European Reference Networks

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Frequently Asked Questions

This document centralises the collection of frequent asked questions and the provision of appropriate answers. It is a shared document being produced by the teams of DG SANTE and IBM, and the group of Product Owners.

The versioning convention has three levels – two for official document releases and a third one for internal work in progress. V x.y.z : x – major revision, y – minor revision, z – work in progress

The official list of frequent asked questions with answers will be issued periodically by DG SANTE, after closing all pending work in progress.

When contributing with a question, tentative answer or comment please always do it with the track changes feature active. This facilitates further contacts for clarification, if needed.

Document history

Version	Date	Who	What
1.0.0	2024.07.19	Joao de Sousa (JdS)	Tentative structure and some policy/business questions
1.0.1	2024.07.23	Ioana Beleiu (IB)	Started drafting technical questions
1.0.2	2024.07.30	IB	Reviewed and updated the technical questions
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1.2.1	2024.10.08	IB	Update of information - Question 16
1.2.2	2024.10.17	JdS	Final editorial review for official release 1.2

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USAGE/TECHNICAL QUESTIONS

In this chapter we collect the most frequent questions about the use of the CPMS 2.0 platform, the use of the EU login authentication mechanism and all technical aspects of the platform.

1. What is the CPMS 2.0 platform?

The new Clinical Patient Management System, known as CPMS 2.0, is a secure web-based IT platform to facilitate cross-border medical discussions and support the European Reference Networks (ERNs) in the diagnosis and treatment of rare or low prevalence complex diseases or conditions. It is provided and maintained by the European Commission, in accordance with article 12 of the directive for patient rights in cross-border healthcare and funded under the EU4HEALTH Programme.

CPMS 2.0 is an open-source project, made freely available for possible modification and redistribution. It started as the European Reference Networks backbone for cross-border clinical discussions in the scope of rare diseases but can be applied to other use cases, at European and national scale.

CPMS 2.0 comes with two interfaces, a desktop interface for complex clinical discussions and a mobile interface for simple and informal discussions, as well as for managing invitations and notifications.

It is a clinical tool, to be used by healthcare professionals (clinicians and non-clinicians of the ERNs and guest clinicians) and not by patients.

[23.07.2024]

2. Which browsers are best to use for CPMS 2.0?

Any modern browser supporting web Real-Time Communications can provide a smooth experience with CPMS 2.0. Users are advised to use Google Chrome, Mozilla Firefox, Safari or Microsoft Edge.

[23.07.2024]

3. How can I request access to CPMS 2.0?

CPMS 2.0 can only be accessed by authorised users via the EU Login Authentication Service. In the login page the user will be requested to use their EU Login to access CPMS 2.0.

[23.07.2024]

4. How to create your EU Login?

To set up your EU Login go to the registration page by navigating to https://webgate.ec.europa.eu/cas/eim/external/register.cgi

[23.07.2024]

5. How do I change my email address in the EU login account details?

If you want to update your email address linked to EU login, you can do so via this link: https://ecas.ec.europa.eu/cas/eim/external/restricted/edit.cgi

[23.07.2024]

6. How do I change my phone number in the EU login account details?

If you want to update your phone number linked to EU login, you can do so via this link: https://ecas.ec.europa.eu/cas/eim/external/restricted/manageMyMobilePhoneNumbers.cgi

[23.07.2024]

7. I have a new mobile device; how can I add it to EU login?

To register your new mobile device, go to your EU login account via this link: Manage my mobile devices (europa.eu). Select “add a mobile device" and fill the required information. You can also delete the device you are not using anymore following the same steps, choosing “delete a mobile device”.

[25.07.2024]

8. How can I enrol a patient in CPMS 2.0?

Navigate to the ‘Add new patient’ in the left-hand side menu and fill in all the required information.

[23.07.2024]

9. How do I add files to *a patient record?*

To upload a new file to a patient record, navigate to Patient Records" page from the left-hand side menu:

- Find the patient profile for which you want to view the files. You can do this by either searching for the patient's name in the search bar at the top of the page or by browsing through the list of patients on the page.
- Once you have accessed the patient's record, go to the "Files" tab.
- Add files by clicking on the ‘Upload’ button.

