

# Strategic Business Plan

2021-2025



Today's catalyst for  
tomorrow's vaccines



# **EVI Strategic Business Plan**

## 2021-2025



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# 1

## Executive Summary

Welcome to our five-year Strategic Business Plan 2021-2025.

The COVID-19 pandemic has made it clearer than ever that immunisation is a global public good and the world needs the ability to develop, manufacture and deploy vaccines as quickly as possible. This Strategic Business Plan will guide our efforts toward a world where vaccines create health and equity for all people. To work towards this goal, our strategic focus areas for the upcoming period are: a) to catalyse the translational development of vaccines for global health, b) to build a strong base of cross-cutting activities to address the weaknesses of the European and global research and development (R&D) system for vaccines, widely revealed during the COVID-19 pandemic, and c) to extend the benefits of vaccines to all people by improving knowledge, access and uptake of vaccines.

**“ Other pandemics and deadly infections will emerge, and an outbreak anywhere is a threat everywhere in today’s interconnected world. ”**

EVI will operate as an independent, science-driven non-profit organization working closely together with partners and like-minded organisations to develop effective and affordable vaccines for global health.

The European Vaccine Initiative (EVI) is a leading non-profit Product Development Partnership (PDP) that works with partners across the world to develop safe, effective and affordable vaccines for global health.

We use the power of collaboration, innovation, open science, partnerships, and advocacy to move vaccines forward.

EVI is renowned for its capability to coordinate and support the development of individual vaccine candidates and for working across Europe and globally to harmonise and streamline processes and protocols for vaccine development. EVI will continue strengthening its footprint in global health and vaccinology by delivering support in specific areas of activity such as project management, consortia building, design and implementation of preclinical research, clinical development, GMP manufacturing and regulatory support. Recent years have demonstrated the necessity for flexibility and adaptability in responding effectively to new global health changes. This will be extended to accompany our broader scope of action and mode of operation.

To uphold these promising changes, EVI has changed its legal structure to be better shaped for the future, giving us the opportunity to build new strategic alliances and partnerships across the world, and to establish long-term business relationships that will continue beyond individual projects.

We are committed to developing *safe, effective, and affordable vaccines for global health through collaboration and coordination*, and this plan is laying the foundation for our growth over the next years.



**Vaccines can bring people together and create a healthier future. Join us today, and let us embark on this journey together.**

## 2

# Introduction

## 2.1 Importance of vaccines for global health

Vaccines are arguably the most successful and cost-effective medical interventions ever developed. Every year, millions of deaths are averted around the world by the use of vaccines<sup>1</sup>. Their widespread use has been instrumental in the remarkable reduction in global child mortality that we have witnessed over the past few decades.

**Vaccination will continue to be an integral part of the public health response to any future emergence of epidemic outbreaks.** As the COVID-19 pandemic has sorely reminded us, in addition to classical public health measures such as hygiene, surveillance, tracing and quarantine, vaccines are powerful tools to successfully control outbreaks, protecting lives and limiting disease spread.

**Vaccines ensure the greatest possible protection of health and well-being, while contributing to reduction of inequalities due to their cost-effectiveness and far-reaching effects.** The United Nations also has acknowledged vaccines' critical role for good health and well-being. A call to the global community to support the R&D of vaccines for diseases that primarily affect developing countries is thus included in target 3B of the Sustainable Development Goals (SDG), and captured by their promise "leave no one behind".

**Novel, safe and efficacious vaccines have an enormous impact on life expectancy and on quality of life worldwide.**

## 2.2 The global landscape for vaccine R&D

Vaccine R&D has seen a remarkable renaissance in the first decades of the 21st century. While the 1980s and 1990s represented a period of great contraction among the largest vaccine producers, the new millennium has seen renewed optimism with an increasing vaccine pipeline and the emergence of new product developers and biotech companies. This development has been driven by scientific breakthroughs such as the full genome sequencing of several infectious pathogens, the refinement of knowledge about the human immune response system, and deepened understanding of host–pathogen interactions. **The devastating toll and disruption to societies by epidemic outbreaks in recent years of swine flu (H1N1), Ebola, Zika and the COVID-19 pandemic have high-**

<sup>1</sup> World Health Organisation (2015). "WHO's vision and mission in immunization and vaccines 2015–2030. Geneva: World Health Organization". Available at: [https://www.who.int/immunization/documents/general/WHO\\_Mission\\_Vision\\_Immunization\\_Vaccines\\_2015\\_2030.pdf?ua=1](https://www.who.int/immunization/documents/general/WHO_Mission_Vision_Immunization_Vaccines_2015_2030.pdf?ua=1)

**lighted the value of vaccines in protecting communities against emerging and re-emerging infectious diseases.** This has been accompanied by increased political attention and establishment of new global initiatives such as the Coalition for Epidemic Preparedness Innovation (CEPI) and COVAX, with the purpose of incentivizing vaccine R&D. Similarly, recent commercial successes like the human papilloma virus (HPV) and meningococcus B (4CMenB) vaccines have contributed to a renewed interest in vaccine R&D from both large pharmaceutical and biotech companies.

