RNEC

User Manual

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

Index

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.*

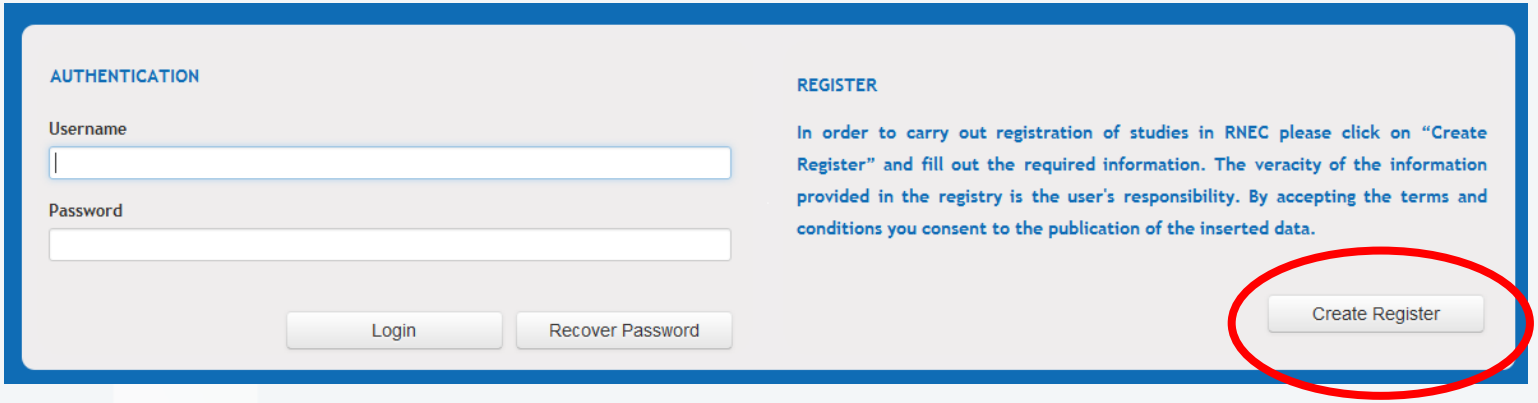
NOTE: All Studies that are submitted to CEIC outsider of the scope of its assessment competences will be automatically stored without any evaluation or associated procedure – Law 21/2016 from April 16.

RNEC

Registration

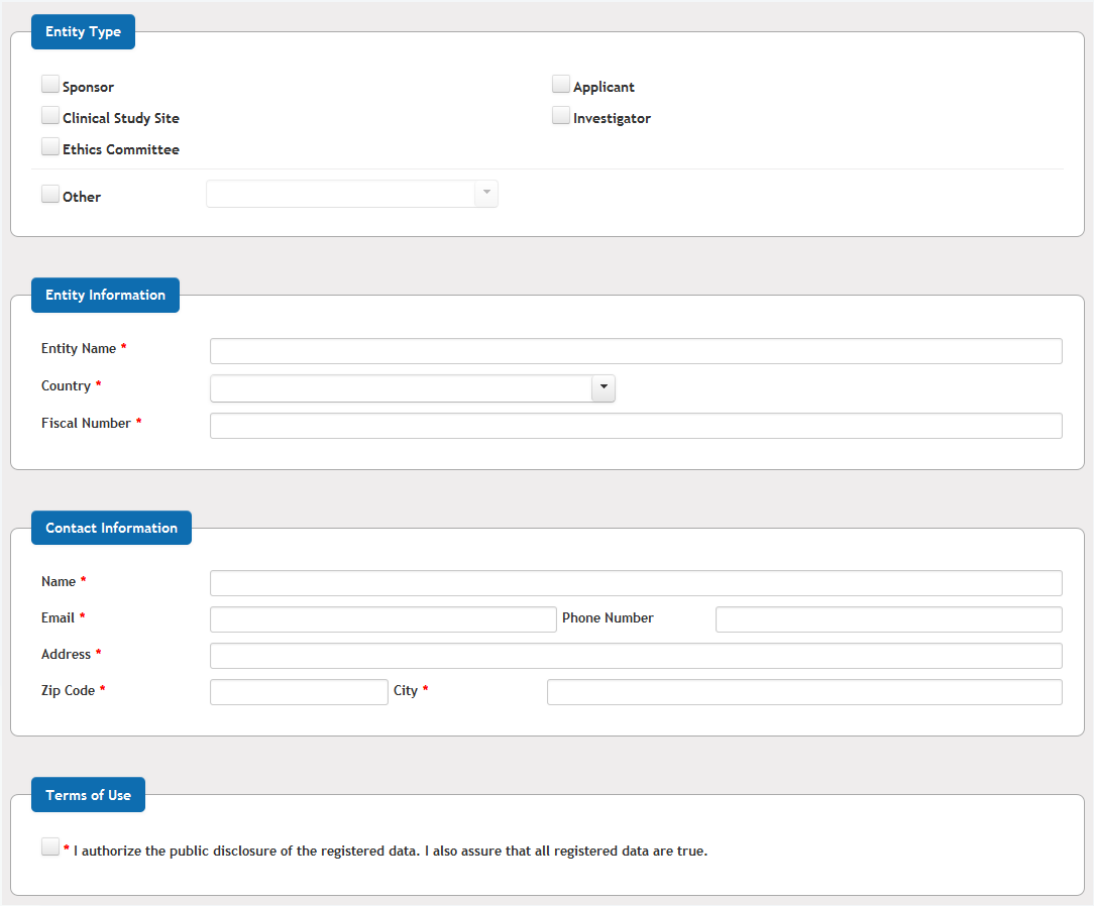
Registration (mandatory)

1. Create Register



2. Fill in the required information depending on the Entity Type;
   - Applicant;
   - Sponsor;
   - Clinical Study Site;
   - Ethics Committee
   - Investigator
   - Other

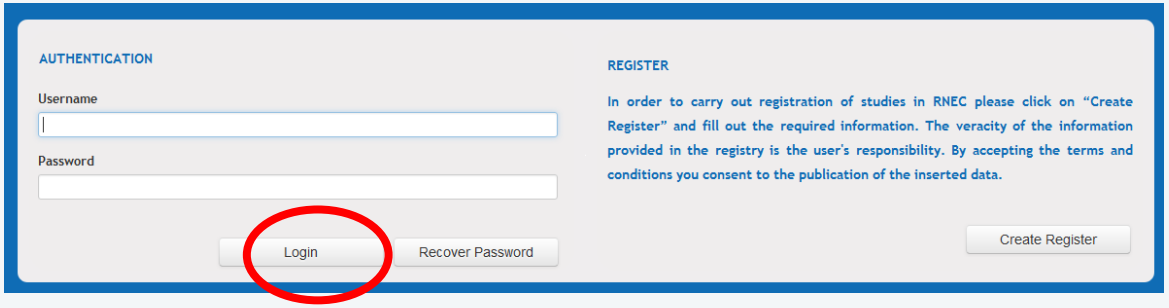
3. System Validation



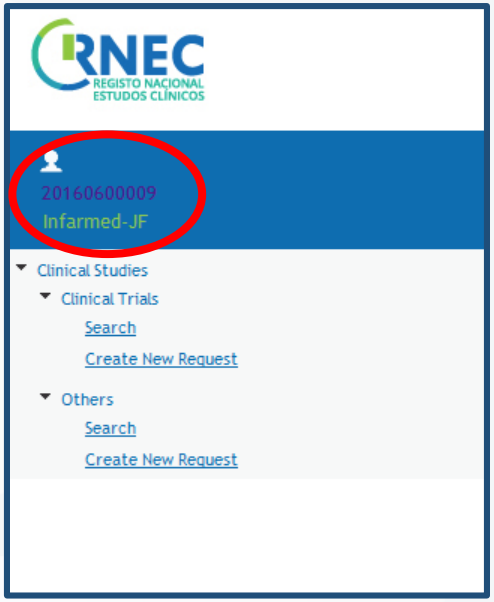
Change Password

3. Change Password

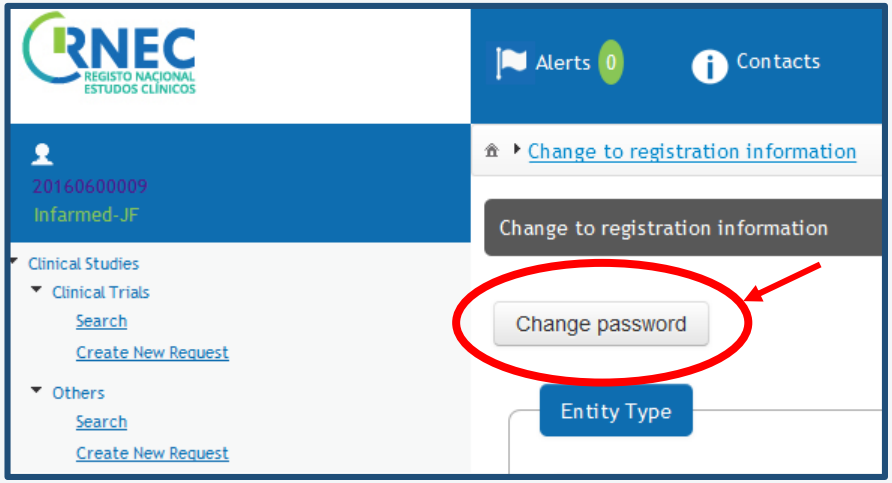
a)Login



b) Select User (Number/Entity)



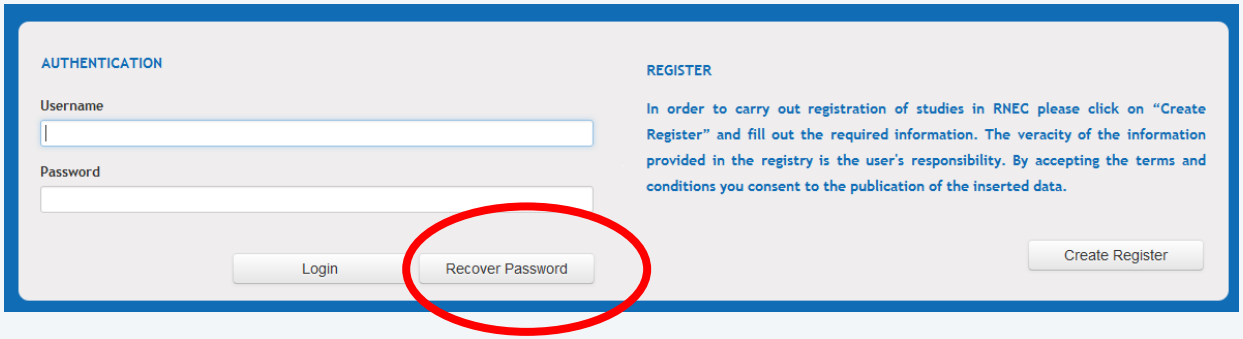
c) Change Password



Recover Password

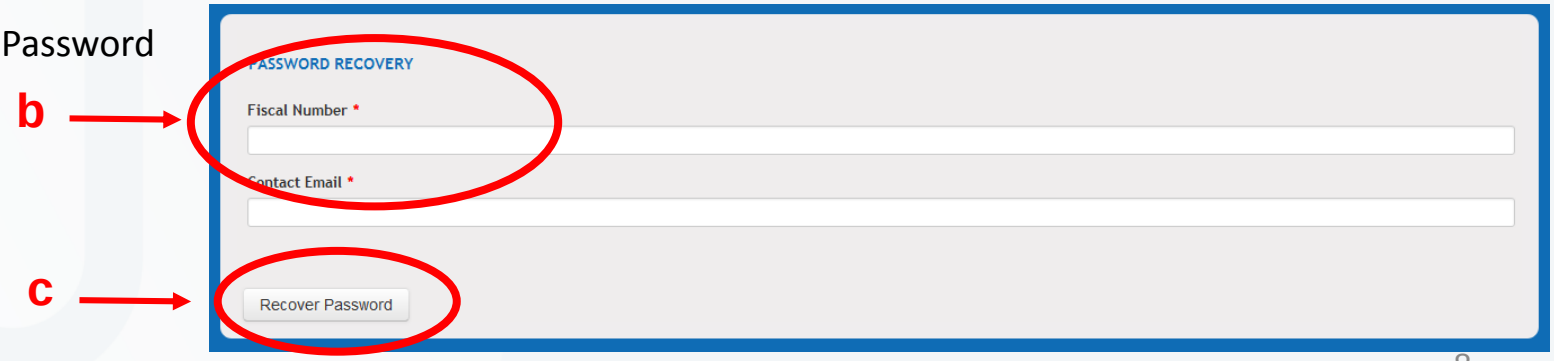
To recover your password:

a) Select “Recover Password” from the login screen



b)Insert NIF/NIPC and email contact

c)Recover Password



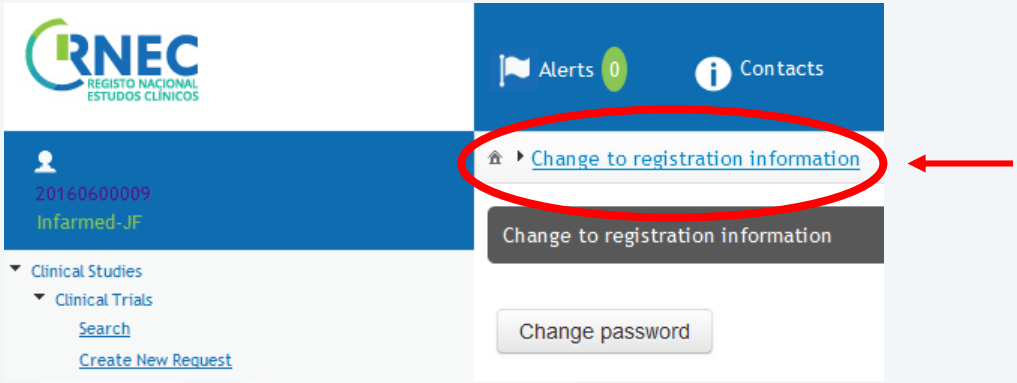
Change to registration information

To change your registration information

a) Login

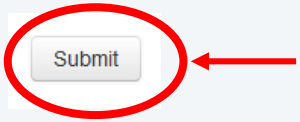
b) Select User (Number/Entity)

c) Click on change to registration information



d) Introduce the new/corrected information

e) Click “Submit” on the left lower corner



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SAÚDE

infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde I.P.

