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Ελληνική Εταιρεία Φαρμακευτικής Ιατρικής

eJOURNAL

L'Arbre de vie de Gustav Klimt

ΔΙΑΒΑΣΤΕ ΣΕ ΑΥΤΟ ΤΟ ΤΕΥΧΟΣ:

Ο Χαιρετισμός Προέδρου

Ο χώρος της υγείας, ένας από τους ταχύτερα αναπτυσσόμενους επιστημονικούς τομείς, αντιμετώπισε τα τελευταία χρόνια πρωτόγνωρες προκλήσεις αλλά και αντίστοιχη εξέλιξη, κάτι που σίγουρα θα συνεχιστεί και τα επόμενα χρόνια.

Η ΕΛ.Ε.Φ.Ι., ως ο επιστημονικός φορέας που εκπροσωπεί τους επιστήμονες υγείας που υπηρετούν τη φαρμακευτική ιατρική, η οποία αποτελεί τη γέφυρα μεταξύ της έρευνας και ανάπτυξης καινοτόμων θεραπειών και της υγειονομικής περίθαλψης, καλείται να βοηθήσει τα μέλη της να αναπτύξουν τις απαραίτητες δεξιότητες για να αντιμετωπίσουν αυτές τις προκλήσεις.

Με αυτό το όραμα διεξήχθησαν οι εκλογές του Οκτωβρίου 2023 που ανέδειξαν το νέο Διοικητικό Συμβούλιο, το οποίο πιστεύω πως έχει όλα τα απαραίτητα εφόδια για να καθοδηγήσει την ΕΛ.Ε.Φ.Ι. στη νέα αυτή περίοδο. Η διάρθρωσή του από στελέχη με διαφορετικά υπόβαθρα, εμπειρίες και επιστημονική κατάρτιση, που καλύπτουν και τους νεότερους και αναπτυσσόμενους τομείς της φαρμακευτικής ιατρικής, μας δίνει την πεποίθηση πως θα ανταπεξέλθουμε στις προκλήσεις και θα γίνουμε αρωγοί των επιστημονικών εξελίξεων στο χώρο.

Θέλω να ευχαριστήσω όλα μας τα μέλη που συμμετείχαν ενεργά τα προηγούμενα χρόνια, προσβλέποντας στην συνεχή υποστήριξή τους και καλώ και όλους τους νέους συναδέλφους να ενταχθούν στην οικογένεια της ΕΛ.Ε.Φ.Ι. Το όραμά μας για επιστημονική και επαγγελματική εξέλιξη μπορεί να γίνει πραγματικότητα μόνο με τη συνεργασία όλων των συναδέλφων στο χώρο.

Γρηγόριος Ρομπόπουλος
Ιατρός Ενδοκρινολόγος, Διαβητολόγος,
Πρόεδρος ΕΛ.Ε.Φ.Ι.

Σύντομο βιογραφικό του νέου Προέδρου σελ.13

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

www.elefi.gr

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Βιβλιογραφική Ανασκόπηση

Επιμέλεια:
Βαρβάρα Μπαρούτσου

1. *Πηγή:* *https://jamanetwork.com/journals/jama-health-forum/fullarticle/2813650*

JAMA Forum

December 28, 2023

Strategies for Regulating Disruptive Medical Technologies

Scott Gottlieb, MD[1]

» Author Affiliations | Article Information

JAMA Health Forum. 2023;4(12):e235460. doi:10.1001/jamahealthforum.2023.5460

The development of artificial intelligence devices that rely on large language models for natural language processing and are trained on clinical datasets offers an unprecedented opportunity to advance the practice of medicine. However, how the US Food and Drug Administration (FDA) will regulate these medical devices is uncertain.[1] In approaching this challenge, lessons can be drawn from how the FDA has approached regulation of other new technologies. I faced some of these issues when I served as the FDA commissioner from 2017 through 2019.

Lesson 1: Begin With Established Processes

The first lesson is the need to route a novel technology through a familiar regulatory pathway. The agency has established methods for evaluating existing technologies, and in almost all cases, new technologies can fit into one of these channels. This strategy enables innovators to enter the market more quickly than if they were to forge a brand-new path, and once marketed, developers can use the experience gained from real-world use to expand the applications of a new technology. Simultaneously, it provides the FDA with the opportunity to

2. *Πηγή: https://www.nejm.org/doi/full/10.1056/NEJMp2308792?query=health-policy&cid=DM2314000_Non_Subscriber&bid=2014321105*

PERSPECTIVE

A NEW ERA FOR RESEARCH FUNDED BY THE U.S. GOVERNMENT

Data Sharing — A New Era for Research Funded by the U.S. Government

Joseph S. Ross, M.D., M.H.S., Joanne Waldstreicher, M.D., and Harlan M. Krumholz, M.D.

In late January 2023, the new Data Management and Sharing (DMS) Policy of the National Institutes of Health (NIH), which requires researchers to share data that were generated with NIH support, went into effect.[1] New proposals and competitive renewals for research grants must now include a DMS Plan that describes how data will be shared or explains why data sharing is not possible. For example, the National Heart, Lung, and Blood Institute (NHLBI) hosts BioLINCC, a biologic specimen and clinical data repository that lists more than 250 available study data sets, including data from many well-known NHLBI-funded studies. Researchers have published several hundred scientific articles using these data — ing in clinical research, and the Institute of Medicine (now the National Academy of Medicine) endorsed data-sharing efforts in its 2015 report *Sharing Clinical Trial Data*.[3] The report also outlined opportunities to maximize the benefits of data sharing — which include avoiding unintentionally duplicative trials, stimu-

3. *Πηγή: https://evidence.nejm.org/doi/10.1056/EVIDoa2300003*

CORRECTION

A New Look at P Values for Randomized Clinical Trials

In the Original Article, "A New Look at P Values for Randomized Clinical Trials", originally published December 22, 2023 (DOI: https://doi.org/10.1056/EVIDoa2300003), the labels of the two curves in Figure 1 should have been reversed.

The corrected article, including the updated figure and corresponding figure legend, has been posted at evidence.nejm.org.

Published December 22, 2023 | NEJM Evid 2024;3(1) | DOI: 10.1056/EVIDoa2300003 | VOL. 3 NO. 1

Abstract

BACKGROUND

We have examined the primary efficacy results of 23,551 randomized clinical trials from the Cochrane Database of Systematic Reviews.

METHODS

We estimate that the great majority of trials have much lower statistical power for actual effects than the 80 or 90% for the stated effect sizes. Consequently, "statistically significant" estimates tend to seriously overestimate actual treatment effects, "nonsignificant" results often correspond to important effects, and efforts to replicate often fail to achieve "significance" and may even appear to contradict initial results. To address these issues, we reinterpret the P value in terms of a reference population of studies that are, or could have been, in the Cochrane Database.

RESULTS

This leads to an empirical guide for the interpretation of an observed P value from a

4. *Πηγή: https://ai.nejm.org/doi/full/10.1056/AIpc2300038*

POLICY CORNER

Development Pipeline and Geographic Representation of Trials for Artificial Intelligence/Machine Learning–Enabled Medical Devices (2010 to 2023)

Authors: Miquel Serra-Burriel, Ph.D., Luca Locher, B.Sc., and Kerstin N. Vokinger, M.D., J.D., Ph.D.
Info & Affiliations

Published November 9, 2023 | NEJM AI 2023;1(1) | DOI: 10.1056/AIpc2300038 | VOL. 1 NO. 1

Abstract

A high number of artificial intelligence/machine learning (AI/ML)-enabled medical devices are currently in development. To understand the development pipeline and worldwide geographic distribution of clinical trials for AI/ML-enabled medical devices that may enter the market in the upcoming years, we analyzed the trends in registration of clinical trials for AI/ML-enabled medical devices between 2010 and 2023 as well as their geographic distribution. We aggregated all registered trials initiated between

5. *Πηγή: https://www.nature.com/articles/d41586-023-03172-6.pdf*

The international journal of science / 12 October 2023

nature

Is AI starting to accelerate drug discovery?

Companies say the technology will lead to faster drug development. Independent verification and clinical trials will determine whether the claim holds up.

For decades, researchers have sought a fast track to drug discovery. Yet the process has been getting slower, as well as riskier and more costly. It generally takes 12–15 years from the initiation of a discovery programme to the point at which national drug-regulatory agencies grant marketing approval[1]. Some nine in ten drugs that enter clinical trials don't get approved. Estimates suggest it costs about US$2.5 billion to bring a drug to market[2], after accounting for the costs of successful and failed programmes across the board.

Although established pharmaceutical companies are struggling to innovate, claims are mounting that the disruptor *du jour* – generative artificial intelligence (AI) – is radically shortening the stages that come before clinical

> **Ultimately, for AI systems to improve, someone needs to make and**

One pharmaceutical company, Insilico Medicine, which is jointly headquartered in New York City and Hong Kong, announced last February that it had progressed to phase I clinical trials with an AI-designed drug candidate. The molecule targets idiopathic pulmonary fibrosis, a serious disease that leads to untreatable lung scarring. The drug candidate had completed the discovery and preclinical stages in just 30 months. In June, the company began phase II trials, which study how well a candidate works in more detail.

These are noteworthy developments, and they will no doubt drive investment. Although the technology is still relatively young, the 20 AI-intensive companies in BCG's 2022 analysis already had 158 drug candidates in discovery and preclinical development. That compared with 333 at the world's 20 biggest pharma companies as measured by revenue.

However, these claims have come from the companies themselves. Until they can be independently verified, some caution is in order. The findings need to be published in the peer-reviewed literature and authenticated by researchers unaffiliated with the companies involved.

