Απρ.2020 Τεύχος 19

ΑΡΧΕΙΑ ΕΛ.Ε.Φ.Ι.

Ελληνική Εταιρεία Φαρμακευτικής Ιατρικής

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David Hockney: «Do remember they can't cancel the spring».

30/03/2020

Αγαπητοί συνάδελφοι, μέλη και φίλοι της ΕΛ.Ε.Φ.Ι.

Στόχος μας ως Διοικητικό Συμβούλιο είναι η ΕΛ.Ε.Φ.Ι. να επαγρυπνεί και να συνεισφέρει στην διαχείριση των προκλήσεων του χώρου της βιοιατρικής έρευνας και της δημόσιας υγείας.

Στα πλαίσια της συνεχούς ενημέρωσης και επικοινωνίας μαζί σας αλλά και της κρισιμότητας της πανδημίας COVID-19, θα θέλαμε να σας υποστηρίξουμε με την πλέον πρόσφατη διαθέσιμη πληροφόρηση και βιβλιογραφία για την διεξαγωγή κλινικών μελετών και έρευνας στην τρέχουσα συγκυρία προς όφελος των ασθενών και της δημόσιας υγείας.

Επιπλέον θα θέλαμε να σας ενημερώσουμε ότι παρακολουθούμε στενά και προσεκτικά τις εξελίξεις και για το λόγο αυτό μεταθέσαμε όλες τις επιστημονικές μας εκδηλώσεις στην διάρκεια του Ιουνίου 2020, με την εκτίμηση ότι οι νέες ημερομηνίες είναι οι ασφαλέστερες επιλογές βάσει των σημερινών δεδομένων.

Τέλος, θα θέλαμε να υπενθυμίσουμε να παρακολουθείτε τα νέα της ιστοσελίδας μας www.elefi.gr, να ακολουθείτε την ΕΛ.Ε.Φ.Ι. στο Linkedin: https://www.linkedin.com/company/34933756/admin/και να μας στηρίξετε με την καταβολή της ετήσιας συνδρομής σας μέσω της νέας δυνατότητας ηλεκτρονικής online πληρωμής με πιστωτική/χρεωστική κάρτα μέσω της ιστοσελίδας: https://www.elefi.gr/on-line-payment-2/

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Ελληνική Εταιρεία Φαρμακευτικής Ιατρικής (ΕΛ.Ε.Φ.Ι.)*
Μέλος της Διεθνούς Ομοσπονδίας Συλλόγων Φαρμακευτικής Ιατρικής (IFAPP)

Μαιάνδρου 23, Αθήνα 11528
Τηλ.: 2107211845, 2107243161 (Ιατρική Εταιρεία Αθηνών)
Fax: 2107226100
email president@elefi.gr

* Στην ΕΛ.Ε.Φ.Ι. συμμετέχουν ως μέλη ιατροί, φαρμακοποιοί ή πτυχιούχοι βιολογικών επιστημών, οι οποίοι ασχολούνται με κλινικές μελέτες (έρευνα), φαρμακοεπαγρύπνηση, εγκρίσεις φαρμάκων και με άλλους τομείς της Φαρμακευτικής Ιατρικής.

Evolution of Ethical Principles in the Practice of Pharmaceutical Medicine from a UK Perspective

Αναδημοσίευση από Frontiers in Pharmacology 10:1525 ·January 2020

Thomas Morris*,
Joshua M. Brostoff ,
Peter David Stonier
and Alan Boyd

Faculty of Pharmaceutical Medicine, Royal College of Physicians, London, United Kingdom

Pharmaceutical medicine has evolved to be a distinct medical scientific discipline over time. Pharmaceutical medicine has distinctive features related to complex innovative medicines development activities in an often commercially focused competitive environment. This sometimes uneasy mix of professionalism and commercialization demands of its medical and scientific researchers alike, a focus on strict adherence to ethical standards, guidelines, practices and behaviors in the interest of delivering new, effective, high-quality lifesaving and life-enhancing medicines quickly and reliably to patients in need. To support the speciality, codes of ethical standards and practices have been developed, with several being recently updated. These various codes are outlined in this paper along with relevant historical perspectives and interrelationship with concepts of professionalism. Reflecting the longer history of pharmaceutical medicine as a speciality in the UK and experience of the authors, there is a focus on the UK for the historical perspectives.

OPEN ACCESS

Edited by:

Sandor Kerpel-Fronius,
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Joao Massud,
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Chieko Kurihara,
National Institutes for Quantum and Radiological Science and Technology, Japan

Anthony Kar Hsing Chan,
Pfizer, Ireland

***Correspondence:**

Thomas Morris
thomas.morris18@icloud.com

Specialty section:

This article was submitted to Pharmaceutical Medicine and Outcomes Research, a section of the journal Frontiers in Pharmacology
Received: 23 September 2019
Accepted: 25 November 2019
Published: 15 January 2020

Citation:

Morris T, Brostoff JM, Stonier PD and Boyd A (2020) Evolution of Ethical Principles in the Practice of Pharmaceutical Medicine From a UK Perspective.
Front. Pharmacol. 10:1525.
doi: 10.3389/fphar.2019.01525

BACKGROUND

The last five decades has witnessed an increased involvement of the medical profession in the development, introduction and maintenance of medicines. Alongside this has come a greater recognition of the multi-disciplinary nature of the development of medicines, as well as increased regulatory oversight of the processes and procedures involved. In relatively recent times, pharmaceutical medicine has evolved as a medical scientific discipline dedicated to the discovery, development, evaluation, registration, monitoring and the medical aspects of marketing of medicines (Stonier et al., 2007). In 1976 the Royal Colleges of Physicians of Edinburgh, Glasgow and London established the first Diploma in Pharmaceutical Medicine to be gained by examination after a 2-year training course for pharmaceutical physicians. Despite having physicians working for pharmaceutical companies, contract research organizations and regulatory agencies worldwide during this period, there has been limited awareness of the discipline by many academic and national medical associations, contributing to a slow recognition of pharmaceutical medicine as a distinct medical specialty. A pharmaceutical physician is a trained expert on the medical aspects of research, development, evaluation, registration, safety monitoring, and marketing of medicines in the best interests of patients.

Professional Organisations

There is vigorous debate about what characterizes a professional group or profession, but the following factors are generally regarded as the most important among various authors: a) the possession of abstract specialized knowledge; b) a high degree of individual autonomy; c) authority/influence over customer groups and subordinate occupational groups; d) a degree of altruism; e) a distinction from other occupational groups by higher status and higher pay (Greenwood, 1957; Hashimoto, 2006; Saks, 2012). Professions also are largely self-regulating in the approach they take to ensure that members acquire and maintain the skills and knowledge necessary to perform their role. It is recognized that individual professionals often lose a degree of autonomy when they are employed by large organizations or in government agencies; degrees of authority and influence are also likely to be diminished in such set-

tings. These hindering factors for the professional can also come about from new government regulations and demands of third-party payers that restrict autonomy and influence. Such hindering factors may be more common for pharmaceutical physicians compared to patient-facing clinicians and perhaps argue for the greater need of these individuals to be supported by professional organizations.

The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) was created in 1975 and currently has some 30 affiliated national professional membership associations, representing around 7,000 pharmaceutical physicians and other biomedical professionals involved in medicines development; with the incorporation of non-physician groups being a relatively recent development. IFAPP is a non-profit organisation with the mission to "advance Pharmaceutical Medicine by enhancing the knowledge, expertise and skills of pharmaceutical physicians and other professionals involved in all scientific disciplines involved in the discovery, development, processing and usage of medicines as well as experimental and clinical research worldwide, leading to the availability and appropriate use of medicines for the benefit of patients and society".

In the UK, the Faculty of Pharmaceutical Medicine (FPM) was founded in 1989 as a faculty of the three Royal Colleges of Physicians of the UK. It is a professional membership organisation and standard-setting body, with around 1,500 members and fellows, a quarter based outside the UK. There are currently some 150 pharmaceutical physicians undergoing post-graduate pharmaceutical medicine specialty training (PMST) through the FPM, and over 360 have achieved the outcome Certificate of Completion of Training (CCT) since pharmaceutical medicine was recognized as a medical specialty in 2002. This certificate allows them to be entered onto the specialist register of the UK General Medical Council.

ETHICAL CODES AND GUIDANCE

One characteristic of a profession, especially a healthcare-related profession, is that the behavior of its members is guided by a formal code of ethics. Pharmaceutical medicine is unusual in embracing two parallel but converging ethical frameworks: one concerning individual medical practice, and the other regarding the physician's role in clinical research.

Ethical codes concerning individual clinical practice have evolved since the time of Hippocrates. The principal purpose of such guidance is to assure the best interests of patients and members of the public. These interests must be protected above the need for income and advancement for healthcare practitioners themselves.

The development of clinical research ethics has followed a different path owing to its comparatively recent appearance. The ethics of clinical research have developed reactively, in response either to scandal or to novel scientific techniques (Faden and Beauchamp, 1986; Berg et al., 2001; Emanuel and Grady, 2007; Kimmelman, 2009). Thankfully, the modern trend is towards proactive modification of ethical codes. No longer are they merely to prevent a repeat of sins from the past but are instead forward-looking.

