NHS
National Institute for
Health Research

Clinical Research Network

Central Portfolio Management System

Unit 1: User Orientation

CPMS Build: - 0.6.13.901

CONTENTS

INTRODUCTION

About this document

This document provides basic information on how to use the CPMS system, and is intended as a ‘first read’ for new users. It is part of a set of document ‘units’, which together form a complete reference to the system. The document set is organised as follows:

- Unit 1: User Orientation
- Unit 2: Commercial Studies
- Unit 3: Non-Commercial Studies
- Unit 4: Recruitment & Research
- Unit 5: Dashboards & Reporting
- Unit 6: Reference

It is recommended that all users familiarise themselves with Units 1 & 5. The remaining units are optional depending on the user role and business area. Unit 6 is provided for those users who need supplementary information about the terminology used in the other documents, and expands on the user roles CPMS recognises.

What is CPMS?

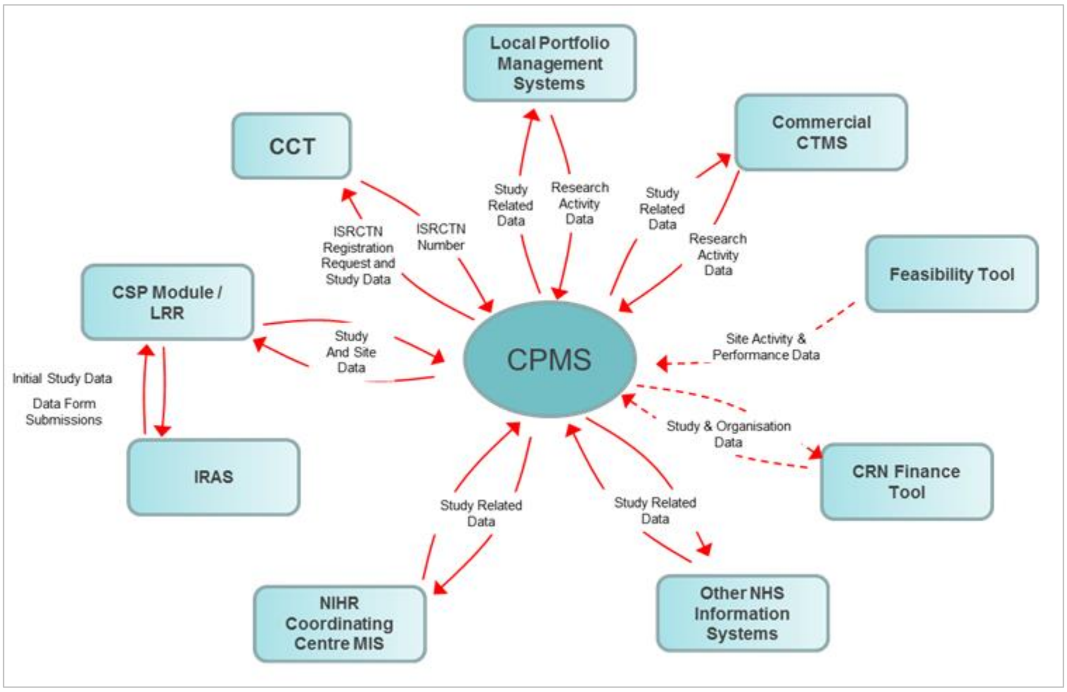
CPMS (Central Portfolio Management System) is an integrated, national data and information system designed to capture, deliver, monitor and manage high quality research study data. It enables the NIHR Clinical Research Network (CRN) to effectively manage its portfolio through the acquisition, processing and reporting of data from commercial and non-commercial study submissions.

The user’s primary interaction with CPMS is through a web-based application which shares information and interacts with a number of other NIHR CRN systems:

- **CSP (Coordinated System for Gaining NHS permission) –** the standardised system for gaining NHS Permission for commercial and non-commercial clinical research studies in England. CSP is used for commercial and non-commercial studies that are either automatically eligible or adopted into the NIHR CRN Portfolio.
- **IDM (Identity Management database**) **–** the database that maintains a list of registered users of research information. New users are able to register for an account in IDM and reminders and password changes will be centrally triggered when logging in.
- **RTS (Reference and Terminology Service) –** the service which provides information on NHS organisations and people.
- **UCM (Universal Content Management)** – the NIHR document storage facility supplying documents relating to research studies.
- **CCT (Current Controlled Trials)** – the database of studies that qualify for controlled trial status.

- **LPMS (Local Portfolio Management System) –** independent localised management systems that are used to manually manage and support a list of studies. Users change, upload and validate recruitment data, input study information into CPMS manually, using bulk upload or through their Local Portfolio Management System (LPMS).
- **CTMS (Commercial Clinical Trials Management System)** – a system for the exchange and management of clinical trials data used by commercial organisations.

The diagram below shows how CPMS shares and exchanges information with a range of other NIHR systems.



What is CPMS replacing?

