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The CTR implementation at national level information session 3

15th of July 2017



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Practical information:

- Attendance list
- Documents you will receive:
 - Slides
 - Procedure selection criteria (current version)
 - CTR Pilot workprocessflow and timelines EC-College-FAMHP (current version)
 - Eudralink: how to get an account
- Next information session participating ECs:
 - Thursday [14/9/2017](#); 19h30; Eurostation
 - Agenda: information on recognition procedure,
- Questions? ct.college@health.belgium.be
 - helpdesk, change of contact details,



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Program

1. CTR Law and Royal Decree (RD): state of affairs
2. Feedback selection criteria:
3. Pilot projects:
 - Feedback working group
 - Update
4. How to use Eudralink
5. Barec: update



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1. State of affairs:

D. Kleinermans (Ministry of Social Affairs and Public Health)

G. Musch (FAMHP)

- Belgian Law:
 - New law: 7 May 2017
 - Law of 7 May 2004 to be revisited
- Royal Decrees (operational and fees)
- Symposium 26/9/2017



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2. Feedback selection criteria

L. Marynen (College, FPS Health)

- Deadline feedback draft version: 18/5/17 (Barec and working group)
- Outstanding issues discussed in the working group: 1/6/17

⇒ Revised text "selection EC v170612"

- Selection within validation period => criteria should be:
Simple, objective, transparent



2. Selection criteria:

1. Recognized EC
2. Additional recognition for phase 1 CTs
3. Independent of participating sites
4. Field expertise (conditions)
5. Extension study preferably assessed by EC evaluating initial CT
6. No major unsolved quality issues



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2. Selection algorithm:

- A. Authorization of a CT or an addition of Belgium as a CMS
 - *Basic system of rotation*
 - *The less often selected, the higher the ranking for the next selection*

- B. Authorization of a substantial modification or an addition, of another CMS
 - *EC initial authorization, unless criteria are no longer met (=> A.)*

- C. Appeal procedure
 - *A. but EC that performed initial evaluation is excluded*



2. Selection EC: remarks

- Refusal only in case of force majeure
- Transition period (old and new system)
- Details selection criteria
 - Procedure
 - Evaluation and optimisation



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3. Pilot projects

P. Vankeerberghen (FAMHP), L. Marynen (College, FPS Health)

- Feedback working group
 - Meetings: 23/2/17; 6/3/17; 23/3/17; 6/4/17, 20/4/17; 4/5/17; 1/6/17...
 - EC representatives: UZ Gent, Erasme, UZ Leuven, J. Bordet, AZ Delta, OLVZ Aalst

- Subjects discussed:
 - Procedure selection criteria (point 2)
 - Workprocessflow and timelines
 - Submission file and validation
 - Experimental learning: timesheeting and survey
 - Eudralink (point 4)



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3. Pilot projects

Workprocessflow and timelines

Document "CTR Pilot workprocessflow & timelines"

- Describes timepoints and flow EC-College-FAMHP
- Guideline throughout your pilot dossier
- Contains good practices
- Will be further developed during the first waves of the pilot project



3. Pilot projects

Submission file and validation

Dossier structure is based on CTR and available for sponsor under:

https://www.fagg-afmps.be/en/human_use/medicines/medicines/research_development/clinical_trials

Submission file Part II:

- All documentation has to be present and complete on T0
- CRF is not required
- Suitability of the site (written statement) consider verification completeness template.
- Financial agreement: needs draft figures, needs to be reasonable
- Financial disclosure: consider template (EMA template is suggested)
- Investigator CV: consider template



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3. Pilot projects

learning by doing: timesheeting and survey

- Timesheeting document (excel template) was developed
 - Template is sent together with the submission file
 - Consolidated table is obligatory (sheet 1)
 - Details would be helpful, workspace is provided (sheets 2-4)
- Post evaluation survey (survey monkey) to rate your experience and give feedback. 3 versions:
 - EC
 - College
 - FAMHP



