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ISMPP Announcements

This webinar is free to all in honor of #MedComms Day!

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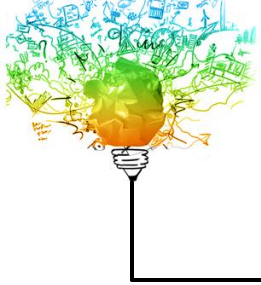
ISMPP Announcements

NEW ISMPP Academy

Save the date: **September 28–29, 2023**

Where: **Convene, Philadelphia**

ISMPP Academy is a new meeting that will deliver
best practices education to professionals:

• Who work at biotechnology, small pharma, and medical device companies •

• Who are newer to the field •

• Who want to build their expertise •

More details to come!
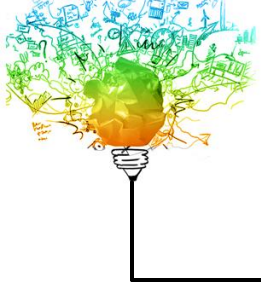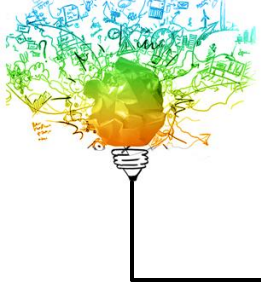
How To Ask Questions

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

To ask a question, open the Q&A window, 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)

Disclaimer

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

Objectives

- Understand the challenges of creating systematic reviews from real-world evidence (RWE) for publication planners and other stakeholders

- Learn how AI/NLP can be used to overcome the challenges of creating systematic reviews from RWE

- Explore the benefits and limitations of using AI/NLP in systematic reviews from RWE

- Understand the regulatory requirements for using AI/NLP in systematic reviews from RWE

- Learn best practices for using AI/NLP in systematic reviews to ensure compliance and quality

Faculty

Tara Cowling
President and Managing Principal,
Medlior Health and Outcomes
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Mark Priatel
VP, Software Engineering,
DistillerSR Inc.

Patti Peeples
President & Founder,
The Peeples Collaborative

Poll Question 1

Have you previously worked with Real World Evidence (RWE) and/or Artificial Intelligence (AI) in the context of creating systematic reviews?

a) Yes, I have experience working with both RWE and AI

b) I have worked with RWE, but not with AI

c) I have worked with AI, but not with RWE

d) No, I have not worked with either RWE or AI

Tara Cowling

President and Managing Principal,
Medlior Health and Outcomes Research
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RWE and SLRs

- RWE studies – **evidence identification**
  - Heterogeneous study designs
    - Any observational study
  - Not indexed as RWE
  - Search results may be large (depending on population)
  - Resource-intensive screening

- RWE studies – **screening**
  - No standardized reporting requirement from journals (vs RCT with PRISMA)
  - Varied reporting of methods (transparency on data provenance and detailed methods for generating results due to IP)
  - Standardized protocols and reporting are in early stages of adoption (e.g. STaRT-RWE and HARmonized templates)
  - Real World Evidence Registry has also been established to promote transparency

Case study: SLR on Gene Therapy

- Gene therapies

  - Due to a lack of <u>gene therapy</u> comparator – all comparators must be reviewed

  - All comparator evidence can lead to a massive volume of hits

  - Medlior SLR on hemophilia had ~**30k hits**

  - Observational studies meeting criteria = **404**

- Opportunity for AI

  - For large screening volumes AI could assist in multiple ways

    - Re-ranking (move high probability to the top)

    - Quality assurance (flag any decisions that may require another review)

RWE and Regulatory/HTA

- Gene and cell therapies are rapidly coming to market with large comparator evidence to summarize

- Currently HTA bodies do not provide guidance on applying AI within the the SLR component of the dossier.

