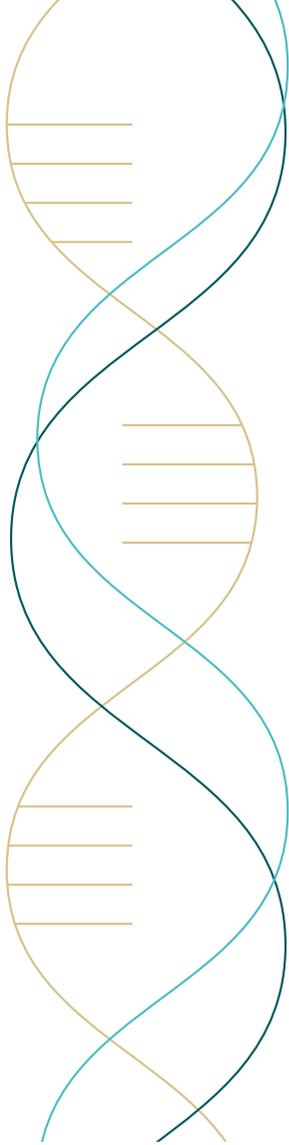


Pioneering Impact. Together.

Impact Report
March 2025

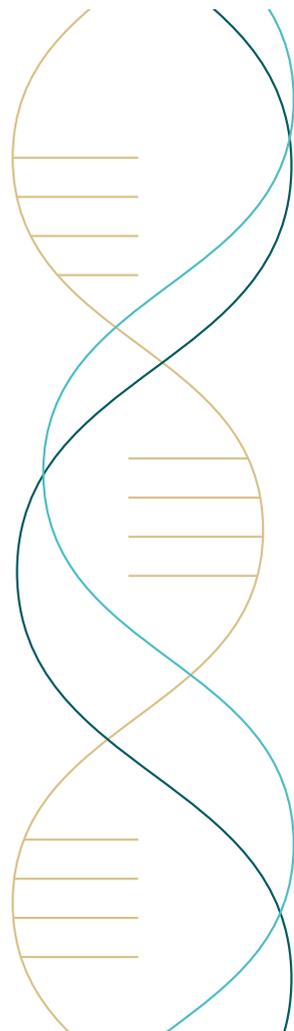


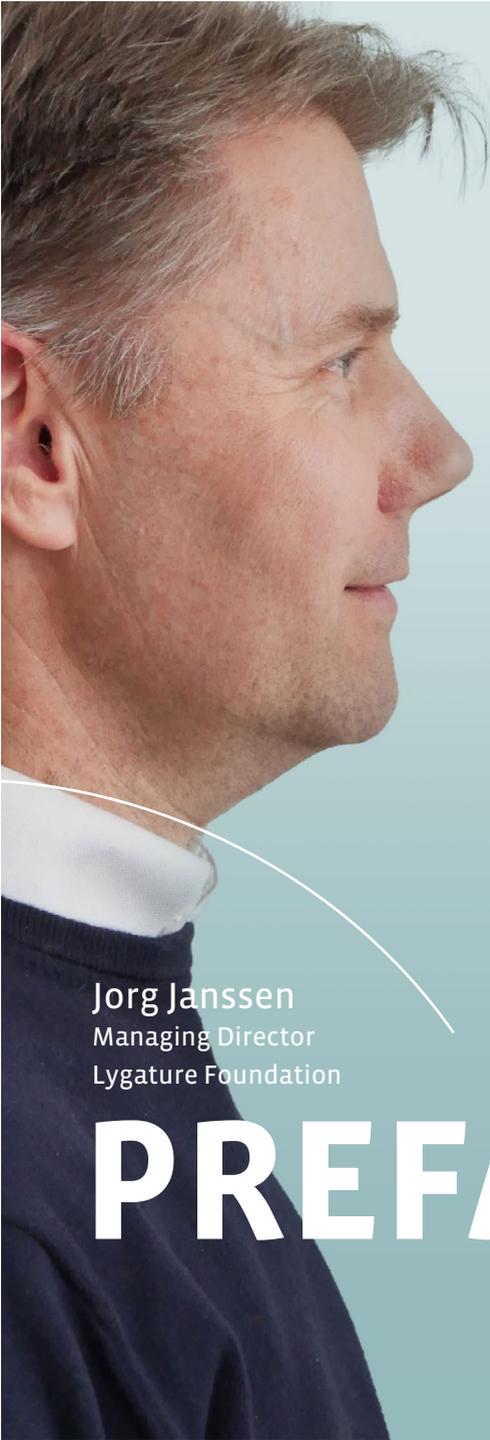


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Jorg Janssen
Managing Director
Lygature Foundation

PREFACE

Dear Reader,

Welcome to the first edition of Lygature’s Impact Report, in which we share the achievements and impacts of our partnerships in addressing health challenges. This report reflects our commitment to pioneering medicine together with our partners around the world and offers a glimpse into future developments.

Before we dive in, we begin with a conversation between Jorg Janssen, Managing Director of Lygature, and Jayasree Iyer, CEO of the Access to Medicine Foundation. Together, they discuss Lygature’s origins, the importance of multi-stakeholder collaborations in healthcare innovation, and their broader societal impact—including how success can be effectively measured.

Jorg: Lygature was founded with a clear purpose: to contribute to finding new therapies for patients by facilitating complex collaborations in healthcare innovation. We believe partnerships are essential for driving innovation and finding new solutions. Over the years, as the number and diversity of stakeholders in healthcare innovation have increased, so too has the complexity of these collaborations, along with the breakthroughs they enable. Twenty years ago, the challenge was to bring industry and academia together; today, we also connect them with societal organizations, regulators, patient advocates, and policymakers. In this environment, the ongoing presence of a neutral and knowledgeable facilitator is crucial to ensuring sustained collaboration and alignment. That’s where Lygature comes in.

Jayasree: That’s an important distinction—being neutral but also having deep expertise. Many organizations offer project management, but Lygature goes beyond

that, continuously steering partnerships and shaping their structure, expected outcomes, and societal impact. Have collaborations in the healthcare space always been this complex, or has the nature of partnerships evolved?

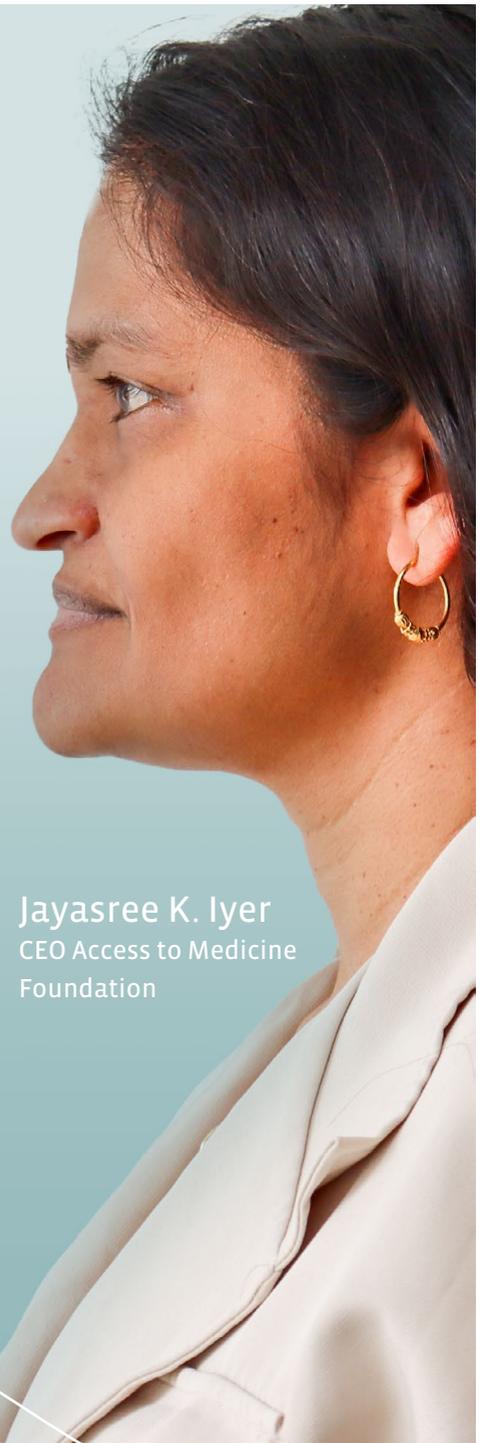
Jorg: Collaboration has always had its challenges, but today's global health landscape requires a new level of coordination. With increasing complexity and urgency in healthcare challenges, multi-stakeholder collaborations are not just beneficial, they are essential. The role of Lygature is to keep partners aligned and focused on the overall goal of the collaboration.

Jayasree: It's no longer just about developing a new drug or technology—it's also about ensuring those innovations reach the people who need them. For nearly 20 years, the Access to Medicine Foundation has worked with the pharmaceutical industry to drive action on global health challenges. This experience reinforces the need for strong

partnerships to achieve health equity. The health system is fragmented, and partnerships help break silos. Of course, complexity is not a goal in itself. Rather, it is an inherent challenge in today's healthcare landscape—one that must be actively managed to drive meaningful impact. At the same time, it can also serve as a catalyst for innovation, leading to solutions that benefit more people.

