Tasks for study designers in Oracle Life Sciences Central Designer

1. Create the Adverse Event forms	2. Create other forms send to Oracle Argus Safety	s to 3. Create a Safe	ety Case 4. Add Or integratic	racle Argus Safety on-specific rules	5. Map Oracle InForm data items to Oracle Argus entities	6. Generate the Annotated Study Book
Tasks for users in Oracle	e Clinical One Digital G	ateway				
7. Set up SFTP server and resources	8. Create an SFTP credential key	9. Create an integration group	10. Create the test integration	11. Test the integration	12. Create a production	13. Monitor an integration

Tasks for sponsor administrators in Oracle Life Sciences InForm Publisher and Oracle Life Sciences Argus Safety

14. Configure the Oracle Argus Safety-only parameters	15. Configure the Axway/Oracle B2B

Tasks for users in Oracle Central Designer, Oracle Life Sciences InForm, and Oracle Argus Safety

16. Deploy the study to Oracle InForm	17. Complete the applicable safety forms	18. Verify that each case comes in	19. Accept or reject cases sent to Oracle Argus

Tasks for study designers in Oracle Central Designer

1 Create one or more Adverse Event forms

When do I do this? At any time during study design, as long as the Safety and Data Management teams have agreed on what data should be sent from Oracle InForm to Oracle Argus.

Why should I do this? To collect adverse event data, which will be sent to Oracle Argus Safety.

You can design the study so that all the adverse event information is on a single Adverse Event form. Or, you can create multiple Adverse Event forms if you have different versions of the form; for example, for pregnancy or other types of adverse events.

- **1.** Create an Adverse Event form.
- 2. Mark the form as Repeating. An Adverse Event form cannot be a common form.
- 3. Add adverse event items as needed, including the following required items:
 - > A date/ time item to capture the onset date of the adverse event.
 - > A Yes/ No item that triggers rules to initiate transmission of the adverse event data.
 - Serious (the item will be reported). The question might be: Was this a Serious Adverse Event?
 - **Reportable** (the item is not serious but should still be reported). The question might be: Should this event be reported?

Design La	ayout Rules Rule Te	1. 1.0.0.0.0	
Days Descention		amplates Data Series Summa	ary General Codi 4
Item Properties	Codelist• Columns	Reorder Sections Delete	Keys Fixed Table
FranAE		Rep	sating 🗖 Common 🛛 🍕
Type	Title	RefName	Question
Date Time Item	Onset Date	Onset	When did this event sta
* Yes No Item	Serious	SeriousTrigger	Was this a Serious adv
* <select type=""></select>			
•			
	FranAE Type Date Time Item * Yes No Item * cselect type>	FrancéE Type Trife Date Time Item Orset Date Yes No Item Serious Credect type>	Fran-LE Die Perlor Type Title Perlor Date Time Item Ornet Date Ornet Yes No Item Serious Serious Trigger elect type (

2 Create other forms to send to Oracle Argus Safety

When do I do this? After you have created the Adverse Event form.

Why should I do this? This is how you send historical or clinical data to Oracle Argus as part of a case (for example, medical history, concomitant medications, lab test results).

- 1. Create one or more forms with data to send to Oracle Argus Safety.
- **2.** For each form either mark the form as repeating, or leave the form as a flat form and create one or more repeating sections on it. Do not mark the form as Common.
- 3. In the form or section(s), add items that capture data related to the adverse event.
 - > If you are using fixed repeating sections, you must assign codelists to the fixed items so that the site user can answer them.

When the site user submits these forms, Oracle InForm Publisher collects the adverse events and sends them to Oracle Argus Safety according to rules you define on the form, or using before and after onset dates configured in Oracle InForm Publisher.

