



Version 2.3.3.0027

# Hot Fix 11 Release Notes



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# 1 Release History

Release	Date	Version	Summary of Changes
<i>Hot Fix 11</i>	08-Feb-2018	2.3.3.0027	This is a Hot fix release that addresses the items listed in <a href="#">Table 1 – Enhancements</a> and <a href="#">Table 2 – Issues Addressed</a> .
<i>Hot Fix 10</i>	23-Aug-2017	2.3.3.0026	This is a Hot fix release to address the issues identified in the 2.3.3.0026 Release Notes.
<i>Hot Fix 9</i>	09-Jun-2017	2.3.3.0025	This is a Hot fix release to address the issues identified in the 2.3.3.0025 Release Notes.
<i>Hot Fix 8</i>	10-Apr-2017	2.3.3.0024	This is a Hot fix release to address the issues identified in the 2.3.3.0024 Release Notes.
<i>Hot Fix 7</i>	19-Jan-2017	2.3.3.0023	This is a Hot fix release to address the issues identified in the 2.3.3.0023 Release Notes.
<i>Hot Fix 6</i>	18-Nov-2016	2.3.3.0022	This is a Hot fix release to address the issues identified in the 2.3.3.0022 Release Notes.
<i>Hot Fix 5</i>	29-Sep-2016	2.3.3.0021	This is a Hot fix release to address the issues identified in the 2.3.3.0021 Release Notes.
<i>Hot Fix 4</i>	09-Aug-2016	2.3.3.0020	This is a Hot fix release to address the issues identified in the 2.3.3.0020 Release Notes.
<i>Hot Fix 3</i>	07-Jul-2016	2.3.3.0019	This is a Hot fix release to address the issues identified in the 2.3.3.0019 Release Notes.
<i>Hot Fix 2</i>	03-Jun-2016	2.3.3.0018	This is a Hot fix release to address the issues identified in the 2.3.3.0018 Release Notes.
<i>Hot Fix 1</i>	27-May-2016	2.3.3.0017	This is a Hot fix release to address the issues identified in the 2.3.3.0017 Release Notes.
<b>Service Pack</b>	04-May-2016	2.3.3.0016	This is a Service Pack release to address enhancements and new features. Also, the issues identified in the 2.3.3.0016 Release Notes.
<i>Hot Fix 2</i>	01-Apr-2016	2.3.2.0022	This is a Hot fix release to address the issues identified in the 2.3.2.0022 Release Notes.
<i>Hot Fix 1</i>	17-Mar-2016	2.3.2.0021	This is a Hot fix release to address the issues identified in the 2.3.2.0021 Release Notes.
<b>Minor</b>	31-Dec-2015	2.3.2.0020	This is a minor release to address enhancements and new features. Also, the issues identified in the 2.3.2.0020 Release Notes.
<i>Hot Fix 7</i>	25-Feb-2016	2.3.1.0021	This is a Hot fix release to address the issues identified in the 2.3.1.0021 Release Notes.
<i>Hot Fix 6</i>	11-Feb-2016	2.3.1.0020	This is a Hot fix release to address the issues identified in the 2.3.1.0020 Release Notes.
<i>Hot Fix 5</i>	23-Dec-2015	2.3.1.0019	This is a Hot fix release to address the issues identified in the 2.3.1.0019 Release Notes.
<i>Hot Fix 4</i>	17-Nov-2015	2.3.1.0018	This is a Hot fix release to address the issues identified in the 2.3.1.0018 Release Notes.
<i>Hot Fix 3</i>	02-Nov-2015	2.3.1.0017	This is a Hot fix release to address the issues identified in the 2.3.1.0017 Release Notes.
<i>Hot Fix 2</i>	21-Oct-2015	2.3.1.0016	This is a Hot fix release to address the issues identified in the 2.3.1.0016 Release Notes.

