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EudraCt – Results Webinar # 3

Presented by Tim Buxton on 03 February 2016

IT Service Strategy Manager, IT Operations

An agency of the European Union

Instructions for sponsors

Frequently asked questions

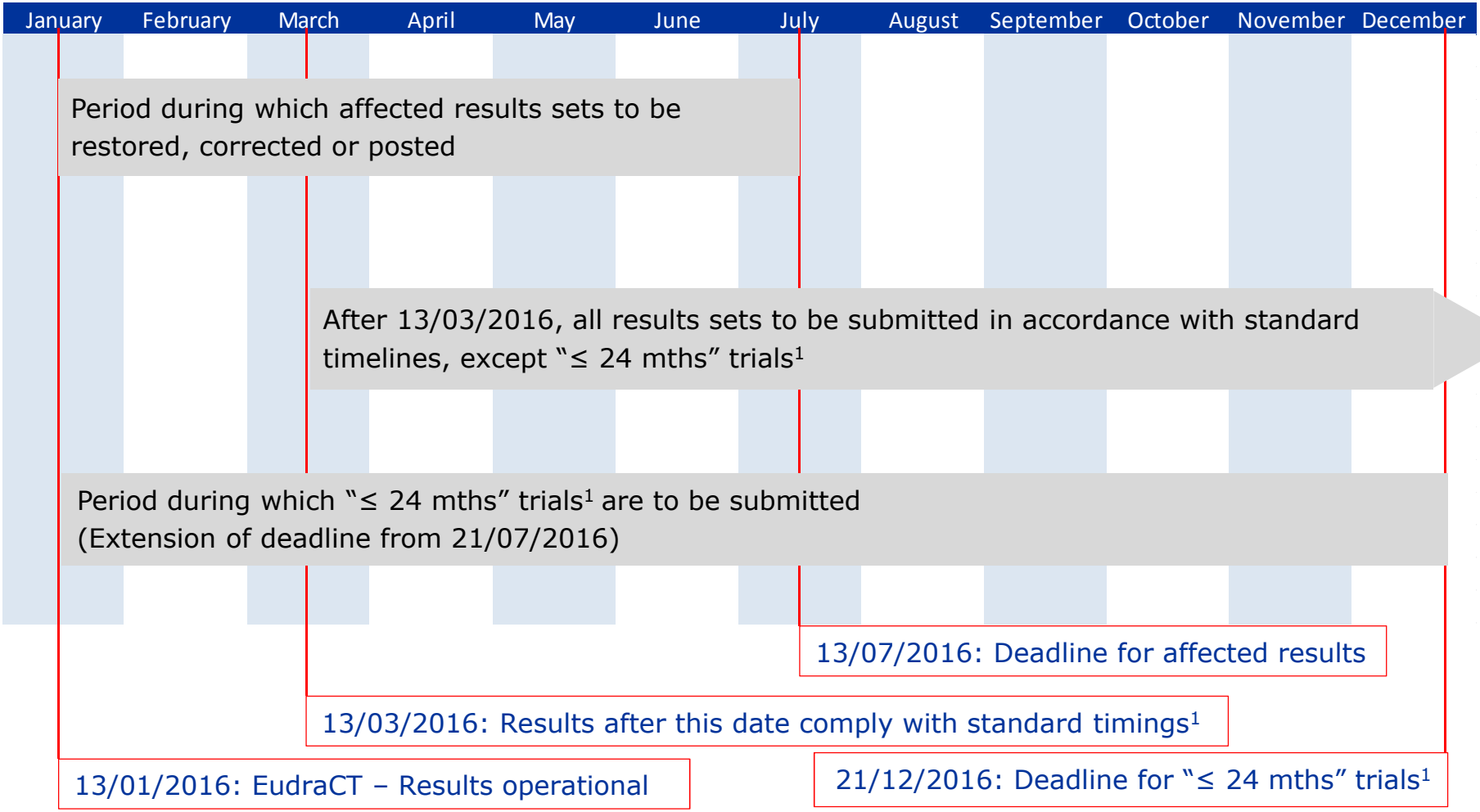
Instructions to sponsors
Main sections

- Timelines
- Status on re-opening of the system
- Review by sponsors of trial results sets within the system
- Posting of results sets due between 31 July 2015 and 13 March 2016
- Posting of results sets due after 13 March 2016
- EMA processes
- Notification processes

