

RNEC

User Manual

For more detailed information please access to: RNEC/ Sponsor Information
October 2016

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RNEC

Submission of Clinical studies through RNEC

The submission of Clinical Studies through RNEC portal is applicable to:

A – Interventional studies with Investigational Medical Products (Human)

B – Interventional studies with Medical Devices

C – Interventional studies with cosmetic products

D – Non-interventional Post Authorization Efficacy Studies (PAES)

E – Non-interventional Post Authorization Safety Studies (PASS)

Only Categories A and B studies should be submitted to ***CEIC***. Studies from categories C,D and E should be submitted to the local Clinical Site's Ethics Committee (CES) according to the respective procedures.

Only when the Clinical Site does not has a local Ethics Committee (CES), categories C,D and E studies should be submitted to CEIC through RNEC.

NOTE: All Studies that are submitted to CEIC outsider of the scope of its assessment competences will be automatically stored without any evaluation or associated procedure – Law 21/2016 from April 16.

RNEC

Registration

Registration (mandatory)

1. Create Register

AUTHENTICATION

Username

Password

REGISTER

In order to carry out registration of studies in RNEC please click on “Create Register” and fill out the required information. The veracity of the information provided in the registry is the user's responsibility. By accepting the terms and conditions you consent to the publication of the inserted data.

2. Fill in the required information depending on the Entity Type;

- Applicant;
- Sponsor;
- Clinical Study Site;
- Ethics Committee
- Investigator
- Other

3. System Validation

Entity Type

Sponsor Applicant

Clinical Study Site Investigator

Ethics Committee

Other

Entity Information

Entity Name *

Country *

Fiscal Number *

Contact Information

Name *

Email * Phone Number

Address *

Zip Code * City *

Terms of Use

* I authorize the public disclosure of the registered data. I also assure that all registered data are true.

Change Password

3. Change Password

a) Login

The screenshot shows the RNEC authentication interface. On the left, under the heading 'AUTHENTICATION', there are two input fields: 'Username' and 'Password'. Below these fields are two buttons: 'Login' and 'Recover Password'. The 'Login' button is circled in red. On the right, under the heading 'REGISTER', there is a paragraph of text: 'In order to carry out registration of studies in RNEC please click on "Create Register" and fill out the required information. The veracity of the information provided in the registry is the user's responsibility. By accepting the terms and conditions you consent to the publication of the inserted data.' Below this text is a 'Create Register' button.

b) Select User (Number/Entity)

The screenshot shows the RNEC user selection menu. At the top is the RNEC logo. Below it is a blue header bar with a user icon, the ID '20160600009', and the entity name 'Infarmed-JF'. This header bar is circled in red. Below the header is a list of menu items: 'Clinical Studies', 'Clinical Trials', and 'Others'. Each item has a 'Search' and 'Create New Request' link.

c) Change Password

The screenshot shows the RNEC user profile page. At the top left is the RNEC logo. At the top right are 'Alerts 0' and 'Contacts' buttons. Below the logo is a blue header bar with a user icon, the ID '20160600009', and the entity name 'Infarmed-JF'. Below the header is a list of menu items: 'Clinical Studies', 'Clinical Trials', and 'Others'. Each item has a 'Search' and 'Create New Request' link. On the right side of the page, there is a 'Change to registration information' button, which is circled in red. Below it is a 'Change password' button, also circled in red. At the bottom right is an 'Entity Type' button.

Recover Password

To recover your password:

a) Select “Recover Password” from the login screen



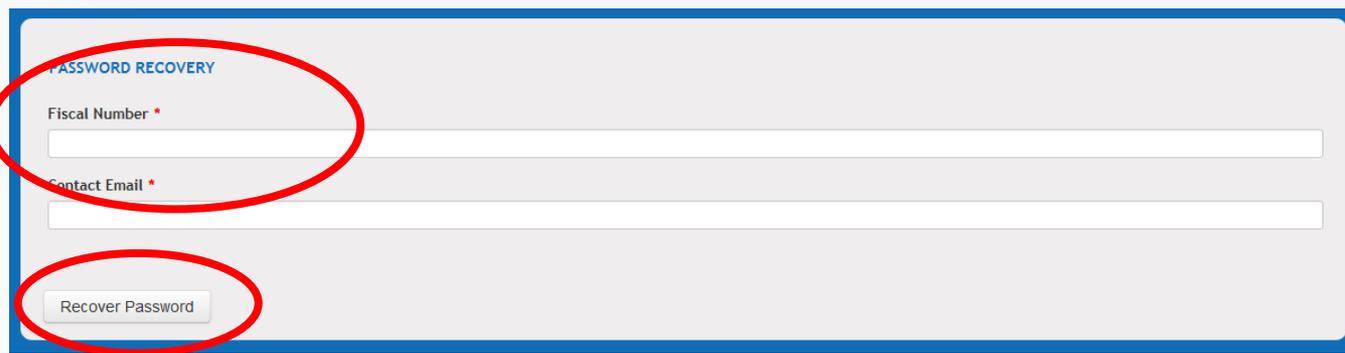
The screenshot shows a login interface with two main sections: 'AUTHENTICATION' and 'REGISTER'. Under 'AUTHENTICATION', there are input fields for 'Username' and 'Password', and buttons for 'Login' and 'Recover Password'. The 'Recover Password' button is circled in red. The 'REGISTER' section contains a paragraph of text and a 'Create Register' button.

b) Insert NIF/NIPC and email contact

c) Recover Password

b →

c →

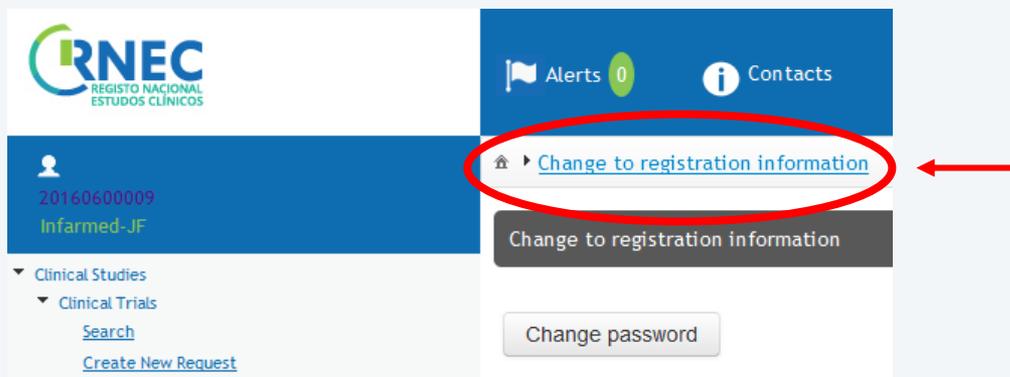


The screenshot shows a 'PASSWORD RECOVERY' form. It has two input fields: 'Fiscal Number *' and 'Contact Email *'. Both fields are circled in red. Below the fields is a 'Recover Password' button, also circled in red. A red arrow labeled 'b' points to the 'Fiscal Number' field, and another red arrow labeled 'c' points to the 'Recover Password' button.

