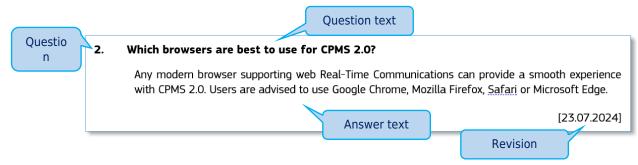
CPMS 2.0 Frequently Asked Questions

This document serves as a centralized repository for frequently asked questions (FAQs) and their corresponding answers. It is a collaborative effort developed by various teams within DG SANTE and the Product Owners group. Official releases of the FAQ list will be issued periodically by DG SANTE, following the completion of all pending work.

Question format



Document history

We employ a three-level versioning convention: x.y.z:

x: Major revision

y: Minor revision

z: Work in progress

When contributing a question, tentative answer, or comment, please always use the Track Changes feature. This facilitates clarification and discussion as needed.

For data privacy reasons, official releases of the document should not include this cover sheet.

Version	Date	Who	What
1.0.0	2024.07.19	Joao de Sousa	Tentative structure and some policy/business
		(JdS)	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
1.0.3	2024.08.05	JdS	Final editorial review for official release 1.0
1.1.0	2024.08.22	IB	Updated as per the feedback received from ERNs
1.1.1	2024.09.10	JdS	Final editorial review for official release 1.1
1.2.0	2024.10.08	IB	Update of question 16
1.2.1	2024.10.17	JdS	Final editorial review for official release 1.3
1.3.0	2024.10.29	JdS	Document history moved to cover sheet
1.3.1	2025.01.17	Michèle Foucart	Added question 19
		(MF)	
1.3.2	2025.04.23	IB	Update of question 16
1.3.3	2025.06.05	IB	Added questions 39 and 40
1.4.0	2025.07.16	MF	Added questions 20-22 (moved from business to
			usage/technical question), and 23-25, 46-48.
1.4.1	2025.08.22	MF	Added 2 more DPIA questions
1.4.2	2025.09.30	JdS	Final editorial review for official release 1.5
1.5.0	2025.10.07	JdS	Document V1.5 released

European Reference Networks

SHARE.CARE.CURE.



Frequently Asked Questions

V1.5 7.10.2025

This document serves as a centralized repository for frequently asked questions (FAQs) and their corresponding answers. It is a collaborative effort developed by various teams within DG SANTE and the Product Owners group. Official releases of the FAQ list will be issued periodically by DG SANTE, following the completion of all pending work.

Send usage and technical questions to <u>SANTE-ERN-CPMS-ITSUPPORT@ec.europa.eu</u>

Send business and policy questions to <u>SANTE-ERN@ec.europa.eu</u>

Table of Contents

USAG	E/TECHNICAL QUESTIONS	1
1.	What is the CPMS 2.0 platform?	1
2.	·	
3.	How can I request access to CPMS 2.0?	1
4.		
5.	· · · · · · · · · · · · · · · · · · ·	
6.	How do I change my phone number in the EU login account details?	
7.		
8.	How can I enrol a patient in CPMS 2.0?	
	How do I add files to a patient record?	