[23.07.2024]

10. How do I invite experts to give written advice?

If you are the lead, you can add a participant to a patient discussion by:

- Navigating to the ‘Patient Records" page from the left-hand side menu:
- Select to the patient record to which you want to add participants.
- Once you have accessed the patient's record, go to the "Participants" tab.
- Add participants by clicking on the ‘Add participant’ button.
- Search for the experts using the available criteria, select one or more experts and confirm by clicking on ‘Add participant’.
- There is also an option to invite multiple experts within a set group created by your ERN. Select the ‘groups’ filter to see your options.

[23.07.2024]

11. Where are the conclusions of patient discussions saved?

To access the outcome report of a discussion, navigate to Patient Records" page from the left-hand side menu. Then:

- Select the patient record.
- Once you have accessed the patient's record, go to the "History" tab.
- The record of conclusions and points discussed about a patient are viewable once you click the expansion button on the right side.

[23.07.2024]

12. Can I download the outcome report after the discussion has been completed?

Yes, you can download the outcome document in the Patient History tab:

- Access the "Patient Records" page from the left-hand side menu.
- Navigate to the patient record for which you want to download an outcome document.
- Click on the "History" tab
- Look for the entry of the closed discussion that you're interested in and click on the "Download" icon. This button is located next to the relevant closed discussion entry.

[23.07.2024]

13. How can I schedule a meeting?

To schedule a meeting in CPMS 2.0:

- From the left-hand side menu select "Meetings".
- Then click on the "Schedule Meeting" button located on the right upper corner of the screen.
- Fill in all required details and check the disclaimer.
- Save your meeting details to view the scheduled meeting in the "Upcoming Meetings" tab.

[23.07.2024]

14. Where can I find next meetings links?

The next meetings scheduled are displayed on the 'Home' screen of CPMS2.0 (with the link to join under the dedicated column).

[23.07.2024]

15. Is video conferencing available in CPMS 2.0?

Yes, CPMS2.0 supports real-time video and audio. This feature enables clinicians to discuss patient cases online, regardless of their geographical location.

[23.07.2024]

16. What should I do when the video conferencing feature is blocked by my hospital?

The video conferencing feature of CPMS 2.0 is based on WebRTC, a web technology that allows for real-time video and audio traffic over the internet. Sometimes this technology is blocked by hospital firewalls. For now, we can advise you to take the following measures:

Ensure you are using a standard browser such as Microsoft Edge, Mozilla Firefox or Google Chrome.

If you are still facing issues, contact your IT team and raise a ticket with the below proposed message:

"To allow CPMS2.0 to properly work, please whitelist the IPs as follows:

- For Acceptance: 63.32.180.56
- For Training: 52.48.153.187
- For Production main IP address: 52.19.244.38
- For Production backup IP address: 34.252.60.133

Also allowing the following network traffic:

- Outgoing and incoming TCP and UDP packets to port 3478 (STUN and TURN)
- Outgoing and incoming TCP connections to port 443 (TURN over TLS)."

Please be aware that, regardless of the video conferencing tool being used, network traffic policies and security measures at your hospital may cause connectivity issues that will require a case-by-case analysis. If you do not receive a positive response from your IT team, please contact DG SANTE central helpdesk (SANTE-ERN-CPMS-ITSUPPORT@ec.europa.eu) to report the issue and receive personalised advice.

[08.10.2024]

17. How can I request access to a second ERN?

Click on your name at the top bar of CPMS 2.0 to expand the user menu.

- From the user menu, select "My Account".
- Under the 'Personal Information' tab you have the 'Change ERN request' button.
- Select the ERN to which you want to request access to and confirm by clicking on 'Save'.

[23.07.2024]

18. Can I adjust my email notifications preferences?

You can change your notification preferences by clicking on the "Bell" icon located in the top menu, then on the Settings wheel for notification settings. You will need to click the "Edit information" button to change the notification settings. After adjusting your preferences, make sure to click the "Save" button.

