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Reporting on Oracle Clinical by JReview

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ABSTRACT

Whatever the tool you use, running a script against any Clinical Database Management System is not without risk. The system might experience some performance issue if your script requires a little bit more resources the system could provide with. Worse, a non optimized script may put the system down. In this presentation, we will show you how we implemented our solution and an example of the use of JReview in Sanofi that used by different people who need to share the same information during a study conduct phase.

INTRODUCTION

Most of time, information and data entered by end-user are stored in a system commonly called database on which it is often plugged another system to produce different types of reporting for the end-users themselves or their management. Thus, the 2 systems work on the same source directly preventing one or both to run correctly. This poster is to illustrate one solution to avoid this conflict.

CLINICAL DATABASE MANAGEMENT SYSTEM (CDMS)

This is a generic term to designate the software to enter and manage all clinical data. The site people who is in charge of the monitoring, i.e. the activity to screen the patients and administer the right investigational drug following the specific protocol, will enter the result of assessments such as physical examination in the CDMS.
Oracle Clinical™ is one of these CDMS.

ORACLE CLINICAL™

A product of Oracle® Corporation, this is one of software that used by different pharmaceutical laboratories to manage their clinical data (data entry, data validation, query management, etc.).
To simply describe Oracle Clinical™, it contains lots of technical tables linked each others. Any user must have an Oracle account to log on the system and a specific role for each clinical study. The clinical data is stored in one table called “Response” and other information goes to other tables. After a hundreds of clinical studies, the “Response” table becomes very huge and it may take long to perform certain tasks.

JREVIEW®

This is not a CDMS as defined above, but software to make some reporting based on the CDMS information.
It offers different visualizations such as listing, patient profile, graphs and curves. It can help you for example to list all serious adverse event happened to the patients of your clinical study and can be reviewed by the investigator who is a physician responsible for the patient’s care.
In that case, the physician will run (double-click) the specific report that is created for him by anyone else (a developer for example), he/she does not need how to query the specific technical table where the adverse events are stored.

PERFORMANCE ISSUE

Any program that runs a query against the Oracle Clinical™ database will introduce a short interruption of its processes because the database will reply to the requestor during the time it continues to collect the data entered by the user. So if JReview® is plugged directly to Oracle Clinical™ database, even if it is the standard installation one, will result in a performance issue that can be observed on the data entry or process of validation (BVS).

ONE SOLUTION

A workaround to avoid this performance issue is to build an intermediate database between Oracle Clinical™ and JReview® that should contain only all the necessary technical tables and you can query each of them separately without involving the whole system.

You need to replicate the corresponding data from the source (Oracle Clinical™ database) to your intermediate database. You have to determine the frequency of this replication, not too often, but enough to have acceptable refreshment for the needs of clinical studies.

CONCLUSION

Each user and each company have their specific needs of reporting that no CDMS can integrate in their native reports. That is why everyone tries to create an alternative solution. However, you should pay attention on the amount of data you will have in a long term. A few data can be managed with simple and classical programs. But if you have to handle a millions of records a time you should think of another logical.

REFERENCES

For more information on Oracle Clinical™, please refer to the official website
http://www.oracle.com/us/products/applications/health-sciences/e-clinical/clinical/index.html

For more information on JReview®, please go to http://www.i-review.com/jreview.html

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