



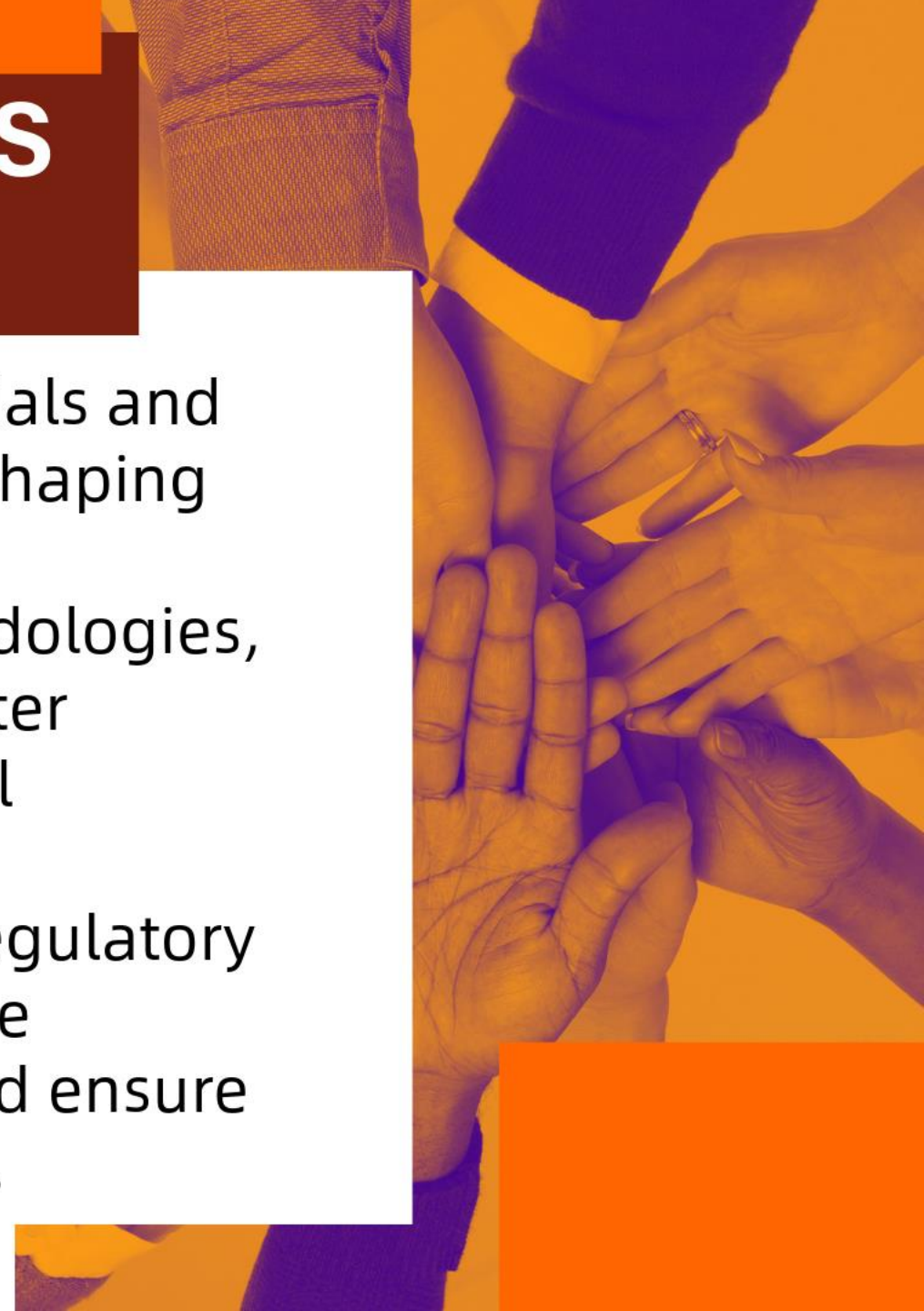
# ISCTM: Bridging Science, Methodology & Innovation in CNS Trials

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President, Luca Pani, MD

# Our Mission: Advancing CNS Research for the Future

- The International Society for CNS Clinical Trials and Methodology (ISCTM) is a global leader in shaping the future of CNS research.
- Our mission is to pioneer innovative methodologies, integrate cutting-edge technology, and foster global collaboration to improve clinical trial outcomes.
- By bringing together academia, industry, regulatory agencies, and policymakers, we address the evolving challenges in CNS therapeutics and ensure the highest scientific and ethical standards.



# Why focus on CNS research methods?



- Clinical trials in CNS disorders face unique challenges: placebo response rates, diagnostic heterogeneity, and the complexity of psychiatric and neurological conditions.
- Advancing trial methodologies improves efficiency, reduces failure rates, and accelerates the development of transformative treatments for neurodegenerative and psychiatric diseases.
- The integration of AI, digital biomarkers, and patient-centered outcomes is reshaping trial design and regulatory frameworks, making methodological advancements more critical than ever.