Such codes ideally support individual members of a profession to maintain high professional standards. To achieve this they share two common features:

- They must be prescriptive to a large degree. A descriptive or analytic moral framework provides insufficient support for an individual practitioner. Endorsing and proscribing certain behaviors gives clarity.

- They are based on mid-level ethical principles such as those proposed by Beauchamp and Childress (Holm, 1995; Beauchamp, 2003). Such principles allow for common ground when discussing ethical dilemmas with other stakeholders.

Medical practice ethics for clinicians and researchers come from three levels: global, national, and local. Global codes of ethics include those of the World Medical Association and CIOMS. Most national bodies also produce ethical guidelines for physicians engaging in patient care and in research with ethics codes for individual clinical practice now embedded in national medical regulatory bodies. In the UK the General Medical Council (a regulatory body) and the British Medical Association (a trade union) both provide guidelines on ethics. Many regulatory guidelines and practices (e.g. CIOMS) have worldwide applicability and irrespective of whether or not the concerned physicians have a specialist registration in pharmaceutical medicine.

Local institutional guidelines—often informal or even unstated—are equally important. While many research institutes have policies and procedures relating to ethical research, the tone of research in a hospital, pharmaceutical company, or research facility may be set by a community of peers or by a few senior researchers. Institutional pressure on individual decision-making is well recognized. “Breaking ranks” with established tradition can have unpleasant repercussions.

The shortcoming of the traditional approach is that most codes focus on the moral guidelines of a single profession. However, most pharmaceutical physicians now work in, and are highly reliant on, cross-functional, inter-disciplinary teams to deliver their ultimate goals. The new Ethics Framework from IFAPP seeks to address this shortcoming and applies to scientists as well as physicians working in pharmaceutical clinical development and research arenas. IFAPP recommends that education in ethics should be integrated into the various training courses provided for individuals in these fields. Achievement of professional excellence can then be fostered, and self-identity and professional aspirations supported.

Why a Specific Code of Ethics for Pharmaceutical Physicians?

There are many codes of practice for healthcare professionals, differing by country, by culture, and by role. Berwick and others have called for a unified code of ethics for everybody involved in healthcare, but it seems that such a code may be too broad to help the individual practitioner (Berwick et al., 1997). Many ethical duties apply to all doctors, but we consider that there are two main reasons why a specific code of conduct for pharmaceutical physicians is warranted: their regular involvement in clinical trials of experimental medicines, and their work in commercially focused organizations.

Many clinicians engage in research at some point in their careers, but for only a few is it the mainstay of their job. Pharmaceutical physicians, however, are almost certain to have regular involvement with clinical trials. This can range from early phase trials with experimental medicines, through to late phase confirmatory and post-authorization studies. This heavy involvement in clinical trials is a distinguishing feature of pharmaceutical medicine.

Pharmaceutical physicians also have different communities from other clinicians. Clinician-researchers in hospitals or academia are swimming in the same ethical waters as their peers and co-workers. They are also likely to have been mentored by another clinician-researcher and to have implicitly bought in to a shared set of values. In contrast, pharmaceutical physicians often work

independently from other clinicians, and are embedded within cross-functional teams.

Pharmaceutical physicians frequently have a business element to their job, or work for pharmaceutical companies that rely on commercial success. They can find their role involving conflicts between commercial imperatives and ethical decisions. Many pharmaceutical physicians also work outside of hospitals or academic centers where a code of medical ethics is part of the institutional culture. In these latter cases a physician's research work remains connected to their clinical practice, and both these elements of work are embedded within an institutional framework that is highly focused on the patient and on biomedical research. There is no over-arching need to make a profit and hence less need to focus on applied or useinspired research.

For a pharmaceutical physician in a commercial organization a clash of values can take many forms, perhaps most clearly where for purely commercial reasons a company discontinues development of a drug that seems highly promising. A physician can indeed advocate for continued development, and here ethical and pro-social arguments compete directly with a broader financial interest. Physicians in industry tend to have little freedom to choose or direct the research in an organization. We note of course that the work of a physician in any setting is often constrained by environmental financial factors: for reasons of cost, some procedures or medications may not be available in a particular country, region, or hospital. However in these cases the ethical argument is around resource allocation, and any trade-off is against the well-being of other patients rather than the profit of a private company.

Pharmaceutical physicians working for government agencies can also face organizational pressures. Regulatory agencies have strong cultures, are often part of other governmental agencies, and there can be implicit or explicit pressure to approve or reject new medicines. The physician is acting on behalf of the state rather than on behalf of an individual patient. There are also close ties between the regulator and the industry itself. As the House of Commons Health Committee noted, "the relationship between the industry and the MHRA is naturally close. There are regular interchanges of staff, common policy objectives, agreed processes, shared perspectives and routine contact and consultation" (United Kingdom House of Commons Health Committee, 2005).

IFAPP International Ethics Framework

The new IFAPP International Ethics Framework for Pharmaceutical Physicians and Medicines Development Scientists was formerly known as the International Code of Ethical Conduct for Pharmaceutical Physicians, published in 2003. It was revised in 2016 considering the rapidly changing and increasingly complex scientific environment of medicines innovation and need to adapt ethical conduct to scientific progress. The present revision aims to provide an ethical framework for both pharmaceutical physicians and medicines development scientists about how to manage pro-actively difficult, and frequently new situations responsibly before they become major problems (Kerpel-Fronius et al., 2018). The new environment has led to re-organization of medicines development teams, with closer, more integrated involvement of specialized basic research groups. Advanced therapies including gene and cell therapies, or tissue engineering cannot be applied in clinical practice without fully integrating basic scientists into the development and treatment teams.

Pharmaceutical physicians have always collaborated with other members of research and development teams as well as with regulatory, marketing and

other colleagues in the pharmaceutical industry or regulatory agencies. It is important to address the ethical responsibilities of the entire medicines development team including both basic research and clinical research experts.

We note that pharmaceutical companies are increasingly including ethical practice in their values and mission statements. There is a global shift towards increasing transparency and promotion of ethical practice within the pharmaceutical industry itself (Shaw and Whitney, 2016).

Pharmaceutical physicians and medicines development scientists must always remain aware that the interests of patients and their own employers are best served by an objective scientific attitude and a rigorous ethical approach. IFAPP recognizes that this may place practicing pharmaceutical physicians and scientists in positions that demand considerable determination, and an ethical code can play a vital role in enabling them to reconcile their professional lives with their personal values.

The ethical framework recognizes that some ethical issues are only relevant to pharmaceutical physicians, and an increasing number of challenges must be faced jointly with scientists. For both groups it should be their primary objective to ensure the protection of the dignity, rights, needs and interests of the research participants.

The bioethical principles of Beauchamp and Childress— respect for autonomy, beneficence, non-maleficence and justice —provide a foundation for determining the ethical behavior of both physicians and scientists working in medicines research. They form a basis for balanced ethical judgment in conflict situations, although it is evident that experts in medicines development weigh these principles differently according to the circumstances. Additional ethical principles of relevance to research and development activities include vulnerability, subsidiarity and solidarity, as well as consideration of the duties to the society regarding objective-setting and appropriate research conduct.

The IFAPP Ethics Framework intends to provide an educational background to guide both pharmaceutical physicians and medicines development scientists through their day-to-day deliberations and decision-making whether they practice within a company, contract research organization, academic department, regulatory authority, or work on ethics committees or as independent consultants.

CIOMS Ethical Guidelines for Biomedical Research

The fourth version of the CIOMS Ethical Guidelines for Biomedical Research was published in 2016 (CIOMS). The scope of the 2002 Guidelines was broadened from “biomedical research” to “health-related research” and the guidelines are now entitled ‘International Ethical Guidelines for Health-related Research Involving Humans’. Despite some debate about the way the guidelines were developed, they are broad and inclusive (Schuklenk, 2017; Schuklenk, 2017).

As also noted by IFAPP several developments had taken place since the last version of their Ethical Guidelines, among them:

- The Declaration of Helsinki had been updated to the 7th revision (2013).
- A heightened emphasis on the importance of translational research.
- A need to clarify what counts as fair research in low and middle-income country settings.
- A greater emphasis on community engagement in research.

- An awareness that exclusion of potentially vulnerable groups in many cases has resulted in weaknesses in the evidence base.
- The increase in the research use of big data.

Following extensive evidence retrieval and synthesis processes, international consultation and peer review the latest CIOMS guidelines form a comprehensive reference tool. The document is over 100 pages and includes 25 guidelines with commentary plus appendices providing guidance on items to be included in a protocol and essential information to be provided to prospective research participants.

FPM Guiding Principles and Good Pharmaceutical Medical Practice

The FPM Guiding principles were developed in 2010 and updated in 2014 to provide an ethical framework for medical practitioners practicing in the field of pharmaceutical medicine, whether in industry, regulatory bodies or an academic environment (Bragman et al., 2010). These were derived from the original publication and full report published in 2006 (Bickerstaffe et al., 2006; Bickerstaffe et al., 2006). The document clarified that pharmaceutical physicians are bound by the same ethical standards that apply to all doctors. However, their work leads to some very specific ethical considerations that may not be fully explored in ethical codes based on clinical practice. It clearly placed the doctor's duties to the wider public and the protection of patients and research participants ahead of responsibilities to an individual employer. It also emphasizes the importance of medical leadership in promoting ethical principles and accountability in decision-making.

