Suomen rokotetutkimus
Finnish Vaccine Research

We have a special assignment: your health

FVR – Finnish Vaccine Research

Overview of 2024

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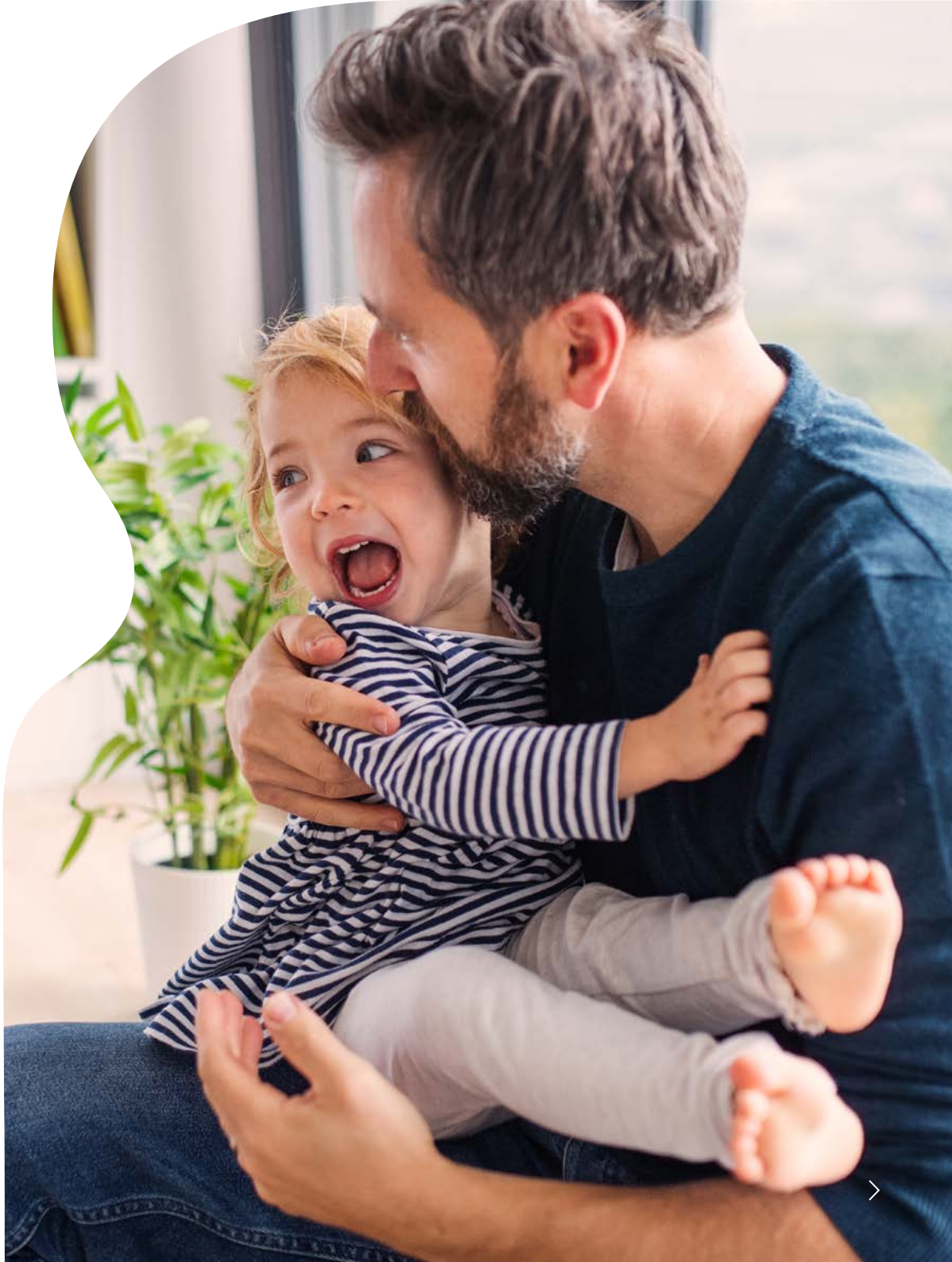
Content



We are investing in increasing the impact made by FVR

Determined work to develop the necessary enablers for the growth and competitiveness of FVR continued in 2024. This means reinforcing partnerships and customer relationships, redesigning operating procedures, roles, and organizational structures, and recruiting complementary competencies. The company's three-year strategy for 2025-2027 was also revised in the course of the year, focusing on increasing impact and productivity.