10.	How do I invite experts to give written advice?	2
11.	Where are the conclusions of patient discussions saved?	2
12.	Can I download the outcome report after the discussion has been completed?	3
13.	How can I schedule a meeting?	3
14.	Where can I find next meetings links?	3
15.	Is video conferencing available in CPMS 2.0?	3
16.	What should I do when the video conferencing feature is blocked by my hospital?	3
17.	How can I request access to a second ERN?	4
18.	Can I adjust my email notifications preferences?	4
19.	What is the difference between the assistant "capability" and the "role" of assistant?	4
20.	As a helpdesk user, I can see the list of meetings organized in my ERN. Why can't I join some of the meetings?	
21.	Mobile app updates, when and how do I need to update the CPMS2.0 Mobile app?	5
22.	Does CPMS 2.0 implements end-to-end encryption?	6
23.	What type of activity is logged in CPMS 2.0? Are logs restricted and for how long are th kept?	-
24.	About CPMS backups: how often are the backups made and for how long are they kept	?.6
25.	Is the CPMS platform operating following the ISO27001 standard?	7
POLIC	Y/BUSINESS QUESTIONS	8
26.	What are the GDPR and EUDPR?	8
27.	What is a data subject?	8
28.	What is a controller?	8
	How are responsibilities allocated among joint controllers?	
30.	What is consent?	9
31.	What is a consent form?	9
32.	Who is responsible for the patient consent form?	9
33.	Who is responsible for the user consent form?	9
34.	Is patient consent necessary for enrolling patients into CPMS 2.0?	9
35.	Are other types of consent present in the CPMS 2.0?	10
36.	What are the differences between the EU and Ukrainian patient consent forms?	10
37.	What is a Data Privacy Impact Assessment?	
38.	Is a DPIA mandatory?	
39.	Did the European Commission carry out a DPIA?	10
40.	Does a DPIA of one joint controller need to be approved by the other joint controllers?	10
41.	Does every HCP need to carry out a DPIA?	10
42.	What are the key steps of a DPIA?	.11
43.	Is there a DPIA template to be used?	
44.	Who should do the DPIA of the HCP activities related to CPMS 2.0?	
45.	Pseudonymization and Anonymization of medical images	.11
46.	How are patient names pseudonymized in CPMS 2.0?	.12

47.	In the consent form, it is indicated that data retention is subject to periodic review. On what criteria is this evaluation based?	12
48.	Is it possible to obtain the Statement of Applicability from the party who is responsible for operating the CPMS platform	
49.	Does CPMS 2.0 have C5 attestation?	
50.	How are GDPR-related requests implemented in CPMS 2.0?	13

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: <u>Manage my mobile devices (europa.eu)</u>. 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 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 (<u>SANTE-ERN-CPMS-ITSUPPORT@ec.europa.eu</u>) to report the issue and receive personalised advice.

[10.09.2024, 08.10.2024, 23.04.2025]

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]

19. What is the difference between the assistant "capability" and the "role" of assistant?

A user with the assistant "capability" has already a role in CPMS 2.0. This user can be an ERN clinician, an assistant (user having the "role" of assistant) or a helpdesk. This user will have the permissions as defined for the role the user has. If the user has the assistant "capability", it means that this user will (in addition to the permissions related to current role) inherit the permissions of the user he/she is assisting. There are 2 situations when a user becomes assistant for someone:

- An ERN clinician has added this user as "assistant" from "my account": in that case
 the user "assisting" will inherit the clinician's permissions and any action performed
 as "assistant" will be preceded by the mention "on behalf".
- Through user migration if this user was "HCP panel manager" in CPMS: in that case the user is migrated as ERN clinician + assistant for all clinicians of his/her HCP.

A user with "assistant" role, is a user that requested the access of "assistant" or that was created by an ERN Admin as "Assistant".

Being "Assistant" without having been appointed by a clinician as "assistant" does not give any permission to the user apart from being able to connect to CPMS 2.0. Once an ERN clinician is appointing the user with role "assistant", the assistant will inherit the

permissions of the ERN clinician that user is assisting, similarly as the assistant "capability". Please note that ERN clinicians can only appoint users from own Hospital as assistant.

As explained, this user is per default not assisting any user, as long as it has not been appointed by a user from the same clinical centre.

Once a user from the same clinical centre has appointed the user as assistant, the user with role "assistant" will inherit the capabilities of the user that this user is assisting.

[17.01.2025]

20. As a helpdesk user, I can see the list of meetings organized in my ERN. Why can't I join some of the meetings?

As a helpdesk user, you have visibility into all meetings organized within your ERN. However, your ability to join a meeting depends on whether you were specifically invited to it.

- If you were invited: You'll see your status as "Invited" in the meeting list. In this case, you can join the meeting
- If you were not invited: You can still see the meeting (due to your helpdesk role), but you won't be able to join unless you take further action

As a helpdesk user, how to join a meeting you weren't invited to?

