



ResearchManager

Onboarding eTMF

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Add a new user




Users and roles

- Users and roles
- Users and roles export
- Audit trail users and roles
- Account activity
- Certifications

Add user ✕

Name	<input type="text" value="Jones"/>
Prefix	<input type="text"/>
Surname	<input type="text" value="Jack"/>
Login	<input type="text" value="JJack"/>
Send activation email	<input checked="" type="checkbox"/>
New password	<input type="text"/>
Re-type new password	<input type="text"/>
Roles	<input style="border-bottom: 1px solid #ccc;" type="text" value="Researcher"/> ▼
Telephone number 1	<input type="text"/> ▼
Telephone number 2	<input type="text"/> ▼
E-mail	<input type="text" value="Jack@reseacher.com"/>
Employee number	<input type="text"/>
User Active	<input type="checkbox"/>
Account expiry date	<input type="text"/> 

- Click on Management  in de mail menu.
 - Then, click on **“Users and Roles”** under the heading **“Users and Roles”**.
 - Click on the bottom left of the list on **“Add User”**.
 - Fill in the all mandatory information*
 - Select all the desired roles in the drop down menu at **“Roles”**
 - Click on **“Save”**
- *if **“Send activation mail is”** chosen the password may be left empty. The user will receive an email with which he/she can access the account and set a password.

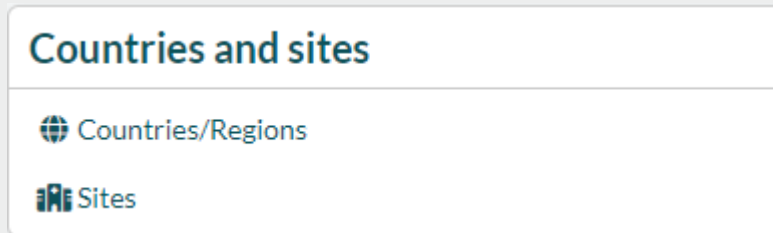



Available roles


- Application Manager
- Module Manager
- User Manager
- Assistant Scientific Officer
- Administrative Assistant
- Department Assistant
- Lawyer
- Researcher
- Reviewer

- **Application Manager** - this role has access to everything including the management section
- **Assistant Scientific Officer**- this role has access to everything and in the management section only to add users
- **Researcher** – this role has access to everything and no access to the management section
- *If more roles are needed please contact support?*

Add a new site or country



- Click on Management  in de mail menu.
- Then, click on “**Countries/Regions**” under the heading “**Countries/Regions**” .
- Click on the bottom left of the list on “**Add**”.
- Add a country name and click “Country / Region is active”*
- Click on “Save & Close”

- Click on Management  in de mail menu.
- Then, click on “**Sites**” under the heading “**Sites**”
- Click on the bottom left of the list on “**Create new site**”.
- Complete the information
- Click on “Save & Close”

Create a new study



CO | Clinical Operations

Start New Study Library

Study details

Study number	Automatically generated
Short title	
Long title	
Study type	Select study type ▼

Principal Researcher

User	Select a user ▼
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Save Back

- Click “New” on the main menu.
- Fill in the information. The following fields are mandatory:
 - Study details**
 - Short title
 - Long title
 - Study type
 - Principal researcher**
 - User
- Select the **study type** from the list.
- Select the **principal researcher** from the list.
- Click “Save” to save the information. The new study has been created.
- Click “Back” to cancel.