In 2013, the UK General Medical Council published the Good Medical Practice (GMP) document (General Medical Council, 2013). This forms the core guidance for all registered doctors in the UK and centers on four Domains. 1: Knowledge, skills and performance; 2: Safety and quality; 3: Communication, partnership and teamwork; 4: Maintaining trust. It is supported by a range of explanatory guidance covering fundamental ethical principles that most doctors will use every day e.g. Consent and Confidentiality. There is guidance that may be more relevant to doctors working in certain specialties, or about specific situations that not all doctors will encounter in their career.

The focus of the GMC guidelines is on clinical specialties; pharmaceutical medicine, as highlighted earlier, does bring very specific ethical considerations which may not be fully explored in ethical codes based in clinical medicine. Hence the FPM established a working group to evaluate the needs of pharmaceutical physicians, and later built on the GMC document to create Good Pharmaceutical Medicine Practice (GPMP) in 2008 and updated November 2014, tailored towards the pharmaceutical physician, and explaining how requirements in GMP should be interpreted for those working in pharmaceutical medicine (Good Pharmaceutical Medical Practice, 2014).

GPMP is being reviewed again with an updated document expected in 2020. The Faculty will need to decide if the older Guiding principles document is now redundant as a separate document and should be withdrawn. This is not straightforward as the Guiding Principles were designed foremost to guide those working in pharmaceutical medicine, while GPMP arises from broader medical codes. The underlying principles that guide the protection of patients and research participants, namely; Individuals Come First, Professional integrity and Confidentiality, are completely in line with GMP requirements, however the Guiding Principles goes further in some specific areas. Examples include the need for training in medical ethics and international good clini-

cal practices (GCPs) and promotion of these principles by leadership and example, as well as seeking to raise standards of ethical conduct amongst colleagues and fellow staff. Regulatory Work and Marketing Work are drawn out with examples, e.g. ensuring proposed labeling of a medicinal product accurately reflects the clinical trial data, there is openness and transparency in publication and sharing of research results, and awareness of possible business and commercial pressures. Other specific points are for promotion of all medicines to be supervised by pharmaceutical physicians and be based on objective, ongoing assessment of all the available information. Promotion must be in accord with the labeling and not involve the use of undue pressures or inducements of any nature on healthcare workers to prescribe a product.

Although a document based on GPMP has more impact and authority for UK registered doctors, the Guiding Principles have the great merits of being relatively short, developed specifically for Pharmaceutical Medicine, and relevant globally wherever FPM fellows and members work.

Embedding Ethical Attitudes in Pharmaceutical Physicians: Clear Communication, Training and Support

A significant challenge is how to embed codes of ethics and standards into the way that professionals think and behave on a day-to-day basis.

Clarity is an important feature of ethical codes. The content must be communicated to those who require it, and length and ease of reading of documents can be substantial barriers to their reading and understanding.

The FPM has made ethical practice a part of its curriculum. All those who train in pharmaceutical medicine must, over the course of their PMST programme, demonstrate integrity and ethical practice. This begins the process of new pharmaceutical physicians developing an ethical grounding.

The FPM sought to develop the original guiding principles as a short document, refer to them in Faculty and other meetings, send printed copies to members and send periodic links to electronic copies available on the website. Alongside the Code and supporting Continuing Professional Development, the FPM has launched a support network and commitment to support those working in the pharmaceutical medicine arena to make the best decisions relating to ethics, probity and integrity.

Future Considerations

We expect ethical principles related to pharmaceutical medicine and health research in general to continue to evolve with time. With the future advancements in treatment approaches and paradigms this seems inevitable and particular ethical issues will surround areas such as advanced therapies utilizing cell and gene therapies and regenerative medicines as these receive an ever increasing number of approvals. Therapies based on gene editing techniques will also bring their own ethical issues which as a specialty, we will have to face. The use of ‘Big Data’, AI and Real World Data will also require special considerations as far as ethics is concerned; questions such as who actually owns and who should own these data, and how consent is obtained to use such data will need to be debated.

In conclusion, the last fifty years has seen great strides in the development of codes of ethical standards and practices plus support structures for the speciality of pharmaceutical medicine and medicines development. It seems clear that ethical issues and principles will continue to be ever present and continue to evolve. Newer entrants into pharmaceutical medicine should also

be encouraged to participate in this evolution. We support the sharing of the principles of medical ethics at undergraduate level for future physicians and healthcare scientists.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct and intellectual contribution to the work, and approved it for publication.

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. The handling editor is currently organizing a Research Topic with one of the authors PS, and confirms the absence of any other collaboration.

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic

Guidance for Industry, Investigators, and Institutional Review Boards

March 2020

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov/. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on clinical trial conduct during the COVID-19 pandemic, please email Clinicaltrialconduct-COVID19@fda.hhs.gov.

U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) Center for Devices and Radiological Health (CDRH) Office of Good Clinical Practice (OGCP)

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Introduction

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from threats including emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support continuity and response efforts to this pandemic.

FDA is issuing this guidance to provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity during the COVID-19 pandemic. The appendix to this guidance further explains those general considerations by providing answers to questions about conducting clinical trials that the Agency has received during the COVID-19 pandemic.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Services (PHS) Act.

Given this public health emergency, and as discussed in the Notice in the Federal Register of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," available at https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARSCoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[1] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[2]

FDA recognizes that the COVID-19 pandemic may impact the conduct of clinical trials of medical products. Challenges may arise, for example, from quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product[3], or other considerations if site personnel or trial subjects become infected with COVID-19. These challenges may lead to difficulties in meeting protocol-specified procedures, including administering or using the investigational product or adhering to protocol-mandated visits and laboratory/diagnostic testing. FDA recognizes that protocol modifications may be required, and that there may be unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures. Although the necessity for, and impact of, COVID-19 control measures on trials will vary depending on many factors, including the nature of disease under study, the trial design, and in what region(s) the study is being conducted, FDA outlines the following general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity. The appendix further explains those general considerations by providing answers to questions about conducting clinical trials that the Agency has received during the COVID-19 pandemic.

III. Discussion

A. Considerations for ongoing trials:

- Ensuring the safety of trial participants is paramount. Sponsors should consider each circumstance, focusing on the potential impact on the safety of trial participants, and modify study conduct accordingly. Study decisions may include those regarding continuing trial recruitment, continuing use of the investigational product for patients already participating in the trial, and the need to change patient monitoring during the trial. In all cases, it is critical that trial participants are kept informed of changes to the study and monitoring plans that could impact them.
- Sponsors, in consultation with clinical investigators and Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs), may determine that the protection of a participant's safety, welfare, and rights is best served by continuing a study participant in the trial as per the protocol or by discontinuing the administration or use of the investigational product or even participation in the trial. Such decisions will depend on specific circumstances, including the nature of the investigational product,

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1 Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).

2 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

3 For the purposes of this guidance, the term *investigational product* refers to human drugs and biological products, and medical devices.

the ability to conduct appropriate safety monitoring, the potential impact on the investigational product supply chain, and the nature of the disease under study in the trial.

- Since trial participants may not be able to come to the investigational site for protocol-specified visits, sponsors should evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible, and would be sufficient to assure the safety of trial participants. Sponsors should determine if in-person visits are necessary to fully assure the safety of trial participants (for example to carry out procedures necessary to assess safety or the safe use of the investigational product appropriately); in making the decision to continue use or administration of the investigational product, the sponsor should consider whether the safety of trial participants can be assured with the implementation of the altered monitoring approach.
- In some cases, trial participants who no longer have access to investigational product or the investigational site may need additional safety monitoring (e.g. withdrawal of an active investigational treatment).
- The need to put new processes in place or to modify existing processes will vary by the protocol and local situation. For example, this assessment could include consideration of whether it is appropriate to delay some assessments for ongoing trials, or, if the study cannot be properly conducted under the existing protocol, whether to stop ongoing recruitment, or even withdraw trial participants.
- COVID-19 screening procedures that may be mandated by the health care system in which a clinical trial is being conducted do not need to be reported as an amendment to the protocol even if done during clinical study visits unless the sponsor is incorporating the data collected as part of a new research objective.
- Changes in a protocol are typically not implemented before review and approval by the IRB/IEC, and in some cases, by FDA. Sponsors and clinical investigators are encouraged to engage with IRBs/IEC as early as possible when urgent or emergent changes to the protocol or informed consent are anticipated as a result of COVID-19. Such changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19) may be implemented without IRB approval or before filing an amendment to the IND or IDE, but are required to be reported afterwards. FDA encourages sponsors and investigators to work with their IRBs to prospectively define procedures to prioritize reporting of deviations that may impact the safety of trial participants.
- The implementation of alternative processes should be consistent with the protocol to the extent possible, and sponsors and clinical investigators should document the reason for any contingency measures implemented. Sponsors and clinical investigators should document how restrictions related to COVID-19 led to the changes in study conduct and duration of those changes and indicate which trial participants were impacted and how those trial participants were impacted.
- Changes in study visit schedules, missed visits, or patient discontinuations may lead to missing information (e.g., for protocol-specified procedures). It will be important to capture *specific* information in the case report form that explains the basis of the missing data, including the relationship to

COVID-19 for missing protocol-specified information (e.g., from missed study visits or study discontinuations due to COVID-19). This information, summarized in the clinical study report, will be helpful to the sponsor and FDA.