If you want to revert all your notification preferences to the default settings, there is an option to do so on the Notification Settings page. Click on the "Reset to default" option.

[25.07.2024]

POLICY/BUSINESS QUESTIONS

In this chapter we collect the most frequent questions about policy and business aspects of the operation of the CPMS 2.0 platform.

19. What are the GDPR and EUDPR?

The GDPR and the EUDPR are regulations related to the protection of personal data. They support the same data protection principles, but they differ in their applicability scope. The EUDPR applies to European Union institutions, bodies, offices and agencies, the GDPR applies to all other natural or legal person, public authority, agency or body.

The GDPR (General Data Protection Regulation) is officially known as Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. It became effective on 25 May 2018.

The EUDPR is the 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.

The goals of both regulations are to enhance individuals' control and rights over their personal information and to simplify the regulation of international business. They also govern the transfer of personal data outside the EU and EEA. They supersede the Data Protection Directive 95/46/EC.

As an EU regulation (instead of a directive), the GDPR is directly applicable with force of law on its own without the need of transposition to national legislation. However, it also provides flexibility for individual member states to modify (derogate from) some of its provisions.

Three important concepts developed in these regulations are data subjects, consent, and data controllers.

[19.07.2024]

20. What is a data subject?

In GDPR terms, a data subject is any natural person that is identified or identifiable, either directly or indirectly. In the CPMS 2.0 platform there are two types of data subjects: patients and users.

[23.07.2024]

21. What is a controller?

A controller is the natural or legal person, public authority, agency or other body, or Union institution, body, office, or agency which, alone or jointly with others, determines the purposes and means of the processing of personal data. For all ERN activities a joint controllership was put in place in the legal base of the ERNs. The joint controllers are the European Commission and every HCP. Joint controllers have different responsibilities.

[19.07.2024]

22. How are responsibilities allocated among joint controllers?

The allocation of responsibilities between the European Commission and each HCP is defined in the legal base of the ERNs. For details, please consult Annex 1 of the COMMISSION IMPLEMENTING DECISION (EU) 2019/1269, of 26 July 2019, amending Implementing Decision 2014/287/EU.

In summary, the European Commission is responsible for all the processing happening inside the IT platform and each HCP is responsible for all the processing happening outside the IT platform.

[31.07.2024]

23. What is consent?

In GDPR terms, consent is the decision of a data subject to authorize a given processing and it's one of the legal bases that allow the processing of personal data (other legal bases are, for example, public interest, national security, etc.). To be valid, consent must be freely given, specific, informed, unambiguous and explicit. The consent shall be a clear indication of the data subjects' wishes by which they, by a statement or by a clear affirmative action, signify agreement to the processing of their personal data. In all ERN activities the processing of personal data is based on consent collected through a consent form.

[19.07.2024]

24. What is a consent form?

A consent form is a paper or electronic form that is used to collect the consent of a data subject.

In the case of the CPMS 2.0 there are two types of data subjects – the patients whose cases will be discussed and the users (clinicians and non-clinicians) of the platform and consequently there are two different consent forms - the patient consent form and the user consent form.

[19.07.2024]

25. Who is responsible for the patient consent form?

The CPMS 2.0 patient consent form for EU patients is a paper form provided, managed, and archived by each HCP. According to the allocation of responsibilities defined in the ERN legal base, the responsible for the patient consent forms is the HCP. To this respect every HCP is accountable to their respective national supervisory authority, not to the European Commission.

The CPMS 2.0 patient consent form for Ukrainian patients is a paper form in English and Ukrainian provided by the European Commission but fully managed and archived by the Ukrainian Hub for rare diseases.

[31.07.2024]

26. Who is responsible for the user consent form?

The CPMS 2.0 user consent form is an electronic form implemented inside the platform. According to the allocation of responsibilities defined in the ERN legal base, the responsible for the user consent form is the European Commission which is accountable to the European Data Protection Supervisor.

[31.07.2024]

27. Is patient consent necessary for enrolling patients into CPMS 2.0?

Yes, to enrol a patient in CPMS 2.0 every clinician must obtain from the patient the consent for clinical care.

