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The environment in which Teamit operates is evolving rapidly, shaped by data-driven approaches, shifting public health priorities and an increasingly complex regulatory environment. These changes bring new challenges, but also create space for collaborative, forward-looking science that is rigorous, responsive and grounded in real-world needs. This is the lens through which to understand the main developments of the past year described in this report.

For Teamit, 2025 was a particularly meaningful year. It marked our fifth anniversary and showed how far we have come as an organisation. That progress is visible in the pages that follow.

In 2025, Teamit reached 320 partners, expanded its active portfolio to 19 projects and studies, supported two research networks, and grew to a team of 30 professionals, reflecting both our expanding reach and the stronger foundations we have built. This progress was also reflected in new initiatives, including the Realised IHI project and the Respiratory Syncytial Virus vaccine safety studies, as well as deeper involvement in proposal development and preparation for Teamit's second strategic plan.

Together, these achievements point to a more mature organisation with broader expertise and a clearer role in collaborative health research and innovation in complex, multi-stakeholder environments.

Throughout this journey, our purpose has remained constant: to contribute to scientific evidence that is robust, relevant and useful for public health and regulatory decision-making that can ultimately translate into progress for patients. At the same time, we continue to embrace innovation and new ways of working when they strengthen the quality and value of what we do.

This Annual Report reflects both Teamit's 5-year journey and the particular momentum of 2025. Across partnerships, projects, expertise, scientific output and organisational development, it shows how Teamit is evolving, and how we are preparing to take on greater complexity, support more ambitious collaborations and continue enabling impactful science.

After these first five years, we move forward with ambition, strong foundations and a clear belief that impactful research, done collaboratively and with purpose, matters more than ever. ●

Rigour and scientific integrity are not optional for us; they are the basis of how we work, how we partner with others, and how we build trust over time

2025 AT A GLANCE

WHAT'S NEW

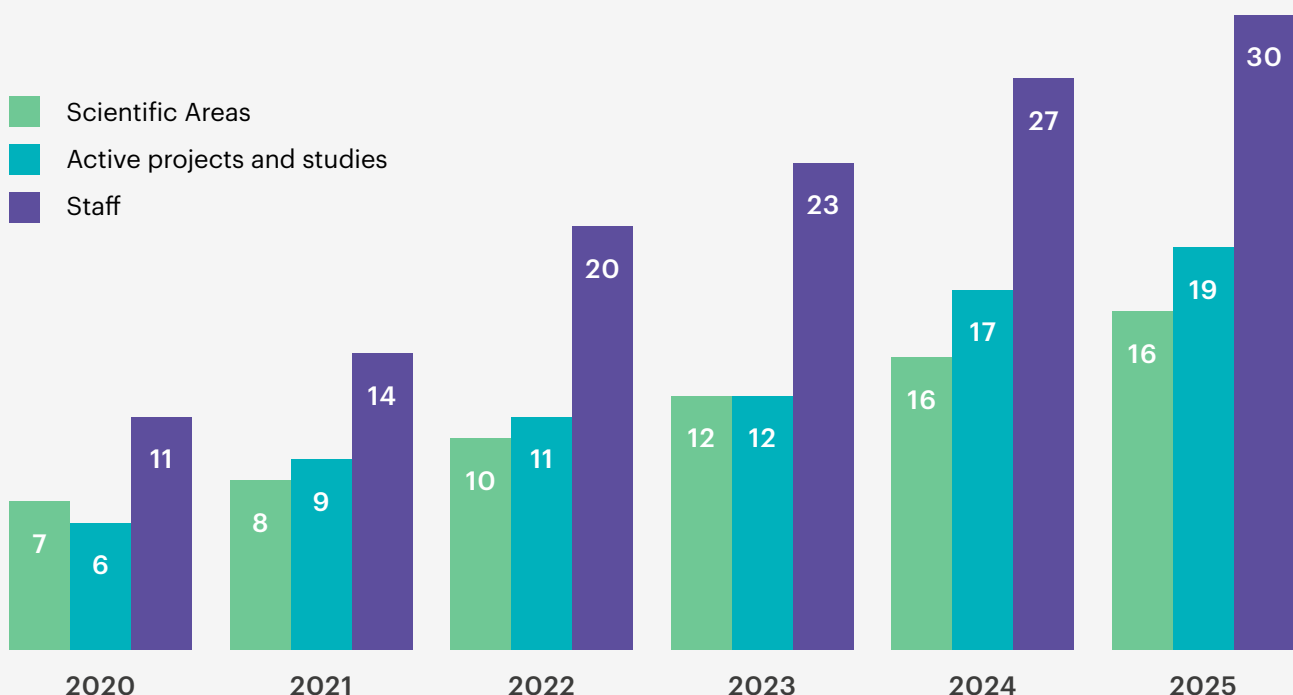
Realised IHI-funded Project
RSV Safety Pharma-funded studies

GROWTH

19 Active Projects & Studies
16 Scientific Areas Broader Scope
Scientific Writing New Expertise
30 Staff Growing Talent
320 Partners Expanding Network

MILESTONES

5 Years of Teamit
5 Years of VAC4EU
ISO Certification Renewed



Seen up close, 2025 was a year of consolidation and momentum. Teamit turned five, and VAC4EU (Vaccine Monitoring Collaboration for Europe), a pan-European network for vaccine safety and effectiveness studies of which Teamit is an active member, also reached its 5-year mark. Together, these anniversaries show how trust, shared commitment and long-term collaboration help build much-needed initiatives in health research.

Teamit's portfolio also continued to grow in areas closely linked to current public health needs. New undertakings included the Realised project, funded by the Innovative Health Initiative, and industry-sponsored studies on Respiratory Syncytial Virus vaccine safety. These additions expanded Teamit's contribution to important and timely areas of health research.

In 2025, Teamit also enhanced its strategic role in the development of EU competitive funding proposals, getting involved from the outset in their conceptualisation and contributing to shape game-changing initiatives. In this context, scientific writing also became a new area of expertise, helping improve the quality, coherence and competitiveness of proposals.

Teamit helped shape ambitious research proposals, bringing strategic input from the start

Within Teamit, 2025 was also a year of internal growth. Professional development and upskilling remained a priority, while the organisation also paid closer attention to new knowledge, tools and ways of working that can help people and projects move forward more effectively.

Digital transformation was another important focus in 2025. Teamit continued to improve internal processes and use digital tools more systematically to support coordination, efficiency and consistency across teams and projects. The renewal of Teamit's ISO certification also reflected this commitment to quality and reliable ways of working.

Strategy also remained central throughout the year. Building on its first strategic plan, Teamit used 2025 to prepare the next one for the period 2026-2029.

