

Oracle Health Sciences Empirica Signal Release Notes



Release 9.2.0.2
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Oracle Health Sciences Empirica Signal Release Notes, Release 9.2.0.2

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Contents

Preface

Documentation accessibility	vii
Related resources	vii
Access to Oracle Support	vii
Additional copyright information	vii

1 System requirements

Client computers	1-1
Software for client computers	1-1
Application server	1-1
Minimum hardware for the application server	1-1
Software for the application server	1-2
Database server	1-2
Minimum hardware for the database server	1-2
Software for the database server	1-2
Reporting server	1-3
Requirements for the Oracle Analytics reporting server	1-3

2 Changes in the 9.2.0.2 release

Enhancements	2-1
Add a Summary of Safety Signals report for use with GVP RPD (33739725)	2-1
Issues fixed	2-1
Subscription data releases in the Oracle Cloud	2-1
33816540 - Report output aliases may not update to the latest configurations after importing subscription data	2-1
Topic management	2-1
33820195 - Editing topics from the Actions tab saves incorrect topic information	2-1
33851254 - Topic attachments made from a report can include tags	2-2
33936500 - Unsaved topic General Information can be lost if additional topics are viewed and edited	2-2

3 Changes in the 9.2.0.1 release

Enhancements	3-1
Data mining	3-1
Change RGPS Minimum Lambda parameter from 1.3 to 1.0 for RGPS (33556979)	3-1
Installation and configuration	3-1
Increase maximum value for Site Option parameter: Max Memory Per Report (33523362)	3-1
Topic management	3-1
Handle special characters in topic comments and attachments (33245223)	3-1
Issues fixed	3-2
Signal management	3-2
33461062 - Data is not refreshed in UI after completion of Scripted Signal Management refresh	3-2
Topic management	3-2
33533414 - Changing TWC associated with SMC without re-login can cause Submit Review to create a topic with an inconsistent topic workflow configuration association	3-2
33580225 - Performance issue in Create Topic PDF when there are a large number of total rows in table attachments	3-2
33596558 - Save on Manage Topic Field Accessibility by State can cause blank screen	3-3
33650743 - LR run fails with long drug name	3-3
User interface	3-3
33473811 - OAS My Profile icon rendering issue for SSO users	3-3
33733730 - My Dashboard missing from OAS report catalog	3-3

4 Changes in the 9.2 release

Enhancements	4-1
Enhancements in Empirica Signal 9.2	4-1
Accessibility	4-1
Support space bar to open menus from the keyboard (31562122)	4-1
Scale the calendar for larger screens (31844545)	4-2
Administration	4-2
Capture work team information in User Activity Audit Trail (27249413)	4-2
Remove Manage Reviewer-User Mapping from Settings page (28165495)	4-2
Feedback menu goes to Oracle Support and the Send to All Users FeedbackEmail field has been replaced with the FromEmailAddress field in Site Options (29285748)	4-2
Argus Mart integration	4-2
Support database link connection to Argus Mart (31849469)	4-2
Data mining	4-2
MGPS runs should not fail if no data is extracted (30916187)	4-2

