

Oracle® Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus Safety

Release Notes

Release 1.0.2

E50819-01

December 2013

Overview

The Oracle® Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus Safety (Adverse Event: InForm and Argus Safety integration) enables you to bring clinical safety events entered in InForm directly to the Argus Safety system, eliminating data reentry and potential missing information while improving the timeliness of this critical task.

The InForm to Argus Integration uses the Oracle Application Integration Architecture (AIA) which replaces traditional enterprise application integration with flexible, pre-built, standards-based business process integration solutions.

As an AIA offering, the Adverse Event: InForm and Argus Safety integration pack includes all the necessary business process models, canonical objects, and Web services you need ready-to-use. Now you can quickly transfer adverse event information from InForm trials to product safety organizations with reduced cost and risk. Additionally, the AIA adaptable framework enables you to extend the integration to accommodate your specific business needs.

Key Features

The Adverse Event: InForm and Argus Safety integration pack focuses on the following key areas:

- Automate the entry of InForm (Electronic Data Capture) captured Serious Adverse Event (SAE) and related information into Argus Safety
- Reduce or eliminate reconciliation needs between EDC and Safety with both new and follow-up data being delivered to Argus Safety
- Accommodate the normal variance in trials form designs
 - Each InForm trial can have a different set of data sent to Argus Safety
 - Actions to trigger SAE delivery to Argus Safety may vary
 - Data changes that force a follow-up refresh to Argus Safety are set up by trial
- Includes related Adverse Events, Medications, and other data automatically
 - Include related information via configurable date ranges
 - Let safety analyst make final determination of related events
- Automatically deliver and update SAE data to Argus Safety

- New reportable event can be transmitted automatically or based on user action
- Any changes to design-specified significant items will send a data update
- Time-based exports provide InForm safety event follow-up data
- Deliver Argus Safety case numbers and status back to InForm
- Maintain openness for optional integrations with additional EDC and Safety solutions
- Deliver a ready-to-use solution that keeps current with newer releases of InForm and Argus Safety

Software Requirements

For information on the Adverse Event: InForm and Argus Safety integration software requirements, see *Oracle® Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus Safety Installation Guide*.

Hardware Requirements

AIA Middle-tier with AIA Database as Part of an Existing Database

Oracle recommends you to use OEL or UNIX operating system (x86-64 platform) for the middle-tier.

AIA Middle-tier

- Minimum RAM: 12 GB
- Minimum CPU cores: 2
- Speed: 2.4 GHz

AIA Middle-tier and AIA Database in the Same Server

Oracle recommends you to use OEL or UNIX operating system (x86-64 platform) for the server.

AIA Middle-tier

- Minimum RAM: 20 GB
- Minimum CPU cores: 4
- Speed: 2.4 GHz

AIA Middle-tier and AIA Database as Separate Servers

Oracle recommends you to use OEL or UNIX operating system (x86-64 platform) for both middle-tiers and database server.

AIA Middle-tier

- Minimum RAM: 12 GB

- Minimum CPU cores: 2
- Speed: 2.4 GHz

AIA Database

- Minimum RAM: 10 to 12 GB
- Minimum CPU cores: 4
- Speed: 2.4 GHz

Minimum RAM of 10 to 12 GB is required to support the MEMORY_MAX_TARGET value set to 5 to 6 GB. The integration related calls are not database intensive. Oracle recommends four cores for troublefree startup, recovery, and adequate processing of background processes.

Workflow and Components of the InForm to Argus Integration Pack

Figure 1 illustrates the data flow of the InForm to Argus Safety Integration.

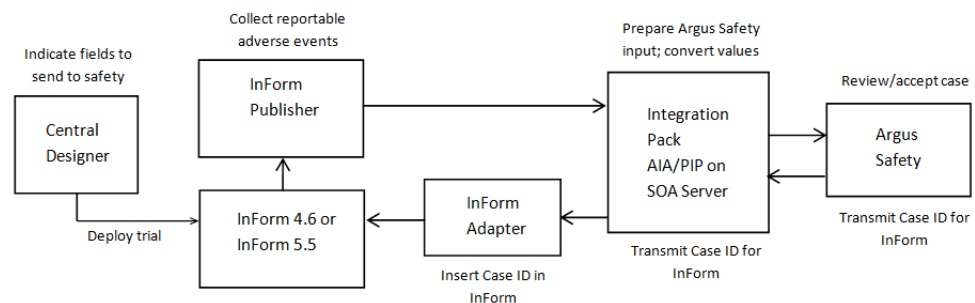
Adverse Event: InForm and Argus Safety integration includes a number of components that provide the data needed by Argus Safety to report on new serious or significant adverse events.

