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COMMENTARY

Ethical principles for project collaboration between academic professionals or institutions and the biomedical industry

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Abstract: Ethics in biomedical research cannot be defined by etymology, and need a semantic definition based on national and contemporary values. In a Nordic cultural and historic context, key values are solidarity with one's fellow man, equality, truth, justice, responsibility, freedom, and professionalism. In contemporary medical research, such ethics are further subgrouped into research ethics, researcher ethics, societal ethics, and distributive ethics. Lately, public and academic debates have addressed the necessary strengthening of the ethical concerns and interests of patients and society. Despite considerable progress, common ethical definitions and control systems still lack uniformity or indeed do not exist. Among the cooperative partners involved, the pharmaceutical industry have preserved an important role. The same is true for the overall judgments reflected by the European Forum for Good Clinical Practice, leading peer-reviewed journals, the Nuffield Council on Bioethics for developing nations, and the latest global initiative, the Singapore Statement on Research Integrity. To help both institutions and countries, it will be valuable to include the following information in academia–industry protocols before starting a project: international authorship names; fixed agendas and time schedules for project meetings; chairperson shifts, meeting reports, and project plan changes; future author memberships; equal blinding and data distribution from disciplinary groups; an equal plan for exchange of project manuscripts at the proofing stage; contractual descriptions of all procedures, disagreements, publishing rights, prevention, and controls for suspected dishonesty; and a detailed description of who is doing what in the working process.

Keywords: ethics, collaboration, academia, biomedical industry

Introduction

The term "ethics" has obtained linguistic citizenship, especially in relation to biomedical research, including clinical and institutional scientific projects. In view of the common misunderstandings, ethics cannot be meaningfully defined by etymology (derived from the Greek for "good life"), and needs instead a semantic definition, such as:[1]

> Ethics is an overall term for the immaterial values and attitudes, which are prevalent in a country or culture, which lie behind the country's or culture's concept of man, the derived laws and codes, and which on this basis determines citizens' personal lives, their lives with each other, and with the legal and private institutions of the society.

From a global perspective, ethics also include a responsibility for the ecologic balance between the planet Earth, its soil, water, and air, and the diversity of its flora and fauna. In the Nordic cultural and historic context, the most important nonmaterial values underlying ethics include solidarity with one's fellow man, equality, truth, justice,

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responsibility, freedom, and professionalism.[1] However, even using existing contemporary semantic definitions of ethics (which are few), there are substantial variations between cultures, national politics, and languages that are substantial, leading to highly variable interpretation by international readers and multicenter project participants. The increasing globalization of research now requires definitions that are understandable and transparent, in both the geographical universe and the multidisciplinary social universe, eg, between epidemiological researchers and the pharmaceutical and biomedical industries.

Research, researcher, and distributional ethics

Since the mid 20th century, the controlled clinical trial has moved from being conducted in existing patients in the departments of the researchers to being based often on randomized cohorts from large and fully representative samples, based on pretrial epidemiological work. Development of the controlled clinical trial and its original ethical perspectives after the Second World War has, during the decades since, needed to supplement the original ethical demands in human biomedical research with several new ethical demands.[2] These include: firstly, researcher ethics, ie, the integrity of the individual scientist in carrying out the project and presenting its results, to prevent fraud and dishonesty; secondly, societal ethics, ie, dealing with patients as the ultimate target group in a globalized perspective, not the drug industry or the ambitious scientist; thirdly, distributional ethics, ie, the democratic distribution of clinical research results to the patient groups in need of them.

From the European perspective alone common definitions and control systems either lack uniformity or do not exist. Based on a few existing national initiatives, eg, the Nordic countries, United States Good Clinical Practice, and European Union initiative, the European Forum for Good Clinical Practice annual conference at Prague in 2009 concluded that common European definitions and coordinated control systems are very much needed. Fortunately, this work has already started in the form of a European Union working group.

International reflections

Biomedical and scientific journals are coming to reflect the strong public interest in, and demand for, an influential debate leading to progress in the ethics of biomedical research, thereby strengthening the interests of patients and society. The spectrum of participating parties is wide, comprising control agencies, professional medical associations, the drug industry, clinical and epidemiological researchers, and health care researchers from developing countries.

Garattini and Chalmers[3] in particular have addressed the interests of patients and the public in relation to evaluation of drugs in controlled clinical trials. They state that "the drug industry has an image problem, and big changes are needed to restore public confidence". Their reasons for this statement are that "… industry research agendas are distorted by priorities that are important to industry but not to patients".[4] Garattini and Chalmers have considered the economic aspects of new drugs from the cambrium of basic research, the costs of which are met mainly by the public, and concluded that "patients and health services are getting a poor return on this investment".

Although drug development and evaluation are not the only components of project collaboration between academia and industry, they have yet to be addressed fully in ethical analyses of unbalanced collaboration. Garattini and Chalmers have also assessed the transparency of drug testing by the European Medicines Evaluation Agency and by the US Food and Drug Administration, and found both to be inadequate, with the European system being the least transparent. Their recommendations are for stronger involvement of patient interests in therapeutic research agendas, transparency in drug evaluation enshrined in law, independent drug evaluation, and demonstration of added value for all new drugs.[4]

A number of influential US authors from professional medical associations, including academia and journal editors, have also investigated their financial relationships with pharmaceutical and medical device companies, and have requested stronger guidelines for controlling conflicts of interest, because the present policies "… are not uniform and often lack stringency".[5]

A recent thought-provoking personal analysis by one clinical scientist strongly supports the conclusions of the professional medical associations, and puts the dilemmas and problems of conflicts of interests into the context of flesh and blood, recognizable to all clinical scientists and members of national ethical control systems.[6]

Particular ethical dilemmas appear in collaboration between industries from developed countries and scientists from both developing and developed countries. A publication by the Nuffield Council on Bioethics in 2002[7] dealt thoroughly with such problems, compared national guidance in Denmark and Uganda, and also presenting a survey of international guidelines for transparency of ethical dilemmas.

Practical guidelines

In 2010, the Singapore Statement on Research Integrity, comprising four principles and 14 responsibilities, now enables readers to put this ethical subtopic into an overall perspective.[8] Instead of providing a detailed description of contemporary project examples with ethical dilemmas, the present commentary concentrates on basic principles which can be practically applied when industries and academic researchers plan to work together on individual projects. These principles aim to balance the rights, interests, and duties of participating patients, volunteers, industry representatives, and biomedical scientists in an equitable manner. The protocol must provide a thorough description of:

- Intended authorship order independent of any hierarchic titular order
- A fixed schedule and key agenda for project meetings
- Any chairperson shifts and obligatory detailed reporting of project meetings and agreements on project plan changes
- Any future members of the author group, balanced between disciplinary groups
- Equal distribution, blinding, and collation of all project data for all disciplinary groups
- A fixed plan for exchange of manuscripts at the proofing stage with the aim of agreement and common authorship
- A contractual description of procedures, if agreement on the final content of the manuscript cannot be reached, eg, a reflection period of three months, and after this, the right for both groups to publish their own version, with due consideration of any patenting issues; if a national independent board for investigation of scientific dishonesty exists, and if suspicions of dishonesty have arisen, the possibility for one of the collaborators to involve such a board must exist
- Role of all members of the project group must be listed and signed by all authors before the final manuscript is submitted to the editor of the intended journal for publication.

Disclosure

The author reports no conflicts of interest in this work.

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