



REVAPA – Reliable Validation Package for Siebel Clinical

Approach

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

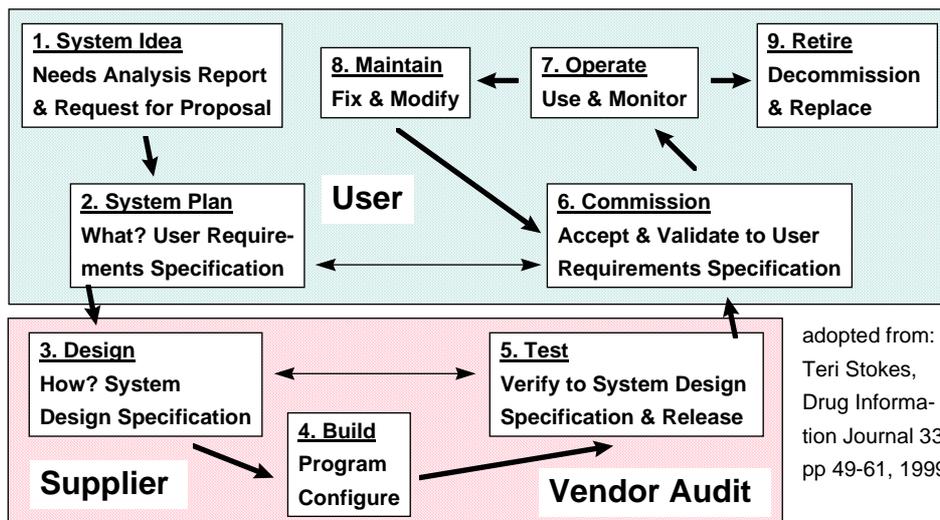
User Acceptance Test	Performance Qualification
System Test	Operational Qualification

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

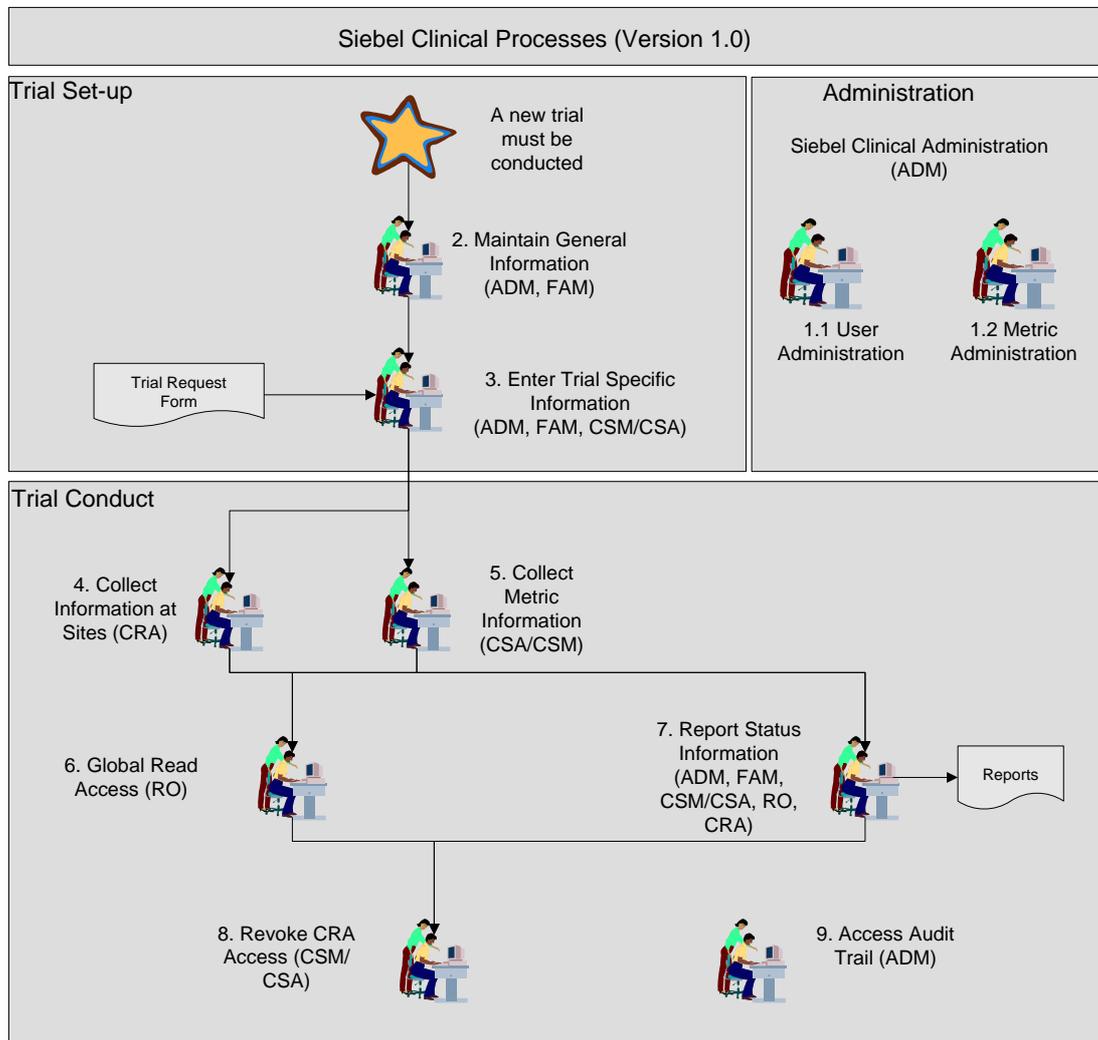
RELICO can either deliver the templates for a fixed price or can support the whole validation process on the user side on a time and materials basis.

