



Recruitment barriers associated to prophylactic vaccine trials in Belgium

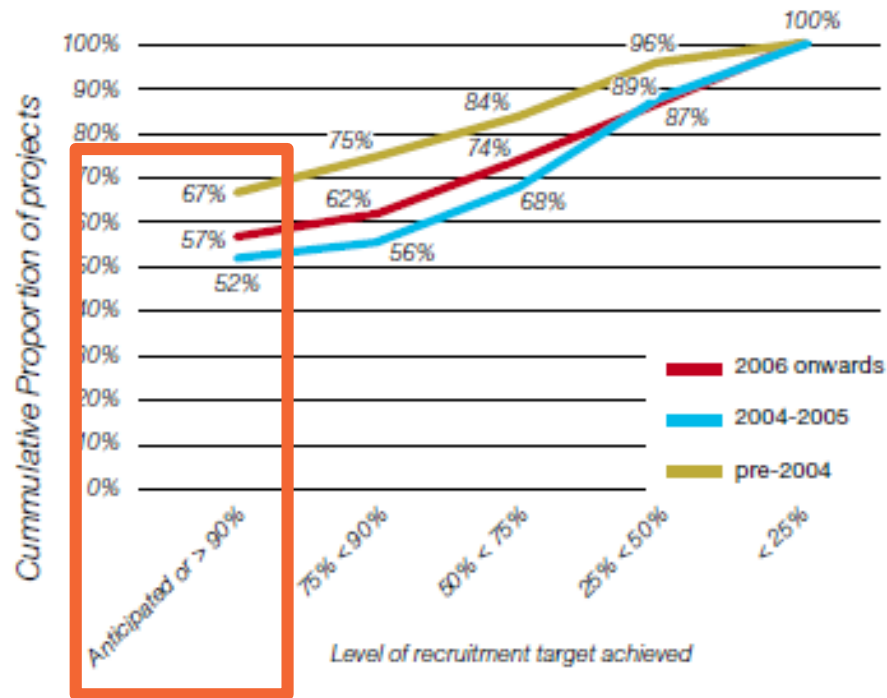
Lauriane Harrington
GSK. Secondee at the Vaccines Centre of Excellence

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- Employee of GSK Biologicals, Belgium
 - Secondment at the Centre of Excellence for Vaccines (hosted at the FAMHP), October 2016 to March 2017
 - GSK had no influence over this project and had no privileged insight to project results

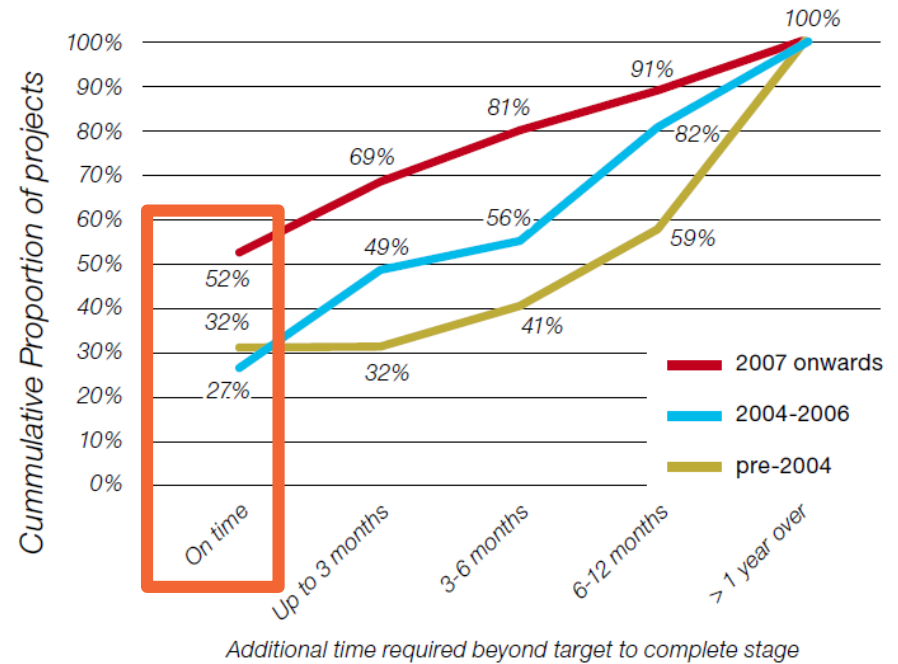
Introduction to clinical trial recruitment



