PHARMA FRONTLINE

Department of Pharmaceutics and Regulatory affairs

NEWS LETTER (BIMONTHLY)

Sri Adichunchanagiri College of Pharmacy

ADICHUNCHANAGIRI UNIVERSITY

May -2023

ISSUE #2

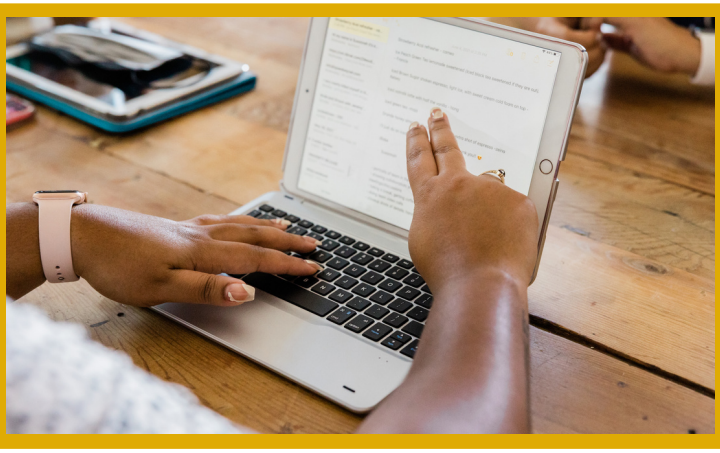
By: Dept. of Pharmaceutics & RA

PRECISION MEDICINE

- Next Generation Sequencing (NGS) Tests
- FDA's Role in Advancing Precision Medicine
- Streamlining FDA's Regulatory Oversight of NGS Tests

IN-SILICO TESTING

- Improve existing products
- Identify potential active molecules for a specific target and vice-versa
- Guide product development and other different possible R&D processes



REAL-WORLD DATA

- Real-world data (RWD) is one of the emerging pharma healthtech trends that play a vital role in health care decisions

PRECISION MEDICINE

What is Precision medicine?

Precision medicine, sometimes known as "personalized medicine" is an innovative approach to tailoring disease prevention and treatment that takes into account differences in people's genes, environments, and lifestyles.

Advances in precision medicine have already led to powerful new discoveries and FDA-approved treatments that are tailored to specific characteristics of individuals, such as a person's genetic makeup, or the genetic profile of an individual's tumor. Patients with a variety of cancers routinely undergo molecular testing as part of patient care, enabling physicians to select treatments that improve chances of survival and reduce exposure to adverse effects.

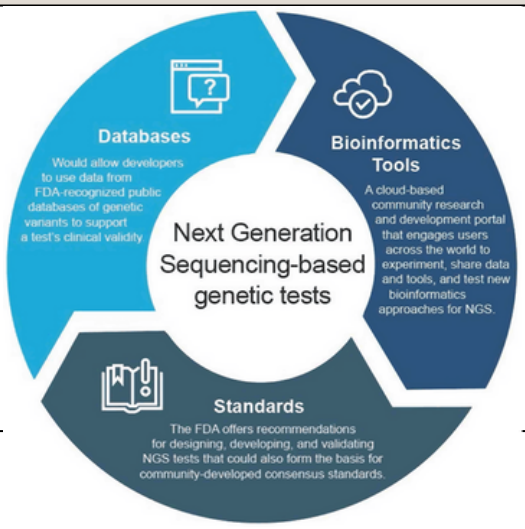
NEXT GENERATION SEQUENCING (NGS) TESTS

Precision care will only be as good as the tests that guide diagnosis and treatment. Next Generation Sequencing (NGS) tests are capable of rapidly identifying or 'sequencing' large sections of a person's genome and are important advances in the clinical applications of precision medicine.

Patients, physicians and researchers can use these tests to find genetic variants that help them diagnose, treat, and understand more about human disease.

FDA'S ROLE IN ADVANCING PRECISION MEDICINE

The FDA is working to ensure the accuracy of NGS tests, so that patients and clinicians can receive accurate and clinically meaningful test results.



