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Review Article

Unveiling the science of drug development: strategies, successes, and challenges

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ABSTRACT

This abstract provides an in-depth exploration of drug development, from historical perspectives to modern challenges and emerging trends. It begins by tracing the evolution of drug development over centuries, highlighting the pivotal role of pharmacy and regulatory oversight. The abstract emphasizes the multifaceted nature of drug development, involving collaboration across scientific disciplines and various stages, from preclinical to post-market monitoring. The challenges inherent in drug development, such as high costs, lengthy timelines, and regulatory hurdles, are thoroughly examined. Despite these challenges, the abstract underscores the importance of drug development in addressing unmet medical needs and improving public health. Furthermore, the abstract delves into specific aspects of drug development, including preclinical research and discovery, clinical trial methodologies, and successes and challenges in the field. It also discusses emerging trends, such as precision medicine, digitalization, and the role of artificial intelligence and machine learning. Overall, this abstract provides a comprehensive overview of drug development, highlighting its significance, challenges, and future directions in advancing healthcare.

Keywords: Drug development, Regulatory oversight, Preclinical research, Artificial intelligence, Emerging trends

INTRODUCTION

The history of drug development spans over 10 centuries and is closely linked with the history of pharmacy. Throughout history, various cultures have employed natural remedies, with some being incorporated into modern medical practices and others being dismissed due to safety or efficacy concerns. Early pharmacies frequently transformed into early pharmaceutical companies. Regulatory oversight emerged in response to tragic events and apprehensions regarding drug safety and effectiveness. In the modern era, the pharmaceutical industry has undergone notable transformations driven by mergers, acquisitions, and the evolution of healthcare.[1] Drug development is a multifaceted, precarious, and costly process that requires significant resources and expertise. It involves the collaboration of hundreds of professionals across various scientific fields to generate evidence on the safety and efficacy of new chemical entities. At each stage of development, specific expertise is crucial for successful progression. The key phases encompass preclinical development, early clinical development, late clinical development, registration, and lifecycle management. Within these stages, a spectrum of activities is undertaken to ensure the drug's viability and regulatory compliance. Both traditional methodologies and innovative strategies are explored with the common goal of expediting development timelines and mitigating expenses.[2] Basic principles of drug discovery and development provides an overview of identifying new drugs, highlighting steps like high throughput screening and molecular modelling. The importance of understanding this process for successful drug development is emphasized. Additionally, effective delivery methods for bioactive proteins are discussed.

Various animal models, particularly rats, are explored for drug screening. Another paper reviews halogenase enzymes for C-H activation. Additionally, new compounds from Vietnamese medicinal plants are examined for drug potential. Lastly, a study introduces a sensing platform for detecting nitrofurantoin in pharmaceuticals.[3]

Drug discovery and development represent intricate processes essential for producing therapeutic substances that are both effective and safe. These endeavours are prompted by the emergence of various diseases, demanding the creation of new treatments and preventative measures. The journey begins with the meticulous identification and characterization of lead compounds, followed by rigorous preclinical studies to confirm safety and efficacy. These studies yield vital insights into formulation, dosage, delivery methods, pharmacokinetics, pharmacodynamics, and potential drug interactions. Subsequent human clinical trials, conducted across different phases, aim to assess the drug's safety, effectiveness, and real-world implications regarding side effects. Through these trials, optimal dosages and potential interactions with other substances are determined, ensuring improved treatment outcomes. Positive outcomes from human trials may pave the way for the drug's application and approval for commercialization, albeit under strict monitoring for unforeseen side effects, particularly within vulnerable groups. Despite being resource-intensive, time-consuming, and fraught with risks, the drug development process remains indispensable. This comprehensive process encompasses steps ranging from initial discovery to eventual commercialization as an over-the-counter medication.[4] Micro- and nanoparticles in medical drug development improve drug effectiveness and enable targeted delivery, potentially enhancing treatments. They also offer prospects for prolonged-release drugs and addressing various pathological conditions. Additionally, they introduce new imaging capabilities for diagnostic procedures.[5] Natural goods, like plants, animals, and microbes, offer health benefits and are used in traditional medicine, especially in underdeveloped regions. Traditional medicine, derived from plant extracts, often has fewer side effects and is more accessible than modern medications. Phytochemicals in therapeutic plants possess diverse beneficial properties. Diabetes mellitus results from metabolic abnormalities in hyperglycaemic pancreatic cells, treated conventionally with medications, but novel plant-derived medicines show promise. Traditional medicine, endorsed by the world health organization, is a promising avenue for diabetes treatment. Preventing diabetes and its consequences is crucial for universal health.[6]

