EUROPEAN MEDICINES AGENCY
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EudraCt – Results Webinar # 2

Presented by Tim Buxton on 27 January 2016

IT Service Strategy Manager, IT Operations

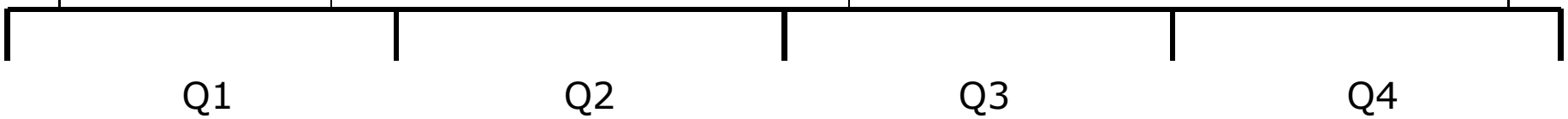
An agency of the European Union

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 ≤ 24 months after finalisation of the programming) should comply with the modalities and timing of trial results
13 July 2016	• Date by which results sets affected by the system closure are to have been posted.
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)



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)

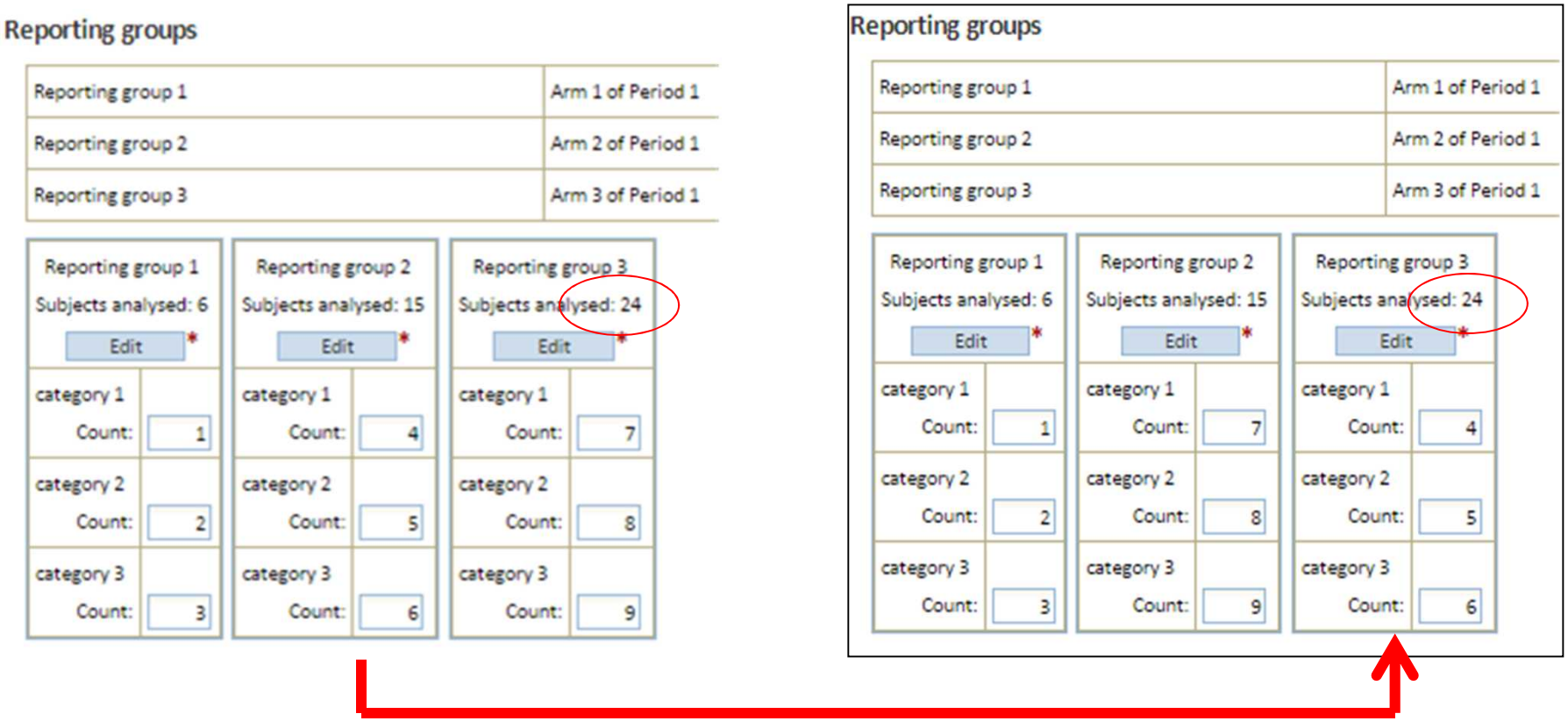
Resources: Schedule of trials assigned to a primary user

