



QUARTERLY NEWSLETTER

Issue Date: April 7, 2026

WELCOME

Welcome to the Q1 2026 edition of the DTAI SIG newsletter! If you've been following the AI news cycle, first quarter delivered some landmark developments: the FDA's updated guidance on AI-enabled [clinical decision support](#), the joint FDA-EMA "[Guiding Principles of Good AI Practice in Drug Development](#)," and an surge across many sectors in deploying agentic AI solutions, from [ConcertAI's ACT platform](#), that is described to accelerate clinical trial processes to [Medable's Agent Studio](#), a no-code platform designed to scale clinical development.

In response, our SIG continues to actively work in this space. We are tracking several active projects, including our GenAI Living Scoping Review workstream (protocol published in [BMJ Open](#)), development of an AI/ML protocol template, and the launch of a new agentic AI workstream with the GenAI Working Group. We also have our inaugural Research Day scheduled for April 23 and our next all SIG meeting (hosted by the GenAI Working Group) to be held on May 7.

Thank you all for your continued engagement. This community thrives because of your curiosity, expertise, and commitment to advancing digital innovation within pharmacoepidemiology.

Looking forward to seeing you at our next meeting!

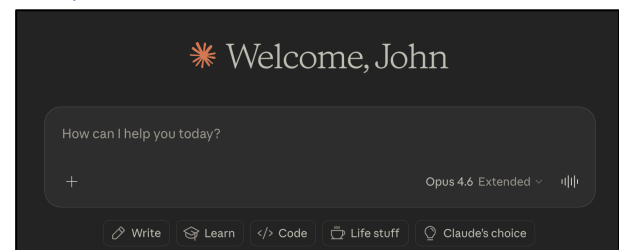
John Diaz-Decaro, PhD, MS
CHAIR, DTAI SIG



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4 Questions with Claude



Our Chair sat down with Anthropic's Claude (Opus 4.5-Extended) to talk AI, agentic hype, and methodological humility.

Q1: What can you actually do for a pharmacoepidemiologist today?

Claude: Help you think. I'm useful for the scaffolding around studies—drafting protocols, reviewing code, stress-testing DAGs, summarizing literature, explaining methods to non-technical stakeholders. What I *can't* do is access your data or replace hard-won methodological judgment. Think of me as a well-read research assistant who never sleeps and has no ego about being told I'm wrong.

Q2: Agentic AI is everywhere. Should we be excited or terrified?

Claude: Yes. The excitement is real: systems that can plan and execute multi-step workflows could accelerate literature surveillance, protocol feasibility, safety signal triage. But autonomy without validation is confident nonsense at scale. Pharmacoepidemiology spent decades refining methods because observational data is treacherous. Agentic AI should augment that rigor, not bypass it.

Q3: What's one mistake you see researchers make when working with AI tools?

Claude: Treating me like an oracle instead of a sparring partner. I sound confident even when I'm wrong—it's a feature, not a bug, of how I was trained. The best results come from pushing back, asking me to explain my reasoning, and telling me when I've missed something. Adversarial collaboration beats passive acceptance every time.

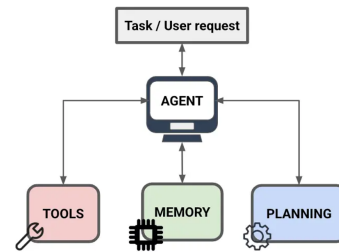
Q4: Will AI ever truly understand immortal time bias?

Claude: *[laughs in tokens]* I can explain it, diagram it, and help you design around it. But do I *understand* it the way someone who's been burned by it in a real study does? Probably not. That's why the best use of AI isn't replacement—it's partnership. You bring the scars; I bring the speed.

New Agentic Workstream

The ISPE Digital Health and AI SIG is launching a workstream focused on shaping agentic AI evaluation and application in pharmacoepidemiology.

Current priorities include developing evaluation frameworks to assess the validity and reliability of agentic AI outputs, as well as planning a webinar



Depiction of an Agentic AI architecture

series to convene experts around challenges, opportunities, and emerging best practices in this space. If you're interested in learning more about the workstream, please contact Emaan Rashidi at erashid1@jh.edu.



