To Freeze or to Lock …

This document gives an overview of the freezing and locking functionalities as available in Oracle Clinical 4.0.3 *(although I don't believe any changes have been made to the Locking and/or Freezing functionalities in 4.5.0 or 4.5.1)*. The purpose of this document is to determine the impact of both features to a clinical study database. Once the whole process of locking and freezing is clear for everyone, it will be easier to move forward to a strategy on how the functionalities will be used within an organization.

1. LOCKING

Basically, locking data can be done on the following levels:

- Site
- Investigator
- Patient
- CPE
- RDCI
- RDCM

For patient and CPE level, you can put in a range if you lock. So, you don't have to lock each single patient but you can simply put patient 1001 to 1005, visits 1 to 6. Another level on which you can lock is on 'accessible data'. Whenever you run BV on data, the data becomes 'accessible'(pass 2 complete). At that time-point, the date of the BV is put in the 'accessible date' field for each data point concerned. This means that you can also lock data that became 'accessible' at a certain time-point. *(I really don't see a lot of benefit in using this option.)*

Important to note as well is that if you lock a RDCI, all RDCMs associated with this RDCI are locked as well. However the converse is not true. When you lock one or more RDCMs, the associated RDCI is not locked.

If data is locked, it means that users without 'Privileged Update' cannot perform updates on the locked data. The 'Privileged Update' DE Configuration Parameter can be set on 3 levels:

- System level – *if enabled at the System level, it gives ALL users Privileged Update*
- Study level – *I also recommend this should never be enabled at the Study level*
- User level – this is where Privileged Update should be set – ONLY for the 1-2 users per company.

Suggestions: 'Privileged Update' should:

- Never be Enabled at the System or Study levels (set System level to 'Disabled' and Study level to 'Not Set' or 'Disabled')
- Be Enabled at the User level – Only for the more Senior Data Manager and/or Manager of the DM group.

DE Update on Locked data:

- Users with 'Privileged Update' Enabled: will receive a pop-up window with the indication that the data is locked but that you can still change it.

- Users without ‘Privileged Update’: will receive the same message but will not be able to alter the data.

Note: you lock data that is already in the database. If you are locking on a patient level, you are locking all the data that is entered so far for that patient. Any update needs to be done by a user who has ‘privileged update’.

However, if you want to enter additional data, you don’t need ‘privileged update’ as this data did not yet exist in the database at the time of lock. Basically, it is the data that is locked, not the patient.

A tricky situation is that if you lock the data, OC does not care about the status of the data: data can be PASS 1 complete, PASS 2 started etc.. So, it is very possible that you lock data that has only PASS 1 complete. If this happens and PASS 2 still needs to be done, PASS 2 cannot be done, even by someone with ‘privileged update’!

Also, OC does not care about the status of discrepancies, etc.: it is possible to lock data on which there are open discrepancies.

The rest of the functionalities within OC stay exactly the same. BV can be ran as usual, discrepancies can be resolved etc, etc..
BV will run on locked data. New discrepancies can be created for locked patients/RDCMs/etc.

Finally, locking cannot be undone. This means that if you accidentally lock a site or investigator or patient and data has to be updated, only users with ‘privileged update’ will be able to modify the data.

2. FREEZING

Freezing can be done only on the following levels:

- Site
- Investigator
- Patient
- Study (noted below)

It is impossible to freeze on a level lower than patient. This might become a bit cumbersome if working with long-term studies and want to do analysis on the first part while data is still collected for follow up or so. It is always good that you can freeze the first part of the data in order to prevent further updates. An alternative is to use SNAPSHOT extract views saved on a secure location in order to make sure there are no changes. If a second part of the data needs to be analyzed later together with the first part, there is a possibility of

- Running the audit trail in OC to see what has changed
- Doing a proc compare in SAS to see what has changed.

As for the locking option, you can also work with ranges here. You can, for example, give a range of patients you want to freeze. If data is locked, you can still log new RDCIs and RDCMs. This is not the case for freezing. You cannot add new data to a

frozen patient. Therefore, you need first to unfreeze the patient, enter the data, and refreeze.

Unlike locking, you can undo a freeze. However the issue is that once you have frozen your data, Oracle Clinical automatically locks the data as well. As indicated earlier on, locking cannot be undone. The consequence is that once the data is frozen, in order to do updates when it gets unfrozen, only 'privileged update' users can make the necessary changes.

Another thing to keep in mind if data is frozen on the study, site or investigator level is that if when they are unfrozen all the lower levels need to be unfrozen separately as well. For example, a site with 10 patients is frozen. To unfreeze the data it is not enough to simple unfreeze the site again. You also have to unfreeze the patient concerned in order to perform your changes.

