

lygature pioneering medicine.
together.

The Science of Partnership Management

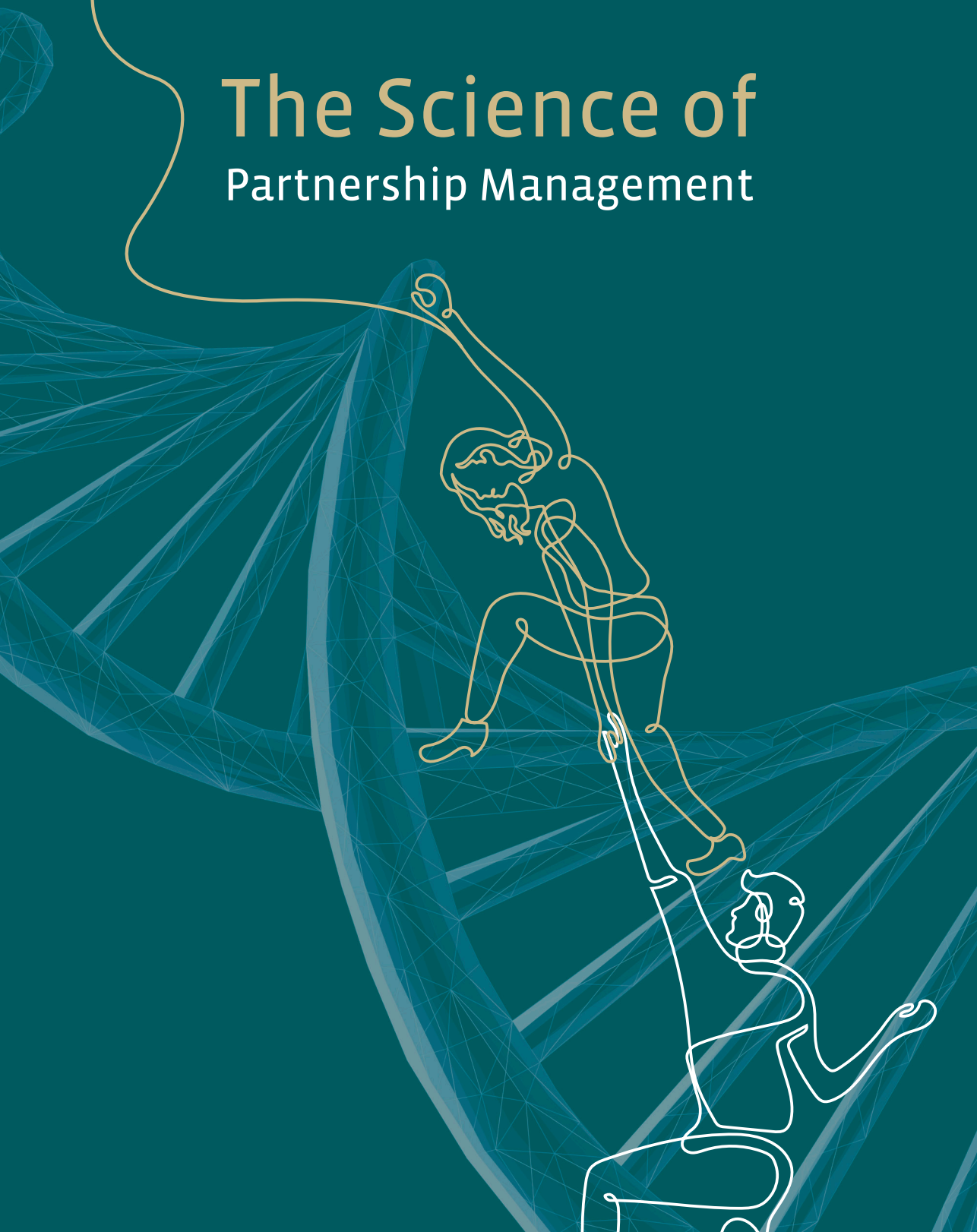




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Introducing Lygature

Pioneering Medicine. Together.

Pioneering, Medicine, Together –
three words that say it all.



