Suomen rokotetutkimus
Finnish Vaccine Research

We have a special assignment: your health

FVR – Finnish Vaccine Research

Overview of 2023

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Content

Focus on international competitiveness

FVR's first full year of operations met and even exceeded expectations in many areas. Key successes include a high level of satisfaction with FVR's activities among enrolled volunteers and study partners, high study volunteer retention rate (average dropout approx. 2%), meeting the set trial volunteer recruitment targets, and the launch of first post-licensure RWE-studies. The results allowed FVR to reward the entire staff by the decision of the Board of Directors.

The company's revenue for 2023 exceeded EUR 14 million and cash flow was positive. Balance sheet items resulting from the transfer of assets from the Tampere University Foundation burdened FVR through 2023 and, as expected, resulted in financial loss. Excluding these balance sheet items, the result of the fiscal year was positive. From 2024 on, the company's balance sheet is solid.

Several development measures were taken throughout the year, such as the development and implementation of a new remuneration system in accordance with the collective agreement, the related salary harmonization, the opening of new clinics in Turku and Tampere, the development of volunteer campaigning in research activities, and development projects implemented on the basis of an employee satisfaction survey. In addition, new tools were introduced to digitalize operations – for example, for the processing of volunteer registrations and the utilization of business data. The utilization of digital tools and remote services is a growing trend also in the field of clinical trials, and FVR is looking for ways to make use of the opportunities offered by this development in collaboration with partners.

A strategy roadmap for years 2024 – 2026 was created and approved by the company's Board of Directors in June 2023. The roadmap sets the priorities for strengthening the conditions for FVR's growth and competitiveness and communicates the company's business goals.

Active value chain collaboration

Throughout the year, input from different sources was gathered to further develop FVR's activities both in terms of strategy work as well as operations. Relationships with regional and local pharmaceutical company organizations were deepened to gain a shared understanding of the possibilities to further develop the value chain collaboration. FVR joined the Pharma Industry Finland, which promotes the operation and development of its member companies and influences the Finnish health policy. FVR sees the membership as an opportunity to impact key industry topics and to deepen collaboration with other organizations in the ecosystem.

In terms of RDI activities, the company took its first concrete steps by participating in the ImmuDocs doctoral training pilot as a consortium partner. The pilot, coordinated by the University of Turku and its InFLAMES Flagship and enabled by the Research Council of Finland, aims to expand the pool of immunology experts in Finland and to boost employment opportunities for PhDs across the society, including the private sector. Going forward, FVR aims to enhance its ability to participate in RDI projects that are seen as having the potential to strengthen and update knowhow and to create new solutions and innovations that benefit the industry. Collaboration with universities and other ecosystem operators is key in this context.

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A horizon full of opportunities

Despite the challenging macroeconomic situation, the investment and growth prospects for the industry have remained favorable. The outlook for vaccine trials is driven primarily by the pharmaceutical industry's willingness to invest in the development of new vaccines, and demand for both clinical vaccine research and post-licensure studies is expected to increase globally in the coming years.

The industry's growth prospects are a positive signal, but growth is also a powerful driver for industry renewal and increasing competition between regions, countries, and research centers. The company's success in the competitive, international field of vaccine research requires not only professional excellence and good cooperation in the ecosystem, but also persistent strategic development of the company's operations and offerings, while ensuring sustainability.

International cooperation to strengthen future pandemic preparedness is also important. In the face of the next pandemic, countries, health authorities and the medicine and vaccine research value chain need to be well-equipped to investigate and implement medical interventions quickly and effectively, without compromising safety. This requires international R&D cooperation, to which FVR is ready to make its own contribution.

We will continue our determined work to ensure the growth of FVR and the entire industry, guided by our strategic roadmap, and in cooperation with our partners and stakeholders.

Ilkka Haukijärvi
Chief Executive Officer

Growth is also a powerful driver for industry renewal and increasing competition.

Developing a company that is more than the sum of its parts

FVR's transformation from a merger of two public sector operators to a public limited company operating in competitive international market conditions continued with determination in 2023. The aim of setting up a special-assignment company of the Finnish state was to create an organization that is more than the sum of its parts. Success requires a bold, purposeful, yet adaptable strategy and its successful implementation.

The company's operational management and Board of Directors have worked actively together during the first full year of operations. The Board was strengthened with two new members in June by a decision of the Annual General Meeting. Kirsi Komi and Timo Lepistö bring many years of solid board work experience to support the company's management.

