EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Getting started with EudraCT to prepare and post results

Raffaella Chersoni
Compliance and Inspection

Agenda

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

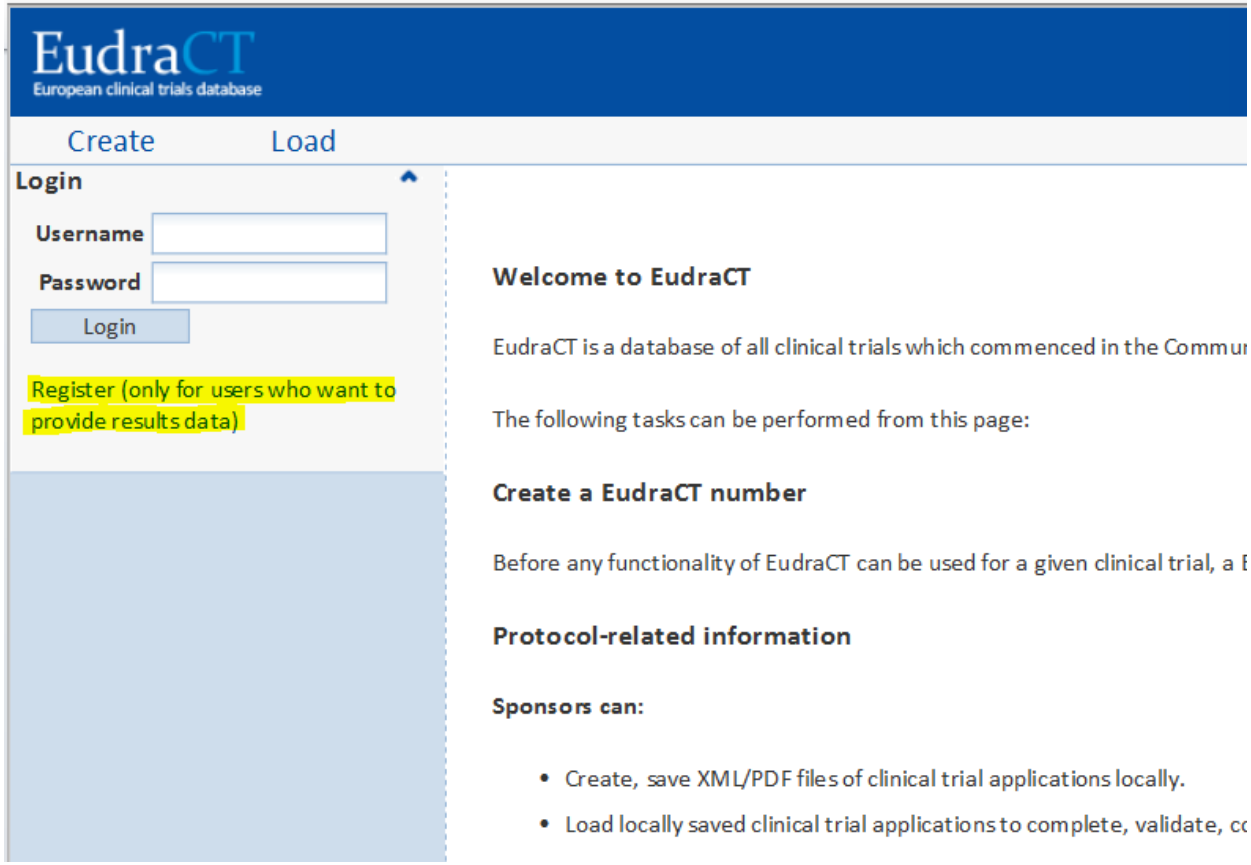
Introduction

- 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

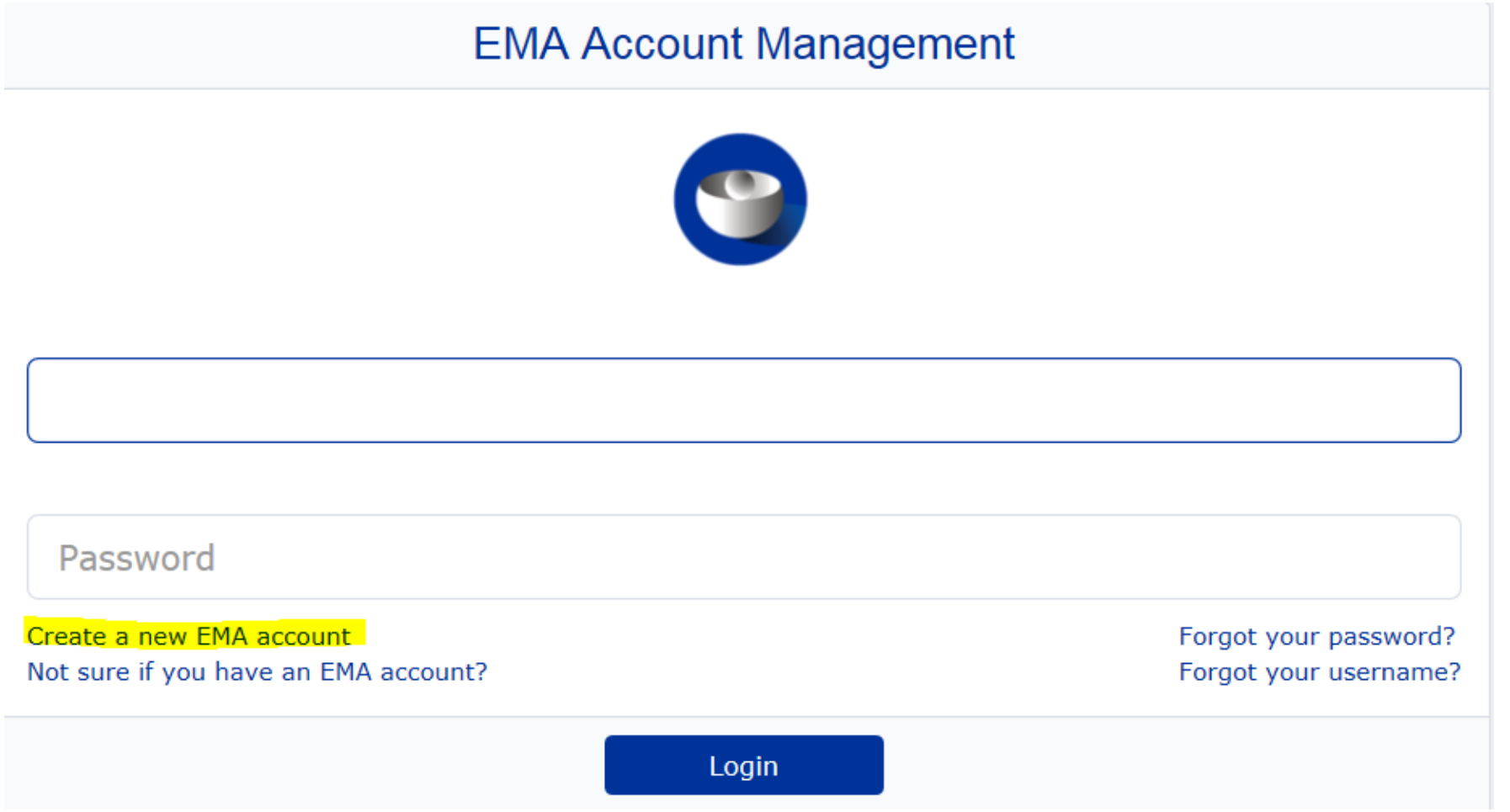
How to register

Log into EudraCT website

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



Register for a EudraCT Account



EMA – Self-service Registration Form

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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.

