Study Lock Checklist

This document lists the items to be checked prior to final lock of a study database. It should be used at the database pre-lock meeting to ensure all processes have been completed before the database is locked.

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|  | **ITEM** | **COMMENTS** | **COMPLETE** |
| 1 | All trial participants have completed their final visit, including follow-up visits. |  |  |
| 2 | For CTIMPs, Serious Adverse Events (SAEs) have been reconciled with the TASC pharmacovigilance system. |  |  |
| 3 | All required external data sources have been added to the database. (List in comments box or enter NA.) |  |  |
| 4 | All queries have been closed and database updated.  |  |  |
| 5 | Detail the trial specific quality control procedures that have been performed e.g. visual verification, database audit, source data verification. |  |  |
| 6 | A list of protocol breaches has been compiled.  |  |  |
| 7 | SAP is signed off |  |  |
| 8 | HEAP (if applicable) is signed off. |  |  |