If your data are frozen BV does not run anymore. Not because it is not possible but because your data has not been changed. As you know BV runs only on patients for which data has been changed. The tricky thing is that if you have updated data for a patient that you want to freeze and you actually freeze that patient without running BV again you might end up with discrepancies for a frozen patient the next time your run BV for that study. Normally you would never freeze a patient or site without running a final BV, but as you can see it is possible to have discrepancies for a frozen patients or site.

There is another possibility to have discrepancies for frozen patients. This is whenever you add new or changed procedures. If, for example, patients are frozen but a new procedure is created, at the next BV, you may get new discrepancies for your frozen patients if their data fail the procedure. The same goes for procedures that have been subject to changes (when they have been made provisional first and active again afterwards). Next time BV is ran, these procedures will run on the complete database.

Yet another possibility exists for creating new discrepancies for frozen patients. Derivation Procedures still run against frozen data – the derived data is not frozen. Therefore, if you have a Derivation Procedure with any Detail Lines of Type = TEST, these may create new discrepancies for frozen patients.

3. Study freeze

This is the most drastic option. Once you do a study freeze, forget about changing something in the study. It won't work

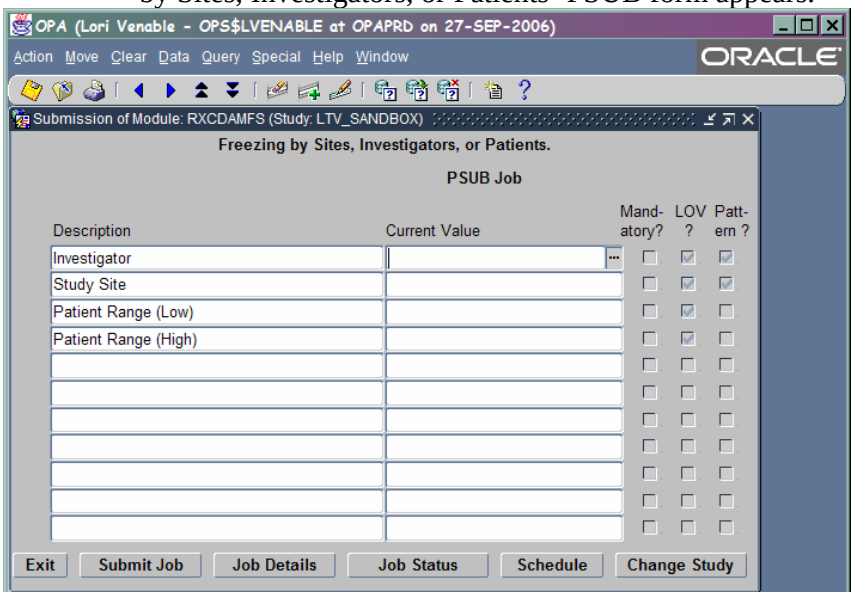
4. How to lock and freeze

There are 2 ways of locking and freezing data in OC. You could either do it interactively (e.g., for a patient, DCI per DCI) or you can do it through PSUB. The latter might be a better option if the locking and freezing are done on potentially large volumes of data.

4.1 Submitting the PSUB job:

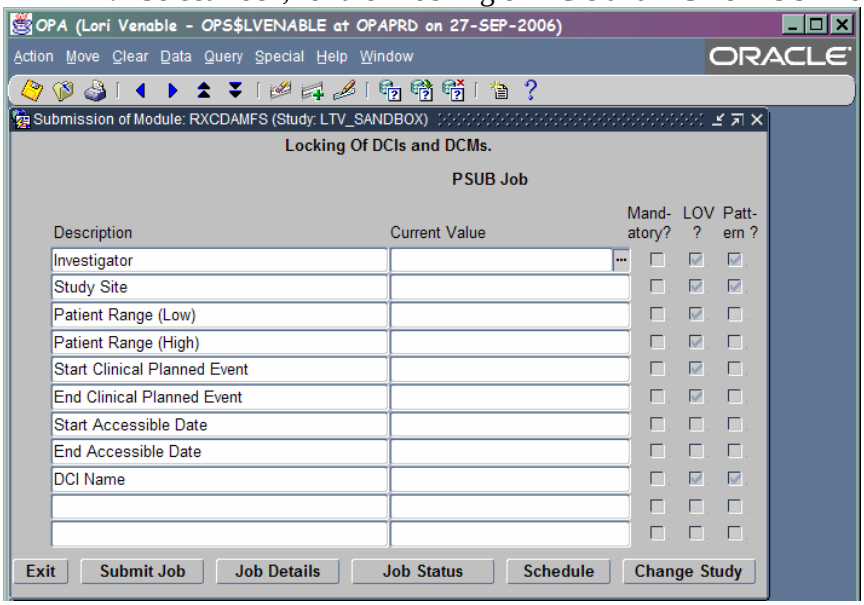
1. Select Conduct → Security.

2. Select Freeze or Lock from the Security menu. If you select Freeze, the ‘Freezing by Sites, Investigators, or Patients’ PSUB form appears.