Finland needs a big, joined effort

Research and innovation in the field of medicine benefit not only the well-being and health of citizens, but also the Finnish economy. Through research, we can attract international investment that further strengthens Finnish expertise and boosts the economic growth and vitality of our country. Our goal is that the knowledge and know-how accumulated through the company's operations will improve health safety here and elsewhere.

According to a survey of the pharmaceutical industry conducted by Pharma Industry Finland in the spring of 2023, the pharmaceutical industry invested EUR 380 million in Finland in 2022. Data for 2023 are not yet available. Investments increased by 6.3% compared to 2021 (EUR 357 million). Most of this, approximately EUR 263 million, was invested in research and development (+12%). EUR 3.6 million (+16%) was invested in register surveys, which are also offered by FVR. Although most of the investments in the industry go towards clinical trials, the pharmaceutical industry expects a clear increase in register studies in the coming years. This is an opportunity for us to significantly expand our role in the future.

Although the company has a significant position and market share in Finland, the competition is almost entirely international. In addition to the efficiency of its own operations, FVR's success is either helped or hindered by the smoothness of the regulatory environment, the introduction processes of new vaccines, as well as the ability of the company and its operating environment to leverage innovative digital solutions. Developing competitiveness is on the shared agenda of the entire industry operating in Finland, as well as the stakeholders and decision-makers who influence it.

At the same time, it is not only Finland's competitiveness that is at stake, but also the competitiveness of the EU in a very important sector. The US and Asia are attracting more and more investment from the pharmaceutical industry, while Europe is falling behind. This has been a wake-up call for strategic cross-sectoral cooperation at the EU level.

It is not only Finland's competitiveness at stake, but also the competitiveness of the EU in a very important sector.

Lifelong vaccination coverage

Childhood vaccination programs are one of the greatest medical success stories of the 20th century. More recently, it has been recognized that infectious diseases can also have a devastating impact on the health of adults, especially when their immune systems are weakened by age or disease. Much remains to be done in terms of adult vaccination coverage and protection. The proportion of adults aged fifty and over in the European Union is projected to reach 50% of the population by 2025. This demographic trend is also reflected in the fact that approximately 80% of the vaccines currently in the development pipeline of pharmaceutical companies are specifically targeted at the adult population (Vaccines Europe). The shared goal of the entire value chain is lifelong vaccination coverage.

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

Approximately 80% of the vaccines currently in the development pipeline are targeted at the adult population.
(Vaccines Europe)

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

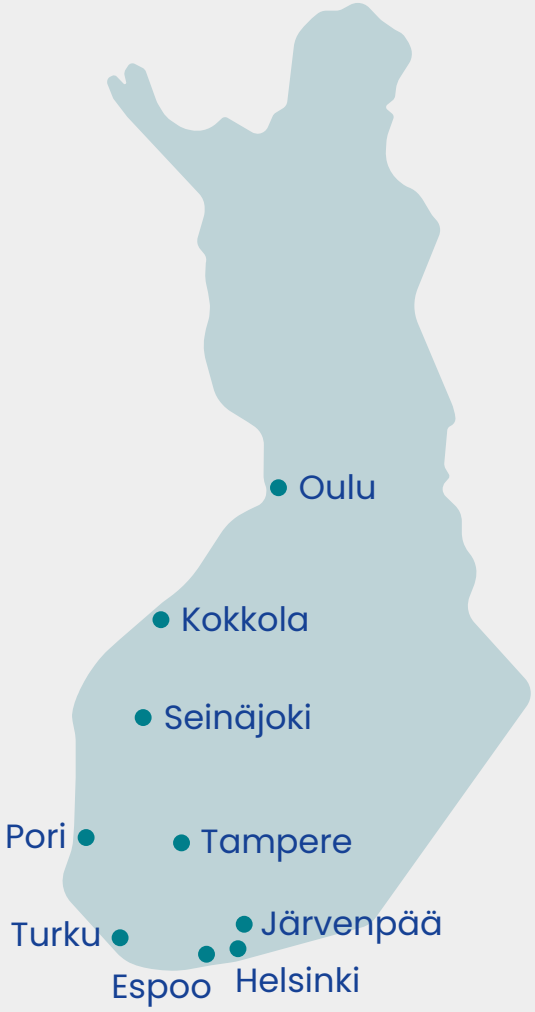
International vaccine manufacturers aiming for commercial license and organizations looking for real-world evidence.

