UNIVERSITY OF Southampton

WPD

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Using EudraCT to Upload Clinical Trial Results

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1 Introduction

1.1 The sponsor is responsible for uploading the end of trial summary results for Clinical Trials of Investigational Medicinal Products (CTIMPs) to the European Clinical Trials Database (EudraCT) as per the commission's guidelines on posting and publication of result-related information. The time frame for posting the summary is within six months of the end of trial for paediatric clinical trials or within one year of the end of trial for non-paediatric clinical trials.

1.2 The Working Practice Documents (WPD) outlines how to access to the EudraCT database and how the results are uploaded.

1.3 It is possible for a non-statistician to complete some of the tables prior to the Trial Statistician (TS) completing the report.

2 Scope

Clinical Trials Unit	**iSolutions**			
☒	☐			
Other	Please write a description of the other areas of scope below			

This Working Practice Document (WPD) describes the process for uploading the end of trial summary results to EudraCT.

This WPD has been written according to CTU/SOP/5000 – Document Management. All WPDs are carried out in accordance with current clinical trials legislation, GCP guidelines and current data protection regulations and their amendments.

3 Process

Comment: Trial results are posted onto the EudraCT online database. The EudraCT help pages are really useful and could be read to aid the processes described below.

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

3.1 Gaining a Login to the System

3.1.1 In order to have access to upload results to the EudraCT the user must first have a log in to https://eudract.ema.europa.eu/results-web/

3.1.2 First time users must register either by using an existing European Medicines Agency (EMA) username or by creating a new account (there is a facility to check if an account exists).

3.1.3 The EMA will email back a username and password.

3.2 Procedure

3.2.1 'Your Page' will display any CTIMP which a sponsor has allowed you to view.

3.2.2 If the trial you are working on does not appear, then the primary user can firstly click on 'Manage Assigned users', to check who has access, then click on 'Add User' to check if others could be added.

Comment: Only users who have been approved by Sponsor to see the results page will be able to access it.

3.2.3 If neither of these results in the person being added or the CTIMP appearing, then a request must be made to sponsor asking them to request access.

3.2.4 Using the template letter (CTU/FORM/5253 - EudraCT Clinical Trial Assignment Request), amend the parts marked in blue, add the relevant information to the table.

3.2.5 Send the letter to the applicable sponsor for signature. This letter formalises a request to add the list of approved CTIMPs to the 'Your Page' list.

3.2.6 The signed letter should be scanned and uploaded to EudraCT. Click on 'Request Assignment' (link at bottom of 'Your Page').

3.2.7 Add the EudraCT Number for each trial, the trial information (N.B. the trial information must match the request in the letter) and attach the scanned letter.

Comment: This must be within 30 days of the date of the latter.

3.2.8 Once approved the requested trials will appear on the 'Your Page' list.

3.2.9 If it does not appear on all requested user's lists, follow step 3.2.2 to add to each person's list.

3.3 Updating the Results

Summary Attachments

3.3.1 A synopsis using ICH E3 Annex 1 can be uploaded or any other appropriate documentation contain the information. There is guidance on the EudraCT website on what should be included.

3.3.2 Then various sections then need to be completed, the information can be gained from the protocol or the statistical report. The TS will request information when required from other groups.

Section	Completed by	Notes
Summary	STM, TS or delegate	Reporting countries, protocol details.
Trial Information	STM, TS or delegate	Data including sponsor information, general trial information and population
Subject Disposition	STM, TS or delegate	Recruitment details, arms,
Baseline disposition	STM, TS or delegate	Baseline characteristics, analysis sub-sets
End points	TS	Primary and secondary end points
Adverse events	TS	Description, dictionary used, counts
More information	STM or delegate	Information about protocol changes

Comment: The TS will check the information provided aligns with the data produced from the Statistical Analysis Plan.

3.3.3 The data can be validated during the upload process. This will raise any specific queries on the information if it does not meet specific criteria e.g. numbers do not add up.

3.3.4 The system may then generate questions if the expected results do not appear. For example, '*The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.'* A sensible response needs to be made e.g. *'x subjects were actively screened and for the reasons presented in the table below, y did not complete the pre-assignment period.'*

3.3.5 Once the information has been validated it can be posted.

4 Risk Assessment

4.1 Not applicable.

5 Glossary of Terms

5.1 **EudraCT:** EudraCT is the EU's electronic database of clinical trials. It contains information submitted by sponsors and informs users about ongoing clinical trials in EU Member States and European Economic Area (EEA) countries, enabling an overview of multi-state trials. It allows results users to create, update, validate and post result data sets, and load summary attachments to the EudraCT database.

6 Roles and Responsibilities

Trial Statistician

6.1 Uploads the trial results onto EudraCT at the end of the trial.

7 Policies, Guidelines, References

- EudraCT website: https://eudract.ema.europa.eu/help/Default.htm

8 Training

A person will be considered trained when they have read this WPD and can effectively use it to upload results to EudraCT.

9 Attachments

- CTU/FORM/5253 - EudraCT Clinical Trial Assignment Request

Revision History

Version Number	Revision	Date
1	New Document	12-Jul-2018