# REVAPA – Reliable Validation Package

## Approach

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

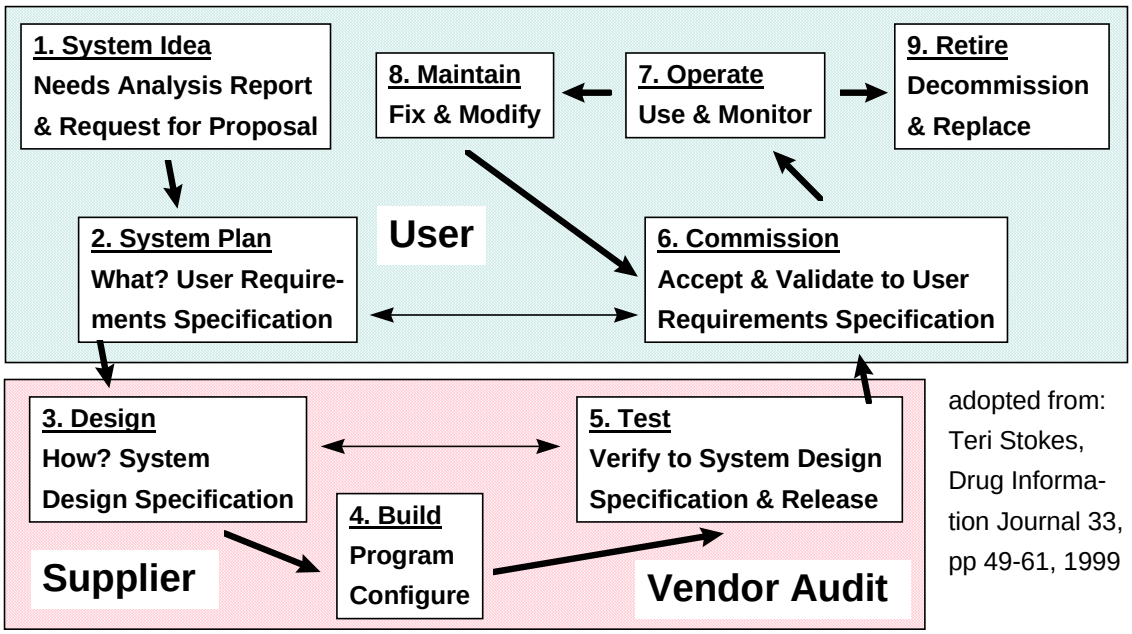
| | |
|---|---|
| User Acceptance Test | Performance Qualification |
| System Test | Operational Qualification |

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.