And there are other challenges to realizing the benefits of AI. Systems based on generative AI that suggest candidate drug molecules work by using patterns learnt from training data to generate new data with similar characteristics. This can cause problems. When responding to user questions, the chatbot ChatGPT sometimes fabricates answers; in drug discovery, the equivalent problem leads it to suggest

6. *Πηγή: https://www.nejm.org/doi/full/10.1056/NEJMoa2300709*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Base-Edited CAR7 T Cells for Relapsed T-Cell Acute Lymphoblastic Leukemia

Robert Chiesa, M.D., Christos Georgiadis, Ph.D., Farhatullah Syed, Ph.D., Hong Zhan, Ph.D., Annie Etuk, Ph.D., Soragia Athina Gkazi, Ph.D., Roland Preece, Ph.D., Giorgio Ottaviano, M.D., Toni Braybrook, M.Bio., Jan Chu, M.Sc., Agnieszka Kubat, B.Sc., Stuart Adams, Ph.D., Rebecca Thomas, Ph.D., Kimberly Gilmour, Ph.D., David O'Connor, M.B., Ch.B., Ajay Vora, M.B., B.S., and Waseem Qasim, M.B., B.S., Ph.D., for the Base-Edited CAR T Group*

ABSTRACT

BACKGROUND

Cytidine deamination that is guided by clustered regularly interspaced short palindromic repeats (CRISPR) can mediate a highly precise conversion of one nucleotide into another — specifically, cytosine to thymine — without generating breaks in DNA. Thus, genes can be base-edited and rendered inactive without inducing translocations and other chromosomal aberrations. The use of this technique in patients with relapsed childhood T-cell leukemia is being investigated.

From Great Ormond Street Hospital for Children NHS Trust (R.C., G.O., T.B., J.C., S.A., R.T., K.G., D.O., A.V., W.Q.) and the UCL Great Ormond Street Institute of Child Health (C.G., F.S., H.Z., A.E., S.A.G., R.P., A.K., W.Q.) — both in London. Dr. Qasim can be contacted at w.qasim@ucl.ac.uk or at Great Ormond

7. *Πηγή: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808057*

August 8, 2023

Review of Evidence Supporting 2022 US Food and Drug Administration Drug Approvals

Robert M. Kaplan, PhD[1]; Amanda J. Koong, MS[2]; Veronica Irvin, PhD[3]

» Author Affiliations | Article Information

JAMA Netw Open. 2023;6(8):e2327650. doi:10.1001/jamanetworkopen.2023.27650

Introduction

The 21st Century Cures Act, enacted in 2017, gave the US Food and Drug Administration (FDA) greater flexibility to apply evidence-based standards for novel drug approvals.[1] To evaluate current practice, we summarize evidence supporting the 37 drugs approved in 2022.

Methods

Using the FDA Novel Drug Approvals website, in a cross-sectional design, we examined 2022 approvals of all novel drugs that had not been previously approved for any indication. The study was conducted from August 1, 2022, to January 1, 2023. For each approved medication, all information in the ClinicalTrials.gov listing was downloaded, compiled into a comprehensive spreadsheet, and analyzed using SPSS, version 28.[2] The study was certified as exempt by Oregon State

8. *Πηγή: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2808242*

Editorial

August 21, 2023

Unique Device Identifiers—Missing in Action

Vinay K. Rathi, MD, MBA[1]; Joseph S. Ross, MD, MHS[2,3]; Rita F. Redberg, MD, MSc[4,5]

» Author Affiliations

JAMA Intern Med. 2023;183(10):1049-1050. doi:10.1001/jamainternmed.2023.3561

Faulty and unsafe medical devices can cause substantial harm to patients, who may experience the consequences of missed diagnoses, unsuccessful procedures, or ineffective treatment. However, the US Food and Drug Administration (FDA) authorizes most medical devices based on nonclinical testing and/or limited clinical evidence.[1,2] A robust postmarket surveillance system is thus essential to gather critical data on safety and effectiveness. However, FDA surveillance is predominantly based on spontaneous adverse event reporting, a passive approach subject to substantial underreporting and bias because health professionals and patients are neither trained nor required to report adverse events; as few as 3% of all adverse events may be reported to the FDA.[3] When safety signals are passively detected, rudimentary reports and missing data often prevent the FDA and manufacturers from tracking all affected products and taking corrective action.[4]

Όλοι Μαζί Μπορούμε να κάνουμε την Χρήση των Φαρμάκων πιο Ασφαλή

Α. Μπίκου, Γ. Καργιολάκης,
Α. Μανιατάκου,
Μ. Πολυδώρου, Α. Σιδέρη,
Χ. Τσούγκου, Α. Φαλάρα,
Ε. Χατζοπούλου,
Β. Μπαρούτσου

Ομάδα Εργασίας
Φαρμακοεπαγρύπνησης ΕΛ.Ε.Φ.Ι.

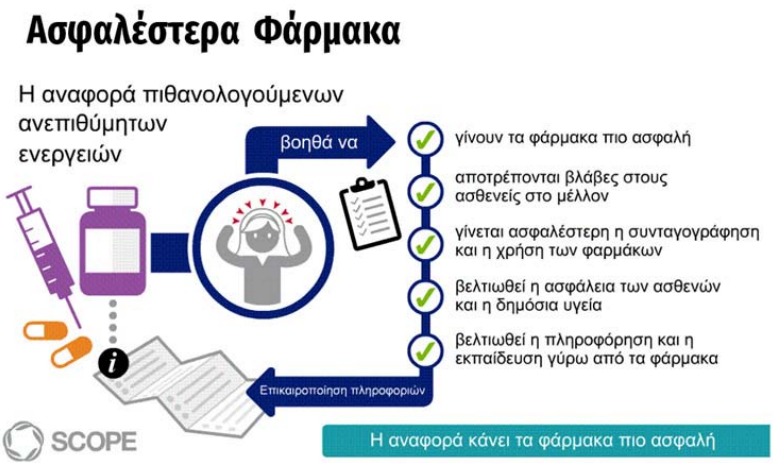
Διαδικτυακή Επιστημονική Εκδήλωση ΕΛ.Ε.Φ.Ι. #MedSafetyWeek Σύνοψη και Κύρια Συμπεράσματα

Με αφορμή την καμπάνια ευαισθητοποίησης #MedSafetyWeek, από το Uppsala Monitoring Centre, η Ομάδα Εργασίας Φαρμακοεπαγρύπνησης της ΕΛ.Ε.Φ.Ι. διοργάνωσε ένα διαδικτυακό διάλογο με στόχο την ευαισθητοποίηση τόσο των υγειονομικών όσο και των ασθενών σχετικά με την αναφορά ανεπιθύμητων ενεργειών (ΑΕ) των φαρμάκων και των εμβολίων.

Ο πρόεδρος της ΕΛ.Ε.Φ.Ι., Γρ. Ρομπόπουλος, στον χαιρετισμό του στην έναρξη της εκδήλωσης τόνισε τη σημασία της αναφοράς των ΑΕ. Επισήμανε πώς η πανδημία COVID-19 αποτέλεσε ένα καλό παράδειγμα, ενεργούς Φαρμακοεπαγρύπνησης που μπορεί να χρησιμοποιηθεί ως παρακίνηση για την συστηματική αναφορά των ΑΕ. Στη συνέχεια, η **Δρ Βαρβ. Μπαρούτσου** υποστήριξε ότι η αναφορά ΑΕ δεν αφορά μόνο τα φάρμακα και τα εμβόλια, αλλά και τις ιατροτεχνολογικές συσκευές, υπογραμμίζοντας ότι η αναφορά ΑΕ αφορά την ασφάλεια των ασθενών.

Το ταξίδι της αναφοράς των ΑΕ ξεκίνησε με μια εισαγωγική παρουσίαση από τον **Βιολόγο, Τοπικό υπεύθυνο Ασφάλειας Ασθενών και Ιατρικής Πληροφόρησης, Boehringer - Ingelheim Γ. Καργιολάκη**, που παρουσίασε τις βασικές έννοιες της φαρμακοεπαγρύπνησης και των ΑΕ. Έγινε λόγος για την εκστρατεία του Εθνικού Οργανισμού Φαρμάκων (ΕΟΦ) και τη διαδικασία ηλεκτρονικής υποβολής αναφορών, συμπεριλαμβανομένης της κίτρινης κάρτας. Επιπλέον, ο ομιλητής τόνι-

σε ότι οποιοσδήποτε μπορεί να αναφέρει μια ΑΕ σε ιστότοπους τοπικών αρχών, στις φαρμακευτικές εταιρίες ή στον ιστότοπο του Παγκόσμιου Οργανισμού Υγείας.Τέλος, δόθηκε ιδιαίτερη έμφαση στην ευθύνη τόσο των φαρμακευτικών εταιριών όσο και των ιατρών και υγειονομικών να δηλώνουν ενεργά πιθανές ΑΕ των φαρμάκων που αναγνωρίζουν.

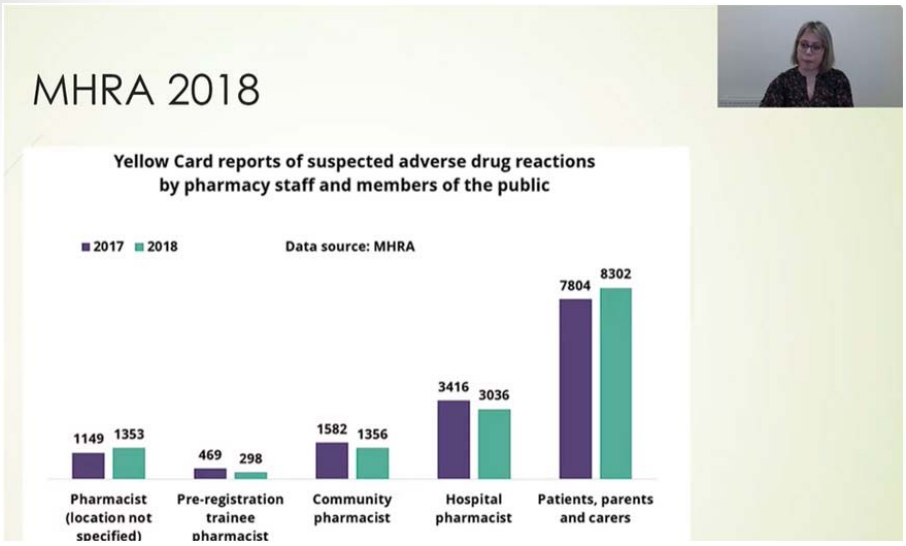


Στην συνέχεια έλαβε τον λόγο ο **πρόεδρος της Ένωσης Ασθενών Ελλάδας Ν. Δέδες**, ο οποίος παρουσίασε την οπτική των ασθενών σχετικά με τις αναφορές ΑΕ. Ανέδειξε το ζήτημα ελλιπούς εγγραματοσύνης υγείας λόγω έλλειψης κατάλληλων εργαλείων για την καθοδήγηση των ασθενών στις αποφάσεις τους. Ειδικότερα, αναφέρθηκε στην εξάρτηση των ασθενών από τους γιατρούς, αναμένοντας από αυτούς την πρώτη ενημέρωση και ενώ παράλληλα υπογραμμίστηκε η σημασία τού να μπορούν οι ασθενείς να διαβάζουν το φύλλο οδηγιών χρήσης των φαρμάκων τους, προκειμένου να ενημερώνονται για τις πιθανές παρενέργειες. Ολοκληρώνοντας, ο κ. Δέδες αναφέρθηκε σε εμπειρία ομάδων ασθενών HIV που στην δεκαετία του 1990 συνέβαλαν σημαντικά στην καταγραφή, αναφορά και διαχείριση ΑΕ για την ασφαλέστερη χρήση των καινοτόμων αντιικών φαρμάκων. Το παράδειγμα αυτό δίνει χρήσιμες πληροφορίες και ενισχύει την κινητοποίηση των ασθενών για ενεργή συμμετοχή στην αναφορά ΑΕ.

