PROTOCOL TITLE

Luxembourg cohort of positive patients for COVID-19: a stratification study to predict patient prognosis

Protocol Number: 6.1

Amendment Number: 5

Short Title: Predicting Covid-19 severity

Acronym: *Predi-COVID*

Sponsor Name: Luxembourg Institute of Health

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Institution	Role in the study
LIH	Sponsor, study management, biosamples analysis, data analysis, statistics, epidemiology
LIH/IBBL	Biosample transport, processing and storage. Biosample analysis
LNS	Biosamples analysis
LCSB (University of Luxembourg)	Scientific advice, Biosamples analysis
CHL	Scientific advice, patient recruitment
HRS	Scientific advice, patient recruitment
CHDN	Patient recruitment

Protocol Amendment Summary of Changes Table:

Version_Date	Version number	Affected Section(s)
08 APR 2020	2.0	2.2 /2.3/6.4/7.1/7.2/9/10/13.1/14/Annex 2
11 MAY 2020	3.0	2/4/5/6/7/9/10/13/14/ Annex 2-3-4-5
19 MAY 2020	3.1	14/Annex 2 and 5
26 JUNE 2020	3.2	7.1/7.2/7.3/14/Annex 2
12 AUG 2020	3.3	5/7.1/7.4/10/14
07 SEP 2020	3.4	14/Annex 2
20 OCT 2020	4.0	2.3/5/6/7/10/11/13
03 DEC 2020	4.1	14
21 JAN 2021	5.0	2.4/13.3/Annex 1
29 JUIN 2021	5.1	Synopsis (Study timelines)
27 SEP 21	6.0	Synopsis/2.4/2.5/2.6/3.2/5/6.1/7.1/7.2/7.3/14 / Annex 2 (Questionnaire permanent) /Annex 3 (CRF)

PROTOCOL APPROVAL

«Luxembourg cohort of positive patients for COVID-19: a stratification study to predict severe prognosi»

«Predi-COVID»

«Luxembourg Institute of Health»

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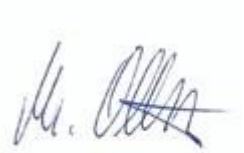
Markus Ollert, Director of Department of Infection & Immunity	+352 26970-829 **markus.ollert@lih.lu**	**01-10-21**	
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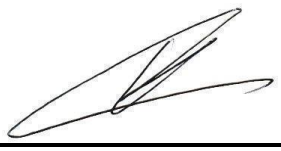
Michel Vaillant, Head of CCMS	+352 26 970 740 **michel.vaillant@lih.lu**	**01-10-21**	

PROTOCOL SIGNATURE PAGE

«Luxembourg cohort of positive patients for COVID-19: a stratification study to predict severe prognosi»

«Predi-COVID»

«Luxembourg Institute of Health»

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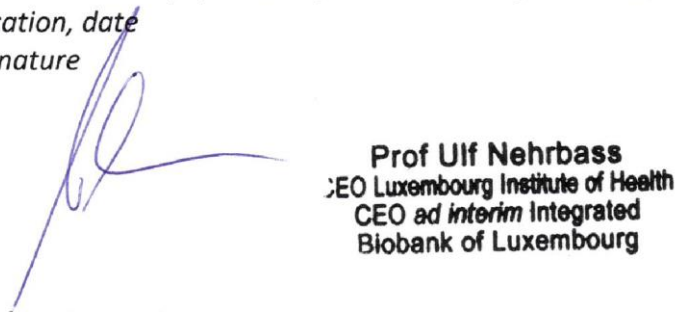

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Table of Contents

1. SYNOPSIS

Study title	*Luxembourg cohort of positive patients for COVID-19: a stratification study to predict severe prognosis*
Study acronym	Predi-COVID
Version Number	**6.1**
Indication	COVID-19 infection
Rationale and background	Pandemics are large-scale outbreaks of infectious disease that can greatly increase morbidity and mortality over a wide geographic area and cause significant economic, social, and political disruption. A major pandemic can overwhelm the capacity of outpatient facilities, emergency departments (EDs), hospitals, and intensive care units, leading to critical shortages of staff, space, and supplies with serious implications for patient outcomes. The World Health Organization (WHO) declared COVID-19 a pandemic on March 11, with more than 300,000 people infected worldwide, as of March 23 2020. By March 23 2020 Luxembourg Ministry of Health has reported over 800 confirmed cases and 8 deaths. Studies on epidemiological and clinical characteristics of adults with COVID-19 show that compared to women, men are more infected and the median age is 49.0 years. Common symptoms at onset of illness are fever, cough, dyspnea and myalgia or fatigue; less common symptoms were sputum production, headache, haemoptysis and diarrhea. Complications included acute respiratory distress syndrome, anaemia, acute cardiac injury and secondary infection. The risk for serious disease and death in COVID-19 cases increases with age. As of 23 March 2020, no vaccine has been successfully developed for COVID-19. The treatments are mainly symptomatic and supportive (only true for mild cases, severe cases have bacterial coinfections, so treatment includes antibiotics and also antivirals now (Kaletra)). Children seem less often affected or develop more often the asymptomatic, aspecific and mild variant of the COVID-19 disease. Recent observations have demonstrated that not all children escape critical illness (example: Pediatric Multisystem Inflammatory syndrome- PIMS) . Clinical characteristics of the disease in children may differ from the adult disease and even more important the critical illness may and or may not be caused by the same pulmonary symptomatology. Whether rare immune mechanisms (IEI - inborn errors of immunity, host genetic susceptibility in innate immunity -related genes) or environmental factors are involved in these cases is unknown. Risk factors for severe disease in children need to be elucidated. We determined that identifying profiles of patients predictive of more severe prognosis would be key to clinical management and would support more efficient public health measures. The purpose of this project is the identification of clinical and socio-demographic characteristics as well as the pathogen and/or host predictive biomarkers for the severity of the disease. We are aiming to better understand the heterogeneity observed in disease severity through a stratification approach of the cohort in Luxembourg.
Objectives	The study aims at identifying factors associated with the COVID-19 disease severity. COVID-19 patients with severity criteria will be compared to patients with mild disease managed at home.

	A deep phenotyping related to the symptoms of the disease as well as biosampling allowing for laboratory-based and computational analytics will be performed.
Evaluation criteria	Severity of symptoms will be evaluated by the occurrence of an hospitalisation, the duration of the hospitalisation, the occurrence of ICU (or equivalent structures) stay, the duration of ICU, the need for supplemental oxygen, the need for ventilation and the duration of both, the need for a transfer to another hospital, the impact of infection on daily activities. As knowledge on covid is evolving very quickly, additional criteria may have to be added.
Study design	Predi-COVID is a prospective cohort study composed of adults and children positively tested for COVID-19 in Luxembourg, followed digitally for monitoring participants' health evolution and symptoms at home. Participants will be actively followed for 14 days from the time of confirmation of diagnosis, whether they are at the hospital or at home in isolation or quarantine. Short evaluations will be also performed at week 3 and week 4 and then monthly for a period up to 12 months to assess potential long term consequences of COVID-19. The last monthly questionnaire will be more detailed to provide a specific focus on long-COVID symptoms evaluation and will be completed at M12, M15 and M24.. All participants will be followed digitally and a subsample will participate in a sample collection.
Intervention	For every adult (a "case") tested positive by RTqPCR, up to 45 mL of blood will be taken, a nasal swab and an oropharyngeal swab will be performed, an induced sputum (or saliva), hair sample and a stool samples will be recovered at the inclusion. As follow-up, 6 months, 15 months and 24 months after inclusion, the same sampling will be performed. Two additional sampling visits will be proposed to adult participants with a reinfection or a post-vaccination infection at 3 weeks and at 2 months. For every child tested positive by RTqPCR, up to 50 mL of blood will be taken, a nasal swab , oro- and naso-pharyngeal swabs, induced sputum or saliva, hair sample, as well as a stool sample will be obtained at inclusion. The follow up visits at 6, 15 and 24 months after inclusion, will include the same samples. For patients at home, an experienced nurse from CIEC will perform the sampling, using all the required precautions and protections in the actual context. For hospitalised patients, a simplified sampling strategy will be put in place and adapted to the patient state, the workload of staff and adapted constantly depending on the evolution of the epidemy. Below is described the maximal sampling strategy.
Study timelines	● Recruitment period: up to 29 months (March 2020-August 2022) - to be adapted to the evolution of the epidemiological situation) First patient in: March 2020 ● Follow-up period : max 24 months ● Analysis of results and study report: 3 months ● Global duration: 54 months (to be adapted on the duration of the epidemiological situation)
Population	**Predi-COVID Inclusion criteria:**

	● Signed informed consent form ● Adult (≥18 years old), child and adolescent (0-17 years old) patients with confirmed SARS-CoV-2 infection as determined by PCR, performed by one of the certified laboratories in Luxembourg ● Hospitalized or at home **Exclusions criteria** : ● Patients not understanding French or German ●
Patient withdrawal criteria	Transfer outside Luxembourg if no information can be collected in the receiving country.
Number of patients/ participants	The objective is to recruit virtually all COVID-19 positive persons in Luxembourg. A sub-sample of a minimum of 200 COVID-19 positive persons in Predi-COVID study would allow to find a risk ratio of severe disease above 2 for the selected risk factor with a power of 80% when the prevalence of the disease is above 7%. A minimum of 100 COVID-19 positive children would allow to find a risk ratio of severe disease above 3.2 for the selected risk factor with a power of 80% when the prevalence of the disease is above 7%.
Safety	*No AE/SAE reporting is planned in this study since no interventional medication involved.*
Statistical methods and data analysis	Descriptive statistics will be produced for hospitalisation, intensive care / resuscitation admission, ventilation, their duration, death and severity of the disease. Other variables including potential prognostic factors of the disease will also be described with mean (+- STD) or frequencies (%) as adequate. Statistical models will be used to study whether the risks of hospitalisation, intensive care admission or intubation as well as death are associated with a specific risk factor. adjustment will be done on age, gender and other potential confounding factors. Further stratification of the patient cohort will be performed through Machine learning techniques to include biological and other omics measurements. According to a deep phenotyping of the symptoms of the disease as well as biosampling allowing for laboratory-based and computational analytics, a stratification approach will include data-driven tools and allow to define disease trajectories that will be translated into clinical and/or biomarker-defined subgroups.
Interim Analyzes	Regular interim analyses will also be performed to inform policy stakeholders. It will be mainly descriptive statistics on the main endpoints defined above.
Regulatory	*The study will be submitted for approval at MS* and CNER**.* *The study will follow the new General Data Protection Regulation (GDPR) of 27 April 2016.* *Written informed consent will be obtained before enrolment in the study.* **Ministry of Health, **National Research Ethics Committee*

Ancillary study	An ancillary study will be added (Predi-COVID-H). For patients included as well as subjects living with positively tested patients on the basis of a volunteer informed consent. Predi-COVID-H is an ancillary cohort study composed of Household members of index cases to monitor symptoms and disease outbreak in this high-risk population. For every asymptomatic member of the family of a "case" included in the Predi-COVID sub-sample (a "contact"), clinical as well as socio-economic characteristics will be collected. Biological samples will also be collected at the same time as the "case" visit by nurses and up to 50 ml of blood, nasopharygeal and oropharyngeal swabs, stool, saliva and hair samples will be taken at baseline for adults and children. According to the new recommendations of the Health Directorate, all Household contacts of positive cases are invited by the Sanitary Inspection to be tested 5 days after the diagnostic test of the "index case". In case of positive result, the "contact" will be proposed to be enrolled in the Predi-COVID study. Otherwise, a second visit will be planned 6 months later, to collect blood, nasopharygeal and oropharyngeal swabs, stool, saliva and hair samples. All "contacts" will be followed digitally. **Predi-COVID-H inclusion criteria:** ● Adult and children (0-17 ans) house members of COVID-19 positive participants. **Exclusions criteria** : ● Patients not understanding French or German **Sample size:** A minimum of 100 participants (adults and children) will be included in the sub-study on house-members. The sample size and the sampling strategy may have to be adapted to the rapidly evolving knowledge on COVID-19.

2. INTRODUCTION AND RATIONAL

2.1 Background

In December 2019 the first case of pneumonia caused by a novel betacoronavirus, the 2019 novel coronavirus (2019-nCoV), was reported from the city of Wuhan, Hubei Province in Mainland China (3). The disease quickly spread to other parts of China and across the globe. The World Health Organization (WHO) declared COVID-19 a pandemic on March 11 (2), with more than 200,000 people infected worldwide, as of March 19 2020. Pandemics are large-scale outbreaks of infectious disease that can greatly increase morbidity and mortality over a wide geographic area and cause significant economic, social, and political disruption. A major pandemic can overwhelm the capacity of outpatient facilities, emergency departments (EDs), hospitals, and intensive care units, leading to critical shortages of staff, space, and supplies with serious implications for patient outcomes (1).

By March 19 2020 Luxembourg Ministry of Health has reported 335 confirmed cases and 4 deaths. In an attempt to limit the speed of COVID-19 propagation, several European countries, including Luxembourg, have ordered an emergency confinement of their population. This is a crucial step to decrease the speed of the infection spreading as much as possible. These measures are giving more time to the health care providers and scientific community to be prepared and to identify an adapted therapy. This time should also be used to improve our understanding of the disease development, its outcome and heterogeneity.

2.2 Rationale

The pathogen for the new outbreak has been identified as a novel enveloped RNA betacoronavirus2 that has currently been named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which has a phylogenetic similarity to SARS-CoV (1). Studies on epidemiological and clinical characteristics of patients with COVID-19 show that compared to women, men are more infected and the median age is 49.0 years (1, 4). Common symptoms at onset of illness are fever, cough, dyspnoea and myalgia or fatigue; less common symptoms were sputum production, headache, haemoptysis and diarrhea. Complications included acute respiratory distress syndrome, anaemia, acute cardiac injury and secondary infection (4). The risk for serious disease and death in COVID-19 cases increases with age (5). In the United States case-fatality percentages increased with increasing age, from no deaths reported among persons aged ≤19 years to highest percentages (10%–27%) among adults aged ≥85 years (5). The findings from the United States are similar to data from China, which indicated >80% of deaths occurred among persons aged ≥60 years (5). As of 19 March 2020, no vaccine has been successfully developed for COVID-19. The treatments are mainly symptomatic and supportive. The study by Huang et al. reported that the most common complications in patients with 2019-nCoV infection were acute respiratory distress syndrome, followed by anemia, acute heart injuries, and secondary infections.

Due to the rapid spread of COVID-19, we determined that identifying profiles of patients predictive of more severe prognosis would be key to clinical management and would support more efficient public health measures. Although there have been some studies on epidemiological and clinical characteristics of patients with COVID-19, there is a lack of research investigating the prognostic factors for the severity of the disease. The accurate prognostic evaluation of COVID-19 can provide a guiding basis for active and effective management of the outbreak.

The purpose of this project is the identification of patients clinical and socio-demographic characteristics as well as pathogen and/or host predictive biomarkers for the severity of the disease. We are aiming to better understand the heterogeneity observed in disease severity through a stratification approach of the cohort in Luxembourg.

Pathogen biomarkers include the SARS CoV-2 strain (sequence) (6, 7). Host biomarkers include clinical phenotypic characteristics, serological history, co-infections, genetic polymorphisms, immune cell phenotypic markers, immune circulating markers, fecal virome and hormones/glucocorticoid concentration. Applicable guidelines have been issued by the WHO and the CDC (8, 9) and quality control materials have been produced by commercial suppliers (10). Previously deposited patent applications include many details on laboratory protocols (11). Very recently, specific preanalytical and analytical guidelines have also been published (12).

Study design: This is a prospective cohort study. The study (Predi-COVID) will include all adults >18 years with confirmed COVID-19 infection (positive by RTqPCR test). Clinical data collection and monitoring of participants' health evolution and symptoms will be proposed to all participants. A subsample of a minimum of 200 patients will be invited to participate in the biological samples collection.

