

Webinar will begin at:
10 December, 9:00 PM NYC
11 December, 7:30 AM Mumbai
11 December, 9:00 AM Beijing
11 December, 10:00 AM Tokyo
11 December, 12:00 PM Sydney



ISMPP University

AP ISMPP U: Generative AI in Medical Publications and Medical Affairs: Guidelines, Applications, and Adoption



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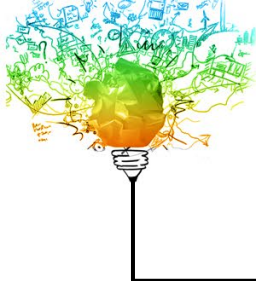
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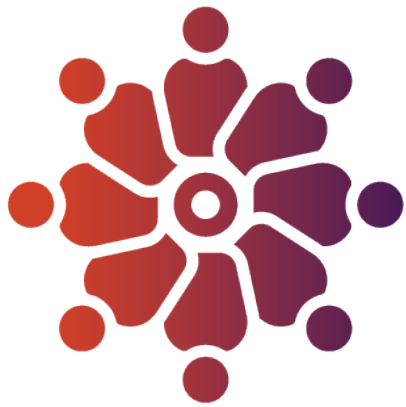
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Save the Date!



2026

September 17
Hong Kong

Asia Pacific Meeting of ISMPP

Look for more information soon from ISMPP:

Call for Program Committee members

Call for Session Proposals

Registration information



Register for upcoming ISMPP Meetings

Registration is Open



JAN
26-28

EUROPEAN MEETING
LONDON



APR
20-22

ANNUAL MEETING
WASHINGTON, DC



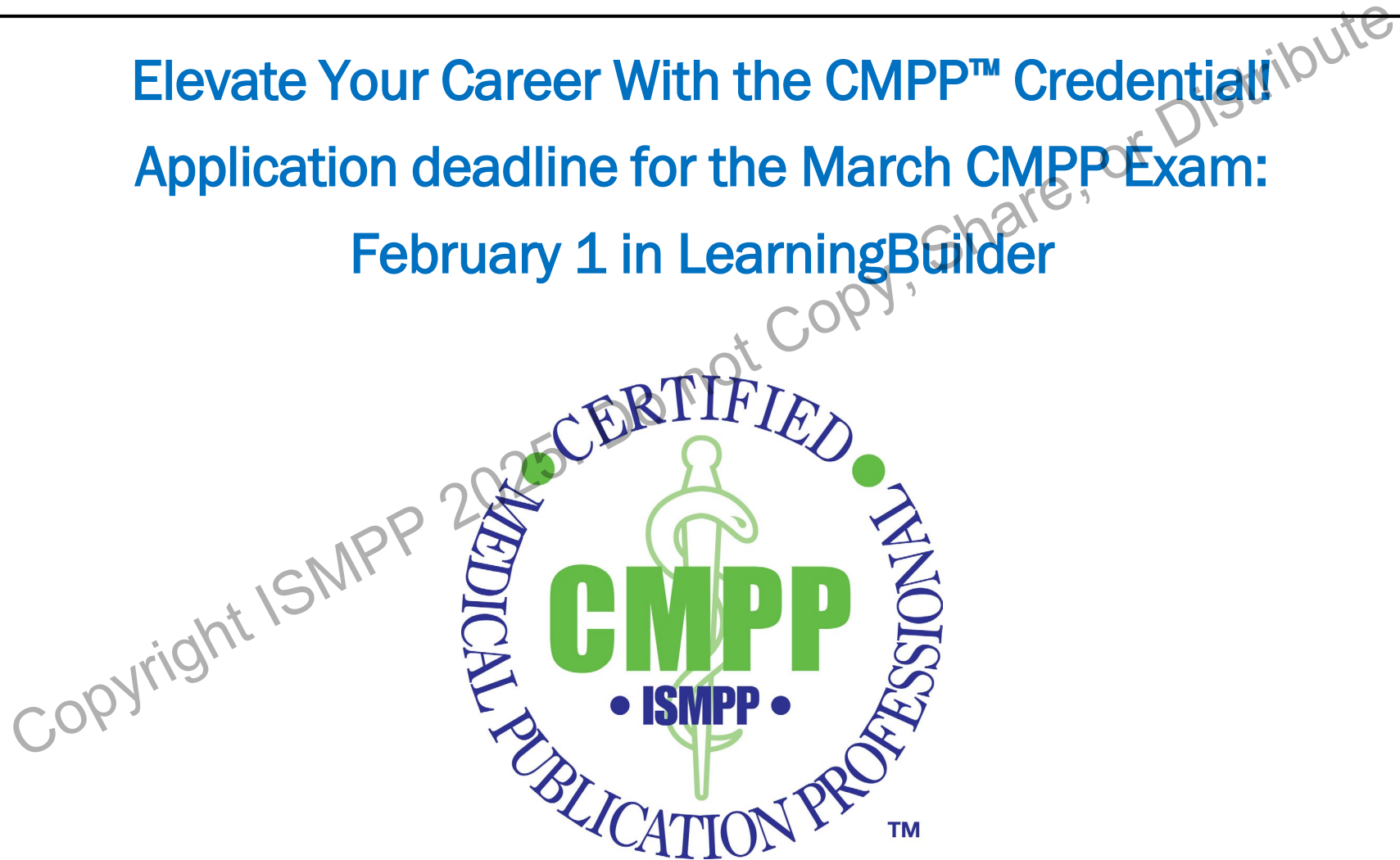


ISMPP announcements

Elevate Your Career With the CMPP™ Credential!

Application deadline for the March CMPP Exam:

February 1 in LearningBuilder





To activate captions

- Access the captions button: In the meeting controls toolbar, click the "Show Captions" icon (usually looks like a "CC")
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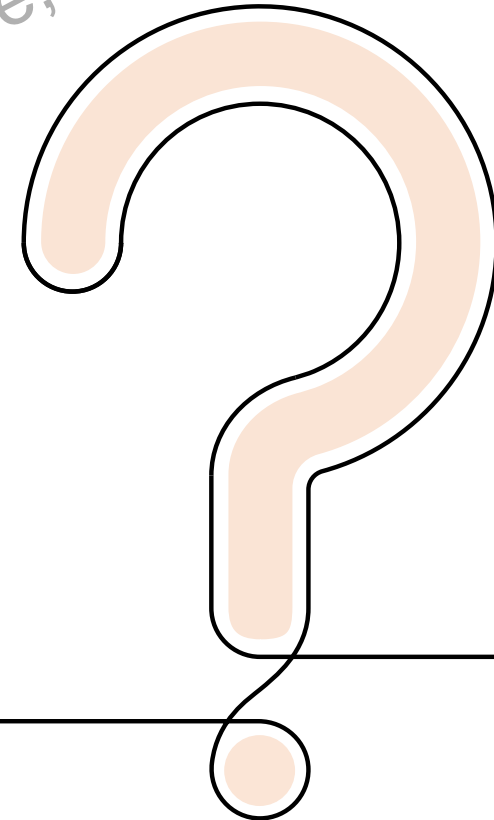
How to ask questions

Feel free to ask a question at any time; however, all questions will be held until the end of the presentation

To ask a question, open the Q&A window and type your question into the Q&A box. **Click Send**

Note: Check **Send Anonymously** if you do not want your name attached to your question in the Q&A

We will make every effort to respond to all questions live (out loud)





Learning Objectives

- Become familiar with ethical and compliance considerations for implementing AI in scientific communication/medical publications.
- Understand how AI could be utilized to streamline literature search and evidence synthesis across the publications lifecycle.
- Recognize opportunities for AI integration in medical affairs activities for insight generation.
- Recognize emerging uses of AI in peer review and their potential impact on authors and publishers



Today's Faculty



Amy Foreman-Wykert,
Executive Director, Scientific
Communication,
Inflammation Therapeutic Area,
Amgen



Angie List,
Director of Corporate Solutions for
Asia Pacific, Wiley



Olga Fadeeva,
Gastroenterology Medical Lead,
Growth & Emerging Markets, Takeda



Moderator: Kirandeeep Kaur,
Professor of Pharmacology,
Dayanand Medical College and Hospital, Ludhiana,
India.



