PISTOIA ALLIANCE

Annual Report
July 2023-June 2024

pistoiaalliance.org

Welcome

We are a global, not-for-profit alliance that advocates for greater collaboration in life sciences R&D. Our mission is to lower the barriers to innovation through pre-competitive collaboration.

We bring together stakeholders from industry, academia, and government. Our members work together on projects and in our specialist communities using our proven framework for open innovation to transform R&D and generate better outcomes for all.

Collaboration that delivers

We bring together the biopharmaceutical ecosystem, powering collaboration to drive innovation and new breakthroughs.

Our global community of more than 200 members from across the biopharma ecosystem collaborates to solve common pre-competitive challenges. Sharing expertise and R&D resources, to move the industry forwards and ensure better outcomes for all.

Together we achieve more

This year we have continued to unite the industry through a diverse range of global initiatives:

- Our rich and evolving portfolio: 20 active projects and expert communities; our biggest pipeline ever of active new ideas; more than 1,000 people engaged in our portfolio.

- Our educational events & training: Annual European and US member conferences; European and USA Informatics Forums; UXLS conference; webinar program; technical training.

Pistoia Alliance in numbers

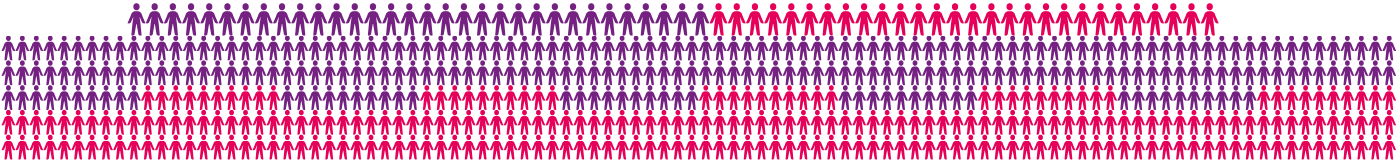1 BIO-IT INNOVATION AWARD

2 GLOBAL CONFERENCES

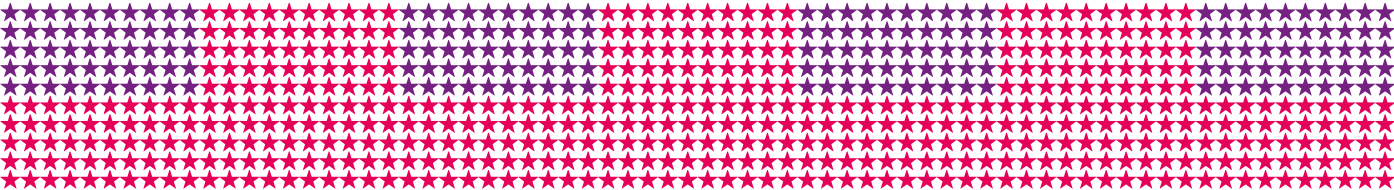4 PEER REVIEWED JOURNAL PUBLICATIONS

5 GLOBAL COMMUNITIES & 15 GLOBAL PROJECTS

99 WEBINARS ONLINE & TRAINING SESSIONS

560 FACE TO FACE GLOBAL EVENT ATTENDEESS

700 GLOBAL PROJECT PARTICIPANTS

56,000 WEBSITE VISITORS

Success delivered - highlights from the portfolio

Delivering Data-Driven Value at Scale

· We launched **IDMP Ontology 1.0** covering all five ISO IDMP standards and won a prestigious 2024 Bio-IT World Innovative Practices Award for Pre-Competitive Collaboration.

· We established a new project to build a **Pharmaceutical CMC process ontology** based on the ISA88/95 framework, to enhance efficiency and transparency throughout the pharmaceutical production lifecycle.

· Our **ClinOps Ontology** project which addresses the need for coherent data standards unveiled a semantic data model for clinical research design.

· We delivered a **FAIR Maturity Matrix** to help organizations track their progress and ROI on their FAIR journeys.

· Our **In Vitro Pharmacology** working group established with the FDA continued its quest to help the industry accelerate regulatory submissions.

· Our **Methods Hub** project achieved an industry first with a cloud-based collaborative tool that enables instant transfer and overlaying of analytical methods and results data in a single platform for cross-company use.

Accelerate Use of RWD/RWE

· We published a peer-reviewed paper in Frontiers in Medicine on Patient Listening on **Social Media for Patient-focused Drug Development**.

Harnessing AI to Accelerate R&D

· We started a **Large Language Models** (LLMs) in Biological Research project focusing on the critical process of target discovery.

Success delivered...continued

Sustainability-Driven R&D

· Our **Carbon Footprint** project in partnership with the Sustainable Healthcare Coalition forged ahead with a database to enable the impact of clinical trials to be measured.

