How-to guide

# PHARMACOVIGILANCE AI AGENT

A practical guide for developers looking to build and use an AI-powered Pharmacovigilance assistant.

***In collaboration with***


AUTOMATION ANYWHERE

# Pharmacovigilance AI Agent – How-to guide

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## Overcoming Traditional Pharmacovigilance Operations Challenges

In a traditional pharmacovigilance setting, drug safety teams face numerous challenges that can hinder the efficiency of adverse event reporting and safety monitoring. These challenges lead to delays in signal detection, missed safety signals, increased regulatory risk, and reduced patient trust.

Safety assessments often rely on manual data entry, extensive case reviews, and detailed evaluation of adverse drug reactions (ADRs), all of which are time-consuming. Pharmacovigilance processes involve numerous sequential tasks, such as individual case safety reports (ICSR) evaluation and risk-benefit analysis, which are labor-intensive and prone to human error. Efforts to speed up these processes can result in incomplete data assessments, negatively impacting patient safety and regulatory compliance.

Differences in experience between seasoned and new pharmacovigilance professionals further complicate the process. Routine tasks, such as duplicate case detection or initial case triage, could be automated, but limited use of technology and fragmented access to global safety data reduce operational efficiency.

Ultimately, challenges in timely access to relevant clinical and safety information reduce the effectiveness of pharmacovigilance teams, highlighting the need for advanced solutions like AI-driven case processing and automated signal detection to enhance workflow efficiency and improve patient safety outcomes.

## Introducing the Pharmacovigilance Agent

The **Pharmacovigilance Assistant** is an AI-powered tool designed to automate and optimize various drug safety tasks, such as adverse event reporting, case triage, and signal detection.

This guide serves as a practical resource for developers, outlining a structured approach to building an effective pharmacovigilance assistant using AI-powered automation through platforms like Automation Anywhere.

The assistant harnesses AI and automation to enhance efficiency, accuracy, and scalability by processing routine safety data, generating data-driven insights, and making informed recommendations through clinical and safety data analysis. By seamlessly integrating with existing pharmacovigilance systems and safety databases, the assistant ensures smooth data flow and improved case processing performance.

Key benefits include faster adverse event reporting, improved signal detection, enhanced data accuracy, reduced regulatory risk, scalability, and proactive safety monitoring, making it a transformative tool in modern pharmacovigilance operations.

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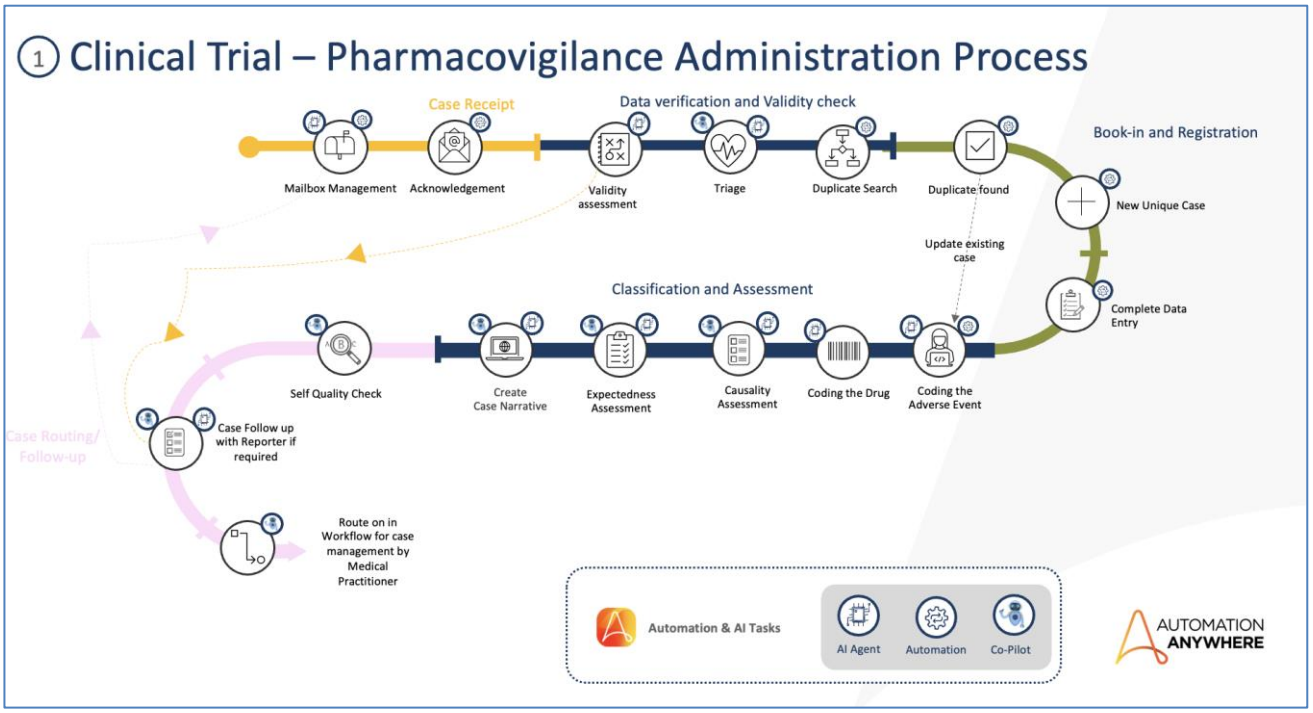


## SOLUTION OVERVIEW

The **Pharmacovigilance Assistant** transforms the pharmacovigilance process by automating critical tasks such as adverse event reporting, case triage, and signal detection, enabling drug safety teams to focus on more complex safety assessments. This leads to faster case processing, improved patient safety, and enhanced employee satisfaction, benefiting both pharmaceutical companies and patients.

**Comprehensive Application**

The AI-powered assistant is highly versatile and can be applied to various stages of the pharmacovigilance process, including adverse event reporting, case triage, signal detection, and benefit-risk evaluation. It can integrate seamlessly with pharmacovigilance databases, regulatory systems, and safety monitoring platforms to streamline operations and enhance compliance.

**Integrated and Adaptive Solution**

Combining your pharmacovigilance system with the capabilities of Automation Anywhere and a generative AI provider of your choice creates a responsive, efficient, and adaptive safety monitoring solution. This setup addresses pharmacovigilance challenges and enhances employee productivity by integrating AI-powered assistance directly into the drug safety workflow. The assistant automates routine tasks, retrieves relevant clinical data quickly, and provides notifications and alerts to ensure timely and accurate case processing.

**Leveraging Generative AI**

By utilizing generative AI (GenAI) from hyperscale frameworks or enterprise-grade AI platforms, the **Pharmacovigilance Assistant** can provide intelligent insights, personalized safety recommendations, and automated workflows. This enables drug safety professionals to focus on core responsibilities, such as complex safety evaluations and risk assessments, while automating repetitive tasks like case triage and data entry. As a result, employees can dedicate more time to strategic safety decisions, improving overall productivity and enhancing patient safety outcomes.

