NAVIGATION

A special foreword

2023 welcomes a strategy pivot at Teamit

- Core strategic areas
- Vision, mission & values
- A stronger value proposition
- An updated mapping of expertise areas and services

Meet Teamit: A new look, familiar faces

- Our year in numbers
- Teamit outreach
- Teamit people

Driving impact across the health research ecosystem

- EU-funded projects
- Pharmacoepidemiologic collaborations and alliances
- Publications & Posters

2024: Health research and innovation opportunities await!

teamit.

2023 ANNUAL REPORT

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A special foreword

The need for impactful science done collaboratively is undeniable if we are to address pressing global health challenges. This firm belief has been our beacon since the very beginning and continues to inspire our work year after year. By the same token, we are mindful that the obstacles we face are immense; but so too are the opportunities. For instance, emerging medical technologies and potentially trustworthy artificial intelligence are now becoming more commonplace, opening the door to important breakthroughs that can create lasting change in the health and well-being of our society.

But what exactly is impactful science?

For Teamit, it goes beyond the mere delivery of results. It is that positive, observable effect across all segments of our society that comes from closing the gap between research ideas and innovative solutions to address real needs.

In this context, Teamit reaffirms its commitment to enabling game changing science. As a research management organisation, we have witnessed what happens when we foster strategic and fertile collaborations in large-scale health research initiatives. Indeed, this past year has underpinned our dedication to continue promoting those meaningful connections and contribute as a partner in projects that seek to make a real difference.

We understand, though, that our commitment can only grow stronger when we are better able to outline bolder objectives, actions, etc. As you'll read in this report, we have revisited our strategy for the coming three years. The essence of this revision is rooted in our belief that transformative research will require a more concerted and conscientious effort. At Teamit, we have solid foundations to continue taking a leading role.

But words alone are not enough. Our 2023 annual report aims to showcase our real-world feats and underpin these achievements as stepping stones to a more fruitful 2024. Indeed, we hope to consolidate our strategic collaborations and fortify our more recent expertise areas, e.g., training, regulatory science, etc. to get us one step closer to fulfilling our vision —empowering collaborative research and innovation for a healthier future.

Kindest regards,
Eva Molero Romen
CEO

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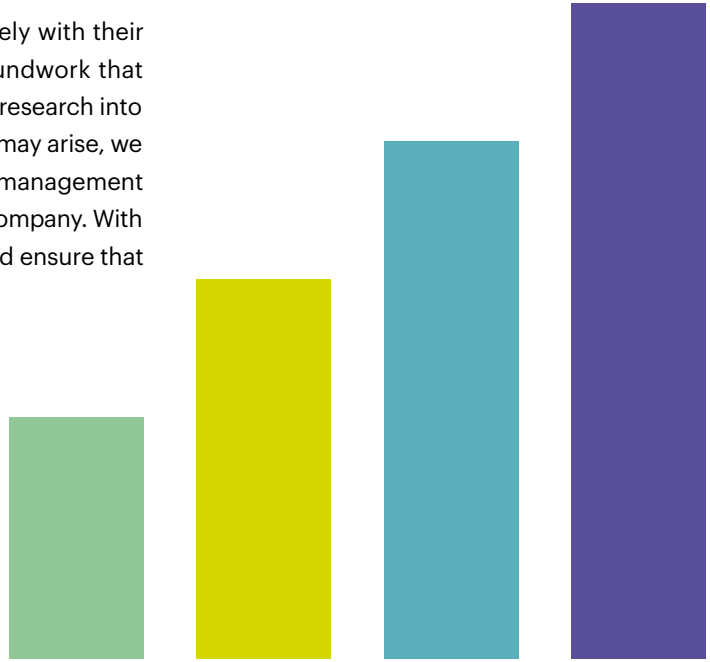
2023 welcomes a strategy pivot at Teamit

Teamit's commitment to impactful science has driven us to proactively reassess our strategy to ensure it aligns seamlessly with the evolving landscape of health research and innovation. This is why the year 2023 saw the rise of the first Teamit Strategic Plan for 2023-2025

To execute this, Teamit welcomed employees to provide their diverse perspectives and expertise and lead core activities of the strategy revision. Doing this would also not only reinforce engagement within our organisation but promote a more nuanced and accurate comprehension of the challenges and opportunities that lie ahead.

For our partners, by aligning our goals more closely with their dynamic needs, we aim to lay down further groundwork that fosters innovation and facilitates the translation of research into positive, real-world outcomes. Although obstacles may arise, we will keep committed to our mission as a research management organisation and to our values as a team-focused company. With this, we can minimise any undesirable setbacks and ensure that the benefits are worth it all.

Impactful science is the positive, observable effect across society that comes from closing the gap between research ideas and innovative solutions that address real needs



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Core strategic areas

The Teamit Strategic Plan was conceived with the aim of enabling the company to achieve its full potential around three specific areas:

1

Impactful science
Revisit corporate culture, value proposition and service offer to guide a sound communication strategy. Strengthen engagement with the ecosystem to collaborate in driving forward impact oriented research.

2

Talent management
Empower teams to boost their expertise through a talent management strategy supported by sound internal procedures, policies, and resources. Explore new areas of expertise and consolidate and acquire fresh knowledge that enhances innovation for research and impactful science. Establish a career plan to enable professional growth.

3

Innovation for research
Create and identify new business opportunities. Pursue those that are better aligned with Teamit strategic goals, expertise and resources and show the highest impact potential.

