



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EudraCt – Results Webinar # 2

Presented by Tim Buxton on 27 January 2016

IT Service Strategy Manager, IT Operations

An agency of the European Union





Instructions for sponsors

Frequently asked questions



Timeline

13 January 2016

- Date from which EudraCT – Results system is available
- Posting and publication process operational

13 March 2016

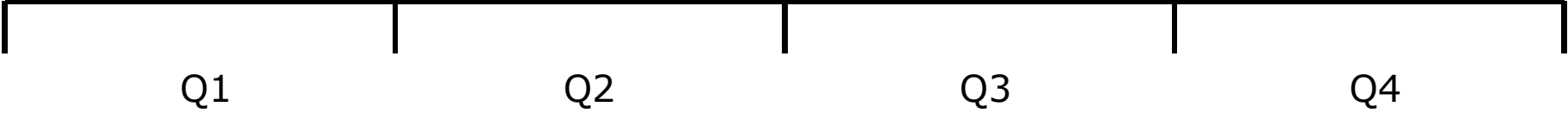
- Results sets falling due after this date (except those for trials categorised as to be posted \leq 24 months after finalisation of the programming) should comply with the modalities and timing of trial results

21 December 2016

- Deadline for submission of summary results for trials categorised as to be posted \leq 24 months after finalisation of the programming (see document [Trial results: modalities and timing of posting](#), published on the EudraCT website)

13 July 2016

- Date by which results sets affected by the system closure are to have been posted.





Activities necessary to return to normal operation

- Review by sponsors of trial results sets within the system leading to:
 - Correction where needed by the sponsor
 - Authorisation to EMA to restore results sets to public view where no correction is needed
- Submission of data
 - Affected results sets
 - Results for trials categorised as to be posted ≤ 24 months after finalisation of the programming



Affected results sets

- Results sets that were posted, published and removed from public view as of 31 July 2015
- Results sets that had been posted but not yet published as of 31 July 2015
- Results sets that fell due in the period that the system was closed (31 July 2015 to 12 January 2016)
- Results sets that fall due in the two months following re-opening of the system (13 January 2016 to 13 March 2016)



Resources: Schedule of trials assigned to a primary user

User	Name	EudraCT No.	Published	Potential timestamp issues	Potential category issues	Data correction applied	State
Ronald.Held@FictitiousPharma.com	a1a1a1	2013-001234-39	Public	Yes	No	No	FINALIZED
Ronald.Held@FictitiousPharma.com	a1a1a1	2015-001234-27	Public	No	Yes	No	FINALIZED
Ronald.Held@FictitiousPharma.com	a1a1a1	2015-001235-28	Public	No	No	Yes	FINALIZED
Ronald.Held@FictitiousPharma.com	a1a1a1	2011-001234-26	Public	Yes	Yes	Yes	FINALIZED
Ronald.Held@FictitiousPharma.com	a1a1a1	2012-001234-70	Not public	No	No	No	FINALIZED
Ronald.Held@FictitiousPharma.com	a1a1a1	2010-000123-68	Not public	Yes	Yes	No	DRAFT
Ronald.Held@FictitiousPharma.com	a1a1a1	2011-000012-13	Not public	Yes	No	Yes	DRAFT



Resources: Release notes for version 10.2.1.0

- Summary of release 10.2.1.0
 - Major items fixed in release 10.2.1.0
 - Known issue in release 10.2.1.0
- Full release contents – Issues fixed
- Known errors
- New Validation Violation Messages (for XML upload) in EudraCT - Results 10.2.1.0
- Additional information
- Installation steps deviating from the deployment guide



Trials potentially affected by timestamp issues

Reporting groups

Reporting group 1	Arm 1 of Period 1
Reporting group 2	Arm 2 of Period 1
Reporting group 3	Arm 3 of Period 1

Reporting group 1		Reporting group 2		Reporting group 3	
Subjects analysed: 6		Subjects analysed: 15		Subjects analysed: 24	
<input type="button" value="Edit"/> *		<input type="button" value="Edit"/> *		<input type="button" value="Edit"/> *	
category 1	Count: <input type="text" value="1"/>	category 1	Count: <input type="text" value="4"/>	category 1	Count: <input type="text" value="7"/>
category 2	Count: <input type="text" value="2"/>	category 2	Count: <input type="text" value="5"/>	category 2	Count: <input type="text" value="8"/>
category 3	Count: <input type="text" value="3"/>	category 3	Count: <input type="text" value="6"/>	category 3	Count: <input type="text" value="9"/>

Reporting groups

Reporting group 1	Arm 1 of Period 1
Reporting group 2	Arm 2 of Period 1
Reporting group 3	Arm 3 of Period 1

