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The Evolving Role of Pharmaceutics in Personalized Medicine: From Conventional Dosage Forms to Nano-Enabled Drug Carriers

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Abstract

Animal models play a key role in personalized medicine because they help define the pharmacokinetics, pharmacodynamics, safety and therapeutic profile of conventional and nano-enabled drug delivery systems. In comparison to conventional dosage forms, current successful targeting and control of drug release are restricted, nano-enabled carriers improve solubility, extend systemic circulation and allow site specific delivery. Inter-individual variability in drug metabolism, enzyme, and immune response are also prominent with animal models, appropriate dose selection, safety testing, and formulations to make therapy more person-specific. High end techniques such as in vivo imaging, biodistribution analysis, histopathology, and toxicological screening enhance these studies in terms of translating their strength. By integrating both animal-based studies with biomarker-based methods, computational modeling, and complimentary in vitro methods, the accuracy of predictive methods increases dramatically. The studies highlight the imperativeness of animal research as mediator between the preclinical research and the clinical implementation, in the establishment of safe, effective, and custom designed pharmaceutic interventions in personal medicine.

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Key Words:

Personalized medicine, Animal models, Nano-enabled drug carriers, Conventional dosage forms, Pharmacokinetics, Pharmacodynamics, Targeted delivery, Translational research.

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1. INTRODUCTION

Exploitation of animal research is a well-established feature in pharmaceutical science that offers a vital insight in the conduct of drugs prior to clinical translation. Animal models allow pharmacokinetics, biodistribution, metabolism, and toxicity to be measured in meticulously controlled conditions by recreating physiologic and pathologic conditions[1]. These models are especially useful in preclinical trials of new dose forms and new delivery methods, because they can be used to extrapolate onto human response, to maximize the dosages that would be used therapeutically, and to detect safety issues at an early point. Absence of such preclinical

explorations would create great risks and uncertainties to the advancement of pharmaceutici innovations into the clinical practice.

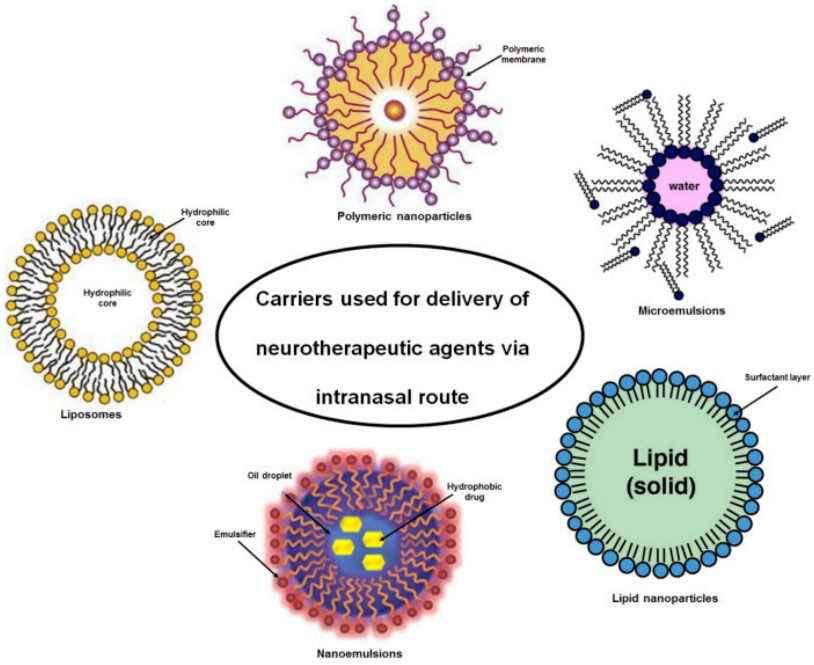

Figure 1: Nano – carries Drug Delivery System[2]

The importance of animal studies has increased over the past few years with the admission of a new form of medicine very critical as one call it; the personalized medicine where medicines will have to be designed according to individual patient and a unique character of the biological profile of the individual patient. By using animal-based tests, the issue of evaluating the inter-individual variability of a drug (e.g. how varied enzymatic activity, targeting different tissues and immune reaction can impact drug performance) can be examined. This leaves animal research as a bridge too far in the development of new pharmaceutic approaches, whether traditional dosage forms or advanced nano-textured carriers, prior to safe introduction of these into human use.