Η οπτική των επαγγελματιών υγείας στο ταξίδι καταγραφής ΑΕ ξεκίνησε με την τοποθέτηση του **Καρδιολόγου Χρήστου Βαρούνη** (MD, MSc, MBA, Καρδιολόγος Area Medical Director EMEA Core Diagnostics, Abbott). Αρχικά ο κος Βαρούνης αναφέρθηκε στην ανάγκη για εκπαίδευση των ιατρών στη φαρμακοεπαγρύπνηση, αναδεικνύοντας τις προκλήσεις στην καθημερινή πρακτική. Έθιξε τη σημασία της ευαισθητοποίησης των ιατρών σε θέματα ασφάλειας, επισημαίνοντας ότι η επαφή του με τη φαρμακοβιομηχανία αποκάλυψε ότι, τελικά, οι γιατροί καταγράφουν και αναφέρουν ΑΕς. Αυτή η ευαισθητοποίηση, ωστόσο, περιορίζεται κυρίως στον τομέα των κλινικών δοκιμών και νέων φαρμάκων. Χαρακτηριστικά ανέφερε ότι γνωστές και συχνές ΑΕ παλαιών φαρμάκων δεν αναφέρονται, παρά μόνον οι σοβαρές και οι μη γνωστές. Καταλήγοντας, ανέδειξε τις προκλήσεις που περιπλέκουν τη δήλωση ΑΕ, όπως ο χρόνος που απαιτείται για επικοινωνία με τους ασθενείς, για την καταγραφή της ΑΕ αλλά και την διαχείρισή της, γεγονός που καθιστά επιτακτική τη συνεχιζόμενη εκπαίδευσή τους στη φαρμακοεπαγρύπνηση.

Η **Φαρμακοποιός Σταυρούλα Χαρίση** (Highly specialist pharmacist, IPP, University Hospital Southampton NHS Foundation Trust) εμπλούτισε το ταξίδι της αναφοράς των ΑΕ με την εργασιακή εμπειρία της στην Ελλάδα και στην Αγγλία. Υπογράμμισε τις διαφορές μεταξύ των συστημάτων, τονίζοντας την πιο άμεση προσβασιμότητα των ασθενών στους επαγγελματίες υγείας στην Ελλάδα. Ωστόσο, υπάρχει μεγάλη ανάγκη για περαιτέρω εμβάθυνση

των επαγγελματιών υγείας στην φαρμακοεπαγρύπνηνση καθώς και στην καθοδήγηση των ασθενών τους για αναγνώριση και αυτοκαταγραφή των ΑΕ.

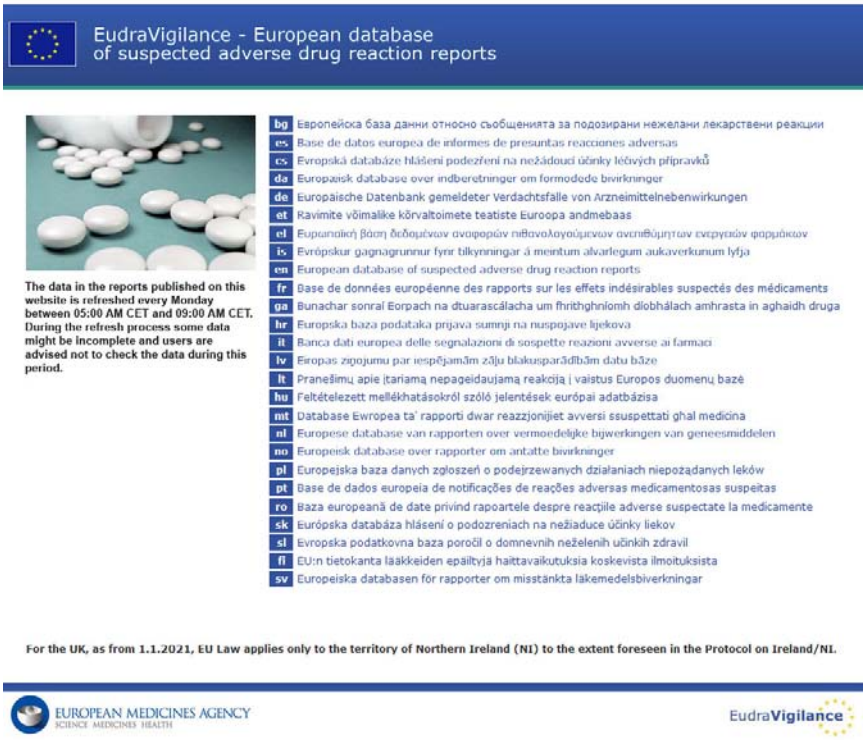


Η κα Χαρίση έκανε ιδιαίτερη αναφορά στην εκπαίδευση των υγειονομικών στην αξία της φαρμακοεπαγρύπνησης καθώς και στην υποχρέωση του υγειονομικού στην ενημέρωση των ασθενών κατά την έναρξη της θεραπείας για τις ενδεχόμενες ΑΕ και της αναφοράς τους.

Τόνισε δε ότι επειδή οι ΑΕ είναι πιθανόν να εμφανιστούν κατά την έναρξη μιας νέας αγωγής, οι ασθενείς θα πρέπει να εκπαιδεύονται στην συμπλήρωση της κίτρινης κάρτας από τον φαρμακοποιό. Με βάση δε στατιστικά δεδομένα από τον Οργανισμό Φαρμάκων της Αγγλίας, MHRA, η κα Χαρίση υπογράμμισε ότι οι ασθενείς αναφέρουν περισσότερες ΑΕ από τους φαρμακοποιούς. Αυτό οφείλεται κυρίως στις προκλήσεις σχετικά με την έλλειψη χρόνου των φαρμακοποιών καθώς και με την δυσκολία αξιολόγησης της συνολικής κλινικής εικόνας ενός ασθενή από τον φαρμακοποιό.

Με την παρουσίασή της η **Αναπλ. Προϊσταμένη Τμήματος Ανεπιθύμητων Ενεργειών (ΕΟΦ) Σοφία Δρούσκα** προχώρησε το ταξίδι των ΑΕ στο στάδιο της αξιολόγησής τους από την τοπική ρυθμιστική αρχή, τον Εθνικό Οργανισμό Φαρμάκων. Επικεντρώνοντας την εισήγησή της στο γεγονός ότι η αναφορά μιας ανεπιθύμητης ενέργειας μπορεί να προέλθει από οποιονδήποτε, ανά πάσα στιγμή, τόνισε ότι οι επαγγελματίες υγείας συχνά παραλείπουν να αναφέρουν ΑΕ σε σχέση με τους ασθενείς, πέραν της έλλειψης χρόνου λόγω εσφαλμένων αντιλήψεων π.χ. μη βεβαιότητα συσχέτισης της ΑΕ με το ύποπτο φάρμακο. Επιβεβαίωσε ότι στην διάρκεια της πανδημίας COVID-19 περισσότεροι ασθενείς απ' ότι ιατροί ανέφεραν ΑΕ των εμβολίων,επεσήμανε δε ότι όταν οι θεράποντες δεν ενημερώνουν τους ασθενείς για πιθανές ΑΕ ανακύπτουν προβλήματα μη συμμόρφωσης ή και διακοπής της θεραπείας αυτοβούλως από τους ασθενείς. Η κα Δρούσκα αναφέρθηκε επίσης στην ανάγκη ιδιαίτερης ευαισθητοποίησης των υγειονομικών κυρίως των ιατρών σε φάρμακα με εγκρίσεις υπό όρους, για σπάνιες ή και σοβαρές παθήσεις. Συμπληρωματικά επεσήμανε την αναγκαιότητα αναφοράς ΑΕ ειδικών πληθυσμών, έγκυες, παιδιά, καθώς και την διατήρηση μητρώων για τη συλλογή μακροχρόνιων δεδομένων νέων θεραπειών στο πλαίσιο της φαρμακευτικής φροντίδας αλλά και της φαρμακοεπαγρύπνησης.

Επιπλέον, έδωσε έμφαση στη σημασία και τα οφέλη της αυθόρμητης αναφοράς ΑΕ μέσω της κίτρινης κάρτας, επισημαίνοντας κακές πρακτικές, επι σκοπόν υποβαλλομένων ΑΕ άνευ επαρκών δεδομένων, προκειμένου να εγκριθεί αλλαγή φαρμακευτικής αγωγής σε ειδικά σοβαρά/σπάνια νοσήματα. Επιπρόσθετα, η κα Δρούσκα αναφέρθηκε σε δράσεις του ΕΟΦ για την προώθηση του θεσμού της φαρμακοεπαγρύπνησης, τόσο με την πρόσφατη ανάρτηση της κίτρινης κάρτας στην ηλεκτρονική συνταγογράφηφη ΗΔΙΚΑ, όπως επίσης και την μελλοντική παραπομπή στην κίτρινη κάρτα, στο φύλλο οδηγιών χρήσεως, στην συσκευασία των φαρμάκων για τους ασθενείς-φροντιστές, καθώς και στην Περίληψη Χαρακτηριστικών Προϊόντος αντιστοίχως για τους υγειονομικούς. Η κα Δρούσκα εξέφρασε την δέσμευση και προσήλωση των επιστημόνων του τμήματος ΑΕ του ΕΟΦ στην ενδελεχή αξιολόγηση των ΑΕ για την υποβολή ποιοτικών αναφορών στην βάση δεδομένων Eudravigilance στον Ευρωπαικό Οργανισμό Φαρμάκων.