Back • 🕸 • 🎓 • 🍘 • 🕼 • 🙀 💈	🔸 🖸 🙆 🕻	View Targets: InF	form	•		
et Explorer 🗸 🕈	Form : CO	NCOMITANT MED	ICATIONS - en-	JS	a	
Find 🚏 Filters 🕈 💣 Options 🕈	Design	Layout Rules	Rule Templates	Data Series Summary	General Codi 4	
ements and Events	Item Proper	ies Codelist* Col	umns Reorder Se	ctions Delete Ke	ys Fixed Table	
AEHiddenJ	CONCOMIT	ANT MEDICATIONS		Repeating	🗖 Common 🛛 🐥	-
SSOCIATED FORM_1	Type	Title	Reff	lame	Question	
H N ASSUCIATED FORM_2	Integer Ite	m Seg Number	CMS	iegNo	Sequence number	1
H SIF	Text Item	Drug Name	Druc	Name	Drug name	
⊞ III SIF1	Text Item	Drug name (Drug) Drug	Name 1	Drug name (JDrug)	
🗉 🛅 FranAE	Text Item	Modified repo	orted term Mod	ifiedreportedterm	Modified reported term	
Baseline	Text Item	Unit dose	Unit	dose	Unit dose	
Core Week 1	Text Item	Units	Unit		Units	
	Text Item	Frequency	Free	uency ConMed	Frequency	-
E S DOSING RECORD	Text Item	Route	Rout		Route	
1 SERUM CHEMISTRY	Integer Ite	m Reason for m	edication Rea	sonformedication	Reason for medication	
🗉 戅 DOSEVS	Text Item	Reason One	Rea	sonΩne		
E 💆 DOSEVS2	Text Item	Reason Othe	c Rea	sonΩther	Other specify	
E DOSEVS3	Text Item	Started Prior	to Study Star	tedPriortoStudy	Started prior to study	
GRIDCheckBoxControls	Date Tim	Item Started Prior	No Star	tedPriorNo	Started Prior No	
E SIFU1	Text Item	Onocioa?	Opg	oina	Ongoing2chroHrMin	
I TranConMeds	Date Tim	Item Ongoing? No	Ong	oingNo	No. specify End Date	
Core Week 100	Text Item	Indication	lodig	ation	Indication	
C	Text Item	Drug Code	Dour	Code	Drug Code	
🍫 🔜 🖼 🔚 🔚 🖕 🔶	* Text Item	Trade Name	Trac	leName	Trade Name	
	i ext item	i rade ivame	Irac	envanne	Trade Name	-

3 Create a Safety Case form

When do I do this? After you have created the Adverse Event form and other relevant forms to send to Oracle Argus Safety.

When do I need a Safety Case form? If you want Oracle InForm site users to be able to group multiple adverse events that relate to a single Oracle Argus case and report them together, you must include a Safety Case form. If each Adverse Event form becomes an Oracle Argus case, or you have configured Oracle InForm Publisher to send adverse events automatically based on their date of occurrence, you don't need a Safety Case form. The site user selects the items to send on the Safety Case form.

- **1.** Create a Safety Case form.
- **2.** Mark the form as Repeating.
- **3.** Create a non-repeating section and add items that relate to the Oracle Argus case as a whole. You might include an item that triggers the case to be sent to Oracle Argus when the user submits the form by adding a question such as "Is this item ready to be sent to Oracle Argus?"
- **4.** Create a repeating Adverse Event section in which the site user will identify the specific adverse events that they want to group together and submit as a single Oracle Argus case. When you create the Adverse Event section on the Safety Case form, create a dynamic grid that groups the adverse events by selecting the Dynamic Grid checkbox. Add the adverse event items to the Dynamic Grid by clicking the Dynamic Grid button at the top of the workspace and moving the items you want to include from the Available items for source list to the Selected items list.
- **5.** Create repeating sections for other relevant information (Concomitant Medications, Medical History, Labs, etc.) that should be grouped together and submitted as a single Oracle Argus case. Create a dynamic grid that groups the other items.

Back • 🕸 • 😭 • 🕼 • 🕼 • 🧏 😓	۶ 🖢	🕽 🚷 🗹 Vie	w Targets: InForm	-	
ect Explorer 🗸 👻 🛪	Fe	orm : SIF en-	US		đ
Find 🌱 Filters 🕶 🕜 Options 🕶		Design Lay	out Rules Rule Templat	es Data Series Summary	General Codi 4 🕨
ements and Events		em Properties	Codelist* Columns Reor	er Sections Delete K	VST Fixed Table
	S	F		Repeating	🗆 Common 🕹 📥
🗄 📷 FranAE		Type	Title	RefName	Question
H Saseline	*	<select type=""></select>			
E DATE OF VISIT	1) m				
H VITAL SIGNS					
1 DOSING RECORD		-			
E 🛃 SERUM CHEMISTRY	A I	E_Section	I✓ Repea	ting 📋 Fixed 🗹 Dynar	nic Grid 🦴 🔟 📫
E DOSEVS		Туре	Title	RefName	Question
DOSEVS2	1 1	Integer Item	Sequence Number	AESegNo	Sequence Number
DUSEVS3 GRIDCheckBoxControls	ΙÉ	Text Item	Event Diagnosis	EventDiagnosis	Event Diagnosis or Si
E SIFU		Text Item	Event Diagnosis (MedDRA,	EventDiagnosisJ	Event Diagnosis or S
		Text Item	Modified term	Modifiedterm	Modified term
H 🛐 SIFU1		Text Item	MedDRA	MedDRA	MedDRA synonym
E SIFU1		Text Item	Failed coding	Failedcoding	Failed coding
SIFU1 FranConMeds Core Week 100					Start data and time
H SIFU1 FranConMeds Core Week 100 Core Week 120 Core Week 120 Core Week 120 Core Week 120		Date Time Item	Start date and time	Startdateandtime	JULI DOLO DI DUI TO VESS
H SIFU1 FranConMeds Core Week 100 Core Week 120 Core Week 124 DAY 1 Core Week 124 DAY 3		Date Time Item	Start date and time Outcome	Startdateandtime Outcome	Outcome br>hr:min
		Date Time Item Integer Item Date Time Item	Start date and time Outcome Outcome Resolved	Startdateandtime Outcome OutcomeResolved	Outcome br>hr:min Recovered/Resolved.
		Date Time Item Integer Item Date Time Item Date Time Item	Start date and time Outcome Outcome Resolved Outcome Sequelae	Startdateandtime Outcome OutcomeResolved OutcomeSeguelae	Outcome Coutcome Recovered/Resolved
H ≤ SIFUT H ≤ FranConMeds H ≤ FranConMeds H ≤ Crore Week 100 H ≤ Crore Week 120 H ≤ Crore Week 120 DAY 1 H ≤ Crore Week 130 DAY 1		Date Time Item Integer Item Date Time Item Date Time Item Date Time Item	Start date and time Outcome Outcome Resolved Outcome Sequelae Outcome Death	Startdateandtime Outcome OutcomeResolved OutcomeSequelae OutcomeDeath	Outcome br>hr:min Recovered/Resolved Recovered/Resolved Fatal, record date and