Timeline 1 of 2

Date	Observation
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 ≤ 24 months after finalisation of the programming) should comply with the modalities and timing of trial results
13 July 2016 *"Affected results sets"*	• Date by which results sets affected by the system closure are to have been posted. Results sets affected by the system closure comprise: ○ 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)
21 December 2016	• Deadline for submission of summary results for trials categorised as to be posted ≤ 24 months after finalisation of the programming (see document "*Trial results: modalities and timing of posting*" published on the EudraCT website) - ***("≤ 24 mths" trials)***

Timeline 2 of 2



[1]See document "Trial results: modalities and timing of posting" published on the EudraCT website

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

Resources: Schedule of trials assigned to a primary user

User	Name	EudraCT No.	Published	Potential timestamp issue	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

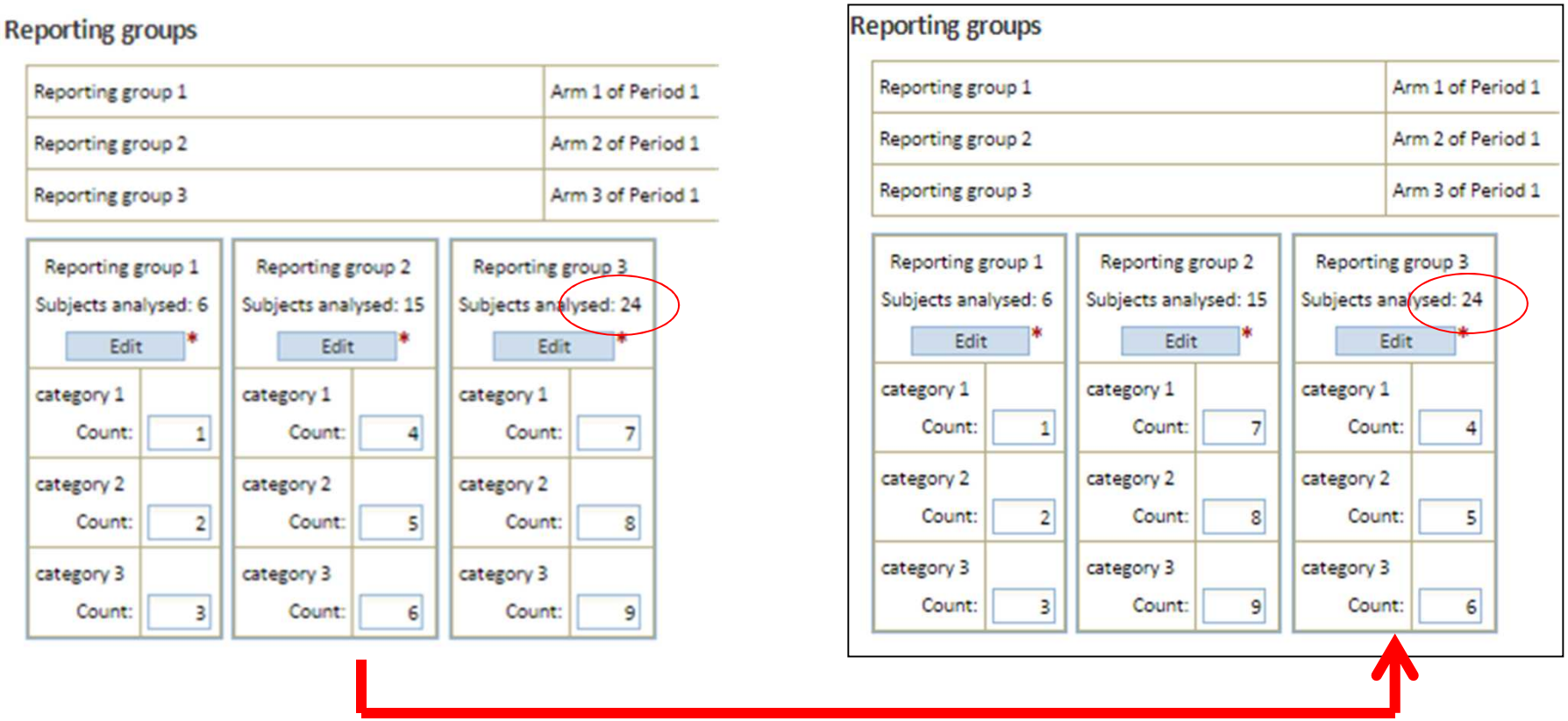
Note:

- "Yes" means symptoms have been identified that indicated that an error in the relevant classification may have occurred
- "Yes" in the Potential issue columns does **not** mean that there will ***always*** be such an error present

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
Edit *	Edit *	Edit *
category 1 Count: 1	category 1 Count: 4	category 1 Count: 7
category 2 Count: 2	category 2 Count: 5	category 2 Count: 8
category 3 Count: 3	category 3 Count: 6	category 3 Count: 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
Edit *	Edit *	Edit *
category 1 Count: 1	category 1 Count: 7	category 1 Count: 4
category 2 Count: 2	category 2 Count: 8	category 2 Count: 5
category 3 Count: 3	category 3 Count: 9	category 3 Count: 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 Edit	Reporting group 2 Subjects analysed: 30 Edit
Strain 22/46 - Baseline Test	**Strain 22/46 - Baseline Test**
number: 40	number: 50
confidence interval: 95% 20 to: 70	confidence interval: 95% 30 to: 90
Strain 22/46 - Post 1st Vaccination	**Strain 22/46 - Post 1st Vaccination**
number: 35	number: 47
confidence interval: 95% 25 to: 69	confidence interval: 95% 35 to: 77
Strain 22/46 - Post 2nd Vaccination	**Strain 22/46 - Post 2nd Vaccination**
number: 30	number: 45
confidence interval: 95% 25 to: 50	confidence interval: 95% 30 to: 60
Strain 22/46 - Post 3rd Vaccination	**Strain 22/46 - Post 3rd Vaccination**
number: 26	number: 30
confidence interval: 95% 25 to: 28	confidence interval: 95% 30 to: 45

Reporting groups

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

Reporting group 1 Subjects analysed: 30 Edit	Reporting group 2 Subjects analysed: 30 Edit
Strain 22/46 - Baseline Test	**Strain 22/46 - Baseline Test**
number: 40	number: 50
confidence interval: 95% 25 to: 28	confidence interval: 95% 30 to: 45
Strain 22/46 - Post 1st Vaccination	**Strain 22/46 - Post 1st Vaccination**
number: 35	number: 47
confidence interval: 95% 20 to: 70	confidence interval: 95% 30 to: 90
Strain 22/46 - Post 2nd Vaccination	**Strain 22/46 - Post 2nd Vaccination**
number: 30	number: 45
confidence interval: 95% 25 to: 69	confidence interval: 95% 35 to: 77
Strain 22/46 - Post 3rd Vaccination	**Strain 22/46 - Post 3rd Vaccination**
number: 26	number: 30
confidence interval: 95% 25 to: 50	confidence interval: 95% 30 to: 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)

Processes

- For results sets finalised as at 31 July 2016
  - Restore status and return to public view
  - Create new version to correct data affected by the system
- For results sets in draft, or not assigned as at 31 July 2016
  - Submit in compliance with revised timelines[1]

- Submit in accordance with standard timelines

[1]Where, due to unavailability of the system, sponsors are or have been unable to comply with the standard timelines