RNEC
REGISTO NACIONAL ESTUDOS CLÍNICOS

RNEC

Navigation Bar
Requests Visualization
and Related Activities

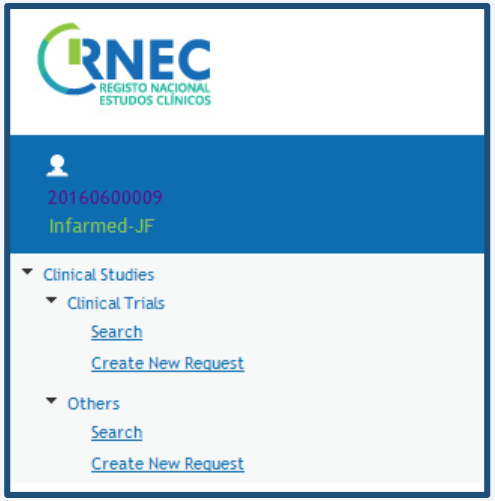
Navigation Bar

Clinical Studies

1. Search
2. Create New Request

Others

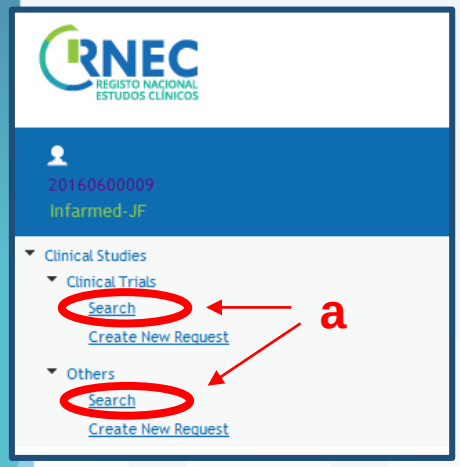
1. Search
2. Create New Request



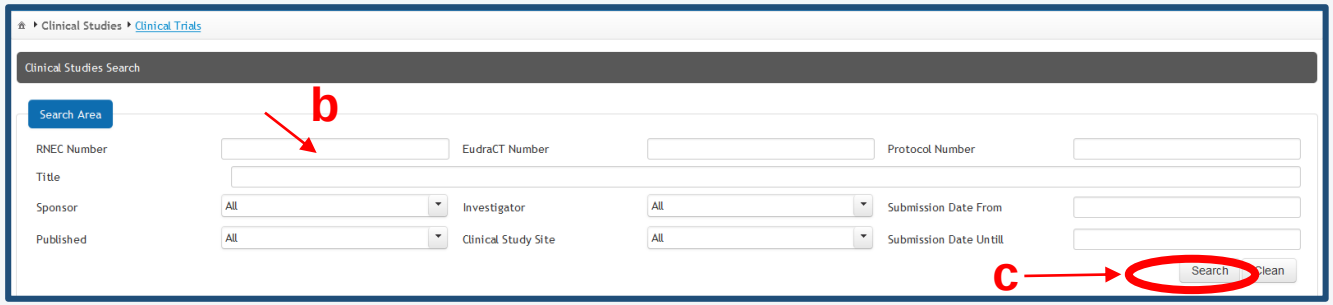
Search (Clinical Studies and Other Studies)

Navigation bar

a) Select Search



b) Select Criteria



c) Click Search

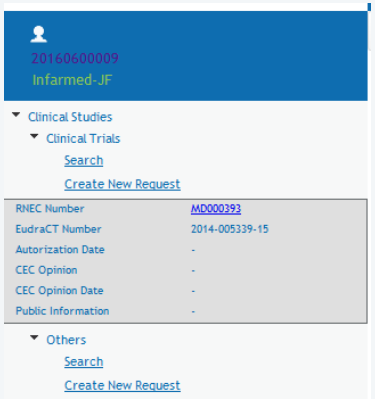
d) Visualize Results

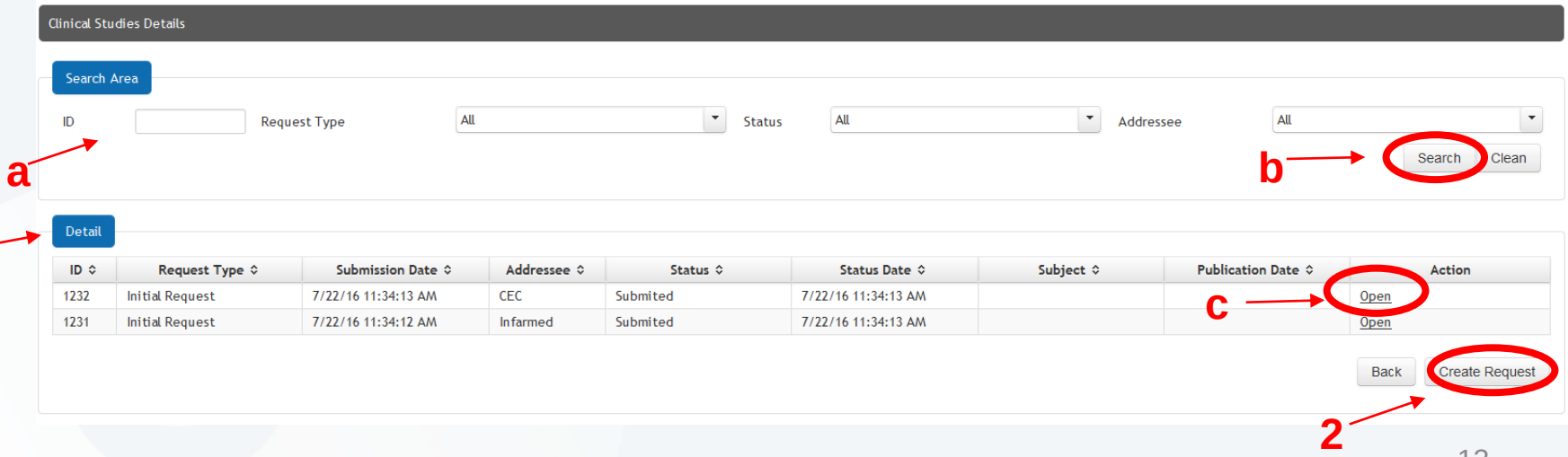
e) Click on “Open” for detailed information about a particular study

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





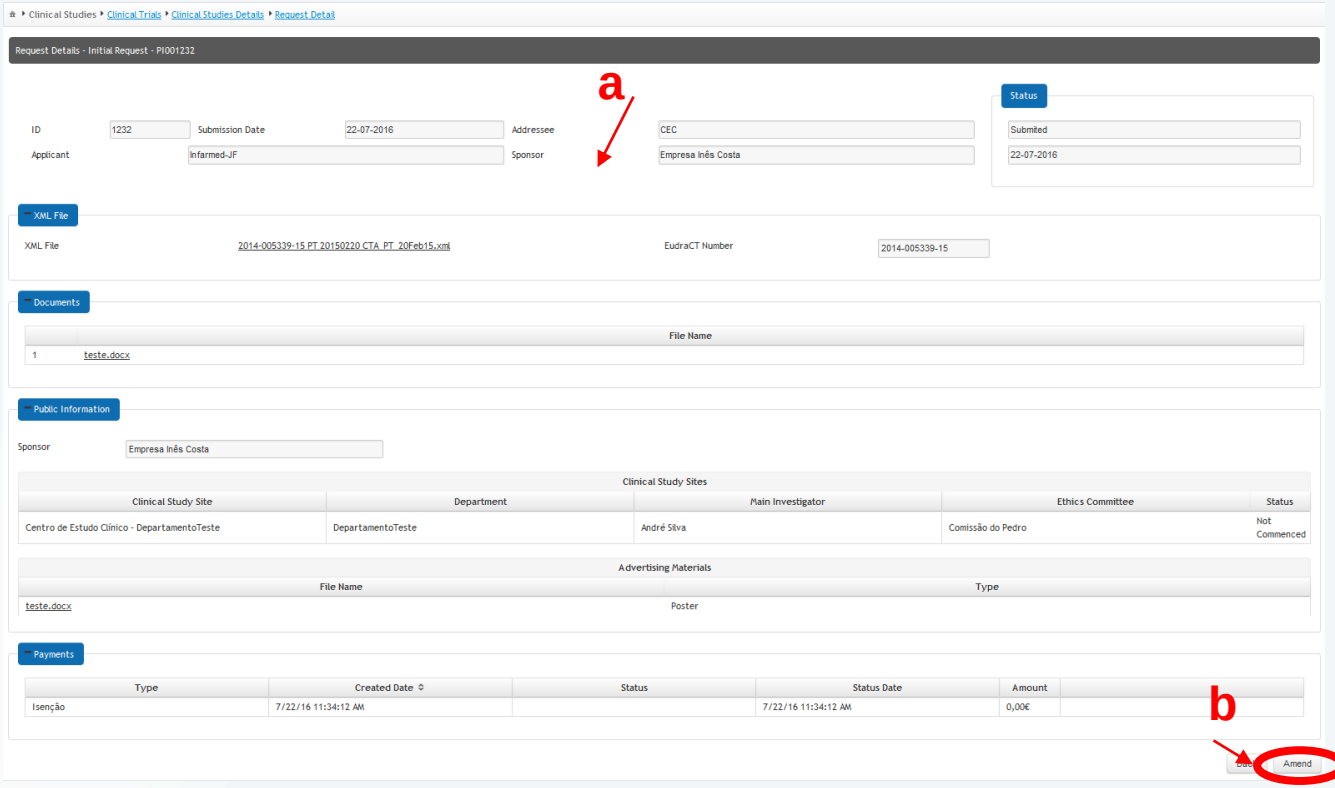
Visualize detailed information on a specific request

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



Visualize list of activities of a specific request

Request Details- Activities List:

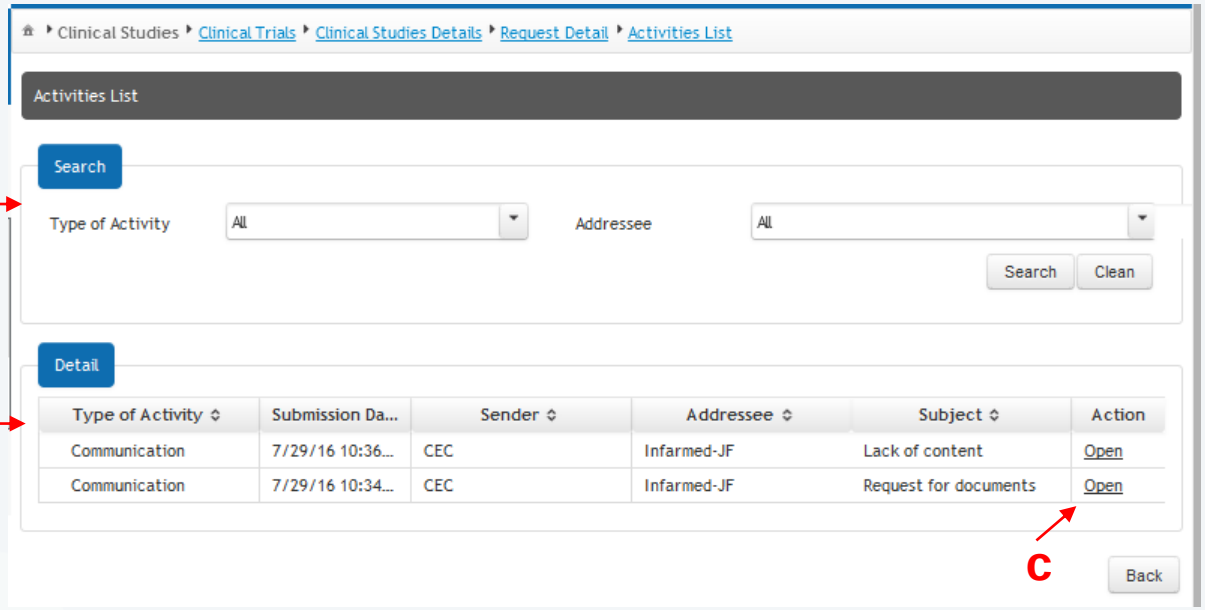
a)Search:

- Type of Activity
- Addressee

b) Detail: Results Visualization

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

c) Open details of specific activity

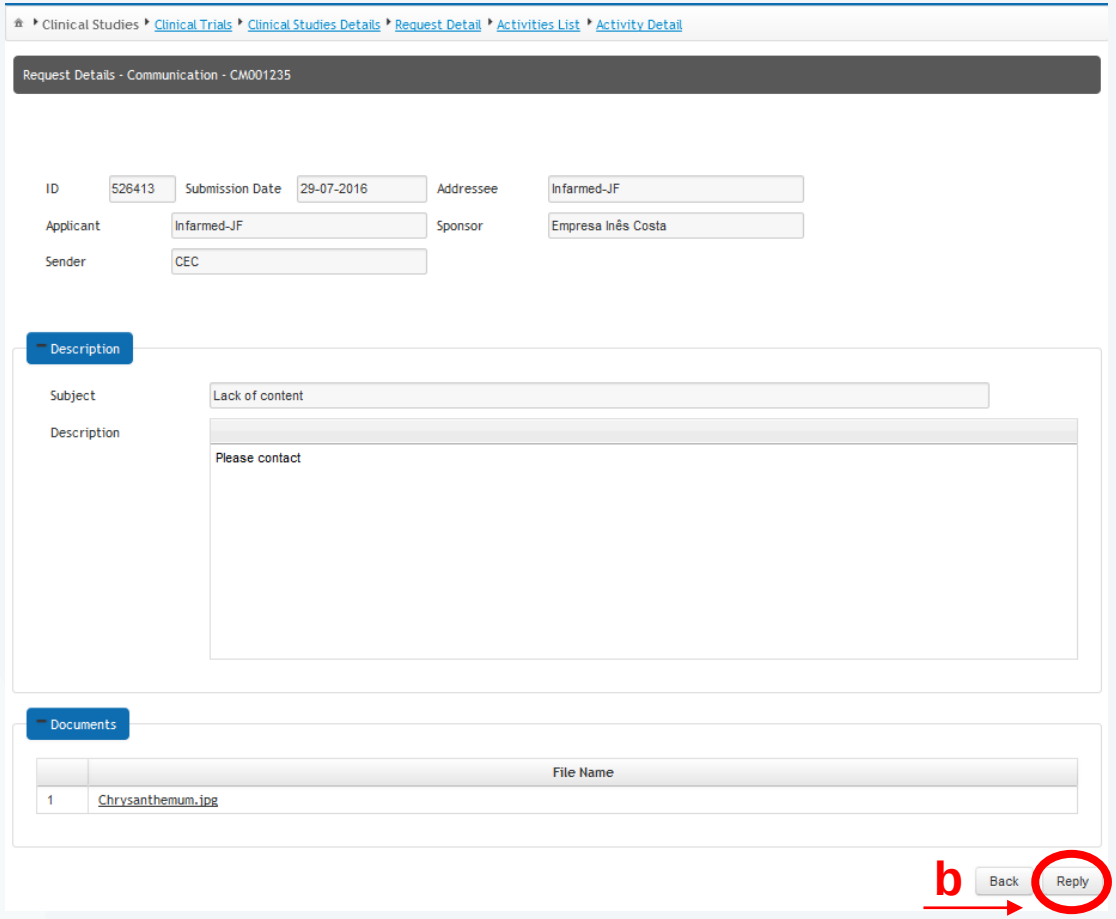


Visualize details of specific activities

a) Visualize details of specific activities:

