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Chapter 1: Overview

The Adverse Event Case Processing (AECP) Framework is a Pega BPM-based solution for managing a wide range of Pharmacovigilance (PV) processes. It helps life sciences companies reduce the overall cost of individual safety case processing and submissions, as well as provide a platform for managing and automating global aggregate reporting and risk management processes. AECP includes PV processes, data models, business rules, forms/templates, case structures, and user interfaces built on the Pega BPM platform. AECP leverages Pega BPM and Pega’s Life Sciences Foundation to provide core business process, business rules, case management, auditability, and integration with conventional safety systems.

Pega BPM and AECP help global life sciences companies reduce both cost and risk:

- **Operational Efficiency** - Significantly reduce per-case processing costs across process areas to support growth and cost reduction mandates
- **Reduce Risk** - De-risk both large scale and acquisition-driven safety system migrations with a Pega business layer. Facilitate global risk management processes
- **Build for Change** - Simplify and speed regulatory and business rules changes, and enable specialized global requirements around process and privacy

**AECP Components**

The Adverse Event Case Processing Framework v6.3.1 uses a componentized architecture to enable targeted and incremental implementations. It includes an Inbound Module with functionality for data capture of Adverse Events and Product Complaints, as well as an Outbound Module that automates the rules-based generation and distribution of adverse event reports and regulatory submissions. These modules can be used individually, together, or in conjunction with other and Pega solutions such as Pega Customer Process Manager. Both AECP Inbound and Outbound modules are covered in this document.

**AECP Inbound**

The AECP Inbound Module provides data capture for adverse events (AEs) and product complaints (PCs). It includes easily configurable user interfaces for combined AE/PC intake.

- Integrate with directory/access control systems
- Extensible data model for AE/PC intake with easy configuration for new/updated data elements
- Configurable dynamic questionnaires adapt on-the-fly to user input
- Manage new and follow-up cases
- System managed status and deadline tracking

Adverse Event Case Processing Business Use Case Guide Inbound & Outbound Modules
Intent-led integrated AE/PC intake process guides users through data capture for AEs, PCs, and combination cases

- Data capture for: subject, reporter, products, AE, PC, causality, and other standard fields
- Manage product complaint specific processes – returns, refunds, replacements
- Integrate with external sources of subject/reporter/product data
- Integrated MedDRA coding tool
- Capture lab results and other attachments
- Case tagging, notes, drag-and-drop case transfer and other collaboration features
- Integrated reports and charts
- Causality/relatedness & assessment matrix
- Configurable review workflows – route cases automatically to different users
- Send cases directly to AECP Outbound for reporting

**AECP Outbound**

The AECP Outbound Module is designed to automate the global distribution of safety reports/submissions to affiliates, business partners, regulators, and other interested parties. AECP Outbound provides the following functionality:

- Receive cases directly from AECP Inbound
- Integrate with directory/access control systems
- Integrate with safety system(s) via XML (E2B), web service, database, or other interfaces
- Listen for cases and trigger automatic AECP case creation
- Integrate with/manage product registration data
- Evaluate global reportability using business rules
- Manage global business rules for reportability
- Auto-approve local submissions based on business rules
- Generate individual case report submissions (E2B/XML, MedWatch/PDF, CIOMS/PDF)
- Distribute cases/reports to affiliates based on country or region for review/update
- Distribute cases/reports to business partners
- Portals for case review and administration
- Alerts & notifications
- Integrate with submissions management systems
- Provide full design-time and run-time audit trails
- Business process and activity reporting

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AECP Inbound and Outbound Combined

AECP can be deployed in various configurations:

- Inbound Only - where AE/Complaint cases are captured with AECP Inbound and then passed to a separate safety system for additional processing
- Outbound-only - where AECP is receiving or extracting cases from a separate safety system for report generation (e.g. PDF/E2B), distribution, review, and submission
- Both Inbound and Outbound with a Safety System – used in conjunction with a separate safety system, performing case intake with AECP, passing cases to a safety system for case processing, then passing cases from the safety system to AECP Outbound for reporting and distribution
- Inbound and Outbound Without a Safety System – performing all case processing activities in AECP, capturing case data with AECP Inbound, performing additional case processing and review in AECP and PRPC, then passing cases to AECP Outbound for reporting and distribution

Alerts, Reports and Other Additional Configuration Options

The default configuration and features for AECP are outlined in this document. However, there are many additional configuration options and capabilities that are supported in Pega BPM that are beyond the scope of this guide. See Pega BPM documentation for more information on configuring alerts, event monitoring, reporting, dashboards, and many other Pega BPM features and capabilities.
Chapter 2: A Typical AECP Configuration

AECP Inbound

AECP Inbound provides comprehensive data capture for AEs and product complaints, and the ability to send case data to safety systems or AECP Outbound for continued processing. AECP Inbound can be run as a stand-alone Pega application, or embedded within Pega Customer Process Manager (CPM/CMPLS) using Pega Federated Case Management. A typical environment may include:

- **Safety System(s)** – one or more “safety systems” (i.e. such as AERS, Argus, ArisG) that are used to record and evaluate safety information. AECP Inbound can be configured to send cases to safety system(s) through a variety of mechanisms, including: relational database connectors, web services, and file transfer (e.g. for XML/E2B files). AECP Inbound can distribute to multiple safety systems through different channels, based on business rules.

- **Document Management System/Repository** – A repository or file system may be used as a source for new cases (FAX/scanned documents). AECP can be configured to create cases from specific folder/repository locations.

- **Master Data** – AECP includes sample tables for products, reporters & subjects. This can be replaced by integration directly to existing data sources and systems.

- **Authentication & Access Control** – AECP uses standard Pega authentication and access control components and may be integrated with existing infrastructure and systems.

- **FAX, email, EDC** – Cases in AECP can be created through data entry, or can be triggered by external sources. FAX and email can automatically trigger creation of new cases, and when structured data from systems such as EDC can be used to automatically create and populate new cases.