Maximum number of rows per table allowed in topic attachments has increased (31692750)	4-2
Drug profiles	4-3
Remove unsupported Copy to Clipboard from Drug Profiles and Data Mining and report graphs (32543497)	4-3
Installation and configuration	4-3
Increase default value for Site Option: Max cache size for LR index tables and data files (31606478)	4-3
Oracle Analytics reporting	4-3
Topics reporting is now performed using Oracle Analytics (32680840)	4-3
Signal management	4-3
Failed runs do not result in a failed ISM refresh; refresh status remains blank (22162647)	4-3
Implement Product-Event Combinations Detail panel (31990612)	4-3
Allow public comments that do not mark the product-event combination as reviewed (32853367)	4-3
Signal History table displays all alerts that have been reviewed (33106343)	4-4
Subscription data releases in the Oracle Cloud	4-4
Add a Release Date column to the Manage Subscription Data Releases page (31844144)	4-4
Handling of Shared Data releases that exist locally (31948609)	4-4
Standard runs and reports created by import should have a Project setting (32366880)	4-4
Implement confirmation questions for third-party dictionary and data licenses (32676295)	4-4
Topic management	4-4
Copying a topic workflow configuration prevents access until copying is complete (26313548)	4-4
Approval for topic state transition (31681940)	4-5
Add ability to change the sort order of bars on a graph (31844072)	4-5
Introduce action type definitions into the topic workflow configuration (31848912)	4-5
Use display names in Calendar List view (31849118)	4-5
Use display names in the Topic and Action Detail panels (31849156)	4-5
All button for the Calendar View items for field now available (31950966)	4-5
Scroll calendar only when necessary (31990846)	4-6
Edit Topic and Add Topic windows know which topic workflow configuration they belong to (32461013)	4-6
Edit Topic Workflow Configuration page streamlines topic workflow configuration management (32688699)	4-6
User interface	4-6
Download to RTF replaced with Download to docx (31980617)	4-6
Drop support for Microsoft Internet Explorer and, instead, support Edge (32360519)	4-6
Issues fixed	4-6

Drug profiles	4-7
32429709 - Options bar can get clipped at the bottom of large graphs on Drug Profiles page	4-7
Reporting	4-7
33441889 - PDF: Report outputs with multiple headers and many breakdown values are not downloading correctly (formally reported as 22690229, 18601654)	4-7
Subscription data releases in the Oracle Cloud	4-7
31745260 - Publishing audit record for runs created with import of subscription data had incorrect run ID	4-7
32132242 - Prevent users from seeing other users' Import succeeded email notifications	4-7
Topic management	4-8
30946248, 31405224, 31707393 - Chrome: Confirm messages dismissed without user interaction	4-8
31636718, 31636737 - The Action Detail panel does not always update when the action is modified	4-8
31721637 - Calendar does not resize correctly if user resizes window while on another tab	4-8
31727554 - Synchronize the List view, Calendar view, and Action details	4-8
31797369 - In Select Topics popup window, selected filter values are not retained	4-9
31860092 - If the topic workflow configuration was not specified in Login Group or Preferences, the Site Option topic workflow configuration was used	4-9
31949872 - Topic tab: Issues with right panel display	4-9
32853072 - Field values are not displayed in History tables when the Display Name is not trimmed of trailing spaces	4-9

Preface

This preface contains the following sections:

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

Related resources

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface of Oracle Health Sciences Customer Support Portal (<https://hsghbu.custhelp.com/>)
- Japanese interface of Oracle Health Sciences Customer Support Portal (<https://hsghbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

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1

System requirements

Client computers

Software for client computers

Component	Requirements
Operating system	Microsoft Windows 10
Internet browsers	Google® Chrome (latest public version) Microsoft® Edge (version 88 or later)
Tools for downloading data	Any or all of the following tools for downloading data: <ul style="list-style-type: none">• Adobe Acrobat Reader.• Microsoft Excel, for XLS or XLSX.• Microsoft Word, for DOCX files.• SAS System Viewer, for XPT files.• Base SAS, for SAS files.• A ZIP archive manager.

Application server

Minimum hardware for the application server

Component	Description
Processor	64-bit Intel 6-core 2.8 GHz or higher processor. Actual requirements are based on the size of the dataset and the expected number of concurrent users.
Memory	16 GB RAM. Actual requirements are based on the size of the dataset and the expected number of concurrent users.
Disk storage	600 GB for data. Actual requirements are based on the size of your dataset.
Connectivity	1 GB recommended.

Software for the application server

Component	Description
Operating system	Oracle Linux 7.6 or later.
Software	<ul style="list-style-type: none">• Oracle Database Client that matches your database version. Select either the developer or the full installation option. The installation must include the SQL*Loader (sqlldr) utility.• WebLogic 12.2.1.4 (includes ADF runtime) with Java 8 version 211 and above.• Required only if you plan to use single sign-on:<ul style="list-style-type: none">– OAM WebGate, OHS version 12.2.1.4.

