indegene™

The future of content review in life sciences organizations

- Review, Approval, and Dissemination in less than 24 hours

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Rapid innovation in the life sciences industry has led to faster product launches and an increase in the volume of product-related content. In 2021, the life sciences industry, witnessed an average of 3x increase in content production, thereby putting pressure on organizational budgets. To add to this, information consumption patterns of healthcare professionals (HCPs) and patients have moved toward on-demand, personalized, and real-time digital content. There is an increasing trend of HCPs and patients to decide on the "What, When, and How" of brand experiences. As per the *Digitally-Savvy HCP survey report* by Indegene, 62% of HCPs stated a preference for relevant personalized content for more insightful interactions.

3x

Increase in content produced across the life sciences industry

Source: Veeva Connect Summit 2021

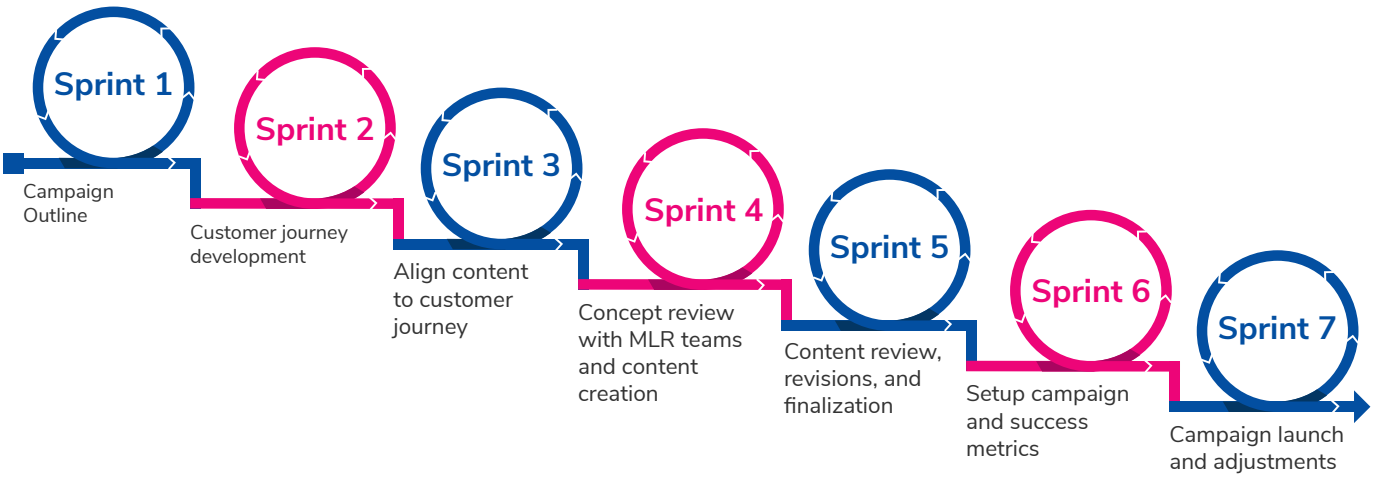
62%

HCPs prefer relevant personalized content for more insightful interactions

Source: Digitally-Savvy HCP survey report by Indegene

Today, understanding the information requirements, preferred content formats, appropriate marketing channels, or preferred time of information consumption of HCPs and patients is not a one-time job. Brands need an iterative and experimental approach to meet the evolving preferences of customers. They need to be agile and responsive to customer feedback and tweak content and campaigns in a quick succession. Healthcare enterprises are increasingly adopting varied strategies such as hyper-personalization of information through the customer journey, micro-customer segmentation, and device-specific content formats, which leads to increased and varied content types deployed in a short period (Figure 1). This, in turn, puts pressure on medical, legal and regulatory (MLR) review teams, to approve and deliver more content at a much faster rate.

Figure 1: Illustrative example of agile marketing approach being experimented by many organizations



MLR review teams are becoming a bottleneck in the content supply chain which is expected to only get worse with time. Current working models are not agile enough and are not able to keep pace with content creation, therefore causing a delay in the time-to-market for assets. In an increasingly competitive world, delays in the distribution of assets to the market result in revenue loss and reduced 'customer share of mind' opportunities. 'Agile brands' that can meet the information needs of an 'empowered, digitally savvy customer' will corner market shares.

The content review function is at the cusp of transformation. Legacy processes are not an option anymore!

67% of companies think that their organization has ambitious digital plans but only 27% are satisfied with their company's progress.