- **AECP Outbound** – AECP Inbound can integrate with and transfer cases directly to AECP Outbound.

- **Pega CPM/CPMLS** – AECP Inbound can be embedded within Pega Customer Process Manager (CPM), including CPM for Life Sciences. AE/Product Complaint capture can occur within CPM using Federated Case Management. Pega CPM adds comprehensive multi-channel capabilities including telephony, FAX, chat, social media, & correspondence.

AECP Outbound

AECP Outbound is designed to “listen” through a variety of channels for new safety cases and manage their distribution across affiliates, business partners, and other recipients. A typical environment involves the following elements:

- **Safety System(s)** – one or more “safety systems” (i.e. such as AERS, Argus, ArisG) that are used to record and evaluate safety information. AECP Outbound can be
configured to monitor safety system(s) and gather completed cases through a variety of mechanisms, including: relational database triggers, web services, and file listener (e.g. for XML/E2B files). Multiple safety systems may feed into AECP Outbound, through different channels, to manage distribution of cases centrally.

- **Document Management System/Repository** – A repository or file system may be used as a destination for outgoing submissions/reports. AECP can be configured to deliver submissions to specific folder/repository locations for automated pickup by submissions management systems.

- **Product Master** – AECP includes a global product master. This can be replaced by integration directly to a global product registration system, or populated manually or automatically by product registration data.

- **Authentication & Access Control** – AECP uses standard Pega authentication and access control components and may be integrated with existing infrastructure and systems. In a typical AECP Outbound environment, Pega access and permissions will manage which affiliate users have access to which countries/destinations. Depending on configuration, a single user may have simultaneous access to affiliate workbaskets for multiple destinations. For example, while the system maintains individual workbaskets for each country in Europe, a single user may simultaneously manage outbound cases for UK, France, and Germany.

- **AECP Inbound** – AECP Outbound can receive cases directly from AECP Inbound or cases that originated in AECP inbound that are subsequently transferred to an intermediary safety system.
Chapter 3: Typical AECP Workflows

AECP Inbound

In a basic implementation, case data is entered by a user into screens in AECP. Users logged into the AECP portal or other environment (e.g. CPM, web browser via Internet Application Composer, etc) can enter data for adverse events and product complaints.

Once a case is created, the user will need to enter and/or review and confirm case data. The system steps the user through a number of screens that can vary depending on the nature of the case.

- Some information will be prepopulated, and the system can be configured to let users over-ride this data or to present it as read only
- Some fields may be required, and will be indicated with an asterisk (“*”)
- Common data entry helpers include date lookups, lists of value, or auto complete fields that suggest answers as users type
- Some fields use conditional display logic – for example, if you select that the subject was hospitalized, additional fields will appear requesting more information
- Complaints and Adverse Events can both be captured in the system, and the data capture process adjusts automatically to the nature of the product issue
Users can add metadata notes and tags, as well as drag-and-drop attachments and collaborate with other participants for any case

**Example AECP Inbound Workflow**

1. User selects “Capture Product Issue” from the “New” menu in the AECP portal

2. User enters information about the case, reporter, and subject. Data for these sections can be entered manually, or populated automatically from external data sources. For example, if the system is integrated with email, it can be configured to automatically suggest a reporter by looking up their email address against CRM database, and populating the reporter data automatically.

3. User enters the products involved, and classifies them as Suspect AE (AE), Suspect Concomitant, Product Complaint (PC), or Combination AE/PC

4. For PCs or Combination AE/PCs, the user enters information about the complaint, and selects actions to resolve it (refund, replace, etc)

5. For AEs or Combination AE/PCs, the user enters information about the AE – MedDRA codes (if required), lab results (including additional attachments)

6. For AEs or Combination AE/PCs, the user may specify causality/relatedness for the suspect products

7. For AEs or Combination AE/PCs, the user completes the AE questionnaire with information about seriousness, hospitalization, drug allergies, treatment received, dechallenge/rechallenge, and outcome

8. The case is then optionally routed to one or more reviewer(s) for assessment and feedback

9. The disposition of the case (serious, expected, etc) is recommended by the system, reviewed by the user, and adjusted by the user if necessary

10. The case data is then sent, via XML, E2B, or other structured data format to a safety system (e.g. Oracle Argus) or to AECP Outbound for report generation, affiliate review, and submission

**AECP Outbound**

When running in a typical deployment, a case starts in the safety system or in AECP Inbound. When it reaches “completed” status, AECP is either sent the case data directly, or retrieves it from the safety system directly to create a new Global Case. This Global Case will then be evaluated by AECP Outbound to (a) determine, based on global product registration data, the possible set of destinations for reporting/submissions. AECP then evaluates the Global Case data against business rules that control reporting requirements for each possible destination. For each instance where the Global Case data matches a

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reportable condition, AECP will create a new Local Subcase. Each Local Subcase is a subcase of the Global Case. For each Local Subcase created, the system further determines whether it should be distributed to an “Affiliate”, which are users with direct access to the AECP system or to a “Business Partner”, or user who is only able to receive one-way distributions (email by default). Finally, for each “Affiliate” subcase, the system determines, using business rules, if case is eligible for “Auto Approval”. Auto approved cases can be immediately completed and their reports submitted without any Affiliate user intervention.

Example AECP Outbound Workflow

1. AECP outbound retrieves a “completed” case from a safety database and creates a new Global Case in AECP Outbound.

2. From the incoming data, AECP Outbound finds that the case originated in the US, so it will use “US” as the source country for determining local/foreign reporting criteria.

3. AECP Outbound compares the products in the case to its global product registration information, and finds that the products in the case are marketed in the US, Spain, and Canada.