Pioneering reflects our collective drive to change the status quo, because developing new solutions to treat diseases provides real hope for people experiencing major health challenges. Those challenges are not only medical in nature, they also have other dimensions. Can we afford them as a society, and can we make them accessible to all? Realizing access to medicines remains a challenge in many parts of the world. Addressing all these different aspects requires an open and inclusive mindset. We can only progress if we welcome new ideas, new suggestions and new ways of working. Whether it is a minor change to today's practice or a ground-breaking shift of the system, ultimately it is the result and its impact on people and society that counts.

Medicine encompasses our determination to facilitate the translation of basic science into health(care) solutions across the entire spectrum of pharmaceuticals and medical technology, or combinations of the two. Examples include developing a paediatric formulation to treat schistosomiasis, finding new drug candidates to develop priority medicines, exploring how wearables can be used to monitor the progression of neurodegenerative diseases, and innovative image-guided treatments for cancers combining radiotherapy and magnetic resonance imaging.

Together highlights our belief that pioneering medicine can only be achieved through partnerships. They are the only way of tackling global health challenges that are too complex for individual organizations to solve. The recent COVID-19 pandemic is a clear case in point. Partnerships can bring together the best of all worlds: large multinationals and academic institutions, medium-sized businesses, start-ups, patient organizations, health foundations, health insurers and regulatory authorities, all joining together to pave the way for better and more affordable healthcare.

As Lygature, we have been pioneering medicine together for 15 years. This brochure shows you the full spectrum of what Lygature does and how we add value. We invite you to learn more about our work and get inspired, and we look forward to hearing from you to discuss how we can pioneer medicine together!

Jorg Janssen, PhD
Managing Director



Our vision and mission

Empowering partnerships

At Lygature, we believe the complex health challenges facing today's world can only be solved by close collaboration between academics, entrepreneurs, governments, and society at large. What lies beyond the power of individual innovators can be achieved through partnerships.

And because all partnerships rely on trust, a trusted third party is in many cases the key to making them work. Ideally, this third party should not only be the custodian of trust and the guarantor of each partner's interests, it should also be the neutral enabler and manager of complex programmes involving many and diverse stakeholders. We are that independent partnership management organization, and we are dedicated to the success of the partnerships we facilitate and manage.

Our mission is to enable the delivery of breakthrough innovations in medical technology and drug development that address unmet medical needs. We provide partnership management and drive partnerships from idea to success.

What makes us unique

Lygature drives partnerships for the development of medical solutions for patients. This is the 'raison d'être' for our organization. What really sets us apart is how we manage partnerships from start to success to achieve our goals.

We believe in the best of all worlds

We bring academia, industry and society together in public-private partnerships to achieve goals that no single party can achieve on its own. We believe each of these groups plays an essential role to accelerate medical innovation.

We believe in bringing people together

Our employees are highly skilled and experienced researchers and professionals who have worked in both academia and industry. They know how to communicate, how to convince, how to involve people and how to run projects. But most importantly, they keep everyone focused on the ultimate goal: developing medical solutions for patients.

We believe in long term relationships

Sustainable medical innovations need long-term public-private partnerships. As a not-for-profit foundation, we have the independence and financial structure to initiate and support these long-term partnerships. We can position our organization to fully serve a partnership's ultimate goal.



Our portfolio

Managing more than 24 projects, serving more than 200 partners

We focus our partnership management activities on four portfolios:



**Data
Infrastructure**



**Strategic Asset
Sharing**



Regulatory Innovation



Global Health

In addition, we execute as partnerships management partner in Strategic Alliances.



Strategic Alliances





Portfolio | Data Infrastructure



Enabling the safe sharing of sensitive data

Health and medical research is increasingly data-driven. The development of novel personalised, predictive and preventative health solutions requires the integration of vast quantities of data contained in diverse data sets from a broad range of sources – ranging from longitudinal health data, biological samples and medical images to data from clinical trials and clinical practice. Lygature manages a mix of projects that realize the infrastructure and create the conditions needed to collect, store and share different types of data from various sources to support researchers and scientific projects.