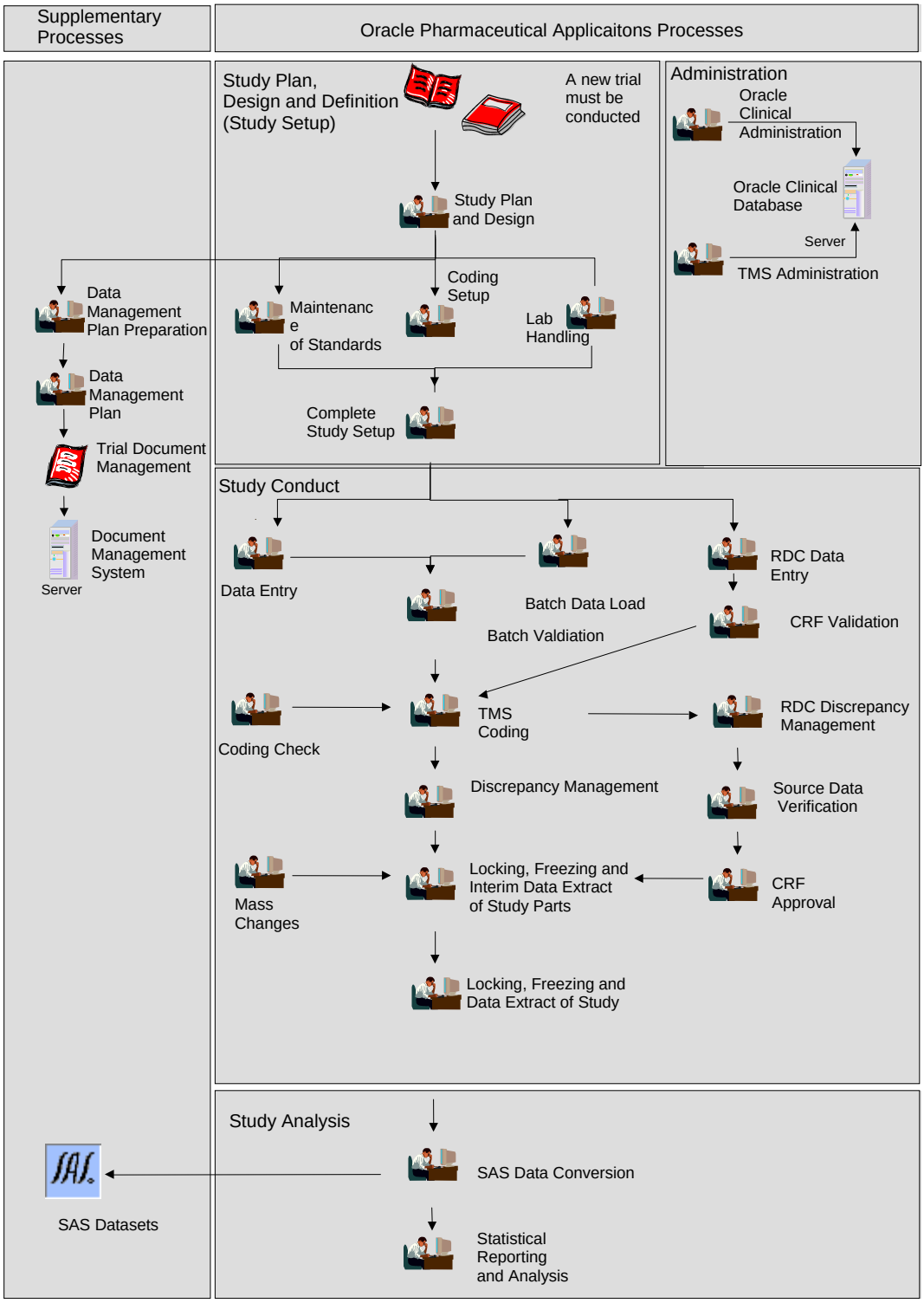
## Overview



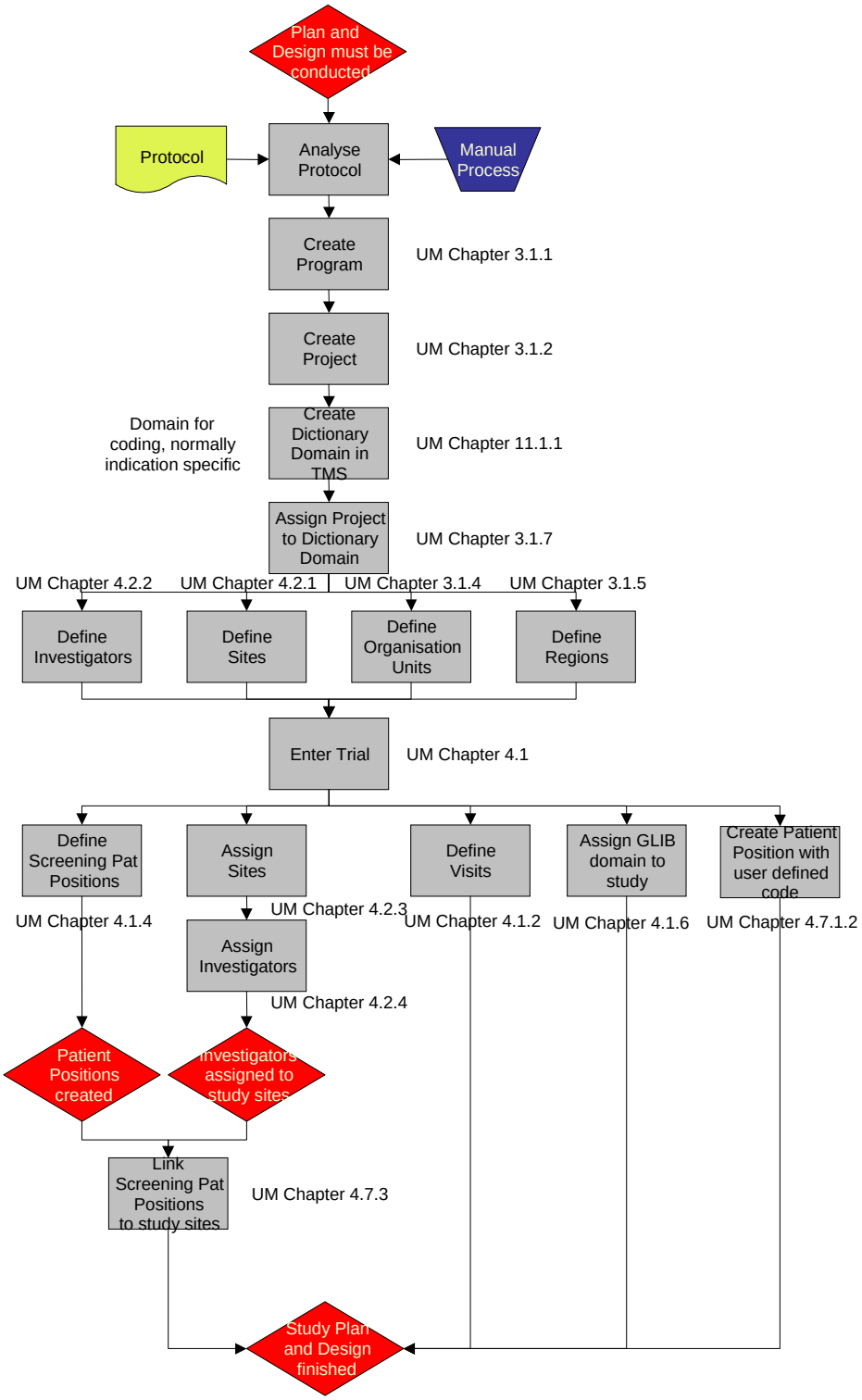

adopted from:
Teri Stokes,
Drug Informa-
tion Journal 33,
pp 49-61, 1999

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



## Detail Workflow



Templates written in Word for Windows with anchors to generate HTML custom help for Oracle Pharmaceutical Applications.

# 3 Planning a Study

## *3.1 Maintaining Programs, Projects, Organizational Units and Regions*

The first step in Oracle Clinical study design is creating your <customer> associations: Programs, Projects, Organizational Units and Regions. Users then name their study and assign these associations. Oracle Clinical groups these tasks under the **Plan** menu path.

### 3.1.1 Programs

A program represents the top level in the hierarchy of user-defined groupings of studies. A program contains projects, which contain studies. This hierarchy organizes research around a drug. You can also use programs to control user access to studies. At <customer> a program is assigned for each drug under investigation.

To create a new program or modify an existing program:

1. Select *Plan => Programs*
2. Start on a blank line, or, if there are none, insert a new record (*Data => Insert Record* or *[F6]*).
3. Enter a new, unique code for the program (e.g. <example>). This code identifies the program throughout Oracle Clinical. The code is compound specific and can be looked up in the Clinical Trials Management System (<CTMS>).
4. Describe the program.
5. The system flags the Active checkbox upon saving this record. You can make it inactive at any time.
6. *[Save]* / *[F10]*