Adopting AI

Presented by:

Amy Foreman-Wykert



Key Considerations of Adopting Generative AI

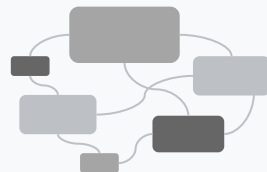
Intellectual Property & Security



Accuracy & Citations



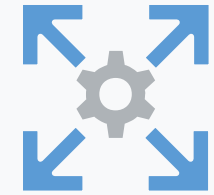
Right model for the purpose



Easy to get started and get value



How to manage at scale



Technology has the power to improve or worsen scientific communications.



ISMPP AI Task Force: Enhanced guidance on artificial intelligence for medical publication and communication professionals

Education and training	Implementation and use	Advocacy and community engagement
<p>Stay updated with advancements in AI</p> <ul style="list-style-type: none">• Take training offered by your company• Collaborate on training activities• Practice life-long learning• Practice with AI to improve AI literacy	<p>Integrate AI into work in ways that are responsible and ethical</p> <ul style="list-style-type: none">• Follow company policies and guidance on the use of AI and AI tools• Work with your IT team• Ensure fair access to AI tools• Follow guidance provided by journals & congresses• Respect academic integrity and copyright restrictions	<p>Be involved in AI policy formation both inside and outside of your company</p> <ul style="list-style-type: none">• Advocate for responsible AI use• Advocate for responsible AI policy and governance standards• Publish your AI research



Considerations When Creating Content

Key Considerations

- Checklist for Ethical AI Use (ISMPP Document)
- Disclose AI involvement
- Ensure copyright and IP compliance
- Avoid using AI for manipulative tasks (data/results)

STM Guidelines

- Human oversight is non-negotiable
- Gen AI tools should be publisher-approved, not public platforms

Ethics

- Authors retain responsibility for content accuracy and integrity



Publisher Considerations

Challenges

- Publisher restrictions on AI usage with content (STM guidelines: avoid public GenAI platforms)
- Rights needed to upload or process copyrighted materials via AI tools

Opportunities

- Open Access under CC-BY allows broad usage, including AI integration

Limitations

- CC-BY-NC (non-commercial use only)
- CC-BY-ND (no derivatives, restricting adaptation for content creation)

Specific Policies

- Rights required before uploading content to AI tools; subscription may not cover use for training AI

Copyright © 2014 Massachusetts Medical Society. All rights reserved, including those for text and data mining, AI training, and similar technologies.

- Permission for derivative works and quoted content



Mitigate Risk

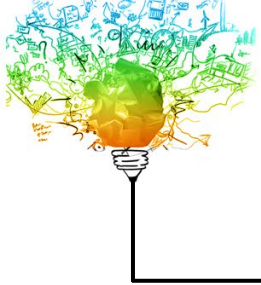
Risk Mitigation

- Use confidential platforms with proper licensing
- Anonymize sensitive data
- Do not upload sensitive or proprietary materials to public GenAI systems

Practical Steps

- Consult specific publisher policies (Elsevier, Springer Nature, Wiley, etc.)
- Work with cross-functional partners to implement data security measures
- Educate teams on GenAI use standards

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Understanding AI Tools

- **How was the tool trained?**
 - Publicly available information only?
 - Access to proprietary data?
- **When was it last updated?**
 - Training cutoff date
- **Opportunity for RAG (Retrieval-Augmented Generation)**
 - Can use your documents
 - Greater context and accuracy

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Can You Train AI Tools on Copyrighted Material

- Copyright laws vary by countries
- Use of copyrighted materials by AI tools is still an evolving legal issue
 - Commercial use is often not allowed
 - Comprehensive permission are essential for compliant use
- Consult your company legal colleagues as they can best advise on the current interpretation of these laws by the courts

Key Takeaway: Do not use copyrighted content to train AI unless you have permission, a license, or openly licensed material as we await greater legal clarity in various jurisdictions and stability in US, EU, and Asia on this issue.

Example 1: Literature Summary - Sources

- Query: Please provide a 3 bullet point summary of the recent publication on rocatinlimab that appeared online in The Lancet on November 23.

Public ChatGPT

- Two large global phase 3 trials (ROCKET-IGNITE and ROCKET-HORIZON) in adults with moderate-to-severe atopic dermatitis showed that subcutaneous rocatinlimab (150 or 300 mg Q4W after loading doses) met both co-primary endpoints at week 24, significantly increasing EASI-75 and vIGA-AD 0/1 response rates versus placebo. [PubMed](#)
- In IGNITE, EASI-75 was achieved by 42% (300 mg) and 36% (150 mg) vs 13% with placebo; in HORIZON, 33% vs 14% with placebo. vIGA-AD 0/1 responses were also higher with rocatinlimab (~19–24% in active arms vs 7–9% with placebo), with treatment effects considered clinically meaningful. [PubMed](#)
- Overall safety was acceptable and broadly similar to placebo; the most common adverse events were mostly mild-to-moderate injection-related pyrexia, chills, and aphthous ulcers, serious adverse events occurred in ~2–5% on rocatinlimab vs 4–6% on placebo, and no treatment-related deaths were reported. [PubMed](#)

Enterprise ChatGPT

- The Phase 3 trials ROCKET-IGNITE and ROCKET-HORIZON showed that Rocatinlimab led to **statistically significant and clinically meaningful improvements** in skin clearance for adults with moderate-to-severe Atopic dermatitis, with improvements measured by co-primary endpoints (EASI-75 and vIGA-AD 0/1) versus placebo. [The Lancet+2](#)[The Lancet+2](#)
- Patients receiving Rocatinlimab were roughly **three times more likely** to achieve significant reduction in eczema severity compared to placebo, and benefits — such as reduced itch, better skin condition, and improved quality of life — were **durable over time**, continuing through the 24-week treatment period and showing trend of increasing benefits beyond week 24. [The Lancet+1](#)
 - Rocatinlimab demonstrated a **favorable safety and tolerability profile**, with adverse events comparable to placebo, supporting its potential as a **first-in-class T-cell rebalancing therapy** targeting the OX40 immune receptor — a different mechanism than existing cytokine-targeting biologics. [The Lancet+2](#)[EurekAlert!+2](#)



Example 2: Literature Summary - Response

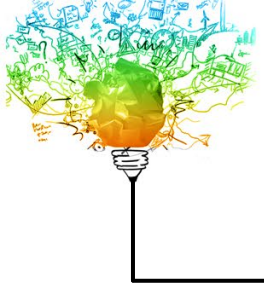
- **Query:** Using the Lipworth et al Tezspire article published in NEJM, and referring to the body of the paper only, not the abstract, please provide a concise 1 paragraph summary of the results.

