

**We have a special assignment:
your health**

FVR – Finnish Vaccine Research
Overview of 2022

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CEO'S REVIEW

2022 was a year of laying the foundations

FVR – Finnish Vaccine Research became fully operational on September 1, 2022, when the founding organizations, Tampere University Foundation and the Finnish Institute for Health and Welfare (THL), transferred their commercial vaccine research operations, assets, and personnel to the newly established special-assignment company of the Finnish state.

Prior to the transfer, a significant amount of preparation and ramp-up of operations took place during the spring and summer of 2022. This work has laid the foundation for responsible and high-quality as well as financially sustainable operations. The Board of Directors appointed the company's Management Team during the spring. At the same time, key personnel were hired in the areas of ICT, contract law, and quality and risk management. Partnerships were established in areas of human resources, finance and accounting, and information technology.

In addition to the main company name (Finnish Vaccine Research Center Finvac Ltd), the auxiliary company name FVR – Finnish Vaccine Research, by which the company is now better known, was registered. Work to create a unified brand and corporate identity was started and will continue in 2023, for example through unifying the customer experience at research clinics.

Through 2022, proactive media and social media work was carried out in order to increase awareness of science-based vaccination expertise and public acceptance on the topics of respiratory syncytial virus (RSV) and Borreliosis (Lyme disease), for example.



CEO's review

Professional, caring, responsible

FVR's mission and forward-looking starting point for the development of the company's operations is to promote health security, science-based vaccination expertise and public acceptance by means of high-quality vaccine research. In addition to the company strategy, the organizational culture of the evolving FVR is based on the values that have been defined together with the company's employees: professional, caring, and responsible.

The Board of Directors and the Management Team worked together over the summer to develop FVR's first strategy. The strategy guides the development of the company's operations with clear focus and priorities. FVR's foundations are based on the solid expertise of vaccine research that was transferred to the company by its owners. The strategy evolves over time and will be regularly reviewed.

Strong position to meet international demand

Despite the challenging global situation, the outlook for investments in vaccine research remains good. The company sees significant future growth potential in the areas of Real-World Evidence studies and large-scale pragmatic trials. At the same time, the relevance of pre-licensure clinical trials remains undisputed, and the company is ready to meet this demand, targeting sustainable growth in the international competitive environment. Comprehensive expertise in clinical vaccine research, an extensive network of research clinics, and solid know-how in national registers and data resources provide excellent prerequisites for success.

Ilkka Haukijärvi

Chief Executive Officer

The strategy guides the development of the company's operations with clear focus and priorities.

FVR's foundations are based on the solid expertise of vaccine research that was transferred to the company by its owners.

REVIEW BY THE CHAIRPERSON OF THE BOARD OF DIRECTORS

Finland invests in vaccine research excellence

Finland has the opportunity to play a key role at the forefront of international vaccine research, contributing significantly to improved health security. In addition to expertise built on decades of experience, the exceptional data resources and reliable operating environment make Finland an attractive market for research investments by international vaccine developers.

The Finnish government and the Tampere University Foundation jointly established a special-assignment company of the state specializing in vaccine research, in order to enable well-researched, effective and safe vaccines both in Finland and around the world. The establishment of the company further strengthens Finland's expertise and reputation as one of the leaders in high-quality vaccine research. The divestment of the commercial vaccine research services previously operated under the Finnish Institute for Health and Welfare (THL) support the independence of THL in its regulatory and expert role.

The establishment of the company and the composition of its Board of Directors was discussed by the Finnish government in December 2021, and the company was registered in the Trade Register in January 2022. On September 1, 2022, the vaccine research services of THL and the Vaccine Research Center of Tampere University were merged into a special-assignment company with a 51% state majority ownership. In order to obtain a majority stake, the state made a capital investment of EUR 6.7 million in the company. Tampere University Foundation owns 49% of the company. After the start-up phase, the company's operations will be financed primarily by revenues generated by the business.



Review by the chairperson of the board of directors

The company's Board of Directors appointed Ilkka Haukijärvi, Ph.D., as the company's CEO. In the spring of 2022, the Board of Directors also appointed the company's Management Team ([see page 17](#)). The operative management of the company combines strong medical and vaccine research expertise, organizational and change management experience, and commercial insight.

During the first year of operations, the Board of Directors of the company has met frequently and worked closely with the Management Team, deciding on matters related to good governance and the development of the company. This work continues in 2023.

