



THL strategy for vaccine trials and the new company with Tampere University

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Terveystieteiden ja hyvinvoinnin laitos

Disclosure

- The Finnish Institute for Health and Welfare (THL) endorses public-private partnership and has received research funding
 - From Sanofi Pasteur
 - from GlaxoSmithKline Biologicals SA
 - from Pfizer Inc.
- AA Palmu
 - Investigator in the research projects above
 - No other personal conflict of interest

Aim of the strategy

- To provide the public health institutes with the best possible evidence for the newly licensed vaccines
- To provide vaccine manufacturers with the possibility to produce best possible postlicensure evidence for the new vaccines in a feasible manner

Strategy for clinical trials at THL

- The most valid designs are needed to evaluate the effects of new vaccines
- Public health perspective
 - Total effects, long-term effects, full population effects
- The best possible design
 - comparative clinical randomized trials (RCT)
 - Large phase III and IV pragmatic field trials
- Use of national competition factors
 - Collaboration with public health care providers, register follow-up
- In-depth balanced collaboration with the vaccine manufacturers
- A new private company to continue the strategy

Surveillance of study participants using national registers

Data are nationwide, complete, real-time, linkable, affordable = UNIQUE

Digital and Population Data Services Agency Digi- ja väestötietovirasto, www.dvv.fi

- Real-time population data

Finnish Institute for Health and Welfare Terveyden ja hyvinvoinnin laitos (THL) www.thl.fi

- Finnish National Infectious Diseases Register
- Care Register for Health Care (hospital discharge register, HILMO), Register of Primary Health Care visits (AvoHILMO)
- Medical Birth Register, Social Welfare Register, Cancer register, etc.

The Social Insurance Institution of Finland Kansaneläkelaitos (KE LA) www.kela.fi

- Data on purchases of prescription medicines, Entitlements to reimbursement for medicine expenses
- National old age, disability and unemployment pensions, Rehabilitation, Sickness allowance, Disability
- Reimbursements for the cost of examinations and treatments performed by private-sector healthcare providers
- Kanta archive (patient data repository)

Statistics Finland Tilastokeskus www.stat.fi

- Cause of deaths

+ national health insurance, public health care , universal accessible health services, skilled personnel and citizen's trust

= EXCEPTIONALLY POWERFUL INFRASTRUCTURE

Examples for Public-Private-Partnership: RCTs and registers

- GSK: FinIP vaccine trial 2008-2018 www.finip.fi
 - Pneumococcal conjugate vaccination in the infants
 - Largest of its kind globally (N=47 000)
 - Publications available
- Sanofi Pasteur 2019- [FinFluHD vaccine trial](#)
 - Influenza vaccine trial in the elderly
 - Protocol: Am Heart J 2021 Jul;237:54-61
 - Globally the biggest vaccine trial of the modern era (N=121 000 planned)
- Additional studies in planning phase
 - To be started in the private company

Finnish Vaccine Research Center Finvac Ltd

- AIMS
 - Promote clinical vaccine research expertise in Finland
 - Need to strengthen THL independence in decisions regarding vaccine procurement
- Rokotetutkimuskeskus Finvac Oy; Vaccinforskningscentralen Finvac Ab
- Formed by merger of
 - Tampere University Vaccine Research Center <https://rokotetutkimus.fi/en/>
 - and
 - THL clinical vaccine research group <https://thl.fi/fi/tutkimus-ja-kehittaminen/tutkimukset-ja-hankkeet>
- Owned by:

Company Board

- Liisa-Maria Voipio-Pulkki (chair, MoH)
- Juhani Eskola (former THL director general)
- Tapio Visakorpi (dean of Tampere University)
- Sirpa Jalkanen (academician, Turku University)
- Saara Hassinen (CEO at Healthtech Finland)

Personnel

- Ilkka Haukijärvi appointed as interim CEO of the company from 1 March 2022
- MD Mika Rämet as medical director and
- MD Arto Palmu as research director
will also join Finvac's management team
- Personnel from TUNI and THL, up to 90 employees
- <https://thl.fi/fi/-/rokotetutkimuskeskus-finvac-oy-aloittaa-toimintansa-maaliskuussa?redirect=%2Ffi%2F>

Actions steps in 2022

- Establishment of the management of the company
 - Transfer of studies and personnel
 - Start of the new studies
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- Unique experience and expertise on all phases of the clinical vaccine trials and observational register studies