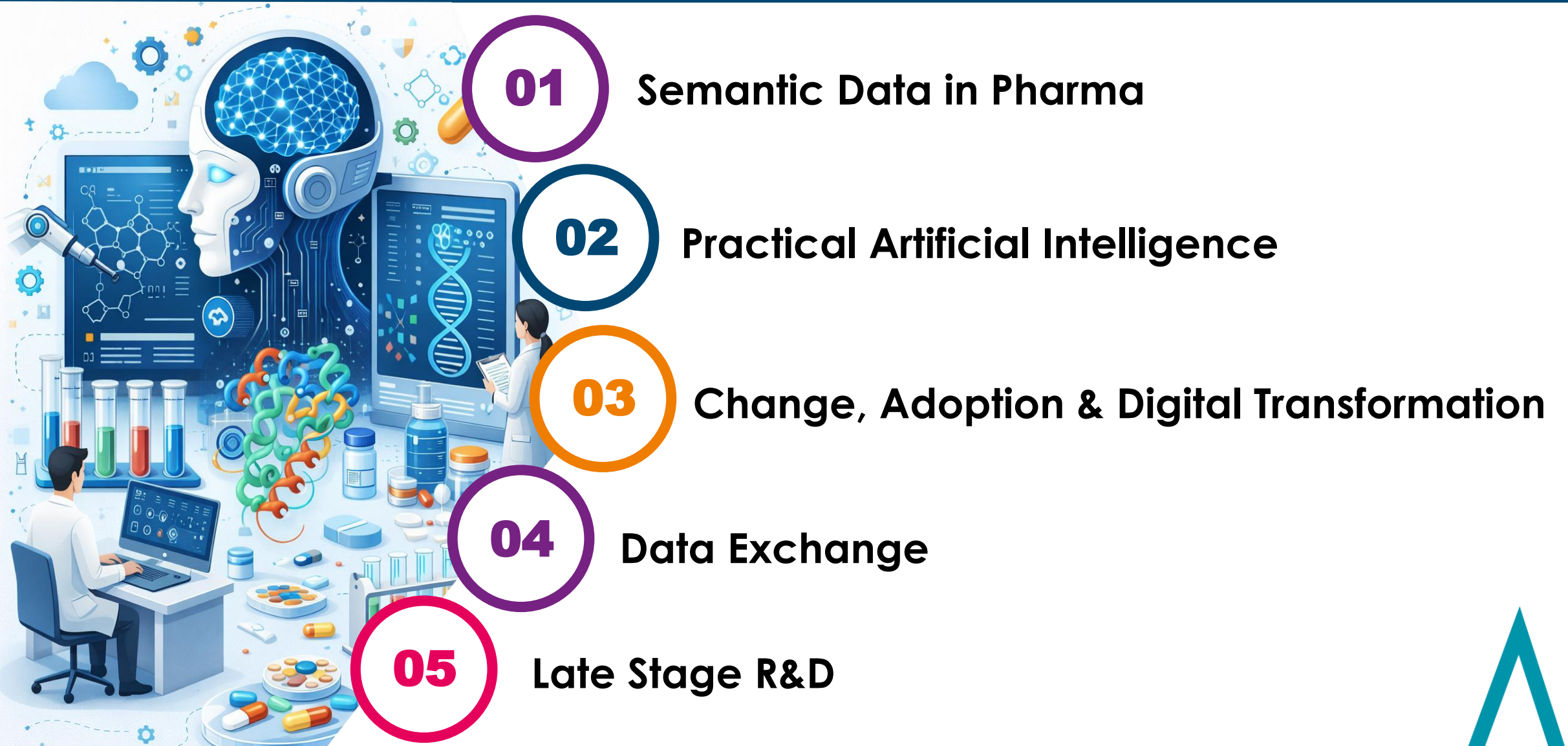


Pistoia Alliance Portfolio

July 2026, JC Baber & T Escudier



Discussion Overview



Our Strategic Priorities



Delivering Data-Driven Value at Scale

Data is the foundation for AI and digital strategies, but we struggle to manage, maintain and consume data



Harnessing AI to Expedite R&D

83% of Life Sciences Execs say they will not achieve growth goals without AI*

* Accenture Report



Accelerate Late-Stage R&D

Increase the effectiveness of the most expensive phases of R&D to benefit patients



Sustainability Driven R&D

ESG is a priority for companies from a growth and public health perspective. We must ensure that the benefits of our therapies are not offset by our operations



Activities Aligned with Strategic Priorities



Delivering Data-Driven Value

Ontologies

- IDMP-O
- Pharma CMC Process Ontology
- Pharma General Ontology

Data Enrichment

- DataFairy Bioassay Annotation
- FAIR-for-Pharma Community
- [Open-source Instrument Data Converter](#)
- [Digital Analytical Methods*2](#)

Data Integration & Management

- *In Vitro* Pharmacology*1
- *In Vivo* Efficacy Data Standards
- Data Governance Community
- GSRS Consortium
- Chemical Exchange Format Community

Harnessing AI to Accelerate R&D

Algorithms

- Benchmarking LLMs for Natural Language Data Mining

Best Practices

- LLM & NLP Use Case Database
- Life Sciences AI Exchange
- [Updated IDMP-O Training](#)

Sustainability Driven R&D

- Carbon Footprint for Decentralized Clinical Trials
- *In Vitro* NAMs Data Standards*
- [Digital Transformation & Change Management Community](#)
- Minimal *In Vivo* Metadata for Data Reuse & Repurposing

Accelerate Late-Stage R&D

- Social Media & RWE
- Pharmovigilance Case Intake & Processing

Other Activities

- Microbiome-Mediated Drug Metabolism Database
- Controlled Substance Compliance & Shipping Community (CSCS)
- User Experience in the Life Sciences Community (UXLS)
- Future Lab Evolution
- Quantum Computing Community

*1 Public Private Partnership with the FDA

*2 In Collaboration with Allotrope

Ideas Aligned with Strategic Priorities



Delivering Data-Driven Value

Ontologies

- Instrument & Equipment Ontology
- Experiment & Assay Ontology

Data Enrichment

- Synthetic Data in Medical Imaging

Data Integration & Management

- Standardized bioinformatics (NGS) computational pipelines
- HELM Format Enhancements
- FAIR Maturity Matrix as a Service
- Knowledge Graph Community

Harnessing AI to Accelerate R&D

Algorithms

- Secure Benchmarking of AI Solutions
- LLM Accelerators for Ontology Development & Adoption
- Federated Foundation AI Models for Pathology and Toxicology

Best Practices

- Utilization of AI/ML results in Regulatory Filings

Sustainability Driven R&D

- Updated IDMP-O Training
- Upcoming Training: Digital Transformation for Labs
- Upcoming Training: AI Ready Data

Accelerate Late-Stage R&D

- Safety & PV AI Forum
- Regulatory Submission of Omics Data Collected in Clinical Trials
- Pharmaceutical Quality Knowledge Model
- ClinCilico : AI in Clinical Trials
- Clinical Trial Patient Matching

Other Activities

- Regional Export Restrictions on Shipping & Data Exchange
- Enabling the Citizen Developer
- The Common Corpus: Literature to Knowledge
- EHRs for Early Disease Detection