4. AECP Outbound then evaluates the case data against each possible destination’s reporting criteria to determine if the case parameters make it reportable for each of these destinations.
5. In this evaluation, AECP Outbound finds that the case requires expedited reporting in the US to the FDA as an E2B XML file to be submitted 7 days from the global case clock date. It also determines that this reporting will be handled by an affiliate for this product. And it determines that based on case parameters, this case can also be auto approved, and does not need to be further evaluated by the US affiliate. AECP Outbound then creates a Local Subcase for the US submission, generates the E2B XML file which it attaches to the US subcase, then places the E2B file into the appropriate US submissions management queue. The system set a Service Level Agreement (SLA) for this case of 7 days from the case clock date, but the case is auto-approved, automatically meeting the SLA. This subcase is resolved automatically and is now closed. AECP Outbound then waits for responses (e.g. ACK/MDN) from the submissions management system for this subcase.

6. AECP Outbound evaluates the global case data against the criteria for Spain and determines that it is also reportable to the Spanish Health Authority, which requires a CIOMS PDF form. AECP Outbound creates a second Local Subcase for Spain, generates the CIOMS PDF from the case data, and attaches the completed form to the Spain subcase. AECP Outbound determines that this subcase is not eligible for auto approval (i.e. requires local evaluation and/or local narrative) so it creates a review task and assigns it to the affiliate for Spain (an affiliate user may cover one or more destinations). The Spanish affiliate user receives an email notification of the new task from AECP Outbound and clicks on a link in the email to log into the Pega AECP Outbound portal to review the case. They can also update designated fields (i.e. local narrative) and the system will automatically update their local copy of the CIOMS form prior to approval. Due date for completion of this task is determined by a clock-date and destination-based SLA, and if the Spanish affiliate user does not complete the task as the due date approaches, they will receive additional notifications from the system. When complete, the Spanish local subcase is closed, and the CIOMS submission is automatically placed in the appropriate submissions queue.

7. AECP Outbound also finds that the global case is also reportable in Canada. However the company has an agreement with another manufacturer for safety reporting for their products in Canada. AECP Outbound is aware of this agreement and will process the local subcase for Canada accordingly. AECP Outbound creates a local subcase for Canada, then automatically emails a copy of the case in E2B XML to the designated Canadian business partner and closes the Canada local subcase.

8. When all subcases are completed, and all acknowledgements are received from submissions management, the Global Case is automatically closed as completed. When the global case completes, AECP Outbound then updates the source safety system with the completed status.

9. The entire history of the Outbound case is retained in AECP Outbound. Any global case can be traced through its lifecycle and all local variants of submissions/reports are available for review at a later time.

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Chapter 4: Integrations

AECP Inbound – Creating Cases Automatically via Incoming Channels

A case can be initiated in AECP Inbound automatically through any of the various channels supported by PRPC Connectors and Services. When new cases are created this way, they can be created and assigned to users automatically. These options require additional configuration in Pega outside of AECP. Cases can be automatically created by:

- **Email** - Incoming email with or without attachments – use a Pega email listener to process and parse emails and create new cases with emails/attachments as case attachments. Extend this connector to automatically detect the probable reporter of a case via a known email address and automatically populate reporter data. The view of a FAX image can be shown in-line or within a pop-up-window for review during data capture.

- **FAX/Image** - Incoming FAX/Image – can be used to place image files/PDFs into a file system or content management system location for automated retrieval by a Pega file listener. Additionally, some FAX systems can be configured to transmit incoming FAXs via email which may use the Pega email connector. Finally, if FAX system APIs are available via web services and/or Java, these can also be used to create new cases.

- **EDC/EHR** – If AE data is already being captured in an Electronic Data Capture (EDC) or Electronic Health Record (EHR) system, Pega can receive data from those systems (XML, Web Services, Java APIs, etc) to automatically create cases in AECP. Data obtained from those systems can be used to populate AE case data automatically.

- **CPM/CPMLS** – AECP can be accessed from within Pega Customer Process Manager (CPM), including CPM for Life Sciences using Pega Federated Case Management. Pega CPM can create new cases in AECP, and can pre-populate cases with reporter data and other information from CPM Accounts and Contacts.

See Pega BPM documentation for more information on configuring automated case creation via Pega BPM Connectors and Services.

AECP Outbound - Listening for and Retrieving Incoming Cases

AECP Outbound uses Pega BPM’s Connectors to enable integration with a variety of systems to retrieve and/or receive incoming cases:

- **Web Service** – New cases can automatically be triggered in AECP Outbound by an incoming SOAP message. By default, AECP Outbound accepts E2B XML via this method, but can be configured to accept other formats as well.

- **File Listener** - AECP Outbound includes a file listener connector that creates new cases whenever a file is placed in a designated location. By default, AECP Outbound accepts E2B XML via this method, but can be configured to accept other formats as well.

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Database Listener – AECP Outbound can use Pega BPM’s support for connecting to relational databases. Triggers, polling, or other database mechanisms can be employed to allow AECP Outbound to initiate a case based on status changes or other events.

AECP Inbound - AECP Outbound can be used in conjunction with AECP Inbound to receive cases created there.

See the AECP Outbound Implementation Guide and Pega BPM documentation for information on configuring how AECP Outbound retrieves/receives cases.

**AECP Outbound - Returning Status Updates for Submitted Cases**

AECP Outbound can use a similar set of services to communicate case status back to the safety system that they originated from.

- **Web Service** – Upon successful submission and/or acknowledgement of receipt, AECP Outbound can send a SOAP message back to a safety system, referencing that system’s case ID to indicate submission status.
- **File Listener** – AECP Outbound may also place an XML file in a specified location for consumption by a safety system to indicate updates or status changes to a case.
- **Database** – AECP Outbound can write status and audit information directly back to the relational database tables to indicate a status update or submission.

See the AECP Outbound Implementation Guide and Pega BPM documentation for information on configuring status updates for submitted cases.