Τέλος, έγινε προαναγγελία εκστρατείας για την προώθηση της αναφοράς ΑΕ με την κίτρινη κάρτα με καμπάνια προς τους πολίτες, καθώς και πρωτοβουλιών υπενθυμίσεων προς τους υγειονομικούς σε ιατρικά συνέδρια για την ηλεκτρονική υποβολή ΑΕ μέσω της κίτρινης κάρτας.

Ακολούθησε εξαιρετικά ενδιαφέρουσα συζήτηση μεταξύ των συμμετεχόντων σχετικά με τις αιτίες υποαναφοράς ΑΕ. Στο επίκεντρο των τοποθετήσεων των ομιλητών και του ακροατηρίου βρέθηκαν η ανάγκη:

1. δημιουργίας ενός συστήματος που θα ενισχύει την αναφορά των ΑΕ από τους ασθενείς ,
2. επισήμανσης της αναφοράς ΑΕ νέων και παλαιών φαρμάκων από ασθενείς, φροντιστές, το περιβάλλον των ασθενών, από γιατρούς, φαρμακοποιούς, νοσηλευτές και άλλους επιστήμονες, οποτεδήποτε για την ενίσχυση της σημασίας των αναφορών ΑΕ στην διαρκή αξιολόγηση των ωφελειών έναντι των κινδύνων των φαρμάκων και της ποιότητας των παρτίδων των προϊόντων,
3. λήψης πλήρους ιατρικού και φαρμακευτικού ιστορικού του ασθενούς προκειμένου να γίνει η πρόληψη, ή η ελαχιστοποίηση ΑΕ, ή η αιτιολογική συσχέτιση μιας πιθανολογούμενης ΑΕ,
4. ενδυνάμωσης των επαγγελματιών υγείας, περιλαμβανομένων και των νοσηλευτών, στην διαδικασία αναφοράς των ΑΕ,
5. ενίσχυσης εγγραματοσύνης υγείας των ασθενών και πολιτών.

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Εν κατακλείδι, ο διάλογος ανέδειξε την κορυφαία σημασία της προπτυχιακής και δια βίου εκπαίδευσης των υγειονομικών, ενώ προτάθηκε η δημιουργία ενός εξειδικευμένου μεταπτυχιακού προγράμματος σπουδών στην φαρμακοεπαγρύπνηση ως μέσο για το θετικό επαναπροσδιορισμό της αντίληψης για την αναφορά ΑΕ και την ασφαλή χρήση των φαρμάκων στην πράξη.

Συμπερασματικά, προκειμένου να διασφαλίσουμε την επιτυχή επιμόρφωση & κινητοποίηση για την αναφορά ΑΕ και την αποτελεσματική εφαρμογή

της Φαρμακοεπαγρύπνησης από όλους τους εμπλεκόμενους απαιτείται η επαγρύπνηση για την συλλογή και ανάλυση δεδομένων σχετικά με την επίγνωση, την πρακτική και τις προκλήσεις που αντιμετωπίζουν οι εταίροι της υγείας, οι ασθενείς και οι πολίτες σε σχέση με την αναφορά των ΑΕ.

Με την διαβεβαίωση ότι όλοι μαζί μπορούμε να κάνουμε την χρήση των φαρμάκων πιο ασφαλή, ολοκληρώθηκε η εκδήλωση με την υπόσχεση της συνέχισης του εποικοδομητικού διαλόγου και δράσεων το 2024.

Βιβλιογραφικές Αναφορές

1. Raising pharmacovigilance awareness on social media.
   https://who-umc.org/pharmacovigilance-communications/medsafetyweek/
2. Πανευρωπαϊκή εκστρατεία ενημέρωσης για την Φαρμακοεπαγρύπνηση (ΕΟΦ-SCOPE) Νοέμβριος 2016.
   https://www.moh.gov.gr/articles/ministry/grafeio-typoy/press-releases/4223-paneyr-wpaikh-ekstrateia-enhmerwshs-gia-thn-farmakoepagrypnhsh-eof-scope
3. Ηλεκτρονική εφαρμογή και υποβολή Ανεπισθυμήτων ενεργειών στον Εθνικό Οργανισμό Φαρμάκων
   https://www.kitrinikarta.gr/
4. Πώς συμπληρώνουμε την κίτρινη κάρτα του ΕΟΦ.
   https://www.youtube.com/watch?v=IZi4gKGNHiU&ab_channel=%CE%97%CE%B1%CE%BB%CE%AE%CE%B8%CE%B5%CE%B9%CE%B1%CE%B3%CE%B9%CE%B1%CF%84%CE%B1%CE%B5%CE%BC%CE%B2%CF%8C%CE%BB%CE%B9%CE%B1
5. EudraVigilance -European database of suspected adverse drug reactions reports. https://www.adrreports.eu/

Embracing a Future of Excellence: A Vision

for the Hellenic Society of Pharmaceutical Medicine (EL.E.F.I.)

Γρηγόριος Ρομπόπουλος
Ιατρός Ενδοκρινολόγος,
Διαβητολόγος, Πρόεδρος
Ελληνικής Εταιρείας
Φαρμακευτικής Ιατρικής
(ΕΛ.Ε.Φ.Ι.)

Stepping into the role of President of the Hellenic Society of Pharmaceutical Medicine (EL.E.F.I.), I am honored and excited to outline my vision for the society's future. The field of pharmaceutical medicine is at the forefront of scientific innovation, and our society plays a crucial role in fostering collaboration between health authorities, researchers, pharmaceutical industry, health care professionals, clinical research organizations, patients and all other stakeholders, in order to advance research, and ensure the highest standards in medical practice. In an era where the intersection of science, medicine, and regulatory affairs is more critical than ever, fostering strong partnerships is central to advancing our society's mission. With a commitment to excellence and a focus on inclusivity, I aim to lead our society into a new era of growth and innovation in order tocontribute to the broader healthcare ecosystem.

Promoting Collaborative Research

One of the primary objectives of my presidency is to strengthen collaborative research initiatives within the society. I envision to further develop the interdisciplinary collaboration among health authorities, academia, researchers, contract research organizations (CROs), industry experts and healthcare providers to accelerate the development of new medicines and therapies.Through dialogue and joint initiatives, we can address industry challenges, explore innovative solutions and collectively advance the standards of pharmaceutical practice.

Enhancing Education and Professional Development

Education is the cornerstone of progress in any field, and pharmaceutical medicine is no exception. Continuous learning is necessary in order to stay at the forefront of the latest scientific innovations, technological advancementand professional development. This includes organizing workshops, seminars, and conferences that cover a wide range of topics, from the latest advances in clinical trial methodologies to emerging trends in regulatory affairs. Additionally, we will explore opportunities for collaboration with academic institutions to provide our members access to cutting-edge knowledge. Through joint programs and initiatives, we can enrich educational experience and provide access to diverse perspectives and expertise.

Embracing Technological Innovation

The pharmaceutical landscape is evolving rapidly, driven by technological advancements. Artificial intelligence,advanced data analytics and digital health applicationsare some examples of new tools to enhance the efficiency of clinical trials&drug development processes, patient outcomes&patient care and contribute to the evolution of personalized medicine. It is crucial for our society to embrace these innovations to stay relevant and effective. We will invest in building relevant skills to take advantage of these technologies.

Advocating for Ethical Practices

Maintaining the highest ethical standards and a patient-centric approach are paramount in pharmaceutical medicine. Hellenic Society of Pharmaceutical

Short cv

Grigorios Rombopoulos
MD, Endocrinology, Diabetes,
President of Hellenic Society
of Pharmaceutical Medicine
(ELEFI)

Graduated from the Medical School of the National and Kapodistrian University of Athens (EKPA).Holds the Specialty of Endocrinology, Diabetes & Metabolism since 2008 and has been practicing since then in Athens as a private physician.Has extensive experience in clinical studies with more than 40 scientific publications & announcements in international scientific journals and conferences.Has more than 25 years of professional experience in the field of medicine and 15 years of experience in the field of pharmaceutical companies. Joined Novartis Hellas in 2008 as Medical Advisor and developed to different positions of increasing responsibly, where from 2016 till end of 2022 served as Chief Scientific Officer & Head of Medical Department Novartis Hellas. Before joining pharmaceutical industry, he served as a rural physician in Viotia, as a specialist in internal medicine at the General Hospital of Nikea and as a specialist in endocrinology at the Hippocration Hospital of Athens from where he also obtained the specialty of Endocrinology.

Medicinetraditionally reinforcing dedication to ethical standards and transparencyin research, drug development and clinical practice. This includes promoting integrity in research, ensuring patient confidentiality and advocating for responsible and sustainable pharmaceutical development. By upholding these principles, we can build trust between the industry, health authorities, patients and public, fostering a positive reputation for the society and its members.

Empowering Patients by collaborating with patient advocacy groups

Our society have strong focus on promoting patient rights, ensuring that the needs and perspectives of patients are at the forefront of decision-making processes.Patient advocacy groups play a pivotal role in the healthcare landscape, acting as powerful voices for individuals facing various medical conditions. In coming years, the concept of patient-reported outcomes (PROs) willemerge as a dynamic force in enhancing patient care and shaping healthcare policies, as PROs will become a prerequisite for the assessment of new treatments by health technology assessment bodies.The society, will continue and enhance further the close collaboration with patient advocacy groups/ societies, not only to advocate for guidelines and practices but also to include actively patients' opinion in decision making in all steps of drug development and access to innovative treatments for the well-being and interests of patients.