Database server

Minimum hardware for the database server

Component	Description
Processor	64-bit Intel 2-core 2.8 GHz or higher processor. Actual requirements are based on the size of the dataset and the expected number of concurrent users.
Memory	16 GB RAM. Actual requirements are based on the size of the dataset and the expected number of concurrent users.
Disk storage	1.2 TB for data. Actual requirements are based on the size of your dataset.
Connectivity	1 GB recommended.

Software for the database server

Component	Description
Operating system	Oracle Linux 7.6 or higher.

Component	Description
Software	Oracle Database 19c or 12c. These databases are supported with the following installation options: <ul style="list-style-type: none">• Block size: 8k• Character set: AL32UTF8• NLS_LENGTH_SEMANTICS: BYTE• EZ Connect

Reporting server

Requirements for the Oracle Analytics reporting server

To use Oracle Analytics to report on Oracle Empirica Signal, your system must meet the Oracle Analytics and Oracle Database instance requirements.

Component	Description
Software	<ul style="list-style-type: none">• Oracle Fusion Middleware 12.2.1.4.• Oracle Analytics Server version 5.9.0 with Java 8 and unlimited encryption extensions (JCE).Linux server name hosting Oracle Analytics.• Linux non-privileged username used for the Oracle Analytics installation.• Oracle Empirica Signal release 9.2 or later, installed and configured.

2

Changes in the 9.2.0.2 release

Enhancements

Add a Summary of Safety Signals report for use with GVP RPD (33739725)

If OAS has been configured to use the RPD model and the report catalog for the Sample GVP Module IX, then a Summary of Safety Signals report is available in OAS. If the Sample GVP Module IX is associated with a Signal configuration the report will provide a tabular summary of the ongoing safety signals during the reporting interval.

Issues fixed

Subscription data releases in the Oracle Cloud

33816540 - Report output aliases may not update to the latest configurations after importing subscription data

Before

After importing data (Manage Subscription Data Releases), report output aliases may not have been updated to the latest configuration.

After

Report output aliases are updated correctly.

Topic management

33820195 - Editing topics from the Actions tab saves incorrect topic information

Before

If the topic editor was opened from the Actions tab and there were unsaved edits to the Topic General Information of a different topic, then under certain circumstances the wrong Topic General Information was displayed and could have been saved.

After

When opening the topic editor from the Actions tab, the Topic General Information displays correctly.

Ported from #33820060 included in 9.1.0.7.

33851254 - Topic attachments made from a report can include tags

Before

Topic attachments made from reports with case ID links included tags.

After

Topic attachments made from reports with case ID links save correctly.

33936500 - Unsaved topic General Information can be lost if additional topics are viewed and edited

Before

When editing a topic, if a second topic is viewed and then edited, unsaved changes made to the first topic's General Information tab can be lost.

After

Unsaved changes to topic General Information are not lost when you view and edit a second topic window.

3

Changes in the 9.2.0.1 release

Enhancements

Data mining

Change RGPS Minimum Lambda parameter from 1.3 to 1.0 for RGPS (33556979)

Based on feedback from recent collaborative research observing RGPS scores with significant case data changes over time, two advanced modelling parameters can be set in the Signal environment: Minimum and Maximum Lambda. These affect the selection of predictors (i.e., set of contributing drugs) to be included in the regression model.

Lowering the Minimum Lambda parameter causes the algorithm to potentially include more predictors (that are positively correlated with the target event) to the adjustment regression. In this context, the Minimum Lambda parameter default was changed from 1.3 to 1.0; this has been found to increase the stability of RGPS results over time by lessening the chance of omitting an important predictor.