◆ Review
◆ Correct
◆ Notify EMA

Restore status and return to public view process

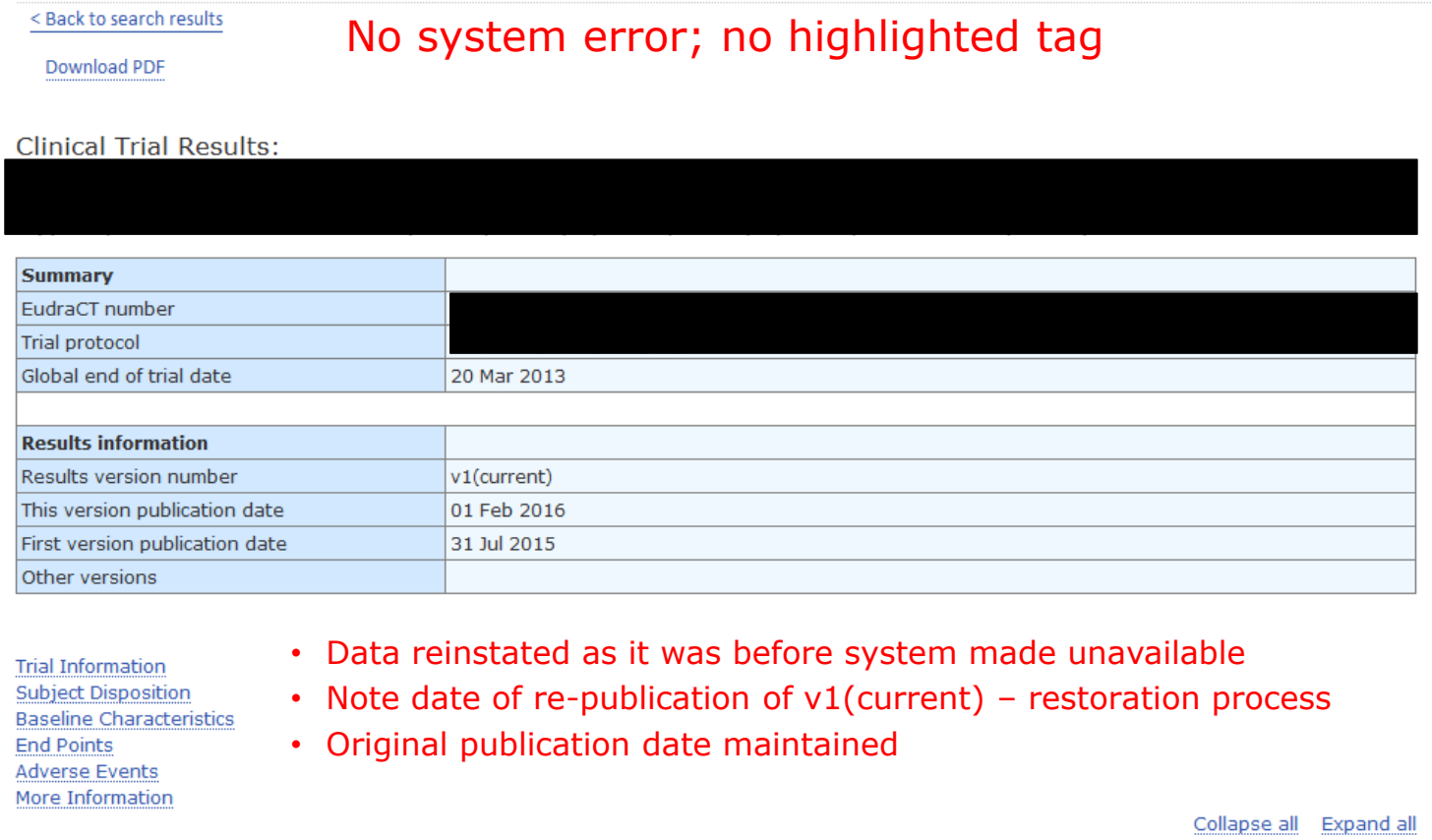
Notifications

- 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"*

Outcome of restore status and return to public view (section 7.1 Instructions to sponsors)