2024 started with operational restructuring aiming at securing future opportunities and growth possibilities in the competitive environment of international research. As a result of the reorganization negotiations, the company decided to merge the two small clinics in Helsinki into one larger clinic and to gradually shut down the Pori clinic. Investing into the flexibility and scalability of operations in the most populous region in Finland will improve our future opportunities for succeeding in volunteer enrollment as best as possible. The new clinic will be located in the Kluuvi shopping center in central Helsinki and is scheduled to be opened on February 1st, 2025.

Strengthening key competencies and promoting sustainability

In connection with the restructuring, the company also improved the efficiency of its operations by redesigning its organizational model and by reallocating roles. Both medical and nursing/study coordination expertise and competencies were strengthened, and the company's expert profile was enhanced by recruiting experts in the international pharmaceutical industry.

The foundations for FVR's research, development, and innovation efforts began to take shape. We hired expertise in the field to reinforce FVR's networks both domestically and internationally and to create growth opportunities in line with the company strategy. We are taking part in a Europe-wide pandemic preparedness project, Be Ready Plus. This project spans across several key European institutions and is funded by the European Commission. The Project will greatly support the continuation of joint European research and development, and most importantly, the readiness to quickly and efficiently respond to any future pandemics. The total funding for the first seven years of the project is 100 million euros. FVR is representing Finland in the project as one of the key partners.

The financial results for 2024 were mostly in line with expectations, partially exceeding targets. Revenue for 2024 was €12.1 million (€14.1 million in 2023). The decline in revenue from 2023 was due to clients' decisions to postpone some of their research assignments globally to 2025. In the industry, the postponement of research assignments is not uncommon, as various factors and dependencies influence whether the development of a research product can proceed to the next phase (phases 1-4). The operating profit for 2024 was €0.7 million, exceeding targets, primarily enabled by improvements in operational productivity, structural reforms, and successful execution of newly initiated research assignments. Overall, the key financial indicators for the year were good.

With regard to sustainability work, FVR is a pioneer among small and medium sized companies in Finland. As a participant in the UN's Global Compact initiative, we report on the advancement of the ten principles of the Global Compact and the UN sustainable development goals in company operations. Over the year, we completed baseline analyses on e.g. energy use,

>30
vaccine trials

Revenue
€12,1M

Operating profit
€0,7M

business travel, and waste management, and surveyed the sustainability maturity-level of our main subcontractors. We also began preparations for important ISO certifications, the first of which (ISO27001) was completed according to plan.

The change curve impact was expected

The significance of our work is reflected in its quality. As an employer, we offer our employees exceptional working conditions: international partnerships, vaccine-positive voluntary clients who greatly appreciate our work, diverse opportunities to develop their skills alongside their job, flexible working hours according to life situations, a sustainable value base, a community committed to continuous improvement, high-quality leadership, regular daytime work, and competitive compensation. According to the Work Pulse survey conducted in the fall, the average work vitality in our community was at a good level (3.9/5). 95% of our employees find their work meaningful. This foundation, which promotes people's well-being, is a good basis to build upon.

The feedback received from the volunteers enrolling in our trials at our clinics has continued at an extremely high level, being >95/100 monthly. This is thanks to our skilled and committed personnel responsible for the customer experience and everyday operations at our clinics.

The sponsor net promoter score remains rather high at 70, and our partners at both international pharmaceutical companies and clinical trial monitoring service provider companies value FVR's high-quality data, professional, smooth, and trustworthy partnerships, and skilled personnel. The changes made to the clinical research organization model and role allocations caused some disturbances to our B2B partners as well. However, going forward, the changes will result in tangible advantages for all stakeholders.

The feedback received from the volunteers enrolling in our trials at our clinics has continued at an extremely high level, being >95/100 monthly.

Europe: it is time to step on the gas

The international pharmaceutical industry continues on a growing path, and investments into vaccine development follow this trend. However, the growth is not evenly distributed in geographical terms: Europe is falling behind the rest of the world – the USA and China in particular. Although the number of clinical trials has increased by 38 percent globally in 2013–2023, the share of trials conducted in the European economic area has halved during this period. Turning this trend around requires strong common will and swift mutual action.

At the global level, the share of commercial pharmaceutical trials in the European economic area has fallen from 22 percent in 2013 to 18 percent in 2018, and even further to 12 percent in 2023. With regard to vaccine studies specifically, the numbers in Europe are no better: although the number of commercial vaccine trials conducted worldwide is growing, the European share has fallen from 17 percent in 2018 to 8 percent in 2023. There are significant differences between European countries, and Southern Europe is growing its share of business here.

