



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Getting started with EudraCT to prepare and post results

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# Agenda

- Introduction
- How to register
- How to become a results user
- How to request trial assignment
- Manage users



# Introduction

- Launch of EudraCT V9 in October 2013 and V10 in May 2014:
  - Initial step of a process through which summary clinical trial results will be made publicly available through the EU Clinical Trials Register (EU CTR)
- Clinical-trial sponsors can register on the EudraCT website to start preparing results for registered trials
- Guidance on posting and publication of result-related information on clinical trials in relation to the implementation [http://ec.europa.eu/health/files/eudralex/vol-10/2012\\_302-03/2012\\_302-03\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf)



# How to register



# Log into EudraCT website

- <https://eudract.ema.europa.eu/results-web/>

**EudraCT**  
European clinical trials database

Create Load

**Login**

Username

Password

Login

Register (only for users who want to provide results data)

**Welcome to EudraCT**

EudraCT is a database of all clinical trials which commenced in the Commu

The following tasks can be performed from this page:

**Create a EudraCT number**

Before any functionality of EudraCT can be used for a given clinical trial, a t

**Protocol-related information**

**Sponsors can:**

- Create, save XML/PDF files of clinical trial applications locally.
- Load locally saved clinical trial applications to complete, validate, cc



# Register for a EudraCT Account

## EMA Account Management



Password

[Create a new EMA account](#)

[Not sure if you have an EMA account?](#)

[Forgot your password?](#)

[Forgot your username?](#)

Login



# EMA – Self-service Registration Form

## EMA - Self-service Registration Form

Submit the following form to register.

**First Name \***

This is used to create your username and to address you in email correspondence.

**Last Name \***

This is used to create your username and to address you in email correspondence.

**Email \***

We require a valid/active email address to create an EMA Account.

**Password \***

Please enter a password that you want to use to access your EMA Account. The password must have at least 8 characters and must contain upper case, lower case, numeric and special characters.

**Confirm Password \***

**Mobile (optional)**

This is an optional field. We will only use this information for security messages or alerts in relation to your account. Please include the international dialling code in front of your mobile number.



# Agreement with data protection statement

## Data Protection Statement

### Policy

#### DATA PROTECTION STATEMENT

Your personal data are processed in accordance with Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. To find out more about your rights and about how the EMA processes personal data, please check the Privacy Statement on EMA's website.

The information we collect is used to manage direct access to EMA's systems and to verify users' accounts. We will collect and use personal data such as your e-mail address and phone number (if provided), to communicate any next steps or key changes to the system. Your data will be deleted after 180 days of inactivity on our systems.

Should you wish to learn more about the way your personal data are being processed please contact AskEMA at [http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/landing/ask\\_ema\\_landing\\_page.jsp&mid=WC0b01ac05806499f0](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0)

Cancel

Register



# Self-registration security questions

## EMA - Self Registration Security Questions

### Security Question 1

What is your mother's maiden name?



### Answer 1 \*

### Security Question 2

What is your favorite color?



### Answer 2 \*

### Security Question 3

What is the name of the first street you lived on?



### Answer 3 \*

### Captcha Question \*

What is the value of  $3 + 49$

### Captcha Answer \*

Cancel

Next



# Self-registration confirmation form

## EMA - Self-service Registration Confirmation Form

### Your EMA Account

Your EMA username is given below. Please make a note of this as you will need it to log in to EMA applications.

Username

[REDACTED]

### Your Details

First Name

[REDACTED]

Last Name

[REDACTED]

Email

[REDACTED]

Mobile (optional)

### One-time Token

Please enter the value of the one-time token you have received by email in the field below.

Confirm Token \*

Cancel

Confirm



# Request submitted

Your request has been submitted. You will receive an email notification containing your registration information.

Login

# Log into EudraCT website

The screenshot shows a web interface with two tabs: 'Create' and 'Load'. Below the tabs is a 'Login' section. It contains two input fields: 'Username' and 'Password', both highlighted in yellow. Below these fields is a 'Login' button. At the bottom of the login section, there is a link that says 'Register (only for users who want to provide results data)'.