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

b)Reply – to a specific activity request



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

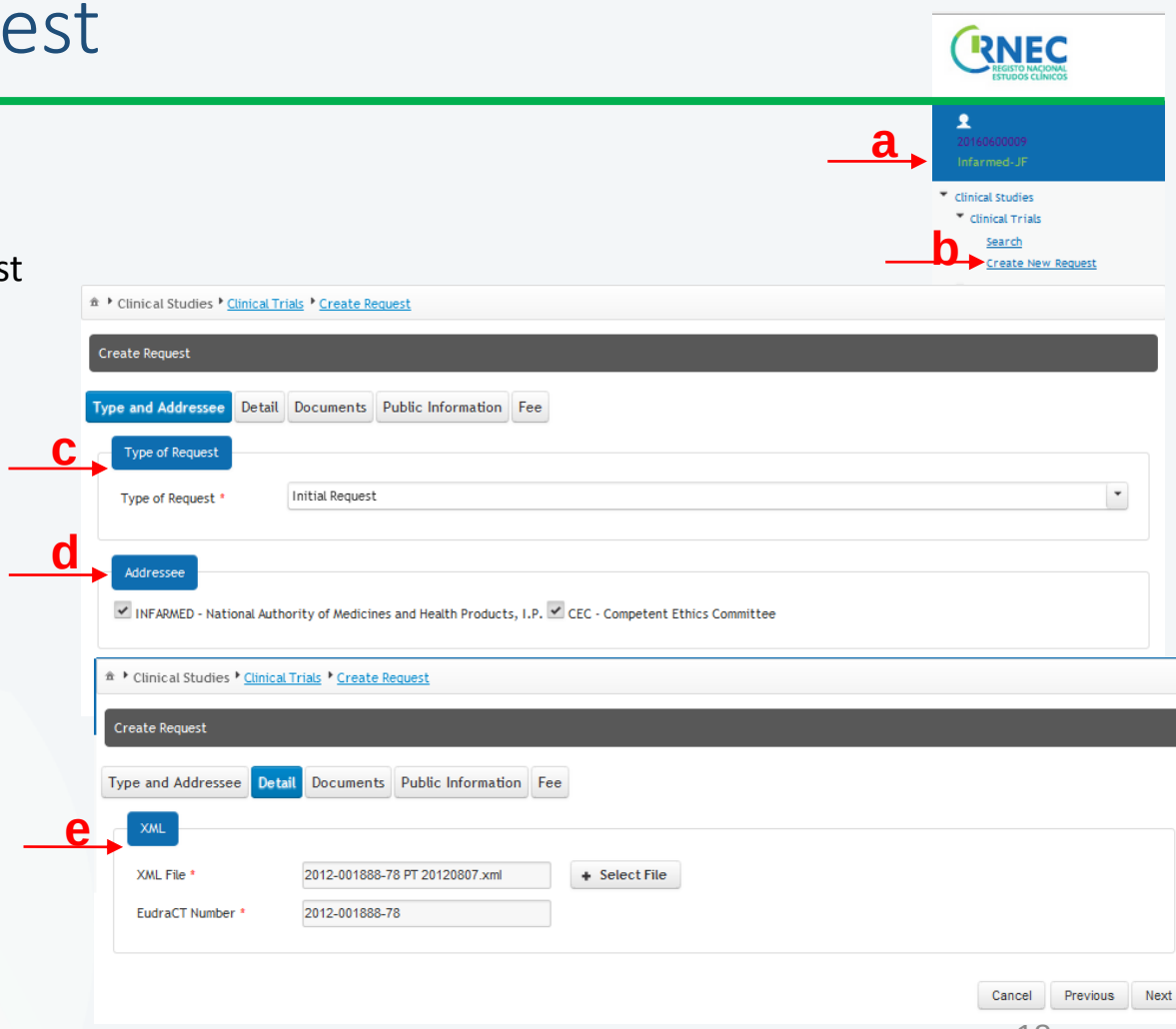
c) Select Type of Request

- Initial Request
- Change of Applicant
- Finantial Agreement

d) Select Addressee

- INFARMED
- CEIC
- INFARMED + CEIC

e) Select and attach XML File

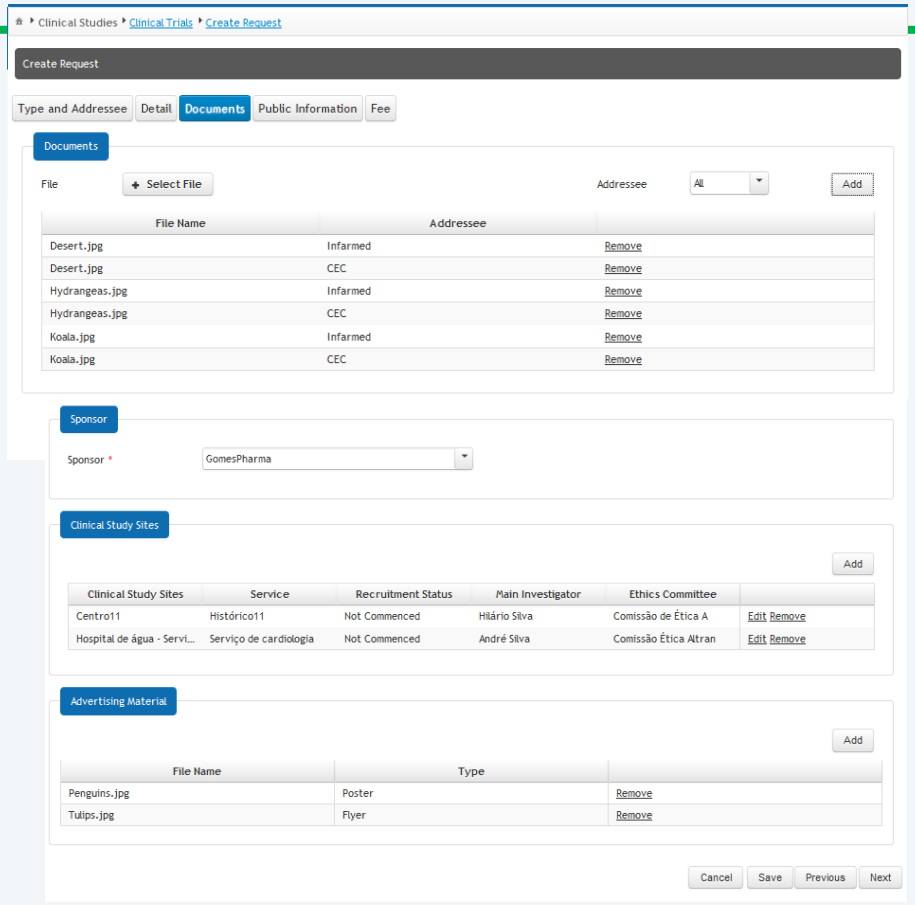


Create New Request (2)

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



*1- Please refer to the guidelines "Estrutura da Documentação" em RNEC/Estudos com Intervenção/Medicamentos Experimentais/Informação ao Promotor.

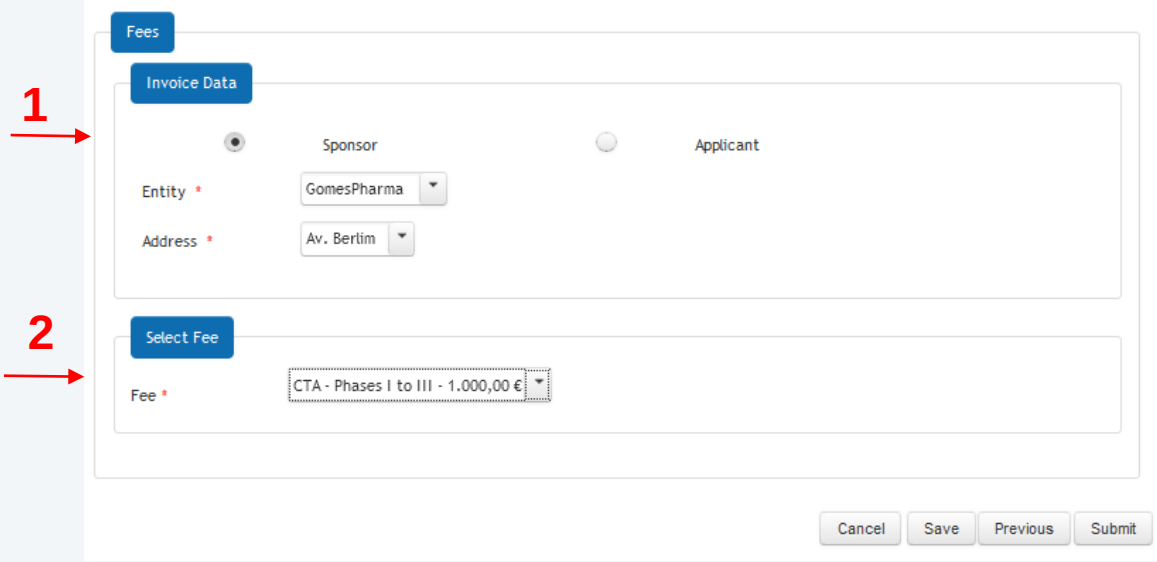
The platform does not support files > 20 mb

Create New Request (3)

h) Fees

1) Select Invoice Data
   - Sponsor/Applicant
   - Entity
   - Address

2) Select Fee*2



*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:

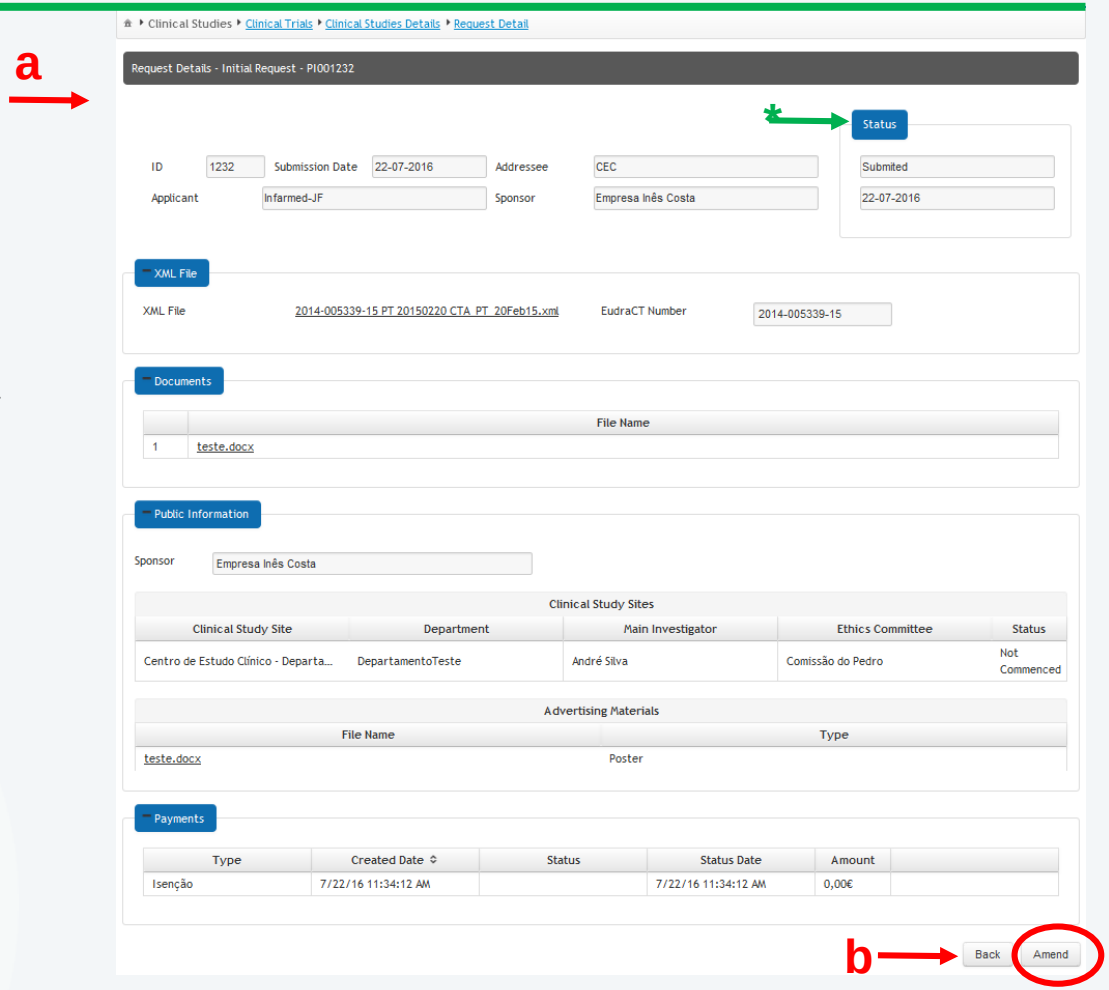
- The Clinical Trial has not been submited to the addresse (Eg: Submission to only **one** of the regulatory authorities)

- 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:“Submited”, “In Validation” or “In Evaluation”)



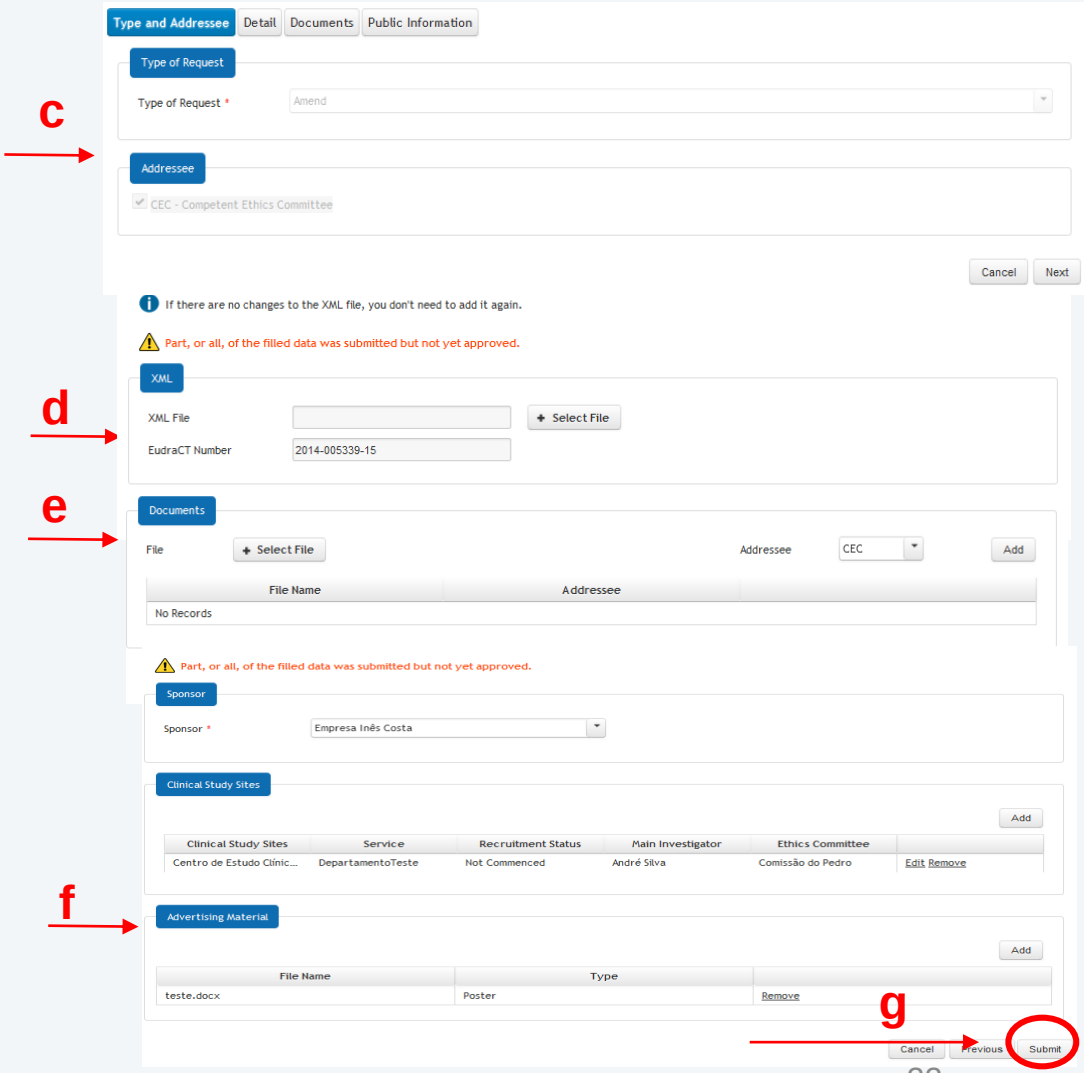
c) Create Request section

d) Update XML file (if aplicable)

e)Attach the required documents to the request

f)Update the Publicly Available documentation (if aplicable)

g) Submit



RNEC

Create Substancial Amendment request

Legal Framework applicable to the submission of Substancial 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 substancial amendments is only possible if the respective Clinical Trial has been previosly submited through RNEC - electronic platform. Substancial amendments refering to all other trials should be submitted according to the usual procedure.