Global Outreach and Collaboration

In an era of globalization, aligning our standards with international best practices is paramount. I aspire to strengthen our society's global presence by fostering partnerships with other scientific societies and international organizations such as International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and collaborating on research projects with institutions from around the world. This not only enhances our members' exposure to diverse perspectives but also enhances the presence of the Hellenic Society of Pharmaceutical Medicine in the global landscape.

Diversity and Inclusion Initiatives

Diversity is a driving force behind innovation. I am dedicated to promoting diversity and inclusion within our society, ensuring that all voices are heard and valued. Recognizing the richness that diversity brings to scientific endeavors, there are plans to implement initiatives that promote equal opportunities for professionals from all backgrounds andcreating a welcoming space for professionals at all career stages. By fostering a diverse and inclusive environment, we can harness the full spectrum of talent and expertise within our membership, driving progress and excellence.

Conclusion

In conclusion, my vision for the Hellenic Society of Pharmaceutical Medicine is rooted in a commitment to excellence,foster active collaboration of all stakeholders and innovation. By promoting collaborative research, enhancing education and training, embracing technological innovation, advocating for ethical practices,empowering patients, expanding global outreach and prioritizing diversity, we can position our society at the forefront of pharmaceutical medicine. Together, we can shape a future where our contributions lead advancements in medical science,improved patient outcomes and drivingpharmaceutical medicine professionals to excellence in their field.

Medical Affairs & Metrics: Focusing on Field Based Roles

Alex Moulis
Head of Medical Sandoz Greece, Cyprus and Malta
Petros Efstathopoulos
Head of Medical & Pharmaceutical Affairs, Chiesi Hellas and Cyprus

Pharmaceutical Medical Affairs plays a crucial role in bridging the gap between the pharmaceutical industry, healthcare professionals, and patients. This multifaceted function encompasses various activities, including among others medical education, scientific communication and collaboration with key stakeholders. The Medical affairs teams are comprised of medical or other life science professionals with deep scientific knowledge in different evolving roles.

(Morgan S, et al. 2018)

Medical directors oversee the medical strategy of a pharmaceutical company, ensuring alignment with regulatory requirements and scientific standards. They provide medical leadership to internal teams and collaborate with external stakeholders (Wharton GT, 2014). Medical Managers/Therapeutic Area Leads within Medical Affairs are responsible for developing and implementing medical strategies for specific therapeutic areas or product portfolios. They play a critical role in bridging the gap between clinical development, regulatory affairs and commercial functions (Doherty GJ, et al. 2016). Another established role is that of the office-based medical advisor. The role of a Medical Advisor in the pharmaceutical industry is critical in providing medical and scientific expertise to support various functions, including clinical development, marketing, market access and sales teams. Cross-functional collaboration and communication skills are among the capabilities requested to successfully liaise with other departments on different projects (Morgan S, et al. 2018).

Other roles within the Medical Affairs that attracts scientists are the **Medical Information Officer/Manager and the Clinical Studies Manager.** The first is responsible for responding to inquiries from healthcare professionals, patients, and internal teams regarding the medical and scientific aspects of pharmaceutical products. They ensure that the information provided is accurate, compliant with regulatory standards, and aligned with the company's policies (Reynolds JM, et al. 2016). The second is pivotal in overseeing the planning, implementation, and execution of clinical trials. Clinical Study Managers work collaboratively with cross-functional teams to ensure that trials are conducted in compliance with regulatory requirements, adhere to ethical standards, and achieve the scientific and clinical objectives.

It's important to note that the above roles and responsibilities may vary across organizations and described with some differences in each organization's official job descriptions and internal policies. Moreover, they are office-based roles focused primarily on strategic planning and internal stakeholders. But there is also the need for Medical Affairs roles that will interact and engage with external stakeholders.

In the search for competitive advantage, the pharmaceutical industry re-

Short cv

Alex Moulis
Head of Medical Sandoz Greece, Cyprus and Malta

An experienced Medical Affairs Executive with track record in both country and regional level. In the changing environment, I strongly believe in the development of the Medical Affairs roles as well as the introduction of both quantitative and qualitative metrics, in order to truly showcase the impact of Medical Affairs. Having been exposed to a variety of roles, I have gathered enough experience to develop, lead and motivate Medical Affairs teams in any challenge. For the past 6 years, I have been leading the Medical Affairs Team for Sandoz (Greece, Cyprus & Malta) focusing on making access happen. The introduction of biosimilars allows the extensive access of high quality medicines to all patients in need.The place of the Medical Affairs is crucial for the success of any organization. As such, I have closely worked within the organizations taking part in all aspects of commercialization (from the clinical development, to the approval and the pricing negotiations) ultimately ensuring that the right medication reaches the right patient.

cently established the role of the **Regional Medical Advisor**, or otherwise known as the **Medical Science Liaison (MSL)**(Gupta & Nayak, 2013). The field based medical roles originated as early as 1967 by the Upjohn Company (Morgan, et al., 2000). With time, the role evolved and currently the Medical Affairs Teams that have been created, are comprised by doctoral trained scientific personnel who interact with the physicians on a peer-to-peer basis (Gupta & Nayak, 2013). Furthermore, the position has evolved into comprehensive, complex, highly interactive, targeted, highly strategic innovative and independent role that offers a distinctive service to the physicians as well as the industry by gathering insights and offering a two-way communication relationship (Melo-Pereira & Dorfman, 2009) (Gupta & Nayak, 2013). Nowadays, the role of the MSL, or alternatively the role of the Medical Affairs team, besides interacting with the Key Opinion Leaders (KOLs) involves a variety of other activities such as Regulatory and Legal Support, training of physicians, Competitive Intelligence, Product Life Cycle Plans, Public-Private Partnership, Medical Writing, Pharmacovigilance, Medico-marketing support etc. (Albert & Sass, 2007) (Marrone, et al., 2007).

Such a diversity of responsibilities lead these field based medical teams to the same challenges that knowledge workers in the fields of strategy and competitive intelligence have been facing: how do you measure the value of ideas and insights that the MSLs currently bring to the organization? (Chin, 2007). Furthermore, how does the unique contribution of the Medical team get translated to the Financial Metrics currently used? How do the Senior Leaders understand the value of the investment behind the MSL role? In essence, it is difficult to measure the value of science-driven interaction and collaboration. The use of quantitative only metrics, as described by the financial approach to metrics (Otley, 1999), is strongly related to sales performance, and increases the compliance risk, as the performance measurement of the MSLs, should not be based on metrics (Marrone, et al., 2007) (Melo-Pereira & Dorfman, 2009). On the other hand, quite often, the use of qualitative metrics alone are often perceived to be insufficient surrogates from a business justification standpoint (Chin, 2007). Indeed, the executive leaders are often challenged to explain and support the dynamic role of the MSLs using non-financial metrics whilst having to increase the financial investment behind the role (Jacobson, et al., 2013). It is therefore evident that the choice of performance measures is very important for the organization. Not only do metrics ensure that the employees are performing in accordance to the company strategy but also the organization is moving towards the long term strategy (Forrest, 2016). Furthermore, “What is measured is managed” and simultaneously “what is not measured merits little or no attention” (Bauer, 2004). A metric acts as an accountability tool that enables the assessment of an action (Dulebohn & Johnson, 2013). In this context, currently, the Medical Affairs teams are faced with an enormous problem trying to identify and implement the metrics that will accurately capture their impact and ultimately lead and transform the organization.

Currently, Medical Affairs Teams are trying to capture and demonstrate their performance to the Senior Management using a variety of creative metrics. More often than not, though, these performance metrics fail to impress when up against more concrete Return on Investment (ROI) metrics (Cutting Edge Information, 2016). In many cases, the Medical Affairs Teams have found that a combination of quantitative and qualitative metrics work best (Cutting Edge Information, 2016). The addition of outcome-based metrics is often commonly suggested as well (Chin, 2007). In fact, various consortia (Best Practices, LCC, 2014)(Chin, 2007)(Cutting Edge Information, 2016) agree that a combination of hard and soft metrics, capturing a variety of Key Performance Indicators (KPIs) such as number of Key Opinion Leader (KOL) engagements,

Short cv

Petros Efstathopoulos
Head of Medical & Pharmaceutical Affairs, Chiesi Hellas and Cyprus

As a pharma industry executive, I have been working in the industry for seventeen years and I have gained a broad experience from different departments both at local and global level. With expertise in Respiratory, Neonatology and Rare Diseases I have a strong background of commercial operations by working closely with the Marketing and Market Access teams. As the responsible for the scientific services including Medical Affairs, Regulatory Affairs, Pharmacovigilance and Quality Assurance I have a track record of building and leading successful teams, committed to placing the patient at the forefront of all initiatives. My vision for Medical Affairs is to act as a primary strategic driver and to impact the outcome for our patients and health care providers through science, patient journey-led innovation and shared value partnership.

Presentations delivered, feedback from the KOLs etc. may reflect the effort and the ROI by the Medical Affairs Teams. In any case, the pharmaceutical industry is facing a real challenge in developing and maintaining the appropriate metrics and especially when considering the impact of the interactions between the MSLs and the KOLs (Melo-Pereira & Dorfman, 2009). By determining which performance metrics to use, and how often, the Medical Affairs Leaders can ensure they are delivering the most value to the organization (Best Practices, LCC, 2014). Recent research (Best Practices, LCC, 2014) has indicated that regardless of the market (both emerging and established alike) the pharmaceutical companies are using similar approaches in performance measurements. The focus on quantitative metrics allow senior leaders to have confidence behind the investment whereas the use of qualitative metrics, such as feedback by the customers, aims to capture the customer satisfaction factor. To conclude, the metrics recommended by the literature can be summarized in the following categories (Melo-Pereira & Dorfman, 2009):

- Number of interactions - shows that the MSL is actually interacting with the KOLs

- Number of meetings prepared - in order for the meeting to be based on science and mutual collaboration, the MSL needs to be prepared for each meeting

- KOL response time - demonstrates the value of the KOL to the MSL

- Time spent with KOL - as developing the relationship is a timely process, this metric demonstrates that MSLs are fulfilling their role.

- Proactive versus reactive - proactive interactions demonstrate business acumen and effective planning

- Medical Insights gathered from KOLs and other HCPs - to add valuable and actionable input to the medical marketing strategy

- Customer Satisfaction Surveys (CSAT Index) - to track HCP satisfaction with physician-led activities (e.g. educational events).