Good prerequisites for operations, despite challenging global economy

- the international market for vaccines is growing
- pharmaceutical manufacturers' R&D investments are increasing
- public acceptance of vaccines is high in Finland
- Finnish health data resources are comprehensive and up-to-date

Review by the chairperson of the board of directors

Finland has a unique opportunity

Vaccine development is thriving internationally in order to control both new and known pathogens. New technologies, such as mRNA, are under intense development. In addition to the traditional pharmaceutical manufacturers, there are some new significant players emerging in the field of vaccine manufacturing.

The market for vaccine research is highly international. A Finnish company competes with similar private companies, public entities and universities in other countries. A competent organization is well positioned to achieve and maintain a significant position in the international competitive arena. Finland's strengths include an educated and health-conscious population willing to participate in studies, and good prerequisites for cooperation with the scientific community and health care providers. FVR's role in the advancement of public health and vaccine awareness is significant. The goal is to maintain and strengthen this role also in the coming years.

Liisa-Maria Voipio-Pulkki

Chairperson of the Board of Directors

FVR's role in the advancement of public health and vaccine awareness is significant.

FVR in brief

Special assignment: commercial vaccine research and related expertise for the needs of society, public authorities, and vaccine manufacturers.

Ownership

Finnish government 51%

Tampere University Foundation 49%

Clients

International vaccine manufacturers aiming for commercial license and, in the future, also universities and research institutes.

Network of clinics

Ten clinics at nine locations. Additional offices in Tampere (head office and Real-World Evidence research unit) and Vantaa.

Research (in 2022)

- 27 trials in various stages, against 10 different pathogens
- 2,300 enrolled new volunteers

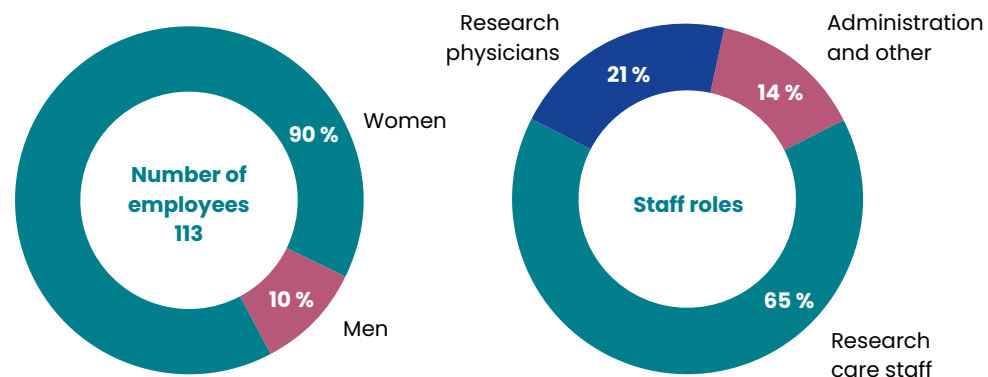


Organization

Two business units and enabling functions.

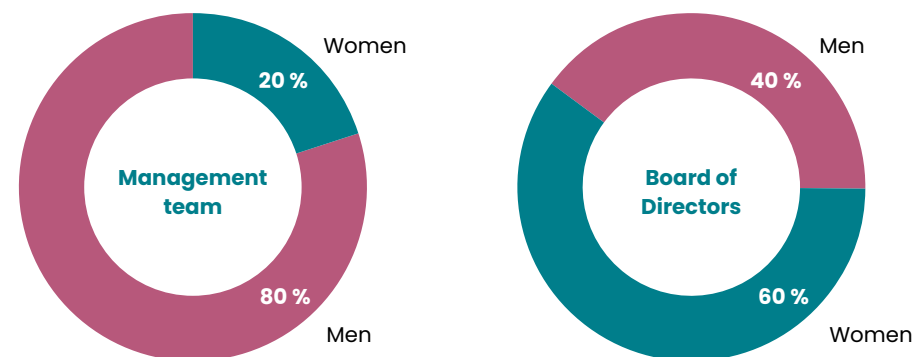


Employees (end of 2022)



- Average age of employees 45 years
- Average length of service in years: 10.5

Management



Clinical Vaccine Research (CVR)

The CVR business unit consists of the staff and assets transferred from the Tampere University's Vaccine Research Center. The business unit employs the majority of FVR's staff and currently covers ten clinics throughout Finland. CVR specializes in commercial clinical vaccine research commissioned by vaccine manufacturers, i.e. international pharmaceutical companies.