# Innovating the Future of CNS Research

René Descartes emphasized structured methodology in the pursuit of truth—modern CNS research must embody this principle through evidence-driven innovation.

René  
Descartes

Discourse on  
Method  
and  
Meditations  
on First  
Philosophy

Fourth Edition

Translated by  
Donald A. Cress

Key trends shaping the future:

- AI-driven predictive modeling for clinical trials
- Digital endpoints and remote monitoring for real-world evidence
- Precision psychiatry: Biomarker-driven drug development
- Regulatory harmonization and adaptive trial designs

ISCTM remains at the forefront, fostering collaboration to translate these innovations into practice.





# The Future of CNS Trials: Actionable AI & Innovation

- AI in CNS trials: Adaptive designs, synthetic control arms, patient recruitment
- AI-driven personalized psychiatry and regulatory challenges
- Digital biomarkers & remote patient monitoring



Feature



## AI: MAKING IT UP

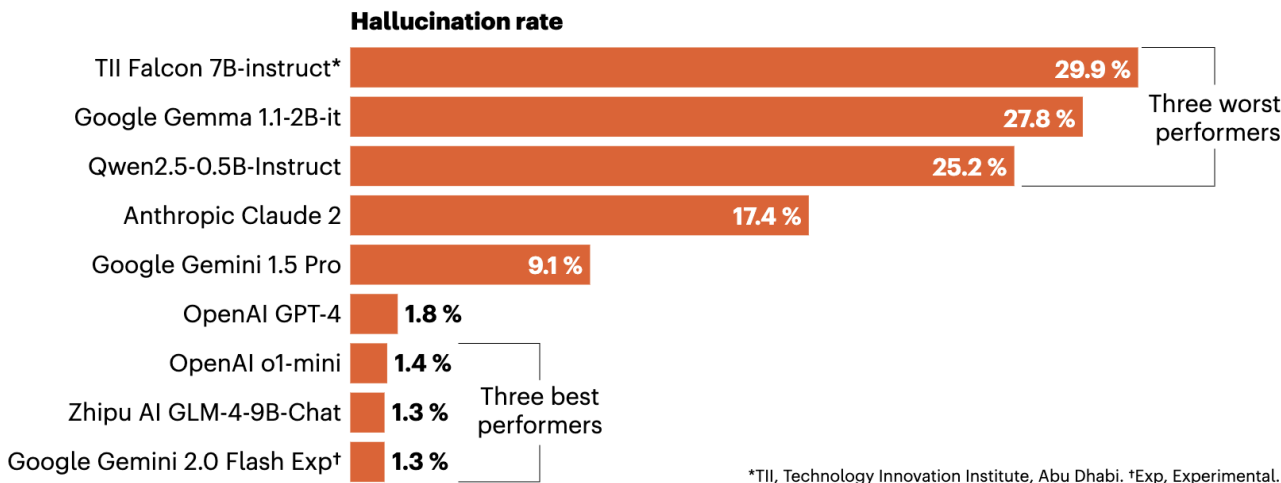
Developers have tricks for stamping out artificial-intelligence hallucinations, but large language models are still struggling to tell the truth, the whole truth and nothing but the truth. **By Nicola Jones**

The particular problem of false scientific references is rife. In one 2024 study, various chatbots made mistakes between about 30% and 90% of the time on references, getting at least two of the paper's title, first author or year of publication wrong<sup>1</sup>. Chatbots come with warning labels telling users to double-check anything important. But if chatbot responses are taken at face value, their hallucinations can lead to serious problems, as in the 2023 case of a US lawyer, Steven Schwartz, who cited non-existent legal cases in a court filing after using ChatGPT.

Chatbots err for many reasons, but

### THE BIGGEST BULLSHITTERS

Vectara's Hallucination Leaderboard grades large language models (LLMs) on the specific task of summarizing a provided document, by tracking how many details they make up. Those that performed best (having the lowest hallucination rates) and worst (highest rates) are shown, along with the rates of selected well-known LLMs.



“Models mostly know what they know, but they sometimes don’t know what they don’t know.”



