Study Build Process Document:

**Study Build Post Production Changes Release Checklist**

**Revision History**

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Effective Date** | **List of Major Changes** |
| 1.0 | 01-Feb-2016 | Initial Release |
| 2.0 | 31-Aug-2016 | * Updated the Purpose section to include the new requirement of implementing the change(s) in PRD once ethics approval has been collected and prior to collection the first associated data point linked to the change(s). * Added step 10 to ensure we are documenting that installation in PRD is taking place at the right timing per the requirements on the previous bullet point. Clarified the case when ethics approval is not available for all sites at the same time, the change will need to be implemented on a site by site basis. * Added step 21 on the Study specific table to ensure communication is sent to all customers across the dataflow once the change is in PRD. * Added execution of the “15376\_detect.sql “ script on step 12 * Step 25 updated to incude the deletion of studies from Clintrial QA. * Document moved to the Change Management Section as this is related to the change management activities. |
| 3.0 | 01-Oct-2017 | * Added clarification to 4 and 10 regarding PPCs typically do not require UAT to be re-installed from scratch. |

**Purpose**

To provide resource document to understand the tasks around moving a trial to production.

Review all steps or activities in the following table and ensure all of them are done at the time of sending the study to the production environment after a PPC has been completed or done to the study.

**The intent** is that in the case of protocol amendment/addenda/study extension, any changes impacting data collection have to be implemented after ethics approval & prior to collection of the first associated data point.

**Instructions**

* Include the study name at the beginning of the next page where the green text is included right now.
* Complete all steps in the table and document the completion of it, if the step is not applicable for your study then include N/A.