Last but not least, climate change is also creating new challenges. For instance, by shifting the geographic range, physiology and behaviour of many pathogen-carrying arthropods, new and old pathogens will affect new areas, previously not endemic, affecting the transmission of diseases that need to be monitored.

### 2.3 Identifying the problems to solve: gaps in global vaccine R&D

Novel, safe and efficacious vaccines have an enormous impact on life expectancy and on quality of life worldwide, by significantly reducing government, individual, and business costs<sup>2</sup>. Developing new or improved vaccines will be increasingly challenging. Many of the target organisms, for which vaccines do not exist or are inadequate have complex structures and life cycles that escape traditional vaccine approaches. This is the case for malaria and leishmaniasis, Mycobacterium tuberculosis, or helminth parasites. Other infectious agents, such as HIV, Group A Streptococcus (GAS) and influenza viruses are very effective at outwitting vaccination attempts through antigenic and strain diversity. Even in the development of more conventional vaccines using established technologies many challenges remain when the biology and epidemiology of the pathogen are largely unknown.

Additionally, the development of new vaccines to meet regulatory standards for approval is expensive and time-consuming. Despite the obvious public health advantages of vaccines, they are therefore far from being fully utilized as a global health tool. **Vaccines against diseases of little commercial interest -typically diseases that are prevalent in low- and middle-income countries (LMICs)- have thus been neglected, even if they target a pathogen of major public health concern.** Similarly, vaccines for special populations such as pregnant women or elderly, vaccines against pathogens developing anti-microbial resistance (AMR), or personalized vaccines also represent major unmet medical needs.

Joint efforts and new approaches are needed to exploit the full potential of vaccines. This requires strengthened collaboration between public and private organisations, different sectors and across borders. It requires open and honest sharing of data and results, and cooperation to deliver new and innovative solutions, such as during the COVID-19 pandemic, throughout which scientists demonstrated unprecedented global collaboration and open access to knowledge.

<sup>2</sup> Bloom et al. (2018). "New and resurgent infectious diseases can have far-reaching economic repercussions". Finance & Development. VOL. 55 (2):46-49. Available at: <https://www.imf.org/external/pubs/ft/fandd/2018/06/economic-risks-and-impacts-of-epidemics/bloom.htm>

# 3

## EVI's contribution to vaccine research

### 3.1 EVI's approach

Ever since EVI's inception, our work focuses on developing vaccines through partnerships. At EVI, we catalyse and support collaborations to assemble a critical mass of know-how and resources in vaccine R&D. By bringing together and bridging skills, expertise and experience of partners, **we create the necessary momentum to move vaccine candidates efficiently and effectively through the development pipeline.**

Multi-stakeholder partnerships have become powerful vehicles for advancing the development of effective and affordable vaccines. The development of many vaccines would not have been possible without sustained support, dedication, and contribution from multiple stakeholders in both the private and public sector, and across different countries.

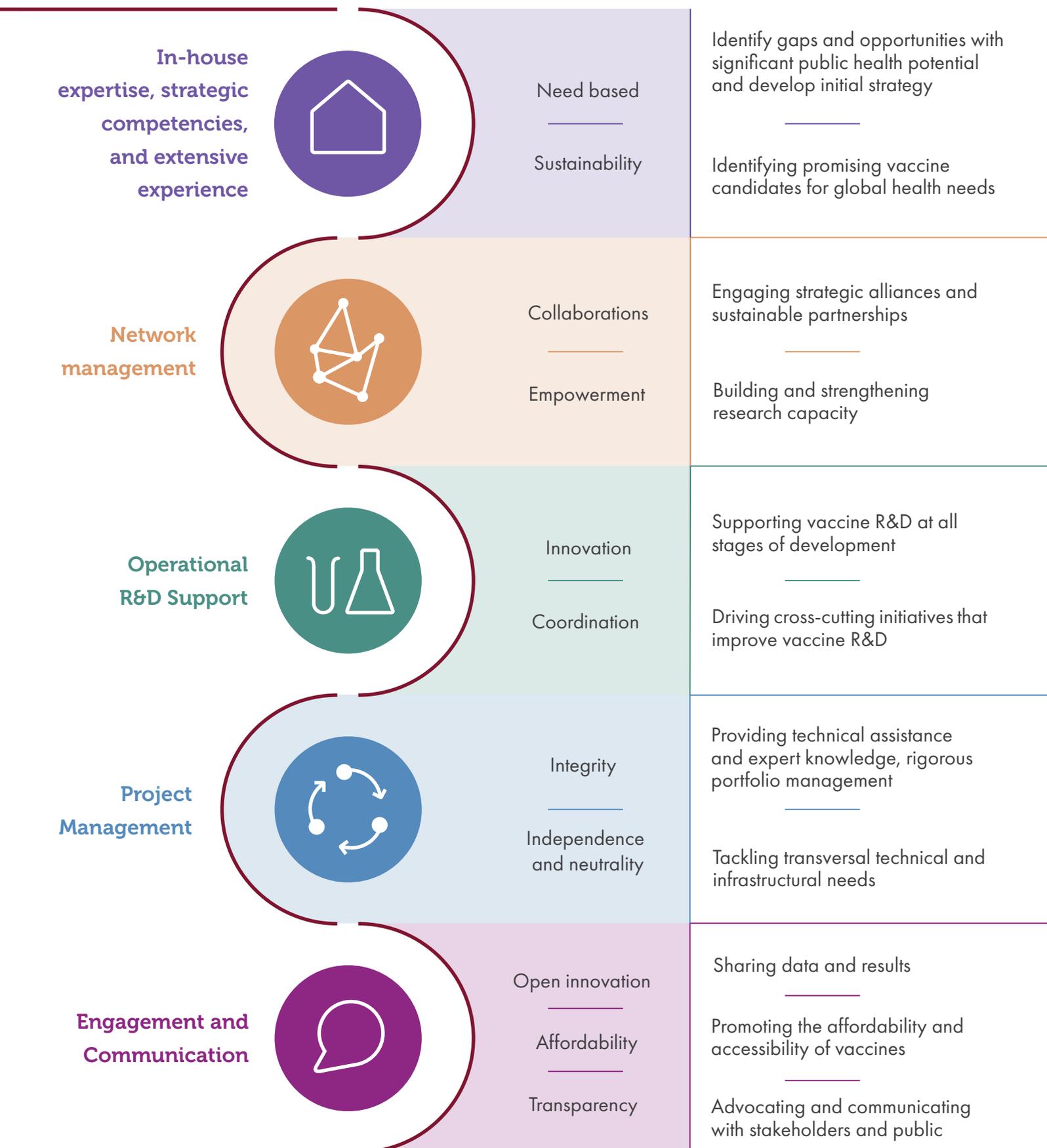
**At EVI, we strategically engage with partners worldwide** from academia, pharmaceutical and biotechnology companies, policy and decision makers, funders, and other stakeholders **to harness the best knowledge and expertise from leaders in the vaccine field.** Through this approach, EVI addresses critical challenges and opportunities, and promotes innovative solutions in vaccine R&D.