After this year, we are proud to announce some major changes underway, such as a refined value proposition, clearer mission and vision, a more robust communications strategy and newly identified services and areas of expertise.

As we continue implementing our plan until 2025, we invite current and new partners to join us on this exciting journey. Their support, collaboration, and feedback are the cornerstones of our success.

Impactful science

Talent management

Innovation for research

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Vision, mission & values

Our Vision

Empowering collaborative research and innovation for a healthier future.

Our Mission

We are a research management organisation, building strong multistakeholder partnerships and providing transversal expertise for impactful health science.

How we do it?
We bring in our knowledge and experience in the areas of:

- project and scientific management
- communication
- sustainability and exploitation
- multi-stakeholder engagement
- regulatory science
- Real World Evidence
- training and education
- quality and risk management

With whom?
We team up with partners from the entire health ecosystem to ideate and implement research and innovation initiatives. We work with:

- academia
- clinical centers
- health industry
- SMEs
- patients and civil society organisations
- regional and national authorities
- regulatory and funding bodies
- policy makers

Our Values

Teamwork
Guided by a shared purpose, we bring together the experience and expertise of Teamit and its partners to stimulate collaboration for game-changing outcomes.

Excellence
Striving constantly for the highest quality, we bridge the gap between research idea and execution for maximum impact.

Positive attitude
By transforming challenges into opportunities, we look optimistically to a horizon of new possibilities.

Foresight
Through innovation, talent and perseverance, we think ahead and explore viable paths that pave the way for success.

Integrity
At the heart of all our actions, we uphold core values based on ethical principles to align what we say with what we do.

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A stronger value proposition

Endorsed by our track record and reputation, leading public and private organisations choose us as a partner to successfully drive forward transformative health research initiatives in Europe.

We are all-hands-in to build a lasting bridge from ground-breaking ideas to far-reaching solutions, bringing our diverse expertise and Teamit spirit. To take health research and innovation one step forward, we:

- Help navigate complex EU funding schemes and procedures efficiently and confidently.
- Forge and leverage quality public-private partnerships to catalyse efforts and support strategic aims.
- Apply sound scientific and project management strategies and tools to EU-funded research initiatives and pharmacoepidemiology studies.
- Facilitate targeted dissemination of scientific findings and stakeholder engagement; build regulatory acceptance pathways; develop actionable business models.

We are committed to maximising scientific, economic and societal impact of research for time to come.

We are your partner in research and innovation

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EU Funding and Proposal Preparation

Scientific and Project Management

Multi-stakeholder Management

Communications and Outreach

Sustainability and Business Development

Regulatory Science

Real-World Evidence

Training and Education

EU Funding and Proposal Preparation

In the highly competitive EU health research landscape, only excellent multi-disciplinary proposals which are impact-oriented make it to the finish line. Creating a winning proposal calls for effective engagement with stakeholders from different disciplines and the application of transversal and managerial skills.

- EU fund scanning
- Call text strategic fit
- General management
- Workplan design
- Budget preparation
- Support for proposal writing

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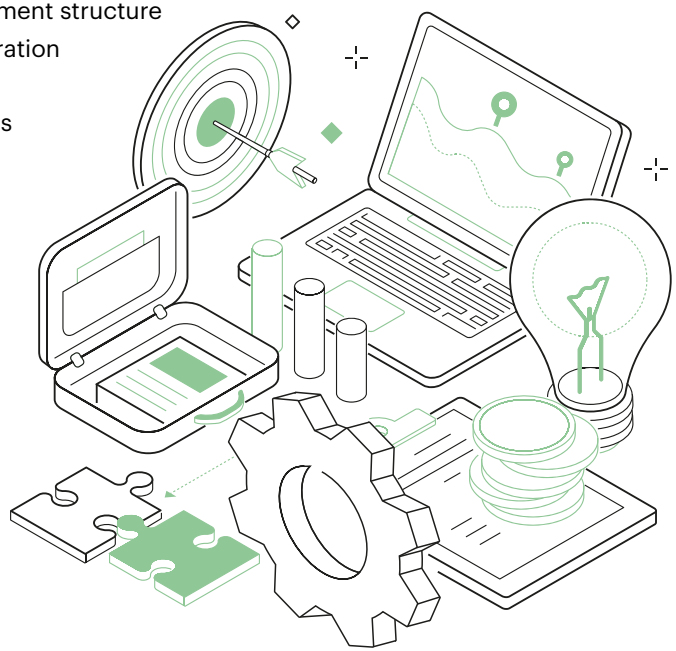
Scientific and Project Management

Scientific and Project Management plays a crucial role in the successful execution of tasks, initiatives, and projects. It provides a structured framework for planning, executing, and closing research initiatives. It ensures efficient use of resources, risk mitigation, effective communication, and overall success in achieving organisational goals and alleviating our partners' challenges.

- Support to the scientific coordination team and the overall management structure
- Reporting and administration
- Risk management
- Internal communications



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Real-World Evidence

Training and Education

Multi-stakeholder Management

We excel at bringing together multiple stakeholders with diverse expertise and unique perspectives who can jointly tackle global challenges in health research.

- Partnership building
- Consortium governance & management
- Alliance management

We promote open collaboration and co-creation practices for the delivery of game-changing results.

