



## 1. PURPOSE

The purpose of this procedure is to establish a standardized and systematic approach to the request and fulfillment of report output based on Argus Safety data.

This procedure is carried out in a controlled and coordinated manner to ensure that report output based on Argus Safety is appropriate, accurate, validated, timely, and consistent.

## 2. SCOPE

This procedure applies to the request and fulfillment of formal report output – *defined as report output generated for regulatory reporting, audits, health authority inspections, clients, client safety partners, ProPharma interdepartmental, and ProPharma intradepartmental use (referred to herein as “report”) that cannot be produced by case management users* – based on Argus Safety data from any ProPharma reporting platform. Informal reports for ProPharma individual use and report output based on data outside of Argus Safety are considered out of scope.

## 3. DEFINITIONS

Refer to approved Definition list (APP-0008203).

## 4. RESPONSIBILITIES

The roles described in the Procedure sections below are accountable for their assigned steps. Delegation to an appropriate resource is permissible, but the role named below remains accountable.

## 5. PROCEDURE

### 5.1. Reports Requiring Oversight by the PV Systems Team

Authorized ProPharma Employees	<ol style="list-style-type: none"><li>1. Manage and track Argus Safety reports requests.<ol style="list-style-type: none"><li>a. Performs documented tracking, planning, execution, and validation/ verification for applicable report requests.</li><li>b. Determine the need for oversight by the PV Systems Team by performing an assessment of the development/validation effort and purpose of the Argus Safety Report as outlined in sections 5.2 through 5.12 in this document (<i>Refer to the tables in Appendix 1: Reports Requiring Oversight by the PV Systems Team</i>).</li><li>c. (Argus Application Trained Users) Generate reports that do not require oversight by the PV Systems Team by following applicable report type-based work instructions.</li></ol></li></ol>
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### 5.2. Report Request Initiation – New Reports or Changes to Existing Reports

Authorized Client Partners/Representatives	<ol style="list-style-type: none"><li>1. Request new reports or changes to existing reports.</li></ol>
Principal PV Specialist, Client Services Contact, Authorized ProPharma Employees	<ol style="list-style-type: none"><li>2. Create a request within the Global Service Desk (GSD) ticketing system if applicable (<i>Refer to Appendix 1: Reports Requiring Oversight by the PV Systems Team</i>).</li><li>3. Complete an Argus Safety Report Request Form using FOR-0008365 in accordance with the Argus Safety Report Request Form completion guidelines or include simple criteria in description of GSD ticket.</li></ol>



	<ol style="list-style-type: none"><li>4. Monitor any client-initiated GSD report requests.</li></ol>
Authorized Client Partners/Representative and Authorized ProPharma Employees	<ol style="list-style-type: none"><li>5. Request recurring fulfillment of existing reports if applicable.<ol style="list-style-type: none"><li>a. Informed of/understands that existing reports with scheduled recurrence outlined in the GSD ticket and/or approved Report Fulfillment Plan do not require initiation before each recurring report is executed. Refer to <i>Section 5.10, Report Fulfillment Recurrence</i>, for further details.</li></ol></li></ol>
Authorized Client Partners/Representative and Authorized ProPharma Employees	<ol style="list-style-type: none"><li>6. Request ad hoc fulfillment of existing reports.<ol style="list-style-type: none"><li>a. Informed of/understands that execution of the ad hoc report recurrence will be performed in alignment with the GSD ticket request and/or approved Report Fulfillment Plan, as appropriate. Refer to <i>Section 5.10, Report Fulfillment Recurrence</i>.</li></ol></li></ol>
Authorized Client Partners/Representatives	<ol style="list-style-type: none"><li>7. Request the ad hoc run of an existing report.</li></ol>
Principal PV Specialist or Client Services Contact	<ol style="list-style-type: none"><li>8. Create a request within the GSD ticketing system.</li><li>9. Complete FOR-0008365, referencing the relevant report identification number or provide details in the description of the GSD ticket.</li><li>10. Monitor any client-initiated GSD report requests.</li></ol>
Authorized ProPharma Employees	<ol style="list-style-type: none"><li>11. Request the ad hoc run of an existing report by creating an Argus Safety report request in the GSD ticketing system, referencing the relevant report identification number</li></ol>