Idea Development

How an idea becomes a project at Pistoia Alliance

Project Flow



Idea



**Business Case
Exploration**

Proposer & Supporters
Deliverable Identification
Benefit Capture



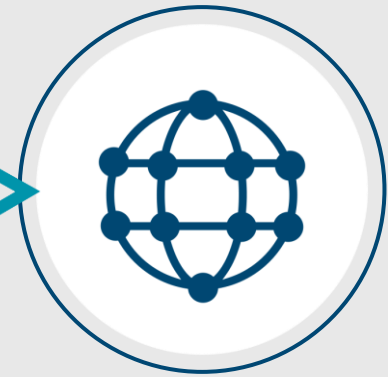
**Business Case
Development**

Outreach & Onboarding
Community Roundtables
Proposal Finalization



**Project
Initiation**

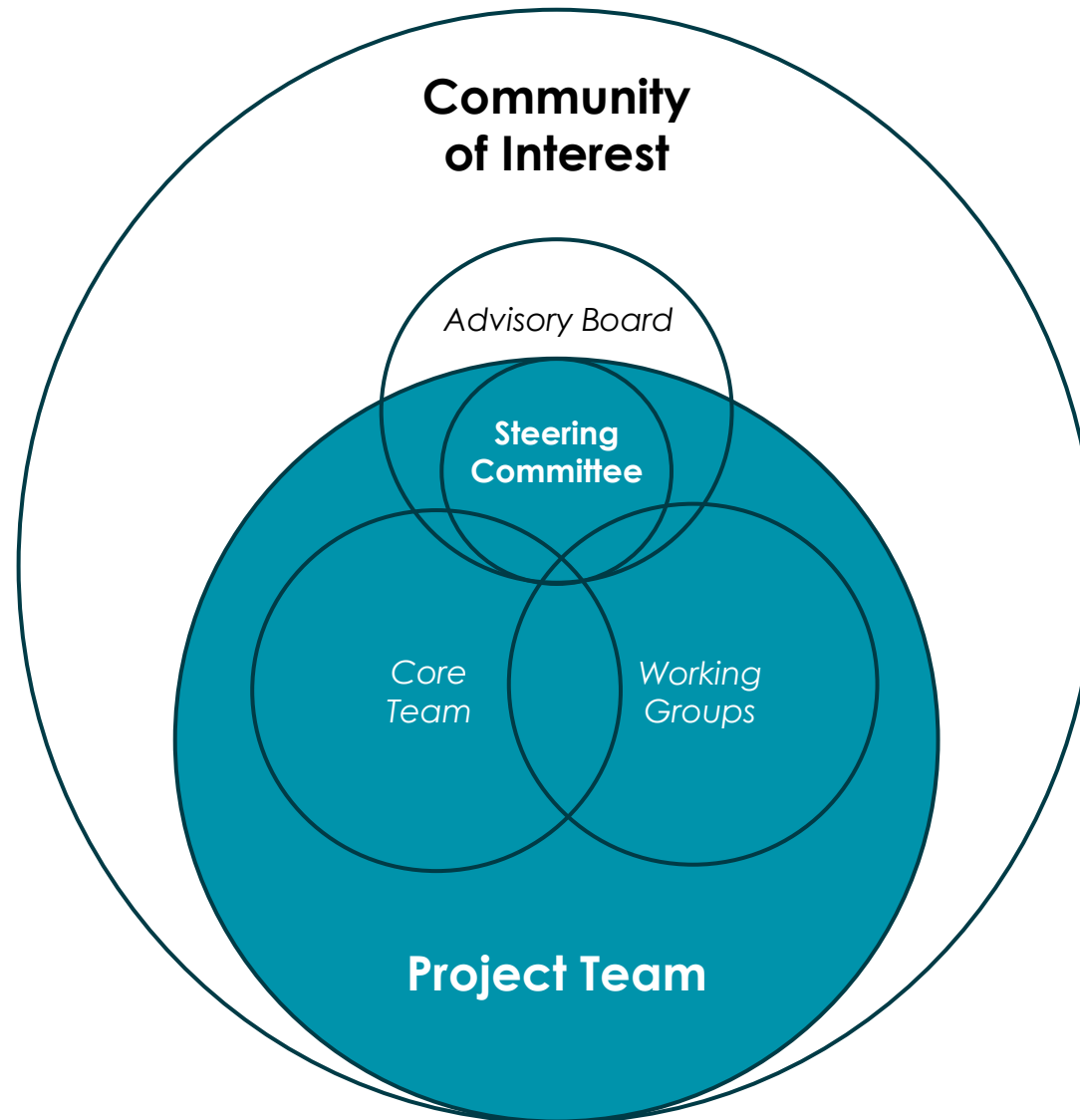
Project Funding
Final Scoping
Charter & Plan



**Member
Funded Project**

Submit Your Ideas via Our Website: [Submit an Idea - Pistoia Alliance](#)

Pistoia Alliance Project Team Structure



Pistoia Alliance
Members

Wider Community

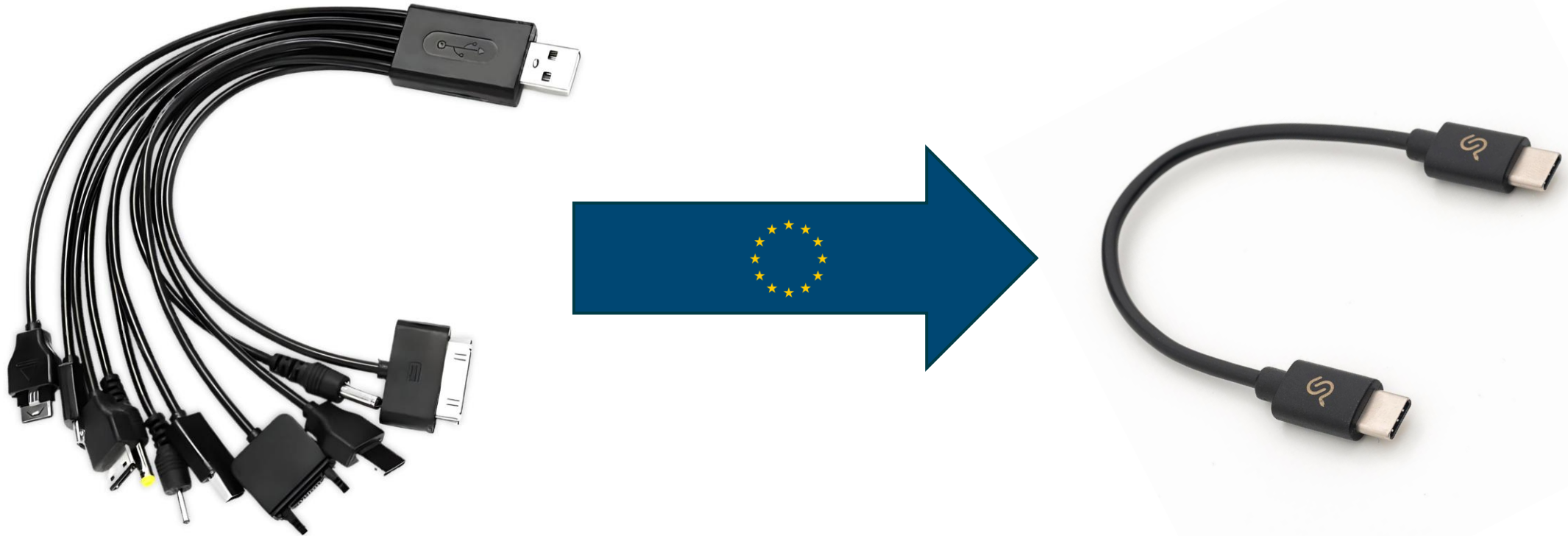
Optional teams in *italics*



Semantic Data in Pharma



Standards Make Life Easier



Why is it so difficult to get people to adopt them?

IDMP-Ontology

Trajectory & Outlook

2021
Initiation

2022 (Phase 1)
IDMP-O MVP

2023 (Phase 2)
IDMP-O v1.0 Build

- Suitable for Production Use

2024 (Phase 3)
Pharma Implementation & Industry Adoption

- V1.0 Public Release
- Production Implementation
- Collaboration with Health Authorities
- Interoperability with other domains
- Introduction of Open-Core Model

2025
Sustainable Release & Focused Development

- Separate Maintenance and Development
- Complete shortages use case (EMA-PMS alignment)
- Develop CMC/PQ use cases (batches)
- Production implementation and industry adoption

2026-2029

Maintained Ontology with Incremental Enhancements

- Focus on implementation and adoption
- On going bug fixing and enhancement
- Extension beyond ISO standard
- Refactoring for usability
- 3-year partnership with ACCURIDS

**1st IDMP-O User Group Meeting
After Pistoia Alliance Conference (Nov 2028)
Hosted by Amgen, Boston**

CMC Process Ontology

A vendor-agnostic semantic architecture to standardize laboratory and plant production process recipes with integration points to analytics, materials, equipment and quality, facilitating tech transfers and interoperability.

Industry Challenge

- 1 There is currently no machine-readable representation of CMC processes and process development.
- 2 CMC data is fragmented and non-interoperable across sites, partners, and systems.
- 3 As a consequence, process knowledge is rarely accessible and reusable across the lifecycle.

Goals and Intended Deliverables

- Expanded, modular ontology with capability-based equipment mapping.

CAR-T manufacturing.

CMC-PO Version 1.0 Released to Members May 2026

(Public Release scheduled for Nov 2026)

Interoperability
ELN, MES
MS



AI-ready and
contextualized
data

Time Savings

Machine-readable recipe exchange cuts rework, errors, and timelines

Faster Innovation

Standardized, contextualized data are ready for analytics and AI

Improved Compliance

Traceability across steps, materials, equipment, QA

Increased Quality

Unambiguous vocabulary from R&D, manufacturing, and quality to regulatory



FAIR Community of Experts (COE)



Our mission is to enable FAIR data principles implementation to accelerate trustworthy, interoperable, and reusable data practices across the life sciences with best practices, enabling methods and tools.