- SLR guidance typically follows Cochrane methodology (e.g. two reviewers)

- More demonstration of validity of AI-assisted reviews and quality control

- Considerations for HTA adoption include transparency on how AI was leveraged and risks/mitigation on the results (e.g. quality of training data)

- For publications transparency is also key on AI methods used – this may be challenging if commercialized (e.g. IP on code/ algorithms)

AI and Product Life Cycle

- Manufacturers can utilize AI technology to **conduct large SLRs** during pipeline stages to inform decision-making

- AI can be **second screener** or complete screening to facilitate faster timelines with lower costs

- AI can be used to **integrate SLR extraction data** to understand trends or insights into subpopulations or outcomes

- AI screening is likely to be more accurate if training data is robust

- AI can provide **insights into large datasets** that would be **resource-intensive for human-only analysis**

Mark Priatel

VP, Software Engineering, DistillerSR Inc.

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Poll Question 2

How would you rate your level of knowledge on AI and Machine Learning?

a) **Beginner** - I have little to no knowledge

b) **Novice** - I have basic familiarity but limited practical experience

c) **Intermediate** - I have a solid understanding and have applied them in some projects

d) **Advanced** - I have extensive knowledge and practical experience

e) **Expert** - I am a recognized authority in this field

AI vs ML vs NLP
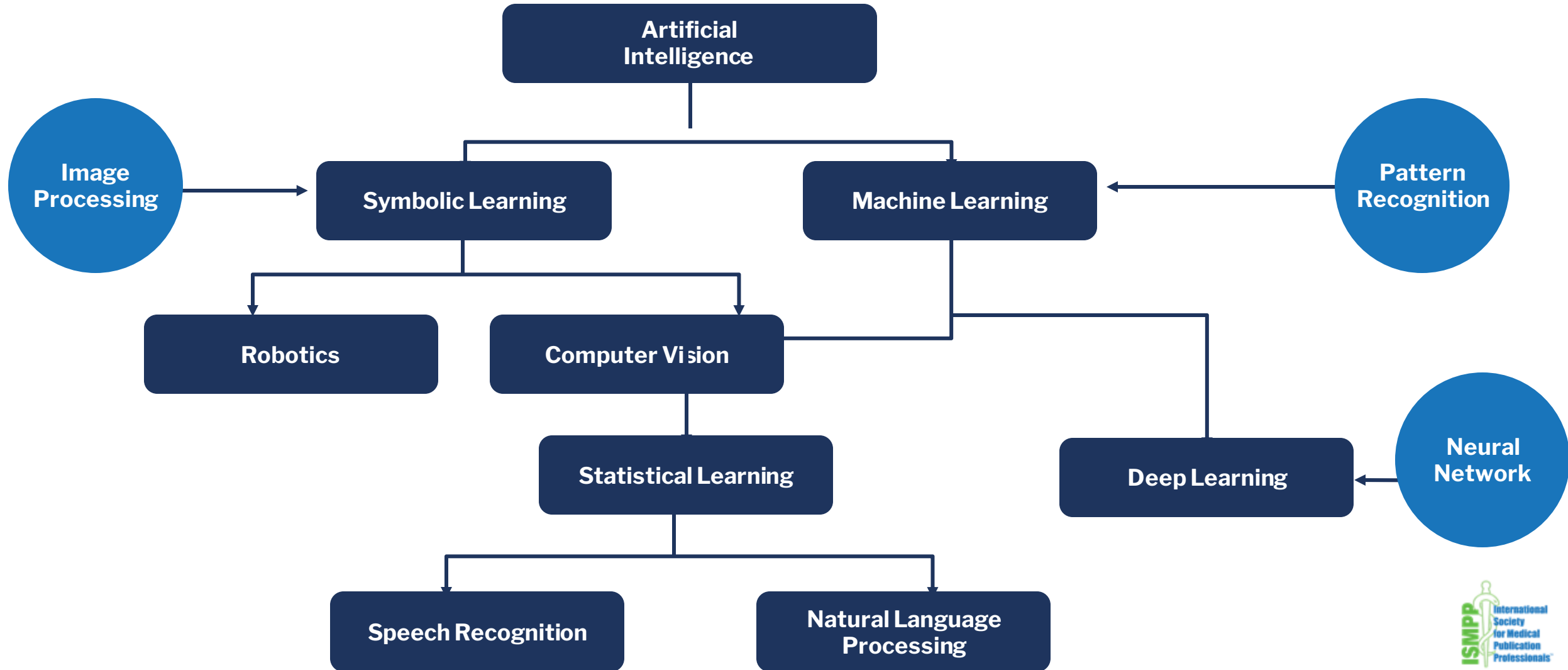
Problem & Solution

What Problems can ML Solve?