3. Enter values. Then go to Step 6.

4. Select Lock, for the ‘Locking of DCIs and DCMs’ PSUB form.



5. Enter values, then go to Step 6.

6. Press the [Job Details] button to move to the Submission Details for Task window.

7. In the Job Details for Task window, fill in the fields to define the name of the batch job, output type, mode of execution, and execution schedule. These may be pre-filled already.

8. To return to the Submission form, press the [Back] button, and then the [Submit Job] button to submit the batch job.

4.2 Unfreezing data with PSUB

1. Select Conduct → Security → Unfreeze.

2. Enter values in the 'Unfreezing by Sites, Investigators, or Patients' PSUB window.

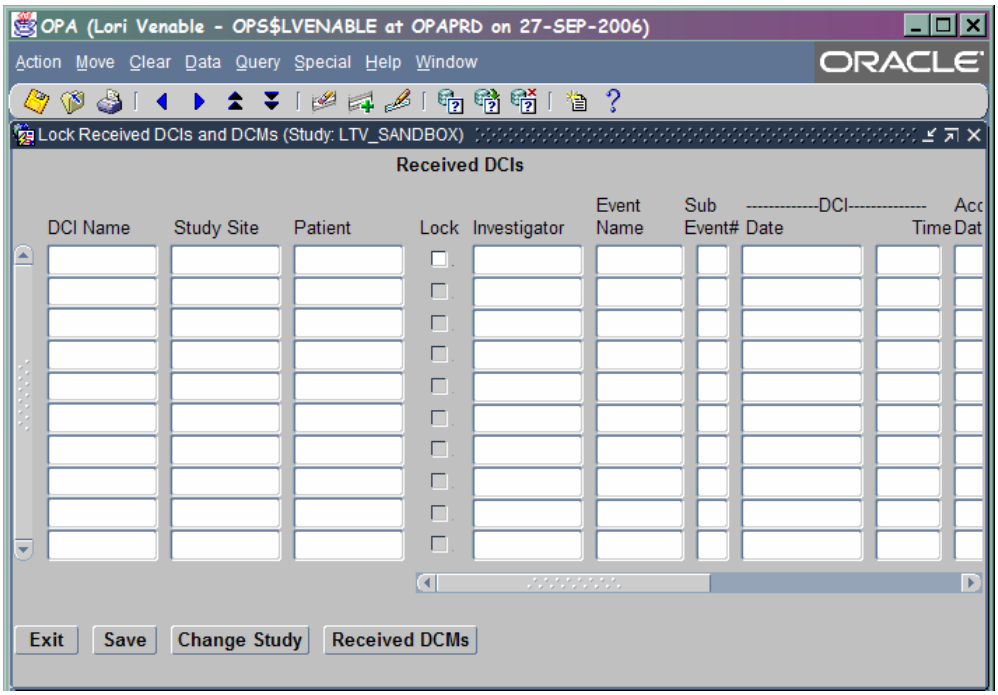
3. Press the 'Job Details' button

4. In the Job Details for Task window, fill in the fields to define the name of the batch job, output type, mode of execution, and execution schedule. Again, these should be pre-filled.

5. To return to the Submission of Task window, press the [Back] button, and then the [Submit Job] button to submit the batch job.

4.3 Interactively locking RDCIs and RDCMs

1. Select Conduct → Security → Lock Received DCIs/DCMs. The Received DCIs window appears. The screen is blank and in Enter Query mode. The cursor is in the DCI Name field.



2. Select one or more RDCIs to lock and perform the locking by one of the following options:

1. To lock all the RDCIs that met your query criteria, select Special → Lock All Recs. This option locks all RDCIs fetched by the query, not just those displayed on the screen.
2. To selectively lock RDCIs from the displayed list, click on the 'Lock' flag of each RDCI record you want to lock.

3. Click [Save]
All the selected RDCIs are now locked. All corresponding RDCMs are also locked. This process may take a few minutes, depending on the number of RDCIs affected by the action.

4. Click [Exit] to return to the main menu.

4.4 Locking RDCMs

1. Query the locked RDCIs. (see below)

2. Retrieve the appropriate RDCI. The value in the 'Lock' flag field must be UNCHECKED, or the action is redundant.

3. Click the [Received DCMs] button. The Received DCMs window for the specified RDCI appears, listing all the RDCMs associated with the selected RDCI.

4. To lock one or more RDCM, use one of the following methods to indicate your selection:

- To lock all the RDCMs for this RDCI, select Special → Lock All Recs. This option locks all RDCMs fetched by the query, not just those displayed on the screen.
- To selectively lock RDCMs from the displayed list, click on the Lock flag of each RDCM record you want to lock.

5. Click [Save].
All the selected RDCMs are now locked. However, the associated RDCI is not locked.

6. Click [Back] to return to the Received DCI window.