- If scheduled visits at clinical sites will be significantly impacted, certain investigational products, such as those that are typically distributed for self-administration, may be amenable to alternative secure delivery methods. For other investigational products that are normally administered in a health care setting, consulting FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel) is recommended. In all cases, existing regulatory requirements for maintaining investigational product accountability remain and should be addressed and documented.
- With respect to efficacy assessments, FDA recommends consultation with the appropriate review division regarding protocol modifications for the collection of efficacy endpoints, such as use of virtual assessments, delays in assessments, and alternative collection of research-specific specimens, if feasible. For individual instances where efficacy endpoints are not collected, the reasons for failing to obtain the efficacy assessment should be documented (e.g., identifying the specific limitation imposed by COVID-19 leading to the inability to perform the protocol-specified assessment).
- If changes in the protocol will lead to amending data management and/or statistical analysis plans, the sponsor should consider doing so in consultation with the applicable FDA review division. Prior to locking the database, sponsors should address in the statistical analysis plan how protocol deviations related to COVID-19 will be handled for the prespecified analyses.
- If planned on-site monitoring visits are no longer possible, sponsors should consider optimizing use of central and remote monitoring programs to maintain oversight of clinical sites.

B. In general, and if policies and procedures are not already in place for applicable trials:

- Sponsors, clinical investigators, and IRBs should consider establishing and implementing policy and procedures, or revise existing policy and procedures, to describe approaches to be used to protect trial participants and manage study conduct during possible disruption of the study as a result of COVID-19 control measures at study sites. Changes to policy and procedures could address, but not be limited to, impact on the informed consent process, study visits and procedures, data collection, study monitoring, adverse event reporting, and changes in investigator(s), site staff, and/or monitor(s) secondary to travel restrictions, quarantine measures, or COVID-19 illness itself. Policy and procedures should be compliant with applicable (regional or national) policy for the management and control of COVID-19. Depending upon the nature of the changes described above, a protocol amendment may be required under the applicable regulations.

C. For all trials that are impacted by the COVID-19 pandemic:

Sponsors should describe in appropriate sections of the clinical study report (or in a separate study-specific document):

1. Contingency measures implemented to manage study conduct during disruption of the study as a result of COVID-19 control measures.
2. A listing of all participants affected by the COVID-19 related study disruption by unique subject number identifier and by investigational site, and a

description of how the individual's participation was altered.

3. Analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., trial participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study.

Robust efforts by sponsors, investigators, and IRBs/IECs to maintain the safety of trial participants and study data integrity are expected, and such efforts should be documented. As stated above, FDA recognizes that protocol modifications may be required, including unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures. Efforts to minimize impacts on trial integrity, and to document the reasons for protocol deviations, will be important.

IV. Additional Resources

For further questions on clinical trial conduct during the COVID 19 pandemic, please email Clinicaltrialconduct-COVID19@fda.hhs.gov.

Contact information for FDA's review divisions is as follows:

CDER: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-new-drugs

CBER: https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/contacts-center-biologics-evaluation-research-cber#indcont

CDRH: https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization

Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic

https://www.ema.europa.eu/en/documents/press-release/guidance-sponsors-how-manage-clinical-trials-during-covid-19-pandemic_en.pdf

Version 2 (27/03/2020)

Key changes from v1 (20-03-2020): additional clarification on obtaining informed consent; link to methodological guidance on statistical considerations in relation to COVID-19 pandemic; advice on IMP stocks, safety reporting, conduct of audits; temporary halts.

The European Medicines Agency (EMA), Good Clinical Practice (GCP) Inspectors Working Group, the Clinical Trials Facilitation and Coordination Group [CTFG, a working group of the Heads of Medicines Agency (HMA)], the Clinical Trials Expert Group (CTEG, a working group of the European Commission representing Ethics Committees and National Competent Authorities) and the European Commission (EC) acknowledge the impact of COVID-19 on the health system and broader society, and the impact it may have on clinical trials and trial participants[1]. Extraordinary measures may need to be implemented and trials adjusted due to e.g. trial participants being in self-isolation/quarantine, limited access to public places (including hospitals) due to the risk of spreading infections, and health care professionals being committed to critical tasks. Therefore, EMA, EC and HMA strongly support the efforts of the GCP Inspectors' Working Group for developing a harmonised EU/EEA-level guidance to mitigate the negative effects of the COVID-19 pandemic on the conduct of clinical trials.

The situation is evolving, and pragmatic actions may be required to deal with the challenges of conducting research, and in ensuring the rights, safety and wellbeing of participants. The points mentioned below are intended to provide guidance for all parties involved in clinical trials during this time.

Due to the urgency, this guidance is issued without prior public consultation. The sponsors should note that due to the rapidly evolving situation further updates to this guidance are possible and likely.

Sponsors and investigators need to take into account that there might be specific national legislation and guidance in place[2], which they should consult and which can be used to complement this guidance, or, with respect to particular matters may take priority over these recommendations. This document is however seeking to include most of the current guidance across Member States with the aim to serve as an EU-level harmonised set of recommendations. Hence, this guidance is agreed by the Clinical Trials Expert Group (CTEG) of the European Commission supported by the EMA, the Clinical Trials Facilitation and Coordination Group (CTFG) of the Heads of Medicines Agencies (HMA) and the GCP Inspectors' Working Group coordinated by the EMA.

1. Introduction

Various challenges exist which result in restrictions of visits to healthcare fa-

1 The word « participant » is used in this text as a synonym for the term "subject", defined in Directive 2001/20/EC as " an individual who participates in a clinical trial as a recipient of the investigational medicinal product or a control".

2 Links to national recommendations can be found at CTFG website (https://www.hma.eu/ctfg.html).

cilities, increased demands on the health service and changes to trial staff availability. Participants may also be required to self-isolate, which introduces difficulties for Investigators to maintain their medical oversight. These challenges could have an impact on the conduct of trials, such as the completion of trial assessments, completion of trial visits and the provision of Investigational Medicinal Products (IMPs).

The impact of COVID-19 on ongoing trials, on opening a new trial site in an existing trial, ongoing recruitment and continued involvement of participants in the trial, or on starting of new trials needs to be considered. This evaluation should take into account national recommendations and restrictive measures including travel restrictions and confinements of trial participants and trial staff and the availability of trial staff to perform visits, enter data in the Case Report Form (CRF), notify serious adverse events and, more generally, follow the protocol. The ability to confirm eligibility and to conduct key safety assessments and trial evaluation is of particular importance. Actions should be proportionate and based on benefit-risk considerations, on contingency provisions taken nationally and locally by the authorities with priority given to the impact on the health and safety of the trial participant. Where a trial participant is unable to attend the site, other measures, such as home nursing, if possible given social distancing needs, or contact via phone or telemedicine means, may be required to identify adverse events and ensure continuous medical care and oversight. However, the limitations and risks of such methods and the requirements for data protection should be taken into account and such alternative arrangements need to be adequately documented.

The International Committee of Medical Journal Editors has made clear that in the event of public health emergencies, information with immediate public health implications should be disseminated without concern that this will preclude subsequent consideration for publication in a journal.[3]

2. Initiating new trials

The feasibility of starting a new clinical trial or including new trial participants in an ongoing trial should be critically assessed by sponsors. **Additional risks to participants should be addressed in the risk benefit section of the protocol along with risk mitigation measures (see also "risk assessment" below)**.

3. Changes in ongoing trials

The sponsors should consider in their risk assessment whether the following measures could be the most appropriate during COVID-19. Measures should generally be agreed with investigators and could be:

- Conversion of physical visits into phone or video visits, postponement or complete cancellation of visits to ensure that only strictly necessary visits are performed at sites;
- A temporary halt of the trial at some or all trial sites;
- Suspension or slowing down of recruitment of new trial participants;
- Extension of the duration of the trial;
- Postponement of trials or activation of sites that have not yet been initiated;
- Closing of sites. In case it is not feasible for a site to continue participation

3 http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/overlapping-publications.html

at all, the sponsor should consider if the trial site should be closed and how this can be done without compromising safety and well-being of patients already participating and data validity;

- If unavoidable (it should be justified that this is a truly exceptional situation based on the personal risk-benefit ratio for the individual trial participant), transfer of participants to investigational sites away from risk zones, or closer to their home, to sites already participating in the trial, or new ones could occur. Initiation of new trial sites is generally not expected in the current situation unless no other solution exists for the trial participant. If there is an urgent need to open a new trial site for critical trial visits for example outside the hospital, this may be implemented as an urgent safety measure (USM) first, with a substantial amendment (SA) application submitted later as for the approval and initiation of an additional site later. The exceptional situation could involve e.g. a trial participant who urgently needs to stay in the trial and for whom no other sites are available. In such cases, it is important that trial participants as well as investigators (both receiving and sending) are in agreement about the transfer and that the receiving site has the possibility to access previously collected information/collected data for the trial participant and that any eCRF can be adjusted accordingly to allow the receiving site to enter new data. The impact on trial participants should be considered and arrangements made to e.g. appropriate transportation; transport;
- There may be a need for critical laboratory tests, imaging or other diagnostic tests to be performed for trial participant safety. In case the trial participant cannot reach the site to have these performed, it is acceptable that laboratory, imaging or other diagnostic tests are done at a local laboratory (or relevant clinical facility for other tests) authorised/certified (as legally required nationally) to perform such tests routinely (e.g. blood cell count, liver function test, X-ray, ECG etc.), if this can be done within local restrictions on social distancing. The sites should inform the sponsor about such cases. Local analysis can be used for safety decisions. If this is a trial endpoint and the samples cannot be shipped to the central lab, analysis should be performed locally and then explained, assessed and reported in the clinical study report following ICH E3.