-Survey by Medical Affairs Digital Strategy Council and DT Consulting, an Indegene consulting business

The Medical Affairs Digital Strategy Council and DT Consulting, an Indegene consulting business, recently conducted a survey on the digital preparedness of Medical Affairs businesses. The survey results revealed that with respect to digital strategy and execution, 67% of companies think that their organization has ambitious digital plans, but only 27% are satisfied with their company's progress.

Organizations are increasingly realizing the importance of relooking at their MLR review processes in order to meet the ever-increasing volumes of content. They acknowledge the value that artificial intelligence (AI) can bring into the processes in taking away the mundane tasks from the reviewers and helping them focus more on new content that comes in. Within the content supply chain, the review and approval processes lend themselves relatively more towards automation when compared to the other processes, given the proportion of repetitive and rule-based work in review and approval.

Typically, the industry takes up to 40 days to complete the review/approval process right from the draft content (promotional materials) to the distribution stage. Today, given the amount of time that review occupies in the supply chain, the opportunity to shorten the time to market is significant.

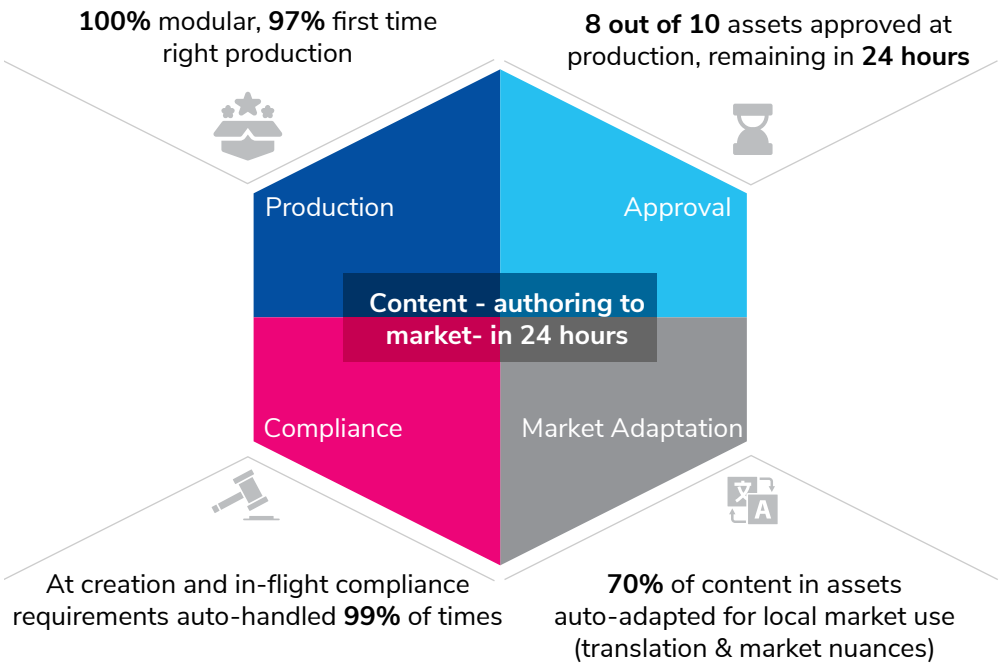
Most companies understand that there is a consistent need for new ways of incorporating data science in the ways of working. Currently there are new ways that are specifically addressing the quality and the quantity of data that comes through. AI will be the best bridge to be able to convert that data into business value.

- Georgia Gayle

Head of Commercial Promotional Review and Marketing Operations (US/Global and Japan)
Alexion Pharmaceuticals

With automation and AI progressively taking over marketing functions such as orchestrating campaigns and learning from market feedback, the future is moving toward “creation to distribution” of content in <24 hours. As customers interact with the campaign, AI will be able to pick up the right content modules to assemble tactics from a bank of approved modules, respond dynamically, and tweak campaigns on-the-go based on content effectiveness scores.