CPMS is intended as a replacement for the following systems and tools:

- **UK Clinical Research Network Portfolio** - the single information system which holds the portfolios for England, Northern Ireland, Scotland and Wales. This database captures activity data, provides analysis tools to facilitate management of current studies, and tracks the feasibility of new submissions. Activity data from the NIHR CRN Portfolio is used to inform the allocation of NHS infrastructure for research (including support costs) and for performance management.
- **Interim Industry Tracker (IIT)**

  The internal network tool that captures and tracks life-sciences industry (company user) applications.
- **Industry Application Gateway (IAG)**

  The tool used by the Life-sciences industry (company user) to submit studies for consideration by the Specialties. CPMS replaces IAG by providing a workflow to analyse and advise if the study is eligible for NIHR CRN support, and match study support with services offerings.

What are the benefits of using CPMS?

There are specific individual benefits for commercial and non-commercial users and in general terms, for all users, CPMS provides the following benefits:

- **Study View** - all users have access to the study view. Returned results are restricted appropriately depending on the user's permissions.
- **Reporting** - the data created and received by CPMS during the lifecycle of a study can be reported on to provide information that supports performance and operational management. Users also have a configurable dashboard page which provides dynamically updated key statistics in graphical form.
- **Public Search –** CPMS provides a public search facility to allow members of the public to view study information once the study has reached a defined stage.
- **Study Record –** CPMS provides a centralised study record, translating the free-text information received from (or through) CSP into more manageable, consistent, and reportable formats.
- **Study Matching** - studies created at the start of the commercial process have the option to be matched against an existing study. Also used when manually creating a study, for example a study led by a devolved administration.
- **Site Identification** - sites identified only by name are "mapped" in order to fully qualify the site information.

Who can use CPMS?

The following table lists the business entities which interact with the system.

Organisation	Description	Interaction with CPMS
Department of Health (DH)	The governmental body responsible for policy implementation	Management information reporting
Clinical Research Network National Coordinating Centre (CRNN CC)	Responsible for implementation of NIHR CRN and delivery of infrastructure to support clinical research	Making decisions regarding a study's eligibility for NIHR CRN support Performance management of specialities through management information Allocation of funding to LCRNs

Organisation	Description	Interaction with CPMS
Specialty Leads	Responsible for management & delivery of portfolio studies within their assigned LCRN	Eligibility and feasibility process for commercial and non-commercial studies (which are not automatically eligible) Performance management of studies Performance management of LCRNs through management information
Local Clinical Research Networks (LCRNs)	Provides the infrastructure and resources to support study activity in a local area	Referencing the list of studies for allocation of network resource Commercial eligibility and feasibility process
Clinical Trials Units (CTU)	Responsible for management of individual studies	Uploading recruitment data, input and management of study information
Researchers	Responsible for managing their study record on the portfolio (if not delegated to a CTU)	Uploading recruitment data, input and management of study information
Funders	Non-commercial organisations which fund research in the NHS	None currently – provided with reports on their funded studies on an *ad hoc* basis
Industry	Commercial organisations which fund research in the NHS	Providing recruitment data. Reports provided on their funded studies
Public	Anyone with an interest in clinical research from a non-professional perspective	Viewing the public list of studies supported by the CRN

System requirements

The minimum specification that your computer needs to run CPMS is as follows:

Browser	Internet Explorer 7+ Firefox 3 Safari 3 JavaScript enabled
Screen resolution	1024x768 (minimum)

User roles

CPMS users each have one or more specific user roles. A role is a collection of permissions which defines what a user can and cannot do within CPMS. Examples of specific user roles within CPMS are:

- Roles for a specific study.
- Roles for an organisation related to a study, e.g. a Company Representative for the company originating a commercial study.
- Specific general roles, e.g. PAT Administrators.
- Roles linked specifically to a specialty, e.g. CSG Member Experts.
- Specific delegated roles, e.g. an Industry Team Representative (ITR**)** for the selected lead and supporting specialties.

For a full list of commercial & non-commercial user roles and the workflow task stages assigned to them, see *Unit 6: Reference*.

GETTING STARTED

Logging in

Before you can access CPMS, you must have a registered user account with the NIHR Identity Management System (IDM) and have been granted a user role that defines what you can do in CPMS. Existing users of the Portfolio database, CSP or NIHR Portal will have their existing accounts migrated to CPMS.

The information you see on the screen is relevant to you and your role. Your role defines exactly which tasks you can perform and what you can see. For example, users assigned the role of PAT Administrator can edit all items in a non-commercial study (apart from a few exception fields), whereas users assigned the role of Industry Team Representative cannot edit any items in a non-commercial study.

You should have received your logon details by email. If you do not received them or need access for yourself or additional staff members, please contact NIHR CPMS support.