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Communications and Outreach

Communications plays a critical role in underpinning scientific reputation, reinforcing trust in science and ultimately, influencing positive change propelled by collaborative cutting-edge research. Teamit offers a winning blend of expertise in (scientific) journalism, political science, digital communications, graphic design and multistakeholder engagement to ensure maximum impact of research.

- Communications strategy design and implementation
- (Digital) content planning and production
- Social media campaigns
- Media outreach
- Engagement activities with policymakers and regulatory bodies

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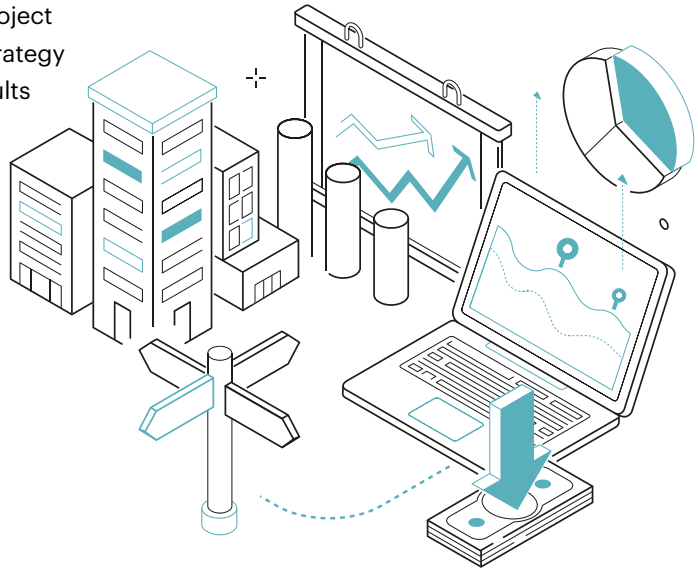
Sustainability and Business Development

Game-changing EU-funded projects require a solid sustainability strategy to underpin long-term impact. At Teamit, we speak the "business language" to help projects sail through this critical post-funding period. We promote the use and sustainability of project results and help bridge the gap between academic and clinical contexts and business development.

- Value proposition definition and customers' profile analysis
- Landscape scan and target market analysis
- Business modelling
- Planning of the post-project phase: sustainability strategy and exploitation of results
- Business development



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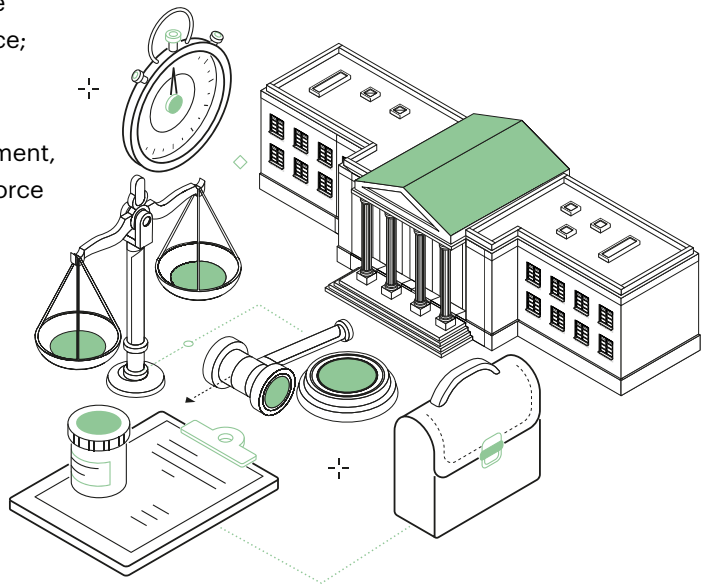
Regulatory Science

Regulatory science connects scientific research with regulatory requirements, supporting a smooth progression from research results to real-world applications. It guides scientists in designing and conducting studies that adhere to regulatory requirements, promoting the future translation of fundamental discoveries into potential therapeutics.

- Guidance and support to development of regulatory strategy
- Study of regulatory landscape
- Regulatory comparator case review
- Early regulatory engagement (EMA Scientific Advice and protocol assistance; qualification of novel methodologies for medicine development, and Innovation Task Force briefing meeting)



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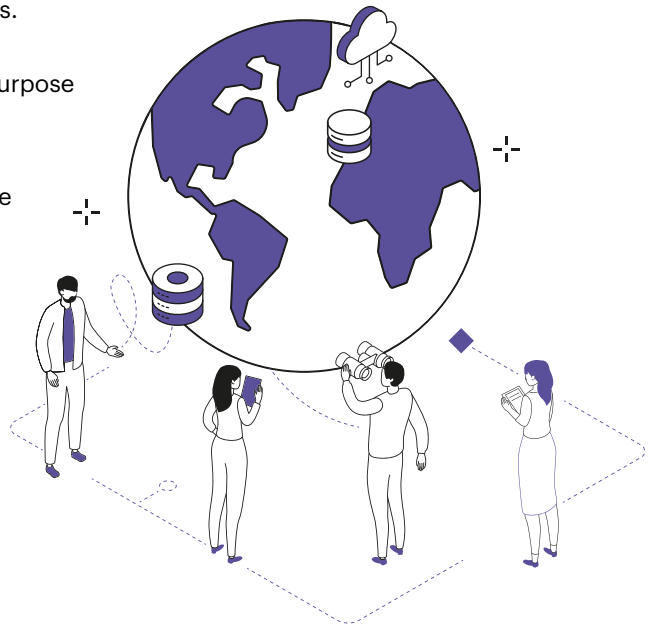
Real-World Evidence

The importance of Real-World Evidence (RWE) lies in its ability to close the gap between the controlled conditions of clinical studies and the real-life use of healthcare interventions. It offers valuable insights into treatment and medical devices' outcomes, safety profiles, and the overall effectiveness of healthcare interventions. This information is extremely important for pharmaceutical companies, healthcare professionals, policymakers, and regulatory agencies in making informed decisions about treatment strategies, patient care, as well as the benefit/risk monitoring of marketed medicinal products, including vaccines.