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No system error; no highlighted tag

Clinical Trial Results:

[redacted]

Summary	
EudraCT number	[redacted]
Trial protocol	
Global end of trial date	20 Mar 2013
Results information	
Results version number	v1(current)
This version publication date	01 Feb 2016
First version publication date	31 Jul 2015
Other versions	

Trial Information
Subject Disposition
Baseline Characteristics
End Points
Adverse Events
More Information

- Data reinstated as it was before system made unavailable
- Note date of re-publication of v1(current) – restoration process
- Original publication date maintained

Collapse all Expand all

Tagging of superseded versions of results sets that included affected data

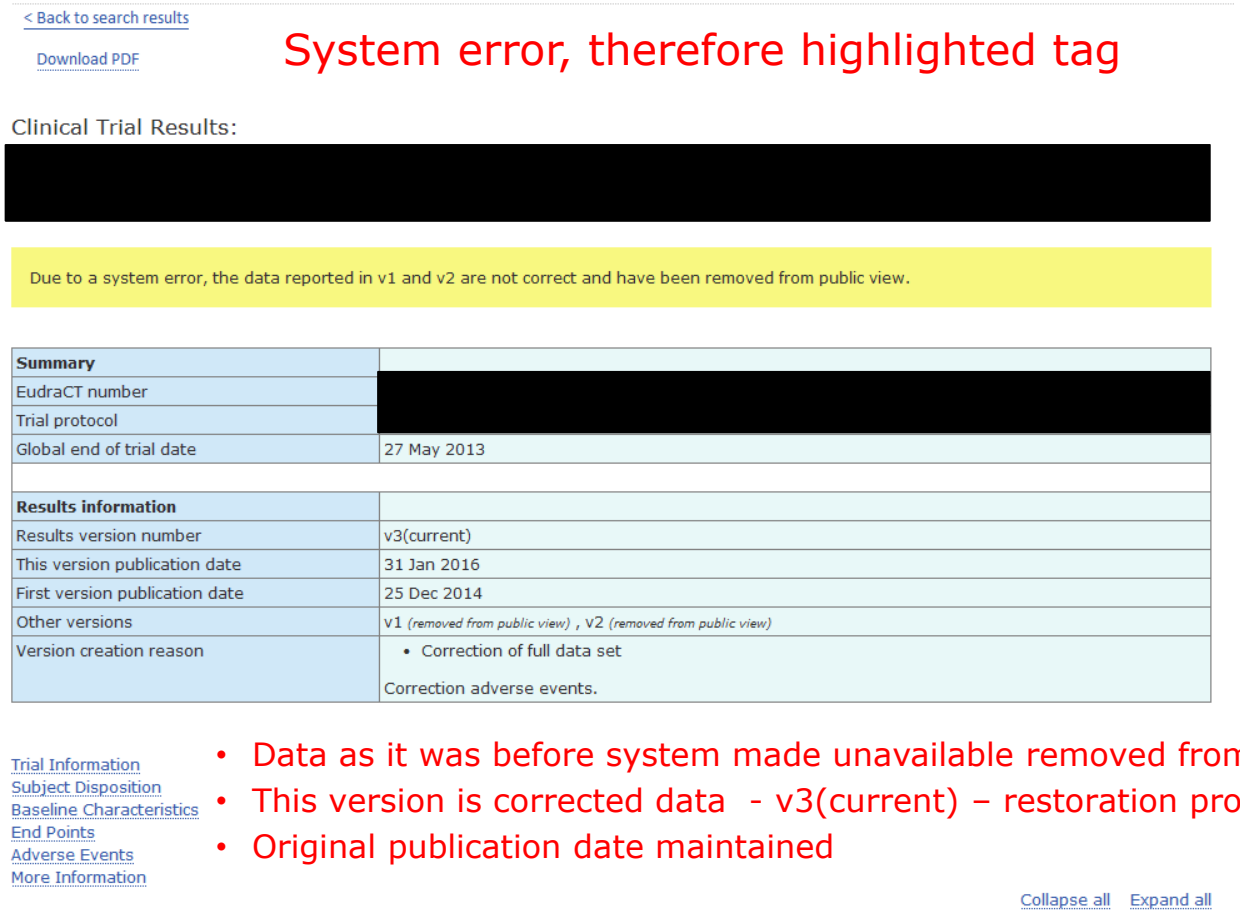
Notifications