The Maximum Lambda parameter regulates the inclusion of predictors that are negatively correlated with the target event. The default value (unchanged in this release) is 0.3; raising that value would potentially allow more predictors that are negatively correlated with the target event to enter the regression model.

Ported from #33556978 included in 9.1.0.6.

Installation and configuration

Increase maximum value for Site Option parameter: Max Memory Per Report (33523362)

The maximum value that you can specify for the **Max Memory Per Report** parameter has been increased to 8000 MB. You can set this parameter on the Site Options page.

Topic management

Handle special characters in topic comments and attachments (33245223)

When a topic is displayed, any invalid characters in its attachments or comments are removed and replaced with the Unicode black square character (■).

Ported from #28057529 included in 9.1.0.5.

Issues fixed

Signal management

33461062 - Data is not refreshed in UI after completion of Scripted Signal Management refresh

Before

After a Scripted Signal Management refresh, the data was not refreshed on the Signal Review page, even after re-login.

After

Data is refreshed in UI after a Scripted Signal Management refresh without re-login.

Ported from #33440691 included in 9.1.0.6.

Topic management

33533414 - Changing TWC associated with SMC without re-login can cause Submit Review to create a topic with an inconsistent topic workflow configuration association

Before

If you changed the topic workflow configuration associated with a signal management configuration without exiting and logging in again, the topic you next created with Submit Review may have been invalid and associated with the wrong topic workflow configuration.

After

The Submit Review dialog saves to the correct topic workflow configuration without the need to re-login.

33580225 - Performance issue in Create Topic PDF when there are a large number of total rows in table attachments

Before

In Signal 9.2, Create Topic PDF could be slow when there are a large number of total rows in table attachments.

After

Create Topic PDF performance with table attachments has been improved.

33596558 - Save on Manage Topic Field Accessibility by State can cause blank screen

Before

If a topic workflow configuration had many topic states and many custom fields and changes were made on the Manage Topic Field Accessibility by State page, then a blank screen appeared after clicking Save. Changes were saved but the application did not return the user to the Manage Fields page as expected.

After

Saving changes on the Manage Topic Field Accessibility by State page returns the user to the Manage Fields page as expected.

Ported from #33596087 included in 9.1.0.6.

33650743 - LR run fails with long drug name

Before

LR data mining runs may have failed if a drug name was longer than 255 characters.

After

LR data mining runs do not fail due to long drug names.

Ported from #33647546 included in 9.1.0.6.

User interface

33473811 - OAS My Profile icon rendering issue for SSO users

Before

For SSO users only, the OAS My Profile icon did not render correctly.

After

The OAS My Profile icon renders as expected for all users.

33733730 - My Dashboard missing from OAS report catalog

Before

The My Dashboard subfolder was missing from the OAS catalog Topics folder.

After

My Dashboard is now available in the OAS catalog Topics folder.

4

Changes in the 9.2 release



Note:

To view release notes for versions prior to 9.2, see the Empirica Signal product page on Oracle Help Center.

Enhancements

Enhancements in Empirica Signal 9.2

Oracle Empirica Signal version 9.2 has the following new features and characteristics.

New analytics and flexible reporting options for Topics reporting in the Cloud

- Oracle Analytics has replaced Oracle Business Intelligence Publisher. In addition to Oracle Analytics, Oracle Data Visualization and Publisher reporting options have been added.
- The Argus Mart integration via database links provides a lighter/more flexible connection.
- Optional customer-specific reporting is supported.

Topic workflow enhancements

- New action types and template enhancements increase efficiency and standardization.
- Explicit approver roles and approval of topic state transitions manage critical decisions.
- Topic Workflow Configuration administration has been improved.

Out-of-the-box interactive signaling for a large set of safety data sources

- A new product-event combinations Detail panel provides information about recent alerts, comments, graphs, and associated topics. You can review details in one place for each selected combination to process potential signals.
- Best-practice configurations for Vigibase, VAERS, and JADER have been added.

Seamless upgrade for all 9.x Cloud customers

Upgrades will be deployed as in-place upgrades, minimizing downtime.

