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

About This Book

This manual contains three chapters:

Chapter 1, "Introduction"
This section provides an overview of the Dossier module.

Chapter 2, "Processing Dossier Reports"
This section describes how to publish and generate a report, how to use reports, and how to assign template users.

Chapter 3, "Writing Template Scripts"
This section provides information about Template Scripts.

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This section lists the manuals for all Oracle Life Sciences products. You can order printed manuals from the Oracle iStore. From the iStore, search for the part number in parentheses.

Oracle Argus Documentation

The Oracle Argus documentation set includes:

- Oracle Argus Installation Guide (E15951)
- Oracle Argus Interchange User’s Guide (E15946)
- Oracle Argus Affiliate User’s Guide (E15947)
- Oracle Argus Safety Console User’s Guide (E15950)
- Oracle Argus Safety User’s Guide (E15952-01)
- Oracle Argus Safety End of Study Unblinding User’s Guide (E15956)

Oracle Clinical Documentation

The Oracle Clinical documentation set (A83790) includes:

- Oracle Clinical Administrator’s Guide (A83791)
- Oracle Clinical Getting Started (B12308)
- Interfacing from Oracle Clinical (A83793)
- Oracle Clinical Conducting a Study (A85201)
- Oracle Clinical Creating a Study (A85200)
- Oracle Clinical Installation Guide (A83779)

Oracle Clinical NLS Option Documentation

The Oracle Clinical NLS Option documentation includes:

- Oracle Clinical NLS Option User Guide (A90473)

Oracle Thesaurus Management System (TMS) Documentation

The TMS documentation includes:

- Oracle Thesaurus Management System User Guide (A82842)
- Oracle Thesaurus Management System Installation Guide (A83780)

Oracle Adverse Event Reporting System (AERS) Documentation

The Oracle AERS documentation set (B10328) includes:

- Oracle Adverse Event Reporting System Administrator’s Guide (B10330)
- Oracle Adverse Event Reporting System Installation Guide (B10331)
- Oracle Adverse Event Reporting System User’s Guide (B10329)
Oracle Adverse Event Reporting System Quick Guide (B14419)

Oracle Clinical Remote Data Capture (RDC) Documentation
The Oracle RDC documentation includes:
- Oracle Clinical Remote Data Capture Classic Data Entry User’s Guide (B13921)
- Oracle Clinical Remote Data Capture PDF Data Entry User’s Guide (B139201)

Oracle Clinical SiteMinder Documentation
The Oracle Clinical SiteMinder documentation includes:
- Oracle Clinical SiteMinder User Guide (B15643)
- Oracle Clinical SiteMinder Installation Guide (B15645)

Oracle Clinical TrialMinder Documentation
The Oracle Clinical TrialMinder documentation includes:
- Oracle Clinical TrialMinder User Guide (B15644)
- Oracle Clinical TrialMinder Installation Guide (B15646)
In addition, Oracle Health Science Global Business Unit (HSGBU) publishes PDF-format Technical Reference Manuals (TRMs) containing proprietary information on internal tables and APIs. If you are a licensed customer, contact Oracle Support to obtain a free electronic copy. This is a list of the available TRMs:
- Oracle Clinical Stable Interface TRM (A83796)
- Oracle Thesaurus Management System TRM (A82841)
- Oracle Adverse Event Reporting System Saved Queries TRM (B10353)
- Oracle Adverse Event Reporting System Reports TRM (B10352)
- Oracle Adverse Event Reporting System Edit Checks TRM (B10355)

Conventions
The following text conventions are used in this document:

<table>
<thead>
<tr>
<th>Convention</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>boldface</td>
<td>Boldface type indicates graphical user interface elements associated</td>
</tr>
<tr>
<td></td>
<td>with an action, or terms defined in text or the glossary.</td>
</tr>
<tr>
<td>italic</td>
<td>Italic type indicates book titles, emphasis, or placeholder variables</td>
</tr>
<tr>
<td></td>
<td>for which you supply particular values.</td>
</tr>
<tr>
<td>monospace</td>
<td>Monospace type indicates commands within a paragraph, URLs, code in</td>
</tr>
<tr>
<td></td>
<td>examples, text that appears on the screen, or text that you enter.</td>
</tr>
</tbody>
</table>
Dossier is a tool that works within the Argus Safety application and enables you to generate period reports. This chapter includes discussions of the following:

- Dossier Report Process
- Logging In and Out
- Getting Started

**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:

- Entering Product Details
- Configuring Periodic Data
- Configuring Periodic Report Templates

**Entering Product Details**

The administrator enters product details using the existing application. This includes entering the following:

- Product Family
- Product Name
- Product Formulations
- Product Licensing Information

**Configuring Periodic Data**

The administrator configures the reports by entering the following:
Dossier Report Process

- Report Name
- Product Name
- Inclusion Criteria
- Line Listings,
- Summary Tabulations
- User-defined Summaries
- Datasheet Information
- Report Scheduling Information

**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 template to one or more groups for the review cycle.
- 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 periodic report and creates an entry on the Reports -> Period 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 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 *Ready for Review*.

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 approved and complete, you can generate a merged PDF for the final report. Once the PDF is created, users can view it.
Logging In and Out

This section provides information about logging in and out of Argus Safety.

Logging In

Before logging in to Argus Safety, verify that the Argus Safety Administrator has created an account for you and that you have the correct system username and password.

1. Open Microsoft Internet Explorer and enter the Uniform Resource Locator (URL) for Argus Safety Web in the Address field.

2. When the Argus Safety Login dialog box opens:
   - Enter your username in the Username field.
   - Enter your password in the Password field.
   - Select the appropriate database from the Database drop-down list.
   - Click Login.

3. The system opens the Argus Personal Status Page.
Getting Started

Logging Out

Click Logout at the top of the Argus Personal Status page to exit from the application.

Getting Started

This section provides information about the following:

- About the Argus Personal Status Page
- Common Fields and Controls
- Using the Quick Launch Toolbar

About the Argus Personal Status Page

If configured to do so, the Argus Personal Status page displays a list of user-specific assigned cases, contact log entries, and action items. This page may also be referred to as the Home page. In most cases, it will be the first page you see each day when you log on to Argus. It includes the following sections:

- Search Case - This section enables you to search for cases.
- Cases Assigned - This section contains a list of assigned cases
- Cases Log Entries
- Action Item Entries

If you move away from the Home page and need to return to it, click the tab at the top of the page.

