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A diagnostic test to improve surveillance and care of COVID-19 patients

HORIZON 2020

A diagnostic test to improve surveillance and care of COVID-19 patients

Rapports

 Informations projet
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 COVIRNA
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Periodic Reporting for period 2 - COVIRNA (A diagnostic test to improve surveillance and care of COVID-19 patients)

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Résumé du contexte et des objectifs généraux du projet

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COVID-19 is caused by SARS-CoV-2 infection and affects individuals with varied severity. Cardiovascular diseases predispose to the severity and mortality after SARS-CoV-2 infection. Prediction of disease severity and mortality could help the management of the patients at the clinics. In the COVIRNA project, we combine blood RNA quantification and artificial intelligence methodologies to predict the severity and mortality of COVID-19. The goal of the COVIRNA study is to deliver an in-vitro diagnostic (IVD) test that can predict COVID-19 severity and mortality which can be used for patient stratification, personalized healthcare and better management of patients at risk.

COVIRNA aims to develop and market a novel IVD test for COVID-19 severity and mortality. This will reduce the socio-economic burden of the COVID-19 pandemic and help clinicians to stratify patients based on their risk and improve personalized healthcare for reduced mortality. In addition, through the establishment of a database (COVIRNAdb) which contains clinical and RNA data from COVID-19 subjects, the COVIRNA project provides researchers around the world with an incredible resource of data which can be applied to current and future pandemics, as well as to the long COVID syndrome which affects a significant portion of COVID-19 patients. This ultimately could have a significant beneficial impact on society, as novel treatments or diagnostic tests could be developed in a timelier manner thus easing the burden on global healthcare systems.

The objectives of the COVIRNA project can be split into technological / research objectives and socio-economic / regulatory objectives.

Technological / research objectives include:

- To build a biobank of 2,000 blood samples from existing cohorts of COVID-19 patients;
- To build a database combining blood RNA data and clinical data;
- To select a subset of blood RNAs predictive of COVID-19 severity and mortality;
- To build a disease evolution prediction model based on RNAs and clinical data;
- To design a reliable, cost-efficient and easy to use IVD test to predict COVID-19 severity and mortality.

At the socio-economic and regulatory levels:

• To achieve CE marking of the COVIRNA IVD test;

• To establish a strategic science-policy-business-society consultation to optimize the design of the test complying with end-users' needs, cost-efficiency, EU regulation and highest quality standards to enable its uptake into clinical practice;

• To raise stakeholders' awareness of advantages of the test as a valuable decision-support tool for healthcare professionals;

• To engage communities of stakeholders in sharing practical knowledge on the use of the test.

Throughout the project, a total of 877 plasma samples and 1590 PAXgene RNA samples have been collected and sequenced. Sequencing data as well as clinical data from subjects have been compiled in a centralized database (COVIRNAdb). This database offers researchers around the world an invaluable tool in the fight against current and future pandemics. Whilst the final panel of RNAs to include in the IVD test is still to be selected, several RNAs have been identified capable of predicting

disease severity and mortality. Public awareness has been raised through the COVIRNA project via meetings, publications and via social media outreach initiatives.

Travail effectué depuis le début du projet jusqu'à la fin de la période considérée dans le rapport et principaux résultats atteints jusqu'à présent

The COVIRNA project is an assembly of six scientific and dissemination work packages (WP) aiming at implementation of a diagnostic test based on blood RNAs and artificial intelligence (AI) to predict the severity and mortality of COVID-19.

A total of 877 plasma and 1590 PAXgene samples from multiple centres across Europe and beyond was received by a centralized facility in WP1. This facility measured by sequencing 3233 RNAs in these blood samples using the FIMICS panel. Results were transferred to the central database and were combined with clinical data of patients in WP2. Data were then made available for downstream analyses using AI and machine learning models to select the best predictors of COVID-19 severity and mortality in WP3. Whilst the final panel of predictors is still to be selected, several RNAs have been identified for their capacity to predict disease severity and mortality. Using clinical samples, cell culture, and animal models, WP4 has studied how COVID-19 and RNAs impact the cardiovascular and immune systems. Moreover, WP4 has developed a cytokine storm model and therapeutic concepts such as blocking the spike protein to counteract the non-infective (e.g. cardiovascular) consequences of infection. These novel tools can be repurposed to combat future viral pandemics. WP5 partners have prepared the necessary files required for the CE-marking of the IVD test. The analytical and clinical validation workflow has been prepared and a first draft of the instructions for use is available. A supply agreement has been put in place for the production of the COVIRNA IVD test. Throughout the COVIRNA project, dissemination activities to the research community, patient organizations and the general public have been prioritized. In this regard, WP6 has developed the project brand identity, the website and social media accounts (LinkedIn, Twitter and YouTube). In line with the communication plan and the identified target groups, dissemination materials such as presentations at scientific meetings, a video, press releases, news items, articles, interviews and newsletters have been produced. Finally, scientific reports have been published in relevant journals.

Progrès au-delà de l'état des connaissances et impact potentiel prévu (y compris l'impact socio-économique et les conséquences sociétales plus larges du projet jusqu'à présent)

Work completed during the COVIRNA project has allowed going beyond the state of the art and has great potential impact, not only for the fight against COVID-19, but also for the longCOVID syndrome and future pandemics. The centralized database COVIRNAdb constitutes a valuable source of combined and curated information to further progress beyond the state of the art, through digging into the capacity of RNA molecules to contribute to disease severity and mortality and to act as predictive biomarkers. Predicting disease severity and mortality at an early stage can potentially have a large

economic impact and societal implications, especially in the case of emergency/pandemic situations when patient triage is of utmost importance to ensure a fair and reasonable access to healthcare to those who will benefit most. The COVIRNAdb will be open access meaning that researchers across the globe can freely use it to discover novel biomarkers and/or therapeutic targets not only for COVID-19 but also for other viral infections or diseases. The progress in the knowledge of the molecular and cellular mechanisms of SARS-CoV-2 infection made within COVIRNA project not only advances the state of the art but also contributes to prepare for future pandemics.

Overall, the work performed during the COVIRNA project provides an incredible toolbox to researchers, clinicians and patients. Alongside this tool box, the lessons which have been learnt during this project stands us in good stead to be able to quickly mobilise and combat new pandemics if/when they emerge in the future.



Overall methodology COVIRNA

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