

WEBINAR PARTNER CIRCLE PROGRAM



Generative Al Application in MLR: Outcomes and Learnings

February 28, 2025

Indegene



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Indegene and Kyowa Kirin disclose they have a financial relationship.





Educational objectives

This session will provide a learning opportunity for our audience by:

Objective 1

Providing a bird's eye view of the state of MLR across the industry

Objective 2

Learn from a pilot implementation of an Al-based solution through a case study

Objective 3

Understand the future that is unfolding with Generative AI

State of MLR/PRC today



-MLR landscape is evolving at an increasingly rapid pace

Content transformation and AI-enabled automation are reshaping the MLR processes, leading to faster product launches and enhanced alignment with global regulatory requirements



MLR process needs to continuously evolve to keep pace with technological advancements, regulatory complexity, and the shift towards digital and personalized marketing strategies



The shift in MLR is being driven across three transformative themes

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Demands on MLR reviewers are increasing due to the rising complexity of content, heightened regulatory scrutiny, and an urgent need for faster and more efficient review processes



Holistically re-imagine MLR as an integrated part of the content supply chain



Reimagine an MLR process that:

- Aligns to the commercialization strategy
- Keeps collaboration at the center
- Is governed by metrics and data-backed insights
- Develops a culture of incremental innovation
- Uses AI that's tailored to its people and processes



A two-layered framework to assess your MLR process and identify solutions that tailor-fit your organization



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Benchmarking

- **Insightful** industry data resulting from a meticulous survey of 75+ life sciences organizations
- **Comprehensive** scoring across 12 key capabilities spanning people, process and technology
- Holistic assessment against industry peers and segmentation into 3 maturity archetypes





- **Integrated** evidence gathering including peer best-practices and the client's custom processes
- **Systematic** categorization of opportunities on effort required against impact created
- Elaborate ranking of key opportunities along with detailed implementation roadmaps



Elevate tactical benefits to strategic value

01

Competitive Edge

Analyze peer best-practices and develop a gold-standard process

02

Turbocharged Process

Accelerate time to market and reduce review cycle time

03

Skyrocketed ROI

Improve content utilization rates and develop priority review mechanisms



Case study and demo

What are your greatest challenges when it comes to MLR?

- Time consuming
- Delay in approvals
- Lack of standardization; inter-reviewer variability
- Assuring common quality and standards
- Modular content requirements
- Other



- Using AI in the MLR process reduces burden and boosts efficiency, making it faster and more agile, allowing focus on strategy and value driven tasks



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The problem statement

Medico Legal Review (MLR) is the process in EMEA for the review of content to be provided to external audiences. This process is time and resource intensive, and can overload reviewers and approvers during busy periods, causing delays and slowing down the process of pushing relevant content to our audiences. Without a standardized and automated solution subjective and inconsistent evaluations can also result in variable quality.

In short:

- Time consuming task
- Prone to **subjectivity** and inter-reviewer **variability**
- Variable quality and standard
- **Overloading** individual medical/non-medical reviewers
- **Delay** to review/approval timeline



-Using AI in the MLR process reduces burden and boosts efficiency, making it faster and more agile, allowing focus on strategy and value driven tasks



The ambition

- AI-powered first-pass review reducing turnaround time. Designed to deliver speed, efficiency and quality enhancements
- Increasing Efficiency: Lower resource burden (possibly higher accuracy) on reviewer/approver
- Higher inter-reviewer/approver consistency
- Increased strategic focus and time spent on more value adding activities



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Where we are today

- Al-based first pass review of the materials :
 - reducing turnaround time
 - allowing quicker approval at each stage of the process
 - Increased inter-reviewer consistency
 - empowering and upskilling content owners by automatically highlighted validation issues within minutes of upload
- Covering different types of materials (speaker slides, social media posts, press release, sales folder etc..)
- Video content under continued feasibility testing
- Review and validation of content (image & text) vs. approved claims, references, SmPC, local industry guidelines and editorial checks (e.g. Grammar, spell checks)
- Automatic highlighting and directing the user towards parts that may require a closer evaluation, providing rationale, reference.





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NEXT STEPS

- Finalization of PoC: validation tests and UAT's (user acceptance testing) with SME's
- Sharing of outcomes and learnings within the organisation
- Evaluation of further possible improvements:
 - Possibility for integration with internal platforms and multiple languages
 - Continuous learning and feedback loop based on human validations
 - Regulatory precedent checks
 - Increasing usage efficiency: e.g. finding summarization for signatories
 - Exploration of other use cases

What's in store for the future?



2025 - the year 'Agents' enter the workforce

"I follow instruction exactly"	"I can create based on prompts"	"I can understand goals and figure out how to	"I can think, reason, and learn like a human in any
RPA is the task automation that eliminates manual effort wasted on repetitive tasks	Gen AI is a productivity amplifier that accelerates creative and analytical work that bottlenecks humans	achieve them" Agentic AI is a collaborative actor that removes the need for constant human oversight of complex processes	domain" AGI is self-directed intelligence that overcomes human cognitive limitations across all domains
RPA	Gen Al	Agentic Al	AGI
Key Characteristics	Key Characteristics	Key Characteristics	Key Characteristics
 Executes structured, rule-based processes 	 Assists with specific tasks (writing, analysis, coding) 	 Acts as virtual co-worker completing end-to-end 	 General problem-solving ability across domains
 Performs repetitive digital tasks 	 Requires human direction and oversight 	processesSelf-directs and coordinates	 Autonomous learning and adaptation Human-level reasoning and understanding
 Operates within defined system boundaries 	 Improved individual productivity 	multiple tasksTransforms entire workflows	 Transfer learning between different types of tasks



What are Agentic Systems?







Peeling the layers with an Agentic MLR example





Agentic future for MLR







What we covered today



Organizations are evaluating adoption of AI for MLR review automation



Using AI in the MLR process reduces burden and boosts efficiency, making it faster and more agile, allowing focus on strategy and value driven tasks



Agentic AI acts as virtual co-worker completing end-to-end processes









MAPS Resources on the Topic {optional list}