Jorg: And that's why Lygature operates the way it does. We take no other interest than the success of the partnership itself. We keep everyone focused on the shared goal while building trust and ensuring transparency.

Jayasree: Trust is key. Without a strong facilitator, partners can get caught up in their own institutional goals, priorities, or even competing interests. The risks are higher now—more regulation, more scrutiny, greater expectations for impact, and increasing competition for



Jayasree K. Iyer
CEO Access to Medicine
Foundation

limited healthcare funding. This makes effective partnerships more essential than ever.

Jorg: Right. We're in a time where there's less funding but higher expectations—we have to do more with less. That means partnerships have to be more efficient, more inclusive, and more results driven.

Jayasree: Indeed. Today, a successful partnership isn't just about innovation—it's about responsibility, equity, and sustainability. There's an expectation, justifiably, that partnerships should last or evolve, and reach the communities that need them most.

Jorg: That's where Lygature's expertise in long-term partnerships comes in, and its ability to innovate in how these partnerships are structured. Many of our projects run for 5 to 10 years, even longer, requiring adaptability as funding landscapes and scientific priorities shift.

Jayasree: And that adaptability and eagerness to innovate is critical. Health challenges—and global health in particular—are unpredictable. The organizations that already have strong partnerships in place are the ones that can respond effectively, as we clearly saw, for example, during COVID.

Jorg: That's why this Impact Report highlights examples of partnerships in action—the Regulatory Science Network Netherlands, BIGPICTURE, the European Lead Factory, and the Pediatric Praziquantel Consortium. These projects demonstrate how structured collaboration can drive breakthrough innovations while ensuring their real-world application.

Jayasree: And looking ahead, the most pressing challenge is that the health landscape is evolving, and we can't keep solving problems in a reactionary way. Together, we need to anticipate where healthcare innovation is heading and shape partnerships accordingly.

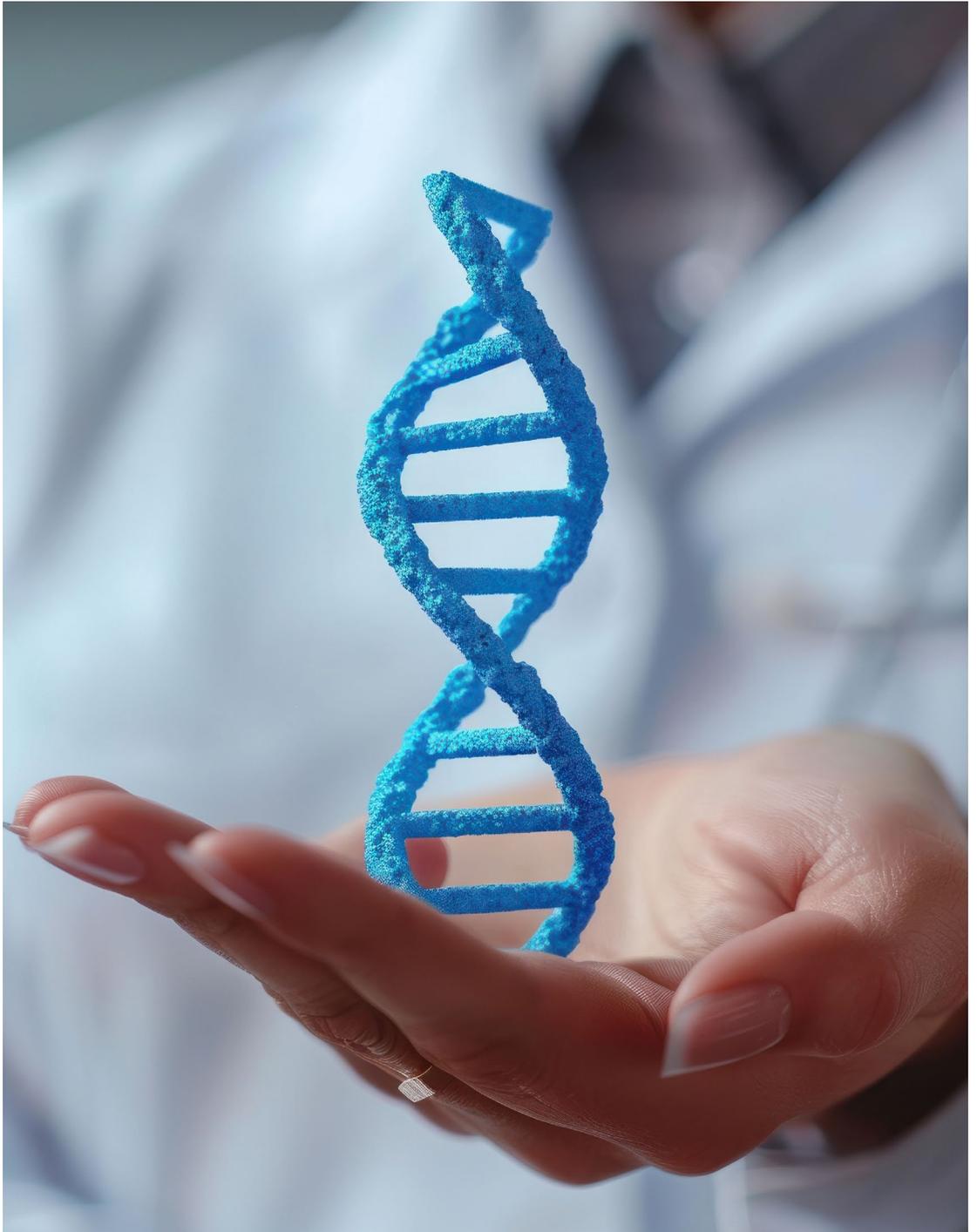
Jorg: That's exactly our vision—not just responding to today's needs but shaping the future of healthcare collaboration. Lygature exists to bring the right people together, challenge the status quo, and ensure that partnerships don't just start—but succeed. That's the challenge for everyone working in this field. Are our partnerships truly maximizing impact, reaching all potential beneficiaries, and standing the test of time?

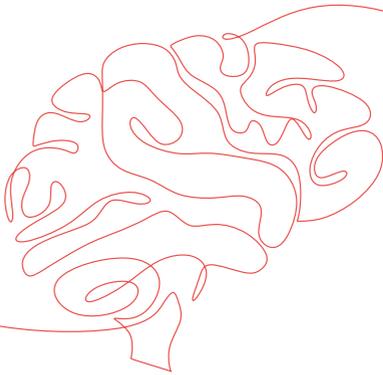
Jayasree: One thing that's critical to partnerships, especially as they become more complex, is measuring their impact. It's not enough to launch initiatives, we need to ensure they deliver meaningful change, because what gets measured is what drives action.

Jorg: At Lygature a successful partnership isn't measured by milestones alone but by how the results translate into better health outcomes. That's why we focus on building collaborations that last. This is what we hope to capture in this Impact Report—not only what has been accomplished, but what is possible. At the end of the day, partnerships should do more than exist—they should make a difference in people's lives.

We hope the stories and data shared in this report offer meaningful insights and highlight the power of partnerships in healthcare innovation. Join us as we continue this journey of Pioneering Medicine. Together.

Enjoy reading!





Introduction

Solving the complex health challenges of the 21st century requires the collaboration of academia, industry, government, and society. At the Lygature Foundation, we unite partners to achieve goals that no single party could accomplish alone. A key focus of our partnerships is improving quality of life, which can only be realized when the voices of individuals with experience in health challenges are meaningfully represented in research and innovation efforts.



Lygature brings a purposeful vision for impact (e.g. driving medicines to the market) and having that as the motivator rather than simply financial gain is great.

Phil Gribbon | Head of Discovery Research | Fraunhofer Institute

The Lygature Foundation believes that a skilled, neutral enabler—a custodian of trust—is essential for the success of large multi-stakeholder research and development partnerships addressing unmet medical needs. Building upon this belief, it is essential to show how such partnerships can solve these challenges by assessing the societal impact or contribution to the ecosystem. That is exactly what this first Impact Report of the Lygature Foundation aims to do.



An important focus of Lygature is creating trust between parties with different interests and ensuring that all interests can be served. Trust is the foundation for collaboration.

Ton Rijnders | former Executive Director Oncode Institute & former Scientific Director Lygature

Rooted in the Netherlands, connected in Europe, realizing global impact

Our work started in the Netherlands in 2006 with pioneering public-private partnership models as part of the national innovation policy. Our legacy organizations—Top Institute Pharma (TI Pharma) and the Center for Translational Molecular Medicine (CTMM)—shared a mission that remains relevant today: creating societal impact by contributing to the development of new therapies through partnerships. Their impact, as outlined in the [New Tracks to Medicines](#) and [Translating Science into Better Healthcare](#) reports, continues today and is reflected in this report.