Our new strategic plan is not only about where Teamit goes next, but about the scale of the contribution we want to make

Overall, the year showed an organisation growing not only in size, but also in clarity, confidence, readiness and long-term vision. ●

5 YEARS OF TEAMIT

19 ACTIVE PROJECTS
AND STUDIES

STRONGER ROLE
IN PROPOSAL
DEVELOPMENT

NEW ADDITIONS
IN OUR PROJECTS/
STUDIES PORTFOLIO:
REALISED AND RSV
SAFETY STUDIES

SCIENTIFIC WRITING
INCORPORATED AS
A NEW EXPERTISE

30 PROFESSIONALS

GREATER
ORGANISATIONAL
MATURITY

DIGITAL
TRANSFORMATION
STRENGTHENED

5 YEARS OF VAC4EU

ISO CERTIFICATION
RENEWED

EUROPEAN
COMMISSION AUDIT

CLOSING OF 2023-2025
STRATEGIC PLAN

PREPARATION OF
THE 2026-2029
STRATEGIC PLAN

2025: FROM ACTIVITY TO IMPACT

EU-funded Projects Portfolio

In 2025, Teamit's active portfolio reflected both the breadth of its work and the direction in which the organisation continues to grow. It included initiatives ranging from new clinical-trial methods for rare and ultra-rare diseases in Realised to AI-enabled stroke care pathways in UMBRELLA, from pan-European rare-disease research in ERDERA to capacity building in enzyme technology through WIDEnzymes.

Alongside these, Teamit continued to contribute to important lines of work in medicines repurposing (REMEDI4ALL), patient-reported outcomes infrastructure (H2O), diagnosis and treatment of intestinal fibrosis (FIBROTARGET), environmental risk assessment of medicines (PREMIER) and light-based therapeutic implants (PHOTOTHERAPORT), as well as the COVID-19, RSV and EMA vaccine study programmes.

Taken together, this portfolio shows a team increasingly at ease across diverse scientific fields, collaborative settings and types of contribution while remaining grounded in the same commitment to rigour, relevance and meaningful impact. ●



Clinical trials in rare and ultra-rare diseases face persistent structural barriers: patient populations are small, geographically dispersed and medically heterogeneous, making recruitment, trial design and evidence generation especially difficult. These challenges are compounded by limited adapted methodologies for rare diseases.

→ Relevance

Realised aims to transform how clinical trials for rare and ultra-rare diseases are designed, conducted and assessed in Europe. By co-creating new methods, practical tools and operational standards with clinicians, patients, regulators, HTA bodies and industry, the project seeks to make trials more feasible, strengthen enrolment pathways and increase confidence in the evidence generated.

In the longer term, this should help accelerate therapy development and improve access to new treatment options for people living with conditions that still face major unmet needs. New knowledge, tools and resources generated by the project will be gathered in a user-friendly Playbook, supporting dissemination and uptake.

→ 2025 highlights

During 2025, Realised kicked off and focused on evidence gathering, scoping reviews on trial design, enrolment and federated data analysis, and broad stakeholder engagement.

Progress included prioritising diseases as use cases for validation with the relevant European Reference Networks (ERNs), launching a multi-stakeholder survey on enrolment barriers, and advancing on other critical aspects such as randomisation, EHR-based pre-screening, cross-border referral and centre certification. Alongside this, Teamit supported coordination across the consortium, helped strengthen visibility in the rare-disease and clinical trial community, and contributed to the initial conceptualisation of the Playbook, patient-engagement activities and multi-stakeholder dialogue.

→ Teamit's contribution

- EU Funding Opportunities and Proposal Preparation
- Project Management
- Communications and Outreach
- Realised Playbook
- Multi-stakeholder Dialogue

FUNDING CALL

**Horizon Europe
Innovative Health
Initiative (IHI)**

FUNDING PERIOD

2025-2029

BUDGET

€17M

PARTNERS

38 organisations

PROJECT COORDINATOR

**Sigmund Freud
Private University**

PROJECT LEADER

AstraZeneca



In stroke care, every minute matters. The faster a patient is diagnosed and treated, the greater the chance of protecting brain cells and reducing serious long-term consequences. Yet today, care is still often fragmented across diagnosis, emergency treatment, rehabilitation and secondary prevention. Gaps also remain in personalised care, equitable access and the use of real-world data to support better clinical decisions.

→ Relevance

UMBRELLA aims to improve stroke management and patient outcomes by enabling more timely, accurate and coordinated decisions across the care pathway. By combining AI, digital technologies and real-world clinical data, the project seeks to support better decision making across the whole care journey— from diagnosis and treatment to recovery and long-term support.

Its long-term ambition is to help set new standards for stroke management in Europe, reduce inequalities between countries and regions and improve outcomes for both new patients and stroke survivors.

→ 2025 Highlights

Over the last year, UMBRELLA advanced on the establishment of the federated platform and common data model needed to support AI-ready integration of stroke data across participating centres. These advances were accompanied by important progress in regulatory and governance work, helping ensure that technical development evolves alongside the conditions needed for trustworthy implementation.

At the same time, UMBRELLA increased its visibility and positioning within the European landscape of AI-enabled health care innovation, reinforcing its role as a project that is moving beyond initial setup towards a more integrated, validated and clinically relevant innovation ecosystem.

→ Teamit's contribution

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

FUNDING CALL

**Horizon Europe
Innovative Health
Initiative (IHI)**

FUNDING PERIOD

2024-2029

BUDGET

€26.9M

PARTNERS

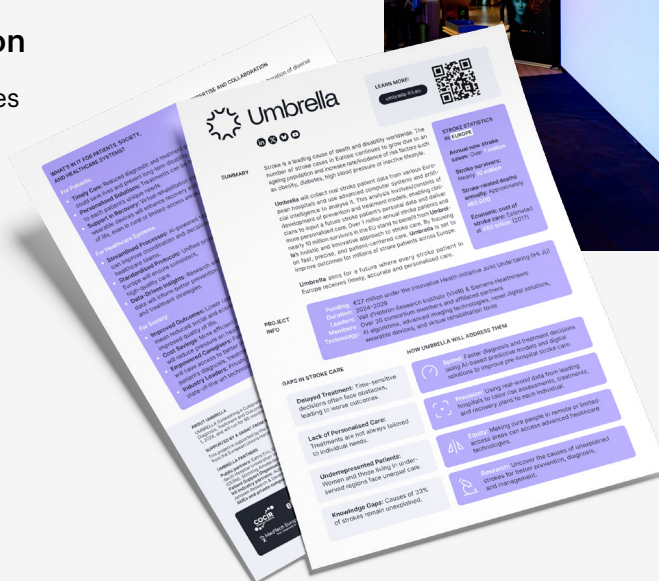
30 organisations

PROJECT COORDINATOR

**Vall d'Hebron
Research Institute
(VHIR)**

PROJECT LEADER

Siemens Healthineers



Rare disease research and care remain deeply fragmented across countries, institutions and disease areas. Patients often face long diagnostic journeys, limited therapeutic options and uneven access to expertise, while data, knowledge and funding efforts are too often dispersed to generate impact at the necessary scale.

→ Relevance

ERDERA, a European partnership uniting over 170 public and private organisations across 37 countries, aims to improve outcomes for people living with rare diseases by making research and care in Europe more coordinated, connected and effective. By aligning research, funding, data, expertise and clinical collaboration across countries, ERDERA seeks to accelerate diagnosis, support the development of new treatments and strengthen Europe's capacity to translate rare disease research into real-world solutions.

→ 2025 Highlights

Last year, ERDERA advanced its role as an enabling infrastructure for rare disease research across Europe. Key activities included the launch and management of joint transnational funding calls, the establishment of governance and coordination mechanisms, and the deployment of services covering diagnostic and clinical research, expertise support, training and international alignment.

ERDERA strengthened collaboration across funders, research centres and clinical networks, and promoted common standards, transparent procedures and cross-border cooperation.

