


| | | | | | | |
|---|--|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title | | | | | |
| | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Scope | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

Details:

Author(s) of Guideline: Emma Armstrong, Kara-Louise Royle

Author(s) Signature: Available on paper copy

Reviewer(s): Vicky Napp (Operations Director), David Cairns (Principal Statistician)

Reviewer Signature(s): Available on paper copy

Effective Date: 16th April 2018

Date Original Guideline Approved: 21st March 2018

Comments:

General comments which may provide advice on the use of the document


Related Documents

| | |
|--|--|
| <u>SOPs</u> T16 Trial and Trial Site Closure | <u>Guidelines</u> G05: Trial Master File |
| | <u>Templates</u> F69: EudraCT review and release |

Version Control:

| Previous Version number: | Edited by | Date version approved: | Details of editions made: |
|--------------------------|-----------|------------------------|---------------------------|
| | | | |
| | | | |

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Scope Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

Contents

| | |
|--|----|
| Details: | 1 |
| Comments: | 1 |
| Related Documents | 1 |
| Version Control: | 1 |
| Contents | 2 |
| Diagram 1 Gaining access to EudraCT to submit trial results | 3 |
| Section A Introduction | 4 |
| Section B EudraCT | 4 |
| 1.0 Responsibilities | 4 |
| 2.0 Timelines for submission | 5 |
| 3.0 Obtaining permission to upload trial results onto EudraCT | 5 |
| 4.0 Registering and becoming a results user. | 6 |
| 5.0 Uploading results | 8 |
| 6.0 Validation of the data set | 33 |
| 7.0 Data review and release | 33 |
| Section C References | 34 |
| Appendix A – Adverse Event XML Work Instruction | 35 |

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document


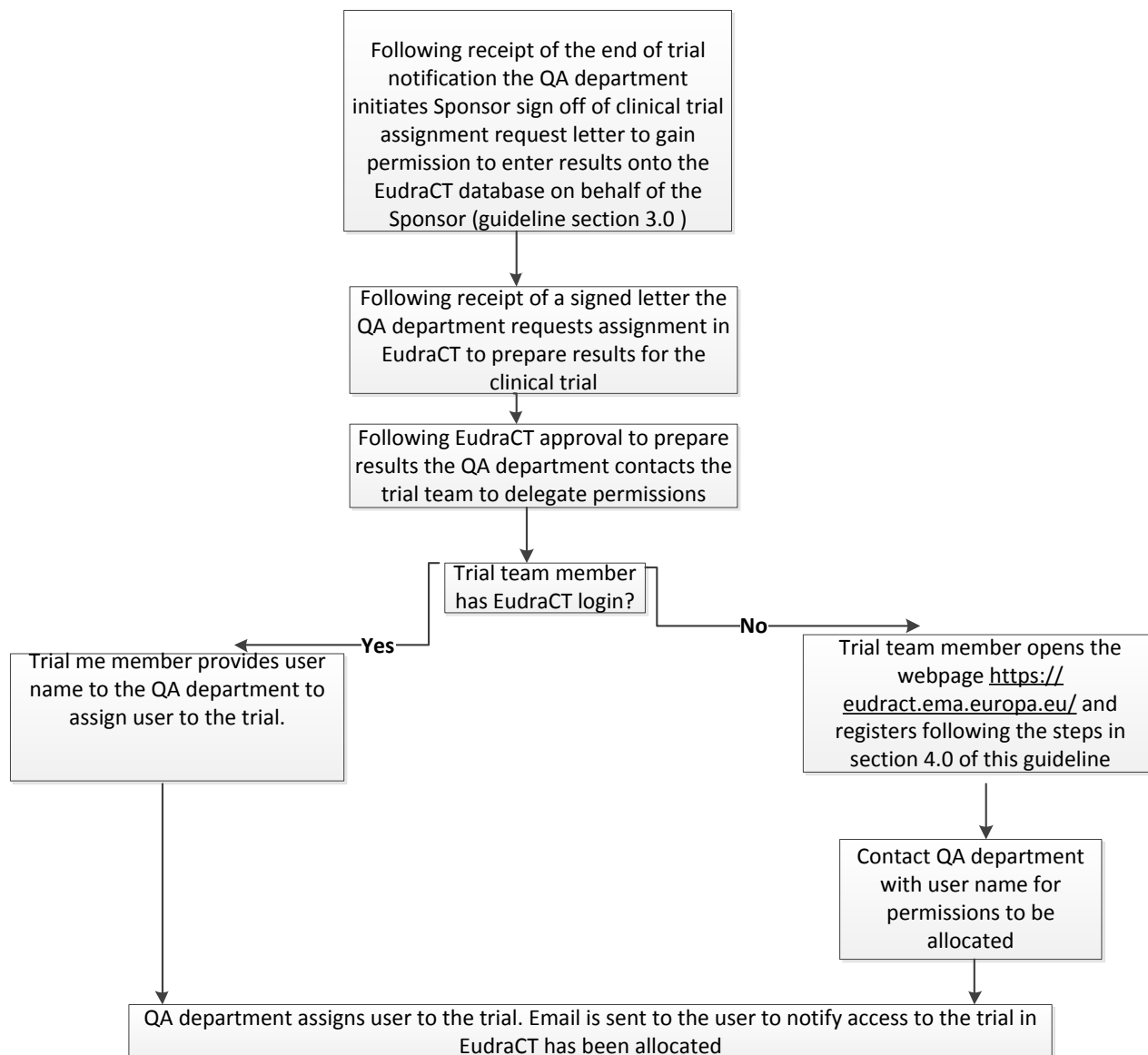

| | | | | | | |
|---|---|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title | | | | | |
| | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

Diagram 1 Gaining access to EudraCT to submit trial results



**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|---|--|---|------|-----------------------------|--------------|-----|
|  Guideline | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Title | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |

Section A Introduction

- Results information released through the EudraCT database is made publically available via the EU Clinical Trials Register (<https://www.clinicaltrialsregister.eu/ctr-search/search>).
- This guideline describes the stages to be followed when making a submission onto the EudraCT database and who is routinely responsible for each step.
- The guideline is based upon the MRC CTU Guidance for uploading onto the EudraCT Database with some additional CTRU requirements.
- CTRU's approach to uploading data onto the EudraCT Database is that the data is similar in breadth and depth to a trial publication. For example, an upload may include the results of the primary analysis conducted within the ITT population for the endpoints specified within the protocol.

Section B EudraCT

1.0 Responsibilities

1.1 Regulatory Affairs and Governance Manager or delegate:

1.1.1 Delegating permissions to the authorised members of the trial team to facilitate upload of trial results onto the EudraCT database.

1.2 STM/SDM or delegate

1.2.1 Creating a EudraCT login (if not an existing user) and registering to become a EudraCT results user.

1.2.3 Entering and ensuring data is correct for the trial management sections within the EudraCT database as defined within this guideline.

1.2.4 Ensuring data is submitted in a timeframe to allow posting of results in line with section 2.0 of this guideline.

1.3 Trial Statistician

1.3.1 Creating a EudraCT login (if not an existing user) and registering to become a EudraCT results user.

1.3.2 Entering and ensuring data is correct for the statistical sections within the EudraCT database as defined within this guideline.

1.3.3 Ensuring data is submitted in a timeframe to allow posting of results in line with section 2.0 of this guideline.


1.4 Delivery and Scientific Leads

1.4.1 Ensuring the data entered into the EudraCT database:

- Is correct.
- Can be released into the public domain, considering the date of the trial publications and any contractual obligations.
- Does not include any patient identifiable data.

1.4.2. Signing the **F69: EudraCT review and release** to evidence the above.

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|---|--|---|------|-----------------------------|--------------|-----|
|  Guideline | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Title | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |


2.0 Timelines for submission

- 2.1 It is a European Medicines Agency requirement (EMA) requirement that results from Clinical Trials of an Investigational Medicinal Product (cTIMP) are posted onto the European Clinical Trials Database (EudraCT) within one year of the end of trial (**T16: Trial and Trial Site Closure**).
- 2.2 In some circumstances it may not be appropriate to release the results entered into the EudraCT database onto the publically accessible EU Clinical Trials Register within one year of the end of trial. For example, if the main trial results have not have been published. The mandatory steps to follow in regards to data entry and delayed release onto the EudraCT database are documented in **T16: Trial and Trial Site Closure** with further information in section 7.0 of this guideline.

3.0 Obtaining permission to upload trial results onto EudraCT

- 3.1 All CTRU trial results are entered onto the EudraCT database using CTRU's central account held by the QA department. The regulatory Affairs and Governance Manager is the primary user for the CTRU's central account.
- 3.2 Following submission of the end of trial notification (**T16: Trial & Site Closure**) the Regulatory Affairs and Governance Manager (or delegate) coordinates sign off of the clinical trial assignment request letter (<https://eudract.ema.europa.eu/result.html>) to gain permission to enter results onto the EudraCT database on behalf of the Sponsor.
- 3.3 To be authorised by EudraCT the sponsor letter submitted to EudraCT needs to be:
- On Sponsor headed paper.the same as that registered with EudraCT at the beginning of the trial (this is usually as given in version 1.0 of the protocol).
 - Signed by hand by the sponsor representative.
- 3.4 Following receipt of a signed clinical trial assignment request letter from the Sponsor the steps to gain access to upload results for the trial within EudraCT are followed within the following link: <https://eudract.ema.europa.eu/results-web/components/yourpage/index.xhtml>.
- 3.5 After submission of the signed clinical trial assignment request letter an email will be received by the Primary user stating that the application to upload results has been successful and, if not, what you need to do to get permission.
- 3.6. Following confirmation of a successful application the Regulatory Affairs and Governance Manager (or delegate) delegates permission to the trial team staff authorised by the Delivery Lead to become a results preparer for the trial. The Scientific and Delivery Leads will be granted permission to become a results preparer and poster. A primary back up user will be allocated for each trial by the Regulatory Affairs and Governance Manager (usually the trial Delivery Lead). The primary back up user has the same permissions as the primary user and can therefore grant result user permissions for the trials they have been allocated to. Before permissions can be delegated users must create and register as a results user in accordance with section 4.0 of this guideline.
- 3.7. The original wet ink copy of the signed sponsor authorisation letter is filed within the TMF (**G05: Trial Master File**) with a copy being held within the QA department.

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|--|---------|---|------|-----------------------------|--------------|-----|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |

4.0 Registering and becoming a results user.

4.1 To become a EudraCT results user the following steps are followed:

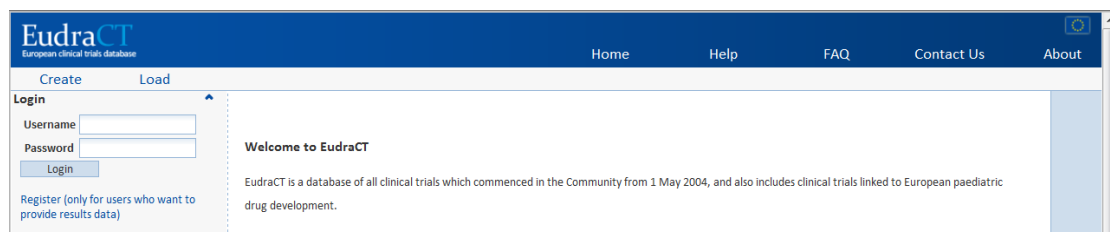
- Open the webpage <https://eudract.ema.europa.eu/> . Click on “Login to EudraCT” on the top left of the screen:




- First time users will need to register. Click on “Register” on the top left hand side of the screen.
- You will need to accept terms and conditions and enter your personal details within the registration screens. Registration must be completed using your University of Leeds email address.

4.2 If the user has never posted results before the user goes through the following process to become a results users to post results following the below steps:

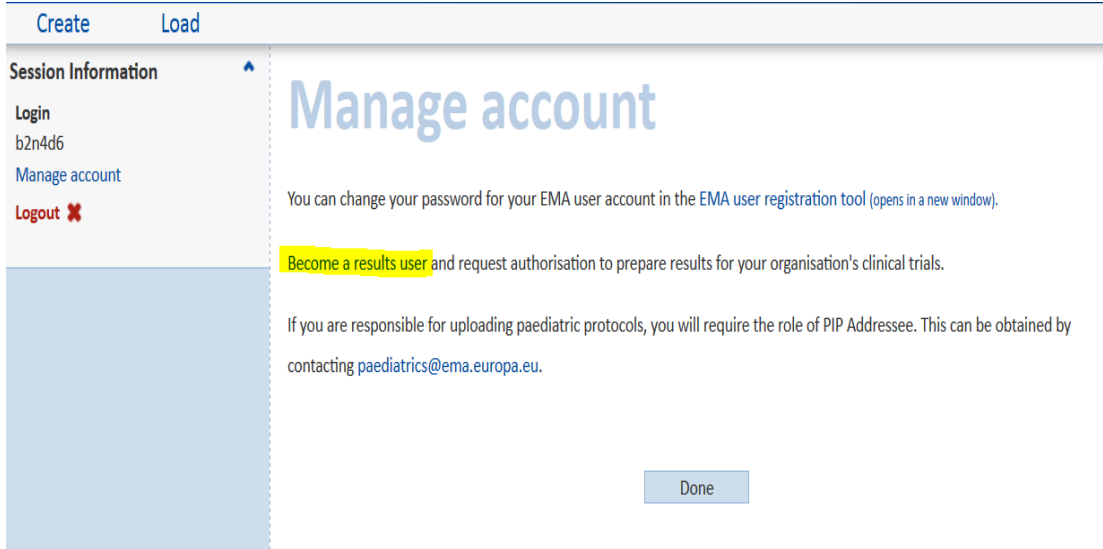
- Login to EudraCT, using the username and password acquired from section 4.1.



Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- Click on “Manage account”; then you will see the following screen - click on “Become a results user”.



