SHOULD AND CAN PUBLIC HEALTH RESEARCH INSTITUTES AND MANUFACTURERS WORK TOGETHER ?

What are the risks and benefits ?

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INSTITUTET FÖR HÄLSA OCH VÄLFÄRD

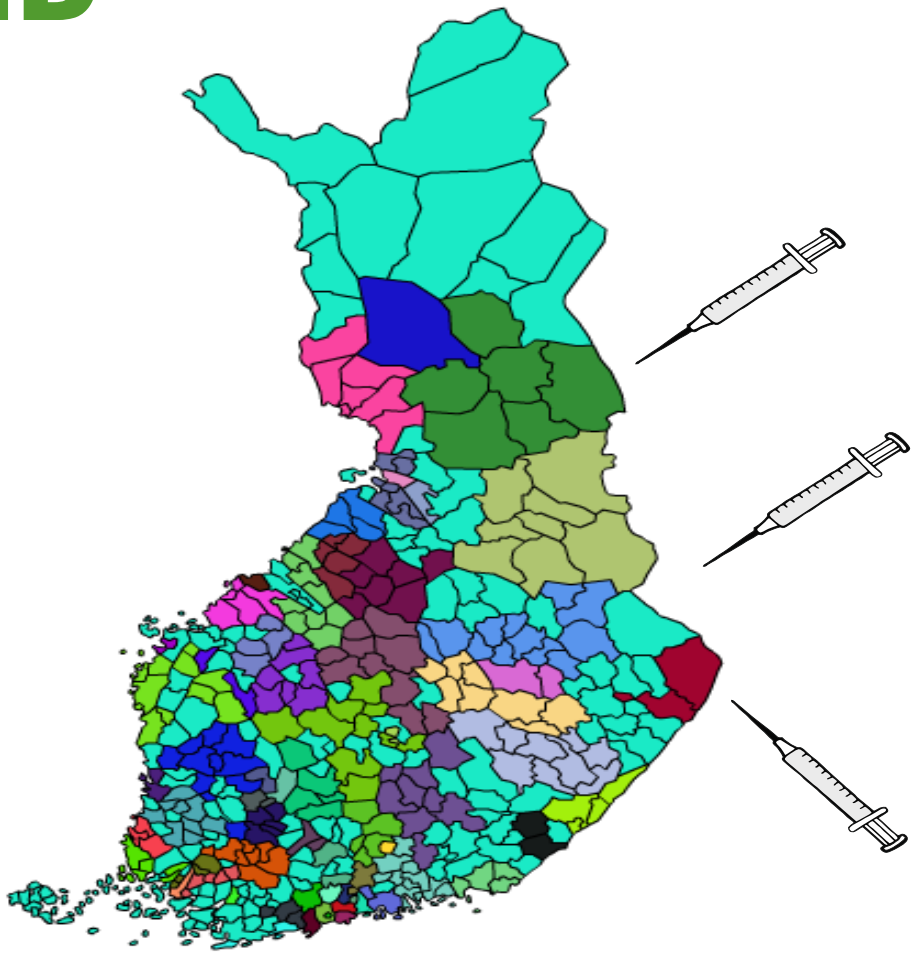
YES ...

... BUT

MISSION STATEMENTS

- Public
- Private

EXAMPLE FINLAND



MAJOR CLINICAL TRIALS / STUDIES

Project	Years	Funders external to THL & KTL
– Meningokokki A –epidemic	1974-1975	Merck, Sharp & Dohme, Medical Board, Sigrid Juselius Association
– Hib-polysaccharide vaccines	1974-1975	As above, in addition NIH/NIAID USA
– Pneumococcal polysaccharide vaccines	1979-1981	Merck, Sharp & Dohme
– Savo pneumonia studies	1982-1985	Finnish associations
– Hib-conjugate phase III studies	1985-1989	Connaught Laboratories, Inc.
– PIR-research	1992-1995	Finnish Academy, Pasteur-Merieux
– **FinOM-studies**	**1994-1999**	**Wyeth-Lederle, Merck, Sanofi Pasteur**
– **ARIVAC-study (Philippines)**	**2000-2004**	**EU, Gates, sanofi pasteur, Finnish academy and foreign ministry**
– **PneumoCARR**	**2006-2011**	**Bill&Melinda Gates Foundation**
– **FinCAP-studies**	**2003-2008**	**GlaxoSmithKline**
– **FinIP-studies**	**2009-2018**	**GlaxoSmithKline**
– **FinStrepB-study**	**2018-**	**Pfizer**

