



REVAPA – Reliable Validation Package Argus

Approach

Validation according to GCP and to CFR 21 part 11 requires a proper software development life cycle. In general the following terms correspond:

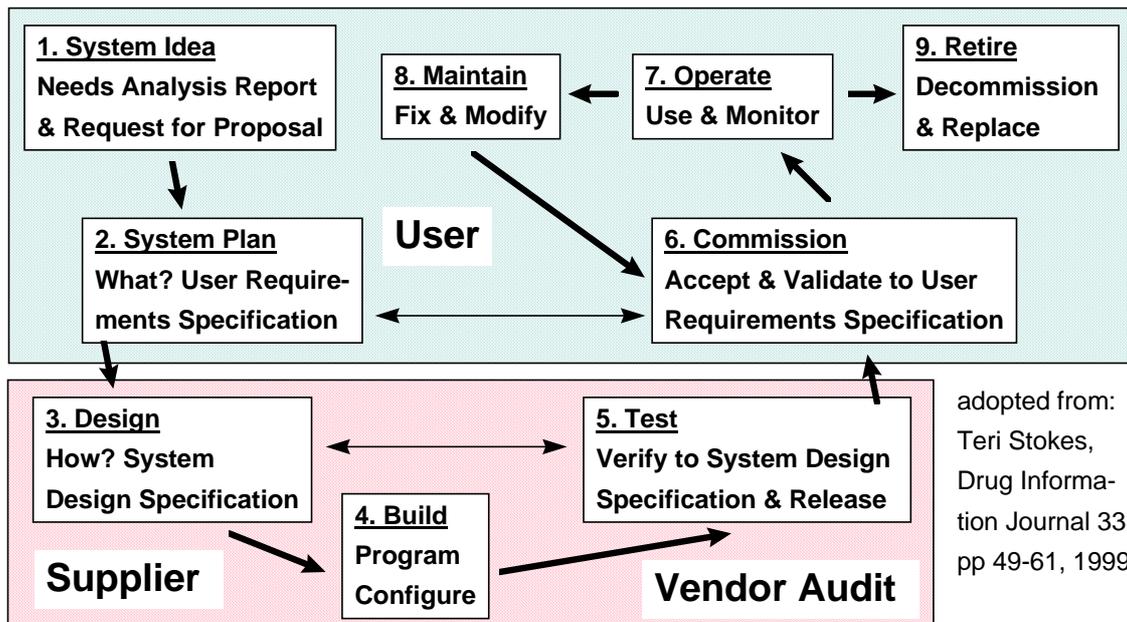
User Acceptance Test	Performance Qualification
System Test	Operational Qualification

RELICO assumes that the client will use a software development life cycle as in the schema below. RELICO has templates available to support the following tasks:

2.	system plan	user requirements/user manual templates
6.	commission	user acceptance test script templates

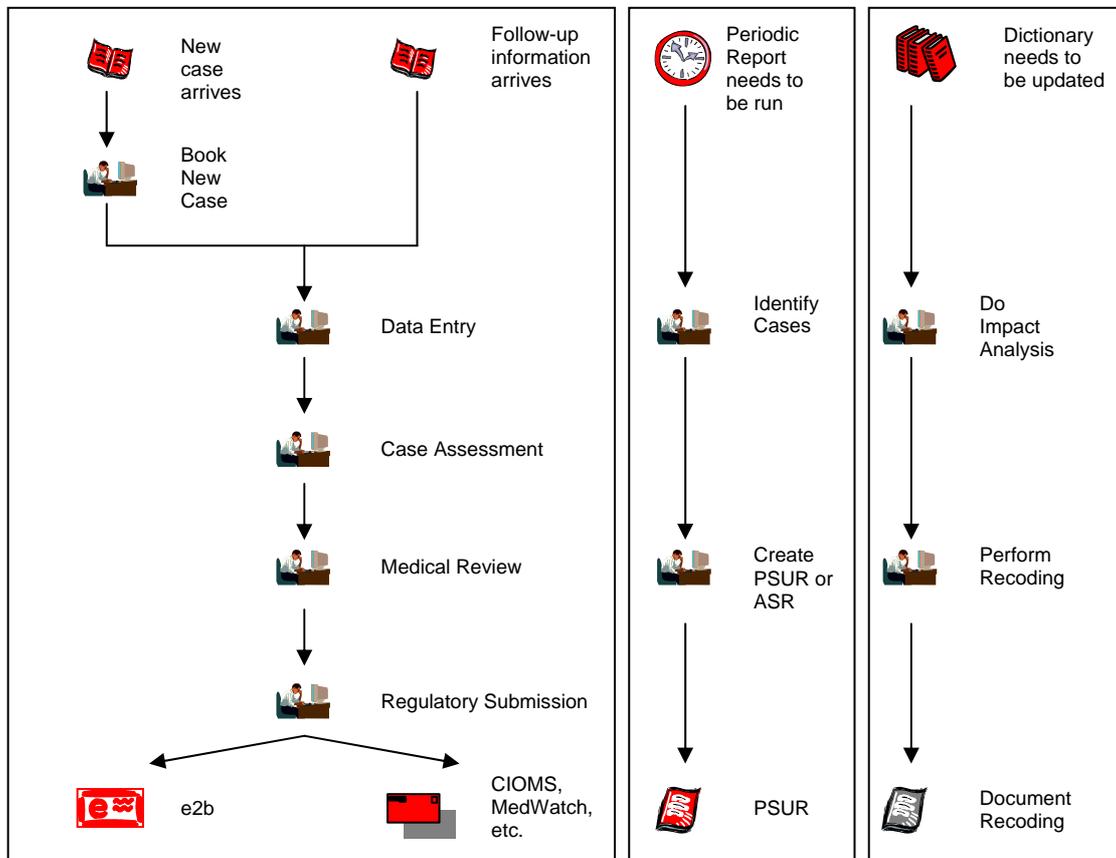
RELICO can either deliver the templates for a fixed price or can support the whole validation process on the user side on a time and materials basis.