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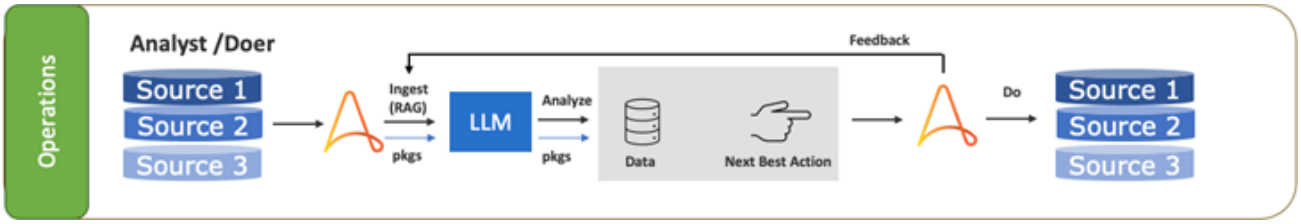
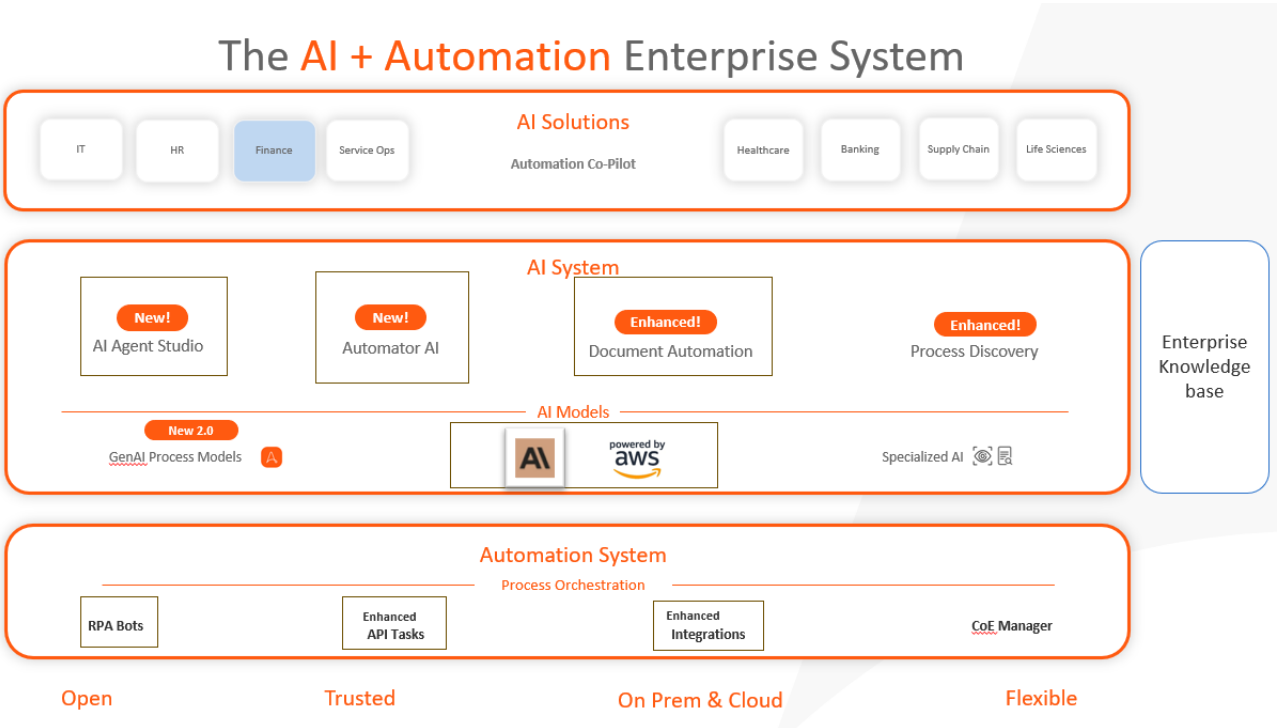



**Key features of the Pharmacovigilance Agent**

- **Extracts patient details** from emails and health management systems, ensuring accurate and timely case initiation.
- **Verifies reported drug details** and retrieves relevant information to assess potential adverse events.
- **Fetches practitioner details** to cross-reference the reported case and validate the medical context.
- **Generates AE (Adverse Event) codes** automatically, reducing manual effort and ensuring compliance.
- **Performs causality and expectedness assessments** using AI-driven analysis to provide a comprehensive evaluation of the reported events.
- **Refers to regulatory and safety guidelines** from the AI-powered Knowledge Base to provide safety recommendations and next steps.

## THE Pharmacovigilance AI Agent COMPONENTS

### Overall Architecture



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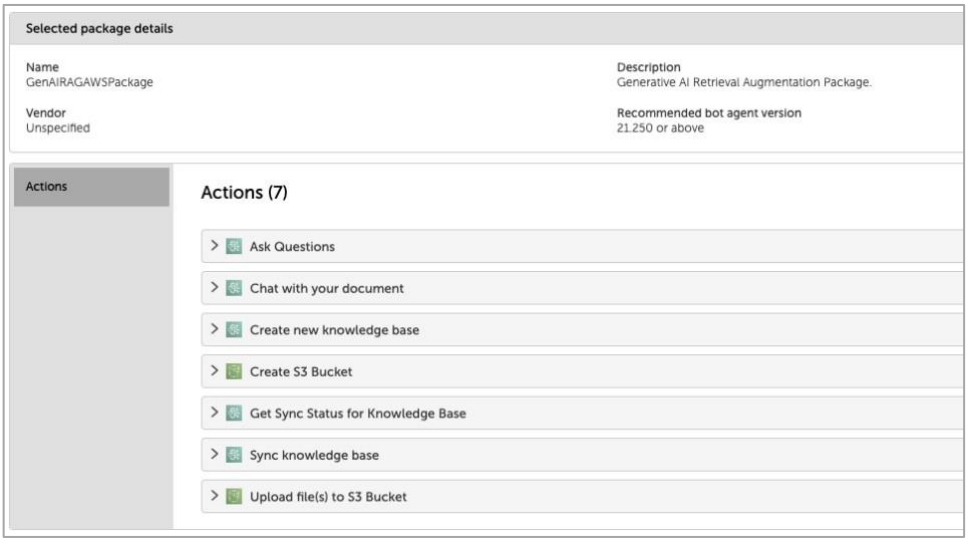
## Customizing your Pharmacovigilance Agent

The **Pharmacovigilance Assistant** is powered by vast datasets and utilizes **retrieval augmented generation (RAG)** for fast indexing and knowledge retrieval. By leveraging robust cloud services like **AWS Bedrock**, we can build advanced knowledge capabilities into our AI agent, enabling complex safety analysis, decision-making, and personalized recommendations.
This knowledge base can include medical guidelines, adverse event reporting regulations, clinical trial data, standard operating procedures (SOPs), and policy documents. Customization is made simple, allowing you to tailor the Pharmacovigilance Assistant to your organization's specific needs using the generative AI provider of your choice.