Network of clinics

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

Research (in 2023)

- 26 trials in various stages, against 11 different pathogens
- 1,945 new volunteers visiting the clinics for research



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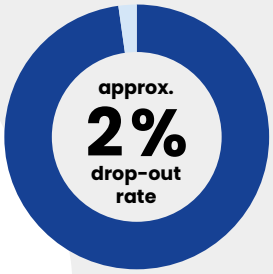
High study volunteer satisfaction and retention

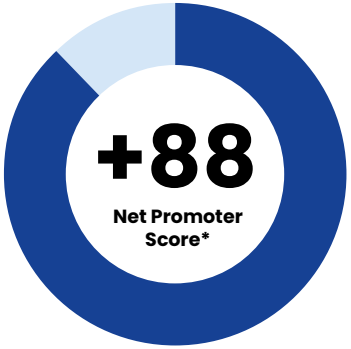


Approx. 100 GCP-qualified research experts

across Finland, with decades of accumulated experience.

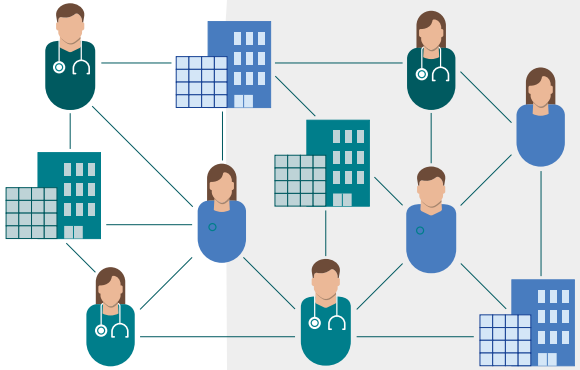
Phases 1–4 of vaccine research

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

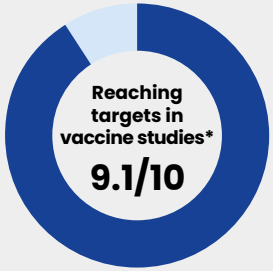


Broad national network of clinics, only one contract

Smooth collaboration with healthcare providers.



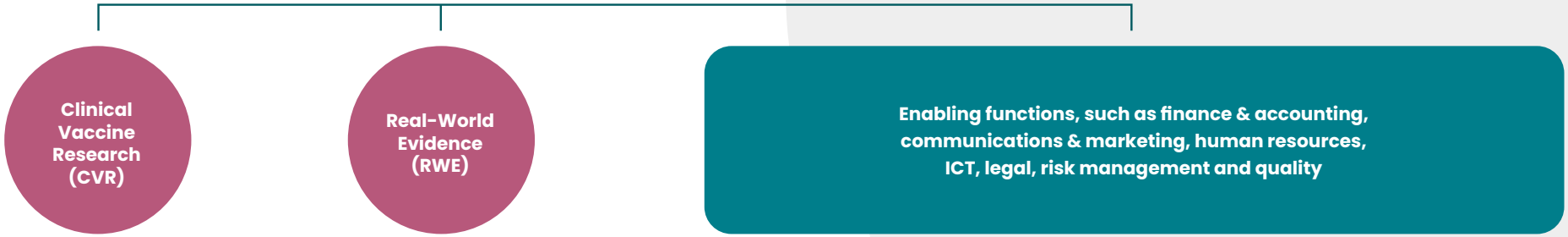
Delivering on promises to study partners



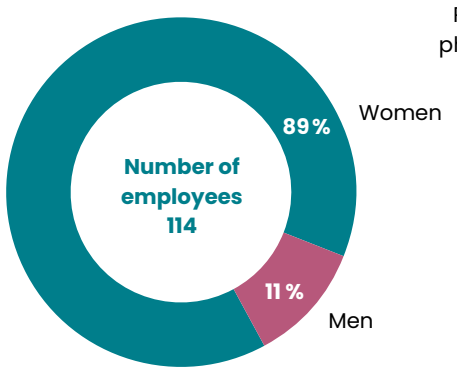
(*Vaccine manufacturer and monitor satisfaction study 2023)

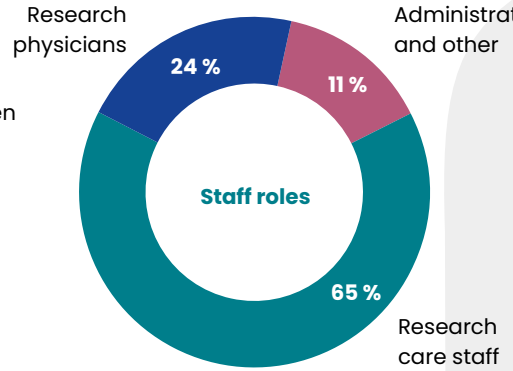
Organization (31.12.2023)

Two business units and enabling functions.



