

Project Book

Clinical Patient Management System (CPMS)

EUROPEAN REFERENCE NETWORKS FOR RARE, LOW PREVALENCE AND COMPLEX DISEASES

Share. Care. Cure.

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I) CPMS User Guide & Reference Manual

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Welcome to the CPMS

Clinical Patient Management System, known as CPMS, is a secure web-based application to support European Reference Networks in the diagnosis and treatment of rare or low prevalence complex diseases or conditions across national borders.

CPMS Made for ERN

European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and concentrated knowledge and resources. The first ERNs were launched in March 2017, involving more than 900 highly-specialised healthcare units from over 370 hospitals in 26 Member States. 24 ERNs are working on a wide range of disease areas such as rare and complex epilepsies, neurological disease, transplantation in children, etc.



(1) Getting Started

1.1) Logging In

The application can be accessed through web-browsers, such as Google Chrome, Mozilla Firefox and Internet Explorer (11.0) by entering the following URL in the address line:

<https://cpms-training.ern-net.eu>

The CPMS can only be accessed by authorized users via the EU Login Authentication Service. In the login page the user will be requested to use their EU Login to access the CPMS in two steps:

1. Click '**Login via EU Login**', to access the EU Login authentication page:

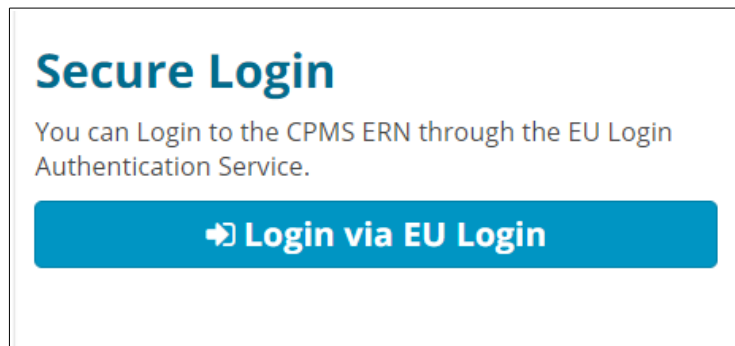


Figure 1: EU Login Link

2. The user should enter their registered email, followed by their password or use another method of authentication to sign in:

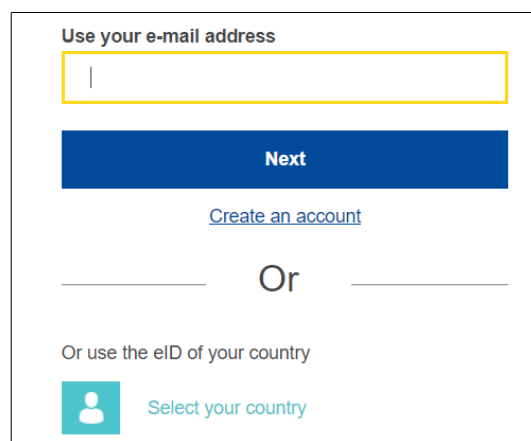
A screenshot of the EU Login authentication form. It has a title "Use your e-mail address" above a text input field. Below the input field is a blue "Next" button. Under the button is a link "Create an account". Below that is a horizontal line with the word "Or" in the center. Below the line is the text "Or use the eID of your country". At the bottom is a teal icon of a person next to the text "Select your country".

Figure 2: EU Login

Note:

- *When using devices with Mac Operating System, all users are requested to access the CPMS with the aforementioned browsers as Safari doesn't yet support the video conference technology used in the CPMS known as WebRTC.*
- *Users should not use private browsing modes such as 'Incognito' on Chrome whilst using the CPMS.*

1.2) Firewalls

A firewall is a network security system that monitors and controls the incoming and outgoing network traffic based on predetermined security rules. TokBox services require access to specific ports. At a minimum the following requirements must be met:

- Open TCP port 443
- Whitelist the following domains: "*.tokbox.com", and "*.opentok.com".

1.3) Network

We recommend a minimum dedicated 350kb/s down per downloaded stream, as well as 350kb/s up per uploaded stream to maintain a stable video connection.

(2) Accessing Your Applications within the CPMS

Successfully logging in to the CPMS will direct the user to the system's Applications Page as displayed below:

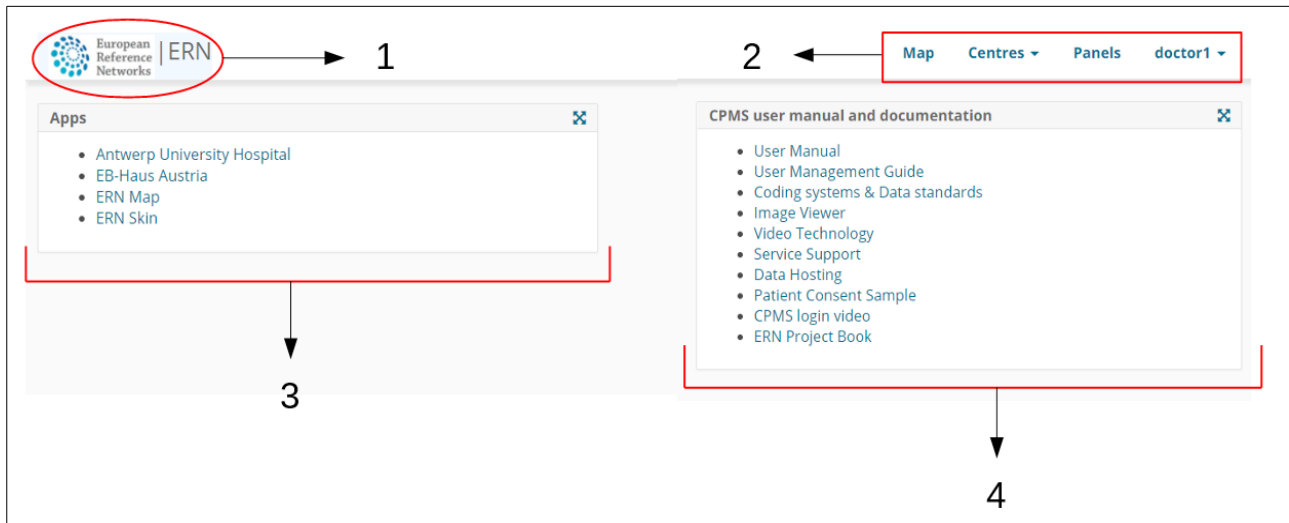


Figure 3: Home Page

1. Clicking here will direct the user back to this Applications Page from anywhere in the system.
2. The upper menu contains links to the user's applications allowing for quick and easy navigation of the CPMS.
3. The 'Apps' section lists and links the applications (ERNs, medical centres etc) that the user can access within the system.
4. The documentation section contains various training materials and documents detailing different parts of the system.

(3) CPMS system navigation

3.1) Medical Centre (Hospital) Dashboard

By clicking on a link to one of their medical centres as detailed in Section 2, the user can navigate to their dashboard for that centre. An example of such a dashboard is shown in Figure 4 below:

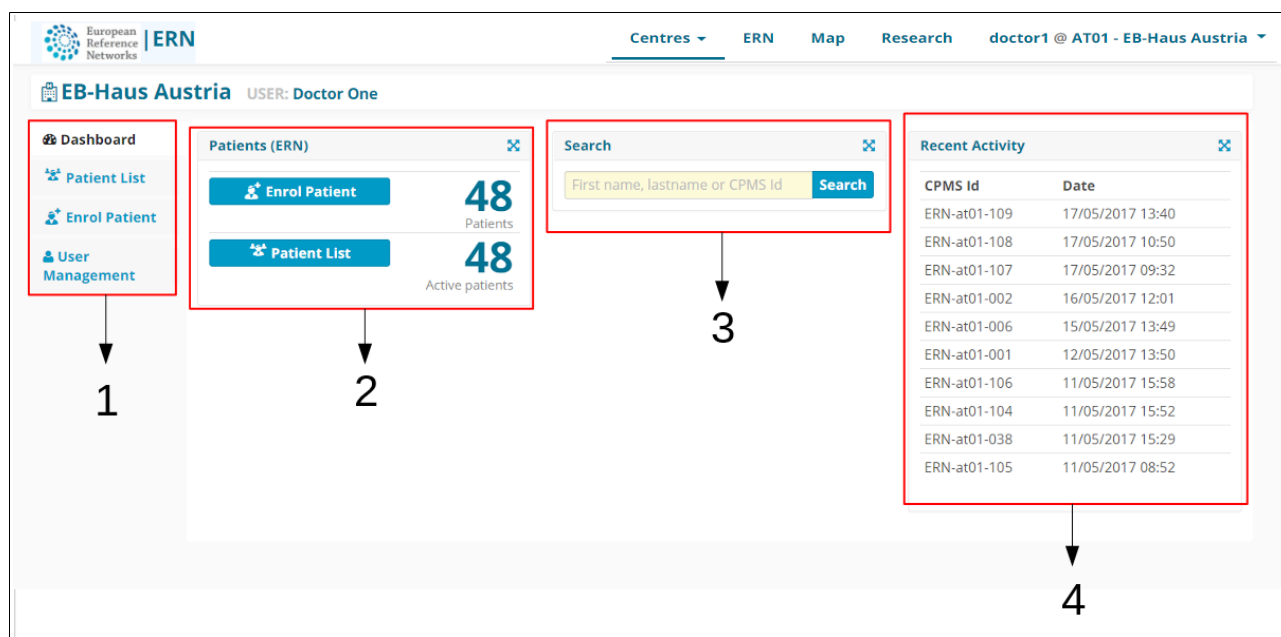


Figure 4: Medical Centre Dashboard

1. The side menu facilitates quick navigation of the CPMS's features, based on the user's role.
2. The 'Patients' section contains links for the user to enrol a new patient to the system (see Section 4) and to view their current patients.
3. The search feature allows the user to quickly find a particular patient, based on their first name, last name, CPMS ID, panel ID and nickname.
4. The 'Recent Activity' section lists the latest patients to have been enrolled or to have had their data updated. Clicking on the patient ID will direct the user to that patient's page.

3.2) ERN Dashboard

ERNs can be accessed in a similar manner to the medical centres, that is by clicking on the appropriate link either from the top menu or from the applications page. Doing so will direct the user to their dashboard for that ERN. An example of an ERN dashboard is shown in Figure 5 below:

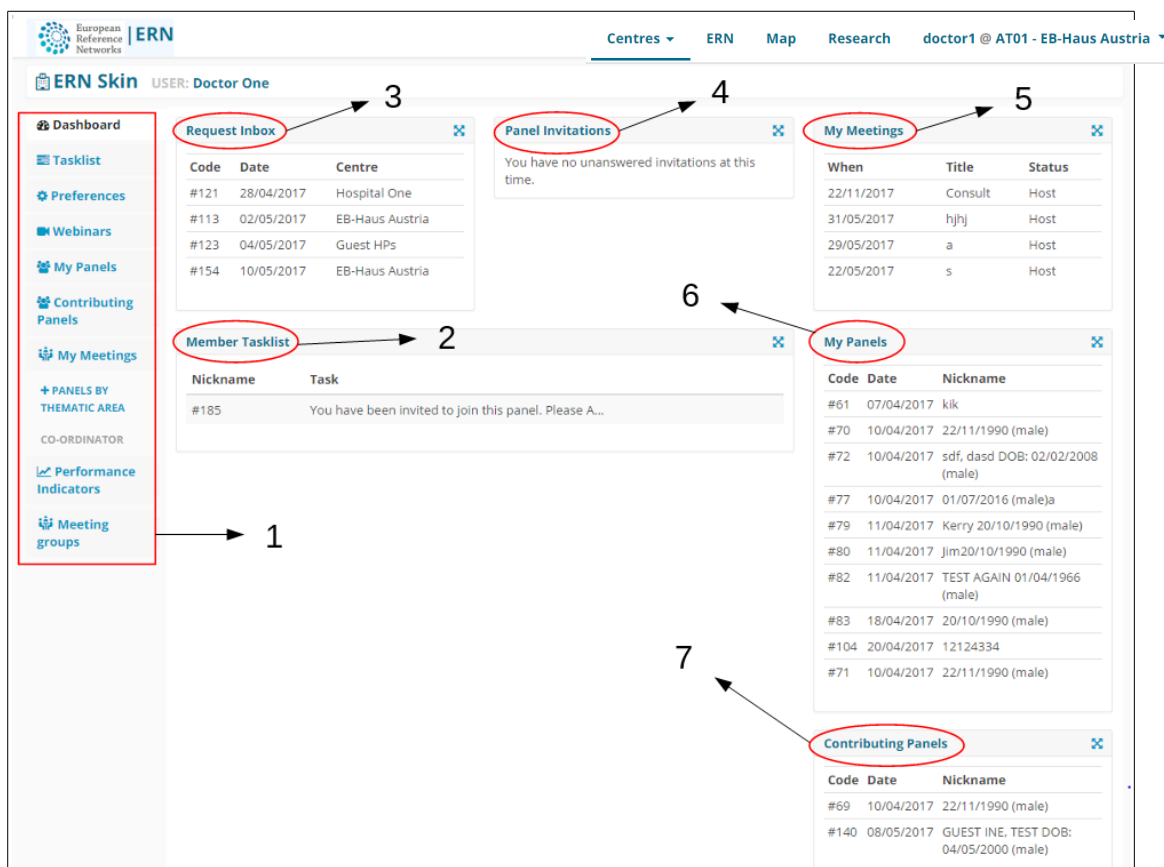
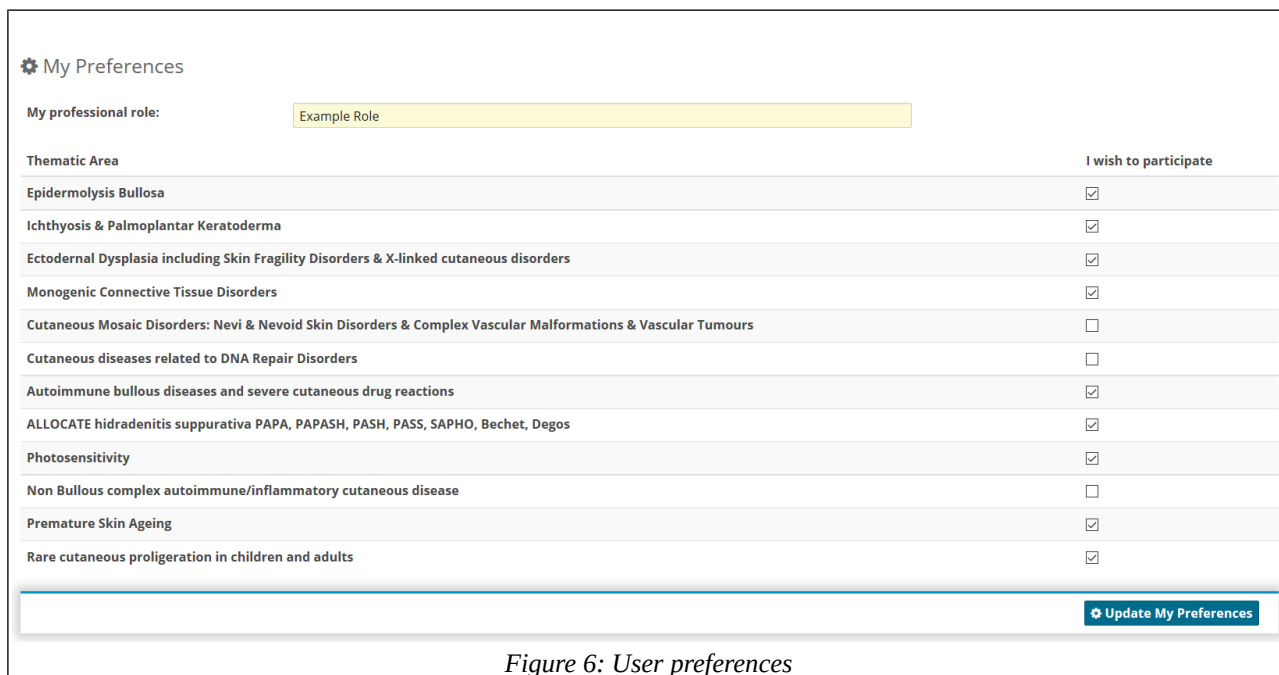


Figure 5: ERN Dashboard

- 1. Side Menu:** Contains links to the features of the ERN to allow for quick and easy navigation.
- 2. Member Tasklist:** Contains a list of pending tasks awaiting the user's interaction.
- 3. Request Inbox:** Contains the requests for assistance sent to the user (as ERN Coordinator or Dispatcher only). Discussed further in Section 9.
- 4. Panel Invitations:** Lists the invitations the user has to join different panels. The invitations can be accepted or declined by clicking on the link.
- 5. My Meetings:** Lists the meetings the user is scheduled to participate in.
- 6. My Panels:** Contains links to the panels on which the user is the Panel Lead.
- 7. Contributing Panels:** Contains links to the panels that user contributes to, but does not lead.

3.3) Preferences

In the 'Preferences' tab, the user can dictate which thematic areas they are interested in within the ERN. This is an important step to ensure that user is listed as an available Health Professionals during the Panel Selection phase (discussed in Section 7). Figure 6 below shows an example of a preference list.



My Preferences

My professional role:

Thematic Area	I wish to participate
Epidermolysis Bullosa	<input checked="" type="checkbox"/>
Ichthyosis & Palmoplantar Keratoderma	<input checked="" type="checkbox"/>
Ectodermal Dysplasia including Skin Fragility Disorders & X-linked cutaneous disorders	<input checked="" type="checkbox"/>
Monogenic Connective Tissue Disorders	<input checked="" type="checkbox"/>
Cutaneous Mosaic Disorders: Nevi & Nevoid Skin Disorders & Complex Vascular Malformations & Vascular Tumours	<input type="checkbox"/>
Cutaneous diseases related to DNA Repair Disorders	<input type="checkbox"/>
Autoimmune bullous diseases and severe cutaneous drug reactions	<input checked="" type="checkbox"/>
ALLOCATE hidradenitis suppurativa PAPA, PAPASH, PASH, PASS, SAPHO, Bechet, Degos	<input checked="" type="checkbox"/>
Photosensitivity	<input checked="" type="checkbox"/>
Non Bullous complex autoimmune/inflammatory cutaneous disease	<input type="checkbox"/>
Premature Skin Ageing	<input checked="" type="checkbox"/>
Rare cutaneous proliferation in children and adults	<input checked="" type="checkbox"/>

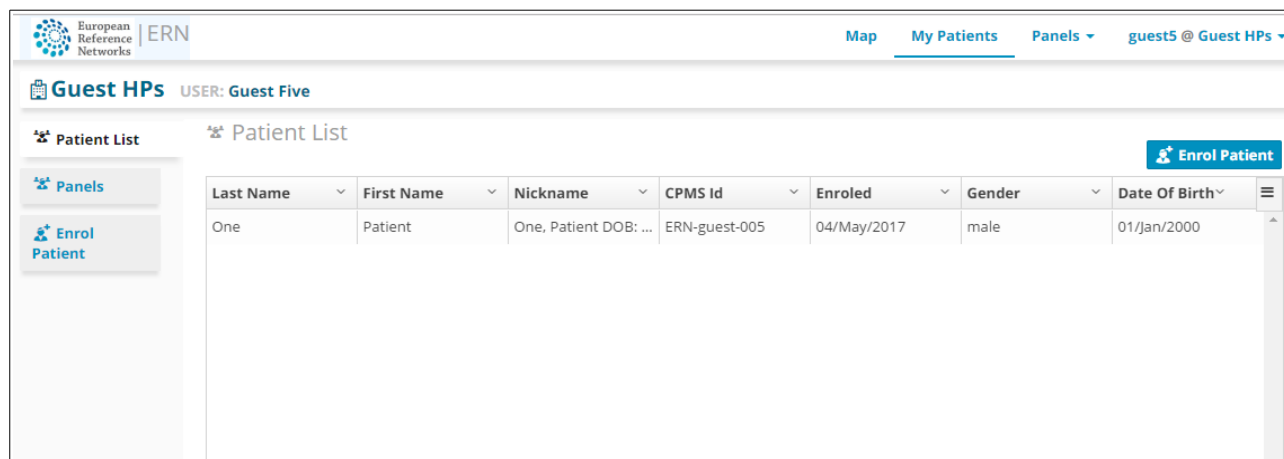
[Update My Preferences](#)

Figure 6: User preferences

The user ticks the checkboxes of the thematic areas that they are interested in, and leaves blank the areas which do not interest them.

3.4) Guest Dashboard

The 'Guest' Dashboard allows guest users to enrol their patients and participate in panels they create themselves or are invited to take part in.



European Reference Networks | ERN

Map My Patients Panels guest5 @ Guest HPs

Guest HPs USER: Guest Five

Patient List

Last Name	First Name	Nickname	CPMS Id	Enroled	Gender	Date Of Birth
One	Patient	One, Patient DOB: ...	ERN-guest-005	04/May/2017	male	01/Jan/2000

[Enrol Patient](#)

Figure 7: Guest Dashboard

(4) Patient Enrolment

In order to enrol a new patient for a certain medical centre, the user can click on either of the 'Enrol Patient' buttons on their dashboard for the medical centre in question.



Figure 8: Enrol Patient Buttons

Clicking on either of these buttons will bring the user to the 'Enrol Patient' form shown in Figure 9. Required fields are indicated by a red field or a 'required' tag. These **must** be filled out in order for the patient to be successfully enrolled.

The 'Enrol Patient' form contains the following sections and fields:

- Patient Id:** ERN-at01-114
- Date enrolled:** dd/Mmm/yyyy (with a calendar icon)
- Pre-qualification check:**
 - Have you sought advice on this patient at a national healthcare provider organisation? ☐ Required
- Consent:**
 - Consent for Care: ☐ Required
 - Consent contact for research: ☐
 - Consent for ERN databases/Registries: ☐
 - Date of consent: dd/Mmm/yyyy (with a calendar icon)
 - [Download Consent Forms](#)
- Identifying data:**
 - First name: [Red field]
 - Last name: [Red field]
 - Gender: [Dropdown menu]
 - Date of birth: dd/Mmm/yyyy (with a calendar icon)
 - Record Label: [Red field]

At the bottom right, there are 'Cancel' and 'Enrol' buttons.


Figure 9: Enrol Patient Form

4.1) Consent


In order to be enrolled in the system, the patient **must** give consent. As can be seen in Figure 9 above, there is a checkbox which the user must use to indicate that consent has been given. The consent forms can be downloaded by clicking the ‘Download Consent Forms’ button located on the right hand side of the consent section. Three types of consents are available on the CPMS:


- Consent for care pathway; required for successful enrolment
- Consent for ERN databases and registries
- Consent to be contacted for research

If a patient revokes their consent for care, all open panels for that patient must be cancelled. An error message to this effect will be displayed on the patient’s page to remind the user, as shown below in Figure 10.


Patient ID: ERN-be04-001 One, emma DOB: 02/05/2003 (female) Enrolled: 29/Jun/2017

Error: This patient has not consented to share their data with ERN members. If you have open Panels, you must **abort** them. If you do get consent from the patient, you must update the enrolment page.


Panels


Enrolment

	Panel ID	Nickname	Started	Lead	ERN	Thematic Area
<input type="checkbox"/>	#330	mo	19/07/2017	Mr. Emma Jackson	ERN LUNG - Respiratory Diseases	Interstitial Lung Disease

Figure 10: Error Message to remind the user to cancel any open panels for a patient who has revoked consent for care.