Gerrit A. Meijer

MD, PhD, Chief Scientific Officer, Health-RI, and Head of the Division of Diagnostic Translational Oncology, Netherlands Cancer Institute

There is an urgent need to bridge the innovation gap between personalised medicine and health research. One of the crucial factors to bridge this gap is high-quality data infrastructure and process support. Lygature has played a huge role within many projects on that topic in the last decennium, which all comes together in Health-RI. The success and impact of Health-RI would have never been possible without Lygature's strategic and tactical support and its involved program managers.





Jan-Willem Boiten, PhD

Program Manager



Jan-Willem Boiten:

“Health research is all about data. Researchers not only have to process more and more of it, the data must also be reliable and reusable, and it must be collected, stored and used ethically with due respect for privacy. It is typically too complex for any one institute to coordinate. At Lygature we have the experience and independence to manage the complexity and ensure that facilities, data and samples can be shared effectively and safely. We are proud of our strategic alliance with Health-RI ([see page 17](#)) to create a national research data infrastructure in the Netherlands.

A second good example of our commitment to the safe sharing of data is our involvement in the *FAIRplus* project, which aims to make data from at least 20 large projects funded by the EU’s Innovative Medicine Initiative (IMI) and internal data from pharmaceutical industry partners ‘FAIR’ – i.e. findable, accessible, interoperable and reusable. The objective is to make the data available to other researchers as well. FAIR data is also a prerequisite for innovative federated analysis methodologies, as symbolized by the [Personal Health Train \(PHT\)](#). Instead of centralizing data from multiple sources, the PHT concept leaves the data at the source – the ‘data station’ – while analysis ‘trains’ visit those data stations, combining what they discover at each of them into a common result. While the concept is technically and organizationally complex, it has great promise for giving carefully controlled access to data and engaging individual patients and citizens.”



Tienek Schaaaij-Visser, PhD

Program Manager



Tienek Schaaaij-Visser:

“The data you use is collected from healthy or diseased individuals. It makes no difference whether it is samples of blood, urine or tissue, images such as MRI or other scans, or data on the progression of an individual’s disease or lifestyle – these are a citizen’s data and must be handled responsibly. That’s why [BBMRI-NL – the Biobanking and BioMolecular Resources Research Infrastructure](#) – has facilitated setting up the [Ethical, Legal and Social Implications \(ELSI\) service desk](#), an initiative led by the Netherlands Cancer Institute. The ELSI service desk fits nicely into the mission of BBMRI-NL to stimulate the responsible use of biosamples, images and data for health research. It offers guidance on ELSI topics, publishes FAQs and lets you consult with ELSI experts on specific issues.

Another example is the Patient and Public Advisory Council (PPAC) that safeguards the roles, interests, concerns and needs of patients and the public in biobank research. At Lygature, we actively enable the work of the PPAC by organizing its meetings, providing secretarial services, and promoting its work. An infrastructure that helps to answer ethical, legal and social questions is indispensable to arriving at solutions that are safe, ethically sound, and fit society’s needs. These questions must be considered and answered together, by researchers, medical professionals, policy makers, citizens and patients. At Lygature, we feel morally obliged as well as privileged to play our part in advancing these critical conversations.”

For more information on our Data Infrastructure projects contact:

[Jan-Willem Boiten, PhD](#) - [Wim-Jan Koot, PhD](#)



Enabling collaboration between competitors

In the life sciences, as in any industry, competition drives innovation. Academics compete to conduct and publish ground-breaking research. Businesses compete to discover, develop and deliver new health solutions. Despite the fact that competition remains a necessary condition, it is no longer sufficient on its own. In today's world, life-science researchers and companies cannot innovate without collaborating with others.

To make the most of their knowledge and resources, they must be prepared to share them, even with their competitors. An increasing number of partnerships already rely on Lygature to provide the independent management and safeguards needed to make it possible.



Prof. Dag Aarsland

Professor of Old Age Psychiatry, King's College London, and Principal Investigator of (a.o.) the IMI RADAR-AD and PD-MIND projects

In multiple projects, I have found that Lygature as a managing partner has a lot of added value - basically leaving room for the scientists to do their work. Furthermore, Lygature can and will take responsibility for communications, regulatory and data-related work of the project, which all helps to make the project a success in many different areas.