# Culture



International



All stakeholders



Independent



Non-promotional collaboration



Multi-disciplinary



Fearless, respectful conversations



Active participation



# Ongoing Activities

- Scientific committee guides bi-annual meeting content  
Members propose and develop many topical sessions
- 15 Active subject-specific working groups  
9 manuscripts currently in development  
4 manuscripts recently published
- Guidance comment working groups
- Trial methodology discussion forum (DocMatter)
- Collaboration with other organizations  
(e.g. ECNP, ASCP, ISTAART NPS PIA)







# Working Groups

## Connect and Collaborate



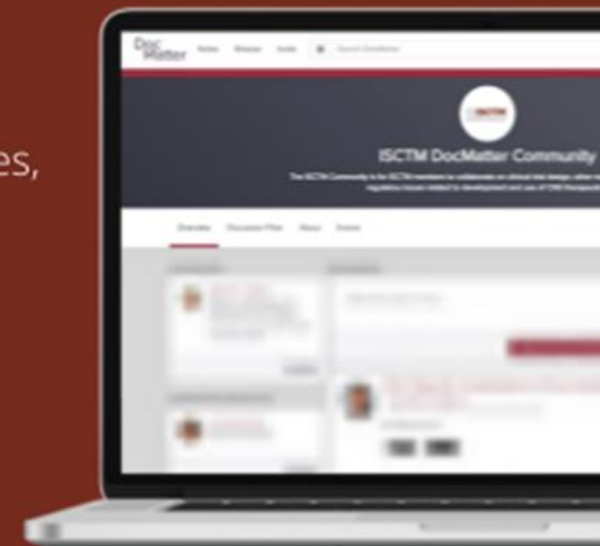
# ISCTM DocMatter Community

ISCTM Member Benefit

Discuss clinical trial design, methodological issues,  
and regulatory affairs with your ISCTM peers



Doc  
Matter



Share and discuss information about clinical trial design,  
methodological issues and more with your ISCTM peers

**Available via:**

**Web**

**Email**

**iOS & Android Apps**



# Collaborations



ISCTM / ASCP

## ADVANCED CNS CLINICAL TRIALS COURSE

11-13 JUNE 2025 | RALEIGH NC

**A brief, intensive,  
interactive program  
for mid-career CNS  
clinical researchers  
who wish to expand  
and refine their trial  
design expertise**



**with other  
Societies**



# 2025 Meetings

**Advanced CNS Clinical Trials Course  
jointly sponsored by ISCTM/ASCP**

**11-13 June 2025**

**Raleigh NC - Apply by 5 March**



**2025 Autumn Conference includes Joint Day with ECNP**

**9-11 October 2025**

**Amsterdam, The Netherlands**

**Registration opens early April**



 **ISCTM 2025 Autumn Conference**  
**includes joint day with ECNP**  
**9-11 October 2025 Amsterdam**



**Poster Deadline**  
**17 July 2025**



**Luca Pani, President**  
**Atul Mahableshwarkar, President Elect**

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**Adam Butler**

**William Potter**

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**Nanco Hefting**

**Siân Ratcliffe**

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**Judith Kando**

**Gary Sachs**

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**Anzalee Khan**

**Jair Soares**

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**Ni Khin**

**Dawn Velligan**

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**Tom Macek**

**Mary Bea Harding**

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**Elizabeth Pappadopulos**





**Adam Butler, Chair**  
**Anzalee Khan, Co-Chair**

|                        |                             |                        |                         |
|------------------------|-----------------------------|------------------------|-------------------------|
| <b>Anzar Abbas</b>     | <b>Joan Fallon</b>          | <b>Ronald Marcus</b>   | <b>Michael Ropacki</b>  |
| <b>Larry Alphas</b>    | <b>Reuven Ferziger</b>      | <b>Stephen Marder</b>  | <b>Gary Sachs</b>       |
| <b>Rebecca Berman</b>  | <b>Philip Harvey</b>        | <b>Raeanne Moore</b>   | <b>Gerard Sanacora</b>  |
| <b>Stephen Brannan</b> | <b>Seth Hopkins</b>         | <b>Kari Nations</b>    | <b>Nina R. Schooler</b> |
| <b>Joan Busner</b>     | <b>Amir Kalali</b>          | <b>Kemi Olugemo</b>    | <b>Daniel Umbricht</b>  |
| <b>Carla Canuso</b>    | <b>Ritu Kapur</b>           | <b>Luca Pani</b>       | <b>Uma Vaidyanathan</b> |
| <b>David Daniel</b>    | <b>Shaheen Lakhan</b>       | <b>Holly Posner</b>    | <b>Mark Weiser</b>      |
| <b>Walter Dunn</b>     | <b>Atul Mahableshwarkar</b> | <b>Steven Potkin</b>   |                         |
| <b>Suresh Durgam</b>   | <b>Ramy Mahmoud</b>         | <b>Abhishek Pratap</b> |                         |
| <b>Jenicka Engler</b>  | <b>Valentina Mantua</b>     | <b>Jill Rasmussen</b>  |                         |

## What's Next? Your Role in Shaping CNS Trials

- Join a working group & contribute to scientific discussions
- Engage in mentorship & training programs
- Shape the future of clinical trial methodology

Thank You to...



# Our Sustaining Corporate Members

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## Bronze



Brooklyn  
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# Our Sustaining Corporate Members

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## Silver



# Our Sustaining Corporate Members

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Gold

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Platinum



**SIGNANT** HEALTH



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methodology

We depend on interaction!  
Please bring your active voice  
to our discussions