Facts & Figures



Established:
July 2006



Partners:
250+ across industry,
academia & society



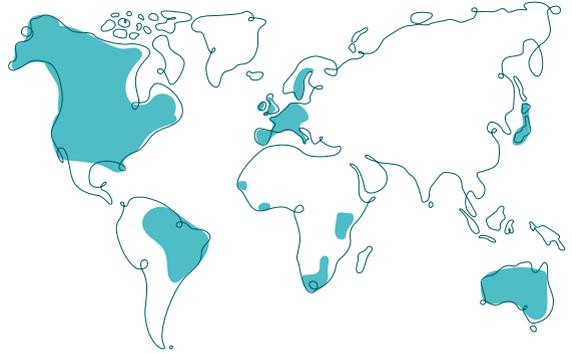
Employees:
43 FTE, 55 persons



Active projects:
33 (as of 2025)

Partners

on four continents



There are very few organizations that know the importance and functioning of public-private collaborations. Lygature is one of these, which means that they can be effective broker. This is the differentiating factor and it's where they should continue developing their expertise by diving deeper into the needs of industry.

Magda Chlebus | Director for Science Policy & Regulatory Affairs | EFPIA

Over the years, Lygature has adapted to a changing landscape, expanding its reach beyond the Netherlands to Europe and key global niches. In addition to working in disease areas such as oncology, neurodegenerative diseases (including Alzheimer's), and global health challenges like antimicrobial resistance (AMR) and parasitic diseases, Lygature has developed specialized

expertise essential for the success of partnerships. This expertise includes an in-depth understanding of data sharing, meaningful involvement of those with lived experience of a disease, regulatory innovation, and navigating the latest developments in health law, privacy & ethics.

In this first Impact Report, we highlight our work in the Netherlands, with an example in regulatory innovation. We also showcase our European collaborations, illustrated with examples in drug discovery and pathology data sharing. Finally, we demonstrate how we realize global impact, such as in the treatment of schistosomiasis.

By leading and supporting these types of partnerships, and mobilizing our network and expertise, we ensure that these initiatives not only achieve their intended outcomes but also drive paradigm shifts in these fields, strengthening the overall healthcare innovation ecosystem.

A tailored framework for measuring impact

Measuring impact is a science in itself. In some cases, assessing impact is straightforward, while in others, it presents significant challenges. For

example, the impacts of a new therapy for a neglected tropical disease are easily explained, but the societal benefits of sharing pathological data are harder to quantify.

In this report, we showcase our impact through our engagement in public-private partnerships in the Life Sciences & Health sector. To assess this impact, we use a three-level model:

1. **Partnership success:** Is it a true collaboration? Do partners move beyond their individual interests?
2. **Tangible results:** What concrete outcomes has the partnership produced?
3. **Broader societal value:** How do these results contribute to society at large?

Ultimately, this societal impact is the reason the Lygature Foundation exists.

These levels shape the impact stories highlighted in this report. The impact framework, focusing on Lygature's role in successful partnerships, is introduced first. The impact stories follow, illustrating how our role contributes to both the tangible results of the partnerships and their broader societal impact.

Empowering partnerships is at the core of everything we do—it's the backbone of our DNA. The three core elements of our DNA form the basis of our tailored framework:

- **Next-level networking:** We connect the right stakeholders across disciplines and sectors, fostering partnerships that accelerate innovation and drive solutions to (global) health challenges.
- **Adding value to research collaborations:** By bringing our expertise and resources in the field of Life Sciences & Health to each project, we enhance its potential, ensuring it delivers a

tangible impact to (global) health solutions.

- **Excelling in the way of working:** We manage partnerships with precision, professionalism, and integrity, ensuring a focus on achieving optimal outcomes through every stage of collaboration.

Together, these three DNA elements drive our approach to partnership success, enabling us to make a lasting impact in the Life Sciences & Health sector.



Methods & framework validation

Schuttelaar & Partners (S&P) developed the DNA framework to assess Lygature's contribution to these partnerships.

1. **Development and validation:** S&P employed an outside-in approach to design and refine the impact framework to assess the role of Lygature within the success of partnerships. To gather diverse insights and external perspectives, S&P conducted 14 in-depth interviews. Eleven of these interviews were with external stakeholders, selected for their involvement in Lygature's projects and their diverse sectoral and geographical backgrounds. The other three interviews were with internal colleagues to integrate organizational insights. This validation step ensured that the framework aligns with both internal and external stakeholders' perceptions of impact. Stakeholders also provided input on future trends, challenges, and opportunities for Lygature's continued growth and societal impact.
2. **Story gathering:** Using the developed impact framework, S&P conducted four additional interviews to collect input for specific impact stories. Each interview showcases the DNA elements in action, complemented by a broader context story outlining Lygature's involvement in a particular topic, its history, and its relationship with other projects. These real-world examples illustrate the societal impact and the depth of Lygature's influence through its DNA.

3. **Quantitative impact data:** Lygature supplemented stakeholder insights and qualitative stories with quantitative data from its initiatives. This data includes measurable outcomes and outputs that showcase the scope and scale of its impact, enriching the external perspectives and storytelling interviews.

Through a combination of stakeholder perspectives, quantitative data, and illustrative stories, this report demonstrates how Lygature's approach not only achieves project-specific objectives but also drives long-term, sustainable change in healthcare innovation.

Next-level networking

Through years of active scouting and collaboration in Life Sciences and Health, Lygature has built a robust network of stakeholders, empowering them to create a greater impact through next-level networking. At Lygature, next-level networking means fostering trust among parties with diverse interests, ensuring balanced and fruitful collaborations.



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The “next level” is that they not only have a wide network and also understand how connections materialize in consortia based on knowledge and expertise. They see the full picture as a spider in the web.

Hubertus Irth | Director | Institute of Biology
Leiden University

Identifying the right expertise for partnerships

Various stakeholders recognize Lygature’s next-level networking capabilities, emphasizing its ability to identify and bridge gaps within consortia and projects by introducing the right collaborators based on the specific expertise needed. They highlight that Lygature has an extensive network and can always connect the right people quickly. Stakeholders also note how Lygature’s employees leverage their background in the life sciences to create meaningful and well-aligned partnerships—setting them apart from other organizations that lack this field-specific knowledge when facilitating collaborations.

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Lygature clearly has a large network which enables them to create productive collaborations. They are able to recognize gaps in the partnership and by using their extensive experience identify groups to fill these gaps.

Phil Jones | Chief Scientific Advisor | BioAscent

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Lygature acts as a catalyst and bridge builder.

Sophie Huiskes-Berends | Partnership Leader |
Lygature

For example, stakeholders point out how Lygature effectively applied insights and expertise gained from its involvement in the UNITE4TB project to support the Pediatric Praziquantel Consortium. By facilitating connections with the appropriate stakeholders across various project phases, Lygature demonstrates its ability to cross-leverage knowledge and networks to enhance outcomes.

Building trust

A robust network is valuable, but meaningful connections require stakeholders to feel comfortable engaging in fruitful discussions. Stakeholders highlight that Lygature provides a powerful and neutral platform that fosters constructive dialogue. By creating such a platform, Lygature allows key stakeholders from academia, industry, regulatory authorities, and societal organizations to engage in critical conversations and build trust by finding common ground among their differing interests.

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Their strength was to activate their network so that they could provide academic contacts. Their organizational role was appreciated.

Stefan Jaroch | Project Coordinator, European
Lead Factory from 2015-2019

Stakeholders believe that as a neutral facilitator, Lygature helps bridge gaps, foster trust, and support the creation of sustainable consortia networks. Trust among key stakeholders is essential for moving projects forward and elevating them to the next level.

Open and inclusive approach

Lygature’s strength in creating a platform for discussion stems from its distinct position outside traditional “old boys’ clubs”—the typical centers of gravity in academia and research groups. According to the stakeholders, Lygature operates beyond these conventional structures, leveraging a more open and inclusive approach to harness knowledge effectively. This unique position allows Lygature to serve as a bridge within networks, a task that is often challenging due to differences in objectives or cultural perspectives among stakeholders and partners. Stakeholders also note that Lygature’s focus on results, collaboration, and transparency—rather than simply on investment returns—further distinguishes it as a trusted and effective partner in advancing shared goals through next-level networking.

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European Lead Factory (ELF¹) is a good example of this, bringing together competitive assets into a public-private project which wasn’t obvious. The continuation of ELF after the IMI-1 funding ended would not have happened without Lygature.

Magda Chlebus | Director for Science Policy & Regulatory Affairs | EFPIA



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Lygature significantly contributes to advancing data sharing by sensitively and methodically initiating and brokering conversations, despite the complex rules and reluctance due to intellectual property concerns.

Derek Sloan | Infectious Disease Clinician and Academic | Unite4TB project

Lygature is very good at connecting their partners and projects together. A good example of this comes from the Tuberculosis program where the partners involved could then be called on to play roles in other neglected-communicable diseases projects.

Jutta Reinhard-Rupp | Former head of the global health institute | Merck

Lygature facilitates complex partnerships worldwide, balancing cultural differences and different interests. The IDERHA partnership is a good example of this, with over 30 partners in Europe and the U.S.

Erwin Boutsma | Senior Communications Manager | Lygature



Adding value to research collaborations

As a trusted and neutral partner, stakeholders highlight Lygature’s reputation as a reliable data broker, strategic advisor, and impact-driven partner. This reputation helps Lygature to add value to research collaborations and guide consortia to maximize societal benefits. Lygature contributes through specialized expertise and a collaborative approach that goes beyond traditional research partnerships, enhancing both project outcomes and societal impact.