For long, Europe has been a leading region in clinical pharmaceutical research. However, increasing competition has become apparent in the recent years. European challenges to clinical trials include a fragmented research ecosystem and a regulatory and financial environment that slows down competitiveness.

In the bigger picture, attracting research investments in Europe is not only about the economic vitality and competitiveness of the region; clinical trials also provide citizens access to new, more efficacious medications and vaccines. In other words, they improve people's well-being and quality of life.

European competitiveness should be supported by means of uniform and agile regulation that is attractive to international research investments.

In order to boost European competitiveness, it should operate as a conjoined region, not as a collection of individual member states. No European country is alone able to challenge the economies or populations of China or the USA. European competitiveness should be supported by means of uniform and agile regulation that is attractive to international research investments.

FVR is doing its part to rise up to the challenge in line with its revised three-year strategy by focusing on improving the impact and productivity of its operations. We seek to increase our research enrollment volumes and invest in the prerequisites that enable this, such as the scalability of our research infrastructure and capacity, and the visibility and networks of our expertise and partnerships. In the pursuit of productivity growth, the focus is on promoting the digitalization of clinical research and operational activities and on developing processes.

We are also reaching out to other operators in the value chain, extending our hand in willing cooperation. Together with the local organizations of pharmaceutical companies, Pharma Industry Finland, and other stakeholders, we are promoting Finland's attractiveness as an entity with specialist capabilities in medical research. The company's ownership is supporting this development. What is needed for success is cooperation across organizational borders, flexibility, and the capability to evolve.

Ilkka Haukijärvi
CEO

Our strategic focus areas in support of greater impact and productivity:

- research infrastructure and capacities
- customer and employee experience
- partnerships and competencies

How does Finland compete in the international market for vaccine trials?

The Finnish government has identified the health industry's potential for contributing to growth and the need to invest in research and development. Even in a challenging economic situation, R&D investment is an investment in the future.

Over the course of 2024, the FVR organisation has been redesigned for increased flexibility and scalability, and to meet the demands of our dynamic operating and competitive situation. The goal was to enable maximum efficacy of the valuable expertise accrued by the company and its predecessors. In addition, we have strengthened our capabilities in the fields of medical expertise and international business. These actions have a strong link to the implementation of the company's strategic objectives: we strive to be a valued and sought-after partner for our international customers, while on the national level, we aim to promote health security, availability and public acceptance of vaccines, and scientific research within our field.

When planning and deciding on the actions, the Board of Directors and the company management have worked in a highly collaborative and future-oriented manner. This also applies to communicating with FVR's owners. Changes in our operating environment further highlight the importance of preparing for threats to public health and, on the other hand, the significance of competitive R&D capabilities. These were among the key focus areas as we established the company, but they have been further highlighted through the insights gained from the COVID pandemic and the acceleration of vaccine research by global pharmaceutical companies.

In comparison to many countries, Finland's challenge is its small population, but our strength is Finns' positive attitude to vaccine studies. As one of the leading countries in digitalization, we have an opportunity to harness operating models enabled by new technologies to our competitive advantage. In this field, we already have gained positive experiences: for example, we have been able to initiate studies faster as participants have been able to book their own appointments. Successfully completed studies are a great showcase as FVR seeks a stronger international position as a reliable, agile and innovative provider of clinical vaccine trials.

Fertile soil for vaccine research is created together

Regardless of national interests and investments, vaccine research is part of a global value chain that cannot exist without other actors in the chain. Finland's attractiveness for investments by the international pharmaceutical industry depends on a number of factors, for example, the overall conditions in Europe impact the equation. Other significant factors include experiences about the proactivity of national authorities, fast and agile operating models, a research-positive outlook, access to health data as well as cooperation between public health organisations and the private sector. These result in strong internal coordination and trust within the value chain.

As a response to the aging population of countries with high standards of living, pharmaceutical companies are currently developing a significant number of vaccines for viral diseases that affect the adult population. New vaccine technologies and combination vaccines are quickly gaining ground. It is in the best interest of both Europe and Finland to ensure that we provide fertile soil for clinical trials. To achieve this, we need each other and a common European ambition – throughout the value chain.

Liisa-Maria Voipio-Pulkki
Chairperson of the FVR Board of Directors

Vaccine research is part of a global value chain that cannot exist without other actors in the chain.