The changes above may also be initiated by the investigator sites contacting the sponsor. There might also be cases where the current principal investigator (PI) of a site is indisposed for a period and may need to delegate parts of his/her duties temporarily to e.g. a sub-investigator. Any permanent changes in PI should be submitted to the National Competent Authority (NCA) and Ethics Committees as appropriate and as soon as possible.

When changes in ongoing trials are considered, the overall well-being and best interests of the participant should be also considered, for example in trials for patients with life-threatening or severely debilitating conditions, when participants require to stay on trial treatment. In cases, when trial halt, even if temporary only, can potentially compromise the overall well-being and best interest of trial participants, all measures need to be considered and taken to avoid this.

Changes should be well balanced, taking into account in particular the legitimate interest of trial sites in avoiding further burden in terms of time and staffing during the COVID-19 pandemic.

Please note that prospective protocol waivers remain unacceptable and that patients should not be included in trials without proper eligibility assessment, including performance of planned tests, and written informed consent ac-

cording to national laws and regulations.

Compliance with the trial protocol should be ensured to such an extent that an ongoing benefit-risk assessment for the clinical trial and its participants is still possible. The impact of protocol changes on clinical data interpretability needs to be properly assessed by the sponsor and the overall evidence generation package could be subsequently discussed within scientific advice with regulatory authorities. A relevant guidance on the implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trialtrialstrial by the CHMP Biostats working party was published on March 25 2020[4].

4. Safety Reporting

Sponsors are expected to continue safety reporting in adherence to EU and national legal frameworks (Directive 2001/20[5]; CT-3[6]). When per protocol physical visits are reduced or postponed, it is important that the investigator continue collecting adverse events from the participant through alternative means , e.g. by phone.

5. Risk assessment

The safety of the participant is of primary importance, and risks of involvement in the trial, in particular with added challenges due to COVID-19, should be weighed against anticipated benefit for the participant and society (ref: principle 2.2 of ICH GCP).

All decisions to adjust clinical trial conduct should be based on a risk assessment by the sponsor (ICH GCP section 5.0). It is expected that the sponsor performs a risk assessment of each individual ongoing trial and the investigator of each individual participant and implements measures which prioritise subject safety and data validity. **In case these two conflict, subject safety always prevails.** These risk assessments should be based on relevant parties' input and should be documented on an ongoing basis. It is important that sponsors in their risk assessment consider prioritisation of critical tasks in the clinical trial and how these are best maintained.

The sponsor should reassess risks as the situation develops. This reassessment should also be documented.

It is possible that with the escalation of the pandemic, local circumstances lead to a local change in risk assessment, therefore the need to implement additional measures may arise, and an investigator-driven risk assessment might be necessary (and communicated to the sponsor).

Regarding participants enrolled in ongoing clinical trials who may be determined as being a risk group for COVID-19 or who are in trials involving treatments, which may increase such risk, the potential impact of COVID-19 on these participant groups should be carefully considered when deciding to start or continue such trials.

6. Communication with authorities

Priority is given to any (new) clinical trial applications for the treatment or

4 https://www.ema.europa.eu/en/implications-coronavirus-disease-covid-19-methodological-aspects-ongoing-clinical-trials

5 Directive 2001/20/EC (OJ L 121, 1.5.2001) https://ec.europa.eu/health/documents/eudralex/vol-10_en

6 Communication from the Commission ('CT-3'; 2011/C 172/01) https://ec.europa.eu/health/documents/eudralex/vol-10_en

prevention of COVID-19 infection, and/or substantial amendment applications to existing clinical trials necessary as a result of COVID-19.

In case the risk assessment leads to actions that affect the trial as described below in a) and b), the relevant competent authorities and Ethics Committees must be informed in accordance with the Directive 2001/20/EC and national laws:

a) When a new event is likely to have a serious effect on the benefit-risk balance of the trial, it is possible that immediate actions are required by the sponsor and investigator to protect the subjects against immediate hazard. These, urgent safety measures may be taken without prior notification, but the information needs to be provided *ex post* to the National Competent Authority (NCA) and the Ethics Committee as soon as possible (CT-1[7]: EC 2010/C82/01; 3.9). In this communication, the sponsor is expected to provide adequate information on the cause, the measures taken and the plan for further actions;

b) If changes are likely to affect the safety or well-being of the participants and/or the scientific value of the trial, but do not require immediate action from sponsor or investigator, it should be possible to submit them as substantial amendment applications. Sponsors are encouraged to take into account the limited capacity of assessors, and submit only high quality, complete applications containing only the necessary changes. Over-reporting should be avoided (Art. 11b of Directive 2001/20/EC CT-1section 3.9).

c) Even when a trial is put on hold for reasons not linked to participant safety (as covered by a) and b)), e.g. to avoid unnecessary strain on health care professionals, the sponsor is expected to notify NCAs and Ethics Committees, unless national regulatory guidance instructs otherwise.[8]

Aggregated submissions to National Competent Authorities and Ethics Committees are encouraged.

Unless otherwise advised by relevant authorities, it is recommended to mark any contact clearly with 'COVID-19' in the subject field.

7. Agreement with and communication to sites and participants

Changes to trial conduct should be agreed with and communicated clearly to investigator sites. To support implementation by sites, it is important that changes and local implications are made clear, including marking of changed documents with track changes. Agreements may be documented as e-mail exchange.

In addition, trial participants should be informed by the investigator, in time, about changes in the conduct of the clinical trial relevant to participants (e.g. cancellation of visits, change in laboratory testing, delivery of IMP).

8. Changes to informed consent

The informed consent procedure in all trials needs to remain compliant with the trial protocol as well as with EU and national rules. It is acknowledged that national provisions and approaches differ.

Sponsors should be mindful of the current pressure on the medical profession and should carefully assess the pertinence of adding new subjects in ongoing

7 Communication from the Commission - ('CT-1') (2010/C 82/01)

8 Links to national recommendations can be found at CTFG website (https://www.hma.eu/ctfg.html)

clinical trials. Absolute priority should be given to clinical trials for the prevention or treatment of COVID-19 and COVID19- related illnesses, or trials on serious diseases with no satisfactory treatment option. In case a sponsor plans to initiate a trial aiming to test new treatments for COVID-19, advice should be sought on alternative procedures to obtain informed consent, as it is likely that the physical consent cannot leave the isolation room, and therefore is not appropriate as trial documentation.

However, the following specific aspects should be taken into account with trials involving COVID-19 patients.

If written consent by the trial participant is not possible (for example because of physical isolation due to COVID-19 infection), consent could be given orally by the trial participant (Art 2(j) of Directive 2001/20/EC) in the presence of an impartial witness. In such cases, the witness is required to sign and date the informed consent document and the investigator is expected to record how the impartial witness was selected.

In addition, it could be considered that the trial participant and the person obtaining consent sign and date separate informed consent forms. In either case, all relevant records should be archived in the investigator site's Trial Master File. A correctly signed and dated informed consent form should be obtained from the trial participant later, as soon as possible.

Where potential COVID-19 trial participants lack capacity to consent due to the severity of their medical condition, or when minors are included, consent has to be obtained from the legal representative(s) according to the Articles 4 and 5 of Directive 2001/20/EC and national rules.

In case of acute life-threatening situations, where it is not possible within the therapeutic window to obtain prior informed consent from the patient (or her/his legal representatives(s)), informed consent will need to be acquired later, when this is allowed in national legislation. In these cases, the investigator is expected to record why it was not possible to obtain consent from the participant prior to enrollment.

For other ongoing trials, there may be a need to re-consent already included trial participants. However, avoid the need for trial participants to visit investigator sites for the sole purpose of obtaining re-consent. If re-consents are necessary for the implementation of new urgent changes in trial conduct (mainly expected for reasons related to COVID-19), alternative ways of obtaining such re-consents should be considered during the pandemic e.g. contacting the trial participants via phone or video-calls and obtaining oral consents supplemented with email confirmation. Approved updated patient information sheet and consent 7 form should be provided to trial participants by e-mail, mail or courier before re-consent is obtained. Any consent obtained this way should be documented and confirmed by way of normal consent procedures at the earliest opportunity when the trial participants will be back at the regular sites.