Proportion of clinical trials reaching their recruitment target



Proportion of clinical trials completing recruitment stage on time



Swan et al., 2009, Warwick Business School

Why specifically assess recruitment barriers for PVTs?



Therapeutic products	Prophylactic vaccines
Aim to reduce disease/symptoms	Aim to prevent disease
Population: those with a disease/symptom	Population: those who do not have the disease
Many case studies published about recruitment barriers and solutions	Some case studies published about recruitment barriers
Numerous meta-analyses/systematic assessments about recruitment barriers	No systematic assessment about recruitment barriers

Identified recruitment barriers for prophylactic vaccine trials in Belgium

Three areas of focus to improve recruitment

Survey about recruitment barriers



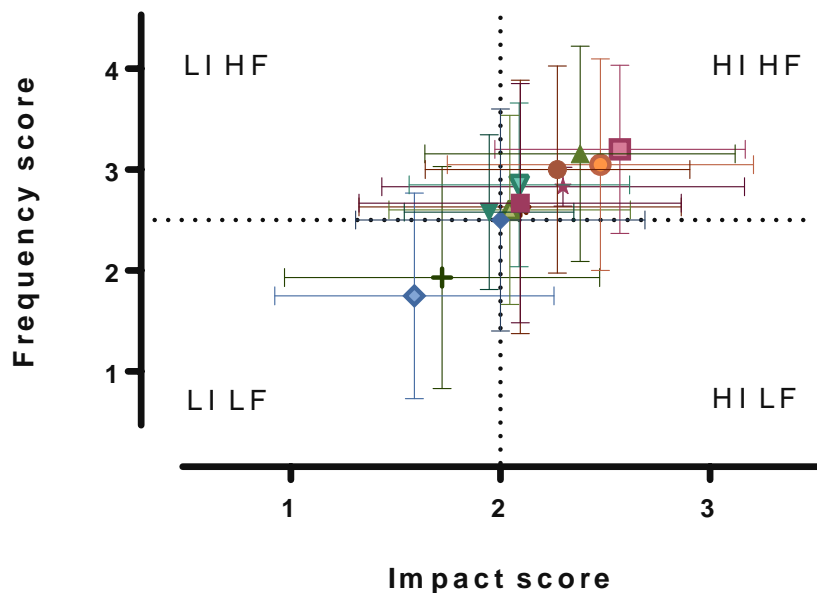
- Sponsor organisation: 20%
- CRO: 28%
- Public investigator site: 32%
- Private investigator site: 8%
- Other: 12%



