



Smarter studies  
Global impact  
Better health



## UPLOADING TRIAL RESULTS TO EudraCT

### VERSION 1.0

#### APPROVALS

Author	Position	Signature
[REDACTED]	Statistician	[REDACTED]
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All appropriate approvals must have been completed prior to uploading to SOPbox.

#### UPLOAD TO SOPBOX

Name	Position	Signature	Date uploaded to SOPbox
[REDACTED]	SOPbox Administrator	[REDACTED]	14 Nov 2017

The effective date of this Working Instruction is the day on which it is uploaded to SOPbox and is available to use. This is the date associated with the signature of the SOPbox Administrator.

For the Revision History please see the Version History Summary in SOPbox.

# UPLOADING TRIAL RESULTS TO EUDRACT

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**Note:** Glossary of terms, acronyms and abbreviations will be provided in a separate document for all SOPs and associated documents

The following symbols may be used in this WI:



Indicates a link to a related document



Indicates instructions to document trial-specific processes elsewhere

Throughout this document the MRC Clinical Trials Unit at UCL will be either referred to as, 'MRC CTU at UCL' or 'the unit'. In instances where neither read well in the sentence, 'the CTU' may be used.

## 1 BACKGROUND AND RATIONALE

Following the completion of a trial with a Clinical Trials Authorisation (CTA) within the European Union (MRC CTU SOP 003 – Regulatory Approval), results must be uploaded to the European Clinical Trials Database (EudraCT). Results must be uploaded within one year of the end of the trial as defined in the protocol (six months for paediatric trials). The amount of time required to obtain permission from EudraCT to upload results and the time needed to upload them should not be underestimated, and sufficient time for this to be completed within these timelines should be allowed. Obtaining permission to upload results should be done as far in advance as possible so as not to delay uploading results. Once uploaded and made public, results will be publicly available through the European Union Clinical Trials Register ([clinicaltrialsregister.eu](http://clinicaltrialsregister.eu)).

## 2 PURPOSE

The purpose of this WI is:

- To define the MRC CTU roles and responsibilities involved in uploading results to EudraCT.
- To outline the procedures for obtaining permission to upload results to EudraCT and enter results from a clinical trial on to the system.

This working instruction does not provide information on which results to upload as this will be trial-specific (decided by the Trial Statistician) but instead provides practical guidance on the process of uploading results.