International and cross-sectorial partnerships will continue to be the foundation for EVI to spearhead vaccine development efforts for global health.

With our network of global partners, our expertise and the experience gained over more than twenty years, EVI is well positioned to support and boost the development of novel and improved vaccines by bringing promising vaccine candidates for global health from the lab to clinical testing.



Edward Jenner / Pexels



**Our Strengths**

**Our Values**

**Our Approach**

### 3.2 History of EVI – delivering innovation for two decades

The predecessor of EVI, the European Malaria Vaccine initiative (EMVI), was established in 1998 with the specific aim of accelerating malaria vaccine development in Europe. In 2010, the legal structure and the name of the organisation were changed, leading to the formation of the European Vaccine Initiative (EVI). The headquarter of the organisation was moved from Copenhagen, Denmark, to Heidelberg, in Germany, and the scope was broadened to include the development of vaccines for other diseases of poverty. **Malaria vaccine development has remained an important activity and focus area for EVI while the portfolio has progressively been enriched with projects and activities** in other important disease areas such as leishmaniasis, diarrheal diseases, influenza, and emerging infectious diseases.

EVI has become increasingly engaged in activities and projects that improve and support vaccine research, development, and manufacturing across diseases. We coordinated and led large, cross-cutting projects that look at fundamental and structural aspects of vaccine development across Europe. **These initiatives have positioned EVI as a focal point for European vaccine research and a leader in managing complex projects in applied vaccinology.**

1998

Malaria

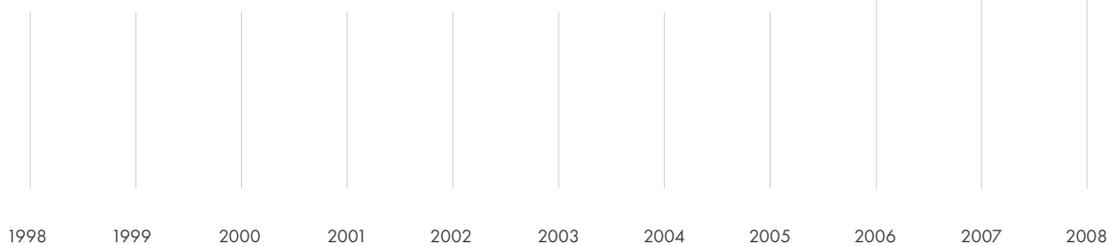
- Placental Malaria
- European network for harmonisation of malaria vaccine development
- 1st Phase I Clinical Trial
- Leading International Vaccinology Education (LIVE) programme

