BRAC UNIVERSITY School of Pharmacy

PHARMA HIGHLIGHTS

ISSUE 104 | May 2023

Workshop on "Essential Statistical Analyses for Clinical Research"

Statistical tools play a crucial role in research by providing researchers with methods to analyze, interpret, and draw conclusions from data. These tools enable researchers to make sense of large datasets, test hypotheses, determine relationships between variables, and support their claims with evidence.

As part of the **'Toolbox for Success'** series, a workshop on "Essential Statistical Analyses for Clinical Research" was organized for the students at the School of Pharmacy, on Wednesday, 3rd May 2023 at BRACU GDLN Center. The workshop provided training on the use of StatFlex, a statistical software package developed by Professor Kiyoshi Ichihara from the Graduate School of Medicine of Yamaguchi University, Japan.

StatFlex is a user-friendly statistical analysis tool that is designed for data analysis and visualization. It provides a range of statistical analysis features and techniques, such as descriptive statistics, hypothesis testing, regression analysis, ANOVA, time series analysis, factor analysis, cluster analysis, and many others. One of the unique features of StatFlex is its graphical interface, which allows users to create custom charts and graphs to visualize their data. The software also supports a wide range of data formats, including Excel spreadsheets, text files, and databases, making it easy to import and export data.

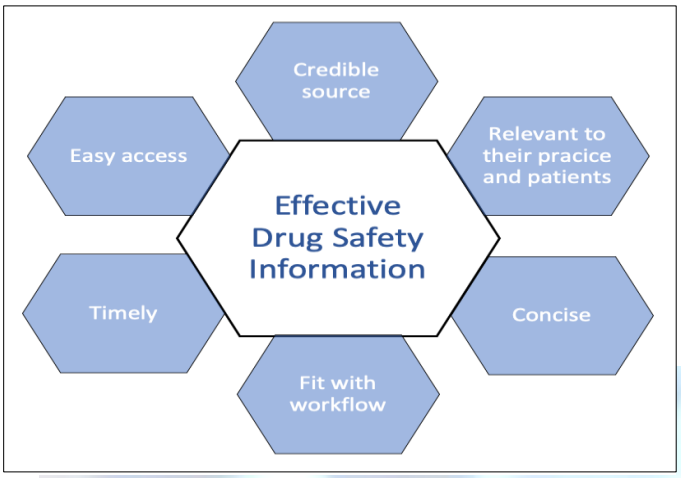
Dr. Kiyoshi Ichihara is a highly accomplished researcher and a medical doctor, currently serving as a Senior Academic Researcher and Emeritus Professor at the Yamaguchi University Graduate School of Medicine in Japan. Dr. Ichihara completed his formal education at the Yamaguchi University School of Medicine, where he graduated in 1975 with a medical degree. He went on to complete his Postgraduate Doctoral course in Laboratory Medicine in 1979. Dr. Ichihara has had an illustrious career in the field of medical research, and his contributions have been widely recognized. He has served as the Chair of the Committee on Plasma Protein at the Japanese Society of Clinical Chemistry (JSCC) and as the Chair of the Committee on Evidence-based Laboratory Medicine at the Japanese Society of Laboratory Medicine (JSLM). He has extensive expertise in laboratory medicine, biostatistics, computer science, and software development. He has published numerous articles in scientific journals and authored five Japanese textbooks on basic statistics. He is also the developer of "StatFlex," a popular statistical software with over 20,000 users. Dr. Ichihara's clinical work is in primary care medicine and endocrinology, with a specialization in thyroid diseases. The seminar was moderated by Ms. Syeda Maliha Ahmed, Lecturer, School of Pharmacy, Brac University. Faculty members, teaching assistants, and students of the School of Pharmacy attended the workshop.