Industry Challenges

- 1 FAIR transformation demands industry-wide engagement. Single company cannot drive this alone.
- 2 Lack of common standards and practices hinder interoperability across teams, service providers and partners
- 3 Legacy systems, processes, culture, skill sets. FAIR data transformation journey requires organizational changes

Goals and Intended Deliverables

framework and calculator
tools and infrastructure
webinars and tutorials

FAIR Maturity Matrix v1.2
Released April 2026

FAIR Business Value
Framework *alpha* Release
June 2026

(Release to Members scheduled for Sept 2026)

Industry

collective
shapes
& delivers
olutions.

Knowledge Exchange

across
companies, among
experts and peers

Community Facilitator

Increasing industry-wide quality reduces errors and rework

Dates & Budget

Jan. Dec. 2026- Min \$50k - Ticket: \$10k for a steering group seat (large pharma)

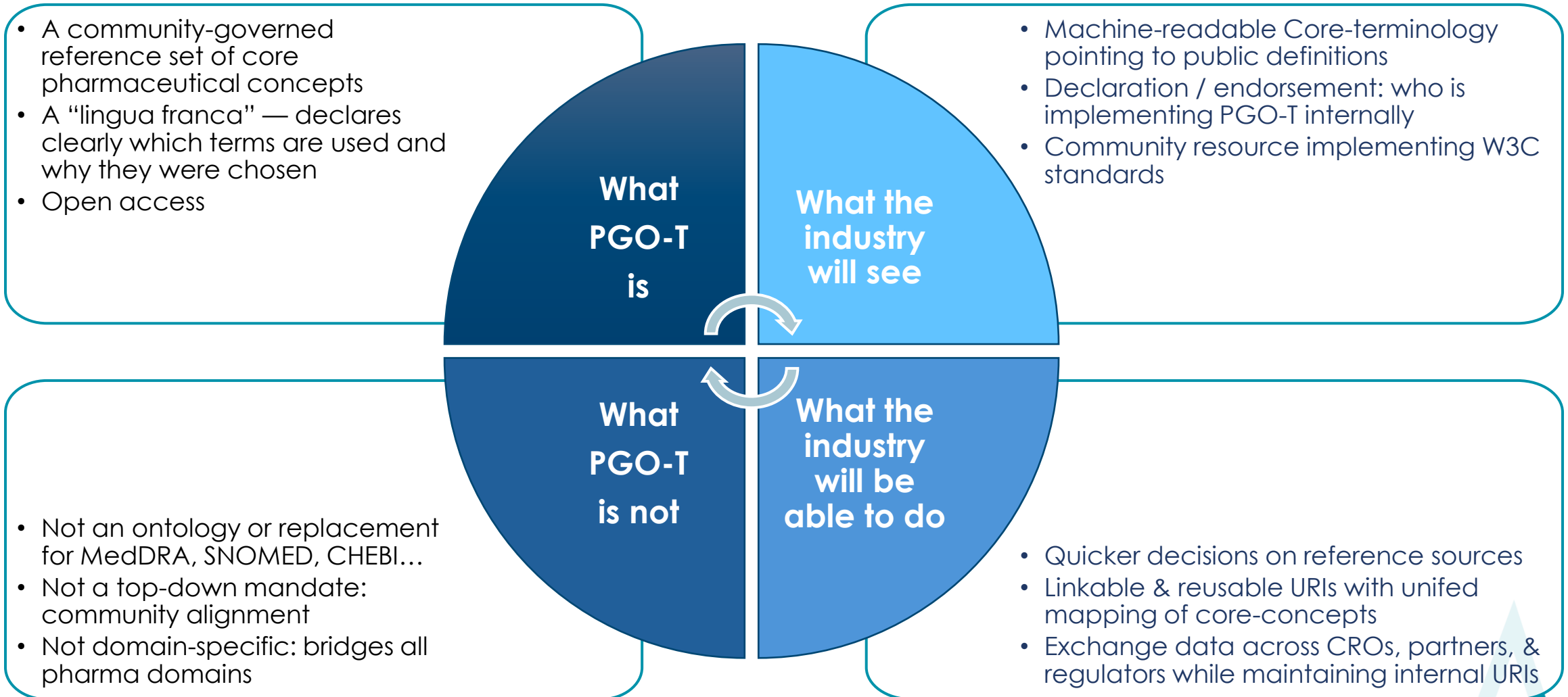


‘The nice thing about standards is that you have so many to choose from’

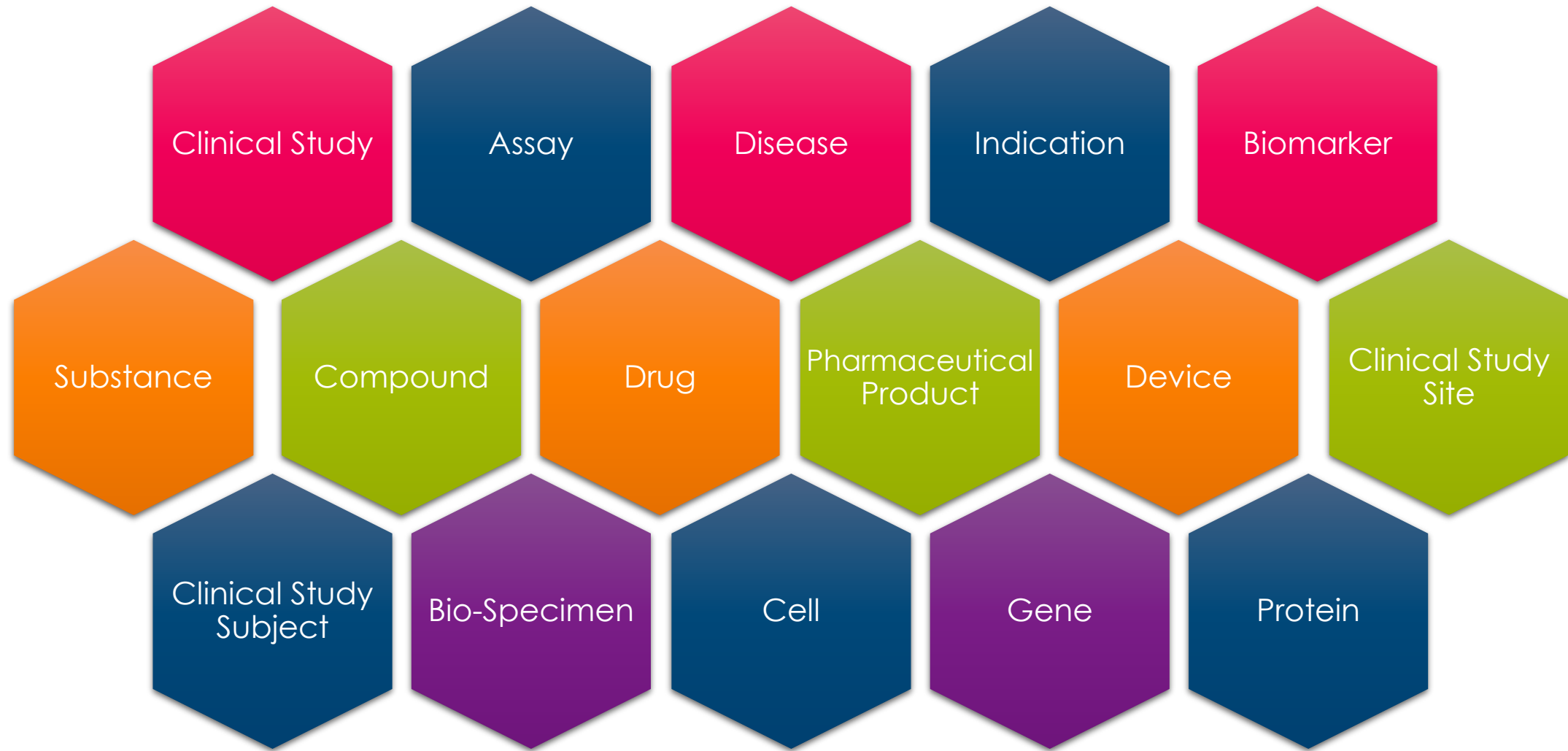
Andrew S. Tanenbaum, Computer Networks (1981)



Pharma General Ontology (PGO)-Terminology



Covered Concepts (v1.0)



Example

Class: Indication

A sign, signal, circumstance, or symptom which serves to indicate or point out the cause, pathology, treatment, or issue of an attack of disease; the basis for initiation of a treatment for a disease or of a diagnostic test (causal, or symptomatic, or disease-specific indication)

<https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncit/C41184>

► Alternative Descriptions

▼ Aliases

- Therapeutic Indication

▼ Examples

Value	Description
abnormal blood glucose concentration	too much or too little glucose in the blood).
Hypotension	A condition in which the blood pressure in the arteries is abnormally low.