### 5.3. Report Fulfillment Expectations

	<ol style="list-style-type: none"><li>1. Informed of/understand that the date of final report delivery may be requested but cannot be guaranteed.</li><li>2. Informed of/understand that the probability of meeting the requested date of final report delivery and ensuring proper fulfillment of the report requirements depend on the performance of the following by the requester:<ol style="list-style-type: none"><li>a. Timely initiation of the report request<ul style="list-style-type: none"><li>• Timelines will vary based on the specifics of the report (Refer to <i>Section 5.4, Report Request Tracking and Triage – Timeline Assessment</i>).</li><li>• A lead time of at least 60 days prior to data lock point is preferred for the request of new or updated existing output in support of PADER/PAER, DSUR, or PBRER/PSUR writing activities.</li><li>• A lead time of at least 30 days prior to the requested due date is preferred for the request of other new or updated existing report output.</li></ul></li><li>b. Sufficient completion of FOR-0008365, including example report output, whenever possible (<i>Of note, the report fulfillment process for new or updates to existing reports will not begin without a completed Report Request Form or specific and clear details in the GSD ticket description</i>).</li><li>c. Participation in Report Fulfillment Plan touchpoints (Refer to <i>Section 5.6, Report Fulfillment Plan Touchpoint</i>) as required.</li></ol></li></ol>
Authorized Client Partners/Representatives and Authorized ProPharma Employees	



	d. Timely Report Fulfillment Plan authorization ( <i>Refer to Section 5.7, Report Fulfillment Plan Authorization</i> ) and report output verification/validation ( <i>Refer to Section 5.9, Report Output Verification/Validation</i> ) in FOR-0008365 or in the communication section of the GSD ticket
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#### 5.4. Report Request Tracking and Triage

PV Systems Team	<ol style="list-style-type: none"><li>1. Review report requests sent to the GSD ticketing system and execute the following:<ol style="list-style-type: none"><li>a. Assign a Lead Argus Technician based on the requested type of report, complexity, and need for technical assistance.</li><li>b. Assess priority and estimate report completion timelines.<ul style="list-style-type: none"><li>• Perform an assessment of report request priority based on the reported urgency and purpose of the request (<i>Refer to the table in Appendix 2: Priority Assessment</i>).</li><li>• Estimate report completion timelines based on priority and validation effort (<i>Refer to the table in Appendix 3: Timeline Assessment; business days are referenced</i>).</li><li>• Understand that initially established timelines are only estimates, as factors impacting report fulfillment may not be known before Report Fulfillment Plan Touchpoint completion (<i>Refer to Section 5.6</i>) and Report Fulfillment Plan authorization (<i>Refer to Section 5.7</i>).</li><li>• Understand that anticipated discrepancies between the requested due date and the estimated due date will be communicated to the Principal PV Specialist and Client Services in advance of Report Fulfillment Touchpoint, as necessary.</li></ul></li><li>c. Escalate report requests supporting regulatory authority inspections to the PV Systems Director immediately upon identification to discuss the Report Development/ Generation Strategy and the Report Output Verification/Validation Strategy (<i>Refer to Sections 5.5 and 5.9</i>) and to affirm the report priority and estimated fulfillment timelines.</li><li>d. Schedule a Report Fulfillment Plan Touchpoint (<i>Refer to Section 5.6</i>) when applicable.</li></ol><ol style="list-style-type: none"><li>2. Oversee the tracking and triage of the reviewed report requests each business day to ensure that report fulfillment timelines are met.</li></ol></li></ol>
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#### 5.5. Report Fulfillment Plan Preparation