Figure 2: “MLR of the future” should meet the demands of content strategy



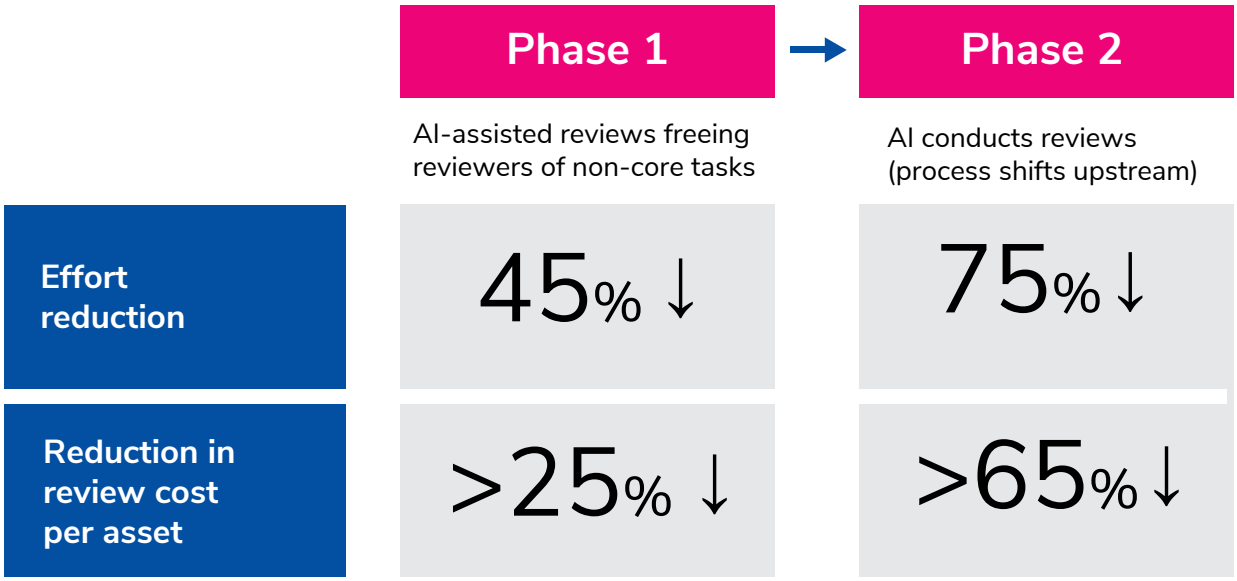
The “First pass right” content – where the first copy created is reviewed and approved for distribution with no or minimal revisions – will become necessary for the majority of content assets, if they are to reach customers on the same day as created. In simpler words, the content has to be created right the first time. Review needs to “shift-left” to the point when content is being authored, that is, 80% of the content is reviewed and approved at creation. This will require a progressive synergy of AI/machine learning (ML) and human involvement. Checks such as accuracy of data facts, right supporting evidence, presence of legal disclaimers, and appropriate medical messaging, all of which today successively happen after creation, will need to be done simultaneously and in a real-time as the author is creating content.

AI, if implemented right, can take over 80% of review and approval responsibilities, while reviewers focus their efforts on high-risk content and cocreation of de-novo content.

Roadmap to the future, defined by AI's maturity progress and "Shift-Left" review

AI, trained to mimic human reviewers, will evolve over the next few years and can be broadly charted across 2 phases (Figure 3).

Figure 3: The roadmap for MLR of the future can be segmented into 2 phases



Phase 1:

In phase 1, AI can be used to address specific point problems or to automate repetitive error-prone tasks, like in the following cases:

- Claims validation against approved repository – To identify and extract claims from assets and verify the extent of deviation against approved versions, thereby allowing reviewers to focus on new/unapproved claims (Figure 4)
- Comparison of content versions – To highlight content changes across asset versions saving reviewers' effort of having to go over the entire asset. This can also be used to identify unapproved content in an asset (Figure 5)
- Proofreading – Checks for basic spelling, grammar, style, and brand guidelines

Figure 4: Claims validation against approved repository

Note: Data and content used is for illustrative purposes only

Figure 5: Content comparator highlights changes compared to previous versions/original content