Enterprise ChatGPT

- I can help you **only if you provide the text of the article body** (or upload the PDF), because:
 - The *Lipworth et al., 2025 NEJM* article is **not publicly accessible**, and
 - I cannot quote, summarize, or rely on paywalled content unless **you provide the actual text**.
- To ensure accuracy and to meet your requirement (“**use only data in the body, not the abstract**”), please upload:
 - the **PDF**, or
 - the **Results section, tables, and figures**, or
 - the **full article body text**.
- Once you provide it, I will generate a **concise, 1-paragraph summary** strictly from the body of the paper.

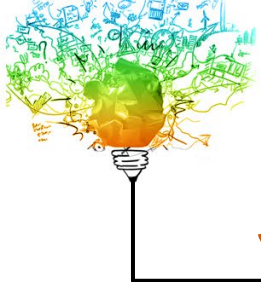
Enterprise ChatGPT (with article provided)

Using only the **body text, tables, and figures** of the Lipworth et al. 2025 NEJM article (not the abstract), the results show that in adults with severe, uncontrolled chronic rhinosinusitis with nasal polyps, **tezepelumab produced large and sustained improvements across all efficacy measures compared with placebo over 52 weeks**. Treatment led to markedly greater reductions in **nasal-polyp size** (LS mean difference -2.08) and **nasal-congestion severity** (-1.04), with improvements evident as early as weeks 4 and 2, respectively. Tezepelumab also significantly improved **loss-of-smell scores, SNOT-22 quality-of-life scores, Lund-Mackay CT scores, and total symptom burden**, with LS mean differences ranging from -1.01 to -27.44 across endpoints. Time-to-event analyses demonstrated substantial reductions in the need for **nasal-polyp surgery** (0.5% vs. 22.0%; HR 0.02) and **systemic glucocorticoids** (5.2% vs. 19.3%; HR 0.11). Safety outcomes were similar between groups, with comparable rates of adverse and serious adverse events. Overall, the body of the paper shows that tezepelumab consistently improved objective and patient-reported measures of disease severity and reduced the need for surgical or systemic-steroid interventions in this population.



In Summary...

- AI enhances discovery, consumption, and creation of scientific content
- Compliance with ethical, copyright, and publishing standards is critical
- AI applications must be disclosed transparently, with appropriate rights and permissions
- Specific challenges exist for medical writers and corporate researchers regarding licensing of content for use with AI
- Follow guidelines (STM, COPE, ISMPP) and ask the experts



Sources

- [New white paper launch: Generative AI in Scholarly Communications - STM Association](#)
- [AI Principles | Wiley](#)
- [Authorship and AI tools | COPE: Committee on Publication Ethics](#)
- [ISMPP AI Tools | <https://www.ismpp.org/artificial-intelligence-ai->](#)
- [<https://www.nature.com/nature-portfolio/editorial-policies/ai>](#)
- [<https://www.wiley.com/en-us/publish/article/ai-guidelines/>](#)
- [<https://www.springer.com/gp/editorial-policies/artificial-intelligence-ai-/25428500>](#)
- [The SPIRIT-AI and CONSORT-AI initiative | The Alan Turing Institute](#)



Applying GenAI in Medical Affairs

Presented by:
Olga Fadeeva

Disclaimer

Information presented today reflects the personal knowledge and opinions of the faculty and does not necessarily represent the position of their current or past employers or ISMPP.

- I am an employee of Takeda Pharmaceuticals International AG - Singapore Branch and own Takeda stock
- The content being presented represents my own opinions and not necessarily those of my employer



Reclaiming Scientific Clarity in a World of Excess

GenAI tools for Medical Affairs in the age of information overload

The explosion of scientific evidence has created an unprecedented challenge: the pace of discovery and growing number of publications now far exceeds our capacity to process it meaningfully.

Traditional Medical Affairs workstreams for searching, interpreting, and applying evidence were designed for a different era.





Medical Affairs Lead with Evidence. The challenge is Interpretation, Not Search

The Old Challenge

- Finding relevant literature
- Database access and search capabilities
- Retrieval speed and efficiency
- Coverage completeness

The Modern Challenge

- Synthesizing across multiple sources
- Identifying meaningful patterns and insights
- Contextualizing within therapeutic landscapes
- Translating evidence into strategic decisions

We don't need better search engines.

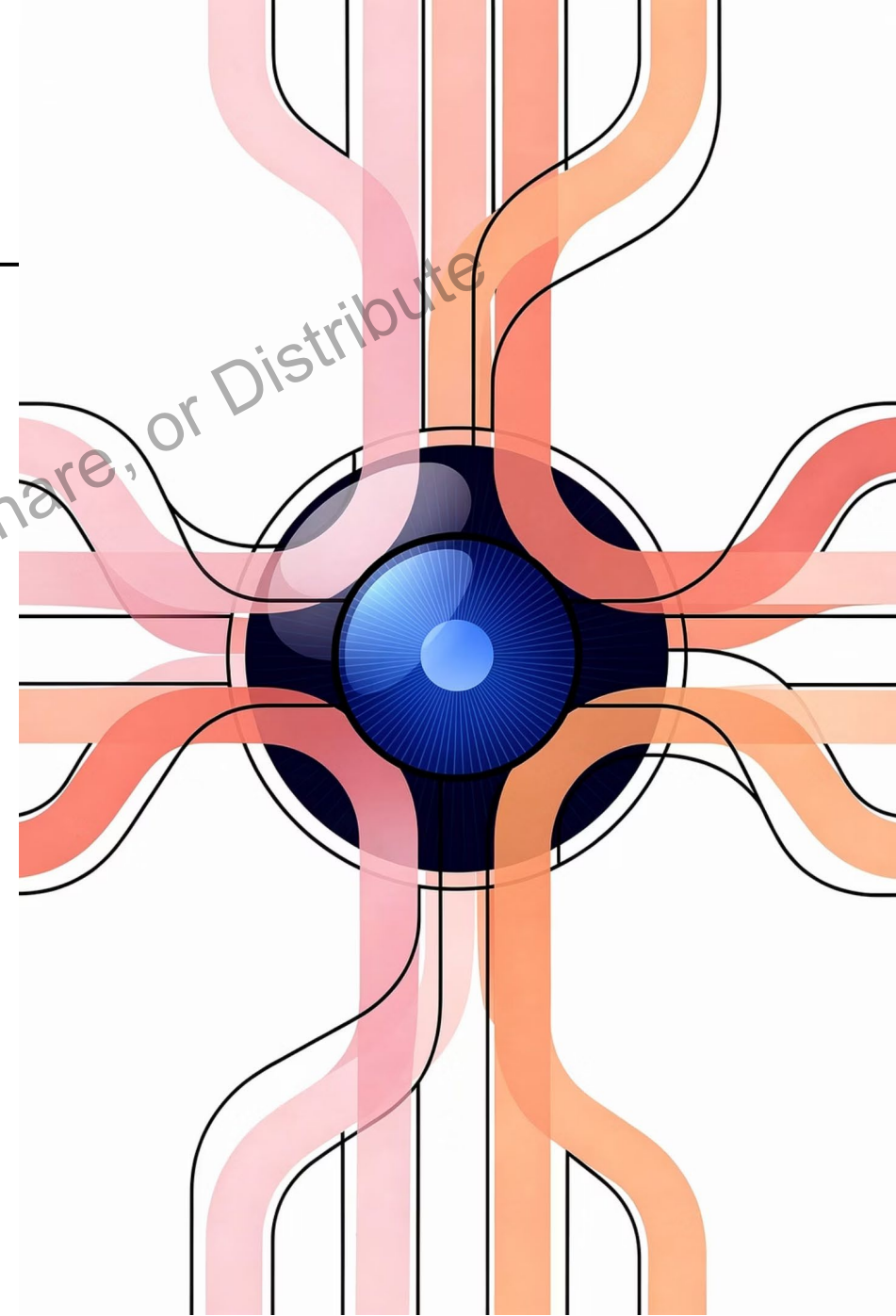
We need systems that understand scientific context, identify patterns, and surface what matters the most.

