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

SUPPORT-E

Supporting high quality evaluation of COVID-19 convalescent plasma throughout Europe

Questions and Answers

- **What is the SUPPORT-E project?**

  The European project SUPPORT-E (SUPPORTing high-quality evaluation of COVID-19 convalescent plasma throughout Europe) brings together major European Blood Establishments, including competent authorities. This project is funded within the EU research program Horizon2020. It will last for 24 months. SUPPORT-E represents the first European Union coordinated research effort on COVID-19 passive immunotherapy, sharing data and protocols in real-time and pooling efforts to decrease as much as possible the time needed for the evidence-based evaluation of CCP as a therapeutic treatment and for providing a basis for further optimization by combined approaches with other anti-viral treatments.

- **What are the most important objectives of the SUPPORT-E project?**

  The main objectives are to
  - support high quality clinical evaluation of COVID-19 convalescent plasma (CCP)
  - achieve a consensus on the appropriate use of CCP in the treatment of COVID-19 across EU Member States
  - promote best practices regarding convalescent plasma use in the current health crisis as well as in subsequent crisis involving novel pathogens.

- **Why are we contacting you?**

  We are contacting you to provide information on the SUPPORT-E project, to get your feedback on a possible involvement in this pan-European effort on COVID-19 passive immunotherapy and to discuss collaboration options, to assess the inclusion monitored access use programmes (compassionate use) in SUPPORT-E (operational aspects and financial support).

- **How are the monitored access use programmes selected? and why?**

Disclaimer: The contents of this document reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 101015756.

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

SUPPORT-E has defined selection criteria, based on the commonalities between the data from assessed studies on compassionate use of CCP in COVID-19 patients, for the CCP use, donors' selection, CCP collection, processing, biological qualification and storage and CCP treatment protocol in a guidance document. Based on this, several studies have been preliminary selected for potential inclusion in the SUPPORT-E project by means of data set accrual in the EU CCP database. The final decision on inclusion still needs to be taken. This will depend on several aspects such as your interest in cooperation as well as operational and feasibility issues, need and availability of support from the SUPPORT-E consortium for your programme.

- **What support can I expect from SUPPORT-E?**

SUPPORT of monitored access use programmes:

In cases where selected monitored access use programmes are considered to lack the necessary resources, they may be eligible to receive additional support from the SUPPORT-E project. It will provide support by means of subcontracting. Subcontracting will be based on the number of completed datasets (supported through acquisition of the right to access and right to use, by the Consortium) entered in the EU CCP database (described below). Financial support can range from 200 € for trials not requiring additional funding but who are submitting recipient data to the EU CCP database and to 2.480 € for those trials which do require additional funding.

Interaction with the Competent Authorities and clinicians will provide an extra source of information which, combined with the information from the entered datasets, can offer further insights into CPP therapy.

SUPPORT of data collection:

Clinically relevant data sets, e.g. on CCP donors, CCP products and CCP recipient-related clinical outcome (after transfusion), will be reported into a web-based open-access, GDPR compliant CCP database, developed by the EC (DG SANTE, DG DIGIT and DG CNECT) in collaboration with EBA. It is hosted by the EC (https://ec.europa.eu/health/blood_tissues_organs/covid-19_en#fragment1).

For more information we also refer to Q&A of the EU CCP database (https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/qa_ccp_db_en.pdf)

Disclaimer: The contents of this document reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 101015756.

Support-e

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

The EU CCP database serves as a centralised mechanism allowing for the timely and secure exchange of information and consultation. There will be intentionally a mix of randomised clinical trials and monitored access programmes (compassionate use) because it is deemed important to have a broader inclusion of patients representing a real-world situation regarding feasibility, safety and efficacy. Importantly, when considering randomized clinical trials, data regarding control patients entered in the trial will not be requested for entry in the database. The EU database will infringe upon outcome analysis and reporting within a given clinical trial or perform meta-analysis of completed CCP clinical trials.

Support of improving plasma potency testing:

SUPPORT-E will provide access to central reference laboratories for performing seroneutralization assays during the early phases of the project. Each participant that does not have direct access to seroneutralization assays will be given the opportunity to send samples to a reference laboratory. Quality assessment rounds will be organised to determine the reproducibility between the reference seroneutralization testing laboratories. An alternative BSL1-compatible (high-throughput) test for seroneutralization will be developed to allow rapid screening of donors. In addition, SUPPORT-E will calibrate the different ELISAs used for antibody determination within the different trials to make results more comparable.

- **What contribution can you provide to the project? What is expected from you?**

  By participating as a subcontractor to this project, you agree to report to the EU CCP database a pre-defined number of complete data sets on plasma collections, plasma units, transfusion and recipient clinical outcomes.

- **What Donor / Patient data is needed?**

  The part of the EU CCP Database on CCP donations covers questions on donor details, collection methods, and characteristics of collected CCP. The goal is to link each donor and product information to the clinical outcome in the recipient.

  The part of the EU CCP Database on clinical outcomes in recipients will cover the clinical development of recipients after CCP treatment, as well as any adverse reactions during transfusion.

- **What does complete data set mean?**

  All data collected by the EU CCP database shall be entered. Just in brief, the EU CCP collects data on donors (demographic characteristics, donor inclusion criteria, type of donation, number/volume of donations,

Disclaimer: The contents of this document reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 101015756.

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

donor adverse events), products (number/volume; antibody titer(s)), and patients (demographic characteristics, disease severity, inclusion criteria, time and volume of CCP treatment, outcome, adverse events). A full list of variables can be provided.
We plan to evaluate and support newly identified data sets that could address knowledge gaps during the course of this evaluation.

- **Who will enter data to the EU CCP database**
  Donor and recipient data into the EU CCP Database shall be made by the blood establishments (BEs) that have supplied the CCP. Data on transfusion and clinical outcomes of patients should therefore be made available to the BE that has supplied them with the CCP. The BE will then enter these data into the database.

- **How will the Data protection be respected?**
  Data on donors and recipients has been assessed as anonymous. Donation and hospital numbers are converted to new codes as the data is transferred into the database. As highlighted in the Q/A of the EU CCP database (https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/qa_ccp_db_en.pdf) the collection and processing of anonymised data is outside of the scope of the General Data Protection Regulation (GDPR) and does not require specific informed consent for entry / transfer to the EU CCP database.

- **How will providing Data to SUPPORT-E interfere with my monitored access use programme?**
  Participation in the SUPPORT-E project shall not interfere with the conduct, analysis and publication of your study.

- **Why should you take part in the SUPPORT-E project?**
  Rapid progress in the field of CCP is very important in this current health crisis. Participation in the SUPPORT-E project shall provide:
  - potential direct support for your project provided by SUPPORT-E as outlined above,
  - access to expert labs or quality assessment rounds for characterization and standardization of antibodies in CCP provided by SUPPORT-E,
  - opportunity to work closely with other experts in the field of CCP with SUPPORT-E,

Disclaimer: The contents of this document reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 101015756.

Support-e

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

- chance to contribute to EU-evidence on the safety and efficacy of CP in a timely manner as member of this pan-European SUPPORT-E effort and thus contribute to the elaboration of standards and recommendations regarding CCP collection and use.

More information: www.support-e.eu

Disclaimer: The contents of this document reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 101015756.