UNDERSTANDING DRUG DEVELOPMENT

Finding new drugs encompasses five primary stages: pre-discovery, drug discovery, preclinical development, clinical stage, and review/approval/post-market monitoring. Despite advancements in biological understanding and technology, the quest for new treatments presents significant challenges marked by a high attrition rate. While innovative methods like artificial intelligence and novel *in vitro* technologies strive to streamline research and development (R and D) processes, various obstacles persist. Authors aspire to swiftly create affordable, precise, potent, safe, and tailored medications, albeit this aspiration remains a distant objective.[7] Drug development encompasses a series of stages, beginning with discovery and progressing through pre-clinical and clinical trials. This intricate process involves the identification, synthesis, characterization, validation, optimization, screening, and assay of chemical compounds for therapeutic efficacy. Once a promising molecule is identified, it advances from laboratory settings to pre-clinical and eventually clinical trials. The primary goal is to pinpoint compounds with therapeutic value for disease treatment and cure. However, this development journey is time-consuming, spanning 5 to 10 years and incurring costs nearing $17 billion. Notably, drug discovery stands out as the most financially demanding phase, attributed to substantial expenses in R and D and clinical trials. On average, it requires 12 to 15 years to usher a single new compound through this rigorous process and into the market.[8]

Drug development encompasses a protracted, expensive, and high-risk journey spanning 10 to 15 years with a notable attrition rate. Identifying drug candidates entails an iterative process, refining molecular attributes until a suitable candidate for human use emerges, where typically only one in a thousand synthesized molecules advances to clinical trials. Pharmacology and biochemistry evaluation involve a range of *in vitro* and *in vivo* tests to ensure legality and adsorbability before human administration. Shifting focus from technical intricacies, the chapter delves into the commercial operations of biopharmaceutical companies, addressing the global prescription drug market, entities engaged in pharmaceutical R and D, customer base, pharmacoeconomics, and portfolio management. Furthermore, the examination extends to intellectual property and generic competition, pivotal in drug development's commercial landscape.[9] Drug discovery costs have risen due to various factors, including time-consuming processes, regulatory requirements, high attrition rates in phase III clinical trials, and decreased R and D productivity. Effective collaboration among stakeholders such as the pharmaceutical industry, academia, regulatory authorities, and end users is crucial for developing drugs that are both efficacious and affordable. Over time, drug discovery has transitioned from trial-and-error methods to more modern approaches fuelled by advancements in chemical and biological sciences. The emergence of stringent regulatory processes, prompted by adverse events, has necessitated changes in drug discovery and development practices. Additionally, digital and disruptive technologies are influencing drug discovery and development, contributing to the creation of safer and more effective medications.[10]