Any validated and secure electronic system already used in the trial in the particular member state for obtaining informed consent can be used as per usual practice and if in compliance with national legislation.

9. Changes in the distribution of the IMP

Changes in the distribution of the IMP may be necessary to remove avoidable visits to sites and to provide the trial participants with needed treatments. Sponsors must assess the risks relating to the product and consider any alternative shipping and storage arrangements.

Such measures raise various practical considerations, including whether the IMP is appropriate for administration and general storage at the trial participant's home, how the stability of the product will be maintained during transit (especially for cold chain product), how safe custody of product will be ensured and how IMP accountability and the evaluation of compliance to treatment (if appropriate) will be managed.

The overriding objective of all changes in distribution is to provide trial participants with the IMP and other medications categorised as non-IMPs as needed according to the trial protocol to ensure the right, safety and well-being of trial participants as well as the integrity of the clinical trial.

Changes in distribution of IMP may include:

- The following measures could be considered provided that they do not create shortages of marketed medicinal products:
  - Larger amounts of trial medications than normally foreseen can be provided to the participant (in particular IMP, when prepared specifically for the purposes of the trial). This is to sustain the trial participant for a longer period and thereby avoid non-critical visits by the participant to the investigator site. This may be done providing that the continuation of treatment is under adequate supervision of the responsible investigator.
  - It is recommended for all IMPs and non-IMPs in clinical trials that appropriate stock is maintained to ensure treatment in case of distribution failure;
- In case of urgent shortage of IMP at some sites or transfer of trial participants from one site to another clinical trial site, there might be a need to potentially re-distribute the IMP between sites in accordance with GMP annex 13 (section 47). This should only be considered in cases where a direct distribution of the IMP to a trial site by the usual distributor is not possible or in the exceptional circumstance where a trial participant is transferred from one site to another. Sponsors should assess whether sites can handle and control such a re-distribution process, especially in case of restricted conditions for storage such as the need for specific conditions other than room temperature (e.g. +2-8° C). Re-distribution should follow a written procedure established in cooperation with the Qualified Person or the person responsible for distribution of the IMP, and sites should be provided with sufficient information to ensure that the process can be performed securely. Associated records should be included in the transfer;
- In line with the reduction of physical site visits, we foresee that there will be a need for delivery of the IMP directly to trial participants during the COVID-19 pandemic to avoid that the trial participant has to reach the site with the consequent risk of spreading/acquiring infection. The delivery is generally expected to happen from investigator sites to trial participants.
- Direct from sponsor to trial participant IMP delivery is accepted only in a few Member States and strictly during this emergency situation. The sponsor should check the NCA guidance regarding the possibility of direct sponsor to trial participant shipment, as it is likely that such measures can only be implemented under specified conditions (e.g. agreement with sites, dedicated couriers with procedures to only allow delivery directly to a trial participant or his/her carer, solid shipment and receipt procedures, informed consent provisions if necessary for the sponsor's third party to handle personal information etc.), and for a limited period. Alternative shipping and storage arrangements should not compromise

the treatment blinding.

Changes in IMP distribution are often associated with additional changes (e.g. in the visits schedule per protocol or replacement of physical visits with virtual ones (eg. through telephone calls)). Such changes need to be reflected in the protocol and communicated to regulatory bodies as described in section 6.

10. Changes in the distribution of in vitro diagnostic and medical devices

It is important to ensure the availability of those in vitro diagnostic devices and medical devices, which are essential for the conduct of the clinical trial (for example to allow enrolment, monitoring trial participants' safety and treatment efficacy, providing data for trial endpoints). Therefore, it is recommended that appropriate stock of these devices is maintained in case of distribution failure, if this can be done without posing any risk to the treatment of patients outside of the trial under standard clinical care. In addition, changes in the distribution of these devices between trial sites may be necessary.

11. Changes to monitoring

Certain sponsor oversight responsibilities, such as monitoring and quality assurance activities need to be re-assessed and temporary, alternative proportionate mechanisms of oversight may be required. The extent of on-site monitoring, if it remains feasible, should take into account national and local restrictions, the urgency (e.g. source data verification can often be postponed) and the availability of site staff, and should only be performed as agreed with investigator sites. The burden of the introduction of any alternative measures for the site staff and facilities should also be considered in order to strike an acceptable balance between appropriate oversight and the capacity of and possibilities at the site. Possible temporary, alternative measures could include:

- Cancelling or postponing of on-site monitoring visits and extending of the period between monitoring visit;
- Implementing phone and video visits (without increased burden to the investigator site and taking into account trial participant integrity and the applicable Directive and legislation thereon/on privacy);
- Adapting the on-site monitoring plan when it is impossible to follow, supplementing it with (additional/increased) centralised monitoring and central review of data if possible and meaningful;
- Remote site selection visits and investigator training for critical trials (without unnecessarily increased burden to the investigator site).

Results of adjusted monitoring/review measures should be reported to the sponsor in monitoring reports and in the clinical study report.

It is essential that robust follow-up measures are planned and ready to be implemented when the situation is normalized. This should likely include increased on-site monitoring for a period that is sufficient to ensure that the impact of the reduced monitoring could be rectified and problems resolved or properly documented for reporting in the clinical study report.

So-called remote source data verification (e.g. providing sponsor with copies of medical records or remote access to electronic medical records) is currently not allowed in most Member States as it might infringe trial participants' rights. In addition, provision of redacted/ de-identified pdfs files will not be

acceptable as it puts disproportionate burden on site staff.

Nevertheless, since the coronavirus emergency situation and containment measures are likely to last for a prolonged period, several NCAs have started to look into temporary options related to remote access and conditions for such, providing that methods can be used that restricts access to participants' trial records, in line with the principles of necessity and proportionality. This should however also be clarified with other relevant authorities in this area (such as, without limitation, Ethics Committees and data protection agencies) and is consequently not allowed unless a member state has given specific guidance allowing this.

12. Changes to auditing

In the current situation, audits should in general be avoided or postponed. Audits should only be conducted if permitted under national, local and/or organizational social distancing restrictions. For critical trials, on-site visits as well as remote audits can be considered, after agreement with the investigator and if the audits are assessed as essential, e.g. triggered audits with the purpose of investigating serious non-compliance.

13. Protocol deviations

We acknowledge that the COVID-19 situation is likely to introduce more protocol deviations than normal. We expect that the sponsor escalates and manages such protocol deviations in accordance with their standard procedures. A proportionate approach will be taken by the GCP inspectors when such deviations are reviewed during inspections, in particular where the best interest of the participant is maintained, and the participant is not put at risk.

An increase in protocol deviations in relation to the COVID-19 situation will in itself not trigger the actions required by GCP § 5.20. They will however need to be assessed and reported in the clinical study report, following ICH E3.

14. Reimbursement of exceptional expenses

Taking into account this exceptional situation, if, in order to implement urgent measures for the protection of participants involved in a clinical trial, expenses may arise which may be borne initially by the participants, these should typically be compensated subsequently by the sponsor via the investigator. If additional financial compensation is provided to sites/investigators (e.g. to cover the cost of using couriers for IMP delivery), this needs to be documented and performed according to national legislation. Handling of reimbursement of such expenses should follow national legislation and/or guidance.

15. Initiation of new trials aiming to test new treatments for COVID-19

The Member States support the submission of large, multinational trial protocols for the investigation of new treatments for COVID-19[9].

In addition, sponsors are encouraged to consider the submission of such applications for an accelerated Voluntary Harmonisation Procedure[10] (VHP) assessment when possible. In order to avoid or minimise delays due to the har-

9 https://www.ema.europa.eu/en/news/call-pool-research-resources-large-multi-centre-multi-arm-clinical-trials-generate-sound-evidence

10 https://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2016_06_CTFG_VHP_guidance_for_sponsor_v4.pdf

monised review, sponsors are recommended to prospectively contact the proposed Ref NCA to explore the feasibility of an accelerated VHP (plus) process.

It should be noted that the developers of medicines or vaccines are invited to contact EMA as soon as possible with information about their proposed development by emailing to 2019-ncov@ema.europa.eu . EMA provides a full fee waiver and a fast-track procedure for scientific advice[11].

11 https://www.ema.europa.eu/en/news/covid-19-developers-medicines-vaccines-benefit-free-scientific-advice

COVID-19 pandemic: IFAPP recommendations to its members

To our members,

IFAPP is aware of the need for a coordinated use of resources including our affiliated biomedical professionals to combat COVID-19, both in terms of the scientific effort to produce vaccines and treatments, and in their experience in clinical settings and patient care.

At the current time we understand those employed by pharmaceutical companies or contracted by them, especially those involved in ongoing research and clinical trials, might be valuable in this coordinated fight.