Create Load

Session Information

Login
b2n4d6
Manage account
Logout X

Manage account

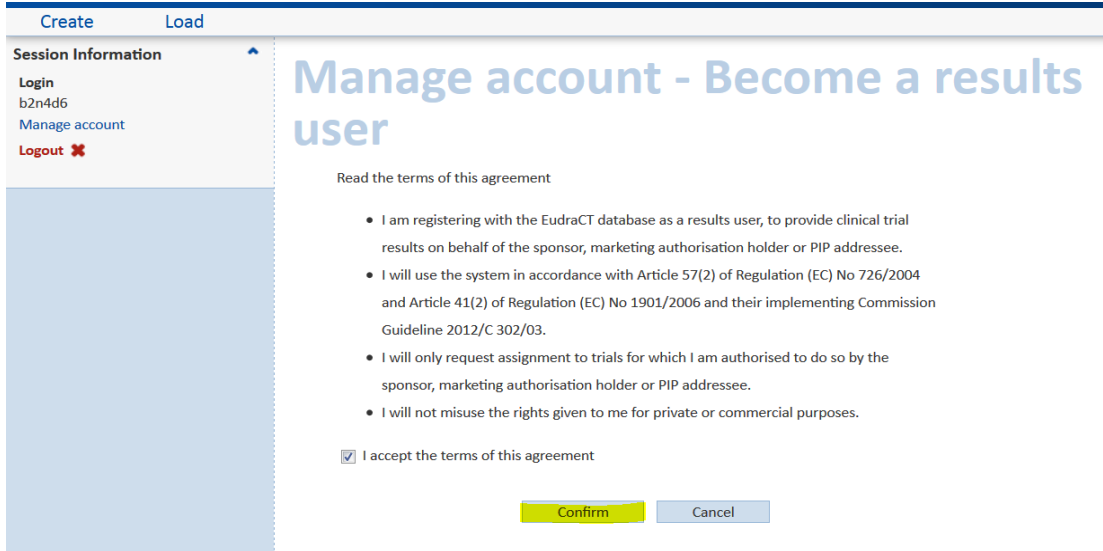
You can change your password for your EMA user account in the [EMA user registration tool](#) (opens in a new window).

Become a results user and request authorisation to prepare results for your organisation's clinical trials.

If you are responsible for uploading paediatric protocols, you will require the role of PIP Addressee. This can be obtained by contacting paediatrics@ema.europa.eu.

Done

- Accept terms and conditions:



Create Load

Session Information

Login
b2n4d6
Manage account
Logout X

Manage account - Become a results user

Read the terms of this agreement

- I am registering with the EudraCT database as a results user, to provide clinical trial results on behalf of the sponsor, marketing authorisation holder or PIP addressee.
- I will use the system in accordance with Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 and their implementing Commission Guideline 2012/C 302/03.
- I will only request assignment to trials for which I am authorised to do so by the sponsor, marketing authorisation holder or PIP addressee.
- I will not misuse the rights given to me for private or commercial purposes.


☒ I accept the terms of this agreement

Confirm Cancel

- Log out and log back in again for changes to take place.

4.3 After permission has been granted contact the QA department who will allocate permissions to prepare or post results for the relevant trial in accordance with section 3.6 of this guideline.

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|---|--|---|-----|------|-----------------------------|----------------------------|
|  Guideline | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Title | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Scope | Version | 1.0 | Date | 21 st March 2018 | Guideline ID G65 |

5.0 Uploading results

- Once permission to become a results user for a trial has been obtained, when next logged on the below screen will be shown. To add results, click on "Create":

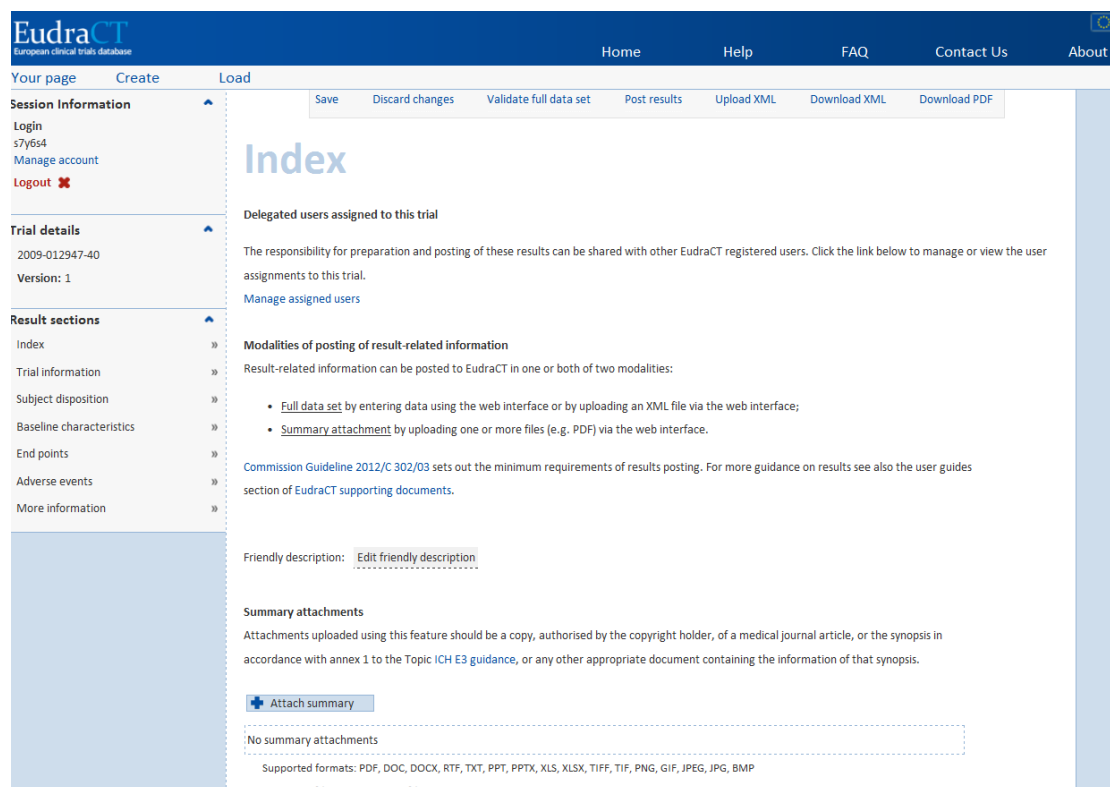
Draft results

| EudraCT number * | Version | Sponsor name * | Friendly description * | Last saved date * | Status * | Options |
|------------------|---------|----------------|------------------------|-------------------|----------|------------------------|
| 2009-012947-40 | | | | | | Create |

- Throughout all of the screens within the database a red asterisk denotes a mandatory field. There may be rare circumstances where a mandatory field cannot be entered, these circumstances are approved by the Scientific Lead and QA department with a justification being entered into the database at the point of validation (see section 6.0 of this guidelines).

5.1 Index Page

- This section will be complete by the Senior Trial Manager (STM) or delegate
- After clicking onto the trial within the EudraCT data base the index page will appear as follows:



EudraCT
European clinical trials database

Home Help FAQ Contact Us About

Your page Create Load

Save Discard changes Validate full data set Post results Upload XML Download XML Download PDF

Session Information

Login
s7y6s4
Manage account
Logout ✖

Trial details

2009-012947-40
Version: 1

Result sections

- Index
- Trial information
- Subject disposition
- Baseline characteristics
- End points
- Adverse events
- More information

Index

Delegated users assigned to this trial

The responsibility for preparation and posting of these results can be shared with other EudraCT registered users. Click the link below to manage or view the user assignments to this trial.
[Manage assigned users](#)

Modalities of posting of result-related information

Result-related information can be posted to EudraCT in one or both of two modalities:

- [Full data set](#) by entering data using the web interface or by uploading an XML file via the web interface;
- [Summary attachment](#) by uploading one or more files (e.g. PDF) via the web interface.

[Commission Guideline 2012/C 302/03](#) sets out the minimum requirements of results posting. For more guidance on results see also the user guides section of [EudraCT supporting documents](#).

Friendly description: [Edit friendly description](#)

Summary attachments

Attachments uploaded using this feature should be a copy, authorised by the copyright holder, of a medical journal article, or the synopsis in accordance with annex 1 to the Topic [ICH E3 guidance](#), or any other appropriate document containing the information of that synopsis.


[+ Attach summary](#)

No summary attachments

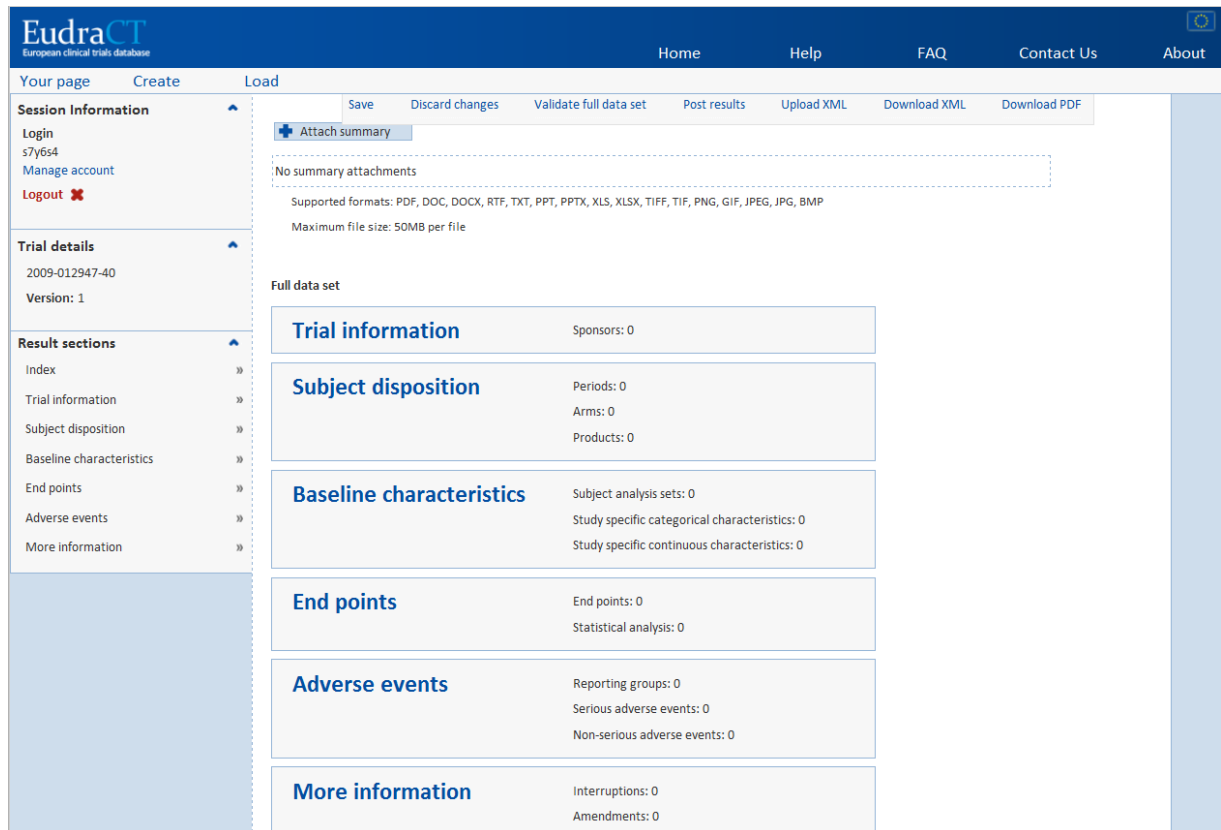
Supported formats: PDF, DOC, DOCX, RTF, TXT, PPT, PPTX, XLS, XLSX, TIFF, TIF, PNG, GIF, JPEG, JPG, BMP
Maximum file size: 50MB max file

- Enter a friendly description of the trial.

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |


- It is standard practice within CTRU to not attach a summary attachment Scroll down to get to the data summary section:



The screenshot shows the EudraCT website interface. On the left is a sidebar with navigation links: 'Your page', 'Create', and 'Load'. Under 'Load', there are sections for 'Session Information' (Login, Manage account, Logout), 'Trial details' (2009-012947-40, Version: 1), and 'Result sections' (Index, Trial information, Subject disposition, Baseline characteristics, End points, Adverse events, More information). The main content area is titled 'Full data set' and contains several summary boxes: 'Trial information' (Sponsors: 0), 'Subject disposition' (Periods: 0, Arms: 0, Products: 0), 'Baseline characteristics' (Subject analysis sets: 0, Study specific categorical characteristics: 0, Study specific continuous characteristics: 0), 'End points' (End points: 0, Statistical analysis: 0), 'Adverse events' (Reporting groups: 0, Serious adverse events: 0, Non-serious adverse events: 0), and 'More information' (Interruptions: 0, Amendments: 0). At the top of the main content area, there is a 'Load' section with buttons for 'Save', 'Discard changes', 'Validate full data set', 'Post results', 'Upload XML', 'Download XML', and 'Download PDF'. Below these buttons is an 'Attach summary' button and a message stating 'No summary attachments' with supported formats and a maximum file size of 50MB per file.

- To upload the results, click in to each of these links and enter the information.

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|---|--|---|------|-----------------------------------|--------------|------------|
|  Guideline | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Title | | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

5.2 Trial Information Page

- This section can be completed by the STM (or delegate) or Trial Statistician as decided by the trial team. The Population of trial subjects section needs input from a statistician.
- Some trial information may already be present on this page (carried over from trial-set up). Check this information is still correct and update as required.
- To enter into a section, click on (for example) “Add sponsor” which will take you to a new page.
- Once you have finished with entering those details, click “Done” at the bottom of the page. The results will then save and you will be redirected back to the “Trial information” page.
- If any fields are unclear, hold the mouse over the “i” sign, and an explanation will appear (for example below):



The sponsor may establish an independent data-monitoring committee (IDMC) to assess at intervals, the progress of a clinical trial, safety data, critical efficacy endpoints, and recommend to the sponsor to continue, modify, or stop a trial. Select 'Yes' if such a committee was in place, or otherwise select 'No'. (See: <http://www.emea.europa.eu/docs/en>

5.2.1 Additional study identifiers section:

- Ensure either the ISRCTN or Clinical Trials.gov number are entered

5.2.2 Sponsor details section:

- Where CTRU are responsible for the uploading of results into EudraCT on behalf of the sponsor “CTRU QA Department” is entered as the scientific and public contact point.
- Enter “Regulatory Affairs and Governance Manager” in the function contact point name
- Enter the email address medctrug@leeds.ac.uk into the Sponsor email address.
- After the above details for the scientific contact have been entered press “copy scientific contact point” so that the details for the scientific and public contact are the same


5.2.3 Paediatric regulatory details section:

- All questions within this section will always be no unless results for a trial that fall under the paediatric regulations are being entered.