# How to become a results user



# Log in and click on 'Become a results user'

Create Load

Session Information 

Login  
b2n4d6  
Manage account  
Logout 

## Manage account

You can change your password for your EMA user account in the [EMA user registration tool](#) (opens in a new window).

**Become a results user** and request authorisation to prepare results for your organisation's clinical trials.

If you are responsible for uploading paediatric protocols, you will require the role of PIP Addressee. This can be obtained by contacting [paediatrics@ema.europa.eu](mailto:paediatrics@ema.europa.eu).

Done



# Confirm terms of agreement

[Create](#)[Load](#)

## Session Information

**Login**

b2n4d6

[Manage account](#)**Logout** 

## Manage account - Become a results user

Read the terms of this agreement

- I am registering with the EudraCT database as a results user, to provide clinical trial results on behalf of the sponsor, marketing authorisation holder or PIP addressee.
- I will use the system in accordance with Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 and their implementing Commission Guideline 2012/C 302/03.
- I will only request assignment to trials for which I am authorised to do so by the sponsor, marketing authorisation holder or PIP addressee.
- I will not misuse the rights given to me for private or commercial purposes.

I accept the terms of this agreement

[Confirm](#)[Cancel](#)



# Log out and in again

Create

Load

## Session Information

Login

b2n4d6

Manage account

Logout ✕

⚠ Please logout and login again for the new role to take effect.

## Welcome to EudraCT

EudraCT is a database of all clinical trials which commenced in the Community from 1 May 2004, and also includes clinical trials linked to European paediatric drug development.

The following tasks can be performed from this page:

### Create a EudraCT number

Before any functionality of EudraCT can be used for a given clinical trial, a EudraCT number must be created in order to provide a unique reference for that trial.



# Click on the link 'request assignment'

## Session Information

[Login](#)[perkinsd](#)[Manage account](#)[Logout](#) ✕

## Your page

You currently are not assigned to any clinical trials with results in a draft state.

If you are to be delegated responsibilities for preparing results of a trial, contact the primary user of that trial in your organisation who will assign the trial to your user account.

If you want to become a primary user for a trial on behalf of your organisation, you first need to **request assignment** of the relevant trial to your user account.



# Select the request method

## Request assignment

### Step 2: Select request method

You can request assignment to trials using either of two ways. You can either provide a signed letter from the Sponsor or you can request assignment based on being involved in the legal process for authorisation of the trial without the need to provide further documentary evidence.

To complete the request for assignment to results using the Sponsor letter, **request assignment to trials via letter.**

To complete the request for assignment to results using previous involvement with the protocol, **request assignment to trials based on protocol information.**

[Back](#)[Cancel](#)



# Request assignment via Protocol Information



## Requested method: based on protocol information (1)

- A user, for whom the email address was included in the CTA submitted to the national competent authority, can request the trial assignment by selecting the option “request assignment based on protocol information”.
- This request will be automatically granted if the email address of the requestor/user matches the one included in the CTA.
- This method is fast and effective and if there is a match between the email addresses, the requestor has immediate access to the result user interface for the trial.



## Requested method: based on protocol information (2)

The following CTA fields are verified against the requestor email during this process:

B.1.6 Sponsor Contact email

B.2.6 Legal Representative email

C.1.4.6 Request for the competent authority email

C.2.5.6 Request for the ethics committee email



## Requested method: based on protocol information – click confirm

request for assignment to results using previous involvement with the protocol,  
ent to trials based on protocol information.

### Make assignment request - confirmation

The system will attempt to assign your user account to the results of the clinical trials listed based on the protocol information.

Do you wish to proceed?

Confirm

Cancel



# Requested method: based on protocol information – outcome of assignment request

## Outcome of assignment request:

We have processed your assignment request. The summary below indicates which of the trials were successfully assigned to your user account and which assignment requests were rejected.

EudraCT number	Outcome
2006-006100-11	Rejected

OK

If rejected use the other request method via letter



# Request assignment via Letter



# Step 1

## Identify trials (up to 50)

Your page   Create   Load

**Session Information** ^

Login  
perkinsd  
Manage account  
Logout ✕

### Request assignment

**Step 1: Identify Trials**

EudraCT number

(max. 50 trials)

1. Enter each EudraCT number on a new line in the format xxxx-xxxxxx-xx where x is a digit.
2. Only trials that appear in this box will be processed.
3. Ensure the list of EudraCT numbers in this box matches those that appear in the letter supporting the request.