Accessibility

Support space bar to open menus from the keyboard (31562122)

You can now open menu items by pressing the **Space bar** on your keyboard.

Scale the calendar for larger screens (31844545)

The Calendar view on the Calendar tab has been optimized for viewing on larger screens.

Administration

Capture work team information in User Activity Audit Trail (27249413)

Work teams activities, such as create, edit, and delete work teams, and the permissions assigned to work teams, are now included in the User Activity Audit Trail.

(previously reported as 16380553)

Remove Manage Reviewer-User Mapping from Settings page (28165495)

The **Manage Reviewer-User Mapping** option has been removed from the Configure System section on the Settings page. This mapping feature is no longer necessary.

Feedback menu goes to Oracle Support and the **Send to All Users FeedbackEmail** field has been replaced with the **FromEmailAddress** field in Site Options (29285748)

The Feedback menu option now displays the Oracle Support page. Also, messages sent using **Send to All Users** now use the **FromEmailAddress** on the Site Options page as the *from* address when sending the email.

Argus Mart integration

Support database link connection to Argus Mart (31849469)

Oracle Empirica Signal 9.2 provides an option to integrate with Argus Mart using a database link in the Oracle Cloud.

Data mining

MGPS runs should not fail if no data is extracted (30916187)

If an MGPS run's extraction job produces no data, then the run's final status is "Completed with warnings" instead of "Error Occurred."

Maximum number of rows per table allowed in topic attachments has increased (31692750)

The maximum number of rows per table allowed in topic attachments has increased from 5,000 to 10,000.

Drug profiles

Remove unsupported Copy to Clipboard from Drug Profiles and Data Mining and report graphs (32543497)

Copy to Clipboard was a feature of Internet Explorer and is no longer available. You can, however, print drug profiles and data mining graphs to PDF.

Installation and configuration

Increase default value for Site Option: Max cache size for LR index tables and data files (31606478)

The maximum default cache size for LR index tables and data files that you can specify on the Site Options page has been increased to 20 GB.

Oracle Analytics reporting

Topics reporting is now performed using Oracle Analytics (32680840)

Topics reporting no longer is done through Oracle Business Intelligence Publisher. Instead, Oracle Empirica Topics integrates with Oracle Analytics Server for Topics reporting in the Cloud. This includes an RPD data model consistent with GVP module IX, additional standard graphical reports, and a workflow configuration aligned with the GVP module available for download.

Signal management

Failed runs do not result in a failed ISM refresh; refresh status remains blank (22162647)

Oracle Empirica Signal detects when a refresh fails due to a failed or cancelled run. The refresh is marked as either *Failed* or *Cancelled* and other runs associated with refresh are cancelled.

Implement Product-Event Combinations Detail panel (31990612)

A new Product-Event Combinations Detail panel appears when you select a product-event combination row on the Signal Review page. This detail panel includes recent product-event alert and comment information, signal statistic graphs for selected statistics, subgroup statistics graphs for selected subgroups, and, if available, associated topic information.

Allow public comments that do not mark the product-event combination as reviewed (32853367)

You can now add a public comment to the Product-Event Combination table without Oracle Empirica Signal marking the alerts as reviewed.

Signal History table displays all alerts that have been reviewed (33106343)

All alerts reviewed for the selected product-event combination appear in the Signal History table in the Alerts column. Alerts are not consolidated; each alert icon represents one alert. Alerts from different refreshes appear on different lines. Hovering over the icons displays the full Alert Type name. Clicking the alert type icon displays alert details.

Subscription data releases in the Oracle Cloud

Add a Release Date column to the Manage Subscription Data Releases page (31844144)

A Release Date column has been added to the Manage Subscription Data Releases page. You can now sort the data offerings by release date.

Handling of Shared Data releases that exist locally (31948609)

The Manage Subscription Data Releases page now has a Local status to denote data releases that exist locally. You can view release notes for those releases but can't re-import them.