Searching for a Case

You can search for a case in either of two ways:

- Type the case number in the Quick Launch field on the Argus Personal Status page
- Locate and select a case from the list of cases that displays on the screen.
To search for a specific case from the Home page:

1. Type the case number in the Case Quick Launch field and click Open.
2. The system opens the Case Form for the case you selected.

To locate a specific case in a list of cases:

1. Open the Argus Personal Status page.
2. Locate the appropriate case in the case lists and click the name link.

   When using the Argus Personal Status page, note the following:
   - Each section and header column is sorted in ascending order by Case Number.
   - If the check box for a section is not selected, the system disables the section and places it at the bottom of the screen. Click the check box to enable the section and return it to its default position.
3. The system opens the selected case.
Common Fields and Controls

This section provides information about fields and controls used throughout Dossier.

**Required Fields**

Throughout the Argus application, required fields are identified by a red flag and have an orange border. You must enter values in such fields.

The following is an illustration of a required field.

![Required Field](image)

**Standard Controls**

The following tables lists and describes common controls used throughout the Argus application.

<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Save</td>
<td>Click <strong>Save</strong> to save changes associated with a section.</td>
</tr>
<tr>
<td>Cancel</td>
<td>Click <strong>Cancel</strong> to abort changes associated with a section.</td>
</tr>
<tr>
<td>Print</td>
<td>Click <strong>Print</strong> to print information associated with a sub-section.</td>
</tr>
<tr>
<td>Add</td>
<td>Click <strong>Add</strong> to add an item in a section.</td>
</tr>
<tr>
<td>Delete</td>
<td>Click <strong>Delete</strong> to remove an item from a section.</td>
</tr>
<tr>
<td>Copy</td>
<td>Click <strong>Copy</strong> to create a new editable copy of an item in a section.</td>
</tr>
<tr>
<td>OK</td>
<td>Click <strong>OK</strong> to confirm an action associated with a section.</td>
</tr>
<tr>
<td>Yes</td>
<td>Click <strong>Yes</strong> to confirm an action associated with a section.</td>
</tr>
<tr>
<td>No</td>
<td>Click <strong>No</strong> to cancel an action associated with a section.</td>
</tr>
<tr>
<td>Help</td>
<td>Click <strong>Help</strong> to open the online documentation.</td>
</tr>
</tbody>
</table>

Using the Quick Launch Toolbar

The **Quick Launch Toolbar** is on the top right side of the page and enables you to navigate through the application more quickly by clicking icons associated with certain actions rather than selecting from a drop-down list. The following is an illustration of the **Quick Launch Toolbar**.

The items that appear on the **Quick Launch Toolbar** depend on your location in the Argus application. When you place the cursor over the icon, the system displays a tool tip that describes the function of the icon. The following table lists and describes the function of each of the icons.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Tool Tip</th>
<th>Description</th>
<th>Shortcut Key</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="New Case from Image" /></td>
<td>New Case from Image</td>
<td>Displays a new case from an image.</td>
<td>CTRL+ALT+G</td>
</tr>
</tbody>
</table>
### Getting Started

**Open Case**
- Displays the Case Search dialog which is similar to performing Case Actions - Open Case.
- **Shortcut Key**: CTRL+ALT+O

**New Case**
- Displays the initial Case Entry dialog. This is similar to performing Case Actions - New Case.
- **Shortcut Key**: CTRL+ALT+N

**Close Case**
- Performs the same functionality as the Case Actions - Close Case option.
- **Shortcut Key**: CTRL+ALT+C

**Print Case**
- Displays the Case Print dialog which is similar to performing Case Actions - Print Case option.
- **Shortcut Key**: CTRL+ALT+P

**Save Case**
- Displays the Case Routing dialog, which is similar to performing Forward Routing from the Case Activities - Routing Comments section.
- **Shortcut Key**: CTRL+ALT+S

**Forward Case**
- Displays the Case Routing dialog which is similar to performing Forward Routing from the Case Activities - Routing Comments section.
- **Shortcut Key**: CTRL+ALT+>

**Return Case**
- Displays the Case Routing dialog which is similar to performing Return Routing from the Case Activities - Routing Comments section.
- **Shortcut Key**: CTRL+ALT+<

**Lock Case**
- Displays the Case Lock or Case Unlock dialog. This is similar to performing Locking or Unlocking Cases in the Activities Tab.
- **Shortcut Key**: CTRL+ALT+L

**Medical Review**
- Displays the Medical Review dialog which is similar to performing Case Actions - Medical Review option.
- **Shortcut Key**: CTRL+ALT+M

---

**Icon** | **Tool Tip** | **Description** | **Shortcut Key**
--- | --- | --- | ---
[Image] | Open Case | Displays the Case Search dialog which is similar to performing Case Actions - Open Case. | CTRL+ALT+O
[Image] | New Case | Displays the initial Case Entry dialog. This is similar to performing Case Actions - New Case. | CTRL+ALT+N
[Image] | Close Case | Performs the same functionality as the Case Actions - Close Case option. | CTRL+ALT+C
[Image] | Print Case | Displays the Case Print dialog which is similar to performing Case Actions - Print Case option. | CTRL+ALT+P
[Image] | Save Case | Displays the Case Routing dialog, which is similar to performing Forward Routing from the Case Activities - Routing Comments section. | CTRL+ALT+S
[Image] | Forward Case | Displays the Case Routing dialog which is similar to performing Forward Routing from the Case Activities - Routing Comments section. | CTRL+ALT+>
[Image] | Return Case | Displays the Case Routing dialog which is similar to performing Return Routing from the Case Activities - Routing Comments section. | CTRL+ALT+<
[Image] | Lock Case | Displays the Case Lock or Case Unlock dialog. This is similar to performing Locking or Unlocking Cases in the Activities Tab. | CTRL+ALT+L
[Image] | Medical Review | Displays the Medical Review dialog which is similar to performing Case Actions - Medical Review option. | CTRL+ALT+M
<table>
<thead>
<tr>
<th>Icon</th>
<th>Tool Tip</th>
<th>Description</th>
<th>Shortcut Key</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Worklist Icon" /></td>
<td>Worklist</td>
<td>Displays the Worklist dialog which is similar to performing Worklist - XXX option. Note: XXX is defined within the User Configuration for the default Worklist option. If there is no default Worklist option defined, then Worklist - New is displayed.</td>
<td>CTRL+ALT+W</td>
</tr>
<tr>
<td><img src="image2" alt="Coding Review Icon" /></td>
<td>Coding Review</td>
<td>Displays the Coding Review dialog which is similar to performing Case Actions - Coding Review option.</td>
<td>CTRL+ALT+Q</td>
</tr>
<tr>
<td><img src="image3" alt="Draft Report Icon" /></td>
<td>Draft Report</td>
<td>Displays the Report List of All the Expedited Reports which is similar to performing a View Draft Report action.</td>
<td>CTRL+ALT+R</td>
</tr>
<tr>
<td><img src="image4" alt="E2B Check Icon" /></td>
<td>E2B Check</td>
<td>Performs the function that prints the E2B Report - DTD Length Check, Warnings and E2B report - DTD Validation.</td>
<td>CTRL+ALT+E</td>
</tr>
<tr>
<td><img src="image5" alt="Validation Check Icon" /></td>
<td>Validation Check</td>
<td>Performs a validation check.</td>
<td>CTRL+ALT+V</td>
</tr>
</tbody>
</table>
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.
Using Templates