### 3 RESPONSIBILITY AND ROLES

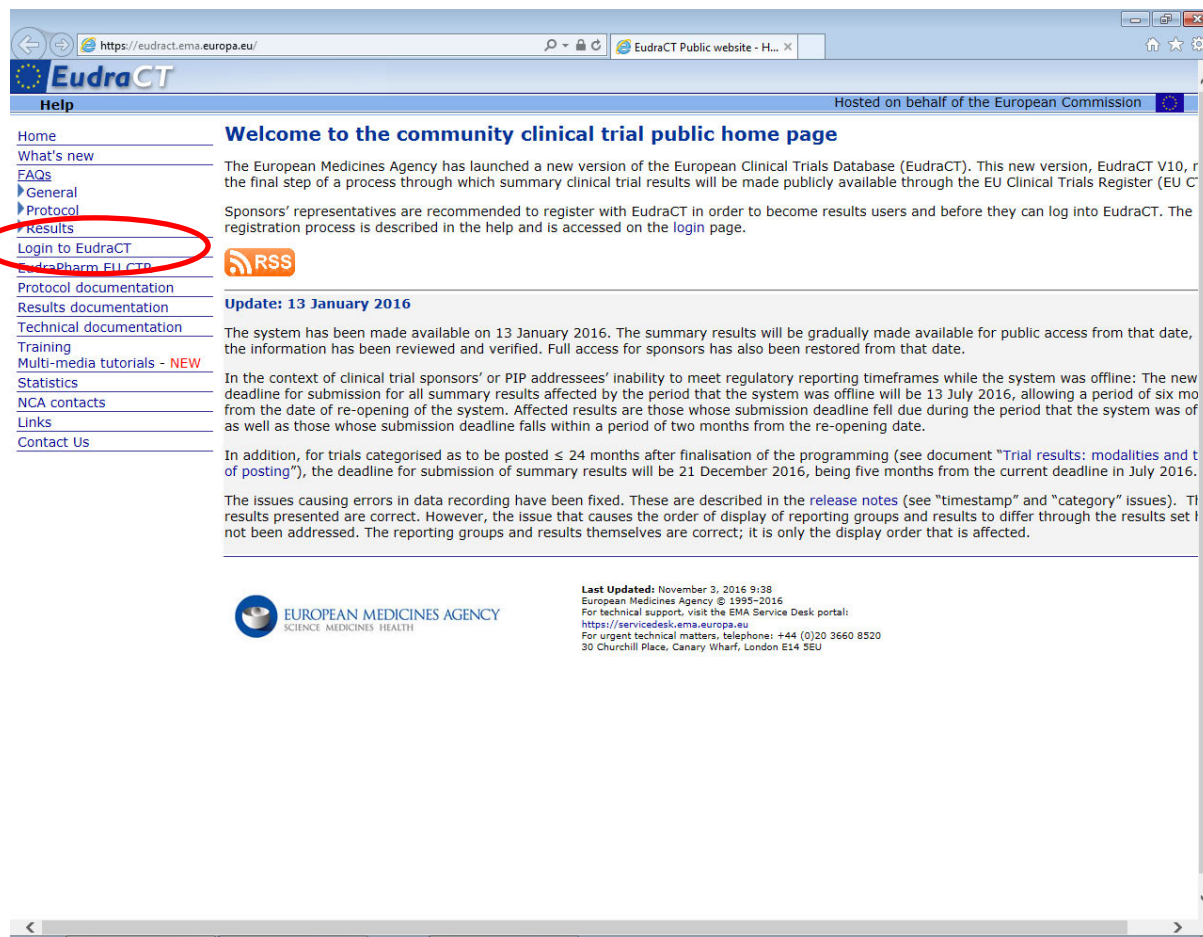
The following table lists the roles relevant to this WI and a brief description of their responsibilities.

ROLE	RESPONSIBILITIES
Trial Statistician	<ul style="list-style-type: none"> <li>• Ensuring permission to upload results to EudraCT is obtained (by Sponsor, themselves or other TMG member)</li> <li>• Posting results</li> <li>• Circulating the PDF for checking by               <ul style="list-style-type: none"> <li>○ Trial manager/data manager (trial information)</li> <li>○ An appropriately experienced statistician other than the statistician who uploaded the results against the final statistical report</li> </ul> </li> <li>• Approving making results public</li> </ul>
Trial Manager/Data Manager	<ul style="list-style-type: none"> <li>• Check trial information section of the PDF circulated by statistician. Raise any discrepancies with the statistician. The Trial/Data Manager is not responsible for checking results. This is the responsibility of an appropriately experienced statistician other than the statistician who uploaded the results</li> </ul>

Throughout this document, Trial Statistician can be replaced with Delegated Statistician as appropriate.

## 4 PROCEDURES

The EudraCT system can be accessed at <https://eudract.ema.europa.eu>. Click “Login to EudraCT” (top left of screen):