(5) Consultation Form

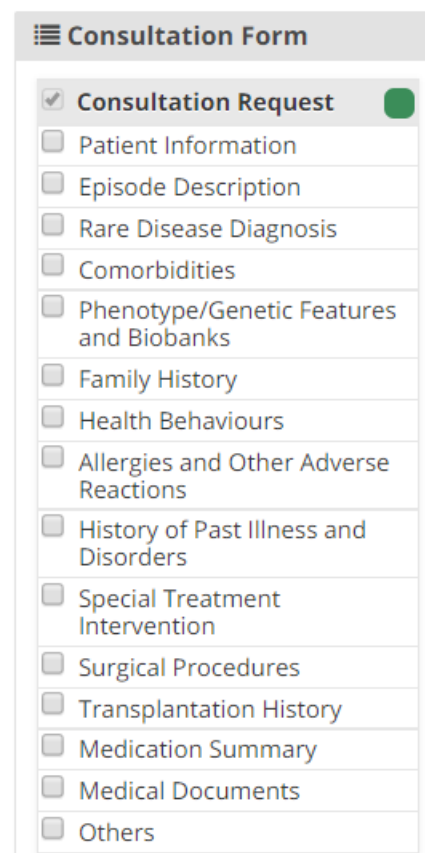
The consultation form is the heart of the consultation process on which experts and specialists can collaborate to reach a consensus for diagnosis and treatment. The Panel lead or the enrolling clinician can fill in patient's data and attach documents, thereafter, panel members will be invited to review the consultation request and decide whether or not they can participate or request more information and procedure results to be provided for making better informed decisions.

The consultation form is composed of multiple sections where users can type in information and record findings relevant to the type of the consultation request. The form can be edited only in the "Edit view" to allow doctors record patient data into the form. Whilst, during the assessment process and the later stages of the workflow, the form will be displayed in view mode only beside to the timeline.

The data model running onto the CPMS conforms with European standards, nomenclatures and strategies to share health data syntactically and semantically in the eHealth sector.

All ERNs will be using one generic data set known as Basic Data Set in the CPMS. Then, further in the development process of the CPMS, an Extended Data Set will be developed based on the customized need of each ERN. It is highly expected that each ERN will have unique requirements for some conditions or specific thematic disease area. The following coding and terminology systems have been used to build the Basic Data-Set in the consultation form. (scroll in the form up and down after you picked several sections)

- ICD
- Orphanet Rare Disease Ontology (ORDO)
- ICCC-3 based on ICD-O-3
- Human Phenotype Ontology (HPO)
- LOINC
- MedDRA
- UCUM Codes
- ISO 3166-1
- HGNC
- EDQM Standard Terms
- NCBI genomic nucleotide RefSeq Id/LRG Id
- Eurostar classification for self-defined current economic status
- ISCED classification



The screenshot shows a web interface titled "Consultation Form". It features a sidebar with a list of sections, each with a checkbox and a green circular indicator. The sections are: Consultation Request (checked), Patient Information, Episode Description, Rare Disease Diagnosis, Comorbidities, Phenotype/Genetic Features and Biobanks, Family History, Health Behaviours, Allergies and Other Adverse Reactions, History of Past Illness and Disorders, Special Treatment Intervention, Surgical Procedures, Transplantation History, Medication Summary, Medical Documents, and Others.

Search widget: Please note that a search widget is provided in some sections to help users select a medical condition without prior knowledge to the coding systems such as ICD-10, Orphanet and ICC-3 in the diagnosis section.

Multi-check coding systems: Users of the CPMS can pick one or more coding systems available in the CPMS to enter data on specific condition or procedure such as ICD-10, Orphanet and ICC-3 in the diagnosis section or MedDRA and LONIC in the surgical procedures.

Furthermore, users can see help text above or next some data fields to help them structure or type in information in certain format e.g. RNA Nucleotide variant description. Additionally, general attachments can be uploaded in some sections or the medical document section particularly the those documents needed to be viewed in the radiology or pathology viewer.

For more information about the data-set and the coding systems, please visit the documentation section in the CPMS.

5.1) File Upload

Files can be uploaded to the consultation form up to, and including, the data completion stage of the consult process (see Section 7). The upload feature is located in the ‘Medical Documents’ section of the form, as shown in Figure 11 below:

Figure 11: Attaching Files in the Consultation Form

After clicking on ‘Attach Files/Images’, the user will be prompted to acknowledge that there is “no identifiable personal data in the uploaded file(s)”. This checkbox must be ticked if the user wants to proceed. The user will then have the opportunity to upload files under the ‘Add Files’ tab as shown.

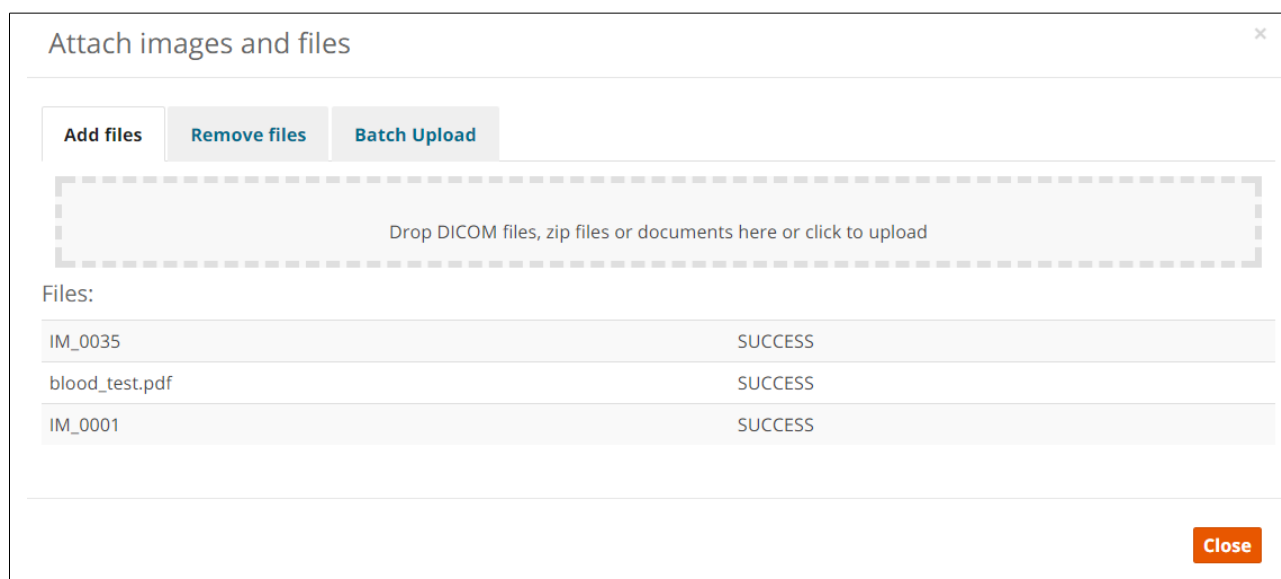


Figure 12: Drag or Browse Files to Upload

The table below contains a complete list of the supported file formats:

PDF	pdf					
Excel	xml	csv	xls	xlsx	xlsm	
PowerPoint	ppt		pptx		pptm	
Word	doc		docx		docm	
Open Doc	odt	ods	odp	odc	odi	
Image	dcm	jpg	jpeg	bmp	tiff	png
Video	avi	flv	wmv	mov	mp4	
Sound	pcm	wav	ogg	flac	mp3	

Files can easily be deleted by clicking 'delete' next to the unwanted files in the 'Remove Files' tab.

Batch Upload

Users can also use FTP Batch Upload via the 'Batch Upload' tab, which is particularly useful for large files exceeding one hundred megabytes.

Note:

- Batch upload requires third party software such as FileZilla or WinSCP to be installed.
- Using the FTP functionality may require higher technical competences that require prior experience. Please ask the IT department at your organization if you experience any difficulty in using the FTP client software.

All the instructions are provided in the pop-up modal to guide users to feed the right information into the FTP client software.

Attach images and files

Add files
Remove files
Batch Upload

This web-interface is suitable for small to medium sized files. If you want to upload large files (> 1 gigabyte), or want more control over your file uploads, e.g. scheduling or throttling internet bandwidth usage, you can use Secure FTP to upload files.

If using WinSCP (available free):

File Protocol:	ftp	Encryption	TLS/SSL Explicit Encryption
Host name:	78.46.49.179	Port number:	1990
User name:	Your login username	Password:	Your FTP password that you provided previous Change FTP Password

- This FTP interface, uses the Explicit Secure variation of the FTP protocol. You will need to install a program to communicate with it. Third party products such as WinSCP (available free), can upload files via Secure FTP.
- For Security reasons, you can upload to the FTP server, but you cannot download from it.
- You can only attach files to forms which are currently in an editable workflow state.

Close

IHE

CPMS supports IHE integration with hospitals that are compliant with the following IHE profiles and interested to share documents with the CPMS:

- XCPD - Patient Discovery (ITI-5)
- XCA - Retrieve Folder List (ITI-38)
- XCA - Retrieve Document List (ITI-38)
- XCA - Retrieve Document Set (ITI-39)
- IHE ATNA (Audit Trail and Node Authentication)
- IHE-STS (Security Token Service)

Users can use the IHE integration profiles to pull documents stored in the local hospital information system into the CPMS. Users in Centres availing of IHE will find an additional 'IHE' tab next to 'Batch Upload' in the Medical Documents section.

Attach images and files

Add files
Remove files
IHE
Batch Upload

* Patient first name(s):

* Patient last name(s):

* Patient Date of Birth:

dd/Mmm/yyyy

Search

Close

5.2) DICOM Viewer

The consultation form contains a DICOM (Digital Imaging and Communications in Medicine) viewer for the viewing, editing and sharing of medical images. The ‘Osimis Pro Web Viewer’ is a certified Class I active medical device.

Once DICOM images have been successfully uploaded as detailed above, they can be viewed on the DICOM viewer by all panel members via the consultation form on the panel’s home page. Clicking on a link for the images on the consultation form opens the viewer as shown in Figure 13 below:



Figure 13: DICOM Viewer

1. This section lists the series of images available to be viewed.
2. The user can cycle through the images in the series manually or automatically, at a frame rate of their choosing.

3. The top menu bar contains a wide range of features such as:
 - Zoom
 - Invert colour
 - Annotations to measure length, area and angles (See Figure 14 below)
 - Flip image – vertically and/or horizontally
 - Rotate image
4. Allows the user to download the series.

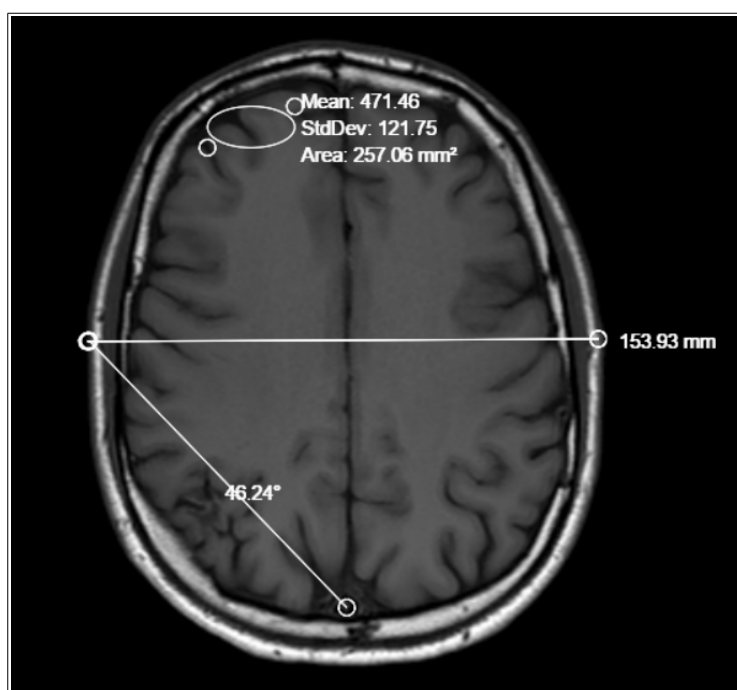


Figure 14: Annotations on a DICOM Image

To remove an annotation from the image, simply click and drag it off the image. This will delete that particular annotation.

5.3) Pedigree

The pedigree tool is located in the Family History section of the Consultation Request. It is used to track the patient's ancestry in the form of a family tree, and shows the family members who possess the genetic mutation in question, classified either as 'affected' or as a 'carrier'.

Figure 15 below shows the initial view of the family tree. The icons in the top right corner allow for functions such as zoom (in and out), full-screen view and printing the pedigree chart. The text boxes in the top left corner next to 'Affected' and 'Carrier' allow the user to specify the condition in question, if required. This is to avoid confusion in cases where comorbidities have been declared by the patient in addition to the condition of interest.

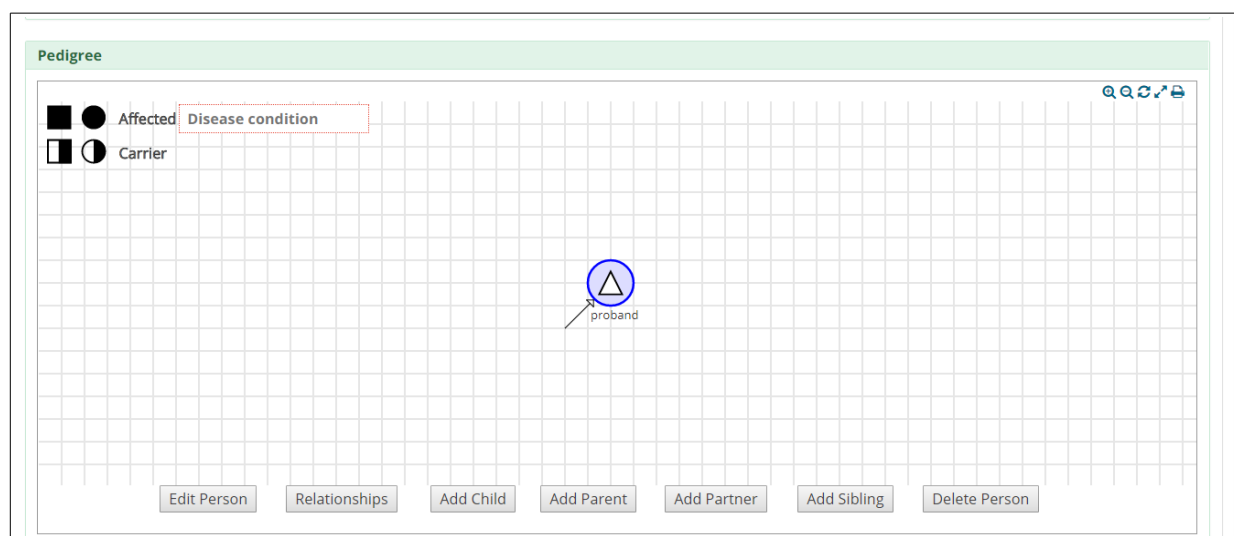


Figure 15: Pedigree Chart

The buttons along the bottom of the screen allow family members of the proband to be added and edited. The 'Edit Person' button allows the user to specify the person's gender, whether or not they are deceased and if they are a carrier, affected or neither. The user can also specify if the person has been tested or not, and the 'Phenotypic Abnormality' they have, if applicable. The 'Relationships' button lets the user set certain relationships (partner, children and parents) between people in the family tree.

Figure 16 below gives an example of a pedigree chart:

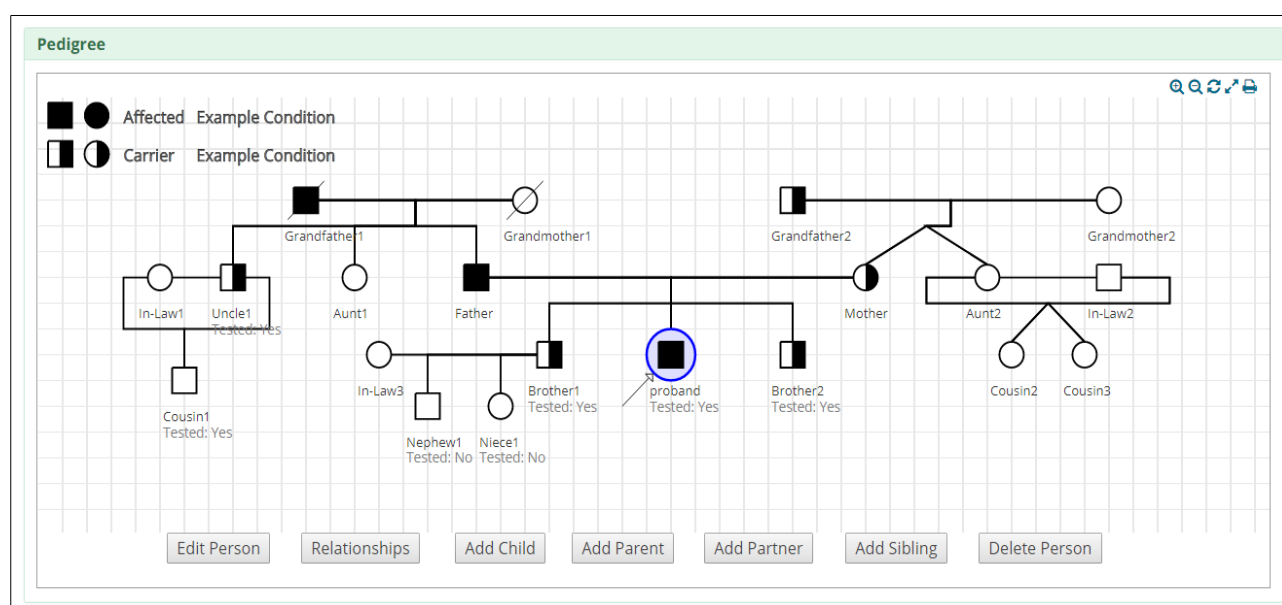


Figure 16: Example of a Pedigree Chart

(6) Panel & Form Layout

All the interactions and communication happening between Health Professionals on a particular case can be seen within the Panel view. The panel view shows two main elements; the Consultation Form on the left hand side, in which the user can always see the updated data and the Timeline on the right hand side which shows near-real time transition of the panel based on the actions triggered by a Panel Member or the Panel Lead.

367 UserGuideDemo

Open Panel Selection Data Completion Assessment Outcome Sign-off Closed Archived Next »

Centre AT01 - EB-Haus Austria
Lead Doctor One

ERN ERN Skin - Skin Disorders
Thematic Area Cutaneous diseases related to DNA Repair Disorders

Invite Members Schedule Meeting

Consultation Form Recorded: 27/Jul/2017 15:09 (Europe/Dublin) by: Doctor One

Consultation Request

Nickname: UserGuideDemo

Is this a repeat of a previous panel for the same patient but a different episode? No

Consultation Request Description Short: Treatment plan required for patient

Consultation Request Reason: Treatment

Consultation Request Reason Description: As above

Healthcare Provider: AT01 - EB-Haus Austria

Point of care specialist: Dr. Example

ERN: ERN Skin

Panel Lead: Doctor One

Primary Thematic Area: Cutaneous diseases related to DNA Repair Disorders

Patient Information

Birth complications:

Gender: Male

Country of Residence (ISO 3166-1): Belgium

Country of birth (ISO 3166-1): Belgium

Education Level (ISCED 2011): ISCED 6: Bachelor's or equivalent level

Occupation: Employee working full-time

Timeline

Meeting: Demo

Description: demo

Invited: Doctor One (Host)

Scheduled: 29/Jul/2017 15:30 (Europe/Dublin) for 20 minutes

Starts in: 1 day(s)

add a comment

Panel Members

Member	Status	Actions
Doctor One	Lead	Invited: 27/Jul/2017

There are no outstanding invitations

add a comment

27/Jul/2017: The Panel is now in state "Panel Selection"

Patient Documents

Figure 17: Panel Home Page

6.1) Timeline

On the right-hand side of the panel interface the user can view all of the panel’s activity to date via the ‘Timeline’ feature. Figure 18 gives an example of a timeline, and the accompanying text explains the main features that it incorporates.

1. The double arrow icon allows the user to toggle the order of events between oldest-newest and newest-oldest.
2. The user can view when their meetings for that panel are due to start, and can access the meeting by clicking on the ‘Join Meeting’ button.
3. The timeline allows users to leave comments on the timeline, which can be seen by all panel members.
4. Clicking on this icon brings up a bigger screen for that particular feature. The user can then interact with that feature.

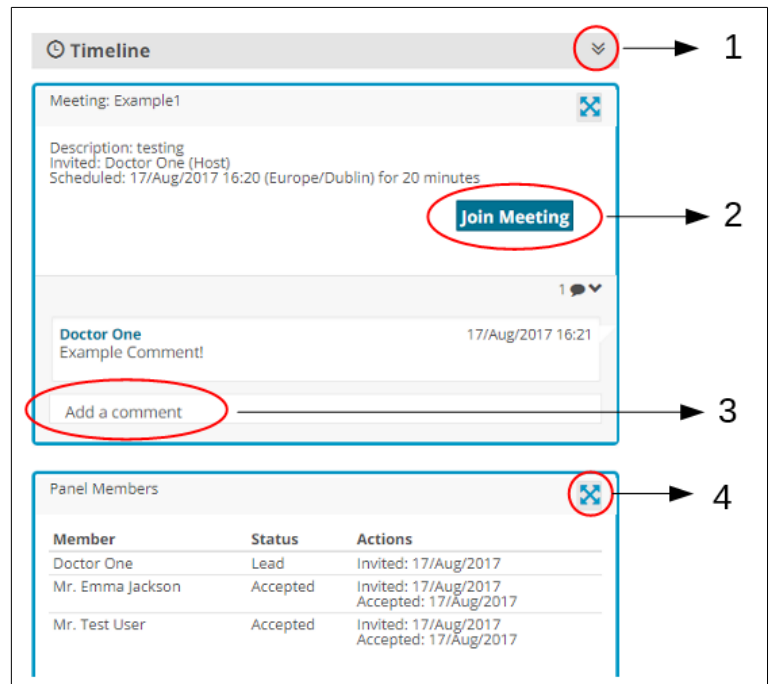


Figure 18: Timeline of Panel

The timeline is not only a chatting mechanism over the panel but rather a secure approach for exchanging messages in several modal types.

It allows panel members make comments on images, contributions and outcome documents.

6.2) Data Entry

Data can be entered using a combination of drop-down lists, check boxes, radio buttons and Date input fields. Here you can see a drop-down list being used. Radio buttons can also be used to select options in lists. The Date input fields (date pickers) allow quick access to the relevant date.

The screenshot displays a data entry form with the following fields and components:

- HPO classification:** A yellow dropdown menu.
- Status of current Diagnosis:** Radio buttons for Active, Confirmed, Inactive, Resolved, and Unconfirmed.
- Date of first symptoms onset:** A date picker showing April 2017.
- Date of current Diagnosis:** A date picker showing April 2017.
- Age at Diagnosis:** A yellow input field.
- Diagnosis centre name:** A yellow input field.
- Country of Diagnosing centre:** A yellow input field.
- Treatment centre name:** A yellow input field.
- Diagnostic Test Description:** A yellow dropdown menu.

A separate inset shows the **Status of diagnosis** dropdown menu with the following options: Relapse, Resolved, In Remission, and Active.

Figure 19: Date Picker

Note: Date pickers are used where an exact date is required. However, there are some instances where the month or year are sufficient. For example, the patient records may not hold the exact date for some data fields. So it may be possible to type in the input field and record the month and year, or use the date picker if the exact date is known. When inputting the date manually the date format must be Month/Year, or the year alone is sufficient in some instances.

(7) Panel Workflow – Virtual Consult Process

7.1) Open a New Panel

To open a panel for a newly enrolled patient, the user can simply click the ‘Open New Panel’ button (Figure 20) that they are presented with after filling out the ‘Enrol Patient’ form from Section 4.