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3. Pilot projects: update

- Learning by doing
 - 1 independent EC
 - Single communication to the sponsor
 - assessment report template and list of questions
- Flexibility is required
- Selection EC within the pilot
- Second wave



3. Updated short list of dossiers for pilot (1)

Proposed list for the pilot	EudraCT	Sponsor	Phase	Sites
002 Ongoing (T0=22/05/2017) (T23=14/05/2017)	2016-004502-34 (CA209-914) (<u>onco</u> : Localized Renal Cell Carcinoma)	BMS	III	Bordet UZ Gent CHU de Liège Virga Jesse Evaluating EC: Erasme
001 Ongoing (T0=29/05/2017)	2016-003100-30 (<u>neuro</u> : paediatric patients with relapsing remitting MS)	Genzyme	III	UZ Gent Evaluating EC : UZ Leuven
003 End of June	2016-000280-16 (<u>neuro</u> : post-herpetic neuralgia)	Novartis	II	UZ Antwerpen UZ Leuven Tivoli Evaluating EC: UZ Gent



3. Updated short list of dossiers for pilot (2)

Proposed list for the pilot	EudraCT	Sponsor	Phase	Sites
005 Early July (3rd of July?)	2014-004140-36 (<u>onco</u> : relapsed or refractory CD22-positive non-Hodgkin's lymphoma)	Bayer	I	2 centers being Bordet institute and UZ Leuven for the part B of this study which is already running for part A in UK and Sweden Evaluating EC: Olvz Aalst
006 Early August	5476414SMM3001 (<u>onco</u> : High- risk Smoldering Multiple Myeloma)	Janssen	III	6 sites (?) (not yet defined on 03-04-2017) Evaluating EC: TBD
004 Early September	2015-005504-28 (<u>onco</u> : thymic carcinoma previously treated with chemotherapy)	EORTC	II	UZA Bordet Evaluating EC: UZBrussel

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3. Pilot projects

Update

- **First findings:**
 - Intense learning curve and change for sponsors, agency, College and EC's.
 - Dossier preparation for Sponsors with the CTC's must be performed well before submission
 - Agency clinical assessment ongoing.
 - EC's evaluate investigation sites and investigators unknown to them

- **Adapted shortlist**
 - Continuous adaptation in function of sponsor's planning and summer holiday.



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4. How to use Eudralink

P. Vankeerberghen (FAMHP)

What is Eudralink ?

How to obtain an account?

How to use Eudralink?



What is Eudralink ?

- Eudralink is a safe European message system,
- will be used in the CTR pilot projects
- allows to safely transfer large dossiers
- uses the mail system, but the dossiers themselves do not travel through the mail



How to obtain an Eudralink account ?

- Is a 4 step process
 1. Fill in the Eudralinkrequestform.doc
 2. Obtain a service desk account: First go to this site:
<https://accounts.ema.europa.eu/registration>
 3. Login to service desk <https://servicedesk.ema.europa.eu>
 4. And create the request
- Login to <https://eudralink.ema.europa.eu/>



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How to obtain an Eudralink account?

Step 1: Fill in a request form

➤ save it as a word document

TIP: Put your name in the file name



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PERSONAL INFORMATION

Gender: → → [] ↑
Title: → → [] ↑
First Name: → → [] ↑
Last Name: → → [] ↑
Nationality: → → [] ↑
E-mail: → → [] → ↑

WORK INFORMATION

Company Name: + → [] → ↑
Company Address: → [] ↑
→ City: → → [] → ↑
Zip Code: → [] → ↑
Country: → [] ↑
Department: → → Ethics Committee ↑
Job Title: → → → [] ↑
Phone Number: → → [] ↑
Web Page: → → [] ↑
Company Position → Others → Not members of EudraNet → Human Domain ↑



||
MOTIVATION

Use of the Eudralink account

Secure communication between college (coordinating ethical evaluation) and ethics committee regarding clinical trial applications in Belgium

↑

Third-country data provider access for EudraCT required

↑

↑

INFORMATION ON EMEA OR MS CONTACT POINT (PTL) FOR ACCOUNT REQUEST (if available)

First Name: → Elisabeth

Last Name: → Marynen

MS Agency → Federal public service Health, Food chain safety and environment

Country: → BE

E-Mail: → Lisa.Marynen@gezondheid.belgie.be

Phone Number: → 0032-2-524-85-46

↑



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How to obtain an Eudralink account?