5.2.4 Results analysis stage section:


- Results will only be entered onto EudraCT for CTRU trials at the end of trial. Therefore mark the analysis stage as “final”.
- For the date of final analysis field enter the date of the data download for the final analysis.
- Select “yes” for the question ‘is this the analysis of the primary completion data?’
- Enter the date the final subject was examined or received an intervention for the purpose of final collection of data for primary endpoint within the field for “primary completion date”.

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | | | | |
|---|---------|--|-----|--|------|-----------------------------|---|--------------|-----|
|  | Title | | | | | | Uploading Clinical Trials Results onto the EudraCT Database | | |
| | Scope | | | | | | Guidance on uploading Clinical Trials Results to the EudraCT database | | |
| | Version | | 1.0 | | Date | 21 st March 2018 | | Guideline ID | G65 |

- If the trial ended early mark this accordingly. For all other trials select yes for 'global end of trial date reached?' and add in the date of the end of trial.

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

5.2.5 General information about the trial section:

- Add in the main trial objective as per the protocol.
- Enter date first patient randomised as the actual start date of recruitment.
- Enter no for 'long term follow up' planned (at the time of data entry into EudraCT the long term follow period will have finished).
- Within the protection of trial subject box enter the information relevant for your trial, this could be taken from the information submitted within the initial REC application.
- Enter information within the background therapy box and evidence of comparators section in line with the level of detail that would be submitted within the trial publication N.B these are not mandatory fields within the database.

5.2.6 Population of trial subjects section:

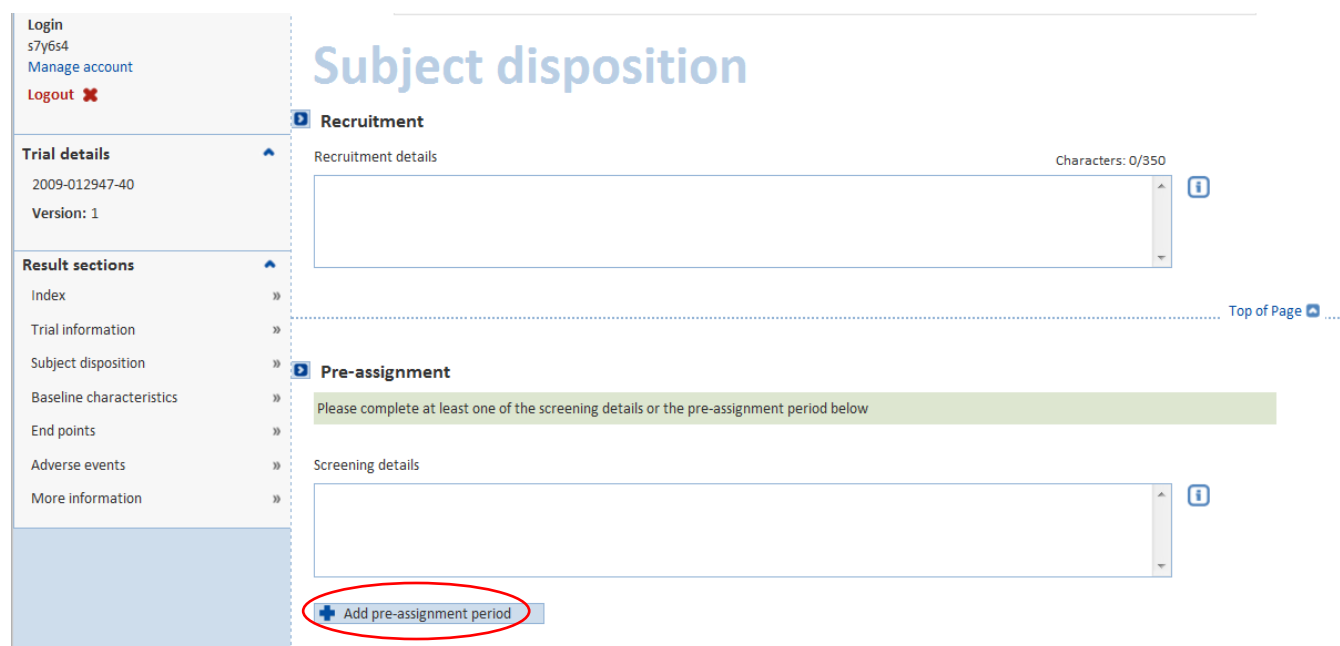
- This section of the trial information page is completed by the Trial Statistician
- The planned number of subjects may already be prepopulated depending on the information submitted to EudraCT at the start of the trial.
- The trial statistician enters the actual number of subjects enrolled broken down into the categories mandated by the database.

5.3 Subject disposition page

- This page is complete by the trial statistician.

5.3.1 Pre-assignment period

- It is required to enter the "Pre assignment" period details – meaning the screening period.
- Click on "Add pre-assignment period":



Subject disposition

Recruitment

Recruitment details Characters: 0/350


Pre-assignment

Please complete at least one of the screening details or the pre-assignment period below

Screening details

[Add pre-assignment period](#)

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---|-----|------|-----------------------------|--------------|-----|
|  Guideline | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |

- Enter the number of patients screened in the “Started” box. For the purposes of the EudraCT upload this is the number of patients consented to the trial. If there are any intermediate milestones in the screening-randomisation period, then you can enter what it was and how many subjects completed follow up until that milestone (usually not applicable).
- Enter the number completed, as well as any reasons for non-completion below, e.g. a trial that screened 227 patients and randomised 199.
- The “Completed” field is usually:
 - For trials with randomisation stage only: the number randomised (as they completed the screening period)
 - For trials with registration stage only: the number registered
 - For trials with a registration and randomisation stage the number randomised

Number of subjects at each milestone

| | |
|-----------|-------------------------|
| Started:* | Number of subjects: 227 |
|-----------|-------------------------|

| | |
|------------------------------|---------------------|
| Intermediate milestone title | Number of subjects: |
|------------------------------|---------------------|

No intermediate milestones have been specified.

| | |
|-------------|-------------------------|
| Completed:* | Number of subjects: 199 |
|-------------|-------------------------|

Subject non-completion reasons

Reason for non-completion

| | |
|------------------|---------------------|
| Please select... | Number of subjects: |
|------------------|---------------------|


| | | |
|---|----|---|
| Consent withdrawn by subject | 3 | ✗ |
| Protocol deviation | 21 | ✗ |
| Car crash prevented them making randomisation visit | 1 | ✗ |
| Unreliable attendance | 1 | ✗ |

Total: 26

[Delete pre-assignment period](#)

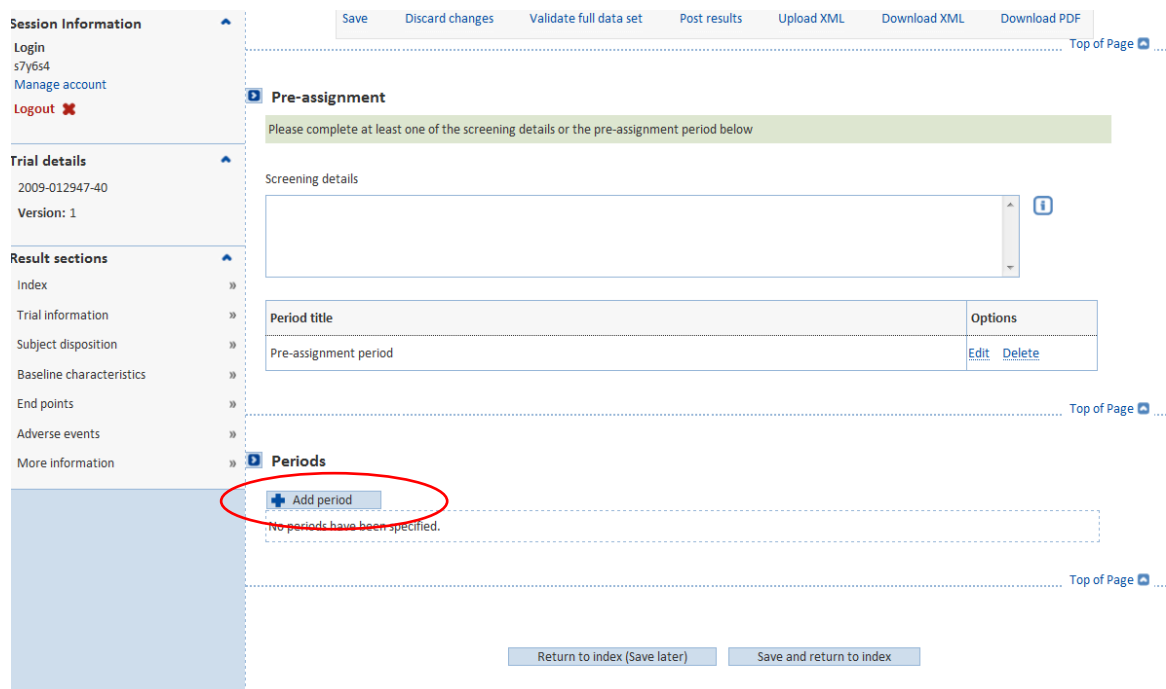
- Click done to return to the “Subject disposition” screen, and the screening period should now appear.

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

5.3.2 Periods


- At least one period needs to be entered.
- Some trials may have multiple periods (e.g. main trial and long term follow up, or cross over trials). However, if it is a simple parallel group trial with one main trial analysis, only one period will have to be added. Click on “Add period”:



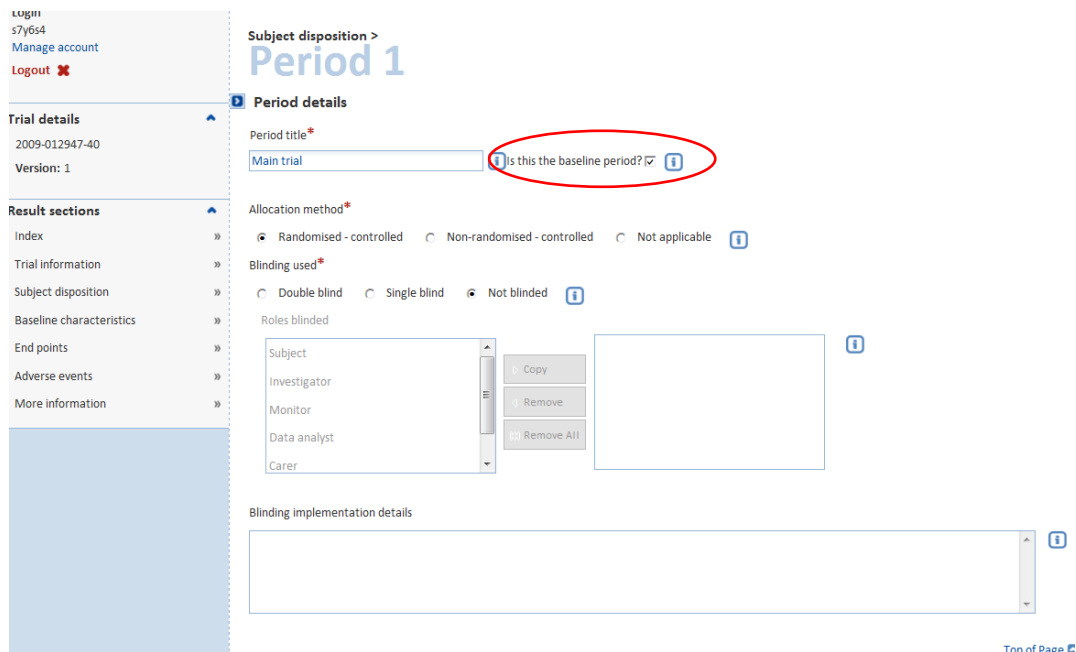
The screenshot shows the EudraCT database upload interface. The left sidebar contains 'Session Information' (Login, Manage account, Logout), 'Trial details' (2009-012947-40, Version: 1), and 'Result sections' (Index, Trial information, Subject disposition, Baseline characteristics, End points, Adverse events, More information). The main content area has tabs for 'Pre-assignment' and 'Periods'. The 'Periods' tab is active, showing a table with one row: 'Pre-assignment period'. Below the table is a red circle around the 'Add period' button. The text 'No periods have been specified.' is visible below the button. At the bottom are buttons for 'Return to index (Save later)' and 'Save and return to index'.

- Enter the name of the period that you are defining. For a parallel group trial with one main trial analysis, “Overall trial” would be an acceptable name. You must tick the “Is this the baseline period” box at some stage. If you only have one period (as in this example) then the baseline period box must be ticked.
- To note the periods entered at this point define how End point and other data needs to be entered in later sections. If it is appropriate to do so it is recommended that just one period is entered within the periods section named “Overall Trial” and baseline period ticked within period 1.

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- Enter the details on blinding (the example is a non-blinded randomised control trial).



Subject disposition > **Period 1**

Period details

Period title*
Main trial ☒ Is this the baseline period? ☒ ⓘ

Allocation method*
☒ Randomised - controlled ☐ Non-randomised - controlled ☐ Not applicable ⓘ

Blinding used*
☐ Double blind ☐ Single blind ☒ Not blinded ⓘ

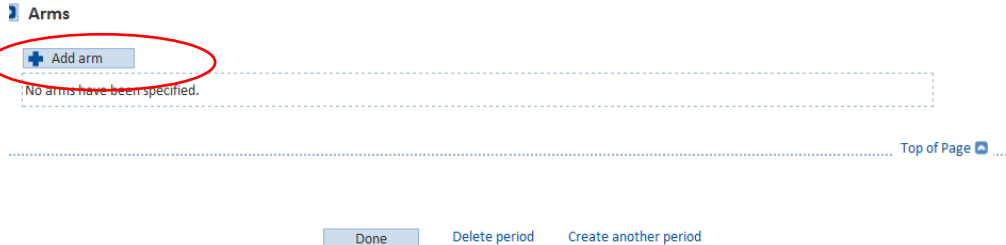
Roles blinded

| | |
|--------------|------------------------------|
| Subject | Copy Remove Remove All |
| Investigator | |
| Monitor | |
| Data analyst | |
| Carer | |

Blinding implementation details

Too of Page ⓘ

- Scroll down and enter the arms in the study (if appropriate) by clicking on “Add arm”:




Arms

No arms have been specified.