Post-laboratory clinical vaccine research involving human subjects focuses particularly on phase 1–3 studies aimed at obtaining a commercial license. These studies are important in order to reliably demonstrate the safety and efficacy of a trial vaccine before large-scale deployment. In particular, phase 3 studies aim to demonstrate the relative efficacy of the vaccine against a well-defined, confirmed case of the disease in relation to a reference product or placebo. This is a prerequisite for obtaining a license from the regulatory authorities. Most of the vaccine studies conducted by CVR are phase 3 trials. The unit studies dozens of vaccines each year, and thousands of Finns volunteer to participate in the studies.

Each clinic has its own team, including professional study nurses, laboratory nurses and physicians. The team is responsible for conducting the studies following a unique research plan, national and international legislation, and the guidelines for Good Clinical Practice (GCP).



Real-World Evidence (RWE)

The RWE business unit consists of the clinical vaccine research group transferred from the Finnish Institute for Health and Welfare (THL). RWE conducts phase 4 post-licensure safety and efficacy vaccine studies based on Real-World Evidence (RWE). The unit utilizes national health registers to study the burden of vaccine-preventable diseases, their complications, and the health care resources required in relation to different population groups.

A particular strength of the RWE unit is the ability to conduct large-scale pragmatic vaccine trials, where research is conducted in collaboration with public health care providers. Large-scale pragmatic trials help in evaluating vaccines for the national vaccination program, for example. Monitoring subjects based on real-world data from national registers significantly reduces the cost of the study and allow for a large sample size.

Up to tens of thousands of volunteers participate in extensive pragmatic trials. Finland has excellent conditions for conducting such studies thanks to its up-to-date and high-quality population information systems and national health registers.



FVR's role in the value chain

Trial sponsors and the ecosystem

The trials are commissioned by international pharmaceutical companies (vaccine manufacturers). The practical implementation of the trials is carried out by research organizations such as FVR. The trials are typically large multinational collaboration projects, involving multiple vaccine research units from different countries and continents. There are also a number of CROs (Clinical Research Organizations) in the market that provide certain elements of related services, such as monitoring, to client companies.

