1.0 Introduction

This Work Instruction is applicable to all Sponsor QA staff working on University of Leeds/Leeds Teaching Hospitals NHS Trust Sponsored Clinical Trials of Investigational Medicinal Products (UoL/LTHT Sponsored CTIMPs) who are required to publish results on the EudraCT database.

This Work Instruction details the procedure the QA Portfolio Coordinator or delegate must follow when assisting research teams to publish trial results as a full data set on the EudraCT database.

This document details how to instruct users to register on the database, delegate access to research teams, how to assist researchers with uploading data, and any assurance checks which must be made.

2.0 Requesting access to trials on the EudraCT system & assigning trials to users

The Sponsor QA team need to request access to the trial record on EudraCT when Confirmation of Sponsorship is confirmed for the clinical trial. It is the QA Portfolio Coordinator's (or delegates) responsibility to:

- request access to the trial record via letter prior to the end of trial declaration being submitted
- contact the research team via email as per the SOP ***LTU_QM_04: Sponsor Notification of the End of a CTIMP***
- assist with arranging the research team's access to the system
- delegate the research team member's account to the role of '**Delegated results preparer and poster'**

To register as a user, please use the following guidance:-

https://eudract.ema.europa.eu/help/Default.htm#eudract/register.htm

Once registered on the system, please direct the research team to follow the below guidance to become a results user, so a trial can be assigned to their account:-
https://eudract.ema.europa.eu/help/content/eudract/results_user_role.htm

To delegate trials to a user, please use the following guidance:-
https://eudract.ema.europa.eu/help/Default.htm#eudract/delegation_for_results.htm

The QA Portfolio Coordinator (or delegate) is responsible for ensuring that any changes or updates to the above guidance are communicated in good time to both the Sponsor QA team and any applicable research teams. This work instruction must also be updated accordingly.

Although the guidance currently refers to submitting a wet ink letter to have a trial assigned to your account, this has been updated to be an electronic PDF. A copy of the PDF Assignment letter used to grant access to the trial can be found at the following link: - https://eudract.ema.europa.eu/result.html

3.0 Registering research teams on the EudraCT database

Immediately following submission of the End of Trial declaration form, the Sponsor QA team will contact the research team as per the SOP ***LTU_QM_04: Sponsor Notification of the End of a CTIMP*** using the template

email found in the 'Templates' folder on the departmental I: Drive. This details the requirements for submission to EudraCT **and all other trial registries the trial is registered on** (ISRCTN, Clinicaltrials.gov etc.), and includes instructions on signing up to the EudraCT system and accessing the individual trial record.

The email directs the user to use the following guidance to register as a user. Prior to sending the email, please check to see if the link is still valid : -
https://eudract.ema.europa.eu/help/Default.htm#eudract/register.htm

The research team have a deadline of two weeks to arrange access to the system, request access to the trial record, and confirm to the Sponsor QA team that they will be uploading information to the database. If the team is unable to meet this deadline due to extenuating circumstances, the deadline can be extended but the decision must be made in consultation with the QA Manager or delegate, and clearly documented. This will be followed up by the QA Portfolio Coordinator (or delegate) via email, who will then record this information and the key staff who will be working on the upload on the internal End of Trial Tracker located in the ***5_LOGS*** folder on the departmental I:Drive , and ensure this is clearly documented in the sponsor oversight file.

4.0 Facilitating researchers with uploading information on the EudraCT database

If a trial team requests assistance with adding information to the EudraCT database, the QA team are only in a position to advise on certain subsections of the trial information section, and the fields contained in the 'more information' section**.** This is due to the fact that these are the only sections where information required for the system can be found within the sponsor oversight file for the trial. Information on which fields can be advised on, and notes for completion can be found in Figure 1.

Some fields will be pre-populated from the MHRA CTA application. These fields are in Figure 2 and should be reviewed for accuracy only.

Figure 1: Fields which Sponsor QA can advise on.

Section	Mandatory or Optional?	Notes for completion
Trial Information Section		
Additional Study Identifiers (ISRCTN, CT.Gov, WHO)	Optional	These fields are optional but can be completed if available.
Scientific Contact Point details	Mandatory	Enter the name of the functional contact point for scientific and/or technical questions. Sponsor QA recommend this is the Chief Investigator for the trial.
Results analysis stage-Global end of trial date Reached? And Global end of trial date	Mandatory	This information should be cross referenced with the information provided on the End of Trial Declaration form.
Independent DMCC Involvement?	Mandatory	This refers to a DMEC. If the trial has a DMEC, it will be listed in the Protocol.
Population of trial subjects-country and actual number of subjects enrolled	Mandatory	Provide the actual number of subjects enrolled on the trial and the country they were enrolled in. This should be recorded on the Master Trials List.
Subject Disposition section		
IMP Name & other name	Mandatory	The details of the IMP can be located on the CTA application.
IMP Route of Administration	Mandatory	This can be located on the CTA application and trial protocol.