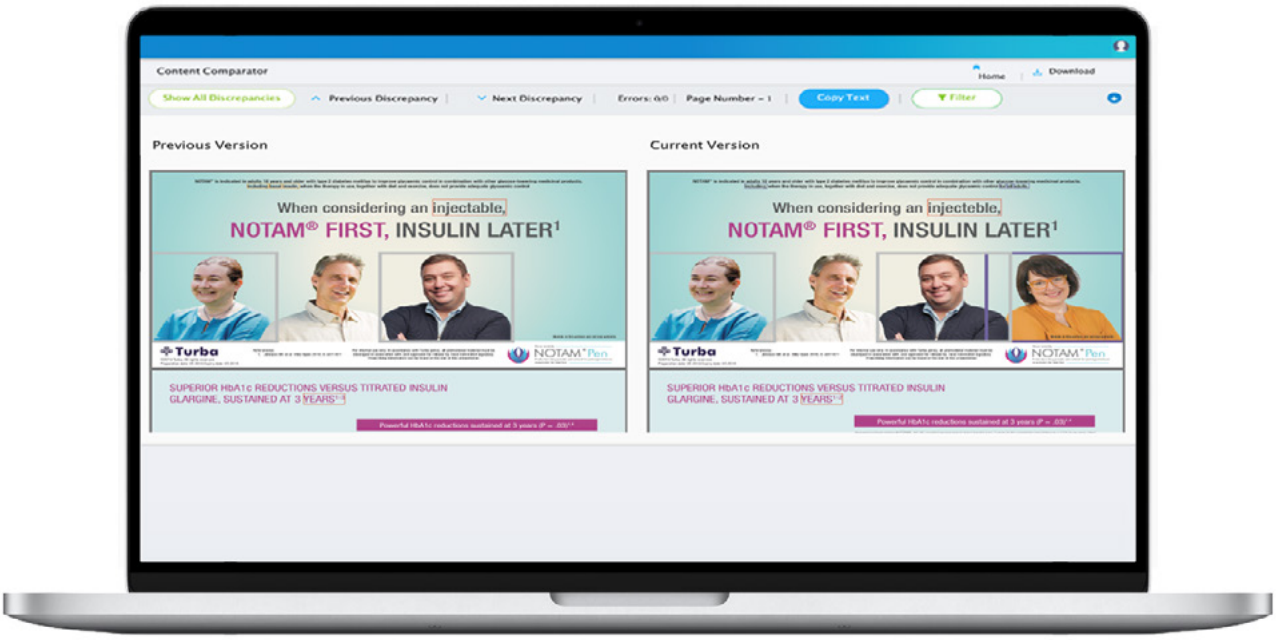


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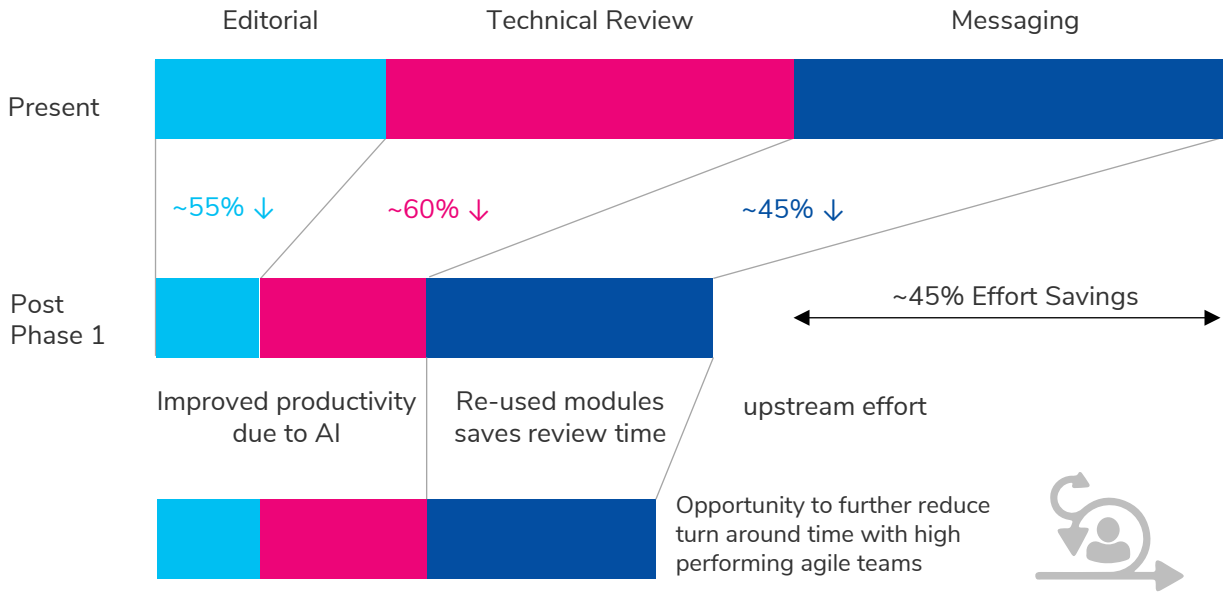
Figure 6: Phase 1 frees up substantial capacity for reviewers



Note: All numbers used are for illustrative purposes only. The actual numbers may vary on a case-to-case basis

Phase 2:

In a few years, AI will mature to “general intelligence” applications and cross the barriers of having to decipher the medical meaning and contextualize business rules into review checks. In Phase 2, AI can be deployed in the background to carry out review checks on assets being created much like how Google today predicts what we might be typing in the search bar in real-time. What it means is that the author will receive real-time alerts to correct any errors while the reviewer is working on the asset, as AI continuously scans the document acting very much like a human reviewer. Following are a few examples:

- Verification of data in the assets for factual and scientific accuracy, against a validated publication reference (Figure 7)
- Suggestions on sentence structure to bring the right medical meaning to correlate with clinical evidence (Figure 8)
- Recommendations on legal disclaimers to be included based on content and learnings from previously approved assets

Figure 7: Verification of data for factual and scientific accuracy

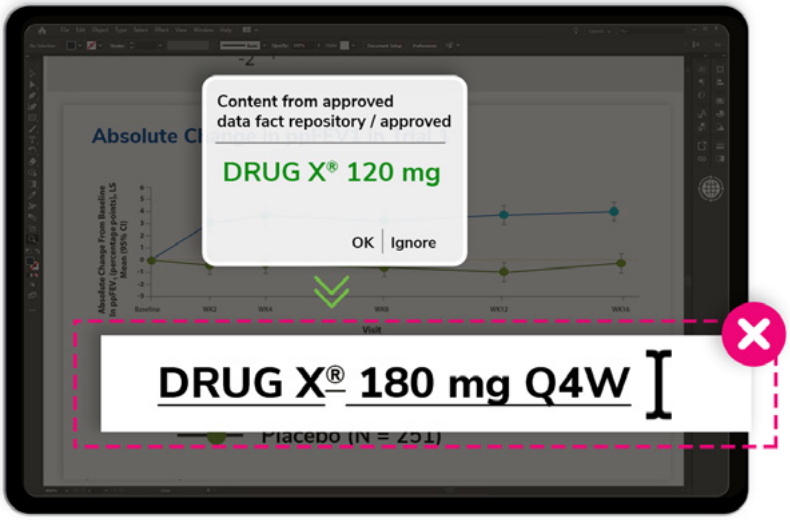
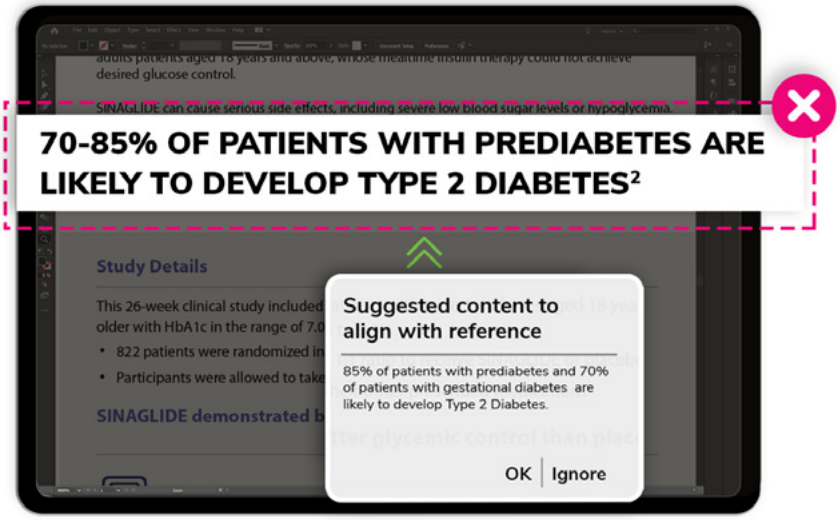


Figure 8: Suggestions on sentence structure to bring the right medical meaning



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While in Phase 2, AI will be ready to take over a majority of review decisions, a concept of "Risk Score" can be used to determine if the asset needs to be reviewed and approved by a human reviewer. A risk score is an indicator of the compliance and quality risk an asset is likely to carry after AI has conducted checks, as well as the subsequent corrective actions made by the author. A low-risk asset is one that is reviewed and approved by AI to meet all the required compliance and quality standards. A high-risk one is where there are deviations to the approved content and is perceived by AI as to requiring human judgment for approval. The process of risk scoring is one that would involve ML to evaluate risk as it reviews multiple assets and learns from the differences between decisions made by itself and that by a human reviewer (Figure 9).

