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EUROPEAN UNION REGULATIONS ON MEDICAL RESEARCH

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ОРГАНИЗАЦИЯ МЕДИЦИНСКИХ ИССЛЕДОВАНИЙ В ЕВРОПЕЙСКОМ СОЮЗЕ

Комитеты по этике нуждаются в четко определенной роли в разработке клинических испытаний. Комитеты по этике наилучшим образом обслуживают пациентов (включая участников исследований), действуя в интересах исследования и общественных интересов.

Регуляция Европейского Союза обеспечивает эффективное стимулирование медицинских исследований и клинических испытаний при систематическом контроле за обеспечением безопасности пациентов и участников испытаний, защитой личный данных и достоинства человека.

Introduction

Provision of efficient health care and advancement of modern medicine demands establishment of extensive regulations. The European Union developed regulations on medical research to provide advancement of medical science and to secure safety of clinical research. To address these objectives several questions should be resolved. The first is how to organize ethical and regulatory oversight of medical research to minimize risks. The second is how to ensure quality, efficiency and reliability of medical research. These two objectives may conflict with each

other compromising a pace of the advancement of medical science and safety of clinical research demanding intrinsic risk management of efficient medical trial.

The European Union Regulations

European Union Regulation (EU) No 536/2014 addresses these complex demands [1]. The Regulation authorizes special institution "Ethics Committee" that means an independent organization established in a Member State of the European Union under the laws of that Member State, which has been empowered to give an opinion (assessment) in accordance with the objectives of the Regulation (EU) No 536/2014 [1], and "taking into account attention to the point of view of society (ordinary people), in particular patients or patient organizations" [1, p. 12]. The Regulations (EU) No 536/2014 obliges a sponsor of a clinical trial to adequately monitor a clinical trial in order to ensure the reliability and robustness of the results, and a subject (participant of the trial) safety, taking into account the characteristics of the clinical trial and respect for fundamental rights of subjects. When establishing the extent of monitoring, the characteristics of the clinical trial should be taken into account [1, p. 6].

The EU Innovative healthcare for the 21st century reflects "increased pressure on public budgets, a steady decline in the number of health personnel, higher incidence of chronic diseases and growing demands and expectations from citizens for higher quality services and social care. Deep-rooted structural reforms are needed to ensure the sustainability of the health systems while securing access to services for all citizens. As part of those efforts, Europe must reduce its overall regulatory burden while ensuring safety. eHealth and wellbeing are areas with high growth potential and possibilities for innovation notably by unlocking effective health data exchange" [2, p. 4]. EU health system is affected by significant budgetary limitation. Moreover, ageing population aggravates misbalance between economically productive and socially dependant citizens. Furthermore, rising expectations of citizens and mobility of patients and health professionals complicates healthcare performance. Despite of the challenges the inspiration of innovations in healthcare is a decisive goal to ensure sustained well being of EU nations. To succeed the EU Commission emphasises on "more transparency and empowerment, more skilled workforce, more efficient and sustainable health and care systems, better and more responsive public administrations, new business opportunities and a more competitive European economy." [2, p. 14].

Especial awareness raised by the "Ethics and data protection" recommendation on data protection as a fundamental issue for research ethics

and human right, an essential part of personal autonomy and human dignity, and individually valued and respected. “For this principle to guide the development of today’s information society, data protection must be rigorously applied by the research community.” [3, p.2]. The failure to protect personal data from abuse and loss compromises integrity of patient followed by legal, reputational and financial responsibilities for the data holder. Individual EU-funded research projects processing personal data must comply with EU and national data protection laws. Particular attention required to special sensitive data, profiling, automated decision-making, data-mining techniques, big-data analytics and artificial intelligence having additional risks to the integrity of data subjects [3, p.3].

It is important to emphasize that in the European Union major responsibilities for the conduct of clinical research lay on the EU Member States. A clear distinction is made between the aspects in which Member States should interact in the assessment and in aspects of ethical assessment. That is informed consent or national or local nature and responsibility as well as suitability to local conditions, in which the assessment is made by each Member State individually. As a consequence, the proposed EU legislation does not specify which organizations within the EU Member State approve (or not) a clinical trial. The proposed EU legislation does not directly regulate or harmonize the functioning of the Ethics Committees, does not establish systematic interaction at the operational level between the Ethics Committees in the EU, does not limit the scope of the Ethics Committees’ responsibilities only to ethical issues, because science and ethics cannot be separated. Rather, the EU proposal leaves the member countries themselves an internal organization, the division of responsibilities among the various organizations.