▼ Annotations

property	value
definition_source	https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncit/C41184
definition_source_attribution	NCI-Thesaurus (NCIT)
definition_source_licence	CC-BY-4.0
definition_access_date	2025-05-30
expert_approval_date	2025-06-12
conceptual_clarification	The group acknowledged the complexity of the term 'Indication', which spans both pre-approval (e.g., clinical investigation) and post-approval (e.g., regulatory labeling) contexts. Core challenges in terminology harmonization included--

- The restrictive use of terms such as 'abnormal' or 'pathological', which may unnecessarily narrow the scope.
- Differentiation between 'sign' and 'symptom'.
- The regulatory distinction between investigational and approved uses of a medicinal product.
- The need for a resolvable and publicly licensed URI, a key requirement for incorporation into PGO.

While definitions from IDMP-O and CDISC were considered valuable, the absence of resolvable unique identifiers in some cases limited their immediate applicability. Notably, the CDISC glossary version of 'Indication' appears to reuse the NCIt concept C41184, but with a modified definition—raising concerns about versioning and semantic traceability. |

PGO-T: Long-Term Vision

To Supply Chain and Beyond!

Phase 2 (2025–2026) — In progress

Expanding Coverage:

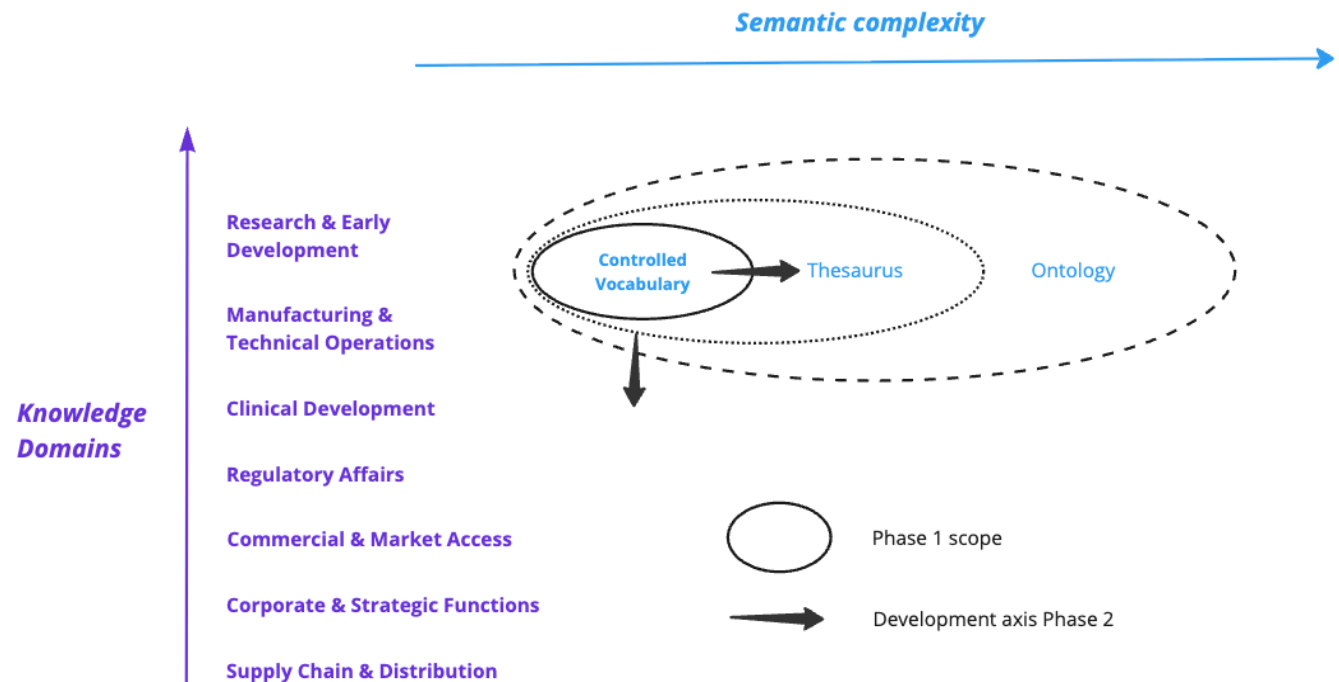
Additional concepts include Adverse Event, Excipient, Instrument, Medical Condition, Molecular Target, Study Site, Study Subject (> 20 concepts)

Expanding Usability:

- Implementing schemas for machine-readable output
- Generating mappings to external ontologies

Ensuring Sustainability:

PGO as permanent, maintained, industry reference data product



Aligned Semantic Activities at Pistoia Alliance

– Pharma General Ontology (PGO-T)

Shared terminology & semantic reference for cross-organisation interoperability

– IDMP Ontology

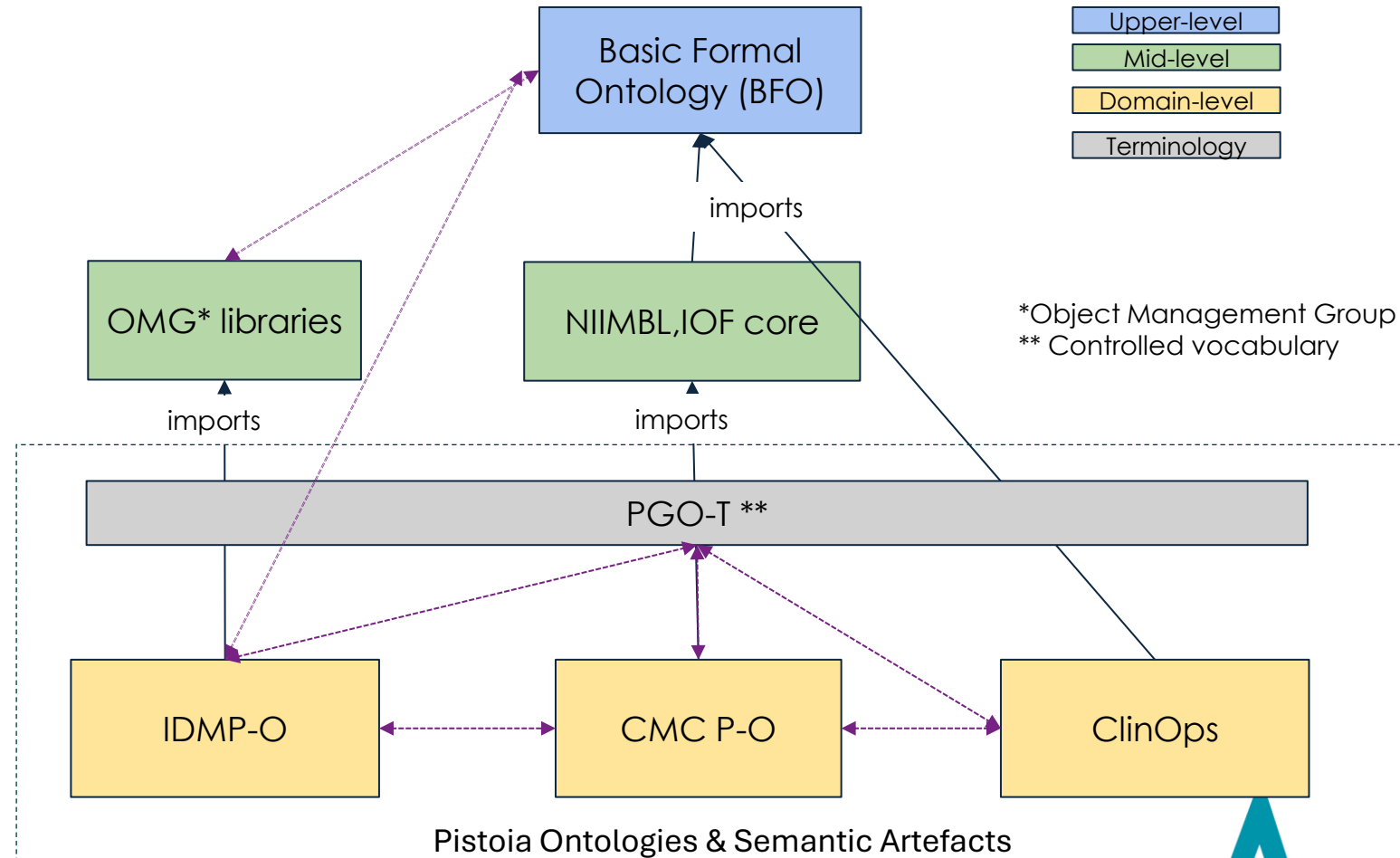
Regulatory identification of medicinal products

– CMC Process Ontology

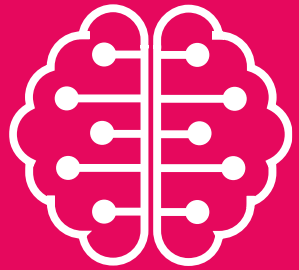
Chemistry, Manufacturing & Controls process semantics

– ClinOps Ontology

Clinical operations shared vocabulary



PISTOIA
ALLIANCE



Practical Artificial Intelligence



LLM & NLP Use Case Database

A Use Case Database built around real-world pharma applications of LLMs that provides an essential foundation for informed decision-making, faster adoption, and risk mitigation.