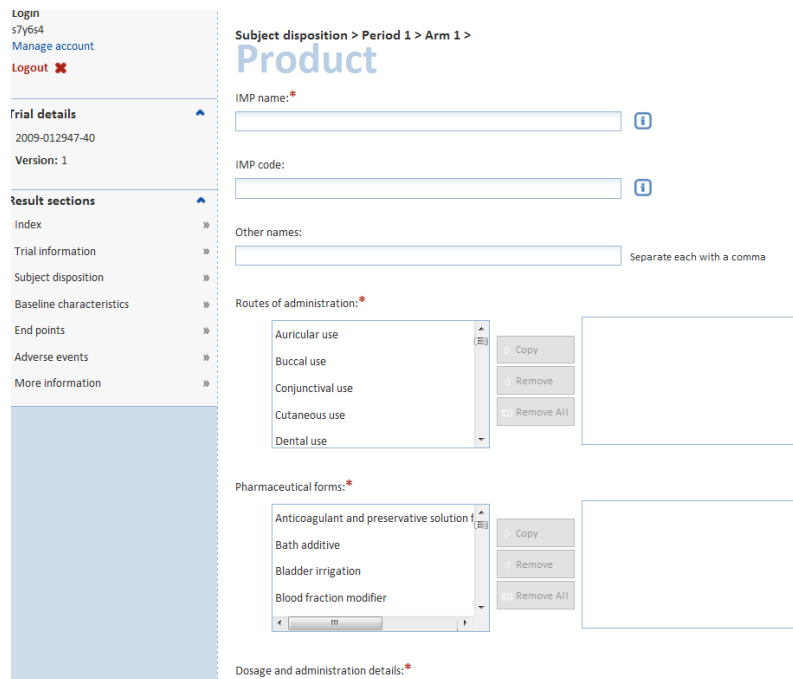
Top of Page ⓘ

Done Delete period Create another period

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title | | | | | |
| | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- Add the name and description of the arm, as well as specifying whether it is an intervention arm or otherwise. Add any products that were used as part of the randomisation by clicking “Add product”, which will take you to the following screen:



Subject disposition > Period 1 > Arm 1 >

Product

IMP name:*

IMP code:

Other names:


Routes of administration:*

Pharmaceutical forms:*

Dosage and administration details:*

- Fill in as much information as possible (red asterisks = mandatory field). Click on “Done” to return to the “Arm 1” screen. The product information should have appeared there. Add other products if applicable. There is no requirement to enter IMP code or other IMP names.


Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title | | | | | |
| | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- Scroll down to “Milestones” where you can enter the number of patients that started the period and how many finished it. Therefore you can enter how many people were lost to follow up/withdrew consent etc. during the study. An example below for an arm which had 100 people randomised but had one lost to follow up by the end of the study:

Milestones

Number of subjects at each milestone

Started:^{*} Number of subjects: 

To add a new intermediate milestone, [return to the Period](#)

No intermediate milestones have been defined for the period.

Completed:^{*} Number of subjects: 

Subject non-completion reasons


Subject non-completion reason

Lost to follow-up  Number of subjects 

No non-completion reasons have been specified.

Subject joining reasons


Subject joining reason

Please select...  Number of subjects 

No joining reasons have been specified.

- Add any other arms in the same way before clicking on “Done”. This should re direct you to the subject disposition page, where details about both periods should be saved. Click on “Save and return to index” to save the information you have entered:

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|---|---------|---|------|-----------------------------|--------------|-----|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |

57y6s4
Manage account
Logout ✕

Trial details
2009-012947-40
Version: 1

Result sections
Index
Trial information
Subject disposition
Baseline characteristics
End points
Adverse events
More information

Pre-assignment
Please complete at least one of the screening details or the pre-assignment period below

Screening details

| Period title | Options |
|-----------------------|---|
| Pre-assignment period | Edit Delete |

Periods
+ Add period

| Period title | Options |
|--------------|---|
| Main trial | Edit Delete |

Return to index (Save later)

Save and return to index

5.4 Baseline characteristics Page

- This section is completed by the Trial Statistician.
- The baseline characteristics are reported for the period which was defined as the baseline period within section 5.3.
- Choose whether you want to report the baseline characteristics by arm or overall. The example here will be presenting them by arm:

57y6s4
Manage account
Logout ✕

Trial details
2009-012947-40
Version: 1

Result sections
Index
Trial information

Baseline characteristics - settings

The baseline Period is: Period 1 - Main trial [Change baseline period](#) ⓘ


How are baseline characteristics being reported?

☒ Per Arm in the baseline period
☐ For the overall baseline period

[Done](#)
[Cancel](#)

- Add additional analysis sets if you want to report in groups different from the arms defined. This will take you to the following screen, where you can enter the details of the analysis set.

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|--|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title | | | | | |
| | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Scope | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

[Your page](#)
[Create](#)
[Load](#)

[Save](#)
[Discard changes](#)
[Validate full data set](#)
[Post results](#)
[Upload XML](#)
[Download XML](#)
[Download PDF](#)

Subject analysis set

Subject analysis set title: *

Subject analysis set type: *

Please select...

Subject analysis set description: *

Number of subjects in subject analysis set: *

[Done](#)
[Delete subject analysis set](#)
[Create another subject analysis set](#)

- Age characteristics (mandatory)
- Complete the categorical or/and continuous values for age, by clicking on “Edit”.

[Manage account](#)
[Logout](#)

Trial details
 2009-012947-40
 Version: 1

Result sections
[Index](#)
[Trial information](#)
[Subject disposition](#)
[Baseline characteristics](#)
[End points](#)
[Adverse events](#)
[More information](#)


Age characteristics *

Complete either the age categorical, age continuous or complete both these characteristics in order to collect values for the reporting groups and optionally the subject analysis sets.

| Age categorical characteristic | Options |
|--|---|
| Age categorical Status: Not ready for collecting values | Edit Enter values |
| Age continuous characteristic | Options |
| Age continuous Status: Not ready for collecting values | Edit Enter values |

- In the categorical option, you will see a list of age categories. You can optionally add more categories if appropriate, then tick the “Ready for collecting values” box.
- To enter values, click on “Done – start collecting values”.

Once printed from PDF, this document is an unofficial copy.
 The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title | | | | | |
| | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Scope | | | | | |
| | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

Session Information
Login
s7y6s4
Manage account
Logout

Trial details
2009-012947-40
Version: 1

Result sections
Index
Trial information
Subject disposition
Baseline characteristics
End points
Adverse events
More information

Characteristics
Save Discard changes Validate full data set Post results Upload XML Download XML Download PDF

Age categorical
Units*
Subjects

Description

Age category title
Add Remove Remove all

Age categories*
In utero
Preterm newborn infants (gestational age < 37 wks)
Newborns (0-27 days)
Infants and toddlers (28 days-23 months)
Children (2-11 years)
Revert to age categories used in Trial information section

☒ Ready for collecting values

Remember to create a category (e.g. called "Not recorded") for subjects who left the period before the characteristic was recorded.

Done - continue defining characteristics Done - start collecting values

- Enter the data for each arm, then the overall total will automatically update:

Your page Create Load

Session Information
Login
s7y6s4
Manage account
Logout

Trial details
2009-012947-40
Version: 1

Result sections
Index
Trial information
Subject disposition
Baseline characteristics
End points
Adverse events
More information


Save Discard changes Validate full data set Post results Upload XML Download XML Download PDF

| subjects: 100* | subjects: 99* |
|--|--|
| In utero 0 | In utero 0 |
| Preterm newborn infants (gestational age < 37 wks) 0 | Preterm newborn infants (gestational age < 37 wks) 0 |
| Newborns (0-27 days) 0 | Newborns (0-27 days) 0 |
| Infants and toddlers (28 days-23 months) 0 | Infants and toddlers (28 days-23 months) 0 |
| Children (2-11 years) 25 | Children (2-11 years) 28 |
| Adolescents (12-17 years) 55 | Adolescents (12-17 years) 49 |
| Adults (18-64 years) 20 | Adults (18-64 years) 22 |
| From 65-84 years 0 | From 65-84 years 0 |
| 85 years and over 0 | 85 years and over 0 |
| Total* 199 | |

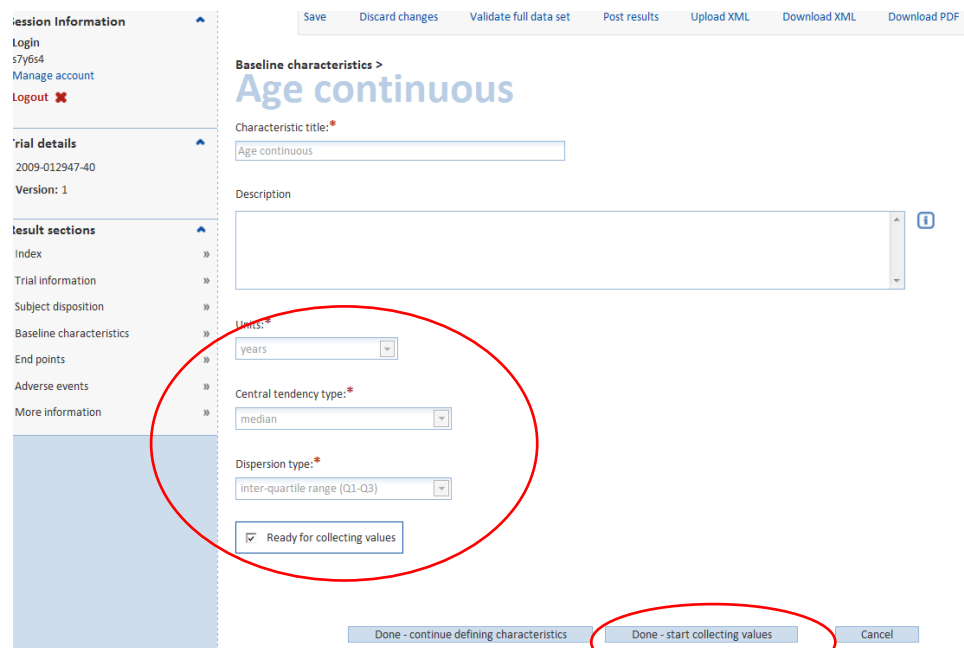
| |
|--|
| In utero 0 |
| Preterm newborn infants (gestational age < 37 wks) 0 |
| Newborns (0-27 days) 0 |
| Infants and toddlers (28 days-23 months) 0 |
| Children (2-11 years) 53 |
| Adolescents (12-17 years) 104 |
| Adults (18-64 years) 42 |
| From 65-84 years 0 |
| 85 years and over 0 |

- Click "Done".
- In the continuous option, you will be able to specify the units, summary statistic and measure of spread reported for the endpoint. For example the median and interquartile range of age in years.

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|--|-----|------|-----------------------------|--------------|-----|
|  Guideline | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Scope Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |

- To enter values, click on “Done – start collecting values”.



Session Information

Login
s7y6s4
Manage account
Logout

Trial details
2009-012947-40
Version: 1

Result sections

- Index
- Trial information
- Subject disposition
- Baseline characteristics
- End points
- Adverse events
- More information

Save Discard changes Validate full data set Post results Upload XML Download XML Download PDF

Baseline characteristics >
Age continuous

Characteristic title: *
Age continuous

Description

Units: *
years

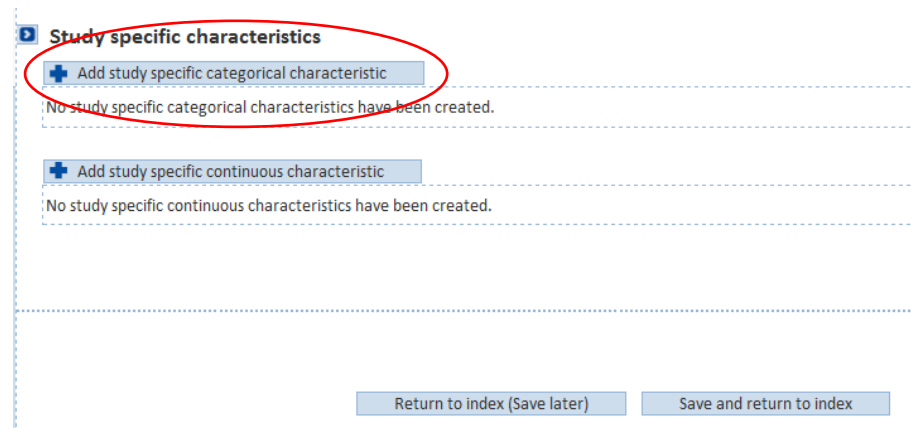
Central tendency type: *
median

Dispersion type: *
inter-quartile range (Q1-Q3)

☒ Ready for collecting values

Done - continue defining characteristics **Done - start collecting values** Cancel

- Enter the data in to each arm, then click “Done”.
- Repeat the process for Gender (categorical).
- You should then add any study specific characteristics – either categorical or continuous. There are likely to be many of these – we present an example of a continuous and a categorical variable here
- For a categorical variable click on “Add study specific categorical characteristic”:



Study specific characteristics

+ Add study specific categorical characteristic


No study specific categorical characteristics have been created.

+ Add study specific continuous characteristic

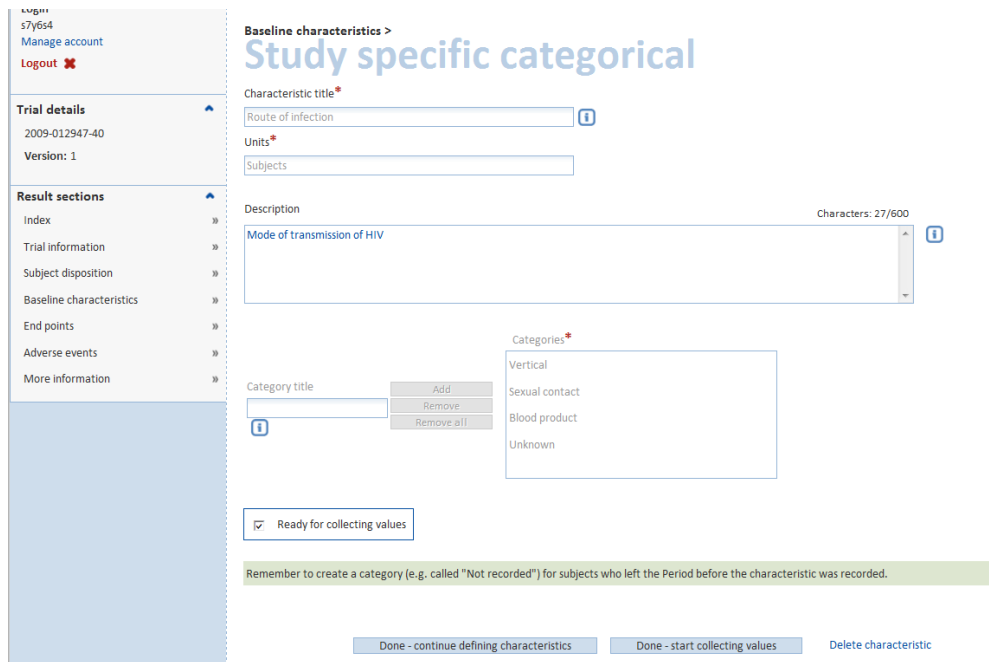
No study specific continuous characteristics have been created.