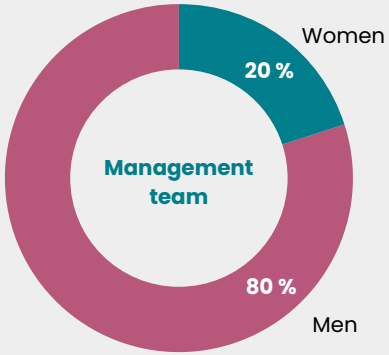
Employees (end of 2023)

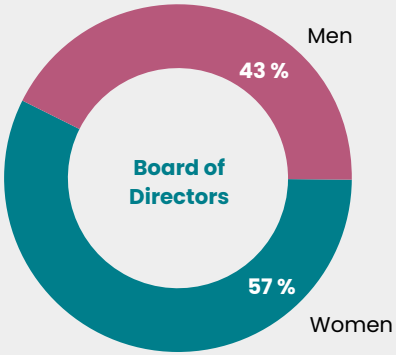




- Average age of employees 46 years
- Average length of service in years: 10

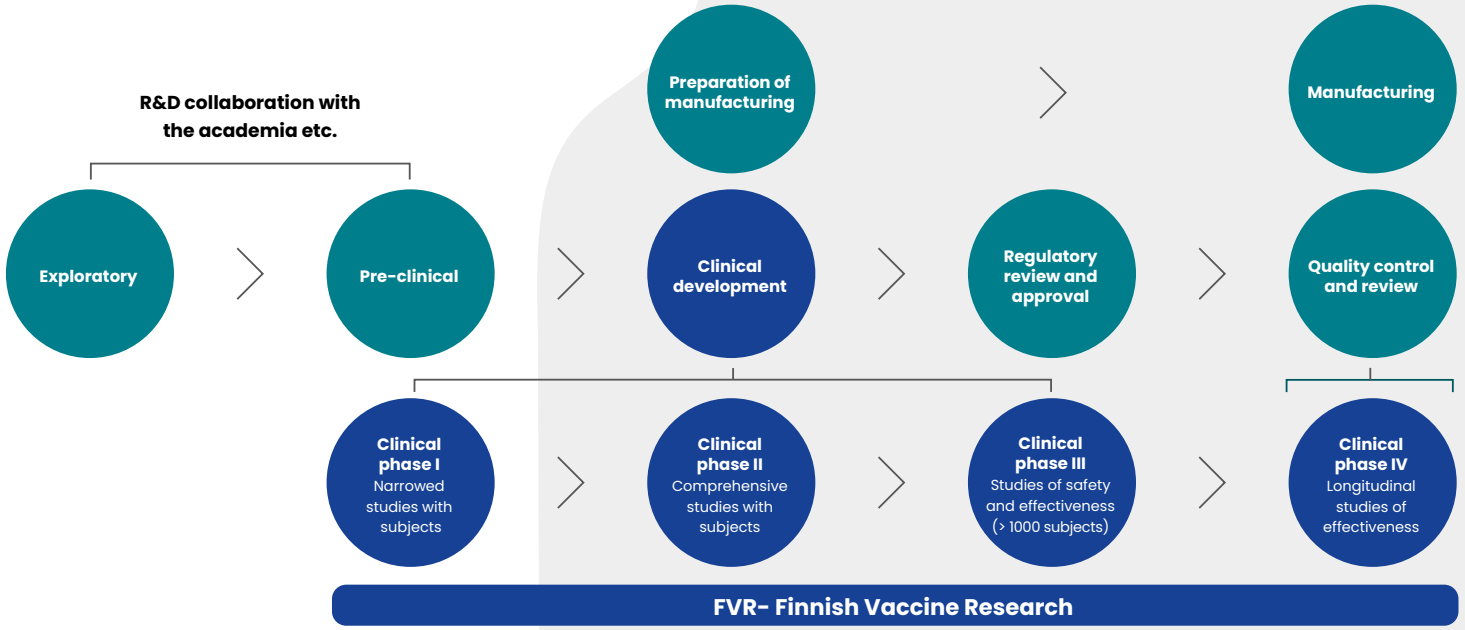
Management





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.



