I should like to report here on practical experience of my own resulting from daily clinical work and colored by local factors. I work in a medium-sized hospital on the southern border of the Federal Republic of Germany in a beautiful area which has a high density of physicians. We treat about 50 new cases of breast cancer in women a year. At present 45 patients are being treated or receiving care in the context of clinical studies. Our noncentral position makes it especially important for us to check our breast cancer therapy in order to carry out our work in accordance with modern standards and to assess it in comparison with the results of larger hospitals and centers. We can discipline our thinking and make a contribution to answering critical questions only on the basis of participation in clinical studies.

Clear, incontestable randomization is present when a patient consents to the randomization decision in full knowledge of the disease and the forms of treatment available and agrees to accept the decision. Women suffering from cancer must arrive at this decision in a state of the most profound inner agitation. Announcement of the diagnosis “breast cancer” negates at a stroke all prior conscious and unconscious notions about the further course of life. The patient is confronted directly and dramatically with the finiteness of life. She must arrive at a new orientation with regard to herself and the rest of her life. Various familiar reaction forms such as aggressive revolt against the diagnosis and against the people who had to communicate it, desperate searching for the causes, ideas of sin and punishment, a feeling of the absolute meaninglessness of all treatment measures, to mention only a few, are intensively experienced.

In this life-determining situation, the physicians who have the task of helping her evidently do not know themselves precisely what to do. On the contrary, they select the measures determining the patient’s future existence on a random basis. This is how the question of randomization may appear in the eyes of the patient concerned.

How can the patient be helped in coming to terms psychologically with her fate, in the outlook on the new future, and in the measures to shape this future, one of which is therapy in accordance with the protocol of a clinical study? Patent recipes of general validity cannot be given here. Naturally, the informative and at the same time therapeutic discussion with the patient must be carried out on a basis appropriate to the individual patient.
The most crucial and important point can actually be stated in a single sentence: it is a matter of gaining the trust of the patient! This confidence must be so stable that it outlasts the patient's doubts that arise in the course of therapy. It must also stand up to the uninformed and insensitive gossiping of neighbors, irresponsible reporting in the media, and the treatment suggestions and requests of other physicians. Trust must be the basis for the patient's decision, and must be her protection in the subsequent weeks of therapy and the years of follow-up treatment which follow.

How can the trust of the cancer patient be gained and consolidated? Again, the solution can be stated in a few words: by the repeated, intensive talks with an experienced and competent physician, talks which combine information and therapy from the beginning. I should like here to mention a few key points. On first contact, the woman should be given factual and straightforward information on the suspicion of cancer or the probability of cancer diagnosis. This should be followed by detailed explanation of the measures required, and then a detailed description of the basic principles of treatment applied in the hospital in question. In my hospital these are:

- Exact substantiation of the cancer diagnosis, if necessary using a two-session procedure
- Concern on the one hand to treat the malignant and potentially fatal disease adequately according to the present state of knowledge, and on the other hand to proceed in a manner appropriate to the degree of disease in each individual
- Not to use the radical methods of surgery and irradiation previously practiced

Fears and worries can thus frequently be responded to and neutralized. If necessary, a further day should be given to allow time for reflection before continuation of the discussion. The wish to talk once more with another physician about the disease should be welcomed and supported. Before the operation, what was said earlier should be gone into in more detail, if possible in the presence of the husband or other relatives, and the information about a stage-related individualized therapy repeated. Fresh references to histological confirmation of the diagnosis and a two-session procedure in small tumors or with equivocal rapid-section findings give the patient the feeling of being secure from unnecessarily extensive operations.

There is then further discussion on the procedure. When all diagnostic results have been obtained and if the study's inclusion criteria are satisfied, the actual randomization discussion can then follow. It must be made clear that a clinical study is not a venture into unknown terrain but that, on the contrary, it entails careful registration, collection, and independent evaluation of the results of all patients during treatment. The duty of the physician to weigh up with the patient the advantages and disadvantages of various treatment procedures which are equivalent according to the general state of knowledge should be emphasized, and it should also be pointed out that our procedures are strictly controlled by our study management.

If trust has been created in the prior discussions, in particular on the basis of the caring attention which the patient has experienced in the previous days, consent to randomization may be obtained. The patient understands it as a part of the