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Information Management Division

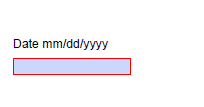
User guidance

Clinical Trial result authorisation PDF form

This document is intended to provide guidance for Sponsors/MAH/Third country data providers who wish to assign Clinical trials to other parties. These users should use the PDF form described below for requesting this access.

**Please follow the guidance below when completing the pdf form.**

1. Ensure that you use the PDF form; you will need to **download** it from the EudraCT web site and **save it** in your local drive.
2. Reopen the form saved in your local drive to fill in the request.
3. Please note that all fields marked within with the red border are mandatory to complete.
4. Please ensure there are **no spaces** before or after the information (i.e, email address, requestor’s name, company name) entered in the box of the required fields.
5. Enter the name of the entity or company requesting access to the results.
6. Enter the date and submit the letter within 30 calendar days. All letters dated more than 30 calendar days from the request submission date will be rejected.
   1. **Please note that the date format is mm/dd/yyyy (US format)**



1. Provide the Sponsor, MAH or Third company data provider details (if relevant) by selecting ‘yes’ in the yes/no choice question and entering their appropriate name. If there is no third party or subsidiary, or you have registered the CTA under a department in your organisation, select ‘no’ in the yes/no question.
2. The below scenarios may help you to complete the form:
   1. If the CTA was registered for the **Department of Neurology** and the <Entity/company name> is **The London Hospital**, then you should tick 'yes' to the question:

“Does one or more of the EudraCT requests belong to a subsidiary, Third party provider or department within your organization?” and in the <Subsidiary or Department name> field you should write **Department of Neurology**, if this is how it was registered with EMA.

* 1. **MT Holdings** is the owner of the trial and registered it with EMA. Then, **Pharma Ltd** acquired **MT Holdings**, so it is **Pharma Ltd** entered under <Entity/company name>. However, the CTA is still under **MT Holdings**, so you need to tick 'yes' to the question:

“Does one or more of the EudraCT requests belong to a subsidiary, Third party provider or department within your organization?” and then write **MT Holdings** in the <Subsidiary or Department name> field.

*Essentially, if the CTA is registered with the Company A and the requester company name has changed or is different e.g. Company B, then you must enter Company A in the <Subsidiary or Department name> field, to ensure the system matches what we have in EMA records.*

1. Enter the name (forename and surname) and the email address associated with the user’s EudraCT account. Ensure the email address is a professional one. Generic emails such as admin@123.org or info@abc.com are not accepted and will result in rejection of the request.
2. List the clinical trials to assign to other parties. The EudraCT numbers must correspond with the trials submitted online, incorrect or missing information will result in rejection of the request. The title description and sponsor must be identical to how the CTA was originally registered as it will be checked against registered records.
3. You will be able to request access to maximum 20 CTs on each form.
4. If you need to request access to more than 20 CTs, please complete and submit a new form in a new results access request.
5. The authoriser must **type in** their name and surname in the signature box. Please ensure the signatory provides their full name, entity and contact details. If the full name or details are missing this will result in rejection of the request.
6. **Save and upload the completed Pdf form to the EudraCT**.
7. Please **DO NOT scan the Pdf form**. Scanned Pdf form will result in request rejection.

*Please view the following sample Clinical Trial assignment request form before completing the request.*