These efforts resulted in early, tangible outputs. ERDERA announced its first funded portfolio of multinational preclinical therapy projects and launched a new call addressing unsolved rare disease cases. The alliance also enabled the harmonisation of large-scale diagnostic datasets, supported clinical research coordination through international conferences, and expanded services for expertise, translation and capacity building.

→ Teamit's contribution

- Project Management
- Multi-stakeholder Management and Governance
- Communications and Outreach
- Sustainability and Business Development

FUNDING CALL

**Horizon Europe
COFUND action**

FUNDING PERIOD

2024-2031

BUDGET

€385.5M

PARTNERS

**Over 170
organisations**

PROJECT COORDINATOR

**INSERM (Institut
National de la Santé
et de la Recherche
Médicale)**

**Through its work, ERDERA
is emerging as a global
leading voice and catalyst
for Europe's rare disease
research community**



Enzyme technology has major potential for biotechnology, sustainability and industrial innovation, but research capacity and innovation opportunities remain unevenly distributed across Europe. Widening countries continue to face structural gaps in visibility, investment, collaboration and talent retention, limiting their ability to contribute fully to this fast-moving field.

→ Relevance

WIDEnzymes is expected to create a more connected and resilient innovation landscape for enzyme technologies in Europe. Beyond strengthening collaboration between widening and non-widening countries, the project is designed to improve skills development, mentoring, mobility and technology transfer, while supporting more effective links between academia, industry and policymakers.

By building a competitive cross-border enzyme technology ecosystem, WIDEnzymes supports more sustainable innovation capacity and greater long-term European competitiveness in biotechnology and bioeconomy.

→ 2025 Highlights

In 2025, WIDEnzymes advanced capacity building, knowledge exchange and cross-border collaboration across the consortium. Key activities included hands-on training workshops hosted by Politecnico di Milano and the University of Crete, delivery of a structured webinar series by Teamit, and implementation of staff and student exchanges to support mobility and mentoring.

The project also strengthened policy dialogue by hosting meetings in widening countries and fostered cohesive collaboration through joint preparation of EU funding proposals.

The consortium increased its visibility through publications, conferences and outreach events, including its first joint scientific publication.

→ Teamit's contribution

- Regulatory Science
- Communication and Outreach
- Training

FUNDING CALL

**Horizon Europe
WIDERA**

FUNDING PERIOD

2024-2027

BUDGET

€1.2M

PARTNERS

5 organisations

PROJECT COORDINATOR

**Latvian Institute
of Organic Synthesis**

More than 55 early-career researchers enhanced practical skills in computational enzyme design and directed evolution, while webinars reached diverse scientific and administrative audiences



Light-based therapies offer important therapeutic potential, but their clinical use is limited by a fundamental challenge: visible light does not penetrate deeply enough into tissues and bones to reach many relevant targets in the body. This restricts their use in conditions such as chronic pain and epilepsy, where more focal, less invasive and better-controlled treatment options are still needed.

→ Relevance

PHOTOTHERAPORT is expected to expand the future therapeutic landscape for chronic pain and epilepsy by enabling highly localised, on-demand light-based interventions with lower systemic exposure.

Over time, this could support safer and more tolerable treatment pathways, strengthen the clinical viability of light-based approaches, and create a translational foundation for broader use in other conditions requiring targeted neuromodulation or anti-inflammatory treatment.

→ 2025 Highlights

Over the last year, PHOTOTHERAPORT made important progress in developing and testing a new light-based therapeutic approach for chronic pain and epilepsy. The project advanced both the implantable materials designed to generate light inside the body and the light-responsive compounds intended to act on specific biological targets.

These components were assessed through laboratory and preclinical studies to understand their performance and therapeutic potential. The results provided early evidence that this approach can produce beneficial effects in preclinical models of pain and epilepsy, supporting the project's proof of concept. Although the work is still at a preclinical stage, these advances strengthen the basis for future treatment strategies that could offer more targeted, more controlled and potentially less invasive alternatives than many current options.

→ Teamit's contribution

● Regulatory Science

- Identifying optimal implant designs from a medical device perspective
- Defining the most impactful clinical contexts of use for delivering light-based therapies
- Developing the regulatory roadmap for medical devices and drug-device combinations
- Initiating interactions with regulatory bodies, including the European Medicines Agency and the Innovation Task Force
- Exploring early engagement with a notified body to inform CE marking strategies

FUNDING CALL

Horizon Europe
European Innovation
Council (EIC) –
Pathfinder

FUNDING PERIOD

2024–2026

BUDGET

€3M

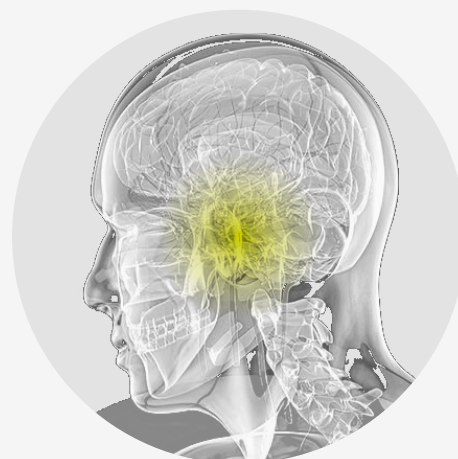
PARTNERS

8 organisations

PROJECT COORDINATOR

Institute for
Bioengineering of
Catalonia (IBEC)

PHOTOTHERAPORT is developing luminescent implants that can emit light locally inside the body, enabling targeted activation of light-based therapies and photoswitchable drugs in deep-seated tissues



Intestinal fibrosis and fibrostenosis remain major unmet needs in inflammatory bowel disease. Although inflammation can often be controlled, there are still no approved therapies to prevent or reverse these complications, and many patients ultimately face bowel damage, strictures and surgery.

→ Relevance

The relevance of FIBROTARGET lies in its potential to shift intestinal fibrosis in inflammatory bowel disease from a late-stage, largely irreversible complication to a condition that can be identified earlier and managed more proactively.

In the medium term, the project is expected to support better risk stratification and more informed clinical decision-making through improved biomarkers and diagnostic approaches. In the longer term, by advancing translational knowledge and opening new therapeutic avenues, it could help reduce the need for surgery, improve long-term outcomes for people living with IBD and contribute to lowering the broader healthcare and societal burden associated with disease progression.

→ 2025 Highlights

In 2025, FIBROTARGET progressed across research, dissemination and patient-engagement activities. A dedicated World IBD Day campaign highlighted the invisible burden of intestinal fibrosis through patient testimonials, educational materials and multilingual resources developed in collaboration with the International Federation of Crohn's and Ulcerative Colitis Associations (IFCCA).

Scientific publications advanced understanding of fibrotic mechanisms and emerging diagnostic approaches, while presence at key conferences facilitated dialogue with clinical, research and industry audiences.

Overall, the project reinforced its translational focus and consolidated foundations for advancing innovative diagnostics and therapeutic strategies in subsequent phases.

→ Teamit's contribution

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

FUNDING CALL

Horizon Europe
Research and
Innovation
Action (RIA)

FUNDING PERIOD

2023-2028

BUDGET

€5.68M

PARTNERS

8 organisations

PROJECT COORDINATOR

KU Leuven (University
of Leuven)



FIBROTARGET investigates the mechanisms that drive fibrosis and develops new biomarkers, diagnostic tools and therapeutic approaches

Drug repurposing offers a faster and more cost-effective route to new treatment options by identifying new therapeutic uses for medicines that are already approved. Yet its potential remains constrained by fragmented expertise, weak coordination across the development pathway, insufficient incentives, and uneven support for patient-centred development and access.