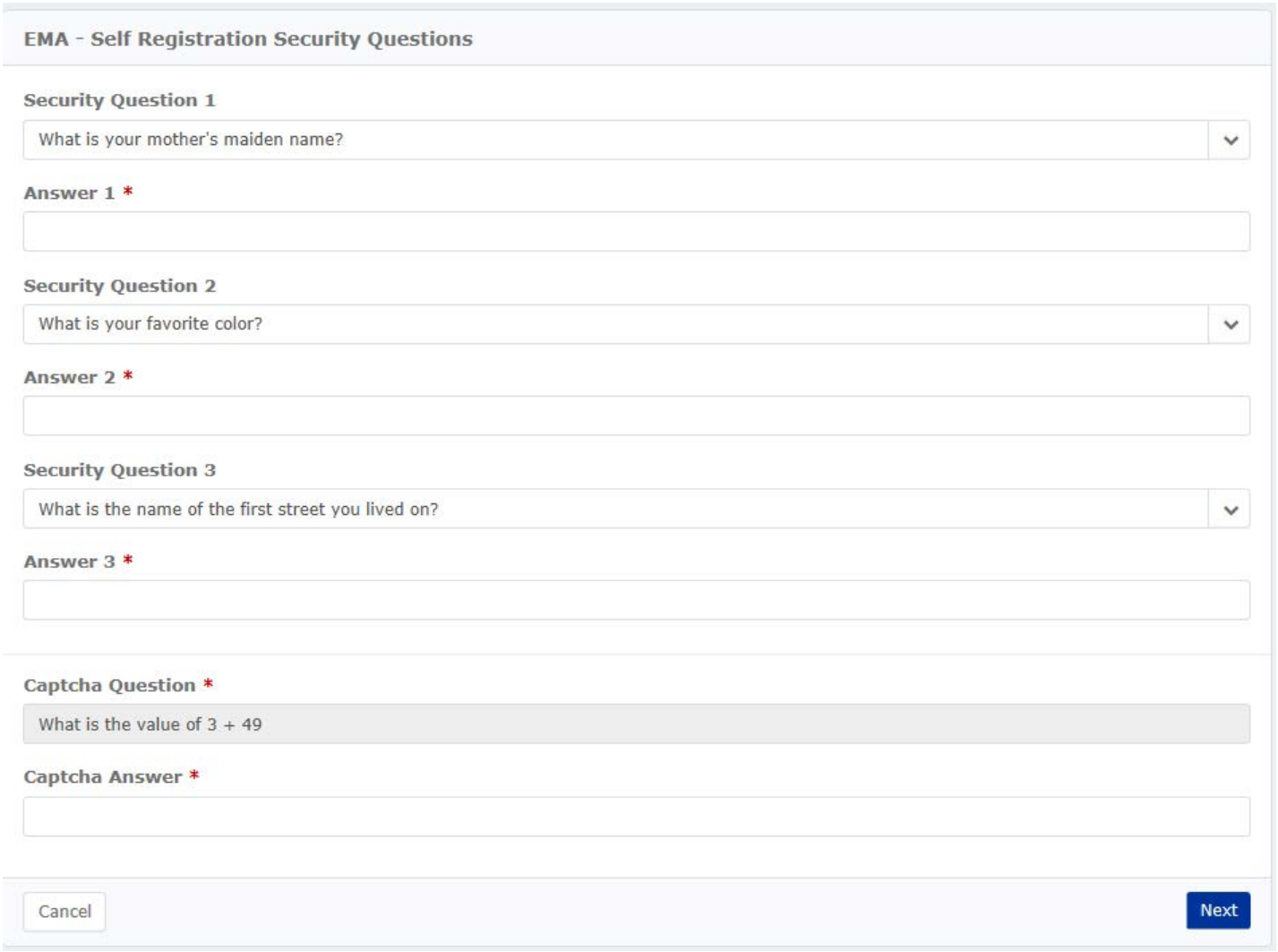
The information we collect is used to manage direct access to EMA's systems and to verify users' accounts. We will collect and use personal data such as your e-mail address and phone number (if provided), to communicate any next steps or key changes to the system. Your data will be deleted after 180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

