PISTOIA ALLIANCE

Establishing Standards for Pharmacovigilance Systems

Today's Presenters – Pharma companies

Henrik Lynge

Vice President of Architecture & Strategy at Novo Nordisk, where he leads enterprise-wide initiatives to align technology strategy with business goals across R&D. With deep experience in designing scalable, compliant, and future-ready digital ecosystems, Henrik has been instrumental in shaping Novo Nordisk's architectural vision to support innovation, patient safety, and operational excellence.

With two decades in pharma and life sciences, Henrik has built a reputation for strategic foresight, cross-functional collaboration, and a commitment to leveraging technology to improve patient outcomes.

James John

IT Director of Patient Safety and R&D Quality systems at AbbVie. He has deep experience implementing advanced pharmacovigilance solutions to enhance drug safety, drive efficiency, turn insights into action, and achieve regulatory compliance.
With 20+ years of consulting experience, he has expertise across pharma and is known for his strategic vision, cross-functional partnership, and his commitment to leveraging technology for better patient outcomes.

Thomas Kuckuk

Head of Pharmacovigilance Systems Management at Novartis. He has extensive experience across pharmacovigilance and clinical development, leading initiatives that strengthen patient safety and regulatory compliance.
Over the course of his career, he has driven system innovation and process improvements to support global drug development and commercial operations. Thomas is passionate about cross-industry collaboration to advance the future of drug safety.

Today's Presenters – Pistoia Alliance

John Wise

John is the Programme Coordinator for the PRISME Forum and is also a consultant at the Pistoia Alliance with responsibilities that include business development and member relations. He specialises in the coordination of pre-competitive collaborations in life science R&D IT and healthcare. John has had a long-time commitment to encouraging pharma to use expert, third-party, cost-effective, regulatory-compliant, secure, hosted information services. Previously, John has held Informatics leadership roles in a variety of organizations including the University of London, Sandoz, the Imperial Cancer Research Fund (now CRUK), Roche, Ipsen and Daiichi Sankyo. John has also worked in the technology supply side of the industry. In these roles, he has gained direct hands-on experience writing analytical software, teaching computation, delivering IT capabilities, and providing computer-based services to the discovery, non-clinical development, clinical development, and regulatory affairs domains of the life-science industry. John graduated in physiology from the University of Oxford and received a post-graduate certificate in education from the University of London

Marc Graber

Marc specializes in helping pharmacovigilance (PV) teams define their technology strategies and implement related solutions.

Marc is a software engineer by training and has over 30 years of experience in IT consulting, project and program management and business partnering. He worked for 17 years supporting PV as a project/program manager and business partner at one of the top 10 pharma companies and was leading their IT Safety team for 7 years.

Marc is now managing the **P**harmacovigilance **S**ystems and **P**rocess **S**tandards (PS^2) - Case Intake project at Pistoia Alliance.

What is the Pistoia Alliance?

Global, Not-For-Profit Members' Organisation

Conceived in 2007 by four cheminformaticians from AstraZeneca, GSK, Novartis and Pfizer and incorporated in 2008