2.3 Interest for children

So far, research around COVID 19 tends to focus on disease evolution and treatment in the adult population. This is based on the observed incidence, disease severity and the high mortality in the adult population, with either intense exposure (health care professionals) or high risk factors for critical disease such as older age, diabetes, cardiovascular disease, hypertension, chronic respiratory disease, immune compromised disease and obesity. In younger adults, obesity seems to be the major risk factor for critical illness. Children seem less often affected or develop more often the asymptomatic, aspecific and mild variant of the COVID-19 disease. However, more recent observations demonstrate that not all children escape critical illness and even more important, that the critical illness may or may not be caused by the same pulmonary symptomatology. In Madrid, 60% of the 41 children with confirmed COVID-19 during the first two weeks of the epidemic were hospitalised, and 9,7% of them had to be admitted to the paediatric intensive care unit . More recent observations suggest that the virus may be involved in the Pediatric Inflammatory Multisystem Syndrome- a new clinical entity characterized by multiple organ inflammation accompanied in some cases by organ failure and up to 40-50% of cases by choc.

In Luxembourg, two previously healthy children (<12 years) have suffered from severe cardiac involvement (myocarditis and Kawasaki disease) induced by the COVID-19, requesting intensive care treatment, based on their clinical condition (personal observation) (retrospective diagnosis of PIMS). Whether rare immune mechanisms (IEI - inborn errors of immunity, host genetic susceptibility in innate immunity -related genes) or environmental factors are involved in these cases is unknown.

Risk factors for severe disease in children need to be elucidated. This would allow not only better understanding of the pathophysiology and dynamics of COVID-19 in children, but also the development of relevant public health measures in order to optimize protection for those children who are vulnerable (ex by vaccination when available in the future).

This pediatric extension of the study aims to identify factors associated with the COVID-19 disease severity (or lack of it) in children with an in-depth characterization of the clinical, biological and microbiological characteristics of COVID-19 in children.

Stools sample have been planned at each study visit in the children sample strategy, both for Covid-19 positive and household contact children, to increase the understanding of virus shedding in stool and the influence of the microbiota on Covid-19 infection in the children population.

2.4 Long-term consequences of Covid-19

Given the current body of knowledge, **there are key unsolved questions around the long-term (beyond 3 weeks) health consequences of Covid-19**, which in the absence of any consensus has been termed as "Long Covid" or "Long Haulers" in recent publications[14]. Also named **Chronic Covid Syndrome (CCS),** this condition needs to be better described and understood. So far, it has been shown that a fraction of the Covid-19 patients who undergo a variable acute symptomatic phase of the disease are coming forward with continuing effects of the disease, with complaints such as mental fog, delayed latent periods in recalling events of recent past, tachycardia, extreme fatigue, inability to perform daily physical tasks[15]. The signs and symptoms are so diverse and related to multiorgan and systems that it is challenging to ascribe it a proper terminology[16]. It has also been recognized that there are Covid-19 affected patients in which renal, cardiac, neural, gastrointestinal, and coagulative features

dominate and threaten the life of the patients[17]. That being said, the majority of the data come from hospitalized patients and few studies report long-term health consequences of asymptomatic or mildly symptomatic forms of Covid-19. However it has been shown that a vast majority of patients with home based recovery had frequent cardiac inflammatory involvement, which was similar to the hospitalised subgroup with regards to severity and extent[18]. A call for more research has been recently released by doctors in the BMJ[19].

Only some of the above-mentioned long-term health related consequences of Covid-19 are covered in the monthly questionnaire in Predi-COVID. The last monthly questionnaire at the end of the follow-up (month 12) has been more detailed, to collect complementary information on a large spectrum of chronic conditions or symptoms potentially related to Covid-19 to increase the value of the Predi-COVID cohort study and associated spin-off projects.

To align with new research questions around Long Covid and its long term presentation, the total follow-up duration for participants has been extended to 2 years, with Long-Covid specific questionnaires at months 15 and 24 for all participants and a new biological sampling at 15 and 24 months.

2.5 Reinfection and infection post-vaccination

The vaccination campaign has picked up speed all over the world but coverage is still not yet sufficient in Luxembourg, as in many countries. Open questions begging to be answered and future risks remain (variants of concern, new waves, vaccination escape, immune response dynamic, reinfections, infections before and after vaccination). In this perspective there is a need for more information on infections post-vaccination but also on reinfections. These results will help to guide the national authorities to adapt its crisis management strategy.

In particular, the short- to mid- term impact of vaccination in relation to the evolution of immunity and breakthrough infections by variants, and how this knowledge could be used to inform the future vaccination strategy in Luxembourg is of high interest.

2.6 Health economics

The impact of the Covid-19 pandemic on the health system, at both the individual and population level is still understudied. Questions related to work ability and long-term care costs remain unanswered questions. By linking data from Predi-COVID with medico-administrative data from the IGSS (Inspection Générale de la Sécurité Sociale), we will have the opportunity to 1) better describe the overall healthcare pathway of individuals with Covid-19 before and after the infection, both in terms of healthcare consumption and costs and 2) assess the impact on the socioeconomic and work environment in Luxembourg.

2.7 Risk/benefits assessment

The risks associated with this study protocol in the population described above are described below:

Procedure – type of sample	Associated risk
Blood sample	Pain, bruising, tiredness or fainting, infection
Nasopharyngeal swab	Discomfort during brushing, bleeding, infection
Oropharyngeal swab	Discomfort during brushing, bleeding, infection
Stool collection	No known risk, infection to person handling sample
Sputum/saliva collection	No known risk, infection to person handling sample
Usage of smartphone app	Minimal associated risks * linked to the use of a healthcare application on a mobile phone
Hair sample	No known risk, infection to person handling sample

*There are some risks linked to the fact that the study is conducted exclusively online (hacking of the participating account, risk of jeopardizing the confidentiality of health data and other personal data). All precautions will be taken for the patients, the family members and nurses during samples and data collection, according to the rules in force at the time of the study.

The benefit for the participant will be to benefit from an additional tool allowing a daily monitoring of their health status and to participate in an innovative research project in the current crisis context and to contribute to the common effort in the fight against the COVID-19 pandemic.

3. OBJECTIVES

3.1 Principal objective

The main objective of Predi-COVID is to identify clinical, epidemiological and omics characteristics associated with the severity of COVID-19, which will then be used to further stratify the study population into clusters of disease severity with similar patterns and disease courses.

3.2 Secondary objectives

Secondary objectives include

- to study the long term (up to 2 Year) health consequences of COVID-19.
- to characterise clinical symptoms and biological markers for individuals with re-infection/infection post-vaccination and Long COVID
- to describe the trajectories of symptoms after being positively diagnosed to COVID-19
- to identify vocal biomarkers associated with respiratory syndromes, fatigue, anxiety or emotions related to COVID-19 which could then further be used for easy remote monitoring of COVID-19 patients.
- to identify the virological factors and the individual characteristics involved in viral escape to COVID-19 vaccines and in reinfections
- to characterize the cellular and antibody responses (type and durability) elicited by vaccines and in uninfected and recovered COVID-19 patients (either vaccinated or not) with an emphasis on the variability of immune responses

4. EVALUATION CRITERIA

4.1 Main Evaluation Criteria

- ➔ **Hospitalization :** Hospitalisation and Duration of hospitalization (days)
- ➔ **Intensive care :** intensive care / resuscitation and duration of intensive care / resuscitation
- ➔ **Ventilation :** ventilation and duration of ventilation
- ➔ **Transfert to a hospital outside Luxembourg**
- ➔ **Clinical severity**
- ➔ **Death**

4.2 Secondary Evaluation Criteria

Analytical endpoints to be evaluated on the sub-cohort with complete data

- **Quantitative**
  - The charlson index
  - Whole blood count parameters

- Plasma cytokine levels
- Peripheral cell immune phenotyping
- TCR repertoire of CD4 and CD8 T cells
- IgG and IgM titers
- hormones/glucocorticoid concentration

- **Qualitative**
  - Syndromic respiratory disease panel results
  - COVID-19 mutations
  - HLA genotypes

Criteria may be modified as we acquire knowledge on the infection. Updates of these criteria will be made as needed.

5. STUDY DESIGN

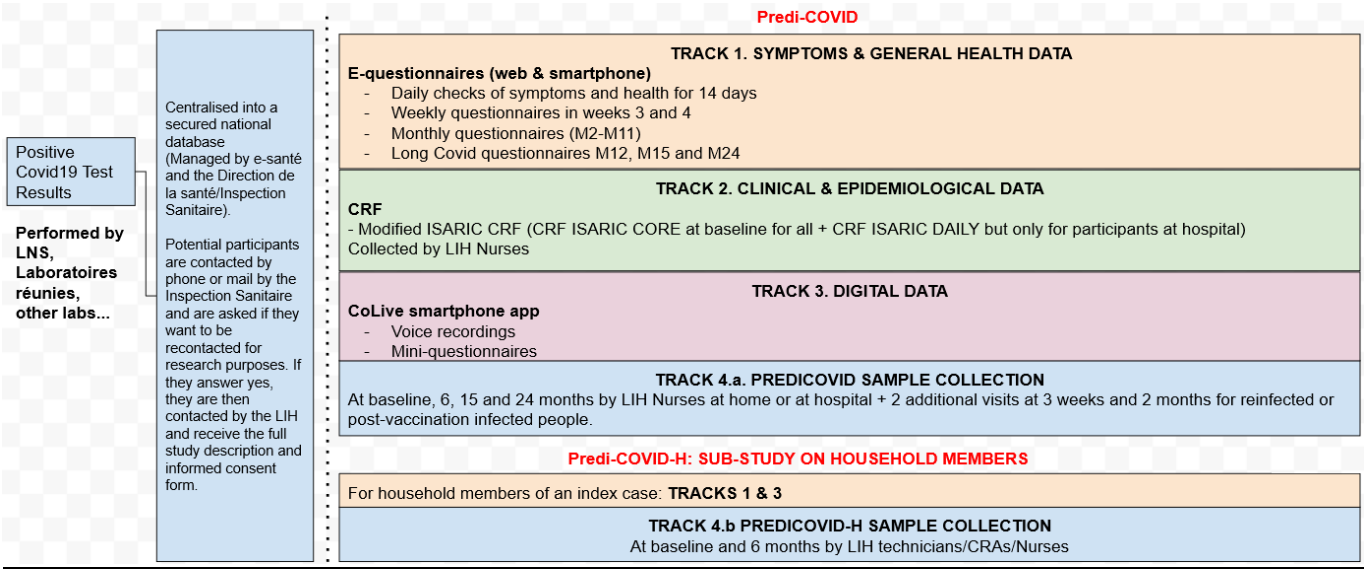

Figure 1. Overview of Predi-COVID design and data collection.

Predi-COVID is a prospective cohort study composed of people positively tested for COVID-19 in Luxembourg, followed with a remote system for monitoring participants' health evolution and symptoms. After explicit consent, virtually all adults ≥ 18 years and all children < 18 years with confirmed COVID-19 infection (positive by RTqPCR test) could be included in the Predi-COVID cohort.

A sub-sample of a minimum 320 adults and 100 children will be included in the deep-phenotyping sub-study. This number will be adapted to quickly evolving knowledge on COVID-19 and to the resources available to include and sample patients.

For hospitalized patients, the protocol encompasses a face-to-face inclusion combined with daily evaluations up to death or discharge (using ISARIC modified CRF (CORE + DAILY modules)). From discharge, participants will then be asked to enter the "Home" protocol. At home, a digital follow-up thanks to a remote system (web or mobile app) and the CoLive LIH smartphone app will be performed for both health status and symptoms checks as well as for research-oriented data collection.

Adult and child participants in Predi-COVID will be actively followed for 14 days from the time of confirmation of diagnosis, whether they are at the hospital or at home in isolation or quarantine. Short evaluations will be also performed at week 3 and week 4 and then monthly for a period up to 12 months to assess potential long term consequences of COVID-19.

A biological sampling is performed at baseline and at 6 months for all Predi-COVID participants.

6. STUDY POPULATION

The Predi-COVID cohort will be composed of volunteered Covid-19 positive patients identified in the centralized database of all diagnostics tests performed in Luxembourg, managed at the Health Directorate.

A sub-sample will be invited to perform complementary clinical data and biological samples collection. Therefore, the study will collect data on all cases and comprise more detailed data and associated samples for a minimum of

200 adult participants and 100 children. The basic sampling scheme for participants will consist in 2 sampling visits, one at baseline and one at 6 months.
In addition, adults presenting a reinfection or a post-vaccination infection will be invited to do 2 specific sampling visits at 3 weeks and 2 months to answer specific research questions on vaccination and reinfections.

6.1 Inclusion criteria

For the **Predi-COVID** cohort, in order to be eligible to participate in this study, an individual must meet all the following criteria:

- Signed informed consent form by the patient (adult) and caregiver/parent (child)
- Adult (≥18 years old), child and adolescent (0-17 years old) patients with *confirmed SARS-CoV-2 infection as determined by PCR, performed by one of the certified laboratories in Luxembourg*
- Hospitalized or at home

6.2 Exclusion criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

- *Patients not able to understand French or German*

6.3 Screen Failures

False positive diagnosis

6.4 Strategies for recruitment and retention

All positive patients (or his/her legal representative) will be contacted by phone by collaborators from Sanitary Inspection and asked if they consent to the communication of their contact details to the LIH with regard to a possible participation in a research project on Covid-19. The cohort will be constituted by virtually all volunteered positive Covid-19 cases detected in Luxembourg and will include a subsample of 200 adult and 100 child patients with visits at home for additional biosampling for research.

People who did agree will be contacted by phone by an experienced nurse or clinical research associate from the CIEC who will explain the study and organize the visits at home or at hospital. The informed consent process is detailed in chapter 14.1. The CIEC team of LIH will be in charge of the follow-up of the participants and of the organization of the visits.

7. Biological samples and data collection

7.1 Data collection and sample collection (for the sub-sample only)

The samples and data collected during the study course are described in the table below. The participants will be able to participate either in data collection only or in both data and sample collection. For sample collection they can choose to do all or part of the sampling.

Predi-COVID								
	Screening	Inclusion	Baseline visit	Visit (3 weeks)*	Visit (2 months)*	Visit (6 months)	Visit (15 months)	Visit (24 months)
Eligibility assessment	x							
Informed consent	x (oral consent to be contacted by LIH)	x (e-consent for data collection)	X Written consent for sample collection, scanned on site and stored electronically at LIH					
Clinical data (ISARIC protocol CRF data)		x Daily data collection for up to 30 days for hospitalized patients or once at baseline for patients at home						
Online questionnaires (for adult participants and children >10 years)		Daily data collection for 14 days and weekly at weeks 3 and 4			Monthly follow up (1 to 11 months after inclusion), detailed questionnaire Long Covid at M12		Detailed questionnaire long covid	Detailed questionnaire long covid

CoLive LIH smartphone application (optional, for adults and children >10 years)		Regular voice recordings + short questionnaires						
Blood sample : up to 50mL (for children, volume adapted to child's weight)			x	x	x	x	x	x
Stool sample			x			x	x	x
Induced sputum or saliva			x			x	x	x
Nasopharyngeal swab			x	*x*		x	x	x
Oropharyngeal swab			x			x	x	x
Hair sample			x			x	x	x

- only for ADULTS, with a re-infection or an infection post-vaccination

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[1] See « Annexe 2 de l'arrêté du 17 février 2021 fixant la liste des recherches mentionnées au 2° de l'article L. 1121-1 du code de la santé publique » - https://www.legifrance.gouv.fr/loda/article_lc/LEGIARTI000033546109/2016-12-07/

7.2 Predi-COVID biological characterization (according to sample type) (not exhaustive)

- Blood sample :
  - Blood Count
  - CRP

- HLA genotype
- **Antibodies to SARS CoV2**
- Antibodies to CoV OC43, NL63 and 229E (optional)
- Immunophenotyping
- TRC repertoire

- Swabs :
  - SARS-CoV-2 and other CoV specific RT-PCR
  - Molecular diagnosis for rhinovirus, adenovirus, picornavirus, RSV, influenza A and B, parainfluenza 1-3, human metapneumovirus, *M. pneumoniae*, *C. pneumoniae, L. pneumophila*
  - Sequencing of viral PCR targets for confirmation and identification of mutations
- Sputum/saliva :
  - cell number, eosinophilic cationic protein, IL8, fibrinogen (optional)
- Hair :
  - hormones/glucocorticoid concentration
- Stool :
  - SARS-CoV-2 and other CoV specific RT-PCR
  - virus isolation, sequencing and characterization (optional)
  - microbiome-omics

7.3 Ancillary study: Predi-COVID-H

The samples and data collected during the study course are described in the table below. The Predi-COVID-H participants will be able to participate either to data collection only or to both data and sample collection. For sample collection they can choose to do all or part of the sampling. Since the national recommendations for the follow-up of contact persons of positive cases have recently changed with the prescription of a PCR test 5 days after the test of the case person, we adapted our sampling strategy with a follow-up visit conditioned by the PCR test result.