[31.07.2024]

28. Are other types of consent present in the CPMS 2.0?

For EU patients, in addition to the consent for care (the primary consent), the CPMS 2.0 needs two other patient consents for certain processing activities: the consent for the patient case to be anonymised and used for educational purposes and the consent for the pseudonymised patient data to be exported to registries (the secondary consents). Both are optional and none of them is required for the patient case to be discussed.

For Ukrainian patients no secondary consents are collected.

[31.07.2024]

29. What are the differences between the EU and Ukrainian patient consent forms?

The EU patient consent form asks for three consents - one mandatory and two optional. The Ukrainian (UA) patient consent form only asks for the mandatory consent (consent for care). Moreover, the UA form cannot be changed by UA HCPs while the EU form must be provided, customised, managed and archived by each EU HCP. It is recommended that EU HCPs follow the EC provided template, but it is not mandatory. The template can be downloaded from the 'Supporting Documents' section of CPMS 2.0 in the left-hand side menu. It is available in all EU languages.

[31.07.2024]

30. What is a Data Privacy Impact Assessment?

A DPIA – Data Privacy Impact Assessment - is an assessment conducted by an organization to determine whether its processes affect or may compromise the privacy of the individuals whose data it holds, collects, or processes.

[19.07.2024]

31. Is a DPIA mandatory?

A DPIA per se is not always mandatory but the assessment of the need to perform a DPIA is a legal obligation of a data controller.

[23.07.2024]

32. Did the European Commission carry out a DPIA?

As any data controller, the European Commission had to assess the need to perform a DPIA of the processing activities under its responsibility and concluded that they may represent a risk to the rights of patients and users. Consequently, a DPIA of the processing happening inside CPMS 2.0 was performed. The platform was considered fully compliant to the data privacy legislation. The DPIA will be updated at each major revision of the platform.

[23.07.2024]

33. Does a DPIA of one joint controller need to be approved by the other joint controllers?

No. Joint controllers do not need mutual authorisation or approval when deciding on their specific remits of responsibility. For the sake of transparency, they should however collaborate and adopt good practices of mutual information.

[19.07.2024]

34. Does every HCP need to carry out a DPIA?

Not necessarily. As a joint controller, an HCP is solely obligated to assess whether a DPIA is required for the processing activities under its responsibility. HCPs with existing DPIAs need not repeat the process unless the processing activities have changed, in which case an update may be necessary.

HCPs joining ERNs as new members or affiliated partners must evaluate the need of a DPIA and conduct one if they conclude that the processing operations under their responsibility may represent a risk to the rights of data subjects. Processing activities happening inside the CPMS 2.0 are not of the responsibility of the HCP but of the European Commission. Processing activities happening outside of the CPMS 2.0 are of the responsibility of the HCP.

[23.07.2024, 10/09/2024]

35. What are the key steps of a DPIA?

A DPIA should begin before the start of the processing activities and should include these steps:

1. identify the need for a DPIA (mandatory step)
2. describe the processing
3. consider consultation of relevant stakeholders
4. assess necessity and proportionality of the processing operations
5. identify and assess risks
6. identify measures to mitigate the risks
7. sign off and record outcomes

After sign-off, HCPs should integrate the outcomes from the DPIA back into the processing and keep the DPIA under review. A DPIA process should be designed to be flexible and scalable. It does not need to be a complex or time-consuming process.

[5.08.2024]

36. Is there a DPIA template to be used?

HCPs can use or adapt any sample DPIA template provided by the competent national supervisory authority or make a template to suit their own needs. They can even use an existing project-management method, as long as it covers all the key elements of the process. If an HCP decides to create its own template it may be helpful to refer to the Criteria for an acceptable DPIA in Annex 2 of the Article 29 working party guidelines.

[5.08.2024]

37. Who should do the DPIA of the HCP activities related to CPMS 2.0?

An HCP can decide who has the responsibility for carrying out the DPIA, and who should sign it off. It can be outsourced but the HCP remain responsible for it. If the HCP has a Data Protection Officer (DPO), their advice on the DPIA must be part of the process.

[23.07.2024]