FVR's study partners

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. In Finland, clinical vaccine trials are supervised and approved by the Finnish Medicines Agency Fimea. In addition, the studies need the approval of the National Committee on Medical Research Ethics (Tukija). All studies follow Good Clinical Practice (GCP) and their implementation is monitored regularly with official inspections.

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 organizations looking for real-world evidence.

Network of clinics

Eight clinics at nine locations. Additional offices in Tampere (head office and Real-World Evidence research unit) and in Greater Helsinki area.

Research (in 2024)

- 24 trials, against 9 different pathogens
- 1594 new volunteers visited our clinics to take part in ongoing trials

In 2024, we piloted new operating tactics to increase enrollment capacity

In 2024, we piloted several new operating tactics to increase our ability to quickly enroll large numbers of voluntary participants for studies. These included collecting a volunteer-pool in advance of studies (thousands of volunteers), enabling self-service appointment booking, flexible opening hours, and the use of temparary laborforce at peak times.

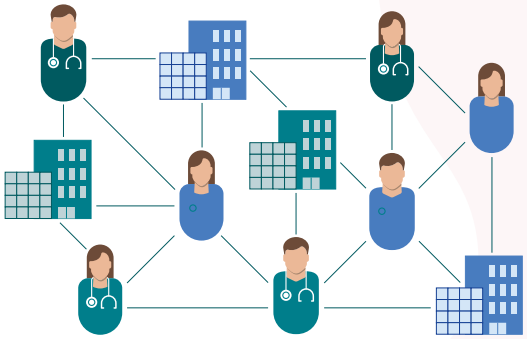
With the help of these measures, we were able to increase the daily number of appointments per clinic to up to 25 per day, which is a significant improvement in the operation of our small units.

Phases 1-4 of vaccine research

including registry / RWE data and large-scale pragmatic studies.

Broad national network of clinics, only one contract

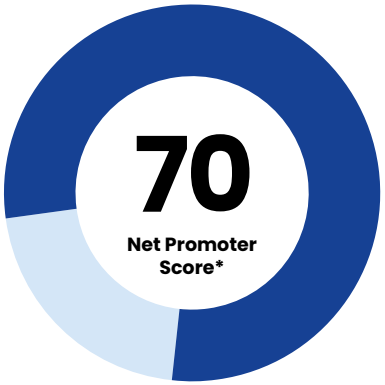
Smooth collaboration with healthcare providers.



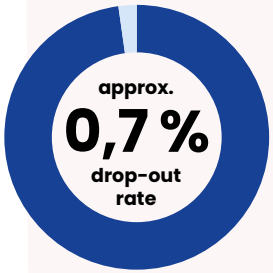
Approx. 100 GCP-qualified research experts

across Finland, with decades of accumulated experience.