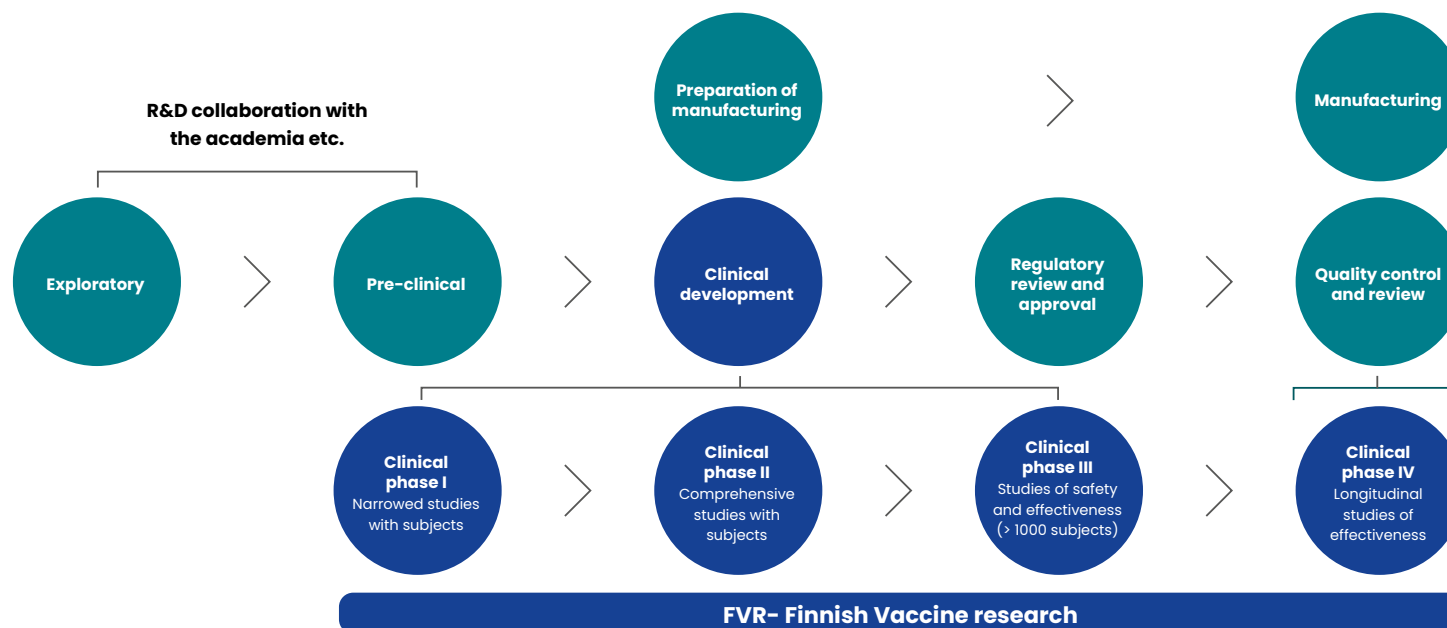
Independent research and quality

Independence and trust are the foundation of FVR's operations. For example, the vaccine manufacturer responsible for the development and commercialization of a new vaccine may not, under any circumstances, own or manage the research units where phase 2–4 clinical trials are conducted. FVR manages and puts in place the necessary processes and expertise to ensure that the trial and its operations meet the requirements for independence and impartiality. The high quality of clinical trials is a key success factor in vaccine development.



The services offered by FVR

FVR offers comprehensive clinical vaccine research expertise aimed at obtaining a license for marketing authorization (phases 1–3), as well as post-licensure investigations into the effectiveness and safety of vaccines already in use (phase 4). Vaccine manufacturers develop new vaccine candidates, and the clinical trials progress from small-scale safety studies in healthy individuals (phase 1), to safety studies in the actual target group (phase 2), to increasingly larger studies (phase 3) with the goal of demonstrating the vaccine efficacy in the target group in order to apply for licensure. The number of post-licensure (phase 4) studies is increasing as authorities increasingly require clinical evidence of the product's efficacy and safety in routine use. These Real-World Evidence (RWE) studies and large-scale pragmatic trials draw on national health registers and may involve extensive collaboration with health care organizations as well as tens of thousands of volunteers.



Company strategy

We specialize in world-class vaccine research as a service

Our strengths in the market are based on four main pillars:

- We offer comprehensive vaccine research expertise, an extensive network of research clinics, and solid know-how on the utilization of data resources.
- We promote research, development, and innovation in our industry through proactive cooperation with higher education institutions and other value-chain operators.
- We make use of Finland's national strengths in the international research landscape.
- We create a company culture that attracts and retains the best talents in the industry and provides meaningful work.

Goals

- internationally sought-after partner for the pharmaceutical industry for the different phases of vaccine research as well as pragmatic vaccine trials and RWE studies
- known for excellent employee experience
- above-the-market profitable growth
- sustainable and bold reformer of the industry and a respected operator in the RDI ecosystem
- joining pilots, forging partnerships, and seeking solutions for the future

Prerequisites for success

- strategic agility, proactive reformation, and client-oriented research
- high level of competence and well-being at work, competitive employer profile
- profitability and channeling the assets of the company in a way that enables future growth
- active player in the field of RDI both nationally and internationally
- proactive development of client and stakeholder relations

Company strategy

Setting up the foundations in 2022

- Nominations and launch of the work of Board of Directors, CEO and Management Team
- Preparations for the transfer of assets
- Creation of the structures for the limited liability company, key processes, tools, policies and support services
- Preparation for health care provider license, external audits of clinics, implementation of the patient record system
- Transfer of employees on September 1st, inductions

Strategy implementation in 2022

- Strategy work and active cooperation between Board of Directors and Management Team
- Development of the management system; updating the project and sales pipeline follow-up and reporting practices
- Identification of development needs in the organizational model
- Establishment of key metrics and KPIs and performance-based rewarding system
- Measurement of baseline employee experience and identification of areas for improvement
- Active recruitment of key personnel, appointments of the Regional Lead Physicians, setting up a career path model for researchers
- Launch of the Occupational Safety and Health Committee and the Cooperation Group
- Ramp-up of brand, internal and external communications, and marketing
- Launch of development projects: e.g. organization and resourcing of work, corporate responsibility, project management, and project monitoring
- Preparation of the first annual business plan
- Set-up of quality and risk management practices, implementation plan for internal audit, external audit of information security

