PISTOIA ALLIANCE

COLLABORATION DELIVERED

Annual Report
July 2024-June 2025

pistoiaalliance.org

Welcome

The Pistoia Alliance brings together the biopharmaceutical ecosystem, powering collaboration to drive innovation and deliver new breakthroughs. Our 200+ members collaborate on pre-competitive shared challenges, pooling expertise and R&D costs to move the industry forward and ensure better outcomes for all.

Collaboration that delivers - Highlights from 2024/2025:

Our diverse portfolio of projects and communities has delivered value to members and received strong industry recognition including the Bio-IT World Innovative Practices Lighthouse Award for our FAIR Maturity Matrix and an Honourable Mention for our IVP Public-Private Partnership.

- We **increased member value** through **education**, **networking** and **research** initiatives. We held our largest annual conference at the Royal Society of Medicine; grew our Life Science Informatics Forum's global footprint; and established a new Cheminformatics Forum with support from of our Steering Committees. Access to historical and new resources including key opinion leader research with ZS and our second Lab of the Future report has been delivered via our new website.

- We **strengthened** our **relationships** with **regulators** and key industry stakeholders with a new Public-Private Partnership with the FDA for Novel Alternative Models and our Carbon Footprint of Decentralized Clinical Trials project with the Sustainable Healthcare Coalition. The FDA published the collective feedback we submitted from our members on the Draft Guidance on AI.

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Becky Upton, PhD, President

- We increased our commitment to **developing industry talent** by introducing new training initiatives for AI/ML, IDMP and general ontology skills. We also established the life science industry's first Young Data Scientist of the Year Award.

Achievements 2024/25 in Numbers

Celebrating Our Global Impact Across Life Sciences

200+
Members

17/20
Top Pharma by R&D Expenditure

30+
Active Global Projects & Communities

14
New ideas submitted by Members

850+
Global Project Participants

2
BIO-IT World Innovation Awards

1st
Young Data Scientist Award

4
Peer Reviewed Journal Publications

800
In-person Forum & Conference Attendees

2920
Training & Webinar Online Attendees

77
Media Opinion Articles

3
Industry Benchmark Surveys

71,000
Website Visitors

Looking ahead

*"The Pistoia Alliance continues to drive **significant progress** in the life sciences by fostering pre-competitive collaboration. Through our continued efforts, we **empower organizations** to unlock the full potential of their data, ultimately contributing to **faster and more effective** delivery of **new therapies** to patients worldwide."*
Chris Waller, Vice President and Chief Scientist, EPAM Systems

**Chris Waller,
EPAM Systems & Chairman**

The global pharmaceutical industry faces a complex landscape of challenges. Navigating a changing regulatory environment, accelerating innovation and R&D, adapting to technological advancements, and addressing sustainability and talent shortages requires collaboration that delivers. We will continue to support our members in these key areas.

In 2025/2026 we will also:

- Further strengthen our relationships with agencies and regulators

- Expand our community events through initiatives including our first Controlled Substance Compliance & Shipping Community (CSCS) conference and User Experience in Life Sciences (UXLS) conference

- Support change management and develop core technology skills through our growing training initiatives and nurture talent through our Young Data Scientist of the Year Award and new Data Science Team of the Year Award

Strategic priorities

Our strategic priorities guide our portfolio of projects and communities, ensuring that we deliver value to members with impactful solutions that address the biggest R&D challenges that lie ahead. Agile solutions that are made possible by working under the umbrella of our robust legal framework, forming the foundations to advance science.

The Pistoia Alliance Portfolio:

DELIVERING DATA-DRIVEN VALUE AT SCALE

Ontologies

IDMP - O

Pharma CMC Process Ontology

Pharma General Ontology

Data Enrichment

DataFairy Bioassay Annotation

FAIR-for-Pharma Community

Integration and Management of Data, Ontologies and Standards

Methods Hub

In-Vitro Pharmacology

Data Governance Community

GSRS Consortium

CORE COMMUNITIES

Controlled Substance Compliance & Shipping Community (CSCS)

UXLS Community

Future Lab Evolution Community

Quantum Computing Community

Microbiome-Mediated Drug Metabolism Database

SUSTAINABILITY DRIVEN R&D

Carbon Footprint for Decentralized Clinical Trails

In Vitro NAMs Data Standards

Digital Transformation & Change Management Community

ACCELERATE LATE-STAGE R&D

Social Media & RWE

Pharmacovigilance Case Intake

HARNESSING AI TO ACCELERATE R&D

Algorithms

Large Language Models in Life Sciences

Best Practices

LLM NLP Use Case Database

AI/ML Expert Community

Delivering Data-Driven Value at Scale

Data is the foundation for AI and digital strategies. It powers insight and innovation. We help the industry to manage, maintain and consume data more efficiently.