The above list is by no means conclusive. For example, an outcome-based metric, such as clinical trials initiated etc., may provide an inclination whether the scientific partnership is fruitful. It is, therefore, evident that gaps exist and the search for the perfect metrics will have to combine both quantitative and qualitative indicators.

In summary, there is extensive literature (Folan & Browne, 2005) (Papalexandris, et al., 2005) (Parker, 2000) (Basu, 2001) on how to devise and implement effective metrics. Generally, the measures should be kept physical (quantitative) and should be taken as close to the customer as possible (qualitative)(Folan & Browne, 2005). In certain cases, these two conditions may not be able to be met. Furthermore, the measures should have top management support, involve employees in their development, be relevant to managers and employees and be part of a feedback loop, to ensure development. The road is long, but certainly, a mix between the quantitative and qualitative metrics offers a concrete and sound first step.

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Digital health era and Real-World Data in Pharmacoepidemiology: Exploring the Greek Landscape

Foteini Dermiki-Gkana
MSc, Medical Advisor at Heal Think
Christiana Tychala
MSc, Health Economic Modeller/ Data Analyst at Heal Think
Marianthi Karaiskou
MSc, Health Economic Modeller/ Real Word Evidence manager at Heal Think
Panagiotis Stafylas
MD, MSc, PhD, Scientific Director at Heal Think

What is pharmacoepidemiology?

Pharmacoepidemiology as a linkage between pharmacology and epidemiology principles, investigates the effects of drugs on human populations, examining the benefits, therisks, and theusage patterns of medicinal products in real-world settings[1]. The aim of pharmacoepidemiology is to improve the "rational drug use"by providing evidence-based insights about crucial drug safety issues for different sub-populations that are missing from randomized clinical trials[2].

Pharmacoepidemiology Meets Digital Health

Digital health is associated with the utilizationof advanced technologies and their implications to the healthcare domain to improve prevention, diagnosis, treatment, monitoring, and disease management. A significant part of digital healthconstitutes the Real-World Data (RWD) and Real-World Evidence (RWE) that derived from RWD analysis. Indeed, the integration of RWD and RWE significantly contribute to this digital revolution in the healthcare domain[3].RWD as part of digital healthincludes data relating to patient health condition and their medical records, collected from a variety of sources such as electronic health records, health apps, and wearable devices. RWD and RWE can complement traditional pharmacoepidemiological research methods by capturing a wider spectrum of patients with different characteristics and offering more generalizing findings[4].

On the other hand, traditional pharmacoepidemiological studies utilise RWD but not necessarilydigital health data or patient-generated health data [5]. The use of digital health tools in pharmacoepidemiology offers a thorough investigation and real-time analysis that traditional pharmacoepidemiological methods could not reach out. Thus, it is important to increase the use of digital tools and databases into the design and the data collection processes of different pharmacoepidemiological studies[6]. To this direction, pharmacoepidemiology obtain a new and innovative dimensionby utilizing more digital data sources and advanced technology such as big data analytics, machine learning, and other advanced data technologiesto provide real-timeinsightsand making an important advancement in the field of drug monitoring efficacy and safety [7]. In addition, by following a digital approach, it is possible to analyze larger datasets more quickly, potentially leading to faster insights. Finally, the existence of digital methods can lead to awider range of available data, including patient-generated data and social mediapublicly available content[8]. However, challenges related to the data quality, privacy, and ethical issues in pharmacoepidemiological studies still exist.

Exploring Pharmacoepidemiology in Greece

Although pharmacoepidemiology in Greece is in early stages, the last decade can be considered a turning point as several pharmacoepidemiological studies have been conducted especially after COVID-19 era. Pharmacoepidemiological studiesthat have been conducted in Greece focused on crucial issues such as the consumption of antibiotics in Greek hospitals[9], the consumption of psychotropics[7], and the prescribing patterns that have been adopted

for a wide range of severe diseases in Greece. Moreover, the majority of pharmacoepidemiological studies [10]that have been conducted, followed more traditional pharmacoepidemiological methods, such as observational study designs, and mainly provide information about disease patterns or drug use patterns without utilizing and integrating any digital data source, an initiative that could enhance the strength of the study findings [11].

Pharmacoepidemiology and the Digital Health in Greece: Opportunities and Challenges

In Greece, pharmacoepidemiology could begradually shaped based on various sources of digital health data including Electronic Patient Records, hospital and prescribing data, medical devices, and insurance data. The integration process of digital health data in Greece has significant opportunitiesresulting in safer and more effective treatments and enhancing public health policies and decision-making[12]. Despite the opportunities, Greece has several challenges to face concerning the complete use of the available digital tools and RWD in pharmacoepidemiology. The most significant challenge concerns the data standardization and integration. In Greece, there are diverse data sources that need to be standardized, integrated, and to follow all the necessary regulatory frameworksto proceed to the effective analysis of digital health data. Finally, there is a need to eliminate the digital literacy of healthcare professionals and build public trust regarding the digital health initiatives in research.

Heal Think

Inspired by the synthesis of the key words Health, IT and Think and their combined significance to today's healthcare systems, Heal Think was founded in 2014 to provide high class research, development (R&D) and market access services for innovative medicines, medical devices, and digital health solutions. The company possesses significant research & consulting experience, designing, coordinating, and successfully completing tenths of projects,covering all therapeutic areas, in collaboration with the industry, scientific associations, universities and research institutes, European consortia and other partners across Europe.

Contact details: Panos Stafylas, MD, MSc, PhD, Scientific Director at Heal Think, email: panos@healthink.info, tel: +30 2310 407200.

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The Lifecycle approach to the Health Technology assessment under the prism of the new EU HTA Regulation 2021/2282

Eugena Stamuli
MSc Health Economics

Overview of the new EU HTA Regulation

The Regulation (EU) 2021/2282 of the European Parliament and of the Council on Health technology assessment (HTA)[1,2] represents a significant step towards harmonizing HTA processes across the European Union. Adopted in December 2021 and effective from January 2022, this initiative amends Directive 2011/24/EU, impacting the pharmaceutical sector and its innovation trajectory. Starting from January 2025, oncology drugs and advanced therapy medicinal products (ATMPs) are required to undergo Joint Clinical Assessment (JCA). Orphan drugs will follow by 2028, with the goal of full implementation of HTA for all centrally approved EU drugs, as well as certain medical devices of Class IIb and III, and specific diagnostic devices by 2030.

HTA is an interdisciplinary process that examines both clinical and non-clinical aspects of health technologies. Specifically, four clinical domains focus on the unmet needs for the disease area under examination and existing health technologies, the technical characteristics of the new technology, safety, and therelative clinical effectiveness. The five non-clinical domains cover costs and economic evaluation, as well as ethical, organizational, social, and legal dimensions of the new technology[3]. This structured approach ensures a comprehensive evaluation, considering different aspects of the new technology.The definition of the HTA has evolved over time[4] to reflect the advancement in the biopharmaceutical products and the accompanying methodsthat are used for their evaluation, as well as the organisational contexts in which the HTA decisions are utilised. Based on the new definition[5],the HTA is a process that employs explicit methods to evaluate the health technology throughout its lifecycle (Figure 1). Hence, the HTA is applicable at various points in a health technology's lifecycle, including pre-market evaluation, market approval, post-market considerations, and potential disinvestment.

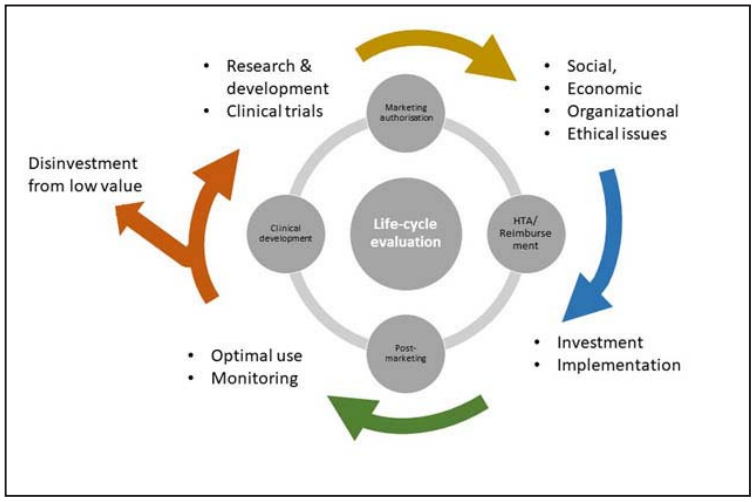

Figure 1: HTA evaluates health technologies throughout their lifecycle (adopted from Ref 13).

The new EU regulation focuses on the clinical domains of HTA, emphasizing the relative clinical effectiveness and safety of health technologies compared to existing ones. The non-clinical domains will fall within the remit of the local HTA bodies across EU member states, to account for the varying economic and other factors influencing the assessment of cost-effectiveness, value for money, and broader societal impacts. This decentralized approach acknowledges the diversity in healthcare systems across Europe, and resource allocation strategies, allowing individual member states to tailor their evaluations according to their specific non-clinical considerations (e.g., affordability, health care structure etc). Hence, the focus of the regulation on the clinical domains is considered more applicable and feasible across different settings and EU member states.

The PICO (Population – Intervention – Comparator – Outcomes) framework is the tool employed to outline the parameters of a JCA. In this framework,

the research question is developed during the scoping phase of the HTA (the other two phases relate to the dossier development and the technology assessment) around the patients or population(s) of interest, the intervention under consideration,the relevant comparator(s) for comparison with the assessed intervention, and the outcomes of interest. The formulation of PICO questions will be significantly influenced by the involvement of member states' HTA bodies, with the expected number of PICOs being around 4 to 6[6] or possibly larger in certain disease areas[7]. The purpose of the JCA is to act as a comprehensive reference for the clinical aspects of HTA, aiming to replace national assessments across all EU countries. While it is intended to be a foundational resource for national decisions, it's important to note that national HTA bodies retain significant autonomy. They have the authority to deviate from the JCA report, request additional data and evidence, and even propose alternative comparators[2].