Lead Argus Technician	<ol style="list-style-type: none"><li>1. Understand that a Report Fulfillment Plan may be generated using FOR-0010194 or documented in GSD ticket to summarize the report requirements, to propose a report generation strategy to meet those requirements, and to detail procedures to ensure the quality of the output and repeatability of the plan.</li><li>2. Understand that sections outlined in FOR-0010194 generally include:<ol style="list-style-type: none"><li>a. Report Requirements Summary, including those requirements</li></ol></li></ol>
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	<p>requested in completed FOR-0008365 and/or those clarified in any Report Fulfillment Plan Touchpoint.</p> <ul style="list-style-type: none"><li>• FOR-0008365 may serve as the primary means by which report requirements are communicated.</li><li>• The attachment of report output examples to the form are encouraged, specifically for non-standard reports.</li></ul> <p>b. Report Development/Generation Strategy, detailing the system and/or the process to be used for report generation, the individual/team responsible for generating the report, the data inclusion/filtering criteria, the report generation criteria, and the specific report configurations.</p> <ul style="list-style-type: none"><li>• Confirm the reporting platform and/or process which will yield the most appropriate output with the fewest resources and most efficient validation effort.</li><li>• If the standard process for report fulfillment is outlined in an existing Work Instruction, the Work Instruction should be referenced in the applicable sections of the Report Fulfillment Plan.</li></ul> <p>c. Report Generation Results, including the number of results that the report logic yielded and a copy of the draft report output.</p> <p>d. Report Verification/Validation Strategy, detailing the process and the individual/team responsible for verification/validation and testing of the report output (<i>Refer to Section 5.9</i>).</p> <p>e. Report Recurrence Strategy, if applicable, detailing the procedure to be used, the criteria to be input, and the individual/team responsible for generating output for each report recurrence.</p> <p>3. Search existing Report Fulfillment Plans to identify an existing plan to update. If an existing plan cannot be found, prepare a new plan.</p> <p>4. Share FOR-0010194 or GSD ticket communications/details and timeline assessment with the requesting Principal PV Specialist and Client Services Contact to support discussions of report fulfillment costing, when appropriate.</p>
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## 5.6. Report Fulfillment Plan Touchpoint

Lead Argus Technician	<ol style="list-style-type: none"><li>1. Understand that a Report Fulfillment Plan Touchpoint may be offered for all client, client partner, audit, and health authority report requests (<i>Refer to the table in Appendix 2: Priority Assessment</i>) that require medium, high, or extensive development and validation effort (<i>Refer to the table in Appendix 1: Reports Requiring Oversight by the PV Systems Team</i>). The touchpoint will help finalize the requirements of the report, explain report fulfillment, and review the draft report output.<ol style="list-style-type: none"><li>a. Existing reports with scheduled or ad hoc recurrence do not require a Report Fulfillment Plan Touchpoint before each report is executed.</li><li>b. Although not required, a requester may ask for a Report Fulfillment Plan Touchpoint for ProPharma internal use reports</li></ol></li></ol>
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	<p>and/or reports that require a low development and validation effort.</p> <ol style="list-style-type: none"><li>2. Lead Report Fulfillment Plan Touchpoint discussions and meetings to ensure that the requirements and plan are clearly communicated and understood.</li></ol>
Authorized Client Partners/Representatives and Authorized ProPharma Employees	<ol style="list-style-type: none"><li>3. Participate in Report Fulfillment Plan Touchpoint to ensure that the requirements are understood, and the plan and draft report output meet those requirements.</li><li>4. Decline participation in Report Fulfillment Plan Touchpoint <i>only</i> if the Report Fulfillment Plan and draft report output are approved and clarification is not required.</li></ol>
Lead Argus Technician	<ol style="list-style-type: none"><li>5. Cancel Report Fulfillment Plan Touchpoint, if the requester declines participation, and consider the Report Fulfillment Plan and draft report output to be approved by the requester.</li><li>6. Document meeting minutes and/or action items, electronic copies of any email exchanges, and/or documentation of a declined meeting invitation from the requester in the GSD ticketing system.</li></ol>

### 5.7. Report Fulfillment Plan Authorization

Lead Argus Technician	<ol style="list-style-type: none"><li>1. Update FOR-0010194 based on feedback received during Report Fulfillment Plan Touchpoint or communicate with requestor via GSD ticket emails.</li><li>2. Exchange the updated plan with the requester via email until the content of the document and the draft report output are deemed acceptable.</li><li>3. When applicable, distribute the final FOR-0010194 for client, client partner, audit, and health authority report requests. (<i>Refer to the table in Appendix 2: Priority Assessment</i>). The final associated IAQS for Custom SQL Reports is authorized by signatures from the Lead Technician, the PV Systems team member, and the Computer Systems Validation team member.</li><li>4. FOR-0010194 must be approved by the requester within the GSD ticket tracking system prior to distribution of the finalized report output for all client, client partner, audit, and health authority report requests.</li><li>5. Understand that approved FOR-0010194 or communications in GSD ticket communications will serve as the basis for the fulfillment of report recurrence. The requester should refer to the plan and/or Report ID in case of changes or requests for report recurrence, ad hoc or otherwise.</li></ol>
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### 5.8. Report Fulfillment Plan Execution