> *"The **introduction of standards** and fairness at scale, **making data AI ready** and having more **reliable insights** based on high quality data **is a booster for productivity** in the industry. The Pistoia Alliance provides the ideal collaborative platform to achieve these goals."*
> *Martin Romacker, Product Owner Roche Terminology & Interoperability System (RTiS)*

Project Showcase

In Vitro Pharmacology

In vitro assays are crucial for assessing the safety and efficacy of active substances, metabolites, and impurities in Investigational New Drug and New Drug Application submissions. However, inconsistent data standards for in vitro pharmacology have hindered efficient in vitro testing and regulatory review. We are addressing this issue through a Public-Private partnership with regulators at the **FDA** and the biopharmaceutical industry. Our initiative received an **Honourable Mention at the Bio-IT World Innovative Practices Awards.**

FAIR Maturity Matrix

We achieved an industry first with the creation of our FAIR Maturity Matrix which won the Bio-IT World 2025 Innovative Practices Lighthouse Award. This easy-to-use self-assessment tool measures organizational leadership and technical maturity. Over 20 industry experts collaborated to create the tool, successfully simplifying and standardizing the many complex processes involved in FAIR data implementation.

In addition we undertook an extensive survey to assess the impact of FAIR data in life science companies and launched From Research and Beyond: The Biggest Business Drivers of Life Science FAIR Initiatives.

Project Showcase continued...

IDMP

We delivered **Accelerating Digital Transformation in Pharma,** an industry report examining the status of the implementation of Identification of Medicinal Products (IDMP) standards in global pharma. These ISO standards are being included in EMA regulations. Research was carried out in partnership with ACCURIDS and MAIN5 and supported by our award-winning IDMP Ontology project team with participants from Abbvie, Amgen, AstraZeneca, Boehringer Ingelheim, Bayer and Novartis.

London Conference, March 2025, Royal Society of Medicine

Harnessing AI to Expedite R&D

83% of Life Sciences Executives say they will not achieve growth goals without AI. We help the industry to harness AI's full potential.

> *"AI in pharmaceutical research is not just a tool, but a catalyst that accelerates the journey from discovery to delivery, transforming potential into breakthroughs. By leveraging AI, we can **navigate the complex** landscape of drug discovery **with unprecedented speed**, precision, and innovation, **turning obstacles into opportunities.**"*
> *Lars Greiffenberg,*
> *Director R&D IT and Translational Informatics, Abbvie*

Project Showcase

Submitting Guidance on AI to the FDA
One of the many benefits of being part of the Pistoia Alliance is the opportunity to help shape regulations. Our AI community members worked together to submit comprehensive feedback to the FDA Draft Guidance on AI which includes guidance on benchmarking of models, the requirement for an AI/ML management system, the use of FAIR data and the inclusion of additional standards. You can read our collaborative feedback published by the FDA here.
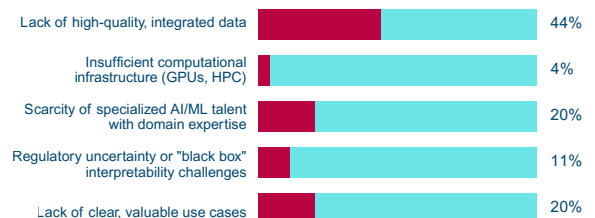
Large Language Models (LLMs) in Life Sciences
The use of LLMs presents a transformative opportunity for life sciences R&D. We completed the first phase of our project to define the role of LLMs in pre-competitive research, demonstrating their potential to accelerate drug discovery and enhance collaboration across the industry. We have written a paper, currently submitted for publication and are raising funds for phase 2 of this project which will focus on the benchmarking of LLM-driven "scientific chat" systems.

Agentic AI
Agentic AI emerged as a key theme at our London member conference and was identified as the technology expected to have the most impact over the next 2-3 years by our LLM project team. We have begun to lay the foundations for a new agentic AI project to define the roles and functions of AI Agents in clinical and preclinical settings and establish industry guidelines for how agents should interact and work together.

What do you see as the single biggest barrier to scaling GenAI initiatives within your organization's drug discovery efforts?

Lack of high-quality, integrated data	44%
Insufficient computational infrastructure (GPUs, HPC)	4%
Scarcity of specialized AI/ML talent with domain expertise	20%
Regulatory uncertainty or "black box" interpretability challenges	11%
Lack of clear, valuable use cases	20%

research provided courtesy of Domino Data sponsored webinar

Sustainability-Driven R&D

ESG is a priority from a growth and public health perspective. We help ensure that the benefits of therapies are not offset by our industry's operations.