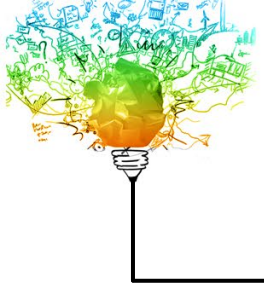


We envision solutions which

enable Medical Affairs to stay ahead of the curve in terms of the latest research and developments

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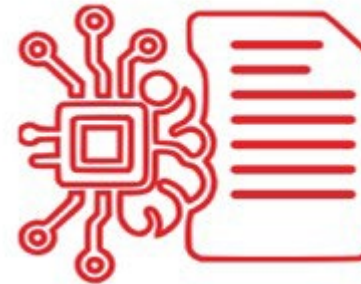


The AI empowered publications curation journey

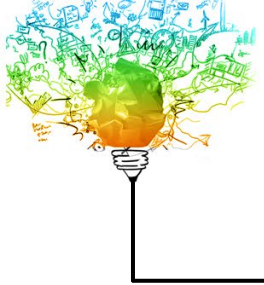
Literature search,
analysis & prioritization
TA/brand - specific



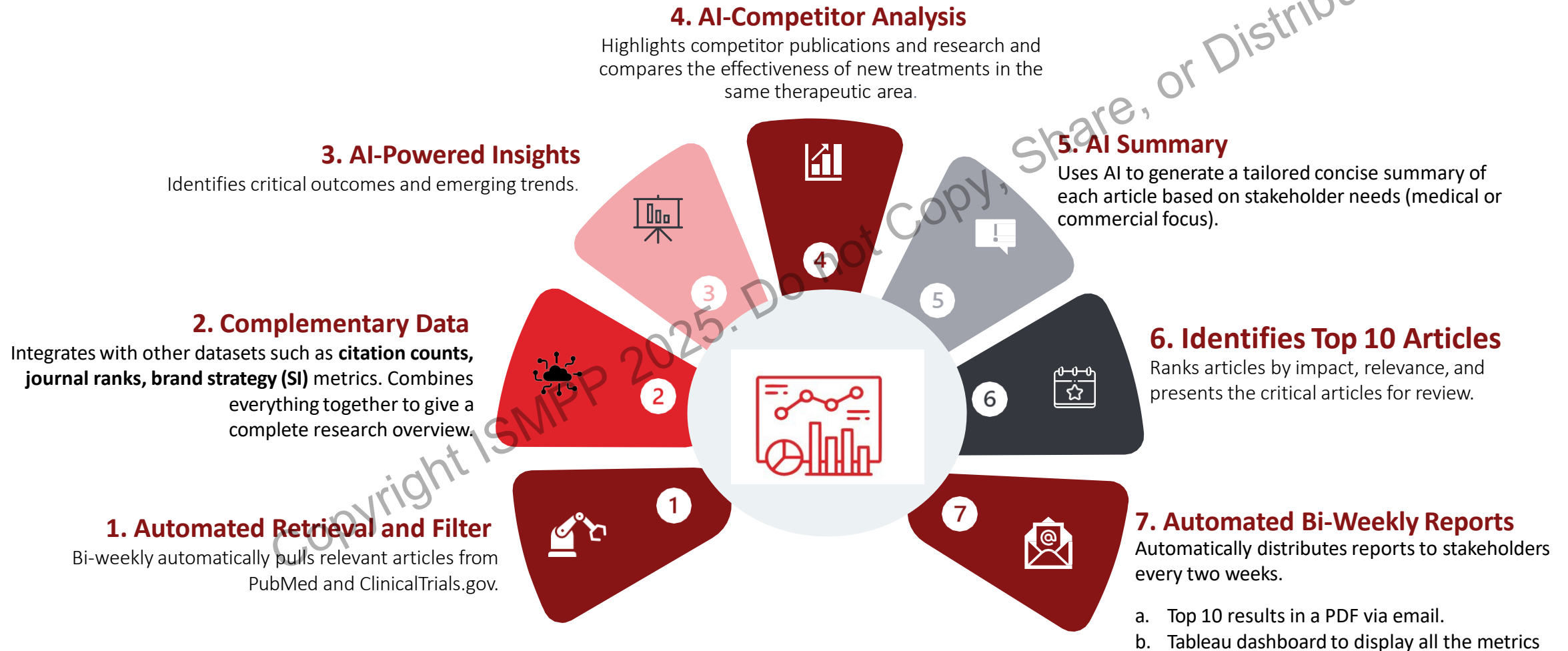
Deep dive into publications
& prepare communication
TA- agnostic



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A Scientific Knowledge Extraction tool: literature search, understanding & Insights empowered by AI





Gen-AI-enabled tool designed to streamline the way we digest and communicate scientific publications



Publication's Summaries: Validated, consistent, customizable

Create consistent, pre-prompted outputs



Interactive Document Chat

Ask questions about publications & receive evidence-based responses, generate discussion points and scientific statements



Figures Extraction

Redraw & extract images



Translation & Copyrights check

Translate and tailor summaries by audience/purpose

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Real word applications of the tool

Content Creation & Insights

- Critical alerts & summaries of key publications
- Enhanced evidenced-based insights for scientific differentiation
- External communication materials

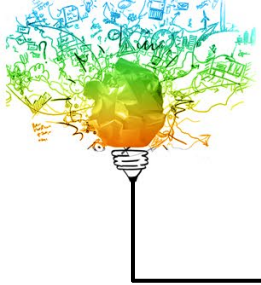
Preparation for external engagement

- Discussion questions for KOL visits
- Tailored summaries for impactful conversations
- Standardized scientific key messages

Upskilling & onboarding

- Self-training on new publication

Future development: AI-Enabled Medical Content Ecosystem;
MSL Companion Platform; Personalized Interfaces; Integrated Literature Intelligence



Faster is not better unless the output is scientifically accurate and relevant

Generative AI tools can automate operational tasks performed by medical affairs team, significantly enhancing productivity & efficiency

When output loses meaning

Prioritization becomes pattern matching.

Summary generation becomes repetition, not synthesis.

Extraction becomes literal, not meaningful.