Industry Challenge

- 1** LLMs are currently the wild west of technology. Many opportunities but lots of unknown.
- 2** Most companies are working on variations of the same things, to different degrees of success.
- 3** Many projects succeed in theory but fail to scale and be adopted.

Goals and Intended Deliverables

- A curated catalogue of real-world pharma applications of LLMs for NLP
- Documentation of both successful deployments and failures with causes
- Analysis of trends to determine the underlying factors driving outcomes
- Exclusive live resource for Pistoia Alliance members

Value Proposition

 Avoid common pitfalls & increase successful adoption	 Enable strategic planning through a broad survey of the landscape	 Find underlying factors determining success & failure	 Know what works and what scales for informed decision making
--	---	---	--

Project Benefits

Cost Savings Avoid wasted expense by learning from the failures of others	Increased Quality Avoid pitfalls that work but ultimately lead to failure	Faster Innovation Stand on the shoulders of giants to push boundrys	Time Savings Understand what works and does not before starting
---	---	---	---



Industry Challenge

- 1 Systematic methods to assess LLM-based natural language (NL) data mining tools used in R&D are missing.
- 2 Lacking performance benchmarks, users risk blind spots in the quality of results.
- 3 The absence of appropriate test sets complicates the development of NL data mining tools.

Pistoia Alliance Value Proposition

 Novel member legal framework expedites collaboration	 Success as a neutral forum for standard, policy building	 Critical mass of members leads to influence and adoption	 Access to third party vendors leads to fit-for-purpose tools/IT
--	--	--	---

Goals and Intended Deliverables

- Deliver benchmarks to assess the true performance of LLM natural language query assistants in the context of Pharma R&D Data.
- Measure and ensure the quality of identified or constructed benchmarks.
- Communicate the findings and lessons learned.

Steering Committee Benefits

Faster Innovation
Accelerate adoption of AI tools

Community and Networking
Share benchmarks & lessons learned

Increased Quality
Drive creation & use of better tools

Pharma and Life Sciences AI/ML Training

Academics and Industry, Live in 2025, Now available on demand

Original Syllabus

- 1 - Introduction to AI for drug discovery
- 2 - Generative AI for Drug Development
- 3 - Computer vision
- 4 - Multimodal Deep Learning
- 5 - LLMs in early discovery
- 6 - LLMs as Agents in DD
- 7 - AI in Computational Medicinal Chemistry
- 8 - Knowledge graphs
- 9 - Digital pharmaceutical manufacturing

2026 Update (Sept-Nov 2026)

- 10 - AI Fundamentals and AI Ready Data
- 11 - Knowledge Management
- 12 - AI Tools and Workflows
- 13 - Governance and Responsible AI
- 14 - UX and Change Management for AI Adoption
- 15 - AI ROI Measurement and Value Realization
- 16 - Building an Enterprise AI Strategy for Pharma
- 17 - Autonomous Pharma R&D and the Future of AI



Confirmed Trainers from

- AbbVie
- AstraZeneca
- Campana & Schott
- GSK
- Ipsen
- Novo Nordisk
- Rancho BioSciences

Change, Adoption & Digital Transformation



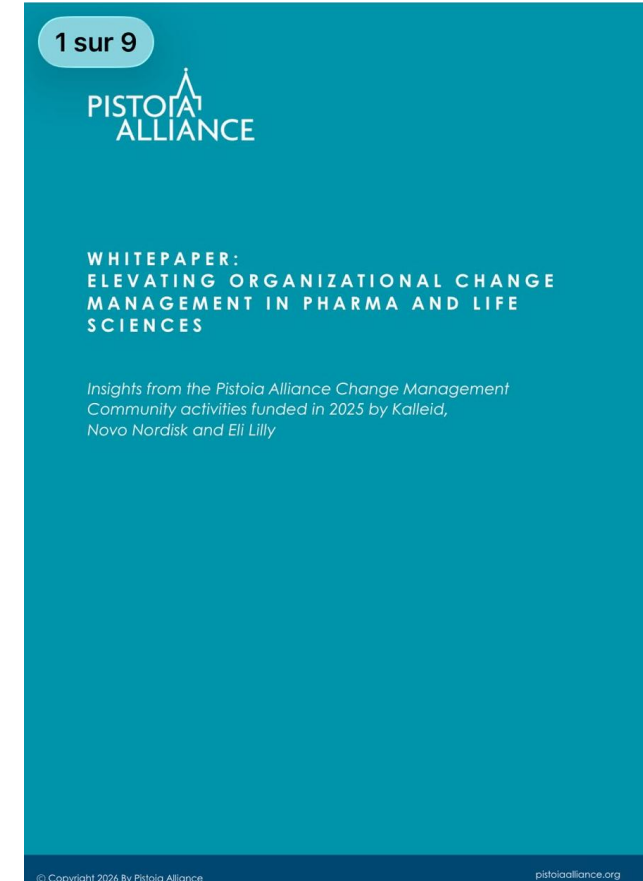
Change Management and Digital Transformation

The Technology is Not the Problem

- Dynamic community to enhance change management practices to for digital transformation across the industry
- Change management does not get the support that it deserves
- White paper released in Jan 26
 - ‘Elevating Organizational Change Management in Pharma and Life Sciences’

At the Core of Digital Transformation

- Successful multi-community workshop run in Spring 2026
 - Combining UXLS, Change management and Future Lab Evolution
 - Accelerating Digital Transformation in Pharma Labs
- Building on the output
 - A series of 6 online sessions from August to November
 - A workshop at the Boston conference
 - Produce guidelines for “Balancing short-term ROI with long-term transformation”



User Experience in Life Sciences (UXLS) Community

A community bringing together life sciences professionals to recognise and embed UX as a key strategic enabler, adapting to AI-driven change and industry trends.



Industry Challenges

- 1 UX remains as mission-critical as the Life Sciences
- 2 UX processes need to be adapted to be regulated, controlled, and developed in the context of the Life Sciences
- 3 AI-driven restructuring and budget pressures create demand that UX prove its strategic value.

2026 User Experience in Life Sciences (UXLS) Conference

October 20 - 21, 2026 | 9:00 - 17:00

GSK, Gunnels Wood Rd, Stevenage, UK

UX experience
Typing and testing
in Q2
Committee & community

Focus on creating and testing truly effective UX for Life Sciences

Access new strategies; avoid known pitfalls, build on best practices

Learn from experts about tools, processes, trends, and practices

Empower UX teams with structures, skills, and roles for UX in LS

Increased Quality
Foster improve usability of LS tools; eliminate friction in value chain



Controlled Substance Compliance & Shipping Expert Community



PM: Birthe Nielsen **Start:** 1-Jan-2026 **End:** 31-Dec-2026 **Next Phase:** 1-Jan-2027

The Challenge

Legislation relating to pharmaceutical R&D continually changes, with each change adding complexity and potentially new controls. Maintaining compliance is a constant challenge with consequences for non-compliance can be severe.

Shipping of pharmaceutical products including biologics, cold chains, dangerous goods and infectious materials under new legislation is particularly complex.

