

Oracle® Argus Dossier

User's Guide

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Preface

Dossier is a tool that works within the Argus Safety application and enables you to generate periodic reports.

Where to Find More Information

Oracle Help Center

The latest user documentation for Oracle Health Sciences products is available at <http://docs.oracle.com/en/industries/health-sciences/>.

My Oracle Support

The latest release notes, patches and white papers are on My Oracle Support (MOS) at <https://support.oracle.com>. For help with using MOS, see https://docs.oracle.com/cd/E74665_01/MOSHHP/toc.htm.

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Introduction

Dossier is a tool that works within the Argus Safety application and enables you to generate periodic reports.

Dossier Report Process

The complete Dossier report process has several steps:

- [Configuring Dossier](#)
- [Creating and Reviewing Report Content](#)
- [Approving Content and Publishing Reports](#)

Configuring Dossier

The task of configuring Dossier is performed by the administrator. It is the first step in the Dossier report process and is initiated as soon as the administrator determines there is a need for a specific report. Normally, this will be as soon as a product is approved for market. Dossier configuration includes the following:

- [Configuring Periodic Data](#)
- [Configuring Periodic Report Templates](#)

Configuring Periodic Data

Refer to the Oracle Argus Safety User Guide for details about configuring Periodic Reports.

Configuring Periodic Report Templates

The administrator configures the report templates as follows:

- Writes the template scripts defining the report content
- Determines whether the report template contains one or more sections
- Uses authoring tools to verify the content of the template
- Assigns each section of the template to one or more groups for the authoring cycle
- Assigns the groups that are notified when Dossier authoring or reviewing is required.
- Assigns groups as the template owner (who can perform any action and can publish the report)

After the report templates are configured, the system does the following:

- Sends an e-mail message to the assigned authors and reviewers on the date the report is to be generated (scheduled date and time)
- Generates the FINAL periodic report and creates an entry on the Reports -> Periodic Reports section of the Argus application
- Places an entry on the Worklist -> Reports section of the Argus application for the assigned users (in any role)
- Notifies the administrator and users that the periodic report has been generated and is ready for review

Creating and Reviewing Report Content

Once a report has been generated and the users have been notified of its existence, the assigned authors and reviewers perform their associated tasks. You can check out documents and edit them manually using the Microsoft Word application on your local desktop. Once the document has been edited, you can check the document in and mark it as *Ready for Build*.

The task of the reviewers is to verify that the report content is correct and complete. Once a report is complete, the reviewer submits it for approval and final build.

Approving Content and Publishing Reports

Once all the sections of a report are marked as Ready for Review, you can generate a merged PDF for the final report. Once the PDF is created, users can view it.

Processing Dossier Reports

Generating Dossier reports requires the use of templates. A *template* is a pre-defined report format created in Microsoft Word. Before you can begin using templates to create reports, you (or someone with script writing or programming background) must create the template scripts. Information about writing template scripts is in [Chapter 3, "Writing Template Scripts"](#).

Using Templates

When using templates, be aware of the following:

- The application parses template elements sequentially. This prevents elements from being used before they are declared.
- The order in which the templates appear on the template tab is the order in which they will appear on the generated report. If you need the sections in a different order, use the **Up** and **Down** keys to change their position.

You should assign users (authors, reviewers, and owner) to each template section.

About the Templates Tab

The Dossier **Template** tab enables you to access report templates used to generate periodic reports (CTPR, ICH PSUR, IND, NDA). The following is an illustration of the **Templates** tab.

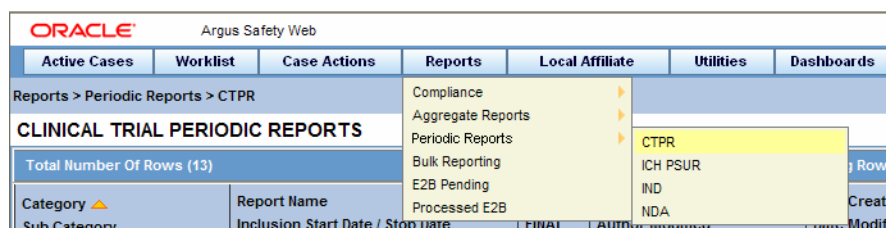
The following table lists and describes the fields and controls on this tab.

Field/Control	Description
Templates	Enables you to add, modify, delete, assign and arrange the sections in your templates.
Add	Click Add to add a new section to the report template.
Delete	Click Delete to delete a section of a template.
Assign	Click Assign to choose who can access a template.
Up	Click Up to move the template section up one level.
Down	Click Down to move the template section down a level.
Print	Click Print to print the report configuration.
#	This column contains the template number. This number changes as you move or change the order of the templates.
Section	This column contains the name of the template.
Description	This column contains a description of the section.
Attachment File Name	This column contains the name of the template file.
Modify	Click Modify to change a template document.
Attach	Click Attach to attach a new template document. Once the document is attached, this changes to Modify .
Header/Footer	This section enables you to attach header/footer information to the template.
Include Header/Footer	Click this checkbox if you want to include header/footer information from a specific Word document in your template.
Portrait Template	Enables you to use header/footer information from a document in portrait orientation in your template
Landscape Template	Enables you to use header/footer information from a document in landscape orientation in your template.

Field/Control	Description
Attach	Enables you to attach a Microsoft Word document to a template.
Include Page Numbering	Enables you to specify whether or not you want page numbering in the template and the location of the page numbers.
Header Left	Click this option to place the page number on the left side of the header.
Header Center	Click this option to place the page number in the center of the header.
Header Right	Click this option to place the page number on the right of the header.
Footer Left	Click this option to place the page number on the left side of the footer.
Footer Center	Click this option to place the page number in the center of the footer.
Footer Right	Click this option to place the page number on the right of the footer.
OK	Click OK update the template page.
Cancel	Click Cancel to exit from the template page without saving.

To access the template tab:

1. Select Reports -> Periodic Reports -> <Report Type>.



2. When the system opens the page for the report type you selected:
 - Locate the report and click the row to highlight it.
 - Click **Modify**.

OR

Click New Report.

Category	Report Name	DRAFT/FINAL	Author Created/Author Modified	Date Created/Date Modified	Justification
CTPR	TEST 09 - Creation Date, Data Elem, Dict 01-JAN-1996 / 31-DEC-1996	DRAFT	admin1 abhj	23-NOV-2009	Not specified
CTPR	TEST 07 - Cumulative and Event Summary 01-FEB-1997 / 30-APR-1997	DRAFT	admin1 abhj	23-NOV-2009	Not specified
CTPR	TEST 05 - Index of Cases, Tab, Death 01-DEC-1997 / 31-DEC-1997	DRAFT	admin1 abhj	23-NOV-2009	Not specified
CTPR	CTPR DSR Test 01-FEB-1997 / 30-APR-1997	FINAL	geetikac User A	31-MAR-2009 01-APR-2009	Not specified
CTPR	TEST 08 - Unsub report, Cioms, DCR 01-SEP-1997 / 30-NOV-1997	DRAFT	admin1 abhj	23-NOV-2009	Not specified
CTPR	Copy of Copy of TEST 09 - Creation Date, D.. 31-MAR-2009 / 31-MAR-2009	DRAFT	akashd akashd	01-APR-2009 01-APR-2009	Not specified
CTPR	TEST 06 - Studies, Country active,UD tab 01-JAN-1997 / 31-DEC-1997	DRAFT	admin1 abhj	23-NOV-2009	Not specified
CTPR	TEST 02 - Data Sheet, Adv Condition 01-JAN-1997 / 31-MAR-1997	DRAFT	admin1 abhj	23-NOV-2009	Not specified
CTPR	TEST 01 - License Selection, DS, Rf Type 01-JAN-1997 / 31-MAR-1997	DRAFT	admin1 abhj	23-NOV-2009	Not specified
CTPR	TEST 10 - Ase Group, CUN Profile	DRAFT	admin1		

- When the application opens the report dialog box, click the **Templates** tab.
- The system opens the Templates tab.

Adding a Template

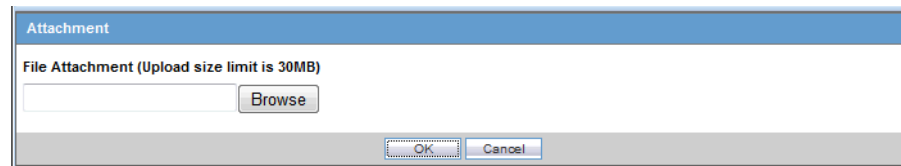
A *template* can consist of single or multiple sections. Multiple sections enable you to assign different authors and reviewers for each section.

When it uploads the template, the application does the following:

- Opens a status dialog box to show the executing process.
- Scans the template for scripting instructions, validates the instructions, and extracts the information to be stored for later use.

To add a template:

- Select Reports -> Periodic Reports -><Report Type>.
- When the system opens the page for the report type you selected:
 - Locate the report and click the row to highlight it.
 - Click **Modify** or **New**.
- When the application opens the report dialog box, click the Templates tab.
- When the system opens the Templates tab, click Add.
- When the application adds a new row in the template section:
 - Enter the section name in the text field in the **Section** column.
 - Enter a description of the section in the text field in the **Description** column.
 - Click **Attach**.
- When the system opens the Attachment dialog box:

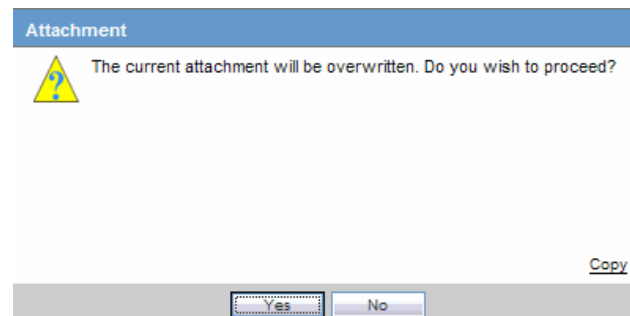


- * Type the template file path name **OR** click **Browse** to locate and select the template file (DOC or DOCX format) to attach.
- * Click **OK**.

Modifying an Existing Template

When you modify a template, the application overwrites the old version of the template with the new version.

1. Select Reports -> Periodic Reports -> <Report Type>.
2. When the system opens the page for the report type you selected:
 - Locate the report and click the row to highlight it.
 - Click **Modify**.
3. When the application opens the report dialog box, click the Templates tab.
4. When the system opens the Templates tab, select the appropriate row you wish to overwrite and click Modify.
5. When the system opens the Attachment message dialog box:



- Click **Yes** to continue modifying the template.
OR
Click **No** to abort the modify operation.
6. When the system opens the Attachment dialog box, enter the attachment name in the File Attachment field and click OK.

The system uploads the new template.

Assigning Template Users

Dossier enables you to assign specific template access levels to template users. Template users can be:

Author: The template *author* can answer any questions and create a draft or final version of a template section. There can be multiple authors for any given section of a template.

Reviewer: The template *reviewer* **does not** have access to authoring functions, but can manually edit individual sections of a template after the author has marked the template *Ready for Review*. Multiple reviewers can be assigned to any section of a template.

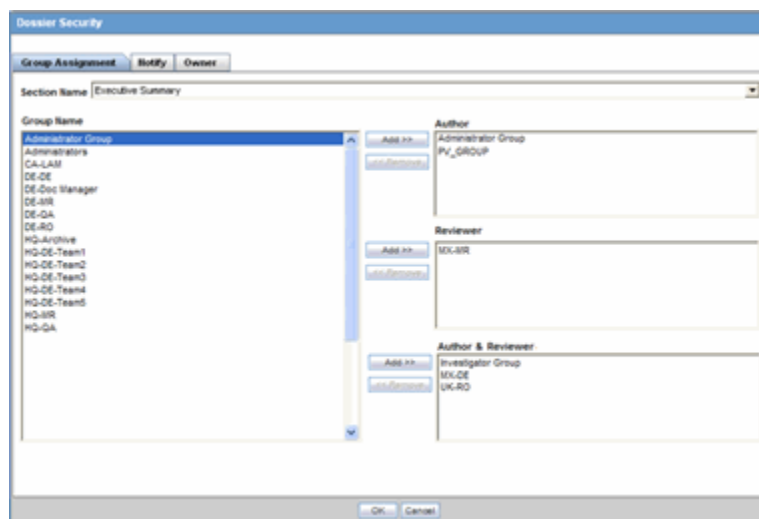
Author & Reviewer: The template *author & reviewer* has access to both authoring and review functions.