Standard runs and reports created by import should have a Project setting (32366880)

You can now add standard runs and reports to a project on the Import a subscription data release page. These fields allow you to add a new or use an existing project for the release and the standard runs.

Implement confirmation questions for third-party dictionary and data licenses (32676295)

Confirmation of valid third-party dictionary and data licenses is now required when importing new data releases on the Subscription Data Releases administration page. The license confirmation is captured in the Import request audit record.

Topic management

Copying a topic workflow configuration prevents access until copying is complete (26313548)

When you click **Save** on the Copy Workflow Configuration page, Oracle Empirica Signal disables the buttons and fields on the page and displays a message stating that copying the topic workflow configuration is in progress. The topic workflow configuration is unavailable until the copy is complete.

Approval for topic state transition (31681940)

Topic state transitions have an additional setting to designate if approval is required. Only users with Approve Topic State Changes permission, a new work team permission, are able to perform a transition requiring approval. A user without this permission will see the transition as requiring approval but cannot transition to that state.

Add ability to change the sort order of bars on a graph (31844072)

The Graphic sections of the Topic and Actions tabs now allow you to change the sort order of the bars or donut sections.

Introduce action type definitions into the topic workflow configuration (31848912)

Topic workflow configurations support the definition of action types as a means of standardizing the creation and use of topic actions. An action type serves both as a template for action fields, as well as a means of reporting about a particular business activity across topics.

- Use action types with action templates to supply default values for action fields and to automatically create actions when topics are transitioned to certain states.
- Preassign actions to users and work teams in templates that include action types.
- Use the standard Start date field to specify a start date for the action to begin.

Once an action has entered the workflow, you can use the action type to identify similar activities in multiple topics.

Additionally, topic workflow configurations now support a Planned action state. Such planned actions can be configured to activate automatically; that is, move to the initial state, when the topic transitions to a specific state. You can also set up rules to automatically send email notifications based on different changes to actions and topics or create a rule to remind users when an action's completion date is near, due, or overdue.

Use display names in Calendar List view (31849118)

On the Calendar tab, labels and hover text now use the **Action Assigned to** field's configured Display Name.

Use display names in the Topic and Action Detail panels (31849156)

On the Topic and Action Detail panels, if display names from the topic workflow configuration are configured, they appear for fields and hover text instead of the default names.

All button for the Calendar View items for field now available (31950966)

The Calendar tab shows actions as a list and on a monthly calendar, along with total counts for past due and upcoming actions. You can now select the **View items for All** selector to include actions assigned to all individuals and work teams that are visible to you.

Scroll calendar only when necessary (31990846)

If you select a date in the Calendar List view, the Calendar view scrolls only if that date doesn't already appear in the current Calendar view.

Edit Topic and Add Topic windows know which topic workflow configuration they belong to (32461013)

If you edit a topic and then change your topic workflow configuration, if you then select **Save** in the Edit Topic popup window, the topic will be correctly saved to the original topic workflow configuration that was associated with this popup window.

Edit Topic Workflow Configuration page streamlines topic workflow configuration management (32688699)

The administration of topic workflow configurations has been improved with a consolidated Edit Topic Workflow Configuration page, providing an overview and support for viewing and editing all configuration details from a single page. This landing page provides access to:

- Fields
- Topic states
- Action states
- Email notifications
- Topic templates
- Action types

User interface

Download to RTF replaced with Download to docx (31980617)

When downloading case details, the file options now include downloading to a Word document (.docx) instead of a Word Rich Text Format (.rtf) file.

Drop support for Microsoft Internet Explorer and, instead, support Edge (32360519)

Because Microsoft has discontinued their Internet Explorer browser and replaced it with the Edge browser, Internet Explorer in Oracle Empirica Signal has been replaced with Edge.

Due to this implementation, the following issues that occurred only in Internet Explorer have been removed from the Oracle Empirica Signal *Known Issues* document: 16376736, 16377251, 21243358, and 23502120.

