EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

Privacy Statement

EU - CONVALESCENT PLASMA DATABASE (CCP DB)
AUTHORISED USERS[1]

1. The Convalescent Plasma Database

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) and the EU blood establishments to face the challenge of responding to the COVID-19 crisis by supporting the development of blood-based treatment options. It is therefore crucial a co-ordinated and effective approach to the collection of convalescent plasma across the EU. The collected convalescent plasma could support the treatment of acutely ill patients (or patients at risk of becoming acutely ill) with this plasma within observational studies or randomised and case-controlled clinical trials, and in the longer term, for the development of immune globulin concentrates by industry.

In collaboration with the European Blood Alliance (EBA), the European Commission (DG DIGIT) has built this database for the collection of data on plasma donation and patient outcome after plasma transfusion. The database is open to all EU/EEA Blood Establishments and Clinical Users that wish to participate, via the EBA. This open-access database gathers data from monitored use, as well as from randomised clinical trials, and aims at consolidating EU evidence on the safety and effectiveness of this therapy. Anonymised data are submitted by Blood Establishments and Clinical Users. Those data are stored, made public by the European Commission Directorate-General for Informatics and analysed through the Big Data Test Infrastructure (BDTI) of the European Commission Directorate-General for Communications Networks, Content and Technology.

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 treatment. In particular, the EU CCP DB provides a centralised mechanism allowing for the timely and secure exchange of information, consultation and coordination at European level.

The EU CCP DB includes some personal data of individuals:

- name and contact details of authorised users of the system, via ECAS, under the responsibility of the authorised Blood Establishment or Clinical Trial/Monitored Use Programme

The abovementioned information is entered in the EU CCP DB by the user nominated by the Blood Establishment or Clinical Trial/Monitored Use Programme and is stored under the

[1] By "CCP DB Authorised users" this text means Commission staff and the users of the CCP DB, working under the responsibility of a Blood Establishment or a Clinical Trial/Monitored Use Programme

responsibility of the European Commission's Directorate-General for Informatics via EU Login and under the responsibility of a local administrator of each Blood Establishment or Clinical Trial/Monitored Use Programme

The related processing of personal data is subject to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

2. What personal information do we collect and for what purpose?

The following personal data relating to users are stored in the EU CCP DB database:

The name and the email of the local correspondent of the Blood Establishment or Clinical Trial/Monitored Use Programme.

These data are processed only with the purpose of granting access to the database.

3. Who has access to your information and to whom is it disclosed?

Data submitted through the EU CCP DB are made available to the European Commission. However, an exchange of information is ensured with the European Blood Alliance, coordinating this initiative.

4. How do we protect and safeguard your information?

The collected personal data are stored in servers of the Data Centre of the European Commission's Directorate-General for Informatics, the operations of which underlie the Commission's security decisions and provisions established by the Security Directorate for this kind of servers and services.
Access to personal data is only granted through personalised user ID and Password.

5. How can you verify, modify or delete your information?

You have specific rights as a 'data subject' under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access your personal data and to rectify them in case your personal data are inaccurate or incomplete. Under certain conditions, you have the right to erase your personal data, to restrict the processing of your personal data, to object to the processing and the right to data portability. You have the right to object to the processing of your personal data, which is lawfully carried out pursuant to Article 5(1)(a), on grounds relating to your particular situation.
If you are a "user" for a given Blood Establishment or Clinical Trial/Monitored Use Programme and would like to have access to your personal data processed within the EU CCP DB, or have them rectified, blocked or deleted, you should be able to retrieve your data in the EU CCP DB database and perform the necessary correction, update or deletion. To exercise your rights with respect to data processing acts executed under the Commission's responsibility, you should contact the Controller at the Commission by using the "Contact information" below and explicitly specifying your request.
Legitimate requests will be replied to by the Controller in the Commission within 30 working days as from receipt of the request.

6. How long do we keep your data?

Personal data of "users" are kept in a form which permits identification and may be consulted by the European Commission. Personal data are deleted from the EU CCP DB as soon as the individual is no longer designated as user of the EU CCP DB or until the database is no longer operational.

7. Contact information

If you have questions concerning the processing of your personal data by the Commission within the EU CCP DB, or your rights with respect to that processing, you may contact the Controller at the following address:

European Commission
Unit B4 – Medical Products: quality, safety, innovation
Directorate-General Health & Food Safety
Rue Froissart 101
B - 1049 Brussels
Belgium
SANTE-SOHO@ec.europa.eu

You may also contact the Data Protection Officer of the European Commission (DATA-PROTECTION-OFFICER@ec.europa.eu) with regard to issues related to the processing of your personal data under Regulation (EU) 2018/1725.

8. Recourse

Complaints against any data processing act executed under the Commission's responsibility can be addressed to the European Data Protection Supervisor at the following address:
European Data Protection Supervisor (EDPS)
Rue Wiertz 60
B-1047 Brussels
Belgium
Phone: +32 2 283 19 00
Fax: +32 2 283 19 50
edps@edps.europa.eu