



# ERN CPMS 2.0 DPIA Results and Next steps

5.11.2024

*European Commission  
Directorate-General for Health and Food Safety  
Unit B3 - Health monitoring and cooperation, Health networks*

# Practical and legal considerations

## 1. Identify yourself correctly: **Affiliation – First Name Last Name**

Example: DG SANTE – Joao de Sousa (if necessary, right-click on your name and “Edit display name”)

## 2. Keep your camera open

Keep your microphone muted when not speaking

The meeting is being recorded for the sole purpose of helping to write the minutes.

By attending you consent to being recorded.

The recording will be destroyed once the minutes are approved.

The chat transcript will NOT be part of the minutes.

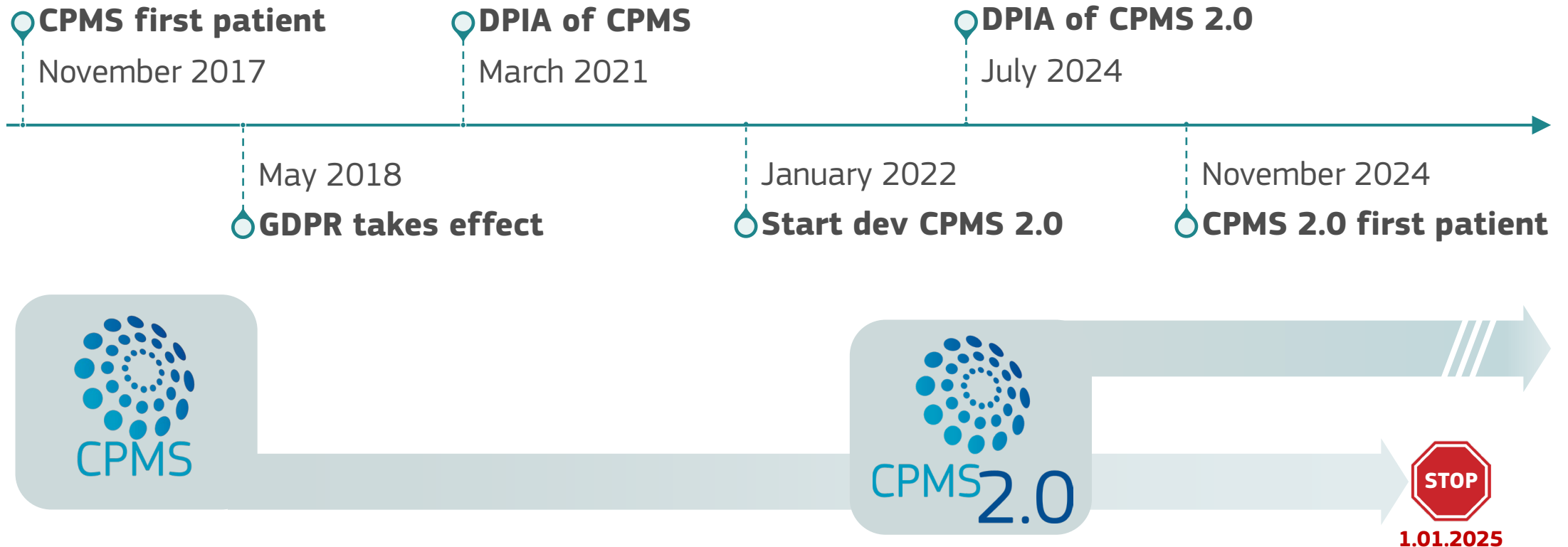
# Agenda

1. Opening remarks, introduction and context (10 min, Commission)
2. DPIA presentation (30 min, NRB)
3. Discussion (20 min, all)
4. How recommendations are being addressed (10 min, Commission)
5. Next steps for hospitals (10 min, Commission)
6. Discussion (10-30 min, all)
7. Closing statements

# Clinical Patient Management System

- IT platform
- Secure environment for cross border medical discussions
  - Sharing of patient cases
  - Audio, video and text interactions, including medical imaging
- Used in the context of **general clinical practice**

# Clinical Patient Management System – timeline



# Clinical Patient Management System – legal base

- Article 12 of the Directive [2011/24/EU](#) on the application of patients' rights in cross-border healthcare.
- Commission Implementing Decision (EU) [2019/1269](#), of 26.7.2019, amending Implementing Decision [2014/287/EU](#).