Survey about recruitment barriers



Recruitment barriers: impact and frequency map

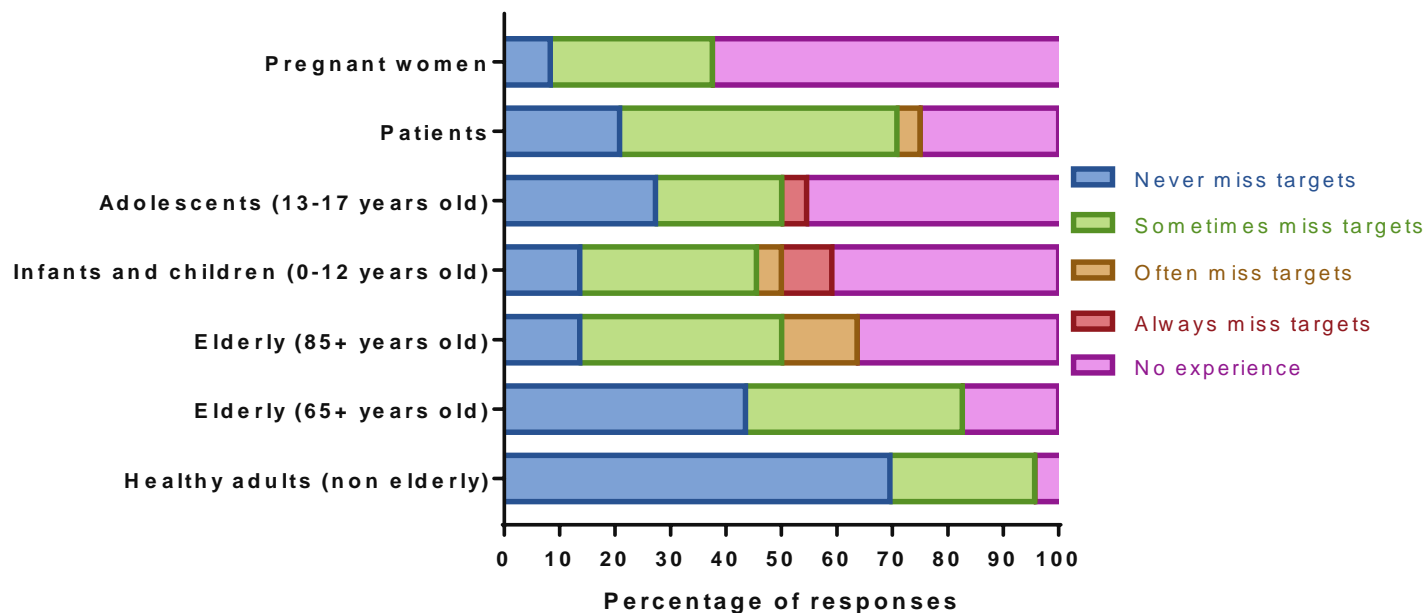


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|--|--------------------------------------|
| ■ Visit schedule | ● Selection criteria |
| ▲ Public knowledge of the disease | ● Recruitment budget |
| ★ Human resources dedicated to recruitment | ▼ Other protocol-related issues |
| ■ Public knowledge of clinical trials | * Training/experience in recruitment |
| ▲ Trial design | ◆ Transport access to trial site |
| ▼ Vaccine hesitancy | + |
| ◆ Consent process | + Disincentives of HCPs to recruit |

Data from Harrington et al., *under peer review*

N=20-23

Recruitment success for different populations



Database of volunteers

- 81% of survey respondents reported that having a database of volunteers is a successful strategy

Dedicated staff for recruitment

- 86% of respondents reported that having dedicated HR for recruitment is a successful strategy

