Expression of Interest (EoI)

Providing next generation SARS-CoV-2 vaccine (& device if applicable) for evaluation in a controlled human infection (CHI) study.

Information Form

The MusiCC consortium is requesting information from vaccine developers, who are currently developing a next generation SARS-CoV-2 vaccine and who are willing to provide clinical trial grade material (vaccine/placebo + device if applicable) for a CHI study conducted within the MusiCC consortium.

This document describes the scope, objectives and process for submission of information via the application form template. This Expression of Interest (EoI) has a deadline of Friday, 23 August 2024, 17:00 CEST.

Information gathered through this EoI will be the basis to pre-select next generation COVID-19 vaccines for a broader evaluation under a Confidentiality Agreement. In the second round more detailed information will be requested such as: safety and efficacy data, vaccine stock, cost of goods & pricing, equitable access, … and will lead to the selection of one vaccine that will enter the CHI study conducted within the MusiCC consortium.

1. Introduction to MusiCC consortium

To address the limitations of existing intramuscular vaccines against SARS-CoV-2 with regard to transmission-reduction and protection against infection, the European Union's Horizon Europe Programme (HERA) and the Coalition for Epidemic Preparedness Innovations (CEPI), are funding the Mucosal Immunity in Human Coronavirus Challenge (MusiCC) consortium.

The five-year MusiCC project will be led by Imperial College London and aims to establish end-to-end capacity for the development and conduct of SARS-CoV-2 controlled human infection (CHI) studies to establish correlates of transmission-reduction, identify mechanisms of cross-protection and test the efficacy of next-generation vaccines in protection against infection and transmission-reduction/blockade. Please see https://cepi.net/global-consortium-plans-coordinated-human-challenge-studies-hunt-transmission-blocking-coronavirus for more information.

Within this consortium one work package will evaluate the efficacy of a next generation COVID-19 vaccine and Comirnaty in the SARS-CoV-2 Omicron Human Infection Challenge (CHI) Model. For this study we are aiming to select a next generation SARS-CoV-2 vaccine.

2. Introduction to CHI study

Study Fact Sheet:

Primary objectives

- To show decrease in SARS-CoV-2 viral shedding, as measured by the cumulative area under the viral load curve (vAUC), following human challenge
- To show vaccine efficacy on preventing SARS-CoV-2 infection, following human challenge

Secondary objectives

- To show vaccine safety, vaccine efficacy on preventing symptomatic SARS-CoV-2 infection, symptom scores, viral shedding and viral transmission
- Humoral and mucosal immune responses and correlation with efficacy

Current Design:

- Randomised, double blind, 3 arms:
  - Next generation vaccine
  - IM vaccine
  - Placebo

Study Phases:

- Outpatient Vaccination Phase
- Inpatient Challenge Phase
- Outpatient Follow-up Phase until Day 360 after challenge

Sites: Up to 6 clinical trial sites in Belgium, UK & Singapore that will vaccinate

Sponsor: Center for the Evaluation of Vaccination operating in Vaccinopolis (UAntwerpen – www.vaccinopolis.be)

The design may change based on outcome of the model development study (currently ongoing) assessing the dose of the challenge agent required to obtain the desired attack rate

3. Objectives and scope of this EoI

The objective of this EoI is to identify vaccine developers, who are currently developing a next generation SARS-CoV-2 vaccine and who are willing to provide unlabelled clinical trial grade material (vaccine + device if applicable) for a CHI study conducted within the MusiCC consortium.

The next generation SARS-CoV-2 vaccine the consortium is looking for is a vaccine that fulfils the following criteria:

- Has a route of administration different then intramuscular.
- Is able to induce mucosal immunity.
- Must be considered safe via phase I data (at a minimum) obtained.
- Final versions of Investigational Medicinal Product Dossier, Investigator's Brochure and phase I Clinical Study Report must be available at the latest by the beginning of November 2024.
- If a medical device is needed for vaccine administration, the device must be approved for its intended use according to the required regulations.
- A vaccine (+ medical device if applicable) that is able to be rolled-out in Low- or Middle-Income Countries (LMIC) according to CEPI's equitable access policy is preferable.

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detailed information will be requested such as: safety and efficacy data, vaccine stock, cost of goods & pricing, equitable access, … and will lead to the selection of one vaccine that will enter the CHI study conducted within the MusiCC consortium.

4. Information requested and submitted

To submit your EoI, please complete the application template and submit in PDF format to musicc.consortium@gmail.com before 17:00 CEST on Friday, 23 August 2024. All information submitted will be stored in a MusiCC and CEPI restricted access repository.

5. Technical and administrative questions

Technical and administrative questions about this EoI should be directed to musicc.consortium@gmail.com.