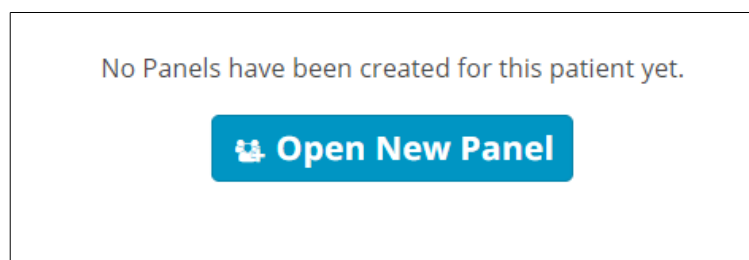


Figure 20: New Panel – New Patient

If the user wishes to open a new panel for a previously enrolled patient, they can do so from the patient’s page. As discussed in Section 3.1, the user can find a patient by viewing the patient list or by using the search function. The ‘Open New Panel’ button is located on the right-hand side of the page, as shown in Figure 21 below. The user will also have the option to cancel or restart any panels on which they are the panel lead.



Figure 21: New Panel - Existing Patient

There are eight stages to the virtual consult process, which the user can easily keep track of via the tracker located just under the top menu.

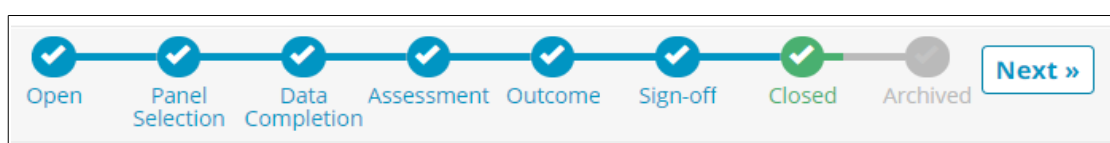


Figure 22: Stages of the consult process

7.2) Open

The panel is considered open as soon as the consultation form has been submitted. This stage allows for the consultation form to be viewed and edited as deemed necessary by any user in that particular medical centre.

7.3) Panel Selection

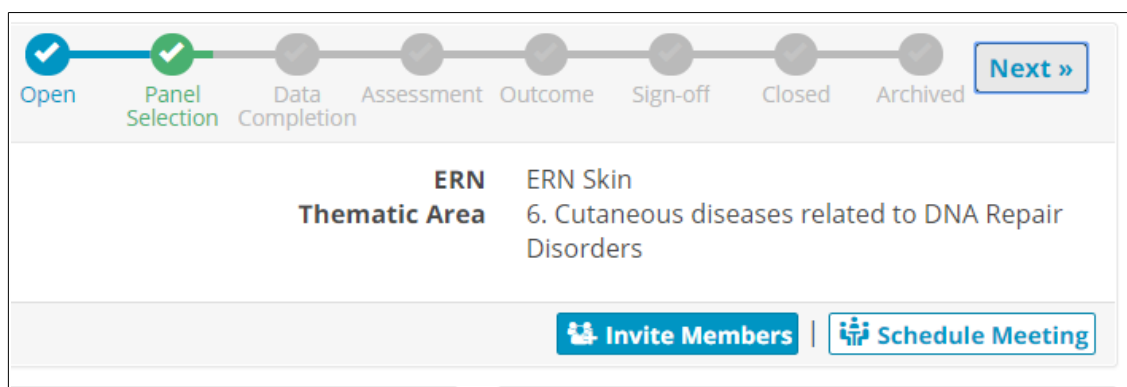


Figure 23: Invite Members and Schedule Meeting

In the 'Panel Selection' stage the user can form the panel by inviting other Health Professionals to join. Meetings can also be scheduled at this stage (see Section 8). Figure 23 above shows the location of the 'Invite Members' and 'Schedule Meetings' buttons.

Available HPs	Role	
Mr. Emma Jackson	Radiologist	Invite

Figure 24: Panel Selection

When forming the panel, the user can invite Health Professionals from a list of those available, sorted by 'Thematic Area' (based on 'Preferences' as discussed in Section 3.3). If the user is unsure of who to invite to the panel, or requires a Health Professional from a different ERN, they can request the assistance of the co-ordinator for their ERN in the 'Co-ordinator Assistance' tab.

7.4) Data Completion

In the 'Data Completion' stage the clinical data is completed if not previously done so, and is available to be viewed by the whole panel. The consultation form is also made available to be edited if necessary.

7.5) Assessment

During the 'Assessment' stage the Panel can all make contributions to the case, via the 'Record Contribution' button that replaces the 'Invite Members' feature. Text can be entered in the textbox and files can be uploaded via the 'attach file' feature. The user can also view the other panel members' contributions by clicking on their tab.

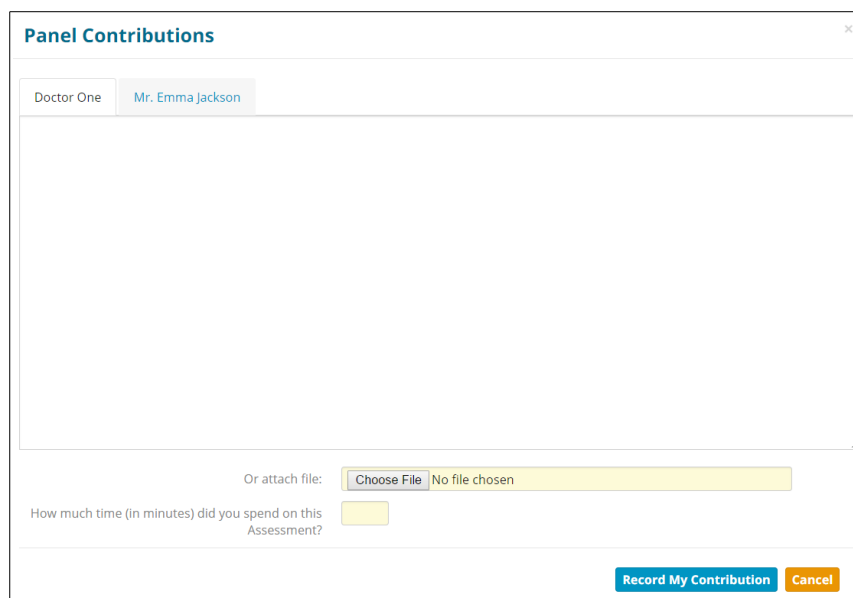


Figure 25: Panel Contributions

7.6) Outcome

After the assessment has been completed and the contributions have been recorded, an outcome for the panel must be considered and decided upon. Users also have the option to return to the Assessment stage if they deem it necessary, as shown in Figure 26.

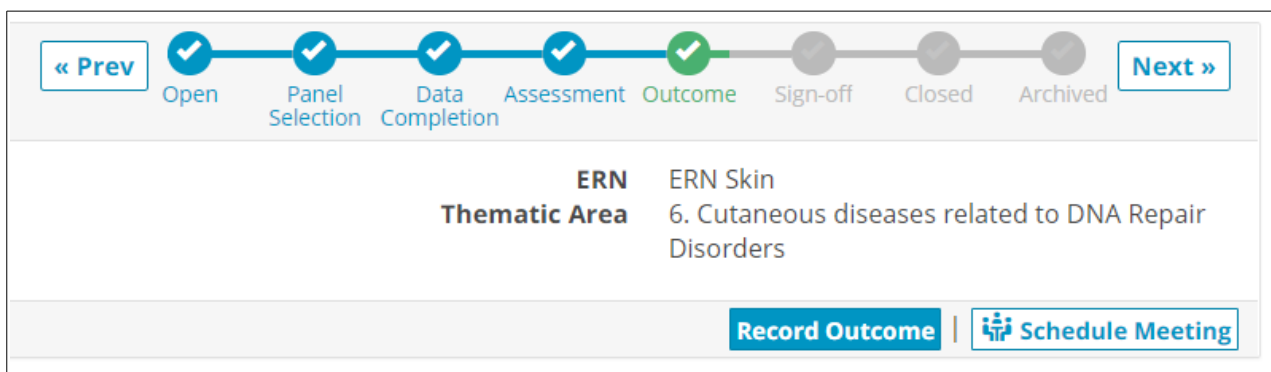


Figure 26: Outcome

The Panel Lead records the outcome at this stage and the rest of the panel have the opportunity to view and comment on it.

7.7) Sign-Off

In the 'Sign-Off' stage the Panel Lead confirms the outcome of the consult process. Once the outcome is signed-off the panel can be closed, and the outcome can no longer be edited. At this state of the workflow, all users can export the outcome as PDF document for personal record or sending it over to POC specialist or patient themselves.

Panel Outcome

Test example

Or attach file:

Choose File No file chosen

1

2

Save Panel Outcome Sign-off Panel Outcome Cancel

Figure 27: Panel Sign-Off

- 1. Save Panel Outcome:** This saves the outcome, but only as a draft. The outcome can still be edited, and saving here does not allow the panel to be closed.
- 2. Sign-off Panel Outcome:** Signing-off the panel outcome will mean that it can no longer be edited, and this must be done before the panel can be closed.

7.8) Closed

Once the outcome has been signed-off, the panel can be closed. Only the Panel Lead can close the panel and he/she must first complete the 'Transition to Closed' form shown in Figure 28 below:

Transition to Closed

You have chosen to transition to a new state, **Closed**.

Questionnaire

How much time did you spend on this Panel? 1 HRS 20 MINS

Was the panel a success? ☒ Yes ☐ No ☐ Not Determined

What was the Outcome? ☒ Diagnosis ☒ Treatment ☐ Clinical Trial ☐ Other

Search All Coding Systems:

Diagnosis Coding System: ☐ ICD-10 ☐ ICC-3 ☒ Orphanet ☐ Other

Orphanet nomenclature:

Figure 28: 'Transition to Closed' Questionnaire

The outcome document will be available for all panel members to view, and the Panel Lead will have the option to make the panel available for research, as shown in Figure 29 below.

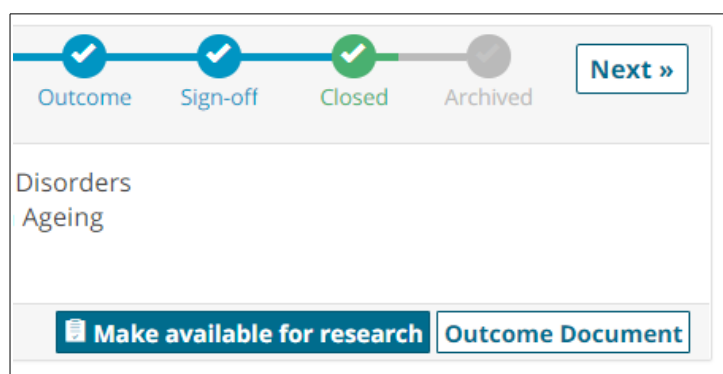


Figure 29: A Closed Panel

7.9) Archived

The Panel Lead can choose to Archive the panel after it is closed. This will mean the panel can only be viewed from the 'Centre' application by members of the centre that the patient was enrolled at, and not from the 'ERN' application.

(8) Meetings

8.1) Create a Meeting

Organising a meeting to discuss a patient typically happens after the Data Completion stage (Section 7.4) is finished, but this can be done in earlier stages if the panel deems it necessary. To set up a meeting the user can click on ‘Schedule Meeting’ from the main page of that particular panel. The user then fills out the details shown in Figure 30 below.

Schedule meeting

Title of meeting:

Description:

Type of meeting ☐ Part of ERN recurring meeting ☐ Individual meeting

Figure 30: Schedule Meeting

If the meeting is an ‘Individual Meeting’, the user simply picks a date, time and duration for the meeting. If, however, the meeting is part of a ‘meeting group’, the user must select an available time slot as shown in Figure 31 below.

Meeting group:

☒ ERN Skin Monday Meetings (Every week on Monday)

29/May/2017	05/Jun/2017	12/Jun/2017	19/Jun/2017	26/Jun/2017	03/Jul/2017
<input type="radio"/> 11:00	<input type="radio"/> 11:00	<input type="radio"/> 11:00	<input type="radio"/> 11:00	<input type="radio"/> 11:00	<input type="radio"/> 11:00
<input type="radio"/> 11:15	<input type="radio"/> 11:15	<input type="radio"/> 11:15	<input type="radio"/> 11:15	<input type="radio"/> 11:15	<input type="radio"/> 11:15
Slot taken	Slot taken	<input type="radio"/> 11:30	<input type="radio"/> 11:30	<input type="radio"/> 11:30	<input type="radio"/> 11:30
<input type="radio"/> 11:45	<input type="radio"/> 11:45	<input type="radio"/> 11:45	<input type="radio"/> 11:45	<input type="radio"/> 11:45	<input type="radio"/> 11:45
<input type="radio"/> 12:00	<input type="radio"/> 12:00	<input type="radio"/> 12:00	<input type="radio"/> 12:00	<input type="radio"/> 12:00	<input type="radio"/> 12:00
<input type="radio"/> 12:15	<input type="radio"/> 12:15	<input type="radio"/> 12:15	<input type="radio"/> 12:15	<input type="radio"/> 12:15	<input type="radio"/> 12:15

☐ ERN Eye Monday Meetings (Every week on Monday)

☐ ERN CRANIO Monday Meetings (Every week on Monday)

☐ CRANIO Tuesday (Every week on Tuesday)

Figure 31: Time slots for group meeting

The user can then invite other Health Practitioners to join the meeting, including those who are not part of the panel. The Panel Lead is invited to all meetings for that particular panel by default, but the other members are not.

Schedule meeting

Time/Place

Participants

Summary

Name	Invited	Status	Is Admin
Doctor One	26/May/2017 12:01	Host	true

Type part of name...

Invite

Close

Figure 32: Invite Participants

8.2) Join a Meeting

When a user is invited to a meeting, he/she must first accept or decline the invitation. The user will receive notification of the invitation in the following locations:

Centre

BE01 - Antwerp University Hospital

Lead

Doctor One

Panel

Mr. Test User (Non-Specialist)
Mr. Emma Jackson (THE COORDINATOR)

You have been invited to a meeting (1708 Test).

Accept / Refuse Invitation

Figure 33: Meeting Notification on the main page of the Panel

- On the ERN Dashboard, under 'My Meetings' and 'Member Tasklist'.
- In the 'My Meetings' section of the ERN Application.
- In the 'Tasklist' section of the ERN Application.
- In the Panel, via a banner as shown above:

Similarly, at the designated time, the user can join a meeting via the 'My Meetings' tab (where they can also view past meetings), the Tasklist and via the Timeline of the panel that the meeting belongs to, as shown.

Meeting: Online

Description: Example1
Invited: Doctor One (Host), Hany Mina (Accepted)
Scheduled: 09/May/2017 16:40 (IST), for 20 minutes

Join Meeting

0

add a comment

Meeting: Online

Description: Example2
Invited: Doctor One (Host), Ms Emma Jackson (Accepted)
Scheduled: 01/Jun/2017 12:00 (IST), for 10 minutes

Starts in: 6 day(s)

0

The following features are available to use within the video environment to facilitate the interaction between participants and ensure efficient communication during the meeting:

- Moderator has full control over the meeting to add/mute/remove participants
- Meeting can be recorded
- Ability to view who is connected to the meeting
- Ability to share screen and documents
- Ability to do live streaming/webcast (e.g. for teaching)

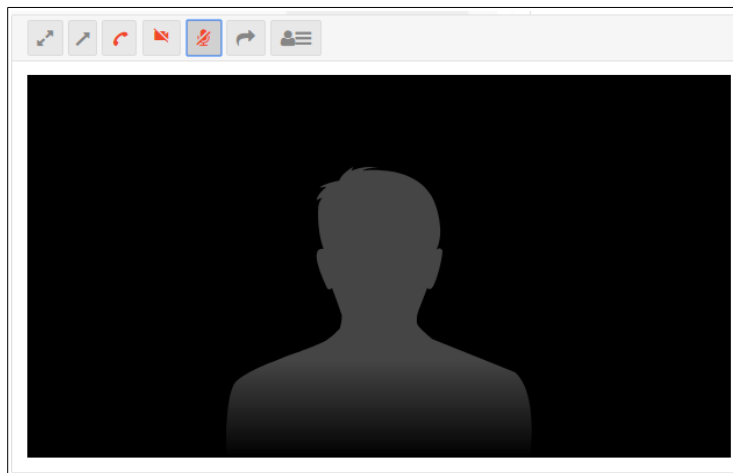


Figure 34: Meeting Interface

8.3) Meeting Summary

When a meeting has finished, the moderator should complete the following steps:

1. Update the meeting status to 'finished', via the 'Time/Place' tab (shown in Figure 32), which can be accessed through the panel Timeline by clicking on the full-screen (arrows) icon shown in Figure 33 above. Alternatively, the status can be updated in 'My Meetings' by clicking edit in general settings of the meeting in question, as shown in Figure 35 below:

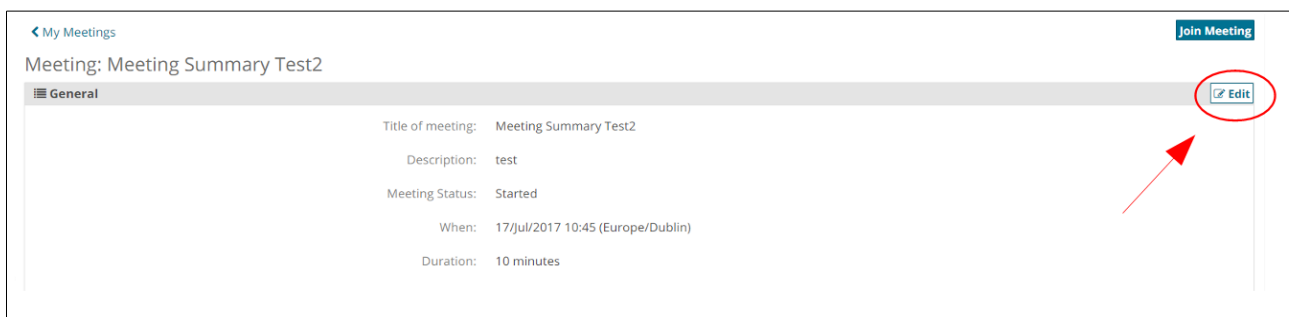


Figure 35: Update the Meeting Status by Clicking on 'Edit'

2. Record a meeting summary via the 'Summary' tab which can also be accessed via the panel Timeline.

Both the meeting moderator and the Panel Lead will receive notifications reminding them that the these steps should be completed. The notifications will appear both in the user's Task List and on the front page of the panel that the meeting is for, as shown in Figure 36 below.

The screenshot displays the ERN Skin user interface for a user named 'Doctor One'. The interface includes a sidebar with navigation options: Dashboard, Tasklist, Preferences, Webinars, My Panels, and Contributing Panels. The main content area shows a meeting titled '# 311 Meeting Tester'. A progress bar at the top right indicates the meeting status: Open (checked), Panel Selection (checked), Data Completion (unchecked), and Assessment (unchecked). Below the progress bar, the meeting details are listed: Centre (EB-Haus Austria), Lead (Doctor One), and Panel (Mr. Emma Jackson). A notification banner at the bottom of the meeting details area, circled in red, reads: 'If meeting "Summary Test" has finished please ensure meeting status is changed to finished and meeting summary is recorded.' Below the notification, there is a 'Consultation Form' section with a 'Recorded' timestamp of '14 Jul 2017 11:16 (Europe/Dublin)' by 'Doctor One' and an 'Edited' timestamp of '14 Jul 2017 11:16 (Europe/Dublin)' by 'Doctor One'. A 'Timelir' button is visible on the right side of the consultation form.

Figure 36: Meeting Summary Reminder

(9) ERN Coordinator

If the ERN Coordinator is simultaneously a coordinator and a health professional in an ERN centre, they can use both the centre and ERN dashboards. Where the ERN Coordinator is a non-medical person and not a member of an ERN centre, he/she is limited to the activities available on the ERN dashboard. ERN Coordinators will use the Key Performance Indicators of the ERN for reporting purposes based on information such as numbers of newly enrolled patients and open and closed panels.

A vital role of an ERN Coordinator will be to receive all requests made by panel leads who seek assistance in inviting suitable members into a particular panel. If the panel lead is not aware of other experts who can help within the same ERN or other ERNs, the ERN Coordinator can assist.

The ERN Coordinator is given the right to change the Panel Lead if needed, in order to ensure the panel workflow is working smoothly.

The ERN Coordinator can also deal with any incoming panel requests that are not relevant to his/her ERN. He/she may transfer the Panel request back to the Coordinator of the originating ERN or forward it to another ERN Coordinator.

Panel Selection

Available

Invited

Co-ordinator Assistance

Invite Guest Members

Forward Panel

Thematic Area: Epidermolysis Bullosa

Available Healthcare Professionals	Role	Invite All
Mr. Nigel Herbert	UK Doc Nigel	Invite
Mr. Video 3	a	Invite
Mr. Video 4	sdfgbh	Invite
Mr. Video One	a	Invite
Video Two	a	Invite

Close

Figure 37: Additional Functionality for the Coordinator during the Panel Selection

Additionally, the ERN Coordinator can schedule a periodic meeting for the health professionals of a particular ERN. If discussing multiple patients, the meeting can be divided into timeslots.

The ERN Coordinator can request offline access for an external health professional to enrol a patient into a particular ERN. Based on the requested access type, the external guest can be permitted to enrol a patient or even become a panel member to interact actively with other Health Professionals in an ERN.

Lastly, the ERN Coordinator can upload or stream live educational videos known as Webinars onto the CPMS.

9.1) ERN Dispatcher

An ERN Coordinator can assign another health professional the role of ERN Dispatcher. The Dispatcher role is similar to that of the Coordinator, but lacks access to features such as the Key Performance Indicators (KPIs).

Therefore, the Dispatcher's primary role might be to ease the workload of the Coordinator during busy periods for example, or to cover for the Coordinator when he/she is on vacation.

9.2) ERN Meetings

The 'ERN Meetings' section allows a co-ordinator for an ERN to establish regular meeting times for panels within their ERN.

ERN meetings				Create ERN meeting
Name	Schedule	Number of slots	Duration of slots	
Example1	Every week on Wednesday	1	00:15:00	
Example2	Every 2 months on the 1st Thursday	2	00:10:00	

Figure 38: Meeting Groups

By clicking on 'Create ERN meeting', shown in the top right corner of Figure 38, the ERN co-ordinator can set up a new recurring meeting for their ERN.

Create ERN meeting

Title of ERN meeting:

Description:

Start time:

hh:mm

Europe/Dublin

Number of meeting slots:

Duration of each slot:

minutes

Commencing after:

16/Aug/2017

Scheduling

Repeating unit:

Weeks

Frequency:

Every 1 weeks

Occurs on:

Monday

Cancel

Create

Figure 39: Create ERN Meeting

The established time slots are then available to be selected by Panel Leads when they are scheduling meetings for their panels.

(10) Webinars

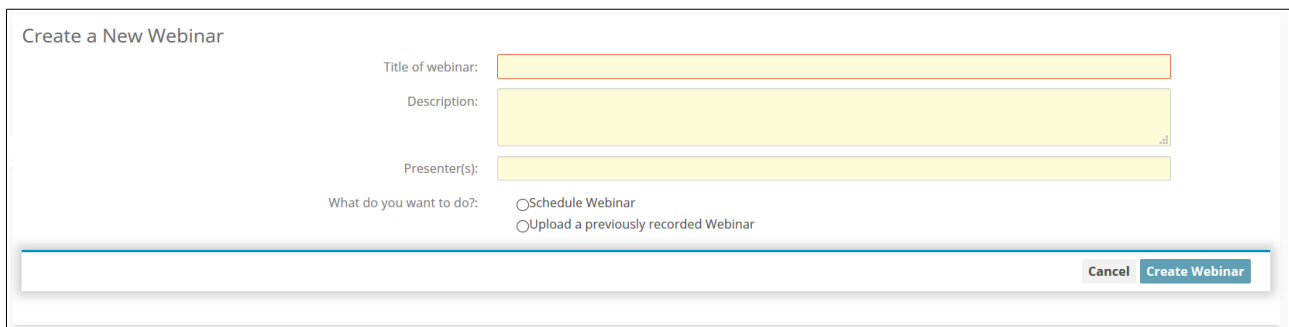
In the 'Webinars' section the user can create a new webinar or upload a previously recorded one.