Starting CPMS

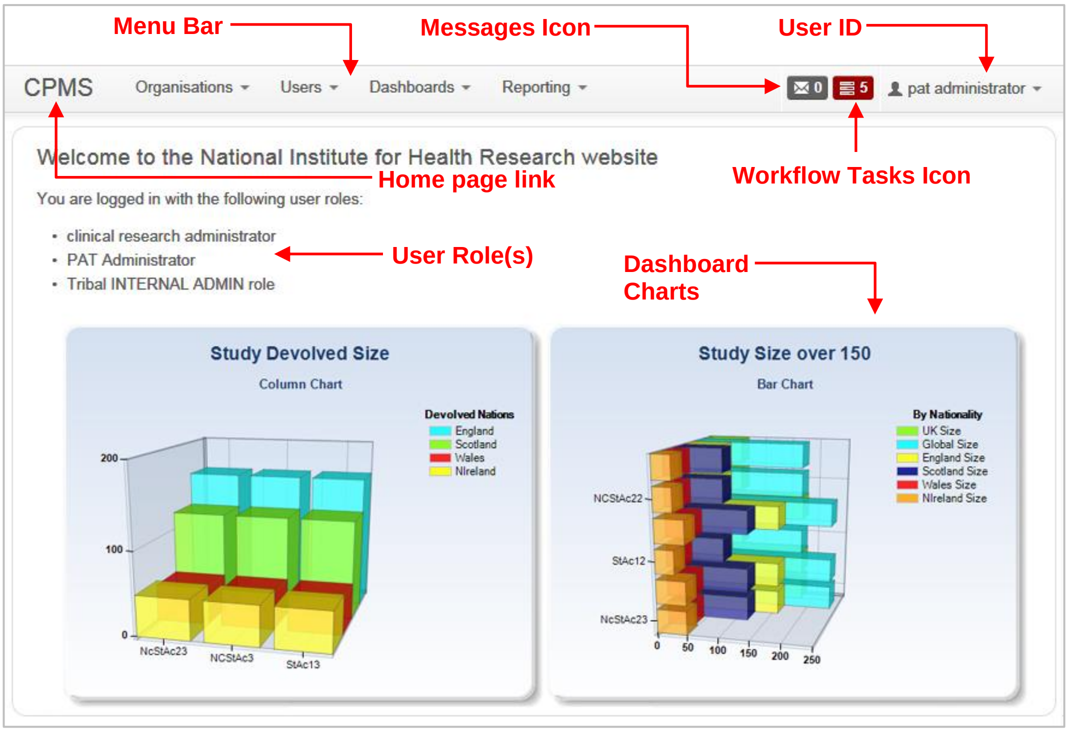
Use the following procedure to start a session in CPMS.

1. Log in to the NIHR IDM using the credentials provided.

   Your **NIHR IDM Portal Home page** is displayed. It contains a list of the NIHR CRN applications that you have permission to access.

2. Click on the CPMS icon.

   The CPMS **Welcome** page appears. This is your gateway to all the features, functions, and data that you have access to. You can return to this page at any time by clicking the **CPMS** home page link at the top left of the screen.



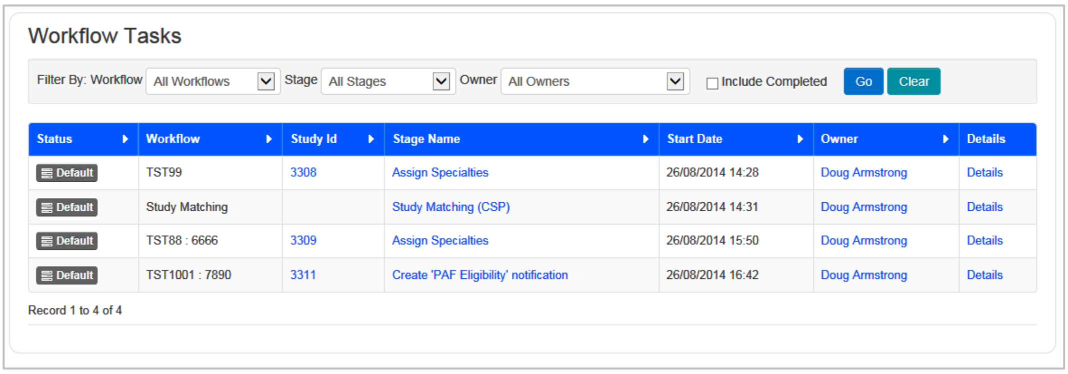
MANAGING WORKFLOW TASKS

Workflow tasks are the primary means of performing actions in CPMS. Tasks may be triggered by another user - for example, a Company Representative making a new study submission. They may also be triggered automatically once a previous task has been completed - for example, if a Central Representative rejects a study submission, the Company Representative will receive a task requiring him/her to update the submission.

Using the Workflow Tasks list

To access your **Workflow Tasks** list, click on the **Workflow Tasks** icon. This displays the number of outstanding tasks you have in your list.

The **Workflow Tasks** list contains a list of all the tasks currently assigned to you (as an individual), or to others in your assigned user group. You can use the **Filter By** controls to specify how many tasks are displayed by selecting the appropriate criteria and then clicking **Go** to refresh the list.