4 Add Oracle Argus Safety integration-specific rules

When do I do this? After the forms are complete.

Why should I do this? So that safety data can be sent from Oracle InForm to Oracle Argus.

- **1.** Select the Adverse Event or Safety Case form, open the **Rules** tab, and create a new rule.
- 2. On the Preconditions tab, for Evaluate on Event, choose Form Submission.
- **3.** On the **Expression** tab, enter the rule itself which specifies when to send the adverse event data to the Oracle InForm Publisher queue.
- **4.** On the **Actions** tab, specify when to execute the rule. Either specify a value that must be True, or choose Always.

Rules for the Adverse Event form:

- > (Required) One of the following rules:
 - Send the safety event, marked as Reportable or Serious on the Adverse Event form, to Oracle Argus Safety only when the Oracle InForm site user responds Yes to the "Ready to Send?" question.
 Note: If you have both an Adverse Event form and a Safety Case form, the rule you choose goes on the Safety Case form.
 - Send the safety event, marked as Reportable or Serious, immediately upon form submission without asking the Oracle InForm site user.
- (Recommended if you are using a Safety Case form) Alert the Safety group or study team via email that there is a serious or reportable adverse event before the Oracle InForm site user completes the Safety Case form.

Rules for the Safety Case form:

If no adverse events are on the form, issue a query to alert the Oracle InForm site user to add an adverse event to the form or delete the entire form if the case is not needed anymore.

Rules for other forms containing adverse event items:

> If there are two places where date of death or autopsy could be reported, check to make sure they are the same and, if not, create a query.

Note: For all other item-level rules that issue a query (for example, a check on onset date), you should reference the form and section as well as the item in the rule in the rule expression. For example, if you reference the full path on the onset date item on the Adverse Event form in a query rule, the query only fires on the Adverse Event form. If only the shared item is referenced, the query opens on both the Adverse Event form and Safety Case form, as the data is the same.

and hyperona.	×	and a second	And the second se			
	Form :	ADVERSE EVE	NTS - en-US			Ξ.
Find 🌱 Filters 🕈 💇 Options 🕶	De	sign Layout F	tules Rule Templa	tes Data Series	Summary Gener	al Codi 4 🕨
lements and Events	New Ru	le Edit Check	Syntax Cut Con	v Paste Delete	Hide Errors Enab	le Disable
🥥 Elements	-	en contin encor	Syntax Cor Cop	, ruste i belete	Inde Errors Errors	
E Study Start Week	Show	v Child Rules				
StudyEXI		Parent	RefName	Description	When	Expression
Events	► <i>n</i>	ADVERSE EVE	rulDateTimeCom	End time must n.	Form Submission	GetDateDiffer
E AE/CM	-		rulDateTimeCom	Stop Date canno	Form Submission	_GetDateDiffer
IREATMENT			rulDateTimeCom	End time must n.	Form Submission	_GetDateDiffer
E CONCOMITANT MEDICATIONS			rul AEClearCod.	Clear J codes on	Form Submission	(this EventDiag
H ASSOCIATED FORM 1			rul AEClearCod	Clear E codes on	Form Submission	(this.EventDiag
H ASSOCIATED FORM 2	· · · · ·					
E DOSEVS3						
🗉 🗊 SIF						
🗄 🛐 SIF1						
E To FranAE						
H Baseline						
Core Week I	Rule Su	mmary (click link to	modify):			
E VITAL SIGNS	and state	- Free C. berterten				
H S DOSING RECORD	evaluate	on rom Submission				<u> </u>
1 SERUM CHEMISTRY	value =	GetDateDifference				
E 🗑 DOSEVS	this Start	dateandtime.Value,this	s.OutcomeDeath.Value	Constants.DateTime	Parts.Seconds) >= 0	
		un in false				_
			and the second second second second	and the second	and the second second second second	

5 Map Oracle InForm data items to Oracle Argus entities

When do I do this? After you have created the forms.