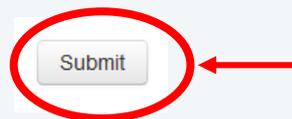
Change to registration information

To change your registration information

- a) Login
- b) Select User (Number/Entity)
- c) Click on change to registration information



- d) Introduce the new/corrected information
- e) Click "Submit" on the left lower corner



RNEC

Navigation Bar
Requests Visualization
and Related Activities

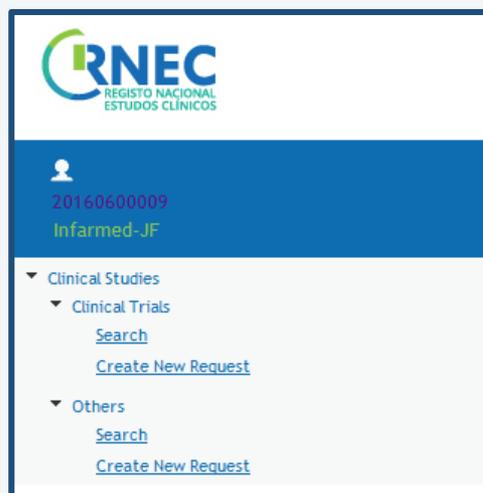
Navigation Bar

Clinical Studies

1. Search
2. Create New Request

Others

1. Search
2. Create New Request



The screenshot shows a navigation bar for the CRNEC (Registo Nacional Estudos Clínicos) website. At the top left is the CRNEC logo. Below it, a blue bar contains a user profile icon, the ID number 20160600009, and the name Infarmed-JF. The main navigation area is a white box with a blue border, containing a dropdown menu with the following items:

- ▼ Clinical Studies
 - ▼ Clinical Trials
 - [Search](#)
 - [Create New Request](#)
 - ▼ Others
 - [Search](#)
 - [Create New Request](#)

Search (Clinical Studies and Other Studies)

Navigation bar

a) Select Search

b) Select Criteria

c) Click Search

d) Visualize Results

e) Click on "Open" for detailed information about a particular study

RNEC
REGISTO NACIONAL
ESTUDOS CLÍNICOS

20140600009
Informed-JF

▼ Clinical Studies

- ▼ Clinical Trials
 - [Search](#)
 - [Create New Request](#)
- ▼ Others
 - [Search](#)
 - [Create New Request](#)

Clinical Studies Search

Search Area

RNEC Number EudraCT Number Protocol Number

Title

Sponsor: All | Investigator: All | Submission Date From:

Published: All | Clinical Study Site: All | Submission Date Until:

Search Result Area

RNEC Number	EudraCT Number	Sponsor	Protocol Number	Title	Addressee	Last Publication Date	Action
393	2014-005339-15	Empresa Inês Costa	CAIN457A3302	Long term clear skin maintena...	CEC Informed		Open
392	2014-000000-00	Baião Vermelho	BM-PET-YRGATQ-7482	A phase 4 open label randomiz...	CEC Informed		Open

Detailed information on a specific Clinical Study

1) Search area

- Select criteria
- Search
- Detail – Visualize Search results
- Open Request/Notification

2) Create Request/Specific notification for this Clinical Study

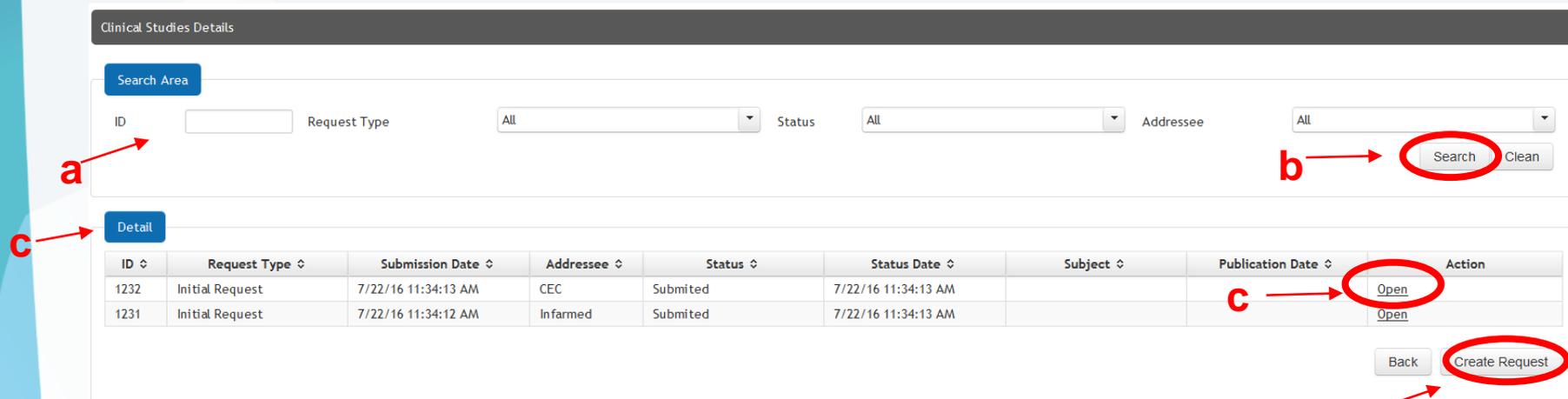


20160600009
Infarmed-JF

- Clinical Studies
 - Clinical Trials
 - [Search](#)
 - [Create New Request](#)

RNEC Number	MD000393
EudraCT Number	2014-005339-15
Authorization Date	-
CEC Opinion	-
CEC Opinion Date	-
Public Information	-

- Others
 - [Search](#)
 - [Create New Request](#)



Clinical Studies Details

Search Area

ID Request Type All Status All Addressee All [Search](#) [Clean](#)