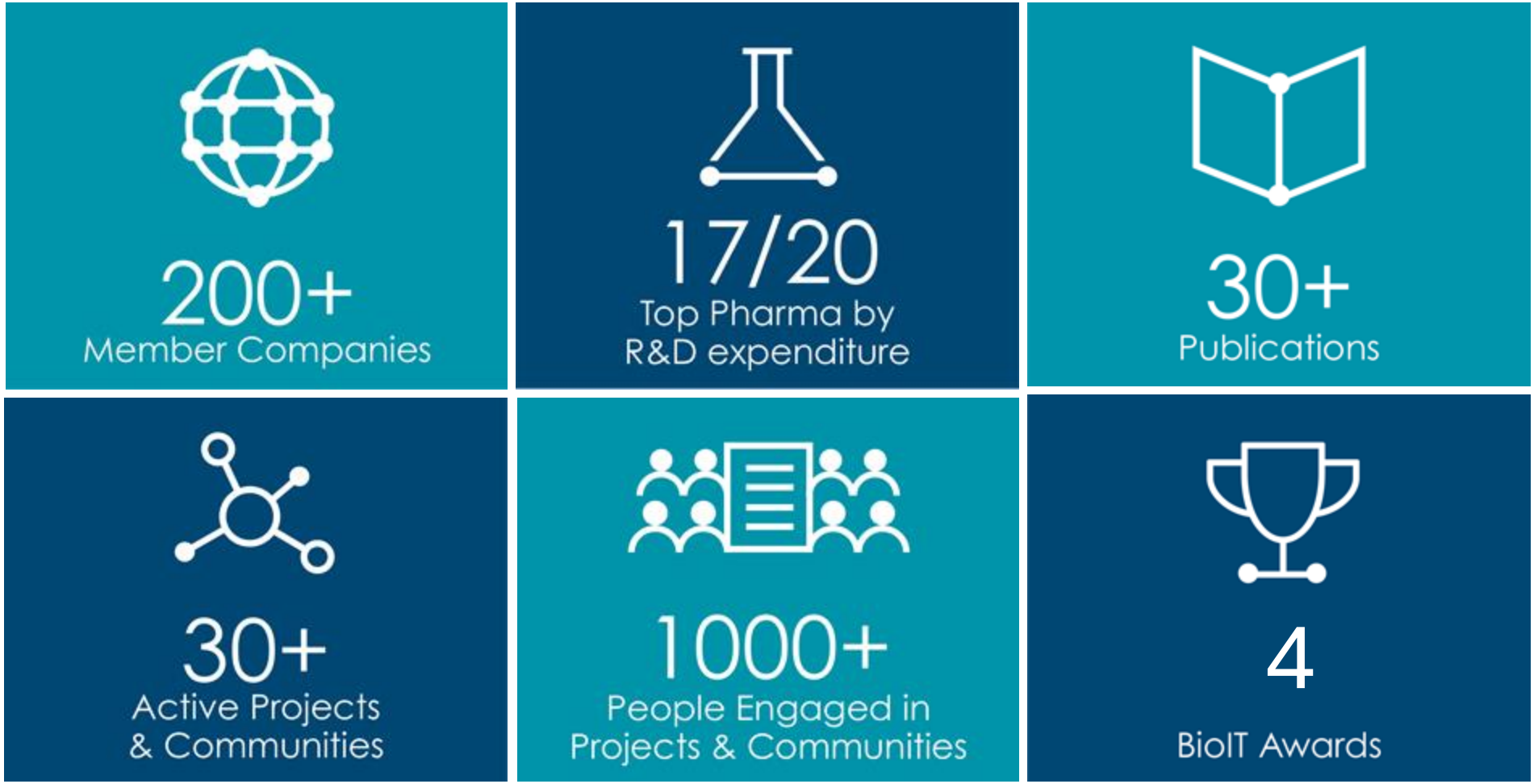
Mission

To lower the barriers to innovation in life science R&D through pre-competitive collaboration

Our Values

Industry value creation | Better Together | Future Focused

Pistoia Alliance by Numbers



2024-2025
Board of Directors

The Board of Directors is designed to reflect the diversity of viewpoints of our membership.

Board elections are held annually, and board members have a 2-year term if the company is newly elected or 1 year term if being re-elected.

AbbVie	Lars Greiffenberg, Director R&D IT and Translational Informatics
Accenture	Robert Pemberton Managing Director
Bayer	Sheila Elz Master Data Manager
Benchling	Lauren Shields Head of Solution and Value Delivery
ChemAxon	Richard Jones CEO
Elsevier	Jane Lomax Head of Ontologies
EPAM Systems	Chris Waller, Vice President , Chief Scientist
Grunenthal	Mara Peccianti Business Partner for R&D – Global IT
GSK	Shuba Chaudhari Head of Clinical Technology Solutions
J & J	Anthony Rowe Vice President, Head of Technology - Research Systems
Novartis	Ralph Haffner Head of Information Products and Data Sciences
Pfizer	Sergio Rotstein, Vice President, R&D Solutions
Roche	Anna Craig, Global Head of Strategy and Governance
Zifo	Paul Denny-Gouldson Chief Scientific Officer
Chan Zuckerberg Initiative Foundation	Genevieve Erwin Haliburton PhD Manager, Computational Biology & Data Science

A sample of our 200+ active members, including 17 of the 20 top pharma companies by R&D expenditure

What does the Pistoia Alliance platform offer its members?