· We delivered our first technical training program with face-to-face and online training in ontologies for life science leaders.

Other initiatives

· We conducted a widely publicized **Lab of the Future** report in partnership with Lab of the Future Congress to support the adoption of emerging technologies such as AI and ML.

· Our **Controlled Substance Compliance & Shipping** expert community collaborated to formulate a practical response to the DEA's Advance Notice of Proposed Rulemaking regarding Controlled Substance Destruction Alternatives to Incineration.
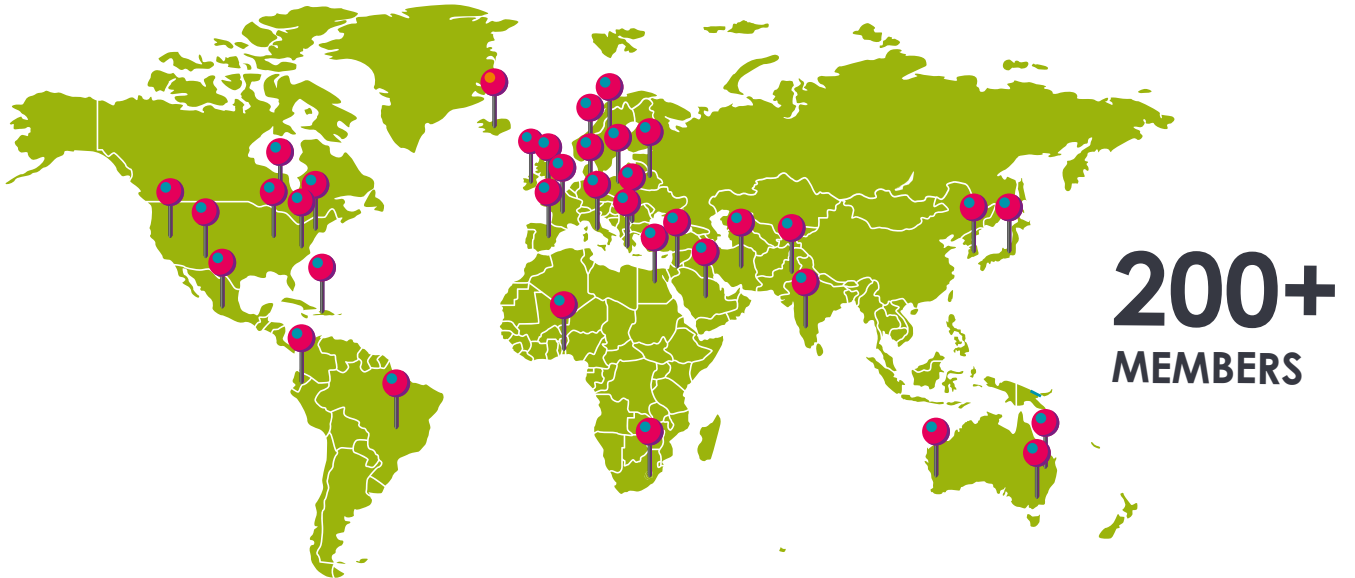
· The FDA approached us to lead a multi-stakeholder Consortium to advance the quality and use of the **Global Substance Registry System (GSRS)** worldwide created by the FDA, NIH and EMA.