Issues fixed

Drug profiles

32429709 - Options bar can get clipped at the bottom of large graphs on Drug Profiles page

Before

When tall graphics, such as sector maps, were opened, the Options bar with links at the bottom of the page was sometimes cut off. On wide graphics, the horizontal scrollbar was cut off.

After

The Options bar and horizontal scrollbar now display correctly at the bottom of tall or wide graphics.

Reporting

33441889 - PDF: Report outputs with multiple headers and many breakdown values are not downloading correctly (formally reported as 22690229, 18601654)

Before

When downloading some reports with multiple header rows to a PDF file type, an error message appeared (22690229). Attachments involving report outputs with more than 40 columns did not appear in the PDF of a topic (18601654).

After

Reports with multiple headers download as expected to a PDF file type. Attachments involving report outputs with more than 40 columns appear in the PDF of a topic correctly.

Subscription data releases in the Oracle Cloud

31745260 - Publishing audit record for runs created with import of subscription data had incorrect run ID

Before

The run ID in the publishing audit record for standard runs created with a subscription data import was from the shared server not the local server it was imported to.

After

Publishing audit records now reference the local ID.

32132242 - Prevent users from seeing other users' *Import succeeded* email notifications

Before

When requesting that all users be notified of a subscription data import, email recipients could see the list of recipients.

After

The list of email recipients is no longer visible.

Topic management

30946248, 31405224, 31707393 - Chrome: Confirm messages dismissed without user interaction

Before

When using Chrome, confirmation messages could be dismissed without user interaction when opening a second Edit Topic or Add Topic window or when leaving the Drug Profiles page.

After

Confirmation messages require confirmation from the user.

31636718, 31636737 - The Action Detail panel does not always update when the action is modified

Before

When on the Actions or Calendar tab, certain edits to actions were not immediately reflected in the Action Detail panel.

After

The Action Detail panel updates whenever the action is modified.

31721637 - Calendar does not resize correctly if user resizes window while on another tab

Before

If you resized the window while on the Topics or Actions tab, the Calendar tab did not correctly resize.

After

The Calendar tab now resizes correctly if you resize the window when on another tab.

31727554 - Synchronize the List view, Calendar view, and Action details

Before

On the Calendar tab, when you quickly changed selections, the List view, Calendar view, or the Action details may not have updated correctly.

After

The List view, Calendar view, and Action details are now synchronized.

31797369 - In Select Topics popup window, selected filter values are not retained

Before

When browsing for an existing topic while **Saving to Topic**, multiple filters may be available. However, when you selected a second filter, the first selection was cleared.

After

You can browse topics based on multiple filters,

31860092 - If the topic workflow configuration was not specified in Login Group or Preferences, the Site Option topic workflow configuration was used

Before

If your user preferences or login group didn't set the topic workflow configuration, the Topic Management page applied the Site Option topic workflow configuration for work teams custom fields setting, if there was one specified.

After

If no topic workflow configuration is assigned to your login group or specified in user preferences, you are prompted to select a configuration from a drop-down list.

31949872 - Topic tab: Issues with right panel display

Before

Updates to information on the Topics tab did not always update the Topic Detail panel.

After

The Detail panel updates correctly as information is added or edited on the Topics tab.

32853072 - Field values are not displayed in History tables when the Display Name is not trimmed of trailing spaces

Before

If you created a custom Topic or Action field with a trailing space after the display name, then the field's saved value was not displayed in the Action type, Topic template, Topic template action, or Topic and Action history tables.

After

Custom field display names are trimmed of leading and trailing spaces and their saved values display correctly in the history tables.

Change log

Date	Revised part number	Description
June 2022	F53643-02	Amended Enhancement #27249413
March 2022	F53643-01	Added release notes for 9.2.0.2 release.
February 2022	F52370-02	Added release notes for 9.2.0.1 release. Removed release notes for versions prior to 9.2.
December 2021	F34873-01	Original version.