Classification

Prediction / Regression

Clustering

Anomaly Detection

Image Processing

How can ML Solve them?

Decision Trees (separate data based on groups)

NLP (teaching computers how to understand and talk like humans)

Linear Regression (to understand how data points are connected)

Deep Learning (smart decisions based on pattern recognition)

Large Language Models (Understanding and generating most probable text)

The solution depends on the problem you are trying to solve and your constraints.

Constraints

Each application of ML has different constraints

Trust
- Explainability
- Transparency
- Bias
- Determinism*

Scale
- Execution & training time
- Cost

Data
- Quantity
- Quality
- Feature set

Performance
- Accuracy
- Metrics and baseline
- Cost-of-failure*

Determinism

Deterministic

Consistent and predictable results based on input.

Not adaptive; Rules-based; Highly explicable; Specific results

Examples: Linear Regression; Decision Trees; Support Vector Machines (SVM); Naive Bayes

Non-Deterministic

Results can be variable (or completely random) based on input.

Adaptive; Creative; Opaque; Can produce both Specific and abstract results.

Examples: Neural Networks; Random Forests; K-Nearest Neighbors; Genetic Algorithms

Determinism helps Publication Planners better assess the reliability and validity of the systematic review findings

DistillerSR: Smarter Reviews: Trusted Evidence
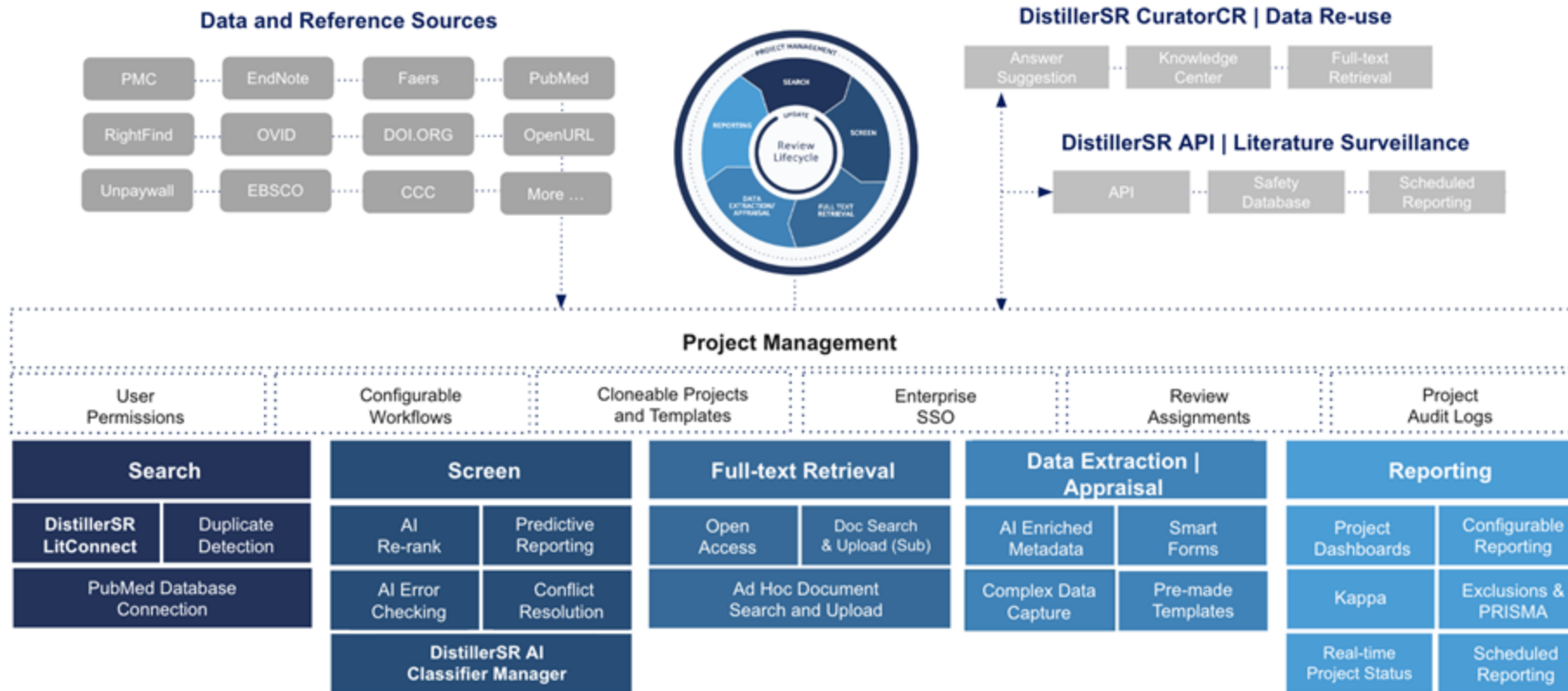
DistillerSR automates and centrally manages the entire review lifecycle to enable faster, more accurate results

