Support-e

SUPPORTing high quality evaluation of covid-19 convalescent plasma throughout EUROPE

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A message to all Support-ers

“With the Support-e project, we are not only assessing the potency of convalescent plasma as a therapeutic means to treat COVID-19, and maybe, in the future, other diseases, but we are also demonstrating that together we work better, and advance faster for the benefit of patients and society who need all the help possible, in a pandemic time. Through Support-e, blood establishments and associated clinical teams from almost the entire European region show that they are part of the solution, with the help of the European Commission, who finances the project. At the year draw to an end, we wish to warmly thank all partners and participants to this project and wish you all a fruitful and successful, healthy new year”.

Pierre Tiberghien
Catherine Hartmann

About

CCP
CCP stands for Covid-19 Convalescent Plasma, plasma collected from former patients who have recovered from Covid-19. CCP contains antibodies that could neutralize SARS-CoV-2 and thus may improve disease course in patients with Covid-19 .

Support-e Project: Covid-19 caused by the newly identified severe acute respiratory syndrome virus 2 (SARS-CoV-2) is spreading worldwide and has provoked a global health crisis.

To date, no specific antiviral treatment has been proven efficient and no vaccine is available yet. Therapeutic options for Covid-19 mainly focus on supportive care, e.g. oxygenation, mechanical ventilation and fluid management, and treatment of secondary infections. Hence there is a need for new curative strategies that preferably have already been used in clinical practice and are widely available and scalable.

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Based on clinical experiences from previous epidemics, the use of convalescent plasma from recovered Covid-19 patients may provide a therapeutic solution.

However, successful adoption of this strategy in clinical practice in Europe still requires extensive clinical testing and would therefore benefit from a coordinated approach between Blood Establishments (BEs), clinical centres and competent authorities across Europe to support and accelerate high-quality evaluation of CCP.

In this context, the formulation of evidence-based recommendations based on scientific and clinical insights coming from newly developed standardized assays and evaluation of CCP donor and recipient data will be of paramount importance.

Objectives

I **Support High Quality CCP donation**

II **Support High Quality CCP Evaluation in clinical trials and monitored access use programmes**

III **Deliver Recommendations for the collection and use of CCP in EU member states to treat Covid-19**

IV **Deliver Recommendations for future outbreaks**

V **Ensure EU wide adoptions of recommendations and project legacy**

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WP1 - Assessing CCP, conducting clinical evaluation and defining best practices

Team Leader – IRCCS OSM, Italy
Vice Leader – ASST di Mantova

The main and initial objective of WP1 was to assess the current state of the art relating the collection, characterization and efficacy of COVID-19 Convalescent Plasma (CCP) in the treatment of patients with COVID-19 through an analysis of published and ongoing studies.

A wide electronic literature and guidelines search was performed to identify both studies on the use of CCP in COVID-19 patients and best practices on monitored access use. Through the definition of inclusion criteria, which referred to donors selection, CCP collection, processing, biological qualification and storage and CCP treatment protocol, articles and trials were selected. Simultaneously, an electronic case report form in the REdCap platform was built-up so to extract and enter the data. After its analysis, the first Status report of EU and International ongoing/upcoming clinical trials was produced.
The second and third tasks were to produce the preliminary Guidance Documents on assessment criteria for clinical trials and monitored access use programmes (compassionate use). On the basis of these documents, two pre-lists were proposed for the selection of both clinical trials and interventional programmes eligible for funding.

WP2 - Supporting high quality clinical evaluation and producing data-sets for inclusion in the database

Team Leader – DRK-BSD, Germany

The main objective of this work package is to support high quality clinical evaluation of CCP throughout the EU. In particular, WP2 will implement specific support to clinical trials and monitored access programmes, which have been identified in WP1. Up-to-now or randomized trials, 17 research groups have been contacted, 13 of them expressed interest to participate in Support-e (4 no responses yet). For non-randomized trials, 9 research groups have been outreached, 5 of them expressed interest to join (4 no responses yet). In addition, WP2 will promote high-quality data sets in the EU CCP database (WP3). An analysis of completed, ongoing and planned clinical trials revealed that the majority of clinical trials on CCP so far enrolled patients with severe COVID-19 or at least hospitalized patients. Therefore WP2 started to promote evaluation of very early administration of CCP in high risk patients.