Detail

ID	Request Type	Submission Date	Addressee	Status	Status Date	Subject	Publication Date	Action
1232	Initial Request	7/22/16 11:34:13 AM	CEC	Submitted	7/22/16 11:34:13 AM			Open
1231	Initial Request	7/22/16 11:34:12 AM	Infarmed	Submitted	7/22/16 11:34:13 AM			Open

[Back](#) [Create Request](#)

Visualize detailed information on a specific request

Detailed Information

a) Visualize all the information of the specific request:

- Request details
- Description
- End of Trial
- XML File
- Documents
- Public Information
- Payments

Request Details - Initial Request - PI001232

ID: 1232 | Submission Date: 22-07-2016 | Addressee: CEC | Status: Submitted
 Applicant: infarmed-JF | Sponsor: Empresa Inês Costa | Status Date: 22-07-2016

XML File: 2014-005339-15.PT.20150220.CTA.PT.20Feb15.xml | EudraCT Number: 2014-005339-15

Documents:

File Name
1 teste.docx

Public Information:

Sponsor: Empresa Inês Costa

Clinical Study Sites				
Clinical Study Site	Department	Main Investigator	Ethics Committee	Status
Centro de Estudo Clínico - DepartamentoTeste	DepartamentoTeste	André Silva	Comissão do Pedro	Not Commenced

Advertising Materials:

File Name	Type
teste.docx	Poster

Payments:

Type	Created Date	Status	Status Date	Amount
Isenção	7/22/16 11:34:12 AM		7/22/16 11:34:12 AM	0,00€

a (points to the 'Status' field)

b (points to the 'Amend' button)

b) Amend

Visualize list of activities of a specific request

Request Details- Activities List:

a) Search:

- Type of Activity
- Addressee

b) Detail: Results Visualization

- Type of Activity
- Submission Date
- Sender
- Addressee
- Subject

c) Open details of specific activity

Activities List

Search

Type of Activity: All Addressee: All

Search Clean

Detail

Type of Activity	Submission Date	Sender	Addressee	Subject	Action
Communication	7/29/16 10:36...	CEC	Infarmed-JF	Lack of content	Open
Communication	7/29/16 10:34...	CEC	Infarmed-JF	Request for documents	Open

Back

Visualize details of specific activities

a) Visualize details of specific activities:

- Request Details
- Description
- End of Trial
- XML File
- Documents
- Public Information



b) Reply – to a specific activity request

▸ Clinical Studies ▸ Clinical Trials ▸ Clinical Studies Details ▸ Request Detail ▸ Activities List ▸ Activity Detail

Request Details - Communication - CM001235

ID: 526413 Submission Date: 29-07-2016 Addressee: Informed-JF
Applicant: Informed-JF Sponsor: Empresa Inês Costa
Sender: CEC

Description

Subject: Lack of content
Description: Please contact

Documents

	File Name
1	Chrysanthemum.jpg

Back Reply



RNEC

Submission a new Clinical Study request

Legal Framework applicable to the submission of Clinical Trials requests:

- [Lei n.º 21/2014, de 16 de abril](#), modified by [Lei n.º 73/2015 de 27 de julho](#).
- [Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial \(CT-1\)](#)
- [Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use \(CT-2\)](#)

How to organize folders:

For simultaneous submissions to CEIC and INFARMED, two separate folders should be attached INFARMED and CEIC, respectively. The submitted folders should be organized according to the guidelines available at websites of each of the entities involved (INFARMED and CEIC).

Create New Request

a) Login

b) Navigation Bar– Create New Request

c) Select Type of Request

- Initial Request
- Change of Applicant
- Financial Agreement

d) Select Addressee

- INFARMED
- CEIC
- INFARMED + CEIC

e) Select and attach XML File

The screenshot shows the 'Create New Request' web form. At the top right, the CRNEC logo is visible. Below it, a user profile bar shows the user 'Infarmed-JF' with ID '20140600009'. A red arrow 'a' points to this profile bar. Below the profile bar, a navigation menu includes 'Clinical Studies', 'Clinical Trials', 'Search', and 'Create New Request'. A red arrow 'b' points to the 'Create New Request' link. The main form area has a breadcrumb trail: 'Clinical Studies > Clinical Trials > Create Request'. Below this, there are tabs for 'Type and Addressee', 'Detail', 'Documents', 'Public Information', and 'Fee'. The 'Type and Addressee' tab is active. Under this tab, there is a 'Type of Request' dropdown menu with 'Initial Request' selected. A red arrow 'c' points to this dropdown. Below it is an 'Addressee' section with checkboxes for 'INFARMED - National Authority of Medicines and Health Products, I.P.' and 'CEC - Competent Ethics Committee'. A red arrow 'd' points to this section. At the bottom of the form, there is an 'XML' section with a 'Select File' button and a text input field containing '2012-001888-78 PT 20120807.xml'. Below this is another text input field for 'EudraCT Number' containing '2012-001888-78'. A red arrow 'e' points to the 'XML' section. At the bottom right of the form, there are 'Cancel', 'Previous', and 'Next' buttons.

Create New Request (2)

f) Attach the requested documents for Authorities submission*1



g) Fill in/attach the information to be Publicly Available :



- Select the Sponsor
- Select the Clinical Study Sites
- Attach the Advertising Materials

Clinical Studies > Clinical Trials > Create Request

Create Request

Type and Addressee | Detail | Documents | Public Information | Fee

Documents

File Addressee All

File Name	Addressee	
Desert.jpg	Infarmed	Remove
Desert.jpg	CEC	Remove
Hydrangeas.jpg	Infarmed	Remove
Hydrangeas.jpg	CEC	Remove
Koala.jpg	Infarmed	Remove
Koala.jpg	CEC	Remove

Sponsor

Sponsor *

Clinical Study Sites

Clinical Study Sites	Service	Recruitment Status	Main Investigator	Ethics Committee	
Centro11	Histórico11	Not Commenced	Hilário Silva	Comissão de Ética A	Edit Remove
Hospital de água - Servi...	Serviço de cardiologia	Not Commenced	André Silva	Comissão Ética Altran	Edit Remove

Advertising Material

File Name	Type	
Penguins.jpg	Poster	Remove
Tulips.jpg	Flyer	Remove

*1- Please refer to the guidelines [“Estrutura da Documentação” em RNEC/Estudos com Intervenção/Medicamentos Experimentais/Informação ao Promotor.](#)

The platform does not support files > 20 mb

Create New Request (3)

h) Fees

1) Select Invoice Data

- Sponsor/Applicant
- Entity
- Address

2) Select Fee^{*2}

1

2

The screenshot shows a web form titled 'Fees'. It contains two main sections. The first section, 'Invoice Data', has two radio buttons: 'Sponsor' (which is selected) and 'Applicant'. Below these are two dropdown menus: 'Entity' with the value 'GomesPharma' and 'Address' with the value 'Av. Bertim'. The second section, 'Select Fee', has a dropdown menu for 'Fee' with the value 'CTA - Phases I to III - 1.000,00 €'. At the bottom right of the form are four buttons: 'Cancel', 'Save', 'Previous', and 'Submit'. Red arrows point from the text '1' to the 'Invoice Data' section and from '2' to the 'Select Fee' section.

