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Abstract

From an ethical perspective, clinical research involving humans is only acceptable if it involves the potential for benefit. Various characteristics can be applied to differentiate research benefit. Often benefit is categorized in direct or indirect benefit, whereby indirect benefit might be further differentiated in collective or benefit for the society, excluding or including the trial patient in the long term. Ethical guidelines, such as the Declaration of Helsinki in its latest version, do not precisely favor a particular type of benefit.

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THE PRINCIPLE OF BENEFIT FROM DRUG DEVELOPMENT FOR PATIENTS IN CLINICAL RESEARCH

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Background: From an ethical perspective, clinical research involving humans is only acceptable if it involves the potential for benefit. Various characteristics can be applied to differentiate research benefit. Often benefit is categorized in direct or indirect benefit, whereby indirect benefit might be further differentiated in collective or benefit for the society, excluding or including the trial patient in the long term. Ethical guidelines, such as the Declaration of Helsinki in its latest version, do not precisely favor a particular type of benefit. However, to conceptualize clinical research benefits it is relevant to differentiate between the potential individual benefit or the social benefit expected from the study, either with or without a potential long term beneficial option for the individual trial participant.

Objectives: The narrative review was designed to screen related literature to identify the most occurring benefits which could be afforded by clinical research and to further detail the beneficial outcomes in order to learn about the characteristics values specifying individual and social benefits.

Methods: Literature on research benefit was identified by searching PubMed database using several combinations of keywords like "benefit" and "clinical research" or "direct benefit" and "clinical research." The search was limited to articles published in English language. Likewise, a google search with the same combinations of keywords was done. Additionally, the reference lists of instantly promising articles were screened for further thematically adapted articles.

Results: Based on the reviewed literature it can be stated that the principle of benefit from drug development is routinely divided into two main classes, namely individual benefits for the patients on one hand and into collective benefits for the society.[1] Thirty-four of an overall 39 articles and publications by governmental medical institutes focused on the personal benefit of the patients. In this group the leading benefits were an increased quality of life (42.2%), access to health care and drugs (29.4%), up-to-date care (29.4%), feeling of altruism and helping future patients (17.6%), payments received (17.6%), and improvement of survival rate (14.7%). The collective benefit was discussed in 18 of the articles. The main benefits in this area were the general knowledge gain (72.2%), subsequent availability of new treatments and drugs (27.8%), better access to medicines (11.1%), sustainability of health care (11.1%), and improvement of health care (11.1%).

Conclusions: Individual patient benefit from drug development appears to be more frequent than benefits concerning the society in general. Though a scientific approach is population based and consequently closer to the social benefit category, the data might not only be purely statistically evaluated. Each individual patient has the right to look and hope for a personal benefit from participating in a clinical trial without putting a feeling of pure altruism on top priority.[2] From an ethical point of view each benefit achieved for individual patients as part of a clinical trial testing new treatments, drugs or medicinal products, might be seen as social benefit as well, and even more in case the tested drug or device will be made available for all patients of the country, where the clinical trial was conducted, after its' market approval.[3]

Key words: Clinical research, patient benefit, social benefit, direct benefit, indirect benefit, clinical trial, ethics.

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