Offering	Description
Legal framework	A legal framework for collaboration
Collaborative Projects	Overcome R&D inefficiencies, FAIR, adopt new standards, e.g., HELM*, IDMP-Ontology*, Drug Repurposing*, PPP with the FDA on in-vitro assay data exchange standards
Expert Communities	Share knowledge and best practices e.g., on AI, real-world data, sustainability, quantum computing, data governance, user experience*, controlled substance compliance & shipping
Training & Networking	Webinars, conferences, training events for knowledge sharing and professional networking

A few of the subject areas covered…

Subject Area	Description
AI & ML Initiatives	Define best practices, explore use cases, educate on AI/ML applications in life sciences
Regulatory Standards	Collaborate with regulatory bodies to develop and improve data standards e.g., ISO IDMP, FDA in-vitro safety pharmacology, CDISC SEND in-vivo efficacy data
Real-World Data	Utilize data from wearables, social media, EHRs to enhance research and patient care
Sustainability Efforts	Projects to reduce environmental impact and promote novel alternative methods

Bio-IT World Award & Mentions: Pistoia Alliance

2014 – Informatics Grand Prize for HELM
Awarded for the Hierarchical Editing Language for Macromolecules (HELM), a system for standardizing macromolecular representations.

2018 – Finalist Mention for UXLS Toolkit
The User Experience for Life Sciences (UXLS) initiative was recognized as a finalist in the Best Practices Awards for improving digital usability in life sciences.

2020 – Innovative Practices Award for Drug Repurposing Datathon
Awarded for a collaborative datathon with Mission: Cure and Elsevier, targeting drug repurposing for chronic pancreatitis.

2024 – Innovative Practices Award for IDMP-O Project
Recognized for a cross-industry ontology project supporting ISO IDMP data interoperability.

2025 – Lighthouse Award for FAIR Maturity Matrix
Awarded for developing a self-assessment tool to support FAIR data implementation in life sciences organizations.

2025 – Honorable Mention for In Vitro Pharmacology (IVP) Project
Acknowledged for efforts to standardize in vitro pharmacology data to support regulatory submissions.

Two complementary Pharmacovigilance initiatives starting up

Pistoia Alliance's Strategic Priorities

Pharmacovigilance Systems & Processes Standards (PS^2) – Case Intake
A project to establish a set of standard solution requirements for PV systems, starting with Case Intake, to avoid replication of effort during solution selection and implementation, facilitate system integration and foster innovation.

Your PA contact: marc.graber@pistoiaalliance.org

Safety & PV AI Community of Experts (CoE)
A forum to address the challenge of effectively integrating AI into PV practices by driving innovation, reducing duplication of efforts, and ensuring that best practices are widely adopted, benefiting the entire industry and the patients

Your PA contact: thierry.escudier@pistoiaalliance.org

PS² – Case Intake: Current State

Status Quo:

- Proprietary monolithic systems, lack of interoperability between vendor solutions
- Limited innovation
- No standards w.r.t. user requirements and interoperability despite very similar needs across industry

Consequences:

- **Sub-optimal PV systems solutions**
  - Difficult in adopting best-of-breed solutions
  - Little innovation – low incentive for vendors to innovate, pharma PV resources spent on maintaining the foundation
- **High costs:**
  - Duplicated efforts (pharma & vendors) on system procurement & implementation
  - Custom solutions required

PS² – Case Intake: Desired Future State

- **Standardized specifications:**
  Pharma companies establish standardized functional and integration specifications, starting with case intake

- **Alignment with Standards:**
  Supply-side companies build product to these specifications

- **Innovation and Differentiation:**
  Differentiation for supply-side companies will be derived from their innovation in how they address requirements, service levels, cost and their customer relationship management