The screenshot shows the 'Webinars' section of the application. At the top left is a camera icon and the word 'Webinars'. At the top right is a blue button labeled 'Create webinar'. Below this, there are two sections: 'Planned Webinars' and 'Recorded Webinars'. Each section contains a table with four columns: 'Title', 'Presenters', 'When', and 'Description'. Both tables are currently empty.

Figure 40: Webinar Section

A webinar is mainly used for education and training purposes, and it differs from a meeting in that all of the users only see the presenters screen.



The screenshot shows the 'Create a New Webinar' form. It has a title 'Create a New Webinar' at the top left. The form contains three input fields: 'Title of webinar:', 'Description:', and 'Presenter(s):'. Below these fields is a section labeled 'What do you want to do?:' with two radio button options: 'Schedule Webinar' and 'Upload a previously recorded Webinar'. At the bottom right of the form are two buttons: 'Cancel' and 'Create Webinar'.

Figure 41: Create a New Webinar

(11) ERN Map

This application allows the users to view all of the medical centres (hospitals) on the CPMS. The side menu allows for filtering based on specific ERNs.

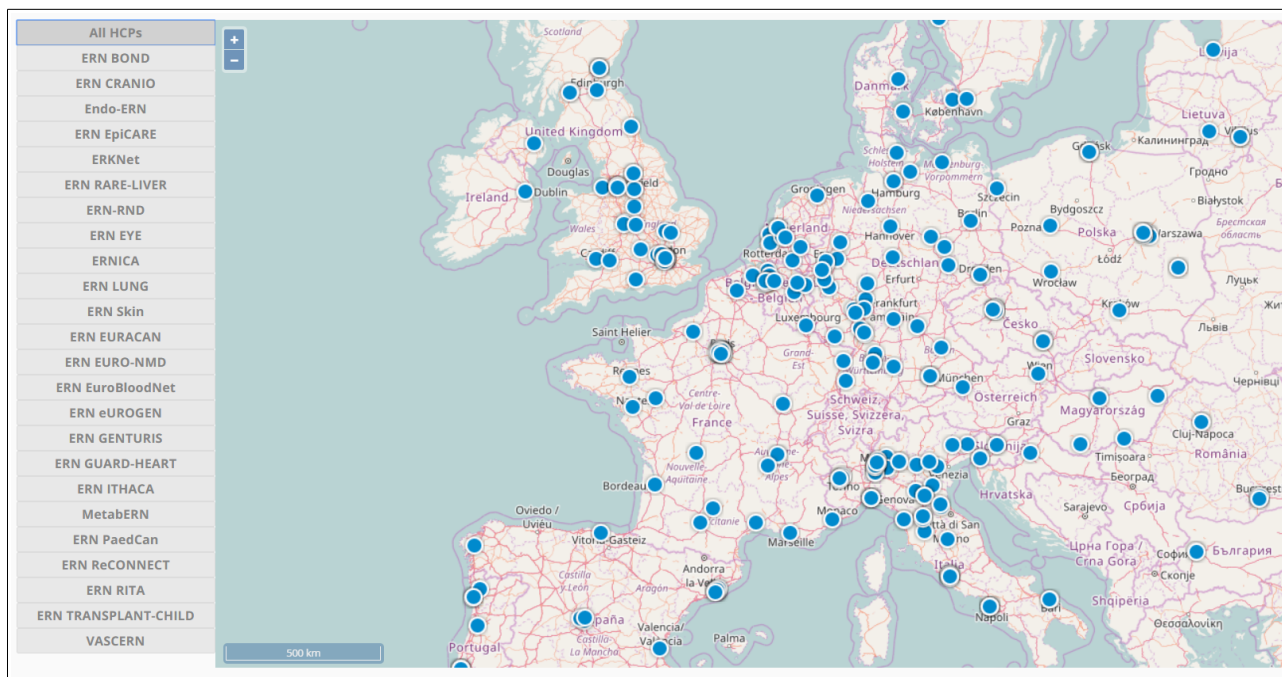
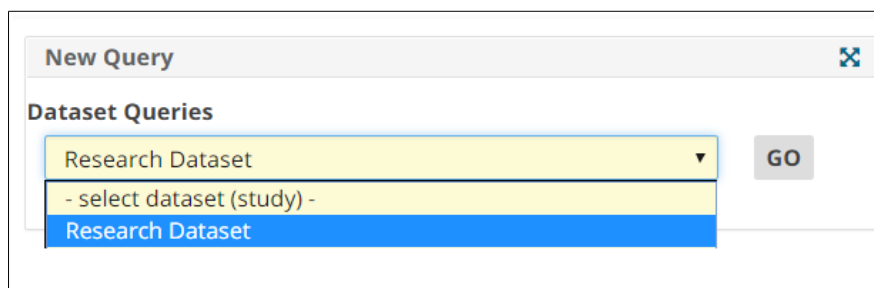


Figure 42: ERN Map

(12) ERN Database

The ERN Database contains a Query Builder which allows the user to generate customised reports. Authorised users can access the app by clicking on the 'Research' link in their top menu.

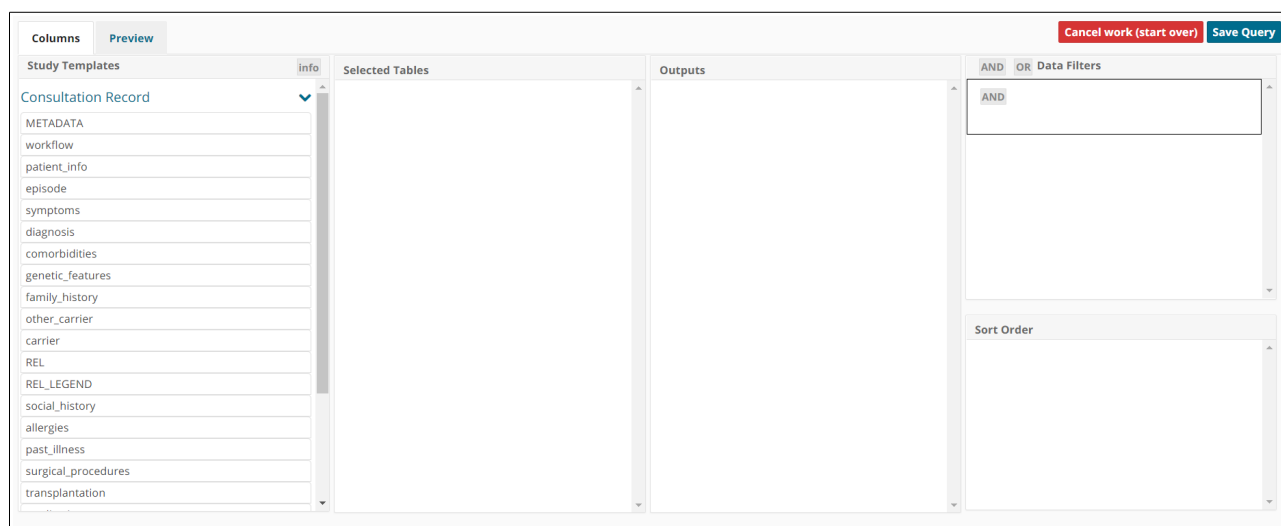
To create a new query, select the 'Research Dataset' and click 'Go'.



The screenshot shows a 'New Query' window. Inside, there's a section titled 'Dataset Queries'. A dropdown menu is open, showing 'Research Dataset' as the selected option. Below it, there's a placeholder text '- select dataset (study) -' and another 'Research Dataset' option. To the right of the dropdown is a 'GO' button.

Figure 43: New Query - Select 'Research Dataset', click 'Go'

This opens a blank report template as shown below.



The screenshot shows a 'Blank Report Template' interface. It has a 'Columns' tab with 'Study Templates' and 'Consultation Record' sections. The 'Selected Tables' and 'Outputs' columns are empty. The 'Data Filters' section is also empty. There are 'Cancel work (start over)' and 'Save Query' buttons at the top right.

Figure 44: Blank Report Template

Under 'Study Templates', the user can see the different sections of the Consultation Record. Hovering the mouse over a field name will show the name as it is displayed in the form. The 'info' button displays all of the fields, allowing the user to quickly search for a specific name.

The user can simply drag and drop sections containing the data they are interested in into the 'Selected Tables' column, and the required fields into the 'Outputs' column. The report can then be previewed in the 'Preview' tab.

II) User Management Guide

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(1) User Roles

1.1) What Roles exist within the CPMS?

1. Health Professional
2. Guest
3. Coordinator
4. Dispatcher
5. Admin
6. Centre/Local Administrator

1.2) Restrictions and Rules

The following should be noted in relation to restrictions and rules within the CPMS:

- A Health Professional **must** be allocated to **both** a Centre and an ERN. There should be no Health Professionals who are just part of a Centre with no allocated to ERN, or vice versa.
- An ERN Coordinator can assign another user the role of ERN Dispatcher. The Dispatcher role is similar to that of the Coordinator, but lacks access to features such as the Key Performance Indicators (KPIs). Therefore there is no need for a case where a user is assigned the role of both Coordinator and Dispatcher for the same ERN.
- A Coordinator for an ERN must also be a Health Professional in the same ERN. Similarly, a Dispatcher of a given ERN must also be a Health Professional allocated to that ERN.
- A Centre Administrator must also possess a clinical role (i.e. must be a Health Professional) for the same centre.
- A user **may** possess the role of both Centre Administrator and ERN Coordinator/Dispatcher **provided** they are also a Health Professional assigned to both the Centre and ERN in question.

Examples of **INVALID** combinations of roles in the CPMS:

- Centre Administrator & Dispatch only
- User Management Console & HP
- Guest & Dispatcher

- Guest & Centre Administrator
- Guest & ERN Coordinator
- ERN Coordinator only
- ERN Coordinator & Dispatcher

(2) User Management Console

2.1) Search Users

The user management console allows the admin to search for any user in the system. This can be done via the 'Users' tab shown in Figure 45 below.

Figure 45: Search for a User

The administrator can search for a user by first name, last name, EU Login ID and email address. Alternatively, by leaving all fields blank, they can also view the entire list of users, and look through them manually. The admin can then view and edit a specific user's details, and the level of access (if any) they have to specific ERNs and Centres. In order to view and edit this information, the admin must click the 'view' button on the right side of the results page, as seen in Figure 46 below.

Search Results						
Login	Name	Email	Phone	Active	Roles	Registration
doctor1	One, Doctor	doctor1@example.mail.ie		true	ERN Map:HP ERN Skin:Dispatcher ERN Skin:HP EB-Haus Austria:Administrator EB-Haus Austria:HP	View

Figure 46: Search Results

2.2) User Details

There are four sections in a user's details that the admin can view and edit: Settings, ERNs, Centres and Guest/Map/Research.

Settings

This section contains a user's basic information, such as their name and contact details.

Insight User: doctor1

Settings ERNs Centres Guest / Map / Research

EU Login User ID doctor1

User is active ☒

Title

First name Doctor

Middle name Middle name

Last name One

Known as Doctor One

Email address doctor1@example.com

Phone Phone

Managed By Hospital One

Country IE: Ireland (Europe/Dublin)

Last updated Jul 28, 2017

Cancel Delete Save

Figure 47: User's Settings

ERNs

By clicking on the 'ERNs' tab the admin can view a list of the ERNs and change whether or not a user has access to them and what role they have within it.

Insight User: doctor1

Settings ERNs Centres Guest / Map / Research

Centre	Allowed	Roles
Demo ERN	<input checked="" type="checkbox"/>	<input type="checkbox"/> Coordinator <input checked="" type="checkbox"/> Dispatcher <input type="checkbox"/> Guest <input checked="" type="checkbox"/> HP
Endo-ERN - Endocrine Conditions	<input type="checkbox"/>	
ERKNet - Kidney Diseases	<input type="checkbox"/>	
ERN BOND - Bone Disorders	<input type="checkbox"/>	
ERN CRANIO - Craniofacial anomalies and ear, nose and throat disorders	<input type="checkbox"/>	

Figure 48: User's ERNs

Centres

On the 'Centres' tab the admin can determine what centres and roles a user has access to. There is a 'Filter by country' drop-down which the admin can use to quickly navigate the list of centres.

Insight User: doctor1

Settings ERNs Centres **Guest / Map / Research**

Filter by country: AT: Austria (Europe/Vienna) ▼

Country	Centre	Allowed	Roles
AT	AT01 - EB-Haus Austria	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Administrator <input checked="" type="checkbox"/> HP
AT	AT02 - St Anna Children's Hospital & St Anna Children's Cancer Research Institute	<input type="checkbox"/>	

Cancel Delete Save

Figure 49: User's Centres

Guest/Map/Research

This section allows the administrator to give users access to features such as the Map, or ERN Database (Query Builder).

Insight User: doctor1

Settings ERNs Centres **Guest / Map / Research**

Country	Centre	Allowed	Roles
	ERN Map	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> HP
	Guest Hps	<input type="checkbox"/>	
	Research	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Researcher

Cancel Delete Save

Figure 50: Additional Features

2.3) Export Users

The admin can download an XML file containing the details of all of the users by clicking on the 'Export Users' button shown in Figure 45.

2.4) New Insight User

The admin can add a new user to the system by clicking 'New Insight User', located beside the 'Export Users' link, and filling out the form shown in Figure 51 below:

New Insight User

Settings

EU Login User ID Username

User is active ☐ Warning: This User cannot login to the system!

Title

First name

Middle name

Last name

Known as

Email address

Phone

Managed By

Form is incomplete

Cancel Create

Figure 51: New User Form

(3) Applications

From the side menu (Figure 52), the admin can view a list of all of the applications that exist in the system by clicking the ‘List Apps’ link. Similarly, the ‘List HCPs’ link contains the details on all of the medical centres in the system.

The applications can be filtered by various columns as shown in Figure 53 below.

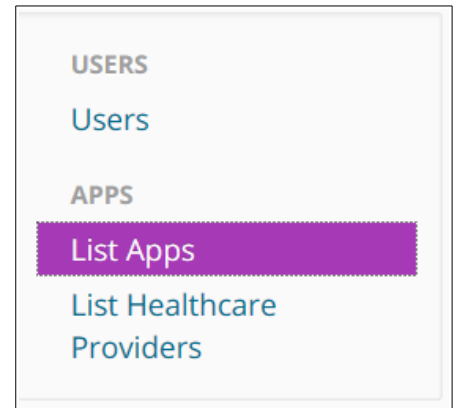


Figure 52: Side Menu

Menu Group	App Label	Namespace	Country	Centre	Application Type
ERN	AT01 - EB-Haus Austria	at01	AT	AT01 - EB-Haus Austria	ERN Centre
ERN	AT02 - St Anna Childre...	at02	AT	AT02 - St Anna Children's Hos...	ERN Centre
ERN	BE01 - Antwerp Univer...	be01	BE	BE01 - Antwerp University Ho...	ERN Centre
ERN	BE02 - AZ Sint-Marteen	be02	BE	BE02 - AZ Sint-Marteen	ERN Centre
ERN	BE03 - Centre Hospitali...	be03	BE	BE03 - Centre Hospitalier Uni...	ERN Centre
ERN	BE04 - Cliniques univer...	be04	BE	BE04 - Cliniques universitaire...	ERN Centre
ERN	BE05 - Cliniques univer...	be05	BE	BE05 - Cliniques universitaire...	ERN Centre
ERN	BE06 - Ghent Universit...	be06	BE	BE06 - Ghent University Hosp...	ERN Centre
ERN	BE07 - HÅ'pital Univer...	be07	BE	BE07 - HÅ'pital Universitaire...	ERN Centre

Figure 53: List of Applications

III) Overview of the Dataset & Coding Systems in the CPMS

Document type: Data-set Coding systems

File name: CPMS data-set coding systems

Document reference: 9417CS-CPMS

Produced by: OpenApp

Version: 0.2

Release date: 08.08.2017

(1) Scope & Purpose

This document summarizes the data-set and the coding systems used in the CPMS to build the consultation form. All the fields listed are intended as generic in order to enable you to customize as per the condition specificities.

(2) Data-set

Patient Enrolment	ERN.3	Patient ID	Auto generated / Matched existing
	ERN.4	Patient Nickname	Text box
	ERN.5	Patient Enrolment Date	Day/Month/Year
Consent	RD3	Consent Care	Yes/No
	RD3	Consent to be contacted for research	Yes/No
	RD3	Consent Databases/Registry	Yes/No
	ERN.6	Registry Name	Text
Referral Request	ERN.7	ERN Name	List of ERN thematic areas
	ERN.8	ERN Subnetwork	List of ERN sub thematic areas
	ERN.9	Healthcare Provider (HCP)	Auto-populate (user info)
	ERN.10	ERN status	ERN member; Affiliated; Non-ERN member
	ERN.11	ERN Specialist (medical/non-medical)	List of ERN users
	ERN.12	Referral Request Description Short	Free-text Alphanumeric (max. char?)
	ERN.13	Referral Request Reason	Diagnosis/Treatment/Other
	ERN.14	Referral Request Reason Description	Free-text Alphanumeric (max. char?)
Patient Information	ERN.1	Panel ID	Auto generated
	ERN.2	Is this a repeat of a previous panel for the same patient but a different episode?	Yes/No/Don't know
	PS1.3	Date of birth	Day/Month/Year loose
	ERN.54	Birth complications	LOINC medDRA free-text
	ERN.55	Age	Auto calculated [today]-[PS1.3 Date of birth]
	PS1.2	Gender	Female/Male/Undifferentiated/Unknown
	PS1.5.6	Country of Residence	ISO 3166-1 Country codes
	EPI.1	Country of Birth	ISO 3166-1 Country codes
	RD4	Education Level	ISCED 0: Early childhood education ('less than primary' for educational attainment) ISCED 1: Primary education ISCED 2: Lower secondary education ISCED 3: Upper secondary education ISCED 4: Post-secondary non-tertiary education ISCED 5: Short-cycle tertiary education ISCED 6: Bachelor's or equivalent level ISCED 7: Master's or equivalent level ISCED 8: Doctoral or equivalent level
	RD5	Occupation	Dropdown Eurostar classification for self-defined current economic status
	PS14	Functional Status and or Disability	LOINC for observation medDRA freetext
	ERN.74	Other relevant information	free text (max char)
Episode Description	ERN.15	History	Free-text Alphanumeric (max. char) + poss attachment
	ERN.16	Main Symptoms	LOINC medDRA ICD-10

			Free-text Alphanumeric (max. char) + poss attachment
	ERN.17	Current Treatment	ATC classification for describing the active ingredient of medicines Free-text Alphanumeric (max. char) + poss attachment
	ERN.18	Exam Findings	LOINC medDRA ICD-10 Free-text Alphanumeric (max. char) + poss attachment
	ERN.19	Laboratory Findings	LOINC medDRA Free-text Alphanumeric (max. char) + poss attachment
	ERN.20	Imaging Findings	LOINC Free-text Alphanumeric (max. char) + poss attachment
	ERN.21	Other Findings	Free-text Alphanumeric (max. char) + poss attachment
	ERN.56	Previous clinical trial participation	Free text
	ERN.22	Other Information	LOINC Free-text Alphanumeric (max. char) + poss attachment
Rare Disease Diagnosis (if diagnosis is selected at ERN13 then this section does not appear)	RD8.2	Rare Disease Diagnosis Code	Orphanet List of rare diseases ICD10 List of diseases ICCC-3 (childhood cancers) ICD-O-3 (International Classification of Diseases for Oncology) Other - free text description below
	RD8.1	Rare Disease Diagnosis Description	Orphanet List of rare diseases ICD10 List of diseases ICCC-3 (childhood cancers) ICD-O-3 (International Classification of Diseases for Oncology) If other selected above Other - free text description
	ECRF.6	Human Phenotype Ontology classification	List of HPO classifications
	RD8.4	Date of first symptoms onset	Day/Month/Year Loose
	RD8.6	Date of current diagnosis	Day/Month/Year Loose
	PO2.4	Age at diagnosis	Auto calculated [RD8.6 Date of current diagnosis] - [PS1.3 Date of Birth]
	RD8.7	Status of current diagnosis CT	free-text
	RD8.9.1	Diagnosing Healthcare Provider	ERN member; Affiliated; Non-ERN member
	RD8.9.1 a	ERN member healthcare provider	List of ERN HCPs
	RD8.9.1 b	Affiliated healthcare provider	List of Affiliated HCPs
	RD8.9.1c	Non-ERN member healthcare provider	Free-text Alphanumeric
	RD8.9.3	Country of diagnosing Healthcare Provider	ISO 3166 Country codes
	RD8.9.1	Treatment Healthcare Provider	ERN member; Affiliated; Non-ERN member
	RD8.9.1 a	ERN member healthcare provider	List of ERN HCPs
	RD8.9.1 b	Affiliated healthcare provider	List of Affiliated HCPs
	RD8.9.1c	Non-ERN member healthcare provider	Free-text Alphanumeric
	PS18.1	Diagnostic Test Code CT	LOINC freetext
	ERN.23	Diagnostic Test Description	Text
	PS18.2	Date of observation	Day/Month/Year Loose
	ERN.24	Result	Attachment
Comorbidities (repeatable section)	PS11.2	Other Diagnosis Code	Orphanet List of rare diseases ICD10 List of diseases ICCC-3 (childhood cancers) ICD-O-3 (International Classification of Diseases for Oncology) Other - free text description below
	RD8.2	Diagnosis Description	Orphanet List of rare diseases ICD10 List of diseases ICCC-3 (childhood cancers) ICD-O-3 (International Classification of Diseases for Oncology) Other - free text description below
	RD8.6	Date of Diagnosis	Day/Month/Year Loose
	RD8.7	Status of diagnosis	Alphanumeric (500 char)
	RD8.7a	Status of diagnosis if other	Free-text Alphanumeric (max. char?)

Phenotype and Genetic Features and Biobanks (repeatable section)	ERN.65	Genetic study performed	LOINC Free text
	RD10.1	Gene affected	HGNC symbols Free-text
	RD10.2	Chromosome number	
		DNA variant	Substitution Deletion Duplication Insertion Inversion Conversion Deletion-insertion Alleles Repeated sequences Complex (hgvs/iscn)
	ERN.58		
	RD10.5	DNA Nucleotide variant description	Coded element: HGVS Sequence variation
	RD10.4	DNA Nucleotide reference sequence	Coded element: NCBI genomic nucleotide RefSeq Id/LRG Id
		RNA Variant	Substitution Deletion Duplication Insertion Inversion Conversion Deletion-insertion Alleles Repeated sequences Splicing
	ERN.66		
	ERN.67	RNA Nucleotide variant description	Coded element: HGVS Sequence variation
	ERN.68	RNA Nucleotide reference sequence	LRG ID
		Protein Variant	Substitution Deletion Duplication Insertion Deletion-Insertion Alleles Repeated sequences Frame shift Extension
	ERN.59		
	ERN.69	Protein sequence	Coded element: NCBI genomic nucleotide RefSeq Id/LRG Id
	ERN.70	Protein reference sequence	Free text to be filled in with the LRG Id
	ERN.71	Other changes: e.g. DNA methylation	Free text
	ERN.57	Allelic State	LOINC
	ERN.73	Somatic Mutation as included in COSMIC	Coded element: NCBI genomic nucleotide RefSeq Id/LRG Id
	RD10.6	Variant description in other formats	RS number (dbSNP identifier)
	ECRF.6	Phenotypic Abnormality	Human Phenotype Ontology vocabulary (HPO)
Family History	ERN.60	Specimens stored at biobank	Alphanumeric (max char.)
	ERN.72	Biobank details	Alphanumeric (max char.)
	EPI.2	Consanguineous Parents?	Yes/No/Unkown
	RD9.3	Healthy carriers in the family?	Yes/No/Unkown
	EPI.3	If Yes – kinship of Carrier	List of Kinships
Health Behaviours	RD9.1	Other cases in the family?	Yes/No/Unkown
	EPI.4	If Yes – kinship of Carrier	List of Kinships
	PS 15.1	Smoke history	Yes/No
	ERN.25	If yes – Please specify	Daily; Weekly; Monthly; Less than Monthly; No longer;
	PS 15.1	Drug use	Yes/No
	ERN.26	If yes – Please specify	Text Box
Allergies and Other Adverse Reactions (repeatable section)	PS 15.1	Alcohol use	Yes/No
	ERN.27	If yes – Please specify	Daily; Weekly; Monthly; Less than Monthly; No longer;
	PSS.1	Allergy Display Name CT	ATC for active substances in medication for other/food, etc. - free-text
	ECRF.1	Status	Active/Confirmed/Inactive/Resolved/Unconfirmed
	ECRF.2	Category	Environment/Food/ Medication/Other
	ECRF.3	Category if other	Free-text Alphanumeric (max. char?)