- Open the meeting details.
- Add yourself as a participant.
- Your status will change to "Invited," and you'll then be able to join the meeting.

This ensures that only authorized participants can access meetings, while still allowing helpdesk users to assist when needed.

[23.05.2025]

21. Mobile app updates, when and how do I need to update the CPMS2.0 Mobile app?

 Do I have to update my mobile app every time a new version of CPMS 2.0 comes out?

Not always. If the new version of the app is still compatible with the version of CPMS 2.0 Web/desktop, you won't see any in-app messages asking you to upgrade immediately.

You can find the version of CPMS 2.0 Web/desktop you're using when you're logged in—it's displayed at the bottom left corner of the screen.

• How can I know if there's an update available for my app?

Your app will show up in the list of available updates in your app store (like the App Store for iPhones or Google Play for Android devices).

How do I update the app?

You can update the app directly from the app store. Just go to the list of available updates and select the option to update the app. No need to uninstall or reinstall it.

Can my app update automatically?

Yes, if you have automatic updates turned on in your device's settings, the app will update itself in the background without any action needed from you.

[25.05.2025]

22. Does CPMS 2.0 implements end-to-end encryption?

CPMS 2.0 **does not** implement end-to-end encryption (E2EE) due to two reasons.

- Firstly, the platform does not rely on services from untrusted providers, which eliminates the need for E2EE in this context.
- Secondly, ERNs requested the ability to record audio and video sessions, which is incompatible with E2EE.

It's essential to emphasize that the absence of E2EE in CPMS 2.0 does not compromise the security of the platform in any way. In fact, E2EE is only necessary when using a service from a third-party provider that cannot be trusted. In such cases, E2EE ensures that the service provider cannot access the data exchanged between the two ends of the communication. However, in the case of CPMS 2.0, there are no external service providers involved. Instead, the platform handles all services needed and even provides its own video and audio, using a dedicated open-source audio and video server module. This approach is used for security reasons and is essential for enabling the recording service in an efficient manner.

The dedicated servers eliminate the need for E2EE, as the platform has complete control over the infrastructure and can ensure the confidentiality, integrity, and availability of data exchanged within the platform.

[06.05.2025]

23. What type of activity is logged in CPMS 2.0? Are logs restricted and for how long are they kept?

The system logs all actions taken within CPMS 2.0 related to business events. Access to the logs is restricted to specific users: SANTE Support, Policy Unit, and other administrative users. No other users can access these logs. The logs are kept for as long as necessary to audit the system in case of issues. The need to keep logs is reviewed every 5 years to ensure compliance to the data privacy policy of CPMS 2.0.

There are also system logs generated at runtime by each component of the system, used for debugging and monitoring alerts. No personal data is stored. System logs are available to the technical team for specific users, identified by username. System logs are stored for 6 months.

[16.07.2025]

24. About CPMS backups: how often are the backups made and for how long are they kept?

The backup policy of CPMS 2.0 is the following:

- Automatic nightly snapshots are kept for 30 days
- Automatic nightly database backups are kept for 6 months
- Manual backups are kept for 6 months

[16.07.2025]

25. Is the CPMS platform operating following the ISO27001 standard?

Yes. CPMS 2.0 is hosted in Amazon Web Services (AWS), an infrastructure that has certification for compliance with ISO/IEC 27001:2022, 27017:2015, 27018:2019, 27701:2019, 22301:2019, 20000-1:2018, 9001:2015, and CSA STAR CCM v4.0.

[16.07.2025]

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.

26. 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]

27. 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]

28. 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]

29. 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

<u>COMMISSION IMPLEMENTING DECISION</u> (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]

30. 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]

31. 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]

32. 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]

33. 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]

34. 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]

35. 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]

36. 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]

37. 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]

38. 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]

39. 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]

40. 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]

41. 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]

42. 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]

43. 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]

44. 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]

45. Pseudonymization and Anonymization of medical images

CPMS 2.0 does not implement automatic de-identification of images, except in specific cases (e.g. DICOM studies) where identification data is stored in a separate layer from the image(s) and is recognized as such by the DICOM server. In any case, it is a clear responsibility of each user to ensure that no personal identifying data is present in any uploaded document. This is also a critical responsibility of hospitals, as joint controllers, which must provide adequate training on awareness and good practices to all users of the platform as the the way to reduce the residual risk to an acceptable level.