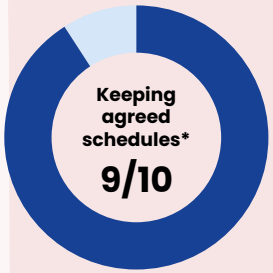
Net promoter score

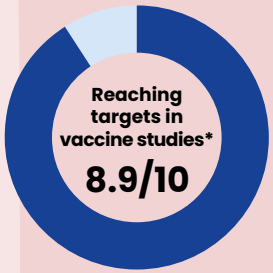


High study volunteer satisfaction and retention



Delivering on promises to study partners





*Vaccine manufacturer and monitor satisfaction study 2024

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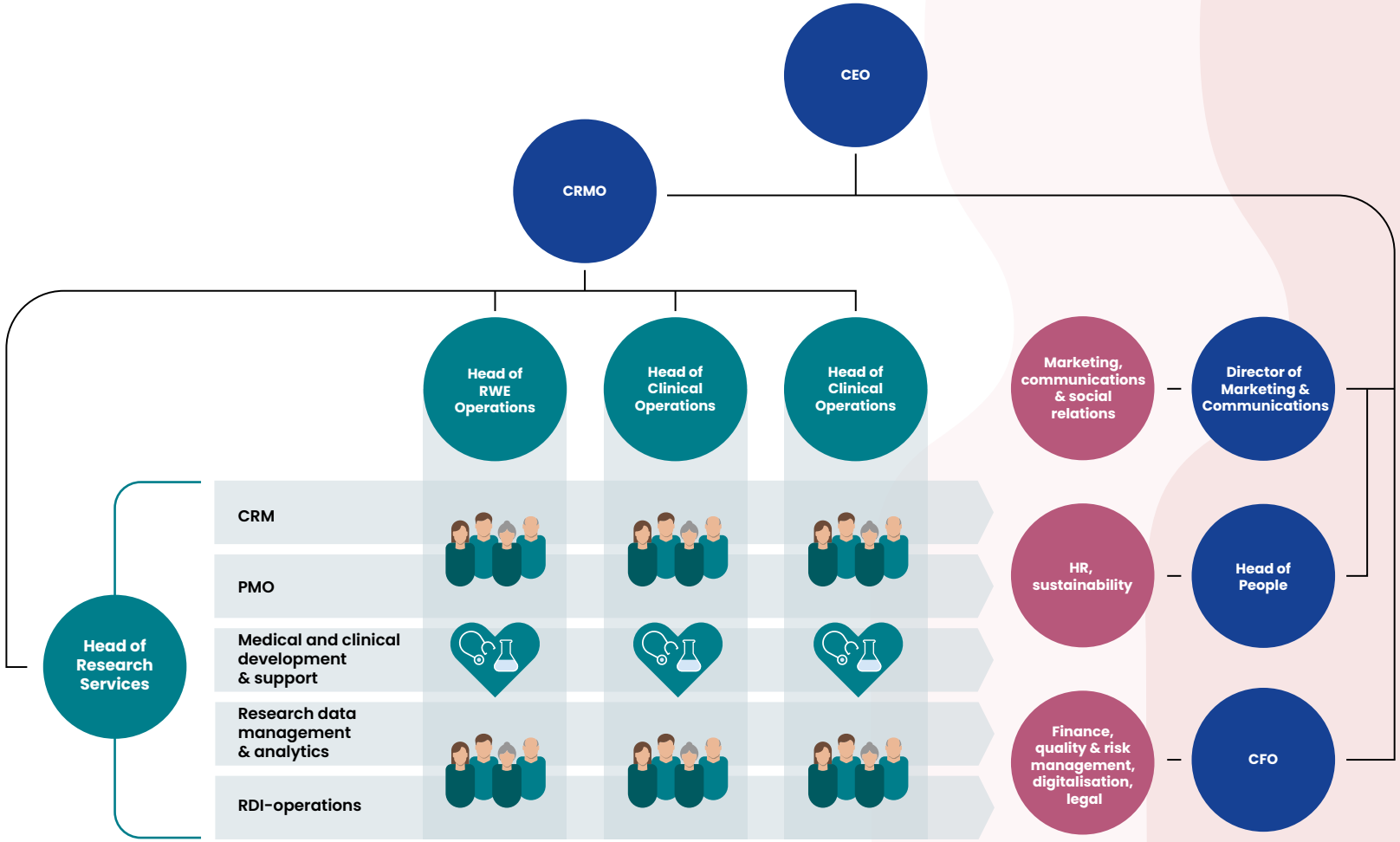
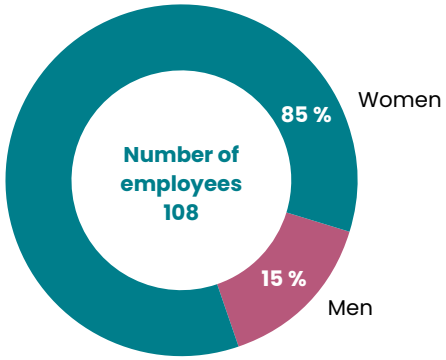
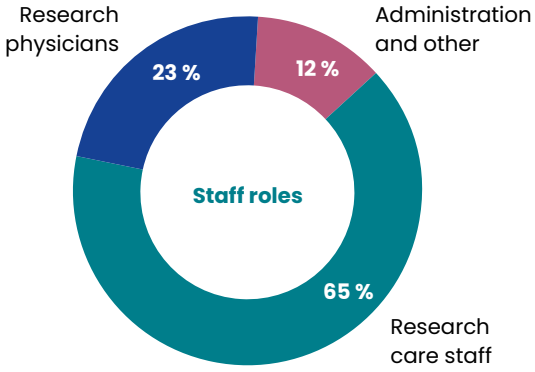
Organisation Chart