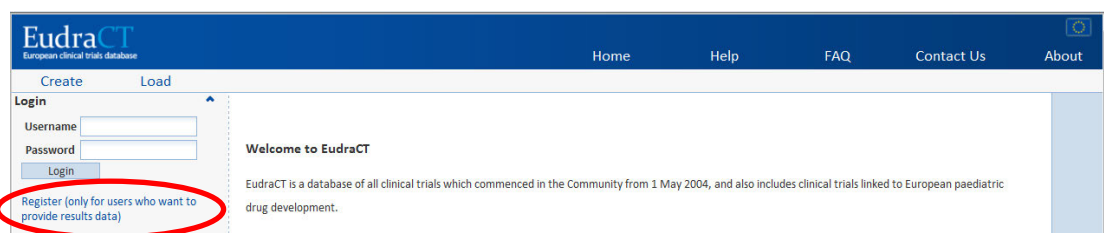


### 4.1 REGISTRATION AND BECOMING A RESULTS USER

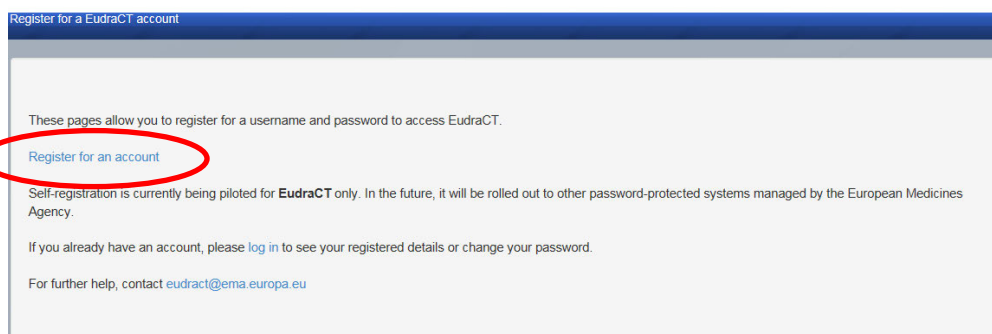
First time users need to register (section 4.1.1) and become a results user (section 4.1.2).

#### 4.1.1 REGISTRATION

1. Click “Register” (top left of screen).



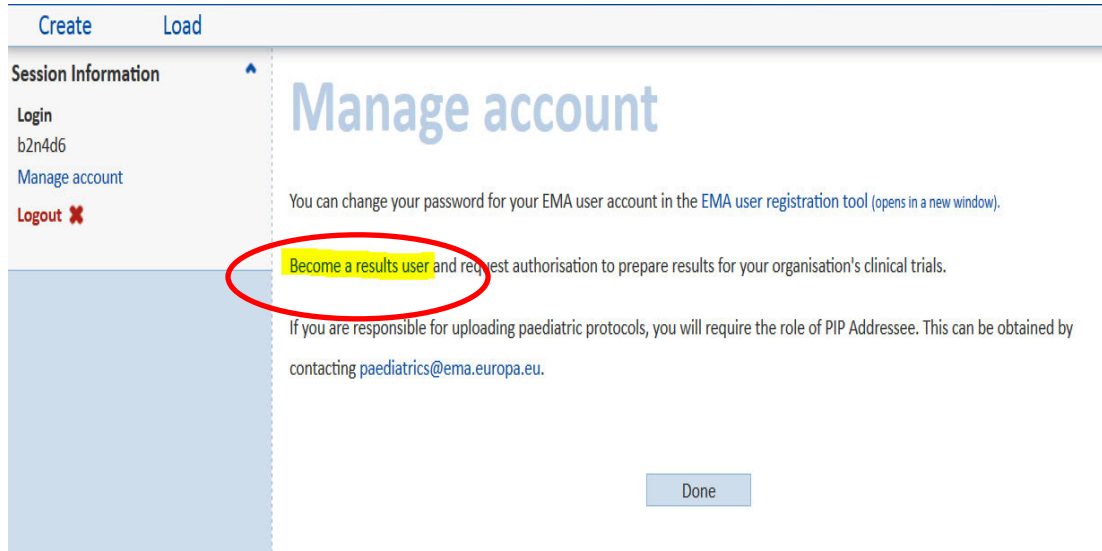
2. Click "Register for an account".



3. Accept terms and conditions.
4. Enter your MRC CTU at UCL details.
5. You will receive an email from the European Medicines Agency. Click the link, then you will receive a username and password.

#### 4.1.2 BECOME A RESULTS USER

1. Login to EudraCT, using the username and password you acquired from section 4.1.1.
2. Click “Manage account”.
3. Click “Become a results user”.