Figure 9: Risk scores can be used to determine if content needs to be reviewed and approved by a human reviewer

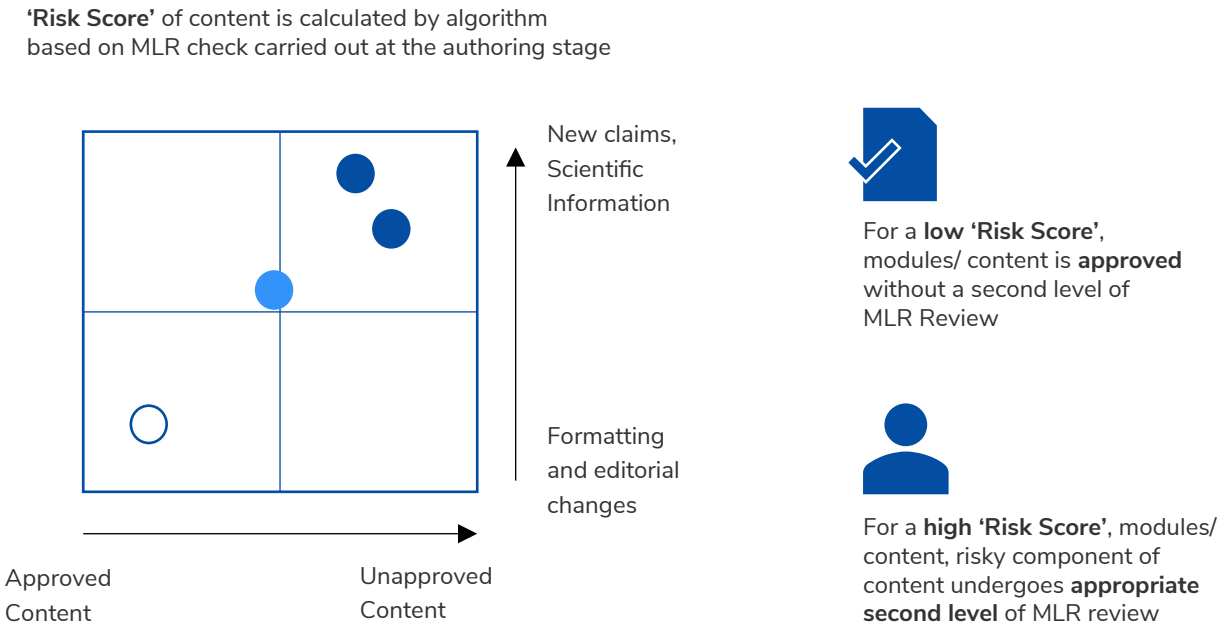
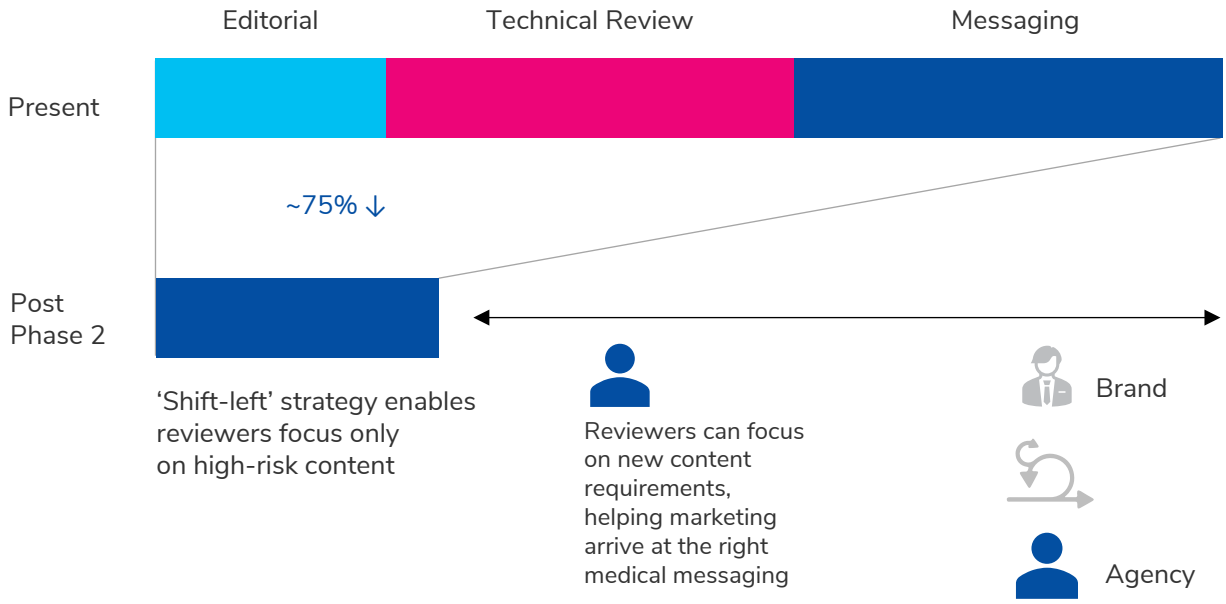