Your **Workflow Tasks** list shows the following information:

- **Status** – indicators appear in different colours depending on the priority level of the workflow. The colours are based on the following rating levels:

Default	Default level used for tasks that have no set limits
Level 1	Start level for workflow tasks
Level 2	Middle range level for workflow tasks
Level 3	Highest level for workflow tasks

- **Workflow** – this column displays the acronym assigned to the study the task relates to.
- **Study Id** – this column displays the CPMS Study ID. You can click on this link to edit the study details. Note that studies which have not yet been matched to a CPMS study record (or created as a new CPMS record) will not display anything in this column.
- **Stage Name** – displays the name of the workflow task. Clicking on this entry allows you to view and/or perform the displayed task.

- **Start Date –** displays the date and time at which the workflow task was created.
- **Completed Date –** displays the date and time at which the workflow task was completed. This column only appears if you select the **Include Completed** check box in the **Filter By** section.
- **Owner** – displays the current owner of the workflow task. See Taking ownership of a task.
- **Details –** this feature is for testing purposes only, and should not be accessed unless you are specifically asked to do so by support staff.

You can sort the entries in the **Workflow Tasks** list on any of the displayed columns by clicking on the arrow next to the column heading. The direction of the arrow indicates the order of sorting.

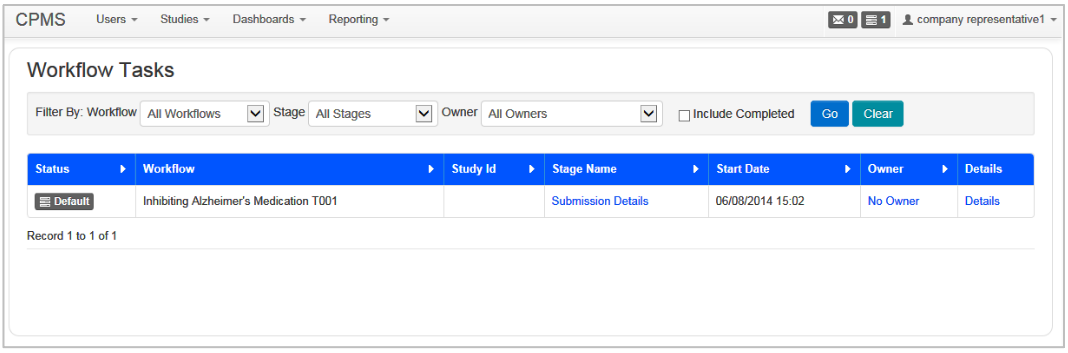
- Column sorted in *ascending* order:

- Column sorted in *descending* order:

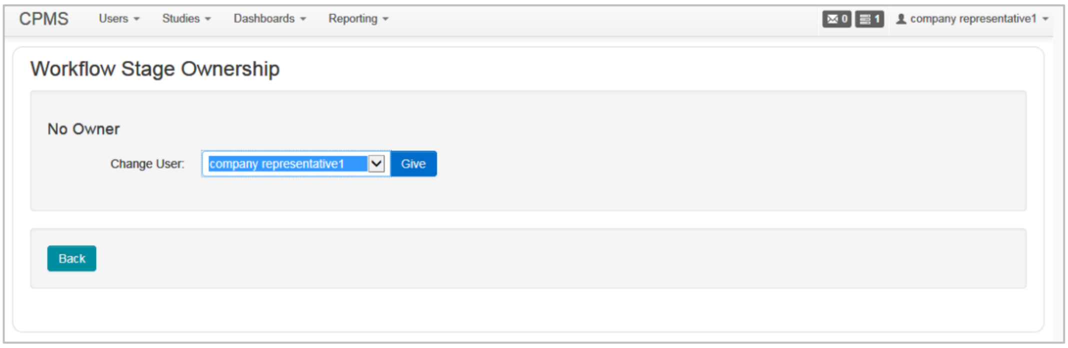
Taking ownership of a task

Before you are able to process tasks in the **Workflow Tasks** list, you must first take ownership of the task. This applies both to tasks without an owner and those with an owner other than yourself.

1. On the toolbar, click **Workflow,** and then select **Workflow Tasks** from the drop-down menu.
2. In the **Owner** column of the task, click **No Owner** (for some tasks, this may show a different owner other than yourself).

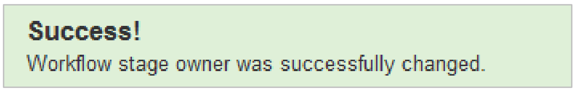


The **Workflow Stage Ownership** page opens.



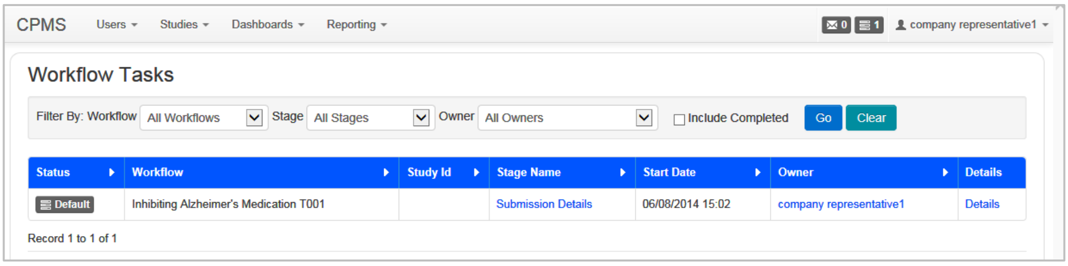
3. Click the down arrow next to the **Change User** field, and select your name from the drop-down menu.
4. Click **Give**.