The vast amount of information generated through NGS poses novel regulatory issues for the FDA. While current regulatory approaches are appropriate for conventional diagnostics that detect a single disease or condition (such as blood glucose or cholesterol levels), these new sequencing techniques contain the equivalent of millions of tests in one. Because of this, the FDA has worked with stakeholders in industry, laboratories, academia, and patient and professional societies to develop a flexible regulatory approach to accommodate this rapidly evolving technology that leverages consensus standards, crowd-sourced data, and state-of-the-art open-source computing technology to support NGS test development. This approach will enable innovation in testing and research, and will speed access to accurate, reliable genetic tests.

Streamlining FDA's Regulatory Oversight of NGS Tests

In April 2018, the FDA issued two final guidances that recommend approaches to streamline the submission and review of data supporting the clinical and analytical validity of NGS-based tests. These recommendations are intended to provide an efficient and flexible regulatory oversight approach: as technology advances, standards can rapidly evolve and be used to set appropriate metrics for fast growing fields such as NGS. Similarly, as clinical evidence improves, new assertions could be supported. This adaptive approach would ultimately foster innovation among test developers and improve patients' access to these new technologies

Market Value & its Development

With a CAGR of 10.7%, the precision medicine market value will exceed $96 billion by 2024. This growth owes much to the success of recently targeted therapies. When fully implemented, precision medicine will revolutionize oncology, making possible personalized treatment for every patient.

While precision medicine is still at the early development stages, offering truly customized treatment to patients will require a total overhaul of how healthcare professionals deliver and develop therapies.

The successful implementation of precision medicine will require a new regulatory, clinical, economic, and technical structure. That way, doctors can administer the right therapy to the right patient at the right time.

If the growth projections are anything to go by, this will be one of the most disruptive pharma healthtech trends of the year.

IN-SILICO TESTING

Product development in cosmetics is costly and time-consuming, especially whenever companies look to discover new ingredients. Now, more companies are turning to in-silico screening to tackle these production problems. The powerful technology uses molecular databases and virtual modeling to make it easier to discover new active ingredients, which can help guide cosmetic product development.

In silico screening tools work together with databases and simulation software that store molecule information and interactions with proteins. In pharmacology, in-silico screening can show how a potential cancer-causing molecule interacts with proteins involved in the cancer process.

WHAT IS IN-SILICO TESTING ?

The term 'in silico' is a modern word usually used to mean experimentation performed by computer and is related to the more commonly known biological terms in vivo and in vitro.

There is a range of possible use cases for in silico screening, as it can help sectors that rely on biological research such as food toxicology research, drug, and cosmetic development achieve the following:

- Improve existing products
- Identify potential active molecules for a specific target and vice-versa
- Guide product development and other different possible R&D processes
- Show the biological activity and health application of certain compounds

One real-world example of in-silico technology is the GPDB database, which stores information about plant extracts and natural molecules.

In silico trials (ISTs) for medical drugs and devices have gained increased popularity as cost-effective alternatives to their clinical counterparts. ISTs promise dramatic reductions in the resources needed for assessing novel technologies and for generating evidence in support of regulatory evaluation for safety and effectiveness. Some have suggested significant cost reductions comparing an all in silico approach versus an equivalent clinical trial with humans. Others have argued for, and reported on, incremental implementation of the in silico methodologies that complement or refine the design of clinical trials based on predictions from the in silico trial outcomes.