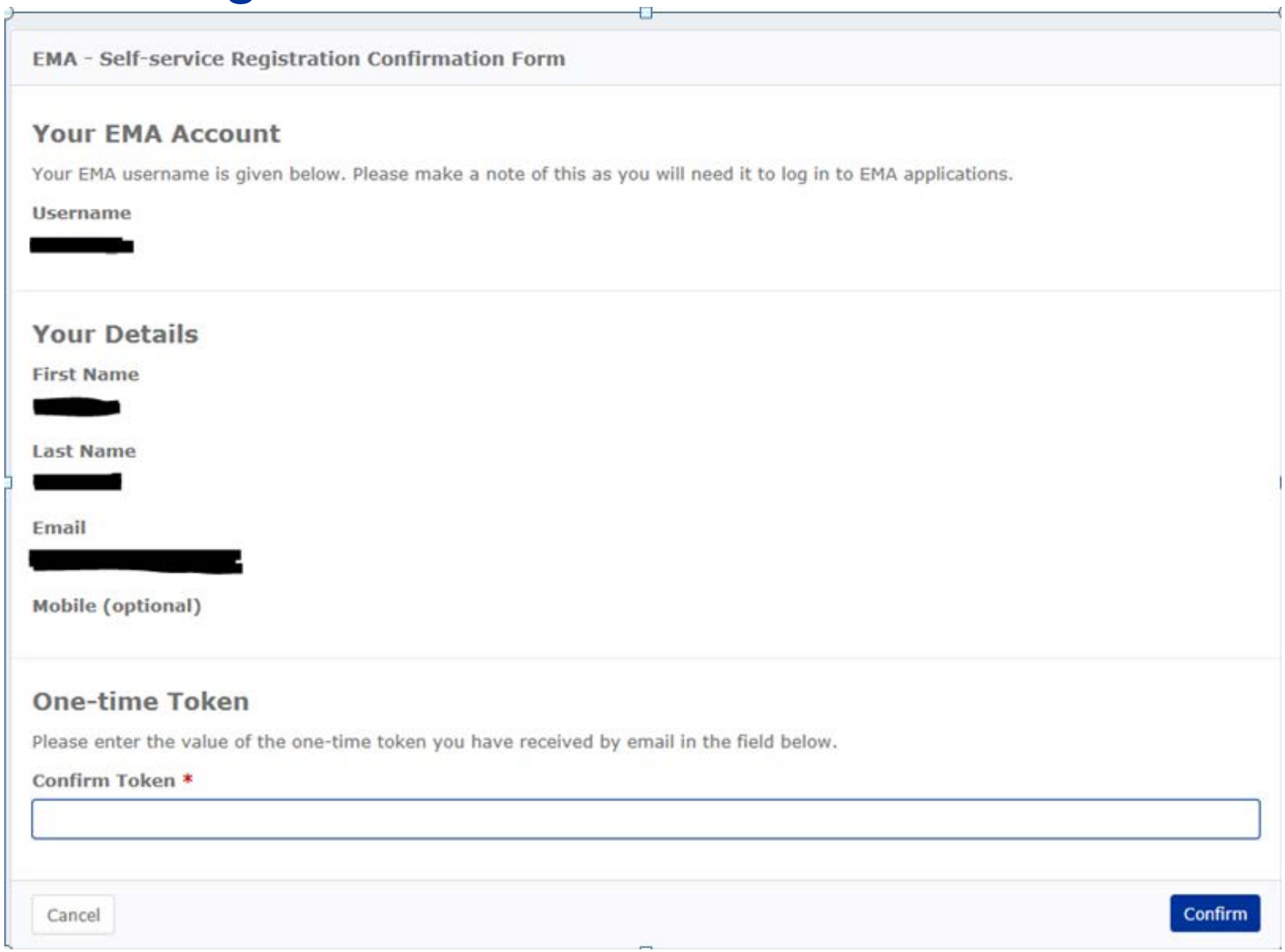
Cancel

Register

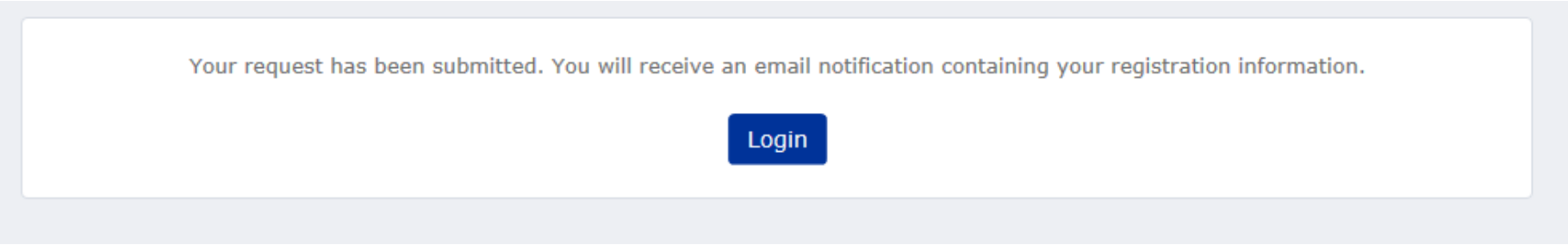
Self-registration security questions