- 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"*

Outcome of tagging of superseded versions of affected data (s7.2 Instructions to sponsors)



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System error, therefore highlighted tag

Clinical Trial Results:

[redacted]

Due to a system error, the data reported in v1 and v2 are not correct and have been removed from public view.

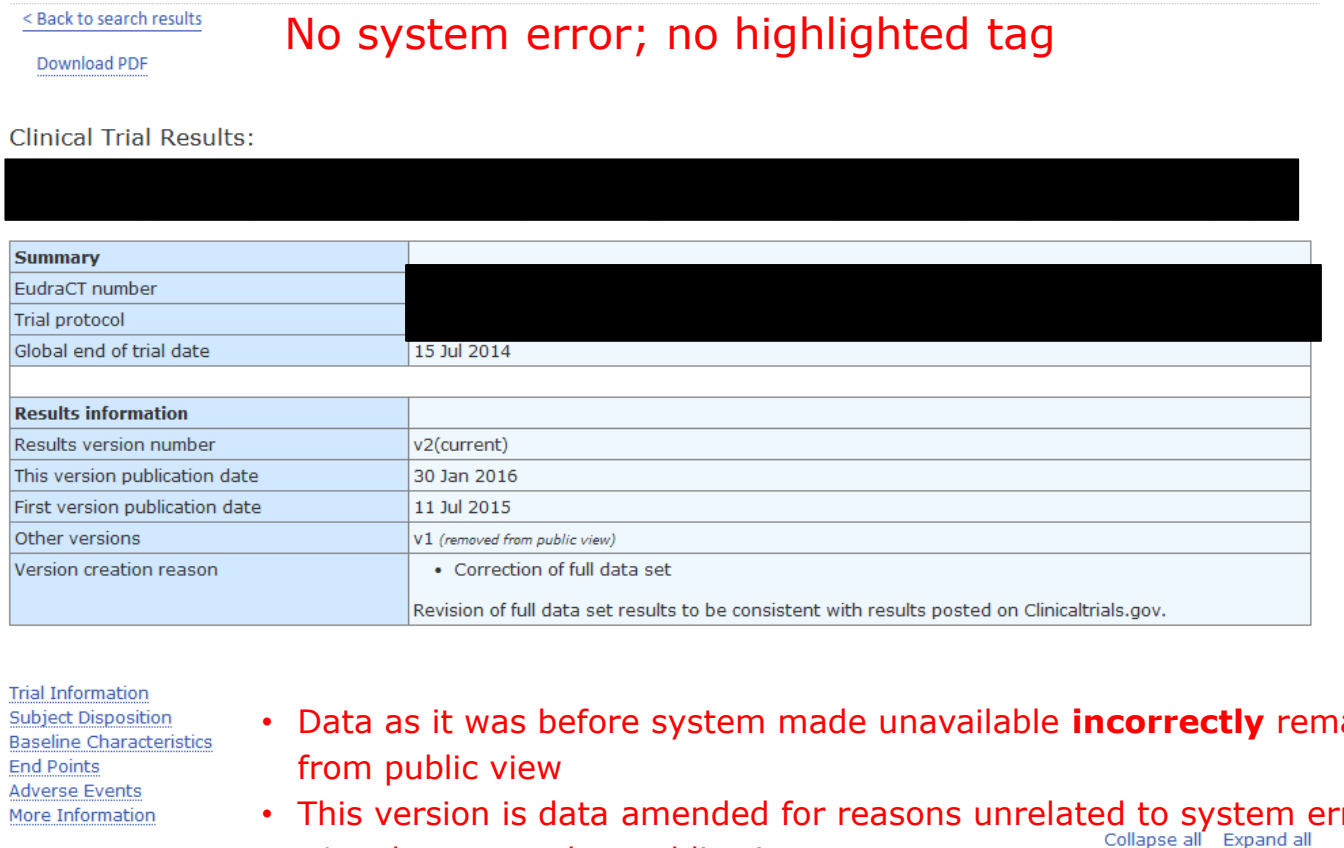
Summary	
EudraCT number	[redacted]
Trial protocol	
Global end of trial date	27 May 2013
Results information	
Results version number	v3(current)
This version publication date	31 Jan 2016
First version publication date	25 Dec 2014
Other versions	v1 *(removed from public view)* , v2 *(removed from public view)*
Version creation reason	• Correction of full data set Correction adverse events.