Aside from the obligation of the member states' HTA bodies to participate in the JCAs, they will also be able to participate in Joint Scientific Consultations (JSCs). These consultations, conducted in collaboration with the European Medicines Agency (EMA), will guide manufacturers on appropriate clinical study designs for generating relevant evidence. Additionally, joint "horizon scanning" exercises at the EU level will identify promising health technologies early on to aid Member States' health systems in their preparation for the JSC/JCA.Furthermore, the Post Launch Evidence Generation (PLEG) activities[8]involve generating evidence after the launch of a health technology within its approved indication, complementing the evidence generated for marketing authorization or the HTA. The JSC and horizon scanning, as well as the PLEG represent a comprehensive, lifecycle approach to the HTA for emerging technologies.These activities can be strategically integrated into the initial stages of product development and life-cycle, with the primary goal of aligning with the requirements of HTA organizations. This approach ensures that the new technologies are not only developed to meet the minimum clinical standards, set by regulators like EMA (efficacy - safety), but are also tailored to address the specific needs crucial for successful reimbursement within the HTA framework (effectiveness - cost/effectiveness).

Implications for the Greek HTA approach

The new regulation, in line with the life-cycle approach to the HTA, requires adjustments from the viewpoint of the Greek HTA (adapted from relevant international literature[9]). The EU's focus on clinical evidence and the PICO framework may reveal differences between Greece's current standard of care and available technologies. To address these variations, the Greek HTA Committee canactively contribute to the PICO generation for the JCA purposes. Timely and structured engagement (e.g., via formal committee meetings) with healthcare professionals, patients, and other stakeholders allows the committee to understand local practices compared to the broader European landscape. This involvement helps establish relevant PICOs that reflect the Greek environment, ensuring that clinical evidence not only complies with EU JCA standards but is also directly applicable to Greek healthcare. This approach aims to prevent duplication of effortsand timely assessment of the new technologies by the Greek HTA committee, a commitment also emphasized by the new EU regulation.

Further, a methodological reference case, which the currentworking framework of the Greek HTA committee lacks, shouldbe developed, in line with other HTA bodies in Europe (e.g., NICE's reference case[10] and guidance[11]). The reference case can serve as a guidance for those involved in producing evidence submissions to the Greek HTA. It should outline the standards and expectations for all the evaluation criteria, including economic evaluations,

toensure a transparent and consistent approach in the decision-making of the Greek HTA. This is more pertinent in the current evolving landscape of the bio-pharmeceutical developments where ATMPs, cell &gene therapies, and high-risk medical devices often receive regulatory approval based on single-arm or non-randomized comparisons, and the utilization of non-traditional outcomes, such as surrogate endpoints.

In the absence of a reference case in HTA, the existing assessment method applied by the Greek HTA appears potentially opaque. It heavily relies on budgetary impact assessments for reimbursement decisions, lacking transparency in evaluating the appropriateness and value of diverse types of evidence, such as single-arm trials and real-world data. This approach raises concerns about the subjectivity inherent in the current decision-making process. In addition, the absence of a reference case, coupled with an exclusive dependence on budget impact analysis, introduces the risk of overlooking the (long-term) cost-effectiveness of interventions. While budget impact analysis provides insights into immediate financial implications of new health technologies, it does not capture the broader concept of "value for money" of new health technologies. This approach restricts the ability to make well-informed decisions regarding the optimal allocation of resources as it deviates from achieving true allocative efficiency[12]—a critical approach within a healthcare system grappling with exceedingly limited financial resources.

Achieving the successful implementation of the new EU Health Technology Assessment (HTA) Regulation in Greece requires a strong and collaborative effort among key stakeholders. This includes close cooperation among the National Medicines Agency (EOF), the Greek HTA Committee, and the healthcare payor EOPYY.

Moreover, the current approach may inadequately address the crucial aspect of affordability in healthcare decision-making without a reference case. A standardized framework ensures consistency in conducting affordability assessments, integrating both short-term budgetary constraints, long-term cost-effectiveness considerations as well as disinvestment decisions for technologies with no incremental effectiveness, as assessed by methodologically sound approaches. This holistic viewpoint is indispensable for evaluating the sustainability of adopting new health technologies and optimizing resource allocation within the constraints of limited healthcare budgets.

Considering that Joint Clinical Assessments (JCAs) will likely partially address these issues (since the focus will be on the clinical elements), the Greek HTA committee can benefit from such a reference case when it comes to local reimbursement decisions. The new EU regulations present, however, an opportunity for collaborative, multi-country post-launch data collection, especially for rare diseases. This highlights the significance of leveraging real-world data (e.g., through the development of patient registries), patient preferences, and experiences to enhance the effectiveness of the implementation process.

Achieving the successful implementation of the new EU Health Technology Assessment (HTA) Regulation in Greece requires a strong and collaborative effort among key stakeholders. This includes close cooperation among the National Medicines Agency (EOF), the Greek HTA Committee, and the healthcare payor EOPYY. The existing sequential/linear process, where patients' access to new medicines hinges on marketing authorization followed by pricing and reimbursement decisions, sometimes results in isolated, often duplicatedactivities of each regulator, and potential delays. This is particularly evident when these decisions, driven by (cost-)effectiveness assessments and budget impact analysis, occur in silos. The outcomes of the collaborative and simultaneous efforts among the three stakeholders in Greece can seamlessly integrate into the scoping phase of the EU JCA, representing a truly life-cycle and efficient approach.

Conclusion

The new EU Health Technology Assessment (HTA) Regulation marks a sig-

nificant step in harmonizing evaluation processes across the European Union. Its focus on clinical domains via the PICO framework and the JCA, and offer the opportunity for a life-cycle approach via the early and Joint Scientific Consultations (JSCs), and PLEG. These developments require adjustments from the Greek HTA. The Greek HTA Committee can proactively contribute to JCAs by addressing local variations through structured consultations and engagement with relevant stakeholders. Importantly, collaborative efforts among key stakeholders, including EOF, the Greek HTA Committee, and healthcare payor EOPYY, are crucial for the successful integration of the new EU HTA Regulation into the Greek HTA and reimbursement process, streamlining processes and avoiding duplicate or in silo activities.

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New Technologies and Digitalization - Reshaping the Future of the Pharmaceutical Industry

Nikos Tsokanas
BSc (Hons), MSc, MBA - VP of BoD of EL.E.F.I.

The pharmaceutical industry, long defined by its meticulous research, development, and stringent regulatory processes, is undergoing a profound transformation fueled by the integration of cutting-edge technologies and digitalization. This evolution is revolutionizing the way medications are discovered, developed, manufactured, and distributed, ultimately enhancing patient care and outcomes.

One of the significant impacts of technology in pharmaceuticals is the acceleration of research and development (R&D) processes. Advanced algorithms and machine learning models are analyzing massive datasets, expediting the identification of potential drug candidates. This has significantly reduced the time and resources traditionally required for drug discovery, allowing for quicker identification of promising molecules.

Digitalization has paved the way for personalized medicine. Through the analysis of genetic information, patient history, and real-time health data, pharmaceutical companies can tailor treatments to individual patients. This targeted approach not only enhances efficacy but also minimizes adverse effects, marking a substantial leap forward in patient-centric care.

The Internet of Things (IoT) has penetrated the healthcare sector, enabling connected devices to monitor patients remotely. In pharmaceuticals, IoT-powered devices are revolutionizing clinical trials by collecting real-time data, ensuring accurate measurements, and providing constant feedback, thereby improving the overall efficiency of trials.

With stringent regulatory standards, compliance is paramount in the pharmaceutical industry. Digitalization has facilitated the development of sophisticated software solutions that aid in regulatory compliance. Automated systems ensure adherence to guidelines, streamlining processes, and reducing errors in documentation and reporting.

Pharmaceutical companies are leveraging virtual reality for employee training, especially in complex manufacturing processes and intricate laboratory procedures. Virtual reality simulations offer an immersive learning experience, enabling trainees to practice in a risk-free environment, ultimately improving accuracy and efficiency in production.

The trail of digitalization in the pharmaceutical industry is promising, with ongoing developments in artificial intelligence, big data analytics, and robotics poised to further revolutionize drug development and patient care. However, challenges such as data privacy concerns, regulatory hurdles, and the integration of these technologies into existing infrastructures remain significant hurdles.

In conclusion, the conjunction of new technologies and digitalization in the pharmaceutical industry is reshaping the landscape, fostering innovation, improving efficiency, and, most importantly, enhancing patient outcomes. As these advancements continue to unfold, the industry stands at the threshold of an era where the intersection of technology and healthcare promises a brighter, more personalized future for all.

Από την Ακαδημαϊκή Έρευνα στο Εξωτερικό, σε Κλινικές Μελέτες στην Ελλάδα

Δάφνη Γυφτάκη -Βενιέρη
PhD, Γενικός Γραμματέας ΕΛ.Ε.Φ.Ι., Clinical Research Asssociate, Qualitis SA (part of Optimapharm Group)

Σε νεότερη ηλικία τροφοδοτούμουν από την περιέργεια, τη δίψα για καινούρια γνώση και συμμετοχή στα επιστημονικά δρώμενα. Έβλεπα πως η ακαδημαϊκή έρευνα καθοδηγείται από την αναζήτηση γνώσης και την επιστημονική ανακάλυψη. Πραγματεύεται την επέκταση του θεωρητικού πλαισίου με έμφαση στις δημοσιεύσεις και το ακαδημαϊκό κύρος. Εξαρτάται όμως απόλυτα από χορηγίες είτε μέσω της κυβέρνησης, είτε μέσω ιδιωτικών και άλλων ακαδημαϊκών ιδρυμάτων, κάτι που υπόκειται σε περιορισμούς προϋπολογισμού. Αυτός ήταν και ο πρωταρχικός λόγος που έφυγα από την Ελλάδα, οι τότε περιορισμένες επιλογές και έλλειψη ερευνητικών κονδυλίων και χρηματοδότησης της έρευνας στη χώρα.