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

<table>
<thead>
<tr>
<th>Field/Control</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Name</td>
<td>The name of the report you are generating.</td>
</tr>
<tr>
<td>Report Category</td>
<td>The category the report belongs to. Select the appropriate category from the drop-down list.</td>
</tr>
<tr>
<td>Report Sub Category</td>
<td>The sub-category the report belongs to, if any.</td>
</tr>
<tr>
<td>Templates</td>
<td>Enables you to add, modify, delete, assign and arrange the sections in your templates.</td>
</tr>
<tr>
<td>Add</td>
<td>Click <strong>Add</strong> to add a new section to the report template.</td>
</tr>
<tr>
<td>Delete</td>
<td>Click <strong>Delete</strong> to delete a section of a template.</td>
</tr>
<tr>
<td>Assign</td>
<td>Click <strong>Assign</strong> to choose who can access a template or portions of a template.</td>
</tr>
<tr>
<td>Up</td>
<td>Click <strong>Up</strong> to move the template section up one level.</td>
</tr>
<tr>
<td>Down</td>
<td>Click <strong>Down</strong> to move the template section down a level.</td>
</tr>
<tr>
<td>Print</td>
<td>Click <strong>Print</strong> to print the report configuration.</td>
</tr>
<tr>
<td>#</td>
<td>This column contains the template number. This number changes as you move or change the order of the templates.</td>
</tr>
<tr>
<td>Section</td>
<td>This column contains the name of the template. If you do not enter a name, the system places the section number in this field.</td>
</tr>
<tr>
<td>Description</td>
<td>This column contains a description of the section.</td>
</tr>
<tr>
<td>Attachment File Name</td>
<td>This column contains the name of the template file.</td>
</tr>
<tr>
<td>Modify</td>
<td>Click <strong>Modify</strong> to change a template document.</td>
</tr>
<tr>
<td>Attach</td>
<td>Click <strong>Attach</strong> to attach a new template document. Once the document is attached, this changes to <strong>Modify</strong>.</td>
</tr>
<tr>
<td>Header/Footer</td>
<td>This section enables you to attach header/footer information to the template.</td>
</tr>
</tbody>
</table>
Using Templates

Processing Dossier Reports

To access the template tab:

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

   ![Image](image.png)

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.

3. When the application opens the report dialog box, click the Templates tab.

<table>
<thead>
<tr>
<th>Field/Control</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Include Header/Footer</td>
<td>Click this checkbox if you want to include header/footer information from a specific Word document in your template.</td>
</tr>
<tr>
<td>Portrait Template</td>
<td>Enables you to use header/footer information from a document in portrait orientation in your template.</td>
</tr>
<tr>
<td>Landscape Template</td>
<td>Enables you to use header/footer information from a document in landscape orientation in your template.</td>
</tr>
<tr>
<td>Attach</td>
<td>Enables you to attach a Microsoft Word document to a template.</td>
</tr>
<tr>
<td>Include Page Numbering</td>
<td>Enables you to specify whether or not you want page numbering in the template and the location of the page numbers.</td>
</tr>
<tr>
<td>Header Left</td>
<td>Click this option to place the page number on the left side of the header.</td>
</tr>
<tr>
<td>Header Center</td>
<td>Click this option to place the page number in the center of the header.</td>
</tr>
<tr>
<td>Header Right</td>
<td>Click this option to place the page number on the right side of the header.</td>
</tr>
<tr>
<td>Footer Left</td>
<td>Click this option to place the page number on the left side of the footer.</td>
</tr>
<tr>
<td>Footer Center</td>
<td>Click this option to place the page number in the center of the footer.</td>
</tr>
<tr>
<td>Footer Right</td>
<td>Click this option to place the page number on the right side of the footer.</td>
</tr>
<tr>
<td>OK</td>
<td>Click OK to update the template page.</td>
</tr>
<tr>
<td>Cancel</td>
<td>Click Cancel to exit from the template page without saving.</td>
</tr>
</tbody>
</table>
Using Templates

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:

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 New.

3. When the application opens the report dialog box, click the Templates tab.

4. When the system opens the Templates tab, click Add.

5. 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.

6. When the system opens the Attachment dialog box:
Assigning Template Users

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:

* Type the template file path name OR click Browse to locate and select the template file (RTF format) to attach.
* Click OK.
Assigning Template Users

**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

You assign group rights from the Owner tab on the Dossier Security screen as shown in the following illustration.

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, select the appropriate row you wish to overwrite and click Assign.
5. When the application opens the Dossier Security dialog box, click the Group Assignments tab:
Assigning Template Users

- 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 Assignments 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:

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

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.
- If a section does not have a template attachment, it does not appear in the Section Name drop down.
- You can add group(s) to each of the three user role lists.
Assigning Template Users

- 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.
  * If the owner user (assigned in the last tab) is part of a group that is being removed, the system displays the following message:
    
    You are removing a group that contains the Dossier Owner user. Please first reassign the owner to another user.

■ 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.
Notify Tab Usage Considerations
When using the Notify tab, be aware of the following:

- If a template is not attached to a section, the section name does not appear in the Section Name drop-down list.
- The Section Name drop-down contains a list of selected template sections from the Group Assignments tab. If you do not select a section, the drop-down list is blank.
- 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.
Assigning Template Users

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

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

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.
  - The system displays the name of an active user once, even if he/she is assigned to multiple groups.
  - The application lists all active users alphabetically in ascending order.
  - An Active user is listed by User Name. For example, flinstone
- 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.
Assigning Template Users

- 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.
Assigning Template Users

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.