Trend detection becomes noisy, not directionally useful.



Moving Beyond the Hype to Practical Impact

BUILD FOR IMPACT: FOUNDATIONS

- **Reduction of operational workload** across literature scanning, extraction, and summarization.
- **Support prioritization of high-relevance evidence** to focus on what matters the most.
- **Reliable, structured synthesis** to shorten time from data to insight.
- **Integration into established Medical Affairs workflows** without adding complexity.
- **Accuracy, consistency,** and scalability

BUILD FOR TRUST: GOVERNANCE

- **Transparent, traceable, auditable outputs** with documented methodology.
- **Clear quality standards and validation criteria** for all AI-assisted workflows.
- **Scientific data governance:** curated inputs, defined relevance criteria, expert oversight.
- **Alignment with emerging regulatory expectations** for responsible AI.
- **Human accountability** for final interpretation and communication.

FUTURE FRONTIERS

- **Ecosystems** and embedded agents?
- Shift from “human-readable” to “**machine-reasonable**” publications?
- Clear **standards** for AI-ready scientific **inputs**- manage risk of systemic distortion?
- Define and govern the **scientific ontology** for each therapeutic area?



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AI Adoption in Scholarly Publishing

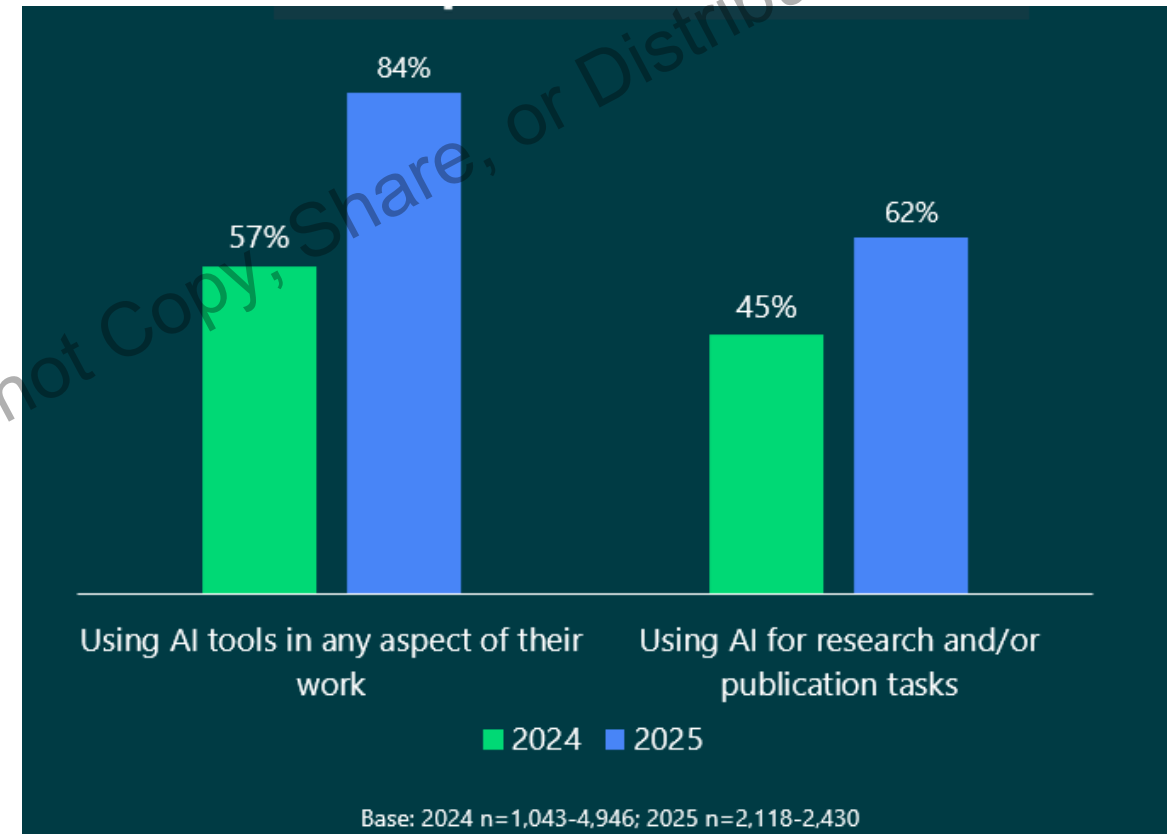
Presented by:

Angie List, Director, Wiley

ExplanAltions 2025: The evolution of AI in research.

- 84% of researchers are using AI tools for any aspect of their work, up from 57% last year
- Researchers using AI for research and/or publication-related tasks increased to 62%, up from 45% in 2024

See the full report here:



ExplanAltions 2025: The evolution of AI in research.



Act

Applies to use cases where interest is high and the consensus among researchers is that AI is already capable of outperforming humans.



ExplanAltions

	Interested in using in the next two years	Who does it better? HUMANS OR AI
Manuscript preparation and writing assistance Includes detecting errors or bias in own writing, writing assistance, formatting manuscript to comply with submission guidelines, and checking own work for unintended plagiarism.	74% 2024: 72%	59% 2024: 62%
Working with large amounts of information (monitoring/summarizing) Includes monitoring/summarizing key new publications in a field of study, reviewing large amounts of published and pre-print studies, creating data visualizations, and building a custom library of information tailored to an area of study.	70% 2024: 67%	56% 2024: 60%

ExplanAltions 2025: The evolution of AI in research.



Watch

Where interest is high but there's a general agreement that humans still outperform available AI tools, our recommendation to researchers is to 'watch' as the technology continues to develop.



ExplanAltions

	Interested in using in the next two years	Who does it better? HUMANS OR AI
Working with large amounts of information (processing/analyzing) Includes identifying key themes in existing published literature*, identifying gaps in the literature, data collection and processing, and processing unstructured or qualitative data.	65% 2024: 67%	57% 2024: 60%
Generating recommendations Includes literature review to select citations that best support my work*, generating reference recommendations, and selecting a journal to submit to based on the content of the article.	67% 2024: 64%	58% 2024: 56%
Making research accessible to a wider audience Includes creating "plain language" summaries of article findings, and generating educational content based on article.	62% 2024: 65%	59% 2024: 58%
Offloading essential but less engaging work Includes handling administrative tasks, writing up documentation, populating citations, and assistance in writing funding applications.	63% 2024: 58%	58% 2024: 57%

ExplanAltions 2025: The evolution of AI in research.



Envision

“Stretch” and ambitious use cases that are not yet feasible or strongly desired, but have the potential to address future needs.