4. Accept the terms and conditions.
5. Log out and back in for changes to take place.



## 4.2 OBTAINING PERMISSION TO UPLOAD RESULTS FOR A SPECIFIC TRIAL

Once you are registered with EudraCT and a “results user,” (if not, you need to complete Section 4.1 first) obtain permission to upload results for the specific trial:

1. The simplest way to obtain this permission is to upload a letter from the Sponsor of the trial. You will need this letter before logging on. A template letter can be found in MRC CTU TT 0416 – Letter to Obtain Permission from EudraCT to Upload Trial Results. The trial name in the letter must be 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). The letter must be **signed by hand** (for trials sponsored by MRC, this can be signed by the CTU Director) and converted to .pdf ready for uploading.
2. Log on.
3. You should see the following page (if not, click on “Your page” at the top of the page):

**EudraCT**  
European clinical trials database

Home Help FAQ Contact Us

Your page Create Load

**Session Information**  
Login  
s7y6s4  
Manage account  
Logout

## Your page

Clinical trials that appear in the list below are those that in a draft state and assigned to you.

Draft results

EudraCT number	Version	Sponsor name	Friendly description	Last saved date	Status	Options
2009-013648-35	1	PENTA foundation		04-Mar-2015, 11:27:56 (s7y6s4)	Draft	<a href="#">Edit</a>   <a href="#">View</a>   <a href="#">Manage assigned users</a>

If you are required to prepare results for other clinical trials, you first need to request assignment to your user account.

4. Click “request assignment”.
5. Enter the EudraCT number of the trial you need to upload results for:

Your page Create Load

**Session Information**  
Login  
s7y6s4  
Manage account  
Logout

## Request assignment

**Step 1: Identify Trials**

EudraCT number

(max. 50 trials)

1. Enter each EudraCT number on a new line in the format xxxx-xxxxxx -xx where x is a digit.  
2. Only trials that appear in this box will be processed.  
3. Ensure the list of EudraCT numbers in this box matches those that appear in the letter supporting the request.

You will not be able to add more later in the process.

Cancel Next

6. Click “Next”.

7. Click “Request assignment to trials via letter”.
8. Enter the full title of the trial and the name of the Sponsor. Ensure the title of the trial is exactly that which the trial was registered with (usually the same as in version 1.0 of the protocol):

**Session Information**  
 Login  
 s7y6s4  
 Manage account  
 Logout

## Request assignment

**Step 3: Enter trial details**

EudraCT number	Full title of trial	Name of Sponsor organisation(s)
2009-012947-40	<div>Characters: 0/2000</div>	<div></div> <span>Delete</span>

Previous page Page 1 of 1 Next page

Cancel Back Next

9. Attach the letter (in .pdf format) from (1) above:

**Session Information**  
 Login  
 s7y6s4  
 Manage account  
 Logout

## Request assignment

**Step 4: Attach letter**

**Authorising letter**

+ Attach authorising letter

No attachments.

Supported file formats: PDF, BMP, JPG, GIF, PNG  
 Maximum file size = 5 MB

**Checklist:**

1. Ensure that all EudraCT numbers entered in this request are also mentioned in the authorising letter.
2. Ensure that all EudraCT numbers mentioned in the authorising letter are also included in this request, **otherwise they will not be considered part of the request.**
3. Ensure the attachment is a scanned image containing the required hand-written signature.

Submit request Back Cancel

10. Click “Submit request”.
11. In due course you should receive an email from EudraCT letting you know your application to upload results has been successful.
12. Each user can assign one backup user and multiple delegated results preparers and posters for each trial. It is standard CTU practice not to use this facility, but to have one user for each trial. This user usually obtains permission to upload results towards the end of the trial (but in sufficient time), as staff can change over the course of a trial.

### 4.3 UPLOADING RESULTS

The data to be entered should be similar in breadth and depth to that reported in a final publication.