Clinical Vaccine Research (CVR)

CVR 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 CVR are phase 3 trials. The unit studies dozens of vaccines each year, and thousands of Finns volunteer to participate in the studies.

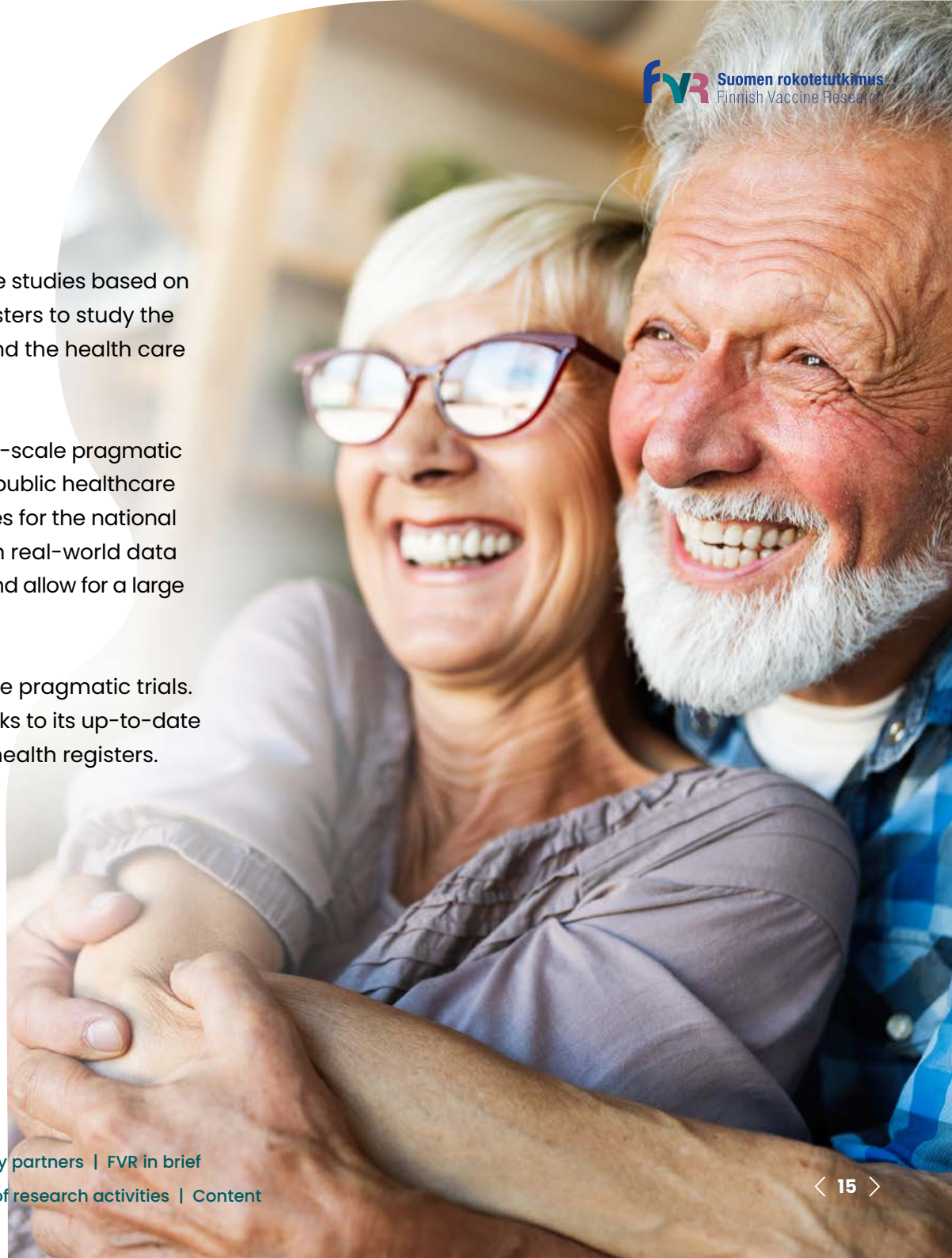
Each clinic has its own team, including professional study nurses, laboratory nurses and physicians. The team is responsible for conducting the studies following a unique research plan, national and international legislation, and the guidelines for Good Clinical Practice (GCP).