- Joint controllership: The diagram consists of two teal-colored rounded rectangular boxes. The left box contains the text "European Commission" and the right box contains the text "Healthcare Providers". A white plus sign "+" is positioned between the two boxes, indicating a joint relationship.

(Annex 1 of Implementing Decision (EU) 2019/1269)

# CPMS 2.0 Data Privacy Impact assessment

To be presented by NRB

- Completed: July 2024
- Result: **CPMS 2.0 is GDPR compliant**
- Recommendations: already implemented or being addressed

# CPMS 2.0 DPIA – recommendations

Recommendation	Status of implementation
Coordinate with and support HCPs, if needed 1. Development of acceptable use policy 2. HCPs DPIA and security awareness of users	SANTE is open to periodically discuss with HCPs on sharing of best practices
3. Establishment of a user access management process based on EC standards	Integrated in the platform. Documentation ongoing.



# CPMS 2.0 DPIA – recommendations

Recommendation	Status of implementation
4. Holistic and full-scale penetration tests executed by an independent party	Included in the acceptance workflow of each major release
5. Development of a disaster Recovery Plan 6. Planning and execution of annual Business Continuity and disaster Recovery tests	Both covered in the yearly contracts with the solution provider (IBM)

# Preparing the transition to CPMS 2.0

1. Mandatory – HCP decision about the patient consent form (PCF)
  - Continue using the current CPMS PCF (first consent only)
  - Adapt and start using the EC-provided CPMS 2.0 PCF template
  - Use a different PCF
2. If deemed necessary – Data Privacy Impact Assessment of the processing activities under HCP responsibility

# Continue using the current Patient Consent Form

- The 1<sup>st</sup> consent of the current CPMS form is still valid
- The 2<sup>nd</sup> and 3<sup>rd</sup> are outdated (but are anyway optional)

Form can still be used  
until an update  
is issued by the HCP

CPMS		CPMS 2.0	
1	I CONSENT to my de-identified data being shared in ERN(s) for my CARE. I understand that my data will be shared with healthcare professionals in the ERN(s) so that they may work together to support my care.	I consent to my pseudonymised data being shared for my diagnosis and treatment. I am aware that my data may be shared with healthcare professionals in other hospitals, in some cases in other EU countries, so that they can discuss my case and advise my treating doctors.	✓
2	I CONSENT to my de-identified data being included in one or more ERN database or registry.	I consent to my clinical case being fully anonymised and then used for educational purposes.	✗
3	I WOULD LIKE TO BE CONTACTED about research. I will decide if I consent to my data being used for a specific project if I am contacted.	I consent to my pseudonymised clinical data being exported to ERN registries for the purpose of scientific research.	✗

# Use the CPMS 2.0 EC recommended template kit

PREFERRED  
OPTION

- GDPR compliant
  - Collects consent to share personal data for specific purposes
  - Fully aligned with the processing of personal data by the CPMS 2.0
- HCPs should follow recommendations of national authorities
  - Guidelines of the national supervisory authority
  - Guidance of the national health authority, if any
    - Local initiative of the hospital
    - Centralised approach led by the national health authorities

# The CPMS 2.0 EC recommended template kit

European Reference Networks  
SHARE.CARE.CURE.

ERN CPMS 2.0 PATIENT CONSENT FORM EU

1 [Name of the hospital]

**WHAT ARE THE EUROPEAN REFERENCE NETWORKS AND HOW CAN THEY HELP YOU?**

European Reference Networks (ERNs) are networks of healthcare professionals working with rare diseases across Europe. ERNs allow healthcare professionals to discuss rare/complex clinical cases like yours, helping your doctors to correctly diagnose or establish a care plan for your health problem.

For an ERN to advise your doctors, the relevant data collected about you in this hospital must be shared with healthcare professionals in other hospitals, some of which may be located in other EU countries.

**WHICH DATA ARE PROCESSED?**

If you give explicit consent, your health data will be pseudonymised and uploaded to a secure EU based IT platform. Only pseudonymised medical data relevant for the purpose of diagnosis and treatment of your disease will be uploaded. This may include age, sex, medical images, laboratory reports and biological sample data. It may also include your clinical history.

This happens in a secure IT platform that ensures protection of your data and your privacy, which is used by the healthcare professionals of the ERNs to participate remotely in the discussion of your case.

After the discussion is closed, your doctor may download an outcome report with the relevant advice.