Owner: A template can be owned by one or more user groups. Users assigned to these groups can:

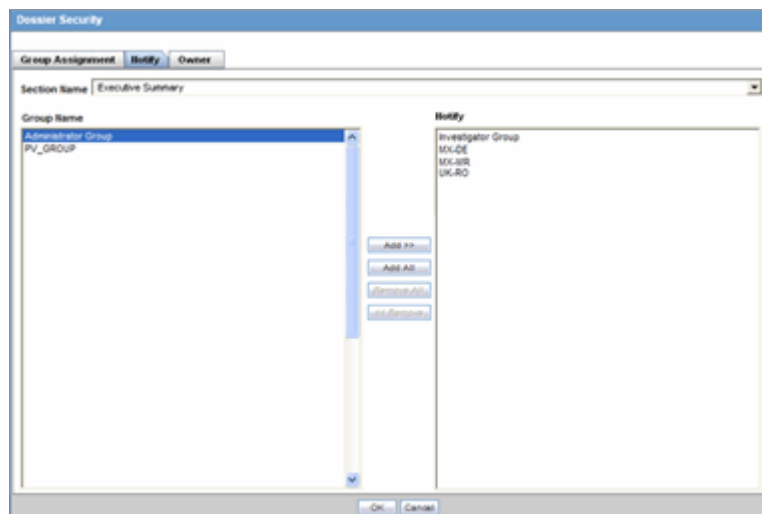
- Access all authoring and reviewing functions
- Assign user access rights as defined for such roles
- Build and publish reports

To assign group rights:

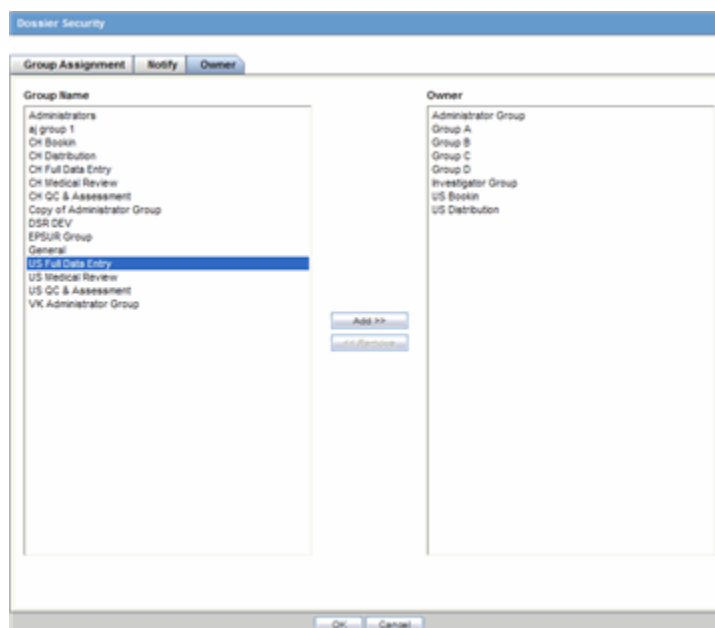
1. Select Reports->Periodic Reports-><Report Type>.
2. When the system opens the page for the report type you selected:
 - Locate the report and click the row to highlight it.
 - Click **Modify**.
3. When the application opens the report dialog box, click the Templates tab.
4. When the system opens the Templates tab, click Assign.
5. When the application opens the Dossier Security dialog box, click the Group Assignments tab:



- Select one or more **authors** from the **Group Name** list, and click **Add** to add the names to the list of authors in the **Authors** list.
 - Select one or more **reviewers** from the **Group Name** list, and click **Add** to add the names to the list of reviewers in the **Reviewers** list.
 - Select one or more **author/reviewers** from the **Group Name** list, and click **Add** to add the names to the list of reviewers in the **Author & Reviewers** list.
 - Click the **Notify** tab.
6. When the system opens the Notify tab:



- Select one or more groups from the **Group Name** list, and click **Add** to add the names to the **Notify** list OR Click **Add All** to add all the names in the **Group Name** list to the **Notify** list.
- Click the **Owner** tab.



7. When the system opens the Owner tab, select one or more groups from the Group Name drop-down list and click Add to add the selected group to the Owner list.
8. Click OK to save the assignments information.

Click **OK** to save your changes, then click the **Print** icon to view and print a PDF document listing associated assignments. The system only prints saved entries.

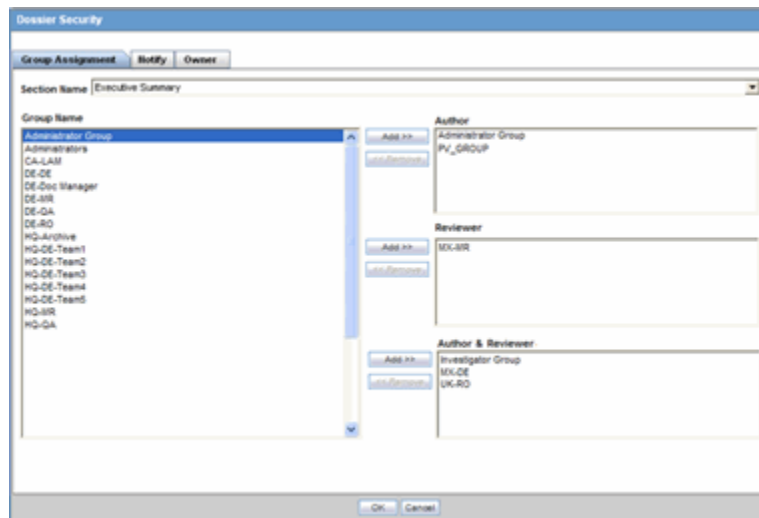
See the following sections for information about the individual tabs and for more information about printing the security assignments:

About the Group Assignment Tab

The **Group Assignment** tab enables you to assign particular roles to users. Any user who is **not** assigned a user role, cannot modify a template or a report. You can assign any of the following roles:

- Author
- Reviewer
- Author & Reviewer

The following is an illustration of the **Group Assignment** tab.



Group Assignment Tab Fields

The following table lists and describes the fields on the **Group Assignment** tab.

Field/Control	Description
Section Name	Enables you to select the template section name for privileges assignment
Group Name	Enables you to select one or more user groups to be authors and/or reviewers.
Author	Enables you to assign the Author role to one or more groups selected in the Group Name list.
Reviewer	Enables you to assign the Reviewer role to one or more groups selected in the Group Name list.
Author & Reviewer	Enables you to assign the Author & Reviewer role to one or more groups selected in the Group Name list.
Add button	Click Add to add a selected group or groups to the Author , Reviewer , or Author & Reviewer lists.
Remove button	Click Remove to move one or more selected groups from the Author , Reviewer , or Author & Reviewer lists and return them to the Group Name list.
OK button	Click OK to save the assignment information.
Cancel button	Click Cancel to abort the assignment operation.

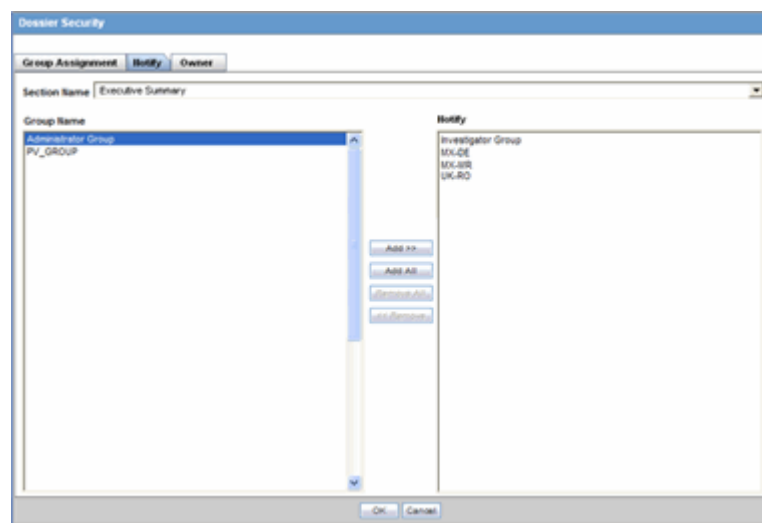
Group Assignment Tab Usage Considerations

When using the **Group Assignment** tab be aware of the following:

- The default tab is the Group Assignment tab.
- The **Section Name** drop down is blank by default.
- The Section Name contains a list of sections as configured in the periodic report configuration screen.
- You can add group(s) to each of the three user role lists.
 - Author
 - Reviewer
 - Author & Reviewer
- You **cannot** assign the same group to more than one user role. In other words, you can assign Group A to either the Author or the Author & Reviewer user role, but you cannot assign it to both.
 - The user can select a group or groups in the Group Name multi-select box (on left) and grant that/those groups privileges by clicking the Add button.
 - The user can select a group or groups in any user role list and click **Remove** to remove the users.
 - * The system returns the names of the removed groups to the **Group Name** list.
- The groups are listed alphabetically in ascending order in all multi-select boxes.
- When you move to another tab, the system temporarily saves your current choices.
- You must click **OK** to save your changes permanently.

About the Notify Tab

The **Notify** tab enables you select users to receive e-mail notification of new or modified assignments. The following is an illustration of the **Notify** tab.



Notify Tab Fields

The following table lists and describes the fields on the **Notify** tab.

Field	Description
Section Name	Enables you to select the template section name for assignment notification.
Group Name	Enables you to select one or more user groups to notify of new assignments or changes to existing assignments.
Add button	Enables you to add one or more groups selected in the Group Name list to the Notify list.
Add All button	Enables you to add all groups in the Group Name list to the Notify list.
Notify	Enables you to notify the users in this list of new assignments or changes to existing assignments.
Remove button	Enables you to remove one or more selected users from the Notify list.
Remove All button	Enables you to remove all users from the Notify list.

Notify Tab Usage Considerations

When using the **Notify** tab, be aware of the following:

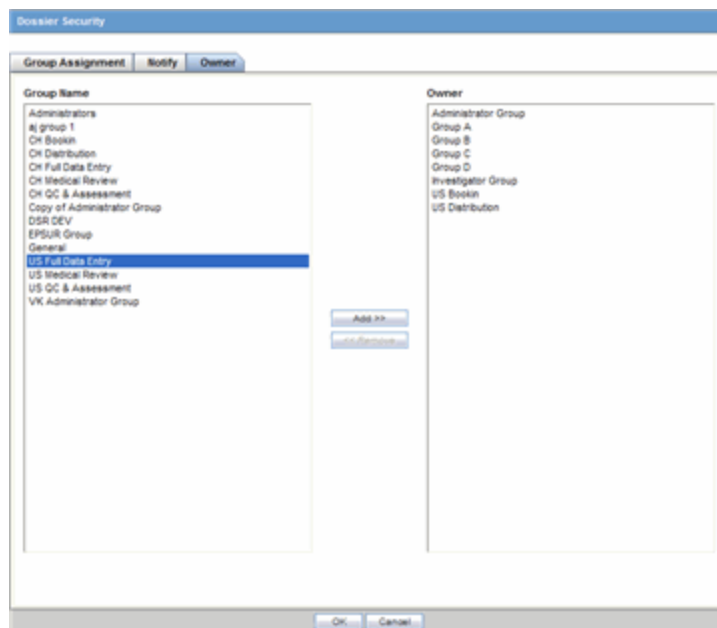
- The **Section Name** drop-down contains a list of template sections. If you do not select a section, the **Add/Remove** buttons are disabled.
- Select one or more groups from the **Group Name** list to include the users in the group in the notification list.
 - Available groups have been granted access from the **Group Assignment** tab.
 - When you click **Add**, the system places the selected group or groups to be notified in the Notify multi-select box (on right).
 - Select one or more groups in the **Notify** list and click **Remove** to remove them from the notification list.
 - The application removes the selected groups from the **Notify** list and returns them to the **Group Name** list.

About the Owner Tab

The **Owner** tab enables you to designate one or more groups to own an entire periodic report. Owner groups can do the following:

- Access all authoring and reviewing functions
- Assign user access rights as defined for such roles
- Build and publish reports

The following is an illustration of the **Owner** tab.



Owner Tab Fields

The following tables lists and describes the fields on the **Owner** tab.

Field	Description
Group Name	Contains a list of user groups who can be designated as owners of a report.
Add button	Enables you to designate groups selected in the Group Name pane as owners of a template by moving the group name from the Group Name pane to the Owner pane.
Remove button	Enables you to remove a selected group from the Owner pane and return it to the Group Name pane.
Owner	Contains a list of user groups who are designated as owners of a report.

Owner Tab Usage Considerations

When using the **Owner** tab, be aware of the following:

- All active groups that have been granted access privileges from the **Group Assignment** tab are included in the **Owner** drop-down list.
- You can select one or more groups as the owner of the entire Periodic Report.
 - The owner can perform the generate and build operations.
 - The owner can be both the author and the reviewer and is assigned the access rights defined for such roles.
- You must select at least one group to be the owner of a Periodic Report.
 - If you fail to select a group to be the owner of the Periodic Report, the system presents the following message:
You must assign a Dossier owner group.
 - Click OK.

- If you remove all the owner groups, the system presents the following message:
You must assign a Dossier owner group.
- AG Service sends e-mail notifications to all Authors, Owners, and Reviewers, if you have selected them for notification when a specific period report is generated or regenerated when the following occur:
 - Report is generated
 - Report is ready to build
 - Build is completed successfully
 - Build is failed in between processing
- The system sends an e-mail notification to the users in the groups listed in the **Notify** list. The application sends e-mail notifications to users when the following occur:
 - A Periodic Report is generated:
 - The author has checked the *Ready for Review* checkbox.
 - * The application sends an e-mail notification to the appropriate reviewers.
 - * If there are multiple reviewers groups specified for a given section, the application sends each reviewer an e-mail notification.
- The email notification includes the following:
 - Subject - Dossier Section for <Periodic Report Name> ready for Review
 - Section Name & Description - The name and description of the completed section.
 - Report Name -- The name of the report this section has been completed for.
- E-Mail Layout
Subject:
<Periodic Report> Section for <Periodic Report Name> is ready for Review
Body: (the following four fields are taken directly from the Reports - Periodic Reports dialog)
Trade Name: <Product Name(s)> Destination: <Submission Destination>
Description: <Description>
Due Date: <Due Date of Periodic Report>
The authoring of the <section name> <Section Description> for the <periodic report> "<PSUR Name>" has been completed and is ready for your review. Please log into Argus to review your section utilizing the menu option "Reports > Periodic Reports" and selecting the "View Argus Dossier" option for the correct report.

Printing a Dossier Security List

On the **Templates** tab, you can click **Print** to print a list of template assignments. This is called a **Dossier Security** report but may also be called a **template assignment list**. When you click **Print**, the application presents the following message:

To print the current Dossier security settings, the system must save the periodic report configuration.

1. Go to the **Template** tab.
2. Select the appropriate template from the template list and click **Print**.
3. Click OK when the system displays the following message:

To print the current Dossier security settings, the system must save the periodic report configuration.

4. The system saves the security settings and prints the Dossier Security report shown in the following illustration.

The screenshot shows a report titled "Dossier Security" with a timestamp of "13-MAR-2009 00:51 GMT -7". It contains three sections:

S3 Template Assignments		
Group Name	Role	Notify
Administrator Group	Author	No
Full Access Group1	Reviewer	No
General	Reviewer	Yes
LAM Group for US	Reviewer	Yes
LAM Group PS	Reviewer	No
Test Group	Author, Reviewer	No

S1 Template Assignments		
Group Name	Role	Notify
Administrator Group	Author	No
Full Access Group	Reviewer	No
Full Access Group1	Reviewer	No
LAM Group for US	Reviewer	Yes
LAM Group PS	Author, Reviewer	Yes
Test Group	Author, Reviewer	No

Report Template Owner	
Group Name	
Administrator Group	
Full Access Group	

At the bottom left of the report is the name "Will Gordon" and at the bottom right is "Page 1 of 1".

The following table lists and describes the elements in the **Dossier Security** report.