**Note:** You must choose the PDF format when printing a final periodic report. The .rtf and .csv formats are not supported.

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.

   ![Dossier Security Report Illustration]

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

<table>
<thead>
<tr>
<th>Report Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Title</td>
<td>The name of the report is always Dossier Security.</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Report Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Save Date and Time</td>
<td>The date and time the template and security assignments were last saved. 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. The format is as follows: ‘Last saved dd-MMMM-yyyy HH:mm GMT -n’ For example: Last saved 21 JUL 2008 16:11 GMT -8</td>
</tr>
<tr>
<td>Template Name</td>
<td>The name of the template. Each template is listed separately</td>
</tr>
<tr>
<td>Report Details</td>
<td>This section contains three columns that contain information about the assigned users: Group Name - The name of the user group sorted alphabetically in ascending order. Role - The role assigned to the group. A group can be assigned multiple roles. Notify - Indicates whether the group should be notified.</td>
</tr>
<tr>
<td>Report Template Owner</td>
<td>The owner or owners of the periodic report.</td>
</tr>
</tbody>
</table>
About the Author Tab

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.
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.

**Author Tab Fields**

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

<table>
<thead>
<tr>
<th>Field/Control</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periodic Report Name</td>
<td>Displays the periodic report name as configured in the Subject Tab</td>
</tr>
<tr>
<td>Start Date</td>
<td>Displays the start date of the periodic reporting period from report configuration</td>
</tr>
<tr>
<td>End Date</td>
<td>Displays the end date of the periodic reporting period from report configuration</td>
</tr>
<tr>
<td>Generated Date</td>
<td>Displays the date the report was generated.</td>
</tr>
<tr>
<td># of Cases</td>
<td>Displays the number of cases that have been included in the PSUR report.</td>
</tr>
<tr>
<td>Agency</td>
<td>Displays name of the agency</td>
</tr>
<tr>
<td>IBD</td>
<td>Displays the IBD name of the configured product</td>
</tr>
<tr>
<td>Templates Section</td>
<td>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.</td>
</tr>
<tr>
<td>Collapse/Expand icons</td>
<td>Click the Collapse icon to collapse the Templates section. Click the Expand icon to expand the Templates section.</td>
</tr>
<tr>
<td>Section</td>
<td>Displays the names of the sections included in the template.</td>
</tr>
<tr>
<td>Description</td>
<td>Display a description of the section contents.</td>
</tr>
<tr>
<td>Author button</td>
<td>Click Author to perform report-related tasks based on your assigned user role.</td>
</tr>
<tr>
<td>Ready for Review</td>
<td>Displays if the section of the template is ready to review.</td>
</tr>
<tr>
<td>Ready for Build</td>
<td>Displays if the section of the template is ready to generate.</td>
</tr>
<tr>
<td>Check Out Button / Check In Button</td>
<td>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.</td>
</tr>
</tbody>
</table>
About the Author Tab

Field/Control | Description
--- | ---
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
Close | Closes active window
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.
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.
Comments | Enables the user to enter any relevant comments.

**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.

<table>
<thead>
<tr>
<th>Report Type</th>
<th>Report Names</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PSUR</strong></td>
<td>Report Configuration</td>
</tr>
<tr>
<td></td>
<td>Line Listing</td>
</tr>
<tr>
<td></td>
<td>Index of Cases in Line Listing</td>
</tr>
<tr>
<td></td>
<td>Summary of Cases missing assessments</td>
</tr>
<tr>
<td></td>
<td>Line Listing Tabulation</td>
</tr>
<tr>
<td></td>
<td>Summary of Unlocked Cases</td>
</tr>
<tr>
<td></td>
<td>CIOIMS reports</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CTPR</strong></td>
<td>Report Configuration</td>
</tr>
<tr>
<td></td>
<td>Line Listing</td>
</tr>
<tr>
<td></td>
<td>Index of Cases in Line Listing</td>
</tr>
<tr>
<td></td>
<td>Summary of Cases missing assessments</td>
</tr>
<tr>
<td></td>
<td>Count of Cases per Report Type</td>
</tr>
<tr>
<td></td>
<td>Event Count per Study Drug (1)</td>
</tr>
<tr>
<td></td>
<td>Event Count per Study Drug (2)</td>
</tr>
<tr>
<td></td>
<td>Line Listing Tabulation</td>
</tr>
<tr>
<td></td>
<td>Summary of Unlocked Cases</td>
</tr>
<tr>
<td></td>
<td>CIOIMS reports</td>
</tr>
<tr>
<td><strong>NDA</strong></td>
<td>Report Configuration</td>
</tr>
<tr>
<td></td>
<td>Tab 1: MW or VAERS forms</td>
</tr>
<tr>
<td></td>
<td>Tab 2: Index of MW or VAERS forms</td>
</tr>
<tr>
<td></td>
<td>Tab 3 Part 1: Line listing of 15-day reports submitted</td>
</tr>
<tr>
<td></td>
<td>Tab 3 Part 2: Tabulation by SOC of all events submitted</td>
</tr>
<tr>
<td></td>
<td>Tab 3 Part 3: Cases sent to FDA under a different NDA</td>
</tr>
<tr>
<td><strong>IND</strong></td>
<td>Report Configuration</td>
</tr>
<tr>
<td></td>
<td>Line Listing of Cases</td>
</tr>
<tr>
<td></td>
<td>Line Listing of Death Cases</td>
</tr>
</tbody>
</table>

- 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.
- A designated Author can check out the Word document to his/her local desktop for manual editing.
- Multiple users cannot check out the same document. Documents can be checked out by one user at a time.
- When you check out a document, the system disables the check out option for other users who might have access to the document.
- After editing a document, check it in (in .doc or .docx format only).
- When you check in a document, the system enables you to mark a section as Ready for Review.
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 in .PDF format.
## Role Security Requirements

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

<table>
<thead>
<tr>
<th>GUI Element</th>
<th>Owner</th>
<th>Reviewer</th>
<th>Author</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author Button</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Final</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Draft</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Save</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Ready for Review</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Ready for Build 2</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Section Checkout 2</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Add Other Content</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Build</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Checkout</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>View</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