	PS5.3	Allergy Onset Date	Day/Month/Year Loose
	ECRF.4	Date of Last Occurrence	Day/Month/Year Loose
	RE12.2.9.2	Adverse effects	medDRA
	ECRF.5	Manifestation	Text Box
History of Past Illness and Disorders (repeatable section)	PS7.2	Problem code	ICD-10
	PS7.1	Problem description	Text
	PS7.3	Date of Onset	Day/Month/Year Loose
	PS7.4	End date	Day/Month/Year Loose
Special Treatment and Intervention (e.g. Diet) (repeatable section)	ERN.61	Special Treatment	Radiation therapy; Chemotherapy; Immunotherapy; Targeted Therapy; Hormone Therapy; Stem Cell Transplant; Precision Medicine; Diet; Other
	ERN.62	Special Treatment - Other	Free-text Alphanumeric (max. char?)
	ERN.63	Comments/Notes	Free-text Alphanumeric (max. char) + poss attachment
Surgical and Transplantation History (repeatable section)	PS9.2	Surgical Procedure Code CT	ICD-10-PCS free-text
	PS9.1	Surgical Procedure Description	ICD-10-PCS free-text
	PS9.3	Surgical Procedure date	Day/Month/Year Loose
	ERN.64	Diagnosis at transplantation	Orphanet List of rare diseases ICD10 List of diseases ICCC-3 (childhood cancers) ICD-O-3 (International Classification of Diseases for Oncology) Other - free text description below
	RD16.1	Patient's received transplant?	Yes/No
	RD16.3	Transplant Material CT	Freetext
	ERN.28	Transplant Material Description	Text
	RD16.2	Date of transplant	Day/Month/Year Loose
Medication (repeatable section)	RD13	Medication for Rare Disease	Yes/No
	ERN.29	Medication for Rare Disease Description	Text Box
	ERN.30	Medication Other	Yes/No/Unkown
	ERN.31	Medication Other Description	Text
	PS19.2	Active Ingredient Code	ATC code
	PS19.1	Active Ingredient Description	
	PS19.3	Strength	Text box
	PS19.4	Number of units per intake	UCUM code system
	PS19.5	Frequency of intake	
	PS19.6	Duration of treatment	Text Box
	PS19.7	Date of onset of treatment	Day/Month/Year Loose
	PS19.8	Pharmaceutical Dose Form	EDQM
	ERN.43	Medication compliance	i) primary non-adherence (occurs when patient does not obtain prescribed medication) ii) discontinuation (occurs when a patient stops taking a prescription too early) iii) compromised execution (patients who are actively engaged in therapy, but use medication inconsistent with provider instructions, i.e. skipping dosages and splitting pills)
Panel Outcome	ERN.32	Did the panel lead to an outcome?	clinical pathway/diagnosis/treatment/clinical trial/other
	RD8.2	Rare Disease Diagnosis Code	Orphanet List of rare diseases ICD10 List of diseases ICCC-3 (childhood cancers) ICD-O (International Classification of Diseases for Oncology) If other selected aboveOther - free text description
	RD8.1	Rare Disease Diagnosis Description	Orphanet List of rare diseases ICD10 List of diseases If other selected aboveOther - free text description
	ERN.39	Outcome document final	Text Box

	ERN.42	Outcome Document sent to Point of Care Specialist	Date/Month/Year
Close/Archive/Delete	ERN.45	Close panel?	Yes/No
	ERN.46	Reason for closing panel	Text Box
	ERN.47	Archive for future use by ERN or Delete record	Archive/Delete
	ERN.48	Has request from patient to delete file been received?	Yes/No
	ERN.49	If yes, what was the date of the request?	Date/Month/Year
	ERN.50	If yes, was patient file deleted from ERNs?	Yes/No
	ERN.51	If yes, what was the date on which the file was deleted?	Date/Month/Year
	ERN.52	If yes, was patient informed that file has been deleted?	Yes/No
	ERN.53	When was patient informed that file has been deleted?	Date/Month/Year
Used to compile Panel Outcome	ERN.33	Panel contribution	Text box
	ERN.34	Panel Contribution Writer	Text box
	ERN.35	Contribution date	Date/Month/Year
	ERN.36	Outcome Document Draft	Text box
	ERN.37	Outcome Document Draft Writer	Text box
	ERN.38	Outcome document draft date	Date/Month/Year
Panel Outcome metadata	ERN.40	Outcome Document Sign-Off writer	Text box
	ERN.41	Outcome final date	Date/Month/Year
Outcome document summarised or translated for patient	ERN.42	Outcome Info Patient Writer	Text box
	ERN.44	Outcome Info Patient Date	Date/Month/Year

(3) Data Collection & Coding Systems

The data model running onto the CPMS conforms with European standards, nomenclatures and strategies to share health data syntactically and semantically in the eHealth sector, in particular the eHealth Action Plan and international standards.

All ERNs will be using one generic data set known as Basic Data Set in the CPMS. Then, further in the development process of the CPMS, an Extended Data Set will be developed based on the customized need of each ERN. It is highly expected that each ERN will have unique requirements for each single condition or specific thematic disease area. Notably to say that the Basic Data Set allow users to add attachments and view images in DICOM viewer. The table below lists all the coding systems and terminology classification used to build the consultation form in the CPMS.

Code System	Basic information	Online access/ reference	Version used in the CPMS
ICD	WHO is the copyright holder of ICD-10 and can grant licenses for its use worldwide for commercial and non-commercial purposes. There are three types of licenses granted by WHO: Licensing WHO classifications for commercial use Licensing WHO classifications for internal use within an organization Licensing WHO classifications for non-commercial use or research purposes.	http://www.who.int/about/licensing/Internettext_FAQ.pdf	ICD-10
Orphanet Rare	Orphanet has chosen to apply the Creative Commons	http://www.orphadata.org/cgi-	Data version

Disease Ontology (ORDO)	Attribution-NoDerivs Licence to all copyrightable parts of our databases. This means that you are free to copy, distribute, display and make commercial use of these databases in all legislations, provided you give us credit. However, if you intend to distribute a modified version of one of our databases, you must ask us for permission first. Orphadata: Free access data from Orphanet. © INSERM 1997.	bin/inc/legal.inc.php	1.2.4 / 4.1.6 [2016-04-08].
ICCC-3 based on ICD-O-3	The classification of childhood cancer is based on tumour morphology and primary site with an emphasis on morphology rather than the emphasis on primary site for adults.	Steliarova-Foucher E, Stiller C, Lacour B, Kaatsch P. International Classification of Childhood Cancer, Third Edition. <i>Cancer</i> 2005;103:1457-67	ICCC-3, Main classification 2011
Human Phenotype Ontology (HPO)	HPO intends to offer a tool that will allow large-scale computational analysis of the human phenome.	http://human-phenotype-ontology.github.io/downloads.html	HPO in format-version: 1.2, data-version: releases/2017-04-13
LOINC	<p>The LOINC Codes, LOINC Table (regardless of format), LOINC Release Notes, LOINC Changes File, and LOINC User's Guide are copyright (c) 1995-2017 of the Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee.</p> <p>The LOINC panels and forms file; LOINC document ontology file; and the LOINC hierarchies, LOINC linguistic variants files, LOINC/RSNA Radiology Playbook, and LOINC/IEEE Medical Device Code Mapping Table (all subject to the copyright above with respect to the LOINC Codes and LOINC Table) are copyright (c) 1995-2017 of the Regenstrief Institute Inc. All these Licensed Materials are granted permission in perpetuity to be used, copied, or distributed without payment of license fees or royalties, for any commercial or non-commercial purpose, subject to the terms and conditions specified in the Copyright Notice and License.</p> <p>First, using LOINC Codes and Table should not pursue the development or promulgation of a different standard that will dilute the purpose of LOINC, i.e. providing a definite standard for identifying clinical information in</p>	https://loinc.org/license/ https://loinc.org/faq/basics/a	version 2.59, release 2017-02-21

	<p>electronicreports. Users are also required to include a specific notice (see Section 9 of the LOINC Copyright Notice and License for the text). It is possible to translate the Licensed Materials into a language other than English and shall be notified to the Regenstrief Institute, Inc. via email at loinc@regenstrief.org. Translations constitute derivative work and users agree to assign all right, title, and interest in and to such derivative work to the Regenstrief Institute, Inc. and the LOINC Committee in the case of translations of the LOINC Codes. Translations shall be electronically transmitted to the Regenstrief Institute, Inc., who will make publicly available all linguistic variants (credit will be given on the LOINC website to the user and/or entity responsible for the translations).</p>		
MedDRA	<p>The CPMS avails from MedDRA free of charge as it was provide though the EC as regulatory authority eligible to receive MedDRA at no charge.</p>	<p>https://www.meddra.org/</p>	<p>Version 20.0 March 2017</p>
UCUM Codes	<p>The UCUM Codes, UCUM table (regardless of format), and UCUM Specification are copyright (c) 1999-2009 of the Regenstrief Institute, Inc. and the Unified Codes for Units of Measures (UCUM) Organization, collectively referred to -in the Copyright Notice and License- as The Organization. The use of those Licensed Materials (UCUM Codes, UCUM Table, and UCUM Specification) is permitted in perpetuity, without any payment of license fees or royalties, as well as copying or distributing them, provided that the terms and conditions specified are followed. Importantly, The Organization stipulates that, to prevent the dilution of the purpose of the Licensed Materials, which is the provision of a definitive standard for identifying units of measures in electronic documents and messages, users shall not use them with the aim of developing or promulgating a different standard for identifying the units of measure. Additionally, the Licensed Materials cannot be modified by the users neither can the users distribute modified versions of the UCUM Table or the UCUM Specifications. UCUM Codes and other information from the UCUM Table may be used in electronic messages to communicate measurements without the need to include the Copyright Notice and License or a reference to it in the message.</p>	<p>http://unitsofmeasure.org/trac/wiki/TermsOfUse</p>	<p>Version: 2.0.1, Revision: 438</p>

	Parts of the UCUM Table and definitions may be incorporated into another master term dictionary or software program for distribution outside the user's organization, provided that such master term dictionary or software program includes a specific notice (see Section 7 of the UCUM Copyright Notice and License for the text).		
ISO 3166-1	ISO 3166-1 alpha-2 codes are two-letter country codes defined in ISO 3166-1, part of the ISO 3166 standard published by the International Organization for Standardization (ISO), to represent countries, dependent territories, and special areas of geographical interest.	https://en.wikipedia.org/wiki/ISO_3166-1_alpha-2	ISO 3166-1 alpha-2 codes accessed on August 2017.
HGNC	HGNC database includes unique symbols and names for human loci, including protein coding genes, ncRNA genes and pseudogenes, to allow unambiguous scientific communication. The work of the HGNC is supported by National Human Genome Research Institute. Terms of Use reflect EMBL-EBI's commitment to OpenScience through its mission to provide freely available online services, databases and software relating to data contributed from life science experiments to the largest possible community. They impose no additional constraints on the use of the contributed data than those provided by the data owner	http://www.ebi.ac.uk/about/terms-of-use	Accessed, May 2017
EDQM Standard Terms	<p>The list of Standard Term was initially prepared by the European Pharmacopoeia Commission following a request from the European Commission to be used in marketing authorization applications, summary of products characteristics, labelling, and in electronic communications. Currently, it is the European Directorate for the Quality of Medicines and Healthcare (EDQM) of the Council of Europe, the organization responsible for continuing issuing the Standard Terms. The use of the web services implies the agreement to specific conditions. When data from the EDQM Standard Terms database is reproduced in any system or website, the conditions mentioned below apply:</p> <p>"It must be clearly stated that the data is from the EDQM Standard Terms database (http://standardterms.edqm.eu), and that it is reproduced with the permission of the European Directorate for the Quality of Medicines & Healthcare, Council of Europe (EDQM).</p> <p>The Standard Terms data must not be modified independently, and no other data may be represented as being part of Standard Terms. If any additional data is presented alongside, it must be made clear that is does not originate from Standard Terms.</p> <p>The date on which the data was retrieved from the Standard Terms database must be clearly stated, with a</p>	https://www.edqm.eu/en/standard-terms-590.html https://www.edqm.eu/register/	Version 1.0.0 – 14 November 2014

	notice that the EDQM Standard Terms database is not a static list and content can change over time." The Standard Terms are created in English after consultation with the Standard Terms Working Party and, where appropriate, adoption by the European Pharmacopoeia Commission. Translations are provided by relevant national authorities on an ongoing basis.		
NCBI genomic nucleotide RefSeq Id/LRG Id	A comprehensive, integrated, non-redundant, well-annotated set of reference sequences including genomic, transcript, and protein.	ftp://ftp.ncbi.nlm.nih.gov/refseq/H_sapiens/RefSeqGene/LRG_RefSeqGene	Released of 08/08/17, 11:03:00 /M
Eurostar classification for self-defined current economic status	The most frequent activity status is the status that individuals declare themselves to have occupied for more than half the total number of months for which information on any status is available.	http://ec.europa.eu/eurostat/statistics-explained/index.php/EU_statistics_on_income_and_living_conditions_(EU-SILC)_methodology_-_definition_of_dimensions	Accessed, August 2017
ISCED classification	ISCED is the reference international classification for organising education programmes and related qualifications by levels and fields.	http://ec.europa.eu/eurostat/statistics-explained/index.php/International_Standard_Classification_of_Education_(ISCED)	Version ISCED 2011

IV) De-Identification Mechanisms in CPMS for European Reference Networks

Document type: De-Identification Techniques in CPMS

File name: De-Identification Methodology

Document reference: 9417DE-CPMS

Produced by: OpenApp

Version: 1.0

Release date: 31.07.2017

Abbreviations

ERN: European Reference Network

CPMS: Clinical Patient Management System for ERNs

DOB: Date of Birth

HP: Health Professional

GUID: Global Unique Identifier

ID: Identifier

DICOM: Digital Imaging and Communications in Medicine

MRN: Medical Record Number

CDA: Clinical Document Architecture

C-CDA: Consolidated Clinical Document Architecture

(1) De-Identification approaches

De-identification, anonymization, and pseudonymization are approaches to remove information from data that are not strictly required for the intended purpose of those data.

- Anonymization is a method to disassociate all identifiers from the data, where pseudonymization supports longitudinal linking and authorized re-identification
- ¹Pseudonymization is the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the personal data are not attributed to an identified or identifiable natural person²

(2) Pseudonymization in CPMS

2.1) CPMS ID

When enrolling a patient into the CPMS, the system generates automatically a unique ID for each patient known as **CPMS ID**. This ID is only visible for health professionals within a particular centre/hospital.

Patient Id: ERN-cy02-001

2.2) Record Label

Within a particular centre, the CPMS proposes by default a structured **Record Label** for each patient to complete the enrolment. This record label is composed of the patient identifying data entered in the enrolment form (e.g. first, last name, etc.). However, authorised medical professionals can edit the record label if they wish. Similarly to the CPMS ID, the record label is only visible to authorised users in a particular centre/hospital.

Identifying data	
* First name	Larry
* Last name	Smith
* Gender:	Male
* Date of birth:	31/Jul/2017
* Record Label	Smith, Larry DOB: 31/07/2017 (male)

¹IHE IT Infrastructure Handbook – De-Identification

²http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_2016.119.01.0001.01.ENG&toc=OJ:L:2016:119:TOC

From the **Security tools** in the CPMS, the system administrator can configure the relevant identifying data in the enrolment form. Thereafter, the CPMS proposes automatically a label for the patient record that contains the patient identifiers and can be edited by authorized users as mentioned above.

Patient Identity Fields

- Collect patient name ☒
- Collect patient name at birth (for GUID) ☐
- Collect date of birth for clinical use ☒
- Collect gender ☒
- Collect patient label ☒
- Collect exact date of birth (for GUID) ☐
- Collect patient CITY of birth (for GUID) ☐
- Collect patient COUNTRY of birth (for GUID) ☐
- Collect patient National Identity Code (for GUID) ☐

2.3) Panel ID

When initiating a panel in an ERN, OpenApp emphasise that none of the invited experts from different centres/hospitals from same/different ERN, can see any patient identifiers (i.e. CPMS ID, Record Label, enrolment data). That means all Panel members from outside the centre to which the patient belong, can not see the real patient identity when participating in a Panel or a Meeting.

Panels are identified uniquely by a **unique Panel ID number**, shown always in the Panel Header.

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Open Panel Selection Data Completion Assessment Outcome Sign-off Closed Archived Next »

Centre Lead Panel: AT01 - EB-Haus Austria, Hany Mina, Mr. Emma Jackson (Radiologist), Doctor One

ERN Thematic Area: ERN Skin - Skin Disorders, Cutaneous diseases related to DNA Repair Disorders

Schedule Meeting

2.4) Nickname

The CPMS allows users to give **Nicknames** to their patients per each individual consultation request. Clinicians will be always requested not to reveal any real patient identifiers. When a user initiate a panel, he/she will be requested to fill in the consultation request as the minimum amount of data required to invite other health professionals to consult the submitted request.

In the consultation request section, users will need to provide a “Nickname” for every individual consultation request for the same patient.

Consultation Request

* Nickname:

Please do not write any identifying data in the Nickname

* Is this a repeat of a previous panel for the same patient but a different episode?

☐ Yes
☐ No
☐ Don't know

* Consultation Request Description Short:

* Consultation Request Reason:

☐ Diagnosis
☐ Treatment
☐ Other

* Consultation Request Reason Description:

* Healthcare Provider:

AT01 - EB-Haus Austria

* Point of care specialist:

2.5) ERN Database/Registry ID

In the ERN Database/Registry known as low accessibility database, all data are made available for research once the Panel lead decides to push anonymized data to the research database when the panel has been closed. A **new patient ID** is given to the Panel and nickname is removed; These database contains only clinical data collected as part of the panel, small amount of panel admin data, decision column as the outcome of the consultation interaction. Data in the ERN database can be exported by authorized researchers in several formats with no identifiable data.

(3) Pseudonymisation of Hospital Relationship

The CPMS always allocates a unique identifier to a patient in the context of a dataset (study). The standard approach is that the hospital copies the patient id to a standard location (patient record), and the patient id is then used to link the data. When a patient presents in the hospital, the hospital patient record is retrieved, and from the data in the patient record, the CPMS record can be retrieved.

The CPMS data model allows multiple identifiers to be linked to the same patient. Each identifier has a “domain” i.e. the owner and identifier type. This mechanism has been used in bespoke deployments to link a hashed version of the hospital’s MRN to a patient. The hashed version of the MRN allows a user with an MRN to retrieve the patient data, but cannot be used to find the hospital record using the hash.

(4) Linking Exported Data

Where a dataset is exported from CPMS and a separate independent consultation, there is difficulty linking the data. It is necessary for both datasets to go to their identifying data and to link the data based on common identifying data. CPMS collects and stores the patient identifying data in encrypted database.

The normal process is that an independent party is given the identifying data from both datasets. The independent party hashes both sets of identifying data in a common way and returns the data plus hashes to the parties with the data. Both datasets are regenerated including the hash for that row and can be joined by the authorised person.

(5) DICOM De-identifications

The CPMS is supported by DICOM viewer to enable health professional browse imaging in files as single instance or full study. The next few pages summarise what de-identification methodologies are used to remove the study tags from an image or a study.

Anonymizing the images comes effectively with erasing most of the tags as specified in Table E.1-1 from PS 3.15 of the DICOM standard 2008 in addition to the following tags:

- Patient's Address
- Requesting Physician
- Patient Telephone Number
- Medical Alerts

However, it is notable to say the CPMS keeps certain non-identifying data on the study/image to help health professionals recognize the examined fields/areas such as study description and its UID. The Viewer will replace the patient name on the image with UID given to patients previously as well as rename the study.

Other than DICOM images, any uploaded non-imaging files might be found within the study containing identifying data (e.g. PDF files) fall within the responsibility of the user.

(6) CDA Document

CDA (Clinical Document Architecture), and C-CDA (Consolidated Clinical Document Architecture) include a header that contains identifying patient data, so a **Redaction mechanism** is used when the CPMS retrieves those documents from hospitals. Users must review the documents to reduce the risk that any identifying data are included and not useful in medical context.

(7) Files Uploads

The CPMS allows authorized users to upload images and other files in specific formats into the consultation form. Notification and warning messages can be seen to remind users to verify the uploaded materials do not contain any identifying data. Another mechanism, **Tick Box** is shown in the attachment section to be ticked confirming the user has acknowledged to upload only documents with no identifying patient data.

V) Multi-Level Role Based Security Boundaries in the CPMS

Document type: Role-based Security Documentation

File name: Multi-level Role-based Security boundaries

Document reference: 9417SB-CPMS

Produced by: OpenApp

Version: 0.1

Release date: 07.07.2017

(1) Centre application

1.1) 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. Therefore, 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.

1.2) Panels within an ERN Centre

Any of the authorized users from a given ERN centre can see all the panels in which all patients who belong to the same centre are involved in. 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.

1.3) Guest Healthcare Professional

The CPMS provides the ability to engage experts and specialists who work for centres that are not part of any ERN. The so-called “Guest Virtual Center” is counted as a Virtual Centre for external clinicians. Through the Guest App, non-ERN clinicians can perform specific activities based on their access rights given at the time of registration.

Two scenarios have been envisaged in which CPMS access is provided to external clinicians:

- A) A Guest user is limited to enrolling a patient and filling in the consultation form. Then 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. This may be particularly useful for a patient enrolled by the Guest user.

It's important to say that Guest users cannot be Panel Leads in the CPMS. In addition, Guest accounts are active for 90 days from the date of registration unless different requirements are needed.

1.4) 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.

(2) 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. You can find out more about the access right and security boundaries built in the CPMS below.

(3) Preferences

All health professionals registered into the CPMS and affiliated to any of the 24 ERNs, will be requested to fill in their professional role and their thematic areas of interest. Their names will then be shown among the invitees when any Panel of interest is being conducted or any meeting in the same disease area is scheduled.

(4) Panels

4.1) My 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 write up and 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.

4.2) Contributing Panels

The Contribution Panels tab in the ERN dashboard 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. Where there are more than one Panel members from the same centre in a particular panel, all can trigger the workflow and edit the consultation form. Thus the CPMS provides the possibility that both junior and senior health professionals can participate actively to provide the data in timely manner.

(5) Meeting Management

5.1) Individual Meeting

Ad-Hoc 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. However, OpenApp's approach is very flexible and can be customized to the needs of each ERN. When a Panel member/lead schedules a meeting, by default, he/she will be considered as the Meeting Host, moderating the discussion within this meeting. Also, 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 unless a special request is submitted to the Developer of the CPMS; as the recorded meeting is deemed to be part of the panel assessment to reach an outcome.