ISSUE #2

MAY, 2023

REAL-WORLD DATA

REAL-WORLD EVIDENCE

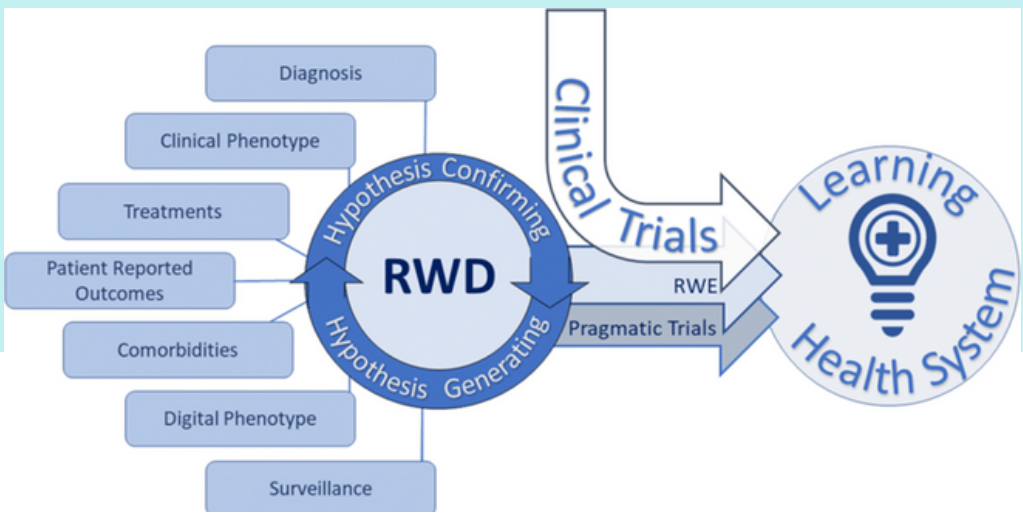
Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status.

Real-world evidence is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.

FDA is committed to realizing the full potential of fit-for-purpose RWD to generate RWE that will advance the development of therapeutic products and strengthen regulatory oversight of medical products across their lifecycle.

Real-world data (RWD) is one of the emerging pharma healthtech trends that play a vital role in health care decisions. For instance, the U.S. Food and Drug Administration (FDA) uses RWD alongside real-world evidence (RWE) to determine a product's safety and identify adverse events before making regulatory decisions.

- Health care professionals use these two technologies to support coverage decisions and make guidelines on medical tools in clinical practice.
- In addition, medical product manufacturers use RWD and RWE to support clinical trial designs such as pragmatic clinical and large simple trials. The developers are also using RWD and RWE to support observational studies and new treatment regimens.
- Because of the sophistication and analytical capabilities of RWD and RWE, the health care community can analyze data and use the results of their analysis to improve product development and approval processes.
- Mobile devices, computers, biosensors, and wearable devices all collect and store health-related data. This data then allows health care professionals to design and conduct better clinical trials, which helps answer questions previously thought impossible.
- As data is so intrinsically linked to technology in all industries, we can expect RWD to remain a core component of pharma healthtech trends for the foreseeable future.



CYBERSECURITY THREATS

STAY ALERT

READ MORE

The pharma industry is a prime target for cyberattacks. With the innovation and massive investment in R&D and intellectual property on patient health data, the sector is a hot spot in the data threat landscape.

According to Deloitte, 70% of pharmaceutical companies say cybersecurity threats are one of their biggest concerns. The data stored by these companies is sensitive, often pertaining to patient's private health matters. Losing control or access to this data could be catastrophic for a company or medical organization's reputation.

Healthtech data breaches affect the company's valuation and erode the trust customers, and patients have in the institution. In addition, companies that fall victim to cybercriminals face hefty fines and overall company disruption.

INTELLECTUAL PROPERTY AND VALUABLE DATA IN THE WRONG HANDS COULD MEAN YEARS OF RESEARCH GOING DOWN THE DRAIN. CYBERCRIMINALS POSE A NEVERENDING THREAT. FURTHERMORE, WITH THE CURRENT RATE OF INNOVATION, PHARMA ORGANIZATIONS ARE IN THE SPOTLIGHT MORE THAN EVER. THEREFORE, COMPANIES MUST MITIGATE ANY INTERNAL AND EXTERNAL RISKS.