**Back**



## 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** | **Study Plan and Design** |
|---|---|
| **Version** | **1.0** |

| **Test goal** | **3.1.1** |
|---|---|
| **Requirement** | **Create program** |

| Test case | 1 |
|---|---|
| Description | • Create a new program |
| Prerequisites | • Test to be performed by role CDM |

| **Test Step** | **Test Data** | **Description of Execution** | **Expected Results / Acceptance criteria** | **Test Outcome (Issue No., Issue Severity, Comment)** | **Documen-tation** |
|---|---|---|---|---|---|
| 01 | | Login as user OPS$CDM | Login successful**.** | | |
| 02 | | Plan ⇒ Programs | The screen **Maintain Programs and Projects** appears. | | |
| 03 | Program code: **VAL1**<br>Description: **Program for UAT1**<br>Active: **Checked** | Enter values<br>Press **Save** button | Message line "*Transaction complete: 1 records applied and saved.*" appears. | | Print and attach screenshot; add test goal, test case, test step, date, OC name, name and signature. |
| 04 | | Press **Exit** button | The window is closed and the **Navigator** screen appears. | | |
| 05 | | Log off from Oracle Clinical | Logoff successful. | | |

| Tester | | | Approver | | |
|---|---|---|---|---|---|
| Name | Signature | Date | Name | Signature | Date |
| | | | | | |

## Current Customer Basis

- 2 mid size pharmaceutical companies
- 1 medical devices manufacturer
- 3 CROs

## Pricing

Fixed price for the templates only:

- User manual templates (150): Euro 10,000.-
- Test script templates (200): Euro 20,000.-

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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