The Value of DistillerSR: Exploring the Cost of Failure

DistillerSR Classifiers

Misclassification can be hard to detect.

It is usually applied across references in bulk.

Can domino into more errors in downstream processes.

DistillerSR exposes training and accuracy data lets users decide when it is safe to apply.

DistillerSR Automatic Re-Rank

Learns over time from user decisions and becomes more accurate.

Runs in the background.

Misclassifying a reference has minimal impact since human reviewers are processing the work.

Human-in-the-loop.

Human-in-the-loop

- Not all AI solutions need to be highly robust to have a big impact on your problem.
- Cost-of-failure can be mitigated by having humans review a decision.
- At scale, decisions must be made quickly for the solution to be viable:
  – Using AI to find product defects on assembly line: can be verified quickly by specialized workers
  – Using AI to automatically extract data/conclusions from medical literature: requires domain experts and is time consuming

How not to human-in-the-loop

- Lawyer used ChatGPT to prepare a legal filing.

- Cited at least six cases that don't exist.

- Didn't review the content because he didn't know ChatGPT could fabricate content.

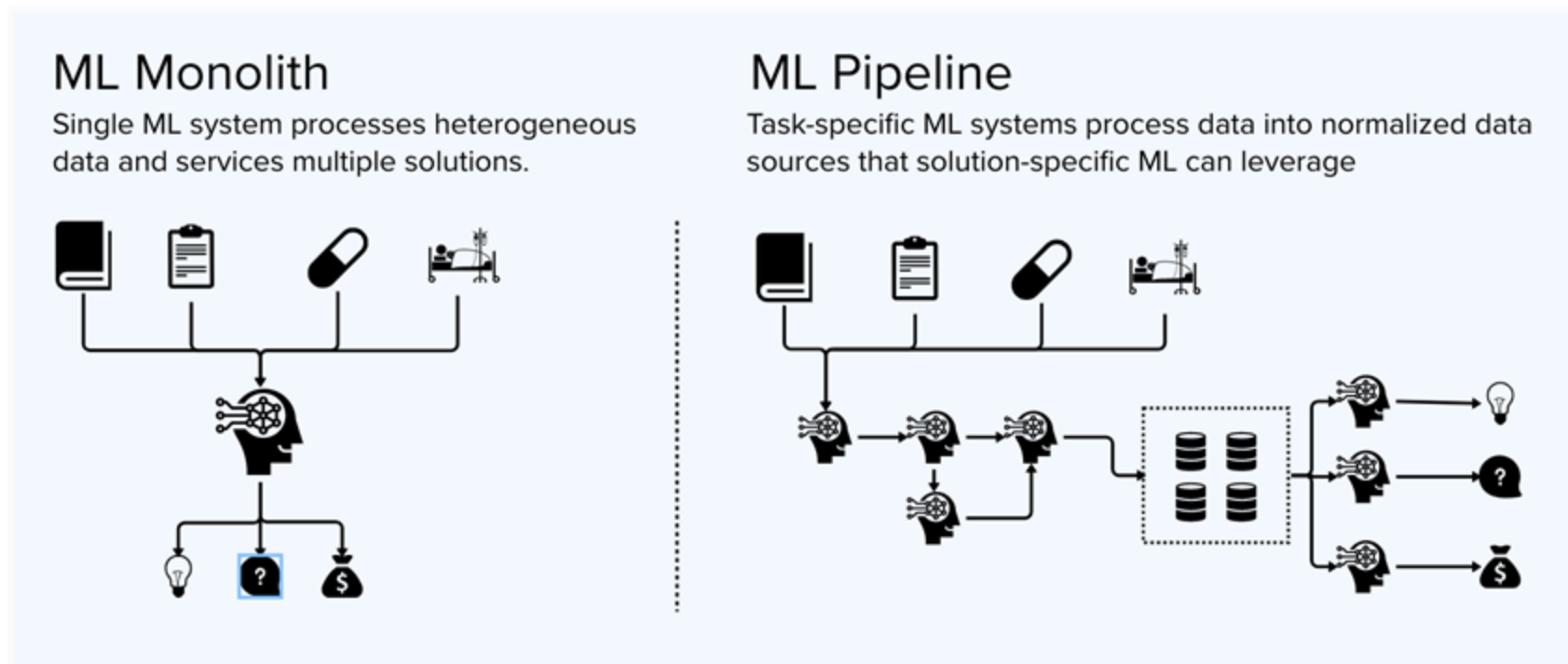**Forbes**

FORBES > INNOVATION > CONSUMER TECH

Lawyer Uses ChatGPT In Federal Court And It Goes Horribly Wrong

Matt Novak Contributor ⊙
FOIA reporter and founder of Paleofuture.com, writing news and opinion on every aspect of...

Follow

RWE: Breaking it down

Solve a big problem by breaking it into smaller ones.

- Rather than build a highly generalized AI that consumes all forms of RWE to service multiple solutions, create a pipeline of AI/ML to normalize data for downstream solutions-specific AI/ML.

ML Monolith
Single ML system processes heterogeneous data and services multiple solutions.

ML Pipeline
Task-specific ML systems process data into normalized data sources that solution-specific ML can leverage

Applications of LLMs and Non-deterministic AI

What are the uses of LLMs and non-deterministic AI?

- Summarization