Real-World Evidence (RWE)

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 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.

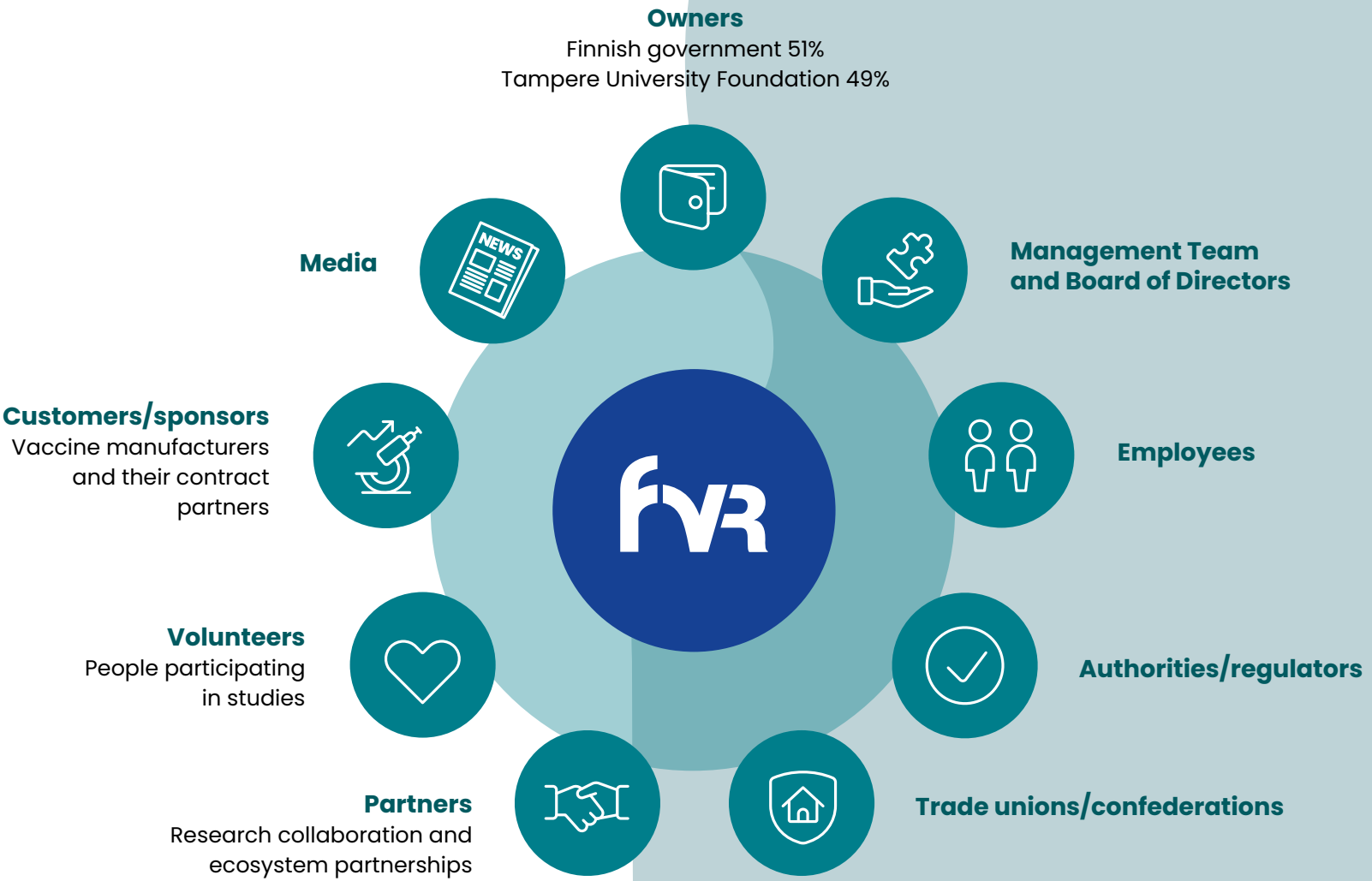
Goals

- 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

Management Team

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

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

Marikka Nevamäki
Chief Communications &
Marketing Officer
Master of Social Sciences

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

Mika Rämet
Chief Medical Officer
M.D., Ph.D.,
Professor of Paediatrics and
Experimental Immunology
(Until 31.1.2024)

Sustainability

FVR offers research as a service. The company has no manufacturing or production activities or own products that generate life-cycle emissions. Due to the focus on vaccine research, the company's greatest impact is created through the advancement of the well-being, health and safety of people.

