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Participation in Clinical Research and Paradigms of Ethical Responsibilities

Abstract

Nowadays the development and epidemics of different diseases drive biopharmaceutics to innovate and develop new therapeutic options due to the urgent need for new biodrugs to ensure the best health benefits for the populations. Through the last epoch, biopharmaceutical innovation had an effective role in improving the mankind health care as well as their life quality. Despite all the advantages and the relief which the biopharmaceutical innovation provides to the mankind health and its benefits, the biopharmaceutical innovation does not escape from a variety of bioethical challenges and moral principles governing the participation in clinical studies. Indeed, such ethical responsibilities are discussed both in the public and in the healthcare sectors.

Surveys in different countries have shown the necessity and the importance of the ethical techniques adherence. Among the ethical responsible criterions in the use of human tissue in the clinical researches is avoiding any kind of infringement of the patient's rights, giving the participants a whole explanation about this research, respecting his privacy and autonomy also respecting his opinions, his freedom of choices and decisions towards the research for determining whether or not to recruit someone in the research represent high ethical standards that all the researchers need to respect. Moreover, taking into consideration the patients and the participants feelings and avoiding exploiting their weak position to urge and push them to participate and join the clinical research is a critical issue as well. In addition, the researchers and clinicians should make a therapeutic, financial and moral follow up and compensation to the participants in case of any research disadvantages. The main aim of any research team is to prevent any serious outcomes which can drive the life of the participant to danger.

Keywords: Clinical research; Ethics; Responsibility; Consent; Privacy

Review Article

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Introduction

The social and political arena has witnessed a vast debate and a big discussion. Among the fundamental issues which have generated this debate is the Responsible research and innovation (RRI), which have pushed the "Horizon 2020" the European's program of research and innovation to take and consider this issue as a synoptic case [1]. For the time being, the biopharmaceutics is among the most successful and appropriate way for improving the mankind health and make an end to different diseases spreading [2]. The physicians, directors and funders of the biopharmaceutical firms are the officials in the first place of the biodrug innovation, research and development process responsibilities, the whole biodrug team is a common healthcare squad which have a combined work and several biopharmaceutics innovation cases [3].

It is required to minimize the danger and avoid any kind of disadvantages which can be generated from the innovations of biopharmaceutics during the whole clinical research process, we find the regulation agency and government, Their main role is to create and ensure a convenient milieu for the clinical trials conduction, and create an environment based upon a high criterion and norms of safety and protection of the patients and the participants from all the sides in this clinical research , this on making ethical rules and standards and also ethical guidelines and regulations which will be like a Primary Reference in every clinical research.

''Do not abuse the participants'' is the title which should be placed in every clinical research. We also need to take into consideration the sensory and moral sides of the human volunteers who are participating in the clinical research, respect the participants decisions and confidentiality and provide an overall explanation about the clinical trial pathways to the participants, in addition of taking care of the participants after the clinical research in case of any disadvantages outcomes. This gives birth to a variety of responsibilities and ethical cases and invites to create a big number of rational guidelines and ethical standards and rules concerning the process of biopharmaceutical innovation which must be as a non-negotiable law that every biodrug innovation staff should adhere to [4].

Informed consent

During the last era, some of the scientific researches and laboratory experiments framework has been dominated by a lack of responsibility towards patients during the clinical experiments,

either via hiding information and not informing the patients that they are participating in clinical researches or giving the patient false promises of recovery and cure. However, now it is totally different and clear, yet informed consent is an essential issue among the clinical research built on the respect and giving the patient the choice whether to participate in research in accordance with what is mentioned in the Nuremberg Code [5,6]. In the new perspective of the clinical research and trials "uninformed consent" is considered as unethical as well as irresponsible and every clinical research involving human subjects must firstly get the acceptance, the approval, confirmation and the willingness from the subject itself to participate in such clinical research [7].

For the time being, the informed consent is a basic issue, the human subject should be clearly informed and get the precise explanation and be provided with the whole details about the expected benefits, harms and disadvantages of this experience, then given the opportunity to ask any questions or request further clarifications, after that the research team should give him enough time for thinking and considering before starting [8-11]. Only when the patient is provided with the whole detailed information about this research and understand the consequences, advantages, disadvantages of the clinical research he can accept especially that his participation in this research is based on volunteerism and the objective of the research becomes valid and in line with the ethics of the profession [12].

The free consent

Some patients have weak health conditions which push them to join the clinical research. For instance, when the patient is hopeless for the therapy and think that he have no curative chances except joining this study tests, because of economic reasons (he does not have financial resources nor access to treatment), or he considers that participating in this research is the only way to receive a therapy. The researchers and physicians should not use the patient weak conditions as an opportunity to push him to join a study research; physicians should reduce the possibilities of using the patient weakness to persuade him to participate in the clinical trials as much as possible [13]. Indeed, such behave is considered as an unethical way to recruit human subjects for clinical trials.