PISTOIA ALLIANCE

CSCS CONFERENCE

29-30 September 2026

Hosted by Johnson & Johnson, Cork, Ireland

A Pistoia Alliance Expert Community

CSCS
CONTROLLED SUBSTANCE COMPLIANCE & SHIPPING

Key-wide Positions on

ing solutions, each other to stay controlled substance

ch) solutions



FAIR and Data Governance Training

Live from Q3 2025-Q1 2026, Now available on demand

- 1: Introduction to **FAIR Principles**
- 2: Making Data **Findable**
- 3: Making Data **Accessible**
- 4: Making Data **Interoperable**
- 5: Making Data **Reusable**
- 6: **FAIR Implementation Frameworks**
- 7 – **FAIR Maturity Indicators**
- 8: **Technical Infrastructure for FAIR**
- 9: **FAIR in Practice (Case Studies)**
- 10: FAIR roles in cultural
Change Management
- 11: **FAIR in Life Science**
from Research to Clinical
- 12: **Business Value of FAIR**
- 13: **FAIR for AI, ML & Digital
Transformation**
- 14: **Data Governance**
- 15: **FAIR Data Strategy & Architecture**

112 Participants so Far

 FAIR and Data Governance Training SPEAKER Chris Day Principal Consultant Perdi	 FAIR and Data Governance Training SPEAKER Peter McQuilton Senior Product Owner GSK	 FAIR and Data Governance Training SPEAKER Andrea Splendiani IQVIA	 FAIR and Data Governance Training SPEAKER Sujeegar Jeevanandam Zilo	 FAIR and Data Governance Training SPEAKER Astrid Kiermaier Roche	 FAIR and Data Governance Training SPEAKER Birgit Meldal Pfizer	 FAIR and Data Governance Training SPEAKER Nancy George Syngenta
 FAIR and Data Governance Training SPEAKER Ranu Sharma Senior Scientist AbbVie	 FAIR and Data Governance Training SPEAKER Abigail Moore Scientific Reference Data Ontologist AbbVie	 FAIR and Data Governance Training SPEAKER Sirarat Samthujai Boehringer Ingelheim	 FAIR and Data Governance Training SPEAKER Baptiste Touzin CSL	 FAIR and Data Governance Training SPEAKER Saritha V. Kuriakose Novo Nordisk	 FAIR and Data Governance Training SPEAKER Prof. Barend Mons LIVES and GO FAIR foundation	 FAIR and Data Governance Training SPEAKER Philippe Rocca-Serra AstraZeneca
 FAIR and Data Governance Training SPEAKER Joshua Valdez Director, Data, Analytics & AI, Digital Transformation AstraZeneca	 FAIR and Data Governance Training SPEAKER Ben Gardner R&D Lead for Data Mesh and Semantic Infrastructure AstraZeneca	 FAIR and Data Governance Training SPEAKER Felix Schwagerl Roche	 FAIR and Data Governance Training SPEAKER Wouter Franke The Hyve	 FAIR and Data Governance Training SPEAKER Nirali Rana Head of R&D Program & Change Management Takeda	 FAIR and Data Governance Training SPEAKER Nick Perry Product Manager Roche	 FAIR and Data Governance Training SPEAKER Ted Slater EPAM
 FAIR and Data Governance Training SPEAKER Flora Zaman Head Organizational Change Management Roche	 FAIR and Data Governance Training SPEAKER Matthias Jurisch Data Architect Bayer	 FAIR and Data Governance Training SPEAKER Alexandra Grebe de Barron Bayer	 FAIR and Data Governance Training SPEAKER Ibrahim Emam AstraZeneca	 FAIR and Data Governance Training SPEAKER Heiner Oberkamp Accurids	 FAIR and Data Governance Training SPEAKER Jörg Warner CureVac	
 FAIR and Data Governance Training SPEAKER Martin Romacker Product Manager Roche Data Marketplace Roche	 FAIR and Data Governance Training SPEAKER Hillary Mosso Senior Team Leader, Data Integrity Rancho BioSciences	 FAIR and Data Governance Training SPEAKER Anuj Uppal VP Life Sciences Transformation Campana Schott	 FAIR and Data Governance Training SPEAKER John Berrisford Director of Curation and Modelling AstraZeneca	 FAIR and Data Governance Training SPEAKER John Wise Facilitator Data Governance COE Pistoia Alliance	 FAIR and Data Governance Training SPEAKER Giovanni Nisato Facilitator FAIR COE Pistoia Alliance	

PISTOIA
ALLIANCE

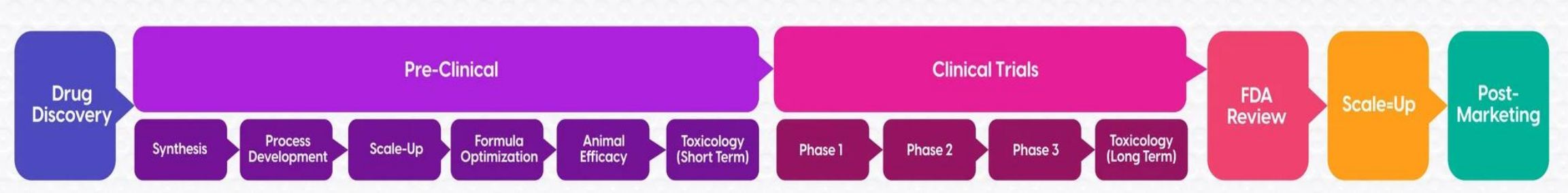


Data Exchange



DATA STANDARDIZATION & AI READINESS INITIATIVES

PISTOL
ALLIANCE



Data Standardization & AI Readiness Initiatives

Driving consistency, efficiency, and innovation in life sciences through data standardization and AI readiness

IVP Result Standardization

- No harmonized IVP result formats
- Inconsistent regulatory submissions

- Standard IVP submission template
- Open-access assay repository

- Reduced duplication & cost
- Improved predictive safety modeling

In Vitro NAM Data Harmonization

- Non-standardized metadata
- Siloed data sources

- Harmonized metadata standards
- Standard result formats

- Human-relevant methods identified
- Increased regulatory confidence

In Vivo Efficacy Data Standards

- Fragmented *in vivo* efficacy datasets
 - Challenging to integrate & analyze

- CDISC SEND-aligned data model
- Pilot implementation

- FAIR datasets enabling AI-driven analysis
 - Faster regulatory submissions

Some Highlights

- **In Vitro Pharmacology (IVP) :**
 - PPP with the FDA
 - Release of v1.0 IVP assay repository
 - A standardized IVP data template for IND/NDA submissions (screening and dose response)
 - An ontology-aligned framework
 - Development of an IVP Glossary
 - **In Vitro Novel Alternative Models (NAM) :**
 - PPP with the FDA
 - Standardised Template for Endpoint Result Data Collection and Assay metadata in Cardiac Safety and Hepatotoxicity In Vitro NAM Assays
 - Controlled Vocabulary and Glossary for In Vitro NAMs
 - Manuscript under preparation
 - **Minimal Metadata Set (MNMS) :**
 - Validation of the minimal metadata set by demonstrating $\geq 95\%$ of MNMS template completion when data from 5 companies are tested
 - Manuscript under preparation
 - **In Vivo Laboratory Efficacy Data Standards :**
 - Mapping of oncology data with SEND IG 4.0 and Animal Rule IG 1.0
 - Development of Standardized SDTM-Compatible Domain(s) for Efficacy Studies (In Progress)
- 

Key Take away messages

- With those 4 projects, we contribute to help our members :
 - to be aligned with 3R rules (Reduce, Reuse, Recycle)
 - to leverage the use of AI
 - to speed up regulatory submissions
 - enabling integrated, interoperable, and FAIR-aligned preclinical data exchange



PISTONAI
ALLIANCE



Late-Stage R&D



Accelerating Innovation in Late-Stage R&D

Late-stage R&D generates enormous volumes of clinical, regulatory, safety, and real-world data. Success increasingly depends on:

- Cross-company collaboration
- Data interoperability
- AI-ready standards
- Faster evidence generation
- Regulatory trust
- Sustainable digital transformation

All the Pistoia Alliance foundational work and models serve to help late-stage R&D processes