- Study design and fit-for-purpose data partner selection
- Study implementation and regulatory compliance
- Reporting and data management
- Contracting, financial monitoring, risk management, and quality assurance



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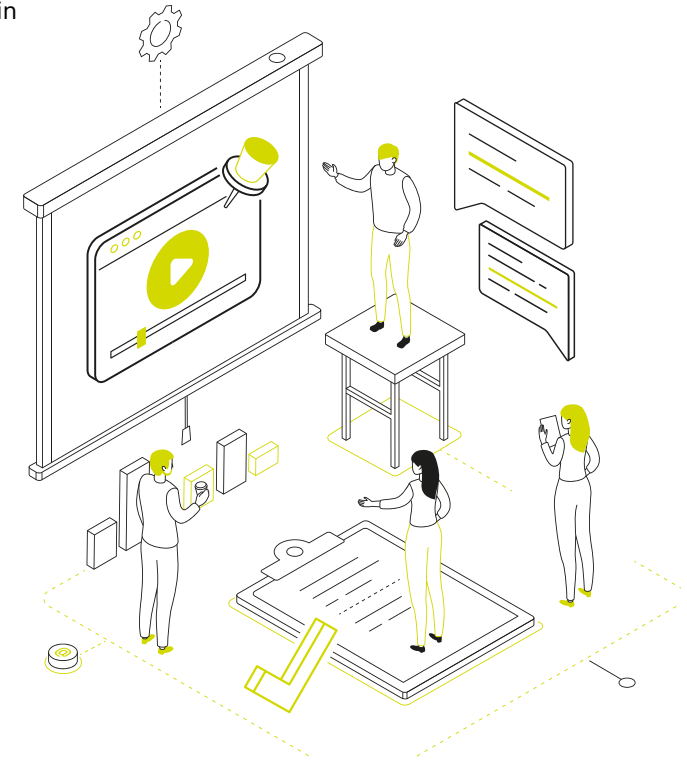
Training and Education

Training and Education

Training and education involve strengthening skills, knowledge, resources, and overall capability of individuals and organisations, to better achieve their goals and objectives.

- Delivery of training programmes on EU project management and multi-stakeholder partnerships
- Design and organisation of training activities within EU-funded projects



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Meet Teamit: A new look, familiar faces

Change, when embraced with purpose, has the potential to exert a positive influence. With this belief at the forefront, we are excited to share the evolution of our identity. Starting now, you will notice a shift in how we present ourselves —we are simplifying, unifying under the name Teamit.

Teamit encompasses both arms of our research management organisation: Teamit Research and Teamit Institute. The former speaks to our contributions in large European Union-funded projects and initiatives whilst the latter covers our scientific management of pharmacoepidemiology research and regulatory science initiatives. The purpose of this is to signify a coming together of our expertise and a singular commitment to taking health research and innovation one step further.

While our presentation evolves, what remains constant is our diverse expertise, friendly demeanours and hands-on, start-to-end approach. As partners, you can continue to expect the same level of dedication and collaborative spirit that has come to define our journey together.

> **The world we have created is a product of our thinking; it cannot be changed without changing our thinking. If we want to change the world we have to change our thinking...**
>
> Albert Einstein

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Our year in numbers

Our success highlights our ability to resonate with stake-holders from across the health research ecosystem.

Whilst more is yet to come, we invite you to take a look below at Teamit's contributions to health and care globally.

Time after time, Teamit continues to exceed expectations and grow

119
Teamit's Partner Community

6
Active EU-funded Projects

+140M
Total Value of Projects and Studies Managed

8
Teamit Institute Pharmacoepidemiologic Studies

10
EU Research Proposals Submitted

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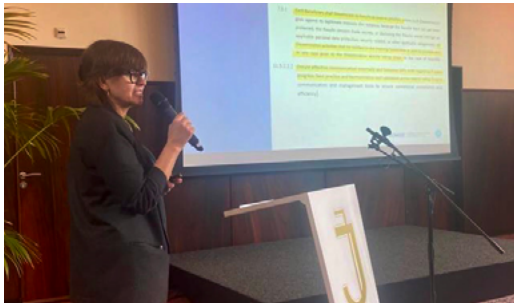
Teamit outreach

Teamit engages with different organisations and publics through both digital and non-digital channels with a multifaceted approach that maximises engagement. Leveraging innovative digital platforms, including social media, we aim to ensure broad online visibility and interaction.

Simultaneously, we take advantage of more traditional methods like in-person meetings and events such as the Black Pearl Awards (which celebrate hard work, innovative thinking and dedication to the rare disease community) or EATRIS@10 to establish and foster professional relationships. We aim to contribute to public discussion with key opinion leaders across different areas of expertise, e.g. World Orphan Drug Congress where our CEO Eva Molero spoke on the topic of repurposing or the International Conference on Pharmacoepidemiology (ICPE) in Halifax (Canada) where we presented several posters. This holistic strategy enables us to effectively reach diverse audiences and amplify our message across various channels, ultimately driving meaningful and lasting connections.