- AWS Knowledge Retrieval & Conversation Package (Link to BotStore)




*For more complex scenarios, use the AWS Bedrock Console.*

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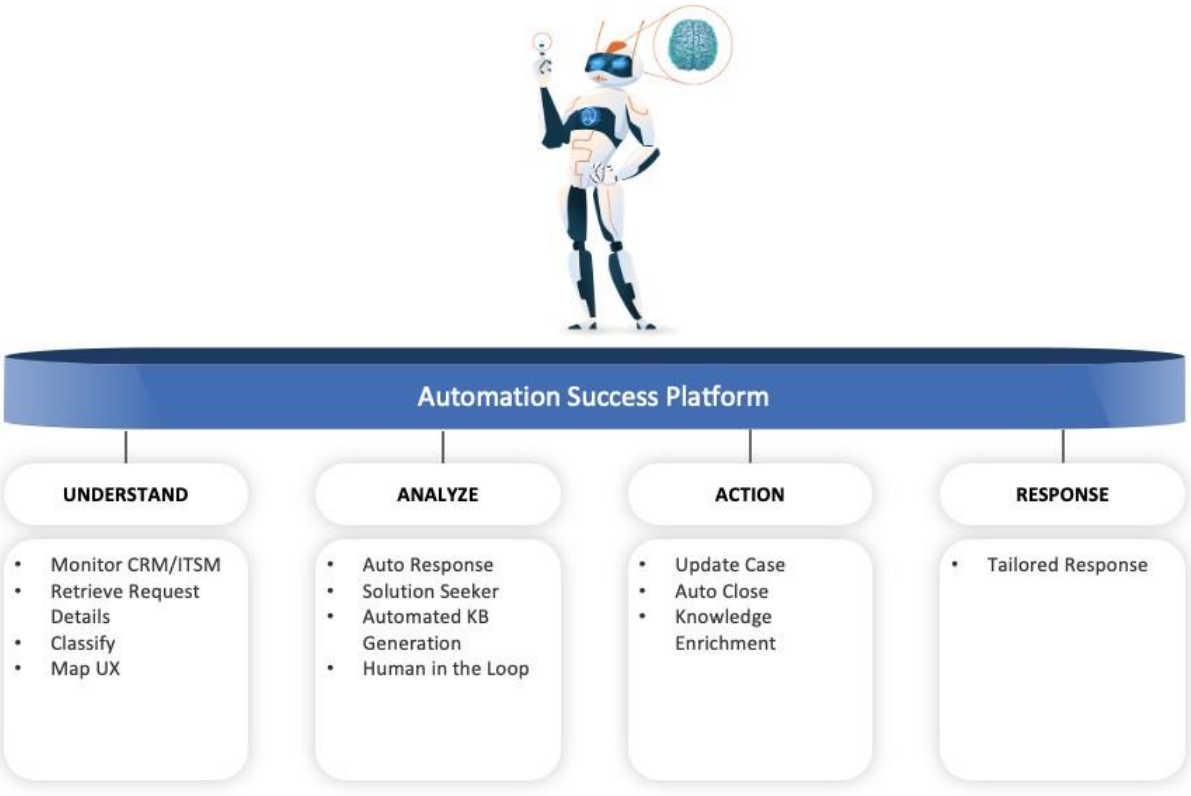
## Connecting the Pharmacovigilance Agent knowledge to an automation

- Automation retrieves relevant data and working knowledge to provide actionable safety recommendations. System and user prompts collaborate to ask targeted questions and retrieve answers, leveraging the Pharmacovigilance Assistant's knowledge and reasoning from the large language model (LLM). System prompts include dynamic data from case reports and persona definitions of the task at hand. Automation serves as the vehicle to pass user data, patient details, case information, and system metrics to the LLM, enabling fully automated dynamic decision-making and case resolution in the pharmacovigilance process.

- Extract Data
    - Automation extracts patient and drug-related data from emails, health management systems, and medical documents, passing this data to the next action in the workflow.
- The Pharmacovigilance Assistant identifies automated and suggested action(s)
    - Automation-based actions with pharmacovigilance systems.
    - Automation within the Automation Success Platform.
    - Automation-based actions with other integrated systems, such as regulatory databases or health records.
- The Pharmacovigilance Assistant identifies response needs
    - Automation-based communications for reporting adverse events or requesting further information.
    - API interactions with safety monitoring platforms and databases.
    - User interface (UI) interactions for safety professionals, ensuring that all critical data is presented for review.

## MAIN FEATURES



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## Understand

- Monitor communication channels like emails and health reporting systems.
- Retrieve patient details and reported adverse event information from emails and health management systems.
- Verify drug and practitioner details, cross-referencing health data with known safety protocols.
- Leverage GenAI tools and Automation Co-Pilot interfaces to assist in processing adverse event reports, performing causality assessments, and calculating expectedness assessments.

## Analyze

- Beyond Basic Automation:
  - This AI-driven solution surpasses traditional pharmacovigilance automation by enhancing the safety reporting process. It provides clear insights for healthcare professionals and delivers detailed, actionable steps for safety assessors, significantly reducing the time needed for report analysis and optimizing resource utilization. Furthermore, it ensures thorough follow-up with both the healthcare provider and the safety team, improving communication and decision-making.
- Knowledge Integration:
  - The assistant matches each adverse event report with relevant drug safety guidelines, regulatory documents, and historical safety assessments from the AI-powered Knowledge Base. This allows for informed decision-making based on established protocols and previous case resolutions.
- Proposes Safety Decisions and Next Steps:
  - The assistant not only suggests whether the reported adverse event is expected or unexpected, but also recommends next steps for safety professionals, such as further clinical investigation or regulatory reporting, streamlining the process for quicker and more accurate outcomes.
- Automated Knowledge Base (KB) Assistant:
  - Utilize GenAI to Generate Summaries and Documentation:
  - AI is used to create comprehensive case summaries, safety assessments, and decision-making steps, compiling the information into PDF or DOCX formats for inclusion in the pharmacovigilance Knowledge Base. This ensures consistency and ease of reference for future safety evaluations.
- Human-in-the-loop:
  - Human Review After AI Recommendation:
  - After GenAI generates recommendations, the safety assessor or medical reviewer can verify the results through the user interface (UI), allowing for a final human validation before completing the case report.

## Action

- **Automation**
  - Update Safety Reporting System Using APIs/Interface:
    Utilize APIs to seamlessly update the pharmacovigilance database with new adverse event reports, risk assessments, and recommended actions.

  - Automated Knowledge Enrichment:
    Leverage the Automated Knowledge Base (KB) Assistant to continuously improve the pharmacovigilance Knowledge Store. This automated process enhances historical relevance by ingesting existing and newly generated clinical documents, creating concise summaries of adverse events, which are then added to the KB. By continuously learning from these summaries, the system improves its understanding and relevance over time. This ensures that the data remains within your control and

aligns with your established practices, minimizing inaccuracies typically associated with LLMs.

