SOP (standard Operating procedure) for PITCH Data Quality Checking
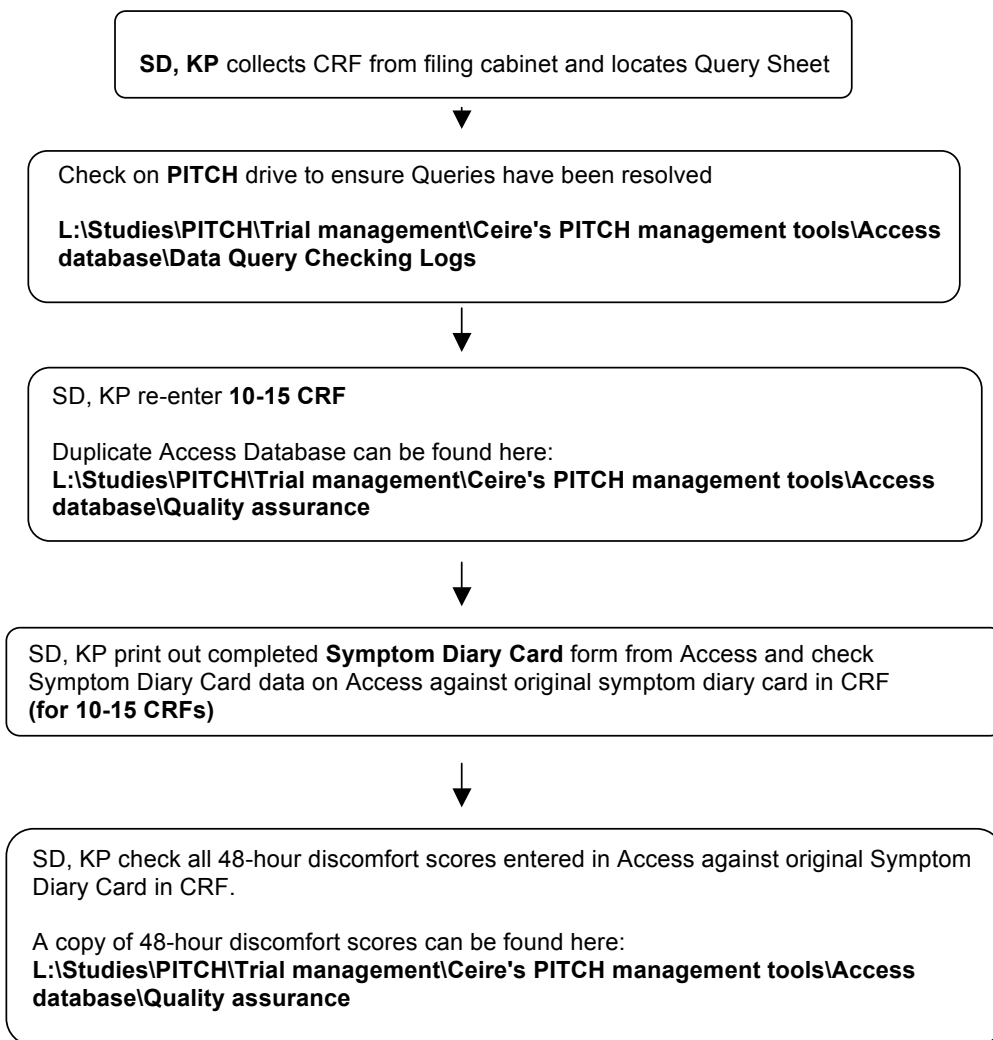
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Data Quality:
Persons responsible for entering the PITCH CRF data into the Access database must carry out checks to ensure correct data entry. The process of data entry is as follows: SD, SB or KP enters Data from CRF into the Access database. Any uncertainty regarding data is entered into a word document Query Sheet for that particular patient. CC, SD and RNs check through Query Sheets and resolve according to Data Query Resolution SOP. Once the query has been resolved the Data can then undergo a quality check. A process of double entry and checking is needed. Aiming for 100% agreement and any disagreements should be corrected for primary outcomes measured.

Data Quality Checking:
The following process needs to be followed in order to ensure data have been entered correctly:

SD, KP collects CRF from filing cabinet and locates Query Sheet

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Check on **PITCH** drive to ensure Queries have been resolved

L:\Studies\PITCH\Trial management\Ceire's PITCH management tools\Access database\Data Query Checking Logs

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SD, KP re-enter **10-15 CRF**

Duplicate Access Database can be found here:
L:\Studies\PITCH\Trial management\Ceire's PITCH management tools\Access database\Quality assurance

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SD, KP print out completed **Symptom Diary Card** form from Access and check Symptom Diary Card data on Access against original symptom diary card in CRF **(for 10-15 CRFs)**

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SD, KP check all 48-hour discomfort scores entered in Access against original Symptom Diary Card in CRF.

A copy of 48-hour discomfort scores can be found here:
L:\Studies\PITCH\Trial management\Ceire's PITCH management tools\Access database\Quality assurance

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SD, KP check baseline data on Access against original CRF for:

- DOB
- Date
- Gender
- Age (months)
- Temperature
- Time Taken
- Fever duration
- Current antibiotic use
- Nurses hydration assessment
- Baseline discomfort score

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SD, KP to update Data Quality Check Log, located here:

L:\Studies\PITCH\Trial management\Ceire's PITCH management tools\Access database\Quality assurance

Double entry ensures 900 points have been checked. TC aids Data Quality checking by generating Access Queries to extrapolate data for 48 hour discomfort scores and Baseline data if necessary.