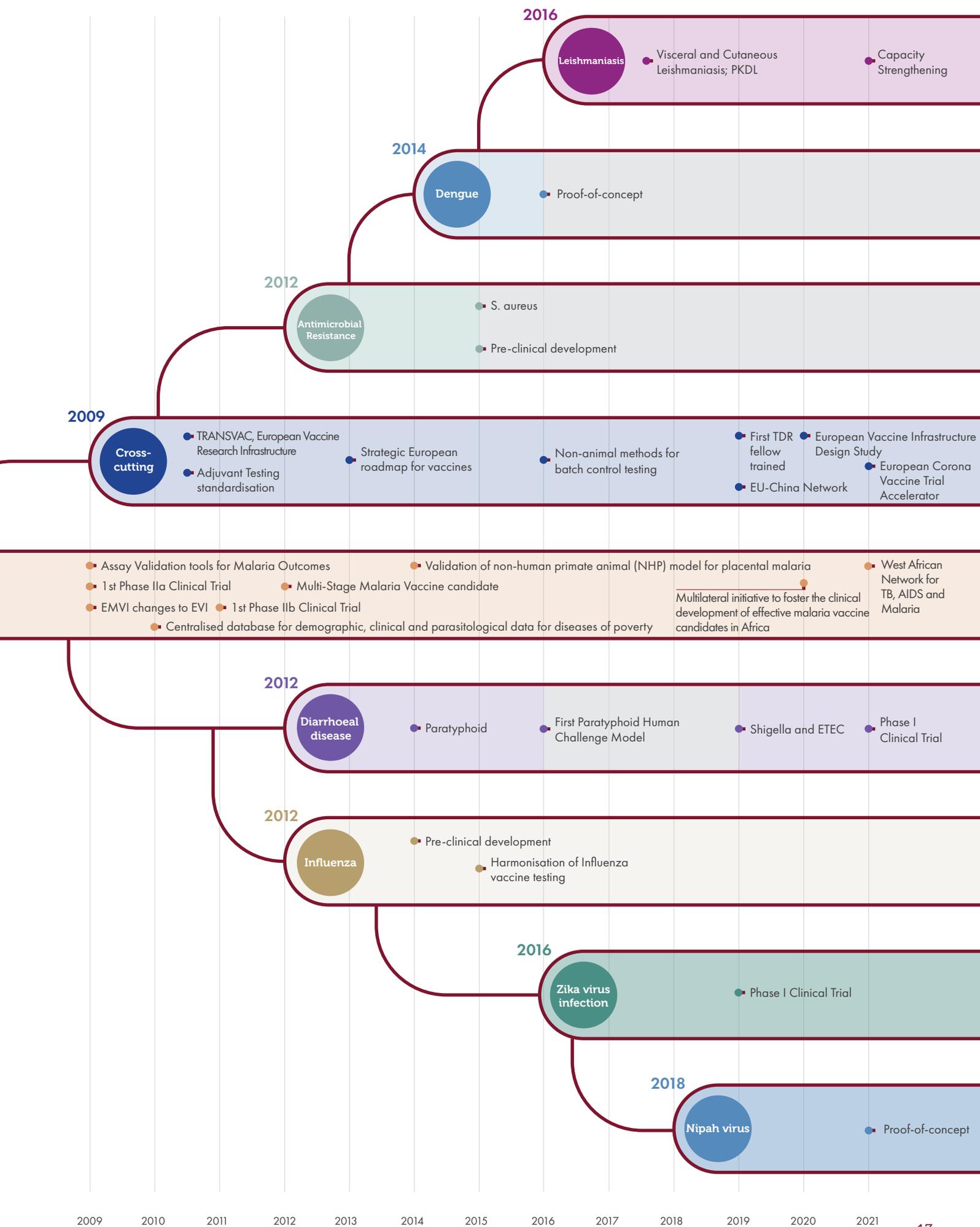
Throughout EVI’s existence, we collaborated with leading vaccine experts from across the globe, including more than 100 different research teams from Europe, USA, India, Japan, Bangladesh, and sub-Saharan Africa. This has enabled EVI to contribute to the testing and development of numerous different vaccine formulations, thirty-nine of which have progressed into clinical development. Subsequently, nine have progressed to mid-stage clinical development (phase II).

Through the cross-cutting TRANSVAC-1 and TRANSVAC-2 projects, EVI has further coordinated the provision of specific vaccine development services to another twenty-nine vaccine projects in several disease areas, including dengue, mumps, tuberculosis, pertussis, melanoma, HIV, ovarian carcinoma and malaria. We have also supported the testing and development of novel adjuvants, as well as the establishment of the first controlled human challenge model for paratyphoid infection<sup>3</sup>.

<sup>3</sup> Dobinson et al. (2017). “Evaluation of the Clinical and Microbiological Response to Salmonella Paratyphi A Infection in the First Paratyphoid Human Challenge Model”. *Clinical Infectious Diseases*. 64(8):1066-1073. doi: 10.1093/cid/cix042

The activities listed in the tree time-line do not represent the full range of EVI activities. This is for illustrative purposes.





# 4

## Strategic focus areas

### 4.1 EVI's vision and mission

EVI's activities are diverse. We support and coordinate research into individual vaccine candidates and work across Europe, and globally, to harmonise processes and protocols for vaccine development. In addition, **we undertake training and support capacity strengthening for vaccine R&D in both Europe and low- and middle-income countries.**

EVI operates as an independent, science-driven non-profit organisation working closely together with partners and like-minded organisations to develop effective and affordable vaccines for global health. The same guiding principles will continue to play a key role in defining EVI's core values and mission in the coming years.