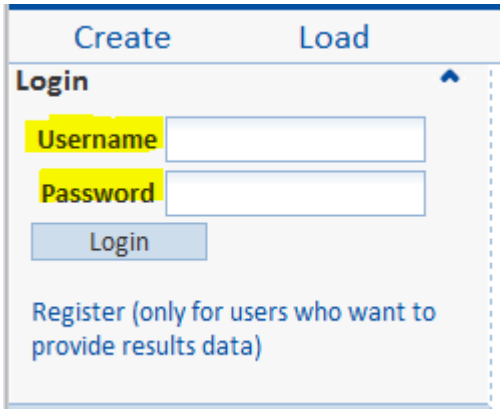
Self-registration confirmation form



Request submitted

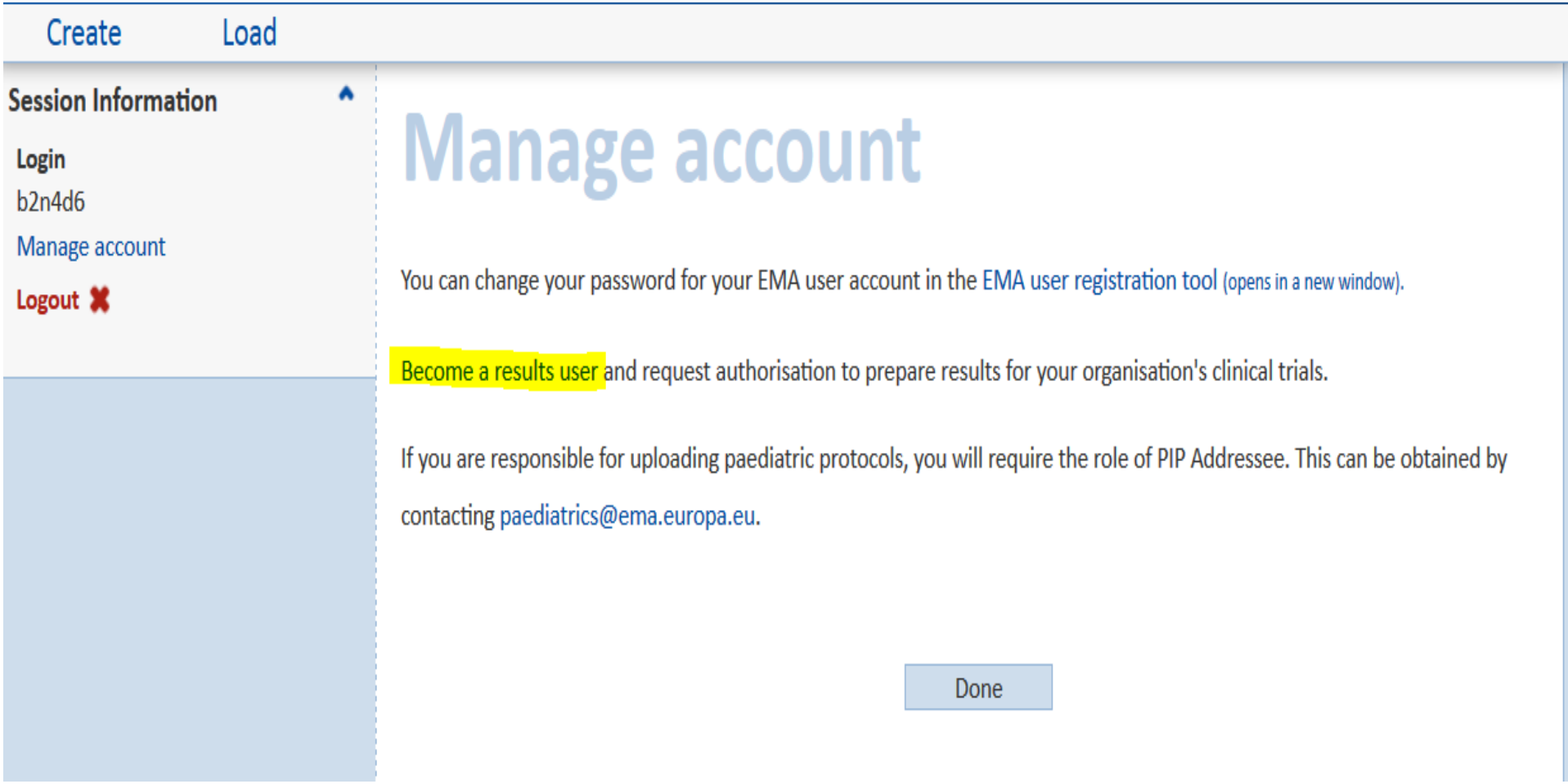


Log into EudraCT website