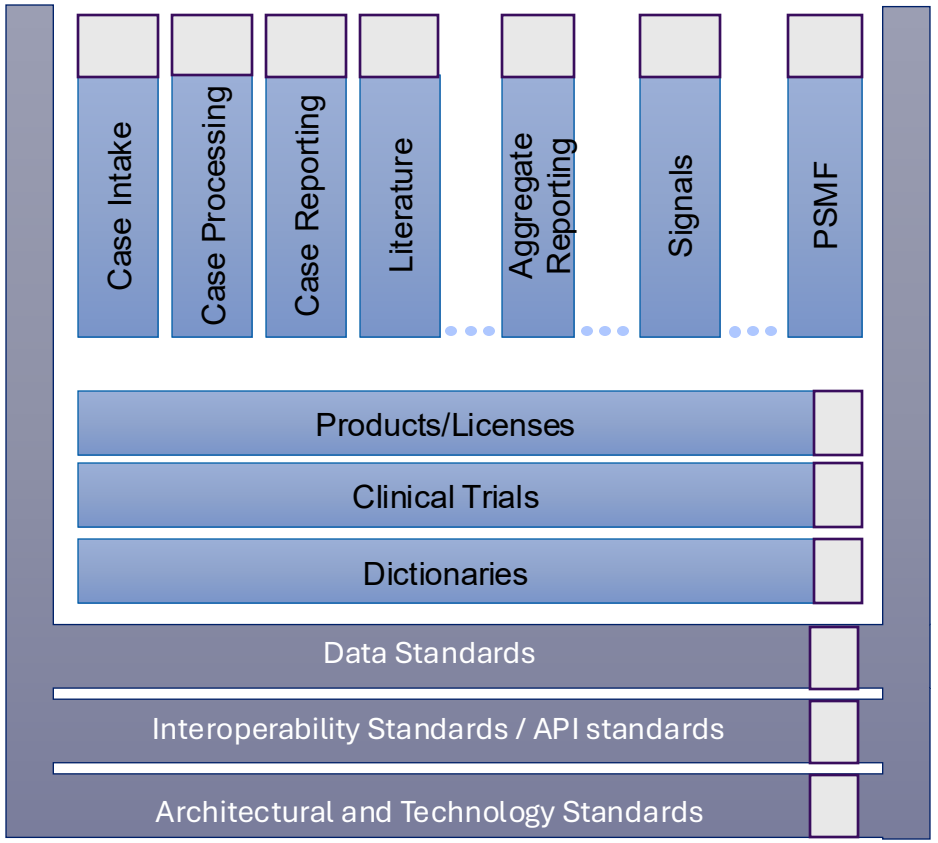
- **Focus on Innovation:**
  Pharma PV resources spend their time on innovating their systems rather than fire-fighting their systems

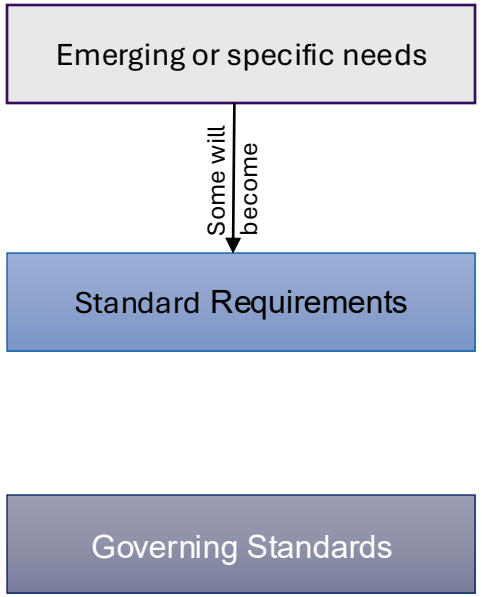
Opportunity to highly standardize PV Systems

Functional modules

Foundational modules

Technology & Data Standards





How we are going to achieve the future state

- Convene a group of business and IT SMEs to elicit cross-company case intake standard solution and integration specifications, starting with Case Intake in 2025
- Establish an approach to sustain standards
- Establish an approach to certify vendor solutions against the standard
- Publish the standard and drive adoption to use it

Benefits (1/2)

For pharma companies:

- **Lower costs**: Standard requirements re-used across sponsor companies, less customizations. Estimated cost reduction only for RFP phase: ~$50-100K
- **Easier and faster solution evaluation** via certification process
- **More innovation**: Ability to integrate best-in-class solutions, PV resources focused on innovation, vendors incentivized to differentiate through innovation

For PV suite suppliers / suppliers of add-on modules:

- **Lower costs**: Answers to RFPs for standard requirements can be re-used, no need to elicit standard requirements
- **Higher requirements maturity**: Standard requirements will have been vetted across sponsors and are less variable
- **Early insights** into emerging requirements
- **Access to PV leaders**: existing or potential customers, but **not** as a sales forum!