Do I have to do this? Yes, Oracle InForm and Oracle Argus Safety use the data mapping feature of Oracle Central Designer to configure how safety event data items on Oracle InForm forms correspond to safety event entities in Oracle Argus Safety.

- **1.** Download SafetyLogicalSchemaLibrary.csml from My Oracle Support (Doc ID 2301999.1). The file is an attachment in the bottom left corner of the Oracle Central Designer Release Notes page.
- **2.** Import the file into your Oracle Central Designer study.
- **3.** Start with the Adverse Event form.
 - a. Add all items and forms to be sent to Oracle Argus to the Safety_Config data set. On the Data Series Summary tab, select SafetyLogicalSchema from the Mapping drop-down and Safety_Config from the Data Set drop-down. For each item, click the arrow at the right end of the data series cell and select Always to add this mapping on every form, study, and the library, or Form, to only map the item when it appears in this section on the form.
 - **b.** Change to the **Safety_Significant** data set and create mappings for those items you want Oracle InForm Publisher to monitor for changes and send a follow-up transmission to Oracle Argus when changes occur.
- 4. Perform the same two steps for the Safety Case form and any other forms with adverse event items on them.

All data mapped in Safety_Config will be sent to Oracle Argus when an update is triggered.

	Section 1				
ujeci Explorei	Ne	w Study : CDD	en-US		
🖻 Find 🜱 Filters 🕈 🕜 Options 🔹	2	New 🍞 📕	Columns Categ	orize Properties Lock and Protect	
oata Mappings		Title	RefName	Description	
Rule Mappings	-	CDDMagoringe	CDDMannings	beschpiten	
InForm Mappings		Safetyl opicalS	Safetyl opicalS		
		Surety Logiculos	Surety Logiculos	•••]	
III 🧇 CDDMappings					
SafetyLogicalSchema					
E Safety_Config					
E Safety_Significant					
🗷 🐲 MedicalDevice					
E Subject_ConMed					
H Subject_Labiest					
E Subject_AdverseEvent					
B Subject					
E Safabi Cara					
E Subject MedicalHistory					
E Subject PastDrugHistory					
E Subject Death					
E Subject CauseOfDeath					
E 🐢 Subject Autopsy					
E MedicalDevice_Evaluation					
E 🐢 Subject_SuspectDrug_Reacti					
🗉 🧆 Subject_SuspectDrug_Reacti	-1				
m - Madainhaite Basebasta	-				



6 Generate the Annotated Study Book and provide it to the integration manager

When do I do this? After the study design is complete.

Why should I do this? So that the integration manager knows what needs to be configured in Oracle Clinical One Digital Gateway.

- **1.** Create an Annotated Study Book, and then print the book to a PDF file.
- 2. Provide the Annotated Study Book to the integration manager.

Read step-by-step instructions.

	Annotated Stud	ly Book for <mark>S</mark> tud	y Design:	: Stud	yDesi	ign		
		Study Design Vers	sion: 1.0					
		Study Desig	jn					
	Gen	erated by Central August 22, 2018 :	Designer ¹ L0:40AM	ГМ				
Ti	Gen ime and Events Schedule Fo Element	erated by Central August 22, 2018 r Study Design: Stud	Designer ¹ L0:40AM dyDesign Syst	ſM	Study	StartW	/eek	Stu
Ti	Gen me and Events Schedule Fo Element Assessment	erated by Central August 22, 2018 : r Study Design: Stud CRF	Designer 1 L0:40AM dyDesign Screen (Screen) [S]	tem Enroll (Enroll) [S]	Studys Base (Base) [S]	StartW Wk 1 (Wk 1) [U]	Veek Wk 2 (Wk 2) [U]	Stu 4 (W 4) [5]
Ti	Gen me and Events Schedule Fo Element Assessment Visit Start Hours	erated by Central August 22, 2018 : r Study Design: Stud CRF	Designer ¹ L0:40AM dyDesign Syst Screen (Screen) [S] [S]	tem Enroll (Enroll) [S] 0	Study: Base (Base) [S]	StartW Wk 1 (Wk 1) [U]	Veek Wk 2 (Wk 2) [U] 2	Stu 4 (W 4) [S] 674

Tasks for users in Oracle Clinical One Digital Gateway

Prepare the SFTP account and resources

Who does this? An integration manager.