Figure 10: Phase 2 enables reviewers to play a key role in content strategy



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The role of technology in automating the review function will not stop at creating content right the first time but will expand in scope to solve for

- Faster adaptation of global content into locally usable assets – where the content is translated automatically into local languages and the translated assets are checked against local market regulations and nuances (eg, verified with locally approved label)
- Ensuring assets in distribution stay compliant with norms and regulations – monitoring for updates (eg, new clinical evidence, new regulation, about to expire content), identifying sections of assets that need to be updated, and triggering auto-update and review

Preparing for full-scale adoption of AI in review functions

Digitization of the knowledge base, IT infrastructure, and processes to maintain the knowledge base and development of AI models will pave the way to full-scale AI adoption in review functions.

For AI to automate review, it needs a knowledge repository of approved claims, data facts, references, clinical and scientific evidence bank, and regulatory and business rules, among others, to conduct checks on the assets. It will also require models that can separate the necessary data for extraction from noise, data pipelines to store the extracted data in a query-able repository, and a model that can use the stored data to conduct asset reviews accurately.

For example, a case for automation of data fact-checking in assets can be divided into

A.

AI model to identify and extract data facts from approved assets/other literature sources

B.

Database that can store the approved data facts and query them based on the need

C.

AI model that can compare the data fact in an asset, against the one in the database to determine a match

D.

AI model that can extract and add new approved data facts into the approved database

The collection of such use cases, AI models, and repositories will help propel organizations toward Phase 2.

The future of MLR will be a machine-plus-human effort model

In the current landscape, the majority of the burden of mundane tasks rests on the shoulders of review teams, but by shifting the review function and the responsibility onto AI, the role of reviewers will transition to be more consultative in nature.

As organizations adopt technology in review, reviewers will play the role of subject matter experts and help design the AI models, train the models to perform better, improve accuracy through vital supervised learning inputs, conduct quality audits, and provide the crucial human judgment required for high-risk material flagged by AI. A few examples could be

- Interpreting the latest privacy laws, arriving at what it means to show patient data in assets, and creating rules that can help the machine check on any compliance issues
- Adjusting weights for different parameters of risk scoring algorithm or risk categorization of assets

Essentially, reviewers will train AI to perform better to reduce the burden of review and help shift their focus toward high-risk content where they can add substantial value. AI-based automation will enable reviewers to shift their focus toward strategic pursuits. With every transformation, there will be early movers who will emerge as the innovators riding the trend, and there will be laggards or late adopters. Phase 1 and the learnings of deploying AI to automate point problems will be a precursor to full-scale adoption of AI in Phase 2. Early adopter organizations are bound to see an advantage of faster time to market of assets and a scalable review function at lower costs much ahead of the average industry player.

It is a journey and a long-term aspiration plan to make sure that we build our confidence in AI. It is not something that will happen overnight, though, we need to consider how can we facilitate it. We need to be partners and engage in proof of concepts, experiments, and try to see how can we help. We need to be in a place where we trust AI and machine learning and natural language processing to truly not require second tech afterward. But that will take time, not only from the AI capabilities point of view, but also from our team's engagement and building the trust with this platform. Experimenting with technology will to some level help us move forward towards big steps in the next few years.

- Georgios Tramountanis
  Head Global Oncology Medical Information and Review, Takeda

Think about where do you want to be in the long term, and start with small baby steps. Each time you move forward, you bring incremental value. And on the change management if you can find a value proposition for medical review teams, then that makes it significantly easier to move forward.

- Luis Albuquerque
  Associate Director Content Factory, Eli Lilly and Company

Change management is going to be key

> When you bring something new, some people are going to embrace it right away, while with others it will take a little bit of time. So change management and putting in some really well thought out and processes around it is a very important aspect.
>
> - Erika Song
> Director, Marketing Operations, Gilead Sciences

To manage the change as organizations progress through Phase 1 and Phase 2, they need to start drawing a roadmap for AI adoption in reviews; identifying use cases for automation; prioritizing them; and mapping capabilities, gaps, and timelines for executing the plan. In parallel, processes and review flows need to be redrafted to weave in automation use cases and reviewers trained to work side by side with technology. That said, change management from a human-acceptance perspective is also going to be a key aspect that organizations will need to consider. Teams will need to be involved in the process right from the strategy phase so that they are able to see the value that AI can bring into their day-to-day review tasks, and how their roles are going to transition towards high-impact and strategic ones, while AI takes care of the mundane tasks for them. By involving teams in the change process from the beginning, acceptance of change can be accelerated; moreover, the machine can be trained faster to tackle more real-world challenges through on-the-ground perspectives that the teams can bring into the picture.