Honest data broker

Lygature plays a valuable role as an honest data broker, expertly managing complex collaborations and addressing one of the key challenges in scientific consortia: data sharing. Stakeholders mention how Lygature helps overcome barriers that could impede scientific progress due to limited data sharing, by fostering sensitive, methodical discussions, even in the face of intellectual property concerns and complex



regulations. Lygature’s reputation for maintaining confidentiality and thorough data management helps streamline processes and unlock the full potential of scientific consortia.



Lygature provides critical intelligence that adds value to research. While they may not be traditional researchers, their contributions are crucial in areas such as strategic decision-making and understanding the market landscape.

Hubertus Irth | Director | Institute of Biology
Leiden University

Hands-on strategic advice

Lygature’s strength lies in bridging science and strategy, a key point stakeholders emphasize. While being able to engage in content-level scientific discussions, Lygature’s expertise in

collaboration and insights gained from previous consortia and projects allow it to add significant value. Lygature excels in strategic decision-making, maintaining a careful balance between offering strategic advice and taking an active, hands-on role in projects.

Stakeholders report how Lygature’s expertise extends beyond science, to areas such as legal and policy regulations, continually expanding its knowledge to support efficient and effective collaboration processes. Lygature’s multidisciplinary approach ensures projects benefit from comprehensive guidance and smooth execution. Moreover, Lygature is recognized for its understanding of international dynamics within Europe. Stakeholders point out Lygature’s profound awareness of the political and structural factors at play and its ability to navigate them effectively. This strategic insight positions Lygature as a valuable partner in navigating the scientific and regulatory landscape.



Lygature’s biggest added value comes from being a neutral platform that facilitates partnerships and finding common ground; it helps train collaboration skills, allowing partners to meet. The human factor is crucial for working together effectively and building trust.

Magda Chlebus | Director for Science Policy &
Regulatory Affairs | EFPIA

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Lygature provides professional support within the Regulatory Science Network Netherlands, facilitating a neutral platform where academia, industry, regulators, and patient representatives collaborate on regulatory science.

Marjon Pasmooij | Head of Science | CBG-MEB

Impact beyond scientific research

Stakeholders praise Lygature’s ability to think strategically beyond the immediate goals of a research consortium. This ensures that scientific research extends beyond the lab and into the real world—reaching beyond scientific journals to society. Lygature proactively identifies key stakeholders and engages with relevant parties—such as regulatory bodies—early in the process to ensure research outcomes are actionable and implementable. Its neutral position serves as a valuable asset in monitoring and safeguarding the broader scientific and societal objectives of projects and consortia.

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Lygature organized for the consortium members to go to Kenya and to see firsthand the impact as well as to have better face-to-face interaction with their colleagues which benefitted the project.

Jutta Reinhard-Rupp | Former head of the global health institute | Merck

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The goal should be to combine their contacts with ‘old boys’ networks which typically are involved in multiple EU-type projects (and can be closed to new innovations), with Lygature’s way of working, which is more open and transparent, and results orientated..

Phil Gribbon | Head of Discovery Research | Fraunhofer Institut

According to stakeholders, this strategic approach ensures that the outcomes of scientific research have a meaningful influence on legislation and policies, guiding funding toward tangible societal benefits rather than purely profit gains. By bridging the gap between the lab and the world, Lygature adds significant value to research collaborations, ensuring they lead to meaningful, real-world impact.

Keeping science in Europe

A challenge identified by some stakeholders is the limited influence and lack of sustainable funding to generate innovative ideas in the Netherlands. As a result, many innovations are acquired by companies outside the EU, along with the potential economic and societal returns. By expanding its expertise in funding strategies and regulatory frameworks, Lygature can ensure sustainable support for Life Sciences & Health initiatives, allowing innovations to thrive locally. With healthcare funding facing cuts in favor of other sectors, such as defense, Lygature’s role in securing stable, long-term investment is more important than ever.



Excelling in way of working

Lygature facilitates effective collaboration within consortia by aligning stakeholders around shared goals and helping to translate them into a strategic direction that drives societal impact. Excelling in this way of working means adopting a pragmatic and neutral approach that keeps projects on track, builds trust, and ensures meaningful outcomes.



Lygature's priority is to ensure that the consortium is successful and not influenced by the specific interests of the parties involved. We are guided by the larger goals of our projects, such as improved care and patient prognosis.

Erwin Boutsma | Senior Communications Manager
| Lygature

Pragmatic and neutral party

Lygature stands out as a pragmatic and neutral party in project coordination. Stakeholders highlight its ability to create the structure necessary for effective collaboration across diverse parties. These qualities enable Lygature to align stakeholders toward a common goal and excel in working within consortia. Lygature's calm and systematic approach helps neutralize dominant voices and personal agendas within a consortium. Moreover, according to the stakeholders, this calm and measured approach allows Lygature to read participants' behavior during meetings and provide valuable debriefs afterward. This insight helps define the necessary next steps and make scientific ideas pragmatic.

“

Lygature plays a crucial role in keeping the consortium aligned with the original goals, preventing partners from steering the project in different directions based on their personal objectives. Their calm, systematic, and level-headed approach helps to harmonize diverse perspectives and ideas within the consortium, ensuring that the project remains on track.

Derek Sloan | Infectious Disease Clinician and Academic | Unite4TB project

Actively coordinating toward broader societal objectives

Stakeholders have observed that Lygature actively coordinates partnership efforts to ensure successful project outcomes as well as broader societal objectives—a focus that distinguishes Lygature from other players in the field, who place less emphasis on the broader societal objectives. By fostering innovative funding approaches and optimizing industry relationships, Lygature reduces inefficiencies, builds trust, and maintains neutrality. This neutral position allows Lygature to facilitate partnerships, even in previously challenging negotiations where consensus seemed impossible. As a neutral party, Lygature not only monitors but also guides consortia and projects toward broader societal objectives, ensuring all partners remain aligned.

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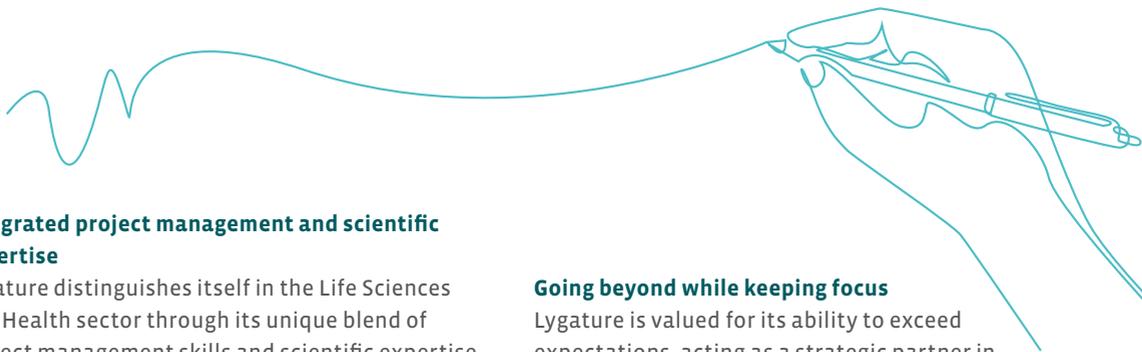
Their way of working was very pragmatic, and it was uncomplicated to work with Lygature. They are open, approachable and open to criticism.

Stefan Jaroch | Project Coordinator, European Lead Factory from 2015-2019

Relieving stakeholders

Effortless collaboration requires hard work. According to stakeholders, Lygature excels at providing the structure that makes working together seamless. One stakeholder highlighted Lygature’s ability to simplify complex interactions through strategic insights, offering the clear structure needed for success. This structured approach extends to consortium meeting management, ensuring that meetings run smoothly and efficiently. Lygature sets clear terms and boundary conditions while creating an efficient (infra)structure for productive collaboration among stakeholders. By handling logistical and administrative tasks, Lygature allows stakeholders to focus on their core work and deliver quality results, reducing the burden of time-consuming tasks.

Additionally, stakeholders emphasize Lygature’s role in ensuring that consortia activities comply with legal and contractual obligations. Lygature evaluates the feasibility of new ideas within the funding structure and prevents shortcuts, which is especially valuable in the complex landscape of European funding. This diligence ensures project advancements are legitimate and that all actions are within regulatory boundaries.



Integrated project management and scientific expertise

Lygature distinguishes itself in the Life Sciences and Health sector through its unique blend of project management skills and scientific expertise. This combination not only sets Lygature apart but also enhances its ability to select topics that align with current challenges, improving the quality and relevance of discussions. Stakeholders appreciate Lygature's clear communication and its ability to frame discussions around practical solutions. This strength enables Lygature to organize relevant stakeholder meetings and actively contribute to industry advancements. Moreover, Lygature's extensive experience in managing large collaborative projects within the Life Sciences and Health sector is recognized as particularly exceptional. Lygature's specialized knowledge and expertise in partnership management are highly valued. This rare blend of project management and subject-matter expertise strengthens collaboration. Additionally, Lygature's integration of deep content insights into its services further distinguishes it, particularly through its understanding of international dynamics and developments across Europe.