→ Relevance

REMEDI4ALL is expected to make the repurposing of medicines in Europe more structured, connected and actionable by improving access to specialised support, strengthening development pathways and increasing the quality and credibility of repurposing initiatives.

The project will help establish a more sustainable European ecosystem in which repurposed therapies reach patients more efficiently across disease areas, while also supporting fairer access and contributing to the resilience and sustainability of healthcare systems.

→ 2025 Highlights

In 2025, REMEDI4ALL broadened its ecosystem through extensive networking, engagement and capacity-building activities. Flagship events such as the iDR25 conference strengthened multidisciplinary exchange, helping connect the people, ideas and expertise needed to move drug repurposing forward, while the consortium welcomed new Associated Partners and expanded its Funders Network.

The project also launched new training initiatives, including the REMEDI4ALL Digital Academy, hackathons and targeted bootcamps for researchers and patient communities. REMEDI4ALL gained international media attention, with coverage in *New York Times*, *Forbes*, *El País*, *Le Figaro*, *The Age* and *The Telegraph* helping raise awareness of drug repurposing challenges and opportunities.

Scientific and policy-oriented publications addressed structural barriers and computational approaches to repurposing, while new tools such as the Expertise Dashboard, Knowledge Graph, Value Framework and funding guidance supported more transparent, coordinated and impactful repurposing initiatives.

Overall, the project consolidated its role as a central European platform for collaborative, patient-centred medicines repurposing.

→ Teamit's contribution

- EU Funding Opportunities and Proposal Preparation
- Project Management
- Multi-stakeholder Management and Governance
- Communications and Outreach
- Training and Capacity Building
- Event Organisation

FUNDING CALL

Horizon Europe
Research and
Innovation
Action (RIA)

FUNDING PERIOD

2022–2027

BUDGET

€23M

PARTNERS

26 organisations

PROJECT COORDINATOR

EATRIS ERIC

REMEDI4ALL is building a European platform that connects the expertise, services, tools and stakeholders needed to help promising repurposing ideas move forward more effectively



Healthcare systems still make limited routine use of patient-reported outcomes, despite their importance for understanding how people experience disease, treatment and care. In practice, these data remain difficult to collect in a standardised way, hard to integrate across settings and countries, and often disconnected from clinical, research and policy decision-making.

→ Relevance

H2O is expected to strengthen shared decision-making and patient self-management by building a European network of Health Outcomes Observatories and the governance, infrastructure and digital tools needed to collect and use patient-reported outcomes at scale while keeping patients in control of their data.

In the longer term, by establishing a trusted and scalable observatory model across countries and disease areas, H2O could help embed patient-reported outcomes more systematically into healthcare delivery, research and policy, contributing to more value-based, patient-centred and sustainable health systems, while reinforcing Europe's competitiveness in health research.

→ 2025 Highlights

During the last year, H2O consolidated its operational and governance framework across national observatories in Austria, Germany, the Netherlands and Spain, alongside the Pan-European Observatory.

Patient participation also increased substantially, with over 4 300 patients enrolled by September 2025 across three disease areas—diabetes, IBD and cancer, including breast and lung cancer—supporting initial analyses and comparisons with external registries.

The expansion of observatory networks across multiple countries increased geographic coverage and representativeness, while structured engagement with European and international institutions strengthened policy relevance.

Overall, H2O demonstrated the feasibility, value and scalability of integrating patient-reported outcomes into routine care and research, laying foundations for continued growth beyond the funded project period.

Through Health Outcomes Observatories across Europe, H2O aims to generate more consistent evidence that supports better evaluation of care, treatments and unmet needs across populations

→ Teamit's contribution

- EU Funding Opportunities and Proposal Preparation
- Project Management

FUNDING CALL

Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU)

FUNDING PERIOD

2020–2026

BUDGET

€20.4M

PARTNERS

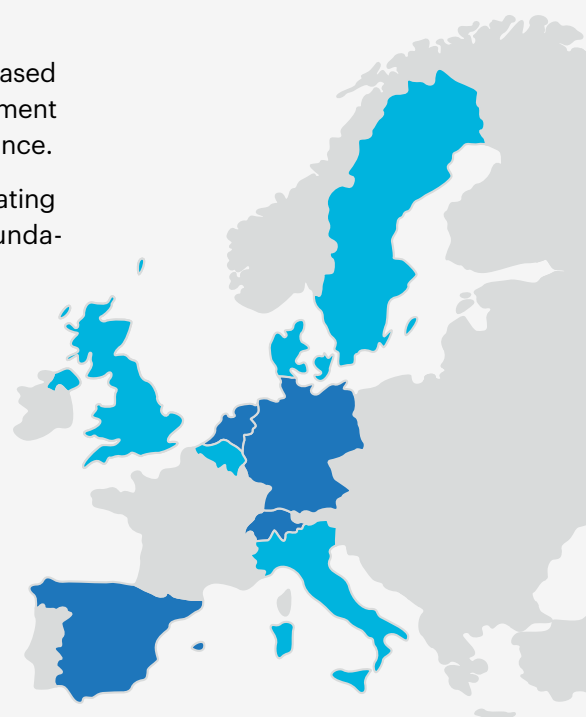
23 organisations

PROJECT COORDINATOR

Medizinische Universität Wien

PROJECT LEADER

Takeda Pharmaceuticals



Environmental risk assessment for medicines still faces major limitations, particularly for the large number of legacy active pharmaceutical ingredients for which data remain incomplete, dispersed or difficult to access. Existing approaches are often too resource-intensive, not well suited to prioritising substances of greatest concern, and rely heavily on animal testing.

→ Relevance

PREMIER aims to improve how regulators, researchers and other stakeholders identify and prioritise pharmaceutical substances of environmental concern by developing a transparent, evidence-based information and accessible assessment system that includes a centralised database and new tools.

The project will help embed more sustainable environmental risk management across the lifecycle of medicines, support the development of greener pharmaceuticals, reduce unnecessary animal testing and contribute to a stronger European standard for protecting ecosystems while maintaining patient access to needed treatments.

→ 2025 Highlights

During 2025, PREMIER advanced development and dissemination of its core tools for environmental risk assessment of medicines.

Key milestones included the launch of publicly available digital resources such as the PREMIER Database and associated tools designed to support screening, prioritisation and evaluation of active pharmaceutical ingredients.

These tools bring together environmental risk assessment data from regulatory authorities and industry, improving transparency and usability for a wide range of stakeholders.

The project also gained visibility through its inclusion in the Innovative Health Initiative Annual Report, reinforcing its relevance in addressing medicines in the environment.

Overall, PREMIER strengthened the evidence base, accessibility and methodological consistency needed to support environmentally responsible pharmaceutical development and regulation.

→ Teamit's contribution

- EU Funding Opportunities and Proposal Preparation
- Project Management
- Communication and Dissemination

FUNDING CALL

Innovative Medicines Initiative (IMI2)

FUNDING PERIOD

2020–2026

BUDGET

€9M

PARTNERS

25 organisations

PROJECT COORDINATOR

Radboud University Nijmegen

PROJECT LEADER

AstraZeneca AB

With the PREMIER Database and related tools, environmental risk assessment data are becoming more visible, usable and actionable



2025: FROM ACTIVITY TO IMPACT

Health Data

In 2025, Teamit's Health Data Unit work focused on post-authorisation studies and continued support in the networks and methods that generate rapid, robust and high-quality real-world evidence.