Jon de Vlieger:

“We challenge our partners to enter into partnerships that are extremely close to their core. In these partnerships, we see an essential role for Lygature as an honest broker. Because we are independent and do not develop any medical product or technology ourselves, we can fully focus on making partnerships work for everybody. That means proving to our partners that we can be trusted to keep their secrets while also allowing them to share data without compromising their competitive position. Take the [European Lead Factory \(ELF\)](#), for example, which involves large pharmaceutical companies sharing their compound libraries with one another and with academics and SMEs, while everyone races to develop new medicines. Amongst many other things, Lygature governs the portfolio to ensure that partners work on complementary projects, leading to public and private resources well spent.

For us, part of the excitement is that we are not just innovating within partnerships – we are innovating the concept of a partnership itself. It is like a sandbox in which we continuously devise, try out, adapt and evolve new models. We also guide partnerships through their natural evolution, keeping them on track as partners come and go. This combined role of providing confidence and pushing partners slightly out of their comfort zones to maximize results suits us. It’s what Lygature is all about.”



Jon de Vlieger, PhD

Business Developer

Herman Verheij:

“Strategic asset sharing works best in the very early stages of drug discovery or technology development. It is where results can surpass what partners can achieve on their own. Such projects are very exploratory. For example, in projects such as [RADAR-CNS](#) and [RADAR-AD](#) we collectively ask questions like “What can we measure?”, “How well do we measure?” and “What will that tell us?” to find new ways of using mobile technology (m-health) to measure patients’ health and well-being. The benefits to patients are obvious: it gives them more and better tools to manage their health and disease, to interact with doctors remotely, and to receive care at home. For researchers and companies, it opens up new opportunities to improve the healthcare system and introduce new products and services. We can even see innovative mobile technology enabling new ways of conducting clinical trials, at home rather than in the lab.

We are continuously investigating what is happening in the field and how we can contribute. More and more pharmaceutical and MedTech companies are interested in joining us. Like us, they recognise the opportunities for new technology and new forms of partnership.”



Herman Verheij, PhD

Program Manager

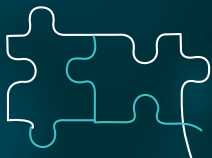
For more information on our Strategic Asset Sharing projects contact:

[Herman Verheij, PhD](#) - [Tale Sliedrecht, PhD](#) - [Jon de Vlieger, PhD](#)



Facts & Figures

15 years of running partnerships



#Projects

>100 varying in size from 1 million to 200 million euros



#Partners

>200, in academia, large, medium and small enterprises, governmental institutions and societal organisations



Project duration

from 2 years to more than 10 years



Geographical scope

Rooted in the Netherlands: active in Europe and work with partners from all continents



Project budget

management of in total >1 billion euros public-private budget

“

Jane Taylor

Patient Council APPROACH

Since patients in APPROACH live in different countries, Lygature enables us to work as and feel part of a team. Their coordination and support ensure we are fully involved and able to play our part in the success of the study.

To me, Lygature is the beating heart of the project, constantly working to maintain and connect all parts together to ensure the best outcomes.

Dr. John P. Christodouleas

SVP of Medical Affairs & Clinical Research

Linac Based RT, Elekta

Lygature has been indispensable for helping us organize and manage our complex international academic industrial collaboration. At each step of our project, Lygature has served as a trusted advisor and manager that can draw on a diverse set of resources within their organization. We are very thankful that we got them involved in our mission.

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Organisation (2020)

Number of employees:

45

Annual turnover

4,6

million euros

running projects:

24

Results

- Lygature always joins forces in multi-stakeholder collaborations.
- Results from these partnerships' efforts cover a wide range:
 - From new diagnostic tools & biomarkers, to vaccines & drugs in clinical trials
 - From understanding new modes of action, to regulatory solutions & patient involvement
 - From tools to share data across research institutions, to biobank collections
 - From patents and publications, to start-ups and follow ups on collaborations
 - From talented young scientists, to professionals able to bridge disciplines
- Examples of results are visible on the webpages of our projects which can be accessed via www.lygature.org/projects



Creating the conditions for better and faster innovation

An effective and efficient regulatory system serves everybody's interests. It speeds up innovation, improves resource allocation and helps to make new products and services available and affordable.