5.2) Group Meeting

only ERN Coordinators can schedule a "Group 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. Although, users can choose either they want to bring their panel into a group meeting or ad-hoc meeting, only ERN coordinators can schedule this type of meetings, and edit the meeting information.

(6) ERN Dispatcher

Besides the administrative roles of the ERN Coordinators, they also receive all requests for assistance submitted by other users within and outside their ERN. Therefore, 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. This assignment of dispatcher role must be initiated upon request by the ERN Coordinators. The assigned dispatcher can help invite the Panel Members and assign a Panel Lead.

(7) 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 other participants in the Panel. Webinars will normally be produced for training purposes and will not be part of any clinical assessment process.

(8) User Management application

8.1) ERN User Management Console

The CPMS user management team will be authorized to register users who have been already authenticated having an active EU Login. The user management team can assign applications to users based on their roles in their centre and in a particular ERN and hospital/centre.

8.2) Centre/Local User Management

With restricted rights, Centre user management personnel can register users at local level. This allows users to create CPMS accounts for members of a hospital/centre and assign them to specific ERNs in which this centre is participating.

(9) System Administration

The system administration team is based at OpenApp to look after the system administration of the different applications within the CPMS. The system administrators aren't allowed to access any patient identifying data.

VI) Encryption in CPMS

Document type: Technical Note

File name: Encryption in CPMS

Document reference: 16082017-EC-CPMS

Produced by: OpenApp

Version: 1.0.0

Release date: 16th August 2017

(1) Introduction

This document describes the encryption used by CPMS. Encryption is used in two areas:

- On the database, identifying data ‘at rest’ is encrypted
- In transit, all communications are encrypted

Furthermore, CPMS is operated under a policy that no data leaves the servers.

(2) Database Encryption

Identifying data stored in the database is encrypted. These fields are:

- extra_info on AuditLogRecordAction
- label (nick-name) on Record
- first_name, family_name, date_of_birth on Record

These fields are encrypted using the Postgres pgcrypto plugin. The encryption uses AES cipher, and a PGP ‘armour’.

There is an encryption key which has been communicated to DGSante separately.

(3) Network Encryption

Network traffic is either over HTTP (browser) or FTP (bulk uploads). The HTTP traffic uses the HTTPS variant. The FTP traffic uses the FTPS variant.

3.1) HTTPS

The following protocols are used: TLSv1 TLSv1.1 TLSv1.2. Older protocols are not supported. The security situation will be reviewed if issues arise and the supported protocols may change if they become inappropriate.

3.2) FTPS

The FTP uses FTP over SSL protocol. The mechanism is explicit security. The encryption uses a 2048 bit rsa cert.

VII) Data Model For CPMS

Document type: Data Model

File name: CPMS Data Model

Document reference: 16082017-DM-CPMS

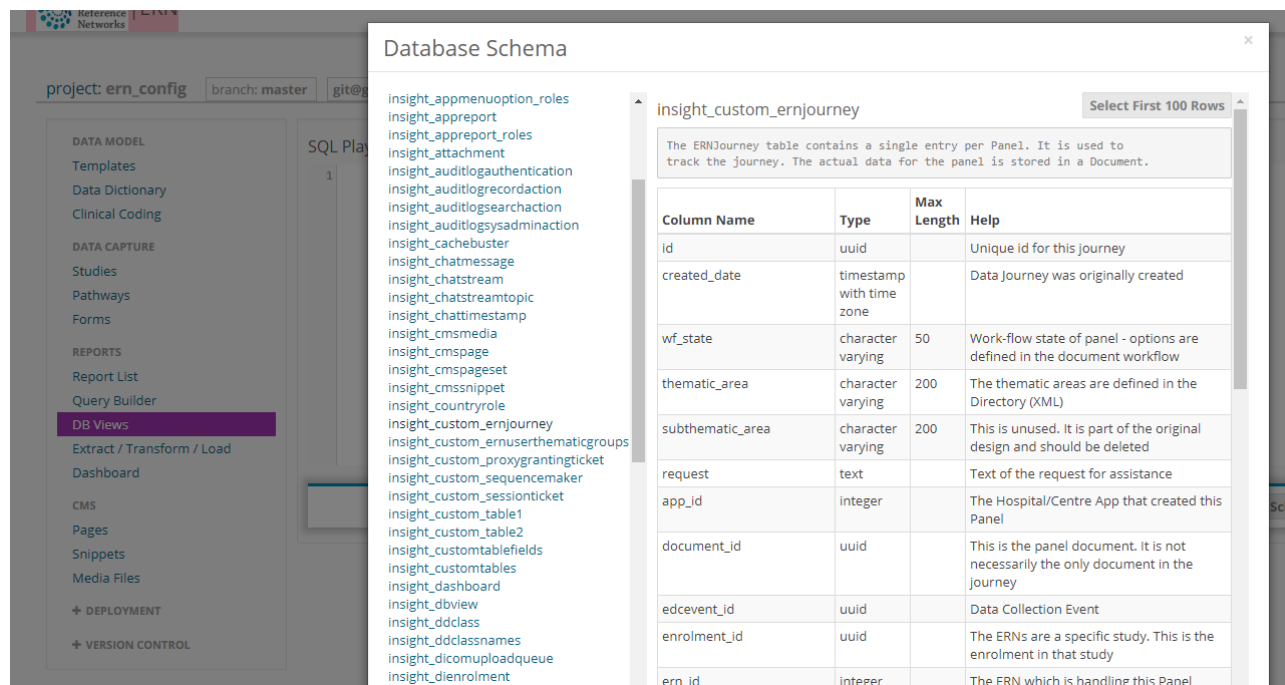
Produced by: OpenApp

Version: 1.0.0

Release date:

(1) Introduction

This document provides the Logical Data Models underlying the CPMS platform. For detail on the database schema, use the design tool which is integrated to the platform. Go to DBViews, and select playground.

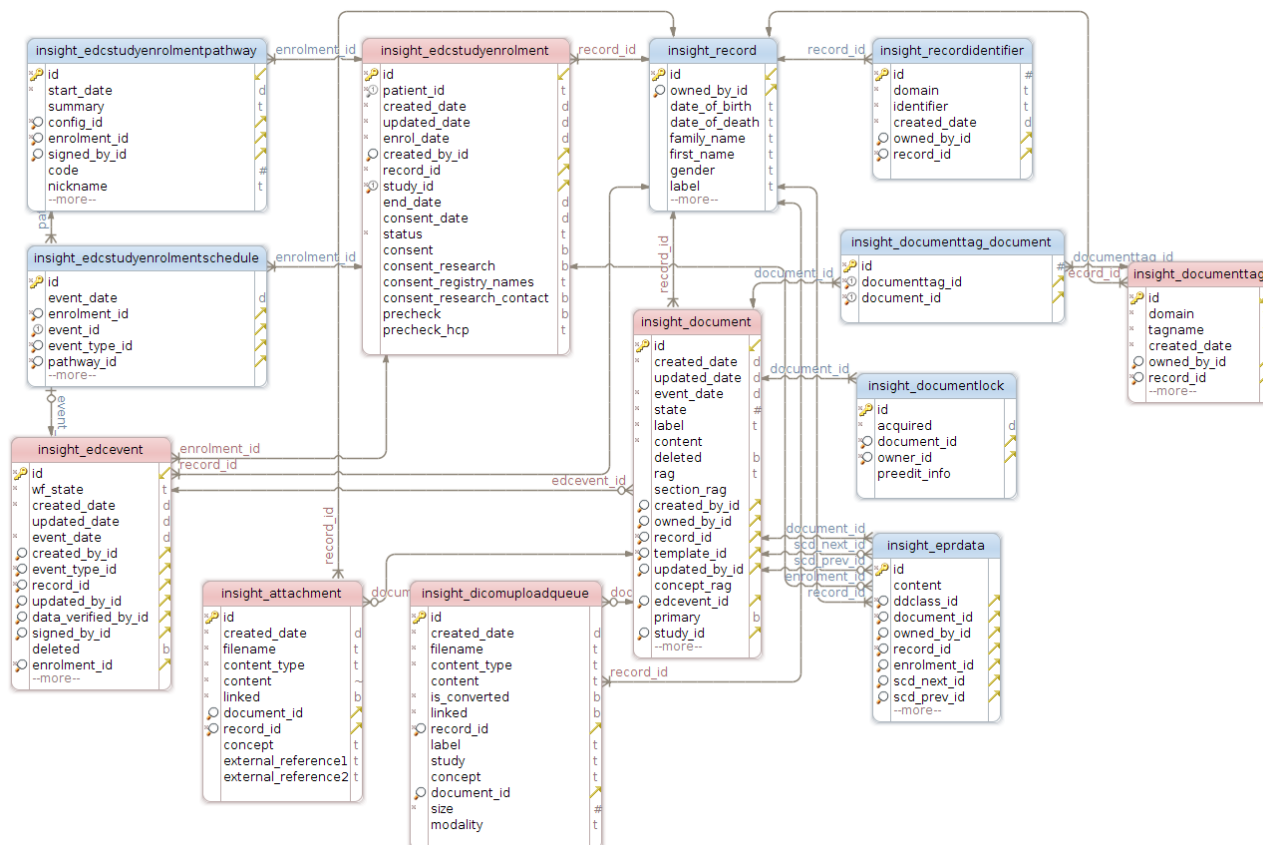


The screenshot shows the OpenApp interface with the 'Database Schema' window open. The left sidebar lists various database components, with 'DB Views' selected. The main window displays the schema for the 'insight_custom_ernjourney' table. A description states: 'The ERNjourney table contains a single entry per Panel. It is used to track the journey. The actual data for the panel is stored in a Document.'

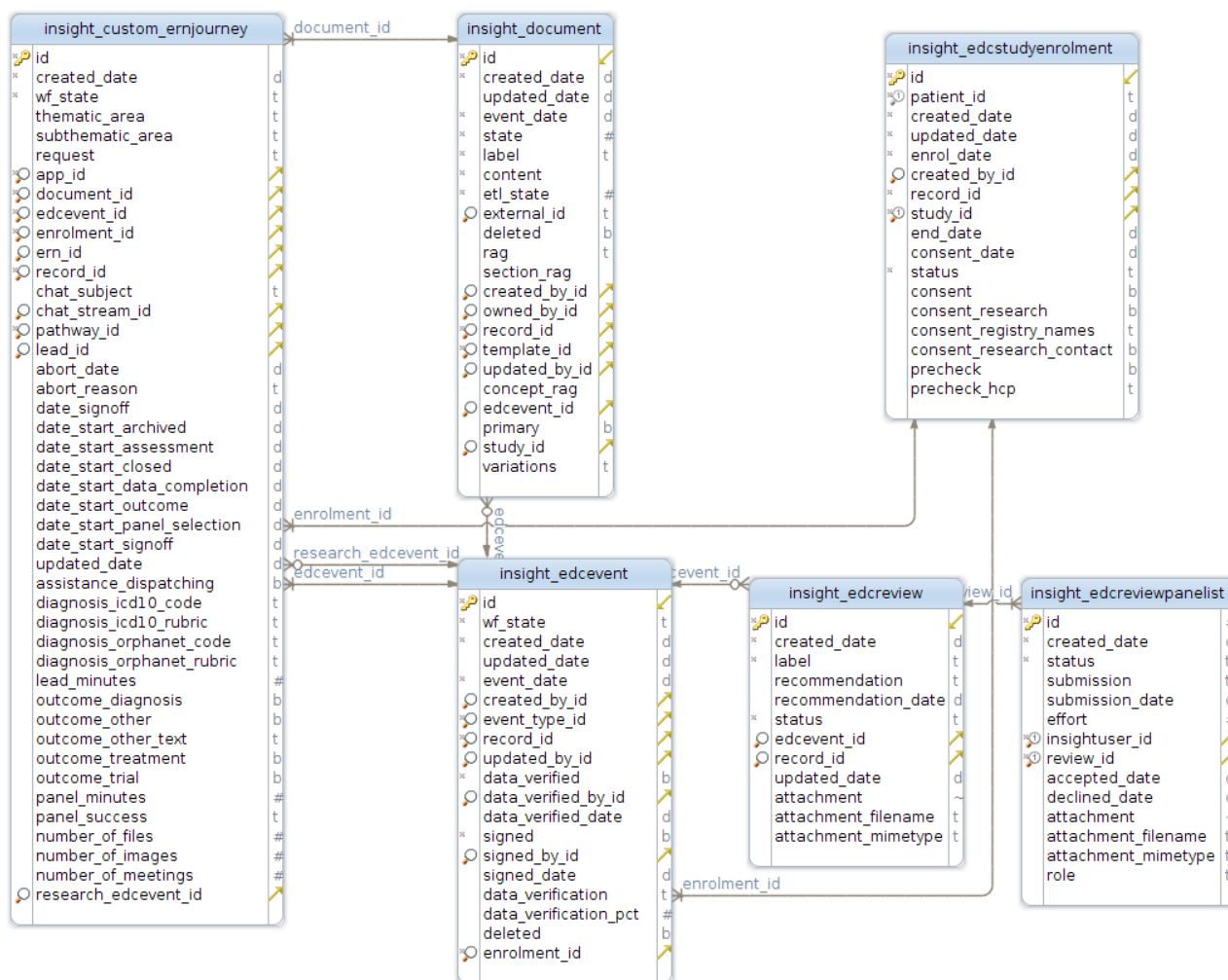
Column Name	Type	Max Length	Help
id	uuid		Unique id for this journey
created_date	timestamp with time zone		Data Journey was originally created
wf_state	character varying	50	Work-flow state of panel - options are defined in the document workflow
thematic_area	character varying	200	The thematic areas are defined in the Directory (XML)
subthematic_area	character varying	200	This is unused. It is part of the original design and should be deleted
request	text		Text of the request for assistance
app_id	integer		The Hospital/Centre App that created this Panel
document_id	uuid		This is the panel document. It is not necessarily the only document in the journey
edevent_id	uuid		Data Collection Event
enrolment_id	uuid		The ERNs are a specific study. This is the enrolment in that study
ern_id	integer		The ERN which is handling this Panel