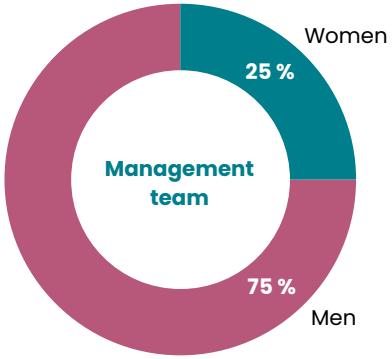


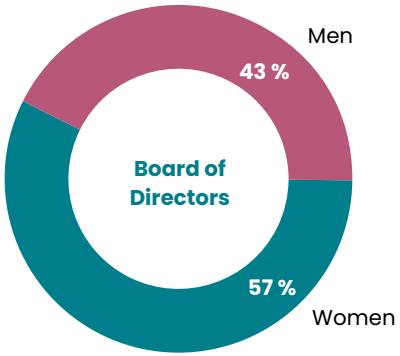
Employees (end of 2024)





Management

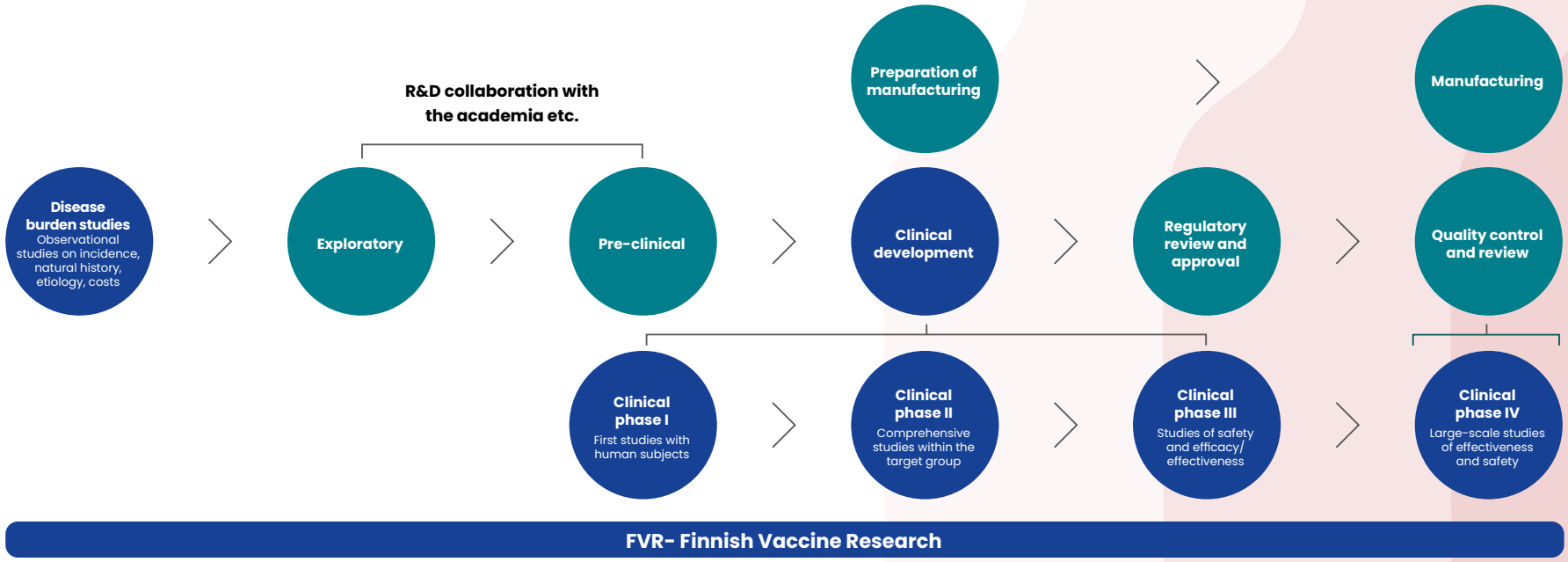




2025 management team will consist of 50% women and 50% men.

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 healthcare organizations as well as tens of thousands of volunteers.



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Clinical Trials (CT)

CT specializes in commercial clinical vaccine research commissioned by vaccine manufacturers, i.e. international pharmaceutical companies.

Post-laboratory clinical vaccine research involving human volunteers 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 CT 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).

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Real-World Evidence (RWE)

RWE conducts phase 4 post-licensure safety and efficacy vaccine studies based on Real-World Evidence. 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 healthcare providers. Large-scale pragmetic 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 can 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.

Strategy

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.