Lygature provides a neutral platform for all stakeholders, including patients, regulatory bodies, Health Technology Assessment (HTA) organizations, research groups and industry partners, to find common ground, align interests and jointly (re)design regulatory frameworks for fast, safe and (cost-)effective innovation. We facilitate scientific discussions and conduct research on regulatory and HTA topics, both on our own initiative and in response to third party proposals.

For more information on our Regulatory Innovation projects contact:

[Pieter Stolk, PhD](#) - [Jon de Vlieger, PhD](#) -
[Irene Kanter-Schlifke, PhD](#)



Pieter Stolk, PhD

Program Manager



Pieter Stolk: "I am often amazed and always excited by the incredibly open and constructive atmosphere in which our partners, who often have very different and sometimes conflicting interests, are prepared to talk about complex topics. They are urgent and relevant to all of us, but it takes real commitment and trust to discuss them so frankly. I like to think that we help to provide that at Lygature.

For example, take the [Regulatory Science Network Netherlands \(RSNN\)](#) – a unique collaboration between regulatory experts from academia, government bodies, the pharmaceutical industry and patient organizations. Lygature is responsible for the programme management, strategic agenda setting and all internal and external communications, including branding and profiling of the network. We bring members of the network together for workshops, expert meetings and scientific conferences. We facilitate discussions and disseminate the outcomes through publications, white papers, reports and responses to public consultations. We also help the network set the agenda and develop new initiatives for further research. Our scientific background and deep understanding of the challenges faced by the partnerships we support makes us credible and our independence trusted. I don't think any other neutral partner could support a scientific network like Lygature can."



**Jon
de Vlieger, PhD**

Business Developer



Jon de Vlieger: “Lygature’s commitment to regulatory innovation goes back to the days of TI Pharma, one of our precursor organizations, over a decade ago. We discovered that the regulatory system had no clear way of dealing with non-biological complex drugs and their follow-on versions – the term did not even exist yet. So, we set up the [Non-Biological Complex Drugs \(NBCD\) working group](#). Together with experts from academia, regulatory agencies, and industry partners, we defined NBCDs and the related terminology. We assessed current practices – what was going well and what wasn’t – and charted a way forward. Today, regulatory authorities around the world, including the FDA and EMA, have NBCDs high on their agenda. The NBCD community is using the terminology we developed, a fit for purpose regulatory framework is taking shape, and our working group has become a model for regulatory improvement and renewal.

The NBCD working group not only taught us that trust and the commitment of senior people with decision-making authority can make a difference, but that it can also be organized by an independent catalyst. We have really created a legacy here – a very tangible result in a niche that is small now but bound to grow, and a model to emulate for other complex (biomedical) innovations. It makes us excited and proud.”



**Irene
Kanter-Schlifke,
PhD**

Program Manager



Irene Kanter-Schlifke: “Not all medical innovations that are safe, effective and affordable make it to the market, and some that are on the market lack solid evidence of their effectiveness.

[Health Innovation Netherlands \(HI-NL\)](#) seeks to address these issues. HI-NL is a multi-stakeholder platform where patients, doctors, healthcare providers, CE-experts, entrepreneurs, insurers, investors and regulatory authorities all work together to stimulate the development of medical innovations that are safe, cost-effective and have a demonstrable benefit for the health and well-being of the people they will diagnose or treat.

HI-NL started as a great idea and Lygature was asked to help make it happen. We have taken responsibility for the programme management, developing the agreements and legal structures, putting in place governance and finance, and taking care of communications. Among other things, we organize HI-NL’s Round Tables, which bring together relevant stakeholders at an early stage of development to give innovators detailed feedback and guidance on how to make new devices more valuable to users and bring them to market more quickly and effectively.”



Bringing the benefits of innovation to all

Health challenges are truly global. They impact us all. But not all of us benefit from (novel) curative and preventative medicine and improved diagnostics. Some of the most urgent medical needs around the world receive the least attention and resources. If setting up public-private partnerships and making them work remains challenging in high-income countries with profitable markets for industry and ample (public) research funding, imagine how much more difficult it is in poorer regions that lack efficient markets, expert knowledge and workable healthcare infrastructures. Lygature's Global Health portfolio focuses on the conceptualization, initiation and implementation of multi-stakeholder partnerships to improve short-term and long-term health in low- and middle-income countries.



