**INTERNATIONAL COVID-19 CLINICAL EVALUATION REGISTRY: HOPE-COVID 19.**

**(Health Outcome Predictive Evaluation for COVID 19)**

**HOPE PROJECT MD.**

**PROTOCOL VERSION 5.2**

**ENGLISH VERSION.** NCT04334291

## INTRODUCTION.

The disease caused by the new respiratory virus (coronavirus) designated as SARS-CoV-2 has recently been classified as a pandemic by the WHO.

With an increasing number of confirmed cases in most countries worldwide, it is responsible for a significant morbidity and mortality and has motivated the implementation of measures at national and international levels with a great impact on the way of life of people throughout the whole planet.

In addition, this condition currently threatens many countries with the collapse of health systems, producing serious logistical problems due to extensive affectation of the population, which can worsen the prognosis of those primarily affected by COVID 19 and other patients with different pathologies and who may have difficulties to get healthcare.

Limited clinical information is available and generally limited to the Asian population, since the first cases were identified in Wuhan (Hubei, China).

## PURPOSE.

The main objective of the present study is to carefully characterize the clinical profile of patients infected with COVID-19 in order to develop a simple prognostic clinical score allowing, in selected cases, rapid logistic decision making (discharge with follow-up, referral to provisional/field hospitals or admission to more complex hospital centers).

As secondary objectives, the analysis of the risk-adjusted influence of treatments (ie. ACEIs, ARBs) and previous comorbidities of patients infected with the disease will be performed.

## DESIGN AND STATISTICAL ANALYSIS

Cross-sectional and ambispective registry, a real life “all comers” type, with voluntary participation, without funding or conflicts of interest. It is a study initiated by researcher that will have advanced statistical support from the IMAS foundation (Institute for the Improvement of Health Care, Madrid, Spain), that will serve as statistical core.

International level.

## PARTICIPANTS PROTOCOL.

The study has been approved by Hospital Clinico San Carlos Ethic´s Committee (20/241-E) and the institutional board of each participating center. It has received an AEMPS classification (EPA-0D).

We propose to select all the patients attended in any health center (with in hospital beds), who have been discharged or have died at the time of the evaluation.

All will be considered eligible with a positive COVID 19 test (any type) or if their attending physicians consider them highly likely to have presented the infection.

Given the anonymous characteristics of the registry and the health alarm situation generated by the virus, in principle, it is not considered necessary to provide written informed consent.

- **Inclusion criteria**

Patients discharged (deceased or alive) from any hospital center with a confirmed diagnosis or a COVID-19 high suspicion.

There are no exclusion criteria, except for the patient's explicit refusal to participate.

## DATA BASE.

An anonymized database is presented in electronic format, to be filled in at each participating center (www.HopeProjectMD.com).

In theory, all information could be obtained from electronic records (medical history).

If deemed necessary, the investigator may call patients in order to establish their vital status (strongly warranted), as well as the results of the PCR test (or others: antibodies…), if they were pending during their stay.

Variables definition, see protocol appendix.

## SAMPLE SIZE.

We consider it would not be possible to estimate for the sample size based on literature reports. Thus, HOPE will aim to get the maximum numbers of patients possible.

Researchers are warranted to recruit their patients in a consecutive manner.

## OUTCOMES.

**Primary:** All-cause mortality. The major contributors of increased mortality will be assessed.

**Secondary:** In stay events, defined by the attending physician.

- Mechanical ventilation (invasive).
- In hospital stay.
- Heart failure.
- Renal failure.
- Respiratory Insufficiency.
- Upper respiratory tract involvement.
- Pneumonia.
- Sepsis.
- Systemic inflammatory response Syndrome.
- Clinically relevant bleeding.
- Hemoptysis.
- Embolic event
- Other complications.
- Causes of death.

See protocol appendix for precise definitions.

Depending the results of the main interim analysis, the main DB could be slightly modified and several sub analyses could be proposed after sensitivity analyses.

## RESEARCHERS AND AUTHORSHIP.

Initially, to avoid potential duplicates, an unique online account is accepted per hospital. Within each center, the researchers will decide themselves the main researcher (maximum 2 principal investigators,) and the collaborators (maximum 10).

They are accepted as collaborators, physicians, nurses, students, and other personnel under the supervision of local MD/DO/PhD investigators.

The order of authorship will be established based on the recruitment (valid cases) in HOPE. All study researchers and collaborators will be included in the HOPE project group.

HOPE is not an audited record, so each researcher is responsible and vouch for the veracity and accuracy of their included data.

The database will be made available to participating researchers who wish to carry out sub-analyzes of their interest.

**AGENDA AND ROADMAP.**

**23rd March 2020:** Research Ethics committee approval. National and international invitations to participate submission.

**23rd March 2020:** Activation of HOPE study invitation links. Once participation in the study is approved, your center will be registered and the researcher will be able to set a login and password. Then, you could enter the data on the web.

**1st April 2020:** DB exportation. Query resolution phase.

**4-7th April 2020:** Analysis and development of statistical models, (propensity scores, etc.). Interim analysis.

**8th April 2020:** preliminary results. **Working clinical score development.**

**30 th April 2020:** DB exportation.

**2-6 th May 2020:** Analysis and development of statistical models, (propensity scores, etc.).

**31st May 2020:** Final HOPE enrollment period.

**2nd June 2020:** DB exportation. Query resolution phase.

**3-8 th June 2020:** Analysis and development of statistical models, (propensity scores, etc.). Final HOPE results.

The final date of registration/follow up is May 31st, 2020 (database closing June 2nd, 2020).

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**SCIENTIFIC COMMITTEE AND LIST OF PARTICIPATING HOSPITALS:** Available updated at www.HopeProjectMD.com.

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