Finally, thanks to our different areas of experience, we offer various capacity-building and training sessions on matters like EU project management and multi-stakeholder partnership.



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Teamit people

The driving force behind Teamit is our people. To reflect on our journey together, celebrate our achievements and find new inspiration to address upcoming challenges, we gather twice a year in July and December. As a team, we look forward to these days that combine work, culture, and fun.

We welcomed the summer in the vineyards of a beautiful Catalan region. Can Lleó hosted us for the day during which we learned about grape varieties and the production of environmentally friendly wines. The day concluded with a delicious wine tasting, accompanied by live music and a breathtaking sunset.

In December, we donned our chef hats. Three teams competed to see who could design and cook the most delicious menu within two hours. The competition was fierce, starting with the distribution of ingredients. There was room for creativity, collaboration, and laughter. Like good project managers, all the dishes were cooked on time. And, surprisingly, all three menus had a distinctly Italian touch!

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Driving impact across the health research ecosystem

In 2023, Teamit has remained steadfast in our commitment to driving impactful advancements in health across society. Together, we've continued to forge partnerships and leverage our collective expertise to propel transformative health research initiatives forward in Europe.

For example, 2023 saw the end of EU-PEARL project and the start of FIBROTARGET. The former laid the groundwork for innovative clinical trials in Europe, whilst the latter began to undertake the great task of advancing fibrosis research in individuals living with inflammatory bowel disease.

At the same time, CVM (COVID Vaccine Monitoring) and COVE (COVID Vaccine Effectiveness) were two relevant, EMA-funded studies that contributed to generating crucial real-world evidence for the regulatory body to make decisions on COVID-19 vaccines safety and effectiveness.

fibrotarget
Advancing IBD fibrosis diagnosis and therapies

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EU-funded projects

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REMEDI4ALL
The European Platform for Medicines Repurposing

PROMISE
Preparing for RSV Immunisation and Surveillance

H2O
Health Outcomes Observatory

PREMIER
Priorisation and Risk Evaluation of Medicines in the Environment

EU-PEARL
EU Patient Centre Clinical Trial Platforms

fibrotarget

Advancing IBD fibrosis diagnosis and therapies

Project Aims

Improve the prevention, diagnosis and treatment of intestinal fibrosis and fibrostenosis by three main pathways:

- discover and validate biomarkers for early detection of fibrosis and a reduced likelihood of irreversible tissue damage;
- develop and test cutting-edge techniques for better diagnosis/prognosis of possible intestinal fibrosis; and
- implement a first-in-human, proof-of-concept trial of immunotherapeutic drugs for inflammatory bowel disease.

Our Contribution

- EU Funding Opportunities and Proposal Preparation
- Project Management
- Multi-stakeholder Management and Governance
- Communications and Outreach
- Regulatory Science

Highlight Achievement

- Set the groundwork to kick off the project and establish a solid working partnership.
- Conceived and launched a comprehensive visual identity and communications strategy to develop a strong and coherent digital presence, including a project website and social media accounts.

Funding call

Horizon Europe
Research and innovation

Timeline

01.04.2023 – 31.03.2028

EU-funded projects

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The European Platform for Medicines Repurposing

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H2O
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PREMIER
Priorisation and Risk Evaluation of Medicines in the Environment

EU-PEARL
EU Patient Centre Clinical Trial Platforms

REPURPOSING OF MEDICINES 4ALL
The European Platform for Medicines Repurposing

teamit RESEARCH

Project Aims

Develop a comprehensive, accessible, and standardised platform that provides the expertise, tools and resources required in all drug repurposing stages to ensure that more (and better) repurposed medicines are available to patients.

Generate a more favourable policy environment for drug repurposing and build a dynamic global community practising drug repurposing.

Funding call

Horizon Europe
Research and innovation

Timeline

01.09.2022 – 31.08.2027

Our Contribution

- EU Funding Opportunities and Proposal Preparation
- Project management
- Multi-stakeholder Management and Governance (Policy)
- Communications and Outreach
- Business development and Sustainability
- Training and Capacity Building

Highlight Achievement

- Organised the first sustainability workshop with consortium members at UNESCO World Heritage Site Art Nouveau Sant Pau to deepen analysis of stakeholders in terms of needs and benefits that will inform the project's future business strategy.

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EU-funded projects

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Fibrotarget
Advancing IBD fibrosis diagnosis and therapies

REMEDI4ALL
The European Platform for Medicines Repurposing

PROMISE
Preparing for RSV Immunisation and Surveillance

H2O
Health Outcomes Observatory

PREMIER
Priorisation and Risk Evaluation of Medicines in the Environment

EU-PEARL
EU Patient Centre Clinical Trial Platforms

PROMISE
Preparing for RSV Immunisation and Surveillance in Europe

Project Aims

Advance scientific knowledge on respiratory syncytial virus (RSV) to better inform public health strategies and support the development and introduction of novel immunisation tools and therapeutics.

PROMISE focuses on evaluating the impact of COVID-19 on RSV epidemiology with a special focus on infants, young children, and older adults; raising awareness about this disease and preventable measures; and developing a peer-support network for parents of RSV-affected children.