### Vision

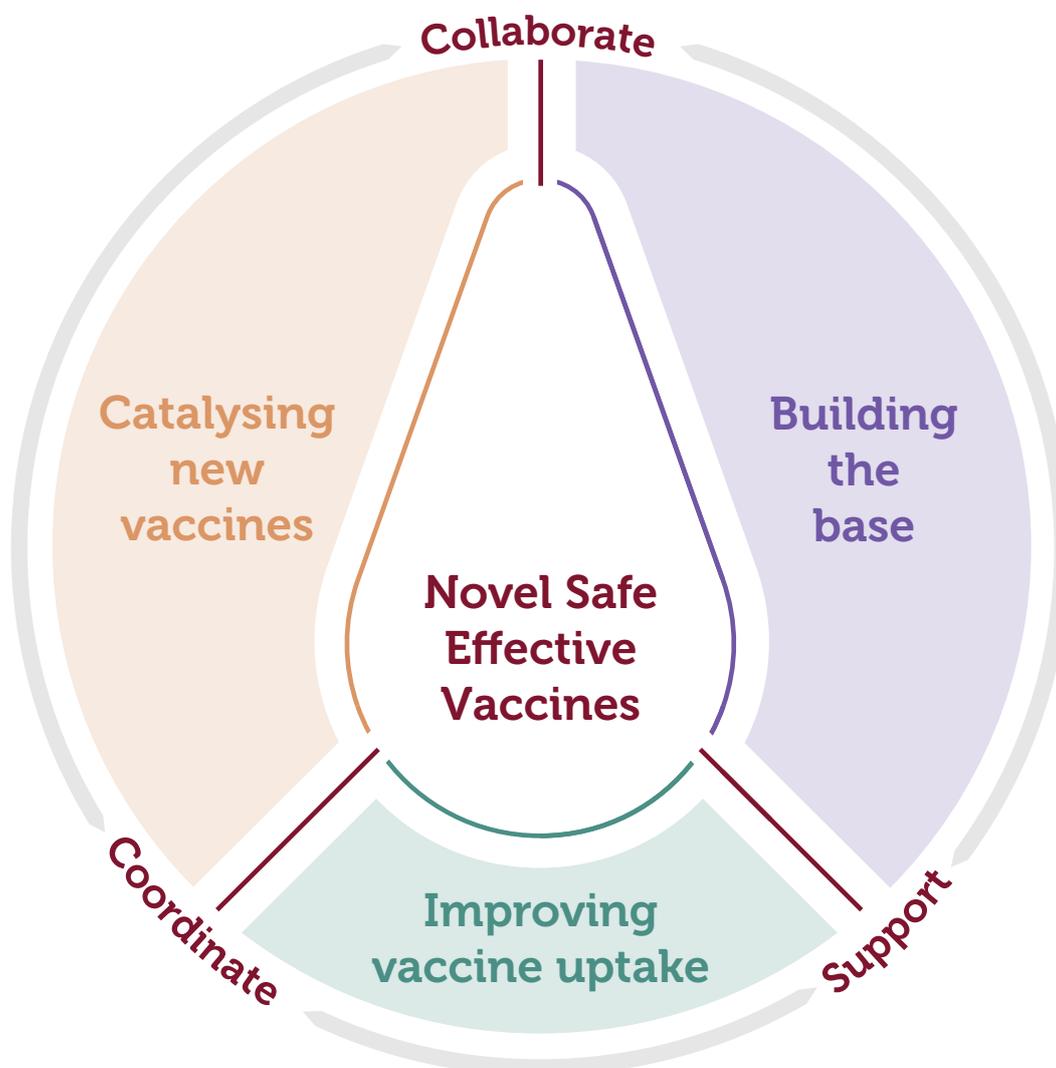
A world where vaccines create health and equity for all people

### Mission

To develop new, safe, effective, and affordable vaccines for global health through collaboration and coordination

## 4.2 EVI's Strategic focus areas 2021-2025:

Building on our existing strengths, experience, and expertise, we will operate as a reliable and active product development organisation to deploy our skills in an efficient and value-creating manner. We will pursue our mission by engaging in three interlinked activity areas: (A) translational product development, (B) strengthening vaccine R&D through cross-cutting activities, and (C) improving vaccine uptake and knowledge-sharing.





## Catalysing new vaccines: translational product development

Our goal is to catalyse the development of vaccines for global health. We will actively engage in product development activities for new vaccine candidates and build on our significant expertise in bringing early-stage vaccine candidates from discovery to early clinical trials.

Translational vaccine development and early clinical testing will remain a priority. We will take a more active role in the development of selected vaccine candidates by contributing to their scientific and technical progress. Preclinical safety and toxicology testing, formulation studies, good manufacturing practices (GMP), and early clinical trials are activities where EVI has a proven track record in delivering results in cooperation with its network of partners, collaborators, and service providers. This will be further strengthened with the ambition of adding expertise and capacity to sponsor clinical trials and design advanced clinical trials and regulatory plans.