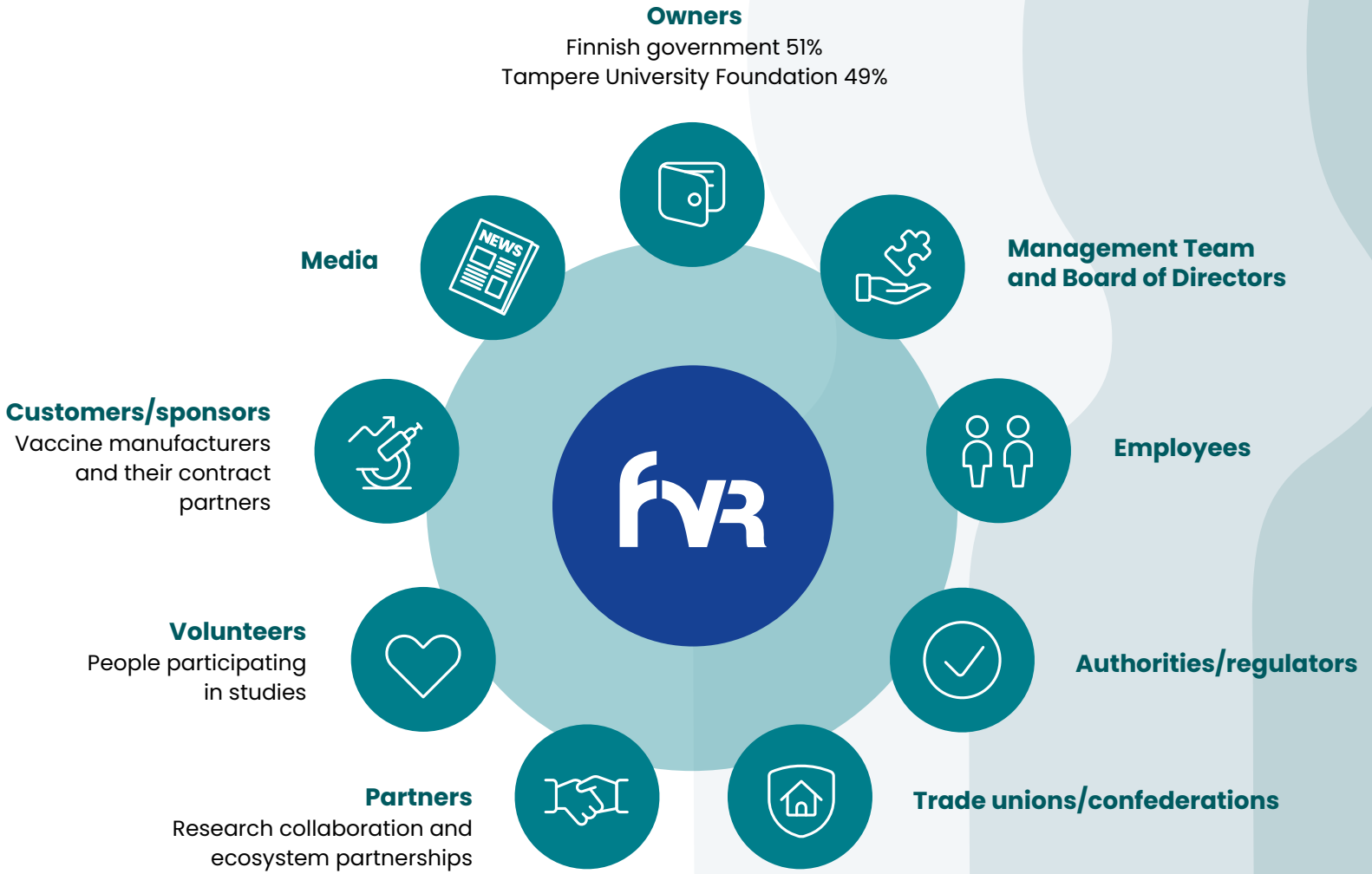
Goals

- 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 customer-driven 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
- active development of customer and stakeholder relations

Company stakeholders



Corporate governance

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

Board of Directors

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

Kirsi Komi
Independent
Master of Laws

Timo Lepistö
Independent
Master of Laws

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

Leadership Team

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

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

Marikka Nevamäki
Chief Marketing & People Officer
Master of Social Sciences
(until 31.12.2024)

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

Satu Grönberg
Head of People
M.Sc. (Econ.)
(Starting in MT on 1.12.2024)

Katja Volanto-Lumppio
Head of Research Services
M.Sc. (Biology)
(Starting in MT on 1.12.2024)

FVR continues to develop and report on its sustainability roadmap

In 2024, FVR completed the first Communication on Progress (CoP) report of the UN Global Compact Communication initiative. In the CoP survey, companies answer approximately 60 questions related to promoting the ten principles of the UN Global Compact and the UN's Sustainable Development Goals as part of the company's business.

