

Multi-level Role-based Access rights in the CPMS

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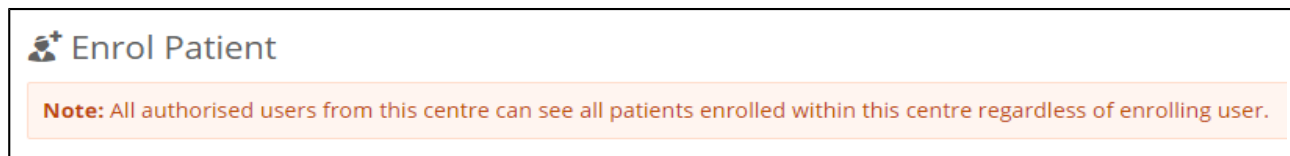
I. Scope and Purpose

This document outlines the access rights for the CPMS user roles in relation to performing tasks in the system.

II. Centre application

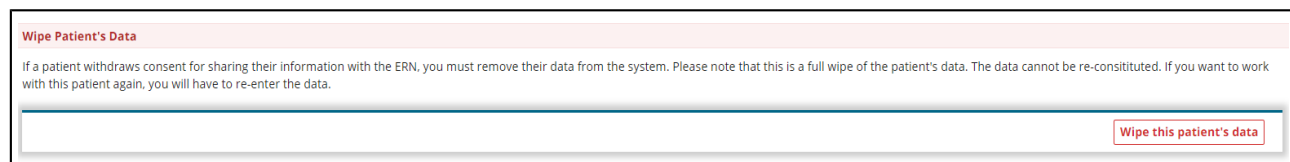
I. Enrolment at an ERN Centre

All authorized users from the same centre can see all patients enrolled within their centre regardless of the enrolling user. Likewise, only users from same centre can see patient identifiable data. The Enrolment form cannot be saved unless the patient “Consent for care” checkbox is ticked indicating valid consent has been given.



II. Patient Deletion

As hospitals and centre are the legal organizations for treating patients, the CPMS allows only users from the enrolling centre/hospital to wipe patient data from the CPMS. Wiping the patient data can be a result of a revoked “Consent for care” in some cases.



III. Panels within an ERN Centre

Any of the authorized users from a given ERN centre can see all panels running on their patients in all ERNs. When a particular user from an ERN centre opens a Panel for a particular patient, any of the authorized users registered from the same centre can be selected as a **Panel Lead**. However, the role of **Panel Lead** may be assigned to another user from same or different centre by the initial Panel Lead or by the ERN Coordinator (if assistance has been sought) at the Panel Selection stage.

When it comes to **Panel Lead**, two use-cases have been identified in the CPMS:

Use-Case 1

A Panel Lead from the originating/enrolling centre (Panel Lead Role NOT assigned to any HP outside the centre):

All Users from this centre can edit the consultation form and transition the workflow. However, the right to sign-off the outcome document is exclusively given to the Panel Lead.

Use-Case 2

A Panel Lead has been assigned/switched to another expert in a different centre within the same ERN:

- Panel Members from the enrolling centre and the Panel Lead from the receiving centre can ONLY edit the consultation form.
- The Panel Lead from the receiving centre can exclusively transition the workflow and sign off the outcome
- No HP from the receiving centre can ever edit the consultation form or transition the workflow
- No HP from the originating centre is longer able to transition the workflow

IV. Forwarding a Panel across ERNs

Use-case 1:

Panel Lead who is HP in both of Referring and Receiving ERNs

As a Panel Lead, I would like to remain the Panel Lead when the Panel is forwarded to another ERN my HCP is part of, so that I can control the Panel workflow with the rights as Lead.

Use-case 2:

Panel Lead who is HP in the referring ERN but NOT the receiving ERN

As a Panel Lead, I would like to become a Guest Member when the Panel is forwarded to another ERN my HCP is NOT a part of, so that I can participate actively and track the updates of the panel.