- When a subject in a trial experiences a reportable adverse event recorded in InForm, the event will become part of a Case in Argus Safety. If subject treatment data is updated in InForm, the data updates the case in Argus Safety. Case IDs can be returned to InForm from Argus for tracking adverse events in InForm to cases in Argus Safety.
- HSGBU product components currently in use include Central Designer, InForm, Argus Safety, and optionally InForm Adapter.
- New components for this integration include InForm Publisher, and the InForm to Argus Safety Integration Pack (AIA/PIP on Oracle's Service Oriented Architecture (SOA) Suite).

InForm to Argus Safety Workflow

Figure 1 illustrates the components involved in preparing InForm safety input for Argus Safety and returning the Argus Safety status and case ID back to InForm.

Figure 1 InForm to Argus Safety



InForm to Argus Safety Integration Product Components

Process Integration Pack

- The InForm to Argus Integration is made available through an Integration Pack - also known as the Process Integration Pack or PIP.
- The PIP uses the Oracle AIA.
 - AIA is an existing Oracle Fusion Middleware based platform for data format and value translations among applications.
 - A PIP is developed to implement the transitions between formats for participating applications being fed through the integrations
 - A PIP integration contains a packaged group of Oracle products under the AIA umbrella. This group of products is called the SOA suite. These products are included under a restricted-use license.

InForm Publisher

InForm Publisher resides on InForm servers and collects safety data automatically from InForm. The InForm Publisher license is included with InForm licenses, as is InForm Adapter.

InForm Adapter

InForm Adapter provides connectivity to update the status results returned from Argus Safety, including Case ID, into the safety event form in InForm.

Solution Requirements and Constraints

Technology Stack

See Chapter 5, *Software Requirements*, in *Oracle® Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus Safety Installation Guide 1.0.2*.

Requirements for Integration with InForm Trials

- InForm trials must be on supported versions of InForm.
 - The integration supports only the trials built using Central Designer on InForm 4.6.
- Only trials not yet providing data to Argus Safety should be used with the Integration to assure that follow-up activity of older cases are not missed.
- InForm trials must be designed with Central Designer and contain integration design elements including integration mappings.

Requirements for Integration with Argus Safety

- Argus Safety must be on supported versions
- Argus Safety must be updated with Argus integration components shipped with the integration
- The Argus Interchange module is required for the E2B import

Limitations

- Vaccine trials are not currently supported with the Argus Safety E2B interface and are therefore not supported for this integration.

Related Documents

The following documentation is available for this integration:

- *Oracle® Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus Safety Release Notes 1.0.2* [this document]
- *Oracle® Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus Safety Installation Guide 1.0.2*
- *Oracle® Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus Safety Implementation Guide 1.0.2*
- *Oracle® Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus Safety Security Guide 1.0.2*

Documentation Accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at

<http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

Oracle® Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus Safety Release Notes, Release 1.0.2
E50819-01

Copyright © 2013, Oracle and/or its affiliates. All rights reserved.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, the following notice is applicable:

U.S. GOVERNMENT RIGHTS Programs, software, databases, and related documentation and technical data delivered to U.S. Government customers are "commercial computer software" or "commercial technical data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, duplication, disclosure, modification, and adaptation shall be subject to the restrictions and license terms set forth in the applicable Government contract, and, to the extent applicable by the terms of the Government contract, the additional rights set forth in FAR 52.227-19, Commercial Computer Software License (December 2007). Oracle America, Inc., 500 Oracle Parkway, Redwood City, CA 94065.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe

use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Xeon are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Opteron, the AMD logo, and the AMD Opteron logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information on content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services.