Trial Information
Subject Disposition
Baseline Characteristics
End Points
Adverse Events
More Information

- Data as it was before system made unavailable removed from public view
- This version is corrected data - v3(current) – restoration process
- Original publication date maintained

Collapse all Expand all

Outcome: No tagging of superseded versions of affected data (s7.2 Instructions to sponsors)



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No system error; no highlighted tag

Clinical Trial Results:

[redacted]

Summary	
EudraCT number	[redacted]
Trial protocol	
Global end of trial date	15 Jul 2014
Results information	
Results version number	v2(current)
This version publication date	30 Jan 2016
First version publication date	11 Jul 2015
Other versions	v1 *(removed from public view)*
Version creation reason	• Correction of full data set Revision of full data set results to be consistent with results posted on Clinicaltrials.gov.

Trial Information
Subject Disposition
Baseline Characteristics
End Points
Adverse Events
More Information

Collapse all Expand all

- Data as it was before system made unavailable **incorrectly** remains removed from public view
- This version is data amended for reasons unrelated to system error; therefore v1 to be restored to public view
- Original publication date maintained

Tagging of results sets submitted in compliance with revised timelines

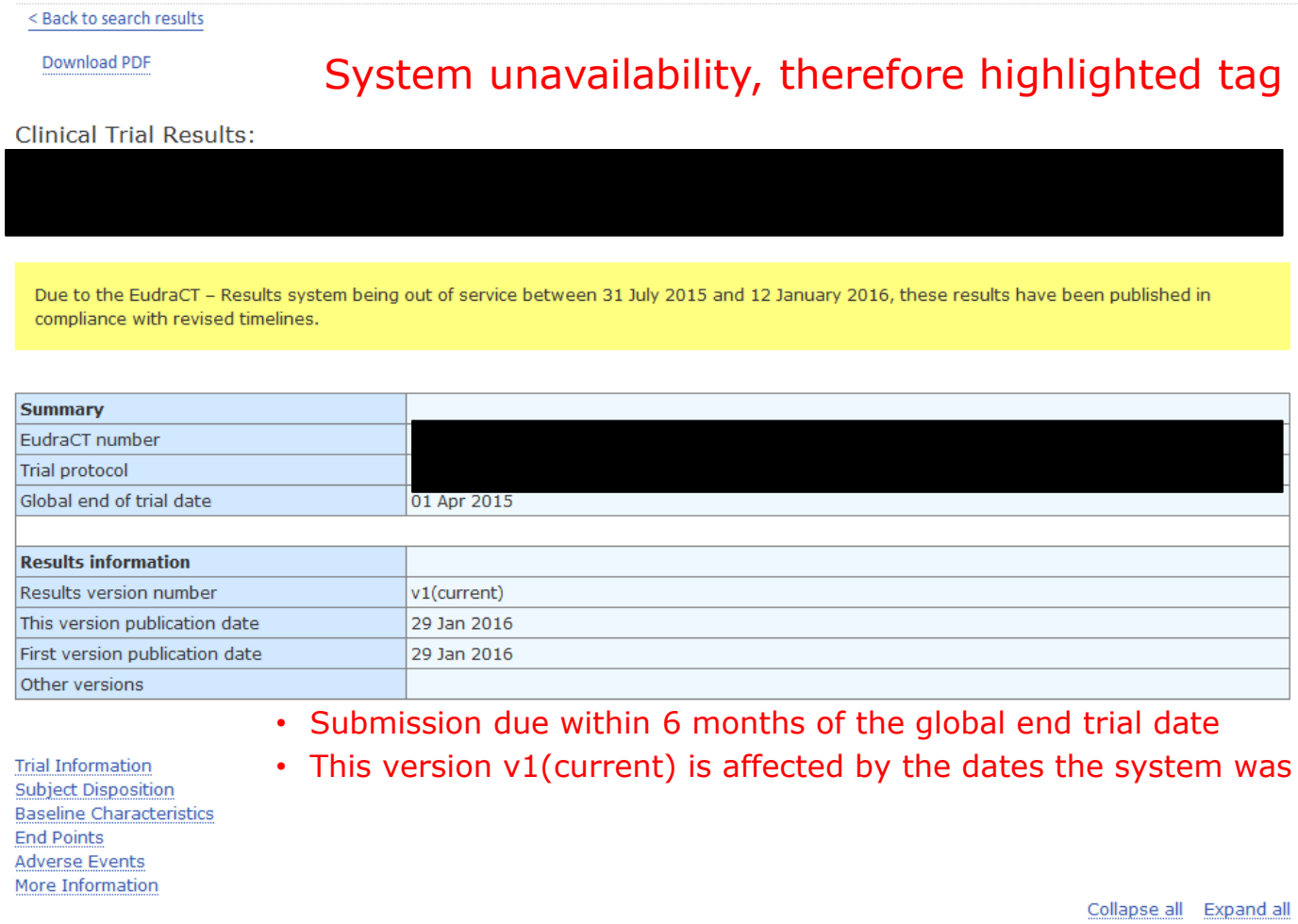
Notifications

- 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"*

Outcome of tagging of results - compliance with revised timelines (s7.3 Instructions for sponsors)



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System unavailability, therefore highlighted tag

Clinical Trial Results:

[redacted]

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.