Release	Date	Version	Summary of Changes
<i>Hot Fix 1</i>	05-Oct-2015	2.3.1.0015	This is a Hot fix release to address the issues identified in the 2.3.1.0015 Release Notes.
<b>Minor</b>	04-Sep-2015	2.3.1.0014	This is a minor release to address enhancements and new features. Also, the issues identified in the 2.3.1.0014 Release Notes.
<i>Hot Fix 1</i>	22-Jul-2015	2.3.0.0050	This is a Hot fix release to address the issues identified in the 2.3.0.0050 Release Notes.
<b>Minor</b>	06-Jul-2015	2.3.0.0049	This is a minor release to address enhancements and new features. Also, the issues identified in the 2.3.0.0049 Release Notes.
<i>Hot Fix 6</i>	17-Jul-2015	2.2.1.0016	This is a Hot fix release to address the issues identified in the 2.2.1.0016 Release Notes.
<i>Hot Fix 5</i>	27-Jun-2015	2.2.1.0015	This is a Hot fix release to address the issues identified in the 2.2.1.0015 Release Notes.
<i>Hot Fix 4</i>	27-May-2015	2.2.1.0014	This is a Hot fix release to address the issues identified in the 2.2.1.0014 Release Notes.
<i>Hot Fix 3</i>	01-Apr-2015	2.2.1.0013	This is a Hot fix release to address the issues identified in the 2.2.1.0013 Release Notes.
<i>Hot Fix 2</i>	10-Mar-2015	2.2.1.0012	This is a Hot fix release to address the issues identified in the 2.2.1.0012 Release Notes.
<i>Hot Fix 1</i>	19-Feb-2015	2.2.1.0011	This is a Hot fix release to address the issues identified in the 2.2.1.0011 Release Notes.
<b>Service Pack</b>	10-Feb-2015	2.2.1.0010	This Service Pack release includes the enhancements or new features identified in the 2.2.1.0010 Release Notes.
<b>Minor</b>	13-Jan-2015	2.2.0.0058	This is a minor release to address enhancements and new features. Also, the issues identified in the 2.2.0.0058 Release Notes.
<i>Hot Fix</i>	26-Sep-2014	2.1.0.0066	This is a Hot fix release to address the issues identified in the 2.1.0.0066 Release Notes.
<i>Hot Fix</i>	08-Sep-2014	2.1.0.0064	This is a Hot fix release to address specific issues identified in the 2.1.0.0064 Release Notes.
<i>Hot Fix</i>	04-Aug-2014	2.1.0.0061	This is a Hot fix release to address specific issues identified in the 2.1.0.0061 Release Notes.
<i>Hot Fix</i>	23-Jul-2014	2.1.0.0059	This is a Hot fix release to address some priority issues found after functional and full regression testing.
<b>Minor</b>	17-Jul-2014	2.1.0.0057	This minor release includes support for the EU, CH, HC regions in the Publisher module and enhancements and bug fixes in the Publisher, Correspondence and Commitments, Viewer and Validator modules.
<b>Service Pack</b>	07-Apr-2014	2.0.1.0008	This Service Pack release includes all fixes from the previous Hot Fix releases along with other items listed in the Release Notes.
<i>Hot Fix</i>	16-Feb-2014	2.0.0.0060	This is a Hot Fix to address issues related to older versions of JRE specifically v1.6 update 17.

Release	Date	Version	Summary of Changes
<b>Major</b>	06-Feb-2014	2.0.0.0056	This release includes: <ul style="list-style-type: none"><li>• Publisher module with Validator functionality (New)</li><li>• Updates to Correspondence &amp; Commitments and Viewer modules. (enhancements &amp; bug fixes)</li></ul>
<b>Minor</b>	20-Sep-2013	1.1.0.0040	This release includes new Viewer module and enhancements to Correspondence and Commitments module.
<b>Major (Initial)</b>	27-Jun-2013	1.0.0.0074	First production release.

