

RNEC

User Manual

For more detailed information please access to: [RNEC/ Sponsor Information](#)
October 2016

Index

• Registration.....	3
• Navigation Bar, Requests Visualization and Related Activities.....	9
• Submission of new Clinical Study request	16
• Submission of a Substantial Amendment Request.....	22
• Submission of End of Trial Notification	27
• Submission of End of Trial Report.....	31
• Submission of Notification	35
• Change of Applicant Request.....	39
• Submission of a Financial Agreement Notification.....	44
• Reply to an additional Information Request/Correction Request.....	49
• Payments and Fees.....	54
• Save/Remove Requests.....	56
• Other Studies.....	58

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

Login Recover 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.

Create Register

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

☐ Clinical Study Site

☐ Ethics Committee

☐ Other

☐ Applicant

☐ Investigator

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 input fields for 'Username' and 'Password', followed by 'Login' and 'Recover Password' buttons. The 'Login' button is circled in red. On the right, under the heading 'REGISTER', there is a paragraph of text and a 'Create Register' button.

b) Select User (Number/Entity)

The screenshot shows the RNEC user selection page. At the top is the RNEC logo. Below it, a user profile is displayed with the ID '20160600009' and the entity name 'Informed-JF'. This profile is circled in red. Below the profile, there are links for 'Clinical Studies', 'Clinical Trials', and 'Others', each with 'Search' and 'Create New Request' options.

c) Change Password

The screenshot shows the RNEC user profile page. At the top is the RNEC logo. Below it, the user profile is displayed with the ID '20160600009' and the entity name 'Informed-JF'. To the right of the profile, there are links for 'Alerts' and 'Contacts'. Below the profile, there are links for 'Clinical Studies', 'Clinical Trials', and 'Others', each with 'Search' and 'Create New Request' options. The 'Change password' button is circled in red.

Recover Password

To recover your password:

a) Select “Recover Password” from the login screen

The screenshot shows the RNEC login interface. On the left, under the heading 'AUTHENTICATION', there are input fields for 'Username' and 'Password', followed by 'Login' and 'Recover Password' buttons. The 'Recover Password' button is circled in red. On the right, under the heading 'REGISTER', there is a paragraph of text and a 'Create Register' button.

b) Insert NIF/NIPC and email contact

c) Recover Password

b →

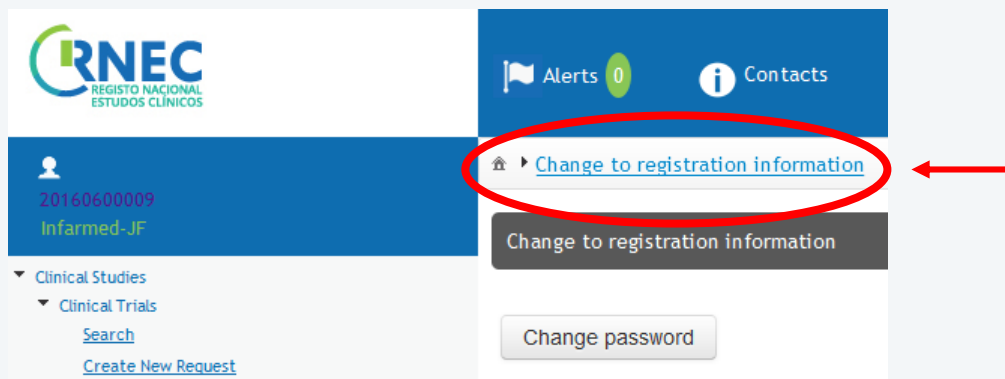
c →

The screenshot shows the 'PASSWORD RECOVERY' form. It has two input fields: 'Fiscal Number *' and 'Contact Email *'. The 'Fiscal Number' field is circled in red, with a red arrow labeled 'b' pointing to it. Below the email field is a 'Recover Password' button, which is also circled in red, with a red arrow labeled 'c' pointing to it.