WP3 - Collecting, monitoring and analysing EU-CCP Database data

Team Leader – EFS, France

WP3 actions are based on the EU open-access database, which gathers and makes available data on convalescent plasma donations and patient outcomes following transfusions. It includes data from blood establishments regarding convalescent plasma donors, the collection process and the plasma components .
(https://ec.europa.eu/health/blood_tissues_organs/covid-19_en)

WP3 has been working diligently since the beginning of the Support-e project to liaise with the Blood Establishments who have registered to the EU CCP Database in order to receive feedback on how to optimise the registration process and submission on data. Currently, WP3 is working on carrying out a basic analysis of the data received so far on donations, patients and plasma. The findings of this analysis will be included in a report which will be submitted at the end of this month. Additionally, WP3 team is working on updating the Data Management Plan for the project as well as a report on the current functionalities of the database Dashboard.

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WP4 - Improving plasma potency assessment

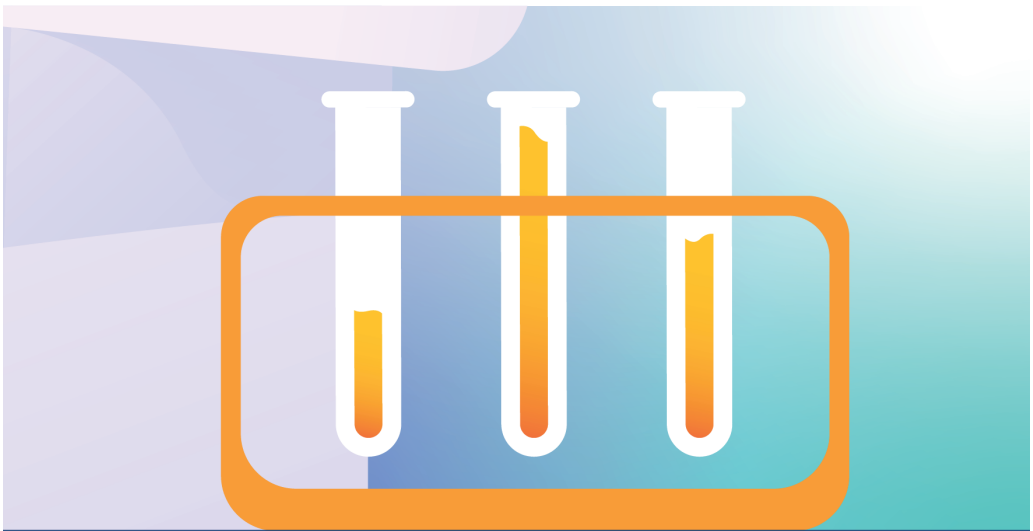
Team Leader – Sanquin, Netherlands
Vice Leaders – Rode Kruis, NHSBT

Based on clinical experiences with convalescent plasma (CP) from previous epidemics, the use of CP from recovered COVID-19 patients may provide a therapeutic solution. Up until now, donors with high anti-SARS-CoV-2 titers have been identified by performing the gold standard plaque reduction neutralization (PRNT) assay. However, PRNT requires an equipped biosafety level 3 (BSL3) facility, trained personnel and is time-consuming. Consequently, focus has shifted to the development of high-throughput alternatives of in vitro virus neutralizing assays. This task within the Support-e consortium involves the development of an ELISA-based alternative test that can be easily transferred to blood establishment laboratories within Europe.
The teams in Belgium and the Netherlands are developing test(s). One is based on competition between CCP and a commercially available anti-SARS-CoV-2 antibody of murine origin for binding to recombinant SARS-CoV-2 receptor binding domain (RBD). The other is based on inhibition of recombinant ACE2 binding to recombinant RBD by CCP. The former approach is in the process of validation using a well characterized set of CCP with known titers. Preliminary results suggest that it enables to discriminate between seronegative and seropositive CCP samples. The latter approach is operational and performance will be reported as the manuscript is being submitted for publication.
In addition, the WP4 team has drafted an Opinion paper for publication in Vox Sanguinis. The paper describes the major issue(s) with testing of CCP for antidodies against SARS-CoV-2. The manuscript was received with minor comments and when appropriately addressed will be published soon.