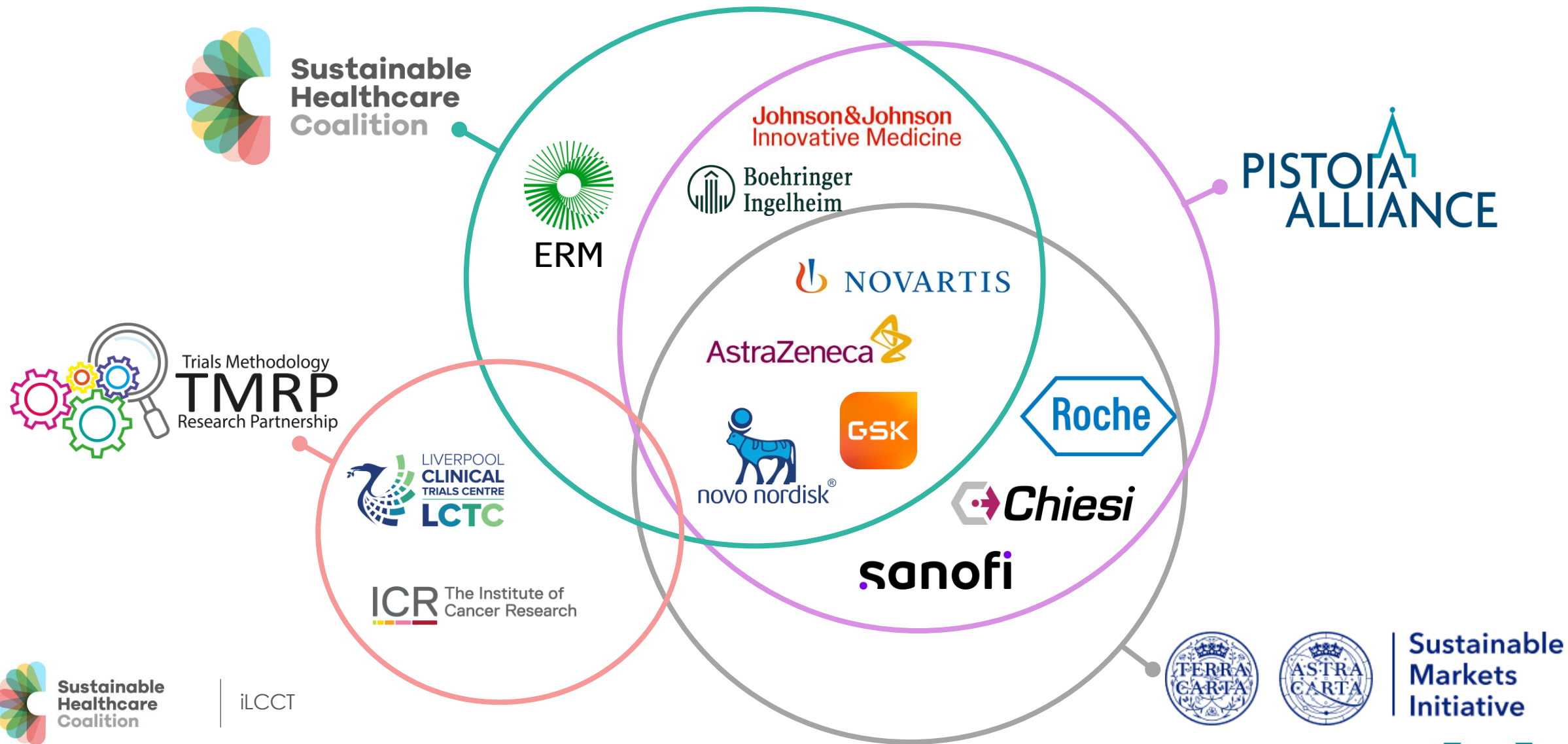


Focus in late stage R&D portfolio

- Carbon footprint clinical trials
- Social Media Listening for RWD
- PV
- AI and Clinical Trials



The industry Low Carbon Clinical Trials consortium (iLCCT)



The iLCCT Clinical Trials Carbon Calculator

Who it's for

The iLCCT Clinical Trials Carbon Calculator is for anyone involved in any stage of clinical trials design and management

What

The iLCCT Clinical Trials Carbon Calculator is free to use and is a step-wise, activity-based process to support design of low-carbon clinical trials and their reporting, including scenarios and Docusaurus functionality for ease of use

Why

To ensure the impact at scale needed to mitigate climate change, we need a consistent approach to reduce the carbon emissions from clinical trials

For entire supply chain adoption of low carbon processes, coordination is also essential



Johnson & Johnson



sanofi



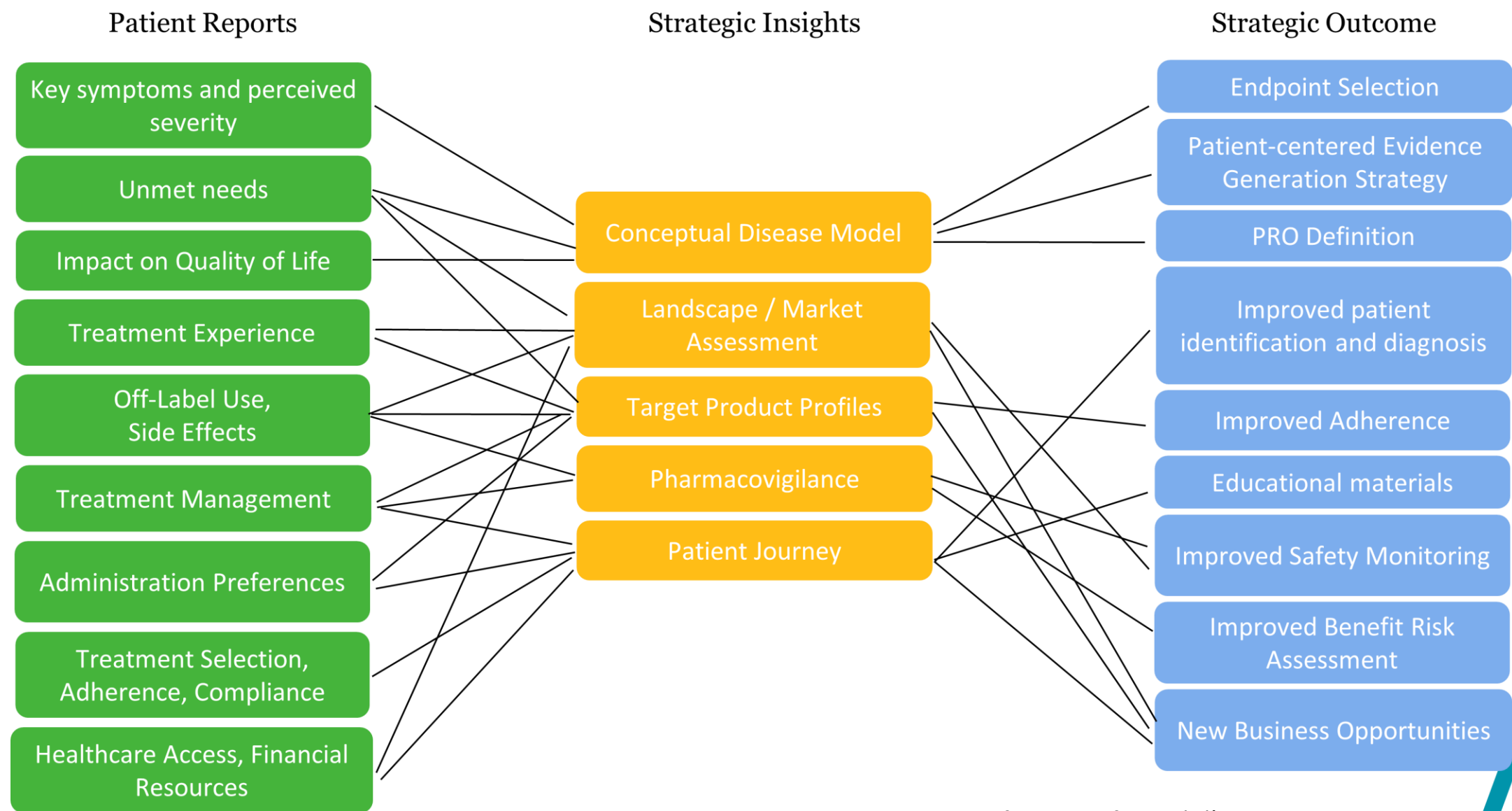
Trials Methodology
TMRP
Research Partnership

Some Highlights

- **Carbon footprint clinical trials :**
 - Calculator V3 launched April 2nd
 - Assessment of impact of “use of digital tools” ongoing :
 - Focus is on saving patients travels and monitors travels
 - Community of Practice is expanding : > 400 members WW



Real World Social Data turns patient voices into strategic outcomes



Source : Semalytix

What have we done ? Key Deliverables

- Defining Best Practices for Data collection, Analysis & validation :
 - 2 publications : one position paper, one methodology

 Frontiers in Medicine

TYPE Policy and Practice Reviews
PUBLISHED 06 March 2024
DOI 10.3389/fmed.2024.1274688

 Check for updates

OPEN ACCESS

EDITED BY
Carla Matos Torre,
University of Lisbon, Portugal

REVIEWED BY
Prathamesh Karmalkar,
Merck Group, India
Carlos Alves,
University of Coimbra, Portugal

*CORRESPONDENCE
Philipp Cimiano
✉ cimiano@cit-ec.uni-bielefeld.de

RECEIVED 08 August 2023
ACCEPTED 12 February 2024
PUBLISHED 06 March 2024

CITATION
Cimiano P, Collins B, De Vuono MC,
Escudier T, Gottowik J, Hartung M, Leddin M,
Neupane B, Rodriguez-Esteban R,
Schmidt AL, Starke-Knäusel C,
Voorhaar M and Wieckowski K (2024) Patient
listening on social media for patient-focused
drug development: a synthesis of

Patient listening on social media for patient-focused drug development: a synthesis of considerations from patients, industry and regulators

Philipp Cimiano^{1,2*}, Ben Collins³, Maria Carmela De Vuono⁴,
Thierry Escudier⁵, Jürgen Gottowik⁶, Matthias Hartung¹,
Mathias Leddin⁶, Bikalpa Neupane⁷, Raul Rodriguez-Esteban⁴,
Ana Lucia Schmidt⁶, Cornelius Starke-Knäusel¹,
Maarten Voorhaar³ and Krzysztof Wieckowski⁸