- Augmented Human-in-the-loop
  - Augment Pharmacovigilance Assessor (Subject Matter Expert - SME):
  - Ensure that a human expert is integrated into the process to confirm suggested steps, complete communications to healthcare providers, and manage oversight and escalation handling.
- Escalation Overview:
  Assess the best path forward when dealing with complex cases. The expert can choose from automated recommendations or work the case manually, ensuring that all critical information is captured for historical detail and continuous improvement.
- Expert Resolution Detail and Summary:
  Document the actions taken during the review process to enhance organizational knowledge. This information can then be used for further automation and improvement of SME practices, raising the overall intelligence and proficiency of the team.
- Review Outbound Communications to Requesters:
  Ensure that communications sent to healthcare providers and stakeholders are accurate, clear, and compliant with regulatory standards.

- Optional
  - Request Intake Automation

  - Multichannel Input:
    Facilitate the intake of adverse event reports through various channels (email, phone, chat, scanned documents).
  - Leverage Document Automation:
    Integrate document automation tools with the pharmacovigilance platform to streamline data extraction from submitted documents.
  - Scheduled or Triggered Processes:
  - Automate the intake process to occur at scheduled intervals or trigger based on specific events in the workflow.
  - Service Requester Management:
    Pharmacovigilance analysts can choose automation paths based on case complexity, with system-generated options for auto-invocation triggered by specific criteria.
  - Auto Assignment:
    Automatically assign open and unassigned reports to appropriate specialists based on time zones, regions, support agreements, and SLAs.
  - Keyword-based or GenAI Triggers:
    Implement keyword recognition or GenAI capabilities to assist in automatically routing cases to the right personnel.
  - Escalation Determination:
    Assess the priority and specialty of each case to ensure timely and appropriate responses.

## Response

- **Auto Response**
  Closed loop communication for adverse event reports.
  Automatic status updates to stakeholders.
  Log requests in the pharmacovigilance platform.
  Notify requesters of report acknowledgment and status.

- **Response to Requester**
  Tailored responses by pharmacovigilance specialists.

- **Status updates:**
  Report in process.
  Application initiated.
  Request for additional information.
  Summary of findings.

- **Update Report Details**
  Update relevant details in the pharmacovigilance database.

- **(Optional)**
- **Escalation Handling**
  Escalate critical reports for urgent review.
  Follow pharmacovigilance platform escalation protocols.

## USING THE CODE

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## WALKTHROUGH

Here is a high-level flow of the Pharmacovigilance solution:

1. Case Receipt
   - Mailbox Management: Monitor and manage incoming reports and communications.
   - Acknowledgement: Send confirmation of receipt to the reporter.

2. Data Verification and Validity Check
   - Validity Assessment: Evaluate the report for completeness and accuracy.
   - Triage: Categorize cases based on urgency and importance.
   - Duplicate Search: Check for existing reports to avoid duplication.
     - If a duplicate is found, update the existing case.
     - If no duplicate is found, proceed with a new case.

3. Book-in and Registration
   - New Unique Case: Register the case as a new entry.
   - Complete Data Entry: Ensure all relevant data is accurately recorded.

4. Classification and Assessment
   - Self-Quality Check: Conduct a preliminary review for quality assurance.
   - Create Case Narrative: Document a detailed narrative of the case.
   - Expectedness Assessment: Determine if the event was expected based on existing knowledge.
   - Causality Assessment: Assess the likelihood that the drug caused the adverse event.
   - Coding the Drug: Assign standardized codes to the drug involved.
   - Coding the Adverse Event: Assign standardized codes to the adverse event.

5. Case Routing/Follow-up
   - Case Follow-up with Reporter if Required: Contact the reporter for additional information if necessary.
   - Route on in Workflow for Case Management by Medical Practitioner: Forward the case for further management by a qualified medical professional.

Automation and AI Integration

1. Utilize AI agents and automation tools for efficiency and accuracy throughout the process.

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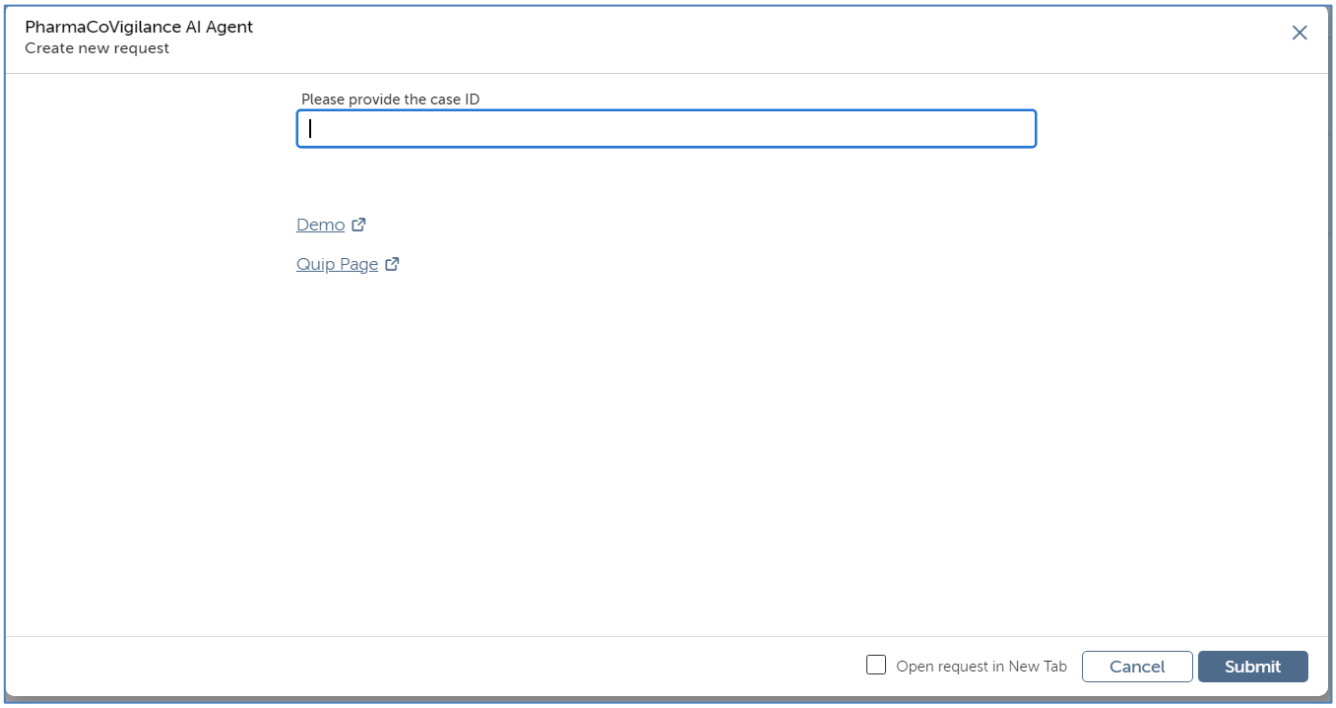
## 1. Provide Case ID




The Pharmacovigilance Case ID can be provided manually using the co-pilot form or customization can be made to read it from Email box.