- **Ready for Review** is available when the Final has been generated for the Template.
- **Ready for Build** is available only when **Ready for Review** is checked.
- **Ready for Build** is available only when **Ready for Review** is checked.
- **Add Other Content** is available if the user is a Reviewer for any of the section templates, then he/she will have access.
- **Add Other Content** is available if the user is an author for any of the section templates, then he/she will have access.
- **Build** is available only when all templates are checked in and **Ready for build** is checked for all templates.
- **Checkout** is only available when the Build Process is complete.
- **Checkout** is only available when the Build Process is complete.
- **View** is only available when the Build Process is complete.
- **View** is only available when the Build Process is complete.
### About the Author Tab

<table>
<thead>
<tr>
<th>GUI Element</th>
<th>Owner</th>
<th>Reviewer</th>
<th>Author</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publish</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Only available when the Build process is complete and the report is checked in.</td>
</tr>
<tr>
<td>View</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>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.</td>
</tr>
<tr>
<td>Include Header/Footer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Landscape Template</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portrait Template</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attach</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Include Page Numbering</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Header Left</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*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.

*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.
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.

---

<table>
<thead>
<tr>
<th>User Type</th>
<th>Owner</th>
<th>Reviewer</th>
<th>Author</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Header Center</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Header Right</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Footer Left</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Footer Center</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Footer Right</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OK</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Click this option to place the page number in the center of the header.
Click this option to place the page number on the right of the header.
Click this option to place the page number on the left side of the footer.
Click this option to place the page number in the center of the footer.
Click OK to update the template page.
Click Cancel to exit from the template page without saving.
Author Window Fields

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

<table>
<thead>
<tr>
<th>Field/Control</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section Name</td>
<td>The name of the section being created for the report.</td>
</tr>
<tr>
<td>Description</td>
<td>A description of the purpose of the section.</td>
</tr>
<tr>
<td>Completed Questions</td>
<td>Click the expand icon to display a list of completed questions. The system places the questions in this section as you answer them.</td>
</tr>
<tr>
<td>Incompleted Questions</td>
<td>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.</td>
</tr>
<tr>
<td>Answer</td>
<td>Enables you to answer the questions presented in the Incompleted Questions section.</td>
</tr>
<tr>
<td>Ignore Question</td>
<td>Enables you to skip a questions by click the check box.</td>
</tr>
<tr>
<td>Save</td>
<td>Saves the answers entered during the session in the database.</td>
</tr>
<tr>
<td>Close</td>
<td>Closes the Authoring window.</td>
</tr>
<tr>
<td>Draft</td>
<td>Generates and displays a draft version (doc/docx file) with current saved answers. It does not save the file to the database.</td>
</tr>
<tr>
<td>Final</td>
<td>Generates and displays a doc/docx file and saves the final version of the template in the database.</td>
</tr>
<tr>
<td>View</td>
<td>Displays the saved doc/docx file.</td>
</tr>
</tbody>
</table>
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 **Uncompleted Questions**.

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

<table>
<thead>
<tr>
<th>Field/Control</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spell Check</td>
<td>Enables you to run spell check on text entered in a text field.</td>
</tr>
</tbody>
</table>

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Providing Report Content

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 document 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 form 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.
Providing Report Content

- 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.

<table>
<thead>
<tr>
<th>Field/Control</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section Name</td>
<td>The name of the section you are checking out.</td>
</tr>
<tr>
<td>Comments</td>
<td>Any relevant comments about the document. The system stores such comments in the Template History.</td>
</tr>
<tr>
<td>Cancel</td>
<td>Click Cancel to abort the check-out operation.</td>
</tr>
<tr>
<td>Download</td>
<td>Click Download to download a Microsoft Word (.doc / .docx) version of the template for manual editing.</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Field/Control</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section Name</td>
<td>The name of the template you have checked out for editing. This can be a maximum of 50 characters.</td>
</tr>
<tr>
<td>File Name</td>
<td>The local path of the file that you have updated. The path name can be a maximum of 200 characters.</td>
</tr>
<tr>
<td>Browse</td>
<td>Click Browse to display the file selection dialog box and enable you to browse the local directory and locate the file to check in.</td>
</tr>
</tbody>
</table>
Providing Report Content

<table>
<thead>
<tr>
<th>Field/Control</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>OK</td>
<td>Click OK to upload the edited file.</td>
</tr>
<tr>
<td>Cancel</td>
<td>Click Cancel to abort the upload operation.</td>
</tr>
<tr>
<td>Undo Checkout</td>
<td>Click Undo Checkout to reverse the check-out operation. This button is available only to the user who has the document checked out.</td>
</tr>
</tbody>
</table>

**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 is 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.

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

### 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
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
Building a Dossier Report

- 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.

<table>
<thead>
<tr>
<th>Section/Field/Control</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Templates / Generated Reports / Additional Content</td>
<td>This section lists and describes the template sections in the report.</td>
</tr>
<tr>
<td>Save button</td>
<td>Enables you to save the current report layout.</td>
</tr>
<tr>
<td>Remove button</td>
<td>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.</td>
</tr>
<tr>
<td>Up button</td>
<td>Enables you to move the selected report section up in the list.</td>
</tr>
<tr>
<td>Down button</td>
<td>Enables you to move the selected report section up in the list.</td>
</tr>
</tbody>
</table>
Arrange Tab Usage Considerations

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

- **Select** the row and click the **Up** or **Down** buttons 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 Upr and Downs 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:
Generating a Dossier Report

- 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 sections 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 as shown in the following illustration.
Generating a Dossier Report

Once all sections have been marked **Ready for Build**, the system enables the **Build** button on the **Arrange** tab as shown in the following illustration.

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
Generating a Dossier Report

- 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.

You can view the content of the report header/footer for a report if it was configured during periodic report configuration if the Include Header and Footer check box is checked in the periodic report configuration window.
The Header and Footer section has the following fields and columns:

- **Portrait (default)**
- **Landscape**
- **File** - displays the current file title as a link. When you click the link, the system opens the header/footer file in its current state. The system displays the file in .doc/.docx format depending on the file type uploaded during report configuration.
- **Check Out**
  Only reviewers and owners can check files in or out.
  The system displays the Check Out button if the file is checked in and the Check In button if the file is currently checked out.
  The header/footer template files must be in .doc or .docx formats. If you attempt to upload any other file format, the application presents the following error message:
  - The header/footer file must be a .doc or .docx formation.
  The header/footer file can be a maximum of 100KB. If you attempt to upload a file that is larger than 100KB, the system presents the following message:
  - The header/footer file size cannot exceed 100KB.