If you are not registered with EudraCT (Section 4.1.1), not a “results user” (Section 4.1.2) or do not have permission to upload results for the relevant trial (Section 4.2), you need to do this first. If you are registered with EudraCT, a “results user” and have permission to upload results for that trial, when you first log on you will see a screen like the following:

Draft results

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

To add results, click on “Create”. You will then enter the index page:

The screenshot shows the EudraCT 'Index' page for trial 2009-012947-40. The page has a blue header with the EudraCT logo and navigation links (Home, Help, FAQ, Contact Us, About). Below the header is a sidebar with 'Your page', 'Create', and 'Load' tabs. The 'Create' tab is active, showing 'Session Information' (Login, s7y654, 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 'Index' and contains sections for 'Delegated users assigned to this trial', 'Modalities of posting of result-related information', and 'Summary attachments'. The 'Summary attachments' section includes an 'Attach summary' button and a list of supported formats (PDF, DOC, DOCX, RTF, TXT, PPT, PPTX, XLS, XLSX, TIFF, TIF, PNG, GIF, JPEG, JPG, BMP) with a maximum file size of 50MB per file.

The screenshot shows the EudraCT interface for uploading trial results. The top navigation bar includes 'Home', 'Help', 'FAQ', 'Contact Us', and 'About'. Below this, there are tabs for 'Your page', 'Create', and 'Load'. The 'Load' tab is active, showing a 'Full data set' section. This section contains several sub-sections for uploading data: '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). A sidebar on the left provides navigation options like 'Session Information', 'Trial details', and 'Result sections'.

This is where trial information and results are uploaded, in the following sections: trial information, subject disposition, baseline characteristics, end points, adverse events and more information. Each of these will be described in the following sections of this working instruction.

On the index page, you have the option to enter a friendly description of the trial and also to attach a summary. It is usual CTU practice to NOT attach a summary, as the results to be included in this summary would be similar in breadth and depth to those requiring uploading separately in the following sections of this working instruction.

#### 4.3.1 TRIAL INFORMATION

Some trial information, entered when the trial was being set up, may already be present in this section. Ensure all information is up-to-date.

#### 4.3.2 SUBJECT DISPOSITION

In the EudraCT system, trials are composed of periods (e.g. screening/pre-assignment, main trial).

1. First of all, enter details of the screening period. In the EudraCT system, this is referred to as the pre-assignment period, so click on "Add pre-assignment period":

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](#)

## 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](#)

[Top of Page](#)

- Enter the number of patients screened in the “Started” section.
- If there are any intermediate milestones in the screening-randomisation period, then you can enter what they were and how many subjects completed follow up until each milestone (usually not applicable at CTU).
- “Completed” is the total number randomised, so enter the total number randomised, as well as any reasons for not randomising. For example for a trial that screened 227 patients and randomised 199:

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	✖
<b>Total:</b>	<b>26</b>	

[Done](#) [Delete pre-assignment period](#)

- Click “Done”.

2. Enter subsequent periods (e.g. main trial) by repeating (a) – (f) below:

a. Click “Add period”:

The screenshot shows the EudraCT interface. On the left is a sidebar with 'Session Information' (Login, s7y6s4, 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 a top bar with 'Save', 'Discard changes', 'Validate full data set', 'Post results', 'Upload XML', 'Download XML', and 'Download PDF'. Below this is the 'Pre-assignment' section with a message: 'Please complete at least one of the screening details or the pre-assignment period below'. The 'Screening details' section is empty. Below that is a table with 'Period title' and 'Options'. The first row is 'Pre-assignment period' with 'Edit' and 'Delete' links. Below the table is the 'Periods' section, which contains a red circle around the '+ Add period' button and the text 'No periods have been specified.'.

b. Enter the name of the period that you are defining (e.g., “Main trial”).

c. If this is the first/only period (excluding the screening/pre-assignment period), tick “Is this the baseline period?”. The baseline period is the period for which baseline characteristics will be reported.

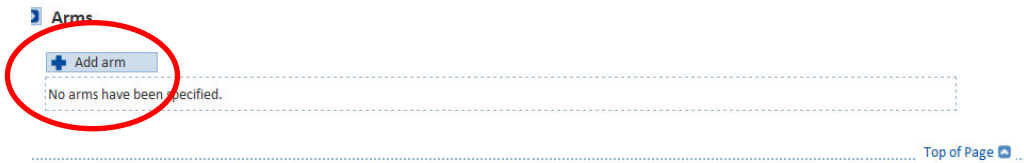
d. Enter allocation method (usually, “Randomised - controlled,” at CTU).

e. Enter details on blinding.