(2) Logical Data Models

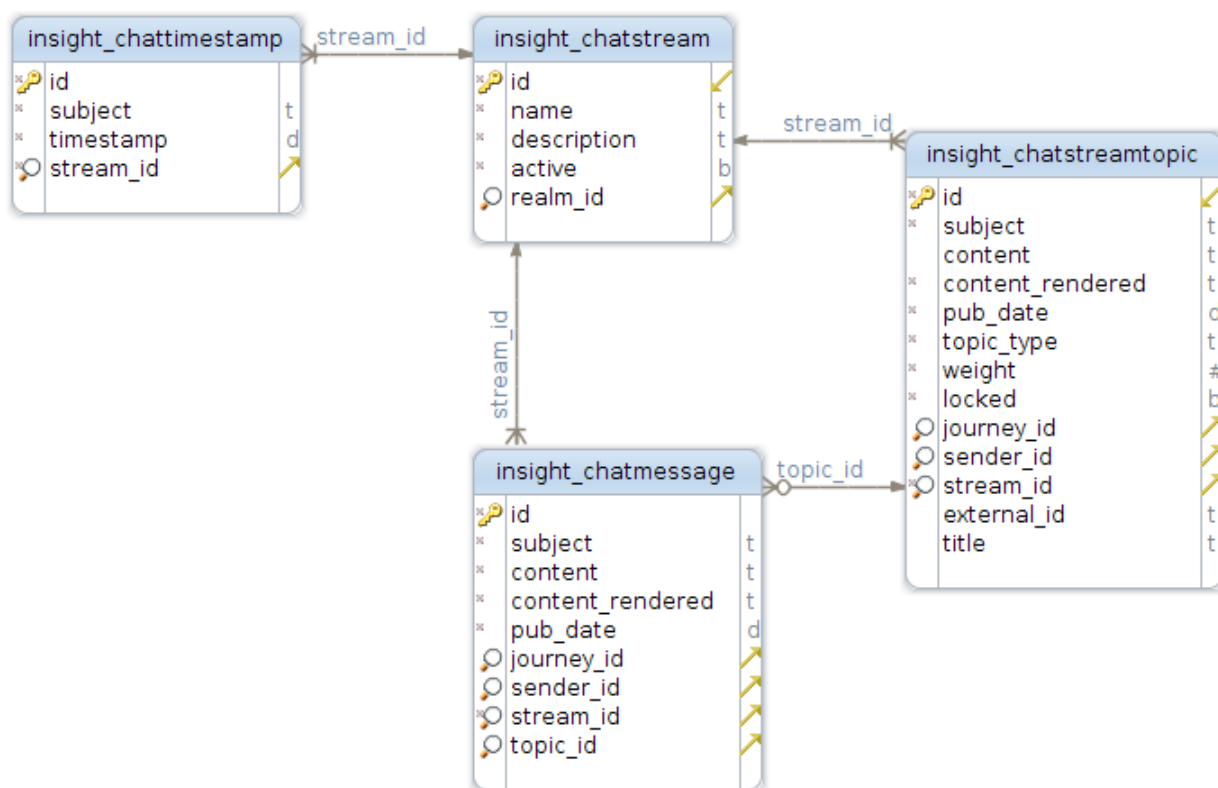
2.1) Clinical Data



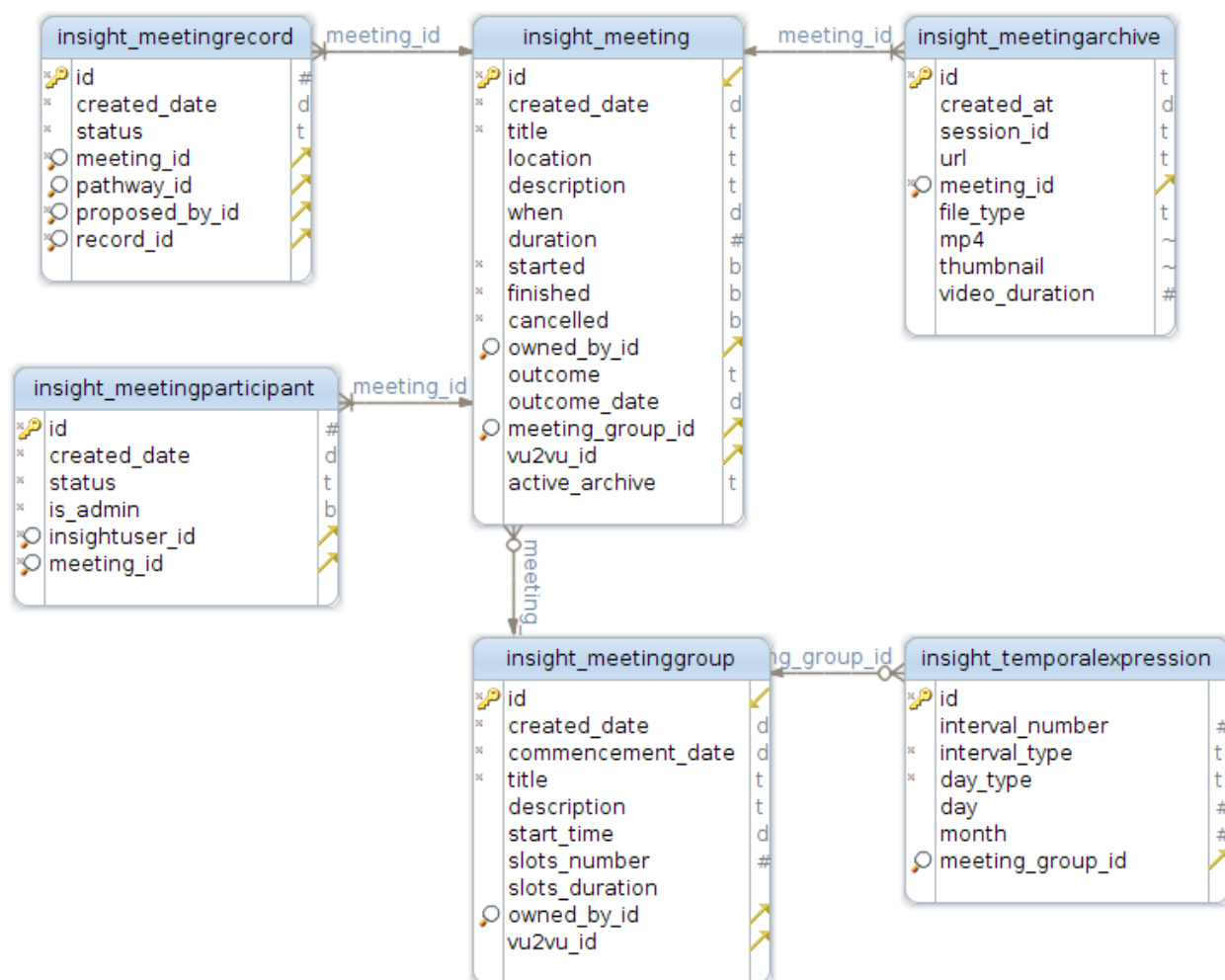
2.2) Panel Data



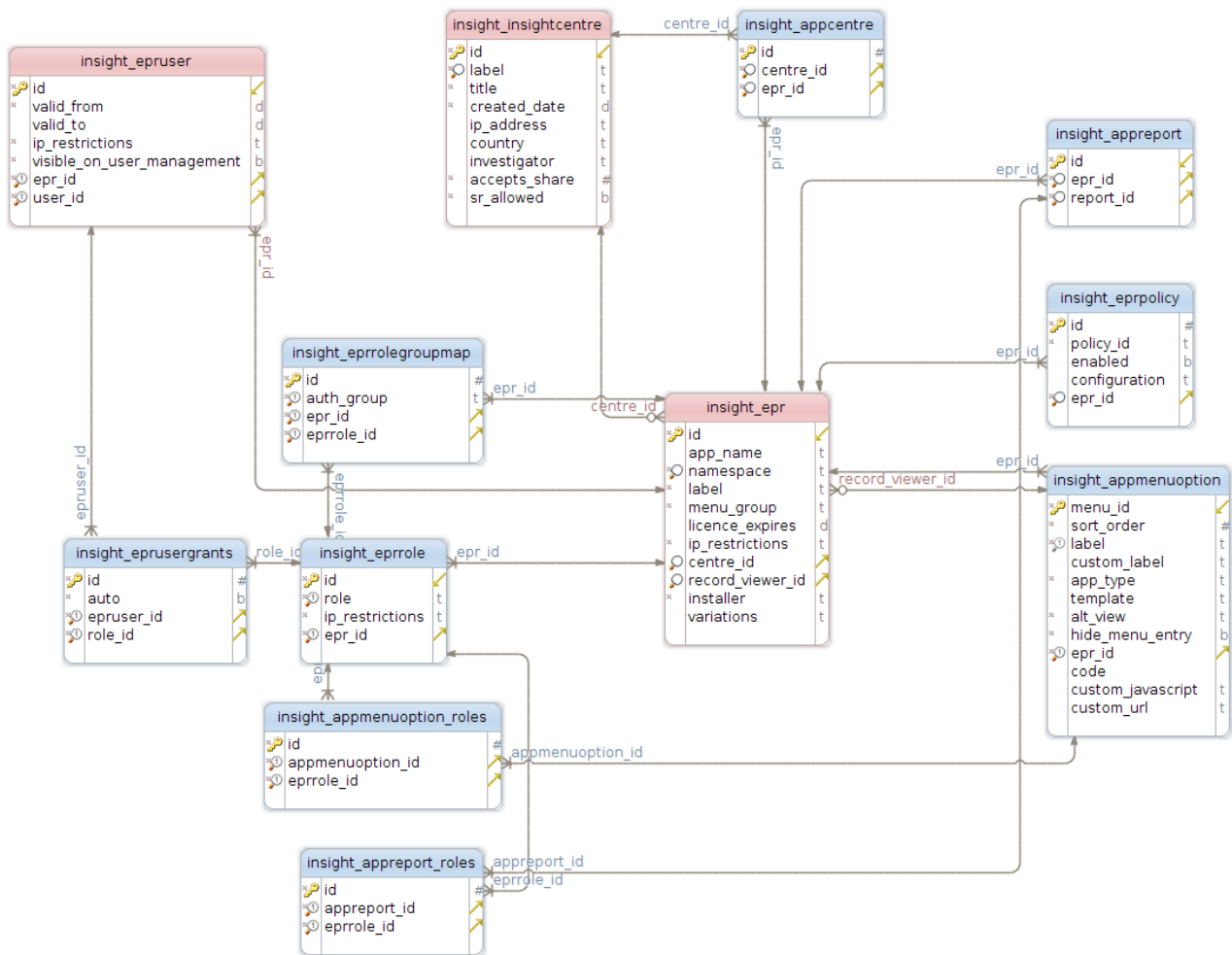
2.3) Chat / Time-line



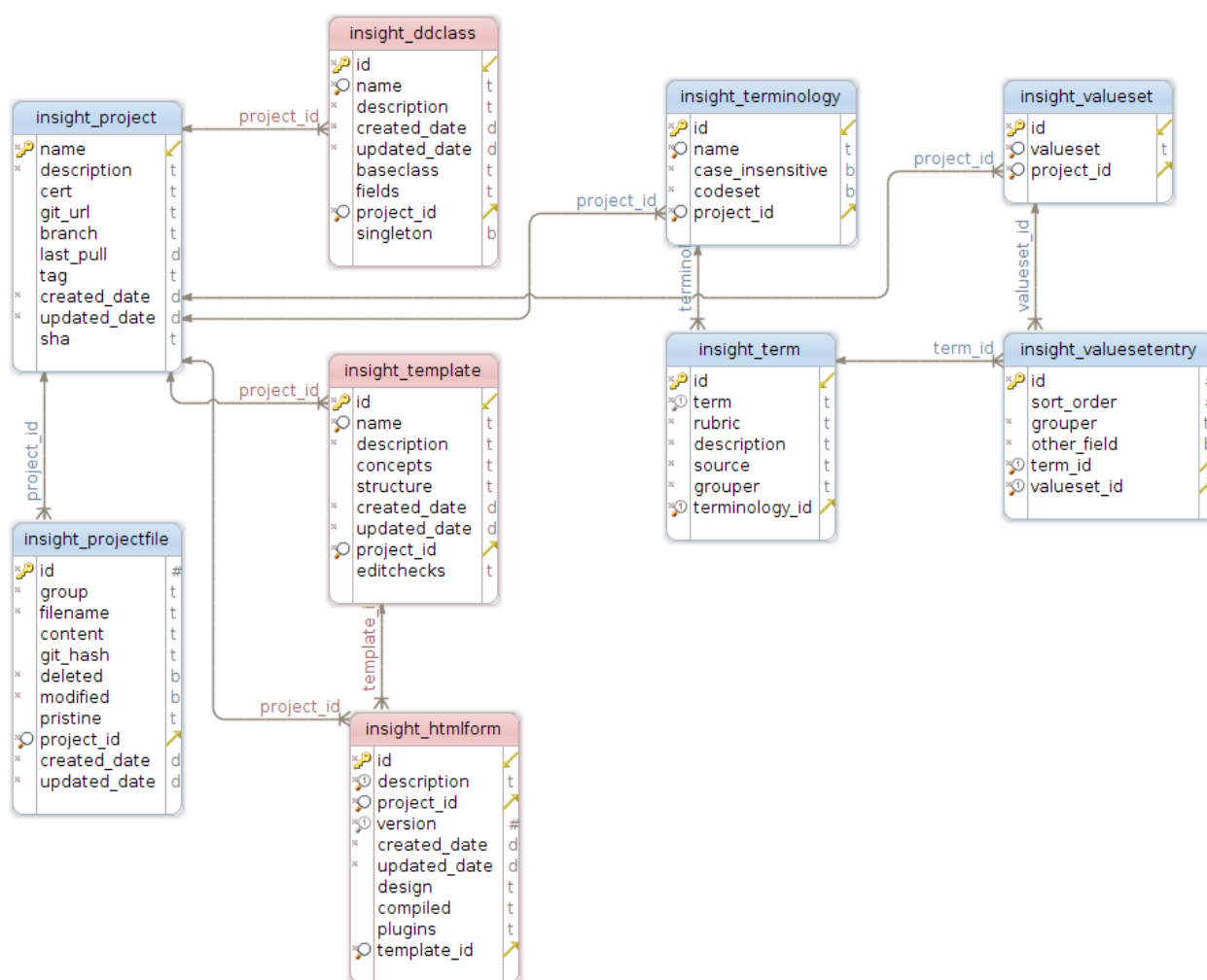
2.4) Meetings



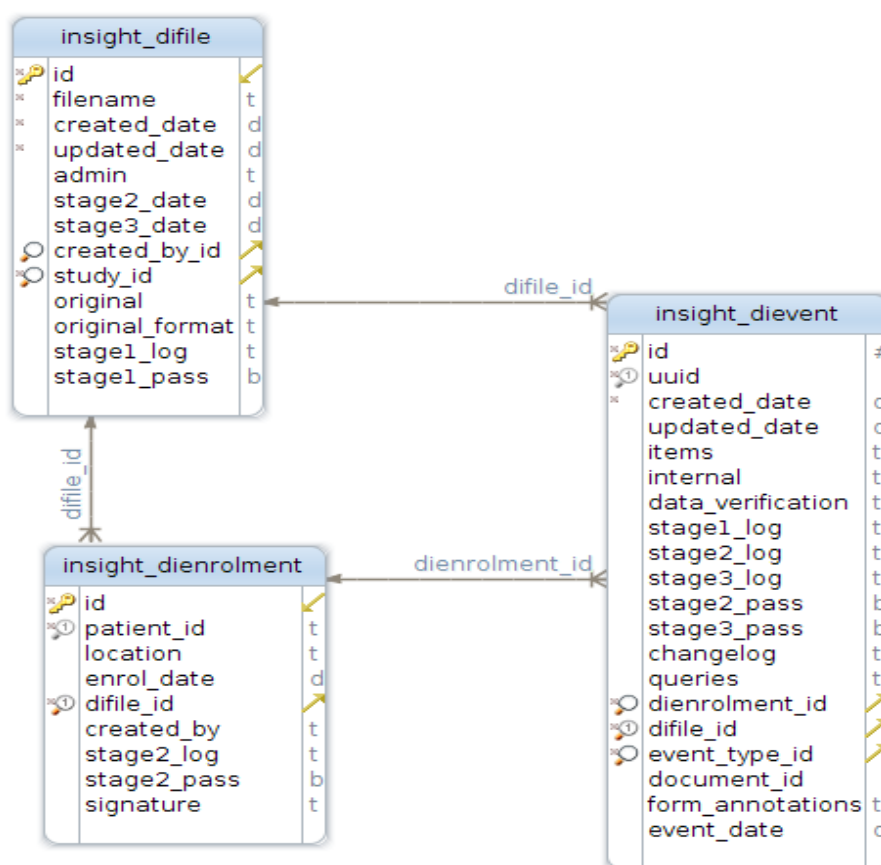
2.5) Deployment



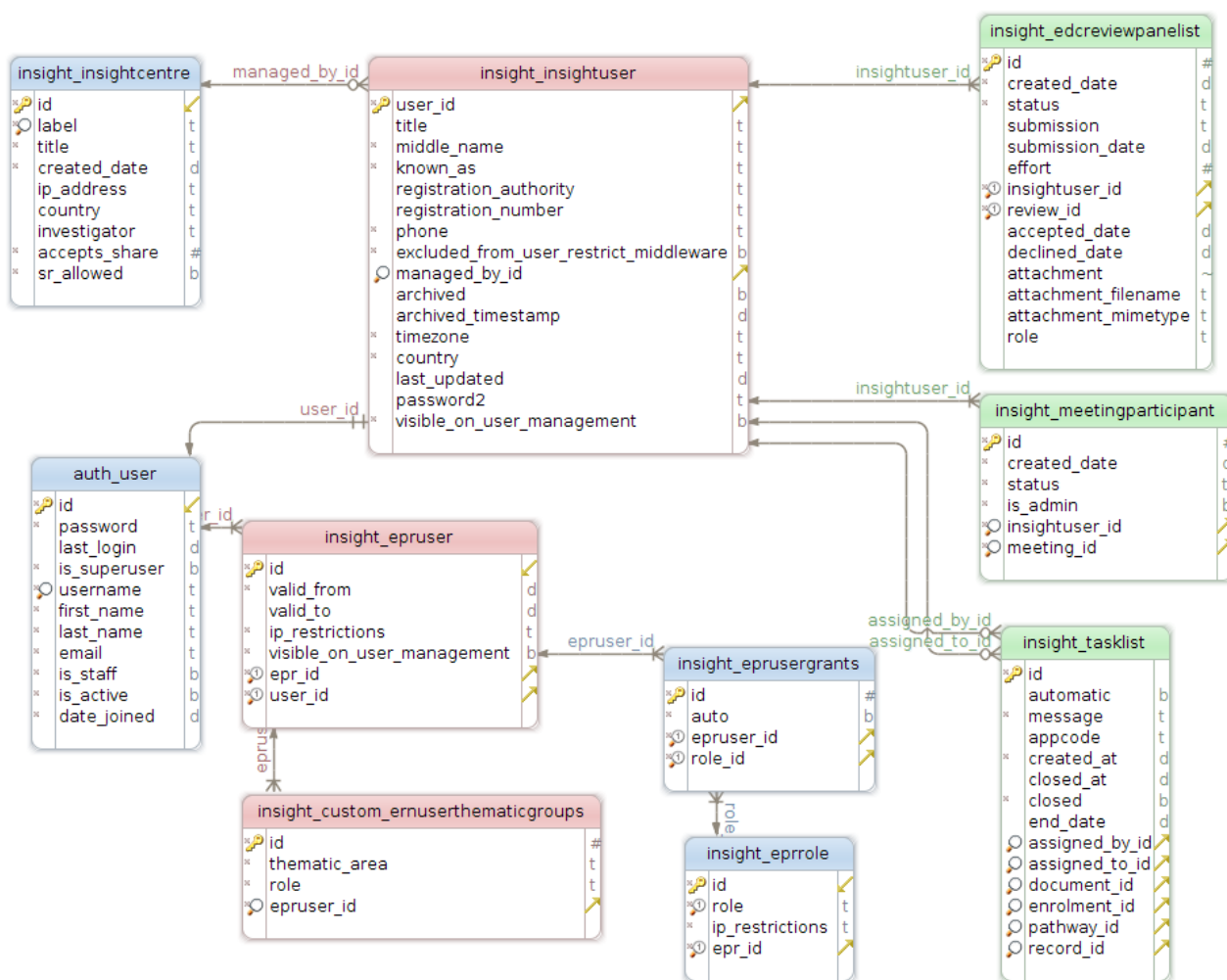
2.6) Form Design



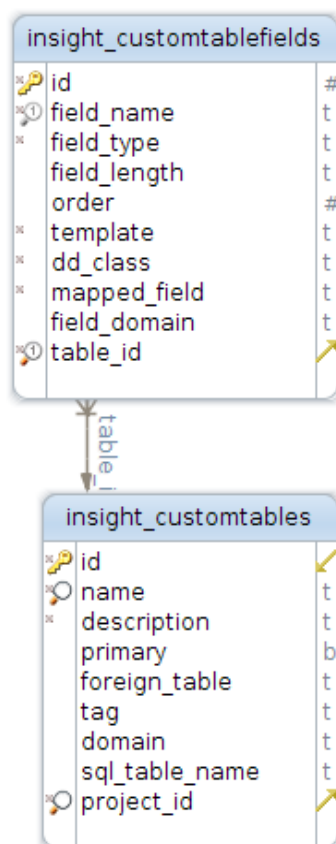
2.7) Import (CDISC)



2.8) Users



2.9) Custom Tables



2.10) CMS











insight_cmssnippet		
id		
slug	t	
content	t	
priority	#	
app_id		
project_id		
customised	b	











insight_cmsmedia		
id		
path	t	
content	~	
content_type	t	
permission	t	
priority	#	
app_id		
project_id		
customised	b	
thumbnail	~	

insight_cmspage		
id		
path	t	
title	t	
content	t	
permission	t	
priority	#	
app_id		
project_id		
customised	b	

insight_cmspageset		
id		
title	t	
priority	#	
customised	b	
pageset	t	
app_id		
project_id		

2.11) Report Definition

insight_report		
	uuid	
	title	t
	definition	t
	project_id	
	source	t
	available_to_dataadmins	b
	owner_id	
	available_to_apps	b
	group_name	t
	sort_order	#

insight_dbview		
	name	
	materialised	b
	description	t
	select	t
	compiled	t
	project_id	
	centrefilter	b
	available_to_sysadmins	b
	available_to_dataadmins	b
	available_to_all	b

VIII) WebRTC video Technology in CPMS

Document type: Technical Note

File name: CPMS- WebRTC TokBox

Document reference: 18082017TB-CPMS

Produced by: OpenApp

Version: 1.0

Release date: 18/08/2017

(1) Video conferencing facility in CPMS

Since video conferencing facility is deemed a vital component in the virtual consultation, the CPMS has implemented the cutting-edge technology in the this area known as “WebRTC”. OpenApp as principle contractor to develop the CPMS has chosen TokBox to provide the video conferencing facility for its reliability and leading position in this novel technology.

(2) What is WebRTC?

WebRTC is a standard enabling plugin-free, Real Time Communications (RTC) in the browser. It includes the fundamental building blocks for high-quality communications such as network, audio, and video components used in voice and video chat applications.

WebRTC provides browsers and mobile applications with Real-Time Communications (RTC) capabilities via simple APIs. The WebRTC components have been optimized to best serve this purpose.

(3) What are the minimum requirements for WebRTC?

WebRTC is currently supported in Google Chrome, and Mozilla Firefox. It can be compiled to support Android and iOS. Additionally, OpenTok plugin is available for Internet Explorer. For sharing screen feature, the user will be requested to install a specifically-developed plug-in for the CPMS.

3.1) Firewalls

A firewall is a network security system that monitors and controls the incoming and outgoing network traffic based on predetermined security rules. TokBox services require access to specific ports. At a minimum the following requirements must be met:

- Open TCP port 443
- Whitelist the following domains: “*.tokbox.com”, and “*.opentok.com”.

3.2) Network

We recommend a minimum dedicated 350kb/s down per downloaded stream, as well as 350kb/s up per uploaded stream to maintain a stable video connection.

(4) Why is WebRTC important?

The WebRTC project is incredibly important as it marks the first time that a powerful real-time communications (RTC) standard has been open sourced for public consumption. It opens the door for a new wave of RTC web applications that will change the way we communicate today.

Significantly better video quality	WebRTC video quality is noticeably better than Flash.
Up to 6x faster connection times	Using JavaScript WebSockets, also an HTML5 standard, improves session connection times and accelerates delivery of other OpenTok events.
Reduced audio/video latency	WebRTC offers significant improvements in latency through WebRTC, enabling more natural and effortless conversations.
Freedom from Flash	With WebRTC and JavaScript WebSockets, you no longer need to rely on Flash for browser-based RTC.
Native HTML5 elements	Customize the look and feel and work with video like you would any other element on a web page with the new video tag in HTML5.

IX) CPMS Service Level Agreements Summary

Document type: SLAs summary

File name: CPMS SLAs overview

Document reference: 9417SLA-CPMS

Produced by: OpenApp

Version: 0.1

Release date: 08.08.2017

(1) SLA Microsoft Azure

Microsoft Cloud Germany provides a separate instance of Microsoft Azure, Office 365, and Dynamics CRM Online delivered from German datacenters with a dedicated network operating inside Germany. A designated German company—a German data trustee—controls access to customer data and the systems and infrastructure that hold customer data. As a result, commercial customers in the European Union (EU) and European Free Trade Association (EFTA) can store and manage customer data in compliance with applicable German laws and regulations as well as key international standards. Microsoft cannot access customer data without approval from and supervision by the German data trustee or customer.

Microsoft Cloud Germany offers customer data storage in two datacenters located in Frankfurt and Magdeburg with georeplication in Germany that supports business continuity and disaster recovery scenarios. Both datacenters adhere to the same rigorous criteria as the global Microsoft commercial cloud. The German data trustee controls and supervises all access by Microsoft or others to equipment used to store customer data for Microsoft Cloud Germany.

All German data trustee personnel adhere to the exacting standards for datacenter operations put forth by Microsoft. Support for Microsoft Cloud Germany comes from 24x7 Germany-based technicians for Office 365 and Dynamics CRM Online, and a hybrid EU-based support staffing model for Azure. The German data trustee supervises all support that requires platform access.

German support business hours are 9 a.m.-5 p.m., Monday to Friday, excluding Bavarian holidays. Initial response time (IRT) shown is for the maximum severity of each offering, and is the fastest IRT available for each offering. Lower severities have a longer IRT.

(2) SLA Osimis

Osimis provide OpenApp with Osimis Enterprise Web Viewer plugin which is a standalone software. The viewer is based on the Orthanc open source Picture Archiving and Communication Server (PACS) which is embedded as part of the CPMS application on Microsoft Azure. This viewer is not only intended for archiving or storage but also manipulating the data, however, Osimis does not host any data recorded in the CPMS.

Availability of the viewers and Orthanc server does not require to be defined since OpenApp is in charge of the deployment of Osimis Enterprise Web Viewer (OEWV) software within the CPMS application. Therefore, the availability of the viewer matches the uptime of the CPMS specified in the framework contract (SANTE/2016/A4/013).

Osimis publish all releases of the viewer in docker containers and make them available to OpenApp to implement within the CPMS. Osimis Business Hours are 8.30 to 18.00 CET, Monday through Friday, excluding Belgian public holidays. Phone: +32 4 353 30 00

(3) SLA TokBox

Availability means that period of time when the CPMS is able to successfully connect to TokBox Enterprise Infrastructure. The enterprise SLA between OpenApp and TokBox is set to provide 99.95% uptime monthly.

TokBox has restricted the media traffic within the European Union based on an approved request provided by OpenApp. That means OpenApp nominated that all API keys for development, test, training, UAT, and production to be associated with geofencing in Europe and all meetings will be streamed within the European Borders. It's important to say that Tokbox servers are used as a relay to connect participants in the meeting. No application data is stored on the tokbox servers.

The Enterprise SLA provide high level of data privacy and compliance with highly-recognized data privacy standards. Through the Enterprise SLA, the CPMS benefit from TokBox HIPAA compliance Business Associate Agreement. TokBox is committed to subjecting all personal data received from European Union (EU) member countries, in reliance on the Privacy Shield Framework, to the Framework's applicable Principles.

All recorded meetings will be stored/archived in Microsoft Azure as the cloud infrastructure hosting the CPMS. None of the recording will be stored/archived in TokBox data centers. TokBox Escalation Service is for customers who have the Enterprise Support package and who need support, 24X7, when a serious issue with the TokBox platform arises. TokBox is dedicated to ensuring you are successful and this team will proactively work with you to ensure you are making effective use of the TokBox platform.

X) CPMS Operational Plan

Document type: Operational documentation

File name: CPMS Operational Plan

Document reference: 18082017OP-CPMS

Produced by: OpenApp

Version: 1.0

Release date: 18/08/2017

(1) Introduction

1.1) Overview

In this document, OpenApp envisages the operational activities and security mechanisms to be done to roll out the Clinical Patient Management System known as CPMS. The CPMS is a secure web-based application to support European Reference Networks in the diagnosis and treatment of rare or low prevalence complex diseases or conditions across national borders. The usage model to benefit from the CPMS is Software as a Service (SaaS).

1.2) Target group

The intended readers of this document are listed in the table below with respect to their roles to create and update this document.

Role	Organizations / Individuals	Document Creation	Document Updates
Contracting authority	DG SANTE	Consulted & Informed	Consulted & Informed
Contractor	OpenApp	Accountable & Responsible	Responsible
Product Owner	OpenApp	Accountable & Responsible	Responsible
Service Desk	OpenApp 2 nd line support team	Consulted	Informed
Development Team	OpenApp and 3 rd line support	Consulted	Informed
System Administrators	OpenApp	Consulted	Responsible

1.3) Scope

Essentially, OpenApp target deliver high quality product that maximises the user experience of the CPMS. Within the scope of this operational plan, OpenApp aims to deliver the following:

- Robust, monitored, measurable, backed-up system
- Appropriate documents for configuring and managing the system
- Comprehensive SLAs with the sub-contracted and third party suppliers
- SOPs (service desk, DR, backup, release management, CCB, and security mechanisms)
- Adequate performance indicators and scalable infrastructure
- Managing resources (nagios, etckeeper, azure tooling, service support)

- Contingency planning (not the expected usage, over usage, security problems, etc.)
- System updates and invoicing/billing scheme
- Security mechanisms

1.4) Milestones

Milestones/activities for Year 1	M1	M3	M6	M9,12,....
CPMS delivered ERNs	24 ERNs	24 ERNs	24 ERNs	24 ERNs
Projected Active users	300	1000	3000	5000
SLA finalization with suppliers	✓			
SLA review with suppliers		✓		
Sub-contractors and Third Party periodic meetings	✓	✓	✓	✓
Manage CCBs / change management	✓	✓	✓	
Calculate and pay suppliers		✓	✓	✓
Invoice EU for usage		✓	✓	✓
CPMS Customization			✓	✓

(2) CPMS Application

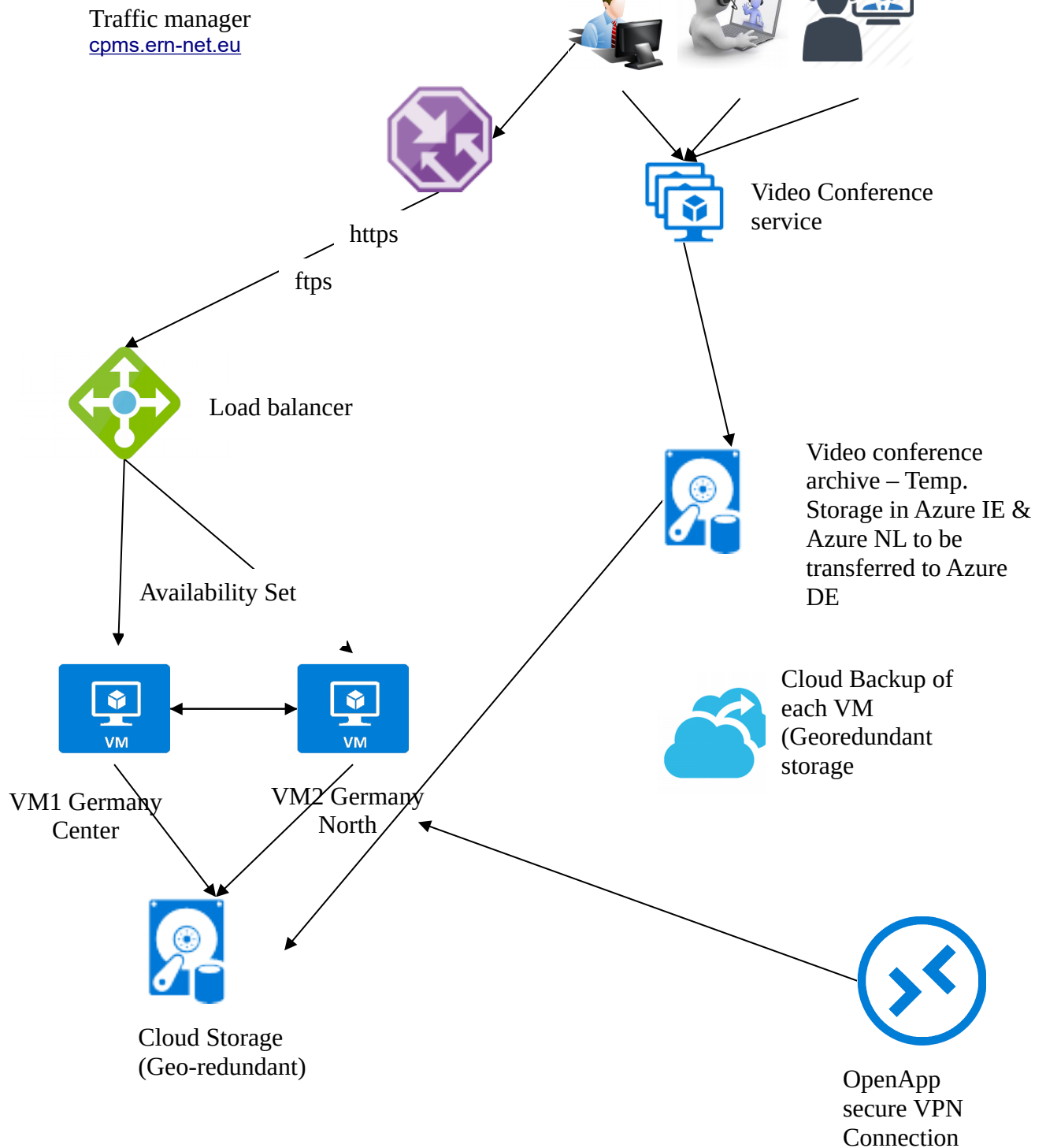
2.1) Infrastructure / URLs and Details

Infrastructure		
Product Name: -	ERN	
System location	Microsoft Azure, Germany	
Hosted by: -	Microsoft Azure	Account #:
DNS: -	ERN controlled	
Tokbox Archive	Microsoft Azure cloud storage	
URLs for applications: -	https://cpms.ern-net.eu	Live system
	https://cpms-acceptance.ern-net.eu	Acceptance system
	https://cpms-training.ern-net.eu	Training System
	https://cpms-test.ern-net.eu	Test system

2.3 Systems Out of Scope for this Manual

The DNS has been provided by DG Sante for the CPMS.