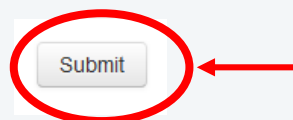
Change to registration information

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

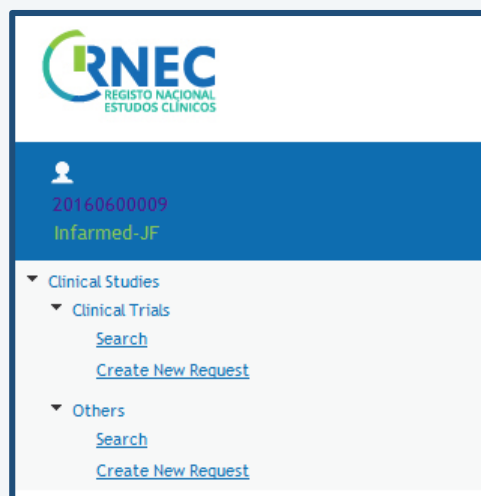
Navigation Bar

Clinical Studies

1. Search
2. Create New Request

Others

1. Search
2. Create New Request



Search (Clinical Studies and Other Studies)

Navigation bar

a) Select Search

b) Select Criteria

» Clinical Studies » Clinical Trials

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

c → **Search** Clean

c) Click Search

d) Visualize Results

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


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		e → Open
392	2014-000000-00	Balão Vermelho	BM-PET-YRGATQ-7482	A phase 4 open label randomiz...	CEC Informed		Open

Detailed information on a specific Clinical Study

- 1) Search area
 - a) Select criteria
 - b) Search
 - c) Detail – Visualize Search results
 - d) Open Request/Notification

- ## 2) Create Request/Specific notification for this Clinical Study



20160600009

Informed-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	Informed	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

b) Amend

Request Details - Initial Request - PI001232

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

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

Documents
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€

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

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 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

b → 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. Red arrows with letters a-e point to specific elements:

- a**: Points to the user profile dropdown in the top right corner, showing '20160600009' and 'Informed-JF'.
- b**: Points to the 'Create New Request' link in the navigation bar.
- c**: Points to the 'Type of Request' dropdown menu, which is currently set to 'Initial Request'.
- d**: Points to the 'Addressee' section, which has checkboxes for 'INFARMED - National Authority of Medicines and Health Products, I.P.' and 'CEC - Competent Ethics Committee', both of which are checked.
- e**: Points to the 'XML' section, which includes a file upload button and a text input field for the 'XML File' (containing '2012-001888-78 PT 20120807.xml'). Below it is a text input field for the 'EudraCT Number' (containing '2012-001888-78').

The form also includes tabs for 'Type and Addressee', 'Detail', 'Documents', 'Public Information', and 'Fee'. At the bottom right, there are 'Cancel', 'Previous', and 'Next' buttons.

Create New Request (2)

f) Attach the requested documents for Authorities submission*1

f

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

g

- 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 + Select File Addressee All Add

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

Sponsor

Sponsor * GomesPharma

Clinical Study Sites

Add

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

Add

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

Cancel Save Previous Next

*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}

Fees

Invoice Data

☒ Sponsor ☐ Applicant

Entity *

Address *

Select Fee

Fee *

Cancel Save Previous Submit

^{*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 addresse (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

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

XML File
XML File: 2014-005339-15 PT 20150220 CTA PT_20Feb15.xml EudraCT Number: 2014-005339-15

Documents
File Name: 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 displays the CRNEC web application interface for creating a request. The interface is divided into several sections, each with a blue header button. Red arrows and letters (c, d, e, f, g) point to specific sections:

- c) Type of Request:** A dropdown menu showing 'Amend'.
- d) XML:** A section for updating the XML file, including a 'Select File' button and a 'EudraCT Number' field with the value '2014-005339-15'.
- e) Documents:** A section for attaching documents, including a 'Select File' button and a table with columns 'File Name' and 'Addressee'. The table is currently empty, showing 'No Records'.
- f) Clinical Study Sites:** A section for updating publicly available documentation, including a table with columns 'Clinical Study Sites', 'Service', 'Recruitment Status', 'Main Investigator', 'Ethics Committee', and 'Edit Remove'. The table contains one row with data: 'Centro de Estudo Clínic...', 'DepartamentoTeste', 'Not Commenced', 'André Silva', 'Comissão do Pedro', and 'Edit Remove'.
- g) Advertising Material:** A section for attaching advertising material, including a table with columns 'File Name', 'Type', and 'Remove'. The table contains one row with data: 'teste.docx', 'Poster', and 'Remove'.