THL RATIONALE FOR PPP COLLABORATION

- Engage in research which is in line with national strategy
- Research is also a learning process to increase / maintain expertice
  - Ability to review evidence
  - New vaccines
- Keeping the focus of product development also in questions of public health importance
- Producing new evidence arising from Finland for Finnish citizens
- Credible, equal partner for vaccine manufacturers
- Lack of significant public funding for major vaccines related projects

WHAT ARE THE CONCERNS?

- Vaccine hesitant
- PPP hesitant

SOLUTION – GOVERNANCE ?

Vaccine 35 (

Contents lists ava

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Review

The ADVANCE Code of Conduct for colla

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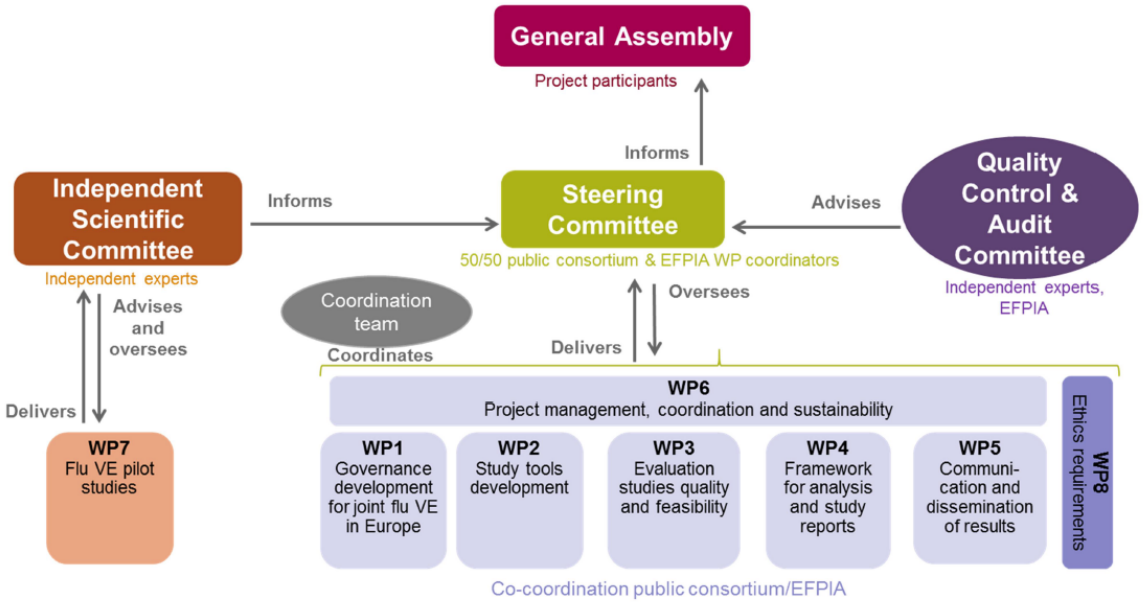

Figure 1: Project Governance

EXAMPLE FROM WORLD OF INFLUENZA VACCINE IMPACT ANALYSIS

None of this will be possible, however, should requirements on funding such networks insist upon industrial partners. There is little point in conducting the assessment of health products if one of the assessors is heavily incentivised to produce results required by their regulatory

"It is therefore vital to the methods and results of I-MOVE+ that vaccine manufacturers are not directly involved in VE (vaccine effectiveness) studies to ensure the scientific independence and credibility of the results of these studies"

effectiveness, impact and cost-effectiveness of vaccines and other healthcare products can only be meaningfully conducted if there is funding for independent, objective and unbiased science.

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RESPONSES TO DRIVE´S OFFER FOR COLLABORATION TO IMOVE/+ PARTNERS

- ”not possible for us to work … under umbrella … involving vaccine industry”
- ”.. does not agree to share data with these PPP consortia as we need to ensure that the studies and interpretation of results are fully independent from other interests than Public Health.”