1.1 Background and Context

Personalized medicine is a significant transformation in contemporary medicine and it aims at establishing an individualized treatment approach in lieu of the generalized approach of treatment with drugs. The traditional dosage forms, namely tablets, capsules and injectables, which have historically been the fulcrum of drug delivery systems, do not incorporate inter-individual variability in the aspects of absorption and metabolism as well as individual responses to the drug therapy. This drawback has fast-tracked the development of novel pharmaceutic technologies, especially nano-enabled drug carriers which are more soluble, have longer circulation and target-specific delivery. During this transition, animal models are an essential platform to assess pharmacokinetics, biodistribution, and safety, therefore, supporting a connection between investigational formulations and clinical use[3].

1.2 Objectives of the Review

The primary objective of this review is:

- To evaluate the pharmacokinetic and pharmacodynamic profiles of conventional and nano-enabled drug delivery systems in animal models for insights into personalized therapy.
- To assess the safety, toxicity, and immunogenic responses of novel nano-carriers compared to conventional formulations using animal-based studies.
- To analyze disease-specific applications of animal-tested pharmaceutics across cancer, neurological, infectious, and inflammatory disorders for targeted therapeutic outcomes.
- To explore methodological approaches—including biodistribution imaging, histopathology, and toxicity screening—in animal studies that support translational and personalized medicine strategies.
- To identify translational challenges and inter-individual variability in drug response in animals, providing guidance for optimizing formulation design and dose personalization for human applications.

1.3 Importance of the Topic

The realities behind the role of pharmaceutic developments enabling a personalized approach to medicine must be understood to close the gap between preclinical development and clinical adoption. As the world seeks to advance precision healthcare, animal-based studies of drug delivery systems have become extremely crucial, as they guarantee effective reliability and safety, and even the personalized therapeutical effect. In this review, the power of the pharmaceutics to influence the future of patient-focused medicine in varied pathological conditions is highlighted[4].

2. ANIMAL-BASED INVESTIGATIONS IN CONVENTIONAL AND NANO-ENABLED PHARMACEUTICS FOR PERSONALIZED MEDICINE

This section summarizes the contribution that studies of animal models can make to the field of personalized pharmaceutics, identifying that traditional dosage forms offer a robust basis of PK/PD data with target specificity limited by target affinity and release but are improved in the area of solubility, controlled delivery and penetration of bilayers using nano-enabled carriers. It also highlights methodologies, including pharmacokinetic profiling, biospecific distribution imaging, histopathology, and toxicity testing, both of the usefulness of these approaches in supporting the validation of innovations and the issues of interspecies variability in the clinical translation of innovation[5].

2.1 Conventional Dosage Forms in Personalized Approaches

The use of conventional dosage forms, including tablets, capsules, suspensions, and injectable formulations has in the past and continues to be the basis of pharmaceutical therapy and a significant undertaking in the personalized treatment approach. These types of forms have been of utmost importance in animal studies of pharmacokinetics and pharmacodynamics. Indicatively, controlled-release tablets in rodent models showed marked disparity in absorption

patterns, which differ based on gastric pH, enzymatic activity and intestinal motility - factors that give prominence to the aspect of patient-specific formulations. Animal models are particularly relevant to determination of dose response relationships, drug metabolism and clearance rates using injectable dosage forms which can then be used in supporting dose optimization during clinical trials. Although these systems have a broad application, they suffer certain intrinsic drawbacks including poor site-specific targeting, impaired target tissue bioavailability, and inability to control release profile[6]. These inadequacies exemplify the disparity between traditional pharmaceutics and the needs of a personalized medicine, in which time- and tissue-specific drug release and tissue-specific drug delivery are vital.

2.2 Emergence of Nano-enabled Drug Carriers

Nanotechnology applied in pharmaceutics has brought new levels of platform that can be able to surpass drugs over the limitations to traditional systems hence, revolutionizing personalized medicine. Nano-enabled loading as liposomes, polymer-based nanoparticles, dendrimers, micelles, and solid lipid nanoparticle carriers offer special strengths related to improved solubility, extended half-life and specificity. Liposomal formulations have been shown to improve biodistribution and tumor concentration and reduce systemic toxicity with animal studies compared to free drug solutions[7]. Polymeric nano artificial of these have demonstrated efficient controlled release and reduced burst effects in rat models, and dendrimer-based carriers have been studied towards site-selective delivery across the blood brain barrier that has the potential to treat neurodegenerative diseases. Notably, animal-based studies also point out the potential of these nano systems to avoid biological barriers, avoid enzymatic degradation of therapeutic agents and respond in real time to physiological situations. These features render nano-enabled carriers as invaluable flankers in the era of developing individualized treatments, where the effectiveness of the product and its safety have to be balanced based on a unique biological constitution of a patient.