Your case will be discussed by EU experts inside the IT platform only if you consent. However, your care remains the responsibility of your doctors in this hospital and even if you choose not to give consent, your doctors will continue to care for you to the best of their knowledge.

If you gave consent for your case to be discussed and you accept to contribute to the advancement of knowledge on rare cases like yours, you may give additional consents, as specified below. Both are

optional and do not affect the discussion for diagnosis and treatment:

a) If you give explicit consent for your data to be used for educational purposes, fully anonymised and may be used by healthcare professionals, including medical students, for advancing and education on rare cases like yours.

b) If you give explicit consent for your data to be exported to ERN registries, your data may be exported to registries for diseases, to be used for scientific research.

**WHAT ARE YOUR RIGHTS?**

Your data will be processed in compliance with protection legislation, including Regulation (EU) 2018/1725 and Regulation (EU) 2018/1725, Commission and each EU health processing patient data in the IT platform.

You have the right to give or refuse your consent and also withdraw your consent at any time. Note that the withdrawal of your consent will affect the lawfulness of the data processing.

You have the right to request an information about the data that is processed and to request the correction of your data and to request the deletion of your data. The point of contact for exercising your rights is your healthcare provider. You also have the right to lodge a complaint with a national supervisory authority or the European Data Protection Supervisor.

Your data will be retained only for the purposes to which you have consented, with a review of the necessity to retain your data after 15 years.

Patient consent form template

**Primary consent (diagnosis and treatment):**  
The primary consent is mandatory for your case to be discussed.

I consent to my pseudonymised data being shared for my diagnosis and treatment. I am aware that my data may be shared with healthcare professionals in other hospitals, in some cases in other EU countries, so that they can discuss my case and advise my treating doctors.

☐ Yes  
☐ No

**Secondary consents (education, export to registries):**  
If you gave the primary consent above AND you accept to contribute to the advancement of knowledge on rare cases like yours, you may give additional consents, as specified below. Both are optional and do not affect the discussion of your case for diagnosis and treatment:

Consent for education:  
I consent to my clinical case being fully anonymised and then used for educational purposes.

☐ Yes  
☐ No

Consent for export to registries:  
I consent to my pseudonymised clinical data being exported to ERN registries for the purpose of scientific research.

☐ Yes  
☐ No

**PATIENT DETAILS:**  
First and last name: \_\_\_\_\_

☐ I am the patient.  
☐ I am \_\_\_\_\_ and I witnessed that the patient was not able to sign by his/her means and gave consent by the following means: \_\_\_\_\_  
☐ I am a parent/guardian of the patient, or I have power of attorney and I am attaching the supporting documents to this form.

**WITNESS/PARENT/GUARDIAN/ATTORNEY DETAILS:**  
First and last name: \_\_\_\_\_  
Date: \_\_\_\_\_ Signature: \_\_\_\_\_

**CONTACT DETAILS OF THE JOINT CONTROLLERS:**

Healthcare provider:

- [Name of the hospital]
- [Address of the hospital]
- Data Protection Officer contact: [email address]
- National Supervisory authority contact: [email address]

European Commission:

- Directorate-General for Health and Food Safety
- 1049 Bruxelles/Brussel, Belgium
- Data Protection Officer contact: [data-protection-officer@ec.europa.eu](mailto:data-protection-officer@ec.europa.eu)
- European Data Protection Supervisor: [edps@edps.europa.eu](mailto:edps@edps.europa.eu)

SHARE.CARE.CURE.

ERN CPMS 2.0 PATIENT CONSENT FORM EU

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- European Data Protection Supervisor: [edps@edps.europa.eu](mailto:edps@edps.europa.eu)

# Use a different patient consent form

- Decision of the HCP
- Accountable to the national supervisory authority
- Should follow recommendations of national authorities:
  - Guidelines of the national supervisory authority
  - Guidance of the national health authority, if any
    - Local initiative of the hospital
    - Centralised approach led by the national health authorities

# DPIA of the activities under HCP responsibility

1. Already have a DPIA for the HCP activities within the current CPMS
  - If changes in the activities – assess the need of revising the DPIA  
If deemed necessary – revise it, following the guidelines of the national supervisory authority
2. Never did a DPIA for the HCP activities within the current CPMS
  - Assess the need of a DPIA  
If deemed necessary – do it, following the guidelines of the national supervisory authority

# Thank you!



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