When can I start working in Oracle Clinical One Digital Gateway? Once you do the following tasks, you are good to go:

- 1. Contact an Oracle Argus administrator and request an account for the Oracle HSGBU hosted customer SFTP server. You need this account to create a credential key.
- 2. Log in to the server with your SFTP account, create the necessary folders to store the E2B+R2 files for Oracle Argus Safety, and note the path to each folder from the server home. You can create one folder for the test integration, and one for the production integration, but you don't have to.
- **3.** Contact an Oracle Argus administrator to get the Oracle Argus StudyID (which is case sensitive), the trade name of the products from the Oracle Argus product, and the license configuration in Oracle Argus.
- 4. Contact an Oracle Central Designer study designer and request the Annotated Study Book for the study you are integrating. You need it to get the study name and to map codelist values from Oracle InForm to the expected values in Oracle Argus Safety as part of setting up the integration.

8 Create an SFTP credential key

Who does this? An integration manager.

Why should I do this? SFTP credential keys are required to run a safe and proper integration between Oracle InForm and Oracle Argus Safety.

When do l do this? After you request the account on the SFTP server, set the folder where Oracle Clinical One Digital Gateway places the E2B+R2 files, get the Annotated Study Book, and have a list of all Oracle InForm fields that contain partial dates.

1. On the Home page, go to **Settings** and click **Create Credentials** to create your credential key for the SFTP server.

Read step-by-step instructions.

9 Create an integration group for the study

Who does this? An integration manager.

Why should I do this? For every Oracle InForm study that you integrate, you typically have at least two integrations: a test integration and a production integration. You can also have other integrations set up for the same study, such as an Oracle Clinical One Platform to Oracle InForm integration. Integration groups are a way to keep these integrations grouped together by study so that you can easily find and manage them.

When do I do this? After you create your SFTP credential key.

1. Click the **Create Integration Group** button to create an integration group for the Oracle InForm study.

Tip: We recommend that you include the Oracle InForm study name in the integration group name to help identify integrations for monitoring.

Digital Gate	way				John Mathews 🔻 💣 Home
Create Credentials) Insfer Protocol (SFTP)		InForm - Orac	le Health Sciences	
Credential Key User Name Password	InFormToArgusSafety jmathews	/8	Credential Key User Name Password	InFormStudy jmathews	×1



0 Create and enable the test integration

Who does this? An integration manager.

Why should I do this? You cannot test using a production integration, so you should create a separate integration for testing purposes.

When do I do this? After you create the credential key and an integration group in the UI.

- 1. On the Home page, download the template for the **Oracle InForm to Oracle Argus** integration.
- 2. Open the integration template in any editor, update it, and save it.
- **3.** Find the integration group that you created, and upload the file.
- 4. Enable the test integration by clicking the **toggle button •** next to it.

Tip: If you want to add multiple integrations in one integration group, you need to upload a separate integration file for each integration.

Read step-by-step instructions on how to create the configuration file for a test integration.

11 Test the integration

Who does this? An integration manager.

Why should I do this? To make sure the integration sends data as expected.

When do I do this? After you've uploaded the integration file and enabled the test integration file.

- 1. Work with SaaS Services to make sure that the test integration is running as expected.
- **2.** When you are satisfied with the results, proceed to create the production integration based on the test integration.

Digital Gateway							😭 Home	Setting
	aansiaden 🐧 🎙 🔺	1998 - 1997 A.	10000	1 24 1912	10. YO	100	VASCANCESCON 🛝 🦷	100
			Last Modif	ied Date (UTC)			
			From	- mit -	То	t	Search Integration Name	0
Create Integration Group	Manage Integrations 🔻	Download Inte	egration Temp	late 💌				
- 6		+ Add Integr	ation Template	55				
Default Study	Group	Clinical On	e to/from Clin	ical Supply	>			~
IE-Study586		Clinical On	e to/from CTN	1S	>			~
		O Clinical On	e to EDC		>			
IFtoAS435		() InForm to a	Argus		Itm			~
		Data Intake	e to Clinical Or	ne -	, C			

2 Create and enable the product integration

Who does this? An integration manager.

Why should I do this? So you can start sending safety case data from Oracle InForm to Oracle Argus Safety.

When do I do this? After you've monitored your testing integration and are satisfied with the results, and after the connection to the Oracle Argus Interchange has been set up.

Tip: Reuse the test integration file that you carefully updated to create the production integration.

- **1.** On the Home page, click the down arrow for the integration group you created for the study.
- 2. Select the checkbox to the left of the test integration that you want to use as the base for this integration.
- 3. Along the top, click Manage Integrations, and click Edit Settings.
- 4. Download the test integration file, and save it locally under a representative name.
- 5. Open the file, and edit the SFTPRoot value and Oracle Argus study ID.
- 6. Go back to Oracle Clinical One Digital Gateway and look for the integration group that you created.
- 7. Expand it, and upload this file for your production integration.
- **8.** Enable the integration.