Last year, several industry-funded vaccine and medicinal product studies involving Teamit as a leading operating centre and/or scientific manager reached final-report stage and moved into dissemination. At the same time, publicly funded studies under the EMA Framework Contracts continued to strengthen Europe's capacity to assess safety signals and generate real-world evidence for regulatory decision-making. Teamit supported this work through project and scientific management, and contributing to the smooth coordination of complex, multi-partner studies.

In parallel, Teamit had an active role in broader European infrastructures, specifically VAC4EU and the EU PE & PV Research Networks, by helping to strengthen the foundations for robust multi-country evidence generation.

A key highlight of 2025 was VAC4EU's 5-year milestone, celebrated at an anniversary event in Brussels that brought together voices from different stakeholders in public health: from regulatory, academia, and industry to patient advocacy communities. As part of the programme, Teamit's CEO, Eva Molero, joined fellow members of VAC4EU's Executive Board (ExBo) as a speaker, underlining Teamit's long-standing commitment to the network and its role in advancing trusted, collaborative vaccine evidence generation across Europe.

Teamit has been involved since VAC4EU's earliest stages, supporting the network's creation and sustainability and contributing to business development and communication.

→ Contributing to scientific dialogue

Teamit's Health Data Unit research was also reflected in scientific presentations during the year, including two posters and one oral presentation at the Annual Meeting of the International Society of Pharmacoepidemiology held in Washington DC, and one poster and one oral presentation at the International Society of Pharmacovigilance held in Cairo, linked to Teamit's contribution to vaccine safety work.

Find out more about these activities in the Publications and Posters as well as Events and Outreach sections of this Annual Report. ●



In 2025, Teamit continued helping turn real-world health data into robust evidence for supporting regulatory and health decision-making

Strengthening VAC4EU's Strategic Position

In 2025, Teamit helped VAC4EU move from study delivery towards a more strategic, business-oriented and multi-stakeholder co-creation approach. Building on our understanding of the vaccine monitoring ecosystem, we supported the development of a forward-looking strategy to make VAC4EU's value clearer, more visible and easier to act on across scientific, regulatory, industry and partnership contexts.

Work included identifying new collaboration opportunities, mapping relevant data sources (mainly in Eastern Europe) to improve network coverage and industry pipelines (with nearly 400 medicinal products identified), supporting engagement with potential partners, and helping position VAC4EU in key spaces for future growth. Through this, Teamit brought business development know-how that supports VAC4EU's long-term sustainability, visibility and capacity to respond to emerging vaccine safety and effectiveness needs.

→ VAC4EU's Study Portfolio Gains Pace

Across the VAC4EU study portfolio, 2025 also marked a clear transition point.

Within the pharma-funded portfolio, the studies finalised in 2025 include two Pfizer/BioNTech Comirnaty® COVID-19 studies and the Janssen Jcovden® COVID-19 study, alongside two Moderna Spikevax® COVID-19 studies. On the public side, SAFETY-VAC also finalised and moved into the dissemination phase.

The studies that remained ongoing through 2025 within the pharma-funded portfolio include two HIPRA Bimervax® COVID-19 studies expected to end in 2030, one Pfizer/BioNTech Comirnaty® COVID-19 study, two Pfizer ABRYVO® RSV studies (ending in 2029) and the development of two additional protocols, and two Pfizer Paxlovid® COVID-19 studies finalising in 2026.

In parallel, VAC4EU is also contributing to TARGET-EU and ADEPT studies led by EU PE & PV Research Network which are expected to end in 2026.

The portfolio has also expanded through a new European Commission funding stream, with the award of IHI 10 FORTIFY where the network will provide specific use cases for secondary use of data within the European Health Data Space (EHDS). ●

Teamit brings health data, business development and communications know-how to help VAC4EU strengthen its capacity to respond collaboratively to emerging vaccine safety and effectiveness needs



Supporting the EU PE & PV Research Network

Teamit supported the European Pharmacoepidemiology & Pharmacovigilance (EU PE & PV) Research Network in its application to new EMA framework contracts during 2025. These have been awarded and will run from 2026 to 2030.

These framework contracts include Qualitative Research (Lot 4) and Pharmacoepidemiologic Research (Lot 5). Both Lots are led by Utrecht University and include UMCU and VAC4EU (only in Lot 5) as partners.

Teamit has participated in some of the studies launched under this and the previous framework, bringing expertise in project management and scientific management support. These studies include SAFETY-VAC that finalised in 2025 and TARGET-EU, ADEPT and CONTROL-EU which are expected to end in 2026. ●

EU PE&PV

RESEARCH NETWORK



Teamit's Real-World Evidence Studies work in focus

Beyond helping research networks grow and strengthen their position, Teamit plays a hands-on role in executing real-world evidence generation (RWE) studies. Our expertise in study implementation combines scientific coordination, project management, and operational support to help turn complex research designs into robust evidence. In 2025, this work translated into Teamit's active involvement in the following portfolio of pharma- and EMA-funded studies:

→ Pharma-Funded Studies

1. Pfizer/BioNTech Comirnaty® Bivalent COVID-19 PASS

Evaluate whether specific adverse events of special interest are more frequent following vaccination with the bivalent formulation of Comirnaty.

● *Teamit's role: Scientific management*

2. Pfizer/BioNTech Comirnaty® COVID-19 PASS Myo & Peri

Assess the clinical course of myocarditis and pericarditis in vaccinated individuals following ≥ 1 dose of Comirnaty and unvaccinated patients, as well as identifying potential risk factors for these conditions.

● *Teamit's role: Scientific management*

3. Pfizer/BioNTech Comirnaty® COVID-19 PASS

Determine whether there is an increased risk of adverse events of special interest following ≥ 1 dose of Comirnaty in the general European population, as well as in sub-populations of interest.

● *Teamit's role: Scientific management*

4. Janssen Jcovden® PASS

Assess the risk of pre-specified and newly identified adverse events of special interest following Ad26.COV2. S vaccination, including assessment in sub-populations of interest.

● *Teamit's role: Lead Operating Center in charge of study negotiation and coordination + Scientific management*

5. Pfizer ABRYSSVO® RSV PASS Pregnancy

Estimate the occurrence of safety events of interest in pregnant women vaccinated with ABRYSSVO and their offspring compared with a matched unvaccinated group.

● *Teamit's role: Lead Operating Center in charge of study negotiation and coordination + Scientific management*

6. UCB Evenity® (Romosozumab) PASS EU-ADR Alliance

- Estimate the risk of serious cardiovascular events, driven by myocardial infarction and stroke, and all-cause mortality associated with the use of romosozumab (PASS OP0004)
- Evaluate the risk of developing serious infection associated with romosozumab treatment (PASS OP0006)
- Validate cardiovascular death, myocardial infarction, stroke and serious infection outcomes in patients eligible for inclusion in PASS OP0004 and PASS OP0006
- Monitor adherence to the Risk Minimisation Measures (RMMs) for romosozumab in routine practice to avoid exposing patients to unnecessary cardiovascular (CV) risk (PASS OP0005).