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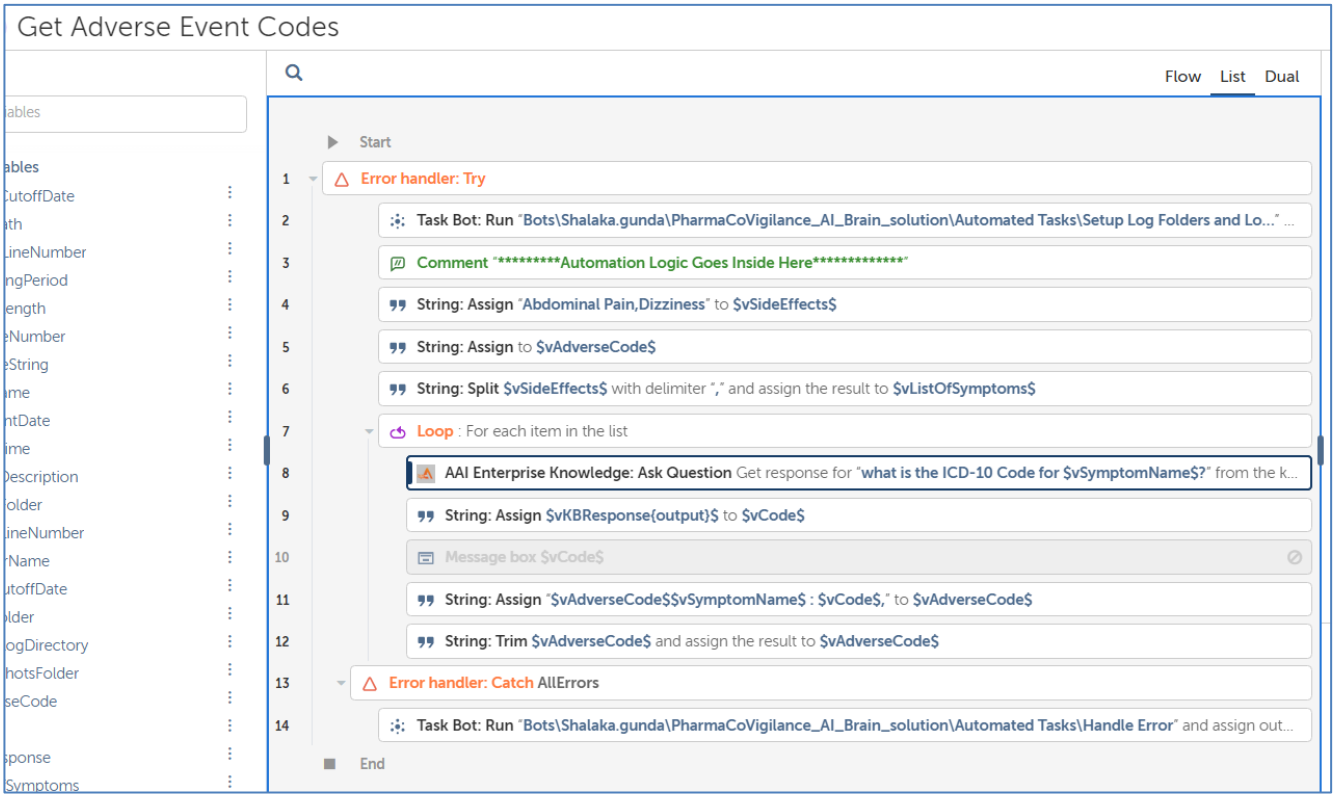
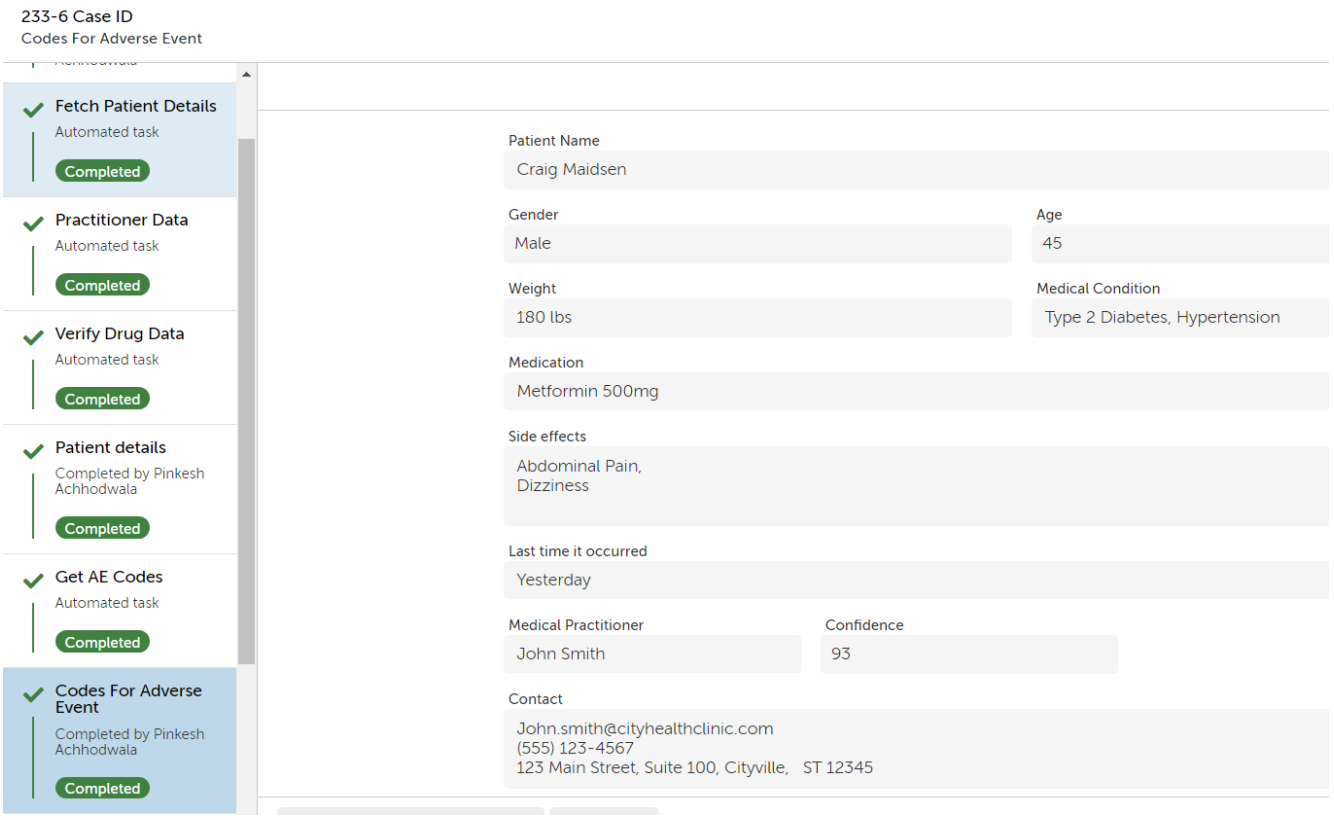
## 2. Get Adverse Event (AE) Codes