Predi-COVID-H			
	Inclusion	Follow-up	
		If RTqPCR prescribed by Sanitary Inspection results = negative	If RTqPCR prescribed by Sanitary Inspection results = positive
Informed consent	*X (e-consent for data collection and written consent for sample collection, but stored electronically)*		
Data collection : online questionnaires (for adult participants and children > 10 years)		*Data collection daily for up to* 14 *days*	
CoLive LIH application (optional, for adults and children >10 years)		Regular voice recordings + short questionnaires	

Blood sample : up to 50mL (for children, volume adapted to child's weight)	*X*	*X (6 months)*	
Nasopharyngeal swab	x	*x (6 months)*	
Oropharygeal swab	x	*x (6 months)*	
Stools	x	x (6 months)	
Hair sample	x	x (6 months)	
Sputum/saliva	x	x (6 months)	
End of study			X (contacts with positive PCR will be proposed to be enrolled in the Predi-COVID cohort and to start the follow-up at inclusion visit Predi-COVID)

- **<u>Predi-COVID-H biological characterization (according to sample type)</u> (not exhaustive)**

Blood sample :

- **Antibodies to SARS CoV2**
- Immunophenotyping
- TRC repertoire
- Antibodies to CoV OC43, NL63 and 229E (optional)

Stool :

- SARS-CoV-2 and other CoV specific RT-PCR
- Microbiome-omics

Sputum/saliva :

- cell number, eosinophilic cationic protein, IL8, fibrinogen (optional)

Hair :

- hormones/glucocorticoid concentration

Swabs :

- SARS-CoV-2 and other CoV specific RT-PCR
- Molecular diagnosis for rhinovirus, adenovirus, picornavirus, RSV, influenza A and B, parainfluenza 1-3, human metapneumovirus, *M. pneumoniae*, *C. pneumoniae, L. pneumophila*
- Sequencing of viral PCR targets for confirmation and identification of mutations

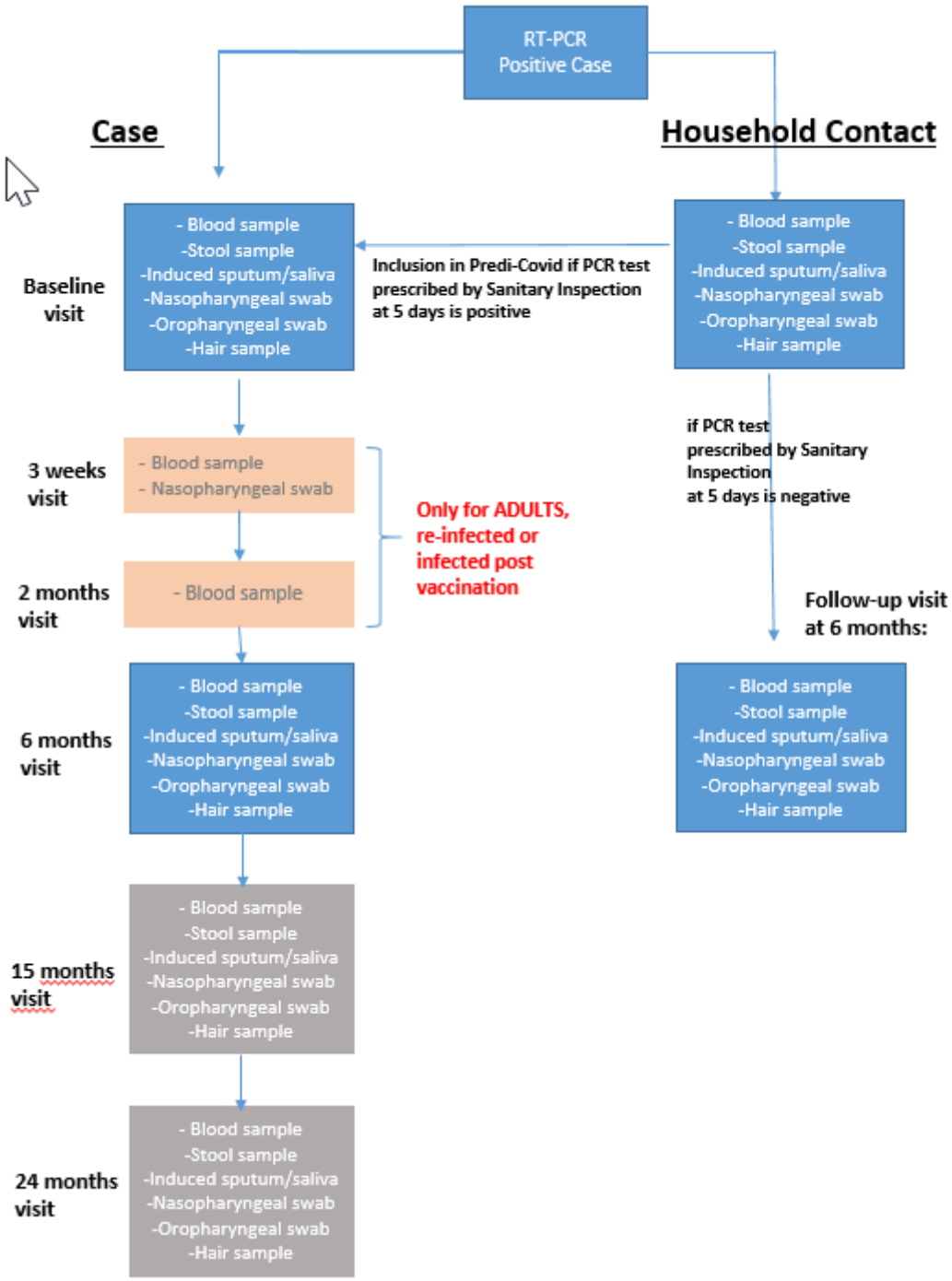


Figure 2 - Summary of the sample strategy in the subsample cohort.

8. PARTICIPANT DISCONTINUATION/WITHDRAWAL

Participant Discontinuation/Withdrawal from the Study

Patients can leave the study at any time for any reason if they wish to do so without any consequences. In this case, the data and samples already used for the study cannot be destroyed.

The subjects enrolled in the study in the Predi-COVID-H cohort (living with positively tested subjects) will be discontinued after 1 week if they returned seronegative results AND are symptome free one week after the inclusion in the study.

Lost to Follow-Up

Participants will receive questionnaires during the 12 months of the study except if they explicitly ask not to be contacted any more. Lost to follow-up participants are those who will not answer any of the questionnaires after baseline.

9. SAFETY

As there is no study medication, there will be no adverse events to report. Risks linked to study procedures are low and described in paragraph 2.3.

Serious Adverse Events (SAE) reporting

Serious Adverse Events can relate to medicines or refer to other domains.

This study is an interventional study because we collect biosamples from the participants, but no treatment interventions are foreseen, and no systematic data collection on medicines will be performed. Therefore no Serious Adverse Events related to medicines can be defined.

Serious Adverse Events related to this interventional study (not medication-related) are defined as events which result in any of the following:
• Death
• Life-threatening experience
• Inpatient hospitalisation during participating in the study
• Persistent or significant disability/incapacity
• Congenital anomaly or birth defect

All Serious Adverse Events (SAE's) identified during the study will be reported to the Sponsors, while only fatal SAE's will be reported to the Sponsors and CNER by the Principal Investigator within seven days. A Follow-up Report will then be sent once the SAE is resolved.

Reports will identify subjects by unique code (Participant ID) rather than by the subjects' names or other Personally Identifiable Information.

Protection of the nurses in contact with the participants will be ensured by several measures :
- Biosafety procedures (dressing/undressing procedure, security equipment to be used, decontamination procedure) have been developed based on procedures from the Sanitary Inspection and validated by Dr Staub. Nurses will also receive training by the Sanitary Inspection.
- Duration of inclusion visit will be shortened as much as possible, by making a maximum of steps by phone, in particular the explanation of the study and the data collection for the ISARIC CRF (see informed consent collection process)

No paper will be taken out of the home from the participants (see also informed consent collection process).

Reporting Pregnancy

Pregnancy is not an AE, but data on pregnancy before study entry or occurring during the study will be collected.

Procedure in case of SARS-CoV-2 detection RT-PCR result within study related sampling

RT-PCR will be performed at each follow-up visits and may allow detection of SARS-Cov-2 in particular during visits at 6, 15 and 24 months. Any positive result for RT-PCR has to be declared to the Sanitary Inspection. So if the RT-PCR test result is positive for SARS-CoV-2, a delegated clinical member of the study team will be informed and proceed to de-identify the participant. Then a delegated clinical team member will contact the participant to inform about the result, instruct him/her to contact the treating physician (or the governmental hotline in case there is no treating physician), and refer him/her for a diagnostic validation in an accredited laboratory. The prescription for the regular, care-based diagnostic test will be provided by a study physician delegated by the PI, or by the treating physician indicated in the (e)ICF. If the participant agrees, the sample taken for research purposes can be forwarded to an accredited laboratory. A referral letter with the laboratory study results will be provided to the treating physician if requested by the study participant.

10 DATA MANAGEMENT

Data will be collected through 3 different ways:

1/ Questionnaires using the ePRO module of Ennov Clinical: health status monitoring data with daily questionnaires during the 14 first days following diagnosis, then weekly questionnaires at weeks 3 and 4 and monthly questionnaires from month 2 to month 12. A unique link to the questionnaires will be sent by email to participants which will fill in the questionnaire online. Participants can choose to answer or not to the questionnaires. For children > 10 years, adapted questionnaires will be filled in directly by the child. For children < 10 years, no questionnaires will be sent.

2/ Adapted ISARIC CRF : at hospital and at inclusion for patients included from home. For patients at home data collection will be performed by phone by the CIEC team.

3/ CoLive LIH smartphone application (LIH in-house solution): innovative data (voice recordings and mini-questionnaires). For adults and children > 10 years.

Data in the ISARIC adapted CRF will be completed by a trained nurse or CRA from CIEC. Access to source data during hospitalisation will be provided by the different participating hospitals and/or by the e-santé national database. Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

In the e-questionnaires and the CoLive-LIH application, the patient will be responsible for the data entry.

Each data collection tool (e-questionnaires, ISARIC, CoLive LIH) implements its own data collection rules and controls, to ensure that data is entered correctly at the earlier stage of the data handling process. Each variable input will be controlled as soon as it is entered by the authorized user with allowable values, min and max values when necessary, consistency controls between relevant variables, allowable values filtering according to the context already fulfilled, etc.

Data handling will be carried out through specific edit checks to test the consistency of the database. Quality controls will also be regularly performed according to the clinical and epidemiological good practice guidelines.

A Clinical Data Management Plan will be provided to authorized people manipulating the data (which includes detailed description of source documentation, CRFs, instructions for completing forms, value coding dictionaries and reconciliation processes, data handling procedure and procedures for data monitoring).
ISARIC adapted CRF and e-questionnaires are provided in annex of the present protocol.

Depending on the data collection path of the different tools provided to patients and the CIEC data collection team (nurses, CRA), each dataset will be centralized at LIH by the research team in order to link the patients' records and analyze them.
Since each collection tool uses its own pseudonym for the patients, LIH's research team manages a unique and secure pseudonymization matrix, enabling them to link all the patients' records coming from different sources.

As each eCRF and collection application manages its own coding standards, pooling of datasets needs to be curated and automated:

- generate an extra pseudonym for each patient in the pseudonyms matrix table, one unique for all datasets to enable the linkage;
- transform each dataset toward a unique coding standard / dictionary (NB: a unique codebook describing the target dataset will be written: each variable name, coding standard, allowable values, limit values, constraints);
- load the result in a central and secured database;
- execute global quality controls to avoid duplicates, check consistency and exhaustiveness.

This process is quite important and will be automated to avoid any quality discrepancy as far as data collection is on different platforms and at different timelines.

Therefore, the research team will be able to analyze collected and centralized data with all the relevant tools: SAS, SPSS, R or machine learning tools. Some extracts may be performed to allow researchers to load sub-datasets into their own analysis environments, but the central database will be secured and organized to avoid updates or deletion operations.

Following the good practices, when data is provided to researchers for further research projects, LIH's Data Management team will generate an extra pseudonym - added to the pseudonyms matrix table - for the extracted patients' records. The central codebook will be shared with the new research team.

11 STATISTICAL CONSIDERATIONS AND PLANNED INTERIM ANALYSES

11.1 Statistical hypotheses

N.A.

11.2 Sample size determination

This is a very early study which aims at understanding the severity associated with a new, poorly understood pathogen. Therefore, the sample size is not formally determined as in a clinical trial study. Recruitment of participants will depend on the emergence and spread of the virus and the resources available to the recruitment centres. The sample size should be as large as feasible and preferably without limit in order to capture as much clinical data as possible early in the outbreak. This is as well feasible because of the implementation of a national digital solution for follow up of patients.
Nevertheless, in the sub-sample study a minimum of 200 COVID-19 positive adult persons in the Predi-COVID study would allow to find a risk ratio of severe disease above 2 for the selected risk factor with a power of 80% when the prevalence of the disease is above 7% (see figure below). This number will be updated depending on new acquired knowledge (amendment to the protocol).
In the pediatric sub-sample study a minimum of 100 COVID-19 positive children in the Predi-COVID study would allow to find a risk ratio of severe disease above 3.2 for the selected risk factor with a power of 80% when the prevalence of the disease is above 7% (see figure below). This number will be updated depending on new acquired knowledge (amendment to the protocol).

11.3 Populations for analyses

All patients enrolled.

11.4 Statistical analyses

Descriptive statistics will be produced for the main endpoints, namely hospitalisation, intensive care / resuscitation admission, ventilation, their duration, death and severity of the disease. Secondary endpoints together with other variables including potential prognostic factors of the disease will also be described with mean (+- STD) or frequencies (%) as adequate.

A logistic model will be used to study whether the risks of hospitalisation, intensive care admission or intubation as well as death are associated with a specific risk factor. adjustment will be done on age, gender and other potential confounding factors.

Factors triggering the severity of the disease will be evaluated with a Mantel-Haenszel chi square to evaluate if different levels of patients' characteristics are associated with a more serious form of the disease.

Further stratification of the patient cohort will be performed through Machine learning techniques to include biological and other omics measurements. A deep phenotyping related to the symptoms of the disease as well as biosampling allowing for laboratory-based and computational analytics will be performed. The stratification approach will include data-driven tools and allow to define disease trajectories that will be translated into clinical and/or biomarker-defined subgroups

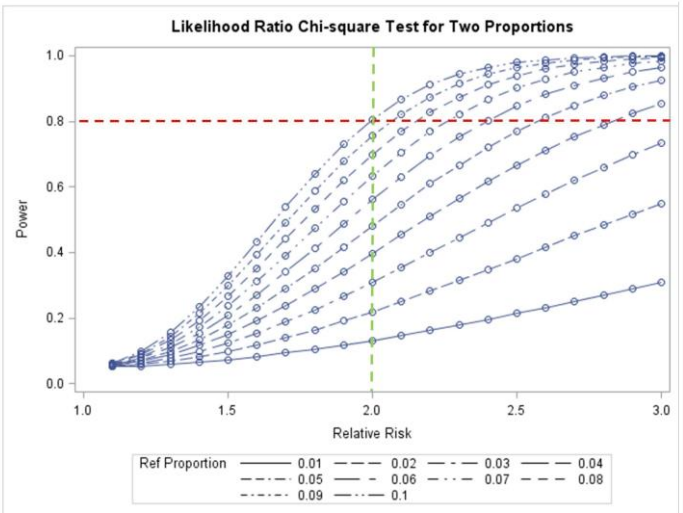
The time to conversion from the PREDI-COVID-H cohort to the PRECOVID cohort will also be studied.