> "Being part of **Pistoia Alliance** has been **incredibly valuable** for Bristol Myers Squibb. The collaborative environment **fosters innovation and accelerates** our efforts at the intersection of **sustainability and R&D** by enabling us to join forces with other industry leaders. It has provided deeper insight into critical topics such as the carbon footprint of clinical trials, which are essential for understanding the healthcare sector's impact on the environment and patient health."
> Adriana Zupa-Fernandez, Director Global Sustainability Strategy, Culture, & Engagement, Bristol Myres Squibb
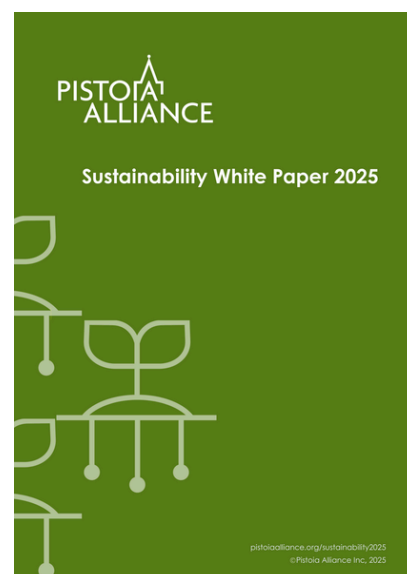
Project Showcase

Carbon Footprint of Decentralized Clinical Trials
We supported the Sustainable Healthcare Coalition and the industry Low Carbon Clinical Trials (iLCCT) community to develop a ground-breaking free carbon calculator with the appropriate methodology and framework to drive practical action to lower the carbon impact of clinical trials. The next phase of our project will assess the environmental impact of digital trial delivery methods and digital health solutions compared to traditional, paper-based approaches.

Public-Private Partnership with the FDA for Novel Alternative Models
We achieved a Public-Private Partnership with the FDA – the second in our history - for our cross-industry project that aims to standardize the measurement of leading edge assay performance, ensure consistent reporting of results, and harmonize the provenance of metadata. This will ensure a sustainable approach to reducing, replacing and refining preclinical in vivo studies.

We launched a white paper exploring the key sustainability challenges in pharmaceutical R&D and the need for better measurement frameworks. It includes insights from industry stakeholders and highlights the need for collaboration to drive change.

Accelerate Late Stage R&D

Bringing a new drug to market is a long and costly process. We aim to help increase the effectiveness of the most expensive phases of R&D to benefit patients. We have expanded the focus of our preceding Real World Data strategic priority to meet this need.

> *"I am supporting the Pistoia Alliance's PS² project because it paves the way for **transformative progress** in pharmacovigilance through standardization and innovation. By fostering **cross-industry collaboration** and aligning requirements, we can channel investments into **innovation**, enhance interoperability, and ultimately **deliver better outcomes** for patients globally."*
> *Thomas Kuckuk, Head Pharmacovigilance Systems Management at Novartis*

Project Showcase

Social Media Listening
Social media listening is a potentially valuable real-world data (RWD) source for patient insights. Yet there are no comprehensive regulatory guidelines for using social media as a source of RWD in patient-focused drug development. We published a synthesis of considerations from patients, industry and regulators in <u>Frontiers in Medicine</u>.

Pharmacovigilance
In response to the growing demand from our members to focus on pharmacovigilance we established a new dedicated <u>AI in Safety & PV Community of Experts (CoE)</u> to explore how to apply AI safely, ethically and effectively within pharmacovigilance workflows. Our Pharmacovigilance Systems & Processes Standards (PS²) project was initiated to establish a set of standard solution and integration requirements for PV systems to reduce duplicated effort and foster greater innovation in common PV workflows using AI.

Core Projects and Communities

The Pistoia Alliance continues to support members through a broad range of initiatives beyond our four strategic priorities, providing industry insight and thought-leadership.

Project Showcase

Future Labs Evolution
We established our new Future Labs Evolution Steering Committee to guide the strategic direction of our community, providing a reinvigorated platform to exchange ideas and best practices and to develop new collaborative projects that will help drive forwards the lab of the future. An Instruments and Data Standards Questionnaire has been developed to drive efficiency, compatibility and collaboration in pharma instrument procurement.

