**Sponsor Approval – DB Lock & Pre-Lock Checks**

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| --- | --- |
| **Study code** | *Study###* |
| **Study name** | *Study Name* |
| **Sponsor** | *Name (in case Sponsor is an institution, name Sponsor Representative)* |

CTU Bern would like to remind you that **the predefined date for conclusion of the pre-lock activities, data cleaning and validation, has been reached**:

As agreed in the DMP / As stated in the study protocol / As communicated in the signed CTU\_DM\_TEM-41 the expected date for data cleaning conclusion and database lock is: **mm/yyyy**

**Please complete and sign** the following sections and send the entire document back to CTU by email to [datamanagement@ctu.unibe.ch](mailto:datamanagement@ctu.unibe.ch).

**Pre-lock checks**

For every pre-lock item below, confirm that the listed requirements have been met.

| **Item** | **Confirmed** | **N/A** | **Prerequisites** |
| --- | --- | --- | --- |
| 1 |  |  | All centres have confirmed completeness and accuracy of data collected in CDMS. (Please note, this also applies for single site studies) |
| 2 |  |  | Data Import:  All external data (e.g. lab data) that needed to be imported have been received and imported. |
| 3 |  |  | Medical Coding:  All coding (e.g. (S)AEs, concomitant medications) have been entered and reviewed as defined in the study protocol. |
| 4 |  |  | The status of all patients is complete. |
| 5 |  |  | SDV: Source Data Verification has been performed and finalized. |
| 6 |  |  | Queries: All queries have been resolved (or at least all critical queries potentially impacting the analysis). |
| 7 |  |  | The end of study form is filled out for every patient. |
| 8 |  |  | Data cleaning on database level has been performed. |
| 9 |  |  | All documents have been downloaded from the Cloud and all remaining documents and the entire study folder can be deleted. |

**Sponsor Approval – Database Lock**

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| --- | --- | --- |
| **I as the sponsor/sponsor representative, herewith confirm that the collected data for the above-mentioned study are complete and clean.**  **The study database can be locked, and all write/editing rights can be revoked:** | | |
| * **YES** |  | Signature / Date: |
| * **NO** | **Data cleaning and validation activities are not yet concluded and that the predefined end date for database locking must be delayed.(1)**  The conclusion of data cleaning and DB lock is postponed to the following date: \_ \_ /\_ \_ \_ \_ |

**(1)** Database Maintenance Fee (Fee II) of 360.- CHF; please note: fee also applies in case no activity is detected in database for 12 months.

**Force Database Lock**

**CTU Bern Data Management reserves itself the right to force a database lock when no answer was obtained from the sponsor/sponsor institution** (after two failed attempts and within 3 months from the day this form was initially sent). This Force Lock is executed, where final statistical analysis is required to be conducted.