● *Teamit's role: Lead Operating Center in charge of study negotiation and coordination + Scientific management*

→ EMA-Funded Studies

1. SAFETY-VAC

A framework for the post-authorization safety monitoring and evaluation of the vaccines in the EU. Consisting of two studies:

- Assess the capacity and fitness for purpose to conduct vaccine safety studies with RWD sources from several networks.
- Create operational phenotypes to estimate the background and cumulative incidence of the flares of ten pre-defined autoimmune diseases and identify immunocompromised populations in the RWD sources, while also analysing the contribution of different provenances of data.

● **Teamit's role: Scientific management**

MORE INFORMATION: EUPAS1000000193
EUPAS1000000233
EUPAS1000000288

2. TARGET-EU

Comparative effectiveness and safety studies using the target trial emulation and estimand frameworks. The overarching goal is to generate evidence that bridges randomised controlled trials (RCTs) and observational studies, supporting regulatory decisions where RCTs are infeasible:

- Advance regulatory use of real-world data (RWD) through application of target trial emulation (TTE) and estimate methodologies.
- Developed target trial protocols, emulation protocols, and conduct feasibility assessments and analyses across ten distinct case studies.

● **Teamit's role: Scientific management**

MORE INFORMATION: EUPAS1000000995
EUPAS1000000987
EUPAS1000000979
EUPAS1000001001
EUPAS1000000989
EUPAS1000001002
EUPAS1000000999
EUPAS1000000993
EUPAS1000001005
EUPAS1000000996
EUPAS1000000539

3. ADEPT

Antiseizure Medication (ASM) Exposure and Pregnancy and neonatal outcomes research.

- Describe the utilisation of antiseizure medications in pregnant women, other women of childbearing potential, and men: a multi-database study from seven European countries.
- Assess the risk of adverse pregnancy, neonatal and child outcomes following either in utero ASM exposure through the mother, or peri-conceptional ASM exposure through the father.

● **Teamit's role: Scientific management**

MORE INFORMATION: EUPAS1000000212
EUPAS1000000246

4. CONTROL-EU

Implementation of controlled access to and distribution of medicinal products in European Union.

- Describe national implementation processes of controlled access programmes (CAP) as well as controlled distribution systems (CDS) on a given sample of eight centrally authorised medicinal products in eight different European health care systems (Austria, Greece, Latvia, Netherlands, Portugal, Slovenia, Spain and Sweden).
- Learn about national barriers and enablers as reported by key stakeholders including national competent authorities (NCAs), Marketing Authorisation Holders (MAHs), health care professionals, and patients.
- Provide evidence that may be used for recommendations for regulators to engage with healthcare professional bodies and other responsible parties to investigate whether CAP/CDS are feasible and needed.

● **Teamit's role: Scientific management**

MORE INFORMATION: EUPAS1000000313

2025: STRENGTHENING OUR ROLE IN THE ECOSYSTEM

A growing partner network

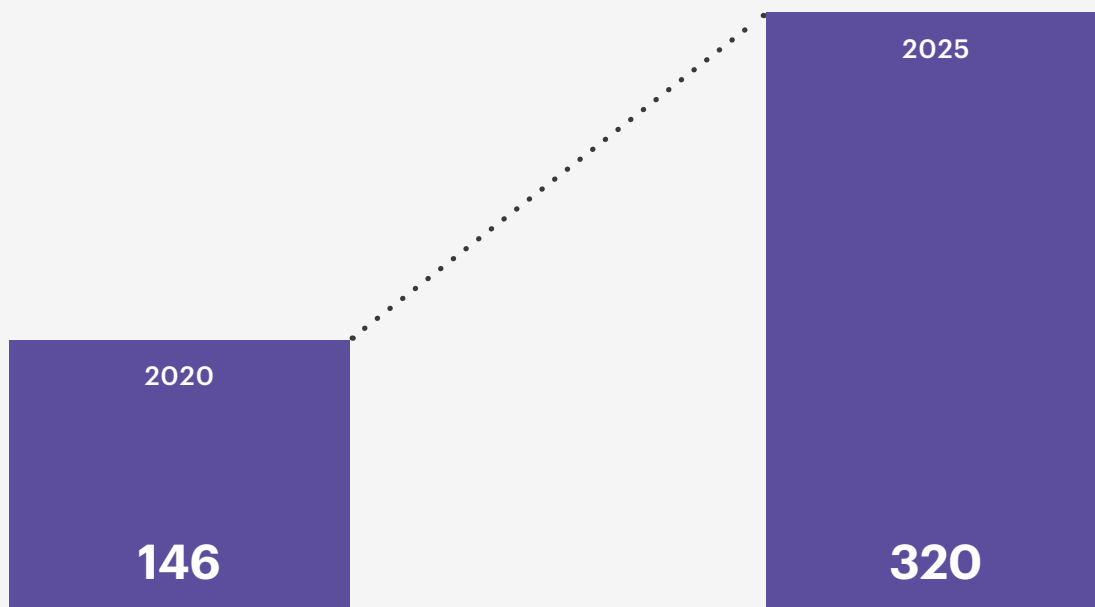
Over the past five years, Teamit has grown steadily. What started in 2020 as a small organisation with seven people, six active projects and a focused offer in project management and communications has become, by 2025, a team of 30 professionals working across 19 projects, real-world evidence studies and networks with a much broader scientific and operational scope.

From the start, partnerships are central to Teamit's mission. In 2025, the network of organisations we work with grew to 320 partners (up from over 100 in 2020), a clear sign of sustained growth built on trust, shared values and a consistent way of working.

The partner base also became broader and more diverse, spanning public infrastructures and authorities, academia and research centres, hospitals, industry, regulatory bodies and patient organisations. This diversity matters: it brings different perspectives together and helps collaborative, multi-stakeholder research work in practice.

As Teamit's track record has strengthened, it has increasingly positioned itself as a trusted partner in shaping impactful research initiatives from the outset. ●

**As our partner network grows,
so does our capacity to bring
people, expertise and ideas
together, making collaboration
the foundation for stronger,
more impactful research**



In 2025, Teamit grew to 30 professionals, bringing together people with diverse academic and professional backgrounds. The team includes profiles with expertise in fields such as pharmacy, biology, biomedicine, public health, policy, communications or law and business, creating a multidisciplinary mix that strengthens how Teamit approaches complex challenges in health research.

This range of profiles makes a real difference in practice. It allows Teamit to bring together different ways of thinking, move more easily across scientific and operational questions, and respond with agility to projects that evolve quickly and require coordination across many partners, disciplines and work groups. It is a team built not only to grow, but to work effectively and creatively in a fast-paced and dynamic environment.