Return to index (Save later) Save and return to index

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

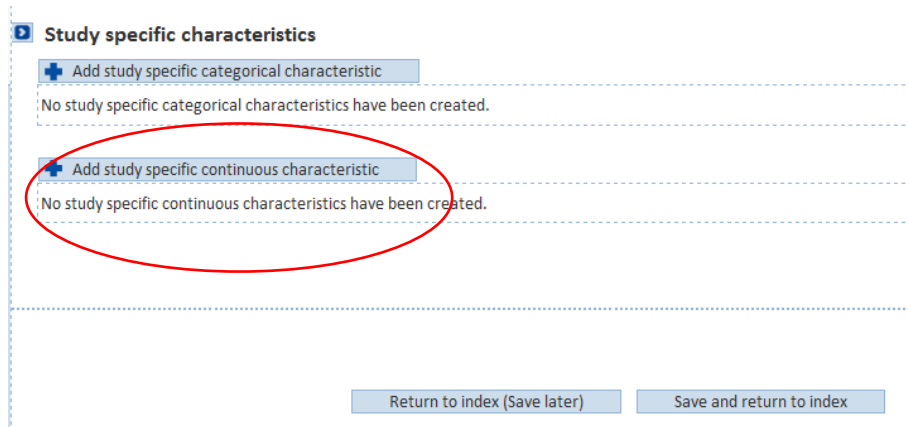
| | | | | | | |
|---|--|---|------|-----------------------------|--------------|-----|
|  Guideline | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Title | | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |

- Give the characteristic a title (in this example we will use “route of infection”). It is more important to add a brief description when it is study specific, so it is clear to the reader what you are entering.
- To add a category, type it into the “Category title” box and then click on “Add” – the category will then appear in the “Categories” box.
- Click “Ready for collecting values”, then the process of entering the data is the same as previously (start by clicking “Done – start collecting values”).




The screenshot shows the 'Baseline characteristics > Study specific categorical' page. On the left is a sidebar with 'Trial details' (2009-012947-40, Version: 1) and 'Result sections' (Index, Trial information, Subject disposition, Baseline characteristics, End points, Adverse events, More information). The main area has a 'Characteristic title' field with 'Route of infection', a 'Units' field with 'Subjects', and a 'Description' field with 'Mode of transmission of HIV'. Below these is a 'Category title' field with an 'Add' button and a 'Categories' dropdown menu showing 'Vertical', 'Sexual contact', 'Blood product', and 'Unknown'. A 'Ready for collecting values' checkbox is checked. At the bottom are buttons: 'Done - continue defining characteristics', 'Done - start collecting values', and 'Delete characteristic'. A green note at the bottom says: 'Remember to create a category (e.g. called "Not recorded") for subjects who left the Period before the characteristic was recorded.'

- The process for adding a continuous study specific baseline characteristic is similar. Click on “Add study specific continuous characteristic”.

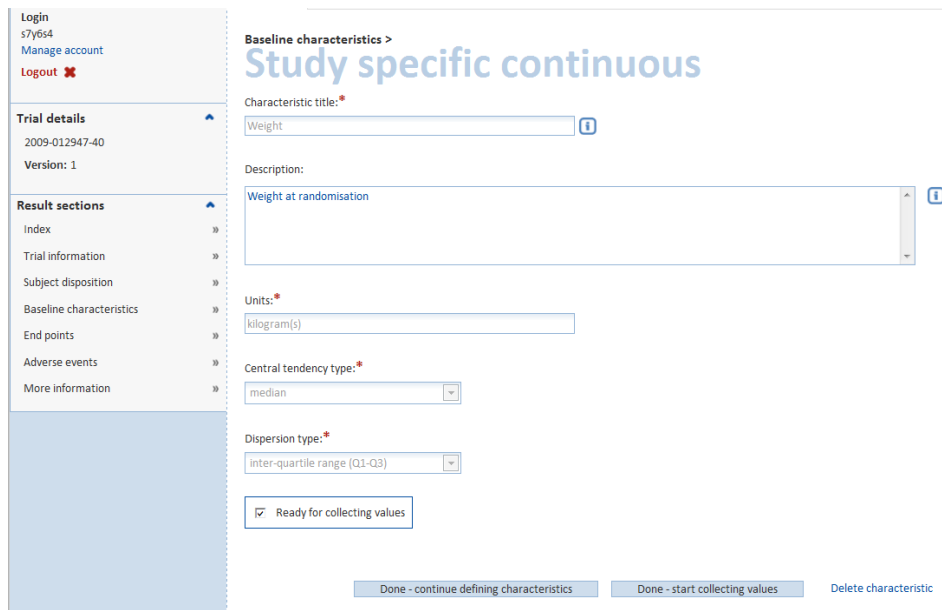


The screenshot shows the 'Study specific characteristics' page. It has two main sections: 'Add study specific categorical characteristic' and 'Add study specific continuous characteristic'. Both sections have a red circle around the 'Add' button and the text 'No study specific categorical characteristics have been created.' and 'No study specific continuous characteristics have been created.' respectively. At the bottom are buttons: 'Return to index (Save later)' and 'Save and return to index'.

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title | | | | | |
| | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- Give the characteristic a title (in this example we will use “Weight”). It is more important to add a brief description when it is study specific, so it is clear to the reader what you are entering.
- Enter the Units used (often when you start typing, EudraCT will suggest units for you), enter the summary statistic and the measure of spread you are to enter.
- Click “Ready for collecting values”, then the process of entering the data is the same as previously (start by clicking “Done – start collecting values”).



The screenshot shows the EudraCT database interface. On the left is a sidebar with navigation links: Login, Manage account, Logout, Trial details, Result sections, Index, Trial information, Subject disposition, Baseline characteristics, End points, Adverse events, and More information. The main content area is titled 'Baseline characteristics > Study specific continuous'. It contains a form for defining a characteristic. The 'Characteristic title' field is filled with 'Weight'. The 'Description' field is filled with 'Weight at randomisation'. The 'Units' field is filled with 'kilogram(s)'. The 'Central tendency type' dropdown is set to 'median'. The 'Dispersion type' dropdown is set to 'inter-quartile range (Q1-Q3)'. There is a checkbox labeled 'Ready for collecting values' which is checked. At the bottom, there are three buttons: 'Done - continue defining characteristics', 'Done - start collecting values', and 'Delete characteristic'.


5.5 End points Page

- This section is completed by the Trial Statistician.

5.5.1 Defining a new end point

- Click on “Add end point”.
- Enter a title for the End point e.g. Overall Survival.
- Enter whether the End point is countable (categorical) or measurable (continuous).
 - If countable state the countable units e.g. participants.
 - If measurable state the measurable units and how this has been summarised (measure type) along with a precision type e.g. time in months, median and IQR.
- Enter the time frame of the variable e.g. time from randomisation to death.
- Enter a description of the variable – this can be the definition of the variable from the statistical analysis plan (SAP).
- If applicable you can also define the categories by specifying the relevant category titles and clicking Add e.g. reached endpoint / did not reach endpoint.
 - In this case you must also define a category for those for which the endpoint was not recorded.
- Finally select the periods and arms for which your endpoint is defined, if you’re uploading the results from different analysis populations you can also select which analysis populations you wish to define your endpoint for here.
- Tick “ready for collecting values” and click “Done start collecting values”.
- The example below is for a secondary endpoint (confirmed viral load ≥ 400 c/ml in a HIV trial over 48 weeks).

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|---|---|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title | | | | | |
| | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

i7y6s4
[Manage account](#)
[Logout](#)

trial details
2009-012947-40
Version: 1

result sections
Index
Trial information
Subject disposition
Baseline characteristics
End points
Adverse events
More information

End points >

End point definition

End point title:
Virological failure (>=400c/ml confirmed).

Countable or measurable?
☒ Countable Countable units:
☐ Measurable People

Measurable units:
Measure type:
Please select...
Precision/Dispersion type:
Please select...

End point type:
Secondary

Timeframe:
Any time from randomisation to 48(+6) weeks after randomisation.

Description:
Confirmed viral load >=400c/ml within 54 weeks of randomisation.

Use categories only if the data for the end point can be categorised

Category title

Add
Remove
Remove all

Categories
Reached endpoint
Did not reach endpoint

Specify the groups of subjects applicable to this end point

Reporting groups*

| Periods | Arms |
|---|--|
| Period 1: Main trial | <input checked="" type="checkbox"/> Arm: Continuous therapy |
| (Baseline) | <input checked="" type="checkbox"/> Arm: Short Cycle Therapy |
| Select all arms | |
| <input checked="" type="checkbox"/> Ready for collecting values | |


Done - continue defining end points

Done - start collecting values

5.5.2 Adding values for an End point

- You will be directed to a screen where you can enter the raw data for each arm selected on the previous screen.
- Enter the number of subjects analysed in each selected arm.

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|---|--|---------|---|------|-----------------------------|----------------------------|
|  Guideline | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Title | | Guidance on uploading Clinical Trials Results to the EudraCT database | | | |
| | Scope | Version | 1.0 | Date | 21 st March 2018 | Guideline ID G65 |

- For categorical data you can specify the number of subjects in each group (as defined on the previous screen) for each selected arm.
- For continuous data you can enter the measure type and precision/dispersion type (as defined on the previous screen) for each selected arm.
 - Note that if your confidence interval has upper or lower limits which have not been reached you cannot input inf (infinity) or NR (not reached) instead you should specify a number e.g. 999 in the endpoint description which represents that the upper / lower limit was not reached.
- The screen shot below shows what you'd see if you continued with the example in section 5.5.2.

Reporting groups

| | |
|-------------------|---------------------|
| Reporting group 1 | Continuous Therapy |
| Reporting group 2 | Short Cycle Therapy |

| | |
|---|---|
| Reporting group 1 Subjects analysed: 100 Edit * | Reporting group 2 Subjects analysed: 100 Edit * |
| Reached endpoint Count: 50 | Reached endpoint Count: 50 |
| Did not reach endpoint Count: 50 | Did not reach endpoint Count: 50 |

Subject analysis sets

No subject analysis sets have been selected for this end point.


Statistical analyses

| + Add statistical analysis | | |
|----------------------------|---------------------------|---|
| Statistical analysis title | Statistical analysis type | Options |
| Virological Failure | superiority | Edit Delete |


5.5.3 Adding analysis for an endpoint

- You can add some statistical analysis for the endpoint by clicking “Add statistical analysis”.
- You can only add one statistical analysis at a time and you can state the following:
 - Analysis title.
 - Analysis description – this can be taken from the SAP, for time to event end points this may be where you specify the date cut off if the some endpoints were not updated following the final download.
 - Comparison groups – which in turn will define the number of subjects analysed.
 - Whether the analysis was pre-specified / post-hoc.
 - Whether the analysis was superiority/non-inferiority/equivalence/other – there is also an opportunity to comment on the analysis type.
 - The p-value for the analysis.
 - The method for the analysis from which the p-value was obtained e.g. General linear regression, Cox proportional hazards regression.
 - The parameter estimate e.g. Hazard ratio (HR).
 - The point estimate for the parameter estimate.
 - The confidence interval for the parameter estimate, along with the level and whether this is one or two sided and/or the type of variability estimate for the parameter along with the value of this estimate.
 - Click “Done” which will return you to the endpoint page.

**Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document**

| | | | | | | |
|---|---------|-----|---|-----------------------------|--------------|-----|
|  | Title | | Uploading Clinical Trials Results onto the EudraCT Database | | | |
| | Scope | | Guidance on uploading Clinical Trials Results to the EudraCT database | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- The screenshots below show what you may enter in the case of the example above.

End points >

Statistical analysis

Statistical analysis details

Statistical analysis title:*

Virological Failure i

Analysis description:

Logistic regression will be used to analyse the proportion of patients experiencing Virological failure whilst accounting for the stratification factors of the trial. i

Comparison groups:*

- ☒ Period 1 Continuous Therapy i
- ☒ Period 1 Short Cycle Therapy

[Select all arms](#)

Subjects in this analysis: * 200

Analysis specification: * ☒ Pre-specified ☐ Post-hoc

Analysis type: * superiority

Statistical hypothesis test

P-value:

= 0.76 i

P-value comment:

i

Method:

Regression, Logistic i Other method:

Required if a P-value is provided

Parameter estimate

Parameter type: Odds ratio (OR) i Other parameter type:

Point estimate: 1.02 i

Confidence interval:

sides: 2-sided level: 95%

lower limit: 0.98 i

upper limit: 1.06 i

Variability estimate: Please select...


Dispersion value:

Done

[Delete statistical analysis](#)

[Create another statistical analysis](#)

[Create a copy of the statistical analysis](#)

| | | | | | | |
|---|--|---------|---|------|-----------------------------|----------------------------|
|  Guideline | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Title | | Guidance on uploading Clinical Trials Results to the EudraCT database | | | |
| | Scope | Version | 1.0 | Date | 21 st March 2018 | Guideline ID G65 |

5.5.4 Additional uploads and completion of endpoint

- The CTRU standard is to not additionally upload attachment(s) to each endpoint
- Once everything for that endpoint is entered click “Done” to return to the endpoint definition page and then “Done – continue defining end points” to define another endpoint.
- Once all your endpoints are added click “Save and return to index”.

5.6 Adverse events Page

- This section needs to be entered by a Trial Statistician
- **Note: SAEs and AEs are reported separately, so ensure SAEs are not reported twice.**
- Enter in the timeframe for adverse event reporting. Select whether the assessment type was systematic or non-systematic. Select the threshold frequency for reporting non-serious adverse events.
- If using a dictionary for reporting events (e.g. MedDRA), select which one, and which version.
- Enter the threshold for reporting. For example where all AEs will be reported a 0% threshold is specified.

