

The PEDVAC-iNTS project represents an important step forward in the development of an urgently needed vaccine against iNTS, a pathogen that is claiming a large number of childhood lives in sub-Saharan Africa and has a huge health and socioeconomic impact in resources-poor countries.



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 PEDVAC-iNTS Project



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E D C T P



**Pediatric Phase I/II
age de-escalation dose finding
study of a vaccine against
invasive non-typhoidal
salmonellosis in sub-Saharan
Africa**

PEDVAC-iNTS project

The overall objective of the **PEDVAC-iNTS** project “**Pediatric Phase I/II age de-escalation dose finding study of a vaccine against invasive non-typhoidal salmonellosis in sub-Saharan Africa**” of an urgently needed vaccine against the invasive Non-Typhoidal Salmonellosis (iNTS). iNTS is an emerging bacterial neglected infectious disease, a condition which disproportionately affects individuals with weak immune systems and children <5 years of age, responsible for a huge health and socioeconomic impact in sub-Saharan Africa (sSA).

There is no licensed vaccine against iNTS and the emergence of multidrug antimicrobial resistant strains poses a major challenge in disease treatment especially in limited-resources settings.

The PEDVAC-iNTS research project aims to advance the clinical development of a novel vaccine against iNTS, based on the highly cost-effective GMMA-technology, developed by GlaxoSmithKline Biologicals SA (GSK) and GSK Vaccines Institute for Global Health, and including outer membrane exosomes released by genetically modified *Salmonella enterica* strains belonging to the most common serovars that cause iNTS in Africa.

PEDVAC-iNTS will conduct Phase I/II clinical trial, using an age de-escalation and dose escalation approach by first assessing safety, in small cohorts of Ghanaian adults, children and infants, and subsequently defining the optimal vaccine dose for further development, in a larger number of infants. Serological and transcriptomic analyses will be also conducted to further profile the vaccine immune response. Additionally, antimicrobial susceptibility of iNTS-causing *Salmonella* strains, isolated in Ghana, will be evaluated to enhance the database of AMR pathogens in sSA.

PEDVAC-iNTS objectives

- Technology transfer, **GMP manufacture** and release of vaccine and placebo lots
- **Pediatric Phase I/II age de-escalation dose finding study** to demonstrate safety and immunogenicity of iNTS-GMMA in Ghana
- In depth analysis of **immunological and molecular signatures** elicited by iNTS-GMMA
- **Study of AMR burden of iNTS in Ghana** to describe the circulating *Salmonella* serogroups and associated antibiotic resistance
- Planning and starting effective **collaboration with public authorities and international organisations to aid in vaccine progression towards licensure and implementation as an effective tool to contain AMR** improving public health in LMIC
- Enhance awareness of iNTS disease and AMR burden through a **collaborative network of experts from academia, industry and non-profit organizations including partners from sSA countries**

PEDVAC-iNTS facts

Project Number: RIA2019AMR- 2658

Coordinator: Sclavo Vaccines Association E.T.S.

EDCTP contribution: 5,698,963.75 €

Start date: 1st March 2021

Duration: 48 months


Partners: 7 from 4 Countries

PEDVAC-iNTS Consortium


PEDVAC-iNTS is a public-private consortium of 7 partners from Europe and Ghana, involving experts from academic institutions, research institutes, small and medium-sized enterprises (SMEs) and non-profit organizations.


The PEDVAC-iNTS project is coordinated by the non-profit organization Sclavo Vaccines Association E.T.S. (www.sclavo.org).


PEDVAC-iNTS Partners


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E.T.S. (Italy)

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