Σπούσαδα Γενετική στο πανεπιστήμιο της Γλασκόβης στην Σκωτία και προχώρησα σε μεταπτυχιακές και διδακτορικές σπουδές στο University College London (UCL) στο Λονδίνο πάνω στην βιοϊατρική και την ρευματολογία. Πριν παραλάβω το διδακτορικό μου πτυχίο, ξεκίνησα ως Research Fellow στο πανεπιστήμιο της Οξφόρδης σε συνεργασία με την φαρμακευτική εταιρεία Bristol Myers Squibb. Βρέθηκα σε ιδανική θέση για μια ακαδημαϊκή ερευνητική καριέρα, καθώς η επιτυχία στον τομέα μετριέται βάσει της ποιότητας και επίδρασης της έρευνας στην υπόλοιπη ερευνητική κοινότητα, κάτι που ήμουν σε θέση να διεκδικήσω.

Άρχισε, όμως, να με απασχολεί περισσότερο η μετάφραση της γνώσης, σε έργο που μπορεί να επωφελήσει πιο άμεσα ανθρώπους επιβαρυμένους από ασθένειες, που ως τώρα έβλεπα θεωρητικά, μέσα σε εργαστηριακό περιβάλλον. Σε συνδυασμό με την ανάγκη για μεγαλύτερη σταθερότητα στο εργασιακό πλαίσιο, καλύτερες αποδοχές, προοπτικές ταχύτερης ανάπτυξης, αλλά και την συνειδητοποίηση ότι ακόμα και σε κορυφαία πανεπιστήμιαη πρόοδος δεν είναι πάντα αξιοκρατική, άρχισα να αναζητώδιαφορετικούς ρόλους και θέσεις εργασίας στον ιδιωτικό τομέα, που να ταιριάζουν με τις δεξιότητες και την ιδεολογία μου.

Η διαδικασία εύρεσης εργασίας δεν ήταν εύκολη καθώς η έλλειψη εμπειρίας στον ιδιωτικό τομέα ήταν καθοριστική για πολλές θέσεις. Ταυτόχρονα, παρόλο που ο τίτλος «Ελληνίδα του εξωτερικού» είχε γίνει μέρος της ταυτότητάς μου, οι βλέψεις μου για το μέλλον συμπεριλάμβαναν πάντα την επιστροφή στην Ελλάδα.

Πολλοί θέλουν τους Έλληνες με καριέρα στο εξωτερικό να επιστρέφουν δύσκολα πίσω στην χώρα τους. Πολλοί βλέπουν την Ελλάδα ως ένα κράτος που υστερεί στους τομείς της οργάνωσης, κοινωνικών παροχών, δικαιωμάτων και σταθερότητας στο φορολογικό και ρυθμιστικό πλαίσιο, ακόμα και σε ευκαιρίες εργασίας. Η αλλαγή στις προτεραιότητές μου ως προς τον τρόπο και την ποιότητα ζωής, και η θέληση να προσφέρω στην χώρα που ποτέ δεν έπαψα να θεωρώ σπίτι μου, με ώθησαν να αναζητήσω θέσεις εργασίας πίσω στην Ελλάδα.

Τότε έμαθα και για την ύπαρξη των CROs όπου εστιάζουν στην βιομηχανία και στην αποτελεσματική και έγκαιρη εκτέλεση κλινικών δοκιμών, με επίκεντρο την βελτίωση της ποιότητας ζωής των ασθενών μέσω τηςδιευκόλυνσης της ανάπτυξης και έγκρισης νέων φαρμάκων, θεραπειών ή και ιατρικών συσκευών. Σε συνεργασία με άλλους ενδιαφερόμενους φορείς, συμβάλλουν σημαντικά

στην διασφάλιση της ποιότητας των κλινικών μελετών, με συμμόρφωση σε αυστηρά κανονιστικά πλαίσια, χρονοδιαγράμματα και προϋπολογισμούς. Η χρηματοδότησή τους προέρχεται από φαρμακευτικές και βιοτεχνολογικές εταιρίες, συνήθως με μεγαλύτερο προϋπολογισμό και εμπορικό ενδιαφέρον. Επαγγελματίες σε CROs έχουν την ευκαιρία να αποκτήσουν σημαντική εμπειρία ως προς την λειτουργία κλινικών δοκιμών, τη διαχείριση διαφορετικών έργων, την επικοινωνία με νοσοκομεία και ιατρικό προσωπικό αλλά και με διαφορετικές φαρμακευτικές εταιρίες, γεμίζοντας την φαρέτρα τους με ποικίλες εμπειρίεςκαι δεξιότητες και θέτοντας σημαντικές βάσεις για μια πολλά υποσχόμενη μελλοντική καριέρα.

Μετά από κάποιους μήνες έρευνας, δικτύωσης και σε συνεργασία με ανθρώπους που πίστεψαν στις δεξιότητές μου, παρουσιάστηκε ευκαιρία σε εταιρεία CROσε ρόλο Clinical Research Associate (CRA) στην Αθήνα, την οποία και αποδέχτηκα. Η επιλογή αυτή ήταν και στρατηγική. Τα τελευταία χρόνια η χώρα επιχειρεί να καταστήσει ένα πιο ελκυστικό περιβάλλον για την προσέλκυση κεφαλαίων για την διεξαγωγή κλινικών μελετών, συμπεριλαμβανομένου και αυτών που βρίσκονται ακόμα σε πρώιμο στάδιο έγκρισης. Παραδείγματα πρόσφατων τέτοιων ενεργειών είναι η θέσπιση του επενδυτικού Clawback, η ρύθμιση της δυνατότητας των νοσοκομείων του ΕΣΥ να χρηματοδοτούνται για την υποστήριξη της διεξαγωγής βιοϊατρικών ερευνών (και κατ' επέκταση κλινικών μελετών), η δυνατότητα σύστασης ανεξάρτητων τμημάτων κλινικών μελετών, η συγκρότηση ομάδας εργασίας από το Υπουργείο Υγείας για την ανάπτυξη των κλινικών μελετών και της βιοϊατρικής έρευνας στη χώρα και η εναρμόνιση των διαδικασιών αξιολόγησης και εποπτείας των κλινικών δοκιμών με την υπόλοιπη ΕΕ. Αποτέλεσμα να σημειωθεί 20% αύξηση στον αριθμό κλινικών μελετών στη χώρα το 2022, ποσοστό που δυστυχώς φαίνεται να είναι μειωμένο το 2023.

Οι συνεχείς προσπάθειες για την ευαισθητοποίηση του κοινού, την βελτίωση του κανονιστικού πλαισίου και προώθησης διεθνών συνεργασιών είναι εμφανείς. Οι πιθανότητες επαγγελματικής ανάπτυξης και η δυνατότητα της συμμετοχής στην διαμόρφωση του μέλλοντος της ιατρικής έρευνας, των θεραπευτικών εξελίξεων και της ποιότητας ζωής ασθενών καθιστά τον τομέα των κλινικών μελετών αρκετά ελκυστικό. Η απάντησή μου λοιπόν, σε αυτούς που με ρωτούν εάν έχω μετανιώσει για την επιστροφή μου, είναι – και ελπίζω να συνεχίσει να είναι – όχι δεν το έχω μετανιώσει. Αντιθέτως, θα ήθελα να εκμεταλλευτώ τις γνώσεις και δεξιότητες που έχω αποκτήσει, για την ανάπτυξητου τομέα των κλινικών μελετών στην χώρα, και την προώθηση δράσεων σε συνεργάτες και νεότερους επαγγελματίες στην Ελλάδα αλλά και στο εξωτερικό.

Navigating the Ethical Issues raised by Digital Health Technology

Georgia Livieri
PhDc, Ethics Research Associate, Department of Rehabilitation Sciences, School of Health Sciences, Cyprus University of Technology

Digital health is undoubtedly revolutionizing healthcare systems globally, bringing about significant changes in the way healthcare is delivered and managed (Brall et al., 2019).

Health systems worldwide are increasingly using digital health methods, but there is a need to adjust existing practices and governance structures to face the challenges they pose (Brall et al., 2019).

The widespread adoption of digital technologies poses ethical concerns in healthcare and public health (Shaw & Donia, 2021).

Ethical issues in digital health exist in multiple dimensions, depending on the various phases of digital health technology use, the differentiation ofstakeholders' engagement, and several technical and also governance issues (Brall et al., 2019).

Picture source https://academic.oup.com/books

To be more specific, before the utilization of digital health, logistic and resource-related issues arise, including equitable access to digital health services with regard to the affordability of and access to technological equipment (Kirigia et al., 2005). Furthermore, the availability of digital health services is of crucial significance, mainly for underserved communities and populations, including people suffering from rare diseases, the elderly and the homeless (Brall et al., 2019). What is more, inequality in access might arise because specific population categories are excluded from the use of digital health technology due to digital illiteracy and age-related socialization (Brall et al., 2019).

On the other hand, during and after theactual usage of digital health technologies, several ethical challenges take place, referring to storage, access, sharing, and ownership of data (Brall et al., 2019), includingsecurity and privacy (Paul et al., 2023), confidentiality (Chen et al., 2016), discrimination issues (Amon, 2020), while also the unintended uses of data and the right to be aware of incidental findings are of key importance (Brall et al., 2019).

It is worth mentioning that trust and empowerment are two key values for establishing fair digital health interventions, including open communication, a common language, and ongoing conversation and partnership, all of which are vital for raising awareness among the public (Brall et al., 2019), while the cultivation of digital literacy would be an effective mechanism, allowing individuals to engage with data-driven technology use, contributing to their empowerment. What is more, it is important to highlight that transparency, accountability, and inclusiveness constitute the most significant procedural

values for enabling fair digital health, leading to better-informed decisions, and diminishing inequities (Brall et al., 2019).

All in all, digital health is not only an issue of technology but also constitutes a cultural shift in healthcare practices, along with policies and partnerships (Nguyen et al., 2023). Specifically, it is about "The cultural transformation of how disruptive technologies that provide digital and objective data accessible to both caregivers and patients leads to an equal level doctor-patient relationship with shared decision-making and the democratization of care" (Meskó et al., 2017).

This is how we can unlock the full potential of healthcare by empowering patients to become engaged in their own care (Nguyen et al., 2023).

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www.elefi.gr

Σχεδιασμός:
Γιάννα Νίκης
ynikis@otenet.gr
6973236595