Overview



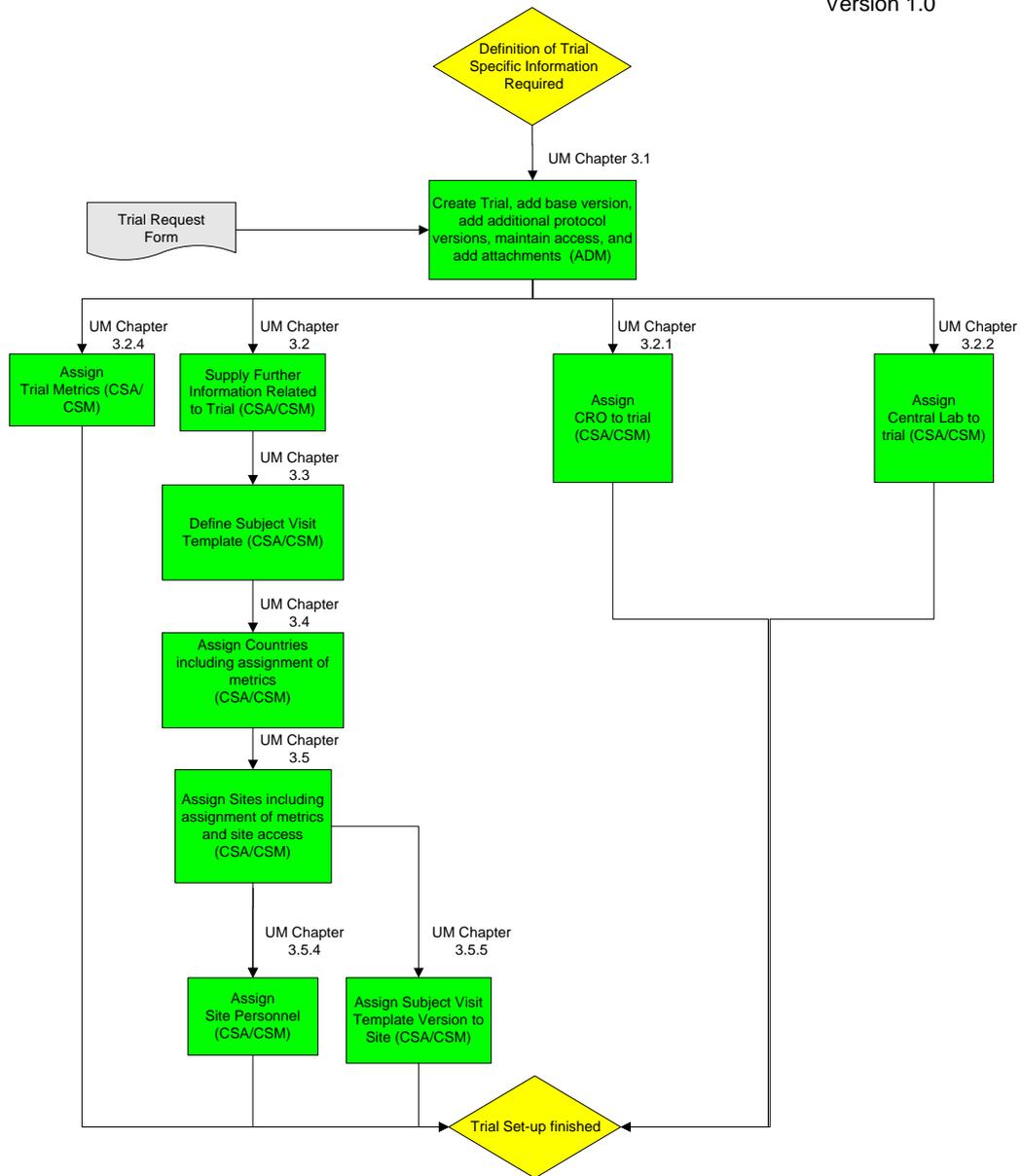
The User Requirement Specification has three layers: Overall Workflow, Detail Workflows, and User Manual Chapters describing Forms and Reports used to conduct workflow.