2.3 Methodological Approaches in Animal-Based Pharmaceutics Research

Pharmaceutics research is conducted using animals to support numerous types of methodological practices to assess delivery of drugs, therapeutic performance, and safety characteristics. Rodent/rabbit pharmacokinetic and pharmacodynamic profiling continues to be a staple as researchers can evaluate parameters of absorption, distribution, metabolism, and excretion in vivo. Quantitative biodistribution investigations, which are being enhanced by the use of sophisticated imaging strategies like fluorescent imaging, positron emission tomography (PET) and magnetic resonance imaging (MRI), allow the accurate determination of the fate of drug carriers in-vivo in real-time[8]. It is also necessary to conduct histopathological examination of tissues after treatment in order to detect local toxicity, inflammation or structural alterations produced by formulations. Furthermore, multiple animal models can be used in order to screen toxicological aspects, in respect to maximum tolerated doses, organ-specific toxicities, and the possible immunogenic reactions. Although achieving these methodologies leads to strong preclinical evidence, they are not devoid of problems. The interspecies differences between metabolism, physiology and immune responses can complicate and require complementary in

vitro and computational methods in order to directly extrapolate outcomes to humans. However, animal research is indispensable to the verification of pharmaceutic innovations prior to translation into the personalized medicine clinical setting.

Table 1: Summary of Key Literature on Nanomedicine and AI-Enabled Drug Delivery Systems[9]

Author(s)	Study	Focus Area	Methodology	Key Finding
Egwuatu et al. (2024)[10]	AI-enabled Diagnostics and Monitoring in Nanomedicine	Role of AI in nanomedicine diagnostics and monitoring	Case studies integrating AI tools with nanoscale drug delivery systems	AI platforms improved precision and efficiency in diagnostics and optimized patient-specific therapeutic outcomes
Fatima et al. (2022)[11]	A review of multifunction smart nanoparticle-based drug delivery systems	Smart nanoparticles for targeted and responsive drug delivery	Literature review of experimental studies on smart nanoparticle design	Smart nanoparticles enabled controlled, targeted, and responsive drug delivery, improving therapeutic efficacy and reducing side effects
Ghosh et al. (2024)[12]	Revolutionizing influenza treatment: a deep dive into targeted drug delivery systems	Nanoparticle-based targeted drug delivery for influenza treatment	Review of preclinical studies and drug delivery platforms	Targeted nanoparticles enhanced antiviral bioavailability and specificity, reducing viral loads more effectively than conventional treatments
Halappanavar et al. (2018)[13]	Promise and peril in nanomedicine: challenges and needs for integrated systems biology	Health risks and safety assessment in nanomedicine	Review and analysis of integrated systems biology approaches	Identified potential nanoparticle toxicity; emphasized integrated systems biology for safe and effective application
Haseeb et al. (2020)[14]	Nanobiotechnology: Paving the way to personalized medicine	Application of nanobiotechnology in personalized medicine	Review of nanotechnology-based therapeutic tools and platforms	Nanobiotechnology enabled precise drug targeting, early diagnostics, and real-time monitoring, enhancing patient-specific treatment efficacy

3. PHARMACOLOGICAL INSIGHTS AND THERAPEUTIC APPLICATIONS OF ANIMAL-BASED PHARMACEUTICS IN PERSONALIZED MEDICINE

The section reveals the pharmacological phenomena and the therapeutic promise of animal-based drug therapy in personalized medicine, with a focus on the pharmacokinetic and pharmacodynamic disparities between the conventional versus the nano-enabled formulations, which underline the necessity of safety and toxicity studies of the novel carriers, as well as outlining the effective implementations of their use in the disease models of cancer, neurological, infectious, and inflammatory disorders, proving their potential to bring targeted and successful personalized treatments[15].

3.1 Pharmacokinetic and Pharmacodynamic Considerations

The effectiveness of the drugs delivery systems in personalized medicine focuses on pharmacokinetic and pharmacodynamic (PK/PD) parameters. Animal models show that the extent of absorption, distribution, metabolism and excretion is significantly different between

the conventional formulations, under independent conditions, and nano-enable carriers operating under the same kind of environment. In an example, controlled-release tablets in rodents have shown varying levels of absorption that depend on gastric pH and enzyme activity, and thus profiling on a per patient basis is necessary[16]. On the other hand, nano-carriers have a higher potential to extend circulation time of the system, attain controlled release of drugs and augment targeting. These characteristics lead to a decreased dosing interval and systemic exposure and thus increase therapeutic effect and patient compliance. PK/PD modeling using animal models also show that the use of nanocarriers has a significant advantage of steadying the plasma concentration perhaps better than conventional systems, a major step towards customizing treatment regimens.