^{*2} Information about fees is available at: Portaria 63/2015 e em [RNEC/Estudos com Intervenção/Medicamentos Experimentais/Informação ao Promotor](#).

Create New Initial Request for an existing Clinical Trial

Only possible when:

- The Clinical Trial has not been submitted to the address (Eg: Submission to only **one** of the regulatory authorities)
- The status of the initial request is either: "Canceled", "Invalid", "Rejected", or "Unfavorable"

Amend the Initial Request

a) Select the Request Details

b) Amend (*only possible if the status of the Clinical Study is either: "Submitted", "In Validation" or "In Evaluation")

a →

[Clinical Studies](#) > [Clinical Trials](#) > [Clinical Studies Details](#) > [Request Detail](#)

Request Details - Initial Request - PI001232

* → **Status**
 Submitted

ID: 1232 Submission Date: 22-07-2016 Addressee: CEC
 Applicant: infarmed-JF Sponsor: Empresa Inês Costa

XML File
 XML File: 2014-005339-15 PT_20150220_CTA_PT_20Feb15.xml EudraCT Number: 2014-005339-15

Documents

	File Name
1	teste.docx

Public Information
 Sponsor: Empresa Inês Costa

Clinical Study Sites				
Clinical Study Site	Department	Main Investigator	Ethics Committee	Status
Centro de Estudo Clínico - Depart...	DepartamentoTeste	André Silva	Comissão do Pedro	Not Commenced

Advertising Materials		
File Name		Type
teste.docx		Poster

Payments

Type	Created Date	Status	Status Date	Amount
Isenção	7/22/16 11:34:12 AM		7/22/16 11:34:12 AM	0,00€

Back **Amend**

b →

c) Create Request section

d) Update XML file (if applicable)

e) Attach the required documents to the request

f) Update the Publicly Available documentation (if applicable)

g) Submit

The screenshot shows the 'Type and Addressee' tab of the infarmed application. The 'Type of Request' dropdown is set to 'Amend'. The 'Addressee' dropdown is set to 'CEC - Competent Ethics Committee'. The 'XML' section shows an 'XML File' field and a 'EudraCT Number' field with the value '2014-005339-15'. The 'Documents' section shows a table with columns for 'File Name' and 'Addressee', and a 'No Records' message. The 'Sponsor' dropdown is set to 'Empresa Inês Costa'. The 'Clinical Study Sites' section shows a table with columns for 'Clinical Study Sites', 'Service', 'Recruitment Status', 'Main Investigator', and 'Ethics Committee'. The 'Advertising Material' section shows a table with columns for 'File Name', 'Type', and 'Remove'. At the bottom right, there are 'Cancel', 'Previous', and 'Submit' buttons. Red arrows labeled c through g point to these sections: c) Type of Request, d) XML File, e) Documents, f) Advertising Material, and g) Submit button.

Type and Addressee | Detail | Documents | Public Information

Type of Request

Type of Request * Amend

Addressee

CEC - Competent Ethics Committee

Cancel Next

i If there are no changes to the XML file, you don't need to add it again.

! Part, or all, of the filled data was submitted but not yet approved.

XML

XML File + Select File

EudraCT Number 2014-005339-15

Documents

File + Select File

Addressee CEC

Add

File Name	Addressee
No Records	

! Part, or all, of the filled data was submitted but not yet approved.

Sponsor

Sponsor * Empresa Inês Costa

Clinical Study Sites

Add

Clinical Study Sites	Service	Recruitment Status	Main Investigator	Ethics Committee	
Centro de Estudo Clinic...	DepartamentoTeste	Not Commenced	André Silva	Comissão do Pedro	Edit Remove

Advertising Material

Add

File Name	Type	Remove
teste.docx	Poster	Remove

Cancel Previous **Submit**

RNEC

Create Substantial Amendment request

Legal Framework applicable to the submission of Substantial Amendments:

- [Lei n.º 21/2014, de 16 de abril](#), alterada pela [Lei n.º 73/2015 de 27 de julho](#).
- [Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial \(CT-1\)](#)
- [Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use \(CT-2\)](#)
- [Formulário de Pedido de Autorização de Alteração Substancial](#)

The electronic submission of substantial amendments is only possible if the respective Clinical Trial has been previously submitted through RNEC - electronic platform. Substantial amendments referring to all other trials should be submitted according to the usual procedure.

How to organize folders:

For simultaneous submissions to CEIC and INFARMED, two separate folders should be attached INFARMED and CEIC, respectively. The submitted folders should be organized according to the guidelines available at websites of each of the entities involved (INFARMED and CEIC).

Create Substantial Amendment request (1)

a) Login

b) Navigation Bar

- Clinical Study Details
- Create Request

d

e

Clinical Studies > Clinical Trials > Clinical Studies Details > Create Request

Create Request

Type and Addressee Detail Documents Public Information Fee

Type of Request

Type of Request * Substantial Amendment

Addressee

INFARMED - National Authority of Medicines and Health Products, I.P. CEC - Competent Ethics Committee

Cancel Next

c) Rules for Substantial Amendments submission:

INFARMED – Time frame between Initial Request's Approval until Final Report Submission

CEIC – Allowed after submission of initial request and as long as the status is diferente from: "Invalid", "Rejected", "concluded", "Early concluded"

d) Select– Substantial Amendment

e) Select Addresses

Create Substantial Amendment request (2)

d) Select/attach XML file if applicable *1

e) Include description of the Substantial Amendment

f) Attach documentation if applicable *1

g) Update/Fill in the Publicly Available Material/Information

h) Fee Payment (slide 18)

- Select Invoice Data
- Select Fee*2

1- Please refer to “[Estrutura da Documentação](#)” in [RNEC/Estudos com Intervenção/Medicamentos Experimentais/Informação ao Promotor](#). The platform does not support files > 20 mb