Dr. Jeremy Burrows VP

Head of Discovery, Medicines for Malaria Venture (MMV)

It has been a pleasure working with Lygature over the last 5 years. Dr. Herman Verheij and Dr. Kristina Orling have been very close collaborators with MMV Discovery, supporting us with the management of the consortium of Dutch Parasitology and Drug Discovery project teams. From my personal experience, I associate Lygature with good governance, a high degree of organization and structure, diligent project management, industrial drug discovery competence and experience, good communication and excellent collaboration.





Kristina Orrling: “In areas such as neglected tropical diseases, HIV/AIDS, tuberculosis, malaria and antimicrobial resistance (AMR), health issues continue to emerge. If they are not tackled, they persist and impact the lives of tens or hundreds of millions of people. Despite the urgent medical need and obvious societal benefits, there is little commercial value in developing solutions for many of these diseases. We need to find alternatives to existing business models to make innovation in these areas sustainable rather than an act of incidental charity.”

We believe multilateral partnerships are key, because pooling expertise and resources enables the partners to collectively achieve what they cannot achieve individually. Take antimicrobial resistance, for example. There are many brilliant researchers and different initiatives but most of the work is stuck in silos or bilateral collaborations. A more concerted effort could lead to faster and better results – as it has for malaria. With the scientific and financial support of [Medicine for Malaria Ventures \(MMV\)](#) and the Dutch Ministry of Foreign Affairs *Product Development Partnership III*, we managed a multi-party cross-sector collaboration that led to a very promising candidate drug. Every year, malaria kills more than 400,000 people, mostly in developing regions. That’s what makes this work so rewarding – we can help to make a real difference.”



Remco de Vruh, PhD

Program Manager



Kristina Orrling, PhD

Program Manager

Remco de Vruh: “As an independent enabler, Lygature focuses both on building the business case for research into poverty-related diseases and on mobilizing the right partnerships to tackle the issues. A good example is our work on schistosomiasis, a major neglected tropical disease that impacts the health of the lowest-income populations. We support one consortium that develops sensitive, affordable and user-friendly diagnostics, and another – [the Pediatric Praziquantel Consortium](#) – that now has a new formulation in clinical development to make the gold standard treatment for schistosomiasis available for young (preschool) children. In the Pediatric Praziquantel Consortium we have helped bring together pharmaceutical companies and labs, research and public-health institutes, and non-profit organizations from Germany, Switzerland, Japan, Brazil, the UK, Kenya, and Ivory Coast. Lygature coordinates the consortium, provides governance for progress monitoring, legal and financial support and collaboration, and takes care of all internal and external communication. We also take the lead in raising funds for clinical trials.

Our added value in such partnerships is typically making sure that the partners work together in an optimal way to reach the partnership’s goal. Working in that role is what gives me energy. Sometimes partners can put a lot of pressure on themselves and each other, and I take some of that pressure away by bringing everyone’s attention to all the things we have already overcome and achieved together – which is usually a lot!”

For more information on our Global Health projects contact:
[Kristina Orrling, PhD](#) - [Remco de Vruh, PhD](#) - [Wim-Jan Koot, PhD](#)



Stewardship for large-scale public-private partnerships

Building on 15 years of experience in partnership management, Lygature is the partner of choice for setting up and running the operations of large public-private initiatives and securing their sustainability. We can help to get funding agreements in place, organize governance, design and staff programmes, connect with stakeholders and provide transparent reporting.

Once they are up and running, the Lygature team also offers expertise in data management, open science, patient engagement, intellectual property (IP) management, regulatory innovation, human resources, event management, communication and finance. We are proud to be allied to some of the most ambitious and promising partnerships in the Netherlands and consider them flagship examples of our capabilities.



Matthias Gottwald

PhD, Former Head of Public-Private Partnerships at Bayer AG and Member of the Scientific Advisory Board at Lygature

Lygature has clearly shown to master the skills of managing complex public-private partnerships in an international setting. I've seen the organization operate within and outside the framework of the Innovative Medicines Initiative and, without doubt, Lygature has significantly contributed to the success of many partnerships. It's great to see the team's drive and focus to 'pioneering medicine together' has such a high impact.