**AECP Outbound - Placing Outgoing Submissions in a Submissions Queue**

AECP Outbound will automatically deliver approved submissions to a submissions management system for pickup and delivery. It can additionally be extended to deliver submissions to any other system using any available Pega services.

- **File System** – By default, AECP Outbound includes a basic method of placing outgoing submissions content into a specified folder in a file system for pickup by a submissions management system.
- **Extending to Other Repository Types** – Outgoing submissions additionally can be delivered to additional types of repositories such as a document management system, or be sent directly to other systems using any of the available Pega BPM services.

See the AECP Outbound Implementation Guide and Pega BPM documentation for information on configuring delivery of submissions and reports.
AECP Outbound - Monitoring for Submission
Acknowledgement Files

AECP Outbound can be configured to monitor for response files from external submissions management systems. This can be used to track information returned from a destination (such as a regulatory gateway) that indicates whether a submission was received and if it was able to be successfully parsed.

- AECP Outbound can be configured to monitor submissions management folders for text or XML response files (such as MDN or ACK). It uses the standard Pega BPM file listener service and can be configured to retrieve response files.

See the AECP Outbound Implementation Guide and Pega BPM documentation for information on configuring status updates for submitted cases.

AECP Outbound - Automated Email to Business Partners

AECP Outbound can automatically deliver submissions to business partners via email. Partners will receive emails containing a PDF or XML submission attachment for any cases that involve products that they are linked to in the Product Table and that meet reportability requirements for the specified destination. For example, if the product "Aspirin" is listed in the product table as a US product, and is linked to partner "GlobalPharma". Any safety reports for Aspirin that evaluate as reportable per the US rules will be automatically delivered in the US submission format to GlobalPharma. The email address that will be used by AECP to generate the email to the recipient partner is also found in the product table.

Partner email endpoints in AECP Outbound can be configured by the administrator using the Manage Product Information Tab. See Section 6, "Managing Products" in this document for information on how to configure partner reporting for products.

Other Integrations

- Storing Reports/Submissions in a Repository with CMIS - You can optionally use PegaBPM’s connector for content management systems (CMIS Connector) to optionally store submissions in a separate repository such as EMC Documentum, IBM FileNet, or Microsoft Sharepoint. See the PegaBPM CMIS Connector documentation for more information on how to configure this feature.

- Using Externally Generated Submissions/Reports – Instead of using the Pega BPM PDF eForm and (XML) file services to generate PDF and XML files, the system may be alternatively configured to retrieve pre-generated submissions/reports from an external repository using Pega BPM file services. See the Pega PBM File Service documentation for more information on how to configure this feature.

- Product Registration/Mapping Data – AECP Outbound includes a basic built-in product management component that enables the mapping of products to regions and partners. Products can be classified by Name, ID, Destination, Market Status, Agency, and Partner. Product mappings to locales and partners can be managed either
internally or externally to AECP Outbound. There are three general approaches to bringing product data into AECP Outbound.

- Product information can be directly entered into AECP Outbound (See Chapter 6 for information on how to manage product/locale/partner mappings)
- Product data can be maintained in an external system (such as a global product registration system) and AECP Outbound can be integrated with that system to extract product registration data on a per-transaction basis. (See Pega BPM documentation for information on using PRPC connectors)
- Product data can be maintained in an external system (such as a global product registration system) and then batch-uploaded to PRPC on a periodic basis. (See Pega BPM documentation for information on using PRPC connectors).
Chapter 5: AECP Inbound – Capturing Case Data

Overview – AECP Inbound Workflow

The following section provides a step-by-step overview of the default AECP Inbound data capture process. Since AECP is built on the Pega BPM platform, everything in this section is highly configurable to your implementation. User interface elements can be adjusted, data elements can be added or removed, business rules may be modified, and even the main workflow can be re-ordered to suit the needs of any individual implementation. What follows below uses the basic out-of-the-box configuration.

Note: Different Operator IDs have different access and permissions depending on your installation. See the AECP Implementation guide for specific Operator information for this workflows.

1. Log in to the AECP application as a User (i.e. aecpuser, aecmuser). Once logged in, the first screen visible will be the portal. The default reports and charts visible in the case manager portal can be reconfigured and/or replaced as needed using the PRPC Reporting Wizard.
2. To enter data for a new case, select “Capture Product Issue” from the “New” menu at the top right of the screen. The first screen to appear will be for capturing Case Type and Receipt & Intake Information.

3. In addition to the main data capture screen, a set of collaboration tabs appears to the left side of the screen. These tabs allow the addition of metadata notes, view of Operators associated with this case, attachments, and related cases.

4. The first field to complete is the Case Type field. Here, you specify whether this case is New or a Follow Up. Selecting “Follow Up” will open a pop-up window where you can look up an earlier case to identify as the original. Upon selecting an original case, Subject, Reporter, and Product data will be automatically copied from the original case to the follow up. You cannot create a follow up case without selecting an original.

5. Other fields on this screen include the Date of Receipt (read-only date/time stamp of the current date/time), Date of Intake (date the case was actually submitted/received), Mode of Receipt, Country of Occurrence, and External Case ID. When you have completed the required fields, click “Next” to continue.

6. The next screen that appears is used to select or enter Reporter information.
7. The Reporter screen enables you to either look up a reporter from an existing linked data source (configured in implementation) or to enter data for a new reporter. You can enter multiple reporters for a single case.

8. To search for an existing reporter, click the “Search Reporters” button to open the search window. Begin typing in the fields at the top of the window to narrow your search.
9. To enter data for a new reporter, select the “Add New Reporter” option above the list. This will open a window that will enable you to enter reporter data. Select Add/Update Reporter to continue.

10. You must have at least one Reporter associated with the report to continue. Select “Next” to continue.
11. The next screen is used to select a subject. Subject information can be added in one of three ways, it can be looked up from an external data source (similar to Reporter lookup – must be configured in implementation), entered manually, or copied from the reporter.