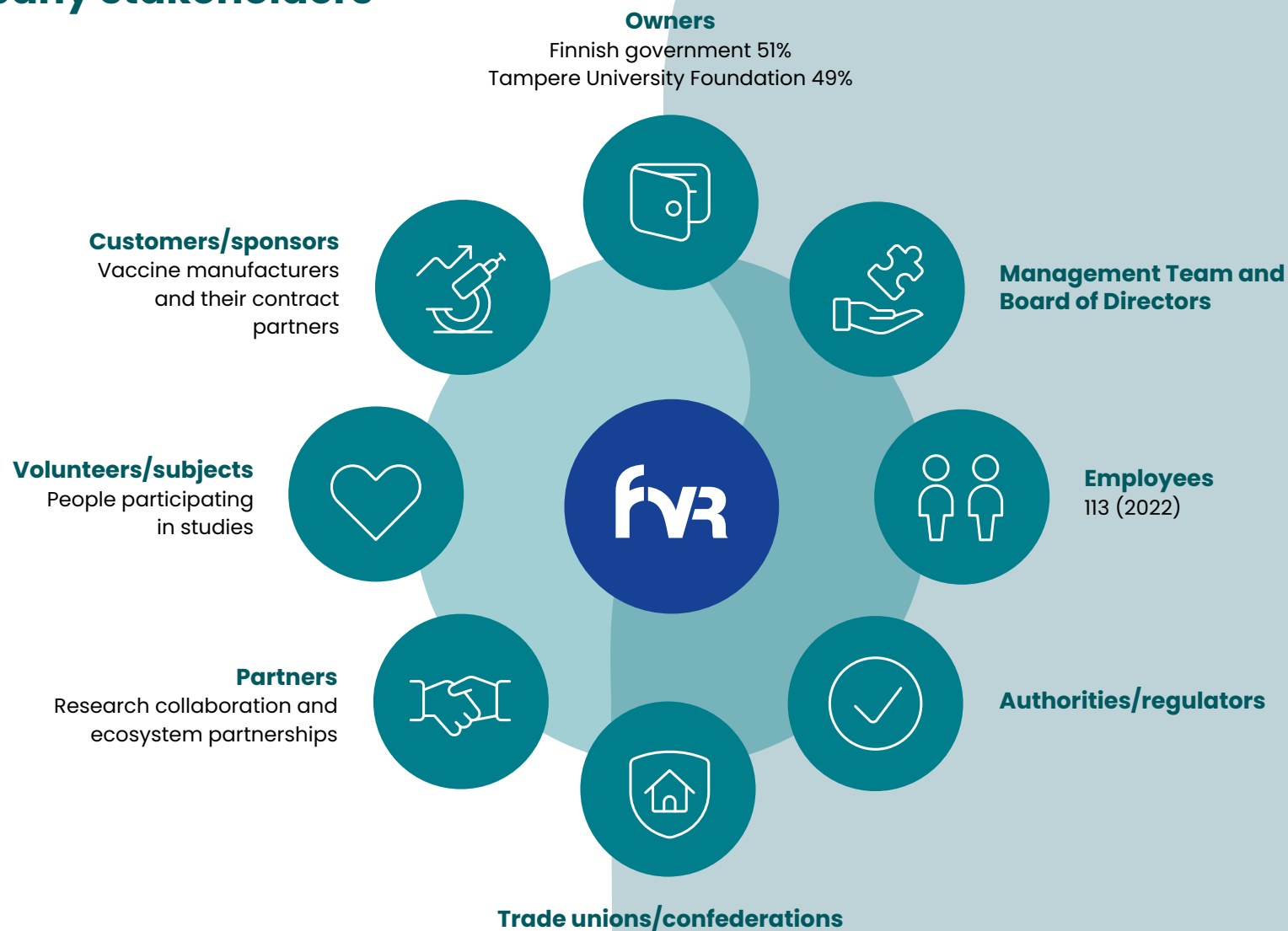
Mission

We promote health security, science-based vaccination expertise and public acceptance by means of high-quality vaccine research.

Vision

We are among the most respected operators in our field worldwide.