The main thing is that the member countries provide independent, high quality assessment within the time limits as established by legislation. Moreover, it is critical to ensure clarity in the division of tasks that are provided by interaction and cooperation between member countries and tasks that are provided individually by each member country, since are tasks of a national, local or ethnic nature. Directive 2001/20 / EC Ethics Committees defines an ethics committee as an independent body in an EU Member State that composed of health professionals and non-medical members whose task is to protect the rights, safety and well-being of the human subjects who take part in research and to provide assurances to the public in such protection [4]. Ethics Committees of the EU Member States should take the measures necessary to organize and operate ethics committees for obtaining a unanimous opinion within time frame of 60

days. CTR 2014 of Regulation EU No 536/2014 determines that Member States remain free to designate the appropriate organizations for evaluating a clinical trial requests within the law time frame to obtain approval for such a clinical trial. In identifying the appropriate organization (s), the member country should ensure that ordinary people are involved, in particular patients or patient organizations. They must also ensure that the required experts are available. CTR 2014 of Regulation EU No 536/2014 demands that according to international guidelines, the assessment should be carried out jointly by a sufficient number of people who jointly possess the required level of qualifications and experience. The professionals evaluating the clinical trial request must be independent of the sponsor, the research centre, and the investigators who are involved and must be free from other undue influences.

Procedure for granting approval to conduct a clinical trial includes specific steps.

Prior Authorization: a clinical research study must undergo a scientific and ethical review process and must be approved for conduct in accordance with this law of the Member State involved in the specific clinical trial. Member countries should ensure that the time frame and procedures for ethics committee review are consistent with the time frame and procedures required by this law for reviewing a clinical trial application.

Clinical trial application procedure: Day 1 submission through the EU portal Sponsor proposes a „speaker – EU member state" (RMS).

Day 6 – the sponsor is notified of the selection of the speaker country via the EU portal.

Day 10 – the reporting country evaluates the application. That includes a short comments (10 days) and response (5 days).

Clinical Trial Application Review Report: Initial draft of the report within 26 days by the reporting country.

Coordinated review phase (12 days) by other involved member countries.

Each Member must also submit a Part 2 Review Report (mostly ethical) within 45 days, including its conclusion.

Decision to apply for a clinical trial: 1. Each member country involved must notify the sponsor via the EU portal whether significant amendments are approved, conditional or rejected.

The notification must be made by a single decision within 5 days from the date of the report.

Belgian law on clinical trials with drugs for use in the treatment of humans of 04/20/2017 aims at strengthening Belgium's position as a leader in medical research in the EU. Meanwhile, Belgium lags only

behind Denmark in terms of research per capita. Also Belgian regulator reduces the number of ethics committees from current 24 to increase competence of ethics committee's expertise. Accordingly to the latest view of the Belgium regulator the ethics committee is not required to be at the centre of the research. Belgian pilot project on ethics committee performance, similar to France and Germany, established a Voluntary joint pilot project between FAMHP (Federal Agency for Medicines and Health Products – Belgian clinical trials regulator), the College of the future, accredited ethics committees and sponsors for processing applications for clinical trials and significant amendments to drugs for use in humans in the spirit of Regulation (EU) No 536/2014 and the Draft Clinical Trials Act. The Belgium 'College' is an independent body that coordinates the operating ethics committees and is responsible for their quality control system. The College also acts as the point of contact between ethics committees and FAMHP. Belgium experience presents creative possibilities for the European Union Member States execute the objectives raised by the Regulation (EU) No 536/2014 in the most efficient and competitive method.

Conclusion

Ethics committees need a clearly defined role in the design of clinical trials and the Regulation (EU) No 536/2014 and other European Union Regulations and Recommendations establish a complex system to invigorate medical research and clinical trial to the highest scientific efficiency. At the same time the EU Regulations secure risk management and human subject protection including date protection and personal integrity. Ethics committees serve patients and research participants' best by acting in the interest of research and public embedding safety measures as intrinsic part of medical research design. Future effective development of medical science and risk management of research and clinical trials demand further sustained regulations and supervision from European Union Council and Parliament as well as the EU Member States to protect public interests, individual and community safety, competitive healthcare provision and secured ethical observation within ethics committees and public scrutiny performance.

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CULTURĂ ȘI MENTALITATE ÎN VREME DE EPIDEMIE

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CULTURE AND MENTALITY IN TIMES OF EPIDEMIC

In this paper we aim to present that one of the consequences of globalization, regardless of the era in which it took place, be it Antiquity, the Middle Ages or the Modern Age, besides the commercial exchanges and interpersonal relations, there was the appearance of epidemics, of the global diseases. Of these, among which we may mention cholera, typhus, syphilis, leprosy, and plague, the latter one had the most notable effects not only on the lives of men, but also on their way of thinking, and was called, when it arrived in medieval Europe, as Black Death. In this sense, we will try to follow some of the most significant changes, which take place both behaviorally and culturally, but also their political and historical consequences during the installation of the Black Death in Western Europe in the fourteenth and seventeenth centuries.

Introducere

La începutul mileniului III, omenirea, după o relativă siguranţă în plan epidemiologic, care s-a manifestat începând cu anii 1950, a început să reexperimenteze într-o maniră nefastă consecinţele epidemiilor globale.

După SIDA, Ebola şi SARS-CoV-1, în anul 2020 SARS-CoV-2 repune în scenă angoasele pe care omenirea le-a experimentat cu secole în urmă în