



Need for an iNTS vaccine

Invasive non-typhoidal salmonellosis (iNTS) is an emerging bacterial neglected infectious disease that mainly affects children under 5 years of age and immunocompromised subjects. In 2017, iNTS was estimated to cause 59,100 deaths globally with an average case fatality rate of 14.5% (Lancet Infect Dis 2018-2019).

The majority of cases are observed in sub-Saharan Africa, where iNTS is among the leading cause of community-acquired bloodstream infections. *Salmonella enterica* serovars Typhimurium and Enteritidis are the most commonly associated with invasive disease, causing 90% of cases (PLoS NTD 2017).

There is no licensed vaccine against iNTS, and the emergence of antimicrobial-resistant strains is compromising efficacy of current affordable antimicrobials. High case fatality rates, difficult diagnosis and increasing antibiotic resistance strongly advocate for rapid development of an effective vaccine.



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Advancing a GMMA-based vaccine against invasive non-typhoidal salmonellosis through Phase 1 trial in Europe and sub-Saharan Africa

Vacc-iNTS project

The overall objective of the **Vacc-iNTS** project - “**Advancing a GMMa-based vaccine against invasive non-typhoidal salmonellosis through Phase 1 trial in Europe and sub-Saharan Africa**” - is to advance the development of the iNTS-GMMA candidate vaccine against the invasive non-typhoidal salmonellosis (iNTS).

iNTS is an emerging bacterial neglected infectious disease responsible for a huge health and socioeconomic impact in sub-Saharan Africa.

There is no licensed vaccine against iNTS and the emergence of antimicrobial-resistant strains poses a major challenge in disease treatment especially in limited-resource settings. The Vacc-iNTS research project aims at bridging the gap between preclinical and early clinical development of a novel vaccine against iNTS.

The **iNTS-GMMA** vaccine, based on the cost-effective GMMA technology, is composed of highly immunogenic outer membrane blebs used as antigen delivery system from the two most common African iNTS serotypes (Typhimurium and Enteritidis).

The objective of the Vacc-iNTS project is to conduct a Phase I clinical study to demonstrate the safety and immunogenicity of the iNTS-GMMA candidate vaccine in healthy European and African adults, and to strengthen a collaborative network of iNTS experts to raise awareness of disease burden and favor vaccine deployment in limited-resource settings.

Vacc-iNTS facts

Start date: 1st October 2019

Duration: 60 months

EC contribution: 6 871 188.73 €

Coordinator: Sclavo Vaccines Association

Partners: 12 from 8 countries

More information: www.vacc-ints.eu



Vacc-iNTS objectives

- **GMP manufacture** of the iNTS-GMMA vaccine and placebo lots;
- Conduction of a **two staged Phase I study** to demonstrate safety and immunogenicity of the iNTS-GMMA vaccine in healthy European and African adults;
- In depth **analysis of the immunological and molecular signatures** elicited by the iNTS-GMMA vaccine;
- **Sero-epidemiology studies** in high-burden African sites to plan for future Phase II and III studies with the iNTS-GMMA vaccine;
- **Epidemiological analysis** and modelling of iNTS transmission for an accurate estimate of disease burden;
- Planning and evaluation of **effective deployment and uptake of the iNTS-GMMA vaccine** in low-resource public health systems;
- **Strengthen a multidisciplinary collaborative network** of iNTS experts from academia and industry to delineate a clear pathway for vaccine uptake by health systems in limited-resource settings.



Vacc-iNTS partnership

Vacc-iNTS is a consortium of 12 partners from 8 different countries, including iNTS-endemic countries.

The project is coordinated by the non-profit organization Sclavo Vaccines Association (www.sclavo.org).

Vacc-iNTS Partners



- Sclavo Vaccines Association (IT)
– Fondazione Achille Sclavo (IT)



- GSK Vaccines Institute for Global Health (IT)
– Glaxosmithkline Biologicals SA (BE)



- University of Oxford (UK)



- Kenya Medical Research Institute (KE)



- University of Cambridge (UK)



- University of Siena (IT)



- Institute of Tropical Medicine Antwerp (BE)



- University of Liverpool (UK)
– University of Malawi (MW)



- University of Otago (NZ)



- Université Ouaga I
Professeur Joseph Ki-Zerbo (BF)



- Kwame Nkrumah University of
Science and Technology Kumasi (GH)



- MMGH Consulting GmbH (CH)