PRECLINICAL RESEARCH AND DISCOVERY

Natural products have historically played a significant role and continue to serve as a rich source of new medications. The advancement in evaluating bioactive compounds extracted from natural sources underscores the necessity of understanding current methodologies.[11] Target-based drug discovery has become dominant in pharmaceutical businesses due to advances in molecular biology, recombinant technology, and genomics. However, despite increased investment, it has not led to a proportional increase in unique molecular components or the identification of specific biological products. Developments in chemical and molecular biology have facilitated the identification of more molecular targets, necessitating the creation of innovative screening techniques. Unfortunately, major improvements in phenotypic screening technologies have caused setbacks in target-based screening in the pharmaceutical sector. To address this, integrating qualities from different drug discovery methodologies, including target-based and phenotypic approaches, has been proposed to bridge the gap and enhance drug discovery.[12] The drug discovery and development process are aimed at providing new pharmacological entities to safely and effectively treat diseases. Key stages of this process encompass target identification, lead compound selection, preclinical research, clinical research, FDA review, and post-market safety monitoring. Preclinical studies are dedicated to pharmaceutical reformulations, development, and toxicity assessments. These studies involve evaluating parameters such as solubility, dissolution, stability, solid-state properties, formulation development, and pharmacokinetics. Various formulation strategies, including controlled release, sustained release, micro, and nanoformulations, receive emphasis. Pharmacokinetic studies are underscored as critical aspects of preclinical formulation development. Additionally, detailed information on excipients is provided to facilitate the design of preclinical formulations.[13]

The FDA modernization act of 2022 eliminates animal testing for drug development, emphasizing human biology methods. This drives a shift from bench to bedside, with increased investment in translational research and innovative tools. Technological fusion in the medical and pharmaceutical industries enhances drug discovery. Four papers discuss innovations, focusing on delivery, efficacy, and reduced toxicity. Human-based models and computer-aided design expedite translation to clinical stages. Organ-on-a-chip technology bridges *in vivo* and *in vitro* studies, enhancing drug discovery. Incorporating predictive organ chips can improve drug development, reducing time and costs for safer medicines.[14]

CLINICAL TRIALS: PHASES AND METHODOLOGIES

Scientific medical studies are conducted to generate new knowledge about health and disease while also informing clinical practice and public health policies. These studies are meticulously planned, often based on hypotheses that justify their necessity. Research questions, arising from perceived knowledge gaps in particular subject areas, serve as the compass guiding the study's direction. Clinical trials, a crucial component of medical research, are designed to address the primary research question or hypothesis at hand. Typically, hypothesis testing stands as the predominant method utilized to ascertain whether clinical study outcomes yield positive or negative results.[15]

Clinical trials are essential research studies conducted on human volunteers to address specific health questions, representing the fastest and safest route to finding effective treatments and enhancing health outcomes. Investigational trials play a crucial role in assessing the safety and effectiveness of experimental treatments or novel applications of established therapies within controlled environments. Additionally, observational trials contribute valuable insights by addressing health issues in large populations under natural conditions. These trials serve as highly specialized biological assays aimed at measuring therapeutic effectiveness. The phases of clinical trials, encompassing phase I through phase IV, delineate a systematic progression in evaluating interventions. Phase I involves studying pharmacokinetics, safety, and gross effects in human volunteers, while phase II examines these factors in selected patients. Phase III trials predominantly focus on safety and therapeutic efficacy in extensive patient cohorts, leading to drug approval and marketing upon successful completion. Even post-marketing, physicians continue to provide feedback on a drug's adverse effects and efficacy, particularly in phase IV.[16] A clinical trial is a vital research endeavour that assesses the safety and efficacy of new diagnostic methods, medications, or treatment modalities involving human participants. These trials play a crucial role in evaluating safety and effectiveness of various medical interventions.[17]

Clinical studies are conducted to investigate factors associated with diseases and evaluate the effectiveness and safety of investigational drugs, procedures, or devices. The design of clinical studies varies depending on the specific characteristics of each type of study, allowing researchers to select the most suitable approach based on their research circumstances. These studies are broadly categorized into observational studies and clinical trials, which differ based on the presence or absence of intervention on human subjects. Observational studies include case-control studies, cohort studies (both prospective and retrospective), nested case-control studies, case-cohort studies, and cross-sectional studies. On the other hand, clinical trials encompass controlled/non-controlled trials, randomized/non-randomized trials, open-label/blind trials, and parallel/cross-over/factorial design trials, as well as pragmatic trials. Each type of clinical study offers advantages and disadvantages, requiring researchers to carefully plan and choose the most appropriate approach to achieve their study objectives effectively within the given circumstances.[18]

