SOP (Standard Operating Procedure) for PITCH Data Entry Query Checking

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Query sheet generation:
Persons responsible for entering the PITCH CRF data into to the Access database create Query sheets to inform the trial co-ordinator (TC) of whether data has been entered successfully or not.
These are located here:
L:\Studies\PITCH\Trial management\Ceire's PITCH management tools\Access database\Data Entry Query Sheets

Occasionally, data enterers come across problems that they cannot resolve alone. These have to be highlighted to the TC via the Query Sheet for that particular participant, identified by their PITCH Enrolment Number. Any uncertainties with regards to the data entered or data that appears missing or cannot be input are grouped via section of the CRF/Access database forms.
These sheets are printed out and placed inside the front cover of the CRF folder by the data enterer. For any new data entered, the Query Sheet must be updated and re-printed and returned to the CRF.

Query Sheet checking:
The following process needs to be followed in order to resolve queries highlight from the CRF Query Sheets.

Collect CRF from filing cabinet and locates Query Sheet

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RN and SD/KP review query sheet problems (per section) and resolves issue. Any queries that involve major changes should be referred to TC to make decisions about appropriate data to be entered and to remain

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RN and SD/KP do the following:
1. Makes changes in the Access database.
2. **Notes these changes** and **signs off initials** and **date** in the following:
   a. The CRF at the point of the query.
   b. The CRF Query Sheet
   c.
3. At the end of the CRF section (e.g. Baseline visit) Sign off that all queries have been resolved.

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TC re-prints the Query Sheet with the resolved information on and places back with the CRF.
- If all queries complete – 'COMPLETE' entered and highlighted
TC logs in **Query Log file** that CRF section has been resolved completely.
Query checking Logs can be found here:
L:\Studies\PITCH\Trial management\Ceire's PITCH management tools\Access database\Data Query Checking Logs