Step 2: Create a service desk account

- Login: <https://accounts.ema.europa.eu/registration>
- Click: Register for an account



Home

Register for a EMA Service Desk portal account

These pages allow you to register for a username and password to access EMA Service Desk portal.

[Register for an account](#)

If you already have an account, please [log in](#) to see your registered details or change your password. [Need help?](#)

Copyright © 2016 European Medicines Agency - ecdmanager.account : 1.1.0.0 (534) built on Tue, Apr 19, 2016 at 09:48

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How to obtain an Eudralink account?

Step 2: Create a service desk account

- Check the thickbox "I have read and understood..."
- Click: submit

I have read and understood the data protection and confidentiality statement.

Cancel Submit



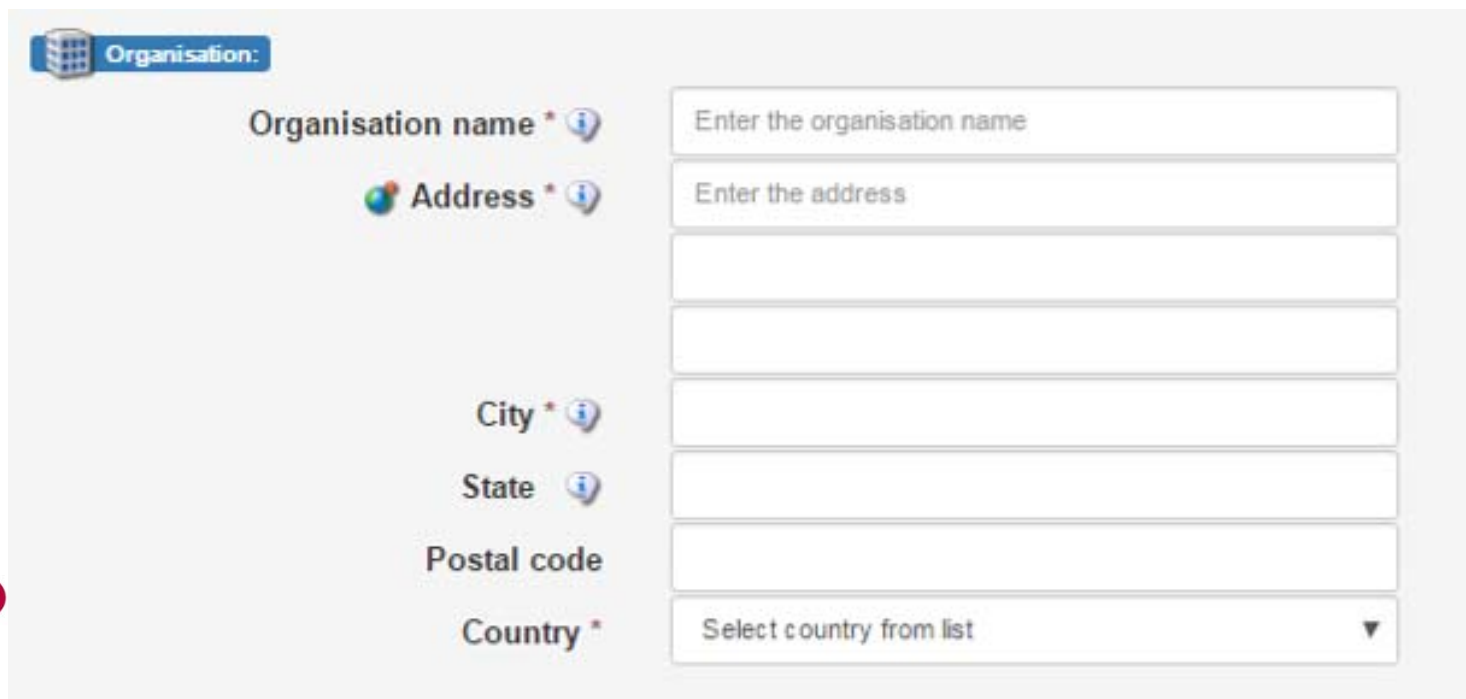
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How to obtain an Eudralink account?