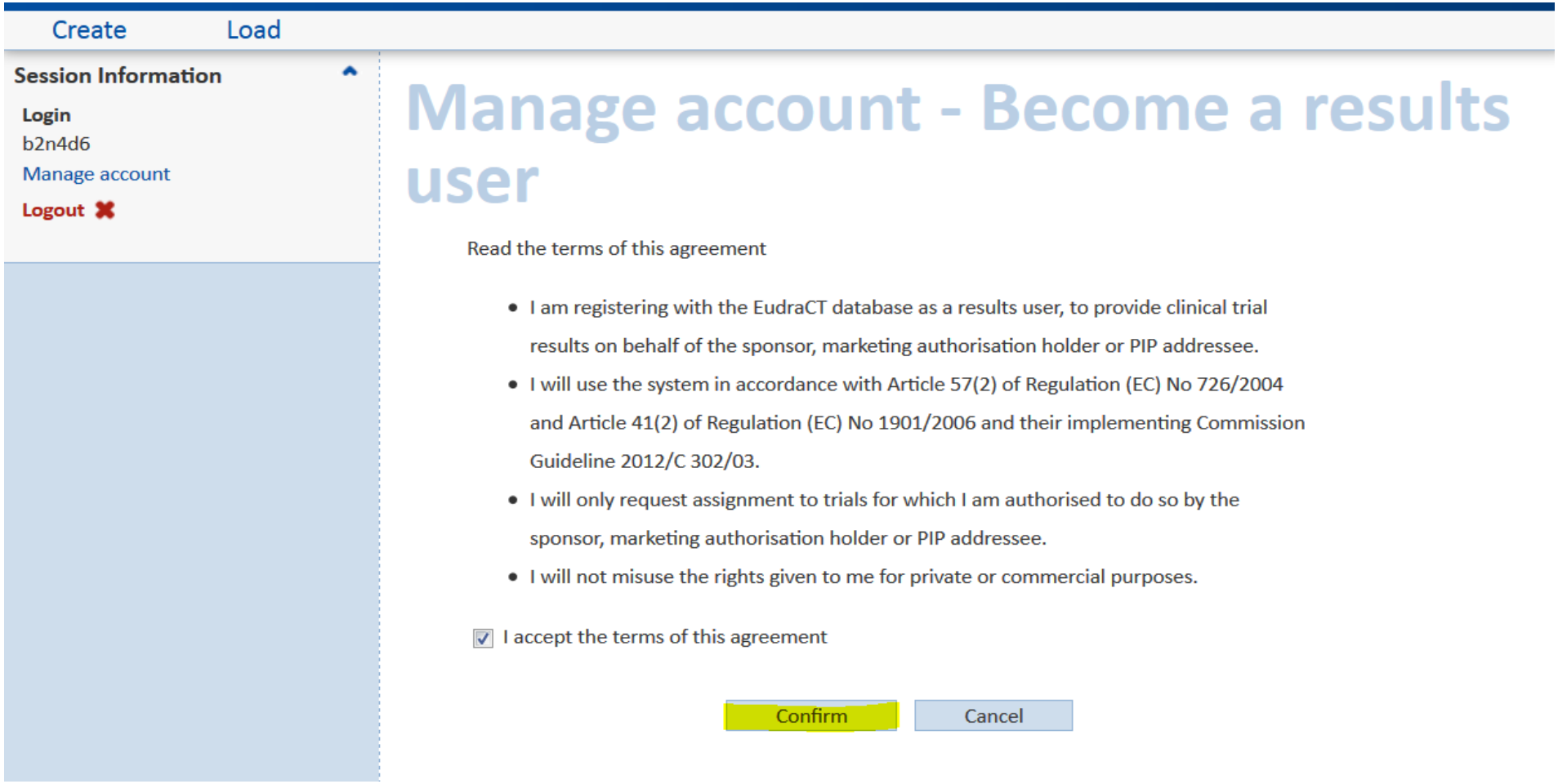


How to become a results user

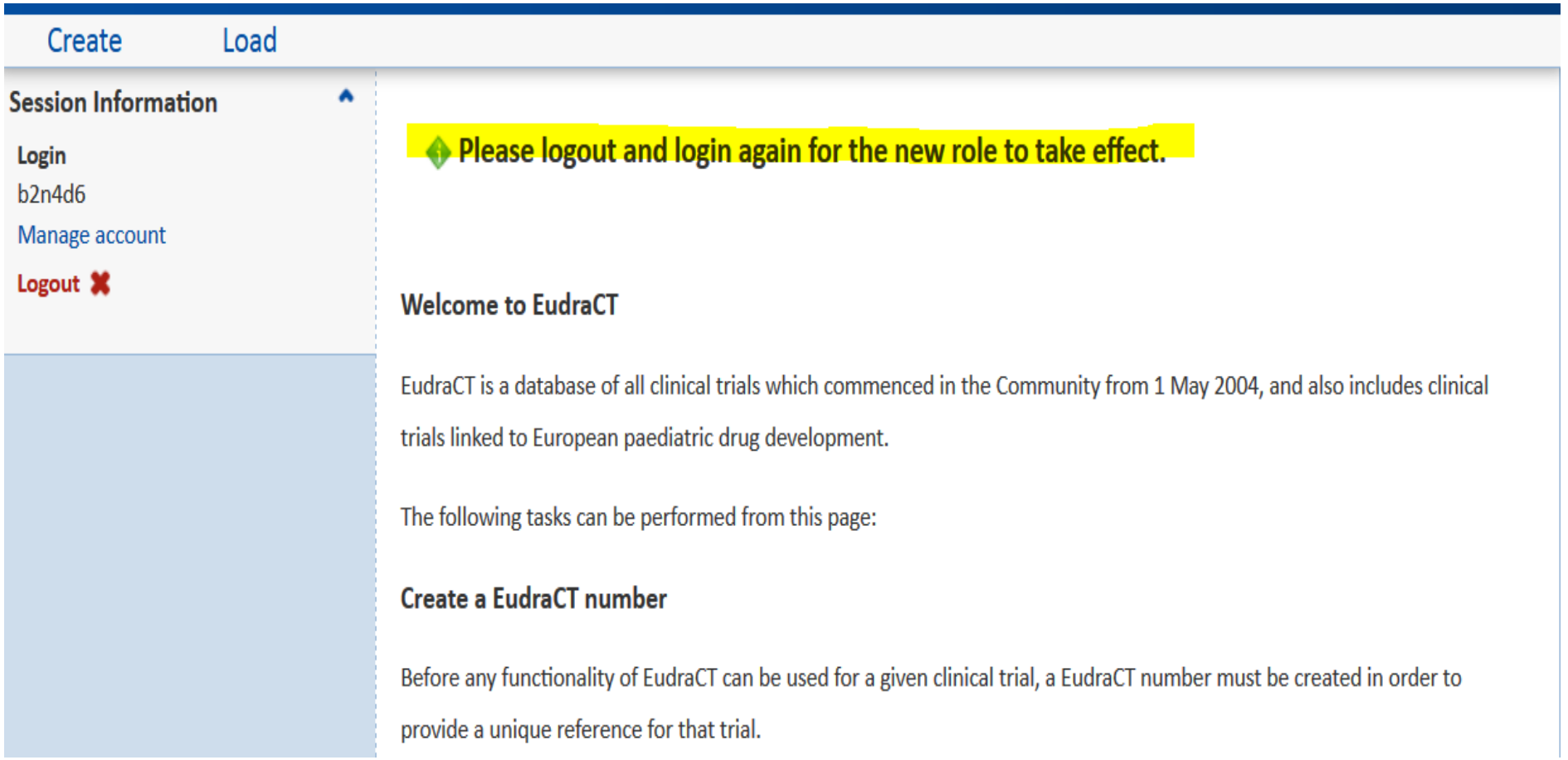
Log in and click on ‘Become a results user’