   The system responds with a confirmation message.



5. Click **Back**.

   You will then return the **Workflow Tasks** web page, which now displays you as the owner of the task.



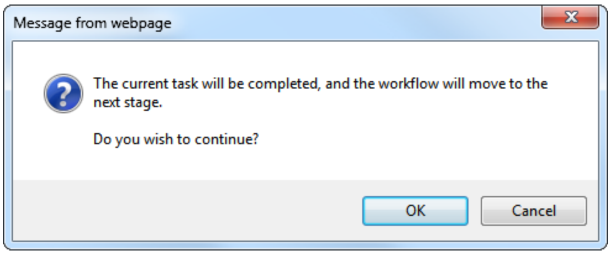
Note: You can also take ownership of a task after selecting it in the list, by clicking on the **Take Ownership** button in the warning box which appears above the **Study Submissions** list as shown below.

Completing workflow tasks

A typical workflow task involves entering a number of data items on a page in the form of free text, drop-down lists, radio buttons and check boxes, and then submitting the page for processing.

There are also a number of standard controls on each page as follows:

The **Submit** button is used to indicate that data entry is complete, and that the workflow should advance to the next stage. A dialog box will appear, asking for confirmation that the task is complete.

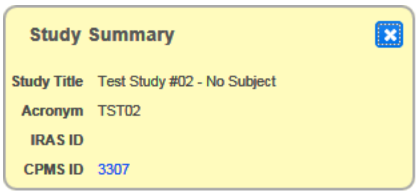


Click **OK** to complete the task, or **Cancel** to return to the current page. Note that on some notification task pages, the button is titled **Next Stage**.

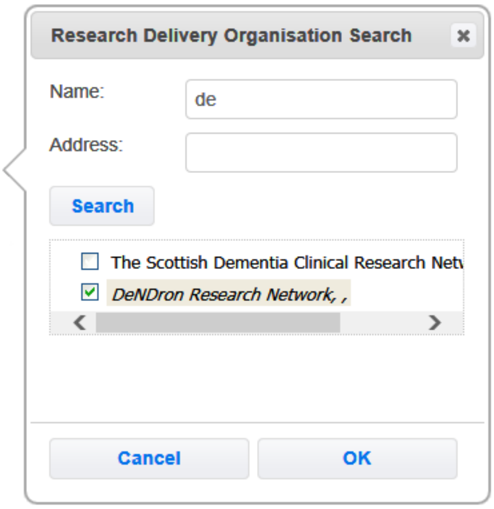
The **Back** button allows you to return to the **Workflow Tasks** list without completing the current task, and functions in the same way as using the 'back' button in your browser. No entered data will be saved when using this button unless you use **Save As Draft** first.

The **Save As Draft** button allows you to save any partial data you have entered on a page, so you can return to the task later and complete the data entry fields. This is particularly useful for entering study data, as there may be a large amount of data entry necessary to complete all the required fields.

Pages related to a matched study (that has a record in CPMS) will display a **Study Link** button in the top right corner. Clicking on this button displays a pop-up with summary information about the study. Clicking on the **CPMS ID** will take you directly to the **Edit Study** page.

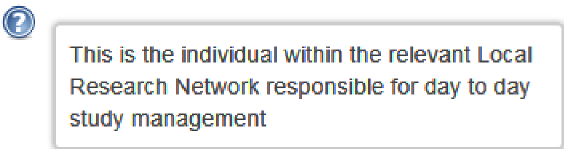


Some data entry fields contain a search feature, indicated by the **Search** icon shown above. Clicking on the icon displays a search box which assists you in looking up a recognized data item from a large list of alternatives.

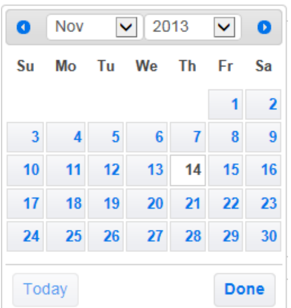


In the example above, you can enter any search text in the **Name** and/or **Address** fields and then click **Search** to bring up a list of entries containing those letters. You can then select one or more entries in the list using the check box next to the entry, and then click **OK** to add your selection to the data entry field on the task page.

Some data entry fields contain pop-up help, which gives you additional information about what to enter in the field. Move your cursor over the **Tip** icon to activate the feature.



Data entry fields which require you to enter a date will display the **Calendar** icon. This allows you to select a valid date from a pop-up calendar. Select a date and then click **Done** to enter it into the field.