This is of particular importance in the case of unique anatomical characteristics, which can be problematic in rare and other diseases. Unfortunately, there is currently no complete solution to this problem and CPMS 2.0 is no exception. For the time being it can just be mitigated through well-established in-house procedures. Hospitals must take proactive steps to mitigate the risks associated with unique anatomical characteristics, such as implementing robust protocols and providing adequate training to their staff.

[06.05.2025]

46. How are patient names pseudonymized in CPMS 2.0?

In CPMS 2.0, each patient is assigned a unique pseudonym in the form of a nickname. This nickname can either be system-generated or manually chosen by the user creating the patient record. The Spider tool **is not** currently used in CPMS 2.0.

System-generated nickname.

 By default, the system automatically generates a nickname using the following pattern:

Word1 Word2 Number

- Word1 and Word2 are randomly selected from a predefined data dictionary. Number is a random integer between 0 and 999.
- It further checks if the resulting nickname is already used for a patient. If yes, the process is repeated (up to 1000 times). In the rare case where 1000 randomly generated nicknames are all used, the system returns an error message and the user must define manually a nickname for the patient.

User-Defined Nicknames

- The user enters a free text nickname.
- The system checks if the suggested nickname is already used for a patient. If yes, the system returns an error message and blocks the Validate button.
- If the nickname is new, the user must click the "Validate" button next to the chosen nickname.

[10.06.2025]

47. In the consent form, it is indicated that data retention is subject to periodic review. On what criteria is this evaluation based?

Based on Annex III par. 2 (ii) of <u>Commission Implementing Decision of 10 March 2014</u> (as amended by Implementing Decision 2019/1269), the healthcare providers are responsible to collect and maintain the "explicit, informed, freely-given and specific consent(s) of the patients"

Regarding the retention period, Article 16b of the same Implementing Decision prescribes the obligations of the healthcare providers which, among others, are to delete data no longer necessary: "Personal data of patients shall only be retained for as long as necessary in the interest of patient care, and of the patients' family members. Every 15 years at the latest, each healthcare provider authorised to access CPMS shall review the need to keep the patients' data it is controller of...".

This means that the healthcare providers are the responsible to interpret and apply the provisions at hand, based on the characteristics of each case. The European Commission is not competent to decide on the retention period of health data.

Additional information about the retention period for CPMS 2.0 user and for patient-related data are available in "CPMS 2.0. Privacy statement V1.1" on page 5 (paragraph 5.1 and 5.2).

[10.06.2025]

48. Is it possible to obtain the Statement of Applicability from the party who is responsible for operating the CPMS platform

No, but all information can be consulted at https://aws.amazon.com/compliance/iso-certified

[16.07.2025]

49. Does CPMS 2.0 have C5 attestation?

Yes, CPMS 2.0 has C5 attestation. The Cloud Computing Compliance Criteria Catalogue (C5) is an audit certificate for cloud services specified by the German Federal Office for Information Security (BSI). While this attestation is not mandatory at the EU level, the cloud provider for CPMS 2.0 has successfully completed the C5 Type 2 attestation for the services used by the system.

For more in-depth information, you can refer to [1] and [2].

[22.08.2025]

50. How are GDPR-related requests implemented in CPMS 2.0?

A specific role has been created within CPMS 2.0 to handle all GDPR-related requests, including the deletion of patient data upon a patient's request. This restricted role is granted by DG SANTE to selected Healthcare Provider (HCP) users - usually the Data Privacy Officer (DPO) - upon a justified request from the HCP. The European Reference Networks (ERNs) do not have access to this role as they are not data controllers.

[22.08.2025]