Report Section	Description
Report Title	The name of the report is always Dossier Security .
Save Date and Time	<p>The date and time the template and security assignments were last saved.</p> <p>The date and time are recorded in GMT (Greenwich Mean Time). The date is actually local time with the GMT offset listed. It is NOT printed in GMT. GMT is only listed to display the offset for GMT.</p> <p>The format is as follows: "Last saved <i>dd-MMM-yyyy HH:mm GMT -n</i>"</p> <p>For example: Last saved 21 JUL 2008 16:11 GMT -8</p>
Template Name	<p>The name of the template.</p> <p>Each template is listed separately</p>

Report Section	Description
Report Details	<p>This section contains three columns that contain information about the assigned users:</p> <p>Group Name - The name of the user group sorted alphabetically in ascending order.</p> <p>Role - The role assigned to the group. A group can be assigned multiple roles.</p> <p>Notify - Indicates whether the group should be notified.</p>
Report Template Owner	The owner or owners of the periodic report.

Accessing the Author Tab

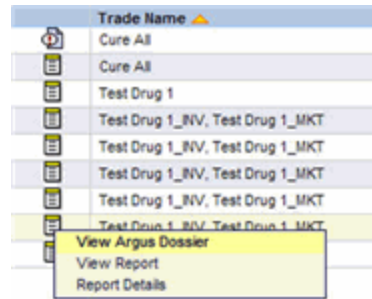
Use the following procedure to access the **Author** tab:

1. Select Reports->Compliance->Periodic to display a list of periodic reports.

The screenshot shows a web application interface with a navigation bar at the top containing tabs: Active Cases, Worklist, Case Actions, Reports, Local Affiliate, Utilities, and Dashboards. Below the navigation bar, the breadcrumb path is 'Reports > Compliance > Periodic'. The main heading is 'PERIODIC REPORTS' with a 'View All' link. Below the heading, it says 'Total Number of Rows (9)'. The table below has two columns: 'Trade Name' and 'Destination'. The first row has a report icon and 'Cure All' in the Trade Name column, and '(No Specific Agency)' in the Destination column. The second row has a document icon and 'Cure All' in the Trade Name column, and '(No Specific Agency)' in the Destination column. The remaining seven rows have document icons and 'Test Drug 1' or 'Test Drug 1_IV, Test Drug 1_MKT' in the Trade Name column, and '[HA] US (FDA)' in the Destination column.

	Trade Name ▲	Destination
	Cure All	(No Specific Agency)
	Cure All	(No Specific Agency)
	Test Drug 1	[HA] US (FDA)
	Test Drug 1_IV, Test Drug 1_MKT	[HA] US (FDA)
	Test Drug 1_IV, Test Drug 1_MKT	[HA] US (FDA)
	Test Drug 1_IV, Test Drug 1_MKT	[HA] US (FDA)
	Test Drug 1_IV, Test Drug 1_MKT	[HA] US (FDA)
	Test Drug 1_IV, Test Drug 1_MKT	[HA] US (FDA)
	Test Drug 1_IV, Test Drug 1_MKT	[HA] US (FDA)

2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.



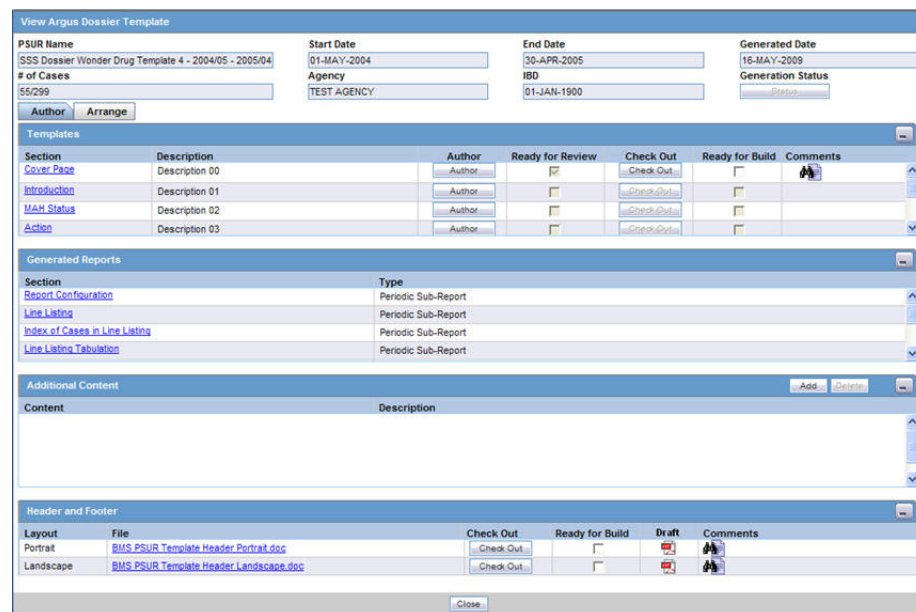
4. The system opens the Author tab for the selected report.

About the Author Tab

All the tasks required to generate a Dossier report can be performed from the **Author** tab in the View <template name> Template. Generating a Dossier report requires you to do the following:

- Provide report content
- Review the report
- Approve the report
- Publish the report

The following is an illustration of the **Author** tab.



Author Tab Fields

The following table lists and describes the fields and controls on the **Author** tab.

Field/Control	Description
Periodic Report Name	Displays the periodic report name as configured in the Subject Tab

Field/Control	Description
Start Date	Displays the start date of the periodic reporting period from report configuration
End Date	Displays the end date of the periodic reporting period from report configuration
Generated Date	Displays the date the report was generated.
# of Cases	Displays the number of cases that have been included in the PSUR report.
Agency	Displays name of the agency
IBD	Displays the IBD name of the configured product
Templates Section	This section displays a list of all PSUR template section names. Click the template name to view the unprocessed template doc or docx file in a separate window.
Collapse/Expand icons	Click the Collapse icon to collapse the Templates section. Click the Expand icon to expand the Templates section.
Section	Displays the names of the sections included in the template.
Description	Display a description of the section contents.
Author button	Click Author to perform report-related tasks based on your assigned user role.
Ready for Review	Displays if the section of the template is ready to review.
Ready for Build	Displays if the section of the template is ready to generate.
Check Out Button / Check In Button	Click Check In to check a template section in. This button displays only if a section has been checked out. Click Check Out to check in a template section. When you click Check Out the system displays the Check Out screen. This button displays only if the authoring task has been successfully completed.
Comments	Enables you to enter comments regarding the template. Click the Zoom icon to view all user comments.
Generated Reports	Provides a list of generated reports.
Collapse/Expand icons	Click the Collapse icon to collapse the Generated Reports section. Click the Expand icon to expand the Generated Reports section.
Section	Provides a link to the unprocessed template file.
Type	Identifies the type of report the system generated
Additional Content	Displays any additional content of the user has added content
Collapse/Expand icons	Enables you to collapse or expand the Additional Contents section.
Add	Enables you to add additional content to the report.
Delete	Enables you to delete any uploaded additional content.
Content	File name of the attached content
Description	This is the additional content Description
Header and Footer	Enables the users to view the header and footer files as they appear on the pages that follow.
Collapse/Expand icons	Displays any additional content of the user has added content
Layout	Indicates whether the document is in portrait or landscape orientation.

Field/Control	Description
File	The name of the current file as a link. When you click this link the system opens the current header/footer file.
Check Out/Check In	Enables you to check out a file for modification and check it back in. Check out and check in are for the user of owners and reviewers.
Ready for Build	Indicates whether the report is ready to build.
Draft	Generates the draft header footer template in PDF format.
Comments	Enables the user to enter any relevant comments.
Close	Closes the active window.

Author Tab Usage Considerations

When using the **Author** tab, consider the following:

- The system disables the **Generation Status** button until you initiate the report build process,
- The screen displays all periodic report configuration elements in sections on the tab.

- Templates Section

This section lists all sections of the template as configured in previous steps

The **Template** name is a hyperlink. When you click the template name, the application opens the raw template from the database.

This section displays all the pre configured templates you added when you created the report.

The templates are listed in the order they were in when the report was created.

Click the report section link to view the template file.

The application displays a minimum of six rows. If there are more rows, a scroll bar is available. The scroll bars appears as necessary

- Generated Reports Section

The application displays the report sections ascending order by **Type** and then by **Section**.

Click the report name to view the latest version of a report. The system displays the report (in PDF format) in a separate window.

Click the report section link to view the section report.

The system displays a minimum of six (6) rows. If there are more than six (6) rows, the system displays a scroll bar

Generated report types are: PSUR, CTPR, NDA, and IND. The following table lists the report names for each report type.

Report Type	Report Names	
PSUR	Report Configuration	Cumulative Summary
	Line Listing	FDA - Adverse Event Summary
	Index of Cases in Line Listing	FDA - Domestic Consumer Report
	Summary of Cases missing assessments	FDA - MedWatch forms
	Line Listing Tabulation	CDA or CL based on cases in Line Listing (*)
	Summary of Unlocked Cases	CDA based on all cases (*)
	CIOMS reports	CDA or CL based on date range
CTPR	Report Configuration	CIOMS reports
	Line Listing	Cumulative Summary
	Index of Cases in Line Listing	FDA - Adverse Event Summary
	Summary of Cases missing assessments	FDA - Domestic Consumer Report
	Count of Cases per Report Type	FDA - MedWatch forms
	Event Count per Study Drug (1)	CDA or CL based on cases in Line Listing (*)
	Event Count per Study Drug (2)	CDA based on all cases (*)
	Line Listing Tabulation	CDA or CL based on date range
NDA	Report Configuration	Summary of Cases missing assessments
	Tab 1: MW or VAERS forms	Summary of Unlocked Cases
	Tab 2: Index of MW or VAERS forms	List of Nullified 15-day cases
	Tab 3 Part 1: Line listing of 15-day reports submitted	Custom Case Summary Tabulation
	Tab 3 Part 2: Tabulation by SOC of all events submitted	CDA based on cases in Line Listing (*)
	Tab 3 Part 3: Cases sent to FDA under a different NDA	CDA based on all cases (*)
		Case Count Summary
IND	Report Configuration	CDA based on cases in Line Listing (*)
	Line Listing of Cases	CDA based on all cases (*)
	Line Listing of Death Cases	

- Additional Content Section

You can upload additional information to attach to the report.

- You can **only** upload the following file types: .PDF, .DOC, and .DOCX
- If you try to upload another file type, the system displays the following error message:

Your file has not been uploaded. File type must be .pdf, .doc, or .docx.

- When you click **Add**, the system opens an upload pop-up box.
- You **must** enter a description of the file you are uploading. If you fail to enter a description and click **OK**, the system displays the following error message:

You must enter a description for the file you are uploading.

- The maximum size of the uploaded file is 30 MB.

The names in the **Additional Content** section are links. Click the link to open the file.

If you select a row and click **Delete**, the system displays a confirmation dialog box with the following message:

Are you sure you want to delete the highlighted Row.

- Click **Yes** to delete the row.
- Click **No** to dismiss the dialog box without deleting the row.

The system displays a minimum of four (4) rows in the section. A scroll bar displays if there are more than four (4) rows.

General Usage Information

- Click the collapse and expand icons to collapse/expand each section.
- The system highlights a selected row.

An **Author** button is available for each template.

- The system enables the **Author** button to all user roles that have access to Dossier.
- Click the **Author** button to open the **Questions** dialog.
- All users can view all questions; however, only **Authors** and **Owners** can change answers.

Only a user assigned an **Author** role can execute individual templates.

- The **Author** operation guides you through all questions (as defined in the template and processed during upload). You are **expected** to answer the questions.
- After the user clicks Draft or Final, the system generates a Word document (.DOC/.DOCX format) that contains the processed content and narratives.
- Once the user clicks Final, the system generates the final version of the template and allows the Author user to check the Ready for Review check box.

The system enables the **Ready for Review** and **Ready for Build** checkboxes and the **Check In** and **Check Out** buttons when a Template is **Final**.

When a template is Final, the system enables the **Ready for Review** check box.

- Only the template Reviewer and the report Owner can check this check box.
- Once this box is checked, the system does the following:
 - Enables the **Ready for Build** option.
 - Prevents you from generating a final template.
 - Disables the **Ready for Review** check box. Once checked, this check box **cannot** be unchecked.

The system enables the **Ready to Build** option when you select **Ready for Review**.

- Only the Author or Owner can check the **Ready for Build** option.
- You can uncheck this option after it has been checked.

The system enables the **Check In** and **Check Out** buttons when you check the **Ready for Review** option.

- Click the **Check Out** button to open the **Check Out** dialog box.
- When a document is checked out, the system hides the **Check Out** button.

- The system displays the **Check In** button only if the final template has been checked out.
- Click the **Check In** button to open the **Check In** dialog.
- The Final template can be checked out by **one** user at a time.
- Only the user who checked the document out can check it in.

The system displays the **Last Check in Comments** in a text box on the screen for each template. Click the **Zoom** icon to open the check in comments in a popup dialog.

When all template sections and Header and Footer sections are checked, the Owner can build the report. The build process does the following:

- Merges all template sections into one.
- Creates a comprehensive .doc or .docx file.
- Saves the final document in the database and opens it on the screen.
- Enables all users (if the build was successful) to check-out the document and edit it manually.
- Enables users to check-in this document after check-out.

The system enables the **Build** button only if the following are true:

- The user is the owner of the periodic report.
- All the templates have been marked as **Ready for Build**.

If Documentum is configured, AG Services picks up the built file and saves it in Documentum.

- If Documentum is not configured, the file is marked **not submitted**.
- The file is saved in .PDF format.

Role Security Requirements

The following table show which user types have access to various elements in the GUI.

User Type				
GUI Element	Owner	Reviewer	Author	Comment
Author Button	Yes	Yes	Yes	
Final	Yes	No	Yes	
Draft	Yes	Yes	Yes	
Save	Yes	No	Yes	
Ready for Review	Yes	No	Yes	Ready for Review is available when the Final has been generated for the Template.
Ready for Build	Yes	Yes	No	Ready for Build is available only when Ready for Review is checked.