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## 2 Definitions

<b>ACRONYM</b>	<b>DEFINITION</b>
ACTS	ACUTA Call Tracking System
ATTP	ACUTA Test Track Pro, system used to track issues and enhancements
eCTD	electronic Common Technical Document
FDA	Food and Drug Administration
HF	Hot Fix
XML	eXtensible Markup Language
EU	European Union
AU	Australia
GCC	Gulf Cooperation Countries
JP	Japan
US	United States (of America)
ZA	South Africa
STF	Study Tagging Files
NeeS	Non-eCTD electronic submission
	EU, AU, GC, JP, US, and ZA defined, plus STF, NeeS

### 3 Scope

These release notes provide an overview of issues and regulatory enhancements addressed in ACUTA Regulatory Information Management (ARIM) version 2.3.3 build 0027, referred to as version 2.3.3.0027. This version has been labeled a Hot Fix Release per ACUTA software maintenance release procedures.

### 4 Items Addressed

Table 1, below includes the list of enhancement(s) addressed in this release of ARIM.

**Table 1 – Enhancements**

ATTP ID	Support ID	Summary
<b>Publisher</b>		
3406	N/A	Support for the new AU eCTD 3.1 schema has been added.
<b>Viewer</b>		
3407	N/A	Support for the new AU eCTD 3.1 schema has been added.
<b>Submission Planning</b>		
3408	N/A	Support for the new AU eCTD 3.1 schema has been added.
<b>C&amp;C</b>		
3409	N/A	Support for the new AU eCTD 3.1 schema has been added.
<b>Validation</b>		
3410	N/A	Support for the new AU eCTD 3.1 schema has been added.
3874	N/A	Validator now supports the CA validation profile version 4.3.
3972	N/A	Users now have the ability to check or uncheck the 'Exclude Font Embedded Validation' checkbox in the validation criteria groups for all regions.



Table 2 - below includes the list of issues addressed in this release of ARIM.

**Table 2 – Issues Addressed**

ATTP ID	Support ID	Issue Summary
<b>Admin</b>		
3946	N/A	In the Audit Trail, despite the fact that the date and time are displayed correctly in the UI, exporting it displayed all dates as the current date. This issue has been resolved.
<b>Publisher</b>		
3119	1628	When cutting and pasting a document, the Folder/File Name in the properties blade had an extra slash inserted into it. This issue has been resolved.
3184	N/A	In certain circumstances the Product and Excipient were not automatically populated when creating a new submission. This issue has been resolved.
3194, 3343	N/A	The value 'Pre-Submission Meeting Request' was not included in the sequence description for the following Regulatory Activity types: NDS, SNDS, NC, DINA, DINB, MPNDS, MPSNDS, MPNC, MPDIN, and PRECTA. This issue has been resolved.
3221	1715	For CA, US, and AU submissions, the user was not able to edit the documents under the sections 5.3.6 and 5.3.7, when the STF was selected in the submission window; instead a message appeared, 'Error, Incorrect Location! Please select a valid Location for this document.' This issue has been resolved.
3475	1177	The file name for a placeholder in ARIM was missing an 's'; according to the EU m1 validation criteria it should have been 'validation-analyt-procedures-var.pdf'. This issue has been resolved.
3601	1865	When '.xlsx' files were added to the submission, the Excel icon was not being displayed in the sequence view; instead a placeholder icon was being displayed. This issue has been resolved.

## 5 Assumptions / Dependencies

It is important to reference the System Requirements Specification (SRS), for the latest hardware and software requirements, prior to installing the latest update. Some requirements may have changed.

## 6 User Instructions

For user instructions, refer to the steps included in the *User Manual* provided with the Release package.

## 7 Installation

This release has 2 installation options.

## 7.1 New Installation

Refer to Install Guide.

*Note: When creating a new database, the following should be set based on the type of database server:*

- MS SQL Collation - SQL\_Latin1\_General\_CP1\_CI\_AS
- Oracle Character Set - Unicode UTF-8

## 7.2 Upgrade from previous versions

### 7.2.1 Upgrade from v2.3.3.0026

This Hot Fix can be installed using one of the 2 options listed below.