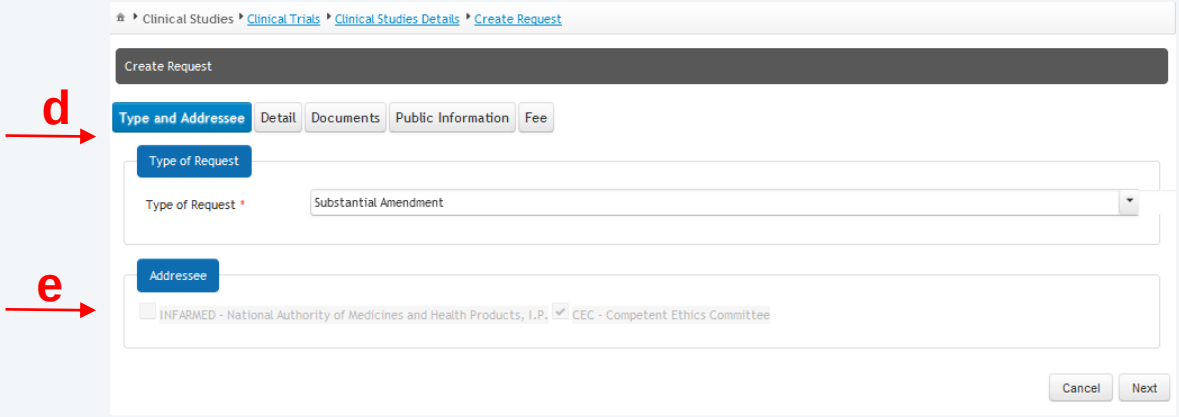
How to organize folders:
For simultaneous submissions to CEIC and INFARMED, two separate folders should be attached INFARMED and CEIC, respectively. The submitted folders should be organized according to the guidelines available at websites of each of the entities involved (INFARMED and CEIC).

Create Substancial Amendment request (1)

a)Login

b) Navigation Bar

- Clinical Study Details
- Create Request



c) Rules for Substancial 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 Substancial Amendment request (2)

d) Select/attach XML file if applicable *1

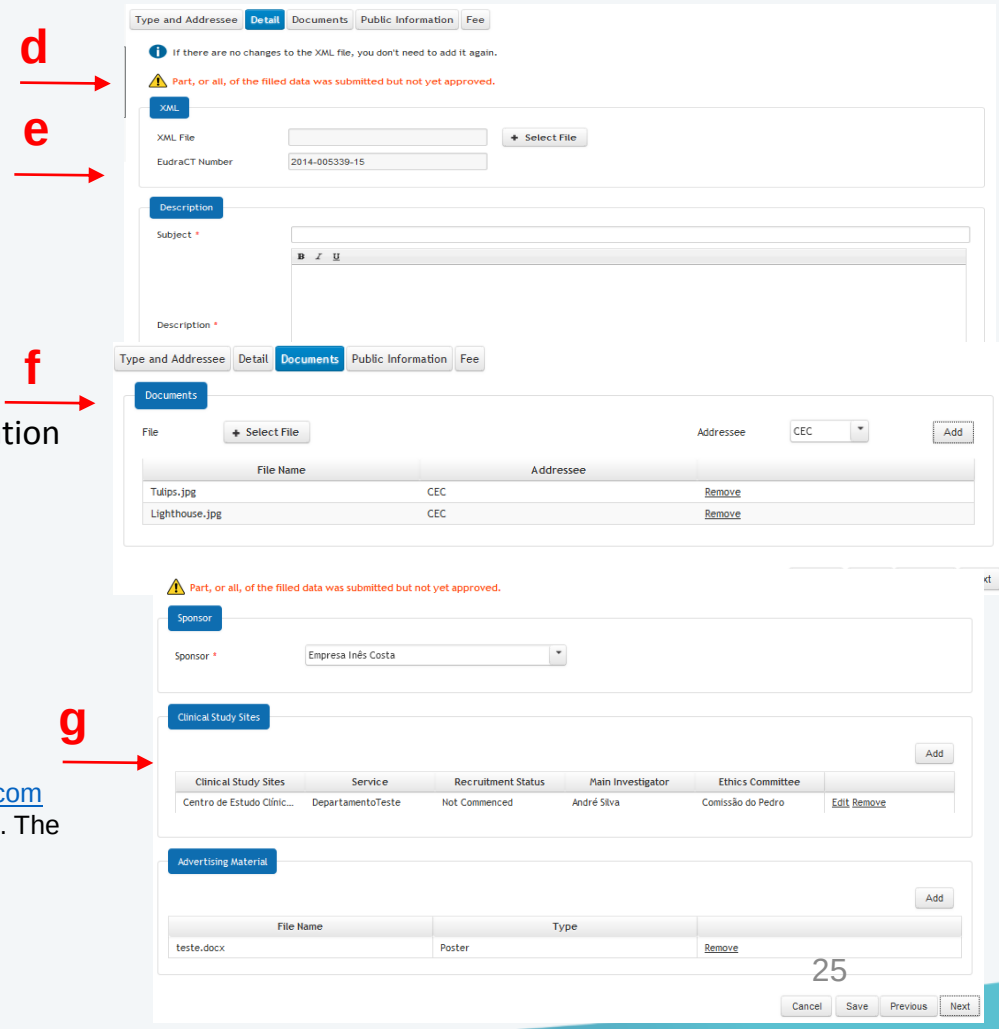
e) Include description of the Substantial Amendment

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.

Amend Request of Substantial Amendement

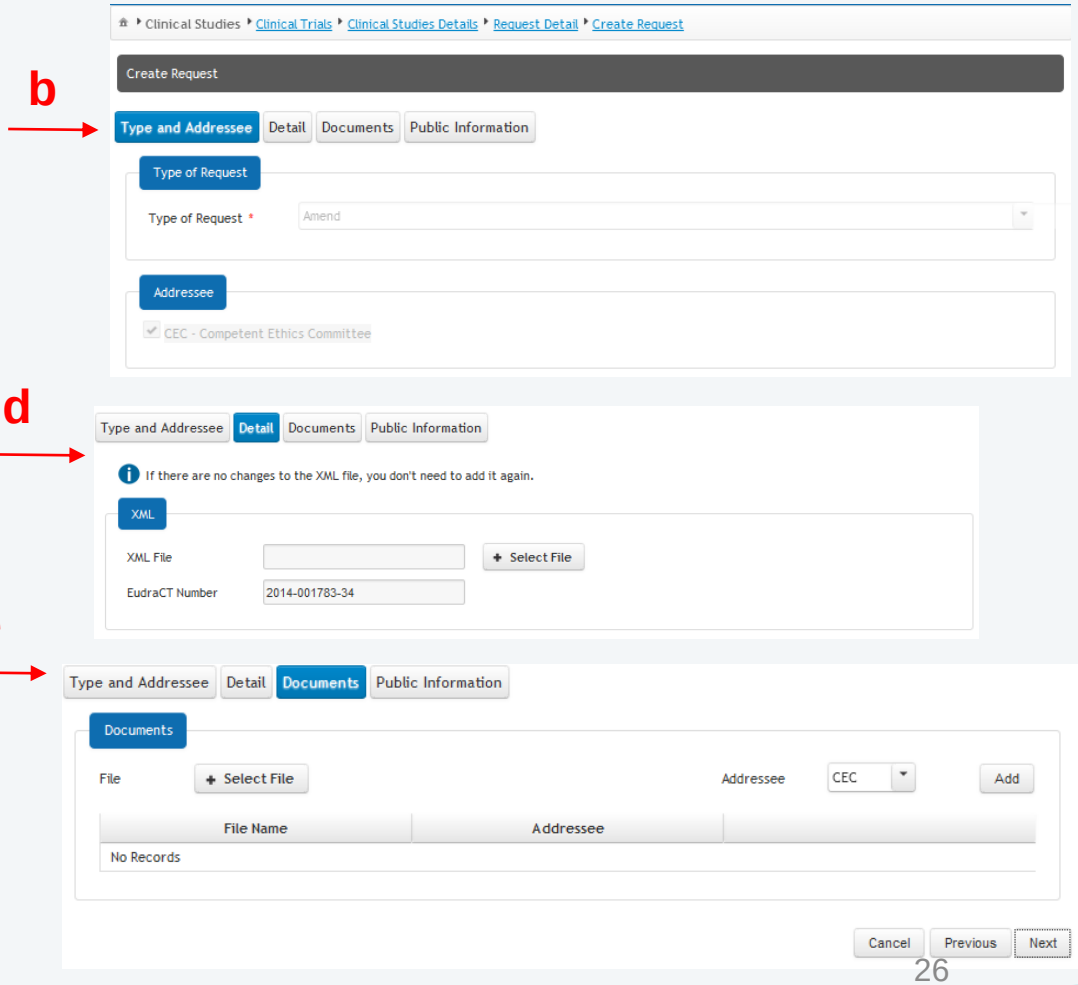
a) Request Details Screen

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 aplicable)

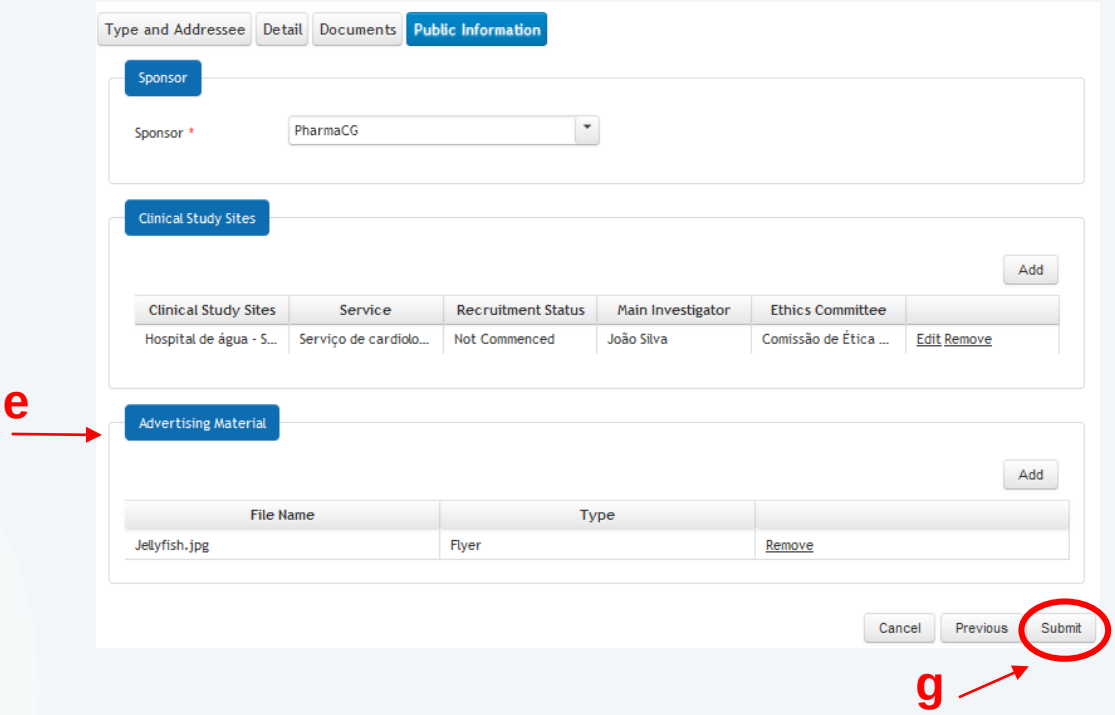
e)Attach the required documents for the amendment;



Amend Request of Substantial Amendement (2)

f) Update of the Advertising Materials (if aplicable)

g) Submit



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 previosly submited through RNEC - electronic platform. All notifications refering 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

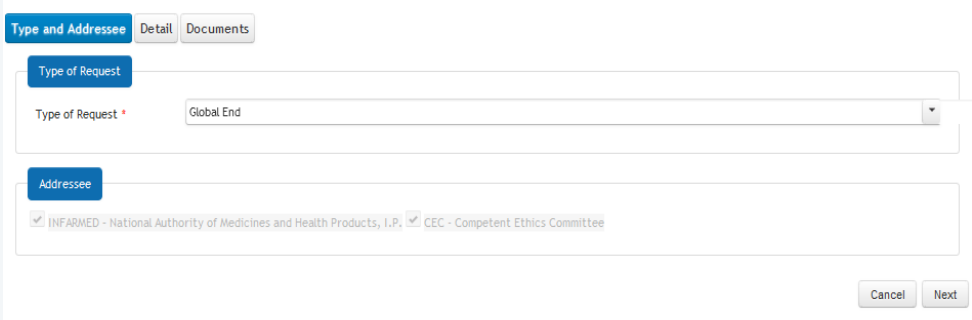
a) Rules for submission for End of Trial declaration:

INFARMED – Status =“Authorized” ou “Suspended”

CEIC – Status =“Favorable”, “Conditioned” ou “Suspended”.

d) Select – Global End

d



Submission of End of Trial Notification(2)

e) Include a description of the declaration

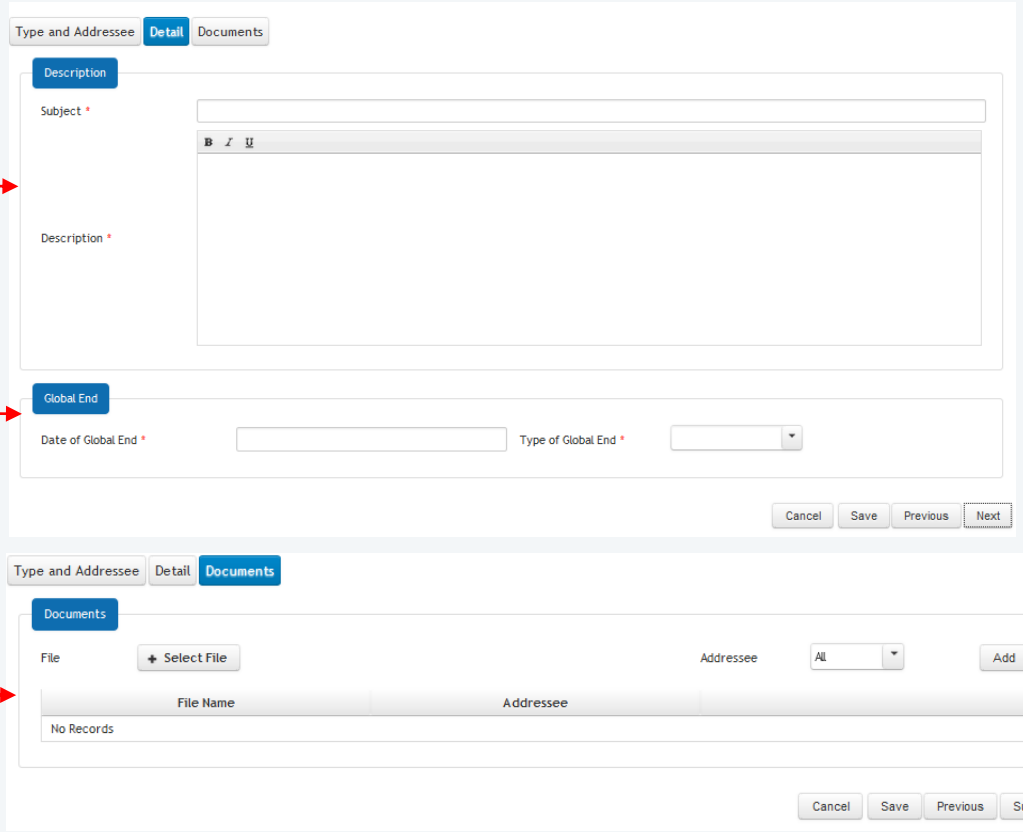
f) Select type of end of trial

- Early End of Trial
- As foreseen in the Protocol

g) Include End of Trial date

h) Attach the relevant documents

f) Submit



Change of a End of Trial Notification (3)