The participants in a clinical trial should be free in taking their decisions regarding the participation. It is unethical to force somebody to participate in the experiment and do not take into consideration this person feelings and desires towards this clinical trial. For instance, it happened that prisoners have been used in clinical trials. This case is very wide and had a huge controversial debate, new biodrugs are tested on prisoners in reason that these prisoners have no right to choose whether they want or not to participate in this clinical trial. Moreover, they are in the prison cage, they have no rights, so the researchers can exploit their limited freedom, this behavior is undesirable in the public sector and in the research sector since this sort of conducts are totally contrary to human dignity. Even if the prisons are full of inmates, and prisoners had limited freedom or there are many mental illnesses, this does not justify nor give legitimacy to the infringement. Whatever the circumstances, prisoners are human being and must be treated humanely and morally commensurate with the research ethics guidelines [14].

Privacy

Regarding the confidentiality and privacy, the appropriate definition of the privacy is that the physicians and the research trial staff are able to manage the use, monitoring and the uncover of patients information [15]. We have a familiar rules and ethical responsibilities and standards within the healthcare staff and the bio pharmacists framework which should be applied during their profession. They should reassure the patient, make him trusting clinicians and show him that his confidentiality and privacy will be respected and preserved because it is an important biopharmaceutical ethical issues. Moreover, the patient needs to feel this reassurance in order to uncover the hidden sensitive information needed by the clinician because this sensitive information can impact the research efficacy [16].

The information collected during the research should be ethically preserved in privacy and in secret, when a patient takes part in a clinical research, such participation will have a diagnosis and a registration, this also is considered as a private information of the patient which should be kept confidential and all the pharmacists and the trial crew should be highly ethical when practicing their profession [17]. The main ethical behavior of the research staff is to maintain and protect personal and confidential information, they should be highly ethical and do the reciprocity. The patients trusted the researchers and declared their confidentiality, so the researchers also should be truthfully honest and respect the patient's privacy (except in some cases when the patients agree that his privacy can be disclosed and shared for specific and defined reasons). The information of the participants in the trial should be anonymized or protected with a key code to safeguard the confidentiality of individuals and maintain the participants' privacy [18].

Clinical Trial Follow-Up Damage and Compensation

After the research trials, the human subject should be kept under surveillance to observe whether the patient need any additional treatment. Indeed, sometimes we can have effects that require from the clinicians to keep the patient under follow-up and predominantly be turned back to his first therapy, sometimes the clinical trial fails, it is the researchers and the company duty to take in charge the whole responsibility of the human subject wellbeing from all sides as well as guarantee and maintain its rights in case of any failure during or after the experiments [19-21]. Most states refer to the need of informing patients if there is compensation, treatment for injuries after the tests, but there are no uniform law about this issue, there are some which provide the compensation and the follow up and there are others which do not [22,23]. In case of any damage, injury or death resulting from the research, it is the company and the clinicians or the insurance or the sponsors responsibility to provide compensations (whether therapeutic or non-therapeutic) for this clinical trial victims or for their families. There is a big debate and controversy dialog about

this clinical failure results and the unfairness of some researchers and sponsors which do not take responsibility for the caused injuries nor take them into consideration. Moreover, compensate them just with a little compensation.

In Parexel's clinical pharmacology research unit, Northwick Park hospital London, March 2006, a research experiment included eight healthy volunteers, they took a T cell agonist at the first stage [24], it was the first time to test this Te Genero's TGN1412 on human subjects. This clinical trial subjects were divided into two groups, one group included six patients who received the active treatment, and the other two patients received a placebo. Those who received an active treatment have quickly been in multiple catastrophic failure disadvantages, conversely those who were provided with the placebo had no harm [25]. This research unfortunately had a catastrophic ending, those affected and injured due to the failure of this clinical trial have received a very modest and useless compensation comparing to the huge disaster of the clinical research outcomes. Furthermore, this compensation could not even cover the therapy duration for these damages results. Of course, this unethical attitude put the patients (victims) in danger, in a big risk and in a bad position therefore made them exposed to several serious diseases which can affect their health conditions and create problems in their future.

Perspective

Biopharmaceutical innovation and the clinical research and experiment are the basic engine to ameliorate and improve the mankind health. In addition, they are also considered the primary reference for the elimination of a big number of viruses and diseases spread within the community. However, unfortunately we find that the clinical research participants abuse and the neglecting, marginalization of the moral side and the violation of rights of the participant in clinical experiments are totally remarkable.

Importantly, clinical research and giving birth to a new bio drug does not only consist of products and making benefits for the company and earning a big amount of financial profits, but it is first of all a question of adhering to the ethical manners and following the moral and responsible rules and guidelines during the bio drug innovation process, because it is the innovation ethics and responsible guidelines which determine the standards of the patient harm or wellbeing. Therefore, the biodrug innovation teams should devote their whole best for reaching and achieving the high moral and ethical methods before, during and after any biodrug innovation. Such approaches will allow to notice the well-being prevalence, the sincerity and the respect between the healthcare community and the patients. This will also give birth to a kind of cooperation between the healthcare community and the patients which can lead to enhanced public health services.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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