Study Build Post Production Changes Checklist for Trial I4V-MC-JAHM

| **Sequence #** | **Task** | **Once done include a “Yes”, if N/A include “N/A”** |
| --- | --- | --- |
|  | Submit CR using the service management request system (i.e. ServiceNow) to track the changes needed for the Study | Yes |
|  | Get CR approval from the SME and the CDA  Complete PPC in CD and proceed with system testing in DEOD | Yes |
|  | Create: CD Version at 2.2, study protected and saved in CD  Note: include the new (or appropriate) study version # above (where the green text is) that will be use in the study after the implementation of the PPC. | Yes |
|  | Once system testing is completed successfully you can proceed with the implementation in UAT. FastForward implementation should be requested. PPCs typically do not require trial to be removed, then re-installed from scratch in the UAT environment. | Yes |
|  | Submit installation requests on the ORACLE Extranet to install InForm UAT  At the same time submit a Trouble ticket using the Service Management request system to track UAT/PRD installation status and history. Review the “[Service Management Requests Guidance](http://lillynetcollaboration.global.lilly.com/sites/CDFTProcess/Business%20Document%20Repository/Service%20Management%20Requests%20Guidance.xlsx) “ for more details.  UAT   * InForm FF Installation | Yes |
|  | If Mappings were impacted by the change and a new protocol needs to be created then remove CIS UAT sync.  Complete the appropriate steps to have the protocol deleted. Review the “ServiceNow Job Aid for Requesting and Approving Study Build Changes” document for details.  Once previous CIS sync has been removed then create a new UAT sync   * InForm UAT trial 🡪 UAT CIS 🡪Clintrial PRD932 without schedule   Notify DM / CDA to request communicate to the J-Review team and the IIP group that a PPC was implemented in UAT. | N/A |
|  | Using protocol account and password log into SQL Plus or TOAD, grant access to INF\_\* tables in the UAT environment. | N/A |
|  | Make sure the following scripts are run at the time of implementing the change in UAT:   |  |  | | --- | --- | | **Script to be run or workaround to be requested to be completed** | **Was the workaround/script submitted to be implemented by Oracle? (Y/N) If the fix is not applicable include N/A** | | Run **Inactivate Triggers Script** – to allow CC to receive and send data from/to InForm | Y | | **Script for INF-16101 CC bug** - Run GetGUIDsCreateUpdateForAll.sql script against InForm db. | Y | | Run the **Workaround\_INF-14628.SQL** which updates the EnteredReason column in PF\_itemData table | N/A | | **CMCLASS** issues after a FF implementation linked to a protocol delete – send a communication to the Data manager, IT representatives and the Central Coding SME (Dorothea Talley) to make them aware of a possible sync issue occurring in the study due to a protocol delete.  *Note: this is only applicable to some CDFM studies.* | N/A | | If needed, complete the execution of the “15376\_detect.sql “ script | Y |   **Note**: for a complete list of system bugs review the following link:  <http://lillynet.global.lilly.com/sites/LRLCOE_ClinicalExec/LRL%20IT%20COE%20Clinical%20Data%20Flow%20Services/Service%20Reviews/Weekly%20Support%20Meetings/Bug%20List.xlsx> | Yes |
|  | As soon as the UAT environment setup is completed and no further UAT testing is needed, please ensure all the email rules have been inactivated to avoid unwanted emails triggered from UAT environment. | Yes |
|  | If PPC required trial to be removed then re-install from scratch in the UAT environment, manually re-add any display overrides changes that were implemented after go-live in UAT environment only. | N/A |
|  | Before moving the change(s) to the PRD environment first ensure that all ethics approval have been collected and also ensure the implementation takes place prior to collection of the first associated data point at the site.  If ethics approval cannot be obtain for all sites within a trial then you will only be able to implement the change on the specific sites for which approval was provided. | N/A |
|  | Once UAT has been completed proceed with the implementation in PRD following the next steps:   * InForm FF Installation * If the change impacts InForm Reporting make sure the reporting tool is setup again in the study | Yes |
|  | Make sure the following scripts are run at the time of implementing the change in PRD:   |  |  | | --- | --- | | **Script to be run or workaround to be requested to be completed** | **Was the workaround/script submitted to be implemented by Oracle? (Y/N) If the script is not applicable include N/A** | | Run **Inactivate Triggers Script** – to allow CC to receive and send data from/to InForm | Y | | **Script for INF-16101 CC bug** - Run GetGUIDsCreateUpdateForAll.sql script against InForm db. | Y | | Run the **Workaround\_INF-14628.SQL** which updates the EnteredReason column in PF\_itemData table | N/A | | **CMCLASS** issues after a FF implementation linked to a protocol delete – send a communication to the Data manager, IT representatives and the Central Coding SME (Dorothea Talley) to make them aware of a possible sync issue occurring in the study due to a protocol delete.  *Note: this is only applicable to some CDFM studies.* | N/A | | If needed, complete the execution of the “**15376\_detect.sql** “ script | Y |   **Note**: for a complete list of system bugs review the following link:  <http://lillynet.global.lilly.com/sites/LRLCOE_ClinicalExec/LRL%20IT%20COE%20Clinical%20Data%20Flow%20Services/Service%20Reviews/Weekly%20Support%20Meetings/Bug%20List.xlsx> | Yes |
|  | If the study has gone through an specific situation where additional workaround or fixes were need to be completed and are not part of the ones listed in the previous step then:   * Identify what those fixes are * Identify if you need to complete those workarounds again after installing the PPC   Note: the impact should have been included on the CR for the PPC | N/A |
|  | If CC was impacted by the PPC and updates to the set up is needed make sure you follow the steps needed to complete the CC set up for UAT and PRD.  Note: If CC was not impacted then you can be skip this step. | N/A |
|  | If changes were done to the Visit Structure that may impact grants, ensure the GCBC department is aware of the changes. | N/A |
|  | Using protocol account and password log into SQL Plus or TOAD, grant access to INF\_\* tables in the PRD environment. | Yes |
|  | Send an email notification to study team (Data Manager, Lilly CDA, etc.,) that the PPC has been implemented in the Live trial. | Yes |
|  | Notify DM / CDA to request communicate to the J-Review team that a PPC was implemented on PRD934. | N/A |
|  | If changes may impact InForm Reporting ensure that the reporting is re-installed into the study, if applicable. | N/A |
|  | If changes were done to the Workflow (new visits/forms) remember/communicate to the DM/CDA that the workflow rule needs to be run through the specific item within the CIV1001 CRF.  The DM will need to select the radio button and submit the form or clear/select the radio button and re-submit the form in order to have the rule(s) running (this includes running calculation rules). | N/A |
|  | Communicate to customers across the study team and dataflow once the change is available in PRD (i.e. CDA, IIP, etc.) | Yes |
|  | Close the Tickets submitted using the Service management request system, at the beginning of the checklist, to track all installation activities and status. | Yes |
|  | Ensure all updated files uploaded to TFS. | Yes |
|  | Request Data Manager to upload all the needed documents to respective location per Lilly’s current record retention guidelines. If official storage location cannot be determined, store in study specific folder in ACE until official location can be determined.  Keep this document once completed in the study specific folder in eTMF for future reference. | Yes |
|  | Always remember to Request the deletion of any deployed trials from DEOD that are not used anymore.  Same apply to the Clintrial QA (QAR934) studies. | Yes |