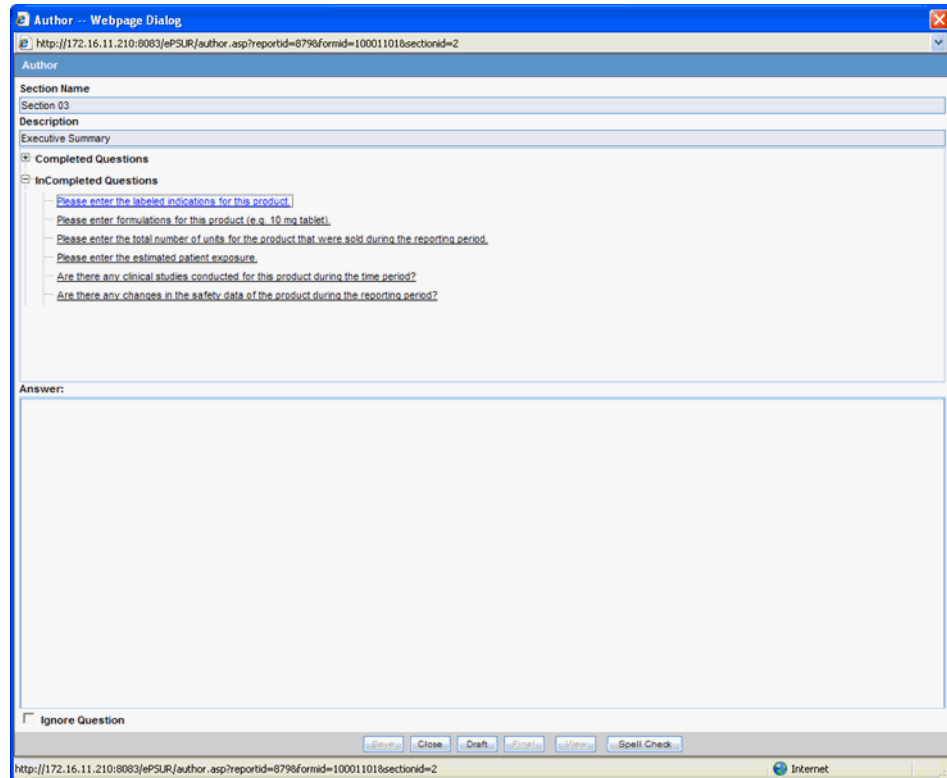
User Type				
GUI Element	Owner	Reviewer	Author	Comment
Section Checkout	Yes	Yes	No	Ready for Build is available only when Ready for Review is checked.
Add Other Content	Yes	Yes	Yes	If the user is a Reviewer for any of the section templates, then he/she will have access If the user is an author for any of the section templates, then he/she will have access.
Build	Yes	No	No	Available only when all templates are checked in and Ready for build is checked for all templates.
Checkout	Yes	Yes	No	Only available when the Build Process is complete. If the user is a Reviewer for any of the section templates, he/she will have access
View	Yes	Yes	Yes	Only available when the Build Process is complete. If the user is a Reviewer for any of the section templates, he/she will have access
Publish	Yes	No	No	Only available when the Build process is complete and the report is checked in.
View	Yes	Yes	Yes	Only available when the Publish is complete. Only available when the Build Process is complete. If the user is a Reviewer for any of the section templates, he/she will have access.

Providing Report Content

Dossier enables you to provide report content if you have one of the following user roles:

- Author
- Author & Reviewer
- Owner

When you click **Author** on the **Author** tab, the system opens the **Author** window shown in the following illustration.



Author Window Fields

The following table lists and describes the fields and controls in the **Author** window.

Field/Control	Description
Section Name	The name of the section being created for the report.
Description	A description of the purpose of the section
Completed Questions	Click the expand icon to display a list of completed questions. The system places the questions in this section as you answer them.
Incompleted Questions	Click the expand icon to display a list of questions that you must answer before building the report. Click the question link to display the list of acceptable answers in the Answer section.
Answer	Enables you to answer the questions presented in the Incompleted Questions section.

Field/Control	Description
Ignore Question	Enables you to skip a questions by click the check box.
Save	Saves the answers entered during the session in the database
Close	Closes the Authoring window.
Draft	Generates and displays a draft version (doc/docx file) with current saved answers. It does not save the file to the database.
Final	Generates and displays a doc/docx file and saves the final version of the template in the database.
View	Displays the saved doc/docx file.
Spell Check	Enables you to run spell check on text entered in a text field.

Author Window Usage Considerations

When entering content in the **Author** window, be aware of the following:

The application processes each section and stores it in the database

The **Author** button is available only to users that have been assigned as authors to the section.

When multiple users are assigned as author to the same section, the application will allow a single section to be "Authored" by a single author at a time.

Clicking **Author** enables you to navigate through the questions and user prompts from the database.

- If there are no questions for this template, the system displays *No Questions Found* in the dialog.
- Clicking a question enables you to select or enter the answer in the **Answer** text box. If the question has been answered during an earlier session, the system displays the previous answer.

The Questions Tree has two sections: **Completed Questions** and **Incompleted Questions**.

- **Completed Questions** - The system displays a list of all answered questions. When you answer a question, the system moves the question from the Incompleted Questions section to this section
- **Incompleted Questions** - The system displays a list of all unanswered questions. If you fail to answer a previously answered questions, the system moves the questions back to the incompleted questions category.

The first part of the screen displays all the questions that have been asked in the template section.

- The first question is selected by default.
- You can scroll to view any question in the list.

The second section of the screen enables you to enter any text or select any option value as required.

Click **Spell Check** to check for spelling errors in a question answered in a text box.

- The system enables the **Spell Check** button only when you are required to enter the answer in a text box and when focus is on the text box.
- If the question requires you to select an answer from a drop-down list, the system disables the **Spell Check** button.

Click **Close** to stop the authoring process.

- If any questions have been answered, the system displays the following messages:

By closing this window will lose any answers that have not been saved. Are you sure you want to continue?

If you click **Yes** (default), the system closes the message and the Author window **without saving** answers that have not been saved.

If you click **No**, the system closes the message box and the **Author** window remains open.

Click **Save** to save all answered questions before moving to the next question.

You can continue the authoring process at any time.

The system lists all completed (saved) questions in the Completed Question section.

You can return to a previous question and change its answer.

Select **Ignore Question** if you wish to skip a question. The unanswered questions remain in raw format in the body of the file itself.

- This check box is active only when a question is selected and unanswered.

Click **Final** to generate a final.doc/.docx for a template. A final documents replaces the questions and operands with answers from the database.

- If one or more of the questions have not been answered, the system displays the following message:

There are unanswered questions. Do you wish to generate the final document?

Click **Yes** to generate the .doc/.docx file and skip any unanswered questions.

- If you choose this option, you will have to check out the document and answer the remaining questions manually.

- If you click **No**, the Authoring window remains open for further entry.

Any values derived from the unanswered questions will be left blank.

Once the final has been generated, click **Final** to open the generated .doc/.docx file from the database.

Click **Draft** to generate a .doc/.docx file using the latest data from the database in a read only state. The .doc/.docx will not be saved to the database.

You can move to the next question without answering the current question.

Only one Author can enter report content at a time.

The Author process can be audited.

Entering Report Content

Use the following process to enter report content:

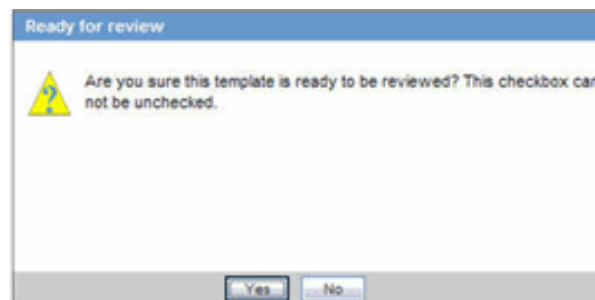
1. Select Reports->Compliance->Periodic to display a list of periodic reports.

2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab for the selected report, click Author.
5. When the system opens the Author window, click the expand icon from the Incompleted Questions section to display a list of questions you must answer.
6. Click the question you want to answer to display open the Answer section, then do the following:
 - Select the answer from the drop-down list in the **Answer** section or enter any text as necessary.
 - Click **Save** to save the answers to the question.
 - Repeat steps 6a and 6b until you have answered all remaining questions.
 - Click **Final** to save the completed section of the report in the database.

Setting Ready for Review

Once the final has been generated, the report author can indicate whether the template section is ready for review.

1. Select Reports->Compliance->Periodic to display a list of periodic reports.
2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab for the selected report, locate the appropriate template and click the associated check box in the Ready for Review column.
5. When the system opens the Ready for review dialog box, click Yes.



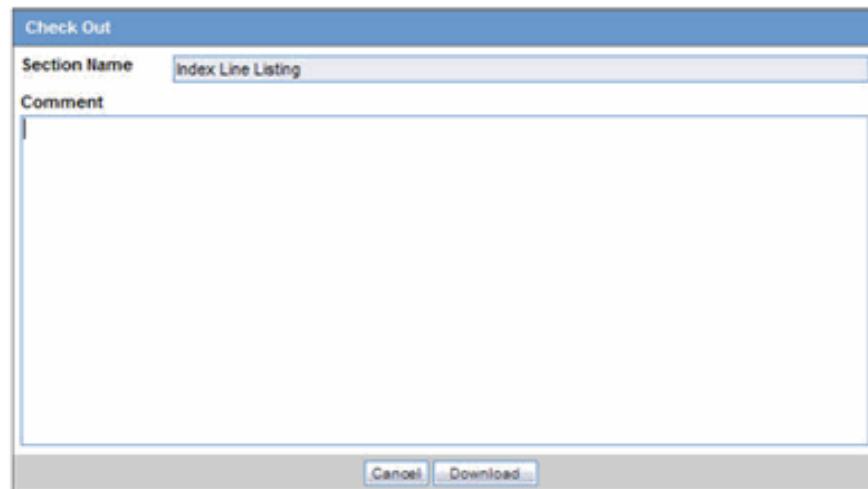
6. The system places a checkmark in the check box and enables the Check Out button.

Editing a Template Manually

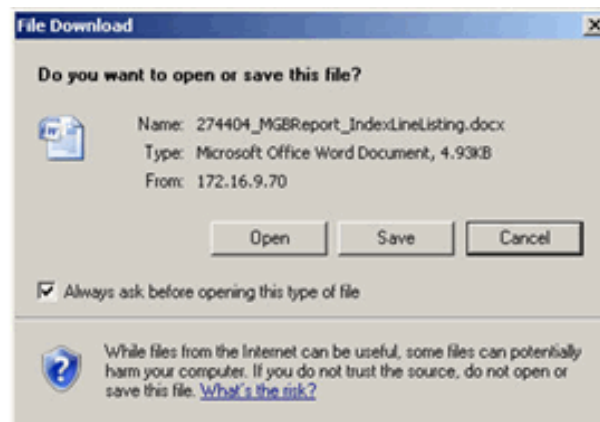
Dossier enables you to use Microsoft Word to manually edit a template. Only one person can check out and edit a document at a time.

1. Select Reports->Compliance->Periodic to display a list of periodic reports.
2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.

3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab, locate the appropriate template and click Check Out.
5. When the system opens the Check Out dialog box, type a relevant comment in the Comment field and click Download.



6. When the system opens the File Download dialog box, click Open to download a copy of the template file and open it in Microsoft Word.



7. Edit the document as required and save it.

Note: You must save the document in one of the standard Microsoft Word file types (.doc or .docx). Otherwise, you will be unable to check the document in.

About the Check Out Dialog Box

The following table lists and describes the fields in the **Check Out** dialog box.

Field/Control	Description
Section Name	The name of the section you are checking out.

Field/Control	Description
Comments	Any relevant comments about the document. The system stores such comments in the Template History.
Cancel	Click Cancel to abort the check-out operation.
Download	Click Download to download a Microsoft Word (.doc/.docx) version of the template for manual editing.

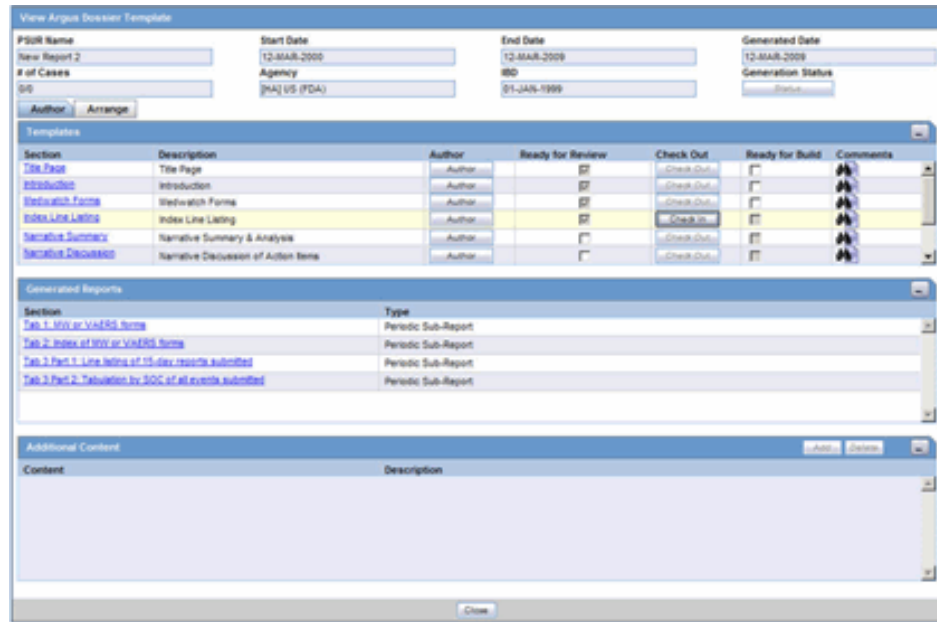
Usage Considerations

When using the **Check Out** dialog box, be aware of the following:

- You can check out a processed template (.doc/.docx) only after the authoring operation is successfully completed and the author has checked **Ready for Review**.
- Any user role (Author/Reviewer/Owner) can check the file out.
- You cannot check a file in unless it has been checked out.
- You can enter comments when checking out a document. Comments are record in the comments field.
- Click **Download** to save the file in .doc/ .docx format to a file location of the your choosing.
- All check-outs are auditable.
- The **Check In** button is disabled except for the person who checked the document out.
- The Check In dialog pop-up has an **Undo Checkout** button that enables you to reverse the check-out operation.
 - When you click **Undo Checkout**, the system dismisses the pop-up dialog box and makes the file available to other users.
 - The system **does not** save any changes you may have made to the template.