Overall Workflow for Siebel Clinical



Detail Workflow “Enter Trial Specific Information”

Version 1.0



User Manual/User Requirement Specification Template Example

Templates written in Word for Windows.

3 Enter Trial Specific Information

3.1 Trial Definition

A trial must be defined in Siebel Clinical before it can be managed.

Only an ADM can create trials, this is done in the *Administration Clinical => Trial List* screen.

Press the button [New] to create a new trial and enter the fields below in the list.

Field	Explanation										
Program	The field selects the program to which the trial belongs. First click in the field and then click in the orange square with the blue check (☑). In the multi-select screen select one record. Click the [OK] button.										
Product	The field selects the product and indication. First click the field and then click the orange square with the blue check (☑). The screen should display exactly one record with a product and indication combination. Click the [OK] button. In addition to the field Product the field Indication is populated.										
Phase	Use the list of values to pick the clinical phase. The phases are: <table border="1"><thead><tr><th>Phase</th></tr></thead><tbody><tr><td>I</td></tr><tr><td>Ib</td></tr><tr><td>II</td></tr><tr><td>IIa</td></tr><tr><td>IIb</td></tr><tr><td>III</td></tr><tr><td>IIIa</td></tr><tr><td>IIIb</td></tr><tr><td>IV</td></tr></tbody></table>	Phase	I	Ib	II	IIa	IIb	III	IIIa	IIIb	IV
Phase											
I											
Ib											
II											
IIa											
IIb											
III											
IIIa											
IIIb											
IV											



Test Script Template Example

Templates are written in Word for Windows. Test scripts correspond to user manual chapters, by that easy tracking of requirements is possible. The example below has been converted from landscape to portrait because of layout reasons.

Test Plan Version 1.0					
Test objective		Trial Definition			
Version		1.0			
Test goal		3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4			
Requirement		Define Trial ADM			
Execution Order		01800			
Test case		1			
Description		<ul style="list-style-type: none"> Define 1st RELICON 1 – AIDS 1 trial 			
Prerequisites		<ul style="list-style-type: none"> Test to be performed by user AADMINI1 logged into Siebel Clinical, file “Protocol of trial <CLIENT>_UAT1.pdf” has been copied to the user’s desktop 			
Test Step	Test Data	Description of Execution	Expected Results / Acceptance criteria	Test Outcome (Issue No., Issue Severity, Comment)	Documentation
01		Login into Siebel Clinical as user AADMINI1	Login successful.		
02		Administration – Clinical => Trial List	A screen appears.		
03	Program: RELICON AIDS 1 Substance: RELICON 1 Phase: IIb Short Title: UAT1	Press [New] button in upper part of the screen (list presentation) Enter values			
04	Design (MVGf): double blind, multicenter, parallel groups, randomized	For MVGF Design click into  , click in column Name to sort alphabetically, multi-select the lines where Name equals <i>values</i> using Ctrl-click, push [Add] button, click [OK] button			
05	Access: CSAMSTA1, CSMART1	For MVGF Access click into  , click in column User ID to sort alphabetically, multi-select the lines where User ID equals <i>values</i> using Ctrl-click, push [Add] button, in right part	Field access displays value CSMART1		



Test Step	Test Data	Description of Execution	Expected Results / Acceptance criteria	Test Outcome (Issue No., Issue Severity, Comment)	Documentation
		of the screen check primary for <i>CSMART1</i> , click [OK] button			
06	EUDRACT #: 2006-123123-77	Enter values Ctrl-S			Print and attach screenshot; add test goal, test case, test step, date, SC name, name and signature.

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

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