WORKING WITH MESSAGES

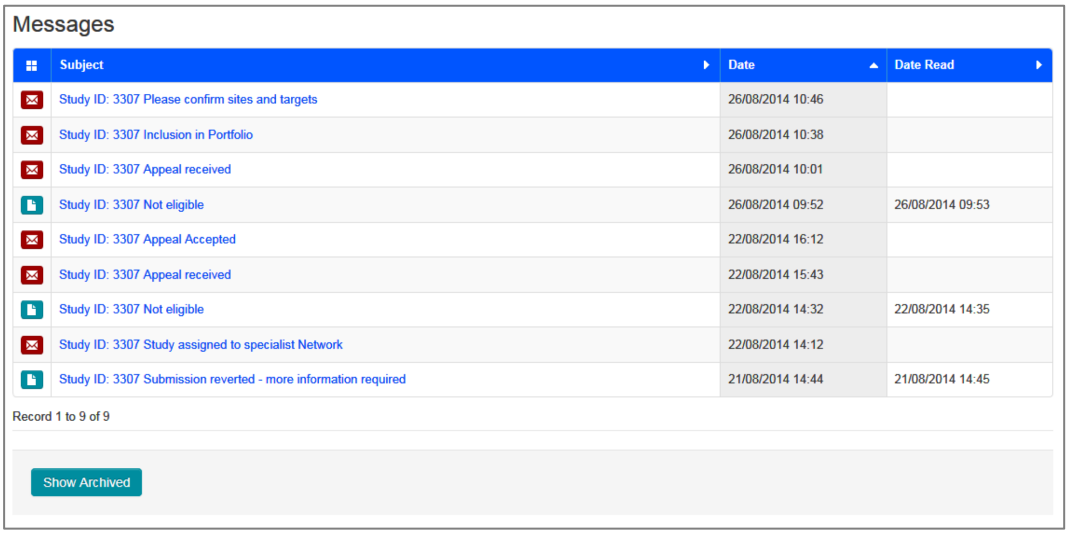
CPMS has a built-in messaging feature which allows efficient communication between all users of the system. Messages are the primary means of notification, for example, when a decision about a study's eligibility has been made. CPMS also permits the sending of messages through the user's own external e-mail system when communicating with users who do not have access.

Using the Messages list

To access your **Messages** list, click on the **Messages** icon. This displays the number of currently unread messages you have in your list.

6

The **Messages** list contains a list of all the messages sent directly to you as a CPMS user, displaying the status of the message, the subject, date sent and date read (if applicable).


Messages

	Subject	Date	Date Read
	Study ID: 3307 Please confirm sites and targets	26/08/2014 10:46	
	Study ID: 3307 Inclusion in Portfolio	26/08/2014 10:38	
	Study ID: 3307 Appeal received	26/08/2014 10:01	
	Study ID: 3307 Not eligible	26/08/2014 09:52	26/08/2014 09:53
	Study ID: 3307 Appeal Accepted	22/08/2014 16:12	
	Study ID: 3307 Appeal received	22/08/2014 15:43	
	Study ID: 3307 Not eligible	22/08/2014 14:32	22/08/2014 14:35
	Study ID: 3307 Study assigned to specialist Network	22/08/2014 14:12	
	Study ID: 3307 Submission reverted - more information required	21/08/2014 14:44	21/08/2014 14:45

Record 1 to 9 of 9

Show Archived

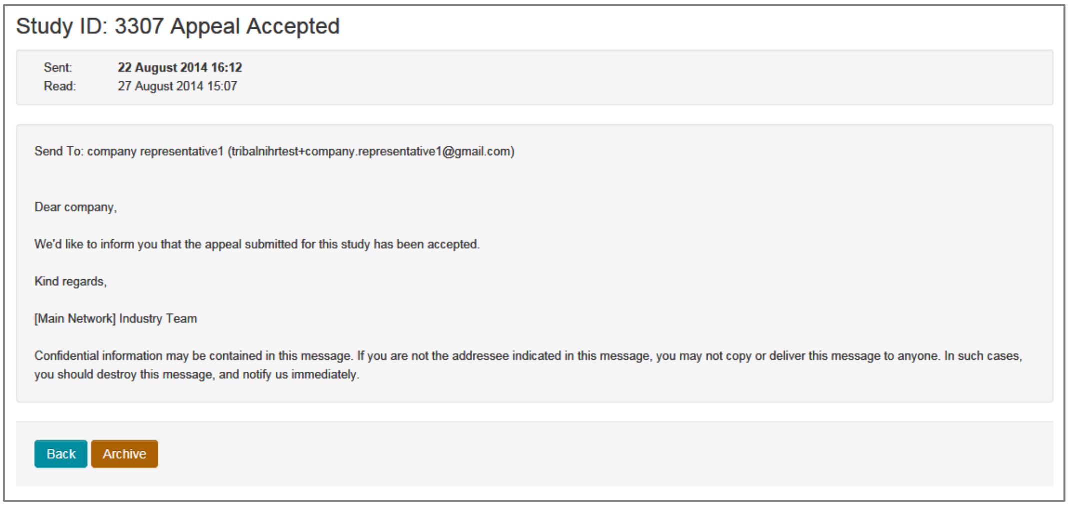
The status of a particular message is shown using one of three status indicators:

	Unread	You have not yet read the message.
	Read	You have read the message. The date and time of reading are displayed in the **Date Read** column.
	Archived	You have archived the message. Archived messages are not displayed in the list unless you click the **Show Archived** button. Clicking **Hide Archived** will re-hide the revealed messages.