12. Use the Search Subjects button to open a new window that will allow you to search for Subjects (similar to Reporters). Use the Add New Subject button to open a new window that will allow you to enter data for a new Subject. Check the “Is Reporter Subject” box to indicate the Reporter as the Subject, then select the “Add as Subject” button to review the Reporter data.
13. Since Reporter does not generally include some required Subject data, some additional data must usually be added before a Reporter can be added as a subject. Upon clicking the Add as Subject button, a new window will appear. Confirm existing Reporter information, and add any additional required information (required fields have an asterisk next to them).

14. Regardless of the method used to add the Subject, once added, select “Next” to advance to Product selection. The Product selection screen lets you add one or more products.
15. Add products from a linked data source by selecting Search Products (similar to Reporter & Subject lookup – must be configured in implementation). You can add blank rows to the list of products (for products not found in the system) by selecting “Add Item” at the top of the list.

16. Enter additional information about each product, including Dose, Unit, and Frequency. Products can be identified as “AE Suspect”, “AE Concomitant”, or “Complaint” using the checkboxes to the right of each item. A product can be listed as either AE Suspect or AE Concomitant, but not both. Both AE Suspects and AE Concomitant products can also be identified as Complaint.
17. Once products have been added and classified, select “Next” to continue. From this point in the process, the next screen will vary depending on how you classify the products. If the classification includes any Complaints (with or without AEs), then the Complaint screens will appear next. If the classification does not include any complaints (only AEs), then the process will move directly to the AE screens.

18. If the product classification includes complaints, the Complaint Products screen will appear.

19. Provide information about the complaint next to each product in the list. Select “Next” to continue to the Complaint questionnaire.
20. Questionnaires are used separately in both Complaints and AE data entry. They are easily defined, modified, and managed using the PegaSurvey component. You can add or modify questions and question logic using the PegaSurvey configuration pages. See PegaSurvey documentation for more information on configuring questionnaires.

21. Complete the complaint questionnaire and click “Next” to continue. If you select to refund or replace the products, the next screen will be the Replacement Details and Address Confirmation screen. Provide or confirm the information and select “Next” to continue.
22. The next screen is for capturing Adverse Event information.

23. Enter each Adverse Event on its own line, providing start/end dates (no end date if ongoing). Provide AE descriptive information in the text box to the right, or select the magnifying glass icon in the AE MedDRA Term box to lookup/search for a MedDRA term.
24. Use the MedDRA Term utility to browse or search for terms. Use the tree view under MedDRA Hierarchy to browse and select one or more terms, or the MedDRA Search to lookup words and terms. Check the box for one or more terms, then use the "Add to List" button to build a list of terms at the top of the window. When you have selected all applicable terms, select “OK” to make the selections and return to the main screen. The MedDRA terms you selected will be entered on lines in the AE section.

25. Add Lab Attachment information in the Lab Results section. You can add attachments of lab documents or images to the attachments section in the tabs to the right. Select “Next” to continue.
26. The next screen is a Product Relatedness Matrix. Here you can identify relatedness of products to the adverse events for different parties. You may add multiple rows per product for any number of parties based on assessments of relatedness. Select “Next” to continue.
27. The Adverse Event questionnaire is similar to the Product Complaint questionnaire, but is used to gather detailed information about Adverse Events. As you respond to the questions, additional questions may appear requesting more information. Questionnaires are easily defined, modified, and managed using the PegaSurvey component. You can add or modify questions and question logic using the PegaSurvey configuration pages. See PegaSurvey documentation for more information on configuring questionnaires. When all required questions are answered, select "Next" to continue.

28. The next screen provides a system-generated assessment of the AE case based on information gathered throughout the data capture process. The logic used to set these parameters is configurable, and by default, the user can adjust the outcomes. However, the system can be configured to make these parameters read-only if needed.
29. Once the user reviews and adjusts the case parameters, clicking “Next” will send it for review by a Specialist. The specialist can review the case and request adjustments if needed. This review, like all steps in the process is configurable. The system may be configured to route the case to multiple reviewers, or to bypass any review and send the case as-is for reporting and distribution. To view the Specialist review step, you need to log out of the system and log back in as an AE Specialist Operator (i.e. aespecialist).
30. When logged in as the AE Specialist, the review task appears as a Subcase – or child object to the main case. From within the Subcase, you can always review the entire parent case, including all data and attachments. Selecting the Subcase task will open the next screen.

31. From here, the reviewer sees the current case assessment, and can review any additional case data. They then have the option of Approving (default action) or Rejecting the case status.

32. The case is then returned to the originating AE User. Log back in as a User (i.e. aecpuser, aecmuser) to complete the case review.
33. You can see the Completed status of the Specialist review on the case view as well as on the Waiting for Reviewers task. When all reviews are complete (in the default configuration there is only one), select “Submit” to continue. This will complete the AECP Inbound process and initiate any additional actions (configuration is required to define additional actions).

34. Additional actions that may be configured typically include either:

   a. Sending the case data directly to a safety system such as Oracle Argus
   b. Or, sending the case to AECP Outbound for report generation, distribution, review, and submission to regulatory authorities

35. If your implementation is configured for both AECP Inbound and AECP Outbound, the user can continue to advance the case, and may review any reports/submissions that have been routed to them by the system.
For example, in the image above, the AECP Inbound system has been configured to directly continue the process from Inbound to Outbound, and on completing the review step, the Operator sees the local report generated by AECP Outbound.
Chapter 6: AECP Outbound - Standard Reports/Submissions

XML Reports

AECP Outbound can generate XML files for submissions or to be sent to business partners. By default, AECP Outbound generates E2B XML files. This base E2B template may be modified and extended as needed, and modifications can be configured for specific regional variants that are linked to individual locales. For more information on configuring and modifying XML reports, see Pega BPM documentation for information on PRPC services.

