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**1. Title:**

Preparedness for the implementation of preventive and therapeutic vaccine clinical trials: from a specialized immunology laboratory to the planning of clinical trial structures in Africa.

**2. Scientific abstract:**

Over 36 million people worldwide are infected with HIV, most of them living in the developing countries. Antiretroviral therapy (ART) has proven to be highly effective to prevent HIV-1 transmission, clinic progression and death. Despite this success, the number of HIV-1 infected individuals continues increasing and ART should be taken for life. Therefore, there are two main priorities: the development of preventive vaccines to protect from HIV infection and immunotherapies (therapeutic vaccines) to achieve an efficacious control of HIV infection in the absence of ART (functional cure of infection). In this sense, in the last few years our group has developed mRNA-based vaccines that could represent a promising alternative to conventional vaccine approaches.

In December 2019 China declared an outbreak of an unknown pneumonia in Wuhan. It was determined that this new disease was caused by a novel coronavirus (SARS-CoV-2) and named it coronavirus disease 2019 (COVID-19). In March 2020 the World Health Organisation designated COVID-19 a global pandemic with an overall mortality of 2-8%. This exceptionally complicated and unknown situation has driven scientists worldwide to finding the best interventions to reduce mortality, sanitary resources burden and prevent new infections. One of the main strategies that have been proposed to prevent new infections is developing vaccines. Currently the average development time for conventional vaccines from preclinical phase is more than 10 years highlighting the dire need for new approaches that allow safe and fast development. Due to the current state of alarm situation we consider that the mRNA platform that we have been using for developing and testing HIV vaccines could be easily adapted to SARS-CoV2 hence have a prototype as soon as possible.

The overall aim of this project is to prepare the implementation of clinical trials with new immunogens.

Specific objectives are:

1. To improve immunologic assays for a more comprehensive evaluation of immune responses to vaccine candidates;
2. To develop and test in preclinical studies new and very innovative mRNA vaccines;
3. To conduct a preparedness study in rural South Africa to evaluate the feasibility of conducting preventive and therapeutic vaccine clinical trials



3. **Keywords:** vaccines, mRNA, HIV, SARS-CoV-2.