Use-case 3:

Panel Member who is HP in both of Referring and Receiving ERNs

As a Panel Member, I would like to remain a Panel Member when the Panel is forwarded to another ERN my HCP is a part of, so that I can participate actively and track the updates of the panel.

Use-case 4:

Panel Member who is HP in the referring ERN but NOT the receiving ERN

As a Panel Member, I would like to become a Guest Member when the Panel is forwarded to another ERN my HCP is NOT part of, so that I can actively participate and track the updates of the panel.

III. Panel Selection

- The Panel lead/HP from the enrolling centre can assign any HP from the centre or the ERN to be the Panel Lead in the consultation request section of the consultation form
- The Panel lead can be switched in the panel selection stage and will be notified to accept or reject
- External Panel Lead/Panel Manager to the enrolling centre gets same rights as Panel Lead from the enrolling centre
- ERN Coordinator assistance can be sought at this stage to assign a lead from the ERN regardless the centre
- ERN Coordinator/Dispatcher/Manager can for the panel and switch the Lead when necessary
- Guests from another ERN can be invited to a panel through seeking the ERN Coordinator assistance
- External Guest Experts can be invited if any exists in the system through seeking ERN Coordinator assistance
- If a HP refuses the invitation to join a panel, no permission for viewing clinical data will be valid any longer.

Guest Health Professional

I. HP in GVC

The CPMS provides the ability to able specialists working for centres not part of any ERN to enrol patients and seek assistance from an ERN. The so-called “**Guest Virtual Centre**” is counted as a Virtual Centre for external clinicians.

Two rights have been envisaged to external clinicians using in CPMS:

- A) Enrolling a patient in the Guest Virtual Centre (GVC) and filling in the consultation form. Where-after a Panel request will be forwarded to the ERN coordinator of the selected ERN to assign a Panel Lead and the regular workflow follows.
- B) A Guest user participates actively as a Panel member into their Patient Panels.
- C) Guest HP in GVC can abort or restart a panel
- D) Guest virtual centre only serve external HP to enrol a patient into CPMS and seek assistance.
- E) Guest can pick any of the 24 ERNs to refer the patient to.

- F) They automatically switch to be Panel Member as soon as the request has been approved by the ERN Coordinator. Upon accepting their request, they get an access to ERN application.
- G) Guest account is valid for 90days unless otherwise the Panel is running for longer term.
- H) Account Validity: The MINIMUM is 90 days from the day the guest is setup. The reason is if the panel is closed before the 90 days the guest might be interested to conduct a follow up request for another purpose.
- I) Access to an ERN: Access is given automatically to the guest based on the ERN selected in the consultation form. Similarly a guest will be dropped out automatically from the ERN they joined as the guest as soon as the panel is closed and archived.
- J) An exception to the rule described above; if a guest has one or more active panels running and has exceeded the 90 days their account will remain active until all active panels are closed and archived.
- K) Guests can not schedule a meeting but can be always invited to meetings and participate actively when necessary
- L) Guests can not be a Panel Lead.

II. Expert Guest in ERN

This expert clinician is a guest in one or multiple ERNs where he/she specify the thematic areas of their expertise. This role ensure the Guest Expert in an ERN will be shown for ERN Coordinators and Leads when inviting Panel members.

