

PART ONE

RATIONALE AND FORMULATION OF THE RESEARCH QUESTION

If money is the sinews of war, it is the medulla of research, of which the clinician is the cortex. The money exists. We have to find it. To get it, you have to argue. This is why this first part: "justification and formulation of the research question" is fundamental. You have to first convince yourself, then convince those around you, potential collaborators, donors, that the research project you have in mind is worth carrying out. There is in the justification a commercialization approach, because one must prove that the answer to the research question, provided by the protocol that one wishes to carry out, will find takers on the medical market. And if so, support may be found for the study.

We must therefore insist on the innovative nature of the project, the importance of the problem considered, the size of the population considered, but also the impact in terms of social, political and economic consequences. A clinical research project is all the more likely to find sponsors if it is multi-disciplinary in nature.

Logistics, like methodology, is one thing. Ethics is another. Four fundamental principles guide the researcher, for the greatest respect of the subjects participating in the research. These are the principles of the interest and benefit of research, of its harmlessness, of respect for individuals, and finally of justice. It is natural to ask whether the randomization process is ethical for the patient. Doesn't he risk being deprived of a possible benefit, because he was in the "wrong" group? But then, it must also be natural to wonder about the ethical nature of medical practices that have never been the subject of evaluation or research protocols. If ethics is a safeguard for research, it is also its own justification.