WP5 – Developing recommendations and preparing for the future

Team Leader – NHSBT, United Kingdom

The main objective of WP5 is to develop recommendations for CCP use to treat COVID-19 and for future outbreaks of SARS-CoV-2 or other novel pathogens. In particular, WP5 will integrate and assess the results from the preceding work-packages in order to determine safety and relative efficacy of convalescent plasma from an EU perspective. Effectiveness and safety information from a global viewpoint for convalescent plasma and hyperimmune globulin (therapeutic and prophylactic indications) will be provided.
Up-to-now, in collaboration with the University of Oxford Health Economics Research Centre, a consultation was carried out with the Support-e consortium to evaluate the costs and benefits associated with CCP collection and testing using different strategies. Later on, a SWOT analysis in terms of CCP collection, CCP testing and CCP use during the first wave of the COVID-19 crisis will be performed.



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WP6 – Dissemination, exploitation and communication

Team Leader – CNS-ISS, Italy

The initial work of WP6 team focused on the visual identity of the Support-e project consisting in the design and realization of the project's logo, the creation of a dedicated website (www.support-e.eu) and a Twitter account, as well as other communication materials such as Word and Powerpoint templates, including a headed formal paper. Furthermore, the initial Dissemination and Exploitation plan was produced with the main goal to map the communication strategies to both present and raise awareness about the project's mission and future results. In these last few months, since the official launch of the project two press releases were issued, in coordination with European Commission. In addition, the interested stakeholders (internal and external target groups) and the teams of other topic-correlated European projects have been contacted in order to explore the possibilities of a coordinated communication approach. Specific communications actions are being carried to support WP2 and WP3.

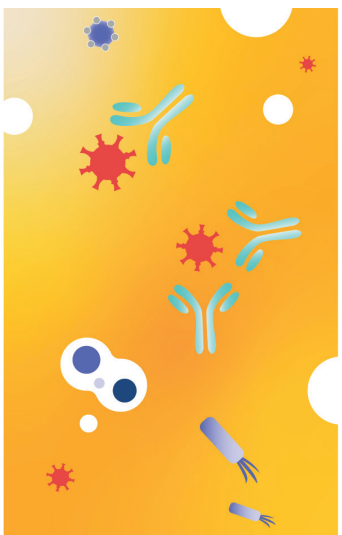
WP7 – Project Management

Team Leader – EBA, Netherlands

WP7 will safeguard the effective execution of the proposed project and the delivery of quality results within time and budget. It will ensure appropriate liaison with the European Commission and with and between the external Advisory Board, the Database Management Board and the internal Project Management Board. It will coordinate the work and progress in all WPs, ensure communication flows among partners and manage common consortium activities. It will oversee all administrative, financial and contractual aspects of the project.

EBA, as WP7 Leaders, lead in the project management and coordination of the project ensuring that project objectives and deliverables are achieved in full within time, cost and resource constraints. Since the start of the project, WP7 has set up the Scientific and Ethical Support-e Advisory Board, which will meet for the first time on December 8th, 2020. As part of the Coordinators task, WP7 has put together the project Consortium Agreement with all partners as well as completed the financial management for the first half of the project.

"This sketch is just a preview of an animated video that will introduce Support-e project and its objectives and it's a call to action for all the potential CCP donors. Stay tuned for further updates."



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Partners

eba Safe blood for Europe

midt Central Denmark Region Aarhus University Hospital

Carlo Poma — Sistema Socio Sanitario Regione Lombardia ASST Mantova

Belgian Red Cross

BLUTSPENDE SRK SCHWEIZ
TRANSFUSION CRS SUISSE
TRASFUSIONE CRS SVIZZERA

Deutsches Rotes Kreuz
DRK-Blutspendedienst
Baden-Württemberg | Hessen
gemeinnützige GmbH

EFS Établissement Français du Sang — Du donneur aux patients

Fondazione IRCCS Policlinico San Matteo
Sistema Socio Sanitario Regione Lombardia

Centro Nazionale Sangue
Istituto Superiore di Sanità

NHS Blood and Transplant

Statens Serum Institut

Sanquin

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