Overview

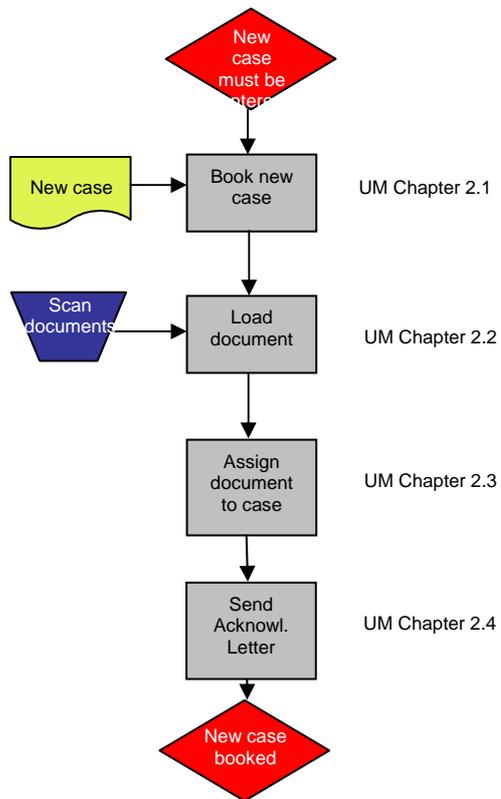


The User Requirement Specification has three layers: Overall Workflow, Detail Workflows, and User Manual Chapters describing Forms and Reports used to conduct workflow.

Overall Workflow for Argus



Detail Workflow "Enter New Case"



User Manual/User Requirement Specification Template Example

Templates are written in Word for Windows.

2 A New Case is Received

2.1 Book New Case

To book a new case:

1. Select *Argus => Case Actions => New, Case Search Criteria*
2. Enter the below fields:

Field	Mandatory	Description
Sub Section: General		
Initial Receipt Date	X	The date when the case was received at the sponsor's affiliate
Central Receipt Date		The date when the case was received at the sponsor's head quarter
Country	X	LOV, country where the event occurred, either type the first or more letter and tab to pick the country from a code list or enter the country completely
Report Type	X	LOV, the two important entries are clinical trial (Compassionate Use, Post Marketing Surv. and Sponsored Trial) and spontaneous (all other), double click to see the choices or enter the first character(s) and press tab to see the choices
Project ID		The field displays the project. The field is greyed out for spontaneous cases and becomes enterable for study cases, press [Select] to pick Project ID, Study ID, and Center ID from the hierarchy
Study ID		The study, see Project ID
Center ID		The center, see Project ID
Initial Justification		You may enter a justification
Product Name	X	In case of a spontaneous case click [select], then mark record in column Trade Name in the list of product available for the country, if necessary enter additional search criteria, click [select] to pick the value. In case of a study case the product is derived.
Generic Name		The derived generic name of the product
Description as Reported	X	Free text, coded against MedDRA, in case of autocoding a green check is displayed, otherwise a red cross (manual coding will be done during data entry)
Onset Date/Time		Date and time of onset of the adverse event
Sub Section: Reporter, press [Select] to pick a reporter from the list or enter a new reporter		
Sal.		The reporter's salutation, e.g. Dr. med.
First Name		The reporter's first name
Middle Name		The reporter's middle name
Last Name		The reporter's last name
Suffix		The reporter's suffix, e.g. PhD
Institution		The reporter's institution



Field	Mandatory	Description
Department		The reporter's institution's department
Country		The reporter's country
State/Province		The reporter's state or province
Postal Code		The reporter's zip code
Intermediary		Double click in field and pick one out of Licensee, Local Affiliate, Other, Regulatory Authority, or Sales Rep
Sub Section: Patient		
First/Last Name or Initials		Subject's name or initials
Pat. ID		If case from study enter Patient ID
Date of Birth		Subject's date of birth
Age		The patient's derived age at the time on onset
Units		The derived age units
Gender		Double click to see list of values
Section: Literature Reference, press [Select] to pick a reference from the list or enter a new reference, the button is only available for literature cases		
ID		An identifier
Keywords		Keywords separated by commas
Journal		Full name of the journal
Title		Full title

3. Check Full Search (Like, soundex) and press [Search]
4. Verify whether a case in the list of similar cases matches your case. If so stop entry. Otherwise enter the below fields.