IV. ERN Application

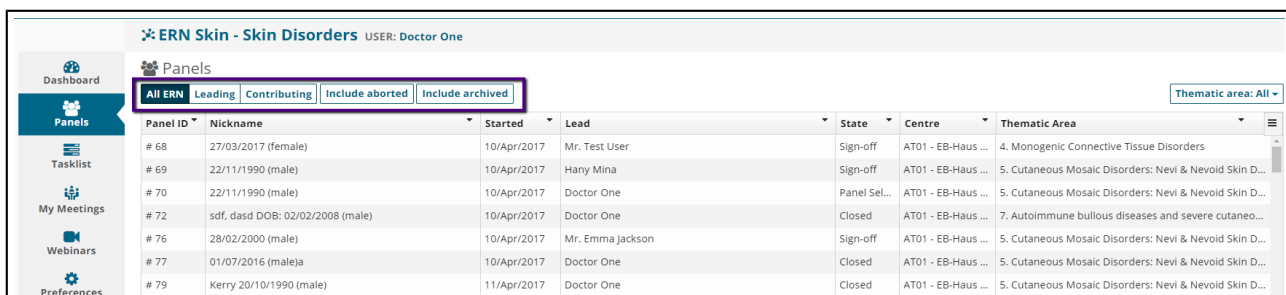
In this application, no patient identifiable data can be seen by unauthorized users outside of the patient enrolling centre. There are a number of activities that are restricted per user role, for instance only ERN Coordinators can generate reports as KPIs of the ERN.

I. Preferences

All health professionals registered into the CPMS, will be requested to fill in their professional role and their thematic areas of interest. Their names will then be shown among the suggested invitees when any Panel of interest is being conducted or any meeting in the same disease area is scheduled.

II. Panels

This tab in the ERN dashboard refers to the Panels running in a given ERN. User can filter panels based on their roles in the panel as a Lead or a Contributing member and see the archived and aborted panels.



Panel ID	Nickname	Started	Lead	State	Centre	Thematic Area
# 68	27/03/2017 (female)	10/Apr/2017	Mr. Test User	Sign-off	AT01 - EB-Haus ...	4. Monogenic Connective Tissue Disorders
# 69	22/11/1990 (male)	10/Apr/2017	Hany Mina	Sign-off	AT01 - EB-Haus ...	5. Cutaneous Mosaic Disorders: Nevi & Nevoid Skin D...
# 70	22/11/1990 (male)	10/Apr/2017	Doctor One	Panel Sel...	AT01 - EB-Haus ...	5. Cutaneous Mosaic Disorders: Nevi & Nevoid Skin D...
# 72	sdf. dasd DOB: 02/02/2008 (male)	10/Apr/2017	Doctor One	Closed	AT01 - EB-Haus ...	7. Autoimmune bullous diseases and severe cutaneo...
# 76	28/02/2000 (male)	10/Apr/2017	Mr. Emma Jackson	Sign-off	AT01 - EB-Haus ...	5. Cutaneous Mosaic Disorders: Nevi & Nevoid Skin D...
# 77	01/07/2016 (male)a	10/Apr/2017	Doctor One	Closed	AT01 - EB-Haus ...	5. Cutaneous Mosaic Disorders: Nevi & Nevoid Skin D...
# 79	Kerry 20/10/1990 (male)	11/Apr/2017	Doctor One	Closed	AT01 - EB-Haus ...	5. Cutaneous Mosaic Disorders: Nevi & Nevoid Skin D...

I. Leading Panels

This tab in the ERN dashboard refers to the Panels to which the user has been assigned as a Panel Lead role. In this role, the user takes responsibility for triggering several actions across various stages of the Panel workflow; such as inviting members, scheduling meetings, and switching the Panel Lead or accepting/declining invitations on behalf of ERN members. The Panel Lead is the only authorized person to sign-off the panel outcome.

As an exception to this rule, if there are two users from the same centre (one is a Panel Lead and the other is a Panel Member) the CPMS allows either of these users to record the panel outcome. But as a quality assurance mechanism, only the Panel Lead can sign-off the Panel Outcome.

II. Contributing Panels

Selecting the “Contribution Panels” enables a user to see all Panels in which they are participating as a panel member. Panel members should access the consultation form and collaborate actively in the timeline with other members in the same Panel. They should also assess the consultation request and write up contributions or upload attachments in the Contribution Modal. If there are multiple Panel members from the same centre in a panel, all of them can trigger the workflow and edit the consultation form but only the Panel lead can exclusively sign off the outcome.