In addition, we conducted a number of baseline analyses related to, for example, business travel, energy use and waste management, and set goals and guidelines in these areas.

- For business travel, the analysis indicated that we have quite a good baseline: 56% of business travel is done by train. We wanted to improve our result by updating the domestic travel policy to further encourage travel by train rather than private car.
- With regard to energy use, we updated our clinics' electricity contracts with ones based on renewable energy. We also set a target of ensuring that all electricity contracts managed by FVR will be based on 100% renewable energy by the end of 2025. Some of the contracts (50%) are managed by the properties' landlords.
- As for waste management, recycling and sorting rates were found high and no further measures were taken. Surplus stock of vaccination supplies was donated to war zones in Ukraine.

In addition, we mapped some of our key suppliers' sustainability maturity and carried out preparations for essential ISO certifications, the first of which (ISO27001) was completed according to plan.

Corporate responsibility priorities

People: the well-being of our employees, the quality experience of our research participants, and maintaining and strengthening our society's acceptance of vaccine research.

Good governance and financial sustainability: ensuring data protection and security, ethically sustainable practices, securing financial viability, and risk and quality management that permeates our operations.

Environment: responsible energy use and energy solutions, minimizing the carbon footprint of travel, and ensuring responsible procurement.

Tools: UN Global Compact, Code of Conduct and Whistleblowing

The implementation of the CSR agenda has gone according to plan, and we have generally done well in achieving our 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

Meningococcal vaccine trial

Meningococcal bacteria (Neisseria meningitidis) cause life-threatening diseases, most commonly meningitis and blood poisoning (sepsis). In Finland, the disease most commonly affects young children and teenagers. Despite treatment, some patients die and many suffer permanent health impacts. In many European countries, the meningococcal vaccine is already part of children's vaccination programme; in Finland, it is currently provided to army conscripts as well as children and adults within medical risk groups.

In 2024, we conducted a phase III study comparing the safety and efficacy of two meningococcal vaccines, i.e. how well they produce antibodies in children of 6–7 months of age who have no previous meningococcal vaccine against ACWY bacterial strains. As part of the study, 327 children made their first visit to an FVR clinic with their guardians over the course of the year. The study is estimated to close in August 2025.

RSV vaccine trial

Respiratory syncytial virus (RSV) can cause serious disease akin to influenza. Symptoms range from mild cold to severe pneumonia and respiratory insufficiency. The disease is common and particularly severe for infants, pregnant women and elderly persons. The disease can recur several times. RSV respiratory tract infections occur as epidemics during the winter. There is no targeted drug for the treatment of RSV infection. The treatment of a person hospitalised for breathing difficulties is symptomatic, if necessary, intensive care.

The first RSV preventative vaccines to protect neonates and the elderly were introduced in Europe in 2023. In 2024, we continued the studies of several RSV vaccines, including a study on the long-term protection efficacy of an already commercially available product. The goal was to establish whether a single booster dose of the vaccine is sufficient to protect against infections over several RSV epidemic seasons. In addition, the impact of different vaccination schedules on the protective efficacy was studied, as well as the safety of the vaccine. As part of various RSV studies, 656 people made their first visit to an FVR clinic over the course of the year.

Register-based study on a pertussis vaccine

Register-based study refers to scientific research, where the research material consists of various kinds of register data. In register-based studies, subjects are not contacted, rather, the studies are conducted based on a research permit from the responsible authority. The use of personal data in scientific research requires a data permit from the register's controller or Findata, the Finnish data permit authority for the social and health care data. Typically, register-based studies concern a very large population; in some cases, the entire population of Finland.

FVR conducts several register-based vaccine studies each year. One example is an ongoing study of a pertussis (whooping cough) vaccine in Finland regarding children under 14 years of age between 1995 and 2019. The study, based on national registers, evaluates the effectiveness of the vaccine administered at preschool age, taking into account previous vaccinations and the time elapsed since vaccination. The impact of the pre-school dose is also evaluated by comparing the occurrence of whooping cough over time. In addition, the incidence of whooping cough is described in relation to age, timing, geographical area, vaccination status and hospitalization.

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Peltokatu 26
33100 Tampere, Finland

Business ID FI32566594

www.fvr.fi

info@fvr.fi