At the bottom right, there are three buttons: 'Cancel', 'Previous', and 'Submit'. The 'Submit' button is circled in red.

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

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

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

EudRACT Number

Description

Subject

Description

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

Documents

File Addressee

File Name	Addressee	
Tulips.jpg	CEC	Remove
Lighthouse.jpg	CEC	Remove

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

Sponsor

Sponsor

Clinical 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

File Name	Type	
teste.docx	Poster	Remove

25

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

d

e

★ 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

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

Type and Addressee Detail Documents Public Information

Documents

File + Select File

Addresssee CEC Add

File Name	Addresssee
No Records	

Cancel Previous Next

Amend Request of Substantial Amendment (2)

f) Update of the
Advertising Materials (if
aplicable)

g) Submit

Type and Addressee Detail Documents **Public Information**

Sponsor

Sponsor * PharmaCG

Clinical Study Sites

Add

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

Advertising Material

Add

File Name	Type	
Jellyfish.jpg	Flyer	Remove

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 titled 'Type and Addressee' with three tabs: 'Type and Addressee' (active), 'Detail', and 'Documents'. Under the 'Type and Addressee' tab, there is a 'Type of Request' dropdown menu currently set to '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

The screenshot displays the 'Submission of End of Trial Notification' form, divided into two main sections: 'Detail' and 'Documents'.

Detail Section:

- At the top, there are three tabs: 'Type and Addressee', 'Detail' (selected), and 'Documents'.
- Under the 'Detail' tab, there is a 'Description' section with a 'Subject' field and a larger 'Description' text area.
- Below the 'Description' section, there is a 'Global End' section with a 'Date of Global End' field and a 'Type of Global End' dropdown menu.
- At the bottom right of the 'Detail' section, there are buttons: 'Cancel', 'Save', 'Previous', and 'Next'.

Documents Section:

- Below the 'Detail' section, there is a 'Documents' section with a 'Documents' tab selected.
- Under the 'Documents' tab, there is a 'File' section with a '+ Select File' button and an 'Addressee' dropdown menu set to 'All'.
- Below the 'File' section, there is a table with columns 'File Name' and 'Addressee'. The table currently shows 'No Records'.
- At the bottom right of the 'Documents' section, there are buttons: 'Cancel', 'Save', 'Previous', and 'Submit'.

Change of a End of Trial Notification (3)

- a) End of Trial Declaration Details screen
- b) Amend
- c) Update the relevant information
- d) Attach the relevant documentation
- e) Submit

Status

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

Create Request

Type and Addressee **Detail** Documents

Description

Subject *

Description *

Cancel Previous Next

Type and Addressee Detail **Documents**

Documents

File Addressee All

File Name	Addressee
No Records	

Cancel Save Previous Submit

f →

g →

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 > Clinical Trials > Clinical Studies Details

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 Clinical Trials Clinical Studies Details

Clinical Studies Details

Search Area

ID Request Type

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 Detail

Request Details - Notification - NT001257

Status

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

Description

Subject: Amend
Description: Amendos

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	
No Results		38

b → **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 (Registo Nacional Estudos Clínicos) web interface. The sidebar on the left shows the 'Clinical Trials' section selected. The main content area shows the 'Create Request' form. The 'Type of Request' dropdown menu is open, showing 'Change of Applicant' as the selected option. The 'Addressee' section shows 'INFORMED - National Authority of Medicines and Health Products, I.P.' selected. The 'Detail' tab is active, and the 'Cancel' and 'Next' buttons are visible at the bottom right.

