

## User guidance

### Clinical Trial Assignment authorisation letter

Sponsors/MAH/Third country data providers who wish to assign Clinical trials to other parties should submit an Assignment letter.

Please follow these instructions when preparing the assignment letter.

1. Ensure the assignment request letter is on Sponsor's, MAH's or Third Country data provider's letterhead paper.
2. Enter the name of the entity or company requesting the assignment.
3. Enter the date and submit the letter within 30 days. If the letter is dated more than 30 days from the request submission date, the request will be rejected.
4. Keep the European Medicines Agency as the addressee.
5. Provide Sponsor, MAH or Third company data provider details and enter the appropriate name.
6. Enter the name (forename and surname) and the email address associated to the user's EudraCT account. Ensure the email address is a professional one. Generic/functional emails such as admin@123.org or info@abc.com are not accepted, and the request will be rejected.
7. Keep the legal text as it is. Do not vary this text without legal consultation. If any text is missing or amended, the request may be rejected.
8. List the clinical trials to assign. The EudraCT numbers correspond with the online submitted EudraCT numbers. The EudraCT numbers must correspond to the trials submitted online. If they are missing, the assignment request will be rejected.
9. The authoriser must sign the Clinical trial assignment request. Provide the signatory's full name, entity and contact details. If the letter is not signed or details are missing the request will be rejected.
10. Scan and upload the scanned copy of the signed assignment letter to EudraCT

Please view the following sample Clinical trial assignment request letter before completing this [template](#).



European Medicines Agency  
EudraCT registration team  
30 Churchill Place,  
Canary Wharf  
London E14 5EU  
United Kingdom

SDC Ltd  
22-Nov-2016

Dear EudraCT registration desk,

**Re: EudraCT - Clinical trial assignment request - result related information**  
**Sponsor: SDC Ltd**

Acting on behalf of the sponsor, the addressee of the decision on a paediatric investigation plan or the marketing authorisation holder, I would like to request assignment of the clinical trials listed below to the following EudraCT user:

Jane Doe jane.doe@abc.org

This assignment will designate the user as the primary user for the listed clinical trials in regards to result related information. It will enable them to prepare and post result related information for these trials on behalf of the sponsor, the addressee of the decision on a paediatric investigation plan or the marketing authorisation holder in accordance with Commission Guideline 2012/C 302/03 and its technical guidance on the format of the data fields of result-related information on clinical trials submitted in accordance with article 57(2) of Regulation (EC) No 726/2004 and article 41(2) of Regulation (EC) No 1901/2006.

Furthermore, this assignment will enable the user to assign one backup user and multiple delegated results preparers and posters for each listed trial.

List of clinical trials:

EudraCT Number	Full title of the trial	Sponsor name
200X-00X410-2X	Anticoagulant therapy	SDC Ltd
200Y-00Y410-2Y	Bone Maintenance Assessment	SDC Ltd
200Z-00Z410-2Z	Deep Venous Obstruction	SDC Ltd

Yours sincerely,

Jill Dole  
Director  
+ 44 12345678  
jill.dole@sdc.org  
SDC Ltd  
456 Bond Lane  
London  
EC14 5xx

**1.** Sponsor/MAH/Third country data provider letterhead

**4.** European Medicines Agency

EudraCT registration team  
30 Churchill Place,  
Canary Wharf  
London E14 5EU  
United Kingdom

**2.** <Entity/company name>

**3.** <DD-MMM-YYYY>

Dear EudraCT registration team,

**5. Re: EudraCT - Clinical trial assignment request - result related information**

**Sponsor/MAH/Third country data provider name:** <NAME of the SPONSOR/MAH/Third country data provider>

Acting on behalf of the sponsor, the addressee of the decision on a paediatric investigation plan or the marketing authorisation holder, I would like to request assignment of the clinical trials listed below to the following EudraCT user:

**6.** < name and surname > <email address>

**7.** This assignment will designate the user as the primary user for the listed clinical trials in regards to result related information. It will enable them to prepare and post result related information for these trials on behalf of the sponsor, the addressee of the decision on a paediatric investigation plan or the marketing authorisation holder in accordance with Commission Guideline 2012/C 302/03 and its technical guidance on the format of the data fields of result-related information on clinical trials submitted in accordance with article 57(2) of Regulation (EC) No 726/2004 and article 41(2) of Regulation (EC) No 1901/2006.

Furthermore, this assignment will enable the user to assign one backup user and multiple delegated results preparers and posters for each listed trial.

**8.** List of clinical trials:

EudraCT Number	Full title of the trial	Sponsor name

Yours sincerely,

**9.** <signature>

**10.** <name and surname of the person signing the letter>

<title of the person signing the letter>

<telephone number of the person signing the letter>

<e-mail address of the person signing the letter>

<name of the entity >

<address of the entity>