**Tale
Slidrecht, PhD**

Program Manager



Tale Slidrecht: “[Oncode Institute](#) is the first of its kind – a virtual institute that proactively brings together more than 800 excellent cancer researchers in the Netherlands with the aim of translating their research results into better patient outcomes and societal and economic benefits. It is built on scientific excellence, collaboration and valorisation. Through our unique combination of services, we made it possible for Oncode to hit the ground running. We provide the institute with programme and operational management, together with additional support in areas such as IT infrastructure, HR expertise, finance and communication.

I am excited to work for Oncode because it creates a fertile ground for discoveries that can truly transform the outlook for cancer patients. It gives creative researchers the freedom and support they need to really make a difference. To help set up the institute and see it mature has been a truly exciting and rewarding experience.”



**Rick
van Nuland, PhD**

Program Manager



Rick van Nuland: “Health research has become ever-more data driven, with researchers often having to spend a lot of time gathering and structuring data because they lack the tools, knowledge and infrastructure to handle the data efficiently. In many cases, there are also insufficient resources and facilities available to keep data available and usable for other research once a project is finished. That’s time, energy and funding wasted, and data lost.

With [Health-RI](#) we want to change that. We want to make it possible for researchers to focus on what the data can tell them so they can build on data generated and collected by others. Health-RI is the strategic alliance in which many of our past and present efforts land. It is a national infrastructure that interconnects and unlocks biomedical data from clinical trials, clinical practice, biobanks in research institutions across the country, and reference data from healthy citizens. It creates the conditions for faster and more efficient development of personalised medicine, preventive approaches, and other health solutions. The whole is truly greater than the sum of its parts.

Lygature was one of the initiators of Health-RI and continues to provide strategy, programme and stakeholder management, as well as communication and finance support.”

For more information on our Strategic Alliances projects contact:

[Jon de Vlieger, PhD](#) - [Wim-Jan Koot, PhD](#)