2- Information about fees available at: Portaria 63/2015 and in [RNEC/Estudos com Intervenção/Medicamentos Experimentais/Informação ao Promotor](#).

d
e

f

g

The screenshot shows the 'Detail' tab of a Substantial Amendment request form. It includes the following sections:

- XML:** A section for uploading an XML file and entering the EudrACT Number (2014-005339-15).
- Description:** A section for entering the Subject and Description of the amendment.
- Documents:** A table listing attached files:

File Name	Addressee	
Tulips.jpg	CEC	Remove
Lighthouse.jpg	CEC	Remove
- Sponsor:** A dropdown menu showing 'Empresa Inês Costa'.
- Clinical Study Sites:** A table listing study sites:

Clinical Study Sites	Service	Recruitment Status	Main Investigator	Ethics Committee	
Centro de Estudo Clinic...	DepartamentoTeste	Not Commenced	André Silva	Comissão do Pedro	Edit Remove
- Advertising Material:** A table listing advertising materials:

File Name	Type	
teste.docx	Poster	Remove

At the bottom of the form, there are navigation buttons: Cancel, Save, Previous, Next.

Amend Request of Substantial Amendment

a) Request Details Screen

b) Amend (only possible if the current state is equal to Submitted, In Validation or in Evaluation)

c) Create Request

d) Update XML file (if applicable)

e) Attach the required documents for the amendment;

b



▲ Clinical Studies > Clinical Trials > Clinical Studies Details > Request Detail > Create Request

Create Request

Type and Addressee Detail Documents Public Information

Type of Request

Type of Request * Amend

Addressee

CEC - Competent Ethics Committee

d



Type and Addressee Detail Documents Public Information

i If there are no changes to the XML file, you don't need to add it again.

XML

XML File + Select File

EudraCT Number 2014-001783-34

e



Type and Addressee Detail Documents Public Information

Documents

File + Select File Addressee CEC Add

File Name	Addressee
No Records	

Cancel Previous Next

Amend Request of Substantial Amendment (2)

f) Update of the Advertising Materials (if applicable)

g) Submit

Type and Addressee Detail Documents **Public Information**

Sponsor

Sponsor * PharmaCG

Clinical Study Sites

Clinical Study Sites	Service	Recruitment Status	Main Investigator	Ethics Committee	
Hospital de água - S...	Serviço de cardiolo...	Not Commenced	João Silva	Comissão de Ética ...	Edit Remove

Add

Advertising Material

File Name	Type	
Jellyfish.jpg	Flyer	Remove

Add

Cancel Previous **Submit**

e

g

RNEC

Submission of a End of Trial Notification

Legal Framework applicable to the submission of a End of Trial Notification:

- [Lei n.º 21/2014, de 16 de abril](#), alterada pela [Lei n.º 73/2015 de 27 de julho](#)
- [Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial \(CT-1\)](#)
- [Formulário de Conclusão de Ensaio Clínico \(pdf\)](#)

The electronic submission of End of Trial Notifications and Final Reports is only possible if the respective Clinical Trial has been previously submitted through RNEC - electronic platform. All notifications referring to all other trials should be submitted according to the usual procedure.

Submission of End of Trial Notification(1)

- a) Clinical Studies details screen
- b) Create New Request
- a) Rules for submission for End of Trial declaration:
 - INFARMED** – Status = “Authorized”
ou “Suspended”
 - CEIC** – Status = “Favorable”,
“Conditioned” ou “Suspended”.
- d) Select – Global End

d →

The screenshot shows a web form with three tabs: 'Type and Addressee' (active), 'Detail', and 'Documents'. Under the 'Type and Addressee' tab, there is a 'Type of Request' section with a dropdown menu currently showing 'Global End'. Below this is an 'Addressee' section with two checked checkboxes: 'INFARMED - National Authority of Medicines and Health Products, I.P.' and 'CEC - Competent Ethics Committee'. At the bottom right of the form are 'Cancel' and 'Next' buttons.

Submission of End of Trial Notification(2)

e) Include a description of the declaration

f) Select type of end of trial

- Early End of Trial
- As foreseen in the Protocol

g) Include End of Trial date

h) Attach the relevant documents

f) Submit

e



f, g



h



Type and Addressee | Detail | Documents

Description

Subject *

Description *

Global End

Date of Global End * | Type of Global End *

Cancel Save Previous Next

Type and Addressee | Detail | Documents

Documents

File | + Select File | Addressee | All | Add

File Name	Addressee
No Records	

Cancel Save Previous Submit

Change of a End of Trial Notification (3)

- End of Trial Declaration Details screen
- Amend
- Update the relevant information
- Attach the relevant documentation
- Submit

ID: 1244 | Submission Date: 01-08-2016 | Addressee: CEC | Status: Submitted
Applicant: Informed-JF | Sponsor: Pedro Prom | 01-08-2016

Description

Subject: END OF TRIAL NOTIFICATION
Description: Tá acabado

Global End

Date of Global End: 7/13/16 | Type of Global End: By Protocol

Documents

	File Name
1	Desert.jpg

Back Amend

RNEC

Submission of Final Report

Legal Framework applicable to the submission of a Final Report:

- [Lei n.º 21/2014, de 16 de abril](#), alterada pela [Lei n.º 73/2015 de 27 de julho](#)
- [Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial \(CT-1\)](#)

All Final Reports must be submitted to INFARMED I.P. and CEIC through RNEC platform up to 12 months after the conclusion of the last participant in the clinical trial.

The electronic submission of Final Reports is only possible if the respective Clinical Trial has been previously submitted through RNEC - electronic platform. Final Reports referring to all other trials should be submitted according to the usual procedure.

Submission of Final Report

a) Clinical Trial Details Screen

b) Create New

- Request Details/Open
- Create Request

c) Rules for submission of Final Report notification:

INFARMED and **CEIC** – request status must be equal to “Concluded” or “Early Concluded”

d) Select Request Type– Final Report

d
→

Clinical Studies > Clinical Trials > Clinical Studies Details > Create Request

Create Request

Type and Addressee Detail Documents

Type of Request

Type of Request * Final Report

Addressee

INFARMED - National Authority of Medicines and Health Products, I.P. CEC - Competent Ethics Committee

Cancel Next

Submission of Final Report

f) Include a description of the Final Report

g) Attach Final Report

The screenshot displays the 'Create Request' interface. The top navigation bar includes 'Type and Addressee', 'Detail', and 'Documents'. The 'Detail' tab is active, showing a 'Description' section with a 'Subject' field and a 'Description' text area. A red arrow labeled 'f' points to the 'Description' section. Below this, the 'Documents' tab is active, showing a 'File' section with a '+ Select File' button and an 'Addressee' dropdown menu. A table below the 'File' section shows 'No Records'. A red arrow labeled 'g' points to the 'Documents' section. Navigation buttons 'Cancel', 'Previous', and 'Next' are visible at the bottom of the interface.