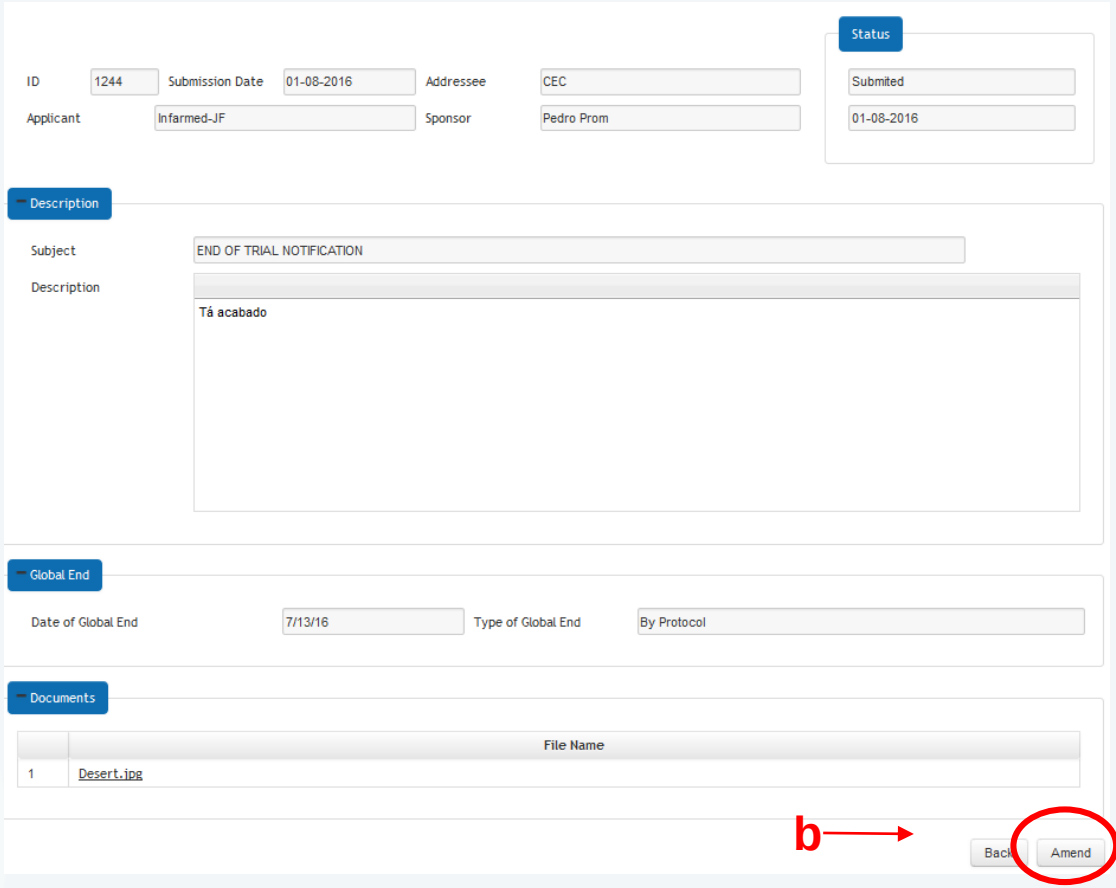
a) End of Trial Declaration Details screen

b) Amend

c) Update the relevant information

d)Attach the relevant documentation

e) Submit



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 submited 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 previosly submited through RNEC - electronic platform. Final Reports refering to all other trials should be submitted according to the usual procedure.

Submission of Final Report

a) Clinical Trial Details Screen

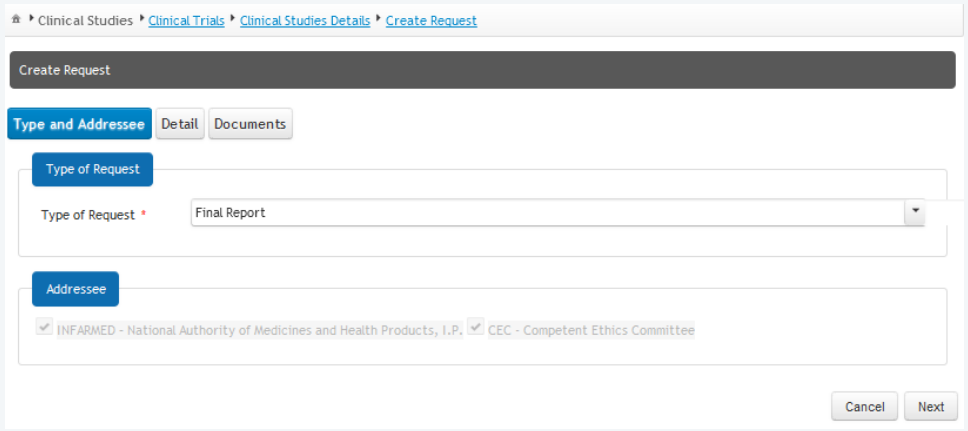
b) Create New

- 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”

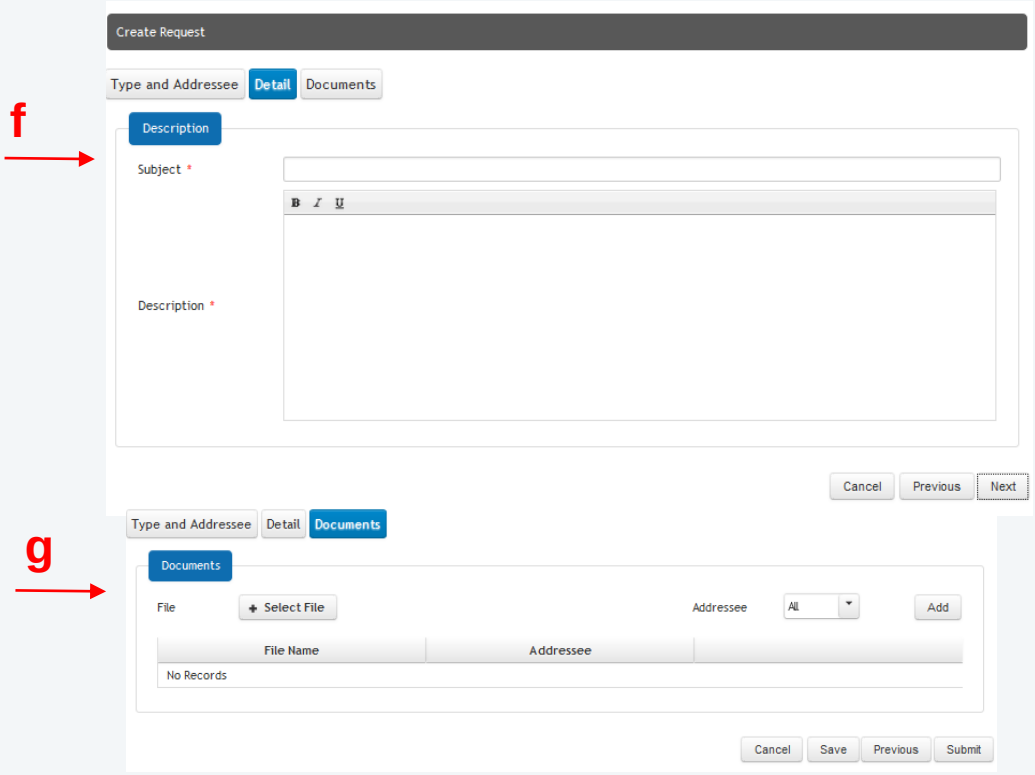
d) Select Request Type– Final Report



Submission of Final Report

f) Include a description of the Final Report

g) Attach Final Report



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 eletronic submission notification is only possible if the respective Clinical Trial has been previously submited through RNEC - electronic platform. Notifications refering 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:

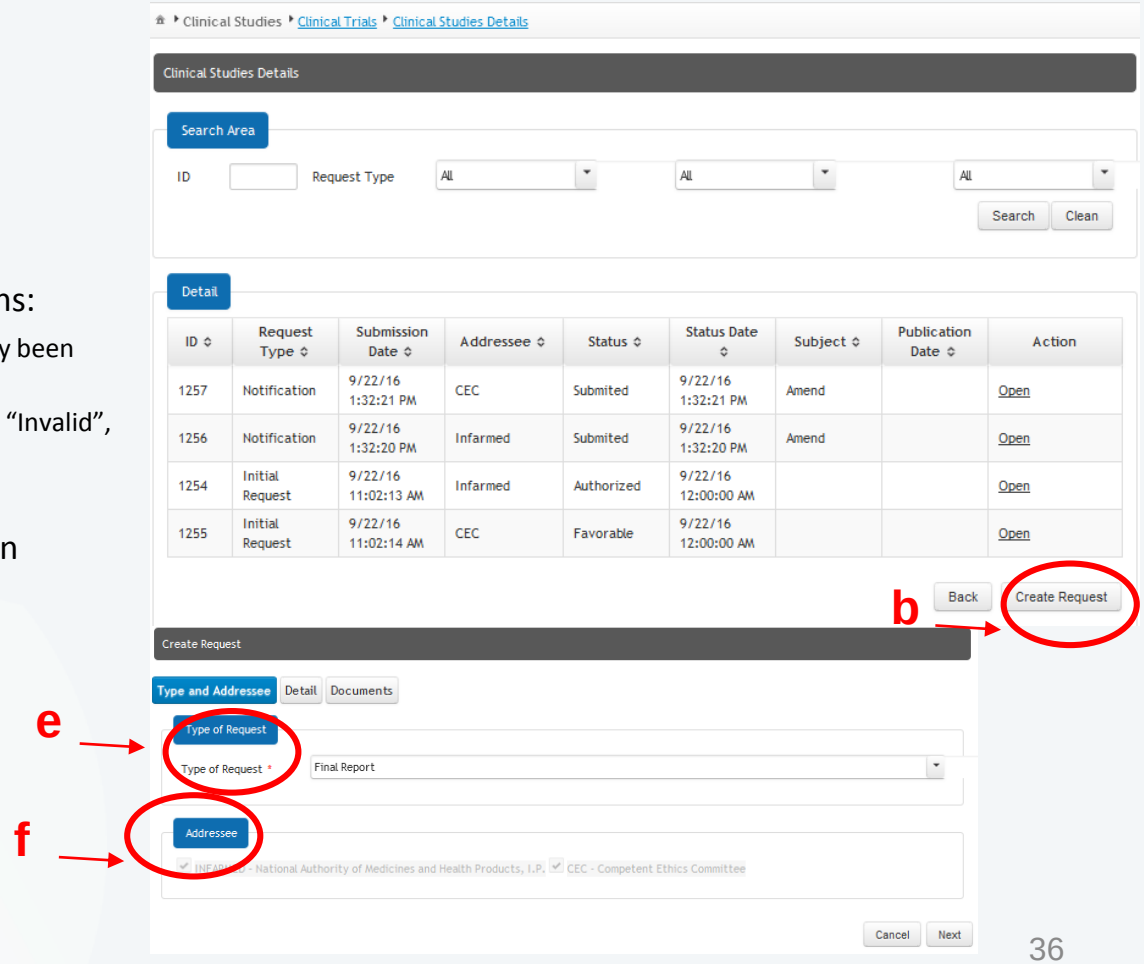
INFARMED – Initial request has previously been authorized

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

e) Select Type of request– Notification

f) Select addressee

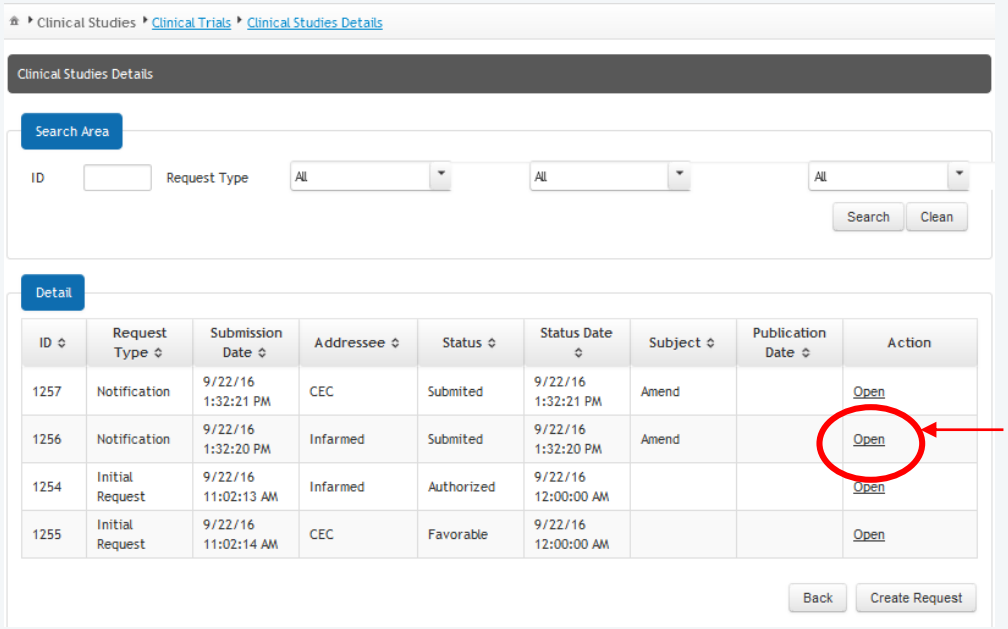
g) Add XML file



Amend a Notification Request

a) Clinical Studies Details screen

b) Open details of the Notification Request



Amend a Notification Request (2)