User	Name	EudraCT No.	Published	Potential timestamp 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

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



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)

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
- 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":

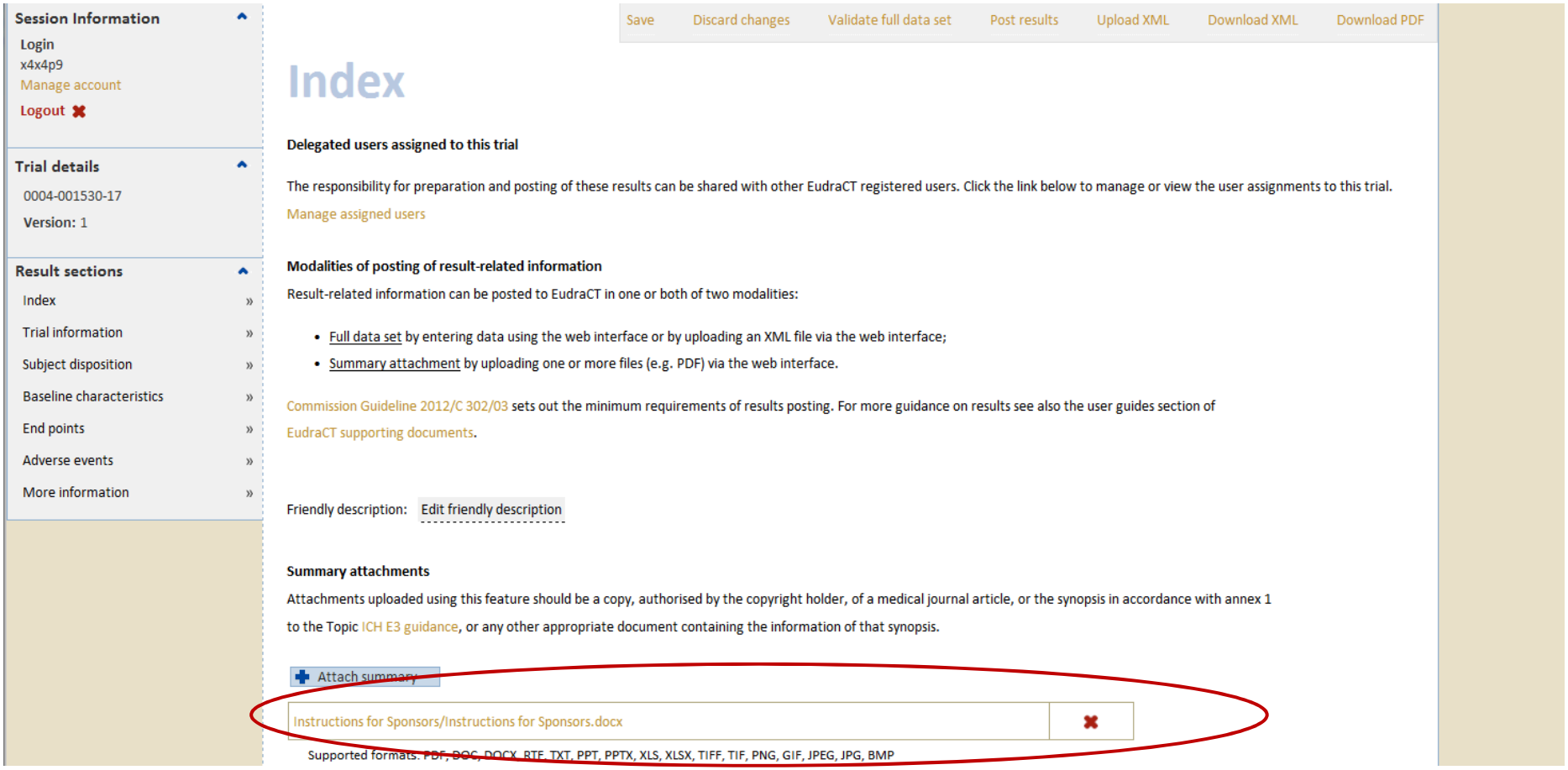
- Affected results or categorised as to be posted ≤ 24 months after finalisation of the programming
  - Section 8.5: Results set submitted in compliance with revised timelines