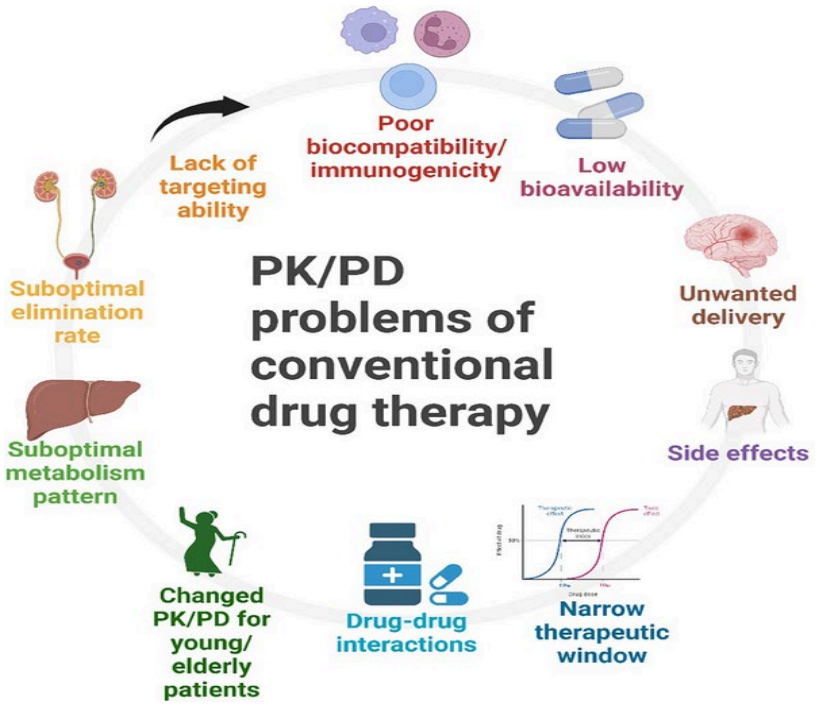

Figure 2: Common Pharmacokinetics and Pharmacodynamics[17]

3.2 Safety and Toxicity Profiles

One of the major pillars of pharmaceutics research is safety appraisal, especially in the case of personalized methods where variability in the tolerance of patients should be taken into account. The expected toxicity trends associated with conventional dosage forms are well documented and can be reliably predicted, therefore, it is even simpler to monitor their effects in animal models. Nevertheless, nano-enabled systems are novel in size, shape, and surface properties that make them possess unique toxicity that need special evaluation[18]. To exemplify, carbon nanotubes have been linked to pulmonary toxicity in rodent-based studies detecting their fibrous shape and bio-persistency, whereas certain metallic nanoparticles have a propensity to settle in the liver and kidneys, which creates concerns related to their safety over the extended period. In addition, immunogenic reactions have been noted in some polymeric carrier and dendrimer carrier. The above findings emphasize the need of developing

standardized safety procedures and predictive tools of nanocarriers. The role of animal studies is therefore important to characterize organ-specific toxicities, inflammatory effects and risks related to biodistribution, before human use in personalized medicine[19].

3.3 Disease-Specific Applications

The translational ability of the conventional systems and nano-enabled systems are demonstrated through the instrumentation of animal-based pharmaceutics research studies in disease models.

- **Cancer models:** The superior tumor suppression effect of doxorubicin-loaded liposomes, combined with a lower cardiotoxicity profile showed a clinical benefit of nano-formulations in oncology. Among these, similar results have also been reported with polymeric micelles loaded with anticancer drugs having selective accumulation in the tumor in xenograft models[20].
- **Neurological disorders:** Neurological conditions represent one of the most important challenges in neurology and concern overcoming the blood brain barrier (BBB). In rat models, polymeric nanoparticle and dendrimer systems have demonstrated potential at delivering anti-Parkinsonian and anti-Alzheimer therapeutic agents directly to the brain that otherwise would have exhibited improved therapeutic benefit and less systemic side effects.
- **Infectious diseases:** Nano-carriers have been investigated in murine models to facilitate delivery of antimicrobial and antiviral agent enhancing delivery. As an example, lipid nanoparticles containing anti-retroviral agents were found to better control the infection in HIV-infected mouse models and nano-formulated antibiotics showed higher rates of bacterial clearance fewer resistant infections.
- **Inflammatory and autoimmune disorders:** Nanocarriers have been used to deliver anti-inflammatory agents to inflamed joints of arthritic rat models with a high degree of success in lowering joint inflammation with minimal gastrointestinal toxicity associated with using systemic NSAIDs[21].