You will not be able to add more later in the process.

Cancel   Next



# Step 2

## Enter details of the trial (full title and name of sponsor)\*

Your page Create Load

Session Information ^

Login  
perkinsd  
Manage account  
Logout ✕

### Request assignment

Step 2: Enter trial details

EudraCT number	Full title of trial	Name of Sponsor organisation(s)	
2009-013886-24	<input type="text" value="A randomized, multicenter 12-Week double-blind placebo-controlled study to assess the efficacy and safety of IMP2 in Excessive Daytime Sleepiness in Parkinson's disease"/>	<input type="text" value="EMA trainer Ltd"/>	Delete

Previous page Page 1 of 1 Next page

Cancel Back Next

- 24 \*If there is a change in the sponsorship/ownership of the trial, the EMA is not involved in this process. The new sponsor acquiring the trials have to make an agreement with the old sponsor.



# Step 3

## Attach letter

Your page Create Load

Session Information  
Login perkinsd  
Manage account  
Logout ✖

### Request assignment

#### Step 3: Attach letter

Authorising letter

Attach authorising letter

No attachments.

Supported file formats: PDF, BMP, JPG, GIF, PNG

Maximum file size = 5 MB

Checklist:

1. Ensure that all EudraCT numbers entered in this request are also mentioned in the authorising letter.
2. Ensure that all EudraCT numbers mentioned in the authorising letter are also included in this request, otherwise they will not be considered part of the request.
3. Ensure the attachment is a scanned image containing the required hand-written signature.

Submit request Back Cancel

### Request assignment

#### Step 3: Attach letter

Authorising letter

Attach authorising letter

No attachments.

Supported file formats: PDF, BMP, JPG, GIF, PNG

Maximum file size = 5 MB

Checklist:

1. Ensure that all EudraCT numbers entered in this request are also mentioned in the authorising letter.
2. Ensure that all EudraCT numbers mentioned in the authorising letter are also included in this request, otherwise they will not be considered part of the request.
3. Ensure the attachment is a scanned image containing the required hand-written signature.

**Attach authorising letter**

Add Clear All

Done Clear

Attach letter Cancel



# Sample letter

[https://eudract.ema.europa.eu/docs/guidance/CT\\_assignment\\_guide.pdf](https://eudract.ema.europa.eu/docs/guidance/CT_assignment_guide.pdf)



The screenshot shows the EudraCT Help menu. The 'Results related documentation' section is highlighted, containing the following items:

- Clinical trial assignment request template letter - Template instructions
- EudraCT result related data dictionary
- Validation rules for posting result related information
- XML schemas and documentation
- Service level agreement

Other menu items include Home, What's new, FAQs, Login to EudraCT, EudraPharm EU CTR, Protocol documentation, Results documentation, Technical documentation, Training, Multi-media tutorials - NEW, Statistics, NCA contacts, Links, and Contact Us.

European Medicines Agency  
 EudraCT registration team  
 7 Westferry Circus  
 Canary Wharf  
 London E14 4HB  
 United Kingdom

<Entity/company name>  
 <DD-MMM-YYYY>

Dear EudraCT registration desk,

**Re: EudraCT - Clinical trial assignment request - result related information**  
**Sponsor/MAH/PIP addressee name: <NAME of the SPONSOR/MAH/PIP Addressee>**

Acting on behalf of the sponsor, the addressee of the decision on a paediatric investigation plan or the marketing authorisation holder, I would like to request assignment of the clinical trials listed below to the following EudraCT user:

< name and surname > <email address >

This assignment will designate the user as the primary user for the listed clinical trials in regards to result related information. It will enable them to prepare and post result related information for these trials on behalf of the sponsor, the addressee of the decision on a paediatric investigation plan or the marketing authorisation holder in accordance with Commission Guideline 2012/C 302/03 and its technical guidance on the format of the data fields of result-related information on clinical trials submitted in accordance with article 57(2) of Regulation (EC) No 726/2004 and article 41(2) of Regulation (EC) No 1901/2006.