Read step-by-step instructions on how to create a production integration.

		Last Modif	ied Date (UTC)			
		From	iii - To		Search Integration Name	C
Create Integration Group	Manage Integrations 🔻	Download Integr	ation Template 🔻			
0	Disable					
Default Study	Rename					~
IF-Study586	Edit Settings					~
	Enable					
IFtoAS435	Delete					^
Upload Integration File	Run Immediate					



Who does this? An integration manager or an integration viewer.

Why should I do this? There are several use cases for integration failures and you should be aware of them. Unmapped data in the integration file can be one of the most common cases. Keep an eye on your integrations and jobs to make sure that everything is running smoothly.

When do I do this? After you upload your integration file in the right integration group and you enable the integration.

1. To check the status of a job or a safety report (after the integration is enabled), click the integration.

Read step-by-step instructions on how to monitor, troubleshoot an existing integration.

Integration Hub								💏 Home	O Setting
			Last Modi	ified	Date (UTC)			
Create Integration Group	Manage Integrations v	Download Integration Template v	From		±	To	曲	Search Integration Name.	
IFStudy-586				~	Succee	ded	20-	Aug-2018 12:00AM	^
Upload Integration File									
IF586-test				~	Succee	ded	20-	Aug-2018 12:00AM	>
IF586-live		Śm							>
IFStudy-345				×	62 Faile	d	17-	Aug-2018 12:10AM	~
IFStudy-246				×	32 Faile	d	16-	Aug-2018 10:45AM	~
IFStudy-976				×	2 Failed	í.	13-	Aug-2018 02:30PM	~



Configure the Oracle Argus Safety-only parameters in Oracle InForm Publisher

When do I do this? After completing all previous tasks in this document.

Why should I do this? To set up how Oracle InForm Publisher moves the adverse event data from Oracle InForm to Oracle Argus Safety.

- 1. Install Oracle InForm Publisher on the Oracle InForm application server, as described in the Oracle InForm Publisher Installation Guide.
- 2. Identify the Oracle Argus Safety-related attributes that apply to the study.

Tips:

- > To configure time frames to trigger Oracle InForm Publisher to send safety data automatically, specify the number of days before and after the onset date of the adverse event (**AE Range Starting Offset (days)** and **AE Range Ending Offset (days)**) that Oracle InForm Publisher should use to include all Adverse Event forms started during the range or to include other forms associated with an adverse event.
- If you are allowing the Oracle InForm site user to choose which AEs are relevant for sending to Oracle Argus Safety, instead of using time frames, you need to set AE Range Starting Offset and AE Range Ending Offset values to -1.
- > If the Oracle InForm site user can select relevant concomitant medications, set ConMed Range Starting Offset and Ending Offset to -1.
- > If the Oracle InForm site user can select relevant labs, set Lab Range Starting Offset and Ending Offset to -1.
- **3.** When you submit a ticket to Oracle Services to set up the integration with Oracle Argus Safety, communicate which attributes to include and their values. Oracle creates the subscriber and populate its settings, and then adds the trial to the subscriber.

15 Set up the connection to Oracle Argus Interchange for Oracle Argus Safety

Who does this? A sponsor administrator.

When do I do this? After you receive your SFTP credentials and before you enable the integration in Oracle Clinical One Digital Gateway.

Why do I do this? So you can get safety cases from SFTP to Oracle Argus Interchange.

- If your organization hosts Oracle Argus Safety, configure Axway or Oracle B2B so that files are pulled from the SFTP site into Oracle Argus Interchange.
- If Oracle hosts Oracle Argus Safety, you don't need to do anything. Oracle B2B will be configured for you in your cloud environment so that files are pulled from the SFTP server into Oracle Argus Interchange.

Tasks for users in Oracle Central Designer, Oracle Life Sciences InForm, and Oracle Life Sciences Argus Safety

16 In Oracle Central Designer, deploy the study to Oracle InForm

Who does this? An Oracle Central Designer study designer.

When do I do this? At any time after the study design is complete and the study has been provisioned.

1. Validate the study to create a deployment package, and then initiate deployment. During deployment, the study design moves directly from Oracle Central Designer to Oracle InForm.



17) In Oracle InForm, complete the applicable safety forms

Who does this? An Oracle InForm site user.

When do I do this? As you meet with subjects.

- 1. Enter each adverse event for a subject on a separate Adverse Event form.
- 2. If the study was built with a Safety Case form:
 - **a.** Select the other instances of the Adverse Event form to send to Oracle Argus. For example, if the subject has had five adverse events and you think three should be part of the case, select the three adverse events in the dynamic grid by clicking the plus sign icon on the right.
 - **b.** Do the same for the other forms, such as Medical History, Concomitant Medications, Labs. For example, if there are 15 concomitant medications entered, but only 1, 4, 7, and 13 apply to the case, select the four medications in the dynamic grid by clicking the plus sign icon on the right.
- **3.** After you have entered the required information and are ready to send the case to Oracle Argus, respond Yes to the Send to Safety question if it is present.