BRAC UNIVERSITY School of Pharmacy

PHARMA HIGHLIGHTS

ISSUE 104 | May 2023

Drug Safety



Drug safety is a crucial aspect of the pharmaceutical industry. It involves monitoring, assessing, and ensuring the safe and effective usage of medications. Drug safety encompasses a range of activities such as identifying, managing, and minimizing the risk of pharmaceutical products. The primary goal of drug safety is to maximize the benefits of drugs while minimizing their potential harm. The pharmaceutical industry has several key factors in drug safety, including preclinical testing, clinical trials, regulatory approval, and post-marketing surveillance.

Preclinical Testing: Before proceeding with human trials, drugs undergo preclinical testing, which involves laboratory experiments using cells and tissues to evaluate the drug's pharmacokinetics, toxicity, and side effects. This step helps to identify potential risks and side effects of the drug before it is administered to humans.

Clinical Trials: In clinical trials, human subjects are tested in multiple stages to assess the drug's efficacy, safety, potential interactions, and dosage form. Strict regulatory protocols and ethical guidelines are followed during clinical trials to protect the well-being of the participants.

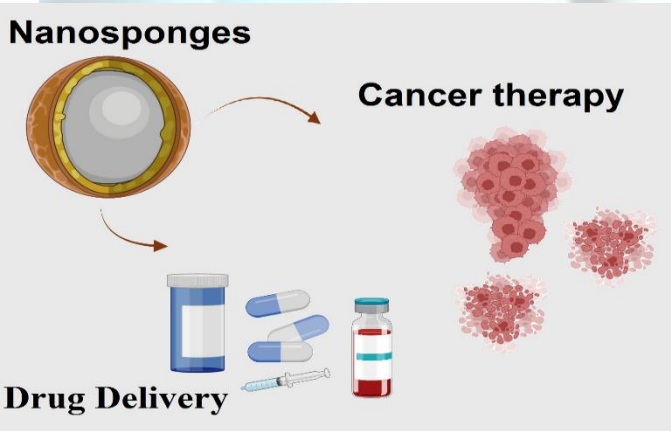
Regulatory Approval: Regulatory authorities such as the FDA and EMA review the data of clinical trials before approving a drug. This step ensures that only safe drugs reach the market.

Post-marketing Surveillance: After approval of the drug, healthcare professionals and pharmaceutical companies monitor the drug's safety by analyzing data and identifying adverse reactions. Pharmacovigilance and risk management strategies are essential steps in post-marketing surveillance.

In summary, drug safety is a continuous and comprehensive process in the pharmaceutical industry. Each step, including preclinical testing, clinical trials, regulatory approval, and post-marketing surveillance, is crucial in ensuring the safety and well-being of patients. By following strict protocols and guidelines, the pharmaceutical industry can maximize the benefits of drugs while minimizing potential harm to patients.

Written by: Masuma Aktar (20346027)

Nanosponges: A Miracle in the Treatment of Breast Cancer



Breast cancer affects a significant proportion of the population, with more than 2.3 million cases occurring annually, making it the most common cancer among adults. Furthermore, in 95% of countries, it is either the primary or secondary cause of cancer deaths (World Health Organization [WHO], 2022). Thus, finding a more effective treatment for breast cancer than the currently available conventional methods is of paramount importance.

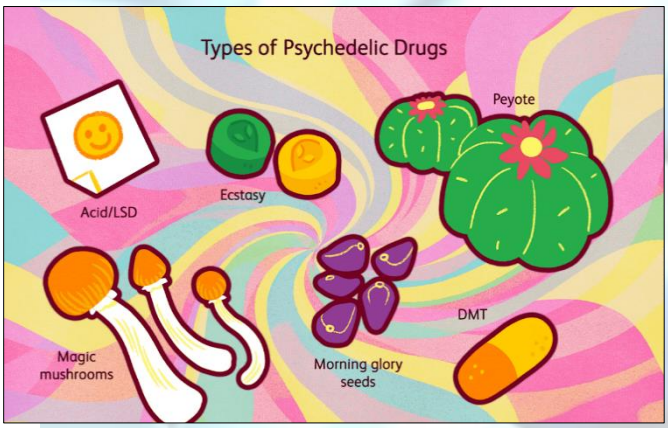
Nanosponges, a type of nanosized molecule made up of crosslinking polymers with a three-dimensional structure, appear to hold the most promise in this regard (Tiwari et al., 2022). With a diameter of less than 1 µm, nanosponges can easily penetrate tumor cells. Doxorubicin (DOX) is an anthracycline used widely in the treatment of breast cancer, but it has a number of significant drawbacks, such as lack of specificity, severe cardiotoxicity, and DNA