SUCCESSES IN DRUG DEVELOPMENT

The FDA implemented the breakthrough therapy designation (BTD) in 2012 to hasten access to medications for severe or life-threatening conditions lacking adequate treatment options. A review spanning 2012 to 2016 scrutinized medications with non-oncology indications approved under the BTD, identifying 15 drugs for eight conditions, ranging from common ailments like chronic hepatitis C infection to rare disorders such as lysosomal acid lipase deficiency. The evidence supporting these approvals exhibited considerable variability, indicating a high degree of heterogeneity. Consequently, significant uncertainty persists regarding the safety and efficacy of numerous agents endorsed through the BTD. Healthcare professionals must recognize these limitations to provide informed education to patients and fellow providers.[19] An independent review of UK drug policy recommends allocating an extra £550 million to local authorities over five years to tackle drug dependency. Additionally, the review highlights the importance of treating drug dependency as a chronic health condition, necessitating follow-up care. It advocates for diverting more individuals who use drugs away from the criminal justice system and into treatment programs. Moreover, the report underscores the significance of providing housing and employment support in conjunction with treatment services.[20]

Mental illnesses significantly contribute to the global public health burden, emphasizing the urgent need for effective interventions. Integrating public health with mental health systems has emerged as a promising approach to improving mental health outcomes on a broader scale. This integration underscores the importance of understanding and applying core principles from community health and population studies, recognizing their profound impact on the biopsychosocial aspects of mental illnesses. Moreover, strategies aimed at reducing the stigma surrounding mental health are explored, highlighting the importance of societal perceptions in shaping access to care and support. In the context of pandemics, there is a timely emphasis on addressing mental health concerns within public health frameworks, acknowledging the unique challenges and vulnerabilities that emerge during such crises.[21]

CHALLENGES IN DRUG DEVELOPMENT

The development of novel therapeutics for rare diseases introduces a complex dynamic between expediting access to breakthrough treatments and ensuring the generation of robust evidence concerning their safety and efficacy. While accelerating drug development and approval holds the promise of swiftly delivering benefits to patients and reducing costs for R and D, thus potentially enhancing drug affordability within the healthcare system, it also poses significant ethical dilemmas. Expedited approval processes, compassionate release of drugs, and the examination of drugs in real-world settings present challenges that must be carefully navigated. This article delves into the evolving landscape of drug approval and the ethical quandaries it poses for various stakeholders, including patients, caregivers, clinicians, and institutions. Moreover, it offers concrete strategies aimed at optimizing the acquisition of real-world data while simultaneously mitigating risks for patients, clinicians, and institutions.[22] This review delves into drug discovery, spanning pharmacology, chemistry, and biology, aiming to find new treatments. It's a complex, lengthy, and expensive process, often taking over a decade and billions of dollars. The pharmaceutical industry is evolving globally, merging traditional methods with modern approaches like digitalization. Challenges persist in translating discoveries to clinical success, while productivity pressures mount. Advanced delivery systems are crucial for optimizing therapeutic outcomes.[23]

Regulatory filings pose significant challenges, irrespective of a company's size or the stage of product development. However, having project leaders well-versed in regulatory submissions can greatly assist in foreseeing, mitigating, and managing these challenges. Successful commercialization of novel pharmaceuticals hinges on adeptly navigating the intricate regulations established by international health authorities. This process necessitates extensive collaboration among internal and external stakeholders across various departments such as R and D, QA, clinical research, manufacturing, and marketing. Ensuring the safety and efficacy of medications at each development phase requires companies to regularly share documentation with health authorities. Moreover, R and D divisions, contract research organizations (CROs), and regulatory agencies encounter their own set of challenges in the regulatory submission process. To ensure timely and accurate regulatory filings at the appropriate level, clear criteria must be established for all businesses involved.[24]