Read step-by-step instructions.



Who does this? A sponsor system administrator.

When do I do this? After the Oracle Clinical One Digital Gateway production integration has been enabled and the connection from SFTP to Oracle Argus Interchange has been made.

1. Follow your regular case workflow in Oracle Argus Safety. If you receive an email that a case is coming and it doesn't arrive when you expect it, contact your system administrator.

A: inf620 - Case	e Re	port Forms - 8	352/GQQ		S	ubject: < 🛛	852/GQQ	• > 😪		3	
🗞 🥵 🚳	9	b 🖻 🛛	1 船	7			¢9				4
Iome Enroll Subjects	Que	ries Monitor Signal	tures Review	Reports	Archives	Documents	Admin			Melissa Ly	nch
Sase Wk 1 Wk	2 Wk	4 Wk 8 Final AE/CM	1 Unsch								•
Visit: >	Labo	oratory Evaluation	Mar/12/201	8 10:01							
ase 💌	1.*	Date of Sample								Q	-
Forms:	Cher	nistry Results									
DOV	2.*	Sodium									
SI DEM	3.*	Potassium									
MHx	4.*	Chloride									
PE	5.*	BUN								2	
VS	6.*	Bilirubin, Total									
HAMD	7.*	AST								2	
LAB	8.*	ALT									
RAND PM	9.*	Alkaline Phosphatase (ALP)									
DOSEVS	10.*	Creatinine								3	
	11.	Were any of the results clinically significant?	C Yes C	No						Q. 🥖	
	Hem	atology Results									
	12.*	Red Blood Count (RBC)									
	13.*	Hemoglobin									
	14.*	Hematocrit									
	15.*	Platelet Count									
	16.*	Total Leukocyte Count (WBC)									Ŧ
	Rev	iew [Select Action]	Apply					Submit & Nex	t Submit	Return)

ORACLE		Argus Sakty							Welco	me jeparton, Thursd	ay, August 23, 2010 (C\$705)
Active Cases	Worklist	Case Actions	Reports	Local Affiliate	USINGES	Deshboerds	Argus Console				
Reports > Processed	E20 Reports		Compliance		*						
PROCESSED E	2B REPOR	TS	Periodic Reports	8							
Search Criteria			Bulk Reporting								
Trading Partner			E28 Pending Processed E28		uct Name				Import Sizius	Report Type	
Cracie								Select	Successful	✓ AI	
					Sate Range		From		To	Range	
					Interchange Proces	sed Date	 15-JAN-2017 		01-AUG-2017	Custom Date P	iango 🗸 🗸
Pending Proce	ssod										
Total Number of Ros											1-100 🗸 P
Originated Case # Initial / F.U / Nullifice	itice	Tracking World W	Partner 📥 Vide Unique #		Import Status - We Case # Imported J	arnings / Errors Ls		Accepted Notes	/ Rejected By	liste Dab	rchange Data a Imported / Rejected
ARTH/5001G Inital		EMA ARTHS	0210		Success / Warning	6		A tommy apruaratu	availated by avagoing receives temper in sol	20-1	EB-2017 17:30 EB-2017 19:04
SUH5 Initial		EMA US-OR	CLE-SUH 54		Success / Warning 2017US01598			A Steven He	alpen	05-	UN-2017 00:29 UN-2017 00:31
5500Arth04		EMA	-		Success / Warning			A tormy		034	44R-2017 20:34