Adverse events information

Timeframe for adverse event reporting: *

Randomisation to 54 weeks after randomisation.



Adverse event reporting additional description:



Assessment type: *

Systematic



Frequency threshold for reporting non-serious adverse events: *

0



(max 5%)

Dictionary name: *

MedDRA




Other dictionary:

Version: *

16.0

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---|------------|-------------|-----------------------------------|---------------------|------------|
|  Guideline | Title | | | | | |
| | Uploading Clinical Trials Results onto the EudraCT Database | | | | | |
| | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- If adverse event data is being entered using an automated process i.e. via xml then the work instruction documented in Appendix A should be followed. The following steps should be followed if entering adverse event data manually.
- First you need to define your adverse event reporting groups. The standard is to use the same arms defined within the baseline period. For each arm you will define within the system:
 - The number of subjects exposed to the treatment
 - The number of subjects experiencing at least one serious adverse event
 - The total number of deaths (all causes)
 - The total number of deaths resulting from adverse events (non-compulsory)

Adverse events >

Adverse event reporting group definition

Reporting group title:*

arm b

Reporting group description:

For this reporting group, provide the following totals:

Subjects exposed:*

Subjects affected by serious adverse events:*


Subjects affected by non-serious adverse events:*

Total number of deaths (all causes):*

Total number of deaths resulting from adverse events:*

Done Delete reporting group Create another reporting group

Once printed from PDF, this document is an unofficial copy.
The user must ensure that they are working to the current version of this document

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |


- To add a serious adverse event, click “Add serious adverse event”.
- For the table of values the columns are defined as follows
 - Subjects affected – number of subjects in each arm who have experienced the event at least once.
 - Subjects exposed – number of subjects in safety population of the arm.
 - Occurrences – Total number of the event observed in each arm
 - Occurrences causally related to treatment – Total number of events in each arm which are related to the treatment
 - Fatalities – Total number of deaths in each arm for those who experienced the event.
 - Fatalities causally related to treatment – Total number of deaths in each arm experiencing the event which are related to treatment.
- An example of how to fill this in for a single serious adverse event (Headache) is below:

Serious adverse event details

System organ class:*


Nervous system disorders 

Event term:*

Headache 

Additional description:

Assessment type:

Systematic 

Default dictionary for reporting Adverse events in these results is: MedDRA 16.0

Do you want to use a different name and version for reporting this adverse event? ☐ Yes ☒ No

Dictionary name:

Please select...  Other dictionary: Version:

[Top of Page](#) 


Values for serious adverse event per reporting group *

| Reporting groups | Subjects affected number | Subjects exposed number | Occurrences all number | Occurrences causally related to treatment number | Fatalities number | Fatalities causally related to treatment number |
|---------------------|--------------------------------|----------------------------------|--------------------------------|--|--------------------------------|---|
| Continuous therapy | <input type="text" value="0"/> | <input type="text" value="100"/> | <input type="text" value="1"/> | <input type="text" value="0"/> | <input type="text" value="0"/> | <input type="text" value="0"/> |
| Short Cycle Therapy | <input type="text" value="1"/> | <input type="text" value="99"/> | <input type="text" value="0"/> | <input type="text" value="0"/> | <input type="text" value="0"/> | <input type="text" value="0"/> |

- Click “Done” to return to adverse event screen.

Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- Less detail is required for the non-serious AEs:
 - For the table of values the columns are defined as follows
 - Subjects affected – number of subjects in each arm who have experienced the event at least once.
 - Subjects exposed – number of subjects in safety population of the arm.
 - Occurrences – Total number of the event observed in each arm

Non-serious adverse event details

System organ class:*

Infections and infestations

Event term:*

Measles

Additional description:

Assessment type:

Systematic

Default dictionary for reporting Adverse events in these results is: MedDRA 16.0

Do you want to use a different name and version for reporting this adverse event? ☐ Yes ☒ No

Dictionary name:

Please select... Other dictionary: Version:

[Top of Page](#)

Values for non-serious adverse event per reporting group *


Threshold for non-serious adverse event reporting is: 0%

| Reporting groups | Subjects affected number | Subjects exposed number | Occurrences all number |
|---------------------|--------------------------|-------------------------|------------------------|
| Continuous therapy | 0 | 100 | 0 |
| Short Cycle Therapy | 1 | 99 | 1 |

- Click “Done” to return to the AE screen.

Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

5.7 More information Page

- To be entered by the STM or delegate.
- All mandatory fields are completed in the below fields:

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? ☐ Yes ☐ No i

Add global substantial protocol amendment

No amendments have been specified.

[Top of Page](#)

Interruptions (globally)

Were there any global interruptions to the trial? ☐ Yes ☐ No i

Add global interruption

No interruptions have been specified.

[Top of Page](#)

Limitations and caveats

Limitations and caveats applicable to this summary of the results

i

[Top of Page](#)


Online references

Provide identifiers to retrieve publications of interest in regards to the results of this clinical trial.

- If there were substantial amendments these must be listed using the date of MHRA approval for the amendment date where regulatory authority approval was required. For substantial amendments requiring ethics approval only the date of ethics approval is entered as the amendment date.

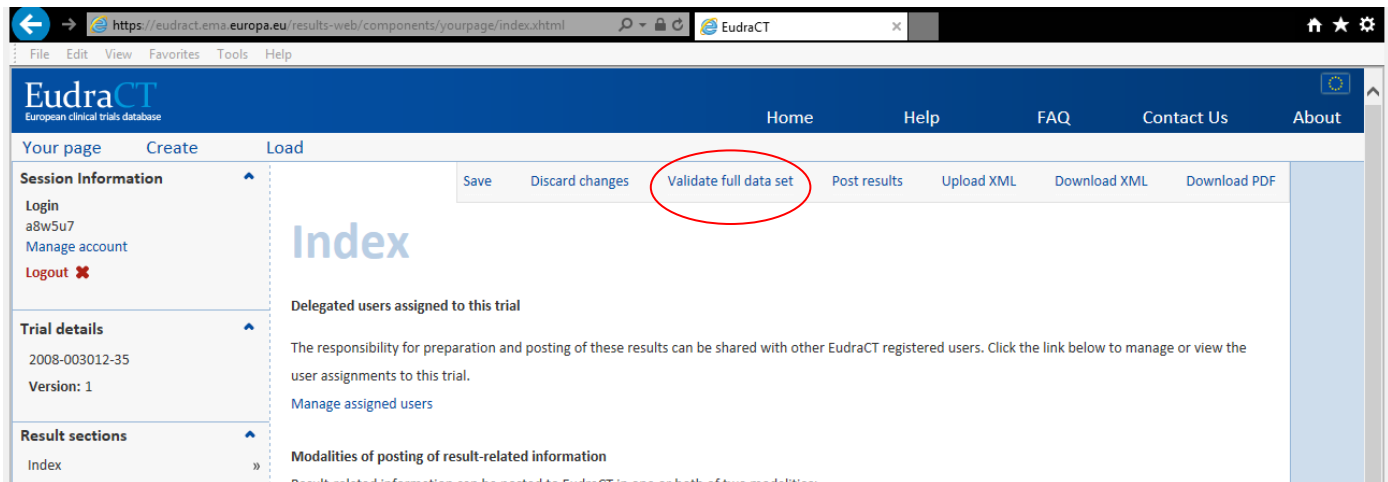
Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

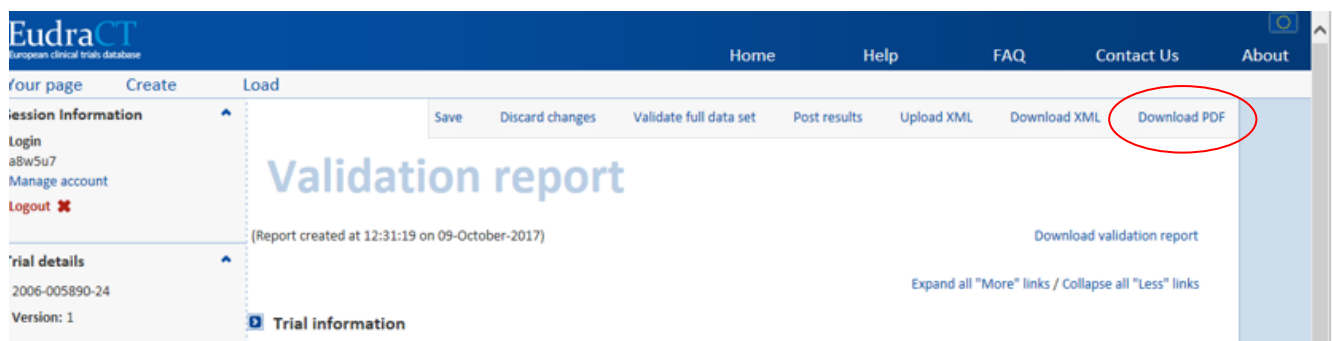
6.0 Validation of the data set

- The validate button will highlight any data that has been entered that does not fall within the validation set within the system linked to a mandatory field. Error messages are reviewed and rectified ahead of review by the Scientific and Delivery Lead
- Where it has been agreed with the Scientific Lead and QA department to not enter data linked to a mandatory field, adding a justification to the validation will allow you to proceed. All justifications are reviewed by the Scientific Lead as part of the review process



7.0 Data review and release


- Following validation the data entered into the EudraCT database is reviewed by the Scientific and Delivery Lead. This can be done through logging on to the EudraCT database or by reviewing a PDF download of the data entered by clicking on the below button:



- A of **F69:EudraCT Review and Release** is completed by the Scientific and Delivery Leads following on from review of the data entered into the EudraCT database. **F69:EudraCT Review and Release** is completed in line with the timelines within **T16:Trial & Site Closure**.
- Data must not be released publically until the Scientific Lead has confirmed it is appropriate to do so. Section B of **F69:EudraCT Review and Release** is completed by the Scientific Lead to document it is appropriate to release the results.

Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- Where it has been formally agreed with QA and the Scientific Lead to not publically release data onto the EudraCT database within one year of the end of trial (**T16: Trial & Site Closure**) the following steps are followed:
 - Confirmation is provided to QA that the data has been entered into the EudraCT database within one year of the end of trial. A copy of the partially completed **F69:EudraCT Review and Release** is provided to the QA department.
 - A courtesy email is sent to the MHRA stating that data has been entered into the EudraCT database but will not be released within the EudraCT system within the 1 year deadline, providing the justification for this. This email is sent to clintrialhelpline@mhra.gsi.gov.uk and a copy saved in the TMF (**G05: Trial Master File**).
- Following authorisation by the Delivery Lead that it is appropriate to release the trial data publically the following steps are followed:
 - The Scientific Lead signs **F69:EudraCT Review and Release** to document it is appropriate to make the data publically available.
 - The data is released within the EudraCT system using the post results tab.
 - QA are notified that the upload has taken place and the date of the upload. A copy of the completed **F69:EudraCT Review and Release** is sent to QA with the original saved in the TMF (**G05: Trial Master File**).
 - The MHRA are contacted to state the results have been uploaded onto the EudraCT system using the email address ct.submission@mhra.gsi.gov.uk and the subject line "End of trial study report: EudraCT XXXX-XXXXXX-XX".


Section C

References

- 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
- MRC CTU. (2017). Uploading Trial Results to EudraCT. Version 1.0

Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------|--------------|-----|
|  | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |

Appendix A – Adverse Event XML Work Instruction

This appendix is applicable for statisticians uploading adverse event data via xml

The programs related to the following sections can be found here:

P:\CTRU\Stats\Programming\SAS\Eudract\EudraCT_Upload_V1.0

Part A: Getting the datasets into the correct form

Whilst the definitions of each variable may differ on a trial by trial basis, the overall process requires three datasets, which include the mandatory variables in a specific form and correspond to specific fields on the EudraCT system.

- EudractGrps – Adverse Event Reporting Groups (safety statistics by reporting group i.e. the arms for which you want to report safety information on)


| Variable Name | Mandatory? | Description | Attributes |
|---------------|------------|---|---------------------|
| idn | Y | Identification number for reporting group | Numeric |
| id | Y | Text identification for reporting group | Text (Length = 62) |
| desc | N | Description of reporting group | Text (Length = 999) |
| patn | Y | Number of patients in reporting group that safety information reported – i.e. the number in the safety population | Numeric |
| patae | Y | Number of patients reporting at least 1 adverse event in reporting group | Numeric |
| Patsae | Y | Number of patients experiencing at least 1 serious adverse event | Numeric |
| death | Y | Number of deaths in reporting group | Numeric |
| deathae | N | Number of drug-related deaths | Numeric |

- EudractSAE – Summaries of SAEs by reporting groups (if an SAE occurred in one group but not another then it needs to be included as zero)

| Variable Name | Mandatory? | Description | Attributes |
|---------------|------------|--|-------------------|
| idn | Y | Identification number for reporting group should match to above. | Numeric |
| SOC | Y | MEDDRA system organ class for SAE. | Text (Length=100) |
| Term | Y | SAE term. | Text (Length=100) |
| desc | N | Additional description. | Text (Length=250) |
| Asstype | Y | Assessment type (1=Systematic, 2=Non-Systematic). | Numeric |
| patn | Y | Number of patients experiencing event. | Numeric |
| occur | Y | Number of occurrences of event. | Numeric |
| occurtrt | Y | Number of occurrences caused by treatment. | Numeric |
| death | Y | Number of deaths for event. | Numeric |
| deathtrt | Y | Number of deaths due to treatment. | Numeric |

Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- EudractAE - Summaries of AEs by reporting groups (if an AE occurred in one group but not another then it needs to be included as zero)

| Variable Name | Mandatory? | Description | Attributes |
|---------------|------------|--|-------------------|
| idn | Y | Identification number for reporting group should match to above. | Numeric |
| SOC | Y | MEDDRA system organ class for SAE. | Text (Length=100) |
| Term | Y | SAE term. | Text (Length=100) |
| desc | N | Additional description. | Text (Length=250) |
| Asstype | Y | Assessment type (1=Systematic, 2=Non-Systematic). | Numeric |
| patsn | Y | Number of patients experiencing event. | Numeric |
| occur | Y | Number of occurrences of event. | Numeric |

The following points should also be considered:

- If AEs are not reported on the trial an empty dataset still needs to be created:

```
data EudractAE;
    length soc $100 term $100 desc $250;
    call missing(idn,soc,term,desc,Asstype,patsn,occur);
    if _N_ = 0 then output;
    stop;
run;
```

- On the EudraCT system there is a large free-text section, which is **not** covered by these programs, to describe the AE timeframe for reporting and also the assessment type. (See Section 5.6)
- Note that the process does not allow different medical dictionaries for individual terms, one overall dictionary is required. Furthermore the process has been fully validated for CTCAE V4.0/27 MedDRA SOC terms (See Part C point V.).