Benefits (2/2)

For PV consulting companies:

- **Better offering for solution evaluation** by leveraging standards for streamlined evaluation
- **More innovation**: Faster alignment on foundational needs (align with standards) and higher focus on innovation
- **Access to PV leaders**: existing or potential customers, but **not** as a sales forum!

For case processing service providers:

- **Lower costs**: Training strategy aligned with standards
- **Early insights** into emerging requirements and **shaping requirements** to meet cross-industry needs
- **Access to PV leaders**: existing or potential customers, but **not** as a sales forum!

Project status

Completed so far:

- ✓ Funding and/or resources secured from 3 companies – Novo Nordisk, AbbVie & Novartis
- ✓ Pistoia Alliance engaged a part-time, domain-aware, experienced project manager / business analyst
- ✓ Project logistics set up
- ✓ Modelling approach for processes, user requirements and integration requirements identified
- ✓ Initial set of processes and requirements produced, ready for formal review

Outlook:

- Formally review and finalize processes and requirements
- Produce API specifications, logical data model and data dictionary
- Define sustainability and certification approaches

The PS^2 – Case Intake project is starting up. Join us on this exciting journey!

Call to action: join us to shape the future of PV Systems!

Pharma companies

- ✓ Produce and review deliverables with team members such as case intake SMEs, data or software architects, business analysts

PV suite suppliers or suppliers of add-on modules

- ✓ Understand current and future needs of your clients across the industry
- ✓ Ensure that standards are usable by your product teams
- ✓ Let us know your needs and help us elaborate solutions
- ✓ Focus on *What*, not *How*. No IP shared with competitors

PV consulting companies

- ✓ Produce and review deliverables with team members equipped with industry-wide experience

Case processing service providers

- ✓ Produce and review deliverables with team members such as case intake SMEs, data or software architects, business analysts

Joining options

As steering committee member[(1)]

- Steer the project via decision-making at steering committee meetings
- Additional benefits such as recognition, approvals, priority access to documentation
- Requires Pistoia Alliance membership
- Requires project funding of $50K each, starting January 2026

As contributor

- Providing team members to produce deliverables

Interested in joining? Contact marc.graber@pistoiaalliance.org for a follow-up session to discuss engagement details.

[(1)] Steering committee members are also encouraged to provide team members

Related opportunities

Safety & PV AI Community of Experts (CoE)
A forum to discuss how to effectively integrate AI into PV.
Interested? Contact thierry.escudier@pistoiaalliance.org

Pistoia Alliance USA Conference 2025

Join us at our annual USA conference, in Boston on Nov 11-12, where new ideas are sparked and new initiatives are activated thanks to the power of collaboration.

Register here: Pistoia Alliance USA Conference 2025 - Pistoia Alliance

BACKUP

Q&A (1/3)

Q: How can I engage with Pistoia Alliance to contribute to the PS2 project?
A: Please contact marc.graber@pistoiaalliance.com to agree on your / your company's role in the project. If you're not yet a Pistoia Alliance member, you'll need to secure your membership before starting. Membership fees can be found here at Become a Member - Pistoia Alliance and standard terms and conditions can be accessed at Membership - Google Drive

Q: What requirements modelling approach will you take for functional and non-functional requirements?
A: Functional requirements will be documented in the form of user stories with acceptance criteria in Gherkin format

Q: Are you planning on defining standards at data and technology level as well?
A: We are planning to define standards at data level, consisting of a logical data model and a corresponding data dictionary. From a technology perspective, we will be as little prescriptive as possible and will specify integration requirements using OpenAPI for RestAPIs and AsyncAPI if asynchronous APIs are required

Q: Will you also be defining business process standards, along with system requirements?
A: Yes, we will also define standard business process requirements, which will form a basis for system requirements

Q: To what level of detail will you define requirements?
A: This still needs to be worked out as we produce requirements. However, as a guiding principle, we will focus on *What* (i.e. the requirement) that are applicable across the PV industry and not on *How* the requirements should be implemented.