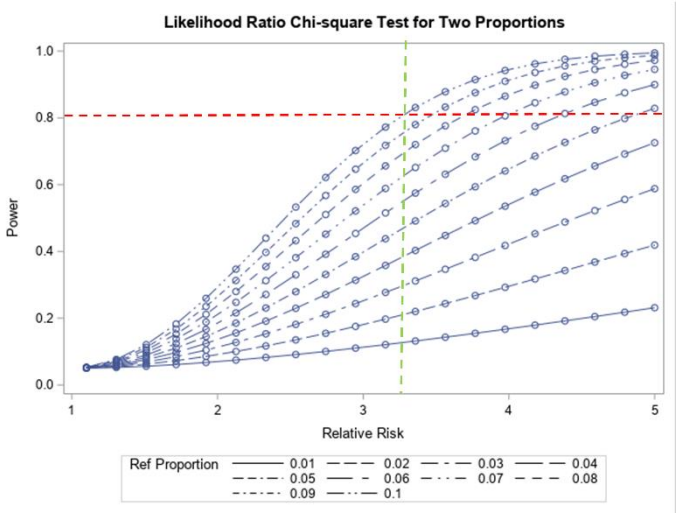
Missing data will not be replaced concerning the endpoints. A replacement method such as multiple imputations through chained equations will be envisaged for the other variables and risk factors.

The limits of the study linked to the size of the sample enrolled, the extent of the effects or the selection of participants and other potential limits will be evaluated and discussed.

11.5 Interim statistical analyses

In order to inform stakeholders on a regular basis interim analyses will be planned every Monday during the course of the study (whatever the number of new patients enrolled in the study).
Descriptive figures on the main endpoints such as hospitalisations, intensive care admissions, ventilations and death as well as the durations of each and the time to death will be provided.





Adults Children

As the analyses will only be descriptive, no correction for multiplicity will be applied.

12 QUALITY ASSURANCE AND QUALITY CONTROL (Monitoring)

The LIH will perform internal quality management of study conduct and data collection. Quality control (QC) procedures will be implemented from the beginning in the data entry system and data QC checks will be generated by the database.

12.1 Monitoring

In order to guarantee the authenticity and the credibility of the data in conformity with Good Clinical Practices, the sponsor has installed a quality assurance system that comprises:

- Conduct, management and follow-up of the trial according to the procedures of the CIEC of the Luxembourg Institute of Health : a Clinical Research Associate (CRA) will be designated as monitor within the CIEC team, this CRA will not have any other role on the project, and will monitor the study

- The quality control of the data of the investigator site by the monitor, whose role will be but will not be limited to :
  - to check the compliance with the clinical trial protocol, Good Clinical Practices (GCP) and local law requirements
  - to check the Informed Consent form and the eligibility criteria of each subject enrolled in the clinical trial
  - to check concordance and coherence of the data reported in the CRF against the source documents
  - compliance with data and samples collection reporting timelines
  - compliance with samples storage and shipment guidelines
  - to check that the samples stored on-site are under the appropriate conditions.

During monitoring visits, the investigator will provide direct access to all source documentation relevant to the subject's participation in the study.

It is the responsibility of the investigator to maintain adequate and accurate CRFs for each enrolled patient.

All personnel, bound by professional secrecy, must maintain the confidentiality of all personal identity or personal medical information.

The monitor will ask the investigator to modify any erroneous, forgotten or unclear data. All the modifications will be explained (if necessary), dated and signed.

12.2 Inspections and audits

To ensure compliance with clinical trial protocol, Good Clinical Practice and applicable regulatory requirements, the investigator and its institution should permit auditing by the sponsor or its representative.

The investigator agrees to allow the auditors to have direct access to all study records and facilities, being understood that auditors are bound to professional secrecy and as such will not disclose any personal identity or personal medical information. The investigator must maintain a comprehensive and centralized filing system of all study-related documentation that is suitable for inspection by auditors. The investigator agrees to participate in an audit conducted at a convenient time in a reasonable manner.

Government regulatory authorities may also perform inspections either during or after the study. In the event of an inspection by any regulatory authority, the investigator should promptly notify the sponsor. The investigator agrees to cooperate fully with inspections conducted by regulatory authorities and to allow representatives of the regulatory authority access to all study records. Inspectors are bound to professional secrecy, as such will not disclose any personal identity or personal medical information. The investigator will forward to the sponsor a copy of any inspection records received.

12.3 Source documents

Source documents provide evidence for the existence of the participant and substantiate the integrity of the data collected. Source documents are filled at the investigator's site. Data entered in the eCRF that are transcribed from source documents must be consistent with the source documents or the discrepancies must be explained.

13. REGULATORY, ETHICAL and OVERSIGHT CONSIDERATIONS

13.1 Informed Consent Process

Screening for eligibility

As mentioned above in the section "**Strategies for recruitment and retention"**, there are two different ways to recruit the participants :

- When the information of a positive test returns to the Sanitary Inspection the patient (or his/her legal representative) is contacted by phone by a collaborator of the Sanitary Inspection. During this call, participants will be asked if they agree to be contacted by LIH for research purposes. The contact details of people who agreed will be communicated to LIH and these people will be contacted by phone by an experienced nurse or clinical research associate from the CIEC to explain them the study, collect the consent and organize the baseline visit if the participant agrees to participate in sample collection.
  Alternatively a letter will be sent with some information about the study and an invitation to contact the CIEC staff if they are interested in participating in this research project.
- For hospitalized patients, patient information and inclusion will be performed by the medical staff or by CIEC staff when possible.

Eligibility will be verified by the CIEC team and an inclusion visit will be organized at home or at hospital. During this initiation visit, the Informed Consent of the participant will be collected as described below.

Obtention of Informed Consent

Informed consent is a process that is initiated prior to a subject agreeing to participate in a clinical research study and continuing throughout the individual's study participation. The investigator, or another member of the investigating team (experienced nurse or clinical research associate from the CIEC), will discuss the study with the subject whereby the subject will be given the opportunity to understand the objectives, risks and inconveniences of the study and the conditions under which it is to be conducted. The language used to inform the subject, both oral and written, should be concise, described in layman's terms and should be understandable to the subject. Neither the investigator nor any member of the study team shall coerce or unduly influence a subject to participate or to continue to participate in a study.

In the present context of Covid-19 pandemic it's not possible for security reasons to have a fully paper consent form. Moreover it's important that the nurses spend a minimum of time in the house of the positively tested persons.

The study will therefore be explained to the potential participants by phone and an electronic version of the Subject Information Sheet (SIS) and Informed Consent Form (ICF) will be sent by email if the person is interested in the study participation.

Participants will have the possibility to participate only in the data collection or in both data and sample collection. In case the subject agrees to participate in data collection only, they will be asked to fill in the consent form electronically (e-consent).

If the subject also agrees to participate in the sample collection, they will be asked to fill in the e-consent and a paper version for the sample collection will be brought by the nurse at baseline visit to fill in this part and obtain a written signature so that the nurse can answer additional questions if necessary. The paper document will be given to the participant and a photo of the document will be stored at LIH.

The subject will have sufficient reflection time between the first contact (description of the study via phone) and the sample collection visit. In addition, the subjects will have the opportunity to ask any question during the phone call or by email, before signing the electronic Informed Consent Form.

Alternatively, if the participant does or can not want to receive the documents by email, the nurse in charge of the inclusion visit will bring directly a paper version of the documents, answer the potential questions and ask the participant to complete and sign the form during the visit.

The informed consent of all persons willing to participate in the study will be collected, while two different SIS and ICF will be given to the subjects, according to the cohort they will belong to (Precovid for subjects with a positive COVID-19 test and Precovid H for the persons adults, living in the same household).

Finally, the subject will be informed that he/she can withdraw from the study at any time, without giving any reason and without any consequences on his/her medical care.

ICFs will be approved by the competent authorities, and the subject will be asked to read and sign the consent form prior to starting any procedures being done specifically for this study. In exceptional cases, when the subject is presented with acute conditions and unable to receive and understand the information about the study, the Informed consent can be first requested from the next relative and from the subject as soon as this becomes possible.

The written ICF must be dated and personally signed by the principal investigator or delegates and the subject giving consent (or next relative in case of emergency situation).

The electronic copy (photo) of the signed ICF will be retained in the study file (ISF) at LIH and will be made available for monitoring, audit or inspection.

No compensation will be offered to the subjects for their participation.

<u>Specificities for participants between 0-17 yrs</u> :
All participants should meet the inclusion criteria and none of the exclusion criteria.
Legal representatives of all subjects between 0-17 years will receive all the required information through the Study Information Sheet and the Informed Consent Form to decide whether or not to allow their child to participate in

the study. He/she will also have the possibility to contact the study team to ask questions related to the study. The children of 10 years or older are invited to give their assent via the Assent Form.

13.2 Ethics Committee/Competent Authority

The study will be submitted by the Luxembourg Institute of Health, in accordance with the local regulations, in particular the 8th MARCH 2018 LAW ON HOSPITALS (Art 27), to and authorized by the Health Minister, after requesting the opinions of the Health Directorate (Direction de la Santé) and the National Research Ethics Committee (Comité National d'Ethique de Recherche).

The principal investigator and the sponsor ensure that the study is conducted in full conformance with the principles of the "Declaration of Helsinki" 1964, as revised from time to time and with the laws and regulations of Luxembourg, whichever affords the greater protection to the individual. The study fully adheres to the principles outlined in "Guideline for Good Clinical Practice" ICH-E6 Tripartite Guideline (January 1997) and with national laws.

The principal investigator ensures compliance with the national laws, the ICH GCP and with the EU General Data Protection Regulation (GDPR) with regard to the processing of personal data (GDPR) and the law of 1 August 2018 on the organization of the national commission for data protection and the general regime on data protection.

13.3 Communication strategy

A newsletter will be prepared periodically (3 or 4 times per year) by the Predicovid team and provided to the study participants. With this newsletter, we aim to inform participants and the public about the progress of the project and keep them motivated to complete the monthly questionnaires. The newsletter will contain an editorial, news including research findings from the Predicovid study and sub-studies linked to the project, infographics about the status of the cohort, answers to frequently asked patient questions or portraits and descriptions of people working in the Predicovid team.

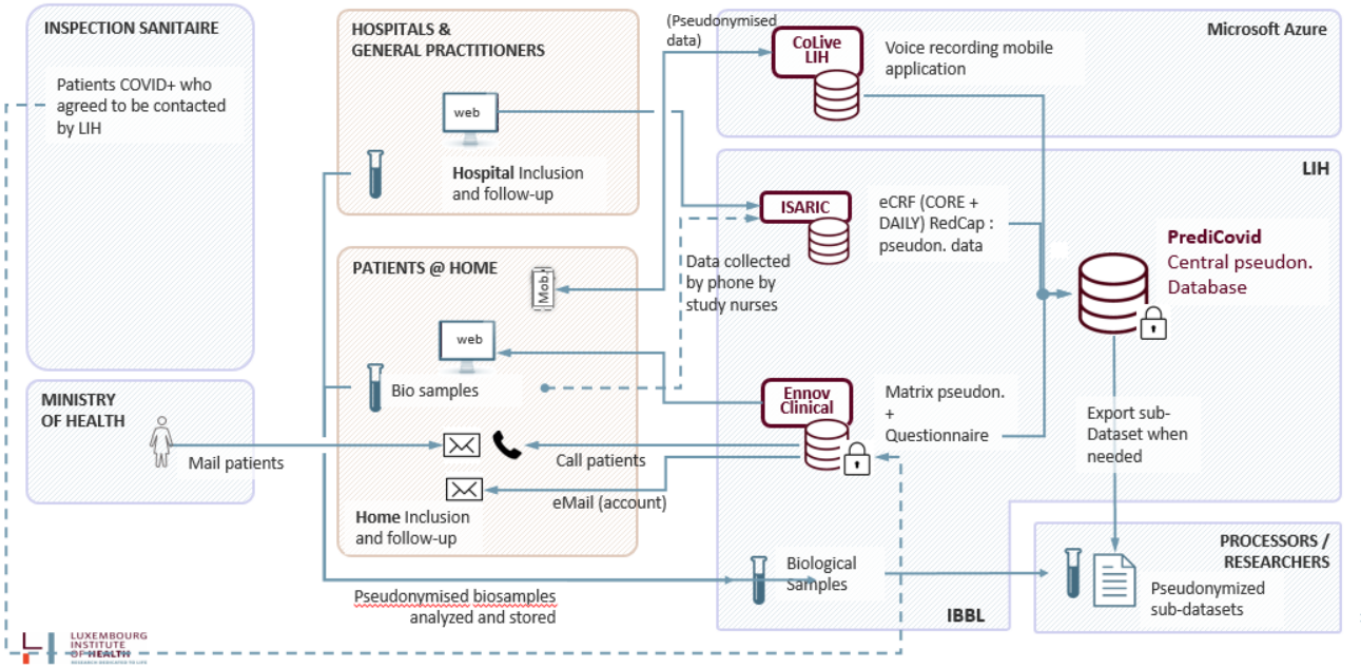
The newsletter will be in an electronic format and will be sent by email to the study participants by the CIEC team to safeguard their privacy.

To ensure a high participation rate in the completion of the last monthly questionnaire, participants will also receive some reminders by phone or email (max 2 emails and 2 phone calls).

A website dedicated to the study will be developed to inform the general public and the scientific community about the PredCovid study and its sub-studies. The content of the newsletter will be available on this website but also scientific articles related to the study more dedicated to researchers or physicians.

14. CONFIDENTIALITY AND PRIVACY

Predi-COVID Architecture



Personal data includes the following information:

- information that identifies the subject directly (such as his/her name, address, telephone number);
- the age and sex of the subject;
- information relating to the subject's state of health, including medical history;
- the subject's medical treatments and his/her response to medical treatments;
- information about the subject's biological samples and the results of analyses performed on these;
- information about the subject's medical images and the results of the evaluation of these.

In every step of data collection, data storage and data access across the Information System of this study, personal data will be processed in compliance to the General Data Protection Regulation (GDPR) of 27 April 2016 in the respect of Data Subjects' privacy by design and by default principles.

Each software used by the different actors during the processing of patients' personal data will require nominative accounts. These accounts will be managed by LIH to be sure that each person only access authorized data for a specific purpose (data partitioning), directly related to the current study. Each software has its own security rules: pseudonymization of data subsets wherever possible, encryption of sensitive data, etc.

In his role of sole controller of this activity, LIH will need to manage the administrative data of the patients included in his study in order to be able to collect their consent, give them access to the different software to collect data and be able to visit them to collect biosamples as well.

The patients may not be in sufficient dispositions to be able to fully accept or refuse and his or her consent could not be considered as being freely given, specific, informed and unambiguous, especially those recruited when at the hospital. It is therefore essential that the Ministry of Health supports LIH in this activity among the population as well as healthcare professionals to be able to contact those patients before having their initial consent.

All Covid-19 positive people are contacted in the context of the national follow-up by the Sanitary Inspection and will be asked if they agree to be contacted by LIH for research purposes. If yes, and once his or her formal consent is obtained, LIH will implement a pseudonymization by application so that only LIH can match information from different sources (CRF, CoLive LIH application): patient tracking applications and additional clinical data collection applications either at the hospital or at the patient's home.

The corresponding matrix table – containing the correspondence between the administrative data of the patient and the different pseudonymes – will be kept at LIH in a secured environment (Ennov Clinical) by authorized persons only related to that study This table will be kept on a physically separate server from the clinical and epidemiological data to minimize the risk of reidentification.

Each time a new patient will be entered in any of the relevant software to collect his or her data, LIH will be responsible to provide the user of this software with the pseudonym (either the GP, a nurse or the patient himself or herself).