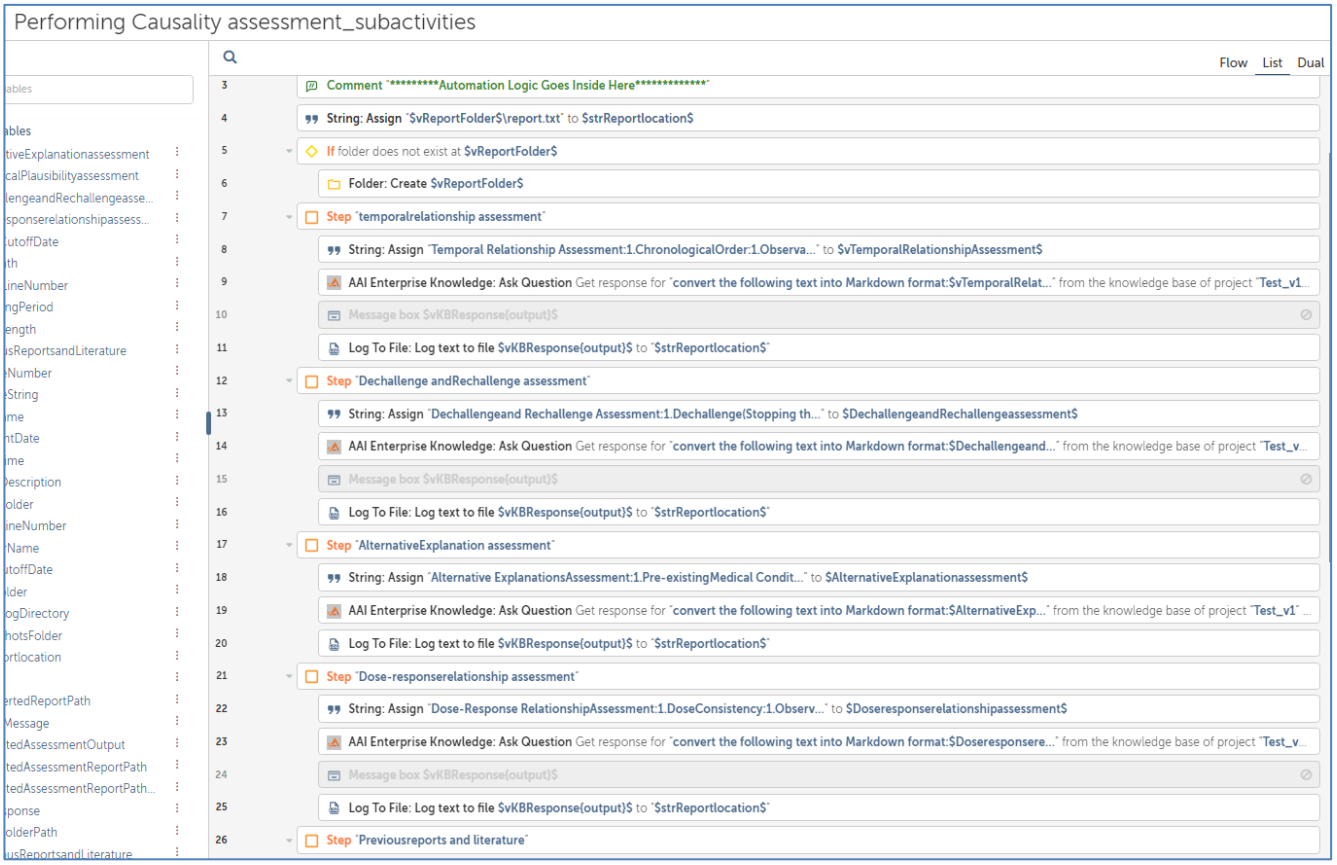



The Task Bot is used to extract the Adverse Event (AE) codes from the knowledge base data.