Q: Are the standards going to be ISO standards or recognized by a standardization body?
A: This will be decided by the Project Team advising the Project Steering Committee

Q&A (2/3)

Q: Are you planning to produce requirements for Case Intake only, or are you considering other PV modules as well? Do you have a roadmap?
A: Our ambition is to cover the whole PV spectrum. We're targeting Case Intake in 2025 and will be scaling up in 2026. The speed at which we can progress will depend on the level of contribution of our member companies

Q: How do you envision adherence/enforcement of these standards by other pharma companies and vendors?
A: This is a conversation yet to be had within the project team and steering committee - but drawing on Pistoia Alliance experience - not least with reference to HELM - the Hierarchical Editing Language for Macromolecules
https://en.wikipedia.org/wiki/Hierarchical_editing_language_for_macromolecules

Q: How will you manage the differences in requirements between pharma companies?
A: We're convinced that while it is a common to hear that people believe that their company have special needs (e.g. due to pas inspection findings or because they've "always done it this way"), it is possible to find a consensus on standard requirements. Differences will be discussed in workshops and common requirements will be agreed upon

Q: What commitment in terms of time, travel, money, etc. may be expected from my company to be part of PS^2?
A: Travel: The Pistoia Alliance is in very large part a virtual organisation. So, travel is not necessary unless your company would like to attend the Annual Conferences and any other in-person events that the Pistoia Alliance runs – when travel and accommodation costs need to be met by the member.
Time: People would need to set aside some time for the project team meetings and scope of work mutually agreed upon. This can go from very little (e.g. attending project team meeting, providing some expert advice) to actively producing deliverables.
Money: If your company wished to become part of the Steering Committee as well, then it would need to pay into the project pot. Membership of the Steering Committee is $50K

Q&A (3/3)

Q: At a high level, when do you expect to start on defining the standards for Case Intake and when do you expect the standards to be available?
A: We're aiming to have a first draft of business process and system requirements ready for review by end of August. This will be followed by a few review and update cycles, with the goal of having a final version by mid-Nov. Data and integration requirements will be developed in parallel, aiming at having final versions by the end of 2025

What Makes the Pistoia Alliance Unique?