Reporting group 1		Reporting group 2		Reporting group 3	
Subjects analysed: 6		Subjects analysed: 15		Subjects analysed: 24	
<input type="button" value="Edit"/> *		<input type="button" value="Edit"/> *		<input type="button" value="Edit"/> *	
category 1	Count: <input type="text" value="1"/>	category 1	Count: <input type="text" value="7"/>	category 1	Count: <input type="text" value="4"/>
category 2	Count: <input type="text" value="2"/>	category 2	Count: <input type="text" value="8"/>	category 2	Count: <input type="text" value="5"/>
category 3	Count: <input type="text" value="3"/>	category 3	Count: <input type="text" value="9"/>	category 3	Count: <input type="text" value="6"/>





Trials potentially affected by category issues

Reporting groups

Reporting group 1	Experimental for Arm 1
Reporting group 2	Experimental for Arm 2

Reporting group 1 Subjects analysed: 30 <input type="button" value="Edit"/> *	Reporting group 2 Subjects analysed: 30 <input type="button" value="Edit"/> *
Strain 22/46 - Baseline Test number: <input type="text" value="40"/> confidence interval: 95% <input type="text" value="20"/> to: <input type="text" value="70"/>	Strain 22/46 - Baseline Test number: <input type="text" value="50"/> confidence interval: 95% <input type="text" value="30"/> to: <input type="text" value="90"/>
Strain 22/46 - Post 1st Vaccination number: <input type="text" value="35"/> confidence interval: 95% <input type="text" value="25"/> to: <input type="text" value="69"/>	Strain 22/46 - Post 1st Vaccination number: <input type="text" value="47"/> confidence interval: 95% <input type="text" value="35"/> to: <input type="text" value="77"/>
Strain 22/46 - Post 2nd Vaccination number: <input type="text" value="30"/> confidence interval: 95% <input type="text" value="25"/> to: <input type="text" value="50"/>	Strain 22/46 - Post 2nd Vaccination number: <input type="text" value="45"/> confidence interval: 95% <input type="text" value="30"/> to: <input type="text" value="60"/>
Strain 22/46 - Post 3rd Vaccination number: <input type="text" value="26"/> confidence interval: 95% <input type="text" value="25"/> to: <input type="text" value="28"/>	Strain 22/46 - Post 3rd Vaccination number: <input type="text" value="30"/> confidence interval: 95% <input type="text" value="30"/> to: <input type="text" value="45"/>

Reporting groups

Reporting group 1	Experimental for Arm 1
Reporting group 2	Experimental for Arm 2

Reporting group 1 Subjects analysed: 30 <input type="button" value="Edit"/> *	Reporting group 2 Subjects analysed: 30 <input type="button" value="Edit"/> *
Strain 22/46 - Baseline Test number: <input type="text" value="40"/> confidence interval: 95% <input type="text" value="25"/> to: <input type="text" value="28"/>	Strain 22/46 - Baseline Test number: <input type="text" value="50"/> confidence interval: 95% <input type="text" value="30"/> to: <input type="text" value="45"/>
Strain 22/46 - Post 1st Vaccination number: <input type="text" value="35"/> confidence interval: 95% <input type="text" value="20"/> to: <input type="text" value="70"/>	Strain 22/46 - Post 1st Vaccination number: <input type="text" value="47"/> confidence interval: 95% <input type="text" value="30"/> to: <input type="text" value="90"/>
Strain 22/46 - Post 2nd Vaccination number: <input type="text" value="30"/> confidence interval: 95% <input type="text" value="25"/> to: <input type="text" value="69"/>	Strain 22/46 - Post 2nd Vaccination number: <input type="text" value="45"/> confidence interval: 95% <input type="text" value="35"/> to: <input type="text" value="77"/>
Strain 22/46 - Post 3rd Vaccination number: <input type="text" value="26"/> confidence interval: 95% <input type="text" value="25"/> to: <input type="text" value="50"/>	Strain 22/46 - Post 3rd Vaccination number: <input type="text" value="30"/> confidence interval: 95% <input type="text" value="30"/> to: <input type="text" value="60"/>



Trials where an automated process has been run to eliminate duplicated non-completion or joining reasons

User	EudraCT Number	Period Title	Arm Title	Reason ID 1	Reason ID 2	No. of Subjects
Ronald.Held@FictitiousPharma.com	2013-001234-39	Phase 1 and Phase 2	Phase 2 Arm C - 40 mg Fictilion	15982		8
Ronald.Held@FictitiousPharma.com	2015-001234-27	Phase 1 and Phase 2	Phase 2 Arm A - 20 mg Fictilion	15982		5
Ronald.Held@FictitiousPharma.com	2015-001235-28			22756		2

Type or text	Subject disposition ID	Period	Reason category
Adverse event	5571	Post-Assignment	Not completed reason having type "Other" with same other reason text
Adverse event	5571	Post-Assignment	Not completed reason having type "Other" with same other reason text
106, Consent withdrawn by subject	11872	Pre-Assignment	Not completed Reason whose type is not "Other" (but from the specified list in R_TERMS table)



Restore status and return to public view process

Notifications

- Sponsor notification to EMA: Finalized results set in the system is correct
- EMA notification to sponsor: Status of finalized results set is restored

Published messages:

- Messages removed:
 - *"Removed from public view"*
 - *"These results have been removed from public view whilst they are reviewed and may need to be corrected before being returned to public view"*



Tagging of superseded versions of results sets that included affected data

Notifications

- Sponsor notification to EMA: New version of finalized results set containing corrected data
- EMA notification to sponsor: Superseded versions tagged

Published messages

- Messages removed:
 - *"Removed from public view"*
 - *"These results have been removed from public view whilst they are reviewed and may need to be corrected before being returned to public view"*
- New message:
 - *"Due to a system error, the data reported in version [v1] is not correct and has been removed from public view"*



Tagging of results sets submitted in compliance with revised timelines

Notifications

- Sponsor notification to EMA: Results set submitted in compliance with revised timelines
- EMA notification to sponsor: Results set submitted in compliance with revised timelines tagged

Published message

- New message:
 - *"Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines"*



Communications 1 of 2

- For the formal notifications outlined in the Instructions for sponsors; and
- The acknowledgement of the email with the Instructions for sponsors:

Use: EudraCT-R@ema.europa.eu

- For **all** other queries related to EudraCT – Results and this exercise until 31 January 2016, please use:

eudract@ema.europa.eu



Communications 2 of 2

From 1 February 2016

- New self-service portal for all technical IT requests and issues in relation to EMA supported IT systems.
 - Replaces functional email addresses on EMA webpages
- Use EudraCT username & password to log in to portal
- If not registered for EudraCT or one of most other EMA hosted systems, create a new account (automated process)

Transition

- Incidents or service requests logged before 1 February managed to closure using previous process
- Existing support email addresses will not be monitored - automated response including a link to the new portal.



Instructions for sponsors

Frequently asked questions



Principles of user management: EudraCT - Results

- Initial assignment of primary user by EMA following sponsor request
- User management during drafting under the control of the sponsor
- Both a primary user and a backup user should be assigned to each trial
 - Both have user assignment rights – risk reduction for leavers
- Where a user leaves a company
 - Primary/backup user to remove assignments to trials
 - EMA to be informed



User management: Finalized trials

- EudraCT – Results does not permit any changes to users (primary, backup or delegated) assigned to a finalized results set
- “Updating” a finalized results set creates a new draft version, re-enabling the capability to assign users
- Where a sponsor wishes to assign delegated users to review a finalized trial, the primary user should
 - Create a new version
 - Assign the (delegated) users
 - Leave the draft version as draft until a revised version is needed
- ¹⁷ Where a new primary user is needed, contact EMA



Restoration to public view: Sponsor notifications 1 of 2

Finalized results as of 31 July 2015:

- No correction needed
 - Section 8.1: Finalized results set in the system is correct
- Correction needed:
 - Section 8.3: New version of finalized results set containing corrected data

Draft results “posted”:

- Affected results or categorised as to be posted \leq 24 months after finalisation of the programming
- Section 8.5: Results set submitted in compliance with revised timelines



Restoration to public view: Sponsor notifications 2 of 2

Finalized results as of 31 July 2015:

- No correction needed
- Sponsor wishes to create a new version for other reasons
 - Section 8.3: New version of finalized results set containing corrected data
 - Note that the correction is unrelated to errors in EudraCT – Results
- EMA will restore previous versions, removing messages
- Previous versions will therefore be visible



Trials with summary only 1 of 3

Session Information

Login
x4x4p9
[Manage account](#)
Logout

Trial details

0004-001530-17
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

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](#)

Instructions for Sponsors/Instructions for Sponsors.docx

Supported formats: PDF, DOC, DOCX, RTF, TXT, PPT, PPTX, XLS, XLSX, TIFF, TIF, PNG, GIF, JPEG, JPG, BMP



Trials with summary only 2 of 3

Your page Create Load

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

Session Information ^

Login
x4x4p9
[Manage account](#)
Logout ✕

Trial details ^

0004-001530-17
Version: 1

Result sections ^

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

Post results >

Composition

This version of the results for this clinical trial is composed of only a summary provided as one or more attachments and does not contain the full data set. If you wish to continue with the posting process, proceed. Otherwise, cancel and amend the composition of the results.

[Proceed](#) [Cancel, return to index](#)



Trials with summary only 3 of 3

Your page Create Load

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

Session Information ▲
Login
x4x4p9
Manage account
Logout ✕

Trial details ▲
0004-001530-17
Version: 2

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

Post results >
Modality of posting

You will now be asked up to 4 questions about the clinical trial. Provide an answer to each question to ascertain whether the modality of posting used (one or more summary attachments only) is permitted.

- Is this clinical trial part of an agreed paediatric investigation plan (PIP)? **No**
- Does article 45 of Regulation (EC) No 1901/2006 apply to this trial? **No**
- Does article 46 of Regulation (EC) No 1901/2006 apply to this trial? **No**
- When was the global end of the trial? **11/01/2011**

Previous Cancel, return to index Next



XML download

- XML download from EudraCT – Results is possible while the results are draft
- It is not possible to download XML from the system for finalized results