Summary	
EudraCT number	[redacted]
Trial protocol	
Global end of trial date	01 Apr 2015
Results information	
Results version number	v1(current)
This version publication date	29 Jan 2016
First version publication date	29 Jan 2016
Other versions	

- Submission due within 6 months of the global end trial date
- This version v1(current) is affected by the dates the system was unavailable

Trial Information
Subject Disposition
Baseline Characteristics
End Points
Adverse Events
More Information

Collapse all Expand all

Communications: Formal notifications only

- 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

Communications: **All** other queries related to EudraCT – Results and this exercise

From 1 March 2016

- New self-service portal for all technical IT requests and issues in relation to EMA supported IT systems (https://servicedesk.ema.europa.eu/).
  - 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 (1 February to 1 March 2016)
  - Incidents or service requests logged before 1 February managed to closure using previous process
  - Existing support email addresses will be monitored
    - incidents or service requests transferred into the new portal
    - 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
- Where a new primary user is needed, contact EMA

Tagging of results sets submitted in compliance with revised timelines

It will only be necessary to tag results sets that are actually submitted beyond the deadline in consequence of the unavailability of the system. Examples:

Global trial end date: 11 December 2014	Global trial end date: 15 July 2015
Due date: 11 December 2015	Due date: 15 July 2016
Submitted date: 18 May 2016	Submitted date: 30 June 2016
Tagging appropriate	No tagging needed – compliant with standard timelines