RNEC

Submission of Notifications

Legal Framework applicable to submission of Notifications/Change of applicant requests:

[Lei n.º 21/2014, de 16 de abril](#), alterada pela [Lei n.º 73/2015 de 27 de julho](#)

[*Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial \(CT-1\)*](#)

The electronic submission notification is only possible if the respective Clinical Trial has been previously submitted through RNEC - electronic platform. Notifications referring to all other trials should be submitted according to the usual procedure.

Submission of a Notification

a) Clinical Studies Details Screen

b) Create Request

d) Rules for submission of notifications:

INFARMED – Initial request has previously been authorized

CEIC – initial request status is different of “Invalid”, “Declined”, “Finished” “Early Finish”

e) Select Type of request– Notification

f) Select addressee

g) Add XML file

Clinical Studies Details

Search Area

ID Request Type All All All

Search Clean

Detail

ID	Request Type	Submission Date	Addressee	Status	Status Date	Subject	Publication Date	Action
1257	Notification	9/22/16 1:32:21 PM	CEC	Submitted	9/22/16 1:32:21 PM	Amend		Open
1256	Notification	9/22/16 1:32:20 PM	Infarmed	Submitted	9/22/16 1:32:20 PM	Amend		Open
1254	Initial Request	9/22/16 11:02:13 AM	Infarmed	Authorized	9/22/16 12:00:00 AM			Open
1255	Initial Request	9/22/16 11:02:14 AM	CEC	Favorable	9/22/16 12:00:00 AM			Open

Back Create Request

Create Request

Type and Addressee Detail Documents

Type of Request

Type of Request * Final Report

Addressee

INFARMED - National Authority of Medicines and Health Products, I.P.
 CEC - Competent Ethics Committee

Cancel Next

Amend a Notification Request

a) Clinical Studies Details screen

b) Open details of the Notification Request

Clinical Studies Details

Search Area

ID Request Type All All All

Search Clean

Detail

ID	Request Type	Submission Date	Addressee	Status	Status Date	Subject	Publication Date	Action
1257	Notification	9/22/16 1:32:21 PM	CEC	Submitted	9/22/16 1:32:21 PM	Amend		Open
1256	Notification	9/22/16 1:32:20 PM	Infarmed	Submitted	9/22/16 1:32:20 PM	Amend		Open
1254	Initial Request	9/22/16 11:02:13 AM	Infarmed	Authorized	9/22/16 12:00:00 AM			Open
1255	Initial Request	9/22/16 11:02:14 AM	CEC	Favorable	9/22/16 12:00:00 AM			Open

Back Create Request

Amend a Notification Request (2)

b) Amend

c) Update Description (if applicable)

d) Update XML file (if applicable)

e) Attach all required documents

e) Update Advertising Materials (if applicable)

f) Submit

Clinical Studies > Clinical Trials > Clinical Studies Details > Request Details

Request Details - Notification - NT001257

Status

ID: 1257 Submission Date: 22-09-2016 Addressee: CEC Status: Submitted
Applicant: infarmed-JF Sponsor: Wally Miguel de Jesus Date: 22-09-2016

Description

Subject: Amend
Description: Amendoas

XML File

XML File: 2014-003382-17_PT_20160803_CTA.xml EudraCT Number: 2014-003382-17

Documents

	File Name
1	Penguins.jpg

Public Information

Sponsor: Wally Miguel de Jesus

Clinical Study Sites				
Clinical Study Site	Department	Main Investigator	Ethics Committee	Status
Centro Clínico	Tirana Norte	ç+ç	Comissão de Ética A	Not Commenced

Advertising Materials			
File Name	Type		38
No Results			

Back Amend

RNEC

Change of applicant

Legal Framework applicable to submission of Notifications/Change of applicant requests:

[Lei n.º 21/2014, de 16 de abril](#), alterada pela [Lei n.º 73/2015 de 27 de julho](#)

[*Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial \(CT-1\)*](#)

The electronic submission notification is only possible if the respective Clinical Trial has been previously submitted through RNEC - electronic platform. Notifications referring to all other trials should be submitted according to the usual procedure.

Change of Applicant

- On the Side Bar menu select Clinical Trials Section
- Create New Request
- Select Request Type - Notification /Change of Applicant
- Select Addressee

The screenshot displays the CRNEC web application interface. The top navigation bar includes 'Alerts' and 'Contacts'. The breadcrumb trail shows 'Clinical Studies > Clinical Trials > Create Request'. The main content area is titled 'Create Request' and features three tabs: 'Type and Addressee', 'Detail', and 'Documents'. The 'Type and Addressee' tab is active, showing a 'Type of Request' dropdown menu with options: 'Initial Request', 'Change of Applicant', and 'Financial Agreement'. The 'Change of Applicant' option is selected. Below this, the 'Addressee' section has a checkbox for 'INFARMED - National Authority of Medicines and Health Products, I.P.' which is checked. At the bottom right, there are 'Cancel' and 'Next' buttons.

Change of Applicant

f) Add XML file

-> Note: Select only XML files of Clinical Studies already submitted in the platform and that have not been submitted by this applicant.

g) Include an accurate description of the request

f) Attach the applicable documents

g) Submit

The screenshot shows the 'Detail' tab of the application form. It is divided into two main sections: 'XML' and 'Description'. The 'XML' section has a 'Select File' button, an 'XML File' input field, and an 'EudraCT Number' input field. A red arrow labeled 'f' points to the 'XML File' field. The 'Description' section has a 'Subject' input field and a 'Description' text area with bold, italic, and underline formatting options. A red arrow labeled 'g' points to the 'Description' text area.

The screenshot shows the 'Documents' tab of the application form. It features a 'Documents' section with a 'File' field, a 'Select File' button, an 'Adressee' dropdown menu set to 'CEC', and an 'Add' button. Below this is a table with columns for 'File Name' and 'Adressee', and a 'No Records' message. At the bottom are 'Cancel', 'Previous', and 'Submit' buttons.