LLM (Model): anthropic.claude-v2:1
Vendor: Amazon Bedrock

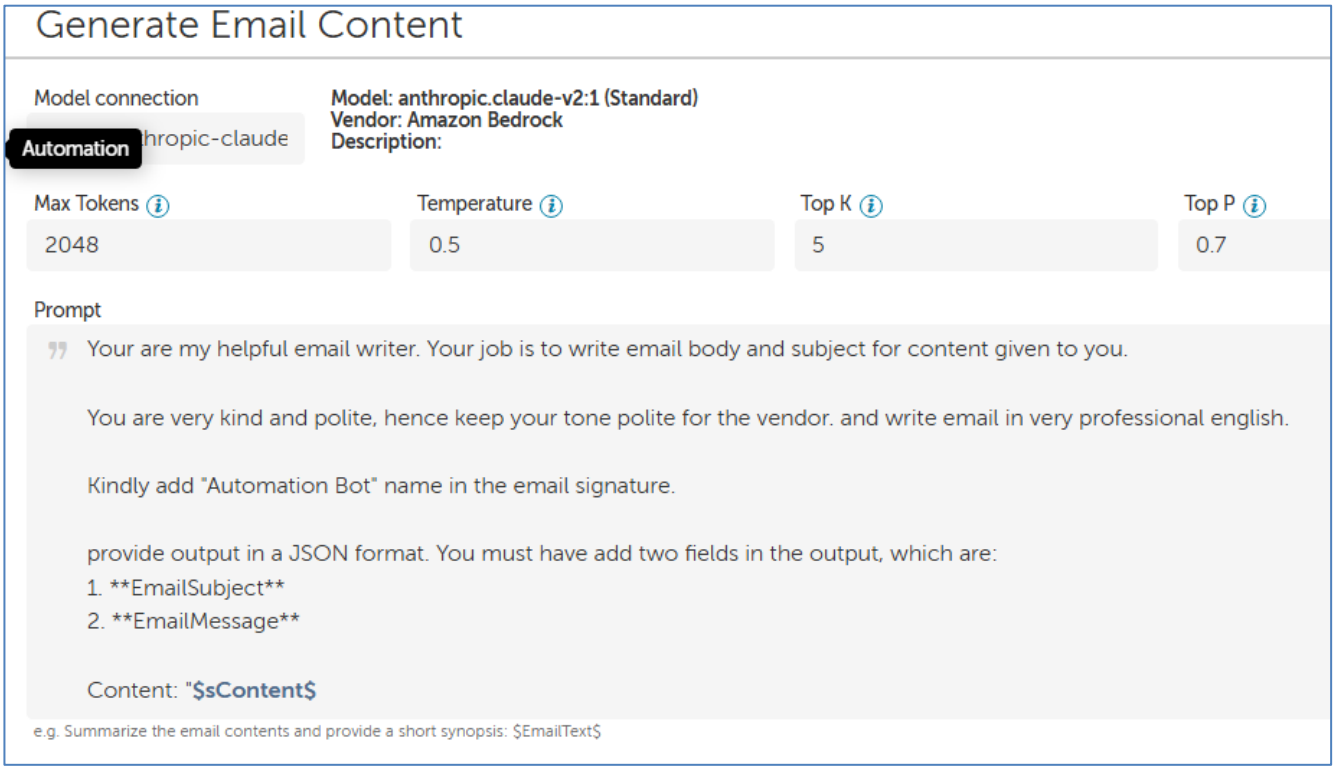


## 3. Causality Assessment

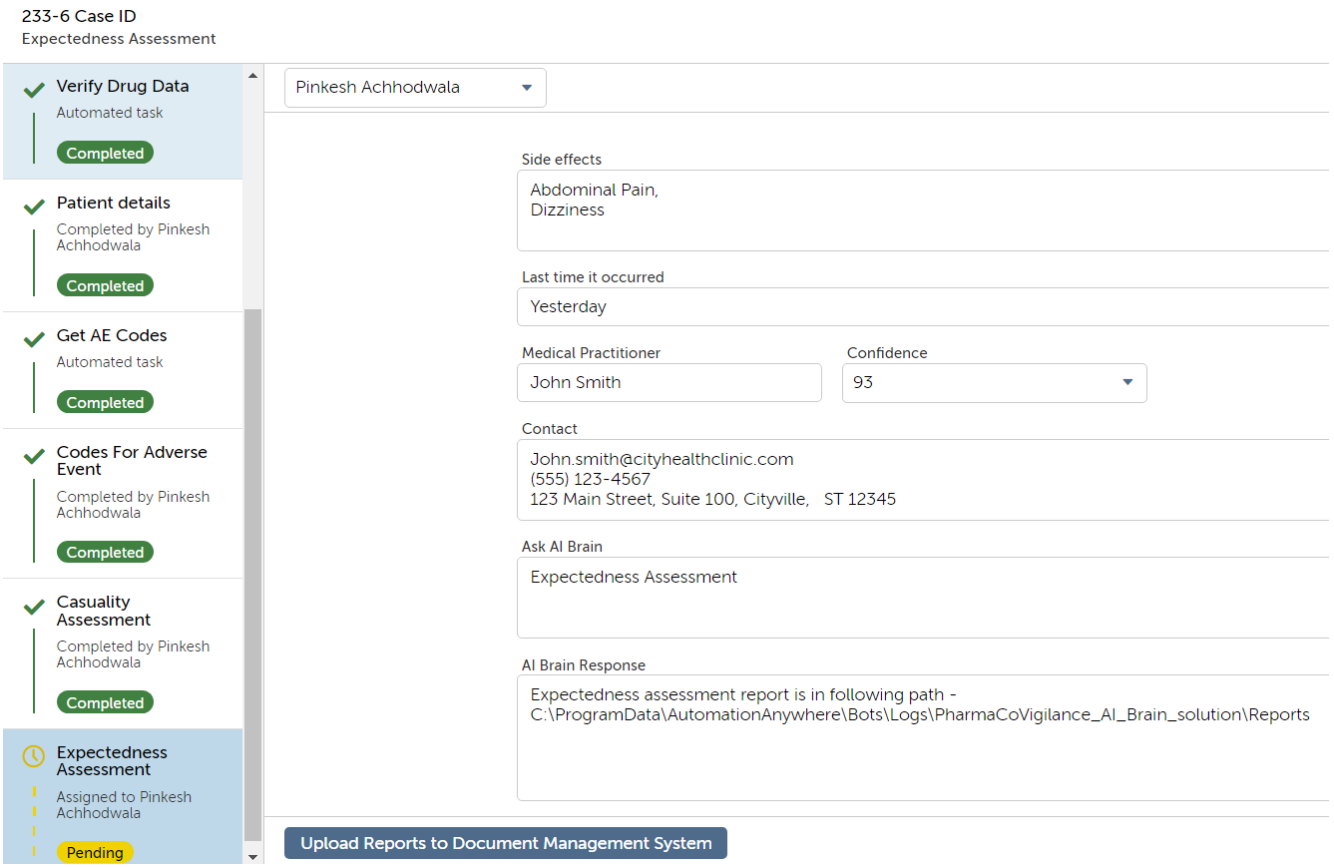



The Task Bot is used to perform 6-way matching, including Temporary relationship, DE challenge or Rechallenge, Alternative Explanation, Dos-response relationship, Previous reports and relationship assessments.

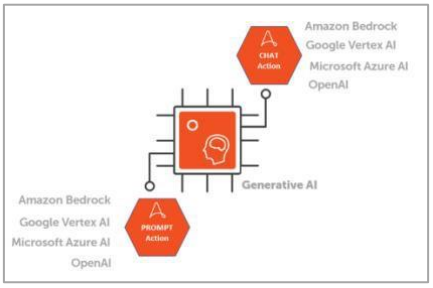
LLM (Model): anthropic.claude-v2:1
Vendor: Amazon Bedrock

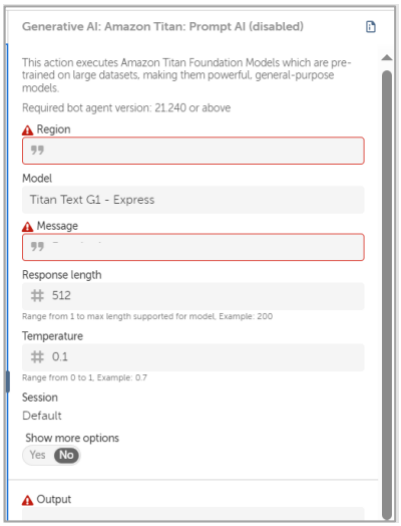

Generate Email Content
Model connection
Automation
hropic-claude
Model: anthropic.claude-v2:1 (Standard)
Vendor: Amazon Bedrock
Description:
Max Tokens
2048
Temperature
0.5
Top K
5
Top P
0.7
Prompt
Your are my helpful email writer. Your job is to write email body and subject for content given to you.
You are very kind and polite, hence keep your tone polite for the vendor. and write email in very professional english.
Kindly add "Automation Bot" name in the email signature.
provide output in a JSON format. You must have add two fields in the output, which are:
1. **EmailSubject**
2. **EmailMessage**
Content: "$sContent$
e.g. Summarize the email contents and provide a short synopsis: $EmailText$

## 4. Expectedness Assessment




These Bots use the Amazon LLM to generate the Email response basis the input provided about pharmacovigilance matters.






1. Authenticate to your chosen LLM Provider.
2. Connect to your LLM Provider via Prompt with proper parameters. *Message* is where your prompt will be inserted.
3. Output maps to output variable, that can be used to send communication emails back to the requestor.

# SOLUTION DEVELOPMENT STEPS

## Prerequisites

### Environment Setup

- Set up Automation 360
- Enable Automation to Automation Co-Pilot

## Preproduction

### Identify Content Store

- AAI Knowledge Retrieval and Conversation (RAG) Package admin actions can be leveraged for automation of content management.
    - Content stores are often shared storage repository (S3 Bucket.)
        - Approved users or processed may submit to the shared content store.
        - Deploy automation to move content to the shared content store.
    - Content can be a URL root, SharePoint library for crawling.
        - If Using AAI Enterprise Knowledge, configure content crawling.
        - If not, configure the necessary automation(s).