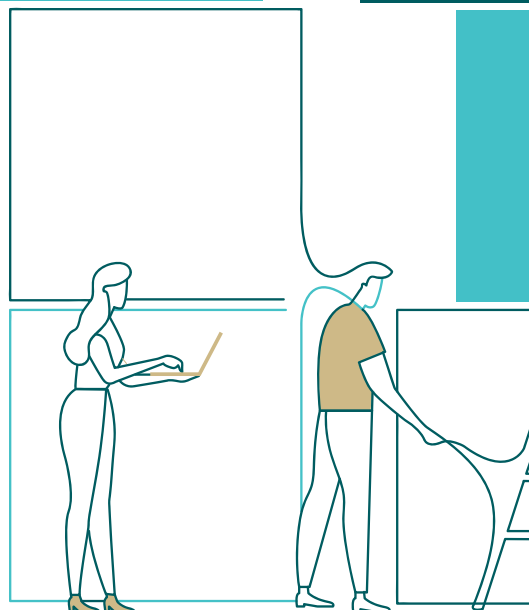
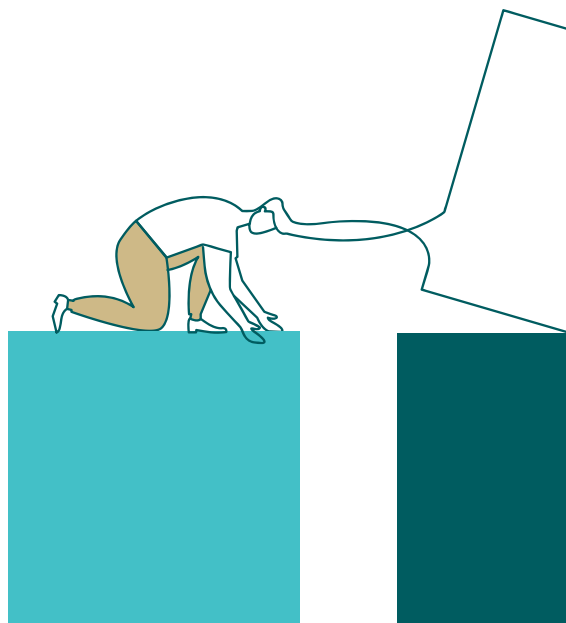
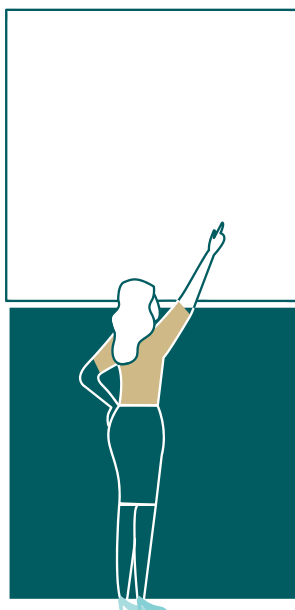
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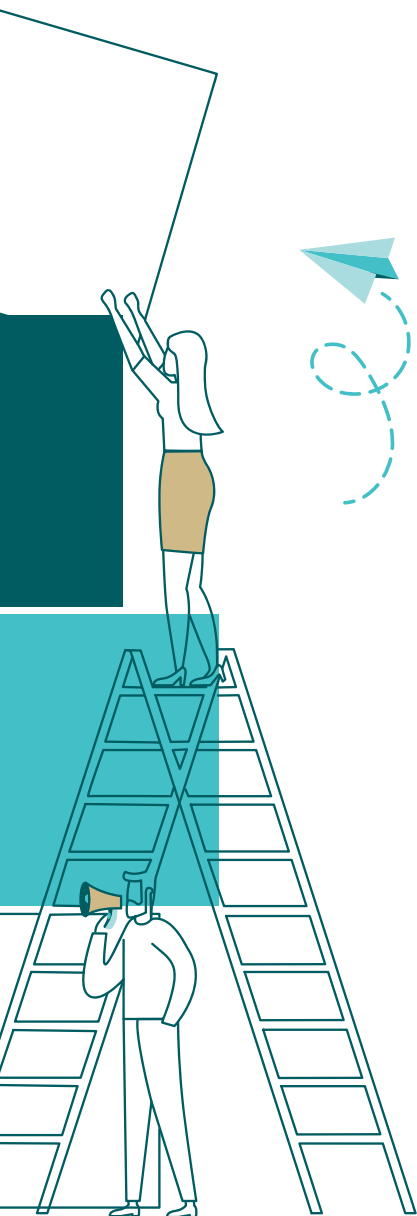
Catherine K. Ohura

MS, PMP, CEO and Executive Director, Global Health Innovative Technology (GHIT) Fund

Working with Lygature over the past seven years has convinced us of the added value that an independent coordinator provides to multi-partner collaborations between public-private entities in global health. Lygature's continuous focus on building understanding, trust, and sound relationships between partners ensures that the interests of all parties within a project are aligned with those of GHIT. This focus is accompanied by a natural ability to intervene when necessary to keep the partnership on track in a timely and transparent manner.

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Our role

Lygature: the secret ingredient for partnership success

At Lygature we believe in the best of all worlds. As a not-for-profit organization, we bring academia, industry and society together to achieve goals that no single party can achieve on its own. People with experience in health challenges are always involved in our partnerships, as they have a crucial role to play in responsible research and innovation aimed at improving their quality of life. Our role integrates three elements:

Creating a safe space for innovation

We are the independent third party, the neutral enabler.

1. Ensuring effective governance and inclusive decision making
2. Enabling efficient and secure data sharing
3. Balancing interests as the neutral broker
4. Facilitating socially responsible innovation

Driving partnerships forward to deliver medical solutions

We focus all efforts towards the success of the partnership.

1. Engage people with experience in health challenges to deliver relevant and accessible medical solutions
2. Ensure sustainability by connecting new partners and funding along the way
3. Initiating collaboration by translating opportunities into operational partnerships
4. Keep momentum by proactively mitigating risks and identifying opportunities

Providing specialized support for partnerships

We make sure all partners can focus on their core activities.

1. Provide day-to-day program management support
2. Provide fit-for-purpose IT and data infrastructure
3. Provide content expertise in data management and regulatory science
4. Provide communication solutions
5. Provide specialized legal and financial support



lygature

pioneering medicine.
together.

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