Amend Change of Applicant Request

a) Change of applicant detail Screen

b) Amend

Request Details - Change of Applicant - AR001266

ID: 1266 Submission Date: 23-09-2016 Addressee: CEC Applicant: Infarmed-JF Sponsor: Joana Oliveira entidade Status: Submitted

Description: This trial will now be managed by applicant JF

XML File: 2012-000793-30 PT 20121228 CTA.xml EudraCT Number: 2012-000793-30

Documents: No Results

Back Amend

Amend Change of Applicant Request

d) Update XML file

e) Attach required documents

f) Submit

The screenshot shows a web application interface for creating a request. The breadcrumb trail is: Clinical Studies > Clinical Trials > Clinical Studies Details > Request Detail > Create Request. The main heading is 'Create Request'. There are three tabs: 'Type and Addressee' (selected), 'Detail', and 'Documents'. Under 'Type and Addressee', there is a 'Type of Request' dropdown menu with 'Amend' selected. Below that is an 'Addressee' section with a checked checkbox for 'CEC - Competent Ethics Committee'. There are three tabs: 'Type and Addressee', 'Detail', and 'Documents'. An information icon indicates: 'If there are no changes to the XML file, you don't need to add it again.' A warning icon indicates: 'Part, or all, of the filled data was submitted but not yet approved.' Under the 'XML' section, there is an 'XML File' field with a '+ Select File' button and an 'EudraCT Number' field with the value '2012-000793-30'. There are three tabs: 'Type and Addressee', 'Detail', and 'Documents' (selected). Under 'Documents', there is a 'File' field with a '+ Select File' button and an 'Addressee' dropdown menu with 'CEC' selected and an 'Add' button. Below this is a table with columns 'File Name' and 'Addressee', showing 'No Records'. At the bottom right, there are three buttons: 'Cancel', 'Previous', and 'Submit'. A red arrow labeled 'f' points to the 'Submit' button, which is circled in red.

RNEC

Submission of a Financial Agreement Notification

Financial Agreements:

In case the Financial Agreement is not signed at the time of documentation submission, the final version should be submitted as soon as possible, in full compliance with the version submitted and approved by the ethics committee (CEIC).

The study site can only be initiated upon approval of the financial agreement contract.

Submission a Financial Agreement Notification

a) Clinical Trial screen

b) Create Request

c) Select type of Request – Financial Agreement

d) Select addressee – CEC- Competent Ethics Committee

f) Attach XML file



Clinical Studies > Clinical Trials > Clinical Studies Details > Create Request

Create Request

Type and Addressee | Detail | Documents | Public Information

Type of Request

Type of Request * Financial Agreement

Addressee

INFARMED - National Authority of Medicines and Health Products, I.P. CEC - Competent Ethics Committee

Create Request

Type and Addressee | Detail | Documents | Public Information

If there are no changes to the XML file, you don't need to add it again.

XML

XML File

EudraCT Number * 2014-003382-17

Description

Subject * Financial Agreements

Description *

Submission of a Financial Agreement Notification

f) Attach the required documents



Create Request

Type and Addressee Detail **Documents** Public Information

Documents

File Addressee CEC

File Name	Addressee
No Records	

g) Update the Recruitment Status of each Clinical Study Site



Type and Addressee Detail Documents **Public Information**

Clinical Study Sites

Clinical Study Sites	Service	Recruitment Status	Main Investigator	Ethics Committee	
Centro Clínico	Tirana Norte	Not Commenced	ç+-ç	Comissão de Ética A	<input type="button" value="Edit"/>

Amend the Financial Agreement Notification

a) Financial Agreement Detail Screen

b) Amend

Request Details - Financial Agreement - CF001258

Status

ID: 1258 | Submission Date: 22-09-2016 | Addressee: CEC | Submitted: 22-09-2016
Sender: infarmed-JF | Sponsor: Wally Miguel de Jesus

Description

Subject: Financial Agreements
Description: ficamos todos a ganhar

XML File

XML File: 2014-003382-17_PT_20160803_CTA.xml | EudraCT Number: 2014-003382-17

Documents

No Results

Public Information

Sponsor: Wally Miguel de Jesus

Clinical Study Sites				
Clinical Study Site	Department	Main Investigator	Ethics Committee	Status
Centro Clínico	Tirana Norte	ç+ç	Comissão de Ética A	Not Commenced

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Back Amend

b

Amend the Financial Agreement Notification

c) Update Description

d) Update XML file

e) Attach required documents

f) Update current Status of Clinical Study Sites

g) Submit

[Clinical Studies](#) > [Clinical Trials](#) > [Clinical Studies Details](#) > [Request Detail](#) > [Create Request](#)

Create Request

Type and Adresse **Detail** Documents Public Information

Type of Request

Type of Request * Amend

Addressee

CEC - Competent Ethics Committee

Type and Adresse **Detail** Documents Public Information

XML

XML File

EudraCT Number 2014-003382-17

Type and Adresse **Detail** **Documents** Public Information

Documents

File Adresse CEC

File Name	Adressee
No Records	

Type and Adresse **Detail** Documents **Public Information**

Clinical Study Sites

Clinical Study Sites	Service	Recruitment Status	Main Investigator	Ethics Committee	
Centro Clínico	Tirana Norte	Not Commenced	ç--ç	Comissão de Ética A	Edit Remove

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RNEC

Reply to an Additional Information/Amend Request

Replying to an additional Information/Correction Request consists in answering to questions/requests for additional elements or correction of the information submitted.

When can I reply to an Additional Information/Correction Request?

It is only possible to Reply to these events when the status of the request is equal to “Additional Information” or “Correction”

Reply to an Additional Information/Amend Request

20160600009
Informed-JF

Clinical Studies
Clinical Trials
Search
Create New Request

RNEC Number: MD000412
EudraCT Number: 2014-003382-17
Authorization Date: -
CEC Opinion: Favorable
CEC Opinion Date: 2016-09-22
Public Information: -
Request P001254
Activities List
Create Request

Others
Search
Create New Request

Clinical Studies > Clinical Trials > Clinical Studies Details > Request Detail > Activities List

Activities List

Search

Type of Activity: All | Addressee: All

Search Clean

Detail

Type of Activity	Submission Dat...	Sender	Addressee	Subject	Action
Request for Additional ...	9/23/16 2:13:3...	Informed	Informed-JF	Request for documents	Open

Back

Reply to an Additional Information/Amend Request

a) Additional Information details screen

b) Reply

c) Create Request

d) Update XML file + description of the answer

e) Attach required documents

g) Submit

b
→

d
→

e
→

Home > Clinical Studies > Clinical Trials > Clinical Studies Details > Request Detail > Activities List > Activity Detail

