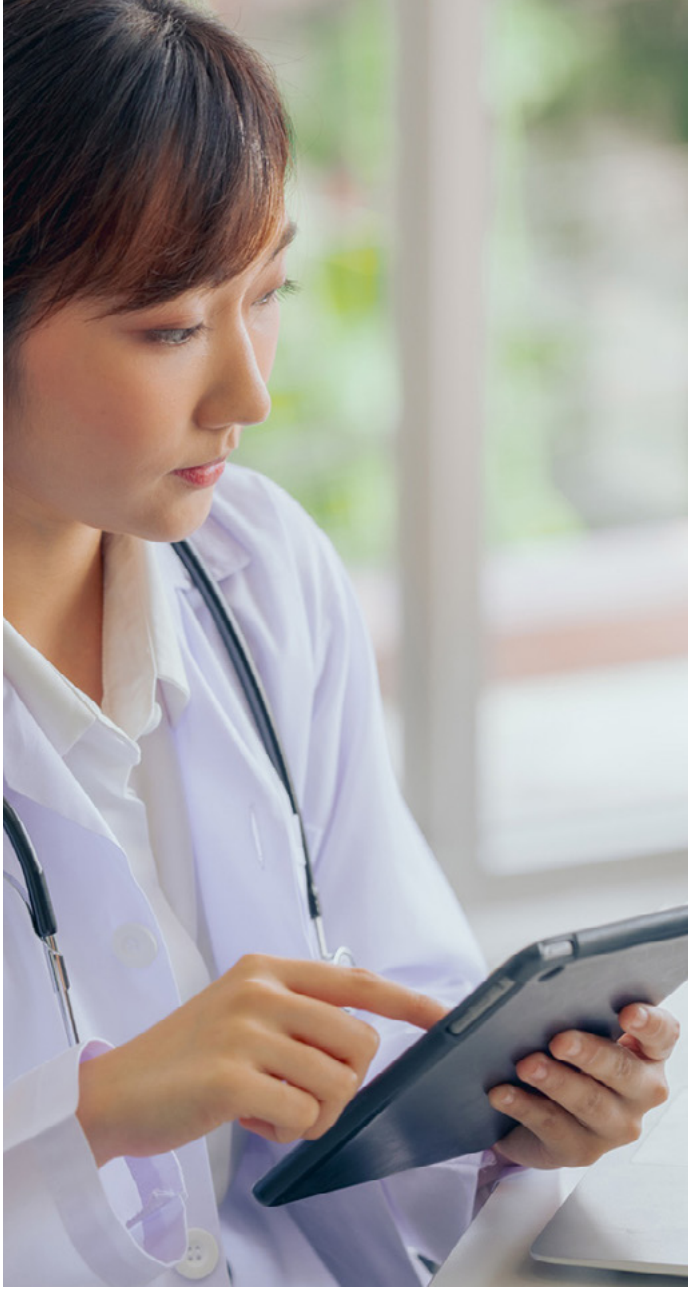
However, comms optimisation of this type, at scale, can be challenging to operationalise, and is not something that the industry has 'cracked'. For instance, according to M3's data, almost 60% of doctors could not name a pharma company that 'stood out for particularly effective digital communication' over the previous 12 months.

This begs the question – how can companies stand out? In an era of information over-abundance, quality serves as a differentiator, capturing and maintaining the attention (and trust) of busy medical professionals amidst the data deluge. This covers both quality of content and the quality of its delivery to individual HCPs. Both are critical components of maximising available opportunities.

Polyakov elaborates: "Pharma brand managers rightly spend their days laser-focused on how they should communicate with their customers, the HCPs. However, pharma is not high on the list of doctors' daily concerns. For instance, while three quarters of our survey respondents identified 'lack of clinical staff' as an issue for delivering optimal patient care, the lack of accessible / convenient information on new treatments was an issue for only 15% of respondents. The amount of headspace that HCPs can give pharma is very limited. Every interaction that pharma can get with doctors is precious, and it's a shame when they are not used in the best possible way."

Mastering the art of HCP communications

Hitting the right note with communications is not simply about marketing finesse; it is understanding and respecting the unique needs and preferences of different HCPs. In a world where informational saturation is the norm, where healthcare professionals are inundated with choices and requests, crafting messages that resonate and engage is a discipline in itself.



But, beyond the challenges, there are abundant opportunities for those who master the craft of precision communication. As M3's research illustrates, many HCPs are struggling to maintain their current workload, and intervention is needed to ensure the system endures. While pharma alone cannot solve all of the challenges HCPs face, companies can help to reduce the pressure by using insights and data to maximise the value that HCPs derive from their contacts.