BY IMPLEMENTING THE RIGHT STRATEGIES SUCH AS STAFF EDUCATION AND AWARENESS, COMPANIES CAN SAFEGUARD INFORMATION AND MAINTAIN DATA PRIVACY

New drug Approvals

- Brixadi (buprenorphine) Extended-Release Injection

Company: Braeburn Inc.
Date of Approval: May 23, 2023
Treatment for: Opioid Use Disorder
Brixadi (buprenorphine) is a partial opioid agonist for use in the treatment of opioid use disorder.

- Yuflyma (adalimumab-aaty) Injection

Company: Celltrion, Inc.
Date of Approval: May 23, 2023
Treatment for: Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis, Hidradenitis Suppurativa

- Xacduro (sulbactam and durlobactam (co-packaged)) Kit for Injection

Company: Innoviva, Inc.
Date of Approval: May 23, 2023
Treatment for: Acinetobacter Pneumonia
Xacduro (sulbactam and durlobactam) is a co-packaged product containing the beta-lactam antibacterial sulbactam, and the beta lactamase inhibitor durlobactam for use in the treatment of serious infections caused by Acinetobacter.

- Opvee (nalmefene hydrochloride) Nasal Spray

Company: Opiant Pharmaceuticals, Inc.
Date of Approval: May 22, 2023
Treatment for: Opioid Overdose
Opvee (nalmefene hydrochloride) is a nasal spray formulation of the approved opioid antagonist nalmefene hydrochloride for use in the treatment of opioid overdose

- Epkinly (epcoritamab-bysp) Injection

Company: AbbVie Inc.
Date of Approval: May 19, 2023
Treatment for: Diffuse Large B-Cell Lymphoma
Epkinly (epcoritamab-bysp) is a bispecific CD20-directed CD3 T-cell engager for use in the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

- Vyjuvek (beremagene geperpavec-svdt) Topical Gel

Company: Krystal Biotech, Inc.
Date of Approval: May 19, 2023
Treatment for: Dystrophic Epidermolysis Bullosa
Vyjuvek (beremagene-geperpavec-svdt) is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy for the treatment of wounds in patients dystrophic epidermolysis bullosa

- Miebo (perfluorohexyloctane) Ophthalmic Solution - formerly NOV03

Company: Bausch & Lomb Inc.
Date of Approval: May 18, 2023
Treatment for: Dry Eye Disease
Miebo (perfluorohexyloctane) is a semifluorinated alkane indicated for treatment of the signs and symptoms of dry eye disease.

DEPARTMENT ACTIVITIES

MAY, 2023 ISSUE #2

STUDENTS ACHIVMENTS

Asha B R of M.Pharma-4th Semester (Pharmaceutics) Harsha T L & Tejaswini K S M.Pharma-1st Semester has been shortlisted to attend the Innovation design and Entrepreneurship (IDE) bootcamp at chennai ,from 22 June,2023 -26 June ,2023 organized by MoE's Innovation Cell (MIC) .

PUBLICATIONS

DESIGNED MONOMERS AND POLYMERS
2023, VOL. 26, NO. 1, 106–116
https://doi.org/10.1080/15685551.2023.2194176

OPEN ACCESS

A spotlight on application of microwave-assisted modifications of plant derive polymers in designing novel drug delivery systems

Girish Meravanige Basavarajappa[a,#], K M Priyanka[b], Prakash Goudanavar[b,#], Lakshmi G Narasimha[c], N. Raghavendra Naveen[b], Buduru Gowthami[d], Santosh Fattepur[e], Predeepkumar Narayanappa Shiroorkar[e], Sreeharsha Nagaraja[f,g], Mallikarjun Telsang[h], Veeriah Chowdary Jasthi[i] and Pavan Kumar Pavagada Sreenivasa[j]