In a joint initiative with the Faculty of Pharmaceutical Medicine and the IFAPP Academy, at the current time IFAPP is recommending that:

- All biomedical professionals employed by pharmaceutical companies and regulatory bodies must follow their organizational guidance and ensure that patient safety is not compromised;
- Pharmaceutical physicians should use their best judgement as to where their own skills and knowledge are best used. This may be in a scientific capacity within their respective organizations or by returning to clinical practice;
- Depending on their personal circumstances, pharmaceutical physicians who have relinquished their licence to practice or have retired and de-registered in the last three years can consider pursuing voluntary temporary registration and join the global efforts. IFAPP urges all our members to consider how they might best support the national and international effort to combat COVID-19;
- If individual members and national member associations feel they need further guidance, advice and support, please contact us at secretariat@ifapp.org

March 23, 2020
The IFAPP Board of Directors

COVID-19: πρόσθετες βιβλιογραφικές πηγές

Βαρβάρα Μπαρούτσου

1. Special report: The simulations driving the world's response to COVID-19

Πηγή:

https://www.nature.com/articles/d41586-020-01003-6

How epidemiologists rushed to model the coronavirus pandemic.

Governments across the world are relying on mathematical projections to help to guide decisions in this pandemic. But much information about how SARS-CoV-2 spreads is still unknown and must be estimated or assumed — limiting the precision of forecasts. Epidemiologist Neil Ferguson, a member of the Imperial College London team that has most influenced the British response to the outbreak, explains exactly how the process works.

NATURE 03 APRIL 2020

Staff at a car-manufacturing plant in Wuhan, China, observe social-distancing measures during their lunch break. Credit: AFP/Getty

2.

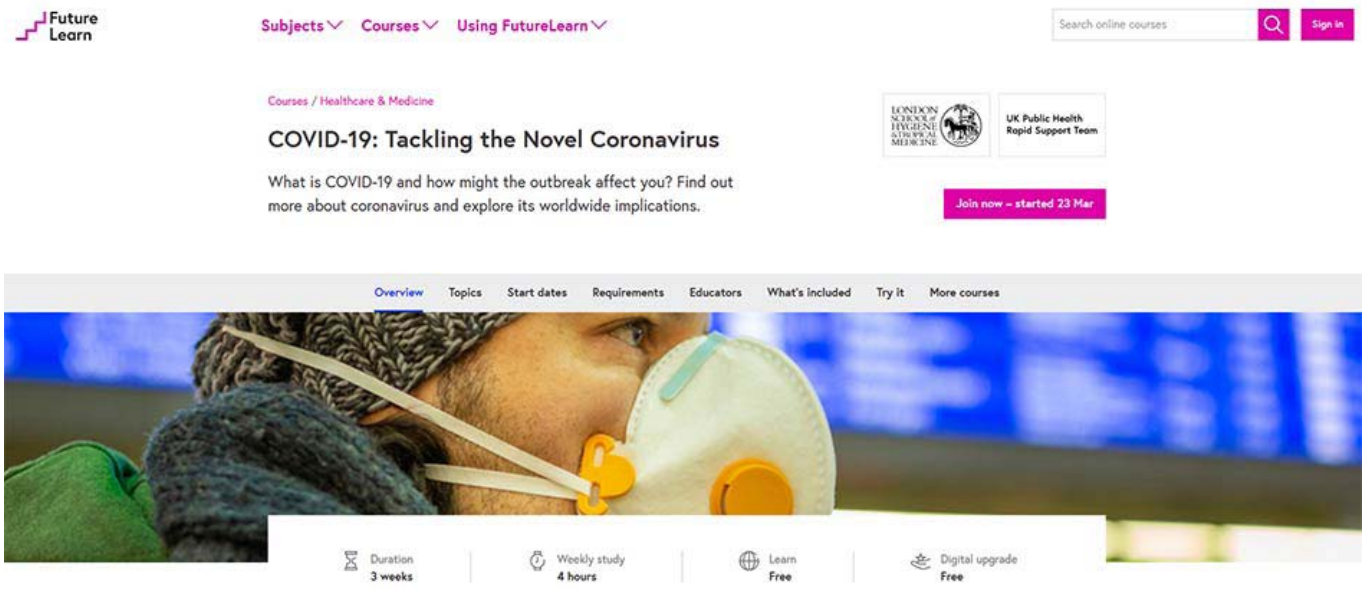
Πηγή:

http://www.ekt.gr/el/covid-19

Το Εθνικό Κέντρο Τεκμηρίωσης και Ηλεκτρονικού Περιεχομένου (ΕΚΤ) δημιούργησε αυτή την ιστοσελίδα με σκοπό να προσφέρει έγκυρη πληροφόρηση στην ερευνητική κοινότητα και σε κάθε πολίτη που ενδιαφέρεται για τις εξελίξεις της επιστημονικής έρευνας για την αντιμετώπιση της πανδημίας COVID-19. Ο νέος κορονοϊός μπήκε βίαια στη ζωή μας και έχει αλλάξει την καθημερινότητα όλων μας. Και σε αυτές τις συνθήκες, η αποστολή μας είναι να ενισχύσουμε την κοινότητα της γνώσης, να συμβάλουμε ώστε να αναδειχθούν έγκυρες επιστημονικές απόψεις και δεδομένα που προσφέρουν στον δημόσιο διάλογο και θωρακίζουν την κοινωνία απέναντι στον ανορθολογισμό και τον φόβο.

3.

London School of Hygiene & Tropical Medicine is offering a free 3-week online course on COVID-19 and its implications.



Πηγή:

https://www.futurelearn.com/courses/covid19-novel-coronavirus?utm_campaign=fl_march_2020&utm_medium=futurelearn_organic_email&utm_source=newsletter_broadcast&utm_term=200310_GNL__0030_&utm_content=course05_copy&fbclid=IwAR0jNll9Yp0VqwzYDfN1MA5YTSluwwzZQHg6dVptOwpcSKtgVF-QtKCwqXI&utm_source=Nature+Briefing&utm_campaign=94a7072063-briefing-dy-20200324&utm_medium=email&utm_term=0_c9dfd39373-94a7072063-44721677

4.α

Πηγή:

https://www.ecdc.europa.eu/en

4.β

An overview of the rapid test situation for COVID-19 diagnosis in the EU/EEA

Πηγή:

https://www.ecdc.europa.eu/sites/default/files/documents/Overview-rapid-test-situation-for-COVID-19-diagnosis-EU-EEA.pdf

Introduction

According to EU recommendations[1],timely andaccurate COVID-19 laboratory testing is an essential part of the management of COVID-19forslowing down the pandemic, supporting decisions on infection control strategies and patient management athealthcare facilities,and detecting asymptomatic cases that could spread the virus further if not isolated.

Wider testing is crucial for COVID-19 control

ECDC and the World Health Organization (WHO)currently recommend COVID-19 diagnosis by molecular testswhichdetectthe SARS-CoV-2 virus RNA. This is generally the current test strategy inMember States. However, these tests require well-equipped laboratory facilities, highly skilled technologists and multiple reagents. Currently,infrastructure limitations and supplyshortages are limiting testing capacity below the growing demand for COVID-19 diagnostics across the EU. Therefore, access to reliable rapid diagnostic tests, in particular rapid antigen testsfor COVID-19,could alleviate the pressure on laboratories and expand testing capacity to meet the most urgent medical and public health needs.

Conference New Dates:
ICPM 2020 = December 2 and 3
SIMeF = December 4

Dear distinguished guests and speakers,

Thank you for your continued support for the forthcoming XX ICPM (International Conference on Pharmaceutical Medicine)and the I SIMeF (the Italian Association of Pharmaceutical Medicine) National Conference, to be jointly organized in Rome.

Considering developing circumstances, IFAPP (the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine) is postponing ICPM2020, March 25-26-27. We do this with deep disappointment. We'll develop ICPM within the year of 2020, and new dates and venue will be announced in our next communication.

Over the last few days concern has mounted rapidly about the COVID-19 coronavirus. The WHO and the national governments raised the threat level. Increasing number of companies are instituting travel bans and restrictions, border health checks are becoming more restrictive and there is growing concern about international conferences with people gathering from different parts of the world.

Our top most concern is the health and safety of delegates and speakers, our partners, our colleagues and vendors.

We recognize the dedication and importance of the IFAPP community. We thank you for your engagement and your commitment to ICPM2020.

Best regards,

Kyoko Imamura
(IFAPP President)

Marco Romano
(SIMeF President)

Saving Lives, Hurting the Environment?

Stavros Goulakos
Bachelor of Science in Environmental Studies

Introduction

The 20th century was an era of progress that humankind had never seen before. Numerous fields of science and technology advanced so much that every new breakthrough gave its place to the next one in a rapid fashion.

Medicine was among the fields that saw the most tremendous progress. The effects of this progress were so successful that the mortality rate dropped significantly within a few decades, while life expectancy was steadily rising. Medicine even underwent a change of focus from mortality to morbidity, meaning that the emphasis shifted from keeping people alive to rather preserving their well-being and extending their life span. This shows us in the most convincing manner, how much of a success the field of medicine turned out to be in the 20th century.

This type of progress however came with its own set of problems. Just as every other kind of industry in this planet, the pharmaceutical one as well, has been contributing to the major problem of environmental pollution. This problem is not only affecting the ecosystem, but humans as well. The rapid decline of the quality of air, soil and water due to human activity is causing many problems for the ecosystem, which end up further deteriorating environmental health. According to the World Health Organization, “Environmental health addresses all the physical, chemical, and biological factors external to a person, and all the related factors impacting behaviors. It encompasses the assessment and control of those environmental factors that can potentially affect health.”