Step 2: Create a service desk account

- Fill in organisation details



The screenshot shows a web form titled "Organisation:" with a grid icon. The form contains the following fields:

- Organisation name *** (with an information icon): A single-line text input field containing the placeholder text "Enter the organisation name".
- Address *** (with a globe icon and an information icon): A multi-line text input area with the placeholder text "Enter the address".
- City *** (with an information icon): A single-line text input field.
- State** (with an information icon): A single-line text input field.
- Postal code**: A single-line text input field.
- Country ***: A dropdown menu with the placeholder text "Select country from list" and a downward arrow.

Decorative elements include a red and green swirl logo on the bottom left and a "be" logo on the bottom right.

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How to obtain an Eudralink account?

Step 2: Create a service desk account

- Fill in personal details
- Click submit

The screenshot shows a web form titled "Personal details:" with the following fields:

- Title * (dropdown menu)
- First name * (text input)
- Last name * (text input)
- Nationality (dropdown menu with "Select country from list" text)
- E-mail address * (text input with "@" symbol)
- Confirm e-mail * (text input with "@" symbol)
- Telephone * (text input with UK flag and "07400 123456")
- Fax (text input with UK flag and "07400 123456")
- Mobile (text input with UK flag and "07400 123456")

At the bottom of the form, there is a "Cancel" button and a "Submit" button. A yellow highlight is drawn around the "Submit" button. A small red asterisk icon indicates a mandatory field. The text "notes mandatory field" is partially visible at the bottom left. The "be" logo is visible at the bottom right.



How to obtain an Eudralink account?

Step 2: Create a service desk account

- You will receive a 1st e-mail with your username & a URL
 - Click on the URL given in that e-mail

- You will receive a 2nd e-mail with your password



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How to obtain an Eudralink account?

Step 3: Login to the service desk with your account

- Username & password
- Click login

Login

Username

pvankeerberghen

Password

.....

Log in

Keep me logged in



.be

How to obtain an account?

Step 3: Login to the service desk with your account

- username & password
- Click login
- Click service desk

EMA Service Desk

Popular

[Service Desk](#)

[Browse all](#)

Recent



[Access Request](#)

EMA Service News

The EMA electronic gateway is now available following earlier technical issues
07:50 (UK time), 05/05/2017
The EMA electronic gateway is now available following earlier technical issues. Thank you for

EMA Service Desk

[Service Desk](#)

Welcome to the EMA Service Desk self-service portal which enables you to request the services you require from the Agency.

How to obtain an account?

Step 4: Login to the service desk with your account

- username & password
- Click login
- Click service desk

EMA Service Desk

🔍 Find a solution

EMA Service News

The EMA electronic gateway is now available following earlier technical issues
07:50 (UK time), 05/05/2017
The EMA electronic gateway is now available following earlier technical issues. Thank you for

Service Desk

Welcome to the EMA Service Desk self-service portal which enables you to request the services you require from the Agency.



How to obtain an account?

Step 4: Request a Eudralink account

- username & password
- Click login
- Click service desk
- Click Request a service

Service Desk

Service Desk

Welcome to the EMA Service
from the Agency.

Ask a Question

Request a Service

Report an Issue

Propose a Change



How to obtain an account?

