



RECLAB – RELICO CDISC 3.1.2 Lab Package

Problem

Most lifesciences companies prefer a vertical lab approach. A lab test/value pair and its derived variables are presented in one line. In contrast Oracle Clinical (OC) from Oracle® supports the horizontal lab approach, however, delivers a vertical view on the lab data, the so-called normlab view. Modifications of this view and adaptations to standards like Common Data Interchange Standards Consortium Study Data Tabulation Model (CDISC SDTM) 3.1.2 are not foreseen.

Solution

RECLAB is a PL/SQL package to be loaded into OC providing a set of helper functions and a main procedure to be called by a derivation procedure that supports vertical lab modelling. RECLAB has the following features:

- RECLAB handles lab tests with numeric, banded, ordinal, and nominal results
- RECLAB comes with a set of helper functions to check the correct format of the values for different lab test types
- RECLAB can cope with lab test synonyms, e. g., thrombocytes, platelets, and platelet count
- RECLAB converts numeric lab tests into standard units using the preferred conversion group functionality of OC
- RECLAB allows to deal with preferred ordinal and nominal lab results as requested by CDISC 3.1.2
- When installing RECLAB Oracle Clinical stays validated, no additional modules are installed in the database server code tree, RECLAB comes with an installation and a de-installation script, usage of stored procedures and functions as RECLAB does is fully supported by Oracle®
- RECLAB delivers all keys and variables that are required and expected in CDISC 3.1.2, most of the permitted variables can be delivered
- Lab Procedures Re-Execution Pre-Process is enabled even if the DCI data is not collected
- Non-existent lab tests, missing lab ranges, wrongly formatted lab values are reported to the discrepancy database allowing to send queries to the vendor and to have an unlimited number of problems in the lab data without preventing derivation
- RECLAB has been validated for OC 4.5.1, 4.5.3, and 4.6

Offer

RECLAB comes as software package with full software development life cycle documentation:



- User requirements
- Module build and test
- User Acceptance Test

The user acceptance test can be customised to address specific customer settings and to include an adequate performance test.

Haematology Example

See similar treatment for synonyms HEMATOCRIT and HAEMATOCRIT. See unit conversion to preferred units for HAEMATOCRIT.

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LBTESTCD	LBTEST	LBORRES	LBORRESU	LBORNLO	LBORNHI	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTNRHI	LENRIND	LBBLFL
HCT	HEMATOCRIT	0.5	M	.35	.47	500	mlL	350	470	H	Y
HCT	HAEMATOCRIT	0.42	M	.35	.47	420	mlL	350	470		Y
LEUCOS	LEUCOCYTES	6	/nl	3.9	10	6	/nl	3.9	10		Y
ERY5	ERYTHROCYTES	5.3	/pl	3.8	5.2	5.3	/pl	3.8	5.2	H	Y

Urinalysis Example

See character normal values 0-0 and 0. See conversion of POS into preferred value +.

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LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESN	LBSTNRNC	LBSTRESU	LENRIND	LBBLFL
LEU_UR	LEUCOCYTES_URINE	0	none	0	0-0	NONE		Y
PROT_UR	PROTEIN_URINE	POS	NONE	+	0	none	H	Y

Current Customer Basis

- 1 large pharmaceutical company
- 2 mid size pharmaceutical company
- 5 CROs

Pricing

- €250 per OC user
- €50 per OC user annual maintenance and support fee
- customisation and implementation on a time and material basis

For more information please contact:

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