The primary legal basis for this study will be the patient's consent (Article 6.1 a) and Article 9.2 a) of the GDPR) as described in paragraph 14.1 above.

Therefore, Luxembourg Institute of Health will be the sole-controller for this activity.

The following actors are considered as Data Provider: patients themselves and healthcare professionals whether at the hospital or outside hospitals. The LNS and certified laboratories via the central platform eSanté will be the initiators of the process for positive patients for COVID-19 and therefore considered as Data Providers as well.

Each actor will only have access to a sub-dataset according to his or her role in the activity (minimization and partionning principles). The study team only at LIH will have access to all pseudonymized datasets in order to execute its missions in the frame of this activity.

Transfer to third party

Some recipients of the data may be located outside your country and outside the European Economic Area (United Kingdom, for example). These may be countries whose level of data protection has not been confirmed by the European Commission as adequate. In this case, security measures equivalent to the security measures required by Luxembourgish and European regulations will be taken in order to protect subject rights in terms of data confidentiality, by entering into specific contractual agreements.

Storage of encoded data

For adults, encoded data will be kept for 15 years after the end of the study. However, 5 years after the end of the study, nominative data and the correspondence table between the identifying data and the study number will be deleted .

For minors, encoded data will be kept for 20 years after the end of the study. A dynamic management of the correspondence table will be retained to allow each person who attained the age of majority to consent to the secondary use of his/her data. On a case-by-case basis, each nominative data will be deleted from the table of correspondence after re-consent or refusal if any.

Subject rights related to personal data

The subject may exercise the following rights related to his/her personal data:

- Request information about the processing of data about him/her.

- Request the correction of the data about him/her if they are incorrect or incomplete. In certain cases (in accordance with the conditions set out by the law), the subject has the right to restrict the scope of his/her data processing.
- Retrieve his/her personal data and transfer then to a third party.
- Withdraw his/her consent at any time without giving a reason.

Lastly, the subject has the right to lodge a complaint with Luxembourg's National Commission for Data Protection (CNPD) in relation to the processing of his/her personal data.

15. FINANCING AND INSURANCE

The study is financed by LIH. Additional funds will be further requested to the FNR. The sponsor has subscribed to an insurance policy (Zurich Insurance plc, Belgium Branch, Da Vincilaan 5, B-1930 Zaventem) in compliance with local laws, covering its responsibility for all the participants for any injury that might be caused by the clinical trial.

16. STUDY CLOSURE

The end of study is declared when all the following criteria have been met:

- 12 months after inclusion of the last subject .
- The data monitoring is closed and all queries are answered, meaning the database is mature for the analysis of the endpoints as defined in the protocol.
- The database has been fully cleaned and frozen for all analyses.

The relevant documents including Electronic Data and other patient records, should be retained after the end of the study until result publication and then will be stored at least for 15 years following LIH standard procedure for archiving.

The end of the study will be reported to the Ministry of Health and to the CNER within 90 days following the end of study.

The end of study report will be prepared and will be available for health authorities within one year after the end of the study.

17. PUBLICATION AND DATA SHARING POLICY

The results of this study may be published or presented at scientific meetings.

Any publication or communication (oral or written) will be defined by mutual agreement between the investigators according to international guidelines. All the authors who participated actively to the conception of the study, its development and writing of results will be cited, i.e :

- The principal investigator, the co-investigator, and all investigators who have included and followed patients.
- The contributors of the coordinating centre team who participated in the drafting of the protocol and the statistical analysis of the study.

The Luxembourg Institute of Health will be cited as a sponsor of the clinical study.

18. FUTURE USE OF STORED SPECIMENS AND DATA

Sample and Data will be stored and used for future research projects, respecting the choices of the participants mentioned in the Informed Consent signed during the inclusion visit.

19. PROTOCOL DEVIATION

In case a subject is transferred outside Luxembourg during the course of the study, the samples and data will not be collected during the time of this transfer. The subjects will however be maintained in the study and will be given the possibility to resume his/her participation in the study once back in Luxembourg.

20. ANNEXES

ANNEX 1 : REFERENCES

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Annex 2 : QUESTIONNAIRES de suivi à distance des patients positifs

Utilisation du module ePRO de l'outil Ennov Clinical

Questionnaires françaisV1.0

ETAPES

1. **Envoi par mail de liens vers les questionnaires**
2. **Remplissage par le participant depuis un smartphone, tablette ou ordinateur :**
   - **1 questionnaire chaque jour pendant 14j**
   - **1 questionnaire par semaine pendant les semaines 3 et 4**
   - **1 questionnaire par mois de M2 à M12**
   - **Des questionnaires permanents à remplir dès que possible après l'inclusion**

Table des matières

Questionnaire J0-J14

Mon état de santé général

Dans le cadre de votre suivi à domicile pendant 14j, veuillez remplir ce questionnaire de suivi quotidien.
1) Vous êtes:
Si A l'hôpital : Lequel : menu déroulant
2) Comment vous sentez-vous aujourd'hui ?
3) Avez-vous bien dormi ?
Si non, pourquoi ?
4) Avez-vous une toux sèche ?

5) Avez-vous une augmentation de votre toux habituelle ces derniers jours ?
6) Avez-vous un mal de gorge apparu ces derniers jours ?
7) Avez-vous noté une forte diminution ou perte de votre goût ou de votre odorat ?
8) Avez-vous de la diarrhée ? Avec au moins 3 selles molles par jour.
9) Avez-vous des douleurs musculaires ou des courbatures inhabituelles ces derniers jours ?
10) Avez-vous des douleurs thoraciques ces derniers jours ?
11) Quel est votre niveau de douleur actuel ? (Notez de 1 à 10)
12) Avez-vous de la fièvre ?
13) Avez-vous un thermomètre ?
Si oui, Veuillez prendre votre température : si > ou = 38°C
14) Avez-vous des difficultés respiratoires ?
15) Avez-vous vu apparaître une gêne respiratoire ou une augmentation de votre gêne respiratoire habituelle ?
16) Quel est votre poids (kg) ? (se peser sans chaussure)
17) Avez-vous des difficultés importantes pour vous alimenter ou boire ?
18) Avez-vous d'autres symptômes ?
Si oui, veuillez préciser lesquels :
Les personnes de votre entourage
Pour éviter la contamination de votre entourage,
19) Avez-vous eu un contact proche avec des personnes de votre entourage aujourd'hui ?
20) Avez-vous noté une apparition subite d'éruptions cutanées au niveau des mains ou des pieds (par exemple engelures, rougeurs persistantes parfois douloureuses, lésions d'urticaire passagères) ?
21) Avez-vous noté l'apparition d'une conjonctivite ou de douleurs dans les yeux (rougeurs persistantes au niveau du blanc de l'œil, démangeaisons au niveau des paupières, sensations de picotements, brûlure, larmoiement fréquent) ?

Questionnaires courts Fin de semaine 3 et Fin de semaine 4.

Mon état de santé général

Dans le cadre de votre suivi à domicile, veuillez remplir ce questionnaire de suivi hebdomadaire.

1) Comment vous sentez-vous aujourd'hui ? Je me sens bien / Je me sens fatigué(e) / Je me sens mal
2) Dans l'ensemble, vous pensez que votre santé est : Excellente / très bonne / bonne / médiocre / mauvaise
3) Vous sentez-vous plein d'énergie ? Oui / Non
4) Avez-vous bien dormi ? Oui/Non
5) Fatigue

 Une valeur basse indique que l'affirmation ne s'applique pas tout à fait ou pas du tout
 Une valeur élevée indique que l'affirmation s'applique fortement à votre état ou à ce que vous avez ressenti au cours de la semaine passée.

Ne me correspond pas → Me correspond tout à fait

Durant la semaine dernière j'ai trouvé que:		SCORE						
FSS1	Je me sens moins motivé du fait de la fatigue	❑1	❑2	❑3	❑4	❑5	❑6	❑7
FSS2	L'exercice physique est pour moi source de fatigue	❑1	❑2	❑3	❑4	❑5	❑6	❑7
FSS3	Je suis facilement fatigué(e)	❑1	❑2	❑3	❑4	❑5	❑6	❑7
FSS4	La fatigue interfère avec mon activité physique	❑1	❑2	❑3	❑4	❑5	❑6	❑7
FSS5	La fatigue est souvent un problème pour moi	❑1	❑2	❑3	❑4	❑5	❑6	❑7
FSS6	Ma fatigue m'empêche de réaliser des taches physiques soutenues et prolongées	❑1	❑2	❑3	❑4	❑5	❑6	❑7
FSS7	La fatigue interfère avec mes facultés pour la réalisation de certaines activités et responsabilités	❑1	❑2	❑3	❑4	❑5	❑6	❑7
FSS8	La fatigue fait partie des mes 3 symptômes les plus gênants	❑1	❑2	❑3	❑4	❑5	❑6	❑7
FSS9	La fatigue intèrfère avec mon travail, ma famille ou ma vie sociale	❑1	❑2	❑3	❑4	❑5	❑6	❑7

SCORE GLOBAL : **moyenne des 9 questions**

5) Qualité de vie respiratoire

Les phrases suivantes expriment des sentiments sur les conséquences de votre maladie respiratoire. Pour chacune, cochez l'intensité qui vous correspond le mieux maintenant. Aucune réponse n'est juste, elle est avant tout personnelle.

		Pas du tout	Un peu	Moyennement	Beaucoup	Extrêmement
1	Je souffre de mon essoufflement	❑	❑	❑	❑	❑
2	Je me fais du souci pour mon état respiratoire	❑	❑	❑	❑	❑
3	Je me sens incompris(e) par mon entourage	❑	❑	❑	❑	❑
4	Mon état respiratoire m'empêche de me déplacer comme je le voudrais	❑	❑	❑	❑	❑
5	Je suis somnolent(e) dans la journée	❑	❑	❑	❑	❑
6	Je me sens incapable de réaliser mes projets	❑	❑	❑	❑	❑
7	Je me fatigue rapidement dans les activités de la vie quotidienne	❑	❑	❑	❑	❑
8	Physiquement, je suis insatisfait(e) de ce que je peux faire	❑	❑	❑	❑	❑
9	Ma maladie respiratoire perturbe ma vie sociale	❑	❑	❑	❑	❑
10	Je me sens triste	❑	❑	❑	❑	❑
11	Mon état respiratoire limite ma vie affective	❑	❑	❑	❑	❑

Questionnaires Mensuels (2-11 mois)

Mon état de santé général

Dans le cadre de votre suivi, veuillez remplir ce questionnaire de suivi.

1) Comment vous sentez-vous aujourd'hui ? Je me sens bien / Je me sens fatigué(e) / Je me sens mal.

2) Sommeil, échelle PSQI

1/ Au cours du mois dernier, quand êtes-vous habituellement allé vous coucher le soir ?

➢ Heure habituelle du coucher : .....

2/ Au cours du mois dernier, combien vous a-t-il habituellement fallu de temps (en minutes) pour vous endormir chaque soir ?

➢ Nombre de minutes : .....

3/ Au cours du mois dernier, quand vous êtes-vous habituellement levé le matin ?

➢ Heure habituelle du lever : .....

4/ Au cours du mois dernier, combien d'heures de sommeil effectif avez-vous eu chaque nuit ?
(Ce nombre peut être différent du nombre d'heures que vous avez passé au lit)

➢ Heures de sommeil par nuit : .....

3) Depuis le remplissage de votre dernier questionnaire, avez-vous consulté pour une raison en lien avec Covid19 ? Oui/Non
-> si oui, pour quel motif ? (Champ libre)

4) Votre qualité de vie (Echelle SF 12)

1. Dans l'ensemble, pensez-vous que votre santé est :

☐ 1 Excellente ☐ 2 Très bonne ☐ 3 Bonne ☐ 4 Médiocre ☐ 5 Mauvaise

2. En raison de votre état de santé actuel, êtes-vous limité pour :

- des efforts physiques modérés (déplacer une table, passer l'aspirateur, jouer aux boules…) ?

☐ 1 Oui, beaucoup limité ☐ 2 Oui, un peu limité ☐ 3 Non, pas du tout limité

- monter plusieurs étages par l'escalier ?

☐ 1 Oui, beaucoup limité ☐ 2 Oui, un peu limité ☐ 3 Non, pas du tout limité

3. Au cours de ces 4 dernières semaines, et en raison de votre état physique :

- avez-vous accompli moins de choses que vous auriez souhaité ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

- avez-vous été limité pour faire certaines choses ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

4. Au cours de ces 4 dernières semaines, et en raison de votre état émotionnel (comme vous sentir triste, nerveux ou déprimé) :

- avez-vous accompli moins de choses que vous auriez souhaité ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

- avez-vous eu des difficultés à faire ce que vous aviez à faire avec autant de soin et d'attention que d'habitude ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

5. Au cours de ces 4 dernières semaines, dans quelle mesure vos douleurs physiques vous ont -elles limité dans votre travail ou vos activités domestiques ?

☐ 1 Pas du tout ☐ 2 Un petit peu ☐ 3 Moyennement ☐ 4 Beaucoup ☐ 5 Enormément

6. Les questions qui suivent portent sur comment vous vous êtes senti au cours de ces 4 dernières semaines. Pour chaque question, indiquez la réponse qui vous semble la plus appropriée.

- y a t-il eu des moments où vous vous êtes senti calme et détendu ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

- y a t-il eu des moments où vous vous êtes senti débordant d'énergie ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

- y a t-il eu des moments où vous vous êtes senti triste et abattu ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

7. Au cours de ces 4 dernières semaines, y a t-il eu des moments où votre état de santé physique ou émotionnel vous a gêné dans votre vie sociale et vos relations avec les autres, votre famille, vos amis, vos connaissances ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

5) Qualité de vie respiratoire (Echelle VQ11)

		Pas du tout	Un peu	Moyennement	Beaucoup	Extrêmement
1	Je souffre de mon essoufflement	❑	❑	❑	❑	❑
2	Je me fais du souci pour mon état respiratoire	❑	❑	❑	❑	❑
3	Je me sens incompris(e) par mon entourage	❑	❑	❑	❑	❑
4	Mon état respiratoire m'empêche de me déplacer comme je le voudrais	❑	❑	❑	❑	❑
5	Je suis somnolent(e) dans la journée	❑	❑	❑	❑	❑
6	Je me sens incapable de réaliser mes projets	❑	❑	❑	❑	❑
7	Je me fatigue rapidement dans les activités de la vie quotidienne	❑	❑	❑	❑	❑
8	Physiquement, je suis insatisfait(e) de ce que je peux faire	❑	❑	❑	❑	❑
9	Ma maladie respiratoire perturbe ma vie sociale	❑	❑	❑	❑	❑
10	Je me sens triste	❑	❑	❑	❑	❑
11	Mon état respiratoire limite ma vie affective	❑	❑	❑	❑	❑

6) Avez-vous repris un rythme de vie comparable à celui que vous aviez avant la survenue des premiers symptômes associés à Covid19 ? Oui/Non
-> Si non, pourquoi ? Champ Libre

7) Avez-vous repris votre activité professionnelle normalement ? Oui/Non/Je suis à la retraite ou sans emploi
-> Si non, avez-vous été arrêté des suites de complications du Covid19 ? Oui/Non

8) Depuis le diagnostic de Covid19 ou la survenue de symptômes associés à Covid19, est-ce que vos relations avec votre entourage (famille, amis) : Se sont Dégradées / Sont Restées les mêmes / Se sont améliorées
-> si Dégradées ou Améliorées : Pourquoi ? Champ Libre

9) Par rapport à <u>avant</u> votre diagnostic à Covid19 ou vos symptômes associés à Covid19, diriez-vous aujourd'hui que :
   a) Votre appétit
   b) Votre activité physique
   c) Votre sommeil

   (Réponses : A diminué / Est identique ou quasiment identique / A augmenté)