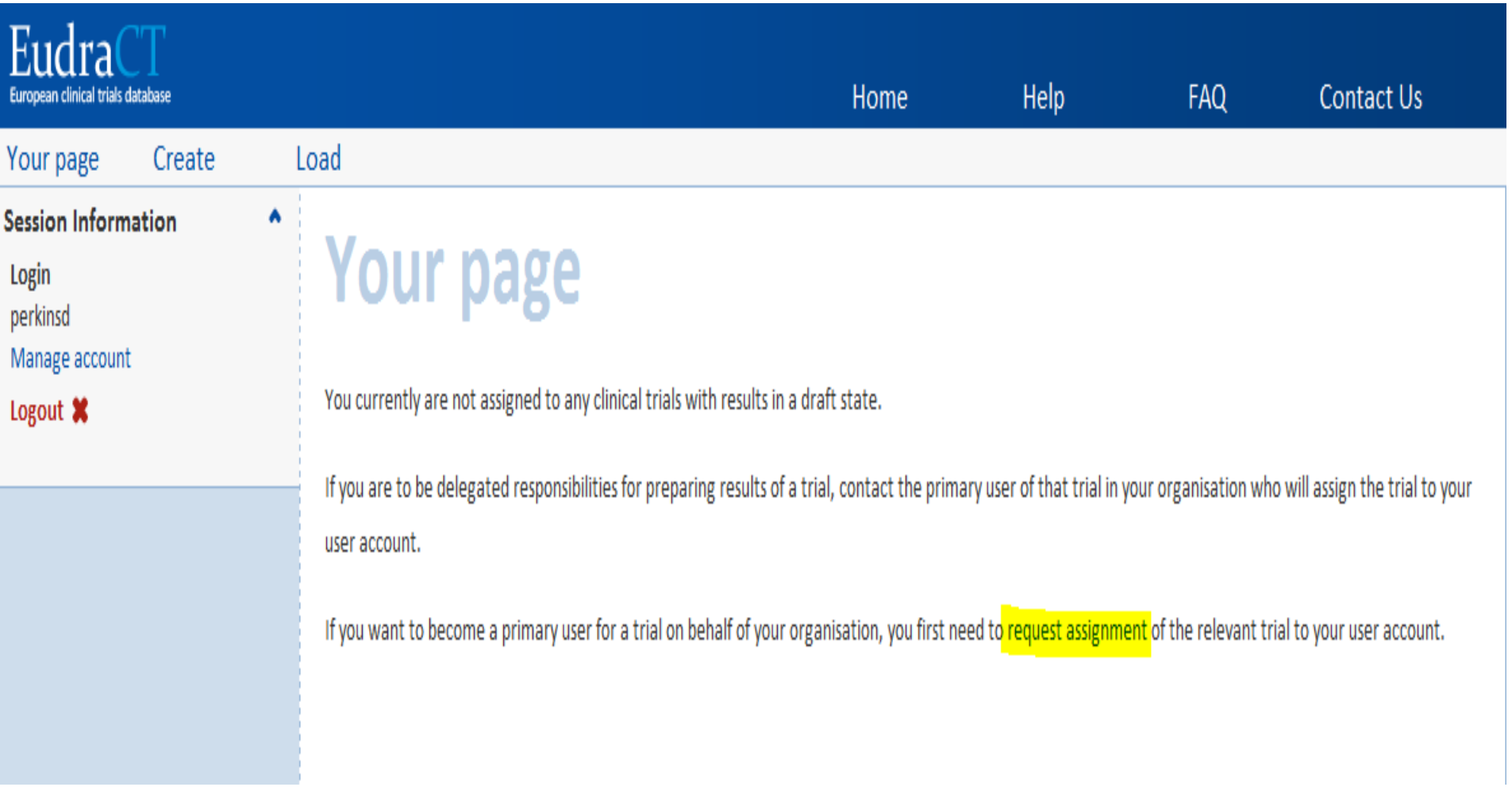
Confirm terms of agreement



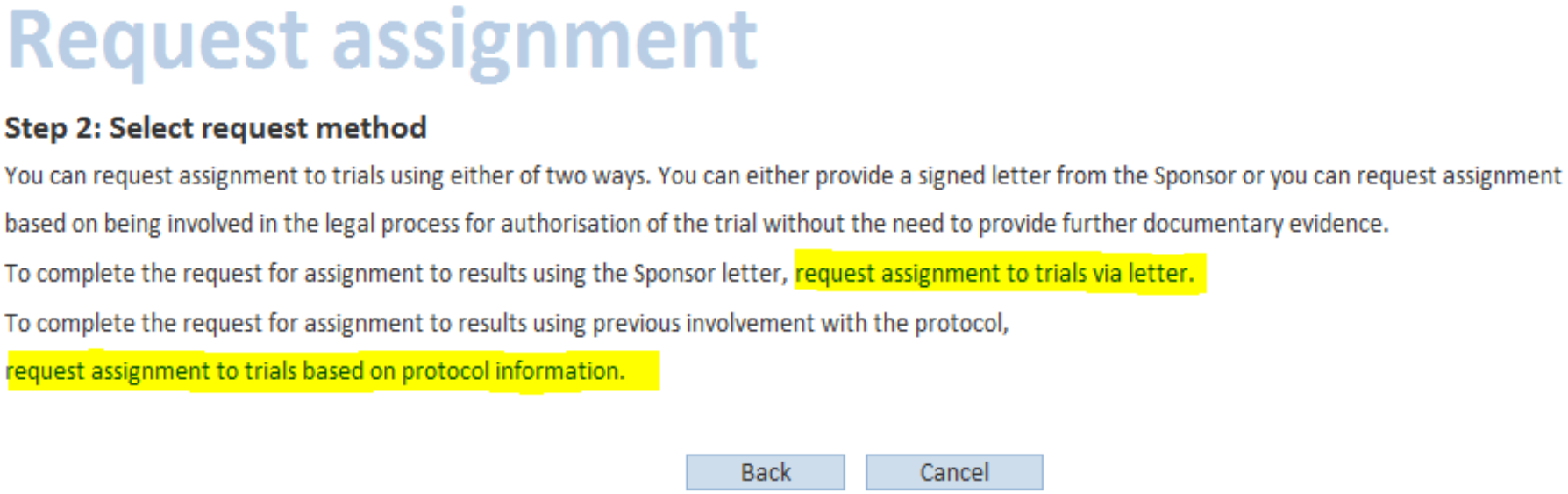
Log out and in again



Click on the link ‘request assignment’



Select the request method



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:

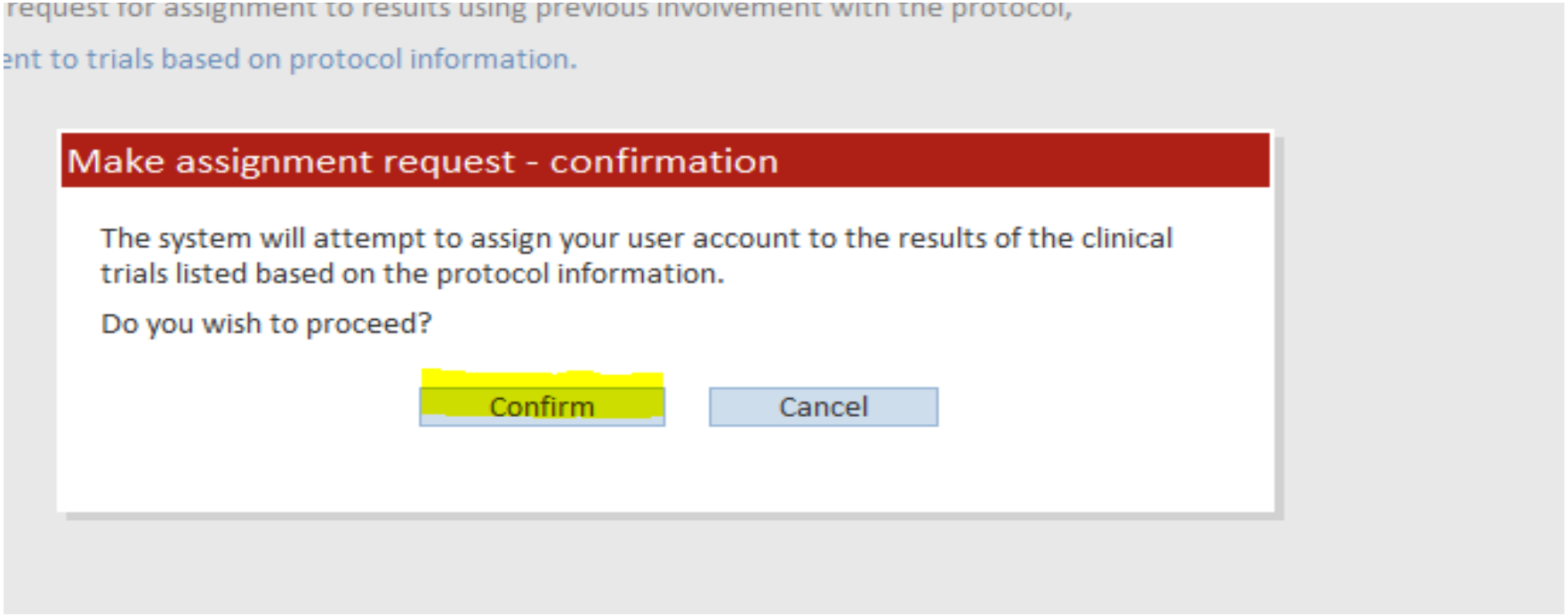
B.1.6 Sponsor Contact email

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



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.