Lygature elevates the organization of consortium meetings, ensuring they run smoothly and efficiently, a task that researchers could handle but Lygature does better and faster.

Derek Sloan | Infectious Disease Clinician and Academic | Unite4TB project

Going beyond while keeping focus

Lygature is valued for its ability to exceed expectations, acting as a strategic partner in navigating challenges, aligning diverse objectives, and fostering effective collaboration. Its understanding of the Life Sciences & Health sector adds unique value, helping consortia achieve their goals. A key strength lies in its role as a neutral platform broker, expertly bridging public and private partners to ensure success. In doing so, it is equally important for Lygature to maintain clarity in its role within each partnership, ensuring that its multifaceted approach aligns with the specific needs of partners. Clearly defining Lygature's role helps partners understand what to expect and which services they can rely on, making it easier for them to know when to seek support. By balancing its broader strategic contributions with a strong focus on the core needs of each partnership, Lygature can further strengthen its position as a trusted and effective facilitator in consortia.



For a pharmaceutical company, compliance is essential. Partnering with Lygature was highly effective because they not only share our values but also understand the industry's compliance standards, ensuring a smooth and productive collaboration.

Beat Flühmann | Global Medical Head Iron Portfolio | CSL Vifor Pharma

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Lygature does project management and operations, but goes a step further, they really are also a partner in discussing strategy, important during difficult times between partners and agreements on decisions to make given all the different objectives. Their knowledge of the medical and scientific field is an additional asset of Lygature, because they understand why partners are joining a consortium.

Jutta Reinhard-Rupp | Former head of the global health institute | Merck

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Lygature has to avoid falling into the trap of focusing only on data related projects as ultimately experimental, clinical and practical based projects are always needed and will continue to be the bedrock of scientific advancement and innovation.

Phil Gribbon | Head of Discovery Research | Fraunhofer Institute

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Future trends include the need to stay ahead in emerging therapeutic areas like personalized and advanced therapies, which may require different approaches and consortium structures.

Hubertus Irth | Director | Institute of Biology Leiden University

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Public Involvement avoided some difficulties in the later stages of the study when the technologies were actually used by the research participants, because the insight and lived experience of people with dementia and MCI had already been considered during the study design phase.

Dianne Gove | Director for Public Involvement and Ethics at Alzheimer Europe | RADAR-AD



Our DNA in action

Impact stories from our partners

S&P interviewed four external partners to capture their perspectives on the partnership experience, Lygature's role, and how the collaboration led to tangible results and societal impact. These stories showcase Lygature's DNA in action, demonstrating its commitment to fostering successful partnerships that drive meaningful change.

Lygature has been a driving force and a pioneer in the regulatory science field in the Netherlands and internationally for over 15 years. This started in the early 2000s when it was a strong ambition of TI Pharma (now Lygature) to form a think tank on ‘regulatory reform’ to push forward a more efficient and effective regulatory system.

To that end, the TI Pharma Escher Project was started in 2007, bringing together key regulatory stakeholders—including regulatory bodies, HTA agencies, academia, and industry—in a neutral platform to identify, evaluate, and remove regulatory barriers in medicine development. The project delivered many new insights and provocative thoughts on how to regulate medicines in the future. Importantly, the multistakeholder collaboration was widely seen as successful for all parties involved.

The Escher project was a blueprint for the current Regulatory Science Network Netherlands (RSNN), launched by the Dutch Medicines Evaluation Board (CBG) and the Association of Innovative Medicines (VIG) in 2017. The Lygature coordinated RSNN is an extensive network of experts and stakeholders from industry, academia, patient representatives, public health bodies, and the broader regulatory science field. Its mission is to advance an efficient and effective regulatory system that supports medicines development, marketing authorization, access, and appropriate use of medicines.

Next to the TI Pharma Escher Project and RSNN, Lygature has also been driving multiple international partnerships in the regulatory field, such as the **NBCD working** group and **ADAPT SMART**.

An effective and efficient regulatory system serves everybody’s interests. It speeds up innovation, improves resource allocation, and helps to make new treatments available and affordable. To establish and maintain such a system, new and

existing regulatory science questions must be addressed timely and properly, and the RSNN has an important role in this.

As phrased in a **recent review article**: “the basic philosophy of the RSNN has always been that partnership, open dialogue, and transparency are critical ingredients of unbiased public innovation, that is, of regulatory systems designed to serve the patient and the public at large. (...) In this context, trust building and investing in shared understanding between stakeholders including also patients, physicians and policymakers, of the complex (regulatory) environment of innovation remain pivotal.”

The RSNN adds value to the regulatory field through its multistakeholder model including its open, neutral way of working. This model was pioneered by the TI Pharma Escher project.

From the same article: “in hindsight, the TI Pharma Escher project has paved in a transdisciplinary research setting the route to a modernized regulatory landscape in the Netherlands and abroad. It shaped a model for multistakeholder and multi-perspective prioritizing in regulatory sciences.”

Lygature believes that partnerships are key to solving modern health challenges. The regulatory examples of the RSNN and Escher projects strengthen this belief. In the future, we expect to see the multistakeholder model being used increasingly in the regulatory field. New RSNN-supported partnerships that are already being developed are: a **Dutch national network focusing on ATMPs** (Advanced Therapeutic Medicinal Products), an initiative initiated by the RSNN special interest group Advanced Therapies and the **Centre for Future Affordable Sustainable Therapy Development (FAST)**, and the **European Platform for Regulatory Science Research**, which the European Medicines Agency and the Heads of Medicines Agency intend to launch in 2025.



A driving force behind regulatory science in the Netherlands

Peter Mol

Peter Mol is the current Dutch Medicines Evaluation Board (CBG) member of the Committee for Medicinal Products for Human use (CHMP), and was previously a member and vice chair of the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA), and is professor of regulatory science at the University Medical Center Groningen (UMCG). He has been involved in the Regulatory Science Network Netherlands (RSNN) since its founding in 2015. As RSNN celebrates its 10th anniversary in 2025, the network continues to focus on fostering collaboration and open dialogue among multiple stakeholders, including academia, industry, patients, and regulatory bodies. The network aims to advance research into the regulatory system for medicines, and to set the agenda for future research by pooling the expertise of all stakeholders. Peter was interviewed about the societal impact of RSNN and the value Lygature adds to RSNN as coordinator.

“My collaboration with Lygature within the RSNN has really shown me how important their role is as an organizational but also a strategic partner. Lygature is like the motor oil that keeps the engine of the network running, they make sure that everything runs smoothly. Their support goes beyond just the logistics – they help shape project ideas, fine-tune plans, and bring the right people together.

What makes Lygature stand out to me is their ability to bring together people from different sectors, whether that’s academia, industry,

or regulatory bodies. But they also bring in stakeholders like patients, HollandBIO, ‘Zorginstituut Nederland’ (ZIN) and the ‘Centrale Commissie Mensgebonden Onderzoek’ (CCMO), to name just a few. It is important to keep talking with each other. Within the RSNN, they facilitate a formal structure for meaningful dialogue where regulation, science and societal values come together. This **way of working** has been key to addressing complex topics that matter not only here in the Netherlands, but also internationally. Topics like new pharmaceutical legislation, reducing animal testing, unmet medical needs, and biomarker-driven development have been central to these discussions. One big theme we’ve been working on together is the conditional approval of medicines, where Lygature, has in addition to the RSNN partners, has played a role in showing different angles of that issue.

What I also really appreciate are the RSNN annual workshops and expert meetings that Lygature organizes in collaboration with the scientific committee of RSNN partners. These events offer a great opportunity to discuss complex topics, such as the future of drug development and international regulations, with a wide range of stakeholders. Lygature’s **added value** lies in their deep understanding of the field which ensures that they not only are responsible for organizing the meeting, but are also actively participating in selecting the right topics for discussion. One of the highlights for me was the workshop on patient preferences. It focused on the patient’s perspective and provided valuable insights into how medicines can truly make a difference in patients’ lives.



Over the years, RSNN has built a **large and relevant network in the regulatory science** in the Netherlands, with many partners and organizations involved. The network is a good example of how to gather various stakeholders around the table. With RSNN, I hope to continue building on this foundation for regulatory science in the Netherlands and ultimately benefit patients with our work.”

Lygature is like the motor oil that keeps the engine running.



- way of working

- added value

- a large and relevant network in regulatory science

GO TO WEBSITE

Facts & Figures

- Connecting >100 key stakeholder organizations in the regulatory field
- Organized or contributed to >50 regulatory sessions
 - 14 expert meetings organized
 - bringing together >200 regulatory experts from industry, academia, regulators and other stakeholder organizations
 - 9 annual workshops organized
 - Connecting >750 stakeholders in total
- Authored or contributed to >20 reports and publications



IMPACT STORY 02

Bigpicture

What is this project about?

For over a decade, the Lygature Foundation has collaborated with national and international partners to enhance biomedical research infrastructure in the Netherlands and beyond. A pivotal project in this journey was TraIT (Translational Research IT), developed to facilitate large-scale data sharing between research organizations. Within this initiative, tEPIS (TraIT Enhanced Pathology Imaging Sharing), was launched in 2012 to integrate pathology imaging data into broader research workflows, supporting collaboration across institutions.