ExplanAltions

	Interested in using in the next two years	Who does it better? HUMANS OR AI
AI-augmented peer review processes Includes helping peer reviewers adjust tone and clarity of feedback*, helping peer reviewers validate sources and claims*, adapting feedback into standardized format, increasing speed and ease of peer review, identifying peer reviewers with relevant expertise, peer reviewer recommendation tools, providing step by step guidance to peer reviewers*, and automated feedback to reviewers to ensure clarity in reviews.	55% 2024: 56%	60% 2024: 59%
Automated content generation for increasing article reach and impact Includes creating science communications tools, knowledge management agent to help make information broadly accessible, generating multimedia to broaden sharing of findings/build interest in article, generating video abstracts, and generating audio articles.	51% 2024: 53%	50% 2024: 51%
AI to enhance research methods Includes optimizing experimental design, advanced simulations that reduce the need for some bench research, and optimizing allocation of shared resources (e.g., lab equipment).	51% 2024: 54%	58% 2024: 58%



Publishing Innovation with AI-Powered Platforms

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Research Exchange: Submission



- Best-in-class author experience, leveraging **AI-powered auto transformation** to revolutionize the submission process
- Advanced metadata extraction **pulls out key information**, building connections through **industry-standard persistent identifiers**
- *Unlocks portfolio-wide metrics for powerful insights, and to enable effortless journal transfer journeys*





Research Exchange: Screening



- Cutting edge **multi-signal detection**, using **27+ innovative, integrated and actionable screening checks** alongside **industry-standard integrations** to preserve the credibility of scientific publication
- A flexible, manageable space for seamless **in-workflow** integrity and quality screening with **intuitive team management** and **SME escalation routes**
- Integrity checks shouldn't take place in silos: **deep cross-portfolio reporting, network analysis** and **early warning dashboards**

WILEY | Manuscript ID: 1030769

Search Q Rae Guzman Logout

Manuscript Info Activity & Messages

Pre-screening Check Info Validation Author Identity Verification

Manuscripts

Archived Manuscripts

User Management

Settings

+ Language & Wordcount Word Count 811 ENGLISH

+ Suspicious Words FOUND

+ iThenticate Score OK

+ Submission Similarity 1 MATCH FOUND

+ Machine-Generated Content Detection (BETA) SUSPICIOUS ACTIVITY

+ Problematic Phrases

- Scope Match NOT ENOUGH INFORMATION

i Learn More

The purpose of "Scope Match" tool is to evaluate manuscripts to assess how well they align with the scope of a journal. The matching score is based on a combination of factors, including topic relevancy and previously published content. We're making this data available to get feedback on whether detection tools like this are useful. This feedback will be used to improve the service going forward, and we hope to share improved methods in the future.

Scope check match: **Not Enough Information**

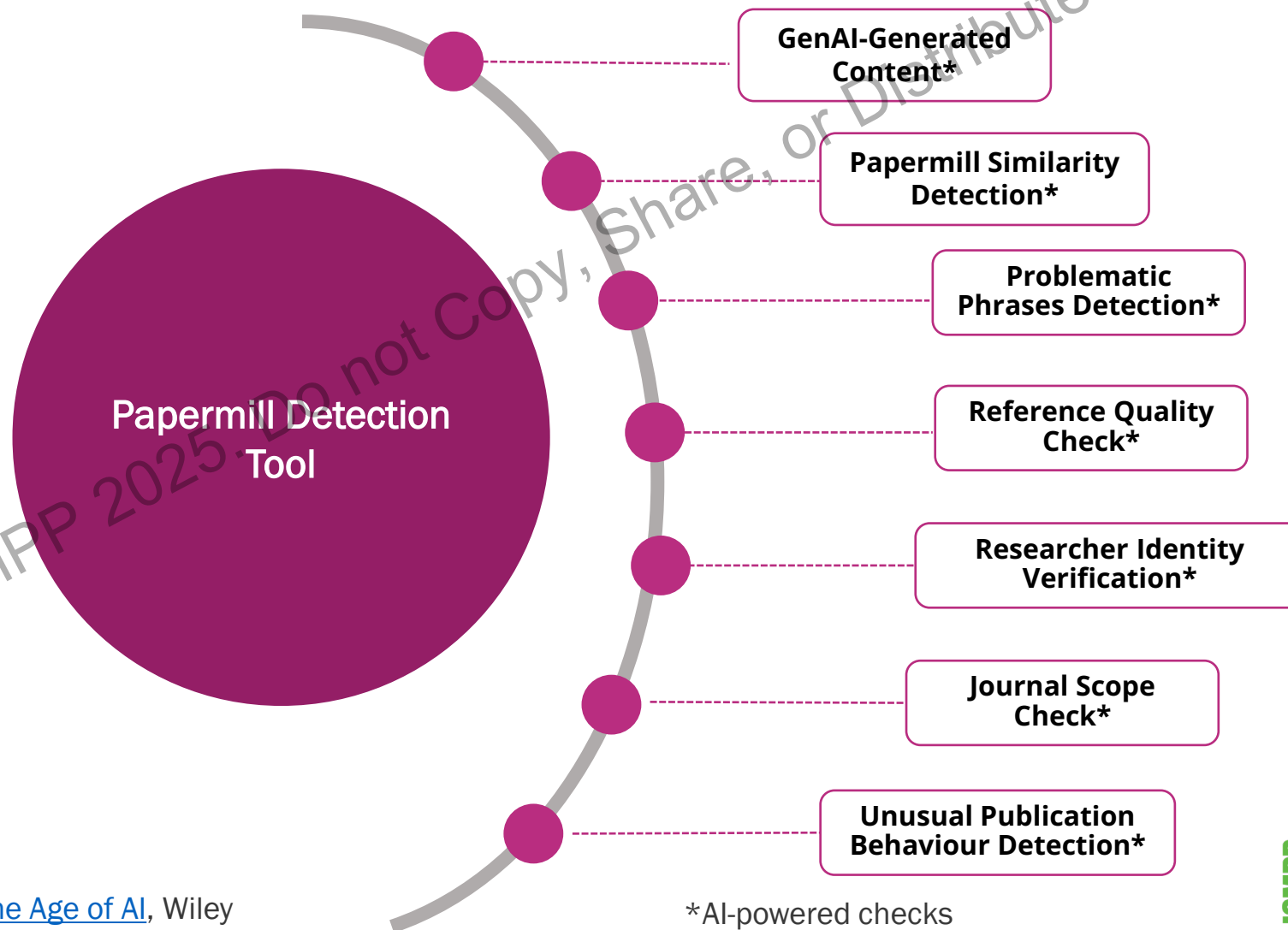
Key themes in the manuscript: targeted drug delivery; brain activity and meditation; neural activity; brain stimulation; brain function; neuroscience; cognition; brain mapping; deep brain stimulation; computer science;

Escalate Void Manuscript Return to Draft Refuse to Consider Approve Manuscript



Spotlight on Papermill Detection Tool

- This early screening tool, integrated into Research Exchange Screening, delivers immediate and actionable insights to users, helping address both the integrity and quality of submissions – and flagging potential concerns early in a paper’s lifecycle
- For journals on this workflow, this early screening phase detects at least one signal requiring further human review in 10-13% of all submissions

