General Data Protection Regulation (GDPR) and the EUCCP Database

Introduction:

Plasma collected from patients that have recovered from an infectious disease has been used over many decades for a variety of different infectious agents. The COVID-19 pandemic is a clear situation where plasma from recovered patients (Convalescent COVID-19 Plasma (CCP)) might be a valuable resource to support disease treatment within randomised or case-control clinical trials or observational studies of plasma transfusion and in the development of a plasma-derived medicinal products.

The European Commission (DG SANTE) has brought together the resources of the EU competent authorities for blood and blood components, the European Centre for Disease Prevention and Control (ECDC), the European Blood Alliance (EBA) and the EU blood establishments to support the development of CCP as a treatment option. It is crucial a co-ordinated and effective approach to the collection of convalescent plasma across the EU is undertaken.

To support a co-ordinated approach and in collaboration with the EBA, the European Commission (DG DIGIT) has built the EU CCP database (EU CCP DB) for the collection of data on the donation of CCP and patient outcome following transfusion with CCP.

The EU CCP Database:

The EU CCP DB is a web-based application designed to collect, in a structured and harmonised way, data related to COVID-19 convalescent plasma collection and treatment. In particular, the EU CCP DB provides a centralised mechanism allowing for the timely and secure exchange of information, consultation, and co-ordination at European level. The database will gather data from monitored use, as well as from randomised clinical trials, and will consolidate evidence from across the EU on the safety and effectiveness of CCP.

The EUCCP DB is hosted by Amazon Web Services EMEA S.c.r.l. (AWS) under a contract with the European Commission. The contract between the European Commission and Amazon Web Services foresees that all data will always be physically hosted in the EU. No data will be released to any third party, including third-country authorities, without obtaining written authorisation from the European Commission.

The ability to enter data into the EU CCP DB is provided to blood establishments (BEs) that have completed their registration and are providing the CCP. Clinicians or hospitals who are treating patients with CCP can make data pertaining to the transfusion and clinical outcomes of patients available to the BE that has supplied them with the CCP. The BE can then enter these data into the database.

Alternatively, the data pertaining to the transfusion and clinical outcomes of patients may be entered directly into the database by clinical trial group(s) or monitored access program(s) who receive the CCP (both later identified as ‘clinical partners’).

The data submitted to the EU database is stored and partially made public in aggregate format by the EC Directorate-General for Informatics (DIGIT) using live dashboards on a dedicated page on the DG SANTE website. These dashboards can be accessed directly at https://www.euccp.dataplatform.tech.ec.europa.eu/

The data is analysed through the Big Data Test Infrastructure (BDTI) of the European Commission Directorate-General for Communications Networks, Content and Technology. The European Commission provides access to the data to the EBA and to the SUPPORT-E Project consortium for analysis and publication in close collaboration with all involved parties.

Data protection aspects of the EUCCP Database:

The data related to donors and patients which is entered into the EU CCP DB is anonymous and is not sufficient to identify natural person to which the data relates. Therefore, this data is not subject to GDPR.

Donation data in the EUCCP database

No donor identification number is entered in the EUCCP DB. Instead, the donated plasma is identified by a donation number assigned by the blood establishment. This donation number is generated in the blood establishment in line with international standards and is used for various purposes, including labelling on the physical packaging of the plasma, and all associated documents, when the plasma is distributed to hospitals. This donation number cannot be related to an identified or identifiable natural person in the EUCCP Data Base, and the European Commission does not have legal or other means, which would enable it to acquire additional data that would allow it to identify the donors. Donation numbers are seen by blood establishment users but are not visible on any public areas of the EUCCP DB and are not provided to researchers when data searches are requested.

In addition, the following donor data is entered in association with each registered donation number: age (10 years range), BMI (range) and gender. Again, this data is not sufficient to allow the identification of the donor.

Patient data in the EUCCP Data Base

Any patient identification number can be used to enter patient data e.g. an identification number assigned by clinical partners, or any code defined at the blood establishment. T**he patient identification number entered is immediately and irreversibly hashed at entry and not retained in the EUCCP Data Base and is not known to the European Commission.** Similarly, to the donation identification number, it is not possible to relate this patient identification number to a person in the EUCCP Data Base and the European Commission does not have legal or other means, which would enable it to acquire additional data that would allow it to identify the patients.

The blood establishment or clinical partner that entered the data can subsequently update outcome data for that patient by using the same identification number they used initially, as it will be hashed in the same manner.

The transfusion and outcome data are linked via the donation number of the plasma unit transfused. The characteristics of the plasma donations transfused will have previously been registered in the database. The data on patients include age range, gender, comorbidities, Covid-19 diagnosis method, number of days from onset of symptoms to transfusion, severity of disease at transfusion

and at certain subsequent time points (WHO scale), viral load data, other treatments given, and adverse reactions.

There is no requirement for donors or patients to give consent before their data can be entered into the EU CCP Database as the collection and processing of anonymised data is outside of the scope of the GDPR.

The ownership of data regarding donors and CCP remains with the BEs who upload the data. The ownership of data regarding recipients remains with involved clinical trial groups, monitored access program groups and hospitals.

There is no requirement for a formal agreement between BEs and the European Commission prior to entering data into the EUCCP.