Pre-competitive & Open Innovation Incubator

Legal framework for collaboration

Support full ecosystem of life sciences R&D

Our mission is to solve common challenges

Deliverable Driven

Proof of Concept

Working, deployable products

Publications

Best Practice Custodians

Networking & Educational Opportunities

Conferences and webinars

Training series, D&I programs

Cross-company networking

Peer collaboration, individual growth, advancing together

Broad based, global membership

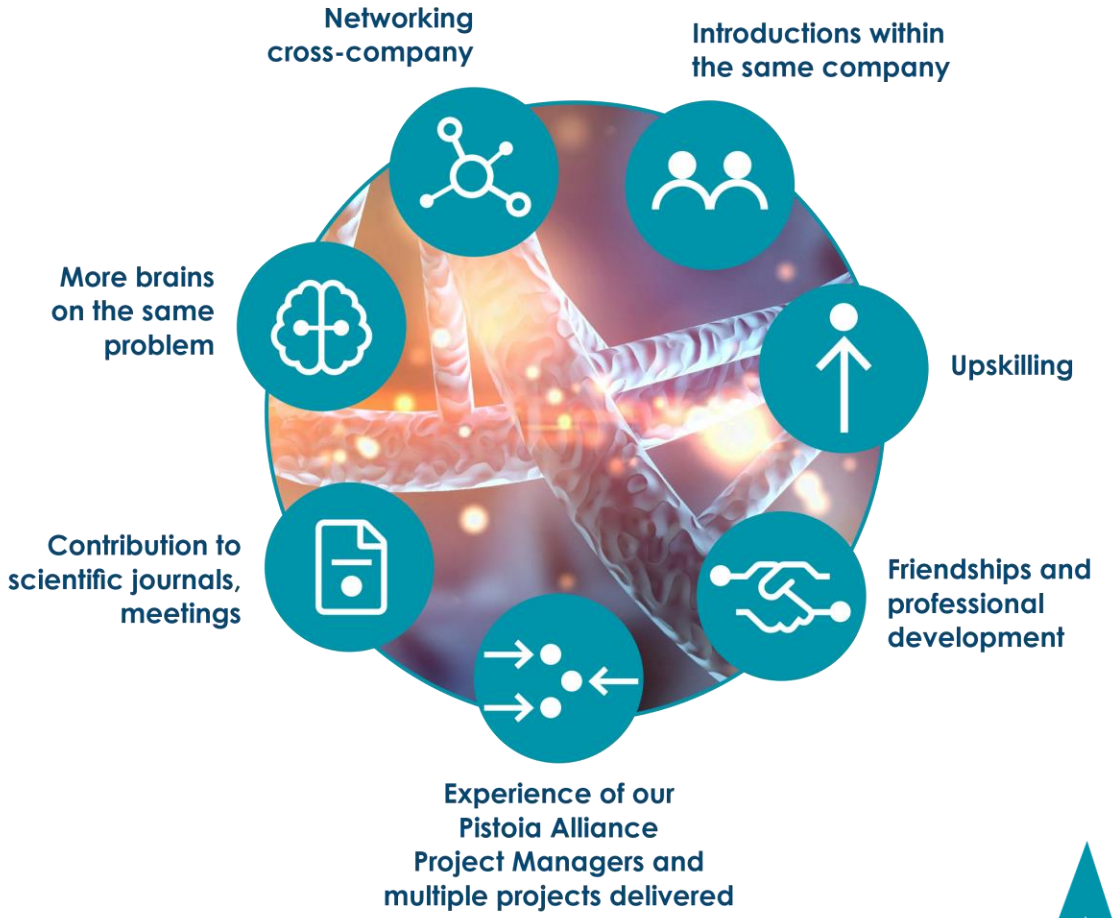
Pistoia Alliance project team

Unique membership make-up, pharma, service, tech provider & academia

Important Intangible Project Benefits

What to expect?

- Project members need to be a member of the Pistoia Alliance
- We have a dedicated domain-aware and experienced project manager
- Project members contribute to the project based on their interests, expertise and when time allows.
- Project funders sit on the steering committee for the project and get to determine and influence the parameters of the project.



Process: From Ideation to Delivery

Project Flow

Ideation

Communities of Interest (CoI)

Validation discussions

Business case exploration

Project starts to take shape

Clear problem statement

Business case written

Member funded project

Member funded Community of Experts (CoE)

Estimated cost reduction – for Case Intake RFP phase

Phase	Stakeholder Group	Activity Description	Person-Days	Costs	Person-Days with PS2-Case Intake	Costs with PS2-Case intake
RFP Creation	Business	Requirements workshops and RFP content drafting (core business reps)	32	$ 13'818	16	$ 6'909
RFP Creation	Business	Participation in review sessions and kickoff/final meetings (additional business reps)	16	$ 6'909	16	$ 6'909
RFP Creation	Business	Final document review	12	$ 5'182	12	$ 5'182
RFP Creation	IT	Project Manager	40	$ 17'273	20	$ 8'636
RFP Creation	IT	Business Analyst	40	$ 17'273	20	$ 8'636
RFP Creation	IT	Quality Manager	8	$ 3'455	4	$ 1'727
RFP Creation	IT	Technical requirement definition	16	$ 6'909	8	$ 3'455
RFP Creation	IT	Workshops and RFP reviews	2	$ 864	2	$ 864
RFP Creation	Procurement	Template setup, compliance, logistics	8	$ 3'455	4	$ 1'727
RFP Creation	External Advisors	Review, best practice input, participation in meetings	12	$ 21'600	4	$ 7'200
Vendor Shortlisting	Business	Review of initial proposals by core group	20	$ 8'636	20	$ 8'636
Vendor Shortlisting	Business	Light review by rest of group and final shortlisting meeting	24	$ 10'364	24	$ 10'364
Vendor Shortlisting	IT	Project Manager	30	$ 12'955	18	$ 7'773
Vendor Shortlisting	IT	Business Analyst	12	$ 5'182	3.6	$ 1'555
Vendor Shortlisting	IT	Quality Manager	0	$ -	0	$ -
Vendor Shortlisting	IT	Review of initial proposals by core group	10	$ 4'318	10	$ 4'318
Vendor Shortlisting	IT	Light review by rest of group and final shortlisting meeting	15	$ 6'477	15	$ 6'477
Vendor Shortlisting	Procurement	Distribute, compile proposals, coordinate Q&A and scoring	8	$ 3'455	4	$ 1'727
Vendor Shortlisting	External Advisors	Expert review of proposals, join shortlisting	12	$ 21'600	4	$ 7'200
Final Selection	Business	Attendance at demos	38.4	$ 16'582	38.4	$ 16'582
Final Selection	Business	Final selection meeting (full team)	6	$ 2'591	6	$ 2'591
Final Selection	Business	Demo/PoC scenario and evaluation prep	4	$ 1'727	4	$ 1'727
Final Selection	IT	Project Manager	20	$ 8'636	20	$ 8'636
Final Selection	IT	Business Analyst	4	$ 1'727	4	$ 1'727
Final Selection	IT	Quality Manager	0	$ -	0	$ -
Final Selection	IT	Attendance at demos (full team)	5.6	$ 2'418	5.6	$ 2'418
Final Selection	IT	Final decision meeting	3.5	$ 1'511	3.5	$ 1'511
Final Selection	IT	Demo/PoC prep and criteria definition	2	$ 864	2	$ 864
Final Selection	Procurement	Demo logistics and final scoring support	4	$ 1'727	4	$ 1'727
Final Selection	External Advisors	Attend demos, advise, help with evaluation framework	6	$ 10'800	4	$ 7'200
TOTAL Costs				**$218'307**		**$144'280**
Net savings with assets from PS2 - Case Intake				**$ 74'027**		