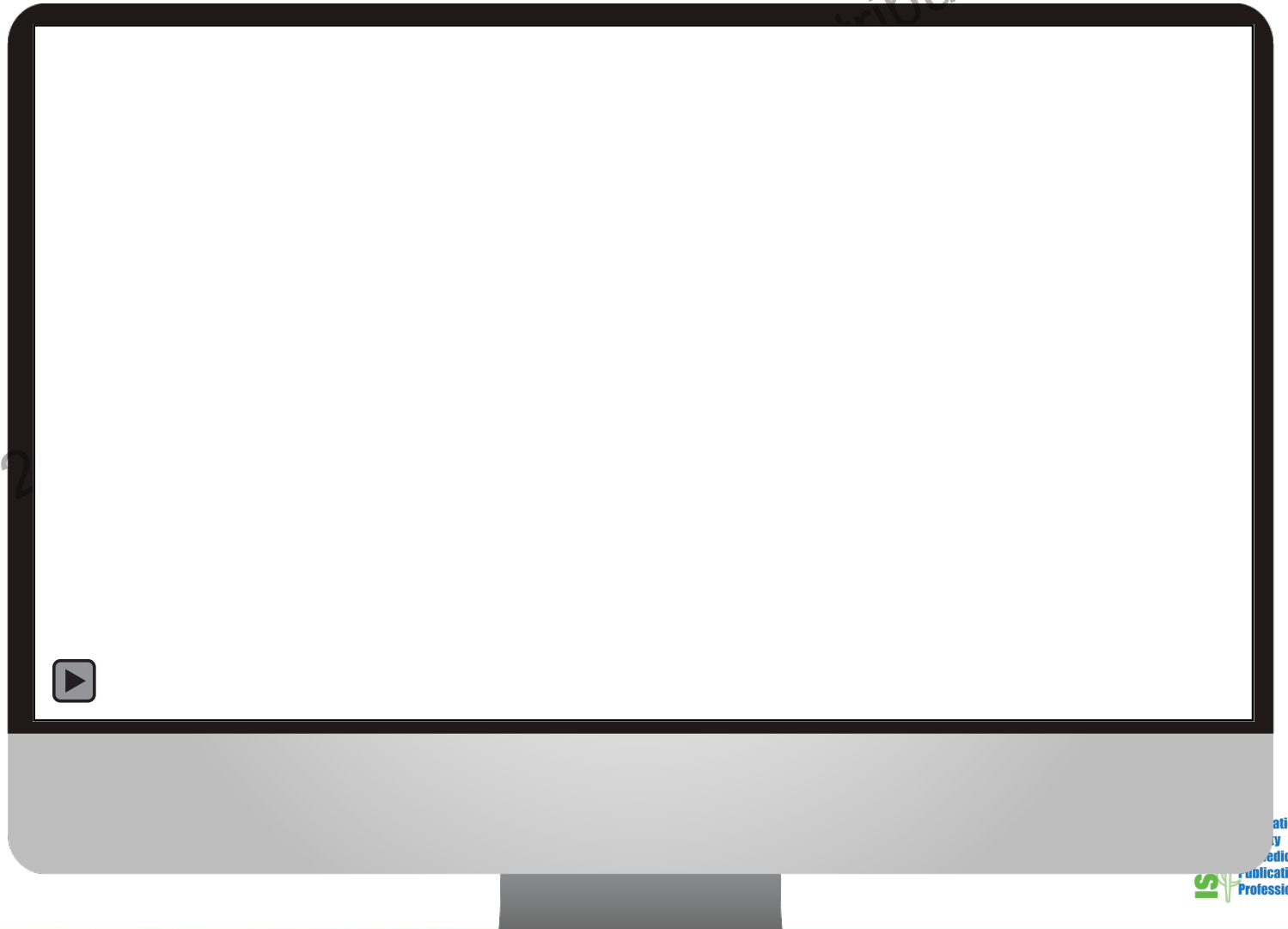




Research Exchange Review



- Smart peer review management tools that serve Authors, Editors and Reviewers. The final piece of our streamlined and output-driven system
- **Advanced AI screening tools** support the rapid identification of qualified reviewers
- AI is used to enhance and clarify reviewer profiles, ensuring that these enriched profiles can be leveraged for various purposes, ultimately benefiting both reviewers and authors.





AI in Peer Review

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Can AI reduce pressure without eroding quality?

Problem

212% increase in publications (2004-2024)

Explosion in research outputs

Not enough reviewers

Finding qualified peer reviewers in a timely manner
a challenge

Variable quality and timeliness

Quality of reviews completed is variable and often
slow

Reviewer burnout

Burnout is a real issue

Opportunity

✓ **New wave of published researchers can become reviewers**

Tapping into early career researchers assisted by AI

✓ **Technology can prompt and guide review process**

Automating steps and tracking

✓ **AI-empowered review, triage. Review as a commodity**

Potential for AI to assist (safely) in peer review

✓ **Transfer systems can reduce review waste**

Automated refer and transfer keep good research in the pipeline



Reducing review waste



Proactive novelty and quality assessment

First pass assessments of suitability and submission quality can help content find a home quicker, and get in front of the right experts at the right time



Empower transfer networks

AI powered-suggestions for journal transfer, and semantic analysis of submissions to journal scope can keep quality research in the pipeline



Better targeting of reviewers

Semantic matching of article content and publication history of potential reviewers, filtering and matching against availability, reviewing history, activity and expertise.



Helping editors make faster decisions

Guiding editors to the best reviewer matches with search filters and re-ranking as well as metadata that supports faster decision-making



Accelerating the publishing process



Methodology and statistical evaluation

Flagging potential weakness in design or analysis early, given editors and reviewers a head start or surfacing things that are less clear to the eye



Literature mapping

Automated synthesis show where a manuscript 'fits', what it builds on, what it's missing, and where it challenges and transforms prior work



Clarity and reproducibility

Scanning for vague methodologies, adherence to reporting guidelines, identify biases, and surface these for reviewers and editors to work with



Structured critique and review drafting

Quickly outline key strengths and weaknesses. Reviewers still refine and judge, but AI can help them get there faster



AI review as a double-edged sword



AI-generated manuscript floods

Mass submissions of AI-written papers (with fabricated data, fake citations, or recycled content) can overwhelm editorial systems, making it harder to identify legitimate research



Detection arms race

Uncertainty about whether manuscripts, reviews, or rebuttals are AI-generated versus human-written can create trust issues and require new verification processes, slowing down review cycles



Overreliance and deskilling

Reviewers may defer to AI assessments without critical evaluation, potentially missing nuanced issues while also losing their own analytical skills over time.



Inconsistency and biases in tools and standards

AI tools may systematically disadvantage certain research approaches, non-English authors, or interdisciplinary work through hidden biases, while confidently flagging false positives that waste reviewer time investigating non-issues.



AI amplifying challenges in research integrity



Fabrication and falsification

AI can generate believable but false data, graph, citations, or paraphrase and combine works - making it harder to know what's genuine



Training data issues:

AI systems are trained on copyrighted or proprietary works (often without permission), raising concerns about intellectual property theft and uncredited reuse.