Drug developers have traditionally prioritized the efficacy, safety, and quality of drug products in line with regulatory expectations. However, there is a shifting focus towards the patient perspective, with regulatory authorities placing greater emphasis on this aspect, leading to heightened requirements for successful product submissions. This shift necessitates adjustments to industrial drug development processes to accommodate increased patient involvement, including human factor tests and feedback integration. Achieving a balance between providing fast patient access to innovative therapies and developing patient-centric product forms poses a significant challenge. The review aims to delve into this delicate balance and explore how various stakeholders such as patients, clinicians, regulators, and others can contribute to achieving desired outcomes.[25]

EMERGING TRENDS AND FUTURE DIRECTIONS

Precision medicine recognizes the intricate interplay of genetics and environments in the manifestation of various subtypes of heterogeneous diseases. Real-valued biomarkers, such as protein levels in plasma, play a pivotal

role in accurately diagnosing and effectively treating these disease subtypes. While conventional methods like fold change (FC) and the area under the receiver operating characteristic curve (AUC) are adept at identifying common biomarkers across all subtypes, they may falter when subtypes represent less than half of the disease group. The introduced machine-learning biomarker evaluation method, difference in bi-cluster distances (DBD), presents a novel approach by clustering data points to screen real-valued data and pinpoint biomarkers associated with disease subtypes. This method is accompanied by efficient software and rigorous validation techniques. Demonstrated on a late-onset Alzheimer's disease (AD) gene expression dataset, DBD unveiled four significant genes and established appropriate thresholds for biomarker diagnostics. Intriguingly, these significant genes eluded identification by FC or AUC for the given dataset but have been independently linked to AD or neurological disorders by other research groups.[26] The pharmaceutical industry has experienced a notable shift towards digitalization of data in recent years. Artificial intelligence (AI) presents a range of advanced tools and networks capable of simulating human physiology, potentially supplanting traditional pharmaceutical research methods. AI and machine learning (ML) play pivotal roles in medicinal development, assisting in the prediction of pharmacological targets and the characterization of small molecules. Additionally, AI- and ML-assisted dataset analysis expedites the development of cellular and genetic therapeutics. Despite its rapid evolution, the field of AI and ML in drug development is still in its early stages, necessitating continuous evaluation of new algorithms, techniques, and tools to support its growth. This chapter provides an overview of existing AI- and ML-based technologies, showcasing their real-world applications in both preclinical and clinical drug research. Furthermore, it offers a balanced perspective by scrutinizing both the advantages and limitations of utilizing AI and ML in drug research.[27]

Our understanding of disease pathogenesis has significantly advanced thanks to technological progress and recent scientific discoveries. This includes the development of network models that integrate genomic regions, molecular phenotyping profiling, and deep clinical phenotyping, thereby impacting the levels of transcripts, proteins, and metabolites, ultimately aiding in disease diagnosis and personalized drug development. Digital biomarkers are instrumental in disease diagnosis, playing a crucial role from patient identification to treatment recommendation. Furthermore, the utilization of "omics" technology and large sample sizes has generated extensive datasets, providing valuable insights into various illnesses and their intrinsic biological connections. Effective analysis of such vast data necessitates sophisticated computational and statistical methods. Moreover, advanced technologies like artificial intelligence, machine learning algorithms, computational biology, and digital biomarkers facilitate the transformation of new data into actionable knowledge, thus expediting diagnosis and treatment decisions. These advancements are poised to play a significant role in combating infectious disorders, epidemics, and pandemics.[28]

CONCLUSION

The introduction outlines the historical evolution of drug development, emphasizing its close association with the history of pharmacy and the transition of early pharmacies into pharmaceutical companies. Regulatory oversight emerged in response to safety concerns, and the modern pharmaceutical industry has undergone significant transformations driven by mergers, acquisitions, and healthcare evolution. Drug development is described as a multifaceted, precarious, and costly process involving collaboration across various scientific fields. The key phases, including preclinical and clinical development, registration, and lifecycle management, are highlighted, along with the exploration of both traditional and innovative methodologies. Despite its challenges, drug development remains indispensable in addressing emerging diseases and improving therapeutic outcomes.

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