2.2) System Diagram



(3) Security Information

Using Azure Network Security Group rules on the VMs, only permit http, and https. and ftps. ssh connections are only permitted from within the OpenApp LAN. Node to node Postgresql database replication is permitted. **All other connections are forbidden.**

Open ports permitted – 80, 443, 990, 1990, 2990, 3990, 60000-60040 (ftps passive ports).

Restricted ports – 22, (OpenApp office), 5432 (VM to VM)

Specific rules are in place to allow Tokbox storage on Azure for video conference archiving.

OpenApp has restricted the media traffic of the video conferences to data centers only within the European Union.

(4) CPMS Monitoring plan

4.1) Nagios

Nagios is used to monitor systems by OpenApp. Nagios will monitor – system ping, system disk usage, URL response, database status, system load, and total system processes.

Check	Load Average	Ssh connect	Processes running	Free space	URL	Database
Django1	OK - load average: 0.12, 0.24, 0.27	OK	256 processes	81% free	https://cpms-acceptance.ern-net.eu https://cpms-test.ern-net.eu https://cpms-training.ern-net.eu	Primary cpms_acceptance cpms-test cpms-training
django2	OK - load average: 0.00, 0.00, 0.02	OK	130 processes	94% free		Standby
Ern-live-primary	OK - load average: 0.12, 0.24, 0.27	OK	256 processes	92% free	https://cpms.ern-net.eu/	Primary cpms
ern-live-secondary	OK - load average: 0.00, 0.00, 0.02	OK	256 processes	92% free	https://cpms.ern-net.eu/	Standby cpms

4.2) Sentry

At OpenApp, we use Django error tracking system with Sentry as it provides complete stack traces. Sentry's real-time error tracking gives insight into the CPMS deployments and information to reproduce and fix crashes.

4.3) Microsoft Azure

Currently Microsoft Azure Germany has limited monitoring capability, however, this is constantly being updated, with more features being rolled out. As these are added, we will monitor more performance. At this time, we monitor CPU load on the nodes, plus the overall Azure network infrastructure.

Backups on each VM are done and monitored within Azure.

(5) Back Up and Verification Policy

Real-time & Daily Maintenance Routines	Frequency	Report
Check the status of Process on servers	Real-time	By exception
Check the status of external interfaces including OpenApp-VPN or other access	Real-time	By exception
Check for Application errors on the contract systems	Real-time	By exception
Check the purge process runs successfully	Real-time	By exception
Database operation to be monitored in real time	Real-time	By exception
Perform a full database backup & check results	Daily	Monthly
Check application process logs / server logs	Daily	By exception
Validate that all scheduled maintenance tasks are running	Daily	By exception
Monitor time synchronisation logs	Daily	By exception
Check Hard disk space to ensure enough storage for uploading documents to server & archiving historical documents.	Weekly	Monthly

Reactive maintenance shall be undertaken in response to a notification by OpenApp of issues arising during system health monitoring. All reactive maintenance undertaken by OpenApp shall be recorded using the Incident Management system to facilitate historical queries and periodic reporting. A full backup of each VM is taken nightly at 00:00, and stored within the Azure

Germany cloud storage. A separate database backup is taken nightly within separate Azure Germany cloud storage. All original application code is stored in a secure area in OpenApp.

5.1) Backup Policy

OpenApp

Associated items
Delete
Save
Discard

Backup frequency

Daily
00:30
(UTC+00:00) Dublin, Edinburgh, Lisb...

Retention range

☒ Retention of daily backup point.

* At
00:30

For
30

Day(s)

☒ Retention of weekly backup point.

* On
Saturday

* At
00:30

For
52

Week(s)

☒ Retention of monthly backup point.

Week Based
Day Based

* On
First

* Day
Saturday

* At
00:30

For
60

Month(s)

☒ Retention of yearly backup point.

Week Based
Day Based

* In
January

* On
First

* Day
Saturday

* At
00:30

For
7

Year(s)

5.2) CPMS Contingency plan

Fail-over & Disaster recovery

VMs operate in a pair, one in standby mode, with a replicated copy of the primary database. With minor manual configuration defined in OpenApp disaster recovery plan, the standby node can be made active.

Each VM is backed up within the Azure Germany cloud storage, nightly. A full restore of a VM can be performed in approx 2hours and a database restore can be performed much quicker.

The Azure traffic managers are geo-located and fully geographically redundant.

Database Integrity

Currently there is a nightly database backup taken, at 03:00. The backup is taken to external storage within Azure. This can be restored in approx 30 min. Database backups are stored for 30 days and can be modified based on DG Sante requests.

(6) Service support

6.1) Overview

In this project, DG Sante support team is the front line to deal with all reported issues with the CPMS. End users can report issues or send their suggestions and complaints via email “Sante-ERN-CPMS-itsupport@ec.europa.eu” to the support team based in Brussels, Belgium.

OpenApp support team will deal with all issues escalated by the team in Brussels through Zendesk ticketing systems and via email too “support@ern-cpms.zendesk.com” or Phone - +353-1-9059214.

6.2) CPMS end-user requirements

Browsers and operating systems

End-users of the CPMS are requested to utilize modern internet browsers and operating systems to maximize computability and adhere to security best practices. OpenApp highly recommend end users to use one of the following browsers:

- Google Chrome
- Mozilla Firefox
- Internet Explorer 11.0

Please note that when using devices with mac Operating System, all users are requested to access the CPMS with the afore-listed browser as Safari isn't yet supporting the video conference technology used in the CPMS known as WebRTC.

Firewalls

TokBox services require access to specific ports. At a minimum the following requirements must be met:

- Open TCP port 443
- Whitelist the following domains: “*.tokbox.com”, and “*.opentok.com”

The URLs are all within our TokBox domain -- we use subdomains to host specific types of resources.

- static.opentok.com : static files such as our JS library
- enterprise.opentok.com : static files for enterprise line customers (the enterprise version of our JS library is hosted here)
- api.opentok.com : API calls from client side SDKs
- anvil.opentok.com : API calls from server side SDKs
- *.tokbox.com : URI for all media servers

6.3) Service Desk Policies

OpenApp Service Desk Agents will not engage in queries of a clinical nature. Where an incident can not be reproduced by OpenApp, the user maybe referred to their own local support personal to investigate, OpenApp can not be held responsible for incidents not related to its solution, software application or solution being used outside its intended design.

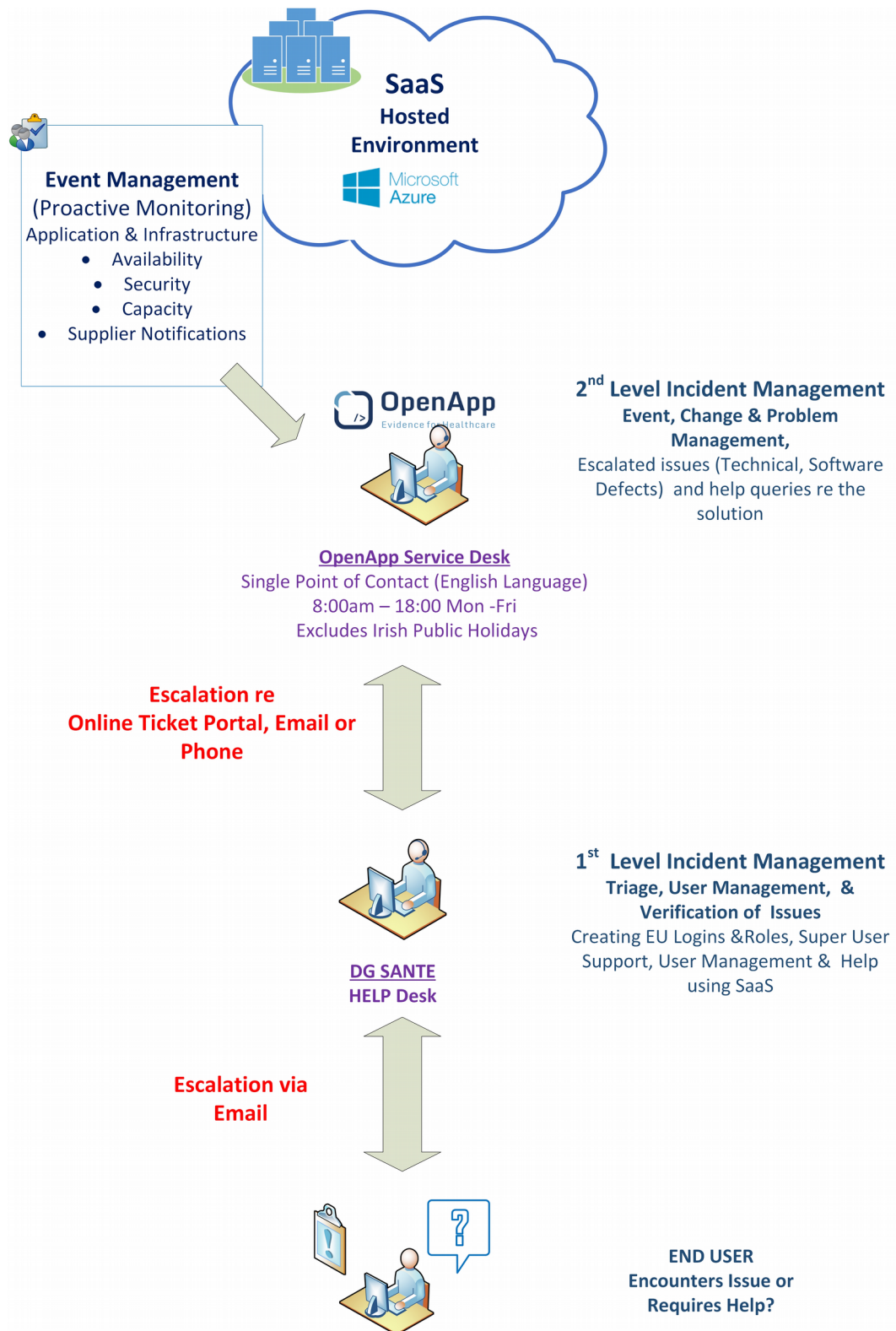
6.4) End User Support and Incident Management

Service Requests that require product enhancements, consultancy or product feedback will be referred to the associated OpenApp project manager. The user will be informed of estimated resolution time where possible. Periodic updates will be made available to the user depending on the incident severity.

An Incident is defined as an unplanned system interruption where there is a significant reduction in the quality of a service or where a software application is not functioning as designed. A Service Request is defined as a request from a user for information, help on using the solution or to request access to a service for a pre-approved change.

Triage is defined as the verification, classification and assignment of incidents and service requests submitted to OpenApp.

The chart below illustrates how the service support team work together in resolving any raised issues by the CPMS end-users.



6.5) SLAs with Sub-contractors and service providers

SLA MS Azure

Microsoft Cloud Germany provides a separate instance of Microsoft Azure, Office 365, and Dynamics CRM Online delivered from German datacenters with a dedicated network operating inside Germany. A designated German company—a German data trustee—controls access to customer data and the systems and infrastructure that hold customer data. As a result, commercial customers in the European Union (EU) and European Free Trade Association (EFTA) can store and manage customer data in compliance with applicable German laws and regulations as well as key international standards. Microsoft cannot access customer data without approval from and supervision by the German data trustee or customer.

Microsoft Cloud Germany offers customer data storage in two datacenters located in Frankfurt and Magdeburg with georeplication in Germany that supports business continuity and disaster recovery scenarios. Both datacenters adhere to the same rigorous criteria as the global Microsoft commercial cloud. The German data trustee controls and supervises all access by Microsoft or others to equipment used to store customer data for Microsoft Cloud Germany. All German data trustee personnel adhere to the exacting standards for datacenter operations put forth by Microsoft.

Support for Microsoft Cloud Germany comes from 24x7 Germany-based technicians for Office 365 and Dynamics CRM Online, and a hybrid EU-based support staffing model for Azure. The German data trustee supervises all support that requires platform access.

German support business hours are 9 a.m.-5 p.m., Monday to Friday, excluding Bavarian holidays. Initial response time (IRT) shown is for the maximum severity of each offering, and is the fastest IRT available for each offering. Lower severities have a longer IRT.

Why Trust the Microsoft Azure (Germany)

Privacy: ISO 27018	Privacy: EU Model Clauses (MCs)	Privacy: Contractual Terms	Regulated Sectors: Financial Services	Regulated Services: Healthcare
Microsoft is the first cloud provider that complies with and commits to this standard for protecting customer content. Salesforce is not ISO 27018 compliant yet. Google does not contractually commit.	First major cloud provider to not only offer MCs, but to receive Article 29 Working Party validation that these meet current EU standards. Google and Salesforce have not received any Article 29 Working Party validation yet.	Microsoft commits to not changing our privacy commitments during the term of the agreement. Google, Amazon, and Salesforce reserve the right to change their privacy commitments during the term of their agreement.	We have created a compliance program specifically tuned for FSI customers and authority to operate or no objection in approximately 20 jurisdictions around the world.	We offer compliance (as a standard part of our offering to all customers) with US health care laws (HIPAA) by providing a Business Associate Agreement built in partnership with customers, partners and health care expert organizations.
Regulated Services: Law Enforcement	Audit Controls	Cybersecurity	Government Requests for Data	Non Assertion of Patent
We offer commitments under Criminal Justice Information Systems (CJIS) Security Policy Requirements for law enforcement agencies that comply with FBI security requirements and background checks. Google, Amazon and SF do not.	Microsoft commits to comply to a yearly audit under a number of security, privacy and audit control standards, like ISO 27001/27002/27018, SSAE 16/ISAE3402. All of our security policies and full audit reports are made available to customers and if necessary, their regulators.	Microsoft is the only company actively targeting cyber criminals and working with law enforcement to take down their ability to infect devices and systems with harmful, criminal malware. Neither Google, Amazon, nor Salesforce are taking this step.	Microsoft makes a contractual commitment to ensure any requests for data must follow due legal process. In addition, we allow the law of the jurisdiction of the data center to govern which authorities may have lawful access.	Microsoft does not request a NAP clause (effectively a license to all of our customer's IP rights) to use our cloud services. Amazon does require a NAP clause in all of its agreements, including click to use.

SLA Osimis

Osimis provide OpenApp with Osimis Enterprise Web Viewer plugin which is a standalone software. viewer is based on the Orthanc open source Picture Archiving and Communication Server (PACS) which is embedded as part of the CPMS on Microsoft Azure. This viewer is not only intended for archiving or storage but also manipulating the data, however, Osimis does not host any data recorded in the CPMS.

Availability of the viewers and Orthanc server does not require to be defined since OpenApp is in charge of the deployment of Osimis Enterprise Web Viewer (OE WV) software within the CPMS application. Therefore, the availability of the viewer matches the uptime of the CPMS specified in the framework contract (SANTE/2016/A4/013).

Osimis publish all releases of the viewer in docker containers and make them available to OpenApp to implement within the CPMS.

Service Desk Services	Osimis	OpenApp
Provide second line support for End Users of the SaaS solution		√
Provide third line support (Email & Telephone) for the Client on OE WV within the SaaS solution	√	
Carry out Incident Management on all tickets raised relating to OE WV within the SaaS solution	√	
Solution Maintenance & Managed Service	Osimis	OpenApp
Software maintenance service to minimise software defects on OE WV within the SaaS solution	√	
Provide packaged versions of the components of the OE WV within the SaaS solution	√	
Maintain CE-marking of the viewers	√	
Service Management	Osimis	OpenApp
Carry out Problem Management and Continual Service Improvements initiatives	√	√
Manage Solution Change Management & Release Management Activities	√	
Collaborate in testing on UAT before the release to EC.	√	√
Provide Escalation contacts for Incident Escalation	√	√

Provide contact to authorize disaster recovery	√	√
Provide contact for security incident escalation	√	√
Participate in monthly and quarterly Service Reviews	√	√

OpenApp will receive all issues reported by the first line support on Zendesk as ticketing system. Subsequently, OpenApp service desk will escalate the relevant tickets to Osimis Zendesk. Osimis support agents may only view Users' screens and make suggestions to resolve issues. OSISD agents will never request remote control of a remote device.

Where an incident can not be reproduced by the Osimis support, the User may be referred to their own local support personnel to investigate, Osimis can not be held responsible for incidents not related to its solution, software application or solution being used outside its intended design. Where Osimis have incurred expense in the investigation of repeated issues that are not related to the Osimis solution or are the responsibility of Client appointed third parties, the Client shall be charged by Osimis.

Client end User may be required to cooperate with the OSISD to resolve issues as organization security policies may be the root cause of technical incidents. The OSISD will endeavour to work with local IT support personnel directly where possible to allow end Users carry out their normal working duties without unnecessary interruption.

Incidents are logged via email to support@osimis.io or via Zendesk (osimis.zendesk.com)

[Business Hours are 8.30 to 18.00 CET, Monday through Friday, excluding Belgian public holidays.](#)
[Phone: +32 4 353 30 00](#)

Osimis Business Hours are 8.30 to 18.00 CET, Monday through Friday, excluding Belgian public holidays. Phone: +32 4 353 30 00

SLA TokBox

Availability

Availability means that period of time when the CPMS is able to successfully connect to TokBox Enterprise Infrastructure. The enterprise SLA between OpenApp and TokBox is set to provide 99.95% uptime monthly.

Regional Routing

TokBox has restricted the media traffic within the European Union based on an approved request provided by OpenApp. That means OpenApp nominated that all API keys for development, test, training, UAT, and production to be associated with geofencing in Europe and all meetings will be

streamed within the European Boarders. It's important to say that Tokbox servers are used as a relay to connect participants in the meeting. No application data is stored on the tokbox servers

Data Privacy

The Enterprise SLA provide high level of data privacy and compliance with highly-recognized data privacy standards. Through the Enterprise SLA, the CPMS benefit from TokBox HIPAA compliance Business Associate Agreement. TokBox is committed to subjecting all personal data received from European Union (EU) member countries, in reliance on the Privacy Shield Framework, to the Framework's applicable Principles. More information is provided in the appendix of this document.

Meeting Archiving

All recorded meetings will be stored/archived in Microsoft Azure as the cloud infrastructure hosting the CPMS. None of the recording will be stored/archived in TokBox data centers.

TokBox Escalation Service is for customers who have the Enterprise Support package and who need support, 24X7, when a serious issue with the TokBox platform arises. This document explains how to use the service. TokBox is dedicated to ensuring you are successful and this team will proactively work with you to ensure you are making effective use of the TokBox platform.

TokBoxer	Title	Account Role	Contact
Paul Reeves	Vice President, Customer Success	Champion	Email: paulr@tokbox.com Cell: 408-655-3918
Taha Syed	Customer Success Manager	Account Manager	Email: taha@tokbox.com Cell: 512-203-1149
Badri Rajasekar	CTO	Champion	Email: badri@tokbox.com Cell: 650.799.0452

To report non-urgent issues or ask questions about the platform 24X7, send an email to “support@tokbox.com” or contact your Account team.

Escalation Service Overview

The TokBox Escalation Service allows you to get assistance when a mission critical service of the TokBox platform is not working as designed. After you report the issue, we'll work to understand the issue and create a plan to address the issue, and communicate progress on resolution.

The best way to start an escalation that can be quickly addressed is to navigate to this form and file a ticket : <https://support.tokbox.com/hc/en-us/requests/new>:

1. Navigate to our ticket submission form here .

2. Enter your name, a summary, and detailed problem description. See below for recommended information we need to rapidly troubleshoot.
3. Click the “Urgent in-Production Failure” box. This will enable notification to relevant team members.
4. Provide the required information and submit the ticket.
5. The Escalation Manager or your Account Manager will reach out to you and keep you posted via email and phone.

For effective service, include sufficient information to allow TokBox to reproduce the problem, including the following: 1) description of the problem; 2) Customer device and OS version; 3) version of the OpenTok SDK being used; 4) the session id and token that had problems; 5) how often this problem has been experienced; 6) type of connection being used (i.e., 3G, LTE, Corporate WiFi, Public WiFi, Home WiFi); 7) the available bandwidth when this problem was experienced, if known; 8) steps on how to reproduce the problem and the expected result; 9) screenshots, if any, of the problem; 10) if reporting a crash, send a copy+paste logs/full back trace ('lldb bt all') to <https://gist.github.com> and link it; and 11) information related to your application necessary to verify that TokBox APIs are correctly implemented.

Escalation Communication

TokBox will respond and address the issue per our agreement but your TokBox Account Manager or the acting Escalation Manager on the 24X7 Support Team will provide timely, ongoing updates to the person who started the escalation, and the list of contacts you share.

The following teams and people will ensure any escalation is handled professionally and efficiently. If you don't receive a timely response after submitting your ticket, contact the following people using steps/times recommended.

TokBox

Step	Time (after ticket submission)	TokBoxer	Title	Account Role	Contact
1	30 minutes	Taha Syed	Customer Success Manager	Account Manager	Email: taha@tokbox.com Cell: 512-203-1149
2	1 hour	Paul Reeves	Vice President, Customer Success	Champion and Sponsor	Email: paulr@tokbox.com Cell: 408-655-3918
3	1.5 hours	Badri Rajasekar	CTO	Champion	Email: badri@tokbox.com Cell: 650-799-0452

6.6) CPMS Technical support

System updates

Code, software, and technology updates may have to be carried out during scheduled releases to ensure performance, capacity management, security standards and avoid vendor obsolescence. Periodic updates will be made available to the contracting authorities on the testing environment before being available on production depending on the incident severity and customer requirements

Second level support

OpenApp has been commissioned as the prime contractor to develop the CPMS, therefore, OpenApp will look after any custom development and all technical fixes.