During 2023, the company conducted a materiality analysis, consulting the company's key stakeholders. Based on the analysis, the company's sustainability goals and related development projects and indicators were set (see next page).

During 2023, FVR also published its own Code of Conduct and a whistleblowing channel for the reporting of any suspected misconduct. In addition, the company joined the UN's Global Compact initiative, which is a voluntary framework for developing, implementing and reporting responsible business practices. This means that FVR is committed to aligning its operations and strategy with ten generally accepted principles in the areas of human rights, labor, environment and anti-corruption, and to support the UN and Sustainable Development Goals (SDG). Of these, goal 3 is particularly relevant from the perspective of the impacts of the company's operations: Ensure healthy lives and promote well-being for all at all ages.

FVR's sustainability goals

People

Own employees

Wellbeing at work

- "I would recommend FVR as an employer" >70% (baseline 2022: 67.6%)

  🔴 Result 2023: 61.7%

Volunteers

Satisfaction of trial volunteers

- Happy Index >80/100 (digital feedback from research clinics)

  🟢 Result 2023: 95/100

Pro-vaccination attitudes

Willingness to participate in vaccine studies of common adult vaccine-preventable diseases

- More registered volunteers than the country-specific target for studies (N)

  🟢 Result 2023: target reached in all new trials where adults were enrolled (extension studies excluded from tracking)

Good governance & financial sustainability

Data protection and data security

ISO 27001 certification qualified by the end of 2024

🟡 Result 2023: in progress

Ethical business conduct

Code of Conduct

- 100% of staff trained each year

🔴 Result 2023: 80%

Financial sustainability

Profitable growth

🟢 Result 2023: revenue & cash flow above target

Risk management and quality

ISO 9001 certification-readiness by the end of 2024 (certification 2025)

🟡 Result 2023: in progress

Environment

Energy consumption

Baseline analysis done and goals set by the end of 2024

🟡 Result 2023: in progress

Travel

Baseline analysis done and goals set by the end of 2024

🟡 Result 2023: in progress

Procurement

Sustainability criteria defined and implemented for procurement by the end of 2024

🟡 Result 2023: in progress

Paperless office

Goals set and roadmap defined by the end of 2023

🔴 Result: digital strategy H1/2024

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.