Restoration to public view: Sponsor notifications 2 of 2

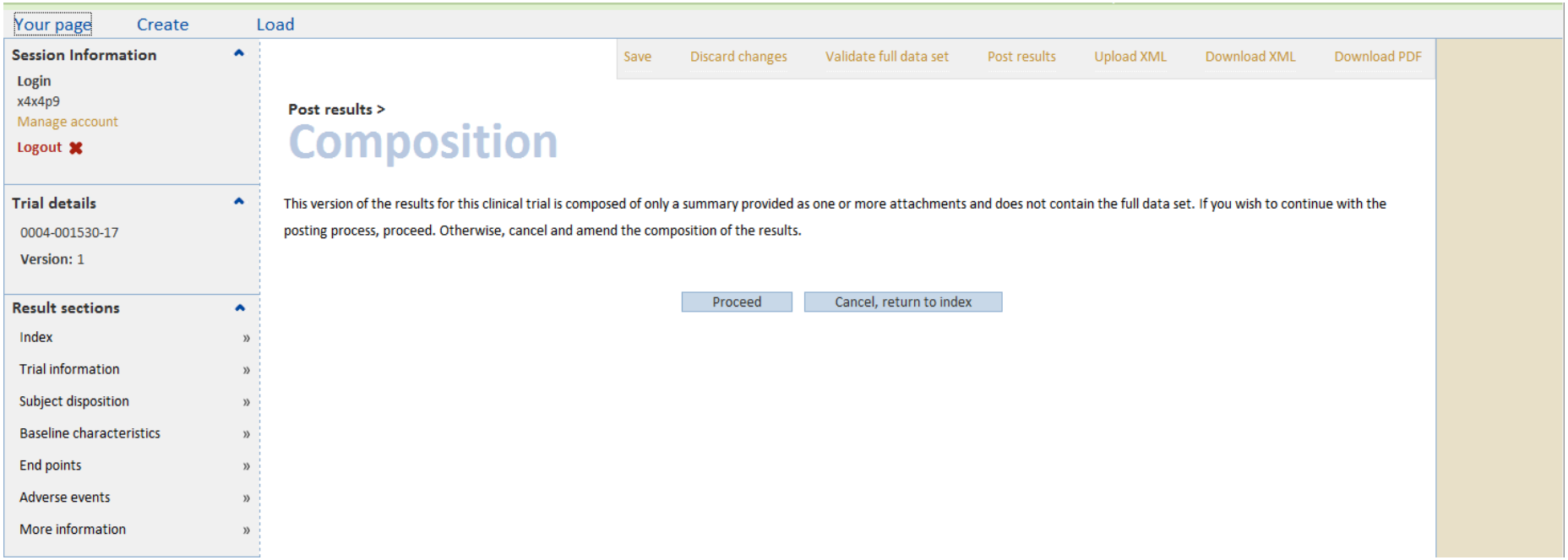
Finalized results as of 31 July 2015:

- 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

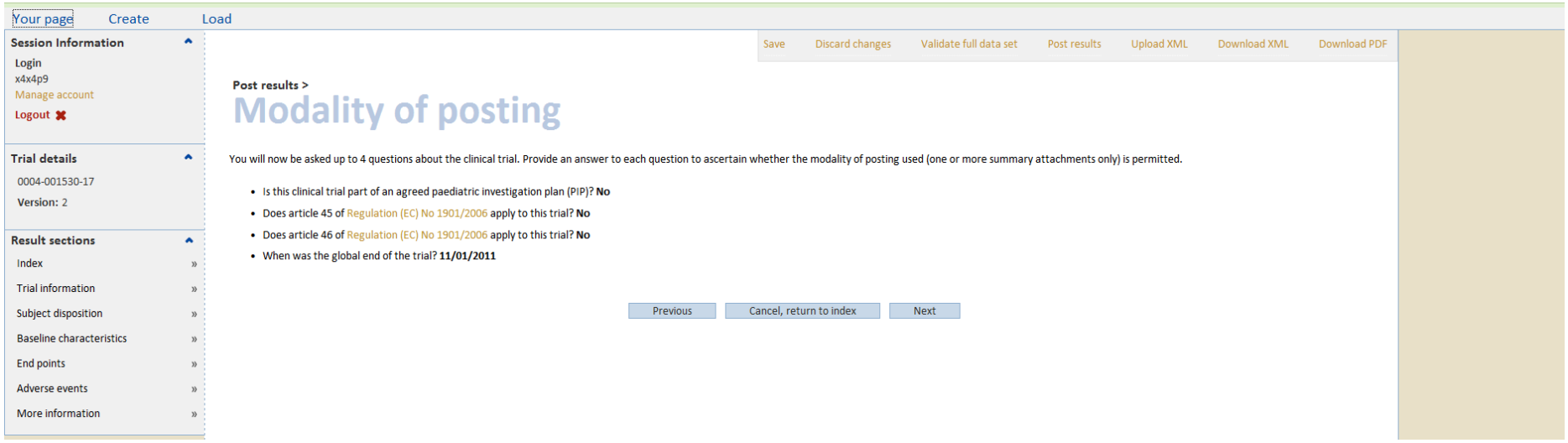
Trials with summary only 1 of 3



Trials with summary only 2 of 3



Trials with summary only 3 of 3



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