b) Amend

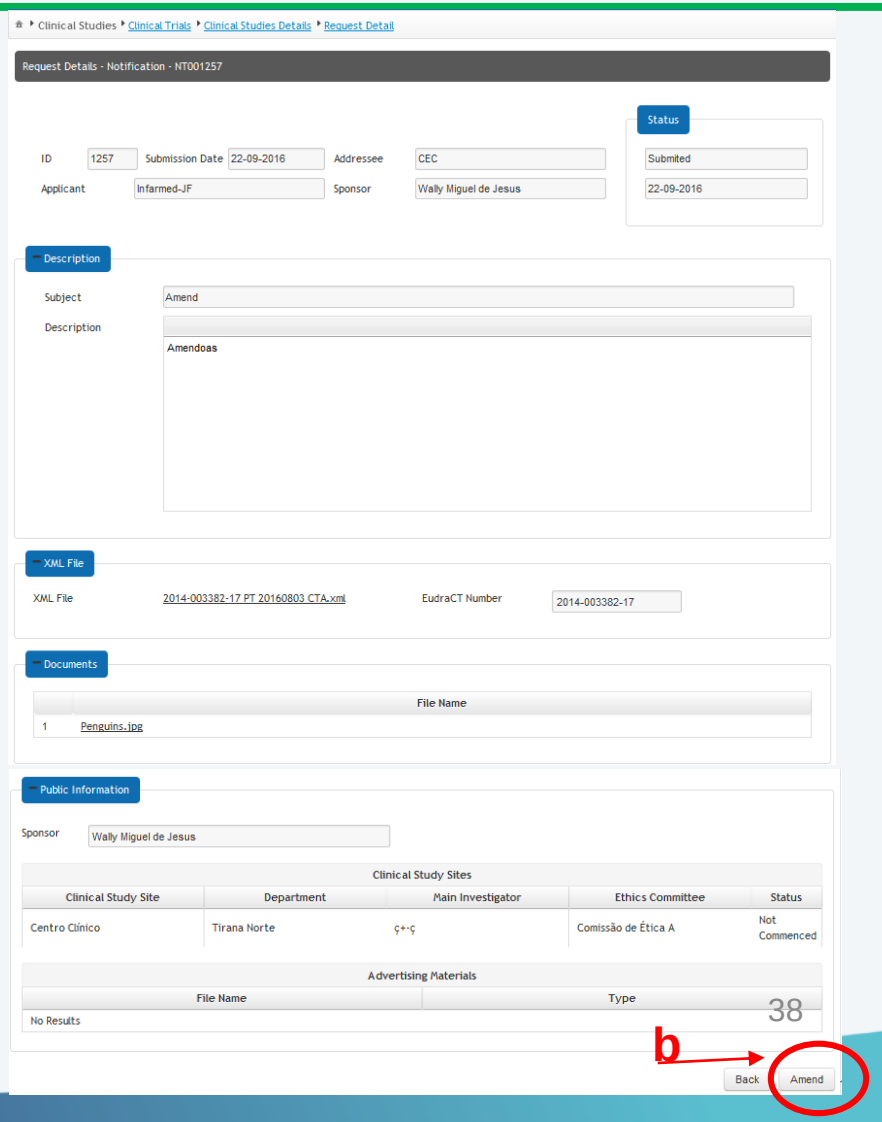
c) Update Description (if aplicable)

d) Update XML file (if aplicable)

e)Attach all required documents

e)Update Advertising Materials (if aplicable)

f) Submit



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

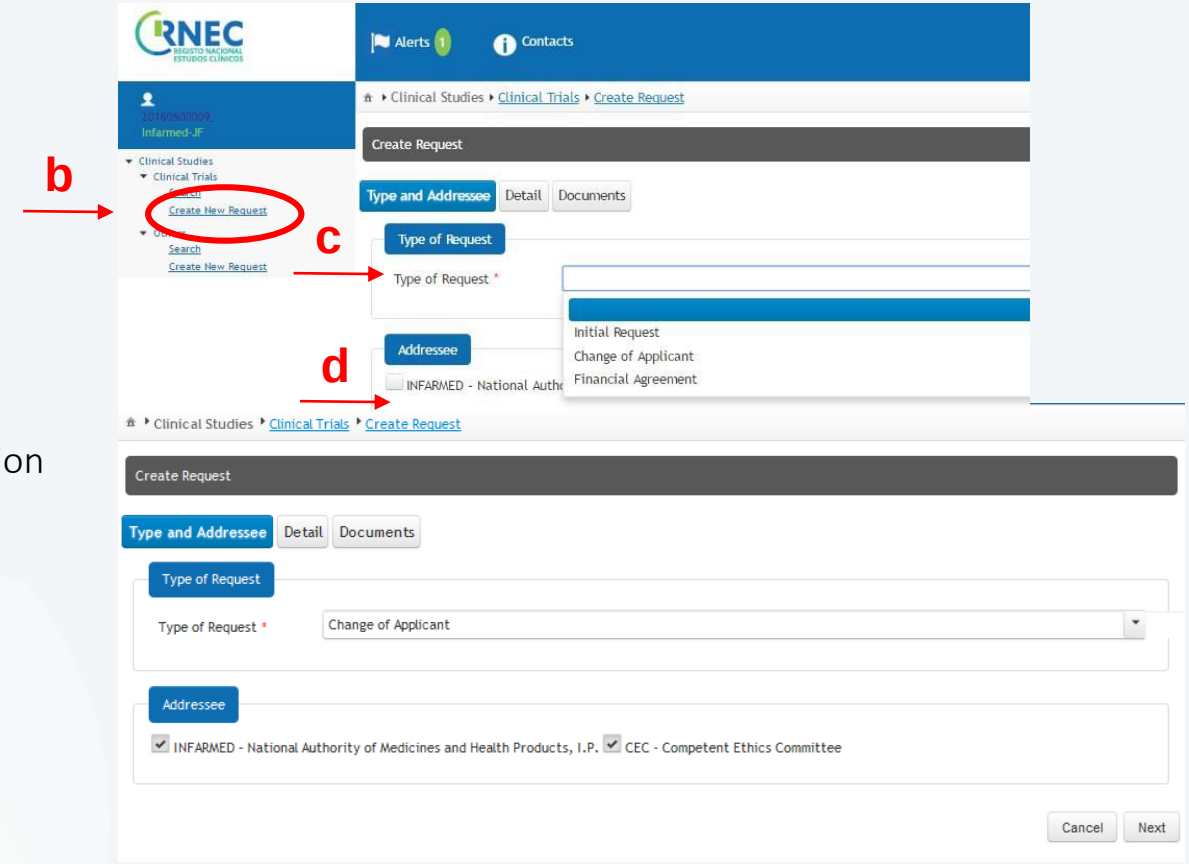
Change of Applicant

a) On the Side Bar menu select Clinical Trials Section

b) Create New Request

c) Select Request Type - Notification /Change of Applicant

d) Select Addressee



Change of Applicant

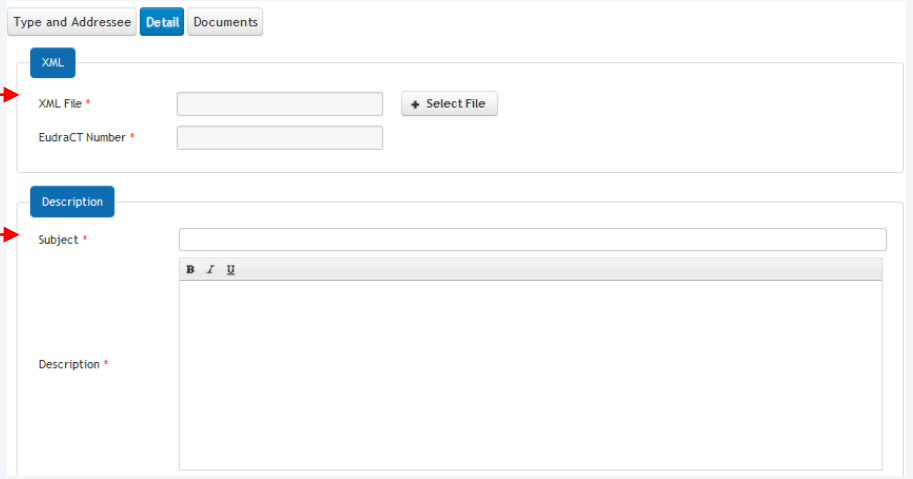
f) Add XML file

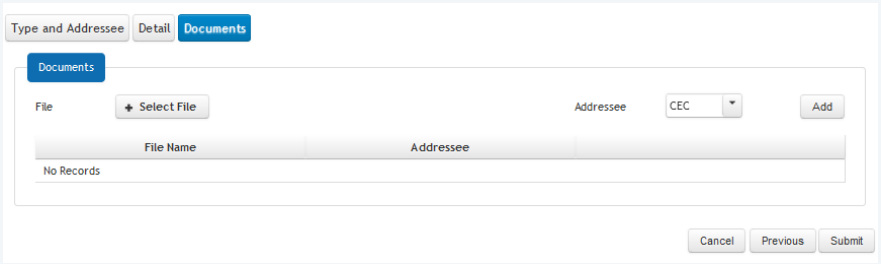
-» Note: Select only XML files of Clinical Studies already submitted in the platform and that have not been submitted by this applicant.

g) Include an accurate description of the request

f) Attach the applicable documents

g) Submit

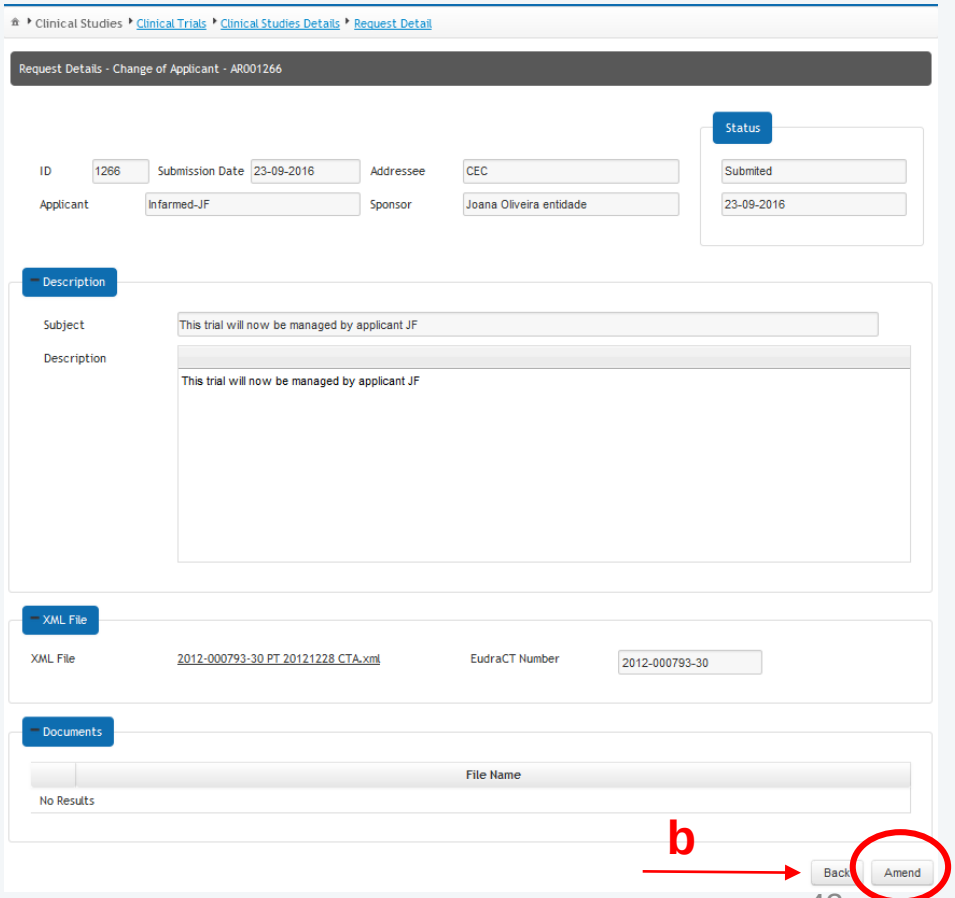




Amend Change of Applicant Request

a) Change of applicant detail Screen

b) Amend

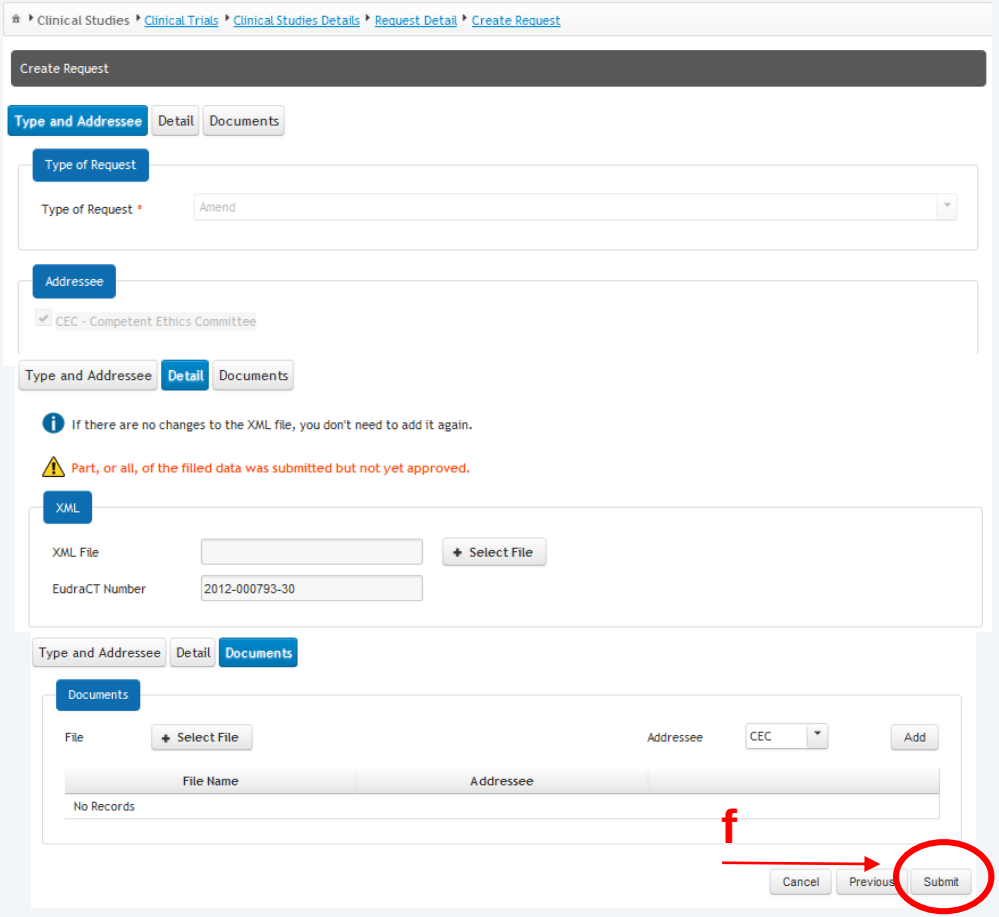


Amend Change of Applicant Request

d) Update XML file

e)Attach required documents

f) 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 commitee (CEIC).

