Abstract:

Background: There is increasing demand and quality-driven pressure from professional organizations for physicians and health care providers to increase participation in clinical studies. But this can have a severe financial impact on the institution, so costs should be identified and calculated in advance. Method: In a diagram, the decision-making process to participate in clinical trials based on economic and budget impact is reviewed and analyzed in detail. Results: This flow chart describes how cost-effective participation in clinical trials is determined. Since its implementation, all trials in our institution have been cost covering. Conclusions: All service and care required within the studies must be distinguished as either medically necessary or study related. Costs for the first category have to be covered by the health care system, but in case of the second category by the study sponsor. The institution’s own costs for study-related services should be known and deducted from the study income to determine the actual study gains. Subsidizing studies from tight clinic budgets is difficult in times of rationed medicine and should be avoided. Non-cost-covering clinical studies should be renegotiated with the sponsor until cost-effectiveness is reached. Otherwise, a rejection of study participation for financial reasons should be seriously considered. The design of cost-covering clinical trials supports better recruitment for studies.

Stichworte:

Clinical study; Study management; Economics; Cost covering; Decision