More Information		
Substantial Amendments -were there any substantial amendments to the protocol?	Mandatory	This information must be consistent with Sponsor QA records which need to be cross referenced to ensure no amendments have been missed. Each amendment must be individually listed on the system, with a free text description of the changes made.
Interruptions- Were there any global interruptions to the trial?	Mandatory	This is referring to temporary halts for the trial. A temporary halt should be clearly documented in the Sponsor Oversight File and amendments will have been submitted to halt and restart the trial. The date of halt, a description of the reasons for the halt and the date of restart must also be added to the system.
Limitations and Caveats	Mandatory	Any limitations imposed on publication by the Sponsor must be clearly listed on the system. Please discuss any potential limitations with the QA Manager. If no limitations have been imposed, please enter 'no'.

Figure 2: Pre-populated from the MHRA CTA application

Section	Mandatory or Optional?	Notes for completion
Trial Information Section		
Title of the trial	Mandatory	This should be cross-referenced with the full title on the protocol at a minimum.
EudraCT number	Optional but should be completed	Located on the protocol and automated email provided in the 'Part C' setup pack (as per CTC01).
Sponsor Protocol code	Optional but should be completed	This is referring to the R&I number and should be entered as per the sponsor file and protocol.
Sponsor Details - Name of organisation	Mandatory	The Sponsor of the trial should be listed as University of Leeds, or Leeds Teaching Hospitals NHS Trust. The sponsor for the trial will be located on the protocol and must be cross referenced with the CTA / IRAS form.
Paediatric Regulatory details	Mandatory	If the trial is a paediatric trial, the 4 fields regarding article 45 should be marked as yes. For all non-paediatric trials, this will be no.

Researchers can also be signposted towards using certain trial documentation in order to assist with the data upload. The latest version of the trial protocol, any draft trial abstracts, final reports to the funder, interim analysis reports, and in some cases the final DSUR and APR reports submitted for the trial can be used to add the information onto the system.

5.0 Troubleshooting

All other queries should be directed to the EMA helpdesk, via their online portal. Username and password is identical to EudraCT, and the portal is accessed via the following link:
https://servicedesk.ema.europa.eu/jira/servicedesk/customer/user/login?nokerberos&destination=portals

If a researcher has a query which cannot be answered via the EMA portal, the query should be directed to the MHRA CT helpline at the following email address: ctdhelpline@mhra.gov.uk

For any queries related to the requested statistical information, please direct researchers to the trial statistician (if applicable), who will be listed as one of the main contacts in the trial protocol and should also be copied into the initial email sent to the team asking them to register on the database. If the query cannot be resolved by the trial statistician, please direct researchers to use the helplines listed above.

All mandatory fields on the system are marked with a red asterisk. If a field does not contain a red asterisk, the team can proceed with the upload without this information being populated on the database. If a team has an issue with adding information to a non-mandatory field, the option of leaving the field blank should be discussed and agreed with the QA Manager (or delegate).

When results are submitted to be posted on the system, the QA office must be notified **prior** to the results being submitted, so the record can be checked for completeness, and as an assurance step to ensure that the team are aware of the correct process for notifying the MHRA that results have been added to the database.

To notify the MHRA that results have been added to the system, the research team must send a confirmation email to ct.submission@mhra.gov.uk once the results information has been uploaded to EudraCT, with "**End of trial: result related information: EudraCT XXXX-XXXXXX-XX"** as the subject line, and the QA team should be copied into the email. This must be filed appropriately in the Sponsor Oversight File and on i:drive.

There is no standard format for final reports to the REC. A PDF copy of the EudraCT upload is sufficient. Following completion of the upload, a copy of the report must be submitted to the REC which originally approved the study, with the trial name and any reference numbers clearly marked in the subject line. For additional guidance, please see ***LTU_QM_04: Sponsor Notification of the End of a CTIMP.***

Once all regulatory bodies have been notified of study closure, the QA Portfolio Coordinator or delegate must then perform the following tasks on the Master Trials List:

- Update the colour coding of the 'End of trial report' field for the trial as per the Key on sheet 1, to accurately convey that the study is completed.
- Ensure the 'Project Status' field is changed to 'completed'
- Ensure the date of submission of the EOT report is added to the 'End of Trial Report' field for the trial.

Alongside the above, The QA Portfolio Coordinator or delegate must also update the EDGE system accordingly to notify LTHT R&I that the report has been submitted. There is an attribute already generated on the system to record this. For more information, please see ***CTGN45- A QA Guide to EDGE.***