EVI is involved in vaccine development against viral, bacterial, as well as parasitic diseases of high importance for global health.

We will have a dynamic approach to our portfolio and will get involved in new product development activities that fall within our scope of expertise. New areas will always have to reflect EVI's profile as a non-profit organisation that develops affordable vaccines for global health. Vaccine candidates will be developed in collaboration with partners, and additional efforts will be invested in actively looking for opportunities for in-licensing from academia, biotech, and pharma companies.

## Targets 2021-2025:

- 🔥 One EVI-supported vaccine candidate entering phase III trial
- 🔥 Completion of four phase II clinical trials
- 🔥 Four malaria vaccine candidates assessed in controlled human infection trials
- 🔥 Five vaccine candidates transitioned from preclinical to first-in-human clinical testing
- 🔥 Five preclinical vaccine candidates designed and evaluated



**EVI is involved in vaccine development against viral, bacterial, as well as parasitic diseases of high importance for global health.**



## B

## Building the base: cross-cutting activities

Our goal is to engage in and lead initiatives that support vaccine development -or key aspects therein- in a disease-overarching manner. This includes continued support to the establishment of a sustainable European vaccine infrastructure that would bring together, under one umbrella, a network of partners with specific expertise and capacities in vaccine development. Jointly, we can create a distributed research infrastructure that will function as an accelerator for different types of vaccines in early stages of development.

EVI has coordinated this initiative since 2009 through the three European Union (EU) supported projects TRANSVAC-1, TRANSVAC-2 and TRANSVAC-DS. **The COVID-19 crisis has exposed several weaknesses and deficits in the European -and global- vaccine R&D system, such as lacking and poorly coordinated capacities, as well as insufficient coordination of R&D activities. New and improved strategies and mechanisms for preventing pandemics and addressing them if they occur are therefore urgently needed.** The establishment of a sustainable vaccine infrastructure offers the unique opportunity to address these gaps and accelerate the development of safe and effective approaches to combat global infectious diseases.

We will also continue our involvement in and lead large scale public-private partnerships that focus on specific, cross-cutting aspects of the vaccine R&D process. These partnerships -collaborative endeavours between industry partners and other key actors in the R&D ecosystem such as academic institutions, small and medium enterprises, regulatory authorities and others- have proven efficient vehicles for driving innovation in pharmaceutical research. Such partnerships will focus on the development and standardisation of assays, GMP manufacturing, the development of human challenge models and the development of in vitro models as alternatives for animal testing.

We will take the leadership in relevant future initiatives in Europe and beyond that are expected to have a wide-spread and transformative impact on vaccine development.

## Targets 2021-2025:

- 💧 Finalise the preparatory steps for a sustainable vaccine infrastructure, including the development of detailed business and implementation plans
- 💧 Support the initial implementation phase and operation phase of the vaccine infrastructure
- 💧 Support the validation and regulatory acceptance of new in vitro assays/ models to replace animal testing in vaccine development/control
- 💧 Initiate at least three new large-scale public-private partnership initiatives with focus on development of tools to accelerate vaccine development, reduction of animals used in vaccine development, reduction of antibiotic use for bacterial infections, and epidemic preparedness



The COVID-19 crisis has exposed several weaknesses and deficits in the European -and global- vaccine R&D system, such as lacking and poorly coordinated capacities, as well as insufficient coordination of R&D activities.



## Improving vaccine uptake and knowledge-sharing

Our goal is to extend the benefits of vaccines to all people by improving knowledge access and uptake of vaccines. We will pursue this objective by creating and disseminating knowledge about vaccines and the optimisation of their use. We will oversee the execution of epidemiological studies to establish disease burden and document the impact of vaccines. We will work alongside stakeholders to reduce vaccine hesitancy in Europe, neighbouring countries and globally, while also encouraging partaking in clinical trials for vaccine development. We will collaborate with health economists, and we will engage in disease modelling, cost-efficiency analysis, and other socio-economic comparisons that can provide evidence for the benefits of vaccines and vaccination.

As an independent non-profit organisation, EVI can operate as a neutral broker and speak with authority when relaying its messages. EVI is therefore well positioned to bring together representatives from the private and public sectors, policy makers, immunization specialists, researchers, and other stakeholders. We will take active part in vaccine advocacy, and supply data and road maps that can enable decision makers to make evidence-based decisions on vaccines and immunisation.

Activities to improve the use and uptake of vaccines will also be extended to the development of strategies against vaccine hesitancy, the involvement in implementation research to secure better access to specific vaccines for specific populations, and the engagement in cutting-edge technology projects that can improve access to healthcare and vaccination.

**Disseminating knowledge, research capacity strengthening, and training are further activities that will improve vaccine R&D and secure a better uptake of vaccines.** We will continue our activities in training and capacity strengthening and will develop a dedicated strategy for delivering practical training, specialist courses and workshops in areas such as project management and translational vaccinology.