Lygature's involvement in Bigpicture is a natural extension of our mission to advance healthcare innovation through collaboration. By facilitating this initiative, Lygature is contributing to the safe, responsible, and impactful exchange of pathology data across Europe.

With the rise of artificial intelligence (AI) in imaging research, validating and scaling AI-driven innovations for clinical use has become a significant challenge. AI models require vast, diverse, and high-quality datasets from multiple institutions to ensure accuracy and reliability. Bigpicture was established to address this need, creating a pan-European, multi-stakeholder platform for digital pathology data sharing, AI validation, and regulatory alignment.

Bigpicture is one of Europe's largest data-sharing initiatives, uniting research infrastructures, digital pathology & AI experts, industry leaders, and healthcare institutions to accelerate AI-driven innovation in diagnostics, research, and personalized medicine.

The project stands out because it tackles two major challenges: (1) the lack of standardized, large-scale pathology datasets, and (2) the need for the validation and clinical implementation of AI models. Furthermore, the initiative aims to set a

new standard in pathology data-sharing, aligning with European Health Data Space requirements. By defining clear guidelines for data use, privacy, and governance, Bigpicture paves the way for a scalable and sustainable AI-driven healthcare ecosystem.

A significant milestone was reached in 2024, when 44 partners signed a pioneering data-sharing agreement. This agreement provides a comprehensive legal and ethical framework for pathology data exchange, ensuring that data-sharing within Bigpicture is conducted safely and transparently. Establishing trust is critical— institutions will only share sensitive data if transparent guidelines are in place.

Bigpicture has the potential to revolutionize digital pathology and AI-driven diagnostics, addressing some of the most pressing challenges in modern healthcare. One of the major health concerns, particularly in Western Europe, is the growing incidence of cancer, driven by an aging population. Pathology plays a crucial role in oncology diagnostics, yet healthcare systems face a looming shortage of pathologists to meet the rising demand. AI integration in pathology is essential to addressing this challenge. Beyond cancer diagnostics, the project's impact extends to other complex diseases requiring high-precision diagnostics.





Digital Pathology Platform for development and validation of Artificial Intelligence

Katrien Grünberg

Katrien Grünberg is a pathologist and department head at Radboudumc. With a passion for translating scientific insights into practical applications, Katrien focuses on creating a broad impact inside and outside Radboudumc. Her work includes research lines in renal research, gastrointestinal pathology, and other areas, with an emphasis on the essential role of data infrastructures. The Bigpicture project is developing a European platform to enhance pathology with AI, focusing on secure, ethical data use and collaboration across various healthcare stakeholders. Katrien participated in an interview regarding the societal value of Bigpicture and Lygature's role in it.

“When we started the Bigpicture project, my network recommended Lygature as a potential partner. I was initially skeptical, but it didn't take long during our first meeting to see their value. They quickly proved themselves as a strategic partner for **building strong, value-added relationships** within our project.

Their ability to align everyone's interests has been priceless. They tailored their advice to the specific needs of both healthcare and scientific communities, and their expertise in crafting data sharing agreements has helped us lay down strong foundations for our **collaboration**.

Even during challenging times, such as the bankruptcy of a participating entity, Lygature’s proactive and robust response ensured the continuation of essential expertise and support.

In managing the project, Lygature excelled in structuring the project involving 44 partners. They clarified roles and timelines using structured tools like spreadsheets and checklists. Lygature’s **way of working** emphasizes teamwork, in which they have a good sense when it comes to human relationships and roles. That is exactly what has made the project run smoother and contributes to the good and accepted outcome. But their support went beyond administrative tasks; they played a significant content-wise role in navigating the interpretations and national differences within the General Data Protection Regulation (GDPR). Also, Lygature actively participated in discussions around the European Health Data Space (EHDS) and shared insights from other projects to refine our data-sharing strategies. I would therefore describe them as a “jack-of-all-trades”.

The robust European data infrastructure we’re working toward is vital. This project has shown that effective collaboration and scalability are important for scientific progress. By working with partners both within and beyond Europe, we aim to not only optimize current healthcare processes but also to be adaptable enough to incorporate more disruptive innovations.

Looking forward, I see a role for Lygature in fostering **knowledge exchange** and innovation in healthcare. Their ability to delve deeply into the material and act as a **facilitator** in complex projects helps to bridge the gap between theory and practice. I anticipate them expanding their role further, not only by providing advice through methods like PowerPoint presentations, as they did with European Health Data Space, but also by organizing symposia. These events could be

important for stimulating knowledge transfer and enhancing visibility within and beyond the academic community.”



- building strong value added relationships
- collaboration
- way of working
- knowledge exchange
- facilitator

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Facts & Figures

- Number of partners: 44
- Pharmaceutical companies involved: 10
- Number of parties to contributing data: 20
- Countries involved: 15
- Total budget: 32M Public + 37M Private
- Total data to be shared: 4,5Pb
- Total amount of Whole Slide Images to be shared: 3 million
- Open-source software packages released so far: 8
- Average participants in annual meetings: 120



IMPACT STORY 03

European Lead Factory

What is this project about?

From its inception, Lygature and its predecessors—TI Pharma and CTMM—have pushed for innovation in drug discovery and development. Over the past decades, early drug discovery has evolved from being predominantly led by large pharmaceutical companies to a more collaborative model involving academia and small biotech companies. This shift reflects Lygature’s collaborative approach, encapsulated in its motto, “Pioneering. Medicine. Together.”

Recognizing the need for an open innovation platform, seven large pharmaceutical companies came together in 2013 to explore the pre-competitive sharing of their compound collections with each other and the European scientific community. This collaboration led to the creation of the **European Lead Factory (ELF)**—a unique public-private partnership designed to accelerate early drug discovery by giving researchers access to a world-class compound screening platform.

Lygature played a central role in establishing and managing this ambitious initiative, ensuring the successful integration of contract research organizations, academic institutions, and industry partners into a coordinated, large-scale drug discovery effort.

The ELF was the first initiative of its kind in Europe. It gave scientists access to an industry-standard screening platform that allowed them to screen their drug targets and phenotypes of interest against one large compound library composed of novel high-quality compounds with drug-like properties.

What set the ELF apart was its ability to:

1. Bridge academia and industry – It opened the door for researchers to access a high-quality, pharma-standard screening infrastructure that was previously out of reach.
2. Foster pre-competitive collaboration –

By enabling pharmaceutical companies to contribute compounds to a Joint European Compound Library, the ELF promoted knowledge-sharing while maintaining confidentiality.

3. Expand the chemical diversity of screening libraries – Over time, industry-supplied compounds were supplemented by newly designed and synthesized compounds, ensuring a broad range of drug-like candidates.

Funded by the Innovative Medicines Initiative (IMI, now the Innovative Health Initiative), the ELF became a flagship program in early-stage drug discovery, demonstrating that collaborative models can drive innovation beyond the capabilities of any single organization.

Over its 11-year duration (2013-2023), through the support of two consecutive grants from the IMI, the ELF established the largest publicly co-funded drug discovery platform in Europe.

Its results have shown that the initiative greatly contributed to the advancement of new therapeutic discoveries and overall education about early drug discovery, benefitting academia, industry, and society as a whole, creating long-lasting, real-world impact for many different disease areas, including those of high unmet medical need.

By democratizing access to drug discovery resources, the ELF helped to accelerate the long, complex, and expensive process of drug discovery that is so critical to developing innovative medicines for health challenges worldwide.

The ELF showcased the power of collaboration in drug discovery. By combining industry expertise, academic innovation, and cutting-edge screening technology, the project paved the way for more accessible, efficient, and impactful early-stage drug development. The lessons learned from the ELF will no doubt help to shape future such public-private partnerships.



Driving innovation and collaboration in European drug discovery

Jeremy Davis

Jeremy Davis is Head of Small Molecule Hit Discovery at UCB, a global biopharmaceutical company with strategic research hubs in the US, UK, and Belgium. Jeremy played a key role throughout the 10-year European Lead Factory (ELF) partnership. The ELF partnership created a European library of high-quality chemical compounds, giving smaller research institutions better access to screening. These screens might eventually pave the way for the development of innovative treatment options for patients. Jeremy talked about the societal impact of ELF and the role of Lygature in this partnership.

“It was clear to me that from the start to the end of the ELF-project, Lygature played a crucial role in creating a constructive environment. One of the biggest challenges we faced during this project was creating a framework, in which highly sensitive data could be shared. In this process, Lygature had a central, trusted and **neutral role** in overseeing the data, demonstrating the consortium’s confidence in its ability to manage sensitive information.

The mixture of Lygature’s academic and industry expertise was essential in facilitating a smooth **collaboration** among 30 participants. In this, Lygature’s impartial leadership was important in resolving issues and driving discussions between the different stakeholders, to eventually come to satisfactory conclusions. As a neutral, third party, they were able to balance contributions

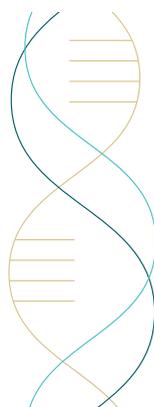


and benefits among the participants. As well as facilitating a smooth collaboration, Lygature used their extensive **network** to expand this project beyond the Benelux area at the time, increasing the impact of the project. Lygature's wide network facilitated connections with diverse organizations, fostering exchange of ideas.

