EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

EU COVID-19 Convalescent Plasma (CCP) Platform

-Questions and answers-

Disclaimer: *This document aims to assist blood establishments in using the EU CCP Platform. It is provided for information purposes only. Neither the Commission nor any person acting on its behalf can be held responsible for the use made of this document.*

This is a working document that is updated, as necessary, to take into account experience and feedback from users.

Version 2.1

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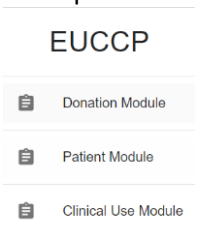
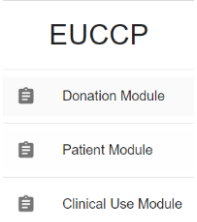
	Question	Answer
	General questions	
1	What is CCP?	COVID-19 convalescent plasma (CCP) is plasma from people who have been infected with the virus and have recovered. The plasma can be separated from a donation of whole blood or donated by plasmapheresis.
2	What is the EUCCP Platform?	The EU CCP Database is an open-access platform that hosts the EUCCP database. The database compiles data on COVID-19 convalescent plasma donations and patient outcomes following transfusions. Information is available on a dedicated page on the DG Santé website. The platform can be accessed from that page or directly at https://www.euccp.dataplatform.tech.ec.europa.eu/
3	Who developed the EU CCP Database	The database was developed by the European Commission in collaboration with the European Blood Alliance (EBA). It is hosted by Amazon Web Services EMEA S.c.r.l. (AWS) under a contract with the European Commission.
4	Where is the database hosted?	The contract between the European Commission and Amazon Web Services foresees that all data of the customer will always be physically hosted in the EU. AWS has furthermore committed to not disclose any customer

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: F101 08/070 - Tel. direct line +32 22951936

Massimo.AMBROSIO@ec.europa.eu

		data to third-country authorities before obtaining written authorisation from the customer[1].
5	Who enters data into the EU CCP Database?	The possibility to enter data into the EU CCP Database is restricted to blood establishments (BEs) that have completed their registration in the platform and are providing the CCP. Clinicians or hospitals who are treating patients with CCP should make data on the transfusion and clinical outcomes of patients available to the BE that has supplied them with the CCP. The BE will then enter these data into the database.
6	How is the EU CCP Database structured?	The EU CCP Database is composed of 4 modules. The first part is a registration and includes the submission of information on the participating BEs and their CCP working protocols. The second part comprises information on the CCP donations. The third records details of the clinical studies for which the BE is providing CCP and the fourth comprises information on the transfusions and clinical outcome in recipients.
7	What is the first step for a BE to participate in the EU CCP Database project?	BEs should send an email to info@europeanbloodalliance.eu to indicate their interest in participation. EBA will give them access to an online EU Survey (hosted by the Commission) to complete their registration (first module). EBA informs the Commission that the registration has been completed in EU Survey. The registration information is They will then receive an email with a link and a password that allows them to enter the database itself and begin to submit data.
8	Can a BE participate if it is not a member of EBA?	You do not need to be a member of the European Blood Alliance to participate in the programme. To register, however, you should send a request to them at info@europeanbloodalliance.eu
	Registration of BEs	
9	What data is collected in the registration form for BEs?	In the registration form, BEs need to provide some information on the BE, as well as the contact details of a contact person within the BE. Information is also requested on the protocols being used for the collection and supply of CCP.
10	Is it necessary to fill in the registration form every time new data is entered into the database?	NO. The registration form only needs to be filled in once.
11	Is it possible to change the information entered in the registration form after submission?	YES. The information entered in the registration module is uploaded to the database from EUSurvey. You can enter the database with your credentials and amend the information as needed.
12	Does the registration form need to be submitted in order to be able to enter data on CCP donations?	YES. You will not receive credentials to access the database itself until the registration in EUSurvey is completed.

[1] This contractual obligation does not affect the application of third-country laws for example, if data were required by a third country authority for the purposes of a criminal investigation.