- Creative work (report generation)
- Solving problems where there is no clear answer (eg., drug/compound discovery)
- Automating knowledge graphs and exploring them
  - Advanced LLMs automatically create knowledge graphs (ontologies) by extracting entities and relationships from text.
  - Although these can be error prone, they can be the foundation of self-serve analytics, exploration, and learning.
- Audience: How would you use it?

Summary

1. Manufacturers can leverage AI for conducting large systematic literature reviews (SLRs) during pipeline stages, aiding decision-making processes.

2. AI can serve as a second screener or complete screening tool, leading to faster timelines and reduced costs.

3. AI enables the integration of SLR extraction data, providing insights into trends and subpopulations or outcomes.

4. The accuracy of AI screening is enhanced when robust training data is available.

5. Human-in-the-loop approach is critical to Life Sciences Research.

Audience Q&A

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

Upcoming ISMPP U Webinars

June 27, 2023:

APAC ISMPP U: Applying GPP 2022 in the Asia Pacific

July 2023

ISMPP U: How Scientific Communication Leaders are Engaging with Digital Opinion Leaders

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We hope you enjoyed today's presentation.

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Faculty Bios

Tara Cowling

- Founder of Medlior Health Outcomes Research in 2008
- Specializes in "Real World Evidence" studies utilizing Canadian health system data
- Expert panelist and presenter on utilizing RWE for faster access to new medicines for Rare Diseases

Mark Priatel

- VP Software Engineering for DistillerSR since 2020
- Formerly CTO of Klipfolio, a leading SaaS Business Intelligence platform
- Over 25 years of experience developing products for the Cloud and SaaS

Moderator: Patti Peeples

- Board Member and Strategic Consultant for Healthcare Technology companies
- Past founder and CEO of world's largest digital ecosystem for HEOR, RWE and Market Access
- Author of more than 100 publications in healthcare value and economics