- **Draft**
  - When you click the PDF icon, the application opens the last file checked in or the current file residing on the server in PDF format.
  - The PDF document should include page numbering in the appropriate zone if the page numbering check box was selected when the periodic report was configured.

- **Ready for Build**
  - Only the Reviewer or Owner can check the build check box.
    - If you check the check box, the application enables the Build button if all other templates and header/footer files have the Read for Build button checked.
This field is disabled when the file is checked out.

Comments
- When you click the Comments icon, the system opens the Comments and Templates History popup.
- When you click OK, the system saves any comments and puts them in the Template History section, and the Template History section retains a history of the actions for each template row:
  - Template Checked Out
  - Template Checked In
  - Template Marked Ready for Build

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.
6. The system publishes the report.
7. 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 activates the Publish button on the Arrange tab after the report has been generated successfully.
- 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.
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, CDA, 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. The 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.**
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 `/`).

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

- 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.

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

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.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>#REPORT_NUMBER</td>
<td>The Report Number entered in the report header configuration in the Subject Tab.</td>
</tr>
<tr>
<td>#TRADE_NAME</td>
<td>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.</td>
</tr>
<tr>
<td>#GENERIC_NAME</td>
<td>The ingredients that the report has been configured to run against.</td>
</tr>
<tr>
<td>#REPORT_START_DATE</td>
<td>The inclusion period start date for the report (Scheduling Tab).</td>
</tr>
<tr>
<td>#REPORT_END_DATE</td>
<td>The inclusion period end date for the report (Scheduling Tab).</td>
</tr>
<tr>
<td>#IBD</td>
<td>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.</td>
</tr>
<tr>
<td>#COUNTRY_IBD</td>
<td>The name of the country with the earliest license date based on the products in the report configuration.</td>
</tr>
<tr>
<td>#TOTAL_COUNTRIES_MARKET</td>
<td>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.</td>
</tr>
<tr>
<td>#TOTAL_CASES</td>
<td>The total number of adverse events being reported on. This value is based on the cases selected for the report.</td>
</tr>
<tr>
<td>#TOTAL_CASES_SERIOUS</td>
<td>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.</td>
</tr>
<tr>
<td>#TOTAL_CASES_NON_SERIOUS</td>
<td>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.</td>
</tr>
<tr>
<td>#TOTAL_CASES_SP</td>
<td>The total number of spontaneous cases included in the generated report. A case is considered spontaneous when the Report Type is not marked as Include in Clinical Trial in List Maintenance.</td>
</tr>
<tr>
<td>#TOTAL_CASES_SP_LIT</td>
<td>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 Include in Clinical Trial Include as Literature is checked in List Maintenance.</td>
</tr>
<tr>
<td>#TOTAL_CASES_SOC_PRIMARY(soc_name)</td>
<td>The total number of cases where the primary event has been encoded using the same System Organ Class as specified in soc_name.</td>
</tr>
<tr>
<td>#TOTAL_CASES_SOC(soc_name)</td>
<td>The total number of cases where any event has been encoded using the same System Organ Class as specified in soc_name.</td>
</tr>
<tr>
<td>#TOTAL_CASES_SOC_SERIOUS(soc_name)</td>
<td>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.</td>
</tr>
</tbody>
</table>
Using the Template Scripting Language

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>#TOTAL_CASES_SOC_NON_SERIOUS(&quot;soc_name&quot;)</td>
<td>The total number of non-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 non-serious.</td>
</tr>
<tr>
<td>#TOTAL_CASES_SOC_UNLISTED(&quot;soc_name&quot;)</td>
<td>The total number of cases where both of the following are true: The event assessment for the product is Unlisted. Any event has been encoded with the specified System Organ Class.</td>
</tr>
<tr>
<td>#TOTAL_CASES_SOC_SERIOUS_UNLISTED(&quot;soc_name&quot;)</td>
<td>The total numbers of cases where both of the following are true: The event assessment for the product is Unlisted. Any serious event has been encoded with the specified System Organ Class.</td>
</tr>
<tr>
<td>#LISTOFTERMS_SOC_SERIOUS_UNLISTED(&quot;soc_name&quot;)</td>
<td>The Event name as coded for cases where both of the following are true: The event assessment for the product is Unlisted. Any serious event has been encoded with the specified System Organ Class. Multiple Terms must be separated with a forward slash ( / ).</td>
</tr>
<tr>
<td>#SUBMISSION_DATE</td>
<td>The date the report is due. The system calculates this date based on the values in the Scheduling tab for the report configuration.</td>
</tr>
<tr>
<td>#SOC_NAME_TOP(x)</td>
<td>The System Organ Class with the highest count based on the cases within report and the specified level. 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. If there is more than one SOC at this level, the application uses a forward slash ( / ) to separate them when it prints the report.</td>
</tr>
<tr>
<td>#SOC_COUNT_TOP(x)</td>
<td>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. 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&quot;.</td>
</tr>
<tr>
<td>#SOC_FREQUENCY_TOP(x)</td>
<td>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. 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</td>
</tr>
<tr>
<td>#SOC_PT_NAME_TOP(x,y)</td>
<td>The PT term name with the yth highest occurrence in the xth highest SOC occurrence. 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.</td>
</tr>
<tr>
<td>#SOC_PT_COUNT_TOP(x,y)</td>
<td>The number of occurrences of the PT name with the yth highest occurrence in the xth highest SOC occurrence. 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.</td>
</tr>
</tbody>
</table>
Using the Template Scripting Language

**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__DRUGINTERACTIONS | The total number of cases where any product on the Case Form (Product tab) has Yes specified for Interactions.
#TOTAL_CASES_COUNT__DRUGABUSE | The total number of cases where any product on the Case Form (Product Tab) has True specified for Abuse.
#TOTAL_CASES_COUNT__PROSPECTPREGNANCY | The total number of cases where both of the following are true:
The patient is Pregnant.
The pregnancy type is Prospective. (Case Form | Patient Tab | Pregnancy Details).
#TOTAL_CASES_COUNT__RETROPREGNANCY | The total number of cases where the following are true:
The patient is Pregnant.
The pregnancy type is Retrospective. (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 Pregnant.
The pregnancy type Prospective.
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 Pregnant.
The pregnancy type is Prospective.
The birth type is Elective Termination (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 Pregnant.
The pregnancy type is Prospective.
The birth type is Spontaneous Abortions (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 Pregnant.
The pregnancy type is Prospective.
The birth type is Spontaneous Abortions and the pregnancy type is either Prospective or Retrospective. Computed as:

\[ \text{(#TOTAL\_CASES\_COUNT\_SPONTANEOUSABORTIONS) / (} \#\text{TOTAL\_CASES\_PROSPECT\_PREGNANCY + } \#\text{TOTAL\_CASES\_RETRO\_PREGNANCY}) \]