By doing so, pharma companies can chart a course for success, not just for their brands, but for the patients whose well-being depends on a commitment to delivering the right message to the right HCP, right from the start.

For more information on how you can deploy data insights to identify various target audiences and utilise diverse marketing strategies contact M3 at reachdoctors@eu.m3.com

About the interviewee

Dr Maxim Polyakov is M3's SVP of business intelligence and research. He is passionate about using data to drive better decisions, and ensuring that the voice and needs of patients and HCPs remain at the centre of healthcare systems.

About M3

M3 is the world's largest network of verified doctors with over six million members across many key markets; our closed and local communities of doctors are trusted by our members as places where they can reach content relevant to their profile and their geography. M3 has over 20 years' experience in building online doctor communities, including Doctors.net.uk for the UK audience. These communities offer clients a unique opportunity to communicate with doctors. M3 is committed to its mission to use technology to help people live longer, healthier lives and reduce costs in healthcare.

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When AI intersects with human life: Navigating ethical terrain

Artificial intelligence (AI) has become an omnipresent force in our lives. From our homes to workplaces, from healthcare to entertainment, AI has permeated every facet of modern existence. AI's ubiquity is evident in our daily routines. It shapes the recommendations we receive while shopping online, the content we encounter on social media, and even the personalised medical advice we access through telehealth platforms.

However, as AI becomes increasingly woven into the fabric of our lives, it brings with it a host of ethical concerns and considerations, raising questions about privacy, bias, and accountability. With so many aspects of AI that are truly beneficial to society and mankind, there's no turning back time on it. Of course, in the wrong hands, AI can be terribly destructive, and that's without talking about scaremongering and exaggerated claims of what AI can become if we let it. To maximise its benefits and mitigate its threats, we must create a framework for AI's responsible development and application, remaining vigilant to ensure that it works for us, instead of allowing ourselves to work for AI.

This is particularly important in the realm of healthcare, where AI intersects with human life.

The human life dimension: AI in fertility

Within the realm of healthcare, AI has made traction in radiology and is beginning to interact with the very creation of life in reproductive care. Playing a pivotal role in offering renewed hope to aspiring parents, AI has the potential to transform the entire landscape of reproductive health analysis and intervention.

Consider IVF as a case study. Success rates for IVF treatments haven't seen much improvement over the last few decades. In fact, only around 30% of women will realise a live birth in their first round of IVF. During an IVF cycle, a woman undergoes a regimen of hormones to stimulate the ovaries. She takes medication to help mature the eggs for collection, which takes place under sedation. A reproductive endocrinologist performs egg retrieval, extracting eggs, which will then be combined with sperm to form embryos – the earliest stages of life.

It is the role of the embryologist to care for the embryos, which are housed in incubators to mature. Embryologists, trained in the study of the formation, growth, and development of embryos, are tasked with assessing the quality of these and then selecting which to transfer in the hopes of that embryo implanting and leading to a live birth. They also determine which should be cryopreserved and which should be discarded. Though embryologists are extremely well educated and highly skilled, success rates for embryo selection are subject to human bias, experience, and expertise, leading to inconsistencies and overall varied and lower success rates than we would want.

Lacking a consistent system for collecting and interpreting end-to-end data on this process, IVF offers an ideal use case for AI to make a positive contribution.

Embryology practice determines the successful formation of life

Typically, embryologists place a fertilised egg in an incubator and manually check the progress under a microscope over a three-to-six-day period. The discretion is up to the embryologist on how many times over the process they assess and make notes on the embryos' development, typically assessing on day one, day two or three, and then deciding on day four or five if the embryos are viable.

The process of carefully removing a developing embryo from an incubator to observe under a microscope and notate the data is time-consuming. Furthermore, removing embryos from the safe and constant environment of the incubator poses a risk of harm. The highly technical task of safely maintaining the beginnings of life outside of the body leaves little room for error. Embryologists assess a developing embryo using approximately five data points, known as the Gardner blastocyst grading system. This leaves IVF professionals to rely on their own education, basic assessment parameters, and their own experience of diagnosis.

In some practices, evaluating the embryo's development is not done at all, instead waiting for the end of the process when a blastocyst is formed to check its quality and viability, and maybe send for genetic testing.

