Le Cornet, Lucian

Von: Le Cornet, Lucian
Gesendet: Montag, 21. März 2022 07:17
An: EudraCT_notification
Cc: Süße, Heike
Betreff: AW: To detected contact contact point: EudraCT clinical trial results still in "draft"
Anlagen: Result-2009-013279-23.xml; Result-2009-016631-35.xml; Result-2013-000064-28.xml; Result-2014-000503-27.xml

Kennzeichnung: Zur Nachverfolgung
Kennzeichnungsstatus: Gekennzeichnet

Dear EudraCT team,

Please find enclosed the 4 xml files.
Please inform us, as soon as you uploaded the results.

Thank you very much and kind regards
NCT team

_____
Dr. Lucian Le Cornet
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German Cancer Research Center (DKFZ)
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lucian.lecornet@nct-heidelberg.de

Von: EudraCT_notification <EudraCT_notification@ema.europa.eu>
Gesendet: Freitag, 18. März 2022 16:09
An: Süße, Heike <heike.suesse@nct-heidelberg.de>
Cc: Le Cornet, Lucian <lucian.lecornet@nct-heidelberg.de>
Betreff: RE: To detected contact contact point: EudraCT clinical trial results still in "draft"

Dear Heike,

Thank you for contacting us. Please provide us with the XML files of the trial results you are trying to upload so that we can assist you properly. In order to extract them, you can click on "download XML" at the top right corner of each of the results' dataset,

Thank you very much and kind regards,

EudraCT team

From: Süße, Heike <heike.suesse@nct-heidelberg.de>
Sent: 18 March 2022 09:46
To: EudraCT_notification <EudraCT_notification@ema.europa.eu>
Cc: Le Cornet, Lucian <lucian.lecornet@nct-heidelberg.de>
Subject: WG: To detected contact contact point: EudraCT clinical trial results still in "draft"

Dear Sir and Madam,

thank you for your message.

Currently we try to upload the results for the following trials :

EudraCT numbers:

2009-016631-35 (CTLA-4)
2009-013279-23 (REMOTUX)
2013-000064-28 (ATACC)
2014-000503-27 (NOA-16)

Unfortunately, we cannot upload our results because the validation report shows still some errors.
According to our biostatistician, those errors cannot be resolved as the information is not available/applicable.

Could you please clarify how we should proceed?

Thank you very much in advance.

Kind regards
Heike Süße

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Von: EudraCT_notification <EudraCT_notification@ema.europa.eu>
Gesendet: Dienstag, 1. März 2022 17:50
An: Seidel-Glätzer, Andrea <Andrea.Seidel-Glaetzer@med.uni-heidelberg.de>
Betreff: To detected contact contact point: EudraCT clinical trial results still in "draft"

Dear Sponsor,

You are receiving this email since your email address was automatically detected by our systems as belonging to or being affiliated with the sponsor of the below clinical trial(s). Please forward the present email to a person of your organisation who may be in charge of the reporting of the below trial(s) results.

In accordance with the "Commission Guideline - Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006" and the Joint European Commission, EMA and HMA **"**LETTER TO STAKEHOLDERS REGARDING THE REQUIREMENTS TO PROVIDE RESULTS FOR AUTHORISED CLINICAL TRIALS IN EUDRACT", the responsibility of posting results in EudraCT lies with the sponsor.

Please note that the below trial(s) is/are not compliant with said guideline and joint EC/HMA/EMA letter.

EudraCT number	Sponsor code	Title	Sponsor
----------	----------	----------	Ruprecht-Karls-University Heidelberg, Med Faculty Represented By University Clinic Hd And Its Comm. Director
2009-013279-23	-	In vivo response monitoring of treatment with the EGFR-monoclonal-antibody Cetuximab in metastatic colorectal cancer – a single center phase II study	
----------	NCT-2008-11-02-1020	----------	
2009-016631-35	----------	Phase II Trial of Ipilimumab in Patients with advanced melanoma and spontaneous preexisting immune response to NY-ESO-1	
	-		
	NCT-2009-11-02-53		

The contact point(s) declared in the Clinical Trial Application(s) were reminded by EMA on 28/29 October, 2021 of their responsibilities as regards posting clinical trial results in EudraCT. In an attempt to address the sponsor's non-compliance, EMA is now reaching out to contact points associated with the same sponsor, that are stored in other EMA databases.

EMA respectfully informs you of the above and requests that the responsible person in your organisation follows the below instructions in order to post results of the trial(s) identified above.

If no action is performed on this/these trials by April 12th, 2022, we may proceed with contacting further contact points within your organisation, if available. Ultimately, in absence of posted results, **the trial(s) will be listed publicly on EU CTR among those ones for which sponsors did not follow up on our request.**

Please liaise with the primary user of this trial in order to post results on the EudraCT database, see below instructions. Please note that publication of results on external sources or having sent the final report to National Competent Authorities is not sufficient. In addition, we take this opportunity to raise your awareness that results of phase 1 trials conducted solely in adults still need to be posted in EudraCT.

In case no results or only partial results are available, please post a pdf document justifying the missing/partial results for your trial (see step 4 below).

Please see below helpful instructions:

1. Contact the primary user of your trial. The primary user is the person who has an EMA account, activated with the results user role and who has requested assignment for the trial as per step 2 of the tutorials on posting results

- It could be that the trial has also a back-up user assigned. You can investigate it in your institution and liaise with the back-up user as well.

2. The primary user can log in the EudraCT website using EMA credentials
   - in case of login problems (inactive accounts/forgotten password): refer to EMA account management
3. The primary user looks for the above-mentioned trial number in "your page" and clicks on "edit"
4. The primary user can **upload results** as:
   - a **summary attachment** (e.g. pdf file), if the end of trial date of your trial is before 21st of July 2013 and your trial is not part of a PIP/Art 46 or in case your trial was prematurely ended, no subjects recruited or only partial results are available
   - a **full data set**, in all other cases. In case you encounter errors or warnings during the process, the validation rules could be of help (look for your error/warning and see the relevant "rule description").

5. The primary user needs to ensure to **post** the trial results by clicking on "post results" at the top right corner of the webpage.

For questions, please refer to our Frequently Asked Questions . If the answer to your question is not there, Contact us.

For your information, results of phase 1 trials conducted in adults that are not part of an agreed PIP still need to be posted in EudraCT.

Thank you very much for posting results, the EMA highly appreciates it.

EudraCT team

European Medicines Agency