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

Submission a Financial Agreement Notification

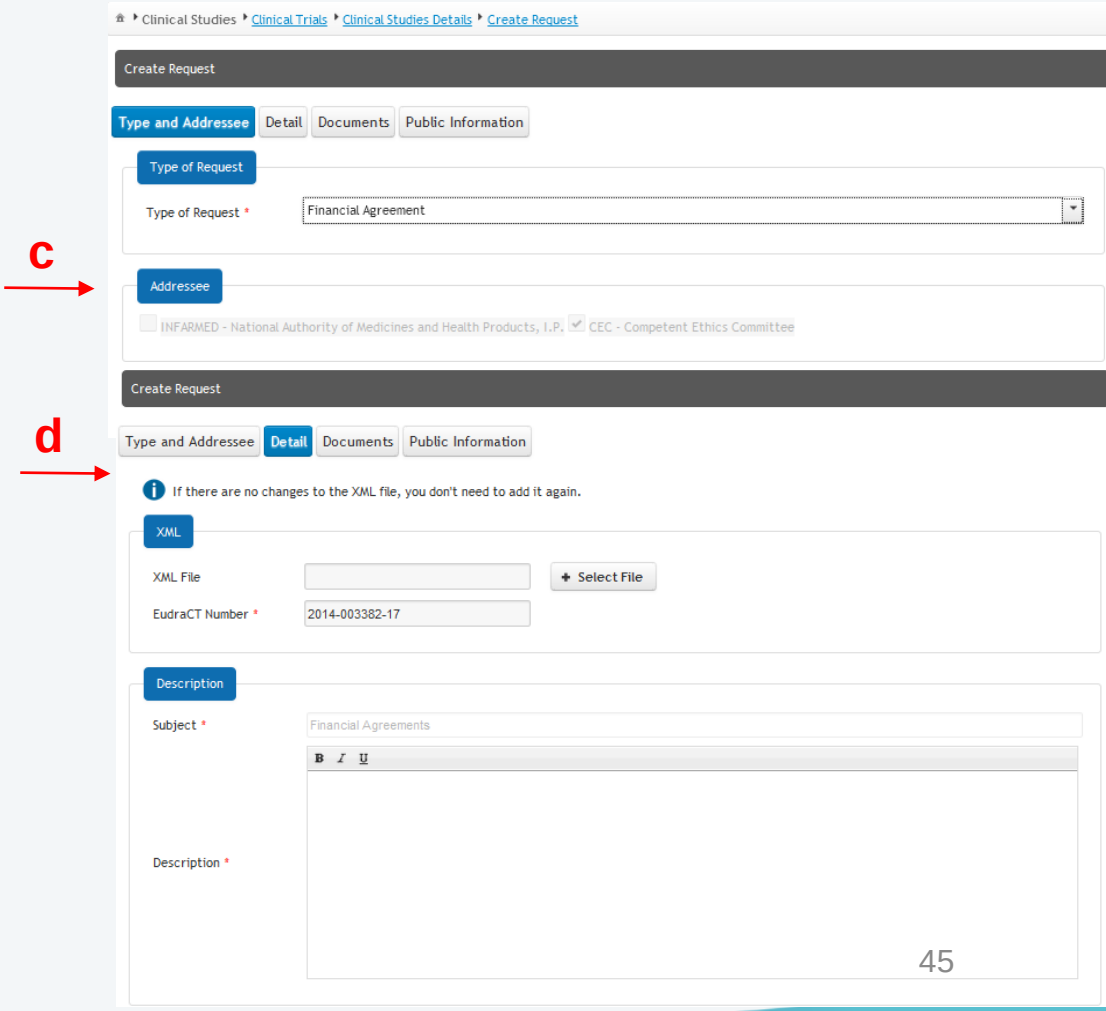
a) Clinical Trial screen

b) Create Request

c) Select type of Request – Financial Agreement

d) Select addressee – CEC- Competent Ethics Committee

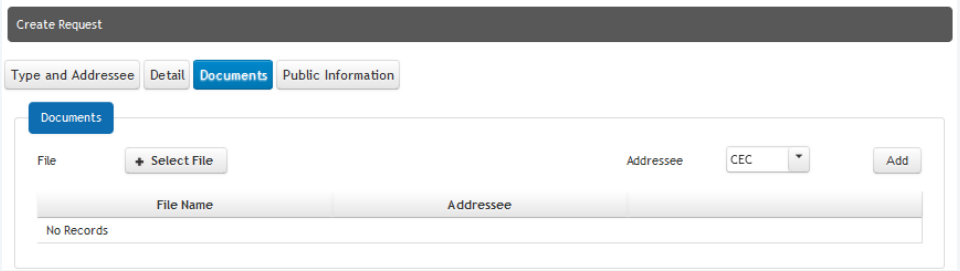
f) Attach XML file



Submission of a Financial Agreement Notification

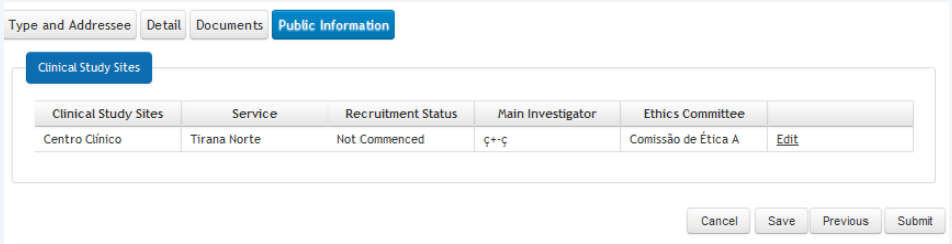
f) Attach the required documents

f



g) Update the Recruitment Status of each Clinical Study Site

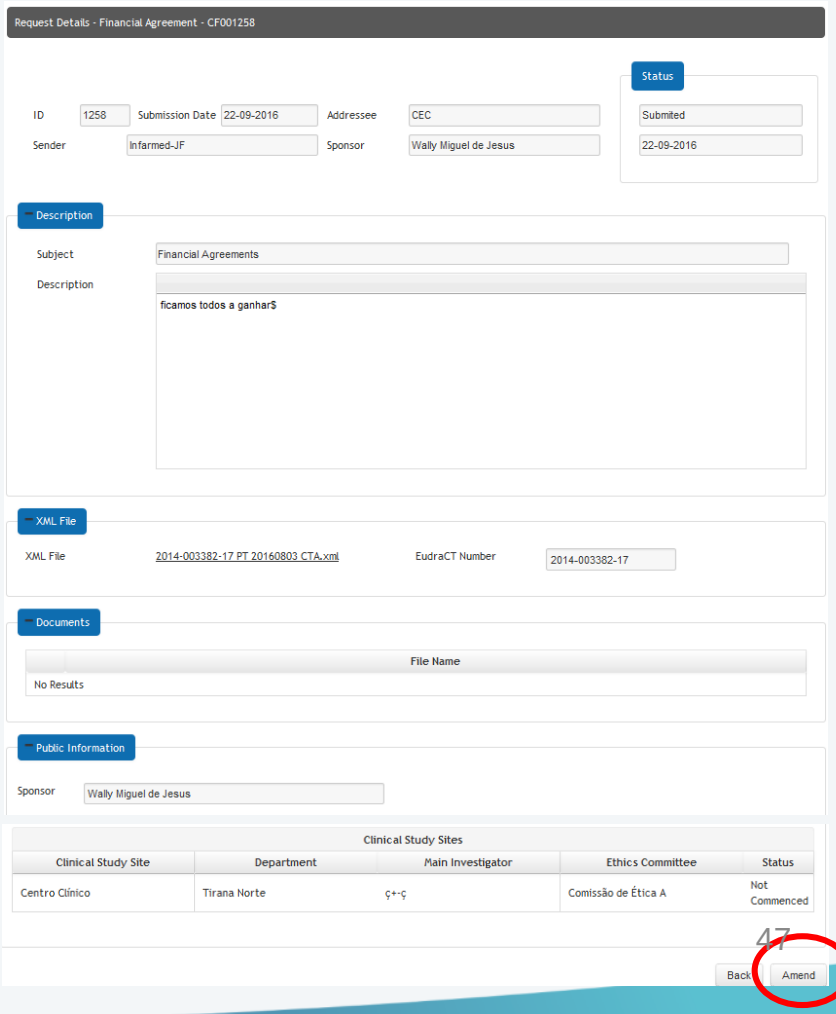
g



Amend the Financial Agreement Notification

a) Financial Agreement Detail Screen

b) Amend



Amend the Financial Agreement Notification

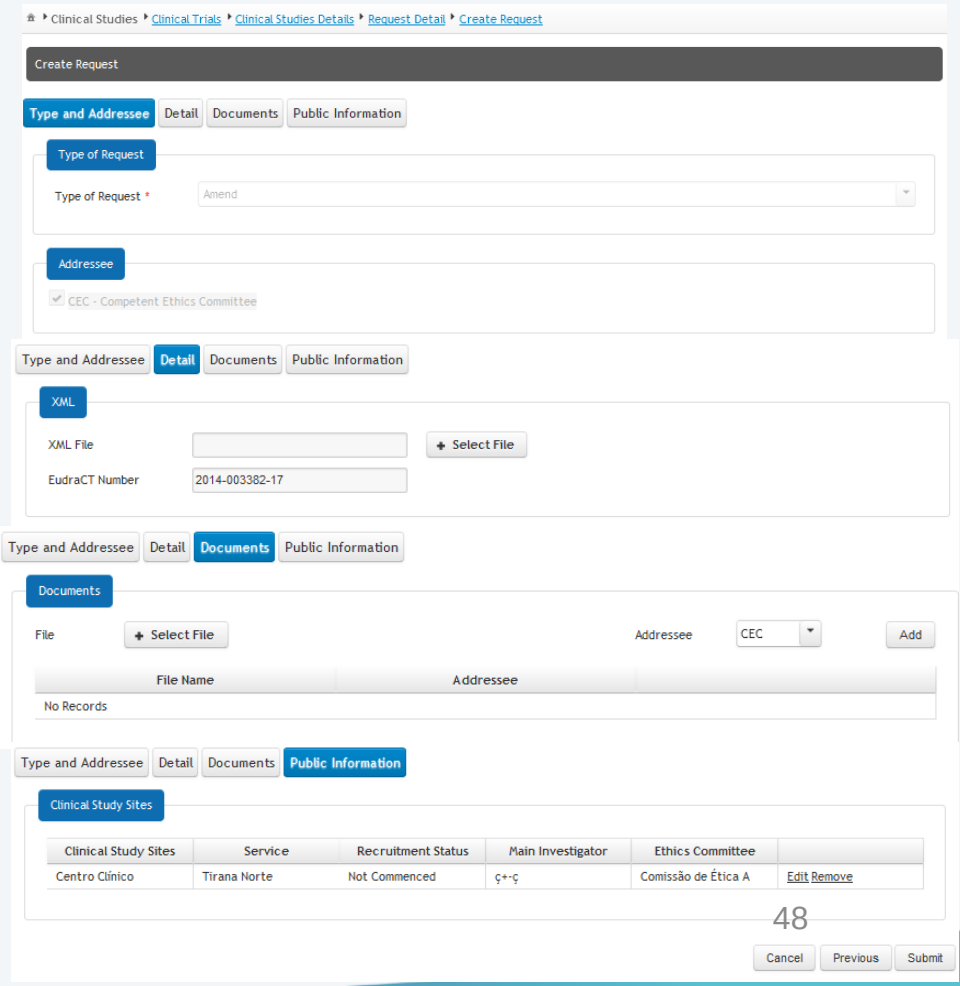
c) Update Description

d) Update XML file

e)Attach required documents

f) Update current Status of Clinical Study Sites

g) Submit



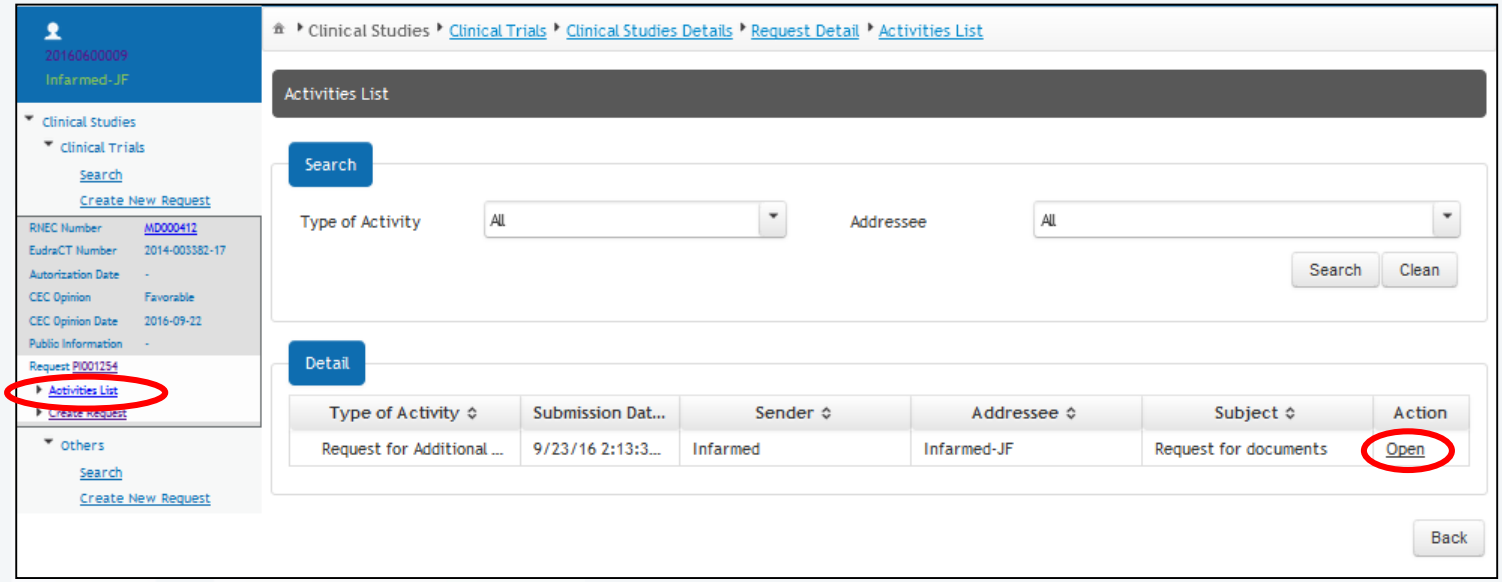
RNEC

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



Reply to an Additional Information/Amend Request

a) Additional Information details screen

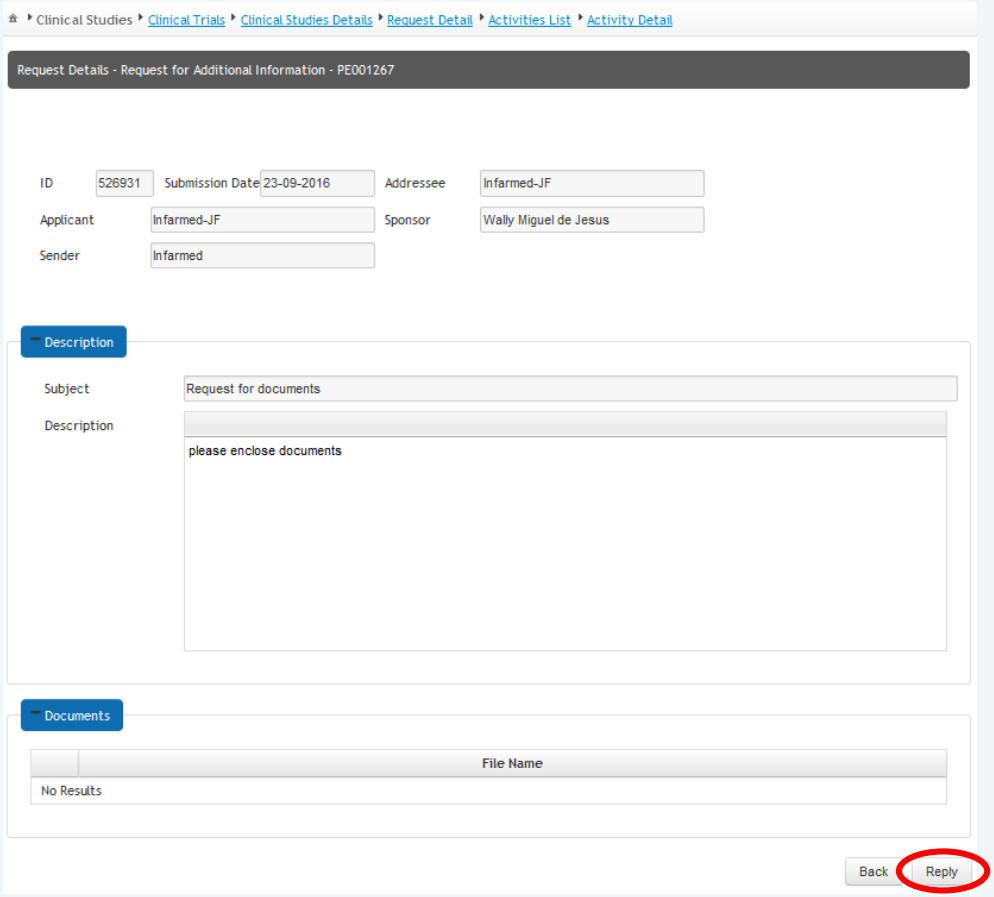
b) Reply

c) Create Request

d) Update XML file + descripiton of the answer

e)Attach required documents

g)Submit



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

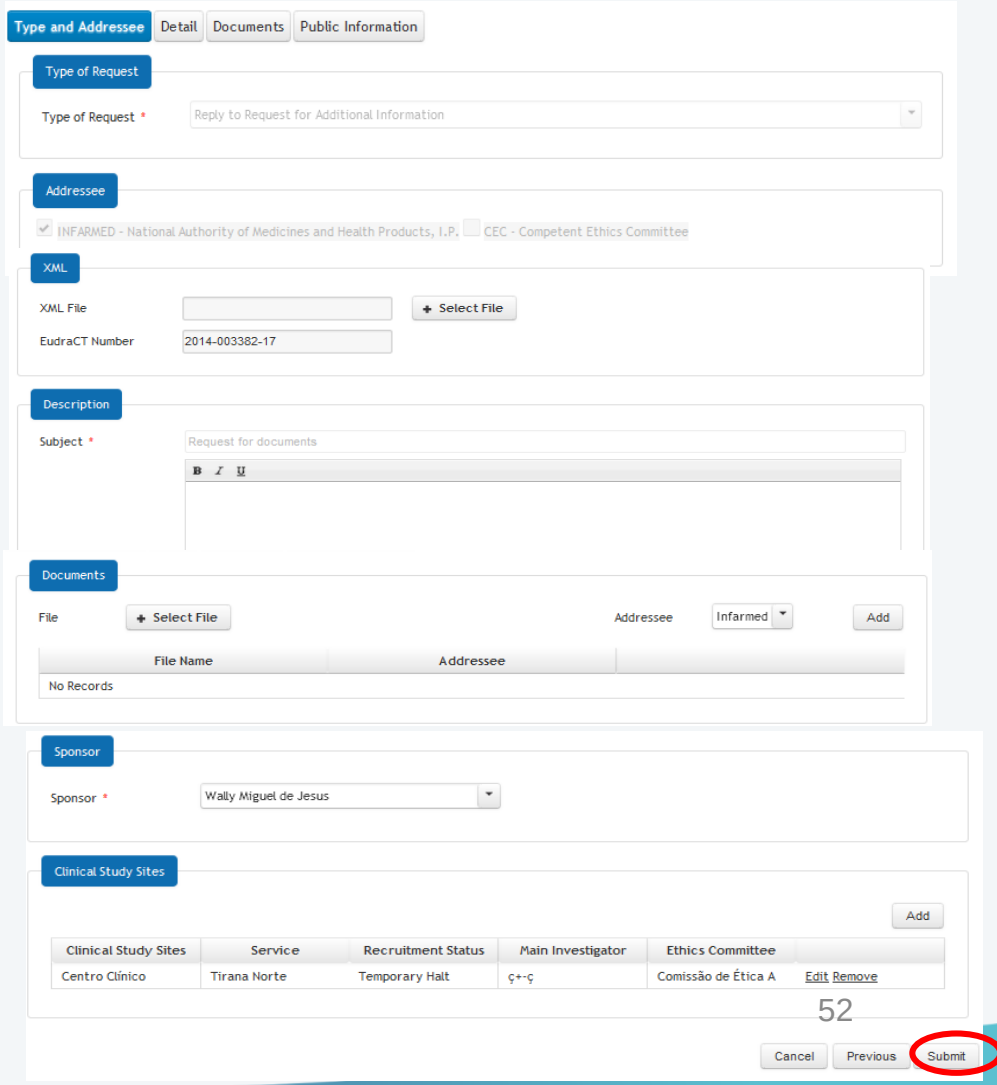
Change of Applicant