Such pathology-specific applications point to the flexibility of nano-enabled pharmaceutics in personalized medicine where the therapeutic response can be actively optimized to the pathology and to the biological profile of the patient[22].

4. TRANSLATIONAL INSIGHTS FROM ANIMAL MODELS TO PERSONALIZED PHARMACEUTICS

Using animal-based research is central in the measure of developing and transferring pharmaceutic ideation into personification drugs[23]. These studies are valuable in the sense that they enable researchers to study the interaction of various formulations of the pharmaceuticals, which is otherwise not possible due to lack of controlled environment in which the behavior of pharmaceuticals can be studied as far as reacting with biological system. Rodents, rabbits, and non-human primates are typically used, owing to their small size, combined with a well-

characterized physiology and genetic similarity to humans, support characterization of absorption, distribution, metabolism, excretion, and toxicity[24].

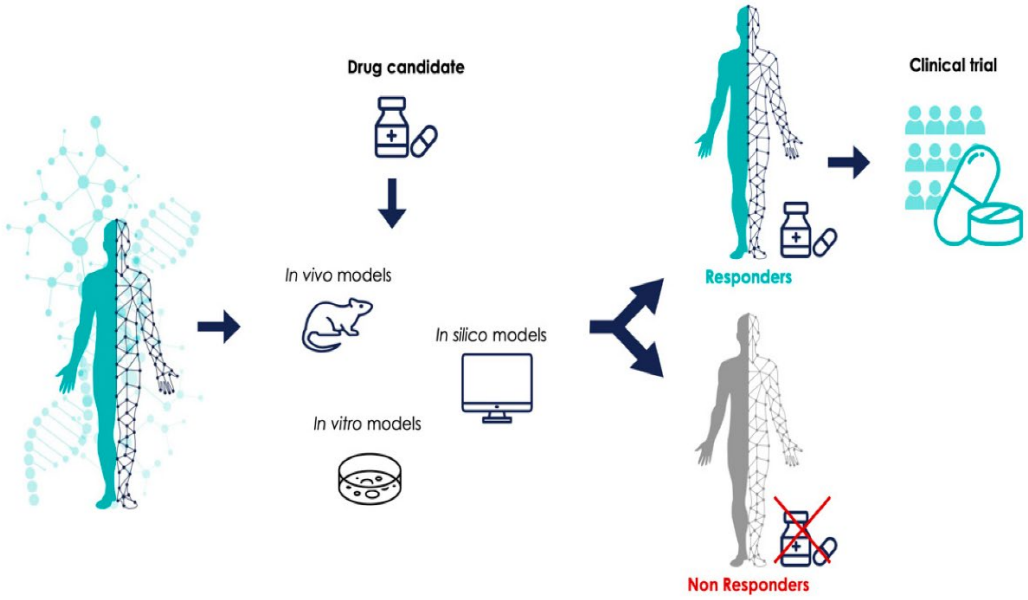

Figure 3: Animal Models to Personalized Therapy: Translational Drug Testing Pipeline[25]

Such experiments are of special interest in determining between-individual differences in response to drugs, where variability in pharmacogenomics is a major cause of concern in personalized medicine[26]. Genetic variations like polymorphisms, enzyme action, organ functionality and the variations in the immune systems of animals can be the sources of the heterogeneity of animals as it is with human populations. As an example, metabolism of a drug in some strains of mice can differ dramatically with others, and provide information on dose adjustments, or release controls over drug administration or targeting approaches that may be patient customised[27].

The information on biodistribution and tissue targeting that is pivotal to nano-enabled carriers is also obtained through animal studies[28]. Imaging may be combined with liposomes, polymeric nanoparticles, or dendrimers to trace their distribution in vivo, so enabling the researcher to assess the efficacy of these carriers to reach a particular organ or pathological location. This allows to finetune strategies of drug delivery, optimisation of therapeutic dose and reduction of antagonist toxicity even before proceeding to human testing[29].