## Targets 2021-2025:

- ◆ Cost-analysis for documenting the benefit of vaccines in one or more specific areas
- ◆ Disseminating knowledge of vaccines to the broader public, decision makers and clinical trial participants
- ◆ Train MSc students, PhD students and fellows from LMIC at EVI or in collaboration with EVI's partner institutions
- ◆ Establish programmes for delivering practical training, specialist courses and workshops in project management and translational vaccinology



As an independent non-profit organisation, EVI can operate as a neutral broker and speak with authority when relaying its messages.



# 5

## Shaping EVI for the future

### 5.1 Introducing a new legal structure

EVI was formerly established as a European Economic Interest Grouping (EEIG) with Stockholm and Heidelberg Universities, as founding institutions. The legal status of EVI was changed in 2021 to a non-profit organisation, registered as an Association under German law. The change in legal structure took place to allow a more flexible membership structure and to pave the way for a broader range of activities by EVI. The constituent members of the EVI Association currently comprises the Biomedical Primate Research Centre, Rijswijk, NL; Heidelberg University, Heidelberg, DE; the Jenner Vaccine Foundation, Oxford, UK; Pasteur Institute, Paris, FR and RCSI University of Medicine and Health Sciences, Dublin, IE. EVI is lead by a Governing Board, representing each of the five constituent institutions of the EVI Association.



Mumtahina Tanni/Pexels -Bangladesh

The Governing Board of EVI is supported by a Strategic & Scientific Advisory Committee (SSAC) that is composed of internationally recognised scientists with expertise in scientific and technical subjects relating to EVI's activities. The committee operates independently and advises the EVI Board and management on strategic, scientific and technical matters.

## 5.2 Budget and fundraising

Financial support to EVI's activities will be sought by strengthening our existing relationships with funders in Europe and globally, but we will also aim to set up new partnerships with industry, biotech, charities, and venture capital firms with a genuine interest in global health. We will build strategic alliances and partnerships with like-minded organisations, including the World Health Organization, European Union, non-for-profit organisations, other product development partnerships, and industry organisations.

EVI's primary funding sources over the last years consisted of competitive grant funding from both European (EU) and national funding agencies. This has increasingly been complemented by funding from other international funders, corporate funding and other sources. New types of funding opportunities may become available as the international landscape evolves. EVI will continuously monitor the international funding landscape and evaluate opportunities as they arise, including for new forms of high impact investment.

Over the coming years we will strive to further diversify our funding base. These efforts will be facilitated by adding new activities and services that can respond to changes in global health priorities and make sure that EVI remains relevant and agile.

We will continue to operate as a lean organisation, where resources are closely monitored and deployed in the most cost-efficient manner to generate maximum value-for-money. EVI intends to maintain a low overhead as it has done since its inception. We will continuously review our working modalities to optimise operations and preserve a financially efficient management. Fixed operating costs will be minimised by introducing a highly flexible working environment and by working dynamically with our many partners.

## 5.3 Operational implementation

Based in Heidelberg, Germany, the EVI Secretariat has a diverse team representing multiple nationalities that bring together experienced professionals with backgrounds in academia, non-profit organizations, the private sector, and public institutions. EVI staff members implement the decisions of the EVI Board, liaise and negotiate with partners, oversee funded programs, and maintain financial and operational control systems.

To implement EVI's renewed commitment to our mission we will continuously optimize the strength and capability of our staff and regularly review our core strategy and disease priorities. We will continue to build an organisational culture that promotes transparency, equality and openness, while also operating as a neutral mediator between our multiple stakeholders.

We will strengthen our internal pool of knowledge and expertise by engaging actively with collaborators, scientific and technical experts across the world, providing training to all employees and by participating actively in relevant international fora and conferences. We will further complement our internal expertise with a comprehensive network of technical consultants in specialised areas.