ORACLE Argus Safety					We	icome joyce.demi a	in@oracle.com, Thu	rsday, August	23, 2018 (OASPD605)	Home Help	Logi
Active Cases Worklist Case Actions	Reports L	ocal Affiliate	Utilises	Dashboards	Args	is Console					
tilities > Logs > View Error Log			Change Passwor	rd						💌 💽 🖬	
RROR LOG			MedDRA Browse	м							
Search Conditions			Logs	View Audit Lo	p						
Inte Range From Castorn Date Range ©1.JNN-2000	To 01-JAN-2999	Search	ICSR Reconciliation Case Undefete	LAM Audit Lo View Error Lo	3						
			End Of Study				Displaying Rows	1-40 🗸	Page Size 100	×	22
rgus User Name OS User Name En	ror Date 🤝	Application	Clear Cache				Error Text				
e russelligoracle.com Administrator 27	-JUL-2017 16:17:21	Argusvr2.eea	Advanced Condit	tion Library		OUPMMSDVM246	Argus Salwty.COM	- Oracle error	1 occurred ORA-00904	COR. DURATION	
e russeliĝoracle.com Administrator 27	-JUL-2017 16:17:20	Argustr2.000	MMSDVM	12493380 V	ORKOR	OUPMMSDVM246	Argus Salety.COM	- Oracle error	1 occurred ORA-00904	COR. DURATION	1
e russelligoracle.com Administrator 27	-JUL-2017 15:43:29	Argusvr2.exe	MMSDVM	£249080 V	ORKOR	OUPMMSDVM246	Argus Salaty.COM	- Oracle error	1 occurred ORA-00934	group function is no	4
e russelligorack.com Administrator 27	-JUL-2017 13:10:00	Argusw2.com	MMSDVM	£248080 V	ORKOR	OUPMMSDVM246	Argus Salvity.COM	- Oracle error -	1 occurred ORA-00904	COR. DURATION	1
e russeliĝoracie.com Administrator 27	JUL-2017 13:09:58	Argusvr2.exe	MMSDVM	1249080 V	ORKOR	OUPMMSDVM246	Argus Salety.COM	Oracle error	1 occurred ORA-00904	COR". DURATION	4
e russelliĝoracie.com Administrator 27	-JUL-2017 12:57:46	Argusw2.eee	MMSDVM	1249080 V	ORKOR	OUPMMSDVM246	Argus Salaty.COM	- Oracle error -	1 occurred ORA-00934	group function is no	
e russeliĝoracle.com Administrator 26	JUL-2017 13:13:02	Argusvr2.exe	MMSDVM	1249080 V	ORKOR	OUP/MMSDVM246	Argus Salety.COM	Oracle error	1 occurred ORA-00934	group function is no	H

19 In Oracle Argus Safety, accept or reject cases

Who does this? An end user.

When do I do this? After the Oracle Clinical One Digital Gateway production integration has been enabled and the connection from SFTP to Oracle Argus Interchange has been made:

- **1.** For all incoming cases, perform a duplicate search.
- **2.** If you find an existing case, accept the case as a follow-up to an existing case. A new case number isn't created.

If you don't find an existing case, accept the new case. A new case number is generated, and the case is available for further processing according to your business process.

You can also reject a case. You can view all rejected cases in the incoming reports list.



Market Barrier (1999) Market International Control (1999) Market International Con	V Balance
Independent (marging) Independent (marging) Construint Construint Construint Marging Marging <th>V Research</th>	V Research
System	Page State 100 V Internet D
Instrument Instrument Part	Page 500 00 V and and Fit Mates Status 10.1 Default 10.1
Ammeri Control Control (b.m.d)	Page State 100 V Federate D
Nather J. Nature J. Description Description <thdescription< th=""> <thdescription< th=""> <th< th=""><th>Page Stat 100 V Concerning State</th></th<></thdescription<></thdescription<>	Page Stat 100 V Concerning State
Control of the state	Page Stat 100 V
Image: section of the marked section of th	Shaty 10 / Deberg 10
Fig. Source Statute Avea Avea Mail Mail Avea Avea Avea Mail Avea Avea Avea Avea Mail Avea Avea Avea Avea Mail Constraints Avea Avea Avea Mail Avea Avea Avea Avea	Reporter Type Reporter
CA State (State) State (State) ADDRCLM-100 mp.GA Rain 1 NUM State (State) NUMO STATES ADDRCLM-100 mp.GA Rain 2 NUM State (State) State (State) ADDRCLM-100 mp.GA Rain 3 NUMO STATES ADDRCLM-100 mp.GA Num Num Num VM CH STATES (NUMMARK) UNITS STATES ADDRCLM-100 mp.GA Num Num	Consumer
10U010340 View Entry / Warning Messages United States	Nutto
TCA Darlinki Sweth 2019 150 Outro: 509 AICDOLLI-1000 mpUSA Ref 3 Ilitica Percel: 201 Darlinki Sweth 2019 151 LMTIG 51/158 (A AICDOLLI-1000 mpUSA Ref 3 Ilitica Darlinki Sweth 2019 151 LMTIG 51/158 (A AICDOLLI-1000 mpUSA Ref 10 Darlinki Sweth 2019 1511 LMMIR AICDOLLI-1000 mpUSA Ref	Nutio
FSA SJJJJJ2019 1636 Memory 2014 No TEL://INSI/ E020H00 Mode 4 Millio	CLHINDROK2102 / 2001008 Physician Istocimilian Peech

Find out more about these Oracle Life Sciences products											
Get more information Browse all Oracle Life Sciences documentation on the Oracle Help Center.	Other resources Watch an overview video for this integration.	Contact Support For contact information, go to Life Sciences Cloud Support and:	Can't find what you need? Write to us at clinical_one_doc_feedback_us_grp@oracle.com.								

© Oracle About Oracle Contact Us Products A-Z Terms of Use & Privacy Cookie Preferences Ad Choices