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



Replying to a Communication

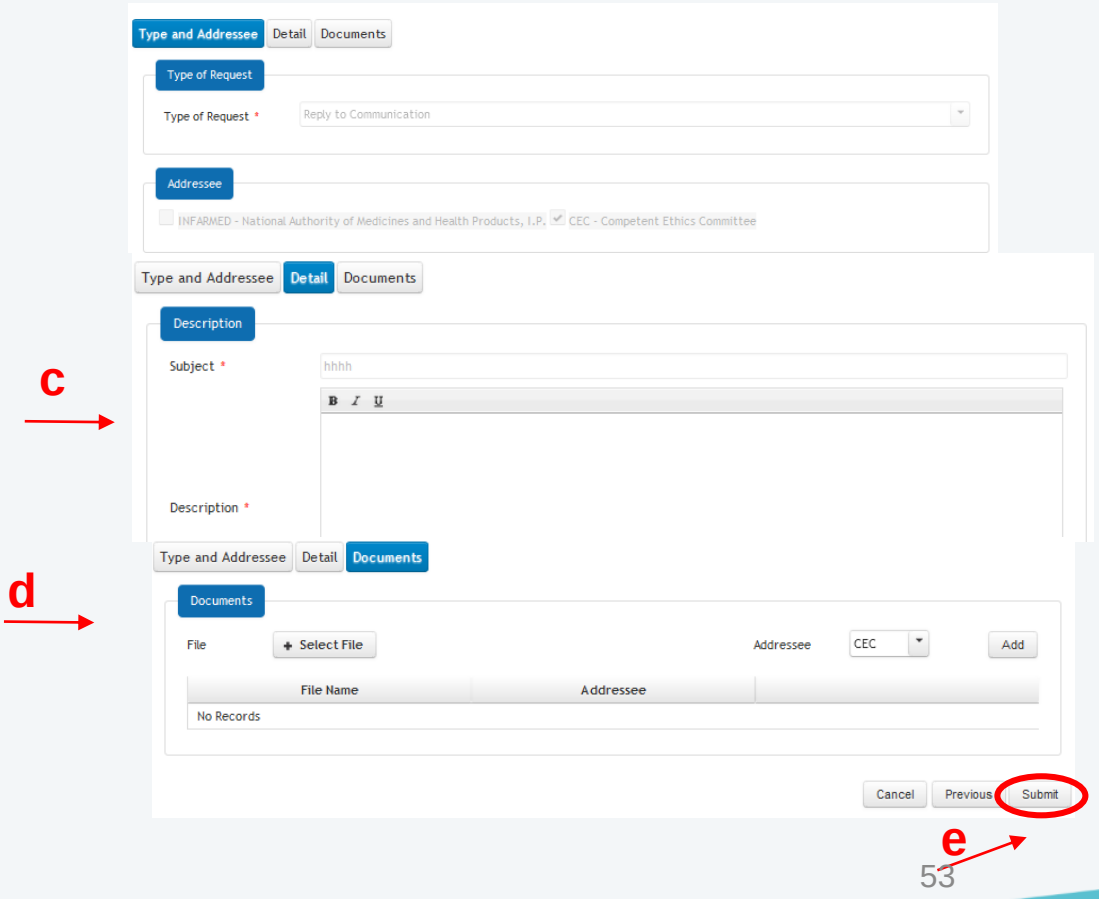
a) Communication Details Screen

b) Reply

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

d) Attach required documents

e) Submit



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 shouls be made according to the regular procedure.

Payment of Fees

a) Clinical Studies Details | Request Details Screen

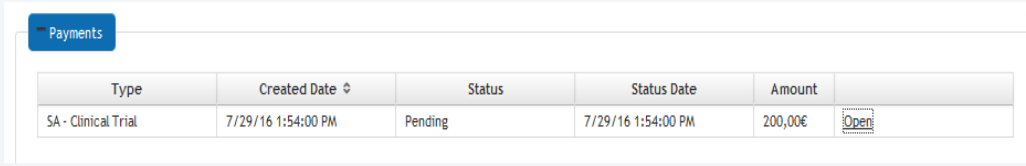
b) Select open on the Payment Section for the selected Fee

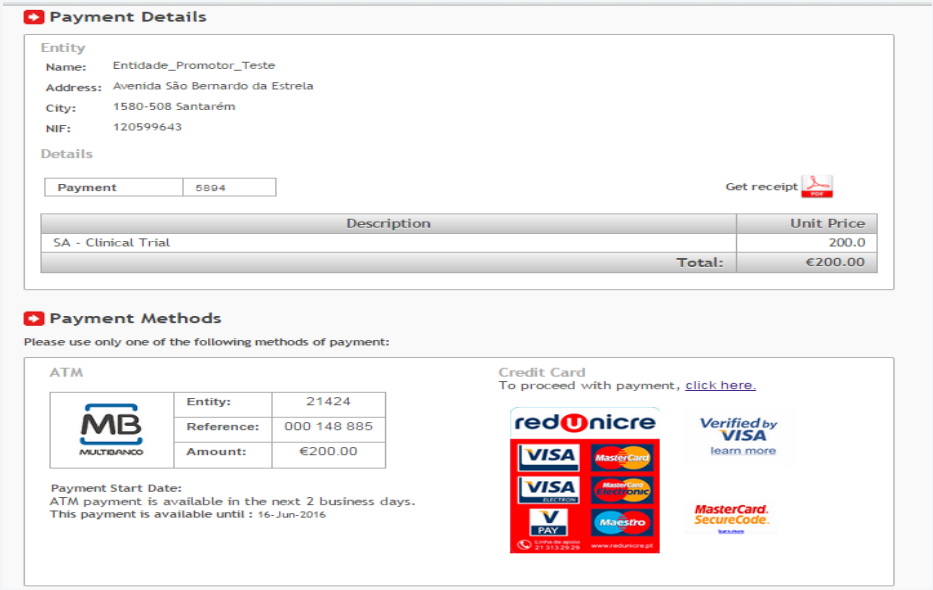
c) Payment Details

d) Submit Payment

e) Wait 5 min

f) Request Status - “Submited”





RNEC

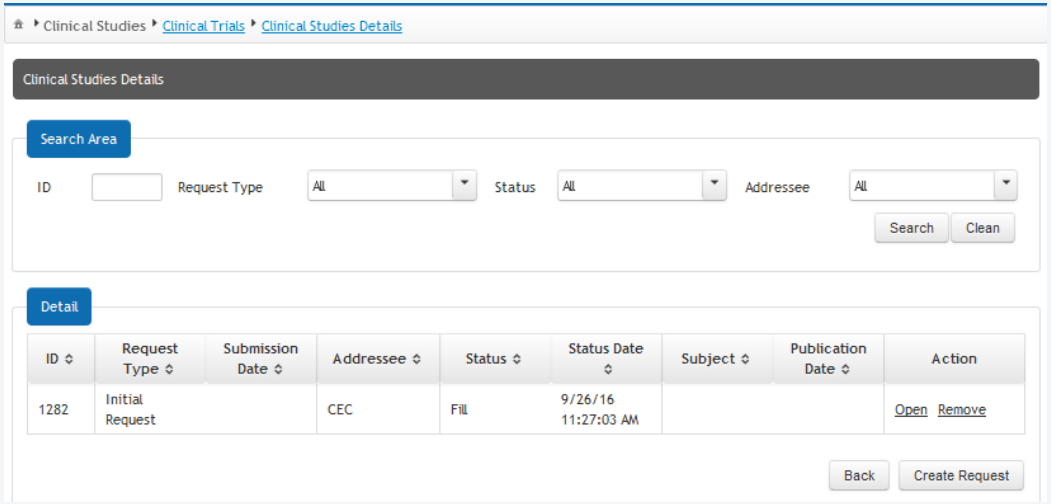
Save/Remove Requests

Save Requests

- Available only for requests (not for activities)

- Save (lower right corner)

- Request Status– “Fill”



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.*

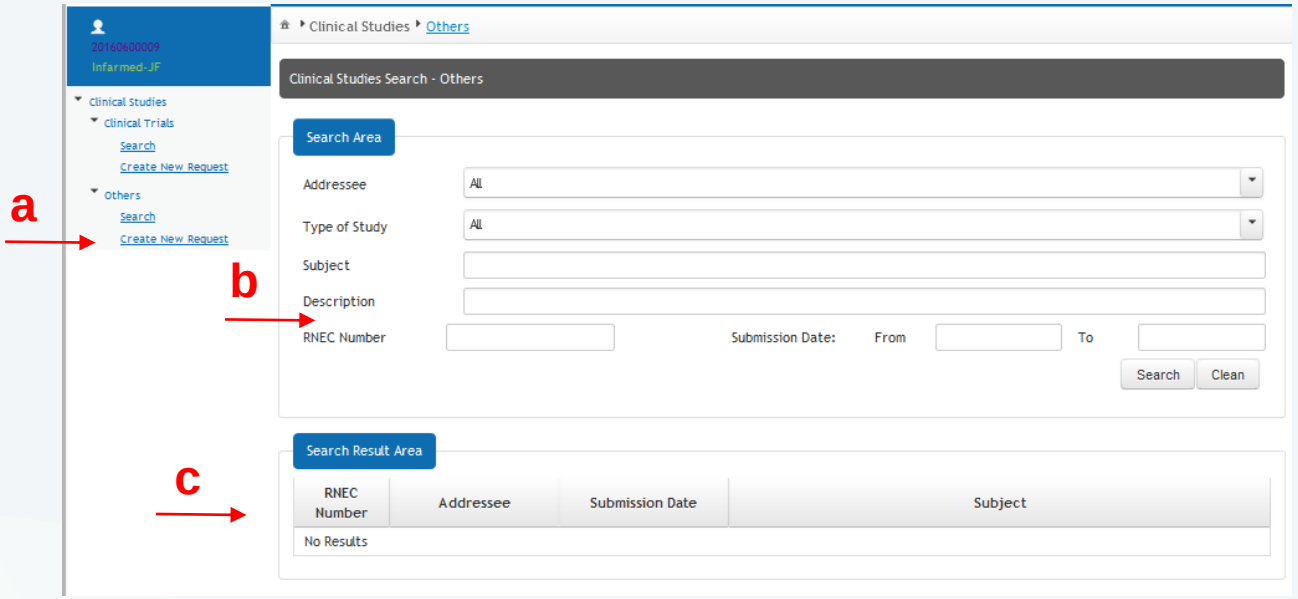
NOTE: All Studies that are submitted to CEIC outsider of the scope of its assessment competences will be automatically stored without any evaluation or associated procedure – Law 21/2016 from April 16.

Search for Other Studies

a) Search for Clinical Studies
Search Others

b) Search Menu

c) Results



Other Studies

b) Create Requests

Navigation Menu – Create New

Select:

- Type of Study
- Addressee

Add

- Description
- Documents