Concluding remarks

Content consumption patterns in the life sciences industry are changing at a very fast pace. Organizations are already seeing and acknowledging the value that AI can bring to their MLR operations, though they are at a juncture where they need a guiding path to take the next step forward. Although adopting AI into the MLR processes might not happen overnight, a phase-wise approach where organizations can transition from manual reviews to AI-assisted reviews, and finally to AI-conducted reviews, which would allow teams with enough time to prepare their organizations to trust the technology as well as to adapt to new ways of working where AI takes on the repetitive tasks, and review teams transition to more strategic review roles.

References

1. The Digitally-Savvy HCP Learnings to Engage HCPs Around the World More Effectively and Efficiently https://www.indegene.com/insights/article/digitally-savvy-hcp
2. Veeva Connect Summit 2021

Note: All quotes in this whitepaper have been sourced from the "Webinar- MLR of the future: Accomplish review, approval, and delivery in <24 hours"

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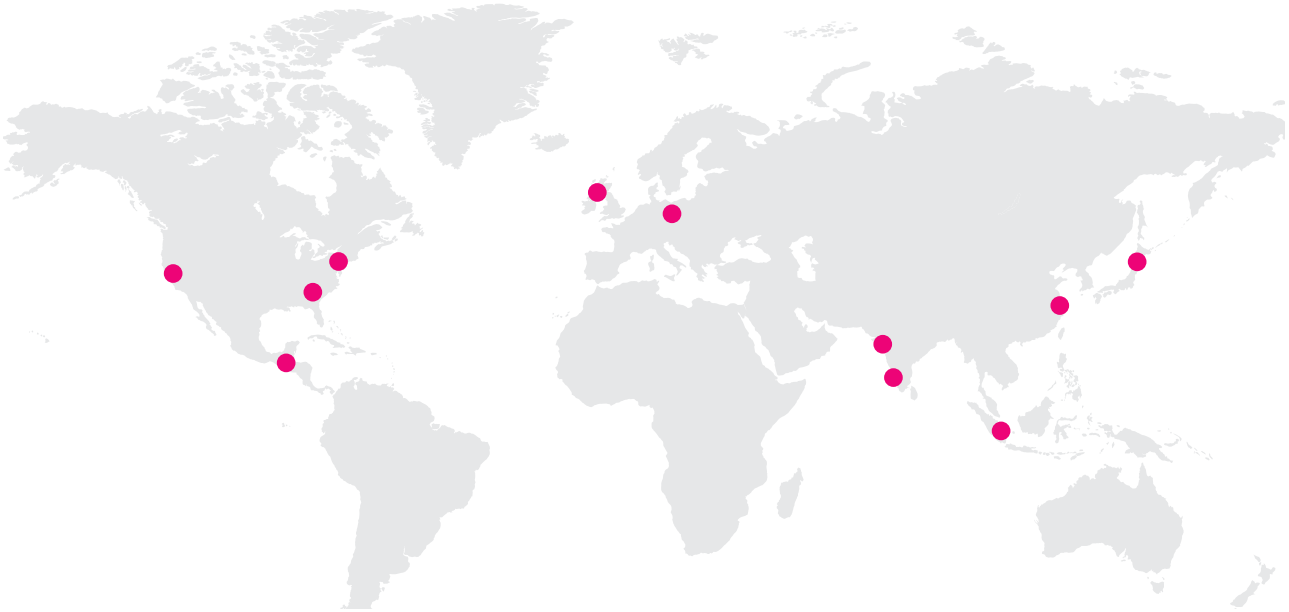
We are a technology-led healthcare solutions provider. We combine deep industry expertise with fit-for-purpose technology in an agile and scalable operating model. Many of the leading, global healthcare organizations rely on us to deliver effective and efficient clinical, medical, and commercial outcomes every day. From strategy to execution, we enable healthcare organizations be future ready.

Through local teams, we support healthcare organizations wherever they are



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