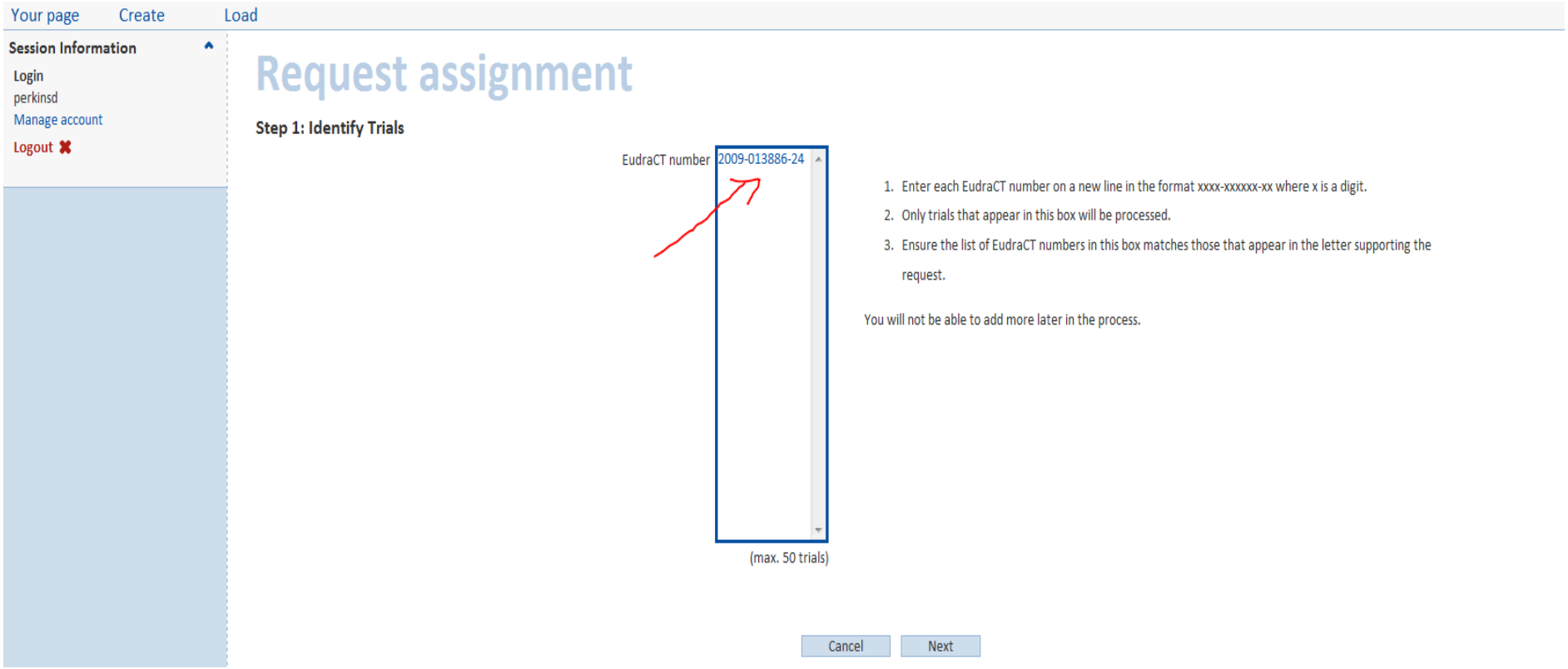
EudraCT number	Outcome
2006-006100-11	Rejected

OK

If rejected use the other request method via letter

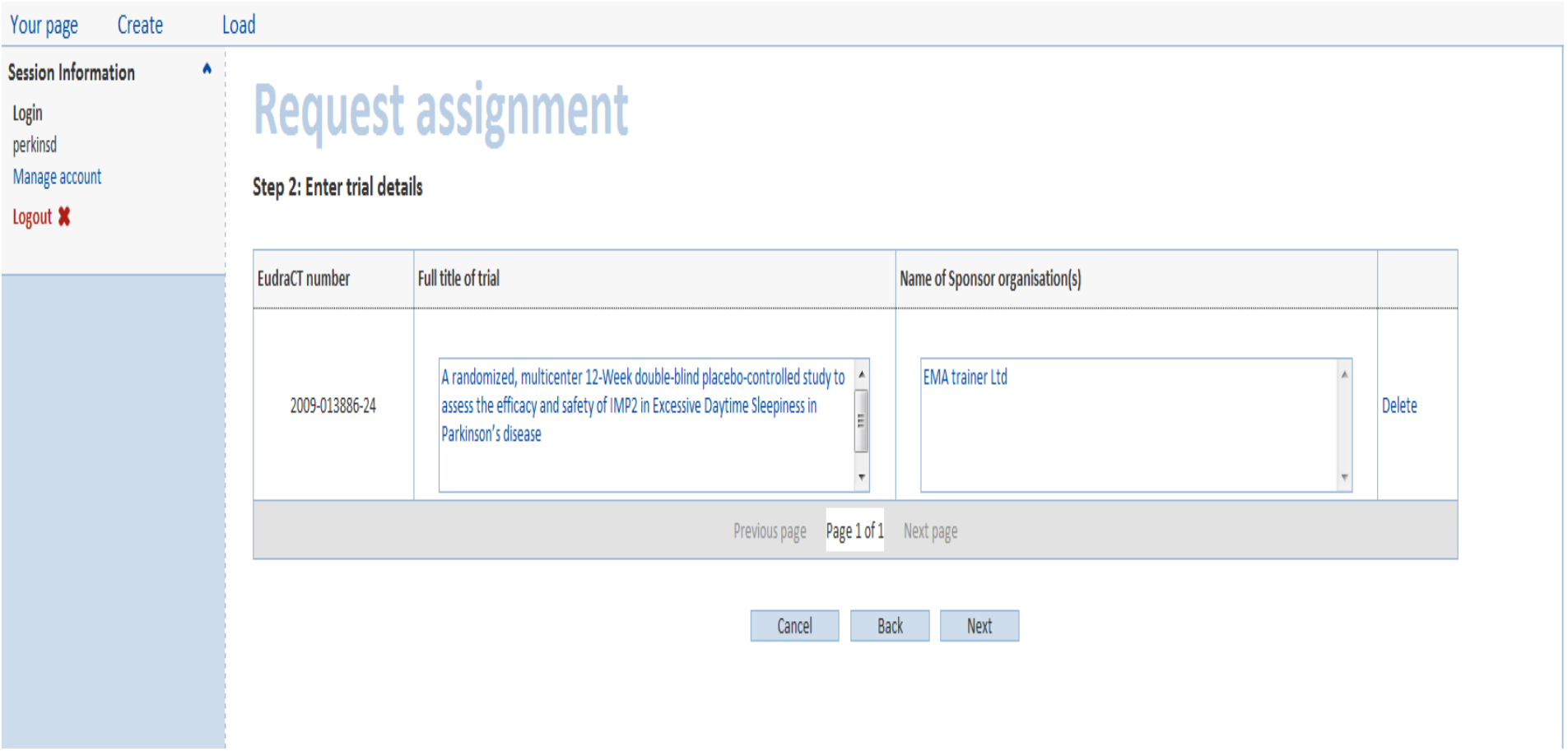
Request assignment via Letter

Step 1
Identify trials (up to 50)