Our Contribution

- EU Funding Opportunities and Proposal Preparation
- Project Management
- Multi-stakeholder Management & Governance
- Communications and Outreach
- Sustainability

Highlight Achievement

- Conceived and implemented various RSV and project progress awareness activities via digital channels, including newsletters and scientific dissemination writing.
- Engaged with key stakeholders like policymakers to transfer results and prepare for sustainability phase.

Funding call
IMI2 JU

Timeline
01.11.2021 – 31.04.2024

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H2O
Health Outcomes Observatory

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Priorisation and Risk Evaluation of Medicines in the Environment

EU-PEARL
EU Patient Centre Clinical Trial Platforms

Project Aims

Create a robust data governance and infrastructure model to collect and incorporate patient reported outcomes (PRO's) at scale into healthcare decision making at an individual and population level.

The H2O approach will give patients ultimate control of their health data and ensure that only they exercise this control.

Funding call
IMI2 JU

Timeline
01.10.2020 – 31.09.2025

Our Contribution

- EU Funding Opportunities and Proposal Preparation
- Project Management
- Multi-stakeholder Management & Governance
- Communications and Outreach

Highlight Achievement

- Provided strategic management advice to reshuffle workplan and accommodate project's changing needs.
- Organised the first face-to-face General Assembly Meeting (GAM) in Barcelona and two in-person Steering Committees (Vienna and Barcelona).

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PREMIER

PRIORITISATION AND RISK EVALUATION OF MEDICINES IN THE ENVIRONMENT

Project Aims

Design a novel information and assessment system for identifying and addressing environmental risks of medicines, especially for those with limited data availability.

Develop tools that identify and focus on medicines of potential concern amongst legacy pharmaceuticals; these tools could also be used to augment the current strategy for assessing the environmental impact of pharmaceuticals in development. Importantly, this system will be based on minimal animal testing.

Our Contribution

- EU Funding Opportunities and Proposal Preparation
- Project Management
- Communications and Outreach

Highlight Achievement

- Provided stakeholder and project management advice to welcome a new industrial partner to the consortium.
- Organised two General Assembly Meetings, one face-to-face in York and another one online.

Funding call
IMI2 JU

Timeline
01.09.2020 - 31.08.2026

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EU-funded projects

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H2O
Health Outcomes Observatory

PREMIER
Priorisation and Risk Evaluation of Medicines in the Environment

EU-PEARL
EU Patient Centre Clinical Trial Platforms

EU-PEARL
EU PATIENT-CENTRIC CLINICAL TRIAL PLATFORMS

Project Aims

Develop a generic framework and set of tools to facilitate the design, set-up and implementation of patient-centric collaborative platform trials in Europe.

This innovative generic framework, known as Integrated Research Platforms (IRPs), can significantly improve and accelerate medicine development processes, thus potentially enabling speedier access to new and more effective treatments.

Funding call
IMI2 JU

Timeline
01.11.2019 – 30.04.2023

Our Contribution

- EU Funding Opportunities and Proposal Preparation
- Project Management
- Communications and Outreach
- Sustainability

Highlight Achievement

- Organised a two-day Final Event in Brussels, Belgium to disseminate project results amongst key stakeholders including policymakers, academia, researchers (>100 in-person attendees).
- Co-authored a peer reviewed publication on insights and learnings in clinical trials.

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Pharmacoepidemiologic collaborations and alliances

COVID-19 Vaccine Monitor (CVM) in collaboration between EU PE&PV Research Network and VAC4EU

Aims

This European Medicines Agency (EMA) two-year project was funded by the EMA and concluded in April 2023.

The purpose of the project was to prepare for and perform a rapid assessment of the association of adverse events of special interest following COVID-19 vaccination. The project also collected data from both general and special populations (pregnant and lactating women, children and adolescents, immuno-compromised people, people with a history of allergies, and people with a prior instance of SARS-CoV-2) via self-report within 48 hours of vaccination, using multiple different reporting systems.

Our Contribution

- EU Funding Opportunities and Proposal Preparation
- Stakeholder Management and Governance
- Scientific and Project Management
- Real-World Evidence

Highlight Publications

- Covid-19 Vaccine Monitor: Final Study Report for Cohort Event Monitoring of vaccinated persons.
- Rapid Safety Assessment of SARS-CoV-2 Vaccines in EU Member States using Electronic Health Care Data Sources (COVID Vaccine Monitor-CVM study): Final Study Report for WP3 (electronic health record data).

Website
Zenodo
EMA Catalogue

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Pharmacoepidemiologic collaborations and alliances

COVID Vaccines Effectiveness (CoVE). In collaboration between EU PE&PV Research Network and VAC4EU

Aims

This EMA-funded project aimed to study waning immunity after primary COVID-19 vaccine regimens as well as booster vaccinations.

The study complemented common test-negative case-control studies, using real-world data pulled from other VAC4EU studies, highlighting the advantages of readiness.

These data sources represented five countries across Southern, Central, and Eastern Europe, and an estimated 67 million patients.

Our Contribution

- EU Funding Opportunities and Proposal Preparation
- Stakeholder Management and Governance
- Scientific and Project Management
- Real-World Evidence

Highlight Publications

- Assessment of the Effectiveness of heterologous and booster COVID-19 vaccination in 5 European countries, using a cohort approach in children and adults with a full primary COVID-19 vaccination regimen
- Assessment of the Effectiveness of homologous/heterologous booster COVID-19 vaccination schedules against severe illness in general population and clinical subgroups in three European countries

VAC4EU

Website
Zenodo
EMA Catalogue

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Pharmacoepidemiologic collaborations and alliances

European non-interventional post-authorisation safety study related to serious cardiovascular events of myocardial infarction and stroke, and all-cause mortality (Study Protocol (1)), serious infections (Study Protocol (2)), and adherence to the risk minimisation measures (Study Protocol (3)) for romosozumab by the EU-ADR Alliance

Aims

(1) Evaluate potential differences in terms of serious cardiovascular adverse events between romosozumab and currently available therapies used in comparable patients in real-world conditions.