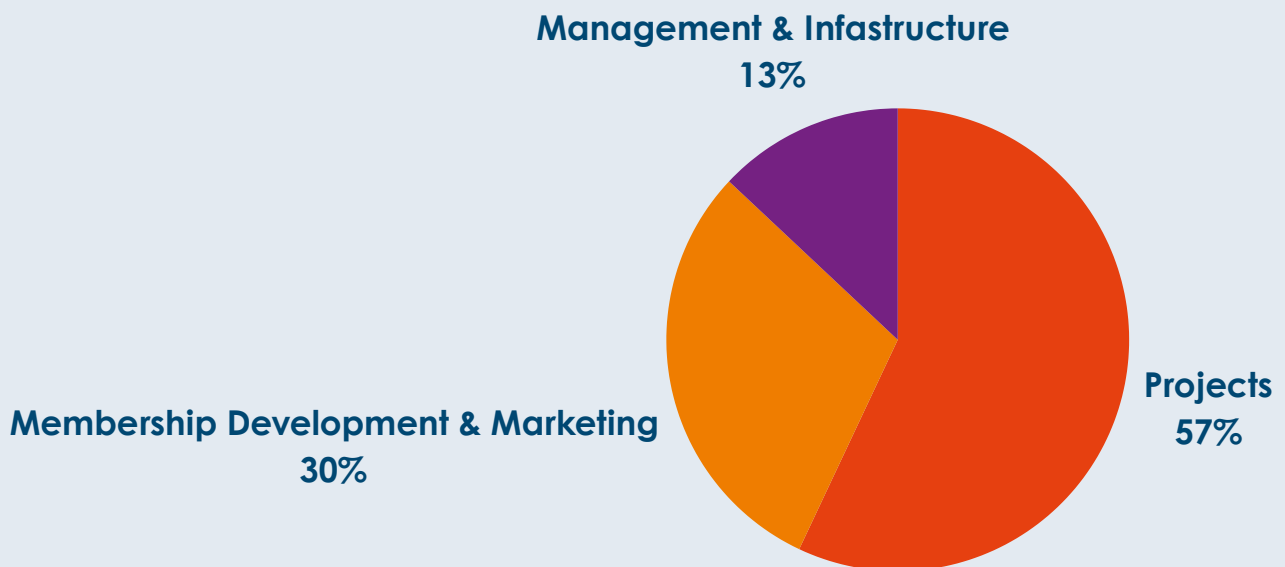**Microbiome-Mediated Drug Metabolism Database**
A new dataset on microbial drug metabolism - generated from both microbial communities and individual strains - is being integrated into ChEMBL to enhance coverage of microbiome–drug metabolism. In parallel, a standardized curation workflow has been established to support the integration of heterogeneous public data, and large language models, trained on manually curated datasets, are being explored to mine the literature for microbiota–drug interaction data. This data will be made available with the next release of ChEMBL.

We conducted and launched our second Lab of the Future global survey in partnership with Lab of the Future Congress, providing deep insight into the adoption of emerging technologies such as AI and ML and the barriers that are holding back innovation in the laboratory. The third year edition will go live September 2025.

Financial Report for FY24/25

In the FY24/25 ending June 30, 2025, the cost of running Pistoia Alliance and its programs was $3.70m split as follows:

Management & Infastructure
13%

Membership Development & Marketing
30%

Projects
57%

Financial growth during 2024/2025 compared to 2023/2024

- Membership dues grew to $2,335k from $2,250k

- Net assets increased by approximately $650k due to overall revenue growth and project activity.

- Total assets increased by approximately $728k due to increased cash balances resulting from the ongoing focus on project funding and general management of working capital throughout the year.
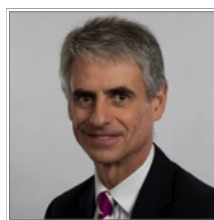
Leading the way - The Executive Team

Becky Upton, PhD, President

Errol Sandler, PhD, Secretary

Steve Hollinshead, FCA, Treasurer

Christian Baber, PhD, Chief Portfolio Offier

Board of Directors*

- Chris Waller, Chairman of Pistoia Alliance, Vice President and Chief Scientist, EPAM Systems

- Lars Greiffenberg, Senior Director R&D, Information Research, Abbvie

- Anna Craig, Global Head of Strategy & Governance, Roche

- Jagat Adhiya, VP, Head of IT & Digital for Pharma R&D & CGT, Bayer

- Lauren Shields, Head of Solutions & Value, Benchling

- Richard Jones, CEO, ChemAxon

- Mirit Eldor, Managing Director, Life Sciences Solutions, Elsevier

- Mara Peccianti, Business Partner for R&D, Global IT, Grunenthal

- Shubha Chaudhari, SVP R&D Digital & Technology, GSK

- Anthony Rowe, Vice President, Head of Technology, Janssen/J&J

- Roman Affentranger, Executive Director, Head of Product Management, Research Informatics, at Novartis BioMedical Research

- Sergio Rotstein, Vice President, R&D Solutions, Pfizer

- Paul Denny-Gouldson, Chief Scientific Officer, Zifo

- Genevieve Erwin Haliburton, PhD Manager, Computational Biology & Data Science, Chan Zuckerberg Initiative Foundation

- Grant Stephen, CEO & President, bPrescient

*As at time of publication

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- Stephanie Pearson

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- Veronique Francois-Newton, PhD
- Vladimir Makarov

We would like to thank our Members, Board of Directors, Strategic Committee Members, Project Champions, Pistoia Alliance Alumni, and Consultants past and present, for their commitment in delivering the Pistoia Alliance mission.