Company stakeholders



Corporate governance

Board of Directors



Liisa-Maria Voipio-Pulkki
Ministry of Social Affairs and Health
Chairperson of the
board of directors
M.D., Ph.D., title of docent



Juhani Eskola
Independent
M.D., Ph.D., professor



Saara Hassinen
Healthtech Finland (part of
Technology Industries Finland)
Master of Science
(chemical engineering)



Sirpa Jalkanen
University of Turku
M.D., Ph.D.,
Research Director,
professor, academician



Tapio Visakorpi
University of Tampere
M.D., Ph.D.,
Professor of Cancer Genetics

Management Team



Ilkka Haukijärvi
Chief Executive Officer
Ph.D., information systems



Mika Rämet
Chief Medical Officer
M.D., Ph.D.,
Professor of Paediatrics and
Experimental Immunology



Arto Palmu
Chief Research Officer
M.D., Ph.D.,
University Lecturer in
Clinical Epidemiology



Harri Leiviskä
Chief Financial Officer
M.Sc. (Econ.), MBA

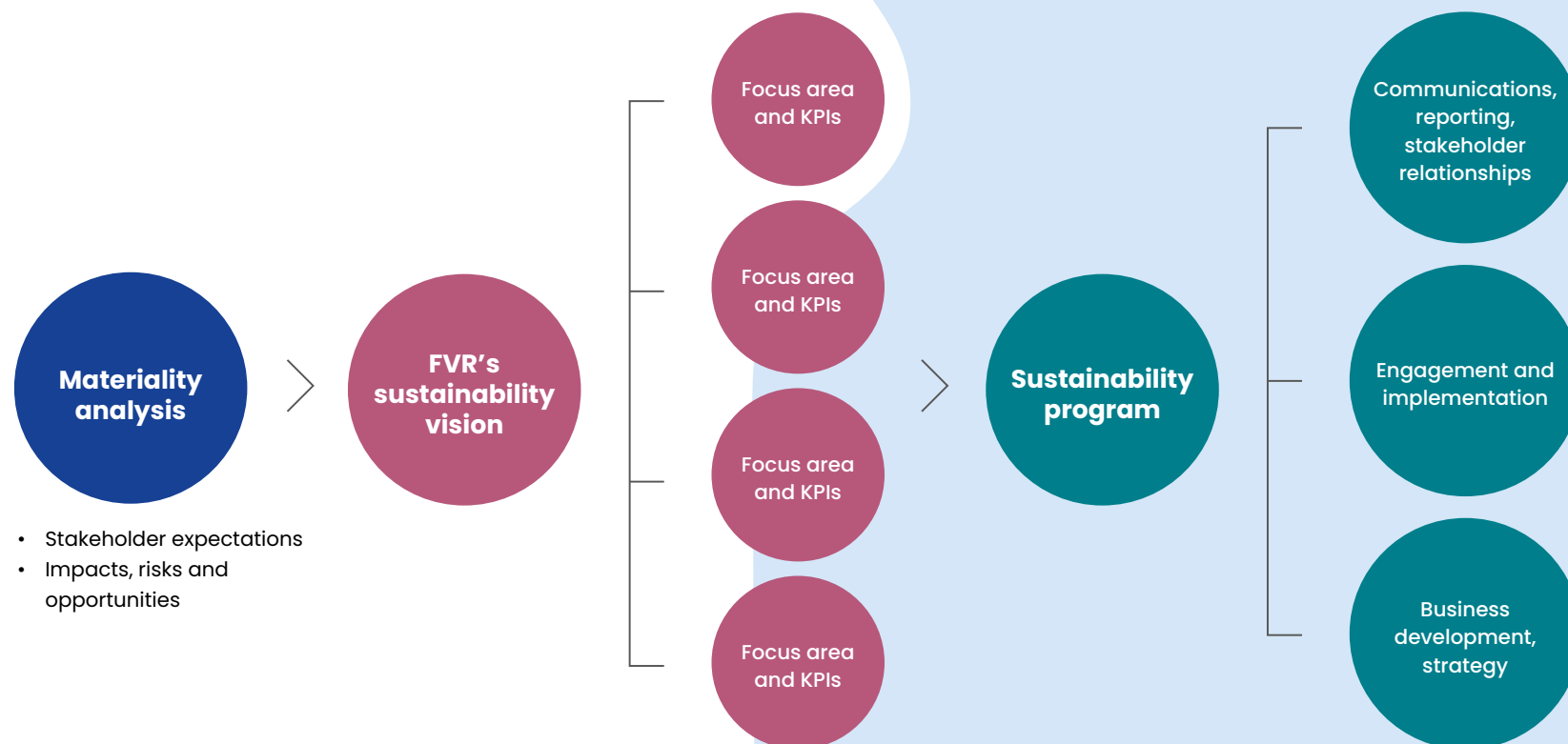


Marikka Nevamäki
Chief Communications &
Marketing Officer
Master of Social Sciences