*Note: it is recommended that a backup copy of the master and company databases is made, as well as the existing ARIM files, which will be replaced as part of this Hot Fix, in case there is a need to restore the previous configuration.*

#### 1. Complete install.

This is the recommended upgrade route that will install a cumulative build, which includes all previous Hot Fixes for this release.

- a. Stop the IIS.
- b. Backup the file named 'jPDFEditor-keys.xml', from the AR-Services\bin folder on the ARIM Application server where ARIM is deployed.
- c. Backup the ARIM license key file from the AR-Services\bin\System\License folder on the ARIM Application server where ARIM is deployed.
- d. Backup the Web.config from AR-Web
- e. Backup the Web.config from AR-Services
- f. Remove the existing AR-Services and AR-Web folders from the deployed location.
- g. Copy the ARIM version 2.3.3.0027, AR-Services and AR-Web folders to the previous deployed location.
- h. Restore the files backed up in Steps b to e above, to their respective folders in the AR-Services and AR-Web deployed location.
- i. Start IIS.
- j. Login to the ARIM application with an admin user.

#### 2. Copy Files only in order provided. (Hot Fix – Files Only)

Note that all previous Hot Fixes should have been installed before using this option, installation using 'ARIM (2.3.3.0027) Files Only' will include fixes listed in the HF11 release and may not include any previous hot fixes.

The setup kit for Hot Fix releases include a kit with updated files only. These files are provided using the folder structure. These files will replace the corresponding files in the existing ARIM application folders.

### 7.2.2 Upgrade from v2.3.2 or v2.3.3

*Note: it is recommended that a backup copy of the master and company databases is made, as well as the existing ARIM files, which will be replaced as part of this Service pack, in case there is a need to restore the previous configuration.*

1. Stop the IIS.
2. Backup the file named 'jPDFEditor-keys.xml' from the AR-Services\bin folder on the ARIM Application server where ARIM is deployed.
3. Backup the ARIM license key file from the AR-Services\bin\System\License folder on the ARIM Application server where ARIM is deployed.

4. Backup the Web.config from AR-Web
5. Backup the Web.config from AR-Services
6. Remove the existing AR-Services and AR-Web folders from the deployed location.
7. Copy the ARIM version 2.3.3.0027, AR-Services and AR-Web folders to the previous deployed location.
8. Restore the files which were backed up in Steps 2 to 5 above, to their respective folders in the AR-Services and AR-Web deployed location.
9. Start IIS.
10. Log in to the ARIM application with an admin user.

### 7.3 Database migration from v2.3.2 or v2.3.3

*Note: Make sure to backup both master and company database.*

1. For users with ARIM v2.3.3.0026, run the upgrade script 'company\_db\_upgrade\_2.3.3.0026 to 2.3.3.0027.sql'.
2. For users with ARIM v2.3.3.0024 to v2.3.3.0025, run the upgrade script 'company\_db\_upgrade\_2.3.3.0025 to 2.3.3.0026.sql'. Then run the upgrade script 'company\_db\_upgrade\_2.3.3.0026 to 2.3.3.0027.sql'.
3. For users with ARIM v2.3.3.0021 to v2.3.3.0024, run the following migration scripts in the order provided:
  - a. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0021 to 2.3.3.0024.sql'.
  - b. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0025 to 2.3.3.0026.sql'.
  - c. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0026 to 2.3.3.0027.sql'.
4. For users with ARIM v2.3.3.0017 to v2.3.3.0020, run the following migration scripts in the order provided:
  - a. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0020 to 2.3.3.0021.sql'
  - b. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0021 to 2.3.3.0024.sql'
  - c. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0025 to 2.3.3.0026.sql'.
  - d. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0026 to 2.3.3.0027.sql'.
5. For users with ARIM v2.3.3.0016, run the following migration scripts in the order provided:
  - a. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0016 to 2.3.3.0017.sql'
  - b. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0020 to 2.3.3.0021.sql'
  - c. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0021 to 2.3.3.0024.sql'
  - d. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0025 to 2.3.3.0026.sql'.
  - e. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0026 to 2.3.3.0027.sql'.
6. For users with ARIM v2.3.2.0020 or v2.3.2.0021 or v2.3.2.0022, run the following migration scripts in the order provided:
  - a. 'company\_db\_script\_2.3.2 to 2.3.3.sql'
  - b. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0016 to 2.3.3.0017.sql'
  - c. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0020 to 2.3.3.0021.sql'
  - d. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0021 to 2.3.3.0024.sql'
  - e. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0025 to 2.3.3.0026.sql'.
  - f. Run the upgrade script 'company\_db\_upgrade\_2.3.3.0026 to 2.3.3.0027.sql'.
7. Log in to ARIM – Admin Console – Go to System Settings and make sure you have enough license available. (If available license count is less than zero, then manually edit user records and remove the license accordingly).

