Fee Payment/Exemption Manual for Clinical trials

After submission of an Initial Clinical Trial application or Substantial Modification, on CTIS, you will receive a no-reply email with information about payment or request for exemption of fees (image 1)

Please select the applicable "link" in order to proceed with payment, or request fee exemption

Note: If you are submitting IMPD-Q only application, please proceed with fee exemption link, and select the option "Exemption already granted".

Subject: Payment or Exemption Request for Clinical Trial Fee | Clinical trial number 202x-xxxx-xx-xx

Dear Sponsor,

We hereby inform you that, in Portugal, the fees associated with clinical trials are established by Ordinance No. 63/2015, dated March 5th.

Please note that you may proceed with the payment of the applicable fee via the following link.

(The payment performed by ATM will be available within 2 days, and should be done until a maximum of 4 days.)

If you believe you are eligible for an exemption, you can request it in accordance with Article 3 of Ordinance No. 63/2015, using the following link.

Article 3 of Ordinance No. 63/2015 states that a fee exemption may be granted by the INFARMED, I.P. management board under the following circumstances:

- If the Sponsor is a non-profit entity, or
- · In the case of non-commercial clinical trials.

Additionally, in case where exemption has already been granted, in the same clinical trial, or under the submission of an SM Part II only, within the scope of Article 11, the applicable exemption reasons should be chosen.

In case you need any assistance with the payment process or exemption request, please contact INFARMED, I.P. directly by e-mail ensaios.clinicos@infarmed.pt.

Thank you for your cooperation.

Best regards,

Clinical Research Unit

INFARMED – National Authority of Medicines and Health Products, I.P.

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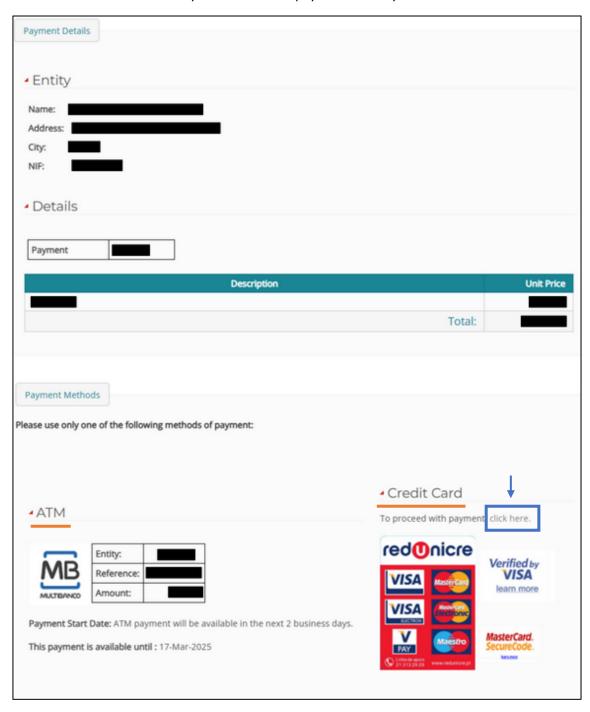
Note: this is an automatic message. Please do not reply to this email.

1) If payment "link" is selected, the panel bellow will appear. Please confirm all the informations, and click "Next" button:

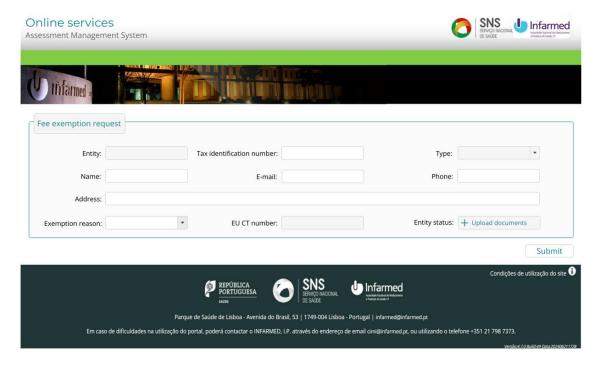


2) Select the payment option ATM or Credit card, and proceed:

Note: ATM references will only be available for payment in 2 days



3) If the link for fee exemption request is selected, the panel below will appear. Some of the fields will be already filed, some are editable, other no. After confirm all the fields, please click on "submit" button



Exemption options are:

- Non-profit organization
- Non-commercial clinical trials
- Exemption already granted
- SM part II only Article 11

Notes:

- Tax identification number is mandatory;
- If you select the exemption reason <u>"Non-profit organization"</u>, is mandatory to submit <u>entity bylaws</u>
- If you are submitting IMPD-Q only application, please proceed with fee exemption link, and select the option "Exemption already granted"
- After submit the request, you will receive a confirmation email, in case the fee exemption is granted.
- If the fee exemption is rejected, you will receive an email also, including a new link in order to perform the payment.