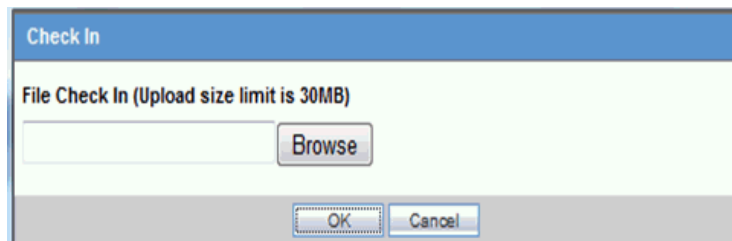
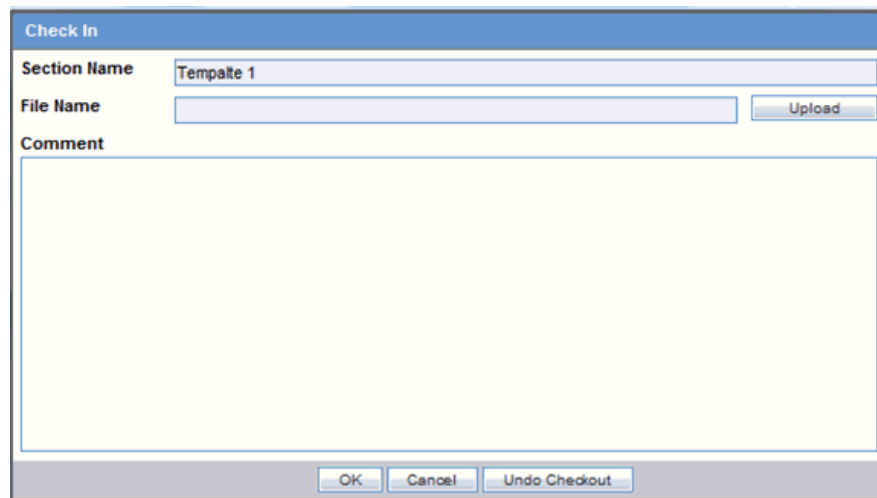
Undoing a Check Out Operation

Under some circumstances, you may find it necessary to reverse a check out operation. When you check a document out, the system changes the **Check Out** button to a **Check In** button as shown in the following illustration.



Note: To reverse a check out operation

1. Go to the **Author** tab.
2. Locate and click the appropriate **Check In** button.
3. When the system opens the Check In dialog box, click Undo Checkout.



4. The system reverses the check out operation without saving changes you may have made to the document.

Checking In an Edited Template

After using Microsoft Word to edit and save a template document, you must check it in using the **Check In** button on the **Author** tab.

To check in an edited document:

1. Go to the **Author** tab.
2. Locate and click the appropriate **Check In** button.
3. When the system opens the Check In dialog box:
 - Type the full path name for the template in the **File Name** field OR Click **Browse** to locate and select the appropriate document.
 - Type any relevant information in the **Comment** field.
 - Click **OK**.
4. The system checks the document in.

About the Check In Dialog Box

The following table lists and describes the fields and controls in the **Check In** dialog box.

Field/Control	Description
Section Name	The name of the template you have checked out for editing. This can be a maximum of 50 characters.
File Name	The local path of the file that you have updated. The path name can be a maximum of 200 characters.
Browse	Click Browse to display the file selection dialog box and enable you to browse the local directory and locate the file to check in.
OK	Click OK to upload the edited file.
Cancel	Click Cancel to abort the upload operation.
Undo Checkout	Click Undo Checkout to reverse the check-out operation. This button is available only to the user who has the document checked out.

Usage Considerations

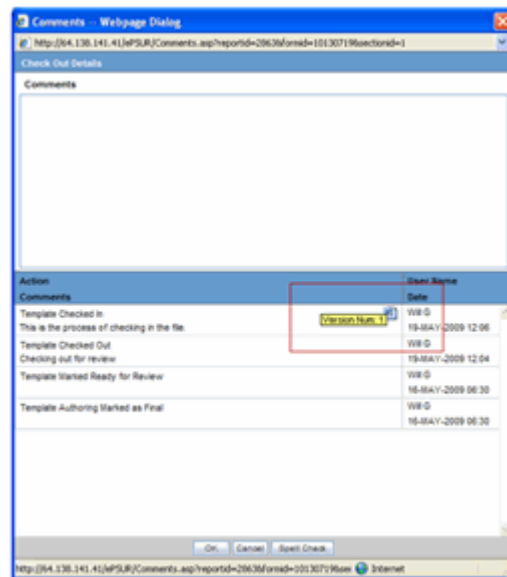
When checking in a document, be aware of the following:

- **Check In** is available only if the file is checked-out previously by the person updating the template.
 - The system disables the **Check In** button for all users except the user who checked the document out.
- You can indicate whether a section is ready for review
- The Check In dialog pop-up enables you to reverse the checkout.
- Click **OK** to initiate the upload process.
- You can identify a section that is ready for generation by clicking the **Ready for Review** checkbox on the **Author** tab.

Retaining Template Versions

The Dossier application provides version control for authored templates. Checking out an authored template initiates the review process and enables you to modify a template as necessary. The Dossier application tracks the template version whether or not has a document management system configured for its use. In other words, if a DMS is not configured for Dossier's use, you can check out and modify templates and the system maintains an updated version of the template when you check it in. Once you check in a template, Dossier retains a version of the modified template and makes it available for later viewing by any user who has access to Dossier comments.

The following is an illustration of the Comments window. You can view the checked-in template by clicking the Version Num icon.



When checking templates in and out, be aware of the following:

- An icon identifies a document that is checked in.
- When you place the mouse cursor on the icon, the system provides the following version information:
 - Version Num: x where: x is the incremental version number.

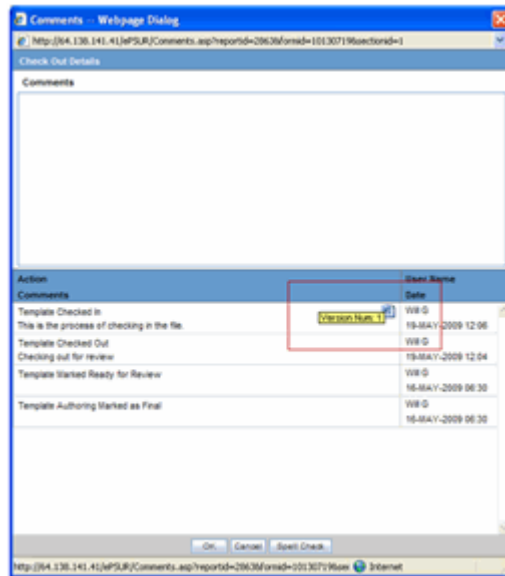
The system version of the document is considered Version 1 and the version number appears on the Word icon.

When you check out the system version (version 1) and check it in again, the system updates the version number to 2.
- When you click the Word icon, the system opens the document in the correct application.
 - If you want to replace a version of the document, you must save the file locally and check out the current template and check in the historical version.
- All checked out files retain the document history.

About the Template History and Comments Log

The **Comments and History** dialog box provides you with information about the whether the document is checked out and who has checked it out, and how the document has been modified and who has modified it.

The following is an illustration of the **Comments and History** dialog box.



Fields and Control

The following table lists and describes the fields and controls in the **Comments and History** dialog box.

Field/Control	Description
Comments (entry)	Enables you to enter comments retained in the Template History.
Action	Displays the action, if any.
Comments (historical)	Enables the user to review comments in the Template History.
Username	Displays the user name of the user that entered the comments
Date	Displays the time date stamp in local user time (GMT offset)
OK	Dismisses the window and records any comments entered by the user.
Cancel	Cancels any action and dismisses the dialog
Spell Check	Checks for spelling errors in the comments text box

Usage Considerations

When using the **Comments and History** dialog box, be aware of the following:

- When you click **OK**, the system records any comments you entered and places them in the Template History.
- The Template History section retains a history of the following actions that have occurred for each template row:

- Template Authoring Marked as Final
- Template Marked Ready for Review
- Template Checked Out
- Template Checked In
- Template Marked Ready for Build
- The template history box is not editable.
- The format of this history is as follows:
 - Row A-Left "Action: <action from the above listed items>"
If no action occurs, do not print any text.
 - Row B-Left "Comments: <any comments entered>"
If no comments exist for the action, do not print any text.
Comments should display up to 255 characters (which is the limit on the comments box) and should wrap if needed.
 - Row 1-Right "<username>" aligned right
Always print row 1-Right.
 - Row 2-Right Time date stamp "dd-mmm-yyyy HH:mm" aligned right.
Always print row 2-Right.
TimeDate Stamp shows the local time.
 - The Template History displays the history in descending order. (i.e., most recent record on top).
 - Template history records are separated by a line (¼ point).
 - You can enter comments without any action being completed. In this case only the comment will be recorded.

Setting Ready for Build

Once the final has been generated, reviewed, and approved the report reviewer and/or report owner can indicate whether the template section is ready for the report build. **Ready to Build** must be checked for all sections of the report before the system can build the report.

To indicate a template section is ready for the report build:

1. Select Reports->Compliance->Periodic to display a list of periodic reports.
2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab for the selected report, locate the appropriate template and click the associated check box in the Ready for Build column.

Building a Dossier Report

Only the assigned owner can build a Dossier report. You can do this from the **Arrange** tab. Steps involved in building the report include the following:

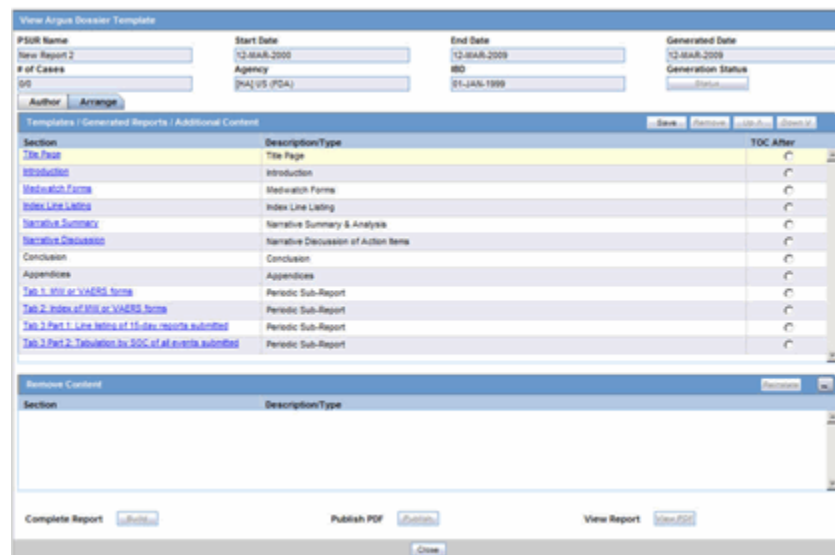
- Setting Section Order
- Creating a Table of Contents
- Generating the Report
- Viewing the PDF

About the Arrange Tab

On the **Arrange** tab, you can change the order in which sections appear in the final report. You can also delete a section as necessary.

To access the Arrange tab:

1. Select Reports->Compliance->Periodic to display a list of periodic reports.
2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab, click Arrange to open the Arrange tab.
5. The system opens the Arrange tab.



Arrange Tab Fields and Controls

The following table lists and describes the sections and fields on the **Arrange** tab.

Section/Field/Control	Description
Templates / Generated Reports / Additional Content	This section lists and describes the template sections in the report.
Save button	Enables you to save the current report layout.
Remove button	Enables you to remove any section. When you click Remove, the application removes the section and places it in the Removed Content section of the tab.
Up button	Enables you to move the selected report section up in the list.

Section/Field/Control	Description
Down button	Enables you to move the selected report section up in the list.
Section	This column contains the name of each section of the report. Click the link to open the report section.
Description / Type	This is either the Description added by the user or the type of file when the item is a generated report
TOC After	Indicates where the TOC will be placed in the report.
Remove Content	This section displays the content of the report that has been removed.
Reinstate button	Allows you to put the removed content back in the report at the bottom of the list. User the Up and Down buttons to put the section in its correct position in the report.
Minimize / Maximize icons	Enables you to collapse (minimize) or expand (maximize) the Remove Content section.
Section	This column contains the name of each section that has been removed. Click the link to open the removed section.
Description / Type	This is either the Description added by the user or the Type of file when the item is a generated report that has been removed
Build button	Allows users to initiate the generate process
Generation Status	Enables you to see the status of the report build. This button is not available until you initiate the build operation.
View PDF button	Enables you to view the compiled report.
Publish	Enables you to initiate the publish operation.

Arrange Tab Usage Considerations

When using the **Arrange** tab, be aware of the following:

- Select the row and click **Up** or **Down** to arrange the report sections in the desired order for the final report.
 - If you select the first row, the system disables the **Up** button.
 - If you select the last row, the system disables the **Down** button.
- If you move reports or attachments, the system does not save them until you click **Save**.
 - The system displays the following message:
The information was saved successfully
 - If you click **Close** to leave the screen, the system displays the following message:
You have made changes to the Dossier report order, if you press OK, changes made will be lost.
- You can remove a section to prevent it from being included in the final build.
 - If you remove a section, the system maintains the order.
 - If the Build process is completed, the system disables the Up and Down buttons.
- You must select a row before clicking **Remove**.
 - If you do not select a row, the system disables the **Remove** button.

When you click **Remove**, the system displays the following message:

Are you sure you want to remove the highlighted row?

- When you click **Remove**, the system moves the selected row to the **Remove Content** section.
 - Click the **Minimize/Maximize** buttons to collapse and expand the **Remove Content** section.
 - Collapsing the section provides more space for the **Templates / Generated Reports / Additional Content** section.
 - When expanded, the **Remove Content** section displays a minimum of three rows.
- Click **Reinstate** to put a removed section back in the report.
 - You must select a row before clicking **Reinstate**.
 - The system disables the **Reinstate** button until you select the row.
 - When you click **Reinstate**, the system displays the following message:
Are you sure you want to reinstate the highlighted row.
 - When you click **Reinstate**, the system moves the selected row to the bottom of the **Templates / Generated Reports / Additional Content** section.
- If the Build process has completed, the **Remove** and **Reinstate** buttons are disabled

Arranging the Sections of a Report

Use the following procedure to arrange the sections of a report.

To arrange the sections of a report:

1. Select Reports->Compliance->Periodic to display a list of periodic reports.
2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab, click Arrange to open the Arrange tab.
5. When the system opens the Arrange tab:
 - Select a row.
 - Click **Up** to move the row up in the list OR Click **Down** to move the row down in the list.
 - Click **Save**.

Removing a Section from a Report

Use the following procedure to remove a section of a report:

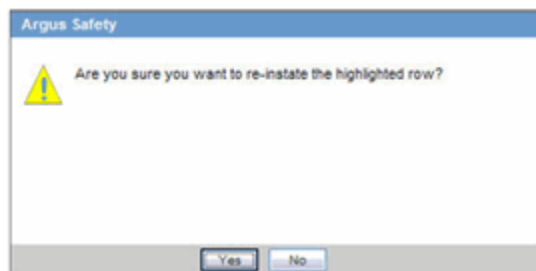
1. Select Reports->Compliance->Periodic to display a list of periodic reports.
2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab, click Arrange to open the Arrange tab.