PDF eForms & Reports

AECP Outbound can generate PDF forms and reports. It includes a standard FDA 3500A (MedWatch) PDF template, as well as a CIOMS PDF. Additional PDF forms and variations of these basic forms may be added using the Pega PDF eForm Accelerator. The PDF eForm Accelerator is part of the Pega Life Sciences Foundation and is included with AECP. It provides a tool for mapping data elements in Pega BPM & AECP Outbound to PDF eForm templates. See the documentation for the Pega Life Sciences Foundation for more information on adding and editing PDF eForm templates.

A PDF MedWatch Form

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Chapter 7: AECP Outbound - Administrator Functions

AECP Outbound includes a default Administrator role (safetyadmin@pegasystems.com) that can view all cases in the system, as well as create new destinations and products. Users & workbaskets for destinations can be added by the Safety Admin from within the Safety Admin portal.

The Safety Administrator has visibility into all cases, tasks, and reports in the system. The Safety Admin can also create and update destinations and products.

Logging in as the Safety Admin

When logging in as the Safety Admin, you begin in the dashboard tab. The dashboard displays all of the system workbaskets & workgroups in the left column. You can view the current cases in any workbasket by selecting it in the left column. Recently resolved work is found in the right column, and recent cases can be viewed by selecting the link in parenthesis. The center section contains standard reports, which can be replaced by other existing or new reports as needed. Other functionality can be accessed using the Navigation Tabs at the top-left of the screen.
Use the Navigation tabs to access other system functionality.

**Dashboard** – This is the first screen presented to the Safety Admin at login. It shows the current overall system activity and lets the Safety Admin access workbaskets and view recent work.

**Case View** – Select this tab for a tree-view for all cases. Cases can be sorted by creation date, urgency, deadline, and status. Selecting the “+” symbol in front of each case icon will expand the case to view subcases and attachments.

**Calendar View** – View and open cases based on task deadlines.

**Reports** - View and create standard and custom productivity and analysis reports for the system. Regulatory submissions are not managed through this tab, they are managed under Manage Reporting Rules.

**Manage Reporting Rules** – View, update, and create reporting rules and destination workbaskets for the system.

**Manage Product Information** – View, update and create products and partner mappings.

**Cases** – These tabs become visible when you open a case in the Safety Admin portal. Selecting these tabs will display information about the global case and its affiliate/partner subcases and processes. You can open multiple cases simultaneously. Select the red “X” in any case tab to close it.

### Managing Destinations

A “destination” is any regulator, partner or other organization that may receive a submission or report as from AECP Outbound. Each Destination contains a user, a workbasket, and a set of reporting rules. The reporting rules set the parameters that will select which Adverse Events will be sent to this destination. By default, AECP outbound provides a mapping of destinations at the country level. Additional destinations can be added through configuration. Destinations are managed under the Manage Reporting Rules tab. Select this tab to view, update, or create destinations.
The Select Destination control lets you choose to view just the information for a particular destination. Select a destination from the list and select “Search” to view that destination.

- Select “View All” to view all destinations in the system.
- Select “View Checked Out” to display any rules that are locked for editing in the system.

When displaying a list of destinations, the information is displayed in columns:

- **Destination** – The name of the destination. May be a country, regulator, or other entity.
- **Operator ID** – The primary user associated with that destination. By default, the relationship between Operators and Workbaskets is 1:1, but any Operator can be given access to any number of Workbaskets. For example, the Operator for Germany can be given additional access to the Workbaskets for Austria and Switzerland. This is configured in the user’s profile or can be managed in the list under the Operator’s ID at the top left of the screen.
- **Workbasket** – The primary Workbasket associated with that destination. A Workbasket is a group queue that local cases will be routed to for this destination. All users with access to this workbasket will see any cases that appear here and will be notified per their individual profile settings.
- **Reporting Rules** – The content of this column may vary by destination. Each destination may have from one to three reporting rules. There are three possible types of rules.
  - **Local Reportability** – Local reportability applies when the adverse event originates in this destination (typically a country/regulatory agency). Click on the LocalReportability rule label to open for review/modification.
  - **Foreign Reportability** – Foreign reportability applies when the adverse event does not originate in this destination, but the product (by name or ID) is relevant/available in this destination. Click on the ForeignReportability rule label to open for review/modification.

<table>
<thead>
<tr>
<th>Destination</th>
<th>Operator ID</th>
<th>Workbasket</th>
<th>Reporting Rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td><a href="mailto:Argentinaadmin@rogersystems.com">Argentinaadmin@rogersystems.com</a></td>
<td>Argentina</td>
<td>AutoApprove for Argentina, Foreign Reportability for Argentina, LocalReportability for Argentina</td>
</tr>
</tbody>
</table>
• Auto Approve – The Auto Approve rule will allow the system to bypass a user review step for any cases meeting its criteria. The case will still be created for this destination but will automatically resolve and be sent to the next step (i.e. submissions system). Auto Approvals will still result in an audit trail being recorded. Click on the AutoApproval rule label to open for review/modification.

_createRules_ – If any of the above Reporting Rules that do not exist for this Destination, you can create them by clicking here.

**Creating a New Destination**

1. Select “Create New” in the information bar to create a new Destination. Creating a new Destination will create a new Operator, Workbasket, and Local Reporting Rule. You can also create new Foreign Reporting and Auto Approval Rules by selecting them at this time.

   ![Create Reporting Rules](image)

   **Note:** If you chose not to create Foreign and Auto Approval rules now, you may also return and create them later using the Create Rules feature.

2. When the new rules are created, click the “Refresh” button and use the Manage Reporting Rules search features to view them. Open any decision rule by clicking it’s link in the list. Decision rules will open in a pop-up window.
Editing Reportability Rules

These decision rules manage the flow of cases to each destination. They operate like any standard Pega Decision Table. You can add conditions to the existing rows and columns, and can add new columns and rows as needed to reflect different case properties and conditions. For more information on configuring and modifying Decision Tables, see Pega BPM documentation on Decision Rules.

