

Before any database export to the sponsor, CardiaBase checks the reliability of the values given by the ECG reading. A set of controls is performed before and after data insertion in the database.

Before study insertion in the database:

ECG administration" phase:

- Validation of the values given by ECG reading compared to usual values of an ECG,
- Identification of absurd values (if any),
- Validation of the differences noticed between the complexes of each ECG.

After study insertion in the database:

"Baseline administration" phase:

- Validation of the reliability of the baseline chosen by the sponsor to qualify the effect of the drug, by comparing the values of ECG intervals recorded on the same patient before therapy.

"Lead administration" phase :

- Checking, for a one single patient, that the chosen lead for analysis remains the same during the study. In case of a lead change, a check is done to make sure this change is a cardiologist decision (in this case, lead change reason has to be documented).

"Final administration" phase :

- Validation of the measurement of critical differences of the intervals as observed under therapy compared to pre-therapy period (baseline),
- Data cross between qualitative and quantitative reading.

After this administration phase, an Excel file, which is the exact mirror of the database, is produced and controlled by an administrator, before being sent to the sponsor.

All those checkings are performed on specific applications that are configured with the level of accuracy that is wished by the sponsor. The parameters chosen by the sponsor for the checkings are archived with the database and are at the sponsor's disposal.