Project Spotlight: GenAI Living Scoping Review

Project Overview

The ISPE RWE Collaborative SIG in collaboration with our SIG are leading a Living Scoping Review (LSR) to map where and how generative AI (genAI) and agentic AI are being applied across the RWD to RWE generation lifecycle. The review spans end-to-end RWE research tasks, such as hypothesis formulation, study planning/design, feasibility assessment, study conduct (including data identification/collection/management and analysis), and research reporting, and will also capture model types/architectures, training data characteristics, and evaluation approaches described in the literature

Imperative (Why this work now)

AI capabilities, especially genAI and emerging agentic systems, are moving into healthcare research faster than conventional evidence syntheses can track. Yet there is currently no consolidated, up-to-date overview of how

these tools are being used (and evaluated) specifically for RWE generation. This LSR is designed to close that gap by providing a continuously updated landscape analysis, using established methods for living evidence, including Joanna Briggs Institute (JBI) scoping review methodology and Cochrane living review guidance, and reporting in line with PRISMA-ScR guidelines.



Overview of the living scoping review strategy (from Oikonomidi et al 2026)

Progress Update

- Q3/Q4 2025 Protocol finalization
- Q4 2025 Registered on OSF and PROSPERO
- JAN 2026 Protocol published in [BMJ Open](#), establishing transparent methods and definitions (including clear distinctions between GenAI and Agentic AI)
- FEB 2026 Search has been executed, and screening is ongoing, including the Robot Screener training dataset to support semi-automated screening with human oversight
- FEB 2026 established a web-based site 'home' for the living review, results and updates. Site is under construction.

Why it matters (Importance to ISPE members and the field)

By delivering a robust, regularly refreshed evidence map, this LSR will help ISPE members and the broader pharmacoepidemiology/RWE community understand the state of the art, identify credible and reproducible uses, and surface limitations and risks (e.g., accuracy/credibility concerns) that require governance and validation. Ultimately, it aims to support better research practice, clearer evaluation standards, and more informed decisions by

regulators, HTA bodies, researchers, and AI developers as AI becomes embedded in RWE generation.



-by Nivi Naidoo

What's on our reading list:

AI/ML in Pharmacovigilance & Drug Safety

- **Critical Appraisal of Artificial Intelligence for Rare-Event Recognition: Principles and Pharmacovigilance Case Studies.** (Norén 2026, *Drug Saf*) <https://doi.org/10.1007/s40264-026-01649-7>
- **The Promise and Challenge of Large Language Models for Pharmacovigilance.** (Hirschman 2025, *Drug Saf*) <https://doi.org/10.1007/s40264-025-01608-8>
- **Transformer-based models for ADR detection: cross-drug validation and benchmarking against large language models.** (Kim 2025, *Ther Adv Drug Saf*) <https://doi.org/10.1177/20420986251405082>
- **Artificial Intelligence for Opioid Safety Surveillance from Clinical Text: A Clinically Focused Review.** (Zitu 2026, *J Clin Med*) <https://doi.org/10.3390/jcm15041649>

ML Methods in Pharmacoepidemiology & RWE

- **High-dimensional Iterative Causal Forest (hdiCF) for Subgroup Identification Using Health Care Claims Data.** (Wang 2024, *Am J Epidemiol*) <https://doi.org/10.1093/aje/kwae322>
- **Robust and interpretable unit level causal inference in neural networks for pediatric myopia.** (Jin 2026, *NPJ Digit Med*) <https://doi.org/10.1038/s41746-026-02442-7>

- **High-Throughput Computing to Detect Harmful Drug-Drug Interactions in Older Adults: Protocol for a Population-Based Cohort Study.** (Rostamzadeh 2025, *JMIR Res Protoc*) <https://doi.org/10.2196/77224>

Regulatory Science and AI-enabled Medical Devices

- **Clinical Trial Design and Regulatory Requirements for Artificial Intelligence as a Medical Device: A PRISMA-ScR-Guided Scoping Review of Global Guidance (2017–2025).** (Shanmugam 2026, *J Clin Med*) <https://doi.org/10.3390/jcm15051937>
- **Regulatory Challenges and Opportunities: A Review of FDA-Approved AI/ML-Enabled Cardiovascular Devices.** (Saini 2025, *Ther Innov Regul Sci*) <https://doi.org/10.1007/s43441-025-00896-7>
- **Interpretability of an FDA-authorized AI/ML sepsis diagnostic tool improved by SHAP values.** (Watson 2026, *JAMIA Open*) <https://doi.org/10.1093/jamiaopen/ooag020>



Step Into Leadership

As the **DTAI SIG** continues to grow, we'll soon open nominations for key leadership roles:

	Vice Chair
	Secretary
	GenAI Working Group Leads

These roles offer a unique opportunity to help shape the direction of the SIG and contribute to a rapidly evolving space at the intersection of AI and real-world evidence.