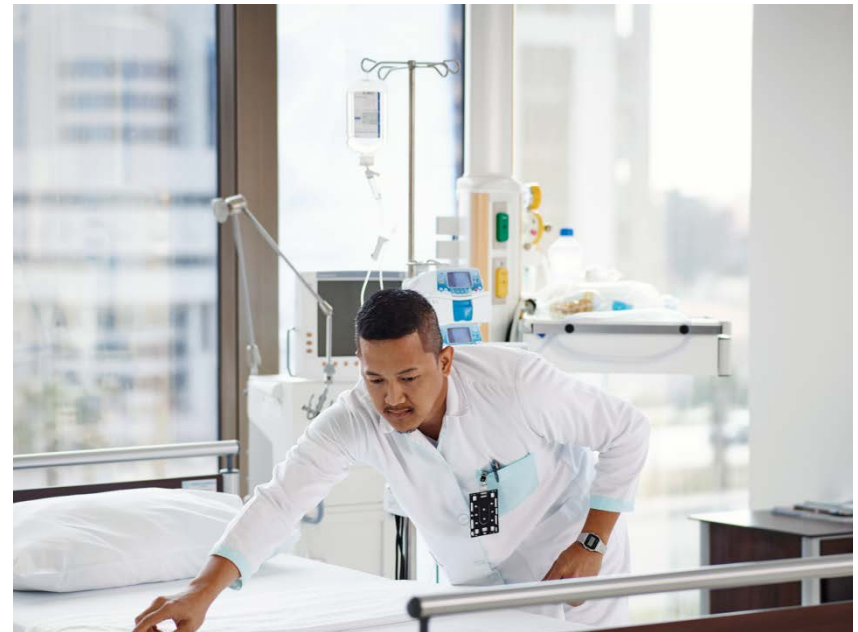
Subjects come back for future studies



Difficult to recruit populations



- Populations are dynamic
- Populations not typically found on a database
- Accessed via hospitals, clinics, other HCPs
- Recruited outside of full-time research setting
 - Fewer resources
 - Must balance care-giving activities with research activities



All populations

A decision of cost versus benefit

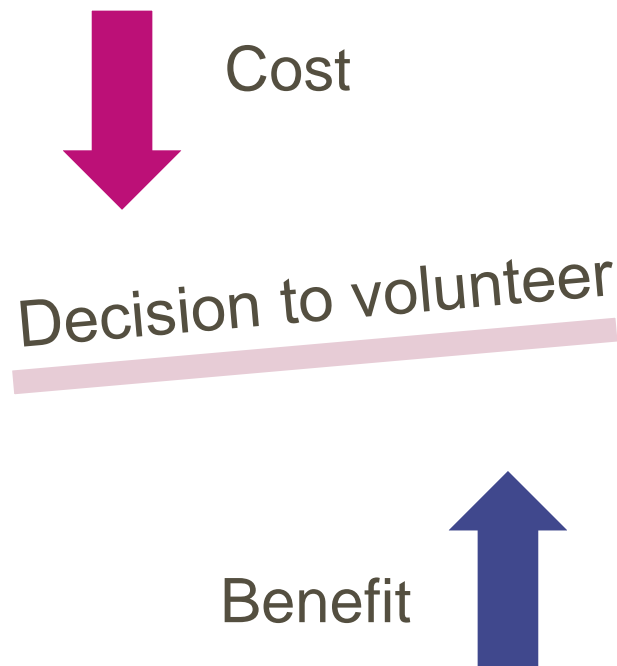


Cost:

- Convenience of visit schedule
- Time off work, school etc
- Getting to the trial site

Benefit:

- Motivation is altruism
- Contributing to science/medicine
- Relies on understanding the burden of disease