Request Details - Request for Additional Information - PE001267

ID	526931	Submission Date	23-09-2016	Addressee	Informed-JF
Applicant	Informed-JF	Sponsor	Wally Miguel de Jesus		
Sender	Informed				

Description

Subject: Request for documents

Description: please enclose documents

Documents

File Name
No Results

Back Reply

Reply to: Additional Information Request/Request for amendment

- Additional Elements Details Screen
- Reply
- Create Request
- Reply to Additional Information Request

End of Trial Notification

1. Include a description
2. Update relevant information for the conclusion
3. Attach required documents

Change of Applicant

1. Include XML file and description of notification
2. Attach required documents

Financial Agreement Notification

1. Attach required documents
2. Update Clinical Sites current Status

- Submit

Type and Adresse
Detail
Documents
Public Information

Type of Request

Type of Request * ▼

Reply to Request for Additional Information

Addressee

INFARMED - National Authority of Medicines and Health Products, I.P. CEC - Competent Ethics Committee

XML

XML File + Select File

EudraCT Number

Description

Subject * ▼

Request for documents

B I U

Documents

File + Select File

Addressee Infarmed Add

File Name	Addressee
No Records	

Sponsor

Sponsor * ▼

Wally Miguel de Jesus

Clinical Study Sites

Clinical Study Sites	Service	Recruitment Status	Main Investigator	Ethics Committee
Centro Clínico	Tirana Norte	Temporary Halt	ç+-ç	Comissão de Ética A Edit Remove

Add

Cancel
Previous
Submit

Replying to a Communication

a) Communication Details Screen

b) Reply

c) Fill in with a description in reply to the communication

d) Attach required documents

e) Submit

Type and Addressee Detail Documents

Type of Request

Type of Request * Reply to Communication

Addressee

INFARMED - National Authority of Medicines and Health Products, I.P. CEC - Competent Ethics Committee

Type and Addressee Detail Documents

Description

Subject * hhhh

Description *

Type and Addressee Detail Documents

Documents

File Addressee CEC

File Name	Addressee
No Records	

Cancel Previous **Submit**

c



d



e

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RNEC

Payment of fees

Information about Payment of Fees is available at: Portaria 63/2015

Valid for Clinical Trials and Substantial Amendments submitted through the RNEC portal. For all other Clinical Trials the Payment of fees should be made according to the regular procedure.

Payment of Fees

a) Clinical Studies Details | Request Details Screen



Type	Created Date	Status	Status Date	Amount	
SA - Clinical Trial	7/29/16 1:54:00 PM	Pending	7/29/16 1:54:00 PM	200,00€	Open

b) Select open on the Payment Section for the selected Fee

c) Payment Details



Payment Details

Entity
 Name: Entidade_Promotor_Testes
 Address: Avenida São Bernardo da Estrela
 City: 1580-508 Santarém
 NIF: 120599643

Details

Payment: 5894 Get receipt

Description	Unit Price
SA - Clinical Trial	200.0
Total:	€200.00

Payment Methods
 Please use only one of the following methods of payment:

ATM

	Entity: 21424
	Reference: 000 148 885
	Amount: €200.00

Payment Start Date:
 ATM payment is available in the next 2 business days.
 This payment is available until : 16-Jun-2016

Credit Card
 To proceed with payment, [click here.](#)

learn more

learn more

d) Submit Payment

e) Wait 5 min

f) Request Status - "Submitted"

RNEC

Save/Remove Requests

Save Requests

- Available only for requests (not for activities)
- Save (lower right corner)
- Request Status– “Fill”

[Clinical Studies](#) > [Clinical Trials](#) > [Clinical Studies Details](#)

Clinical Studies Details

Search Area

ID Request Type All Status All Addressee All

Detail

ID ↕	Request Type ↕	Submission Date ↕	Addressee ↕	Status ↕	Status Date ↕	Subject ↕	Publication Date ↕	Action
1282	Initial Request		CEC	Fill	9/26/16 11:27:03 AM			Open Remove

Remove Request

- Available only for Unfinished requests (it is not allowed to remove an Activity)
- Search for Clinical Trial- Open
- Remove

RNEC

Other Studies

RNEC

Submission of Clinical studies through RNEC

The submission of Clinical Studies through RNEC portal is applicable to:

A – Interventional studies with Investigational Medical Products (Human)

B – Interventional studies with Medical Devices

C – Interventional studies with cosmetic products

D – Non-interventional Post Authorization Efficacy Studies (PAES)

E – Non-interventional Post Authorization Safety Studies (PASS)

Only Categories A and B studies should be submitted to ***CEIC***. Studies from categories C,D and E should be submitted to the local Clinical Site's Ethics Committee (CES) according to the respective procedures.

Only when the Clinical Site does not has a local Ethics Committee (CES), categories C,D and E studies should be submitted to CEIC through RNEC.

NOTE: All Studies that are submitted to CEIC outsider of the scope of its assessment competences will be automatically stored without any evaluation or associated procedure – Law 21/2016 from April 16.

Search for Other Studies

a) Search for Clinical Studies
Search Others

b) Search Menu

c) Results

The screenshot shows a web application interface for searching clinical studies. On the left is a navigation menu with a tree structure: 'Clinical Studies' (expanded) contains 'Clinical Trials' (with sub-links 'Search' and 'Create New Request') and 'Others' (with sub-links 'Search' and 'Create New Request'). A red arrow labeled 'a' points to the 'Others' section. The main content area is titled 'Clinical Studies Search - Others' and contains a 'Search Area' with several input fields: 'Addressee' (dropdown menu), 'Type of Study' (dropdown menu), 'Subject' (text input), 'Description' (text input), and 'RNEC Number' (text input). There are also 'Submission Date' fields for 'From' and 'To'. 'Search' and 'Clean' buttons are at the bottom right of the search area. A red arrow labeled 'b' points to the 'Search' button. Below the search area is a 'Search Result Area' with a table header: 'RNEC Number', 'Addressee', 'Submission Date', and 'Subject'. The table body contains the text 'No Results'. A red arrow labeled 'c' points to the table header.

Other Studies

b) Create Requests

Navigation Menu – Create New

Select:

- Type of Study
- Addressee

Add

- Description
- Documents

a →

Home > Clinical Studies > Others > Create Request

Create Request

Study Type

Study Type *

Description

Addressees *

Subject *

Description *

Documents

File

File Name
No Records

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