Estimated cost reduction – Case Intake RFP
Assumptions

Phase	Parameter	Value current state	Comment	Value with PS2 - Case Intake	Comment
All	Nb of initial proposals	10		10	
RFP Creation	Duration Phase 1 - RFP creation (weeks)	8		4	Less time to write requirements. Focus on company specifics
Vendor Shortlisting	Duration Phase 2 - Vendor Shortlisting (weeks)	6		3.6	Less time for vendor responses, less time for Q&A
Final Selection	Duration Phase 3 - Final Selection (weeks)	4		4	
RFP Creation	% Allocation Project Manager	100%		100%	
RFP Creation	% Allocation Business Analyst	100%		100%	
RFP Creation	Nb of core business representatives	4	1 EU, 1 US, 1 Japan, 1 ROW	4	
RFP Creation	% Allocation core business representatives	20%		20%	
RFP Creation	Nb of additional business reviewers	8		8	
RFP Creation	Effort for each additional reviewer (days)	2		2	
RFP Creation	Effort for final review (days per reviewer)	1		1	
RFP Creation	Nb of experts for technical requirements definition	2	1 Solution Architect, 1 Technical Design Expert	2	
RFP Creation	% Allocation technical experts	20%		20%	
RFP Creation	Nb of additional tech reviewers	5		5	
RFP Creation	Effort for additional technical reviewer (days)	2		2	
RFP Creation	% Allocation Quality Manager	20%		20%	
RFP Creation	% Allocation Quality Assurance	0%		0%	
RFP Creation	% Allocation procurement	20%		20%	
RFP Creation	Nb external advisors	2		2	
RFP Creation	% Allocation external advisors	15%		10%	
Vendor Shortlisting	% Allocation Project Manager	100%	Includes attending demos, meetings	100%	
Vendor Shortlisting	% Allocation Business Analyst	40%	Includes attending demos, meetings	20%	
Vendor Shortlisting	% Allocation Quality Manager	0%		0%	
Vendor Shortlisting	Effort to review and rate a proposal for core team member(days)	0.5		0.5	
Vendor Shortlisting	Effort for light review and rating proposal for additional member(days)	0.3		0.3	
Vendor Shortlisting	% Allocation procurement	20%		20%	
Vendor Shortlisting	Nb external advisors	2		2	
Vendor Shortlisting	% Allocation external advisors	15%		10%	
Final Selection	% Allocation Project Manager	100%	Includes attending demos, meetings	100%	
Final Selection	% Allocation Business Analyst	20%	Includes attending demos, meetings	20%	
Final Selection	% Allocation Quality Manager	0%		0%	
Final Selection	Nb of finalists	4		4	
Final Selection	Duration of demo and rating	0.8		0.8	
Final Selection	Duration of final selection meeting	0.5		0.5	
Final Selection	Effort for Demo/PoC prep	1		1	
Final Selection	% Allocation procurement	20%		20%	
Vendor Shortlisting	Nb external advisors	2		2	
Final Selection	% Allocation external advisors	15%		10%	
All	Daily rate high cost country for internal staff (in USD)	$ 909		$ 909	
All	Daily rate low cost country for internal staff (in USD)	$ 227		$ 227	
All	Distribution high cost vs low cost country	30%		30%	
All	Average internal rate	$ 432		$ 432	
All	Daily rate external advisors	$ 1’800		$ 1’800	