### Ways of partnering

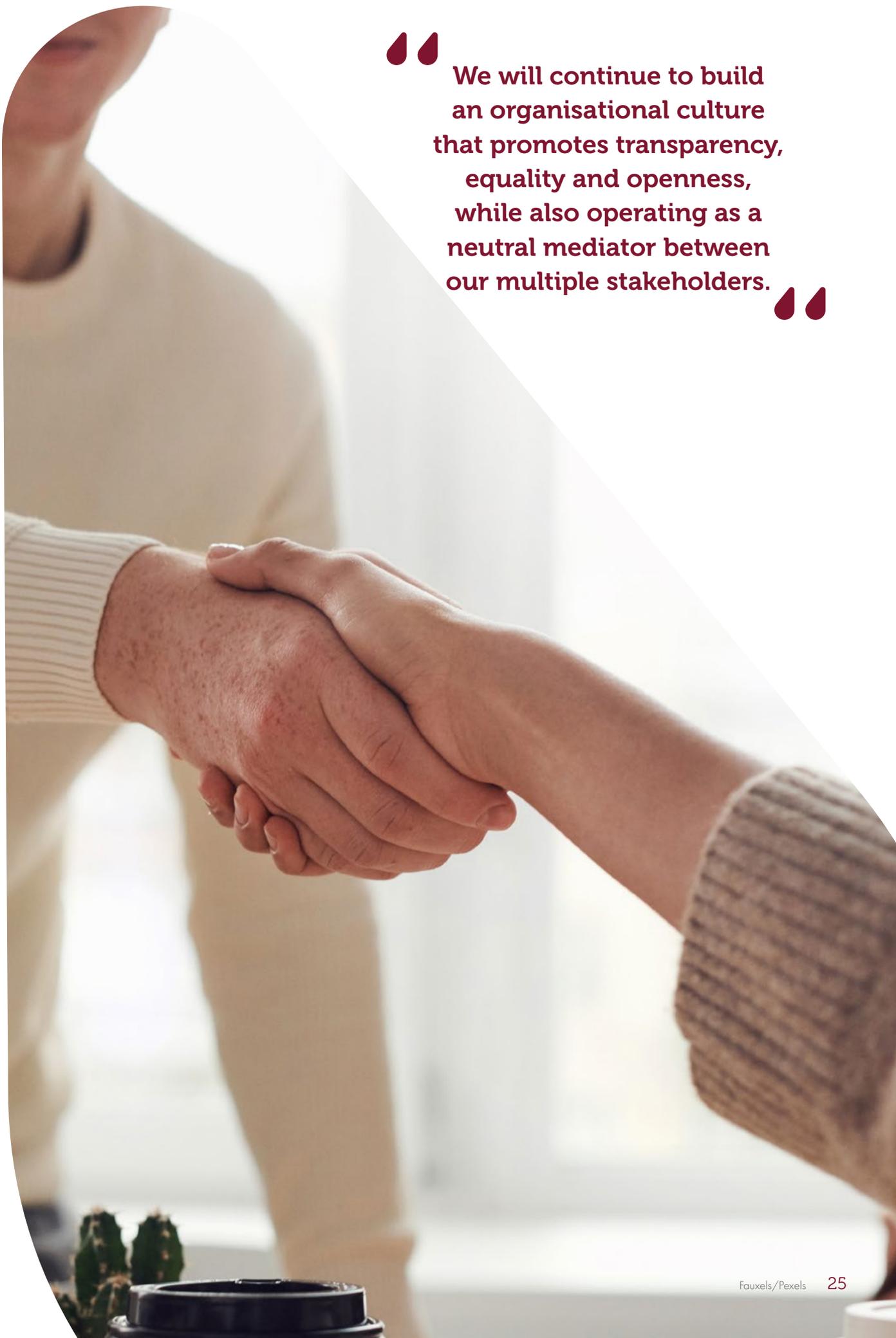
EVI has a proven track record of accomplishment in harnessing the power of alliances and therefore we will further engage in a variety of activities related to coordination of complex research projects, grant administration and communication, as well as sub-contracting and partnering related to GMP manufacturing, toxicology studies, regulatory advice and clinical trials activities. In doing so, we will build on existing partnerships while also seeking new partnerships with like-minded organisations across the world. We particularly aim to establish long-term business relationships that extend beyond individual projects.

In addition to our long-term partnerships, we will also extend our capability to provide specific services such as project management, grant administration, consortia set up, support with regulatory activities, design and implementation of preclinical and clinical development plans and GMP manufacturing through commercial consultancy contracts, among other services and activities.

### Risk management

To minimise our operational and financial risk, we have implemented a comprehensive set of checks and mitigation procedures. These include first and foremost a comprehensive audit program, including internal as well as external managerial, technical, financial and HR audits. This will continue.

Operational risks are equally monitored through a comprehensive risk management log, which identifies potential operational risks and their potential impact on EVI, both at the individual project level and for the organisation as a whole.



**“ We will continue to build an organisational culture that promotes transparency, equality and openness, while also operating as a neutral mediator between our multiple stakeholders. ”**



**Working with partners globally to catalyse a world where vaccines create health and equity for all people.**



## Abbreviations:

<b>4CMenB</b>	Meningococcus B
<b>AMR</b>	Anti-microbial Resistance
<b>CEPI</b>	Coalition for Epidemic Preparedness Innovation
<b>EEIG</b>	European Economic Interest Grouping
<b>EMVI</b>	European Malaria Vaccine Initiative
<b>EU</b>	European Union
<b>EVI</b>	European Vaccine Initiative
<b>GAS</b>	Group A Streptococcus
<b>GMP</b>	Good Manufacturing Practices
<b>HIV</b>	Human Immunodeficiency Virus
<b>HPV</b>	Human Papilloma Virus
<b>LMICs</b>	Low- and Middle-income Countries
<b>MSc</b>	Master of Science
<b>NHP</b>	non-human primate animal
<b>PhD</b>	Doctor of Philosophy
<b>PKDL</b>	Post-kala-azar dermal leishmaniasis
<b>R&amp;D</b>	Research and Development
<b>SDG</b>	Sustainable Development Goal
<b>SSAC</b>	Strategic & Scientific Advisory Committee
<b>TDR</b>	Special Programme for Research and Training in Tropical Diseases

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