Questionnaires permanents

A remplir une seule fois sur l'application pendant le suivi

Profil

- J'accepte que mes données collectées dans le cadre de mon suivi à distance puissent être utilisées à des fins de recherche (Oui/Non)
-
- Pays de naissance
-
- Etes-vous propriétaire de votre logement ? oui/non
- Quelle est la superficie de votre logement ?
    - Moins de 30 m²
    - 30-60m²
    - 60-90 m²
    - 90-120m²
    - 120m² - 150m²
    - Plus de 150m²
- Combien de personnes vivent dans le même foyer que vous ?
    - Adultes (18 ans et plus) : _ _
    - Adolescents (14 ans et 18 ans) : _ _
    - Enfants (13 ans et moins) : _ _
- Quel est le revenu annuel de votre foyer ?
    - Moins de 750 €/mois (soit moins que 9000 €/an)
    - 750 à 1499 €/mois (soit 9000 à 17999 €/an)
    - 1500 à 2249 €/mois (soit 18000 à 26999 €/an)
    - 2250 à 2999 €/mois (soit 27000 à 35999 €/an)
    - 3000 à 4999 €/mois (soit 36000 à 59999 €/an)
    - 5000 à 10000 €/mois (soit 60000 à 119999 €/an)
    - Plus que 10000 €/mois (or more than 120000 €/an)
- Quel est votre niveau d'éducation le plus élevé ?
    - Enseignement primaire
    - Premier cycle de l'enseignement secondaire (p.ex. 5e secondaire général, 9e régime technique, 9e régime préparatoire modulaire, 9e de la 2e voie de qualification)
    - Deuxième cycle de l'enseignement secondaire (p.ex. diplôme de fin d'études secondaires, diplôme de fin d'études secondaires techniques, diplôme de technicien, diplôme de fin d'apprentissage (CCP, DAP, CITP, CCM, CATP))
    - Enseignement postsecondaire non tertiaire (p.ex. Brevet de Maîtrise)
    - Enseignement supérieur ; cycle court d'études supérieures à orientation pratique, technique ou professionnelle après la fin de l'enseignement secondaire (p.ex. BTS)
    - Enseignement supérieur; niveau licence ou équivalent (p.ex. Bachelor)
    - Enseignement supérieur; niveau Master ou équivalent (p.ex. Master, ancienne licence ou diplôme universitaire d'au moins 4 ans)
    - Enseignement supérieur; niveau doctorat ou équivalent (PhD)

- Exercez-vous actuellement une activité professionnelle ? oui/non
    - Si non, pourquoi ? préretraite retraite chômage invalidité autre
- Quelle est votre profession ou la dernière profession que vous avez exercée ?
    - Agriculteur exploitant
    - Artisan, commerçant ou chef d'entreprise
    - Cadre ou profession intellectuelle supérieure
    - Profession libérale
    - Profession intermédiaire
    - Employé
    - Ouvrier (y compris ouvrier agricole)

Activité physique

- Aviez-vous pratiqué une activité physique intense durant les 10 jours qui ont précédé les premiers symptômes liés à Covid19 ? (Oui/Non/Je ne sais pas)
    - Si oui, laquelle ? : Champ libre
- Quand vous répondez aux questions suivantes, merci de décrire votre pratique d'activité physique habituelle sur l'année passée, à savoir celle que vous pratiquiez habituellement avant les premiers symptômes liés à Covid19. Cette année, combien d'heures avez-vous consacré en moyenne par semaine (indiquez le nombre d'heures pleines en moyenne, Ex. Aucune=0, 2h15=2, 2h30=3)

Activité Physique	**En hiver**	**En été**
À la marche (y compris pour aller au travail, faire des courses, pour vos loisirs…)	_ _ h	_ _ h
A faire du vélo (y compris pour aller au travail, pour vos loisirs…)	_ _ h	_ _ h
Au jardinage et/ou bricolage	_ _ h	_ _ h
Aux tâches ménagères (cuisine, ménage,...)	_ _ h	_ _ h
Au sport (natation, gymnastique, tennis,	_ _ h	_ _ h

- En moyenne, avant les premiers symptômes liés à Covid19, combien d'heures par jours restiez-vous assis (au travail, pendant les repas, devant un écran, à lire etc…) _ _ h

Alimentation

- Avant les premiers symptômes liés à Covid19, à quelle fréquence consommiez-vous habituellement les aliments ou boissons suivants, quel que soit leur mode de conservation (frais, en conserve ou surgelé), le moment de consommation (repas ou hors repas) et le lieu (domicile ou hors domicile) ?

Aliments	**Jamais ou presque**	**Moins d'une fois par semaine**	**Environ 1 fois par semaine**	**2 à 3 fois par semaine**	**4 à 6 fois par semaine**	**1 fois par jour ou plus. Dans ce cas, combien de fois ou d'unités par jour**

Fruits et légumes						_ _ /j
Pains, céréales, pommes de terre et légumineuses						_ _/j
Produits complets						_ _/j
Lait & produits laitiers						_ _/j
Charcuterie et viande transformée						_ _/j
Viandes, volaille, produits de la mer, œufs						
Produits de la mer						_ _/j
Matières grasses ajoutées						_ _/j
Type de matières grasses						_ _/j
Produits sucrés						_ _/j
Boissons non alcoolisées						_ _/j
Boissons alcoolisées						
Sel						

- Avant les premiers symptômes liés à Covid19, preniez-vous régulièrement des compléments alimentaires ou vitamines riches en :
    - Vitamine D (oui/non)
    - Vitamine C (oui/non)
    - Zinc (oui/non)
    - Fer (oui/non)
    - Magnésium (oui/non)
    - Multivitamines (oui/non)
    - Autres (oui/non)

For all patients

ANNEX 3 :

CRF PREDI-COVID

Utilisation de la plateforme REDcap
Protocole ISARIC modifié

Version française
V1.0

Le CRF Predi-COVID est composé des socles CORE et DAILY du consortium ISARIC auquel des modules complémentaires ont été ajoutés. Les parties ISARIC peuvent être remplies à l'aide d'information du dossier médical ou à l'aide du patient. Les modules complémentaires sont à renseigner avec le patient.

Table des matières

CRF ISARIC Français

NOUVEAU CORONAVIRUS (nCoV) 2019

BASE DE DONNEES POUR LA CARACTERISATION CLINIQUE D'UNE INFECTION RESPIRATOIRE AIGÜE

CAHIER D'OBSERVATION PATIENT (CASE REPORT FORM – CRF)

STRUCTURATION DU CRF

Ce CRF comporte une section « PRINCIPALE» et une section « QUOTIDIENNE » pour les données clinico-biologiques.

Ce CRF est à compléter pour la section PRINCIPALE et QUOTIDIENNE lors du premier jour d'admission du patient à l'hôpital ou en service de réanimation, puis pour la section QUOTIDIENNE tous les jours jusqu'à la sortie du patient ou son décès.

Instructions générales

- Ce CRF a été créé dans le but de collecter des données obtenues lors d'un examen clinique, d'un interrogatoire, ou à partir de données médicales hospitalières inscrites dans le dossier du patient.
- Le Numéro d'Identification anonymisé du Participant se présente sous la forme d'un numéro à 3 chiffres correspondant au site, suivi d'un numéro à 4 chiffres correspondant au numéro du participant.
  Vous pouvez obtenir le code qui correspond au site et vous enregistrer en contactant par e-mail le data manager du système : *ncov@isaric.org*. Les numéros d'identification des participants devront être assignés séquentiellement pour chaque site, en commençant par le numéro 0001. Pour un centre qui recruterait des participants dans différents services hospitaliers, ou s'il est impossible d'attribuer ces numéros de manière séquentielle, il est possible d'attribuer ces numéros par bloc, ou en y ajoutant une lettre. Par exemple, le service X assignera les numéros à partir de 0001 ou A001, le service Y assignera des numéros à partir de 5001 ou B001.
  Le numéro d'identification du patient doit être inscrit en haut à droite de chaque page de ce CRF.
  Les données récoltées sont à intégrer dans la base de donnée REDCap disponible à l'adresse suivante : https://ncov.medsci.ox.ac.uk, ou directement dans la base de données du centre participant. Des CRF "papier" pourront être utilisés et les données saisies secondairement dans la base de données électronique.
- Dans le cas où un participant se verrait transféré dans un autre centre participant, il est préférable de conserver son numéro d'identification initial. Si cela s'avérait impossible, il y a de la place pour enregistrer le nouveau numéro d'identification.
- Le CRF doit être complété pour chaque ligne de chaque section, sauf s'il est mentionné de passer certaines parties du questionnaire selon les réponses.
- Les cases à cocher carrées (☐) correspondent à des questions à réponse unique (ne choisir qu'une seule réponse). Les cases à cocher en forme de cercle (□) correspondent à des questions à choix multiples (choisir toutes les réponses appropriées).
- Notez 'N/A' pour les valeurs des résultats de laboratoire qui sont non disponibles, non applicables ou inconnues.
- Evitez de remplir le questionnaire hors des zones de réponses. Des sections spécifiques pour renseigner des informations supplémentaires sont prévues.

- Si vous complétez un CRF 'papier' :
    - Ecrivez au stylo, de manière claire et lisible, en utilisant des LETTRES MAJUSCULES.
    - Mettez un (X) en regard de la réponse choisie. Pour effectuer des corrections, barrez ( ) l'information

      que vous souhaitez corriger et corrigez au-dessus. Les initiales du correcteur ainsi que la date de chaque correction doivent être renseignées en regard de chaque correction.
    - Toutes les pages d'un même CRF doivent être agrafées ou réunies dans une pochette individuelle.
    - Merci de saisir toutes les réponses du CRF 'papier' dans la base de données électronique. Tous les CRF 'papier' doivent être conservés au niveau du centre participant. Merci de n'envoyer aucun document contenant des informations susceptibles d'identifier les participants de l'étude, par e- mail ou courrier postal. Toutes les données doivent être transférées dans la base de données électronique sécurisée.
    - Merci de saisir les données sur : https://redcap.medsci.ox.ac.uk/. Si un centre participant souhaite collecter les données de manière indépendante, nous pouvons aider à construire une base de données hébergée localement.
- Merci de nous contacter via l'adresse *ncov@isaric.org* si nous pouvons apporter de l'aide sur les bases de données, si vous souhaitez faire un commentaire, et enfin pour nous tenir informés de l'utilisation de la documentation.

SECTION PRINCIPALE

CRITERE D'INCLUSION CLINIQUE
Suspicion ou infection aiguë prouvée au nouveau Coronavirus (nCoV) 2019 comme principal motif d'admission : ● OUI ☐ NON

FACTEURS EPIDEMIOLOGIQUES
Dans les 14 jours qui ont précédé la survenue de la maladie, le patient a-t-il présenté une ou plusieurs des caractéristiques suivantes : **Voyage dans une zone où sont survenus des cas documentés d'infection par nCoV** ☐ OUI ☐ NON ☐ NC **Contact étroit avec un cas probable ou confirmé d'infection par nCoV, alors que ce patient était symptomatique** ☐ OUI ☐ NON ☐ NC **Fréquentation d'un établissement de santé où des cas d'infections par nCoV ont été pris en charge** ☐ OUI ☐ NON ☐ NC **Passage dans un laboratoire manipulant des échantillons de cas suspects ou confirmés d'infection à nCoV** ☐ OUI ☐ NON ☐ NC **Contact direct avec des animaux dans des pays où le virus nCoV est connu pour circuler dans la population animale, ou dans des zones où des cas d'infection humaine résultant d'une possible transmission animale ont été enregistrés** ● OUI ☐ NON ☐ NC * Le contact rapproché est défini comme suit : ● Exposition associées aux soins, comprenant la délivrance de soins à un patient infecté par nCoV par exemple professionnels de santé, toute personne travaillant avec un professionnel de santé infecté par nCoV, visiteurs d'un patient infecté ou personne restant dans le même environnement proche d'un patient infecté par nCoV, ou exposition directe à des fluides corporels ou échantillons incluant les aérosols. ● Collègue de travail partageant une promiscuité physique avec un patient infecté au nCoV. ● Toute personne ayant voyagé avec un patient infecté par nCoV, par n'importe quel mode de transports. ● Toute personne vivant dans même foyer qu'un patient infecté par nCoV.

SECTION PRINCIPALE

DONNEES DEMOGRAPHIQUES
Nom du centre participant :___Pays : __
Date d'inclusion : [_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _]

Groupe ethnique *(Veuillez cocher toutes les cases qui s'appliquent)* : □Arabe □Noir □Asiatique (EST) □ Asiatique (SUD)

- Asiatique (OUEST)

- Latino-américain □ Caucasien □ Aborigène/Peuples autochtones □ Autre :__ □NC

Employé en tant que professionnel de santé ? □OUI

□NON □N/A **Employé dans un laboratoire d'analyses**

biologiques ? □OUI □NON □N/A **Sexe à la naissance :**

☐ Masculin ☐ Féminin ☐ Non spécifié

Si inconnue, âge estimé [__][__][__]années OU [__][__]mois

Enceinte ? ☐ OUI ☐ NON ☐ NC ☐ N/A **Si OUI : âge gestationnel (*en semaines d'aménorrhée*) :** [__][__] semaines

POST PARTUM ? □ OUI □NON □ N/A *(Si "NON" ou "N/A" passer cette section et continuer sur la section « ENFANT »)* **Issue de grossesse :** □Né vivant □Mort-né **Date d'accouchement :** [_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _] **Recherche de l'agent responsable de l'infection respiratoire maternelle chez l'enfant ?** □ OUI □NON □N/A

Si OUI : □Positif □Négatif

Méthode : □PCR □Autre : __

ENFANT – Agé de moins d'1 an ? □ OUI □NON *(Si "NON", passer cette section)*

Poids de naissance : [__][__],[__]□kg □N/A

Naissance : □à terme (≥37 SA) □prématuré (<37 SA) □N/A

Allaitement maternel ? □ OUI □NON □N/A **Si OUI :** □ en cours □ arrêté à [__][__]semaines □N/A

Développement normal pour l'âge ? □ OUI □ NON □ NC

Statut vaccinal à jour (calendrier Français) ? □ OUI □ NON □ NC □N/A

SECTION PRINCIPALE

COMORBIDITES							
Comorbidités et facteurs de risque – Le score de Charlson sera calculé pour chaque patient lors de l'analyse.							
Maladie chronique cardiaque, incluant maladie congénitale cardiaque *(sauf hypertension)*	• OUI	• NON	• N/A	Obésité *(définie par le personnel médical)*	• OUI	• NON	• N/A
Maladie pulmonaire chronique *(sauf asthme)*	• OUI	• NON	• N/A	Diabète avec complications associées	• OUI	• NON	• N/A
Asthme *(diagnostic médical posé)*	• OUI	• NON	• N/A	Diabète non compliqué	• OUI	• NON	• N/A
Maladie rénale chronique	• OUI	• NON	• N/A	Maladie rhumatologique	• OUI	• NON	• N/A
Maladie hépatique, modérée ou sévère	• OUI	• NON	• N/A	Démence	• OUI	• NON	• N/A
Maladie hépatique légère	• OUI	• NON	• N/A	Malnutrition	• OUI	• NON	• N/A
Trouble neurologique chronique	• OUI	• NON	• N/A	Tabagisme	• OUI ☐Jamais • Ancien fumeur		
Néoplasie maligne	• OUI	• NON	• N/A	Autre facteur de risque notable ☐ OUI ☐NON ☐N/A Si OUI, lesquels : ____			
Maladie hématologique chronique	• OUI	• NON	• N/A				
VIH/SIDA	• OUI	• NON	• N/A				

Hypertension
COPD
Maladie inflammatoire chronique (ex: syndrome du côlon irritable)

DEBUT DE SYMPTOMES & ADMISSION

Date du premier symptôme : [_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _]

Date d'admission dans l'établissement : [_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _]

Heure d'admission (Format 24 heures) : [_ _][_ _]/[_ _][_ _]

Transfert depuis un autre établissement de santé ? ☐OUI, d'un autre centre participant ☐OUI, d'un centre non participant

- NON ☐N/A

Si OUI : **Nom de l'établissement d'origine** :__ ☐N/A

Si OUI : **Date d'admission dans l'établissement d'origine** *(JJ/MM/AAAA)* :
[_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_A] ☐N/A