Ways to improve recruitment



Facilitate HCP participation in clinical trials of prophylactic vaccines

HCP networks. Sharing knowledge and resources
Training in research



Increase public awareness of infectious diseases

Public campaigning
Education



Increase the flexibility of clinical trials, to reduce the burden to volunteer

Mobile units: bringing the trial to the subject

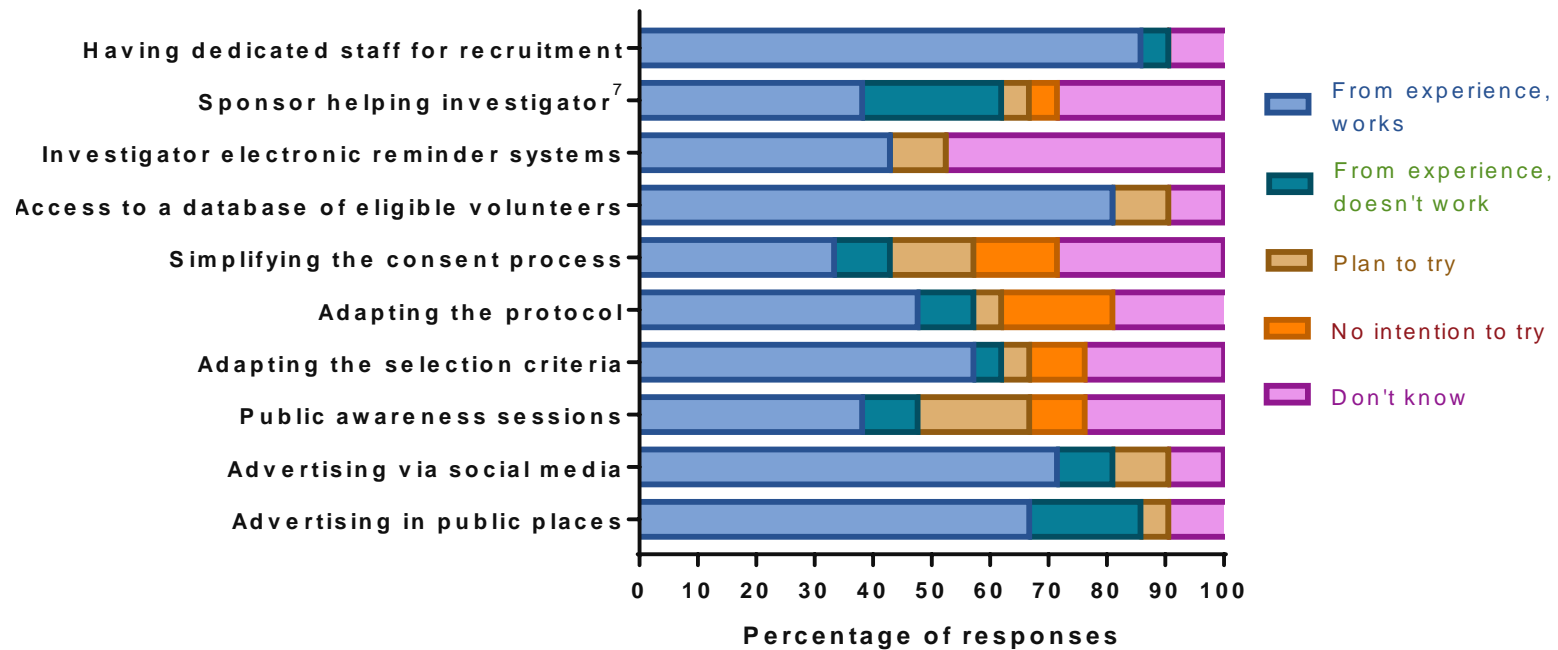
Increase the pool of people willing to volunteer for a prophylactic vaccine trial

Increase the probability of success in recruiting eligible people



Thank you for your attention

Recruitment strategies



The situation in Belgium



Study	Subject population
Phase 1 Study on the Safety and Reactogenicity of a Single Dose of Monovalent High-dose Inactivated Poliovirus Type 2 Vaccine (m-IPV2 HD) Given Intramuscularly Compared to Standard Trivalent Inactivated Poliovirus Vaccine (IPV) in Healthy Adults	Healthy adults 18-45 years of age
Safety and Immunogenicity of a Trivalent Influenza Vaccine When Administered to Elderly Subjects	Male and female volunteers of ≥ 65 years of age
Pertussis Immunization During Pregnancy: Effect in Term and Preterm Infants	(Pre)term infants born from pertussis (un)vaccinated women
An Efficacy Study of GlaxoSmithKline (GSK) Biologicals' Candidate Influenza Vaccine GSK2321138A in Children	Healthy infants 6-35 months of age
Study to Evaluate the Dosage and Safety of Two Intramuscular Injections of an Investigational Clade B HIV Vaccine	Healthy adults 18-27 years of age
Study in Healthy Adults to Evaluate Gene Activation After Vaccination With GlaxoSmithKline (GSK) Biologicals' Candidate Tuberculosis (TB) Vaccine GSK 692342	Healthy adults 18-50 years of age
Influenza A/H1N1/2009-adjuvanted Vaccine in Renal Disease Patients	Adults with renal transplant. Stable renal function for the last 3 months

Source: clinicaltrials.gov 17 Sep 2017 Search terms: Vaccines, Belgium, 01/01/2011-17/09/2017