Field	Mandatory	Description
Sub Section: General		
Seriousness Criteria	X	Determine whether the case is serious, if the case is serious select one or more seriousness criteria
Reported Causality		The causality as reported by the investigator, if the information is available select one value from the list
Sub Section: Attachments and References, press [Add] to insert a record		
#		The derived line number
Classification		Double click to select a value from the list, otherwise leave empty
Description		The description of the attachment
4 th column		The file name, use the [Search] button for loading a file into Argus
5 th column		The type, a document can be loaded or referenced by a URL

5. After entering the mandatory fields the [BookIn] button shows up, press [BookIn] to book the case. Either choose to continue with data entry or book further cases.

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Test Script Template Example

Templates written in Word for Windows. Test script corresponds to user manual chapter, by that easy tracking of requirements possible. The example below has been converted from landscape to portrait because of layout reasons.

Test Plan Version 1.0					
Test objective		Enter New Case			
Version		1.0			
Test goal		2.1			
Requirement		Create new case			
Test case		1			
Description		<ul style="list-style-type: none"> Create a new case 			
Prerequisites		<ul style="list-style-type: none"> Test to be performed by role drug_entry 			
Test Step	Test Data	Description of Execution	Expected Results / Acceptance criteria	Test Outcome (Issue No., Issue Severity, Comment)	Documentation
01		Login as user DATA_ENTRY	Login successful.		
02		Argus => Case Actions => New	The screen Initial Case Entry appears.		
03	<u>Section: Case Search Criteria</u> Initial Receipt Date: <12APR10> Central Receipt Date: <14APR10> Country: FRANCE Report Type (double click to select): SPONTANEOUS Product Name (click [select], mark record in column Trade Name, click [select]) : RELICON 10mg Description as Reported: vomiting Onset Date/Time: 10APR10 17:00	Enter values	Field Generic Name is populated with RELICON and the field Description as Reported is marked with a green check		Print and attach screenshot; add test goal, test case, test step, date, Argus user name, name and signature.
04	<u>Section: Case Search Criteria</u>	Press [Select] Press [Cancel]	Screen Reporter Lookup pops up with Name Address Rudi Holzapfel		Print and attach screenshot; add test goal, test case, test step, date, Argus user name, name



Test Step	Test Data	Description of Execution	Expected Results / Acceptance criteria	Test Outcome (Issue No., Issue Severity, Comment)	Documentation
					and signature.
05	<u>Section: Case Search Criteria</u> Last Name: Estrider First/Last Name or Initials: AB Birthdate: 12SEP56 Gender: Female	Enter values	Field Age is populated correctly with 53 Field Unit is populated correctly with Years		Print and attach screenshot; add test goal, test case, test step, date, Argus user name, name and signature.
06	<u>Section: Case Search Criteria</u>	Check Full Search/Soundex Press [Search]	A screen with an empty list of cases appears		Print and attach screenshot; add test goal, test case, test step, date, Argus user name, name and signature.
07	<u>Section: Case Search Criteria</u>	Close the screen Press [Continue]	The section BookIn appears		
08	<u>Section: BookIn</u> Seriousness Criteria: Disability, Intervention Required	Enter values	The [BookIn] button becomes visible in the bottom		
09		Press [Add]	A line is inserted into the section		
010	<u>Section: Attachments and References</u> #: Classification (double click): Report File (no column heading, press [Search] button to load file, 4 th column): UAT SAE 001.pdf File Type (no column heading, 5 th column): File Attachment	Enter values			Print and attach screenshot; add test goal, test case, test step, date, Argus user name, name and signature.
011		Press [BookIn]	A windows opens with the text "New Case <New Case> has been successfully created. Do you wish to open the case?"	New Case:	Print and attach screenshot; add test goal, test case, test step, date, Argus user name, name and signature.
012		Press [No]	The Case Actions > New case screen appears		



Test Step	Test Data	Description of Execution	Expected Results / Acceptance criteria	Test Outcome (Issue No., Issue Severity, Comment)	Documentation
013		Log off from Argus	Logoff successful.		

Tester			Approver		
Name	Signature	Date	Name	Signature	Date

Pricing

Fixed price for the templates only:

- User manual templates (120): Euro 7,500.-
- Test script templates (65): Euro 15,000.-

Time and material:

- Templates purchased for above fix price with 50% reduction.
- Customisation and implementation on a time and material basis

For more information please contact:

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