Part B: Obtaining the formats library

The EudraCT system requires that free text SOC terms defined in the EudractAE and EudractSAE datasets are uploaded as a formatted variable. This step allows formats to be applied in the upload process.

- Copy the file P:\CTRU\Stats\Programming\SAS\Eudract\EudraCT_Upload_V1.0\EUTCT_formats_V22.sas into your trials EudraCT folder which should be a subfolder within trial's stats folder.
- Update the header and directories as required.
- Run the program.
- Check the log for any issues and to ensure the formats library has been successfully created in the formats library you specified in the program.


Part C: Checking that your datasets are in the correct form

- Copy the file: P:\CTRU\Stats\Programming\SAS\Eudract\EudraCT_Upload_V1.0\XML_input_checkerV1.0.sas, into your trial's EudraCT directory.
- Update the header and directory as required.
- Update the libname statement for the EudraCT formats library.
- The program is split into clearly defined sections for each validation check. Run the program one section at a time and check for errors. If error messages are produced correct the appropriate input dataset (referring back to the dataset specification) before moving onto the next section.
- If SOC terms are not matching to the Eutct formats because you believe the set of SOC terms defined in the formats are using a different version of the dictionary to the that defined in your trial the formats version may need updating and re-validating. To do this please refer to: P:\CTRU\Stats\Programming\SAS\Eudract\EudraCT_FormatsValidation\README V1.0.
- The program should be run in its entirety without errors prior to moving onto the next section.

Part D: Creating the XML file

Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

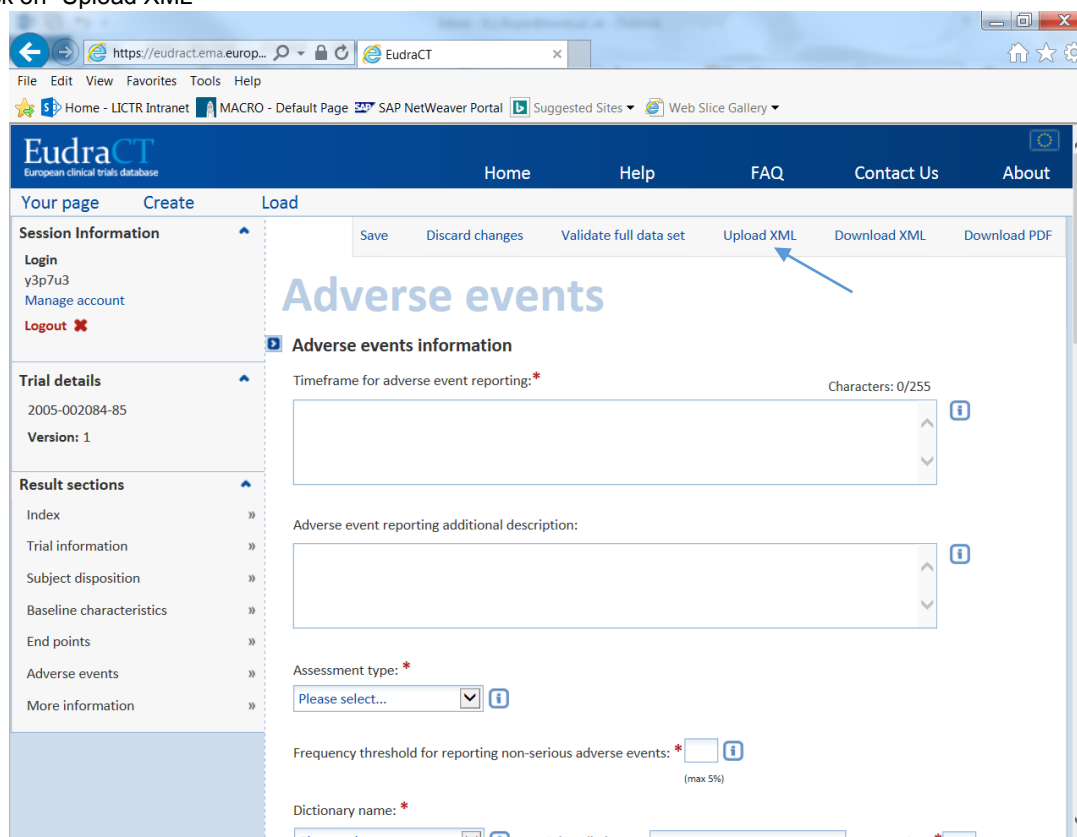
| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

- I. Copy the file: P:\CTRU\Stats\Programming\SAS\Eudract\EudraCT_Upload_V1.0\XML_creator_V1.0.sas into your trial's EudraCT directory.
- II. Update the header, directory, libname statements, file string, sasout string and saslog string as required.
- III. Run the program
- IV. Check that the xml file has been created in the output of the study directory
- V. Check the log for errors.

Part E: Uploading to EudraCT

This step describes uploading the XML file to EudraCT. Log into the system and navigate to the Adverse event page as described within the main body of this guideline.


- I. Click on "Upload XML"



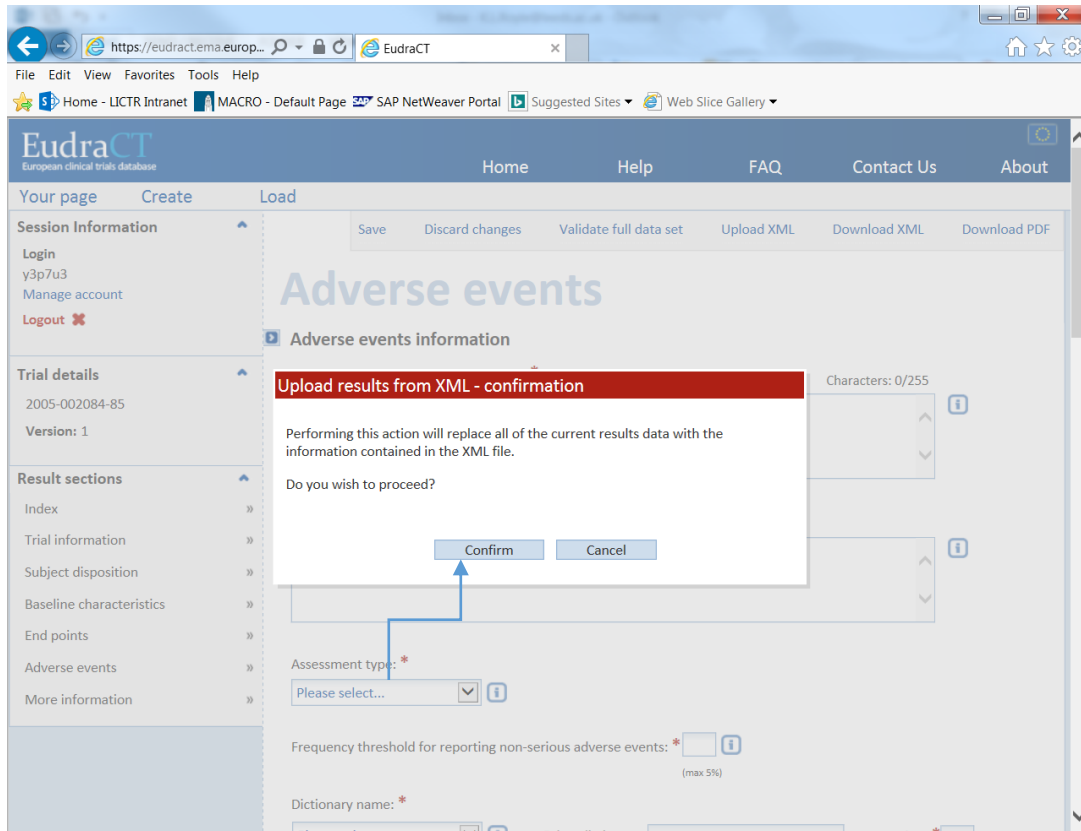
The screenshot shows the EudraCT web application interface. The browser address bar displays 'https://eudract.ema.europ...'. The page title is 'EudraCT European clinical trials database'. The navigation bar includes 'Home', 'Help', 'FAQ', 'Contact Us', and 'About'. The main content area is titled 'Adverse events' and contains a sidebar with 'Session Information', 'Trial details', and 'Result sections'. The 'Adverse events information' section is active, showing fields for 'Timeframe for adverse event reporting', 'Adverse event reporting additional description', 'Assessment type', 'Frequency threshold for reporting non-serious adverse events', and 'Dictionary name'. The 'Upload XML' button is highlighted with a blue arrow.

Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

II. Click confirm




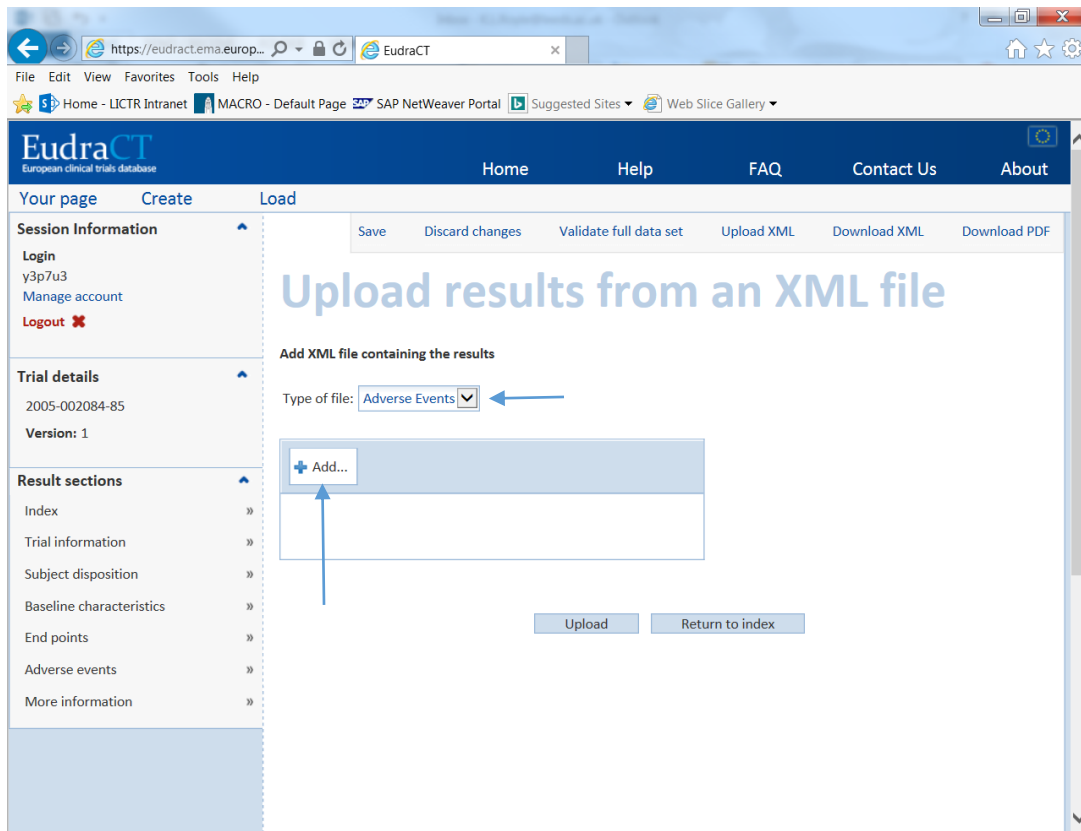
The screenshot shows the EudraCT web interface. The main content area is titled 'Adverse events'. A confirmation dialog box is open, titled 'Upload results from XML - confirmation'. The dialog contains the text: 'Performing this action will replace all of the current results data with the information contained in the XML file. Do you wish to proceed?'. There are 'Confirm' and 'Cancel' buttons. A blue arrow points from the 'Confirm' button to the 'Adverse events' section in the sidebar.

III. Change the type of file to “Adverse Events” and click +Add...

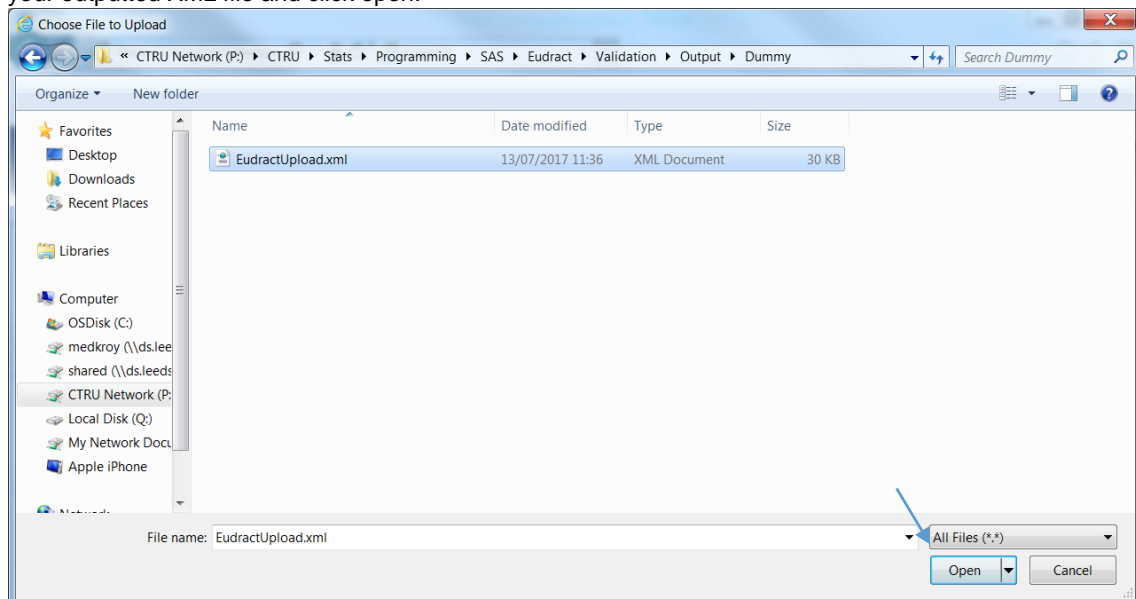
Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------|--------------|-----|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21 st March 2018 | Guideline ID | G65 |