[a]Department of Biomedical Sciences, College of Medicine, King Faisal University, Al Ahsa, Saudi Arabia; [b]Department of Pharmaceutics, Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, B.G.Nagar, Karnataka, India; [c]Medical Writer, Scientimed Solutions Private Limited, Mumbai, India; [d]Annamacharya College of Pharmacy, New Boyanapalli, Rajampet, Andhra Pradesh, India; [e]School of Pharmacy, Management and Science University, Shah Alam, Selangor, Malaysia; [f]Department of Pharmaceutical Sciences, College of Clinical Pharmacy, King Faisal University, Al-Hofuf, Al-Ahsa, Kingdom of Saudi Arabia; [g]Department of Pharmaceutics, Vidya Siri College of Pharmacy, Off Sarjapura Road, Bangalore, India; [h]Department of Surgery, College of Medicine, King Faisal University, Al-Ahsa, Saudi Arabia; [i]Department of Oral and Maxillofacial Surgery and Diagnostic Sciences, College of Dentistry, King Faisal University, Al-Ahsa, Saudi Arabia; [j]Department of Restorative Dentistry and Endodontics, College of Dentistry, King Faisal University, Al-Ahsa, Saudi Arabia

ABSTRACT

Polymers are a fundamental part of numerous industries and can be conjugated with many other materials and components to have a vast array of products. Biomaterials have been extensively studied for their application in pharmaceutical formulation development, tissue engineering, and biomedical areas. However, the native form of many polymers has limitations concerning microbial contamination, susceptibility, solubility, and stability. Chemical or physical modifications can overcome these limitations by tailoring the properties of polymers to meet several requirements. The polymer modifications are interdisciplinary, cutting across conventional materials, physics, biology, chemistry, medicine, and engineering limitations. Microwave irradiation has become a well-established technique for a few decades to drive and promote chemical modification reactions. This technique allows ease of temperature and power control to perform the synthesis protocols efficiently. Additionally, microwave irradiation contributes to green and sustainable chemistry. In this contribution, microwave-assisted polymer modifications were described with a special focus on their application in developing several novel dosage forms.

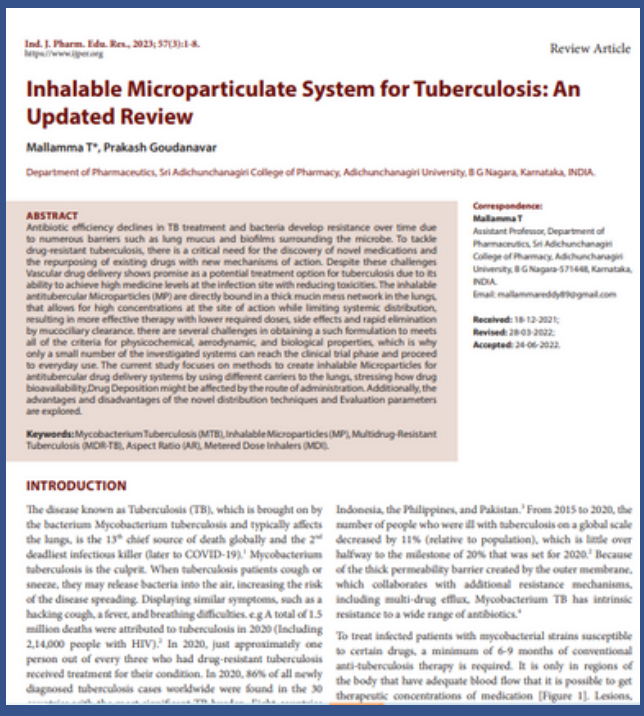
ARTICLE HISTORY
Received 6 October 2022
Accepted 19 March 2023

KEYWORDS
Natural polymers; microwave-assisted; polym modifications; grafting; polysaccharides

1. Introduction

Polymer research has access to a wide and inexpensive supply of resources nature provides. Natural polymers are widely available in huge quantities. They serve as raw materials for developing different drug delivery systems, including but not limited to the packaging, paper, and textile industries. In many of the novel drug delivery systems, synthetic and natural polymers will plays a crucial role [1,2]. Natural polymers, alternatively, are more appealing for pharmaceutical applications owing to their biocompatibility, low cost, and therapeutic efficiency of drug molecules contain in them [3]. The viscosity, microbial degradation, part or low solubility, stability issues, antigenicity, and no uniform features from batch to batch are some of t most significant drawbacks to using natural polyme as carriers.