Human and Animal Medicinal Products

With that in mind we have to acknowledge that, the field of medicine is not only concerned with the well-being of humans but of animals, domesticated or pets, as well.

The technological and economical advancements of the last century have also changed our eating habits. The consumption of meat has risen rapidly and is nowadays a primary component of our diet. In order to cover the ever-increasing demand the attention has shifted from traditional husbandry practices into industrial livestock production. The key characteristics of the latter are cramped spaces and extremely unhygienic conditions. Apart from the moral problems that arise from these kind of practices, there is also the problem of diseases.In order to combat the latter, the daily use of huge amounts of antibiotics is the only solution in these types of factories.

At this point, we have to point out the differences between human and animal pharmaceutical products. According to the Directive 2001/83/EC provided by the European Union the definition of medicinal products designed for human consumption is:

“Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic

action, or to making a medical diagnosis."

As far as the definition of medicinal products for veterinary use is concerned, the Directive 2001/82/EC of the European Union states that:

"Any substance or combination of substances presented for treating or preventing disease in animals, or any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals is likewise considered a veterinary medicinal product."

Medicinal Products and their Effects on the Environment

As with any other industrial product, pharmaceuticals, as well, have a life cycle. According to the Bio Intelligence Service in their publication *"Study on the environmental risks of medicinal products",*the main points of this cycle are Research & Development, Manufacturing, Distribution, Consumption and finally, Waste Management. From one point to the other, these products have to undergo transportation and storage. Environmental pollution may occur at each of those points as well as during the intermediate stages of storage and transportation.

The most common types of pollution associated with pharmaceutical products are air and water pollution. According to Dayaram Patel in his article *"Impact of Pharmaceutical Industries on Environment, Health and Safety"*, among the major air pollutants are carbon monoxide, nitrogen dioxide, sulphur dioxide, particulate matter of 10 microns or less, total suspended particulate matter and volatile organic compounds. Moreover, as far as water pollution is concerned the biggest danger comes from toxic and not easily biodegradable substances that find their way into water bodies, either as effluents, or from bodily excretions, humans and animals included.

As stated in the report *"The Global Perspective Occurrence, Effects, and Potential Cooperative Action under SAICM"*by the German Environment Agency, current literature suggests that pharmaceutical residuals can be traced in manure, soil, surface water, ground water as well as in sewage effluent worldwide. The authors claim that over 600 active pharmaceutical substances, including their transformation products and metabolites, have infiltrated the environment. The substances belong to a wide range of therapeutic groups such as synthetic estrogens, antibiotics, lipid-lowering drugs, analgesics, beta-blockers and x-ray contrast media.

Moreover, the report provides us with two indicative examples of extreme eco-toxicological damage that display to us the need not to overlook this problem. The first case has to do with the near extinction of a vulture population. The reason behind this seems to be an anti-inflammatory drug found in the cattle carcasses that the vultures were eating. Finally, the report provides us with a case regarding the transformation of a male fish population into feminized males due to a synthetic estrogen during a lake experiment.

Declaration of Pharmaceutical Industry Stakeholders in Europe

Recognizing this emerging problem, the major European stakeholders of the

Pharmaceutical Industry have issued a declaration expressing their commitment to act in meaningful ways aiming to solve the problem. As reported by the declaration, the only way forward is to engage in discussion with European Commission policy makers taking into account not only public health and environmental aspects but the possible consequences of the policies as well.

Furthermore, the stakeholders have launched the #medsdisposal campaign, an initiative aspiring to inform the public about the proper way of disposal of both unused and expired medicinal products. According to the declaration, around 8-10% of medicinal environmental pollution derive by improper disposal, occurring in either households or medical institutions.

Additional steps of the stakeholders include the concept of Eco-Pharmaco-Stewardship put together by AESGP, EFPIA and Medicines for Europe. The goal of the initiative is the effective reduction of possible environmental pollution stemming from medicinal products throughout their life cycle.

Moreover, the declaration highlights the importance of informing the public about the risks of improper disposal. It is their belief that a change in attitude can be very beneficial for all of us. Finally, the stakeholders indicate that even thoughthe potential environmental damage from medicinal products remains yet unidentified, they fully pledge to promote and support research regarding these matters.

Conclusion

It is important to note, that even with something as beneficial to society as medicinal products, there can be several negative unintentional consequences. The need to address them is of great importance and that it is why many pharmaceutical companies are collaborating with the European Union and other agencies to tackle this problem. A balance between the benefits of medicinal products and their consequences would be the ideal solution to this problem keeping in mind that even though medicines will save lives in the present, their improper production methods or disposal might claim lives in the future.

References

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4. Patel, Dayaram. “Impact of Pharmaceutical Industries on Environment, Health and Safety”. Journal Of Critical Reviews, vol 2, no. 4, 2015, pp. 25-30., Accessed 31 Mar 2020.
5. Weber, Frank-Andreas et al. Pharmaceuticals in the Environment – The Global Perspective Occurrence, Effects, and Potential Cooperative Action under SAICM. German Environment Agency, 2014, Accessed 31 Mar 2020.

EL.E.F.I.: Scientific Events -New Save the Dates


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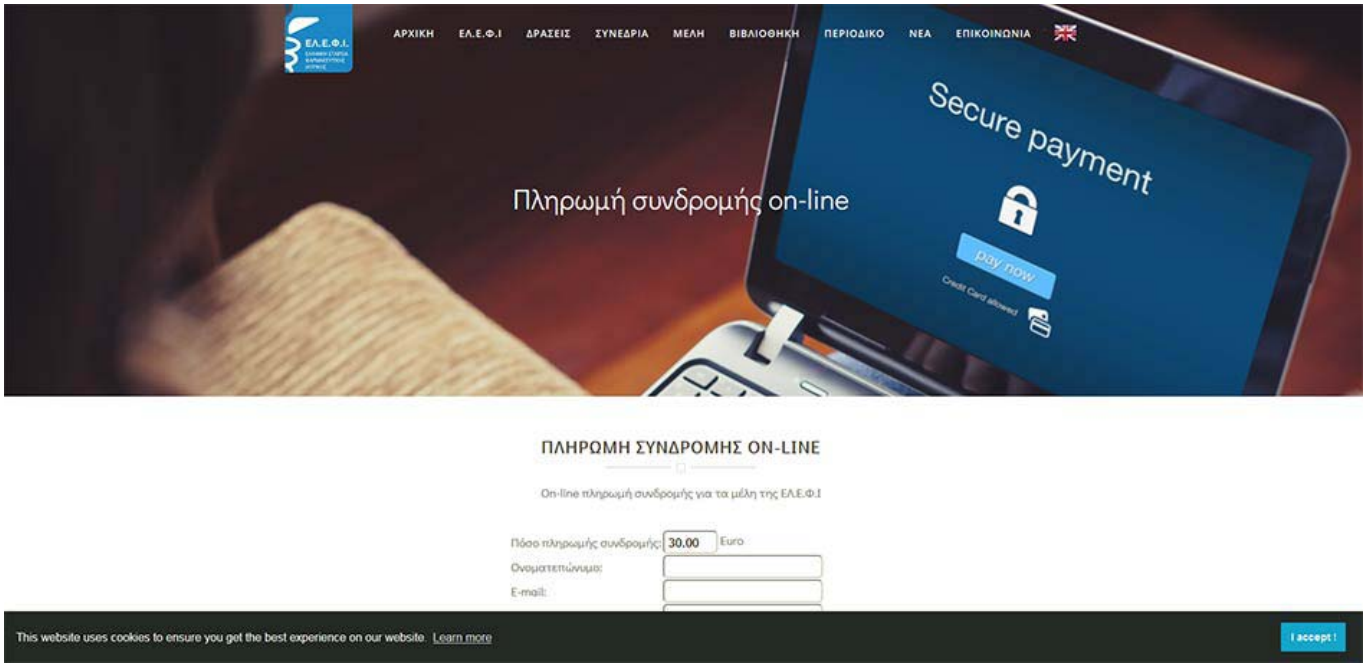

Καταβολή Ετήσιας Συνδρομής Online

Αγαπητοί συνάδελφοι,

Εκ μέρους του Διοικητικού Συμβουλίου, επικοινωνούμε για να σας ενημερώσουμε σχετικά με το εκσυγχρονιστικό βήμα της νέας δυνατότητας online πληρωμής της ετήσιας συνδρομής με πιστωτική/χρεωστική κάρτα μέσω της ιστοσελίδας προς διευκόλυνσή σας.

Σας ευχαριστούμε για την έμπρακτη στήριξη και εμπιστοσύνη σας.

Η Πρόεδρος
Βαρβάρα Μπαρούτσου

Η Γενική Γραμματέας
Άντζελα Βερναδάκη

Η Ταμίας
Δρ. Veronique Schaaf

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Σχεδιασμός:
Γιάννα Νίκης,
ynikis@otenet.gr
6973236595