|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Process name** | Yes/No | **Time estimated** (in days) | **Deadline Date** (optional) | **Date process performed** |
| CRF Design |  |  |  |  |
| Codebook |  |  |  |  |
| **Cross disciplinary CRF Design and Codebook Approval** |  |  |  |  |
| Data Entry Masks |  |  |  |  |
| ePRO Masks |  |  |  |  |
| Monitoring Masks |  |  |  |  |
| Edit Checks document |  |  |  |  |
| Edit Checks programming |  |  |  |  |
| End-Users Trainings |  |  |  |  |
| Draft database tested by End-Users |  |  |  |  |
| End-Users Competencies Testings |  |  |  |  |
| **Cross disciplinary Draft mode Database Approval** |  |  |  |  |
| All sites open and trained |  |  |  |  |
| All legal documents/approvals signed |  |  |  |  |
| **Database Final Approval for Production mode** |  |  |  |  |
| Data Entry database A |  |  |  |  |
| Data Entry database B |  |  |  |  |
| Data Entry Comparison |  |  |  |  |
| Concomitant TT Coding |  |  |  |  |
| Edit-Checks RUN |  |  |  |  |
| Medical History Coding |  |  |  |  |
| AE Coding |  |  |  |  |
| SAE Reconciliation |  |  |  |  |
| Last DM query solved |  |  |  |  |
| Monitoring performed and Last Monitor query solved |  |  |  |  |
| Database Locked |  |  |  |  |
| Database Signed |  |  |  |  |
| Data Review |  |  |  |  |

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| --- | --- | --- | --- |
| **Name** | **Position** | **Date** | **Signature** |
|  |  |  |  |