5. When the system opens the Arrange tab, select a row and click Remove.
6. When the system removes the section and places it in the Remove Content section of the tab, click Save to save the changes to the report.

Reinstating a Section in a Report

Use the following procedure to reinstate a section in a report:

1. Select Reports->Compliance->Periodic to display a list of periodic reports.
2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab, click Arrange to open the Arrange tab.
5. When the system opens the Arrange tab, go to the Remove Content section, select the section to put back in the report, and click Reinstate.
6. When the system displays the following message, click Yes to put the section back in the report.



7. When the system places the reinstate section at the bottom of the section list:
Leave the document in its present position OR Select the row and use the **Up** and **Down** buttons to move the section to its correct position.

Creating a Table of Contents

The table of contents for a Dossier report is created at run time. Therefore, you must specify the location of the table of contents in the document on the **Arrange** tab. If you do not specify a location, the system automatically prints the table of contents as the first page of the report. Click the appropriate option button in the **TOC After** column to indicate where to place the TOC. For example, if you want the TOC to appear **after** the title page, click the TOC After option button associated with the Title Page section.

When specifying the location of the table of contents, be aware of the following:

- On the **Arrange** tab, you can specify, at any time, which content section the TOC follows.
 - You can select the **TOC After** option button for the section the TOC will be placed after during the final build.
 - Pages before the table of contents **will not** be numbered automatically.
 - Pages before the table of contents **will not** include the header and footer. However, the header and footer will be included on the TOC pages.

A section must be specified as **TOC After**; otherwise the TOC begins printing on the first page of the report

If you remove a row specified as **TOC After**, the system removes the row from the build content. None of the remaining section will have **TOC After** specified.

If you reinstate the removed section, TOC After **will not** be specified.

- The system generates the Table of Contents based on the order of the report sections when the final build is started.
 - Each section row is a new chapter.
 - The chapter name comes from the section name.
- The system creates Acrobat bookmarks for each section row of the report using the section name given by the user or the system.
- The system creates up to 10,000 bookmarks for each MedWatch, CIOMS, or VAERS form. If there are more than 10,000 forms, the system creates a single bookmark for all forms.
- The system generates and displays the TOC in portrait orientation.

Generating a Dossier Report

The build process merges the report sections and generates a comprehensive period report. Since there is no need to modify a generated report, the system produces all reports in PDF format.

The periodic report owner is the only person who can generate a report and can start the build process **only** after all sections of the periodic report have been marked **Ready for Build**.

Once all sections have been marked **Ready for Build**, the system enables the **Build** button on the **Arrange** tab.

To generate a report:

1. Select Reports->Compliance->Periodic to display a list of periodic reports.
2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab, verify that all parts of the report are marked Ready for Build and click the Arrange tab.
5. When the system opens the Arrange tab, click Build to generate the report.
6. The system generates the report.

Report Generation Usage Considerations

When building a report, consider the following:

- Only the owner of the periodic report can initiate the generate process.
- The owner can initiate the build process **only** after all sections of the periodic report have been marked **Ready for Build**.
- The **Build** button active if the **Ready for Build** check box on the **Author** tab is checked.

- When you click **Build**, the system compiles the report in the order on the **Arrange** tab.
 - The system converts all files to PDF (if not already PDF) and adds any required header, footers, and page numbers to the report.
 - The system displays a message box with the following message:
Your Dossier report has been submitted to final build.
 - The system saves the current arrangement before it starts the **Build** process.
- The Build process does the following:
Merges all template sections into a single PDF file.
Ignores instructional comments.
- You **cannot** modify a periodic report while the Dossier build process is running, and the system disables the **Modify** and **Print** buttons until the build process is complete.
- The system prevents you from moving any section on the **Arrange** tab while the system is building the report. The **Arrange** section should be grayed out and you cannot move any sections of the report.
- Once the final build is completed, the system disables the **Build** button.
- If you make any changes on the **Arrange** tab and click **Save** after the build is successfully completed, the system displays the following message:
Your dossier is already built. Saving any changes will require that you rebuild the dossier again. Are you sure you want to save these changes.
If you click **Yes**, the system does the following:
 - Dismisses the message.
 - Removes the existing report.
 - Enables the **Build** button.
 - Disables the **View PDF** button.
 - Disables the **Publish** button.If you click **No**, the system retains the existing report.
- Status Button
 - The system activates this button **after** you start the build process.
 - This button remains active once the build process is completed
 - If you click this button after the build process starts, the system displays the status of the build process in the standard report generation pop.
 - When you click Close on the status window, the system does the following:
 - * Closes the status window.
 - * Continues to generate the report.
 - The status window displays the progress of the build process.



- The system displays the following statuses, in order of occurrence:

Dossier Report Generation Request Received

- Status is followed by a date and time stamp for when this action kicked off the report in local user GMT offset date/time: "dd mmm yyyy HH:mm" (i.e. "02-FEB-2008 15:43")

Dossier Report Generation Started

- The system displays a grayed out check mark until this process starts (picked up by AG Service)
- Once AG Service picks up the process, the system displays a date and time stamp showing when this action started in local user GMT offset date/time: "dd mmm yyyy HH:mm" (i.e. "02-FEB-2008 15:43")

Report Converting Templates to PDF

- The system displays a grayed out checkmark until this process starts.
- While the process is in progress, the system displays "Processing..."
- When the process is complete, the system displays the total processing time in minutes and the gray checkmark changes to green.
- Processing time displays as follows: "(completed in xx min.)"

Merging Sections before Table of Contents

- The system displays a grayed out checkmark until this process starts.
- While the process is in progress, the system displays "Processing..."
- When the process is complete, the system displays the total processing time in minutes and the gray checkmark changes to green.
- Processing time displays as follows: "(completed in xx min.)"

Merging Sections after Table of Contents

- The system displays a grayed out checkmark until this process starts.
- While the process is in progress, the system displays "Processing..."
- When the process is complete, the system displays the total processing time in minutes and the gray checkmark changes to green.
- Processing time displays as follows: "(completed in xx min.)"

Creating Table Of Contents and Bookmarks

- The system displays a grayed out checkmark until this process starts.
- While the process is in progress, the system displays "Processing..."

- When the process is complete, the system displays the total processing time in minutes and the gray checkmark changes to green.
- Processing time displays as follows: "(completed in xx min.)"

Creating Final Dossier

- The system displays a grayed out checkmark until this process starts.
- While the process is in progress, the system displays "Processing..."
- When the process is complete, the system displays the total processing time in minutes and the gray checkmark changes to green.
- Processing time displays as follows: "(completed in xx min.)"

Dossier Report Generation Completed

- A grayed out checkmark is displayed until this process is started
- Once the process is complete, the system displays a date and time stamp showing when this action started in local user GMT offset date/time: "dd mmm yyyy HH:mm" (i.e. "02-FEB-2008 15:43"). Errors in the build process are logged into the Safety Error Log.
- The system displays a grayed out check mark until this process starts (picked up by AG Service)
- If an error occurs during any of the build process, a status box displays the following error message:

"Failure, please refer to the Argus Safety Error Log for details."

Any final build error(s) are recorded in the Argus Safety error log.

When an error occurs, the system destroys any compiled documents. You must restart the process

View PDF Button

- Once the final build process is completed, the system enables the **View PDF** button.
- Click this button to display the report.

Publish PDF Button

- Once the final build process is completed, the system enables the **Publish** button.
- If you make changes to the report, the system disables this button until a new build process is completed.

If you make any changes in the Arrange window (i.e., move a report section up or down or add or remove a report section) after the build is completed, the following occurs:

- The system displays the following message:

"The final dossier has been generated. Making changes now will require the report to be rebuilt. Are you sure you want to make changes?" Options OK or Cancel."
- If you click **OK**, the system does the following:
 - Disables the **View PDF** button.
 - Disables the **Status** button.
 - Disables the **Publish** button.

- Enables the **Build** button.
- If you click **Cancel**, the system closes the message box and cancels the change action.

When the system opens the Argus Dossier Template window, only the following are enabled. All other buttons, icons, or links are disabled.

Status Button

Author Tab Section Links

- Template Section Links
- Generated Report Links
- Additional Content Links
- Header/Footer Links

Author Tab Comments Icon

- The comments are read-only, and you **cannot** enter new comments for the Templates Comment icon and the Header and Footer Comments icon.

Arrange Tab

- Arrange Tab Section Links including links to templates, generated reports, and additional content links
- Removed content links.
- View PDF Button

Per the regulation "Guidance for Industry, Providing Regulatory Submissions in Electronic Format - General Considerations" (1999), "the initial page of the paper document should be numbered page 1."

- Set the common profile switch to "Starting from the First Page" so that the first page of the report is page 1, no matter where the table of contents is placed on the Dossier Arrange tab.
- If page numbering is turned off, no page number prints. However, the first page of the report is considered page 1.

Publishing a Dossier Report

The **Publish** function is available only after the report has been successfully generated.

To publish a report:

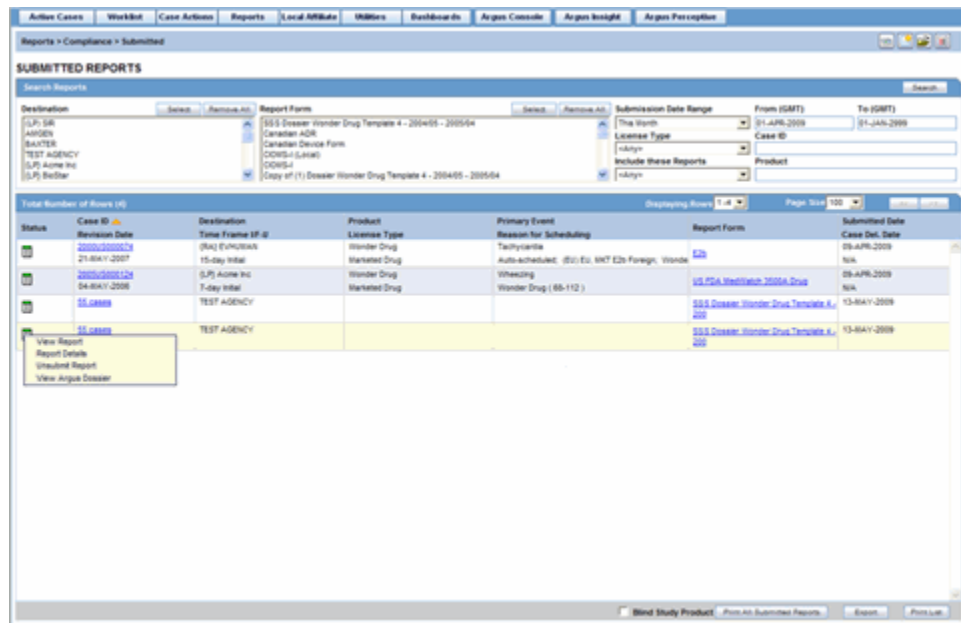
1. Select Reports -> Compliance -> Periodic to display a list of periodic reports.
2. When the application opens the list of periodic reports, locate the appropriate report and click its associated report icon.
3. Select View Argus Dossier from the pop-up menu.
4. When the system opens the Author tab, verify that all parts of the report are marked Ready for Build and click the Arrange tab.
5. When the system opens the Arrange tab, click **Publish** to publish the report. The report gets pushed to Documentum after **Publish** is clicked. The system activates the **Publish** button on the **Arrange** tab after the report has been generated successfully.
6. The system publishes the report.

- Click **View PDF** to view the completed report.

Publish Usage Considerations

When publishing a report, be aware of the following:

- The Publish function is available **after** a report has been successfully generated.
- The system will publish the report only **after** the report has been built.
- The system displays the status of the **Publish** process.



- Users can have access to information used to create the Dossier Report even after Dossier generates the report. Left-click the Status icon to the left of the submitted report and select **View Argus Dossier** from the menu.

Writing Template Scripts

Before you can use templates to generate reports, you (or someone with script writing or programming background) must create *template scripts*. Template scripts define the format for the report. This chapter provides information about writing template scripts and includes discussions of the following:

- Using Microsoft Word to Write Templates
- Using the Template Scripting Language

About Templates

Templates are tools that an administrator or template writer uses to define the structure of a periodic report and the way this report will be laid out when it prints. Once a template is processed, the resulting report is a Microsoft Word (.doc or .docx). A template:

- Can be scripted for the entire periodic report and/or can be split into sections that can be allocated to different users for processing. Once processed, the resulting report is a Microsoft Word document (.doc/.docx)
- Normally has a one-to-one relationship with a single product (active ingredient) and agency
- Can be used to create a template for another product/agency

Template writers use predefined syntax and elements to script templates. The basic objective of the syntax and elements is to provide tools that enable the template writer to:

- Author predefined textual narratives in the body of the template
- Pre-populate values in the body of the document directly from the database
- Prompt users for values not available in the database
- Process user entered values and insert narratives in the document
- Insert instructional text for the report authors
- Insert referential text with links to non-submission content. (Example - Attached Case Listings, CDAs, CIOMSII reports etc.)

The template automates the report generation process as much as possible. However, report authors have the ability to manually edit the content of a report as necessary.

Using Microsoft Word to Write Templates

Dossier supports the use of templates written in Microsoft Word 2000 or higher.

Note: If you are using Word 2007, contact your system administrator to verify that Word 2007 is installed on the Report Server.

To begin writing a template

1. Open a new, blank document in Microsoft Word and save it.
2. Save the document in .DOC or .DOCX format before editing it.

When writing a template, adhere to the following guidelines:

- Standardize the Microsoft Word template (Normal.dot).

Standardize the Normal.dot template for all users designated as owners. This reduces amount of formatting required after the *build* process. Because the output file from the *build* process automatically uses the **Normal.dot** template on the owner's desktop, the output document may not retain formatting used in the original template.

- **Avoid** using the *cut and paste* operations.

The cut/paste operations introduce unknown formatting objects from the source document. Such formatting objects may cause the file to be rejected during the template upload process.

- Do not define special formatting styles in the templates.

Avoid defining any special formatting styles in the templates. Maintain the same styles as defined in Normal.dot.

- **Do not** cut and paste a table from another document into the template.

