THIRD PART: DEVELOPMENT OF THE PROTOCOL

When engaging in a research project, the researcher must develop a protocol, which is a plan or guide describing their study.

Through the description of the different types of study that he has at his disposal, we have seen the importance for the researcher of finding the best match between the objective of his research and the type of study chosen, but also the best compromise between an optimal level of proof linked to a very complex study plan and the feasibility of the project.

The data of a study constitute the central point of it. It is from them that we evaluate the size of an effect, a difference between two groups, or more generally, that we provide useful information to the scientific community.

If the analysis of the data is capital, their method of collection is just as important. This involves measurements, and therefore measuring instruments, which must be described and evaluated within the framework of the protocol. The questionnaire makes up a special type of data.

A protocol must lead to an exact description of the phenomenon studied. All clinical research carries the risk of straying from the truth, by overestimating, underestimating, falsely asserting or falsely ignoring an effect. Major contradictions can exist between the conclusions of different studies on the same subject.

It is therefore necessary, at the protocol design stage, to identify and take into account all sources of potential errors, biases and difficulties in interpreting the study.

It is also necessary to provide the means to highlight an effect if it exists. This is the fundamental constraint of the power of the study, linked to the size of the sample studied, and depending on the hypothesis that the researcher has formulated.

Finally, the researcher does not only live on "love and fresh water". His study will only see the day light if he has foreseen and solved the material constraints in advance.