Invisible or accidental plagiarism:

AI can reproduce or remix content without attribution. This risk is heightened for early career researchers who may not spot recycled content, content undergoing translation, or for researchers from academic cultures with different citation norms



Gaming peer review:

AI can be used to write fake reviews, impersonate individuals, or mass submit fabricated feedback, undermining the trust and transparency of peer review processes



Choosing a path forward

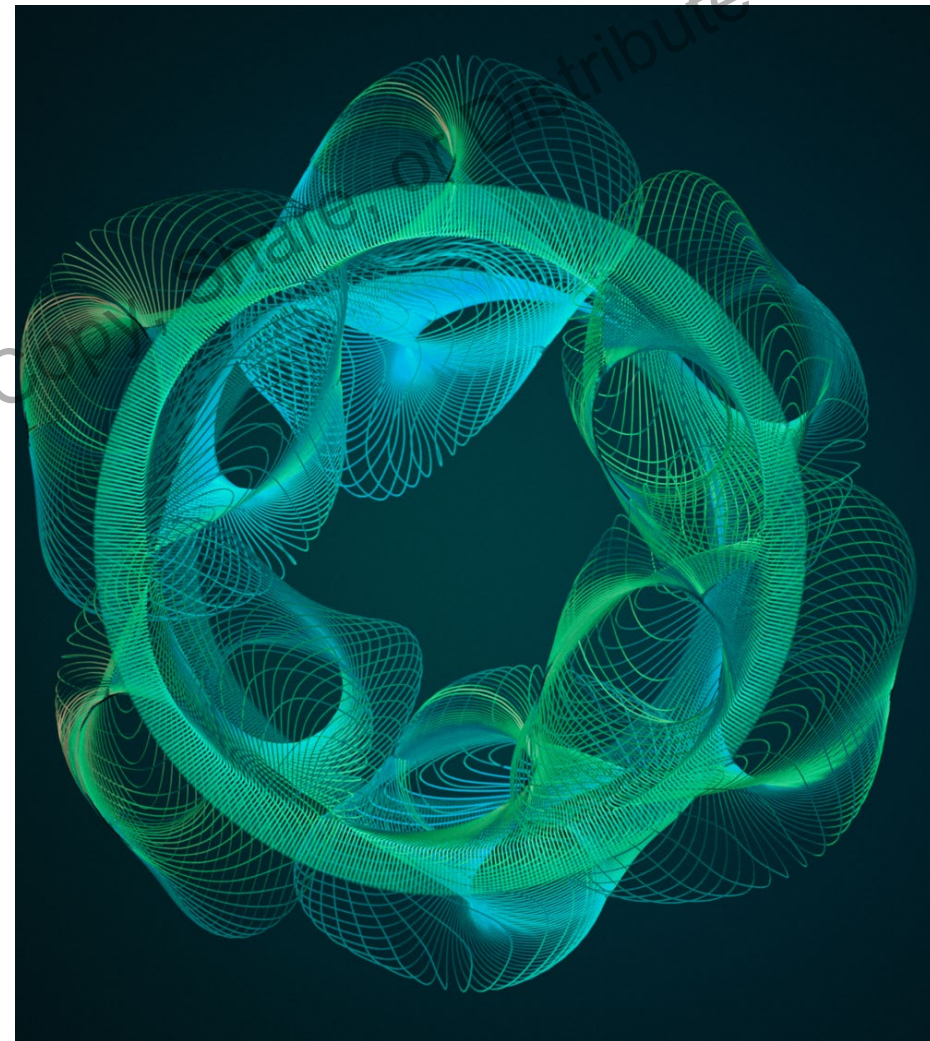
AI in research isn't about whether to use it, but how to use it **responsibly**.

The ecosystem needs to create environments where researchers can feel more confident to use AI effectively and ethically in their work. This requires:

- Guidelines which balance transparency with practicality
- A focus on building AI competence across all career stages
- Clear frameworks for bias detection and privacy protection
- Wide support for innovation, policies, and research integrity

Wiley AI guidelines:

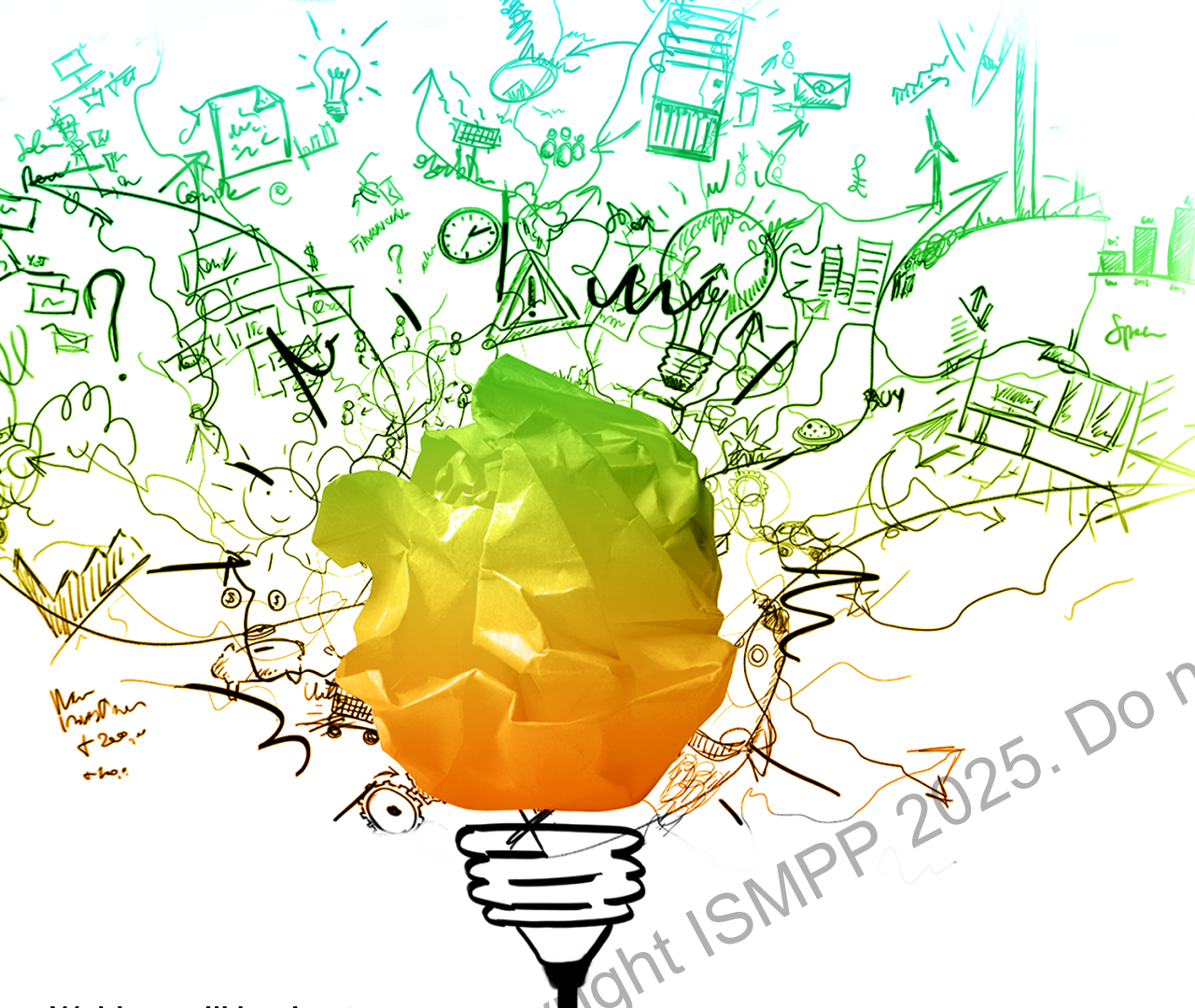
<https://www.wiley.com/en-us/publish/article/ai-guidelines/#author>





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To ask a question, open the Q&A window and type your question into the Q&A box. [Click Send](#).



ISMPP University

AP ISMPP U: Generative AI in Medical Publications and Medical Affairs: Guidelines, Applications, and Adoption

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- 11 December, 9:00 AM Beijing
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