You can sort the contents of the **Messages** list by clicking on the arrow at the right of each column heading in the list. By default, the list is sorted in ascending order (A to Z).

Viewing messages

To view a message, click on the link in the **Subject** column.


Study ID: 3307 Appeal Accepted

Sent: **22 August 2014 16:12**
Read: 27 August 2014 15:07

Send To: company representative1 (tribalnihrtest+company.representative1@gmail.com)

Dear company,

We'd like to inform you that the appeal submitted for this study has been accepted.

Kind regards,

[Main Network] Industry Team

Confidential information may be contained in this message. If you are not the addressee indicated in this message, you may not copy or deliver this message to anyone. In such cases, you should destroy this message, and notify us immediately.

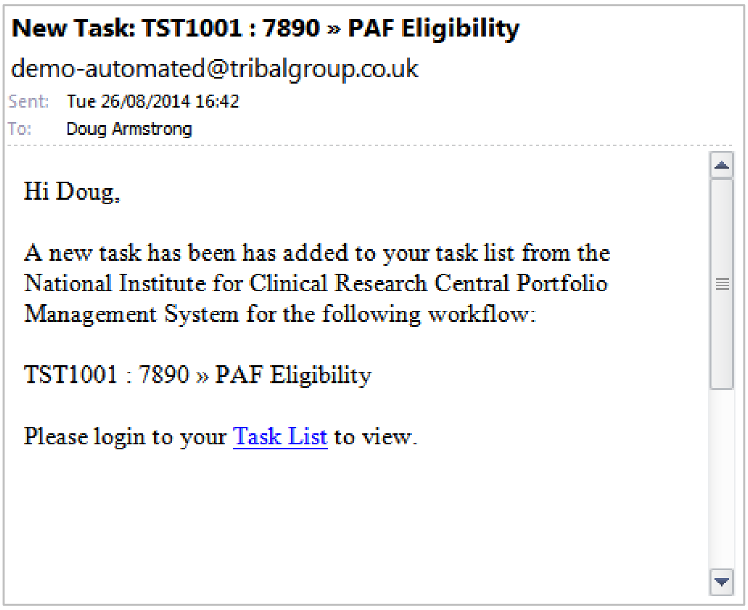
Back Archive

Once you have read the message, click **Back** to return to the message list. The message status will change to **Read**. If you click **Archive**, the message status will be set to **Archived**.

You can use the **Show Archived** and **Hide Archived** buttons to control whether or not archived messages are shown in the **Messages** list. This is useful if you have accumulated a large list of read messages which you don't want to see every time you access the list.

Using e-mail notifications

E=mail notifications are messages sent to your personal (external) e-mail address by CPMS when a new task requires your attention.


New Task: TST1001 : 7890 » PAF Eligibility
demo-automated@tribalgroup.co.uk
Sent: Tue 26/08/2014 16:42
To: Doug Armstrong

Hi Doug,

A new task has been has added to your task list from the National Institute for Clinical Research Central Portfolio Management System for the following workflow:

TST1001 : 7890 » PAF Eligibility

Please login to your Task List to view.

The notification will contain a link to the CPMS **Workflow Tasks** list. If you are not logged into the system, you will first be prompted for login details before gaining access.

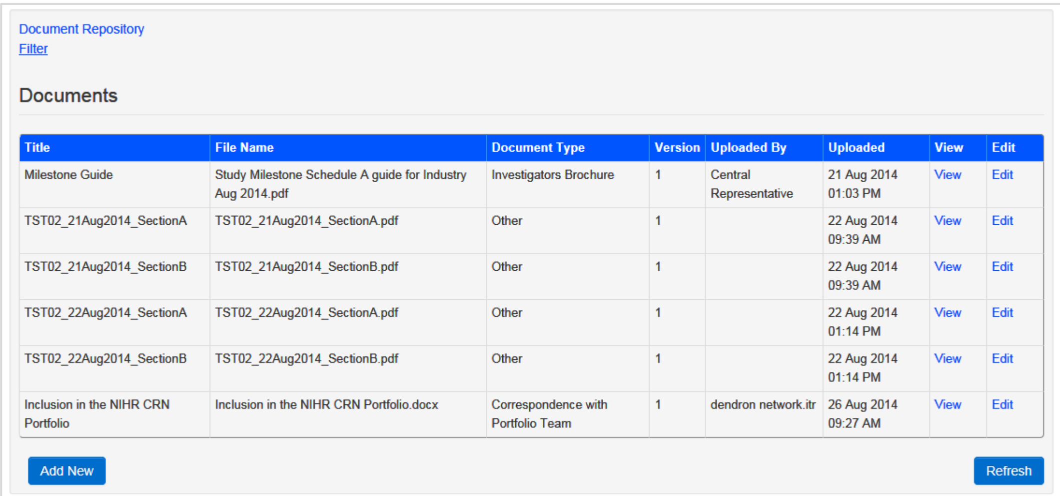
WORKING WITH DOCUMENTS

The **Document Repository** feature allows you to view and/or attach documentation to a study submission. This is useful when you need to supply supporting information to another user who will be processing tasks related to the study. Documents can also be attached to specific study sites, or during review tasks to provide lists of questions for reviewers.