The screenshot shows the 'Subject disposition > Period 1' form. The 'Period details' section includes: 'Period title\*' with 'Main trial' entered; 'Is this the baseline period?' with a checked checkbox; 'Allocation method\*' with 'Randomised - controlled' selected; 'Blinding used\*' with 'Not blinded' selected; 'Roles blinded' with a list of roles (Subject, Investigator, Monitor, Data analyst, Carer) and buttons for 'Copy', 'Remove', and 'Remove All'; and 'Blinding implementation details' with a large text area. The 'Add period' button from the previous screenshot is circled in red.

f. Enter arms by repeating (i) – (iv) below:

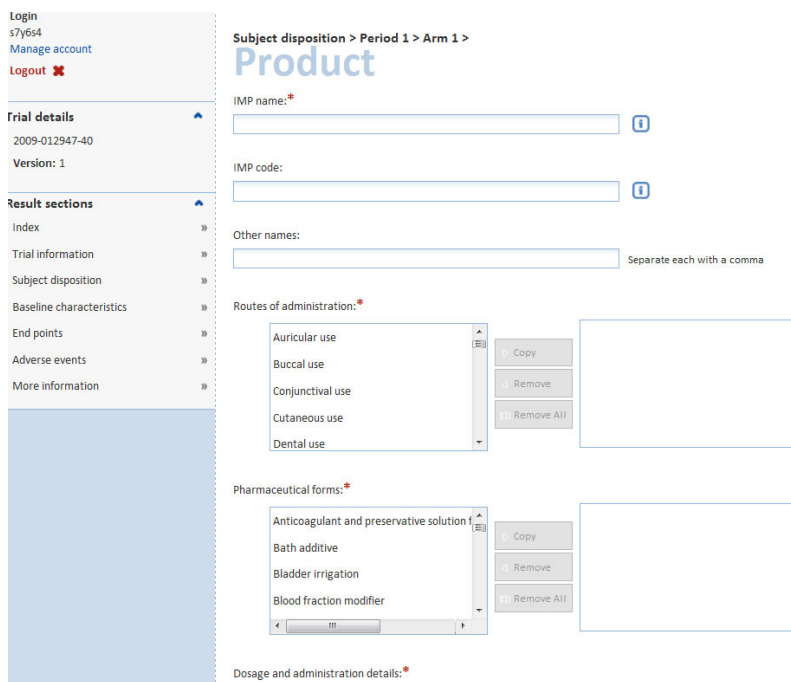
i. Click “Add arm”:



ii. Add the name and description of the arm, as well as specifying whether it is an intervention arm or otherwise.

iii. Enter medicinal products by repeating (i) – (iii) below:

i. Click “Add product”, which will take you to the following screen:



ii. Fill in as much information as possible. Take particular care with route(s) of administration, pharmaceutical form(s) and dosage.

iii. Click on “Done”.

iv. Scroll down to “Milestones” where you can enter the number of patients that started the arm, how many finished it and non-completion reasons (e.g. lost to follow up/withdrew consent). For example for an arm which had 100 people randomised but had one lost to follow up by the end of the period:

## Milestones

Number of subjects at each milestone

Started: \* Number of subjects: 100 ⓘ

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

No intermediate milestones have been defined for the period.

Completed: \* Number of subjects: 99 ⓘ

Subject non-completion reasons

Subject non-completion reason

Lost to follow-up ⓘ Number of subjects 1 +

No non-completion reasons have been specified.

Subject joining reasons

Subject joining reason

Please select... ⓘ Number of subjects +

No joining reasons have been specified.

### 4.3.3 BASELINE CHARACTERISTICS

Baseline characteristics are reported for the baseline period defined in Section 4.3.2.