IV. Find your outputted XML file and click open.

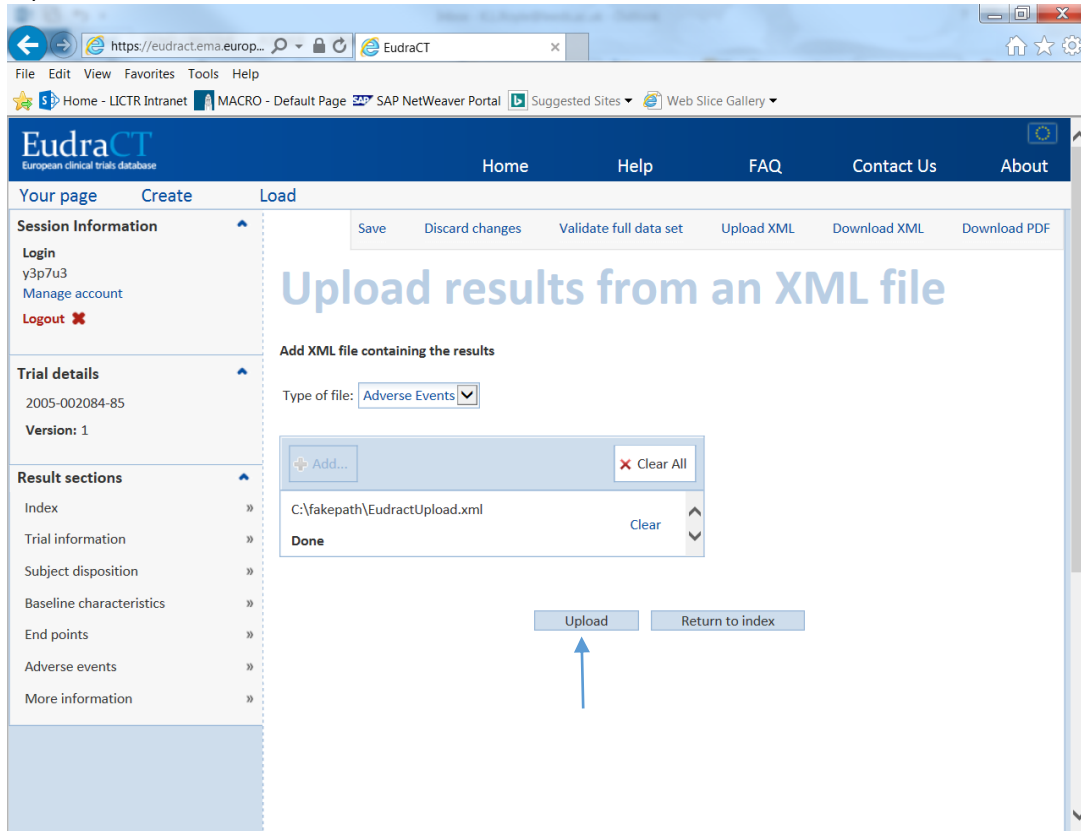


Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |


V. Click upload



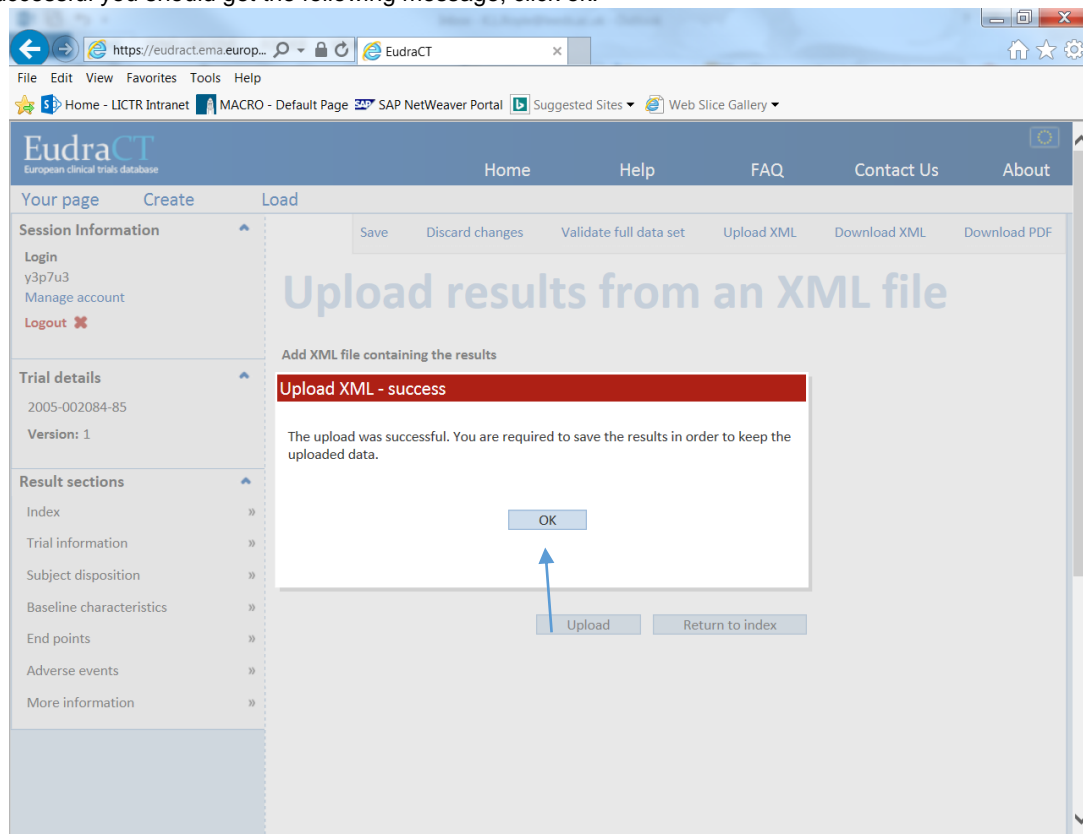
The screenshot shows the EudraCT website interface for uploading XML results. The browser address bar shows 'https://eudract.ema.europ...'. The page title is 'Upload results from an XML file'. The sidebar on the left contains sections for 'Session Information' (Login, Logout), 'Trial details' (2005-002084-85, Version: 1), and 'Result sections' (Index, Trial information, Subject disposition, Baseline characteristics, End points, Adverse events, More information). The main content area has a 'Type of file' dropdown set to 'Adverse Events'. Below this is a file selection box showing 'C:\fakepath\EudractUpload.xml'. There are buttons for 'Add...', 'Clear All', 'Clear', and 'Done'. At the bottom, there are 'Upload' and 'Return to index' buttons. A blue arrow points to the 'Upload' button.

Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.


| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |

VI. If successful you should get the following message, click ok.



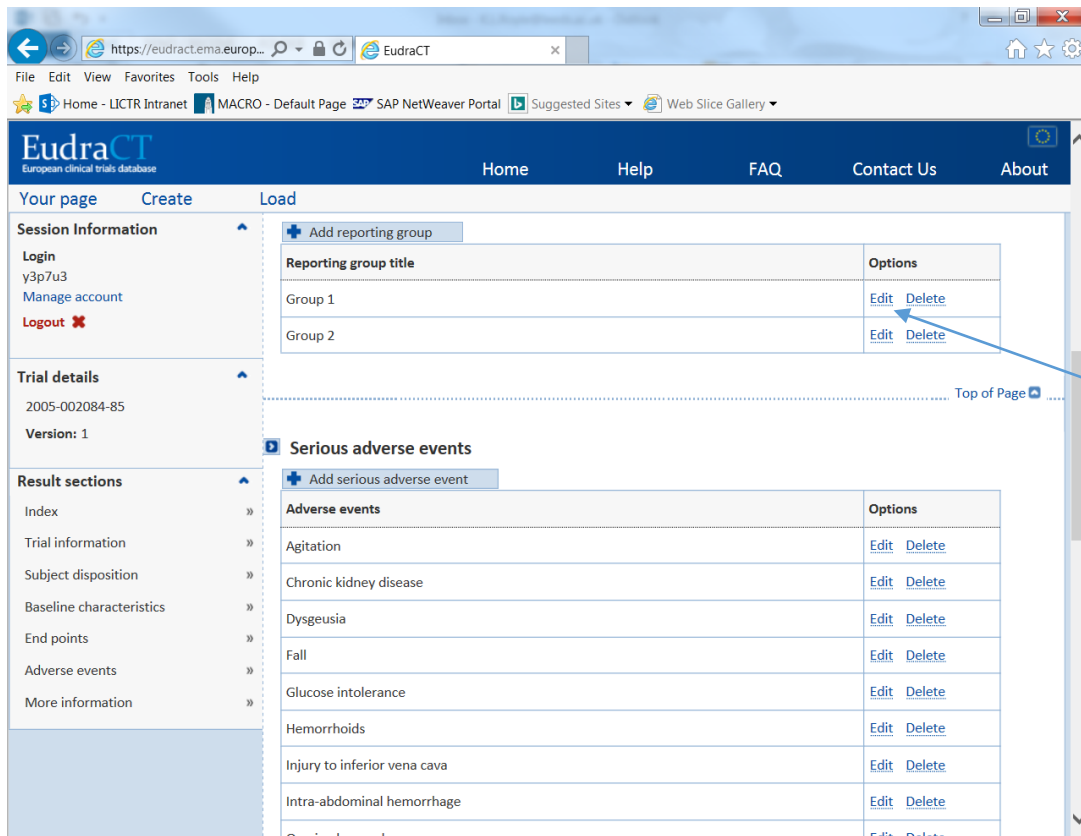
Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |


VII. This will take you back to the homepage, click on Adverse events and check that your data has uploaded correctly.
For example:

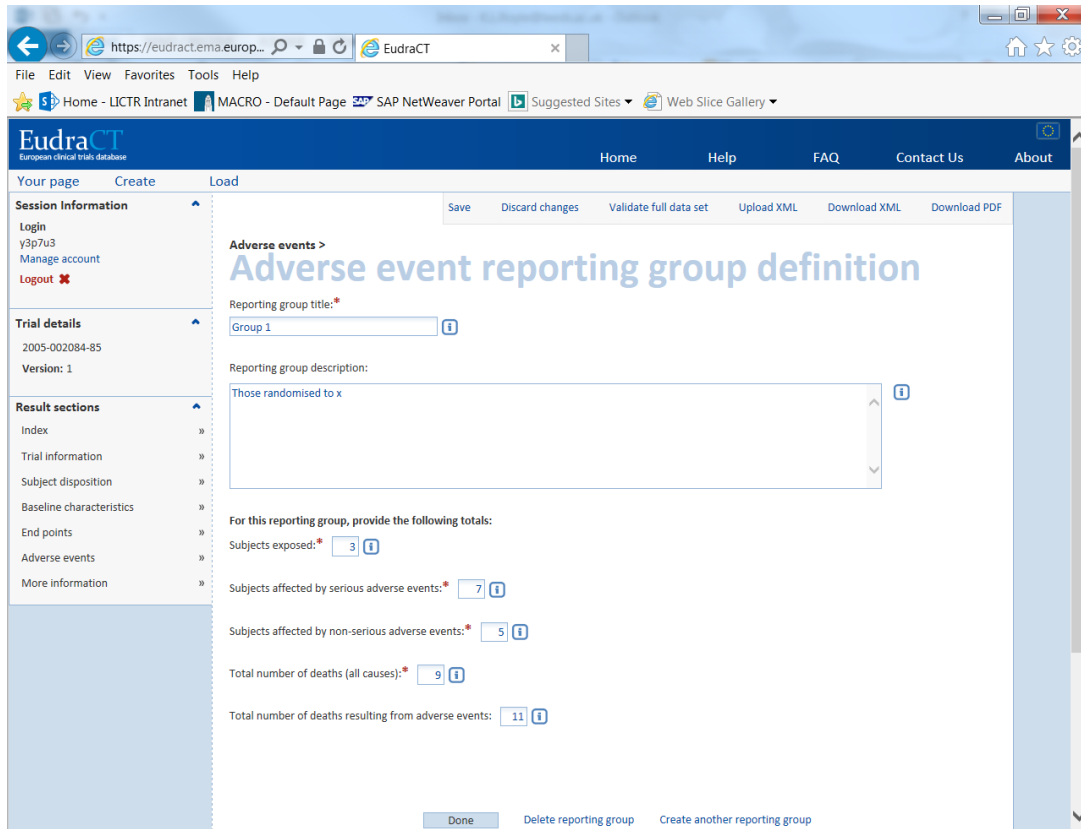
| | A | B | C | D | E | F | G | H | I |
|---|-----|-----------|-----------------------|------|-------|--------|-------|---------|---|
| 1 | idn | id | desc | patn | patae | patsae | death | deathae | |
| 2 | | 1 Group 1 | Those randomised to x | 3 | 5 | 7 | 9 | 11 | |
| 3 | | 2 Group 2 | Those randomised to y | 4 | 6 | 8 | 10 | 12 | |
| 4 | | | | | | | | | |
| 5 | | | | | | | | | |



Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.

| | | | | | | |
|---|---------|---|------|-----------------------------------|--------------|------------|
|  Guideline | Title | Uploading Clinical Trials Results onto the EudraCT Database | | | | |
| | Scope | Guidance on uploading Clinical Trials Results to the EudraCT database | | | | |
| | Version | 1.0 | Date | 21st March 2018 | Guideline ID | G65 |



The screenshot shows the EudraCT website interface. The browser address bar displays 'https://eudract.ema.europ...'. The website header includes 'EudraCT European clinical trials database' and navigation links: Home, Help, FAQ, Contact Us, About. A sidebar on the left contains 'Your page', 'Create', and 'Load' sections. The 'Adverse events' section is active, showing 'Adverse event reporting group definition'. The form includes fields for 'Reporting group title' (Group 1), 'Reporting group description' (Those randomised to x), and 'For this reporting group, provide the following totals:'. The totals are: Subjects exposed: 3, Subjects affected by serious adverse events: 7, Subjects affected by non-serious adverse events: 5, Total number of deaths (all causes): 9, and Total number of deaths resulting from adverse events: 11. At the bottom, there are buttons for 'Done', 'Delete reporting group', and 'Create another reporting group'.

Once printed from PDF, this document is an unofficial copy.

The user must ensure that they are working to the current version of this document.