Lead Argus Technician	<ol style="list-style-type: none"><li>1. Execute FOR-0010194 and/or details in GSD ticket request.<ol style="list-style-type: none"><li>a. Understand execution will be carried out for a particular report request based on priority, estimated timelines, and available resources.</li></ol></li><li>2. Generate configuration and/or procedural artifacts to document that</li></ol>
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	<p>the report was generated in accordance with the plan.</p> <p>3. Complete the applicable section of FOR-0010194.</p> <p>4. Assign verification/validation and testing efforts in accordance with the applicable section of FOR-0010194 or GSD ticket description and deliver to the individual/team responsible.</p>
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### 5.9. Report Output Verification/Validation

Lead Argus Technician, Authorized client Partners/Representatives and Authorized ProPharma Employees	<p>1. Understand that verification/validation efforts are performed to ensure that the report output both meets requirements and appropriately and accurately satisfies the intended purpose.</p> <p>a. <i>Lead Argus Technician</i> – Responsible for ensuring that the report output meets the defined requirements by generating an excel listing of <b>ALL cases and events</b> associated with company products in the client tenant and filtering for criteria listed in FOR-0010194 and/or details in GSD ticket to ensure the final report results are logical and reasonable. If discrepancies are noted between ALL case listing and the requested output, explanations will be documented in FOR-0010194 and/or details in GSD ticket. This will be used to support the final report results and should be attached to the GSD ticket.</p> <p>b. <i>Clients, authorized client partners / representatives, or authorized ProPharma employee</i> – Responsible for ensuring that the report output appropriately and accurately satisfies the intended purpose (<i>Did they develop what we need?</i>).</p> <ul style="list-style-type: none"><li>Understand that processes, data entry conventions, and system use impacting the report output may not be known to the lead technician. Therefore, review of the report output by the operational team is necessary to identify miscommunicated or misinterpreted requirements.</li></ul>
PV Systems Team	<p>2. Custom Standard Query Language (SQL) Reports</p> <p>a. Understand that report output generated using custom SQL code requires the greatest level of effort and is associated with the greatest degree of risk (GAMP Category 5). As such, verification/validation efforts for these reports require the greatest level of rigor to ensure that report output accurately and completely reflects the data within the safety database.</p> <p>b. Prepare verification/validation documentation, ensuring that the minimum documentation requirements are met:</p> <ul style="list-style-type: none"><li>Outline a summary of the verification/validation strategy in the Report Fulfillment Plan.</li><li>Complete the verification section of the Report Fulfillment Plan to document and attest that appropriate verification/validation efforts were completed.</li><li><i>Single Client/Tenant Output</i> - Additionally develop an IAQS document prior to development of a custom SQL report specific to a single client/tenant. The IAQS will be referenced in the Report Fulfillment Plan.</li></ul>