1. Choose whether you would like to report the baseline characteristics by arm or overall (it is usual CTU practice to report baseline characteristics by arm):

**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](#)

2. Age characteristics:

**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	<a href="#">Edit</a> Enter values

Age continuous characteristic	Options
Age continuous Status: Not ready for collecting values	<a href="#">Edit</a> Enter values



- a. Age categorical characteristics: you will see a list of specific age categories (in utero, preterm newborn infants, newborns, infants and toddlers, children (2 – 11 years), adolescents (12 – 17 years), adults, from 65-84 years, 85 years and over). Tick “Ready for collecting values” and click “Done – start collecting values”. Enter values carefully:

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 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)

Age category title  
Add  
Remove  
Remove all

☒ 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

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: 95*
In utero	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0
Newborns (0-27 days)	0	0
Infants and toddlers (28 days-23 months)	0	0
Children (2-11 years)	25	28
Adolescents (12-17 years)	55	49
Adults (18-64 years)	20	22
From 65-84 years	0	0
85 years and over	0	0
<b>Total*</b>	<b>199</b>	
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	

Done - start collecting values

- b. Age continuous characteristic: select which units (years), the summary statistic (central tendency type, e.g. median) and measure of spread (dispersion type, e.g. inter-quartile range) you are reporting. As before, tick “Ready for collecting values” and click “Done – start collecting values”

Session Information

Login  
s7y6s4  
Manage account  
Logout

Trial details  
2009-Q12947-40  
Version: 1

Result sections

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

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

- Gender characteristics (categorical). As per age categorical characteristics, tick “Ready for collecting values” and click “Done – start collecting values”.
- You should then add study specific characteristics, for example, those in the overall baseline table for the study. There are likely to be many of these.
  - For a categorical variable, click “Add study specific categorical characteristic”. Add categories (remember to create a category – e.g. called “Not recorded” – for any subjects for whom the characteristic was not recorded), tick “Ready for collecting values” and click “Done – start collecting values”:

**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

57y654  
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

**Baseline characteristics >**  
**Study specific categorical**

Characteristic title\*  
Route of infection ⓘ

Units\*  
Subjects

Description Characters: 27/600 ⓘ  
Mode of transmission of HIV

Category title ⓘ  
Add  
Remove  
Remove all

Categories\*  
Vertical  
Sexual contact  
Blood product  
Unknown

☒ 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 Delete characteristic

- b. For a continuous variable, click “Add study specific continuous characteristic”. Select the summary statistic (central tendency type) and measure of spread (dispersion type) you will be reporting, tick “Ready for collecting values” and click “Done – start collecting values”

**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

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

Baseline characteristics >

## Study specific continuous

Characteristic title:  
Weight

Description:  
Weight at randomisation

Units:  
kilogram(s)

Central tendency type:  
median

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

☒ Ready for collecting values

Done - continue defining characteristics
Done - start collecting values
Delete characteristic

#### 4.3.4 END POINTS

1. Click “Add end point”.
2. Enter endpoint title, whether it is countable or measurable (*either* countable *or* measurable must be selected), units (if measurable, measure and precision/dispersion types must also be selected), whether it is primary/secondary/other/post-hoc and the time frame (e.g. “any time from randomisation to 48 weeks after randomisation”). The optional description field should be used if the full definition of the endpoint is not completely clear from the other details entered.

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

End points >

## End point definition

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

Countable or measurable?  
☒ Countable  
☐ Measurable

Countable units:  
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.

3. If the data for the end point can be categorised, add categories (e.g. “Reached endpoint”, and “Did not reach endpoint”, but more descriptive names can also be used). Create a

category – e.g. called “Not recorded” – for any subjects for whom the end point was not recorded.