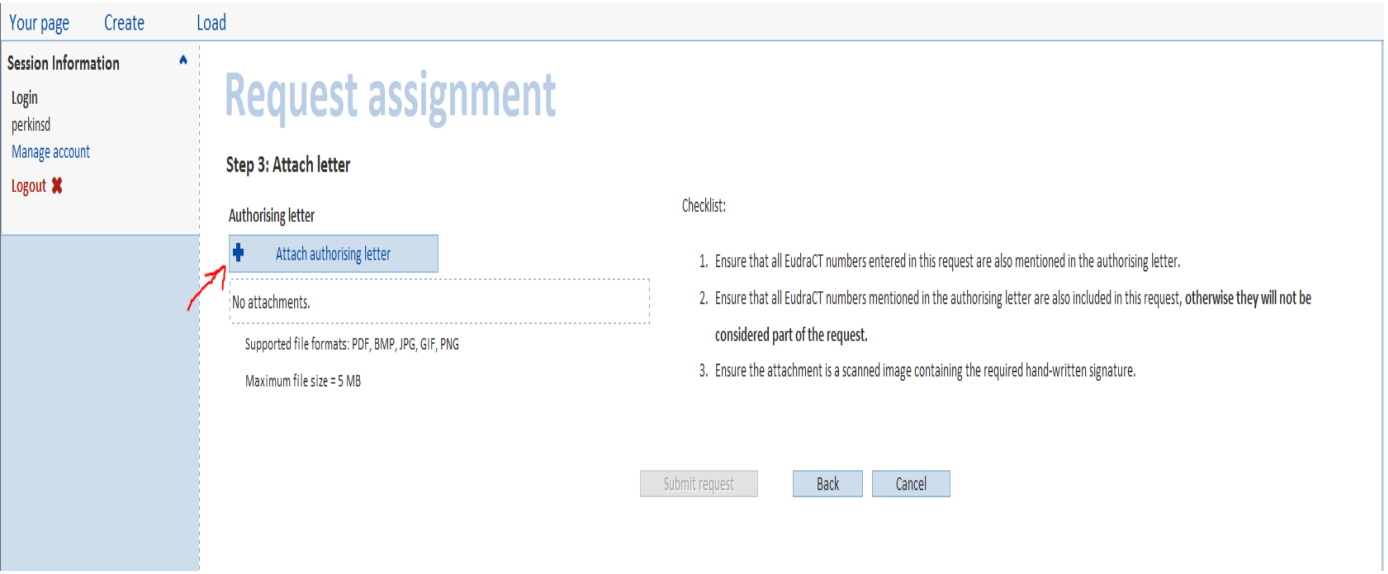
Step 2

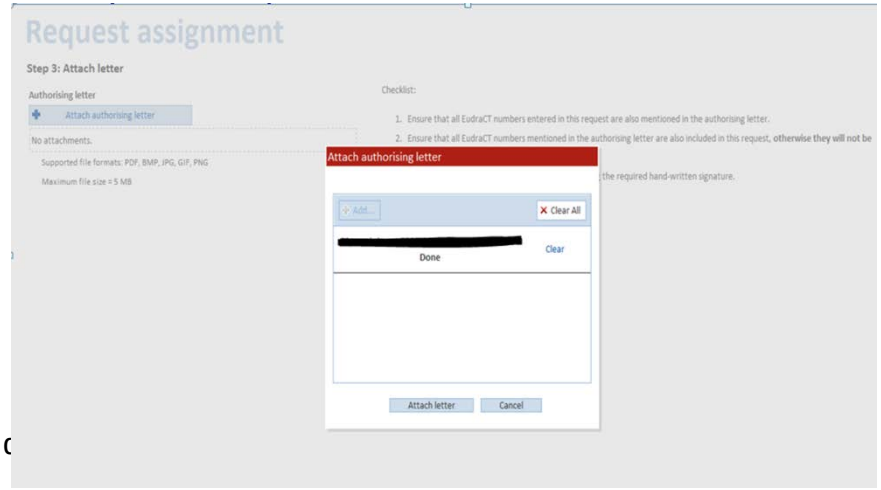
Enter details of the trial (full title and name of sponsor)*



*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.

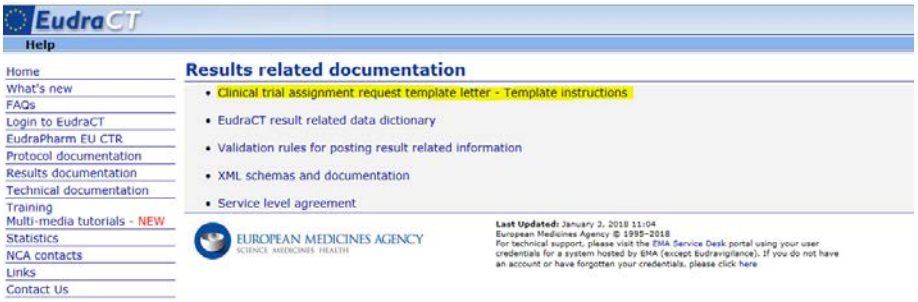
Step 3
Attach letter





Sample letter

https://eudract.ema.europa.eu/docs/guidance/CT_assignment_guide.pdf



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**

Request assignment – screen confirmation

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.

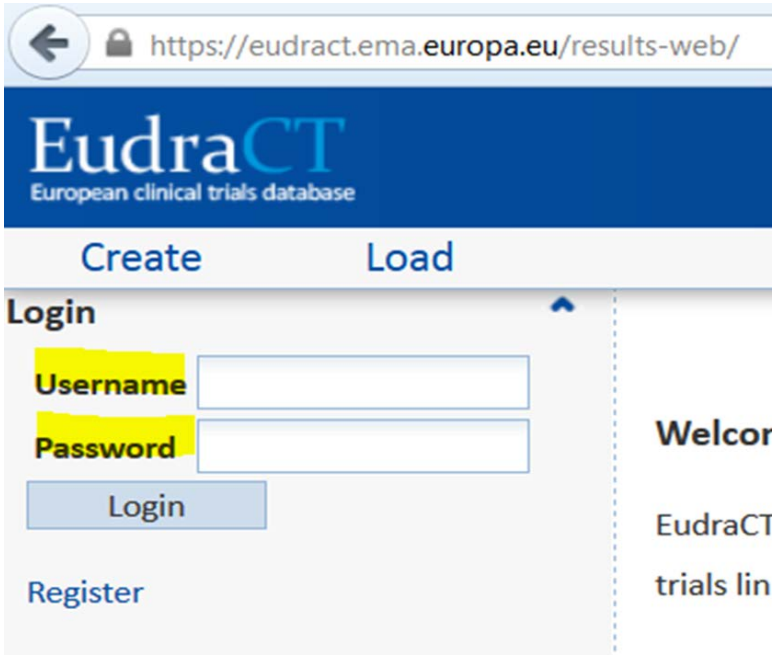
Kind regards

EudraCT

Please note you cannot reply to this email.

*Any technical issue with the system users can contact service desk https://servicedesk.ema.europa.eu

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		ich-test	26-Sep-2013	Draft	Edit | View | View assigned users
[redacted]	1			25-Sep-2013	Draft	Edit | View | View assigned users
[redacted]	1		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