Partners

The PERISCOPE consortium brings together internationally renowned scientists with many years of experience in *Bordetella pertussis (Bp)* research, clinical trials, bioinformatics, immunology and public health.

- Radboud University Medical Center, The Netherlands
- University of Oxford, United Kingdom
- Public Health England, United Kingdom
- Institut Pasteur de Lille, France
- Trinity College Dublin, Ireland
- University of Turku, Finland
- Commissariat à l'énergie atomique et aux energies alternatives, France
- Imperial College of Science Technology and Medicine, United Kingdom
- National Institute for Public Health and the Environment, The Netherlands
- Institute of Microbiology of the CAS, v. v. i., Czech Republic
- Universitaet Basel/University of Basel Children's Hospital, Switzerland
- University of Bath, United Kingdom
- Leiden University Medical Center, The Netherlands
- Universidad de Salamanca, Spain
- Université libre de Bruxelles, Belgium
- Centre Hospitalier Universitaire Vaudois CHUV, Switzerland
- University of Southampton, United Kingdom
- Q-Biologicals NV, Belgium
- Medical Research Council Unit The Gambia, The Gambia
- Eurice European Research and Project Office GmbH, Germany
- Sanofi Pasteur SA, France
- GSK Vaccines, Belgium

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PERISCOPE has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 115910. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and BMGF.











PERtussIS Correlates of Protection Europe

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Project

Despite the availability of effective prophylactic pertussis vaccines, there has been a rise in the incidence of pertussis. Globally, there are 16 million pertussis cases and about 195,000 pertussis deaths in children per year (estimates by WHO), making it one of the leading causes of vaccine-preventable deaths. The WHO has recommended more extensive vaccination in low income countries and in particular the implementation of maternal (i.e. in pregnancy) immunization programmes to protect young infants who are most vulnerable to pertussis.

The development and licensing of improved next generation vaccines for *Bordetella pertussis* (*Bp*) depends on:

- A more thorough understanding of immune response to infection;
- Identification of biomarkers of protective immunity;
- Development of human and pre-clinical models as well as bioassays to predict and evaluate vaccine efficacy.

PERISCOPE addresses these issues by developing novel functional antibody and cellular assays and employs cutting edge methods to characterise innate immune responses and cell-mediated systemic and mucosal immunity.

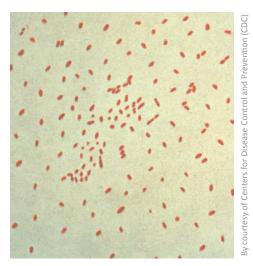
PERISCOPE combines two major industrial partners with public researchers from academic and public health institutes and small and medium-sized enterprises (SMEs) with expertise in clinical trials, vaccinology, immunology, molecular microbiology, challenge models and bioinformatics.



"Given the resurgence and changing epidemiology of pertussis in industrialized countries and the high infant mortality caused by pertussis in low income countries, PERISCOPE represents a concerted effort aiming to accelerate the development of improved vaccination strategies that ensure solid, long-lasting protection against Bordetella pertussis infection."

Prof. Ronald de Groot from Radboud University Medical Center and coordinator of PERISCOPE





Purpose

Acceleration of development of improved vaccines and vaccination strategies

- Identification of novel candidate biomarkers which may predict protection or quality and persistence of immunity
- Roadmap for identification and verification of candidate biomarkers in (pre-)clinical studies
- Understand the impact of maternal immunization on infant immune response

Foster Scientific Innovation in Europe and the capacity to evaluate novel pertussis vaccine candidates

- Establish human and pre-clinical models
- Develop, harmonize and standardize a set of core immunological assays
- Establish a state-of-the-art clinical and laboratory network
- Develop a bioinformatics analysis platform and establish a biobank

Improve understanding of the pathogenesis of Bp infection and potential impact on changes in epidemiology

- Elaborate on dynamics of bacterial infections and development of immunity
- Research on *Bp* immune escape during infection
- Insight into the role of systemic and mucosal immunity in preventing Bp infection

Procedures

Biomarkers of protection

PERISCOPE adopts two parallel strategies to develop immunological read-outs that can be assessed for use as biomarkers of lasting immunity and/or vaccine-mediated protection against pertussis.

The first strategy investigates the predictive power of functional *Bp* (antigen)-specific immune responses generated by vaccination. PERISCOPE develops a set of core immunological read-outs to measure the quantity and functional activity of pertussis-specific circulating antibodies in human blood.

The second strategy focuses on the exploration of novel immunological technologies, systems biology tools and computational modelling to identify response patterns (both innate and adaptive) to vaccination and infection, and ultimately discover if discrete immune signatures may be used as markers and eventually surrogates of effective and long lasting vaccination.

(Pre-)clinical studies and models to identify biomarkers of protection

To identify potential biomarkers of lasting immunity to pertussis, our experienced clinical partners will compare immune responses to primary vaccination with acellular (aP) and whole-cell pertussis (wP) vaccines in a range of age groups, including infants. These studies are performed both in Europe as well as in The Gambia and provide information on immunity to *Bp* in populations with different epidemiologic and genetic backgrounds.

Biomarker substantiation

Broad implementation of the core immunological read-outs in the pre-clinical and clinical studies allow us to identify which readouts correlate best with protection, lasting immunity or a discrete immune response pattern to aP or wP. In consultation with regulatory authorities, core immunoassays are selected as candidate biomarkers and further substantiated in a number of models. PERISCOPE evaluates the correlation of these biomarkers with protection through a cohort of pertussis patients and their exposed family contacts.

Effect of maternal antibodies on response of infants to primary immunization

By applying the core immunological assays to investigate the functional humoral and cellular responses to pertussis in these infants, we are able to address the question if and how maternal antibodies to antigens included in the booster vaccine affect the development and maintenance of immunity to *Bp* vaccination in infants, as well as to other vaccines in the EPI (Expanded Programme on Immunization) schedule. These studies are pivotal to accelerate implementation of immunization with aP during pregnancy.

PERISCOPE follows a highly ambitious yet realistic course to dissect the mechanisms required to achieve long-term protection against *Bp*.