Each row in a decision table has a result or Action that will be set when that row evaluates to true. Select the Results tab in a decision rule to view the results parameters. By default, for AECP Outbound, those Actions are used to set:

- **Report Deadline** – Sets the number of days from the case clock date in which this report/submission will be due. This will be reflected in the SLA for each destination’s subcase.
- **Report Name** – Sets the report that will be generated for this subcase. AECP Outbound includes MedWatch PDF, CIOMS PDF, and E2B XML
- **Report Scope** – Reflects whether the report is Local or Foreign
- **Report Type** – Reflects the type of report Expedited, Periodic, Alert, or other options
- **Other Options** – These 4 parameters are provided as base functionality for the system. Any other actions or parameters can be added to results as needed. Results can be standardized (e.g. “10-Day Expedited CIOMS Report), and may also be extended and configured (e.g. 2-Day Emergency Alert Report for Boston Hospital IRB for Premarket Drugs)
While basic Decision tables are created by default, you can use any other features of Pega Decision Tables to configure your reporting rules as needed for any destination. For example, when local labeledness information is available in coded/structured form, you can add columns to assess local labeledness to determine if an upgrade/downgrade needs to occur and if necessary, result in an auto approval of cases.

Decision rules for destinations can also be delegated within the system. Delegation means enabling the local user to configure their own decision rules. For example, when reportability rules for the United Kingdom are delegated, then both the Safety Administrator and the United Kingdom user will have access to modify those rules. Rule modification is still subject to check-in/check-out and all other audit and permissions features, but it allows for the local management of reportability rules if desired.

**Managing Product Mappings**

In addition to reportability rules that determine the criteria for reporting to each destination, the Safety Administrator or delegated user can map different products to different destinations using the Manage Product Information tab.
From within the Manage Product Information tab, select the Search button to display product mappings in the system. The list will display 10 products per screen. If more than 10 products are returned, you can page through them using the navigation tools at the lower right of the Product List. You can also enter filter/search criteria in one or more of the fields at the top of the screen to reduce the number of products returned by the search.

- **Destination Name** – By default, this is a list of countries. It can be configured to display other destination types if required. Select/enter a destination here to return only those products listed as available/relevant to that destination.

- **Product Name** – Filter the list to a specific product name. By default this is a plain-text field, but can be configured as a lookup from valid product names.

- **Partner Name** – Filter the list to those managed by a specific partner. By default, qualifying AE reports for this product and region combination will be automatically emailed to this email address in the region-specific format. Other methods of delivery may be configured if required. A subcase will still be created for partner cases, but will be automatically emailed and resolved.

- **Agency Name** – Can be used to filter by specific agencies. Does not necessarily need to be a top-level government agency. For example, products can be listed as FDA-CDER or FDA-CBER to differentiate product types.

- **Market Status** – Used to filter products by market status – e.g. premarket, marketed-prescription, marketed-OTC.

The products returned by a search are displayed in a list. The columns display the following information:

- **Product ID** – Unique or destination ID of the product

- **Product Name** – Global or destination name of the product

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Destination Name – Name of associated destination
Market Status – Current market status in destination
Partner Email – If not blank, the email address of the partner who will receive this case via email if it evaluates to reportable for this destination
Agency Name – Name of agency or other recipient for this destination
Deprecate – Check here to retain the product information in the system, but not process cases for this item

By default, product fields in the list are editable. Select a field in a row to edit the values for that row.

New product rows may be added by selecting at the bottom left of the list.

**External Product Data**

Product information can be managed exclusively in AECP outbound, however, for organizations with large product catalogs or existing global product registration data, it may be advisable to populate or integrate the information in this list with an external system. Options include direct integration to product registration data, where the data is accessed by AECP Outbound in real-time, or if performance is negatively impacted, providing a batch upload of product master data into this system. The information displayed here may be altered to reflect external product data models, with corresponding AECP properties being populated by that data to enable assessment by AECP’s business rules.

**Adjusting the Clock Date**

Adjusting the clock date will reset one or more SLAs for a case. Adjusting the Clock date may be performed manually to reflect new case information in the case. Clock date adjustments can also be configured to happen automatically based on other events if required. Clock date adjustments are performed with the “Modify SLA” command. There are two types of “Modify SLA” that can be performed.

- **Modify Parent Case SLA** – By default, only the Safety Administrator can modify the SLA for the entire (top-level) case, which will result in all subcases being re-evaluated and each of their SLAs reset.
- **Modify Subcase SLA** – An Affiliate can modify SLA(s) for their subcase(s) only. This does not impact the parent case, only the subcases in their workbasket(s). The Safety Administrator can also modify individual subcase SLAs.
- Modifying an SLA is an auditable event that will result in an audit trail entry.
Modifying a Parent Case SLA

To modify a Parent Case SLA:

1. Open the case in the Safety Admin portal, and under “Actions”, select “Modify SLA”.

2. Updating an SLA requires a new start date and a reason for the change. The reason will be recorded along with the user ID to the audit trail for this case. Select “Update SubCases” to confirm that all subcases under this parent case will have their SLAs updated as well.

3. Click “Submit” to update the SLA. This will update the SLA for the parent case and all subcases. Modifying an SLA is an auditable event that will result in an audit trail entry.
Modifying a Subcase SLA

To modify a SubCase SLA:

1. Open a case in the Safety Admin portal and select the subcase with the SLA you want to modify to open this subcase.

2. While viewing the subcase, under “Actions”, select “Modify SLA”.

3. Click “Submit” to update the SLA.
This will update the SLA for the subcase. Modifying an SLA is an auditable event that will result in an audit trail entry.