#TOTAL_CASES_COUNT__NORMALOUTCOME_PROSPECT | The total number of cases where all of the following are true:
The patient is Pregnant.
The pregnancy type is Prospective.
The fetal outcome is Normal. (Case Form | Patient Tab | Pregnancy Details)
**Using the Template Scripting Language**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>#TOTAL_CASES_COUNT_ FOLLOWUPLIT_PROSPECT</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The birth type is Lost to F/U (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_ FOLLOWUPDONE_PROSPECT</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The birth type is not Lost to F/U (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_ ABNORMALOUTCOME_PROSPECT</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The fetal outcome is not Normal (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_ CAMAJOR_PROSPECT</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The fetal outcome is CA Major (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_FREQUENCY_ CAMAJOR_PROSPECT</td>
<td>The frequency of occurrence of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The fetal outcome is CA Major and is not Normal (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_ CAMINOR_PROSPECT</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The fetal outcome is CA Minor (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_FREQUENCY_ CAMINOR_PROSPECT</td>
<td>The frequency of occurrence of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The fetal outcome is CA Minor and is not Normal (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_ PREMATURE_PROSPECT</td>
<td>Total # of Cases w/ProsPregnancy with premature birth type.</td>
</tr>
<tr>
<td>#TOTAL_CASES_FREQUENCY_ PREMATURE_PROSPECT</td>
<td>The frequency of occurrence of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The birth type is Premature and the pregnancy type is Prospective (Case Form</td>
</tr>
</tbody>
</table>

3-8 Oracle Argus Dossier User's Guide
Using the Template Scripting Language

The total number of cases where all of the following are true:
The patient is Pregnant.
The pregnancy type is Prospective.
The birth type is Still Birth (Case Form | Patient Tab | Pregnancy Details).

The frequency of occurrence of cases where all of the following are true:
The patient is Pregnant.
The pregnancy type is Prospective.
The birth type is Still Birth (Case Form | Patient Tab | Pregnancy Details).

The total number of cases where all of the following are true:
The patient is Pregnant.
The pregnancy type is Prospective.
The birth type is Still Birth and the pregnancy type is Prospective (Case Form | Patient Tab | Pregnancy Details).

If delivery date is not entered, the application ignores the case.

The total number of cases where all of the following are true:
The patient is Pregnant.
The pregnancy type is Prospective.
The delivery date is greater than the current date. (Case Form | Patient Tab | Pregnancy Details)

If delivery date is not entered, the application ignores the case.

The total number of cases where all of the following are true:
The patient is Pregnant.
The pregnancy type is Retrospective.
The birth type is Elective Termination (Case Form | Patient Tab | Pregnancy Details)

The total number of cases where all of the following are true:
The patient is Pregnant.
The pregnancy type is Retrospective.
The birth type is Spontaneous Abortion (Case Form | Patient Tab | Pregnancy Details)

The frequency of occurrence in cases where all of the following are true:
The patient is Pregnant.
The pregnancy type is Retrospective.
The birth type is Spontaneous Abortion. 
The pregnancy type is either Prospective or Retrospective.

Computed as:

\[ (= \#TOTAL\_CASES\_COUNT\_SPONTANEOUSABORTIONS\_RETRO / \#TOTAL\_CASES_PROSPECT_PREGNANCY+\#TOTAL\_CASES_RETRO_PREGNANCY) \]

The total number of cases where all of the following are true:
The patient is Pregnant.
The pregnancy type is Retrospective.
The fetal outcome is Normal (Case Form | Patient Tab | Pregnancy Details).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>#TOTAL_CASES_COUNT_STILLBIRTH_PROSPECT</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The birth type is Still Birth (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_FREQUENCY_STILLBIRTH_PROSPECT</td>
<td>The frequency of occurrence of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Prospective. The birth type is Still Birth and the pregnancy type is Prospective (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_PENDINGDELIVERY_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The delivery date is greater than the current date. (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_ELECTIVETERMINATIONS_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The birth type is Elective Termination (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_SPONTANEOUSABORTIONS_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The birth type is Spontaneous Abortion (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_FREQUENCY_SPONTANEOUSABORTIONS_RETRO</td>
<td>The frequency of occurrence in cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The birth type is Spontaneous. And the pregnancy type is either Prospective or Retrospective. Computed as: [ (= #TOTAL_CASES_COUNT_SPONTANEOUSABORTIONS_RETRO / #TOTAL_CASES_PROSPECT_PREGNANCY+#TOTAL_CASES_RETRO_PREGNANCY) ]</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_NORMALOUTCOME_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The fetal outcome is Normal (Case Form</td>
</tr>
</tbody>
</table>
### Variable Description

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>#TOTAL_CASES_COUNT_FOLLOWUPLOST_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The birth type is Lost to F/U (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_FOLLOWUPODONE_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The birth type is not Lost to F/U (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_ABNORMALOUTCOME_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The fetal outcome is not Normal (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_CAMAJOR_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The fetal outcome is CA Major (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_FREQUENCY_CAMAJOR_RETRO</td>
<td>The frequency of occurrence of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The fetal outcome is CA Major and is not Normal (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_CAMINOR_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The fetal outcome is CA Minor (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_FREQUENCY_CAMINOR_RETRO</td>
<td>The frequency of occurrence of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The fetal outcome is CA Minor and is not Normal (Case Form</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_PREMATURE_RETRO</td>
<td>The total number of cases where all of the following are true: The patient is Pregnant. The pregnancy type is Retrospective. The birth type is Premature (Case Form</td>
</tr>
</tbody>
</table>
### Variable Description