	<ul style="list-style-type: none"><li>• <i>Multiple Clients/Tenants Output</i> - Additionally develop more formal verification/validation documentation (e.g., design specifications, Installation Qualification (IQ) scripts, Operational Qualification (OQ) scripts, and/or Performance Qualification (PQ) scripts) prior to development of a custom SQL report for multiple clients/tenants. The formal verification/validation documentation will be referenced in the Report Fulfillment Plan.</li><li>c. Perform verification/validation activities in accordance with the Report Fulfillment Plan and/or Impact Analysis and Quality Strategy (IAQS) document, ensuring that the minimum verification/validation requirements are met:<ul style="list-style-type: none"><li>• <i>Single Client/Tenant Output</i> - Peer review and verify the SQL code.</li><li>• <i>Multiple Clients/Tenants Output</i> - Perform formal test scripts (e.g., IQs, OQs, and PQs, as necessary).</li></ul></li><li>d. Complete the applicable section of the Report Fulfillment Plan.</li></ul>
Authorized Client Partners/Representatives and Authorized ProPharma Employees	<ul style="list-style-type: none"><li>3. Perform verification/validation activities in accordance with FOR-0010194 and/or Impact Analysis and Quality Strategy (IAQS) document, ensuring that the minimum operational verification/validation requirements are met.</li><li>4. Perform this verification/validation against the case data in the database or a secondary, comprehensive line listing with columns representing inclusion and exclusion criteria or as otherwise directed by formal test script, where applicable.</li><li>5. Complete the applicable section of the Report Fulfillment Plan.</li></ul>
Computer Systems Validation Representative	<ul style="list-style-type: none"><li>6. Review and approve the verification/ validation approach and deliverables.</li></ul>
Lead Argus Technician	<ul style="list-style-type: none"><li>7. Generate non-SQL Argus Safety and non-Argus Safety system generated reports.<ul style="list-style-type: none"><li>a. Understand that standard report templates within commercially available or internally developed systems, such as Argus Safety or Case Explorer, have undergone rigorous verification/validation efforts by the system vendor and/or by ProPharma. However, configurations must be applied to standard report templates by the user to yield the appropriate report-specific output. As such, verification/validation efforts for system generated report output are focused on proper execution of report-specific configuration requirements and the appropriateness of the requirements and the resulting output.</li><li>b. Prepare verification/validation documentation, ensuring that the minimum documentation requirements are met:<ul style="list-style-type: none"><li>• Outline a summary of the verification/validation strategy in FOR-0010194.</li><li>• Complete FOR-0010194 to document and attest that appropriate verification/validation efforts were completed.</li></ul></li></ul></li></ul>



	<ul style="list-style-type: none"><li>• Attach ALL case listing used to confirm/reconcile report data</li><li>c. Perform verification/validation activities in accordance with FOR-0010194, ensuring that the minimum verification/validation requirements are met:<ul style="list-style-type: none"><li>• Peer review and verify the executed user-defined, report-specific configurations.</li></ul></li><li>d. Complete the applicable section of FOR-0010194.</li></ul>
Authorized ProPharma Employees	<ul style="list-style-type: none"><li>8. Perform verification/validation activities in accordance with FOR-0010194 ensuring that the minimum operational verification/validation requirements are met. Validate/ verify the appropriateness of:<ul style="list-style-type: none"><li>a. The report-specific configurations,</li><li>b. The included row data (<i>e.g., if each row represents a case, event, or submission record, were cases, events, or submission records included/excluded as expected?</i>), and</li><li>c. The displayed columns (<i>e.g., were the columns displayed, as expected?</i>).</li></ul></li><li>9. Perform this verification/validation against the case data in the database or a secondary, comprehensive line listing with columns representing inclusion and exclusion criteria.</li><li>10. Complete the applicable sections of FOR-0010194.</li></ul>
Lead Argus Technician/ PV Systems Team	<ul style="list-style-type: none"><li>11. Manually generate reports or manually change custom SQL or system-generated report output.<ul style="list-style-type: none"><li>a. Understand that while not associated with the risk of a code or system configuration error, manually generated report output or manual changes to custom SQL or system-generated report output are associated with a substantial risk of human error. As such, rigorous quality control efforts are required to ensure that the report output accurately and completely reflects the data within the safety database.</li><li>b. Prepare verification/validation documentation, ensuring that the minimum documentation requirements are met:<ul style="list-style-type: none"><li>• Outline a summary of the quality control strategy in FOR-0010194.</li><li>• Complete FOR-0010194 to document all manual changes made to custom SQL or system-generated report output, and document and attest that appropriate quality control efforts were performed.</li></ul></li><li>c. Perform verification/validation in accordance with FOR-0010194 ensuring that the minimum verification/validation requirements are met. Validate / verify the appropriateness of:<ul style="list-style-type: none"><li>• The included row data (<i>e.g., if each row represents a case, event, or submission record, were cases, events, or submission records included/excluded as expected?</i>), and</li><li>• The displayed column data elements (<i>e.g., was the appropriate data displayed in all column data elements for every row (100% data verification; all data represented in the</i></li></ul></li></ul></li></ul>