Sustainability

Sustainability agenda-setting started with a materiality analysis

The work to define FVR's sustainability program started in January 2023 with a materiality analysis. The analysis will be used to identify the sustainability focus areas that are material to the company's operations. This includes consultation with the company's key stakeholders. After the completion of the materiality analysis, FVR's corporate sustainability agenda and related indicators will be defined, and an action plan and monitoring procedures will be established to achieve the set goals.

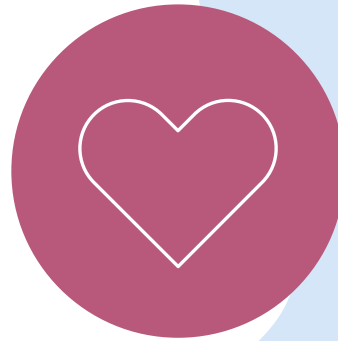


FVR's values have been defined together with the employees



Professional

- We produce reliable research evidence and share our expertise.
- Our work is founded on the best scientific practices.
- We actively seek ways to develop our skills, ways of working, and industry.



Caring

- We are kind and respectful when interacting with others.
- We care for the safety and well-being of each other.
- We demonstrate good collaboration skills towards each other and our partners.



Responsible

- We want to provide people with a better quality of life through good immunization coverage.
- We work ethically, diligently, and in a trustworthy way.
- We take responsibility for our actions.
- We communicate honestly and transparently.

Examples of research activities

Pneumococcal vaccine

Pneumococcus (*Streptococcus pneumoniae*) is a bacterium that thrives in the human respiratory tract. In mild cases, it causes ear and sinus infections. However, it can cause more serious conditions that require hospitalization, such as pneumonia, sepsis, or meningitis.

The pneumococcal bacterium is spread by droplet transmission when a person coughs or sneezes. There are approximately 100 known serotypes of *Streptococcus pneumoniae* and new strains of the bacterium are constantly emerging, so efforts are being made to develop vaccines that are more broadly effective. Children, the elderly, and people with chronic illnesses are more susceptible to pneumococcal diseases due to a weakened or less developed immune system. The pneumococcal vaccine was added to Finland's national vaccination program in 2010.

Due to vaccinations, the types of pneumococcal bacteria that cause serious diseases have changed in recent years, and current vaccines do not protect against all subtypes of the pneumococcal bacterium. The pneumococcal bacterium has also become more resistant to antibiotics, making it even more important to prevent infections through vaccination.

FVR has participated in several pneumococcal vaccine trials over the years. In 2022, we participated in a pneumococcal vaccine trial commissioned by MSD (Merck Sharp & Dohme). The trial aims to introduce a more broadly effective vaccine that also protects against the altered forms of pneumococcal bacteria. The target was to enroll more than two thousand adults between the ages of 18 and 49 internationally for the trial. During 2022, approximately 140 Finns received either the research vaccine or the already licensed control vaccine from FVR. Study results are expected to be published at the end of May 2023.


Vaccine for RS virus infection

RSV (respiratory syncytial virus) is an infectious virus and a common cause of respiratory diseases. The virus can affect the lungs and the respiratory tract of an infected person and can be life-threatening for infants, older adults, and people with certain chronic illnesses. In addition to infants, people over the age of 65 who have a heart or lung disease or a disease or medication that weakens the immune system are particularly at risk. The RS virus is especially prevalent during the winter months.

FVR has been involved in several studies of RSV vaccines for young children, pregnant mothers, and the elderly. For example, during 2022, FVR studied a vaccine candidate in a trial commissioned by GlaxoSmithKline (GSK), aiming to protect older adults against RSV respiratory infections. In the trial, adults aged 65 years and older received the RSV vaccine and the influenza vaccine either separately or at the same time. The target was to enroll 1,030 participants internationally, and 110 Finns received the vaccines in 2022. Results are expected to be published in July 2023.






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