(2) Monitor the potential risk of serious infection associated with the use of romosozumab in comparison with other available osteoporosis medications in routine clinical practice in Europe.

(3) Study the adherence to the risk minimisation measures in the product information by estimating the compliance with contraindications and target indication amongst incident romosozumab users and analysing the utilisation patterns.

Our Contribution

- Stakeholder Management and Governance
- Scientific and Project Management
- Real-World Evidence

Highlights

- From 2020 to January 2024, 13 interim reports (5 interim reports regarding cardiovascular events; 3 about serious infections; and 5 about risk minimisation measures) have been produced and submitted to EMA.
- Monitoring of romosozumab usage is ongoing; conclusions are expected to be drawn for publication in future reports in 2026.
- The study will finish in 2026.

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Pharmacoepidemiologic collaborations and alliances

An Observational Post-Authorization Safety Study to Assess the Safety of Ad26.COV2.S Using European Healthcare Data through VAC4EU (COVID-19). Sponsored by Johnson & Johnson Innovative Medicine in collaboration with VAC4EU

Aims

This study has two chronologically consecutive aims: (1) to conduct a feasibility assessment aiming to inform the safety evaluation study and (2) to assess the risk of developing pre-specified and newly identified AESIs following administration of Ad26.COV2.S vaccine.

Highlights

- Real-World Evidence generated.
- From the beginning of the project (2022) until 2023, two feasibility assessments have been conducted.
- The study is expected to finish in 2025.

Our Contribution

- Stakeholder Management and Governance
- Scientific and Project Management

VAC4EU

Study Design

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Pharmacoepidemiologic collaborations and alliances

Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine. Sponsored by Pfizer in collaboration with VAC4EU

Aims

The main objective of the study is to determine whether an increased risk of prespecified AESI exists following the administration of at least one dose of the Pfizer-BioNTech COVID-19 vaccine using two approaches: (a) a cohort design comparing risk in vaccinated and non-vaccinated individuals and (b) a SCRI design.

Our Contribution

- Stakeholder Management and Governance
- Scientific and Project Management
- Real-World Evidence

Highlights

- A total of 5 interim reports have been submitted to the EMA since the beginning of the project (2020).
- The study is expected to finish in 2024, by which then the final report will be submitted to the EMA.

VAC4EU

Study Design

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Pharmacoepidemiologic collaborations and alliances

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Post-Authorisation Active Surveillance Study of Myocarditis and Pericarditis Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine. Sponsored by Pfizer in collaboration with VAC4EU

Aims

This study is addressing the following research question: "What is the clinical course of myocarditis and of pericarditis cases after being vaccinated with the Pfizer-BioNTech COVID-19 vaccine in European countries?"

The study is divided in two objectives:

- To describe the clinical course (treatment, survival, hospitalisations, long-term cardiac outcomes) of myocarditis or pericarditis among individuals diagnosed with myocarditis and/or pericarditis after receiving at least one dose of the Pfizer-BioNTech COVID-19 vaccine and among individuals diagnosed with myocarditis and/or pericarditis who had no prior COVID-19 vaccination, using a cohort study design.
- To examine and identify potential risk factors for myocarditis and pericarditis, such as age, sex, Pfizer-BioNTech COVID-19 vaccination status, vaccine doses received (e.g., first, second, third, and booster doses), and history of COVID-19, using a cohort study design.

Our Contribution

- Stakeholder Management and Governance
- Scientific and Project Management
- Real-World Evidence

Highlights

- An interim report has been submitted to the EMA since the beginning of the project (2023).
- The study is expected to finish in 2024, when the final report will be submitted to the EMA.

VAC4EU

Study Design

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Publications & Posters

Our team has a proven track record of their work being relevant from a scientific and management standpoint. Amongst the publications that are publicly available, Teamit has contributed to the following:

1 Franz Koenig, Cécile Spiertz, Daniel Millar, **Sarai Rodríguez-Navarro**, **Núria Machín**, Ann Van Dessel, Joan Genescà, Juan M. Pericàs, Martin Posch, EU-PEARL Consortium. **Current state-of-the-art and gaps in platform trials: 10 things you should know, insights from EU-PEARL.** *eClinicalMedicine, December 2023.* DOI: https://doi.org/10.1016/j.eclinm.2023.102384

2 **Fabio Riefolo**, Belén Castillo-Cano, Mar Martín-Pérez, Davide Messina, Roel Elbers, Dorieke Brink-Kwakkel, Felipe Villalobos, Ylenia Ingrasciotta, Patricia Garcia-Poza, Karin Swart-Polinder, Patrick Souverein, Luis Carlos Saiz, Carlo Alberto Bissacco, Leire Leache, Michele Tari, Salvatore Crisafulli, Lamiae Grimaldi, Tiago Vaz, Rosa Gini, Olaf Klungel, Elisa Martín-Merino. **Effectiveness of homologous/heterologous booster COVID-19 vaccination schedules against severe illness in general population and clinical subgroups in three European countries.** *Vaccine Volume 41, Issue 47, 13 November 2023, Pages 7007-7018.* DOI: https://doi.org/10.1016/j.vaccine.2023.10.011

3 **Yefimenko N**, **Boric K**, and **Di Mauro G**. **Quality compliance while conducting NIS studies: critical success factors assessment and the use of key performance indicators.** Poster presentation at the International Conference of Pharmacoepidemiology 2023 (ICPE). Access poster here.