Overview



- Dubbel click on a study to open

All studies + All studies ▾ ▾

Study number	Short title	Study type	Principal Researcher	Status	Status duration	Sponsor	
		▾		▾		▾	
2024.02	Study SG	CustomS	Researcher R Researcher	In Review	9 days	Self initiated	
2024.04	Study TMF	Study type 2	Demo User	Application Submitted	105 days	Other	
2024.05	Study COM	Study type 3	Demo User	In Review	106 days	Other	
2024.06	Study HOSP	Study type 4	Researcher R Researcher	Application	106 days	Self initiated	

Page size: 50 ▾ 4 items in 1 pages

- Create a personal overview:
- Select the preferred columns from the list under
- Click on the plus
- Give your overview a name and “Save”



Add participating sites

Main process
Status: Application Submitted

- General information
- Contacts
- Documents (eTMF)
- Participating sites (eISF)**

- Click on “Participating sites” in the left menu .
- In the “Main-process - Participating sites” click on “Add”.
- Here you can link the sites to this study.
- Click on “Save & Close”

- To (un)lock the site(s) click on the icon in the column “Edit status”

Main process - Participating sites (eISF) Edit status Save eSign Cancel

+ Add

Site	City	Status	Max number of participants	Number of participants	Edit status	
Hospital A - HOSA	CITYA	Active		0		
Hospital B - HOSB	CITYB	Active		0		
Hospital C - HOSC	CITYC	Active		0		

Adding documents (eTMF)

Add contacts



Main process
Status: Application Submitted

General information

Contacts

Documents (eTMF)

Participating sites (eISF)

- Click on “**Contacts**” in the left menu .
- In the “Internal Research team” click on “**Add**”.
- Here you can link the contacts to the sites. Make sure the user has been added under “Users and roles”
- Click on “Save & Close”

- To add (GCP) certificates to a users; go to the Management section , “Users&Roles”.
- Select the user
- On the tab “documents” add the certificate
- On the tab “certifications” add the validity and add the option to send a reminder

Internal research team							
+ Add							
Name	Job title	Department	Site	Role within study	GCP certified	GCP valid until	
Demo User		Cardiology	Hospital A	Principal investigator	No		
Researcher R Researcher		Cardiology	Hospital A	Investigator	Yes	10/2/2024	
A Monitor		Cardiology	Hospital A	Other	Yes	2/26/2025	
Saskia_DM van Gastel		Cardiology	Hospital A	Other	No		



Adding documents (eTMF)

Documents			
+ Add + Add multiple documents Download selected documents			
<input type="checkbox"/>	Category	Type ▼	Description
<input type="checkbox"/>	02 Central Trial Documents	02.02.04 Subject Information Sheet	

Add document

Category and type

Description

Version number

Document date

Country/Region Open the calendar popup. ▼

Status ▼

My Documents ▼

Upload document

Mandatory for transition ▼

- Go to a study
- Click on tab “Documents (eTMF)”
- Click “Add”
- Select the **Category and Type** from the list.
- Complete the necessary information (eg date, version, status)
- Then upload the document with the “Upload” button
- Click “Save” to save the information. The new document has been added.



Adding site documents

Participating sites contacts & progress

+ Add				
	Site number	Country	Site name	Local PI
▶	002	Country A	Hospital B	Demo User
▶	001	Country A	Hospital A	Researcher R Researcher

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Add document ×

Category and type

Description

Version number

Document date

Country/Region Open the calendar popup. ▼

Status ▼

My Documents ▼

Upload document

Mandatory for transition ▼

- Go to a study
- Click on tab “Participating sites” and “Add” the site or dubbel click on the site
- Click on tab “Documents”
- Click “Upload”
- Select one or more documents
- Select the **Category and Type** from the list.
- Complete the necessary information (eg date, version)
- Click “Save” to save the information. The new document has been added.

Status transitions



Status: Approved

→ Edit status ▼ Save eSign × Cancel

Open for enrollment

Close study

- Go to a study
- Click on “Edit status”
- Choose the new status from the dropdown menu

Icons



download



export



view pdf



view



calendar



edit



lock



unlock/activate



delete



add



save



close

Overview



Offices

The Netherlands

Striksteeg 7
7411 KR
Deventer

New York - USA

401 Park Avenue South
10th Floor
10016
New York

Production environment

<https://company.myresearchmanager.com>

Support

Technical documentation

[Click here](#)

For technical questions:

support@myresearchmanager.com

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