**Alerts, Events, Reports and Additional Safety Administrator Tasks**

The default tasks for Safety Administrator users are described above. However, there are many additional configuration options that are beyond the scope of this guide. See Pega BPM documentation for more information on configuring alerts, event monitoring, reporting, dashboards, and many other Pega BPM features and capabilities.
Chapter 8: AECP Outbound - Affiliate User Functions

Affiliate users are internal users who manage one or more destinations. By default, Affiliate Users are mapped to countries, however, an Affiliate User are any internal user (has access to AECP Outbound via the web browser) who manage any reporting destination. An Affiliate User can be:

- A single user for a single destination – In this case, there is a single workbasket and a single user, with one set of products and one set of decision rules.
  - Example, a user managing safety submission for only the US, with a single destination for all FDA submissions.
- A single user managing multiple destinations – In this case, each destination has a workbasket, but one of the affiliate users is provided access to multiple workbaskets. Access to multiple workbaskets is managed with standard Pega BPM administrative controls. For example, a
  - Example, a user managing safety submissions for the US, Canada, and Mexico
  - Example, a user managing safety submissions for the US, but splitting the US/FDA into multiple destinations for Drugs, Devices, Biologics, and Vaccines
  - Example, a user managing safety submissions to multiple IRBs, with each IRB having its own destination
  - Example, a user performing automated reviews of certain cases, monitoring all destinations for a certain subset of products

Each of these can be configured within AECP Outbound using destinations, product mapping, and decision rules.
Logging in as an Affiliate

An affiliate logs in with the user ID and password. By default, the system will generate affiliate user IDs with the format (countryname)admin@pegasystems.com, with a default password of “rules”.

An affiliate can perform the following tasks:

- Review Case Data & Attachments
- Approve/Reject Local Cases
- Local Narrative Updates
- Adjusting the Clock Date
- Extending Local Operator Tasks
- Configuring an Affiliate to View Multiple Workbaskets

Review Local Case Report/Submission

Affiliate users are assigned review tasks for cases that meet their local reportability and product mapping requirements. Each task includes attachments for review. To review attachments, from the affiliate user portal, double-click a task in the "My Work" tab to view it.
The case view displays information about the subcase to enable the affiliate reviewer to evaluate it for approval/rejection.

- **Task to Complete** – This section displays the task that the user is being requested to complete, along with any other information that may be required. Clicking “Submit” in this section will execute the action in left of the title bar – in this case “Approve” the subcase. The user can select other available actions from the “Other Actions” menu, then click “Submit” to execute those instead.

- **Attachments** – Items here are the reports/submissions that will be submitted to a regulator or other destination. The user should open and review these prior to approving or rejecting the case. Attachments will typically open in a new window, an application such as a PDF Reader. Depending on browser security settings, you may need to provide additional input/acknowledgements to allow attachments to open.

- **Link to Parent Case Data** – These hyperlinks allow the user to navigate up the case tree to the parent case, where they can review the full case information for this task. This can be useful for E2B/XML submissions, which may not be easily viewable for review. The user can navigate up to the parent case, review the information, then return to the task and approve or reject it.
**Approve/Reject Local Cases**

Affiliate users can approve or reject local cases. The Approve/Reject options may be modified to reflect different status options (e.g. “Upgrade”, “Downgrade”) by configuring AECP Outbound.

To approve a case, click “Submit”. To reject or perform another action, select other available actions from the “Other Actions” menu, then click “Submit” to execute those instead.

Example – the Affiliate user for Spain receives a task to review a CIOMS PDF submission. The user can navigate to the parent case to review the case data and/or open the attached CIOMS PDF. Upon reviewing this information, the user can approve and submit it or reject it to close the subcase for Spain.

**Local Narrative Updates**

The Affiliate user can be requested to make updates to data in their local report/submission. By default, the system provides an example using the “Local Narrative” field. If the user adds information to the field before approving/submitting this local case, the attachment will be updated with this data. By default, the system will not delete the information in the existing field, but will append the new information to this. This functionality is configurable in AECP Outbound.

Example – the Affiliate user for Spain receives a task to review a CIOMS PDF submission. The user can navigate to the parent case to review the case data and/or open the attached CIOMS PDF. Upon reviewing this information, the user decides that they need to provide a Spanish language narrative in the PDF that they submit to the Spanish health authority. The user enters this information in the Local Narrative field in the task, then selects “Submit” to update the PDF with the translated narrative and approve and submit the subcase for Spain.

**Adjusting the Clock Date**

See “Modifying an SLA in the Safety Administrator section of this document. By default, affiliate users can only modify SLAs for subcases that they have been assigned.

**Alerts and Additional Affiliate User Tasks**

The default tasks for Affiliate users are review, approve/reject, modify SLA, and update local narrative. There are many additional configuration options that are beyond the scope of this guide. See Pega BPM documentation for more information on configuring alerts, event monitoring, reporting, dashboards, and many other Pega BPM features and capabilities.
Chapter 9: AECP Outbound - Distributing Submissions to External Parties

In addition to managing distribution and review of submissions and reports for affiliate users, AECP Outbound supports automatic distribution of submissions/reports to external users via email. This feature enables the management of affiliate and external/partner distributions from within the same case. This capability is driven by partner mappings in the product information tab.

When the system evaluates reportability for a case, if it qualifies a case as reportable to a destination that includes a partner email, it will create a subcase, but instead of routing it to an affiliate for that region, it will generate the appropriate report/submission along with an email message (created using a configurable template) and automatically sends the email to the partner email address associated with that product.

Since any product for any region can have its own partner contact, this can support any scenario from a single partner managing a single product for a single country, all the way to complex multi-region/multi-product agreements. Full auditability is always provided, as each case retains the partner distribution record, so even if partner mappings change over time with new agreements, each case will still retain its historical distribution information.

The default template for outbound email can be found in the Pega Developer Portal here: PegaLS-AECPFW-Work -> Process -> Correspondence -> AECPReport

![Image of AECP Outbound interface](image)

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The default template can be configured or replaced, and can be specialized to automatically deliver different email content to different partners as required.