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

4. Select the periods and arms (as defined in Section 4.3.2 – Subject Disposition) you will be reporting for:

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) <a href="#">Select all arms</a>	<input checked="" type="checkbox"/> Arm: Short Cycle Therapy

5. Tick “Ready for collecting values”.
6. Click “Done – start collecting values”
7. Enter values carefully. For each period/arm, first specify the number of subjects analysed. For a countable end point, enter the number of individuals in each period/arm that are in each category defined in (3) above:

Reporting group 1	Continuous therapy
Reporting group 2	Short Cycle Therapy

Reporting group 1		Reporting group 2	
Subjects analysed: unspecified		Subjects analysed: unspecified	
<a href="#">Edit</a> *		<a href="#">Edit</a> *	
Reached endpoint		Reached endpoint	
Count: <input type="text"/>		Count: <input type="text"/>	
Did not reach endpoint		Did not reach endpoint	
Count: <input type="text"/>		Count: <input type="text"/>	

8. You will then have the option to add some statistical analyses for the endpoint. You must add one at a time and follow the self-explanatory guidance after clicking in “Add statistical analysis”.

### 4.3.5 ADVERSE EVENTS

Serious adverse events (SAEs) and non-serious adverse events are reported separately.

1. Enter in the overall timeframe for adverse event reporting in the trial (e.g. “any time from randomisation to 48 weeks after randomisation”), assessment type (systematic/non-systematic), threshold frequency for reporting non-serious adverse events (all = 0), dictionary name (e.g. MedDRA) and version:

#### 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

2. Serious adverse events:

- a. Click “Add serious adverse event”.
- b. For example for the serious adverse event of headache, enter the system organ class and event term (e.g. as per MedDRA dictionary) and assessment type (systematic/non-systematic):

#### 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:

- c. Subjects affected = number of subjects with one or more event; subjects exposed = number of subjects; occurrences = number of events; occurrences causally related to treatment = number of events causally related to treatment; fatalities = number of fatalities; fatalities causally related to treatment = number of fatalities causally related to treatment. For example, 3 events in 2/100 subjects would be entered as 2 subjects affected, 100 subjects exposed and 3 occurrences. If 0/3 occurrences were causally related to treatment, occurrences causally related to treatment would be entered as 0. 0 fatalities would be entered as 0 fatalities and 0 fatalities causally related to treatment.

**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	0	100	1	0	0	0
Short Cycle Therapy	1	99	0	0	0	0

3. Non-serious adverse events:

- a. Click “Add non-serious adverse event”.
- b. For example for the non-serious adverse event of measles, enter the system organ class and event term (e.g. as per MedDRA dictionary) and assessment type (systematic/non-systematic):

**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:

- c. Subjects affected = number of subjects with one or more event; subjects exposed = number of subjects; occurrences = number of events. For example, 3 events in 2/100 subjects would be entered as 2 subjects affected, 100 subjects exposed and 3 occurrences.

**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

#### 4.3.6 MORE INFORMATION

Enter whether there were any global substantial amendments to the protocol, interruptions to the trial, limitations and caveats applicable to this summary of results and references to publications of interest in regards to the results of this clinical trial.

### More information

**Substantial protocol amendments (globally)**

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

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 ?

Add global interruption

No interruptions have been specified.

Top of Page

**Limitations and caveats**

Limitations and caveats applicable to this summary of the results

Top of Page

**Online references**

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

#### 4.4 CHECKING TRIAL INFORMATION AND RESULTS

Return to the index page (Section 4.3) and download a PDF of all the trial information and results (in the top-right hand corner of the screen). As per Section 3 (responsibility and roles), an appropriately experienced statistician other than the statistician who uploaded the results is responsible for checking results from the PDF against the final statistical report (raising any discrepancies with the statistician who uploaded the results). The Trial Manager/Data Manager is responsible for checking the trial information section of the PDF (raising any discrepancies with the statistician who uploaded the results). The Trial/Data Manager is not responsible for checking results.

#### 4.5 APPROVING MAKING RESULTS PUBLIC

Every effort should be made to ensure the main trial results are published (in the public domain) prior to posting the results on the EudraCT website. When the uploaded results have been checked and amended as necessary, go to the index page (Section 4.3) and click, “post results,” (top of the screen). Follow the instructions.

Once the results have been uploaded, ask your Trial Manager to send a short confirmatory email to CT.Submission@mhra.gsi.gov.uk, with ‘End of trial study report: EudraCT XXXX-XXXXXX-XX’ as the subject line (MRC CTU SOP 014 – Trial Reporting and Communication).