	<p><i>report will be verified).</i></p> <ul style="list-style-type: none"><li>d. Perform this verification/validation against the case data in the database or a secondary, comprehensive line listing with columns representing inclusion and exclusion criteria.</li><li>e. Complete the applicable section of the Report Fulfillment Plan.</li></ul>
Authorized Client Partners/Representatives and Authorized ProPharma Employees	<ul style="list-style-type: none"><li>12. Perform verification/validation activities in accordance with FOR-0010194 ensuring that the minimum operational verification/validation requirements are met. Validate/ verify the appropriateness of:<ul style="list-style-type: none"><li>a. The included row data (e.g., <i>if each row represents a case, event, or submission record, were all cases, events, or submission records included/excluded as expected?</i>) and</li><li>b. The displayed data elements in each associated columns (e.g., <i>was the appropriate column data displayed for a minimum three, data-rich rows of varying types, if available</i>).</li></ul></li><li>13. Perform this verification/validation against the case data in the database or a secondary, comprehensive line listing with columns representing inclusion and exclusion criteria.</li><li>14. Complete the applicable section of FOR-0010194.</li></ul>

#### 5.10. Report Fulfillment Distribution and Notification

Lead Argus Technician	<ul style="list-style-type: none"><li>1. Distribute the final report output directly to requesting Authorized ProPharma employees or to the Principal PV Specialist or Client Services Contact, when the client is the requester for reporting platforms without automated notification in GSD ticketing system.</li><li>2. Document confirmation of report distribution to the requesting Authorized ProPharma employees or to the Principal PV Specialist or Client Services Contact, when the client is the requester for reporting platforms with automated notification in GSD ticketing system.</li></ul>
Principal PV Specialist or Client Services Contact	<ul style="list-style-type: none"><li>3. Distribute the final report and ALL case listing used to verify output to the requesting client.</li></ul>

#### 5.11. Report Fulfillment Recurrence

Lead Argus Technician	<ul style="list-style-type: none"><li>1. Track the fulfillment of each report recurrence in the GSD ticketing system if applicable.</li><li>2. Fulfill the report recurrence.<ul style="list-style-type: none"><li>a. Understand that FOR-0010194 will dictate the timelines, inputs, procedures, and responsibilities of the individuals who will fulfill the request on a recurring basis.</li><li>b. Understand that if report recurrence is executed in accordance with approved FOR-0010194, the report can be fulfilled without re-initiating the Report Fulfillment procedure.</li></ul></li></ul>
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### 5.12. Report Request Oversight and Closure

Authorized Client Partners/Representatives and Authorized ProPharma Employees	<ol style="list-style-type: none"><li>Review the list of open report requests each week within the Argus Safety Updates Meeting to determine if the active list is comprehensive, ensuring that all tickets have been properly logged in the GSD ticketing system, and that timelines for fulfillment are met.</li></ol>
Lead Argus Technician	<ol style="list-style-type: none"><li>Review each report request prior to ticket closure to determine if the report request was fulfilled in accordance with FOR-0010194 in a manner that was satisfactory to the requester.<ol style="list-style-type: none"><li>If not, the request will be reviewed with the Argus Safety Managed Services Team, for custom SQL reports or Argus Safety-generated reports, or with the team/individual that fulfilled the report request, per FOR-0010194, to ensure that proper deviations/service complaints are filed.</li></ol></li></ol>
PV Systems Teams	<ol style="list-style-type: none"><li>Document time spent on report fulfillment in GSD ticketing system.</li><li>Send log of time spent on report fulfillment to Client Services, upon request.</li></ol>

## 6. REFERENCES

Number	Title
FOR-0008365	GLOB Argus Safety Report Request Form
FOR-0010194	GLOB Argus Safety Report Fulfilment Plan Form

## 7. APPENDICES

Number	Title
Appendix 1	Reports Requiring Oversight by the PV Systems Team
Appendix 2	Priority Assessment
Appendix 3	Timeline Assessment
Appendix 4	Argus Safety Report Fulfillment Workflow

**APPENDIX 1: REPORTS REQUIRING OVERSIGHT BY THE PV SYSTEMS TEAM**

Development and Validation Effort	Types of Argus Safety Reports
Low	<ul style="list-style-type: none"><li>UltraAnalytics: Available Reports</li><li>Tableau: Available Reports</li></ul>
Medium	<ul style="list-style-type: none"><li>Argus Safety: CIOMS II Listing with Advanced Conditions</li><li>Argus Safety: Case Listing with Advanced Conditions</li><li>Argus Safety: Case Data Analysis</li></ul>
High	<ul style="list-style-type: none"><li>Argus Safety: Custom Reports, Including SQL-Coded</li></ul>
Extensive	<ul style="list-style-type: none"><li>UltraAnalytics: Custom Reports</li><li>Tableau: Custom Reports</li></ul>