Lygature's strong connections with funding bodies helped support the program's sustainability. They played a crucial role in extending the ELF project for another 5 years, **adding value** to the project. With these extra years, the library and screening facilities were made more accessible to the European research community. And in addition to this, we were able to expand access to a part of the library for phenotypic screening.

To conclude, Lygature was the engine at the heart of the ELF consortium. They provided drive and encouraged positive collaboration for more than a decade. They were never a passive partner. In fact, from the get-go, they were totally engaged to make the European Lead Factory a success."

Lygature was the engine at the heart of the ELF consortium.



- neutral role
- collaboration
- network
- adding value

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Facts & Figures

- Total budget: €234 Million
- Number of partners: 33
- Size of the ELF compound collection: 535,000 compounds
- >300 drug discovery programs pursued
- Geographical spread of the initiative:
 - Consortium partners were spread over 9 countries
 - Public screening proposals received from 20 countries



IMPACT STORY 04

Pediatric Praziquantel Consortium

What is this consortium about?

Photo credit @Merck

Lygature’s commitment to global health dates back to the early stages of our organization. One of our legacy organizations, TI Pharma, was established to address the needs outlined in the World Health Organization (WHO) report *Priority Medicines for Europe and the World*. TI Pharma organized a workshop in Leiden in January 2007, gathering together nearly all product development partnerships to discuss “the new landscape of neglected disease drug development”, an important part of this WHO report. Since then, infectious and neglected diseases, and related global health topics, have had a prominent place in Lygature’s portfolio of activities.

In addition to our focus on diseases of neglect like schistosomiasis (Pediatric Praziquantel Consortium), Lygature has been or is involved in several partnerships tackling other pressing global health challenges, such as Malaria (MMV-PDP), Tuberculosis (UNITE4TB) and Antimicrobial Resistance (GNA-NOW). We’ve furthermore contributed to stimulating drug discovery efforts in these areas through our coordination of the European Lead Factory. Projects like these demonstrate Lygature’s role in bridging expertise across academia, industry and society to develop sustainable solutions for unmet medical needs.

In the realm of global health, where commercial incentives are limited, partnerships are essential to drive innovation. Collaborations like the Pediatric Praziquantel Consortium exemplify how we are able to bring together the expertise needed to share costs and risks. This pioneering partnership model has mobilized leading research groups from Europe, Brazil and sub-Saharan Africa, pharmaceutical companies, national control programs, and global funders such as the Gates Foundation, the Japanese Global Health Innovative Technology Fund (GHIT), and the European & Developing Countries Clinical Trial Partnership (EDCTP).

The Consortium’s stands out for its ambitious goal of addressing the lack of treatment options for preschool-aged children with schistosomiasis, a population previously left untreated in global health strategies. By focusing on developing a pediatric treatment, the Consortium has created a pathway that is expected to contribute to the elimination of this neglected tropical disease. Moreover, the Consortium’s work includes designing an effective access strategy tailored to preschoolers, accompanied by policy and guideline updates at the national level. This innovative approach ensures sustainable benefits for affected populations, first in Kenya, Cote d’Ivoire, and Uganda, with plans to scale these solutions across other schistosomiasis-endemic countries in sub-Saharan Africa.

Addressing unmet medical needs—such as the absence of an appropriate treatment for preschoolers with schistosomiasis—requires a level of collaboration that no single organization can achieve alone.

The success of this project underscores the importance of multi-actor partnerships. By pooling resources, knowledge, and expertise, the Consortium has been able to mitigate the risks and challenges associated with neglected disease drug development, paving the way for future collaborative efforts in global health.

The impact of the Pediatric Praziquantel Consortium extends beyond the development of a pediatric treatment for schistosomiasis. The clinical trial sites in Kenya and Cote d’Ivoire successfully passed Good Clinical Practice inspections as part of the European Medicines Agency (EMA) product assessment, demonstrating a direct contribution to strengthening clinical trial capacities in sub-Saharan Africa. This capacity-building effort has long-term implications for the region’s ability to address other public health challenges.

The Consortium's **ADOPT Program** aims to expand access to schistosomiasis control in children, contributing directly to the United Nations Sustainable Development Goals (SDGs), specifically SDG 3: 'Ensure healthy lives and promote well-being for all at all ages'. The program's work will inform policies and strategies for integrating the new treatment into routine national schistosomiasis control programs. These efforts are critical for securing funding and ensuring sustainable procurement, logistics, and distribution of the treatment—ultimately improving health outcomes for millions of preschool-aged children across endemic regions.

In early March 2025, the Consortium reached a **major milestone** when the first children were successfully treated with its newly developed pediatric treatment, marking a significant step toward closing the treatment gap for schistosomiasis.

In summary, the Pediatric Praziquantel Consortium's work highlights the transformative power of multi-actor partnerships in addressing global health challenges. By fostering collaboration and driving innovation, this project provides an immediate solution to a pressing health issue while setting a precedent for future collaborations aimed at eliminating diseases of neglect.

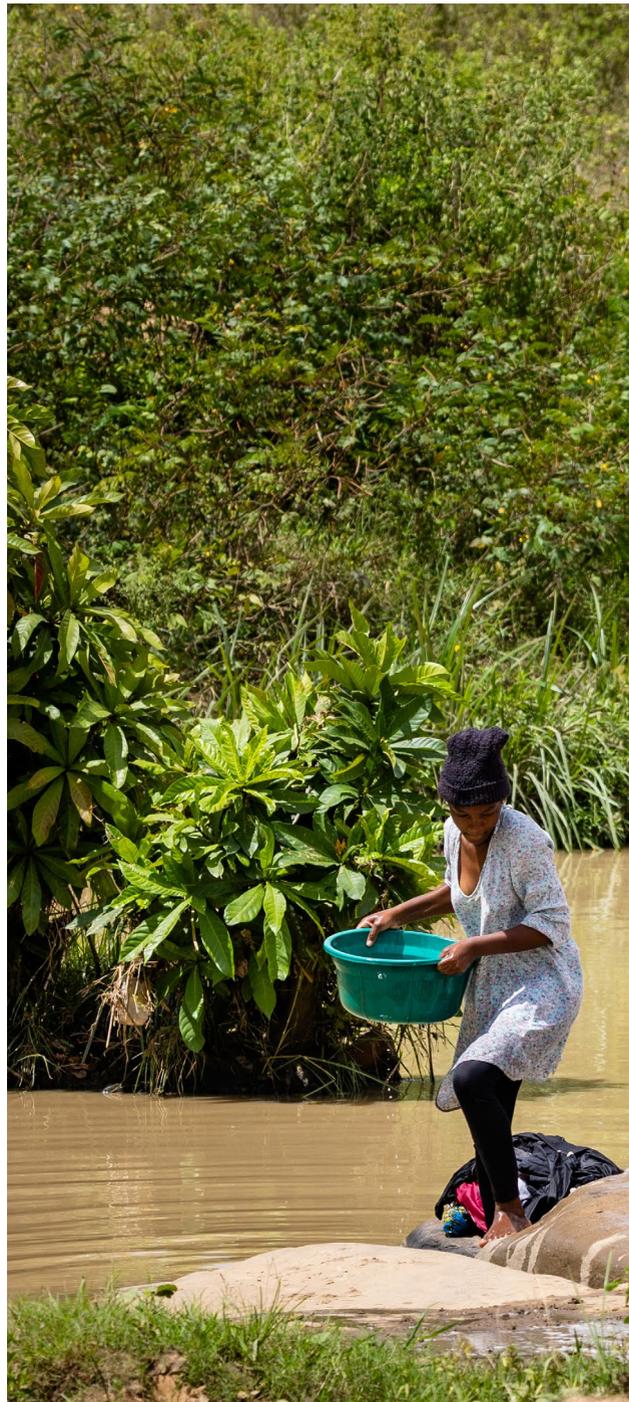




Photo credit @Merck



Shifting paradigms to close global health gaps

Peter Steinmann

Peter Steinmann is an epidemiologist and consultant specializing in neglected tropical diseases (NTDs), and the Head of the Diseases and Programs Unit at Swiss Tropical and Public Health Institute. He is dedicated to enhancing intervention effectiveness, a commitment that led to his involvement as Program co-lead in the Pediatric Praziquantel Consortium. The Consortium is an ambitious initiative set out to address a pressing need in global health: the lack of accessible treatment options for preschoolers suffering from schistosomiasis. Despite the longstanding requirement for a solution for this treatment gap, no single organization could develop an accessible and effective treatment alone. To answer to this global health priority, the Pediatric Praziquantel Consortium was formed—using strong collaborative power to reach this underserved population. Peter talked about the Consortium’s societal impact and the added value of the Lygature Foundation as the independent coordinator of the Consortium.

