

# European Reference Networks

## SHARE.CARE.CURE.

### Clinical Patient Management System (CPMS 2.0) Procedure for Ukrainian patients

This document outlines the procedure required for the implementation of the Administrative Arrangement (AA) on facilitating Ukrainian healthcare providers to seek advice on Ukrainian rare or complex disease patients from members of the European Reference Networks, as per Section 5 'Procedure' of the AA.

#### Procedure CPMS 2.0

The discussion of a clinical case of a Ukrainian patient must follow the procedure as shown below. All interactions undertaken under the auspices of the AA with Ukrainian hospitals and clinicians are done through the Ukraine rare disease hub (UA Hub).

#### 1. Consent form available to UA Hub.

A special CPMS 2.0 patient consent form is made available to the UA hub by DG SANTE. This consent form may not be modified and is provided in both Ukrainian and English.

#### 2. UA clinician seeks support.

- 2.1. UA clinician contacts UA hub for support.
- 2.2. UA hub analyses if request is medically valid<sup>1</sup>.

#### 3. UA Hub identifies ERN.

- 3.1. If it is a medically valid request, UA hub identifies the appropriate ERN and initiates contact. If not a medically valid request, UA hub informs UA clinician that the request is not medically valid and why.
- 3.2. ERN confirms medical validity of the request and confirms availability of ERN to discuss patient case with UA clinician and assigns a contact person. If not medically valid, ERN informs the UA hub why, which in turn informs UA clinician that the request is not medically valid and why.
- 3.3. ERN informs UA hub of the assigned contact person.

#### 4. UA Hub requests signed patient consent.

- 4.1. UA hub sends patient consent form to UA clinician.
- 4.2. UA clinician obtains consent from the patient and sends the signed patient consent form to UA hub.
- 4.3. UA hub receives the signed patient consent form and checks it for correctness.
- 4.4. If the consent is deemed correct, the UA hub archives the consent form.
- 4.5. UA hub informs UA clinician that consent form is correct, informs the UA clinician of the assigned contact person in the ERN and explicitly authorizes the UA clinician to proceed to the next step of the procedure.

#### 5. UA clinician requests the ERN guest access to CPMS 2.0

- 5.1. UA clinician creates an EU login account and configures it to use double factor authentication<sup>2</sup>.
- 5.2. UA clinician logs in to the CPMS 2.0 and requests the relevant ERN to receive guest access to use the IT system (signs-up).

#### 6. UA Clinician enrolls patient in the CPMS 2.0

- 6.1. UA clinician logs in and completes the user profile, including their own user consent.
- 6.2. UA clinician confirms patient consent was given by ticking the relevant check box and enrolls the patient.
- 6.3. UA Clinician builds the patient case by uploading all the relevant information.

---

<sup>1</sup> It is classified as a rare or low prevalence complex condition within the scope of the ERNs.

<sup>2</sup> Please note that this step is only required in case you have never received an EU login account. In case you already have, please proceed to 5.2.

## **7. UA Clinician contacts the ERN to agree on the way forward**

- 7.1. UA clinician uses the chat function to contact the ERN assigned contact person.
- 7.2. UA clinician and ERN contact person agree on the way to proceed with the discussion of the patient case.

## **8. Discussions take place inside the CPMS 2.0**

- 8.1. Discussions are scheduled aiming at establishing a diagnostic or a treatment advice.
- 8.2. The discussion is closed by the decision of the ERN and the outcome report is generated with the relevant advice for the UA clinician.
- 8.3. UA clinician downloads the outcome report.

## **9. Closure of discussion and guest access inside the CPMS 2.0**

- 9.1. Relevant ERN deletes the UA clinician's guest access to CPMS 2.0.

## **10. Deletion of patient data**

- 10.1. Deletion of patient data is possible at any time.
- 10.2. The patient can withdraw its consent and/or request the deletion of its data by contacting the healthcare provider, the UA Hub or the European Commission.
- 10.3. The European Commission will delete the concerned patient data.