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

f →

g →

The screenshot shows the 'Detail' tab of the application form. The 'XML' section has a 'Select File' button. The 'Description' section has a 'Subject' field and a 'Description' text area.

The screenshot shows the 'Documents' tab of the application form. It displays a table with columns 'File Name' and 'Addressee'. The 'Addressee' dropdown is set to 'CEC'. There are 'Cancel', 'Previous', and 'Submit' buttons at the bottom.

Amend Change of Applicant Request

a) Change of applicant detail Screen

b) Amend

⌕ Clinical Studies Clinical Trials Clinical Studies Details Request Detail

Request Details - Change of Applicant - AR001266

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

Description

Subject This trial will now be managed by applicant JF

Description This trial will now be managed by applicant JF

XML File

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

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

Create Request

Type and Addressee Detail Documents

Type of Request

Type of Request * Amend

Addressee

☒ CEC - Competent Ethics Committee

Type and Addressee Detail Documents

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

EudraCT Number

Type and Addressee Detail Documents

Documents

File Addressee CEC

File Name	Addressee
No Records	

Cancel Previous **Submit**

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

c

d

🏠 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

i 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

B *I* U

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	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: Informed-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

47

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 Addressee Detail Documents Public Information

Type of Request

Type of Request * Amend

Addressee

☒ CEC - Competent Ethics Committee

Type and Addressee Detail Documents Public Information

XML

XML File

EudraCT Number 2014-003382-17

Type and Addressee Detail Documents Public Information

Documents

File Addressee CEC

File Name	Addressee
No Records	

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	Edit Remove

48

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

201606000009
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

- a) Additional Elements Details Screen
- b) Reply
- c) Create Request
- e) 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

- f) Submit

Type and Addressee
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
2014-003382-17

Description

Subject *
Request for documents

Documents

File
+ Select File

Addressee
Informed
Add

File Name
Addressee

No Records

Sponsor

Sponsor *
Wally Miguel de Jesus

Clinical Study Sites

Add

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

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

c

d

The screenshot displays the 'Replying to a Communication' workflow in the infarmed system. The interface is divided into three main sections: 'Type and Addressee', 'Detail', and 'Documents'. The 'Detail' tab is currently active, showing a 'Description' section with a 'Subject' field containing 'hhhh' and a 'Description' field. The 'Documents' tab is also visible, showing a 'File' section with a 'Select File' button and an 'Addressee' dropdown set to 'CEC'. At the bottom right, there are 'Cancel', 'Previous', and 'Submit' buttons, with the 'Submit' button circled in red. Red arrows labeled 'c' and 'd' point to the 'Detail' and 'Documents' tabs respectively.

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



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

c) Payment Details



d) Submit Payment

e) Wait 5 min

f) Request Status - "Submitted"

Payments

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

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

Credit Card

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

Verified by VISA

learn more

MasterCard SecureCode

learn more

Payment Start Date:

ATM payment is available in the next 2 business days.

This payment is available until : 16-Jun-2016

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

Search Clean

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

Back Create Request

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 the 'Clinical Studies Search - Others' interface. On the left, a sidebar menu is visible with the following structure:

- 20160600009
Informed-JP
 - Clinical Studies
 - Clinical Trials
 - [Search](#)
 - [Create New Request](#)
 - Others
 - [Search](#) (labeled 'a')
 - [Create New Request](#)

The main content area is titled 'Clinical Studies Search - Others' and contains a 'Search Area' with the following fields:

- Addressee:
- Type of Study:
- Subject:
- Description:
- RNEC Number:
- Submission Date: From To

Buttons for 'Search' and 'Clean' are located at the bottom right of the search area. Below the search area is a 'Search Result Area' which contains a table with the following columns: RNEC Number, Addressee, Submission Date, and Subject. The table currently displays 'No Results' (labeled 'c').

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

61