If a table is required in a template, do not cut/paste the table from another document. Instead, create a new table in the RTF template.

- **Do not** generate the TOC until the build process is complete.

Wait to generate the final table of contents until after the build process is complete. This enables you to include merged documents and updated page numbers in the template.

- The application creates PDF bookmarks only for heading styles created in the Word document.

The publish process ignores all other styles-even if they appear in the table of contents in the Word document.

- Put processing instructions in a `<% . . . %>` block.

The application processes instructions embedded in a `<% . . . %>` block. Each block can contain a set of instructions. To enable the application to process the instructions, embed each instruction in a specific tag.

In other words, make sure the contents of the `<% . . . %>` block are tags that Dossier supports. The system ignores other tags and will output them as a blank string in the report. Any text outside the `<% . . . %>` block will be replicated in its actual form in the output document.

- Apply uniform formatting.

Apply the same formatting to a single block of instructions (i.e., the contents in the `<% . . . %>` block) in the template.

- Make sure scripting tags meet XML standards.

The scripting tags should comply with XML standards. The contents of the `<% . . . %>` tag should be well-formatted XML.

- Use lowercase characters for all tags and variable (implicit/explicit).

Use lowercase character for all tags and variables (implicit and explicit). Explicit variables are case-sensitive.

- **Do not** use scripting tags (i.e., `<%`, `%>`, `\ . . . \`, `<`, `>`) in any content that needs to appear in the output document.

Using the Template Scripting Language

This section provides information about using the template scripting language. It includes a Template Writing Quick Reference and discussions of the following:

- [Template Scripting Elements](#)
- [Template Writing Quick Reference](#)

Template Scripting Elements

A template script includes the following elements:

- Implicit Variables
- Explicit Variables
- Operands
- Nested Questions

Using Implicit Variables

Implicit variables are pre-defined, named elements that correspond to implicit variables defined by the system and are available to the author of the template without declaring them.

Rules for Using Implicit Variable

When using implicit variables, be aware of the following:

- Begin periodic report variables with pound (#) sign (e.g., `#TRADE_NAME`)
- Values to these variables are always used in the context of the periodic report configuration. For example, if you configure a periodic report for Product A (ICH PSUR - Subject Tab), this variable **only** appears as the Product A trade name.

Consider the following usage example:

"There were no cases related to `{#TRADE_NAME}`."

where:

`#TRADE_NAME` maps to a defined value known by the parser.

- You can map these variables to a formula or to the result of a specific SQL statement that is pre-encoded in the parser.
- These variables may return a single or multiple values (separated by `"/`)/

- You can use these variables in any template.
- Some implicit variables are considered to be multiple instances of values. Variables of this type require you to use indexes to indicate a particular position in the list. For example, a list of SOC terms sorted by occurrence where the most frequently used term is listed first. For example, this variable is included as #SOC_COUNT_TOP(x), where x indicates the "x" highest occurrence based on the count where the SOC term with the highest occurrence is listed first.

Creating and Using Custom Variables

Dossier enables you to create and use custom variables. Ideally, you should define custom variables **after** Argus has been completely configured to allow for correct and complete SQL statements. Before attempting to create and use custom variables, please seek help from IT personnel.

To define custom variables:

1. Open the CFG_PSUR_TEMPLATE_VARIABLES table
2. Enter values in the following fields.

Field	Field Value
ID	Enter a unique number in this field. This number must be the next number in the number sequence. For example, if ID number for the last row is 100, the new row must have an ID number of 101
VARIABLE_NAME	Enter the name of the variable to be used in the template. Use lowercase characters when entering this value. Do not use the # sign in the name.
SQL_QUERY	Enter the actual SQL statement to be executed when the template parser processes the variable name.
REPORT_RELATED	Enter a 1. The application ignores any other value.
DELETE	This must be a NULL value. If you place any other value in this field, the application considers the variable deleted.

Pre-defined Periodic Report Variables

Dossier provides a number of pre-defined periodic report variables. When using these variables in your template scripts, be aware of the following:

- The system only considers encoded events for SOC-based variables; it ignores all unencoded events.
- For all variables that return a count, return a 0 when the result is NULL.
- When a variable returns multiple values, those values are separated with a forward slash (/) character.
- For all variables that return a frequency value, print the value with a % sign and round it to two (2) decimal places.
- All SQL statements for pregnancy cases consider any populated neonate.

The following table lists and describes the pre-defined periodic report variables available for your use.

Variable	Description
#REPORT_NUMBER	The Report Number entered in the report header configuration in the Subject Tab.
#TRADE_NAME	The Trade Name entered in the report header configuration. By default, Argus pre-populates the configured Trade Name for the ingredients. You may change these defaults by editing the name.
#GENERIC_NAME	The ingredients that the report has been configured to run against.
#REPORT_START_DATE	The inclusion period start date for the report (Scheduling Tab).
#REPORT_END_DATE	The inclusion period end date for the report (Scheduling Tab).
#IBD	The earliest birth date for the product licenses included in the report. If configured to do so, Argus pre-populates this value. This value can be changed if necessary.
#COUNTRY_IBD	The name of the country with the earliest license date based on the products in the report configuration.
#TOTAL_COUNTRIES_MARKET	The total number of countries where both of the following are true: The selected products have a marketed license. The selected products do not have a withdrawn date.
#TOTAL_CASES	The total number of adverse events being reported on. This value is based on the cases selected for the report.
#TOTAL_CASES_SERIOUS	The total number of serious cases included in the generated report. A case is considered serious if any event in the case has a seriousness check box checked.
#TOTAL_CASES_NON_SERIOUS	The total number of non-serious cases included in the generated report. A case is considered non-serious if all of the events do not have the Seriousness check box checked.
#TOTAL_CASES_SP	The total number of spontaneous cases included in the generated report. A case is considered spontaneous when the Report Type is not marked as <i>Include in Clinical Trial</i> in List Maintenance.
#TOTAL_CASES_SP_LIT	The total number of spontaneous literature cases included in the generated report. A case is considered spontaneous literature when both of the following are true: The Report Type is not marked as <i>Include in Clinical Trial</i> <i>Include as Literature</i> is checked in List Maintenance.
#TOTAL_CASES_SOC_PRIMARY("soc_name")	The total number of cases where the primary event has been encoded using the same System Organ Class as specified in <i>soc_name</i> .
#TOTAL_CASES_SOC("soc_name")	The total number of cases where any event has been encoded using the same System Organ Class as specified in <i>soc_name</i> .
#TOTAL_CASES_SOC_SERIOUS("soc_name")	The total number of serious cases where both of the following are true: Any event has been encoded using the same System Organ Class as specified. The same event is serious.

Variable	Description
#TOTAL_CASES_SOC_NON_SERIOUS ("soc_name")	<p>The total number of non-serious cases where both of the following are true:</p> <p>Any event has been encoded using the same System Organ Class as specified.</p> <p>The same event is non-serious.</p>
#TOTAL_CASES_SOC_UNLISTED ("soc_name")	<p>The total number of cases where both of the following are true:</p> <p>The event assessment for the product is <i>Unlisted</i>.</p> <p>Any event has been encoded with the specified System Organ Class.</p>
#TOTAL_CASES_SOC_SERIOUS_UNLISTED ("soc_name")	<p>The total numbers of cases where both of the following are true:</p> <p>The event assessment for the product is <i>Unlisted</i>.</p> <p>Any serious event has been encoded with the specified System Organ Class.</p>
#LISTOFTERMS_SOC_SERIOUS_UNLISTED ("soc_name")	<p>The Event name as coded for cases where both of the following are true:</p> <p>The event assessment for the product is <i>Unlisted</i>.</p> <p>Any serious event has been encoded with the specified System Organ Class.</p> <p>Multiple Terms must be separated with a forward slash (/).</p>
#SUBMISSION_DATE	<p>The date the report is due. The system calculates this date based on the values in the Scheduling tab for the report configuration.</p>
#SOC_NAME_TOP(x)	<p>The <i>System Organ Class</i> with the highest count based on the cases within report and the specified level.</p> <p>SOC term name with the xth highest occurrence in the case series. For example; #SOC_NAME_TOP(2) returns the name of the SOC with the second highest occurrence in the line listings.</p> <p>If there is more than one SOC at this level, the application uses a forward slash (/) to separate them when it prints the report.</p>
#SOC_COUNT_TOP(x)	<p>The total count of the System Organ Class that has the highest count based on the cases within the PSUR Report and the level as specified.</p> <p>SOC term count that has the xth highest occurrence in the case series. For example, #SOC_COUNT_TOP(2) returns the total number of occurrences for the SOC with the second highest occurrence in the line listings".</p>
#SOC_FREQUENCY_TOP(x)	<p>The frequency of occurrence (across all cases in the report) of the System Organ Class that has the xth highest count based on the cases in the report.</p> <p>Frequency of occurrence of events in the SOC that has the xth highest occurrence. For example, #SOC_FREQUENCY_TOP(2) = #SOC_COUNT_TOP(2) / #TOTAL_CASES</p>
#SOC_PT_NAME_TOP(x,y)	<p>The PT term name with the yth highest occurrence in the xth highest SOC occurrence.</p> <p>For example; #SOC_PT_NAME_TOP(2,3) returns the third most frequent Preferred Term name of the second most frequent SOC for the cases in the PSUR.</p>
#SOC_PT_COUNT_TOP(x,y)	<p>The number of occurrences of the PT name with the yth highest occurrence in the xth highest SOC occurrence.</p> <p>For example; #SOC_PT_COUNT_TOP(2,3) returns the number of the third most frequent Preferred Term of the second most frequent SOC for the line listings.</p>

Variable	Description
#TOTAL_COUNTRIES_COUNT__REPORT	The total number of countries from the Country of Incidence field (in the Case Form) based on the cases in the report.
#TOTAL_CASES_COUNT_DRUGINTECTIONS	The total number of cases where any product on the Case Form (Product tab) has <i>Yes</i> specified for Interactions
#TOTAL_CASES_COUNT_DRUGABUSE	The total number of cases where any product on the Case Form (Product Tab) has <i>True</i> specified for Abuse
#TOTAL_CASES_COUNT_PROSPECTPREGNANCY	The total number of cases where both of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_COUNT_RETROPREGNANCY	The total number of cases where the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Retrospective</i> . (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_COUNT_PENDINGDELIVERY_PROSPECT	The total number of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type <i>Prospective</i> . The delivery date is greater than the current date. (Case Form Patient Tab Pregnancy Details). If you do not enter a delivery date, the application ignores the case.
#TOTAL_CASES_COUNT_ELECTIVETERMINATIONS__PROSPECT	The total number of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The birth type is <i>Elective Termination</i> (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_COUNT_SPONTANEOUSABORTIONS__PROSPECT	The total number of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The birth type is <i>Spontaneous Abortions</i> (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_FREQUENCY_SPONTANEOUSABORTIONS__PROSPECT	The frequency of occurrence of cases where all of the following are true: The patient is <i>Pregnant</i> The pregnancy type is <i>Prospective</i> The birth type is <i>Spontaneous Abortions</i> and the pregnancy type is either <i>Prospective</i> or <i>Retrospective</i> . Computed as: ($= \#TOTAL_CASES_COUNT_SPONTANEOUSABORTIONS / (\#TOTAL_CASES_PROSPECT_PREGNANCY + \#TOTAL_CASES_RETRO_PREGNANCY)$)"
#TOTAL_CASES_COUNT_NORMALOUTCOME__PROSPECT	The total number of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The fetal outcome is <i>Normal</i> . (Case Form Patient Tab Pregnancy Details)

Variable	Description
#TOTAL_CASES_COUNT_FOLLOWUPLOST_PROSPECT	The total number of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The birth type is <i>Lost to F/U</i> (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_COUNT_FOLLOWUPDONE_PROSPECT	The total number of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The birth type is not <i>Lost to F/U</i> (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_COUNT_ABNORMALOUTCOME_PROSPECT	The total number of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The fetal outcome is not <i>Normal</i> . (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_COUNT_CAMAJOR_PROSPECT	The total number of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The fetal outcome is <i>CA Major</i> (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_FREQUENCY_CAMAJOR_PROSPECT	The frequency of occurrence of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The fetal outcome is <i>CA Major</i> and is not <i>Normal</i> (Case Form Patient Tab Pregnancy Details)
#TOTAL_CASES_COUNT_CAMINOR_PROSPECT	The total number of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The fetal outcome is <i>CA Minor</i> (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_FREQUENCY_CAMINOR_PROSPECT	The frequency of occurrence of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The fetal outcome is <i>CA Minor</i> and is not <i>Normal</i> (Case Form Patient Tab Pregnancy Details).
#TOTAL_CASES_COUNT_PREMATURE_PROSPECT	Total # of Cases w/ProsPregnancy with premature birth type.
#TOTAL_CASES_FREQUENCY_PREMATURE_PROSPECT	The frequency of occurrence of cases where all of the following are true: The patient is <i>Pregnant</i> . The pregnancy type is <i>Prospective</i> . The birth type is <i>Premature</i> and the pregnancy type is <i>Prospective</i> (Case Form Patient Tab Pregnancy Details)

Variable	Description
#TOTAL_CASES_COUNT_STILLBIRTH_PROSPECT	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Prospective</i>.</p> <p>The birth type is <i>Still Birth</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_FREQUENCY_STILLBIRTH_PROSPECT	<p>The frequency of occurrence of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Prospective</i>.</p> <p>The birth type is <i>Still Birth</i> and the pregnancy type is <i>Prospective</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_PENDINGDELIVERY_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The delivery date is greater than the current date. (Case Form Patient Tab Pregnancy Details)</p> <p>If delivery date is not entered, the application ignores the case.</p>
#TOTAL_CASES_COUNT_ELECTIVETERMINATIONS_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The birth type is <i>Elective Termination</i> (Case Form Patient Tab Pregnancy Details)".</p>
#TOTAL_CASES_COUNT_SPONTANEOUSABORTIONS_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The birth type is <i>Spontaneous Abortion</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_FREQUENCY_SPONTANEOUSABORTIONS_RETRO	<p>The frequency of occurrence in cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The birth type is <i>Spontaneous</i> and the pregnancy type is either <i>Prospective</i> or <i>Retrospective</i>.</p> <p>Computed as: $(= \#TOTAL_CASES_COUNT_SPONTANEOUSABORTIONS_RETRO / (\#TOTAL_CASES_PROSPECT_PREGNANCY + \#TOTAL_CASES_RETRO_PREGNANCY))$".</p>
#TOTAL_CASES_COUNT_NORMALOUTCOME_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The fetal outcome is <i>Normal</i> (Case Form Patient Tab Pregnancy Details).</p>