8. In Admin Console – Go to Roles – Verify the roles assigned to users and make sure you have proper 'Sign', 'Approve', and 'Comment' permissions options are set. If not manually make the changes.

## **8 Deliverables**

### **8.1 List of Documents**

The following are the list of documents provided as part of the ARIM 2.3.3.0027.

- User Manual
- Install Guide
- System Requirements Specifications
- Release Notes (this document)

## 9 Known Issues List

Table 3 below includes the list of the known issues identified in this release of ARIM.

**Table 3 – Known Issues**

ATTP ID	Issue Summary
<b>Common</b>	
ATTP – 190 (ACTS – 1142)	System Settings: An exception error appears when cache value is entered applied.
ATTP – 342 (ACTS – 2688)	ARIM does not allow the creation of a company if the DB is configured for Windows Authentication.
ATTP – 354 (ACTS – 2785)	Issues with extracting the attached zip file in Correspondence and Publisher modules.
ATTP – 516 (ACTS – 3614)	Exception message appears when trying to view a document in the Document Viewer, when byte serve is checked in the Administrator System Settings window.
ATTP – 725 (ACTS – 4637)	LDAP User Import: Users are not displayed in the LDAP search window when exclamation marks are present. Workaround: Modify the title in LDAP to remove the exclamation marks.
ATTP – 1359	<ol style="list-style-type: none"> <li>1. The stylesheet provided by the agency manages/dictates the display of regional.xml when opened in IE or any supported browser.</li> <li>2. The stylesheet provided by GCC seems to expect following criteria to display documents under the section 1-3-1, 1-3-2, and 1-3-3. <ol style="list-style-type: none"> <li>a). It expects to have document added under the section 1-3-1. If no documents are added under 1-3-1, and documents are added in 1-3-2 and/or 1-3-3, then it doesn't not display any leaf entry under 1.3 at all.</li> <li>b). If documents are added under 1-3-1 only, then it displays the leaf entry.</li> <li>c). If documents are added under 1-3-1 and 1-3-2 and/or 1-3-3, then it expects to have them sorted in same order under all 3 sections to display the documents. If documents are not sorted in same order, it still displays but might miss a few document leaf entries.</li> </ol> </li> </ol>
<b>Correspondence and Commitments</b>	
ATTP – 351 (ACTS – 2748)	Running a quarterly report across multiple years produces data in the "Period" column that is not sortable by time.
<b>Publisher</b>	
ATTP – 181 (ACTS – 1077)	There is a delay in the refresh of the Application Browser Screen after creating a new application and then immediately editing and saving it.
ATTP – 225 (ACTS – 1287)	Audit Trail frame: In the Select Module/Select Users dropdown, when a user selects the checkbox for the first time it does not select.
ATTP – 298 (ACTS – 2217)	EU (MRP/DCP): Tab order not working for Country tabs in the Add/Edit Submission window.