Technology advancing the field of embryology

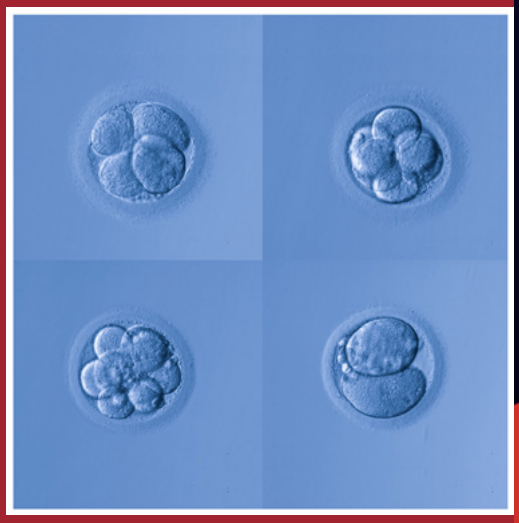
When assessing the embryo under a microscope, embryologists examine several morphologic characteristics to determine its viability. However, with the introduction of Time Lapse Incubators (TLIs) to the IVF lab, technologies, including machine vision and AI, can begin to have a greater impact. TLIs have advanced camera technology integrated into the incubator, capturing images of the developing embryos at regular intervals to create a "live stream". While embryologists also have access to live stream images, they are humans like all of us, with limited capacity to absorb and analyse so much information. This is where AI outperforms humans. Having hundreds of images of developing embryos enables computer vision and AI technologies to assess the developmental stages of embryos based on millions of data points that are not obtainable by the human eye, to analyse that data, and even make predictions – objectively, consistently, and in seconds.

By training AI systems of large and diverse datasets that are representative of patients of varying ages, BMIs, races, and more, the AI can assist embryologists in assessing the viability of embryos. AI algorithms can automatically capture and process live data in TLIs, analysing the data in combination with additional patient data. Based on this, the AI provides additional insights and information to help embryologists make consistent, data-driven decisions. This, in turn, should result in more streamlined decision-making processes in clinics and among embryologists and lead to improved outcomes: pregnancy and live birth results.

AI calculates – it does not think. It calculates more effectively than humans: faster, more accurately, and more consistently, in order to bring new insights, so that humans can decide upon the best way forwards. Specifically, regarding both embryo and egg quality assessment, this ability to analyse vast, complex data maximises the potential success rates of IVF. The ability to analyse big data paves the way for improving human decision-making and the development of evidence-based parameters to establish a consistent standard of care.

AI enables a new era of precision embryo selection that streamlines the entire reproductive care journey for practitioners, augmenting operational efficiency and enabling a focus on personalised care, ultimately translating into superior patient outcomes. For patients, it can reduce the emotional and financial burdens associated with multiple IVF cycles and offer prospective parents a more engaged and transparent experience throughout the care journey.

Yet, this vision is only possible if AI is developed and implemented responsibly. And if clinicians use it wisely.



Transparency and explainability drive responsible AI development

This brings us back to the initial question of responsible AI development and use, particularly when AI intersects with human life. It is not enough for AI to simply automate processes and provide a quality score. Rather, AI used in the field of reproductive care should qualify outcomes with explanations of how the AI arrived at a given conclusion, offering transparency on the process in quantifiable biological terms that practitioners understand.

Explainability and transparency form the cornerstone of 'Responsible AI' principles. It is only through transparent AI practices that we can strike a balance between technological innovation and ethical responsibility.

Beyond the specific domain of fertility, the requirement for transparency in AI development can shape the broader narrative surrounding AI's responsible integration into healthcare and society at large. Transparency serves to demystify AI mechanisms, ensuring that algorithms are comprehensible to stakeholders. This commitment to transparency nurtures trust and engenders accountability of those who utilise this powerful technology.

Active participation in discussions, collaborations, and initiatives aimed at ensuring ethical and responsible AI use helps to advance judicious AI integration. As AI continues to weave its way into every aspect of human life, the ethical considerations surrounding its use become increasingly pressing. The realm of fertility serves as a poignant case study in balancing AI's potential with ethical responsibility, illuminating the broader path forwards for responsible AI integration in society.

About the author

Eran Eshed is the CEO & co-founder of Fairtility, the transparent AI innovator powering in vitro fertilisation (IVF) for improved outcomes. He is a multidisciplinary business executive and serial entrepreneur with over 25 years of experience spanning numerous product and business domains. Eran was a co-founder and chief business officer of Altair Semiconductor, a wireless chipset innovator acquired by Sony in 2016. Eran holds a BsCEE in electronics engineering from Tel Aviv University.

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Event details

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Event details

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Event details

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Event details

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13-14 March 2024
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Event details

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Event details

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Event details

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Barcelona, Spain
Event details

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22-23 April 2024
Amsterdam, the Netherlands
Event details

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Event details

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