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
</tr>
</thead>
</table>
| #TOTAL_CAS_FREQUENCY_PREMATURE_RETRO | The frequency of occurrence of cases where all of the following are true:  
- The patient is Pregnant.  
- The pregnancy type is Retrospective.  
- The birth type is Premature and the pregnancy type is Prospective (Case Form | Patient Tab | Pregnancy Details). |
| #TOTAL_CAS_COUNT_STILLBIRTH_RETRO | The total number of cases where all of the following are true:  
- The patient is Pregnant.  
- The pregnancy type is Retrospective.  
- The birth type is Still Birth (Case Form | Patient Tab | Pregnancy Details). |
| #TOTAL_CAS_FREQUENCY_STILLBIRTH_RETRO | The frequency of occurrence of cases where all of the following are true:  
- The patient is Pregnant.  
- The pregnancy type is Retrospective.  
- The birth type is Still Birth and the pregnancy type is Prospective (Case Form | Patient Tab | Pregnancy Details). |
| #TOTAL_CAS_COUNT_CA_ALL | The total number of cases where both of the following are true:  
- The patient is Pregnant.  
- The fetal outcome is either CA Major OR CA Minor (Case Form | Patient Tab | Pregnancy Details). |
| #TOTAL_CAS_COUNT_PERINATAL_PROSPECT | The total number of cases where all of the following are true:  
- The patient is Pregnant.  
- The pregnancy type is Prospective.  
- The fetal outcome is Perinatal complication (Case Form | Patient Tab | Pregnancy Details). |
| #TOTAL_CAS_COUNT_PERINATAL_RETRO | The total number of cases where all of the following are true:  
- The patient is Pregnant.  
- The pregnancy type is Retrospective.  
- The fetal outcome is Perinatal complication (Case Form | Patient Tab | Pregnancy Details). |
| #TOTAL_CAS_COUNT_POSTNATAL_PROSPECT | The total number of cases where all of the following are true:  
- The patient is Pregnant.  
- The pregnancy type is Prospective.  
- The fetal outcome is Post-perinatal complication (Case Form | Patient Tab | Pregnancy Details). |
| #TOTAL_CAS_COUNT_POSTNATAL_RETRO | The total number of cases where all of the following are true:  
- The patient is Pregnant.  
- The pregnancy type is Retrospective.  
- The fetal outcome is Post-perinatal complication (Case Form | Patient Tab | Pregnancy Details). |
| #TOTAL_CAS_COUNT_PEDIATRICS | 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 either 1, 2 or 3 in list maintenance. |
Using the Template Scripting Language

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:

```xml
<var name = "var1">text</var>
```

where:

cvar1 is the name of the variable

---

<table>
<thead>
<tr>
<th>Variable Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>#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.</td>
</tr>
<tr>
<td>#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.</td>
</tr>
<tr>
<td>#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).</td>
</tr>
<tr>
<td>#TOTAL_CASES_COUNT_ELDERLY The total number of cases where both of the following are true: The patient's age group has been selected and the group has been configured with the E2B codes of 6 in list maintenance.</td>
</tr>
<tr>
<td>#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.</td>
</tr>
<tr>
<td>#SOC_COUNT_TOP_ELDERLY(x) The largest number of SOC based on the level specified where the patient's age group is with the E2B code value of 6 in list maintenance.</td>
</tr>
<tr>
<td>#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).</td>
</tr>
</tbody>
</table>
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:

```xml
<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:

```
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.

<table>
<thead>
<tr>
<th>For this operator</th>
<th>Use this HTML encoded format</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;</td>
<td>&lt;</td>
</tr>
<tr>
<td>&gt;</td>
<td>&gt;</td>
</tr>
<tr>
<td>&lt;=</td>
<td>&lt;=</td>
</tr>
<tr>
<td>&gt;=</td>
<td>&gt;=</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Element Name</th>
<th>Syntax</th>
<th>Usage Rules</th>
</tr>
</thead>
</table>
| IF           | <if>…</if> | Use the IF element or condition to logically
direct template processing flow.
   IF elements must begin with <if> and end with
   </if>. |
**Element Name** | **Syntax** | **Usage Rules**
--- | --- | ---
COND | `<cond> . . . </cond>` | Use the COND node to evaluate a logical Boolean based on the following operations:
- Equals To: `=`
- Not Equal To: `!=`
- Greater Than: `>`
- Greater Than or Equal To: `>=`
- Less Than: `<`
- Less Than or Equal to: `<=`
Logical AND: `AND`
Logical OR: `OR`
Each operator in a condition can be:
- Declared in the template
- A constant placed within quotation marks (""")
- An implicit variable
Use the AND or OR logical operators to combine multiple conditions and to evaluate a combined result.
Enclose each condition in parentheses [{}{}] to separate them
The application evaluates the combined conditions from left to right
All COND elements must start with `<cond>` and end with `</cond>`.

THEN | `<then> . . . </then>` | If the specified condition is TRUE, the application executes the THEN block.
This block can have single or multiple instruction tags including `<if> . . . </if>`.
All THEN elements must start with `<then>` and end with `</then>`.

ELSE | `<else> . . . </else>` | If the specified condition is FALSE, the application executes the ELSE block.
The ELSE block can have single or multiple instruction tags including `<if> . . . </if>`.
All ELSE elements must start with `<else>` and end with `</else>`.

LET | `<let> . . . </let>` | Use the LET element to assign a value to a variable or a narrative.
The value you assign must be enclosed in double quotes ("VAR1") and can be one of the following:
A string with variables
Another variable
Use the `<var>` or `<narrative>` tag to declare the variable before assigning it.
Using the Template Scripting Language

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

**Element Name** | **Syntax** |
--- | --- |
INCLUDE | `<include name=""/>` |

**Usage Rules**

Use the INCLUDE element to include the contents of an existing RTF document in a report during the template build process. All INCLUDE elements must be written in the following manner:

```html
<include name ""/>
```

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.

Periodic reports support the page layouts for the source documents. For example, the application retains a landscape layout in the resulting document.

The name of the files must exactly match the name specified in the report configuration (View ePSUR Template screen).

You can include files in one of the following sections of the output document:

- Line Listing
- Summary Tabulation
- UD Summary
- Other Content

If the file you are including is from the Other Contents section, the file name must have an RTF extension.

You must use Microsoft Word or another tool to convert document files to RTF format. For example, `<include name = "CDA-PSUR1.rtf"/>

All files in the Other Contents section must have unique names.

**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.

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.

For example: `<include name = "List Listing"/>`
Using the Template Scripting Language

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

**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 (<var>) as one of the operands.
  - Must include both a question variable and a constant (e.g., <cond>{q1}="Yes"</cond>)
### Template Writing Quick Reference

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