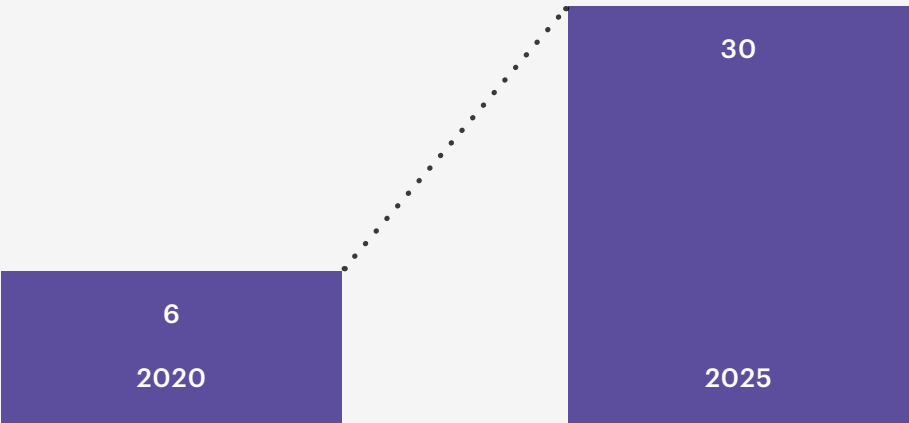
Individual development remained a strong focus throughout the year. Teamit continued to strengthen its career development plan as a way to support professional growth, clarify progression and help people build their contribution over time.

Training also remained an important part of this effort, combining soft and technical skills through sessions on topics such as effective communication, managing complexity and finance in EU-funded projects, alongside other learning opportunities linked to each person's role and development path.

Team building also remained an important part of how Teamit works together. During the year, dedicated moments were created to step back from day-to-day delivery and reflect collectively on where the organisation had come from and where it was heading next, including internal sessions linked to the first strategic plan and preparation of the new one.

These moments were complemented by the summer anniversary event marking Teamit's first five years and by the winter gathering at Poble Espanyol, helping strengthen team cohesion while creating space for shared reflection, celebration and forward thinking. ●

At Teamit, career development means giving people the clarity, support and confidence to recognise their potential and grow into roles where they can make a meaningful contribution



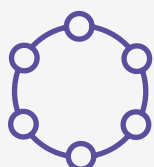
Teamit's expertise is built for collaborative research: it helps multi-stakeholder initiatives move from ambition to delivery with clarity, quality and shared direction.

The work is transversal by design, combining scientific understanding with the practical craft of running complex programmes and keeping them coherent across partners, work packages and scientific priorities.



Scientific and Project Management

sits at the centre of that offer. It holds the moving parts together —ideation, governance, planning, coordination and follow-through— so that science can progress without losing structure or pace.



Regulatory Science and Real-World Evidence Research

bring the evidence lens into focus. These capabilities support work that needs to stand up to scrutiny, remain grounded in real settings and speak to the questions that matter for public health and decision-making.



Scientific Writing and Communications

shape how that work is understood and used. They translate technical concepts and results into clear narratives and materials that partners, stakeholders and wider audiences can engage with —without flattening the science or oversimplifying it.



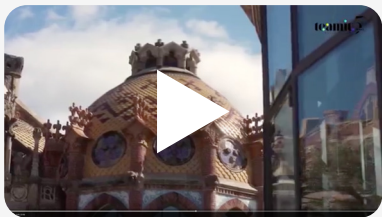
Business Development and Sustainability

together with cross-team transversal work, reflect how Teamit operates day to day: connecting expertise across functions, spotting where partnerships can add value and supporting collaborations with a long view in mind.

Celebrating our first five years



This 5-year milestone was also marked in the summer with a special anniversary event that brought together Teamit and close partners. It was a moment to celebrate what had been achieved together and recognise the trust, collaboration and shared effort that have shaped Teamit’s journey since 2020.



Teamit’s scientific areas now form a wide health research map, shaped by the questions our projects need to answer rather than by disciplinary boundaries. That map has expanded steadily over time, moving from a compact set of focus areas in 2020 to a far more extensive span by 2025.

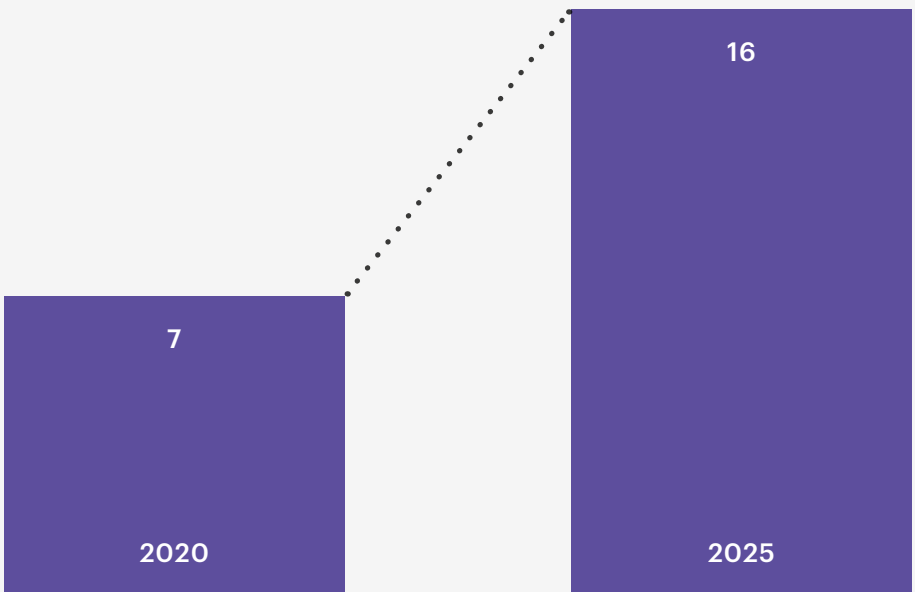
Some domains sit close to evidence generation: Drug Safety, Pharmaco-epidemiology, Vaccines, Real-World Evidence, Patient Engagement and Clinical Trials. They deal with what happens in real settings, how outcomes are measured, and how signals are interpreted when decisions cannot wait for perfect conditions.

Other domains capture the “how” of modern health research: Regulatory Science, Digital Health and Repurposing. These areas bring methods, governance and translation into the frame —helping good science travel further, remain usable and stay aligned with the standards that determine whether it can influence practice.

The map also reaches into disease and technology frontiers where progress depends on collaboration across specialties: Rare Diseases, Stroke and Immunotherapies. These fields bring distinctive scientific challenges and sharpen the need for robust design, careful interpretation and practical routes from insight to impact.

Alongside them sit domains that push into different scientific environments and modalities, including Light-Based Therapies, Enzyme Technology and Ecotoxicity. Their presence reflects a portfolio that can move between human health, emerging technologies and environmental questions without losing rigour. ●

Teamit’s scientific areas reflect a portfolio that has grown beyond boundaries, shaped by the complex health challenges that research needs to answer



Publications and Outreach

Research only moves forward when results are shared, questioned and reused. Publications, conference contributions and scientific events are part of that cycle: they invite scrutiny, connect methods across teams, and help evidence travel from project work into the wider research community.

In 2025, Teamit's scientific outputs included peer-reviewed publications and contributions as co-authors across vaccine safety and effectiveness topics, alongside posters and an oral presentation at events such as ISPE 2025.

The year also included a steady calendar of scientific and project-related activity, from kick-off meetings and general assemblies to external conferences and training. These moments matter because they strengthen collaboration, sharpen shared approaches and keep work aligned with evolving practice in the field.

Teamit's outreach activities had a clear international footprint, spanning Europe, the United States and Africa. This reflects our active presence in the spaces where scientific communities meet, debate and set direction.