· Our **Microbiome** project continues to help advance the understanding of microbiome-drug interactions with the development of a database.
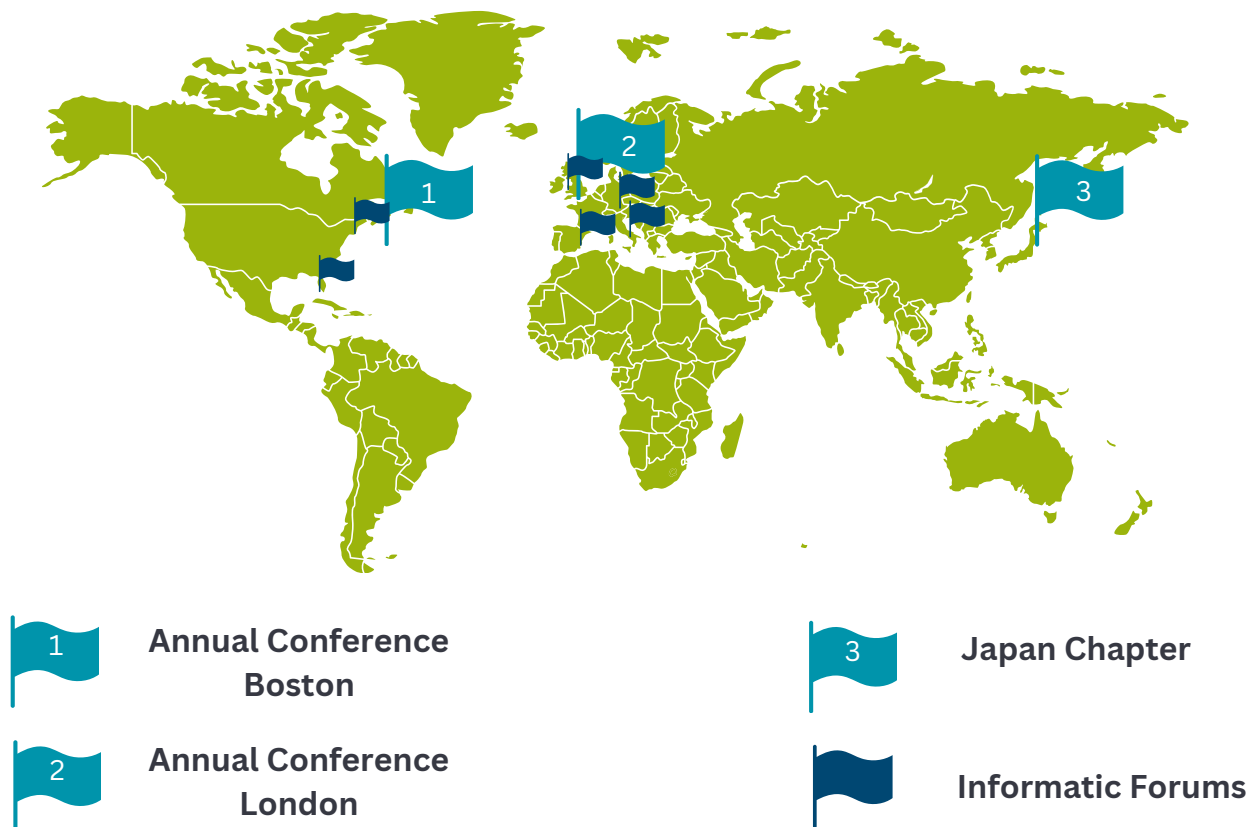
· Our **Quantum Computing** community of interest continued to educate stakeholders so that they are ready to embrace quantum computing's potential in life sciences and held a pivotal event in Basel as well as developing a dedicated webinar program.

Our global reach

200+
MEMBERS

In person events

1 Annual Conference Boston	**3** Japan Chapter
2 Annual Conference London	Informatic Forums

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 Four Strategic Priorities are:

DELIVERING DATA-DRIVEN VALUE AT SCALE

ONTOLOGIES:

IDMP - O

CLINICAL TRIAL OPERATIONS

CMC ONTOLOGY

PHARMA GENERAL ONTOLOGY

DATA ENRICHMENT:

FAIR IMPLEMENTATION

DATAFAIRY BIOASSAY ANNOTATION

FAIR COMMUNITY

COMMUNITIES:

METHODS HUB

IN-VITRO PHARMACOLOGY

DATA GOVERNANCE COMMUNITIES

GSRS CONSORTIUM

HARNESSING AI TO ACCELERATE R&D

ALGORITHMS

LARGE LANGUAGE MODELS IN LIFE SCIENCES

BEST PRACTICES

NLP USE CASE DATABASE

AI/ML COMMUNITY

SUSTAINABILITY DRIVEN R&D

CARBON FOOTPRINT FOR DECENTRALIZED CLINICAL TRIALS

3R INITIATIVES

DIGITAL TRANSFORMATION & CHANGE MANAGEMENT COMMUNITY

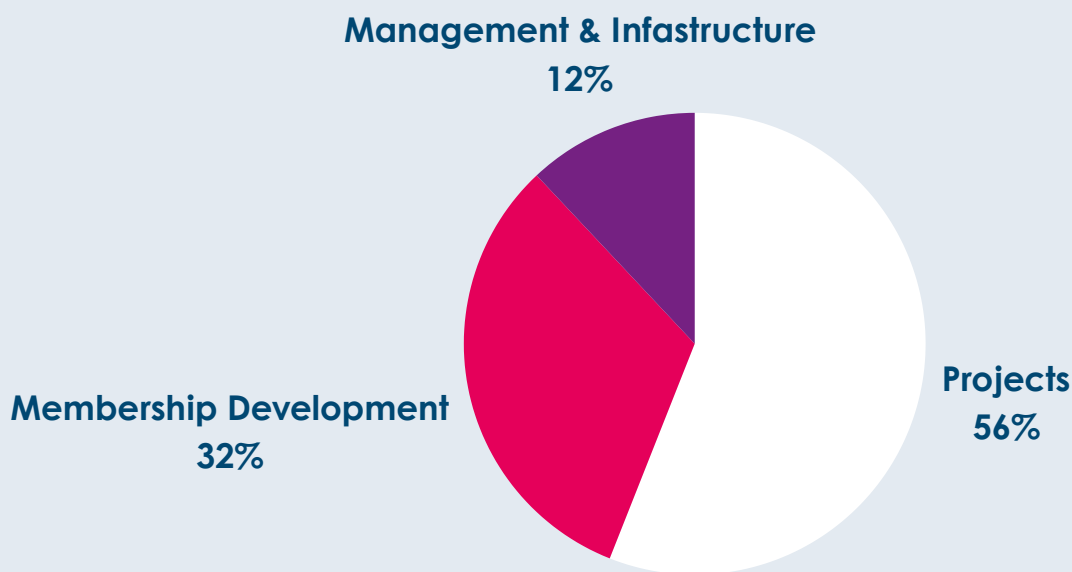**ACCELERATE USE OF RWD/RWE**

SOCIAL MEDIA FOR RWD

CORE COMMUNITIES

CONTROLLED SUBSTANCE COMPLIANCE & SHIPPING COMMUNITY

UXLS COMMUNITY

CHEMICAL SAFETY LIBRARY

LAB OF THE FUTURE COMMUNITY

QUANTUM COMPUTING COMMUNITY

MICROBIOME-MEDIATED DRUG METABOLISM DATABASE

Financials

In the FY23/24 ending June 30, 2024, the cost of running Pistoia Alliance and its programmes was $3.90m split as follows:

Financial growth during 2023/2024 compared to 2022/2023:

·   Net assets increased by approximately $500k due to overall revenue growth and project activity.

·   Total assets increased by approximately $523k due to increased cash balances resulting from the ongoing focus on project funding and general management of working capital throughout the year.

·   Membership dues grew to $2,250k from $2,121k.

**Management & Infastructure
12%**

**Membership Development
32%**

**Projects
56%**

Looking ahead

"There is no other pre-competitive collaboration organization that unites the entire biopharmaceutical ecosystem and delivers value through such a broad range of specialist projects and communities."
Lars Greiffenberg

The potential of AI and ML is rapidly becoming a reality. Meanwhile quantum computing and other technologies are coming and we need to ensure we are ready to use these technologies to our best advantage. Our mission is to help the pharma R&D value chain prepare for the data-driven future, supporting the drive to greater efficiency, sustainability and ultimately faster drug development.
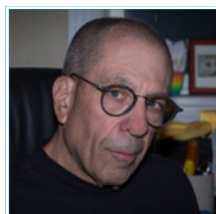
·   Making the Pistoia Alliance the home for ontologies by building out our strong portfolio and providing semantic data models to help the industry transform data into knowledge

·   Developing technology skills through our education and training program while encouraging rising stars through our new Young Data Scientist of the Year Award

·   Further strengthening our relationships with agencies and regulators

·   Continuing to activate the growing number of new ideas we receive from our members to drive collaborative innovation that delivers tangible outcomes

·   Continuing to collaborate with other organisations including NIMBLL and Sustainable Healthcare Coalition to power innovation
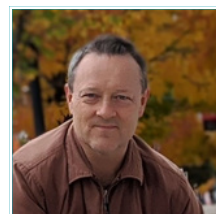
Leading the way - The Executive Team

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

- Kailash Swarna, Managing Director, Accenture

- Joe Donahue, Chief Business Officer, Aitia

- Sheila Elz, Master Data Manager, Bayer

- Lauren Shields, Head of Solutions & Value, Benchling

- Julie Frearson, SVP and Chief Scientific Officer, Charles River Labs

- Richard Jones, CEO, ChemAxon

- Jane Lomax, Head of Ontologies, SciBite

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

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

- Ralph Haffner, Head of Information Products & Data Sciences, Novartis

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

- Martin Erkens, Head Pharma Research and Early Development Informatics, Roche

Pistoia Alliance Consultants

- Aditya Tyagi
- Anca Ciobanu
- Asiyah Yu Lin
- Birthe Nielsen, PhD
- Catherine Maskell
- Cristina Fasca
- Daniel Webster
- David Prior
- Dalila Nafi
- Gabrielle Whittick
- Giovanni Nasato, PhD

- John Wise
- Helen Taylor
- Miffy Wilson
- Shaun Tamblin
- Stephanie Pearson
- Tanya Randall
- Thierry Escudier
- Veronique Francois-Newton, PhD
- Vladimir Makarov
- Zahid Tharia

Acknowledgements

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.

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