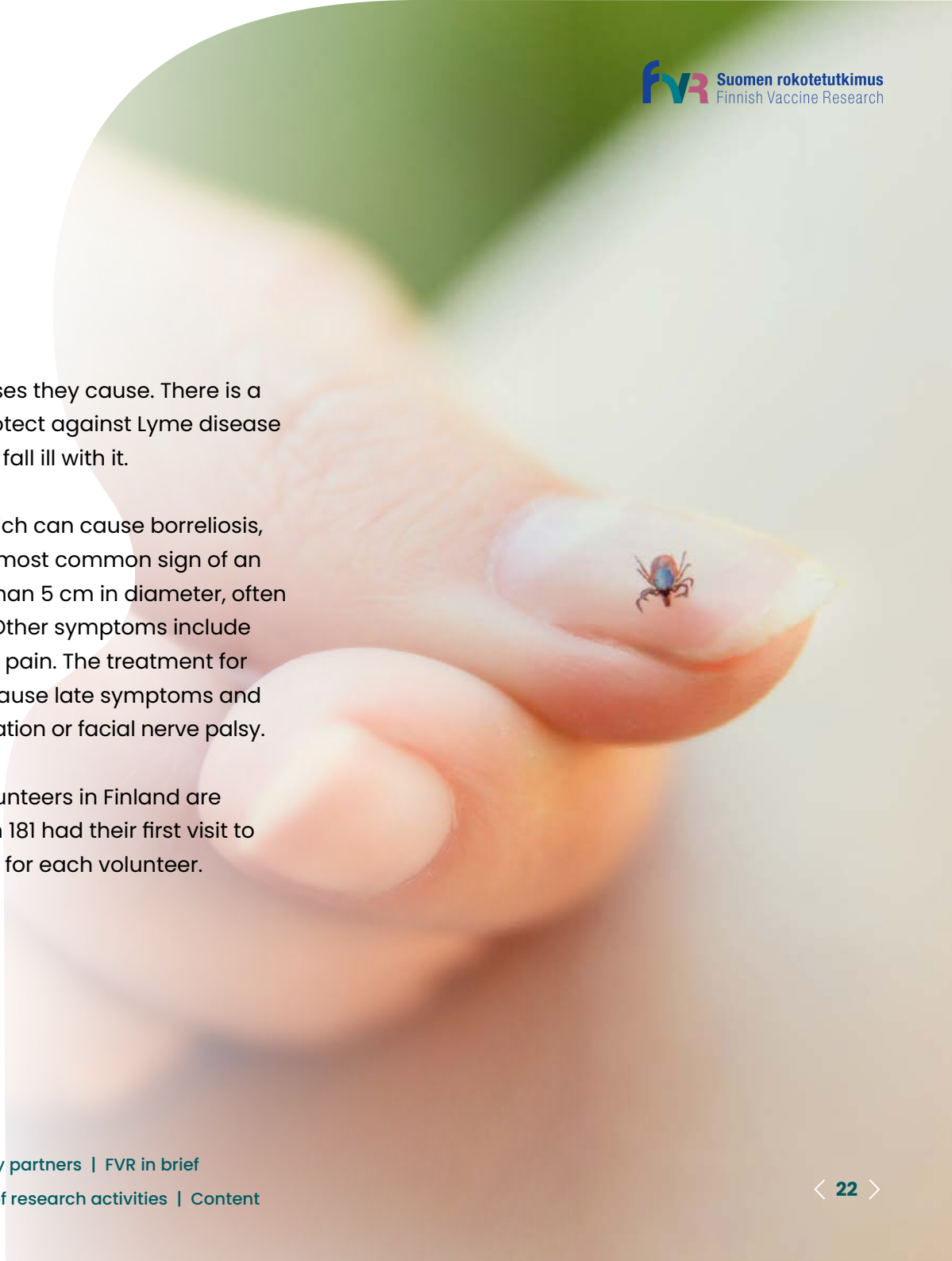
Examples of research activities

Vaccine for Lyme disease

Ticks have spread geographically, and with them also the diseases they cause. There is a vaccine against tick-borne encephalitis (TBE), but it does not protect against Lyme disease (borreliosis). Every year, almost half a million people in the world fall ill with it.

About a fifth of ticks carry the Borrelia burgdorferi bacterium, which can cause borreliosis, i.e. Lyme disease, when transmitted to a person from a bite. The most common sign of an early-stage borreliosis infection is a skin inflammation of more than 5 cm in diameter, often ring-shaped, which appears within 1-2 weeks after the tick bite. Other symptoms include fatigue, fever, headache, mild neck stiffness, joint pain or muscle pain. The treatment for early-stage infection is an antibiotic. Untreated borreliosis can cause late symptoms and chronic infection, such as arthritis, meningitis, nerve root inflammation or facial nerve palsy.

A vaccine is now being developed against Lyme disease. 313 volunteers in Finland are participating in an international study launched in 2022, of which 181 had their first visit to FVR's clinics during 2023. The study continues for about 2.5 years for each volunteer.



Cytomegalovirus vaccine (CMV)

Cytomegalovirus threatens the health of the fetus during pregnancy. It can cause a miscarriage or the unborn child to become seriously ill. About 2/3 of people get an infection caused by cytomegalovirus by adulthood, and it often goes unnoticed. The risk group includes women who get CMV infection during pregnancy. The infection is usually asymptomatic for the expectant mother, but the baby is at risk of getting sick. In a newborn, CMV infection can cause severe development delay and hearing loss. There is no curative treatment for CMV infection.

FVR participates in a study of a CMV vaccine produced with mRNA technology. The vaccine under study aims to prevent CMV infections during pregnancy and thus protect newborns. The study started in 2022 and a total of approximately 680 women in the 16–40 age group in Finland are participating in it. 332 of these volunteers had their first visit to FVR's clinics in 2023 to participate in the CMV study. The study continues for about 2.5 years for each volunteer.

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