Taken together, the publications, posters and activities listed below provide a concrete view of how Teamit contributes to the research ecosystem: through authored evidence, scientific exchange and the day-to-day work of building networks that support high-quality, multi-stakeholder research. ●



Teamit's international presence continued to grow, bringing its contribution into scientific forums across Europe, the United States and Africa



→ PUBLICATIONS

GVDN

Risk of Guillain-Barré syndrome after COVID-19 vaccination or SARS-CoV-2 infection: A multinational self-controlled case series study

Co-Author: **Gianmarco Di Mauro**
Journal: **Vaccine**

Collaborating lead: **UMCU/GVD**
Status: **Published**

In this large multinational study analysing data from over 230 million people examining the relationship between COVID-19 vaccination, SARS-CoV-2 infection and GBS, a rare neurological condition, researchers found that COVID-19 infection increases the risk of GBS, there is an increased risk of GBS following adenoviral vector COVID-19 vaccines, and there is no increased risk following mRNA or inactivated vaccines. This highlights the importance of mRNA vaccines as safe tools to combat COVID-19. **DOI: 10.1016/J.VACCINE.2025.127291**

COVE

Impact and Effectiveness of COVID-19 mRNA Vaccination Against COVID-19 Hospitalisation in Paediatrics: A Cohort Study Using Two Linked Data Sources in Spain

Co-Author: **Fabio Riefolo**
Journal: **Pharmacoepidemiology & Drug Safety**

Collaborating lead: **AEMPS & EU PE&PV**
Status: **Published**

In Spain, over 2 million COVID-19 cases were reported in the paediatric population; however, few required hospitalisation. This retrospective study found that vaccination with a two-dose series of COVID-19 mRNA vaccine may protect against hospitalisation with/for COVID-19 compared to unvaccinated individuals. If paediatric severe COVID-19 remains rare, larger databases are required to understand precisely the effectiveness and impact of new vaccines. **DOI: 10.1002/pds.70239**

EU PE&PV (EMA)

Cohort event monitoring of booster COVID-19 vaccine safety using patient-reported outcomes in pregnant women

Co-Author: **Fabio Riefolo**
Journal: **Frontiers in Drug Safety and Regulation**

Collaborating lead: **University Hospital, Zürich**
Status: **Published**

Pregnant women are a key COVID-19 vaccine hesitant population. More evidence on safety of COVID-19 vaccines in pregnancy could reduce vaccine hesitancy. This prospective observational study on COVID-19 vaccine safety monitoring showed that pregnant women from the general population reported solicited and unsolicited adverse drug reactions following COVID-19 vaccination less frequently than non-pregnant women. **DOI: 10.3389/fdsfr.2025.1689349**

→ POSTERS

ISPE 2025

2024 Interim Results from the VAC4EU* Post-authorisation Safety Study (PASS) of the Pfizer-BioNTech COVID-19 Vaccine (COMIRNATY) in Europe

Co-Author: **Elena Palà**

Collaborating institution: **UMCU**

ISPE 2025

Evaluating the Diagnostic Accuracy of Adverse Events of Special Interest Following Janssen COVID-19 Vaccine (JCOVDEN) Using the VAC4EU Validation Pipeline

Co-Authors: **Anna Brutau, Elena Palà**

Collaborating institution: **UMCU**

→ ORAL PRESENTATIONS

ISPE 2025

Evaluating the safety profile of the Janssen COVID-19 vaccine (JCOVDEN): A VAC4EU post-authorization safety study

Co-Authors: **Anna Brutau, Elena Palà**

Collaborating institution: **UMCU**

JANUARY

Realised Kick-off Meeting *Vienna*

Co organised

International Think Tank in Preclinical Drug Discovery *Santiago de Compostela*

FEBRUARY

BioRegion of Catalonia Report 2025 *Barcelona*

ITGP Horizon Europe Training *Online*

MARCH

Mobile World Congress - 4YFN *Barcelona*

RE(ACT) Congress 2025 *Brussels*

FIBROTARGET General Assembly Meeting *Milan* Co organised

APRIL

Face-to-face Steering Committee Meeting for H2O *Barcelona* Co organised

VAC4EU General Assembly *Valencia* Co organised

Conference "Towards an EU Action Plan on Rare Diseases: National Plans and European Cooperation" *Warsaw*

MAY

#iDR25 Conference on Drug Repurposing *Amsterdam* Co-organised by REMEDI4ALL and Beacon for Rare Diseases.

JUNE

Teamit's 5th Anniversary *Barcelona*

ERDERA National Mirror Groups Event *Riga* Co organised

AUGUST

ISPE 2025 *Washington, DC* Poster + stand

SEPTEMBER

Training session for WIDEnzymes *Online* Delivered

XV Jornades de Comunicació i Divulgació Científica at Campus Gutenberg *Barcelona*

General Assembly UMBRELLA *Nuremberg* Co organised

General Assembly REMEDI4ALL *Ljubljana* Co organised

H2O Final Event and General Assembly Meeting *Brussels* Co organised

11th General Assembly PREMIER *Barcelona* Co organised

REPO25 Conference by REPO4EU *Barcelona*

OCTOBER

2025 REMEDI4ALL Hackathon *Montserrat (Barcelona)* Co organised

The World Vaccine Congress Europe with VAC4EU *Amsterdam* Speaker

NOVEMBER

Innovative Health Initiative (IHI) Brokerage Event *Brussels* Speaker

Brokerage 25th Anniversary Meeting of the International Society for Pharmacovigilance (ISOP) *Cairo* Speaker

World Orphan Drug Congress Europe 2025 and ERDERA General Assembly *Amsterdam* Co organised – Booth

PRBB (Barcelona Biomedical Research Park) Meet the Companies 2025 *Barcelona* Booth

VAC4EU – 5th Anniversary Celebration *Brussels* Co organised

DECEMBER

ERDERA JTC Meeting + CRN Conference *Heidelberg* Co organised

Strategic Plan Meeting — *Barcelona*

CLOSING REMARKS

Teamit closes 2025 with a stronger sense of maturity, purpose and direction. Over the year, the organisation has continued to consolidate its expertise, strengthen the way it works and clarify where it can make the greatest contribution within an increasingly complex research landscape. 2026 will mark the start of two new EU-funded initiatives on EHDS implementation and advanced therapies for diabetes Type 1, alongside the roll out of Teamit's second strategic plan.

That landscape is shifting. The gradual closure of COVID-related studies marks the end of an intense research period, while other health challenges continue to demand rigorous, relevant and impactful science. At the same time, evolving European priorities and the growing role of artificial intelligence are opening new questions about how research is designed, delivered and translated into value.

Teamit approaches this context with greater confidence and a clear commitment to quality. Its work remains anchored in robust science and in the ability to support projects that connect ambition with practical, meaningful outcomes.

Internally, this progress is sustained by continuous learning, curiosity and collaboration across teams. By bringing different perspectives into closer exchange, Teamit is strengthening both the scientific content of its work and the way that work is conceived, delivered and shared.

Looking ahead, Teamit is ready to keep adapting with rigour and creativity. The organisation enters the next phase of its journey better equipped to respond to change, support excellent research and help turn knowledge into impact. ●

As competitiveness pressures grow and AI reshapes how we work, clarity, quality and sound judgement matter more than ever



Barcelona Health Hub

Recinte Modernista de Sant Pau
c/Sant Antoni Maria Claret, 167

08025 Barcelona

T +34 930 180 163

www.teamitresearch.com



AUGUST 2026