ATTP ID	Issue Summary
ATTP – 305 (ACTS – 2332)	When the TOC panel is placed in the right side of the Publisher window, it may go behind the Document Viewer. It is advised not to place the TOC panels on the right side of the Publisher window. Workaround: To get the TOC pane back minimize the Document Viewer.
ATTP – 314 (ACTS – 2472)	Blank screen appears when Current/Sequence/Cumulative view is moved with Float enabled.
ATTP – 317 (ACTS – 2478)	Import: A “Stack overflow at line: 24” message may appear on opening a document in the Document Viewer for some imported submissions.
ATTP – 425 (ACTS – 3250)	Copy-Paste: For a cross referenced application, if the user changes the Repository/Application Location, the cross reference link will be broken between the source and target documents.
ATTP – 529 (ACTS – 3821)	US v3.3- The default Select... option is not displayed in the Supplement Effective Date Type dropdown list.
ATTP – 545 (ACTS – 3936)	Performance issue in Optimize PDF functionality for large PDF documents.
ATTP – 549 (ACTS – 3944)	Performance issue when the user tries to Fix Link/BM Magnification for large PDF documents.
ATTP – 879 (ACTS – 5001)	The country order display within the Global Dossier should be in the same order that was set while creating the Global Dossier.
ATTP – 1120 (ACTS – 5266)	US 3.3 – Application can be selected from different repositories, while creating a bundle submission.
ATTP – 1396	Starting with version 2.3.2.20, it is possible for a user to edit the predefined folder and filename for file tags for U.S, AU and CA, for the following: - Annotated CRF (FDA) Data Tabulation Datasets – LEGACY (FDA) Data Tabulation Datasets – SDTM (FDA) Data Tabulation Datasets – SEND (FDA) Data Tabulation Data Definitions – LEGACY (FDA) Data Definitions for Analysis Datasets (FDA) Analysis Datasets – Legacy (FDA) Analysis Datasets – AdaM (FDA)
ATTP – 1397	For US M1 v3.3: It is not possible to select an existing Submission ID when creating a new ‘Presubmission’ sequence.

ATTP ID	Issue Summary
ATTP – 1669	<p>FDA requirements on external PDF links/Bookmarks:            FDA has updated PDF requirements in which the link properties for external links and bookmarks should include a property “Open in” with value “New Window”.</p> <p>Currently in ARIM when users create links and bookmarks this value is set to “User Preference” instead of “New Window”. This has been addressed in our 3.0 release.</p> <p>Work around:            Users, can submit without any changes, as this is only a recommendation at this time and not a requirement. Alternatively users can update the link /bookmark properties outside ARIM prior to finalizing the submission in ARIM.</p>
ATTP - 3184	In certain circumstances the excipient is not automatically selected. When this occurs, the user has to reselect the excipient.
<b>Submission Planning</b>	
ATTP - 862 (ACTS – 4983)	The created plan is not visible when the first plan is created for a specific Country without associating it with an application and submission.
<b>Viewer</b>	
ATTP - 11 (ACTS – 103)	Highlighting on any row in the Life cycle frame/Cross reference frame doesn't display the corresponding leaf document in Current/Cumulative view frame and vice versa.
ATTP - 23 (ACTS – 214)	In the Document Viewer frame when the Document is opened by Hyperlinks/Bookmarks, it doesn't highlight to the corresponding leaf in the Current/Cumulative view frame.
ATTP - 510 (ACTS – 3601)	Clicking on GoToR link always navigates to page number 1 even though the link is mapped to other page numbers.
ATTP - 625 (ACTS – 4300)	<p>Right-click options in the Submission browser are not displayed on navigating from other modules.</p> <p>Workaround: Navigate to any other module and then to Viewer select application first and then right click on the submission the options will be displayed.</p>
ATTP - 752 (ACTS – 4703)	Clone Submission: Node extension exists in US submission (M2 and M3), when the user clones an EU submission which has a node extension to a US submission.
ATTP - 753 (ACTS – 4706)	Register an Application with status ‘In Publish’ or ‘In Review’, then later cannot change the status to "Submitted to Agency".
ATTP - 769 (ACTS – 4747)	Submission Date does not sort Descending.