damage. In an experiment conducted by Argenziano et al. (2020), a new formulation of β-cyclodextrin nanosponges containing DOX (BNS-DOX) was compared to the current drug. The results demonstrated that BNS-DOX significantly inhibited cancer cell proliferation by inducing apoptosis with greater efficiency than free DOX. Furthermore, a BNS-DOX dose five times lower than the therapeutic dose of DOX inhibited breast cancer growth by 60% in BALB-neuT mice, and in all cell lines, BNS-DOX was more effective at reducing cell growth than DOX. Additionally, BNS-DOX functioned as a sustained-release form, and its cardiotoxicity was lower than DOX, with the drug content in the heart of BNS-DOX mice being five times lower than that of DOX mice. BNS-DOX even decreased the growth of DOX-resistant EMT6/AR10r cells, as well as the ER/PR+ and TNBC cell lines. Finally, BNS-DOX had no severe toxic side-effects and did not affect the mice's health.

Nanosponge versions of other anti-cancer drugs, such as Ferulic acid and Bortezomib, are also superior to their current form (Gore et al., 2022). In conclusion, nanosponges could be the most effective tool for improving the clinical management of breast cancer. By reducing the side-effects and increasing the effectiveness of the treatment, nanosponges could play a crucial role in the fight against breast cancer. However, more research is needed to evaluate the safety and effectiveness of nanosponges as a treatment for breast cancer in human clinical trials.

Written by: Mahin Ferdous Chowdhury (20346005)

"Exploring the Therapeutic Potential of Psychedelic Drugs for Treatment-Resistant Depression: A Review of Current Research and Controversies"



The burgeoning psychedelic industry has regained pharmaceutical interest due to the increasing prevalence of mood and anxiety disorders worldwide, growing scientific research, and decriminalization efforts.

Amidst complaints from many individuals who have not found relief from conventionally prescribed antidepressants, many people have turned to recreational dosing and micro-dosing of psychedelics, such as LSD and psilocybin mushrooms, as a form of self-treatment for anxiety, depression, and PTSD, which has become a subject of great interest to researchers. Because of their structural similarity to serotonin, hallucinogens such as LSD and psilocybin bind to serotonin 5-HT2A receptors and have a longer duration of action compared to serotonin itself. Unlike conventional selective serotonin reuptake inhibitors (SSRIs), psilocybin, a compound found in psilocybin mushrooms, increases amygdala activation to positive emotional stimuli, whereas SSRIs work by inhibiting amygdala hyperactivity to fearful emotional stimuli. Micro-dosing is an emerging trend for self-treatment of depression, as it involves a tenth of the recreational dose, which minimizes cognitive impairment and physiological effects, allowing individuals to carry out normal daily activities. Several micro-dosing studies have reported an increase in positive mood, a decrease in negative mood, and an improvement in relationships with others and the environment. However, these studies are limited by the absence of a control group and may be influenced by expectancy effects.

While the potential of psychedelic drugs is gaining attention, it is important to note that self-treatment and micro-dosing of these substances can be dangerous. The use of psychedelics without proper medical guidance or supervision can lead to adverse effects, such as increased anxiety, paranoia, or even psychosis. Moreover, the purity and quality of these substances obtained are questionable and may contain harmful contaminants or adulterants. There is also the risk of drug interactions with other medications that a person may be taking, leading to serious health consequences. Therefore, it is crucial to use psychedelic drugs with the guidance of a qualified healthcare professional.

Written by: Kazi Samiha Islam (20346012)