



QUESTIONNAIRE TO ERN COORDINATORS ON THE PILOT PHASE OF THE CPMS

1. Background:

On 20 November 2017, the Clinical Patient Management System (CPMS) has been released. At the WebEx conference in November on the release of the CPMS it was highlighted that the pilot phase will be an important part of the roll-out plan. This phase will last until end of February 2018. It is an opportunity for users to gain experience in the system with real clinical data and with real consultations. During that meeting the Commission services were asked to provide a template questionnaire that can be completed by the users in the ERN.

ERN Coordinators are asked to collect and consolidate the feedback and **send them to the Commission by 15 March 2018**. Replies can be sent to SANTE-COORDINATORS-ERN@ec.europa.eu.

2. Scope:

The scope of this questionnaire does not include technical feedback or new feature requests for the clinical patient management system, this will be addressed through existing channels and an opportunity for more comprehensive feedback will be made available in quarter 2 of 2018. The scope of this questionnaire is to review and analyse your business process needs.

3. Questions:

a. Information on the ERN

- 1) ERN name: **ERN-EuroBloodNet (ERN on Rare Hematological Diseases)**

b. Launch of the CPMS

- 1) Do you consider that you were sufficiently well prepared in your ERN or HCP to start working with the CPMS? If not, can you please explain why?

“CPMS guide is clear and platform is pretty intuitive.”

“I think the CPMS is completely unknown in my HCP and in the ERN. We are not prepared to use CPMS, because it is a completely new option that did not exist before. A lot of physicians are completely unknown about this option to ask peers for advise. On the other hand; HCPs in C of E, maybe think they don't need it. The question remains, DO WE REALLY NEED CPMS”

“Yes”

“Yes”

“Yes”

c. Approval touse CPMS by your ERN Coordinator

Before getting access to CPMS, your ERN Coordinator after consultation by the Commission services must approve the request.

- 1) Do you agree that local administration rights should be attributed to the ERN Coordinator or even on HCP level in order to streamline the access process? If not, can you please explain why?

“We think the access should be extended to healthcare professionals, other to ERN Coordinator, involved in clinical case, in order to give their contributions and allow a complete overview on the case.”

“I think it could help that local administration rights are attributed to CoE HCP level. It makes them more involved and they will notice that when no HCP registers for the CPMS there is a job to do on informing about CPMS”

“Yes”

“Yes”

“Yes”

- 2) Currently we grant access to CPMS for health professionals¹¹ in the first place. Do you think that non-health professionals should have access to CPMS under certain conditions? Can you give examples of such non-health professionals? If so, can you briefly describe the tasks and permissions that should be attributed to them?

“According to our experience on CPMS until now, it is not necessary. It could be useful in the future if the platform will be provided with supplementary fields, not strictly clinical. For example, it could be useful to have a contribution by a psychologist or a biologist or a pharmacist.”

“I think that supporting personnel (data managers e.g.) could help getting the patient data in the CPMS to decrease the administrative burden of the HPs. “

“For the current characteristics of the platform, I think that only health-professionals have a suitable preparation for describing or giving advice to such complex cases”

“No, I think that access to CPMS data should be given to health professionals only”

“Yes, I think they should have access to CPMS. For example, for the ERN EuroBloodNet, the test of the insertion of the first patient was done by Mariangela Pellegrini, ERN manager and Coordinator Pierre Fenaux assistant. Her tasks were: to collect the patient’s consent, to insert patient data in the CPMS, to ask to Saint Louis hospital to anonymise the patient exams, to check if the viewer of radiology worked. Finally she passed the lead of the panel to Pierre Fenaux.”

d. Selection of patient

For this pilot phase, ERNs were invited to enrol at least 5 patients per ERN in order to have a meaningful experience with the system.

- 1) Can you confirm you easily found and enrolled 5 patients? If not, can you please explain why and indicate how many patients you enrolled in the end?

¹¹ Health professional: a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession, or a person considered to be a health professional according to the legislation of the Member State of treatment.

5 patients in total have been enrolled during the pilot phase for the ERN.

- 2) When looking for a patient, were there specific selection criteria that you applied? Can you explain why the specific patient was selected: case, urgency, complexity, other reason? If it weren't to be the pilot phase, would you still have selected the same patient?

“Our selection criteria are based on complexity of the case, questions not resolved and clinical interest. If it weren't to be the pilot phase, we still have selected the same patient.”

“I would have selected this patient again because it was severe enough to put a lot of effort in, and the case was complex enough that I had the Idea I couldn't be solved by my CoE alone”

“I think that the major criteria is complexity and the need of an expert advice (also in a non-pilot phase)”

“I selected a patient for complexity. Yes, if it weren't the pilot phase I would still select the same patient”

“Patients were selected according to pilot phase. First criteria was to pick patients according to certain medical exams done (e.g. PET SCAN) in order to verify the right compatibility between the hospital viewer and the CPMS viewer. In a non-pilot phase, patient would have picked according to complexity case, asking for a second advice.”

e. Panel set-up

- 1) Did you easily manage to put together a panel of experts to assess your patient file? If not, can you please explain what the difficulty was?

