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CONSIDERATIONS FOR EFFECTIVE COMMUNICATION OF MEDICAL INFORMATION

It is our pleasure to provide readers with an interesting publication from Academy Board member Dr. Eddie G.M. Power. As we know, medical terminology can be difficult for the general public to understand, a conclusion supported by surveys within the arena of clinical trials.

Dr. Power's article "describes considerations in how the healthcare community, and Medical Affairs organizations in biopharma, can effectively harness these channels to communicate effectively, and incorporate changes in behaviors and approaches to redefine what medical information and data look like." Continue reading on page 2.

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As we know, medical terminology can be difficult for the general public to understand, a conclusion supported by surveys within the arena of clinical trials. Several surveys have shown that information required to be provided to patients to participate in clinical trials (Informed Consent form and Clinical Trial information sheet) are difficult to comprehend and may even detract from their ultimate goal of providing simple, concise information to informed patients. The use of digital media to deliver medical information may further exacerbate the challenges of communicating medical information.

In the abstract, Dr. Power states, "An ongoing and increasing shift is occurring in ways in which the healthcare community (healthcare providers, patients, biopharma) disseminates and consumes information. Adoption of digital technologies, accelerated by the virtual environment created by the COVID-19 pandemic, are leading to new and innovative ways in which medical and scientific information and data are communicated. Digital technologies have largely enabled these approaches and led to an explosive increase in availability of information."

Dr. Power concludes, "Society at large has expanded its horizons with new technologies and new generations displaying their preferences of how to receive information. Medical Affairs, with its unique position at the interface of biopharma and the healthcare and patient communities, is poised to shape and lead the new wave of medical and scientific communication. A final thought: the stakeholder, not the technology, determines the optimal means of delivering information." Click here to read more.

Dr. Eddie Power

Dr Eddie Power is currently the VP, North America Medical Affairs, Hospital Business, Pfizer Biopharmaceuticals Group and has held positions of increasing responsibility during his career in the pharmaceutical industry. He started at Pfizer in September 2010 as the Team Leader, US Medical Affairs Infectious Diseases in SCBU, before assuming the position of Group Leader, US Medical Affairs, Vaccines and Infectious Diseases in 2012 and Head, US Medical Affairs, Vaccines in 2014.

Before joining Pfizer, Eddie served as the Global Medical Director for Cubist Pharmaceuticals since 2008, working internationally with alliance partners to develop Medical Affairs strategies for Cubist's anti-infective portfolio. Previously, Eddie was the Therapy Area head at Schering-Plough leading the Anti-Infectives/Virology/ Addiction Medicine portfolio in Global Medical Affairs.

He was also with Bayer Healthcare, where he was Director of Global Scientific Affairs, responsible for global opinion leader interactions, scientific communications and overseeing a corporate antimicrobial stewardship program. Prior to joining Bayer in 2002, Eddie was Director, Strategic Microbiology at GlaxoSmithKline supporting GSK's Infectious Disease portfolio. Eddie held a faculty position at United Medical and Dental Schools, Guy's & St Thomas' Hospitals, London, UK.

He holds a PhD degree from the Welsh School of Pharmacy, University of Wales and an MBA from Henley Management College, UK, and is a past recipient of the WH Pierce Memorial Prize (UK) for an outstanding contribution to microbiology. He is married with three children and enjoys sport and cycling in his spare time.

FDA APPROVES ALZHEIMER'S DRUG LECANEMAB AMID SAFETY CONCERNS

The US FDA approved lecanemab, the second-ever treatment for Alzheimer's disease that is intended to tackle the root of the condition and the slow cognitive decline that results. Clinicians welcome the decision, but their excitement is clouded by reports of patient deaths and that the FDA acted improperly last year when approving the first drug of this kind.

Lecanemab (named Leqembi) is the first Alzheimer's treatment of its kind shown to slow cognitive decline in a robust clinical trial and is the second treatment to be approved in under two years. It is made by the bio-pharmaceutical companies Eisai in Tokyo, and Biogen in Cambridge, Massachusetts.

The drug, a monoclonal antibody, is infused into a patient intravenously. It then enters their brain and clears the amyloid plaques thought to cause cognitive impairment and dementia in Alzheimer's disease.[2]

Continue reading here.

NEWS FROM THE EMA

The EMA is pleased to announce the distribution of the January 2023 issue of the monthly newsletter. It contains news on new drug approvals in the areas of Covid-19 vaccines, cancer, cardiovascular medicine, hematology, hepatology, HIV, hormones, immune system, metabolism, nephrology, CNS, ophthalmology, respiratory, rheumatology, and vaccines.