Variable	Description
#TOTAL_CASES_COUNT_FOLLOWUPLOST_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The birth type is <i>Lost to F/U</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_FOLLOWUPDONE_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The birth type is not <i>Lost to F/U</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_ABNORMALOUTCOME_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The fetal outcome is not <i>Normal</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_CAMAJOR_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The fetal outcome is <i>CA Major</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_FREQUENCY_CAMAJOR_RETRO	<p>The frequency of occurrence of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The fetal outcome is <i>CA Major</i> and is not <i>Normal</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_CAMINOR_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The fetal outcome is <i>CA Minor</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_FREQUENCY_CAMINOR_RETRO	<p>The frequency of occurrence of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The fetal outcome is <i>CA Minor</i> and is not <i>Normal</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_PREMATURE_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The birth type is <i>Premature</i> (Case Form Patient Tab Pregnancy Details).</p>

Variable	Description
#TOTAL_CASES_FREQUENCY_PREMATURE_RETRO	<p>The frequency of occurrence of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The birth type is <i>Premature</i> and the pregnancy type is <i>Prospective</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_STILLBIRTH_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The birth type is <i>Still Birth</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_FREQUENCY_STILLBIRTH_RETRO	<p>The frequency of occurrence of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The birth type is <i>Still Birth</i> and the pregnancy type is <i>Prospective</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_CA_ALL	<p>The total number of cases where both of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The fetal outcome is either <i>CA Major</i> OR <i>CA Minor</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_PERINATAL_PROSPECT	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Prospective</i>.</p> <p>The fetal outcome is <i>Perinatal complication</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_PERINATAL_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The fetal outcome is <i>Perinatal complication</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_POSTNATAL_PROSPECT	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Prospective</i>.</p> <p>The fetal outcome is <i>Post-perinatal complication</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_POSTNATAL_RETRO	<p>The total number of cases where all of the following are true:</p> <p>The patient is <i>Pregnant</i>.</p> <p>The pregnancy type is <i>Retrospective</i>.</p> <p>The fetal outcome is <i>Post-perinatal complication</i> (Case Form Patient Tab Pregnancy Details).</p>
#TOTAL_CASES_COUNT_PEDIATRICS	<p>The total number of cases where both of the following are true:</p> <p>The patient's age group has been selected</p> <p>The group has been configured with the E2B codes of either 1,2 or 3 in list maintenance.</p>

Variable	Description
#SOC_NAME_TOP_PEDIATRICS(x)	The SOC with the largest number based on the level specified where the patient's age group is with the E2B code value of 1,2 or 3 in list maintenance.
#SOC_COUNT_TOP_PEDIATRICS(x)	The largest number of SOC based on the level specified where the patient's age group is with the E2B code value of 1,2 or 3 in list maintenance.
#SOC_FREQUENCY_TOP_PEDIATRICS(x)	The frequency of occurrence of events in the SOC that has the xth highest occurrence in pediatrics (E2B code of 1, 2 or 3 in list maintenance).
#TOTAL_CASES_COUNT_ELDERLY	The total number of cases where both of the following are true: The patient's age group has been selected The group has been configured with the E2B codes of 6 in list maintenance.
#SOC_NAME_TOP_ELDERLY(x)	The SOC with the largest number based on the level specified where the patient's age group is with the E2B code value of 6 in list maintenance.
#SOC_COUNT_TOP_ELDERLY(x)	The largest number of SOC based on the level specified where the patient's age group is with the of 6 in list maintenance.
#SOC_FREQUENCY_TOP_ELDERLY(x)	The frequency of occurrence of events in the SOC that has the xth highest occurrence in pediatrics (E2B code of 6 in list maintenance).
#DEV_INTERNATIONAL_BIRTHDATE	The DIBD date of the product.

Using Explicit Variables

Explicit variables are not available in the Argus database and require the script author to populate them manually using such methods as free text entry, yes/no options, multiple options, etc. There are two kinds of explicit variables:

- Declared Variables <var>
- Author Questions <q>

Using Declared Variables <var>

The VAR (variable element) enables the template author to define logical storage for variables that are defined and used in the template. When using declared variables, be aware of the following:

- A declared variable is valid **only** for the template in which it is declared.
- Unless a new value is specifically assigned to the variable, the parser uses the declared value of the variable as VAR1 throughout the template.
- Names can be a maximum of 50 characters.
- Values can be a maximum of 10,000 characters.
- All declared variables are case-sensitive.
- All variables must be enclosed in curly braces ({ . . . }) in the script.
- The application **does not** process the VAR value but replaces it in its place holder. Consider the following example:

```
<var name = "var1">nn</var>
```

where:

var1 is the name of the variable

nm is the value of the variable

Using Author Questions <q>

Use the *QUESTION* (<q>) element to capture information from the author of the report. When using the *QUESTION* element, be aware of the following:

- All question elements must begin with <q name=" " > and end with </q>.
- The application uses the *name* element as a variable to hold the value of the answer provided by the author of the report.
- When using the *DISPLAY* node, be aware of the following:
 - The system uses the *DISPLAY* node containing the text to display as the question to the author.
 - All *DISPLAY* elements must with <display> and end with </display>.
- When using the *OPTIONS* node, be aware of the following:
 - The application uses the *OPTIONS* node to:
 - Present pre-defined multiple answers to the author. All *OPTIONS* elements must start with <options> and end with </options>.
 - Represent a single pre-defined answer.
 - The total character limit is 1,000 characters across all options.
 - All *OPTION* elements must start with <option> and end with </option>.
 - All *OPTION* values display in drop-down lists. The application truncates the option value after 160 characters.
 - If no *OPTIONS* are used, with the <q> operand, the application will present a free text field to the author to enter any value. The character limit for free text entries is 10,000.
- You **cannot** use variables as a part of *DISPLAY* or *OPTION*.
- All declared variables are case-sensitive.

Consider the following usage example:

```
<q name="q1"> <display>What is your favorite color?</display> <options>
<option>Some Value 1</option> <option>Some Value 2</option> </options>
```

Using Operands

Operands enable you to define logical template processing using the following statement types:

<if>, <then>, <else>

<narrative>

<include>

<comment>

<write>

Using the <if> <then> <else> Statement

The basic syntax for the <if> <then> <else> statement is as follows:

`<if> ... </if> <cond> ... </cond> <then> ... </then> <else> ... </else>`

The following general rules govern the use of the `<if>` `<then>` `<else>` statement:

The application ignores any statements inside `<if>...</if>` but not inside either `<then>...</then>` or `<else>...</else>`.

All `<if>` statements must be followed by a `<then>` statement.

Usage of the `<else>` statement is optional.

You must enclose pre-defined values in double-quotes.

The `<then>` and `<else>` nodes assign values to VAR or NARRATIVE.

Do not use operator symbols (`>`, `<`, `>=`, or `<=`) in text within the conditional statements. Instead, use HTML encoded formats as follows:

For this operator	Use this HTML encoded format
<code><</code>	<code>&lt;</code>
<code>></code>	<code>&gt;</code>
<code><=</code>	<code>&lt;=</code>
<code>>=</code>	<code>&gt;=</code>

In the following example, the statement checks the value of Q1. If Q1 is equal to 3, then the application assigns the a value of 4 to VAR1. Otherwise, it assigns the string value for the narrative NAR1.

```
<if> <cond>Q1="3"</cond> <then><let>VAR1="4"</let></then>
<else><let>{NAR1}="There were no cases related to {#TRADE_NAME}"</let></else>
</if>
```

The following table lists and describes how to use each of the elements in the template script.

Element Name	Syntax	Usage Rules
IF	<code><if> ... </if></code>	Use the IF element or condition to logically direct template processing flow. IF elements must begin with <code><if></code> and end with <code></if></code> .

Element Name	Syntax	Usage Rules
COND	<cond> ... </cond>	<p>Use the COND node to evaluate a logical Boolean based on the following operations:</p> <p>Equals To: =</p> <p>Not Equal To: !=</p> <p>Greater Than: ></p> <p>Greater Than or Equal To: >=</p> <p>Less Than: <</p> <p>Less Than or Equal to: <=</p> <p>Logical AND: AND</p> <p>Logical OR: OR</p> <p>Each operator in a condition can be:</p> <p>Declared in the template</p> <p>A constant placed within quotation marks (" ")</p> <p>An implicit variable</p> <p>Use the AND or OR logical operators to combine multiple conditions and to evaluate a combined result.</p> <p>Enclose each condition in parentheses [(. . .)] to separate them</p> <p>The application evaluates the combined conditions from left to right</p> <p>All COND elements must start with <cond> and end with </cond>.</p>
THEN	<then> ... </then>	<p>If the specified condition is TRUE, the application executes the THEN block.</p> <p>This block can have single or multiple instruction tags including <if> ... </if>.</p> <p>All THEN elements must start with <then> and end with </then>.</p>
ELSE	<else> ... </else>	<p>If the specified condition is FALSE, the application executes the ELSE block.</p> <p>The ELSE block can have single or multiple instruction tags including <if> ... </if>.</p> <p>All ELSE elements must start with <else> and end with </else>.</p>
LET	<let> ... </let>	<p>Use the LET element to assign a value to a variable or a narrative.</p> <p>The value you assign must be enclosed in double quotes ("VAR1") and can be one of the following:</p> <p>A string with variables</p> <p>Another variable</p> <p>Use the <var> or <narrative> tag to declare the variable before assigning it.</p>

Element Name	Syntax	Usage Rules
NARRATIVE	<code><narrative> . . . </narrative></code>	<p>Use the NARRATIVE element to assign pre-defined paragraphs.</p> <p>NARRATIVE values can be a maximum of 10,000 characters.</p> <p>All NARRATIVE elements must start with <code><narrative></code> and end with <code></narrative></code>.</p> <p>You can include variables or other elements in the NARRATIVE. During processing, the application replaces these variables or other elements with their current values.</p> <p>Use one of these tags to declare all user-defined narrative variables used in the template.</p> <p>Use one of the following methods to assign a value when declaring the variable:</p> <pre><narrative name ="nar1"> This is a paragraph for patient history . . . </narrative></pre> <pre><narrative name = "nar1"> </narrative></pre> <p>Let {nar1}= "This is a paragraph for patient history . . . " </let></p>

Element Name	Syntax	Usage Rules
INCLUDE	<include name=" "/>	<p>Use the INCLUDE element to include the contents of an existing RTF document in a report during the template build process.</p> <p>All INCLUDE elements must be written in the following manner:</p> <pre data-bbox="911 390 1133 415"><include name " "/></pre> <p>The source files can be Argus reports or user-created custom reports that have been created off line and uploaded to the server in the Other Content section of the View ePSUR screen.</p> <p>Periodic reports support the page layouts for the source documents. For example, the application retains a landscape layout in the resulting document.</p> <p>The name of the files must exactly match the name specified in the report configuration (View ePSUR Template screen).</p> <p>You can include files in one of the following sections of the output document:</p> <ul style="list-style-type: none"> Line Listing Summary Tabulation UD Summary Other Content <p>If the file you are including is from the Other Contents section, the file name must have an RTF extension.</p> <p>You must use Microsoft Word or another tool to convert document files to RTF format. For example, <include name = "CDA-PSUR1.rtf"/></p> <p>All files in the Other Contents section must have unique names.</p> <p>Do not use the same filename in the <include> tag more than once in a single configuration. This can cause processing error. If you need to include the same content more than once, add multiple files with the same content and different filenames and <include> tags.</p> <p>Argus-generated include files (Line Listing, Summary Tabulation, and reports in UD Summary) must not have an extension and must be exactly as displayed on the View ePSUR screen.</p> <p>For example: <include name = "List Listing"/></p>

Element Name	Syntax	Usage Rules
COMMENT	<code><comment> . . . </comment></code>	<p>Use the COMMENT element to provide the report author with instructions for editing the report.</p> <p>All COMMENT elements must start with <code><comment></code> and end with <code></comment></code>.</p> <p>The comment text:</p> <p>Remains in the report until the report is published. When the report is published, the application removes the comment.</p> <p>Will not be used to replace any variables, if used.</p> <p>Usage Example</p> <pre><comment>Please review the document and verified top 5 BODY systems affected.</comment></pre>
WRITE	<code><write> . . . </write></code>	<p>The WRITE elements output content to the RTF document.</p> <p>All WRITE elements must start with <code><write></code> and end with <code></write></code>.</p> <p>The application applies formatting defined in the <code><write> . . . </write></code> tags to the content of the output document.</p> <p>Usage Example</p> <pre><write>example text to be written</write></pre> <p>OR</p> <pre><write> The following paragraph has {VAR1} cases</write></pre> <p>OR</p> <pre><write>{NAR1}</write></pre> <p>where:</p> <p>NAR 1 is a previously declared narrative and the content of NAR 1 is written to the document</p>

Using Nested Questions

When using nested questions, be aware of the following:

- You can up to five (5) levels of nested questions.
- You can include questions in the ELSE (`<else>..</else>`) statement.
- If a question is to be nested, it must include a condition. The condition:
 - **Cannot** include a logical operator (AND/OR)
 - Must have a question variable (`<q>`) as one of the operands.
 - Must include both a question variable and a constant (e.g., `<cond>{q1}="Yes"</cond>`)

Template Writing Quick Reference

Element Type	Usage Rules	Usage Examples
Explicit Variables	<p>Must be declared in the document using <var>, <narrative> or <q> tags</p> <p>Must be enclosed in curly braces ({ . . . }) when used in the script</p>	<p>Correct usage:</p> <pre><var name="var1">10</var> <write>{var1}</write> <cond>{var1}="4"</cond> <let>{var1}</pre> <p>Incorrect Usage</p> <pre>{var1 + var2} <write>{var1, var2}</write></pre>
Implicit Variables	<p>These variables are available in Argus and are always based on the cases in a specific periodic report, as configured</p> <p>Must start with a pound (#) sign (e.g., #total_cases_soc)</p> <p>Must be enclosed in curly braces ({ . . . }) when used in the script</p>	<p>Correct Usage:</p> <pre><write>{#report_number}</write> <write>Total Cases for Cardiac disorders are {#total_cases_soc("Cardiac disorders")}</write> <write>{#soc_pt_count_top(3,1) }</write></pre> <p>Incorrect Usage:</p> <pre><let>{#report_number}="10"</let></pre>