	Data collection on CCP donations	
13	How do I switch between modules in the database?	To switch between modules click on the top left tab Switch module That opens the modules menu. 
14	How should I enter data on individual donations?	Ensure that you are in the DONATIONS module and select the tab 'Enter a New donation'
15	How should I enter bulk data on donations?	Ensure that you are in the DONATIONS module and select the tab 'Upload an Excel'. You will see the option to download the Excel template from that tab if you have not done this already.
16	What data is collected on CCP donations?	The part of the EU CCP Database on CCP donations covers questions on details of the donor, the collection method, and the CCP that was collected. This information will later be linked to the clinical outcome in the recipient.
17	Is it necessary to have all the data on the CCP donation available before making an entry in the database?	NO. For information that requires some time until it is available, such as the results of laboratory tests, it is possible to choose the option "not available yet" and to add the remaining data at a later time.
	Registration of Clinical Use protocols	
18	When should I complete the Clinical Use module?	This module should be completed before you enter and patient transfusion and outcome data. This will allow patients to be linked to specific clinical trials or studies.
19	How should I enter the clinical use protocols?	To switch between modules click on the top left tab Switch module That opens the modules menu.  Select the Clinical Use Module
20	Should I complete this module only once?	YES. This is a one-time registration of the clinical trials or other clinical use protocols that you are supporting with CCP supply. You may re-enter to update information when required.
	Data collection on transfusions and clinical outcomes in recipients	
21	Where should I enter transfusion and outcome data?	To switch between modules click on the top left tab Switch module That opens the modules menu.

		 Select the Patient Module
22	What data is collected on clinical outcomes in recipients?	The part of the EU CCP Database on clinical outcomes in recipients covers the clinical development of recipients after CCP treatment, as well as any adverse reactions during transfusion. The aim of the collection of these data is to gain insight into the safety and effectiveness of CCP treatment.
23	Which transfusions are documented in the database?	The aim is to collect minimum information on ALL transfusions of CCP, whether in the framework of a randomised trial or in a monitored access setting. Since the EU CCP Database only gathers data on CCP treatments, data on comparator/control treatments in randomised/controlled trials cannot be entered.
	Access to the data on the EU CCP Database	
24	Who is able to access the detailed data in the EU CCP Database?	Access to the EU CCP platform is public. On the landing page, a series of dashboards provide general aggregated data from the database. To enter data in the database, or to see more detailed data, it is necessary to log in. Log in credentials are provided to all BEs that have completed their registration, the European Commission, the EBA, key individuals in the SUPPORT-E project led by EBA that will conduct the in-depth analysis.
25	Which data are made available to the public?	Currently, the data that are made available publicly are limited to very general parameters. The data can be extended according to the requests of the EBA.
26	How can detailed aggregated data on the EU CCP Database be accessed by participating BEs?	More detailed aggregated data are made available on dashboards in the password secured part of the database. These are currently under review by EBA and the developers. Sophisticated dashboards for BE users can be created and customised by them for their own use. BEs will be able to see all their own detailed data and how this compares to all the aggregated data. **This work is ongoing**.
27	Can Blood competent authorities access all the detailed data of their own countries?	This functionality can be added if participating BEs agree. **This is under discussion.**
28	Who will analyse the data as it is gathered	Analysis of the data will be carried out by the European Blood Alliance, in particular by Work Package 3 of the SUPPORT-E project that will have access to all detailed data from all BEs.
29	Can I request additional specific analyses of the data?	YES. Queries can be sent to Sante-soho@ec.europa.eu who will review the request and organise the analysis as appropriate.

30	Can participating BEs only access the data they have entered themselves, or are they also able to access the data of other BEs?	Every participating BE has access to the detailed data they have entered. They can download it and use it as the record of their own CCP activity. The platform has the capacity to allow all BEs to see and make analyses of all the BE data in the database. If and how this functionality will be made available and used is to be agreed with EBA and all parties involved. **This is under discussion.**
	Data protection	
31	Does the database contain data that allows identification of natural persons?	Contact details of individuals in participating blood establishments are stored, though not publicly visible. A privacy statement is provided at registration. Apart from BE contact persons, data in the database is anonymous. **Donors**: No donor identification number is entered in the EUCCP database. Blood Establishments enter data regarding the plasma donation itself. The donated plasma is identified by a donation number attributed by the blood establishment. This donation number cannot be related to an identified or identifiable natural person in the EUCCP database, as there is no link between the EUCCP database and the databases of the participating blood establishments. **Patients**: Any patient identification number can be used by the blood establishment to enter these data, the number used in the hospital or a number invented at the blood establishment. **It is immediately and irreversibly hashed at entry and not retained in the EU database**. The blood establishment 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. To avoid having to keep a record of the patient identifier used at entry, blood establishments that choose to enter all patient data at the end of their treatment, at one time. This approach will mean that the establishment will not then be able to update the patient record in the EU database.
32	Is there a need for donors or patients to give specific informed consent before their data can be entered into the EU CCP Database?	NO. 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.
33	Who owns the data in the CCP database?	The CCP database does not own the data. 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 and

		monitored access programs groups and hospitals.
34	What is the role of the European Commission for the EU CCP database?	The European Commission hosts the CCP database and provides the data to the EBA and to the SUPPORT-E consortium for analysis and publication in close collaboration with all involved parties.
35	Is there a need for a formal agreement between BEs and the European Commission prior to participation?	NO, unless required by national rules. The involved party remains the owner of, and responsible for, its own data.