III. Managing Panels

ERN Coordinator/Dispatcher can assign/overwrite Panel Manager to any active panels in their ERN. The Panel Management console can be accessed from the ERN Dashboard by clicking on **Panel Management** Tab. ERN Coordinator/Dispatcher can assign a Panel Manager by clicking on the drop-down menu on the right hand side for each panel active in their ERN. More filters are also available on the top for better search.

III. Meeting Management

I. Individual Meeting

Individual meetings take place as part of one single consultation request within a specific Panel. The logic applied here allows users from the same centre to convene a meeting. When a Panel member/lead schedules a meeting, by default, he/she will be considered as the Meeting Host, moderating the discussion with more rights over the meeting control. The Meeting Host will be always requested to update the meeting status and write up a meeting summary. It is important to mention that the recorded meetings cannot be deleted as it is deemed as part of the panel assessment to reach an outcome. However, a special request can be submitted to the developer of the CPMS (i.e. OpenApp) through the support team to delete any recorded meeting.

II. ERN Meeting

Only ERN Coordinators can schedule an “ERN Meeting” for all members of the ERN. Such meetings can be split into time slots to allow users from the same ERN discuss multiple patients in one meeting. However, it’s up to users to choose either they want to bring their panel into an ERN meeting or Individual Meeting.

IV. ERN Dispatcher

Beside to the administrative roles of the ERN Coordinators, they also receive all requests for assistance submitted by other users from and outside their ERN. In this role, ERN Coordinators can dispatch all the received requests from the Request Inbox in the ERN Dashboard. Further to this, ERN Coordinators can process valid requests by inviting members, assigning Panel Leads or returning the invalid/irrelevant requests to another ERN Coordinator.

The dispatcher role can be assigned to other expert clinicians in the same ERN, allowing them to evaluate and dispatch the incoming requests for Panels.

V. Panel Manager

Panel Manager role in CPMS is quite similar to the Panel Lead. This role focuses on monitoring the panel performance and make sure no impediment is blocking the workflow is move smoothly from the State **Open** and up to **Outcome** when the Panel Lead is drafting the outcome.

Panel Managers can not edit the data in the consultation form and their role is limited to transitioning the workflow, and assist in panel selection, scheduling meetings, and monitor the requests for additional data if any. They also can record the Contribution on behalf of the Panel Lead but can’t record an outcome or Sign off the panel outcome document.

HCP Panel Manager

HCP Panel Manager is assigned by a centre to look after all panel originated from this particular centre to one or multiple ERNs. Panel Manager in HCP can also be a Panel Manager and ERNs too. This is an internal business process which is defined by each centre and ERN if necessary. A widget appears on the Centre Dashboard when the user is involved in a panel as Panel Manager in their Centre.

ERN Panel Manager

ERN Panel Manager is assigned to a specific panel by the ERN Coordinator or the ERN Dispatcher. Please note that Panel Managers assigned to panels from the centre or ERN can be overwritten if necessary to distribute the workload better among the Panel Manager available in Centre or ERN. A

widget appears on the ERN Dashboard when the user is involved in a panel as Panel Manager in their ERN.

VI. Data Manager/Researcher

Here are two use-cases when it comes to assigning roles of “Researcher” or “Data Manager” to users:

Researcher use-case 1:

By giving access to only the ERN Databases/Registries application (from the third tab in the user management app), the user (HP or Non-HP) can have a global view of the whole data collected in the CPMS by all ERNs.

Researcher use-case 2:

Check the box of the role of Data Manager/Researcher in the ERN application to give access to a user to data only pushed by one individual ERN as requested. This role in ERN Application doesn't require a HP role as it works independently from the clinical tasks in CPMS.

V. Webinars

All authorized users of a particular ERN can create webinars but the deletion rights is only given to the creator of the webinars not to any of the attendees. Webinars will normally be produced for training purposes and will not be part of any clinical assessment process.

VI. System Administration

The system administration team is based at OpenApp to look after the system operations. The system administrators do not have access to any patient identifying data.



Identifying data

- * First name: #####
- * Last name: #####
- * Gender: #####
- * Date of birth:
- * Record Label: #####