¹Semalytix GmbH, Bielefeld, Germany, ²CITEC, Bielefeld University, Bielefeld, Germany, ³Boehringer
Ingelheim International GmbH, Ingelheim, Germany, ⁴Chiesi Farmaceutici SpA, Parma, Italy, ⁵Pistoia
Alliance, Wakefield, MA, United States, ⁶Roche Innovation Center Basel, F. Hoffmann-La Roche Ltd.,
Basel, Switzerland, ⁷Takeda Pharmaceuticals Co., Ltd., Cambridge, MA, United States, ⁸SageFiber,
Ustron, Poland

 Frontiers in Medicine

TYPE Policy and Practice Reviews
PUBLISHED 30 January 2026
DOI 10.3389/fmed.2025.1703923

 Check for updates

OPEN ACCESS

EDITED BY
Cristiana Sessa,
Oncology Institute of Southern Switzerland
(IOSI), Switzerland

REVIEWED BY
Md Sadique Hussain,
Uttaranchal University, India
Diana M. J. Delnoij,
National Health Care Institute (ZIN),
Netherlands
Chantal Britt,
Bern University of Applied Sciences,
Switzerland

*CORRESPONDENCE
Philipp Cimiano
✉ cimiano@semalytix.com

RECEIVED 12 September 2025
REVISED 18 November 2025
ACCEPTED 03 December 2025
PUBLISHED 30 January 2026

Best practices for the collection and analysis of patient experience data from social media for patient-focused drug development

Philipp Cimiano^{1,2*}, Nicole Brazda¹, Matthias Hartung³,
Cornelius Starke-Knäusel¹, Ana Lucia Schmidt⁴,
Maria Carmela De Vuono⁵, Aditya Tyagi⁷, Jürgen Gottowik⁴,
Raul Rodriguez-Esteban⁴, Ben Collins⁶, Krzysztof Wieckowski⁶
and Thierry Escudier⁷

¹Semalytix GmbH, Bielefeld, Germany, ²Faculty of Technology, Bielefeld University, Bielefeld, Germany,
³Boehringer Ingelheim GmbH, Ingelheim, Germany, ⁴Roche Innovation Center Basel, Basel,
Switzerland, ⁵Chiesi Farmaceutici S.p.A., Parma, Italy, ⁶Boehringer Ingelheim International GmbH,
Ingelheim, Germany, ⁷Pistoia Alliance, Wakefield, MA, United States

POMELO : Protocol for social media listening online

Presented at ISPOR
May 18th 2026

Applying the Best Practices Framework to Enhance Reporting Standards in Patient Listening Studies from Social Media

PCR45

POMELO: PROTOCOL FOR SOCIAL MEDIA LISTENING ONLINE

Philipp Cimiano^{1,2}, Nicole Brazda¹, Matthias Hartung³, Cornelius Starke-Knäusel¹, Ana Lucia Schmidt⁴, Maria Carmela De Vuono⁵, Aditya Tyagi⁶, Jürgen Gottowick⁴, Raul Rodriguez-Esteban⁴, Ben Collins⁷, Krzysztof Wieckowski⁷, Thierry Escudier⁷

¹Semalytix GmbH, Bielefeld, Germany, ²Faculty of Technology, Bielefeld University, Bielefeld, Germany, ³Boehringer Ingelheim GmbH, Ingelheim, Germany, ⁴Roche Innovation Center Basel, Basel, Switzerland, ⁵Chiesi Farmaceutici S.p.A., Parma, Italy, ⁶Pistoia Alliance, Wakefield, MA, United States, ⁷Boehringer Ingelheim International GmbH, Ingelheim, Germany

01 BACKGROUND & OBJECTIVES

- Social media listening (SML) can capture real-world patient experience.
- Reporting standards remain inconsistent across studies.
- POMELO provides structured best-practice guidance.
- Validation of framework using a T2DM case study.

02 RESEARCH METHODS

- The research team **successfully applied the comprehensive POMELO framework** to evaluate a specific T2DM clinical case study.
- We analyzed social media discussions from **32 online forums between 28 Feb 2023 and 28 Feb 2025**.
- The primary research study focused heavily on **symptoms reported by patients, daily burdens, and various related comorbidities**.

Validated POMELO as a **reporting standard** through a review of **peer-reviewed SML studies** in published over the past two years. Assessed reporting quality based on the presence and clarity of:



05 CONCLUSION

- **POMELO** consolidates best and widely used practices for **SML**.
- Integrates existing methodological standards into one structured framework.
- Addresses key gaps and inconsistencies in study reporting.
- Supports improved **study quality and interpretability**.
- Enhances the **credibility** and broader **acceptance** of SML evidence.

FULL PUBLICATION

^[1]Cimiano P, Brazda N, Hartung M, et al. Best practices for the collection and analysis of patient experience data from social media for patient-focused drug development. Frontiers in Medicine. 2025;12

Funding
www.pistoiaalliance.org

Contact Information
cimiano@semalytix.com



JOIN US!

We are looking for more companies to act as funders and contributors, if you are interested, please contact: aditya.tyagi@PistoiaAlliance.org

TO DOWNLOAD
POMELO FRAMEWORK,
SCAN THIS QR CODE

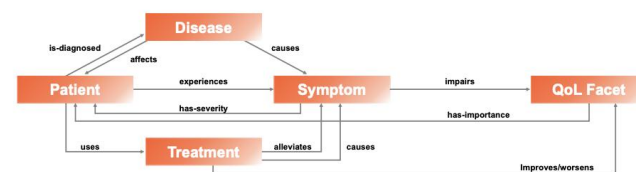


Fig. 1: Conceptual patient experience model (CPEM) to define the relevant information types/variables that can be extracted from patients' posts in the context of SML studies.

03 T2DM CASE STUDY SNAPSHOT

527,268 Document Analysed 3,243 Patients Identified

OBSERVATION PERIOD

February 2023 – February 2025 32 Online Forums

FOCUS

Symptoms Burden Comorbidities in T2DM

Experienced Co-morbidities by Severity

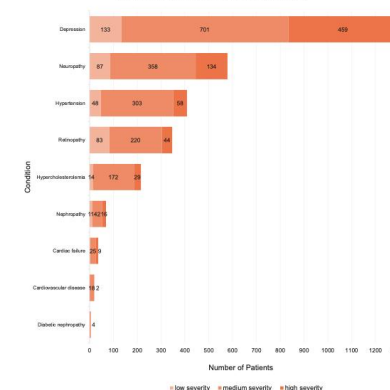


Fig. 2: Bar chart of the experienced comorbidities by severity in the T2DM example case study. Total number of patients reporting a certain symptom, broken down into three severity levels: 1, low; 2, medium; and 3, high. The severity was assessed automatically. From [1].

04 VALIDATION

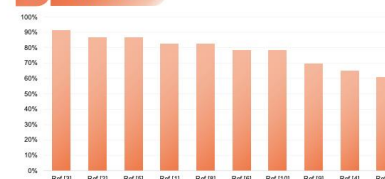


Fig. 3: Bar chart of POMELO concept mapping to published SML studies.

Patient perspective and regulatory interaction

- To investigate and document patient attitudes toward sharing health information on social media and evaluate the potential use of these data in drug development : patient survey conducted in
 - 3 countries
 - 3 therapeutic areas
 - 57 patients interviewed
- Survey is completed, analysis finished, publication under preparation
- Next phase under discussion with Steer Co members
- Interaction with EMA following publication of their “Patient Experience Data position paper”



More in late stage R&D

- **Pharmacovigilance :**
 - case intake project ongoing
 - Forum “Safety and PV AI” ready to start
- **New : AI in Clinical Trials : “ClinSilico”**
 - Collaboration between Pistoia Alliance and CUHP (Cambridge University Health Partners) and CCAIM (Cambridge Center for AI in Medicine) : several use cases planned
 - A range of digital twins
 - Patient recruitment tools
 - Adaptive trial design tools
 - AI clinical trial agents
 - More to be announced in a webinar September 15th



A photograph of the Boston skyline across the harbor, with a teal diagonal graphic element on the right side.

PISTONAI
ALLIANCE

BOSTON 2026 ANNUAL MEMBERS CONFERENCE

Data Driven Innovations

November 10 & 11, 2026

Convene, One Boston Place, Boston

Pre-Conference Workshops (Morning of 10th November)

- From Recipes to Knowledge Graphs: A Hands-On Intro to the CMC Process Ontology
- Defining AI-Ready Data for Life Sciences
- Accelerating Digital Transformation in Pharma Labs



Q & A