Step 4: Request a Eudralink account

- username & password
- Click login
- Click service desk
- Click Request a service
- Click Access, permission, ...



Access, permission, content updates and password requests

Request access to an application or system (e.g. Eudralink), permission changes (e.g. public folders in Outlook, ACL for Documentum), content update (e.g. update profiles in ECD) and password resets



How to obtain an account?

Step 4: Request a Eudralink account

- username & password
- Click login
- Click service desk
- Click Request a service
- Click Access, permission, ...
- Fill in the form as indicated in next slide &
- via "Choose files" you can upload the word doc (saved in step 1)
- Click Create
- EMA will set up your Eudralink account





Access, permission, content updates and

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Subject

access to Eudralink please

Software (optional)

EudraLink

Description

Dear Mrs, Sir, I would like to have a Eudralink account to participate in the Belgium Clinical trial regulation Pilot project. Sincerely, Pieter

Attachment (optional)

Choose file(s)

Create

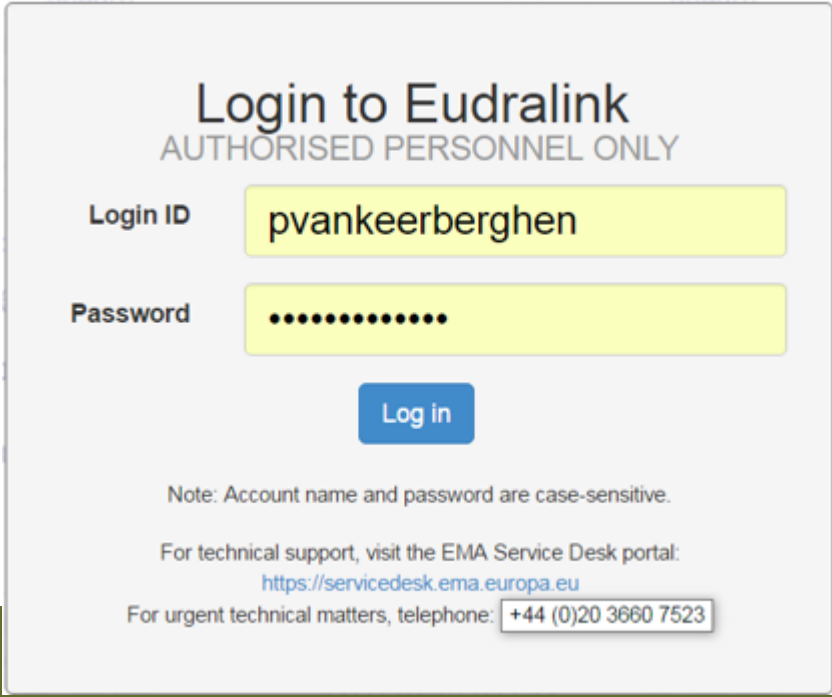
Cancel



How to use Eudralink?

Login <https://eudralink.ema.europa.eu/>

➤ With username & password



The screenshot shows a login form titled "Login to Eudralink" with the subtitle "AUTHORISED PERSONNEL ONLY". It features two input fields: "Login ID" containing the text "pvankeerberghen" and "Password" containing ten dots. A blue "Log in" button is positioned below the fields. Below the button, there is a note: "Note: Account name and password are case-sensitive." followed by technical support information: "For technical support, visit the EMA Service Desk portal: <https://servicedesk.ema.europa.eu>" and "For urgent technical matters, telephone: +44 (0)20 3660 7523".



How to use Eudralink?

Login <https://eudralink.ema.europa.eu/>

- With username & password
- Click New package

1.Fill in To:

2.Fill in Subject &
Message

Tracking
New Package
Drafts
Address
Options
Logout

1. Enter the e-mail addresses you wish to send this package to, or clicking the button below).

Address Book

Add e-mail addresses to the Address Book.

Make e-mail addresses visible to all recipients.