“One of the remarkable parts contributing to the Consortium’s efficiency was its **flexible way of working**. A lot of consortia struggle with phasing out partners when they’re no longer needed. But with Lygature clearly defining the role before a partner joined, the Consortium managed to get past that issue and partners were added or phased out based on specific needs of the project. Through effective transition management Lygature ensured continuity within the Consortium and made sure the project remained on course with the

Consortium's goals. The flexible way of working allowed us to always include the most suitable partners at each phase of the project.

In addition to defining roles, Lygature's structured and neutral management enhanced the project's credibility and acceptance among country partners and donors. Lygature's **neutral** position prevented competition and role confusion, promoting trust and effective collaboration among partners. By presenting the project as a strong collaboration toward a shared goal rather than a single partner's initiative, it strengthened the Consortium's legitimacy.

Perhaps the most groundbreaking and unique part of the Consortium is that it spans the entire value chain, from developing the treatment to patient access. Lygature's experience in similar projects was invaluable for the implementation of an access program in the first three sub-Saharan African countries (Kenya, Côte d'Ivoire, and Uganda). It seamlessly integrated the right partners into the Consortium and gave practical input on how to set up the access program. Under its guidance, the Consortium is also developing a sustainable drug production model, independent from donation-based funding. The model aims to maintain production of the drug through qualified manufacturers in Brazil and Kenya.

The Pediatric Praziquantel Consortium shows how R&D **collaborations** can bridge a global health gap with an innovative access program, but it also shows how collaborations can shift paradigms in healthcare. It was always known that if an at-risk group is excluded from treatment, disease transmission goes on. By creating a treatment specifically for an at-risk group, in this case preschoolers, the Consortium not only fills a critical treatment gap but is also in a position to show how inclusive and accessible healthcare can contribute to the overall goal: disruption of disease

transmission. This could shift the focus from merely controlling morbidity due to the parasite to actively interrupting its spread. The Consortium sets a new standard for global health, paving the way for solutions aimed at eradicating diseases rather than simply managing them.”

Lygature strengthened the Consortium's legitimacy.



- flexible way of working
- neutral
- collaborations

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Facts & Figures

- Founded in 2012 as the first international, non-profit, public-private partnership in schistosomiasis
- Number of partners & collaborators: 14
- Current regulatory status: EMA positive opinion & WHO-prequalified
- Aimed annual capacity: 60 million tablets
- Product to be made available in Sub-Saharan Africa on a at-cost basis
- Current status: pilot treatment studies in Uganda, Côte d'Ivoire, and Kenya

Future outlook

This first Impact Report for the Lygature Foundation marks an important step in our commitment to facilitating complex collaborations in healthcare innovation. Through the lens of our three-level impact model, we have highlighted how Lygature influences partnerships, the results that our collaborations deliver, and how these contribute to positive societal change. The case studies in this report are just a starting point. As we continue our mission to shape healthcare innovation through collaborations, we will provide ongoing insights into the impact of our work.

Rooted in the Netherlands, one way we bring our impact to life is through our involvement in various national initiatives. While this report includes insights into our role in the regulatory science field, our impact extends across multiple initiatives. These include, for example, our contributions to integrating various data infrastructure programs in Health-RI, our partner role in the establishment of Oncode Institute and Oncode Accelerator, and our efforts to connect stakeholders in Health Innovation Netherlands (HI-NL).

Building on this national foundation, Lygature is also **widely connected across Europe**, where we play a significant role in projects funded by the Innovative Health Initiative (IHI). In addition to the ELF and Bigpicture, we have served as a partner or coordinator in more than 10% of the current 212 IHI projects, helping to mobilize €181 million in funding for the Netherlands. Beyond our involvement in 22 IHI projects, we have contributed to European projects that have shaped the data infrastructure landscape, advanced global health objectives and progressed developments for neurodegenerative diseases.

Furthermore, beyond the Netherlands and Europe, our work is **realizing global impact**. The Pediatric Praziquantel Consortium, highlighted in this report, is a clear case, but there are many more. For example, we have driven advancements in non-biological complex drugs. This is evident through our facilitation of an international working group focused on ensuring patient benefit through a science-based approach for the approval of this special class of drugs.

For nearly two decades, Lygature has provided stability in a constantly evolving healthcare innovation landscape. Our role as a trusted partner in complex collaborations, combined with our proactive approach, enables us to drive positive change. For example, our leadership in establishing a shared office space in the heart of the Netherlands, fostering a spirit of synergy among key stakeholders. With our involvement in over 30 projects and initiatives and a network of more than 250 partners, we remain at the forefront of healthcare innovation, leveraging insights from our diverse collaborations.

The interviews conducted by Schuttelaar & Partners, featured in this report, have identified additional key emerging trends for us to consider. These trends, and how we envision our role in addressing them, are summarized below as we conclude this first Impact Report.



KEY TRENDS SHAPING OUR FUTURE

Artificial Intelligence and Data Sharing

Artificial intelligence (AI) is transforming scientific research and society, but its impact on healthcare is still unfolding. AI relies on data; without it, AI cannot function. As such, data sharing is becoming increasingly important. Initiatives like the European Health Data Space exemplify this trend, aiming to create a more connected healthcare system. Despite this progress, the still largely decentralized organization of health data brings challenges that demand a strong collaborative culture to ensure data quality, security, and ethical use. A robust data-sharing framework is essential for accelerating research and improving health outcomes. Lygature plays a pivotal role in aligning data-driven insights with broader scientific goals to arrive at real impacts for patients and society.

Understanding the technological developments—such as distributed learning, decentralized data storage, and cloud analytics—alongside the need for machine-readable data is key in this field. It requires collaboration among diverse stakeholders and sensitivity to their priorities and concerns in this rapidly changing environment. As demonstrated in the BigPicture project, high-quality, large-scale data collection is only possible through multi-stakeholder partnerships. As AI continues to evolve, neutral yet knowledgeable enablers like Lygature will be more essential than ever.

Diversity, Equity & Inclusion and Personalized Medicine

Promoting diversity, equity and inclusion in scientific research is critical for addressing health disparities and broadening the scope of innovation. Scientific advancements should benefit everyone, regardless of age, gender or



background. To realize meaningful research results, it is important to secure diverse participation in clinical trials, ensure technologies like remote monitoring devices are accessible to all populations, and develop tailored solutions for specific groups, such as children or the elderly.

As the healthcare landscape evolves, personalized healthcare is becoming increasingly important—not only as part of the shift to a more preventative model but also in terms of refining existing treatments that better serve diverse patient populations. Empowering individuals in managing their health and ensuring diversity, equity, and inclusion is central to this evolution. Lygature is an advocate of this and will continue to support partnerships that drive this transformation.

Patient and Public Involvement

Engaging patients and the wider public in research is not just a best practice, it is essential for impactful healthcare innovation. Meaningful involvement ensures that research is aligned with real-world needs and promotes trust in emerging healthcare solutions. From shaping study designs to influencing policy decisions, patient voices must be heard.

Lygature remains committed to embedding patient and public perspectives at every stage of a project, improving the quality, relevance, and effectiveness of healthcare initiatives.

Regulatory Challenges and Policy Making

The regulatory system has to respond efficiently and effectively to scientific developments, particularly in areas such as advanced therapy medicinal (ATMPs), AI-driven healthcare, and data sharing. For example, using remote monitoring technologies for diagnosing neurodegenerative diseases like Alzheimer's and multiple sclerosis requires new regulatory approaches. As a neutral facilitator and enabler, Lygature has the necessary expertise to navigate these changes, assess current and future trends, and foster impact-oriented dialogue between regulators, industry, and academia. This support ensures that partnerships remain at the forefront of developments and are compliant with regulatory standards. Our expertise in this area will continue to be a cornerstone of our work.

LOOKING AHEAD: PARTNERING FOR IMPACT

Lygature's impact is built on collaboration. The key challenges faced by the Life Sciences and Health sector—embedding AI, ensuring equitable inclusion, and contributing to an evolving regulatory environment—are too complex for any single organization to tackle alone. We need the combined expertise, insights, and commitment of our partners to drive meaningful change, with Lygature playing a central role in facilitating these efforts.

As we look ahead, we invite you—our colleagues, collaborators and stakeholders—to join us in shaping the future of healthcare innovation. By working together, we can create solutions that are transformative, inclusive, and effective. Let's move forward in Pioneering Medicine—Together.



Acknowledgement

We sincerely appreciate the time, insights, and perspectives shared by our partners in contributing to this report. Your expertise and thoughtful input have enriched this report, helping to ensure a comprehensive and meaningful assessment of Lygature's impact.

We look forward to many more impactful collaborations in the future.

Collaborators for this report:

Beat Flühmann
Derek Sloan
Dianne Gove
Erwin Boutsma
Hubertus Irth
Jayasree Iyer
Jeremy Davis
Jutta Reinhard-Rupp
Katrien Grünberg
Magda Chlebus
Marjon Pasmooij
Peter Mol
Peter Steinmann
Phil Gribbon
Phil Jones
Sophie Huiskes-Berends
Stefan Jaroch
Ton Rijnders
& the Lygature team

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Design

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Contact

For inquiries, please contact us at info@lygature.org.

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