Our position is that, in the interest of scientific integrity and independence, postmarketing studies on vaccine effectiveness should be conducted by Member States' health institutions completely independent of the pharmaceutical industry.

DRIVE´S OFFER FOR COLLABORATION (CTD)

Vaccine effectiveness research (post-marketing evaluation studies) funded in part by the private pharmaceutical sector may impact on the public perception of the scientific integrity, transparency and independence of the studies. This in turn may result in the loss of public trust in national vaccination programmes and subsequently in vaccine hesitancy. In this context, we would not be in a positon to participate in research involving a PPP at this time.

research team decided to maintain the previous position of not participating or to directly collaborate with the DRIVE consortium. This position is based on the non-desirable involvement of the industry in the design of the vaccine effectiveness, jeopardizing the needed independence of the research team.

scientific independence for researchers undertaking post marketing estimates of seasonal influenza vaccine effectiveness is assured. It is with regret that despite clearly articulated concerns that DRIVE have not yet moved their position to consider the valid points made by IMOVE/IMOVE+ about the steps that would be required to ensure this scientific independence.

such as scientific independence. On the topic of influenza vaccine effectiveness, we have committed ourselves to the (publicly funded) I-MOVE consortium and therefore do not participate in DRIVE.

ESKOLA & KILPI

Public–private collaboration in vaccine research

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See Series page 428
See Series Lancet 2011; 378: 360

Public sector scientists, for example those based in universities or in public health institutes, often collaborate with commercial organisations—including vaccine manufacturers—while taking on various advisory roles, mainly to regulatory agencies and policy makers.[1] To what extent do these many roles constitute unacceptable bias or compromise? At one extreme, scientific independence of an individual or organisation might be inevitably compromised by commercial collaboration,[2] whereas a contrary perspective argues that to systematically uncouple public health organisations from links to industry would deny or compromise the provision of crucial advocacy.[3] Research and expertise in relation to immunisation policy decisions deserve special attention, because they affect the future health of large numbers of individuals. We believe that the public–private interface in vaccine research should be preserved.

The research, development, and implementation of a vaccine are complex and costly processes. Provision of vaccines is a necessarily public–private partnership because, with few exceptions, only commercial vaccine companies have found it feasible to follow through on the difficult and expensive responsibility of development of a high-quality, safe, and effective product. However, the public sector is the only sensible and practical source of much of the epidemiological, microbiological, and immunological data that are essential to the development and implementation of a vaccine. Furthermore, outsourcing of clinical trials to established and approved research organisations, in accordance with strict regulatory guidelines, is an essential step in the registration of any new vaccine.

Two articles in *The Lancet*'s Vaccine Series describe some of these scientific challenges from the perspective of the vaccine industry.[4,5] Private companies are in a position to provide essential information for judicious immunisation policies, but the primary responsibility for protection of the interests of the public lies in the public sector. In the past, fruitful collaboration has resulted in the development of vaccines with significant public health benefit.

The US National Institutes of Health and its Vaccine Treatment and Evaluation Units played a crucial part in early development of several important vaccines:[6,7] eg, *Haemophilus influenzae* type b conjugates, hepatitis A, rotavirus, and human papillomavirus vaccines. In Canada, many vaccine-related organisations and universities were essential for the development of an acellular pertussis vaccine, research and development of vaccine adjuvants, and assessment of vaccines for immunisation programmes.[8] The UK Health Protection Agency lists vaccine development and evaluation as one of the science themes essential for the evidence-based protection of the health of the population.[9] The UK's Department of Health

***Panel:* Suggested criteria for vaccine research projects when public health institutes consider partnership with private industry**

- Public health impact of vaccine could be substantial
- Expertise inside institute is appropriate to the task (and, preferably, institute is better placed to take the project than other alternatives)
- Project competes well in internal prioritisation of use of resources inside institute
- Intellectual property issues and ownership of data can be agreed on
- All scientific results can be published without censorship
- Funds for infrastructure and basic functions of institute do not depend on research contracts with industry

AFP/Getty Images

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SOLUTION - NEXT GENERATION COLLABORATION IN VAC4EU