BRAC UNIVERSITY
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Department of Pharmacy

PHARMA HIGHLIGHTS

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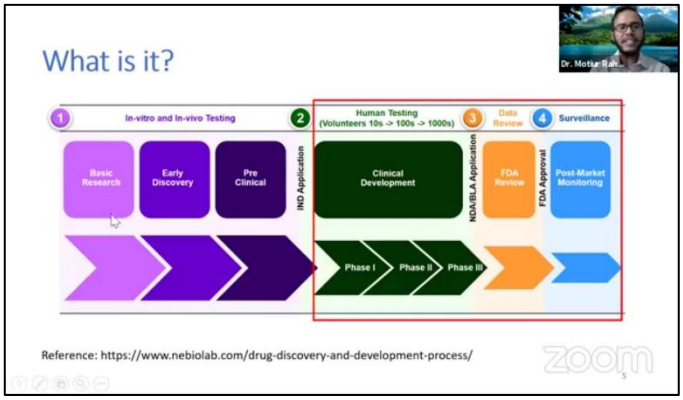
Webinar on 'The Scopes of Health Outcomes Research in the US'



Health Outcomes Research mainly deals with the effectiveness of a treatment/intervention in the vast majority of the patient population beyond the clinical trial setting. These patient-generated data can help treatment and/or regulatory decision making. Health outcomes research is a rapidly expanding, interdisciplinary field. As part of the 'Toolbox for Success' series designed by the Department of Pharmacy, Brac University, a webinar on 'The Scopes of Health Outcomes Research in the US' was organized on March 20, 2021. The speaker of the webinar was Dr. Motiur Rahman, MPS, Manager, Center for Observational Research at Amgen, USA. Dr. Motiur Rahman is an epidemiologist, currently working at Amgen Inc., USA as an Observational Research Manager. He is contributing to generate real-world evidence across safety and effectiveness of oncology products in the US. Prior to joining Amgen, he worked in the Medical Device Epidemiology at Johnson & Johnson and in the Office of Clinical Pharmacology at the US Food and Drug Administration. Dr. Rahman completed his PhD in Pharmacoepidemiology from Harrison School Pharmacy, Auburn University, USA and also obtained a Masters in Statistics from Auburn University.

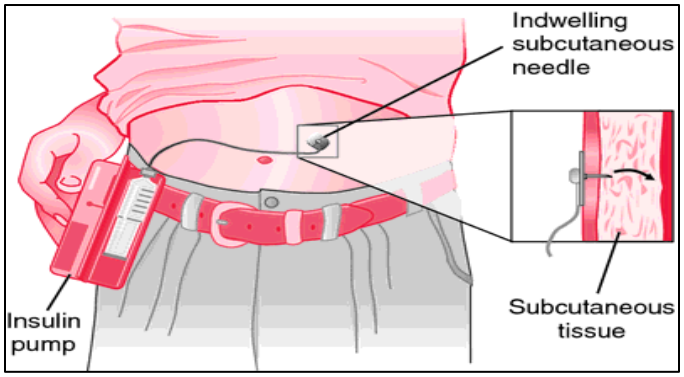
The webinar was moderated by Ms Marzia Alam, Lecturer, Department of Pharmacy, Brac University. The webinar was open to students and professionals from all areas and was live streamed on Facebook from the Department of Pharmacy, Brac University Facebook page.

The speaker emphasized on the important role of health outcomes research in drug and medical device development. In addition, he also discussed the route students can take to pursue graduate studies in this emerging field in the US and its career prospects. The questions asked by the attendees were insightful and reflected their enthusiasm towards growing as competent professionals. The webinar was very interactive and the participants also shared their opinion on how the session will help them to focus on their goals.

Written by: Department of Pharmacy

3D Printed Microneedle Patches Using Stereolithography (SLA) for Intradermal Insulin Delivery

The study focuses on 3D printed microneedles by utilizing biocompatible polymer for transdermal insulin delivery in order to attain lower glucose level along with excellent hypoglycemia control. 3D microneedles were manufactured employing stereolithography and inkjet printing to optimize skin penetration capacity with minimum applied forces and strong adhesion of the coated films even after penetration. Transdermal route of insulin delivery is an intriguing concept to treat diabetes with rapid insulin action, combined with steady state plasma glucose level over a longer period of time compared to subcutaneous infusion.



3D printed microneedles utilizing stereolithography is a recent approach to facilitate insulin delivery by penetrating skin with low forces compared to metallic MNs and obtain lower glucose level within short time. In addition, a thin uniform layer of insulin-sugar was coated on the surface of MNs through inkjet printing without any loss of satellite droplets and insulin integrity was preserved by carrier sugars, xylitol being the most preferable. The conducted in vivo study in diabetic mice

demonstrated significant outcome of rapid low glucose level with longer duration in comparison of subcutaneous injections.

The study signifies following aspects:

- Rapid insulin action and lower glucose level within short time
- Piercing impermeable layer of human skin with unique shape of 3D microneedle
- Biocompatible polymer resin is incorporated for dissolvable microneedle system.
- Uniform layer of thin insulin-sugar films prevent insulin loss during microneedle insertion.
- Transdermal delivery of insulin ensures sustained hypoglycemic effect and good relative bioavaibility compared to subcutaneous injection.

Written by: Sinthia Masud (ID: 17346049)

Trikafta Combination Therapy for Cystic Fibrosis

Cystic fibrosis (CF), though being rare, it is rather a comparatively common life-threatening monogenic disorder among the Caucasian population. It is a progressive genetic disorder affecting lung predominantly along with the digestive system and other organs; mainly causing persistent lung infection along with limited the breathing ability over time.

For the root cause, it is caused due to the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene which produces faulty CFTR protein if produces at all or in sufficient amount. The CFTR protein is actually a chloride ion channel present in the epithelial cells of the mucus membranes which moves chloride ion out of the cell along with attracting water into the lungs to keep it lubricated making the breathing activity easy. Alongside, it keeps the cilia moving to excrete dust and pathogens outside. Due to the dysfunctional protein, breathing problem and frequent infection occur shortening expected life expectancy.

1 in every 30 Caucasians are carriers of at least 1 out of 700 types of mutated CFTR gene; the most common being the delta F508 mutation occurring 70% of the time. 1 in every 2500-4000 newborn is diagnosed with CF in the specific population. The estimated cases are more than 70,000 cases worldwide among which >30,000 present in Europe solely. Until recently, CF patients were mainly treated by managing their symptoms through antibiotics, anti-inflammatory drugs, mucus-thinners, bronchodilators etc. But on October 21, 2019, 'Trikafta', a triple-combination modulator therapy was approved for treating the 'F508del mutation'. It is a combination of two correctors (Tezacaftor and Elexacaftor) and one potentiator (Ivacaftor) for modification of the primary faults in mis assembly-misprocessing-mis trafficking and improved CFTR protein channel opening respectively. Two separate randomized, double-blind, placebo controlled and active controlled (Trikafta Vs. Tezacaftor & Ivacaftor) studies were done for the therapy with single and double F508del mutated CF patients respectively. As for the result, the Trikafta group had their mean ppFEV1 (percent predicted forced expiratory volume in one second, an established biomarker of CF related lung disease progression) increased by 13.8% and 10% respectively. For the first study, the Trikafta group also showed improved sweat chloride, pulmonary exacerbation number and body mass index compared to the placebo group. This therapy is capable of treating 90% of the CF patients worldwide which makes it a revolutionary innovation in the medicinal as well as the pharmaceutical field.

Written by: Samarah Arjumand (ID: 18146068)