### Define Knowledge Store

- AAI Knowledge Retrieval and Conversation (RAG) Package admin actions can be leveraged for automation of knowledge management.
- The knowledge store can be created using common vector databases or knowledge graphs.
- Hyperscale's provide cloud-provisioned solutions that are readily adaptable.
- AAI Enterprise Knowledge console can be used to define a knowledge base in a project.
- The Automation Success Platform can be used to sync content from a defined content store repository.
    - Consider the following seeding documents:
        - Procedure Guides
        - History of Successfully Closed Incidents
        - Whitepapers
        - Existing Knowledge Base Articles
        - Training materials
        - Troubleshooting tips and ticks
        - Pertinent articles
    - Once the Agent is configured, you can create knowledge base articles from your prior and day-forward requests.

# APPENDIX A

## Prompt Examples

**Temporal Relationship Assessment Prompt Template:**

Temporal Relationship Assessment:1. Chronological Order:1. Observation: The patient, Michael Johnson, began experiencing severe abdominal pain and dizziness on June 15, 2024, after starting the new Metformin on June 1, 2024. The symptoms recurred for the next three days after taking the medication.2.Assessment: The adverse effects occurred after the initiation of Metformin treatment, establishing a chronological order where the exposure (Metformin) precedes the outcome (abdominal pain and dizziness).2.LatencyPeriod:1.Observation: The adverse events appeared 14 days after the initiation of Metformin and continued for three days following the first occurrence.2.Assessment: The latency period of 14 days between the start of the medication and the onset of symptoms is reasonable and could suggest a delayed adverse reaction to Metformin, which is consistent with known side effects that may take some time to manifest.3.Consistencywith Known Patterns:1.Observation: Severe abdominal pain and dizziness are known side effects of Metformin, and previous cases have reported similar adverse effects. The patient's symptoms appeared consistently after taking the medication with meals.2.Assessment: The patient's experience is consistent with known adverse effects associated with Metformin, supporting the likelihood of a causal relationship.4.Timeof Onset:1.Observation: The symptoms appeared after taking the medication with meals, which aligns with the expected timing of gastrointestinal side effects from Metformin, particularly when the medications taken on a full stomach.2.Assessment: The predictable onset of symptoms after taking the medication suggests a strong temporal relationship.5.Dose-ResponseRelationship:1.Observation: The patient reported taking the medication at the prescribed dose (500 mg thrice daily) and did not increase the dose at any point during the treatment cycle.2.Assessment: While the dose-response relationship is not explored in detail, the consistent appearance of symptoms at the prescribed dose still supports the potential for a dose-related effect at the standarddose.6.Reversibility(Dechallengeand Rechallenge):1.Observation: The report does not indicate whether the patient discontinued the medication or if the symptoms resolved after stopping the medication.2.Assessment: The absence of information on dechallenge rechallenge limits the assessment, but if the patient were to stop the medication and the symptoms resolved, it would further support the causal relationship. Conclusion: The temporal relationship in this case is strong. The adverse effects appeared after starting Metformin and were consistent with known side effects of the drug. The latency period and timing of symptom onset align with what is expected from Metformin. While additional information on reversibility would strengthen the assessment, the existing details suggest a plausible causal link between Metformin and the reported adverse effects.

**Dechallenge and Rechallenge Assessment Prompt Template:**

Dechallengeand Rechallenge Assessment:1. Dechallenge(Stopping the Drug): 1.Observation: The report does not indicate whether Michael Johnson discontinued the new Metformin after experiencing the adverse events (severe abdominal pain and dizziness). 2.Potential Action: If the patient were to stop taking Metformin and the symptoms resolved or significantly improved, this would support a causal relationship between the drug and the adverse effects. It is important to monitor the patient's symptoms after discontinuation to assess whether they subside. 3.Assessment: Without information

on whether a dechallenge was performed, the assessment cannot definitively conclude the role of Metformin in causing the symptoms. However, if dechallenge is conducted and symptoms resolve, this would strongly suggest that Metformin was the cause.2.Rechallenge(Reintroducing the Drug):1.Observation: The email does not mention whether Metformin was reintroduced after symptoms subsided to see if the adverse eventsreoccurred.2.Potential Action: If Metformin is reintroduced and the symptoms of severe abdominal pain and dizziness reappear, this would provide compelling evidence of a causal relationship. Rechallenge is a crucial step in confirming the drug's role in the adverse events.3 Assessment: Rechallenge has not been conducted based on the available information. If performed and the symptoms return, it would significantly strengthen the evidence for a causal link between Metforminand the adverse events. Conclusion: The Dechallenge and Rechallenge assessments have not been completed based on the information provided in the email. For a more conclusive assessment of the causal relationship, it is recommended to perform a dechallenge by discontinuing the drug and observing whether the symptoms resolve. If necessary, a rechallenge can be conducted to determine if the adverse effects reoccur upon reintroduction of the medication. If further information becomes available regarding the outcome of a dechallenge or rechallenge, a more definitive conclusion can be reached regarding the association between Metformin and the adverse events experienced by Michael Johnson.

# APPENDIX B

## Pharmacovigilance Agent Definitions

**Pharmaceutical Company**

- The pharmaceutical company is responsible for developing, manufacturing, and distributing drugs, as well as monitoring their safety and efficacy.

**Pharmacovigilance Platform**

- **Adverse Event Reporting Systems**: Platforms that facilitate the reporting and collection of adverse event data from healthcare professionals and patients.
- **Drug Safety Management Systems**: Integrated solutions like ARISg or Argus Safety that streamline the management of adverse event data and regulatory reporting.
- **Case Management Systems**: Used to track individual adverse event cases, document assessments, and communicate with reporters and regulatory bodies.
- **Regulatory Compliance Modules**: Systems that ensure adherence to regulatory requirements like those from the FDA or EMA, integrating safety data with compliance workflows.
- **Cloud-Based Safety Solutions**: Cloud platforms that offer scalable and flexible pharmacovigilance services to manage safety data globally.
- **Combinations of one or more of the above**: Pharmacovigilance platforms can integrate several systems for a comprehensive safety management process.

**Pharmacovigilance Specialist**

- **Pharmacovigilance Subject Matter Expert (SME)**: A professional responsible for assessing adverse event reports, determining causality, and ensuring compliance with regulatory standards.
- **Examples**: Drug safety officer, pharmacovigilance associate, clinical safety scientist, regulatory affairs specialist.

**Reporter**

- **Reporter**: The individual or entity reporting an adverse event, which could be a healthcare professional, patient, or caregiver.
- **Examples**: Doctors, nurses, pharmacists, patients.

**Automation**

- Automation interacts with pharmacovigilance systems, such as adverse event reporting platforms and regulatory databases. This includes communication between safety specialists, reporters, and regulatory agencies. Automation ensures efficient data processing, signal detection, and compliance tracking.
- Automation uses AI to assist pharmacovigilance specialists by automating routine tasks, suggesting next steps, and analyzing safety data to enhance efficiency.

**Augmented Human Interaction**

- Augmented human interaction for the pharmacovigilance specialist prepares them for complex decisions by providing summaries, recommendations, and insights from safety data. This includes causality assessment, risk evaluation, and regulatory reporting suggestions based on data analysis.
- Automation Co-Pilot offers an interface for the pharmacovigilance specialist to oversee actions and make decisions when AI or automated processes require additional human input, such as confirming causality assessments or finalizing regulatory submissions.