TO: ct.college@health.belgium.be

CC:

(in the form name1@example.com, name2@example.com ...)

2. Write a subject and message (optional).

Subject: CTR Pilot dossier 2017-001908-02

Message: Dear Lisa,
Please find hereafter the dossier.
Sincerely, Pieter

.be

How to use Eudralink?

Login <https://eudralink.ema.europa.eu/>

- With username & password
- Click New package

1.Fill in To:

2.Fill in Subject & Message

3.Choose a file & click add

3. Choose the files you wish to send or select 'No File Attachments'.

File Attachments
 No File Attachments

Click the "Browse" button to select file for delivery, then click the "Add" button.
To include other files, repeat this two-step process for each file.

Choose File Sanofi_PILO...1_TEST.zip

Add

(Warning: There is a size limit of 200Mb per file. There is no maximum package size.
Uploading large files may take some time, please be patient.)



How to use Eudralink?

Login <https://eudralink.ema.europa.eu/>

- With username & password
- Click New package

1.Fill in To:

2.Fill in Subject & Message

3.Choose a file & click add

4.Choose level of security

5.Set availability to 90 days



4. Choose the level of security for this package.

The recipient(s) must have a Eudralink account to access the package.

The recipient(s) must enter this password:

confirm password:

No password.

5. Choose how long the package will remain available to be collected.

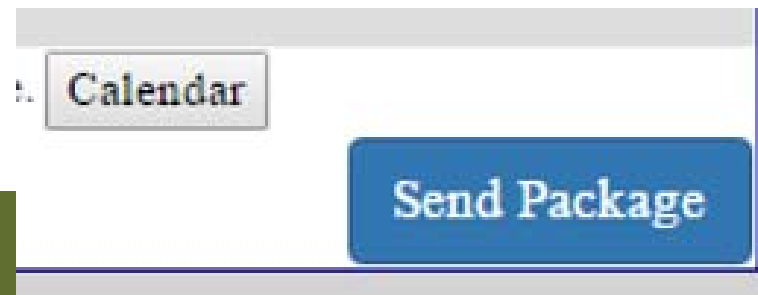
This package will be available for day(s). Or select the expiry date.

How to use Eudralink?

Login <https://eudralink.ema.europa.eu/>

- With username & password
- Click New package

- 1.Fill in To:
- 2.Fill in Subject & Message
- 3.Choose a file & click add
- 4.Choose level of security
- 5.Set availability to 90 days
- 6.Click "Send Package"



5. Barec: update

C. Vansteenkiste (BAREC)

- 04-05-2017:
 - *General assembly and election board of directors (10 members)*
- 18-05-2017
 - *Board meeting: election treasurer/secretary/vice-president and president*
- 14-06-2017:
 - *Board meeting: designation goals/program/responsibilities boardmembers*
 - *35 EC member or intention to become member*
- participation CTR meetings



Info: see www.BAREC.be



5. Barec: update

- President :** Mevr. C. Vansteenkiste, Commissie voor Medische Ethiek UZ Brussel
- Vice-President :** Prof. Dr. J.M. Maloteaux, Comité d'Ethique Cliniques Universitaire St.Luc
- Treasurer :** Dr. A. Leloup, Commissie voor Medische Ethiek OLV Aalst
- Secretary :** Dr. S. Graux, Commissie voor Medische Ethiek UZ KU Leuven
- Members :** Dr. K. Ackaert, Commissie Medische Ethiek AZT Turnhout
Prof. Dr. P. Evrard, Comité d'Ethique Cliniques Universitaires Mont-Godinne
Prof. Dr. A. Herchuelz, Comité d'Ethique ISPPC
Mr. G. Niset, Comité d'Ethique Erasme-ULB
Prof. Dr. R. Rubens, Commissie voor Medische Ethiek UZ Gent
E.H.B. Vanderhaegen, Commissie voor Medische Ethiek AZ St.-Lucas, Gent



Thank you for your attention