Si OUI, il s'agit d'un autre centre participant : **Numéro d'identification d'origine du patient :** ☐Inchangé ☐Différent : [___][___][___]-[___][___][___][___] ☐N/A

Antécédent de voyage dans les 14 jours précédant la survenue des premiers symptômes ? ☐OUI ☐NON ☐NC

Si OUI, localisation géographique et dates du séjour : Pays : __ Ville ou zone géographique : __

Date de retour : [_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _] ☐ N/A *(espace supplémentaire à la fin du document si besoin)* **Contact avec des animaux, consommation de viande crue, piqûre d'insecte dans les 14 jours précédant la survenue des symptômes ?**

- OUI ☐ NON ☐NC ☐ N/A *Si OUI, compléter la section EXPOSITION ANIMALE*

SECTION PRINCIPALE

SIGNES ET SYMPTÔMES A L'ADMISSION *(Données disponibles dès l'admission – dans les 24 premières heures)*	
Température : [__] [__][_].[_]☐°C **FC :** [___][___][___] battements/min **FR :** [___][___] respiration/min **PAS :** [___] [___] [___]mmHg **PAD :** [___][___][___]mmHg **Déshydratation sévère :** ☐ OUI ☐NON ☐NC **Temps de recoloration cutanée** *(sternum)* **>2 secondes :** ☐ OUI ☐NON ☐NC **Saturation en oxygène :** [___][___][___]% **Sous air ambient :** ☐OUI ☐NON ☐N/A ou **Oxygénothérapie :** ☐OUI ☐NON	• N/A

SIGNES ET SYMPTÔMES A L'ADMISSION *(observés/reportés à l'admission et associés à l'événement en cours)*			
Antécédents de fièvre	• OUI	• NON	• NC
Toux	• OUI	• NON	• NC
Expectorations associées	• OUI	• NON	• NC
Hémoptysie associée	• OUI	• NON	• NC

Maux de gorge	• OUI	• NON	• NC
Rhinorrhée	• OUI	• NON	• NC
Otalgie	• OUI	• NON	• NC
Sifflement	• OUI	• NON	• NC
Douleur thoracique	• OUI	• NON	• NC
Myalgies	• OUI	• NON	• NC
Arthralgies	• OUI	• NON	• NC
Fatigue / Malaise	• OUI	• NON	• NC
Dyspnée	• OUI	• NON	• NC
Tirage sous-costal	• OUI	• NON	• NC
Céphalée	• OUI	• NON	• NC
Confusion	• OUI	• NON	• NC
Epilepsie	• OUI	• NON	• NC
Douleur abdominale	• OUI	• NON	• NC
Nausées/vomissements	• OUI	• NON	• NC
Diarrhée	• OUI	• NON	• NC
Conjonctivite	• OUI	• NON	• NC
Eruption cutanée	• OUI	• NON	• NC
Ulcère cutané	• OUI	• NON	• NC
Lymphadénopathie	• OUI	• NON	• NC
Hémorragie	• OUI	• NON	• NC
Si hémorragie, préciser la/les localisation(s)			
A chuté	• OUI	• NON	• NC

TESTS MICROBIOLOGIQUES :

Examen microbiologique de l'agent pathogène responsable du tableau Clinique ? ☐ OUI *(compléter la section correspondante)*

- NON ☐N/A

Influenza : ☐ OUI - Confirmé ☐ OUI - Probable ☐ NON **si** OUI **:** ☐ A/H3N2 ☐ A/H1N1pdm09 ☐ A/H7N9

- A/H5N1 ☐ A, non typé ☐ B ☐ Autre : __

Coronavirus : ☐ OUI - Confirmé ☐ OUI - Probable ☐ NON **si** OUI **:** ☐ Nouveau CoV ☐ MERS CoV ☐ Autre CoV : __

VRS : ☐ OUI - Confirmé ☐ OUI - Probable

☐ NON **Adénovirus :** ☐ OUI - Confirmé ☐

OUI - Probable ☐ NON **Bactérie :** ☐ OUI -

Confirmé ☐ NON

Autre diagnostic d'infection respiratoire : ☐ OUI - Confirmé ☐ OUI - Probable ☐ NON

Si OUI, préciser :__ Pneumonie (diagnostic

clinique) : ☐ OUI ☐ NON ☐ NC

Si aucun des arguments ci-dessus, suspicion de maladie non infectieuse ? ☐ OUI ☐ N/A

Date de prélèvement	**Type de prélèvement**	**Méthode d'analyse**	**Résultat**	**Agent pathogène détecté**	
__/__/20__	• Ecouvillon nasal ☐Ecouvillon oropharyngé • Combinaison écouvillon nasal/ oropharyngé • Crachats ☐LBA ☐Aspiration endotrachéale • Urine ☐Ecouvillonnage rectal ☐Sang • Autre, *spécifier :* __	• PCR • Culture • Autre, *préciser :*	• Positif • Négatif • N/A		
__/__/20__	• Ecouvillon nasal ☐Ecouvillon oropharyngé • Combinaison écouvillon nasal/ oropharyngé • Crachats ☐LBA ☐ Aspiration endotrachéale • Urine ☐Ecouvillonnage rectal ☐Sang • Autre, *spécifier :* __	• PCR • Culture • Autre, *préciser :*	• Positif • Négatif • N/A		
__/__/20__	• Ecouvillon nasal ☐Ecouvillon oropharyngé • Combinaison écouvillon nasal/ oropharyngé • Crachats ☐LBA ☐ Aspiration endotrachéale • Urine ☐Ecouvillonnage rectal ☐Sang • Autre, *spécifier :* __	• PCR • Culture • Autre, *préciser :*	• Positif • Négatif • N/A		

__/__/20__	● Ecouvillon nasal ☐Ecouvillon oropharyngé ● Combinaison écouvillon nasal/ oropharyngé ● Crachats ☐LBA ☐ Aspiration endotrachéale ● Urine ☐Ecouvillonnage rectal ☐Sang ● Autre, *spécifier :* __	● PCR ● Culture ● Autre, *préciser :*	● Positif ● Négatif ● N/A		
__/__/20__	● Ecouvillon nasal ☐Ecouvillon oropharyngé ● Combinaison écouvillon nasal/ oropharyngé ● Crachats ☐LBA ☐ Aspiration endotrachéale ● Urine ☐Ecouvillonnage rectal ☐Sang ● Autre, *spécifier :* __	● PCR ● Culture ● Autre, *préciser :*	● Positif ● Négatif ● N/A		

SECTION QUOTIDIENNE (compléter un exemplaire à l'admission à l'hôpital, un à l'admission en Unité de Soins Intensifs, et quotidiennement jusqu'au 14e jour ou sortie du patient ou décès)

SECTION QUOTIDIENNE
DATE de l'examen *(JJ/MM/AAAA):* [_ _][_ _]/[_ _][_ _]/[2_][0_][_ _][_ _]
Renseigner la valeur la plus mauvaise observée entre 00h00 à 24:h00 le jour de l'examen (si non disponible marquer 'N/A') :
Admission en cours en en Unité de Soins Intensifs ou réanimation ? ☐OUI ☐NON ☐N/A Renseigner la moins bonne valeur *(dans les 24 dernières heures)* **Fait** ☐ OUI ☐NON FiO_2 *(0.21-1.0)* [__],[__][__] ou [__][__]L/min **Fait** ☐ OUI ☐NON SaO_2 [__][__][__]% **Fait** ☐ OUI ☐NON PaO_2 *au moment de la prise de la* FiO_2 *inscrite au-dessus* [__][__][__] ☐kPa *ou* ☐mmHg **Fait** ☐ OUI ☐NON PaO_2 type d'échantillon : ☐ Artériel ☐ Veineux ☐ Capillaire ☐N/A **Fait** ☐ OUI ☐NON du même gaz du sang que pour la mesure de la PaO_2 : PCO_2 __☐kPa *ou* ☐mmHg **Fait** ☐ OUI ☐NON pH __ **Fait** ☐ OUI ☐NON HCO_3-__mEq/L **Fait** ☐ OUI ☐NON Excès de bases__mmol/L **Echelle AVPU** Alerte [__] Réponse verbale [__] Réponse à un stimulus douloureux [__] Pas de réponse [__] **Score de Glasgow (GCS / 15)** [__][__] **Fait** ☐ OUI ☐NON Echelle de Richmond Agitation-Sedation (RASS) [__] **Fait** ☐ OUI ☐NON Echelle de Riker Sedation-Agitation (SAS**)** [__] **Fait** ☐ OUI ☐NON Pression artérielle systolique [_____][_____][_____]mmHg **Fait** ☐ OUI ☐NON Pression artérielle diastolique [_____][_____][_____]mmHg **Fait** ☐ OUI ☐NON Pression artérielle moyenne [__][__][__]mmHg **Fait** ☐ OUI ☐NON Diurèse [__][__][__][__][__]mL/24 h ☐ à cocher si estimée

Le patient reçoit-il ou a-t-il reçu (entre 00:00 et 24:00 le jour de l'examen) *(répondre à toutes les questions de cette section)* :

Ventilation non-invasive *(par exemple VSPPC, VSPPBI)* ? ☐ OUI ☐ NON ☐ N/A

Ventilation mécanique ? ☐ OUI ☐ NON ☐N/A

ECMO *(par membrane extracorporelle)* ☐ OUI ☐ NON
☐ N/A **Oxygénothérapie à haut débit par canule nasale** ☐ OUI ☐NON ☐N/A
Dialyse/Hémofiltration ? ☐ OUI ☐NON ☐N/A
Agents vasopresseurs et inotropes ? ☐ OUI ☐ NON *(Si NON, répondre NON aux trois prochaines questions)*
☐N/A

Dopamine <5µg/kg/min OU Dobutamine OU milrinone OU levosimendan : ☐ OUI ☐ NON

Dopamine 5-15µg/kg/min OU Epinéphrine/Norépinéphrine <0.1µg/kg/min OU vasopressine OU phenyléphrine : ☐ OUI ☐
NON

Dopamine >15µg/k/min OU Epinéphrine/Norépinéphrine >0.1µg/kg/min : ☐ OUI ☐ NON

Agents bloquant la transmission neuromusculaire ? ☐ OUI ☐ NON ☐ N/A

Inhalation de Monoxyde d'Azote ? ☐ OUI ☐NON ☐N/A
Trachéotomie ? ☐ OUI ☐NON ☐N/A **Décubitus ventral ?** ☐ OUI ☐ NON ☐ N/A

Autre intervention ou procédure : ☐ OUI ☐ NON ☐ N/A Si OUI, préciser : __

SECTION QUOTIDIENNE

RESULTATS BIOLOGIQUES QUOTIDIENS

Date de prélèvement *(JJ/MM/AAAA) :* [_ _][_ _]/[_ _][_ _]/[_2_][
0_][_ _][_ _] Renseigner la valeur la plus mauvaise *(dans les 24 dernières heures)*

Fait ☐ OUI ☐NON **Hémoglobine**__☐g/L *ou* ☐g/dL

Fait ☐ OUI ☐NON **Leucocytes**_____☐x10^9/L

ou ☐x10^3/µL **Fait** ☐

OUI ☐NON **Lymphocytes**_____☐ x10^3/µL **Fait**

☐ OUI ☐NON **Neutrophiles**_____☐ x10^3/µL

Fait ☐ OUI ☐NON **Hématocrite** [__][__]%

Fait ☐ OUI ☐NON **Plaquettes**__☐x10^9/L *ou* ☐x10^3/µL

Fait ☐ OUI ☐NON **TCA** __

Fait ☐ OUI ☐NON **TP**__secondes

Fait ☐ OUI ☐NON **INR**__

Fait □ OUI □NON **ALAT**__U/L

Fait □ OUI □NON **ASAT** U/L

Fait □ OUI □NON **Bilirubine totale** □µmol/L *ou* □mg/dL

Fait □ OUI □NON **Glucose**__□mmol/L *ou* □mg/dL **Fait** □ OUI □NON **Urée**____□mmol/L *ou* □mg/dL **Fait** □ OUI □NON **Lactate**_____□mmol/L *ou* □mg/dL

Fait □ OUI □NON **Créatinine**__□µmol/L *ou* □mg/dL

Fait □ OUI □NON **Sodium** [__][__][__][__]mEq/L

Fait □ OUI □NON **Potassium** [__][__],[__]mEq/L

Fait □ OUI □NON **Procalcitonine** [__][__],[__][__]ng/mL

Fait □ OUI □NON **CRP** [__][__][__],[__]mg/L

Réalisation d'une radiographie du thorax ? □ OUI □NON □N/A Si OUI **: Présence d'infiltrat ?** □ OUI □NON □N/A

SECTION PRINCIPALE

COMPLICATIONS : Le patient a-t-il présenté un de ces symptômes pendant l'hospitalisation ?							
Pneumonie virale	• OUI	• NON	• N/A	**Arrêt cardiaque**	• OUI	• NON	• N/A
Pneumonie bactérienne	• OUI	• NON	• N/A	**Bactériémie**	• OUI	• NON	• N/A
Syndrome de détresse respiratoire aiguë	• OUI	• NON	• N/A	**Trouble de la coagulation/CIVD**	• OUI	• NON	• N/A
Si OUI, préciser □ Légère □ Modérée □ Sévère • NC				**Anémie**	• OUI	• NON	• N/A
Pneumothorax	• OUI	• NON	• N/A	**Rhabdomyolyse**	• OUI	• NON	• N/A
Epanchement pleural	• OUI	• NON	• N/A	**Maladie rénale aiguë/Insuffisance rénale aiguë**	• OUI	• NON	• N/A
Pneumonie organisée cryptogénique (POC)	• OUI	• NON	• N/A	**Hémorragie digestive**	• OUI	• NON	• N/A
Bronchiolite	• OUI	• NON	• N/A	**Pancréatite**	• OUI	• NON	• N/A

Méningite/Encéphalite	● OUI	● NON	● N/A	**Dysfonction hépatique**	● OUI	● NON	● N/A
Crise d'épilepsie	● OUI	● NON	● N/A	**Hyperglycémie**	● OUI	● NON	● N/A
AVC	● OUI	● NON	● N/A	**Hypoglycémie**	● OUI	● NON	● N/A
Insuffisance cardiaque congestive	● OUI	● NON	● N/A	**Autre**	● OUI	● NON	● N/A
Endocardites /Myocardite /Péricardite	● OUI	● NON	● N/A	**Si OUI, préciser : __**			
Arythmie cardiaque	● OUI	● NON	● N/A				
Ischémie cardiaque	● OUI	● NON	● N/A				

SECTION PRINCIPALE

TRAITEMENT : Le patient a-t-il reçu/nécessité pendant son hospitalisation ?