Reports Requiring Oversight by the PV Systems a Team				
Purpose	Development and Validation Effort			
	Low	Medium	High	Extensive
ProPharma Internal Use	Not Required	Not Required	Required	Required
Client / Client Partner Use	Not Required	Required	Required	Required
Audits and Health Authority Use, Including Inspections	Required	Required	Required	Required



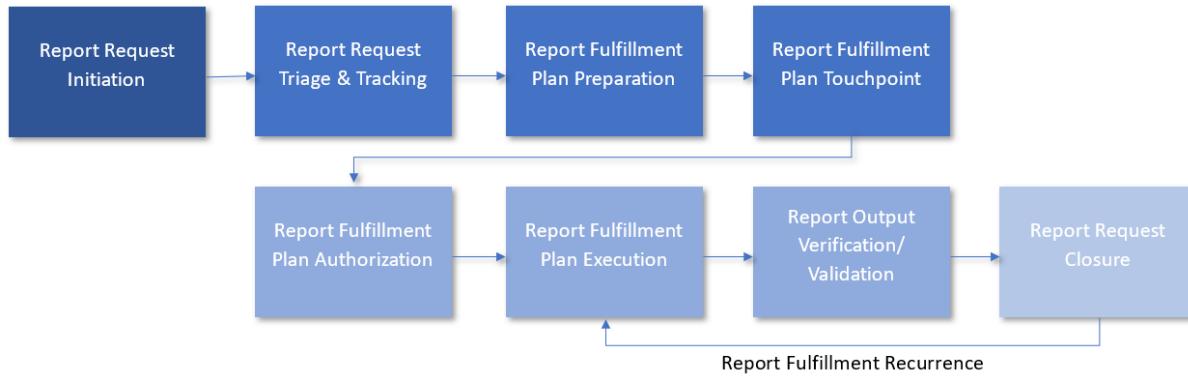
## APPENDIX 2: PRIORITY ASSESSMENT

Priority				
Purpose	Urgency			
	Low	Normal	High	Urgent
ProPharma Internal Use	Low	Medium	Medium	High
Client / Client Partner Use	Medium	Medium	High	High
Audits and Health Authority Use, Including Inspections	Medium	High	High	Critical

**APPENDIX 3: TIMELINE ASSESSMENT**

<b>Timelines</b>				
<i>*Business Days</i>				
<b>Priority</b>	<b>Development and Validation Effort</b>			
	Low	Medium	High	Extensive
Critical	1 Day	1 Day	1-2 Days	> 30 Days
High	1 Day	1-2 Days	4-10 Days	> 30 Days
Medium	1-2 Days	4-10 Days	11-30 Days	> 30 Days
Low	1-2 Days	11-30 Days	> 30 Days	> 30 Days

*\*The timeline is reset if the report requirements change more than once*

**APPENDIX 4: ARGUS SAFETY REPORT FULFILLMENT WORKFLOW**



This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

## Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Angela Robertson	Director Systems and Submissions	21-May-2024 00:09 (GMT)
Review	Thomas Chatzopoulos	Vice President QPPV Office	22-May-2024 16:14 (GMT)
Review	Chastine Hoffmann	Senior Manager Post-Marketing Case Processing	22-May-2024 18:36 (GMT)
Review	Joseph Ferri	Principal Specialist Systems and Submissions	28-May-2024 08:26 (GMT)
Review	Audrey Williams	Director Global Pharmacovigilance Quality	29-May-2024 15:23 (GMT)
Send for Approval	Angela Robertson	Director Systems and Submissions	21-Jun-2024 17:45 (GMT)
Approve	Thomas Chatzopoulos	Vice President QPPV Office	26-Jun-2024 16:08 (GMT)
Approve	Audrey Williams	Director Global Pharmacovigilance Quality	27-Jun-2024 21:28 (GMT)
Approve	Chastine Hoffmann	Senior Manager Post-Marketing Case Processing	01-Jul-2024 13:24 (GMT)
QA Approval	Sharon Andrews	Senior eQMS Specialist	05-Jul-2024 08:17 (GMT)