Some documents are also attached automatically at certain points in the workflow – for example, when a study is included in the NIHR Portfolio, an explanatory document is attached for viewing by the study originator which provides additional notes and guidance on what actions they need to take to continue the process.

To view attached documents

To view documents already attached to a study submission, click on the **Document Repository** link (this usually appears below the data entry section of a page). The **Documents list** appears, showing all currently attached documents.


Document Repository
Filter

Documents

Title	File Name	Document Type	Version	Uploaded By	Uploaded	View	Edit
Milestone Guide	Study Milestone Schedule A guide for Industry Aug 2014.pdf	Investigators Brochure	1	Central Representative	21 Aug 2014 01:03 PM	View	Edit
TST02_21Aug2014_SectionA	TST02_21Aug2014_SectionA.pdf	Other	1		22 Aug 2014 09:39 AM	View	Edit
TST02_21Aug2014_SectionB	TST02_21Aug2014_SectionB.pdf	Other	1		22 Aug 2014 09:39 AM	View	Edit
TST02_22Aug2014_SectionA	TST02_22Aug2014_SectionA.pdf	Other	1		22 Aug 2014 01:14 PM	View	Edit
TST02_22Aug2014_SectionB	TST02_22Aug2014_SectionB.pdf	Other	1		22 Aug 2014 01:14 PM	View	Edit
Inclusion in the NIHR CRN Portfolio	Inclusion in the NIHR CRN Portfolio.docx	Correspondence with Portfolio Team	1	dendron network.itr	26 Aug 2014 09:27 AM	View	Edit

Add New Refresh

Click on the link in the **View** column to open the document. Depending on which browser you are using, a dialog box may appear prompting you to either open the document directly, or save it to a location on your computer.

To edit attached documents

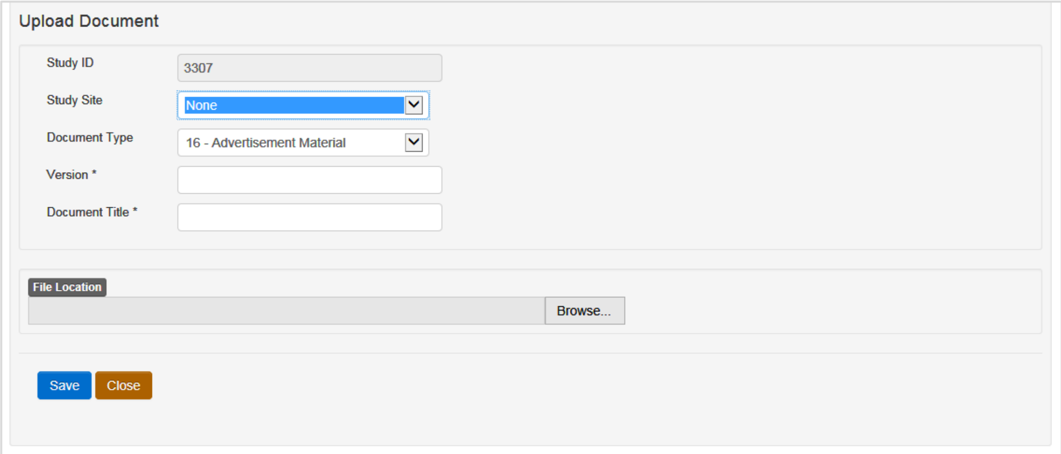
Click on the link in the **Edit** column to display the **Edit Document Details** section

You can now change the **Document Title** and **Document Type** attributes for the document, and then click **Update**, or **Cancel** to abandon the operation.

These attributes should always be set to meaningful values, to aid other users when they search large lists of documents for particular keywords in titles or by document category. For example, you can change the document title for an automatically generated document (which defaults to the file name) to something more descriptive of the contents.

To add a new document

1. Click the **Add New** button to display the **Upload Document** section.



2. Click **Browse**, and then use the controls provided to navigate to a location on your computer and select the desired document file.
3. Use the data entry fields provided to enter a **Document Type**, **Version** and **Document Title** for the new document.
4. If relevant, select a particular **Study Site** from the drop-down list, or select **None** if this isn't relevant to the document being uploaded.
5. Click **Save** to add the document to the repository.

   You can now continue to add more documents as described above, or click **Close** to return to the **Documents** list.

To search for a document

If there are many entries in the **Documents** list, you can narrow the range of documents displayed by clicking the **Filter** link.

Enter any values in the fields displayed in this section and then click **Go** to restrict the **Documents** list to only those entries which match the entered criteria.

Note: You can also hide the **Documents** list entirely by clicking again on the **Document Repository** link.