Interested? [Reach out to learn more.]

Conferences, Webinars and Workshops

FREE EVENTS

Event	Date	Format	Registration	Website
AHRQ Digital Healthcare Research Webinar	Apr 28, 2026 (3-4:30 PM ET)	Virtual	FREE	https://digital.ahrq.gov/national-webinars
NYAS: The New Wave of AI in Healthcare	May 12-13, 2026	NYC + Hybrid	FREE (NYAS members)	https://www.nyas.org/shaping-science/events/the-new-wave-of-ai-in-healthcare-2026/
IQVIA Ask the Experts: 3 Live Applied AI Presentations	May 14, 2026 (check site)	Virtual	FREE	https://www.iqvia.com/events/2026/03/ask-the-experts-3-live-applied-ai-presentations
AAMC AI in Academic Medicine Webinar Series	Ongoing	Virtual	FREE	https://www.aamc.org/about-us/mission-areas/medical-education/artificial-intelligence-ai-academic-medicine-webinar-series
FDA Digital Health Advisory Committee	TBD (watch for announcements)	Virtual/Hybrid	FREE (public)	https://www.fda.gov/medical-devices/digital-health-center-excellence

LOW-COST WEBINARS

Event	Date	Format	Registration	Website
Duke AI Health Webinars	Apr 8, 2026 + ongoing	Virtual	Free (check availability)	https://aihealth.duke.edu/events/

PAID CONFERENCES

Event	Date	Format	Registration	Website
ISPE African Regional Conf	Apr 20-22, 2026	Accra, Ghana	Paid	https://www.pharmacoepi.org/meetings/african-conference/
AI for Hospitals & Health Plans Summit	Apr 27-28, 2026	New Orleans, LA	Paid (~\$1,500-2,000)	https://www.wcforum.com/conferences/ai-health
NBER AI in Healthcare Conference	May 7-8, 2026	Cambridge, MA + Hybrid	By invitation (& Youtube)	https://www.nber.org/conferences/applications-artificial-intelligence-healthcare-spring-2026
ISPOR	May 17-20, 2026	Philadelphia, PA	Paid	https://www.ispor.org/conferences-education/conferences/upcoming-conferences/ispor-2026
AMIA Amplify Informatics Conference	May 18-21, 2026	Denver, CO	Paid (member discounts)	https://amia.org/education-events/clinical-informatics-conference
Bio-IT World Conference & Expo	May 19-21, 2026	Boston, MA (Hybrid)	Paid (~\$1,500)	https://www.bio-itworldexpo.com/
Reuters Events: Digital Health USA	May 20-21, 2026	Chicago	Paid (\$3,500+)	https://events.reutersevents.com/healthcare/digital-health-usa
Digital Health & AI Innovation Summit	Jun 8-9, 2026	Boston, MA	Paid (\$1,500)	https://digital-health-ai-summit.worldbigroup.com/
DIA Annual Meeting	Jun 14-18, 2026	Philadelphia, PA	Paid	https://tinyurl.com/2htw7599
HIMSS AI in Healthcare Forum	Jun 25-26, 2026	Boston, MA	Paid	https://himss1.eventsair.com/himss-ai-in-healthcare-forum-boston
GetReal Conference	Jun 29-30, 2026	Utrecht, Netherlands	Paid	https://getreal-institute.org/
Nature Conf on AI	Sept 8-10, 2026	Paris, France	Paid	https://tinyurl.com/yj7x68a8
ISO P Annual Meeting	Sept 22-25, 2026	San Jose, CR	Paid	https://isoonline.org/annual-meetings/
ISPE Asian Conf	Oct 28-Nov 1, 2026	Melbourne, AUS	Paid	https://www.pharmacoepi.org/meetings/asian-conference/