Furthermore, this assignment will enable the user to assign one backup user and multiple delegated results preparers and posters for each listed trial.

List of clinical trials:

EudraCT Number	Full title of the trial	Sponsor name

Yours sincerely,

<signature>

<name and surname of the person signing the letter>  
 <title of the person signing the letter>  
 <telephone number of the person signing the letter>  
 <e-mail address of the person signing the letter>  
 <name of the entity >  
 <address of the entity>

**\*Letter has to be prepared on the sponsor's headed-paper**  
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# Request assignment – screen confirmation

Your page   Create   Load

**Session Information** ^

Login  
perkinsd  
Manage account  
Logout ✖

## Request assignment

**Confirmation**

Your request has been received and will be processed in accordance with EMA's [service level agreement](#).  
You will receive an email after your request has been processed.

Done

The service level agreement (SLA) to process requests to become primary user for results takes 25 calendar days.



# Facsimile automated email received once the request is approved

Dear Dorothy perkins,

Your request for assignment to clinical trials for the purpose of preparing and posting results has been processed.

Request number: perkinsd635359 Request date: 29-Oct-2013

The following trial assignment requests were approved:

- 2009-013886-24

If you have any query in relation to this matter, please contact the legal representative of the sponsor, marketing authorisation holder or PIP addressee concerned before getting in touch with the [EudraCT service desk](#).

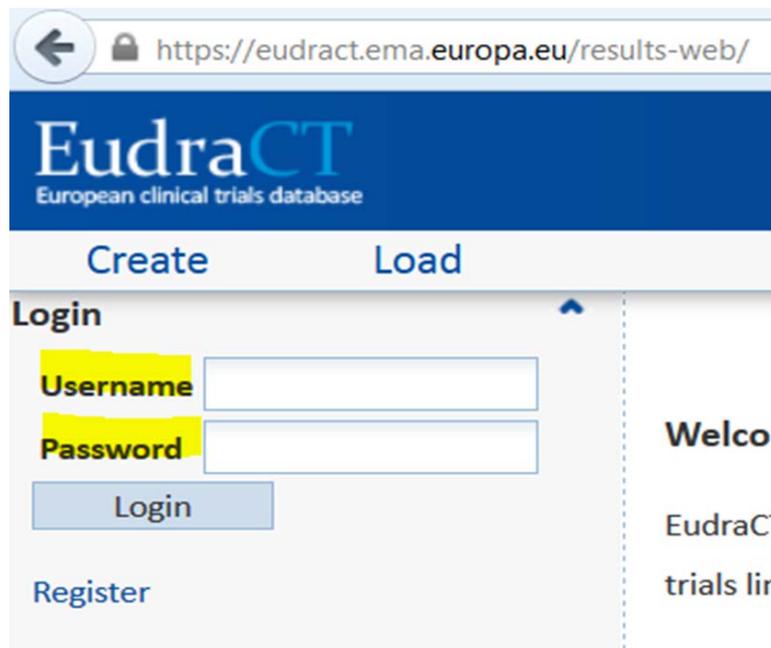
Kind regards

EudraCT

Please note you cannot reply to this email.



Once request approved, log into EudraCT and go to 'Your Page'



## Your page

Clinical trials that appear in the list below are those that in a draft state and assigned to you.

### Draft results

EudraCT number	Version	Sponsor name	Friendly description	Last saved	Status	Options
[REDACTED]	1	[REDACTED]	bioavailability	27-Sep-2013	Draft	Edit   View   View assigned users
[REDACTED]	2	[REDACTED]	ich-test	26-Sep-2013	Draft	Edit   View   View assigned users
[REDACTED]	1	[REDACTED]		25-Sep-2013	Draft	Edit   View   View assigned users
[REDACTED]	1	[REDACTED]	ICH E3	25-Sep-2013	Draft	Edit   View   View assigned users



# Manage users



# Manage users

- Done at the trial level
- Performed by the sponsor via the primary user
- The primary user assigns other users (who are results users) to a trial
- The other roles are:
  - Primary user back up (can remove the primary user if needed)
  - Preparer and poster
  - Preparer
- Sponsor can manage users also when the results are in a finalised status=published



Thank you