“We easily manage the panel of expert selection, but at the moment they were very few.”

“The strength of CPMS should be that you get advice from people you don't know. Why bother to insert a patient in CPMS if I just can call my friends in Barcelona about PK thermostability. I want advice from unexpected corner. E.G. a hematologist from Germany I don't know of who is an expert on T-LGL and suggest to do a T-cell flow cytometry analysis (which solved the case). The experts shouldn't be hand picked, by the one who asked advice in diagnostic cases. For treatment advice this is different”

“I have participated as a contributor for a patient of another center”

“No, I wanted to invite a specific colleague with whom I had already discussed the case, but she never appeared in the list of experts”

“Not applicable”

- 1) How many members were involved in the panel? How many HCPs and how many Member States were represented?

“For the first case we uploaded, there were 3 members, of 3 different members states. For the second one, there was one more expert, from a fourth member state.”

“3 and 3 (the HCP/MS who presented the case and two experts where invited to give advise”

“5 HCPs of 4 MS”

“Not applicable”

“Not applicable”

- 2) Was there a need to consult experts from non-ERN HCPs or from other ERNs?

At this pilot phase no experts out of the ERN or from other ERNs have participated in the panels.

f. Consultation

- 1) Once the panel was established, how many meetings were held?

No meetings have been held during this phase.

g. Outcome

After the assessment has been completed and contributions from the panel members have been recorded, the outcome of the consultation can be prepared and 'signed-off'.

- 1) Can you inform if the outcome has been prepared and signed-off? If not, why is the assessment still on-going?

“Our cases are at the Assessment level, so we did not arrived yet at sign-off. It would be useful to have a printable report also at temporary levels.”

“Yes, it was signed off”

“The case in which I'm involved is still ongoing because the other contributors haven't recorded their advice yet.”

“I didn't reach this point for the reason above (I did not find the expert I wanted to invite)”

“Not applicable”

h. Panel Closure

- 1) In case the outcome was signed-off, has the panel been closed? If not, can you please explain why?

“Not applicable”

“It is pending to be signed off”

“The case in which I'm involved is still ongoing”

“Not applicable”

“Not applicable”

- 2) Can you provide an indication on the duration of the whole process? Would you consider this being a realistic timing?

“Not applicable”

“The expert panel didn't give me any advise so, In this case CPMS really didn't work”

“The case in which I'm involved is still ongoing”

“Not applicable”

“I cannot provide the duration of the whole process, but 2 hours per patient to insert data and medical analysis. However it was the first attempt to the use of CPMS, so slower.”

i. Standardised Consent Form

The Standardised Consent Form uploaded in CPMS aims to make the consent given legally acceptable under Directive 95/46/EC² and the GDPR.³In its Opinion, the EDPS has also considered the Standardised Consent Form as a "best practice".As some variations may exist between the Member States in their implementation or interpretation of particular requirements of Directive 95/46/EC and the GDPR, healthcare providers may need to adapt the Standardised Consent Form, adding those elements that would ensure full compliance with national law, and, in particular, with relevant data protection provisions.

²Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

³Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).Please note that the GDPR will be applicable as from 25 May 2018.

- 1) While a number of comments have already been received, do you think that the provided Standardised Consent Form can easily be used for the purpose of ERN patient consultations in your hospital? If not, can you please explain why?

“We think the Standardised Consent Form is easy to use in the clinical practice and understandable for patients.”

“I think it is ok. However if the data will be used for research purposes instead of clinical purposes/advise it needs to be approved by at least one Dutch METC and all local quality coordinators.”

“Yes”

“Yes”

“Yes. On the other hand the difficulty was that the patient signed a lot of consent forms in the moment he/she is hospitalized. It was difficult to make them accept to sign another additional consent for a not yet well-known project. “

- 1) If changes needed to be done, do they apply to the layout of the form or rather to the content?

“We did not need to do any change.”

“Content”

“Not applicable”

“Not applicable”

“Both layout and content of ERN consent Form fit with French one used in the hospital/HCP.”

j. Other comments or suggestions

Please provide any other comments you may have or suggestions that can help us for further improvement of the CPMS.

“We suggest to open the possibility of contribution in cases also for experts not registered on CPMS (but members of ERN).”

“I think the access to CPMS should be easier. The documentation should be less extensive. The whole process of entering data should be easier.”

“No comments”

“No comments”

“ 1. CPMS Should provide a tool for anonymize the medical exams and analysis. It is indeed an overload for HCP workers and it is slow and not very easy to get.

2. Check that the RHD category are exhaustive

3. Translation of medical documents”