On the other hand, natural precursors qualities mu frequently be adjusted to make them acceptable f certain uses. This is when polymer modification pr cesses come in handy. The reformation should be do so that the current polymers physical and biologic properties are not compromised. Functional groups de



Ind. J. Pharm. Edu. Res., 2023; 57(3):1-8.
https://www.ijper.org

Review Article

Inhalable Microparticulate System for Tuberculosis: An Updated Review

Mallamma T*, Prakash Goudanavar

Department of Pharmaceutics, Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, B G Nagara, Karnataka, INDIA.

ABSTRACT

Antibiotic efficiency declines in TB treatment and bacteria develop resistance over time due to numerous barriers such as lung mucus and biofilms surrounding the microbe. To tackle drug-resistant tuberculosis, there is a critical need for the discovery of novel medications and the repurposing of existing drugs with new mechanisms of action. Despite these challenges Vascular drug delivery shows promise as a potential treatment option for tuberculosis due to its ability to achieve high medicine levels at the infection site with reducing toxicities. The inhalable antitubercular Microparticles (MP) are directly bound in a thick mucin mess network in the lungs, that allows for high concentrations at the site of action while limiting systemic distribution, resulting in more effective therapy with lower required doses, side effects and rapid elimination by mucociliary clearance. there are several challenges in obtaining a such formulation to meets all of the criteria for physicochemical, aerodynamic, and biological properties, which is why only a small number of the investigated systems can reach the clinical trial phase and proceed to everyday use. The current study focuses on methods to create inhalable Microparticles for antitubercular drug delivery systems by using different carriers to the lungs, stressing how drug bioavailability.Drug Deposition might be affected by the route of administration. Additionally, the advantages and disadvantages of the novel distribution techniques and Evaluation parameters are explored.

Keywords: Mycobacterium Tuberculosis (MTB), Inhalable Microparticles (MP), Multidrug-Resistant Tuberculosis (MDR-TB), Aspect Ratio (AR), Metered Dose Inhalers (MDI).

Correspondence:
Mallamma T
Assistant Professor, Department of Pharmaceutics, Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, B G Nagara-571448, Karnataka, INDIA.
Email: mallammareddy@hotmail.com

Received: 18-12-2021;
Revised: 28-03-2022;
Accepted: 24-06-2022.

INTRODUCTION

The disease known as Tuberculosis (TB), which is brought on by the bacterium Mycobacterium tuberculosis and typically affects the lungs, is the 13th chief source of death globally and the 2nd deadliest infectious killer (later to COVID-19).[1] Mycobacterium tuberculosis is the culprit. When tuberculosis patients cough or sneeze, they may release bacteria into the air, increasing the risk of the disease spreading. Displaying similar symptoms, such as a hacking cough, a fever, and breathing difficulties. e.g A total of 1.5 million deaths were attributed to tuberculosis in 2020 (Including 2,14,000 people with HIV).[2] In 2020, just approximately one person out of every three who had drug-resistant tuberculosis received treatment for their condition. In 2020, 86% of all newly diagnosed tuberculosis cases worldwide were found in the 30 Indonesia, the Philippines, and Pakistan.[3] From 2015 to 2020, the number of people who were ill with tuberculosis on a global scale decreased by 11% (relative to population), which is little over halfway to the milestone of 20% that was set for 2020.[3] Because of the thick permeability barrier created by the outer membrane, which collaborates with additional resistance mechanisms, including multi-drug efflux, Mycobacterium TB has intrinsic resistance to a wide range of antibiotics.[4]

To treat infected patients with mycobacterial strains susceptible to certain drugs, a minimum of 6-9 months of conventional anti-tuberculosis therapy is required. It is only in regions of the body that have adequate blood flow that it is possible to get therapeutic concentrations of medication [Figure 1]. Lesions,