Admission en unité de soins intensifs ou unité de réanimation ? ☐

OUI ☐NON ☐N/A Si OUI, durée totale du séjour :__jour(s)

Si OUI, date d'admission :

[_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _] ☐N/A date de

sortie : [_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _] ☐N/A

Oxygénothérapie ? ☐OUI ☐NON ☐N/A

Ventilation non-invasive ? *(par exemple **VSPPC, VSPPBI**)* ☐ OUI ☐NON ☐N/A

Ventilation mécanique ? ☐OUI ☐NON ☐N/A SI OUI, durée totale :__jours

Ventilation en décubitus ventrale ? ☐OUI ☐NON ☐N/A **Inhalation de Monoxyde d'Azote ?** ☐OUI ☐NON ☐N/A **Trachéotomie** ☐OUI ☐NON ☐N/A

ECMO ? ☐ OUI ☐NON ☐N/A

Epuration/hemofiltration rénale /dialyse ? ☐OUI ☐NON ☐N/A

Inotropes/vasopresseurs ? ☐ OUI ☐NON ☐N/A

: date première fois/début :
[_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _] ☐N/A date dernière fois/fin : [_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _] ☐N/A

Autre intervention ou procédure *(préciser)* **: __**

TRAITEMENTS REÇUS PENDANT L'HOSPITALISATION OU A LA SORTIE :

Antiviral ? ☐ OUI ☐NON ☐N/A **Si OUI :** ☐Ribavirine ☐Lopinavir/Ritonavir ☐Interféron alpha ☐Interféron beta

- Inhibiteur de la neuraminidase ☐Autre __

Antibiotique ? ☐ OUI ☐NON ☐N/A **Si OUI**, préciser : __

Corticostéroïdes ? ☐ OUI ☐NON ☐N/A **Si OUI, voie d'administration :** ☐Oral ☐Intraveineuse ☐Inhalée **Si OUI, merci de préciser le type et la dose : __ Antifongique ?** ☐ OUI ☐NON ☐N/A

World Health Organization ISARIC

SECTION PRINCIPALE

EVOLUTION

Statut final : ☐ Sortie vivant ☐ Hospitalisation ☐ Transfert dans un autre établissement ☐ Décès

- Transfert en soins palliatifs ☐ NC

Date de la sortie, du transfert ou du décès : [_ _][_ _]/[_ _][_ _]/[_2_][_0_][_ _][_ _] ☐ N/A

Si sortie vivant :

Capacité de prendre soin de soi avant la maladie versus après la sortie : ☐ Identique ☐ Moins bonne ☐ Meilleure ☐ N/A

Si sortie vivant, traitement de sortie :

Oxygénothérapie ? ☐ OUI ☐ NON ☐ N/A **Dialyse, épuration rénale ?** ☐ OUI ☐ NON ☐ N/A

Autre intervention, procédure ? ☐ OUI ☐ NON ☐ N/A

Si OUI, préciser *(plusieurs réponses possibles) :* _____ **Si transfert, nom de l'établissement d'accueil :**___ ☐ N/A **Si transfert, l'établissement d'accueil est-il un centre participant à l'étude ?** ☐ OUI ☐ NON ☐ N/A

Si oui, n° d'identification du patient dans l'établissement d'accueil : ☐Identique ☐Différent : [_][_][_]–[ ][_][_][_] ☐N/A

SECTION PRINCIPALE

Voyage *: le patient a-t-il voyagé dans les 14 jours avant le début des premiers symptômes ? (plusieurs destinations possibles)*

Pays :___Ville, région géographique :___Date de retour *(JJ/MM/20AA) :* ___/___/20___ Pays :___Ville, région géographique :___Date de retour *(JJ/MM/20AA) :* ___/___/20___

Pays :___Ville, région géographique :___Date de retour *(JJ/MM/20AA) :* ___/___/20___

EXPOSITION ANIMALE : le patient a-t-il eu un contact avec des animaux morts ou vivants ou était piqué par un insecte dans les 14 jours avant le début des premiers symptômes ? ☐OUI ☐NON ☐N/A

Si OUI, complétez chaque ligne ci-dessous.

Si OUI, préciser l'animal ou l'insecte concerné, le type de contact et la date d'exposition (JJ/MM/AAAA) ici :

Oiseau/volaille (par exemple poulet, dinde, canards…)	• OUI	• NON	• N/A	
Chauve-souris	• OUI	• NON	• N/A	
Bétail (par exemple chèvre, bovins, chameau)	• OUI	• NON	• N/A	
Cheval	• OUI	• NON	• N/A	
Lièvre/Lapin	• OUI	• NON	• N/A	

Cochon	● OUI	● NON	● N/A	
Primates non-humains	● OUI	● NON	● N/A	
Rongeurs (par exemple rats, souris, écureuils)	● OUI	● NON	● N/A	
Piqûre d'insecte/morsure de tique	● OUI	● NON	● N/A	
Reptile/amphibien	● OUI	● NON	● N/A	
Animaux domestiques vivant au sein du foyer (par exemple chats, chiens, autres)	● OUI	● NON	● N/A	
Déjections d'animaux, nids	● OUI	● NON	● N/A	
Animal malade ou cadavre d'animal	● OUI	● NON	● N/A	
Viande crue, sang d'animaux	● OUI	● NON	● N/A	
Dépeçage, découpage ou consommation d'animal sauvage	● OUI	● NON	● N/A	
Visite d'un marché animalier, ferme ou zoo	● OUI	● NON	● N/A	
Participation à une chirurgie ou autopsie animale	● OUI	● NON	● N/A	
Autres contacts avec un animal :	● OUI	● NON	● N/A	

Modules complémentaires

Compléments d'informations en supplément du CRF ISARIC

Profil

1. Poids (kg)
2. Avant le diagnostic de Covid19, avez-vous perdu, sans le vouloir, 3 kg ou plus dans les 6 derniers mois ? (Oui/non)
3. Taille (cm)
4. Groupe Sanguin/Rhésus
    - O+
    - O-
    - A+
    - A-
    - B+
    - B-
    - AB+
    - AB-
    - Je ne sais pas
5. Portez-vous des lunettes de vue ? (Oui toute la journée, oui uniquement pour la lecture ou la conduite, Non)
6. Etes-vous gaucher ou droitier?

Traitements actuels (hors traitements liés à Covid19)

1. Prenez-vous habituellement, au moins 3 fois par semaine, des médicaments :
   - contre le cholestérol (oui/non)
   - pour le diabète (oui/non)
   - pour l'hypertension (oui/non)
   - contre la douleur ou l'inflammation (oui/non)
   - contre l'acidité gastrique ou le reflux (oui/non)
   - pour fluidifier le sang (dont l'aspirine à faible dose) (oui/non)
   - pour dormir (oui/non)
   - contre l'angoisse, l'anxiété (oui/non)

2. Avez-vous déjà eu de l'asthme ? (oui/non)

3. Avant le diagnostic de Covid19, combien de médicaments différents preniez-vous au moins 3 fois par semaine ?
4. Dans les deux derniers mois avez-vous pris des antibiotiques ? (oui/non)

6. Juste avant votre diagnostic de Covid19, fumiez-vous du tabac (Tous les jours, moins d'une fois par jour, pas du tout, je ne sais pas)

Si Réponse "Moins d'une fois par jour"
- Par le passé, avez-vous fumé du tabac tous les jours ? (Oui/Non/Je ne sais pas)

Si Réponse "Pas du tout"
- Par le passé, avez-vous fumé : (Tous les jours, moins d'une fois par jour, pas du tout, je ne sais pas)

Statut Covid-19

Depuis mars 2020 aviez-vous deja été précédemment testé positif/ve pour le Coronavirus (Sars-Cov-2)?
Si oui: Indiquer la date de test positif (si multiple tests positifs indiquer la date de chaque test positif)
Si oui: Quel type de test a été fait? (PCR, Rapid LAMP test, test antigénique rapide/test sérologique / ne sait pas
Si oui: Au moment des tests aviez-vous des symptômes?
Si oui: Avez-vous été hospitalisé pour Covid-19?
Si oui: Un membre de votre foyer a-t-il été testé positif pendant cette même période?
Si oui: Quel est l'âge des membres du foyer testés positifs (vous inclus)
Participez-vous ou avez-vous participé à une autre étude en lien avec Covid-19? (SéroCov2, Convince, Prédicovid, Orchestra, Cov-Escape, autre?)

Vaccination

Etes-vous vaccinés contre COVID-19?	oui/non

Si oui: quand?(dates doses)	
Si oui zone de vaccination	
Si oui : Connaissez-vous la marque de vaccin?	
Si 2nd dose pas faite, raison?	
Si oui: Avez-vous eu des effets secondaires après la vaccination?	
Si oui: Spécifier le type d'effets secondaires :	
Réactions au niveau du site d'injection :	Oui/Non
rougeur	Oui/Non
chaleur	Oui/Non
douleur	Oui/Non
démangeaisons	Oui/Non
hématome	Oui/Non
gonflement	Oui/Non
induration	Oui/Non
ecchymose	Oui/Non
sensibilité	Oui/Non
Effets secondaires systémiques :	
Avez-vous eu un gonflement important des membres?	oui/non
Fièvre	oui/non
Frissons	oui/non
Maux de têtes	oui/non
Nausée/vertige	oui/non
Augmentation soudaine de fatigue / Malaise	oui/non
Douleurs musculaires	oui/non
Douleurs articulaires	oui/non
Réaction cutanée (éruption, peau qui brûle..)	oui/non
Arythmies	oui/non
Myocardites	oui/non
Péricardites	Oui/non
Autre effet indésirable? spécifier	oui/non
Si oui après dose 2, combien de temps a duré cet effet indésirable?	Less than 1 day / 1 day / 2 days / 3 days / 4 days / 5 days / 6 days / 1 week / 2 weeks / 1 month / Still unresolved

Si oui après dose 1, combien de temps a duré cet effet indésirable?	Less than 1 day / 1 day / 2 days / 3 days / 4 days / 5 days / 6 days / 1 week / 2 weeks / 1 month / Still unresolved
Date des premiers effets indésirables après dose 1	
Date des premiers effets indésirables après dose 2	
Avez-vous été vacciné contre la grippe saisonnière?	oui / non / ne sais pas
Si oui date de vaccination	
Avez-vous reçu un vaccin Pneumocoque?	oui / non / ne sais pas
Si oui date de vaccination	
Avez-vous été vacciné contre rougeole, oreillons, rubéole?	oui / non / ne sais pas
Si oui date de vaccination	

Co-infections

Avez-vous une maladie inflammatoire chronique comme le syndrome du côlon irritable?
Vous a-t-on diagnostiqué une infection virale (autre que Covid-19) comme la grippe saisonnière depuis mars 2020?
Si oui, savez-vous quelle était la cause de l'infection?
Si oui, était-ce une infection respiratoire?
Si oui, quels médicaments vous ont été prescrits?
Si oui, avez-vous été hospitalisé pour cette infection?
Vous a-t-on diagnostiqué une infection bactérienne depuis mars 2020?
Si oui, savez-vous quelle était la cause de l'infection?
Si oui, était-ce une infection respiratoire?
Si oui vous a-t-on prescrit des antibiotiques? Si oui lesquels?
Si oui, quels autres médicaments vous a-t-on prescrits?
Si oui, avez-vous été hospitalisé pour cette infection?
Souffrez-vous d'infections persistantes?
Si oui, savez-vous quels micro-organismes causent cette infection?
Si oui, quels médicaments vous a-t-on prescrits?

ANNEX 4 :

COLLECTE DE DONNEES PREDI-COVID

Utilisation de l'application smartphone CoLive LIH (optionnel)

Français

V1.0

Suivi à distance depuis un smartphone ou tablette :

- **1 enregistrement vocal tous les jours de J0-J14 puis une fois par semaine dans les semaines 3 et 4, puis une fois par mois de M2 à M12**

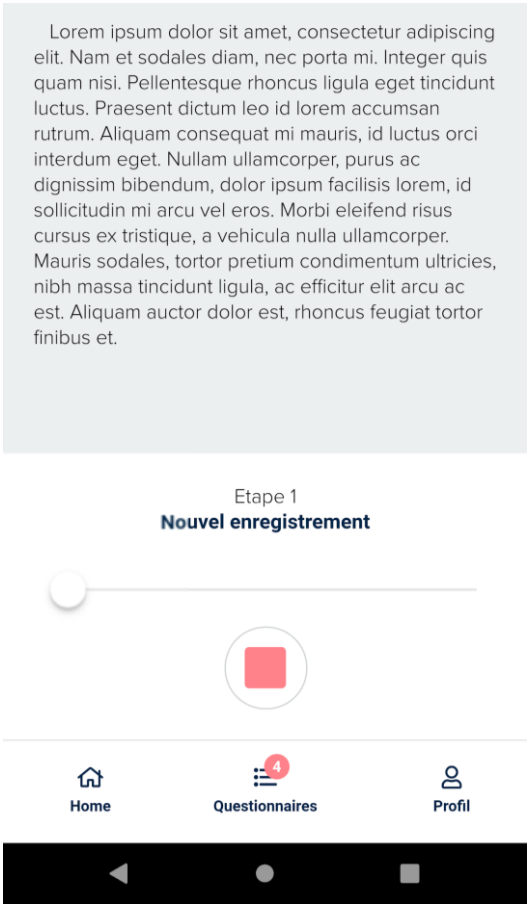
Table des matières

Enregistrement de la voix sur smartphone

Pour l'identification de biomarqueurs vocaux associés à un syndrome respiratoire, la fatigue, à l'anxiété ou aux émotions en lien avec Covid19

Composé de 2 enregistrements

1. Enregistrement standardisé d'un texte pendant 30 secondes
2. Enregistrement d'un son "AAAAAA" le plus longtemps possible par l'individu sans reprendre sa respiration.



Only for up to 300 household members of Predi-Covid participants

ANNEX 5 :

QUESTIONNAIRE PREDI-COVID-H

Utilisation du module e-PRO de Ennov Clinical

Questionnaires français

V1.0

Suivi à distance depuis un smartphone, tablette ou ordinateur :

- **1 questionnaire court par jour tant qu'il n'y a pas eu de confirmation de Covid19 par test positif et pendant 14 jours**

Table des matières

Questionnaire quotidien

Mon état de santé général

Vous êtes un membre du foyer d'une personne diagnostiqué positif à Covid19. Veuillez remplir ce questionnaire de suivi quotidien.

1) Date du questionnaire :
2) Avez-vous été testé et diagnostiqué positif à Covid19 ? Oui/Non

3) Vous êtes: A la maison / A l'hôpital / Autre
   Si A l'hôpital : Lequel : menu déroulant
   Centre Hospitalier de Luxembourg / Fondation Hôpitaux Robert Schuman / Centre Hospitalier Emile Mayrisch / Centre Hospitalier du Nord / Autre

4) Comment vous sentez-vous aujourd'hui ? Je me sens bien / Je me sens fatigué(e) / Je me sens mal

5) Avez-vous bien dormi ? Oui/Non
   Si non, pourquoi ? [Champ libre]

6) Avez-vous une toux sèche ? Oui/Non

7) Avez-vous une augmentation de votre toux habituelle ces derniers jours ? Oui/Non

8) Avez-vous un mal de gorge apparu ces derniers jours ? Oui/Non

9) Avez-vous noté une forte diminution ou perte de votre goût ou de votre odorat ? Oui/Non

10) Avez-vous de la diarrhée ? Avec au moins 3 selles liquides/molles par jour. Oui/Non

11) Avez-vous des douleurs musculaires ou des courbatures inhabituelles ces derniers jours ? Oui/Non

12) Avez-vous des douleurs thoraciques ces derniers jours ? Oui/Non

13) Quel est votre niveau de douleur actuel ? (Notez de 1 à 10)

14) Avez-vous de la fièvre ? Oui/Non
   Avez-vous un thermomètre ? Oui/ Non
      Si oui, Veuillez prendre votre température :

15) Avez-vous des difficultés respiratoires ? Oui/Non

16) Avez-vous vu apparaître une gêne respiratoire ou une augmentation de votre gêne respiratoire habituelle ? Oui/Non

17) Quel est votre poids ? (se peser sans chaussure) _ _ kg ou Je ne sais pas

18) Avez-vous des difficultés importantes pour vous alimenter ou boire ? Oui/Non

19) Avez-vous d'autres symptômes ? Oui/Non
Si oui, veuillez préciser lesquels : [champ libre]

Questionnaire permanent

A ne remplir qu'une fois

Profil

-
- Sexe
- Date de naissance
- Poids (kg)
- Avant le diagnostic de Covid19, avez-vous perdu, sans le vouloir, 3 kg ou plus dans les 6 derniers mois ? (Oui/non)
- Taille (cm)
- Groupe Sanguin/Rhésus
- Avez-vous
    - De l'hypertension ? Oui/Non
    - Du diabète (type 1 ou type 2) ? Oui/Non
    - Eu un cancer ? Oui/Non
    - Une maladie respiratoire ou êtes-vous suivi par un pneumologue ? Oui/Non
    - Une insuffisance rénale chronique dialysée ? Oui/Non
    - Une maladie chronique du foie ? Oui/Non
    - Une maladie connue pour diminuer vos défenses immunitaires ? Oui/Non
- Etes-vous enceinte ? Oui/Non/Non applicable
- Prenez-vous un traitement immunosuppresseur ? C'est un traitement qui diminue vos défenses contre les infections. Voici quelques exemples : corticoïdes, méthotrexate, ciclosporine, tacrolimus, azathioprine, cyclophosphamide (liste non exhaustive). Oui/Non