4 **Yefimenko N**, Weinrib R, **Boric K**, **Riefolo F**, Jansen M, Weibel D. **The challenges and lessons learnt from conducting COVID-19 monitoring studies through VAC4EU: coordination and management perspective. P-395.** *Poster presented at the 39th ICPE Annual Conference; August 25, 2023. Halifax, Canada.* DOI: 10.1002/pds.5687

5 Monika Raethke, Nicoletta Luxi, Gianluca Trifirò, Nicolas H. Thurin, Dirk Mentzer, Evelien De Clercq, Barbara Kovačić, Kathryn Morton, Carlos Miguel Costa Alves, Simona Sonderlichová, Felipe Villalobos, **Fabio Riefolo**, Florence van Hunsel, Miriam Sturkenboom. **Safety monitoring of COVID-19 vaccines in multiple European countries: initial results from the COVID-19 Vaccine Monitor (CVM).** *Poster presented at the 39th ICPE Annual Conference; August 25, 2023. Halifax, Canada.* Access poster here.

6 Ahmadizar F, Fortuny J, Cid-Royo A, Plana E, Weinrib R, Garcia Esteban R, **Boric K**, **Yefimenko N**, Carreras JJ, Urcheguia A, Correcher-Martinez E, Mira-Iglesias A, Swart KMA, van den Berg JM, Overbeek JA, Villalonos F, Bissacco CA, Newbern C, Praet N, Willame C, Sturkenboom M. (2023). **Safety of the Janssen COVID-19 vaccine (JCOVDEN) using VAC4EU European healthcare data: methods and results of the first study feasibility assessment. P-415.** *Poster presented at the 39th ICPE Annual Conference; August 25, 2023. Halifax, Canada.* DOI: 10.1002/pds.5687

7 Weibel D, De Luise C, Elbers R, van den Bor R, Martin I, Cid-Royo A, Plana E, Garcia de Albeniz Martinez X, Weinrib R, **Yefimenko N**, Poblador-Plou B, Marconi E, Barbieri E, Stona L, Swart KMA, Roy D, Hyeraci G, Bartolini C, Lupattelli A, Villalobos F, Kendrick K, Garg R, Rubino H, Eijkemans R, Sturkenboom M, Arana A. (October 23) **Utilisation patterns of the COVID-19 mRNA vaccine (Comirnaty®) from the VAC4EU active safety surveillance study in five European countries. P-384.** *Poster presented at the 39th ICPE Annual Conference; August 25, 2023. Halifax, Canada.* DOI: 10.1002/pds.5687

8 Fariba Ahmadizar, Nicoletta Luxi, Monika Raethke, Sandor Schmikli, **Fabio Riefolo**, Putri Widi Saraswati, Camelia Bucsa, Alhadi Osman, Megan Liddiard, Francisco Batel Maques, Giuliana Petrelli, Simona Sonderlichová, Nicolas H. Thurin, Felipe Villalobos, Gianluca Trifirò, Miriam Sturkenboom & ilmiovaccinoCOVID19 collaborating group. **Safety of COVID-19 Vaccines Among the Paediatric Population: Analysis of the European Surveillance Systems and Pivotal Clinical Trials.** *Drug Safety, Vol. 46, pages 575–585, (April 2023).* DOI: https://doi.org/10.1007/s40264-023-01304-5

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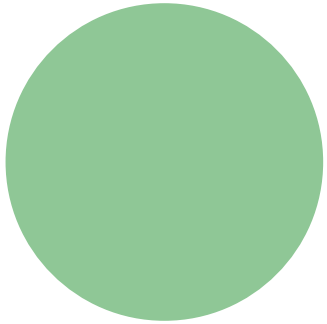
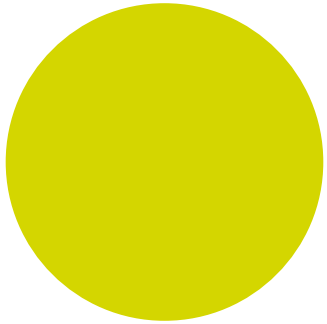
2024 brings exciting new adventures that will forge new strategic relationships and pave the way into explored fields. We are optimistic about how we are continuing to advance our vision of empowering collaborative research and innovation for a healthier future.

Indeed, we are excited to announce that Teamit is participating in three promising initiatives: PHOTOTHERAPORT, WIDEnzymes and EMA ROC 18. The former focuses on the development of luminescent implants and light-activated drugs for innovative neuromodulation therapies, whilst the second aims to develop a novel enzyme development ecosystem in Eastern and Western European countries. This pursuit of initiatives underpins our leap into other areas of the European Research landscape where Teamit can play a pivotal and contributing role.

As we begin to finalise and implement our ambitious yet rooted strategic plan over the next two years, we can expect to uphold our normal activities whilst building upon our team's capabilities and experience. Current and new challenges will come and go, but **our tenacity, creativity and hard work will ensure that impactful science translates into real solutions.**

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