It also includes several updates on clinical guidelines and a list of reports of scientific events, most of them devoted to clarifications about the new CTIS (Clinical Trials Information System), in place in all EU countries from January 2022, and which is now mandatory for all sponsors planning to activate a new clinical trial.

Access the newsletter here.

NEWS FROM ARTIFICIAL INTELLIGENCE

Large language models such as ChatGPT can produce increasingly realistic text, with unknown information on the accuracy and integrity of using these models in scientific writing. In order to test the ability to detect artificially generated texts, the authors gathered ten research abstracts from five high-impact factor medical journals (n=50) and asked ChatGPT to generate research abstracts based on their titles and journals. Then they evaluated the abstracts using an artificial intelligence (AI) output detector, plagiarism detector, and had blinded human reviewers try to distinguish whether abstracts were original or generated.

All ChatGPT-generated abstracts were written clearly but only 8% correctly followed the specific journal's formatting requirements.

Most generated abstracts were detected using the AI output detector, with scores (higher meaning more likely to be generated) of median of 99.98% compared with very low probability of AI-generated output in the original abstracts of 0.02%. The AUROC of the AI output detector was 0.94.[3]

Continue reading here.

EMA ANNOUNCES CANCER PREVENTION INITIATIVE

The EMA is pleased to inform that the European Commission has launched a call for evidence for cancer prevention – action to promote vaccination against cancer-causing viruses.

Europe's Beating Cancer Plan (the 'Cancer Plan') is a key priority of the Commission in the area of public health and a cornerstone of the European Health Union. Together with the Horizon Europe Cancer Mission, it is the EU's response to the increasing number of cancer cases and deaths across the EU population.

This initiative is included in the 2023 Commission work program under the Commission priority 'Promoting our European Way of Life' as part of a prevention package, which also includes a revised proposal for a Council Recommendation on smoke-free environments. Continue reading here.

NEWS REGARDING CLINICAL TRIALS

The EMA informs of the launch of a public consultation concerning the development of a multi-stakeholder platform to promote collaboration for improving clinical trials in the EU as foreseen by Accelerating Clinical Trials in the EU (ACT EU) priority action 3.

This platform will enable regular dialogue between all EU stakeholders on clinical trials and facilitate the evolution of the clinical trials environment by helping to identify key advances in clinical trial methodologies, technology and science. The platform will serve as a neutral space for the discussion of challenges and the development of practical solutions to enable and drive change.

It is envisaged that there will be several phases of development before reaching its final design. A concept paper outlining the proposal for the creation of the platform has been published together with the public consultation.

Continue reading here.

EMA, FDA DIFFERENCES IN GENE & CELL THERAPY REQUIREMENTS

Cell and gene therapies (CGT) are the new frontier of medicine, offering life extension and sometimes cures for previously untreatable conditions. These revolutionary therapies are expensive and follow non-traditional routes to approval.

There are different approaches to the requirements and how they are established including an additional reimbursement approval step required in the European Economic Area (EEA). When comparing requirements to obtain approval for cell and gene therapies between the FDA and the European Medicines Agency (EMA), you may be struck by large variations in terminology. However, a closer look quickly indicates that sponsors face similar challenges in both markets.

Click here to learn more about the differences and similarities between FDA and EMA in their approaches to CGT.

REFERENCES

1. Power, E. G. M. (2023). Considerations for Effective Communication of Medical Information. Pharmaceutical Medicine. https://doi.org/10.1007/s40290-023-00461-3
2. FDA approves Alzheimer's drug lecanemab amid safety concerns. (2023, January 10). Nature. https://www.nature.com/articles/d41586-023-00030-3?utm_source=Nature+Briefing&utm_campaign=33d9dd6146-briefing-dy-20230109&utm_medium=email&utm_term=0_c9dfd39373-33d9dd6146-47677880
3. Gao, C. A., Howard, F. M., Markov, N. S., Dyer, E. C., Ramesh, S., Wang, F., & Pearson, A. T. (2022). Comparing scientific abstracts generated by ChatGPT to original abstracts using an artificial intelligence output detector, plagiarism detector, and blinded human reviewers. BioRxiv (Cold Spring Harbor Laboratory). https://doi.org/10.1101/2022.12.23.521610
4. How Do Cell & Gene Therapy Requirements Differ Between FDA & EMA? (n.d.). https://www.bioprocessonline.com/doc/how-do-cell-gene-therapy-requirements-differ-between-fda-ema-000

Thanks for reading!

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