Nevertheless, species-dependent differences in metabolism, immune, and physiological processing are encountered in terms of translation[30]. What is effective in rodent or rabbit model does not necessarily translate into identical reproducible human-like results[31]. This short-coming raises the importance of comparative analyzes among several species, incorporation of biomarker-based strategies, and the use of complementary in vitro or computational models to yield more accurate predictions of human response. When these approaches are used together,

animal research provides an important link in the development of safe, effective, and personalized pharmaceutic treatments that can be successfully applied in clinical practice[32].

5. DISCUSSION

The use of animal-based studies is essential to the development and translation of the pharmaceutic innovations into personalized medicine[33]. Although the conventional dosage forms offer the essential pharmacokinetics and safety data, their approaches lack targeting and controlled release. Nano-enabled carriers, including liposomes, polymeric nanoparticle and dendrimers, have enhanced solubility and targeting capabilities, longer circulating life, and the ability to penetrate cellular barriers, and provide enhanced therapeutic effects in disease models. In animal studies, inter-individual variability is identified, dose optimization is performed, and safety assessment aids, although translational difficulties occur because of species differences. Standardization of safety evaluations, biomarker-based methods and new predictive measures should be investigated in the future as well in order to further personalize drug treatments[34].

5.1 Interpretation and Analysis of Findings

The current review has established that animal-based research is invaluable in offering knowledge on the pharmacological behavior of both traditional and nano-enabled drug delivery system in custom-made drug delivery[35]. Although conventional dosage forms form the basis of therapy, they have limitations due to unpredictable absorption, low site-specific concentration, and uncontrolled delivery that may affect the outcomes of therapy. Conversely, nano-enabled carriers which possess the attributes of liposomes, polymer linked nanoparticles, dendrimers, and micelles have been shown to have increased solubility, long duration, targeted delivery and competence to cross biological barriers such as the blood-brain barrier. Analyses carried out on animal models in terms of pharmacokinetics and pharmacodynamics confirm that nano-carriers create more uniform plasma levels, cause less systemic binding and a more successful response to therapeutic activity as compared with conventional preparations. Moreover, animal models that are specific to the diseases depict the translational promise of these carriers in areas of oncology, neurology, infectious diseases, and inflammatory disorders[36].

5.2 Implications and Significance

These results highlight the central position of animal study research towards trapping preclinical research and clinical use. Animal models enable dose optimization, selection of formulation, and safety assessment by exposing inter-individual variability in drug sensitive (genetic, enzymatic, metabolic, and physiological)[37]. Nano-enabled carriers in particular provide the prospect of downright personal interfaces, matching drug release and targeting to the individual biological signature of the patient. Combining high-level imaging, biodistribution investigations, and histopathological analyses will complement our knowledge of therapeutic effector and safety positions and help contour precision medicine approaches[38].

5.3 Gaps and Future Research Directions

Although these breakthroughs are achieved, there still exist some serious problems of translational issues[39]. There is such a lack of direct generalizability of preclinical research findings to humans because of interspecies differences in metabolism, immune systems and physiology. Standardized approaches to testing nanocarrier safety, to predict immunogenicity, and to determine long-term toxicity are required. Future directions should be on the comparative studies among models of different animals, involvement of biomarker-based methodology and involving the mixture of computational and in vitro methods to enhance the rate of predictability. Besides, further investigations on pathological areas that have received less attention, combination, and responsive/ stimuli-activated nanocarriers are feasible and have opportunity to advance the applicability of personalized pharmaceutics further[40].

6. CONCLUSION

Animal-based research is indispensable to the progression of personalized medicine whereby it offers insights regarding the pharmacokinetics, pharmacodynamics, safety, and efficacy of the pathway administered and nano-enabled methods delivered, in the medical world. Although traditional dosage forms have some basic data at hand, they lack specificity, controlled release and biological barriers resistance. Such nano-enabled carriers, which have exhibited solubility, prolonged circulation, targeted delivery, and can elude complex physiological barriers, include liposomes, polymeric nanoparticle, and dendrimer carriers and have enhanced therapeutic outcomes of cancer, neurology, infectious and inflammatory disease models. The use of animal research also illustrates inter-individual variability data and helps in dose optimization matters in addition to contributing to safety assessment and translational potential, allowing the continuation between preclinical and clinical uses. Despite interspecies differences, standardized methodologies, biomarker-driven methods, and the use of in vitro and computational models hold great potentials to even further increase the predictive accuracy of these studies, highlighting the immense significance of such studies to the future of safe, effective, and patient-specific pharmaceutic therapies.

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